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CHAPTER 1—THE PUBLIC HEALTH SERVICE

SUBCHAPTER I—GENERALLY

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SUBCHAPTER I—GENERALLY

§§1 to 1j. Repealed. July 1, 1944, ch. 373, title XIII, §1313, 58 Stat. 714

Section 1, acts July 1, 1902, ch. 1370, §1, 32 Stat. 712; Aug. 14, 1912, ch. 288, §1, 37 Stat. 309, provided that Public Health and Marine Hospital Service should be known as the Public Health Service. See section 202 of this title.

Section 1a, act Nov. 11, 1943, ch. 298, §1, 57 Stat. 587, provided for organization and function of Public Health Service. See section 203 of this title.

Section 1b, act Nov. 11, 1943, ch. 298, §2, 57 Stat. 587, provided for appointment of Assistant Surgeons General, their grade, pay, and allowances. See sections 206, 207, and 210 of this title.

Section 1c, act Nov. 11, 1943, ch. 298, §3, 57 Stat. 587, provided for chiefs of divisions, their grade, pay and allowances, and creation of a Dental Division and a Sanitary Engineering Division. See sections 206, 207, and 210 of this title.

Section 1d, act Nov. 11, 1943, ch. 298, §4, 57 Stat. 587, provided for temporary promotions in regular corps in time of war. See section 211 of this title.

Section 1e, act Nov. 11, 1943, ch. 298, §5, 58 Stat. 588, provided for review of record of officers above grade of assistant surgeon and their separation from service. See section 211 of this title.

Section 1f, act Nov. 11, 1943, ch. 298, §6, 58 Stat. 588, provided for an acting Surgeon General during absence of Surgeon General and Assistant to Surgeon General. See section 206 of this title.

Section 1g, act Nov. 11, 1943, ch. 298, §7, 57 Stat. 588, provided for death and disability benefits of commissioned officers during war and for transfer of Service to military forces. See sections 213 and 217 of this title.

Section 1h, act Nov. 11, 1943, ch. 298, §8, 57 Stat. 589, provided for commissioned officers' benefits as civil officers and employees of United States and election of benefits. See Title 5, Government Organization and Employees.

Section 1i, act Nov. 11, 1943, ch. 298, §9, 57 Stat. 589, provided for beneficiaries' benefits where commissioned officer lost his life on active duty between Dec. 7, 1941, and Nov. 11, 1943.

Section 1j, act Nov. 11, 1943, ch. 298, §11, 57 Stat. 589, provided for transfer of appropriations to continue transferred functions. See note set out under section 201 of this title.

STATUTORY NOTES AND RELATED SUBSIDIARIES

RENUMBERING AND REPEAL OF REPEALING ACT

Title XIII, §1313, formerly title VI, §611, of act July 1, 1944, which repealed these sections, was renumbered title VII, §711, by act Aug. 13, 1946, ch. 958, §5, 60 Stat. 1049; §713, by act Feb. 28, 1948, ch. 83, §9(b), 62 Stat. 47; title VIII, §813, by act July 30, 1956, ch. 779, §3(b), 70 Stat. 721; title IX, §913, by Pub. L. 88–581, §4(b), Sept. 4, 1964, 78 Stat. 919; title X, §1013, by Pub. L. 89–239, §3(b), Oct. 6, 1965, 79

Stat. 931; title XI, §1113, by Pub. L. 91–572, §6(b), Dec. 24, 1970, 84 Stat. 1506; title XII, §1213, by Pub. L. 92–294, §3(b), May 16, 1972, 86 Stat. 137; title XIII, §1313, by Pub. L. 93–154, §2(b)(2), Nov. 16, 1973, 87 Stat. 604, and was repealed by Pub. L. 93–222, §7(b), Dec. 29, 1973, 87 Stat. 936.

§2. Omitted

EDITORIAL NOTES

CODIFICATION

Section, acts Feb. 3, 1905, ch. 297, 33 Stat. 650; Aug. 14, 1912, ch. 288, §1, 37 Stat. 309; 1939 Reorg. Plan No. I, eff. July 1, 1939, §201, 4 F.R. 2728, 53 Stat. 1424, which provided for jurisdiction of Federal Security Agency over the Service, was superseded by section 202 of this title.

STATUTORY NOTES AND RELATED SUBSIDIARIES

REPEALS

Act Aug. 14, 1912, ch. 288, §1, 37 Stat. 309, which changed name of Public Health and Marine Hospital Service of the United States to Public Health Service was repealed by act July 1, 1944, ch. 373, title XIII, §1313, formerly title VI, §611, 58 Stat. 714, as renumbered by act Aug. 13, 1946, ch. 958, §5, 60 Stat. 1049; act Feb. 28, 1948, ch. 83, §9(b), 62 Stat. 47; act July 30, 1956, ch. 779, §3(b), 70 Stat. 721; Pub. L. 88–581, §4(b), Sept. 4, 1964, 78 Stat. 919; Pub. L. 89–239, §3(b), Oct. 6, 1965, 79 Stat. 931; Pub. L. 91–572, §6(b), Dec. 24, 1970, 84 Stat. 1506; Pub. L. 92–294, §3(b), May 16, 1972, 86 Stat. 137; Pub. L. 93–154, §2(b)(2), Nov. 16, 1973, 87 Stat. 604; and repealed by Pub. L. 93–222, §7(b), Dec. 29, 1973, 87 Stat. 936. Act July 1, 1944, retained the name Public Health Service.

§§3, 4. Repealed. July 1, 1944, ch. 373, title XIII, §1313, 58 Stat. 714

Section 3, acts July 1, 1902, ch. 1370, §9, 32 Stat. 714; Aug. 14, 1912, ch. 288, §1, 37 Stat. 309, provided for rules and regulations of service by the President. See section 216 of this title.

Section 4, R.S. §4802; acts July 1, 1902, ch. 1370, §9, 32 Stat. 714; Aug. 14, 1912, ch. 288, §1, 37 Stat. 309, provided for an annual report by Surgeon General to Federal Security Administrator. See section 229 of this title.

STATUTORY NOTES AND RELATED SUBSIDIARIES

RENUMBERING AND REPEAL OF REPEALING ACT

Title XIII, §1313, formerly title VI, §611, of act July 1, 1944, which repealed these sections, was renumbered title VII, §711, by act Aug. 13, 1946, ch. 958, §5, 60 Stat. 1049; §713, by act Feb. 28, 1948, ch. 83, §9(b), 62 Stat. 47; title VIII, §813, by act July 30, 1956, ch. 779, §3(b), 70 Stat. 721; title IX, §913, by Pub. L. 88–581, §4(b), Sept. 4, 1964, 78 Stat. 919; title X, §1013, by Pub. L. 89–239, §3(b), Oct. 6, 1965, 79 Stat. 931; title XI, §1113, by Pub. L. 91–572, §6(b), Dec. 24, 1970, 84 Stat. 1506; title XII, §1213, by Pub. L. 92–294, §3(b), May 16, 1972, 86 Stat. 137; title XIII, §1313, by Pub. L. 93–154, §2(b)(2), Nov. 16, 1973, 87 Stat. 604, and was repealed by Pub. L. 93–222, §7(b), Dec. 29, 1973, 87 Stat. 936.

§5. Omitted

EDITORIAL NOTES

CODIFICATION

Section, act Mar. 4, 1915, ch. 167, §4, 38 Stat. 1191, provided for appointment to higher grade of officers of Public Health Service detailed with the former Isthmian Canal Commission.

§§6 to 15a. Repealed. July 1, 1944, ch. 373, title XIII, §1313, 58 Stat. 714

Section 6, acts July 1, 1902, ch. 1370, §1, 32 Stat. 712; Aug. 14, 1912, ch. 288, §1, 37 Stat. 309, provided for care of sick and disabled seamen. See section 249 of this title.

Section 6a, act Mar. 31, 1936, ch. 161, 49 Stat. 1185, provided for care of seamen on Government vessels not in Military or Naval Establishments and of cadets on State school ships. See section 249 of this title.

Section 7, act Aug. 14, 1912, ch. 288, §1, 37 Stat. 309, provided for investigations by Service into diseases, etc., and publications relating thereto. See section 241 of this title.

Section 8, acts July 1, 1902, ch. 1370, §4, 32 Stat. 713; Aug. 14, 1912, ch. 288, §1, 37 Stat. 309, provided for use of Service in time of war. See section 217 of this title.

Section 8a, act Apr. 9, 1930, ch. 125, §2(a), 46 Stat. 150, provided for extension of facilities of Service to health officials and scientists. See section 241 of this title.

Section 9, act Oct. 1, 1918, ch. 179, §2, 40 Stat. 1008, provided for suppression of Spanish influenza and other communicable diseases. See section 264 of this title.

Section 9a, act Apr. 9, 1930, ch. 125, §3, 46 Stat. 150, provided that administrative office and bureau divisions in District of Columbia be a part of departmental organization and scientific offices and research laboratories as part of field services. See section 203 of this title.

Section 10, acts Mar. 3, 1875, ch. 130, 18 Stat. 377; July 1, 1902, ch. 1370, §1, 32 Stat. 712; Aug. 14, 1912, ch. 288, §1, 37 Stat. 309, provided for appointment of Surgeon General. See section 205 of this title.

Section 11, R.S. §4802; acts July 1, 1902, ch. 1370, §1, 32 Stat. 712; Aug. 14, 1912, ch. 288, §1, 37 Stat. 309, provided for supervisory powers of Surgeon General. See section 203 of this title.

Section 11a, act Apr. 9, 1930, ch. 125, §10(b), 46 Stat. 152, provided for pay and allowances of Surgeon General and for reversion in grade on expiration of term. See sections 205 and 207 of this title.

Section 11b, act Aug. 9, 1939, ch. 606, 53 Stat. 1266, provided for rank and pay of Assistant to Surgeon General. See sections 206 and 207 of this title.

Section 12, acts Jan. 4, 1889, ch. 19, §1, 25 Stat. 639; July 1, 1902, ch. 1370, §1, 32 Stat. 712; Aug. 14, 1912, ch. 288, §1, 37 Stat. 309, provided for appointment of medical officers after examination. See section 209 of this title.

Section 13, act Jan. 4, 1889, ch. 19, §2, 25 Stat. 639, provided for original appointments as assistant surgeons and promotion of passed assistant surgeon. See sections 209 and 211 of this title.

Section 14, act Aug. 14, 1912, ch. 288, §2, 37 Stat. 309, provided for help as provided by Congress. See section 209 of this title.

Section 15, acts Mar. 3, 1891, ch. 541, 26 Stat. 923; July 31, 1894, ch. 174, 28 Stat. 179; July 1, 1902, ch. 1370, §1, 32 Stat. 712, provided for details for duty in bureau. See section 215 of this title.

Section 15a, acts Mar. 2, 1895, ch. 177, §1, 28 Stat. 780; July 1, 1902, ch. 1370, §1, 32 Stat. 712; Aug. 14, 1912, ch. 288, §1, 37 Stat. 309, provided for detail of two hospital attendants for duty in laboratory. See section 215 of this title.

STATUTORY NOTES AND RELATED SUBSIDIARIES

RENUMBERING AND REPEAL OF REPEALING ACT

Title XIII, §1313, formerly title VI, §611, of act July 1, 1944, which repealed these sections, was renumbered title VII, §711, by act Aug. 13, 1946, ch. 958, §5, 60 Stat. 1049; §713, by act Feb. 28, 1948, ch. 83, §9(b), 62 Stat. 47; title VIII, §813, by act July 30, 1956, ch. 779, §3(b), 70 Stat. 721; title IX, §913, by Pub. L. 88–581, §4(b), Sept. 4, 1964, 78 Stat. 919; title X, §1013, by Pub. L. 89–239, §3(b), Oct. 6, 1965, 79 Stat. 931; title XI, §1113, by Pub. L. 91–572, §6(b), Dec. 24, 1970, 84 Stat. 1506; title XII, §1213, by Pub. L. 92–294, §3(b), May 16, 1972, 86 Stat. 137; title XIII, §1313, by Pub. L. 93–154, §2(b)(2), Nov. 16, 1973, 87 Stat. 604, and was repealed by Pub. L. 93–222, §7(b), Dec. 29, 1973, 87 Stat. 936.

§16. Omitted

EDITORIAL NOTES

CODIFICATION

Section, which was from the Interior Department Appropriation Act, 1950, act Oct. 12, 1949, ch. 680, title I, 63 Stat. 791, was not repeated in the General Appropriation Act, 1951, act Sept. 6, 1950, ch. 896, 64 Stat. 595. It related to detail of Public Health medical officers to the Bureau of Mines. For provisions for details to executive departments, see section 215 of this title.

Similar provisions were contained in the following prior acts:

June 29, 1948, ch. 754, 62 Stat. 1139.
July 25, 1947, ch. 337, 61 Stat. 483.
July 1, 1946, ch. 529, 60 Stat. 375.
July 3, 1945, ch. 262, 59 Stat. 351.
June 28, 1944, ch. 298, 58 Stat. 499.
July 12, 1943, ch. 219, 57 Stat. 485.
July 2, 1942, ch. 473, 56 Stat. 548.
June 28, 1941, ch. 259, 55 Stat. 345.
June 18, 1940, ch. 395, 54 Stat. 444.
May 10, 1939, ch. 119, 53 Stat. 725.
May 9, 1938, ch. 187, 52 Stat. 330.
Aug. 9, 1937, ch. 570, 50 Stat. 602.
June 22, 1936, ch. 691, 49 Stat. 1791.
May 9, 1935, ch. 101, 49 Stat. 205.
Apr. 7, 1934, ch. 104, title III, 48 Stat. 564.
Mar. 1, 1933, ch. 144, title III, 47 Stat. 1406.
July 1, 1932, ch. 361, title III, 47 Stat. 516.
Feb. 23, 1931, ch. 280, title III, 46 Stat. 1349.
Apr. 18, 1930, ch. 184, title III, 46 Stat. 212.
Jan. 25, 1929, ch. 102, title III, 45 Stat. 1133.
Feb. 15, 1928, ch. 57, title III, 45 Stat. 103.
Feb. 24, 1927, ch. 189, title III, 44 Stat. 1219.
Apr. 29, 1926, ch. 195, title III, 44 Stat. 368.
Jan. 24, 1923, ch. 42, 42 Stat. 1210.
Mar. 4, 1921, ch. 161, 41 Stat. 1401.
June 5, 1920, ch. 235, 41 Stat. 911.
July 19, 1919, ch. 24, 41 Stat. 199.
July 1, 1918, ch. 113, 40 Stat. 671.

STATUTORY NOTES AND RELATED SUBSIDIARIES

REPEALS

Act July 1, 1944, ch. 373, title XIII, §1313, formerly title VI, §611, 58 Stat. 714, as renumbered by act Aug. 13, 1946, ch. 958, §5, 60 Stat. 1049; act Feb. 28, 1948, ch. 83, §9(b), 62 Stat. 47; act July 30, 1956, ch. 779, §3(b), 70 Stat. 721; Pub. L. 88–581, §4(b), Sept. 4, 1964, 78 Stat. 919; Pub. L. 89–239, §3(b), Oct. 6, 1965, 79 Stat. 931; Pub. L. 91–572, §6(b), Dec. 24, 1970, 84 Stat. 1506; Pub. L. 92–294, §3(b), May 16, 1972, 86 Stat. 137; Pub. L. 93–154, §2(b)(2), Nov. 16, 1973, 87 Stat. 604, and repealed by Pub. L. 93–222, §7(b), Dec. 29, 1973, 87 Stat. 936, repealed portions of Appropriations Acts June 12, 1917, ch. 27, §1, 40 Stat. 146; May 24, 1922, ch. 199, 42 Stat. 588; Jan. 24, 1923, ch. 42, 42 Stat. 1210; June 5, 1924, ch. 264, 43 Stat. 422; Mar. 3, 1925, ch. 462, 43 Stat. 1175, which contained similar provisions to those of this section, but later appropriation acts containing such provisions were not repealed.

§§17 to 25e. Repealed. July 1, 1944, ch. 373, title XIII, §1313, 58 Stat. 714

Section 17, act Oct. 1, 1918, ch. 178, 40 Stat. 992, provided for a detail for duty with Department of Agriculture. See section 215 of this title.

Section 17a, act Apr. 9, 1930, ch. 125, §1, 46 Stat. 150, provided for a detail for duty with executive and independent departments carrying on public health activities. See section 215 of this title.

Section 17b, act Apr. 9, 1930, ch. 125, §2(a), 46 Stat. 150, provided for a detail for duty with educational and research institutions. See section 215 of this title.

Section 17c, act Apr. 26, 1939, ch. 92, §1, 53 Stat. 620, provided for a detail for duty on vessels of Coast and Geodetic Survey. See section 215 of this title.

Section 18, act Oct. 27, 1918, ch. 196, 40 Stat. 1017, provided for a Reserve of the Public Health Service. See sections 204, 207, 209, and 210 of this title.

Section 18a, act Apr. 9, 1930, ch. 125, §6, 46 Stat. 151, provided for assignment of Reserve officers to active duty and for such service counting for promotion credits. See section 204 of this title.

Section 18b, act Mar. 18, 1943, ch. 17, title I, 57 Stat. 24, provided for distribution of Reserve officers among the several grades. See section 209 of this title.

Section 19, acts Feb. 19, 1897, ch. 265, 29 Stat. 554; Aug. 14, 1912, ch. 288, §1, 37 Stat. 309, provided for leaves of absence for medical officers. See section 210–1 of this title.

Section 20, act July 9, 1917, ch. 37, 40 Stat. 242, provided for pensions to officers detailed for service with Coast Guard, Army, or Navy. See section 213 of this title.

Section 21, acts July 1, 1902, ch. 1370, §5, 32 Stat. 713; Aug. 14, 1912, ch. 288, §1, 37 Stat. 309; Apr. 9, 1930, ch. 125, §13, 46 Stat. 152; May 26, 1930, ch. 320, §1, 46 Stat. 379, provided for establishment of National Advisory Health Council as an advisory board for National Institute of Health. See section 218 of this title.

Section 21a, act Aug. 10, 1939, ch. 636, 53 Stat. 1338, provided for compensation of National Advisory Health Council. See section 210 of this title.

Section 22, acts July 1, 1902, ch. 1370, §6, 32 Stat. 713; Aug. 14, 1912, ch. 288, §1, 37 Stat. 309; May 26, 1930, ch. 320, §1, 46 Stat. 379, provided for appointment of chiefs of divisions and director of institute, and their pay and allowances. See sections 206 and 210 of this title.

Section 23, act Mar. 4, 1913, ch. 149, 37 Stat. 915, provided for pay of director of Hygienic Laboratory which is now known as the National Institute of Health. See section 210 of this title.

Section 23a, act May 26, 1930, ch. 320, §1, 46 Stat. 379, provided that Hygienic Laboratory should be succeeded by the National Institute of Health and that all laws, authorizations, and appropriations of Hygienic Laboratory should become applicable to its successor.

Section 23b, act May 26, 1930, ch. 320, §2, 46 Stat. 379, provided for acceptance of gifts by Federal Security Administrator. See section 219 of this title.

Section 23c, act May 26, 1930, ch. 320, §3, 46 Stat. 380, provided for detailing to duty of scientists receiving fellowships. See sections 209 and 241 of this title.

Section 23d, act May 26, 1930, ch. 320, §4, 46 Stat. 380, provided for appointment and compensation of personnel of the National Institute of Health. See section 209 of this title.

Section 23e, act May 26, 1930, ch. 320, §5, 46 Stat. 380, provided that facilities of the National Institute of Health be available to States, counties, and municipalities. See section 241 of this title.

Section 23f, act May 26, 1930, ch. 320, §6, 46 Stat. 380, provided for rank, pay, and allowances of Director of the Institute. See sections 206, 207, and 210 of this title.

Section 23g, acts Apr. 9, 1930, ch. 125, §2(b), 46 Stat. 150; May 26, 1930, ch. 320, §1, 46 Stat. 379, provided for additional divisions in Institute as authorized by Administrator. See section 203 of this title.

Section 24, act July 9, 1918, ch. 143, ch. XV, §3, 40 Stat. 886, provided for establishment of a Division of Venereal Diseases.

Section 25, act July 9, 1918, ch. 143, ch. XV, §4, 40 Stat. 886, provided for duties of Division of Venereal Diseases.

Section 25a, act July 9, 1918, ch. 143, ch. XV, §4a, as added May 24, 1938, ch. 267, 52 Stat. 439, provided for appropriations to assist political subdivisions in venereal disease work. See sections 241 and 246 of this title.

Section 25b, act July 9, 1918, ch. 143, ch. XV, §4b, as added May 24, 1938, ch. 267, 52 Stat. 439, provided for allotments to political subdivisions for venereal disease work. See section 246 of this title.

Section 25c, act July 9, 1918, ch. 143, ch. XV, §4c, as added May 24, 1938, ch. 267, 52 Stat. 439, provided for payments from allotments to political subdivisions. See section 246 of this title.

Section 25d, act July 9, 1918, ch. 143, ch. XV, §4d, as added May 24, 1938, ch. 267, 52 Stat. 439, provided for rules and regulations governing the Division of Venereal Diseases, is covered by section 216 of this title.

Section 25e, act July 9, 1918, ch. 143, ch. XV, §4e, as added May 24, 1938, ch. 267, 52 Stat. 439, provided for construction of sections 25a to 25e of this title.

STATUTORY NOTES AND RELATED SUBSIDIARIES

RENUMBERING AND REPEAL OF REPEALING ACT

Title XIII, §1313, formerly title VI, §611, of act July 1, 1944, which repealed these sections, was renumbered title VII, §711, by act Aug. 13, 1946, ch. 958, §5, 60 Stat. 1049; §713, by act Feb. 28, 1948, ch. 83, §9(b), 62 Stat. 47; title VIII, §813, by act July 30, 1956, ch. 779, §3(b), 70 Stat. 721; title IX, §913, by

Pub. L. 88–581, §4(b), Sept. 4, 1964, 78 Stat. 919; title X, §1013, by Pub. L. 89–239, §3(b), Oct. 6, 1965, 79 Stat. 931; title XI, §1113, by Pub. L. 91–572, §6(b), Dec. 24, 1970, 84 Stat. 1506; title XII, §1213, by Pub. L. 92–294, §3(b), May 16, 1972, 86 Stat. 137; title XIII, §1313, by Pub. L. 93–154, §2(b)(2), Nov. 16, 1973, 87 Stat. 604, and was repealed by Pub. L. 93–222, §7(b), Dec. 29, 1973, 87 Stat. 936.

§26. Isolation of civilians for protection of military, air and naval forces

The Secretary of the Army, the Secretary of the Air Force and the Secretary of the Navy are authorized and directed to adopt measures for the purpose of assisting the various States in caring for civilian persons whose detention, isolation, quarantine, or commitment to institutions may be found necessary for the protection of the military, air and naval forces of the United States against venereal diseases.

(July 9, 1918, ch. 143, ch. XV, §2, 40 Stat. 886.)

EDITORIAL NOTES

CODIFICATION

The Secretary of the Air Force was inserted in text under the authority of section 207(a), (f) of act July 26, 1947, ch. 343, title II, 61 Stat. 501, and Secretary of Defense Transfer Order No. 40 [App. A(73)], July 22, 1949. The Department of War was designated the Department of the Army and the title of the Secretary of War was changed to Secretary of the Army by section 205(a) of act July 26, 1947. Sections 205(a) and 207 (a), (f) of act July 26, 1947, were repealed by section 53 of act Aug. 10, 1956, ch. 1041, 70A Stat. 641. Section 1 of act Aug. 10, 1956, enacted "Title 10, Armed Forces", which in sections 3010 to 3013 and 8010 to 8013 continued the Departments of the Army and Air Force under the administrative supervision of a Secretary of the Army and a Secretary of the Air Force, respectively.

EXECUTIVE DOCUMENTS

TRANSFER OF FUNCTIONS

For transfer of certain functions insofar as they pertain to the Air Force, and to the extent that they were not previously transferred to the Secretary of the Air Force from the Secretary of the Army, see Secretary of Defense Transfer Order No. 40 [App. A(73)], July 22, 1949.

§27. Definitions

The terms "State" and "States," as used in this chapter, shall be held to include the District of Columbia.

(July 9, 1918, ch. 143, ch. XV, §8, 40 Stat. 887.)

EDITORIAL NOTES

REFERENCES IN TEXT

This chapter, referred to in text, means chapter XV of act July 9, 1918, ch. 143, 40 Stat. 887, which, insofar as classified to the Code, enacted sections 24 to 27 of this title and amended section 28 of this title. For complete classification of this Act to the Code, see Tables.

§§28 to 43. Repealed. July 1, 1944, ch. 373, title XIII, §1313, 58 Stat. 714

Section 28, acts July 1, 1902, ch. 1370, §3, 32 Stat. 712; Aug. 14, 1912, ch. 288, §1, 37 Stat. 309; July 9, 1918, ch. 143, ch. XV, §3, 40 Stat. 886, provided divisions under Assistant Surgeons General and the rank, pay, and allowances of said Assistants. See sections 206, 207, and 210 of this title.

Section 28a, act Apr. 9, 1930, ch. 125, §10(c), 46 Stat. 152, provided for a chief of the narcotics division. See section 206 of this title.

Section 29, acts July 1, 1902, ch. 1370, §7, 32 Stat. 713; Aug. 14, 1912, ch. 288, §1, 37 Stat. 309, provided for conferences with State and Territorial boards of health. See section 242n of this title.

Section 30, acts July 1, 1902, ch. 1370, §8, 32 Stat. 714; Aug. 14, 1912, ch. 288, §1, 37 Stat. 309, provided for compilation of mortality, morbidity, and vital statistics. See section 242k(g) of this title.

Section 31, act June 5, 1920, ch. 235, §1, 41 Stat. 883, provided that officers of Service could make allotments of their pay. See section 704 of Title 37, Pay and Allowances of the Uniformed Services.

Section 32, act Mar. 6, 1920, ch. 94, §1, 41 Stat. 507, provided for purchase of quartermaster supplies by officers of Service. See section 210 of this title.

Section 33, act Mar. 4, 1921, ch. 161, §1, 41 Stat. 1378, provided for limitations on expenditure of appropriations. See section 227 of this title.

Section 33a, act May 14, 1935, ch. 110, 49 Stat. 229, provided for covering into Treasury moneys collected for treatment of foreign seamen and other pay patients. See section 221 of this title.

Section 34, acts July 1, 1902, ch. 1370, §1, 32 Stat. 712; Aug. 14, 1912, ch. 288, §2, 37 Stat. 309; Apr. 9, 1930, ch. 125, §10(a), 46 Stat. 152, provided for titles for officers of the Service. See section 207 of this title.

Section 35, act Apr. 9, 1930, ch. 125, §10(a), 46 Stat. 152, provided titles for officers other than medical officers of Service. See section 207 of this title.

Section 36, act Apr. 9, 1930, ch. 125, §10(a), 46 Stat. 152, provided titles for officers in grade of Assistant Surgeons General. See section 206 of this title.

Section 37, acts Apr. 9, 1930, ch. 125, §9, 46 Stat. 151; Nov. 11, 1943, ch. 298, §7, 57 Stat. 588, provided for promotions, pay and allowances, and severance from Service of commissioned officers. See sections 209 et seq. of this title.

Section 38, act Apr. 9, 1930, ch. 125, §4, 46 Stat. 150, provided for appointment and grades of medical, dental, sanitary engineer, and pharmacist officers. See section 209 of this title.

Section 39, Apr. 9, 1930, ch. 125, §5, 46 Stat. 150, provided for number, pay and allowances, and service credits for pay purposes of medical, dental, sanitary engineer, and pharmacist officers. See sections 209 et seq. of this title.

Section 40, act Apr. 9, 1930, ch. 125, §11, 46 Stat. 152, provided for appointment and qualifications of employees other than commissioned officers. See section 209 of this title.

Section 41, act Apr. 9, 1930, ch. 125, §7, 46 Stat. 151, provided for appointment of persons other than commissioned officers for scientific research. See section 209 of this title.

Section 42, act Apr. 9, 1930, ch. 125, §12, 46 Stat. 152, provided for medical and hospital services to officers disabled by sickness or injury. See sections 213 and 248 of this title.

Section 43, act Mar. 3, 1919, ch. 98, §3, 40 Stat. 1303, related to transfer of property and equipment to Service. Act Mar. 4, 1921, ch. 156, 41 Stat. 1365, formerly cited to section 43, was repealed by act Aug. 10, 1956, ch. 1041, §53, 70A Stat. 641.

STATUTORY NOTES AND RELATED SUBSIDIARIES

RENUMBERING AND REPEAL OF REPEALING ACT

Title XIII, §1313, formerly title VI, §611, of act July 1, 1944, which repealed these sections, was renumbered title VII, §711, by act Aug. 13, 1946, ch. 958, §5, 60 Stat. 1049; §713, by act Feb. 28, 1948, ch. 83, §9(b), 62 Stat. 47; title VIII, §813, by act July 30, 1956, ch. 779, §3(b), 70 Stat. 721; title IX, §913, by Pub. L. 88–581, §4(b), Sept. 4, 1964, 78 Stat. 919; title X, §1013, by Pub. L. 89–239, §3(b), Oct. 6, 1965, 79 Stat. 931; title XI, §1113, by Pub. L. 91–572, §6(b), Dec. 24, 1970, 84 Stat. 1506; title XII, §1213, by Pub. L. 92–294, §3(b), May 16, 1972, 86 Stat. 137; title XIII, §1313, by Pub. L. 93–154, §2(b)(2), Nov. 16, 1973, 87 Stat. 604, and was repealed by Pub. L. 93–222, §7(b), Dec. 29, 1973, 87 Stat. 936.

§§44, 45. Repealed. Oct. 31, 1951, ch. 654, §1(45), 65 Stat. 703

Section 44, act Mar. 15, 1920, ch. 100, §1, 41 Stat. 530; 1939 Reorg. Plan No. I, §201, eff. July 1, 1939, 4 F.R. 2728, 53 Stat. 1424, related to transfer of surplus motor-propelled vehicles in War Department (now Department of the Army) to Federal Security Agency for use of Public Health Service.

Section 45, act Mar. 15, 1920, ch. 100, §4, 41 Stat. 531; 1939 Reorg. Plan No. I, §201, eff. July 1, 1939, 4 F.R. 2728, 53 Stat. 1424, related to freight charges for transfer of motor-propelled vehicles in War Department (now Department of the Army) to Federal Security Agency for use of Public Health Service.

§46. Omitted

EDITORIAL NOTES

CODIFICATION

Section, which related to relocation of physicians and dentists, was from the First Supplemental National Defense Appropriation Act, 1944, act Dec. 23, 1943, ch. 380, title I, §101, 57 Stat. 617, and was not repeated in subsequent appropriation acts.

SUBCHAPTER II—PAY

§61. Omitted

EDITORIAL NOTES

CODIFICATION

Section, acts Jan. 22, 1925, ch. 87, title I, 43 Stat. 774; Mar. 2, 1926, ch. 43, title I, §1, 44 Stat. 147, related to travel expenses for travel on Government owned vessels and was superseded by section 404 et seq. of Title 37, Pay and Allowances of the Uniformed Services.

§62. Repealed. Aug. 10, 1956, ch. 1041, §53, 70A Stat. 641

Section, act May 18, 1920, ch. 190, §11 (proviso), 41 Stat. 604, related to longevity pay and credit for service in other branches. See section 517 of Title 10, Armed Forces, and sections 201, and 203 to 205 of Title 37, Pay and Allowances of the Uniformed Services.

§63. Omitted

EDITORIAL NOTES

CODIFICATION

Section, acts May 28, 1924, ch. 203, 43 Stat. 194; Feb. 11, 1925, ch. 209, 43 Stat. 872; May 21, 1926, ch. 355, 44 Stat. 604, which related to time spent at the Military and Naval Academies, expired with the appropriation acts of which it was a part.

§64. Repealed. Aug. 10, 1956, ch. 1041, §53, 70A Stat. 641

Section, act May 18, 1920, ch. 190, §12, 41 Stat. 604, related to transportation of dependents.

§§64a to 64c. Omitted

EDITORIAL NOTES

CODIFICATION

Section 64a, act Feb. 21, 1929, ch. 288, 45 Stat. 1254, defined child and children as used in section 64 of this title, and was superseded by section 401 of Title 37, Pay and Allowances of the Uniformed Services.

Section 64b, act June 24, 1935, ch. 291, §3, 49 Stat. 421, defined permanent change in station as used in section 64 of this title and was superseded by section 411 of Title 37.

Provisions of section 64c, which related to use of government automobiles to transport school children at isolated stations, were enacted as permanent legislation by the 1948 amendment to section 227 of this title. Section 64c was based upon the following prior appropriation acts:

June 14, 1948, ch. 465, title II, 62 Stat. 400.
July 8, 1947, ch. 210, title II, 61 Stat. 267.
July 26, 1946, ch. 672, title II, 60 Stat. 690.
July 3, 1945, ch. 263, title II, 59 Stat. 368.
June 28, 1944, ch. 302, title II, 58 Stat. 559.
July 12, 1943, ch. 221, title II, 57 Stat. 507.
July 2, 1942, ch. 475, title II, 56 Stat. 582.
July 1, 1941, ch. 269, title II, 55 Stat. 483.
June 26, 1940, ch. 428, title II, 54 Stat. 587.

§65. Repealed. Aug. 10, 1956, ch. 1041, §53, 70A Stat. 641

Section, acts Mar. 2, 1923, ch. 178, title I, 42 Stat. 1385; Aug. 4, 1949, ch. 393, §11, 63 Stat. 559, prohibited issuance of heat or light in kind to any person in Public Health Service while such person is receiving an allowance for rental of quarters.

§§66 to 69. Repealed. July 1, 1944, ch. 373, title XIII, §1313, 58 Stat. 714

Section 66, act Apr. 9, 1930, ch. 125, §8, 46 Stat. 151, provided for disability pay for commissioned officers. See section 212 of this title.

Section 67, act May 14, 1937, ch. 180, title I, 50 Stat. 148, provided for compensation of field employees rendering part-time and call services. See section 210 of this title.

Section 68, acts June 26, 1940, ch. 428, title II, 54 Stat. 584; July 1, 1941, ch. 269, title II, 55 Stat. 480, provided transportation funds for shipment of deceased officers. See section 224 of this title.

Section 69, acts May 27, 1908, ch. 200, 35 Stat. 373; May 13, 1938, ch. 213, 52 Stat. 352; Oct. 28, 1943, ch. 289, 57 Stat. 583, provided for settlement of accounts of deceased officers and men. See section 2771 of Title 10, Armed Forces.

STATUTORY NOTES AND RELATED SUBSIDIARIES

RENUMBERING AND REPEAL OF REPEALING ACT

Title XIII, §1313, formerly title VI, §611, of act July 1, 1944, which repealed these sections, was renumbered title VII, §711, by act Aug. 13, 1946, ch. 958, §5, 60 Stat. 1049; §713, by act Feb. 28, 1948, ch. 83, §9(b), 62 Stat. 47; title VIII, §813, by act July 30, 1956, ch. 779, §3(b), 70 Stat. 721; title IX, §913, by Pub. L. 88–581, §4(b), Sept. 4, 1964, 78 Stat. 919; title X, §1013, by Pub. L. 89–239, §3(b), Oct. 6, 1965, 79 Stat. 931; title XI, §1113, by Pub. L. 91–572, §6(b), Dec. 24, 1970, 84 Stat. 1506; title XII, §1213, by Pub. L. 92–294, §3(b), May 16, 1972, 86 Stat. 137; title XIII, §1313, by Pub. L. 93–154, §2(b)(2), Nov. 16, 1973, 87 Stat. 604, and was repealed by Pub. L. 93–222, §7(b), Dec. 29, 1973, 87 Stat. 936.

§70. Repealed. Pub. L. 89–554, §8(a), Sept. 6, 1966, 80 Stat. 655

Section, act June 30, 1949, ch. 286, title I, 63 Stat. 365, provided for a per diem allowance of officers detailed to the Coast Guard.

Acts June 26, 1943, ch. 147, title I, 57 Stat. 210; Mar. 31, 1943, ch. 30, §1, 57 Stat. 55; June 22, 1944, ch. 269, title I, 58 Stat. 315; May 29, 1945, ch. 130, 59 Stat. 216; July 12, 1946, ch. 569, §1, 60 Stat. 530; July 1, 1947, ch. 186, title I, 61 Stat. 225; June 19, 1948, ch. 558, title I, 62 Stat. 562, which contained provisions similar to section 70 of this title, were repealed by Pub. L. 89–554, §8(a), Sept. 6, 1966, 80 Stat. 651–654.

§70a. Repealed. Dec. 28, 1945, ch. 597, §4, 59 Stat. 662

Section, act Oct. 27, 1943, ch. 287, §6, 57 Stat. 583, provided for reimbursement for property lost or destroyed in service while serving with the Navy.

CHAPTER 1A—THE PUBLIC HEALTH SERVICE; SUPPLEMENTAL PROVISIONS

§§71 to 71*l*. Transferred

EDITORIAL NOTES

CODIFICATION

Section 71, act Apr. 9, 1930, ch. 125, §1, 46 Stat. 150, which provided for a detail for duty with executive and independent departments carrying on public health activities, was transferred to section 17a of this title.

Section 71a, act Apr. 9, 1930, ch. 125, §2(a), 46 Stat. 150, which provided for a detail for duty with educational and research institutions, was transferred to section 17b of this title.

Section 71b, act Apr. 9, 1930, ch. 125, §2(a), 46 Stat. 150, which provided for extension of facilities of Service to health officials and scientist, was transferred to section 8a of this title.

Section 71c, acts Apr. 9, 1930, ch. 125, §2(b), 46 Stat. 150; May 26, 1930, ch. 320, §1, 46 Stat. 379, which provided for additional divisions in Institute as authorized by Federal Security Administrator, was transferred to section 23g of this title.

Section 71d, act Apr. 9, 1930, ch. 125, §3, 46 Stat. 150, which provided that administrative office and bureau divisions in District of Columbia be a part of departmental organization and scientific offices and research laboratories be a part of the field service, was transferred to section 9a of this title.

Section 71e, act Apr. 9, 1930, ch. 125, §4, 46 Stat. 150, which provided for appointment and grades of medical, dental, sanitary, engineer, and pharmacist officers, was transferred to section 38 of this title.

Section 71f, act Apr. 9, 1930, ch. 125, §5, 46 Stat. 150, which provided for number, pay and allowances, and service credits for pay purposes of medical, dental, sanitary, engineer, and pharmacist officers, was transferred to section 39 of this title.

Section 71g, act Apr. 9, 1930, ch. 125, §6, 46 Stat. 151, which provided for assignment of Reserve officers to active duty and for such service counting for promotion credits, was transferred to section 18a of this title.

Section 71h, act Apr. 9, 1930, ch. 125, §7, 46 Stat. 151, which provided for appointment of persons other than commissioned officers for scientific research, was transferred to section 41 of this title.

Section 71i, act Apr. 9, 1930, ch. 125, §8, 46 Stat. 151, which provided for disability pay for commissioned officers, was transferred to section 66 of this title.

Section 71j, act Apr. 9, 1930, ch. 125, §9, 46 Stat. 151, which provided for promotions and pay and allowances of commissioned officers, was transferred to section 37 of this title.

Section 71k, act Apr. 9, 1930, ch. 125, §10(a), 46 Stat. 152, which provided titles for officers other than medical officers of Service, was transferred to section 35 of this title.

Section 71l, act Apr. 9, 1930, ch. 125, §10(a), 46 Stat. 152, which provided titles for officers in grade of Assistant Surgeon General, was transferred to section 36 of this title.

§71m. Omitted

EDITORIAL NOTES

CODIFICATION

Section, act Apr. 9, 1930, ch. 125, §10(a), 46 Stat. 152, which provided for repeal of limitation upon number of senior surgeons and Assistant Surgeons General at large of Public Health Service on active duty, was executed to section 34 of this title.

§§71n to 71q. Transferred

EDITORIAL NOTES

CODIFICATION

Section 71n, act Apr. 9, 1930, ch. 125, §10(b), 46 Stat. 152, which provided for pay and allowances of Surgeon General and for reversion in grade on expiration of term, was transferred to section 11a of this title.

Section 71o, act Apr. 9, 1930, ch. 125, §10(c), 46 Stat. 152, which provided for a Chief of the Narcotics Division, was transferred to section 28a of this title.

Section 71p, act Aug. 9, 1930, ch. 125, §11, 46 Stat. 152, which provided for appointment and qualifications of employees other than commissioned officers, was transferred to section 40 of this title.

Section 71q, act Apr. 9, 1930, ch. 125, §12, 46 Stat. 152, which provided for medical and hospital services to officers disabled by sickness or injury, was transferred to section 42 of this title.

§71r. Omitted

EDITORIAL NOTES

CODIFICATION

Section, acts Apr. 9, 1930, ch. 125, §13, 46 Stat. 152; May 26, 1930, ch. 320, §1, 46 Stat. 379, which changed the name of the Advisory board for National Institute of Health to the National Advisory Health Council and provided for appointment of additional members and the terms of service, compensation, and allowances for such additional members and an additional function for the Council, was executed to section 21 of this title.

CHAPTER 2—SANITATION AND QUARANTINE

Sec.

81 to 87. Repealed.
88. Discharge of cargo of vessel in quarantine.
89. Quarantine warehouses; erection.
90. Deposit of goods in warehouses.
91. Extending time for entry of vessels subject to quarantine.
92 to 96. Repealed.
97. State health laws observed by United States officers.
98. Vessels for quarantine officers.
99 to 111. Repealed.
112. Removal of revenue officers from port during epidemic.
113, 114. Repealed.

§§81 to 87. Repealed. July 1, 1944, ch. 373, title XIII, §1313, 58 Stat. 714

Section 81, act Feb. 15, 1893, ch. 114, §1, 27 Stat. 449, provided penalties for entry of vessels in violation of quarantine laws. See section 271 of this title.

Section 82, acts Feb. 15, 1893, ch. 114, §2, 27 Stat. 450; Aug. 18, 1894, ch. 300, 28 Stat. 372; Feb. 27, 1921, ch. 80, 41 Stat. 1149; Feb. 7, 1925, ch. 146, 43 Stat. 809; July 10, 1940, ch. 566, 54 Stat. 747, provided for bills of health. See section 269 of this title.

Section 82a, act Feb. 15, 1893, ch. 114, §13, as added Mar. 3, 1931, ch. 409, §1, 46 Stat. 1491, provided for duplicate bills of health. See section 269 of this title.

Section 83, act Feb. 15, 1893, ch. 114, §11, as added Mar. 3, 1901, ch. 836, 31 Stat. 1087, provided that vessels from foreign ports without bill of health not entering the United States were subject to quarantine regulations.

Section 84, act Feb. 15, 1893, ch. 114, §6, 27 Stat. 452, provided for disposition of infected vessels.

Section 85, act June 19, 1906, ch. 3433, §4, 34 Stat. 300, provided penalties for infractions of quarantine. See section 271 of this title.

Section 86, act Apr. 29, 1878, ch. 66, §1, 20 Stat. 37, prohibited entry of vessels and vehicles contrary to State quarantine laws. See sections 264 to 272 of this title. Compliance with State laws, see section 97 of this title.

Section 87, act Apr. 17, 1917, ch. 3, 40 Stat. 6, provided for payment of cost of fumigation and disinfection of foreign vessels.

STATUTORY NOTES AND RELATED SUBSIDIARIES

RENUMBERING AND REPEAL OF REPEALING ACT

Title XIII, §1313, formerly title VI, §611, of act July 1, 1944, which repealed these sections, was renumbered title VII, §711, by act Aug. 13, 1946, ch. 958, §5, 60 Stat. 1049; §713, by act Feb. 28, 1948, ch. 83, §9(b), 62 Stat. 47; title VIII, §813, by act July 30, 1956, ch. 779, §3(b), 70 Stat. 721; title IX, §913, by Pub. L. 88–581, §4(b), Sept. 4, 1964, 78 Stat. 919; title X, §1013, by Pub. L. 89–239, §3(b), Oct. 6, 1965, 79 Stat. 931; title XI, §1113, by Pub. L. 91–572, §6(b), Dec. 24, 1970, 84 Stat. 1506; title XII, §1213, by Pub. L. 92–294, §3(b), May 16, 1972, 86 Stat. 137; title XIII, §1313, by Pub. L. 93–154, §2(b)(2), Nov. 16, 1973, 87 Stat. 604, and was repealed by Pub. L. 93–222, §7(b), Dec. 29, 1973, 87 Stat. 936.

§88. Discharge of cargo of vessel in quarantine

Whenever, by the health laws of any State, or by the regulations made pursuant thereto, any vessel arriving within a collection district of such State is prohibited from coming to the port of entry by law established for such district, and such health laws require or permit the cargo of the vessel to be unladen at some other place within or near to such district, the collector, after due report to him of the whole of such cargo, may grant his warrant or permit for the unlading and discharge thereof, under the care of the surveyor, or of one or more inspectors, at some other place where such health laws permit, and upon the conditions and restrictions which shall be directed by the Secretary of Health and Human Services, or which such collector may, for the time, deem expedient for the security of the public revenue.

(R.S. §4793; 1939 Reorg. Plan No. I, §201, eff. July 1, 1939, 4 F.R. 2728, 53 Stat. 1424; 1953 Reorg. Plan No. 1, §§5, 8, eff. Apr. 11, 1953, 18 F.R. 2053, 67 Stat. 631; Pub. L. 96–88, title V, §509(b), Oct. 17, 1979, 93 Stat. 695.)

EDITORIAL NOTES

CODIFICATION

Words "or delivery" after "port of entry" which were included in this section as originally enacted were omitted as ports of delivery were abolished pursuant to the President's Message to Congress on Mar. 3, 1913, set out in Codification note under section 1 of Title 19, Customs Duties.

R.S. §4793 derived from act Feb. 23, 1799, ch. 12, §2, 1 Stat. 619.

STATUTORY NOTES AND RELATED SUBSIDIARIES

CHANGE OF NAME

"Secretary of Health and Human Services" substituted in text for "Secretary of Health, Education, and Welfare" pursuant to section 509(b) of Pub. L. 96–88, which is classified to section 3508(b) of Title 20, Education.

EXECUTIVE DOCUMENTS

TRANSFER OF FUNCTIONS

Functions of Federal Security Administrator transferred to Secretary of Health, Education, and Welfare and

all agencies of Federal Security Agency transferred to Department of Health, Education, and Welfare by section 5 of Reorg. Plan No. 1 of 1953, set out as a note under section 3501 of this title. Federal Security Agency and office of Administrator abolished by section 8 of Reorg. Plan No. 1 of 1953.

Functions of Department of the Treasury relating to public health transferred to Federal Security Agency pursuant to Reorg. Plan No. I of 1939, set out in the Appendix to Title 5, Government Organization and Employees.

§89. Quarantine warehouses; erection

There shall be purchased or erected, under the orders of the President, suitable warehouses, with wharves and inclosures, where merchandise may be unladen and deposited, from any vessel which shall be subject to a quarantine, or other restraint, pursuant to the health laws of any State, at such convenient places therein as the safety of the public revenue and the observance of such health laws may require.

(R.S. §4794.)

EDITORIAL NOTES

CODIFICATION

R.S. §4794 derived from act Feb. 23, 1799, ch. 12, §3, 1 Stat. 620.

§90. Deposit of goods in warehouses

Whenever the cargo of a vessel is unladen at some other place than the port of entry under sections 88 and 89 of this title, all the articles of such cargo shall be deposited, at the risk of the parties concerned therein, in such public or other warehouses or inclosures as the collector shall designate, there to remain under the joint custody of such collector and of the owner, or master, or other person having charge of such vessel, until the same are entirely unladen or discharged, and until the articles so deposited may be safely removed without contravening such health laws. And when such removal is allowed, the collector having charge of such articles may grant permits to the respective owners or consignees, their factors or agents, to receive all merchandise which has been entered, and the duties accruing upon which have been paid, upon the payment by them of a reasonable rate of storage; which shall be fixed by the Secretary of Health and Human Services for all public warehouses and inclosures.

(R.S. §4795; 1939 Reorg. Plan No. I, §201, eff. July 1, 1939, 4 F.R. 2728, 53 Stat. 1424; 1953 Reorg. Plan No. 1, §§5, 8 eff. Apr. 11, 1953, 18 F.R. 2053, 67 Stat. 631; Pub. L. 96–88, title V, §509(b), Oct. 17, 1979, 93 Stat. 695.)

EDITORIAL NOTES

CODIFICATION

R.S. §4795 derived from act Feb. 23, 1799, ch. 12, §2, 1 Stat. 619.

Omission of words "or delivery" after "port of entry", see Codification note set out under section 88 of this title.

STATUTORY NOTES AND RELATED SUBSIDIARIES

CHANGE OF NAME

"Secretary of Health and Human Services" substituted in text for "Secretary of Health, Education, and Welfare" pursuant to section 509(b) of Pub. L. 96–88, which is classified to section 3508(b) of Title 20, Education.

EXECUTIVE DOCUMENTS

TRANSFER OF FUNCTIONS

Functions of Federal Security Administrator transferred to Secretary of Health, Education, and Welfare and all agencies of Federal Security Agency transferred to Department of Health, Education, and Welfare by section 5 of Reorg. Plan No. 1 of 1953, set out as a note under section 3501 of this title. Federal Security Agency and office of Administrator abolished by section 8 of Reorg. Plan No. 1 of 1953.

Functions of Department of the Treasury relating to public health transferred to Federal Security Agency pursuant to Reorg. Plan No. I of 1939, set out in the Appendix to Title 5, Government Organization and Employees.

§91. Extending time for entry of vessels subject to quarantine

The Secretary of Health and Human Services is authorized, whenever a conformity to such quarantines and health laws requires it, and in respect to vessels subject thereto, to prolong the terms limited for the entry of the same, and the report or entry of their cargoes, and to vary or dispense with any other regulations applicable to such reports or entries. No part of the cargo of any vessel shall, however, in any case, be taken out or unladen therefrom, otherwise than is allowed by law, or according to the regulations established by sections 88 and 90 of this title.

(R.S. §4796; 1939 Reorg. Plan No. I, §201, eff. July 1, 1939, 4 F.R. 2728, 53 Stat. 1424; 1953 Reorg. Plan No. 1, §§5, 8, eff. Apr. 11, 1953, 18 F.R. 2053, 67 Stat. 631; Pub. L. 96–88, title V, §509(b), Oct. 17, 1979, 93 Stat. 695.)

EDITORIAL NOTES

CODIFICATION

R.S. §4796 derived from act Feb. 23, 1799, ch. 12, §1, 1 Stat. 619.

STATUTORY NOTES AND RELATED SUBSIDIARIES

CHANGE OF NAME

"Secretary of Health and Human Services" substituted in text for "Secretary of Health, Education, and Welfare" pursuant to section 509(b) of Pub. L. 96–88, which is classified to section 3508(b) of Title 20, Education.

EXECUTIVE DOCUMENTS

TRANSFER OF FUNCTIONS

Functions of Federal Security Administrator transferred to Secretary of Health, Education, and Welfare and all agencies of Federal Security Agency transferred to Department of Health, Education and Welfare by section 5 of 1953 Reorg. Plan No. 1 of 1953, set out as a note under section 3501 of this title. Federal Security Agency and office of Administrator abolished by section 8 of Reorg. Plan No. 1 of 1953.

Functions of Department of the Treasury relating to public health transferred to Federal Security Agency pursuant to Reorg. Plan No. I of 1939, set out in the Appendix to Title 5, Government Organization and Employees.

§§92 to 96. Repealed. July 1, 1944, ch. 373, title XIII, §1313, 58 Stat. 714

Section 92, acts Feb. 15, 1893, ch. 114, §3, 27 Stat. 450; July 1, 1902, ch. 1370, §1, 32 Stat. 712; Aug. 14, 1912, ch. 288, §1, 37 Stat. 309, provided for enforcement of quarantine regulations. See sections 264 to 267 of this title.

Section 92a, acts Apr. 29, 1878, ch. 66, §5, 20 Stat. 38; July 1, 1902, ch. 1370, §1, 32 Stat. 712; Aug. 14, 1912, §1, 37 Stat. 309, provided for a national quarantine system. See sections 264 to 267 of this title.

Section 93, acts Feb. 15, 1893, ch. 114, §4, 27 Stat. 451; July 1, 1902, ch. 1370, §1, 32 Stat. 712; Aug. 14,

1912, ch. 288, §1, 37 Stat. 309, provided for duties of Surgeon General relating to quarantine. See sections 264 to 270 of this title.

Section 94, act Feb. 15, 1893, ch. 114, §5, 27 Stat. 451, provided for regulations to secure sanitary conditions of vessels. See section 269 of this title.

Section 94a, act Feb. 15, 1893, ch. 114, §14, as added Mar. 3, 1931, ch. 409, §1, 46 Stat. 1492, provided for hours of inspection at quarantine stations. See section 267 of this title.

Section 94b, act Feb. 15, 1893, ch. 114, §16, as added Mar. 3, 1931, ch. 409, §1, 46 Stat. 1492, provided for schedule of charges and payment of them. See section 269 of this title.

Section 94c, act Feb. 15, 1893, ch. 114, §15, as added Mar. 3, 1931, ch. 409, §1, 46 Stat. 1492, provided for procurement of health certificates. See section 269 of this title.

Section 94d, act Feb. 15, 1893, ch. 114, §17, as added Mar. 3, 1931, ch. 409, §1, 46 Stat. 1492, provided medical and hospital benefits to officers and employees of national quarantine service. See section 253 of this title.

Section 94e, act Mar. 3, 1931, ch. 409, §3, 46 Stat. 1492, provided for extended quarantine service. See section 267 of this title.

Section 95, acts Mar. 27, 1890, ch. 51, §1, 26 Stat. 31; July 1, 1902, ch. 1370, §1, 32 Stat. 712; Aug. 14, 1912, ch. 288, §1, 37 Stat. 309, related to regulations to prevent spread of communicable diseases. See section 264 of this title.

Section 96, act June 19, 1906, ch. 3433, §6, 34 Stat. 301, provided that jurisdiction over established station acquired by the United States be ceded before payment of compensation.

STATUTORY NOTES AND RELATED SUBSIDIARIES

RENUMBERING AND REPEAL OF REPEALING ACT

Title XIII, §1313, formerly title VI, §611, of act July 1, 1944, which repealed these sections, was renumbered title VII, §711, by act Aug. 13, 1946, ch. 958, §5, 60 Stat. 1049; §713, by act Feb. 28, 1948, ch. 83, §9(b), 62 Stat. 47; title VIII, §813, by act July 30, 1956, ch. 779, §3(b), 70 Stat. 721; title IX, §913, by Pub. L. 88–581, §4(b), Sept. 4, 1964, 78 Stat. 919; title X, §1013, by Pub. L. 89–239, §3(b), Oct. 6, 1965, 79 Stat. 931; title XI, §1113, by Pub. L. 91–572, §6(b), Dec. 24, 1970, 84 Stat. 1506; title XII, §1213, by Pub. L. 92–294, §3(b), May 16, 1972, 86 Stat. 137; title XIII, §1313, by Pub. L. 93–154, §2(b)(2), Nov. 16, 1973, 87 Stat. 604, and was repealed by Pub. L. 93–222, §7(b), Dec. 29, 1973, 87 Stat. 936.

§97. State health laws observed by United States officers

The quarantines and other restraints established by the health laws of any State, respecting any vessels arriving in, or bound to, any port or district thereof, shall be duly observed by the officers of the customs revenue of the United States, by the masters and crews of the several Coast Guard vessels, and by the military officers commanding in any fort or station upon the seacoast; and all such officers of the United States shall faithfully aid in the execution of such quarantines and health laws, according to their respective powers and within their respective precincts, and as they shall be directed, from time to time, by the Secretary of Health and Human Services. But nothing in title 58 of the Revised Statutes shall enable any State to collect a duty of tonnage or impost without the consent of Congress.

(R.S. §4792; Jan. 28, 1915, ch. 20, §1, 38 Stat. 800; 1939 Reorg. Plan No. I, §201, eff. July 1, 1939, 4 F.R. 2728, 53 Stat. 1424; Aug. 4, 1949, ch. 393, §§1, 20, 63 Stat. 496, 561; 1953 Reorg. Plan No. 1, §§5, 8, eff. Apr. 11, 1953, 18 F.R. 2053, 67 Stat. 631; Pub. L. 96–88, title V, §509(b), Oct. 17, 1979, 93 Stat. 695.)

EDITORIAL NOTES

REFERENCES IN TEXT

Title 58 of the Revised Statutes, referred to in text, was in the original "this Title" meaning title 58 of the Revised Statutes, consisting of R.S. §§4792 to 4800, which were classified to sections 88 to 91, 97, and 112 to 114 of this title and section 8 of former Title 4, Flag and Seal, Seat of Government, and the States. Such section 8 of former Title 4 was repealed by act July 30, 1947, ch. 389, §2, 61 Stat. 645, and reenacted by the

first section thereof as section 73 of Title 4. For complete classification of R.S. §§4792 to 4800 to the Code, see Tables.

CODIFICATION

R.S. §4792 derived from act Feb. 23, 1799, ch. 12, §1, 1 Stat. 619.

STATUTORY NOTES AND RELATED SUBSIDIARIES

CHANGE OF NAME

"Secretary of Health and Human Services" substituted in text for "Secretary of Health, Education, and Welfare" pursuant to section 509(b) of Pub. L. 96–88, which is classified to section 3508(b) of Title 20, Education.

TRANSFER OF FUNCTIONS

For transfer of authorities, functions, personnel, and assets of the Coast Guard, including the authorities and functions of the Secretary of Transportation relating thereto, to the Department of Homeland Security, and for treatment of related references, see sections 468(b), 551(d), 552(d), and 557 of Title 6, Domestic Security, and the Department of Homeland Security Reorganization Plan of November 25, 2002, as modified, set out as a note under section 542 of Title 6.

"Coast Guard vessels" substituted in text for "revenue-cutters", Revenue Cutter Service and Life-Saving Service having been combined to form Coast Guard by section 1 of act Jan. 28, 1915. That act was repealed by section 20 of act Aug. 4, 1949, section 1 of which reestablished the Coast Guard by enacting Title 14, Coast Guard.

EXECUTIVE DOCUMENTS

TRANSFER OF FUNCTIONS

Functions of Federal Security Administrator transferred to Secretary of Health, Education, and Welfare and all agencies of Federal Security Agency transferred to Department of Health, Education, and Welfare by section 5 of Reorg. Plan No. 1 of 1953, set out as a note under section 3501 of this title. Federal Security Agency and office of Administrator abolished by section 8 of Reorg. Plan No. 1 of 1953.

Functions of Department of the Treasury relating to public health transferred to Federal Security Agency pursuant to Reorg. Plan No. I of 1939, set out in the Appendix to Title 5, Government Organization and Employees.

§98. Vessels for quarantine officers

The Secretary of the Navy is authorized, in his discretion, at the request of the Secretary of Health and Human Services, to place gratuitously, at the disposal of the proper quarantine authorities, at any of the ports of the United States, to be used temporarily for quarantine purposes, such vessels or hulks belonging to the United States as are not required for other uses of the national government, subject to such restrictions and regulations as the Secretary of the Navy may deem necessary to impose for the preservation thereof.

(June 14, 1879, No. 6, 21 Stat. 50; Feb. 15, 1893, ch. 114, 27 Stat. 449; July 1, 1902, ch. 1370, §1, 32 Stat. 712; Aug. 14, 1912, ch. 288, §1, 37 Stat. 309; 1939 Reorg. Plan No. I, §201, eff. July 1, 1939, 4 F.R. 2728, 53 Stat. 1424; 1953 Reorg. Plan No. 1, §§5, 8, eff. Apr. 11, 1953, 18 F.R. 2053, 67 Stat. 631; Pub. L. 96–88, title V, §509(b), Oct. 17, 1979, 93 Stat. 695.)

STATUTORY NOTES AND RELATED SUBSIDIARIES

CHANGE OF NAME

"Secretary of Health and Human Services" substituted in text for "Secretary of Health, Education, and Welfare" pursuant to section 509(b) of Pub. L. 96–88, which is classified to section 3508(b) of Title 20, Education.

REPEALS

Act Feb. 15, 1893, ch. 114, 27 Stat. 449, cited as a credit to this section and which abolished the National Board of Health and placed all duties relating to quarantines and quarantine regulations with the Marine Hospital Service, was repealed by act July 1, 1944, ch. 373, title XIII, §1313, formerly title VI, §611, 58 Stat. 714, renumbered title VII, §711, by act Aug. 13, 1946, ch. 958, §5, 60 Stat. 1049; §713 by act Feb. 28, 1948, ch. 83, §9(b), 62 Stat. 47; title VIII, §813, by act July 30, 1956, ch. 779, §3(b), 70 Stat. 721; title IX, §913, by Pub. L. 88–581, §4(b), Sept. 4, 1964, 78 Stat. 919; title X, §1013, by Pub. L. 89–239, §3(b), Oct. 6, 1965, 79 Stat. 931; title XI, §1113, by Pub. L. 91–572, §6(b), Dec 24, 1970, 84 Stat. 1506; title XII, §1213, by Pub. L. 92–294, §3(b), May 16, 1972, 86 Stat. 137; title XIII, §1313, by Pub. L. 93–154, §2(b)(2), Nov. 16, 1973, 87 Stat. 604, which was itself repealed by Pub. L. 93–222, §7(b), Dec. 29, 1973, 87 Stat. 936.

TRANSFER OF FUNCTIONS

Marine Hospital Service was redesignated Public Health and Marine Hospital Service by act July 1, 1902, ch. 1370, §1, 32 Stat. 712, which in turn was redesignated Public Health Service by act Aug. 14, 1912, ch. 288, §1, 37 Stat. 309.

National Board of Health was abolished and all duties relating to quarantines and quarantine regulations were placed in Marine Hospital Service by act Feb. 15, 1893, ch. 114, 27 Stat. 449.

EXECUTIVE DOCUMENTS

TRANSFER OF FUNCTIONS

Functions of Federal Security Administrator transferred to Secretary of Health, Education, and Welfare and all agencies of Federal Security Agency transferred to Department of Health, Education, and Welfare by section 5 of Reorg. Plan No. 1 of 1953, set out as a note under section 3501 of this title. Federal Security Agency and office of Administrator abolished by section 8 of Reorg. Plan No. 1 of 1953.

Public Health Service and its functions and personnel transferred from Department of the Treasury to Federal Security Agency pursuant to Reorg. Plan No. I of 1939, set out in the Appendix to Title 5, Government Organization and Employees.

§§99 to 108. Repealed. July 1, 1944, ch. 373, title XIII, §1313, 58 Stat. 714

Section 99, act Feb. 15, 1893, ch. 114, §12, as added Mar. 3, 1901, ch. 836, 31 Stat. 1087, authorized medical officers performing duties as quarantine officers to administer oaths. See section 272 of this title.

Section 100, act Feb. 15, 1893, ch. 114, §8, 27 Stat. 452, provided compensation for use of State buildings for quarantine purposes.

Section 101, act June 19, 1906, ch. 3433, §5, 34 Stat. 301, provided for acquisition of quarantine stations. See section 267 of this title.

Section 102, act Feb. 15, 1893, ch. 114, §10, as added Mar. 3, 1901, ch. 836, 31 Stat. 1086; amended July 1, 1902, ch. 1370, §1, 32 Stat. 712, provided for establishment of quarantine grounds. See sections 267 and 271 of this title.

Section 103, act June 19, 1906, ch. 3433, §1, 34 Stat. 299, provided for control and management of quarantine grounds. See section 267 of this title.

Section 104, acts June 19, 1906, ch. 3433, §2, 34 Stat. 299; Aug. 14, 1912, ch. 288, §1, 37 Stat. 309, provided for transferal of title of land and water from other departments to Service for its use.

Section 105, act June 19, 1906, ch. 3433, §3, 34 Stat. 300, provided for notice of selection of places for quarantine stations and anchorages.

Section 106, acts Aug. 1, 1888, ch. 727, 25 Stat. 355; July 1, 1902, ch. 1370, §1, 32 Stat. 712; Aug. 14, 1912, ch. 288, §1, 37 Stat. 309, provided penalties for trespass on quarantine stations. See section 271 of this title.

Section 107, act Mar. 27, 1890, ch. 51, §2, 26 Stat. 31, provided penalties for the violation of quarantine laws by officers of Service. See section 271 of this title.

Section 108, act Mar. 27, 1890, ch. 51, §3, 26 Stat. 32, provided penalties for the violation of quarantine laws by common carriers. See section 271 of this title.

STATUTORY NOTES AND RELATED SUBSIDIARIES

RENUMBERING AND REPEAL OF REPEALING ACT

Title XIII, §1313, formerly title VI, §611, of act July 1, 1944, which repealed these sections, was renumbered title VII, §711, by act Aug. 13, 1946, ch. 958, §5, 60 Stat. 1049; §713, by act Feb. 28, 1948, ch. 83, §9(b), 62 Stat. 47; title VIII, §813, by act July 30, 1956, ch. 779, §3(b), 70 Stat. 721; title IX, §913, by Pub. L. 88–581, §4(b), Sept. 4, 1964, 78 Stat. 919; title X, §1013, by Pub. L. 89–239, §3(b), Oct. 6, 1965, 79 Stat. 931; title XI, §1113, by Pub. L. 91–572, §6(b), Dec. 24, 1970, 84 Stat. 1506; title XII, §1213, by Pub. L. 92–294, §3(b), May 16, 1972, 86 Stat. 137; title XIII, §1313, by Pub. L. 93–154, §2(b)(2), Nov. 16, 1973, 87 Stat. 604, and was repealed by Pub. L. 93–222, §7(b), Dec. 29, 1973, 87 Stat. 936.

§109. Repealed. May 29, 1928, ch. 901, §1(24), 45 Stat. 986, 988

Section, acts June 12, 1917, ch. 27, 40 Stat. 121; June 5, 1920, ch. 235, 41 Stat. 885; Feb. 17, 1922, ch. 55, 42 Stat. 380; Jan. 3, 1923, ch. 22, 42 Stat. 1102; Apr. 4, 1924, ch. 84, title I, 43 Stat. 76; Jan. 20, 1925, ch. 85, 43 Stat. 757; Jan. 22, 1925, ch. 87, title I, 43 Stat. 775, required a detailed report to be made to Congress of expenditures to prevent epidemics.

§§110, 111. Repealed. July 1, 1944, ch. 373, title XIII, §1313, 58 Stat. 714

Section 110, acts June 5, 1920, ch. 235, 41 Stat. 875; June 16, 1921, ch. 23, 42 Stat. 38, provided for a schedule of charges for vessels at New York quarantine station. See section 269 of this title.

Section 111, act Feb. 15, 1893, ch. 114, §7, 27 Stat. 452, provided for suspension of immigration. See section 265 of this title.

STATUTORY NOTES AND RELATED SUBSIDIARIES

RENUMBERING AND REPEAL OF REPEALING ACT

Title XIII, §1313, formerly title VI, §611, of act July 1, 1944, which repealed these sections, was renumbered title VII, §711, by act Aug. 13, 1946, ch. 958, §5, 60 Stat. 1049; §713, by act Feb. 28, 1948, ch. 83, §9(b), 62 Stat. 47; title VIII, §813, by act July 30, 1956, ch. 779, §3(b), 70 Stat. 721; title IX, §913, by Pub. L. 88–581, §4(b), Sept. 4, 1964, 78 Stat. 919; title X, §1013, by Pub. L. 89–239, §3(b), Oct. 6, 1965, 79 Stat. 931; title XI, §1113, by Pub. L. 91–572, §6(b), Dec. 24, 1970, 84 Stat. 1506; title XII, §1213, by Pub. L. 92–294, §3(b), May 16, 1972, 86 Stat. 137; title XIII, §1313, by Pub. L. 93–154, §2(b)(2), Nov. 16, 1973, 87 Stat. 604, and was repealed by Pub. L. 93–222, §7(b), Dec. 29, 1973, 87 Stat. 936.

§112. Removal of revenue officers from port during epidemic

Whenever, by the prevalence of any contagious or epidemic disease in or near the place by law established as the port of entry for any collection district, it becomes dangerous or inconvenient for the officers of the revenue employed therein to continue the discharge of their respective offices at such port, the Secretary of the Treasury, or, in his absence, the Undersecretary of the Treasury, may direct the removal of the officers of the revenue from such port to any other more convenient place, within, or as near as may be to, such collection district. And at such place such officers may exercise the same powers, and shall be liable to the same duties, according to existing circumstances, as in the port or district established by law. Public notice of any such removal shall be given as soon as may be.

(R.S. §4797; July 31, 1894, ch. 174, §4, 28 Stat. 205; June 10, 1921, ch. 18, §301, 42 Stat. 23; Feb. 17, 1922, ch. 55, 42 Stat. 366.)

EDITORIAL NOTES

CODIFICATION

R.S. 4797 derived from act Feb. 23, 1799, ch. 12, §4, 1 Stat. 620.

Acts July 31, 1894, and June 10, 1921, abolished offices of First Comptroller and Comptroller of the

Treasury.

"Undersecretary of the Treasury" was substituted in text for "the First Comptroller" on authority of act Feb. 17, 1922.

§113. Repealed. June 25, 1948, ch. 646, §39, 62 Stat. 992, eff. Sept. 1, 1948

Section, R.S. §4799, act Mar. 3, 1911, ch. 231, §291, 36 Stat. 1167, related to adjournment of courts during an epidemic.

§114. Repealed. June 25, 1948, ch. 645, §21, 62 Stat. 862, eff. Sept. 1, 1948

Section, R.S. §4800, related to removal of prisoners during an epidemic.

CHAPTER 3—LEPROSY

§§121 to 125. Repealed. July 1, 1944, ch. 373, title XIII, §1313, 58 Stat. 714

Section 121, acts Mar. 3, 1905, ch. 1443, §1, 33 Stat. 1009; Aug. 14, 1912, ch. 288, §1, 37 Stat. 309, provided for establishment in perpetuity of a hospital station and laboratory at Molokai, Hawaii.

Section 122, act Mar. 3, 1905, ch. 1443, §3, 33 Stat. 1009, provided for admission and treatment of leper patients. See section 255 of this title.

Section 123, acts Mar. 3, 1905, ch. 1443, §4, 33 Stat. 1009; Aug. 14, 1912, ch. 288, §1, 37 Stat. 309, provided for detail of officers and employees for leprosy work. See section 215 of this title.

Section 124, acts Mar. 3, 1905, ch. 1443, §6, 33 Stat. 1010; Aug. 14, 1912, ch. 288, §1, 37 Stat. 309, provided regulations for administration of hospital station and laboratory.

Section 125, acts Mar. 3, 1905, ch. 1443, §7, 33 Stat. 1010; Mar. 4, 1911, ch. 285, §1, 36 Stat. 1394; Aug. 14, 1912, ch. 288, §1, 37 Stat. 309, provided for additional pay and allowances to officers detailed on leprosy duty. See section 210 of this title.

STATUTORY NOTES AND RELATED SUBSIDIARIES

RENUMBERING AND REPEAL OF REPEALING ACT

Title XIII, §1313, formerly title VI, §611, of act July 1, 1944, which repealed these sections, was renumbered title VII, §711, by act Aug. 13, 1946, ch. 958, §5, 60 Stat. 1049; §713, by act Feb. 28, 1948, ch. 83, §9(b), 62 Stat. 47; title VIII, §813, by act July 30, 1956, ch. 779, §3(b), 70 Stat. 721; title IX, §913, by Pub. L. 88–581, §4(b), Sept. 4, 1964, 78 Stat. 919; title X, §1013, by Pub. L. 89–239, §3(b), Oct. 6, 1965, 79 Stat. 931; title XI, §1113, by Pub. L. 91–572, §6(b), Dec. 24, 1970, 84 Stat. 1506; title XII, §1213, by Pub. L. 92–294, §3(b), May 16, 1972, 86 Stat. 137; title XIII, §1313, by Pub. L. 93–154, §2(b)(2), Nov. 16, 1973, 87 Stat. 604, and was repealed by Pub. L. 93–222, §7(b), Dec. 29, 1973, 87 Stat. 936.

§§131 to 135. Repealed. July 1, 1944, ch. 373, title XIII, §1313, 58 Stat. 714

Section 131, act Feb. 3, 1917, ch. 26, §1, 39 Stat. 872, provided for establishment of a leprosy home in the United States.

Section 132, act Feb. 3, 1917, ch. 26, §4, 39 Stat. 873, provided for erection of buildings for the home.

Section 133, act Feb. 3, 1917, ch. 26, §2, 39 Stat. 873, provided for receipt of lepers into the home. See section 255 of this title.

Section 134, act Feb. 3, 1917, ch. 26, §3, 39 Stat. 873, provided for regulations governing the home. See section 255 of this title.

Section 135, act Feb. 3, 1917, ch. 26, §5, 39 Stat. 873, provided for additional pay of officers detailed to duty at said home. See section 210 of this title.

STATUTORY NOTES AND RELATED SUBSIDIARIES

RENUMBERING AND REPEAL OF REPEALING ACT

Title XIII, §1313, formerly title VI, §611, of act July 1, 1944, which repealed these sections, was renumbered title VII, §711, by act Aug. 13, 1946, ch. 958, §5, 60 Stat. 1049; §713, by act Feb. 28, 1948, ch. 83, §9(b), 62 Stat. 47; title VIII, §813, by act July 30, 1956, ch. 779, §3(b), 70 Stat. 721; title IX, §913, by Pub. L. 88–581, §4(b), Sept. 4, 1964, 78 Stat. 919; title X, §1013, by Pub. L. 89–239, §3(b), Oct. 6, 1965, 79 Stat. 931; title XI, §1113, by Pub. L. 91–572, §6(b), Dec. 24, 1970, 84 Stat. 1506; title XII, §1213, by Pub. L. 92–294, §3(b), May 16, 1972, 86 Stat. 137; title XIII, §1313, by Pub. L. 93–154, §2(b)(2), Nov. 16, 1973, 87 Stat. 604, and was repealed by Pub. L. 93–222, §7(b), Dec. 29, 1973, 87 Stat. 936.

CHAPTER 3A—CANCER

§§137 to 137g. Repealed. July 1, 1944, ch. 373, title XIII, §1313, 58 Stat. 714

Section 137, act Aug. 5, 1937, ch. 565, §1, 50 Stat. 559, provided for establishment of National Cancer Institute. See section 281 of this title.

Section 137a, act Aug. 5, 1937, ch. 565, §2, 50 Stat. 559, provided for powers and duties of Surgeon General. See section 282 of this title.

Section 137b, act Aug. 5, 1937, ch. 565, §3, 50 Stat. 560, provided for establishment of National Advisory Cancer Council. See section 218 of this title.

Section 137c, act Aug. 5, 1937, ch. 565, §4, 50 Stat. 560, provided for powers and functions of Council. See section 284 of this title.

Section 137d, act Aug. 5, 1937, ch. 565, §5, 50 Stat. 561, provided for administration of powers by Surgeon General. See section 283 of this title.

Section 137e, act Aug. 5, 1937, ch. 565, §6, 50 Stat. 561, provided for acceptance of gifts. See section 283 of this title.

Section 137f, act Aug. 5, 1937, ch. 565, §7, 50 Stat. 561, provided for appropriations. See section 285 of this title.

Section 137g, act Aug. 5, 1937, ch. 565, §8, 50 Stat. 562, related to appointment of officers, functions under other provisions, regulations, reports, effective date, and citation. See sections 209, 216, 229, and 286 of this title.

STATUTORY NOTES AND RELATED SUBSIDIARIES

RENUMBERING AND REPEAL OF REPEALING ACT

Title XIII, §1313, formerly title VI, §611, of act July 1, 1944, which repealed these sections, was renumbered title VII, §711, by act Aug. 13, 1946, ch. 958, §5, 60 Stat. 1049; §713, by act Feb. 28, 1948, ch. 83, §9(b), 62 Stat. 47; title VIII, §813, by act July 30, 1956, ch. 779, §3(b), 70 Stat. 721; title IX, §913, by Pub. L. 88–581, §4(b), Sept. 4, 1964, 78 Stat. 919; title X, §1013, by Pub. L. 89–239, §3(b), Oct. 6, 1965, 79 Stat. 931; title XI, §1113, by Pub. L. 91–572, §6(b), Dec. 24, 1970, 84 Stat. 1506; title XII, §1213, by Pub. L. 92–294, §3(b), May 16, 1972, 86 Stat. 137; title XIII, §1313, by Pub. L. 93–154, §2(b)(2), Nov. 16, 1973, 87 Stat. 604, and was repealed by Pub. L. 93–222, §7(b), Dec. 29, 1973, 87 Stat. 936.

CHAPTER 4—VIRUSES, SERUMS, TOXINS, ANTITOXINS, ETC.

§§141 to 148. Repealed. July 1, 1944, ch. 373, title XIII, §1313, 58 Stat. 714

Section 141, act July 1, 1902, ch. 1378, §1, 32 Stat. 728, provided for regulation of sale of and interstate traffic of viruses, serums, toxins, antitoxins, etc. See section 262 of this title.

Section 142, act July 1, 1902, ch. 1378, §2, 32 Stat. 729, related to falsely labeling or marking container or

package. See section 262 of this title.

Section 143, act July 1, 1902, ch. 1378, §3, 32 Stat. 729, provided for inspection of manufacturing establishments. See section 262 of this title.

Section 144, act July 1, 1902, ch. 1378, §4, 32 Stat. 729, provided for inspection of foreign manufacturing establishments. See section 262 of this title.

Section 145, acts July 1, 1902, ch. 1370, §1, 32 Stat. 712; July 1, 1902, ch. 1378, §4, 32 Stat. 729; Aug. 14, 1912, ch. 288, 37 Stat. 309, provided for issuing of licenses to manufacturing establishments. See section 262 of this title.

Section 146, act July 1, 1902, ch. 1378, §5, 32 Stat. 729, provided for enforcement of regulations. See section 262 of this title.

Section 147, act July 1, 1902, ch. 1378, §6, 32 Stat. 729, provided against interfering with officers. See section 262 of this title.

Section 148, act July 1, 1902, ch. 1378, §7, 32 Stat. 729, related to penalties for offenses. See section 262 of this title.

STATUTORY NOTES AND RELATED SUBSIDIARIES

RENUMBERING AND REPEAL OF REPEALING ACT

Title XIII, §1313, formerly title VI, §611, of act July 1, 1944, which repealed these sections, was renumbered title VII, §711, by act Aug. 13, 1946, ch. 958, §5, 60 Stat. 1049; §713, by act Feb. 28, 1948, ch. 83, §9(b), 62 Stat. 47; title VIII, §813, by act July 30, 1956, ch. 779, §3(b), 70 Stat. 721; title IX, §913, by Pub. L. 88–581, §4(b), Sept. 4, 1964, 78 Stat. 919; title X, §1013, by Pub. L. 89–239, §3(b), Oct. 6, 1965, 79 Stat. 931; title XI, §1113, by Pub. L. 91–572, §6(b), Dec. 24, 1970, 84 Stat. 1506; title XII, §1213, by Pub. L. 92–294, §3(b), May 16, 1972, 86 Stat. 137; title XIII, §1313, by Pub. L. 93–154, §2(b)(2), Nov. 16, 1973, 87 Stat. 604, and was repealed by Pub. L. 93–222, §7(b), Dec. 29, 1973, 87 Stat. 936.

CHAPTER 5—MATERNITY AND INFANCY WELFARE AND HYGIENE

§§161 to 175. Repealed. Jan. 22, 1927, ch. 53, §2, 44 Stat. 1024, eff. June 30, 1929

Section 161, act Nov. 23, 1921, ch. 135, §3, 42 Stat. 224, related to creation of Board of Maternity and Infant Hygiene and administration of this chapter by Children's Bureau.

Section 162, act Nov. 23, 1921, ch. 135, §1, 42 Stat. 224, related to authorization of appropriations.

Section 163, acts Nov. 23, 1921, ch. 135, §2, 42 Stat. 224; Jan. 22, 1927, ch. 53, §1, 44 Stat. 1024, related to amount and apportionment of appropriations.

Section 164, act Nov. 23, 1921, ch. 135, §4, 42 Stat. 225, related to acceptance of provisions of this chapter by the States.

Section 165, act Nov. 23, 1921, ch. 135, §5, 42 Stat. 225, related to deduction of administrative expenses from appropriation.

Section 166, act Nov. 23, 1921, ch. 135, §6, 42 Stat. 225, related to clerical assistants for Children's Bureau.

Section 167, act Nov. 23, 1921, ch. 135, §7, 42 Stat. 225, related to apportionment of appropriation to States.

Section 168, act Nov. 23, 1921, ch. 135, §8, 42 Stat. 225, related to submission and approval of plans by States.

Section 169, act Nov. 23, 1921, ch. 135, §9, 42 Stat. 225, related to power of representatives of Children's Bureau to enter homes and to take charge of children.

Section 170, act Nov. 23, 1921, ch. 135, §10, 42 Stat. 225, related to certification of amounts apportioned to States.

Section 171, act Nov. 23, 1921, ch. 135, §11, 42 Stat. 226, related to reports by States.

Section 172, act Nov. 23, 1921, ch. 135, §12, 42 Stat. 226, related to limitation on expenditure of amounts apportioned to States.

Section 173, act Nov. 23, 1921, ch. 135, §13, 42 Stat. 226, related to requirement that Children's Bureau perform duties assigned to it by this chapter.

Section 174, act Nov. 23, 1921, ch. 135, §14, 42 Stat. 226, related to construction of this chapter.

Section 175, act Mar. 10, 1924, ch. 46, §3, 43 Stat. 17, related to extension of this chapter to Hawaii.

CHAPTER 6—THE CHILDREN'S BUREAU

Sec.

191. Bureau established.
192. Chief of bureau; investigations and reports.
193. Assistant chief.
194. Quarters for bureau.

§191. Bureau established

There shall be established in the Department of Health and Human Services a bureau to be known as the Children's Bureau.

(Apr. 9, 1912, ch. 73, §1, 37 Stat. 79; Mar. 4, 1913, ch. 141, §3, 37 Stat. 737; 1946 Reorg. Plan No. 2, §1, eff. July 16, 1946, 11 F.R. 7873, 60 Stat. 1095; 1953 Reorg. Plan No. 1, §§5, 8, eff. Apr. 11, 1953, 18 F.R. 2053, 67 Stat. 631; Pub. L. 96–88, title V, §509(b), Oct. 17, 1979, 93 Stat. 695.)

EDITORIAL NOTES

CODIFICATION

Section was formerly classified to section 18 of Title 29, Labor.

STATUTORY NOTES AND RELATED SUBSIDIARIES

CHANGE OF NAME

"Department of Health and Human Services" substituted in text for "Department of Health, Education, and Welfare" pursuant to section 509(b) of Pub. L. 96–88, which is classified to section 3508(b) of Title 20, Education.

TRANSFER OF FUNCTIONS

Functions authorized by section 192 of this title and such other functions of Federal Security Agency as Administrator might designate were to be administered through Children's Bureau under his direction and control.

Functions of Children's Bureau under sections 201 to 216, 217 to 219 of Title 29, Labor, transferred to Secretary of Labor.

Act Apr. 9, 1912, established Children's Bureau in Department of Commerce and Labor. Act Mar. 4, 1913, transferred Children's Bureau to Department of Labor, which was created by that act, and was authority for substitution of "Department of Labor" for "Department of Commerce and Labor".

EXECUTIVE DOCUMENTS

TRANSFER OF FUNCTIONS

Functions of Federal Security Administrator transferred to Secretary of Health, Education, and Welfare and all agencies of Federal Security Agency transferred to Department of Health, Education, and Welfare by section 5 of Reorg. Plan No. 1 of 1953, set out as a note under section 3501 of this title. Federal Security Agency and office of Administrator abolished by section 8 of Reorg. Plan No. 1 of 1953.

"Federal Security Agency" substituted for "Department of Labor" pursuant to Reorg. Plan No. 2 of 1946, set out in the Appendix to Title 5, Government Organization and Employees, which transferred Children's Bureau, exclusive of its Industrial Division, from Department of Labor to Federal Security Agency. Functions of Bureau, its Chief, and of Secretary of Labor relating to such functions transferred to Federal Security Administrator.

For transfer of personnel, property, records and funds, see section 12 of Reorg. Plan No. 2 of 1946.

§192. Chief of bureau; investigations and reports

The Children's Bureau shall be under the direction of a chief, to be appointed by the President, by and with the advice and consent of the Senate. The said bureau shall investigate and report to the Secretary of Health and Human Services, upon all matters pertaining to the welfare of children and child life among all classes of our people, and shall especially investigate the questions of infant mortality, the birth rate, orphanage, juvenile courts, desertion, dangerous occupations, accidents and diseases of children, employment, legislation affecting children in the several States and Territories. But no official, or agent, or representative of said bureau shall, over the objection of the head of the family, enter any house used exclusively as a family residence. The chief of said bureau may from time to time publish the results of these investigations in such manner and to such extent as may be prescribed by the Secretary.

(Apr. 9, 1912, ch. 73, §2, 37 Stat. 79; Mar. 4, 1913, ch. 141, §§3, 6, 37 Stat. 737, 738; 1946 Reorg. Plan No. 2, §1, eff. July 16, 1946, 11 F.R. 7873, 60 Stat. 1095; 1953 Reorg. Plan No. 1, §§5, 8, eff. Apr. 11, 1953, 18 F.R. 2053, 67 Stat. 631; Pub. L. 96–88, title V, §509(b), Oct. 17, 1979, 93 Stat. 695.)

EDITORIAL NOTES

CODIFICATION

In the first sentence of this section, provisions which specified an annual compensation of $5,000 for the chief of the Childrens Bureau have been omitted superseded. Following enactment of the Classification Act of 1923, the compensation was fixed in accordance with that Act. See act Feb. 27, 1925, title IV, 43 Stat. 1050. Sections 1202 and 1204 of the Classification Act of 1949, 63 Stat. 972, 973, repealed the Classification Act of 1923 and all other laws or parts of laws inconsistent with the 1949 Act. The Classification Act of 1949 was repealed by Pub. L. 89–554, Sept. 6, 1966, §8(a), 80 Stat. 632, and reenacted as chapter 51 and subchapter III of chapter 53 of Title 5, Government Organization and Employees. Section 5102 of Title 5 now contains the applicability provisions of the 1949 Act, and section 5103 of Title 5 authorizes the Office of Personnel Management to determine the applicability to specific positions and employees.

Section was formerly classified to section 18a of Title 29, Labor.

STATUTORY NOTES AND RELATED SUBSIDIARIES

CHANGE OF NAME

"Secretary of Health and Human Services" substituted in text for "Secretary of Health, Education, and Welfare" pursuant to section 509(b) of Pub. L. 96–88, which is classified to section 3508(b) of Title 20, Education.

"Secretary of Labor" substituted for "Secretary of Commerce and Labor" pursuant to act Mar. 4, 1913. See note set out under section 191 of this title.

EXECUTIVE DOCUMENTS

TRANSFER OF FUNCTIONS

Functions of Federal Security Administrator transferred to Secretary of Health, Education, and Welfare and all agencies of Federal Security Agency transferred to Department of Health, Education, and Welfare by section 5 of Reorg. Plan No. 1 of 1953, set out as a note under section 3501 of this title. Federal Security Agency and office of Administrator abolished by section 8 of Reorg. Plan No. 1 of 1953.

"Federal Security Administrator" substituted for "said department" and for "Secretary of Labor" pursuant to Reorg. Plan No. 2 of 1946. See note set out under section 191 of this title.

§193. Assistant chief

There shall be in the Children's Bureau, until otherwise provided for by law, an assistant chief, to

be appointed by the Secretary of Health and Human Services.

(Apr. 9, 1912, ch. 73, §3, 37 Stat. 80; Mar. 4, 1913, ch. 141, §§3, 6, 37 Stat. 737, 738; 1946 Reorg. Plan No. 2, §1, eff. July 16, 1946, 11 F.R. 7873, 60 Stat. 1095; 1953 Reorg. Plan No. 1, §§5, 8, eff. Apr. 11, 1953, 18 F.R. 2053, 67 Stat. 631; Pub. L. 96–88, title V, §509(b), Oct. 17, 1979, 93 Stat. 695.)

EDITORIAL NOTES

CODIFICATION

Section 3 of act Apr. 9, 1912, also provided for compensation of assistant chief and for appointment and compensation of other employees of the bureau.

Section was formerly classified to section 18b of Title 29, Labor.

STATUTORY NOTES AND RELATED SUBSIDIARIES

CHANGE OF NAME

"Secretary of Health and Human Services" substituted in text for "Secretary of Health, Education, and Welfare" pursuant to section 509(b) of Pub. L. 96–88, which is classified to section 3508(b) of Title 20, Education.

"Secretary of Labor" substituted for "Secretary of Commerce and Labor" pursuant to act Mar. 4, 1913. See note set out under section 191 of this title.

EXECUTIVE DOCUMENTS

TRANSFER OF FUNCTIONS

Functions of Federal Security Administrator transferred to Secretary of Health, Education, and Welfare and all agencies of Federal Security Agency transferred to Department of Health, Education, and Welfare by section 5 of Reorg. Plan No. 1 of 1953, set out in as a note under section 3501 of this title. Federal Security Agency and office of Administrator abolished by section 8 of Reorg. Plan No. 1 of 1953.

"Federal Security Administrator" substituted for "Secretary of Labor" pursuant to Reorg. Plan No. 2 of 1946. See note set out under section 191 of this title.

§194. Quarters for bureau

The Secretary of Health and Human Services is directed to furnish sufficient quarters for the work of this bureau at an annual rental not to exceed $2,000.

(Apr. 9, 1912, ch. 73, §4, 37 Stat. 80; Mar. 4, 1913, ch. 141, §3, 37 Stat. 737; 1946 Reorg. Plan No. 2, §1, eff. July 16, 1946, 11 F.R. 7873, 60 Stat. 1095; 1953 Reorg. Plan No. 1, §§5, 8, eff. Apr. 11, 1953, 18 F.R. 2053, 67 Stat. 631; Pub. L. 96–88, title V, §509(b), Oct. 17, 1979, 93 Stat. 695.)

EDITORIAL NOTES

CODIFICATION

Section was formerly classified to section 18c of Title 29, Labor.

STATUTORY NOTES AND RELATED SUBSIDIARIES

CHANGE OF NAME

"Secretary of Health and Human Services" substituted in text for "Secretary of Health, Education, and Welfare" pursuant to section 509(b) of Pub. L. 96–88, which is classified to section 3508(b) of Title 20, Education.

"Secretary of Labor" substituted for "Secretary of Commerce and Labor" pursuant to act Mar. 4, 1913. See note set out under section 191 of this title.

EXECUTIVE DOCUMENTS

TRANSFER OF FUNCTIONS

Functions of Federal Security Administrator transferred to Secretary of Health, Education, and Welfare and all agencies of Federal Security Agency transferred to Department of Health, Education, and Welfare by section 5 of Reorg. Plan No. 1 of 1953, set out as a note under section 3501 of this title. Federal Security Agency and office of Administrator abolished by section 8 of Reorg. Plan No. 1 of 1953.

"Federal Security Administrator" substituted for "Secretary of Labor" pursuant to Reorg. Plan No. 2 of 1946. See note set out under section 191 of this title.

CHAPTER 6A—PUBLIC HEALTH SERVICE

SUBCHAPTER I—ADMINISTRATION AND MISCELLANEOUS PROVISIONS

Sec.

201. Definitions.

PART A—ADMINISTRATION

202. Administration and supervision of Service.
203. Organization of Service.
204. Commissioned Corps and Ready Reserve Corps.
204a. Deployment readiness.
205. Appointment and tenure of office of Surgeon General; reversion in rank.
206. Assignment of officers.
207. Grades, ranks, and titles of commissioned corps.
208. Repealed.
209. Appointment of personnel.
209a to 209c. Omitted or Repealed.
209d. Appointment of osteopaths as commissioned officers.
210. Pay and allowances.
210–1. Annual and sick leave.
210a. Repealed.
210b. Professional categories.
211. Promotion of commissioned officers.
211a, 211b. Repealed.
211c. Promotion credit for medical officers in assistant grade.
212. Retirement of commissioned officers.
212a, 212b. Repealed.
213. Military benefits.
213a. Rights, benefits, privileges, and immunities for commissioned officers or beneficiaries; exercise of authority by Secretary or designee.
214. Presentation of United States flag upon retirement.
214a. Repealed.
215. Detail of Service personnel.
216. Regulations.
217. Use of Service in time of war or emergency.
217a. Advisory councils or committees.
217a–1. Advisory committees; prohibition of consideration of political affiliations.
217b. Volunteer services.

218. National Advisory Councils on Migrant Health.
218a. Training of officers.
219 to 230. Transferred, Repealed, or Omitted.
231. Service and supply fund; uses; reimbursement.
232. National Institute of Mental Health; authorization of appropriation; construction; location.
233. Civil actions or proceedings against commissioned officers or employees.
234. Health care professionals assisting during a public health emergency.
235. Administration of grants in multigrant projects; promulgation of regulations.
236. Orphan Products Board.
237. Silvio O. Conte Senior Biomedical Research and Biomedical Product Assessment Service.
237a. Health and Human Services Office on Women's Health.

PART B—MISCELLANEOUS PROVISIONS

238. Gifts for benefit of Service.
238a. Use of immigration station hospitals.
238b. Disposition of money collected for care of patients.
238c. Transportation of remains of officers.
238d. Availability of appropriations for grants to Federal institutions.
238e. Transfer of funds.
238f. Availability of appropriations.
238g. Wearing of uniforms.
238h. Biennial report.
238i. Memorials and other acknowledgments for contributions to health of Nation.
238j. Evaluation of programs.
238k. Contract authority.
238*l.* Recovery.
238m. Use of fiscal agents.
238n. Abortion-related discrimination in governmental activities regarding training and licensing of physicians.
238*o.* Restriction on use of funds for assisted suicide, euthanasia, and mercy killing.
238p. Recommendations and guidelines regarding automated external defibrillators for Federal buildings.
238q. Liability regarding emergency use of automated external defibrillators.

PART C—SMALLPOX EMERGENCY PERSONNEL PROTECTION

239. General provisions.
239a. Determination of eligibility and benefits.
239b. Smallpox vaccine injury table.
239c. Medical benefits.
239d. Compensation for lost employment income.
239e. Payment for death.
239f. Administration.
239g. Authorization of appropriations.
239h. Relationship to other laws.

PART D—UNITED STATES PUBLIC HEALTH SCIENCES TRACK

239*l.* Establishment.
239l–1. Administration.
239l–2. Students; selection; obligation.
239l–3. Funding.

SUBCHAPTER II—GENERAL POWERS AND DUTIES

PART A—RESEARCH AND INVESTIGATIONS

241. Research and investigations generally.

242. Studies and investigations on use and misuse of narcotic drugs and other drugs; annual report to Attorney General; cooperation with States.
242a. Repealed.
242b. General authority respecting research, evaluations, and demonstrations in health statistics, health services, and health care technology.
242c. Appointment and authority of the Director of the Centers for Disease Control and Prevention.
242c–1. Advisory committee to the Director.
242d to 242j. Repealed or Transferred.
242k. National Center for Health Statistics.
242*l*. International cooperation.
242m. General provisions respecting effectiveness, efficiency, and quality of health services.
242n. Repealed.
242*o*. Health conferences; publication of health educational information.
242p. National disease prevention data profile.
242q. Task Force on Aging Research; establishment and duties.
242q–1. Membership.
242q–2. Administrative staff and support.
242q–3. Repealed.
242q–4. Definitions.
242q–5. Authorization of appropriations.
242r. Improvement and publication of data on food-related allergic responses.
242s. Centers for Disease Control and Prevention Office of Women's Health.
242t. CDC surveillance and data collection for child, youth, and adult trauma.
242u. Improving State, local, and Tribal information sharing.
242v. Foreign talent recruitment programs.
242v–1. Securing identifiable, sensitive information and addressing other national security risks related to research.
242v–2. Protecting America's biomedical research enterprise.
242v–3. Report on progress to address undue foreign influence.

PART B—FEDERAL-STATE COOPERATION

243. General grant of authority for cooperation.
244. Public access defibrillation programs.
244–1. Repealed.
244a. Materials and resources to increase education and awareness of cardiomyopathy among school administrators, educators, and families.
244b. Activities relating to cardiomyopathy.
244c. Cardiomyopathy research.
244d. Promoting student access to AEDs and CPR.
245. Public awareness campaign on the importance of vaccinations.
245a. Repealed.
246. Grants and services to States.
246a. Bureau of State Services management fund; establishment; advancements; availability.
247. Assisting veterans with military emergency medical training to meet requirements for becoming civilian health care professionals.
247a. Family support groups for Alzheimer's disease patients.
247b. Project grants for preventive health services.
247b–1. Screenings, referrals, and education regarding lead poisoning.
247b–2. Repealed.
247b–3. Education, technology assessment, and epidemiology regarding lead poisoning.
247b–3a. Training and reports by the Health Resources and Services Administration.
247b–4. National Center on Birth Defects and Developmental Disabilities.

247b–4a. Early detection, diagnosis, and interventions for newborns and infants with hearing loss.
247b–4b to 247b–4e. Repealed.
247b–4f. Research relating to preterm labor and delivery and the care, treatment, and outcomes of preterm and low birthweight infants.
247b–4g. Repealed.
247b–5. Preventive health measures with respect to prostate cancer.
247b–6. National strategy for combating and eliminating tuberculosis.
247b–7. Loan repayment program.
247b–8. Fellowship and training programs.
247b–9. Diabetes in children and youth.
247b–9a. Better diabetes care.
247b–10. Compilation of data on asthma.
247b–11. Effects of folic acid in prevention of birth defects.
247b–12. Safe motherhood.
247b–13. Prenatal and postnatal health.
247b–13a. Screening and treatment for maternal mental health and substance use disorders.
247b–14. Oral health promotion and disease prevention.
247b–14a. Identification of interventions that reduce the burden and transmission of oral, dental, and craniofacial diseases in high risk populations; development of approaches for pediatric oral and craniofacial assessment.
247b–15. Surveillance and education regarding infections associated with illicit drug use and other risk factors.
247b–16. Grants for lead poisoning related activities.
247b–17. Human papillomavirus (Johanna's Law).
247b–18. Surveillance and research regarding muscular dystrophy.
247b–19. Information and education.
247b–20. Food safety grants.
247b–21. Mosquito-borne diseases; coordination grants to States; assessment and control grants to political subdivisions.
247b–22. Microbicide research.
247b–23. National strategy and regional centers of excellence in vector-borne diseases.
247b–24. Addressing factors related to improving health outcomes.
247c. Sexually transmitted diseases; prevention and control projects and programs.
247c–1. Infertility and sexually transmitted diseases.
247c–2. Data collection regarding programs under subchapter XXIV.
247d. Public health emergencies.
247d–1. Vaccine tracking and distribution.
247d–2. Earlier development of diagnostic tests.
247d–3. Repealed.
247d–3a. Improving State and local public health security.
247d–3b. Partnerships for State and regional hospital preparedness to improve surge capacity.
247d–3c. Guidelines for regional health care emergency preparedness and response systems.
247d–4. Facilities and capacities of the Centers for Disease Control and Prevention.
247d–4a. Infectious Diseases Rapid Response Reserve Fund.
247d–4b. Children's Preparedness Unit.
247d–5. Combating antimicrobial resistance.
247d–5a. Repealed.
247d–6. Public health countermeasures to a bioterrorist attack.
247d–6a. Authority for use of certain procedures regarding qualified countermeasure research and development activities.
247d–6b. Strategic National Stockpile and security countermeasure procurements.
247d–6c. Repealed.
247d–6d. Targeted liability protections for pandemic and epidemic products and security

countermeasures.
247d–6e. Covered countermeasure process.
247d–6f. Provision of medical countermeasures to Indian programs and facilities.
247d–7. Repealed.
247d–7a. Grants regarding training and education of certain health professionals.
247d–7b. Emergency system for advance registration of volunteer health professional.
247d–7c. Supplies and services in lieu of award funds.
247d–7d. Security for countermeasure development and production.
247d–7e. Biomedical Advanced Research and Development Authority.
247d–7f. Collaboration and coordination.
247d–7g. National Biodefense Science Board and working groups.
247d–8. Coordinated program to improve pediatric oral health.
247d–9. Dental education for parents of newborns.
247d–10. Pilot program for public health laboratories to detect fentanyl and other synthetic opioids.
247d–11. State All Payer Claims Databases.
247d–12. Coordination and collaboration regarding blood supply.

PART C—HOSPITALS, MEDICAL EXAMINATIONS, AND MEDICAL CARE

247e. National Hansen's Disease Programs Center.
248. Control and management of hospitals; furnishing prosthetic and orthopedic devices; transfer of patients; disposal of articles produced by patients; disposal of money and effects of deceased patients; payment of burial expenses.
248a. Closing or transfer of hospitals; reduction of services; Congressional authorization required.
248b. Transfer or financial self-sufficiency of public health service hospitals and clinics.
248c, 248d. Repealed.
249. Medical care and treatment of quarantined and detained persons.
250. Medical care and treatment of Federal prisoners.
250a. Transfer of appropriations.
251. Medical examination and treatment of Federal employees; medical care at remote stations.
252. Medical examination of aliens.
253. Medical services to Coast Guard, National Oceanic and Atmospheric Administration, and Public Health Service.
253a. Medical services to retired personnel of National Oceanic and Atmospheric Administration.
253b. Former Lighthouse Service employees; medical service eligibility.
254. Interdepartmental work.
254a. Sharing of medical care facilities and resources.

PART D—PRIMARY HEALTH CARE

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254b. Health centers.
254b–1. State grants to health care providers who provide services to a high percentage of medically underserved populations or other special populations.
254b–2. Community health centers and the National Health Service Corps Fund.
254c. Rural health care services outreach, rural health network development, and small health care provider quality improvement grant programs.
254c–1. Grants for health services for Pacific Islanders.
254c–1a. Grants to nurse-managed health clinics.
254c–1b. Rural obstetric network grants.
254c–2. Special diabetes programs for type I diabetes.
254c–3. Special diabetes programs for Indians.

254c–4. Repealed.
254c–5. Epilepsy; seizure disorder.
254c–6. Certain services for pregnant women.
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285m–2. Data System and Information Clearinghouse.
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285*o*. Purpose of Institute.
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290aa–0a. Behavioral health crisis coordinating office.
290aa–0b. Interdepartmental Serious Mental Illness Coordinating Committee.
290aa–1. Advisory councils.
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290aa–2a. Report on individuals with co-occurring mental illness and substance abuse disorders.
290aa–3. Peer review.

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290aa–4. Center for behavioral health statistics and quality.
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290aa–17. Assisted outpatient treatment grant program for individuals with serious mental illness.
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290bb–2. Priority substance use disorder treatment needs of regional and national significance.
290bb–2a. Medical treatment of narcotics addiction; report to Congress.
290bb–3 to 290bb–5. Repealed.
290bb–6. Action by Center for Substance Abuse Treatment and States concerning military facilities.
290bb–7. Substance use disorder treatment and early intervention services for children, adolescents, and young adults.
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290bb–21. Center for Substance Abuse Prevention.
290bb–22. Priority substance use disorder prevention needs of regional and national significance.
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290bb–25c. Repealed.
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SUBCHAPTER I—ADMINISTRATION AND MISCELLANEOUS PROVISIONS

§201. Definitions

When used in this chapter—

(a) The term "Service" means the Public Health Service;

(b) The term "Surgeon General" means the Surgeon General of the Public Health Service;

(c) Unless the context otherwise requires, the term "Secretary" means the Secretary of Health and Human Services.

(d) The term "regulations", except when otherwise specified, means rules and regulations made by the Surgeon General with the approval of the Secretary;

(e) The term "executive department" means any executive department, agency, or independent establishment of the United States or any corporation wholly owned by the United States;

(f) Except as provided in sections 246(g)(4)(B),[1] 247c(c)(1),[1] 254d(h)(3),[1] 263c(5),[1] 264(d), 292a(9),[1] 300a(c), 300f(13), and 300n(1) [1] of this title, the term "State" includes, in addition to the several States, only the District of Columbia, Guam, the Commonwealth of Puerto Rico, the Northern Mariana Islands, the Virgin Islands, American Samoa, the Federated States of Micronesia, the Republic of the Marshall Islands, and the Republic of Palau.

(g) The term "possession" includes, among other possessions, Puerto Rico and the Virgin Islands;

(h) Repealed. Pub. L. 97–35, title IX, §986(a), Aug. 13, 1981, 95 Stat. 603.

(i) The term "vessel" includes every description of watercraft or other artificial contrivance used, or capable of being used, as a means of transportation on water, exclusive of aircraft and amphibious contrivances;

(j) The term "habit-forming narcotic drug" or "narcotic" means opium and coca leaves and the several alkaloids derived therefrom, the best known of these alkaloids being morphia, heroin, and codeine, obtained from opium, and cocaine derived from the coca plant; all compounds, salts, preparations, or other derivatives obtained either from the raw material or from the various alkaloids; Indian hemp and its various derivatives, compounds, and preparations, and peyote in its various forms; isonipecaine and its derivatives, compounds, salts, and preparations; opiates (as defined in section 4731(g) [1] of title 26);

(k) The term "addict" means any person who habitually uses any habit-forming narcotic drugs so as to endanger the public morals, health, safety, or welfare, or who is or has been so far addicted to the use of such habit-forming narcotic drugs as to have lost the power of self-control with reference to his addiction;

(l) The term "psychiatric disorders" includes diseases of the nervous system which affect mental health;

(m) The term "State mental health authority" means the State health authority, except that, in the case of any State in which there is a single State agency, other than the State health authority, charged with responsibility for administering the mental health program of the State, it means such other State agency;

(n) The term "heart diseases" means diseases of the heart and circulation;

(o) The term "dental diseases and conditions" means diseases and conditions affecting teeth and their supporting structures, and other related diseases of the mouth; and

(p) The term "uniformed service" means the Army, Navy, Air Force, Marine Corps, Coast Guard, Public Health Service, or National Oceanic and Atmospheric Administration.

(q) The term "drug dependent person" means a person who is using a controlled substance (as defined in section 802 of title 21) and who is in a state of psychic or physical dependence, or both, arising from the use of that substance on a continuous basis. Drug dependence is characterized by behavioral and other responses which include a strong compulsion to take the substance on a continuous basis in order to experience its psychic effects or to avoid the discomfort caused by its absence.

(July 1, 1944, ch. 373, title I, §2, 58 Stat. 682; July 3, 1946, ch. 538, §3, 60 Stat. 421; Feb. 28, 1948, ch. 83, §1, 62 Stat. 38; June 16, 1948, ch. 481, §6(a), 62 Stat. 469; June 24, 1948, ch. 621, §6(a), 62 Stat. 601; 1953 Reorg. Plan No. 1, §§5, 8, eff. Apr. 11, 1953, 18 F.R. 2053, 67 Stat. 631; Pub. L. 86–70, §31(a), June 25, 1959, 73 Stat. 148; Pub. L. 86–415, §5(a), Apr. 8, 1960, 74 Stat. 34; Pub. L. 86–624, §29(a), July 12, 1960, 74 Stat. 419; 1965 Reorg. Plan No. 2, eff. July 13, 1965, 30 F.R. 8819, 79 Stat. 1318; Pub. L. 91–212, §11, Mar. 13, 1970, 84 Stat. 67; 1970 Reorg. Plan No. 4, eff. Oct. 3, 1970, 35 F.R. 15627, 84 Stat. 2090; Pub. L. 91–513, title I, §2(b), Oct. 27, 1970, 84 Stat. 1240; Pub. L. 93–523, §2(b), Dec. 16, 1974, 88 Stat. 1693; Pub. L. 94–317, title III, §301(a), June 23, 1976, 90 Stat. 707; Pub. L. 94–484, title IX, §905(a), Oct. 12, 1976, 90 Stat. 2325; Pub. L. 95–83, title I, §107, Aug. 1, 1977, 91 Stat. 386; Pub. L. 96–79, title II, §203(e)(2), Oct. 4, 1979, 93 Stat. 635; Pub. L. 97–35, title IX, §§902(d)(5), 986(a), Aug. 13, 1981, 95 Stat. 560, 603; Pub. L. 103–43, title XX, §2008(e), June 10, 1993, 107 Stat. 212; Pub. L. 118–42, div. G, title II, §209(l)(1), Mar. 9, 2024, 138 Stat. 448.)

EDITORIAL NOTES

REFERENCES IN TEXT

Section 246(g) of this title, referred to in subsec. (f), was repealed by Pub. L. 96–398, title I, §107(d), Oct. 7, 1980, 94 Stat. 1571.

Section 247c(c)(1) of this title, referred to in subsec. (f), was repealed by Pub. L. 94–317, title II, §203(f)(1), June 23, 1976, 90 Stat. 704.

Section 254d(h)(3) of this title, referred to in subsec. (f), was redesignated section 254d(i)(4) of this title by Pub. L. 100–177, title II, §202(b)(5), title III, §301(1), Dec. 1, 1987, 101 Stat. 996, 1003, and was subsequently redesignated section 254d(j)(4) of this title by Pub. L. 107–251, title III, §301(b)(1), Oct. 26, 2002, 116 Stat. 1643.

Section 263c(5) of this title, referred to in subsec. (f), was in the original a reference to section 355(5) of the Public Health Service Act which was redesignated section 531(5) of the Federal Food, Drug, and Cosmetic Act by Pub. L. 101–629, §19(a)(3), Nov. 28, 1990, 104 Stat. 4530, and is now classified to section 360hh(5) of Title 21, Food and Drugs.

Section 292a of this title, referred to in subsec. (f), contained definitions for purposes of subchapter V of this chapter prior to the general revision of subchapter V by Pub. L. 102–408, title I, §102, Oct. 13, 1992, 106 Stat. 1994. See sections 292o and 295p of this title.

Section 300n of this title, referred to in subsec. (f), was repealed by Pub. L. 99–660, title VII, §701(a), Nov. 14, 1986, 100 Stat. 3799.

Section 4731(g) of title 26, referred to in subsec. (j), was repealed by Pub. L. 91–513, title III, §1101(b)(3)(A), Oct. 27, 1970, 84 Stat. 1292. A definition of "opiate" is contained in section 102 of Pub. L. 91–513, which is classified to section 802 of Title 21, Food and Drugs. Reference to section 4731(g) of title 26 was substituted for "section 3228(f) of title 26" on authority of section 7852(b) of Title 26, Internal Revenue Code, which provides that a reference in other laws to the Internal Revenue Code of 1939 is deemed a reference to the corresponding provision of the Internal Revenue Code of 1986.

CODIFICATION

Section was enacted as part of title I of act July 1, 1944, ch. 373, 58 Stat. 682, and not as part of title II of such Act which comprises this subchapter.

AMENDMENTS

2024—Subsec. (f). Pub. L. 118–42 substituted "the Federated States of Micronesia, the Republic of the Marshall Islands, and the Republic of Palau" for "and the Trust Territory of the Pacific Islands".

1993—Subsec. (c). Pub. L. 103–43 substituted "Health and Human Services" for "Health, Education, and Welfare".

1981—Subsec. (f). Pub. L. 97–35, §902(d)(5), struck out reference to section 300d(2) of this title.

Subsec. (h). Pub. L. 97–35, §986(a), struck out subsec. (h) which defined "seamen".

1979—Subsec. (f). Pub. L. 96–79 struck out from enumeration of excepted sections reference to section 300s–3(1) of this title.

1977—Subsec. (f). Pub. L. 95–83 expanded definition of "State" to include American Samoa and the Trust Territory of the Pacific Islands.

1976—Subsec. (f). Pub. L. 94–484 amended subsec. (f) generally.

Pub. L. 94–317 substituted provisions defining, with certain specific exceptions, "State" to include the several States, the District of Columbia, Guam, Puerto Rico and the Virgin Islands for provisions defining "State" to include a State or the District of Columbia, Puerto Rico, or the Virgin Islands, except in section 264(d) of this title such term means a State or the District of Columbia, and in subchapter XII of this chapter such term includes Guam, American Samoa, and the Trust Territory of the Pacific Islands.

1974—Subsec. (f). Pub. L. 93–523 designated existing provisions as cl. (1) and added cl. (2).

1970—Subsec. (c). Pub. L. 91–212 amended subsec. (c) generally. Prior to amendment, subsec. (c) read as follows: "The term 'Administrator' means the Federal Security Administrator;".

Subsec. (q). Pub. L. 91–513 added subsec. (q).

1960—Subsec. (f). Pub. L. 86–624 struck out "Hawaii," before "Puerto Rico".

Subsec. (p). Pub. L. 86–415 added subsec. (p).

1959—Subsec. (f). Pub. L. 86–70 struck out "Alaska," after "Hawaii," and substituted "or the District of Columbia" for ", the District of Columbia, or Alaska".

1948—Subsec. (j). Act Feb. 28, 1948, inserted "isonipecaine and its derivatives, compounds, salts, and preparations; opiates (as defined in section 4731(g) of title 26)".

Subsec. (n). Act June 16, 1948, added subsec. (n).

Subsec. (o). Act June 24, 1948, added subsec. (o).

1946—Subsecs. (l), (m). Act July 3, 1946, added subsecs. (l) and (m).

STATUTORY NOTES AND RELATED SUBSIDIARIES

CHANGE OF NAME

"Secretary of Health and Human Services" substituted in text for "Secretary of Health, Education, and Welfare" pursuant to section 509(b) of Pub. L. 96–88, which is classified to section 3508(b) of Title 20, Education.

EFFECTIVE DATE OF 2000 AMENDMENT

Pub. L. 106–310, div. A, title XXIX, §2901, Oct. 17, 2000, 114 Stat. 1168, provided that: "This division [see Tables for classification] and the amendments made by this division take effect October 1, 2000, or upon the date of the enactment of this Act [Oct. 17, 2000], whichever occurs later."

EFFECTIVE DATE OF 1993 AMENDMENT

Pub. L. 103–43, title XXI, §2101, June 10, 1993, 107 Stat. 219, provided that: "Subject to section 203(c) [enacting provisions set out as a note under section 283c of this title], this Act [see Short Title of 1993 Amendment note below] and the amendments made by this Act take effect upon the date of the enactment of this Act [June 10, 1993]."

EFFECTIVE DATE OF 1981 AMENDMENT

Amendment by section 902(d)(5) of Pub. L. 97–35 effective Oct. 1, 1981, see section 902(h) of Pub. L. 97–35, set out as a note under section 238l of this title.

Amendment by section 986(a) of Pub. L. 97–35 effective Oct. 1, 1981, see section 986(c) of Pub. L. 97–35, set out as a note under section 249 of this title.

EFFECTIVE DATE OF 1979 AMENDMENT

Amendment by Pub. L. 96–79 effective Oct. 1, 1979, see section 204 of Pub. L. 96–79, set out as a note under section 300q of this title.

EFFECTIVE DATE OF 1970 AMENDMENT

Pub. L. 91–212, §12(b), Mar. 16, 1970, 84 Stat. 67, provided that: "The amendments made by sections 10(d) and 11 [amending this section and sections 276, 277, 278, 280, 280a–1, 280b–2 to 280b–9, and 280b–11 of this title] shall take effect on the date of enactment of this Act [Mar. 13, 1970]."

EFFECTIVE DATE OF 1960 AMENDMENT

Pub. L. 86–624, §47(f), July 12, 1960, 74 Stat. 423, provided that: "The amendments made by subsection (c), paragraphs (3) and (4) of subsection (b), and paragraph (4) of subsection (d) of section 14 [amending sections 15i, 15jj, 15ggg, 244, and 645 of Title 20, Education], by section 20(a) [amending section 41 of Title 29, Labor], by section 23(b) [amending section 466j of Title 33, Navigation and Navigable Waters], by subsections (a), (b), and (c), and paragraph (4) of subsection (d), of section 29 [amending this section and sections 255, 264, and 291i of this title], and by subsection (d), and paragraph (2) of subsection (c), of section 30 [amending sections 410 and 1301 of this title] shall become effective on August 21, 1959."

EFFECTIVE DATE OF 1959 AMENDMENT

Amendment by Pub. L. 86–70 effective Jan. 3, 1959, see section 47(d) of Pub. L. 86–70.

SHORT TITLE OF 2026 AMENDMENT

Pub. L. 119–118, §1, Sept. 30, 2026, 140 Stat. 1062, provided that: "This Act [amending sections 247b–23 and 300hh–32 of this title] may be cited as the 'Kay Hagan Tick Reauthorization Act'."

SHORT TITLE OF 2025 AMENDMENT

Pub. L. 119–44, §1(a), Dec. 1, 2025, 139 Stat. 669, provided that: "This Act [see Tables for classification] may be cited as the 'SUPPORT for Patients and Communities Reauthorization Act of 2025'."

Pub. L. 118–228, §1, Jan. 4, 2025, 138 Stat. 2822, provided that: "This Act [amending sections 282 and 282a of this title] may be cited as the 'Gabriella Miller Kids First Research Act 2.0'."

SHORT TITLE OF 2024 AMENDMENT

Pub. L. 118–180, §1, Dec. 23, 2024, 138 Stat. 2614, provided that: "This Act [amending sections 280i to 280i–4 and 284g of this title and enacting provisions set out as a note under section 280i of this title] may be cited as the 'Autism Collaboration, Accountability, Research, Education, and Support Act of 2024' or the 'Autism CARES Act of 2024'."

Pub. L. 118–178, §1, Dec. 23, 2024, 138 Stat. 2612, provided that: "This Act [amending section 300w–9 of this title] may be cited as the 'Emergency Medical Services for Children Reauthorization Act of 2024'."

Pub. L. 118–176, §1, Dec. 23, 2024, 138 Stat. 2605, provided that: "This Act [enacting sections 244a to 244d of this title] may be cited as the 'Cardiomyopathy Health Education, Awareness, and Research, and AED Training in the Schools Act of 2024' or the 'HEARTS Act of 2024'."

Pub. L. 118–158, div. C, §3001(a), Dec. 21, 2024, 138 Stat. 1761, provided that: "This division [amending sections 247d, 247d–7e, 247d–7f, 254b–2, 254c–2, 254c–3, 256h, 300hh–10b to 300hh–10d, 300hh–11, 701, 710, 713, 1395f, 1395m, 1395w–4, 1395w–102, 1395cc–7, 1395ww, 1395aaa, 1395iii, and 1396r–4 of this title and section 3014 of Title 18, Crimes and Criminal Procedure, enacting provisions set out as notes under sections 1395m and 1395ww of this title, and amending provisions set out as notes under sections 1395b–3 and 1395ww of this title] may be cited as the 'Health Extensions and Other Matters Act, 2025'."

Pub. L. 118–147, §1, Dec. 12, 2024, 138 Stat. 1674, provided that: "This Act [amending section 280e–5 of this title] may be cited as the 'Firefighter Cancer Registry Reauthorization Act of 2023'."

Pub. L. 118–142, §1, Dec. 11, 2024, 138 Stat. 1662, provided that: "This Act [amending section 280c–5 of this title] may be cited as the 'BOLD Infrastructure for Alzheimer's Reauthorization Act of 2024'."

Pub. L. 118–107, §1, Nov. 21, 2024, 138 Stat. 1594, provided that: "This Act [amending section 280g–13 of this title] may be cited as the 'Congenital Heart Futures Reauthorization Act of 2024'."

Pub. L. 118–86, §1, Sept. 26, 2024, 138 Stat. 1549, provided that: "This Act [amending sections 300d–71 to 300d–73 of this title] may be cited as the 'Poison Control Centers Reauthorization Act of 2024'."

Pub. L. 118–84, §1, Sept. 26, 2024, 138 Stat. 1544, provided that: "This Act [transferring section 254c–15 of this title to section 290ee–10 of this title and amending section 254c–15 of this title] may be cited as the 'Supporting and Improving Rural EMS Needs Reauthorization Act' or the 'SIREN Reauthorization Act'."

Pub. L. 118–66, §1, July 2, 2024, 138 Stat. 1443, provided that: "This Act [enacting part W of subchapter II of this chapter] may be cited as the 'Dr. Emmanuel Bilirakis and Honorable Jennifer Wexton National Plan to End Parkinson's Act'."

SHORT TITLE OF 2023 AMENDMENT

Pub. L. 118–14, §1, Sept. 22, 2023, 137 Stat. 69, provided that: "This Act [amending sections 273, 274, 274b, 274c, and 274d of this title] may be cited as the 'Securing the U.S. Organ Procurement and Transplantation Network Act'."

Pub. L. 117–356, §1, Jan. 5, 2023, 136 Stat. 6282, provided that: "This Act [amending section 254r of this title] may be cited as the 'State Offices of Rural Health Program Reauthorization Act of 2022'."

Pub. L. 117–350, §1, Jan. 5, 2023, 136 Stat. 6262, provided that: "This Act [amending sections 285a–11 and 285a–11a of this title] may be cited as the 'Childhood Cancer Survivorship, Treatment, Access, and Research Reauthorization Act of 2022' or the 'Childhood Cancer STAR Reauthorization Act'."

SHORT TITLE OF 2022 AMENDMENT

Pub. L. 117–328, div. FF, §1, Dec. 29, 2022, 136 Stat. 5627, provided that: "This division [see Tables for classification] may be cited as the 'Health Extenders, Improving Access to Medicare, Medicaid, and CHIP, and Strengthening Public Health Act of 2022'."

Pub. L. 117–328, div. FF, title I, §1001, Dec. 29, 2022, 136 Stat. 5634, provided that: "This title [see Tables for classification] may be cited as the 'Restoring Hope for Mental Health and Well-Being Act of 2022'."

Pub. L. 117–328, div. FF, title II, §2001, Dec. 29, 2022, 136 Stat. 5706, provided that: "This title [see Tables for classification] may be cited as the 'Prepare for and Respond to Existing Viruses, Emerging New Threats, and Pandemics Act' or the 'PREVENT Pandemics Act'."

Pub. L. 117–244, §1, Dec. 20, 2022, 136 Stat. 2340, provided that: "This Act [enacting section 285b–9 of this title] may be cited as the 'Cardiovascular Advances in Research and Opportunities Legacy Act'."

Pub. L. 117–241, §1, Dec. 20, 2022, 136 Stat. 2332, provided that: "This Act [amending section 280g–1 of this title] may be cited as the 'Early Hearing Detection and Intervention Act of 2022'."

Pub. L. 117–204, §1, Oct. 17, 2022, 136 Stat. 2231, provided that: "This Act [amending section 254b of this title and enacting provisions set out as a note under section 254b of this title] may be cited as the 'Maximizing Outcomes through Better Investments in Lifesaving Equipment for (MOBILE) Health Care Act'."

Pub. L. 117–105, §1, Mar. 18, 2022, 136 Stat. 1118, provided that: "This Act [enacting section 294t of this title and provisions set out as notes under section 294t of this title] may be cited as the 'Dr. Lorna Breen Health Care Provider Protection Act'."

Pub. L. 117–104, §1, Mar. 18, 2022, 136 Stat. 1117, provided that: "This Act [amending section 285t of this title] may be cited as the 'John Lewis NIMHD Research Endowment Revitalization Act of 2021'."

Pub. L. 117–103, div. W, title XIII, §1315(a), Mar. 15, 2022, 136 Stat. 938, provided that: "This section [amending section 300u–7 of this title] may be cited as 'Bree's Law'."

Pub. L. 117–100, §1, Mar. 15, 2022, 136 Stat. 44, provided that: "This Act [enacting section 290bb–33 of this title and provisions set out as a note under section 290bb–33 of this title] may be cited as the 'Suicide Training and Awareness Nationally Delivered for Universal Prevention Act of 2021' or the 'STANDUP Act of 2021'."

SHORT TITLE OF 2021 AMENDMENT

Pub. L. 117–15, §1, May 26, 2021, 135 Stat. 277, provided that: "This Act [amending sections 274k, 274m, and 282 of this title and enacting and amending provisions set out as notes under section 274k of this title] may be cited as the 'Timely ReAuthorization of Necessary Stem-cell Programs Lends Access to Needed Therapies Act of 2021' or the 'TRANSPLANT Act of 2021'."

Pub. L. 117–8, §1, Apr. 23, 2021, 135 Stat. 254, provided that: "This Act [enacting section 263–1 of this title] may be cited as the 'Advancing Education on Biosimilars Act of 2021'."

Pub. L. 116–324, §1, Jan. 5, 2021, 134 Stat. 5085, provided that: "This Act [amending sections 300ii–3 and 300ii–4 of this title] may be cited as the 'Lifespan Respite Care Reauthorization Act of 2020'."

Pub. L. 116–292, §1, Jan. 5, 2021, 134 Stat. 4896, provided that: "This Act [amending section 280g of this title] may be cited as the 'School-Based Allergies and Asthma Management Program Act'."

SHORT TITLE OF 2020 AMENDMENT

Pub. L. 116–273, §1, Dec. 31, 2020, 134 Stat. 3352, provided that: "This Act [enacting sections 300c–11 and 300c–14 of this title] may be cited as the 'Scarlett's Sunshine on Sudden Unexpected Death Act'."

Pub. L. 116–260, div. BB, title I, §101, Dec. 27, 2020, 134 Stat. 2758, provided that: "This title [see Tables for classification] may be cited as the 'No Surprises Act'."

Pub. L. 116–136, div. A, title III, §3001, Mar. 27, 2020, 134 Stat. 360, provided that: "This subtitle [subtitle A (§§3001–3404) of title III of div. A of Pub. L. 116–136, see Tables for classification] may be cited as the 'Coronavirus Aid, Relief, and Economic Security Act'."

SHORT TITLE OF 2019 AMENDMENT

Pub. L. 116–94, div. N, title I, §404(a), Dec. 20, 2019, 133 Stat. 3116, provided that: "This section [enacting sections 247b–23 and 300hh–32 of this title] may be cited as the 'Kay Hagan Tick Act'."

Pub. L. 116–60, §1, Sept. 30, 2019, 133 Stat. 1110, provided that: "This Act [amending sections 280i to 280i–4 and 284g of this title] may be cited as the 'Autism Collaboration, Accountability, Research, Education, and Support Act of 2019' or the 'Autism CARES Act of 2019'."

Pub. L. 116–49, §1, Aug. 22, 2019, 133 Stat. 1072, provided that: "This Act [amending section 300w–9 of this title] may be cited as the 'Emergency Medical Services for Children Program Reauthorization Act of 2019'."

Pub. L. 116–22, §1(a), June 24, 2019, 133 Stat. 905, provided that: "This Act [see Tables for classification] may be cited as the 'Pandemic and All-Hazards Preparedness and Advancing Innovation Act of 2019'."

SHORT TITLE OF 2018 AMENDMENT

Pub. L. 115–408, §1, Dec. 31, 2018, 132 Stat. 5384, provided that: "This Act [amending section 254r of this title] may be cited as the 'State Offices of Rural Health Reauthorization Act of 2018'."

Pub. L. 115–406, §1, Dec. 31, 2018, 132 Stat. 5362, provided that: "This Act [enacting section 280c–4 of this title, amending sections 280c–3 and 280c–5 of this title, and repealing section 280c–4 of this title] may be cited as the 'Building Our Largest Dementia Infrastructure for Alzheimer's Act' or the 'BOLD Infrastructure for Alzheimer's Act'."

Pub. L. 115–398, §1, Dec. 31, 2018, 132 Stat. 5328, provided that: "This Act [enacting section 300d–54 of this title] may be cited as the 'Stop, Observe, Ask, and Respond to Health and Wellness Act of 2018' or the 'SOAR to Health and Wellness Act of 2018'."

Pub. L. 115–377, §1, Dec. 21, 2018, 132 Stat. 5114, provided that: "This Act [amending sections 280b–1d, 280b–3, 300d–52 and 300d–53 of this title, and repealing section 280b–1e of this title] may be cited as the 'Traumatic Brain Injury Program Reauthorization Act of 2018'."

Pub. L. 115–344, §1, Dec. 21, 2018, 132 Stat. 5047, provided that: "This Act [amending section 247b–12 of this title] may be cited as the 'Preventing Maternal Deaths Act of 2018'."

Pub. L. 115–342, §1, Dec. 21, 2018, 132 Stat. 5040, provided that: "This Act [amending section 280g–13 of this title] may be cited as the 'Congenital Heart Futures Reauthorization Act of 2017'."

Pub. L. 115–328, §1, Dec. 18, 2018, 132 Stat. 4471, provided that: "This Act [amending sections 247b–4f and 280g–5 of this title and provisions set out as a note under section 247b–4f of this title] may be cited as the 'Prematurity Research Expansion and Education for Mothers who deliver Infants Early Reauthorization Act of 2018' or the 'PREEMIE Reauthorization Act of 2018'."

Pub. L. 115–327, §1, Dec. 18, 2018, 132 Stat. 4468, provided that: "This Act [enacting and amending section 300b–5 of this title and amending provisions set out as a note under section 300b–1 of this title] may be cited as the 'Sickle Cell Disease and Other Heritable Blood Disorders Research, Surveillance, Prevention, and Treatment Act of 2018'."

Pub. L. 115–320, §1, Dec. 17, 2018, 132 Stat. 4437, provided that: "This Act [amending section 254e of this title] may be cited as the 'Improving Access to Maternity Care Act'."

Pub. L. 115–302, §1, Dec. 11, 2018, 132 Stat. 4396, provided that: "This Act [amending sections 256g, 280k, and 280k–1 of this title] may be cited as the [']Action for Dental Health Act of 2018[']."

Pub. L. 115–263, §1, Oct. 10, 2018, 132 Stat. 3672, provided that: "This Act [enacting section 300gg–19b of this title and amending provisions set out as a note under section 355 of Title 21, Food and Drugs] may be cited as the 'Patient Right to Know Drug Prices Act'."

Pub. L. 115–241, §1, Sept. 18, 2018, 132 Stat. 2892, provided that: "This Act [amending section 256e of this title] may be cited as the 'Dr. Benjy Frances Brooks Children's Hospital GME Support Reauthorization Act of 2018'."

Pub. L. 115–194, §1, July 7, 2018, 132 Stat. 1506, provided that: "This Act [enacting section 280e–5 of this title] may be cited as the [']Firefighter Cancer Registry Act of 2018[']."

Pub. L. 115–180, §1(a), June 5, 2018, 132 Stat. 1382, provided that: "This Act [enacting sections 285a–11a and 285a–11b of this title, amending sections 280e–3a, 284a, 285a–10, and 285a–11 of this title, and enacting provisions set out as notes under sections 285a–10 and 285a–11 of this title] may be cited as the 'Childhood Cancer Survivorship, Treatment, Access, and Research Act of 2018' or the 'Childhood Cancer STAR Act'."

SHORT TITLE OF 2017 AMENDMENT

Pub. L. 115–96, div. C, Dec. 22, 2017, 131 Stat. 2052, provided that: "This division [amending sections 254b–2, 254c–2, 254c–3, 256h, 300u–11, and 1397dd of this title and section 3014 of Title 18, Crimes and Criminal Procedure, and enacting provisions set out as notes under section 1397dd of this title] may be cited as the 'CHIP and Public Health Funding Extension Act'."

Pub. L. 115–71, §1, Oct. 18, 2017, 131 Stat. 1218, provided that: "This Act [amending section 280g–1 of this title] may be cited as the 'Early Hearing Detection and Intervention Act of 2017'."

SHORT TITLE OF 2016 AMENDMENT

Pub. L. 114–322, title II, §2001, Dec. 16, 2016, 130 Stat. 1716, provided that: "This title [enacting sections 300j–3d, 300j–19a, 300j–19b, and 300j–27 of this title, repealing section 300j–25 of this title, amending

sections 300f, 300g–3, 300g–6, 300j–1, 300j–12, 300j–24, and 6945 of this title, and enacting provisions set out as notes under sections 300j–1, 300j–3d, and 300j–12 of this title] may be cited as the 'Water and Waste Act of 2016'."

Pub. L. 114–255, §1(a), Dec. 13, 2016, 130 Stat. 1033, provided that: "This Act [see Tables for classification] may be cited as the '21st Century Cures Act'."

Pub. L. 114–255, div. A, §1000, Dec. 13, 2016, 130 Stat. 1039, provided that: "This Division [see Tables for classification] may be cited as the '21st Century Cures Act'."

Pub. L. 114–255, div. B, §6000, Dec. 13, 2016, 130 Stat. 1202, provided that: "This division [see Tables for classification] may be cited as the 'Helping Families in Mental Health Crisis Reform Act of 2016'."

Pub. L. 114–198, §1(a), July 22, 2016, 130 Stat. 695, provided that: "This Act [see Tables for classification] may be cited as the 'Comprehensive Addiction and Recovery Act of 2016'."

SHORT TITLE OF 2015 AMENDMENT

Pub. L. 114–113, div. O, title III, §301, Dec. 18, 2015, 129 Stat. 2996, provided that: "This title [amending sections 300mm, 300mm–4, 300mm–21, 300mm–22, 300mm–31, 300mm–41, 300mm–52, and 300mm–61 of this title] may be cited as the 'James Zadroga 9/11 Health and Compensation Reauthorization Act'."

Pub. L. 114–104, §1, Dec. 18, 2015, 129 Stat. 2216, provided that: "This Act [amending sections 274k and 274m of this title, enacting provisions set out as a note under section 274e of this title and amending provisions set out as a note under section 274k of this title] may be cited as the 'Stem Cell Therapeutic and Research Reauthorization Act of 2015'."

Pub. L. 114–98, §1, Dec. 11, 2015, 129 Stat. 2199, provided that: "This Act [amending section 300j–1 of this title and enacting provisions set out as a note under section 300j–1 of this title] may be cited as the 'Grassroots Rural and Small Community Water Systems Assistance Act'."

Pub. L. 114–91, §1, Nov. 25, 2015, 129 Stat. 723, provided that: "This Act [enacting provisions set out as a note under section 247b–13 of this title] may be cited as the 'Protecting Our Infants Act of 2015'."

Pub. L. 114–60, §1, Oct. 7, 2015, 129 Stat. 543, provided that: "This Act [amending sections 300gg–91, 1395iii, and 18024 of this title] may be cited as the 'Protecting Affordable Coverage for Employees Act'."

Pub. L. 114–45, §1, Aug. 7, 2015, 129 Stat. 473, provided that: "This Act [enacting section 300j–19 of this title] may be cited as the 'Drinking Water Protection Act'."

SHORT TITLE OF 2014 AMENDMENT

Pub. L. 113–265, §1, Dec. 18, 2014, 128 Stat. 2942, provided that: "This Act [amending section 280m of this title] may be cited as the 'EARLY Act Reauthorization of 2014'."

Pub. L. 113–240, §1(a), Dec. 18, 2014, 128 Stat. 2851, provided that: "This Act [enacting sections 300b–16 and 300b–17 of this title, amending sections 300b–8 to 300b–15 of this title, and enacting provisions set out as a note under section 289 of this title] may be cited as the 'Newborn Screening Saves Lives Reauthorization Act of 2014'."

Pub. L. 113–236, §1, Dec. 18, 2014, 128 Stat. 2831, provided that: "This Act [enacting section 300c–13 of this title] may be cited as the 'Sudden Unexpected Death Data Enhancement and Awareness Act'."

Pub. L. 113–196, §1, Nov. 26, 2014, 128 Stat. 2052, provided that: "This Act [amending sections 280b–1c, 280b–3, 300d–52, and 300d–53 of this title] may be cited as the 'Traumatic Brain Injury Reauthorization Act of 2014'."

Pub. L. 113–180, §1, Sept. 26, 2014, 128 Stat. 1915, provided that: "This Act [amending section 300w–9 of this title] may be cited as the 'Emergency Medical Services for Children Reauthorization Act of 2014'."

Pub. L. 113–166, §1, Sept. 26, 2014, 128 Stat. 1879, provided that: "This Act [amending sections 247b–18, 247b–19, and 283g of this title] may be cited as the 'Paul D. Wellstone Muscular Dystrophy Community Assistance, Research and Education Amendments of 2014'."

Pub. L. 113–157, §1, Aug. 8, 2014, 128 Stat. 1831, provided that: "This Act [amending sections 280i to 280i–4 of this title and enacting provisions set out as a note under section 280i of this title] may be cited as the 'Autism Collaboration, Accountability, Research, Education, and Support Act of 2014' or the 'Autism CARES Act of 2014'."

Pub. L. 113–152, §1, Aug. 8, 2014, 128 Stat. 1825, provided that: "This Act [amending sections 300d–31 and 300d–61 of this title] may be cited as the 'Improving Trauma Care Act of 2014'."

Pub. L. 113–98, §1, Apr. 7, 2014, 128 Stat. 1140, provided that: "This Act [amending section 256e of this title] may be cited as the 'Children's Hospital GME Support Reauthorization Act of 2013'."

Pub. L. 113–77, §1, Jan. 24, 2014, 128 Stat. 644, provided that: "This Act [amending sections 300d–71 to 300d–73 of this title and enacting provisions set out as a note under section 300d–73 of this title] may be cited as the 'Poison Center Network Act'."

SHORT TITLE OF 2013 AMENDMENT

Pub. L. 113–64, §1, Dec. 20, 2013, 127 Stat. 668, provided that: "This Act [amending section 300g–6 of this title and enacting provisions set out as a note under section 300g–6 of this title] may be cited as the 'Community Fire Safety Act of 2013'."

Pub. L. 113–55, title I, §101, Nov. 27, 2013, 127 Stat. 641, provided that: "This title [amending sections 247b–4f, 254c–14, and 280g–5 of this title, repealing section 247b–4g of this title, and enacting provisions set out as a note under section 247b–4f of this title] may be cited as the 'Prematurity Research Expansion and Education for Mothers who deliver Infants Early Reauthorization Act' or the 'PREEMIE Reauthorization Act'."

Pub. L. 113–55, title II, §201, Nov. 27, 2013, 127 Stat. 644, provided that: "This title [amending section 284h of this title] may be cited as the 'National Pediatric Research Network Act of 2013'."

Pub. L. 113–55, title III, §301, Nov. 27, 2013, 127 Stat. 646, provided that: "This title [amending section 283m of this title] may be cited as the 'CHIMP Act Amendments of 2013'."

Pub. L. 113–51, §1, Nov. 21, 2013, 127 Stat. 579, provided that: "This Act [enacting section 274f–5 of this title and amending sections 273 and 274 of this title and section 1122 of Title 18, Crimes and Criminal Procedure] may be cited as the 'HIV Organ Policy Equity Act'."

Pub. L. 113–48, §1, Nov. 13, 2013, 127 Stat. 575, provided that: "This Act [amending section 280g of this title] may be cited as the 'School Access to Emergency Epinephrine Act'."

Pub. L. 113–5, §1(a), Mar. 13, 2013, 127 Stat. 161, provided that: "This Act [enacting section 300hh–10a of this title and sections 360bbb–3a and 360bbb–3b of Title 21, Food and Drugs, amending sections 247d, 247d–1, 247d–3a to 247d–4, 247d–6 to 247d–6b, 247d–6d, 247d–7b, 247d–7e, 247d–7f, 284m, 284m–1, 300hh–1, 300hh–10, 300hh–11, 300hh–15, and 300hh–16 of this title, sections 355, 355–1, 355a, 360bbb–3, and 360bbb–4 of Title 21, and section 8117 of Title 38, Veterans' Benefits, repealing section 247d–6c of this title, enacting provisions set out as notes under sections 247d–6a and 300hh–10 of this title, and amending provisions set out as a note under section 247d–6a of this title] may be cited as the 'Pandemic and All-Hazards Preparedness Reauthorization Act of 2013'."

SHORT TITLE OF 2012 AMENDMENT

Pub. L. 112–202, §1, Dec. 4, 2012, 126 Stat. 1483, provided that: "This Act [amending section 263a of this title] may be cited as the 'Taking Essential Steps for Testing Act of 2012'."

SHORT TITLE OF 2011 AMENDMENT

Pub. L. 112–32, §1, Sept. 30, 2011, 125 Stat. 361, provided that: "This Act [amending sections 280i to 280i–4 of this title] may be cited as the 'Combating Autism Reauthorization Act of 2011'."

Pub. L. 111–380, §1, Jan. 4, 2011, 124 Stat. 4131, provided that: "This Act [amending section 300g–6 of this title and enacting provisions set out as a note under section 300g–6 of this title] may be cited as the 'Reduction of Lead in Drinking Water Act'."

Pub. L. 111–347, §1(a), Jan. 2, 2011, 124 Stat. 3623, provided that: "This Act [enacting subchapter XXXI of this chapter, section 5000C of Title 26, Internal Revenue Code, and provisions set out as a note under section 5000C of Title 26 and amending provisions set out as notes under section 1101 of Title 8, Aliens and Nationality, and section 40101 of Title 49, Transportation] may be cited as the 'James Zadroga 9/11 Health and Compensation Act of 2010'."

SHORT TITLE OF 2010 AMENDMENT

Pub. L. 111–337, §1, Dec. 22, 2010, 124 Stat. 3588, provided that: "This Act [amending section 280g–1 of this title] may be cited as the 'Early Hearing Detection and Intervention Act of 2010'."

Pub. L. 111–264, §1, Oct. 8, 2010, 124 Stat. 2789, provided that: "This Act [amending sections 274k and 274m of this title and amending provisions set out as a note under section 274k of this title] may be cited as the 'Stem Cell Therapeutic and Research Reauthorization Act of 2010'."

Pub. L. 111–148, title VII, §7001(a), Mar. 23, 2010, 124 Stat. 804, provided that: "This subtitle [subtitle A (§§7001–7003) of title VII of Pub. L. 111–148, amending sections 262 and 284m of this title, sections 355, 355a, 355c, and 379g of Title 21, Food and Drugs, section 2201 of Title 28, Judiciary and Judicial Procedure, and section 271 of Title 35, Patents, and enacting provisions set out as notes under section 262 of this title] may be cited as the 'Biologics Price Competition and Innovation Act of 2009'."

Pub. L. 111–148, title VIII, §8001, Mar. 23, 2010, 124 Stat. 828, which provided that title VIII of Pub. L. 111–148, enacting subchapter XXX of this chapter, amending section 1396a of this title, enacting provisions set out as notes under section 300ll of this title, and amending provisions set out as a note under section 1396p of this title, could be cited as the "Community Living Assistance Services and Supports Act" or the "CLASS Act", was repealed by Pub. L. 112–240, title VI, §642(b)(1), Jan. 2, 2013, 126 Stat. 2358.

Pub. L. 111–148, title X, §10409(a), Mar. 23, 2010, 124 Stat. 978, provided that: "This section [enacting section 282d of this title and amending sections 282 and 290b of this title] may be cited as the 'Cures Acceleration Network Act of 2009'."

Pub. L. 111–148, title X, §10410(a), Mar. 23, 2010, 124 Stat. 984, provided that: "This section [enacting section 290bb–33 of this title] may be cited as the 'Establishing a Network of Health-Advancing National Centers of Excellence for Depression Act of 2009' or the 'ENHANCED Act of 2009'."

Pub. L. 111–148, title X, §10411(a), Mar. 23, 2010, 124 Stat. 988, provided that: "This subtitle [probably means this section, enacting sections 280g–13 and 285b–8 of this title] may be cited as the 'Congenital Heart Futures Act'."

Pub. L. 111–148, title X, §10413(a), Mar. 23, 2010, 124 Stat. 990, provided that: "This section [enacting part V of subchapter II of this chapter] may be cited as the 'Young Women's Breast Health Education and Awareness Requires Learning Young Act of 2009' or the 'EARLY Act'."

SHORT TITLE OF 2009 AMENDMENT

Pub. L. 111–87, §1(a), Oct. 30, 2009, 123 Stat. 2885, provided that: "This Act [enacting section 300ff–87a of this title and part G of subchapter XXIV of this chapter, amending sections 300ff–11 to 300ff–17, 300ff–19 to 300ff–27, 300ff–28, 300ff–29, 300ff–29a, 300ff–30, 300ff–31a, 300ff–31b, 300ff–33, 300ff–34, 300ff–37, 300ff–37a, 300ff–38, 300ff–51 to 300ff–55, 300ff–61 to 300ff–67, 300ff–71, 300ff–81 to 300ff–88, 300ff–101, 300ff–111, and 300ff–121 of this title, enacting provisions set out as notes under section 300ff–11 of this title, and repealing provisions set out as a note under section 300ff–11 of this title] may be cited as the 'Ryan White HIV/AIDS Treatment Extension Act of 2009'."

Pub. L. 111–11, title XIV, §14001, Mar. 30, 2009, 123 Stat. 1452, provided that: "This title [enacting sections 280g–9, 284o, and 284p of this title] may be cited as the 'Christopher and Dana Reeve Paralysis Act'."

Pub. L. 111–5, div. A, title XIII, §13001(a), Feb. 17, 2009, 123 Stat. 226, provided that: "This title [enacting subchapter XXVIII of this chapter and chapter 156 of this title, amending sections 1320d, 1320d–5, and 1320d–6 of this title, and enacting provisions set out as a note under section 17931 of this title] (and title IV of division B [amending sections 1395f, 1395r, 1395w, 1395w–4, 1395w–21, 1395w–23, 1395ww, 1395iii, and 1396b of this title, enacting provisions set out as a note under section 1395ww of this title, and amending provisions set out as notes under section 1395ww of this title]) may be cited as the 'Health Information Technology for Economic and Clinical Health Act' or the 'HITECH Act'."

SHORT TITLE OF 2008 AMENDMENT

Pub. L. 110–426, §1, Oct. 15, 2008, 122 Stat. 4835, provided that: "This Act [amending section 274 of this title and enacting provisions set out as a note under section 274 of this title] may be cited as the 'Stephanie Tubbs Jones Organ Transplant Authorization Act of 2008'."

Pub. L. 110–413, §1, Oct. 14, 2008, 122 Stat. 4338, provided that: "This Act [enacting sections 274i to 274i–4 of this title] may be cited as the 'Stephanie Tubbs Jones Gift of Life Medal Act of 2008'."

Pub. L. 110–392, §1(a), Oct. 13, 2008, 122 Stat. 4195, provided that: "This Act [enacting section 285b–7c of this title, amending section 247b–6 of this title, and enacting provisions set out as notes under sections 247b–6 and 264 of this title] may be cited as the 'Comprehensive Tuberculosis Elimination Act of 2008'."

Pub. L. 110–381, §1, Oct. 9, 2008, 122 Stat. 4081, provided that: "This Act [enacting sections 300gg–7 and 300gg–54 of this title, section 9813 of Title 26, Internal Revenue Code, and section 1185c of Title 29, Labor, and enacting provisions set out as a note under section 9813 of Title 26] may be cited as 'Michelle's Law'."

Pub. L. 110–377, §1, Oct. 8, 2008, 122 Stat. 4063, provided that: "This Act [amending sections 300d–71 to 300d–73 of this title and enacting provisions set out as notes under sections 300d–71 to 300d–73 of this title] may be cited as the 'Poison Center Support, Enhancement, and Awareness Act of 2008'."

Pub. L. 110–374, §1, Oct. 8, 2008, 122 Stat. 4051, provided that: "This Act [enacting section 280g–8 of this title and provisions set out as a note under section 280g–8 of this title] may be cited as the 'Prenatally and Postnatally Diagnosed Conditions Awareness Act'."

Pub. L. 110–373, §1, Oct. 8, 2008, 122 Stat. 4047, provided that: "This Act [enacting section 280g–7 of this title] may be cited as the 'ALS Registry Act'."

Pub. L. 110–361, §1, Oct. 8, 2008, 122 Stat. 4010, provided that: "This Act [amending sections 247b–18, 247b–19, and 283g of this title] may be cited as the 'Paul D. Wellstone Muscular Dystrophy Community Assistance, Research, and Education Amendments of 2008'."

Pub. L. 110–355, §1, Oct. 8, 2008, 122 Stat. 3988, provided that: "This Act [enacting section 300hh–17 of this title, amending sections 254b, 254c, 254e, 254f, 254h–1, 254k, 254q, 254q–1, 256g, and 1395x of this title, and enacting provisions set out as notes under sections 254b and 1395x of this title] may be cited as the 'Health Care Safety Net Act of 2008'."

Pub. L. 110–354, §1, Oct. 8, 2008, 122 Stat. 3984, provided that: "This Act [enacting section 285a–12 of this title] may be cited as the 'Breast Cancer and Environmental Research Act of 2008'."

Pub. L. 110–343, div. C, title V, §511, Oct. 3, 2008, 122 Stat. 3881, provided that: "This subtitle [subtitle B (§§511, 512) of title V of div. C of Pub. L. 110–343, amending section 300gg–5 of this title, section 9812 of Title 26, Internal Revenue Code, and section 1185a of Title 29, Labor, and enacting provisions set out as notes under section 300gg–5 of this title] may be cited as the 'Paul Wellstone and Pete Domenici Mental Health Parity and Addiction Equity Act of 2008'."

Pub. L. 110–339, §1, Oct. 3, 2008, 122 Stat. 3733, provided that: "This Act [amending section 254c–8 of this title] may be cited as the 'Healthy Start Reauthorization Act of 2007'."

Pub. L. 110–285, §1, July 29, 2008, 122 Stat. 2628, provided that: "This Act [enacting sections 280e–3a and 285a–11 of this title, amending section 280e–4 of this title, and enacting provisions set out as a note under section 280e–3a of this title] may be cited as the 'Caroline Pryce Walker Conquer Childhood Cancer Act of 2008'."

Pub. L. 110–206, §1, Apr. 28, 2008, 122 Stat. 714, provided that: "This Act [enacting section 280b–1e of this title and amending sections 280b–1b, 280b–1c, 280b–1d, 300d–52, 300d–53, and 300d–61 of this title] may be cited as the 'Traumatic Brain Injury Act of 2008'."

Pub. L. 110–204, §1, Apr. 24, 2008, 122 Stat. 705, as amended by Pub. L. 110–237, §1(b)(1), May 27, 2008, 122 Stat. 1557, provided that: "This Act [enacting sections 300b–11 to 300b–15 of this title and amending sections 300b–8 to 300b–10 of this title] may be cited as the 'Newborn Screening Saves Lives Act of 2008'."

Pub. L. 110–202, §1, Apr. 23, 2008, 122 Stat. 697, provided that: "This Act [enacting section 280b–1f of this title] may be cited as the 'Safety of Seniors Act of 2007'."

SHORT TITLE OF 2007 AMENDMENT

Pub. L. 110–170, §1, Dec. 26, 2007, 121 Stat. 2465, provided that: "This Act [amending sections 287a–3a and 287a–4 of this title] may be cited as the 'Chimp Haven is Home Act'."

Pub. L. 110–144, §1, Dec. 21, 2007, 121 Stat. 1813, provided that: "This Act [enacting section 273b of this title, amending section 274e of this title, and enacting provisions set out as a note under section 274e of this title] may be cited as the 'Charlie W. Norwood Living Organ Donation Act'."

Pub. L. 110–23, §1, May 3, 2007, 121 Stat. 90, provided that: "This Act [enacting section 300d–5 of this title, amending sections 300d, 300d–3, 300d–12 to 300d–15, 300d–22, 300d–32, 300d–51, and 300d–52 of this title, and repealing sections 300d–2 and 300d–16 of this title] may be cited as the 'Trauma Care Systems Planning and Development Act of 2007'."

Pub. L. 110–18, §1, Apr. 20, 2007, 121 Stat. 80, provided that: "This Act [amending sections 300k, 300m, 300n–4, and 300n–5 of this title] may be cited as the 'National Breast and Cervical Cancer Early Detection Program Reauthorization Act of 2007'."

Pub. L. 109–482, §1, Jan. 15, 2007, 120 Stat. 3675, provided that: "This Act [see Tables for classification] may be cited as the 'National Institutes of Health Reform Act of 2006'."

Pub. L. 109–475, §1, Jan. 12, 2007, 120 Stat. 3565, provided that: "This Act [amending section 247b–17 of this title] may be cited as the 'Gynecologic Cancer Education and Awareness Act of 2005' or 'Johanna's Law'."

SHORT TITLE OF 2006 AMENDMENT

Pub. L. 109–450, §1, Dec. 22, 2006, 120 Stat. 3341, provided that: "This Act [enacting sections 247b–4f, 247b–4g, and 280g–5 of this title, amending sections 241 and 280g–4 of this title, and enacting provisions set out as a note under section 247b–4f of this title] may be cited as the 'Prematurity Research Expansion and Education for Mothers who deliver Infants Early Act' or the 'PREEMIE Act'."

Pub. L. 109–442, §1, Dec. 21, 2006, 120 Stat. 3291, provided that: "This Act [enacting sections 300ii to 300ii–4 of this title] may be cited as the 'Lifespan Respite Care Act of 2006'."

Pub. L. 109–422, §1, Dec. 20, 2006, 120 Stat. 2890, provided that: "This Act [amending section 290bb–25b of this title] may be cited as the 'Sober Truth on Preventing Underage Drinking Act' or the 'STOP Act'."

Pub. L. 109–417, §1(a), Dec. 19, 2006, 120 Stat. 2831, provided that: "This Act [enacting sections 204a, 247d–7e, 247d–7f, 254u, 300hh–1, 300hh–2, 300hh–10, 300hh–15, and 300hh–16 of this title and section 360bbb–4 of Title 21, Food and Drugs, amending sections 215, 247d–1, 247d–3a, 247d–3b, 247d–4, 247d–6, 247d–6a, 247d–6b, 247d–7b, 254d, 254q–1, 300hh, 300hh–11, and 1320b–5 of this title, sections 313, 314, and 321j of Title 6, Domestic Security, and section 8117 of Title 38, Veterans' Benefits, repealing sections 247d–2 and 247d–3 of this title, and enacting provisions set out as notes under sections 204a, 247d–6a, 262a, 300hh–10, 300hh–11, and 1320b–5 of this title and section 313 of Title 6] may be cited as the 'Pandemic and All-Hazards Preparedness Act'."

Pub. L. 109–416, §1, Dec. 19, 2006, 120 Stat. 2821, provided that: "This Act [enacting sections 280i to

280i–4 and 283j of this title, amending section 284g of this title, and repealing sections 247b–4b to 247b–4e of this title] may be cited as the 'Combating Autism Act of 2006'."

Pub. L. 109–415, §1(a), Dec. 19, 2006, 120 Stat. 2767, provided that: "This Act [enacting sections 300ff–19, 300ff–20, 300ff–29a, 300ff–31a, 300ff–31b, and 300ff–121 of this title, amending sections 300ff–11 to 300ff–17, 300ff–19 to 300ff–27, 300ff–28, 300ff–29, 300ff–29a, 300ff–30, 300ff–31a, 300ff–31b, 300ff–33, 300ff–34, 300ff–37, 300ff–37a, 300ff–38, 300ff–51 to 300ff–55, 300ff–61 to 300ff–67, 300ff–71, 300ff–81 to 300ff–88, 300ff–101, 300ff–111, and 300ff–121 of this title, and enacting provisions set out as a note under section 300ff–11 of this title] may be cited as the 'Ryan White HIV/AIDS Treatment Modernization Act of 2006'."

Pub. L. 109–307, §1, Oct. 6, 2006, 120 Stat. 1721, provided that: "This Act [amending section 256e of this title] may be cited as the 'Children's Hospital GME Support Reauthorization Act of 2006'."

Pub. L. 109–242, §1, July 19, 2006, 120 Stat. 570, provided that: "This Act [amending section 289g–2 of this title] may be cited as the 'Fetus Farming Prohibition Act of 2006'."

Pub. L. 109–172, §1, Feb. 10, 2006, 120 Stat. 185, provided that: "This Act [amending section 300gg–45 of this title] may be cited as the 'State High Risk Pool Funding Extension Act of 2006'."

SHORT TITLE OF 2005 AMENDMENTS

Pub. L. 109–148, div. C, §1, Dec. 30, 2005, 119 Stat. 2818, provided that: "This division [enacting sections 247d–6d and 247d–6e of this title] may be cited as the 'Public Readiness and Emergency Preparedness Act'."

Pub. L. 109–129, §1, Dec. 20, 2005, 119 Stat. 2550, provided that: "This Act [enacting section 274l–1 of this title, amending sections 274k, 274l, and 274m of this title, and enacting provisions set out as a note under section 274k of this title] may be cited as the 'Stem Cell Therapeutic and Research Act of 2005'."

Pub. L. 109–60, §1, Aug. 11, 2005, 119 Stat. 1979, provided that: "This Act [enacting section 280g–3 of this title and provisions set out as a note under section 280g–3 of this title] may be cited as the 'National All Schedules Prescription Electronic Reporting Act of 2005'."

Pub. L. 109–41, §1(a), July 29, 2005, 119 Stat. 424, provided that: "This Act [enacting part C (§299b–21 et seq.) of subchapter VII of this chapter, redesignating former part C (§299c et seq.) as part D of subchapter VII of this chapter, and amending sections 299c–6 and 299c–7 of this title] may be cited as the 'Patient Safety and Quality Improvement Act of 2005'."

Pub. L. 109–18, §1, June 29, 2005, 119 Stat. 340, provided that: "This Act [enacting section 256a of this title] may be cited as the 'Patient Navigator Outreach and Chronic Disease Prevention Act of 2005'."

SHORT TITLE OF 2004 AMENDMENTS

Pub. L. 108–377, §1, Oct. 30, 2004, 118 Stat. 2202, provided that: "This Act [amending section 280g of this title and enacting provisions set out as notes under section 280g of this title] may be cited as the 'Asthmatic Schoolchildren's Treatment and Health Management Act of 2004'."

Pub. L. 108–365, §1, Oct. 25, 2004, 118 Stat. 1738, provided that: "This Act [amending section 263b of this title] may be cited as the 'Mammography Quality Standards Reauthorization Act of 2004'."

Pub. L. 108–362, §1, Oct. 25, 2004, 118 Stat. 1703, provided that: "This Act [amending sections 273 and 285c–3 of this title] may be cited as the 'Pancreatic Islet Cell Transplantation Act of 2004'."

Pub. L. 108–355, §1, Oct. 21, 2004, 118 Stat. 1404, provided that: "This Act [enacting sections 290bb–36 and 290bb–36b of this title, amending sections 290bb–34 and 290bb–36 of this title, renumbering former section 290bb–36 of this title as section 290bb–36a of this title, and enacting provisions set out as a note under section 290bb–36 of this title] may be cited as the 'Garrett Lee Smith Memorial Act'."

Pub. L. 108–276, §1, July 21, 2004, 118 Stat. 835, provided that: "This Act [enacting sections 247d–6a and 247d–6c of this title and section 320 of Title 6, Domestic Security, amending sections 247d–6, 247d–6b, 287a–2, 300aa–6, and 1320b–5 of this title, sections 312 and 313 of Title 6, and section 360bbb–3 of Title 21, Food and Drugs, renumbering section 300hh–12 of this title as section 247d–6b of this title, enacting provisions set out as notes under sections 247d–6a and 247d–6b of this title, and repealing provisions set out as a note under section 1107a of Title 10, Armed Forces] may be cited as the 'Project BioShield Act of 2004'."

Pub. L. 108–216, §1, Apr. 5, 2004, 118 Stat. 584, provided that: "This Act [enacting sections 273a and 274f–1 to 274f–4 of this title and amending sections 273 and 274f of this title] may be cited as the 'Organ Donation and Recovery Improvement Act'."

SHORT TITLE OF 2003 AMENDMENTS

Pub. L. 108–197, §1, Dec. 19, 2003, 117 Stat. 2898, provided that: "This Act [amending section 300gg–5 of this title and section 1185a of Title 29, Labor] may be cited as the 'Mental Health Parity Reauthorization Act of 2003'."

Pub. L. 108–194, §1, Dec. 19, 2003, 117 Stat. 2888, provided that: "This Act [enacting part G (§300d–71 et

seq.) of subchapter X of this chapter, repealing chapter 142 of this title, enacting provisions set out as a note under section 300d–71 of this title, and repealing provisions set out as a note under section 14801 of this title] may be cited as the 'Poison Control Center Enhancement and Awareness Act Amendments of 2003'."

Pub. L. 108–163, §1, Dec. 6, 2003, 117 Stat. 2020, provided that: "This Act [enacting section 254c–18 of this title, amending sections 233, 247b–1, 247b–6, 247c–1, 254b, 254c, 254c–14, 254c–16, 254e to 254g, 254l, 254l–1, 254o, 300e–12, and 300ff–52 of this title, repealing section 254c–17 of this title, enacting provisions set out as a note under section 233 of this title, amending provisions set out as notes under sections 254b and 1396a of this title, and repealing provisions set out as notes under sections 254e and 254o of this title] may be cited as the 'Health Care Safety Net Amendments Technical Corrections Act of 2003'."

Pub. L. 108–154, §1, Dec. 3, 2003, 117 Stat. 1933, provided that: "This Act [amending sections 247b–4 and 15022 of this title and enacting provisions set out as notes under sections 247b–4b and 15022 of this title] may be cited as the 'Birth Defects and Developmental Disabilities Prevention Act of 2003'."

Pub. L. 108–75, §1, Aug. 15, 2003, 117 Stat. 898, provided that: "This Act [enacting sections 247b–21 and 285l–6 of this title and amending section 247b–20 of this title] may be cited as the 'Mosquito Abatement for Safety and Health Act'."

Pub. L. 108–41, §1, July 1, 2003, 117 Stat. 839, provided that: "This Act [amending section 244 of this title] may be cited as the 'Automatic Defibrillation in Adam's Memory Act'."

Pub. L. 108–20, §1, Apr. 30, 2003, 117 Stat. 638, provided that: "This Act [enacting part C (§239 et seq.) of subchapter I of this chapter, amending section 233 of this title, and enacting provisions set out as a note under section 233 of this title] may be cited as the 'Smallpox Emergency Personnel Protection Act of 2003'."

SHORT TITLE OF 2002 AMENDMENTS

Pub. L. 107–313, §1, Dec. 2, 2002, 116 Stat. 2457, provided that: "This Act [amending section 300gg–5 of this title and section 1185a of Title 29, Labor] may be cited as the 'Mental Health Parity Reauthorization Act of 2002'."

Pub. L. 107–280, §1, Nov. 6, 2002, 116 Stat. 1988, provided that: "This Act [enacting sections 283h and 283i of this title and provisions set out as a note under section 283h of this title] may be cited as the 'Rare Diseases Act of 2002'."

Pub. L. 107–260, §1, Oct. 29, 2002, 116 Stat. 1743, provided that: "This Act [amending section 280e of this title and enacting provisions set out as a note under section 280e of this title] may be cited as the 'Benign Brain Tumor Cancer Registries Amendment Act'."

Pub. L. 107–251, §1(a), Oct. 26, 2002, 116 Stat. 1621, provided that: "This Act [enacting subparts V (§256) and X (§256f et seq.) of part D of subchapter II of this chapter and sections 254c–14 to 254c–17, 254g, and 254t of this title, amending sections 233, 247b–1, 247b–6, 247c–1, 254b, 254c, 254d to 254f–1, 254h to 254i, 254k to 254o, 254q, 254q–1, 256d, 290cc–34, 294o, 295p, 300e–12, and 300ff–52 of this title, repealing sections 254g and 254t of this title, and enacting provisions set out as notes under this section and sections 254b, 254e, 254l, 254o, 256, and 1396a of this title] may be cited as the 'Health Care Safety Net Amendments of 2002'."

Pub. L. 107–251, title II, §211, Oct. 26, 2002, 116 Stat. 1632, provided that: "This subtitle [subtitle B (§§211, 212) of title II of Pub. L. 107–251, enacting section 254c–14 of this title] may be cited as the 'Telehealth Grant Consolidation Act of 2002'."

Pub. L. 107–205, §1, Aug. 1, 2002, 116 Stat. 811, provided that: "This Act [enacting sections 297n–1, 297w, 297x, and 298 of this title, amending sections 294c, 296, 296p, and 297n of this title, and enacting provisions set out as a note under section 296 of this title] may be cited as the 'Nurse Reinvestment Act'."

Pub. L. 107–188, §1(a), June 12, 2002, 116 Stat. 594, provided that: "This Act [see Tables for classification] may be cited as the 'Public Health Security and Bioterrorism Preparedness and Response Act of 2002'."

Pub. L. 107–188, title I, §159(a), June 12, 2002, 116 Stat. 634, provided that: "This section [enacting sections 244 and 245 of this title and provisions set out as a note under section 244 of this title] may be cited as the 'Community Access to Emergency Defibrillation Act of 2002'."

Pub. L. 107–172, §1, May 14, 2002, 116 Stat. 541, provided that: "This Act [enacting section 285a–10 of this title and provisions set out as a note under section 285a–10 of this title] may be cited as the 'Hematological Cancer Research Investment and Education Act of 2002'."

SHORT TITLE OF 2001 AMENDMENT

Pub. L. 107–84, §1, Dec. 18, 2001, 115 Stat. 823, provided that: "This Act [enacting sections 247b–18, 247b–19, and 283g of this title and enacting provisions set out as notes under sections 247b–18 and 281 of this title] may be cited as the 'Muscular Dystrophy Community Assistance, Research and Education Amendments of 2001', or the 'MD–CARE Act'."

SHORT TITLE OF 2000 AMENDMENTS

Pub. L. 106–580, §1, Dec. 29, 2000, 114 Stat. 3088, provided that: "This Act [enacting section 285r of this title, amending section 281 of this title, and enacting provisions set out as notes under section 285r of this title] may be cited as the 'National Institute of Biomedical Imaging and Bioengineering Establishment Act'."

Pub. L. 106–551, §1, Dec. 20, 2000, 114 Stat. 2752, provided that: "This Act [enacting section 287a–3a of this title and provisions set out as a note under section 287a–3a of this title] may be cited as the 'Chimpanzee Health Improvement, Maintenance, and Protection Act'."

Pub. L. 106–545, §1, Dec. 19, 2000, 114 Stat. 2721, provided that: "This Act [enacting sections 285l–2 to 285l–5 of this title] may be cited as the 'ICCVAM Authorization Act of 2000'."

Pub. L. 106–525, §1(a), Nov. 22, 2000, 114 Stat. 2495, provided that: "This Act [enacting sections 287c–31 to 287c–34, 293e, 296e–1, and 299a–1 of this title, amending sections 281, 296f, 299a, 299c–6, and 300u–6 of this title, repealing section 283b of this title, and enacting provisions set out as notes under sections 281, 287c–31, 293e, and 3501 of this title] may be cited as the 'Minority Health and Health Disparities Research and Education Act of 2000'."

Pub. L. 106–505, §1(a), Nov. 13, 2000, 114 Stat. 2314, provided that: "This Act [enacting sections 238p, 238q, 247d to 247d–7, 254c–9 to 254c–13, 284k, 284l, 285d–6a, 285e–10a, 285f–3, 287a–4 and 288–5a of this title, amending sections 273, 274b–5, 284d, 285a–8, 285e–11, 285f–3, 287a–2 and 287a–3 of this title, repealing former section 247d of this title, enacting provisions set out as notes under this section and sections 238p, 254c, 273, 284k, 285d–6a, 287, 287a–2 and 289 of this title, and amending provisions set out as a note under section 289 of this title] may be cited as the 'Public Health Improvement Act'."

Pub. L. 106–505, title I, §101, Nov. 13, 2000, 114 Stat. 2315, provided that: "This title [enacting sections 247d to 247d–7 of this title and repealing former section 247d of this title] may be cited as the 'Public Health Threats and Emergencies Act'."

Pub. L. 106–505, title II, §201, Nov. 13, 2000, 114 Stat. 2325, provided that: "This title [enacting sections 284k, 284l, 287a–4 and 288a–5 of this title, amending section 284d of this title, and enacting provisions set out as notes under section 284k of this title] may be cited as the 'Clinical Research Enhancement Act of 2000'."

Pub. L. 106–505, title III, §301, Nov. 13, 2000, 114 Stat. 2330, provided that: "This title [enacting section 287a–2 of this title, amending section 287a–3 of this title, and enacting provisions set out as notes under sections 287 and 287a–2 of this title] may be cited as the 'Twenty-First Century Research Laboratories Act'."

Pub. L. 106–505, title IV, §401, Nov. 13, 2000, 114 Stat. 2336, provided that: "This subtitle [subtitle A (§§401–404) of title IV of Pub. L. 106–505, enacting sections 238p and 238q of this title and provisions set out as a note under section 238p of this title] may be cited as the 'Cardiac Arrest Survival Act of 2000'."

Pub. L. 106–505, title V, §501, Nov. 13, 2000, 114 Stat. 2342, provided that: "This title [enacting sections 254c–9 to 254c–13 and 285d–6a of this title and provisions set out as a note under section 285d–6a of this title] may be cited as the 'Lupus Research and Care Amendments of 2000'."

Pub. L. 106–505, title VI, §601, Nov. 13, 2000, 114 Stat. 2345, provided that: "This title [amending sections 247b–5 and 285a–8 of this title] may be cited as the 'Prostate Cancer Research and Prevention Act'."

Pub. L. 106–505, title VII, §701(a), Nov. 13, 2000, 114 Stat. 2346, provided that: "This section [amending section 273 of this title and enacting provisions set out as a note under section 273 of this title] may be cited as the 'Organ Procurement Organization Certification Act of 2000'."

Pub. L. 106–345, §1, Oct. 20, 2000, 114 Stat. 1319, provided that: "This Act [enacting subpart III (§300ff–38) of part B of subchapter XXIV of this chapter and sections 247c–2, 300ff–30, 300ff–37a, 300ff–75a, and 300ff–75b of this title, redesignating subparts II (§300ff–51 et seq.) and III (§300ff–61 et seq.) of part C of subchapter XXIV of this chapter as subparts I and II, respectively, of part C of subchapter XXIV of this chapter, amending sections 300ff–12 to 300ff–15, 300ff–21 to 300ff–23, 300ff–26 to 300ff–28, 300ff–33, 300ff–34, 300ff–37, 300ff–53 to 300ff–55, 300ff–61, 300ff–62, 300ff–64, 300ff–71, 300ff–73 to 300ff–75, 300ff–77, and 300ff–111 of this title, repealing former subpart I (§300ff–41 et seq.) of part C of subchapter XXIV of this chapter and sections 300ff–31, 300ff–35, and 300ff–36 of this title, and enacting provisions set out as notes under sections 300cc, 300ff–11, 300ff–12, and 300ff–111 of this title] may be cited as the 'Ryan White CARE Act Amendments of 2000'."

Pub. L. 106–310, §1, Oct. 17, 2000, 114 Stat. 1101, provided that: "This Act [see Tables for classification] may be cited as the 'Children's Health Act of 2000'."

Pub. L. 106–310, div. B, §3001, Oct. 17, 2000, 114 Stat. 1168, provided that: "This division [see Tables for classification] may be cited as the 'Youth Drug and Mental Health Services Act'."

Pub. L. 106–310, div. B, title XXXVI, §3661, Oct. 17, 2000, 114 Stat. 1241, provided that: "This subtitle [subtitle C (§§3661–3665) of title XXXVI of Pub. L. 106–310, enacting section 290aa–5b of this title and

provisions set out as notes under section 290aa–5b of this title and section 994 of Title 28, Judiciary and Judicial Procedure] may be cited as the 'Ecstasy Anti-Proliferation Act of 2000'."

SHORT TITLE OF 1999 AMENDMENT

Pub. L. 106–129, §1, Dec. 6, 1999, 113 Stat. 1653, provided that: "This Act [enacting subchapter VII of this chapter and sections 254c–4 and 256e of this title, amending sections 203, 242b, 242q–1, 286d, 288, 289c–1, 290aa, 300cc–18, 300ff–73, 1320b–12, 11221, and 11261 of this title, enacting provisions set out as notes under sections 241, 254c, 295k, and 299 of this title, and amending provisions set out as a note under section 299a of this title] may be cited as the 'Healthcare Research and Quality Act of 1999'."

SHORT TITLE OF 1998 AMENDMENTS

Pub. L. 105–392, §1(a), Nov. 13, 1998, 112 Stat. 3524, provided that: "This Act [see Tables for classification] may be cited as the 'Health Professions Education Partnerships Act of 1998'."

Pub. L. 105–392, title I, §121, Nov. 13, 1998, 112 Stat. 3562, provided that: "This subtitle [subtitle B (§§121–124) of title I of Pub. L. 105–392, enacting sections 296, 296a to 296f, 296j, 296m, 296p, 297q, and 297t of this title, transferring section 298b–2 of this title to section 296g of this title, repealing sections 296k to 296m, 296r, 297, 297–1, 297c, 298, 298a, 298b, 298b–1, 298b–3 to 298b–5, and 298b–7 of this title, and enacting provisions set out as notes under section 296 of this title] may be cited as the 'Nursing Education and Practice Improvement Act of 1998'."

Pub. L. 105–392, title IV, §419(a), Nov. 13, 1998, 112 Stat. 3591, provided that: "This section [enacting sections 280f to 280f–3 of this title and provisions set out as a note under section 280f of this title] may be cited as the 'Fetal Alcohol Syndrome and Fetal Alcohol Effect Prevention and Services Act'."

Pub. L. 105–340, §1, Oct. 31, 1998, 112 Stat. 3191, provided that: "This Act [enacting sections 285b–7a and 300u–9 of this title and amending sections 242k, 280e–4, 283a, 284e, 285a–8, 285e–10, 287d, 300k, 300n–4a, 300n–5, and 300u–5 of this title] may be cited as the 'Women's Health Research and Prevention Amendments of 1998'."

Pub. L. 105–277, div. A, §101(f) [title IX, §901], Oct. 21, 1998, 112 Stat. 2681–337, 2681–436, provided that: "This title [enacting sections 300gg–6 and 300gg–52 of this title and section 1185b of Title 29, Labor, and provisions set out as notes under sections 300gg–6 and 300gg–52 of this title and section 1185b of Title 29] may be cited as the 'Women's Health and Cancer Rights Act of 1998'."

Pub. L. 105–248, §1, Oct. 9, 1998, 112 Stat. 1864, provided that: "This Act [amending section 263b of this title] may be cited as the 'Mammography Quality Standards Reauthorization Act of 1998'."

Pub. L. 105–196, §1, July 16, 1998, 112 Stat. 631, provided that: "This Act [enacting sections 274l and 274m of this title, amending sections 274g and 274k of this title, repealing former section 274l of this title, and enacting provisions set out as notes under section 274k of this title] may be cited as the 'National Bone Marrow Registry Reauthorization Act of 1998'."

Pub. L. 105–168, §1(a), Apr. 21, 1998, 112 Stat. 43, provided that: "This Act [amending section 247b–4 of this title and enacting provisions set out as a note under section 247b–4 of this title] may be cited as the 'Birth Defects Prevention Act of 1998'."

SHORT TITLE OF 1997 AMENDMENT

Pub. L. 105–78, title VI, §603(a), Nov. 13, 1997, 111 Stat. 1519, provided that: "This section [enacting section 284f of this title and provisions set out as a note under section 284f of this title] may be cited as the 'Morris K. Udall Parkinson's Disease Research Act of 1997'."

SHORT TITLE OF 1996 AMENDMENTS

Pub. L. 104–299, §1, Oct. 11, 1996, 110 Stat. 3626, provided that: "This Act [enacting sections 254b and 254c of this title, amending sections 233, 256c, 1395x, and 1396d of this title, repealing sections 256 and 256a of this title, and enacting provisions set out as notes under sections 233 and 254b of this title] may be cited as the 'Health Centers Consolidation Act of 1996'."

Pub. L. 104–204, title VI, §601, Sept. 26, 1996, 110 Stat. 2935, provided that: "This title [enacting sections 300gg–4 and 300gg–51 of this title and section 1185 of Title 29, Labor, amending sections 300gg–21, 300gg–23, 300gg–44, 300gg–61, and 300gg–62 of this title and sections 1003, 1021, 1022, 1024, 1132, 1136, 1144, 1181, 1191, and 1191a of Title 29, and enacting provisions set out as notes under section 300gg–4 and 300gg–44 of this title and section 1003 of Title 29] may be cited as the 'Newborns' and Mothers' Health Protection Act of 1996'."

Pub. L. 104–204, title VII, §701, Sept. 26, 1996, 110 Stat. 2944, provided that: "This title [enacting section 300gg–5 of this title and section 1185a of Title 29, Labor, and enacting provisions set out as notes under section 300gg–5 of this title and section 1185a of Title 29] may be cited as the 'Mental Health Parity Act of

1996'."

Pub. L. 104–191, §1(a), Aug. 21, 1996, 110 Stat. 1936, provided that: "This Act [see Tables for classification] may be cited as the 'Health Insurance Portability and Accountability Act of 1996'."

Pub. L. 104–182, §1(a), Aug. 6, 1996, 110 Stat. 1613, provided that: "This Act [enacting sections 300g–7 to 300g–9, 300h–8, 300j–3c, and 300j–12 to 300j–18 of this title and section 1263a of Title 33, Navigation and Navigable Waters, amending sections 300f, 300g–1 to 300g–6, 300h, 300h–5 to 300h–7, 300i, 300i–1, 300j to 300j–2, 300j–4 to 300j–8, 300j–11, and 300j–21 to 300j–25 of this title, sections 4701 and 4721 of Title 16, Conservation, and section 349 of Title 21, Food and Drugs, repealing section 13551 of this title, enacting provisions set out as notes under this section, sections 300f, 300g–1, 300j–1, and 300j–12 of this title, section 1281 of Title 33, and section 45 of former Title 40, Public Buildings, Property, and Works, and amending provisions set out as a note under this section] may be cited as the 'Safe Drinking Water Act Amendments of 1996'."

Pub. L. 104–146, §1, May 20, 1996, 110 Stat. 1346, provided that: "This Act [enacting sections 300ff–27a, 300ff–31, 300ff–33 to 300ff–37, 300ff–77, 300ff–78, 300ff–101, and 300ff–111 of this title, amending sections 294n, 300d, 300ff–11 to 300ff–17, 300ff–21 to 300ff–23, 300ff–26 to 300ff–29, 300ff–47 to 300ff–49, 300ff–51, 300ff–52, 300ff–54, 300ff–55, 300ff–64, 300ff–71, 300ff–74, 300ff–76, and 300ff–84 of this title, transferring section 294n of this title to section 300ff–111 of this title, repealing sections 300ff–18 and 300ff–30 of this title, and enacting provisions set out as notes under sections 300cc, 300ff–11, and 300ff–33 of this title and section 4103 of Title 5, Government Organization and Employees] may be cited as the 'Ryan White CARE Act Amendments of 1996'."

SHORT TITLE OF 1995 AMENDMENT

Pub. L. 104–73, §1(a), Dec. 26, 1995, 109 Stat. 777, provided that: "This Act [amending section 233 of this title and enacting provisions set out as a note under section 233 of this title] may be cited as the 'Federally Supported Health Centers Assistance Act of 1995'."

SHORT TITLE OF 1993 AMENDMENTS

Pub. L. 103–183, §1(a), Dec. 14, 1993, 107 Stat. 2226, provided that: "This Act [enacting sections 247b–6, 247b–7, 256d, 280b–1a, 285f–2, 300n–4a, and 300u–8 of this title, amending sections 233, 238j, 242b, 242k, 242l, 242m, 247b, 247b–1, 247b–5, 247c, 247c–1, 254j, 280b, 280b–1, 280b–2, 280b–3, 280e–4, 300d, 300d–2, 300d–3, 300d–12, 300d–13, 300d–16, 300d–22, 300d–31, 300d–32, 300k, 300m, 300n, 300n–1, 300n–4, 300n–5, 300u–5, 300w, and 300aa–26 of this title, repealing sections 300d–1 and 300d–33 of this title, and enacting provisions set out as notes under sections 238j, 263b, 285f–2, and 300m of this title] may be cited as the 'Preventive Health Amendments of 1993'."

Pub. L. 103–43, §1(a), June 10, 1993, 107 Stat. 122, provided that: "This Act [see Tables for classification] may be cited as the 'National Institutes of Health Revitalization Act of 1993'."

SHORT TITLE OF 1992 AMENDMENTS

Pub. L. 102–539, §1, Oct. 27, 1992, 106 Stat. 3547, provided that: "This Act [enacting section 263b of this title and provisions set out as a note under section 263b of this title] may be cited as the 'Mammography Quality Standards Act of 1992'."

Pub. L. 102–531, §1(a), Oct. 27, 1992, 106 Stat. 3469, provided that: "This Act [enacting sections 247b–3 to 247b–5, 247c–1, 256c, 280d–11, 300l–1, and 300u–7 of this title, amending sections 236, 242l, 247b–1, 247d, 254b, 254c, 256, 256a, 280b to 280b–2, 285c–4, 285d–7, 285m–4, 289c, 290aa–9, 290bb–1, 292y, 293j, 293l, 294n, 295j, 295l, 295n, 295o, 296k, 298b–7, 300u, 300u–1, 300u–5, 300w, 300w–3 to 300w–5, 300aa–2, 300aa–15, 300aa–19, 300aa–26, 300cc, 300cc–2, 300cc–15, 300cc–17, 300cc–20, 300cc–31, 300ee–1, 300ee–2, 300ee–31, 300ee–32, 300ee–34, 300ff–11 to 300ff–13, 300ff–17, 300ff–27, 300ff–28, 300ff–41, 300ff–43, 300ff–49, 300ff–75, 4841, and 9604 of this title, section 1341 of Title 15, Trade and Commerce, and section 2001 of Title 25, Indians, repealing section 297j of this title, enacting provisions set out as notes under sections 236, 292y, 300e, and 300w–4 of this title, amending provisions set out as notes under sections 241, 281, and 295k of this title and section 303 of Title 38, Veterans' Benefits, and repealing provisions set out as notes under section 246 and 300e of this title] may be cited as the 'Preventive Health Amendments of 1992'."

Pub. L. 102–515, §1, Oct. 24, 1992, 106 Stat. 3372, provided that: "This Act [enacting sections 280e to 280e–4 of this title and provisions set out as a note under section 280e of this title] may be cited as the 'Cancer Registries Amendment Act'."

Pub. L. 102–501, §1, Oct. 24, 1992, 106 Stat. 3268, provided that: "This Act [amending section 233 of this title and enacting provisions set out as notes under section 233 of this title] may be cited as the 'Federally Supported Health Centers Assistance Act of 1992'."

Pub. L. 102–493, §1, Oct. 24, 1992, 106 Stat. 3146, provided that: "This Act [enacting sections 263a–1 to 263a–7 of this title and provisions set out as a note under section 263a–1 of this title] may be cited as the 'Fertility Clinic Success Rate and Certification Act of 1992'."

Pub. L. 102–410, §1(a), Oct. 13, 1992, 106 Stat. 2094, provided that: "This Act [amending sections 299 to 299a–2, 299b to 299b–3, 299c to 299c–3, 299c–5, and 300w–9 of this title and enacting provisions set out as notes under sections 299a–2, 299b–1, and 299b–2 of this title] may be cited as the 'Agency for Health Care Policy and Research Reauthorization Act of 1992'."

Pub. L. 102–409, §1, Oct. 13, 1992, 106 Stat. 2092, provided that: "This Act [enacting section 283a of this title] may be cited as the 'DES Education and Research Amendments of 1992'."

Pub. L. 102–408, §1(a), Oct. 13, 1992, 106 Stat. 1992, provided that: "This Act [enacting subchapter V of this chapter and sections 297n, 298b–7, and 300d–51 of this title, amending sections 242a, 296k to 296m, 296r, 297, 297–1, 297b, 297d, 297e, 298, 298b, and 298b–6 of this title and section 1078–3 of Title 20, Education, repealing sections 295g–10a, 297c–1, and 297n of this title, enacting provisions set out as notes under this section, sections 292, 295j, 295k, 296k, and 297b of this title, section 1078–3 of Title 20, and section 343–1 of Title 21, Food and Drugs, and amending provisions set out as a note under section 300x of this title] may be cited as the 'Health Professions Education Extension Amendments of 1992'."

Pub. L. 102–408, title II, §201, Oct. 13, 1992, 106 Stat. 2069, provided that: "This title [enacting sections 297n and 298b–7 of this title, amending sections 296k to 296m, 296r, 297, 297–1, 297b, 297d, 297e, 298, 298b, and 298b–6 of this title, repealing sections 297c–1 and 297n of this title, and enacting provisions set out as notes under sections 296k and 297b of this title] may be referred to as the Nurse Education and Practice Improvement Amendments of 1992."

Pub. L. 102–352, §1, Aug. 26, 1992, 106 Stat. 938, provided that: "This Act [amending sections 285n, 285n–2, 285o, 285o–2, 285p, 290aa–1, 290aa–3, 290cc–21, 290cc–28, 290cc–30, 300x–7, 300x–27, 300x–33, 300x–53, and 300y of this title, enacting provisions set out as a note under section 285n of this title, and amending provisions set out as notes under sections 290aa and 300x of this title] may be cited as the 'Public Health Service Act Technical Amendments Act'."

Pub. L. 102–321, §1(a), July 10, 1992, 106 Stat. 323, provided that: "This Act [see Tables for classification] may be cited as the 'ADAMHA Reorganization Act'."

SHORT TITLE OF 1991 AMENDMENTS

Pub. L. 102–168, §1, Nov. 26, 1991, 105 Stat. 1102, provided that: "This Act [amending sections 300u, 300u–5, 300aa–11, 300aa–12, 300aa–15, 300aa–16, 300aa–19, and 300aa–21 of this title, enacting provisions set out as a note under section 300aa–11 of this title, and amending provisions set out as a note under section 300aa–1 of this title] may be cited as the 'Health Information, Health Promotion, and Vaccine Injury Compensation Amendments of 1991'."

Pub. L. 102–96, §1, Aug. 14, 1991, 105 Stat. 481, provided that: "This Act [amending section 300cc–13 of this title and enacting provisions set out as a note under section 300cc–13 of this title] may be cited as the 'Terry Beirn Community Based AIDS Research Initiative Act of 1991'."

SHORT TITLE OF 1990 AMENDMENTS

Pub. L. 101–639, §1, Nov. 28, 1990, 104 Stat. 4600, provided that: "This Act [amending sections 290cc–13, 299a, 300x–3, and 300x–10 to 300x–12 of this title] may be cited as the 'Mental Health Amendments of 1990'."

Pub. L. 101–616, §1, Nov. 16, 1990, 104 Stat. 3279, provided that: "This Act [enacting sections 274f, 274g, 274k, and 274l of this title, amending sections 273 to 274d of this title, enacting provisions set out as notes under sections 273, 274, and 274k of this title, and repealing provisions set out as a note under section 273 of this title] may be cited as the 'Transplant Amendments Act of 1990'."

Pub. L. 101–613, §1, Nov. 16, 1990, 104 Stat. 3224, provided that: "This Act [enacting sections 285g–4 and 290b of this title and provisions set out as a note under section 285g–4 of this title] may be cited as the 'National Institutes of Health Amendments of 1990'."

Pub. L. 101–597, §1, Nov. 16, 1990, 104 Stat. 3013, provided that: "This Act [enacting sections 254f–1, 254o–1, and 254r of this title, amending sections 242a, 254d to 254i, 254k, 254l to 254q–1, 254s, 294h, 294n, 294aa, 295g–1, 296m, 1320c–5, 1395l, 1395u, 1395x, 3505d, and 9840 of this title and section 2123 of Title 10, Armed Forces, and enacting provisions set out as notes under sections 242a, 254l–1, and 254o of this title] may be cited as the 'National Health Service Corps Revitalization Amendments of 1990'."

Pub. L. 101–590, §1, Nov. 16, 1990, 104 Stat. 2915, provided that: "This Act [enacting subchapter X of this chapter, amending sections 300w–4 and 300w–9 of this title, and enacting provisions set out as a note under section 300d of this title] may be cited as the 'Trauma Care Systems Planning and Development Act of 1990'."

Pub. L. 101–558, §1, Nov. 15, 1990, 104 Stat. 2772, provided that: "This Act [amending sections 280b to

280b–3 of this title] may be cited as the 'Injury Control Act of 1990'."

Pub. L. 101–557, §1, Nov. 15, 1990, 104 Stat. 2766, provided that: "This Act [enacting sections 242q to 242q–5 of this title, amending sections 280c, 280c–2, 280c–3, 280c–5, 285e–2, 285e–3, 300u–6, 300ff–17, 300ff–51, and 300ff–52 of this title and section 4512 of Title 20, Education, and enacting provisions set out as a note under section 300u–6 of this title] may be cited as the 'Home Health Care and Alzheimer's Disease Amendments of 1990'."

Pub. L. 101–527, §1(a), Nov. 6, 1990, 104 Stat. 2311, provided that: "This Act [enacting sections 254c–1, 254t, 256a, 294bb, 294cc, and 300u–6 of this title, amending sections 242k, 242m, 254b, 254c, 294m, 294o, and 295g–2 of this title, enacting provisions set out as notes under sections 242k and 300u–6 of this title, and repealing provisions set out as a note under section 292h of this title] may be cited as the 'Disadvantaged Minority Health Improvement Act of 1990'."

Pub. L. 101–502, §1, Nov. 3, 1990, 104 Stat. 1285, provided that: "This Act [amending sections 207, 247b, 300aa–6, 300aa–11 to 300aa–13, 300aa–15, 300aa–16, 300aa–21, 300ff–13, 300ff–47, and 300ff–49 of this title, section 331 of Title 21, Food and Drugs, and section 201 of Title 37, Pay and Allowances of the Uniformed Services, enacting provisions set out as notes under sections 300aa–2, 300aa–11, and 300aa–12 of this title and section 201 of Title 37, and amending provisions set out as a note under section 300aa–1 of this title] may be cited as the 'Vaccine and Immunization Amendments of 1990'."

Pub. L. 101–381, §1, Aug. 18, 1990, 104 Stat. 576, provided that: "This Act [enacting subchapter XXIV of this chapter, transferring section 300ee–6 of this title to section 300ff–48 of this title, amending sections 284a, 286, 287a, 287c–2, 289f, 290aa–3a, 299c–5, 300ff–48, and 300aaa to 300aaa–13 of this title, and enacting provisions set out as notes under sections 300x–4, 300ff–11, 300ff–46, and 300ff–80 of this title] may be cited as the 'Ryan White Comprehensive AIDS Resources Emergency Act of 1990'."

Pub. L. 101–374, §1, Aug. 15, 1990, 104 Stat. 456, provided that: "This Act [amending sections 290aa–12, 290cc–2, and 300x–4 of this title, enacting provisions set out as notes under sections 289e, 290aa–12, 290cc–2, and 300x–4 of this title, and amending provisions set out as a note under section 289e of this title] may be cited as the 'Drug Abuse Treatment Waiting Period Reduction Amendments of 1990'."

Pub. L. 101–368, §1, Aug. 15, 1990, 104 Stat. 446, provided that: "This Act [amending section 247b of this title] may be cited as the 'Tuberculosis Prevention Amendments of 1990'."

Pub. L. 101–354, §1, Aug. 10, 1990, 104 Stat. 409, provided that: "This Act [enacting subchapter XIII of this chapter] may be cited as the 'Breast and Cervical Cancer Mortality Prevention Act of 1990'."

SHORT TITLE OF 1989 AMENDMENT

Pub. L. 101–93, §1, Aug. 16, 1989, 103 Stat. 603, provided that: "This Act [see Tables for classification] may be cited as the 'Drug Abuse Treatment Technical Corrections Act of 1989'."

SHORT TITLE OF 1988 AMENDMENTS

Pub. L. 100–690, §2011, Nov. 18, 1988, 102 Stat. 4193, provided that: "This subtitle [subtitle A (§§2011–2081) of title II of Pub. L. 100–690, enacting sections 290aa–11 to 290aa–14, 290cc–11 to 290cc–13, 290ff, 300x–1a, 300x–4a, 300x–9a, and 300x–9b of this title, amending sections 242a, 290aa, 290aa–3, 290aa–6, 290aa–8, 290bb–2, 290cc to 290cc–2, 300x, 300x–1a to 300x–4, 300x–5, 300x–9, and 300x–10 to 300x–12 of this title and section 484 of former Title 40, Public Buildings, Property, and Works, repealing sections 300y to 300y–2 of this title, enacting provisions set out as notes under this section and sections 290aa, 290cc–11, 300x–9a, and 300x–11 of this title, and amending provisions set out as a note under section 801 of Title 21, Food and Drugs] may be cited as the 'Comprehensive Alcohol Abuse, Drug Abuse, and Mental Health Amendments Act of 1988'."

Pub. L. 100–607, §1(a), Nov. 4, 1988, 102 Stat. 3048, provided that: "This Act [see Tables for classification] may be cited as the 'Health Omnibus Programs Extension of 1988'."

Pub. L. 100–607, title I, §100(a), Nov. 4, 1988, 102 Stat. 3048, provided that: "This title [see Tables for classification] may be cited as the 'National Institute on Deafness and Other Communication Disorders and Health Research Extension Act of 1988'."

Pub. L. 100–607, title II, §200, Nov. 4, 1988, 102 Stat. 3062, provided that: "This title [see Tables for classification] may be cited as the 'AIDS Amendments of 1988'."

Pub. L. 100–607, title IV, §401(a), Nov. 4, 1988, 102 Stat. 3114, provided that: "This title [enacting sections 300y–21 to 300y–27 of this title, amending sections 273 to 274e of this title, and enacting provisions set out as notes under sections 273 and 300y–21 of this title] may be cited as the 'Organ Transplant Amendments Act of 1988'."

Pub. L. 100–607, title VI, §601(a), Nov. 4, 1988, 102 Stat. 3122, as amended by Pub. L. 100–690, title II, §2603(a)(1), Nov. 18, 1988, 102 Stat. 4234, provided that: "This title [see Tables for classification] may be cited as the 'Health Professions Reauthorization Act of 1988'."

Pub. L. 100–607, title VII, §700(a), Nov. 4, 1988, 102 Stat. 3153, provided that: "This title [enacting sections 296r, 297c–1, 297j, 297n, and 298b–6 of this title, amending sections 210, 294a, 296k, 296l, 296m, 297, 297–1, 297a, 297b, 297d, 297e, 298, and 298b–3 of this title, and enacting provisions set out as a note under section 297d of this title] may be cited as the 'Nursing Shortage Reduction and Education Extension Act of 1988'."

Pub. L. 100–607, title IX, §901, Nov. 4, 1988, 102 Stat. 3171, provided that: "This title [enacting section 300ee–6 of this title and provisions set out as notes under such section] may be cited as the 'Prison Testing Act of 1988'."

Pub. L. 100–578, §1, Oct. 31, 1988, 102 Stat. 2903, provided that: "This Act [amending section 263a of this title and enacting provisions set out as notes under section 263a of this title] may be cited as the 'Clinical Laboratory Improvement Amendments of 1988'."

Pub. L. 100–572, §1, Oct. 31, 1988, 102 Stat. 2884, provided that: "This Act [enacting sections 247b–1 and 300j–21 to 300j–26 of this title, and amending section 300j–4 of this title] may be cited as the 'Lead Contamination Control Act of 1988'."

Pub. L. 100–553, §1, Oct. 28, 1988, 102 Stat. 2769, provided that: "This Act [enacting sections 285m to 285m–6 of this title, amending sections 281 and 285j of this title, and enacting provisions set out as a note under section 285m of this title] shall be cited as the 'National Deafness and Other Communication Disorders Act of 1988'."

Pub. L. 100–517, §1(a), Oct. 24, 1988, 102 Stat. 2578, provided that: "This Act [amending sections 300e, 300e–1, 300e–9, and 300e–10 of this title, enacting provisions set out as notes under sections 300e, 300e–9, and 1302 of this title, and repealing provisions set out as notes under section 300e–1 of this title] may be cited as the 'Health Maintenance Organization Amendments of 1988'."

Pub. L. 100–386, §1(a), Aug. 10, 1988, 102 Stat. 919, provided that: "This Act [amending sections 254b and 254c of this title and enacting provisions set out as a note under section 254b of this title] may be cited as the 'Community and Migrant Health Centers Amendments of 1988'."

SHORT TITLE OF 1987 AMENDMENTS

Pub. L. 100–203, title IV, §4301(a), Dec. 22, 1987, 101 Stat. 1330–221, provided that: "This subtitle [subtitle D (§§4301–4307) of title IV of Pub. L. 100–203, enacting section 300aa–34 of this title, amending sections 300aa–11 to 300aa–13, 300aa–15 to 300aa–17, 300aa–19, 300aa–21 to 300aa–23, 300aa–25 to 300aa–28, and 300aa–31 of this title, repealing section 300aa–18 of this title, and amending provisions set out as a note under section 300aa–1 of this title] may be cited as the 'Vaccine Compensation Amendments of 1987'."

Pub. L. 100–177, §1(a), Dec. 1, 1987, 101 Stat. 986, provided that: "This Act [enacting sections 254l–1, 254q, and 254q–1 of this title, amending sections 242a, 242c, 242k, 242m, 242n, 242p, 247b, 254d to 254g, 254h–1, 254k, 254m to 254q, 254r, 295g–8, and 11137 of this title, repealing former section 254q of this title, and enacting provisions set out as notes under sections 242c, 242k, 242m, 254l–1, 254o, 300aa–2, and 11137 of this title] may be cited as the 'Public Health Service Amendments of 1987'."

Pub. L. 100–175, title VI, §601, Nov. 29, 1987, 101 Stat. 979, provided that: "This title [enacting part K (§280c et seq.) of subchapter II of this chapter] may be cited as the 'Health Care Services in the Home Act of 1987'."

Pub. L. 100–97, §1, Aug. 18, 1987, 101 Stat. 713, provided: "That this Act [enacting section 295g–8a of this title and provisions set out as a note under section 295g–8a of this title] may be cited as the 'Excellence in Minority Health Education and Care Act'."

SHORT TITLE OF 1986 AMENDMENTS

Pub. L. 99–660, title III, §301, Nov. 14, 1986, 100 Stat. 3755, provided that: "This title [enacting sections 300aa–1 to 300aa–33 of this title, amending sections 218, 242c, 262, 286, and 289f of this title, redesignating former sections 300aa to 300aa–15 of this title as sections 300cc to 300cc–15 of this title, and enacting provisions set out as notes under sections 300aa–1 and 300aa–4 of this title] may be cited as the 'National Childhood Vaccine Injury Act of 1986'."

Pub. L. 99–660, title V, §501, Nov. 14, 1986, 100 Stat. 3794, provided that: "This title [enacting sections 300x–10 to 300x–13 of this title and amending sections 290aa–3 and 300x–4 of this title] may be cited as the 'State Comprehensive Mental Health Services Plan Act of 1986'."

Pub. L. 99–660, title VIII, §801, Nov. 14, 1986, 100 Stat. 3799, provided that: "This title [amending sections 300e–1, 300e–4, 300e–5 to 300e–10, 300e–16, and 300e–17 of this title, repealing sections 300e–2, 300e–3, and 300e–4a of this title, and enacting provisions set out as notes under sections 300e, 300e–1, 300e–4, and 300e–5 of this title] may be cited as the 'Health Maintenance Organization Amendments of 1986'."

Pub. L. 99–649, §1, Nov. 10, 1986, 100 Stat. 3633, provided: "That this Act [enacting sections 280b to 280b–3 of this title and provisions set out as a note under section 280b of this title] may be cited as the 'Injury Prevention Act of 1986'."

Pub. L. 99–570, title IV, §4001(a), Oct. 27, 1986, 100 Stat. 3207–103, provided that: "This subtitle [subtitle A (§§4001–4022) of title IV of Pub. L. 99–570, enacting sections 290aa–3a, 290aa–6 to 290aa–10, and 300y to 300y–2 of this title, amending sections 218, 241, 290aa to 290aa–3, 290aa–4, 290aa–5, 290bb–1, 290bb–2, 290cc, and 290cc–2 of this title and sections 331 and 350a of Title 21, Food and Drugs, and enacting provisions set out as notes under sections 290aa–3, 290aa–3a, and 290bb of this title] may be cited as the 'Alcohol and Drug Abuse Amendments of 1986'."

Pub. L. 99–339, §1, June 19, 1986, 100 Stat. 642, provided that: "This Act [enacting sections 300g–6, 300h–5 to 300h–7, 300i–1, and 300j–11 of this title, amending sections 300f, 300g–1 to 300g–5, 300h to 300h–2, 300h–4, 300h–6, 300h–7, 300i, 300j to 300j–4, 300j–7, and 6979a of this title and sections 1261 and 1263 of Title 15, Commerce and Trade, transferring section 6939b of this title to 6979a of this title, and enacting provisions set out as notes under sections 300g–6 and 300j–1 of this title and section 1261 of Title 15] may be cited as the 'Safe Drinking Water Act Amendments of 1986'."

Pub. L. 99–280, §1(a), Apr. 24, 1986, 100 Stat. 399, provided that: "This Act [amending sections 254b and 254c of this title and repealing sections 300y to 300y–11 of this title] may be cited as the 'Health Services Amendments Act of 1986'."

SHORT TITLE OF 1985 AMENDMENTS

Pub. L. 99–158, §1(a), Nov. 20, 1985, 99 Stat. 820, provided that: "This Act [enacting sections 275, 281 to 283, 284 to 284c, 285 to 285a–5, 285b to 285b–6, 285c to 285c–7, 285d to 285d–7, 285e to 285e–2, 285f, 285g to 285g–3, 285h, 285i, 285j to 285j–2, 285k, 285l, 286 to 286a–1, 286b to 286b–8, 287 to 287a–1, 287b, 287c to 287c–3, 288 to 288b, and 289 to 289h of this title, amending sections 217a, 218, 241, 290aa–5, and 300c–12 of this title, repealing sections 275 to 280a–1, 280b to 280b–2, 280b–4, 280b–5, and 280b–7 to 280b–11 of this title, omitting sections 286c to 286e, 287d to 287i, 288c, 289, 289c–1 to 289c–3, 289c–4 to 289c–7, 289i to 289k, 289k–2 to 289k–5, and 289l to 289l–8 of this title, enacting provisions set out as notes under sections 218, 281, 285c, 285e, 285e–2, 285j–1 and 289d of this title, and repealing provisions set out as a note under section 287i of this title] may be cited as the 'Health Research Extension Act of 1985'."

Pub. L. 99–129, §1, Oct. 22, 1985, 99 Stat. 523, provided: "That this Act [enacting sections 294q–1 to 294q–3 of this title, amending sections 254l, 292a, 292b, 292h, 292j, 293c, 294a, 294b, 294d, 294e, 294g, 294j, 294m to 294p, 294z, 295f to 295f–2, 295g, 295g–1, 295g–3, 295g–4, 295g–6 to 295g–8, 295g–8b, 295h, 295h–1a to 295h–1c, 296k, 296l, 296m, 297a, 298b–5, and 300aa–14 of this title, repealing sections 292c, 295 to 295e–5, 295g–2, 295g–5, 295g–8a, and 295g–9 of this title, enacting provisions set out as notes under sections 254l, 292h, 293c, 294d, 294n, and 300aa–14 of this title and section 3811 of Title 50, War and National Defense, and amending provisions set out as a note under section 298b–5 of this title] may be cited as the 'Health Professions Training Assistance Act of 1985'."

Pub. L. 99–117, §1(a), Oct. 7, 1985, 99 Stat. 491, provided that: "this Act [amending sections 207, 210, 213a, 242c, 242n, 243, 246, 247b, 247e, 253, 290aa–3, 300x–4, 300x–5, and 300x–9 of this title and section 1333 of Title 15, Commerce and Trade, repealing sections 247, 254a–1, 299 to 299j, 300d–4, 300d–6, and 300aa–4 of this title, and enacting provisions set out as notes under sections 210, 241, and 242n of this title] may be cited as the 'Health Services Amendments of 1985'."

Pub. L. 99–92, §1, Aug. 16, 1985, 99 Stat. 393, provided: "That this Act [enacting section 297i of this title, transferring section 296c of this title to section 298b–5 of this title, amending sections 296k to 296m, 297, 297–1, 297a, 297b, 297d, 297e, 298, 298b, and 298b–5 of this title, sections 1332, 1333, 1336, and 1341 of Title 15, Commerce and Trade, and section 6103 of Title 26, Internal Revenue Code, repealing sections 296 to 296b, 296d to 296f, 296j, 297h, and 297j of this title, and enacting provisions set out as notes under sections 296k and 298b–5 of this title and section 1333 of Title 15] may be cited as the 'Nurse Education Amendments of 1985'."

SHORT TITLE OF 1984 AMENDMENTS

Pub. L. 98–555, §1(a), Oct. 30, 1984, 98 Stat. 2854, provided that: "this Act [enacting sections 300w–9 and 300w–10 of this title and amending sections 247b, 247c, 255, 300, 300w, 300w–4, and 300w–5 of this title] may be cited as the 'Preventive Health Amendments of 1984'."

Pub. L. 98–551, §1, Oct. 30, 1984, 98 Stat. 2815, provided: "That this Act [enacting section 300u–5 of this title, amending sections 242b, 242c, 242m, 242n, 254r, 300u, and 300u–3 of this title and sections 360bb and 360ee of Title 21, Food and Drugs, and repealing sections 300u–5 to 300u–9 of this title] may be cited as the 'Health Promotion and Disease Prevention Amendments of 1984'."

Pub. L. 98–509, §1(a), Oct. 19, 1984, 98 Stat. 2353, provided that: "this Act [enacting sections 290bb–1a,

290cc–1, 290cc–2, and 300x–1a of this title, amending sections 218, 290aa, 290aa–1 to 290aa–3, 290bb, 290bb–2, 290cc, 290dd, 290dd–1, 300x, 300x–1, and 300x–2 to 300x–9 of this title and section 802 of Title 21, Food and Drugs, repealing sections 1161 to 1165 of Title 21, and enacting provisions set out as notes under sections 300x and 300x–1a of this title and section 802 of Title 21] may be cited as the 'Alcohol Abuse, Drug Abuse, and Mental Health Amendments of 1984'."

Pub. L. 98–507, §1, Oct. 19, 1984, 98 Stat. 2339, provided: "That this Act [enacting sections 273 to 274e of this title and provisions set out as notes under section 273 of this title] may be cited as the 'National Organ Transplant Act'."

SHORT TITLE OF 1983 AMENDMENTS

Pub. L. 98–194, §1, Dec. 1, 1983, 97 Stat. 1345, provided: "That this Act [amending section 254g of this title and enacting provisions set out as notes under section 254g of this title] may be cited as the 'Rural Health Clinics Act of 1983'."

Pub. L. 98–24, §1(a), Apr. 26, 1983, 97 Stat. 175, provided that: "This Act [enacting sections 290aa–4 and 290aa–5 of this title, transferring sections 219 to 224, 225a to 227, 228 to 229d, 289k–1, 3511, 4551, 4585, 4587, 4588, 4571, 4561, 4581, and 4582 of this title to sections 300aa to 300aa–5, 300aa–6 to 300aa–8, 300aa–9 to 300aa–14, 290aa–3, 290aa, 290aa–1, 290bb, 290bb–1, 290bb–2, 290dd, 290dd–1, 290dd–2, and 290dd–3 of this title, respectively, and sections 1173(a), 1174, 1175, 1180, 1191, 1192, and 1193 of Title 21, Food and Drugs, to sections 290aa–2(e), 290ee–2, 290ee–3, 290ee–1, 290aa–2, 290ee, and 290cc of this title, respectively, amending sections 218, 278, 289l–4, 290aa to 290aa–2, 290bb to 290bb–2, 290cc, 290dd to 290dd–2, 290ee to 290ee–3, and 4577 of this title and sections 1165, 1173, and 1177 of Title 21, repealing sections 4552, 4553, and 4586 of this title and sections 1117, 1172, and 1194 of Title 21, enacting provisions set out as a note under section 290aa of this title, amending provisions set out as a note under section 4541 of this title, and repealing provisions set out as a note under section 242 of this title] may be cited as the 'Alcohol and Drug Abuse Amendments of 1983'."

SHORT TITLE OF 1981 AMENDMENT

Pub. L. 97–35, title IX, §940(a), Aug. 13, 1981, 95 Stat. 572, provided that: "This subtitle [subtitle F (§§940–949) of title IX of Pub. L. 97–35, amending sections 300e to 300e–4a, 300e–6 to 300e–9, 300e–11, 300e–17, and 300m–6 of this title, repealing sections 300e–13 and 300e–15 of this title, and enacting provisions set out as notes under sections 300e–9 and 300m–6 of this title] may be cited as the 'Health Maintenance Organization Amendments of 1981'."

SHORT TITLE OF 1980 AMENDMENT

Pub. L. 96–538, §1(a), Dec. 17, 1980, 94 Stat. 3183, provided that: "this Act [enacting sections 289c–3, 289c–4, 289c–7 of this title, amending sections 286e, 287c, 287i, 289a, 289c–1, 289c–2, 289c–5, 289c–6, 294a, 294d, 294v, 300k–1, 300l–5, 300m, 300m–3, 300m–6, 300n, and 300n–1 of this title and section 1182 of Title 8, Aliens and Nationality, repealing sections 289c–3a and 289c–8 and former sections 289c–3, 289c–4, and 289c–7 of this title, and enacting provisions set out as notes under sections 289, 300l–5, and 300m–6 of this title] may be cited as the 'Health Programs Extension Act of 1980'."

SHORT TITLE OF 1979 AMENDMENTS

Pub. L. 96–142, title I, §101, Dec. 12, 1979, 93 Stat. 1067, provided that: "This title [amending sections 295g–9, 300d–1, 300d–3, 300d–5, 300d–6, 300d–8, and 300d–21 of this title and enacting provisions set out as a note under section 295g–9 of this title] may be cited as the 'Emergency Medical Services Systems Amendments of 1979'."

Pub. L. 96–142, title II, §201, Dec. 12, 1979, 93 Stat. 1070, provided that: "This title [enacting section 300c–12 and amending section 300c–11 of this title] may be cited as the 'Sudden Infant Death Syndrome Amendments of 1979'."

Pub. L. 96–79, §1(a), Oct. 4, 1979, 93 Stat. 592, provided that: "This Act [enacting sections 300m–6, 300s, 300s–1, 300s–6, and 300t–11 to 300t–14 of this title, amending this section and sections 246, 300k–1 to 300k–3, 300l to 300*l*–5, 300m to 300m–5, 300n, 300n–1, 300n–3, 300n–5, 300q, 300q–2, 300r, 300s–3, 300s–5, 300t, 1396b, 2689t, and 4573 of this title and section 1176 of Title 21, Food and Drugs, repealing sections 300o to 300*o*–3, 300p to 300p–3, 300q–1, and former section 300s of this title, redesignating former section 300s–1 as 300s–1a of this title, and enacting provisions set out as notes under sections 300k–1, 300l, 300*l*–1, 300*l*–4, 300*l*–5, 300m, 300m–6, 300n, 300q, and 300t–11 of this title] may be cited as the 'Health Planning and Resources Development Amendments of 1979'."

Pub. L. 96–76, title I, §101(a), Sept. 29, 1979, 93 Stat. 579, provided that: "This title [enacting section 297–1 of this title, amending sections 296, 296d, 296e, 296k to 296m, 297 to 297c, 297e, and 297j of this title,

and enacting provisions set out as notes under sections 296 and 297j of this title] may be cited as the 'Nurse Training Amendments of 1979'."

Pub. L. 96–76, title III, §301, Sept. 29, 1979, 93 Stat. 584, provided that: "This title [amending sections 204, 206, 207, 209, 210–1, 210b, 211, 212, 213a, 215, and 218a of this title and sections 201, 415, and 1006 of Title 37, Pay and Allowances of the Uniformed Services, and enacting provisions set out as a note under section 206 of this title] may be cited as the 'Public Health Service Administrative Amendments of 1979'."

SHORT TITLE OF 1978 AMENDMENTS

Pub. L. 95–626, §1(a), Nov. 10, 1978, 92 Stat. 3551, provided that: "This Act [enacting sections 242p, 247, 247a, 247b–1, 254a–1, 255, 256, 256a, 300a–21 to 300a–29, 300a–41, 300b–6, and 300u–6 to 300u–9 of this title, amending sections 218, 246, 247b, 247c, 247e, 254a, 254b, 254c, 254k, 294t, 294u, 295h–1, 300b, 300b–3, 300c–21, 300c–22, 300d–2, 300d–3, 300d–5, 300d–6, 300e–12, 300e–14a, 300u–5, 1396b, and 4846 of this title, repealing sections 256, 4801, 4811, 4844, and 4845 of this title, enacting provisions set out as notes under this section and sections 246, 247a, 247c, 254a–1, 254b to 254d, 256, 256a, 289b, 289d, 300a–21, 300d–2, and 300d–3 of this title, and amending provisions set out as notes under sections 300b and 1395x of this title] may be cited as the 'Health Services and Centers Amendments of 1978'."

Pub. L. 95–626, title I, §101, Nov. 10, 1978, 92 Stat. 3551, provided that: "This part [part A (§§101–107) of title I of Pub. L. 95–626, enacting section 256a of this title, amending sections 218, 247e, 254b, 254c, 255, 300e–12, 300e–14a, and 1396b of this title, repealing section 256 of this title, and enacting provisions set out as notes under sections 254b, 254c, and 256a of this title] may be cited as the 'Migrant and Community Health Centers Amendments of 1978'."

Pub. L. 95–626, title I, §111, Nov. 10, 1978, 92 Stat. 3562, provided that: "This part [part B (§§111–116) of title I of Pub. L. 95–626, enacting sections 254a–1 and 256 of this title, amending sections 294t and 294u of this title, and enacting provisions set out as notes under sections 254a–1, 254d, and 256 of this title] may be cited as the 'Primary Health Care Act of 1978'."

Pub. L. 95–626, title II, §200, Nov. 10, 1978, 92 Stat. 3570, provided that: "This title [enacting sections 247, 247a, 255, and 300b–6 of this title, amending sections 246, 247b, 247c, 300b, 300b–3, 300c–21, 300c–22, 300d–2, 300d–3, 300d–5, 300d–6, and 4846 of this title, repealing sections 4801, 4811, 4844, and 4845 of this title, enacting provisions set out as notes under sections 246, 247a, 247c, 289d, 300d–2, and 300d–3 of this title, and amending provisions set out as notes under sections 300b and 1395x of this title] may be cited as the 'Health Services Extension Act of 1978'."

Pub. L. 95–623, §1(a), Nov. 9, 1978, 92 Stat. 3443, provided that: "This Act [enacting sections 229c, 242n, and 4362a of this title, amending sections 210, 242b, 242c, 242k, 242m, 242o, 289k, 289*l*–1, 292e, 292h, 292i, 294t, 295f–1, 295f–2, 295g–2, 295g–8, 295h–2, 7411, 7412, 7417, and 7617 of this title, repealing section 280c of this title, enacting provisions set out as a note under section 242m of this title, and amending provisions set out as notes under sections 292h, 295h–4, and 296 of this title] may be cited as the 'Health Services Research, Health Statistics, and Health Care Technology Act of 1978'."

Pub. L. 95–622, title II, §201(a), Nov. 9, 1978, 92 Stat. 3420, provided that: "This title [enacting sections 289l–6 to 289l–8 of this title, amending sections, 241, 248, 277, 280b, 281 to 286g, 287a to 287d, 287g, 287i, 289c–6, 289l to 289l–2, 289l–4, 4541, 4573, and 4585 of this title, and enacting provisions set out as notes under sections 241, 286b, 286f, 289a, and 289l–1 of this title] may be cited as the 'Biomedical Research and Research Training Amendments of 1978'."

Pub. L. 95–559, §1(a), Nov. 1, 1978, 92 Stat. 2131, provided that: "This Act [enacting sections 300e–4a, 300e–16, and 300e–17 of this title, amending sections 300e, 300e–1, 300e–3, 300e–4, 300e–5, 300e–7, 300e–8, 300e–9, 300e–11 to 300e–13, 1320a–1, 1396a, and 1396b of this title, and enacting provisions set out as notes under sections 300e–3, 300e–4, 300e–16, and 1396a of this title] may be cited as the 'Health Maintenance Organization Amendments of 1978'."

SHORT TITLE OF 1977 AMENDMENTS

Pub. L. 95–190, §1, Nov. 16, 1977, 91 Stat. 1393, provided that: "This Act [enacting sections 300j–10 and 7625a of this title, amending sections 300f, 300g–1, 300g–3, 300g–5, 300h, 300h–1, 300j to 300j–2, 300j–4, 300j–6, 300j–8, 7410, 7411, 7413, 7414, 7416, 7419, 7420, 7426, 7472 to 7475, 7478, 7479, 7502, 7503, 7506, 7521, 7522, 7525, 7541, 7545, 7549, 7602, 7604, 7607, 7623, and 7626 of this title, enacting provisions set out as notes under section 300f of this title, and section 5108 of Title 5, Government Organization and Employees, and amending provisions set out as notes under sections 300f, 7401, and 7502 of this title] may be cited as the 'Safe Drinking Water Amendments of 1977'."

Pub. L. 95–83, title I, §101, Aug. 1, 1977, 91 Stat. 383, provided that: "This title [amending this section and sections 242m, 300e–8, 300k–3, 300l to 300*l*–5, 300m, 300m–2, 300m–4, 300m–5, 300n–3, 300n–5, 300*o*–1 to 300*o*–3, 300p, 300p–3, 300q, 300q–2, 300r, 300s–3, 300t, and 1396b of this title, and enacting provisions

set out as a note under section 1396b of this title] may be cited as the 'Health Planning and Health Services Research and Statistics Extension Act of 1977'."

Pub. L. 95–83, title II, §201, Aug. 1, 1977, 91 Stat. 386, provided that: "This title [amending sections 280b, 286b, 286c, 286d, 286f, 286g, 287c, 287d, 287f, 287h, 287i, and 289*l*–1 of this title] may be cited as the 'Biomedical Research Extension Act of 1977'."

Pub. L. 95–83, title III, §301, Aug. 1, 1977, 91 Stat. 387, provided that: "This title [enacting section 294y–1 of this title, amending sections 210, 246, 247d, 254c, 292g, 292h, 293a, 294d, 294e, 294h, 294i, 294j, 294n, 294r, 294s, 294w, 294z, 295f–1, 295g–1, 295g–9, 295h–5, 295h–5c, 296e, 296m, 297, 300, 300a–1, 300a–2, 300a–3, 300c–11, 300c–21, 300c–22, 701, 2689a to 2689e, 2689h, 2689p, 2689q, 4572, 4573, and 4577 of this title, sections 1101 and 1182 of Title 8, Aliens and Nationality, sections 1112 and 1176 of Title 21, Food and Drugs, and section 1614 of Title 25, Indians, enacting provisions set out as notes under sections 242b, 242l, 294d, 294i, 294n, 294r, 294t, 294y–1, 294z, 295f–1, 295g–1, 295h–5, and 296m of this title and sections 1101 and 1182 of Title 8, and amending provisions set out as notes under sections 289k–2, 1395x, and 1396b of this title] may be cited as the 'Health Services Extension Act of 1977'."

SHORT TITLE OF 1976 AMENDMENTS

Pub. L. 94–573, §1(a), Oct. 21, 1976, 90 Stat. 2709, provided that: "This Act [enacting section 300d–21 of this title, amending sections 295f–6 and 300d to 300d–9 of this title, enacting provisions set out as notes under sections 242b, 300d, 300d–7, and 300d–9 of this title, and amending provisions set out as notes under sections 218, 289c–1, and 289*l*–1 of this title] may be cited as the 'Emergency Medical Services Amendments of 1976'."

Pub. L. 94–562, §1(a), Oct. 19, 1976, 90 Stat. 2645, provided that: "This Act [enacting sections 289c–3a, 289c–7, and 289c–8 of this title, amending sections 289c–2, 289c–5, and 289c–6 of this title, and enacting provisions set out as notes under sections 289a, 289c–3a, and 289c–7 of this title] may be cited as the 'Arthritis, Diabetes, and Digestive Disease Amendments of 1976'."

Pub. L. 94–484, §1(a), Oct. 12, 1976, 90 Stat. 2243, provided that: "This Act [enacting sections 254 to 254k, 292, 292e to 292k, 294 to 294l, 294r to 294z, 294aa, 295f–1, 295g to 295g–8, 295g–10, 295h to 295h–2, and 295h–4 to 295h–7 of this title; renumbering sections 293d as 292a, 293e as 292b, 295h–8 as 292c, 295h–9 as 292d, 293g to 293i as 293d to 293f, 294 to 294c as 294m to 294p, 294e as 294q, 295f–5 as 295f–2, and 295f–6 as 295g–9 of this title; amending this section and sections 234, 244–1, 245a, 246, 247c, 254b, 263c, 292a to 292c, 293 to 293d, 293f, 294g, 294m to 294p, 295e–1 to 295e–4, 295f to 295f–4, 295g, 295g–11, 295g–23, 295h–1 to 295h–3, 297, 300a, 300d, 300d–7, 300f, 300l–1, 300n, and 300s–3 of this title and sections 1101 and 1182 of Title 8, Aliens and Nationality; repealing sections 234, 244–1, 245a, 254b, 292 to 292j, 293f, 294d, 294f, 294g, 295f–1, to 295f–4, 295g, 295g–1, 295g–11, and 295g–21 to 295g–23 of this title; omitting sections 295h to 295h–2, 295h–3a to 295h–3d, 295h–4, 295h–5, and 295h–7 of this title; and enacting provisions set out as notes under sections 254d, 292, 292b, 292h, 293, 293f, 294, 294n, 294o, 294q, 294r, 294t, 294z, 295g, 295g–1, 295g–9, 295g–10, 295h, 295h–4, and 300l–1 of this title and section 1182 of Title 8] may be cited as the 'Health Professions Educational Assistance Act of 1976'."

Pub. L. 94–460, §1(a), Oct. 8, 1976, 90 Stat. 1945, provided that: "This Act [enacting section 300e–15 of this title, amending sections 242c, 289k–2, 300e, 300e–1 to 300e–11, 300e–13, 300n–1, 1395x note, 1395mm, and 1396b of this title, section 8902 of Title 5, Government Organization and Employees, and section 360d of Title 21, Food and Drugs, and enacting provisions set out as notes under sections 300e and 1396b of this title] may be cited as the 'Health Maintenance Organization Amendments of 1976'."

Pub. L. 94–380, §1, Aug. 12, 1976, 90 Stat. 1113, provided: "That this Act [amending section 247b of this title and enacting provisions set out as a note under section 247b of this title] may be cited as the 'National Swine Flu Immunization Program of 1976'."

Pub. L. 94–317, title I, §101, June 23, 1976, 90 Stat. 695, provided that: "This title [enacting subchapter XV of this chapter] may be cited as the 'National Consumer Health Information and Health Promotion Act of 1976'."

Pub. L. 94–317, title II, §201, June 23, 1976, 90 Stat. 700, provided that: "This title [amending sections 243, 247b, 247c, 4801, 4831, and 4841 to 4843 of this title and enacting provisions set out as notes under sections 247b and 247c of this title] may be cited as the 'Disease Control Amendments of 1976'."

Pub. L. 94–278, §1(a), Apr. 22, 1976, 90 Stat. 401, provided that: "This Act [enacting sections 217a–1, 289 *l*–5, 300b, 300b–1 to 300b–5 of this title and sections 350 and 378 of Title 21, Food and Drugs, and amending sections 213e, 225a, 234, 241, 247d, 254c, 287, 287a to 287d, 287f to 287i, 289a, 289c–1, 289c–5, 289c–6, 289l–1, 289l–2, 294b, 295g–23, 300c–11, 300l, 300p–3, 300s–1, 6062 and 6064 of this title and sections 321,

333, 334 and 343 of Title 21, and enacting provisions set out as notes under sections 218, 287, 289c–1, 289c–2, 289*l*–1, 300b and 6001 of this title and sections 334 and 350 of Title 21] may be cited as the 'Health Research and Health Services Amendment of 1976'."

Pub. L. 94–278, title IV, §401, Apr. 22, 1976, 90 Stat. 407, provided that: "This title [enacting part A of subchapter IX of this chapter, omitting former Part B of subchapter IX of this chapter relating to Cooley's Anemia Programs, redesignating former Parts C and D of subchapter IX of this chapter as Parts B and C of subchapter IX of this chapter, respectively, and amending section 300c–11 of this title] may be cited as the 'National Sickle Cell Anemia, Cooley's Anemia, Tay-Sachs, and Genetic Diseases Act'."

Pub. L. 94–278, title VI, §601, Apr. 22, 1976, 90 Stat. 413, provided that: "This title [amending sections 289a, 289c–1, 289c–5, and 289c–6 of this title and amending provisions set out as notes under section 289c–1 of this title] may be cited as the 'National Arthritis Act Technical Amendments of 1976'."

SHORT TITLE OF 1975 AMENDMENTS

Pub. L. 94–63, title I, §101, July 29, 1975, 89 Stat. 304, provided that: "This title [amending section 246 of this title and enacting provisions set out as a note under section 246 of this title] may be cited as the 'Special Health Revenue Sharing Act of 1975'."

Pub. L. 94–63, title II, §201, July 29, 1975, 89 Stat. 306, provided that: "This title [enacting sections 300a–6a and 300a–8 of this title, amending sections 300, 300a–1 to 300a–4 of this title, and repealing section 3505c of this title] may be cited as the 'Family Planning and Population Research Act of 1975'."

Pub. L. 94–63, title IX, §901(a), July 29, 1975, 89 Stat. 354, provided that: "This title [enacting sections 296j to 296m and 298b–3 of this title, amending sections 296 to 296i, 297 to 297e, 297g to 297h, 298 to 298b–2, 298c, 298c–1 and 298c–7 of this title, repealing sections 296g, 296i, 297f, 298c–7, and 298c–8 of this title, and enacting provisions set out as notes under sections 296, 296a, 296d, 296e, 296m, 297, and 297b of this title and former section 297f of this title] may be cited as the 'Nurse Training Act of 1975'."

Pub. L. 93–641, §1, Jan. 4, 1975, 88 Stat. 2225, provided that: "This Act [enacting subchapter XIII of this chapter amending section 300e–4 of this title, repealing section 247a of this title, and enacting provisions set out as notes under sections 217a, 229, 291b, 300l–4, and 300m of this title] may be cited as the 'National Health Planning and Resources Development Act of 1974'."

SHORT TITLE OF 1974 AMENDMENTS

Pub. L. 93–640, §1, Jan. 4, 1975, 88 Stat. 2217, provided that: "This Act [enacting sections 289c–4, 289c–5, and 289c–6 of this title, amending sections 289a and 289c–1 of this title, and enacting provisions set out as notes under section 289c–1 of this title] may be cited as the 'National Arthritis Act of 1974'."

Pub. L. 93–523, §1, Dec. 16, 1974, 88 Stat. 1660, as amended by Pub. L. 104–182, title V, §501(e), Aug. 6, 1996, 110 Stat. 1691, provided that: "This Act [enacting subchapter XII of this chapter and section 349 of Title 21, Food and Drugs, amending this section, and enacting provisions set out as a note under section 300f of this title] may be cited as the 'Safe Drinking Water Act of 1974'."

Pub. L. 93–354, §1, July 23, 1974, 88 Stat. 373, provided that: "This Act [enacting sections 289c–1a, 289c–2, and 289c–3 of this title, amending sections 247b and 289c–1 of this title, and enacting provisions set out as notes under section 289c–2 of this title] may be cited as the 'National Diabetes Mellitus Research and Education Act'."

Pub. L. 93–353, §1(a), July 23, 1974, 88 Stat. 362, provided that: "This Act [enacting sections 242k, 242m to 242o, and 253b of this title, renumbering former sections 242i, 242j, 242f, 242d, 242g, and 242h as sections 235, 236, 242l, 244–1, 245a, and 247d of this title, amending sections 236, 242b, 242c, 242l, 244–1, 245a, 280b, 280b–1, 280b–2, 280b–4, 280b–5, and 280b–7 to 280b–9, and repealing sections 242e, 244, 244a, 245, 247, 280b–3, and 280b–12 of this title, and enacting provisions set out as notes under sections 242m, 253b, and 280b of this title] may be cited as the 'Health Services Research, Health Statistics, and Medical Libraries Act of 1974'."

Pub. L. 93–353, title I, §101, July 23, 1974, 88 Stat. 362, provided that: "This title [enacting sections 242k, 242m to 242o, and 253b, renumbering former sections 242i, 242j, 242f, 242d, 242g, and 242h as sections 235, 236, 242l, 244–1, 245a, and 247d of this title, amending sections 236, 242b, 242c, 242l, 244–1, and 245a, repealing sections 242e, 244, 244a, 245, and 247 of this title, and enacting provisions set out as notes under sections 242m and 253b of this title] may be cited as the 'Health Services Research and Evaluation and Health Statistics Act of 1974'."

Pub. L. 93–352, title I, §101, July 23, 1974, 88 Stat. 358, provided that: "This title [enacting section 289l–4 of this title, amending sections 241, 282, 286a, 286b, 286c, 286d, 286g, and 289l of this title, enacting provisions set out as notes under sections 289l and 289*l*–1 of this title, and amending provisions set out as a note under this section] may be cited as the 'National Cancer Act Amendments of 1974'."

Pub. L. 93–348, title I, §1, July 12, 1974, 88 Stat. 342, provided that: "This Act [enacting sections 289l–1 to

289l–3 of this title, amending sections 218, 241, 242a, 282, 286a, 286b, 287a, 287b, 287d, 288a, 289c, 289c–1, 289g, 289k, and 300a–7 of this title, and enacting provisions set out as notes under sections 218, 241, 289*l*–1, and 289*l*–3 of this title] may be cited as the 'National Research Act'."

Pub. L. 93–348, title I, §101, July 12, 1974, 88 Stat. 342, provided that: "This title [enacting sections 289l–1 and 289*l*–2 and amending sections 241, 242a, 282, 286a, 286b, 287a, 287b, 287d, 288a, 289c, 289c–1, 289g, 289k, 295f–3, and 295h–9 of this title] may be cited as the 'National Research Service Award Act of 1974'."

Pub. L. 93–296, §1, May 31, 1974, 88 Stat. 184, provided that: "This Act [enacting Part H of subchapter III of this chapter and provisions set out as notes under section 289k–2 of this title] may be cited as the 'Research on Aging Act of 1974'."

Pub. L. 93–270, §1, Apr. 22, 1974, 88 Stat. 90, provided that: "This Act [enacting part B of subchapter IX of this chapter, amending sections 289d and 289g of this title, and enacting provisions set out as a note under section 289g of this title] may be cited as the 'Sudden Infant Death Syndrome Act of 1974'."

SHORT TITLE OF 1973 AMENDMENTS

Pub. L. 93–222, §1, Dec. 29, 1973, 87 Stat. 914, provided in part that Pub. L. 93–222 [enacting subchapter XI of this chapter and section 280c of this title, amending section 2001 of this title and section 172 of Title 12, Bank and Banking, repealing section 763c of Title 33, Navigation and Navigable Waters, enacting provisions set out as notes under sections 300e and 300e–1 of this title, amending provisions set out as notes under this section, and repealing provisions set out as notes under this section and sections 211a, 212a, and 222 of this title] shall be cited as the "Health Maintenance Organization Act of 1973."

Pub. L. 93–154, §1, Nov. 16, 1973, 87 Stat. 594, provided that: "This Act [enacting subchapter X of this chapter and section 295f–6 of this title, amending sections 295f–2 and 295f–4 of this title, and enacting provisions set out as a note under this section] may be cited as the 'Emergency Medical Services Systems Act of 1973'."

Pub. L. 93–45, §1, June 18, 1973, 87 Stat. 91, provided that: "This Act [enacting section 300a–7 of this title, amending sections 242b, 242c, 244–1, 245a, 246, 280b–4, 280b–5 280b–7, 280b–8, 280b–9, 291a, 291j–1, 291j–5, 295h–1, 295h–2, 295h–3a, 299a, 300, 300a–1, 300a–2, 300a–3, 2661, 2671, 2677, 2681, 2687, 2688a, 2688d, 2688j–1, 2688j–2, 2688l, 2688l–1, 2688n–1, 2688o, and 2688u of this title, and enacting provisions set out as amendment to note provisions under this section] may be cited as the 'Health Programs Extension Act of 1973'."

SHORT TITLE OF 1972 AMENDMENTS

Pub. L. 92–585, §1, Oct. 27, 1972, 86 Stat. 1290, provided that: "This Act [enacting section 234 of this title, amending sections 254b and 294a of this title, and enacting provisions set out as a note under section 246 of this title] may be cited as the 'Emergency Health Personnel Act Amendments of 1972'."

Pub. L. 92–449, §1, Sept. 30, 1972, 86 Stat. 748, provided that: "This Act [enacting section 247c of this title, amending sections 247b and 300 of this title, and enacting provisions set out as notes under section 247c of this title] may be cited as the 'Communicable Disease Control Amendments Act of 1972'."

Pub. L. 92–449, title II, §201, Sept. 30, 1972, 86 Stat. 750, provided that: "This title [enacting section 247c of this title and provisions set out as notes under section 247c of this title] may be cited as the 'National Venereal Disease Prevention and Control Act'."

Pub. L. 92–423, §1, Sept. 19, 1972, 86 Stat. 679, provided that: "This Act [enacting sections 287b to 287f and 287i of this title, amending sections 218, 241, 287, 287a, 287g, and 287h of this title, and enacting provisions set out as notes under section 287 of this title] may be cited as the 'National Heart, Blood Vessel, Lung, and Blood Act of 1972'."

SHORT TITLE OF 1971 AMENDMENTS

Pub. L. 92–218, §1, Dec. 23, 1971, 85 Stat. 778, provided that: "This Act [enacting sections 286a to 286g and 289l of this title, amending sections 218, 241, 282, 283, and 284 of this title, and enacting provisions set out as notes under sections 281, 286, and 289l of this title] may be cited as 'The National Cancer Act of 1971'."

Pub. L. 92–158, §1(a), Nov. 18, 1971, 85 Stat. 465, provided that: "This Act [enacting sections 296h, 296i, 297i, 298b–1, and 298b–2 of this title, amending sections 296, 296a, 296b, 296c, 296d, 296e, 296f, 296g, 297, 297a, 297b, 297c, 297e, 297f, 298, 298b, 298c, and 298c–7 of this title and enacting provisions set out as notes under sections 296, 296a, 296d, 296e, 297b, and 298c of this title] may be cited as the 'Nurse Training Act of 1971'."

Pub. L. 92–157, title I, §101(a), Nov. 18, 1971, 85 Stat. 431, provided that: "This title [enacting sections 293i, 294g, 295e–1 to 295e–5, 295f–5, 295g–11, 295g–21 to 295g–23, and 3505d of this title, amending sections 210 to 218, 242i, 254, 276, 277, 280, 280a–1, 292b, 292d to 292f, 292h to 292j, 293 to 293e, 293g,

293h, 294 to 294f, 295f to 295f–4, 295g, 295g–1, 295h–3d, 295h–4, 295h–8, 295h–9, 1857c–6, 1857c–8, 1857f–6c, 1857h–5, and 2676 of this title and section 346a of Title 21, Food and Drugs, and enacting provisions set out as notes under section 295h–8 of this title] may be cited as the 'Comprehensive Health Manpower Training Act of 1971'."

SHORT TITLE OF 1970 AMENDMENTS

Pub. L. 91–623, §1, Dec. 31, 1970, 84 Stat. 1868, provided: "That this Act [enacting sections 233 and 254b of this title] may be cited as the 'Emergency Health Personnel Act of 1970'."

Pub. L. 91–572, §1, Dec. 24. 1970, 84 Stat. 1504, provided that: "This Act [enacting sections 300 to 300a–6 and 3505a to 3505c of this title, amending sections 211a, 212a of this title and section 763c of Title 33, Navigation and Navigable Waters, and enacting provisions set out as notes under sections 201, 222, and 300 of this title] may be cited as the 'Family Planning Services and Population Research Act of 1970'."

Pub. L. 91–519, §1, Nov. 2, 1970, 84 Stat. 1342, provided that: "This Act [enacting sections 295h–3a to 295h–3d, 295h–8, and 296h–9 of this title, amending sections 295f–1, 295f–2, 295h to 295h–2, 295h–4, and 295h–7 of this title, repealing section 295h–3 of this title, and enacting provisions set out as notes under sections 295f–1, 295–f2, and 295h–4 of this title] may be cited as the 'Health Training Improvement Act of 1970'."

Pub. L. 91–515, title I, §101, Oct. 30, 1970, 84 Stat. 1297, provided that: "This title [amending sections 299 to 299g, 299i, and 299j of this title] may be cited as the 'Heart Disease, Cancer, Stroke, and Kidney Disease Amendments of 1970'."

Pub. L. 91–464, §1, Oct. 16, 1970, 84 Stat. 988, provided: "That this Act [amending section 247b of this title] may be cited as the 'Communicable Disease Control Amendments of 1970'."

Pub. L. 91–296, §1(a), June 30, 1970, 84 Stat. 336, provided that: "This Act [enacting sections 229b, 291j–1 to 291j–10, and 291o–1 of this title, amending sections 291a, 242b, 245a, 246, 291 note, 291b, 291c, 291d, 291e, 291f, 291i, 291k to 291m–1, 291o, and 299a of this title and section 1717 of Title 12, Banks and Banking, enacting provisions set out as notes under this section and sections 242, 245a, 246, 291a, 291b, 291c, 291e, 291f, 291o, 295h–6, and 2688p of this title, and repealing sections 295h–6 and 2688p of this title] may be cited as the 'Medical Facilities Construction and Modernization Amendments of 1970'."

Pub. L. 91–212, §1, Mar. 13, 1970, 84 Stat. 63, provided that: "This Act [enacting section 280b–12 of this title and amending this section and sections 276 to 278, 280, 280a–1, 280b, 280b–2 to 280b–9, and 280b–11 of this title] may be cited as the 'Medical Library Assistance Extension Act of 1970'."

SHORT TITLE OF 1968 AMENDMENTS

Pub. L. 90–574, title IV, §401, Oct. 15, 1968, 82 Stat. 1011, provided that: "This title [amending sections 291a and 291b of this title] may be cited as the 'Hospital and Medical Facilities Construction and Modernization Assistance Amendments of 1968'."

Pub. L. 90–490, §1, Aug. 16, 1968, 82 Stat. 773, provided: "That this Act [enacting sections 294f, 295g–1, 295h–6, 295h–7, 296f, 296g, and 297h of this title, amending sections 242d, 242g, 292b to 292e, 293 to 293d, 294 to 294d, 295f to 295f–4, 295g, 295h to 295h–3, 296 to 296b, 296d, 296e, 297 to 297f, 298b, 298c, and 298c–1 of this title, omitting sections 298c–2 to 298c–6 of this title, and enacting provisions set out as notes under sections 292b, 292e, 293 to 293c, 294f, 295f, 295f–2, 295g, 296, 296d, 296f, and 297a of this title] may be cited as the 'Health Manpower Act of 1968'."

SHORT TITLE OF 1967 AMENDMENTS

Pub. L. 90–174, §1, Dec. 5, 1967, 81 Stat. 533, provided: "That this Act [enacting sections 217b, 254a, 263a, and 291m–1 of this title, amending sections 241, 242, 242b, 243, 244, 246, 249, 251, 293e, 295h–4, and 296e of this title, repealing section 291n of this title, and enacting provisions set out as notes under this section and sections 242b, 242c, 246, 263a, and 296e of this title] may be cited as the 'Partnership for Health Amendments of 1967'."

Pub. L. 90–174, §5(c), Dec. 5, 1967, 81 Stat. 539, provided that: "This section [enacting section 263a of this title and provisions set out as notes under section 263a of this title] may be cited as the 'Clinical Laboratories Improvement Act of 1967'."

Pub. L. 90–31, §1, June 24, 1967, 81 Stat. 79, provided: "That this Act [enacting section 225a of this title and amending sections 2681, 2684, 2687, 2688a, 2688d, and 2691 of this title] may be cited as the 'Mental Health Amendments of 1967'."

SHORT TITLE OF 1966 AMENDMENTS

Pub. L. 89–751, §1, Nov. 3, 1966, 80 Stat. 1222, provided: "That this Act [enacting sections 295h to 295h–5 and 298c to 298c–8 of this title, amending sections 292b, 294d, 294n to 294p, 296, 297c to 297f, and

298 of this title and section 1717 of Title 12, Banks and Banking, and enacting provisions set out as notes under sections 294, 294d, 297c, and 297f of this title] may be cited as the 'Allied Health Professions Personnel Training Act of 1966'."

Pub. L. 89–749, §1, Nov. 3, 1966, 80 Stat. 1180, provided: "That this Act [amending 243, 245a, and 246 of this title, repealing sections 247a and 247c of this title, and enacting provisions set out as notes under this section and sections 243 and 245a of this title] may be cited as the 'Comprehensive Health Planning and Public Health Services Amendments of 1966'."

Pub. L. 89–709, §1, Nov. 2, 1966, 80 Stat. 1103, provided: "That this Act [amending sections 293, 293a, 293d, 293e, 294, 294a, and 294b of this title] may be cited as the 'Veterinary Medical Education Act of 1966'."

SHORT TITLE OF 1965 AMENDMENTS

Pub. L. 89–291, §1, Oct. 22, 1965, 79 Stat. 1059, provided that: "This Act [enacting section 280a–1 of this title and Part J of subchapter II of this chapter and amending section 277 of this title] may be cited as the 'Medical Library Assistance Act of 1965'."

Pub. L. 89–290, §1, Oct. 22, 1965, 79 Stat. 1052, provided that: "This Act [enacting sections 295f to 295f–4 and 295g of this title and amending sections 293, 293a, 293d, 294 to 294d, 297b, and 298b of this title] may be cited as the 'Health Professions Educational Assistance Amendments of 1965'."

Pub. L. 89–239, §1, Oct. 6, 1965, 79 Stat. 926, provided: "That this Act [enacting sections 299 to 299i of this title, amending sections 211a and 212a of this title, sections 757, 790, 800 of former Title 5, Executive Departments and Government Officers and Employees, and section 763c of Title 33, Navigation and Navigable Waters, and enacting provisions set out as notes under sections 201, 214, 222, and 249 of this title] may be cited as the 'Heart Disease, Cancer, and Stroke Amendments of 1965'."

Pub. L. 89–115, §1, Aug. 9, 1965, 79 Stat. 448, provided: "That this Act [amending sections 241, 292c, and 292d of this title and section 2211 of former Title 5, Executive Departments and Government Officers and Employees, and enacting section 623h of former Title 5 and provisions set out as a note thereunder] may be cited as the 'Health Research Facilities Amendments of 1965'."

Pub. L. 89–109, §1, Aug. 5, 1965, 79 Stat. 435, provided: "That this Act [amending sections 246, 247a, 247b, and 247d of this title] may be cited as the 'Community Health Services Extension Amendments of 1965'."

SHORT TITLE OF 1964 AMENDMENTS

Pub. L. 88–581, §1, Sept. 4, 1964, 78 Stat. 908, provided: "That this Act [enacting subchapter VI of this chapter, amending sections 291c, 291o, 293, 293a, 293e, and 293h of this title, and enacting provisions set out as notes under sections 201, 211a, 212a, 222, 291c, 293, 293e, and 293h of this title, sections 757, 790, and 800 of former Title 5, Executive Departments and Government Officers and Employees, and section 763c of Title 33, Navigation and Navigable Waters] may be cited as the 'Nurse Training Act of 1964'."

Pub. L. 88–497, §1, Aug. 27, 1964, 78 Stat. 613, provided that: "This Act [amending sections 244–1 and 245a of this title] may be cited as the 'Graduate Public Health Training Amendments of 1964'."

Pub. L. 88–443, §1, Aug. 18, 1964, 78 Stat. 447, provided that: "This Act [enacting sections 247c, 291 to 291j, 291k to 291m, 291n, and 291o of this title and enacting provisions set out as notes under section 291 of this title] may be cited as the 'Hospital and Medical Facilities Amendments of 1964'."

SHORT TITLE OF 1963 AMENDMENT

Pub. L. 88–129, §1, Sept. 24, 1963, 77 Stat. 164, provided: "That this Act [enacting sections 292j, 293 to 293h, and 294 to 294e and amending sections 292 to 292b and 292d to 292i of this title] may be cited as the 'Health Professions Educational Assistance Act of 1963'."

SHORT TITLE OF 1962 AMENDMENT

Pub. L. 87–868, §1, Oct. 23, 1962, 76 Stat. 1155, provided that this Act [enacting section 247b of this title] may be cited as the "Vaccination Assistance Act of 1962."

SHORT TITLE OF 1961 AMENDMENT

Pub. L. 87–395, §1, Oct. 5, 1961, 75 Stat. 824, provided: "That this Act [enacting section 247a of this title, amending sections 246, 289c, 291i, 291n, 291s, 291t, 291w, and 292c to 292g of this title, and enacting provisions set out as a note under section 291s of this title] may be cited as the 'Community Health Services and Facilities Act of 1961'."

SHORT TITLE OF 1960 AMENDMENT

Pub. L. 86–415, §1, Apr. 8, 1960, 74 Stat. 32, provided: "That this Act [amending this section and sections

209, 210, 211, 212, 253, and 415 of this title and section 2251 of former Title 5, Executive Departments and Government Officers and Employees, and enacting provisions set out as notes under sections 209 and 212 of this title and section 2253 of former Title 5] may be cited as the 'Public Health Service Commissioned Corps Personnel Act of 1960'."

SHORT TITLE OF 1956 AMENDMENTS

Act Aug. 3, 1956, ch. 907, §2, 70 Stat. 962, provided that: "This Act [enacting part I of subchapter II of this chapter] may be cited as the 'National Library of Medicine Act'."

Act July 3, 1956, ch. 510, §1, 70 Stat. 489, provided that: "This Act [enacting section 246 of this title, amended section 241 of this title, and enacting provisions set out as a note under section 246 of this title] may be cited as the 'National Health Survey Act'."

SHORT TITLE OF 1955 AMENDMENT

Joint Res. July 28, 1955, ch. 417, §1, 69 Stat. 382, provided that: "This joint resolution [enacting section 242b of this title and provisions set out as a note under section 242b of this title] may be cited as the 'Mental Health Study Act of 1955'."

SHORT TITLE OF 1948 AMENDMENTS

Act June 24, 1948, ch. 621, §1, 62 Stat. 598, provided that: "This Act [enacting part C of subchapter III of this chapter and amending this section and sections 210, 218, and 241 of this title] may be cited as the 'National Dental Research Act'."

Act June 16, 1948, §1, 62 Stat. 464, provided that: "This Act [enacting sections 287 to 287c of this title and amending this section and sections 203, 206, 210, 218, 219, 241, 246, 281, 283, and 286 of this title] may be cited as the 'National Heart Act'."

SHORT TITLE OF 1946 AMENDMENT

Act July 3, 1946, ch. 538, §1, 60 Stat. 421, provided: "That this Act [enacting sections 232 and 242a of this title, amending this section and sections 209, 210, 215, 218, 219, 241, 244, and 246 of this title, and enacting provisions set out as a note under this section] may be cited as the 'National Mental Health Act'."

SHORT TITLE

Act July 1, 1944, ch. 373, title I, §1, 58 Stat. 682, as amended by acts Aug. 13, 1946, ch. 958, §4, 60 Stat. 1049; July 30, 1956, ch. 779, §3(a), 70 Stat. 720; Sept. 4, 1964, Pub. L. 88–581, §4(a), 78 Stat. 919; Oct. 6, 1965, Pub. L. 89–239, §3(a), 79 Stat. 930; Dec. 24, 1970, Pub. L. 91–572, §6(a), 84 Stat. 1506; May 16, 1972, Pub. L. 92–294, §3(a), 86 Stat. 137; Nov. 16, 1973, Pub. L. 93–154, §2(b)(1), 87 Stat. 604; Dec. 29, 1973, Pub. L. 93–222, §7(a), 87 Stat. 936, provided that: "This Act [enacting this chapter] may be cited as the 'Public Health Service Act'."

Act July 1, 1944, ch. 373, title III, §329, formerly §310, as added by Pub. L. 87–692, Sept. 25, 1962, 76 Stat. 592, amended and renumbered, formerly classified to section 254b of this title, was popularly known as the "Migrant Health Act".

Act July 1, 1944, ch. 373, title XIV, §1400, as added Aug. 6, 1996, Pub. L. 104–182, title V, §501(e), 110 Stat. 1691, provided that: "This title [enacting subchapter XII of this chapter] may be cited as the 'Safe Drinking Water Act'."

RENUMBERING AND REPEAL OF REPEALING ACT

Act July 1, 1944, ch. 373, title XIII, §1313, formerly title VI, §611, 58 Stat. 714; renumbered title VII, §711, by act Aug. 13, 1946, ch. 958, §5, 60 Stat. 1049; renumbered §713 by act Feb. 28, 1948, ch. 83, §9(b), 62 Stat. 47; renumbered title VIII, §813, by act July 30, 1956, ch. 779, §3(b), 70 Stat. 721; renumbered title IX, §913, by Pub. L. 88–581, §4(b), Sept. 4, 1964, 78 Stat. 919; renumbered title X, §1013, by Pub. L. 89–239, §3(b), Oct. 6, 1965, 79 Stat. 931; renumbered title XI, §1113, by Pub. L. 91–572, §6(b), Dec. 24, 1970, 84 Stat. 1506; renumbered title XII, §1213, by Pub. L. 92–294, §3(b), May 16, 1972, 86 Stat. 137; renumbered title XIII, §1313, by Pub. L. 93–154, §2(b)(2), Nov. 16, 1973, 87 Stat. 604, repealed and amended sections in this title and in Title 8, Aliens and Nationality, Title 14, Coast Guard, Title 21, Food and Drugs, Title 24, Hospitals and Asylums, former Title 31, Money and Finance, Title 33, Navigation and Navigable Waters, former Title 34, Navy, Title 44, Public Printing and Documents, former Title 46, Shipping, Title 48, Territories and Insular Possessions, and former Title 49, Transportation, and was itself repealed by Pub. L. 93–222, §7(b), Dec. 29, 1973, 87 Stat. 936.

SAVINGS PROVISION

Act July 1, 1944, ch. 373, title XIII, §1314, formerly title VI, §612, 58 Stat. 720, as renumbered by acts Aug. 13, 1946, ch. 958, §5, 60 Stat. 1049; Feb. 28, 1948, ch. 83, §9(b), 62 Stat. 47; July 30, 1956, ch. 779, §3(b), 70 Stat. 720; Pub. L. 88–581, §4(b), Sept. 4, 1964, 78 Stat. 919; Pub. L. 89–239, §3(b), Oct. 6, 1965, 79 Stat. 931; Pub. L. 91–572, §6(b), Dec. 24, 1970, 84 Stat. 1506; Pub. L. 92–294, §3(b), May 16, 1972, 86 Stat. 137; Pub. L. 93–154, §2(b)(2), Nov. 16, 1973, 87 Stat. 604, provided that the repeal of statutes and parts of statutes by sections 1313, formerly §611, of act July 1, 1944, not affect any act done, right accruing or accrued, or suit or proceeding had or commenced in any civil cause before such repeal, and was repealed by Pub. L. 93–222, §7(b), Dec. 29, 1973, 87 Stat. 936.

TRANSFER OF FUNCTIONS

For transfer of authorities, functions, personnel, and assets of the Coast Guard, including the authorities and functions of the Secretary of Transportation relating thereto, to the Department of Homeland Security, and for treatment of related references, see sections 468(b), 551(d), 552(d), and 557 of Title 6, Domestic Security, and the Department of Homeland Security Reorganization Plan of November 25, 2002, as modified, set out as a note under section 542 of Title 6.

CONGRESSIONAL DECLARATION OF PURPOSE FOR COMPREHENSIVE ALCOHOL ABUSE, DRUG ABUSE, AND MENTAL HEALTH AMENDMENTS ACT OF 1988

Pub. L. 100–690, title II, §2012, Nov. 18, 1988, 102 Stat. 4193, provided that: "The purposes of this subtitle [subtitle A (§§2011–2081) of title II of Pub. L. 100–690, see Tables for classification] with respect to substance abuse are—

"(1) to prevent the transmission of the etiologic agent for acquired immune deficiency syndrome by ensuring that treatment services for intravenous drug abuse are available to intravenous drug abusers;

"(2) to continue the Federal Government's partnership with the States in the development, maintenance, and improvement of community-based alcohol and drug abuse programs;

"(3) to provide financial and technical assistance to the States and communities in their efforts to develop and maintain a core of prevention services for the purpose of reducing the incidence of substance abuse and the demand for alcohol and drug abuse treatment;

"(4) to assist and encourage States in the initiation and expansion of prevention and treatment services to underserved populations;

"(5) to increase, to the greatest extent possible, the availability and quality of treatment services so that treatment on request may be provided to all individuals desiring to rid themselves of their substance abuse problem; and

"(6) to increase understanding about the extent of alcohol abuse and other forms of drug abuse by expanding data collection activities and supporting research on the comparative cost and efficacy of substance abuse prevention and treatment services."

PURPOSE OF ACT JULY 3, 1946

Act July 3, 1946, ch. 538, §2, 60 Stat. 421, provided: "The purpose of this Act [see Short Title of 1946 Amendment note above] is the improvement of the mental health of the people of the United States through the conducting of researches, investigations, experiments, and demonstrations relating to the cause, diagnosis, and treatment of psychiatric disorders; assisting and fostering such research activities by public and private agencies, and promoting the coordination of all such researches and activities and the useful application of their results; training personnel in matters relating to mental health; and developing, and assisting States in the use of, the most effective methods of prevention, diagnosis, and treatment of psychiatric disorders."

EXISTING POSITIONS, PROCEDURES, REGULATIONS, FUNDS, APPROPRIATIONS, AND PROPERTY

Act July 1, 1944, ch. 373, title XIII, §§1301–1303, formerly title VI, §§601–603, 58 Stat. 711, 712, as renumbered by acts Aug. 13, 1946, ch. 958, §5, 60 Stat. 1049; July 30, 1956, ch. 779, §3(b), 70 Stat. 720; Pub. L. 88–581, §4(b), Sept. 3, 1964, 78 Stat. 919; Pub. L. 89–239, §3(b), Oct. 6, 1965, 79 Stat. 931; Pub. L. 91–572, §6(b), Dec. 24, 1970, 84 Stat. 1506; Pub. L. 92–294, §3(b), May 16, 1972, 86 Stat. 137; Pub. L. 93–154, §2(b)(2), Nov. 16, 1973, 87 Stat. 604, related to the effect of this chapter on existing positions, procedures, regulations, funds, appropriations, and property, and was repealed by Pub. L. 93–222, §7(b), Dec. 29, 1973, 87 Stat. 936.

APPROPRIATIONS FOR EMERGENCY HEALTH AND SANITATION ACTIVITIES

Act July 1, 1944, title XIII, §1304, formerly title VI, §604, 58 Stat. 712, as renumbered by acts Aug. 13, 1946, ch. 958, §5, 60 Stat. 1049; July 30, 1956, ch. 779, §3(b), 70 Stat. 720; Pub. L. 88–581, §4(b), Sept. 4,

1964, 78 Stat. 919; Pub. L. 89–239, §3(b), Oct. 6, 1965, 79 Stat. 931; Pub. L. 91–572, §6(b), Dec. 24, 1970, 84 Stat. 1506; Pub. L. 92–294, §3(b), May 16, 1972, 86 Stat. 137; Pub. L. 93–154, §2(b)(2), Nov. 16, 1973, 87 Stat. 604, authorized annual appropriations during World War II and during period of demobilization to conduct health and sanitation activities in military, naval, or industrial areas, and was repealed by Pub. L. 93–222, §7(b), Dec. 29, 1973, 87 Stat. 936. Joint Res. July 25, 1947, ch. 327, §3, 61 Stat. 451, provided that in the interpretation of section 1004 of act July 1, 1944, the date July 25, 1947, shall be deemed to be the date of termination of any state of war theretofore declared by Congress and of the national emergencies proclaimed by the President on September 8, 1939, and May 27, 1941.

AVAILABILITY OF APPROPRIATIONS

Pub. L. 91–296, title VI, §601, June 30, 1970, 84 Stat. 353, as amended Pub. L. 93–45, title IV, §401(a), June 18, 1973, 87 Stat. 95; Pub. L. 93–352, title I, §113, July 23, 1974, 88 Stat. 360, provided that: "Notwithstanding any other provision of law, unless enacted after the enactment of this Act [June 30, 1970] expressly in limitation of the provisions of this section, funds appropriated for any fiscal year to carry out any program for which appropriations are authorized by the Public Health Service Act (Public Law 410, Seventy-eighth Congress, as amended) [42 U.S.C. 201 et seq.] or the Mental Retardation Facilities and Community Mental Health Centers Construction Act of 1963 (Public Law 88–164, as amended) [former 42 U.S.C. 2689 et seq., 6001 et seq.] shall remain available for obligation and expenditure until the end of such fiscal year."

FEDERAL ACCOUNTABILITY

Pub. L. 102–321, title II, §203(b), July 10, 1992, 106 Stat. 410, provided that: "Any rule or regulation of the Department of Health and Human Services that is inconsistent with the amendments made by this Act [see Tables for classification] shall not have any legal effect, including section 50(e) of part 96 of title 45, Code of Federal Regulations (45 CFR 96.50(e))."

HAZARDOUS SUBSTANCES

Federal Hazardous Substances Act as not modifying this chapter, see Pub. L. 86–613, §18, July 12, 1960, 74 Stat. 380, set out as a note under section 1261 of Title 15, Commerce and Trade.

DEFINITION OF "SECRETARY"

Pub. L. 90–574, title V, §507, Oct. 15, 1968, 82 Stat. 1013, as amended by Pub. L. 96–88, title V, §509(b), 93 Stat. 695, provided that: "As used in the amendments made by this Act [enacting sections 229a, 299j, 2688e to 2688q, and 2697a of this title, amending sections 210g, 242h, 291a, 291b, 299a to 299e, 2693, and 3259 of this title, repealing section 3442 of this title, and enacting provisions set out as notes under sections 291a, 2688e, 3442 of this title, section 278 of Title 22, Foreign Relations and Intercourse, and section 3681 of Title 38, Veterans' Benefits], the term 'Secretary' means the Secretary of Health and Human Services."

Pub. L. 90–174, §15, Dec. 5, 1967, 81 Stat. 542, as amended by Pub. L. 96–88, title V, §509(b), Oct. 17, 1979, 93 Stat. 695, provided that: "As used in the amendments made by this Act [enacting sections 217b, 243(c), 251(b), 254a, 263a, and 291m–1 and amending sections 242b, 242g(c), 246(d)(1), (e), and 296e(c)(1) of this title] the term 'Secretary' means the Secretary of Health and Human Services."

EXECUTIVE DOCUMENTS

CHANGE OF NAME

Coast and Geodetic Survey consolidated with Weather Bureau to form a new agency in Department of Commerce to be known as Environmental Science Services Administration, and commissioned officers of Survey transferred to ESSA, by Reorg. Plan No. 2 of 1965, eff. July 13, 1965, 30 F.R. 8819, 79 Stat. 1318, set out in the Appendix to Title 5, Government Organization and Employees. Reorg. Plan No. 4 of 1970, eff. Oct. 3, 1970, 35 F.R. 15627, 84 Stat. 2090, abolished Environmental Science Services Administration, established National Oceanic and Atmospheric Administration, and redesignated Commissioned Officer Corps of ESSA as Commissioned Officer Corps of NOAA. For further details, see Transfer of Functions note set out under section 851 of Title 33, Navigation and Navigable Waters.

TRANSFER OF FUNCTIONS

Functions of Public Health Service, Surgeon General of Public Health Service, and all other officers and employees of Public Health Service, and functions of all agencies of or in Public Health Service transferred to Secretary of Health, Education, and Welfare by Reorg. Plan No. 3, of 1966, eff. June 25, 1966, 31 F.R. 8855, 80 Stat. 1610, set out as a note under section 202 of this title.

Functions of Federal Security Administrator transferred to Secretary of Health, Education, and Welfare and all agencies of Federal Security Agency transferred to Department of Health, Education, and Welfare by section 5 of Reorg. Plan No. 1 of 1953, set out as a note under section 3501 of this title. Federal Security Agency and office of Administrator abolished by section 8 of Reorg. Plan No. 1 of 1953.

TERMINATION OF TRUST TERRITORY OF THE PACIFIC ISLANDS

For termination of Trust Territory of the Pacific Islands, see note set out preceding section 1681 of Title 48, Territories and Insular Possessions.

EXECUTIVE ORDER NO. 13507

Ex. Ord. No. 13507, Apr. 8, 2009, 74 F.R. 17071, which established the White House Office of Health Reform, was revoked by Ex. Ord. No. 13569, §6, Apr. 5, 2011, 76 F.R. 19891, set out as a note preceding section 101 of Title 3, The President.

EX. ORD. NO. 14212. ESTABLISHING THE PRESIDENT'S MAKE AMERICA HEALTHY AGAIN COMMISSION

Ex. Ord. No. 14212, Feb. 13, 2025, 90 F.R. 9833, provided:

By the authority vested in me as President by the Constitution and the laws of the United States of America, it is hereby ordered:

SECTION 1. *Purpose*. American life expectancy significantly lags behind other developed countries, with pre-COVID-19 United States life expectancy averaging 78.8 years and comparable countries averaging 82.6 years. This equates to 1.25 billion fewer life years for the United States population. Six in 10 Americans have at least one chronic disease, and four in 10 have two or more chronic diseases. An estimated one in five United States adults lives with a mental illness.

These realities become even more painful when contrasted with nations around the globe. Across 204 countries and territories, the United States had the highest age-standardized incidence rate of cancer in 2021, nearly double the next-highest rate. Further, from 1990–2021, the United States experienced an 88 percent increase in cancer, the largest percentage increase of any country evaluated. In 2021, asthma was more than twice as common in the United States than most of Europe, Asia, or Africa. Autism spectrum disorders had the highest prevalence in high-income countries, including the United States, in 2021. Similarly, autoimmune diseases such as inflammatory bowel disease, psoriasis, and multiple sclerosis are more commonly diagnosed in high-income areas such as Europe and North America. Overall, the global comparison data demonstrates that the health of Americans is on an alarming trajectory that requires immediate action.

This concern applies urgently to America's children. In 2022, an estimated 30 million children (40.7 percent) had at least one health condition, such as allergies, asthma, or an autoimmune disease. Autism spectrum disorder now affects 1 in 36 children in the United States—a staggering increase from rates of 1 to 4 out of 10,000 children identified with the condition during the 1980s. Eighteen percent of late adolescents and young adults have fatty liver disease, close to 30 percent of adolescents are prediabetic, and more than 40 percent of adolescents are overweight or obese.

These health burdens have continued to increase alongside the increased prescription of medication. For example, in the case of Attention Deficit Disorder/Attention Deficit Hyperactivity Disorder, over 3.4 million children are now on medication for the disorder—up from 3.2 million children in 2019–2020—and the number of children being diagnosed with the condition continues to rise.

This poses a dire threat to the American people and our way of life. Seventy-seven percent of young adults do not qualify for the military based in large part on their health scores. Ninety percent of the Nation's $4.5 trillion in annual healthcare expenditures is for people with chronic and mental health conditions. In short, Americans of all ages are becoming sicker, beset by illnesses that our medical system is not addressing effectively. These trends harm us, our economy, and our security.

To fully address the growing health crisis in America, we must re-direct our national focus, in the public and private sectors, toward understanding and drastically lowering chronic disease rates and ending childhood chronic disease. This includes fresh thinking on nutrition, physical activity, healthy lifestyles, over-reliance on medication and treatments, the effects of new technological habits, environmental impacts, and food and drug quality and safety. We must restore the integrity of the scientific process by protecting expert recommendations from inappropriate influence and increasing transparency regarding existing data. We must ensure our healthcare system promotes health rather than just managing disease.

SEC. 2. *Policy*. It shall be the policy of the Federal Government to aggressively combat the critical health challenges facing our citizens, including the rising rates of mental health disorders, obesity, diabetes, and other chronic diseases. To do so, executive departments and agencies (agencies) that address health or healthcare must focus on reversing chronic disease. Under this policy:

(a) all federally funded health research should empower Americans through transparency and open-source data, and should avoid or eliminate conflicts of interest that skew outcomes and perpetuate distrust;

(b) the National Institutes of Health and other health-related research funded by the Federal Government should prioritize gold-standard research on the root causes of why Americans are getting sick;

(c) agencies shall work with farmers to ensure that United States food is the healthiest, most abundant, and most affordable in the world; and

(d) agencies shall ensure the availability of expanded treatment options and the flexibility for health insurance coverage to provide benefits that support beneficial lifestyle changes and disease prevention.

SEC. 3. *Establishment and Composition of the President's Make America Healthy Again Commission*. (a) There is hereby established the President's Make America Healthy Again Commission (Commission), chaired by the Secretary of Health and Human Services (Chair), with the Assistant to the President for Domestic Policy serving as Executive Director (Executive Director).

(b) In addition to the Chair and the Executive Director, the Commission shall include the following officials, or their designees:

(i) the Secretary of Agriculture;

(ii) the Secretary of Housing and Urban Development;

(iii) the Secretary of Education;

(iv) the Secretary of Veterans Affairs;

(v) the Administrator of the Environmental Protection Agency;

(vi) the Director of the Office of Management and Budget;

(vii) the Assistant to the President and Deputy Chief of Staff for Policy;

(viii) the Director of the National Economic Council;

(ix) the Chairman of the Council of Economic Advisers;

(x) the Director of the Office of Science and Technology Policy;

(xi) the Commissioner of Food and Drugs;

(xii) the Director for the Centers for Disease Control and Prevention;

(xiii) the Director of the National Institutes of Health; and

(xiv) other members of my Administration invited to participate, at the discretion of the Chair and the Executive Director.

SEC. 4. *Fighting Childhood Chronic Disease*. The initial mission of the Commission shall be to advise and assist the President on how best to exercise his authority to address the childhood chronic disease crisis. Therefore, the Commission shall:

(a) study the scope of the childhood chronic disease crisis and any potential contributing causes, including the American diet, absorption of toxic material, medical treatments, lifestyle, environmental factors, Government policies, food production techniques, electromagnetic radiation, and corporate influence or cronyism;

(b) advise and assist the President on informing the American people regarding the childhood chronic disease crisis, using transparent and clear facts; and

(c) provide to the President Government-wide recommendations on policy and strategy related to addressing the identified contributing causes of and ending the childhood chronic disease crisis.

SEC. 5. *Initial Assessment and Strategy from the Make America Healthy Again Commission*. (a) *Make our Children Healthy Again Assessment*. Within 100 days of the date of this order [Feb. 13, 2025], the Commission shall submit to the President, through the Chair and the Executive Director, the Make Our Children Healthy Again Assessment, which shall:

(i) identify and describe childhood chronic disease in America compared to other countries;

(ii) assess the threat that potential over-utilization of medication, certain food ingredients, certain chemicals, and certain other exposures pose to children with respect to chronic inflammation or other established mechanisms of disease, using rigorous and transparent data, including international comparisons;

(iii) assess the prevalence of and threat posed by the prescription of selective serotonin reuptake inhibitors, antipsychotics, mood stabilizers, stimulants, and weight-loss drugs;

(iv) identify and report on best practices for preventing childhood health issues, including through proper nutrition and the promotion of healthy lifestyles;

(v) evaluate the effectiveness of existing educational programs with regard to nutrition, physical activity, and mental health for children;

(vi) identify and evaluate existing Federal programs and funding intended to prevent and treat childhood health issues for their scope and effectiveness;

(vii) ensure transparency of all current data and unpublished analyses related to the childhood chronic disease crisis, consistent with applicable law;

(viii) evaluate the effectiveness of current Federal Government childhood health data and metrics, including those from the Federal Interagency Forum on Child and Family Statistics and the National Survey of Children's Health;

(ix) restore the integrity of science, including by eliminating undue industry influence, releasing findings and underlying data to the maximum extent permitted under applicable law, and increasing methodological rigor; and

(x) establish a framework for transparency and ethics review in industry-funded projects.

(b) *Make our Children Healthy Again Strategy*. Within 180 days of the date of this order, the Commission shall submit to the President, through the Chair and the Executive Director, a Make Our Children Healthy Again Strategy (Strategy), based on the findings from the Make Our Children Healthy Again Assessment described in subsection (a) of this section. The Strategy shall address appropriately restructuring the Federal Government's response to the childhood chronic disease crisis, including by ending Federal practices that exacerbate the health crisis or unsuccessfully attempt to address it, and by adding powerful new solutions that will end childhood chronic disease.

(c) The Chair may hold public hearings, meetings, roundtables, and similar events, as appropriate, and may receive expert input from leaders in public health and Government accountability.

SEC. 6. *Additional Reports*. (a) Following the submission to the President of the Strategy, and any final strategy reports thereafter, the Chair and the Executive Director shall recommend to the President updates to the Commission's mission, including desired reports.

(b) The Commission shall not reconvene, following submission of the Strategy, until an updated mission is submitted to the President through the Executive Director.

SEC. 7. *General Provisions*. (a) Nothing in this order shall be construed to impair or otherwise affect:

(i) the authority granted by law to an executive department or agency, or the head thereof; or

(ii) the functions of the Director of the Office of Management and Budget relating to budgetary, administrative, or legislative proposals.

(b) This order shall be implemented consistent with applicable law and subject to the availability of appropriations.

(c) This order is not intended to, and does not, create any right or benefit, substantive or procedural, enforceable at law or in equity by any party against the United States, its departments, agencies, or entities, its officers, employees, or agents, or any other person.

DONALD J. TRUMP.

[1] *See References in Text note below.*

PART A—ADMINISTRATION

§202. Administration and supervision of Service

The Public Health Service in the Department of Health and Human Services shall be administered by the Assistant Secretary for Health under the supervision and direction of the Secretary.

(July 1, 1944, ch. 373, title II, §201, 58 Stat. 683; 1953 Reorg. Plan No. 1, §§5, 8 eff. Apr. 11, 1953, 18 F.R. 2053, 67 Stat. 631; Pub. L. 103–43, title XX, §2008(f), June 10, 1993, 107 Stat. 212.)

EDITORIAL NOTES

AMENDMENTS

1993—Pub. L. 103–43 substituted "Health and Human Services" for "Health, Education, and Welfare" and "Assistant Secretary for Health" for "Surgeon General".

STATUTORY NOTES AND RELATED SUBSIDIARIES

CHANGE OF NAME

"Secretary of Health and Human Services" and "Department of Health and Human Services" substituted in

text for "Secretary of Health, Education, and Welfare" and "Department of Health, Education, and Welfare", respectively, pursuant to section 509(b) of Pub. L. 96–88, which is classified to section 3508(b) of Title 20, Education.

EXECUTIVE DOCUMENTS

TRANSFER OF FUNCTIONS

Functions of Federal Security Administrator transferred to Secretary of Health, Education, and Welfare and all agencies of Federal Security Agency transferred to Department of Health, Education, and Welfare by section 5 of Reorg. Plan No. 1 of 1953, set out as a note under section 3501 of this title. Federal Security Agency and office of Administrator abolished by section 8 of Reorg. Plan No. 1 of 1953.

REORGANIZATION PLAN NO. 3 OF 1966

EFF. JUNE 25, 1966, 31 F.R. 8855, 80 STAT. 1610

Prepared by the President and transmitted to the Senate and the House of Representatives in Congress assembled, April 25, 1966, pursuant to the provisions of the Reorganization Act of 1949, 63 Stat. 203, as amended [see 5 U.S.C. 901 et seq.].

PUBLIC HEALTH SERVICE

SECTION 1. TRANSFER OF FUNCTIONS

(a) Except as otherwise provided in subsection (b) of this section, there are hereby transferred to the Secretary of Health, Education, and Welfare (hereinafter referred to as the Secretary) all functions of the Public Health Service, of the Surgeon General of the Public Health Service, and of all other officers and employees of the Public Health Service, and all functions of all agencies of or in the Public Health Service.

(b) This section shall not apply to the functions vested by law in any advisory council, board, or committee of or in the Public Health Service which is established by law or is required by law to be established.

SEC. 2. PERFORMANCE OF TRANSFERRED FUNCTIONS

The Secretary may from time to time make such provisions as he shall deem appropriate authorizing the performance of any of the functions transferred to him by the provisions of this reorganization plan by any officer, employee, or agency of the Public Health Service or of the Department of Health, Education, and Welfare.

SEC. 3. ABOLITIONS

(a) The following agencies of the Public Health Service are hereby abolished:

(1) The Bureau of Medical Services, including the office of Chief of the Bureau of Medical Services.

(2) The Bureau of State Services, including the office of Chief of the Bureau of State Services.

(3) The agency designated as the National Institutes of Health (42 U.S.C. 203), including the office of Director of the National Institutes of Health (42 U.S.C. 206(b)) but excluding the several research Institutes in the agency designated as the National Institutes of Health.

(4) The agency designated as the Office of the Surgeon General (42 U.S.C. 203(1)), together with the office held by the Deputy Surgeon General (42 U.S.C. 206(a)).

(b) The Secretary shall make such provisions as he shall deem necessary respecting the winding up of any outstanding affairs of the agencies abolished by the provisions of this section.

SEC. 4. INCIDENTAL TRANSFERS

As he may deem necessary in order to carry out the provisions of this reorganization plan, the Secretary may from time to time effect transfers within the Department of Health, Education, and Welfare of any of the records, property, personnel and unexpended balances (available or to be made available) of appropriations, allocations, and other funds of the Department which relate to functions affected by this reorganization plan.

[The Secretary and Department of Health, Education, and Welfare were redesignated the Secretary and Department of Health and Human Services, respectively, by 20 U.S.C. 3508.]

MESSAGE OF THE PRESIDENT

To the Congress of the United States:

I transmit herewith Reorganization Plan No. 3 of 1966, prepared in accordance with the Reorganization Act of 1949, as amended, and providing for reorganization of health functions of the Department of Health,

Education, and Welfare.

I

Today we face new challenges and unparalleled opportunities in the field of health. Building on the progress of the past several years, we have truly begun to match the achievements of our medicine to the needs of our people.

The task ahead is immense. As a nation, we will unceasingly pursue our research and learning, our training and building, our testing and treatment. But now our concern must also turn to the organization of our Federal health programs.

As citizens we are entitled to the very best health services our resources can provide.

As taxpayers, we demand the most efficient and economic health organizations that can be devised.

I ask the Congress to approve a reorganization plan to bring new strength to the administration of Federal health programs.

I propose a series of changes in the organization of the Public Health Service that will bring to all Americans a structure modern in design, more efficient in operation and better prepared to meet the great and growing needs of the future. Through such improvements we can achieve the full promise of the landmark health legislation enacted by the 89th Congress.

I do not propose these changes lightly. They follow a period of careful deliberation. For many months the Secretary of Health, Education, and Welfare, and the Surgeon General have consulted leading experts in the Nation—physicians, administrators, scientists, and public health specialists. They have confirmed my belief that modernization and reorganization of the Public Health Service are urgently required and long overdue.

II

The Public Health Service is an operating agency of the Department of Health, Education, and Welfare. It is the principal arm of the Federal Government in the field of health. Its programs are among those most vital to our well-being.

Since 1953 more than 50 new programs have been placed in the Public Health Service. Its budget over the past 12 years has increased tenfold—from $250 million to $2.4 billion.

Today the organization of the Public Health Service is clearly obsolete. The requirement that new and expanding programs be administered through an organizational structure established by law more than two decades ago stands as a major obstacle to the fulfillment of our Nation's health goals.

As presently constituted, the Public Health Service is composed of four major components:

National Institutes of Health.

Bureau of State Services.

Bureau of Medical Services.

Office of the Surgeon General.

Under present law, Public Health Service functions must be assigned only to these four components.

This structure was designed to provide separate administrative arrangements for health research, programs of State and local aid, health services, and executive staff resources. At a time when these functions could be neatly compartmentalized, the structure was adequate. But today the situation is different.

Under recent legislation many new programs provide for an integrated attack on specific disease problems or health hazards in the environment by combining health services, State and local aid, and research. Each new program of this type necessarily is assigned to one of the three operating components of the Public Health Service. Yet none of these components is intended to administer programs involving such a variety of approaches.

Our health problems are difficult enough without having them complicated by outmoded organizational arrangements.

But if we merely take the step of integrating the four agencies within the Public Health Service we will not go far enough. More is required.

III

The Department of Health, Education, and Welfare performs major health or health-related functions which are not carried out through the Public Health Service, although they are closely related to its functions. Among these are:

Health insurance for the aged, administered through the Social Security Administration;

Medical assistance for the needy, administered through the Welfare Administration;

Regulation of the manufacture, labeling, and distribution of drugs, carried out through the Food and Drug Administration; and

Grants-in-aid to States for vocational rehabilitation of the handicapped, administered by the Vocational Rehabilitation Administration.

Expenditures for health and health-related programs of the Department administered outside the Public Health Service have increased from $44 million in 1953 to an estimated $5.4 billion in 1967.

As the head of the Department, the Secretary of Health, Education, and Welfare is responsible for the Administration and coordination of all the Department's health functions. He has clear authority over the programs I have just mentioned.

But today he lacks this essential authority over the Public Health Service. The functions of that agency are vested in the Surgeon General and not in the Secretary.

This diffusion of responsibility is unsound and unwise.

To secure the highest possible level of health services for the American people the Secretary of Health, Education, and Welfare must be given the authority to establish—and modify as necessary—the organizational structure for Public Health Service programs.

He must also have the authority to coordinate health functions throughout the Department. The reorganization plan I propose will accomplish these purposes. It will provide the Secretary with the flexibility to create new and responsive organizational arrangements to keep pace with the changing and dynamic nature of our health programs.

My views in this respect follow a basic principle of good government set by the Hoover Commission in 1949 when it recommended that "the Department head should be given authority to determine the organization within his Department."

IV

In summary, the reorganization plan would:

Transfer to the Secretary of Health, Education, and Welfare the functions now vested in the Surgeon General of the Public Health Service and in its various subordinate units (this transfer will not affect certain statutory advisory bodies such as the National Advisory Cancer and Heart Councils);

Abolish the four principal statutory components of the Public Health Service, including the offices held by their heads (the Bureau of Medical Services, the Bureau of State Services, the National Institutes of Health exclusive of its several research institutes such as the National Cancer and Heart Institutes, and the Office of the Surgeon General); and

Authorize the Secretary to assign the functions transferred to him by the plan to officials and entities of the Public Health Service and to other agencies of the Department as he deems appropriate.

Thus, the Secretary would be—

Enabled to assure that all health functions of the Department are carried out as effectively and economically as possible;

Given authority commensurate with his responsibility; and

Made responsible in fact for matters for which he is now, in any case, held accountable by the President, the Congress, and the people.

V

I have found, after investigation, that each reorganization included in the accompanying reorganization plan is necessary to accomplish one or more of the purposes set forth in section 2(a) of the Reorganization Act of 1949, as amended.

Should the reorganizations in the accompanying reorganization plan take effect, they will make possible more effective and efficient administration of the affected health programs. It is, however, not practicable at this time to itemize the reductions in expenditures which may result.

I strongly recommend that the Congress allow the reorganization plan to become effective.

LYNDON B. JOHNSON.

THE WHITE HOUSE, April 25, 1966.

INTERNATIONAL HEALTH ADMINISTRATION

Ex. Ord. No. 10399, Sept. 27, 1952, 17 F.R. 8648, designated Surgeon General to perform certain duties under International Sanitary Regulations of World Health Organization.

EXECUTIVE ORDER NO. 10506

Ex. Ord. No. 10506, Dec. 10, 1953, 18 F.R. 8219, which delegated certain functions of the President relating to the Public Health Service, was superseded by Ex. Ord. No. 11140, Jan. 30, 1964, 29 F.R. 1637, set

out below.

EX. ORD. NO. 11140. DELEGATION OF FUNCTIONS

Ex. Ord. No. 11140, Jan. 30, 1964, 29 F.R. 1637, as amended by Ex. Ord. No. 12608, Sept. 9, 1987, 52 F.R. 34617, provided:

By virtue of the authority vested in me by Section 301 of Title 3 of the United States Code, and as President of the United States, it is ordered as follows:

SECTION 1. The Secretary of Health and Human Services is hereby authorized and empowered, without the approval, ratification, or other action of the President, to perform the following-described functions vested in the President under the Public Health Service Act (58 Stat. 682), as amended [42 U.S.C. 201 et seq.]:

(a) The authority under Section 203 (42 U.S.C. 204): to appoint commissioned officers of the Reserve Corps [now Ready Reserve Corps].

(b) The authority under Section 206(b) (42 U.S.C. 207(b)) to prescribe titles, appropriate to the several grades, for commissioned officers of the Public Health Service other than medical officers.

(c) The authority under Section 207(a)(2) (42 U.S.C. 209(a)(2)) to terminate commissions of officers of the Reserve Corps without the consent of the officers concerned.

(d) The authority under Section 210(a), (k), and (l) (42 U.S.C. 211(a), (k), and (l)) to make or terminate temporary promotions of commissioned officers of the Regular Corps and Reserve Corps.

(e) The authority under Section 211(a)(5) (42 U.S.C. 212(a)(5)) to approve voluntary retirements under that section.

(f) The authority to prescribe regulations under the following-designated Sections: 207(a), 207(b), 208(e), 210(a), 210(b), 210(d)(1), 210(h), 210(i), 210(j)(1), 210(k), 215(a), 218(a), 219(a), and 510 (42 U.S.C. 209(a), 209(b), 210(e), 211(a), 211(b), 211(d)(1), 211(h), 211(i), 211(j)(1), 211(k), 216(a), 218a(a), 210–1(a), and 228).

(g) The authority under Sections 321(a) and 364(a) (42 U.S.C. 248(a) and 267(a)) to approve the selection of suitable sites for and the establishment of additional institutions, hospitals, stations, grounds, and anchorages; subject, however, to the approval of the Director of the Office of Management and Budget, except as he may otherwise provide.

SEC. 2. The Surgeon General is hereby authorized and empowered, without the approval, ratification, or other action of the President, to perform the function vested in the President by Sections 203 and 207(a)(2) of the Public Health Service Act (58 Stat. 683, 685), as amended (42 U.S.C. 204 and 209(a)(2)), or otherwise, of accepting voluntary resignations of commissioned officers of the Regular Corps or the Reserve Corps [now Ready Reserve Corps].

SEC. 3. The Secretary of Health and Human Services is hereby authorized and empowered, without the approval, ratification, or other action of the President, to exercise the authority vested in the President by Section 704 of Title 37 of the United States Code to prescribe regulations.

SEC. 4. The Secretary of Health and Human Services is hereby authorized to redelegate all or any part of the functions set forth under (a), (b), (c), and (d) of Section 1 hereof to the Surgeon General of the Public Health Service or other official of that Service who is required to be appointed by and with the advice and consent of the Senate.

SEC. 5. All actions heretofore taken by appropriate authority with respect to the matters affected by this order and in force at the time of the issuance of this order, including any regulations prescribed or approved with respect to such matters, shall, except as they may be inconsistent with the provisions of this order, remain in effect until amended, modified, or revoked pursuant to the authority conferred by this order.

SEC. 6. As used in this order, the term "functions" embraces duties, powers, responsibilities, authority, or discretion, and the term "perform" may be construed to mean "exercise".

SEC. 7. (a) Executive Order No. 10506 of December 10, 1953, entitled "Delegating Certain Functions of the President under the Public Health Service Act," is hereby superseded.

(b) Executive Orders Nos. 9993 of August 31, 1948, 10031 of January 26, 1949, 10280 of August 16, 1951, 10354 of May 26, 1952, and 10497 of October 27, 1953, which prescribed regulations relating to commissioned officers and employees of the Public Health Service, are hereby revoked. Nothing in this subsection shall be deemed to alter or otherwise affect the regulations prescribed by the Surgeon General (42 CFR Parts 21 and 22) to replace the regulations prescribed by the orders described in the preceding sentence.

§203. Organization of Service

The Service shall consist of (1) the Office of the Surgeon General, (2) the National Institutes of

Health, (3) the Bureau of Medical Services, and [1] (4) the Bureau of State Services, and [2] the Agency for Healthcare Research and Quality. The Secretary is authorized and directed to assign to the Office of the Surgeon General,[3] to the National Institutes of Health, to the Bureau of Medical Services, and to the Bureau of State Services, respectively, the several functions of the Service, and to establish within them such divisions, sections, and other units as he may find necessary; and from time to time abolish, transfer, and consolidate divisions, sections, and other units and assign their functions and personnel in such manner as he may find necessary for efficient operation of the Service. No division shall be established, abolished, or transferred, and no divisions shall be consolidated, except with the approval of the Secretary. The National Institutes of Health shall be administered as a part of the field service. The Secretary may delegate to any officer or employee of the Service such of his powers and duties under this chapter, except the making of regulations, as he may deem necessary or expedient.

(July 1, 1944, ch. 373, title II, §202, 58 Stat. 683; June 16, 1948, ch. 481, §6(b), 62 Stat. 469; 1953 Reorg. Plan No. 1, §§5, 8, eff. Apr. 11, 1953, 18 F.R. 2053, 67 Stat. 631; Pub. L. 103–43, title XX, §2008(g), June 10, 1993, 107 Stat. 212; Pub. L. 106–129, §2(b)(2), Dec. 6, 1999, 113 Stat. 1670.)

EDITORIAL NOTES

AMENDMENTS

1999—Pub. L. 106–129 substituted "Agency for Healthcare Research and Quality" for "Agency for Health Care Policy and Research".

1993—Pub. L. 103–43, §2008(g)(2), inserted ", and the Agency for Health Care Policy and Research" in first sentence.

Pub. L. 103–43, §2008(g)(1), which directed the amendment of this section by striking "Surgeon General" the second and subsequent times that such term appears and inserting "Secretary", was executed by making the substitution before "is authorized and directed" and before "may delegate to any officer" and by leaving unchanged "Surgeon General" in the phrase "assign to the Office of the Surgeon General" in second sentence, to reflect the probable intent of Congress.

1948—Act June 16, 1948, substituted "National Institutes of Health" for "National Institute of Health" in cl. (2).

STATUTORY NOTES AND RELATED SUBSIDIARIES

CHANGE OF NAME

"Secretary of Health and Human Services" substituted in text for "Secretary of Health, Education, and Welfare" pursuant to section 509(b) of Pub. L. 96–88, which is classified to section 3508(b) of Title 20, Education.

EXECUTIVE DOCUMENTS

TRANSFER OF FUNCTIONS

Bureau of Medical Services, Bureau of State Services, National Institutes of Health, excluding several research Institutes in agency, and Office of Surgeon General abolished by section 3 of Reorg. Plan No. 3 of 1966, eff. June 25, 1966, 31 F.R. 8855, 80 Stat. 1610, and all functions thereof transferred to Secretary of Health, Education, and Welfare by section 1 of Reorg. Plan No. 3 of 1966, set out as a note under section 202 of this title. Office of Surgeon General reestablished within the Office of the Assistant Secretary for Health, see Notice of Department of Health and Human Services, Office of the Assistant Secretary for Health, Mar. 30, 1987, 52 F.R. 11754.

Functions of Federal Security Administrator transferred to Secretary of Health, Education, and Welfare, and all agencies of Federal Security Agency transferred to Department of Health, Education, and Welfare by section 5 of Reorg. Plan No. 1 of 1953, set out as a note under section 3501 of this title. Federal Security Agency and office of Administrator abolished by section 8 of Reorg. Plan No. 1 of 1953.

[1] So in original. The "and" probably should not appear.

[2] *So in original. Probably should be followed by "(5)".*

[3] *See 1993 Amendment note below.*

§204. Commissioned Corps and Ready Reserve Corps

(a) Establishment

(1) In general

There shall be in the Service a commissioned Regular Corps and, for service in time of a public health or national emergency, a Ready Reserve Corps.

(2) Requirement

All commissioned officers shall be citizens of the United States and shall be appointed without regard to the civil-service laws and compensated without regard to the Classification Act of 1923, as amended.

(3) Appointment

Commissioned officers of the Ready Reserve Corps shall be appointed by the President and commissioned officers of the Regular Corps shall be appointed by the President.

(4) Active duty

Commissioned officers of the Ready Reserve Corps shall at all times be subject to call to active duty by the Surgeon General, including active duty for the purpose of training.

(5) Warrant officers

Warrant officers may be appointed to the Service for the purpose of providing support to the health and delivery systems maintained by the Service and any warrant officer appointed to the Service shall be considered for purposes of this chapter and title 37 to be a commissioned officer within the Commissioned Corps of the Service.

(b) Assimilating Reserve Corps officers into the Regular Corps

Effective on March 23, 2010, all individuals classified as officers in the Reserve Corps under this section (as such section existed on the day before March 23, 2010) and serving on active duty shall be deemed to be commissioned officers of the Regular Corps.

(c) Purpose and use of Ready Reserve Corps

(1) Purpose

The purpose of the Ready Reserve Corps is to fulfill the need to have additional Commissioned Corps personnel available on short notice (similar to the uniformed service's reserve program) to assist regular Commissioned Corps personnel to meet both routine public health and emergency response missions during public health or national emergencies.

(2) Uses

The Ready Reserve Corps shall, consistent with paragraph (1)—

(A) participate in routine training to meet the general and specific needs of the Commissioned Corps;

(B) be available and ready for involuntary calls to active duty during national emergencies and public health crises, similar to the uniformed service reserve personnel;

(C) be available for backfilling critical positions left vacant during deployment of active duty Commissioned Corps members during such emergencies, as well as for deployment to respond to public health emergencies, both foreign and domestic; and

(D) be available for service assignment in isolated, hardship, and medically underserved communities (as defined in section 295p of this title) to improve access to health services,

consistent with subparagraph (C).

(3) Statutory references to reserve

A reference in any Federal statute, except in the case of subsection (b), to the "Reserve Corps" of the Public Health Service or to the "reserve" of the Public Health Service shall be deemed to be a reference to the Ready Reserve Corps.

(d) Funding

For the purpose of carrying out the duties and responsibilities of the Commissioned Corps under this section, there are authorized to be appropriated $5,000,000 for each of fiscal years 2010 through 2014 for recruitment and training and $12,500,000 for each of fiscal years 2010 through 2014 for the Ready Reserve Corps.

(July 1, 1944, ch. 373, title II, §203, 58 Stat. 683; Feb. 28, 1948, ch. 83, §2, 62 Stat. 39; Oct. 28, 1949, ch. 782, title XI, §1106(a), 63 Stat. 972; Pub. L. 96–76, title III, §302(a), Sept. 29, 1979, 93 Stat. 584; Pub. L. 111–148, title V, §5210, Mar. 23, 2010, 124 Stat. 614; Pub. L. 112–166, §2(ff)(1), Aug. 10, 2012, 126 Stat. 1290; Pub. L. 116–136, div. A, title III, §3214(a), Mar. 27, 2020, 134 Stat. 372.)

EDITORIAL NOTES

REFERENCES IN TEXT

The Classification Act of 1923, as amended, referred to in subsec. (a)(2), is act Mar. 4, 1923, ch. 265, 42 Stat. 1488, which was classified to section 661 et seq. of former Title 5, Executive Departments and Government Officers and Employees, and was repealed by act Oct. 28, 1949, ch. 782, title XII, §1202, 63 Stat. 972.

AMENDMENTS

2020—Subsec. (a)(1). Pub. L. 116–136, §3214(a)(1), substituted ", for service in time of a public health or national emergency, a Ready Reserve Corps" for "a Ready Reserve Corps for service in time of national emergency".

Subsec. (c). Pub. L. 116–136, §3214(a)(2)(A), substituted "Reserve Corps" for "Research" in heading.

Subsec. (c)(1). Pub. L. 116–136, §3214(a)(2)(B), inserted "during public health or national emergencies" before period at end.

Subsec. (c)(2). Pub. L. 116–136, §3214(a)(2)(C)(i), inserted ", consistent with paragraph (1)" after "shall" in introductory provisions.

Subsec. (c)(2)(C). Pub. L. 116–136, §3214(a)(2)(C)(ii), inserted "during such emergencies" after "members".

Subsec. (c)(2)(D). Pub. L. 116–136, §3214(a)(2)(C)(iii), inserted ", consistent with subparagraph (C)" before period at end.

Subsec. (c)(3). Pub. L. 116–136, §3214(a)(2)(D), added par. (3).

2012—Subsec. (a)(3). Pub. L. 112–166 struck out "with the advice and consent of the Senate" before period at end.

2010—Pub. L. 111–148 inserted section catchline and amended text generally. Prior to amendment, text read as follows: "There shall be in the Service a commissioned Regular Corps and, for the purpose of securing a reserve for duty in the Service in time of national emergency, a Reserve Corps. All commissioned officers shall be citizens and shall be appointed without regard to the civil-service laws and compensated without regard to chapter 51 and subchapter III of chapter 53 of title 5. Commissioned officers of the Reserve Corps shall be appointed by the President and commissioned officers of the Regular Corps shall be appointed by him by and with the advice and consent of the Senate. Commissioned officers of the Reserve Corps shall at all times be subject to call to active duty by the Surgeon General, including active duty for the purpose of training and active duty for the purpose of determining their fitness for appointment in the Regular Corps. Warrant officers may be appointed to the Service for the purpose of providing support to the health and delivery systems maintained by the Service and any warrant officer appointed to the Service shall be considered for purposes of this chapter and title 37 to be a commissioned officer within the commissioned corps of the Service."

1979—Pub. L. 96–76 inserted provisions relating to appointment and status of warrant officers.

1949—Act Oct. 28, 1949, substituted "Classification Act of 1949" for "Classification Act of 1923".

1948—Act Feb. 28, 1948, struck out provision that all active service in Reserve Corps, as well as service in Regular Corps, shall be credited for purpose of promotion in Regular Corps.

STATUTORY NOTES AND RELATED SUBSIDIARIES

CHANGE OF NAME

Reference in any Federal statute, except in the case of subsec. (b) of this section, to "Reserve Corps" of the Public Health Service or to the "reserve" of the Public Health Service deemed to be a reference to the Ready Reserve Corps, see subsec. (c)(3) of this section.

EFFECTIVE DATE OF 2012 AMENDMENT

Amendment by Pub. L. 112–166 effective 60 days after Aug. 10, 2012, and applicable to appointments made on and after that effective date, including any nomination pending in the Senate on that date, see section 6(a) of Pub. L. 112–166, set out as a note under section 113 of Title 6, Domestic Security.

REPEALS

Act Oct. 28, 1949, cited as a credit to this section, was repealed (subject to a savings clause) by Pub. L. 89–554, Sept. 6, 1966, §8, 80 Stat. 632, 655.

REPORTS

Pub. L. 111–148, title V, §5701, Mar. 23, 2010, 124 Stat. 684, provided that:

"(a) REPORTS BY SECRETARY OF HEALTH AND HUMAN SERVICES.—On an annual basis, the Secretary of Health and Human Services shall submit to the appropriate Committees of Congress a report on the activities carried out under the amendments made by this title [see Tables for classification], and the effectiveness of such activities.

"(b) REPORTS BY RECIPIENTS OF FUNDS.—The Secretary of Health and Human Services may require, as a condition of receiving funds under the amendments made by this title, that the entity receiving such award submit to such Secretary such reports as the such Secretary may require on activities carried out with such award, and the effectiveness of such activities."

OSTEOPATHS AS RESERVE OFFICERS

Section 709 of act July 1, 1944, formerly §609, renumbered §709 by act Aug. 13, 1946, ch. 958, §5, 60 Stat. 1049, which provided for appointment of osteopaths as reserve officers until six months after World War II, was repealed by Joint Res. July 25, 1947, ch. 327, §1, 61 Stat. 449.

EXECUTIVE DOCUMENTS

DELEGATION OF AUTHORITY TO APPOINT COMMISSIONED OFFICERS OF THE READY RESERVE CORPS OF THE PUBLIC HEALTH SERVICE

Memorandum of President of the United States, June 1, 2010, 75 F.R. 32245, provided:

Memorandum for the Secretary of Health and Human Services

By virtue of the authority vested in me as President by the Constitution and the laws of the United States, including section 301 of title 3, United States Code, I hereby assign to you the functions of the President under section 203 of the Public Health Service Act, as amended by Public Law 111–148, to appoint commissioned officers of the Ready Reserve Corps. The exercise of this authority is limited to appointments of individuals who were extended offers of employment for appointment and call to active duty in the Reserve Corps of the Public Health Service with an appointment date subsequent to March 23, 2010, the date of enactment of Public Law 111–148, but who were not on active duty on that date, and those individuals who are selected for the 2010 Commissioned Officer Student Training and Extern Program. This authority may not be re-delegated.

You are authorized and directed to publish this memorandum in the Federal Register.

BARACK OBAMA.

Memorandum of President of the United States, May 31, 2011, 76 F.R. 33117, which delegated functions of the President under section 203 of the Public Health Service Act to the Secretary of Health and Human Services, was revoked by Memorandum of President of the United States, Mar. 29, 2013, 78 F.R. 20225, set out below.

Memorandum of President of the United States, Mar. 29, 2013, 78 F.R. 20225, provided:

Memorandum for the Secretary of Health and Human Services

By virtue of the authority vested in me as President by the Constitution and the laws of the United States, including section 301 of title 3, United States Code, I hereby assign to you the functions of the President under section 203 of the Public Health Service Act, as amended by Public Law 111–148, to appoint commissioned officers of the Ready Reserve Corps of the Public Health Service. Commissions issued under this delegation of authority may not be for a term longer than 6 months except for commissions that place officers in the Centers for Disease Control and Prevention's Epidemiological Intelligence Service, the Senior Commissioned Officer Student Training and Extern Program, the Indian Health Service Pharmacy Residency Program, the Indian Health Service Health Professions Scholarship Program, or the National Health Service Corps Scholarship Program, which may not be for a term longer than 2 years. Officers appointed pursuant to this delegation may not be appointed to the Ready Reserve Corps of the Public Health Service for a term greater than those outlined in this memorandum other than by the President. This authority may not be re-delegated.

My memorandum of May 31, 2011 (Delegation of Authority to Appoint Commissioned Officers of the Ready Reserve Corps of the Public Health Service), is hereby revoked.

You are authorized and directed to publish this memorandum in the Federal Register.

BARACK OBAMA.

§204a. Deployment readiness

(a) Readiness requirements for Commissioned Corps officers

(1) In general

The Secretary, with respect to members of the following Corps components, shall establish requirements, including training and medical examinations, to ensure the readiness of such components to respond to urgent or emergency public health care needs that cannot otherwise be met at the Federal, State, and local levels:

(A) Active duty Regular Corps.

(B) Ready Reserve Corps.

(2) Annual assessment of members

The Secretary shall annually determine whether each member of the Corps meets the applicable readiness requirements established under paragraph (1).

(3) Failure to meet requirements

A member of the Corps who fails to meet or maintain the readiness requirements established under paragraph (1) or who fails to comply with orders to respond to an urgent or emergency public health care need shall, except as provided in paragraph (4), in accordance with procedures established by the Secretary, be subject to disciplinary action as prescribed by the Secretary.

(4) Waiver of requirements

(A) In general

The Secretary may waive one or more of the requirements established under paragraph (1) for an individual who is not able to meet such requirements because of—

(i) a disability;

(ii) a temporary medical condition; or

(iii) any other extraordinary limitation as determined by the Secretary.

(B) Regulations

The Secretary shall promulgate regulations under which a waiver described in subparagraph (A) may be granted.

(5) Urgent or emergency public health care need

For purposes of this section and section 215 of this title, the term "urgent or emergency public health care need" means a health care need, as determined by the Secretary, arising as the result of—

(A) a national emergency declared by the President under the National Emergencies Act (50 U.S.C. 1601 et seq.);

(B) an emergency or major disaster declared by the President under the Robert T. Stafford Disaster Relief and Emergency Assistance Act (42 U.S.C. 5121 et seq.);

(C) a public health emergency declared by the Secretary under section 247d of this title; or

(D) any emergency that, in the judgment of the Secretary, is appropriate for the deployment of members of the Corps.

(b) Corps management for deployment

The Secretary shall—

(1) organize members of the Corps into units for rapid deployment by the Secretary to respond to urgent or emergency public health care needs;

(2) establish appropriate procedures for the command and control of units or individual members of the Corps that are deployed at the direction of the President or the Secretary in response to an urgent or emergency public health care need of national, State or local significance;

(3) ensure that members of the Corps are trained, equipped and otherwise prepared to fulfill their public health and emergency response roles; and

(4) ensure that deployment planning takes into account—

(A) any deployment exemptions that may be granted by the Secretary based on the unique requirements of an agency and an individual's functional role in such agency; and

(B) the nature of the urgent or emergency public health care need.

(c) Deployment of detailed or assigned officers

For purposes of pay, allowances, and benefits of a Commissioned Corps officer who is detailed or assigned to a Federal entity, the deployment of such officer by the Secretary in response to an urgent or emergency public health care need shall be deemed to be an authorized activity of the Federal entity to which the officer is detailed or assigned.

(July 1, 1944, ch. 373, title II, §203A, as added Pub. L. 109–417, title II, §206(b), Dec. 19, 2006, 120 Stat. 2851; amended Pub. L. 116–136, div. A, title III, §3214(b), Mar. 27, 2020, 134 Stat. 373.)

EDITORIAL NOTES

REFERENCES IN TEXT

The National Emergencies Act, referred to in subsec. (a)(5)(A), is Pub. L. 94–412, Sept. 14, 1976, 90 Stat. 1255, which is classified principally to chapter 34 (§1601 et seq.) of Title 50, War and National Defense. For complete classification of this Act to the Code, see Short Title note set out under section 1601 of Title 50 and Tables.

The Robert T. Stafford Disaster Relief and Emergency Assistance Act, referred to in subsec. (a)(5)(B), is Pub. L. 93–288, May 22, 1974, 88 Stat. 143, which is classified principally to chapter 68 (§5121 et seq.) of this title. For complete classification of this Act to the Code, see Short Title note set out under section 5121 of this title and Tables.

AMENDMENTS

2020—Subsec. (a)(1)(B). Pub. L. 116–136 substituted "Ready Reserve Corps" for "Active Reserves".

STATUTORY NOTES AND RELATED SUBSIDIARIES

PURPOSE

Pub. L. 109–417, title II, §206(a), Dec. 19, 2006, 120 Stat. 2851, provided that: "It is the purpose of this section [enacting this section and amending sections 215 and 254d of this title] to improve the force management and readiness of the Commissioned Corps to accomplish the following objectives:

"(1) To ensure the Corps is ready to respond rapidly to urgent or emergency public health care needs and challenges.

"(2) To ensure the availability of the Corps for assignments that address clinical and public health needs in isolated, hardship, and hazardous duty positions, and, when required, to address needs related to

the well-being, security, and defense of the United States.

"(3) To establish the Corps as a resource available to Federal and State Government agencies for assistance in meeting public health leadership and service roles."

§205. Appointment and tenure of office of Surgeon General; reversion in rank

The Surgeon General shall be appointed from the Regular Corps for a four-year term by the President by and with the advice and consent of the Senate. The Surgeon General shall be appointed from individuals who (1) are members of the Regular Corps, and (2) have specialized training or significant experience in public health programs. Upon the expiration of such term the Surgeon General, unless reappointed, shall revert to the grade and number in the Regular Corps or Ready Reserve Corps that he would have occupied had he not served as Surgeon General.

(July 1, 1944, ch. 373, title II, §204, 58 Stat. 684; Pub. L. 97–25, title III, §303(a), July 27, 1981, 95 Stat. 145; Pub. L. 97–35, title XXVII, §2765(b), Aug. 13, 1981, 95 Stat. 932; Pub. L. 116–136, div. A, title III, §3214(e)(1), Mar. 27, 2020, 134 Stat. 373.)

EDITORIAL NOTES

AMENDMENTS

2020—Pub. L. 116–136 substituted "Regular Corps or Ready Reserve Corps" for "Regular or Reserve Corps".

1981—Pub. L. 97–35 inserted reference to Reserve Corps and substituted provisions relating to appointment of an individual from the Regular Corps and with specialized training and significant experience, for provisions relating to appointment of an individual sixty-four years of age or older.

Pub. L. 97–25 inserted provision that the President may appoint to office of Surgeon General an individual who is sixty-four years of age or older.

STATUTORY NOTES AND RELATED SUBSIDIARIES

CHANGE OF NAME

"Secretary of Health and Human Services" substituted for "Secretary of Health, Education, and Welfare" pursuant to section 509(b) of Pub. L. 96–88, which is classified to section 3508(b) of Title 20, Education.

EXECUTIVE DOCUMENTS

TRANSFER OF FUNCTIONS

Office of Surgeon General abolished by section 3 of Reorg. Plan No. 3 of 1966, eff. June 25, 1966, 31 F.R. 8855, 80 Stat. 1610, and functions thereof transferred to Secretary of Health, Education, and Welfare by section 1 of Reorg. Plan No. 3 of 1966, set out as a note under section 202 of this title. Office of Surgeon General reestablished within the Office of the Assistant Secretary for Health, see Notice of Department of Health and Human Services, Office of the Assistant Secretary for Health, Mar. 30, 1987, 52 F.R. 11754.

§206. Assignment of officers

(a) Deputy Surgeon General

The Surgeon General shall assign one commissioned officer from the Regular Corps to administer the Office of the Surgeon General, to act as Surgeon General during the absence or disability of the Surgeon General or in the event of a vacancy in that office, and to perform such other duties as the Surgeon General may prescribe, and while so assigned he shall have the title of Deputy Surgeon General.

(b) Assistant Surgeons General

The Surgeon General shall assign eight commissioned officers from the Regular Corps to be,

respectively, the Director of the National Institutes of Health, the Chief of the Bureau of State Services, the Chief of the Bureau of Medical Services, the Chief Medical Officer of the United States Coast Guard, the Chief Dental Officer of the Service, the Chief Nurse Officer of the Service, the Chief Pharmacist Officer of the Service, and the Chief Sanitary Engineering Officer of the Service, and while so serving they shall each have the title of Assistant Surgeon General.

(c) Creation of temporary positions as Assistant Surgeons General

(1) The Surgeon General, with the approval of the Secretary, is authorized to create special temporary positions in the grade of Assistant Surgeons General when necessary for the proper staffing of the Service. The Surgeon General may assign officers of either the Regular Corps or the Ready Reserve Corps to any such temporary position, and while so serving they shall each have the title of Assistant Surgeon General.

(2) Except as provided in this paragraph, the number of special temporary positions created by the Surgeon General under paragraph (1) shall not on any day exceed 1 per centum of the highest number, during the ninety days preceding such day, of officers of the Regular Corps on active duty and officers of the Ready Reserve Corps on active duty for more than thirty days. If on any day the number of such special temporary positions exceeds such 1 per centum limitation, for a period of not more than one year after such day, the number of such special temporary positions shall be reduced for purposes of complying with such 1 per centum limitation only by the resignation, retirement, death, or transfer to a position of a lower grade, of any officer holding any such temporary position.

(d) Designation of Assistant Surgeon General with respect to absence, disability, or vacancy in offices of Surgeon General and Deputy Surgeon General

The Surgeon General shall designate the Assistant Surgeon General who shall serve as Surgeon General in case of absence or disability, or vacancy in the offices, of both the Surgeon General and the Deputy Surgeon General.

(July 1, 1944, ch. 373, title II, §205, 58 Stat. 684; Feb. 28, 1948, ch. 83, §3, 62 Stat. 39; June 16, 1948, ch. 481, §6(b), 62 Stat. 469; 1953 Reorg. Plan No. 1, §§5, 8, eff. Apr. 11, 1953, 18 F.R. 2053, 67 Stat. 631; Pub. L. 96–76, title III, §§302(b), 303, Sept. 29, 1979, 93 Stat. 584; Pub. L. 116–136, div. A, title III, §3214(e)(3), Mar. 27, 2020, 134 Stat. 373.)

EDITORIAL NOTES

AMENDMENTS

2020—Subsec. (c). Pub. L. 116–136 substituted "Ready Reserve Corps" for "Reserve Corps" in pars. (1) and (2).

1979—Subsec. (b). Pub. L. 96–76, §302(b), inserted provisions relating to assignment of Chief Nurse Officer and Chief Pharmacist Officer, and substituted "eight" for "six".

Subsec. (c). Pub. L. 96–76, §303, designated existing provisions as par. (1), struck out provisions relating to maximum number of special temporary positions, and added par. (2).

1948—Subsec. (b). Act June 16, 1948, substituted "National Institutes of Health" for "National Institute of Health".

Subsecs. (c), (d). Act Feb. 28, 1948, added subsec. (c) and redesignated former subsec. (c) as (d).

STATUTORY NOTES AND RELATED SUBSIDIARIES

CHANGE OF NAME

"Secretary of Health and Human Services" substituted for "Secretary of Health, Education, and Welfare" in subsec. (c)(1) pursuant to section 509(b) of Pub. L. 96–88, which is classified to section 3508(b) of Title 20, Education.

EFFECTIVE DATE OF 1979 AMENDMENT

Pub. L. 96–76, title III, §314, Sept. 29, 1979, 93 Stat. 587, provided that: "The amendments made by sections 303, 304, 305, 306, 307, and 313 [amending this section, sections 207, 209, 210b, and 211 of this title, and sections 201, 415, and 1006 of Title 37, Pay and Allowances of the Uniformed Services] shall take

effect on October 1, 1979."

TRANSFER OF FUNCTIONS

For transfer of authorities, functions, personnel, and assets of the Coast Guard, including the authorities and functions of the Secretary of Transportation relating thereto, to the Department of Homeland Security, and for treatment of related references, see sections 468(b), 551(d), 552(d), and 557 of Title 6, Domestic Security, and the Department of Homeland Security Reorganization Plan of November 25, 2002, as modified, set out as a note under section 542 of Title 6.

EXECUTIVE DOCUMENTS

TRANSFER OF FUNCTIONS

Office of Surgeon General, together with office held by Deputy Surgeon General, Bureau of Medical Services, including office of Chief of Bureau of Medical Services, Bureau of State Services, including office of Chief of Bureau of State Services, and National Institutes of Health, including office of Director of National Institutes of Health, abolished by section 3 of Reorg. Plan No. 3 of 1966, eff. June 25, 1966, 31 F.R. 8855, 80 Stat. 1610, and functions thereof transferred to Secretary of Health, Education, and Welfare by section 1 of Reorg. Plan No. 3 of 1966, set out as a note under section 202 of this title.

Functions of Federal Security Administrator transferred to Secretary of Health, Education, and Welfare and all agencies of Federal Security Agency transferred to Department of Health, Education, and Welfare, by section 5 of Reorg. Plan No. 1 of 1953, set out as a note under section 3501 of this title. Federal Security Agency and office of Administrator abolished by section 8 of Reorg. Plan No. 1 of 1953.

§207. Grades, ranks, and titles of commissioned corps

(a) Grades of commissioned officers

The Surgeon General, during the period of his appointment as such, shall be of the same grade as the Surgeon General of the Army; the Deputy Surgeon General and the Chief Medical Officer of the United States Coast Guard, while assigned as such, shall have the grade corresponding with the grade of major general; and the Chief Dental Officer, while assigned as such, shall have the grade as is prescribed by law for the officer of the Dental Corps selected and appointed as Assistant Surgeon General of the Army. During the period of appointment to the position of Assistant Secretary for Health, a commissioned officer of the Public Health Service shall have the grade corresponding to the grade of General of the Army. Assistant Surgeons General, while assigned as such, shall have the grade corresponding with either the grade of brigadier general or the grade of major general, as may be determined by the Secretary after considering the importance of the duties to be performed: *Provided*, That the number of Assistant Surgeons General having a grade higher than that corresponding to the grade of brigadier general shall at no time exceed one-half of the number of positions created by subsection (b) of section 206 of this title or pursuant to subsection (c) of section 206 of this title. The grades of commissioned officers of the Service shall correspond with grades of officers of the Army as follows:

(1) Officers of the director grade—colonel;
(2) Officers of the senior grade—lieutenant colonel;
(3) Officers of the full grade—major;
(4) Officers of the senior assistant grade—captain;
(5) Officers of the assistant grade—first lieutenant;
(6) Officers of the junior assistant grade—second lieutenant;
(7) Chief warrant officers of (W–4) grade—chief warrant officer (W–4);
(8) Chief warrant officers of (W–3) grade—chief warrant officer (W–3);
(9) Chief warrant officers of (W–2) grade—chief warrant officer (W–2); and
(10) Warrant officers of (W–1) grade—warrant officer (W–1).

(b) Titles of medical officers

The titles of medical officers of the foregoing grades shall be respectively (1) medical director, (2)

senior surgeon, (3) surgeon, (4) senior assistant surgeon, (5) assistant surgeon, and (6) junior assistant surgeon. The President is authorized to prescribe titles, appropriate to the several grades, for commissioned officers of the Service other than medical officers. All titles of the officers of the Ready Reserve Corps shall have the suffix "Reserve".

(c) Repealed. Pub. L. 96–76, title III, §304(b), Sept. 29, 1979, 93 Stat. 584

(d) Maximum number in grade for each fiscal year

Within the total number of officers of the Regular Corps authorized by the appropriation Act or Acts for each fiscal year to be on active duty, the Secretary shall by regulation prescribe the maximum number of officers authorized to be in each of the grades from the warrant officer (W–1) grade to the director grade, inclusive. Such numbers shall be determined after considering the anticipated needs of the Service during the fiscal year, the funds available, the number of officers in each grade at the beginning of the fiscal year, and the anticipated appointments, the anticipated promotions based on years of service, and the anticipated retirements during the fiscal year. The number so determined for any grade for a fiscal year may not exceed the number limitation (if any) contained in the appropriation Act or Acts for such year. Such regulations for each fiscal year shall be prescribed as promptly as possible after the appropriation Act fixing the authorized strength of the corps for that year, and shall be subject to amendment only if such authorized strength or such number limitation is thereafter changed. The maxima established by such regulations shall not require (apart from action pursuant to other provisions of this chapter) any officer to be separated from the Service or reduced in grade.

(e) Exception to grade limitations for officers assigned to Department of Defense

In computing the maximum number of commissioned officers of the Public Health Service authorized by law to hold a grade which corresponds to the grade of brigadier general or major general, there may be excluded from such computation not more than three officers who hold such a grade so long as such officers are assigned to duty and are serving in a policymaking position in the Department of Defense.

(f) Exception to maximum number limitations for officers assigned to Department of Defense

In computing the maximum number of commissioned officers of the Public Health Service authorized by law or administrative determination to serve on active duty, there may be excluded from such computation officers who are assigned to duty in the Department of Defense.

(July 1, 1944, ch. 373, title II, §206, 58 Stat. 684; Feb. 28, 1948, ch. 83, §4, 62 Stat. 39; Oct. 31, 1951, ch. 653, 65 Stat. 700; July 17, 1952, ch. 931, 66 Stat. 758; 1953 Reorg. Plan No. 1, §§5, 8, eff. Apr. 11, 1953, 18 F.R. 2053, 67 Stat. 631; Pub. L. 87–649, §11(1), Sept. 7, 1962, 76 Stat. 497; Pub. L. 95–215, §8(b), Dec. 19, 1977, 91 Stat. 1507; Pub. L. 96–76, title III, §304, Sept. 29, 1979, 93 Stat. 584; Pub. L. 99–117, §9, Oct. 7, 1985, 99 Stat. 494; Pub. L. 101–93, §5(p), Aug. 16, 1989, 103 Stat. 614; Pub. L. 101–502, §5(k)(1), Nov. 3, 1990, 104 Stat. 1289; Pub. L. 104–201, div. A, title V, §582, Sept. 23, 1996, 110 Stat. 2538; Pub. L. 116–136, div. A, title III, §3214(e)(3), Mar. 27, 2020, 134 Stat. 373.)

EDITORIAL NOTES

AMENDMENTS

2020—Subsec. (b). Pub. L. 116–136, which directed amendment of subsec. (c) by substituting "Ready Reserve Corps" for "Reserve Corps", was executed by making the substitution in subsec. (b) to reflect the probable intent of Congress.

1996—Subsec. (f). Pub. L. 104–201 added subsec. (f).

1990—Subsec. (a). Pub. L. 101–502 inserted after first sentence "During the period of appointment to the position of Assistant Secretary for Health, a commissioned officer of the Public Health Service shall have the grade corresponding to the grade of General of the Army."

1989—Subsec. (e). Pub. L. 101–93, which directed the substitution of "the Department of Defense" for "the office of Assistant Secretary of Defense for Health Affairs", was executed by making the substitution for "the

office of the Assistant Secretary of Defense for Health Affairs" as the probable intent of Congress.

1985—Subsec. (e). Pub. L. 99–117 added subsec. (e).

1979—Subsec. (a). Pub. L. 96–76, §304(a), added pars. (7) to (10).

Subsec. (c). Pub. L. 96–76, §304(b), struck out subsec. (c) setting forth the grade and pay and allowances as director for a commissioned officer below the grade of director assigned to serve as chief of a division.

Subsec. (d). Pub. L. 96–76, §304(c), substituted "warrant officer (W–1)" for "junior assistant".

1977—Subsec. (b)(6). Pub. L. 95–215 substituted "junior assistant" for "senior assistant".

1962—Subsec. (a). Pub. L. 87–649 struck out provisions which related to pay and allowances.

1952—Subsec. (a). Act July 17, 1952, provided that the Chief Medical Officer of the Coast Guard should have the grade, pay, and allowances of a major general.

1951—Subsec. (a). Act Oct. 31, 1951, provided equality of grade, pay, and allowances between the Chief Dental Officer and the comparable officer in the Army.

1948—Subsec. (a). Act Feb. 28, 1948, increased grade of Deputy Surgeon General from brigadier general to major general and increased grade of certain Assistant Surgeons General from brigadier general to major general as the Federal Security Administrator might determine.

Subsecs. (c), (d). Act Feb. 28, 1948, added subsecs. (c) and (d).

STATUTORY NOTES AND RELATED SUBSIDIARIES

CHANGE OF NAME

"Secretary of Health and Human Services" substituted for "Secretary of Health, Education, and Welfare" in subsecs. (a) and (d) pursuant to section 509(b) of Pub. L. 96–88, which is classified to section 3508(b) of Title 20, Education.

EFFECTIVE DATE OF 1990 AMENDMENT

Amendment by Pub. L. 101–502 effective Dec. 1, 1990, see section 5(k)(3) of Pub. L. 101–502, set out as a note under section 201 of Title 37, Pay and Allowances of the Uniformed Services.

EFFECTIVE DATE OF 1979 AMENDMENT

Amendment by Pub. L. 96–76 effective Oct. 1, 1979, see section 314 of Pub. L. 96–76, set out as a note under section 206 of this title.

EFFECTIVE DATE OF 1962 AMENDMENT

Amendment by Pub. L. 87–649 effective Nov. 1, 1962, see section 15 of Pub. L. 87–649, set out as an Effective Date note preceding section 101 of Title 37, Pay and Allowances of the Uniformed Services.

TRANSFER OF FUNCTIONS

For transfer of authorities, functions, personnel, and assets of the Coast Guard, including the authorities and functions of the Secretary of Transportation relating thereto, to the Department of Homeland Security, and for treatment of related references, see sections 468(b), 551(d), 552(d), and 557 of Title 6, Domestic Security, and the Department of Homeland Security Reorganization Plan of November 25, 2002, as modified, set out as a note under section 542 of Title 6.

EXECUTIVE DOCUMENTS

TRANSFER OF FUNCTIONS

Office of Surgeon General, together with office held by Deputy Surgeon General, abolished by section 3 of Reorg. Plan No. 3 of 1966, eff. June 25, 1966, 31 F.R. 8855, 80 Stat. 1610, and functions thereof transferred to Secretary of Health, Education, and Welfare by section 1 of Reorg. Plan No. 3 of 1966, set out as a note under section 202 of this title. Office of Surgeon General reestablished within the Office of the Assistant Secretary for Health, see Notice of Department of Health and Human Services, Office of the Assistant Secretary for Health, Mar. 30, 1987, 52 F.R. 11754.

Functions of Federal Security Administrator transferred to Secretary of Health, Education, and Welfare and all agencies of Federal Security Agency transferred to Department of Health, Education, and Welfare by section 5 of Reorg. Plan No. 1 of 1953, set out as a note under section 3501 of this title. Federal Security Agency and office of Administrator abolished by section 8 of Reorg. Plan No. 1 of 1953.

DELEGATION OF FUNCTIONS

Functions of President delegated to Secretary of Health and Human Services, see Ex. Ord. No. 11140, Jan. 30, 1964, 29 F.R. 1637, as amended, set out as a note under section 202 of this title.

§208. Repealed. Feb. 28, 1948, ch. 83, §5(a), 62 Stat. 40

Section, act July 1, 1944, ch. 373, title II, §207, 58 Stat. 685, related to establishment of special temporary provisions. See sections 206(c) and 207(c) of this title.

§209. Appointment of personnel

(a) Original appointments to Regular and Ready Reserve Corps; limitation on appointment and call to active duty

(1) Except as provided in subsections (b) and (e) of this section, original appointments to the Regular Corps may be made only in the warrant officer (W–1), chief warrant officer (W–2), chief warrant officer (W–3), chief warrant officer (W–4), junior assistant, assistant, and senior assistant grades and original appointments to a grade above junior assistant shall be made only after passage of an examination, given in accordance with regulations of the President, in one or more of the several branches of medicine, dentistry, hygiene, sanitary engineering, pharmacy, psychology, nursing, or related scientific specialties in the field of public health.

(2) Original appointments to the Ready Reserve Corps may be made to any grade up to and including the director grade but only after passage of an examination given in accordance with regulations of the President. Reserve commissions shall be for an indefinite period and may be terminated at any time, as the President may direct.

(3) No individual who has attained the age of forty-four shall be appointed to the Regular Corps, or called to active duty in the Ready Reserve Corps for a period in excess of one year, unless (A) he has had a number of years of active service (as defined in section 212(d) of this title) equal to the number of years by which his age exceeds forty-four, or (B) the Surgeon General determines that he possesses exceptional qualifications, not readily available elsewhere in the Commissioned Corps of the Public Health Service, for the performance of special duties with the Service, or (C) in the case of an officer of the Ready Reserve Corps, the Commissioned Corps of the Service has been declared by the President to be a military service.

(b) Grade and number of original appointments

(1) Not more than 10 per centum of the original appointments to the Regular Corps authorized to be made during any fiscal year may be made to grades above that of senior assistant, but no such appointment (other than an appointment under section 205 of this title) may be made to a grade above that of director. For the purpose of this subsection the number of original appointments authorized to be made during a fiscal year shall be (1) the excess of the number of officers of the Regular Corps authorized by the appropriation Act or Acts for such year over the number of officers on active duty in the Regular Corps on the first day of such year, plus (2) the number of such officers of the Regular Corps who, during such fiscal year, have been or will be retired upon attainment of age sixty-four or have for any other reason ceased to be on active duty. In determining the number of appointments authorized by this subsection an appointment shall be deemed to be made in the fiscal year in which the nomination is transmitted by the President to the Senate.

(2) In addition to the number of original appointments to the Regular Corps authorized by paragraph (1) to be made to grades above that of senior assistant, original appointments authorized to be made to the Regular Corps in any year may be made to grades above that of senior assistant, but not above that of director, in the case of any individual who—

(A)(i) was on active duty in the Ready Reserve Corps on July 1, 1960, (ii) was on such active duty continuously for not less than one year immediately prior to such date, and (iii) applies for appointment to the Regular Corps prior to July 1, 1962; or

(B) does not come within clause (A)(i) and (ii) but was on active duty in the Ready Reserve Corps continuously for not less than one year immediately prior to his appointment to the Regular

Corps and has not served on active duty continuously for a period, occurring after June 30, 1960, of more than three and one-half years prior to applying for such appointment.

(3) No person shall be appointed pursuant to this subsection unless he meets standards established in accordance with regulations of the President.

(c) Issuance of commissions

Commissions evidencing the appointment by the President of officers of the Regular Corps or Ready Reserve Corps shall be issued by the Secretary under the seal of the Department of Health and Human Services.

(d) Date of appointment; credit for service

(1) For purposes of basic pay and for purposes of promotion, any person appointed under subsection (a) to the grade of senior assistant in the Regular Corps, and any person appointed under subsection (b), shall, except as provided in paragraphs (2) and (3) of this subsection, be considered as having had on the date of appointment the following length of service: Three years if appointed to the senior assistant grade, ten years if appointed to the full grade, seventeen years if appointed to the senior grade, and eighteen years if appointed to the director grade.

(2) For purposes of basic pay, any person appointed under subsection (a) to the grade of senior assistant in the Regular Corps, and any person appointed under subsection (b), shall, in lieu of the credit provided in paragraph (1) of this subsection, be credited with the service for which he is entitled to credit under any other provision of law if such service exceeds that to which he would be entitled under such paragraph.

(3) For purposes of promotion, any person originally appointed in the Regular Corps to the senior assistant grade or above who has had active service in the Ready Reserve Corps shall be considered as having had on the date of appointment the length of service provided for in paragraph (1) of this subsection, plus whichever of the following is greater: (A) The excess of his total active service in the Ready Reserve Corps (above the grade of junior assistant) over the length of service provided in such paragraph, to the extent that such excess is on account of service in the Ready Reserve Corps in or above the grade to which he is appointed in the Regular Corps or (B) his active service in the same or any higher grade in the Ready Reserve Corps after the first day on which, under regulations in effect on the date of his appointment to the Regular Corps, he would have had the training and experience necessary for such appointment.

(4) For purposes of promotion, any person whose original appointment is to the assistant grade in the Regular Corps shall be considered as having had on the date of appointment service equal to his total active service in the Ready Reserve Corps in and above the assistant grade.

(e) Reappointment; credit for service

(1) A former officer of the Regular Corps may, if application for appointment is made within two years after the date of the termination of his prior commission in the Regular Corps, be reappointed to the Regular Corps without examination, except as the Surgeon General may otherwise prescribe, and without regard to the numerical limitations of subsection (b).

(2) Reappointments pursuant to this subsection may be made to the permanent grade held by the former officer at the time of the termination of his prior commission, or to the next higher grade if such officer meets the eligibility requirements prescribed by regulation for original appointment to such higher grade. For purposes of pay, promotion, and seniority in grade, such reappointed officer shall receive the credits for service to which he would be entitled if such appointment were an original appointment, but in no event less than the credits he held at the time his prior commission was terminated, except that if such officer is reappointed to the next higher grade he shall receive no credit for seniority in grade.

(3) No former officer shall be reappointed pursuant to this subsection unless he shall meet such standards as the Secretary may prescribe.

(f) Special consultants

In accordance with regulations, special consultants may be employed to assist and advise in the

operations of the Service. Such consultants may be appointed without regard to the civil-service laws.

(g) Designation for fellowships; duties; pay

In accordance with regulations, individual scientists, other than commissioned officers of the Service, may be designated by the Surgeon General to receive fellowships, appointed for duty with the Service without regard to the civil-service laws, may hold their fellowships under conditions prescribed therein, and may be assigned for studies or investigations either in this country or abroad during the terms of their fellowships.

(h) Aliens

Persons who are not citizens may be employed as consultants pursuant to subsection (f) and may be appointed to fellowships pursuant to subsection (g). Unless otherwise specifically provided, any prohibition in any other Act against the employment of aliens, or against the payment of compensation to them, shall not be applicable in the case of persons employed or appointed pursuant to such subsections.

(i) Civil service appointments by Secretary

The appointment of any officer or employee of the Service made in accordance with the civil-service laws shall be made by the Secretary, and may be made effective as of the date on which such officer or employee enters upon duty.

(July 1, 1944, ch. 373, title II, §207, formerly §208, 58 Stat. 685; July 3, 1946, ch. 538, §4, 60 Stat. 421; Aug. 13, 1946, ch. 958, §3, 60 Stat. 1049; renumbered §207 and amended Feb. 28, 1948, ch. 83, §5(a)–(d), 62 Stat. 40; Oct. 12, 1949, ch. 681, title V, §521(a), 63 Stat. 834; 1953 Reorg. Plan No. 1, §§5, 8, eff. Apr. 11, 1953, 18 F.R. 2053, 67 Stat. 631; Apr. 27, 1956, ch. 211, §3(a)–(c)(1), 70 Stat. 116; Pub. L. 86–415, §§2, 3, Apr. 8, 1960, 74 Stat. 32; Pub. L. 96–76, title III, §305, Sept. 29, 1979, 93 Stat. 585; Pub. L. 96–88, title V, §509(b), Oct. 17, 1979, 93 Stat. 695; Pub. L. 97–35, title XXVII, §2765(c), Aug. 13, 1981, 95 Stat. 933; Pub. L. 97–414, §8(a), Jan. 4, 1983, 96 Stat. 2060; Pub. L. 116–136, div. A, title III, §3214(e)(1), (3), Mar. 27, 2020, 134 Stat. 373.)

EDITORIAL NOTES

CODIFICATION

In subsec. (f), the words "and their compensation may be fixed without regard to the Classification Act of 1923, as amended", and in subsec. (g), the words "and compensated without regard to the Classification Act of 1923, as amended" were omitted as obsolete. Sections 1202 and 1204 of the Classification Act of 1949, 63 Stat. 972, 973, repealed the 1923 Act and all laws or parts of laws inconsistent with the 1949 Act. While section 1106(a) of the 1949 Act provided that references in other laws to the 1923 Act should be held and considered to mean the 1949 Act, it did not have the effect of continuing the exceptions contained in subsecs. (f) and (g) because of section 1106(b) which provided that the application of the 1949 Act to any position, officer, or employee shall not be affected by section 1106(a). The Classification Act of 1949 was repealed by Pub. L. 89–554, Sept. 6, 1966, §8(a), 80 Stat. 632 (of which section 1 revised and enacted Title 5, Government Organization and Employees, into law). Section 5102 of Title 5 contains the applicability provisions of the 1949 Act, and section 5103 of Title 5 authorizes the Office of Personnel Management to determine the applicability to specific positions and employees.

In subsec. (h), the references to subsections (f) and (g) of this section were, in the original, references to subsections (e) and (f) and were changed to reflect the probable intent of Congress.

PRIOR PROVISIONS

A prior section 207 of act July 1, 1944, was classified to section 208 of this title, prior to repeal by act Feb. 28, 1948, ch. 83, §5(a), 62 Stat. 40.

AMENDMENTS

2020—Subsecs. (a), (b). Pub. L. 116–136, §3214(e)(3), substituted "Ready Reserve Corps" for "Reserve Corps" wherever appearing.

Subsec. (c). Pub. L. 116–136, §3214(e)(1), substituted "Regular Corps or Ready Reserve Corps" for

"Regular or Reserve Corps".

Subsec. (d). Pub. L. 116–136, §3214(e)(3), substituted "Ready Reserve Corps" for "Reserve Corps" wherever appearing.

1983—Subsec. (a)(1). Pub. L. 97–414 inserted "psychology," after "pharmacy,".

1981—Subsec. (b)(1). Pub. L. 97–35 inserted provisions relating to exception for an appointment under section 205 of this title.

1979—Subsec. (a)(1). Pub. L. 96–76 inserted applicability to warrant officers and chief warrant officers.

1960—Subsec. (a)(3). Pub. L. 86–415, §2, added par. (3).

Subsec. (b). Pub. L. 86–415, §3, designated first, second and third sentences as par. (1), fourth sentence as par. (3), and added par. (2).

1956—Subsec. (a)(1). Act Apr. 27, 1956, §3(a), inserted reference to subsection (e) of this section.

Subsec. (a)(2). Act Apr. 27, 1956, §3(c)(1), substituted "an indefinite period" for "a period of not more than five years".

Subsecs. (e) to (i). Act Apr. 27, 1956, §3(b), added subsec. (e) and redesignated former subsecs. (e) to (h) as (f) to (i), respectively.

1949—Subsec. (d). Act Oct. 12, 1949, substituted "base pay" for "pay and pay period" wherever appearing.

1948—Subsec. (a)(1). Act Feb. 28, 1948, struck out "surgery" after "several branches of medicine".

Subsec. (a)(2). Act Feb. 28, 1948, struck out "any such commission" before "may be terminated", and "in his discretion" after "at any time".

Subsec. (b). Act Feb. 28, 1948, provided for grade and number of original appointments.

Subsecs. (c) to (f). Act Feb. 28, 1948, added subsecs. (c) and (d) and redesignated former subsecs. (c) and (d) as (e) and (f), respectively. Former subsecs. (e) and (f) redesignated (g) and (h).

Subsec. (g). Act Feb. 28, 1948, redesignated former subsec. (e) as (g) and changed reference in text from "subsection (c)" to "subsection (e)", and "subsection (d)" to "subsection (g)".

Subsec. (h). Act Feb. 28, 1948, redesignated former subsec. (f) as (h).

1946—Subsec. (b). Act July 3, 1946, authorized appointment of additional officers to grades above that of senior assistant but not above that of director, and limits the number so appointed to 20.

Subsec. (b)(2). Act Aug. 13, 1946, inserted "(A)" before "to assist", substituted "clause" for "paragraphs", and inserted cl. (B).

STATUTORY NOTES AND RELATED SUBSIDIARIES

CHANGE OF NAME

"Secretary of Health and Human Services" substituted for "Secretary of Health, Education, and Welfare" in subsecs. (c), (e)(3), and (i), and "Department of Health and Human Services" substituted for "Department of Health, Education, and Welfare" in subsec. (c), pursuant to section 509(b) of Pub. L. 96–88, which is classified to section 3508(b) of Title 20, Education.

EFFECTIVE DATE OF 1979 AMENDMENT

Amendment by Pub. L. 96–76 effective Oct. 1, 1979, see section 314 of Pub. L. 96–76, set out as a note under section 206 of this title.

EFFECTIVE DATE OF 1960 AMENDMENT

Pub. L. 86–415, §8(a), Apr. 8, 1960, 74 Stat. 36, provided that: "The amendments made by sections 2 and 5(b) [amending this section and section 210 of this title] shall become effective July 1, 1960."

EFFECTIVE DATE OF 1949 AMENDMENT

Amendment by act Oct. 12, 1949, effective Oct. 1, 1949, see section 533(a) of act Oct. 12, 1949, set out as a note under section 854a of Title 33, Navigation and Navigable Waters.

PERSONAL SERVICES CONTRACTING

Pub. L. 109–149, title II, §216, Dec. 30, 2005, 119 Stat. 2861, provided that: "The Division of Federal Occupational Health hereafter may utilize personal services contracting to employ professional management/administrative and occupational health professionals."

SIMILAR PROVISIONS

Similar provisions were contained in the following prior appropriation acts:

Pub. L. 108–447, div. F, title II, §216, Dec. 8, 2004, 118 Stat. 3141.

Pub. L. 108–199, div. E, title II, §216, Jan. 23, 2004, 118 Stat. 255.
Pub. L. 108–7, div. G, title II, §216, Feb. 20, 2003, 117 Stat. 325.
Pub. L. 107–116, title II, §216, Jan. 10, 2002, 115 Stat. 2201.
Pub. L. 106–554, §1(a)(1) [title II], Dec. 21, 2000, 114 Stat. 2763, 2763A–13.
Pub. L. 106–113, div. B, §1000(a)(4) [title II], Nov. 29, 1999, 113 Stat. 1535, 1501A–225.
Pub. L. 105–277, div. A, §101(f) [title II], Oct. 21, 1998, 112 Stat. 2681–337, 2681–347.
Pub. L. 105–78, title II, Nov. 13, 1997, 111 Stat. 1477.
Pub. L. 104–208, div. A, title I, §101(e) [title II], Sept. 30, 1996, 110 Stat. 3009–233, 3009–242.
Pub. L. 104–134, title I, §101(d) [title II], Apr. 26, 1996, 110 Stat. 1321–211, 1321–221; renumbered title I, Pub. L. 104–140, §1(a), May 2, 1996, 110 Stat. 1327.

TERM OF RESERVE COMMISSIONS IN EFFECT ON APRIL 27, 1956

Act Apr. 27, 1956, ch. 211, §3(c)(2), 70 Stat. 117, provided that: "The enactment of paragraph (1) of this subsection [amending this section] shall not affect the term of the commission of any officer in the Reserve Corps in effect on the date of such enactment [Apr. 27, 1956] unless such officer consents in writing to the extension of his commission for an indefinite period, in which event his commission shall be so extended without the necessity of a new appointment."

EXECUTIVE DOCUMENTS

TRANSFER OF FUNCTIONS

Functions of Public Health Service, Surgeon General of Public Health Service, and all other officers and employees of Public Health Service, and functions of all agencies of or in Public Health Service transferred to Secretary of Health, Education, and Welfare by Reorg. Plan No. 3 of 1966, eff. June 25, 1966, 31 F.R. 8855, 80 Stat. 1610, set out as a note under section 202 of this title.

Functions of Federal Security Administrator transferred to Secretary of Health, Education, and Welfare and all agencies of Federal Security Agency transferred to Department of Health, Education, and Welfare by section 5 of Reorg. Plan No. 1 of 1953, set out as a note under section 3501 of this title. Federal Security Agency and office of Administrator abolished by section 8 of Reorg. Plan No. 1 of 1953.

DELEGATION OF FUNCTIONS

Functions of President delegated to Secretary of Health and Human Services and Surgeon General, see Ex. Ord. No. 11140, Jan. 30, 1964, 29 F.R. 1637, as amended, set out as a note under section 202 of this title.

§§209a, 209b. Omitted

EDITORIAL NOTES

CODIFICATION

Section 209a, act Dec. 22, 1944, ch. 660, title I, 58 Stat. 856, which related to number of regular commissioned nurses to be appointed, their grades, and their length of service for purposes of pay and pay periods, was not repeated in subsequent appropriation acts.

Section 209b, act Dec. 22, 1944, ch. 660, title I, 58 Stat. 857, which authorized appointment of fifty additional regular commissioned officers of which twenty-four were to be in grades above that of senior assistant, was not repeated in subsequent appropriation acts.

§209c. Repealed. Pub. L. 87–649, §14b, Sept. 7, 1962, 76 Stat. 499

Section, act July 3, 1945, ch. 263, title II, 59 Stat. 370, provided that for purposes of pay and pay period officers appointed to grades above that of senior assistant pursuant to section 209b of this title shall be considered as having had on date of appointment service equal to that of junior officer of grade to which appointed.

§209d. Appointment of osteopaths as commissioned officers

Graduates of colleges of osteopathy whose graduates are eligible for licensure to practice medicine or osteopathy in a majority of the States of the United States, or approved by a body or bodies acceptable to the Secretary, shall be eligible, subject to the other provisions of this Act, for appointment as commissioned medical officers in the Public Health Service.

(Feb. 28, 1948, ch. 83, §5(b), 62 Stat. 40; 1953 Reorg. Plan No. 1, §§5, 8, eff. Apr. 11, 1953, 18 F.R. 2053, 67 Stat. 631.)

EDITORIAL NOTES

REFERENCES IN TEXT

This Act, referred to in text, is act Feb. 28, 1948, ch. 83, 62 Stat. 38. For complete classification of this Act to the Code, see Tables.

CODIFICATION

Section was not enacted as a part of the Public Health Service Act which comprises this chapter.

STATUTORY NOTES AND RELATED SUBSIDIARIES

CHANGE OF NAME

"Secretary of Health and Human Services" substituted in text for "Secretary of Health, Education, and Welfare" pursuant to section 509(b) of Pub. L. 96–88, which is classified to section 3508(b) of Title 20, Education.

EXECUTIVE DOCUMENTS

TRANSFER OF FUNCTIONS

Functions of Public Health Service, Surgeon General of Public Health Service, and all other officers and employees of Public Health Service, and functions of all agencies of or in Public Health Service transferred to Secretary of Health, Education, and Welfare by Reorg. Plan No. 3 of 1966, eff. June 25, 1966, 31 F.R. 8855, 80 Stat. 1610, set out as a note under section 202 of this title.

Functions of Federal Security Administrator transferred to Secretary of Health, Education, and Welfare and all agencies of Federal Security Agency transferred to Department of Health, Education, and Welfare by section 5 of Reorg. Plan No. 1 of 1953, set out as a note under section 3501 of this title. Federal Security Agency and office of Administrator abolished by section 8 of Reorg. Plan No. 1 of 1953.

§210. Pay and allowances

(a) Commissioned officers of Regular Corps and Ready Reserve Corps; special pay for active duty; incentive special pay for Public Health Service nurses

(1) Commissioned officers of the Regular Corps and Ready Reserve Corps shall be entitled to receive such pay and allowances as are now or may hereafter be authorized by law.

(2) For provisions relating to the receipt of special pay by commissioned officers of the Regular Corps and Ready Reserve Corps while on active duty, see section 303a(b) or 373 of title 37.

(b) Purchase of supplies

Commissioned officers on active duty and retired officers entitled to retired pay pursuant to section 211(g)(3), 212, or 213a(a) of this title, shall be permitted to purchase supplies from the Army, Navy, Air Force, and Marine Corps at the same price as is charged officers thereof.

(c) Members of national advisory or review councils or committees

Members of the National Advisory Health Council and members of other national advisory or review councils or committees established under this chapter, including members of the Technical

Electronic Product Radiation Safety Standards Committee and the Board of Regents of the National Library of Medicine, but excluding ex officio members, while attending conferences or meetings of their respective councils or committees or while otherwise serving at the request of the Secretary, shall be entitled to receive compensation at rates to be fixed by the Secretary, but at rates not exceeding the daily equivalent of the rate specified at the time of such service for grade GS–18 of the General Schedule, including traveltime; and while away from their homes or regular places of business they may be allowed travel expenses, including per diem in lieu of subsistence, as authorized by section 5703 of title 5 for persons in the Government service employed intermittently.

(d) Field employees

Field employees of the Service, except those employed on a per diem or fee basis, who render part-time duty and are also subject to call at any time for services not contemplated in their regular part-time employment, may be paid annual compensation for such part-time duty and, in addition, such fees for such other services as the Surgeon General may determine; but in no case shall the total paid to any such employee for any fiscal year exceed the amount of the minimum annual salary rate of the classification grade of the employee.

(e) Additional pay for service at Gillis W. Long Hansen's Disease Center

Any civilian employee of the Service who is employed at the Gillis W. Long Hansen's Disease Center on April 7, 1986, shall be entitled to receive, in addition to any compensation to which the employee may otherwise be entitled and for so long as the employee remains employed at the Center, an amount equal to one-fourth of such compensation.

(f) Allowances included in fellowships

Individuals appointed under section 209(g) of this title shall have included in their fellowships such stipends or allowances, including travel and subsistence expenses, as the Surgeon General may deem necessary to procure qualified fellows.

(g) Positions in professional, scientific and executive service; compensation; appointment

The Secretary is authorized to establish and fix the compensation for, within the Public Health Service, not more than one hundred and seventy-nine positions, of which not less than one hundred and fifteen shall be for the National Institutes of Health, not less than five shall be for the National Institute on Alcohol Abuse and Alcoholism for individuals engaged in research on alcohol abuse and alcoholism, not less than ten shall be for the National Center for Health Services Research, not less than twelve shall be for the National Center for Health Statistics, and not less than seven shall be for the National Center for Health Care Technology, in the professional, scientific, and executive service, each such position being established to effectuate those research and development activities of the Public Health Service which require the services of specially qualified scientific, professional and administrative personnel: *Provided*, That the rates of compensation for positions established pursuant to the provisions of this subsection shall not be less than the minimum rate of grade 16 of the General Schedule nor more than (1) the highest rate of grade 18 of the General Schedule, or (2) in the case of two such positions, the rate specified, at the time the service in the position is performed, for level II of the Executive Schedule (5 U.S.C. 5313); and such rates of compensation for all positions included in this proviso shall be subject to the approval of the Director of the Office of Personnel Management. Positions created pursuant to this subsection shall be included in the classified civil service of the United States, but appointments to such positions shall be made without competitive examination upon approval of the proposed appointee's qualifications by the Director of the Office of Personnel Management or such officers or agents as it may designate for this purpose.

(July 1, 1944, ch. 373, title II, §208, formerly §209, 58 Stat. 686; July 3, 1946, ch. 538, §5(a), 60 Stat. 422; renumbered §208 and amended Feb. 28, 1948, ch. 83, §5(a), (g), (h), 62 Stat. 40; June 16, 1948, ch. 481, §4(d), 62 Stat. 467; June 24, 1948, ch. 621, §4(d), 62 Stat. 601; Oct. 12, 1949, ch. 681, title V, §521(b), 63 Stat. 834; Aug. 9, 1950, ch. 654, §1, 64 Stat. 426; Aug. 15, 1950, ch. 714, §§3(e), 4(b), 64 Stat. 447; 1953 Reorg. Plan No. 1, §§5, 8 eff. Apr. 11, 1953, 18 F.R. 2053, 67 Stat. 631; Aug. 1, 1955, ch. 437, title II, §201, 69 Stat. 407; June 29, 1956, ch. 477, title II, §201, 70 Stat. 430; July 31, 1956, ch. 804, title I, §117(b), 70 Stat. 741; Pub. L. 85–462, §12(e), June 20, 1958, 72

Stat. 214; Pub. L. 85–929, §9, Sept. 6, 1958, 72 Stat. 1789; Pub. L. 86–415, §5(b), Apr. 8, 1960, 74 Stat. 34; Pub. L. 86–703, title II, §201, Sept. 2, 1960, 74 Stat. 764; Pub. L. 87–649, §§11(3), 14b, Sept. 7, 1962, 76 Stat. 497, 499; Pub. L. 87–793, title VI, §1001(d), Oct. 11, 1962, 76 Stat. 864; Pub. L. 88–426, title III, §305(1), Aug. 14, 1964, 78 Stat. 422; Pub. L. 90–574, title V, §501, Oct. 15, 1968, 82 Stat. 1012; Pub. L. 91–515, title VI, §601(b)(1), Oct. 30, 1970, 84 Stat. 1310; Pub. L. 92–157, title III, §301(a), Nov. 18, 1971, 85 Stat. 463; Pub. L. 95–83, title III, §312, Aug. 1, 1977, 91 Stat. 398; Pub. L. 95–623, §11(a), Nov. 9, 1978, 92 Stat. 3455; 1978 Reorg. Plan No. 2, §102, eff. Jan. 1, 1979, 43 F.R. 36037, 92 Stat. 3783; Pub. L. 96–32, §7(g), July 10, 1979, 93 Stat. 84; Pub. L. 96–398, title VIII, §805, Oct. 7, 1980, 94 Stat. 1608; Pub. L. 99–117, §3(a), Oct. 7, 1985, 99 Stat. 491; Pub. L. 99–272, title XVII, §17002(a)(1), (b), Apr. 7, 1986, 100 Stat. 359; Pub. L. 100–607, title VII, §706, Nov. 4, 1988, 102 Stat. 3159; Pub. L. 106–398, §1 [[div. A], title VI, §634(b)], Oct. 30, 2000, 114 Stat. 1654, 1654A–159; Pub. L. 115–91, div. A, title VI, §618(i), Dec. 12, 2017, 131 Stat. 1427; Pub. L. 116–136, div. A, title III, §3214(e)(2), Mar. 27, 2020, 134 Stat. 373.)

EDITORIAL NOTES

REFERENCES IN TEXT

Classified civil service, referred to in subsec. (g), as meaning "competitive service", see section 2102(c) of Title 5, Government Organization and Employees.

PRIOR PROVISIONS

A prior section 208 of act July 1, 1944, was renumbered section 207 and is classified to section 209 of this title.

AMENDMENTS

2020—Subsec. (a). Pub. L. 116–136 substituted "Regular Corps and Ready Reserve Corps" for "Regular and Reserve Corps" wherever appearing.

2017—Subsec. (a)(2). Pub. L. 115–91 inserted "or 373" after "section 303a(b)".

2000—Subsec. (a)(2). Pub. L. 106–398 added par. (2) and struck out former par. (2) which read as follows: "(2)(A) Except as provided in subparagraph (B), commissioned medical and dental officers in the Regular and Reserve Corps shall while on active duty be paid special pay in the same amounts as, and under the same terms and conditions which apply to, the special pay now or hereafter paid to commissioned medical and dental officers of the Armed Forces under chapter 5 of title 37.

"(B) A commissioned medical officer in the Regular or Reserve Corps (other than an officer serving in the Indian Health Service) may not receive additional special pay under section 302(a)(4) of title 37 for any period during which the officer is providing obligated service under (i) section 254m of this title, (ii) section 234(e) of this title (as such section was in effect prior to October 1, 1977), or (iii) section 294u of this title (as such section was in effect between October 1, 1977, and August 13, 1981)."

Subsec. (a)(3). Pub. L. 106–398, §1 [[div. A], title VI, §634(b)(1)], struck out par. (3) which read as follows: "Commissioned nurse officers in the Regular and Reserve Corps shall, while in active duty, be paid incentive special pay in the same amounts as, and under the same terms and conditions which apply to, the incentive special pay now or hereafter paid to commissioned nurse officers of the Armed Forces under chapter 5 of title 37."

1988—Subsec. (a)(3). Pub. L. 100–607 added par. (3).

1986—Subsec. (a)(2)(B). Pub. L. 99–272, §17002(a)(1), inserted "(other than an officer serving in the Indian Health Service)".

Subsec. (e). Pub. L. 99–272, §17002(b), amended subsec. (e) generally. Prior to amendment, subsec. (e) read as follows: "Whenever any noncommissioned officer or other employee of the Service is assigned for duty which the Surgeon General finds requires intimate contact with persons afflicted with leprosy, he may be entitled to receive, as provided by regulations of the President, in addition to any pay or compensation to which he may otherwise be entitled, not more than one-half of such pay or compensation."

1985—Subsec. (a)(2). Pub. L. 99–117 substituted "(A) Except as provided in subparagraph (B), commissioned" for "Commissioned", and added subpar. (B).

1980—Subsec. (a). Pub. L. 96–398 designated existing provisions as par. (1) and added par. (2).

1979—Subsec. (c). Pub. L. 96–32 substituted "section 5703 of title 5" for "section 5703(b) of title 5".

1978—Subsec. (g). Pub. L. 95–623 increased limitation on establishment of positions to one hundred and

seventy-nine from one hundred and fifty-five and required minimum number of positions for certain National Centers: ten, National Center for Health Services Research; twelve, National Center for Health Statistics; and seven, National Center for Health Care Technology.

1977—Subsec. (g). Pub. L. 95–83 increased limitation on establishment of positions to one hundred and fifty-five from one hundred and fifty and required not less than five for the National Institute on Alcohol Abuse and Alcoholism for individuals engaged in research on alcohol abuse and alcoholism.

1971—Subsec. (f). Pub. L. 92–157, which directed that "subsection (g)" be substituted for "section 209(f)", was executed by substituting "section 209(g) of this title" for "section 209(f) of this title", to reflect the probable intent of Congress.

1970—Subsec. (c). Pub. L. 91–515 extended coverage to encompass members of other national review councils or national advisory or review committees established under this chapter, including members of the Technical Electronic Product Radiation Safety Standards Committee and the Board of Regents of the National Library of Medicine, authorized service to be at the request of the Secretary in place of the Surgeon General, and revised rates of compensation and travel allowances.

1968—Subsec. (g). Pub. L. 90–574 inserted "(1)" after "nor more than" and added cl. (2).

1962—Subsec. (b). Pub. L. 87–649 struck out sentence which permitted commissioned officers on active duty to make allotments from their pay, and substituted "Commissioned officers on active duty and retired officers" for "Such officers, and retired officers." See section 704 of Title 37, Pay and Allowances of the Uniformed Services.

Subsec. (g). Pub. L. 87–793 substituted provisions requiring the rates of compensation to be not less than the minimum rate of grade 16 nor more than the highest rate of grade 18 of the General Schedule, for provisions which prescribed annual rates of compensation of not less than $12,500 nor more than $19,000.

1960—Subsec. (b). Pub. L. 86–415 authorized retired officers entitled to retired pay pursuant to section 211(g)(3), 212, or 213a(a) of this title, to purchase supplies, and included the purchase of supplies from the Air Force.

Subsec. (g). Pub. L. 86–703 substituted "one hundred and fifty" for "eighty-five" and "one hundred and fifteen" for "seventy-three".

1958—Subsec. (g). Pub. L. 85–929 substituted "in the professional, scientific, and executive service" for "in the professional and scientific service", and substituted "of specially qualified scientific, professional, and administrative personnel" for "of specially qualified scientific or professional personnel".

Pub. L. 85–462, substituted "eighty-five positions, of which not less than seventy-three shall be for the National Institutes of Health" for "sixty positions".

1956—Subsec. (g). Act June 29, 1956, substituted "$20,000" for "$15,000".

1955—Subsec. (g). Act Aug. 1, 1955, increased from thirty to sixty the number of positions which the Administrator may establish in the professional and scientific service.

1950—Subsec. (b). Act Aug. 9, 1950, struck out "and may be granted leaves of absence without any deduction from their pay" after "allotments from their pay" in first sentence.

Subsec. (c). Act Aug. 15, 1950, §3(e), made provisions applicable to members of all national advisory councils.

Subsec. (g). Act Aug. 15, 1950, §4(b), added subsec. (g).

1949—Subsec. (a). Act Oct. 12, 1949, made section applicable to Reserve officers.

Subsec. (b). Act Oct. 12, 1949, redesignated subsec. (c) as (b) and repealed former subsec. (b) relating to Reserve officers.

Subsec. (c). Act Oct. 12, 1949, redesignated subsec. (e) as (c). Former subsec. (c) redesignated (b).

Subsec. (d). Act Oct. 12, 1949, redesignated subsec. (f) as (d) and repealed former subsec. (d) relating to female commissioned officers and defining "dependent".

Subsec. (e). Act Oct. 12, 1949, redesignated subsec. (g) as (e) and struck out references to allowances. Former subsec. (e) redesignated (c).

Subsec. (f). Act Oct. 12, 1949, redesignated subsec. (h) as (f). Former subsec. (f) redesignated (d).

Subsecs. (g), (h). Act Oct. 12, 1949, redesignated subsecs. (g) and (h) as (e) and (f), respectively.

1948—Subsec. (b). Act Feb. 28, 1948, inserted "except as otherwise provided by law".

Subsec. (e). Acts June 16, 1948, §4(d), and June 24, 1948, §4(d), made section applicable to the National Advisory Heart Council and increased the per diem of all members from $25 to $50, and made section applicable to the National Advisory Dental Research Council, respectively.

Subsec. (h). Act Feb. 28, 1948, substituted "section 209(f) of this title" for "section 209(d) of this title".

1946—Subsec. (e). Act July 3, 1946, inserted "members of the National Advisory Mental Health Council".

STATUTORY NOTES AND RELATED SUBSIDIARIES

CHANGE OF NAME

Reference to the Gillis W. Long Hansen's Disease Center deemed to refer to the National Hansen's Disease Programs Center, pursuant to section 2 of Pub. L. 107–220, set out as a note under section 247e of this title.

"Secretary of Health and Human Services" substituted for "Secretary of Health, Education, and Welfare" in subsecs. (c) and (g) pursuant section 509(b) of Pub. L. 96–88, which is classified to section 3508(b) of Title 20, Education.

EFFECTIVE DATE OF 1986 AMENDMENT

Pub. L. 99–272, title XVII, §17002(a)(2), Apr. 7, 1986, 100 Stat. 359, provided that: "The amendment made by paragraph (1) [amending this section] shall take effect as of October 7, 1985."

EFFECTIVE DATE OF 1985 AMENDMENT

Pub. L. 99–117, §3(b), Oct. 7, 1985, 99 Stat. 492, provided that: "The amendment made by subsection (a) [amending this section] shall not diminish any benefits under an agreement entered into before the date of enactment of this Act [Oct. 7, 1985] by a commissioned medical officer in the Regular Corps or the Reserve Corps of the Public Health Service."

EFFECTIVE DATE OF 1962 AMENDMENTS

Amendment by Pub. L. 87–793 effective first day of first pay period which begins on or after Oct. 11, 1962, see Pub. L. 87–793, title VI, §1008, Oct. 11, 1962, 76 Stat. 868.

Amendment by Pub. L. 87–649 effective Nov. 1, 1962, see section 15 of Pub. L. 87–649, set out as an Effective Date note preceding section 101 of Title 37, Pay and Allowances of the Uniformed Services.

EFFECTIVE DATE OF 1960 AMENDMENT

Amendment by Pub. L. 86–415 effective July 1, 1960, see section 8(a) of Pub. L. 86–415, set out as a note under section 209 of this title.

EFFECTIVE DATE OF 1958 AMENDMENTS

Amendment by Pub. L. 85–929 effective Sept. 6, 1958, see section 6(a) of Pub. L. 85–929, set out as a note under section 342 of Title 21, Food and Drugs.

Amendment by Pub. L. 85–462 effective June 20, 1958, see section 17(b) of Pub. L. 85–462.

EFFECTIVE DATE OF 1956 AMENDMENT

Amendment by act July 31, 1956, effective at beginning of first pay period commencing after June 30, 1956, see section 120 of act July 31, 1956.

EFFECTIVE DATE OF 1950 AMENDMENT

Act Aug. 9, 1950, ch. 654, §3(a), 64 Stat. 426, provided that: "Sections 1 and 2 of this Act [amending this section and enacting section 210–1 of this title] shall become effective on July 1, 1950."

EFFECTIVE DATE OF 1949 AMENDMENT

Amendment by act Oct. 12, 1949, effective Oct. 1, 1949, see section 533(a) of act Oct. 12, 1949, set out as a note under section 854a of Title 33, Navigation and Navigable Waters.

REPEALS

Act July 31, 1956, ch. 804, title I, §117(b), 70 Stat. 741, cited as a credit to this section, which amended subsec. (g) of this section to increase the salary rates, was repealed by Pub. L. 88–426, title III, §305(1), Aug. 14, 1964, 78 Stat. 422.

TERMINATION OF ADVISORY COMMITTEES

Pub. L. 93–641, §6, Jan. 4, 1975, 88 Stat. 2275, set out as a note under section 217a of this title, provided that an advisory committee established pursuant to the Public Health Service Act shall terminate at such time as may be specifically prescribed by an Act of Congress enacted after Jan. 4, 1975.

REFERENCES IN OTHER LAWS TO GS–16, 17, OR 18 PAY RATES

References in laws to the rates of pay for GS–16, 17, or 18, or to maximum rates of pay under the General Schedule, to be considered references to rates payable under specified sections of Title 5, Government Organization and Employees, see section 529 [title I, §101(c)(1)] of Pub. L. 101–509, set out in a note under

section 5376 of Title 5.

MAXIMUM PAY AND ALLOWANCES FOR SPECIFIC FISCAL YEARS

Pub. L. 100–436, title II, §208, Sept. 20, 1988, 102 Stat. 1699, provided in part that: "No funds appropriated for the fiscal year ending September 30, 1989, by this or any other Act, may be used to pay basic pay, special pays, basic allowances for subsistence and basic allowances for quarters of the commissioned corps of the Public Health Service described in section 204 of title 42, United States Code, at a level that exceeds 110 percent of the Executive Level I [5 U.S.C. 5312] annual rate of basic pay".

Similar provisions were contained in the following prior appropriation acts:

Pub. L. 100–202, §101(h) [title II, §208], Dec. 22, 1987, 101 Stat. 1329–256, 1329–274.

Pub. L. 99–500, §101(i) [H.R. 5233, title II, §208], Oct. 18, 1986, 100 Stat. 1783–287, and Pub. L. 99–591, §101(i) [H.R. 5233, title II, §208], Oct. 30, 1986, 100 Stat. 3341–287.

Pub. L. 99–178, title II, §208, Dec. 12, 1985, 99 Stat. 1119.

Pub. L. 98–619, title II, §208, Nov. 8, 1984, 98 Stat. 3321.

Pub. L. 98–139, title II, §208, Oct. 31, 1983, 97 Stat. 888.

NURSES AND ALLIED HEALTH PROFESSIONALS

Pub. L. 100–436, title II, §214, Sept. 20, 1988, 102 Stat. 1700, provided that: "Funds made available for fiscal year 1989 and hereafter to the National Institutes of Health shall be available for payment of nurses and allied health professionals using pay, schedule options, benefits, and other authorities as provided for the nurses of the Veterans' Administration under 38 U.S.C. chapter 73."

EXECUTIVE DOCUMENTS

TRANSFER OF FUNCTIONS

"Director of the Office of Personnel Management" substituted for "Civil Service Commission" in subsec. (g) pursuant to Reorg. Plan No. 2 of 1978, §102, 43 F.R. 36037, 92 Stat. 3783, set out under section 1101 of Title 5, Government Organization and Employees, which transferred functions vested by statute in United States Civil Service Commission to Director of Office of Personnel Management (except as otherwise specified), effective Jan. 1, 1979, as provided by section 1–102 of Ex. Ord. No. 12107, Dec. 28, 1978, 44 F.R. 1055, set out under section 1101 of Title 5.

Functions of Public Health Service, Surgeon General of Public Health Service, and all other officers and employees of Public Health Service, and functions of all agencies of or in Public Health Service transferred to Secretary of Health, Education, and Welfare by Reorg. Plan No. 3 of 1966, eff. June 25, 1966, 31 F.R. 8855, 80 Stat. 1610, set out as a note under section 202 of this title.

Functions of Federal Security Administrator transferred to Secretary of Health, Education, and Welfare and all agencies of Federal Security Agency transferred to Department of Health, Education, and Welfare by section 5 of Reorg. Plan No. 1 of 1953, set out as a note under section 3501 of this title. Federal Security Agency and office of Administrator abolished by section 8 of Reorg. Plan No. 1 of 1953.

DELEGATION OF FUNCTIONS

Functions of President delegated to Secretary of Health and Human Services, see Ex. Ord. No. 11140, eff. Jan. 30, 1964, 29 F.R. 1637, as amended, set out as a note under section 202 of this title.

§210–1. Annual and sick leave

(a) Regulations

In accordance with regulations of the President, commissioned officers of the Regular Corps and officers of the Ready Ready [1] Reserve Corps on active duty may be granted annual leave and sick leave without any deductions from their pay and allowances.

(b) Limitation

The regulations described in subsection (a) may authorize accumulated annual leave of not more than 120 days for any commissioned officer of the Regular Corps or officer of the Ready Reserve Corps on active duty.

(c) [2] Definitions

For purposes of this section the term "accumulated annual leave" means unused accrued annual leave carried forward from one leave year into a succeeding leave year, and the term "accrued annual leave" means the annual leave accruing to an officer during one leave year.

(July 1, 1944, ch. 373, title II, §219, as added Aug. 9, 1950, ch. 654, §2, 64 Stat. 426; amended Pub. L. 87–649, §14b, Sept. 7, 1962, 76 Stat. 499; Pub. L. 96–76, title III, §311, Sept. 29, 1979, 93 Stat. 586; Pub. L. 116–136, div. A, title III, §3214(e)(3), Mar. 27, 2020, 134 Stat. 373; Pub. L. 117–328, div. FF, title II, §2225(a), Dec. 29, 2022, 136 Stat. 5750.)

EDITORIAL NOTES

AMENDMENTS

2022—Subsec. (a). Pub. L. 117–328, §2225(a)(1), substituted "Ready Reserve Corps" for "Reserve Corps" and struck out ": *Provided*, That such regulations shall not authorize annual leave to be accumulated in excess of sixty days" after "allowances".

Subsec. (b). Pub. L. 117–328, §2225(a)(2), added subsec. (b).

Subsecs. (c), (d). Pub. L. 117–328, §2225(a)(3), redesignated subsec. (d) as (c).

2020—Subsec. (a). Pub. L. 116–136 substituted "Ready Reserve Corps" for "Reserve Corps".

1979—Subsec. (c). Pub. L. 96–76, repealed subsec. (c) which set forth limitations on granting of annual leave under subsec. (a) of this section.

1962—Subsec. (b). Pub. L. 87–649 repealed subsec. (b) which required forfeiture of all pay and allowances of an officer absent without leave. See section 503 of Title 37, Pay and Allowances of the Uniformed Services.

Subsec. (c). Pub. L. 87–649 repealed last sentence which authorized a lump-sum payment for unused accumulated and accrued annual leave on date of separation, retirement, or release from active duty. See section 501 of Title 37, Pay and Allowances of the Uniformed Services.

Subsec. (d). Pub. L. 87–649 repealed subsec. (d) insofar as it was applicable to the last sentence of subsec. (c). See Amendment note above.

STATUTORY NOTES AND RELATED SUBSIDIARIES

EFFECTIVE DATE OF 2022 AMENDMENT

Pub. L. 117–328, div. FF, title II, §2225(b), Dec. 29, 2022, 136 Stat. 5750, provided that: "The amendments made by subsection (a) [amending this section] shall apply with respect to accumulated annual leave (as defined in section 219 of the Public Health Service Act (42 U.S.C. 210–1)) that a commissioned officer of the Regular Corps or officer of the Ready Reserve Corps on active duty would, but for the regulations described in such section, lose at the end of fiscal year 2022 or a subsequent fiscal year."

EFFECTIVE DATE OF 1962 AMENDMENT

Amendment by Pub. L. 87–649 effective Nov. 1, 1962, see section 15 of Pub. L. 87–649, set out as an Effective Date note preceding section 101 of Title 37, Pay and Allowances of the Uniformed Services.

EFFECTIVE DATE

Section effective July 1, 1950, see section 3(a) of act Aug. 9, 1950, set out as an Effective Date of 1950 Amendment note under section 210 of this title.

AUTHORIZATION TO ACCUMULATE EXCESS ANNUAL LEAVE

Pub. L. 117–180, div. D, title III, §302, Sept. 30, 2022, 136 Stat. 2136, provided that: "For purposes of annual leave accumulated in fiscal year 2022, the authority provided in section 2106 of division C of Public Law 116–159 (42 U.S.C. 210–1 note) shall apply to such leave by substituting '2022' for '2020' in subsections (a) and (d)(2)."

Pub. L. 116–159, div. C, title I, §2106, Oct. 1, 2020, 134 Stat. 729, provided that:

"(a) IN GENERAL.—Notwithstanding section 219 of the Public Health Service Act (42 U.S.C. 210–1), a commissioned officer of the Public Health Service who, except for this section, would lose at the end of the fiscal year 2020 accumulated annual leave in excess of 60 days, may retain such amounts of accumulated annual leave in excess of 60 days.

"(b) USE OF EXCESS LEAVE.—Annual leave retained pursuant to subsection (a) shall be lost unless it is used by the officer no later than September 30, 2023.

"(c) APPLICABILITY.—This section shall not apply to an officer on terminal leave preceding separation, retirement, or release from active duty, as of the effective date specified in subsection (d).

"(d) EFFECTIVE DATE.—This section shall become effective on the earlier of—

"(1) the date of the enactment of this Act [Oct. 1, 2020]; or

"(2) September 30, 2020."

COMPENSATION FOR PRIOR ACCUMULATED AND ACCRUED LEAVE; LIMITATION; INAPPLICABLE TO OFFICERS ON TERMINAL LEAVE PRIOR TO JULY 1, 1950

Act Aug. 9, 1950, ch. 654, §3(b), (c), 64 Stat. 426, 427, provided that any officer credited with more than sixty days of accumulated and accrued leave on June 30, 1949, be compensated for so much of such leave as exceeds sixty days, that such compensation be due and payable on July 1, 1950, and that the provisions of this Act not apply to any officer on terminal leave preceding separation, retirement, or release from active duty.

AVAILABILITY OF FUNDS

Act Aug. 9, 1950, ch. 654, §4, 64 Stat. 427, provided for the availability of funds for payment of compensation for prior accumulated and accrued leave for any officer under section 3 of this Act.

LEAVE REGULATIONS

Act Aug. 9, 1950, ch. 654, §5, 64 Stat. 427, provided that: "Except insofar as the provisions of this Act [enacting this section, amending section 210 of this title, and enacting provisions set out as notes under this section and section 210 of this title] are inconsistent therewith, leave regulations adopted prior to the enactment of this Act [Aug. 9, 1950], pursuant to the Public Health Service Act [42 U.S.C. 201 et seq.], shall remain in effect until repealed, amended, or superseded."

EXECUTIVE DOCUMENTS

TRANSFER OF FUNCTIONS

Functions of Public Health Service, of Surgeon General of Public Health Service, and all other officers and employees of Public Health Service, and functions of all agencies of or in Public Health Service transferred to Secretary of Health, Education, and Welfare by Reorg. Plan No. 3 of 1966, eff. June 25, 1966, 31 F.R. 8855, 80 Stat. 1610, set out as a note under section 202 of this title.

DELEGATION OF FUNCTIONS

Functions of President delegated to Secretary of Health and Human Services, see Ex. Ord. No. 11140, Jan. 30, 1964, 29 F.R. 1637, as amended, set out as a note under section 202 of this title.

[1] So in original.

[2] See 1962 Amendment note for subsec. (d) below.

§210a. Repealed. Pub. L. 87–649, §14b, Sept. 7, 1962, 76 Stat. 499

Section, act Feb. 28, 1948, ch. 83, §5(e), (f), 62 Stat. 41, related to service credit for commissioned officers on active duty Feb. 28, 1948, and to service credit for pay and promotion purposes of certain appointees during period Feb. 28, 1948, to July 1, 1948.

§210b. Professional categories

(a) Division of corps; basis of categories

For the purpose of establishing eligibility of officers of the Regular Corps for promotions, the Surgeon General shall by regulation divide the corps into professional categories. Each category shall, as far as practicable, be based upon one of the subjects of examination set forth in section 209(a)(1) of this title or upon a subdivision of such subject, and the categories shall be designed to

group officers by fields of training in such manner that officers in any one grade in any one category will be available for similar duty in the discharge of the several functions of the Service.

(b) Assignment of officers

Each officer of the Regular Corps on active duty shall, on the basis of his training and experience, be assigned by the Surgeon General to one of the categories established by regulations under subsection (a). Except upon amendment of such regulations, no assignment so made shall be changed unless the Surgeon General finds (1) that the original assignment was erroneous, or (2) that the officer is equally well qualified to serve in another category to which he has requested to be transferred, and that such transfer is in the interests of the Service.

(c) Maximum number of officers in each category

Within the limits fixed by the Secretary in regulations under section 207(d) of this title for any fiscal year, the Surgeon General shall determine for each category in the Regular Corps the maximum number of officers authorized to be in each of the grades from the warrant officer (W–1) grade to the director grade, inclusive.

(d) Vacancies in grade for purposes of promotion

The excess of the number so fixed for any grade in any category over the number of officers of the Regular Corps on active duty in such grade in such category (including in the case of the director grade, officers holding such grade in accordance with section 207(c) of this title) shall for the purpose of promotions constitute vacancies in such grade in such category. For purposes of this subsection, an officer who has been temporarily promoted or who is temporarily holding the grade of director in accordance with section 207(c) of this title shall be deemed to hold the grade to which so promoted or which he is temporarily holding; but while he holds such promotion or grade, and while any officer is temporarily assigned to a position pursuant to section 206(c) of this title, the number fixed under subsection (c) of this section for the grade of his permanent rank shall be reduced by one.

(e) Absence of vacancy in grade as affecting promotion

The absence of a vacancy in a grade in a category shall not prevent an appointment to such grade pursuant to section 209 of this title, a permanent length of service promotion, or the recall of a retired officer to active duty; but the making of such an appointment, promotion, or recall shall be deemed to fill a vacancy if one exists.

(f) Vacancy in grade as affecting maximum number for each category

Whenever a vacancy exists in any grade in a category the Surgeon General may increase by one the number fixed by him under subsection (c) for the next lower grade in the same category, without regard to the numbers fixed in regulations under section 207(d) of this title; and in that event the vacancy in the higher grade shall not be filled except by a permanent promotion, and upon the making of such promotion the number for the next lower grade shall be reduced by one.

(July 1, 1944, ch. 373, title II, §209, as added Feb. 28, 1948, ch. 83, §5(i), 62 Stat. 41; amended 1953 Reorg. Plan No. 1, §§5, 8, eff. Apr. 11, 1953, 18 F.R. 2053, 67 Stat. 631; Pub. L. 96–76, title III, §306, Sept. 29, 1979, 93 Stat. 585.)

EDITORIAL NOTES

PRIOR PROVISIONS

A prior section 209 of act July 1, 1944, was renumbered section 208 and is classified to section 210 of this title.

AMENDMENTS

1979—Subsec. (c). Pub. L. 96–76 substituted "warrant officer (W–1)" for "assistant".

STATUTORY NOTES AND RELATED SUBSIDIARIES

CHANGE OF NAME

"Secretary of Health and Human Services" substituted for "Secretary of Health, Education, and Welfare" in subsec. (a) pursuant to section 509(b) of Pub. L. 96–88, which is classified to section 3508(b) of Title 20, Education.

EFFECTIVE DATE OF 1979 AMENDMENT

Amendment by Pub. L. 96–76 effective Oct. 1, 1979, see section 314 of Pub. L. 96–76, set out as a note under section 206 of this title.

EXECUTIVE DOCUMENTS

TRANSFER OF FUNCTIONS

Office of Surgeon General abolished by section 3 of Reorg. Plan No. 3 of 1966, eff. June 25, 1966, 31 F.R. 8855, 80 Stat. 1610, and functions thereof transferred to Secretary of Health, Education, and Welfare by section 1 of Reorg. Plan No. 3 of 1966, set out as a note under section 202 of this title. Office of Surgeon General reestablished within the Office of the Assistant Secretary for Health, see Notice of Department of Health and Human Services, Office of the Assistant Secretary for Health, Mar. 30, 1987, 52 F.R. 11754.

Functions of Federal Security Administrator transferred to Secretary of Health, Education, and Welfare and all agencies of Federal Security Agency transferred to Department of Health, Education, and Welfare by section 5 of Reorg. Plan No. 1 of 1953, set out as a note under section 3501 of this title. Federal Security Agency and office of Administrator abolished by section 8 of Reorg. Plan No. 1 of 1953.

§211. Promotion of commissioned officers

(a) Permanent or temporary promotions; examination

Promotions of officers of the Regular Corps to any grade up to and including the director grade shall be either permanent promotions based on length of service, other permanent promotions to fill vacancies, or temporary promotions. Permanent promotions shall be made by the President, and temporary promotions shall be made by the President. Each permanent promotion shall be to the next higher grade, and shall be made only after examination given in accordance with regulations of the President.

(b) Promotion to certain grades only to fill vacancies; regulations; "restricted grade" defined

The President may by regulation provide that in a specified professional category permanent promotions to the senior grade, or to both the full grade and the senior grade, shall be made only if there are vacancies in such grade. A grade in any category with respect to which such regulations have been issued is referred to in this section as a "restricted grade".

(c) Examinations

Examinations to determine qualification for permanent promotions may be either noncompetitive or competitive, as the Surgeon General shall in each case determine; except that examinations for promotions to the assistant or senior assistant grade shall in all cases be noncompetitive. The officers to be examined shall be selected by the Surgeon General from the professional category, and in the order of seniority in the grade, from which promotion is to be recommended. In the case of a competitive examination the Surgeon General shall determine in advance of the examination the number (which may be one or more) of officers who, after passing the examination, will be recommended to the President for promotion; but if the examination is one for promotions based on length of service, or is one for promotions to fill vacancies other than vacancies in the director grade or in a restricted grade, such number shall not be less than 80 per centum of the number of officers to be examined.

(d) Permanent promotions to qualified officers on length of service

Officers of the Regular Corps, found pursuant to subsection (c) to be qualified, shall be given permanent promotions based on length of service, as follows:

(1) Officers in the warrant officer (W–1) grade, chief warrant officer (W–2) grade, chief warrant

officer (W–3) grade, chief warrant officer (W–4) grade, and junior assistant grade shall be promoted at such times as may be prescribed in regulations of the President.

(2) Officers with permanent rank in the assistant grade, the senior assistant grade, and the full grade shall (except as provided in regulations under subsection (b)) be promoted after completion of three, ten, and seventeen years, respectively, of service in grades above the junior assistant grade; and such promotions, when made, shall be effective, for purposes of pay and seniority in grade, as of the day following the completion of such years of service. An officer with permanent rank in the assistant, senior assistant, or full grade who has not completed such years of service shall be promoted at the same time, and his promotion shall be effective as of the same day, as any officer junior to him in the same grade in the same professional category who is promoted under this paragraph.

(e) Promotion of professional category officers to fill certain vacancies

Officers in a professional category of the Regular Corps, found pursuant to subsection (c) to be qualified, may be given permanent promotions to fill any or all vacancies in such category in the senior assistant grade, the full grade, the senior grade, or the director grade; but no officer who has not had one year of service with permanent or temporary rank in the next lower grade shall be promoted to any restricted grade or to the director grade.

(f) Reexamination upon failure of promotion; effective date of promotion

If an officer who has completed the years of service required for promotion to a grade under paragraph (2) of subsection (d) fails to receive such promotion, he shall (unless he has already been twice examined for promotion to such grade) be once reexamined for promotion to such grade. If he is thereupon promoted (otherwise than under subsection (e)), the effective date of such promotion shall be one year later than it would have been but for such failure. Upon the effective date of any permanent promotion of such officer to such grade, he shall be considered as having had only the length of service required for such promotion which he previously failed to receive.

(g) Separation from service upon failure of promotion

If, for reasons other than physical disability, an officer of the Regular Corps in the warrant officer (W–1) grade or junior assistant grade is found pursuant to subsection (c) not to be qualified for promotion he shall be separated from the Service. If, for reasons other than physical disability, an officer of the Regular Corps in the chief warrant officer (W–2), chief warrant officer (W–3), assistant, senior assistant, or full grade, after having been twice examined for promotion (other than promotion to a restricted grade), fails to be promoted—

(1) if in the chief warrant officer (W–2) or assistant grade he shall be separated from the Service and paid six months' basic pay and allowances;

(2) if in the chief warrant officer (W–3) or senior assistant grade he shall be separated from the Service and paid one year's basic pay and allowances;

(3) if in the full grade he shall be considered as not in line for promotion and shall, at such time thereafter as the Surgeon General may determine, be retired from the Service with retired pay (unless he is entitled to a greater amount by reason of another provision of law)—

(A) in the case of an officer who first became a member of a uniformed service before September 8, 1980, at the rate of 2½ percent of the retired pay base determined under section 1406(h) of title 10 for each year, not in excess of 30, of his active commissioned service in the Service; or

(B) in the case of an officer who first became a member of a uniformed service on or after September 8, 1980, at the rate determined by multiplying—

(i) the retired pay base determined under section 1407 of title 10; by

(ii) the retired pay multiplier determined under section 1409 of such title for the number of years of his active commissioned service in the Service.

(h) Separation from service upon refusal to stand examination

If an officer of the Regular Corps, eligible to take an examination for promotion, refuses to take such examination, he may be separated from the Service in accordance with regulations of the

President.

(i) Review of record; separation from service

At the end of his first three years of service, the record of each officer of the Regular Corps originally appointed to the senior assistant grade or above, shall be reviewed in accordance with regulations of the President and, if found not qualified for further service, he shall be separated from the Service and paid six months' pay and allowances.

(j) Determination of order of seniority

(1) The order of seniority of officers in a grade in the Regular Corps shall be determined, subject to the provisions of paragraph (2) of this subsection, by the relative length of time spent in active service after the effective date of each such officer's original appointment or permanent promotion to that grade. When permanent promotions of two or more officers to the same grade are effective on the same day, their relative seniority shall be the same as it was in the grade from which promoted. In all other cases of original appointments or permanent promotions (or both) to the same grade effective on the same day, relative seniority shall be determined in accordance with regulations of the President.

(2) In the case of an officer originally appointed in the Regular Corps to the grade of assistant or above, his seniority in the grade to which appointed shall be determined after inclusion, as service in such grade, of any active service in such grade or in any higher grade in the Ready Reserve Corps, but (if the appointment is to the grade of senior assistant or above) only to the extent of whichever of the following is greater: (A) His active service in such grade or any higher grade in the Ready Reserve Corps after the first day on which, under regulations in effect on the date of his appointment to the Regular Corps, he had the training and experience necessary for such appointment, or (B) the excess of his total active service in the Ready Reserve Corps (above the grade of junior assistant) over three years if his appointment in the Regular Corps is to the senior assistant grade, over ten years if the appointment is to the full grade, or over seventeen years if the appointment is to the senior grade.

(k) Temporary promotions; fill vacancy in higher grade; war or national emergency; selection of officers; termination of appointment

Any commissioned officer of the Regular Corps in any grade in any professional category may be recommended to the President for temporary promotion to fill a vacancy in any higher grade in such category, up to and including the director grade. In time of war, or of national emergency proclaimed by the President, any commissioned officer of the Regular Corps in any grade in any professional category may be recommended to the President for promotion to any higher grade in such category, up to and including the director grade, whether or not a vacancy exists in such grade. The selection of officers to be recommended for temporary promotions shall be made in accordance with regulations of the President. Promotion of an officer recommended pursuant to this subsection may be made without regard to length of service, without examination, and without vacating his permanent appointment, and shall carry with it the pay and allowances of the grade to which promoted. Such promotions may be terminated at any time, as may be directed by the President.

(l) Determination of requirements of Service by Secretary; assignment of Reserve Officers to professional categories; temporary promotions; termination of temporary promotions

Whenever the number of officers of the Regular Corps on active duty, plus the number of officers of the Ready Reserve Corps who have been on active duty for thirty days or more, exceeds the authorized strength of the Regular Corps, the Secretary shall determine the requirements of the Service in each grade in each category, based upon the total number of officers so serving on active duty and the tasks being performed by the Service; and the Surgeon General shall thereupon assign each officer of the Ready Reserve Corps on active duty to a professional category. If the Secretary finds that the number of officers fixed under section 210b(c) of this title for any grade and category (or the number of officers, including officers of the Ready Reserve Corps, on active duty in such grade in such category, if such number is greater than the number fixed under section 210b(c) of this title) is insufficient to meet such requirements of the Service, officers of either the Regular Corps or

the Ready Reserve Corps may be recommended for temporary promotion to such grade in such category. Any such promotion may be terminated at any time, as may be directed by the President.

(m) Acceptance of promotion; oath and affidavit

Any officer of the Regular Corps, or any officer of the Ready Reserve Corps on active duty, who is promoted to a higher grade shall, unless he expressly declines such promotion, be deemed for all purposes to have accepted such promotion; and shall not be required to renew his oath of office, or to execute a new affidavit as required by section 3332 of title 5.

(July 1, 1944, ch. 373, title II, §210, 58 Stat. 687; Feb. 28, 1948, ch. 83, §6(a), 62 Stat. 42; Oct. 12, 1949, ch. 681, title V, §521(c), 63 Stat. 835; 1953 Reorg. Plan No. 1, §§5, 8, eff. Apr. 11, 1953, 18 F.R. 2053, 67 Stat. 631; Apr. 27, 1956, ch. 211, §4(a), 70 Stat. 117; Pub. L. 86–415, §5(c), Apr. 8, 1960, 74 Stat. 34; Pub. L. 87–649, §11(2), Sept. 7, 1962, 76 Stat. 497; Pub. L. 96–76, title III, §307, Sept. 29, 1979, 93 Stat. 585; Pub. L. 96–342, title VIII, §813(h)(1), Sept. 8, 1980, 94 Stat. 1110; Pub. L. 99–348, title II, §207(a), July 1, 1986, 100 Stat. 701; Pub. L. 112–166, §2(ff)(2), Aug. 10, 2012, 126 Stat. 1290; Pub. L. 116–136, div. A, title III, §3214(e)(3), Mar. 27, 2020, 134 Stat. 373.)

EDITORIAL NOTES

CODIFICATION

In subsec. (m), "section 3332 of title 5" substituted for "the Act of December 11, 1926, as amended (5 U.S.C. 21a)" on authority of Pub. L. 89–554, §7(b), Sept. 6, 1966, 80 Stat. 631, the first section of which enacted Title 5, Government Organization and Employees.

AMENDMENTS

2020—Subsecs. (j)(2), (l), (m). Pub. L. 116–136 substituted "Ready Reserve Corps" for "Reserve Corps" wherever appearing.

2012—Subsec. (a). Pub. L. 112–166 struck out ", by and with the advice and consent of the Senate" after "Permanent promotions shall be made by the President".

1986—Subsec. (g)(3). Pub. L. 99–348 added subpars. (A) and (B) and struck out former subpars. (A) and (B) which read as follows:

"(A) in the case of an officer who first became a member of a uniformed service before September 8, 1980, at the rate of 2½ per centum of basic pay of the permanent grade held by him at the time of retirement for each year, not in excess of thirty, of his active commissioned service in the Service; or

"(B) in the case of an officer who first became a member of a uniformed service on or after September 8, 1980, 2½ per centum of the monthly retired pay base computed under section 1407(h) of title 10, for each year, not in excess of thirty, of his active commissioned service in the Service."

1980—Subsec. (g)(3). Pub. L. 96–342 revised provisions into subpars. (A) and (B) and substituted provisions respecting computation of retired pay for officers who became members of the uniformed service before Sept. 8, 1980, and for officers who became members of the uniformed service on or after Sept. 8, 1980, for provisions respecting computation of retired pay for officers.

1979—Subsec. (d)(1). Pub. L. 96–76, §307(a), inserted applicability to warrant officers and chief warrant officers.

Subsec. (g). Pub. L. 96–76, §307(b), in provision before par. (1), inserted applicability to separation from Service of warrant officers and chief warrant officers subsequent to one examination or two examinations, respectively, in par. (1), inserted applicability to a chief warrant officer (W–2), and in par. (2), inserted applicability to a chief warrant officer (W–3).

1962—Subsec. (g). Pub. L. 87–649 substituted "basic pay" for "pay" in cls. (1) and (2).

1960—Subsec. (g). Pub. L. 86–415 substituted "of the basic pay of the permanent grade held by him at the time of retirement for each year" for "of his active duty pay at the time of retirement for each complete year" in cl. (3).

1956—Subsec. (d)(2). Act Apr. 27, 1956, struck out "pay period and for purposes of" before "seniority in grade".

1949—Subsec. (g). Act Oct. 12, 1949, struck out "incurred in line of duty" wherever appearing.

1948—Act Feb. 28, 1948, amended subsecs. (a) to (c) generally and added subsecs. (d) to (m).

STATUTORY NOTES AND RELATED SUBSIDIARIES

CHANGE OF NAME

"Secretary of Health and Human Services" substituted for "Secretary of Health, Education, and Welfare" in subsec. (l) pursuant to section 509(b) of Pub. L. 96–88, which is classified to section 3508(b) of Title 20, Education.

EFFECTIVE DATE OF 2012 AMENDMENT

Amendment by Pub. L. 112–166 effective 60 days after Aug. 10, 2012, and applicable to appointments made on and after that effective date, including any nomination pending in the Senate on that date, see section 6(a) of Pub. L. 112–166, set out as a note under section 113 of Title 6, Domestic Security.

EFFECTIVE DATE OF 1979 AMENDMENT

Amendment by Pub. L. 96–76 effective Oct. 1, 1979, see section 314 of Pub. L. 96–76, set out as a note under section 206 of this title.

EFFECTIVE DATE OF 1962 AMENDMENT

Amendment by Pub. L. 87–649 effective Nov. 1, 1962, see section 15 of Pub. L. 87–649, set out as an Effective Date note preceding section 101 of Title 37, Pay and Allowances of the Uniformed Services.

EFFECTIVE DATE OF 1949 AMENDMENT

Amendment by act Oct. 12, 1949, effective Oct. 1, 1949, see section 533(a) of act Oct. 12, 1949, set out as a note under section 854a of Title 33, Navigation and Navigable Waters.

EXECUTIVE DOCUMENTS

TRANSFER OF FUNCTIONS

Functions of Public Health Service, Surgeon General of Public Health Service, and all other officers and employees of Public Health Service, and functions of all agencies of or in Public Health Service transferred to Secretary of Health, Education, and Welfare by Reorg. Plan No. 3 of 1966, eff. June 25, 1966, 31 F.R. 8855, 80 Stat. 1610, set out as a note under section 202 of this title.

Functions of Federal Security Administrator transferred to Secretary of Health, Education, and Welfare and all agencies of Federal Security Agency transferred to Department of Health, Education, and Welfare by section 5 of Reorg. Plan No. 1 of 1953, set out as a note under section 3501 this title. Federal Security Agency and office of Administrator abolished by section 8 of Reorg. Plan No. 1 of 1953.

DELEGATION OF FUNCTIONS

Functions of President delegated to Secretary of Health and Human Services, see Ex. Ord. No. 11140, Jan. 30, 1964, 29 F.R. 1637, as amended, set out as a note under section 202 of this title.

§211a. Repealed. Pub. L. 93–222, §7(b), Dec. 29, 1973, 87 Stat. 936

Section, act July 1, 1944, ch. 373, title XIII, §1311, formerly title VII, §711, as added Feb. 28, 1948, ch. 83, §9(b), 62 Stat. 47; renumbered title VIII, §811, July 30, 1956, ch. 779, §3(b), 70 Stat. 721; renumbered title IX, §911, Sept. 4, 1964, Pub. L. 88–581, §4(b), 78 Stat. 919; renumbered title X, §1011, Oct. 6, 1965, Pub. L. 89–239, §3(b), 79 Stat. 931; renumbered title XI, §1111, Dec. 24, 1970, Pub. L. 91–572, §6(b), 84 Stat. 1506; renumbered title XII, §1211, May 16, 1972, Pub. L. 92–294, §3(b), 86 Stat. 137; renumbered title XIII, §1311, Nov. 16, 1973, Pub. L. 93–154, §2(b)(2), 87 Stat. 604, provided for appointment to higher grades of Public Health Service officers for mental health and hospital construction activities.

§211b. Repealed. Pub. L. 94–412, title V, §501(f), Sept. 14, 1976, 90 Stat. 1258

Section, act Feb. 28, 1948, ch. 83, §6(b)–(f), 62 Stat. 45, dealt with promotion of Public Health Service officers.

STATUTORY NOTES AND RELATED SUBSIDIARIES

SAVINGS PROVISION

Repeal not to affect any action taken or proceeding pending at the time of repeal, see section 501(h) of Pub. L. 94–412, set out as a note under section 1601 of Title 50, War and National Defense.

§211c. Promotion credit for medical officers in assistant grade

Any medical officer of the Regular Corps of the Public Health Service who—

(1)(A) was appointed to the assistant grade in the Regular Corps and whose service in such Corps has been continuous from the date of appointment or (B) may hereafter be appointed to the assistant grade in the Regular Corps, and

(2) had or will have completed a medical internship on the date of such appointment,

shall be credited with one year for purposes of promotion and seniority in grade, except that no such credit shall be authorized if the officer has received or will receive similar credit for his internship under other provisions of law. In the case of an officer on active duty on the effective date of this section who is entitled to the credit authorized herein, the one year shall be added to the promotion and seniority-in-grade credits with which he is credited on such date.

(July 1, 1944, ch. 373, title II, §220, as added Apr. 30, 1956, ch. 223, §3, 70 Stat. 121.)

EDITORIAL NOTES

REFERENCES IN TEXT

For "the effective date of this section", referred to in text, see section 7 of act Apr. 30, 1956, which provided in part that this section shall become effective the first day of the month following the day of enactment, Apr. 30, 1956.

STATUTORY NOTES AND RELATED SUBSIDIARIES

CHANGE OF NAME

"Secretary of Health and Human Services" substituted for "Secretary of Health, Education, and Welfare" pursuant to section 509(b) of Pub. L. 96–88, which is classified to section 3508(b) of Title 20, Education.

EXECUTIVE DOCUMENTS

TRANSFER OF FUNCTIONS

Functions of Public Health Service, Surgeon General of Public Health Service, and all other officers and employees of Public Health Service, and functions of all agencies of or in Public Health Service transferred to Secretary of Health, Education, and Welfare by Reorg. Plan No. 3 of 1966, eff. June 25, 1966, 31 F.R. 8855, 80 Stat. 1610, set out as a note under section 202 of this title.

§212. Retirement of commissioned officers

(a) Age; voluntariness; length of service; computation of retired pay

(1) A commissioned officer of the Regular Corps shall, if he applies for retirement, be retired on or after the first day of the month following the month in which he attains the age of sixty-four years. This paragraph does not permit or require the involuntary retirement of any individual because of the age of the individual.

(2) A commissioned officer of the Regular Corps may be retired by the Secretary, and shall be retired if he applies for retirement, on the first day of any month after completion of thirty years of active service.

(3) Any commissioned officer of the Regular Corps who has had less than thirty years of active service may be retired by the Secretary, with or without application by the officer, on the first day of any month after completion of twenty or more years of active service of which not less than ten are

years of active commissioned service in any of the uniformed services.

(4) Except as provided in paragraph (6), a commissioned officer retired pursuant to paragraph (1), (2), or (3) who was on active duty with the Regular Corps on the day preceding such retirement shall be entitled to receive retired pay calculated by multiplying the retired pay base determined under section 1406 of title 10 by the retired pay multiplier determined under section 1409 of such title for the numbers of years of service credited to the officer under this paragraph and in which, in the case of a temporary promotion to such grade, he has performed active duty for not less than six months, (A) for each year of active service, or (B) if it results in higher retired pay, for each of the following years:

(i) his years of active service (determined without regard to subsection (d)) as a member of a uniformed service; plus

(ii) in the case of a medical or dental officer, four years and, in the case of a medical officer, who has completed one year of medical internship or the equivalent thereof, one additional year, the four years and the one year to be reduced by the period of active service performed during such officer's attendance at medical school or dental school or during his medical internship; plus

(iii) the number of years of service with which he was entitled to be credited for purposes of basic pay on May 31, 1958, or (if higher) on any date prior thereto, reduced by any such year included under clause (i) and further reduced by any such year with which he was entitled to be credited under paragraphs (7) and (8) of section 205(a) of title 37 on any date before June 1, 1958;

except that (C) in the case of any officer whose retired pay, so computed, is less than 50 per centum of such basic pay, who retires pursuant to paragraph (1) of this subsection, who has not less than twelve whole years of active service (computed without the application of subsection (e)), and who does not use, for purposes of a retirement annuity under subchapter III of chapter 83 of title 5, any service which is also creditable in computing his retired pay from the Regular Corps, it shall, instead, be 50 per centum of such pay, (D) the retired pay of an officer shall in no case be more than 75 per centum of such basic pay, and (E) in the case of any officer who participates in the modernized retirement system by reason of section 1409(b) of title 10 (including pursuant to an election under subparagraph (B) of that section), subparagraph (C) shall be applied by substituting "40 per centum" for "50 per centum" each place the term appears.

(5) With the approval of the President, a commissioned officer whose service as Surgeon General, Deputy Surgeon General, or Assistant Surgeon General has totaled four years or more and who has had not less than twenty-five years of active service in the Regular Corps may retire voluntarily at any time; and except as provided in paragraph (6), his retired pay shall be at the rate of 75 per centum of the basic pay of the highest grade held by him as such officer.

(6) The retired pay of a commissioned officer retired under this subsection who first became a member of a uniformed service after September 7, 1980, is determined by multiplying—

(A) the retired pay base determined under section 1407 of title 10; by

(B) the retired pay multiplier determined under section 1409 of such title for the number of years of service credited to the officer under paragraph (4).

(7) Retired pay computed under section 211(g)(3) of this title or under paragraph (4) or (5) of this subsection, if not a multiple of $1, shall be rounded to the next lower multiple of $1.

(b) Basic pay of highest temporary grade

For purposes of subsection (a), the basic pay of the highest grade to which a commissioned officer has received a temporary promotion means the basic pay to which he would be entitled if serving on active duty in such grade on the date of his retirement.

(c) Recall to active duty

A commissioned officer, retired for reasons other than for failure of promotion to the senior grade, may (1) if an officer of the Regular Corps entitled to retired pay under subsection (a) or under section 213a(a)(19) of this title, be involuntarily recalled to active duty during such times as the Commissioned Corps constitutes a branch of the land or naval forces of the United States, and (2) if

an officer of either the Regular Corps or Ready Reserve Corps, be recalled to active duty at any time with his consent.

(d) "Active service" defined

The term "active service", as used in subsection (a), includes:

(1) all active service in any of the uniformed services;

(2) active service with the Public Health Service, other than as a commissioned officer, which the Surgeon General determines is comparable to service performed by commissioned officers of the Regular Corps, except that, if there are more than five years of such service only the last five years thereof may be included;

(3) all active service (other than service included under the preceding provisions of this subsection) which is creditable for retirement purposes under laws governing the retirement of members of any of the uniformed services; and

(4) service performed as a member of the Senior Biomedical Research Service established by section 237 of this title, except that, if there are more than 5 years of such service, only the last 5 years thereof may be included.

(e) Crediting of part of year

For the purpose of determining the number of years by which a percentage of the basic pay of an officer is to be multiplied in computing the amount of his retired pay pursuant to section 211(g)(3) of this title or paragraph (4) of subsection (a) of this section, each full month of service that is in addition to the number of full years of service credited to an officer is counted as one-twelfth of a year and any remaining fractional part of a month is disregarded.

(f) Retirement or separation for physical disability

For purposes of retirement or separation for physical disability under chapter 61 of title 10, a commissioned officer of the Regular Corps shall be credited, in addition to the service described in section 1208(a)(2) of that title, with active service with the Public Health Service, other than as a commissioned officer, which the Surgeon General determines is comparable to service performed by commissioned officers of the Regular Corps, except that, if there are more than five years of such service, only the last five years thereof may be so credited. For such purposes, such section 1208(a)(2) shall be applicable to officers of the Regular Corps.

(July 1, 1944, ch. 373, title II, §211, 58 Stat. 688; Feb. 28, 1948, ch. 83, §7, 62 Stat. 46; Oct. 12, 1949, ch. 681, title V, §521(d), 63 Stat. 835; 1953 Reorg. Plan No. 1, §§5, 8, eff. Apr. 11, 1953, 18 F.R. 2053, 67 Stat. 631; Apr. 27, 1956, ch. 211, §5(a)–(c), 70 Stat. 117; Aug. 10, 1956, ch. 1041, §5, 70A Stat. 620; Pub. L. 86–415, §4, Apr. 8, 1960, 74 Stat. 33; Pub. L. 91–253, §1, May 14, 1970, 84 Stat. 216; Pub. L. 96–76, title III, §308, Sept. 29, 1979, 93 Stat. 585; Pub. L. 96–342, title VIII, §813(h)(2), Sept. 8, 1980, 94 Stat. 1110; Pub. L. 97–25, title III, §303(b), July 27, 1981, 95 Stat. 145; Pub. L. 97–35, title XXVII, §2765(a), Aug. 13, 1981, 95 Stat. 932; Pub. L. 98–94, title IX, §§922(d), 923(f), Sept. 24, 1983, 97 Stat. 642, 643; Pub. L. 99–348, title II, §207(b), July 1, 1986, 100 Stat. 702; Pub. L. 101–509, title V, §529 [title III, §304(b)], Nov. 5, 1990, 104 Stat. 1427, 1464; Pub. L. 114–92, div. A, title VI, §631(c)(4), Nov. 25, 2015, 129 Stat. 845; Pub. L. 116–136, div. A, title III, §3214(c), Mar. 27, 2020, 134 Stat. 373.)

EDITORIAL NOTES

CODIFICATION

In subsec. (a)(4), "subchapter III of chapter 83 of title 5" substituted for "the Civil Service Retirement Act" on authority of Pub. L. 89–554, §7(b), Sept. 6, 1966, 80 Stat. 631, the first section of which enacted Title 5, Government Organization and Employees.

AMENDMENTS

2020—Pub. L. 116–136, §3214(c)(1), substituted "the Regular Corps" for "the Service" wherever appearing except in subsec. (c)(1), where "the Regular Corps" already appeared.

Subsec. (a)(4). Pub. L. 116–136, §3214(c)(2), struck out "(in the case of an officer in the Reserve Corps)"

after "who was" in introductory provisions.

Subsec. (c)(1). Pub. L. 116–136, §3214(c)(3)(A), struck out "or an officer of the Reserve Corps" after "Regular Corps" and inserted "or under section 213a(a)(19) of this title" after "subsection (a)".

Subsec. (c)(2). Pub. L. 116–136, §3214(c)(3)(B), substituted "Regular Corps or Ready Reserve Corps" for "Regular or Reserve Corps".

Subsec. (f). Pub. L. 116–136, §3214(c)(4), struck out "the Regular or Reserve Corps of" after "applicable to officers of".

2015—Subsec. (a)(4). Pub. L. 114–92, §631(c)(4)(A), substituted "calculated by multiplying the retired pay base determined under section 1406 of title 10 by the retired pay multiplier determined under section 1409 of such title for the numbers of years of service credited to the officer under this paragraph" for "at the rate of 2½ per centum of the basic pay of the highest grade held by him as such officer".

Subsec. (a)(4)(E). Pub. L. 114–92, §631(c)(4)(B), added subpar. (E).

1990—Subsec. (d)(4). Pub. L. 101–509 added par. (4).

1986—Subsec. (a)(6). Pub. L. 99–348 amended par. (6) generally. Prior to amendment, par. (6) read as follows: "In computing retired pay under paragraph (4) or (5) in the case of any commissioned officer who first became a member of a uniformed service on or after September 8, 1980, the monthly retired pay base computed under section 1407(h) of title 10 shall be used in lieu of using the basic pay of the highest grade held by him as such officer."

1983—Subsec. (a)(7). Pub. L. 98–94, §922(d), added par. (7).

Subsec. (e). Pub. L. 98–94, §923(f), substituted "each full month of service that is in addition to the number of full years of service credited to an officer is counted as one-twelfth of a year and any remaining fractional part of a month is disregarded" for "a part of a year that is six months or more is counted as a whole year, and a part of a year that is less than six months is disregarded".

1981—Subsec. (a)(1). Pub. L. 97–35 substituted "shall, if he applies for retirement, be retired on or after" for "shall be retired on", and substituted provisions relating to involuntary retirement as a result of age, for provisions relating to inapplicability to the Surgeon General.

Pub. L. 97–25 inserted provision that this paragraph does not apply to Surgeon General.

1980—Subsec. (a)(4). Pub. L. 96–342, §813(h)(2)(A), substituted "Except as provided in paragraph (6), a" for "A".

Subsec. (a)(5). Pub. L. 96–342, §813(h)(2)(B), substituted "except as provided in paragraph (6), his" for "his".

Subsec. (a)(6). Pub. L. 96–342, §813(h)(2)(C), added par. (6).

1979—Subsec. (e). Pub. L. 96–76 struck out requirement respecting active service for purposes of credit.

1970—Subsec. (a)(4). Pub. L. 91–253 inserted "plus" after the semicolon at end of cl. (ii) and added cl. (iii).

1960—Pub. L. 86–415 amended section generally, and among other changes, authorized retirement of commissioned officers who have had less than 30 years of active service any time after the completion of 20 years of active service, permitted persons who have served as Deputy Surgeons General or Assistant Surgeons General for four or more years and who have had at least 25 years of active service to retire voluntarily at any time, provided for the recall to active duty of officers of the Reserve Corps entitled to retired pay under subsection (a) of this section during such times as the Corps constitutes a branch of the land or naval forces of the United States, authorized credit, for retirement purposes, of active service in the uniformed services and limited to five years the crediting of active service with the Public Health Service other than as a commissioned officer, and established the methods for computation of retired pay for active duty officers retiring for age or length of service.

1956—Subsec. (a). Act Apr. 27, 1956, §5(a), authorized crediting of noncommissioned service for purposes of retirement.

Subsec. (b)(1). Act Apr. 27, 1956, §5(b), authorized crediting of noncommissioned service in the Service for purposes of retirement.

Subsec. (c). Act Apr. 27, 1956, §5(c), permitted recall of retired officers of the Regular Corps without their consent whenever the Regular Corps has military status, and authorized recall of retired officers of the Regular or Reserve Corps with their consent at any time.

Subsec. (g). Act Aug. 10, 1956, provided for crediting of service for purposes of retirement or separation for physical disability under chapter 61 of title 10.

1949—Subsec. (a). Act Oct. 12, 1949, redesignated subsec. (b) as (a), substituted "subsection (b)" for "subsection (c)" and repealed former subsec. (a) relating to retirement for disability or disease.

Subsec. (b). Act Oct. 12, 1949, redesignated subsec. (c) as (b) and struck out reference to retirement for disability or disease. Former subsec. (b) redesignated (a).

Subsec. (c). Act Oct. 12, 1949, redesignated subsec. (d) as (c) and struck out reference to recovery from a disability. Former subsec. (c) redesignated (b).

Subsecs. (d) to (f). Act Oct. 12, 1949, redesignated subsecs. (e) to (g) as (d) to (f), respectively. Former subsec. (d) redesignated (c).

Subsecs. (g), (h). Act Oct. 12, 1949, redesignated subsec. (h) as (g) and amended subsection generally to relate to retirement or separation for physical disability. Former subsec. (g) redesignated (f).

1948—Subsec. (b). Act Feb. 28, 1948, inserted length of service for retirement purposes.

Subsec. (c)(2). Act Feb. 28, 1948, made subdivision applicable to grade of Assistant Surgeon General.

Subsec. (d). Act Feb. 28, 1948, substituted "under the provisions of subsection (b) of this section" for "for age".

Subsecs. (g), (h). Act Feb. 28, 1948, added subsecs. (g) and (h).

STATUTORY NOTES AND RELATED SUBSIDIARIES

CHANGE OF NAME

Senior Biomedical Research Service changed to Silvio O. Conte Senior Biomedical Research Service by Pub. L. 103–43, title XX, §2001, June 10, 1993, 107 Stat. 208. See section 237 of this title.

"Secretary of Health and Human Services" substituted for "Secretary of Health, Education, and Welfare" in subsec. (a) pursuant to section 509(b) of Pub. L. 96–88, which is classified to section 3508(b) of Title 20, Education.

EFFECTIVE DATE OF 2015 AMENDMENT; IMPLEMENTATION

Amendment by Pub. L. 114–92 effective Jan. 1, 2018, with certain implementation requirements, see section 635 of Pub. L. 114–92, set out as a note under section 8432 of Title 5, Government Organization and Employees.

EFFECTIVE DATE OF 1990 AMENDMENT

Pub. L. 101–509, title V, §529 [title III, §304(c)], Nov. 5, 1990, 104 Stat. 1427, 1464, provided that: "Except as otherwise provided, the provisions of this section [enacting section 237 of this title and amending this section] shall be effective on the 90th day following the date of the enactment of this Act [Nov. 5, 1990]."

EFFECTIVE DATE OF 1983 AMENDMENT

Amendment by section 922(d) of Pub. L. 98–94 effective Oct. 1, 1983, see section 922(e) of Pub. L. 98–94, set out as a note under section 1401 of Title 10, Armed Forces.

Amendment by section 923(f) of Pub. L. 98–94 applicable with respect to the computation of retired or retainer pay of any individual who becomes entitled to that pay after Sept. 30, 1983, see section 923(g) of Pub. L. 98–94, set out as a note under section 1174 of Title 10.

EFFECTIVE DATE OF 1970 AMENDMENT

Pub. L. 91–253, §2, May 14, 1970, 84 Stat. 217, provided that: "The amendments made by this Act [amending this section] shall apply in the case of retired pay for any period after the month in which this Act is enacted [May 1970]."

EFFECTIVE DATE OF 1960 AMENDMENT

Pub. L. 86–415, §8(b), Apr. 8, 1960, 74 Stat. 36, provided that: "The amendment made by section 4 [amending this section] shall become effective on the date of enactment of this Act [Apr. 8, 1960] in the case of commissioned officers of the Regular Corps of the Public Health Service, and on July 1, 1960, in the case of commissioned officers of the Reserve Corps of the Public Health Service."

EFFECTIVE DATE OF 1949 AMENDMENT

Amendment by act Oct. 12, 1949, effective Oct. 1, 1949, see section 533(a) of act Oct. 12, 1949, set out as a note under section 854a of Title 33, Navigation and Navigable Waters.

SAVINGS PROVISION

Pub. L. 86–415, §8(c), (d), Apr. 8, 1960, 74 Stat. 36, provided that:

"(c) An officer in the Regular Corps on active duty on the date of enactment of this Act [Apr. 8, 1960] may be retired and have his retired pay computed under section 211 of the Public Health Service Act [42 U.S.C. 212], as amended by this Act, or, if he so elects, under such section as in effect prior to the date of enactment of this Act [Apr. 8, 1960].

"(d) The limitation under subsection (f) of section 211 of the Public Health Service Act [42 U.S.C. 212(f)], as amended by this Act, on the amount of active service with the Public Health Service, other than as a commissioned officer, which may be counted for purposes of retirement or separation for physical disability, shall not apply in the case of any officer of the Reserve Corps of the Public Health Service on active duty on June 30, 1960."

COVERAGE UNDER CIVIL SERVICE RETIREMENT ACT

Creditable service for purposes of the Civil Service Retirement Act for certain commissioned officers of the Regular or Reserve Corps of the Public Health Service, see section 6(a), (b) of Pub. L. 86–415, set out as a note under section 8332 of Title 5, Government Organization and Employees.

EXECUTIVE DOCUMENTS

TRANSFER OF FUNCTIONS

Functions of Public Health Service, Surgeon General of Public Health Service, and all other officers and employees of Public Health Service, and functions of all agencies of or in Public Health Service transferred to Secretary of Health, Education, and Welfare by Reorg. Plan No. 3 of 1966, eff. June 25, 1966, 31 F.R. 8855, 80 Stat. 1610, set out as a note under section 202 of this title.

Functions of Federal Security Administrator transferred to Secretary of Health, Education, and Welfare and all agencies of Federal Security Agency transferred to Department of Health, Education, and Welfare by section 5 of Reorg. Plan No. 1 of 1953, set out as a note under section 3501 of this title. Federal Security Agency and office of Administrator abolished by section 8 of Reorg. Plan No. 1 of 1953.

DELEGATION OF FUNCTIONS

Functions of President delegated to Secretary of Health and Human Services, see Ex. Ord. No. 11140, eff. Jan. 30, 1964, 29 F.R. 1637, as amended, set out as a note under section 202 of this title.

§212a. Repealed. Pub. L. 93–222, §7(b), Dec. 29, 1973, 87 Stat. 936

Section, act July 1, 1944, ch. 373, title XIII, §1312, formerly title VII, §712, as added Feb. 28, 1948, ch. 83, §9(b), 62 Stat. 47; renumbered title VIII, §812, July 30, 1956, ch. 779, §3(b), 70 Stat. 721; renumbered title IX, §912, Sept. 4, 1964, Pub. L. 88–581, §4(b), 78 Stat. 919; renumbered title X, §1012, Oct. 6, 1965, Pub. L. 89–239, §3(b), 79 Stat. 931; renumbered title XI, §1112, Dec. 24, 1970, Pub. L. 91–572, §6(b), 84 Stat. 1506; renumbered title XII, §1212, May 16, 1972, Pub. L. 92–294, §3(b), 86 Stat. 137; renumbered title XIII, §1312, Nov. 16, 1973, Pub. L. 93–154, §2(b)(2), 87 Stat. 604, provided for retirement of certain officers of Reserve Corps of the Public Health Service for disability.

§212b. Repealed. Apr. 27, 1956, ch. 211, §5(d), 70 Stat. 117

Section, act July 31, 1953, ch. 296, title II, §201, 67 Stat. 254, authorized recall of retired officers of the Service. See section 212(c) of this title.

§213. Military benefits

(a) Rights, privileges, immunities, and benefits accorded to commissioned officers or their survivors

Except as provided in subsection (b), commissioned officers of the Service and their surviving beneficiaries shall, with respect to active service performed by such officers—

(1) in time of war;

(2) on detail for duty with the Army, Navy, Air Force, Marine Corps, or Coast Guard; or

(3) while the Service is part of the military forces of the United States pursuant to Executive order of the President;

be entitled to all rights, privileges, immunities, and benefits now or hereafter provided under any

law of the United States in the case of commissioned officers of the Army or their surviving beneficiaries on account of active military service, except retired pay and uniform allowances.

(b) Award of decorations

The President may prescribe the conditions under which commissioned officers of the Service may be awarded military ribbons, medals, and decorations.

(c) Authority of Surgeon General

The authority vested by law in the Department of the Army, the Secretary of the Army, or other officers of the Department of the Army with respect to rights, privileges, immunities, and benefits referred to in subsection (a) shall be exercised, with respect to commissioned officers of the Service, by the Surgeon General.

(d) Active service deemed active military service with respect to laws administered by Secretary of Veterans Affairs

Active service of commissioned officers of the Service shall be deemed to be active military service in the Armed Forces of the United States for the purposes of all laws administered by the Secretary of Veterans Affairs (except the Servicemen's Indemnity Act of 1951) and section 417 of this title.

(e) Active service deemed active military service with respect to Servicemembers Civil Relief Act

Active service of commissioned officers of the Service shall be deemed to be active military service in the Armed Forces of the United States for the purposes of all rights, privileges, immunities, and benefits now or hereafter provided under the Servicemembers Civil Relief Act (50 App. U.S.C. 501 et seq.) [now 50 U.S.C. 3901 et seq.].

(f) Active service deemed active military service with respect to anti-discrimination laws

Active service of commissioned officers of the Service shall be deemed to be active military service in the Armed Forces of the United States for purposes of all laws related to discrimination on the basis of race, color, sex, ethnicity, age, religion, and disability.

(July 1, 1944, ch. 373, title II, §212, 58 Stat. 689; July 15, 1954, ch. 507, §14(a), 68 Stat. 481; Aug. 1, 1956, ch. 837, title V, §501(b)(1), 70 Stat. 881; Pub. L. 94–278, title XI, §1101, Apr. 22, 1976, 90 Stat. 415; Pub. L. 102–54, §13(q)(1)(C), June 13, 1991, 105 Stat. 278; Pub. L. 105–392, title IV, §402(a), Nov. 13, 1998, 112 Stat. 3587; Pub. L. 108–189, §2(e), Dec. 19, 2003, 117 Stat. 2866.)

EDITORIAL NOTES

REFERENCES IN TEXT

The Servicemen's Indemnity Act of 1951, referred to in subsec. (d), is act Apr. 25, 1951, ch. 39, pt. I, 65 Stat. 33, which was classified generally to subchapter II (§851 et seq.) of chapter 13 of former Title 38, Pensions, Bonuses, and Veterans' Relief, and was repealed by act Aug. 1, 1956, ch. 837, title V, §502(9), 70 Stat. 886.

The Servicemembers Civil Relief Act, referred to in subsec. (e), is act Oct. 17, 1940, ch. 888, 54 Stat. 1178, which was classified to section 501 et seq. of the former Appendix to Title 50, War and National Defense, prior to editorial reclassification and renumbering as chapter 50 (§3901 et seq.) of Title 50. For complete classification of this Act to the Code, see Tables.

AMENDMENTS

2003—Subsec. (e). Pub. L. 108–189 substituted "Servicemembers Civil Relief Act" for "Soldiers' and Sailors' Civil Relief Act of 1940".

1998—Subsec. (f). Pub. L. 105–392 added subsec. (f).

1991—Subsec. (d). Pub. L. 102–54 substituted "Secretary of Veterans Affairs" for "Veterans' Administration".

1976—Subsec. (e). Pub. L. 94–278 added subsec. (e).

1956—Act Aug. 1, 1956, amended section generally to extend all rights, privileges, immunities, and

benefits provided for commissioned officers of the Army or their surviving beneficiaries to commissioned officers of the Service, with the exception of retired pay and uniform allowances, when performing duty under certain circumstances, and to provide that active service of commissioned officers shall be deemed to be active military service in the Armed Forces for the purposes of all laws administered by the Veterans' Administration (except the Servicemen's Indemnity Act of 1951) and section 417 of this title.

1954—Subsec. (a)(1). Act July 15, 1954, struck out "burial payments in the event of death," after "limited to,".

STATUTORY NOTES AND RELATED SUBSIDIARIES

CHANGE OF NAME

"Secretary of Health and Human Services" substituted for "Secretary of Health, Education, and Welfare" pursuant to section 509(b) of Pub. L. 96–88, which is classified to section 3508(b) of Title 20, Education.

EFFECTIVE DATE OF 1956 AMENDMENT; APPLICABILITY

Act Aug. 1, 1956, ch. 837, title V, §501(b)(2), 70 Stat. 882, provided that: "The amendment made by this subsection [amending this section] (A) shall apply only with respect to service performed on or after July 4, 1952, (B) shall not be construed to affect the entitlement of any person to benefits under the Veterans' Readjustment Assistance Act of 1952 [act July 16, 1952, ch. 875, 66 Stat. 633], (C) shall not be construed to authorize any payment under section 202(i) of the Social Security Act [42 U.S.C. 402(i)], or under Veterans Regulation Numbered 9(a), for any death occurring prior to January 1, 1957, and (D) shall not be construed to authorize payment of any benefits for any period prior to January 1, 1957."

TRANSFER OF FUNCTIONS

For transfer of authorities, functions, personnel, and assets of the Coast Guard, including the authorities and functions of the Secretary of Transportation relating thereto, to the Department of Homeland Security, and for treatment of related references, see sections 468(b), 551(d), 552(d), and 557 of Title 6, Domestic Security, and the Department of Homeland Security Reorganization Plan of November 25, 2002, as modified, set out as a note under section 542 of Title 6.

RECOMPUTATION OF SOCIAL SECURITY BENEFITS FOR OFFICERS ENTITLED TO OLD-AGE INSURANCE BENEFITS PRIOR TO JANUARY 1, 1957, OR FOR SURVIVORS OF OFFICERS WHO DIED PRIOR TO JANUARY 1, 1957

Act Aug. 1, 1956, ch. 837, title V, §501(b)(3), 70 Stat. 882, provided that: "In the case of any individual—

"(A) who performed active service (i) as a commissioned officer of the Public Health Service at any time during the period beginning July 4, 1952, and ending December 31, 1956, or (ii) as a commissioned officer of the Coast and Geodetic Survey at any time during the period beginning July 29, 1945, and ending December 31, 1956; and

"(B)(i) who became entitled to old-age insurance benefits under section 202(a) of the Social Security Act [42 U.S.C. 402(a)] prior to January 1, 1957, or

"(ii) who died prior to January 1, 1957, and whose widow, child, or parent is entitled for the month of January 1957, on the basis of his wages and self-employment income, to a monthly survivor's benefit under section 202 of such act [42 U.S.C. 402]; and

"(C) any part of whose service described in subparagraph (A) was not included in the computation of his primary insurance amount under section 215 of such act [42 U.S.C. 415] but would have been included in such computation if the amendment made by paragraph (1) of this subsection or paragraph (1) of subsection (d) had been effective prior to the date of such computation,

the Secretary of Health, Education, and Welfare [now Health and Human Services] shall, notwithstanding the provisions of section 215(f)(1) of the Social Security Act [42 U.S.C. 415(f)(1)], recompute the primary insurance amount of such individual upon the filing of an application, after December 1956, by him or (if he dies without filing such an application) by any person entitled to monthly survivor's benefits under section 202 of such act [42 U.S.C. 402] on the basis of his wages and self-employment income. Such recomputation shall be made only in the manner, provided in title II of the Social Security Act [42 U.S.C. 401 et seq.] as in effect at the time of the last previous computation or recomputation of such individual's primary insurance amount, and as though application therefor was filed in the month in which application for such last previous computation or recomputation was filed. No recomputation made under this paragraph shall be regarded as a

recomputation under section 215(f) of the Social Security Act [42 U.S.C. 415(f)]. Any such recomputation shall be effective for and after the twelfth month before the month in which the application was filed, but in no case for any month before January 1957."

DISPOSITION OF REMAINS OF DECEASED PERSONNEL

Recovery, care, and disposition of the remains of deceased members of the uniformed services and other deceased personnel, see section 1481 et seq. of Title 10, Armed Forces.

BURIAL OF CERTAIN COMMISSIONED OFFICERS

Act Apr. 30, 1956, ch. 227, 70 Stat. 124, provided: "That burial in national cemeteries of the remains of commissioned officers of the United States Public Health Service who were detailed for duty with the Army or Navy during World War I pursuant to the act of July 1, 1902 (32 Stat. 712, 713), as amended, and Executive Order Numbered 2571 dated April 3, 1917, and of the wife, widow, minor child and, in the discretion of the Secretary of the Army, unmarried adult child of these officers is authorized: *Provided*, That the remains of the wife, widow, and children may, in the discretion of the Secretary of the Army, be removed from a national cemetery proper and interred in the post section of a national cemetery if, upon death, the related officer is not buried in the same or an adjoining gravesite."

EXECUTIVE DOCUMENTS

TRANSFER OF FUNCTIONS

Functions of Public Health Service, Surgeon General of Public Health Service, and all other officers and employees of Public Health Service and functions of all agencies of or in Public Health Service transferred to Secretary of Health, Education, and Welfare by Reorg. Plan No. 3 of 1966, eff. June 25, 1966, 31 F.R. 8855, 80 Stat. 1610, set out as a note under section 202 of this title.

DELEGATION OF AUTHORITY

Memorandum of President of the United States, Dec. 30, 1992, 58 F.R. 3485, provided:

Memorandum for the Secretary of Defense, the Secretary of Health and Human Services

The authority of the President under section 212(b) of the Public Health Service Act (42 U.S.C. 213(b)) is hereby delegated to the Secretary of Defense. In the exercise of that authority, the Secretary of Defense shall ensure that no military ribbon, medal, or decoration is awarded to an officer of the Public Health Service without the approval of the Secretary of Health and Human Services.

The Secretary of Defense shall ensure the publication of this memorandum in the Federal Register.

GEORGE BUSH.

§213a. Rights, benefits, privileges, and immunities for commissioned officers or beneficiaries; exercise of authority by Secretary or designee

(a) Commissioned officers of the Service or their surviving beneficiaries are entitled to all the rights, benefits, privileges, and immunities now or hereafter provided for commissioned officers of the Army or their surviving beneficiaries under the following provisions of title 10:

(1) Section 1036,[1] Escorts for dependents of members: transportation and travel allowances.

(2) Chapter 61, Retirement or Separation for Physical Disability, except that sections 1201, 1202, and 1203 do not apply to commissioned officers of the Public Health Service who have been ordered to active duty for training for a period of more than 30 days.

(3) Chapter 69, Retired Grade, except sections 1370,[1] 1374,[1] 1375 and 1376(a).[1]

(4) Chapter 71, Computation of Retired Pay, except formula No. 3 of section 1401.[1]

(5) Chapter 73, Retired Serviceman's Family Protection Plan; Survivor Benefit Plan.

(6) Chapter 75, Death Benefits.

(7) Section 2771, Final settlement of accounts: deceased members.

(8) Chapter 163, Military Claims, but only when commissioned officers of the Service are entitled to military benefits under section 213 of this title.

(9) Section 2603, Acceptance of fellowships, scholarships, or grants.

(10) Section 2634,[1] Motor vehicles: for members on permanent change of station.
(11) Section 1035, Deposits of Savings.
(12) Section 1552, Correction of military records: claims incident thereto.
(13) Section 1553, Review of discharge or dismissal.
(14) Section 1554, Review of retirement or separation without pay for physical disability.
(15) Section 1124, Cash awards for suggestions, inventions, or scientific achievements.
(16) Section 1052, Reimbursement for adoption expenses.
(17) Section 1059, Transitional compensation and commissary and exchange benefits for dependents of members separated for dependent abuse.
(18) Section 1034, Protected Communications; Prohibition of Retaliatory Personnel Actions.
(19) Chapter 1223, Retired Pay for Non-Regular Service.
(20) Section 12601, Compensation: Reserve on active duty accepting from any person.
(21) Section 12684, Reserves: separation for absence without authority or sentence to imprisonment.

(b)(1) The authority vested by title 10 in the "military departments", "the Secretary concerned", or "the Secretary of Defense" with respect to the rights, privileges, immunities, and benefits referred to in subsection (a) shall be exercised, with respect to commissioned officers of the Service, by the Secretary of Health and Human Services or the designee of such Secretary.
(2) For purposes of paragraph (18) of subsection (a), the term "Inspector General" in section 1034 of such title 10 shall mean the Inspector General of the Department of Health and Human Services.
(3) For purposes of paragraph (19) of subsection (a), the terms "Military department", "Secretary concerned", and "Armed forces" in such title 10 shall be deemed to include, respectively, the Department of Health and Human Services, the Secretary of Health and Human Services, and the Commissioned Corps.

(July 1, 1944, ch. 373, title II, §221, as added Aug. 10, 1956, ch. 1041, §4, 70A Stat. 619; amended Pub. L. 85–861, §4, Sept. 2, 1958, 72 Stat. 1547; Pub. L. 86–160, §3, Aug. 14, 1959, 73 Stat. 359; Pub. L. 87–555, §2, July 27, 1962, 76 Stat. 244; Pub. L. 88–132, §5(k), Oct. 2, 1963, 77 Stat. 214; Pub. L. 88–431, §1(d), Aug. 14, 1964, 78 Stat. 440; Pub. L. 89–538, §3(b), Aug. 14, 1966, 80 Stat. 348; Pub. L. 92–425, §5, Sept. 21, 1972, 86 Stat. 713; Pub. L. 96–76, title III, §312, Sept. 29, 1979, 93 Stat. 586; Pub. L. 96–513, title V, §507(f)(2), Dec. 12, 1980, 94 Stat. 2920; Pub. L. 99–117, §4, Oct. 7, 1985, 99 Stat. 492; Pub. L. 105–85, div. A, title VI, §653(a), Nov. 18, 1997, 111 Stat. 1804; Pub. L. 107–107, div. A, title VI, §653(a), Dec. 28, 2001, 115 Stat. 1153; Pub. L. 112–144, title XI, §1129, July 9, 2012, 126 Stat. 1118; Pub. L. 116–136, div. A, title III, §3214(d), Mar. 27, 2020, 134 Stat. 373.)

EDITORIAL NOTES

REFERENCES IN TEXT

Section 1036 of title 10, referred to in subsec. (a)(1), was repealed by Pub. L. 113–66, div. A, title VI, §621(a)(2)(A), Dec. 26, 2013, 127 Stat. 783.

Section 1370 of title 10, referred to in subsec. (a)(3), was repealed and new sections 1370 and 1370a of Title 10, Armed Forces, were enacted by Pub. L. 116–283, div. A, title V, §508(a)(1), Jan. 1, 2021, 134 Stat. 3580. For provisions stating that in determining retired grade of certain commissioned officers of the Armed Forces who retire after Jan. 1, 2021, any reference to section 1370 of Title 10 in such determination with respect to such officers is deemed to be a reference to section 1370a of Title 10, see section 508(c) of Pub. L. 116–283, set out as a note under section 1370 of Title 10.

Sections 1374 and 1376(a) of title 10, referred to in subsec. (a)(3), were repealed by Pub. L. 103–337, div. A, title XVI, §1662(k)(2), (3)(A)(i), Oct. 5, 1994, 108 Stat. 3006. See sections 12771 to 12774 of Title 10, Armed Forces.

Formula No. 3 of section 1401 of title 10, referred to in subsec. (a)(4), was struck from the table set forth in section 1401(a) of title 10 by Pub. L. 103–337, div. A, title XVI, §1662(j)(2), Oct. 5, 1994, 108 Stat. 3004.

Section 2634 of title 10, referred to in subsec. (a)(10), was repealed by Pub. L. 113–66, div. A, title VI, §621(g)(1), Dec. 26, 2013, 127 Stat. 784.

CODIFICATION

Section was formerly classified to section 316 of title 37 prior to the general revision and enactment of Title 37, Pay and Allowances of the Uniformed Services, by Pub. L. 87–649, §1, Sept. 7, 1962, 76 Stat. 451.

AMENDMENTS

2020—Subsec. (a)(19) to (21). Pub. L. 116–136, §3214(d)(1), added pars. (19) to (21).

Subsec. (b). Pub. L. 116–136, §3214(d)(2)(B)–(D), designated first and second sentences as pars. (1) and (2), respectively, and added par. (3).

Pub. L. 116–136, §3214(d)(2)(A), substituted "Secretary of Health and Human Services or the designee of such Secretary" for "Secretary of Health, Education, and Welfare or his designee".

2012—Subsec. (a)(18). Pub. L. 112–144, §1129(a), added par. (18).

Subsec. (b). Pub. L. 112–144, §1129(b), inserted at end "For purposes of paragraph (18) of subsection (a), the term 'Inspector General' in section 1034 of such title 10 shall mean the Inspector General of the Department of Health and Human Services."

2001—Subsec. (a)(17). Pub. L. 107–107 added cl. (17).

1997—Subsec. (a)(16). Pub. L. 105–85 added cl. (16).

1985—Subsec. (a)(15). Pub. L. 99–117 added cl. (15).

1980—Subsec. (a)(3). Pub. L. 96–513 inserted reference to section 1370 of title 10.

1979—Subsec. (a)(12) to (14). Pub. L. 96–76 added cls. (12) to (14).

1972—Subsec. (a)(5). Pub. L. 92–425 substituted "Retired Serviceman's Family Protection Plan; Survivor Benefit Plan" for "Annuities Based on Retired or Retainer Pay".

1966—Subsec. (a)(11). Pub. L. 89–538 added cl. (11).

1964—Subsec. (a)(10). Pub. L. 88–431 added cl. (10).

1963—Subsec. (b). Pub. L. 88–132 inserted reference to Secretary of Defense.

1962—Subsec. (a). Pub. L. 87–555 added cl. (9). Notwithstanding directory language that section be amended by "adding the following new clause at the end thereof", the amendment was executed to subsec. (a) to reflect the probable intent of Congress since the "new" clause was numbered "(9)" and subsec. (a) contained cls. (1) to (8).

1959—Subsec. (a). Pub. L. 86–160 added cl. (1) and renumbered former cls. (1) to (7) as (2) to (8).

1958—Subsec. (a). Pub. L. 85–861 substituted "provisions" for "chapters" in opening clause, struck out former cl. (1) which related to chapter 55 of title 10, renumbered former cls. (2) to (6) as (1) to (5), amended cl. (1), as renumbered, to make sections 1201 to 1203 of title 10, inapplicable to commissioned officers of the Public Health Service who have been ordered to active duty for training for a period of more than 30 days, inserted a reference to section 1374 of title 10 in cl. (2), as renumbered, struck out "Care of the Dead" after "Benefits" in cl. (5), as renumbered, and added cl. (6).

STATUTORY NOTES AND RELATED SUBSIDIARIES

CHANGE OF NAME

"Secretary of Health and Human Services" substituted for "Secretary of Health, Education, and Welfare" in subsec. (b) pursuant to section 509(b) of Pub. L. 96–88, which is classified to section 3508(b) of Title 20, Education.

EFFECTIVE DATE OF 1997 AMENDMENT

Pub. L. 105–85, div. A, title VI, §653(c), Nov. 18, 1997, 111 Stat. 1804, provided that: "The amendments made by this section [amending this section and former section 857a of Title 33, Navigation and Navigable Waters] shall apply only to adoptions that are completed on or after the date of the enactment of this Act [Nov. 18, 1997]."

EFFECTIVE DATE OF 1980 AMENDMENT

Amendment by Pub. L. 96–513 effective Sept. 15, 1981, see section 701 of Pub. L. 96–513, set out as a note under section 101 of Title 10, Armed Forces.

EFFECTIVE DATE OF 1963 AMENDMENT

Amendment by Pub. L. 88–132 effective Oct. 1, 1963, see section 14 of Pub. L. 88–132, set out as an Effective Date note under section 201 of Title 37, Pay and Allowances of the Uniformed Services.

RULES AND REGULATIONS; SAVINGS DEPOSIT BENEFITS

Regulations prescribed by the Secretary of Health, Education, and Welfare [now Health and Human Services] concerning savings deposit benefits for Public Health Service personnel to be prescribed jointly with regulations prescribed by the Secretaries concerned under section 1035 of Title 10, Armed Forces, see section 3(c) of Pub. L. 89–538, set out as a note under section 1035 of Title 10.

DESIGNATION OF BENEFICIARY MADE BEFORE JANUARY 1, 1956

Designation of beneficiary made before Jan. 1, 1956, considered as the designation of a beneficiary for the purposes of section 4 of Pub. L. 85–861, which amended this section, see section 31 of Pub. L. 85–861, set out as a note under section 2771 of Title 10, Armed Forces.

EXECUTIVE DOCUMENTS

TRANSFER OF FUNCTIONS

Functions of Public Health Service, Surgeon General of Public Health Service, and all other officers and employees of Public Health Service, and functions of all agencies of or in Public Health Service transferred to Secretary of Health, Education, and Welfare by Reorg. Plan No. 3 of 1966, eff. June 25, 1966, 31 F.R. 8855, 80 Stat. 1610, set out as a note under section 202 of this title.

[1] *See References in Text note below.*

§214. Presentation of United States flag upon retirement

(a) Presentation of flag

Upon the release of an officer of the commissioned corps of the Service from active commissioned service for retirement, the Secretary of Health and Human Services shall present a United States flag to the officer.

(b) Multiple presentations not authorized

An officer is not eligible for presentation of a flag under subsection (a) if the officer has previously been presented a flag under this section or any other provision of law providing for the presentation of a United States flag incident to release from active service for retirement.

(c) No cost to recipient

The presentation of a flag under this section shall be at no cost to the recipient.

(July 1, 1944, ch. 373, title II, §213, as added Pub. L. 106–65, div. A, title VI, §652(b), Oct. 5, 1999, 113 Stat. 665.)

EDITORIAL NOTES

PRIOR PROVISIONS

A prior section 214, acts July 1, 1944, ch. 373, title II, §213, 58 Stat. 689; Apr. 27, 1956, ch. 211, §2(a), 70 Stat. 116, authorized allowances for uniforms, prior to repeal by Pub. L. 87–649, §14b, Sept. 7, 1962, 76 Stat. 499. See section 415 of Title 37, Pay and Allowances of the Uniformed Services.

STATUTORY NOTES AND RELATED SUBSIDIARIES

EFFECTIVE DATE

Section applicable with respect to releases from service described in section on or after Oct. 1, 1999, see section 652(d) of Pub. L. 106–65, set out as a note under section 12605 of Title 10, Armed Forces.

§214a. Repealed. Sept. 1, 1954, ch. 1211, §5, 68 Stat. 1130

Section, act July 31, 1953, ch. 296, title II, §204, 67 Stat. 257, related to allowances for use of taxicabs, etc.,

around duty posts.

§215. Detail of Service personnel

(a) Other Government departments

The Secretary is authorized, upon the request of the head of an executive department, to detail officers or employees of the Service to such department for duty as agreed upon by the Secretary and the head of such department in order to cooperate in, or conduct work related to, the functions of such department or of the Service. When officers or employees are so detailed their salaries and allowances may be paid from working funds established as provided by law or may be paid by the Service from applicable appropriations and reimbursement may be made as agreed upon by the Secretary and the head of the executive department concerned. Officers detailed for duty with the Army, Air Force, Navy, or Coast Guard shall be subject to the laws for the government of the service to which detailed.

(b) State health or mental health authorities

Upon the request of any State health authority or, in the case of work relating to mental health, any State mental health authority, personnel of the Service may be detailed by the Surgeon General for the purpose of assisting such State or a political subdivision thereof in work related to the functions of the Service.

(c) Congressional committees and nonprofit educational, research, or other institutions engaged in health activities for special studies and dissemination of information

The Surgeon General may detail personnel of the Service to any appropriate committee of the Congress or to nonprofit educational, research [1] or other institutions engaged in health activities for special studies of scientific problems and for the dissemination of information relating to public health.

(d) Availability of funds; reimbursement by State; detailed services deemed service for computation of pay, promotion, etc.

Personnel detailed under subsections (b) and (c) shall be paid from applicable appropriations of the Service, except that, in accordance with regulations such personnel may be placed on leave without pay and paid by the State, subdivision, or institution to which they are detailed. In the case of detail of personnel under subsections (b) or (c) to be paid from applicable Service appropriations, the Secretary may condition such detail on an agreement by the State, subdivision, or institution concerned that such State, subdivision, or institution concerned shall reimburse the United States for the amount of such payments made by the Service. The services of personnel while detailed pursuant to this section shall be considered as having been performed in the Service for purposes of the computation of basic pay, promotion, retirement, compensation for injury or death, and the benefits provided by section 213 of this title.

(e) Commissioned Corps officers; urgent or emergency public health care needs

Except with respect to the United States Coast Guard and the Department of Defense, and except as provided in agreements negotiated with officials at agencies where officers of the Commissioned Corps may be assigned, the Secretary shall have the sole authority to deploy any Commissioned Corps officer assigned under this section to an entity outside of the Department of Health and Human Services for service under the Secretary's direction in response to an urgent or emergency public health care need (as defined in section 204a(a)(5) of this title).

(July 1, 1944, ch. 373, title II, §214, 58 Stat. 690; July 3, 1946, ch. 538, §6, 60 Stat. 423; Oct. 12, 1949, ch. 681, title V, §521(e), 63 Stat. 835; 1953 Reorg. Plan No. 1, §§5, 8, eff. Apr. 11, 1953, 18 F.R. 2053, 67 Stat. 631; Pub. L. 96–76, title III, §309, Sept. 29, 1979, 93 Stat. 585; Pub. L. 109–417, title II, §206(c)(1), Dec. 19, 2006, 120 Stat. 2853.)

EDITORIAL NOTES

CODIFICATION

In subsec. (a), Air Force was inserted on the authority of section 207(a), (f) of act July 26, 1947, ch. 343, title II, 61 Stat. 502, which established a separate Department of the Air Force, and Secretary of Defense Transfer Order No. 40 [App. A(74)], July 22, 1949, which transferred certain functions, insofar as they pertain to the Air Force, which were not previously transferred to the Department of the Air Force and Secretary of the Air Force. Section 207(a), (f) of act July 26, 1947, was repealed by section 53 of act Aug. 10, 1956, ch. 1041, 70A Stat. 641. Section 1 of act Aug. 10, 1956, enacted "Title 10, Armed Forces", which in sections 8010 to 8013 continued the Department of the Air Force under the administrative supervision of a Secretary of the Air Force.

AMENDMENTS

2006—Subsec. (e). Pub. L. 109–417 added subsec. (e).

1979—Subsec. (c). Pub. L. 96–76, §309(a), inserted provisions authorizing detail of personnel to appropriate committees of Congress.

Subsec. (d). Pub. L. 96–76, §309(b), inserted provisions relating to agreements by States, etc., for reimbursement upon detail of personnel.

1949—Subsec. (d). Act Oct. 12, 1949, substituted "the computation of basic pay" for "longevity pay".

1946—Subsec. (b). Act July 3, 1946, provided for detail of personnel on request from a State mental health authority.

STATUTORY NOTES AND RELATED SUBSIDIARIES

CHANGE OF NAME

"Secretary of Health and Human Services" substituted for "Secretary of Health, Education, and Welfare" in subsecs. (a), (d), and (e), and "Department of Health and Human Services" substituted for "Department of Health, Education, and Welfare" in subsec. (e), pursuant to section 509(b) of Pub. L. 96–88, which is classified to section 3508(b) of Title 20, Education.

EFFECTIVE DATE OF 1949 AMENDMENT

Amendment by act Oct. 12, 1949, effective Oct. 1, 1949, see section 533(a) of act Oct. 12, 1949, set out as a note under section 854a of Title 33, Navigation and Navigable Waters.

TRANSFER OF FUNCTIONS

For transfer of authorities, functions, personnel, and assets of the Coast Guard, including the authorities and functions of the Secretary of Transportation relating thereto, to the Department of Homeland Security, and for treatment of related references, see sections 468(b), 551(d), 552(d), and 557 of Title 6, Domestic Security, and the Department of Homeland Security Reorganization Plan of November 25, 2002, as modified, set out as a note under section 542 of Title 6.

TRANSFERS OF PERSONNEL OCCASIONED BY CREATION OF THE ENVIRONMENTAL PROTECTION AGENCY

Pub. L. 91–604, §15(b)(1)–(8)(A), Dec. 31, 1970, 84 Stat. 1710–1712, as amended by Pub. L. 112–81, div. A, title VI, §631(f)(4)(B), Dec. 31, 2011, 125 Stat. 1465; Pub. L. 112–239, div. A, title X, §1076(a)(9), Jan. 2, 2013, 126 Stat. 1948, provided that:

"(1) Subject to such requirements as the Civil Service Commission may prescribe, any commissioned officer of the Public Health Service (other than an officer who retires under section 211 of the Public Health Service Act [42 U.S.C. 212] after his election but prior to his transfer pursuant to this paragraph and paragraph (2)) who, upon the day before the effective date of Reorganization Plan Numbered 3 of 1970 (hereinafter in this subsection referred to as the 'plan'), is serving as such officer (A) primarily in the performance of functions transferred by such plan to the Environmental Protection Agency or its Administrator (hereinafter in this subsection referred to as the 'Agency' and the 'Administrator,' respectively), may, if such officer so elects, acquire competitive status and be transferred to a competitive position in the Agency; or (B) primarily in the performance of functions determined by the Secretary of Health, Education, and Welfare (hereinafter in this subsection referred to as the 'Secretary') to be materially related to the functions so transferred, may, if authorized by agreement between the Secretary and the Administrator, and if such officer so elects, acquire such status and be so transferred.

"(2) An election pursuant to paragraph (1) shall be effective only if made in accordance with such procedures as may be prescribed by the Civil Service Commission (A) before the close of the 24th month after the effective date of the plan [Dec. 2, 1970], or (B) in the case of a commissioned officer who would be liable for training and service under the Military Selective Service Act of 1967 [50 U.S.C. 3801 et seq.] but for the operation of section 6(b)(3) thereof (50 U.S.C. App. 456(b)(3)) [now 50 U.S.C. 3806(b)(3)], before (if it occurs later than the close of such 24th month) the close of the 90th day after the day upon which he has completed his 24th month of service as such officer.

"(3)(A) Except as provided in subparagraph (B), any commissioned officer of the Public Health Service who, pursuant to paragraphs (1) and (2), elects to transfer to a position in the Agency which is subject to chapter 51 and subchapter III of chapter 53 of title 5, United States Code (hereinafter in this subsection referred to as the 'transferring officer'), shall receive a pay rate of the General Schedule grade of such position which is not less than the sum of the following amounts computed as of the day preceding the date of such election:

"(i) the basic pay, the special pay, the continuation pay, and the subsistence and quarters allowances, to which he is annually entitled as a commissioned officer of the Public Health Service pursuant to title 37, United States Code;

"(ii) the amount of Federal income tax, as determined by estimate of the Secretary, which the transferring officer, had he remained a commissioned officer, would have been required to pay on his subsistence and quarters allowances for the taxable year then current if they had not been tax free;

"(iii) an amount equal to the biweekly average cost of the coverages designated 'high option, self and family' under the Government-wide Federal employee health benefits programs plans, multiplied by twenty-six; and

"(iv) an amount equal to 7 per centum of the sum of the amounts determined under clauses (i) through (iii), inclusive.

"(B) A transferring officer shall in no event receive, pursuant to subparagraph (A), a pay rate in excess of the maximum rate applicable under the General Schedule to the class of position, as established under chapter 51 of title 5, United States Code, to which such officer is transferred pursuant to paragraphs (1) and (2).

"(4)(A) A transferring officer shall be credited, on the day of his transfer pursuant to his election under paragraphs (1) and (2), with one hour of sick leave for each week of active service, as defined by section 211(d) of the Public Health Service Act [42 U.S.C. 212(d)].

"(B) The annual leave to the credit of a transferring officer on the day before the day of his transfer, shall, on such day of transfer, be transferred to his credit in the Agency on an adjusted basis under regulations prescribed by the Civil Service Commission. The portion of such leave, if any, that is in excess of the sum of (i) 240 hours, and (ii) the number of hours that have accrued to the credit of the transferring officer during the calendar year then current and which remain unused, shall thereafter remain to his credit until used, and shall be reduced in the manner described by subsection (c) of section 6304 of title 5, United States Code.

"(5) A transferring officer who is required to change his official station as a result of his transfer under this subsection shall be paid such travel, transportation, and related expenses and allowances, as would be provided pursuant to subchapter II of chapter 57 of title 5, United States Code, in the case of a civilian employee so transferred in the interest of the Government. Such officer shall not (either at the time of such transfer or upon a subsequent separation from the competitive service) be deemed to have separated from, or changed permanent station within, a uniformed service for purposes of [former] section 474 of title 37, United States Code.

"(6) Each transferring officer who prior to January 1, 1958, was insured pursuant to the Federal Employees' Group Life Insurance Act of 1954, and who subsequently waived such insurance, shall be entitled to become insured under chapter 87 of title 5, United States Code, upon his transfer to the Agency regardless of age and insurability.

"(7)(A) Effective as of the date a transferring officer acquires competitive status as an employee of the Agency, there shall be considered as the civilian service of such officer for all purposes of chapter 83, title 5, United States Code, (i) his active service as defined by section 211(d) of the Public Health Service Act [42 U.S.C. 212(d)], or (ii) any period for which he would have been entitled, upon his retirement as a commissioned officer of the Public Health Service, to receive retired pay pursuant to section 211(a)(4)(B) of such Act [42 U.S.C. 212(a)(4)(B)]; however, no transferring officer may become entitled to benefits under both subchapter III of such chapter and title II of the Social Security Act [42 U.S.C. 401 et seq.] based on service as such a commissioned officer performed after 1956, but the individual (or his survivors) may irrevocably elect to waive benefit credit for the service under one such law to secure credit under the other.

"(B) A transferring officer on whose behalf a deposit is required to be made by subparagraph (C) and who, after transfer to a competitive position in the Agency under paragraphs (1) and (2), is separated from Federal

service or transfers to a position not covered by subchapter III of chapter 83 of title 5, United States Code, shall not be entitled, nor shall his survivors be entitled, to a refund of any amount deposited on his behalf in accordance with this section. In the event he transfers, after transfer under paragraphs (1) and (2), to a position covered by another Government staff requirement system under which credit is allowable for service with respect to which a deposit is required under subparagraph (C), no credit shall be allowed under such subchapter III with respect to such service.

"(C) The Secretary shall deposit in the Treasury of the United States to the credit of the Civil Service Retirement and Disability Fund, on behalf of and to the credit of such transferring officer, an amount equal to that which such individual would be required to deposit in such fund to cover the years of service credited to him for purposes of his retirement under subparagraph (A), had such service been service as an employee as defined in section 8331(1) of title 5, United States Code. The amount so required to be deposited with respect to any transferring officer shall be computed on the basis of the sum of each of the amounts described in paragraph (3)(A) which were received by, or accrued to the benefit of, such officer during the years so credited. The deposits which the Secretary is required to make under this subparagraph with respect to any transferring officer shall be made within two years after the date of his transfer as provided in paragraphs (1) and (2), and the amounts due under this subparagraph shall include interest computed from the period of service credited to the date of payment in accordance with section 8334(e) of title 5, United States Code.

"(8)(A) A commissioned officer of the Public Health Service, who, upon the day before the effective date of the plan, is on active service therewith primarily assigned to the performance of functions described in paragraph (1)(A), shall, while he remains in active service, as defined by section 211(d) of the Public Health Service Act [42 U.S.C. 212(d)], be assigned to the performance of duties with the Agency, except as the Secretary and the Administrator may jointly otherwise provide."

EXECUTIVE DOCUMENTS

TRANSFER OF FUNCTIONS

Functions of Public Health Service, Surgeon General of Public Health Service, and all other officers and employees of Public Health Service, and functions of all agencies of or in Public Health Service transferred to Secretary of Health, Education, and Welfare by Reorg. Plan No. 3 of 1966, eff. June 25, 1966, 31 F.R. 8855, 80 Stat. 1610, set out as a note under section 202 of this title. Office of Surgeon General, abolished by section 3 of Reorg. Plan No. 3 of 1966, reestablished within the Office of the Assistant Secretary for Health, see Notice of Department of Health and Human Services, Office of the Assistant Secretary for Health, Mar. 30, 1987, 52 F.R. 11754.

Functions of Federal Security Administrator transferred to Secretary of Health, Education, and Welfare and all agencies of Federal Security Agency transferred to Department of Health, Education, and Welfare by section 5 of Reorg. Plan No. 1 of 1953, set out as a note under section 3501 of this title. Federal Security Agency and office of Administrator abolished by section 8 of Reorg. Plan No. 1 of 1953.

[1] *So in original. Probably should be followed by a comma.*

§216. Regulations

(a) Prescription by President: appointments, retirement, etc.

The President shall from time to time prescribe regulations with respect to the appointment, promotion, retirement, termination of commission, titles, pay, uniforms, allowances (including increased allowances for foreign service), and discipline of the commissioned corps of the Service.

(b) Promulgation by Surgeon General; administration of Service

The Surgeon General, with the approval of the Secretary, unless specifically otherwise provided, shall promulgate all other regulations necessary to the administration of the Service, including regulations with respect to uniforms for employees, and regulations with respect to the custody, use, and preservation of the records, papers, and property of the Service.

(c) Preference to school of medicine

No regulation relating to qualifications for appointment of medical officers or employees shall

give preference to any school of medicine.

(July 1, 1944, ch. 373, title II, §215, 58 Stat. 690; Oct. 12, 1949, ch. 681, title V, §521(f), 63 Stat. 835; 1953 Reorg. Plan No. 1, §§5, 8, eff. Apr. 11, 1953, 18 F.R. 2053, 67 Stat. 631.)

EDITORIAL NOTES

AMENDMENTS

1949—Subsec. (b). Act Oct. 12, 1949, struck out references to travel and transportation of household goods and effects.

STATUTORY NOTES AND RELATED SUBSIDIARIES

CHANGE OF NAME

"Secretary of Health and Human Services" substituted for "Secretary of Health, Education, and Welfare" in subsec. (b) pursuant to section 509(b) of Pub. L. 96–88, which is classified to section 3508(b) of Title 20, Education.

EFFECTIVE DATE OF 1949 AMENDMENT

Amendment by act Oct. 12, 1949, effective Oct. 1, 1949, see section 533(a) of act Oct. 12, 1949, set out as a note under section 854a of Title 33, Navigation and Navigable Waters.

EXECUTIVE DOCUMENTS

TRANSFER OF FUNCTIONS

Functions of Public Health Service, Surgeon General of Public Health Service, and all other officers and employees of Public Health Service, and functions of all agencies of or in Public Health Service transferred to Secretary of Health, Education, and Welfare by Reorg. Plan No. 3 of 1966, eff. June 25, 1966, 31 F.R. 8855, 80 Stat. 1610, set out as a note under section 202 of this title.

Functions of Federal Security Administrator transferred to Secretary of Health, Education, and Welfare and all agencies of Federal Security Agency transferred to Department of Health, Education, and Welfare by section 5 of Reorg. Plan No. 1 of 1953, set out as a note under section 3501 of this title. Federal Security Agency and office of Administrator abolished by section 8 of Reorg. Plan No. 1 of 1953.

DELEGATION OF FUNCTIONS

Functions of President delegated to Secretary of Health and Human Services, see Ex. Ord. No. 11140, January 30, 1964, 29 F.R. 1637, as amended, set out as a note under section 202 of this title.

§217. Use of Service in time of war or emergency

In time of war, or of emergency proclaimed by the President, he may utilize the Service to such extent and in such manner as shall in his judgment promote the public interest. In time of war, or of emergency involving the national defense proclaimed by the President, he may by Executive order declare the commissioned corps of the Service to be a military service. Upon such declaration, and during the period of such war or such emergency or such part thereof as the President shall prescribe, the commissioned corps (a) shall constitute a branch of the land and naval forces of the United States, (b) shall, to the extent prescribed by regulations of the President, be subject to the Uniform Code of Military Justice [10 U.S.C. 801 et seq.], and (c) shall continue to operate as part of the Service except to the extent that the President may direct as Commander in Chief.

(July 1, 1944, ch. 373, title II, §216, 58 Stat. 690; Apr. 27, 1956, ch. 211, §1, 70 Stat. 116.)

EDITORIAL NOTES

REFERENCES IN TEXT

The Uniform Code of Military Justice, referred to in text, is classified to chapter 47 (§801 et seq.) of Title

10, Armed Forces.

AMENDMENTS

1956—Act Apr. 27, 1956, empowered President to declare commissioned corps of the Service to be a military service in time of emergency involving national defense, and substituted "the Uniform Code of Military Justice" for "the Articles of War and to the Articles for the Government of the Navy".

STATUTORY NOTES AND RELATED SUBSIDIARIES

CHANGE OF NAME

"Secretary of Health and Human Services" substituted for "Secretary of Health, Education, and Welfare" pursuant to section 509(b) of Pub. L. 96–88, which is classified to section 3508(b) of Title 20, Education.

REPEAL OF PRIOR ACTS CONTINUING SECTION

Section 6 of Joint Res. July 3, 1952, ch. 570, 66 Stat. 334, repealed Joint Res. Apr. 14, 1952, ch. 204, 66 Stat. 54 as amended by Joint Res. May 28, 1952, ch. 339, 66 Stat. 96; Joint Res. June 14, 1952, ch. 437, 66 Stat. 137; Joint Res. June 30, 1952, ch. 526, 66 Stat. 296, which continued provisions until July 3, 1952. This repeal shall take effect as of June 16, 1952, by section 7 of said Joint Res. July 3, 1952.

EXECUTIVE DOCUMENTS

TRANSFER OF FUNCTIONS

Functions of Public Health Service, Surgeon General of Public Health Service, and all other officers and employees of Public Health Service, and functions of all agencies of or in Public Health Service transferred to Secretary of Health, Education, and Welfare by Reorg. Plan No. 3 of 1966, eff. June 25, 1966, 31 F.R. 8855, 80 Stat. 1610, set out as a note under section 202 of this title.

EXECUTIVE ORDER NO. 9575

Ex. Ord. No. 9575, eff. June 28, 1945, 10 F.R. 7895, which declared the Commissioned Corps of the Public Health Service to be a military service subject to the Articles for the Government of the Navy as therein prescribed, was superseded by Ex. Ord. No. 10349, eff. Apr. 28, 1952, 17 F.R. 3769.

EXECUTIVE ORDER NO. 10349

Ex. Ord. No. 10349, eff. Apr. 28, 1952, 17 F.R. 3769, superseded Ex. Ord. No. 9575, and subjected the Commissioned Corps of the Public Health Service to the provisions of the Uniform Code of Military Justice until June 1, 1952.

EXECUTIVE ORDER NO. 10356

Ex. Ord. No. 10356, eff. June 2, 1952, 17 F.R. 4967, amended Ex. Ord. No. 10349, and extended from June 1, 1952, to June 15, 1952, the period during which the Commissioned Corps of the Public Health Service was subject to the provisions of the Uniform Code of Military justice.

EXECUTIVE ORDER NO. 10362

Ex. Ord. No. 10362, eff. June 14, 1952, 17 F.R. 5413, amended Ex. Ord. No. 10356, and extended from June 15, 1952, to June 30, 1952, the period during which the Commissioned Corps of the Public Health Service was subject to the Uniform Code of Military Justice.

EXECUTIVE ORDER NO. 10367

Ex. Ord. No. 10367, eff. June 30, 1952, 17 F.R. 5929, amended Ex. Ord. No. 10362, and extended from June 30, 1952, to July 3, 1952, the period during which the Commissioned Corps of the Public Health Service was subject to the Uniform Code of Military Justice.

§217a. Advisory councils or committees

(a) Appointment; purpose

The Secretary may, without regard to the provisions of title 5 governing appointments in the competitive service, and without regard to the provisions of chapter 51 and subchapter III of chapter

53 of such title relating to classification and General Schedule pay rates, from time to time, appoint such advisory councils or committees (in addition to those authorized to be established under other provisions of law), for such periods of time, as he deems desirable with such period commencing on a date specified by the Secretary for the purpose of advising him in connection with any of his functions.

(b) Compensation and allowances of members not full-time employees of United States

Members of any advisory council or committee appointed under this section who are not regular full-time employees of the United States shall, while attending meetings or conferences of such council or committee or otherwise engaged on business of such council or committee receive compensation and allowances as provided in section 210(c) of this title for members of national advisory councils established under this chapter.

(c) Delegation of functions

Upon appointment of any such council or committee, the Secretary may delegate to such council or committee such advisory functions relating to grants-in-aid for research or training projects or programs, in the areas or fields with which such council or committee is concerned, as the Secretary determines to be appropriate.

(July 1, 1944, ch. 373, title II, §222, as added Pub. L. 87–838, §3, Oct. 17, 1962, 76 Stat. 1073; amended Pub. L. 91–515, title VI, §601(a)(3), (c), Oct. 30, 1970, 84 Stat. 1310, 1311; Pub. L. 99–158, §3(a)(4), Nov. 20, 1985, 99 Stat. 879.)

EDITORIAL NOTES

REFERENCES IN TEXT

The General Schedule, referred to in subsec. (a), is set out under section 5332 of Title 5.

AMENDMENTS

1985—Subsec. (c). Pub. L. 99–158 amended subsec. (c) generally. Prior to amendment, subsec. (c) read as follows: "Upon appointment of any such council or committee, the Surgeon General, with the approval of the Secretary, may transfer such of the functions of the National Advisory Health Council relating to grants-in-aid for research or training projects or programs in the areas or fields with which such council or committee is concerned as he determines to be appropriate."

1970—Subsec. (a). Pub. L. 91–515, §601(c)(1), substituted provisions authorizing the Secretary to appoint advisory councils or committees without regard to specified provisions governing appointments in the competitive service and relating to classification and General Schedule pay rates, for provisions authorizing the Surgeon General to appoint advisory committees without regard to the civil service laws and subject to the Secretary's approval in such cases as he prescribed.

Subsec. (b). Pub. L. 91–515, §601(a)(3), inserted "council or" before "committee" wherever appearing.

Subsec. (c). Pub. L. 91–515, §601(a)(3), (c)(2), inserted "council or" before "committee" wherever appearing, and "or programs" after "projects".

STATUTORY NOTES AND RELATED SUBSIDIARIES

CHANGE OF NAME

"Secretary of Health and Human Services" substituted for "Secretary of Health, Education, and Welfare" in subsecs. (a) and (c) pursuant to section 509(b) of Pub. L. 96–88, which is classified to section 3508(b) of Title 20, Education.

TERMINATION OF ADVISORY COMMITTEES; REPORT BY SECRETARY TO CONGRESSIONAL COMMITTEES RELATING TO TERMINATION

Pub. L. 93–641, §6, Jan. 4, 1975, 88 Stat. 2275, provided that:

"(a) An advisory committee established by or pursuant to the Public Health Service Act [42 U.S.C. 201 et seq.], the Mental Retardation Facilities and Community Mental Health Centers Construction Act of 1963 [former 42 U.S.C. 2689 et seq., 6001 et seq.], or the Comprehensive Alcohol Abuse and Alcoholism Prevention, Treatment, and Rehabilitation Act of 1970 [42 U.S.C. 4541 et seq.] shall terminate at such time as

may be specifically prescribed by an Act of Congress enacted after the date of the enactment of this Act [Jan. 4, 1975].

"(b) The Secretary of Health, Education, and Welfare shall report, within one year after the date of the enactment of the Act [Jan. 4, 1975], to the Committee on Labor and Public Welfare of the Senate and the Committee on Interstate and Foreign Commerce of the House of Representatives (1) the purpose and use of each advisory committee established by or pursuant to the Public Health Service Act, the Mental Retardation Facilities and Community Mental Health Centers Construction Act of 1963, or the Comprehensive Alcohol Abuse and Alcoholism Prevention, Treatment, and Rehabilitation Act of 1970 and (2) his recommendations respecting the termination of each such advisory committee."

EXECUTIVE DOCUMENTS

TRANSFER OF FUNCTIONS

Office of Surgeon General abolished by section 3 of Reorg. Plan No. 3 of 1966, eff. June 25, 1966, 31 F.R. 8855, 80 Stat. 1610, and functions thereof transferred to Secretary of Health, Education, and Welfare by section 1 of Reorg. Plan No. 3 of 1966, set out as a note under section 202 of this title. Office of Surgeon General reestablished within the Office of the Assistant Secretary for Health, see Notice of Department of Health and Human Services, Office of the Assistant Secretary for Health, Mar. 30, 1987, 52 F.R. 11754.

§217a–1. Advisory committees; prohibition of consideration of political affiliations

All appointments to advisory committees established to assist in implementing the Public Health Service Act [42 U.S.C. 201 et seq.],[1] and the Comprehensive Alcohol Abuse and Alcoholism Prevention, Treatment, and Rehabilitation Act of 1970 [42 U.S.C. 4541 et seq.], shall be made without regard to political affiliation.

(Pub. L. 94–278, title X, §1001, Apr. 22, 1976, 90 Stat. 415; Pub. L. 111–256, §2(e), Oct. 5, 2010, 124 Stat. 2643.)

EDITORIAL NOTES

REFERENCES IN TEXT

The Public Health Service Act, referred to in text, is act July 1, 1944, ch. 373, 58 Stat. 682, which is classified generally to this chapter (§201 et seq.). For complete classification of this Act to the Code, see Short Title note set out under section 201 of this title and Tables.

The Comprehensive Alcohol Abuse and Alcoholism Prevention, Treatment, and Rehabilitation Act of 1970, referred to in text, is Pub. L. 91–616, Dec. 31, 1970, 84 Stat. 1848, which is classified principally to chapter 60 (§4541 et seq.) of this title. For complete classification of this Act to the Code, see Short Title note set out under section 4541 of this title and Tables.

CODIFICATION

Section was not enacted as a part of the Public Health Service Act which comprises this chapter.

AMENDMENTS

2010—Pub. L. 111–256 struck out "the Mental Retardation Facilities and Community Mental Health Centers Construction Act of 1963," after "Public Health Service Act,".

[1] *So in original. The comma probably should not appear.*

§217b. Volunteer services

Subject to regulations, volunteer and uncompensated services may be accepted by the Secretary, or by any other officer or employee of the Department of Health and Human Services designated by

him, for use in the operation of any health care facility or in the provision of health care.

(July 1, 1944, ch. 373, title II, §223, as added Pub. L. 90–174, §6, Dec. 5, 1967, 81 Stat. 539; amended Pub. L. 103–43, title XX, §2008(h), June 10, 1993, 107 Stat. 212.)

EDITORIAL NOTES

AMENDMENTS

1993—Pub. L. 103–43 substituted "Health and Human Services" for "Health, Education, and Welfare".

§218. National Advisory Councils on Migrant Health

(a) Appointment; duties

Within 120 days of July 29, 1975, the Secretary shall appoint and organize a National Advisory Council on Migrant Health (hereinafter in this subsection referred to as the "Council") which shall advise, consult with, and make recommendations to, the Secretary on matters concerning the organization, operation, selection, and funding of migrant health centers and other entities under grants and contracts under section 254b [1] of this title.

(b) Membership

The Council shall consist of fifteen members, at least twelve of whom shall be members of the governing boards of migrant health centers or other entities assisted under section 254b [1] of this title. Of such twelve members who are members of such governing boards, at least nine shall be chosen from among those members of such governing boards who are being served by such centers or grantees and who are familiar with the delivery of health care to migratory agricultural workers and seasonal agricultural workers. The remaining three Council members shall be individuals qualified by training and experience in the medical sciences or in the administration of health programs.

(c) Terms of office

Each member of the Council shall hold office for a term of four years, except that (1) any member appointed to fill a vacancy occurring prior to the expiration of the term for which his predecessor was appointed shall be appointed for the remainder of such term; and (2) the terms of the members first taking office after July 29, 1975, shall expire as follows: four shall expire four years after such date, four shall expire three years after such date, four shall expire two years after such date, and three shall expire one year after such date, as designated by the Secretary at the time of appointment.

(d) Applicability of section 1013(a) of title 5

Section 1013(a) of title 5 shall not apply to the Council.

(July 1, 1944, ch. 373, title II, §217, 58 Stat. 691; July 3, 1946, ch. 538, §5(b)–(d), 60 Stat. 422; June 16, 1948, ch. 481, §§4(a)–(c), 6(b), 62 Stat. 467, 469; June 24, 1948, ch. 621, §4(a)–(c), 62 Stat. 600; Aug. 15, 1950, ch. 714, §3(a)–(d), 64 Stat. 446; 1953 Reorg. Plan No. 1, §§5, 8, eff. Apr. 11, 1953, 18 F.R. 2053, 67 Stat. 631; Pub. L. 91–515, title VI, §601(a)(1), Oct. 30, 1970, 84 Stat. 1310; Pub. L. 91–616, title IV, §401, Dec. 31, 1970, 84 Stat. 1853; Pub. L. 92–157, title III, §301(b), Nov. 18, 1971, 85 Stat. 463; Pub. L. 92–218, §6(a)(1), Dec. 23, 1971, 85 Stat. 785; Pub. L. 92–255, title V, §502(a), Mar. 21, 1972, 86 Stat. 85; Pub. L. 92–423, §7(a), Sept. 19, 1972, 86 Stat. 687; Pub. L. 93–348, title II, §211(a), July 12, 1974, 88 Stat. 351; Pub. L. 94–63, title IV, §401(b), July 29, 1975, 89 Stat. 341; Pub. L. 94–371, §9, July 26, 1976, 90 Stat. 1040; Pub. L. 95–622, title III, §302(b), Nov. 9, 1978, 92 Stat. 3442; Pub. L. 95–626, title I, §102(b)(1), Nov. 10, 1978, 92 Stat. 3551; Pub. L. 96–180, §13, Jan. 2, 1980, 93 Stat. 1304; Pub. L. 96–181, §14, Jan. 2, 1980, 93 Stat. 1315; Pub. L. 98–24, §2(a)(2), Apr. 26, 1983, 97 Stat. 176; Pub. L. 98–509, title III, §302, Oct. 19, 1984, 98 Stat. 2364; Pub. L. 99–158, §3(a)(2), (3), Nov. 20, 1985, 99 Stat. 878, 879; Pub. L. 99–570, title IV, §4004(c), Oct. 27, 1986, 100 Stat. 3207–111; Pub. L. 99–660, title III, §311(b)(1), Nov. 14, 1986, 100 Stat. 3779; Pub. L. 117–286, §4(a)(227), Dec. 27, 2022, 136 Stat. 4330.)

EDITORIAL NOTES

REFERENCES IN TEXT

Section 254b of this title, referred to in subsecs. (a) and (b), was in the original a reference to section 329, meaning section 329 of act July 1, 1944, which was omitted in the general amendment of subpart I (§254b et seq.) of part D of subchapter II of this chapter by Pub. L. 104–299, §2, Oct. 11, 1996, 110 Stat. 3626. Section 2 of Pub. L. 104–299 enacted a new section 330 of act July 1, 1944, which is classified to section 254b of this title.

AMENDMENTS

2022—Subsec. (d). Pub. L. 117–286 substituted "Section 1013(a) of title 5" for "Section 14(a) of the Federal Advisory Committee Act".

1986—Pub. L. 99–570 redesignated former subsec. (e)(1) to (4) as subsecs. (a) to (d), respectively, in subsec. (c), further redesignated former cls. (A) and (B) as (1) and (2), respectively, and struck out former subsecs. (a) to (d), which related, respectively, to composition, qualifications, appointment and tenure of the National Advisory Mental Health Council and the National Advisory Council on Alcohol Abuse and Alcoholism; duties of the National Advisory Mental Health Council; duties of the National Advisory Council on Alcohol Abuse and Alcoholism; and the composition, qualifications, and duties of the National Advisory Council on Drug Abuse.

Subsec. (c). Pub. L. 99–660 which directed that "section 300cc of this title" be substituted for "section 300aa of this title" could not be executed because the reference in question appeared in former subsec. (c) which was repealed by Pub. L. 99–570.

1985—Subsec. (a). Pub. L. 99–158, §3(a)(2)(A), in first sentence substituted "National Advisory Mental Health Council and the National Advisory Council on Alcohol Abuse and Alcoholism" for "National Advisory Health Council, the National Advisory Mental Health Council, the National Advisory Council on Alcohol Abuse and Alcoholism, and the National Advisory Dental Research Council", and substituted "by the Secretary" for "by the Surgeon General with the approval of the Secretary of Health, Education, and Welfare".

Pub. L. 99–158, §3(a)(2)(B)(i), in second sentence struck out "in the case of the National Advisory Health Council, are skilled in the sciences related to health, and" after "scientific authorities who,".

Pub. L. 99–158, §3(a)(2)(B)(ii), which directed the substitution in second sentence of "the National Advisory Mental Health Council and the National Advisory Council on Alcohol Abuse and Alcoholism" for "the National Advisory Mental Health Council, the National Advisory Council on Alcohol Abuse and Alcoholism, the National Advisory Heart Council, and the National Advisory Dental Research Council" was executed by making the substitution for "the National Advisory Mental Health Council, the National Advisory Council on Alcohol Abuse and Alcoholism, and the National Advisory Dental Research Council" as the probable intent of Congress in view of the prior deletion of "the National Advisory Heart Council," by Pub. L. 92–423. See 1972 Amendment note below.

Pub. L. 99–158, §3(a)(2)(B)(iii), in second sentence substituted "and alcohol abuse and alcoholism" for ", alcohol abuse and alcoholism, and dental diseases and conditions".

Pub. L. 99–158, §3(a)(2)(C), struck out third sentence which provided that in the case of the National Advisory Dental Research Council, four of the six members selected from among the leading medical or scientific authorities be dentists.

Subsec. (b). Pub. L. 99–158, §3(a)(3), redesignated subsec. (c) as (b) and struck out former subsec. (b) which related to the duties of the National Advisory Health Council.

Subsecs. (c) to (e), (g). Pub. L. 99–158, §3(a)(3), redesignated subsecs. (d), (e), and (g) as (c), (d), and (e), respectively.

1984—Subsec. (a). Pub. L. 98–509 inserted provision requiring the Secretary to assure that the membership of the National Advisory Council on Alcohol Abuse and Alcoholism is broadly representative of experts in the fields of prevention, research, and treatment of alcohol abuse, alcoholism, and rehabilitation of alcohol abusers.

1983—Subsecs. (c), (d). Pub. L. 98–24 substituted "section 300aa of this title" for "section 219 of this title".

1980—Subsec. (a). Pub. L. 96–180 authorized appointees to serve after the expiration of their terms until their successors have taken office.

Subsec. (e)(1). Pub. L. 96–181, in provisions relating to the eligibility for selection of members, inserted officers or employees of State and local drug abuse agencies, and inserted provision that appointed members may serve after the expiration of their terms until their successors have taken office.

1978—Subsec. (f). Pub. L. 95–622 struck out subsec. (f) which related to the establishment of a National

Advisory Council for the Protection of Subjects of Biomedical and Behavioral Research.

Subsec. (g)(1), (2). Pub. L. 95–626 substituted "section 254b" for "section 247d".

1976—Subsec. (d). Pub. L. 94–371 inserted provision that the Council advise the Secretary regarding policies and priorities with respect to grants and contracts in the field of alcohol abuse and alcoholism.

1975—Subsec. (g). Pub. L. 94–63 added subsec. (g).

1974—Subsec. (f). Pub. L. 93–348 added subsec. (f).

1972—Subsec. (a). Pub. L. 92–423, §7(a)(1), (2), struck out "the National Advisory Heart Council," after "the National Advisory Council on Alcohol Abuse and Alcoholism" in two places and "heart diseases," after "alcohol abuse and alcoholism,", respectively.

Subsec. (b). Pub. L. 92–423, §7(a)(2), struck out "heart," after "alcohol abuse and alcoholism,".

Subsec. (e). Pub. L. 92–255 added subsec. (e).

1971—Subsec. (a). Pub. L. 92–218, §6(a)(1)(A), (B), struck out reference to National Advisory Cancer Council before National Advisory Mental Health Council in two places and struck out "cancer," before "psychiatric disorders".

Pub. L. 92–157 substituted "National Advisory Council on Alcohol Abuse and Alcoholism" for "National Advisory Council on Alcoholic Abuse and Alcoholism" in second sentence.

Subsec. (b). Pub. L. 92–218, §6(a)(1)(B), struck out "cancer," before "mental health" in listing of various diseases.

1970—Subsec. (a). Pub. L. 91–616, §401(a), made subsection applicable to National Advisory Council on Alcohol Abuse and Alcoholism, and inserted alcohol abuse and alcoholism to enumeration of diseases concerning which members of such Council must be skilled, and prescribed manner in which terms of members of Council would expire.

Subsec. (b). Pub. L. 91–616, §401(b), inserted reference to National Advisory Council on Alcohol Abuse and Alcoholism authorizing the Surgeon General to utilize the services of members of such Council for additional periods.

Pub. L. 91–515 inserted "or committees" after "councils".

Subsec. (d). Pub. L. 91–616, §401(c), added subsec. (d).

1950—Act Aug. 15, 1950, §3(d), amended section catchline to reflect addition of new advisory councils.

Subsec. (a). Act Aug. 15, 1950, §3(a), applied provisions to all of the advisory councils with regard to composition, qualifications, and appointment and tenure of members.

Subsec. (b). Act Aug. 15, 1950, §3(b), made subsection also applicable to new advisory councils.

Subsec. (c). Act Aug. 15, 1950, §3(c), redesignated subsec. (e) as (c) and repealed former subsec. (c).

Subsecs. (d), (f), (g). Act. Aug. 15, 1950, §3(c), repealed subsecs. (d), (f), and (g).

1948—Acts June 16, 1948, §4(c), and June 24, 1948, §4(c), included in section catchline the National Advisory Heart and Dental Research Councils, respectively.

Subsec. (a). Act June 16, 1948, §6(b), substituted "National Institutes of Health" for "National Institute of Health" in second sentence.

Subsec. (b). Acts June 16, 1948, §4(b), and June 24, 1948, §4(b), made subsection applicable to the National Advisory Heart Council and the National Advisory Dental Research Council, respectively.

Subsec. (f). Act June 16, 1948, §4(a), added subsec. (f) which established the National Advisory Heart Council.

Subsec. (g). Act June 24, 1948, §4(a), added subsec. (g) which established the National Advisory Dental Research Council.

1946—Act July 3, 1946, inserted "Mental Health" in section catchline.

Subsec. (b). Act July 3, 1946, inserted "or of the National Advisory Mental Health Council".

Subsecs. (d), (e). Act July 3, 1946, added subsecs. (d) and (e).

STATUTORY NOTES AND RELATED SUBSIDIARIES

CHANGE OF NAME

"Secretary of Health and Human Services" substituted for "Secretary of Health, Education, and Welfare" in subsecs. (a) and (c) pursuant to section 509(b) of Pub. L. 96–88, which is classified to section 3508(b) of Title 20, Education.

EFFECTIVE DATE OF 1978 AMENDMENT

Pub. L. 95–622, title III, §302(b), Nov. 9, 1978, 92 Stat. 3442, provided that the amendment made by that section is effective Nov. 1, 1978.

EFFECTIVE DATE OF 1975 AMENDMENT

Amendment by Pub. L. 94–63 effective July 1, 1975, see section 608 of Pub. L. 94–63, set out as a note under section 247b of this title.

EFFECTIVE DATE OF 1974 AMENDMENT

Pub. L. 93–348, title II, §211(b), July 12, 1974, 88 Stat. 352, as amended by Pub. L. 94–278, title III, §301(b), Apr. 22, 1976, 90 Stat. 407; Pub. L. 94–573, §18(b), Oct. 21, 1976, 90 Stat. 2720; Pub. L. 95–203, §5(b), Nov. 23, 1977, 91 Stat. 1454, provided that: "The amendment made by subsection (a) [amending this section] shall take effect November 1, 1978."

EFFECTIVE DATE OF 1972 AMENDMENT

Pub. L. 92–423, §9, Sept. 19, 1972, 86 Stat. 687, provided that: "This Act and the amendments made by this Act [see Short Title of 1972 Amendment note under section 201 of this title] shall take effect sixty days after the date of enactment of this Act [Sept. 19, 1972] or on such prior date after the date of enactment of this Act as the President shall prescribe and publish in the Federal Register."

EFFECTIVE DATE OF 1971 AMENDMENT

Pub. L. 92–218, §7, Dec. 23, 1971, 85 Stat. 785, provided that:

"(a) This Act and the amendments made by this Act [enacting sections 286a to 286g and 289l of this title, amending this section and sections 241, 282, 283, and 284 of this title, and enacting provisions set out as notes under sections 281 and 286 of this title] shall take effect sixty days after the date of enactment of this Act [Dec. 23, 1971] or on such prior date after the date of enactment of this Act as the President shall prescribe and publish in the Federal Register.

"(b) The first sentence of section 454 of the Public Health Service Act [former 42 U.S.C. 289l] (added by section 5 of this Act) shall apply only with respect to appointments made after the effective date of this Act (as prescribed by subsection (a)).

"(c) Notwithstanding the provisions of subsection (a), members of the National Cancer Advisory Board (authorized under section 410B of the Public Health Service Act, as added by this Act) [former 42 U.S.C. 286f] may be appointed, in the manner provided for in such section, at any time after the date of enactment of this Act [Dec. 23, 1971]. Such officers shall be compensated from the date they first take office, at the rates provided for in such section 410B."

EFFECTIVE DATE OF 1950 AMENDMENT

Act Aug. 15, 1950, ch. 714, §3(a), (c), 64 Stat. 446, provided that the amendments and repeals made by section 3(a) and (c) are effective Oct. 1, 1950.

REFERENCE TO COMMUNITY, MIGRANT, PUBLIC HOUSING, OR HOMELESS HEALTH CENTER CONSIDERED REFERENCE TO HEALTH CENTER

Reference to community health center, migrant health center, public housing health center, or homeless health center considered reference to health center, see section 4(c) of Pub. L. 104–299, set out as a note under section 254b of this title.

EXPIRATION OF TERMS OF OFFICE ON SEPTEMBER 30, 1950

Act Aug. 15, 1950, ch. 714, §3(c), 64 Stat. 446, provided in part that terms of office as members of national advisory councils pursuant to this section subsisting on Sept. 30, 1950, shall expire at the close of business on such day.

TERMINATION OF NATIONAL ADVISORY HEALTH COUNCIL

Pub. L. 99–158, §3(a)(1), Nov. 20, 1985, 99 Stat. 878, provided that: "The National Advisory Health Council established under section 217 [42 U.S.C. 218] is terminated."

TERMINATION OF ADVISORY COMMITTEES

Pub. L. 93–641, §6, Jan. 4, 1975, 88 Stat. 2275, set out as a note under section 217a of this title, provided that an advisory committee established pursuant to the Public Health Service Act shall terminate at such time as may be specifically prescribed by an Act of Congress enacted after Jan. 4, 1975.

EXECUTIVE DOCUMENTS

TRANSFER OF FUNCTIONS

Functions of Public Health Service, Surgeon General of Public Health Service, and all other officers and employees of Public Health Service, and functions of all agencies of or in Public Health Service transferred to Secretary of Health, Education, and Welfare by Reorg. Plan No. 3 of 1966, eff. June 25, 1966, 31 F.R. 8855, 80 Stat. 1610, set out as a note under section 202 of this title.

Functions of Federal Security Administrator transferred to Secretary of Health, Education, and Welfare and all agencies of Federal Security Agency transferred to Department of Health, Education, and Welfare by section 5 of Reorg. Plan No. 1 of 1953, set out as a note under section 3501 of this title. Federal Security Agency and office of Administrator abolished by section 8 of Reorg. Plan No. 1 of 1953.

For transfer of certain membership functions, insofar as they pertain to the Air Force, which functions were not previously transferred from Secretary of the Army to Secretary of the Air Force and from Department of the Army to Department of the Air Force, see Secretary of Defense Transfer Order No. 40 [App. C(7)], July 22, 1949.

[1] *See References in Text note below.*

§218a. Training of officers

(a) In general

Appropriations available for the pay and allowances of commissioned officers of the Service shall also be available for the pay and allowances of any such officer on active duty while attending any Federal or non-Federal educational institution or training program and, subject to regulations of the President and to the limitation prescribed in such appropriations, for payment of his tuition, fees, and other necessary expenses incident to such attendance.

(b) Voluntary separation within period subsequent to attendance

Any officer whose tuition, fees, and other necessary expenses are paid pursuant to subsection (a) while attending an educational institution or training program for a period in excess of thirty days shall be obligated to pay to the Service an amount equal to two times the total amount of such tuition, fees, and other necessary expenses received by such officer during such period, and two times the total amount of any compensation received by, and any allowance paid to, such officer during such period, if after return to active service such officer voluntarily leaves the Service within (1) six months, or (2) twice the period of such attendance, whichever is greater. Such subsequent period of service shall commence upon the cessation of such attendance and of any further continuous period of training duty for which no tuition and fees are paid by the Service and which is part of the officer's prescribed formal training program, whether such further training is at a Service facility or otherwise. The Surgeon General may waive, in whole or in part, any payment which may be required by this subsection upon a determination that such payment would be inequitable or would not be in the public interest.

(c) Training in leave without pay status

A commissioned officer may be placed in leave without pay status while attending an educational institution or training program whenever the Secretary determines that such status is in the best interest of the Service. For purposes of computation of basic pay, promotion, retirement, compensation for injury or death, and the benefits provided by sections 213 and 233 of this title, an officer in such status pursuant to the preceding sentence shall be considered as performing service in the Service and shall have an active service obligation as set forth in subsection (b) of this section.

(July 1, 1944, ch. 373, title II, §218, as added Feb. 28, 1948, ch. 83, §8, 62 Stat. 47; amended Apr. 27, 1956, ch. 211, §6, 70 Stat. 117; Pub. L. 96–76, title III, §310, Sept. 29, 1979, 93 Stat. 585; Pub. L. 105–392, title IV, §402(b), Nov. 13, 1998, 112 Stat. 3588.)

EDITORIAL NOTES

AMENDMENTS

1998—Subsec. (c). Pub. L. 105–392 added subsec. (c).

1979—Subsec. (b). Pub. L. 96–76 substituted provisions relating to payment by an officer to the Service upon voluntary separation of two times the total amount of tuition, fees, and other necessary expenses received by such officer and two times the total amount of any compensation received by, and any allowance paid to, such officer, for provisions relating to reimbursement by the officer to the Service upon voluntary separation of tuition and fees and in last sentence substituted "payment" for "reimbursement" wherever appearing.

1956—Subsec. (a). Act Apr. 27, 1956, §6(a), authorized training of all officers of the Service, and substituted "any Federal or non-Federal educational institution or training program" for "any educational institution".

Subsec. (b). Act Apr. 27, 1956, §6(b), required reimbursement of tuition and fees by officers who receive training in excess of 30 days and who voluntarily leave the Service within a period of time which is equal to twice the period of such training, with a minimum period of six months of service, and a maximum period of two years, and permitted the Surgeon General to waive any reimbursement.

STATUTORY NOTES AND RELATED SUBSIDIARIES

CHANGE OF NAME

"Secretary of Health and Human Services" substituted for "Secretary of Health, Education, and Welfare" in subsec. (c) pursuant to section 509(b) of Pub. L. 96–88, which is classified to section 3508(b) of Title 20, Education.

EXECUTIVE DOCUMENTS

TRANSFER OF FUNCTIONS

Functions of Public Health Service, Surgeon General of Public Health Service, and all other officers and employees of Public Health Service, and functions of all agencies of or in Public Health Service transferred to Secretary of Health, Education, and Welfare by Reorg. Plan No. 3 of 1966, eff. June 25, 1966, 31 F.R. 8855, 80 Stat. 1610, set out as a note under section 202 of this title.

DELEGATION OF FUNCTIONS

Functions of President delegated to Secretary of Health and Human Services, see Ex. Ord. No. 11140, Jan. 30, 1964, 29 F.R. 1637, as amended, set out as a note under section 202 of this title.

§§219 to 224. Transferred

EDITORIAL NOTES

CODIFICATION

Section 219, acts July 1, 1944, ch. 373, title V, §501, 58 Stat. 709; July 3, 1946, ch. 538, §10, 60 Stat. 425; June 16, 1948, ch. 481, §6(b), 62 Stat. 469; 1953 Reorg. Plan No. 1, §§5, 8, eff. Apr. 11, 1953, 18 F.R. 2053, 67 Stat. 631; Oct. 15, 1968, Pub. L. 90–574, title V, §503(b), 82 Stat. 1012; Oct. 17, 1979, Pub. L. 96–88, title V, §509(b), 93 Stat. 695, which related to gifts for the benefit of the Service, was successively renumbered by subsequent acts and transferred, see section 238 of this title.

Section 220, act July 1, 1944, ch. 373, title V, §502, 58 Stat. 710, which related to use of immigration station hospitals, was successively renumbered by subsequent acts and transferred, see section 238a of this title.

Section 221, act July 1, 1944, ch. 373, title V, §503, 58 Stat. 710, which related to disposition of money collected for care of patients, was successively renumbered by subsequent acts and transferred, see section 238b of this title.

Section 222, acts July 1, 1944, ch. 373, title V, §504, 58 Stat. 710, June 25, 1948, ch. 654, §6, 62 Stat. 1018; 1953 Reorg. Plan No. 1, §§5, 8, eff. Apr. 11, 1953, 18 F.R. 2053, 67 Stat. 631, which related to care of Service patients at Saint Elizabeths Hospital, was renumbered section 2104 of act July 1, 1944, by Pub. L.

98–24 and transferred to section 300aa–3 of this title, renumbered section 2304 of act July 1, 1944, by Pub. L. 99–660 and transferred to section 300cc–3 of this title, and was repealed by Pub. L. 98–621, §10(s), Nov. 8, 1984, 98 Stat. 3381.

Section 223, act July 1, 1944, ch. 373, title V, §505, 58 Stat. 710; 1953 Reorg. Plan No. 1, §§5, 8, eff. Apr. 11, 1953, 18 F.R. 2053, 67 Stat. 631, which related to settlement of claims, was renumbered section 2105 of act July 1, 1944, by Pub. L. 98–24 and transferred to section 300aa–4 of this title, and was repealed by Pub. L. 99–117, §12(f), Oct. 7, 1985, 99 Stat. 495. See section 300cc–4 of this title.

Section 224, acts July 1, 1944, ch. 373, title V, §506, 58 Stat. 710; July 15, 1954, ch. 507, §14(b), 68 Stat. 481, which related to transportation of remains of officers, was successively renumbered by subsequent acts and transferred, see section 238c of this title.

A new title V (§501 et seq.) of the Public Health Service Act was added by Pub. L. 98–24, §2(b), Apr. 26, 1983, 97 Stat. 177, and is classified to subchapter III–A (§290aa et seq. of this title).

§225. Repealed. July 12, 1955, ch. 328, §5(4), 69 Stat. 296

Section, acts July 1, 1944, ch. 373, title V, §507, 58 Stat. 711; Feb. 25, 1946, ch. 35, §2, 60 Stat. 30, provided for settlement of accounts of deceased officers. See section 2771 of Title 10, Armed Forces, and section 714 of Title 32, National Guard.

STATUTORY NOTES AND RELATED SUBSIDIARIES

EFFECTIVE DATE OF REPEAL

Repeal effective as of effective date of payment provisions of sections 361 to 365 of former Title 37, Pay and Allowances, except with respect to the deaths of members, see section 5 of act July 12, 1955.

§§225a to 227. Transferred

EDITORIAL NOTES

CODIFICATION

Section 225a, act July 1, 1944, ch. 373, title V, §507, as added June 24, 1967, Pub. L. 90–31, §5, 81 Stat. 79; amended Oct. 27, 1970, Pub. L. 91–513, title I, §3(c), 84 Stat. 1241; Apr. 22, 1976, Pub. L. 94–278, title XI, §1102(b), 90 Stat. 415; Oct. 7, 1980, Pub. L. 96–398, title VIII, §804(b), 94 Stat. 1603; Aug. 13, 1981, Pub. L. 97–35, title IX, §902(g)(2), 95 Stat. 560, which related to availability of appropriations for grants to Federal institutions, was successively renumbered by subsequent acts and transferred, see section 238d of this title.

A prior section 507 of act July 1, 1944, ch. 373, title V, providing for settlement of accounts of deceased officers, was classified to section 225 of this title and subsequently repealed.

Section 226, act July 1, 1944, ch. 373, title V, §508, 58 Stat. 711; 1953 Reorg. Plan No. 1, §§5, 8, eff. Apr. 11, 1953, 18 F.R. 2053, 67 Stat. 631; 1970 Reorg. Plan No. 2, §102, eff. July 1, 1970, 35 F.R. 7959, 84 Stat. 2085, which related to transfer of funds between appropriations, was successively renumbered by subsequent acts and transferred, see section 238e of this title.

Section 227, acts July 1, 1944, ch. 373, title V, §509 58 Stat. 711; June 16, 1948, ch. 481, §6(b), 62 Stat. 469; June 25, 1948, ch. 654, §7, 62 Stat. 1018; Reorg. Plan No. 1 of 1953 §§5, 8, eff. Apr. 11, 1953, 18 F.R. 2053, 67 Stat. 631, which related to availability of appropriations for carrying out purposes of this chapter, was successively renumbered by subsequent acts and transferred, see section 238f of this title.

§227a. Omitted

EDITORIAL NOTES

CODIFICATION

Section, Pub. L. 90–132, title II, §204, Nov. 8, 1967, 81 Stat. 407, which provided that appropriations to the Public Health Service be available for research grants to hospitals of the Service, the Bureau of Prisons, Department of Justice, and to Saint Elizabeths Hospital, on the same terms and conditions as grants to non-Federal institutions, was enacted as part of the Department of Health, Education, and Welfare Appropriation Act, 1968, and not as part of the Public Health Service Act which comprises this chapter, and was not repeated in subsequent appropriation acts. See section 300cc–6 of this title. Similar provisions were contained in the following prior appropriation acts:

Pub. L. 89–787, title II, §204, Nov. 7, 1966, 80 Stat. 1400.
Pub. L. 89–156, title II, §204, Aug. 31, 1965, 79 Stat. 609.
Pub. L. 88–605, title II, §204, Sept. 19, 1964, 78 Stat. 979.
Pub. L. 88–136, title II, §204, Oct. 11, 1963, 77 Stat. 244.
Pub. L. 87–582, title II, §204, Aug. 14, 1962, 76 Stat. 379.
Pub. L. 87–290, title II, §206, Sept. 22, 1961, 75 Stat. 608.
Pub. L. 86–703, title II, §207, Sept. 2, 1960, 74 Stat. 773.
Pub. L. 86–158, title II, §210, Aug. 14, 1959, 73 Stat. 355.

§§228 to 229d. Transferred

EDITORIAL NOTES

CODIFICATION

Section 228, acts July 1, 1944, ch. 373, title V, §510, 58 Stat. 711; June 25, 1948, ch. 645, §5, 62 Stat. 859, which related to wearing of uniforms, was successively renumbered by subsequent acts and transferred, see section 238g of this title.

Section 229, act July 1, 1944, ch. 373, title V, §511, 58 Stat. 711; 1953 Reorg. Plan No. 1, §§5, 8, eff. Apr. 11, 1953, 18 F.R. 2053, 67 Stat. 631, which related to an annual report by Surgeon General, was successively renumbered by subsequent acts and transferred, see section 238h of this title.

Section 229a, act July 1, 1944, ch. 373, title V, §512, as added Oct. 15, 1968, Pub. L. 90–574, title V, §503(a), 82 Stat. 1012, which related to memorials and other acknowledgments for contributions to health of the Nation, was successively renumbered by subsequent acts and transferred, see section 238i of this title.

Section 229b, act July 1, 1944, ch. 373, title V, §513, as added June 30, 1970, Pub. L. 91–296, title IV, §401(a), 84 Stat. 351; amended Oct. 7, 1980, Pub. L. 96–398, title VIII, §804(c), 94 Stat. 1608; Aug. 13, 1981, Pub. L. 97–35, title IX, §902(g)(3), 95 Stat. 560, which related to evaluation of programs, was successively renumbered by subsequent acts and transferred, see section 238j of this title.

Section 229c, act July 1, 1944, ch. 373, title V, §514, as added Nov. 9, 1978, Pub. L. 95–623, §11(e), 92 Stat. 3456, which related to contract authority of Secretary, was successively renumbered by subsequent acts and transferred, see section 238k of this title.

Section 229d, act July 1, 1944, ch. 373, title V, §515, formerly Pub. L. 88–164, title II, §225, as added Pub. L. 94–63, title III, §303, July 29, 1975, 89 Stat. 326; amended Pub. L. 95–622, title I, §110(c), Nov. 9, 1978, 92 Stat. 3420; renumbered and amended Pub. L. 97–35, title IX, §902(e)(2)(A), Aug. 13, 1981, 95 Stat. 560, which related to recovery of payments, was successively renumbered by subsequent acts and transferred, see section 238l of this title.

§230. Repealed. Apr. 27, 1956, ch. 211, §5(e), 70 Stat. 117

Section, act July 1, 1944, ch. 373, title VII, §706, formerly title VI, §606, 58 Stat. 713; renumbered title VII, §706, Aug. 13, 1946, ch. 958, §5, 60 Stat. 1049; amended Feb. 28, 1948, ch. 83, §9(a), 62 Stat. 47; Oct. 12, 1949, ch. 681, title V, §521(g), 63 Stat. 835, provided for computation of retired pay. See section 212 of this title.

§231. Service and supply fund; uses; reimbursement

A service and supply fund of $250,000 is established, without fiscal year limitation, for the payment of salaries, travel, and other expenses necessary to the maintenance and operation of (1) a

supply service for the purchase, storage, handling, issuance, packing, or shipping of stationery, supplies, materials, equipment, and blank forms, for which stocks may be maintained to meet, in whole or in part, requirements of the Public Health Service and requisitions of other Government Offices, and (2) such other services as the Surgeon General, with the approval of the Secretary of Health and Human Services, determines may be performed more advantageously as central services; [1] said fund to be reimbursed from applicable appropriations or funds available when services are performed or stock furnished, or in advance, on a basis of rates which shall include estimated or actual charges for personal services, materials, equipment (including maintenance, repairs, and depreciation), and other expenses.

(July 3, 1945, ch. 263, title II, 59 Stat. 370; 1953 Reorg. Plan No. 1, §§5, 8 eff. Apr. 11, 1953, 18 F.R. 2053, 67 Stat. 631; Pub. L. 96–88, title V, §509(b), Oct. 17, 1979, 93 Stat. 695; Pub. L. 97–414, §9(i), Jan. 4, 1983, 96 Stat. 2064.)

EDITORIAL NOTES

CODIFICATION

Section is from the Federal Security Appropriation Act, 1946, act July 3, 1945, and was not enacted as part of the Public Health Service Act which comprises this chapter.

AMENDMENTS

1983—Pub. L. 97–414 inserted ", or in advance," after "stock furnished".

STATUTORY NOTES AND RELATED SUBSIDIARIES

CHANGE OF NAME

"Secretary of Health and Human Services" substituted in text for "Secretary of Health, Education, and Welfare" pursuant to section 509(b) of Pub. L. 96–88, which is classified to section 3508(b) of Title 20, Education.

HHS SERVICES AND SUPPLY FUND

Pub. L. 116–159, div. C, title I, §2107, Oct. 1, 2020, 134 Stat. 730, provided that: "Effective as if included in the enactment of the paragraph beginning with 'Service and supply fund:' under the heading 'Public Health Service' in the Federal Security Agency Appropriation Act, 1946 (42 U.S.C. 231), such paragraph shall be applied with respect to any fiscal year as though the phrase 'central services' referred to central services for any Federal agency."

EXECUTIVE DOCUMENTS

TRANSFER OF FUNCTIONS

Functions of Public Health Service, Surgeon General of Public Health Service, and all other officers and employees of Public Health Service, and functions of all agencies of or in Public Health Service transferred to Secretary of Health, Education, and Welfare by Reorg. Plan No. 3 of 1966, eff. June 25, 1966, 31 F.R. 8855, 80 Stat. 1610, set out as a note under section 202 of this title.

Functions of Federal Security Administrator transferred to Secretary of Health, Education, and Welfare and all agencies of Federal Security Agency transferred to Department of Health, Education, and Welfare by section 5 of Reorg. Plan No. 1 of 1953, set out as a note under section 3501 of this title. Federal Security Agency and office of Administrator abolished by section 8 of Reorg. Plan No. 1 of 1953.

[1] *See HHS Services and Supply Fund note below.*

§232. National Institute of Mental Health; authorization of appropriation; construction; location

There is authorized to be appropriated a sum not to exceed $7,500,000 for the erection and equipment, for the use of the Public Health Service in carrying out the provisions of this Act, of suitable and adequate hospital buildings and facilities, including necessary living quarters for personnel, and of suitable and adequate laboratory buildings and facilities, and such buildings and facilities shall be known as the National Institute of Mental Health. The Administrator of General Services is authorized to acquire, by purchase, condemnation, donation, or otherwise, a suitable and adequate site or sites, selected on the advice of the Surgeon General of the Public Health Service, in or near the District of Columbia for such buildings and facilities, and to erect thereon, furnish, and equip such buildings and facilities. The amount authorized to be appropriated in this section shall include the cost of preparation of drawings and specifications, supervision of construction, and other administrative expenses incident to the work: *Provided*, That the Administrator of General Services shall prepare the plans and specifications, make all necessary contracts, and supervise construction.

(July 3, 1946, ch. 538, §11, 60 Stat. 425; June 30, 1949, ch. 288, title I, §103(a), 63 Stat. 380.)

EDITORIAL NOTES

REFERENCES IN TEXT

This Act, referred to in text, is act July 3, 1946, ch. 538, 60 Stat. 421, known as the National Mental Health Act, which enacted sections 232 and 242a of this title, amended sections 201, 209, 210, 215, 218, 219, 241, 244, and 246 of this title, and enacted provisions set out as notes under section 201 of this title. For complete classification of this Act to the Code, see Short Title of 1946 Amendment note set out under section 201 of this title and Tables.

CODIFICATION

Section was enacted as a part of the National Mental Health Act, and not as a part of the Public Health Service Act which comprises this chapter.

STATUTORY NOTES AND RELATED SUBSIDIARIES

CHANGE OF NAME

"Secretary of Health and Human Services" substituted for "Secretary of Health, Education, and Welfare" pursuant to section 509(b) of Pub. L. 96–88, which is classified to section 3508(b) of Title 20, Education.

TRANSFER OF FUNCTIONS

Functions of Federal Works Agency and of all agencies thereof, together with functions of Federal Works Administrator transferred to Administrator of General Services by section 103(a) of act June 30, 1949. Both Federal Works Agency and office of Federal Works Administrator abolished by section 103(b) of that act. See Historical and Revision Notes under section 303(b) of Title 40, Public Buildings, Property, and Works. Section 303(b) of Title 40 was amended generally by Pub. L. 109–313, §2(a)(1), Oct. 6, 2006, 120 Stat. 1734, and, as so amended, no longer relates to the Federal Works Agency and Commissioner of Public Buildings. See 2006 Amendment note under section 303 of Title 40.

EFFECTIVE DATE OF TRANSFER OF FUNCTIONS

Transfer of functions by act June 30, 1949, effective July 1, 1949, see section 605, formerly section 505, of act June 30, 1949, ch. 288, 63 Stat. 403; renumbered by act Sept. 5, 1950, ch. 849, §6(a), (b), 64 Stat. 583.

EXECUTIVE DOCUMENTS

TRANSFER OF FUNCTIONS

Functions of Public Health Service, Surgeon General of Public Health Service, and all other officers and employees of Public Health Service, and functions of all agencies of or in Public Health Service transferred to Secretary of Health, Education, and Welfare by Reorg. Plan No. 3 of 1966, eff. June 25, 1966, 31 F.R. 8855, 80 Stat. 1610, set out as a note under section 202 of this title.

§233. Civil actions or proceedings against commissioned officers or employees

(a) Exclusiveness of remedy

The remedy against the United States provided by sections 1346(b) and 2672 of title 28, or by alternative benefits provided by the United States where the availability of such benefits precludes a remedy under section 1346(b) of title 28, for damage for personal injury, including death, resulting from the performance of medical, surgical, dental, or related functions, including the conduct of clinical studies or investigation, by any commissioned officer or employee of the Public Health Service while acting within the scope of his office or employment, shall be exclusive of any other civil action or proceeding by reason of the same subject-matter against the officer or employee (or his estate) whose act or omission gave rise to the claim.

(b) Attorney General to defend action or proceeding; delivery of process to designated official; furnishing of copies of pleading and process to United States attorney, Attorney General, and Secretary

The Attorney General shall defend any civil action or proceeding brought in any court against any person referred to in subsection (a) of this section (or his estate) for any such damage or injury. Any such person against whom such civil action or proceeding is brought shall deliver within such time after date of service or knowledge of service as determined by the Attorney General, all process served upon him or an attested true copy thereof to his immediate superior or to whomever was designated by the Secretary to receive such papers and such person shall promptly furnish copies of the pleading and process therein to the United States attorney for the district embracing the place wherein the proceeding is brought, to the Attorney General, and to the Secretary.

(c) Removal to United States district court; procedure; proceeding upon removal deemed a tort action against United States; hearing on motion to remand to determine availability of remedy against United States; remand to State court or dismissal

Upon a certification by the Attorney General that the defendant was acting in the scope of his employment at the time of the incident out of which the suit arose, any such civil action or proceeding commenced in a State court shall be removed without bond at any time before trial by the Attorney General to the district court of the United States of the district and division embracing the place wherein it is pending and the proceeding deemed a tort action brought against the United States under the provisions of title 28 and all references thereto. Should a United States district court determine on a hearing on a motion to remand held before a trial on the merit that the case so removed is one in which a remedy by suit within the meaning of subsection (a) of this section is not available against the United States, the case shall be remanded to the State Court: *Provided*, That where such a remedy is precluded because of the availability of a remedy through proceedings for compensation or other benefits from the United States as provided by any other law, the case shall be dismissed, but in the event the running of any limitation of time for commencing, or filing an application or claim in, such proceedings for compensation or other benefits shall be deemed to have been suspended during the pendency of the civil action or proceeding under this section.

(d) Compromise or settlement of claim by Attorney General

The Attorney General may compromise or settle any claim asserted in such civil action or proceeding in the manner provided in section 2677 of title 28 and with the same effect.

(e) Assault or battery

For purposes of this section, the provisions of section 2680(h) of title 28 shall not apply to assault or battery arising out of negligence in the performance of medical, surgical, dental, or related functions, including the conduct of clinical studies or investigations.

(f) Authority of Secretary or designee to hold harmless or provide liability insurance for assigned or detailed employees

The Secretary or his designee may, to the extent that he deems appropriate, hold harmless or provide liability insurance for any officer or employee of the Public Health Service for damage for

personal injury, including death, negligently caused by such officer or employee while acting within the scope of his office or employment and as a result of the performance of medical, surgical, dental, or related functions, including the conduct of clinical studies or investigations, if such employee is assigned to a foreign country or detailed to a State or political subdivision thereof or to a non-profit institution, and if the circumstances are such as are likely to preclude the remedies of third persons against the United States described in section 2679(b) of title 28, for such damage or injury.

(g) Exclusivity of remedy against United States for entities deemed Public Health Service employees; coverage for services furnished to individuals other than center patients; application process; subrogation of medical malpractice claims; applicable period; entity and contractor defined

(1)(A) For purposes of this section and subject to the approval by the Secretary of an application under subparagraph (D), an entity described in paragraph (4), and any officer, governing board member, or employee of such an entity, and any contractor of such an entity who is a physician or other licensed or certified health care practitioner (subject to paragraph (5)), shall be deemed to be an employee of the Public Health Service for a calendar year that begins during a fiscal year for which a transfer was made under subsection (k)(3) (subject to paragraph (3)). The remedy against the United States for an entity described in paragraph (4) and any officer, governing board member, employee, or contractor (subject to paragraph (5)) of such an entity who is deemed to be an employee of the Public Health Service pursuant to this paragraph shall be exclusive of any other civil action or proceeding to the same extent as the remedy against the United States is exclusive pursuant to subsection (a).

(B) The deeming of any entity or officer, governing board member, employee, or contractor of the entity to be an employee of the Public Health Service for purposes of this section shall apply with respect to services provided—

(i) to all patients of the entity, and

(ii) subject to subparagraph (C), to individuals who are not patients of the entity.

(C) Subparagraph (B)(ii) applies to services provided to individuals who are not patients of an entity if the Secretary determines, after reviewing an application submitted under subparagraph (D), that the provision of the services to such individuals—

(i) benefits patients of the entity and general populations that could be served by the entity through community-wide intervention efforts within the communities served by such entity;

(ii) facilitates the provision of services to patients of the entity; or

(iii) are otherwise required under an employment contract (or similar arrangement) between the entity and an officer, governing board member, employee, or contractor of the entity.

(D) The Secretary may not under subparagraph (A) deem an entity or an officer, governing board member, employee, or contractor of the entity to be an employee of the Public Health Service for purposes of this section, and may not apply such deeming to services described in subparagraph (B)(ii), unless the entity has submitted an application for such deeming to the Secretary in such form and such manner as the Secretary shall prescribe. The application shall contain detailed information, along with supporting documentation, to verify that the entity, and the officer, governing board member, employee, or contractor of the entity, as the case may be, meets the requirements of subparagraphs (B) and (C) of this paragraph and that the entity meets the requirements of paragraphs (1) through (4) of subsection (h).

(E) The Secretary shall make a determination of whether an entity or an officer, governing board member, employee, or contractor of the entity is deemed to be an employee of the Public Health Service for purposes of this section within 30 days after the receipt of an application under subparagraph (D). The determination of the Secretary that an entity or an officer, governing board member, employee, or contractor of the entity is deemed to be an employee of the Public Health Service for purposes of this section shall apply for the period specified by the Secretary under subparagraph (A).

(F) Once the Secretary makes a determination that an entity or an officer, governing board

member, employee, or contractor of an entity is deemed to be an employee of the Public Health Service for purposes of this section, the determination shall be final and binding upon the Secretary and the Attorney General and other parties to any civil action or proceeding. Except as provided in subsection (i), the Secretary and the Attorney General may not determine that the provision of services which are the subject of such a determination are not covered under this section.

(G) In the case of an entity described in paragraph (4) that has not submitted an application under subparagraph (D):

(i) The Secretary may not consider the entity in making estimates under subsection (k)(1).

(ii) This section does not affect any authority of the entity to purchase medical malpractice liability insurance coverage with Federal funds provided to the entity under section 254b, 254b, or 256a of this title.[1]

(H) In the case of an entity described in paragraph (4) for which an application under subparagraph (D) is in effect, the entity may, through notifying the Secretary in writing, elect to terminate the applicability of this subsection to the entity. With respect to such election by the entity:

(i) The election is effective upon the expiration of the 30-day period beginning on the date on which the entity submits such notification.

(ii) Upon taking effect, the election terminates the applicability of this subsection to the entity and each officer, governing board member, employee, and contractor of the entity.

(iii) Upon the effective date for the election, clauses (i) and (ii) of subparagraph (G) apply to the entity to the same extent and in the same manner as such clauses apply to an entity that has not submitted an application under subparagraph (D).

(iv) If after making the election the entity submits an application under subparagraph (D), the election does not preclude the Secretary from approving the application (and thereby restoring the applicability of this subsection to the entity and each officer, governing board member, employee, and contractor of the entity, subject to the provisions of this subsection and the subsequent provisions of this section).

(2) If, with respect to an entity or person deemed to be an employee for purposes of paragraph (1), a cause of action is instituted against the United States pursuant to this section, any claim of the entity or person for benefits under an insurance policy with respect to medical malpractice relating to such cause of action shall be subrogated to the United States.

(3) This subsection shall apply with respect to a cause of action arising from an act or omission which occurs on or after January 1, 1993.

(4) An entity described in this paragraph is a public or non-profit private entity receiving Federal funds under section 254b of this title.

(5) For purposes of paragraph (1), an individual may be considered a contractor of an entity described in paragraph (4) only if—

(A) the individual normally performs on average at least 32½ hours of service per week for the entity for the period of the contract; or

(B) in the case of an individual who normally performs an average of less than 32½ hours of services per week for the entity for the period of the contract, the individual is a licensed or certified provider of services in the fields of family practice, general internal medicine, general pediatrics, or obstetrics and gynecology.

(h) Qualifications for designation as Public Health Service employee

The Secretary may not approve an application under subsection (g)(1)(D) unless the Secretary determines that the entity—

(1) has implemented appropriate policies and procedures to reduce the risk of malpractice and the risk of lawsuits arising out of any health or health-related functions performed by the entity;

(2) has reviewed and verified the professional credentials, references, claims history, fitness, professional review organization findings, and license status of its physicians and other licensed or certified health care practitioners, and, where necessary, has obtained the permission from these

individuals to gain access to this information;

(3) has no history of claims having been filed against the United States as a result of the application of this section to the entity or its officers, employees, or contractors as provided for under this section, or, if such a history exists, has fully cooperated with the Attorney General in defending against any such claims and either has taken, or will take, any necessary corrective steps to assure against such claims in the future; and

(4) will fully cooperate with the Attorney General in providing information relating to an estimate described under subsection (k).

(i) Authority of Attorney General to exclude health care professionals from coverage

(1) Notwithstanding subsection (g)(1), the Attorney General, in consultation with the Secretary, may on the record determine, after notice and opportunity for a full and fair hearing, that an individual physician or other licensed or certified health care practitioner who is an officer, employee, or contractor of an entity described in subsection (g)(4) shall not be deemed to be an employee of the Public Health Service for purposes of this section, if treating such individual as such an employee would expose the Government to an unreasonably high degree of risk of loss because such individual—

(A) does not comply with the policies and procedures that the entity has implemented pursuant to subsection (h)(1);

(B) has a history of claims filed against him or her as provided for under this section that is outside the norm for licensed or certified health care practitioners within the same specialty;

(C) refused to reasonably cooperate with the Attorney General in defending against any such claim;

(D) provided false information relevant to the individual's performance of his or her duties to the Secretary, the Attorney General, or an applicant for or recipient of funds under this chapter; or

(E) was the subject of disciplinary action taken by a State medical licensing authority or a State or national professional society.

(2) A final determination by the Attorney General under this subsection that an individual physician or other licensed or certified health care professional shall not be deemed to be an employee of the Public Health Service shall be effective upon receipt by the entity employing such individual of notice of such determination, and shall apply only to acts or omissions occurring after the date such notice is received.

(j) Remedy for denial of hospital admitting privileges to certain health care providers

In the case of a health care provider who is an officer, employee, or contractor of an entity described in subsection (g)(4), section 254h(e) of this title shall apply with respect to the provider to the same extent and in the same manner as such section applies to any member of the National Health Service Corps.

(k) Estimate of annual claims by Attorney General; criteria; establishment of fund; transfer of funds to Treasury accounts

(1)(A) For each fiscal year, the Attorney General, in consultation with the Secretary, shall estimate by the beginning of the year the amount of all claims which are expected to arise under this section (together with related fees and expenses of witnesses) for which payment is expected to be made in accordance with section 1346 and chapter 171 of title 28 from the acts or omissions, during the calendar year that begins during that fiscal year, of entities described in subsection (g)(4) and of officers, employees, or contractors (subject to subsection (g)(5)) of such entities.

(B) The estimate under subparagraph (A) shall take into account—

(i) the value and frequency of all claims for damage for personal injury, including death, resulting from the performance of medical, surgical, dental, or related functions by entities described in subsection (g)(4) or by officers, employees, or contractors (subject to subsection (g)(5)) of such entities who are deemed to be employees of the Public Health Service under subsection (g)(1) that, during the preceding 5-year period, are filed under this section or, with

respect to years occurring before this subsection takes effect, are filed against persons other than the United States,

(ii) the amounts paid during that 5-year period on all claims described in clause (i), regardless of when such claims were filed, adjusted to reflect payments which would not be permitted under section 1346 and chapter 171 of title 28, and

(iii) amounts in the fund established under paragraph (2) but unspent from prior fiscal years.

(2) Subject to appropriations, for each fiscal year, the Secretary shall establish a fund of an amount equal to the amount estimated under paragraph (1) that is attributable to entities receiving funds under each of the grant programs described in paragraph (4) of subsection (g), but not to exceed a total of $10,000,000 for each such fiscal year. Appropriations for purposes of this paragraph shall be made separate from appropriations made for purposes of sections 254b, 254b and 256a of this title.[1]

(3) In order for payments to be made for judgments against the United States (together with related fees and expenses of witnesses) pursuant to this section arising from the acts or omissions of entities described in subsection (g)(4) and of officers, governing board members, employees, or contractors (subject to subsection (g)(5)) of such entities, the total amount contained within the fund established by the Secretary under paragraph (2) for a fiscal year shall be transferred not later than the December 31 that occurs during the fiscal year to the appropriate accounts in the Treasury.

(l) Timely response to filing of action or proceeding

(1) If a civil action or proceeding is filed in a State court against any entity described in subsection (g)(4) or any officer, governing board member, employee, or any contractor of such an entity for damages described in subsection (a), the Attorney General, within 15 days after being notified of such filing, shall make an appearance in such court and advise such court as to whether the Secretary has determined under subsections (g) and (h), that such entity, officer, governing board member, employee, or contractor of the entity is deemed to be an employee of the Public Health Service for purposes of this section with respect to the actions or omissions that are the subject of such civil action or proceeding. Such advice shall be deemed to satisfy the provisions of subsection (c) that the Attorney General certify that an entity, officer, governing board member, employee, or contractor of the entity was acting within the scope of their employment or responsibility.

(2) If the Attorney General fails to appear in State court within the time period prescribed under paragraph (1), upon petition of any entity or officer, governing board member, employee, or contractor of the entity named, the civil action or proceeding shall be removed to the appropriate United States district court. The civil action or proceeding shall be stayed in such court until such court conducts a hearing, and makes a determination, as to the appropriate forum or procedure for the assertion of the claim for damages described in subsection (a) and issues an order consistent with such determination.

(m) Application of coverage to managed care plans

(1) An entity or officer, governing board member, employee, or contractor of an entity described in subsection (g)(1) shall, for purposes of this section, be deemed to be an employee of the Public Health Service with respect to services provided to individuals who are enrollees of a managed care plan if the entity contracts with such managed care plan for the provision of services.

(2) Each managed care plan which enters into a contract with an entity described in subsection (g)(4) shall deem the entity and any officer, governing board member, employee, or contractor of the entity as meeting whatever malpractice coverage requirements such plan may require of contracting providers for a calendar year if such entity or officer, governing board member, employee, or contractor of the entity has been deemed to be an employee of the Public Health Service for purposes of this section for such calendar year. Any plan which is found by the Secretary on the record, after notice and an opportunity for a full and fair hearing, to have violated this subsection shall upon such finding cease, for a period to be determined by the Secretary, to receive and to be eligible to receive any Federal funds under titles XVIII or XIX of the Social Security Act [42 U.S.C. 1395 et seq., 1396 et seq.].

(3) For purposes of this subsection, the term "managed care plan" shall mean health maintenance

organizations and similar entities that contract at-risk with payors for the provision of health services or plan enrollees and which contract with providers (such as entities described in subsection (g)(4)) for the delivery of such services to plan enrollees.

(n) Report on risk exposure of covered entities

(1) Not later than one year after December 26, 1995, the Comptroller General of the United States shall submit to the Congress a report on the following:

(A) The medical malpractice liability claims experience of entities that have been deemed to be employees for purposes of this section.

(B) The risk exposure of such entities.

(C) The value of private sector risk-management services, and the value of risk-management services and procedures required as a condition of receiving a grant under section 254b, 254b, or 256a of this title.[1]

(D) A comparison of the costs and the benefits to taxpayers of maintaining medical malpractice liability coverage for such entities pursuant to this section, taking into account—

(i) a comparison of the costs of premiums paid by such entities for private medical malpractice liability insurance with the cost of coverage pursuant to this section; and

(ii) an analysis of whether the cost of premiums for private medical malpractice liability insurance coverage is consistent with the liability claims experience of such entities.

(2) The report under paragraph (1) shall include the following:

(A) A comparison of—

(i) an estimate of the aggregate amounts that such entities (together with the officers, governing board members, employees, and contractors of such entities who have been deemed to be employees for purposes of this section) would have directly or indirectly paid in premiums to obtain medical malpractice liability insurance coverage if this section were not in effect; with

(ii) the aggregate amounts by which the grants received by such entities under this chapter were reduced pursuant to subsection (k)(2).

(B) A comparison of—

(i) an estimate of the amount of privately offered such insurance that such entities (together with the officers, governing board members, employees, and contractors of such entities who have been deemed to be employees for purposes of this section) purchased during the three-year period beginning on January 1, 1993; with

(ii) an estimate of the amount of such insurance that such entities (together with the officers, governing board members, employees, and contractors of such entities who have been deemed to be employees for purposes of this section) will purchase after December 26, 1995.

(C) An estimate of the medical malpractice liability loss history of such entities for the 10-year period preceding October 1, 1996, including but not limited to the following:

(i) Claims that have been paid and that are estimated to be paid, and legal expenses to handle such claims that have been paid and that are estimated to be paid, by the Federal Government pursuant to deeming entities as employees for purposes of this section.

(ii) Claims that have been paid and that are estimated to be paid, and legal expenses to handle such claims that have been paid and that are estimated to be paid, by private medical malpractice liability insurance.

(D) An analysis of whether the cost of premiums for private medical malpractice liability insurance coverage is consistent with the liability claims experience of entities that have been deemed as employees for purposes of this section.

(3) In preparing the report under paragraph (1), the Comptroller General of the United States shall consult with public and private entities with expertise on the matters with which the report is

concerned.

(o) Volunteer services provided by health professionals at free clinics

(1) For purposes of this section, a free clinic health professional shall in providing a qualifying health service to an individual, or an officer, governing board member, employee, or contractor of a free clinic shall in providing services for the free clinic, be deemed to be an employee of the Public Health Service for a calendar year that begins during a fiscal year for which a transfer was made under paragraph (6)(D). The preceding sentence is subject to the provisions of this subsection.

(2) In providing a health service to an individual, a health care practitioner shall for purposes of this subsection be considered to be a free clinic health professional if the following conditions are met:

(A) The service is provided to the individual at a free clinic, or through offsite programs or events carried out by the free clinic.

(B) The free clinic is sponsoring the health care practitioner pursuant to paragraph (5)(C).

(C) The service is a qualifying health service (as defined in paragraph (4)).

(D) Neither the health care practitioner nor the free clinic receives any compensation for the service from the individual or from any third-party payor (including reimbursement under any insurance policy or health plan, or under any Federal or State health benefits program). With respect to compliance with such condition:

(i) The health care practitioner may receive repayment from the free clinic for reasonable expenses incurred by the health care practitioner in the provision of the service to the individual.

(ii) The free clinic may accept voluntary donations for the provision of the service by the health care practitioner to the individual.

(E) Before the service is provided, the health care practitioner or the free clinic provides written notice to the individual of the extent to which the legal liability of the health care practitioner is limited pursuant to this subsection (or in the case of an emergency, the written notice is provided to the individual as soon after the emergency as is practicable). If the individual is a minor or is otherwise legally incompetent, the condition under this subparagraph is that the written notice be provided to a legal guardian or other person with legal responsibility for the care of the individual.

(F) At the time the service is provided, the health care practitioner is licensed or certified in accordance with applicable law regarding the provision of the service.

(3)(A) For purposes of this subsection, the term "free clinic" means a health care facility operated by a nonprofit private entity meeting the following requirements:

(i) The entity does not, in providing health services through the facility, accept reimbursement from any third-party payor (including reimbursement under any insurance policy or health plan, or under any Federal or State health benefits program).

(ii) The entity, in providing health services through the facility, either does not impose charges on the individuals to whom the services are provided, or imposes a charge according to the ability of the individual involved to pay the charge.

(iii) The entity is licensed or certified in accordance with applicable law regarding the provision of health services.

(B) With respect to compliance with the conditions under subparagraph (A), the entity involved may accept voluntary donations for the provision of services.

(4) For purposes of this subsection, the term "qualifying health service" means any medical assistance required or authorized to be provided in the program under title XIX of the Social Security Act [42 U.S.C. 1396 et seq.], without regard to whether the medical assistance is included in the plan submitted under such program by the State in which the health care practitioner involved provides the medical assistance. References in the preceding sentence to such program shall as applicable be considered to be references to any successor to such program.

(5) Subsection (g) (other than paragraphs (3) through (5)) and subsections (h), (i), and (l) apply to

a health care practitioner for purposes of this subsection to the same extent and in the same manner as such subsections apply to an officer, governing board member, employee, or contractor of an entity described in subsection (g)(4), subject to paragraph (6) and subject to the following:

(A) The first sentence of paragraph (1) applies in lieu of the first sentence of subsection (g)(1)(A).

(B) This subsection may not be construed as deeming any free clinic to be an employee of the Public Health Service for purposes of this section.

(C) With respect to a free clinic, a health care practitioner is not a free clinic health professional unless the free clinic sponsors the health care practitioner. For purposes of this subsection, the free clinic shall be considered to be sponsoring the health care practitioner if—

(i) with respect to the health care practitioner, the free clinic submits to the Secretary an application meeting the requirements of subsection (g)(1)(D); and

(ii) the Secretary, pursuant to subsection (g)(1)(E), determines that the health care practitioner is deemed to be an employee of the Public Health Service.

(D) In the case of a health care practitioner who is determined by the Secretary pursuant to subsection (g)(1)(E) to be a free clinic health professional, this subsection applies to the health care practitioner (with respect to the free clinic sponsoring the health care practitioner pursuant to subparagraph (C)) for any cause of action arising from an act or omission of the health care practitioner occurring on or after the date on which the Secretary makes such determination.

(E) Subsection (g)(1)(F) applies to a health care practitioner for purposes of this subsection only to the extent that, in providing health services to an individual, each of the conditions specified in paragraph (2) is met.

(6)(A) For purposes of making payments for judgments against the United States (together with related fees and expenses of witnesses) pursuant to this section arising from the acts or omissions of free clinic health professionals, there is authorized to be appropriated $10,000,000 for each fiscal year.

(B) The Secretary shall establish a fund for purposes of this subsection. Each fiscal year amounts appropriated under subparagraph (A) shall be deposited in such fund.

(C) Not later than May 1 of each fiscal year, the Attorney General, in consultation with the Secretary, shall submit to the Congress a report providing an estimate of the amount of claims (together with related fees and expenses of witnesses) that, by reason of the acts or omissions of free clinic health professionals, will be paid pursuant to this section during the calendar year that begins in the following fiscal year. Subsection (k)(1)(B) applies to the estimate under the preceding sentence regarding free clinic health professionals to the same extent and in the same manner as such subsection applies to the estimate under such subsection regarding officers, governing board members, employees, and contractors of entities described in subsection (g)(4).

(D) Not later than December 31 of each fiscal year, the Secretary shall transfer from the fund under subparagraph (B) to the appropriate accounts in the Treasury an amount equal to the estimate made under subparagraph (C) for the calendar year beginning in such fiscal year, subject to the extent of amounts in the fund.

(7)(A) This subsection takes effect on the date of the enactment of the first appropriations Act that makes an appropriation under paragraph (6)(A), except as provided in subparagraph (B)(i).

(B)(i) Effective on August 21, 1996—

(I) the Secretary may issue regulations for carrying out this subsection, and the Secretary may accept and consider applications submitted pursuant to paragraph (5)(C); and

(II) reports under paragraph (6)(C) may be submitted to the Congress.

(ii) For the first fiscal year for which an appropriation is made under subparagraph (A) of paragraph (6), if an estimate under subparagraph (C) of such paragraph has not been made for the

calendar year beginning in such fiscal year, the transfer under subparagraph (D) of such paragraph shall be made notwithstanding the lack of the estimate, and the transfer shall be made in an amount equal to the amount of such appropriation.

(p) Administration of smallpox countermeasures by health professionals

(1) In general

For purposes of this section, and subject to other provisions of this subsection, a covered person shall be deemed to be an employee of the Public Health Service with respect to liability arising out of administration of a covered countermeasure against smallpox to an individual during the effective period of a declaration by the Secretary under paragraph (2)(A).

(2) Declaration by Secretary concerning countermeasure against smallpox

(A) Authority to issue declaration

(i) In general

The Secretary may issue a declaration, pursuant to this paragraph, concluding that an actual or potential bioterrorist incident or other actual or potential public health emergency makes advisable the administration of a covered countermeasure to a category or categories of individuals.

(ii) Covered countermeasure

The Secretary shall specify in such declaration the substance or substances that shall be considered covered countermeasures (as defined in paragraph (7)(A)) for purposes of administration to individuals during the effective period of the declaration.

(iii) Effective period

The Secretary shall specify in such declaration the beginning and ending dates of the effective period of the declaration, and may subsequently amend such declaration to shorten or extend such effective period, provided that the new closing date is after the date when the declaration is amended.

(iv) Publication

The Secretary shall promptly publish each such declaration and amendment in the Federal Register.

(B) Liability of United States only for administrations within scope of declaration

Except as provided in paragraph (5)(B)(ii), the United States shall be liable under this subsection with respect to a claim arising out of the administration of a covered countermeasure to an individual only if—

(i) the countermeasure was administered by a qualified person, for a purpose stated in paragraph (7)(A)(i), and during the effective period of a declaration by the Secretary under subparagraph (A) with respect to such countermeasure; and

(ii)(I) the individual was within a category of individuals covered by the declaration; or

(II) the qualified person administering the countermeasure had reasonable grounds to believe that such individual was within such category.

(C) Presumption of administration within scope of declaration in case of accidental vaccinia inoculation

(i) In general

If vaccinia vaccine is a covered countermeasure specified in a declaration under subparagraph (A), and an individual to whom the vaccinia vaccine is not administered contracts vaccinia, then, under the circumstances specified in clause (ii), the individual—

(I) shall be rebuttably presumed to have contracted vaccinia from an individual to whom such vaccine was administered as provided by clauses (i) and (ii) of subparagraph (B); and

(II) shall (unless such presumption is rebutted) be deemed for purposes of this

subsection to be an individual to whom a covered countermeasure was administered by a qualified person in accordance with the terms of such declaration and as described by subparagraph (B).

(ii) Circumstances in which presumption applies

The presumption and deeming stated in clause (i) shall apply if—

(I) the individual contracts vaccinia during the effective period of a declaration under subparagraph (A) or by the date 30 days after the close of such period; or

(II) the individual has resided with, or has had contact with, an individual to whom such vaccine was administered as provided by clauses (i) and (ii) of subparagraph (B) and contracts vaccinia after such date.

(D) Acts and omissions deemed to be within scope of employment

(i) In general

In the case of a claim arising out of alleged transmission of vaccinia from an individual described in clause (ii), acts or omissions by such individual shall be deemed to have been taken within the scope of such individual's office or employment for purposes of—

(I) subsection (a); and

(II) section 1346(b) and chapter 171 of title 28.

(ii) Individuals to whom deeming applies

An individual is described by this clause if—

(I) vaccinia vaccine was administered to such individual as provided by subparagraph (B); and

(II) such individual was within a category of individuals covered by a declaration under subparagraph (A)(i).

(3) Exhaustion; exclusivity; offset

(A) Exhaustion

(i) In general

A person may not bring a claim under this subsection unless such person has exhausted such remedies as are available under part C of this subchapter, except that if the Secretary fails to make a final determination on a request for benefits or compensation filed in accordance with the requirements of such part within 240 days after such request was filed, the individual may seek any remedy that may be available under this section.

(ii) Tolling of statute of limitations

The time limit for filing a claim under this subsection, or for filing an action based on such claim, shall be tolled during the pendency of a request for benefits or compensation under part C of this subchapter.

(iii) Construction

This subsection shall not be construed as superseding or otherwise affecting the application of a requirement, under chapter 171 of title 28, to exhaust administrative remedies.

(B) Exclusivity

The remedy provided by subsection (a) shall be exclusive of any other civil action or proceeding for any claim or suit this subsection encompasses, except for a proceeding under part C of this subchapter.

(C) Offset

The value of all compensation and benefits provided under part C of this subchapter for an incident or series of incidents shall be offset against the amount of an award, compromise, or settlement of money damages in a claim or suit under this subsection based on the same incident or series of incidents.

(4) Certification of action by Attorney General

Subsection (c) applies to actions under this subsection, subject to the following provisions:

(A) Nature of certification

The certification by the Attorney General that is the basis for deeming an action or proceeding to be against the United States, and for removing an action or proceeding from a State court, is a certification that the action or proceeding is against a covered person and is based upon a claim alleging personal injury or death arising out of the administration of a covered countermeasure.

(B) Certification of Attorney General conclusive

The certification of the Attorney General of the facts specified in subparagraph (A) shall conclusively establish such facts for purposes of jurisdiction pursuant to this subsection.

(5) Covered person to cooperate with United States

(A) In general

A covered person shall cooperate with the United States in the processing and defense of a claim or action under this subsection based upon alleged acts or omissions of such person.

(B) Consequences of failure to cooperate

Upon the motion of the United States or any other party and upon finding that such person has failed to so cooperate—

(i) the court shall substitute such person as the party defendant in place of the United States and, upon motion, shall remand any such suit to the court in which it was instituted if it appears that the court lacks subject matter jurisdiction;

(ii) the United States shall not be liable based on the acts or omissions of such person; and

(iii) the Attorney General shall not be obligated to defend such action.

(6) Recourse against covered person in case of gross misconduct or contract violation

(A) In general

Should payment be made by the United States to any claimant bringing a claim under this subsection, either by way of administrative determination, settlement, or court judgment, the United States shall have, notwithstanding any provision of State law, the right to recover for that portion of the damages so awarded or paid, as well as interest and any costs of litigation, resulting from the failure of any covered person to carry out any obligation or responsibility assumed by such person under a contract with the United States or from any grossly negligent, reckless, or illegal conduct or willful misconduct on the part of such person.

(B) Venue

The United States may maintain an action under this paragraph against such person in the district court of the United States in which such person resides or has its principal place of business.

(7) Definitions

As used in this subsection, terms have the following meanings:

(A) Covered countermeasure

The term "covered countermeasure" or "covered countermeasure against smallpox", means a substance that is—

(i)(I) used to prevent or treat smallpox (including the vaccinia or another vaccine); or

(II) used to control or treat the adverse effects of vaccinia inoculation or of administration of another covered countermeasure; and

(ii) specified in a declaration under paragraph (2).

(B) Covered person

The term "covered person", when used with respect to the administration of a covered

countermeasure, means a person who is—

(i) a manufacturer or distributor of such countermeasure;

(ii) a health care entity under whose auspices—

(I) such countermeasure was administered;

(II) a determination was made as to whether, or under what circumstances, an individual should receive a covered countermeasure;

(III) the immediate site of administration on the body of a covered countermeasure was monitored, managed, or cared for; or

(IV) an evaluation was made of whether the administration of a countermeasure was effective;

(iii) a qualified person who administered such countermeasure;

(iv) a State, a political subdivision of a State, or an agency or official of a State or of such a political subdivision, if such State, subdivision, agency, or official has established requirements, provided policy guidance, supplied technical or scientific advice or assistance, or otherwise supervised or administered a program with respect to administration of such countermeasures;

(v) in the case of a claim arising out of alleged transmission of vaccinia from an individual—

(I) the individual who allegedly transmitted the vaccinia, if vaccinia vaccine was administered to such individual as provided by paragraph (2)(B) and such individual was within a category of individuals covered by a declaration under paragraph (2)(A)(i); or

(II) an entity that employs an individual described by clause (I) [2] or where such individual has privileges or is otherwise authorized to provide health care;

(vi) an official, agent, or employee of a person described in clause (i), (ii), (iii), or (iv);

(vii) a contractor of, or a volunteer working for, a person described in clause (i), (ii), or (iv), if the contractor or volunteer performs a function for which a person described in clause (i), (ii), or (iv) is a covered person; or

(viii) an individual who has privileges or is otherwise authorized to provide health care under the auspices of an entity described in clause (ii) or (v)(II).

(C) Qualified person

The term "qualified person", when used with respect to the administration of a covered countermeasure, means a licensed health professional or other individual who—

(i) is authorized to administer such countermeasure under the law of the State in which the countermeasure was administered; or

(ii) is otherwise authorized by the Secretary to administer such countermeasure.

(D) Arising out of administration of a covered countermeasure

The term "arising out of administration of a covered countermeasure", when used with respect to a claim or liability, includes a claim or liability arising out of—

(i) determining whether, or under what conditions, an individual should receive a covered countermeasure;

(ii) obtaining informed consent of an individual to the administration of a covered countermeasure;

(iii) monitoring, management, or care of an immediate site of administration on the body of a covered countermeasure, or evaluation of whether the administration of the countermeasure has been effective; or

(iv) transmission of vaccinia virus by an individual to whom vaccinia vaccine was administered as provided by paragraph (2)(B).

(q) Health professional volunteers at public or non-profit private entities

(1) For purposes of this section, a health professional volunteer at a deemed entity described in

subsection (g)(4) shall, in providing a health professional service eligible for funding under section 254b of this title to an individual, be deemed to be an employee of the Public Health Service for a calendar year that begins during a fiscal year for which a transfer was made under paragraph (4)(C). The preceding sentence is subject to the provisions of this subsection.

(2) In providing a health service to an individual, a health care practitioner shall for purposes of this subsection be considered to be a health professional volunteer at an entity described in subsection (g)(4) if the following conditions are met:

(A) The service is provided to the individual at the facilities of an entity described in subsection (g)(4), or through offsite programs or events carried out by the entity.

(B) The entity is sponsoring the health care practitioner pursuant to paragraph (3)(B).

(C) The health care practitioner does not receive any compensation for the service from the individual, the entity described in subsection (g)(4), or any third-party payer (including reimbursement under any insurance policy or health plan, or under any Federal or State health benefits program), except that the health care practitioner may receive repayment from the entity described in subsection (g)(4) for reasonable expenses incurred by the health care practitioner in the provision of the service to the individual, which may include travel expenses to or from the site of services.

(D) Before the service is provided, the health care practitioner or the entity described in subsection (g)(4) posts a clear and conspicuous notice at the site where the service is provided of the extent to which the legal liability of the health care practitioner is limited pursuant to this subsection.

(E) At the time the service is provided, the health care practitioner is licensed or certified in accordance with applicable Federal and State laws regarding the provision of the service.

(F) At the time the service is provided, the entity described in subsection (g)(4) maintains relevant documentation certifying that the health care practitioner meets the requirements of this subsection.

(3) Subsection (g) (other than paragraphs (3) and (5)) and subsections (h), (i), and (l) apply to a health care practitioner for purposes of this subsection to the same extent and in the same manner as such subsections apply to an officer, governing board member, employee, or contractor of an entity described in subsection (g)(4), subject to paragraph (4), and subject to the following:

(A) The first sentence of paragraph (1) applies in lieu of the first sentence of subsection (g)(1)(A).

(B) With respect to an entity described in subsection (g)(4), a health care practitioner is not a health professional volunteer at such entity unless the entity sponsors the health care practitioner. For purposes of this subsection, the entity shall be considered to be sponsoring the health care practitioner if—

(i) with respect to the health care practitioner, the entity submits to the Secretary an application meeting the requirements of subsection (g)(1)(D); and

(ii) the Secretary, pursuant to subsection (g)(1)(E), determines that the health care practitioner is deemed to be an employee of the Public Health Service.

(C) In the case of a health care practitioner who is determined by the Secretary pursuant to subsection (g)(1)(E) to be a health professional volunteer at such entity, this subsection applies to the health care practitioner (with respect to services performed on behalf of the entity sponsoring the health care practitioner pursuant to subparagraph (B)) for any cause of action arising from an act or omission of the health care practitioner occurring on or after the date on which the Secretary makes such determination.

(D) Subsection (g)(1)(F) applies to a health care practitioner for purposes of this subsection only to the extent that, in providing health services to an individual, each of the conditions specified in paragraph (2) is met.

(4)(A) Amounts in the fund established under subsection (k)(2) shall be available for transfer

under subparagraph (C) for purposes of carrying out this subsection.

(B)(i) Not later than May 1 of each fiscal year, the Attorney General, in consultation with the Secretary, shall submit to the Congress a report providing an estimate of the amount of claims (together with related fees and expenses of witnesses) that, by reason of the acts or omissions of health professional volunteers, will be paid pursuant to this section during the calendar year that begins in the following fiscal year.

(ii) Subsection (k)(1)(B) applies to the estimate under clause (i) regarding health professional volunteers to the same extent and in the same manner as such subsection applies to the estimate under such subsection regarding officers, governing board members, employees, and contractors of entities described in subsection (g)(4).

(iii) The report shall include a summary of the data relied upon for the estimate in clause (i), including the number of claims filed and paid from the previous calendar year.

(C) Not later than December 31 of each fiscal year, the Secretary shall transfer from the fund under subsection (k)(2) to the appropriate accounts in the Treasury an amount equal to the estimate made under subparagraph (B) for the calendar year beginning in such fiscal year, subject to the extent of amounts in the fund.

(5)(A) This subsection shall take effect on October 1, 2017, except as provided in subparagraph (B).

(B) Effective on December 13, 2016—

(i) the Secretary may issue regulations for carrying out this subsection, and the Secretary may accept and consider applications submitted pursuant to paragraph (3)(B); and

(ii) reports under paragraph (4)(B) may be submitted to Congress.

(July 1, 1944, ch. 373, title II, §224, formerly §223, as added Pub. L. 91–623, §4, Dec. 31, 1970, 84 Stat. 1870; renumbered §224, Pub. L. 92–157, title III, §301(c), Nov. 18, 1971, 85 Stat. 463; amended Pub. L. 102–501, §§2–4, Oct. 24, 1992, 106 Stat. 3268–3270; Pub. L. 103–183, title VII, §706(a), Dec. 14, 1993, 107 Stat. 2241; Pub. L. 104–73, §§2–5(b), 6–11, Dec. 26, 1995, 109 Stat. 777–781; Pub. L. 104–191, title I, §194, Aug. 21, 1996, 110 Stat. 1988; Pub. L. 104–299, §4(a)(1), Oct. 11, 1996, 110 Stat. 3644; Pub. L. 107–251, title VI, §601(a), Oct. 26, 2002, 116 Stat. 1664; Pub. L. 107–296, title III, §304(c), Nov. 25, 2002, 116 Stat. 2165; Pub. L. 108–20, §3(a)–(i), Apr. 30, 2003, 117 Stat. 646–648; Pub. L. 108–163, §2(m)(1), Dec. 6, 2003, 117 Stat. 2023; Pub. L. 111–148, title X, §10608(a), Mar. 23, 2010, 124 Stat. 1014; Pub. L. 114–255, div. B, title IX, §9025, Dec. 13, 2016, 130 Stat. 1254; Pub. L. 117–180, div. D, title III, §301, Sept. 30, 2022, 136 Stat. 2136.)

EDITORIAL NOTES

REFERENCES IN TEXT

The references to section 254b of this title the first place appearing in subsecs. (g)(1)(G)(ii), (k)(2), and (n)(1)(C), were in the original references to section 329, meaning section 329 of act July 1, 1944, which was omitted in the general amendment of subpart I (§254b et seq.) of part D of subchapter II of this chapter by Pub. L. 104–299, §2, Oct. 11, 1996, 110 Stat. 3626.

Section 256a of this title, referred to in subsecs. (g)(1)(G)(ii), (k)(2), and (n)(1)(C), was repealed by Pub. L. 104–299, §4(a)(3), Oct. 11, 1996, 110 Stat. 3645.

The Social Security Act, referred to in subsecs. (m)(2) and (o)(4), is act Aug. 14, 1935, ch. 531, 49 Stat. 620. Titles XVIII and XIX of the Act are classified generally to subchapters XVIII (§1395 et seq.) and XIX (§1396 et seq.), respectively, of chapter 7 of this title. For complete classification of this Act to the Code, see section 1305 of this title and Tables.

AMENDMENTS

2022—Subsec. (g)(1)(H)(iv). Pub. L. 117–180, §301(b)(1), substituted "this section)." for "this section."

Subsec. (k)(3). Pub. L. 117–180, §301(b)(2), inserted "governing board members," after "officers,".

Subsec. (p)(7)(A)(i)(II). Pub. L. 117–180, §301(b)(3), realigned margin.

Subsec. (q)(5)(A). Pub. L. 117–180, §301(b)(4), struck out "and paragraph (6)" after "subparagraph (B)".

Subsec. (q)(6). Pub. L. 117–180, §301(a), struck out par. (6) which read as follows: "Beginning on October 1, 2022, this subsection shall cease to have any force or effect."

2016—Subsec. (q). Pub. L. 114–255 added subsec. (q).

2010—Subsec. (o)(1). Pub. L. 111–148 inserted ", or an officer, governing board member, employee, or contractor of a free clinic shall in providing services for the free clinic," after "to an individual".

2003—Subsec. (g)(1)(G)(ii). Pub. L. 108–163 substituted "254b" for "254c, 254b(h)" before ", or".

Subsec. (k)(2). Pub. L. 108–163 substituted "254b" for "254c, 254b(h)" before "and".

Subsec. (n)(1)(C). Pub. L. 108–163 substituted "254b" for "254c, 254b(h)" before ", or".

Subsec. (p)(2)(A)(ii). Pub. L. 108–20, §3(i), substituted "paragraph (7)(A)" for "paragraph(8)(A)".

Subsec. (p)(2)(C)(ii)(II). Pub. L. 108–20, §3(a), substituted "has resided with, or has had contact with," for "resides or has resided with".

Subsec. (p)(2)(D). Pub. L. 108–20, §3(b), added subpar. (D).

Subsec. (p)(3). Pub. L. 108–20, §3(c), amended heading and text of par. (3) generally. Prior to amendment, text read as follows: "The remedy provided by subsection (a) of this section shall be exclusive of any other civil action or proceeding for any claim or suit this subsection encompasses."

Subsec. (p)(5). Pub. L. 108–20, §3(d), substituted "Covered person" for "Defendant" in heading.

Subsec. (p)(7)(A)(i)(II). Pub. L. 108–20, §3(e), amended subcl. (II) generally. Prior to amendment, subcl. (II) read as follows: "vaccinia immune globulin used to control or treat the adverse effects of vaccinia inoculation; and".

Subsec. (p)(7)(B). Pub. L. 108–20, §3(f)(1), substituted "means a person" for "includes any person" in introductory provisions.

Subsec. (p)(7)(B)(ii). Pub. L. 108–20, §3(f)(2), substituted "auspices—" for "auspices", designated "such countermeasure was administered;" as subcl. (I), and added subcls. (II) to (IV).

Subsec. (p)(7)(B)(iv) to (viii). Pub. L. 108–20, §3(f)(3), (4), added cls. (iv) to (viii) and struck out former cl. (iv) which read as follows: "an official, agent, or employee of a person described in clause (i), (ii), or (iii)."

Subsec. (p)(7)(C). Pub. L. 108–20, §3(g), substituted "individual who—" for "individual who", designated "is authorized to administer such countermeasure under the law of the State in which the countermeasure was administered." as cl. (i), substituted "; or" for period at end of cl. (i), and added cl. (ii).

Subsec. (p)(7)(D). Pub. L. 108–20, §3(h), added subpar. (D).

2002—Subsecs. (g)(1)(G)(ii), (k)(2), (n)(1)(C). Pub. L. 107–251 substituted "254b(h)" for "256".

Subsec. (p). Pub. L. 107–296 added subsec. (p).

1996—Subsec. (g)(4). Pub. L. 104–299 substituted "under section 254b of this title." for "under any of the following grant programs:" and struck out subpars. (A) to (D) which read as follows:

"(A) Section 254b of this title (relating to grants for migrant health centers).

"(B) Section 254c of this title (relating to grants for community health centers).

"(C) Section 256 of this title (relating to grants for health services for the homeless).

"(D) Section 256a of this title (relating to grants for health services for residents of public housing)."

Subsec. (o). Pub. L. 104–191 added subsec. (o).

1995—Subsec. (g)(1). Pub. L. 104–73, §§3(1), 4, 5(a), designated existing provisions as subpar. (A), inserted "and subject to the approval by the Secretary of an application under subparagraph (D)" after "For purposes of this section", substituted "an entity described in paragraph (4), and any officer, governing board member, or employee of such an entity, and any contractor of such an entity who is a physician or other licensed or certified health care practitioner (subject to paragraph (5)), shall be deemed to be an employee of the Public Health Service for a calendar year that begins during a fiscal year for which a transfer was made under subsection (k)(3) (subject to paragraph (3)). The remedy against the United States for an entity described in paragraph (4) and any officer, governing board member, employee, or contractor" for ", an entity described in paragraph (4) and any officer, employee, or contractor (subject to paragraph (5)) of such an entity who is a physician or other licensed or certified health care practitioner shall be deemed to be an employee of the Public Health Service for a calendar year that begins during a fiscal year for which a transfer of the full amount estimated under subsection (k)(1)(A) of this section was made under subsection (k)(3) of this section (subject to paragraph (3)). The remedy against the United States for an entity described in paragraph (4) and any officer, employee, or contractor", and added subpars. (B) to (H).

Subsec. (g)(3). Pub. L. 104–73, §2(a), struck out at end "This subsection shall not apply with respect to a cause of action arising from an act or omission which occurs on or after January 1, 1996."

Subsec. (g)(5)(B). Pub. L. 104–73, §8, amended subpar. (B) generally. Prior to amendment, subpar. (B) read as follows: "in the case of an individual who normally performs on average less than 32½ hours of services per week for the entity for the period of the contract and is a licensed or certified provider of obstetrical services—

"(i) the individual's medical malpractice liability insurance coverage does not extend to services performed by the individual for the entity under the contract, or

"(ii) the Secretary finds that patients to whom the entity furnishes services will be deprived of

obstetrical services if such individual is not considered a contractor of the entity for purposes of paragraph (1)."

Subsec. (h). Pub. L. 104–73, §5(b)(1), in introductory provisions substituted "The Secretary may not approve an application under subsection (g)(1)(D) unless the Secretary determines that the entity—" for "Notwithstanding subsection (g)(1) of this section, the Secretary, in consultation with the Attorney General, may not deem an entity described in subsection (g)(4) of this section to be an employee of the Public Health Service Act for purposes of this section unless the entity—".

Subsec. (h)(4). Pub. L. 104–73, §5(b)(2), substituted "will fully cooperate" for "has fully cooperated".

Subsec. (i)(1). Pub. L. 104–73, §9, substituted "may on the record determine, after notice and opportunity for a full and fair hearing" for "may determine, after notice and opportunity for a hearing".

Subsec. (k)(1)(A). Pub. L. 104–73, §2(b)(1), substituted "For each fiscal year" for "For each of the fiscal years 1993, 1994, and 1995" and struck out "(except that an estimate shall be made for fiscal year 1993 by December 31, 1992, subject to an adjustment within 90 days thereafter)" after "beginning of the year".

Subsec. (k)(2). Pub. L. 104–73, §§2(b)(2), 10, substituted "for each fiscal year" for "for each of the fiscal years 1993, 1994, and 1995" and "$10,000,000" for "$30,000,000".

Subsec. (k)(3). Pub. L. 104–73, §3(2), which directed amendment of subsec. (k)(3) by inserting "governing board member," after "officer,", could not be executed because "officer," did not appear.

Subsec. (l). Pub. L. 104–73, §6, added subsec. (l).

Subsec. (m). Pub. L. 104–73, §7, added subsec. (m).

Subsec. (n). Pub. L. 104–73, §11, added subsec. (n).

1993—Subsec. (k)(2). Pub. L. 103–183 inserted at end "Appropriations for purposes of this paragraph shall be made separate from appropriations made for purposes of sections 254b, 254c, 256 and 256a of this title."

1992—Subsecs. (g) to (k). Pub. L. 102–501 added subsecs. (g) to (k).

STATUTORY NOTES AND RELATED SUBSIDIARIES

EFFECTIVE DATE OF 2010 AMENDMENT

Pub. L. 111–148, title X, §10608(b), Mar. 23, 2010, 124 Stat. 1014, provided that: "The amendment made by this section [amending this section] shall take effect on the date of enactment of this Act [Mar. 23, 2010] and apply to any act or omission which occurs on or after that date."

EFFECTIVE DATE OF 2003 AMENDMENTS

Pub. L. 108–163, §3, Dec. 6, 2003, 117 Stat. 2023, provided that: "This Act [see Short Title of 2003 Amendments note set out under section 201 of this title] is deemed to have taken effect immediately after the enactment of Public Law 107–251 [Oct. 26, 2002]."

Pub. L. 108–20, §3(j), Apr. 30, 2003, 117 Stat. 649, provided that: "This section [amending this section] shall take effect as of November 25, 2002."

EFFECTIVE DATE OF 2002 AMENDMENT

Amendment by Pub. L. 107–296 effective 60 days after Nov. 25, 2002, see section 4 of Pub. L. 107–296, set out as an Effective Date note under section 101 of Title 6, Domestic Security.

EFFECTIVE DATE OF 1996 AMENDMENT

Pub. L. 104–299, §5, Oct. 11, 1996, 110 Stat. 3645, as amended by Pub. L. 104–208, div. A, title I, §101(e) [title V, §521], Sept. 30, 1996, 110 Stat. 3009–233, 3009–275, provided that: "This Act [enacting sections 254b and 254c of this title, amending this section and sections 256c, 1395x, and 1396d of this title, repealing sections 256 and 256a of this title, and enacting provisions set out as notes under sections 201 and 254b of this title] and the amendments made by this Act shall become effective on October 1, 1996."

[Pub. L. 104–208, div. A, title I, §101(e) [title V, §521], Sept. 30, 1996, 110 Stat. 3009–233, 3009–275, provided that the amendment made by that section is effective on the day after Oct. 11, 1996.]

EFFECTIVE DATE OF 1995 AMENDMENT

Pub. L. 104–73, §5(c), Dec. 26, 1995, 109 Stat. 779, provided that: "If, on the day before the date of the enactment of this Act [Dec. 26, 1995], an entity was deemed to be an employee of the Public Health Service for purposes of section 224(g) of the Public Health Service Act [42 U.S.C. 233(g)], the condition under paragraph (1)(D) of such section (as added by subsection (a) of this section) that an application be approved with respect to the entity does not apply until the expiration of the 180-day period beginning on such date."

EFFECTIVE DATE OF 1992 AMENDMENT

Pub. L. 102–501, §6, Oct. 24, 1992, 106 Stat. 3272, provided that: "The amendments made by this Act [amending this section] shall take effect on the date of the enactment of this Act [Oct. 24, 1992]."

REPORT ON RISK EXPOSURE OF COVERED ENTITIES

Pub. L. 102–501, §5, Oct. 24, 1992, 106 Stat. 3271, provided that the Attorney General, by Apr. 1, 1995, and in consultation with the Secretary of Health and Human Services, was to submit a report to Congress on the medical malpractice liability claims experience of entities subject to subsec. (g) of this section, including their risk exposure and the effect of liability protections on costs incurred.

[1] *See References in Text notes below.*

[2] *So in original. Probably should be "subclause".*

§234. Health care professionals assisting during a public health emergency

(a) Limitation on liability

Notwithstanding any other provision of law, a health care professional who is a member of the Medical Reserve Corps under section 300hh–15 of this title or who is included in the Emergency System for Advance Registration of Volunteer Health Professionals under section 247d–7b of this title and who—

(1) is responding—

(A) to a public health emergency determined under section 247d(a) of this title, during the initial period of not more than 90 days (as determined by the Secretary) of the public health emergency determination (excluding any period covered by a renewal of such determination); or

(B) to a major disaster or an emergency as declared by the President under section 5170 of this title or under section 1621 of title 50 during the initial period of such declaration;

(2) is alleged to be liable for an act or omission—

(A) during the initial period of a determination or declaration described in paragraph (1) and related to the treatment of individuals in need of health care services due to such public health emergency, major disaster, or emergency;

(B) in the State or States for which such determination or declaration is made;

(C) in the health care professional's capacity as a member of the Medical Reserve Corps or a professional included in the Emergency System for Advance Registration of Volunteer Health Professionals under section 247d–7b of this title; and

(D) in the course of providing services that are within the scope of the license, registration, or certification of the professional, as defined by the State of licensure, registration, or certification; and

(3) prior to the rendering of such act or omission, was authorized by the State's authorization of deploying such State's Emergency System for Advance Registration of Volunteer Health Professionals described in section 247d–7b of this title or the Medical Reserve Corps established under section 300hh–15 of this title, to provide health care services,

shall be subject only to the State liability laws of the State in which such act or omission occurred, in the same manner and to the same extent as a similar health care professional who is a resident of such State would be subject to such State laws, except with respect to the licensure, registration, and certification of such individual.

(b) Volunteer Protection Act

Nothing in this section shall be construed to affect an individual's right to protections under the Volunteer Protection Act of 1997 [42 U.S.C. 14501 et seq.].

(c) Preemption

This section shall supersede the laws of any State that would subject a health care professional described in subsection (a) to the liability laws of any State other than the State liability laws to which such individual is subject pursuant to such subsection.

(d) Definitions

In this section:

(1) The term "health care professional" means an individual licensed, registered, or certified under Federal or State laws or regulations to provide health care services.

(2) The term "health care services" means any services provided by a health care professional, or by any individual working under the supervision of a health care professional, that relate to—

(A) the diagnosis, prevention, or treatment of any human disease or impairment; or

(B) the assessment or care of the health of human beings.

(e) Effective date

(1) In general

This section shall take effect 90 days after June 24, 2019.

(2) Application

This section shall apply to a claim for harm only if the act or omission that caused such harm occurred on or after the effective date described in paragraph (1).

(July 1, 1944, ch. 373, title II, §225, as added Pub. L. 116–22, title II, §208(a), June 24, 2019, 133 Stat. 927.)

EDITORIAL NOTES

REFERENCES IN TEXT

The Volunteer Protection Act of 1997, referred to in subsec. (b), is Pub. L. 105–19, June 18, 1997, 111 Stat. 218, which is classified generally to chapter 139 (§14501 et seq.) of this title. For complete classification of this Act to the Code, see Short Title note set out under section 14501 of this title and Tables.

PRIOR PROVISIONS

A former section 234, act July 1, 1944, ch. 373, title II, §225, as added Oct. 27, 1972, Pub. L. 92–585, §5, 86 Stat. 1293; amended Aug. 23, 1974, Pub. L. 93–385, §1, 88 Stat. 741; Apr. 22, 1976, Pub. L. 94–278, title IX, §901, 90 Stat. 415; Sept. 30, 1976, Pub. L. 94–437, title I, §104, 90 Stat. 1403; Oct. 12, 1976, Pub. L. 94–484, title I, §101(t), 90 Stat. 2246, related to Public Health and National Health Service Corps Scholarship Training program, prior to repeal by Pub. L. 94–484, title IV, §408(b)(1), Oct. 12, 1976, 90 Stat. 2281, effective Oct. 1, 1977.

STATUTORY NOTES AND RELATED SUBSIDIARIES

LIMITATION ON LIABILITY FOR VOLUNTEER HEALTH CARE PROFESSIONALS DURING COVID–19 EMERGENCY RESPONSE

Pub. L. 116–136, div. A, title III, §3215, Mar. 27, 2020, 134 Stat. 374, provided that:

"(a) LIMITATION ON LIABILITY.—Except as provided in subsection (b), a health care professional shall not be liable under Federal or State law for any harm caused by an act or omission of the professional in the provision of health care services during the public health emergency with respect to COVID–19 declared by the Secretary of Health and Human Services (referred to in this section as the 'Secretary') under section 319 of the Public Health Service Act (42 U.S.C. 247d) on January 31, 2020, if—

"(1) the professional is providing health care services in response to such public health emergency, as a volunteer; and

"(2) the act or omission occurs—

"(A) in the course of providing health care services;

"(B) in the health care professional's capacity as a volunteer;

"(C) in the course of providing health care services that—

"(i) are within the scope of the license, registration, or certification of the volunteer, as defined by the State of licensure, registration, or certification; and

"(ii) do not exceed the scope of license, registration, or certification of a substantially similar health professional in the State in which such act or omission occurs; and

"(D) in a good faith belief that the individual being treated is in need of health care services.

"(b) EXCEPTIONS.—Subsection (a) does not apply if—

"(1) the harm was caused by an act or omission constituting willful or criminal misconduct, gross negligence, reckless misconduct, or a conscious flagrant indifference to the rights or safety of the individual harmed by the health care professional; or

"(2) the health care professional rendered the health care services under the influence (as determined pursuant to applicable State law) of alcohol or an intoxicating drug.

"(c) PREEMPTION.—

"(1) IN GENERAL.—This section preempts the laws of a State or any political subdivision of a State to the extent that such laws are inconsistent with this section, unless such laws provide greater protection from liability.

"(2) VOLUNTEER PROTECTION ACT.—Protections afforded by this section are in addition to those provided by the Volunteer Protection Act of 1997 (Public Law 105–19) [42 U.S.C. 14501 et seq.].

"(d) DEFINITIONS.—In this section—

"(1) the term 'harm' includes physical, nonphysical, economic, and noneconomic losses;

"(2) the term 'health care professional' means an individual who is licensed, registered, or certified under Federal or State law to provide health care services;

"(3) the term 'health care services' means any services provided by a health care professional, or by any individual working under the supervision of a health care professional that relate to—

"(A) the diagnosis, prevention, or treatment of COVID–19; or

"(B) the assessment or care of the health of a human being related to an actual or suspected case of COVID–19; and

"(4) the term 'volunteer' means a health care professional who, with respect to the health care services rendered, does not receive compensation or any other thing of value in lieu of compensation, which compensation—

"(A) includes a payment under any insurance policy or health plan, or under any Federal or State health benefits program; and

"(B) excludes—

"(i) receipt of items to be used exclusively for rendering health care services in the health care professional's capacity as a volunteer described in subsection (a)(1); and

"(ii) any reimbursement for travel to the site where the volunteer services are rendered and any payments in cash or kind to cover room and board, if services are being rendered more than 75 miles from the volunteer's principal place of residence.

"(e) EFFECTIVE DATE.—This section shall take effect upon the date of enactment of this Act [Mar. 27, 2020], and applies to a claim for harm only if the act or omission that caused such harm occurred on or after the date of enactment.

"(f) SUNSET.—This section shall be in effect only for the length of the public health emergency declared by the Secretary of Health and Human Services (referred to in this section as the 'Secretary') under section 319 of the Public Health Service Act (42 U.S.C. 247d) on January 31, 2020 with respect to COVID–19."

§235. Administration of grants in multigrant projects; promulgation of regulations

For the purpose of facilitating the administration of, and expediting the carrying out of the purposes of, the programs established by subchapters V, VI, and VII,[1] and sections 242b, 246(a), 246(b), 246(c), 246(d),[1] and 246(e) [1] of this title in situations in which grants are sought or made under two or more of such programs with respect to a single project, the Secretary is authorized to promulgate regulations—

(1) under which the administrative functions under such programs with respect to such project will be performed by a single administrative unit which is the administrative unit charged with the administration of any of such programs or is the administrative unit charged with the supervision of two or more of such programs;

(2) designed to reduce the number of applications, reports, and other materials required under such programs to be submitted with respect to such project, and otherwise to simplify, consolidate, and make uniform (to the extent feasible), the data and information required to be contained in such applications, reports, and other materials; and

(3) under which inconsistent or duplicative requirements imposed by such programs will be revised and made uniform with respect to such project;

except that nothing in this section shall be construed to authorize the Secretary to waive or suspend, with respect to any such project, any requirement with respect to any of such programs if such requirement is imposed by law or by any regulation required by law.

(July 1, 1944, ch. 373, title II, §226, formerly title III, §310A, as added Pub. L. 91–515, title II, §270, Oct. 30, 1970, 84 Stat. 1306; amended Pub. L. 92–157, title II, §201, Nov. 18, 1971, 85 Stat. 461; renumbered §226, Pub. L. 93–353, title I, §102(e), July 23, 1974, 88 Stat. 362.)

EDITORIAL NOTES

REFERENCES IN TEXT

Subchapters V and VI, referred to in text, are classified to sections 292 et seq. and 296 et seq., respectively, of this title.

Subchapter VII, referred to in text, which was classified to section 299 et seq. of this title, was repealed by Pub. L. 99–117, §12(d), Oct. 7, 1985, 99 Stat. 495.

Section 246(d) of this title, referred to in text, was repealed by Pub. L. 97–35, title IX, §902(b), Aug. 13, 1981, 95 Stat. 559.

Section 246(e) of this title, referred to in text, was repealed by Pub. L. 94–63, title V, §501(b), July 29, 1975, 89 Stat. 346.

CODIFICATION

Section was formerly classified to section 242i of this title.

AMENDMENTS

1971—Pub. L. 92–157 provided for administration of programs established under subchapters V and VI of this chapter.

[1] *See References in Text note below.*

§236. Orphan Products Board

(a) Establishment; composition; chairman

There is established in the Department of Health and Human Services a board for the development of drugs (including biologics) and devices (including diagnostic products) for rare diseases or conditions to be known as the Orphan Products Board. The Board shall be comprised of the Assistant Secretary for Health of the Department of Health and Human Services and representatives, selected by the Secretary, of the Food and Drug Administration, the National Institutes of Health, the Centers for Disease Control and Prevention, and any other Federal department or agency which the Secretary determines has activities relating to drugs and devices for rare diseases or conditions. The Assistant Secretary for Health shall chair the Board.

(b) Function

The function of the Board shall be to promote the development of drugs and devices for rare diseases or conditions and the coordination among Federal, other public, and private agencies in carrying out their respective functions relating to the development of such articles for such diseases or conditions.

(c) Duties with respect to drugs for rare diseases or conditions

In the case of drugs for rare diseases or conditions the Board shall—

(1) evaluate—

(A) the effect of subchapter B of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 360aa et seq.] on the development of such drugs, and

(B) the implementation of such subchapter; [1]

(2) evaluate the activities of the National Institutes of Health for the development of drugs for such diseases or conditions,

(3) assure appropriate coordination among the Food and Drug Administration, the National Institutes of Health and the Centers for Disease Control and Prevention in the carrying out of their respective functions relating to the development of drugs for such diseases or conditions to assure that the activities of each agency are complementary,

(4) assure appropriate coordination among all interested Federal agencies, manufacturers, and organizations representing patients, in their activities relating to such drugs,

(5) with the consent of the sponsor of a drug for a rare disease or condition exempt under section 505(i) of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 355(i)] or regulations issued under such section, inform physicians and the public respecting the availability of such drug for such disease or condition and inform physicians and the public respecting the availability of drugs approved under section 505(c) of such Act [21 U.S.C. 355(c)] or licensed under section 262 of this title for rare diseases or conditions,

(6) seek business entities and others to undertake the sponsorship of drugs for rare diseases or conditions, seek investigators to facilitate the development of such drugs, and seek business entities to participate in the distribution of such drugs, and

(7) recognize the efforts of public and private entities and individuals in seeking the development of drugs for rare diseases or conditions and in developing such drugs.

(d) Consultation

The Board shall consult with interested persons respecting the activities of the Board under this section and as part of such consultation shall provide the opportunity for the submission of oral views.

(e) Annual report; contents

The Board shall submit to the Committee on Labor and Human Resources of the Senate and the Committee on Energy and Commerce of the House of Representatives an annual report—

(1) identifying the drugs which have been designated under section 526 of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 360bb] for a rare disease or condition,

(2) describing the activities of the Board, and

(3) containing the results of the evaluations carried out by the Board.

The Director of the National Institutes of Health shall submit to the Board for inclusion in the annual report a report on the rare disease and condition research activities of the Institutes of the National Institutes of Health; the Secretary of the Treasury shall submit to the Board for inclusion in the annual report a report on the use of the credit against tax provided by section 44H [2] of title 26; and the Secretary of Health and Human Services shall submit to the Board for inclusion in the annual report a report on the program of assistance under section 360ee of title 21 for the development of drugs for rare diseases and conditions. Each annual report shall be submitted by June 1 of each year for the preceding calendar year.

(July 1, 1944, ch. 373, title II, §227, as added Pub. L. 97–414, §3, Jan. 4, 1983, 96 Stat. 2051; amended Pub. L. 99–514, §2, Oct. 22, 1986, 100 Stat. 2095; Pub. L. 102–321, title I, §163(b)(1), July 10, 1992, 106 Stat. 375; Pub. L. 102–531, title III, §312(d)(1), Oct. 27, 1992, 106 Stat. 3504.)

EDITORIAL NOTES

REFERENCES IN TEXT

The Federal Food, Drug, and Cosmetic Act, referred to in subsec. (c)(1)(A), is act June 25, 1938, ch. 675, 52 Stat. 1040. Subchapter B of the Federal Food, Drug, and Cosmetic Act probably means subchapter B of chapter V of the Federal Food, Drug, and Cosmetic Act which is classified generally to part B (section 360aa et seq.) of subchapter V of chapter 9 of Title 21, Food and Drugs. For complete classification of this Act to the Code, see section 301 of Title 21 and Tables.

Section 44H of title 26, referred to in subsec. (e), was renumbered section 28 of title 26, by Pub. L. 98–369, div. A, title IV, §471(c)(1), July 18, 1984, 98 Stat. 826, and subsequently renumbered section 45C of title 26 by Pub. L. 104–188, title I, §1205(a)(1), Aug. 20, 1996, 110 Stat. 1775.

PRIOR PROVISIONS

A prior section 236, act July 1, 1944, ch. 373, title II, §227, formerly title III, §310B, as added Oct. 30, 1970, Pub. L. 91–515, title II, §280, 84 Stat. 1307; renumbered §227 and amended July 23, 1974, Pub. L. 93–353, title I, §102(f), 88 Stat. 362, related to an annual report by Secretary on activities related to health facilities and services and expenditure of funds, prior to repeal by Pub. L. 97–35, title XXI, §2193(b)(4), Aug. 13, 1981, 95 Stat. 827.

AMENDMENTS

1992—Subsec. (a). Pub. L. 102–531 substituted "Centers for Disease Control and Prevention" for "Centers for Disease Control".

Subsec. (c)(2). Pub. L. 102–321, §163(b)(1)(A), which directed the striking out of ", and the Alcohol, Drug Abuse, and Mental Health Administration", was executed by striking "and the Alcohol, Drug Abuse, and Mental Health Administration" after "National Institutes of Health" to reflect the probable intent of Congress.

Subsec. (c)(3). Pub. L. 102–531 substituted "Centers for Disease Control and Prevention" for "Centers for Disease Control".

Pub. L. 102–321, §163(b)(1)(B), struck out ", the Alcohol, Drug Abuse, and Mental Health Administration," after "National Institutes of Health".

Subsec. (e). Pub. L. 102–321, §163(b)(1)(C), (D), in concluding provisions, struck out "and the Administrator of the Alcohol, Drug Abuse, and Mental Health Administration" after "National Institutes of Health" the first place appearing and "and the Alcohol, Drug Abuse, and Mental Health Administration" after "National Institutes of Health" the second place appearing.

1986—Subsec. (e). Pub. L. 99–514 substituted "Internal Revenue Code of 1986" for "Internal Revenue Code of 1954", which for purposes of codification was translated as "title 26" thus requiring no change in text.

STATUTORY NOTES AND RELATED SUBSIDIARIES

CHANGE OF NAME

Committee on Labor and Human Resources of Senate changed to Committee on Health, Education, Labor, and Pensions of Senate by Senate Resolution No. 20, One Hundred Sixth Congress, Jan. 19, 1999.

Committee on Energy and Commerce of House of Representatives treated as referring to Committee on Commerce of House of Representatives by section 1(a) of Pub. L. 104–14, set out as a note preceding section 21 of Title 2, The Congress. Committee on Commerce of House of Representatives changed to Committee on Energy and Commerce of House of Representatives, and jurisdiction over matters relating to securities and exchanges and insurance generally transferred to Committee on Financial Services of House of Representatives by House Resolution No. 5, One Hundred Seventh Congress, Jan. 3, 2001.

EFFECTIVE DATE OF 1992 AMENDMENT

Pub. L. 102–321, title VIII, §801, July 10, 1992, 106 Stat. 441, provided that:

"(a) IN GENERAL.—This Act [See Tables for classification] takes effect on the date of the enactment of this Act [July 10, 1992], subject to subsections (b) through (d).

"(b) AMENDMENTS.—The amendments described in this Act are made on the date of the enactment of this Act and take effect on such date, except as provided in subsections (c) and (d).

"(c) REORGANIZATION UNDER TITLE I.—Title I [§§101–171] takes effect on October 1, 1992. The amendments described in such title are made on such date and take effect on such date.

"(d) PROGRAMS PROVIDING FINANCIAL ASSISTANCE.—

"(1) FISCAL YEAR 1993 AND SUBSEQUENT YEARS.—In the case of any program making awards of grants, cooperative agreements, or contracts, the amendments made by this Act are effective for awards made on or after October 1, 1992.

"(2) PRIOR FISCAL YEARS.—

"(A) Except as provided in subparagraph (B), in the case of any program making awards of grants, cooperative agreements, or contracts, if the program began operation prior to the date of the enactment of this Act [July 10, 1992] and the program is amended by this Act, awards made prior to October 1, 1992, shall continue to be subject to the terms and conditions upon which such awards were made, notwithstanding the amendments made by this Act.

"(B) Subparagraph (A) does not apply with respect to the amendments made by this Act to part B of title XIX of the Public Health Service Act [42 U.S.C. 300x et seq.]. Section 205(a) [42 U.S.C. 300x note] applies with respect to the program established in such part."

TERMINATION OF REPORTING REQUIREMENTS

For termination, effective May 15, 2000, of provisions in subsec. (e) of this section relating to the requirement to submit an annual report to certain committees of Congress, see section 3003 of Pub. L. 104–66, as amended, set out as a note under section 1113 of Title 31, Money and Finance, and page 101 of House Document No. 103–7.

USE OF "CDC" AS ACRONYM FOR CENTERS FOR DISEASE CONTROL AND PREVENTION

Pub. L. 102–531, title III, §312(i), Oct. 27, 1992, 106 Stat. 3506, provided that: "The amendments made by this section [amending this section, sections 247d, 280b to 280b–2, 285c–4, 285d–7, 285m–4, 289c, 290aa–9, 290bb–1, 300u–5, 300aa–2, 300aa–19, 300aa–26, 300cc, 300cc–2, 300cc–15, 300cc–17, 300cc–20, 300cc–31, 300ee–1, 300ee–2, 300ee–31, 300ee–32, 300ee–34, 300ff–11 to 300ff–13, 300ff–17, 300ff–27, 300ff–28, 300ff–41, 300ff–43, 300ff–49, 300ff–75, 4841, and 9604 of this title, section 1341 of Title 15, Commerce and Trade, section 2001 of Title 25, Indians, and provisions set out as notes under sections 241 and 281 of this title and section 303 of Title 38, Veterans' Benefits] may not be construed as prohibiting the Director of the Centers for Disease Control and Prevention from utilizing for official purposes the term 'CDC' as an acronym for such Centers."

NATIONAL COMMISSION ON ORPHAN DISEASES

Pub. L. 99–91, §4, Aug. 15, 1985, 99 Stat. 388, as amended by Pub. L. 100–290, §4, Apr. 18, 1988, 102 Stat. 92; Pub. L. 102–321, title I, §163(c)(1), July 10, 1992, 106 Stat. 376, provided that:

"(a) ESTABLISHMENT.—There is established the National Commission on Orphan Diseases (hereinafter referred to as the 'Commission').

"(b) DUTY.—The Commission shall assess the activities of the National Institutes of Health, the Food and Drug Administration, other public agencies, and private entities in connection with—

"(1) basic research conducted on rare diseases;

"(2) the use in research on rare diseases of knowledge developed in other research;

"(3) applied and clinical research on the prevention, diagnosis, and treatment of rare diseases; and

"(4) the dissemination to the public, health care professionals, researchers, and drug and medical device manufacturers of knowledge developed in research on rare diseases and other diseases which can be used in the prevention, diagnosis, and treatment of rare diseases.

"(c) REVIEW REQUIREMENTS.—In assessing the activities of the National Institutes of Health, and the Food and Drug Administration in connection with research on rare diseases, the Commission shall review—

"(1) the appropriateness of the priorities currently placed on research on rare diseases;

"(2) the relative effectiveness of grants and contracts when used to fund research on rare diseases;

"(3) the appropriateness of specific requirements applicable to applications for funds for research on rare diseases taking into consideration the reasonable capacity of applicants to meet such requirements;

"(4) the adequacy of the scientific basis for such research, including the adequacy of the research facilities and research resources used in such research and the appropriateness of the scientific training of the personnel engaged in such research;

"(5) the effectiveness of activities undertaken to encourage such research;

"(6) the organization of the peer review process applicable to applications for funds for such research to determine if the organization of the peer review process could be revised to improve the effectiveness of the review provided to proposals for research on rare diseases;

"(7) the effectiveness of the coordination between the national research institutes of the National Institutes of Health, the Food and Drug Administration, and private entities in supporting such research; and

"(8) the effectiveness of activities undertaken to assure that knowledge developed in research on nonrare diseases is, when appropriate, used in research on rare diseases.

"(d) COMPOSITION.—The Commission shall be composed of twenty members appointed by the Secretary of Health and Human Services as follows:

"(1) Ten members shall be appointed from individuals who are not officers or employees of the Government and who by virtue of their training or experience in research on rare diseases or in the treatment of rare diseases are qualified to serve on the Commission.

"(2) Five members shall be appointed from individuals who are not officers or employees of the Government and who have a rare disease or are employed to represent or are members of an organization concerned about rare disease.

"(3) Four nonvoting members shall be appointed for the directors of the national research institutes of the National Institutes of Health which the Secretary determines are involved with rare diseases.

"(4) One nonvoting member shall be appointed from officers or employees of the Food and Drug Administration who the Secretary determines are involved with rare diseases.

A vacancy in the Commission shall be filled in the manner in which the original appointment was made. If any member of the Commission who was appointed to the Commission as a director of a national research institute or as an officer or employee of the Food and Drug Administration leaves that office or position, or if any member of the Commission who was appointed from persons who are not officers or employees of the Government becomes an officer or employee of the Government, such member may continue as a member of the Commission for not longer than the ninety-day period beginning on the date such member leaves that office or position or becomes such an officer or employee, as the case may be.

"(e) TERM.—Members shall be appointed for the life of the Commission.

"(f) COMPENSATION.—

"(1) Except as provided in paragraph (2), members of the Commission shall each be entitled to receive compensation at a rate not to exceed the daily equivalent of the annual rate of basic pay in effect for grade GS–18 of the General Schedule for each day (including traveltime) during which they are engaged in the actual performance of duties as members of the Commission.

"(2) Members of the Commission who are full-time officers or employees of the Government shall receive no additional pay by reason of their service on the Commission.

"(g) CHAIRMAN.—The Chairman of the Commission shall be designated by the members of the Commission.

"(h) STAFF.—Subject to such rules as may be prescribed by the Commission, the Commission may appoint and fix the pay of such personnel as it determines are necessary to enable the Commission to carry out its functions. Personnel shall be appointed subject to the provisions of title 5, United States Code, governing appointments in the competitive service, and shall be paid in accordance with the provisions of chapter 51 and subchapter III of chapter 53 of such title relating to classification and General Schedule pay rates.

"(i) EXPERTS AND CONSULTANTS.—Subject to such rules as may be prescribed by the Commission, the Commission may procure temporary and intermittent services under section 3109(b) of title 5 of the United States Code, but at rates for individuals not to exceed the daily equivalent of the basic pay payable for grade GS–15 of the General Schedule.

"(j) DETAIL OF PERSONNEL.—Upon request of the Commission, the head of any Federal agency is authorized to detail, on a reimbursable basis, any of the personnel of such agency to the Commission to assist the Commission in carrying out its functions.

"(k) ADMINISTRATIVE SUPPORT SERVICES.—The Administrator of General Services shall provide to the Commission on a reimbursable basis such administrative support services as the Commission may request.

"(l) GENERAL AUTHORITY.—The Commission may, for the purpose of carrying out this section, hold such hearings, sit and act at such times and places, take such testimony, and receive such evidence, as the Commission considers appropriate.

"(m) INFORMATION.—The Commission may secure directly from any department or agency of the United States information necessary to enable it to carry out this section. Upon request of the Chairman, the head of such department or agency shall furnish such information to the Commission.

"(n) REPORT.—The Commission shall transmit to the Secretary and to each House of the Congress a report not later than February 1, 1989, on the activities of the Commission. The report shall contain a detailed statement of the findings and conclusions of the Commission, together with its recommendations for—

"(1) a long range plan for the use of public and private resources to improve research into rare diseases and to assist in the prevention, diagnosis, and treatment of rare diseases; and

"(2) such legislation or administrative actions as it considers appropriate.

"(o) TERMINATION.—The Commission shall terminate 90 days after the date of the submittal of its report under subsection (n).

"(p) FUNDS.—The Director of the National Institutes of Health shall make available $1,000,000 to the Commission from appropriations for fiscal year 1986 for the National Institutes of Health."

[1] *So in original. The semicolon probably should be a comma.*

[2] *See References in Text note below.*

§237. Silvio O. Conte Senior Biomedical Research and Biomedical Product Assessment Service

(a) Creation; number of members

(1) There shall be in the Public Health Service a Silvio O. Conte Senior Biomedical Research and Biomedical Product Assessment Service (in this section referred to as the "Service"), not to exceed 2,000 members, the purpose of which is to recruit and retain outstanding and qualified scientific and technical experts in the fields of biomedical research, clinical research evaluation, and biomedical product assessment.

(2) The authority established in paragraph (1) may not be construed to require the Secretary to reduce the number of employees serving under any other employment system in order to offset the number of members serving in the Service.

(3) The Secretary shall assign experts under this section to agencies within the Department of Health and Human Services taking into account the need for the expertise of such expert.

(b) Appointments; qualifications; provisions inapplicable to members

The Service shall be appointed by the Secretary without regard to the provisions of title 5 regarding appointment, and shall consist of individuals outstanding in the field of biomedical research, clinical research evaluation, or biomedical product assessment. No individual may be appointed to the Service unless such individual (1) has earned a doctoral level degree in biomedicine or a related field, or a doctoral or master's level degree in engineering, bioinformatics, or a related or emerging field, and (2) meets the qualification standards prescribed by the Office of Personnel Management for appointment to a position at GS–15 of the General Schedule. Notwithstanding any previous applicability to an individual who is a member of the Service, the provisions of subchapter I of chapter 35 (relating to retention preference), chapter 43 (relating to performance appraisal and performance actions), chapter 51 (relating to classification), subchapter III of chapter 53 (relating to General Schedule pay rates), and chapter 75 (relating to adverse actions) of title 5 shall not apply to any member of the Service.

(c) Performance appraisal system

The Secretary shall develop a performance appraisal system designed to—

(1) provide for the systematic appraisal of the performance of members, and

(2) encourage excellence in performance by members.

(d) Pay of members

(1) The Secretary shall determine, subject to the provisions of this subsection, the pay of members of the Service.

(2) The pay of a member of the Service shall not be less than the minimum rate payable for GS–15 of the General Schedule and shall not exceed the amount of annual compensation (excluding expenses) specified in section 102 of title 3.

(e) Career and noncareer appointment of certain individuals

Subject to the following sentence, the Secretary may, notwithstanding the provisions of title 5 regarding appointment, appoint an individual who is separated from the Service involuntarily and without cause to a position in the competitive civil service at GS–15 of the General Schedule, and such appointment shall be a career appointment. In the case of such an individual who immediately prior to his appointment to the Service was not a career appointee in the civil service or the Senior Executive Service, such appointment shall be in the excepted civil service and may not exceed a period of 2 years.

(f) Rules and regulations

The Secretary shall promulgate such rules and regulations, not inconsistent with this section, as may be necessary for the efficient administration of the Service.

(July 1, 1944, ch. 373, title II, §228, as added Pub. L. 101–509, title V, §529 [title III, §304(a)], Nov. 5, 1990, 104 Stat. 1427, 1463; amended Pub. L. 103–43, title XX, §2001, June 10, 1993, 107 Stat. 208; Pub. L. 114–255, div. A, title III, §3071(a), Dec. 13, 2016, 130 Stat. 1133.)

EDITORIAL NOTES

REFERENCES IN TEXT

The General Schedule, referred to in subsecs. (b), (d)(2), and (e), is set out under section 5332 of Title 5, Government Organization and Employees.

The provisions of title 5 regarding appointments, referred to in subsecs. (b) and (e), are classified to section 3301 et seq. of Title 5.

AMENDMENTS

2016—Pub. L. 114–255, §3071(a)(1), inserted "and Biomedical Product Assessment" after "Research" in section catchline.

Subsec. (a)(1). Pub. L. 114–255, §3071(a)(2)(A), substituted "Silvio O. Conte Senior Biomedical Research and Biomedical Product Assessment Service (in this section referred to as the 'Service'), not to exceed 2,000 members, the purpose of which is to recruit and retain outstanding and qualified scientific and technical experts in the fields of biomedical research, clinical research evaluation, and biomedical product assessment" for "Silvio O. Conte Senior Biomedical Research Service, not to exceed 500 members".

Subsec. (a)(2). Pub. L. 114–255, §3071(a)(2)(B), amended par. (2) generally. Prior to amendment, par. (2) read as follows: "The authority established in paragraph (1) regarding the number of members in the Silvio O. Conte Senior Biomedical Research Service is in addition to any authority established regarding the number of members in the commissioned Regular Corps, in the Reserve Corps, and in the Senior Executive Service. Such paragraph may not be construed to require that the number of members in the commissioned Regular Corps, in the Reserve Corps, or in the Senior Executive Service be reduced to offset the number of members serving in the Silvio O. Conte Senior Biomedical Research Service (in this section referred to as the 'Service')."

Subsec. (a)(3). Pub. L. 114–255, §3071(a)(2)(C), added par. (3).

Subsec. (b). Pub. L. 114–255, §3071(a)(3)(A), substituted ", clinical research evaluation, or biomedical product assessment" for "or clinical research evaluation" in introductory provisions.

Subsec. (b)(1). Pub. L. 114–255, §3071(a)(3)(B), inserted "or a doctoral or master's level degree in engineering, bioinformatics, or a related or emerging field," after "related field,".

Subsec. (d)(2). Pub. L. 114–255, §3071(a)(4), substituted "and shall not exceed the amount of annual compensation (excluding expenses) specified in section 102 of title 3" for "and shall not exceed the rate payable for level I of the Executive Schedule unless approved by the President under section 5377(d)(2) of title 5".

Subsecs. (e) to (g). Pub. L. 114–255, §3071(a)(5), (6), redesignated subsecs. (f) and (g) as (e) and (f), respectively, and struck out former subsec. (e). Prior to amendment, text of subsec. (e) read as follows: "The Secretary may, upon the request of a member who—

"(1) performed service in the employ of an institution of higher education immediately prior to his appointment as a member of the Service, and

"(2) retains the right to continue to make contributions to the retirement system of such institution, "contribute an amount not to exceed 10 percent per annum of the member's basic pay to such institution's retirement system on behalf of such member. A member who requests that such contribution be made shall not be covered by, or earn service credit under, any retirement system established for employees of the United States under title 5, but such service shall be creditable for determining years of service under section 6303(a) of such title."

1993—Pub. L. 103–43, §2001(b), substituted "Silvio O. Conte Senior Biomedical Research Service" for "Senior Biomedical Research Service" in section catchline.

Subsec. (a). Pub. L. 103–43, §2001(a), amended subsec. (a) generally. Prior to amendment, subsec. (a) read as follows: "There shall be in the Public Health Service a Senior Biomedical Research Service (hereinafter in this section referred to as the 'Service'), not to exceed 350 members at any time."

STATUTORY NOTES AND RELATED SUBSIDIARIES

EFFECTIVE DATE

Section effective on the 90th day following Nov. 5, 1990, see section 529 [title III, §304(c)] of Pub. L. 101–509, set out as an Effective Date of 1990 Amendment note under section 212 of this title.

§237a. Health and Human Services Office on Women's Health

(a) Establishment of Office

There is established within the Office of the Secretary, an Office on Women's Health (referred to in this section as the "Office"). The Office shall be headed by a Deputy Assistant Secretary for Women's Health who may report to the Secretary.

(b) Duties

The Secretary, acting through the Office, with respect to the health concerns of women, shall—

(1) establish short-range and long-range goals and objectives within the Department of Health and Human Services and, as relevant and appropriate, coordinate with other appropriate offices on activities within the Department that relate to disease prevention, health promotion, service delivery, research, and public and health care professional education, for issues of particular concern to women throughout their lifespan; [1]

(2) provide expert advice and consultation to the Secretary concerning scientific, legal, ethical, and policy issues relating to women's health;

(3) monitor the Department of Health and Human Services' offices, agencies, and regional activities regarding women's health and identify needs regarding the coordination of activities, including intramural and extramural multidisciplinary activities;

(4) establish a Department of Health and Human Services Coordinating Committee on Women's Health, which shall be chaired by the Deputy Assistant Secretary for Women's Health and composed of senior level representatives from each of the agencies and offices of the Department of Health and Human Services;

(5) establish a National Women's Health Information Center to—

(A) facilitate the exchange of information regarding matters relating to health information, health promotion, preventive health services, research advances, and education in the appropriate use of health care;

(B) facilitate access to such information;

(C) assist in the analysis of issues and problems relating to the matters described in this paragraph; and

(D) provide technical assistance with respect to the exchange of information (including facilitating the development of materials for such technical assistance);

(6) coordinate efforts to promote women's health programs and policies with the private sector; and

(7) through publications and any other means appropriate, provide for the exchange of information between the Office and recipients of grants, contracts, and agreements under subsection (c), and between the Office and health professionals and the general public.

(c) Grants and contracts regarding duties

(1) Authority

In carrying out subsection (b), the Secretary may make grants to, and enter into cooperative agreements, contracts, and interagency agreements with, public and private entities, agencies, and organizations.

(2) Evaluation and dissemination

The Secretary shall directly or through contracts with public and private entities, agencies, and

organizations, provide for evaluations of projects carried out with financial assistance provided under paragraph (1) and for the dissemination of information developed as a result of such projects.

(d) Reports

Not later than 1 year after March 23, 2010, and every second year thereafter, the Secretary shall prepare and submit to the appropriate committees of Congress a report describing the activities carried out under this section during the period for which the report is being prepared.

(e) Authorization of appropriations

For the purpose of carrying out this section, there are authorized to be appropriated such sums as may be necessary for each of the fiscal years 2010 through 2014.

(July 1, 1944, ch. 373, title II, §229, as added Pub. L. 111–148, title III, §3509(a)(1), Mar. 23, 2010, 124 Stat. 531.)

STATUTORY NOTES AND RELATED SUBSIDIARIES

CONSTRUCTION

Pub. L. 111–148, title III, §3509(j), Mar. 23, 2010, 124 Stat. 537, provided that: "Nothing in this section [enacting this section, sections 242s, 299b–24a, and 914 of this title and section 399b of Title 21, Food and Drugs, amending sections 287d, 290aa, 299b–25, and 299b–26 of this title, and enacting provisions set out as notes under this section] (or the amendments made by this section) shall be construed to limit the authority of the Secretary of Health and Human Services with respect to women's health, or with respect to activities carried out through the Department of Health and Human Services on the date of enactment of this section [Mar. 23, 2010]."

TRANSFER OF FUNCTIONS

Pub. L. 111–148, title III, §3509(a)(2), Mar. 23, 2010, 124 Stat. 533, provided that: "There are transferred to the Office on Women's Health (established under section 229 of the Public Health Service Act [42 U.S.C. 237a], as added by this section), all functions exercised by the Office on Women's Health of the Public Health Service prior to the date of enactment of this section [Mar. 23, 2010], including all personnel and compensation authority, all delegation and assignment authority, and all remaining appropriations. All orders, determinations, rules, regulations, permits, agreements, grants, contracts, certificates, licenses, registrations, privileges, and other administrative actions that—

"(A) have been issued, made, granted, or allowed to become effective by the President, any Federal agency or official thereof, or by a court of competent jurisdiction, in the performance of functions transferred under this paragraph; and

"(B) are in effect at the time this section takes effect, or were final before the date of enactment of this section and are to become effective on or after such date,

shall continue in effect according to their terms until modified, terminated, superseded, set aside, or revoked in accordance with law by the President, the Secretary, or other authorized official, a court of competent jurisdiction, or by operation of law."

INFORMATION AND AWARENESS ON EATING DISORDERS

Pub. L. 114–255, div. B, title XIII, §13005, Dec. 13, 2016, 130 Stat. 1286, provided that:

"(a) INFORMATION.—The Secretary of Health and Human Services, acting through the Director of the Office on Women's Health, may—

"(1) update information, related fact sheets, and resource lists related to eating disorders that are available on the public Internet website of the National Women's Health Information Center sponsored by the Office on Women's Health, to include—

"(A) updated findings and current research related to eating disorders, as appropriate; and

"(B) information about eating disorders, including information related to males and females;

"(2) incorporate, as appropriate, and in coordination with the Secretary of Education, information from publicly available resources into appropriate obesity prevention programs developed by the Office on Women's Health; and

"(3) make publicly available (through a public Internet website or other method) information, related fact sheets, and resource lists, as updated under paragraph (1), and the information incorporated into

appropriate obesity prevention programs under paragraph (2).

"(b) AWARENESS.—The Secretary of Health and Human Services may advance public awareness on—

"(1) the types of eating disorders;

"(2) the seriousness of eating disorders, including prevalence, comorbidities, and physical and mental health consequences;

"(3) methods to identify, intervene, refer for treatment, and prevent behaviors that may lead to the development of eating disorders;

"(4) discrimination and bullying based on body size;

"(5) the effects of media on self-esteem and body image; and

"(6) the signs and symptoms of eating disorders."

NO NEW REGULATORY AUTHORITY

Pub. L. 111–148, title III, §3509(h), Mar. 23, 2010, 124 Stat. 537, provided that: "Nothing in this section [enacting this section, sections 242s, 299b–24a, and 914 of this title and section 399b of Title 21, Food and Drugs, amending sections 287d, 290aa, 299b–25, and 299b–26 of this title, and enacting provisions set out as notes under this section] and the amendments made by this section may be construed as establishing regulatory authority or modifying any existing regulatory authority."

LIMITATION ON TERMINATION

Pub. L. 111–148, title III, §3509(i), Mar. 23, 2010, 124 Stat. 537, provided that: "Notwithstanding any other provision of law, a Federal office of women's health (including the Office of Research on Women's Health of the National Institutes of Health) or Federal appointive position with primary responsibility over women's health issues (including the Associate Administrator for Women's Services under the Substance Abuse and Mental Health Services Administration) that is in existence on the date of enactment of this section [Mar. 23, 2010] shall not be terminated, reorganized, or have any of it's [sic] powers or duties transferred unless such termination, reorganization, or transfer is approved by Congress through the adoption of a concurrent resolution of approval."

EXECUTIVE DOCUMENTS

EX. ORD. NO. 14120. ADVANCING WOMEN'S HEALTH RESEARCH AND INNOVATION

Ex. Ord. No. 14120, Mar. 18, 2024, 89 F.R. 20095, provided:

By the authority vested in me as President by the Constitution and the laws of the United States of America, it is hereby ordered as follows:

SECTION 1. *Policy*. My Administration is committed to getting women the answers they need about their health. For far too long, scientific and biomedical research excluded women and undervalued the study of women's health. The resulting research gaps mean that we know far too little about women's health across women's lifespans, and those gaps are even more prominent for women of color, older women, and women with disabilities.

The notion of including women in clinical trials used to be revolutionary—which means many diagnostics and treatments were developed without women in mind and thus failed to account for women's health. Over 30 years ago, the Congress passed the landmark National Institutes of Health Revitalization Act of 1993 (Public Law 103–43) [see Tables for classification] to direct the National Institutes of Health (NIH), the largest public funder of biomedical research in the world, to include women and people of color in NIH-funded clinical research. In 2016, the Congress built on these requirements in the 21st Century Cures Act (Public Law 114–255) [see Tables for classification], which directed the NIH to further its pursuit of women's health research, including by strengthening clinical trial inclusion and data analysis, developing research and data standards to advance the study of women's health, and improving NIH-wide coordination on women's health research.

These policies led to significant increases in women's participation in clinical trials, and ongoing investments in biomedical research have supported breakthroughs in women's health. Through the discovery of genetic factors that increase the risk of breast cancer and innovations in mammography, we have transformed our approach to prevention, early detection, and treatment, and have improved outcomes for women facing a breast cancer diagnosis. We have improved access to life-saving treatments for women with severe heart failure by ensuring that the devices they need are the right size for a woman's body. We have also identified some of the most characteristic symptoms of heart attack in women, which are different from those in men—discoveries that have helped deliver faster treatment to women when every second counts. This is what we can achieve when we invest in women's health research.

It is time, once again, to pioneer the next generation of discoveries in women's health. My Administration seeks to fundamentally change how we approach and fund women's health research in the United States. That is why I established the first-ever White House Initiative on Women's Health Research (Initiative)—which is within the Office of the First Lady and includes a wide array of executive departments and agencies (agencies) and White House offices—to accelerate research that will provide the tools we need to prevent, diagnose, and treat conditions that affect women uniquely, disproportionately, or differently.

Together with the First Lady's tireless efforts, the Initiative is already galvanizing the Federal Government to advance women's health, including through investments in innovation and improved coordination within and across agencies. We are also mobilizing leaders across a wide range of sectors, including industry, philanthropy, and the medical and research communities, to improve women's health.

It is the policy of my Administration to advance women's health research, close health disparities, and ensure that the gains we make in research laboratories are translated into real-world clinical benefits for women. It is also the policy of my Administration to ensure that women have access to high-quality, evidence-based health care and to improve health outcomes for women across their lifespans and throughout the country.

I will continue to call on the Congress to provide the transformative investments necessary to help our researchers and scientists answer today's most pressing questions related to women's health. Investing in innovation in women's health is an investment in the future of American families and the economy. At the same time, agencies must use their existing authorities to advance and integrate women's health across the Federal research portfolio, close research gaps, and make investments that maximize our ability to prevent, diagnose, and treat health conditions in women.

SEC. 2. *Definitions*. For purposes of this order:

(a) The term "women's health research" means research aimed at expanding knowledge of women's health across their lifespans, which includes the study and analysis of conditions specific to women, conditions that disproportionately impact women, and conditions that affect women differently.

(b) The term "White House Initiative on Women's Health Research" means the interagency, advisory body established by the Presidential Memorandum of November 13, 2023 (White House Initiative on Women's Health Research) [set out below], to advance women's health research.

(c) The term "agency Members of the Initiative" refers to the Secretary of Defense, the Secretary of Agriculture, the Secretary of Health and Human Services, the Secretary of Veterans Affairs, the Administrator of the Environmental Protection Agency, and the Director of the National Science Foundation.

SEC. 3. *Further Integrating Women's Health Research in Federal Research Programs*. (a) Building on research and data standards issued by the NIH in 2016, agency Members of the Initiative shall consider actions to develop or strengthen research and data standards that enhance the study of women's health across all relevant, federally funded research and other Federal funding opportunities. Agency Members of the Initiative shall consider issuing new guidance, application materials, reporting requirements, and research dissemination strategies to advance the study of women's health, including to:

(i) require applicants for Federal research funding, as appropriate, to explain how their proposed study designs will consider and advance our knowledge of women's health, including through the adoption of standard application language;

(ii) consider women's health, as appropriate, during the evaluation of research proposals that address medical conditions that may affect women differently or disproportionately;

(iii) improve accountability for grant recipients, including, as appropriate, by requiring regular reporting on their implementation of, and compliance with, research and data standards related to women's health, including compliance with recruitment milestones; and

(iv) improve the recruitment, enrollment, and retention of women in clinical trials, including, as appropriate, by reducing barriers through technological and data sciences advances.

(b) Within 30 days of the date of this order [Mar. 18, 2024], the Chair of the Initiative and the Director of the NIH Office of Research on Women's Health, in consultation with the Director of the Office of Management and Budget (OMB), shall establish and co-chair a subgroup of the Initiative to promote interagency alignment and consistency in the development of agency research and data standards to enhance the study of women's health.

(c) Within 90 days of the date of this order, agency Members of the Initiative shall report to the Chair of the Initiative on actions taken to strengthen research and data standards to enhance the study and analysis of women's health and related conditions.

(d) Within 180 days of the date of this order and on an annual basis thereafter, agency Members of the Initiative shall report to the President on the status of implementation of research and data standards.

SEC. 4. *Prioritizing Federal Investments in Women's Health Research*. (a) Agency Members of the

Initiative shall identify and, as appropriate and consistent with applicable law, prioritize grantmaking and other awards to advance women's health research, with an emphasis on:

(i) promoting collaborative, interdisciplinary research across fields and areas of expertise;

(ii) addressing health disparities and inequities affecting women, including those related to race, ethnicity, age, socioeconomic status, disability, and exposure to environmental factors and contaminants that can directly affect health; and

(iii) supporting the translation of research advancements into improved health outcomes.

(b) Agency Members of the Initiative shall take steps to promote the availability of federally funded research and other Federal funding opportunities to advance women's health, including through the development and inclusion of standard language related to women's health, as appropriate, in all relevant notices of funding opportunity and through better facilitating potential grant applicants' access to information about funding opportunities related to women's health research.

(c) To advance innovation, commercialization, and risk mitigation, agency Members of the Initiative shall:

(i) identify and, as appropriate and consistent with applicable law, seek ways to use innovation funds, challenges, prizes, and other mechanisms to spur innovation in women's health;

(ii) invest in innovation to accelerate women's health research, including through or in collaboration with the Advanced Research Projects Agency for Health and the Congressionally Directed Medical Research Programs;

(iii) support the role of small businesses and entrepreneurs in advancing innovation in women's health research, including through Small Business Innovation Research Programs and Small Business Technology Transfer Programs; and

(iv) invest in translational science to convert research findings and discoveries into treatments and interventions that improve women's health outcomes and reduce health disparities, including through the Department of Agriculture National Institute of Food and Agriculture research programs.

(d) In implementing section 8(b) of Executive Order 14110 of October 30, 2023 (Safe, Secure, and Trustworthy Development and Use of Artificial Intelligence) [15 U.S.C. 9401 note], the Secretary of Health and Human Services, in consultation with the Director of the National Science Foundation, shall consider the opportunities for and challenges that affect women's health research in the responsible deployment and use of artificial intelligence (AI) and AI-enabled technologies in the health and human services sector.

SEC. 5. *Galvanizing Research on Women's Midlife Health*. (a) Within 90 days of the date of this order, to address research gaps in understanding women's health and diseases and conditions associated with women's midlife and later years, the Secretary of Health and Human Services shall:

(i) launch a comprehensive assessment of the current state of the science on menopause to develop an evidence-based research agenda that will guide Federal and private sector investments in menopause-related research;

(ii) evaluate evidence-based interventions and strategies to improve women's experiences in the menopausal and perimenopausal periods, including the delivery of treatments for women experiencing menopause in clinical care settings;

(iii) consider developing new common data elements and survey tools to expand the ethical and equitable collection of data on issues related to women's midlife health; and

(iv) develop new comprehensive resources to help ensure that the public has evidence-based information about menopause, including menopause-related research initiatives, findings, and symptom-prevention and treatment options.

(b) The Secretary of Defense and the Secretary of Veterans Affairs shall evaluate the needs of women service members and veterans related to midlife health and shall develop recommendations to support improved treatment and targeted research of midlife health issues, including menopausal symptoms.

SEC. 6. *Assessing Unmet Needs to Support Women's Health Research*. The Director of OMB and the Assistant to the President and Director of the Gender Policy Council (Directors) shall lead an effort, in collaboration with the Initiative, to identify current gaps in Federal funding for women's health research and shall submit recommendations to the President describing the additional funding and programming necessary to catalyze research on women's health, including in priority areas within women's health as identified by the Initiative, as follows:

(a) Within 90 days of the date of this order, the Directors shall, in consultation with the Initiative, develop guidance for assessing additional funding that agencies need to close research gaps in women's health.

(b) Within 180 days of the date of this order, Members of the Initiative shall consult the guidance described in subsection (a) of this section and shall each submit a report to the Directors that identifies the funding needed to catalyze research on women's health.

(c) Based on the reports described in subsection (b) of this section, the Directors shall develop and submit

recommendations to the President on steps the Federal Government should take to catalyze research on women's health. These recommendations shall identify any statutory, regulatory, budgetary, or other changes that may be necessary to ensure that Federal laws, policies, practices, and programs support women's health research more effectively.

(d) Following the submission of the recommendations described in subsection (c) of this section, each Member of the Initiative shall report annually to the Directors on progress made in response to those recommendations and to improve the study of women's health. The Director of OMB shall provide a summary of Members' progress and any new recommendations to the President on an annual basis, consult with each Member on their women's health research funding needs during the annual budget process, and calculate Federal funding for women's health research on an annual basis.

SEC. 7. *General Provisions*. (a) Nothing in this order shall be construed to impair or otherwise affect:

(i) the authority granted by law to an executive department or agency, or the head thereof; or

(ii) the functions of the Director of the Office of Management and Budget relating to budgetary, administrative, or legislative proposals.

(b) This order shall be implemented consistent with applicable law and subject to the availability of appropriations.

(c) This order is not intended to, and does not, create any right or benefit, substantive or procedural, enforceable at law or in equity by any party against the United States, its departments, agencies, or entities, its officers, employees, or agents, or any other person.

J.R. BIDEN, JR.

WHITE HOUSE INITIATIVE ON WOMEN'S HEALTH RESEARCH

Memorandum of President of the United States, Nov. 13, 2023, 88 F.R. 80085, provided:

Memorandum for the Heads of Executive Departments and Agencies

By the authority vested in me as President by the Constitution and the laws of the United States of America, it is hereby ordered as follows:

SECTION 1. *Policy*. Women make up half of the United States population, but for too long, a lack of timely research and data on women's health has left health care providers without important tools to diagnose and treat millions of women with debilitating conditions, including cardiovascular disease, Alzheimer's disease, autoimmune disorders, mental health conditions, and conditions specific to women such as endometriosis and fibroids.

Beyond the immediate health consequences, underinvesting in women's health research can decrease women's well-being and quality of life, hold women back in the workplace, and affect their families' economic security. By contrast, increasing investments in women's health research can yield broad societal gains, including lower health care costs and a more productive and inclusive workforce.

To address pervasive gaps in our knowledge of women's health, we must accelerate research on the unique health needs of women across their lifespans. Research gaps are especially acute for diseases and conditions that are more prevalent among women and for health conditions associated with women's midlife and later years, including perimenopause and menopause. Gaps are often even more significant for those who have been historically underrepresented in, or excluded from, research.

We can—and must—increase our efforts to invest in research that maximizes our ability to prevent, diagnose, and treat health conditions in women across the United States. Meaningful progress requires robust, dedicated research infrastructure—including a strong, diverse research workforce—and investment within and beyond the Federal Government. We all have a part to play in galvanizing women's health research, developing innovative and cutting-edge interventions that promote women's health, and ensuring that women across the United States have access to high-quality health care.

Accordingly, I hereby direct the following actions:

SEC. 2. *Establishment*. There is established, within the Office of the First Lady, a White House Initiative on Women's Health Research (Initiative).

SEC. 3. *Membership*. (a) The Initiative shall be led by a Chair designated by the President who shall hold a dual role in the Office of the First Lady and on the staff of the White House Gender Policy Council.

(b) In addition to the Chair, the members of the Initiative shall consist of the heads of the following executive departments and agencies (agencies) and offices, or their designees:

(i) the Office of the Vice President;

(ii) the Department of Defense;

(iii) the Department of Agriculture;

(iv) the Department of Health and Human Services;

(v) the Department of Veterans Affairs;

(vi) the Environmental Protection Agency;
(vii) the Office of Management and Budget;
(viii) the Domestic Policy Council;
(ix) the Office of Science and Technology Policy;
(x) the National Science Foundation;
(xi) the National Institutes of Health;
(xii) the Food and Drug Administration;
(xiii) the Centers for Disease Control and Prevention;
(xiv) the Indian Health Service;
(xv) the Centers for Medicare and Medicaid Services;
(xvi) the Health Resources and Services Administration;
(xvii) the Substance Abuse and Mental Health Services Administration;
(xviii) the Agency for Healthcare Research and Quality;
(xix) the Advanced Research Projects Agency for Health;
(xx) the National Institutes of Health Office of Research on Women's Health; and
(xxi) the heads of such other agencies and offices as the Chair may, from time to time, designate.

(c) The Department of Health and Human Services shall provide funding and administrative support as may be necessary for the performance and functions of the Initiative, to the extent permitted by law and within existing appropriations.

(d) At the direction of the Chair, the Initiative may establish subgroups consisting exclusively of Initiative members or their designees, as appropriate, including to coordinate across agency offices dedicated to women's health.

SEC. 4. *Mission and Functions*. (a) The mission of the Initiative is to advance women's health research in the United States. The functions of the Initiative are advisory only and shall include, consistent with applicable law, the following actions with the goal of advancing women's health research:

(i) assessing the Federal research landscape to identify opportunities for additional investments that could catalyze significant progress in addressing women's health needs;

(ii) setting Initiative-wide priorities to help guide strategic Federal research investments;

(iii) improving coordination among agencies and offices pursuing women's health research, including by better integrating research efforts and facilitating interdisciplinary research;

(iv) developing policy recommendations to better ensure that the health needs of women are considered, assessed, and reported for Federal research and data collection efforts, where feasible and in accordance with current research and data collection and analysis guidelines;

(v) forming targeted recommendations to address health disparities and inequities affecting women, including those related to race, ethnicity, age, socioeconomic status, disability, and exposure to environmental factors and contaminants that can directly affect health;

(vi) developing recommendations to support the translation of research advancements into practical benefits for patients and providers;

(vii) identifying opportunities to develop public-private partnerships and to increase coordination of Federal efforts with the private and philanthropic sectors in order to drive innovation;

(viii) engaging the scientific and research communities, including by helping promote the publication and dissemination of actionable research and data on women's health and by making Federal datasets available to support research;

(ix) assessing opportunities to recruit, train, and support women pursuing health and biomedical research careers to help strengthen and diversify the research workforce; and

(x) identifying ways to increase public awareness of the need for greater investment in and attention to women's health research, as well as women's health outcomes.

(b) Consistent with the objectives of this memorandum and applicable law, the Initiative may gather relevant information from external stakeholders, including Federal, State, local, Tribal, and territorial government officials; researchers and academics; women's health organizations; philanthropic leaders; industry stakeholders; and other entities and persons that may assist the Initiative in accomplishing the objectives of this memorandum.

SEC. 5. *Recommendations to the President*. (a) Within 45 days of the date of this memorandum [Nov. 13, 2023], the members of the Initiative or their designees shall provide recommendations to the President, through the Chair, on concrete actions that agencies and offices can take to advance women's health research.

(b) The heads of agencies and offices participating in the Initiative shall assist and provide information to the Chair, consistent with applicable law, as may be necessary to carry out the functions of the Initiative. Each participating agency and office shall bear its own expense for participating in the Initiative.

(c) The heads of agencies and offices participating in the Initiative, or their designees, shall inform the President, through the Chair, on progress implementing this memorandum at least twice each year.

SEC. 6. *General Provisions*. (a) Nothing in this memorandum shall be construed to impair or otherwise affect:

(i) the authority granted by law to an executive department or agency, or the head thereof; or

(ii) the functions of the Director of the Office of Management and Budget relating to budgetary, administrative, or legislative proposals.

(b) This memorandum shall be implemented consistent with applicable law and subject to the availability of appropriations.

(c) This memorandum is not intended to, and does not, create any right or benefit, substantive or procedural, enforceable at law or in equity by any party against the United States, its departments, agencies, or entities, its officers, employees, or agents, or any other person.

(d) The Secretary of Health and Human Services is authorized and directed to publish this memorandum in the Federal Register.

J.R. BIDEN, JR.

[1] *So in original. Probably should be "lifespans;".*

PART B—MISCELLANEOUS PROVISIONS

EDITORIAL NOTES

CODIFICATION

This part was classified to subchapter XXV (§300aaa et seq.) of this chapter prior to its renumbering by Pub. L. 103–43, title XX, §2010(a)(1)–(3), June 10, 1993, 107 Stat. 213.

§238. Gifts for benefit of Service

(a) Acceptance by Secretary

The Secretary of Health and Human Services is authorized to accept on behalf of the United States gifts made unconditionally by will or otherwise for the benefit of the Service or for the carrying out of any of its functions. Conditional gifts may be so accepted if recommended by the Surgeon General, and the principal of and income from any such conditional gift shall be held, invested, reinvested, and used in accordance with its conditions, but no gift shall be accepted which is conditioned upon any expenditure not to be met therefrom or from the income thereof unless such expenditure has been approved by Act of Congress.

(b) Depository of funds; availability for expenditure

Any unconditional gift of money accepted pursuant to the authority granted in subsection (a) of this section, the net proceeds from the liquidation (pursuant to subsection (c) or subsection (d) of this section) of any other property so accepted, and the proceeds of insurance on any such gift property not used for its restoration, shall be deposited in the Treasury of the United States and are hereby appropriated and shall be held in trust by the Secretary of the Treasury for the benefit of the Service, and he may invest and reinvest such funds in interest-bearing obligations of the United States or in obligations guaranteed as to both principal and interest by the United States. Such gifts and the income from such investments shall be available for expenditure in the operation of the Service and the performance of its functions, subject to the same examination and audit as is provided for appropriations made for the Service by Congress.

(c) Evidences of unconditional gifts of intangible property

The evidences of any unconditional gift of intangible personal property, other than money, accepted pursuant to the authority granted in subsection (a) of this section shall be deposited with the

Secretary of the Treasury and he, in his discretion, may hold them, or liquidate them except that they shall be liquidated upon the request of the Secretary of Health and Human Services, whenever necessary to meet payments required in the operation of the Service or the performance of its functions. The proceeds and income from any such property held by the Secretary of the Treasury shall be available for expenditure as is provided in subsection (b) of this section.

(d) Real property or tangible personal property

The Secretary of Health and Human Services shall hold any real property or any tangible personal property accepted unconditionally pursuant to the authority granted in subsection (a) of this section and he shall permit such property to be used for the operation of the Service and the performance of its functions or he may lease or hire such property, and may insure such property, and deposit the income thereof with the Secretary of the Treasury to be available for expenditure as provided in subsection (b) of this section: *Provided,* That the income from any such real property or tangible personal property shall be available for expenditure in the discretion of the Secretary of Health and Human Services for the maintenance, preservation, or repair and insurance of such property and that any proceeds from insurance may be used to restore the property insured. Any such property when not required for the operation of the Service or the performance of its functions may be liquidated by the Secretary of Health and Human Services, and the proceeds thereof deposited with the Secretary of the Treasury, whenever in his judgment the purposes of the gifts will be served thereby.

(July 1, 1944, ch. 373, title II, §231, formerly title V, §501, 58 Stat. 709; July 3, 1946, ch. 538, §10, 60 Stat. 425; June 16, 1948, ch. 481, §6(b), 62 Stat. 469; 1953 Reorg. Plan No. 1, §§5, 8, eff. Apr. 11, 1953, 18 F.R. 2053, 67 Stat. 631; Pub. L. 90–574, title V, §503(b), Oct. 15, 1968, 82 Stat. 1012; Pub. L. 96–88, title V, §509(b), Oct. 17, 1979, 93 Stat. 695; renumbered title XXI, §2101, Pub. L. 98–24, §2(a)(1), Apr. 26, 1983, 97 Stat. 176; renumbered title XXIII, §2301, Pub. L. 99–660, title III, §311(a), Nov. 14, 1986, 100 Stat. 3755; renumbered title XXV, §2501, Pub. L. 100–607, title II, §201(1), (2), Nov. 4, 1988, 102 Stat. 3062; renumbered title XXVI, §2601, Pub. L. 100–690, title II, §2620(a), Nov. 18, 1988, 102 Stat. 4244; renumbered title XXVII, §2701, Pub. L. 101–381, title I, §101(1), (2), Aug. 18, 1990, 104 Stat. 576; renumbered title II, §231, Pub. L. 103–43, title XX, §2010(a)(1)–(3), June 10, 1993, 107 Stat. 213.)

EDITORIAL NOTES

CODIFICATION

Section was formerly classified to section 300aaa of this title prior to renumbering by Pub. L. 103–43, to section 300cc of this title prior to renumbering by Pub. L. 100–607, to section 300aa of this title prior to renumbering by Pub. L. 99–660, and to section 219 of this title prior to renumbering by Pub. L. 98–24.

AMENDMENTS

1968—Subsec. (e). Pub. L. 90–574 struck out subsec. (e) which provided for acknowledgment of donations of $50,000 or more in aid of research by the establishment of suitable memorials within the National Institutes of Health and the National Institute of Mental Health.

1948—Subsec. (e). Act June 16, 1948, substituted "National Institutes of Health" for "National Institute of Health".

1946—Subsec. (e). Act July 3, 1946, inserted reference to National Institute of Mental Health.

STATUTORY NOTES AND RELATED SUBSIDIARIES

CHANGE OF NAME

"Secretary of Health and Human Services" substituted for "Secretary of Health, Education, and Welfare" in subsecs. (a), (c), and (d) pursuant to section 509(b) of Pub. L. 96–88, which is classified to section 3508(b) of Title 20, Education.

EXECUTIVE DOCUMENTS

TRANSFER OF FUNCTIONS

Functions of Public Health Service, Surgeon General of Public Health Service, and all other officers and employees of Public Health Service, and functions of all agencies of or in Public Health Service transferred to Secretary of Health, Education, and Welfare by Reorg. Plan No. 3 of 1966, eff. June 25, 1966, 31 F.R. 8855, 80 Stat. 1610, set out as a note under section 202 of this title.

Functions of Federal Security Administrator transferred to Secretary of Health, Education, and Welfare and all agencies of Federal Security Agency transferred to Department of Health, Education, and Welfare by section 5 of Reorg. Plan No. 1 of 1953, set out as a note under section 3501 of this title. Federal Security Agency and office of Administrator abolished by section 8 of Reorg. Plan No. 1 of 1953.

§238a. Use of immigration station hospitals

The Immigration and Naturalization Service may, by agreement of the heads of the departments concerned, permit the Public Health Service to use hospitals at immigration stations for the care of Public Health Service patients. The Surgeon General shall reimburse the Immigration and Naturalization Service for the actual cost of furnishing fuel, light, water, telephone, and similar supplies and services, which reimbursement shall be covered into the proper Immigration and Naturalization Service appropriation, or such costs may be paid from working funds established as provided by law, but no charge shall be made for the expense of physical upkeep of the hospitals. The Immigration and Naturalization Service shall reimburse the Surgeon General for the care and treatment of persons detained in hospitals of the Public Health Service at the request of the Immigration and Naturalization Service unless such persons are entitled to care and treatment under section 249(a) [1] of this title.

(July 1, 1944, ch. 373, title II, §232, formerly title V, §502, 58 Stat. 710, renumbered title XXI, §2102, Pub. L. 98–24, §2(a)(1), Apr. 26, 1983, 97 Stat. 176; renumbered title XXIII, §2302, Pub. L. 99–660, title III, §311(a), Nov. 14, 1986, 100 Stat. 3755; renumbered title XXV, §2502, Pub. L. 100–607, title II, §201(1), (2), Nov. 4, 1988, 102 Stat. 3062; renumbered title XXVI, §2602, Pub. L. 100–690, title II, §2620(a), Nov. 18, 1988, 102 Stat. 4244; renumbered title XXVII, §2702, Pub. L. 101–381, title I, §101(1), (2), Aug. 18, 1990, 104 Stat. 576; renumbered title II, §232, Pub. L. 103–43, title XX, §2010(a)(1)–(3), June 10, 1993, 107 Stat. 213.)

EDITORIAL NOTES

REFERENCES IN TEXT

Subsec. (a) of section 249 of this title, referred to in text, which related to persons entitled to care and treatment without charge, was repealed, and subsec. (c) of section 249 of this title was redesignated as subsec. (a), by Pub. L. 97–35, title IX, §986(a), (b)(2), Aug. 13, 1981, 95 Stat. 603.

CODIFICATION

Section was formerly classified to section 300aaa–1 of this title prior to renumbering by Pub. L. 103–43, to section 300cc–1 of this title prior to renumbering by Pub. L. 100–607, to section 300aa–1 of this title prior to renumbering by Pub. L. 99–660, and to section 220 of this title prior to renumbering by Pub. L. 98–24.

STATUTORY NOTES AND RELATED SUBSIDIARIES

CHANGE OF NAME

"Secretary of Health and Human Services" substituted for "Secretary of Health, Education, and Welfare" pursuant to section 509(b) of Pub. L. 96–88, which is classified to section 3508(b) of Title 20, Education.

ABOLITION OF IMMIGRATION AND NATURALIZATION SERVICE AND TRANSFER OF FUNCTIONS

For abolition of Immigration and Naturalization Service, transfer of functions, and treatment of related references, see note set out under section 1551 of Title 8, Aliens and Nationality.

EXECUTIVE DOCUMENTS

TRANSFER OF FUNCTIONS

Functions of Public Health Service, Surgeon General of Public Health Service, and all other officers and employees of Public Health Service, and functions all agencies of or in Public Health Service transferred to Secretary of Health, Education, and Welfare by Reorg. Plan No. 3 of 1966, eff. June 25, 1966, 31 F.R. 8855, 80 Stat. 1610, set out as a note under section 202 of this title.

Functions of all other officers of Department of Justice and functions of all agencies and employees of such Department, with a few exceptions, transferred to Attorney General, with power vested in him to authorize their performance or performance of any of his functions by any of such officers, agencies, and employees, by sections 1 and 2 of Reorg. Plan No. 2 of 1950, eff. May 24, 1950, 15 F.R. 3173, 64 Stat. 1261, which were repealed by Pub. L. 89–554, §8(a), Sept. 6, 1966, 80 Stat. 662. Immigration and Naturalization Service, referred to in this section, was a bureau in Department of Justice.

[1] *See References in Text note below.*

§238b. Disposition of money collected for care of patients

Money collected as provided by law for expenses incurred in the care and treatment of foreign seamen, and money received for the care and treatment of pay patients, including any amounts received from any executive department on account of care and treatment of pay patients, shall be covered into the appropriation from which the expenses of such care and treatment were paid.

(July 1, 1944, ch. 373, title II, §233, formerly title V, §503, 58 Stat. 710, renumbered title XXI, §2103, Pub. L. 98–24, §2(a)(1), Apr. 26, 1983, 97 Stat. 176; renumbered title XXIII, §2303, Pub. L. 99–660, title III, §311(a), Nov. 14, 1986, 100 Stat. 3755; renumbered title XXV, §2503, Pub. L. 100–607, title II, §201(1), (2), Nov. 4, 1988, 102 Stat. 3062; renumbered title XXVI, §2603, Pub. L. 100–690, title II, §2620(a), Nov. 18, 1988, 102 Stat. 4244; renumbered title XXVII, §2703, Pub. L. 101–381, title I, §101(1), (2), Aug. 18, 1990, 104 Stat. 576; renumbered title II, §233, Pub. L. 103–43, title XX, §2010(a)(1)–(3), June 10, 1993, 107 Stat. 213.)

EDITORIAL NOTES

CODIFICATION

Section was formerly classified to section 300aaa–2 of this title prior to renumbering by Pub. L. 103–43, to section 300cc–2 of this title prior to renumbering by Pub. L. 100–607, to section 300aa–2 of this title prior to renumbering by Pub. L. 99–660, and to section 221 of this title prior to renumbering by Pub. L. 98–24.

§238c. Transportation of remains of officers

Appropriations available for traveling expenses of the Service shall be available for meeting the cost of preparation for burial and of transportation to the place of burial of remains of commissioned officers, and of personnel specified in regulations, who die in line of duty. Appropriations available for carrying out the provisions of this chapter shall also be available for the payment of such expenses relating to the recovery, care and disposition of the remains of personnel or their dependents as may be authorized under other provisions of law.

(July 1, 1944, ch. 373, title II, §234, formerly title V, §506, 58 Stat. 710; July 15, 1954, ch. 507, §14(b), 68 Stat. 481; renumbered title XXI, §2106, Pub. L. 98–24, §2(a)(1), Apr. 26, 1983, 97 Stat. 176; renumbered title XXIII, §2306, Pub. L. 99–660, title III, §311(a), Nov. 14, 1986, 100 Stat. 3755; renumbered title XXV, §2504, Pub. L. 100–607, title II, §201(1), (3), Nov. 4, 1988, 102 Stat. 3062, 3063; renumbered title XXVI, §2604, Pub. L. 100–690, title II, §2620(a), Nov. 18, 1988, 102 Stat. 4244; renumbered title XXVII, §2704, Pub. L. 101–381, title I, §101(1), (2), Aug. 18, 1990, 104 Stat. 576; renumbered title II, §234, Pub. L. 103–43, title XX, §2010(a)(1)–(3), June 10, 1993, 107 Stat. 213.)

EDITORIAL NOTES

CODIFICATION

Section was formerly classified to section 300aaa–3 of this title prior to renumbering by Pub. L. 103–43, to section 300cc–5 of this title prior to renumbering by Pub. L. 100–607, to section 300aa–5 of this title prior to renumbering by Pub. L. 99–660, and to section 224 of this title prior to renumbering by Pub. L. 98–24.

AMENDMENTS

1954—Act July 15, 1954, inserted sentence at end relating to availability of appropriations for paying expenses relating to recovery, care, and disposition of the remains of personnel or their dependents.

STATUTORY NOTES AND RELATED SUBSIDIARIES

CHANGE OF NAME

"Secretary of Health and Human Services" substituted for "Secretary of Health, Education, and Welfare" pursuant to section 509(b) of Pub. L. 96–88, which is classified to section 3508(b) of Title 20, Education.

DISPOSITION OF REMAINS OF DECEASED PERSONNEL

Recovery, care and disposition of the remains of deceased members of the uniformed services and other deceased personnel, see section 1481 et seq. of Title 10, Armed Forces.

EXECUTIVE DOCUMENTS

TRANSFER OF FUNCTIONS

Functions of Public Health Service, Surgeon General of Public Health Service, and all other officers and employees of Public Health Service, and functions of all agencies of or in Public Health Service transferred to Secretary of Health, Education, and Welfare by Reorg. Plan No. 3 of 1966, eff. June 25, 1966, 31 F.R. 8855, 80 Stat. 1610, set out as a note under section 202 of this title.

§238d. Availability of appropriations for grants to Federal institutions

Appropriations to the Public Health Service available under this chapter for research, training, or demonstration project grants or for grants to expand existing treatment and research programs and facilities for alcoholism, narcotic addiction, drug abuse, and drug dependence and appropriations under title VI of the Mental Health Systems Act [42 U.S.C. 9511 et seq.] shall also be available on the same terms and conditions as apply to non-Federal institutions, for grants for the same purpose to Federal institutions, except that grants to Federal institutions may be funded at 100 per centum of the costs.

(July 1, 1944, ch. 373, title II, §235, formerly title V, §507, as added Pub. L. 90–31, §5, June 24, 1967, 81 Stat. 79; amended Pub. L. 91–513, title I, §3(c), Oct. 27, 1970, 84 Stat. 1241; Pub. L. 94–278, title XI, §1102(b), Apr. 22, 1976, 90 Stat. 415; Pub. L. 96–398, title VIII, §804(b), Oct. 7, 1980, 94 Stat. 1608; Pub. L. 97–35, title IX, §902(g)(2), Aug. 13, 1981, 95 Stat. 560; renumbered title XXI, §2107, Pub. L. 98–24, §2(a)(1), Apr. 26, 1983, 97 Stat. 176; renumbered title XXIII, §2307, Pub. L. 99–660, title III, §311(a), Nov. 14, 1986, 100 Stat. 3755; renumbered title XXV, §2505, Pub. L. 100–607, title II, §201(1), (3), Nov. 4, 1988, 102 Stat. 3062, 3063; renumbered title XXVI, §2605, Pub. L. 100–690, title II, §2620(a), Nov. 18, 1988, 102 Stat. 4244; renumbered title XXVII, §2705, Pub. L. 101–381, title I, §101(1), (2), Aug. 18, 1990, 104 Stat. 576; renumbered title II, §235, Pub. L. 103–43, title XX, §2010(a)(1)–(3), June 10, 1993, 107 Stat. 213.)

EDITORIAL NOTES

REFERENCES IN TEXT

The Mental Health Systems Act, referred to in text, is Pub. L. 96–398, Oct. 7, 1980, 94 Stat. 1564. Title VI

of the Mental Health Systems Act is classified generally to subchapter V (§9511 et seq.) of chapter 102 of this title. For complete classification of this Act to the Code, see Short Title note set out under section 9401 of this title and Tables.

CODIFICATION

Section was formerly classified to section 300aaa–4 of this title prior to renumbering by Pub. L. 103–43, to section 300cc–6 of this title prior to renumbering by Pub. L. 100–607, to section 300aa–6 of this title prior to renumbering by Pub. L. 99–660, and to section 225a of this title prior to renumbering by Pub. L. 98–24.

AMENDMENTS

1981—Pub. L. 97–35 struck out provisions relating to appropriations available under Community Mental Health Centers Act for construction, etc.

1980—Pub. L. 96–398 struck out "and" after "drug dependence," and inserted reference to title VI of the Mental Health Systems Act.

1976—Pub. L. 94–278 substituted "Federal institutions, except that grants to" for "hospitals of the Service, of the Veterans' Administration, or of the Bureau of Prisons of the Department of Justice, and to Saint Elizabeths Hospital, except grants to such".

1970—Pub. L. 91–513 inserted references to appropriations available for grants to expand existing treatment and research programs and facilities for alcoholism, narcotic addiction, drug abuse, and drug dependence, and appropriations available under Community Mental Health Centers Act for construction and staffing of community mental health centers and alcoholism and narcotic addiction, drug abuse, and drug dependence facilities, and inserted provision that grants to specified Federal institutions may be funded at 100 per centum of the costs.

STATUTORY NOTES AND RELATED SUBSIDIARIES

EFFECTIVE DATE OF 1981 AMENDMENT

Amendment by Pub. L. 97–35 effective Oct. 1, 1981, see section 902(h) of Pub. L. 97–35, set out as a note under section 238l of this title.

EFFECTIVE DATE

Pub. L. 90–31, §5, June 24, 1967, 81 Stat. 79, provided that this section is effective July 1, 1968.

§238e. Transfer of funds

For the purpose of any reorganization under section 203 of this title, the Secretary, with the approval of the Director of the Office of Management and Budget, is authorized to make such transfers of funds between appropriations as may be necessary for the continuance of transferred functions.

(July 1, 1944, ch. 373, title II, §236, formerly title V, §508, 58 Stat. 711; 1953 Reorg. Plan No. 1, §§5, 8, eff. Apr. 11, 1953, 18 F.R. 2053, 67 Stat. 631; 1970 Reorg. Plan No. 2, §102, eff. July 1, 1970, 35 F.R. 7959, 84 Stat. 2085; renumbered title XXI, §2108, Pub. L. 98–24, §2(a)(1), Apr. 26, 1983, 97 Stat. 176; renumbered title XXIII, §2308, Pub. L. 99–660, title III, §311(a), Nov. 14, 1986, 100 Stat. 3755; renumbered title XXV, §2506, Pub. L. 100–607, title II, §201(1), (3), Nov. 4, 1988, 102 Stat. 3062, 3063; renumbered title XXVI, §2606, Pub. L. 100–690, title II, §2620(a), Nov. 18, 1988, 102 Stat. 4244; renumbered title XXVII, §2706, Pub. L. 101–381, title I, §101(1), (2), Aug. 18, 1990, 104 Stat. 576; renumbered title II, §236, Pub. L. 103–43, title XX, §2010(a)(1)–(3), June 10, 1993, 107 Stat. 213.)

EDITORIAL NOTES

CODIFICATION

Section was formerly classified to section 300aaa–5 of this title prior to renumbering by Pub. L. 103–43, to section 300cc–7 of this title prior to renumbering by Pub. L. 100–607, to section 300aa–7 of this title prior to renumbering by Pub. L. 99–660, and to section 226 of this title prior to renumbering by Pub. L. 98–24.

STATUTORY NOTES AND RELATED SUBSIDIARIES

CHANGE OF NAME

"Secretary of Health and Human Services" substituted in text for "Secretary of Health, Education, and Welfare" pursuant to section 509(b) of Pub. L. 96–88, which is classified to section 3508(b) of Title 20, Education.

EXECUTIVE DOCUMENTS

TRANSFER OF FUNCTIONS

Functions vested by law (including reorganization plan) in Bureau of the Budget or Director of Bureau of the Budget transferred to President of the United States by section 101 of Reorg. Plan No. 2 of 1970, eff. July 1, 1970, 35 F.R. 7959, 84 Stat. 2085, set out in the Appendix to Title 5, Government Organization and Employees. Section 102 of Reorg. Plan No. 2 of 1970 redesignated Bureau of the Budget as Office of Management and Budget.

Functions of Federal Security Administrator transferred to Secretary of Health, Education, and Welfare and all agencies of Federal Security Agency transferred to Department of Health, Education, and Welfare by section 5 of Reorg. Plan No. 1 of 1953, set out as a note under section 3501 of this title. Federal Security Agency and office of Administrator abolished by section 8 of Reorg. Plan No. 1 of 1953.

§238f. Availability of appropriations

Appropriations for carrying out the purposes of this chapter shall be available for expenditure for personal services and rent at the seat of Government; books of reference, periodicals, and exhibits; printing and binding; transporting in Government-owned automotive equipment, to and from school, children of personnel who have quarters for themselves and their families at stations determined by the Surgeon General to be isolated stations; expenses incurred in pursuing, identifying, and returning prisoners who escape from any hospital, institution, or station of the Service or from the custody of any officer or employee of the Service, including rewards for the capture of such prisoners; furnishing, repairing, and cleaning such wearing apparel as may be prescribed by the Surgeon General for use by employees in the performance of their official duties; reimbursing officers and employees, subject to regulations of the Secretary, for the cost of repairing or replacing their personal belongings damaged or destroyed by patients while such officers or employees are engaged in the performance of their official duties; and maintenance of buildings of the National Institutes of Health.

(July 1, 1944, ch. 373, title II, §237, formerly title V, §509, 58 Stat. 711; June 16, 1948, ch. 481, §6(b), 62 Stat. 469; June 25, 1948, ch. 654, §7, 62 Stat. 1018; 1953 Reorg. Plan No. 1, §§5, 8, eff. Apr. 11, 1953, 18 F.R. 2053, 67 Stat. 631; renumbered title XXI, §2109, Pub. L. 98–24, §2(a)(1), Apr. 26, 1983, 97 Stat. 176; renumbered title XXIII, §2309, Pub. L. 99–660, title III, §311(a), Nov. 14, 1986, 100 Stat. 3755; renumbered title XXV, §2507, Pub. L. 100–607, title II, §201(1), (3), Nov. 4, 1988, 102 Stat. 3062, 3063; renumbered title XXVI, §2607, Pub. L. 100–690, title II, §2620(a), Nov. 18, 1988, 102 Stat. 4244; renumbered title XXVII, §2707, Pub. L. 101–381, title I, §101(1), (2), Aug. 18, 1990, 104 Stat. 576; renumbered title II, §237, Pub. L. 103–43, title XX, §2010(a)(1)–(3), June 10, 1993, 107 Stat. 213.)

EDITORIAL NOTES

CODIFICATION

Section was formerly classified to section 300aaa–6 of this title prior to renumbering by Pub. L. 103–43, to section 300cc–8 of this title prior to renumbering by Pub. L. 100–607, to section 300aa–8 of this title prior to renumbering by Pub. L. 99–660, and to section 227 of this title prior to renumbering by Pub. L. 98–24.

AMENDMENTS

1948—Act June 25, 1948, amended section generally to make it apply to all appropriations to carry out the purposes of the Service instead of merely to appropriations to carry out the research functions of the Service.

Act June 16, 1948, substituted "National Institutes of Health" for "National Institute of Health".

STATUTORY NOTES AND RELATED SUBSIDIARIES

CHANGE OF NAME

"Secretary of Health and Human Services" substituted in text for "Secretary of Health, Education, and Welfare" pursuant to section 509(b) of Pub. L. 96–88, which is classified to section 3508(b) of Title 20, Education.

PROHIBITION

Pub. L. 117–328, div. FF, title I, §1261, Dec. 29, 2022, 136 Stat. 5681, provided that: "Notwithstanding any provision of this title [see Tables for classification] and the amendments made by this title, no funds made available to carry out this title or any amendment made by this title shall be used to purchase, procure, or distribute pipes or cylindrical objects intended to be used to smoke or inhale illegal scheduled substances."

BUY AMERICAN PROVISIONS

Pub. L. 103–43, title XX, §2004, June 10, 1993, 107 Stat. 209, as amended by Pub. L. 105–392, title IV, §416(a), (b), Nov. 13, 1998, 112 Stat. 3590, provided that:

"(a) SENSE OF CONGRESS REGARDING PURCHASE OF AMERICAN-MADE EQUIPMENT AND PRODUCTS.—In the case of any equipment or product that may be authorized to be purchased with financial assistance provided pursuant to this Act for any of the fiscal years 1994 through 1996, it is the sense of the Congress that entities receiving such assistance should, in expending the assistance, purchase only American-made equipment and products.

"(b) NOTICE TO RECIPIENTS OF ASSISTANCE.—In providing financial assistance pursuant to this Act, the Secretary of Health and Human Services shall provide to each recipient of the assistance a notice describing the statement made in subsection (a) by the Congress."

[Pub. L. 105–392, title IV, §416(c), Nov. 13, 1998, 112 Stat. 3591, provided that: "This section [amending section 2004 of Pub. L. 103–43, set out above] is deemed to have taken effect immediately after the enactment of Public Law 103–43 [June 10, 1993]."]

AVAILABILITY OF APPROPRIATIONS FOR ACTIVE COMMISSIONED OFFICERS AND OTHER EXPENSES

Pub. L. 102–394, title II, §202, Oct. 6, 1992, 106 Stat. 1810, as amended by Pub. L. 111–8, div. F, title II, §222, Mar. 11, 2009, 123 Stat. 784; Pub. L. 111–148, title V, §5209, Mar. 23, 2010, 124 Stat. 613, provided that: "Appropriations in this or any other Act or subsequent Departments of Labor, Health and Human Services, and Education, and Related Agencies Appropriations Acts shall be available for expenses for active commissioned officers in the Public Health Service Reserve Corps [now Ready Reserve Corps] and for commissioned officers in the Regular Corps; expenses incident to the dissemination of health information in foreign countries through exhibits and other appropriate means; advances of funds for compensation, travel, and subsistence expenses (or per diem in lieu thereof) for persons coming from abroad to participate in health or scientific activities of the Department pursuant to law; expenses of primary and secondary schooling of dependents in foreign countries, of Public Health Service commissioned officers stationed in foreign countries, at costs for any given area not in excess of those of the Department of Defense for the same area, when it is determined by the Secretary that the schools available in the locality are unable to provide adequately for the education of such dependents, and for the transportation of such dependents, between such schools and their places of residence when the schools are not accessible to such dependents by regular means of transportation; expenses for medical care for civilian and commissioned employees of the Public Health Service and their dependents assigned abroad on a permanent basis in accordance with such regulations as the Secretary may provide; rental or lease of living quarters (for periods not exceeding five years), and provision of heat, fuel, and light and maintenance, improvement, and repair of such quarters, and advance payments therefor, for civilian officers and employees of the Public Health Service who are United States citizens and who have a permanent station in a foreign country; purchase, erection, and maintenance of temporary or portable structures; and for the payment of compensation to consultants or individual scientists appointed for limited periods of time pursuant to section 207(f) or section 207(g) of the Public Health Service Act [42

U.S.C. 209(f), (g)], at rates established by the Assistant Secretary for Health, or the Secretary where such action is required by statute, not to exceed the per diem rate equivalent to the maximum rate payable for senior-level positions under 5 U.S.C. 5376."

[Pub. L. 111–148, §5209, which directed amendment of Pub. L. 102–394, §202, set out above, by striking out "not to exceed 2,800", was executed by striking out "not to exceed 4,000" before "commissioned officers in the Regular Corps", to reflect the probable intent of Congress.]

[For reference to maximum rate under section 5376 of Title 5, Government Organization and Employees, see section 2(d)(3) of Pub. L. 110–372, set out as an Effective Date of 2008 Amendment note under section 5376 of Title 5.]

Similar provisions were contained in the following prior appropriation acts:

Pub. L. 102–170, title II, §202, Nov. 26, 1991, 105 Stat. 1126.

Pub. L. 101–517, title II, §202, Nov. 5, 1990, 104 Stat. 2208.

Pub. L. 101–166, title II, §203, Nov. 21, 1989, 103 Stat. 1176.

Pub. L. 100–202, §101(h) [title II, §203], Dec. 22, 1987, 101 Stat. 1329–256, 1329–273.

Pub. L. 99–500, §101(i) [H.R. 5233, title II, §203], Oct. 18, 1986, 100 Stat. 1783–287, and Pub. L. 99–591, §101(i) [H.R. 5233, title II, §203], Oct. 30, 1986, 100 Stat. 3341–287.

Pub. L. 99–178, title II, §203, Dec. 12, 1985, 99 Stat. 1118.

Pub. L. 98–619, title II, §203, Nov. 8, 1984, 98 Stat. 3320.

Pub. L. 98–139, title II, §203, Oct. 31, 1983, 97 Stat. 887.

Pub. L. 97–377, title I, §101(e)(1) [title II, §203], Dec. 21, 1982, 96 Stat. 1878, 1893.

CREDITING OF PAYMENTS FOR ROOM AND BOARD TO APPROPRIATION ACCOUNTS

Pub. L. 102–394, title II, §206, Oct. 6, 1992, 106 Stat. 1811, provided that: "Hereafter amounts received from employees of the Department in payment for room and board may be credited to the appropriation accounts which finance the activities of the Public Health Service."

Similar provisions were contained in the following prior appropriation acts:

Pub. L. 102–170, title II, §206, Nov. 26, 1991, 105 Stat. 1126.

Pub. L. 101–517, title II, §206, Nov. 5, 1990, 104 Stat. 2209.

Pub. L. 101–166, title II, §207, Nov. 21, 1989, 103 Stat. 1177.

EXECUTIVE DOCUMENTS

TRANSFER OF FUNCTIONS

Functions of Public Health Service, Surgeon General of Public Health Service, and all other officers and employees of Public Health Service, and functions of all agencies of or in Public Health Service transferred to Secretary of Health, Education, and Welfare by Reorg. Plan No. 3 of 1966, eff. June 25, 1966, 31 F.R. 8855, 80 Stat. 1610, set out as a note under section 202 of this title.

Functions of Federal Security Administrator transferred to Secretary of Health, Education, and Welfare and all agencies of Federal Security Agency transferred to Department of Health, Education, and Welfare by section 5 of Reorg. Plan No. 1 of 1953, set out as a note under section 3501 of this title. Federal Security Agency and office of Administrator abolished by section 8 of Reorg. Plan No. 1 of 1953.

§238g. Wearing of uniforms

Except as may be authorized by regulations of the President, the insignia and uniform of commissioned officers of the Service, or any distinctive part of such insignia or uniform, or any insignia or uniform any part of which is similar to a distinctive part thereof, shall not be worn, after the promulgation of such regulations, by any person other than a commissioned officer of the Service.

(July 1, 1944, ch. 373, title II, §238, formerly title V, §510, 58 Stat. 711; June 25, 1948, ch. 645, §5, 62 Stat. 859; renumbered title XXI, §2110, Pub. L. 98–24, §2(a)(1), Apr. 26, 1983, 97 Stat. 176; renumbered title XXIII, §2310, Pub. L. 99–660, title III, §311(a), Nov. 14, 1986, 100 Stat. 3755; renumbered title XXV, §2508, Pub. L. 100–607, title II, §201(1), (3), Nov. 4, 1988, 102 Stat. 3062, 3063; renumbered title XXVI, §2608, Pub. L. 100–690, title II, §2620(a), Nov. 18, 1988, 102 Stat.

4244; renumbered title XXVII, §2708, Pub. L. 101–381, title I, §101(1), (2), Aug. 18, 1990, 104 Stat. 576; renumbered title II, §238, Pub. L. 103–43, title XX, §2010(a)(1)–(3), June 10, 1993, 107 Stat. 213.)

EDITORIAL NOTES

CODIFICATION

Section was formerly classified to section 300aaa–7 of this title prior to renumbering by Pub. L. 103–43, to section 300cc–9 of this title prior to renumbering by Pub. L. 100–607, to section 300aa–9 of this title prior to renumbering by Pub. L. 99–660, and to section 228 of this title prior to renumbering by Pub. L. 98–24.

AMENDMENTS

1948—Act June 25, 1948, struck out penal provisions. See section 702 of Title 18, Crimes and Criminal Procedure.

STATUTORY NOTES AND RELATED SUBSIDIARIES

CHANGE OF NAME

"Secretary of Health and Human Services" substituted for "Secretary of Health, Education, and Welfare" pursuant to section 509(b) of Pub. L. 96–88, which is classified to section 3508(b) of Title 20, Education.

EFFECTIVE DATE OF 1948 AMENDMENT

Amendment effective Sept. 1, 1948, see section 20 of act June 25, 1948.

EXECUTIVE DOCUMENTS

TRANSFER OF FUNCTIONS

Functions of Public Health Service, Surgeon General of Public Health Service, and all other officers and employees of Public Health Service, and functions of all agencies of or in Public Health Service transferred to Secretary of Health, Education, and Welfare by Reorg. Plan No. 3 of 1966, eff. June 25, 1966, 31 F.R. 8855, 80 Stat. 1610, set out as a note under section 202 of this title.

DELEGATION OF FUNCTIONS

Functions of President delegated to Secretary of Health and Human Services, see Ex. Ord. No. 11140, Jan. 30, 1964, 29 F.R. 1637, as amended, set out as a note under section 202 of this title.

§238h. Biennial report

The Surgeon General shall transmit to the Secretary, for submission to the Congress, on January 1, 1995, and on January 1, every 2 years thereafter, a full report of the administration of the functions of the Service under this chapter, including a detailed statement of receipts and disbursements.

(July 1, 1944, ch. 373, title II, §239, formerly title V, §511, 58 Stat. 711; 1953 Reorg. Plan No. 1, §§5, 8, eff. Apr. 11, 1953, 18 F.R. 2053, 67 Stat. 631; renumbered title XXI, §2111, Pub. L. 98–24, §2(a)(1), Apr. 26, 1983, 97 Stat. 176; renumbered title XXIII, §2311, Pub. L. 99–660, title III, §311(a), Nov. 14, 1986, 100 Stat. 3755; renumbered title XXV, §2509, Pub. L. 100–607, title II, §201(1), (3), Nov. 4, 1988, 102 Stat. 3062, 3063; renumbered title XXVI, §2609, Pub. L. 100–690, title II, §2620(a), Nov. 18, 1988, 102 Stat. 4244; renumbered title XXVII, §2709, Pub. L. 101–381, title I, §101(1), (2), Aug. 18, 1990, 104 Stat. 576; renumbered title II, §239, Pub. L. 103–43, title XX, §2010(a)(1)–(3), June 10, 1993, 107 Stat. 213; Pub. L. 104–66, title I, §1062(a), Dec. 21, 1995, 109 Stat. 720.)

EDITORIAL NOTES

CODIFICATION

Section was formerly classified to section 300aaa–8 of this title prior to renumbering by Pub. L. 103–43, to section 300cc–10 of this title prior to renumbering by Pub. L. 100–607, to section 300aa–10 of this title prior to renumbering by Pub. L. 99–660, and to section 229 of this title prior to renumbering by Pub. L. 98–24.

AMENDMENTS

1995—Pub. L. 104–66 amended section catchline and text generally. Prior to amendment, text read as follows: "The Surgeon General shall transmit to the Secretary, for submission to the Congress at the beginning of each regular session, a full report of the administration of the functions of the Service under this chapter, including a detailed statement of receipts and disbursements."

STATUTORY NOTES AND RELATED SUBSIDIARIES

CHANGE OF NAME

"Secretary of Health and Human Services" substituted in text for "Secretary of Health, Education, and Welfare" pursuant to section 509(b) of Pub. L. 96–88, which is classified to section 3508(b) of Title 20, Education.

TERMINATION OF REPORTING REQUIREMENTS

For termination, effective May 15, 2000, of provisions of law requiring submittal to Congress of any annual, semiannual, or other regular periodic report listed in House Document No. 103–7 (in which item 3 on page 101 identifies a reporting provision which, as subsequently amended, is contained in this section), see section 3003 of Pub. L. 104–66, as amended, and section 1(a)(4) [div. A, §1402(1)] of Pub. L. 106–554, set out as notes under section 1113 of Title 31, Money and Finance.

AGENCY REPORTING REQUIREMENTS; REPORT BY SECRETARY OF HEALTH, EDUCATION, AND WELFARE TO CONGRESSIONAL COMMITTEES RELATING TO REQUIREMENTS, TERMINATION, ETC.

Pub. L. 93–641, §7, Jan. 4, 1975, 88 Stat. 2275, provided that by Jan. 4, 1976, the Secretary of Health, Education, and Welfare report to specific committees of the Senate and the House of Representatives on the identity, due date, etc., of certain reports required under the Public Health Service Act, the Mental Retardation Facilities and Community Mental Health Centers Construction Act of 1963, or the Comprehensive Alcohol Abuse and Alcoholism Prevention, Treatment and Rehabilitation Act of 1970.

EXECUTIVE DOCUMENTS

TRANSFER OF FUNCTIONS

Office of Surgeon General abolished by section 3 of Reorg. Plan No. 3 of 1966, eff. June 25, 1966, 31 F.R. 8855, 80 Stat. 1610, and functions thereof transferred to Secretary of Health, Education, and Welfare by section 1 of Reorg. Plan No. 3 of 1966, set out as a note under section 202 of this title. Office of Surgeon General reestablished within the Office of the Assistant Secretary for Health, see Notice of Department of Health and Human Services, Office of the Assistant Secretary for Health, Mar. 30, 1987, 52 F.R. 11754.

Functions of Federal Security Administrator transferred to Secretary of Health, Education, and Welfare and all agencies of Federal Security Agency transferred to Department of Health, Education, and Welfare by section 5 of Reorg. Plan No. 1 of 1953, set out as a note under section 202 of this title. Federal Security Agency and office of Administrator abolished by section 8 of Reorg. Plan No. 1 of 1953.

§238i. Memorials and other acknowledgments for contributions to health of Nation

The Secretary may provide for suitably acknowledging, within the Department (whether by memorials, designations, or other suitable acknowledgments), (1) efforts of persons who have contributed substantially to the health of the Nation and (2) gifts for use in activities of the Department related to health.

(July 1, 1944, ch. 373, title II, §240, formerly title V, §512, as added Pub. L. 90–574, title V, §503(a), Oct. 15, 1968, 82 Stat. 1012; renumbered title XXI, §2112, Pub. L. 98–24, §2(a)(1), Apr.

26, 1983, 97 Stat. 176; renumbered title XXIII, §2312, Pub. L. 99–660, title III, §311(a), Nov. 14, 1986, 100 Stat. 3755; renumbered title XXV, §2510, Pub. L. 100–607, title II, §201(1), (3), Nov. 4, 1988, 102 Stat. 3062, 3063; renumbered title XXVI, §2610, Pub. L. 100–690, title II, §2620(a), Nov. 18, 1988, 102 Stat. 4244; renumbered title XXVII, §2710, Pub. L. 101–381, title I, §101(1), (2), Aug. 18, 1990, 104 Stat. 576; renumbered title II, §240, Pub. L. 103–43, title XX, §2010(a)(1)–(3), June 10, 1993, 107 Stat. 213.)

EDITORIAL NOTES

CODIFICATION

Section was formerly classified to section 300aaa–9 of this title prior to renumbering by Pub. L. 103–43, to section 300cc–11 of this title prior to renumbering by Pub. L. 100–607, to section 300aa–11 of this title prior to renumbering by Pub. L. 99–660, and to section 229a of this title prior to renumbering by Pub. L. 98–24.

§238j. Evaluation of programs

(a) In general

Such portion as the Secretary shall determine, but not less than 0.2 percent nor more than 1 percent, of any amounts appropriated for programs authorized under this chapter shall be made available for the evaluation (directly, or by grants of contracts) of the implementation and effectiveness of such programs.

(b) Report on evaluations

Not later than February 1 of each year, the Secretary shall prepare and submit to the Committee on Labor and Human Resources of the Senate and the Committee on Energy and Commerce of the House of Representatives a report summarizing the findings of the evaluations conducted under subsection (a).

(July 1, 1944, ch. 373, title II, §241, formerly title V, §513, as added Pub. L. 91–296, title IV, §401(a), June 30, 1970, 84 Stat. 351; amended Pub. L. 96–398, title VIII, §804(c), Oct. 7, 1980, 94 Stat. 1608; Pub. L. 97–35, title IX, §902(g)(3), Aug. 13, 1981, 95 Stat. 560; renumbered title XXI, §2113, Pub. L. 98–24, §2(a)(1), Apr. 26, 1983, 97 Stat. 176; renumbered title XXIII, §2313, Pub. L. 99–660, title III, §311(a), Nov. 14, 1986, 100 Stat. 3755; renumbered title XXV, §2511, Pub. L. 100–607, title II, §201(1), (3), Nov. 4, 1988, 102 Stat. 3062, 3063; renumbered title XXVI, §2611, Pub. L. 100–690, title II, §2620(a), Nov. 18, 1988, 102 Stat. 4244; renumbered title XXVII, §2711, Pub. L. 101–381, title I, §101(1), (2), Aug. 18, 1990, 104 Stat. 576; renumbered title II, §241, Pub. L. 103–43, title XX, §2010(a)(1)–(3), June 10, 1993, 107 Stat. 213; Pub. L. 103–183, title VII, §701, Dec. 14, 1993, 107 Stat. 2239.)

EDITORIAL NOTES

CODIFICATION

Section was formerly classified to section 300aaa–10 of this title prior to renumbering by Pub. L. 103–43, to section 300cc–12 of this title prior to renumbering by Pub. L. 100–607, to section 300aa–12 of this title prior to renumbering by Pub. L. 99–660, and to section 229b of this title prior to renumbering by Pub. L. 98–24.

AMENDMENTS

1993—Pub. L. 103–183 amended section generally. Prior to amendment, section read as follows: "Such portion as the Secretary may determine, but not more than 1 per centum, of any appropriation for grants, contracts, or other payments under any provision of this chapter, the Mental Health Systems Act, the Act of August 5, 1954 (Public Law 568, Eighty–third Congress), or the Act of August 16, 1957 (Public Law 85–151), for any fiscal year beginning after June 30, 1970, shall be available for evaluation (directly, or by grants or contracts) of any program authorized by this chapter or any of such other Acts, and, in the case of allotments from any such appropriation, the amount available for allotment shall be reduced accordingly."

1981—Pub. L. 97–35 struck out references to Mental Retardation Facilities Construction Act and Community Mental Health Centers Act.

1980—Pub. L. 96–398 inserted reference to Mental Health Systems Act.

STATUTORY NOTES AND RELATED SUBSIDIARIES

CHANGE OF NAME

Committee on Labor and Human Resources of Senate changed to Committee on Health, Education, Labor, and Pensions of Senate by Senate Resolution No. 20, One Hundred Sixth Congress, Jan. 19, 1999.

Committee on Energy and Commerce of House of Representatives treated as referring to Committee on Commerce of House of Representatives by section 1(a) of Pub. L. 104–14, set out as a note preceding section 21 of Title 2, The Congress. Committee on Commerce of House of Representatives changed to Committee on Energy and Commerce of House of Representatives, and jurisdiction over matters relating to securities and exchanges and insurance generally transferred to Committee on Financial Services of House of Representatives by House Resolution No. 5, One Hundred Seventh Congress, Jan. 3, 2001.

EFFECTIVE DATE OF 1993 AMENDMENT

Pub. L. 103–183, title VII, §701, Dec. 14, 1993, 107 Stat. 2239, provided that the amendment made by that section is effective Oct. 1, 1994.

EFFECTIVE DATE OF 1981 AMENDMENT

Amendment by Pub. L. 97–35 effective Oct. 1, 1981, see section 902(h) of Pub. L. 97–35, set out as a note under section 238l of this title.

§238k. Contract authority

The authority of the Secretary to enter into contracts under this chapter shall be effective for any fiscal year only to such extent or in such amounts as are provided in advance by appropriation Acts.

(July 1, 1944, ch. 373, title II, §242, formerly title V, §514, as added Pub. L. 95–623, §11(e), Nov. 9, 1978, 92 Stat. 3456; renumbered title XXI, §2114, Pub. L. 98–24, §2(a)(1), Apr. 26, 1983, 97 Stat. 176; renumbered title XXIII, §2314, Pub. L. 99–660, title III, §311(a), Nov. 14, 1986, 100 Stat. 3755; renumbered title XXV, §2512, Pub. L. 100–607, title II, §201(1), (3), Nov. 4, 1988, 102 Stat. 3062, 3063; renumbered title XXVI, §2612, Pub. L. 100–690, title II, §2620(a), Nov. 18, 1988, 102 Stat. 4244; renumbered title XXVII, §2712, Pub. L. 101–381, title I, §101(1), (2), Aug. 18, 1990, 104 Stat. 576; renumbered title II, §242, Pub. L. 103–43, title XX, §2010(a)(1)–(3), June 10, 1993, 107 Stat. 213.)

EDITORIAL NOTES

CODIFICATION

Section was formerly classified to section 300aaa–11 of this title prior to renumbering by Pub. L. 103–43, to section 300cc–13 of this title prior to renumbering by Pub. L. 100–607, to section 300aa–13 of this title prior to renumbering by Pub. L. 99–660, and to section 229c of this title prior to renumbering by Pub. L. 98–24.

STATUTORY NOTES AND RELATED SUBSIDIARIES

OBLIGATIONS RELATED TO AGREEMENT WITH PRIVATE ENTITIES

Pub. L. 105–277, div. A, §101(f) [title II], Oct. 21, 1998, 112 Stat. 2681–337, 2681–349, provided in part: "That hereinafter obligations may be incurred related to agreement with private entities without receipt of advance payment."

§238*l*. Recovery

(a) Right of United States to recover base amount plus interest

If any facility with respect to which funds have been paid under the Community Mental Health Centers Act [42 U.S.C. 2689 et seq.] (as such Act was in effect prior to October 1, 1981) is, at any time within twenty years after the completion of remodeling, construction, or expansion or after the date of its acquisition—

(1) sold or transferred to any entity (A) which would not have been qualified to file an application under section 222 of such Act [42 U.S.C. 2689j] (as such section was in effect prior to October 1, 1981) or (B) which is disapproved as a transferee by the State mental health agency or by another entity designated by the chief executive officer of the State, or

(2) ceases to be used by a community mental health center in the provision of comprehensive mental health services,

the United States shall be entitled to recover from the transferor, transferee, or owner of the facility, the base amount prescribed by subsection (c)(1) plus the interest (if any) prescribed by subsection (c)(2).

(b) Notice of sale, transfer, or change

The transferor and transferee of a facility that is sold or transferred as described in subsection (a)(1), or the owner of a facility the use of which changes as described in subsection (a)(2), shall provide the Secretary written notice of such sale, transfer, or change within 10 days after the date on which such sale, transfer, or cessation of use occurs or within 30 days after October 22, 1985, whichever is later.

(c) Base amount; interest

(1) The base amount that the United States is entitled to recover under subsection (a) is the amount bearing the same ratio to the then value (as determined by the agreement of the parties or in an action brought in the district court of the United States for the district in which the facility is situated) of so much of the facility as constituted an approved project or projects as the amount of the Federal participation bore to the cost of the remodeling, construction, expansion, or acquisition of the project or projects.

(2)(A) The interest that the United States is entitled to recover under subsection (a) is the interest for the period (if any) described in subparagraph (B) at a rate (determined by the Secretary) based on the average of the bond equivalent rates of ninety-one-day Treasury bills auctioned during that period.

(B) The period referred to in subparagraph (A) is the period beginning—

(i) if notice is provided as prescribed by subsection (b), 191 days after the date on which such sale, transfer, or cessation of use occurs, or

(ii) if notice is not provided as prescribed by subsection (b), 11 days after such sale, transfer, or cessation of use occurs,

and ending on the date the amount the United States is entitled to recover is collected.

(d) Waiver of recovery rights

The Secretary may waive the recovery rights of the United States under subsection (a) with respect to a facility (under such conditions as the Secretary may establish by regulation) if the Secretary determines that there is good cause for waiving such rights.

(e) Pre-judgment lien

The right of recovery of the United States under subsection (a) shall not, prior to judgment, constitute a lien on any facility.

(July 1, 1944, ch. 373, title II, §243, formerly title V, §515, formerly Pub. L. 88–164, title II, §225, as added Pub. L. 94–63, title III, §303, July 29, 1975, 89 Stat. 326; amended Pub. L. 95–622, title I, §110(c), Nov. 9, 1978, 92 Stat. 3420; renumbered title V, §515, and amended Pub. L. 97–35, title IX, §902(e)(2)(A), Aug. 13, 1981, 95 Stat. 560; renumbered title XXI, §2115, Pub. L. 98–24, §2(a)(1),

Apr. 26, 1983, 97 Stat. 176; Pub. L. 99–129, title II, §226(a), Oct. 22, 1985, 99 Stat. 546; renumbered title XXIII, §2315, Pub. L. 99–660, title III, §311(a), Nov. 14, 1986, 100 Stat. 3755; renumbered title XXV, §2513, Pub. L. 100–607, title II, §201(1), (3), Nov. 4, 1988, 102 Stat. 3062, 3063; renumbered title XXVI, §2613, Pub. L. 100–690, title II, §2620(a), Nov. 18, 1988, 102 Stat. 4244; renumbered title XXVII, §2713, Pub. L. 101–381, title I, §101(1), (2), Aug. 18, 1990, 104 Stat. 576; Pub. L. 102–229, title II, §208, Dec. 12, 1991, 105 Stat. 1716; Pub. L. 102–239, §1, Dec. 17, 1991, 105 Stat. 1912; renumbered title II, §243, Pub. L. 103–43, title XX, §2010(a)(1)–(3), June 10, 1993, 107 Stat. 213.)

EDITORIAL NOTES

REFERENCES IN TEXT

The Community Mental Health Centers Act, referred to in subsec. (a), is title II of Pub. L. 88–164, as added by Pub. L. 94–63, title III, §303, July 29, 1975, 89 Stat. 309, and amended, which was classified principally to subchapter III (§2689 et seq.) of chapter 33 of this title prior to its repeal by Pub. L. 97–35, title IX, §902(e)(2)(B), Aug. 13, 1981, 95 Stat. 560. Section 222 of the Community Mental Health Centers Act was classified to section 2689j of this title prior to its repeal.

CODIFICATION

Section was classified to section 300aaa–12 of this title prior to renumbering by Pub. L. 103–43, to section 300cc–14 of this title prior to renumbering by Pub. L. 100–607, to section 300aa–14 of this title prior to renumbering by Pub. L. 99–660, to section 229d of this title prior to renumbering by Pub. L. 98–24, and to section 2689m of this title prior to renumbering by Pub. L. 97–35.

AMENDMENTS

1991—Subsec. (d). Pub. L. 102–229 and Pub. L. 102–239 amended subsec. (d) identically, substituting "subsection (a)" for "subsection (a)(2)".

1985—Pub. L. 99–129 amended section generally. Prior to amendment, section read as follows: "If any facility of a community mental health center acquired, remodeled, constructed, or expanded with funds provided under the Community Mental Health Centers Act is, at any time within twenty years after the completion of such remodeling, construction, or expansion or after the date of its acquisition with such funds—

"(1) sold or transferred to any person or entity (A) which is not qualified to file an application under section 222 of the Community Mental Health Centers Act, or (B) which is not approved as a transferee by the State agency of the State in which such facility is located, or its successor; or

"(2) not used by a community mental health center in the provision of comprehensive mental health services, and the Secretary has not determined that there is good cause for termination of such use,

the United States shall be entitled to recover from either the transferor or the transferee in the case of a sale or transfer or from the owner in the case of termination of use an amount bearing the same ratio to the then value (as determined by the agreement of the parties or by action brought in the United States district court for the district in which the center is situated) of so much of such facility or center as constituted an approved project or projects, as the amount of the Federal participation bore to the acquisition, remodeling, construction, or expansion cost of such project or projects. Such right of recovery shall not constitute a lien upon such facility or center prior to judgment."

1981—Pub. L. 97–35 substituted "the Community Mental Health Centers Act" for "this subchapter" and "section 222 of the Community Mental Health Centers Act" for "section 2689j of this title".

1978—Pub. L. 95–622 substituted "this subchapter" for "this part".

STATUTORY NOTES AND RELATED SUBSIDIARIES

EFFECTIVE DATE OF 1985 AMENDMENT

Pub. L. 99–129, title II, §226(b), Oct. 22, 1985, 99 Stat. 547, provided that: "In the case of any facility that was or is constructed, remodeled, expanded, or acquired on or before the date of enactment of this Act [Oct. 22, 1985] or within 180 days after the date of enactment of this Act, the period described in clause (i) or (ii), as the case may be, of section 2115(c)(2)(B) [now 243(c)(2)(B)] of the Public Health Service Act [42 U.S.C. 238l(c)(2)(B)(i), (ii)] (as amended by subsection (a) of this section) shall begin no earlier than 181 days after the date of enactment of this Act."

EFFECTIVE DATE OF 1981 AMENDMENT

Pub. L. 97–35, title IX, §902(h), Aug. 13, 1981, 95 Stat. 561, provided that: "The amendments made by this section [amending this section and sections 201, 225a [now 238d], 229b [now 238j], 243, 246, 289k–1, 300d–4, 300d–6, 300l–2, 300m, 300m–3, 9412, and 9511 of this title, repealing sections 247b–1, 247b–2, 255, 300d to 300d–3, 300d–5, 300d–7 to 300d–9, 300d–21, 2689 to 2689l, 2689n to 2689p, 2689r to 2689aa, 9411, 9421 to 9423, 9431 to 9438, 9451, 9452, 9461 to 9465, 9471 to 9473, 9481, 9491 to 9493, 9502, 9512, 9521, and 9523 of this title, repealing provisions set out as notes under sections 246 and 2689 of this title, and transferring section 2689m to section 229d [now 238l] of this title] shall take effect October 1, 1981."

EFFECTIVE DATE OF 1978 AMENDMENT

Pub. L. 95–622, title I, §110(c), Nov. 9, 1978, 92 Stat. 3420, provided that the amendment made by that section is effective July 29, 1975.

EFFECTIVE DATE

Section effective July 1, 1975, see section 608 of Pub. L. 94–63, set out as an Effective Date of 1975 Amendment note under section 247b of this title.

OTHER LEGAL RIGHTS OF UNITED STATES NOT ADVERSELY AFFECTED BY 1985 AMENDMENT

Pub. L. 99–129, title II, §226(c), Oct. 22, 1985, 99 Stat. 547, provided that: "The amendments made by subsection (a) of this section [amending this section] shall not adversely affect other legal rights of the United States."

§238m. Use of fiscal agents

(a) Contracting authority

The Secretary may enter into contracts with fiscal agents—

(1)(A) to determine the amounts payable to persons who, on behalf of the Indian Health Service, furnish health services to eligible Indians,

(B) to determine the amounts payable to persons who, on behalf of the Public Health Service, furnish health services to individuals pursuant to section 247d or 249 of this title,

(2) to receive, disburse, and account for funds in making payments described in paragraph (1),

(3) to make such audits of records as may be necessary to assure that these payments are proper, and

(4) to perform such additional functions as may be necessary to carry out the functions described in paragraphs (1) through (3).

(b) Contracting prerequisites

(1) Contracts under subsection (a) may be entered into without regard to section 6101 of title 41 or any other provision of law requiring competition.

(2) No such contract shall be entered into with an entity unless the Secretary finds that the entity will perform its obligations under the contract efficiently and effectively and will meet such requirements as to financial responsibility, legal authority, and other matters as he finds pertinent.

(c) Advances under contracts

A contract under subsection (a) may provide for advances of funds to enable entities to make payments under the contract.

(d) Applicable statutory provisions

Subsections (d) and (e) [1] of section 1395u of this title shall apply to contracts with entities under subsection (a) in the same manner as they apply to contracts with carriers under that section.

(e) "Fiscal agent" defined

In this section, the term "fiscal agent" means a carrier described in section 1395u(f)(1) [1] of this title and includes, with respect to contracts under subsection (a)(1)(A), an Indian tribe or tribal

organization acting under contract with the Secretary under the Indian Self-Determination Act (Public Law 93–638) [25 U.S.C. 5321 et seq.].

(July 1, 1944, ch. 373, title II, §244, formerly title XXI, §2116, as added Pub. L. 99–272, title XVII, §17003, Apr. 7, 1986, 100 Stat. 359; renumbered title XXIII, §2316, Pub. L. 99–660, title III, §311(a), Nov. 14, 1986, 100 Stat. 3755; renumbered title XXV, §2514, Pub. L. 100–607, title II, §201(1), (3), Nov. 4, 1988, 102 Stat. 3062, 3063; renumbered title XXVI, §2614, Pub. L. 100–690, title II, §2620(a), Nov. 18, 1988, 102 Stat. 4244; renumbered title XXVII, §2714, Pub. L. 101–381, title I, §101(1), (2), Aug. 18, 1990, 104 Stat. 576; renumbered title II, §244, Pub. L. 103–43, title XX, §2010(a)(1)–(3), June 10, 1993, 107 Stat. 213.)

EDITORIAL NOTES

REFERENCES IN TEXT

Subsections (d), (e), and (f) of section 1395u of this title, referred to in subsecs. (d) and (e), were repealed by Pub. L. 108–173, title IX, §911(c)(5), Dec. 8, 2003, 117 Stat. 2384.

The Indian Self-Determination Act, referred to in subsec. (e), is title I of Pub. L. 93–638, Jan. 4, 1975, 88 Stat. 2206, which is classified principally to subchapter I (§5321 et seq.) of chapter 46 of Title 25, Indians. For complete classification of this Act to the Code, see Short Title note set out under section 5301 of Title 25 and Tables.

CODIFICATION

In subsec. (b)(1), "section 6101 of title 41" substituted for "section 3709 of the Revised Statutes (41 U.S.C. 5)" on authority of Pub. L. 111–350, §6(c), Jan. 4, 2011, 124 Stat. 3854, which Act enacted Title 41, Public Contracts.

Section was classified to section 300aaa–13 of this title prior to renumbering by Pub. L. 103–43, to section 300cc–15 of this title prior to renumbering by Pub. L. 100–607, and to section 300aa–15 of this title prior to renumbering by Pub. L. 99–660.

[1] *See References in Text note below.*

§238n. Abortion-related discrimination in governmental activities regarding training and licensing of physicians

(a) In general

The Federal Government, and any State or local government that receives Federal financial assistance, may not subject any health care entity to discrimination on the basis that—

(1) the entity refuses to undergo training in the performance of induced abortions, to require or provide such training, to perform such abortions, or to provide referrals for such training or such abortions;

(2) the entity refuses to make arrangements for any of the activities specified in paragraph (1); or

(3) the entity attends (or attended) a post-graduate physician training program, or any other program of training in the health professions, that does not (or did not) perform induced abortions or require, provide or refer for training in the performance of induced abortions, or make arrangements for the provision of such training.

(b) Accreditation of postgraduate physician training programs

(1) In general

In determining whether to grant a legal status to a health care entity (including a license or certificate), or to provide such entity with financial assistance, services or other benefits, the Federal Government, or any State or local government that receives Federal financial assistance, shall deem accredited any postgraduate physician training program that would be accredited but

for the accrediting agency's reliance upon an accreditation standards [1] that requires an entity to perform an induced abortion or require, provide, or refer for training in the performance of induced abortions, or make arrangements for such training, regardless of whether such standard provides exceptions or exemptions. The government involved shall formulate such regulations or other mechanisms, or enter into such agreements with accrediting agencies, as are necessary to comply with this subsection.

(2) Rules of construction

(A) In general

With respect to subclauses (I) and (II) of section 292d(a)(2)(B)(i) of this title (relating to a program of insured loans for training in the health professions), the requirements in such subclauses regarding accredited internship or residency programs are subject to paragraph (1) of this subsection.

(B) Exceptions

This section shall not—

(i) prevent any health care entity from voluntarily electing to be trained, to train, or to arrange for training in the performance of, to perform, or to make referrals for induced abortions; or

(ii) prevent an accrediting agency or a Federal, State or local government from establishing standards of medical competency applicable only to those individuals who have voluntarily elected to perform abortions.

(c) Definitions

For purposes of this section:

(1) The term "financial assistance", with respect to a government program, includes governmental payments provided as reimbursement for carrying out health-related activities.

(2) The term "health care entity" includes an individual physician, a postgraduate physician training program, and a participant in a program of training in the health professions.

(3) The term "postgraduate physician training program" includes a residency training program.

(July 1, 1944, ch. 373, title II, §245, as added Pub. L. 104–134, title I, §101(d) [title V, §515], Apr. 26, 1996, 110 Stat. 1321–211, 1321–245; renumbered title I, Pub. L. 104–140, §1(a), May 2, 1996, 110 Stat. 1327.)

[1] *So in original. Probably should be "standard".*

§238*o*. Restriction on use of funds for assisted suicide, euthanasia, and mercy killing

Appropriations for carrying out the purposes of this chapter shall not be used in a manner inconsistent with the Assisted Suicide Funding Restriction Act of 1997 [42 U.S.C. 14401 et seq.].

(July 1, 1944, ch. 373, title II, §246, as added Pub. L. 105–12, §9(e), Apr. 30, 1997, 111 Stat. 27.)

EDITORIAL NOTES

REFERENCES IN TEXT

The Assisted Suicide Funding Restriction Act of 1997, referred to in text, is Pub. L. 105–12, Apr. 30, 1997, 111 Stat. 23, which is classified principally to chapter 138 (§14401 et seq.) of this title. For complete classification of this Act to the Code, see Short Title note set out under section 14401 of this title and Tables.

STATUTORY NOTES AND RELATED SUBSIDIARIES

EFFECTIVE DATE

Section effective Apr. 30, 1997, and applicable to Federal payments made pursuant to obligations incurred after Apr. 30, 1997, for items and services provided on or after such date, subject to also being applicable with respect to contracts entered into, renewed, or extended after Apr. 30, 1997, as well as contracts entered into before Apr. 30, 1997, to the extent permitted under such contracts, see section 11 of Pub. L. 105–12, set out as a note under section 14401 of this title.

§238p. Recommendations and guidelines regarding automated external defibrillators for Federal buildings

(a) Guidelines on placement

The Secretary shall establish guidelines with respect to placing automated external defibrillator devices in Federal buildings. Such guidelines shall take into account the extent to which such devices may be used by lay persons, the typical number of employees and visitors in the buildings, the extent of the need for security measures regarding the buildings, buildings or portions of buildings in which there are special circumstances such as high electrical voltage or extreme heat or cold, and such other factors as the Secretary determines to be appropriate.

(b) Related recommendations

The Secretary shall publish in the Federal Register the recommendations of the Secretary on the appropriate implementation of the placement of automated external defibrillator devices under subsection (a), including procedures for the following:

(1) Implementing appropriate training courses in the use of such devices, including the role of cardiopulmonary resuscitation.

(2) Proper maintenance and testing of the devices.

(3) Ensuring coordination with appropriate licensed professionals in the oversight of training of the devices.

(4) Ensuring coordination with local emergency medical systems regarding the placement and incidents of use of the devices.

(c) Consultations; consideration of certain recommendations

In carrying out this section, the Secretary shall—

(1) consult with appropriate public and private entities;

(2) consider the recommendations of national and local public-health organizations for improving the survival rates of individuals who experience cardiac arrest in nonhospital settings by minimizing the time elapsing between the onset of cardiac arrest and the initial medical response, including defibrillation as necessary; and

(3) consult with and counsel other Federal agencies where such devices are to be used.

(d) Date certain for establishing guidelines and recommendations

The Secretary shall comply with this section not later than 180 days after November 13, 2000.

(e) Definitions

For purposes of this section:

(1) The term "automated external defibrillator device" has the meaning given such term in section 238q of this title.

(2) The term "Federal building" includes a building or portion of a building leased or rented by a Federal agency, and includes buildings on military installations of the United States.

(July 1, 1944, ch. 373, title II, §247, as added Pub. L. 106–505, title IV, §403, Nov. 13, 2000, 114 Stat. 2337.)

STATUTORY NOTES AND RELATED SUBSIDIARIES

FINDINGS

Pub. L. 106–505, title IV, §402, Nov. 13, 2000, 114 Stat. 2336, provided that: "Congress makes the following findings:

"(1) Over 700 lives are lost every day to sudden cardiac arrest in the United States alone.

"(2) Two out of every three sudden cardiac deaths occur before a victim can reach a hospital.

"(3) More than 95 percent of these cardiac arrest victims will die, many because of lack of readily available life saving medical equipment.

"(4) With current medical technology, up to 30 percent of cardiac arrest victims could be saved if victims had access to immediate medical response, including defibrillation and cardiopulmonary resuscitation.

"(5) Once a victim has suffered a cardiac arrest, every minute that passes before returning the heart to a normal rhythm decreases the chance of survival by 10 percent.

"(6) Most cardiac arrests are caused by abnormal heart rhythms called ventricular fibrillation. Ventricular fibrillation occurs when the heart's electrical system malfunctions, causing a chaotic rhythm that prevents the heart from pumping oxygen to the victim's brain and body.

"(7) Communities that have implemented programs ensuring widespread public access to defibrillators, combined with appropriate training, maintenance, and coordination with local emergency medical systems, have dramatically improved the survival rates from cardiac arrest.

"(8) Automated external defibrillator devices have been demonstrated to be safe and effective, even when used by lay people, since the devices are designed not to allow a user to administer a shock until after the device has analyzed a victim's heart rhythm and determined that an electric shock is required.

"(9) Increasing public awareness regarding automated external defibrillator devices and encouraging their use in Federal buildings will greatly facilitate their adoption.

"(10) Limiting the liability of Good Samaritans and acquirers of automated external defibrillator devices in emergency situations may encourage the use of automated external defibrillator devices, and result in saved lives."

CERTAIN TECHNOLOGIES AND PRACTICES REGARDING SURVIVAL RATES FOR CARDIAC ARREST

Pub. L. 106–129, §7, Dec. 6, 1999, 113 Stat. 1676, provided that: "The Secretary of Health and Human Services shall, in consultation with the Administrator of the General Services Administration and other appropriate public and private entities, develop recommendations regarding the placement of automatic external defibrillators in Federal buildings as a means of improving the survival rates of individuals who experience cardiac arrest in such buildings, including recommendations on training, maintenance, and medical oversight, and on coordinating with the system for emergency medical services."

§238q. Liability regarding emergency use of automated external defibrillators

(a) Good Samaritan protections regarding AEDs

Except as provided in subsection (b), any person who uses or attempts to use an automated external defibrillator device on a victim of a perceived medical emergency is immune from civil liability for any harm resulting from the use or attempted use of such device; and in addition, any person who acquired the device is immune from such liability, if the harm was not due to the failure of such acquirer of the device—

(1) to notify local emergency response personnel or other appropriate entities of the most recent placement of the device within a reasonable period of time after the device was placed;

(2) to properly maintain and test the device; or

(3) to provide appropriate training in the use of the device to an employee or agent of the acquirer when the employee or agent was the person who used the device on the victim, except that such requirement of training does not apply if—

(A) the employee or agent was not an employee or agent who would have been reasonably expected to use the device; or

(B) the period of time elapsing between the engagement of the person as an employee or agent and the occurrence of the harm (or between the acquisition of the device and the occurrence of the harm, in any case in which the device was acquired after such engagement of the person) was not a reasonably sufficient period in which to provide the training.

(b) Inapplicability of immunity

Immunity under subsection (a) does not apply to a person if—

(1) the harm involved was caused by willful or criminal misconduct, gross negligence, reckless misconduct, or a conscious, flagrant indifference to the rights or safety of the victim who was harmed;

(2) the person is a licensed or certified health professional who used the automated external defibrillator device while acting within the scope of the license or certification of the professional and within the scope of the employment or agency of the professional;

(3) the person is a hospital, clinic, or other entity whose purpose is providing health care directly to patients, and the harm was caused by an employee or agent of the entity who used the device while acting within the scope of the employment or agency of the employee or agent; or

(4) the person is an acquirer of the device who leased the device to a health care entity (or who otherwise provided the device to such entity for compensation without selling the device to the entity), and the harm was caused by an employee or agent of the entity who used the device while acting within the scope of the employment or agency of the employee or agent.

(c) Rules of construction

(1) In general

The following applies with respect to this section:

(A) This section does not establish any cause of action, or require that an automated external defibrillator device be placed at any building or other location.

(B) With respect to a class of persons for which this section provides immunity from civil liability, this section supersedes the law of a State only to the extent that the State has no statute or regulations that provide persons in such class with immunity for civil liability arising from the use by such persons of automated external defibrillator devices in emergency situations (within the meaning of the State law or regulation involved).

(C) This section does not waive any protection from liability for Federal officers or employees under—

(i) section 233 of this title; or

(ii) sections 1346(b), 2672, and 2679 of title 28 or under alternative benefits provided by the United States where the availability of such benefits precludes a remedy under section 1346(b) of title 28.

(2) Civil actions under Federal law

(A) In general

The applicability of subsections (a) and (b) includes applicability to any action for civil liability described in subsection (a) that arises under Federal law.

(B) Federal areas adopting State law

If a geographic area is under Federal jurisdiction and is located within a State but out of the jurisdiction of the State, and if, pursuant to Federal law, the law of the State applies in such area regarding matters for which there is no applicable Federal law, then an action for civil liability described in subsection (a) that in such area arises under the law of the State is subject to subsections (a) through (c) in lieu of any related State law that would apply in such area in the absence of this subparagraph.

(d) Federal jurisdiction

In any civil action arising under State law, the courts of the State involved have jurisdiction to apply the provisions of this section exclusive of the jurisdiction of the courts of the United States.

(e) Definitions

(1) Perceived medical emergency

For purposes of this section, the term "perceived medical emergency" means circumstances in which the behavior of an individual leads a reasonable person to believe that the individual is

experiencing a life-threatening medical condition that requires an immediate medical response regarding the heart or other cardiopulmonary functioning of the individual.

(2) Other definitions

For purposes of this section:

(A) The term "automated external defibrillator device" means a defibrillator device that—

(i) is commercially distributed in accordance with the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 301 et seq.];

(ii) is capable of recognizing the presence or absence of ventricular fibrillation, and is capable of determining without intervention by the user of the device whether defibrillation should be performed;

(iii) upon determining that defibrillation should be performed, is able to deliver an electrical shock to an individual; and

(iv) in the case of a defibrillator device that may be operated in either an automated or a manual mode, is set to operate in the automated mode.

(B)(i) The term "harm" includes physical, nonphysical, economic, and noneconomic losses.

(ii) The term "economic loss" means any pecuniary loss resulting from harm (including the loss of earnings or other benefits related to employment, medical expense loss, replacement services loss, loss due to death, burial costs, and loss of business or employment opportunities) to the extent recovery for such loss is allowed under applicable State law.

(iii) The term "noneconomic losses" means losses for physical and emotional pain, suffering, inconvenience, physical impairment, mental anguish, disfigurement, loss of enjoyment of life, loss of society and companionship, loss of consortium (other than loss of domestic service), hedonic damages, injury to reputation and all other nonpecuniary losses of any kind or nature.

(July 1, 1944, ch. 373, title II, §248, as added Pub. L. 106–505, title IV, §404, Nov. 13, 2000, 114 Stat. 2338.)

EDITORIAL NOTES

REFERENCES IN TEXT

The Federal Food, Drug, and Cosmetic Act, referred to in subsec. (e)(2)(A)(i), is act June 25, 1938, ch. 675, 52 Stat. 1040, which is classified generally to chapter 9 (§301 et seq.) of Title 21, Food and Drugs. For complete classification of this Act to the Code, see section 301 of Title 21 and Tables.

PART C—SMALLPOX EMERGENCY PERSONNEL PROTECTION

§239. General provisions

(a) Definitions

For purposes of this part:

(1) Covered countermeasure

The term "covered countermeasure" means a covered countermeasure as specified in a Declaration made pursuant to section 233(p) of this title.

(2) Covered individual

The term "covered individual" means an individual—

(A) who is a health care worker, law enforcement officer, firefighter, security personnel, emergency medical personnel, other public safety personnel, or support personnel for such occupational specialities [1];

(B) who is or will be functioning in a role identified in a State, local, or Department of Health and Human Services smallpox emergency response plan (as defined in paragraph (7)) approved by the Secretary;

(C) who has volunteered and been selected to be a member of a smallpox emergency response plan described in subparagraph (B) prior to the time at which the Secretary publicly announces that an active case of smallpox has been identified either within or outside of the United States; and

(D) to whom a smallpox vaccine is administered pursuant to such approved plan during the effective period of the Declaration (including the portion of such period before April 30, 2003).

(3) Covered injury

The term "covered injury" means an injury, disability, illness, condition, or death (other than a minor injury such as minor scarring or minor local reaction) determined, pursuant to the procedures established under section 239a of this title, to have been sustained by an individual as the direct result of—

(A) administration to the individual of a covered countermeasure during the effective period of the Declaration; or

(B) accidental vaccinia inoculation of the individual in circumstances in which—

(i) the vaccinia is contracted during the effective period of the Declaration or within 30 days after the end of such period;

(ii) smallpox vaccine has not been administered to the individual; and

(iii) the individual has been in contact with an individual who is (or who was accidentally inoculated by) a covered individual.

(4) Declaration

The term "Declaration" means the Declaration Regarding Administration of Smallpox Countermeasures issued by the Secretary on January 24, 2003, and published in the Federal Register on January 28, 2003.

(5) Effective period of the Declaration

The term "effective period of the Declaration" means the effective period specified in the Declaration, unless extended by the Secretary.

(6) Eligible individual

The term "eligible individual" means an individual who is (as determined in accordance with section 239a of this title)—

(A) a covered individual who sustains a covered injury in the manner described in paragraph (3)(A); or

(B) an individual who sustains a covered injury in the manner described in paragraph (3)(B).

(7) Smallpox emergency response plan

The term "smallpox emergency response plan" or "plan" means a response plan detailing actions to be taken in preparation for a possible smallpox-related emergency during the period prior to the identification of an active case of smallpox either within or outside the United States.

(b) Voluntary program

The Secretary shall ensure that a State, local, or Department of Health and Human Services plan to vaccinate individuals that is approved by the Secretary establishes procedures to ensure, consistent with the Declaration and any applicable guidelines of the Centers for Disease Control and Prevention, that—

(1) potential participants are educated with respect to contraindications, the voluntary nature of the program, and the availability of potential benefits and compensation under this part;

(2) there is voluntary screening provided to potential participants that can identify health conditions relevant to contraindications; and

(3) there is appropriate post-inoculation medical surveillance that includes an evaluation of adverse health effects that may reasonably appear to be due to such vaccine and prompt referral of,

or the provision of appropriate information to, any individual requiring health care as a result of such adverse health event.

(July 1, 1944, ch. 373, title II, §261, as added Pub. L. 108–20, §2, Apr. 30, 2003, 117 Stat. 638.)

[1] *So in original. Probably should be "specialties".*

§239a. Determination of eligibility and benefits

(a) In general

The Secretary shall establish procedures for determining, as applicable with respect to an individual—

(1) whether the individual is an eligible individual;

(2) whether an eligible individual has sustained a covered injury or injuries for which medical benefits or compensation may be available under sections 239c and 239d of this title, and the amount of such benefits or compensation; and

(3) whether the covered injury or injuries of an eligible individual caused the individual's death for purposes of benefits under section 239e of this title.

(b) Covered individuals

The Secretary may accept a certification, by a Federal, State, or local government entity or private health care entity participating in the administration of covered countermeasures under the Declaration, that an individual is a covered individual.

(c) Criteria for reimbursement

(1) Injuries specified in injury table

In any case where an injury or other adverse effect specified in the injury table established under section 239b of this title as a known effect of a vaccine manifests in an individual within the time period specified in such table, such injury or other effect shall be presumed to have resulted from administration of such vaccine.

(2) Other determinations

In making determinations other than those described in paragraph (1) as to the causation or severity of an injury, the Secretary shall employ a preponderance of the evidence standard and take into consideration all relevant medical and scientific evidence presented for consideration, and may obtain and consider the views of qualified medical experts.

(d) Deadline for filing request

The Secretary shall not consider any request for a benefit under this part with respect to an individual, unless—

(1) in the case of a request based on the administration of the vaccine to the individual, the individual files with the Secretary an initial request for benefits or compensation under this part not later than one year after the date of administration of the vaccine; or

(2) in the case of a request based on accidental vaccinia inoculation, the individual files with the Secretary an initial request for benefits or compensation under this part not later than two years after the date of the first symptom or manifestation of onset of the adverse effect.

(e) Structured settlements at Secretary's option

In any case in which there is a reasonable likelihood that compensation or payment under section 239c, 239d, or 239e(b) of this title will be required for a period in excess of one year from the date an individual is determined eligible for such compensation or payment, the Secretary shall have the discretion to make a lump-sum payment, purchase an annuity or medical insurance policy, or execute an appropriate structured settlement agreement, provided that such payment, annuity, policy, or agreement is actuarially determined to have a value equal to the present value of the projected total

amount of benefits or compensation that the individual is eligible to receive under such section or sections.

(f) Review of determination

(1) Secretary's review authority

The Secretary may review a determination under this section at any time on the Secretary's own motion or on application, and may affirm, vacate, or modify such determination in any manner the Secretary deems appropriate. The Secretary shall develop a process by which an individual may file a request for reconsideration of any determination made by the Secretary under this section.

(2) Judicial and administrative review

No court of the United States, or of any State, District, territory or possession thereof, shall have subject matter jurisdiction to review, whether by mandamus or otherwise, any action by the Secretary under this section. No officer or employee of the United States shall review any action by the Secretary under this section (unless the President specifically directs otherwise).

(July 1, 1944, ch. 373, title II, §262, as added Pub. L. 108–20, §2, Apr. 30, 2003, 117 Stat. 640.)

§239b. Smallpox vaccine injury table

(a) [1] Smallpox vaccine injury table

(1) Establishment required

The Secretary shall establish by interim final regulation a table identifying adverse effects (including injuries, disabilities, illnesses, conditions, and deaths) that shall be presumed to result from the administration of (or exposure to) a smallpox vaccine, and the time period in which the first symptom or manifestation of onset of each such adverse effect must manifest in order for such presumption to apply.

(2) Amendments

The Secretary may by regulation amend the table established under paragraph (1). An amendment to the table takes effect on the date of the promulgation of the final rule that makes the amendment, and applies to all requests for benefits or compensation under this part that are filed on or after such date or are pending as of such date. In addition, the amendment applies retroactively to an individual who was not with respect to the injury involved an eligible individual under the table as in effect before the amendment but who with respect to such injury is an eligible individual under the table as amended. With respect to a request for benefits or compensation under this part by an individual who becomes an eligible individual as described in the preceding sentence, the Secretary may not provide such benefits or compensation unless the request (or amendment to a request, as applicable) is filed before the expiration of one year after the effective date of the amendment to the table in the case of an individual to whom the vaccine was administered and before the expiration of two years after such effective date in the case of a request based on accidental vaccinia inoculation.

(July 1, 1944, ch. 373, title II, §263, as added Pub. L. 108–20, §2, Apr. 30, 2003, 117 Stat. 641.)

[1] So in original. No subsec. (b) has been enacted.

§239c. Medical benefits

(a) In general

Subject to the succeeding provisions of this section, the Secretary shall make payment or reimbursement for medical items and services as reasonable and necessary to treat a covered injury of an eligible individual, including the services, appliances, and supplies prescribed or recommended

by a qualified physician, which the Secretary considers likely to cure, give relief, reduce the degree or the period of disability, or aid in lessening the amount of monthly compensation.

(b) Benefits secondary to other coverage

Payment or reimbursement for services or benefits under subsection (a) shall be secondary to any obligation of the United States or any third party (including any State or local governmental entity, private insurance carrier, or employer) under any other provision of law or contractual agreement, to pay for or provide such services or benefits.

(July 1, 1944, ch. 373, title II, §264, as added Pub. L. 108–20, §2, Apr. 30, 2003, 117 Stat. 641.)

§239d. Compensation for lost employment income

(a) In general

Subject to the succeeding provisions of this section, the Secretary shall provide compensation to an eligible individual for loss of employment income (based on such income at the time of injury) incurred as a result of a covered injury, at the rate specified in subsection (b).

(b) Amount of compensation

(1) In general

Compensation under subsection (a) shall be at the rate of 662/3 percent of the relevant pay period (weekly, monthly, or otherwise), except as provided in paragraph (2).

(2) Augmented compensation for dependents

If an eligible individual has one or more dependents, the basic compensation for loss of employment income as described in paragraph (1) shall be augmented at the rate of 81/3 percent.

(3) Consideration of other programs

(A) In general

The Secretary may consider the provisions of sections 8114, 8115, and 8146a of title 5, and any implementing regulations, in determining the amount of payment under subsection (a) and the circumstances under which such payments are reasonable and necessary.

(B) Minors

With respect to an eligible individual who is a minor, the Secretary may consider the provisions of section 8113 of title 5, and any implementing regulations, in determining the amount of payment under subsection (a) and the circumstances under which such payments are reasonable and necessary.

(4) Treatment of self-employment income

For purposes of this section, the term "employment income" includes income from self-employment.

(c) Limitations

(1) Benefits secondary to other coverage

(A) In general

Any compensation under subsection (a) shall be secondary to the obligation of the United States or any third party (including any State or local governmental entity, private insurance carrier, or employer), under any other law or contractual agreement, to pay compensation for loss of employment income or to provide disability or retirement benefits.

(B) Relation to other obligations

Compensation under subsection (a) shall not be made to an eligible individual to the extent that the total of amounts paid to the individual under such subsection and under the other obligations referred to in subparagraph (A) is an amount that exceeds the rate specified in

subsection (b)(1). If under any such other obligation a lump-sum payment is made, such payment shall, for purposes of this paragraph, be deemed to be received over multiple years rather than received in a single year. The Secretary may, in the discretion of the Secretary, determine how to apportion such payment over multiple years.

(2) No benefits in case of death

No payment shall be made under subsection (a) in compensation for loss of employment income subsequent to the receipt, by the survivor or survivors of an eligible individual, of benefits under section 239e of this title for death.

(3) Limit on total benefits

(A) In general

Except as provided in subparagraph (B)—

(i) total compensation paid to an individual under subsection (a) shall not exceed $50,000 for any year; and

(ii) the lifetime total of such compensation for the individual may not exceed an amount equal to the amount authorized to be paid under section 239e of this title.

(B) Permanent and total disability

The limitation under subparagraph (A)(ii) does not apply in the case of an eligible individual who is determined to have a covered injury or injuries meeting the definition of disability in section 416(i) of this title.

(4) Waiting period

(A) In general

Except as provided in subparagraph (B), an eligible individual shall not be provided compensation under this section for the first 5 work days of loss of employment income.

(B) Exception

Subparagraph (A) does not apply if the period of loss of employment income of an eligible individual is 10 or more work days.

(5) Termination of benefits

No payment shall be made under subsection (a) in compensation for loss of employment income once the eligible individual involves [1] reaches the age of 65.

(d) Benefit in addition to medical benefits

A benefit under subsection (a) shall be in addition to any amounts received by an eligible individual under section 239c of this title.

(July 1, 1944, ch. 373, title II, §265, as added Pub. L. 108–20, §2, Apr. 30, 2003, 117 Stat. 642.)

[1] So in original. Probably should be "involved".

§239e. Payment for death

(a) Death benefit

(1) In general

The Secretary shall pay, in the case of an eligible individual whose death is determined to have resulted from a covered injury or injuries, a death benefit in the amount determined under paragraph (2) to the survivor or survivors in the same manner as death benefits are paid pursuant to the Public Safety Officers' Benefits Program under subpart 1 of part L of title I of the Omnibus

Crime Control and Safe Streets Act of 1968 (42 U.S.C. 3796 et seq.) [1] with respect to an eligible deceased (except that in the case of an eligible individual who is a minor with no living parent, the legal guardian shall be considered the survivor in the place of the parent).

(2) Benefit amount

(A) In general

The amount of the death benefit under paragraph (1) in a fiscal year shall equal the amount of the comparable benefit calculated under the Public Safety Officers' Benefits Program under subpart 1 of part L of title I of the Omnibus Crime Control and Safe Streets Act of 1968 (42 U.S.C. 3796 et seq.) [1] in such fiscal year, without regard to any reduction attributable to a limitation on appropriations, but subject to subparagraph (B).

(B) Reduction for payments for lost employment income

The amount of the benefit as determined under subparagraph (A) shall be reduced by the total amount of any benefits paid under section 239d of this title with respect to lost employment income.

(3) Limitations

(A) In general

No benefit is payable under paragraph (1) with respect to the death of an eligible individual if—

(i) a disability benefit is paid with respect to such individual under the Public Safety Officers' Benefits Program under subpart 1 of part L of title I of the Omnibus Crime Control and Safe Streets Act of 1968 (42 U.S.C. 3796 et seq.); [1] or

(ii) a death benefit is paid or payable with respect to such individual under the Public Safety Officers' Benefits Program under subpart 1 of part L of title I of the Omnibus Crime Control and Safe Streets Act of 1968 (42 U.S.C. 3796 et seq.).[1]

(B) Exception in the case of a limitation on appropriations for disability benefits under PSOB

In the event that disability benefits available to an eligible individual under the Public Safety Officers' Benefits Program under subpart 1 of part L of title I of the Omnibus Crime Control and Safe Streets Act of 1968 (42 U.S.C. 3796 et seq.) [1] are reduced because of a limitation on appropriations, and such reduction would affect the amount that would be payable under subparagraph (A) without regard to this subparagraph, benefits shall be available under paragraph (1) to the extent necessary to ensure that the survivor or survivors of such individual receives a total amount equal to the amount described in paragraph (2).

(b) Election in case of dependents

(1) In general

In the case of an eligible individual whose death is determined to have resulted from a covered injury or injuries, if the individual had one or more dependents under the age of 18, the legal guardian of the dependents may, in lieu of the death benefit under subsection (a), elect to receive on behalf of the aggregate of such dependents payments in accordance with this subsection. An election under the preceding sentence is effective in lieu of a request under subsection (a) by an individual who is not the legal guardian of such dependents.

(2) Amount of payments

Payments under paragraph (1) with respect to an eligible individual described in such paragraph shall be made as if such individual were an eligible individual to whom compensation would be paid under subsection (a) of section 239d of this title, with the rate augmented in accordance with subsection (b)(2) of such section and with such individual considered to be an eligible individual described in subsection (c)(3)(B) of such section.

(3) Limitations

(A) Age of dependents

No payments may be made under paragraph (1) once the youngest of the dependents involved reaches the age of 18.

(B) Benefits secondary to other coverage

(i) In general

Any payment under paragraph (1) shall be secondary to the obligation of the United States or any third party (including any State or local governmental entity, private insurance carrier, or employer), under any other law or contractual agreement, to pay compensation for loss of employment income or to provide disability benefits, retirement benefits, life insurance benefits on behalf of dependents under the age of 18, or death benefits.

(ii) Relation to other obligations

Payments under paragraph (1) shall not be made to with respect to [2] an eligible individual to the extent that the total of amounts paid with respect to the individual under such paragraph and under the other obligations referred to in clause (i) is an amount that exceeds the rate of payment that applies under paragraph (2). If under any such other obligation a lump-sum payment is made, such payment shall, for purposes of this subparagraph, be deemed to be received over multiple years rather than received in a single year. The Secretary may, in the discretion of the Secretary, determine how to apportion such payment over multiple years.

(c) Benefit in addition to medical benefits

A benefit under subsection (a) or (b) shall be in addition to any amounts received by an eligible individual under section 239c of this title.

(July 1, 1944, ch. 373, title II, §266, as added Pub. L. 108–20, §2, Apr. 30, 2003, 117 Stat. 643.)

EDITORIAL NOTES

REFERENCES IN TEXT

The Omnibus Crime Control and Safe Streets Act of 1968, referred to in subsec. (a)(1), (2)(A), (3), is Pub. L. 90–351, June 19, 1968, 82 Stat. 197. Subpart 1 of part L of title I of the Act was classified generally to part A (§3796 et seq.) of subchapter XII of chapter 46 of this title prior to editorial reclassification and renumbering as part A (§10281 et seq.) of subchapter XI of chapter 101 of Title 34, Crime Control and Law Enforcement. For complete classification of this Act to the Code, see Short Title of 1968 Act note set out under section 10101 of Title 34 and Tables.

[1] See References in Text note below.

[2] So in original.

§239f. Administration

(a) Administration by agreement with other agency or agencies

The Secretary may administer any or all of the provisions of this part through Memorandum of Agreement with the head of any appropriate Federal agency.

(b) Regulations

The head of the agency administering this part or provisions thereof (including any agency head administering such Act [1] or provisions through a Memorandum of Agreement under subsection (a)) may promulgate such implementing regulations as may be found necessary and appropriate. Initial

implementing regulations may be interim final regulations.

(July 1, 1944, ch. 373, title II, §267, as added Pub. L. 108–20, §2, Apr. 30, 2003, 117 Stat. 645.)

[1] So in original. Probably should be "part".

§239g. Authorization of appropriations

For the purpose of carrying out this part, there are authorized to be appropriated such sums as may be necessary for each of the fiscal years 2003 through 2007, to remain available until expended, including administrative costs and costs of provision and payment of benefits. The Secretary's payment of any benefit under section 239c, 239d, or 239e of this title shall be subject to the availability of appropriations under this section.

(July 1, 1944, ch. 373, title II, §268, as added Pub. L. 108–20, §2, Apr. 30, 2003, 117 Stat. 645.)

§239h. Relationship to other laws

Except as explicitly provided herein, nothing in this part shall be construed to override or limit any rights an individual may have to seek compensation, benefits, or redress under any other provision of Federal or State law.

(July 1, 1944, ch. 373, title II, §269, as added Pub. L. 108–20, §2, Apr. 30, 2003, 117 Stat. 645.)

PART D—UNITED STATES PUBLIC HEALTH SCIENCES TRACK

§239*l*. Establishment

(a) United States Public Health Services Track

(1) In general

There is hereby authorized to be established a United States Public Health Sciences Track (referred to in this part as the "Track"), at sites to be selected by the Secretary, with authority to grant appropriate advanced degrees in a manner that uniquely emphasizes team-based service, public health, epidemiology, and emergency preparedness and response. It shall be so organized as to graduate not less than—

(A) 150 medical students annually, 10 of whom shall be awarded studentships to the Uniformed Services University of Health Sciences;

(B) 100 dental students annually;

(C) 250 nursing students annually;

(D) 100 public health students annually;

(E) 100 behavioral and mental health professional students annually;

(F) 100 physician assistant or nurse practitioner students annually; and

(G) 50 pharmacy students annually.

(2) Locations

The Track shall be located at existing and accredited, affiliated health professions education training programs at academic health centers located in regions of the United States determined appropriate by the Surgeon General, in consultation with the National Health Care Workforce Commission established in section 294q of this title.

(b) Number of graduates

Except as provided in subsection (a), the number of persons to be graduated from the Track shall be prescribed by the Secretary. In so prescribing the number of persons to be graduated from the Track, the Secretary shall institute actions necessary to ensure the maximum number of first-year enrollments in the Track consistent with the academic capacity of the affiliated sites and the needs of the United States for medical, dental, and nursing personnel.

(c) Development

The development of the Track may be by such phases as the Secretary may prescribe subject to the requirements of subsection (a).

(d) Integrated longitudinal plan

The Surgeon General shall develop an integrated longitudinal plan for health professions continuing education throughout the continuum of health-related education, training, and practice. Training under such plan shall emphasize patient-centered, interdisciplinary, and care coordination skills. Experience with deployment of emergency response teams shall be included during the clinical experiences.

(e) Faculty development

The Surgeon General shall develop faculty development programs and curricula in decentralized venues of health care, to balance urban, tertiary, and inpatient venues.

(July 1, 1944, ch. 373, title II, §271, as added Pub. L. 111–148, title V, §5315, Mar. 23, 2010, 124 Stat. 637.)

§239*l*–1. Administration

(a) In general

The business of the Track shall be conducted by the Surgeon General with funds appropriated for and provided by the Department of Health and Human Services. The National Health Care Workforce Commission shall assist the Surgeon General in an advisory capacity.

(b) Faculty

(1) In general

The Surgeon General, after considering the recommendations of the National Health Care Workforce Commission, shall obtain the services of such professors, instructors, and administrative and other employees as may be necessary to operate the Track, but utilize when possible, existing affiliated health professions training institutions. Members of the faculty and staff shall be employed under salary schedules and granted retirement and other related benefits prescribed by the Secretary so as to place the employees of the Track faculty on a comparable basis with the employees of fully accredited schools of the health professions within the United States.

(2) Titles

The Surgeon General may confer academic titles, as appropriate, upon the members of the faculty.

(3) Nonapplication of provisions

The limitations in section 5373 of title 5 shall not apply to the authority of the Surgeon General under paragraph (1) to prescribe salary schedules and other related benefits.

(c) Agreements

The Surgeon General may negotiate agreements with agencies of the Federal Government to utilize on a reimbursable basis appropriate existing Federal medical resources located in the United States (or locations selected in accordance with section 239l(a)(2) of this title). Under such agreements the facilities concerned will retain their identities and basic missions. The Surgeon

General may negotiate affiliation agreements with accredited universities and health professions training institutions in the United States. Such agreements may include provisions for payments for educational services provided students participating in Department of Health and Human Services educational programs.

(d) Programs

The Surgeon General may establish the following educational programs for Track students:

(1) Postdoctoral, postgraduate, and technological programs.

(2) A cooperative program for medical, dental, physician assistant, pharmacy, behavioral and mental health, public health, and nursing students.

(3) Other programs that the Surgeon General determines necessary in order to operate the Track in a cost-effective manner.

(e) Continuing medical education

The Surgeon General shall establish programs in continuing medical education for members of the health professions to the end that high standards of health care may be maintained within the United States.

(f) Authority of the Surgeon General

(1) In general

The Surgeon General is authorized—

(A) to enter into contracts with, accept grants from, and make grants to any nonprofit entity for the purpose of carrying out cooperative enterprises in medical, dental, physician assistant, pharmacy, behavioral and mental health, public health, and nursing research, consultation, and education;

(B) to enter into contracts with entities under which the Surgeon General may furnish the services of such professional, technical, or clerical personnel as may be necessary to fulfill cooperative enterprises undertaken by the Track;

(C) to accept, hold, administer, invest, and spend any gift, devise, or bequest of personal property made to the Track, including any gift, devise, or bequest for the support of an academic chair, teaching, research, or demonstration project;

(D) to enter into agreements with entities that may be utilized by the Track for the purpose of enhancing the activities of the Track in education, research, and technological applications of knowledge; and

(E) to accept the voluntary services of guest scholars and other persons.

(2) Limitation

The Surgeon General may not enter into any contract with an entity if the contract would obligate the Track to make outlays in advance of the enactment of budget authority for such outlays.

(3) Scientists

Scientists or other medical, dental, or nursing personnel utilized by the Track under an agreement described in paragraph (1) may be appointed to any position within the Track and may be permitted to perform such duties within the Track as the Surgeon General may approve.

(4) Volunteer services

A person who provides voluntary services under the authority of subparagraph (E) of paragraph (1) shall be considered to be an employee of the Federal Government for the purposes of chapter 81 of title 5, relating to compensation for work-related injuries, and to be an employee of the Federal Government for the purposes of chapter 171 of title 28, relating to tort claims. Such a person who is not otherwise employed by the Federal Government shall not be considered to be a Federal employee for any other purpose by reason of the provision of such services.

(July 1, 1944, ch. 373, title II, §272, as added Pub. L. 111–148, title V, §5315, Mar. 23, 2010, 124 Stat. 637.)

§239*l*–2. Students; selection; obligation

(a) Student selection

(1) In general

Medical, dental, physician assistant, pharmacy, behavioral and mental health, public health, and nursing students at the Track shall be selected under procedures prescribed by the Surgeon General. In so prescribing, the Surgeon General shall consider the recommendations of the National Health Care Workforce Commission.

(2) Priority

In developing admissions procedures under paragraph (1), the Surgeon General shall ensure that such procedures give priority to applicant medical, dental, physician assistant, pharmacy, behavioral and mental health, public health, and nursing students from rural communities and underrepresented minorities.

(b) Contract and service obligation

(1) Contract

Upon being admitted to the Track, a medical, dental, physician assistant, pharmacy, behavioral and mental health, public health, or nursing student shall enter into a written contract with the Surgeon General that shall contain—

(A) an agreement under which—

(i) subject to subparagraph (B), the Surgeon General agrees to provide the student with tuition (or tuition remission) and a student stipend (described in paragraph (2)) in each school year for a period of years (not to exceed 4 school years) determined by the student, during which period the student is enrolled in the Track at an affiliated or other participating health professions institution pursuant to an agreement between the Track and such institution; and

(ii) subject to subparagraph (B), the student agrees—

(I) to accept the provision of such tuition and student stipend to the student;

(II) to maintain enrollment at the Track until the student completes the course of study involved;

(III) while enrolled in such course of study, to maintain an acceptable level of academic standing (as determined by the Surgeon General);

(IV) if pursuing a degree from a school of medicine or osteopathic medicine, dental, public health, or nursing school or a physician assistant, pharmacy, or behavioral and mental health professional program, to complete a residency or internship in a specialty that the Surgeon General determines is appropriate; and

(V) to serve for a period of time (referred to in this part as the "period of obligated service") within the Commissioned Corps of the Public Health Service equal to 2 years for each school year during which such individual was enrolled at the College, reduced as provided for in paragraph (3);

(B) a provision that any financial obligation of the United States arising out of a contract entered into under this part and any obligation of the student which is conditioned thereon, is contingent upon funds being appropriated to carry out this part;

(C) a statement of the damages to which the United States is entitled for the student's breach of the contract; and

(D) such other statements of the rights and liabilities of the Secretary and of the individual, not inconsistent with the provisions of this part.

(2) Tuition and student stipend

(A) Tuition remission rates

The Surgeon General, based on the recommendations of the National Health Care Workforce

Commission, shall establish Federal tuition remission rates to be used by the Track to provide reimbursement to affiliated and other participating health professions institutions for the cost of educational services provided by such institutions to Track students. The agreement entered into by such participating institutions under paragraph (1)(A)(i) shall contain an agreement to accept as payment in full the established remission rate under this subparagraph.

(B) Stipend

The Surgeon General, based on the recommendations of the National Health Care Workforce Commission, shall establish and update Federal stipend rates for payment to students under this part.

(3) Reductions in the period of obligated service

The period of obligated service under paragraph (1)(A)(ii)(V) shall be reduced—

(A) in the case of a student who elects to participate in a high-needs speciality residency (as determined by the National Health Care Workforce Commission), by 3 months for each year of such participation (not to exceed a total of 12 months); and

(B) in the case of a student who, upon completion of their residency, elects to practice in a Federal medical facility (as defined in section 781(e)) [1] that is located in a health professional shortage area (as defined in section 254e of this title), by 3 months for year [2] of full-time practice in such a facility (not to exceed a total of 12 months).

(c) Second 2 years of service

During the third and fourth years in which a medical, dental, physician assistant, pharmacy, behavioral and mental health, public health, or nursing student is enrolled in the Track, training should be designed to prioritize clinical rotations in Federal medical facilities in health professional shortage areas, and emphasize a balance of hospital and community-based experiences, and training within interdisciplinary teams.

(d) Dentist, physician assistant, pharmacist, behavioral and mental health professional, public health professional, and nurse training

The Surgeon General shall establish provisions applicable with respect to dental, physician assistant, pharmacy, behavioral and mental health, public health, and nursing students that are comparable to those for medical students under this section, including service obligations, tuition support, and stipend support. The Surgeon General shall give priority to health professions training institutions that train medical, dental, physician assistant, pharmacy, behavioral and mental health, public health, and nursing students for some significant period of time together, but at a minimum have a discrete and shared core curriculum.

(e) Elite Federal disaster teams

The Surgeon General, in consultation with the Secretary, the Director of the Centers for Disease Control and Prevention, and other appropriate military and Federal government agencies, shall develop criteria for the appointment of highly qualified Track faculty, medical, dental, physician assistant, pharmacy, behavioral and mental health, public health, and nursing students, and graduates to elite Federal disaster preparedness teams to train and to respond to public health emergencies, natural disasters, bioterrorism events, and other emergencies.

(f) Student dropped from Track in affiliate school

A medical, dental, physician assistant, pharmacy, behavioral and mental health, public health, or nursing student who, under regulations prescribed by the Surgeon General, is dropped from the Track in an affiliated school for deficiency in conduct or studies, or for other reasons, shall be liable to the United States for all tuition and stipend support provided to the student.

(July 1, 1944, ch. 373, title II, §273, as added Pub. L. 111–148, title V, §5315, Mar. 23, 2010, 124 Stat. 639.)

[1] So in original. Act July 1, 1944, does not contain a section 781.

[2] *So in original. Probably should be preceded by "each".*

§239*l*–3. Funding

Beginning with fiscal year 2010, the Secretary shall transfer from the Public Health and Social Services Emergency Fund such sums as may be necessary to carry out this part.

(July 1, 1944, ch. 373, title II, §274, as added Pub. L. 111–148, title V, §5315, Mar. 23, 2010, 124 Stat. 642.)

STATUTORY NOTES AND RELATED SUBSIDIARIES

TRANSFER OF APPROPRIATED FUNDS

Pub. L. 112–10, div. B, title VIII, §1828, Apr. 15, 2011, 125 Stat. 162, provided that: "Hereafter, no funds appropriated by this division or by any previous or subsequent Act shall be available for transfer under section 274 [42 U.S.C. 239l–3] of the PHS Act [Public Health Service Act]."

SUBCHAPTER II—GENERAL POWERS AND DUTIES

PART A—RESEARCH AND INVESTIGATIONS

§241. Research and investigations generally

(a) Authority of Secretary

The Secretary shall conduct in the Service, and encourage, cooperate with, and render assistance to other appropriate public authorities, scientific institutions, and scientists in the conduct of, and promote the coordination of, research, investigations, experiments, demonstrations, and studies relating to the causes, diagnosis, treatment, control, and prevention of physical and mental diseases and impairments of man, including water purification, sewage treatment, and pollution of lakes and streams. In carrying out the foregoing the Secretary is authorized to—

(1) collect and make available through publications and other appropriate means, information as to, and the practical application of, such research and other activities;

(2) make available research facilities of the Service to appropriate public authorities, and to health officials and scientists engaged in special study;

(3) make grants-in-aid to universities, hospitals, laboratories, and other public or private institutions, and to individuals for such research projects as are recommended by the advisory council to the entity of the Department supporting such projects and make, upon recommendation of the advisory council to the appropriate entity of the Department, grants-in-aid to public or nonprofit universities, hospitals, laboratories, and other institutions for the general support of their research;

(4) secure from time to time and for such periods as he deems advisable, the assistance and advice of experts, scholars, and consultants from the United States or abroad;

(5) for purposes of study, admit and treat at institutions, hospitals, and stations of the Service, persons not otherwise eligible for such treatment;

(6) make available, to health officials, scientists, and appropriate public and other nonprofit institutions and organizations, technical advice and assistance on the application of statistical methods to experiments, studies, and surveys in health and medical fields;

(7) enter into contracts, including contracts for research in accordance with and subject to the

provisions of law applicable to contracts entered into by the military departments under sections 3861 and 4141 of title 10, except that determination, approval, and certification required thereby shall be by the Secretary of Health and Human Services; and

(8) adopt, upon recommendations of the advisory councils to the appropriate entities of the Department or, with respect to mental health, the National Advisory Mental Health Council, such additional means as the Secretary considers necessary or appropriate to carry out the purposes of this section.

(b) Testing for carcinogenicity, teratogenicity, mutagenicity, and other harmful biological effects; consultation

(1) The Secretary shall conduct and may support through grants and contracts studies and testing of substances for carcinogenicity, teratogenicity, mutagenicity, and other harmful biological effects. In carrying out this paragraph, the Secretary shall consult with entities of the Federal Government, outside of the Department of Health and Human Services, engaged in comparable activities. The Secretary, upon request of such an entity and under appropriate arrangements for the payment of expenses, may conduct for such entity studies and testing of substances for carcinogenicity, teratogenicity, mutagenicity, and other harmful biological effects.

(2)(A) The Secretary shall establish a comprehensive program of research into the biological effects of low-level ionizing radiation under which program the Secretary shall conduct such research and may support such research by others through grants and contracts.

(B) The Secretary shall conduct a comprehensive review of Federal programs of research on the biological effects of ionizing radiation.

(3) The Secretary shall conduct and may support through grants and contracts research and studies on human nutrition, with particular emphasis on the role of nutrition in the prevention and treatment of disease and on the maintenance and promotion of health, and programs for the dissemination of information respecting human nutrition to health professionals and the public. In carrying out activities under this paragraph, the Secretary shall provide for the coordination of such of these activities as are performed by the different divisions within the Department of Health and Human Services and shall consult with entities of the Federal Government, outside of the Department of Health and Human Services, engaged in comparable activities. The Secretary, upon request of such an entity and under appropriate arrangements for the payment of expenses, may conduct and support such activities for such entity.

(4) The Secretary shall publish a biennial report which contains—

(A) a list of all substances (i) which either are known to be carcinogens or may reasonably be anticipated to be carcinogens and (ii) to which a significant number of persons residing in the United States are exposed;

(B) information concerning the nature of such exposure and the estimated number of persons exposed to such substances;

(C) a statement identifying (i) each substance contained in the list under subparagraph (A) for which no effluent, ambient, or exposure standard has been established by a Federal agency, and (ii) for each effluent, ambient, or exposure standard established by a Federal agency with respect to a substance contained in the list under subparagraph (A), the extent to which, on the basis of available medical, scientific, or other data, such standard, and the implementation of such standard by the agency, decreases the risk to public health from exposure to the substance; and

(D) a description of (i) each request received during the year involved—

(I) from a Federal agency outside the Department of Health and Human Services for the Secretary, or

(II) from an entity within the Department of Health and Human Services to any other entity within the Department,

to conduct research into, or testing for, the carcinogenicity of substances or to provide information described in clause (ii) of subparagraph (C), and (ii) how the Secretary and each such other entity, respectively, have responded to each such request.

(5) The authority of the Secretary to enter into any contract for the conduct of any study, testing, program, research, or review, or assessment under this subsection shall be effective for any fiscal year only to such extent or in such amounts as are provided in advance in appropriation Acts.

(c) Diseases not significantly occurring in United States

The Secretary may conduct biomedical research, directly or through grants or contracts, for the identification, control, treatment, and prevention of diseases (including tropical diseases) which do not occur to a significant extent in the United States.

(d) Protection of privacy of individuals who are research subjects

(1)(A) If a person is engaged in biomedical, behavioral, clinical, or other research, in which identifiable, sensitive information is collected (including research on mental health and research on the use and effect of alcohol and other psychoactive drugs), the Secretary, in coordination with other agencies, as applicable—

(i) shall issue to such person a certificate of confidentiality to protect the privacy of individuals who are the subjects of such research if the research is funded wholly or in part by the Federal Government; and

(ii) may, upon application by a person engaged in research, issue to such person a certificate of confidentiality to protect the privacy of such individuals if the research is not so funded.

(B) Except as provided in subparagraph (C), any person to whom a certificate is issued under subparagraph (A) to protect the privacy of individuals described in such subparagraph shall not disclose or provide to any other person not connected with the research the name of such an individual or any information, document, or biospecimen that contains identifiable, sensitive information about such an individual and that was created or compiled for purposes of the research.

(C) The disclosure prohibition in subparagraph (B) shall not apply to disclosure or use that is—

(i) required by Federal, State, or local laws, excluding instances described in subparagraph (D);

(ii) necessary for the medical treatment of the individual to whom the information, document, or biospecimen pertains and made with the consent of such individual;

(iii) made with the consent of the individual to whom the information, document, or biospecimen pertains; or

(iv) made for the purposes of other scientific research that is in compliance with applicable Federal regulations governing the protection of human subjects in research.

(D) Any person to whom a certificate is issued under subparagraph (A) to protect the privacy of an individual described in such subparagraph shall not, in any Federal, State, or local civil, criminal, administrative, legislative, or other proceeding, disclose or provide the name of such individual or any such information, document, or biospecimen that contains identifiable, sensitive information about the individual and that was created or compiled for purposes of the research, except in the circumstance described in subparagraph (C)(iii).

(E) Identifiable, sensitive information protected under subparagraph (A), and all copies thereof, shall be immune from the legal process, and shall not, without the consent of the individual to whom the information pertains, be admissible as evidence or used for any purpose in any action, suit, or other judicial, legislative, or administrative proceeding.

(F) Identifiable, sensitive information collected by a person to whom a certificate has been issued under subparagraph (A), and all copies thereof, shall be subject to the protections afforded by this section for perpetuity.

(G) The Secretary shall take steps to minimize the burden to researchers, streamline the process, and reduce the time it takes to comply with the requirements of this subsection.

(2) The Secretary shall coordinate with the heads of other applicable Federal agencies to ensure that such departments have policies in place with respect to the issuance of a certificate of confidentiality pursuant to paragraph (1) and other requirements of this subsection.

(3) Nothing in this subsection shall be construed to limit the access of an individual who is a subject of research to information about himself or herself collected during such individual's

participation in the research.

(4) For purposes of this subsection, the term "identifiable, sensitive information" means information that is about an individual and that is gathered or used during the course of research described in paragraph (1)(A) and—

(A) through which an individual is identified; or

(B) for which there is at least a very small risk, as determined by current scientific practices or statistical methods, that some combination of the information, a request for the information, and other available data sources could be used to deduce the identity of an individual.

(e) Preterm labor and delivery and infant mortality

The Secretary, acting through the Director of the Centers for Disease Control and Prevention, shall expand, intensify, and coordinate the activities of the Centers for Disease Control and Prevention with respect to preterm labor and delivery, preventable maternal mortality and severe maternal morbidity, and infant mortality.

(f) Exemption of certain biomedical information from disclosure

(1) The Secretary may exempt from disclosure under section 552(b)(3) of title 5 biomedical information that is about an individual and that is gathered or used during the course of biomedical research if—

(A) an individual is identified; or

(B) there is at least a very small risk, as determined by current scientific practices or statistical methods, that some combination of the information, the request, and other available data sources could be used to deduce the identity of an individual.

(2)(A) Each determination of the Secretary under paragraph (1) to exempt information from disclosure shall be made in writing and accompanied by a statement of the basis for the determination.

(B) Each such determination and statement of basis shall be available to the public, upon request, through the Office of the Chief FOIA Officer of the Department of Health and Human Services.

(3) Nothing in this subsection shall be construed to limit a research participant's access to information about such participant collected during the participant's participation in the research.

(g) Inapplicability of Federal information policy

Subchapter I of chapter 35 of title 44 shall not apply to the voluntary collection of information during the conduct of research by the National Institutes of Health.

(h) Availability of substances and living organisms for biomedical and behavioral research

(1) The Secretary may make available to individuals and entities, for biomedical and behavioral research, substances and living organisms. Such substances and organisms shall be made available under such terms and conditions (including payment for them) as the Secretary determines appropriate.

(2) Where research substances and living organisms are made available under paragraph (1) through contractors, the Secretary may direct such contractors to collect payments on behalf of the Secretary for the costs incurred to make available such substances and organisms and to forward amounts so collected to the Secretary, in the time and manner specified by the Secretary.

(3) Amounts collected under paragraph (2) shall be credited to the appropriations accounts that incurred the costs to make available the research substances and living organisms involved, and shall remain available until expended for carrying out activities under such accounts.

(July 1, 1944, ch. 373, title III, §301, 58 Stat. 691; July 3, 1946, ch. 538, §7(a), (b), 60 Stat. 423; June 16, 1948, ch. 481, §4(e), (f), 62 Stat. 467; June 24, 1948, ch. 621, §4(e), (f), 62 Stat. 601; June 25, 1948, ch. 654, §1, 62 Stat. 1017; July 3, 1956, ch. 510, §4, 70 Stat. 490; Pub. L. 86–798, Sept. 15, 1960, 74 Stat. 1053; Pub. L. 87–838, §2, Oct. 17, 1962, 76 Stat. 1073; Pub. L. 89–115, §3, Aug. 9, 1965, 79 Stat. 448; Pub. L. 90–174, §9, Dec. 5, 1967, 81 Stat. 540; Pub. L. 91–513, title I, §3(a), Oct. 27, 1970, 84 Stat. 1241; Pub. L. 91–515, title II, §292, Oct. 30, 1970, 84 Stat. 1308; Pub. L. 92–218, §6(a)(2), Dec. 23, 1971, 85 Stat. 785; Pub. L. 92–423, §7(b), Sept. 19, 1972, 86 Stat. 687;

Pub. L. 93–282, title I, §122(b), May 14, 1974, 88 Stat. 132; Pub. L. 93–348, title I, §104(a)(1), July 12, 1974, 88 Stat. 346; Pub. L. 93–352, title I, §111, July 23, 1974, 88 Stat. 360; Pub. L. 94–278, title I, §111, Apr. 22, 1976, 90 Stat. 405; Pub. L. 95–622, title II, §§261, 262, Nov. 9, 1978, 92 Stat. 3434; Pub. L. 96–88, title V, §509(b), Oct. 17, 1979, 93 Stat. 695; Pub. L. 99–158, §3(a)(5), Nov. 20, 1985, 99 Stat. 879; Pub. L. 99–570, title IV, §4021(b)(2), Oct. 27, 1986, 100 Stat. 3207–124; Pub. L. 99–660, title I, §104, Nov. 14, 1986, 100 Stat. 3751; Pub. L. 100–607, title I, §163(1), (2), Nov. 4, 1988, 102 Stat. 3062; Pub. L. 103–43, title XX, §2009, June 10, 1993, 107 Stat. 213; Pub. L. 109–450, §3(a), Dec. 22, 2006, 120 Stat. 3341; Pub. L. 114–255, div. A, title II, §§2012(a), 2013, 2035, 2043, Dec. 13, 2016, 130 Stat. 1049, 1050, 1062, 1074; Pub. L. 117–81, div. A, title XVII, §1702(j)(1)(A), Dec. 27, 2021, 135 Stat. 2159; Pub. L. 117–103, div. P, title I, §141(a), Mar. 15, 2022, 136 Stat. 797.)

EDITORIAL NOTES

AMENDMENTS

2022—Subsec. (e). Pub. L. 117–103 inserted ", preventable maternal mortality and severe maternal morbidity," after "delivery".

2021—Subsec. (a)(7). Pub. L. 117–81 substituted "sections 3861 and 4141" for "sections 2353 and 2354".

2016—Subsec. (a). Pub. L. 114–255, §2043(1), redesignated concluding provisions of subsec. (a) as par. (1) of subsec. (h).

Subsec. (d). Pub. L. 114–255, §2012(a), amended subsec. (d) generally. Prior to amendment, text read as follows: "The Secretary may authorize persons engaged in biomedical, behavioral, clinical, or other research (including research on mental health, including research on the use and effect of alcohol and other psychoactive drugs) to protect the privacy of individuals who are the subject of such research by withholding from all persons not connected with the conduct of such research the names or other identifying characteristics of such individuals. Persons so authorized to protect the privacy of such individuals may not be compelled in any Federal, State, or local civil, criminal, administrative, legislative, or other proceedings to identify such individuals."

Subsec. (f). Pub. L. 114–255, §2013, added subsec. (f).

Subsec. (g). Pub. L. 114–255, §2035, added subsec. (g).

Subsec. (h). Pub. L. 114–255, §2043, redesignated concluding provisions of subsec. (a) as par. (1) of subsec. (h) and added pars. (2) and (3).

2006—Subsec. (e). Pub. L. 109–450 added subsec. (e).

1993—Subsec. (b)(4). Pub. L. 103–43 substituted "a biennial report" for "an annual report" in introductory provisions.

1988—Subsec. (d). Pub. L. 100–607 redesignated concluding provisions of subsec. (a) of section 242a of this title as subsec. (d) of this section, substituted "biomedical, behavioral, clinical, or other research (including research on mental health, including" for "research on mental health, including", and substituted "drugs)" for "drugs,".

1986—Subsec. (a)(3). Pub. L. 99–570 struck out "or, in the case of mental health projects, by the National Advisory Mental Health Council;" after "Department supporting such projects" and struck out "or the National Advisory Mental Health Council" after "appropriate entity of the Department".

Subsec. (c). Pub. L. 99–660 added subsec. (c).

1985—Subsec. (a)(3). Pub. L. 99–158, §3(a)(5)(A), substituted "as are recommended by the advisory council to the entity of the Department supporting such projects or, in the case of mental health projects, by the National Advisory Mental Health Council; and make, upon recommendation of the advisory council to the appropriate entity of the Department or the National Advisory Mental Health Council, grants-in-aid to public or nonprofit universities, hospitals, laboratories, and other institutions for the general support of their research" for "as are recommended by the National Advisory Health Council, or, with respect to cancer, recommended by the National Cancer Advisory Board, or, with respect to mental health, recommended by the National Advisory Mental Health Council, or with respect to heart, blood vessel, lung, and blood diseases and blood resources, recommended by the National Heart, Lung, and Blood Advisory Council, or, with respect to dental diseases and conditions, recommended by the National Advisory Dental Research Council; and include in the grants for any such project grants of penicillin and other antibiotic compounds for use in such project; and make, upon recommendation of the National Advisory Health Council, grants-in-aid to public or nonprofit universities, hospitals, laboratories, and other institutions for the general support of their research: *Provided*,

That such uniform percentage, not to exceed 15 per centum, as the Secretary may determine, of the amounts provided for grants for research projects for any fiscal year through the appropriations for the National Institutes of Health may be transferred from such appropriations to a separate account to be available for such research grants-in-aid for such fiscal year".

Subsec. (a)(8). Pub. L. 99–158, §3(a)(5)(B), substituted "recommendations of the advisory councils to the appropriate entities of the Department or, with respect to mental health, the National Advisory Mental Health Council, such additional means as the Secretary considers" for "recommendation of the National Advisory Health Council, or, with respect to cancer, upon recommendation of the National Cancer Advisory Board, or, with respect to mental health, upon recommendation of the National Advisory Mental Health Council, or, with respect to heart, blood vessel, lung, and blood diseases and blood resources, upon recommendation of the National Heart, Lung and Blood Advisory Council, or, with respect to dental diseases and conditions, upon recommendations of the National Advisory Dental Research Council, such additional means as he deems".

1978—Pub. L. 95–622 designated existing provisions as subsec. (a), redesignated former pars. (a) to (h) as (1) to (8), respectively, substituted "Secretary" for "Surgeon General" wherever appearing, and inserted following par. (8) provisions relating to authority of Secretary to make available to individuals and entities substances and living organisms, and added subsec. (b).

1976—Subsecs. (c), (h). Pub. L. 94–278 substituted "heart, blood vessel, lung, and blood diseases and blood resources" for "heart diseases" and "National Heart, Lung and Blood Advisory Council" for "National Heart and Lung Advisory Council".

1974—Subsec. (c). Pub. L. 93–348, §104(a)(1), redesignated subsec. (d) as (c) and substituted "research projects" for "research or research training projects" in two places, "general support of their research" for "general support of their research and research training programs" and "research grants-in-aid" for "research and research training program grants-in-aid". Former subsec. (c), authorizing Surgeon General to establish and maintain research fellowships in the Public Health Service with such stipends and allowances, including traveling and subsistence expenses, as he may deem necessary to procure the assistance of the most brilliant and promising research fellows from the United States and abroad, was struck out.

Subsec. (d). Pub. L. 93–348, §104(a)(1)(C), redesignated subsec. (e) as (d).

Pub. L. 93–282 substituted "mental health, including research on the use and effect of alcohol and other psychoactive drugs" for "the use and effect of drugs" in former concluding provisions of section 242a(a) of this title. See 1988 Amendment note above.

Subsecs. (e), (f). Pub. L. 93–348, §104(a)(1)(C), redesignated subsecs. (f) and (g) as (e) and (f), respectively. Former subsec. (e) redesignated (d).

Subsec. (g). Pub. L. 93–352 struck out "during the fiscal year ending June 30, 1966, and each of the eight succeeding fiscal years" after "Enter into contracts". Notwithstanding directory language that amendment be made to subsec. (h), the amendment was executed to subsec. (g) to reflect the probable intent of Congress and the intervening redesignation of subsec. (h) as (g) by Pub. L. 93–348.

Pub. L. 93–348, §104(a)(1)(C), redesignated subsec. (h) as (g). Former subsec. (g) redesignated (f).

Subsecs. (h), (i). Pub. L. 93–348, §104(a)(1)(C), redesignated subsecs. (h) and (i) as (g) and (h), respectively.

1972—Subsecs. (d), (i). Pub. L. 92–423 substituted "National Heart and Lung Advisory Council" for "National Advisory Heart Council".

1971—Subsecs. (d), (i). Pub. L. 92–218 substituted "National Cancer Advisory Board" for "National Advisory Cancer Council".

1970—Subsec. (d). Pub. L. 91–513 added subsec. (d). See 1988 Amendment note above.

Subsec. (h). Pub. L. 91–515 substituted "eight" for "five" succeeding fiscal years.

1967—Subsec. (h). Pub. L. 90–174 substituted "five" for "two" succeeding fiscal years.

1965—Subsecs. (h), (i). Pub. L. 89–115 added subsec. (h) and redesignated former subsec. (h) as (i).

1962—Subsec. (d). Pub. L. 87–838 inserted "or research training" in two places.

1960—Subsec. (d). Pub. L. 86–798 authorized the Surgeon General, upon recommendation of the National Advisory Health Council, to make grants to public or non-profit universities, hospitals, laboratories, and other institutions to support research and research training programs, and to make available for such research and research training programs, up to 15 per centum of amounts provided for research grants through the appropriations for the National Institutes of Health.

1956—Subsecs. (g), (h). Act July 3, 1956, added subsec. (g) and redesignated former subsec. (g) as (h).

1948—Subsec. (d). Acts June 16, 1948, §4(e), and June 24, 1948, §4(e), made provisions applicable to the National Advisory Heart Council and the National Advisory Dental Research Council, respectively.

Subsec. (d). Act June 25, 1948, continued in basic legislation the authority to purchase penicillin and other antibiotic compounds for use in research projects.

Subsec. (g). Acts June 16, 1948, §4(f), and June 24, 1948, §4(f), made provisions applicable to the National Advisory Heart Council and the National Advisory Dental Research Council, respectively.

1946—Subsec. (d). Act July 3, 1946, made the National Advisory Mental Health Council the body to make recommendations to the Surgeon General on awarding of grants-in-aid for research projects with respect to mental health.

Subsec. (g). Act July 3, 1946, gave National Advisory Health Council the right to make recommendations to carry out purposes of this section.

STATUTORY NOTES AND RELATED SUBSIDIARIES

CHANGE OF NAME

"Secretary of Health and Human Services" substituted for "Secretary of Health, Education, and Welfare" in subsec. (a)(7), and "Department of Health and Human Services" substituted for "Department of Health, Education, and Welfare" in subsec. (b)(1), (3), and (4)(D)(I), (II), pursuant to section 509(b) of Pub. L. 96–88, which is classified to section 3508(b) of Title 20, Education.

EFFECTIVE DATE OF 1978 AMENDMENT

Sections 261 and 262 of Pub. L. 95–622 provided that the amendments made by those sections are effective Oct. 1, 1978.

EFFECTIVE DATE OF 1974 AMENDMENT

Section 104(b) of Pub. L. 93–348 provided that: "The amendments made by subsection (a) [amending this section and sections 242a, 282, 286a, 286b, 287a, 287b, 287d, 288a, 289c, 289c–1, 289g, 289k, and heading preceding section 289l of this title] shall not apply with respect to commitments made before the date of the enactment of this Act [July 12, 1974] by the Secretary of Health, Education, and Welfare for research training under the provisions of the Public Health Service Act amended or repealed by subsection (a)."

EFFECTIVE DATE OF 1972 AMENDMENT

Amendment by Pub. L. 92–423 effective 60 days after Sept. 19, 1972, or on such prior date after Sept. 19, 1972, as the President shall prescribe and publish in the Federal Register, see section 9 of Pub. L. 92–423, set out as a note under section 218 of this title.

EFFECTIVE DATE OF 1971 AMENDMENT

Amendment by Pub. L. 92–218 effective 60 days after Dec. 23, 1971, or on such prior date after Dec. 23, 1971, as the President shall prescribe and publish in the Federal Register, see section 7 of Pub. L. 92–218, set out as a note under section 218 of this title.

APPLICABILITY OF 2016 AMENDMENT

Pub. L. 114–255, div. A, title II, §2012(b), Dec. 13, 2016, 130 Stat. 1050, provided that: "Beginning 180 days after the date of enactment of this Act [Dec. 13, 2016], all persons engaged in research and authorized by the Secretary of Health and Human Services to protect information under section 301(d) of the Public Health Service Act (42 U.S.C. 241(d)) prior to the date of enactment of this Act shall be subject to the requirements of such section (as amended by this Act)."

PROHIBITION AGAINST REINSTATING INTERDISCIPLINARY REVIEW PROCESS FOR NON-NIH-FUNDED RESEARCHERS

Pub. L. 117–215, title I, §106, Dec. 2, 2022, 136 Stat. 2264, provided that: "The Secretary of Health and Human Services may not—

"(1) reinstate the Public Health Service interdisciplinary review process described in the guidance entitled 'Guidance on Procedures for the Provision of Marijuana for Medical Research' (issued on May 21, 1999); or

"(2) require another review of scientific protocols that is applicable only to research on marijuana or its components."

[For definition of "marijuana" as used in section 106 of Pub. L. 117–215, set out above, see section 2(a) of Pub. L. 117–215, set out as a note under section 801 of Title 21, Food and Drugs.]

DIRECTOR OF ADVANCED RESEARCH PROJECTS FOR HEALTH

Pub. L. 117–328, div. H, title II, Dec. 29, 2022, 136 Stat. 4878, provided in part: "That the President shall appoint in the Department of Health and Human Services a director of advanced research projects for health

(Director): *Provided further*, That funds may be used to make or rescind appointments of scientific, medical, and professional personnel without regard to any provision in title 5 governing appointments under the civil service laws: *Provided further*, That funds may be used to fix the compensation of such personnel at a rate to be determined by the Director, up to the amount of annual compensation (excluding expenses) specified in section 102 of title 3, United States Code: *Provided further*, That the Director may use funds made available under this heading to make awards in the form of grants, contracts, cooperative agreements, and cash prizes, and enter into other transactions (as defined in section 319L(a)(3) of the PHS [Public Health Service] Act [42 U.S.C. 247d–7e(a)(3)]): *Provided further*, That activities supported with funds provided under this heading shall not be subject to the requirements of sections [sic] 406(a)(3)(A)(ii) or 492 of the PHS [Public Health Service] Act [42 U.S.C. 284a(a)(3)(A)(ii), 289a]: *Provided further*, That the Secretary [of Health and Human Services] may transfer the Advanced Research Projects Agency for Health, including the functions, personnel, missions, activities, authorities, and funds, within 30 days of enactment of this Act [Dec. 29, 2022] to any agency or office of the Department of Health and Human Services, including the National Institutes of Health: *Provided further*, That the Committees on Appropriations of the House of Representatives and the Senate shall be notified at least 15 days in advance of any transfer pursuant to the preceding proviso."

[For transfer of all functions, personnel, missions, activities, authorities, and funds of the Advanced Research Projects Agency for Health to the Advanced Research Projects Agency–Health within the National Institutes of Health, see section 290c of this title.]

Similar provisions were contained in the following prior appropriation act:

Pub. L. 117–103, div. H, title II, Mar. 15, 2022, 136 Stat. 465.

COORDINATION OF DATA SURVEYS AND REPORTS

Pub. L. 106–113, div. B, §1000(a)(6) [title VII, §703(e)], Nov. 29, 1999, 113 Stat. 1536, 1501A–402, provided that: "The Secretary of Health and Human Services, through the Assistant Secretary for Planning and Evaluation, shall establish a clearinghouse for the consolidation and coordination of all Federal databases and reports regarding children's health."

FEMALE GENITAL MUTILATION

Pub. L. 104–134, title I, §101(d) [title V, §520], Apr. 26, 1996, 110 Stat. 1321–211, 1321–250; renumbered title I, Pub. L. 104–140, §1(a), May 2, 1996, 110 Stat. 1327, provided that:

"(a) Congress finds that—

"(1) the practice of female genital mutilation is carried out by members of certain cultural and religious groups within the United States; and

"(2) the practice of female genital mutilation often results in the occurrence of physical and psychological health effects that harm the women involved.

"(b) The Secretary of Health and Human Services shall do the following:

"(1) Compile data on the number of females living in the United States who have been subjected to female genital mutilation (whether in the United States or in their countries of origin), including a specification of the number of girls under the age of 18 who have been subjected to such mutilation.

"(2) Identify communities in the United States that practice female genital mutilation, and design and carry out outreach activities to educate individuals in the communities on the physical and psychological health effects of such practice. Such outreach activities shall be designed and implemented in collaboration with representatives of the ethnic groups practicing such mutilation and with representatives of organizations with expertise in preventing such practice.

"(3) Develop recommendations for the education of students of schools of medicine and osteopathic medicine regarding female genital mutilation and complications arising from such mutilation. Such recommendations shall be disseminated to such schools.

"(c) For purposes of this section the term 'female genital mutilation' means the removal or infibulation (or both) of the whole or part of the clitoris, the labia minor, or the labia major.

"(d) The Secretary of Health and Human Services shall commence carrying out this section not later than 90 days after the date of enactment of this Act [Apr. 26, 1996]."

SENTINEL DISEASE CONCEPT STUDY

Pub. L. 103–43, title XIX, §1910, June 10, 1993, 107 Stat. 205, directed Secretary of Health and Human Services, in cooperation with Agency for Toxic Substances and Disease Registry and Centers for Disease Control and Prevention, to design and implement a pilot sentinel disease surveillance system for identifying relationship between occupation of household members and incidence of subsequent conditions or diseases in other members of household, and required Director of the National Institutes of Health to prepare and submit to Congress, not later than 4 years after June 10, 1993, a report concerning this project.

STUDY OF THYROID MORBIDITY FOR HANFORD, WASHINGTON

Pub. L. 100–607, title I, §161, Nov. 4, 1988, 102 Stat. 3059, as amended by Pub. L. 102–531, title III, §312(e)(1), Oct. 27, 1992, 106 Stat. 3506, directed Secretary of Health and Human Services, acting through Director of Centers for Disease Control and Prevention, to conduct a study of thyroid morbidity of the population, including Indian tribes and tribal organizations, in vicinity of Hanford, in State of Washington, authorized Director to contract out portions of study, and required Director, not later than 42 months after Nov. 4, 1988, to transmit a report, including such study, to Congress, chief executive officers of States of Oregon and Washington, and governing officials of Indian tribes in vicinity of Hanford, Washington.

NATIONAL COMMISSION ON SLEEP DISORDERS RESEARCH

Pub. L. 100–607,title I, §162, Nov. 4, 1988, 102 Stat. 3060, directed Secretary of Health and Human Services, after consultation with Director of National Institutes of Health, to establish a National Commission on Sleep Disorders Research to conduct a comprehensive study of present state of knowledge of incidence, prevalence, morbidity, and mortality resulting from sleep disorders, and of social and economic impact of such disorders, evaluate public and private facilities and resources (including trained personnel and research activities) available for diagnosis, prevention, and treatment of, and research into, such disorders, and identify programs (including biological, physiological, behavioral, environmental, and social programs) by which improvement in management and research into sleep disorders could be accomplished and, not later than 18 months after initial meeting of Commission, to submit to appropriate Committees of Congress a final report, and provided for termination of the Commission 30 days after submission of final report.

RESEARCH WITH RESPECT TO HEALTH RESOURCES AND SERVICES ADMINISTRATION

Pub. L. 100–607, title VI, §632, Nov. 4, 1988, 102 Stat. 3147, provided that with respect to any program of research pursuant to this chapter, any such program carried out in fiscal year 1987 by an agency other than Health Resources and Services Administration (or appropriate to be carried out by such an agency) could not, for each of fiscal years 1989 through 1991, be carried out by such Administration.

CONTINUING CARE FOR PSYCHIATRIC PATIENTS IN FORMER CLINICAL RESEARCH CENTER AT NATIONAL INSTITUTE ON DRUG ABUSE

Pub. L. 99–117, §10, Oct. 7, 1985, 99 Stat. 494, provided that: "In any fiscal year beginning after September 30, 1981, from funds appropriated for carrying out section 301 of the Public Health Service Act [42 U.S.C. 241] with respect to mental health, the Secretary of Health and Human Services may provide, by contract or otherwise, for the continuing care of psychiatric patients who were under active and continuous treatment at the National Institute on Drug Abuse Clinical Research Center on the date such Clinical Research Center ceased operations."

ANALYSIS OF THYROID CANCER; CREATION AND PUBLICATION OF RADIOEPIDEMIOLOGICAL TABLES

Pub. L. 97–414, §7, Jan. 4, 1983, 96 Stat. 2059, as amended by Pub. L. 109–482, title I, §104(b)(3)(A), Jan. 15, 2007, 120 Stat. 3694, provided that:

"(a) In carrying out section 301 of the Public Health Service Act [42 U.S.C. 241], the Secretary of Health and Human Services shall—

"(1) conduct scientific research and prepare analyses necessary to develop valid and credible assessments of the risks of thyroid cancer that are associated with thyroid doses of Iodine 131;

"(2) conduct scientific research and prepare analyses necessary to develop valid and credible methods to estimate the thyroid doses of Iodine 131 that are received by individuals from nuclear bomb fallout; and

"(3) conduct scientific research and prepare analyses necessary to develop valid and credible assessments of the exposure to Iodine 131 that the American people received from the Nevada atmospheric nuclear bomb tests.

"(b)(1) Within one year after the date of enactment of this Act [Jan. 4, 1983], the Secretary of Health and Human Services shall devise and publish radioepidemiological tables that estimate the likelihood that persons who have or have had any of the radiation related cancers and who have received specific doses prior to the onset of such disease developed cancer as a result of these doses. These tables shall show a probability of causation of developing each radiation related cancer associated with receipt of doses ranging from 1 millirad to 1,000 rads in terms of sex, age at time of exposure, time from exposure to the onset of the cancer in question, and such other categories as the Secretary, after consulting with appropriate scientific experts, determines to be relevant. Each probability of causation shall be calculated and displayed as a single percentage figure.

"(2) At the time the Secretary of Health and Human Services publishes the tables pursuant to paragraph (1), such Secretary shall also publish—

"(A) for the tables of each radiation related cancer, an evaluation which will assess the credibility, validity, and degree of certainty associated with such tables; and

"(B) a compilation of the formulas that yielded the probabilities of causation listed in such tables. Such formulas shall be published in such a manner and together with information necessary to determine the probability of causation of any individual who has or has had a radiation related cancer and has received any given dose.

"(3) The tables specified in paragraph (1) and the formulas specified in paragraph (2) shall be devised from the best available data that are most applicable to the United States, and shall be devised in accordance with the best available scientific procedures and expertise."

TERMINATION OF ADVISORY COMMITTEES

Pub. L. 93–641, §6, Jan. 4, 1975, 88 Stat. 2275, set out as a note under section 217a of this title, provided that an advisory committee established pursuant to the Public Health Service Act shall terminate at such time as may be specifically prescribed by an Act of Congress enacted after Jan. 4, 1975.

EXECUTIVE DOCUMENTS

EXECUTIVE ORDER NO. 13435

Ex. Ord. No. 13435, June 20, 2007, 72 F.R. 34591, which directed research with stem cells not derived from the creation or destruction of a human embryo or fetus, was revoked by Ex. Ord. No. 13505, §5(b), Mar. 9, 2009, 74 F.R. 10668, set out below.

EX. ORD. NO. 13505. REMOVING BARRIERS TO RESPONSIBLE SCIENTIFIC RESEARCH INVOLVING HUMAN STEM CELLS

Ex. Ord. No. 13505, Mar. 9, 2009, 74 F.R. 10667, provided:

By the authority vested in me as President by the Constitution and the laws of the United States of America, it is hereby ordered as follows:

SECTION 1. *Policy*. Research involving human embryonic stem cells and human non-embryonic stem cells has the potential to lead to better understanding and treatment of many disabling diseases and conditions. Advances over the past decade in this promising scientific field have been encouraging, leading to broad agreement in the scientific community that the research should be supported by Federal funds.

For the past 8 years, the authority of the Department of Health and Human Services, including the National Institutes of Health (NIH), to fund and conduct human embryonic stem cell research has been limited by Presidential actions. The purpose of this order is to remove these limitations on scientific inquiry, to expand NIH support for the exploration of human stem cell research, and in so doing to enhance the contribution of America's scientists to important new discoveries and new therapies for the benefit of humankind.

SEC. 2. *Research*. The Secretary of Health and Human Services (Secretary), through the Director of NIH, may support and conduct responsible, scientifically worthy human stem cell research, including human embryonic stem cell research, to the extent permitted by law.

SEC. 3. *Guidance*. Within 120 days from the date of this order, the Secretary, through the Director of NIH, shall review existing NIH guidance and other widely recognized guidelines on human stem cell research, including provisions establishing appropriate safeguards, and issue new NIH guidance on such research that is consistent with this order. The Secretary, through NIH, shall review and update such guidance periodically, as appropriate.

SEC. 4. *General Provisions*. (a) This order shall be implemented consistent with applicable law and subject to the availability of appropriations.

(b) Nothing in this order shall be construed to impair or otherwise affect:

(i) authority granted by law to an executive department, agency, or the head thereof; or

(ii) functions of the Director of the Office of Management and Budget relating to budgetary, administrative, or legislative proposals.

(c) This order is not intended to, and does not, create any right or benefit, substantive or procedural, enforceable at law or in equity, by any party against the United States, its departments, agencies, or entities, its officers, employees, or agents, or any other person.

SEC. 5. *Revocations*. (a) The Presidential statement of August 9, 2001, limiting Federal funding for research involving human embryonic stem cells, shall have no further effect as a statement of governmental policy.

(b) Executive Order 13435 of June 20, 2007, which supplements the August 9, 2001, statement on human embryonic stem cell research, is revoked.

BARACK OBAMA.

GUIDELINES FOR HUMAN STEM CELL RESEARCH

Memorandum of President of the United States, July 30, 2009, 74 F.R. 38885, provided:

Memorandum for the Heads of Executive Departments and Agencies

As outlined in Executive Order 13505 of March 9, 2009, my Administration is committed to supporting and conducting ethically responsible, scientifically worthy human stem cell research, including human embryonic stem cell research, to the extent permitted by law. Pursuant to that order, the National Institutes of Health (NIH) published final "National Institutes of Health Guidelines for Human Stem Cell Research" (Guidelines), effective July 7, 2009. These Guidelines apply to the expenditure of NIH funds for research using human embryonic stem cells and certain uses of human induced pluripotent stem cells. The Guidelines are based on the principles that responsible research with human embryonic stem cells has the potential to improve our understanding of human biology and aid in the discovery of new ways to prevent and treat illness, and that individuals donating embryos for research purposes should do so freely, with voluntary and informed consent. These Guidelines will ensure that NIH-funded research adheres to the highest ethical standards.

In order to ensure that all federally funded human stem cell research is conducted according to these same principles and to promote a uniform Federal policy across the executive branch, I hereby direct the heads of executive departments and agencies that support and conduct stem cell research to adopt these Guidelines, to the fullest extent practicable in light of legal authorities and obligations. I also direct those departments and agencies to submit to the Director of the Office of Management and Budget (OMB), within 90 days, proposed additions or revisions to any other guidance, policies, or procedures related to human stem cell research, consistent with Executive Order 13505 and this memorandum. The Director of the OMB shall, in coordination with the Director of NIH, review these proposals to ensure consistent implementation of Executive Order 13505 and this memorandum.

This memorandum is not intended to, and does not, create any right or benefit, substantive or procedural, enforceable at law or in equity by any party against the United States, its departments, agencies, or entities, its officers, employees, or agents, or any other person. Executive departments and agencies shall carry out the provisions of this memorandum to the extent permitted by law and consistent with their statutory and regulatory authorities and their enforcement mechanisms.

The Director of the OMB is hereby authorized and directed to publish this memorandum in the Federal Register.

BARACK OBAMA.

ENGAGING IN PUBLIC HEALTH RESEARCH ON THE CAUSES AND PREVENTION OF GUN VIOLENCE

Memorandum of President of the United States, Jan. 16, 2013, 78 F.R. 4295, provided that:

Memorandum for the Secretary of Health and Human Services

In addition to being a law enforcement challenge, gun violence is also a serious public health issue that affects thousands of individuals, families, and communities across the Nation. Each year in the United States there are approximately 30,000 firearm-related deaths, and approximately 11,000 of those deaths result from homicides. Addressing this critical issue requires a comprehensive, multifaceted approach.

Recent research suggests that, in developing such an approach, a broader public health perspective is imperative. Significant strides can be made by assessing the causes of gun violence and the successful efforts in place for preventing the misuse of firearms. Taking these steps will improve our understanding of the gun violence epidemic and will aid in the continued development of gun violence prevention strategies.

Therefore, by the authority vested in me as President by the Constitution and the laws of the United States of America, I hereby direct the following:

SECTION 1. *Research*. The Secretary of Health and Human Services (Secretary), through the Director of the Centers for Disease Control and Prevention and other scientific agencies within the Department of Health and Human Services, shall conduct or sponsor research into the causes of gun violence and the ways to prevent it. The Secretary shall begin by identifying the most pressing research questions with the greatest potential public health impact, and by assessing existing public health interventions being implemented across the Nation to prevent gun violence.

SEC. 2. *General Provisions*. (a) Nothing in this memorandum shall be construed to impair or otherwise affect:

(i) the authority granted by law to an executive department or agency, or the head thereof; or

(ii) the functions of the Director of the Office of Management and Budget relating to budgetary, administrative, or legislative proposals.

(b) This memorandum shall be implemented consistent with applicable law and subject to the availability of appropriations.

(c) This memorandum is not intended to, and does not, create any right or benefit, substantive or procedural, enforceable at law or in equity by any party against the United States, its departments, agencies, or entities, its officers, employees, or agents, or any other person.

SEC. 3. *Publication*. You are hereby authorized and directed to publish this memorandum in the Federal Register.

BARACK OBAMA.

§242. Studies and investigations on use and misuse of narcotic drugs and other drugs; annual report to Attorney General; cooperation with States

(a) In carrying out the purposes of section 241 of this title with respect to drugs the use or misuse of which might result in drug abuse or dependency, the studies and investigations authorized therein shall include the use and misuse of narcotic drugs and other drugs. Such studies and investigations shall further include the quantities of crude opium, coca leaves, and their salts, derivatives, and preparations, and other drugs subject to control under the Controlled Substances Act [21 U.S.C. 801 et seq.] and Controlled Substances Import and Export Act [21 U.S.C. 951 et seq.], together with reserves thereof, necessary to supply the normal and emergency medicinal and scientific requirements of the United States. The results of studies and investigations of the quantities of narcotic drugs or other drugs subject to control under such Acts, together with reserves of such drugs, that are necessary to supply the normal and emergency medicinal and scientific requirements of the United States, shall be reported not later than the first day of April of each year to the Attorney General, to be used at his discretion in determining manufacturing quotas or importation requirements under such Acts.

(b) The Surgeon General shall cooperate with States for the purpose of aiding them to solve their narcotic drug problems and shall give authorized representatives of the States the benefit of his experience in the care, treatment, and rehabilitation of narcotic addicts to the end that each State may be encouraged to provide adequate facilities and methods for the care and treatment of its narcotic addicts.

(July 1, 1944, ch. 373, title III, §302, 58 Stat. 692; Pub. L. 91–513, title II, §701(j), Oct. 27, 1970, 84 Stat. 1282.)

EDITORIAL NOTES

REFERENCES IN TEXT

The Controlled Substances Act, referred to in subsec. (a), is title II of Pub. L. 91–513, Oct. 27, 1970, 84 Stat. 1242, which is classified principally to subchapter I (§801 et seq.) of chapter 13 of Title 21, Food and Drugs. For complete classification of this Act to the Code, see Short Title note set out under section 801 of Title 21 and Tables.

The Controlled Substances Import and Export Act, referred to in subsec. (a), is title III of Pub. L. 91–513, Oct. 27, 1970, 84 Stat. 1285, which is classified principally to subchapter II (§951 et seq.) of chapter 13 of Title 21. For complete classification of this Act to the Code, see Short Title note set out under section 951 of Title 21 and Tables.

AMENDMENTS

1970—Subsec. (a). Pub. L. 91–513 inserted references to drug dependency, drugs other than narcotic drugs, and substances subject to control under the Controlled Substances Act and the Controlled Substances Import and Export Act, substituted the first day of April of each year for the first day of September of each year as the date by which the study results must be submitted, substituted the Attorney General for the Secretary of the Treasury as the officer to whom the report is to be submitted, and struck out references to the Narcotic Drugs Import and Export Act.

STATUTORY NOTES AND RELATED SUBSIDIARIES

CHANGE OF NAME

"Secretary of Health and Human Services" substituted for "Secretary of Health, Education, and Welfare" pursuant to section 509(b) of Pub. L. 96–88, which is classified to section 3508(b) of Title 20, Education.

EFFECTIVE DATE OF 1970 AMENDMENT

Amendment by Pub. L. 91–513 effective on first day of seventh calendar month that begins after Oct. 26, 1970, see section 704 of Pub. L. 91–513, set out as an Effective Date note under section 801 of Title 21, Food and Drugs.

SAVINGS PROVISION

Amendment by Pub. L. 91–513 not to affect or abate any prosecutions for violation of law or any civil seizures or forfeitures and injunctive proceedings commenced prior to the effective date of such amendment, and all administrative proceedings pending before the Bureau of Narcotics and Dangerous Drugs on Oct. 27, 1970, to be continued and brought to final determination in accord with laws and regulations in effect prior to Oct. 27, 1970, see section 702 of Pub. L. 91–513, set out as a note under section 321 of Title 21, Food and Drugs.

MARIHUANA AND HEALTH REPORTING

Pub. L. 91–296, title V, June 30, 1970, 84 Stat. 352, as amended by Pub. L. 95–461, §3(a), Oct. 14, 1978, 92 Stat. 1268; Pub. L. 96–88, title V, §509(b), Oct. 17, 1979, 93 Stat. 695, known as the Marihuana and Health Reporting Act, which required the Secretary of Health and Human Services, after consultation with the Surgeon General and other appropriate individuals, to transmit a report to the Congress on or before January 31, 1971, and biennially thereafter (1) containing current information on the health consequences of using marihuana, and (2) containing such recommendations for legislative and administrative action as he may deem appropriate, was repealed by Pub. L. 98–24, §2(d), Apr. 26, 1983, 97 Stat. 182.

EXECUTIVE DOCUMENTS

TRANSFER OF FUNCTIONS

Office of Surgeon General abolished by section 3 of Reorg. Plan No. 3 of 1966, eff. June 25, 1966, 31 F.R. 8855, 80 Stat. 1610, and functions thereof transferred to Secretary of Health, Education, and Welfare by section 1 of Reorg. Plan No. 3 of 1966, set out as a note under section 202 of this title. Office of Surgeon General reestablished within the Office of the Assistant Secretary for Health, see Notice of Department of Health and Human Services, Office of the Assistant Secretary for Health, Mar. 30, 1987, 52 F.R. 11754.

§242a. Repealed. Pub. L. 106–310, div. B, title XXXII, §3201(b)(1), Oct. 17, 2000, 114 Stat. 1190

Section, act July 1, 1944, ch. 373, title III, §303, as added July 3, 1946, ch. 538, §7(c), 60 Stat. 423; amended Aug. 2, 1956, ch. 871, title V, §501, 70 Stat. 929; Pub. L. 91–513, title I, §3(a), Oct. 27, 1970, 84 Stat. 1241; Pub. L. 93–282, title I, §122(b), May 14, 1974, 88 Stat. 132; Pub. L. 93–348, title I, §104(a)(2), July 12, 1974, 88 Stat. 346; Pub. L. 95–633, title I, §108(b), Nov. 10, 1978, 92 Stat. 3773; Pub. L. 96–398, title VIII, §803(a), Oct. 7, 1980, 94 Stat. 1607; Pub. L. 100–177, title II, §202(a), Dec. 1, 1987, 101 Stat. 996; Pub. L. 100–607, title I, §163(1)(A), Nov. 4, 1988, 102 Stat. 3062; Pub. L. 100–690, title II, §2058(b), Nov. 18, 1988, 102 Stat. 4214; Pub. L. 101–597, title IV, §401(b)[(a)], Nov. 16, 1990, 104 Stat. 3035; Pub. L. 102–321, title I, §115(b), July 10, 1992, 106 Stat. 348; Pub. L. 102–408, title III, §305, Oct. 13, 1992, 106 Stat. 2084; Pub. L. 105–392, title IV, §403, Nov. 13, 1998, 112 Stat. 3588, related to mental health.

§242b. General authority respecting research, evaluations, and demonstrations in health statistics, health services, and health care technology

(a) Scope of activities

The Secretary may, through the Agency for Healthcare Research and Quality or the National Center for Health Statistics, or using Ruth L. Kirschstein National Research Service Awards or other appropriate authorities, undertake and support training programs to provide for an expanded and continuing supply of individuals qualified to perform the research, evaluation, and demonstration projects set forth in section 242k of this title and in subchapter VII.

(b) Additional authority; scope of activities

To implement subsection (a) and section 242k of this title, the Secretary may, in addition to any other authority which under other provisions of this chapter or any other law may be used by him to implement such subsection, do the following:

(1) Utilize personnel and equipment, facilities, and other physical resources of the Department of Health and Human Services, permit appropriate (as determined by the Secretary) entities and individuals to utilize the physical resources of such Department, provide technical assistance and advice, make grants to public and nonprofit private entities and individuals, and, when appropriate, enter into contracts with public and private entities and individuals.

(2) Admit and treat at hospitals and other facilities of the Service persons not otherwise eligible for admission and treatment at such facilities.

(3) Secure, from time to time and for such periods as the Secretary deems advisable but in accordance with section 3109 of title 5, the assistance and advice of consultants from the United States or abroad. The Secretary may for the purpose of carrying out the functions set forth in sections 242c,[1] 242k, and 242n [1] of this title, obtain (in accordance with section 3109 of title 5, but without regard to the limitation in such section on the number of days or the period of service) for each of the centers the services of not more than fifteen experts who have appropriate scientific or professional qualifications.

(4) Acquire, construct, improve, repair, operate, and maintain laboratory, research, and other necessary facilities and equipment, and such other real or personal property (including patents) as the Secretary deems necessary; and acquire, without regard to section 8141 of title 40, by lease or otherwise, through the Administrator of General Services, buildings or parts of buildings in the District of Columbia or communities located adjacent to the District of Columbia.

(c) Coordination of activities through units of Department

(1) The Secretary shall coordinate all health services research, evaluations, and demonstrations, all health statistical and epidemiological activities, and all research, evaluations, and demonstrations respecting the assessment of health care technology undertaken and supported through units of the Department of Health and Human Services. To the maximum extent feasible such coordination shall be carried out through the Agency for Healthcare Research and Quality and the National Center for Health Statistics.

(2) The Secretary shall coordinate the health services research, evaluations, and demonstrations, the health statistical and (where appropriate) epidemiological activities, and the research, evaluations, and demonstrations respecting the assessment of health care technology authorized by this chapter through the Agency for Healthcare Research and Quality and the National Center for Health Statistics.

(July 1, 1944, ch. 373, title III, §304, as added July 28, 1955, ch. 417, §3, 69 Stat. 382; amended Aug. 2, 1956, ch. 871, title V, §502, 70 Stat. 930; Pub. L. 90–174, §3(a), Dec. 5, 1967, 81 Stat. 534; Pub. L. 91–296, title IV, §401(b)(1)(A), June 30, 1970, 84 Stat. 352; Pub. L. 91–515, title II, §§201(a)–(c), 202, 203, Oct. 30, 1970, 84 Stat. 1301–1303; Pub. L. 93–45, title I, §102, June 18, 1973, 87 Stat. 91; Pub. L. 93–353, title I, §103, July 23, 1974, 88 Stat. 362; Pub. L. 95–623, §§3, 7, Nov. 9, 1978, 92 Stat. 3443, 3451; Pub. L. 96–32, §5(a)–(c), July 10, 1979, 93 Stat. 82; Pub. L. 97–35, title IX, §918, Aug. 13, 1981, 95 Stat. 565; Pub. L. 98–551, §5(c), Oct. 30, 1984, 98 Stat. 2819; Pub. L. 101–239, title VI, §6103(e)(1), Dec. 19, 1989, 103 Stat. 2205; Pub. L. 103–183, title V, §501(b), Dec. 14, 1993, 107 Stat. 2237; Pub. L. 106–129, §2(b)(2), Dec. 6, 1999, 113 Stat. 1670; Pub. L. 107–206, title I, §804(c), Aug. 2, 2002, 116 Stat. 874.)

EDITORIAL NOTES

REFERENCES IN TEXT

Sections 242c and 242n of this title, referred to in subsec. (b)(3), were repealed by Pub. L. 101–239, title VI, §6103(d)(1), Dec. 19, 1989, 103 Stat. 2205.

CODIFICATION

In subsec. (b)(4), "section 8141 of title 40" substituted for "the Act of March 3, 1877 (40 U.S.C. 34)" on authority of Pub. L. 107–217, §5(c), Aug. 21, 2002, 116 Stat. 1303, the first section of which enacted Title 40, Public Buildings, Property, and Works.

AMENDMENTS

2002—Subsec. (a). Pub. L. 107–206 substituted "Ruth L. Kirschstein National Research Service Awards" for "National Research Service Awards".

1999—Subsecs. (a), (c). Pub. L. 106–129 substituted "Agency for Healthcare Research and Quality" for "Agency for Health Care Policy and Research" wherever appearing.

1993—Subsec. (d). Pub. L. 103–183 struck out subsec. (d) which directed Secretary to conduct an ongoing study of present and projected future health costs of pollution and other environmental conditions resulting from human activity and to submit to Congress reports on the study.

1989—Subsec. (a). Pub. L. 101–239, §6103(e)(1)(B), substituted "the Agency for Health Care Policy and Research" for "the National Center for Health Services Research and Health Care Technology Assessment" and "in section 242k of this title and in subchapter VII" for "in sections 242c, 242k, and 242n of this title".

Pub. L. 101–239, §6103(e)(1)(A), redesignated par. (3) as entire subsec. (a) and struck out pars. (1) and (2) which required Secretary to conduct and support research, demonstrations, evaluations, and statistical and epidemiological activities for purpose of improving health services in the United States, and which specified types of activities Secretary was to emphasize in carrying out par. (1).

Subsec. (b). Pub. L. 101–239, §6103(e)(1)(C), substituted "subsection (a) and section 242k of this title" for "subsection (a)".

Subsec. (c)(1), (2). Pub. L. 101–239, §6103(e)(1)(D), substituted "the Agency for Health Care Policy and Research" for "the National Center for Health Services Research and Health Care Technology Assessment".

1984—Subsec. (a)(1). Pub. L. 98–551, §5(c)(1), (2), substituted "the National Center for Health Services Research and Health Care Technology Assessment and the National Center for Health Statistics" for "the National Center for Health Services Research, the National Center for Health Statistics, and the National Center for Health Care Technology".

Subsec. (a)(3). Pub. L. 98–551, §5(c)(1), (3), substituted "the National Center for Health Services Research and Health Care Technology Assessment or the National Center for Health Statistics" for "the National Center for Health Services Research, the National Center for Health Statistics, or the National Center for Health Care Technology".

Subsec. (c)(1), (2). Pub. L. 98–551, §5(c)(1), (2), substituted "the National Center for Health Services Research and Health Care Technology Assessment and the National Center for Health Statistics" for "the National Center for Health Services Research, the National Center for Health Statistics, and the National Center for Health Care Technology".

1981—Subsec. (a)(3). Pub. L. 97–35, §918(a), substituted "may" for "shall", "or the" for "and the", "or using" for "and using", and "or other" for "and other".

Subsecs. (b)(1), (c)(1). Pub. L. 97–35, §918(d)(1), substituted "Health and Human Services" for "Health, Education, and Welfare".

Subsec. (d)(1). Pub. L. 97–35, §918(b)(1), (2), substituted provisions relating to advice and assistance of the National Academy of Sciences, for provisions relating to joint authority of the National Academy of Sciences, and struck out definition of "Academy" as meaning the National Academy of Sciences.

Subsec. (d)(3). Pub. L. 97–35, §918(b)(3), (c), (d)(2), substituted "every three years" for "every two years", and "Energy and" for "Interstate and Foreign", and struck out references to the Academy.

1979—Subsec. (b)(1), (3). Pub. L. 96–32, §5(a), (b), amended directory language of Pub. L. 95–623, §3(b), (d), and required no change in text. See 1978 Amendment note below.

Subsec. (d). Pub. L. 96–32, §5(c), substituted "(d)" for "(e)" as designation of subsection added by Pub. L. 95–623, §7, thereby correcting the subsection designation.

1978—Subsec. (a)(1). Pub. L. 95–623, §3(a), substituted provision for the Secretary acting through the National Center for Health Care Technology for such action through other units of the Department of Health, Education, and Welfare and "conduct" for "undertake", included epidemiological activities, and declared as an

objective the improvement of the effectiveness, efficiency, and quality of Federal health services.

Subsec. (a)(2). Pub. L. 95–623, §3(a), provided for emphasis to demonstrations, evaluations, and epidemiological activities; redesignated as subpar. (A) former subpar. (C); struck out "technology" and "quality" after "organization," and "utilization,", respectively, and end clause "including systems for the delivery of preventive, personal, and mental health care" and former subpar. (A) activities respecting "the determination of an individual's health"; added subpars. (B) through (D); struck out former subpar. (D) activities respecting "individual and community knowledge of individual health and the systems for the delivery of health care"; added subpars. (E) through (I); and redesignated as subpar. (J) former subpar. (B).

Subsec. (a)(3). Pub. L. 95–623, §3(a), added par. (3).

Subsec. (b)(1). Pub. L. 95–623, §3(b), as amended by Pub. L. 96–32, §5(a), substituted ", when appropriate, enter into contracts with public and private entities and individuals" for "enter into contracts with public and private entities and individuals, for (A) health services research, evaluation, and demonstrations, and (B) health services research and health statistics training, and (C) health statistical activities".

Subsec. (b)(3). Pub. L. 95–623, §3(d), as amended by Pub. L. 96–32, §5(b), substituted "advisable but in accordance with section 3109 of title 5" for "advisable", struck out "experts and" before "consultants", and authorized the Secretary to obtain for the centers the services of experts with appropriate scientific or professional qualifications.

Subsec. (c). Pub. L. 95–623, §3(c), designated existing text as par. (1), substituted "evaluations, and demonstrations, all health statistical and epidemiological activities, and all research, evaluations, and demonstrations respecting the assessment of health care technology" for "evaluation, demonstration, and health statistical activities" before "undertaken and supported", required coordination of activities to also be carried out through the National Center for Health Care Technology, and added par. (2).

Subsec. (d). Pub. L. 95–623, §7, as amended by Pub. L. 96–32, §5(c), added subsec. (d).

1974—Pub. L. 93–353, in revising generally provisions of subsecs. (a) to (c), provided for general authority respecting health statistics and health services research, evaluation, and demonstrations, subsec. (a) relating to scope of activities, subsec. (b) relating to additional authority and scope of activities, and subsec. (c) relating to coordination of activities through units of the Department. Former provisions related to research and demonstrations relating to health facilities and services, subsec. (a) relating to grants and contracts for projects for research, experiments, or demonstrations and related training, cost limitation, wage rates, labor standards, and other conditions, and payments (former subsec. (a)(2) and (3) now being covered by section 242m(h) and (e), respectively), subsec. (b) relating to systems analysis of national health care plans, and cost and coverage report on existing legislative proposals, and subsec. (c) relating to authorization of appropriations.

1973—Subsec. (c)(1). Pub. L. 93–45 authorized appropriations of $42,617,000 for fiscal year ending June 30, 1974.

1970—Subsec. (a)(1). Pub. L. 91–515, §§201(a)(1), 203, redesignated subsec. (a) as (a)(1), substituted "(A)" and "(B)" for "(1)" and "(2)", and "(i) to (iii)" for "(A) to (C)", and added cls. (iv) and (v).

Subsec. (a)(2). Pub. L. 91–515, §201(a)(2), redesignated subsec. (b) as (a)(2), and substituted "subsection" for "section" wherever appearing.

Subsec. (a)(3). Pub. L. 91–515, §§201(a)(3), 202, redesignated subsec. (c) as (a)(3)(A), substituted "subsection" for "section" wherever appearing, and added subsec. (a)(3)(B).

Subsec. (b). Pub. L. 91–515, §201(a)(2)(A), (b), added subsec. (b). Former subsec. (b) redesignated (a)(2).

Subsecs. (c), (d). Pub. L. 91–515, §§201(a)(3)(A), (c), 202(1), redesignated subsec. (d) as (c), and substituted provisions authorizing appropriations for the fiscal years ending June 30, 1971, June 30, 1972, and June 30, 1973, and authorizing to be appropriated such additional sums for each fiscal year as may be necessary to carry out the provisions of subsec. (b), for provisions authorizing appropriations of $20,000,000 for the fiscal year ending June 30, 1968, $40,000,000 for the fiscal year ending June 30, 1969, and $60,000,000 for the fiscal year ending June 30, 1970. Former subsec. (c) redesignated (a)(3)(A).

Pub. L. 91–296 struck out provisions authorizing use of appropriated funds for evaluation of program authorized by this section. See section 229b of this title.

1967—Pub. L. 90–174 substituted provisions of subsecs. (a) to (d) for research and demonstrations relating to health facilities (incorporated from former section 291n of this title) for provisions of former subsecs. (a) to (d) for mental health study including grants for special projects, conditions thereof, and definition of "organization", authorization of appropriations, terms of grant, availability of amounts otherwise appropriated and noninterference with research and study programs of the National Institute of Mental Health, and acceptance of additional financial support.

1956—Act Aug. 2, 1956, changed heading of section 304 of act July 1, 1944 from "Grants for special projects in mental health" to "Mental health study grants". Section heading has been changed for purposes of codification.

STATUTORY NOTES AND RELATED SUBSIDIARIES

CHANGE OF NAME

"Secretary of Health and Human Services" substituted in text for "Secretary of Health, Education, and Welfare" pursuant to section 509(b) of Pub. L. 96–88, which is classified to section 3508(b) of Title 20, Education.

EFFECTIVE DATE OF 1970 AMENDMENTS

Pub. L. 91–515, title II, §201(d), Oct. 30, 1970, 84 Stat. 1303, provided that: "The amendments made by subsection (c) of this section [amending this section] shall be effective only with respect to fiscal years ending after June 30, 1970."

Pub. L. 91–296, title IV, §401(b)(1), June 30, 1970, 84 Stat. 352, provided that the amendment made by that section is effective with respect to appropriations for fiscal years beginning after June 30, 1970.

EFFECTIVE DATE OF 1956 AMENDMENT

Amendment of section by act Aug. 2, 1956, effective July 1, 1956, see section 503 of act Aug. 2, 1956.

COMMISSION ON SYSTEMIC INTEROPERABILITY

Pub. L. 108–173, title X, §1012, Dec. 8, 2003, 117 Stat. 2435, directed the Secretary of Health and Human Services to establish a commission to be known as the "Commission on Systemic Interoperability", which would develop a comprehensive strategy for the adoption and implementation of health care information technology standards, and which would terminate 30 days after submitting a report, not later than Oct. 31, 2005, to the Secretary and to Congress, describing the strategy developed.

MODEL STANDARDS WITH RESPECT TO PREVENTIVE HEALTH SERVICES IN COMMUNITIES

Pub. L. 95–83, title III, §314, Aug. 1, 1977, 91 Stat. 398, required the Secretary of Health, Education, and Welfare, within two years of Aug. 1, 1977, to establish model standards with respect to preventive health services in communities and report such standards to Congress.

TRANSFER OF EQUIPMENT

Pub. L. 94–573, §15, Oct. 21, 1976, 90 Stat. 2719, provided that notwithstanding any other provision of law, the Secretary of Health, Education, and Welfare could vest title to equipment purchased with funds under the seven contracts for emergency medical services demonstration projects entered into in 1972 and 1973 under this section (as in effect at the time the contracts were entered into), and by contractors with the United States under such contracts or subcontractors under such contracts, in such contractors or subcontractors without further obligation to the Government or on such terms as the Secretary considered appropriate.

CONGRESSIONAL DECLARATION OF PURPOSE

Joint Res. July 28, 1955, ch. 417, §2, 69 Stat. 382, provided a Congressional statement of the critical need for an analysis and reevaluation of the human and economic problems of mental illness and of the resources, methods, and practices utilized in diagnosing, treating, caring for, and rehabilitating the mentally ill, both within and outside of institutions, as might lead to the development of recommendations for such better utilization of those resources or such improvements on and new developments in methods of diagnosis, treatment, care, and rehabilitation as give promise of resulting in a marked reduction in the incidence or duration of mental illness and, in consequence, a lessening of the appalling emotional and financial drain on the families of those afflicted or on the economic resources of the States and of the Nation and a declaration of the policy to promote mental health and to help solve the complex and the interrelated problems posed by mental illness by encouraging the undertaking of nongovernmental, multidisciplinary research into and reevaluation of all aspects of our resources, methods, and practices for diagnosing, treating, caring for, and rehabilitating the mentally ill, including research aimed at the prevention of mental illness.

CHILDREN'S EMOTIONAL ILLNESS STUDY; PROGRAM GRANTS; CONDITIONS; DEFINITIONS; APPROPRIATIONS; TERMS OF GRANT

Pub. L. 89–97, title II, §231, July 30, 1965, 79 Stat. 360, as amended by Pub. L. 90–248, title III, §305, Jan. 2, 1968, 81 Stat. 929, authorized the Secretary of Health, Education, and Welfare upon the recommendation of the National Advisory Mental Health Council and after securing the advice of experts in pediatrics and child welfare, to make grants to organizations on certain conditions for carrying out a program of research into and

study of resources, methods, and practices for diagnosing or preventing emotional illness in children and of treating, caring for, and rehabilitating children with emotional illnesses, defined "organization", and authorized appropriations for the making of such grants for fiscal years ending June 30, 1966, and June 30, 1967, with such research and study to be completed not later than three years from the date it was inaugurated.

EXECUTIVE DOCUMENTS

TRANSFER OF FUNCTIONS

Office of Surgeon General abolished by section 3 of Reorg. Plan No. 3 of 1966, eff. June 25, 1966, 31 F.R. 8855, 80 Stat. 1610, and functions thereof transferred to Secretary of Health, Education, and Welfare by section 1 of Reorg. Plan No. 3 of 1966, set out as a note under section 202 of this title. Office of Surgeon General reestablished within the Office of the Assistant Secretary for Health, see Notice of Department of Health and Human Services, Office of the Assistant Secretary for Health, Mar. 30, 1987, 52 F.R. 11754.

[1] *See References in Text note below.*

§242c. Appointment and authority of the Director of the Centers for Disease Control and Prevention

(a) In general

The Centers for Disease Control and Prevention (referred to in this section as the "CDC") shall be headed by the Director of the Centers for Disease Control and Prevention (referred to in this section as the "Director"), who shall be appointed by the President, by and with the advice and consent of the Senate. Such individual shall also serve as the Administrator of the Agency for Toxic Substances and Disease Registry consistent with section 9604(i) of this title. The Director shall perform functions provided for in subsection (b) and such other functions as the Secretary may prescribe.

(b) Functions

The Secretary, acting through the Director, shall—

(1) implement and exercise applicable authorities and responsibilities provided for in this chapter or other applicable law related to the investigation, detection, identification, prevention, or control of diseases or conditions to preserve and improve public health domestically and globally and address injuries and occupational and environmental hazards, as appropriate;

(2) be responsible for the overall direction of the CDC and for the establishment and implementation of policies related to the management and operation of programs and activities within the CDC;

(3) coordinate and oversee the operation of centers, institutes, and offices within the CDC;

(4) support, in consultation with the heads of such centers, institutes, and offices, program coordination across such centers, institutes, and offices, including through priority setting reviews and the development of strategic plans, to reduce unnecessary duplication and encourage collaboration between programs;

(5) oversee the development, implementation, and updating of the strategic plan established pursuant to subsection (c);

(6) ensure that appropriate strategic planning, including the use of performance metrics, is conducted by such centers, institutes, and offices to facilitate and improve CDC programs and activities; [1]

(7) communicate, including through convening annual meetings, with public and private entities regarding relevant public health programs and activities, and, as applicable, the strategic plan established pursuant to subsection (c).

(c) Strategic plan

(1) In general

Not later than 1 year after December 29, 2022, and at least every 4 years thereafter, the Director shall develop and submit to the Committee on Health, Education, Labor, and Pensions and the Committee on Appropriations of the Senate and the Committee on Energy and Commerce and the Committee on Appropriations of the House of Representatives, and post on the website of the CDC, a coordinated strategy to provide strategic direction and facilitate collaboration across the centers, institutes, and offices within the CDC. Such strategy shall be known as the "CDC Strategic Plan".

(2) Requirements

The CDC Strategic Plan shall—

(A) identify strategic priorities and objectives related to—

(i) preventing, reducing, and eliminating the spread of communicable and noncommunicable diseases or conditions, and addressing injuries, and occupational and environmental hazards;

(ii) supporting the efforts of State, local, and Tribal health departments to prevent and reduce the prevalence of the diseases or conditions under clause (i);

(iii) containing, mitigating, and ending disease outbreaks;

(iv) enhancing global and domestic public health capacity, capabilities, and preparedness, including public health data, surveillance, workforce, and laboratory capacity and safety; and

(v) other priorities, as established by the Director;

(B) describe the capacity and capabilities necessary to achieve the priorities and objectives under subparagraph (A), and progress towards achieving such capacity and capabilities, as appropriate; and

(C) include a description of how the CDC Strategic Plan incorporates—

(i) strategic communications;

(ii) partnerships with private sector entities, and State, local, and Tribal health departments, and other public sector entities, as appropriate; and

(iii) coordination with other agencies and offices of the Department of Health and Human Services and other Federal departments and agencies, as appropriate.

(3) Use of plans

Strategic plans developed and updated by the centers, institutes, and offices of the CDC shall be prepared regularly and in such a manner that such plans will be informed by the CDC Strategic Plan developed and updated under this subsection.

(d) Appearances before Congress

(1) In general

Each fiscal year, the Director shall appear before the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives at hearings on topics such as—

(A) support for State, local, and Tribal public health preparedness and responses to any recent or ongoing public health emergency, including—

(i) any objectives, activities, or initiatives that have been carried out, or are planned, by the Director to prepare for, or respond to, the public health emergency, including relevant strategic communications or partnerships and any gaps or challenges identified in such objectives, activities, or initiatives;

(ii) any objectives and planned activities for the upcoming fiscal year to address gaps in, or otherwise improve, State, local, and Tribal public health preparedness; and

(iii) other potential all-hazard threats that the Director is preparing to address;

(B) activities related to public health and functions of the Director described in subsection (b); and

(C) updates on other relevant activities supported or conducted by the CDC, or in

collaboration or coordination with the heads of other Federal departments, agencies, or stakeholders, as appropriate.

(2) Clarifications

(A) Waiver authority

The Chair of the Committee on Health, Education, Labor, and Pensions of the Senate or the Chair of the Committee on Energy and Commerce of the House of Representatives may waive the requirements of paragraph (1) for the applicable fiscal year with respect to the applicable Committee.

(B) Scope of requirements

The requirements of this subsection shall not be construed to impact the appearance of other Federal officials or the Director at hearings of either Committee described in paragraph (1) at other times and for purposes other than the times and purposes described in paragraph (1).

(3) Closed hearings

Information that is not appropriate for disclosure during an open hearing under paragraph (1) in order to protect national security may instead be discussed in a closed hearing that immediately follows the open hearing.

(e) Other transactions

(1) In general

In carrying out activities of the Centers for Disease Control and Prevention, the Director may enter into transactions other than a contract, grant, or cooperative agreement for purposes of infectious disease research, biosurveillance, infectious disease modeling, and public health preparedness and response.

(2) Written determination

With respect to a project that is expected to cost the Centers for Disease Control and Prevention more than $40,000,000, the Director may exercise the authority under paragraph (1) only upon a written determination by the Assistant Secretary for Financial Resources of the Department of Health and Human Services, that the use of such authority is essential to promoting the success of the project. The authority of the Assistant Secretary for Financial Resources under this paragraph may not be delegated.

(3) Guidelines

The Director, in consultation with the Secretary, shall establish guidelines regarding the use of the authority under paragraph (1). Such guidelines shall include auditing requirements.

(July 1, 1944, ch. 373, title III, §305, as added Pub. L. 117–328, div. FF, title II, §2101(a), Dec. 29, 2022, 136 Stat. 5706.)

EDITORIAL NOTES

REFERENCES IN TEXT

Section 9604(i) of this title, referred to in subsec. (a), was in the original "section 104(i) of the Comprehensive Environmental Response, Compensation, and Liability Act", and was translated as reading "section 104(i) of the Comprehensive Environmental Response, Compensation, and Liability Act of 1980", meaning section 104(i) of Pub. L. 96–510, to reflect the probable intent of Congress.

PRIOR PROVISIONS

A prior section 242c, act July 1, 1944, ch. 373, title III, §305, as added July 3, 1956, ch. 510, §3, 70 Stat. 490; amended Oct. 30, 1970, Pub. L. 91–515, title II, §210, 84 Stat. 1303; June 18, 1973, Pub. L. 93–45, title I, §103, 87 Stat. 91; July 23, 1974, Pub. L. 93–353, title I, §104, 88 Stat. 363; Oct. 8, 1976, Pub. L. 94–460, title III, §301, 90 Stat. 1960; Nov. 9, 1978, Pub. L. 95–623, §4, 92 Stat. 3445; Aug. 13, 1981, Pub. L. 97–35, title IX, §919(a)(1), (2)(A), (3), (b)(1), (c), (d), 95 Stat. 565, 566; Oct. 30, 1984, Pub. L. 98–551, §§5(a), (b), 6, 98 Stat. 2817, 2819, 2820; Oct. 7, 1985, Pub. L. 99–117, §6, 99 Stat. 492; Nov. 14, 1986, Pub. L. 99–660,

title III, §311(b)(2), 100 Stat. 3779; Dec. 1, 1987, Pub. L. 100–177, title I, §§101, 102, 101 Stat. 987; Nov. 4, 1988, Pub. L. 100–607, title II, §204(1), 102 Stat. 3079; Nov. 18, 1988, Pub. L. 100–690, title II, §2620(b)(3), 102 Stat. 4244; Aug. 16, 1989, Pub. L. 101–93, §5(e)(3), 103 Stat. 612, related to National Center for Health Services Research and Health Care Technology Assessment, prior to repeal by Pub. L. 101–239, title VI, §6103(d)(1)(A), Dec. 19, 1989, 103 Stat. 2205.

STATUTORY NOTES AND RELATED SUBSIDIARIES

EFFECTIVE DATE

Pub. L. 117–328, div. FF, title II, §2101(b), Dec. 29, 2022, 136 Stat. 5709, provided that: "The first sentence of section 305(a) of the Public Health Service Act [42 U.S.C. 242c(a)], as added by subsection (a), shall take effect on January 20, 2025."

[1] *So in original. Probably should be followed by "and".*

§242c–1. Advisory committee to the Director

(a) In general

Not later than 60 days after December 29, 2022, the Secretary, acting through the Director of the Centers for Disease Control and Prevention (referred to in this section as the "Director"), shall maintain or establish an advisory committee within the Centers for Disease Control and Prevention to advise the Director on policy and strategies that enable the agency to fulfill its mission.

(b) Functions and activities

The Advisory Committee may—

(1) make recommendations to the Director regarding ways to prioritize the activities of the agency in alignment with the CDC Strategic Plan required under section 242c(c) of this title;

(2) advise on ways to achieve or improve performance metrics in relation to the CDC Strategic Plan, and other relevant metrics, as appropriate;

(3) provide advice and recommendations on the development of the CDC Strategic Plan, and any subsequent updates, as appropriate;

(4) advise on grants, cooperative agreements, contracts, or other transactions, as applicable;

(5) provide other advice to the Director, as requested, to fulfill duties under sections 241 and 243 of this title; and

(6) appoint subcommittees.

(c) Membership

(1) In general

The Advisory Committee shall consist of not more than 15 non-Federal members, including the Chair, to be appointed by the Secretary under paragraph (3).

(2) Ex officio members

Any ex officio members of the Advisory Council [1] may consist of—

(A) the Secretary;

(B) the Assistant Secretary for Health;

(C) the Director; and

(D) such additional officers or employees of the United States as the Secretary determines necessary for the advisory committee to effectively carry out its functions.

(3) Appointed members

Individuals shall be appointed to the Advisory Committee under paragraph (1) as follows:

(A) Twelve of the members shall be appointed by the Director from among the leading representatives of the health disciplines (including public health, global health, health

disparities, biomedical research, public health preparedness, and other fields, as applicable) relevant to the activities of the agency or center, as applicable.

(B) Three of the members may be appointed by the Secretary from the general public and may include leaders in fields of innovation, public policy, public relations, law, economics, or management.

(4) Compensation

Ex officio members of the Advisory Council [1] who are officers or employees of the United States shall not receive any compensation for service on the advisory committee. The remaining members of the advisory committee may receive, for each day (including travel time) they are engaged in the performance of the functions of the advisory committee, compensation at rates not to exceed the daily equivalent to the annual rate of basic pay for level III of the Executive Schedule under section 5314 of title 5.

(5) Terms of office

(A) In general

The term of office of a member of the advisory committee appointed under paragraph (3) shall be 4 years, except that any member appointed to fill a vacancy for an unexpired term shall serve for the remainder of such term. The Secretary shall make appointments to the advisory committee in such a manner as to ensure that the terms of the members not all expire in the same year. A member of the advisory committee may serve after the expiration of such member's term until a successor has been appointed and taken office.

(B) Reappointments

A member who has been appointed to the advisory committee for a term of 4 years may not be reappointed to the advisory committee during the 2-year period beginning on the date on which such 4-year term expired.

(C) Time for appointment

If a vacancy occurs in the advisory committee among the members appointed under paragraph (3), the Secretary shall make an appointment to fill such vacancy within 90 days from the date the vacancy occurs.

(d) Chair

The Secretary shall select a member of the advisory committee to serve as the Chair of the committee. The Secretary may so select an individual from among the appointed members. The term of office of the chair shall be 2 years.

(e) Meetings

The advisory committee shall meet at the call of the Chair or upon request of the Director, but in no event less than 2 times during each fiscal year.

(f) Executive secretary and staff

The Director shall designate a member of the staff of the agency to serve as the executive secretary of the advisory committee. The Director shall make available to the advisory committee such staff, information, and other assistance as it may require to carry out its functions. The Director shall provide orientation and training for new members of the advisory committee to provide for their effective participation in the functions of the advisory committee.

(July 1, 1944, ch. 373, title III, §305A, as added Pub. L. 117–328, div. FF, title II, §2102, Dec. 29, 2022, 136 Stat. 5709.)

[1] *So in original.*

§242d. Transferred

EDITORIAL NOTES

CODIFICATION

Section, act July 1, 1944, ch. 373, title III, §306, as added Aug. 2, 1956, ch. 871, title I, §101, 70 Stat. 923; amended July 23, 1959, Pub. L. 86–105, §1, 73 Stat. 239; Sept. 8, 1960, Pub. L. 88–497, §2, 78 Stat. 613; Aug. 16, 1968, Pub. L. 90–490, title III, §302(b), 82 Stat. 789; Mar. 12, 1970, Pub. L. 91–208, §3, 84 Stat. 52; Oct. 30, 1970, Pub. L. 91–515, title VI, §601(b)(2), 84 Stat. 1311; June 18, 1973, Pub. L. 93–45, title I, §104(a), 87 Stat. 91, which related to graduate or specialized training for physicians, engineers, nurses, and other professional personnel, was renumbered section 312 of act July 1, 1944, by Pub. L. 93–353 and transferred to section 244–1 of this title, and was subsequently repealed.

§242e. Repealed. Pub. L. 93–353, title I, §102(a), July 23, 1974, 88 Stat. 362

Section, act July 1, 1944, ch. 373, title III, §307, as added Aug. 2, 1956, ch. 871, title II, §201, 70 Stat. 924; amended July 23, 1959, Pub. L. 86–105, §2, 73 Stat. 239; Oct. 30, 1970, Pub. L. 91–515, title VI, §601(b)(2), 84 Stat. 1311, provided for a professional nurse traineeship program for which authorization of appropriations were made through fiscal year ending June 30, 1964. Provision for the continuation of the program was made by the Nurse Training Act of 1964, which enacted section 297 et seq. of this title.

§§242f to 242j. Transferred

EDITORIAL NOTES

CODIFICATION

Section 242f, act July 1, 1944, ch. 373, title III, §308, as added July 12, 1960, Pub. L. 86–610, §3, 74 Stat. 364, which related to international cooperation with respect to biomedical research and health services research and statistical activities, was renumbered section 307 of act July 1, 1944, by Pub. L. 93–353 and transferred to section 242l of this title.

Section 242g, act July 1, 1944, ch. 373, title III, §309, as added Sept. 8, 1960, Pub. L. 86–720, §1(a), 74 Stat. 819; amended Aug. 27, 1964, Pub. L. 88–497, §3, 78 Stat. 613; Nov. 3, 1966, Pub. L. 89–749, §4, 80 Stat. 1190; Dec. 5, 1967, Pub. L. 90–147, §§2(g), 8(c), 81 Stat. 534, 540; Aug. 16, 1968, Pub. L. 90–490, title III, §302(a), 82 Stat. 788; Mar. 12, 1970, Pub. L. 91–208, §§1, 2, 84 Stat. 52; June 30, 1970, Pub. L. 91–296, title IV, §401(b)(1)(B), 84 Stat. 352; June 18, 1973, Pub. L. 93–45, title I, §104(b), (c), 87 Stat. 91, which related to graduate public health training grants, was renumbered section 313 of act July 1, 1944, by Pub. L. 93–353 and transferred to section 245a of this title, and was subsequently repealed.

Section 242h, act July 1, 1944, ch. 373, title III, §310, as added Sept. 25, 1962, Pub. L. 87–692, 76 Stat. 592, and amended and renumbered, which related to health services for domestic agricultural migrants, was renumbered section 319 of act July 1, 1944, by Pub. L. 93–353, title I, §102(d), July 23, 1974, 88 Stat. 362, transferred to section 247d of this title, and subsequently renumbered and transferred to section 254b of this title, prior to being omitted in the general amendment of subpart I (§254b et seq.) of part D of this subchapter by Pub. L. 104–299, §2.

Section 242i, act July 1, 1944, ch. 373, title III, §310A, as added Oct. 30, 1970, Pub. L. 91–515, title II, §270, 84 Stat. 1306; amended Nov. 18, 1971, Pub. L. 92–157, title II, §201, 85 Stat. 461, which related to administration of grants in multigrant projects, was renumbered section 226 of act July 1, 1944, by Pub. L. 93–353 and transferred to section 235 of this title.

Section 242j, act July 1, 1944, ch. 373, title III, §310B, as added Oct. 30, 1970, Pub. L. 91–515, title II, §280, 84 Stat. 1307, which provided for and annual report by Secretary on activities related to health facilities and services and expenditure of funds, was renumbered section 227 of act July 1, 1944, by Pub. L. 93–353 and transferred to section 236 of this title, and was subsequently repealed.

§242k. National Center for Health Statistics

(a) Establishment; appointment of Director; statistical and epidemiological activities

There is established in the Department of Health and Human Services the National Center for Health Statistics (hereinafter in this section referred to as the "Center") which shall be under the direction of a Director who shall be appointed by the Secretary. The Secretary, acting through the Center, shall conduct and support statistical and epidemiological activities for the purpose of improving the effectiveness, efficiency, and quality of health services in the United States.

(b) Duties

In carrying out subsection (a), the Secretary, acting through the Center,

(1) shall collect statistics on—

(A) the extent and nature of illness and disability of the population of the United States (or of any groupings of the people included in the population), including life expectancy, the incidence of various acute and chronic illnesses, and infant and maternal morbidity and mortality,

(B) the impact of illness and disability of the population on the economy of the United States and on other aspects of the well-being of its population (or of such groupings),

(C) environmental, social, and other health hazards,

(D) determinants of health,

(E) health resources, including physicians, dentists, nurses, and other health professionals by specialty and type of practice and the supply of services by hospitals, extended care facilities, home health agencies, and other health institutions,

(F) utilization of health care, including utilization of (i) ambulatory health services by specialties and types of practice of the health professionals providing such services, and (ii) services of hospitals, extended care facilities, home health agencies, and other institutions,

(G) health care costs and financing, including the trends in health care prices and cost, the sources of payments for health care services, and Federal, State, and local governmental expenditures for health care services, and

(H) family formation, growth, and dissolution;

(2) shall undertake and support (by grant or contract) research, demonstrations, and evaluations respecting new or improved methods for obtaining current data on the matters referred to in paragraph (1);

(3) may undertake and support (by grant or contract) epidemiological research, demonstrations, and evaluations on the matters referred to in paragraph (1); and

(4) may collect, furnish, tabulate, and analyze statistics, and prepare studies, on matters referred to in paragraph (1) upon request of public and nonprofit private entities under arrangements under which the entities will pay the cost of the service provided.

Amounts appropriated to the Secretary from payments made under arrangements made under paragraph (4) shall be available to the Secretary for obligation until expended.

(c) Statistical and epidemiological compilations and surveys

The Center shall furnish such special statistical and epidemiological compilations and surveys as the Committee on Labor and Human Resources and the Committee on Appropriations of the Senate and the Committee on Energy and Commerce and the Committee on Appropriations of the House of Representatives may request. Such statistical and epidemiological compilations and surveys shall not be made subject to the payment of the actual or estimated cost of the preparation of such compilations and surveys.

(d) Technical aid to States and localities

To insure comparability and reliability of health statistics, the Secretary shall, through the Center, provide adequate technical assistance to assist State and local jurisdictions in the development of model laws dealing with issues of confidentiality and comparability of data.

(e) Cooperative Health Statistics System

For the purpose of producing comparable and uniform health information and statistics, there is established the Cooperative Health Statistics System. The Secretary, acting through the Center, shall—

(1) coordinate the activities of Federal agencies involved in the design and implementation of the System;

(2) undertake and support (by grant or contract) research, development, demonstrations, and evaluations respecting the System;

(3) make grants to and enter into contracts with State and local health agencies to assist them in meeting the costs of data collection and other activities carried out under the System; and

(4) review the statistical activities of the Department of Health and Human Services to assure that they are consistent with the System.

States participating in the System shall designate a State agency to administer or be responsible for the administration of the statistical activities within the State under the System. The Secretary, acting through the Center, shall prescribe guidelines to assure that statistical activities within States participating in the system [1] produce uniform and timely data and assure appropriate access to such data.

(f) Federal-State cooperation

To assist in carrying out this section, the Secretary, acting through the Center, shall cooperate and consult with the Departments of Commerce and Labor and any other interested Federal departments or agencies and with State and local health departments and agencies. For such purpose he shall utilize insofar as possible the services or facilities of any agency of the Federal Government and, without regard to section 6101 of title 41, of any appropriate State or other public agency, and may, without regard to such section, utilize the services or facilities of any private agency, organization, group, or individual, in accordance with written agreements between the head of such agency, organization, or group and the Secretary or between such individual and the Secretary. Payment, if any, for such services or facilities shall be made in such amounts as may be provided in such agreement.

(g) Collection of health data; data collection forms

To secure uniformity in the registration and collection of mortality, morbidity, and other health data, the Secretary shall prepare and distribute suitable and necessary forms for the collection and compilation of such data.

(h) Registration area records

(1) There shall be an annual collection of data from the records of births, deaths, marriages, and divorces in registration areas. The data shall be obtained only from and restricted to such records of the States and municipalities which the Secretary, in his discretion, determines possess records affording satisfactory data in necessary detail and form. The Secretary shall encourage States and registration areas to obtain detailed data on ethnic and racial populations, including subpopulations of Hispanics, Asian Americans, and Pacific Islanders with significant representation in the State or registration area. Each State or registration area shall be paid by the Secretary the Federal share of its reasonable costs (as determined by the Secretary) for collecting and transcribing (at the request of the Secretary and by whatever method authorized by him) its records for such data.

(2) There shall be an annual collection of data from a statistically valid sample concerning the general health, illness, and disability status of the civilian noninstitutionalized population. Specific topics to be addressed under this paragraph, on an annual or periodic basis, shall include the incidence of illness and accidental injuries, prevalence of chronic diseases and impairments, disability, physician visits, hospitalizations, and the relationship between demographic and socioeconomic characteristics and health characteristics.

(i) Technical assistance in effective use of statistics

The Center may provide to public and nonprofit private entities technical assistance in the effective use in such activities of statistics collected or compiled by the Center.

(j) Coordination of health statistical and epidemiological activities

In carrying out the requirements of section 242b(c) of this title and paragraph (1) of subsection (e) of this section, the Secretary shall coordinate health statistical and epidemiological activities of the Department of Health and Human Services by—

(1) establishing standardized means for the collection of health information and statistics under laws administered by the Secretary;

(2) developing, in consultation with the National Committee on Vital and Health Statistics, and maintaining the minimum sets of data needed on a continuing basis to fulfill the collection requirements of subsection (b)(1);

(3) after consultation with the National Committee on Vital and Health Statistics, establishing standards to assure the quality of health statistical and epidemiological data collection, processing, and analysis;

(4) in the case of proposed health data collections of the Department which are required to be reviewed by the Director of the Office of Management and Budget under section 3509 [2] of title 44, reviewing such proposed collections to determine whether they conform with the minimum sets of data and the standards promulgated pursuant to paragraphs (2) and (3), and if any such proposed collection is found not to be in conformance, by taking such action as may be necessary to assure that it will conform to such sets of data and standards, and

(5) periodically reviewing ongoing health data collections of the Department, subject to review under such section 3509,[2] to determine if the collections are being conducted in accordance with the minimum sets of data and the standards promulgated pursuant to paragraphs (2) and (3) and, if any such collection is found not to be in conformance, by taking such action as may be necessary to assure that the collection will conform to such sets of data and standards not later than the ninetieth day after the date of the completion of the review of the collection.

(k) National Committee on Vital and Health Statistics; establishment; membership; term of office; compensation; functions; consultations of Secretary with Committee and professional advisory groups

(1) There is established in the Office of the Secretary a committee to be known as the National Committee on Vital and Health Statistics (hereinafter in this subsection referred to as the "Committee") which shall consist of 18 members.

(2) The members of the Committee shall be appointed from among persons who have distinguished themselves in the fields of health statistics, electronic interchange of health care information, privacy and security of electronic information, population-based public health, purchasing or financing health care services, integrated computerized health information systems, health services research, consumer interests in health information, health data standards, epidemiology, and the provision of health services. Members of the Committee shall be appointed for terms of 4 years.

(3) Of the members of the Committee—

(A) 1 shall be appointed, not later than 60 days after August 21, 1996, by the Speaker of the House of Representatives after consultation with the Minority Leader of the House of Representatives;

(B) 1 shall be appointed, not later than 60 days after August 21, 1996, by the President pro tempore of the Senate after consultation with the Minority Leader of the Senate; and

(C) 16 shall be appointed by the Secretary.

(4) Members of the Committee shall be compensated in accordance with section 210(c) of this title.

(5) The Committee—

(A) shall assist and advise the Secretary—

(i) to delineate statistical problems bearing on health and health services which are of

national or international interest;

(ii) to stimulate studies of such problems by other organizations and agencies whenever possible or to make investigations of such problems through subcommittees;

(iii) to determine, approve, and revise the terms, definitions, classifications, and guidelines for assessing health status and health services, their distribution and costs, for use (I) within the Department of Health and Human Services, (II) by all programs administered or funded by the Secretary, including the Federal-State-local cooperative health statistics system referred to in subsection (e), and (III) to the extent possible as determined by the head of the agency involved, by the Department of Veterans Affairs, the Department of Defense, and other Federal agencies concerned with health and health services;

(iv) with respect to the design of and approval of health statistical and health information systems concerned with the collection, processing, and tabulation of health statistics within the Department of Health and Human Services, with respect to the Cooperative Health Statistics System established under subsection (e), and with respect to the standardized means for the collection of health information and statistics to be established by the Secretary under subsection (j)(1);

(v) to review and comment on findings and proposals developed by other organizations and agencies and to make recommendations for their adoption or implementation by local, State, national, or international agencies;

(vi) to cooperate with national committees of other countries and with the World Health Organization and other national agencies in the studies of problems of mutual interest;

(vii) to issue an annual report on the state of the Nation's health, its health services, their costs and distributions, and to make proposals for improvement of the Nation's health statistics and health information systems; and

(viii) in complying with the requirements imposed on the Secretary under part C of title XI of the Social Security Act [42 U.S.C. 1320d et seq.];

(B) shall study the issues related to the adoption of uniform data standards for patient medical record information and the electronic exchange of such information;

(C) shall report to the Secretary not later than 4 years after August 21, 1996, recommendations and legislative proposals for such standards and electronic exchange; and

(D) shall be responsible generally for advising the Secretary and the Congress on the status of the implementation of part C of title XI of the Social Security Act [42 U.S.C. 1320d et seq.].

(6) In carrying out health statistical activities under this part, the Secretary shall consult with, and seek the advice of, the Committee and other appropriate professional advisory groups.

(7) Not later than 1 year after August 21, 1996, and annually thereafter, the Committee shall submit to the Congress, and make public, a report regarding the implementation of part C of title XI of the Social Security Act [42 U.S.C. 1320d et seq.]. Such report shall address the following subjects, to the extent that the Committee determines appropriate:

(A) The extent to which persons required to comply with part C of title XI of the Social Security Act are cooperating in implementing the standards adopted under such part.

(B) The extent to which such entities are meeting the security standards adopted under such part and the types of penalties assessed for noncompliance with such standards.

(C) Whether the Federal and State Governments are receiving information of sufficient quality to meet their responsibilities under such part.

(D) Any problems that exist with respect to implementation of such part.

(E) The extent to which timetables under such part are being met.

(l) Data specific to particular ethnic and racial populations

In carrying out this section, the Secretary, acting through the Center, shall collect and analyze adequate health data that is specific to particular ethnic and racial populations, including data collected under national health surveys. Activities carried out under this subsection shall be in addition to any activities carried out under subsection (m).

(m) Grants for assembly and analysis of data on ethnic and racial populations

(1) The Secretary, acting through the Center, may make grants to public and nonprofit private entities for—

(A) the conduct of special surveys or studies on the health of ethnic and racial populations or subpopulations;

(B) analysis of data on ethnic and racial populations and subpopulations; and

(C) research on improving methods for developing statistics on ethnic and racial populations and subpopulations.

(2) The Secretary, acting through the Center, may provide technical assistance, standards, and methodologies to grantees supported by this subsection in order to maximize the data quality and comparability with other studies.

(3) Provisions of section 242m(d) of this title do not apply to surveys or studies conducted by grantees under this subsection unless the Secretary, in accordance with regulations the Secretary may issue, determines that such provisions are necessary for the conduct of the survey or study and receives adequate assurance that the grantee will enforce such provisions.

(4)(A) Subject to subparagraph (B), the Secretary, acting through the Center, shall collect data on Hispanics and major Hispanic subpopulation groups and American Indians, and for developing special area population studies on major Asian American and Pacific Islander populations.

(B) The provisions of subparagraph (A) shall be effective with respect to a fiscal year only to the extent that funds are appropriated pursuant to paragraph (3) of subsection (n), and only if the amounts appropriated for such fiscal year pursuant to each of paragraphs (1) and (2) of subsection (n) equal or exceed the amounts so appropriated for fiscal year 1997.

(n) Authorization of appropriations

(1) For health statistical and epidemiological activities undertaken or supported under subsections (a) through (l), there are authorized to be appropriated such sums as may be necessary for each of the fiscal years 1991 through 2003.

(2) For activities authorized in paragraphs (1) through (3) of subsection (m), there are authorized to be appropriated such sums as may be necessary for each of the fiscal years 1999 through 2003. Of such amounts, the Secretary shall use not more than 10 percent for administration and for activities described in subsection (m)(2).

(3) For activities authorized in subsection (m)(4), there are authorized to be appropriated $1,000,000 for fiscal year 1998, and such sums as may be necessary for each of the fiscal years 1999 through 2002.

(July 1, 1944, ch. 373, title III, §306, as added Pub. L. 93–353, title I, §105, July 23, 1974, 88 Stat. 365; amended Pub. L. 95–623, §§5, 8(a), Nov. 9, 1978, 92 Stat. 3445, 3453; Pub. L. 97–35, title IX, §920, Aug. 13, 1981, 95 Stat. 566; Pub. L. 97–414, §8(b), Jan. 4, 1983, 96 Stat. 2060; Pub. L. 100–177, title I, §§104, 105(a), Dec. 1, 1987, 101 Stat. 988; Pub. L. 101–239, title VI, §6103(e)(2), Dec. 19, 1989, 103 Stat. 2206; Pub. L. 101–527, §7(a), (b)(1), (c), Nov. 6, 1990, 104 Stat. 2327, 2328; Pub. L. 102–54, §13(q)(1)(A)(i), June 13, 1991, 105 Stat. 278; Pub. L. 103–183, title V, §501(a), (d), Dec. 14, 1993, 107 Stat. 2237, 2238; Pub. L. 104–191, title II, §263, Aug. 21, 1996, 110 Stat. 2031; Pub. L. 105–340, title II, §201, Oct. 31, 1998, 112 Stat. 3193; Pub. L. 105–392, title II, §201(b), Nov. 13, 1998, 112 Stat. 3585.)

EDITORIAL NOTES

REFERENCES IN TEXT

Section 3509 of title 44, referred to in subsec. (j)(4), (5), which required submission of certain plans and forms for collection of information to the Director of the Office of Management and Budget for approval, was omitted in the general amendment of chapter 35 of Title 44, Public Printing and Documents, by Pub. L.

96–511, §2(a), Dec. 11, 1980, 94 Stat. 2812. Pub. L. 104–13 subsequently enacted a new section 3509 of Title 44 relating to designation of a central collection agency. Provisions appearing in former section 3509 are contained in section 3507 of Title 44.

The Social Security Act, referred to in subsec. (k)(5)(A)(viii), (D), (7), is act Aug. 14, 1935, ch. 531, 49 Stat. 620. Part C of title XI of the Act is classified generally to part C (§1320d et seq.) of subchapter XI of chapter 7 of this title. For complete classification of this Act to the Code, see section 1305 of this title and Tables.

CODIFICATION

In subsec. (f), "section 6101 of title 41" substituted for "section 3709 of the Revised Statutes (41 U.S.C. 5)" on authority of Pub. L. 111–350, §6(c), Jan. 4, 2011, 124 Stat. 3854, which Act enacted Title 41, Public Contracts.

PRIOR PROVISIONS

Provisions similar to those comprising subsec. (g) of this section were contained in section 313 of act July 1, 1944, ch. 373, title III, 58 Stat. 693; Oct. 30, 1970, Pub. L. 91–516, title II, §282, 84 Stat. 1308 (formerly classified to section 245 of this title), prior to repeal by Pub. L. 93–353, §102(a).

Provisions similar to those comprising subsec. (h) of this section were contained in section 312a of act July 1, 1944, ch. 373, title III, as added Aug. 31, 1954, ch. 1158, §2, 68 Stat. 1025 (formerly classified to section 244a of this title), prior to repeal by Pub. L. 93–353, §102(a).

AMENDMENTS

1998—Subsec. (m)(4). Pub. L. 105–392, §201(b)(1), added par. (4).

Subsec. (n)(1). Pub. L. 105–340, §201(1), and Pub. L. 105–392, §201(b)(2), amended par. (1) identically, substituting "2003" for "1998".

Subsec. (n)(2). Pub. L. 105–392, §201(b)(3)(A), in first sentence, substituted "paragraphs (1) through (3) of subsection (m)" for "subsection (m)" and substituted "such sums as may be necessary for each of the fiscal years 1999 through 2003." for "$5,000,000 for fiscal year 1991, $7,500,000 for fiscal year 1992, $10,000,000 for fiscal year 1993, and $10,000,000 for each of the fiscal years 1994 through 2003."

Pub. L. 105–340, §201(2), substituted "2003" for "1998".

Subsec. (n)(3). Pub. L. 105–392, §201(b)(3)(B), added par. (3).

1996—Subsec. (k)(1). Pub. L. 104–191, §263(1), substituted "18" for "16".

Subsec. (k)(2). Pub. L. 104–191, §263(2), amended par. (2) generally. Prior to amendment, par. (2) read as follows: "The members of the Committee shall be appointed by the Secretary from among persons who have distinguished themselves in the fields of health statistics, health planning, epidemiology, and the provision of health services. Members of the Committee shall be appointed for terms of 4 years."

Subsec. (k)(3), (4). Pub. L. 104–191, §263(3), added par. (3) and redesignated former par. (3) as (4). Former par. (4) redesignated (5).

Subsec. (k)(5). Pub. L. 104–191, §263(4), amended par. (5) generally. Prior to amendment, par. (5) consisted of subpars. (A) to (G) relating to Committee functions in assisting and advising the Secretary.

Pub. L. 104–191, §263(3), redesignated par. (4) as (5). Former par. (5) redesignated (6).

Subsec. (k)(6). Pub. L. 104–191, §263(3), redesignated par. (5) as (6).

Subsec. (k)(7). Pub. L. 104–191, §263(5), added par. (7).

1993—Subsec. (c). Pub. L. 103–183, §501(a)(1), substituted "Committee on Labor and Human Resources" for "Committee on Human Resources".

Subsec. (g). Pub. L. 103–183, §501(a)(2), substituted "data" for "data which shall be published as a part of the health reports published by the Secretary".

Subsec. (i). Pub. L. 103–183, §501(a)(3), struck out "engaged in health planning activities" after "entities".

Subsec. (k)(2). Pub. L. 103–183, §501(a)(4), struck out subpar. (A) designation, substituted "Members" for "Except as provided in subparagraph (B), members", and struck out subpar. (B) which related to extensions of membership terms of members of National Committee on Vital and Health Statistics whose terms were to expire in calendar years 1988, 1989, and 1990.

Subsec. (l). Pub. L. 103–183, §501(a)(5)(A)–(C), redesignated subsec. (m) as (l), substituted "subsection (m)" for "subsection (n)", and struck out former subsec. (l) which related to development of plan for collection and coordination of statistical and epidemiological data on effects of environment on health and establishment of guidelines for compilation, analysis, and distribution of statistics and information necessary for coordinated determination of effects of conditions of employment and indoor and outdoor environmental conditions on public health.

Subsec. (m). Pub. L. 103–183, §501(a)(5)(B), redesignated subsec. (n) as (m). Former subsec. (m)

redesignated (l).

Subsecs. (n), (o). Pub. L. 103–183, §501(a)(5)(B), (D), (d), redesignated subsec. (o) as (n), in par. (1) substituted "(l)" for "(m)" and "1998" for "1993", and in par. (2) substituted "(m)" for "(n)", struck out "and" after "1992,", inserted ", and $10,000,000 for each of the fiscal years 1994 through 1998", and substituted "(m)(2)" for "(n)(2)". Former subsec. (n) redesignated (m).

1991—Subsec. (k)(4)(C). Pub. L. 102–54 substituted "Department of Veterans Affairs" for "Veterans' Administration".

1990—Subsec. (h). Pub. L. 101–527, §7(a), designated existing text as par. (1), inserted after second sentence "The Secretary shall encourage States and registration areas to obtain detailed data on ethnic and racial populations, including subpopulations of Hispanics, Asian Americans, and Pacific Islanders with significant representation in the State or registration area.", and added par. (2).

Subsecs. (m) to (o). Pub. L. 101–527, §7(b)(1), (c), added subsecs. (m) and (n) and redesignated former subsec. (m) as (o) and amended it generally. Prior to amendment, subsec. (o) read as follows: "For health statistical and epidemiological activities undertaken or supported under this section, there are authorized to be appropriated $55,000,000 for fiscal year 1988 and such sums as may be necessary for each of the fiscal years 1989 and 1990."

1989—Subsec. (a). Pub. L. 101–239, §6103(e)(2)(A), inserted at end "The Secretary, acting through the Center, shall conduct and support statistical and epidemiological activities for the purpose of improving the effectiveness, efficiency, and quality of health services in the United States."

Subsec. (b). Pub. L. 101–239, §6103(e)(2)(B), substituted "subsection (a)" for "section 242b(a) of this title".

Subsec. (m). Pub. L. 101–239, §6103(e)(2)(C), added subsec. (m).

1987—Subsec. (a). Pub. L. 100–177, §104, struck out "and supervised by the Assistant Secretary for Health (or such other officer of the Department as may be designated by the Secretary as the principal adviser to him for health programs)".

Subsec. (k)(1). Pub. L. 100–177, §105(a)(1), substituted "16 members" for "fifteen members".

Subsec. (k)(2)(A). Pub. L. 100–177, §105(a)(2), substituted "terms of 4 years" for "terms of three years".

Subsec. (k)(2)(B). Pub. L. 100–177, §105(a)(3), added subpar. (B) and struck out former subpar. (B) which read as follows: "Of the members first appointed—

"(i) five shall be appointed for terms of one year,

"(ii) five shall be appointed for terms of two years, and

"(iii) five shall be appointed for terms of three years,

as designated by the Secretary at the time of appointment. Any member appointed to fill a vacancy occurring prior to the expiration of the term for which his predecessor was appointed shall be appointed only for the remainder of such term. A member may serve after the expiration of his term until his successor has taken office."

1983—Subsec. (l)(2)(D). Pub. L. 97–414 redesignated subpar. (E) as (D) and struck out former subpar. (D) which provided that the Center would serve as a clearinghouse for statistics and information with respect to which guidelines had been established under subpar. (A).

Subsec. (l)(2)(E) to (G). Pub. L. 97–414 redesignated subpars. (F) and (G) as (E) and (F), respectively. Former subpar. (E) redesignated (D).

1981—Subsec. (a). Pub. L. 97–35, §920(d)(1), substituted "Health and Human Services" for "Health, Education, and Welfare".

Subsec. (c). Pub. L. 97–35, §920(d)(2), substituted "Energy and" for "Interstate and Foreign".

Subsec. (e). Pub. L. 97–35, §920(a), (d)(1), in par. (3) inserted applicability to other activities, and in par. (4) substituted "Health and Human Services" for "Health, Education, and Welfare".

Subsecs. (j), (k)(4)(C), (D). Pub. L. 97–35, §920(d)(1), substituted "Health and Human Services" for "Health, Education, and Welfare".

Subsec. (l)(2). Pub. L. 97–35, §920(b), (c), (d)(1), in subpar. (A) inserted reference to Office of Federal Statistical Policy and Standards, in subpar. (B)(v) substituted "Health and Human Services" for "Health, Education, and Welfare", and in subpar. (D) struck out provisions relating to assistance to executive departments.

1978—Subsec. (b). Pub. L. 95–623, §5(a), struck out "may" after "through the Center,", substituted in pars. (1) and (2) "shall collect" and "shall undertake" for "collect" and "undertake", respectively, and added pars. (3) and (4) and provision for availability of certain appropriated funds from par. (4) payments until expended.

Subsec. (c). Pub. L. 95–623, §5(b), substituted "statistical and epidemiological compilations" for "statistical compilations" in two places and "Committee on Human Resources" for "Committee on Labor and Public Welfare" of the Senate.

Subsec. (e). Pub. L. 95–623, §5(c)(1), incorporated in introductory text prior cl. (1) provision requiring the

Secretary to assist State and local health agencies and Federal agencies involved in health matters in the design and implementation of a cooperative system for producing comparable and uniform health information and statistics at the Federal, State, and local levels; enacted in pars. (1) and (2) provisions almost identical to prior cls. (2) and (3); enacted par. (3); struck out former cl. (4) provision for the Federal share of the data collection costs under the system; enacted in par. (4) provisions almost identical to former cl. (5); and required State designation of a State administrative agency to be responsible for the statistical activities within the State under the System and Federal guidelines for production of uniform and timely data and appropriate access to the data.

Subsec. (f). Pub. L. 95–623, §5(d), substituted "the Secretary, acting through the Center, shall cooperate and consult" for "the Secretary shall cooperate and consult".

Subsecs. (i), (j). Pub. L. 95–623, §5(f), added subsecs. (i) and (j). Former subsec. (i) redesignated (k).

Subsec. (k). Pub. L. 95–623, §5(c)(2), (e), (f), struck from par. (1) "United States" before "National Committee on Vital and Health Statistics"; authorized in par. (2)(A) the appointment of Committee members from distinguished persons in field of health planning; required the Committee to assist and advise the Secretary with respect to the Cooperative Health Statistics System and the standardized means for the collection of health information and statistics to be established by the Secretary; and redesignated such amended subsec. (i) as (k).

Subsec. (l). Pub. L. 95–623, §8(a), added subsec. (l).

STATUTORY NOTES AND RELATED SUBSIDIARIES

CHANGE OF NAME

Committee on Labor and Human Resources of Senate changed to Committee on Health, Education, Labor, and Pensions of Senate by Senate Resolution No. 20, One Hundred Sixth Congress, Jan. 19, 1999.

Committee on Energy and Commerce of House of Representatives treated as referring to Committee on Commerce of House of Representatives by section 1(a) of Pub. L. 104–14, set out as a note preceding section 21 of Title 2, The Congress. Committee on Commerce of House of Representatives changed to Committee on Energy and Commerce of House of Representatives, and jurisdiction over matters relating to securities and exchanges and insurance generally transferred to Committee on Financial Services of House of Representatives by House Resolution No. 5, One Hundred Seventh Congress, Jan. 3, 2001.

EFFECTIVE DATE OF 1990 AMENDMENT

Pub. L. 101–527, §12, Nov. 6, 1990, 104 Stat. 2335, provided that: "This Act and the amendments made by this Act [enacting sections 254c–1, 254t, 256a, 294bb, 294cc, and 300u–6 of this title, amending this section and sections 242m, 254b, 254c, 294m, 294o, and 295g–2 of this title, enacting provisions set out as notes under sections 201 and 300u–6 of this title, and repealing provisions set out as a note under section 292h of this title] shall take effect October 1, 1990, or upon the date of the enactment of this Act [Nov. 6, 1990], whichever occurs later."

EFFECTIVE DATE OF 1987 AMENDMENT

Pub. L. 100–177, title I, §105(b), Dec. 1, 1987, 101 Stat. 988, provided that: "The amendments made by this section [amending this section] shall become effective on January 1, 1988."

MONEY RECEIVED BY CENTER FROM REIMBURSEMENTS, INTERAGENCY AGREEMENTS, AND SALE OF DATA TAPES TO REMAIN AVAILABLE UNTIL EXPENDED

Pub. L. 103–333, title II, Sept. 30, 1994, 108 Stat. 2550, provided in part: "That for fiscal year 1995 and subsequent fiscal years amounts received by the National Center for Health Statistics from reimbursements and interagency agreements and the sale of data tapes may be credited to this appropriation and shall remain available until expended".

[1] So in original. Probably should be capitalized.

[2] See References in Text note below.

§242*l*. International cooperation

(a) Cooperative endeavors

The Secretary may participate with other countries in cooperative endeavors in—

(1) biomedical research, health care technology, and the health services research and statistical analysis authorized under section 242k of this title and subchapter VII; and

(2) biomedical research, health care services, health care research, or other related activities in furtherance of the activities, objectives or goals authorized under the Tom Lantos and Henry J. Hyde United States Global Leadership Against HIV/AIDS, Tuberculosis, and Malaria Reauthorization Act of 2008.

(b) Authority of Secretary; building construction prohibition

In connection with the cooperative endeavors authorized by subsection (a), the Secretary may—

(1) make such use of resources offered by participating foreign countries as he may find necessary and appropriate;

(2) establish and maintain fellowships in the United States and in participating foreign countries;

(3) make grants to public institutions or agencies and to nonprofit private institutions or agencies in the United States and in participating foreign countries for the purpose of establishing and maintaining the fellowships authorized by paragraph (2);

(4) make grants or loans of equipment and materials, for use by public or nonprofit private institutions or agencies, or by individuals, in participating foreign countries;

(5) participate and otherwise cooperate in any international meetings, conferences, or other activities concerned with biomedical research, health services research, health statistics, or health care technology;

(6) facilitate the interchange between the United States and participating foreign countries, and among participating foreign countries, of research scientists and experts who are engaged in experiments or programs of biomedical research, health services research, health statistical activities, or health care technology activities, and in carrying out such purpose may pay per diem compensation, subsistence, and travel for such scientists and experts when away from their places of residence at rates not to exceed those provided in section 5703(b) [1] of title 5 for persons in the Government service employed intermittently;

(7) procure, in accordance with section 3109 of title 5, the temporary or intermittent services of experts or consultants;

(8) enter into contracts with individuals for the provision of services (as defined in section 104 of part 37 of title 48, Code of Federal Regulations (48 CFR 37.104)) in participating foreign countries, which individuals may not be deemed employees of the United States for the purpose of any law administered by the Office of Personnel Management;

(9) provide such funds by advance or reimbursement to the Secretary of State, as may be necessary, to pay the costs of acquisition, lease, construction, alteration, equipping, furnishing or management of facilities outside of the United States; and

(10) in consultation with the Secretary of State, through grant or cooperative agreement, make funds available to public or nonprofit private institutions or agencies in foreign countries in which the Secretary is participating in activities described under subsection (a) to acquire, lease, construct, alter, or renovate facilities in those countries.

(c) Benefits for overseas assignees

The Secretary may provide to personnel appointed or assigned by the Secretary to serve abroad, allowances and benefits similar to those provided under chapter 9 of title I of the Foreign Service Act of 1980 (22 U.S.C. 4081 et seq.). Leaves of absence for personnel under this subsection shall be on the same basis as that provided under subchapter I of chapter 63 of title 5 or section 903 of the Foreign Service Act of 1980 (22 U.S.C. 4083) to individuals serving in the Foreign Service.

(d) Strategies to improve injection safety

In carrying out immunization programs and other programs in developing countries for the prevention, treatment, and control of infectious diseases, including HIV/AIDS, tuberculosis, and

malaria, the Director of the Centers for Disease Control and Prevention, in coordination with the Coordinator of United States Government Activities to Combat HIV/AIDS Globally, the National Institutes of Health, national and local government, and other organizations, such as the World Health Organization and the United Nations Children's Fund, shall develop and implement effective strategies to improve injection safety, including eliminating unnecessary injections, promoting sterile injection practices and technologies, strengthening the procedures for proper needle and syringe disposal, and improving the education and information provided to the public and to health professionals.

(July 1, 1944, ch. 373, title III, §307, formerly §308, as added Pub. L. 86–610, §3, July 12, 1960, 74 Stat. 364; renumbered §307 and amended Pub. L. 93–353, title I, §106, July 23, 1974, 88 Stat. 367; Pub. L. 97–35, title IX, §921, Aug. 13, 1981, 95 Stat. 566; Pub. L. 101–239, title VI, §6103(e)(3), Dec. 19, 1989, 103 Stat. 2206; Pub. L. 102–531, title III, §310, Oct. 27, 1992, 106 Stat. 3503; Pub. L. 103–183, title VII, §702, Dec. 14, 1993, 107 Stat. 2239; Pub. L. 108–25, title III, §306, May 27, 2003, 117 Stat. 739; Pub. L. 110–293, title II, §205, July 30, 2008, 122 Stat. 2943.)

EDITORIAL NOTES

REFERENCES IN TEXT

The Tom Lantos and Henry J. Hyde United States Global Leadership Against HIV/AIDS, Tuberculosis, and Malaria Reauthorization Act of 2008, referred to in subsec. (a)(2), is Pub. L. 110–293, July 30, 2008, 122 Stat. 2918. For complete classification of this Act to the Code, see Short Title of 2008 Amendment note set out under section 7601 of Title 22, Foreign Relations and Intercourse, and Tables.

Section 5703 of title 5, referred to in subsec. (b)(6), was amended generally by Pub. L. 94–22, §4, May 19, 1975, 89 Stat. 85, and, as so amended, does not contain a subsec. (b).

The Foreign Service Act of 1980, referred to in subsec. (c), is Pub. L. 96–465, Oct. 17, 1980, 94 Stat. 2071. Chapter 9 of title I of the Act is classified generally to subchapter IX (§4081 et seq.) of chapter 52 of Title 22, Foreign Relations and Intercourse. For complete classification of this Act to the Code, see Short Title note set out under section 3901 of Title 22 and Tables.

CODIFICATION

Section was formerly classified to section 242f of this title.

PRIOR PROVISIONS

A prior section 307 of act July 1, 1944, was classified to section 242e of this title, prior to repeal by Pub. L. 93–353, title I, §102(a), July 23, 1974, 88 Stat. 362.

AMENDMENTS

2008—Subsec. (a). Pub. L. 110–293, §205(1), amended subsec. (a) generally. Prior to amendment, text read as follows: "For the purpose of advancing the status of the health sciences in the United States (and thereby the health of the American people), the Secretary may participate with other countries in cooperative endeavors in biomedical research, health care technology, and the health services research and statistical activities authorized by section 242k of this title and by subchapter VII of this chapter."

Subsec. (b). Pub. L. 110–293, §205(2)(B), struck out concluding provisions which read as follows: "The Secretary may not, in the exercise of his authority under this section, provide financial assistance for the construction of any facility in any foreign country."

Subsec. (b)(8). Pub. L. 110–293, §205(2)(C), substituted "for the purpose of any law administered by the Office of Personnel Management;" for "for any purpose."

Subsec. (b)(9), (10). Pub. L. 110–293, §205(2)(A), (D), added pars. (9) and (10).

Subsec. (c). Pub. L. 110–293, §205(3), substituted "1980" for "1990" and inserted "or section 903 of the Foreign Service Act of 1980 (22 U.S.C. 4083)" after "title 5".

2003—Subsec. (d). Pub. L. 108–25 added subsec. (d).

1993—Subsec. (c). Pub. L. 103–183 added subsec. (c).

1992—Subsec. (b)(8). Pub. L. 102–531, which directed amendment of subsec. (b) by adding par. (8) at the end thereof, was executed by adding par. (8) after par. (7) to reflect the probable intent of Congress.

1989—Subsec. (a). Pub. L. 101–239 substituted "section 242k of this title and by subchapter VII of this chapter" for "sections 242b, 242c, 242k, and 242n of this title".

1981—Subsec. (a). Pub. L. 97–35, §921(a), inserted reference to health care technology and section 242n of this title.

Subsec. (b). Pub. L. 97–35, §921(b), in par. (5) inserted reference to health care technology, and in par. (6) inserted reference to health care technology activities.

1974—Pub. L. 93–353 amended section generally.

STATUTORY NOTES AND RELATED SUBSIDIARIES

INTERNATIONAL HEALTH STUDY

Pub. L. 95–83, title III, §315, Aug. 1, 1977, 91 Stat. 398, provided that the Secretary of Health, Education, and Welfare arrange through the National Academy of Sciences or other nonprofit private groups or associations, for a study to determine opportunities for broadened Federal program activities in areas of international health, which study was to consider biomedical and behavioral research, health services research, health professions education, immunization and public health activities, and other areas that might improve our and other nations' capacities to prevent, diagnose, control, or cure disease, and to organize and deliver effective and efficient health services, with an interim report on such study completed no later than Oct. 1, 1977 and a final report completed no later than Jan. 1, 1978 and both reports submitted to the Secretary, the Committee on Human Resources of the Senate, and the Committee on Interstate and Foreign Commerce of the House of Representatives.

[1] *See References in Text note below.*

§242m. General provisions respecting effectiveness, efficiency, and quality of health services

(a) Reports to Congress and President; preparation; review by Office of Management and Budget

(1) Not later than March 15 of each year, the Secretary shall submit to the President and Congress the following reports:

(A) A report on health care costs and financing. Such report shall include a description and analysis of the statistics collected under section 242k(b)(1)(G) of this title.

(B) A report on health resources. Such report shall include a description and analysis, by geographical area, of the statistics collected under section 242k(b)(1)(E) of this title.

(C) A report on the utilization of health resources. Such report shall include a description and analysis, by age, sex, income, and geographic area, of the statistics collected under section 242k(b)(1)(F) of this title.

(D) A report on the health of the Nation's people. Such report shall include a description and analysis, by age, sex, income, and geographic area, of the statistics collected under section 242k(b)(1)(A) of this title.

(2) The reports required in paragraph (1) shall be prepared through the National Center for Health Statistics.

(3) The Office of Management and Budget may review any report required by paragraph (1) of this subsection before its submission to Congress, but the Office may not revise any such report or delay its submission beyond the date prescribed for its submission, and may submit to Congress its comments respecting any such report.

(b) Grants or contracts; applications, submittal; application peer review group, findings and recommendations; necessity of favorable recommendation; appointments

(1) No grant or contract may be made under section 242b, 242k, or 242l of this title unless an application therefor has been submitted to the Secretary in such form and manner, and containing such information, as the Secretary may by regulation prescribe and unless a peer review group referred to in paragraph (2) has recommended the application for approval.

(2)(A) Each application submitted for a grant or contract under section 242k of this title in an amount exceeding $50,000 of direct costs and for a health services research, evaluation, or demonstration project, or for a grant under section 242k(m) of this title, shall be submitted to a peer review group for an evaluation of the technical and scientific merits of the proposals made in each such application. The Director of the National Center for Health Statistics shall establish such peer review groups as may be necessary to provide for such an evaluation of each such application.

(B) A peer review group to which an application is submitted pursuant to subparagraph (A) shall report its finding and recommendations respecting the application to the Secretary, acting through the Director of the National Center for Health Statistics, in such form and manner as the Secretary shall by regulation prescribe. The Secretary may not approve an application described in such subparagraph unless a peer review group has recommended the application for approval.

(C) The Secretary, acting through the Director of the National Center for Health Statistics, shall make appointments to the peer review groups required in subparagraph (A) from among persons who are not officers or employees of the United States and who possess appropriate technical and scientific qualifications, except that peer review groups regarding grants under section 242k(m) of this title may include appropriately qualified such officers and employees.

(c) Development and dissemination of statistics

The Secretary shall take such action as may be necessary to assure that statistics developed under sections 242b and 242k of this title are of high quality, timely, comprehensive as well as specific, standardized, and adequately analyzed and indexed, and shall publish, make available, and disseminate such statistics on as wide a basis as is practicable.

(d) Information; publication restrictions

No information, if an establishment or person supplying the information or described in it is identifiable, obtained in the course of activities undertaken or supported under section 242b, 242k, or 242l of this title may be used for any purpose other than the purpose for which it was supplied unless such establishment or person has consented (as determined under regulations of the Secretary) to its use for such other purpose; and in the case of information obtained in the course of health statistical or epidemiological activities under section 242b or 242k of this title, such information may not be published or released in other form if the particular establishment or person supplying the information or described in it is identifiable unless such establishment or person has consented (as determined under regulations of the Secretary) to its publication or release in other form.

(e) Payment procedures; advances or reimbursement; installments; conditions; reductions

(1) Payments of any grant or under any contract under section 242b, 242k, or 242l of this title may be made in advance or by way of reimbursement, and in such installments and on such conditions, as the Secretary deems necessary to carry out the purposes of such section.

(2) The amounts otherwise payable to any person under a grant or contract made under section 242b, 242k, or 242l of this title shall be reduced by—

(A) amounts equal to the fair market value of any equipment or supplies furnished to such person by the Secretary for the purpose of carrying out the project with respect to which such grant or contract is made, and

(B) amounts equal to the pay, allowances, traveling expenses, and related personnel expenses attributable to the performance of services by an officer or employee of the Government in connection with such project, if such officer or employee was assigned or detailed by the Secretary to perform such services,

but only if such person requested the Secretary to furnish such equipment or supplies, or such services, as the case may be.

(f) Contracts without regard to section 3324 of title 31 and section 6101 of title 41

Contracts may be entered into under section 242b or 242k of this title without regard to section 3324 of title 31 and section 6101 of title 41.

(July 1, 1944, ch. 373, title III, §308, as added Pub. L. 93–353, title I, §107(a), July 23, 1974, 88 Stat.

368; amended Pub. L. 94–273, §7(2), Apr. 21, 1976, 90 Stat. 378; Pub. L. 95–83, title I, §104, Aug. 1, 1977, 91 Stat. 384; Pub. L. 95–623, §§2, 6(d), 8(b), Nov. 9, 1978, 92 Stat. 3443, 3451, 3455; Pub. L. 97–35, title IX, §§917(a), (b), 919(a)(2)(B), 922, Aug. 13, 1981, 95 Stat. 564, 565, 567; Pub. L. 97–414, §8(c), Jan. 4, 1983, 96 Stat. 2060; Pub. L. 98–551, §7, Oct. 30, 1984, 98 Stat. 2820; Pub. L. 100–177, title I, §§106(a), 107, 108, Dec. 1, 1987, 101 Stat. 988–990; Pub. L. 100–690, title II, §2612, Nov. 18, 1988, 102 Stat. 4235; Pub. L. 101–239, title VI, §6103(e)(4), Dec. 19, 1989, 103 Stat. 2206; Pub. L. 101–527, §7(b)(2), (d), Nov. 6, 1990, 104 Stat. 2328; Pub. L. 103–183, title V, §501(c), Dec. 14, 1993, 107 Stat. 2237; Pub. L. 105–392, title IV, §401(d), Nov. 13, 1998, 112 Stat. 3587.)

EDITORIAL NOTES

CODIFICATION

In subsec. (f), "section 6101 of title 41" substituted for "section 3709 of the Revised Statutes (41 U.S.C. 5)" on authority of Pub. L. 111–350, §6(c), Jan. 4, 2011, 124 Stat. 3854, which Act enacted Title 41, Public Contracts.

PRIOR PROVISIONS

Provisions similar to those comprising subsec. (e) of this section were contained in subsec. (a)(3) of section 304 of act July 1, 1944, ch. 373, title III, as added July 28, 1955, ch. 417, §3, 69 Stat. 382, and amended (formerly classified to section 242b(a)(3) of this title), prior to general amendment of section 304 by Pub. L. 93–353, §103.

AMENDMENTS

1998—Subsec. (b)(2)(A), (C). Pub. L. 105–392 substituted "242k(m)" for "242k(n)".

1993—Subsec. (a)(1). Pub. L. 103–183, §501(c)(1)(A), redesignated subpars. (B) to (E) as (A) to (D), respectively, and struck out former subpar. (A) which read as follows: "A report on—

"(i) the administration of sections 242b, 242k, and 242l of this title and subchapter VII of this chapter during the preceding fiscal year; and

"(ii) the current state and progress of health services research, health statistics, and health care technology."

Subsec. (a)(2). Pub. L. 103–183, §501(c)(1)(B), substituted "reports required in paragraph (1) shall be prepared through the National Center" for "reports required by subparagraphs (B) through (E) of paragraph (2) shall be prepared through the Agency for Health Care Policy and Research and the National Center".

Subsec. (c). Pub. L. 103–183, §501(c)(2)(A)–(D), (3), redesignated subsec. (g)(2) as subsec. (c), substituted "shall take" for "shall (A) take" and "and shall publish" for "and (B) publish", and struck out former subsec. (c) which read as follows: "The aggregate number of grants and contracts made or entered into under sections 242b and 242c of this title for any fiscal year respecting a particular means of delivery of health services or another particular aspect of health services may not exceed twenty; and the aggregate amount of funds obligated under grants and contracts under such sections for any fiscal year respecting a particular means of delivery of health services or another particular aspect of health services may not exceed $5,000,000."

Subsec. (f). Pub. L. 103–183, §501(c)(4), substituted "section 3324 of title 31 and section 5 of title 41" for "sections 3648 and 3709 of the Revised Statutes (31 U.S.C. 529; 41 U.S.C. 5)".

Subsec. (g). Pub. L. 103–183, §501(c)(2)(B), (C), (E), redesignated par. (2) as subsec. (c) and struck out par. (1) which read as follows: "The Secretary shall—

"(A) publish, make available and disseminate, promptly in understandable form and on as broad a basis as practicable, the results of health services research, demonstrations, and evaluations undertaken and supported under sections 242b and 242c of this title;

"(B) make available to the public data developed in such research, demonstrations, and evaluations; and

"(C) provide indexing, abstracting, translating, publishing, and other services leading to a more effective and timely dissemination of information on health services research, demonstrations, and evaluations in health care delivery to public and private entities and individuals engaged in the improvement of health care delivery and the general public; and undertake programs to develop new or improved methods for making such information available."

Subsec. (h). Pub. L. 103–183, §501(c)(5), struck out subsec. (h) which read as follows:

"(1) Except where the Secretary determines that unusual circumstances make a larger percentage necessary

in order to effectuate the purposes of section 242k of this title, a grant or contract under any of such sections of this title with respect to any project for construction of a facility or for acquisition of equipment may not provide for payment of more than 50 per centum of so much of the cost of the facility or equipment as the Secretary determines is reasonably attributable to research, evaluation, or demonstration purposes.

"(2) Laborers and mechanics employed by contractors and subcontractors in the construction of such a facility shall be paid wages at rates not less than those prevailing on similar work in the locality, as determined by the Secretary of Labor in accordance with the Act of March 3, 1931 (40 U.S.C. 267a—267a–5, known as the Davis-Bacon Act); and the Secretary of Labor shall have with respect to any labor standards specified in this paragraph the authority and functions set forth in Reorganization Plan Numbered 14 of 1950 (5 U.S.C. Appendix) and section 276c of title 40.

"(3) Such grants and contracts shall be subject to such additional requirements as the Secretary may by regulation prescribe."

1990—Subsec. (b)(2)(A). Pub. L. 101–527, §7(b)(2)(A), inserted "or for a grant under section 242k(n) of this title," after "demonstration project,".

Subsec. (b)(2)(C). Pub. L. 101–527, §7(b)(2)(B), inserted before period at end ", except that peer review groups regarding grants under section 242k(n) of this title may include appropriately qualified such officers and employees".

Subsec. (b)(3). Pub. L. 101–527, §7(d), struck out par. (3) which related to applications submitted under section 242k of this title for which a grant or contract may be made under another provision of this chapter.

1989—Pub. L. 101–239, §6103(e)(4)(A), amended section catchline.

Subsec. (a)(1)(A)(i). Pub. L. 101–239, §6103(e)(4)(B)(i), substituted "sections 242b, 242k, and 242l of this title and subchapter VII of this chapter" for "sections 242b, 242c, 242k, and 242l of this title and section 242n of this title".

Subsec. (a)(2). Pub. L. 101–239, §6103(e)(4)(B)(ii), substituted "the Agency for Health Care Policy and Research" for "the National Center for Health Services Research and Health Care Technology Assessment".

Subsec. (b)(1). Pub. L. 101–239, §6103(e)(4)(C)(i), which directed amendment of par. (1) by substituting "section 242b, 242k, or 242l of this title" for "sections 242b, 242c, 242k, 242l, and 242n of this title", was executed by making the substitution for "section 242b, 242c, 242k, 242l, or 242n of this title" as the probable intent of Congress.

Subsec. (b)(2)(A). Pub. L. 101–239, §6103(e)(4)(C)(ii), substituted "under section 242k of this title" for "under section 242b or 242c of this title," in first sentence, struck out second sentence which read as follows: "Each application for a grant, contract, or cooperative agreement in an amount exceeding $50,000 of direct costs for the dissemination of research findings or the development of research agendas (including conferences, workshops, and meetings) shall be submitted to a standing peer review group with persons with appropriate expertise and shall not be submitted to any peer review group established to review applications for research, evaluation, or demonstration projects.", and amended last sentence generally. Prior to amendment, last sentence read as follows: "The Secretary, acting through the Director of the National Center for Health Services Research and Health Care Technology Assessment (or, as appropriate, through the Director of the National Center for Health Statistics), shall establish such peer review groups as may be necessary to provide for such an evaluation of an application described in the first two sentences of this subparagraph."

Subsec. (b)(2)(B). Pub. L. 101–239, §6103(e)(4)(C)(iii), substituted "the Director of the National Center for Health Statistics" for "the Director involved".

Subsec. (b)(2)(C). Pub. L. 101–239, §6103(e)(4)(C)(iv), substituted "the Director of the National Center for Health Statistics" for "the Directors".

Subsec. (b)(3). Pub. L. 101–239, §6103(e)(4)(C)(v), substituted "submitted under section 242k of this title" for "submitted under section 242b, 242c, or 242k of this title" and "approved under any of such sections" for "approved under section 242b, 242c, or 242k of this title".

Subsec. (d). Pub. L. 101–239, §6103(e)(4)(D), substituted "section 242b, 242k, or 242l of this title" for "section 242b, 242c, 242k, 242l, or 242n of this title", struck out "(1)" after "for such other purpose; and", and substituted "publication or release in other form." for "publication or release in other form, and (2) in the case of information obtained in the course of health services research, evaluations, or demonstrations under section 242b or 242c of this title or in the course of health care technology activities under section 242n of this title, such information may not be published or released in other form if the person who supplied the information or who is described in it is identifiable unless such person has consented (as determined under regulations of the Secretary) to its publication or release in other form."

Subsec. (e)(1), (2). Pub. L. 101–239, §6103(e)(4)(E), substituted "section 242b, 242k, or 242l of this title" for "section 242b, 242c, 242k, 242l, or 242n of this title".

Subsec. (f). Pub. L. 101–239, §6103(e)(4)(F), substituted "section 242b or 242k of this title" for "section 242b, 242c, 242k, or 242n of this title".

Subsec. (g)(1). Pub. L. 101–239, §6103(e)(4)(G)(i), struck out at end "Except as provided in subsection (d) of this section, the Secretary may not restrict the publication and dissemination of data from, and results of projects undertaken by, centers supported under section 242c(d) of this title."

Subsec. (g)(2). Pub. L. 101–239, §6103(e)(4)(G)(ii), substituted "sections 242b and 242k of this title" for "sections 242b, 242c, 242k, and 242n of this title".

Subsec. (h)(1). Pub. L. 101–239, §6103(e)(4)(H), substituted "effectuate the purposes of section 242k of this title" for "effectuate the purposes of section 242b, 242c, 242k, or 242n of this title" and "contract under any of such sections" for "contract under section 242b, 242c, 242k, or 242n of this title".

Subsec. (i). Pub. L. 101–239, §6103(e)(4)(I), struck out subsec. (i) which authorized appropriations for carrying out certain programs under sections 242b, 242c, 242k, and 242n of this title during fiscal years 1988 to 1990.

1988—Subsec. (b)(2)(A). Pub. L. 100–690 inserted after first sentence "Each application for a grant, contract, or cooperative agreement in an amount exceeding $50,000 of direct costs for the dissemination of research findings or the development of research agendas (including conferences, workshops, and meetings) shall be submitted to a standing peer review group with persons with appropriate expertise and shall not be submitted to any peer review group established to review applications for research, evaluation, or demonstration projects." and substituted "an application described in the first two sentences of this subparagraph" for "each such application" in last sentence.

1987—Subsec. (a)(1), (2). Pub. L. 100–177, §106(a)(1), added pars. (1) and (2) and struck out former pars. (1) and (2) which read as follows:

"(1) Not later than December 1 of each year, the Secretary shall make a report to Congress respecting (A) the administration of sections 242b, 242c, 242k, and 242l and section 242n of this title during the preceding fiscal year, and (B) the current state and progress of health services research and, health statistics, and health care technology.

"(2) The Secretary, acting through the National Center for Health Services Research and the National Center for Health Statistics, shall assemble and submit to the President and the Congress not later than December 1 of each year the following reports:

"(A) A report on health care costs and financing. Such report shall include a description and analysis of the statistics collected under section 242k(b)(1)(G) of this title.

"(B) A report on health resources. Such report shall include a description and analysis, by geographic area, of the statistics collected under section 242k(b)(1)(E) of this title.

"(C) A report on the utilization of health resources. Such report shall include a description and analysis, by age, sex, income, and geographic area, of the statistics collected under section 242k(b)(1)(F) of this title.

"(D) A report on the health of the Nation's people. Such report shall include a description and analysis, by age, sex, income, and geographic area, of the statistics collected under section 242k(b)(1)(A) of this title."

Subsec. (a)(3). Pub. L. 100–177, §106(a)(2), struck out "or (2)" after "paragraph (1)".

Subsec. (b)(1). Pub. L. 100–177, §107(1), inserted "and unless a peer review group referred to in paragraph (2) has recommended the application for approval" before period at end.

Subsec. (b)(2). Pub. L. 100–177, §107(2), added par. (2) and struck out former par. (2) which read as follows: "Each application submitted for a grant or contract under section 242b or 242c of this title, in an amount exceeding $50,000 of direct costs and for a health services research, evaluation, or demonstration project, shall be submitted by the Secretary for review for scientific merit to a panel of experts appointed by him from persons who are not officers or employees of the United States and who possess qualifications relevant to the project for which the application was made. A panel to which an application is submitted under this paragraph shall report its findings and recommendations respecting the application to the Secretary in such form and manner as the Secretary shall by regulation prescribe."

Subsec. (i). Pub. L. 100–177, §108, amended subsec. (i) generally, substituting provisions authorizing appropriations for fiscal years 1988 to 1990 for carrying out activities under sections 242b, 242c, 242k, and 242n of this title for former provisions authorizing appropriations for fiscal years 1975 to 1987 for carrying out activities under those sections.

1984—Subsec. (i)(1). Pub. L. 98–551, §7(a), inserted provisions authorizing appropriations for fiscal years ending Sept. 30, 1985, 1986, and 1987, inserted "and Health Care Technology Assessment" after "Research", substituted "and at least 10 per centum of such amount or $1,500,000, whichever is less, shall be available only for the user liaison program and the technical assistance program referred to in section 242c(c)(2) of this

title and for dissemination activities directly undertaken through such Center" for "and at least 5 per centum of such amount or $1,000,000, whichever is less, shall be available only for dissemination activities directly undertaken through such Center", inserted "For health care technology assessment activities undertaken under subsections (b)(5), (e), (f), and (g) of section 242c of this title the Secretary shall obligate from funds appropriated under this paragraph not less than $3,000,000 for the fiscal year ending September 30, 1985, $3,500,000 for the fiscal year ending September 30, 1986, and $4,000,000 for the fiscal year ending September 30, 1987. For grants under section 242n of this title the Secretary shall obligate from funds appropriated under this paragraph not less than $500,000 for the fiscal year ending September 30, 1985, $750,000 for the fiscal year ending September 30, 1986, and $750,000 for the fiscal year ending September 30, 1987.", and in last sentence substituted "for any fiscal year" for "for each of the fiscal years ending September 30, 1982, September 30, 1983, and September 30, 1984,".

Subsec. (i)(2). Pub. L. 98–551, §7(b), inserted provisions authorizing appropriations for fiscal years ending Sept. 30, 1985, 1986, and 1987.

1983—Subsec. (d). Pub. L. 97–414 inserted ", if an establishment or person supplying the information or described in it is identifiable," after "No information", and substituted "such establishment or person has consented (as determined under regulations of the Secretary) to its use for such other purpose" for "authorized by guidelines in effect under section 242k(l)(2) of this title or under regulations of the Secretary".

1981—Subsec. (a)(2). Pub. L. 97–35, §922(a), substituted "December" for "September", which change had already been made by Pub. L. 94–273.

Subsec. (b)(2). Pub. L. 97–35, §922(b), substituted "$50,000" for "$35,000".

Subsec. (d)(2). Pub. L. 97–35, §922(c), inserted applicability to health care technology activities under section 242n of this title.

Subsec. (i)(1). Pub. L. 97–35, §§917(a), 919(a)(2)(B), inserted provisions respecting amounts of and limitations on uses for appropriations for the fiscal years ending Sept. 30, 1982, 1983, and 1984.

Subsec. (i)(2). Pub. L. 97–35, §917(b), inserted provisions respecting appropriations for the fiscal years ending Sept. 30, 1982, 1983, and 1984.

1978—Subsec. (a)(1). Pub. L. 95–623, §6(d)(1), required the report to cover the administration of section 242n of this title and the current state and progress of health care technology.

Subsec. (b)(1). Pub. L. 95–623, §6(d)(2), inserted reference to grant or contract under section 242n of this title.

Subsec. (d). Pub. L. 95–623, §§6(d)(3), 8(b), inserted reference to section 242n of this title and substituted in cl. (1) "statistical or epidemiological activities" for "statistical activities"; and authorized use of information for purposes other than for which supplied when authorized by guidelines in effect under section 242k(l)(2) of this title.

Subsecs. (e), (f), (g)(2), (h)(1). Pub. L. 95–623, §6(d)(4)–(7), inserted references to section 242n of this title.

Subsec. (i)(1). Pub. L. 95–623, §2(a), authorized appropriation of $35,000,000; $40,000,000; and $45,000,000 for fiscal years ending Sept. 30, 1979, through 1981, and substituted minimum amounts of the lesser of 20 per centum of appropriated funds or $6,000,000 for health services research, evaluation and demonstration activities of the National Center for Health Services Research and 5 per centum of such funds or $1,000,000 for dissemination activities of such Center for prior similar requirement of 25 per centum of appropriated funds for the applicable fiscal years for health services research, evaluation, and demonstration activities of the Secretary.

Subsec. (i)(2). Pub. L. 95–623, §2(b), authorized appropriation of $50,000,000; $65,000,000; and $70,000,000 for fiscal years ending Sept. 30, 1979, through 1981.

1977—Subsec. (i)(1). Pub. L. 95–83, §104(a), authorized appropriation of $28,600,000 for fiscal year ending Sept. 30, 1978.

Subsec. (i)(2). Pub. L. 95–83, §104(b), authorized appropriation of $33,600,000 for fiscal year ending Sept. 30, 1978.

1976—Subsec. (a). Pub. L. 94–273 substituted "December" for "September" wherever appearing.

STATUTORY NOTES AND RELATED SUBSIDIARIES

EFFECTIVE DATE OF 1998 AMENDMENT

Pub. L. 105–392, title IV, §401(e), Nov. 13, 1998, 112 Stat. 3587, provided that: "This section [amending this section and sections 247b–5, 247b–6, 247c, 285f–2, 300d–1 to 300d–3, 300d–13, 300d–32, 300k, and 300n–1 of this title] is deemed to have taken effect immediately after the enactment of Public Law 103–183

[Dec. 14, 1993]."

EFFECTIVE DATE OF 1988 AMENDMENT

Pub. L. 100–690, title II, §2600, Nov. 18, 1988, 102 Stat. 4233, provided that: "Except as provided in section 2613(b)(1) [42 U.S.C. 285m note], the amendments made by this subtitle [subtitle G (§§2600–2641) of title II of Pub. L. 100–690, enacting sections 285m–4 to 285m–6 of this title, amending this section, sections 242c, 281, 284, 284c, 285j, 285m, 285m–1 to 285m–6, 286, 289f, 290cc–28, 290cc–36, 292h, 294a, 295g–4, 295g–7, 295g–8b, 295h, 295h–5, 295j, 297j, 297n, 300cc–3, 300cc–13, 300cc–17, 300cc–20, 300cc–31, 300dd–1, 300dd–3, 300dd–8, 300dd–10, 300dd–12 to 300dd–14, 300dd–21, 300dd–32, 300ee, 300ee–2, 300ee–5, 300ee–12, 300ee–13, 300ee–15 to 300ee–18, 300ee–20, 300ee–22, 300ee–34, 300ff–48, and 300aaa to 300aaa–13 of this title, and section 393 of Title 21, Food and Drugs, enacting provisions set out as notes under section 285m of this title, amending provisions set out as notes under sections 201, 292h, 300cc, 300ee–1, and 300ff–48 of this title, and repealing provisions set out as a note under section 285m of this title] shall take effect immediately after the enactment of the Health Omnibus Programs Extension of 1988 [Nov. 4, 1988]."

EFFECTIVE DATE OF 1987 AMENDMENT

Pub. L. 100–177, title I, §106(c), Dec. 1, 1987, 101 Stat. 989, provided that: "The amendments made by subsections (a) and (b) [amending this section and section 242p of this title] shall apply to reports and profiles required to be submitted after November 1, 1987."

MINE WORKERS STUDY; REPORT COMPLETED AND SUBMITTED NO LATER THAN 30 MONTHS AFTER NOVEMBER 9, 1978

Pub. L. 95–623, §10, Nov. 9, 1978, 92 Stat. 3455, as amended by S. Res. 30, Mar. 7, 1979; H. Res. 549, Mar. 25, 1980, required the Secretary, acting through the National Center for Health Services Research, to arrange for the conduct of a study to evaluate the impact upon the utilization of health services by and the health status of members of the United Mine Workers and their dependents as a result of changes in the United Mine Workers' collective-bargaining agreements of Mar. 1978 with a report to be submitted to the Secretary and specific committees of the Senate and House of Representatives within 30 months after Nov. 9, 1978.

AUTHORIZATION OF APPROPRIATIONS FOR FISCAL YEAR ENDING JUNE 30, 1977

Pub. L. 93–353, title I, §107(b), July 23, 1974, 88 Stat. 371, provided that the authorizations provided by subsec. (i) of this section would be extended for the fiscal year ending June 30, 1977, unless before June 30, 1976, Congress passed legislation repealing the extension.

§242n. Repealed. Pub. L. 101–239, title VI, §6103(d)(1)(B), Dec. 19, 1989, 103 Stat. 2205

Section, act July 1, 1944, ch. 373, title III, §309, as added Nov. 9, 1978, Pub. L. 95–623, §6(c), 92 Stat. 3447; amended July 10, 1979, Pub. L. 96–32, §5(d), 93 Stat. 83; Aug. 13, 1981, Pub. L. 97–35, title IX, §§917(c), 923, 95 Stat. 565, 567; Oct. 30, 1984, Pub. L. 98–551, §8, 98 Stat. 2820; Oct. 7, 1985, Pub. L. 99–117, §8(a), 99 Stat. 493; Dec. 1, 1987, Pub. L. 100–177, title I, §109, 101 Stat. 990, related to grants for a council on health care technology.

STATUTORY NOTES AND RELATED SUBSIDIARIES

TERMINATION OF COUNCIL ON HEALTH CARE TECHNOLOGY

Pub. L. 101–239, title VI, §6103(d)(1)(B), Dec. 19, 1989, 103 Stat. 2205, provided in part that the council on health care technology established under this section is terminated.

TRANSITIONAL AND SAVINGS PROVISIONS FOR PUB. L. 101–239

For provision transferring personnel of Department of Health and Human Services employed on Dec. 19, 1989, in connection with functions vested in Administrator for Health Care Policy and Research pursuant to amendments made by section 6103 of Pub. L. 101–239, and assets, liabilities, etc., of Department arising from or employed, held, used, or available on that date, or to be made available after that date, in connection with those functions, to Administrator for appropriate allocation, and for provisions for continued effectiveness of

actions, orders, rules, official documents, etc., of Department that have been issued, made, granted, or allowed to become effective in performance of those functions, and that were effective on Dec. 19, 1989, see section 6103(f) of Pub. L. 101–239, set out as a note under section 299 of this title.

§242*o*. Health conferences; publication of health educational information

(a) A conference of the health authorities in and among the several States shall be called annually by the Secretary. Whenever in his opinion the interests of the public health would be promoted by a conference, the Secretary may invite as many of such health authorities and officials of other State or local public or private agencies, institutions, or organizations to confer as he deems necessary or proper. Upon the application of health authorities of five or more States it shall be the duty of the Secretary to call a conference of all State health authorities joining in the request. Each State represented at any conference shall be entitled to a single vote. Whenever at any such conference matters relating to mental health are to be discussed, the mental health authorities of the respective States shall be invited to attend.

(b) From time to time the Secretary shall issue information related to public health, in the form of publications or otherwise, for the use of the public, and shall publish weekly reports of health conditions in the United States and other countries and other pertinent health information for the use of persons and institutions concerned with health services.

(July 1, 1944, ch. 373, title III, §310, formerly §§309, 310, as added Pub. L. 93–353, title I, §107(a), July 23, 1974, 88 Stat. 371; renumbered §310, Pub. L. 95–623, §6(a), (b), Nov. 9, 1978, 92 Stat. 3447.)

EDITORIAL NOTES

CODIFICATION

Subsec. (a) of this section consists of former section 309 of act July 1, 1944, prior to the renumbering of that section as section 310(a) by Pub. L. 95–623. Subsec. (b) of this section consists of former section 310 of act July 1, 1944, prior to the renumbering of that section as section 310(b) by Pub. L. 95–623.

PRIOR PROVISIONS

A prior section 310 of act July 1, 1944, was renumbered section 329, and was classified to section 254b of this title prior to the general amendment of subpart I (§254b et seq.) of part D of this subchapter by Pub. L. 104–299.

Provisions similar to those comprising subsec. (a) of this section were contained in section 312 of act July 1, 1944, ch. 373, title III, 58 Stat. 693, as amended (formerly classified to section 244 of this title), prior to repeal by Pub. L. 93–353, §102(a).

Provisions similar to those comprising subsec. (b) of this section were contained in section 315 of act July 1, 1944, ch. 373, title III, 58 Stat. 695; Oct. 30, 1970, Pub. L. 91–515, title II, §282, 84 Stat. 1308 (formerly classified to section 247 of this title), prior to repeal by Pub. L. 93–353, §102(a).

§242p. National disease prevention data profile

(a) The Secretary, acting through the National Center for Health Statistics, shall submit to Congress on March 15, 1990, and on March 15 of every third year thereafter, a national disease prevention data profile in order to provide a data base for the effective implementation of this Act and to increase public awareness of the prevalence, incidence, and any trends in the preventable causes of death and disability in the United States. Such profile shall include at a minimum—

(1) mortality rates for preventable diseases;

(2) morbidity rates associated with preventable diseases;

(3) the physical determinants of health of the population of the United States and the relationship between these determinants of health and the incidence and prevalence of preventable causes of death and disability; and

(4) the behavioral determinants of health of the population of the United States including, but not limited to, smoking, nutritional and dietary habits, exercise, and alcohol consumption, and the relationship between these determinants of health and the incidence and prevalence of preventable causes of death and disability.

(b) In preparing the profile required by subsection (a), the Secretary, acting through the National Center for Health Statistics, shall comply with all relevant provisions of sections 242k and 242m of this title.

(Pub. L. 95–626, title IV, §404, Nov. 10, 1978, 92 Stat. 3591; Pub. L. 100–177, title I, §106(b), Dec. 1, 1987, 101 Stat. 989.)

EDITORIAL NOTES

REFERENCES IN TEXT

This Act, referred to in subsec. (a), is Pub. L. 95–626, Nov. 10, 1978, 92 Stat. 3551, known as the Health Services and Centers Amendments of 1978. For complete classification of this Act to the Code, see Short Title of 1978 Amendments note set out under section 201 of this title and Tables.

CODIFICATION

Section was enacted as part of the Health Services and Centers Amendments of 1978, and not as part of the Public Health Service Act which comprises this chapter.

AMENDMENTS

1987—Subsec. (a). Pub. L. 100–177 substituted "on March 15, 1990, and on March 15 of every third year thereafter" for "on December 1, 1980, and on December 1 of every third year thereafter" in first sentence.

STATUTORY NOTES AND RELATED SUBSIDIARIES

EFFECTIVE DATE OF 1987 AMENDMENT

Amendment by Pub. L. 100–177 applicable to reports and profiles required to be submitted after Nov. 1, 1987, see section 106(c) of Pub. L. 100–177, set out as a note under section 242m of this title.

§242q. Task Force on Aging Research; establishment and duties

(a) Establishment

The Secretary of Health and Human Services shall establish a Task Force on Aging Research.

(b) Duties

With respect to aging research (as defined in section 242q–4 [1] of this title), the Task Force each fiscal year shall—

(1) make recommendations to the Secretary specifying the particular projects of research, or the particular categories of research, that should be conducted or supported by the Secretary;

(2) of the projects specified under paragraph (1), make recommendations to the Secretary of the projects that should be given priority in the provision of funds; and

(3) make recommendations to the Secretary of the amount of funds that should be appropriated for such research.

(c) Provision of information to public

The Task Force may make available to health professionals, and to other members of the public, information regarding the research described in subsection (b).

(Pub. L. 101–557, title III, §301, Nov. 15, 1990, 104 Stat. 2768.)

EDITORIAL NOTES

REFERENCES IN TEXT

Section 242q–4 of this title, referred to in subsec. (b), was in the original "section 305", meaning section 305 of Pub. L. 101–557. Section 305 was renumbered section 304 by Pub. L. 109–482, title I, §104(b)(3)(B), Jan. 15, 2007, 120 Stat. 3694.

CODIFICATION

Section was enacted as part of the Home Health Care and Alzheimer's Disease Amendments of 1990, and not as part of the Public Health Service Act which comprises this chapter.

[1] *See References in Text note below.*

§242q–1. Membership

(a) Composition

The Task Force shall be composed of—

(1) the Assistant Secretary for Health;

(2) the Surgeon General of the Public Health Service;

(3) the Assistant Secretary for Planning and Evaluation;

(4) the Director of the National Institute on Aging, and the Directors of such other agencies of the National Institutes of Health as the Secretary determines to be appropriate;

(5) the Commissioner of the Administration on Aging;

(6) the Commissioner of Food and Drugs;

(7) the Under Secretary for Health of the Department of Veterans Affairs;

(8) the Administrator of the the [1] Substance Abuse and Mental Health Services Administration;

(9) the Administrator of the Centers for Medicare & Medicaid Services;

(10) the Commissioner of Social Security;

(11) the Director of the Agency for Healthcare Research and Quality;

(12) two Members of the House of Representatives appointed by the Speaker of the House in consultation with the Minority Leader, and two members of the Senate appointed by the Majority Leader in consultation with the Minority Leader, not more than one of whom from each body shall be members of the same political party; and

(13) three members of the general public, to be appointed by the Secretary, that shall include one representative each from—

(A) a nonprofit group representing older Americans;

(B) a private voluntary health organization concerned with the health problems affecting older Americans; and

(C) a nonprofit organization concerned with research related to the health and independence of older Americans.

(b) Chair

The Secretary, acting through either the Assistant Secretary for Health or the Director of the National Institute on Aging, shall serve as the Chair of the Task Force.

(c) Quorum

A majority of the members of the Task Force shall constitute a quorum, and a lesser number may hold hearings.

(d) Meetings

The Task Force shall meet periodically at the call of the Chair, but in no event less than twice each year.

(e) Compensation and expenses

(1) Compensation

Members of the Task Force who are not regular full-time employees of the United States Government shall, while attending meetings and conferences of the Task Force or otherwise engaged in the business of the Task Force (including traveltime), be entitled to receive compensation at a rate fixed by the Secretary, but not exceeding the rate specified at the time of such service under GS–18 of the General Schedules established under section 5332 of title 5.

(2) Expenses

While away from their homes or regular places of business on the business of the Task Force, members of such Task Force may be allowed travel expenses, including per diem in lieu of subsistence, as is authorized under section 5703 of title 5 for persons employed intermittently in the Government service.

(Pub. L. 101–557, title III, §302, Nov. 15, 1990, 104 Stat. 2769; Pub. L. 102–321, title I, §161, July 10, 1992, 106 Stat. 375; Pub. L. 102–405, title III, §302(e)(1), Oct. 9, 1992, 106 Stat. 1985; Pub. L. 106–129, §2(b)(2), Dec. 6, 1999, 113 Stat. 1670; Pub. L. 108–173, title IX, §900(e)(6)(D), Dec. 8, 2003, 117 Stat. 2373.)

EDITORIAL NOTES

CODIFICATION

Section was enacted as part of the Home Health Care and Alzheimer's Disease Amendments of 1990, and not as part of the Public Health Service Act which comprises this chapter.

AMENDMENTS

2003—Subsec. (a)(9). Pub. L. 108–173 substituted "Centers for Medicare & Medicaid Services" for "Health Care Financing Administration".

1999—Subsec. (a)(11). Pub. L. 106–129 substituted "Director of the Agency for Healthcare Research and Quality" for "Administrator for Health Care Policy and Research".

1992—Subsec. (a)(7). Pub. L. 102–405 substituted "Under Secretary for Health of the Department of Veterans Affairs" for "Chief Medical Director of the Department of Veterans Affairs".

Subsec. (a)(8). Pub. L. 102–321 substituted "Substance Abuse and Mental Health Services Administration" for "Alcohol, Drug Abuse and Mental Health Administration".

STATUTORY NOTES AND RELATED SUBSIDIARIES

EFFECTIVE DATE OF 1992 AMENDMENT

Amendment by Pub. L. 102–321 effective Oct. 1, 1992, with provision for programs providing financial assistance, see section 801(c), (d) of Pub. L. 102–321, set out as a note under section 236 of this title.

REFERENCES IN OTHER LAWS TO GS–16, 17, OR 18 PAY RATES

References in laws to the rates of pay for GS–16, 17, or 18, or to maximum rates of pay under the General Schedule, to be considered references to rates payable under specified sections of Title 5, Government Organization and Employees, see section 529 [title I, §101(c)(1)] of Pub. L. 101–509, set out in a note under section 5376 of Title 5.

[1] *So in original.*

§242q–2. Administrative staff and support

The Secretary, acting through either the Assistant Secretary for Health or the Director of the National Institute on Aging, shall appoint an Executive Secretary for the Task Force and shall provide the Task Force with such administrative staff and support as may be necessary to enable the Task Force to carry out subsections (b) and (c) of section 242q of this title.

(Pub. L. 101–557, title III, §303, Nov. 15, 1990, 104 Stat. 2770.)

EDITORIAL NOTES

CODIFICATION

Section was enacted as part of the Home Health Care and Alzheimer's Disease Amendments of 1990, and not as part of the Public Health Service Act which comprises this chapter.

§242q–3. Repealed. Pub. L. 109–482, title I, §104(b)(3)(B), Jan. 15, 2007, 120 Stat. 3694

Section, Pub. L. 101–557, title III, §304, Nov. 15, 1990, 104 Stat. 2770, related to reports that provided recommendations required in section 242q(b) of this title.

STATUTORY NOTES AND RELATED SUBSIDIARIES

EFFECTIVE DATE OF REPEAL

Repeal applicable only with respect to amounts appropriated for fiscal year 2007 or subsequent fiscal years, see section 109 of Pub. L. 109–482, set out as an Effective Date of 2007 Amendment note under section 281 of this title.

§242q–4. Definitions

For purposes of sections 242q to 242q–5 of this title:

(1) Aging research

(A) The term "aging research" means research on the aging process and on the diagnosis and treatment of diseases, disorders, and complications related to aging, including menopause. Such research includes research on such treatments, and on medical devices and other medical interventions regarding such diseases, disorders, and complications, that can assist individuals in avoiding institutionalization and prolonged hospitalization and in otherwise increasing the independence of the individuals.

(B) For purposes of subparagraph (A), the term "independence", with respect to diseases, disorders, and complications of aging, means the functional ability of individuals to perform activities of daily living or instrumental activities of daily living without assistance or supervision.

(2) Secretary

The term "Secretary" means the Secretary of Health and Human Services.

(3) Task Force

The term "Task Force" means the Task Force on Aging Research established under section 242q(a) of this title.

(Pub. L. 101–557, title III, §304, formerly §305, Nov. 15, 1990, 104 Stat. 2770; renumbered §304, Pub. L. 109–482, title I, §104(b)(3)(B), Jan. 15, 2007, 120 Stat. 3694.)

EDITORIAL NOTES

CODIFICATION

Section was enacted as part of the Home Health Care and Alzheimer's Disease Amendments of 1990, and not as part of the Public Health Service Act which comprises this chapter.

PRIOR PROVISIONS

A prior section 304 of Pub. L. 101–557 was classified to section 242q–3 of this title, prior to repeal by Pub. L. 109–482.

§242q–5. Authorization of appropriations

For the purpose of carrying out sections 242q to 242q–5 of this title, there are authorized to be appropriated such sums as may be necessary for each of the fiscal years 1991 through 1993.

(Pub. L. 101–557, title III, §305, formerly §306, Nov. 15, 1990, 104 Stat. 2770; renumbered §305, Pub. L. 109–482, title I, §104(b)(3)(B), Jan. 15, 2007, 120 Stat. 3694.)

EDITORIAL NOTES

CODIFICATION

Section was enacted as part of the Home Health Care and Alzheimer's Disease Amendments of 1990, and not as part of the Public Health Service Act which comprises this chapter.

PRIOR PROVISIONS

A prior section 305 of Pub. L. 101–557 was renumbered section 304 and is classified to section 242q–4 of this title.

§242r. Improvement and publication of data on food-related allergic responses

(a) In general

The Secretary of Health and Human Services, acting through the Director of the Centers for Disease Control and Prevention and in consultation with the Commissioner of Food and Drugs, shall improve (including by educating physicians and other health care providers) the collection of, and publish as it becomes available, national data on—

(1) the prevalence of food allergies;

(2) the incidence of clinically significant or serious adverse events related to food allergies; and

(3) the use of different modes of treatment for and prevention of allergic responses to foods.

(b) Authorization of appropriations

For the purpose of carrying out this section, there are authorized to be appropriated such sums as may be necessary.

(Pub. L. 108–282, title II, §207, Aug. 2, 2004, 118 Stat. 910.)

EDITORIAL NOTES

CODIFICATION

Section was enacted as part of the Food Allergen Labeling and Consumer Protection Act of 2004, and not as part of the Public Health Service Act which comprises this chapter.

§242s. Centers for Disease Control and Prevention Office of Women's Health

(a) Establishment

There is established within the Office of the Director of the Centers for Disease Control and Prevention, an office to be known as the Office of Women's Health (referred to in this section as the "Office"). The Office shall be headed by a director who shall be appointed by the Director of such Centers.

(b) Purpose

The Director of the Office shall—

(1) report to the Director of the Centers for Disease Control and Prevention on the current level of the Centers' activity regarding women's health conditions across, where appropriate, age,

biological, sociocultural (including among American Indians, Native Hawaiians, and Alaska Natives), and geographical contexts, in all aspects of the Centers' work, including prevention programs, public and professional education, services, and treatment;

(2) establish short-range and long-range goals and objectives within the Centers for women's health and, as relevant and appropriate, coordinate with other appropriate offices on activities within the Centers that relate to prevention, research, education and training, service delivery, and policy development, for issues of particular concern to women;

(3) identify projects in women's health that should be conducted or supported by the Centers;

(4) consult with health professionals, nongovernmental organizations, consumer organizations, women's health professionals, and other individuals and groups, as appropriate, on the policy of the Centers with regard to women; and

(5) serve as a member of the Department of Health and Human Services Coordinating Committee on Women's Health (established under section 237a(b)(4) of this title).

(c) Definition

As used in this section, the term "women's health conditions", with respect to women of all age, ethnic, and racial groups, means diseases, disorders, and conditions—

(1) unique to, significantly more serious for, or significantly more prevalent in women; and

(2) for which the factors of medical risk or type of medical intervention are different for women, or for which there is reasonable evidence that indicates that such factors or types may be different for women.

(d) Authorization of appropriations

For the purpose of carrying out this section, there are authorized to be appropriated such sums as may be necessary for each of the fiscal years 2010 through 2014.

(July 1, 1944, ch. 373, title III, §310A, as added Pub. L. 111–148, title III, §3509(b), Mar. 23, 2010, 124 Stat. 533; amended Pub. L. 117–103, div. P, title I, §141(b), Mar. 15, 2022, 136 Stat. 797.)

EDITORIAL NOTES

PRIOR PROVISIONS

A prior section 310A of act July 1, 1944, was renumbered section 226 and transferred to section 235 of this title.

AMENDMENTS

2022—Subsec. (b)(1). Pub. L. 117–103 substituted "sociocultural (including among American Indians, Native Hawaiians, and Alaska Natives), and geographical contexts," for "and sociocultural contexts,".

§242t. CDC surveillance and data collection for child, youth, and adult trauma

(a) Data collection

The Director of the Centers for Disease Control and Prevention (referred to in this section as the "Director") may, in cooperation with the States, collect and report data on adverse childhood experiences through the Behavioral Risk Factor Surveillance System, the Youth Risk Behavior Surveillance System, and other relevant public health surveys or questionnaires.

(b) Timing

The collection of data under subsection (a) may occur biennially.

(c) Data from rural areas

The Director shall encourage each State that participates in collecting and reporting data under subsection (a) to collect and report data from rural areas within such State, in order to generate a statistically reliable representation of such areas.

(d) Data from tribal areas

The Director may, in cooperation with Indian Tribes (as defined in section 5304 of title 25) and pursuant to a written request from an Indian Tribe, provide technical assistance to such Indian Tribe to collect and report data on adverse childhood experiences through the Behavioral Risk Factor Surveillance System, the Youth Risk Behavior Surveillance System, or another relevant public health survey or questionnaire.

(e) Authorization of appropriations

To carry out this section, there is authorized to be appropriated $9,000,000 for each of fiscal years 2026 through 2030.

(Pub. L. 115–271, title VII, §7131, Oct. 24, 2018, 132 Stat. 4046; Pub. L. 119–44, title I, §109, Dec. 1, 2025, 139 Stat. 677.)

EDITORIAL NOTES

CODIFICATION

Section was enacted as part of the Substance Use–Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act, also known as the SUPPORT for Patients and Communities Act, and not as part of the Public Health Service Act which comprises this chapter.

AMENDMENTS

2025—Subsec. (e). Pub. L. 119–44 substituted "$9,000,000 for each of fiscal years 2026 through 2030" for "$2,000,000 for each of fiscal years 2019 through 2023".

§242u. Improving State, local, and Tribal information sharing

(a) In general

The Secretary may, in consultation with State, local, and Tribal public health officials, carry out activities to improve the availability of appropriate and applicable public health data related to communicable diseases, and information sharing between, the Director of the Centers for Disease Control and Prevention, the Assistant Secretary for Preparedness and Response, and such State, local, and Tribal public health officials, which may include such data from—

(1) health care providers and facilities;
(2) public health and clinical laboratories;
(3) health information exchanges and health information networks; and
(4) State, local, and Tribal health departments.

(b) Content, form, and manner

The Secretary shall, consistent with the requirements of this section, work with such officials and relevant stakeholders to provide information on the content, form, and manner in which such data, deidentified as applicable, may most effectively support the ability of State, local, and Tribal health departments to respond to such communicable diseases, including related to the collection and reporting of demographic and other relevant data elements. Such form and manner requirements shall align with the standards and implementation specifications adopted by the Secretary under section 300jj–14 of this title, as applicable.

(c) Decreased burden

In facilitating the coordination of efforts under subsection (a), the Secretary shall make reasonable efforts to limit reported public health data to the minimum necessary information needed to accomplish the intended public health purpose.

(d) Exemption of certain public health data from disclosure

The Secretary, acting through the Director of the Centers for Disease Control and Prevention, may exempt from disclosure under section 552(b)(3) of title 5 public health data that are gathered under this section if—

(1) an individual is identified through such data; or

(2) there is at least a very small risk, as determined by current scientific practices or statistical methods, that some combination of the information, the request, and other available data sources or the application of technology could be used to deduce the identity of an individual.

(July 1, 1944, ch. 373, title III, §310B, as added Pub. L. 117–328, div. FF, title II, §2213(d), Dec. 29, 2022, 136 Stat. 5737.)

STATUTORY NOTES AND RELATED SUBSIDIARIES

RULES OF CONSTRUCTION

Pub. L. 117–328, div. FF, title II, §2213(f), Dec. 29, 2022, 136 Stat. 5738, provided that: "Nothing in this section [enacting this section, amending section 300hh–33 of this title, and enacting provisions set out as notes under sections 300hh and 300hh–33 of this title] shall be construed to—

"(1) supplant, in whole or in part, State, local, or Tribal activities or responsibilities related to public health surveillance, as applicable;

"(2) alter the authority of the Secretary with respect to the types of data the Secretary may receive through systems supported or established in this section or other laws; or

"(3) modify applicable Federal or State information privacy or security law."

§242v. Foreign talent recruitment programs

(a) Intramural research

(1) In general

Not later than 60 days after December 29, 2022, the Secretary of Health and Human Services (referred to in sections 242v to 242v–3 of this title as the "Secretary") shall prohibit personnel of the National Institutes of Health engaged in intramural research from participation in foreign talent recruitment programs.

(2) Exemption

Paragraph (1) shall not apply to participation in international conferences or other international exchanges, partnerships, or programs, for which such participation has been approved by the National Institutes of Health. In such circumstances, the National Institutes of Health shall ensure appropriate training is provided to the participant on how to respond to overtures from individuals associated with foreign talent recruitment programs.

(b) Extramural research

The Secretary shall require disclosure of participation in foreign talent recruitment programs, including the provision of copies of all grants, contracts, or other agreements related to such programs, and other supporting documentation related to such programs, as a condition of receipt of Federal extramural biomedical research funding awarded through the Department of Health and Human Services.

(c) Consistency

The Secretary shall ensure that the policies developed, updated, or issued pursuant to subsections (a) and (b) are, to the greatest extent practicable, consistent with the requirements of subtitle D of title VI of division B of Public Law 117–167 (42 U.S.C. 19231 et seq.) related to foreign talent recruitment programs.

(Pub. L. 117–328, div. FF, title II, §2321, Dec. 29, 2022, 136 Stat. 5765.)

EDITORIAL NOTES

REFERENCES IN TEXT

Sections 242v to 242v–3 of this title, referred to in subsec. (a)(1), was in the original "this chapter",

meaning chapter 3 (§§2321–2326) of title II of div. FF of Pub. L. 117–328, 136 Stat. 5765, which enacted this section and sections 242v–1 to 242v–3 of this title and amended section 282 of this title.

CODIFICATION

Section was enacted as part of the Prepare for and Respond to Existing Viruses, Emerging New Threats, and Pandemics Act, also known as PREVENT Pandemics Act, and also as part of the Health Extenders, Improving Access to Medicare, Medicaid, and CHIP, and Strengthening Public Health Act of 2022, and not as part of the Public Health Service Act which comprises this chapter.

§242v–1. Securing identifiable, sensitive information and addressing other national security risks related to research

(a) In general

The Secretary of Health and Human Services, in consultation with the Director of National Intelligence, the Secretary of State, the Secretary of Defense, and other national security experts, as appropriate, shall ensure that biomedical research conducted or supported by the National Institutes of Health and other relevant agencies and offices within the Department of Health and Human Services is conducted or supported in a manner that appropriately considers national security risks, including national security implications related to research involving the sequencing of human genomic information, and collection, analysis, or storage of identifiable, sensitive information, as defined in section 241(d)(4) of this title, and the potential misuse of such data. Not later than 2 years after December 29, 2022, the Secretary shall ensure that the National Institutes of Health and other relevant agencies and offices within the Department of Health and Human Services, in consultation with the heads of agencies and national security experts, including the Office of the National Security within the Department of Health and Human Services—

(1) develop a comprehensive framework and policies for assessing and managing such national security risks that includes, or review and update, as appropriate, the current (as of the date of review) such framework and policies to include—

(A) criteria for how and when to conduct risk assessments for projects that may have national security implications;

(B) security controls and training for researchers or entities, including peer reviewers, that manage or have access to such data that may present national security risks; and

(C) methods to incorporate risk mitigation in the process for funding such projects that may have national security implications and monitor associated research activities following issuance of an award, including changes in the terms and conditions related to the use of such funds, as appropriate;

(2) not later than 1 year after the framework and policies are developed or reviewed and updated, as applicable, under paragraph (1), develop and implement controls to ensure that—

(A) researchers or entities involved in projects reviewed under the framework and relevant policies, including such projects that manage or have access to sensitive, identifiable information, have complied with the requirements of paragraph (1) and ongoing requirements with such paragraph;

(B) consideration of funding for projects that may have national security implications takes into account the extent to which the country in which the proposed research will be conducted or supported poses a risk to the integrity of the United States biomedical research enterprise; and

(C) data access committees reviewing data access requests for projects that may have national security risks, as appropriate, include members with expertise in current and emerging national security threats, in order to make appropriate decisions, including related to access to such identifiable, sensitive information; and

(3) not later than 2 years after the framework and relevant policies are developed or reviewed

and updated, as applicable, under paragraph (1), update data access and sharing policies related to human genomic data, as applicable, based on current and emerging national security threats.

(b) Congressional briefing

Not later than 1 year after December 29, 2022, the Secretary shall provide a briefing to the Committee on Health, Education, Labor, and Pensions and the Select Committee on Intelligence of the Senate and the Committee on Energy and Commerce and the Permanent Select Committee on Intelligence of the House of Representatives on the activities required under subsection (a).

(Pub. L. 117–328, div. FF, title II, §2322, Dec. 29, 2022, 136 Stat. 5765.)

EDITORIAL NOTES

CODIFICATION

Section was enacted as part of the Prepare for and Respond to Existing Viruses, Emerging New Threats, and Pandemics Act, also known as the PREVENT Pandemics Act, and also as part of the Health Extenders, Improving Access to Medicare, Medicaid, and CHIP, and Strengthening Public Health Act of 2022, and not as part of the Public Health Service Act which comprises this chapter.

§242v–2. Protecting America's biomedical research enterprise

(a) In general

The Secretary, in consultation with the Assistant to the President for National Security Affairs, the Director of National Intelligence, the Director of the Federal Bureau of Investigation, and the heads of other relevant departments and agencies, and in consultation with research institutions and research advocacy organizations or other relevant experts, as appropriate, shall—

(1) identify ways to improve the protection of intellectual property and other proprietary information, as well as identifiable, sensitive information of participants in biomedical research and development, from national security risks and other applicable threats, including the identification of gaps in policies and procedures in such areas related to biomedical research and development supported by the Department of Health and Human Services, and make recommendations to institutions of higher education or other entities that have traditionally received Federal funding for biomedical research to protect such information;

(2) identify or develop strategies to prevent, mitigate, and address national security risks and threats in biomedical research and development supported by the Federal Government, including such threats associated with foreign talent programs, by countries seeking to exploit United States technology and other proprietary information as it relates to such biomedical research and development, and make recommendations for additional policies and procedures to protect such information;

(3) identify national security risks and potential misuse of proprietary information, and identifiable, sensitive information of biomedical research participants and other applicable risks, including with respect to peer review, and make recommendations for additional policies and procedures to protect such information;

(4) develop a framework to identify areas of biomedical research and development supported by the Federal Government that are emerging areas of interest for state actors and would compromise national security if they were to be subjected to undue foreign influence; and

(5) regularly review recommendations or policies developed under this section and make additional recommendations or updates, as appropriate.

(b) Report to President and to Congress

Not later than 1 year after December 29, 2022, the Secretary shall prepare and submit, in a manner that does not compromise national security, to the President and the Committee on Health, Education, Labor, and Pensions and the Select Committee on Intelligence of the Senate, the Committee on Energy and Commerce and the Permanent Select Committee on Intelligence of the

House of Representatives, and other congressional committees as appropriate, a report on the findings and recommendations pursuant to subsection (a).

(Pub. L. 117–328, div. FF, title II, §2324, Dec. 29, 2022, 136 Stat. 5767.)

EDITORIAL NOTES

CODIFICATION

Section was enacted as part of the Prepare for and Respond to Existing Viruses, Emerging New Threats, and Pandemics Act, also known as the PREVENT Pandemics Act, and also as part of the Health Extenders, Improving Access to Medicare, Medicaid, and CHIP, and Strengthening Public Health Act of 2022, and not as part of the Public Health Service Act which comprises this chapter.

STATUTORY NOTES AND RELATED SUBSIDIARIES

DEFINITION OF "SECRETARY"

"Secretary" means the Secretary of Health and Human Services, see section 242v(a)(1) of this title.

§242v–3. Report on progress to address undue foreign influence

Not later than 1 year after December 29, 2022, and annually thereafter, the Secretary shall prepare and submit to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce in the House of Representatives, in a manner that does not compromise national security, a report on actions taken by the Secretary—

(1) to address cases of noncompliance with disclosure requirements or research misconduct related to foreign influence, including—

(A) the number of potential noncompliance cases investigated by the National Institutes of Health or reported to the National Institutes of Health by a research institution, including relating to undisclosed research support, undisclosed conflicts of interest or other conflicts of commitment, and peer review violations;

(B) the number of cases referred to the Office of Inspector General of the Department of Health and Human Services, the Office of National Security of the Department of Health and Human Services, the Federal Bureau of Investigation, or other law enforcement agencies;

(C) a description of enforcement actions taken for noncompliance related to undue foreign influence; and

(D) any other relevant information; and

(2) to prevent, address, and mitigate instances of noncompliance with disclosure requirements or research misconduct related to foreign influence.

(Pub. L. 117–328, div. FF, title II, §2326, Dec. 29, 2022, 136 Stat. 5769.)

EDITORIAL NOTES

CODIFICATION

Section was enacted as part of the Prepare for and Respond to Existing Viruses, Emerging New Threats, and Pandemics Act, also known as the PREVENT Pandemics Act, and also as part of the Health Extenders, Improving Access to Medicare, Medicaid, and CHIP, and Strengthening Public Health Act of 2022, and not as part of the Public Health Service Act which comprises this chapter.

STATUTORY NOTES AND RELATED SUBSIDIARIES

DEFINITION OF "SECRETARY"

"Secretary" means the Secretary of Health and Human Services, see section 242v(a)(1) of this title.

PART B—FEDERAL-STATE COOPERATION

§243. General grant of authority for cooperation

(a) Enforcement of quarantine regulations; prevention of communicable diseases

The Secretary is authorized to accept from State and local authorities any assistance in the enforcement of quarantine regulations made pursuant to this chapter which such authorities may be able and willing to provide. The Secretary shall also assist States and their political subdivisions in the prevention and suppression of communicable diseases and with respect to other public health matters, shall cooperate with and aid State and local authorities in the enforcement of their quarantine and other health regulations, and shall advise the several States on matters relating to the preservation and improvement of the public health.

(b) Comprehensive and continuing planning; training of personnel for State and local health work; fees

The Secretary shall encourage cooperative activities between the States with respect to comprehensive and continuing planning as to their current and future health needs, the establishment and maintenance of adequate public health services, and otherwise carrying out public health activities. The Secretary is also authorized to train personnel for State and local health work. The Secretary may charge only private entities reasonable fees for the training of their personnel under the preceding sentence.

(c) Development of plan to control epidemics and meet emergencies or problems resulting from disasters; cooperative planning; temporary assistance; reimbursement of United States

(1) The Secretary is authorized to develop (and may take such action as may be necessary to implement) a plan under which personnel, equipment, medical supplies, and other resources of the Service and other agencies under the jurisdiction of the Secretary may be effectively used to control epidemics of any disease or condition and to meet other health emergencies or problems. The Secretary may enter into agreements providing for the cooperative planning between the Service and public and private community health programs and agencies to cope with health problems (including epidemics and health emergencies).

(2) The Secretary may, at the request of the appropriate State or local authority, extend temporary (not in excess of six months) assistance to States or localities in meeting health emergencies of such a nature as to warrant Federal assistance. The Secretary may require such reimbursement of the United States for assistance provided under this paragraph as he may determine to be reasonable under the circumstances. Any reimbursement so paid shall be credited to the applicable appropriation for the Service for the year in which such reimbursement is received.

(July 1, 1944, ch. 373, title III, §311, 58 Stat. 693; Pub. L. 89–749, §5, Nov. 3, 1966, 80 Stat. 1190; Pub. L. 90–174, §4, Dec. 5, 1967, 81 Stat. 536; Pub. L. 91–515, title II, §282, Oct. 30, 1970, 84 Stat. 1308; Pub. L. 94–317, title II, §202(b), (c), June 23, 1976, 90 Stat. 703; Pub. L. 97–35, title IX, §902(c), Aug. 13, 1981, 95 Stat. 559; Pub. L. 97–414, §8(d), Jan. 4, 1983, 96 Stat. 2060; Pub. L. 99–117, §11(a), Oct. 7, 1985, 99 Stat. 494.)

EDITORIAL NOTES

AMENDMENTS

1985—Subsec. (c)(1). Pub. L. 99–117 struck out "referred to in section 247b(f) of this title" after "epidemics of any disease or condition", "involving or resulting from disasters or any such disease" after "health emergencies or problems" in first sentence, and struck out "resulting from disasters or any disease or condition referred to in section 247b(f) of this title" after "(including epidemics and health emergencies)" in second sentence.

1983—Subsec. (c)(2). Pub. L. 97–414 substituted "six months" for "forty-five days" after "not in excess of".

1981—Subsec. (a). Pub. L. 97–35, §902(c)(1), inserted applicability to other public health matters, and struck out reference to section 246 of this title.

Subsec. (b). Pub. L. 97–35, §902(c)(2), substituted "public health activities" for "the purposes of section 246 of this title".

1976—Subsec. (b). Pub. L. 94–317, §202(c), inserted provision authorizing Secretary to charge only private entities reasonable fees for training of their personnel.

Subsec. (c). Pub. L. 94–317, §202(b), made changes in phraseology and restructured provisions into pars. (1) and (2) and, in par. (1), as so restructured, inserted provisions authorizing Secretary to develop a plan utilizing Public Health Service personnel, equipment, medical supplies and other resources to control epidemics of any disease referred to in section 247b of this title.

1970—Subsecs. (a), (b). Pub. L. 91–515 substituted "Secretary" for "Surgeon General" wherever appearing.

1967—Subsec. (c). Pub. L. 90–174 added subsec. (c).

1966—Pub. L. 89–749 designated existing provisions as subsec. (a), added subsec. (b), and amended subsec. (b) to permit Surgeon General to train personnel for State and local health work.

STATUTORY NOTES AND RELATED SUBSIDIARIES

EFFECTIVE DATE OF 1981 AMENDMENT

Amendment by Pub. L. 97–35 effective Oct. 1, 1981, see section 902(h) of Pub. L. 97–35, set out as a note under section 238l of this title.

EFFECTIVE DATE OF 1966 AMENDMENT

Pub. L. 89–749, §5(a), Nov. 3, 1966, 80 Stat. 1190, provided that subsec. (b) of this section is effective July 1, 1966.

Pub. L. 89–749, §5(b), Nov. 3, 1966, 80 Stat. 1190, provided that the amendment of subsec. (b) of this section, permitting the Surgeon General to train personnel for State and local health work, is effective July 1, 1967.

FOOD ALLERGENS IN THE FOOD CODE

Pub. L. 108–282, title II, §209, Aug. 2, 2004, 118 Stat. 910, provided that: "The Secretary of Health and Human Services shall, in the Conference for Food Protection, as part of its efforts to encourage cooperative activities between the States under section 311 of the Public Health Service Act (42 U.S.C. 243), pursue revision of the Food Code to provide guidelines for preparing allergen-free foods in food establishments, including in restaurants, grocery store delicatessens and bakeries, and elementary and secondary school cafeterias. The Secretary shall consider guidelines and recommendations developed by public and private entities for public and private food establishments for preparing allergen-free foods in pursuing this revision."

TRAINING OF PRIVATE PERSONS SUBJECT TO REIMBURSEMENT OR ADVANCES TO APPROPRIATIONS

Pub. L. 103–333, title II, Sept. 30, 1994, 108 Stat. 2550, provided in part: "That for fiscal year 1995 and subsequent fiscal years training of private persons shall be made subject to reimbursement or advances to this appropriation for not in excess of the full cost of such training".

§244. Public access defibrillation programs

(a) In general

The Secretary shall award grants to States, political subdivisions of States, Indian tribes, and tribal organizations to develop and implement public access defibrillation programs—

(1) by training and equipping local emergency medical services personnel, including firefighters, police officers, paramedics, emergency medical technicians, and other first responders, to administer immediate care, including cardiopulmonary resuscitation and automated external defibrillation, to cardiac arrest victims;

(2) by purchasing automated external defibrillators, placing the defibrillators in public places where cardiac arrests are likely to occur, and training personnel in such places to administer cardiopulmonary resuscitation and automated external defibrillation to cardiac arrest victims;

(3) by setting procedures for proper maintenance and testing of such devices, according to the guidelines of the manufacturers of the devices;

(4) by providing training to members of the public in cardiopulmonary resuscitation and automated external defibrillation;

(5) by integrating the emergency medical services system with the public access defibrillation programs so that emergency medical services personnel, including dispatchers, are informed about the location of automated external defibrillators in their community; and

(6) by encouraging private companies, including small businesses, to purchase automated external defibrillators and provide training for their employees to administer cardiopulmonary resuscitation and external automated defibrillation to cardiac arrest victims in their community.

(b) Preference

In awarding grants under subsection (a), the Secretary shall give a preference to a State, political subdivision of a State, Indian tribe, or tribal organization that—

(1) has a particularly low local survival rate for cardiac arrests, or a particularly low local response rate for cardiac arrest victims; or

(2) demonstrates in its application the greatest commitment to establishing and maintaining a public access defibrillation program.

(c) Use of funds

A State, political subdivision of a State, Indian tribe, or tribal organization that receives a grant under subsection (a) may use funds received through such grant to—

(1) purchase automated external defibrillators that have been approved, or cleared for marketing, by the Food and Drug Administration;

(2) provide automated external defibrillation and basic life support training in automated external defibrillator usage through nationally recognized courses;

(3) provide information to community members about the public access defibrillation program to be funded with the grant;

(4) provide information to the local emergency medical services system regarding the placement of automated external defibrillators in public places;

(5) produce materials to encourage private companies, including small businesses, to purchase automated external defibrillators;

(6) establish an information clearinghouse, that shall be administered by an organization that has substantial expertise in pediatric education, pediatric medicine, and electrophysiology and sudden death, that provides information to increase public access to defibrillation in schools; and

(7) further develop strategies to improve access to automated external defibrillators in public places.

(d) Application

(1) In general

To be eligible to receive a grant under subsection (a), a State, political subdivision of a State, Indian tribe, or tribal organization shall prepare and submit an application to the Secretary at such time, in such manner, and containing such information as the Secretary may reasonably require.

(2) Contents

An application submitted under paragraph (1) shall—

(A) describe the comprehensive public access defibrillation program to be funded with the grant and demonstrate how such program would make automated external defibrillation accessible and available to cardiac arrest victims in the community;

(B) contain procedures for implementing appropriate nationally recognized training courses in performing cardiopulmonary resuscitation and the use of automated external defibrillators;

(C) contain procedures for ensuring direct involvement of a licensed medical professional and coordination with the local emergency medical services system in the oversight of training and notification of incidents of the use of the automated external defibrillators;

(D) contain procedures for proper maintenance and testing of the automated external defibrillators, according to the labeling of the manufacturer;

(E) contain procedures for ensuring notification of local emergency medical services system personnel, including dispatchers, of the location and type of devices used in the public access defibrillation program; and

(F) provide for the collection of data regarding the effectiveness of the public access defibrillation program to be funded with the grant in affecting the out-of-hospital cardiac arrest survival rate.

(e) Authorization of appropriations

For the purpose of carrying out this section, there are authorized to be appropriated $25,000,000 for for [1] each of fiscal years 2003 through 2014. Not more than 10 percent of amounts received under a grant awarded under this section may be used for administrative expenses.

(July 1, 1944, ch. 373, title III, §312, as added Pub. L. 107–188, title I, §159(c), June 12, 2002, 116 Stat. 634; amended Pub. L. 108–41, §2, July 1, 2003, 117 Stat. 839; Pub. L. 111–148, title X, §10412, Mar. 23, 2010, 124 Stat. 990.)

EDITORIAL NOTES

PRIOR PROVISIONS

A prior section 244, acts July 1, 1944, ch. 373, title III, §312, 58 Stat. 693; July 3, 1946, ch. 538, §8, 60 Stat. 424; Dec. 5, 1967, Pub. L. 90–174, §12(b), 81 Stat. 541; Oct. 30, 1970, Pub. L. 91–515, title II, §282, 84 Stat. 1308, provided for health conferences, prior to repeal by Pub. L. 93–353, title I, §102(a), July 23, 1974, 88 Stat. 362. See section 242o(a) of this title.

A prior section 312 of act July 1, 1944, was classified to section 244–1 of this title prior to repeal by Pub. L. 94–484.

AMENDMENTS

2010—Subsec. (c)(6). Pub. L. 111–148, §10412(1), inserted ", that shall be administered by an organization that has substantial expertise in pediatric education, pediatric medicine, and electrophysiology and sudden death," after "clearinghouse".

Subsec. (e). Pub. L. 111–148, §10412(2), substituted "for each of fiscal years 2003 through 2014" for "fiscal year 2003, and such sums as may be necessary for each of the fiscal years 2004 through 2006".

2003—Subsec. (c)(6), (7). Pub. L. 108–41 added par. (6) and redesignated former par. (6) as (7).

STATUTORY NOTES AND RELATED SUBSIDIARIES

FINDINGS

Pub. L. 107–188, title I, §159(b), June 12, 2002, 116 Stat. 634, provided that: "Congress makes the following findings:

"(1) Over 220,000 Americans die each year from cardiac arrest. Every 2 minutes, an individual goes into cardiac arrest in the United States.

"(2) The chance of successfully returning to a normal heart rhythm diminishes by 10 percent each minute following sudden cardiac arrest.

"(3) Eighty percent of cardiac arrests are caused by ventricular fibrillation, for which defibrillation is the only effective treatment.

"(4) Sixty percent of all cardiac arrests occur outside the hospital. The average national survival rate for out-of-hospital cardiac arrest is only 5 percent.

"(5) Communities that have established and implemented public access defibrillation programs have achieved average survival rates for out-of-hospital cardiac arrest as high as 50 percent.

"(6) According to the American Heart Association, wide use of defibrillators could save as many as 50,000 lives nationally each year.

"(7) Successful public access defibrillation programs ensure that cardiac arrest victims have access to early 911 notification, early cardiopulmonary resuscitation, early defibrillation, and early advanced care."

[1] *So in original.*

§244–1. Repealed. Pub. L. 94–484, title V, §503(b), Oct. 12, 1976, 90 Stat. 2300

Section, act July 1, 1944, ch. 373, title III, §312, formerly §306, as added Aug. 2, 1956, ch. 871, title I, §101, 70 Stat. 923; amended July 23, 1959, Pub. L. 86–105, §1, 73 Stat. 239; Sept 8, 1960, Pub. L. 86–720, §1(b), 74 Stat. 820; Aug. 27, 1964, Pub. L. 88–497, §2, 78 Stat. 613; Aug. 16, 1968, Pub. L. 90–490, title III, §302(b), 82 Stat. 789; Mar. 12, 1970, Pub. L. 91–208, §3, 84 Stat. 52; Oct. 30, 1970, Pub. L. 91–515, title VI, §601(b)(2), 84 Stat. 1311; June 18, 1973, Pub. L. 93–45, title I, §104(a), 87 Stat. 91; renumbered §312 and amended July 23, 1974, Pub. L. 93–353, title I, §102(b), 88 Stat. 362; Oct. 12, 1976, Pub. L. 94–484, title I, §101(a)(1), 90 Stat. 2244, related to graduate or specialized training for physicians, engineers, nurses, and other professional personnel.

STATUTORY NOTES AND RELATED SUBSIDIARIES

EFFECTIVE DATE OF REPEAL

Pub. L. 94–484, title V, §503(c), Oct. 12, 1976, 90 Stat. 2300, provided that: "The amendments made by this section [amending former section 295f–2 of this title and repealing this section and section 245a of this title] shall take effect October 1, 1977."

§244a. Materials and resources to increase education and awareness of cardiomyopathy among school administrators, educators, and families

(a) Materials and resources

Not later than 18 months after December 23, 2024, the Secretary, in consultation with the Director of the Centers for Disease Control and Prevention, shall develop public education materials and resources to be disseminated to school administrators, educators, school health professionals, coaches, families, guardians, caregivers, and other appropriate individuals. The materials and resources shall include—

(1) information on the signs, symptoms, and risk factors associated with high-risk cardiac conditions and genetic heart rhythm abnormalities that may cause sudden cardiac arrest in children, adolescents, and young adults, including—

(A) cardiomyopathy;

(B) long QT syndrome, Brugada syndrome, catecholaminergic polymorphic ventricular tachycardia, short QT syndrome, and Wolff-Parkinson-White syndrome; and

(C) other high-risk cardiac conditions, as determined by the Secretary;

(2) guidelines regarding the placement of automated external defibrillators in schools, early childhood education programs, and child care centers;

(3) training information on automated external defibrillators and cardiopulmonary resuscitation; and

(4) recommendations for how schools, early childhood education programs, and child care centers can develop and implement a cardiac emergency response plan.

(b) Dissemination of materials and resources

Not later than 30 months after December 23, 2024, the Secretary shall disseminate the materials and resources developed under subsection (a) in accordance with the following:

(1) Distribution by State educational agencies

The Secretary shall make available such materials and resources to State educational agencies to distribute—

(A) to school administrators, educators, school health professionals, coaches, families, guardians, caregivers, and other appropriate individuals, the information developed under

subsection (a)(1);

(B) to parents, guardians, or other caregivers, the cardiomyopathy risk assessment developed pursuant to section 244b(b)(1) of this title; and

(C) to school administrators, educators, school health professionals, and coaches—

(i) the guidelines described in subsection (a)(2);

(ii) the training information described in subsection (a)(3); and

(iii) the recommendations described in subsection (a)(4).

(2) Dissemination to health departments and professionals

The Secretary shall make available the materials and resources developed under subsection (a) to State and local health departments, pediatricians, hospitals, and other health professionals, such as nurses and first responders.

(3) Posting on website

(A) CDC

(i) In general

The Secretary, through the Director, shall post the materials and resources developed under subsection (a) on the public Internet website of the Centers for Disease Control and Prevention.

(ii) Additional information

The Director is encouraged to maintain on such public Internet website such additional information regarding cardiomyopathy as deemed appropriate by the Director.

(B) State educational agencies

State educational agencies are encouraged to create public Internet webpages dedicated to cardiomyopathy and post the materials and resources developed under subsection (a) on such webpages.

(c) Definitions

In this section:

(1) The term "cardiomyopathy" means a heart disease that affects the heart's muscle (myocardium)—

(A) the symptoms of which may vary from case to case, including—

(i) cases in which no symptoms are present (asymptomatic); and

(ii) cases in which there are symptoms of a progressive condition that may result from an impaired ability of the heart to pump blood, such as fatigue, irregular heartbeats (arrhythmia), heart failure, and, potentially, sudden cardiac death; and

(B) the recognized types of which include dilated, hypertrophic, restrictive, arrhythmogenic right ventricular dysplasia, and left ventricular non-compaction.

(2) The term "Director" means the Director of the Centers for Disease Control and Prevention.

(3) The terms "early childhood education program", "elementary school", and "secondary school" have the meanings given to those terms in section 7801 of title 20.

(4) The term "school administrator" means a principal, director, manager, or other supervisor or leader within an elementary school, secondary school, State-based early childhood education program, or child care center.

(5) The term "school health professional" means a health professional serving at an elementary school, secondary school, State-based early childhood education program, or child care center.

(July 1, 1944, ch. 373, title III, §312A, as added Pub. L. 118–176, §2(a), Dec. 23, 2024, 138 Stat. 2605.)

EDITORIAL NOTES

PRIOR PROVISIONS

A prior section 244a, act July 1, 1944, ch. 373, title III, §312a, as added Aug. 31, 1954, ch. 1158, §2, 68 Stat. 1025, related to birth and death statistics, annual collection, and compensation for transcription, prior to repeal by Pub. L. 93–353, title I, §102(a), July 23, 1974, 88 Stat. 362. See section 242k(h)(1) of this title.

§244b. Activities relating to cardiomyopathy

(a) Report on CDC national cardiomyopathy activities

(1) In general

Not later than 18 months after December 23, 2024, the Secretary, acting through the Director of the Centers for Disease Control and Prevention, shall submit to Congress a report on findings generated from existing activities conducted by the Centers for Disease Control and Prevention to improve the understanding of the prevalence and epidemiology of cardiomyopathy across the lifespan, from birth to adulthood, with particular interest in the following:

(A) The natural history of individuals with cardiomyopathy, in both the pediatric and adult population.

(B) Estimates of cardiomyopathy-related emergency department visits and hospitalizations, in both the pediatric and adult population.

(2) Public access

Subject to paragraph (3), the report submitted under this subsection shall be made available to the public.

(3) Privacy protections

The Secretary shall ensure that this subsection is carried out in a manner that complies with all applicable privacy laws under Federal and State law.

(b) Improving risk assessments for individuals with cardiomyopathy

(1) In general

The Secretary shall develop and make publicly available a cardiomyopathy risk assessment for health care providers and individuals. Such risk assessment shall, at a minimum, include the following:

(A) Background information on the prevalence, incidence, and health impact of cardiomyopathy, including all forms of cardiomyopathy and their effects on pediatric, adolescent, and adult individuals.

(B) A worksheet with variables and conditions for an individual or health care provider to use in assessing whether an individual is at risk for cardiomyopathy.

(C) A worksheet with variables and stages of progression for an individual or health care provider to use in assessing whether and to what extent cardiomyopathy has progressed in an individual.

(D) Guidelines on cardiomyopathy screenings for individuals who are at risk for, or have a family history of, cardiomyopathy.

(2) Stakeholder input

In carrying out paragraph (1), the Director of the Centers for Disease Control and Prevention shall seek input from external stakeholders including—

(A) representatives from national patient advocacy organizations expert in all forms of cardiomyopathy;

(B) representatives from medical professional societies that specialize in the care of adults and pediatrics with cardiomyopathy; and

(C) representatives from other relevant Federal agencies.

(c) Definition

In this section, the term "cardiomyopathy" has the meaning given to such term in section 244a of this title.

(July 1, 1944, ch. 373, title III, §312B, as added Pub. L. 118–176, §2(a), Dec. 23, 2024, 138 Stat. 2607.)

§244c. Cardiomyopathy research

(a) In general

The Secretary, in consultation with the Director of the National Institutes of Health, may expand and coordinate research and related activities of the National Institutes of Health with respect to cardiomyopathy, which may include research with respect to—

(1) causation of cardiomyopathy, including genetic causes and molecular biomarkers;

(2) long-term health outcomes in individuals with cardiomyopathy, including infants, children, teenagers, adults, and elderly individuals; and

(3) studies using longitudinal data and retrospective analysis to identify effective treatments and outcomes for individuals with cardiomyopathy.

(b) Nonduplication

The Secretary shall ensure that any research and activities related to cardiomyopathy under this section do not unnecessarily duplicate activities, programs, or efforts of other agencies and offices within the Department of Health and Human Services.

(c) NIH report

Not later than 18 months after December 23, 2024, the Secretary, in consultation with the Director of the National Institutes of Health, shall submit to Congress a report—

(1) outlining the ongoing research efforts of the National Institutes of Health regarding cardiomyopathy; and

(2) identifying—

(A) a research agenda regarding adult forms of cardiomyopathy;

(B) plans for researching cardiomyopathy affecting the pediatric population; and

(C) the areas of greatest need for such research.

(d) Cardiomyopathy defined

In this section, the term "cardiomyopathy" has the meaning given to such term in section 244a of this title.

(July 1, 1944, ch. 373, title III, §312C, as added Pub. L. 118–176, §2(a), Dec. 23, 2024, 138 Stat. 2608.)

§244d. Promoting student access to AEDs and CPR

(a) In general

The Secretary may award grants to eligible entities to develop and implement a comprehensive program to promote student access to automated external defibrillators (in this section referred to as "AEDs") and cardiopulmonary resuscitation (in this section referred to as "CPR") in public elementary schools and secondary schools.

(b) Use of funds

An eligible entity receiving a grant under subsection (a) may use funds received through such grant to carry out any of the following activities:

(1) Developing and providing comprehensive materials to establish AED and CPR programs in public elementary schools and secondary schools.

(2) Providing support for CPR and AED training programs in such schools for students, staff,

and related sports volunteers.

(3) Providing support for developing a cardiac emergency response plan within such schools.

(4) Purchasing AEDs that have been approved under section 360e of title 21, cleared under section 360(k) of such title, or classified under section 360c(f)(2) of such title.

(5) Purchasing necessary AED batteries and performing necessary AED maintenance (such as by replacing AED pads) in accordance with the labeling of the AED involved.

(6) Replacing old and outdated AED and CPR equipment, machinery, and educational materials.

(c) Eligibility; application

To be eligible for a grant under subsection (a), an entity shall—

(1) be a local educational agency (including a public charter school operating as a local educational agency under State law), in consultation with a qualified health care entity; and

(2) submit to the Secretary an application at such time, in such manner, and containing such information as the Secretary may reasonably require.

(d) Definitions

In this section:

(1) ESEA terms

The terms "elementary school", "local educational agency", and "secondary school" have the meanings given such terms in section 7801 of title 20.

(2) Qualified health care entity

The term "qualified health care entity" means a health care entity that—

(A) is—

(i) a public entity; or

(ii) an organization that is described in section 501(c) of title 26 and exempt from taxation under section 501(a) of such title;

(B) demonstrates an ability to develop, train, and implement a comprehensive program to promote student access to defibrillation in public elementary and secondary schools; and

(C) is qualified in providing technical assistance in AED and CPR training.

(July 1, 1944, ch. 373, title III, §312D, as added Pub. L. 118–176, §2(a), Dec. 23, 2024, 138 Stat. 2608.)

§245. Public awareness campaign on the importance of vaccinations

(a) In general

The Secretary, acting through the Director of the Centers for Disease Control and Prevention and in coordination with other offices and agencies, as appropriate, shall award competitive grants or contracts to one or more public or private entities to carry out a national, evidence-based campaign to increase awareness and knowledge of the safety and effectiveness of vaccines for the prevention and control of diseases, combat misinformation about vaccines, and disseminate scientific and evidence-based vaccine-related information, with the goal of increasing rates of vaccination across all ages, as applicable, particularly in communities with low rates of vaccination, to reduce and eliminate vaccine-preventable diseases.

(b) Consultation

In carrying out the campaign under this section, the Secretary shall consult with appropriate public health and medical experts, including the National Academy of Medicine and medical and public health associations and nonprofit organizations, in the development, implementation, and evaluation of the evidence-based public awareness campaign.

(c) Requirements

The campaign under this section shall—

(1) be a nationwide, evidence-based media and public engagement initiative;

(2) include the development of resources for communities with low rates of vaccination, including culturally and linguistically appropriate resources, as applicable;

(3) include the dissemination of vaccine information and communication resources to public health departments, health care providers, and health care facilities, including such providers and facilities that provide prenatal and pediatric care;

(4) be complementary to, and coordinated with, any other Federal, State, local, or Tribal efforts, as appropriate; and

(5) assess the effectiveness of communication strategies to increase rates of vaccination.

(d) Additional activities

The campaign under this section may—

(1) include the use of television, radio, the internet, and other media and telecommunications technologies;

(2) include the use of in-person activities;

(3) be focused to address specific needs of communities and populations with low rates of vaccination; and

(4) include the dissemination of scientific and evidence-based vaccine-related information, such as—

(A) advancements in evidence-based research related to diseases that may be prevented by vaccines and vaccine development;

(B) information on vaccinations for individuals and communities, including individuals for whom vaccines are not recommended by the Advisory Committee for Immunization Practices, and the effects of low vaccination rates within a community on such individuals;

(C) information on diseases that may be prevented by vaccines; and

(D) information on vaccine safety and the systems in place to monitor vaccine safety.

(e) Evaluation

The Secretary shall—

(1) establish benchmarks and metrics to quantitatively measure and evaluate the awareness campaign under this section;

(2) conduct qualitative assessments regarding the awareness campaign under this section; and

(3) prepare and submit to the Committee on Health, Education, Labor, and Pensions of the Senate and Committee on Energy and Commerce of the House of Representatives an evaluation of the awareness campaign under this section.

(f) Supplement not supplant

Funds appropriated under this section shall be used to supplement and not supplant other Federal, State, and local public funds provided for activities described in this section.

(g) Authorization of appropriations

There are authorized to be appropriated to carry out this section and subsections (k) and (n) of section 247b of this title, $15,000,000 for each of fiscal years 2021 through 2025.

(July 1, 1944, ch. 373, title III, §313, as added Pub. L. 116–260, div. BB, title III, §311(a), Dec. 27, 2020, 134 Stat. 2923.)

EDITORIAL NOTES

PRIOR PROVISIONS

A prior section 245, act July 1, 1944, ch. 373, title III, §313, as added Pub. L. 107–188, title I, §159(c), June 12, 2002, 116 Stat. 636, provided for public access defibrillation demonstration projects, prior to repeal by Pub. L. 116–260, div. BB, title III, §311(a), Dec. 27, 2020, 134 Stat. 2923.

Another prior section 245, acts July 1, 1944, ch. 373, title III, §313, 58 Stat. 693; Oct. 30, 1970, Pub. L. 91–515, title II, §282, 84 Stat. 1308, provided for collection of vital statistics, prior to repeal by Pub. L.

93–353, title I, §102(a), July 23, 1974, 88 Stat. 362. See section 242k(g) of this title.

A prior section 313 of act July 1, 1944, was classified to section 245a of this title prior to repeal by Pub. L. 94–484.

STATUTORY NOTES AND RELATED SUBSIDIARIES

MATERNAL VACCINATION AWARENESS

Pub. L. 117–103, div. P, title I, §135, Mar. 15, 2022, 136 Stat. 797, provided that: "In carrying out the public awareness initiative related to vaccinations pursuant to section 313 of the Public Health Service Act (42 U.S.C. 245), the Secretary of Health and Human Services shall take into consideration the importance of increasing awareness and knowledge of the safety and effectiveness of vaccines to prevent disease in pregnant and postpartum women and in infants and the need to improve vaccination rates in communities and populations with low rates of vaccination."

§245a. Repealed. Pub. L. 94–484, title V, §503(b), Oct. 12, 1976, 90 Stat. 2300

Section, act July 1, 1944, ch. 373, title III, §313, formerly §309, as added Sept. 8, 1960, Pub. L. 86–720, §1(a), 74 Stat. 819; amended Aug. 27, 1964, Pub. L. 88–497, §3, 78 Stat. 613; Nov. 3, 1966, Pub. L. 89–749, §4, 80 Stat. 1190; Dec. 5, 1967, Pub. L. 90–174, §§2(g), 8(c), 81 Stat. 534, 540; Aug. 16, 1968, Pub. L. 90–490, title III, §302(a), 82 Stat. 788; Mar. 12, 1970, Pub. L. 91–208, §§1, 2, 84 Stat. 52; June 30, 1970, Pub. L. 91–296, title IV, §401(b)(1)(B), 84 Stat. 352; June 18, 1973, Pub. L. 93–45, title I, §104(b), (c), 87 Stat. 91; renumbered §313 and amended July 23, 1974, Pub. L. 93–353, title I, §102(c), 88 Stat. 362; Oct. 12, 1976, Pub. L. 94–484, title I, §101(a)(2), (3), 90 Stat. 2244, related to graduate public health training grants.

STATUTORY NOTES AND RELATED SUBSIDIARIES

EFFECTIVE DATE OF REPEAL

Repeal effective Oct. 1, 1977, see section 503(c) of Pub. L. 94–484, set out as a note under section 244–1 of this title.

§246. Grants and services to States

(a) Comprehensive health planning and services

(1) In order to assist the States in comprehensive and continuing planning for their current and future health needs, the Secretary is authorized during the period beginning July 1, 1966, and ending June 30, 1973, to make grants to States which have submitted, and had approved by the Secretary, State plans for comprehensive State health planning. For the purposes of carrying out this subsection, there are hereby authorized to be appropriated $2,500,000 for the fiscal year ending June 30, 1967, $7,000,000 for the fiscal year ending June 30, 1968, $10,000,000 for the fiscal year ending June 30, 1969, $15,000,000 for the fiscal year ending June 30, 1970, $15,000,000 for the fiscal year ending June 30, 1971, $17,000,000 for the fiscal year ending June 30, 1972, $20,000,000 for the fiscal year ending June 30, 1973, and $10,000,000 for the fiscal year ending June 30, 1974.

(2) In order to be approved for purposes of this subsection, a State plan for comprehensive State health planning must—

(A) designate, or provide for the establishment of, a single State agency, which may be an interdepartmental agency, as the sole agency for administering or supervising the administration of the State's health planning functions under the plan;

(B) provide for the establishment of a State health planning council, which shall include representatives of Federal, State, and local agencies (including as an ex officio member, if there is located in such State one or more hospitals or other health care facilities of the Department of Veterans Affairs, the individual whom the Secretary of Veterans Affairs shall have designated to serve on such council as the representative of the hospitals or other health care facilities of such Department which are located in such State) and nongovernmental organizations and groups

concerned with health (including representation of the regional medical program or programs included in whole or in part within the State), and of consumers of health services, to advise such State agency in carrying out its functions under the plan, and a majority of the membership of such council shall consist of representatives of consumers of health services;

(C) set forth policies and procedures for the expenditure of funds under the plan, which, in the judgment of the Secretary, are designed to provide for comprehensive State planning for health services (both public and private and including home health care), including the facilities and persons required for the provision of such services, to meet the health needs of the people of the State and including environmental considerations as they relate to public health;

(D) provide for encouraging cooperative efforts among governmental or nongovernmental agencies, organizations and groups concerned with health services, facilities, or manpower, and for cooperative efforts between such agencies, organizations, and groups and similar agencies, organizations, and groups in the fields of education, welfare, and rehabilitation;

(E) contain or be supported by assurances satisfactory to the Secretary that the funds paid under this subsection will be used to supplement and, to the extent practicable, to increase the level of funds that would otherwise be made available by the State for the purpose of comprehensive health planning and not to supplant such non-Federal funds;

(F) provide such methods of administration (including methods relating to the establishment and maintenance of personnel standards on a merit basis, except that the Secretary shall exercise no authority with respect to the selection, tenure of office, and compensation of any individual employed in accordance with such methods) as are found by the Secretary to be necessary for the proper and efficient operation of the plan;

(G) provide that the State agency will make such reports, in such form and containing such information, as the Secretary may from time to time reasonably require, and will keep such records and afford such access thereto as the Secretary finds necessary to assure the correctness and verification of such reports;

(H) provide that the State agency will from time to time, but not less often than annually, review its State plan approved under this subsection and submit to the Secretary appropriate modifications thereof;

(I) effective July 1, 1968, (i) provide for assisting each health care facility in the State to develop a program for capital expenditures for replacement, modernization, and expansion which is consistent with an overall State plan developed in accordance with criteria established by the Secretary after consultation with the State which will meet the needs of the State for health care facilities, equipment, and services without duplication and otherwise in the most efficient and economical manner, and (ii) provide that the State agency furnishing such assistance will periodically review the program (developed pursuant to clause (i)) of each health care facility in the State and recommend appropriate modification thereof;

(J) provide for such fiscal control and fund accounting procedures as may be necessary to assure proper disbursement of and accounting for funds paid to the State under this subsection; and

(K) contain such additional information and assurances as the Secretary may find necessary to carry out the purposes of this subsection.

(3)(A) From the sums appropriated for such purpose for each fiscal year, the several States shall be entitled to allotments determined, in accordance with regulations, on the basis of the population and the per capita income of the respective States; except that no such allotment to any State for any fiscal year shall be less than 1 per centum of the sum appropriated for such fiscal year pursuant to paragraph (1). Any such allotment to a State for a fiscal year shall remain available for obligation by the State, in accordance with the provisions of this subsection and the State's plan approved thereunder, until the close of the succeeding fiscal year.

(B) The amount of any allotment to a State under subparagraph (A) for any fiscal year which the Secretary determines will not be required by the State, during the period for which it is available, for the purposes for which allotted shall be available for reallotment by the Secretary from time to time, on such date or dates as he may fix, to other States with respect to which such a determination has

not been made, in proportion to the original allotments to such States under subparagraph (A) for such fiscal year, but with such proportionate amount for any of such other States being reduced to the extent it exceeds the sum the Secretary estimates such State needs and will be able to use during such period; and the total of such reductions shall be similarly reallotted among the States whose proportionate amounts were not so reduced. Any amount so reallotted to a State from funds appropriated pursuant to this subsection for a fiscal year shall be deemed part of its allotment under subparagraph (A) for such fiscal year.

(4) From each State's allotment for a fiscal year under this subsection, the State shall from time to time be paid the Federal share of the expenditures incurred during that year or the succeeding year pursuant to its State plan approved under this subsection. Such payments shall be made on the basis of estimates by the Secretary of the sums the State will need in order to perform the planning under its approved State plan under this subsection, but with such adjustments as may be necessary to take account of previously made underpayments or overpayments. The "Federal share" for any State for purposes of this subsection shall be all, or such part as the Secretary may determine, of the cost of such planning, except that in the case of the allotments for the fiscal year ending June 30, 1970, it shall not exceed 75 per centum of such cost.

(b) Project grants for areawide health planning; authorization of appropriations; prerequisites for grants; application; contents

(1)(A) The Secretary is authorized, during the period beginning July 1, 1966, and ending June 30, 1974, to make, with the approval of the State agency administering or supervising the administration of the State plan approved under subsection (a), project grants to any other public or nonprofit private agency or organization (but with appropriate representation of the interests of local government where the recipient of the grant is not a local government or combination thereof or an agency of such government or combination) to cover not to exceed 75 per centum of the costs of projects for developing (and from time to time revising) comprehensive regional, metropolitan area, or other local area plans for coordination of existing and planned health services, including the facilities and persons required for provision of such services; and including the provision of such services through home health care; except that in the case of project grants made in any State prior to July 1, 1968, approval of such State agency shall be required only if such State has such a State plan in effect at the time of such grants. No grant may be made under this subsection after June 30, 1970, to any agency or organization to develop or revise health plans for an area unless the Secretary determines that such agency or organization provides means for appropriate representation of the interests of the hospitals, other health care facilities, and practicing physicians serving such area, and the general public. For the purposes of carrying out this subsection, there are hereby authorized to be appropriated $5,000,000 for the fiscal year ending June 30, 1967, $7,500,000 for the fiscal year ending June 30, 1968, $10,000,000 for the fiscal year ending June 30, 1969, $15,000,000 for the fiscal year ending June 30, 1970, $20,000,000 for the fiscal year ending June 30, 1971, $30,000,000 for the fiscal year ending June 30, 1972, $40,000,000 for the fiscal year ending June 30, 1973, and $25,100,000 for the fiscal year ending June 30, 1974.

(B) Project grants may be made by the Secretary under subparagraph (A) to the State agency administering or supervising the administration of the State plan approved under subsection (a) with respect to a particular region or area, but only if (i) no application for such a grant with respect to such region or area has been filed by any other agency or organization qualified to receive such a grant, and (ii) such State agency certifies, and the Secretary finds, that ample opportunity has been afforded to qualified agencies and organizations to file application for such a grant with respect to such region or area and that it is improbable that, in the foreseeable future, any agency or organization which is qualified for such a grant will file application therefor.

(2)(A) In order to be approved under this subsection, an application for a grant under this subsection must contain or be supported by reasonable assurances that there has been or will be established, in or for the area with respect to which such grant is sought, an areawide health planning council. The membership of such council shall include representatives of public, voluntary, and nonprofit private agencies, institutions, and organizations concerned with health (including representatives of the interests of local government of the regional medical program for such area,

and of consumers of health services). A majority of the members of such council shall consist of representatives of consumers of health services.

(B) In addition, an application for a grant under this subsection must contain or be supported by reasonable assurances that the areawide health planning agency has made provision for assisting health care facilities in its area to develop a program for capital expenditures for replacement, modernization, and expansion which is consistent with an overall State plan which will meet the needs of the State and the area for health care facilities, equipment, and services without duplication and otherwise in the most efficient and economical manner.

(c) Project grants for training, studies, and demonstrations; authorization of appropriations

The Secretary is also authorized, during the period beginning July 1, 1966, and ending June 30, 1974, to make grants to any public or nonprofit private agency, institution, or other organization to cover all or any part of the cost of projects for training, studies, or demonstrations looking toward the development of improved or more effective comprehensive health planning throughout the Nation. For the purposes of carrying out this subsection, there are hereby authorized to be appropriated $1,500,000 for the fiscal year ending June 30, 1967, $2,500,000 for the fiscal year ending June 30, 1968, $5,000,000 for the fiscal year ending June 30, 1969, $7,500,000 for the fiscal year ending June 30, 1970, $8,000,000 for the fiscal year ending June 30, 1971, $10,000,000 for the fiscal year ending June 30, 1972, $12,000,000 for the fiscal year ending June 30, 1973, and $4,700,000 for the fiscal year ending June 30, 1974.

(July 1, 1944, ch. 373, title III, §314, 58 Stat. 693; July 3, 1946, ch. 538, §9, 60 Stat. 424; June 16, 1948, ch. 481, §5, 62 Stat. 468; 1953 Reorg. Plan No. 1, §§5, 8, eff. Apr. 11, 1953, 18 F.R. 2053, 67 Stat. 631; Aug. 1, 1956, ch. 852, §18, 70 Stat. 910; Pub. L. 85–544, §1, July 22, 1958, 72 Stat. 400; Pub. L. 87–395, §2(a)–(d), Oct. 5, 1961, 75 Stat. 824; Pub. L. 87–688, §4(a)(1), Sept. 25, 1962, 76 Stat. 587; Pub. L. 89–109, §4, Aug. 5, 1965, 79 Stat. 436; Pub. L. 89–749, §3, Nov. 3, 1966, 80 Stat. 1181; Pub. L. 90–174, §§2(a)–(f), 3(b)(2), 8(a), (b), 12(d), Dec. 5, 1967, 81 Stat. 533–535, 540, 541; Pub. L. 91–296, title I, §111(b), title IV, §401(b)(1)(C), (D), June 30, 1970, 84 Stat. 340, 352; Pub. L. 91–513, title I, §3(b), Oct. 27, 1970, 84 Stat. 1241; Pub. L. 91–515, title II, §§220, 230, 240, 250, 260(a)–(c)(1), 282, Oct. 30, 1970, 84 Stat. 1304–1306, 1308; Pub. L. 91–616, title III, §331, Dec. 31, 1970, 84 Stat. 1853; Pub. L. 91–648, title IV, §403, Jan. 5, 1971, 84 Stat. 1925, as amended Pub. L. 95–454, title VI, §602(c), Oct. 13, 1978, 92 Stat. 1189; Pub. L. 92–255, title IV, §403(a), Mar. 21, 1972, 86 Stat. 77; Pub. L. 93–45, title I, §106, June 18, 1973, 87 Stat. 92; Pub. L. 93–151, §8, Nov. 9, 1973, 87 Stat. 568; Pub. L. 94–63, title I, §102, title V, §501(b), title VII, §701(a), (b), July 29, 1975, 89 Stat. 304, 346, 352; Pub. L. 94–484, title IX, §905(b)(1), Oct. 12, 1976, 90 Stat. 2325; Pub. L. 95–83, title III, §302, Aug. 1, 1977, 91 Stat. 387; Pub. L. 95–454, title VI, §602(c), Oct. 13, 1978, 92 Stat. 1189; Pub. L. 95–622, title I, §109, Nov. 9, 1978, 92 Stat. 3417; Pub. L. 95–626, title II, §201(a), (b)(2), Nov. 10, 1978, 92 Stat. 3570; Pub. L. 96–32, §6(e), (f), July 10, 1979, 93 Stat. 83; Pub. L. 96–79, title I, §115(k)(2), Oct. 4, 1979, 93 Stat. 610; Pub. L. 96–398, title I, §107(d), Oct. 7, 1980, 94 Stat. 1571; Pub. L. 97–35, title IX, §902(b), Aug. 13, 1981, 95 Stat. 559; Pub. L. 99–117, §12(a), Oct. 7, 1985, 99 Stat. 495; Pub. L. 102–54, §13(q)(1)(D), June 13, 1991, 105 Stat. 279.)

EDITORIAL NOTES

AMENDMENTS

1991—Subsec. (a)(2)(B). Pub. L. 102–54 substituted "Department of Veterans Affairs" for "Veterans' Administration", "Secretary of Veterans Affairs" for "Administrator of Veterans' Affairs" and "such Department" for "such Administration".

1985—Subsec. (g). Pub. L. 99–117 directed that subsec. (g) be repealed. Previously, subsec. (g) was repealed by Pub. L. 96–398. See 1980 Amendment note below.

1981—Subsec. (d). Pub. L. 97–35 struck out subsec. (d) which related to grants for services, form, manner, etc., of application, review of activities undertaken, allotments, and authorization of appropriations.

1980—Subsec. (g). Pub. L. 96–398 struck out subsec. (g) which related to application, procedures applicable, amount, etc., for State mental health program grants.

1979—Subsec. (d)(2)(C)(ii). Pub. L. 96–32, §6(e), substituted "uniform national health program reporting

system" for "uniform national reporting system".

Subsec. (d)(4)(A). Pub. L. 96–32, §6(f), in provision following subd. (II) of cl. (ii), substituted "the preceding provisions of this subparagraph" for "clauses (i) and (ii)" and "amount" for "amounts" and inserted provision that if the amount appropriated for a fiscal year is equal to or less than the amount appropriated for fiscal year ending Sept. 30, 1979, the total amount of grants for a State health authority shall be an amount which bears the same ratio to the amount appropriated as the total amount of grants received by such authority from appropriations for fiscal year ending Sept. 30, 1979, bears to the amount appropriated for that fiscal year.

Subsec. (g)(2)(D)(iv). Pub. L. 96–79 substituted "a plan which is consistent with the State health plan in effect for the State under section 300m–3(c) of this title and" for "a plan".

1978—Subsec. (d). Pub. L. 95–626, §201(b)(2), completely revised subsec. (d) under which the Secretary is authorized to make grants to State health authorities to assist in meeting the costs of providing comprehensive public health services by including requirements that the States submit an application outlining how funds will be used to supplement non-Federal support for the provision of public health services in the State, by setting out formulae under which funds will be made available to States including definitions of "applicable grant computation percentage" and "State and local expenditures for comprehensive public health services", by requiring implementation of a national health program reporting system to assure accountability for expenditure of funds, and by authorizing appropriations of $150,000,000 for fiscal year ending Sept. 30, 1980, and $170,000,000 for fiscal year ending Sept. 30, 1981.

Subsec. (d)(7)(A). Pub. L. 95–626, §201(a)(1), inserted provision authorizing an appropriation of $103,000,000 for fiscal year ending Sept. 30, 1979.

Subsec. (d)(7)(B). Pub. L. 95–626, §201(a)(2), inserted provision authorizing an appropriation of $20,000,000 for fiscal year ending Sept. 30, 1979.

Subsec. (f). Pub. L. 95–454 designated existing provisions of section 403 of Pub. L. 91–648 (see 1971 Amendment note below) as subsec. (a) thereof and added subsec. (b) thereto repealing subsec. (f) of this section as subsec. (f) of this section had applied to commissioned officers of the Public Health Service.

Subsec. (g). Pub. L. 95–622 substituted provisions relating to grants for State mental health programs for provisions relating to regulations and amendments with respect to grants to States under subsecs. (a) and (d) and reduction and suspension of subsec. (a) and (d) grant payments.

1977—Subsec. (d)(7)(A). Pub. L. 95–83, §302(a), substituted provision for an appropriation authorization for fiscal year ending Sept. 30, 1977, for prior such authorization for fiscal year 1977, and authorized appropriation of $106,750,000 for fiscal year ending Sept. 30, 1978.

Subsec. (d)(7)(B). Pub. L. 95–83, §302(b), substituted provision for an appropriation authorization for fiscal year ending Sept. 30, 1977, for prior such authorization for fiscal year 1977, and authorized appropriation of $12,680,000 for fiscal year ending Sept. 30, 1978.

1976—Subsec. (g)(4)(B). Pub. L. 94–484 defined "State" to include the Northern Mariana Islands.

1975—Subsec. (d). Pub. L. 94–63, §§102, 701(a), substituted provisions relating to grants made pursuant to allotments to State health and mental health authorities for meeting the costs of providing comprehensive public health services, for provisions relating to grants made pursuant to appropriations for fiscal year ending June 30, 1968 to fiscal year ending June 30, 1975, to State health or mental health authorities to aid in the establishment and maintenance of adequate public health services, including the training of personnel for State and local health work.

Subsec. (e). Pub. L. 94–63, §§501(b), 701(b), struck out subsec. (e) which authorized appropriations from fiscal year ending June 30, 1968 through fiscal year ending June 30, 1975 for project grants for health services and related training, set forth procedures for making such grants, and prohibited grants after the fiscal year ending June 30, 1975, for provisions of this chapter amended by title VII of the Health Revenue Sharing and Health Services Act of 1975.

1973—Subsec. (a)(1). Pub. L. 93–45, §106(a)(1), authorized appropriations of $10,000,000 for fiscal year ending June 30, 1974.

Subsec. (b)(1)(A). Pub. L. 93–45, §106(a)(2), (b), authorized appropriations of $25,100,000 for fiscal year ending June 30, 1974, and extended period for making project grants from June 30, 1973, to June 30, 1974.

Subsec. (c). Pub. L. 93–45, §106(a)(3), (b), authorized appropriations of $4,700,000 for fiscal year ending June 30, 1974, and extended period for grants from June 30, 1973, to June 30, 1974.

Subsec. (d)(1). Pub. L. 93–45, §106(a)(4), authorized appropriations of $90,000,000 for fiscal year ending June 30, 1974.

Subsec. (e). Pub. L. 93–151 prohibited use of appropriated funds for lead based paint poisoning control.

Pub. L. 93–45, §106(a)(5), authorized appropriations of $230,700,000 for fiscal year ending June 30, 1974, and prohibited any grant for such fiscal year to cover cost of services described in cl. (1) or (2) of the first sentence if a grant or contract to cover cost of such services may be made or entered into from funds

authorized to be appropriated for such fiscal year under an appropriations authorization in any provision of this chapter (other than this subsection) amended by title I of the Health Programs Extension Act of 1973.

1972—Subsec. (d)(2)(K). Pub. L. 92–255 required State plans to provide for licensing of facilities for treatment and rehabilitation of persons with drug abuse and other drug dependence problems and for expansion of State mental health programs and other prevention and treatment programs in the field of drug abuse and drug dependence.

1971—Subsec. (f). Pub. L. 91–648, §403(a), as amended by Pub. L. 94–454, §602(c), repealed subsec. (f) which authorized the Secretary to arrange the interchange of personnel with States to aid in discharge of responsibilities in field of health care, except as subsec. (b) applied to commissioned officers of the Public Health Service. See 1978 Amendment note above.

1970—Pub. L. 91–515, §282, substituted "Secretary" for "Surgeon General" in subsecs. (a)(1), (a)(2)(C), (E) to (H), (K), (a)(3)(B), (a)(4), (b)(1)(A), (c), (d)(1), (d)(2)(C), (F) to (H), (J), (d)(4)(A), (d)(6), and (g)(1) to (3).

Subsec. (a)(1). Pub. L. 91–515, §220(a), extended period for making grants to States from June 30, 1970 to June 30, 1973, and authorized appropriations for the fiscal years ending June 30, 1971, June 30, 1972, and June 30, 1973.

Subsec. (a)(2)(B). Pub. L. 91–515, §220(b), (c), inserted provisions authorizing appointment of an exofficio member from representatives of Federal, State, and local agencies involved, and requiring representation of the regional medical program or programs included in whole or in part within the State.

Subsec. (a)(2)(C). Pub. L. 91–515, §220(d), inserted "and including home health care" after "private" and "and including environmental considerations as they relate to public health" after "people of the State".

Subsec. (b). Pub. L. 91–515, §230, redesignated existing provisions as subsec. (b)(1)(A), and, as so redesignated, extended period for making project grants from June 30, 1970 to June 30, 1973, inserted "and including the provision of such services through home health care" after "such services", and authorized appropriations for the fiscal years ending June 30, 1971, June 30, 1972, and June 30, 1973, and added subsec. (b)(1)(B) and (b)(2).

Pub. L. 91–296, §111(b), inserted provisions requiring that before grants be made to agencies or organizations to develop or revise health plans for an area the Secretary determine that the agency or organization provides means for appropriate representation of the interests of the hospitals, practicing physicians, and the general public.

Subsec. (c). Pub. L. 91–515, §240, extended period for making grants from June 30, 1970, to June 30, 1973, and authorized appropriations for the fiscal years ending June 30, 1971, June 30, 1972, and June 30, 1973.

Subsec. (d)(1). Pub. L. 91–515, §250(a), authorized appropriations for fiscal years ending June 30, 1971, June 30, 1972, and June 30, 1973.

Pub. L. 91–296, §401(b)(1)(C), struck out except which provided for use of up to 1 per centum by Secretary for evaluation.

Subsec. (d)(2)(C). Pub. L. 91–515, §250(b), inserted provisions requiring State plan to contain assurances that the plan is compatible with total health program of the State.

Subsec. (d)(2)(K). Pub. L. 91–513 added subpar. (K).

Subsec. (d)(2)(L). Pub. L. 91–616 added subpar. (L).

Subsec. (e). Pub. L. 91–515, §260(a), (b), (c)(1), inserted provisions authorizing appropriations for fiscal years ending June 30, 1971, June 30, 1972, and June 30, 1973, provisions authorizing grants to cover part of cost of equity requirements and amortization of loans on facilities acquired from the Office of Economic Opportunity or construction in connection with any program or project transferred from the Office of Economic Opportunity, and provisions requiring the application for any grant made under this subsection to be referred for review and comment to the appropriate areawide health planning agency, or, if no such agency is in the area, then to such other public or nonprofit private agency or organization (if any) which performs similar functions.

Pub. L. 91–296, §401(b)(1)(D), struck out provision for use of up to 1 per centum of appropriation for grants under subsec. (e) by the Secretary for evaluation.

1967—Subsec. (a)(1). Pub. L. 90–174, §2(a)(1), extended period for making grants to States from June 30, 1968, to June 30, 1970, increased appropriations authorization for fiscal year ending June 30, 1968, from $5,000,000 to $7,000,000, and authorized appropriations of $10,000,000 and $15,000,000 for fiscal years ending June 30, 1969, and 1970, respectively.

Subsec. (a)(2)(I) to (K). Pub. L. 90–174, §2(a)(2), added subpar. (I) and redesignated former subpars. (I) and (J) as (J) and (K), respectively.

Subsec. (a)(4). Pub. L. 90–174, §2(a)(3), limited Federal share of expenditures, in case of allotments for fiscal year ending June 30, 1968, to 75 per centum of cost of planning.

Subsec. (b). Pub. L. 90–174, §2(b)(1), (2), extended period for making grants to public or nonprofit private organizations from June 30, 1968, to June 30, 1970, and authorized appropriations of $10,000,000 and $15,000,000 for fiscal years ending June 30, 1969, and 1970, respectively, and provided for appropriate representation of interests of local government where recipient of grant is not a local government or combination thereof or an agency of such government or combination, respectively.

Subsec. (c). Pub. L. 90–174, §2(c), extended period for making grants to public or nonprofit private organizations from June 30, 1968, to June 30, 1970, and authorized appropriations of $5,000,000 and $7,500,000 for fiscal years ending June 30, 1969, and 1970, respectively.

Subsec. (d)(1). Pub. L. 90–174, §§2(d)(1), 8(a), increased appropriations authorization for fiscal year ending June 30, 1968, from $62,500,000 to $70,000,000, and authorized appropriations of $90,000,000 and $100,000,000 for fiscal years ending June 30, 1969, and 1970, respectively, and made program evaluation funds available for any fiscal year ending after June 30, 1968, respectively.

Subsec. (d)(5). Pub. L. 90–174, §2(d)(2), made Federal share of 662/3 per centum applicable to the Trust Territory of the Pacific Islands.

Subsec. (d)(7). Pub. L. 90–174, §2(d)(3), provided for an allocation of 70 per centum of funds for provision under the State plan of services in communities of the State.

Subsec. (e). Pub. L. 90–174, §§2(e), 3(b)(2), 8(b), increased appropriations authorization for fiscal year ending June 30, 1968, from $62,500,000 to $90,000,000, authorized appropriations of $95,000,000 and $80,000,000 for fiscal years ending June 30, 1969, and 1970, respectively, inserted "(including related training)" after "providing services" in cl. (1), substituted "developing" for "stimulating" and inserted "(including related training)" after "health services" in cl. (2), struck out cl. (3) which authorized grants to cover part of cost of undertaking studies, demonstrations, or training designed to develop new methods or improve existing methods of providing health services, and made program evaluation funds available for any fiscal year ending after June 30, 1968.

Subsec. (f)(5). Pub. L. 90–174, §12(d)(1), inserted "for" before "the expenses of travel".

Subsec. (f)(6), (8). Pub. L. 90–174, §12(d)(2), substituted "Department" for "Service".

Subsec. (g)(4)(B). Pub. L. 90–174, §2(f), defined "State" to include the Trust Territory of the Pacific Islands.

1966—Subsec. (a). Pub. L. 89–749 substituted provisions authorizing the Surgeon General to make grants to States to assist in comprehensive and continuing planning for their current and future health needs, authorizing appropriations therefor, setting out the requirements for an acceptable State plan for comprehensive State health planning, covering the allotting of the appropriated sums to the States, and the payment of the allotted funds, for provisions authorizing the Surgeon General, through the use of grants and other assistance, to help local programs of prevention, treatment, and control of venereal diseases, covering the payment of the costs of assistance by personnel of the Public Health Service to assist in carrying out the purposes of the section with respect to venereal disease, and authorizing the appropriation of funds.

Subsec. (b). Pub. L. 89–749 substituted provisions for project grants by the Surgeon General covering the development of comprehensive regional, metropolitan, or local coordination of existing and planned health facilities and persons required for providing services and the authorization of appropriations of $5,000,000 for fiscal 1967 and $7,500,000 for fiscal 1968 for provisions authorizing the appropriation of funds to enable the Surgeon General to aid in the development of measures for the local prevention, treatment, and control of tuberculosis.

Subsec. (c). Pub. L. 89–749 substituted provisions for project grants for the development of improved or more effective comprehensive health planning throughout the United States and the authorization of appropriations of $1,500,000 for fiscal 1967 and $2,500,000 for fiscal 1968 for provisions authorizing the Surgeon General to assist, through grants and otherwise, in the establishment and maintenance of adequate public health services by States, counties, health districts, and other political subdivisions, authorizing appropriations therefor, and covering the allotment, payment, and allocation of appropriated funds.

Subsec. (d). Pub. L. 89–749 substituted provisions authorizing grants by the Surgeon General to State health or mental health authorities to assist in establishing and maintaining adequate public health services, setting out the requirements for an acceptable State plan for the supplying of public health services, authorizing an appropriation of $62,500,000 for fiscal 1968, the allotment of appropriated funds, payments to States, and the determination of the Federal share for provisions covering the allotment of appropriated funds among the several States on the basis of population, incidence of venereal disease, tuberculosis, mental health problems, and the financial needs of the various States.

Subsec. (e). Pub. L. 89–749 substituted provisions for project grants for health services development to public or private nonprofit agencies and for the authorization of an appropriation of $62,500,000 for fiscal 1968 for provisions covering the establishment and maintenance of community programs of heart disease

control and the allotments and appropriations therefor.

Subsec. (f). Pub. L. 89–749 substituted provisions covering the interchange of personnel with States, the application of statutes covering Federal employees to interchanged personnel, and the coverage of State officers and employees, for provisions for the determination and certification of amounts paid to each State from allotments thereto.

Subsec. (g). Pub. L. 89–749 substituted provisions for consultation with State health planning agencies concerning regulations and amendments with respect to grants to States, the reduction of payments, cessation of payments for non-compliance, and definitions, for provisions limiting the expending of grant funds for purposes specified by statute and by the agency, organization, or institution to which payment was made.

Subsecs. (h) to (m). Pub. L. 89–749 struck out subsecs. (h) to (m) which dealt, respectively, with requirement that State funds be provided for same purpose as that for which allotted funds are spent, cessation of Federal aid and procedures in connection therewith, promulgation of rules and regulations and consultation with State health authorities precedent thereto, availability of appropriated funds for administrative expenses including printing and travel expenses, applicability of section to Guam and Samoa, and reduction of payments commensurate to expense of detailing of Public Health Service personnel to States.

1965—Subsec. (c). Pub. L. 89–109 substituted "first six fiscal years ending after June 30, 1961" for "first five fiscal years ending after June 30, 1961" and "$5,000,000" for "$2,500,000".

1962—Subsec. (l). Pub. L. 87–688 inserted "and American Samoa", "or American Samoa", and "or American Samoa, respectively" after "Guam".

1961—Subsec. (c). Pub. L. 87–395, §2(a)–(c), substituted "of the first five fiscal years ending after June 30, 1961, the sum of $50,000,000" for "fiscal year a sum not to exceed $30,000,000", "such amount as may be necessary" for "an amount, not to exceed $3,000,000", "$2,500,000" for "$1,000,000", and provided that when an appropriating act provides that the amounts it specifies are available only for allotments and payments for such services and activities under this subsection as specified in such act, the requirements of subsec. (h) shall apply to such allotments and payments.

Subsec. (m). Pub. L. 87–395, §2(d), added subsec. (m).

1958—Subsec. (c). Pub. L. 85–544 designated existing provisions of second sentence as cl. (1) and added cl. (2).

1956—Subsec. (l). Act Aug. 1, 1956, added subsec. (l).

1948—Subsec. (e). Act June 16, 1948, §5(a), added subsec. (e) to provide for community programs of heart disease control. Former subsec. (e) redesignated (f).

Subsec. (f). Act June 16, 1948, §5(a), (b), redesignated former subsec. (e) as (f) and inserted proviso relating to determination and certification of amounts to be paid under subsec. (e). Former subsec. (f) redesignated (g).

Subsec. (g). Act June 16, 1948, §5(a), (c), redesignated former subsec. (f) as (g) and brought subsecs. (e) and (f)(1) within the provisions of this subsection. Former subsec. (g) redesignated (h).

Subsec. (h). Act June 16, 1948, §5(a), (d), redesignated former subsec. (g) as (h) and made subsection applicable to agencies, institutions or other organizations specified in subsec. (f)(1). Former subsec. (h) redesignated (i).

Subsec. (i). Act June 16, 1948, §5(a), (e), redesignated former subsec. (h) as (i), made subsection applicable to subsec. (e), and made technical changes as a result of the renumbering of subsections. Former subsec. (i) redesignated (j).

Subsecs. (j), (k). Act June 16, 1948, §5(a), redesignated former subsecs. (i) and (j) as (j) and (k), respectively.

1946—Subsec. (c). Act July 3, 1946, increased annual appropriation from $20,000,000 to $30,000,000, and increased annual amount available to provide demonstrations and to train personnel for State and local health work from $2,000,000 to $3,000,000.

Subsec. (d). Act July 3, 1946, provided that Surgeon General shall give special consideration to the extent of the mental health problem as well as other special problems.

Subsecs. (f), (h), (i). Act July 3, 1946, provided that in matters relating to work in field of mental health Surgeon General shall deal with State mental health authorities where they differ from general health authorities.

STATUTORY NOTES AND RELATED SUBSIDIARIES

CHANGE OF NAME

"Secretary of Health and Human Services" substituted in text for "Secretary of Health, Education, and

Welfare" pursuant to section 509(b) of Pub. L. 96–88, which is classified to section 3508(b) of Title 20, Education.

EFFECTIVE DATE OF 1981 AMENDMENT

Amendment by Pub. L. 97–35 effective Oct. 1, 1981, see section 902(h) of Pub. L. 97–35, set out as a note under section 238l of this title.

EFFECTIVE DATE OF 1980 AMENDMENT

Section 107(d) of Pub. L. 96–398 provided that the amendment made by that section is effective Sept. 30, 1981. See Repeals note below.

EFFECTIVE DATE OF 1979 AMENDMENT

Amendment by Pub. L. 96–79 effective one year after Oct. 4, 1979, see section 129(a) of Pub. L. 96–79.

EFFECTIVE DATE OF 1978 AMENDMENTS

Pub. L. 95–626, title II, §201(b)(2), Nov. 10, 1978, 92 Stat. 3570, provided that the amendment made by section is effective Oct. 1, 1979.

Pub. L. 91–648, title IV, §403(b), as added by Pub. L. 95–454, title VI, §602(c), Oct. 13, 1978, 92 Stat. 1189, provided that the repeal of subsec. (f) of this section (as applicable to commissioned officers of the Public Health Service) is effective beginning on the effective date of the Civil Service Reform Act of 1978, i.e., 90 days after Oct. 13, 1978.

EFFECTIVE DATE OF 1975 AMENDMENT

Pub. L. 94–63, title I, §102, July 29, 1975, 89 Stat. 304, provided that the amendment made by that section is effective with respect to grants made under subsec. (d) of this section from appropriations under such subsection for fiscal years beginning after June 30, 1975.

Amendment by section 501(b) of Pub. L. 94–63 effective July 1, 1975, see section 608 of Pub. L. 94–63, set out as a note under section 247b of this title.

EFFECTIVE DATE OF 1971 AMENDMENT

Repeal of subsec. (f) of this section (less applicability to commissioned officers of the Public Health Service) by section 403(a) of Pub. L. 91–648, as amended by Pub. L. 94–454, §602(c), effective sixty days after Jan. 5, 1971, see section 404 of Pub. L. 91–648, set out as an Effective Date note under section 3371 of Title 5, Government Organization and Employees.

EFFECTIVE DATE OF 1970 AMENDMENTS

Pub. L. 91–515, title II, §260(c)(2), Oct. 30, 1970, 84 Stat. 1306, provided that: "The amendment made by paragraph (1) [amending this section] shall be effective with respect to grants under section 314(c) of the Public Health Service Act [42 U.S.C. 246(e)] which are made after the date of enactment of this Act [Oct. 30, 1970.]"

Pub. L. 91–296, title IV, §401(b)(1), June 30, 1970, 84 Stat. 352, provided that the amendment made by that section is effective with respect to appropriations for fiscal years beginning after June 30, 1970.

EFFECTIVE DATE OF 1967 AMENDMENT

Pub. L. 90–174, §2(d)(2), (f), Dec. 5, 1967, 81 Stat. 534, provided that the amendments made by that section are effective July 1, 1968.

Pub. L. 90–174, §3(b), Dec. 5, 1967, 81 Stat. 535, provided that the amendment of this section, the repeal of section 291n of this title, and the enactment of provisions set out as a note under section 242b of this title by such section 3(b) is effective with respect to appropriations for fiscal years ending after June 30, 1967.

EFFECTIVE DATE OF 1966 AMENDMENT

Pub. L. 89–749, §6, Nov. 3, 1966, 80 Stat. 1190, provided in part that: "The amendments made by section 3 [amending this section] shall become effective as of July 1, 1966, except that the provisions of section 314 of the Public Health Service Act [42 U.S.C. 246] as in effect prior to the enactment of this Act shall be effective until July 1, 1967, in lieu of the provisions of subsections (d) and (e), and the provisions of subsections (g) insofar as they relate to such subsections (d) and (e), of section 314 of the Public Health Service Act as amended by this Act."

EFFECTIVE DATE OF 1962 AMENDMENT

Pub. L. 87–688, §4(b), Sept. 25, 1962, 76 Stat. 587, provided that: "The amendments made by this section

[amending this section and sections 291g, 291i, and 291t of this title] shall become effective July 1, 1962."

EFFECTIVE AND TERMINATION DATE OF 1958 AMENDMENT

Pub. L. 85–544, §2, July 22, 1958, 72 Stat. 401, provided that: "The amendment made by the first section of this Act [amending this section] shall be applicable only to the fiscal years beginning July 1, 1958, and July 1, 1959."

EFFECTIVE DATE OF 1956 AMENDMENT

Act Aug. 1, 1956, ch. 852, §18, 70 Stat. 910, provided that the amendment made by that section is effective July 1, 1956.

REPEALS

The directory language of, but not the amendment made by, Pub. L. 96–398, title I, §107(d), cited as a credit to this section and set out as an Effective Date of 1980 Amendment note above, which provided for repeal of subsec. (g) of this section, effective Sept. 30, 1981, was repealed by section 902(e)(1) of Pub. L. 97–35, title IX, Aug. 13, 1981, 95 Stat. 560, effective Oct. 1, 1981.

TRANSFER OF FUNCTIONS

Functions, powers, and duties of Secretary of Health and Human Services under subsecs. (a)(2)(F) and (d)(2)(F) of this section, insofar as relates to the prescription of personnel standards on a merit basis, transferred to Office of Personnel Management, see section 4728(a)(3)(C) of this title.

YEAR 2000 HEALTH OBJECTIVES PLANNING

Pub. L. 101–582, Nov. 15, 1990, 104 Stat. 2867, provided for grants for State plans regarding health objectives for year 2000, prior to repeal by Pub. L. 102–531, title I, §105, Oct. 27, 1992, 106 Stat. 3474.

CONGRESSIONAL FINDINGS AND DECLARATION

Pub. L. 95–626, title II, §201(b)(1), Nov. 10, 1978, 92 Stat. 3570, provided that: "The Congress finds and declares that—

"(A) individual health status can be effectively and economically improved through an adequate investment in community public health programs and services;

"(B) the Federal Government and the States and their communities share in the financial responsibility for funding public health programs;

"(C) the Federal contribution to funds for public health programs should serve as an incentive to an additional investment by State and local governments;

"(D) existing categorical programs of Federal financial assistance to combat specific public health problems should be supplemented by a national program of stable generic support for such public health activities as the prevention and control of environmental health hazards, prevention and control of diseases, prevention and control of health problems of particularly vulnerable population groups, and development and regulation of health care facilities and health services delivery systems; and

"(E) the States and their communities, not the Federal Government, should have primary responsibility for identifying and measuring the impact of public health problems and the allocation of resources for their amelioration."

Pub. L. 89–749, §2, Nov. 3, 1966, 80 Stat. 1180, provided that:

"(a) The Congress declares that fulfillment of our national purpose depends on promoting and assuring the highest level of health attainable for every person, in an environment which contributes positively to healthful individual and family living; that attainment of this goal depends on an effective partnership, involving close intergovernmental collaboration, official and voluntary efforts, and participation of individuals and organizations; that Federal financial assistance must be directed to support the marshaling of all health resources—national, State, and local—to assure comprehensive health services of high quality for every person, but without interference with existing patterns of private professional practice of medicine, dentistry, and related healing arts.

"(b) To carry out such purpose, and recognizing the changing character of health problems, the Congress finds that comprehensive planning for health services, health manpower, and health facilities is essential at every level of government; that desirable administration requires strengthening the leadership and capacities of State health agencies; and that support of health services provided people in their communities should be broadened and made more flexible."

Act July 3, 1956, ch. 852, §2, 70 Stat. 908, provided that:

"(a) The Congress hereby finds and declares—

"(1) that the latest information on the number and relevant characteristics of persons in the country suffering from heart disease, cancer, diabetes, arthritis and rheumatism, and other diseases, injuries, and handicapping conditions is now seriously out of date; and

"(2) that periodic inventories providing reasonably current information on these matters are urgently needed for purposes such as (A) appraisal of the true state of health of our population (including both adults and children), (B) adequate planning of any programs to improve their health, (C) research in the field of chronic diseases, and (D) measurement of the numbers of persons in the working ages so disabled as to be unable to perform gainful work.

"(b) It is, therefore, the purpose of this Act [see Short Title of 1956 Amendment note set out under section 201 of this title] to provide (1) for a continuing survey and special studies to secure on a non-compulsory basis accurate and current statistical information on the amount, distribution, and effects of illness and disability in the United States and the services received for or because of such conditions; and (2) for studying methods and survey techniques for securing such statistical information, with a view toward their continuing improvement."

LIMITATION ON GRANTS-IN-AID TO SCHOOLS OF PUBLIC HEALTH

Pub. L. 85–544, §2, July 22, 1958, 72 Stat. 401, which had limited the authority of the Surgeon General to make grants-in-aid totaling not to exceed $1,000,000 annually to schools of public health for fiscal year beginning July 1, 1958, and July 1, 1959, was repealed by section 2 of Pub. L. 86–720, Sept. 8, 1960, 74 Stat. 820.

GRANTS TO STATES TO PROVIDE FOR VACCINATION AGAINST POLIOMYELITIS

The Poliomyelitis Vaccination Assistance Act of 1955, act Aug. 12, 1955, ch. 863, 69 Stat. 704, as amended Feb. 15, 1956, ch. 39, 70 Stat. 18, authorized appropriations to remain available until close of June 30, 1957 and provided for allotments to States, State application for funds, payments to States, use of funds paid to States, furnishing of vaccine by Surgeon General, diversion of Federal funds, supervision over exercise of functions, and definitions.

APPLICABILITY OF REORGANIZATION PLAN NO. 3 OF 1966

Pub. L. 89–749, §7, Nov. 3, 1966, 80 Stat. 1190, provided that: "The provisions enacted by this Act [amending this section and sections 242g and 243 of this title] shall be subject to the provisions of Reorganization Plan No. 3 of 1966 [42 U.S.C. 202 note]."

EXECUTIVE DOCUMENTS

TRANSFER OF FUNCTIONS

Functions of Federal Security Administrator transferred to Secretary of Health, Education, and Welfare and all agencies of Federal Security Agency transferred to Department of Health, Education, and Welfare by section 5 of Reorg. Plan No. 1 of 1953, set out as a note under section 3501 of this title. Federal Security Agency and office of Administrator abolished by section 8 of Reorg. Plan No. 1 of 1953.

§246a. Bureau of State Services management fund; establishment; advancements; availability

For the purpose of facilitating the economical and efficient conduct of operations in the Bureau of State Services which are financed by two or more appropriations where the costs of operation are not readily susceptible of distribution as charges to such appropriations, there is established the Bureau of State Services management fund. Such amounts as the Secretary may determine to represent a reasonable distribution of estimated costs among the various appropriations involved may be advanced each year to this fund and shall be available for expenditure for such costs under such regulations as may be prescribed by the Secretary: *Provided,* That funds advanced to this fund shall be available only in the fiscal year in which they are advanced: *Provided further,* That final adjustments of advances in accordance with actual costs shall be effected wherever practicable with the appropriations from which such funds are advanced.

(Pub. L. 86–703, title II, §201, Sept. 2, 1960, 74 Stat. 765; Pub. L. 91–515, title II, §282, Oct. 30, 1970, 84 Stat. 1308.)

EDITORIAL NOTES

CODIFICATION

Section was not enacted as part of the Public Health Service Act which comprises this chapter.

AMENDMENTS

1970—Pub. L. 91–515 substituted "Secretary" for "Surgeon General" wherever appearing.

§247. Assisting veterans with military emergency medical training to meet requirements for becoming civilian health care professionals

(a) Program

(1) In general

The Secretary may establish a program, in consultation with the Secretary of Labor, consisting of awarding demonstration grants to States to streamline State requirements and procedures in order to assist veterans who held certain military occupational specialties related to medical care or who have completed certain medical training while serving in the Armed Forces of the United States to meet certification, licensure, and other requirements applicable to civilian health care professions (such as emergency medical technician, paramedic, licensed practical nurse, registered nurse, physical therapy assistant, or physician assistant professions) in the State.

(2) Consultation and collaboration

In determining the eligible military occupational specialties or training courses and the assistance required as described in paragraph (1), the Secretary shall consult with the Secretary of Defense, the Secretary of Veterans Affairs, and the Assistant Secretary of Labor for Veterans' Employment and Training, and shall collaborate with the initiatives carried out under section 4114 of title 38 and sections 1142 through 1144 of title 10.

(b) Use of funds

Amounts received as a demonstration grant under this section shall be used to—

(1) prepare and implement a plan to streamline State requirements and procedures as described in subsection (a), including by—

(A) determining the extent to which the requirements for the education, training, and skill level of civilian health care professions (such as emergency medical technicians, paramedics, licensed practical nurses, registered nurses, physical therapy assistants, or physician assistants) in the State are equivalent to requirements for the education, training, and skill level of veterans who served in medical related fields while a member of the Armed Forces of the United States; and

(B) identifying methods, such as waivers, for veterans who served in medical related fields while a member of the Armed Forces of the United States to forgo or meet any such equivalent State requirements; and

(2) if necessary to meet workforce shortages or address gaps in education, training, or skill level to meet certification, licensure or other requirements applicable to becoming a civilian health care professional (such as an emergency medical technician, paramedic, licensed practical nurse, registered nurse, physical therapy assistant, or physician assistant professions) in the State, develop or expand career pathways at institutions of higher education to support veterans in meeting such requirements.

(c) Report

Upon the completion of the demonstration program under this section, the Secretary shall submit to Congress a report on the program.

(d) Funding

No additional funds are authorized to be appropriated for the purpose of carrying out this section. This section shall be carried out using amounts otherwise available for such purpose.

(e) Sunset

The demonstration program under this section shall not exceed 5 years.

(July 1, 1944, ch. 373, title III, §315, as added Pub. L. 114–198, title I, §105, July 22, 2016, 130 Stat. 701.)

EDITORIAL NOTES

PRIOR PROVISIONS

A prior section 247, act July 1, 1944, ch. 373, title III, §315, as added Oct. 4, 1988, Pub. L. 100–471, §1, 102 Stat. 2284, which related to grants for treatment drugs for acquired immune deficiency syndrome, ceased to exist Mar. 31, 1989, pursuant to subsec. (d) thereof.

Another prior section 247, act July 1, 1944, ch. 373, title III, §315, as added Nov. 10, 1978, Pub. L. 95–626, title II, §203, 92 Stat. 3578; amended July 10, 1979, Pub. L. 96–32, §6(h), 93 Stat. 83, related to formula grants to States for preventive health service programs, prior to repeal by Pub. L. 99–117, §12(b), Oct. 7, 1985, 99 Stat. 495.

Another prior section 247, acts July 1, 1944, ch. 373, title III, §315, 58 Stat. 695; Oct. 30, 1970, Pub. L. 91–515, title II, §282, 84 Stat. 1308, provided for publication of health educational information, prior to repeal by Pub. L. 93–353, title I, §102(a), July 23, 1974, 88 Stat. 362. See section 242o(b) of this title.

§247a. Family support groups for Alzheimer's disease patients

(a) Establishment; priorities

Subject to available appropriations, the Secretary, acting through the National Institute of Mental Health, the National Institutes of Health, and the Administration on Aging, shall promote the establishment of family support groups to provide, without charge, educational, emotional, and practical support to assist individuals with Alzheimer's disease or a related memory disorder and members of the families of such individuals. In promoting the establishment of such groups, the Secretary shall give priority to—

(1) university medical centers and other appropriate health care facilities which receive Federal funds from the Secretary and which conduct research on Alzheimer's disease or provide services to individuals with such disease; and

(2) community-based programs which receive funds from the Secretary, acting through the Administration on Aging.

(b) National network to coordinate groups

The Secretary shall promote the establishment of a national network to coordinate the family support groups described in subsection (a).

(July 1, 1944, ch. 373, title III, §316, as added Pub. L. 99–319, title IV, §401, May 23, 1986, 100 Stat. 489; amended Pub. L. 103–43, title XX, §2008(a), June 10, 1993, 107 Stat. 210.)

EDITORIAL NOTES

PRIOR PROVISIONS

A prior section 247a, act July 1, 1944, ch. 373, title III, §316, as added Nov. 10, 1978, Pub. L. 95–626, title II, §208(a), 92 Stat. 3586; amended Aug. 13, 1981, Pub. L. 97–35, title XXI, §2193(a)(1)(A), 95 Stat. 826, related to lead-based paint poisoning prevention programs, prior to repeal by Pub. L. 97–35, title XXI, §2193(b)(1), Aug. 13, 1981, 95 Stat. 827.

Another prior section 247a, act July 1, 1944, ch. 373, title III, §316, as added Oct. 30, 1970, Pub. L. 91–515, title II, §281, 84 Stat. 1307, provided for establishment, composition, qualifications of members,

terms of office, vacancies, reappointment, compensation, travel expenses, and functions of National Advisory Council on Comprehensive Health Planning Programs, prior to repeal by Pub. L. 93–641, §5(d), Jan. 4, 1975, 88 Stat. 2275.

AMENDMENTS

1993—Subsec. (c). Pub. L. 103–43 struck out subsec. (c) which read as follows: "The Secretary shall report to Congress, not later than one year after May 23, 1986, on family support groups and the network of such groups established pursuant to this section."

§247b. Project grants for preventive health services

(a) Grant authority

The Secretary may make grants to States, and in consultation with State health authorities, to political subdivisions of States and to other public entities to assist them in meeting the costs of establishing and maintaining preventive health service programs.

(b) Application

No grant may be made under section (a) [1] unless an application therefor has been submitted to, and approved by, the Secretary. Such an application shall be in such form and be submitted in such manner as the Secretary shall by regulation prescribe and shall provide—

(1) a complete description of the type and extent of the program for which the applicant is seeking a grant under subsection (a);

(2) with respect to each such program (A) the amount of Federal, State, and other funds obligated by the applicant in its latest annual accounting period for the provision of such program, (B) a description of the services provided by the applicant in such program in such period, (C) the amount of Federal funds needed by the applicant to continue providing such services in such program, and (D) if the applicant proposes changes in the provision of the services in such program, the priorities of such proposed changes, reasons for such changes, and the amount of Federal funds needed by the applicant to make such changes;

(3) assurances satisfactory to the Secretary that the program which will be provided with funds under a grant under subsection (a) will be provided in a manner consistent with the State health plan in effect under section 300m–3(c) [2] of this title and in those cases where the applicant is a State, that such program will be provided, where appropriate, in a manner consistent with any plans in effect under an application approved under section 247 [2] of this title;

(4) assurances satisfactory to the Secretary that the applicant will provide for such fiscal control and fund accounting procedures as the Secretary by regulation prescribes to assure the proper disbursement of and accounting for funds received under grants under subsection (a);

(5) assurances satisfactory to the Secretary that the applicant will provide for periodic evaluation of its program or programs;

(6) assurances satisfactory to the Secretary that the applicant will make such reports (in such form and containing such information as the Secretary may by regulation prescribe) as the Secretary may reasonably require and keep such records and afford such access thereto as the Secretary may find necessary to assure the correctness of, and to verify, such reports;

(7) assurances satisfactory to the Secretary that the applicant will comply with any other conditions imposed by this section with respect to grants; and

(8) such other information as the Secretary may by regulation prescribe.

(c) Approval; annual project review

(1) The Secretary shall not approve an application submitted under subsection (b) for a grant for a program for which a grant was previously made under subsection (a) unless the Secretary determines—

(A) the program for which the application was submitted is operating effectively to achieve its stated purpose,

(B) the applicant complied with the assurances provided the Secretary when applying for such previous grant, and

(C) the applicant will comply with the assurances provided with the application.

(2) The Secretary shall review annually the activities undertaken by each recipient of a grant under subsection (a) to determine if the program assisted by such grant is operating effectively to achieve its stated purposes and if the recipient is in compliance with the assurances provided the Secretary when applying for such grant.

(d) Amount of grant; payment

The amount of a grant under subsection (a) shall be determined by the Secretary. Payments under such grants may be made in advance on the basis of estimates or by the way of reimbursement, with necessary adjustments on account of underpayments or overpayments, and in such installments and on such terms and conditions as the Secretary finds necessary to carry out the purposes of such grants.

(e) Reduction

The Secretary, at the request of a recipient of a grant under subsection (a), may reduce the amount of such grant by—

(1) the fair market value of any supplies (including vaccines and other preventive agents) or equipment furnished the grant recipient, and

(2) the amount of the pay, allowances, and travel expenses of any officer or employee of the Government when detailed to the grant recipient and the amount of any other costs incurred in connection with the detail of such officer or employee,

when the furnishing of such supplies or equipment or the detail of such an officer or employee is for the convenience of and at the request of such grant recipient and for the purpose of carrying out a program with respect to which the grant under subsection (a) is made. The amount by which any such grant is so reduced shall be available for payment by the Secretary of the costs incurred in furnishing the supplies or equipment, or in detailing the personnel, on which the reduction of such grant is based, and such amount shall be deemed as part of the grant and shall be deemed to have been paid to the grant recipient.

(f) Recordkeeping; audit authority

(1) Each recipient of a grant under subsection (a) shall keep such records as the Secretary shall by regulation prescribe, including records which fully disclose the amount and disposition by such recipient of the proceeds of such grant, the total cost of the undertaking in connection with which such grant was made, and the amount of that portion of the cost of the undertaking supplied by other sources, and such other records as will facilitate an effective audit.

(2) The Secretary and the Comptroller General of the United States, or any of their duly authorized representatives, shall have access for the purpose of audit and examination to any books, documents, papers, and records of the recipient of grants under subsection (a) that are pertinent to such grants.

(g) Use of grant funds; mandatory treatment prohibited

(1) Nothing in this section shall limit or otherwise restrict the use of funds which are granted to a State or to an agency or a political subdivision of a State under provisions of Federal law (other than this section) and which are available for the conduct of preventive health service programs from being used in connection with programs assisted through grants under subsection (a).

(2) Nothing in this section shall be construed to require any State or any agency or political subdivision of a State to have a preventive health service program which would require any person, who objects to any treatment provided under such a program, to be treated or to have any child or ward treated under such program.

(h) Reports

The Secretary shall include, as part of the report required by section 300u–4 of this title, a report

on the extent of the problems presented by the diseases and conditions referred to in subsection (j); on the amount of funds obligated under grants under subsection (a) in the preceding fiscal year for each of the programs listed in subsection (j); and on the effectiveness of the activities assisted under grants under subsection (a) in controlling such diseases and conditions.

(i) Technical assistance

The Secretary may provide technical assistance to States, State health authorities, and other public entities in connection with the operation of their preventive health service programs.

(j) Authorization of appropriations

(1) Except for grants for immunization programs the authorization of appropriations for which are established in paragraph (2), for grants under subsections (a) and (k)(1) for preventive health service programs to immunize without charge children, adolescents, and adults against vaccine-preventable diseases, there are authorized to be appropriated such sums as may be necessary. Not more than 10 percent of the total amount appropriated under the preceding sentence for any fiscal year shall be available for grants under subsection (k)(1) for such fiscal year.

(2) For grants under subsection (a) for preventive health service programs for the provision without charge of immunizations with vaccines approved for use, and recommended for routine use, there are authorized to be appropriated such sums as may be necessary.

(k) Additional grants to States, political subdivisions, and other public and nonprofit private entities

(1) The Secretary may make grants to States, political subdivisions of States, and other public and nonprofit private entities for—

(A) research into the prevention and control of diseases that may be prevented through vaccination;

(B) demonstration projects for the prevention and control of such diseases;

(C) public information and education programs for the prevention and control of such diseases;

(D) education, training, and clinical skills improvement activities in the prevention and control of such diseases for health professionals (including allied health personnel);

(E) planning, implementation, and evaluation of activities to address vaccine-preventable diseases, including activities to—

(i) identify communities at high risk of outbreaks related to vaccine-preventable diseases, including through improved data collection and analysis;

(ii) pilot innovative approaches to improve vaccination rates in communities and among populations with low rates of vaccination;

(iii) reduce barriers to accessing vaccines and evidence-based information about the health effects of vaccines;

(iv) partner with community organizations and health care providers to develop and deliver evidence-based interventions, including culturally and linguistically appropriate interventions, to increase vaccination rates;

(v) improve delivery of evidence-based vaccine-related information to parents and others; and

(vi) improve the ability of State, local, Tribal, and territorial public health departments to engage communities at high risk for outbreaks related to vaccine-preventable diseases, including, as appropriate, with local educational agencies, as defined in section 7801 of title 20; and

(F) research related to strategies for improving awareness of scientific and evidence-based vaccine-related information, including for communities with low rates of vaccination, in order to understand barriers to vaccination, improve vaccination rates, and assess the public health outcomes of such strategies.

(2) The Secretary may make grants to States, political subdivisions of States, and other public and

nonprofit private entities for—

(A) research into the prevention and control of diseases and conditions;

(B) demonstration projects for the prevention and control of such diseases and conditions;

(C) public information and education programs for the prevention and control of such diseases and conditions; and

(D) education, training, and clinical skills improvement activities in the prevention and control of such diseases and conditions for health professionals (including allied health personnel).

(3) No grant may be made under this subsection unless an application therefor is submitted to the Secretary in such form, at such time, and containing such information as the Secretary may by regulation prescribe.

(4) Subsections (d), (e), and (f) of this section shall apply to grants under this subsection in the same manner as such subsections apply to grants under subsection (a) of this section.

(l) Authority to purchase recommended vaccines for adults

(1) In general

The Secretary may negotiate and enter into contracts with manufacturers of vaccines for the purchase and delivery of vaccines for adults as provided for under subsection (e).

(2) State purchase

A State may obtain additional quantities of such adult vaccines (subject to amounts specified to the Secretary by the State in advance of negotiations) through the purchase of vaccines from manufacturers at the applicable price negotiated by the Secretary under this subsection.

(m) Demonstration program to improve immunization coverage

(1) In general

The Secretary, acting through the Director of the Centers for Disease Control and Prevention, shall establish a demonstration program to award grants to States to improve the provision of recommended immunizations for children, adolescents, and adults through the use of evidence-based, population-based interventions for high-risk populations.

(2) State plan

To be eligible for a grant under paragraph (1), a State shall submit to the Secretary an application at such time, in such manner, and containing such information as the Secretary may require, including a State plan that describes the interventions to be implemented under the grant and how such interventions match with local needs and capabilities, as determined through consultation with local authorities.

(3) Use of funds

Funds received under a grant under this subsection shall be used to implement interventions that are recommended by the Task Force on Community Preventive Services (as established by the Secretary, acting through the Director of the Centers for Disease Control and Prevention) or other evidence-based interventions, including—

(A) providing immunization reminders or recalls for target populations of clients, patients, and consumers;

(B) educating targeted populations and health care providers concerning immunizations in combination with one or more other interventions;

(C) reducing out-of-pocket costs for families for vaccines and their administration;

(D) carrying out immunization-promoting strategies for participants or clients of public programs, including assessments of immunization status, referrals to health care providers, education, provision of on-site immunizations, or incentives for immunization;

(E) providing for home visits that promote immunization through education, assessments of need, referrals, provision of immunizations, or other services;

(F) providing reminders or recalls for immunization providers;

(G) conducting assessments of, and providing feedback to, immunization providers;

(H) any combination of one or more interventions described in this paragraph; or

(I) immunization information systems to allow all States to have electronic databases for immunization records.

(4) Consideration

In awarding grants under this subsection, the Secretary shall consider any reviews or recommendations of the Task Force on Community Preventive Services.

(5) Evaluation

Not later than 3 years after the date on which a State receives a grant under this subsection, the State shall submit to the Secretary an evaluation of progress made toward improving immunization coverage rates among high-risk populations within the State.

(6) Report to Congress

Not later than 4 years after March 23, 2010,[2] the Secretary shall submit to Congress a report concerning the effectiveness of the demonstration program established under this subsection together with recommendations on whether to continue and expand such program.

(7) Authorization of appropriations

There is authorized to be appropriated to carry out this subsection, such sums as may be necessary for each of fiscal years 2010 through 2014.

(n) Vaccination data

The Secretary, acting through the Director of the Centers for Disease Control and Prevention, shall expand and enhance, and, as appropriate, establish and improve, programs and conduct activities to collect, monitor, and analyze vaccination coverage data to assess levels of protection from vaccine-preventable diseases, including by assessing factors contributing to underutilization of vaccines and variations of such factors, and identifying communities at high risk of outbreaks associated with vaccine-preventable diseases.

(July 1, 1944, ch. 373, title III, §317, as added Pub. L. 87–868, §2, Oct. 23, 1962, 76 Stat. 1155; amended Pub. L. 89–109, §2, Aug. 5, 1965, 79 Stat. 435; Pub. L. 91–464, §2, Oct. 16, 1970, 84 Stat. 988; Pub. L. 92–449, title I, §101, Sept. 30, 1972, 86 Stat. 748; Pub. L. 93–354, §4, July 23, 1974, 88 Stat. 376; Pub. L. 94–63, title VI, §601, July 29, 1975, 89 Stat. 346; Pub. L. 94–317, title II, §202(a), June 23, 1976, 90 Stat. 700; Pub. L. 94–380, §2, Aug. 12, 1976, 90 Stat. 1113; Pub. L. 95–626, title II, §§202, 204(b)(2), Nov. 10, 1978, 92 Stat. 3574, 3583; Pub. L. 96–32, §6(i), July 10, 1979, 93 Stat. 83; Pub. L. 97–35, title IX, §928, Aug. 13, 1981, 95 Stat. 569; Pub. L. 98–555, §2, Oct. 30, 1984, 98 Stat. 2854; Pub. L. 99–117, §11(c), Oct. 7, 1985, 99 Stat. 495; Pub. L. 100–177, title I, §§110(a), 111, Dec. 1, 1987, 101 Stat. 990, 991; Pub. L. 101–368, §2, Aug. 15, 1990, 104 Stat. 446; Pub. L. 101–502, §2(a), Nov. 3, 1990, 104 Stat. 1285; Pub. L. 103–183, title III, §301(b), Dec. 14, 1993, 107 Stat. 2235; Pub. L. 105–392, title III, §303, Nov. 13, 1998, 112 Stat. 3586; Pub. L. 106–310, div. A, title XVII, §1711, Oct. 17, 2000, 114 Stat. 1152; Pub. L. 111–148, title IV, §4204(a)–(c), Mar. 23, 2010, 124 Stat. 571, 572; Pub. L. 116–260, div. BB, title III, §311(b), Dec. 27, 2020, 134 Stat. 2924.)

EDITORIAL NOTES

REFERENCES IN TEXT

Section 300m–3 of this title, referred to in subsec. (b)(3), was repealed by Pub. L. 99–660, title VII, §701(a), Nov. 14, 1986, 100 Stat. 3799.

Section 247 of this title, referred to in subsec. (b)(3), was repealed by Pub. L. 99–117, §12(b), Oct. 7, 1985, 99 Stat. 495.

March 23, 2010, referred to in subsec. (m)(6), was in the original "the date of enactment of the Affordable Health Choices Act", and was translated as meaning the date of enactment of the Patient Protection and Affordable Care Act, Pub. L. 111–148, to reflect the probable intent of Congress. No act named the

"Affordable Health Choices Act" has been enacted.

AMENDMENTS

2020—Subsec. (k)(1)(E), (F). Pub. L. 116–260, §311(b)(1), added subpars. (E) and (F).

Subsec. (n). Pub. L. 116–260, §311(b)(2), added subsec. (n).

2010—Subsec. (j)(1). Pub. L. 111–148, §4204(c)(1), struck out "for each of the fiscal years 1998 through 2005" after "necessary".

Subsec. (j)(2). Pub. L. 111–148, §4204(c)(2), struck out "after October 1, 1997," after "routine use,".

Subsecs. (l), (m). Pub. L. 111–148, §4204(a), (b), added subsecs. (l) and (m).

2000—Subsec. (j)(1). Pub. L. 106–310 substituted "1998 through 2005" for "1998 through 2002" in first sentence.

1998—Subsec. (j)(1). Pub. L. 105–392, §303(1), substituted "children, adolescents, and adults against vaccine-preventable diseases, there are authorized to be appropriated such sums as may be necessary for each of the fiscal years 1998 through 2002." for "individuals against vaccine-preventable diseases, there are authorized to be appropriated $205,000,000 for fiscal year 1991, and such sums as may be necessary for each of the fiscal years 1992 through 1995."

Subsec. (j)(2). Pub. L. 105–392, §303(2), substituted "1997" for "1990".

1993—Subsec. (j). Pub. L. 103–183, §301(b)(1), redesignated subpars. (A) and (B) of par. (1) as pars. (1) and (2), respectively, substituted "established in paragraph (2)" for "established in subparagraph (B)" in par. (1), and struck out former par. (2), which read as follows: "For grants under subsection (a) of this section for preventive health service programs for the prevention, control, and elimination of tuberculosis, and for grants under subsection (k)(2) of this section, there are authorized to be appropriated $24,000,000 for fiscal year 1988, $31,000,000 for fiscal year 1989, $36,000,000 for fiscal year 1990, $36,000,000 for fiscal year 1991, and such sums as may be necessary for each of the fiscal years 1992 through 1995. Not more than 10 percent of the total amount appropriated under the preceding sentence for any fiscal year shall be available for grants under subsection (k)(2) of this section for such fiscal year."

Subsec. (k)(2). Pub. L. 103–183, §301(b)(2)(A), (B), redesignated par. (3) as (2) and struck out former par. (2) which read as follows: "The Secretary may make grants to States, political subdivisions of States, and other public and nonprofit private entities for—

"(A) research into the prevention, control, and elimination of tuberculosis, especially research concerning strains of tuberculosis resistant to drugs and research concerning cases of tuberculosis that affect certain populations;

"(B) demonstration projects for the prevention, control, and elimination of tuberculosis;

"(C) public information and education programs for prevention, control, and elimination of tuberculosis; and

"(D) education, training, and clinical skills improvement activities in the prevention, control, and elimination of tuberculosis for health professionals, including allied health personnel."

Subsec. (k)(3). Pub. L. 103–183, §301(b)(2)(B), redesignated par. (4) as (3). Former par. (3) redesignated (2).

Subsec. (k)(4), (5). Pub. L. 103–183, §301(b)(2)(B), (C), redesignated par. (5) as (4) and made technical amendments to references to subsections (d), (e), and (f) of this section and subsection (a) of this section, to reflect change in references to corresponding provisions of original act. Former par. (4) redesignated (3).

Subsec. (l). Pub. L. 103–183, §301(b)(3), struck out subsec. (l) which related to establishment and function of Advisory Council for the Elimination of Tuberculosis.

1990—Subsec. (j)(1)(A). Pub. L. 101–502, §2(a)(1), substituted provisions authorizing appropriations for fiscal years 1991 through 1995 for provisions authorizing appropriations for fiscal years 1988 through 1990.

Subsec. (j)(1)(B). Pub. L. 101–502, §2(a)(2), substituted Oct. 1, 1990, for Dec. 1, 1987, and provisions authorizing appropriations as may be necessary for provisions authorizing appropriations for fiscal years 1988 to 1990.

Subsec. (j)(1)(C). Pub. L. 101–502, §2(a)(3), struck out subpar. (C) which, on the implementation of part 2 of subchapter XIX of this chapter, authorized appropriations for grants under subsec. (a) of this section for fiscal years 1988 to 1990.

Subsec. (j)(2). Pub. L. 101–368, §2(c), inserted provisions authorizing appropriations of $36,000,000 for fiscal year 1991, and such sums as may be necessary for fiscal years 1992 through 1995.

Pub. L. 101–368, §2(a)(1), substituted "preventive health service programs for the prevention, control, and elimination of tuberculosis" for "preventive health service programs for tuberculosis".

Subsec. (k)(2)(A) to (D). Pub. L. 101–368, §2(a)(2), substituted "prevention, control, and elimination" for "prevention and control".

Subsec. (l). Pub. L. 101–368, §2(b), added subsec. (l).

1987—Subsec. (j). Pub. L. 100–177, §§110(a), 111(a), amended subsec. (j) generally, substituting provisions authorizing appropriations for fiscal years 1988 to 1990 for grants under subsecs. (a) and (k) of this section for former provisions authorizing appropriations for fiscal years 1982 to 1987 for grants under subsec. (a) of this section.

Subsec. (k). Pub. L. 100–177, §111(b), added subsec. (k).

1985—Subsec. (j). Pub. L. 99–117 amended directory language of Pub. L. 97–35, §928(b), to correct a technical error. See 1981 Amendment note below.

1984—Subsec. (j)(1). Pub. L. 98–555, §2(a), substituted "immunize individuals against vaccine-preventable diseases" for "immunize children against immunizable diseases" and inserted provisions authorizing appropriations for fiscal years ending Sept. 30, 1985, 1986, and 1987.

Subsec. (j)(2). Pub. L. 98–555, §2(b), inserted provisions authorizing appropriations for fiscal years ending Sept. 30, 1985, 1986, and 1987.

1981—Subsec. (a). Pub. L. 97–35, §928(a), struck out par. (1) which related to grants to State health authorities, and redesignated par. (2) as entire section and, as so redesignated, struck out reference to former par. (1).

Subsec. (j). Pub. L. 97–35, §928(b), as amended by Pub. L. 99–117, substituted provisions authorizing appropriations for fiscal years ending Sept. 30, 1982, 1983, and 1984, for provisions setting forth appropriations through fiscal year ending Sept. 30, 1981, and provisions setting forth limitations, conditions, etc., for appropriations.

1979—Subsec. (j)(4), (5). Pub. L. 96–32 added par. (4), redesignated former par. (4) as (5) and, in par. (5) as so redesignated, substituted "paragraph (1), (2), (3), or (4)" for "paragraph (1), (2), or (3)".

1978—Pub. L. 95–626, §202, amended section generally, substituting provisions relating to project grants for preventive health services for provisions relating to grants for disease control programs.

Subsec. (g)(2). Pub. L. 95–626, §204(b)(2), struck out "Except as provided in section 247c of this title," before "No funds appropriated under any provision of this chapter".

1976—Pub. L. 94–317 amended section generally to include many non-communicable diseases as well as expanding coverage of communicable diseases, increased appropriations for grants, widened scope of Secretary's authority to make grants and enter into contracts to include nonprofit private entities, and required a report from the Secretary on the effectiveness of all Federal and other public and private activities in controlling the diseases covered under this section.

Subsecs. (j) to (l). Pub. L. 94–380 added subsecs. (j) to (l).

1975—Subsec. (d)(3). Pub. L. 94–63, §601(b), inserted authorization of appropriation for fiscal year 1976.

Subsec. (h)(1). Pub. L. 94–63, §601(a), inserted reference to diseases borne by rodents.

1974—Subsec. (a). Pub. L. 93–354, §4(1)–(3), substituted "communicable and other disease control" for "communicable disease control", "communicable and other diseases" for "communicable diseases", and "communicable and other disease control program" for "communicable disease program".

Subsec. (b)(2)(C). Pub. L. 93–354, §4(1), (4), substituted "communicable or other disease" for "communicable disease" in cl. (i) and "communicable and other disease control" for "communicable disease control" in cl. (ii).

Subsecs. (b)(3), (d)(1), (2), (3), (f)(1). Pub. L. 93–354, §4(1), substituted "communicable and other disease control" for "communicable disease control".

Subsec. (h)(1). Pub. L. 93–354, §4(1), (5), substituted "communicable and other disease control" for "communicable disease control" in two places and inserted reference to diabetes mellitus.

Subsec. (i). Pub. L. 93–354, §4(1), substituted "communicable and other disease control" for "communicable disease control".

1972—Subsec. (a). Pub. L. 92–449 substituted provision for grants by the Secretary in consultation with the State health authority to agencies and political subdivisions of States, for former provision for grants by the Secretary with the approval of the State health authority to political subdivisions or instrumentalities of States, incorporated existing provisions in provision designated as cl. (1), inserting ", in the area served by the applicant for the grant,", substituted a cl. (2) reading "design of the applicant's communicable disease program to determine its effectiveness", for former provision reading "levels of performance in preventing and controlling such diseases", struck out appropriations authorization of $75,000,000 and $90,000,000 for fiscal years ending June 30, 1971, and 1972, now covered for subsequent years in subsec. (d), and struck out provision for use of grants to meet cost of studies to determine the control needs of communities and the means of best meeting such needs, now covered in subsec. (h)(1) of this section.

Subsec. (b). Pub. L. 92–449 substituted provisions of par. (1) respecting applications for grants, submission, approval, form, and content of applications; par. (2) respecting application requirements; and par. (3)

incorporating former subsec. (g) provisions respecting consent of individuals for former definitions provision now incorporated in subsec. (h) of this section.

Subsec. (c). Pub. L. 92–449 designated existing provisions as par. (1) and among minor punctuation changes inserted "under grants" after "Payments"; and redesignated former subsec. (d) as par. (2), inserted "of the Government" after "officer or employee", substituted "in detailing the personnel" for "personal services", and struck out provision that reduced amount shall, for purposes of subsec. (c), be deemed to have been paid to the agency.

Subsec. (d). Pub. L. 92–449 substituted provisions respecting authorization of appropriations and limitation on use of funds for provisions respecting grant reduction.

Subsec. (e). Pub. L. 92–449 substituted provisions for emergency plan development and authorization of appropriations for provisions relating to use of funds.

Subsec. (f). Pub. L. 92–449 substituted provisions respecting conditional limitation on use of funds for provisions for an annual report.

Subsec. (g). Pub. L. 92–449 incorporated former subsec. (f) provisions in introductory text and cl. (3), prescribed a January 1 submission date, and inserted provisions of cls. (1), (2), and (4). Former subsec. (g) consent of individuals provision respecting communicable disease control and vaccination assistance were covered in subsec. (b)(3) of this section and section 247c(h) of this title.

Subsec. (h). Pub. L. 92–449 redesignated former subsec. (b) as (h), substituted in introductory text "this section" for "this subsection", and in par. (1) struck out "venereal disease" after "tuberculosis,", inserted "(other than venereal disease)" after "other communicable diseases", and included in definition of "communicable disease control program" vaccination programs, laboratory services, and control studies.

Subsec. (i). Pub. L. 92–449 redesignated former subsec. (e) as (i), inserted reference to agency of a State, and substituted "under provisions of Federal law (other than this chapter)" for "under other provisions of this chapter or other Federal law".

1970—Subsec. (a). Pub. L. 91–464 authorized appropriation of $75,000,000 for fiscal year ending June 30, 1971, and $90,000,000 for fiscal year ending June 30, 1972, and made award of grants dependent upon extent of communicable disease and success of programs and permitted use of grants for meeting cost of programs and studies to control communicable diseases and struck out reference to purchase of vaccines and use of grants for salaries and expenses of personnel and to authority of the Surgeon General.

Subsec. (b). Pub. L. 91–464 substituted definitions of "communicable disease control program" and "State" for definition of "immunization program".

Subsec. (c). Pub. L. 91–464 substituted reference to Secretary for reference to Surgeon General and struck out provisions relating to purchasing and furnishing of vaccines and requirement of obtaining assurances from recipients of grants.

Subsec. (d). Pub. L. 91–464 substituted reference to Secretary for reference to Surgeon General and struck out reference to Public Health Service.

Subsec. (e). Pub. L. 91–464 struck out reference to title V of the Social Security Act and substituted provisions for the use of funds for the conduct of communicable disease control programs for provisions for the purchase of vaccine or for organizing, promoting, conducting, or participating in immunization programs.

Subsecs. (f), (g). Pub. L. 91–464 added subsecs. (f) and (g).

1965—Subsec. (a). Pub. L. 89–109, §2(a), (b), (d)(1), inserted "and each of the next three fiscal years", substituted "any fiscal year ending prior to July 1, 1968" for "the fiscal years ending June 30, 1963, and June 30, 1964", "tetanus, and measles" for "and tetanus", "of preschool age" for "under the age of five years", and "immunization" for "intensive community vaccination", and permitted grants to be used to pay costs in connection with immunization of other infectious diseases.

Subsec. (b). Pub. L. 89–109, §2(c), (d)(1), substituted "against the diseases referred to in subsection (a) of this section" for "against poliomyelitis, diphtheria, whooping cough, and tetanus", "of preschool age" for "who are under the age of five years" and "immunization" for "intensive community vaccination" in two places.

Subsec. (c). Pub. L. 89–109, §2(d)(1), (e), inserted "on the basis of estimates" and "(with necessary adjustments on account of underpayments or overpayments)" in par. (1), and substituted "immunization" for "intensive community vaccination" in pars. (2) and (3).

STATUTORY NOTES AND RELATED SUBSIDIARIES

EFFECTIVE DATE OF 1978 AMENDMENT

Pub. L. 95–626, title II, §202, Nov. 10, 1978, 92 Stat. 3574, as amended by Pub. L. 96–32, §6(g), July 10, 1979, 93 Stat. 83, provided that the amendment made by that section is effective Oct. 1, 1978.

EFFECTIVE DATE OF 1976 AMENDMENT

Pub. L. 94–317, title II, §202(a), Nov. 10, 1978, 92 Stat. 3574, provided that the amendment made by that section is effective with respect to grants under this section for fiscal years beginning after June 30, 1975.

EFFECTIVE DATE OF 1975 AMENDMENT

Pub. L. 94–63, title VI, §608, July 29, 1975, 89 Stat. 352, provided that: "Except as may otherwise be specifically provided, the amendments made by this title [enacting sections 300c–21 and 300c–22 of this title, amending this section, and enacting provisions set out as notes under sections 289, 289k–2, and 1395x of this title] and by titles I [amending section 246 of this title and enacting provisions set out as notes under section 246 of this title], II [enacting sections 300a–6a and 300a–8 of this title, amending sections 300 and 300a–1 to 300a–4 of this title, repealing section 3505c of this title, and enacting provision set out as a note under section 300 of this title], III [enacting sections 2689 to 2689aa of this title, amending sections 2691 and 2693 to 2696 of this title, and enacting provisions set out as notes under section 2689 of this title], IV [amending sections 218 and 254b of this title and enacting provision set out as a note under section 254b of this title], and V [enacting section 254c of this title and amending section 246 of this title] of this Act shall take effect July 1, 1975. The amendments made by this title and by such titles to the provisions of law amended by this title and by such titles are made to such provisions as amended by title VII of this Act [amending sections 246, 254b, 300, 300a–1 to 300a–3 of this title and sections 2681, 2687, 2688a, 2688d, 2688j–1, 2688j–2, 2688l, 2688l–1, 2688n–1, 2688o, and 2688u of this title]."

EFFECTIVE DATE OF 1972 AMENDMENT

Pub. L. 92–449, title I, §102, Sept. 30, 1972, 86 Stat. 750, provided that: "The amendment made by section 101 of this title [amending this section] shall apply to grants made under section 317 of the Public Health Service Act [42 U.S.C. 247b] after June 30, 1972, except that subsection (d) of such section as amended by section 101 shall take effect on the date of enactment of this Act [Sept. 30, 1972]."

RULE OF CONSTRUCTION REGARDING ACCESS TO IMMUNIZATIONS

Pub. L. 111–148, title IV, §4204(d), Mar. 23, 2010, 124 Stat. 572, provided that: "Nothing in this section [amending this section] (including the amendments made by this section), or any other provision of this Act [see Tables for classification] (including any amendments made by this Act) shall be construed to decrease children's access to immunizations."

ASSISTANCE OF ADMINISTRATOR OF VETERANS' AFFAIRS IN ADMINISTRATION OF NATIONAL SWINE FLU IMMUNIZATION PROGRAM OF 1976; CLAIMS FOR DAMAGES

Pub. L. 94–420, §3, Sept. 23, 1976, 90 Stat. 1301, provided that, in order to assist Secretary of Health, Education, and Welfare in carrying out National Swine Flu Immunization Program of 1976 pursuant to 42 U.S.C. 247b(j), as added by Pub. L. 94–380, Administrator of Veterans' Affairs, in accordance with 42 U.S.C. 247b(j), could authorize administration of vaccine, procured under such program and provided by Secretary at no cost to Veterans' Administration, to eligible veterans (voluntarily requesting such vaccine) in connection with provision of care for a disability under chapter 17 of title 38, in any health care facility under jurisdiction of Administrator, and provided for consideration and processing of claims and suits for damages for personal injury or death, in connection with administration of vaccine.

STUDY BY SECRETARY OF SCOPE AND EXTENT OF LIABILITY ARISING OUT OF IMMUNIZATION PROGRAM; ALTERNATIVE PROTECTIVE APPROACHES; REPORT TO CONGRESS

Pub. L. 94–380, §3, Aug. 12, 1976, 90 Stat. 1118, directed Secretary to conduct a study of liability for personal injuries or death arising out of immunization programs and of alternative approaches to provide protection against such liability and report to Congress on findings of such study by Aug. 12, 1977.

[1] *So in original. Probably should be "subsection (a)".*

[2] *See References in Text note below.*

§247b–1. Screenings, referrals, and education regarding lead poisoning

(a) Authority for grants

(1) In general

Subject to paragraph (2), the Secretary, acting through the Director of the Centers for Disease Control and Prevention, may make grants to States and political subdivisions of States for the initiation and expansion of community programs designed—

(A) to provide, for infants and children—

(i) screening for elevated blood lead levels;

(ii) referral for treatment of such levels; and

(iii) referral for environmental intervention associated with such levels; and

(B) to provide education about childhood lead poisoning.

(2) Authority regarding certain entities

With respect to a geographic area with a need for activities authorized in paragraph (1), in any case in which neither the State nor the political subdivision in which such area is located has applied for a grant under paragraph (1), the Secretary may make a grant under such paragraph to any grantee under section 254b, 254b, or 256a of this title [1] for carrying out such activities in the area.

(3) Provision of all services and activities through each grantee

In making grants under paragraph (1), the Secretary shall ensure that each of the activities described in such paragraph is provided through each grantee under such paragraph. The Secretary may authorize such a grantee to provide the services and activities directly, or through arrangements with other providers.

(b) Status as medicaid provider

(1) In general

Subject to paragraph (2), the Secretary may not make a grant under subsection (a) unless, in the case of any service described in such subsection that is made available pursuant to the State plan approved under title XIX of the Social Security Act [42 U.S.C. 1396 et seq.] for the State involved—

(A) the applicant for the grant will provide the service directly, and the applicant has entered into a participation agreement under the State plan and is qualified to receive payments under such plan; or

(B) the applicant will enter into an agreement with a provider under which the provider will provide the service, and the provider has entered into such a participation agreement and is qualified to receive such payments.

(2) Waiver regarding certain secondary agreements

(A) In the case of a provider making an agreement pursuant to paragraph (1)(B) regarding the provision of services, the requirement established in such paragraph regarding a participation agreement shall be waived by the Secretary if the provider does not, in providing health care services, impose a charge or accept reimbursement available from any third-party payor, including reimbursement under any insurance policy or under any Federal or State health benefits plan.

(B) A determination by the Secretary of whether a provider referred to in subparagraph (A) meets the criteria for a waiver under such subparagraph shall be made without regard to whether the provider accepts voluntary donations regarding the provision of services to the public.

(c) Priority in making grants

In making grants under subsection (a), the Secretary shall give priority to applications for programs that will serve areas with a high incidence of elevated blood lead levels in infants and children.

(d) Grant application

No grant may be made under subsection (a), unless an application therefor has been submitted to, and approved by, the Secretary. Such an application shall be in such form and shall be submitted in

such manner as the Secretary shall prescribe and shall include each of the following:

(1) A complete description of the program which is to be provided by or through the applicant.

(2) Assurances satisfactory to the Secretary that the program to be provided under the grant applied for will include educational programs designed to—

(A) communicate to parents, educators, and local health officials the significance and prevalence of lead poisoning in infants and children (including the sources of lead exposure, the importance of screening young children for lead, and the preventive steps that parents can take in reducing the risk of lead poisoning) which the program is designed to detect and prevent; and

(B) communicate to health professionals and paraprofessionals updated knowledge concerning lead poisoning and research (including the health consequences, if any, of low-level lead burden; the prevalence of lead poisoning among all socioeconomic groupings; the benefits of expanded lead screening; and the therapeutic and other interventions available to prevent and combat lead poisoning in affected children and families).

(3) Assurances satisfactory to the Secretary that the applicant will report on a quarterly basis the number of infants and children screened for elevated blood lead levels, the number of infants and children who were found to have elevated blood lead levels, the number and type of medical referrals made for such infants and children, the outcome of such referrals, and other information to measure program effectiveness.

(4) Assurances satisfactory to the Secretary that the applicant will make such reports respecting the program involved as the Secretary may require.

(5) Assurances satisfactory to the Secretary that the applicant will coordinate the activities carried out pursuant to subsection (a) with related activities and services carried out in the State by grantees under title V or XIX of the Social Security Act [42 U.S.C. 701 et seq., 1396 et seq.].

(6) Assurances satisfactory to the Secretary that Federal funds made available under such a grant for any period will be so used as to supplement and, to the extent practical, increase the level of State, local, and other non-Federal funds that would, in the absence of such Federal funds, be made available for the program for which the grant is to be made and will in no event supplant such State, local, and other non-Federal funds.

(7) Assurances satisfactory to the Secretary that the applicant will ensure complete and consistent reporting of all blood lead test results from laboratories and health care providers to State and local health departments in accordance with guidelines of the Centers for Disease Control and Prevention for standardized reporting as described in subsection (m).

(8) Such other information as the Secretary may prescribe.

(e) Relationship to services and activities under other programs

(1) In general

A recipient of a grant under subsection (a) may not make payments from the grant for any service or activity to the extent that payment has been made, or can reasonably be expected to be made, with respect to such service or activity—

(A) under any State compensation program, under an insurance policy, or under any Federal or State health benefits program; or

(B) by an entity that provides health services on a prepaid basis.

(2) Applicability to certain secondary agreements for provision of services

Paragraph (1) shall not apply in the case of a provider through which a grantee under subsection (a) provides services under such subsection if the Secretary has provided a waiver under subsection (b)(2) regarding the provider.

(f) Method and amount of payment

The Secretary shall determine the amount of a grant made under subsection (a). Payments under such grants may be made in advance on the basis of estimates or by way of reimbursement, with

necessary adjustments on account of underpayments or overpayments, and in such installments and on such terms and conditions as the Secretary finds necessary to carry out the purposes of such grants. Not more than 10 percent of any grant may be obligated for administrative costs.

(g) Supplies, equipment, and employee detail

The Secretary, at the request of a recipient of a grant under subsection (a), may reduce the amount of such grant by—

(1) the fair market value of any supplies or equipment furnished the grant recipient; and

(2) the amount of the pay, allowances, and travel expenses of any officer or employee of the Government when detailed to the grant recipient and the amount of any other costs incurred in connection with the detail of such officer or employee;

when the furnishing of such supplies or equipment or the detail of such an officer or employee is for the convenience of and at the request of such grant recipient and for the purpose of carrying out a program with respect to which the grant under subsection (a) is made. The amount by which any such grant is so reduced shall be available for payment by the Secretary of the costs incurred in furnishing the supplies or equipment, or in detailing the personnel, on which the reduction of such grant is based, and such amount shall be deemed as part of the grant and shall be deemed to have been paid to the grant recipient.

(h) Records

Each recipient of a grant under subsection (a) shall keep such records as the Secretary shall prescribe, including records which fully disclose the amount and disposition by such recipient of the proceeds of such grant, the total cost of the undertaking in connection with which such grant was made, and the amount of that portion of the cost of the undertaking supplied by other sources, and such other records as will facilitate an effective audit.

(i) Audit and examination of records

The Secretary and the Comptroller General of the United States, or any of their duly authorized representatives, shall have access for the purpose of audit and examination to any books, documents, papers, and records of the recipient of a grant under subsection (a), that are pertinent to such grant.

(j) Annual report

(1) In general

Not later than May 1 of each year, the Secretary shall submit to the Congress a report on the effectiveness during the preceding fiscal year of programs carried out with grants under subsection (a) and of any programs that are carried out by the Secretary pursuant to subsection (l)(2).

(2) Certain requirements

Each report under paragraph (1) shall include, in addition to any other information that the Secretary may require, the following information:

(A) The number of infants and children screened.

(B) Demographic information on the population of infants and children screened, including the age and racial or ethnic status of such population.

(C) The number of screening sites.

(D) A description of the severity of the extent of the blood lead levels of the infants and children screened, expressed in categories of severity.

(E) The sources of payment for the screenings.

(F) The number of grantees that have established systems to ensure mandatory reporting of all blood lead tests from laboratories and health care providers to State and local health departments.

(G) A comparison of the data provided pursuant to subparagraphs (A) through (F) with the equivalent data, if any, provided in the report under paragraph (1) preceding the report involved.

(k) Indian tribes

For purposes of this section, the term "political subdivision" includes Indian tribes.

(l) Funding

(1) Authorization of appropriations

For the purpose of carrying out this section, there are authorized to be appropriated $40,000,000 for fiscal year 1993, and such sums as may be necessary for each of the fiscal years 1994 through 2005.

(2) Allocation for other programs

Of the amounts appropriated under paragraph (1) for any fiscal year, the Secretary may reserve not more than 20 percent for carrying out programs regarding the activities described in subsection (a) in addition to the program of grants established in such subsection.

(m) Guidelines for standardized reporting

The Secretary, acting through the Director of the Centers for Disease Control and Prevention, shall develop national guidelines for the uniform reporting of all blood lead test results to State and local health departments.

(July 1, 1944, ch. 373, title III, §317A, as added Pub. L. 100–572, §3, Oct. 31, 1988, 102 Stat. 2887; amended Pub. L. 102–531, title III, §303(a), Oct. 27, 1992, 106 Stat. 3484; Pub. L. 103–183, title VII, §705(a), Dec. 14, 1993, 107 Stat. 2241; Pub. L. 105–392, title IV, §404, Nov. 13, 1998, 112 Stat. 3588; Pub. L. 106–310, div. A, title XXV, §§2501(a), (b), 2504, Oct. 17, 2000, 114 Stat. 1161, 1164; Pub. L. 107–251, title VI, §601(a), Oct. 26, 2002, 116 Stat. 1664; Pub. L. 108–163, §2(m)(1), Dec. 6, 2003, 117 Stat. 2023.)

EDITORIAL NOTES

REFERENCES IN TEXT

The reference to section 254b of this title the first place appearing, referred to in subsec. (a)(2), was in the original a reference to section 329, meaning section 329 of act July 1, 1944, which was omitted in the general amendment of subpart I (§254b et seq.) of part D of this subchapter by Pub. L. 104–299, §2, Oct. 11, 1996, 110 Stat. 3626.

Section 256a of this title, referred to in subsec. (a)(2), was repealed by Pub. L. 104–299, §4(a)(3), Oct. 11, 1996, 110 Stat. 3645.

The Social Security Act, referred to in subsecs. (b)(1) and (d)(5), is act Aug. 14, 1935, ch. 531, 49 Stat. 620. Titles V and XIX of the Act are classified generally to subchapters V (§701 et seq.) and XIX (§1396 et seq.), respectively, of chapter 7 of this title. For complete classification of this Act to the Code, see section 1305 of this title and Tables.

PRIOR PROVISIONS

A prior section 247b–1, Pub. L. 95–626, title IV, §401, Nov. 10, 1978, 92 Stat. 3590; S. Res. 30, Mar. 7, 1979; Pub. L. 96–88, title V, §509(b), Oct. 17, 1979, 93 Stat. 695; H. Res. 549, Mar. 25, 1980, related to demonstration and evaluation of optimal methods for organizing and delivering comprehensive preventive health services to defined populations, prior to repeal by Pub. L. 97–35, title IX, §902(a), (h), Aug. 13, 1981, 95 Stat. 559, 561, eff. Oct. 1, 1981.

AMENDMENTS

2003—Subsec. (a)(2). Pub. L. 108–163 substituted "254b" for "254c, 254b(h)" before ", or".

2002—Subsec. (a)(2). Pub. L. 107–251 substituted "254b(h)" for "256".

2000—Subsec. (d)(7), (8). Pub. L. 106–310, §2501(a)(1), added par. (7) and redesignated former par. (7) as (8).

Subsec. (j)(2)(F), (G). Pub. L. 106–310, §2501(a)(2), added subpar. (F), redesignated former subpar. (F) as (G), and substituted "(F)" for "(E)".

Subsec. (l)(1). Pub. L. 106–310, §2504, substituted "1994 through 2005" for "1994 through 2002".

Subsec. (m). Pub. L. 106–310, §2501(b), added subsec. (m).

1998—Subsec. (l)(1). Pub. L. 105–392 substituted "2002" for "1998".

1993—Subsec. (l)(1). Pub. L. 103–183 substituted "through 1998" for "through 1997".

1992—Pub. L. 102–531 amended section generally, substituting present provisions for provisions relating to grants to States for lead poisoning prevention, grant applications, conditions for approval, method and amount of payment, reduction of amount, recordkeeping and audits, inclusion of Indian tribes as grant recipients, and authorization of appropriations.

STATUTORY NOTES AND RELATED SUBSIDIARIES

EFFECTIVE DATE OF 2003 AMENDMENT

Amendment by Pub. L. 108–163 deemed to have taken effect immediately after the enactment of Pub. L. 107–251, see section 3 of Pub. L. 108–163, set out as a note under section 233 of this title.

DEVELOPMENT AND IMPLEMENTATION OF EFFECTIVE DATA MANAGEMENT BY THE CENTERS FOR DISEASE CONTROL AND PREVENTION

Pub. L. 106–310, div. A, title XXV, §2501(c), Oct. 17, 2000, 114 Stat. 1161, provided that:

"(1) IN GENERAL.—The Director of the Centers for Disease Control and Prevention shall—

"(A) assist with the improvement of data linkages between State and local health departments and between State health departments and the Centers for Disease Control and Prevention;

"(B) assist States with the development of flexible, comprehensive State-based data management systems for the surveillance of children with lead poisoning that have the capacity to contribute to a national data set;

"(C) assist with the improvement of the ability of State-based data management systems and federally-funded means-tested public benefit programs (including the special supplemental food program for women, infants and children (WIC) under section 17 of the Child Nutrition Act of 1966 (42 U.S.C. 1786) and the early head start program under section 645A of the Head Start Act (42 U.S.C. 9840a(h)) to respond to ad hoc inquiries and generate progress reports regarding the lead blood level screening of children enrolled in those programs;

"(D) assist States with the establishment of a capacity for assessing how many children enrolled in the Medicaid, WIC, early head start, and other federally-funded means-tested public benefit programs are being screened for lead poisoning at age-appropriate intervals;

"(E) use data obtained as result of activities under this section to formulate or revise existing lead blood screening and case management policies; and

"(F) establish performance measures for evaluating State and local implementation of the requirements and improvements described in subparagraphs (A) through (E).

"(2) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated to carry out this subsection such sums as may be necessary for each [sic] the fiscal years 2001 through 2005.

"(3) EFFECTIVE DATE.—This subsection takes effect on the date of the enactment of this Act [Oct. 17, 2000]."

[1] *See References in Text notes below.*

§247b–2. Repealed. Pub. L. 97–35, title IX, §902(a), Aug. 13, 1981, 95 Stat. 559

Section, Pub. L. 95–626, title IV, §402, Nov. 10, 1978, 92 Stat. 3591; Pub. L. 96–88, title V, §509(b), Oct. 17, 1979, 93 Stat. 695, related to deterrence of smoking and alcoholic beverage use among children and adolescents.

STATUTORY NOTES AND RELATED SUBSIDIARIES

EFFECTIVE DATE OF REPEAL

Repeal effective Oct. 1, 1981, see section 902(h) of Pub. L. 97–35, set out as an Effective Date of 1981 Amendment note under section 300aaa–12 of this title.

§247b–3. Education, technology assessment, and epidemiology regarding lead poisoning

(a) Prevention

(1) Public education

The Secretary, acting through the Director of the Centers for Disease Control and Prevention, shall carry out a program to educate health professionals and paraprofessionals and the general public on the prevention of lead poisoning in infants and children. In carrying out the program, the Secretary shall make available information concerning the health effects of low-level lead toxicity, the causes of lead poisoning, and the primary and secondary preventive measures that may be taken to prevent such poisoning.

(2) Interagency Task Force

(A) Not later than 6 months after October 27, 1992, the Secretary shall establish a council to be known as the Interagency Task Force on the Prevention of Lead Poisoning (in this paragraph referred to as the "Task Force"). The Task Force shall coordinate the efforts of Federal agencies to prevent lead poisoning.

(B) The Task Force shall be composed of—

(i) the Secretary, who shall serve as the chair of the Task Force;

(ii) the Secretary of Housing and Urban Development;

(iii) the Administrator of the Environmental Protection Agency; and

(iv) senior staff of each of the officials specified in clauses (i) through (iii), as selected by the officials respectively.

(C) The Task Force shall—

(i) review, evaluate, and coordinate current strategies and plans formulated by the officials serving as members of the Task Force, including—

(I) the plan of the Secretary of Health and Human Services entitled "Strategic Plan for the Elimination of Lead Poisoning", dated February 21, 1991;

(II) the plan of the Secretary of Housing and Urban Development entitled "Comprehensive and Workable Plan for the Abatement of Lead-Based Paint in Privately Owned Housing", dated December 7, 1990; and

(III) the strategy of the Administrator of the Environmental Protection Agency entitled "Strategy for Reducing Lead Exposures", dated February 21, 1991;

(ii) develop a unified implementation plan for programs that receive Federal financial assistance for activities related to the prevention of lead poisoning;

(iii) establish a mechanism for sharing and disseminating information among the agencies represented on the Task Force;

(iv) identify the most promising areas of research and education concerning lead poisoning;

(v) identify the practical and technological constraints to expanding lead poisoning prevention;

(vi) annually carry out a comprehensive review of Federal programs providing assistance to prevent lead poisoning, and not later than May 1 of each year, submit to the Committee on Labor and Human Resources of the Senate and the Committee on the Environment and Public Works of the Senate, and to the Committee on Energy and Commerce of the House of Representatives, a report that summarizes the findings made as a result of such review and that contains the recommendations of the Task Force on the programs and policies with respect to which the Task Force is established, including related budgetary recommendations; and

(vii) annually review and coordinate departmental and agency budgetary requests with respect to all lead poisoning prevention activities of the Federal Government.

(b) Technology assessment and epidemiology

The Secretary, acting through the Director of the Centers for Disease Control and Prevention, shall, directly or through grants or contracts—

(1) provide for the development of improved, more cost-effective testing measures for detecting

lead toxicity in children;

(2) provide for the development of improved methods of assessing the prevalence of lead poisoning, including such methods as may be necessary to conduct individual assessments for each State;

(3) provide for the collection of data on the incidence and prevalence of lead poisoning of infants and children, on the demographic characteristics of infants and children with such poisoning (including racial and ethnic status), and on the source of payment for treatment for such poisoning (including the extent to which insurance has paid for such treatment); and

(4) provide for any applied research necessary to improve the effectiveness of programs for the prevention of lead poisoning in infants and children.

(July 1, 1944, ch. 373, title III, §317B, as added Pub. L. 102–531, title III, §303(b), Oct. 27, 1992, 106 Stat. 3488; amended Pub. L. 103–43, title XX, §2008(i)(1)(B)(i), June 10, 1993, 107 Stat. 212.)

EDITORIAL NOTES

AMENDMENTS

1993—Pub. L. 103–43 made technical amendment to directory language of Pub. L. 102–531, §303(b), which enacted this section.

STATUTORY NOTES AND RELATED SUBSIDIARIES

CHANGE OF NAME

Committee on Labor and Human Resources of Senate changed to Committee on Health, Education, Labor, and Pensions of Senate by Senate Resolution No. 20, One Hundred Sixth Congress, Jan. 19, 1999.

Committee on Energy and Commerce of House of Representatives treated as referring to Committee on Commerce of House of Representatives by section 1(a) of Pub. L. 104–14, set out as a note preceding section 21 of Title 2, The Congress. Committee on Commerce of House of Representatives changed to Committee on Energy and Commerce of House of Representatives, and jurisdiction over matters relating to securities and exchanges and insurance generally transferred to Committee on Financial Services of House of Representatives by House Resolution No. 5, One Hundred Seventh Congress, Jan. 3, 2001.

§247b–3a. Training and reports by the Health Resources and Services Administration

(a) Training

The Secretary of Health and Human Services, acting through the Administrator of the Health Resources and Services Administration and in collaboration with the Administrator of the Centers for Medicare & Medicaid Services and the Director of the Centers for Disease Control and Prevention, shall conduct education and training programs for physicians and other health care providers regarding childhood lead poisoning, current screening and treatment recommendations and requirements, and the scientific, medical, and public health basis for those policies.

(b) Report

The Secretary of Health and Human Services, acting through the Administrator of the Health Resources and Services Administration, annually shall report to Congress on the number of children who received services through health centers established under section 254b of this title and received a blood lead screening test during the prior fiscal year, noting the percentage that such children represent as compared to all children who received services through such health centers.

(c) Authorization of appropriations

There are authorized to be appropriated to carry out this section such sums as may be necessary for each [1] the fiscal years 2001 through 2005.

(Pub. L. 106–310, div. A, title XXV, §2503, Oct. 17, 2000, 114 Stat. 1163; Pub. L. 108–173, title IX,

§900(e)(6)(E), Dec. 8, 2003, 117 Stat. 2374.)

EDITORIAL NOTES

CODIFICATION

Section was enacted as part of the Children's Health Act of 2000, and not as part of the Public Health Service Act which comprises this chapter.

AMENDMENTS

2003—Subsec. (a). Pub. L. 108–173 substituted "Centers for Medicare & Medicaid Services" for "Health Care Financing Administration".

[1] *So in original. Probably should be followed by "of".*

§247b–4. National Center on Birth Defects and Developmental Disabilities

(a) In general

(1) National Center

There is established within the Centers for Disease Control and Prevention a center to be known as the National Center on Birth Defects and Developmental Disabilities (referred to in this section as the "Center"), which shall be headed by a director appointed by the Director of the Centers for Disease Control and Prevention.

(2) General duties

The Secretary shall carry out programs—

(A) to collect, analyze, and make available data on birth defects, developmental disabilities, and disabilities and health (in a manner that facilitates compliance with subsection (c)(2)), including data on the causes of such defects and disabilities and on the incidence and prevalence of such defects and disabilities;

(B) to operate regional centers for the conduct of applied epidemiological research on the prevention of such defects and disabilities;

(C) to provide information and education to the public on the prevention of such defects and disabilities;

(D) to conduct research on and to promote the prevention of such defects and disabilities, and secondary health conditions among individuals with disabilities; and

(E) to support a National Spina Bifida Program to prevent and reduce suffering from the Nation's most common permanently disabling birth defect.

(3) Folic acid

The Secretary shall carry out section 247b–11 of this title through the Center.

(4) Certain programs

(A) Transfers

All programs and functions described in subparagraph (B) are transferred to the Center, effective upon the expiration of the 180-day period beginning on October 17, 2000.

(B) Relevant programs

The programs and functions described in this subparagraph are all programs and functions that—

(i) relate to birth defects; folic acid; cerebral palsy; intellectual disabilities; child development; newborn screening; autism; fragile X syndrome; fetal alcohol syndrome; pediatric genetic disorders; disability prevention; or other relevant diseases, disorders, or conditions as determined [1] the Secretary; and

(ii) were carried out through the National Center for Environmental Health as of the day before October 17, 2000.

(C) Related transfers

Personnel employed in connection with the programs and functions specified in subparagraph (B), and amounts available for carrying out the programs and functions, are transferred to the Center, effective upon the expiration of the 180-day period beginning on October 17, 2000. Such transfer of amounts does not affect the period of availability of the amounts, or the availability of the amounts with respect to the purposes for which the amounts may be expended.

(b) Grants and contracts

(1) In general

In carrying out subsection (a), the Secretary may make grants to and enter into contracts with public and nonprofit private entities.

(2) Supplies and services in lieu of award funds

(A) Upon the request of a recipient of an award of a grant or contract under paragraph (1), the Secretary may, subject to subparagraph (B), provide supplies, equipment, and services for the purpose of aiding the recipient in carrying out the purposes for which the award is made and, for such purposes, may detail to the recipient any officer or employee of the Department of Health and Human Services.

(B) With respect to a request described in subparagraph (A), the Secretary shall reduce the amount of payments under the award involved by an amount equal to the costs of detailing personnel and the fair market value of any supplies, equipment, or services provided by the Secretary. The Secretary shall, for the payment of expenses incurred in complying with such request, expend the amounts withheld.

(3) Application for award

The Secretary may make an award of a grant or contract under paragraph (1) only if an application for the award is submitted to the Secretary and the application is in such form, is made in such manner, and contains such agreements, assurances, and information as the Secretary determines to be necessary to carry out the purposes for which the award is to be made.

(c) Biennial report

Not later than February 1 of fiscal year 1999 and of every second such year thereafter, the Secretary shall submit to the Committee on Commerce of the House of Representatives, and the Committee on Labor and Human Resources of the Senate, a report that, with respect to the preceding 2 fiscal years—

(1) contains information regarding the incidence and prevalence of birth defects, developmental disabilities, and the health status of individuals with disabilities and the extent to which these conditions have contributed to the incidence and prevalence of infant mortality and affected quality of life;

(2) contains information under paragraph (1) that is specific to various racial and ethnic groups (including Hispanics, non-Hispanic whites, Blacks, Native Americans, and Asian Americans);

(3) contains an assessment of the extent to which various approaches of preventing birth defects, developmental disabilities, and secondary health conditions among individuals with disabilities have been effective;

(4) describes the activities carried out under this section;

(5) contains information on the incidence and prevalence of individuals living with birth defects and disabilities or developmental disabilities, information on the health status of individuals with disabilities, information on any health disparities experienced by such individuals, and recommendations for improving the health and wellness and quality of life of such individuals;

(6) contains a summary of recommendations from all birth defects research conferences sponsored by the Centers for Disease Control and Prevention, including conferences related to

spina bifida; and

(7) contains any recommendations of the Secretary regarding this section.

(d) Applicability of privacy laws

The provisions of this section shall be subject to the requirements of section 552a of title 5. All Federal laws relating to the privacy of information shall apply to the data and information that is collected under this section.

(e) Advisory committee

Notwithstanding any other provision of law, the members of the advisory committee appointed by the Director of the National Center for Environmental Health that have expertise in birth defects, developmental disabilities, and disabilities and health shall be transferred to and shall advise the National Center on Birth Defects and Developmental Disabilities effective on December 3, 2003.

(f) Authorization of appropriations

For the purpose of carrying out this section, there are authorized to be appropriated such sums as may be necessary for each of fiscal years 2003 through 2007.

(July 1, 1944, ch. 373, title III, §317C, as added Pub. L. 102–531, title III, §306(a), Oct. 27, 1992, 106 Stat. 3494; amended Pub. L. 103–43, title XX, §2008(i)(1)(B)(iii), June 10, 1993, 107 Stat. 213; Pub. L. 105–168, §2, Apr. 21, 1998, 112 Stat. 43; Pub. L. 106–310, div. A, title VI, §611, Oct. 17, 2000, 114 Stat. 1119; Pub. L. 108–154, §2, Dec. 3, 2003, 117 Stat. 1933; Pub. L. 111–256, §2(f)(1), Oct. 5, 2010, 124 Stat. 2644.)

EDITORIAL NOTES

AMENDMENTS

2010—Subsec. (a)(4)(B)(i). Pub. L. 111–256 substituted "intellectual disabilities;" for "mental retardation;".

2003—Subsec. (a)(2)(A). Pub. L. 108–154, §2(1)(A), substituted ", developmental disabilities, and disabilities and health" for "and developmental disabilities" and "subsection (c)(2)" for "subsection (d)(2)".

Subsec. (a)(2)(D), (E). Pub. L. 108–154, §2(1)(B)–(D), added subpars. (D) and (E).

Subsecs. (b), (c). Pub. L. 108–154, §2(2),(4), redesignated subsecs. (c) and (d) as (b) and (c), respectively, and struck out former subsec. (b) which related to additional provisions regarding collection of data.

Subsec. (d). Pub. L. 108–154, §2(4), redesignated subsec. (e) as (d). Former subsec. (d) redesignated (c).

Subsec. (d)(1). Pub. L. 108–154, §2(3)(A), added par. (1) and struck out former par. (1) which read as follows: "contains information regarding the incidence and prevalence of birth defects and the extent to which birth defects have contributed to the incidence and prevalence of infant mortality;".

Subsec. (d)(3). Pub. L. 108–154, §2(3)(B), inserted ", developmental disabilities, and secondary health conditions among individuals with disabilities" after "defects".

Subsec. (d)(5) to (7). Pub. L. 108–154, §2(3)(C)–(E), added pars. (5) and (6) and redesignated former par. (5) as (7).

Subsec. (e). Pub. L. 108–154, §2(5), added subsec. (e). Former subsec. (e) redesignated (d).

Subsec. (f). Pub. L. 108–154, §2(6) substituted "such sums as may be necessary for each of fiscal years 2003 through 2007." for "$30,000,000 for fiscal year 1999, $40,000,000 for fiscal year 2000, and such sums as may be necessary for each of the fiscal years 2001 and 2002."

2000—Pub. L. 106–310, §611(1), substituted "National Center on Birth Defects and Developmental Disabilities" for "Programs regarding birth defects" in section catchline.

Subsec. (a). Pub. L. 106–310, §611(2), added subsec. (a) and struck out heading and text of former subsec. (a) relating to Secretary's responsibility, acting through the Centers for Disease Control and Prevention, to carry out programs regarding birth defects.

Subsec. (b)(1). Pub. L. 106–310, §611(3), substituted "subsection (a)(2)(A) of this section" for "subsection (a)(1) of this section" in introductory provisions.

1998—Pub. L. 105–168 amended section generally, substituting present provisions for provisions which directed Secretary to encourage and assist States in collection and analysis of epidemiological data on birth defects and to establish and maintain National Information Clearinghouse on Birth Defects, required report not later than July 1, 1993, and biennially thereafter, and authorized appropriations for fiscal years 1993, 1994, and 1995.

1993—Pub. L. 103–43 made technical amendment to directory language of Pub. L. 102–531, §306(a), which enacted this section.

STATUTORY NOTES AND RELATED SUBSIDIARIES

CHANGE OF NAME

Committee on Commerce of House of Representatives changed to Committee on Energy and Commerce of House of Representatives, and jurisdiction over matters relating to securities and exchanges and insurance generally transferred to Committee on Financial Services of House of Representatives by House Resolution No. 5, One Hundred Seventh Congress, Jan. 3, 2001.

Committee on Labor and Human Resources of Senate changed to Committee on Health, Education, Labor, and Pensions of Senate by Senate Resolution No. 20, One Hundred Sixth Congress, Jan. 19, 1999.

CONGRESSIONAL FINDINGS

Pub. L. 105–168, §1(b), Apr. 21, 1998, 112 Stat. 43, provided that: "Congress makes the following findings:

"(1) Birth defects are the leading cause of infant mortality, directly responsible for one out of every five infant deaths.

"(2) Thousands of the 150,000 infants born with a serious birth defect annually face a lifetime of chronic disability and illness.

"(3) Birth defects threaten the lives of infants of all racial and ethnic backgrounds. However, some conditions pose excess risks for certain populations. For example, compared to all infants born in the United States, Hispanic-American infants are more likely to be born with anencephaly spina bifida and other neural tube defects and African-American infants are more likely to be born with sickle-cell anemia.

"(4) Birth defects can be caused by exposure to environmental hazards, adverse health conditions during pregnancy, or genetic mutations. Prevention efforts are slowed by lack of information about the number and causes of birth defects. Outbreaks of birth defects may go undetected because surveillance and research efforts are underdeveloped and poorly coordinated.

"(5) Public awareness strategies, such as programs using folic acid vitamin supplements to prevent spina bifida and alcohol avoidance programs to prevent Fetal Alcohol Syndrome, are essential to prevent the heartache and costs associated with birth defects."

DEFINITIONS

For meaning of references to an intellectual disability and to individuals with intellectual disabilities in provisions amended by section 2 of Pub. L. 111–256, see section 2(k) of Pub. L. 111–256, set out as a note under section 1400 of Title 20, Education.

[1] *So in original. Probably should be followed by the word "by".*

§247b–4a. Early detection, diagnosis, and interventions for newborns and infants with hearing loss

(a) Definitions

For the purposes of this section only, the following terms in this section are defined as follows:

(1) Hearing screening

Newborn and infant hearing screening consists of objective physiologic procedures to detect possible hearing loss and to identify newborns and infants who, after rescreening, require further audiologic and medical evaluations.

(2) Audiologic evaluation

Audiologic evaluation consists of procedures to assess the status of the auditory system; to establish the site of the auditory disorder; the type and degree of hearing loss, and the potential effects of hearing loss on communication; and to identify appropriate treatment and referral options. Referral options should include linkage to State IDEA part C coordinating agencies or

other appropriate agencies, medical evaluation, hearing aid/sensory aid assessment, audiologic rehabilitation treatment, national and local consumer, self-help, parent, and education organizations, and other family-centered services.

(3) Medical evaluation

Medical evaluation by a physician consists of key components including history, examination, and medical decision making focused on symptomatic and related body systems for the purpose of diagnosing the etiology of hearing loss and related physical conditions, and for identifying appropriate treatment and referral options.

(4) Medical intervention

Medical intervention is the process by which a physician provides medical diagnosis and direction for medical and/or surgical treatment options of hearing loss and/or related medical disorder associated with hearing loss.

(5) Audiologic rehabilitation

Audiologic rehabilitation (intervention) consists of procedures, techniques, and technologies to facilitate the receptive and expressive communication abilities of a child with hearing loss.

(6) Early intervention

Early intervention (e.g., nonmedical) means providing appropriate services for the child with hearing loss and ensuring that families of the child are provided comprehensive, consumer-oriented information about the full range of family support, training, information services, communication options and are given the opportunity to consider the full range of educational and program placements and options for their child.

(b) Purposes

The purposes of this section are to clarify the authority within the Public Health Service Act [42 U.S.C. 201 et seq.] to authorize statewide newborn and infant hearing screening, evaluation and intervention programs and systems, technical assistance, a national applied research program, and interagency and private sector collaboration for policy development, in order to assist the States in making progress toward the following goals:

(1) All babies born in hospitals in the United States and its territories should have a hearing screening before leaving the birthing facility. Babies born in other countries and residing in the United States via immigration or adoption should have a hearing screening as early as possible.

(2) All babies who are not born in hospitals in the United States and its territories should have a hearing screening within the first 3 months of life.

(3) Appropriate audiologic and medical evaluations should be conducted by 3 months for all newborns and infants suspected of having hearing loss to allow appropriate referral and provisions for audiologic rehabilitation, medical and early intervention before the age of 6 months.

(4) All newborn and infant hearing screening programs and systems should include a component for audiologic rehabilitation, medical and early intervention options that ensures linkage to any new and existing statewide systems of intervention and rehabilitative services for newborns and infants with hearing loss.

(5) Public policy in regard to newborn and infant hearing screening and intervention should be based on applied research and the recognition that newborns, infants, toddlers, and children who are deaf or hard-of-hearing have unique language, learning, and communication needs, and should be the result of consultation with pertinent public and private sectors.

(c) Statewide newborn and infant hearing screening, evaluation and intervention programs and systems

Under the existing authority of the Public Health Service Act [42 U.S.C. 201 et seq.], the Secretary of Health and Human Services (in this section referred to as the "Secretary"), acting through the Administrator of the Health Resources and Services Administration, shall make awards of grants or cooperative agreements to develop statewide newborn and infant hearing screening, evaluation and intervention programs and systems for the following purposes:

(1) To develop and monitor the efficacy of statewide newborn and infant hearing screening, evaluation and intervention programs and systems. Early intervention includes referral to schools and agencies, including community, consumer, and parent-based agencies and organizations and other programs mandated by part C of the Individuals with Disabilities Education Act [20 U.S.C. 1431 et seq.], which offer programs specifically designed to meet the unique language and communication needs of deaf and hard-of-hearing newborns, infants, toddlers, and children.

(2) To collect data on statewide newborn and infant hearing screening, evaluation and intervention programs and systems that can be used for applied research, program evaluation and policy development.

(d) Technical assistance, data management, and applied research

(1) Centers for Disease Control and Prevention

Under the existing authority of the Public Health Service Act [42 U.S.C. 201 et seq.], the Secretary, acting through the Director of the Centers for Disease Control and Prevention, shall make awards of grants or cooperative agreements to provide technical assistance to State agencies to complement an intramural program and to conduct applied research related to newborn and infant hearing screening, evaluation and intervention programs and systems. The program shall develop standardized procedures for data management and program effectiveness and costs, such as—

(A) to ensure quality monitoring of newborn and infant hearing loss screening, evaluation, and intervention programs and systems;

(B) to provide technical assistance on data collection and management;

(C) to study the costs and effectiveness of newborn and infant hearing screening, evaluation and intervention programs and systems conducted by State-based programs in order to answer issues of importance to State and national policymakers;

(D) to identify the causes and risk factors for congenital hearing loss;

(E) to study the effectiveness of newborn and infant hearing screening, audiologic and medical evaluations and intervention programs and systems by assessing the health, intellectual and social developmental, cognitive, and language status of these children at school age; and

(F) to promote the sharing of data regarding early hearing loss with State-based birth defects and developmental disabilities monitoring programs for the purpose of identifying previously unknown causes of hearing loss.

(2) National Institutes of Health

Under the existing authority of the Public Health Service Act, the Director of the National Institutes of Health, acting through the Director of the National Institute on Deafness and Other Communication Disorders, shall for purposes of this section, continue a program of research and development on the efficacy of new screening techniques and technology, including clinical studies of screening methods, studies on efficacy of intervention, and related research.

(e) Coordination and collaboration

(1) In general

Under the existing authority of the Public Health Service Act [42 U.S.C. 201 et seq.], in carrying out programs under this section, the Administrator of the Health Resources and Services Administration, the Director of the Centers for Disease Control and Prevention, and the Director of the National Institutes of Health shall collaborate and consult with other Federal agencies; State and local agencies, including those responsible for early intervention services pursuant to title XIX of the Social Security Act [42 U.S.C. 1396 et seq.] (Medicaid Early and Periodic Screening, Diagnosis and Treatment Program); title XXI of the Social Security Act [42 U.S.C. 1397aa et seq.], (State Children's Health Insurance Program); title V of the Social Security Act [42 U.S.C. 701 et seq.] (Maternal and Child Health Block Grant Program); and part C of the Individuals with Disabilities Education Act [20 U.S.C. 1431 et seq.]; consumer groups of and that serve individuals who are deaf and hard-of-hearing and their families; appropriate national medical and other health and education specialty organizations; persons who are deaf and hard-of-hearing and their

families; other qualified professional personnel who are proficient in deaf or hard-of-hearing children's language and who possess the specialized knowledge, skills, and attributes needed to serve deaf and hard-of-hearing newborns, infants, toddlers, children, and their families; third-party payers and managed care organizations; and related commercial industries.

(2) Policy development

Under the existing authority of the Public Health Service Act, the Administrator of the Health Resources and Services Administration, the Director of the Centers for Disease Control and Prevention, and the Director of the National Institutes of Health shall coordinate and collaborate on recommendations for policy development at the Federal and State levels and with the private sector, including consumer, medical and other health and education professional-based organizations, with respect to newborn and infant hearing screening, evaluation and intervention programs and systems.

(3) State early detection, diagnosis, and intervention programs and systems; data collection

Under the existing authority of the Public Health Service Act, the Administrator of the Health Resources and Services Administration and the Director of the Centers for Disease Control and Prevention shall coordinate and collaborate in assisting States to establish newborn and infant hearing screening, evaluation and intervention programs and systems under subsection (c) and to develop a data collection system under subsection (d).

(f) Rule of construction

Nothing in this section shall be construed to preempt any State law.

(g) Authorization of appropriations

(1) Statewide newborn and infant hearing screening, evaluation and intervention programs and systems

For the purpose of carrying out subsection (c) under the existing authority of the Public Health Service Act [42 U.S.C. 201 et seq.], there are authorized to the Health Resources and Services Administration appropriations in the amount of $5,000,000 for fiscal year 2000, $8,000,000 for fiscal year 2001, and such sums as may be necessary for fiscal year 2002.

(2) Technical assistance, data management, and applied research; Centers for Disease Control and Prevention

For the purpose of carrying out subsection (d)(1) under the existing authority of the Public Health Service Act, there are authorized to the Centers for Disease Control and Prevention, appropriations in the amount of $5,000,000 for fiscal year 2000, $7,000,000 for fiscal year 2001, and such sums as may be necessary for fiscal year 2002.

(3) Technical assistance, data management, and applied research; National Institute on Deafness and Other Communication Disorders

For the purpose of carrying out subsection (d)(2) under the existing authority of the Public Health Service Act, there are authorized to the National Institute on Deafness and Other Communication Disorders appropriations for such sums as may be necessary for each of the fiscal years 2000 through 2002.

(Pub. L. 106–113, div. B, §1000(a)(4) [title VI, §601], Nov. 29, 1999, 113 Stat. 1535, 1501A–276.)

EDITORIAL NOTES

REFERENCES IN TEXT

The Public Health Service Act, referred to in subsecs. (b) to (e) and (g), is act July 1, 1944, ch. 373, 58 Stat. 682, which is classified generally to this chapter (§201 et seq.). For complete classification of this Act to the Code, see Short Title note set out under section 201 of this title and Tables.

The Individuals with Disabilities Education Act, referred to in subsecs. (c)(1) and (e)(1), is title VI of Pub. L. 91–230, Apr. 13, 1970, 84 Stat. 175. Part C of the Act is classified generally to subchapter III (§1431 et

seq.) of chapter 33 of Title 20, Education. For complete classification of this Act to the Code, see section 1400 of Title 20 and Tables.

The Social Security Act, referred to in subsec. (e)(1), is act Aug. 14, 1935, ch. 531, 49 Stat. 620. Titles V, XIX, and XXI of the Act are classified generally to subchapters V (§701 et seq.), XIX (§1396 et seq.), and XXI (§1397aa et seq.), respectively, of chapter 7 of this title. For complete classification of this Act to the Code, see section 1305 of this title and Tables.

CODIFICATION

Section was enacted as part of the Departments of Labor, Health, and Human Services, and Education, and Related Agencies Appropriations Act, 2000, and not as part of the Public Health Service Act which comprises this chapter.

§§247b–4b to 247b–4d. Repealed. Pub. L. 109–416, §3(b)(1)–(3), Dec. 19, 2006, 120 Stat. 2829

Section 247b–4b, Pub. L. 106–310, div. A, title I, §102, Oct. 17, 2000, 114 Stat. 1107, related to developmental disabilities surveillance and research programs.

Section 247b–4c, Pub. L. 106–310, div. A, title I, §103, Oct. 17, 2000, 114 Stat. 1108, related to information and education.

Section 247b–4d, Pub. L. 106–310, div. A, title I, §104, Oct. 17, 2000, 114 Stat. 1109, related to Inter-agency Autism Coordinating Committee.

§247b–4e. Repealed. Pub. L. 109–416, §3(b)(4), Dec. 19, 2006, 120 Stat. 2829; Pub. L. 109–482, title I, §104(b)(3)(D), Jan. 15, 2007, 120 Stat. 3694

Section, Pub. L. 106–310, div. A, title I, §105, Oct. 17, 2000, 114 Stat. 1109, related to annual report to Congress concerning the implementation of this section and sections 247b–4b to 247b–4d and 284g of this title.

STATUTORY NOTES AND RELATED SUBSIDIARIES

EFFECTIVE DATE OF REPEAL

Repeal by Pub. L. 109–482 applicable only with respect to amounts appropriated for fiscal year 2007 or subsequent fiscal years, see section 109 of Pub. L. 109–482, set out as an Effective Date of 2007 Amendment note under section 281 of this title.

§247b–4f. Research relating to preterm labor and delivery and the care, treatment, and outcomes of preterm and low birthweight infants

(a) Omitted

(b) Studies and activities on preterm birth

(1) In general

The Secretary of Health and Human Services, acting through the Director of the Centers for Disease Control and Prevention, may, subject to the availability of appropriations—

(A) conduct epidemiological studies on the factors relating to prematurity, such as clinical, biological, social, environmental, genetic, and behavioral factors, and other determinants that contribute to health disparities and are related to prematurity, as appropriate;

(B) conduct activities to improve national data to facilitate tracking the burden of preterm birth; and

(C) continue efforts to prevent preterm birth, including late preterm birth, through the identification of opportunities for prevention and the assessment of the impact of such efforts.

(2) Report

Not later than 2 years after November 27, 2013, and every 2 years thereafter, the Secretary of Health and Human Services, acting through the Director of the Centers for Disease Control and Prevention, shall submit to the appropriate committees of Congress reports regarding activities and studies conducted under paragraph (1), including any applicable analyses of preterm birth. Such report shall be posted on the Internet website of the Department of Health and Human Services..[1]

(c) Pregnancy risk assessment monitoring survey

The Secretary of Health and Human Services, acting through the Director of the Centers for Disease Control and Prevention, shall—

(1) continue systems for the collection of maternal-infant clinical and biomedical information, including electronic health records, electronic databases, and biobanks, to link with the Pregnancy Risk Assessment Monitoring System (PRAMS) and other epidemiological studies of prematurity in order to track, to the extent practicable, all pregnancy outcomes and prevent preterm birth; and

(2) provide technical assistance, as appropriate, to support States in improving the collection of information pursuant to this subsection.

(d) Evaluation of existing tools and measures

The Secretary of Health and Human Services shall review existing tools and measures to ensure that such tools and measures include information related to the known risk factors of low birth weight and preterm birth.

(e) Authorization of appropriations

There is authorized to be appropriated to carry out this section, $2,000,000 for each of fiscal years 2026 through 2030.

(Pub. L. 109–450, §3, Dec. 22, 2006, 120 Stat. 3341; Pub. L. 113–55, title I, §102, Nov. 27, 2013, 127 Stat. 641; Pub. L. 115–328, §2, Dec. 18, 2018, 132 Stat. 4471; Pub. L. 119–75, div. J, title V, §6507(a), Feb. 3, 2026, 140 Stat. 693.)

EDITORIAL NOTES

CODIFICATION

Section is comprised of section 3 of Pub. L. 109–450. Subsec. (a) of section 3 of Pub. L. 109–450 amended section 241 of this title.

Section was enacted as part of the Prematurity Research Expansion and Education for Mothers who deliver Infants Early Act or the PREEMIE Act, and not as part of the Public Health Service Act which comprises this chapter.

AMENDMENTS

2026—Pub. L. 119–75, §6507(a)(2), made technical amendment to directory language of Pub. L. 115–328, §2. See 2018 Amendment notes below.

Subsec. (e). Pub. L. 119–75, §6507(a)(1), substituted "fiscal years 2026 through 2030" for "fiscal years 2019 through 2023".

2018—Subsec. (b)(1)(A). Pub. L. 115–328, §2(1)(A), as amended by Pub. L. 119–75, §6507(a)(2), substituted "factors relating to prematurity, such as clinical, biological, social, environmental, genetic, and behavioral factors, and other determinants that contribute to health disparities and are related" for "clinical, biological, social, environmental, genetic, and behavioral factors relating".

Subsec. (b)(2). Pub. L. 115–328, §2(1)(B), as amended by Pub. L. 119–75, §6507(a)(2), substituted "regarding activities and studies conducted under paragraph (1), including any applicable analyses of preterm birth. Such report shall be posted on the Internet website of the Department of Health and Human Services." for "concerning the progress and any results of studies conducted under paragraph (1)".

Subsec. (c). Pub. L. 115–328, §2(2), as amended by Pub. L. 119–75, §6507(a)(2), added subsec. (c) and struck out former subsec. (c) which established a pregnancy risk assessment monitoring survey and authorized appropriations.

Subsec. (e). Pub. L. 115–328, §2(3), as amended by Pub. L. 119–75, §6507(a)(2), substituted "$2,000,000 for each of fiscal years 2019 through 2023" for "except for subsection (c), $1,880,000 for each of fiscal years

2014 through 2018".

2013—Subsec. (b). Pub. L. 113–55, §102(a), added subsec. (b) and struck out former subsec. (b) which related to studies and reports on the relationship between prematurity and birth defects.

Subsec. (e). Pub. L. 113–55, §102(b), substituted "$1,880,000 for each of fiscal years 2014 through 2018." for "$5,000,000 for each of fiscal years 2007 through 2011."

STATUTORY NOTES AND RELATED SUBSIDIARIES

EFFECTIVE DATE OF 2025 AMENDMENT

Pub. L. 119–75, div. J, title V, §6507(a)(2), Feb. 3, 2026, 140 Stat. 693, provided that the amendment made by section 6507(a)(2) is effective as if included in the enactment of Pub. L. 115–328.

ADVISORY COMMITTEE ON INFANT MORTALITY

Pub. L. 113–55, title I, §104(b), Nov. 27, 2013, 127 Stat. 643, as amended by Pub. L. 115–328, §4, Dec. 18, 2018, 132 Stat. 4473, provided that:

"(1) ESTABLISHMENT.—The Secretary of Health and Human Services (referred to in this section [enacting this note and repealing section 247b–4g of this title] as the 'Secretary') may establish an advisory committee known as the 'Advisory Committee on Infant Mortality' (referred to in this section as the 'Advisory Committee').

"(2) DUTIES.—The Advisory Committee shall provide advice, recommendations, or information to the Secretary as may be necessary to improve activities and programs to reduce severe maternal morbidity, maternal mortality, infant mortality, and preterm birth, which may include recommendations, advice, or information related to the following:

"(A) Programs of the Department of Health and Human Services that are directed at reducing infant mortality, preterm birth, and improving the health status of pregnant women and infants, and information on cost-effectiveness and outcomes of such programs.

"(B) Strategies to coordinate the various Federal programs and activities with State, local, and private programs and efforts that address factors that affect infant mortality.

"(C) The Healthy Start program under section 330H of the Public Health Service Act (42 U.S.C. 254c–8) and Healthy People 2020 infant mortality objectives.

"(D) Implementation of Healthy People objectives related to maternal and infant health.

"(E) Strategies to reduce racial, ethnic, geographic, and other health disparities in birth outcomes, including by increasing awareness of Federal programs related to appropriate access to, or information regarding, prenatal care to address risk factors for preterm labor and delivery.

"(F) Strategies, including the implementation of such strategies, to address gaps in Federal research, programs, and education efforts related to the prevention of severe maternal morbidity, maternal mortality, infant mortality, and other adverse birth outcomes.

"(3) MEMBERSHIP.—The Secretary shall ensure that the membership of the Advisory Committee includes the following:

"(A) Representatives provided for in the original charter of the Advisory Committee.

"(B) A representative of the National Center for Health Statistics.

"(4) BIENNIAL REPORT.—Not later than 1 year after the date of enactment of the PREEMIE Reauthorization Act of 2018 [Dec. 18, 2018], and every 2 years thereafter, the Advisory Committee shall—

"(A) publish a report summarizing activities and recommendations of the Advisory Committee since the publication of the previous report;

"(B) submit such report to the Secretary and the appropriate Committees of Congress; and

"(C) post such report on the Internet website of the Department of Health and Human Services."

PURPOSE

Pub. L. 109–450, §2, Dec. 22, 2006, 120 Stat. 3341, provided that: "It is the purpose of this Act [enacting this section and sections 247b–4g and 280g–5 of this title and amending sections 241 and 280g–4 of this title] to—

"(1) reduce rates of preterm labor and delivery;

"(2) work toward an evidence-based standard of care for pregnant women at risk of preterm labor or other serious complications, and for infants born preterm and at a low birthweight; and

"(3) reduce infant mortality and disabilities caused by prematurity."

[1] *So in original.*

§247b–4g. Repealed. Pub. L. 113–55, title I, §104(a), Nov. 27, 2013, 127 Stat. 643

Section, Pub. L. 109–450, §5, Dec. 22, 2006, 120 Stat. 3343, related to establishment and activities of the Interagency Coordinating Council on Prematurity and Low Birthweight.

§247b–5. Preventive health measures with respect to prostate cancer

(a) In general

The Secretary, acting through the Director of the Centers for Disease Control and Prevention, may make grants to States and local health departments for the purpose of enabling such States and departments to carry out programs that may include the following:

(1) To identify factors that influence the attitudes or levels of awareness of men and health care practitioners regarding screening for prostate cancer.

(2) To evaluate, in consultation with the Agency for Health Care Policy and Research and the National Institutes of Health, the effectiveness of screening strategies for prostate cancer.

(3) To identify, in consultation with the Agency for Health Care Policy and Research, issues related to the quality of life for men after prostrate [1] cancer screening and followup.

(4) To develop and disseminate public information and education programs for prostate cancer, including appropriate messages about the risks and benefits of prostate cancer screening for the general public, health care providers, policy makers and other appropriate individuals.

(5) To improve surveillance for prostate cancer.

(6) To address the needs of underserved and minority populations regarding prostate cancer.

(7) Upon a determination by the Secretary, who shall take into consideration recommendations by the United States Preventive Services Task Force and shall seek input, where appropriate, from professional societies and other private and public entities, that there is sufficient consensus on the effectiveness of prostate cancer screening—

(A) to screen men for prostate cancer as a preventive health measure;

(B) to provide appropriate referrals for the medical treatment of men who have been screened under subparagraph (A) and to ensure, to the extent practicable, the provision of appropriate followup services and support services such as case management;

(C) to establish mechanisms through which State and local health departments can monitor the quality of screening procedures for prostate cancer, including the interpretation of such procedures; and

(D) to improve, in consultation with the Health Resources and Services Administration, the education, training, and skills of health practitioners (including appropriate allied health professionals) in the detection and control of prostate cancer.

(8) To evaluate activities conducted under paragraphs (1) through (7) through appropriate surveillance or program monitoring activities.

(b) Requirement of matching funds

(1) In general

The Secretary may not make a grant under subsection (a) unless the applicant involved agrees, with respect to the costs to be incurred by the applicant in carrying out the purpose described in such section, to make available non-Federal contributions (in cash or in kind under paragraph (2)) toward such costs in an amount equal to not less than $1 for each $3 of Federal funds provided in the grant. Such contributions may be made directly or through donations from public or private entities.

(2) Determination of amount of non-Federal contribution

(A) Non-Federal contributions required in paragraph (1) may be in cash or in kind, fairly

evaluated, including equipment or services (and excluding indirect or overhead costs). Amounts provided by the Federal Government, or services assisted or subsidized to any significant extent by the Federal Government, may not be included in determining the amount of such non-Federal contributions.

(B) In making a determination of the amount of non-Federal contributions for purposes of paragraph (1), the Secretary may include only non-Federal contributions in excess of the average amount of non-Federal contributions made by the applicant involved toward the purpose described in subsection (a) for the 2-year period preceding the fiscal year for which the applicant involved is applying to receive a grant under such subsection.

(C) In making a determination of the amount of non-Federal contributions for purposes of paragraph (1), the Secretary shall, subject to subparagraphs (A) and (B) of this paragraph, include any non-Federal amounts expended pursuant to title XIX of the Social Security Act [42 U.S.C. 1396 et seq.] by the applicant involved toward the purpose described in paragraphs (1) and (2) of subsection (a).

(c) Education on significance of early detection

The Secretary may not make a grant under subsection (a) unless the applicant involved agrees that, in carrying out subsection (a)(3), the applicant will carry out education programs to communicate to men, and to local health officials, the significance of the early detection of prostate cancer.

(d) Requirement of provision of all services by date certain

The Secretary may not make a grant under subsection (a) unless the applicant involved agrees—

(1) to ensure that, initially and throughout the period during which amounts are received pursuant to the grant, not less than 60 percent of the grant is expended to provide each of the services or activities described in paragraphs (1) and (2) of such subsection;

(2) to ensure that, by the end of any second fiscal year of payments pursuant to the grant, each of the services or activities described in such subsection is provided; and

(3) to ensure that not more than 40 percent of the grant is expended to provide the services or activities described in paragraphs (3) through (6) of such section.[2]

(e) Additional required agreements

(1) Priority for low-income men

The Secretary may not make a grant under subsection (a) unless the applicant involved agrees that low-income men, and men at risk of prostate cancer, will be given priority in the provision of services and activities pursuant to paragraphs (1) and (2) of such subsection.

(2) Limitation on imposition of fees for services

The Secretary may not make a grant under subsection (a) unless the applicant involved agrees that, if a charge is imposed for the provision of services or activities under the grant, such charge—

(A) will be made according to a schedule of charges that is made available to the public;

(B) will be adjusted to reflect the income of the man involved; and

(C) will not be imposed on any man with an income of less than 100 percent of the official poverty line, as established by the Director of the Office of Management and Budget and revised by the Secretary in accordance with section 9902(2) of this title.

(3) Relationship to items and services under other programs

The Secretary may not make a grant under subsection (a) unless the applicant involved agrees that the grant will not be expended to make payment for any item or service to the extent that payment has been made, or can reasonably be expected to be made, with respect to such item or service—

(A) under any State compensation program, under an insurance policy, or under any Federal or State health benefits program; or

(B) by an entity that provides health services on a prepaid basis.

(4) Coordination with other prostate cancer programs

The Secretary may not make a grant under subsection (a) unless the applicant involved agrees that the services and activities funded through the grant will be coordinated with other Federal, State, and local prostate cancer programs.

(5) Limitation on administrative expenses

The Secretary may not make a grant under subsection (a) unless the applicant involved agrees that not more than 10 percent of the grant will be expended for administrative expenses with respect to the grant.

(6) Restrictions on use of grant

The Secretary may not make a grant under subsection (a) unless the applicant involved agrees that the grant will not be expended to provide inpatient hospital services for any individual.

(7) Records and audits

The Secretary may not make a grant under subsection (a) unless the applicant involved agrees that—

(A) the applicant will establish such fiscal control and fund accounting procedures as may be necessary to ensure the proper disbursal of, and accounting for, amounts received by the applicant under such section; [3] and

(B) upon request, the applicant will provide records maintained pursuant to paragraph (1) to the Secretary or the Comptroller of the United States for purposes of auditing the expenditures by the applicant of the grant.

(f) Reports to Secretary

The Secretary may not make a grant under subsection (a) unless the applicant involved agrees to submit to the Secretary such reports as the Secretary may require with respect to the grant.

(g) Description of intended uses of grant

The Secretary may not make a grant under subsection (a) unless—

(1) the applicant involved submits to the Secretary a description of the purposes for which the applicant intends to expend the grant;

(2) the description identifies the populations, areas, and localities in the applicant [4] with a need for the services or activities described in subsection (a);

(3) the description provides information relating to the services and activities to be provided, including a description of the manner in which the services and activities will be coordinated with any similar services or activities of public or nonprivate entities; and

(4) the description provides assurances that the grant funds will be used in the most cost-effective manner.

(h) Requirement of submission of application

The Secretary may not make a grant under subsection (a) unless an application for the grant is submitted to the Secretary, the application contains the description of intended uses required in subsection (g), and the application is in such form, is made in such manner, and contains such agreements, assurances, and information as the Secretary determines to be necessary to carry out this section.

(i) Method and amount of payment

The Secretary shall determine the amount of a grant made under subsection (a). Payments under such grants may be made in advance on the basis of estimates or by way of reimbursement, with necessary adjustments on account of the underpayments or overpayments, and in such installments and on such terms and conditions as the Secretary finds necessary to carry out the purposes of such grants.

(j) Technical assistance and provision of supplies and services in lieu of grant funds

(1) Technical assistance

The Secretary may provide training and technical assistance with respect to the planning, development, and operation of any program or service carried out pursuant to subsection (a). The Secretary may provide such technical assistance directly or through grants to, or contracts with, public and private entities.

(2) Provision of supplies and services in lieu of grant funds

(A) Upon the request of an applicant receiving a grant under subsection (a), the Secretary may, subject to subparagraph (B), provide supplies, equipment, and services for the purpose of aiding the applicant in carrying out such section and, for such purpose, may detail to the applicant any officer or employee of the Department of Health and Human Services.

(B) With respect to a request described in subparagraph (A), the Secretary shall reduce the amount of payments under the grant under subsection (a) to the applicant involved by an amount equal to the costs of detailing personnel (including pay, allowances, and travel expenses) and the fair market value of any supplies, equipment, or services provided by the Secretary. The Secretary shall, for the payment of expenses incurred in complying with such request, expend the amounts withheld.

(k) "Units of local government" defined

For purposes of this section, the term "units of local government" includes Indian tribes.

(l) Authorization of appropriations

(1) In general

For the purpose of carrying out this section, there are authorized to be appropriated $20,000,000 for fiscal year 1993, and such sums as may be necessary for each of the fiscal years 1994 through 2004.

(2) Allocation for technical assistance

Of the amounts appropriated under paragraph (1) for a fiscal year, the Secretary shall reserve not more than 20 percent for carrying out subsection (j)(1).

(July 1, 1944, ch. 373, title III, §317D, as added Pub. L. 102–531, title III, §308, Oct. 27, 1992, 106 Stat. 3495; amended Pub. L. 103–43, title XX, §2010(i)(1)(B)(iv), June 10, 1993, 107 Stat. 213; Pub. L. 103–183, title VII, §705(b), Dec. 14, 1993, 107 Stat. 2241; Pub. L. 105–392, title IV, §401(a)(3), Nov. 13, 1998, 112 Stat. 3587; Pub. L. 106–505, title VI, §602(a), Nov. 13, 2000, 114 Stat. 2345.)

EDITORIAL NOTES

REFERENCES IN TEXT

The Social Security Act, referred to in subsec. (b)(2)(C), is act Aug. 14, 1935, ch. 531, 49 Stat. 620. Title XIX of the Act is classified generally to subchapter XIX (§1396 et seq.) of chapter 7 of this title. For complete classification of this Act to the Code, see section 1305 of this title and Tables.

AMENDMENTS

2000—Subsec. (a). Pub. L. 106–505, §602(a)(1), added subsec. (a) and struck out heading and text of former subsec. (a). Text read as follows: "The Secretary, acting through the Director of the Centers for Disease Control and Prevention, may make grants to States and local health departments for the purpose of enabling such States and departments to carry out programs—

"(1) to screen men for prostate cancer as a preventive health measure;

"(2) to provide appropriate referrals for medical treatment of men screened pursuant to paragraph (1) and to ensure, to the extent practicable, the provision of appropriate follow-up services;

"(3) to develop and disseminate public information and education programs for the detection and control of prostate cancer;

"(4) to improve the education, training, and skills of health professionals (including appropriate allied health professionals) in the detection and control of prostate cancer;

"(5) to establish mechanisms through which the States and such departments can monitor the quality of screening procedures for prostate cancer, including the interpretation of such procedures; and

"(6) to evaluate activities conducted under paragraphs (1) through (5) through appropriate surveillance

or program monitoring activities."

Subsec. (l)(1). Pub. L. 106–505, §602(a)(2), substituted "2004" for "1998".

1998—Subsec. (l)(1). Pub. L. 105–392 made technical amendment to directory language of Pub. L. 103–183. See 1993 Amendment note below.

1993—Pub. L. 103–43 made technical amendment to directory language of Pub. L. 102–531, §308, which enacted this section.

Subsec. (l)(1). Pub. L. 103–183, as amended by Pub. L. 105–392, substituted "through 1998" for "through 1996".

STATUTORY NOTES AND RELATED SUBSIDIARIES

EFFECTIVE DATE OF 1998 AMENDMENT

Amendment by Pub. L. 105–392 deemed to have taken effect immediately after enactment of Pub. L. 103–183, see section 401(e) of Pub. L. 105–392, set out as a note under section 242m of this title.

[1] So in original. Probably should be "prostate".

[2] So in original. Probably should be "subsection."

[3] So in original. Probably should be "subsection;".

[4] So in original. Probably should be "application".

§247b–6. National strategy for combating and eliminating tuberculosis

(a) In general

The Secretary, acting through the Director of the Centers for Disease Control and Prevention, may make grants to States, political subdivisions, and other public entities for preventive health service programs for the prevention, control, and elimination of tuberculosis.

(b) Research and development; demonstration projects; education and training

With respect to the prevention, treatment, control, and elimination of tuberculosis, the Secretary may, directly or through grants to public or nonprofit private entities, carry out the following:

(1) Research, with priority given to research and development concerning latent tuberculosis infection, strains of tuberculosis resistant to drugs, and research concerning cases of tuberculosis that affect certain populations at risk for tuberculosis.

(2) Research and development and related activities to develop new tools for the elimination of tuberculosis, including drugs, diagnostics, vaccines, and public health interventions, such as directly observed therapy and non-pharmaceutical intervention, and methods to enhance detection and response to outbreaks of tuberculosis, including multidrug resistant tuberculosis. The Secretary is encouraged to give priority to programmatically relevant research so that new tools can be utilized in public health practice.

(3) Demonstration projects for—

(A) the development of regional capabilities to prevent, control, and eliminate tuberculosis and prevent multidrug resistant and extensively drug resistant strains of tuberculosis;

(B) the intensification of efforts to reduce health disparities in the incidence of tuberculosis;

(C) the intensification of efforts to control tuberculosis along the United States-Mexico border and among United States-Mexico binational populations, including through expansion of the scope and number of programs that—

(i) detect and treat binational cases of tuberculosis; and

(ii) treat high-risk cases of tuberculosis referred from Mexican health departments;

(D) the intensification of efforts to prevent, detect, and treat tuberculosis among foreign-born

persons who are in the United States;

(E) the intensification of efforts to prevent, detect, and treat tuberculosis among populations and settings documented as having a high risk for tuberculosis; and

(F) tuberculosis detection, control, and prevention.

(4) Public information and education activities.

(5) Education, training, clinical skills improvement activities, and workplace exposure prevention for health professionals, including allied health personnel and emergency response employees.

(6) Support of Centers to carry out activities under paragraphs (1) through (4).

(7) Collaboration with international organizations and foreign countries in carrying out such activities.

(8) Develop, enhance, and expand information technologies that support tuberculosis control including surveillance and database management systems with cross-jurisdictional capabilities, which shall conform to the standards and implementation specifications for such information technologies as recommended by the Secretary.

(c) Cooperation with providers of primary health services

The Secretary may make a grant under subsection (a) or (b) only if the applicant for the grant agrees that, in carrying out activities under the grant, the applicant will cooperate with public and nonprofit private providers of primary health services or substance abuse services, including entities receiving assistance under section 254b, 254b, or 256a of this title [1] or under subchapter III–A or XVII.

(d) Application for grant

(1) In general

The Secretary may make a grant under subsection (a) or (b) only if an application for the grant is submitted to the Secretary and the application, subject to paragraph (2), is in such form, is made in such manner, and contains such agreements, assurances, and information as the Secretary determines to be necessary to carry out the subsection involved.

(2) Plan for prevention, control, and elimination

The Secretary may make a grant under subsection (a) only if the application under paragraph (1) contains a plan regarding the prevention, control, and elimination of tuberculosis in the geographic area with respect to which the grant is sought.

(3) Determination of amount of nonfederal contributions

(A) Priority

In awarding grants under subsection (a) or (b), the Secretary shall give highest priority to an applicant that provides assurances that the applicant will contribute non-Federal funds to carry out activities under this section, which may be provided directly or through donations from public or private entities and may be in cash or in kind, including equipment or services.

(B) Federal amounts not to be included as contributions

Amounts provided by the Federal Government, or services assisted or subsidized to any significant extent by the Federal Government, may not be included in determining the amount of non-Federal contributions as described in subparagraph (A).

(e) Supplies and services in lieu of grant funds

(1) In general

Upon the request of a grantee under subsection (a) or (b), the Secretary may, subject to paragraph (2), provide supplies, equipment, and services for the purpose of aiding the grantee in carrying out the subsection involved and, for such purpose, may detail to the State any officer or employee of the Department of Health and Human Services.

(2) Corresponding reduction in payments

With respect to a request described in paragraph (1), the Secretary shall reduce the amount of payments under the grant involved by an amount equal to the costs of detailing personnel and the fair market value of any supplies, equipment, or services provided by the Secretary. The Secretary shall, for the payment of expenses incurred in complying with such request, expend the amounts withheld.

(f) Advisory Council

(1) In general

The Secretary shall establish an advisory council to be known as the Advisory Council for the Elimination of Tuberculosis (in this subsection referred to as the "Council").

(2) Duties

The Council shall provide advice and recommendations regarding the elimination of tuberculosis to the Secretary. In addition, the Council shall, with respect to eliminating such disease, provide to the Secretary and other appropriate Federal officials advice on—

(A) coordinating the activities of the Department of Health and Human Services and other Federal agencies that relate to the disease, including activities under subsection (b);

(B) responding rapidly and effectively to emerging issues in tuberculosis; and

(C) efficiently utilizing the Federal resources involved.

(3) Comprehensive plan

(A) In general

In carrying out paragraph (2), the Council shall make or update recommendations on the development, revision, and implementation of a comprehensive plan to eliminate tuberculosis in the United States.

(B) Consultation

In carrying out subparagraph (A), the Council may consult with appropriate public and private entities, which may, subject to the direction or discretion of the Secretary, include—

(i) individuals who are scientists, physicians, laboratorians, and other health professionals, who are not officers or employees of the Federal Government and who represent the disciplines relevant to tuberculosis elimination;

(ii) members of public-private partnerships or private entities established to address the elimination of tuberculosis;

(iii) members of national and international nongovernmental organizations whose purpose is to eliminate tuberculosis;

(iv) members from the general public who are knowledgeable with respect to tuberculosis elimination including individuals who have or have had tuberculosis; and

(v) scientists, physicians, laboratorians, and other health professionals who reside in a foreign country with a substantial incidence or prevalence of tuberculosis, and who represent the specialties and disciplines relevant to the research under consideration.

(C) Certain components of plan

In carrying out subparagraph (A), the Council shall, subject to the direction or discretion of the Secretary—

(i) consider recommendations for the involvement of the United States in continuing global and cross-border tuberculosis control activities in countries where a high incidence of tuberculosis directly affects the United States; and

(ii) review the extent to which progress has been made toward eliminating tuberculosis.

(4) Biennial report

(A) In general

The Council shall submit a biennial report to the Secretary, as determined necessary by the

Secretary, on the activities carried under this section. Each such report shall include the opinion of the Council on the extent to which its recommendations regarding the elimination of tuberculosis have been implemented, including with respect to—

(i) activities under subsection (b); and

(ii) the national plan referred to in paragraph (3).

(B) Public

The Secretary shall make a report submitted under subparagraph (A) public.

(5) Composition

The Council shall be composed of—

(A) ex officio representatives from the Centers for Disease Control and Prevention, the National Institutes of Health, the United States Agency for International Development, the Agency for Healthcare Research and Quality, the Health Resources and Services Administration, the United States-Mexico Border Health Commission, and other Federal departments and agencies that carry out significant activities related to tuberculosis;

(B) State and local tuberculosis control and public health officials;

(C) individuals who are scientists, physicians, laboratorians, and other health professionals who represent disciplines relevant to tuberculosis elimination; and

(D) members of national and international nongovernmental organizations established to address the elimination of tuberculosis.

(6) Staff, information, and other assistance

The Secretary shall provide to the Council such staff, information, and other assistance as may be necessary to carry out the duties of the Council.

(g) Federal Tuberculosis Task Force

(1) Duties

The Federal Tuberculosis Task Force (in this subsection referred to as the "Task Force") shall provide to the Secretary and other appropriate Federal officials advice on research into new tools under subsection (b)(2), including advice regarding the efficient utilization of the Federal resources involved.

(2) Comprehensive plan for new tools development

In carrying out paragraph (1), the Task Force shall make recommendations on the development of a comprehensive plan for the creation of new tools for the elimination of tuberculosis, including drugs, diagnostics, and vaccines.

(3) Consultation

In developing the comprehensive plan under paragraph (1),[2] the Task Force shall consult with external parties including representatives from groups such as—

(A) scientists, physicians, laboratorians, and other health professionals who represent the specialties and disciplines relevant to the research under consideration;

(B) members from public-private partnerships, private entities, or foundations (or both) engaged in activities relevant to research under consideration;

(C) members of national and international nongovernmental organizations established to address tuberculosis elimination;

(D) members from the general public who are knowledgeable with respect to tuberculosis including individuals who have or have had tuberculosis; and

(E) scientists, physicians, laboratorians, and other health professionals who reside in a foreign country with a substantial incidence or prevalence of tuberculosis, and who represent the specialties and disciplines relevant to the research under consideration.

(h) Authorization of appropriations

(1) General program

(A) In general

For the purpose of carrying out this section, there are authorized to be appropriated $200,000,000 for fiscal year 2009, $210,000,000 for fiscal year 2010, $220,500,000 for fiscal year 2011, $231,525,000 for fiscal year 2012, and $243,101,250 for fiscal year 2013.

(B) Reservation for emergency grants

Of the amounts appropriated under subparagraph (A) for a fiscal year, the Secretary may reserve not more than 25 percent for emergency grants under subsection (a) for any geographic area, State, political subdivision of a State, or other public entity in which there is, relative to other areas, a substantial number of cases of tuberculosis, multidrug resistant tuberculosis, or extensively drug resistant tuberculosis or a substantial rate of increase in such cases.

(C) Priority

In allocating amounts appropriated under subparagraph (A), the Secretary shall give priority to allocating such amounts for grants under subsection (a).

(D) Allocation of funds

(i) Requirement of formula

Of the amounts appropriated under subparagraph (A), not reserved under subparagraph (B), and allocated by the Secretary for grants under subsection (a), the Secretary shall distribute a portion of such amounts to grantees under subsection (a) on the basis of a formula.

(ii) Relevant factors

The formula developed by the Secretary under clause (i) shall take into account the level of tuberculosis morbidity and case complexity in the respective geographic area and may consider other factors relevant to tuberculosis in such area.

(iii) No change to formula required

This subparagraph does not require the Secretary to modify the formula that was used by the Secretary to distribute funds to grantees under subsection (a) for fiscal year 2009.

(2) Limitation

The authorization of appropriations established in paragraph (1) for a fiscal year is effective only if the amount appropriated under such paragraph for such year equals or exceeds the amount appropriated to carry out this section for fiscal year 2009.

(July 1, 1944, ch. 373, title III, §317E, as added Pub. L. 103–183, title III, §301(a), Dec. 14, 1993, 107 Stat. 2233; amended Pub. L. 105–392, title IV, §§401(b)(1), 405, Nov. 13, 1998, 112 Stat. 3587, 3588; Pub. L. 107–251, title VI, §601(a), Oct. 26, 2002, 116 Stat. 1664; Pub. L. 108–163, §2(m)(1), Dec. 6, 2003, 117 Stat. 2023; Pub. L. 110–392, title I, §§101, 111(a), (c), 131, Oct. 13, 2008, 122 Stat. 4196, 4197, 4199, 4200.)

EDITORIAL NOTES

REFERENCES IN TEXT

The reference to section 254b of this title the first place appearing, referred to in subsec. (c), was in the original a reference to section 329, meaning section 329 of act July 1, 1944, which was omitted in the general amendment of subpart I (§254b et seq.) of part D of this subchapter by Pub. L. 104–299, §2, Oct. 11, 1996, 110 Stat. 3626.

Section 256a of this title, referred to in subsec. (c), was repealed by Pub. L. 104–299, §4(a)(3), Oct. 11, 1996, 110 Stat. 3645.

AMENDMENTS

2008—Pub. L. 110–392, §101(1), substituted "National strategy for combating and eliminating tuberculosis" for "Preventive health services regarding tuberculosis" in section catchline.

Subsec. (b). Pub. L. 110–392, §101(2), amended subsec. (b) generally. Prior to amendment, subsec. (b)

related to research, demonstration projects, education, and training for the purpose of prevention, control, and elimination of tuberculosis.

Subsec. (d)(3). Pub. L. 110–392, §101(3), added par. (3).

Subsec. (f)(2) to (6). Pub. L. 110–392, §111(a), added pars. (2) to (5), redesignated former par. (5) as (6), and struck out former pars. (2) to (4) which related to general duties, certain activities, and composition of the Council, respectively.

Subsec. (g). Pub. L. 110–392, §111(c)(2), added subsec. (g). Former subsec. (g) redesignated (h).

Subsec. (h). Pub. L. 110–392, §131, added subsec. (h) and struck out former subsec. (h) which authorized appropriations for grants, research, demonstration projects, education, and training for fiscal years 1994 to 2002.

Pub. L. 110–392, §111(c)(1), redesignated subsec. (g) as (h).

2003—Subsec. (c). Pub. L. 108–163 substituted "254b" for "254c, 254b(h)" before ", or".

2002—Subsec. (c). Pub. L. 107–251 substituted "254b(h)" for "256".

1998—Subsec. (g)(1)(A). Pub. L. 105–392, §405(1)(A), substituted "2002" for "1998".

Subsec. (g)(1)(B). Pub. L. 105–392, §405(1)(B), substituted "25 percent" for "$50,000,000".

Subsec. (g)(2). Pub. L. 105–392, §405(2), substituted "2002" for "1998".

Pub. L. 105–392, §401(b)(1), substituted "carrying out subsection (b)" for "making grants under subsection (b)".

STATUTORY NOTES AND RELATED SUBSIDIARIES

EFFECTIVE DATE OF 2003 AMENDMENT

Amendment by Pub. L. 108–163 deemed to have taken effect immediately after the enactment of Pub. L. 107–251, see section 3 of Pub. L. 108–163, set out as a note under section 233 of this title.

EFFECTIVE DATE OF 1998 AMENDMENT

Amendment by section 401(b)(1) of Pub. L. 105–392 deemed to have taken effect immediately after enactment of Pub. L. 103–183, see section 401(e) of Pub. L. 105–392, set out as a note under section 242m of this title.

CONSTRUCTION OF 2008 AMENDMENT

Pub. L. 110–392, title I, §111(b), Oct. 13, 2008, 122 Stat. 4199, provided that: "With respect to the advisory council under section 317E(f) of the Public Health Service Act [42 U.S.C. 247b–6(f)], the amendments made by subsection (a) [amending this section] may not be construed as terminating the membership on such council of any individual serving as such a member as of the day before the date of the enactment of this Act [Oct. 13, 2008]."

TERMINATION OF ADVISORY COUNCILS

Advisory councils established after Jan. 5, 1973, to terminate not later than the expiration of the 2-year period beginning on the date of their establishment, unless, in the case of a council established by the President or an officer of the Federal Government, such council is renewed by appropriate action prior to the expiration of such 2-year period, or in the case of a council established by Congress, its duration is otherwise provided by law. See sections 1001(2) and 1013 of Title 5, Government Organization and Employees.

Pub. L. 93–641, §6, Jan. 4, 1975, 88 Stat. 2275, set out as a note under section 217a of this title, provided that an advisory committee established pursuant to the Public Health Service Act shall terminate at such time as may be specifically prescribed by an Act of Congress enacted after Jan. 4, 1975.

[1] See References in Text notes below.

[2] So in original. Probably should be "paragraph (2),".

§247b–7. Loan repayment program

(a) In general

(1) Authority

Subject to paragraph (2), the Secretary may carry out a program of entering into contracts with appropriately qualified health professionals under which such health professionals agree to conduct prevention activities or preparedness and response activities, including rapid response to public health emergencies and significant public health threats, as employees of the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry, in consideration of the Federal Government agreeing to repay, for each year of such service, not more than $50,000 of the principal and interest of the educational loans of such health professionals.

(2) Limitation

The Secretary may not enter into an agreement with a health professional pursuant to paragraph (1) unless such professional—

(A) has a substantial amount of educational loans relative to income; and

(B) agrees to serve as an employee of the Centers for Disease Control and Prevention or the Agency for Toxic Substances and Disease Registry for purposes of paragraph (1) for a period of not less than 2 years.

(b) Applicability of certain provisions

With respect to the National Health Service Corps Loan Repayment Program established in subpart III of part D of this subchapter, the provisions of such subpart shall, except as inconsistent with subsection (a), apply to the program established in this section in the same manner and to the same extent as such provisions apply to the National Health Service Corps Loan Repayment Program.

(c) Authorization of appropriations

(1) In general

For the purpose of carrying out this section, except as described in paragraph (2), there are authorized to be appropriated $500,000 for fiscal year 1994, and such sums as may be necessary for each of the fiscal years 1995 through 2002.

(2) Epidemic Intelligence Service program

For purposes of carrying out this section with respect to qualified health professionals serving in the Epidemic Intelligence Service, as authorized under section 247b–8 of this title, there is authorized to be appropriated $1,000,000 for each of fiscal years 2019 through 2023.

(d) Availability of appropriations

Amounts appropriated for a fiscal year for contracts under subsection (a) shall remain available until the expiration of the second fiscal year beginning after the fiscal year for which the amounts were appropriated.

(July 1, 1944, ch. 373, title III, §317F, as added Pub. L. 103–183, title VII, §703, Dec. 14, 1993, 107 Stat. 2240; amended Pub. L. 105–392, title IV, §406, Nov. 13, 1998, 112 Stat. 3588; Pub. L. 116–22, title III, §301(c), June 24, 2019, 133 Stat. 932.)

EDITORIAL NOTES

AMENDMENTS

2019—Subsec. (a)(1). Pub. L. 116–22, §301(c)(1)(A), inserted "or preparedness and response activities, including rapid response to public health emergencies and significant public health threats" after "conduct prevention activities" and substituted "$50,000" for "$35,000".

Subsec. (a)(2)(B). Pub. L. 116–22, §301(c)(1)(B), substituted "2 years" for "3 years".

Subsec. (c). Pub. L. 116–22, §301(c)(2), designated existing provisions as par. (1), inserted heading, substituted "For the purpose of carrying out this section, except as described in paragraph (2)" for "For the purpose of carrying out this section", and added par. (2).

1998—Subsec. (a)(1). Pub. L. 105–392, §406(1), substituted "$35,000" for "$20,000".

Subsec. (c). Pub. L. 105–392, §406(2), substituted "2002" for "1998".

Subsec. (d). Pub. L. 105–392, §406(3), added subsec. (d).

§247b–8. Fellowship and training programs

The Secretary, acting through the Director of the Centers for Disease Control and Prevention, shall establish fellowship and training programs to be conducted by such Centers to train individuals to develop skills in epidemiology, surveillance, laboratory analysis, and other disease detection and prevention methods. Such programs shall be designed to enable health professionals and health personnel trained under such programs to work, after receiving such training, in local, State, national, and international efforts toward the prevention and control of diseases, injuries, and disabilities. Such fellowships and training may be administered through the use of either appointment or nonappointment procedures.

(July 1, 1944, ch. 373, title III, §317G, as added Pub. L. 105–115, title IV, §408(b)(1), Nov. 21, 1997, 111 Stat. 2371.)

STATUTORY NOTES AND RELATED SUBSIDIARIES

EFFECTIVE DATE

Pub. L. 105–115, title IV, §408(b)(2), Nov. 21, 1997, 111 Stat. 2371, provided that: "The amendment made by this subsection [enacting this section] is deemed to have taken effect July 1, 1995."

§247b–9. Diabetes in children and youth

(a) Surveillance on juvenile diabetes

The Secretary, acting through the Director of the Centers for Disease Control and Prevention, shall develop a sentinel system to collect data on juvenile diabetes, including with respect to incidence and prevalence, and shall establish a national database for such data.

(b) Type 2 diabetes in youth

The Secretary shall implement a national public health effort to address type 2 diabetes in youth, including—

(1) enhancing surveillance systems and expanding research to better assess the prevalence and incidence of type 2 diabetes in youth and determine the extent to which type 2 diabetes is incorrectly diagnosed as type 1 diabetes among children; and

(2) developing and improving laboratory methods to assist in diagnosis, treatment, and prevention of diabetes including, but not limited to, developing noninvasive ways to monitor blood glucose to prevent hypoglycemia and improving existing glucometers that measure blood glucose.

(c) Authorization of appropriations

For the purpose of carrying out this section, there are authorized to be appropriated such sums as may be necessary for each of the fiscal years 2001 through 2005.

(July 1, 1944, ch. 373, title III, §317H, as added Pub. L. 106–310, div. A, title IV, §401, Oct. 17, 2000, 114 Stat. 1112.)

§247b–9a. Better diabetes care

(a) Short title

This section may be cited as the "Catalyst to Better Diabetes Care Act of 2009".

(b) National diabetes report card

(1) In general

The Secretary, in collaboration with the Director of the Centers for Disease Control and Prevention (referred to in this section as the "Director"), shall prepare on a biennial basis a national diabetes report card (referred to in this section as a "Report Card") and, to the extent possible, for each State.[1]

(2) Contents

(A) In general

Each Report Card shall include aggregate health outcomes related to individuals diagnosed with diabetes and prediabetes including—

(i) preventative care practices and quality of care;
(ii) risk factors; and
(iii) outcomes.

(B) Updated reports

Each Report Card that is prepared after the initial Report Card shall include trend analysis for the Nation and, to the extent possible, for each State, for the purpose of—

(i) tracking progress in meeting established national goals and objectives for improving diabetes care, costs, and prevalence (including Healthy People 2010); and
(ii) informing policy and program development.

(3) Availability

The Secretary, in collaboration with the Director, shall make each Report Card publicly available, including by posting the Report Card on the Internet.

(c) Improvement of vital statistics collection

(1) In general

The Secretary, acting through the Director of the Centers for Disease Control and Prevention and in collaboration with appropriate agencies and States, shall—

(A) promote the education and training of physicians on the importance of birth and death certificate data and how to properly complete these documents, including the collection of such data for diabetes and other chronic diseases;

(B) encourage State adoption of the latest standard revisions of birth and death certificates; and

(C) work with States to re-engineer their vital statistics systems in order to provide cost-effective, timely, and accurate vital systems data.

(2) Death certificate additional language

In carrying out this subsection, the Secretary may promote improvements to the collection of diabetes mortality data, including the addition of a question for the individual certifying the cause of death regarding whether the deceased had diabetes.

(d) Study on appropriate level of diabetes medical education

(1) In general

The Secretary shall, in collaboration with the Institute of Medicine and appropriate associations and councils, conduct a study of the impact of diabetes on the practice of medicine in the United States and the appropriateness of the level of diabetes medical education that should be required prior to licensure, board certification, and board recertification.

(2) Report

Not later than 2 years after March 23, 2010, the Secretary shall submit a report on the study under paragraph (1) to the Committees on Ways and Means and Energy and Commerce of the House of Representatives and the Committees on Finance and Health, Education, Labor, and Pensions of the Senate.

(e) Authorization of appropriations

There are authorized to be appropriated to carry out this section such sums as may be necessary.

(Pub. L. 111–148, title X, §10407, Mar. 23, 2010, 124 Stat. 976.)

EDITORIAL NOTES

CODIFICATION

Section was enacted as part of the Patient Protection and Affordable Care Act, and not as part of the Public Health Service Act which comprises this chapter.

[1] *So in original.*

§247b–10. Compilation of data on asthma

(a) In general

The Secretary, acting through the Director of the Centers for Disease Control and Prevention, shall—

(1) conduct local asthma surveillance activities to collect data on the prevalence and severity of asthma and the quality of asthma management;

(2) compile and annually publish data on the prevalence of children suffering from asthma in each State; and

(3) to the extent practicable, compile and publish data on the childhood mortality rate associated with asthma nationally.

(b) Surveillance activities

The Director of the Centers for Disease Control and Prevention, acting through the representative of the Director on the National Asthma Education Prevention Program Coordinating Committee, shall, in carrying out subsection (a), provide an update on surveillance activities at each Committee meeting.

(c) Collaborative efforts

The activities described in subsection (a)(1) may be conducted in collaboration with eligible entities awarded a grant under section 280g of this title.

(d) Authorization of appropriations

For the purpose of carrying out this section, there are authorized to be appropriated such sums as may be necessary for each of the fiscal years 2001 through 2005.

(July 1, 1944, ch. 373, title III, §317I, as added Pub. L. 106–310, div. A, title V, §531, Oct. 17, 2000, 114 Stat. 1117.)

§247b–11. Effects of folic acid in prevention of birth defects

(a) In general

The Secretary, acting through the Director of the Centers for Disease Control and Prevention, shall expand and intensify programs (directly or through grants or contracts) for the following purposes:

(1) To provide education and training for health professionals and the general public for purposes of explaining the effects of folic acid in preventing birth defects and for purposes of encouraging each woman of reproductive capacity (whether or not planning a pregnancy) to consume on a daily basis a dietary supplement that provides an appropriate level of folic acid.

(2) To conduct research with respect to such education and training, including identifying effective strategies for increasing the rate of consumption of folic acid by women of reproductive

capacity.

(3) To conduct research to increase the understanding of the effects of folic acid in preventing birth defects, including understanding with respect to cleft lip, cleft palate, and heart defects.

(4) To provide for appropriate epidemiological activities regarding folic acid and birth defects, including epidemiological activities regarding neural tube defects.

(b) Consultations with States and private entities

In carrying out subsection (a), the Secretary shall consult with the States and with other appropriate public or private entities, including national nonprofit private organizations, health professionals, and providers of health insurance and health plans.

(c) Technical assistance

The Secretary may (directly or through grants or contracts) provide technical assistance to public and nonprofit private entities in carrying out the activities described in subsection (a).

(d) Evaluations

The Secretary shall (directly or through grants or contracts) provide for the evaluation of activities under subsection (a) in order to determine the extent to which such activities have been effective in carrying out the purposes of the program under such subsection, including the effects on various demographic populations. Methods of evaluation under the preceding sentence may include surveys of knowledge and attitudes on the consumption of folic acid and on blood folate levels. Such methods may include complete and timely monitoring of infants who are born with neural tube defects.

(e) Authorization of appropriations

For the purpose of carrying out this section, there are authorized to be appropriated such sums as may be necessary for each of the fiscal years 2001 through 2005.

(July 1, 1944, ch. 373, title III, §317J, as added Pub. L. 106–310, div. A, title VI, §601, Oct. 17, 2000, 114 Stat. 1118.)

§247b–12. Safe motherhood

(a) Surveillance

(1) Purpose

The purposes of this subsection are to establish or continue a Federal initiative to support State and tribal maternal mortality review committees, to improve data collection and reporting around maternal mortality, and to develop or support surveillance systems at the local, State, and national level to better understand the burden of maternal complications and mortality and to decrease the disparities among populations at risk of death and severe complications from pregnancy.

(2) Activities

For the purpose described in paragraph (1), the Secretary, acting through the Director of the Centers for Disease Control and Prevention, may carry out the following activities:

(A) The Secretary may continue and improve activities related to a national maternal mortality data collection and surveillance program to identify and support the review of pregnancy-associated deaths and pregnancy-related deaths that occur during, or within 1 year following, pregnancy, including improving disaggregation of data (in a manner consistent with applicable State and Federal privacy laws).

(B) The Secretary may expand the Pregnancy Risk Assessment Monitoring System to provide surveillance and collect data in each State.

(C) The Secretary may expand the Maternal and Child Health Epidemiology Program to provide technical support, financial assistance, or the time-limited assignment of senior epidemiologists to maternal and child health programs in each State.

(D) The Secretary may, in cooperation with States, Indian tribes, and tribal organizations,

develop a program to support States, Indian tribes, and tribal organizations in establishing or operating maternal mortality review committees, in accordance with subsection (d).

(b) Prevention research

(1) Purpose

The purpose of this subsection is to provide the Secretary with the authority to further expand research concerning risk factors, prevention strategies, and the roles of the family, health care providers and the community in safe motherhood.

(2) Research

The Secretary may carry out activities to expand research relating to—

(A) prepregnancy counseling, especially for at risk populations such as women with diabetes and women with substance use disorder;

(B) the identification of critical components of prenatal delivery and postpartum care;

(C) the identification of outreach and support services, such as folic acid education, that are available for pregnant women;

(D) the identification of women who are at high risk for complications;

(E) preventing preterm delivery;

(F) preventing urinary tract infections;

(G) preventing unnecessary caesarean sections;

(H) the identification of the determinants of disparities in maternal care, health risks, and health outcomes, including an examination of the higher rates of maternal mortality among African American women and other groups of women with disproportionately high rates of maternal mortality;

(I) activities to reduce disparities in maternity services and outcomes;

(J) an examination of the relationship between interpersonal violence and maternal complications and mortality;

(K) preventing and reducing adverse health consequences that may result from smoking and substance abuse and misuse before, during and after pregnancy;

(L) preventing infections that cause maternal and infant complications;

(M) an examination of the relationship between maternal health and obstetric services in rural areas and outcomes in delivery and postpartum care; and

(N) other areas determined appropriate by the Secretary.

(c) Prevention programs

The Secretary may carry out activities to promote safe motherhood, including—

(1) public education campaigns on healthy pregnancies;

(2) education programs for physicians, nurses and other health care providers;

(3) activities to promote community support services for pregnant women; and

(4) activities to promote physical, mental, and behavioral health during, and up to 1 year following, pregnancy, with an emphasis on prevention of, and treatment for, mental health disorders and substance use disorder.

(d) Maternal mortality review committees

(1) In general

In order to participate in the program under subsection (a)(2)(D), the applicable maternal mortality review committee of the State, Indian tribe, or tribal organization shall—

(A) include multidisciplinary and diverse membership that represents a variety of clinical specialties (including obstetricians and gynecologists), State, tribal, or local public health officials, epidemiologists, statisticians, community organizations, geographic regions within the area covered by such committee, and individuals or organizations that represent the populations in the area covered by such committee that are most affected by pregnancy-related deaths or pregnancy-associated deaths and lack of access to maternal health care services; and

(B) demonstrate to the Centers for Disease Control and Prevention that such maternal

mortality review committee's methods and processes for data collection and review, as required under paragraph (3), use best practices to reliably determine and include all pregnancy-associated deaths and pregnancy-related deaths, regardless of the outcome of the pregnancy.

(2) Process for confidential reporting

States, Indian tribes, and tribal organizations that participate in the program described in this subsection shall, through the State maternal mortality review committee, develop a process that—

(A) provides for confidential case reporting of pregnancy-associated and pregnancy-related deaths to the appropriate State or tribal health agency, including such reporting by—

(i) health care professionals;

(ii) health care facilities;

(iii) any individual responsible for completing death records, including medical examiners and medical coroners; and

(iv) other appropriate individuals or entities; and

(B) provides for voluntary and confidential case reporting of pregnancy-associated deaths and pregnancy-related deaths to the appropriate State or tribal health agency by family members of the deceased, and other appropriate individuals, for purposes of review by the applicable maternal mortality review committee; and

(C) shall include—

(i) making publicly available contact information of the committee for use in such reporting; and

(ii) conducting outreach to local professional organizations, community organizations, and social services agencies regarding the availability of the review committee.

(3) Data collection and review

States, Indian tribes, and tribal organizations that participate in the program described in this subsection shall—

(A) annually identify pregnancy-associated deaths and pregnancy-related deaths—

(i) through the appropriate vital statistics unit by—

(I) matching each death record related to a pregnancy-associated death or pregnancy-related death in the State or tribal area in the applicable year to a birth certificate of an infant or fetal death record, if available;

(II) to the extent practicable, identifying an underlying or contributing cause of each pregnancy-associated death and each pregnancy-related death in the State or tribal area in the applicable year; and

(III) collecting data from medical examiner and coroner reports and coordinating with individuals responsible for certifying deaths to improve the collection and quality of death record reports, including by amending errors and missing or incomplete information to cause-of-death information on a death certificate, as appropriate;

(ii) using other appropriate methods or information to identify pregnancy-associated deaths and pregnancy-related deaths, including deaths from pregnancy outcomes not identified through clause (i)(I);

(B) through the maternal mortality review committee, review data and information to identify adverse outcomes that may contribute to pregnancy-associated death and pregnancy-related death, and to identify trends, patterns, and disparities in such adverse outcomes to allow the State, Indian tribe, or tribal organization to make recommendations to individuals and entities described in paragraph (2)(A), as appropriate, to improve maternal care and reduce pregnancy-associated death and pregnancy-related death;

(C) identify training available to the individuals and entities described in paragraph (2)(A) for accurate identification and reporting of pregnancy-associated and pregnancy-related deaths;

(D) ensure that, to the extent practicable, the data collected and reported under this paragraph is in a format that allows for analysis by the Centers for Disease Control and Prevention; and

(E) publicly identify the methods used to identify pregnancy-associated deaths and pregnancy-related deaths in accordance with this section.

(4) Confidentiality

States, Indian tribes, and tribal organizations participating in the program described in this subsection shall establish confidentiality protections to ensure, at a minimum, that—

(A) there is no disclosure by the maternal mortality review committee, including any individual members of the committee, to any person, including any government official, of any identifying information about any specific maternal mortality case; and

(B) no information from committee proceedings, including deliberation or records, is made public unless specifically authorized under State and Federal law.

(5) Reports to CDC

For fiscal year 2019, and each subsequent fiscal year, each maternal mortality review committee participating in the program described in this subsection shall submit to the Director of the Centers for Disease Control and Prevention a report that includes—

(A) data, findings, and any recommendations of such committee; and

(B) as applicable, information on the implementation during such year of any recommendations submitted by the committee in a previous year.

(6) State partnerships

States may partner with one or more neighboring States to carry out the activities under this subparagraph. With respect to the States in such a partnership, any requirement under this subparagraph relating to the reporting of information related to such activities shall be deemed to be fulfilled by each such State if a single such report is submitted for the partnership.

(7) Appropriate mechanisms for Indian tribes and tribal organizations

The Secretary, in consultation with Indian tribes, shall identify and establish appropriate mechanisms for Indian tribes and tribal organizations to demonstrate, report data, and conduct the activities as required for participation in the program described in this subsection. Such mechanisms may include technical assistance with respect to grant application and submission procedures, and award management activities.

(8) Research availability

The Secretary shall develop a process to ensure that data collected under paragraph (5) is made available, as appropriate and practicable, for research purposes, in a manner that protects individually identifiable or potentially identifiable information and that is consistent with State and Federal privacy law.

(e) Best practices relating to the prevention of maternal mortality

(1) In general

The Secretary, acting through the Director of the Centers for Disease Control and Prevention, shall, in consultation with the Administrator of the Health Resources and Services Administration, identify and disseminate to health care providers, relevant professional societies, and perinatal quality collaboratives, best practices related to preventing maternal morbidity and mortality, taking into consideration any relevant findings from other Federal maternal health programs.

(2) Frequency

The Secretary, acting through the Director of the Centers for Disease Control and Prevention, shall disseminate the best practices referred to in paragraph (1) not less than once per fiscal year.

(f) Definitions

In this section—

(1) the terms "Indian tribe" and "tribal organization" have the meanings given such terms in

section 5304 of title 25;

(2) the term "pregnancy-associated death" means a death of a woman, by any cause, that occurs during, or within 1 year following, her pregnancy, regardless of the outcome, duration, or site of the pregnancy; and

(3) the term "pregnancy-related death" means a death of a woman that occurs during, or within 1 year following, her pregnancy, regardless of the outcome, duration, or site of the pregnancy—

(A) from any cause related to, or aggravated by, the pregnancy or its management; and

(B) not from accidental or incidental causes.

(g) Authorization of appropriations

For the purpose of carrying out this section, there are authorized to be appropriated $100,000,000 for each of fiscal years 2026 through 2030.

(July 1, 1944, ch. 373, title III, §317K, as added Pub. L. 106–310, div. A, title IX, §901, Oct. 17, 2000, 114 Stat. 1125; amended Pub. L. 115–344, §2, Dec. 21, 2018, 132 Stat. 5047; Pub. L. 117–103, div. P, title I, §141(c), Mar. 15, 2022, 136 Stat. 798; Pub. L. 119–75, div. J, title V, §6501, Feb. 3, 2026, 140 Stat. 689.)

EDITORIAL NOTES

AMENDMENTS

2026—Subsec. (d)(1)(A). Pub. L. 119–75, §6501(a)(1), inserted "(including obstetricians and gynecologists)" after "clinical specialties".

Subsec. (d)(3)(A)(i)(I). Pub. L. 119–75, §6501(a)(2)(A), substituted "if available" for "as applicable".

Subsec. (d)(3)(A)(i)(III). Pub. L. 119–75, §6501(a)(2)(B), substituted "and coordinating with individuals responsible for certifying deaths to improve the collection and quality of death record reports, including by amending errors and missing or incomplete information to cause-of-death information on a death certificate, as appropriate" for ", as appropriate".

Subsecs. (e), (f). Pub. L. 119–75, §6501(b), added subsec. (e) and redesignated former subsec. (e) as (f). Former subsec. (f) redesignated (g).

Subsec. (g). Pub. L. 119–75, §6501(b)(1), (c), redesignated subsec. (f) as (g) and substituted "$100,000,000 for each of fiscal years 2026 through 2030" for "$58,000,000 for each of fiscal years 2019 through 2023".

2022—Subsec. (a)(2)(A). Pub. L. 117–103, §141(c)(1), inserted before period at end ", including improving disaggregation of data (in a manner consistent with applicable State and Federal privacy laws)".

Subsec. (b)(2)(M), (N). Pub. L. 117–103, §141(c)(2), added subpar. (M) and redesignated former subpar. (M) as (N).

2018—Subsec. (a)(1). Pub. L. 115–344, §2(1)(A), substituted "purposes of this subsection are to establish or continue a Federal initiative to support State and tribal maternal mortality review committees, to improve data collection and reporting around maternal mortality, and to develop or support" for "purpose of this subsection is to develop" and "populations at risk of death and severe" for "population at risk of death and".

Subsec. (a)(2)(A). Pub. L. 115–344, §2(1)(B)(i), amended subpar. (A) generally. Prior to amendment, subpar. (A) read as follows: "The Secretary may establish and implement a national surveillance program to identify and promote the investigation of deaths and severe complications that occur during pregnancy."

Subsec. (a)(2)(D). Pub. L. 115–344, §2(1)(B)(ii), added subpar. (D).

Subsec. (b)(2)(A). Pub. L. 115–344, §2(2)(A), substituted "prepregnancy" for "encouraging preconception" and "women with diabetes and women with substance use disorder" for "diabetics".

Subsec. (b)(2)(H). Pub. L. 115–344, §2(2)(B), inserted "the identification of the determinants of disparities in maternal care, health risks, and health outcomes, including" before "an examination" and "and other groups of women with disproportionately high rates of maternal mortality" before semicolon at end.

Subsec. (b)(2)(I). Pub. L. 115–344, §2(2)(E), added subpar. (I). Former subpar. (I) redesignated (J).

Pub. L. 115–344, §2(2)(C), substituted "interpersonal" for "domestic".

Subsec. (b)(2)(J). Pub. L. 115–344, §2(2)(D), redesignated subpar. (I) as (J). Former subpar. (J) redesignated (K).

Subsec. (b)(2)(K). Pub. L. 115–344, §2(2)(D), (F), redesignated subpar. (J) as (K) and substituted "and substance abuse and misuse" for ", alcohol and illegal drug use". Former subpar. (K) redesignated (L).

Subsec. (b)(2)(L), (M). Pub. L. 115–344, §2(2)(D), redesignated subpars. (K) and (L) as (L) and (M), respectively.

Subsec. (c). Pub. L. 115–344, §2(3)(A), (B), struck out par. (1) designation and heading "In general" before "The Secretary" and redesignated subpars. (A) to (C) of former par. (1) as pars. (1) to (3), respectively. Amendment was executed to reflect the probable intent of Congress notwithstanding minor error in quoted par. (1) heading in original text directed to be struck out.

Subsec. (c)(1). Pub. L. 115–344, §2(3)(C), struck out "and the building of partnerships with outside organizations concerned about safe motherhood" after "pregnancies".

Subsec. (c)(4). Pub. L. 115–344, §2(3)(D)–(F), added par. (4).

Subsecs. (d), (e). Pub. L. 115–344, §2(5), added subsecs. (d) and (e). Former subsec. (d) redesignated (f).

Subsec. (f). Pub. L. 115–344, §2(4), (6), redesignated subsec. (d) as (f) and substituted "$58,000,000 for each of fiscal years 2019 through 2023" for "such sums as may be necessary for each of the fiscal years 2001 through 2005".

§247b–13. Prenatal and postnatal health

(a) In general

The Secretary, acting through the Director of the Centers for Disease Control and Prevention, shall carry out programs—

(1) to collect, analyze, and make available data on prenatal smoking and alcohol and other substance abuse and misuse, including—

(A) data on—

(i) the incidence, prevalence, and implications of such activities; and

(ii) the incidence and prevalence of implications and outcomes, including neonatal abstinence syndrome and other maternal and child health outcomes associated with such activities; and

(B) additional information or data, as appropriate, on family health history, medication exposures during pregnancy, demographic information, such as race, ethnicity, geographic location, and family history, and other relevant information, to inform such analysis;

(2) to conduct applied epidemiological research on the prevention and long-term outcomes associated with prenatal and postnatal smoking, alcohol and other substance abuse and misuse;

(3) to support, conduct, and evaluate the effectiveness of educational, treatment, and cessation programs;

(4) to provide information and education to the public on the prevention and implications of prenatal and postnatal smoking, alcohol and other substance abuse and misuse; and

(5) to issue public reports on the analysis of data described in paragraph (1), including analysis of—

(A) long-term outcomes of children affected by neonatal abstinence syndrome;

(B) health outcomes associated with prenatal smoking, alcohol, and substance abuse and misuse; and

(C) relevant studies, evaluations, or information the Secretary determines to be appropriate.

(b) Grants

In carrying out subsection (a), the Secretary may award grants to and enter into contracts with States, local governments, tribal entities, scientific and academic institutions, federally qualified health centers, and other public and nonprofit entities, and may provide technical and consultative assistance to such entities.

(c) Coordinating activities

To carry out this section, the Secretary may—

(1) provide technical and consultative assistance to entities receiving grants under subsection (b);

(2) ensure a pathway for data sharing between States, tribal entities, and the Centers for Disease Control and Prevention;

(3) ensure data collection under this section is consistent with applicable State, Federal, and Tribal privacy laws; and

(4) coordinate with the National Coordinator for Health Information Technology, as appropriate, to assist States and Tribes in implementing systems that use standards recognized by such National Coordinator, as such recognized standards are available, in order to facilitate interoperability between such systems and health information technology systems, including certified health information technology.

(d) Authorization of appropriations

For the purpose of carrying out this section, there are authorized to be appropriated such $4,250,000 for each of fiscal years 2026 through 2030.

(July 1, 1944, ch. 373, title III, §317L, as added Pub. L. 106–310, div. A, title IX, §911, Oct. 17, 2000, 114 Stat. 1127; amended Pub. L. 115–271, title VII, §7064, Oct. 24, 2018, 132 Stat. 4021; Pub. L. 119–44, title I, §101, Dec. 1, 2025, 139 Stat. 670.)

EDITORIAL NOTES

AMENDMENTS

2025—Subsec. (d). Pub. L. 119–44 substituted "$4,250,000 for each of fiscal years 2026 through 2030" for "such sums as may be necessary for each of the fiscal years 2019 through 2023".

2018—Subsec. (a)(1). Pub. L. 115–271, §7064(1)(A), amended par. (1) generally. Prior to amendment, par. (1) read as follows: "to collect, analyze, and make available data on prenatal smoking, alcohol and illegal drug use, including data on the implications of such activities and on the incidence and prevalence of such activities and their implications;".

Subsec. (a)(2). Pub. L. 115–271, §7064(1)(B), substituted "prevention and long-term outcomes associated with" for "prevention of" and "other substance abuse and misuse" for "illegal drug use".

Subsec. (a)(3). Pub. L. 115–271, §7064(1)(C), substituted ", treatment, and cessation programs;" for "and cessation programs; and".

Subsec. (a)(4). Pub. L. 115–271, §7064(1)(D), substituted "other substance abuse and misuse; and" for "illegal drug use."

Subsec. (a)(5). Pub. L. 115–271, §7064(1)(E), added par. (5).

Subsec. (b). Pub. L. 115–271, §7064(2), inserted "tribal entities," after "local governments,".

Subsec. (c). Pub. L. 115–271, §7064(4), added subsec. (c). Former subsec. (c) redesignated (d).

Subsec. (d). Pub. L. 115–271, §7064(3), (5), redesignated subsec. (c) as (d) and substituted "2019 through 2023" for "2001 through 2005".

STATUTORY NOTES AND RELATED SUBSIDIARIES

IMPROVING DATA AND THE PUBLIC HEALTH RESPONSE

Pub. L. 114–91, §4, Nov. 25, 2015, 129 Stat. 725, provided that: "The Secretary [of Health and Human Services] may continue activities, as appropriate, related to—

"(1) providing technical assistance to support States and Federally recognized Indian Tribes in collecting information on neonatal abstinence syndrome through the utilization of existing surveillance systems and collaborating with States and Federally recognized Indian Tribes to improve the quality, consistency, and collection of such data; and

"(2) providing technical assistance to support States in implementing effective public health measures, such as disseminating information to educate the public, health care providers, and other stakeholders on prenatal opioid use and neonatal abstinence syndrome."

§247b–13a. Screening and treatment for maternal mental health and substance use disorders

(a) Grants

The Secretary shall make grants to States, Indian Tribes and Tribal organizations (as such terms

are defined in section 5304 of title 25) to establish, improve, or maintain programs for screening, assessment, and treatment services, including culturally and linguistically appropriate services, as appropriate, for women who are postpartum, pregnant, or have given birth within the preceding 12 months, for maternal mental health and substance use disorders.

(b) Application

To seek a grant under this section, an entity listed in subsection (a) shall submit an application to the Secretary at such time, in such manner, and containing such information as the Secretary may require. At a minimum, any such application shall include explanations of—

(1) how a program, or programs, will increase the percentage of women screened and treated, as appropriate, for maternal mental health and substance use disorders in 1 or more communities; and

(2) how a program, or programs, if expanded, would increase access to screening and treatment services for maternal mental health and substance use disorders.

(c) Priority

In awarding grants under this section, the Secretary shall, as appropriate, give priority to entities listed in subsection (a) that—

(1) are proposing to create, improve, or enhance screening, prevention, and treatment services for maternal mental health and substance use disorders in primary care settings;

(2) are currently partnered with, or will partner with, one or more community-based organizations to address maternal mental health and substance use disorders;

(3) are located in, or provide services under this section in, an area with disproportionately high rates of maternal mental health or substance use disorders or other related disparities; and

(4) operate in a health professional shortage area designated under section 254e of this title, including maternity care health professional target areas.

(d) Use of funds

The activities eligible for funding through a grant under subsection (a)—

(1) shall include—

(A) providing appropriate training on maternal mental health and substance use disorder screening, brief intervention, treatment (as applicable for health care providers), and referrals for treatment to health care providers in the primary care setting and, as applicable, relevant health paraprofessionals;

(B) providing information on maternal mental health and substance use disorder screening, brief intervention, treatment (as applicable for health care providers) and referrals for treatment, follow-up support services, and linkages to community-based resources to health care providers in the primary care setting and, as applicable, relevant health paraprofessionals; and

(C) to the extent practicable and appropriate, enabling health care providers (such as obstetrician-gynecologists, nurse practitioners, nurse midwives, pediatricians, psychiatrists, mental and other behavioral health care providers, and adult primary care clinicians) to provide or receive real-time psychiatric consultation (in-person or remotely), including through the use of technology-enabled collaborative learning and capacity building models (as defined in section 254c–20 of this title), to aid in the treatment of pregnant and postpartum women; and

(2) may include—

(A) establishing linkages with and among community-based resources, including mental health resources, primary care resources, and support groups;

(B) utilizing telehealth services, including for rural areas and medically underserved areas (as defined in section 254c–14(a) of this title);

(C) providing assistance to pregnant and postpartum women to receive maternal mental health and substance use disorder treatment, including patient consultation, care coordination, and navigation for such treatment;

(D) coordinating, as appropriate, with maternal and child health programs of State, local, and Tribal governments, including child psychiatric access programs;

(E) conducting public outreach and awareness regarding grants under subsection (a);

(F) creating multistate consortia to carry out the activities required or authorized under this subsection; and

(G) training health care providers in the primary care setting and relevant health paraprofessionals on trauma-informed care, culturally and linguistically appropriate services, and best practices related to training to improve the provision of maternal mental health and substance use disorder care for racial and ethnic minority populations and reduce related disparities in the delivery of such care.

(e) Technical assistance

The Secretary shall provide technical assistance to grantees and entities listed in subsection (a) for carrying out activities pursuant to this section.

(f) Dissemination of best practices

The Secretary, based on evaluation of the activities funded pursuant to this section, shall identify and disseminate evidence-based or evidence-informed practices for screening, assessment, treatment, and referral to treatment services for maternal mental health and substance use disorders, including culturally and linguistically appropriate services, for women during pregnancy and 12 months following pregnancy.

(g) Matching requirement

The Federal share of the cost of the activities for which a grant is made to an entity under subsection (a) shall not exceed 90 percent of the total cost of such activities.

(h) Authorization of appropriations

To carry out this section, there are authorized to be appropriated $24,000,000 for each of fiscal years 2023 through 2027.

(July 1, 1944, ch. 373, title III, §317L–1, as added Pub. L. 114–255, div. B, title X, §10005, Dec. 13, 2016, 130 Stat. 1266; amended Pub. L. 117–328, div. FF, title I, §1111, Dec. 29, 2022, 136 Stat. 5640.)

EDITORIAL NOTES

AMENDMENTS

2022—Pub. L. 117–328, §1111(a)(1), substituted "maternal mental health and substance use disorders" for "maternal depression" in section catchline.

Subsec. (a). Pub. L. 117–328, §1111(a)(2), inserted ", Indian Tribes and Tribal organizations (as such terms are defined in section 5304 of title 25)" after "States" and substituted "for women who are postpartum, pregnant, or have given birth within the preceding 12 months, for maternal mental health and substance use disorders" for "for women who are pregnant, or who have given birth within the preceding 12 months, for maternal depression".

Subsec. (b). Pub. L. 117–328, §1111(b)(1), substituted "an entity listed in subsection (a) shall submit" for "a State shall submit" in introductory provisions.

Subsec. (b)(1), (2). Pub. L. 117–328, §1111(b)(2), substituted "maternal mental health and substance use disorders" for "maternal depression".

Subsec. (c). Pub. L. 117–328, §1111(c), substituted "shall, as appropriate, give priority to entities listed in subsection (a) that—" for "may give priority to States proposing to improve or enhance access to screening", inserted par. (1) designation and "are proposing to create, improve, or enhance screening, prevention, and treatment" before "services", substituted "maternal mental health and substance use disorders" for "maternal depression" and added pars. (2) to (4).

Subsec. (d)(1)(A). Pub. L. 117–328, §1111(d)(1)(A), substituted "on maternal mental health and substance use disorder screening, brief intervention, treatment (as applicable for health care providers), and referrals for treatment to health care providers in the primary care setting and, as applicable, relevant health paraprofessionals;" for "to health care providers; and".

Subsec. (d)(1)(B). Pub. L. 117–328, §1111(d)(1)(B), substituted "on maternal mental health and substance use disorder screening, brief intervention, treatment (as applicable for health care providers) and referrals for

treatment, follow-up support services, and linkages to community-based resources to health care providers in the primary care setting and, as applicable, relevant health paraprofessionals; and" for "to health care providers, including information on maternal depression screening, treatment, and followup support services, and linkages to community-based resources; and".

Subsec. (d)(1)(C). Pub. L. 117–328, §1111(d)(1)(C), added subpar. (C).

Subsec. (d)(2)(A). Pub. L. 117–328, §1111(d)(2)(A), (B), redesignated subpar. (B) as (A) and struck out former subpar. (A) which read as follows: "enabling health care providers (including obstetrician-gynecologists, pediatricians, psychiatrists, mental health care providers, and adult primary care clinicians) to provide or receive real-time psychiatric consultation (in-person or remotely) to aid in the treatment of pregnant and parenting women;".

Subsec. (d)(2)(B). Pub. L. 117–328, §1111(d)(2)(B), (D)(i), redesignated subpar. (C) as (B) and inserted ", including" before "for rural areas". Former subpar. (B) redesignated (A).

Subsec. (d)(2)(C) to (G). Pub. L. 117–328, §1111(d)(2)(C), (D)(ii), (E), added subpars. (C) to (G). Former subpar. (C) redesignated (B).

Subsecs. (e) to (g). Pub. L. 117–328, §1111(e)(2), added subsecs. (e) to (g). Former subsec. (e) redesignated (h).

Subsec. (h). Pub. L. 117–328, §1111(e)(1), (f), redesignated subsec. (e) as (h) and substituted "$24,000,000" for "$5,000,000" and "2023 through 2027" for "2018 through 2022".

§247b–14. Oral health promotion and disease prevention

(a) Grants to increase resources for community water fluoridation

(1) In general

The Secretary, acting through the Director of the Centers for Disease Control and Prevention, may make grants to States and Indian tribes for the purpose of increasing the resources available for community water fluoridation.

(2) Use of funds

A State shall use amounts provided under a grant under paragraph (1)—

(A) to purchase fluoridation equipment;

(B) to train fluoridation engineers;

(C) to develop educational materials on the benefits of fluoridation; or

(D) to support the infrastructure necessary to monitor and maintain the quality of water fluoridation.

(b) Community water fluoridation

(1) In general

The Secretary, acting through the Director of the Centers for Disease Control and Prevention and in collaboration with the Director of the Indian Health Service, shall establish a demonstration project that is designed to assist rural water systems in successfully implementing the water fluoridation guidelines of the Centers for Disease Control and Prevention that are entitled "Engineering and Administrative Recommendations for Water Fluoridation, 1995" (referred to in this subsection as the "EARWF").

(2) Requirements

(A) Collaboration

In collaborating under paragraph (1), the Directors referred to in such paragraph shall ensure that technical assistance and training are provided to tribal programs located in each of the 12 areas of the Indian Health Service. The Director of the Indian Health Service shall provide coordination and administrative support to tribes under this section.

(B) General use of funds

Amounts made available under paragraph (1) shall be used to assist small water systems in improving the effectiveness of water fluoridation and to meet the recommendations of the

EARWF.

(C) Fluoridation specialists

(i) In general

In carrying out this subsection, the Secretary shall provide for the establishment of fluoridation specialist engineering positions in each of the Dental Clinical and Preventive Support Centers through which technical assistance and training will be provided to tribal water operators, tribal utility operators and other Indian Health Service personnel working directly with fluoridation projects.

(ii) Liaison

A fluoridation specialist shall serve as the principal technical liaison between the Indian Health Service and the Centers for Disease Control and Prevention with respect to engineering and fluoridation issues.

(iii) CDC

The Director of the Centers for Disease Control and Prevention shall appoint individuals to serve as the fluoridation specialists.

(D) Implementation

The project established under this subsection shall be planned, implemented and evaluated over the 5-year period beginning on the date on which funds are appropriated under this section and shall be designed to serve as a model for improving the effectiveness of water fluoridation systems of small rural communities.

(3) Evaluation

In conducting the ongoing evaluation as provided for in paragraph (2)(D), the Secretary shall ensure that such evaluation includes—

(A) the measurement of changes in water fluoridation compliance levels resulting from assistance provided under this section;

(B) the identification of the administrative, technical and operational challenges that are unique to the fluoridation of small water systems;

(C) the development of a practical model that may be easily utilized by other tribal, State, county or local governments in improving the quality of water fluoridation with emphasis on small water systems; and

(D) the measurement of any increased percentage of Native Americans or Alaskan Natives who receive the benefits of optimally fluoridated water.

(c) School-based dental sealant program

(1) In general

The Secretary, acting through the Director of the Centers for Disease Control and Prevention and in collaboration with the Administrator of the Health Resources and Services Administration, shall award a grant to each of the 50 States and territories and to Indians, Indian tribes, tribal organizations and urban Indian organizations (as such terms are defined in section 1603 of title 25) to provide for the development of school-based dental sealant programs to improve the access of children to sealants.

(2) Use of funds

A State shall use amounts received under a grant under paragraph (1) to provide funds to eligible school-based entities or to public elementary or secondary schools to enable such entities or schools to provide children with access to dental care and dental sealant services. Such services shall be provided by licensed dental health professionals in accordance with State practice licensing laws.

(3) Eligibility

To be eligible to receive funds under paragraph (1), an entity shall—

(A) prepare and submit to the State an application at such time, in such manner and containing such information as the State may require; and

(B) be a public elementary or secondary school—

(i) that is located in an urban area in which and [1] more than 50 percent of the student population is participating in Federal or State free or reduced meal programs; or

(ii) that is located in a rural area and, with respect to the school district in which the school is located, the district involved has a median income that is at or below 235 percent of the poverty line, as defined in section 9902(2) of this title.

(d) Oral health infrastructure

(1) Cooperative agreements

The Secretary, acting through the Director of the Centers for Disease Control and Prevention, shall enter into cooperative agreements with State, territorial, and Indian tribes or tribal organizations (as those terms are defined in section 1603 of title 25) to establish oral health leadership and program guidance, oral health data collection and interpretation,[2] (including determinants of poor oral health among vulnerable populations), a multi-dimensional delivery system for oral health, and to implement science-based programs (including dental sealants and community water fluoridation) to improve oral health.

(2) Authorization of appropriations

There is authorized to be appropriated such sums as necessary to carry out this subsection for fiscal years 2010 through 2014.

(e) Definitions

For purposes of this section, the term "Indian tribe" means an Indian tribe or tribal organization as defined in section 5304(b) and section 5304(c) [3] of title 25.

(f) Authorization of appropriations

For the purpose of carrying out this section, there are authorized to be appropriated such sums as may be necessary for each of the fiscal years 2001 through 2005.

(July 1, 1944, ch. 373, title III, §317M, as added Pub. L. 106–310, div. A, title XVI, §1602, Oct. 17, 2000, 114 Stat. 1148; amended Pub. L. 111–148, title IV, §4102(b), (c), Mar. 23, 2010, 124 Stat. 551, 552.)

EDITORIAL NOTES

REFERENCES IN TEXT

Section 5304 of title 25, referred to in subsec. (e), has been amended, and subsecs. (b) and (c) of section 5304 no longer define the terms "Indian tribe" and "tribal organization". However, such terms are defined elsewhere in that section.

AMENDMENTS

2010—Subsec. (c)(1). Pub. L. 111–148, §4102(b), substituted "shall award a grant to each of the 50 States and territories and to Indians, Indian tribes, tribal organizations and urban Indian organizations (as such terms are defined in section 1603 of title 25)" for "may award grants to States and Indian tribes".

Subsecs. (d) to (f). Pub. L. 111–148, §4102(c), added subsec. (d) and redesignated former subsecs. (d) and (e) as (e) and (f), respectively.

[1] So in original. The word "and" probably should not appear.

[2] So in original. The comma probably should not appear.

[3] See References in Text note below.

§247b–14a. Identification of interventions that reduce the burden and transmission of oral, dental, and craniofacial diseases in high risk populations; development of approaches for pediatric oral and craniofacial assessment

(a) In general

The Secretary of Health and Human Services, through the Maternal and Child Health Bureau, the Indian Health Service, and in consultation with the National Institutes of Health and the Centers for Disease Control and Prevention, shall—

(1) support community-based research that is designed to improve understanding of the etiology, pathogenesis, diagnosis, prevention, and treatment of pediatric oral, dental, craniofacial diseases and conditions and their sequelae in high risk populations;

(2) support demonstrations of preventive interventions in high risk populations including nutrition, parenting, and feeding techniques; and

(3) develop clinical approaches to assess individual patients for the risk of pediatric dental disease.

(b) Compliance with State practice laws

Treatment and other services shall be provided pursuant to this section by licensed dental health professionals in accordance with State practice and licensing laws.

(c) Authorization of appropriations

There are authorized to be appropriated such sums as may be necessary to carry out this section for each [1] the fiscal years 2001 through 2005.

(Pub. L. 106–310, div. A, title XVI, §1601, Oct. 17, 2000, 114 Stat. 1148.)

EDITORIAL NOTES

CODIFICATION

Section was enacted as part of the Children's Health Act of 2000, and not as part of the Public Health Service Act which comprises this chapter.

[1] So in original. Probably should be followed by "of".

§247b–15. Surveillance and education regarding infections associated with illicit drug use and other risk factors

(a) In general

The Secretary, acting through the Director of the Centers for Disease Control and Prevention, may (directly or through grants to public and nonprofit private entities) provide for programs for the following:

(1) To cooperate with States and Indian tribes in implementing or maintaining a national system to determine the incidence of infections commonly associated with illicit drug use, such as viral hepatitis, human immunodeficiency virus, and infective endocarditis, and to assist the States in determining the prevalence of such infections, which may include the reporting of cases of such infections.

(2) To identify, counsel, and offer testing to individuals who are at risk of infections described in paragraph (1) resulting from illicit drug use, receiving blood transfusions prior to July 1992, or other risk factors.

(3) To provide appropriate referrals for counseling, testing, and medical treatment of individuals identified under paragraph (2) and to ensure, to the extent practicable, the provision of appropriate

follow-up services.

(4) To develop and disseminate public information and education programs for the detection and control of infections described in paragraph (1), with priority given to high-risk populations as determined by the Secretary.

(5) To improve the education, training, and skills of health professionals in the detection and control of infections described in paragraph (1), including to improve coordination of treatment of substance use disorders and infectious diseases, with priority given to substance use disorder treatment providers, pediatricians and other primary care providers, obstetrician-gynecologists, and infectious disease clinicians, including HIV clinicians.

(b) Laboratory procedures

The Secretary may (directly or through grants to public and nonprofit private entities) carry out programs to provide for improvements in the quality of clinical-laboratory procedures regarding infections described in subsection (a)(1).

(c) Definition

In this section, the term "Indian tribe" has the meaning given that term in section 5304 of title 25.

(d) Authorization of appropriations

For the purpose of carrying out this section, there are authorized to be appropriated $40,000,000 for each of the fiscal years 2026 through 2030.

(July 1, 1944, ch. 373, title III, §317N, as added Pub. L. 106–310, div. A, title XVIII, §1801, Oct. 17, 2000, 114 Stat. 1152; amended Pub. L. 115–271, title VII, §7141, Oct. 24, 2018, 132 Stat. 4056; Pub. L. 119–44, title I, §102, Dec. 1, 2025, 139 Stat. 670.)

EDITORIAL NOTES

AMENDMENTS

2025—Subsec. (d). Pub. L. 119–44 substituted "fiscal years 2026 through 2030" for "fiscal years 2019 through 2023".

2018—Pub. L. 115–271 amended section generally. Prior to amendment, section related to surveillance and education regarding hepatitis C virus.

STATUTORY NOTES AND RELATED SUBSIDIARIES

STUDY AND DEMONSTRATION PROJECTS REGARDING CASES OF HEPATITIS C AMONG CERTAIN EMERGENCY RESPONSE EMPLOYEES

Pub. L. 106–398, §1 [[div. A], title XVII, §1704], Oct. 30, 2000, 114 Stat. 1654, 1654A–365, provided that:

"(a) STUDY REGARDING PREVALENCE AMONG CERTAIN EMERGENCY RESPONSE EMPLOYEES.—

"(1) IN GENERAL.—The Secretary of Health and Human Services (referred to in this section as the 'Secretary'), in consultation with the Secretary of Labor, shall conduct a study to determine—

"(A) an estimate of the prevalence of hepatitis C among designated emergency response employees in the United States; and

"(B) the likely means through which such employees become infected with such disease in the course of performing their duties as such employees.

"(2) DESIGNATED EMERGENCY RESPONSE EMPLOYEES.—For purposes of this section, the term 'designated emergency response employees' means firefighters, paramedics, and emergency medical technicians who are employees or volunteers of units of local government.

"(3) DATE CERTAIN FOR COMPLETION; REPORT TO CONGRESS.—The Secretary shall commence the study under paragraph (1) not later than 90 days after the date of the enactment of this Act [Oct. 30, 2000]. Not later than one year after such date, the Secretary shall complete the study and submit to the Congress a report describing the findings of the study.

"(b) DEMONSTRATION PROJECTS REGARDING TRAINING AND TREATMENT.—

"(1) IN GENERAL.—The Secretary, in consultation with the Secretary of Labor, shall make grants to qualifying local governments for the purpose of carrying out demonstration projects that (directly or

through arrangements with nonprofit private entities) carry out each of the following activities:

"(A) Training designated emergency response employees in minimizing the risk of infection with hepatitis C in performing their duties as such employees.

"(B) Testing such employees for infection with the disease.

"(C) Treating the employees for the disease.

"(2) QUALIFYING LOCAL GOVERNMENTS.—For purposes of this section, the term 'qualifying local government' means a unit of local government whose population of designated emergency response employees has a prevalence of hepatitis C that is not less than 200 percent of the national average for the prevalence of such disease in such populations.

"(3) CONFIDENTIALITY.—A grant may be made under paragraph (1) only if the qualifying local government involved agrees to ensure that information regarding the testing or treatment of designated emergency response employees pursuant to the grant is maintained confidentially in a manner not inconsistent with applicable law.

"(4) EVALUATIONS.—The Secretary shall provide for an evaluation of each demonstration project under paragraph (1) in order to determine the extent to which the project has been effective in carry [sic] out the activities described in such paragraph.

"(5) REPORT TO CONGRESS.—Not later than 180 days after the date on which all grants under paragraph (1) have been expended, the Secretary shall submit to Congress a report providing—

"(A) a summary of evaluations under paragraph (4); and

"(B) the recommendations of the Secretary for administrative or legislative initiatives regarding the activities described in paragraph (1).

"(c) AUTHORIZATION OF APPROPRIATIONS.—For the purpose of carrying out this section, there is authorized to be appropriated to the Department of Health and Human Services and the Department of Labor $10,000,000 for fiscal year 2001."

§247b–16. Grants for lead poisoning related activities

(a) Authority to make grants

(1) In general

The Secretary shall make grants to States to support public health activities in States and localities where data suggests that at least 5 percent of preschool-age children have an elevated blood lead level through—

(A) effective, ongoing outreach and community education targeted to families most likely to be at risk for lead poisoning;

(B) individual family education activities that are designed to reduce ongoing exposures to lead for children with elevated blood lead levels, including through home visits and coordination with other programs designed to identify and treat children at risk for lead poisoning; and

(C) the development, coordination and implementation of community-based approaches for comprehensive lead poisoning prevention from surveillance to lead hazard control.

(2) State match

A State is not eligible for a grant under this section unless the State agrees to expend (through State or local funds) $1 for every $2 provided under the grant to carry out the activities described in paragraph (1).

(3) Application

To be eligible to receive a grant under this section, a State shall submit an application to the Secretary in such form and manner and containing such information as the Secretary may require.

(b) Coordination with other children's programs

A State shall identify in the application for a grant under this section how the State will coordinate operations and activities under the grant with—

(1) other programs operated in the State that serve children with elevated blood lead levels, including any such programs operated under title V, XIX, or XXI of the Social Security Act [42

U.S.C. 701 et seq., 1396 et seq., 1397aa et seq.]; and

(2) one or more of the following—

(A) the child welfare and foster care and adoption assistance programs under parts B and E of title IV of such Act [42 U.S.C. 620 et seq., 670 et seq.];

(B) the head start program established under the Head Start Act (42 U.S.C. 9831 et seq.);

(C) the program of assistance under the special supplemental nutrition program for women, infants and children (WIC) under section 1786 of this title;

(D) local public and private elementary or secondary schools; or

(E) public housing agencies, as defined in section 1437a of this title.

(c) Performance measures

The Secretary shall establish needs indicators and performance measures to evaluate the activities carried out under grants awarded under this section. Such indicators shall be commensurate with national measures of maternal and child health programs and shall be developed in consultation with the Director of the Centers for Disease Control and Prevention.

(d) Authorization of appropriations

There are authorized to be appropriated to carry out this section such sums as may be necessary for each of the fiscal years 2001 through 2005.

(July 1, 1944, ch. 373, title III, §317O, as added Pub. L. 106–310, div. A, title XXV, §2502(a), Oct. 17, 2000, 114 Stat. 1162.)

EDITORIAL NOTES

REFERENCES IN TEXT

The Social Security Act, referred to in subsec. (b)(1), (2)(A), is act Aug. 14, 1935, ch. 531, 49 Stat. 620. Parts B and E of title IV of the Act are classified generally to parts B (§620 et seq.) and E (§670 et seq.), respectively, of subchapter IV of chapter 7 of this title. Titles V, XIX, and XXI of the Act are classified generally to subchapters V (§701 et seq.), XIX (§1396 et seq.), and XXI (§1397aa et seq.), respectively, of chapter 7 of this title. For complete classification of this Act to the Code, see section 1305 of this title and Tables.

The Head Start Act, referred to in subsec. (b)(2)(B), is subchapter B (§§635–657) of chapter 8 of subtitle A of title VI of Pub. L. 97–35, Aug. 13, 1981, 95 Stat. 499, which is classified generally to subchapter II (§9831 et seq.) of chapter 105 of this title. For complete classification of this Act to the Code, see Short Title note set out under section 9801 of this title and Tables.

§247b–17. Human papillomavirus (Johanna's Law)

(a) Surveillance

(1) In general

The Secretary, acting through the Centers for Disease Control and Prevention, shall—

(A) enter into cooperative agreements with States and other entities to conduct sentinel surveillance or other special studies that would determine the prevalence in various age groups and populations of specific types of human papillomavirus (referred to in this section as "HPV") in different sites in various regions of the United States, through collection of special specimens for HPV using a variety of laboratory-based testing and diagnostic tools; and

(B) develop and analyze data from the HPV sentinel surveillance system described in subparagraph (A).

(2) Report

The Secretary shall make a progress report to the Congress with respect to paragraph (1) no later than 1 year after the effective date of this section.

(b) Prevention activities; education program

(1) In general

The Secretary, acting through the Centers for Disease Control and Prevention, shall conduct prevention research on HPV, including—

(A) behavioral and other research on the impact of HPV-related diagnosis on individuals;

(B) formative research to assist with the development of educational messages and information for the public, for patients, and for their partners about HPV;

(C) surveys of physician and public knowledge, attitudes, and practices about genital HPV infection; and

(D) upon the completion of and based on the findings under subparagraphs (A) through (C), develop and disseminate educational materials for the public and health care providers regarding HPV and its impact and prevention.

(2) Report; final proposal

The Secretary shall make a progress report to the Congress with respect to paragraph (1) not later than 1 year after the effective date of this section, and shall develop a final report not later than 3 years after such effective date, including a detailed summary of the significant findings and problems and the best strategies to prevent future infections, based on available science.

(c) HPV education and prevention

(1) In general

The Secretary shall prepare and distribute educational materials for health care providers and the public that include information on HPV. Such materials shall address—

(A) modes of transmission;

(B) consequences of infection, including the link between HPV and cervical cancer;

(C) the available scientific evidence on the effectiveness or lack of effectiveness of condoms in preventing infection with HPV; and

(D) the importance of regular Pap smears, and other diagnostics for early intervention and prevention of cervical cancer purposes in preventing cervical cancer.

(2) Medically accurate information

Educational material under paragraph (1), and all other relevant educational and prevention materials prepared and printed from this date forward for the public and health care providers by the Secretary (including materials prepared through the Food and Drug Administration, the Centers for Disease Control and Prevention, and the Health Resources and Services Administration), or by contractors, grantees, or subgrantees thereof, that are specifically designed to address STDs including HPV shall contain medically accurate information regarding the effectiveness or lack of effectiveness of condoms in preventing the STD the materials are designed to address. Such requirement only applies to materials mass produced for the public and health care providers, and not to routine communications.

(d) Johanna's Law

(1) National public awareness campaign

(A) In general

The Secretary shall carry out a national campaign to increase the awareness and knowledge of health care providers and women with respect to gynecologic cancers.

(B) Written materials

Activities under the national campaign under subparagraph (A) shall include—

(i) maintaining a supply of written materials that provide information to the public on gynecologic cancers; and

(ii) distributing the materials to members of the public upon request.

(C) Public service announcements

Activities under the national campaign under subparagraph (A) shall, in accordance with

applicable law and regulations, include developing and placing, in telecommunications media, public service announcements intended to encourage women to discuss with their physicians their risks of gynecologic cancers. Such announcements shall inform the public on the manner in which the written materials referred to in subparagraph (B) can be obtained upon request, and shall call attention to early warning signs and risk factors based on the best available medical information.

(2) Report and strategy

(A) Report

Not later than 6 months after January 12, 2007, the Secretary shall submit to the Congress a report including the following:

(i) A description of the past and present activities of the Department of Health and Human Services to increase awareness and knowledge of the public with respect to different types of cancer, including gynecologic cancers.

(ii) A description of the past and present activities of the Department of Health and Human Services to increase awareness and knowledge of health care providers with respect to different types of cancer, including gynecologic cancers.

(iii) For each activity described pursuant to clause (i) or (ii), a description of the following:

(I) The funding for such activity for fiscal year 2006 and the cumulative funding for such activity for previous fiscal years.

(II) The background and history of such activity, including—

(aa) the goals of such activity;

(bb) the communications objectives of such activity;

(cc) the identity of each agency within the Department of Health and Human Services responsible for any aspect of the activity; and

(dd) how such activity is or was expected to result in change.

(III) How long the activity lasted or is expected to last.

(IV) The outcomes observed and the evaluation methods, if any, that have been, are being, or will be used with respect to such activity.

(V) For each such outcome or evaluation method, a description of the associated results, analyses, and conclusions.

(B) Strategy

(i) Development; submission to Congress

Not later than 3 months after submitting the report required by subparagraph (A), the Secretary shall develop and submit to the Congress a strategy for improving efforts to increase awareness and knowledge of the public and health care providers with respect to different types of cancer, including gynecological cancers.

(ii) Consultation

In developing the strategy under clause (i), the Secretary should consult with qualified private sector groups, including nonprofit organizations.

(3) Full compliance

(A) IN GENERAL.—Not later than March 1, 2008, the Secretary shall ensure that all provisions of this section, including activities directed to be carried out by the Centers for Disease Control and Prevention and the Food and Drug Administration, are fully implemented and being complied with. Not later than April 30, 2008, the Secretary shall submit to Congress a report that certifies compliance with the preceding sentence and that contains a description of all activities undertaken to achieve such compliance.

(B) If the Secretary fails to submit the certification as provided for under subparagraph (A), the Secretary shall, not later than 3 months after the date on which the report is to be submitted under subparagraph (A), and every 3 months thereafter, submit to Congress an explanation as to why the

Secretary has not yet complied with the first sentence of subparagraph (A), a detailed description of all actions undertaken within the month for which the report is being submitted to bring the Secretary into compliance with such sentence, and the anticipated date the Secretary expects to be in full compliance with such sentence.

(4) Consultation with nonprofit gynecologic cancer organizations

In carrying out the national campaign under this subsection, the Secretary shall consult with nonprofit gynecologic cancer organizations, with a mission both to conquer ovarian or other gynecologic cancer and to provide outreach to State and local governments and communities, for the purpose of determining the best practices for providing gynecologic cancer information and outreach services to varied populations.

(6) [1] Authorization of appropriations

For the purpose of carrying out this subsection, there is authorized to be appropriated $16,500,000 for the period of fiscal years 2007 through 2009 and $18,000,000 for the period of fiscal years 2012 through 2014.

(July 1, 1944, ch. 373, title III, §317P, as added Pub. L. 106–554, §1(a)(1) [title V, §516(a)], Dec. 21, 2000, 114 Stat. 2763, 2763A–72; amended Pub. L. 109–475, §2, Jan. 12, 2007, 120 Stat. 3565; Pub. L. 111–324, §1, Dec. 22, 2010, 124 Stat. 3536.)

EDITORIAL NOTES

REFERENCES IN TEXT

Johanna's Law, referred to in section catchline and subsec. (d), is Pub. L. 109–475, Jan. 12, 2007, 120 Stat. 3565, also known as the Gynecologic Cancer Education and Awareness Act of 2005, which amended this section. For complete classification of this Act to the Code, see Short Title of 2007 Amendment note set out under section 201 of this title and Tables.

The effective date of this section, referred to in subsecs. (a)(2) and (b)(2), is the date of enactment of Pub. L. 106–554, which was approved Dec. 21, 2000.

AMENDMENTS

2010—Subsec. (d)(4). Pub. L. 111–324, §1(b), added par. (4). Former par. (4) redesignated (6).

Pub. L. 111–324, §1(a)(1), inserted "and $18,000,000 for the period of fiscal years 2012 through 2014" after "2009".

Subsec. (d)(6). Pub. L. 111–324, §1(a)(2), redesignated par. (4) as (6).

2007—Pub. L. 109–475, §2(1), inserted "(Johanna's Law)" after "papillomavirus" in section catchline.

Subsec. (d). Pub. L. 109–475, §2(2), added subsec. (d).

[1] So in original. No par. (5) has been enacted.

§247b–18. Surveillance and research regarding muscular dystrophy

(a) In general

The Secretary, acting through the Director of the Centers for Disease Control and Prevention, may award grants and cooperative agreements to public or nonprofit private entities (including health departments of States and political subdivisions of States, and including universities and other educational entities) for the collection, analysis, and reporting of data on Duchenne and other forms of muscular dystrophy. In making such awards, the Secretary may provide direct technical assistance in lieu of cash.

(b) National muscular dystrophy epidemiology program

The Secretary, acting through the Director of the Centers for Disease Control and Prevention, may award grants to public or nonprofit private entities (including health departments of States and political subdivisions of States, and including universities and other educational entities) for the

purpose of carrying out epidemiological activities regarding Duchenne and other forms of muscular dystrophies, including collecting and analyzing information on the number, incidence, correlates, and symptoms of cases. In carrying out the preceding sentence, the Secretary shall provide for a national surveillance program and, to the extent possible, ensure that data be representative of all affected populations and shared in a timely manner. In making awards under this subsection, the Secretary may provide direct technical assistance in lieu of cash.

(c) Coordination with centers of excellence

The Secretary shall ensure that epidemiological information under subsections (a) and (b) is made available to centers of excellence supported under section 283g(b) of this title by the Director of the National Institutes of Health.

(d) Data

In carrying out this section, the Secretary may ensure that any data on patients that is collected as part of the Muscular Dystrophy STARnet (under a grant under this section) is regularly updated to reflect changes in patient condition over time.

(e) Reports and study

(1) Annual report

Not later than 18 months after October 8, 2008, and annually thereafter, the Director of the Centers for Disease Control and Prevention shall submit to the appropriate committees of the Congress a report—

(A) concerning the activities carried out by MD STARnet site [1] funded under this section during the year for which the report is prepared;

(B) containing the data collected and findings derived from the MD STARnet sites each fiscal year (as funded under a grant under this section during fiscal years 2008 through 2012); and

(C) that every 2 years outlines prospective data collection objectives and strategies.

(2) Tracking health outcomes

The Secretary may provide health outcome data on the health and survival of people with muscular dystrophy.

(f) Authorization of appropriations

There are authorized to be appropriated such sums as may be necessary to carry out this section.

(July 1, 1944, ch. 373, title III, §317Q, as added Pub. L. 107–84, §4, Dec. 18, 2001, 115 Stat. 828; amended Pub. L. 110–361, §3, Oct. 8, 2008, 122 Stat. 4010; Pub. L. 113–166, §3, Sept. 26, 2014, 128 Stat. 1880.)

EDITORIAL NOTES

AMENDMENTS

2014—Subsec. (b). Pub. L. 113–166 inserted "and, to the extent possible, ensure that data be representative of all affected populations and shared in a timely manner" after "surveillance program".

2008—Subsecs. (d) to (f). Pub. L. 110–361 added subsecs. (d) and (e) and redesignated former subsec. (d) as (f).

STATUTORY NOTES AND RELATED SUBSIDIARIES

FINDINGS

Pub. L. 107–84, §2, Dec. 18, 2001, 115 Stat. 823, provided that: "Congress makes the following findings:

"(1) Of the childhood muscular dystrophies, Duchenne Muscular Dystrophy (DMD) is the world's most common and catastrophic form of genetic childhood disease, and is characterized by a rapidly progressive muscle weakness that almost always results in death, usually by 20 years of age.

"(2) Duchenne muscular dystrophy is genetically inherited, and mothers are the carriers in

approximately 70 percent of all cases.

"(3) If a female is a carrier of the dystrophin gene, there is a 50 percent chance per birth that her male offspring will have Duchenne muscular dystrophy, and a 50 percent chance per birth that her female offspring will be carriers.

"(4) Duchenne is the most common lethal genetic disorder of childhood worldwide, affecting approximately 1 in every 3,500 boys worldwide.

"(5) Children with muscular dystrophy exhibit extreme symptoms of weakness, delay in walking, waddling gait, difficulty in climbing stairs, and progressive mobility problems often in combination with muscle hypertrophy.

"(6) Other forms of muscular dystrophy affecting children and adults include Becker, limb girdle, congenital, facioscapulohumeral, myotonic, oculopharyngeal, distal, and Emery-Dreifuss muscular dystrophies.

"(7) Myotonic muscular dystrophy (also known as Steinert's disease and dystrophia myotonica) is the second most prominent form of muscular dystrophy and the type most commonly found in adults. Unlike any of the other muscular dystrophies, the muscle weakness is accompanied by myotonia (delayed relaxation of muscles after contraction) and by a variety of abnormalities in addition to those of muscle.

"(8) Facioscapulohumeral muscular dystrophy (referred to in this section as 'FSHD') is a neuromuscular disorder that is inherited genetically and has an estimated frequency of 1 in 20,000. FSHD, affecting between 15,000 to 40,000 persons, causes a progressive and sever [sic] loss of skeletal muscle gradually bringing weakness and reduced mobility. Many persons with FSHD become severely physically disabled and spend many decades in a wheelchair.

"(9) FSHD is regarded as a novel genetic phenomenon resulting from a crossover of subtelomeric DNA and may be the only human disease caused by a deletion-mutation.

"(10) Each of the muscular dystrophies, though distinct in progressivity and severity of symptoms, have a devastating impact on tens of thousands of children and adults throughout the United States and worldwide and impose severe physical and economic burdens on those affected.

"(11) Muscular dystrophies have a significant impact on quality of life—not only for the individual who experiences its painful symptoms and resulting disability, but also for family members and caregivers.

"(12) Development of therapies for these disorders, while realistic with recent advances in research, is likely to require costly investments and infrastructure to support gene and other therapies.

"(13) There is a shortage of qualified researchers in the field of neuromuscular research.

"(14) Many family physicians and health care professionals lack the knowledge and resources to detect and properly diagnose the disease as early as possible, thus exacerbating the progressiveness of symptoms in cases that go undetected or misdiagnosed.

"(15) There is a need for efficient mechanisms to translate clinically relevant findings in muscular dystrophy research from basic science to applied work.

"(16) Educating the public and health care community throughout the country about this devastating disease is of paramount importance and is in every respect in the public interest and to the benefit of all communities."

REPORT TO CONGRESS

Pub. L. 107–84, §6, Dec. 18, 2001, 115 Stat. 829, which directed the Secretary of Health and Human Services to prepare and submit to appropriate committees of Congress a report concerning the implementation of Pub. L. 107–84 not later than Jan. 1, 2003, and each Jan. 1 thereafter, was repealed by Pub. L. 109–482, title I, §104(b)(3)(H), Jan. 15, 2007, 120 Stat. 3694.

[1] *So in original. Probably should be plural.*

§247b–19. Information and education

(a) In general

The Secretary of Health and Human Services (referred to in this Act as the "Secretary") shall establish and implement a program to provide information and education on muscular dystrophy to health professionals and the general public, including information and education on advances in the

diagnosis and treatment of muscular dystrophy and training and continuing education through programs for scientists, physicians, medical students, and other health professionals who provide care for patients with muscular dystrophy.

(b) Stipends

The Secretary may use amounts made available under this section provides [1] stipends for health professionals who are enrolled in training programs under this section.

(c) Requirements

In carrying out this section, the Secretary may—

(1) partner with leaders in the muscular dystrophy patient community;

(2) cooperate with professional organizations and the patient community in the development and issuance of care considerations for pediatric and adult patients, including acute care considerations, for Duchenne-Becker muscular dystrophy, and various other forms of muscular dystrophy, and in periodic review and updates, as appropriate;

(3) in developing and updating care considerations under paragraph (2), incorporate strategies specifically responding to the findings of the national transitions survey of minority, young adult, and adult communities of muscular dystrophy patients; and

(4) widely disseminate the Duchenne-Becker muscular dystrophy and various other forms of muscular dystrophy care considerations as broadly as possible, including through partnership opportunities with the muscular dystrophy patient community.

(d) Authorization of appropriations

There are authorized to be appropriated such sums as may be necessary to carry out this section.

(Pub. L. 107–84, §5, Dec. 18, 2001, 115 Stat. 828; Pub. L. 110–361, §4, Oct. 8, 2008, 122 Stat. 4011; Pub. L. 113–166, §4, Sept. 26, 2014, 128 Stat. 1880.)

EDITORIAL NOTES

REFERENCES IN TEXT

This Act, referred to in subsec. (a), is Pub. L. 107–84, Dec. 18, 2001, 115 Stat. 823, known as the Muscular Dystrophy Community Assistance, Research and Education Amendments of 2001 and also as the MD–CARE Act. For complete classification of this Act to the Code, see Short Title of 2001 Amendment note set out under section 201 of this title and Tables.

CODIFICATION

Section was enacted as part of the Muscular Dystrophy Community Assistance, Research and Education Amendments of 2001, also known as the MD–CARE Act, and not as part of the Public Health Service Act which comprises this chapter.

AMENDMENTS

2014—Subsec. (c)(2). Pub. L. 113–166, §4(1), inserted "for pediatric and adult patients, including acute care considerations," after "issuance of care considerations" and "various" before "other forms of muscular dystrophy" and struck out "and" at end.

Subsec. (c)(3), (4). Pub. L. 113–166, §4(2)–(4), added par. (3), redesignated former par. (3) as (4), and, in par. (4), inserted "various" before "other forms of muscular dystrophy".

2008—Subsecs. (c), (d). Pub. L. 110–361 added subsec. (c) and redesignated former subsec. (c) as (d).

[1] *So in original. Probably should be "to provide".*

§247b–20. Food safety grants

(a) In general

The Secretary may award grants to States and Indian tribes (as defined in section 5304(e) of title

25) to expand participation in networks to enhance Federal, State, and local food safety efforts, including meeting the costs of establishing and maintaining the food safety surveillance, technical, and laboratory capacity needed for such participation.

(b) Authorization of appropriations

For the purpose of carrying out this section, there are authorized to be appropriated $19,500,000 for fiscal year 2010, and such sums as may be necessary for each of the fiscal years 2011 through 2015.

(July 1, 1944, ch. 373, title III, §317R, as added Pub. L. 107–188, title III, §312, June 12, 2002, 116 Stat. 674; amended Pub. L. 108–75, §2(1), Aug. 15, 2003, 117 Stat. 898; Pub. L. 111–353, title II, §205(d), Jan. 4, 2011, 124 Stat. 3939.)

EDITORIAL NOTES

AMENDMENTS

2011—Subsec. (b). Pub. L. 111–353 substituted "2010" for "2002" and "2011 through 2015" for "2003 through 2006".

2003—Pub. L. 108–75 made technical amendment relating to placement of section within original act.

§247b–21. Mosquito-borne diseases; coordination grants to States; assessment and control grants to political subdivisions

(a) Coordination grants to States; assessment grants to political subdivisions

(1) In general

With respect to mosquito control programs to prevent and control mosquito-borne diseases (referred to in this section as "control programs"), the Secretary, acting through the Director of the Centers for Disease Control and Prevention, may make grants to States for the purpose of—

(A) coordinating control programs in the State involved; and

(B) assisting such State in making grants to political subdivisions of the State to conduct assessments to determine the immediate needs in such subdivisions for control programs, including programs to address emerging infectious mosquito-borne diseases, and to develop, on the basis of such assessments, plans for carrying out control programs in the subdivisions or improving existing control programs.

(2) Preference in making grants

In making grants under paragraph (1), the Secretary shall give preference to States that have one or more political subdivisions with an incidence, prevalence, or high risk of mosquito-borne disease, or a population of infected mosquitoes, that is substantial relative to political subdivisions in other States.

(3) Certain requirements

A grant may be made under paragraph (1) only if—

(A) the State involved has developed, or agrees to develop, a plan for coordinating control programs in the State, and the plan takes into account any assessments or plans described in subsection (b)(3) that have been conducted or developed, respectively, by political subdivisions in the State;

(B) in developing such plan, the State consulted or will consult (as the case may be under subparagraph (A)) with political subdivisions in the State that are carrying out or planning to carry out control programs;

(C) the State agrees to monitor control programs in the State in order to ensure that the programs are carried out in accordance with such plan, with priority given to coordination of control programs in political subdivisions described in paragraph (2) that are contiguous;

(D) the State agrees that the State will make grants to political subdivisions as described in

paragraph (1)(B), and that such a grant will not exceed $10,000; and

(E) the State agrees that the grant will be used to supplement, and not supplant, State and local funds available for the purpose described in paragraph (1).

(4) Reports to Secretary

A grant may be made under paragraph (1) only if the State involved agrees that, promptly after the end of the fiscal year for which the grant is made, the State will submit to the Secretary a report that—

(A) describes the activities of the State under the grant; and

(B) contains an evaluation of whether the control programs of political subdivisions in the State were effectively coordinated with each other, which evaluation takes into account any reports that the State received under subsection (b)(5) from such subdivisions.

(5) Number of grants

A State may not receive more than one grant under paragraph (1).

(b) Prevention and control grants to political subdivisions

(1) In general

The Secretary, acting through the Director of the Centers for Disease Control and Prevention, may make grants to political subdivisions of States or consortia of political subdivisions of States, for the operation, including improvement, of control programs.

(2) Preference in making grants

In making grants under paragraph (1), the Secretary shall give preference to a political subdivision or consortium of political subdivisions that—

(A) has—

(i) a history of elevated incidence or prevalence of mosquito-borne disease;

(ii) a population of infected mosquitoes;

(iii) met criteria determined by the Secretary to suggest an increased risk of elevated incidence or prevalence of mosquito-borne disease in the pending fiscal year, including an emerging infectious mosquito-borne disease that presents a serious public health threat; or

(iv) a public health emergency due to the incidence or prevalence of a mosquito-borne disease that presents a serious public health threat;

(B) demonstrates to the Secretary that such political subdivision or consortium of political subdivisions will, if appropriate to the mosquito circumstances involved, effectively coordinate the activities of the control programs with contiguous political subdivisions;

(C) demonstrates to the Secretary (directly or through State officials) that the State in which such a political subdivision or consortium of political subdivisions is located has identified or will identify geographic areas in such State that have a significant need for control programs and will effectively coordinate such programs in such areas; and

(D)(i) is located in a State that has received a grant under subsection (a); or

(ii) that [1] demonstrates to the Secretary that the control program is consistent with existing State mosquito control plans or policies, or other applicable State preparedness plans.

(3) Requirement of assessment and plan

A grant may be made under paragraph (1) only if the political subdivision or consortium of political subdivisions involved—

(A) has conducted an assessment to determine the immediate needs in such subdivision or consortium for a control program, including an entomological survey of potential mosquito breeding areas; and

(B) has, on the basis of such assessment, developed a plan for carrying out such a program.

(4) Requirement of matching funds

(A) In general

With respect to the costs of a control program to be carried out under paragraph (1) by a political subdivision or consortium of political subdivisions, a grant under such paragraph may be made only if the subdivision or consortium agrees to make available (directly or through donations from public or private entities) non-Federal contributions toward such costs in an amount that is not less than 1/3 of such costs ($1 for each $2 of Federal funds provided in the grant).

(B) Determination of amount contributed

Non-Federal contributions required in subparagraph (A) may be in cash or in kind, fairly evaluated, including plant, equipment, or services. Amounts provided by the Federal Government, or services assisted or subsidized to any significant extent by the Federal Government, may not be included in determining the amount of such non-Federal contributions.

(C) Waiver

The Secretary may waive the requirement established in subparagraph (A) if the Secretary determines that—

(i) extraordinary economic conditions in the political subdivision or consortium of political subdivisions involved justify the waiver; or

(ii) the geographical area covered by a political subdivision or consortium for a grant under paragraph (1) has an extreme mosquito control need due to—

(I) the size or density of the potentially impacted human population;

(II) the size or density of a mosquito population that requires heightened control; or

(III) the severity of the mosquito-borne disease, such that expected serious adverse health outcomes for the human population justify the waiver.

(5) Reports to Secretary

A grant may be made under paragraph (1) only if the political subdivision or consortium of political subdivisions involved agrees that, promptly after the end of the fiscal year for which the grant is made, the subdivision or consortium will submit to the Secretary, and to the State within which the subdivision or consortium is located, a report that describes the control program and contains an evaluation of whether the program was effective.

(6) Number of grants

A political subdivision or a consortium of political subdivisions may not receive more than one grant under paragraph (1).

(c) Applications for grants

A grant may be made under subsection (a) or (b) only if an application for the grant is submitted to the Secretary and the application is in such form, is made in such manner, and contains such agreements, assurances, and information as the Secretary determines to be necessary to carry out this section.

(d) Technical assistance

Amounts appropriated under subsection (f) may be used by the Secretary to provide training and technical assistance with respect to the planning, development, and operation of assessments and plans under subsection (a) and control programs under subsection (b). The Secretary may provide such technical assistance directly or through awards of grants or contracts to public and private entities.

(e) Definition of political subdivision

In this section, the term "political subdivision" means the local political jurisdiction immediately below the level of State government, including counties, parishes, and boroughs. If State law recognizes an entity of general government that functions in lieu of, and is not within, a county, parish, or borough, the Secretary may recognize an area under the jurisdiction of such other entities of general government as a political subdivision for purposes of this section.

(f) Authorization of appropriations

(1) In general

For the purpose of carrying out this section, there are authorized to be appropriated $100,000,000 for each of fiscal years 2019 through 2023.

(2) Public health emergencies

In the case of control programs carried out in response to a mosquito-borne disease that constitutes a public health emergency, the authorization of appropriations under paragraph (1) is in addition to applicable authorizations of appropriations under this chapter and other medical and public health preparedness and response laws.

(3) Fiscal year 2019 appropriations

For fiscal year 2019, 50 percent or more of the funds appropriated under paragraph (1) shall be used to award grants to political subdivisions or consortia of political subdivisions under subsection (b).

(July 1, 1944, ch. 373, title III, §317S, as added Pub. L. 108–75, §2(2), Aug. 15, 2003, 117 Stat. 898; amended Pub. L. 116–22, title VI, §607(a), June 24, 2019, 133 Stat. 959.)

EDITORIAL NOTES

AMENDMENTS

2019—Subsec. (a)(1)(B). Pub. L. 116–22, §607(a)(1), inserted "including programs to address emerging infectious mosquito-borne diseases," after "subdivisions for control programs," and "or improving existing control programs" after "in the subdivisions".

Subsec. (b)(1). Pub. L. 116–22, §607(a)(2)(A), inserted ", including improvement," after "operation".

Subsec. (b)(2)(A)(iii). Pub. L. 116–22, §607(a)(2)(B)(i)(II), substituted ", including an emerging infectious mosquito-borne disease that presents a serious public health threat; or" for semicolon at end.

Subsec. (b)(2)(A)(iv). Pub. L. 116–22, §607(a)(2)(B)(i)(I), (III), added cl. (iv).

Subsec. (b)(2)(D). Pub. L. 116–22, §607(a)(2)(B)(ii), amended subpar. (D) generally. Prior to amendment, subpar. (D) read as follows: "is located in a State that has received a grant under subsection (a)."

Subsec. (b)(4)(C). Pub. L. 116–22, §607(a)(2)(C), substituted "that—" for "that extraordinary economic conditions in the political subdivision or consortium of political subdivisions involved justify the waiver." and added cls. (i) and (ii).

Subsec. (b)(6). Pub. L. 116–22, §607(a)(2)(D), amended par. (6) generally. Prior to amendment, par. (6) related to amount of grant and number of grants.

Subsec. (f)(1). Pub. L. 116–22, §607(a)(3)(A), substituted "for each of fiscal years 2019 through 2023" for "for fiscal year 2003, and such sums as may be necessary for each of fiscal years 2004 through 2007".

Subsec. (f)(2). Pub. L. 116–22, §607(a)(3)(B), substituted "this chapter and other medical and public health preparedness and response laws" for "the Public Health Security and Bioterrorism Preparedness and Response Act of 2002".

Subsec. (f)(3). Pub. L. 116–22, §607(a)(3)(C), substituted "2019" for "2004" in heading and "2019," for "2004," in text.

[1] *So in original.*

§247b–22. Microbicide research

(a) In general

The Director of the Centers for Disease Control and Prevention is strongly encouraged to fully implement the Centers' microbicide agenda to support research and development of microbicides for use to prevent the transmission of the human immunodeficiency virus.

(b) Authorization of appropriations

There are authorized to be appropriated such sums as may be necessary for each of fiscal years 2009 through 2013 to carry out this section.

(July 1, 1944, ch. 373, title III, §317T, as added Pub. L. 110–293, title II, §203(d), July 30, 2008, 122 Stat. 2941.)

§247b–23. National strategy and regional centers of excellence in vector-borne diseases

(a) In general

The Secretary shall—

(1)(A) ensure the development and implementation of a national strategy to address vector-borne diseases, including tick-borne diseases, that—

(i) identifies and assesses gaps and any unnecessary duplication in federally-funded programs; and

(ii) identifies strategic goals to address such diseases and appropriate benchmarks to measure progress toward achieving such goals; and

(B) update such strategy, as appropriate; and

(2) coordinate programs and activities, including related to data collection, research, and the development of diagnostics, treatments, vaccines, and other related activities, to address vector-borne diseases, including tick-borne diseases, across the Department of Health and Human Services and with other Federal agencies or departments, as appropriate.

(b) Consultation

In carrying out subsection (a)(1), the Secretary shall consult with appropriate individuals, such as—

(1) epidemiologists with experience in vector-borne diseases;

(2) representatives of patient advocacy and research organizations that focus on vector-borne diseases, including such organizations that have demonstrated experience in related research, public health, data collection, or patient access to care;

(3) health information technology experts or other information management specialists;

(4) clinicians, entomologists, vector management professionals, public health professionals, and others with expertise in vector-borne diseases; and

(5) researchers, including researchers with experience conducting translational research.

(c) Centers of excellence

The Secretary, acting through the Director of the Centers for Disease Control and Prevention, shall award grants, contracts, or cooperative agreements to institutions of higher education for the establishment or continued support of regional centers of excellence in vector-borne diseases to address vector-borne diseases, including tick-borne diseases, by—

(1) facilitating collaboration between academia and public health organizations for public health surveillance, prevention, and response activities related to vector-borne diseases, including tick-borne diseases;

(2) providing training for public health entomologists and other health care professionals, as appropriate, to address vector-borne diseases, including tick-borne diseases;

(3) conducting research to develop and validate prevention and control tools and methods, including evidence-based and innovative, evidence-informed tools and methods to anticipate and respond to disease outbreaks; or

(4) preparing for and responding to outbreaks of vector-borne diseases, including tick-borne diseases.

(d) Eligibility

To be eligible to receive a grant, contract, or cooperative agreement under subsection (c), an entity shall submit to the Secretary an application at such time, in such manner, and containing such information as the Secretary may require, including a description of how the entity will conduct the

activities described in such subsection.

(e) Reports

(1) Program summary

An entity receiving an award under subsection (c) shall, not later than one year after receiving such award, and annually thereafter, submit to the Secretary a summary of programs and activities funded under the award.

(2) Progress report

Not later than 4 years after December 20, 2019, the Secretary shall submit to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives, a report on the progress made in addressing vector-borne diseases, including tick-borne diseases, through activities carried out under this section.

(f) Authorization of appropriations

For the purpose of carrying out this section, there are authorized to be appropriated $10,000,000 for each of fiscal years 2026 through 2030.

(July 1, 1944, ch. 373, title III, §317U, as added Pub. L. 116–94, div. N, title I, §404(b), Dec. 20, 2019, 133 Stat. 3116; amended Pub. L. 119–118, §2(a), Sept. 30, 2026, 140 Stat. 1062.)

EDITORIAL NOTES

AMENDMENTS

2026—Subsec. (b). Pub. L. 119–118, §2(a)(1), substituted "appropriate individuals" for "the Tick-Borne Disease Working Group established under section 284s of this title and other individuals, as appropriate" in introductory provisions.

Subsec. (c). Pub. L. 119–118, §2(a)(2), substituted "acting through" for "in coordination with" in introductory provisions.

Subsec. (f). Pub. L. 119–118, §2(a)(3), substituted "2026 through 2030" for "2021 through 2025".

§247b–24. Addressing factors related to improving health outcomes

(a) In general

The Secretary may, as appropriate, award grants, contracts, or cooperative agreements to eligible entities for the conduct of evidence-based or evidence-informed projects, which may include the development of networks to improve health outcomes by improving the capacity of such entities to address factors that contribute to negative health outcomes in communities.

(b) Eligible entities

To be eligible to receive an award under this section, an entity shall—

(1)(A) be a State, local, or Tribal health department, community-based organization, Indian Tribe or Tribal organization (as such terms are defined in section 5304 of title 25), urban Indian organization (as defined in section 1603 of title 25), or other public or private entity, as the Secretary determines appropriate; or

(B) be a consortia of entities described in subparagraph (A) or a public-private partnership, including a community partnership;

(2) submit to the Secretary an application at such time, in such manner, and containing such information as the Secretary shall require;

(3) in the case of an entity other than a community-based organization, demonstrate a history of successfully working with an established community-based organization to address health outcomes; and

(4) submit a plan to conduct activities described in subsection (a) based on a community needs assessment that takes into account community input.

(c) Use of funds

An entity described in subsection (b) shall use funds received under subsection (a), in consultation with State, local, and Tribal health departments, community-based organizations, entities serving medically underserved communities, and other entities, as applicable, for one or more of the following purposes:

(1) Supporting the implementation, evaluation, and dissemination of strategies, through evidence-informed or evidence-based programs and through the support and use of public health and health care professionals to address factors related to health outcomes.

(2) Establishing, maintaining, or improving, in consultation with State, local, or Tribal health departments, technology platforms or networks to support, in a manner that is consistent with applicable Federal and State privacy law—

(A) coordination among appropriate entities, and, as applicable and appropriate, activities to improve such coordination;

(B) information sharing on health and related social services; and

(C) technical assistance and related support for entities participating in the platforms or networks.

(3) Implementing best practices for improving health outcomes and reducing disease among underserved populations.

(4) Supporting consideration of factors related to health outcomes in preparing for, and responding to, public health emergencies, through outreach, education, research, and other relevant activities.

(d) Best practices and technical assistance

The Secretary, in consultation with the Director of the Office of Minority Health, the National Coordinator for Health Information Technology, and the Administrator of the Administration for Community Living, may award grants, contracts, and cooperative agreements to public or nonprofit private entities, including minority serving institutions (defined, for purposes of this subsection, as institutions and programs described in section 1063b(e)(1) of title 20 and institutions described in section 1067q(a) of title 20), to—

(1) identify or facilitate the development of best practices to support improved health outcomes for underserved populations;

(2) provide technical assistance, training, and evaluation assistance to award recipients under subsection (a);

(3) disseminate best practices, including to award recipients under subsection (a); and

(4) leverage, establish, or operate regional centers to develop, evaluate, and disseminate effective strategies on factors related to health outcomes, including supporting research and training related to such strategies.

(e) Award periods

The Secretary shall issue awards under this section for periods of not more than 5 years and may issue extensions of such award periods for an additional period of up to 3 years.

(f) Report

Not later than September 30, 2026, the Secretary shall submit to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives a report that includes information on activities funded under this section. Such report shall include a description of—

(1) changes in the capacity of public health entities to address factors related to health outcomes in communities, including any applicable platforms or networks developed or utilized to coordinate health and related social services and any changes in workforce capacity or capabilities;

(2) improvements in health outcomes and in reducing health disparities in medically underserved communities;

(3) activities conducted to support consideration of factors related to health outcomes in preparing for, and responding to, public health emergencies, through outreach, education, and other relevant activities;

(4) communities and populations served by recipients of awards under subsection (a);

(5) activities supported under subsection (e); and

(6) other relevant activities and outcomes, as determined by the Secretary.

(g) Authorization of appropriations

To carry out this section, there are authorized to be appropriated $35,000,000 for each of fiscal years 2023 through 2027. Of the amounts appropriated under this subsection for a fiscal year, 5 percent shall be reserved for awards under subsection (a) to Indian Tribes and Tribal organizations (as such terms are defined in section 5304 of title 25), urban Indian organizations (as defined in section 1603 of title 25), and Tribal health departments.

(July 1, 1944, ch. 373, title III, §317V, as added Pub. L. 117–328, div. FF, title II, §2201(a)(1), Dec. 29, 2022, 136 Stat. 5727.)

§247c. Sexually transmitted diseases; prevention and control projects and programs

(a) Technical assistance to public and nonprofit private entities and scientific institutions

The Secretary may provide technical assistance to appropriate public and nonprofit private entities and to scientific institutions for their research in, and training and public health programs for, the prevention and control of sexually transmitted diseases.

(b) Research, demonstration, and public information and education projects

The Secretary may make grants to States, political subdivisions of States, and any other public and nonprofit private entity for—

(1) research into the prevention and control of sexually transmitted diseases;

(2) demonstration projects for the prevention and control of sexually transmitted diseases;

(3) public information and education programs for the prevention and control of such diseases; and

(4) education, training, and clinical skills improvement activities in the prevention and control of such diseases for health professionals (including allied health personnel).

(c) Project grants to States

The Secretary is also authorized to make project grants to States and, in consultation with the State health authority, to political subdivisions of States, for—

(1) sexually transmitted diseases surveillance activities, including the reporting, screening, and followup of diagnostic tests for, and diagnosed cases of, sexually transmitted diseases;

(2) casefinding and case followup activities respecting sexually transmitted diseases, including contact tracing of infectious cases of sexually transmitted diseases and routine testing, including laboratory tests and followup systems;

(3) interstate epidemiologic referral and followup activities respecting sexually transmitted diseases; and

(4) such special studies or demonstrations to evaluate or test sexually transmitted diseases prevention and control strategies and activities as may be prescribed by the Secretary.

(d) Grants for innovative, interdisciplinary approaches

The Secretary may make grants to States and political subdivisions of States for the development, implementation, and evaluation of innovative, interdisciplinary approaches to the prevention and control of sexually transmitted diseases.

(e) Authorization of appropriations; terms and conditions; payments; recordkeeping; audit; grant reduction; information disclosure

(1) For the purpose of making grants under subsections (b) through (d), there are authorized to be appropriated $85,000,000 for fiscal year 1994, and such sums as may be necessary for each of the fiscal years 1995 through 1998.

(2) Each recipient of a grant under this section shall keep such records as the Secretary shall prescribe, including records which fully disclose the amount and disposition by such recipient of the proceeds of such grant, the total cost of the project or undertaking in connection with which such grant was given or used, and the amount of that portion of the cost of the project or undertaking supplied by other sources, and such other records as will facilitate an effective audit.

(3) The Secretary and the Comptroller General of the United States, or any of their duly authorized representatives, shall have access for the purpose of audit and examination to any books, documents, papers, and records of the recipients of grants under this section that are pertinent to such grants.

(4) The Secretary, at the request of a recipient of a grant under this section, may reduce such grant by the fair market value of any supplies or equipment furnished to such recipient and by the amount of pay, allowances, travel expenses, and any other costs in connection with the detail of an officer or employee of the United States to the recipient when the furnishing of such supplies or equipment or the detail of such an officer or employee is for the convenience of and at the request of such recipient and for the purpose of carrying out the program with respect to which the grant under this section is made. The amount by which any such grant is so reduced shall be available for payment by the Secretary of the costs incurred in furnishing the supplies, equipment, or personal services on which the reduction of such grant is based.

(5) All information obtained in connection with the examination, care, or treatment of any individual under any program which is being carried out with a grant made under this section shall not, without such individual's consent, be disclosed except as may be necessary to provide service to him or as may be required by a law of a state or political subdivision of a State. Information derived from any such program may be disclosed—

(A) in summary, statistical, or other form; or

(B) for clinical or research purposes;

but only if the identity of the individuals diagnosed or provided care or treatment under such program is not disclosed.

(f) Consent of individuals

Nothing in this section shall be construed to require any State or any political subdivision of a State to have a sexually transmitted diseases program which would require any person, who objects to any treatment provided under such a program, to be treated under such a program.

(July 1, 1944, ch. 373, title III, §318, as added Pub. L. 92–449, title II, §203, Sept. 30, 1972, 86 Stat. 751; amended Pub. L. 94–317, title II, §203(b)–(i), June 23, 1976, 90 Stat. 704, 705; Pub. L. 94–484, title IX, §905(b)(2), Oct. 12, 1976, 90 Stat. 2325; Pub. L. 95–626, title II, §204(b)(1), (c), (d), Nov. 10, 1978, 92 Stat. 3583; Pub. L. 96–32, §6(j), July 10, 1979, 93 Stat. 84; Pub. L. 97–35, title IX, §929, Aug. 13, 1981, 95 Stat. 569; Pub. L. 98–555, §3, Oct. 30, 1984, 98 Stat. 2854; Pub. L. 100–607, title III, §311, Nov. 4, 1988, 102 Stat. 3112; Pub. L. 103–183, title IV, §401, Dec. 14, 1993, 107 Stat. 2236; Pub. L. 105–392, title IV, §401(b)(2), (c), Nov. 13, 1998, 112 Stat. 3587.)

EDITORIAL NOTES

PRIOR PROVISIONS

A prior section 247c, act July 1, 1944, ch. 373 title III, §318, as added Aug. 18, 1964, Pub. L. 88–443, §2, 78 Stat. 447, related to grants for assisting in the areawide planning of health and related facilities, prior to repeal by Pub. L. 89–749, §6, Nov. 3, 1966, 80 Stat. 1190 eff. July 1, 1967.

AMENDMENTS

1998—Subsec. (e). Pub. L. 105–392, §401(b)(2), redesignated subsec. (e), relating to consent of individuals, as (f).

Subsec. (e)(5). Pub. L. 105–392, §401(c), made technical amendment to directory language of Pub. L.

103–183, §401(c)(3). See 1993 Amendment note below.

Subsec. (f). Pub. L. 105–392, §401(b)(2), redesignated subsec. (e), relating to consent of individuals, as (f).

1993—Subsec. (b)(3). Pub. L. 103–183, §401(c)(1), substituted "; and" for ", and".

Subsec. (c)(3). Pub. L. 103–183, §401(c)(2), which directed the substitution of "; and" for ", and", could not be executed because ", and" did not appear.

Subsec. (d). Pub. L. 103–183, §401(a)(2), added subsec. (d). Former subsec. (d) redesignated (e).

Subsec. (e). Pub. L. 103–183, §401(a)(1), redesignated subsec. (d), relating to authorization of appropriations, etc., as (e).

Subsec. (e)(1). Pub. L. 103–183, §401(b), amended par. (1) generally. Prior to amendment, par. (1) read as follows: "For the purpose of making grants under subsections (b) and (c) of this section there are authorized to be appropriated $45,000,000 for the fiscal year ending September 30, 1979, $51,500,000 for the fiscal year ending September 30, 1980, $59,000,000 for the fiscal year ending September 30, 1981, $40,000,000 for the fiscal year ending September 30, 1982, $46,500,000 for the fiscal year ending September 30, 1983, $50,000,000 for the fiscal year ending September 30, 1984, $57,000,000 for the fiscal year ending September 30, 1985, $62,500,000 for the fiscal year ending September 30, 1986, $68,000,000 for the fiscal year ending September 30, 1987, $78,000,000 for fiscal year 1989, and such sums as may be necessary for each of the fiscal years 1990 and 1991. For grants under subsection (b) of this section in any fiscal year, the Secretary shall obligate not less than 10 per centum of the amount appropriated for such fiscal year under the preceding sentence. Grants made under subsection (b) or (c) of this section shall be made on such terms and conditions as the Secretary finds necessary to carry out the purposes of such subsection, and payments under any such grants shall be made in advance or by way of reimbursement and in such installments as the Secretary finds necessary."

Subsec. (e)(5). Pub. L. 103–183, §401(c)(3), as amended by Pub. L. 105–392, §401(c), substituted "form; or" for "form, or" in subpar. (A) and "purposes;" for "purposes," in subpar. (B).

1988—Pub. L. 100–607, §311(1), amended section catchline.

Subsec. (d). Pub. L. 100–607, §311(2), (3), redesignated subsec. (e) as (d) and struck out former subsec. (d) which related to acquired immune deficiency syndrome.

Subsec. (d)(1). Pub. L. 100–607, §311(4), substituted "(b) and (c)" for "(b), (c), and (d)", struck out "and" after "1986,", and inserted ", $78,000,000 for fiscal year 1989, and such sums as may be necessary for each of the fiscal years 1990 and 1991" before period at end of first sentence; substituted "(b) or (c)" for "(b), (c), or (d)" in third sentence; and struck out at end "If the appropriations under the first sentence for fiscal year 1985 exceed $50,000,000, one-half of the amount in excess of $50,000,000 shall be made available for grants under subsection (d) of this section; if the appropriations under the first sentence for fiscal year 1986 exceed $52,500,000, one-half of the amount in excess of $52,500,000 shall be made available for such grants; and if the appropriations under the first sentence for fiscal year 1987 exceed $55,000,000, one-half of the amount in excess of $55,000,000 shall be made available for such grants."

Subsecs. (e) to (g). Pub. L. 100–607, §311(2), (3), struck out subsec. (f) which related to conditional limitation on use of funds and redesignated subsecs. (e) and (g) as (d) and (e), respectively.

1984—Subsec. (a). Pub. L. 98–555, §3(b)(1), substituted "research in, and training and public health programs for, the prevention and control of sexually transmitted diseases" for "research, training, and public health programs for the prevention and control of venereal disease".

Subsec. (b). Pub. L. 98–555, §3(b)(2), in amending subsec. (b) generally, designated existing provisions as pars. (1) to (3), added par. (4), and substituted references to sexually transmitted diseases for reference to venereal disease.

Subsec. (c). Pub. L. 98–555, §3(b)(3), (6)(A), substituted "sexually transmitted diseases" for "venereal disease" wherever appearing, struck out par. (4) relating to professional venereal disease education, training and clinical skills improvement activities, and redesignated par. (5) as (4).

Subsec. (d). Pub. L. 98–555, §3(b)(5)(A), added subsec. (d). Former subsec. (d) redesignated (e).

Subsec. (e). Pub. L. 98–555, §3(a), (b)(4), (5), redesignated subsec. (d) as (e), and in par. (1) of subsec. (e) as so redesignated, substituted "(b), (c), and (d)" for "(b) and (c)", inserted provisions authorizing appropriations for fiscal years ending Sept. 30, 1985, 1986, and 1987, substituted "10 per centum" for "5 per centum", and inserted provisions directing that one-half the excess of appropriations in fiscal years 1985, 1986, and 1987 over certain amounts be made available for grants under subsec. (d). Notwithstanding language of section 3(b)(5)(B)(ii) directing the substitution of "(b), (c), or (d)" for "(b) or (c)" in second sentence of subsec. (e)(1), the amendment was executed by making the substitution in third sentence of subsec. (e)(1) to reflect the probable intent of Congress because "(b) or (c)" did not appear in second sentence. Former subsec. (e) redesignated (f).

Subsecs. (f), (g). Pub. L. 98–555, §3(b)(5)(A), (6)(A), (C), redesignated subsecs. (e) and (f) as (f) and (g),

respectively, in subsecs. (f) and (g) as so redesignated, substituted "sexually transmitted diseases" for "venereal disease", and struck out former subsec. (g) which defined venereal disease.

1981—Subsec. (d)(1). Pub. L. 97–35 inserted provisions authorizing appropriations for fiscal years ending Sept. 30, 1982, 1983, and 1984.

1979—Subsec. (b). Pub. L. 96–32 amended directory language of Pub. L. 95–626, §204(c)(2), and required no change in text. See 1978 Amendment note below.

1978—Subsec. (b). Pub. L. 95–626, §204(c)(2), as amended by Pub. L. 96–32, substituted "research, demonstrations, and public information and education for the prevention and control of venereal disease" for "research, demonstrations, education, and training for the prevention and control of venereal disease", struck out "(1)" preceding provisions thus amended, and struck out par. (2) which authorized appropriation of $5,000,000 for fiscal year 1976, $6,600,000 for fiscal year 1977, and $7,600,000 for fiscal year 1978 for purpose of carrying out this subsection.

Subsec. (c). Pub. L. 95–626, §204(d), struck out "(1)" after "(c)" at beginning of existing provisions, changed designations at beginning of each of the five clauses from "(A)", "(B)", "(C)", "(D)", and "(E)" to "(1)", "(2)", "(3)", "(4)", and "(5)", respectively, substituted "The Secretary is also authorized" for "The Secretary is authorized" in provisions preceding cl. (1) as redesignated, substituted "professional (including appropriate allied health personnel) venereal disease education, training and clinical skills improvement activities" for "professional and public venereal disease education activities" in cl. (4) as redesignated, and struck out former par. (2) which had authorized appropriations of $32,000,000 for fiscal year 1976, $41,500,000 for fiscal year 1977, and $43,500,000 for fiscal year 1978.

Subsec. (d)(1). Pub. L. 95–626, §204(c)(1), inserted provisions authorizing appropriations of $45,000,000 for fiscal year ending Sept. 30, 1979, $51,500,000 for fiscal year ending Sept. 30, 1980, and $59,000,000 for fiscal year ending Sept. 30, 1981, for purpose of making grants under subsecs. (b) and (c) of this section, and inserted provisions directing Secretary to obligate not less than 5 per centum of amount appropriated for any fiscal year.

Subsec. (f). Pub. L. 95–626, §204(b)(1), redesignated subsec. (g) as (f). Former subsec. (f), requiring that not to exceed 50 per centum of amounts appropriated for any fiscal year under subsecs. (b) and (c) of this section could be used by Secretary for grants for such fiscal year under section 247b of this title, was struck out.

Subsec. (g). Pub. L. 95–626, §204(b)(1), redesignated subsec. (h) as (g). Former subsec. (g) redesignated (f).

1976—Subsec. (a). Pub. L. 94–317, §203(c), substituted "public and nonprofit private entities and to" for "public authorities and".

Subsec. (b)(1). Pub. L. 94–317, §203(i), inserted "education," before "and training".

Subsec. (b)(2). Pub. L. 94–317, §203(b)(1), substituted provisions authorizing appropriations of $5,000,000 for fiscal year 1976, $6,600,000 for fiscal year 1977, and $7,600,000 for fiscal year 1978, for provisions authorizing appropriations of $7,500,000 for fiscal year ending June 30, 1973, and for each of the next two fiscal years.

Subsec. (c). Pub. L. 94–484, purported to amend former subsec. (c)(1) by defining "State" to include the Northern Mariana Islands. Former subsec. (c) of this section had been previously repealed by section 203(f)(1) of Pub. L. 94–317. See par. below.

Pub. L. 94–317, §203(b)(2), (d), (e), (f)(1), (3), (8), redesignated subsec. (d) as (c), inserted, in par. (1)(B), reference to routine testing, including laboratory tests and followup systems and substituted in par. (1)(E). "prevention and control strategies and activities" for "control" and, in par. (2), provisions authorizing appropriations of $32,000,000 for fiscal year 1976, $41,500,000 for fiscal year 1977, and $43,500,000 for fiscal year 1978, for provisions authorizing appropriations of $30,000,000 for the fiscal year ending June 30, 1973, and for each of the next two succeeding fiscal years. Former subsec. (c), which provided for authorization of appropriations to enable the Secretary to make grants to state health authorities to establish and maintain programs for diagnosis and treatment of venereal disease was amended by striking out reference to dark-field microscope techniques for diagnosis of both gonorrhea an syphilis, and as so amended, was repealed.

Subsec. (d). Pub. L. 94–317, §203(f)(2), (4), (5), (8), redesignated subsec. (e) as (d), substituted in par. (1) "or (c)" for "or (d)", struck out in par. (4) provisions relating to the amount of reduction of a grant under former subsec. (c) whereby such amount shall be deemed a part of the grant to the recipient of the grant and shall be deemed to have been paid to such recipient, and inserted in par. (5) reference to requirement by law of a State or political subdivision of a state. Former subsec. (d) redesignated (c).

Subsec. (e). Pub. L. 94–317, §203(f)(8), (g), redesignated subsec. (f) as (e) and substituted "247b(g)(2) of this title" for "247b(d)(4) of this title". Former subsec. (e) redesignated (d).

Subsec. (f). Pub. L. 94–317, §203(f)(6), (8), redesignated subsec. (g) as (f) and substituted "and (c)" for ", (c), and (d)". Former subsec. (f) redesignated (e).

Subsec. (g). Pub. L. 94–317, §203(f)(7), (8), redesignated subsec. (h) as (g) and struck out "treated or to have any child or ward of his" after "a program, to be". Former subsec. (g) redesignated (f).

Subsec. (h). Pub. L. 94–317, §203(h), added subsec. (h). Former subsec. (h) redesignated (g).

STATUTORY NOTES AND RELATED SUBSIDIARIES

EFFECTIVE DATE OF 1998 AMENDMENT

Amendment by Pub. L. 105–392 deemed to have taken effect immediately after enactment of Pub. L. 103–183, see section 401(e) of Pub. L. 105–392, set out as a note under section 242m of this title.

DISTRIBUTION OF INFORMATION ON ACQUIRED IMMUNE DEFICIENCY SYNDROME BY DIRECTOR OF CENTERS FOR DISEASE CONTROL TO EVERY AMERICAN HOUSEHOLD

Pub. L. 100–202, §101(h) [title II], Dec. 22, 1987, 101 Stat. 1329–256, 1329–365, provided: "That the Director shall cause to be distributed without necessary clearance of the content by any official, organization or office, an AIDS mailer to every American household by June 30, 1988, as approved and funded by the Congress in Public Law 100–71 [July 11, 1987, 101 Stat. 391]."

CONGRESSIONAL FINDINGS AND DECLARATIONS

Pub. L. 95–626, title II, §204(a), Nov. 10, 1978, 92 Stat. 3582, provided that: "The Congress finds and declares that—

"(1) the number of reported cases of venereal disease persists in epidemic proportions in the United States;

"(2) the number of persons affected by venereal disease and reported to public health authorities is only a fraction of those actually affected;

"(3) the incidence of venereal disease continues to be particularly high among American youth, ages fifteen to twenty-nine, and among populations in metropolitan areas;

"(4) venereal disease accounts for severe permanent disabilities and sometimes death in newborns and causes reproductive dysfunction in women of childbearing age;

"(5) it is conservatively estimated that the public cost of health care for persons suffering from complications of venereal disease exceeds one-half billion dollars annually;

"(6) the number of trained Federal venereal disease prevention and control personnel has fallen to a dangerously inadequate level;

"(7) no vaccine for syphilis, gonorrhea, or any other venereal disease has yet been developed, nor does a blood test for the detection of asymptomatic gonorrhea in women exist, nor are safe and effective therapeutic agents available for some other venereal diseases;

"(8) school health education programs, public information and awareness campaigns, mass diagnostic screening and case followup have all been found to be effective venereal disease prevention and control methodologies;

"(9) skilled and knowledgeable health care providers, informed and concerned individuals and active, well-coordinated voluntary groups are fundamental to venereal disease prevention and control;

"(10) biomedical research toward improved diagnostic and therapeutic tools is of singular importance to the elimination of venereal disease; and

"(11) an increasing number of sexually transmissible diseases besides syphilis and gonorrhea have become a public health hazard."

Pub. L. 94–317, title II, §203(a), June 23, 1976, 90 Stat. 703, provided that: "The Congress finds and declares that—

"(1) the number of reported cases of venereal disease continues in epidemic proportions in the United States;

"(2) the number of patients with venereal disease reported to public health authorities is only a fraction of those actually infected;

"(3) the incidence of venereal disease is particularly high in the 15–29-year age group, and in metropolitan areas;

"(4) venereal disease accounts for needless deaths and leads to such severe disabilities as sterility, insanity, blindness, and crippling conditions;

"(5) the number of cases of congenital syphilis, a preventable disease, tends to parallel the incidence of syphilis in adults;

"(6) it is conservatively estimated that the public cost of care for persons suffering the complications of venereal disease exceed $80,000,000 annually;

"(7) medical researchers have no successful vaccine for syphilis or gonorrhea, and have no blood test for the detection of gonorrhea among the large reservoir of asymptomatic females;

"(8) school health education programs, public information and awareness campaigns, mass diagnostic screening and case followup activities have all been found to be effective disease intervention methodologies;

"(9) knowledgeable health providers and concerned individuals and groups are fundamental to venereal disease prevention and control;

"(10) biomedical research leading to the development of vaccines for syphilis and gonorrhea is of singular importance for the eventual eradication of these dreaded diseases; and

"(11) a variety of other sexually transmitted diseases, in addition to syphilis and gonorrhea, have become of public health significance."

Pub. L. 92–449, title II, §202, Sept. 30, 1972, 86 Stat. 750, provided that:

"(a) The Congress finds and declares that—

"(1) the number or reported cases of venereal disease has reached epidemic proportions in the United States;

"(2) the number of patients with venereal disease reported to public health authorities is only a fraction of those treated by physicians;

"(3) the incidence of venereal disease is particularly high among individuals in the 20–24 age group, and in metropolitan areas;

"(4) venereal disease accounts for needless deaths and leads to such severe disabilities as sterility, insanity, blindness, and crippling conditions;

"(5) the number of cases of congenital syphilis, a preventable disease, in infants under one year of age increased by 331/3 per centum between 1970 and 1971;

"(6) health education programs in schools and through the mass media may prevent a substantial portion of the venereal disease problem; and

"(7) medical authorities have no successful vaccine for syphilis or gonorrhea and no blood test for the detection of gonorrhea among the large reservoir of asymptomatic females.

"(b) In order to preserve and protect the health and welfare of all citizens, it is the purpose of this Act [enacting this section, amending sections 247b and 300 of this title, and enacting provisions set out as notes under sections 201 and 247b of this title] to establish a national program for the prevention and control of venereal disease."

§247c–1. Infertility and sexually transmitted diseases

(a) In general

The Secretary, acting through the Director of the Centers for Disease Control and Prevention, may make grants to States, political subdivisions of States, and other public or nonprofit private entities for the purpose of carrying out the activities described in subsection (c) regarding any treatable sexually transmitted disease that can cause infertility in women if treatment is not received for the disease.

(b) Authority regarding individual diseases

With respect to diseases described in subsection (a), the Secretary shall, in making a grant under such subsection, specify the particular disease or diseases with respect to which the grant is to be made. The Secretary may not make the grant unless the applicant involved agrees to carry out this section only with respect to the disease or diseases so specified.

(c) Authorized activities

With respect to any sexually transmitted disease described in subsection (a), the activities referred to in such subsection are—

(1) screening women for the disease and for secondary conditions resulting from the disease, subject to compliance with criteria issued under subsection (f);

(2) providing treatment to women for the disease;

(3) providing counseling to women on the prevention and control of the disease (including, in

the case of a woman with the disease, counseling on the benefits of locating and providing such counseling to any individual from whom the woman may have contracted the disease and any individual whom the woman may have exposed to the disease);

(4) providing follow-up services;

(5) referrals for necessary medical services for women screened pursuant to paragraph (1), including referrals for evaluation and treatment with respect to acquired immune deficiency syndrome and other sexually transmitted diseases;

(6) in the case of any woman receiving services pursuant to any of paragraphs (1) through (5), providing to the partner of the woman the services described in such paragraphs, as appropriate;

(7) providing outreach services to inform women of the availability of the services described in paragraphs (1) through (6);

(8) providing to the public information and education on the prevention and control of the disease, including disseminating such information; and

(9) providing training to health care providers in carrying out the screenings and counseling described in paragraphs (1) and (3).

(d) Requirement of availability of all services through each grantee

The Secretary may make a grant under subsection (a) only if the applicant involved agrees that each activity authorized in subsection (c) will be available through the applicant. With respect to compliance with such agreement, the applicant may expend the grant to carry out any of the activities directly, and may expend the grant to enter into agreements with other public or nonprofit private entities under which the entities carry out the activities.

(e) Required providers regarding certain services

The Secretary may make a grant under subsection (a) only if the applicant involved agrees that, in expending the grant to carry out activities authorized in subsection (c), the services described in paragraphs (1) through (7) of such subsection will be provided only through entities that are State or local health departments, grantees under section 254b, 254b, 256a, or 300 of this title,[1] or are other public or nonprofit private entities that provide health services to a significant number of low-income women.

(f) Quality assurance regarding screening for diseases

For purposes of this section, the Secretary shall establish criteria for ensuring the quality of screening procedures for diseases described in subsection (a).

(g) Confidentiality

The Secretary may make a grant under subsection (a) only if the applicant involved agrees, subject to applicable law, to maintain the confidentiality of information on individuals with respect to activities carried out under subsection (c).

(h) Limitation on imposition of fees for services

The Secretary may make a grant under subsection (a) only if the applicant involved agrees that, if a charge is imposed for the provision of services or activities under the grant, such charge—

(1) will be made according to a schedule of charges that is made available to the public;

(2) will be adjusted to reflect the income of the individual involved; and

(3) will not be imposed on any individual with an income of less than 150 percent of the official poverty line, as established by the Director of the Office of Management and Budget and revised by the Secretary in accordance with section 9902(2) of this title.

(i) Limitations on certain expenditures

The Secretary may make a grant under subsection (a) only if the applicant involved agrees that not less than 80 percent of the grant will be expended for the purpose of carrying out paragraphs (1) through (7) of subsection (c).

(j) Reports to Secretary

(1) Collection of data

The Secretary may make a grant under subsection (a) only if the applicant involved agrees, with respect to any disease selected under subsection (b) for the applicant, to submit to the Secretary, for each fiscal year for which the applicant receives such a grant, a report providing—

(A) the incidence of the disease among the population of individuals served by the applicant;

(B) the number and demographic characteristics of individuals in such population;

(C) the types of interventions and treatments provided by the applicant, and the health conditions with respect to which referrals have been made pursuant to subsection (c)(5);

(D) an assessment of the extent to which the activities carried pursuant to subsection (a) have reduced the incidence of infertility in the geographic area involved; and

(E) such other information as the Secretary may require with respect to the project carried out with the grant.

(2) Utility and comparability of data

The Secretary shall carry out activities for the purpose of ensuring the utility and comparability of data collected pursuant to paragraph (1).

(k) Maintenance of effort

With respect to activities for which a grant under subsection (a) is authorized to be expended, the Secretary may make such a grant only if the applicant involved agrees to maintain expenditures of non-Federal amounts for such activities at a level that is not less than the average level of such expenditures maintained by the applicant for the 2-year period preceding the fiscal year for which the applicant is applying to receive such a grant.

(l) Requirement of application

(1) In general

The Secretary may make a grant under subsection (a) only if an application for the grant is submitted to the Secretary, the application contains the plan required in paragraph (2), and the application is in such form, is made in such manner, and contains such agreements, assurances, and information as the Secretary determines to be necessary to carry out this section.

(2) Submission of plan for program of grantee

(A) In general

The Secretary may make a grant under subsection (a) only if the applicant involved submits to the Secretary a plan describing the manner in which the applicant will comply with the agreements required as a condition of receiving such a grant, including a specification of the entities through which activities authorized in subsection (c) will be provided.

(B) Participation of certain entities

The Secretary may make a grant under subsection (a) only if the applicant provides assurances satisfactory to the Secretary that the plan submitted under subparagraph (A) has been prepared in consultation with an appropriate number and variety of—

(i) representatives of entities in the geographic area involved that provide services for the prevention and control of sexually transmitted diseases, including programs to provide to the public information and education regarding such diseases; and

(ii) representatives of entities in such area that provide family planning services.

(m) Duration of grant

The period during which payments are made to an entity from a grant under subsection (a) may not exceed 3 years. The provision of such payments shall be subject to annual approval by the Secretary of the payments and subject to the availability of appropriations for the fiscal year involved to make the payments in such year. The preceding sentence may not be construed to establish a limitation on the number of grants under such subsection that may be made to an entity.

(n) Technical assistance, and supplies and services in lieu of grant funds

(1) Technical assistance

The Secretary may provide training and technical assistance to grantees under subsection (a) with respect to the planning, development, and operation of any program or service carried out under such subsection. The Secretary may provide such technical assistance directly or through grants or contracts.

(2) Supplies, equipment, and employee detail

The Secretary, at the request of a recipient of a grant under subsection (a), may reduce the amount of such grant by—

(A) the fair market value of any supplies or equipment furnished the grant recipient; and

(B) the amount of the pay, allowances, and travel expenses of any officer or employee of the Government when detailed to the grant recipient and the amount of any other costs incurred in connection with the detail of such officer or employee;

when the furnishing of such supplies or equipment or the detail of such an officer or employee is for the convenience of and at the request of such grant recipient and for the purpose of carrying out a program with respect to which the grant under subsection (a) is made. The amount by which any such grant is so reduced shall be available for payment by the Secretary of the costs incurred in furnishing the supplies or equipment, or in detailing the personnel, on which the reduction of such grant is based, and such amount shall be deemed as part of the grant and shall be deemed to have been paid to the grant recipient.

(o) Evaluations and reports by Secretary

(1) Evaluations

The Secretary shall, directly or through contracts with public or private entities, provide for annual evaluations of programs carried out pursuant to subsection (a) in order to determine the quality and effectiveness of the programs.

(2) Report to Congress

Not later than 1 year after the date on which amounts are first appropriated pursuant to subsection (q), and biennially thereafter, the Secretary shall submit to the Committee on Energy and Commerce of the House of Representatives, and to the Committee on Labor and Human Resources of the Senate, a report—

(A) summarizing the information provided to the Secretary in reports made pursuant to subsection (j)(1), including information on the incidence of sexually transmitted diseases described in subsection (a); and

(B) summarizing evaluations carried out pursuant to paragraph (1) during the preceding fiscal year.

(p) Coordination of Federal programs

The Secretary shall coordinate the program carried out under this section with any similar programs administered by the Secretary (including coordination between the Director of the Centers for Disease Control and Prevention and the Director of the National Institutes of Health).

(q) Authorization of appropriations

For the purpose of carrying out this section, other than subsections (o) and (r), there are authorized to be appropriated $25,000,000 for fiscal year 1993, and such sums as may be necessary for each of the fiscal years 1994 through 1998.

(r) Separate grants for research on delivery of services

(1) In general

The Secretary may make grants for the purpose of conducting research on the manner in which the delivery of services under subsection (a) may be improved. The Secretary may make such grants only to grantees under such subsection and to public and nonprofit private entities that are carrying out programs substantially similar to programs carried out under such subsection.

(2) Authorization of appropriations

For the purpose of carrying out paragraph (1), there are authorized to be appropriated such sums as may be necessary for each of the fiscal years 1993 through 1998.

(July 1, 1944, ch. 373, title III, §318A, as added Pub. L. 102–531, title III, §304, Oct. 27, 1992, 106 Stat. 3490; amended Pub. L. 103–43, title XX, §2008(i)(1)(B)(ii), June 10, 1993, 107 Stat. 212; Pub. L. 103–183, title IV, §402, Dec. 14, 1993, 107 Stat. 2236; Pub. L. 107–251, title VI, §601(a), Oct. 26, 2002, 116 Stat. 1664; Pub. L. 108–163, §2(m)(1), Dec. 6, 2003, 117 Stat. 2023.)

EDITORIAL NOTES

REFERENCES IN TEXT

The reference to section 254b of this title the first place appearing, referred to in subsec. (e), was in the original a reference to section 329, meaning section 329 of act July 1, 1944, which was omitted in the general amendment of subpart I (§254b et seq.) of part D of this subchapter by Pub. L. 104–299, §2, Oct. 11, 1996, 110 Stat. 3626.

Section 256a of this title, referred to in subsec. (e), was repealed by Pub. L. 104–299, §4(a)(3), Oct. 11, 1996, 110 Stat. 3645.

AMENDMENTS

2003—Subsec. (e). Pub. L. 108–163 substituted "254b" for "254c, 254b(h)" before ", 256a".

2002—Subsec. (e). Pub. L. 107–251 substituted "254b(h)" for "256".

1993—Pub. L. 103–43 made technical amendment to directory language of Pub. L. 102–531, §304, which enacted this section.

Subsec. (o)(2). Pub. L. 103–183, §402(a), substituted "subsection (q)" for "subsection (s)".

Subsec. (q). Pub. L. 103–183, §402(b)(1), substituted "through 1998" for "and 1995".

Subsec. (r)(2). Pub. L. 103–183, §402(b)(2), substituted "1998" for "1995".

STATUTORY NOTES AND RELATED SUBSIDIARIES

CHANGE OF NAME

Committee on Labor and Human Resources of Senate changed to Committee on Health, Education, Labor, and Pensions of Senate by Senate Resolution No. 20, One Hundred Sixth Congress, Jan. 19, 1999.

Committee on Energy and Commerce of House of Representatives treated as referring to Committee on Commerce of House of Representatives by section 1(a) of Pub. L. 104–14, set out as a note preceding section 21 of Title 2, The Congress. Committee on Commerce of House of Representatives changed to Committee on Energy and Commerce of House of Representatives, and jurisdiction over matters relating to securities and exchanges and insurance generally transferred to Committee on Financial Services of House of Representatives by House Resolution No. 5, One Hundred Seventh Congress, Jan. 3, 2001.

EFFECTIVE DATE OF 2003 AMENDMENT

Amendment by Pub. L. 108–163 deemed to have taken effect immediately after the enactment of Pub. L. 107–251, see section 3 of Pub. L. 108–163, set out as a note under section 233 of this title.

[1] *See References in Text notes below.*

§247c–2. Data collection regarding programs under subchapter XXIV

For the purpose of collecting and providing data for program planning and evaluation activities under subchapter XXIV, there are authorized to be appropriated to the Secretary (acting through the Director of the Centers for Disease Control and Prevention) such sums as may be necessary for each of the fiscal years 2001 through 2005. Such authorization of appropriations is in addition to other authorizations of appropriations that are available for such purpose.

(July 1, 1944, ch. 373, title III, §318B, as added Pub. L. 106–345, title IV, §412, Oct. 20, 2000, 114 Stat. 1350.)

§247d. Public health emergencies

(a) Emergencies

If the Secretary determines, after consultation with such public health officials as may be necessary, that—

(1) a disease or disorder presents a public health emergency; or

(2) a public health emergency, including significant outbreaks of infectious diseases or bioterrorist attacks, otherwise exists,

the Secretary may take such action as may be appropriate to respond to the public health emergency, including making grants, providing awards for expenses, and entering into contracts and conducting and supporting investigations into the cause, treatment, or prevention of a disease or disorder as described in paragraphs (1) and (2). Any such determination of a public health emergency terminates upon the Secretary declaring that the emergency no longer exists, or upon the expiration of the 90-day period beginning on the date on which the determination is made by the Secretary, whichever occurs first. Determinations that terminate under the preceding sentence may be renewed by the Secretary (on the basis of the same or additional facts), and the preceding sentence applies to each such renewal. Not later than 48 hours after making a determination under this subsection of a public health emergency (including a renewal), the Secretary shall submit to the Congress written notification of the determination.

(b) Public Health Emergency Fund

(1) In general

There is established in the Treasury a fund to be designated as the "Public Health Emergency Fund" to be made available to the Secretary without fiscal year limitation to carry out subsection (a) only if a public health emergency has been declared by the Secretary under such subsection or if the Secretary determines there is the significant potential for a public health emergency, to allow the Secretary to rapidly respond to the immediate needs resulting from such public health emergency or potential public health emergency. The Secretary shall plan for the expedited distribution of funds to appropriate agencies and entities. There is authorized to be appropriated to the Fund such sums as may be necessary.

(2) Uses

The Secretary may use amounts in the Fund established under paragraph (1), to—

(A) facilitate coordination between and among Federal, State, local, Tribal, and territorial entities and public and private health care entities that the Secretary determines may be affected by a public health emergency or potential public health emergency referred to in paragraph (1) (including communication of such entities with relevant international entities, as applicable);

(B) make grants, provide for awards, enter into contracts, and conduct supportive investigations pertaining to a public health emergency or potential public health emergency, including further supporting programs under section 247d–3a, 247d–3b, or 247d–3c of this title;

(C) facilitate and accelerate, as applicable, advanced research and development of security countermeasures (as defined in section 247d–6b of this title), qualified countermeasures (as defined in section 247d–6a of this title), or qualified pandemic or epidemic products (as defined in section 247d–6d of this title), that are applicable to the public health emergency or potential public health emergency under paragraph (1);

(D) strengthen biosurveillance capabilities and laboratory capacity to identify, collect, and analyze information regarding such public health emergency or potential public health emergency, including the systems under section 247d–4 of this title;

(E) support initial emergency operations and assets related to preparation and deployment of intermittent disaster response personnel under section 300hh–11 of this title and the Medical Reserve Corps under section 300hh–15 of this title;

(F) support the initial deployment and distribution of contents of the Strategic National Stockpile, as appropriate; and

(G) carry out other activities, as the Secretary determines applicable and appropriate.

(3) Report

Not later than 90 days after the end of each fiscal year, the Secretary shall prepare and submit to the Committee on Health, Education, Labor, and Pensions and the Committee on Appropriations of the Senate and the Committee on Commerce and the Committee on Appropriations of the House of Representatives a report describing—

(A) the expenditures made from the Public Health Emergency Fund in such fiscal year, including—

(i) the amount obligated;

(ii) the recipient or recipients of such obligated funds;

(iii) the specific response activities such obligated funds will support; and

(iv) the declared or potential public health emergency for which such funds were obligated; and

(B) each public health emergency for which the expenditures were made and the activities undertaken with respect to each emergency which was conducted or supported by expenditures from the Fund.

(4) Review

Not later than 2 years after June 24, 2019, the Secretary, in coordination with the Assistant Secretary for Preparedness and Response, shall conduct a review of the Fund under this section and provide recommendations to the Committee on Health, Education, Labor, and Pensions and the Committee on Appropriations of the Senate and the Committee on Energy and Commerce and the Committee on Appropriations of the House of Representatives on policies to improve such Fund for the uses described in paragraph (2).

(5) GAO report

Not later than 4 years after June 24, 2019, the Comptroller General of the United States shall—

(A) conduct a review of the Fund under this section, including its uses and the resources available in the Fund; and

(B) submit to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives a report on such review, including recommendations related to such review, as applicable.

(c) Supplement not supplant

Funds appropriated under this section shall be used to rapidly respond to public health emergencies or potential public health emergencies and supplement and not supplant other Federal, State, and local public funds provided for activities under this chapter or funds otherwise provided for emergency response.

(d) Data submittal and reporting deadlines

In any case in which the Secretary determines that, wholly or partially as a result of a public health emergency that has been determined pursuant to subsection (a), individuals or public or private entities are unable to comply with deadlines for the submission to the Secretary of data or reports required under any law administered by the Secretary, the Secretary may, notwithstanding any other provision of law, grant such extensions of such deadlines as the circumstances reasonably require, and may waive, wholly or partially, any sanctions otherwise applicable to such failure to comply. Before or promptly after granting such an extension or waiver, the Secretary shall notify the Congress of such action and publish in the Federal Register a notice of the extension or waiver.

(e) Temporary reassignment of State and local personnel during a public health emergency

(1) Emergency reassignment of federally funded personnel

Notwithstanding any other provision of law, and subject to paragraph (2), upon request by the Governor of a State or a tribal organization or such Governor or tribal organization's designee, the Secretary may authorize the requesting State or Indian tribe to temporarily reassign, for purposes of immediately addressing a public health emergency in the State or Indian tribe, State and local public health department or agency personnel funded in whole or in part through programs authorized under this chapter, as appropriate.

(2) Activation of emergency reassignment

(A) Public health emergency

The Secretary may authorize a temporary reassignment of personnel under paragraph (1) only during the period of a public health emergency determined pursuant to subsection (a).

(B) Contents of request

To seek authority for a temporary reassignment of personnel under paragraph (1), the Governor of a State or a tribal organization shall submit to the Secretary a request for such reassignment flexibility and shall include in the request each of the following:

(i) An assurance that the public health emergency in the geographic area of the requesting State or Indian tribe cannot be adequately and appropriately addressed by the public health workforce otherwise available.

(ii) An assurance that the public health emergency would be addressed more efficiently and effectively through the requested temporary reassignment of State and local personnel described in paragraph (1).

(iii) An assurance that the requested temporary reassignment of personnel is consistent with any applicable All-Hazards Public Health Emergency Preparedness and Response Plan under section 247d–3a of this title.

(iv) An identification of—

(I) each Federal program from which personnel would be temporarily reassigned pursuant to the requested authority; and

(II) the number of personnel who would be so reassigned from each such program.

(v) Such other information and assurances upon which the Secretary and Governor of a State or tribal organization agree.

(C) Consideration

In reviewing a request for temporary reassignment under paragraph (1), the Secretary shall consider the degree to which the program or programs funded in whole or in part by programs authorized under this chapter would be adversely affected by the reassignment.

(D) Termination and extension

(i) Termination

A State or Indian tribe's temporary reassignment of personnel under paragraph (1) shall terminate upon the earlier of the following:

(I) The Secretary's determination that the public health emergency no longer exists.

(II) Subject to clause (ii), the expiration of the 30-day period following the date on which the Secretary approved the State or Indian tribe's request for such reassignment flexibility.

(ii) Extension of reassignment flexibility

The Secretary may extend reassignment flexibility of personnel under paragraph (1) beyond the date otherwise applicable under clause (i)(II) if the public health emergency still exists as of such date, but only if—

(I) the State or Indian tribe that submitted the initial request for a temporary reassignment of personnel submits a request for an extension of such temporary reassignment; and

(II) the request for an extension contains the same information and assurances necessary for the approval of an initial request for such temporary reassignment pursuant to subparagraph (B).

(3) Voluntary nature of temporary reassignment of State and local personnel

(A) In general

Unless otherwise provided under the law or regulation of the State or Indian tribe that receives authorization for temporary reassignment of personnel under paragraph (1), personnel eligible for reassignment pursuant to such authorization—

(i) shall have the opportunity to volunteer for temporary reassignment; and

(ii) shall not be required to agree to a temporary reassignment.

(B) Prohibition on conditioning Federal awards

The Secretary may not condition the award of a grant, contract, or cooperative agreement under this chapter on the requirement that a State or Indian tribe require that personnel eligible for reassignment pursuant to an authorization under paragraph (1) agree to such reassignment.

(4) Notice to Congress

The Secretary shall give notice to the Congress in conjunction with the approval under this subsection of—

(A) any initial request for temporary reassignment of personnel; and

(B) any request for an extension of such temporary reassignment.

(5) Guidance

The Secretary shall—

(A) not later than 6 months after March 13, 2013, issue proposed guidance on the temporary reassignment of personnel under this subsection; and

(B) after providing notice and a 60-day period for public comment, finalize such guidance.

(6) Report to Congress

Not later than 4 years after March 13, 2013, the Comptroller General of the United States shall conduct an independent evaluation, and submit to the appropriate committees of the Congress a report, on temporary reassignment under this subsection, including—

(A) a description of how, and under what circumstances, such temporary reassignment has been used by States and Indian tribes;

(B) an analysis of how such temporary reassignment has assisted States and Indian tribes in responding to public health emergencies;

(C) an evaluation of how such temporary reassignment has improved operational efficiencies in responding to public health emergencies;

(D) an analysis of the extent to which, if any, Federal programs from which personnel have been temporarily reassigned have been adversely affected by the reassignment; and

(E) recommendations on how medical surge capacity could be improved in responding to public health emergencies and the impact of the reassignment flexibility under this section on such surge capacity.

(7) Definitions

In this subsection—

(A) the terms "Indian tribe" and "tribal organization" have the meanings given such terms in section 5304 of title 25; and

(B) the term "State" includes, in addition to the entities listed in the definition of such term in section 201 of this title, the Freely Associated States.

(8) Sunset

This subsection shall terminate on December 31, 2026.

(f) Determination with respect to Paperwork Reduction Act waiver during a public health

emergency

(1) Determination

If the Secretary determines, after consultation with such public health officials as may be necessary, that—

(A)(i) the criteria set forth for a public health emergency under paragraph (1) or (2) of subsection (a) has been met; or

(ii) a disease or disorder, including a novel and emerging public health threat, is significantly likely to become a public health emergency; and

(B) the circumstances of such public health emergency, or potential for such significantly likely public health emergency, including the specific preparation for and response to such public health emergency or threat, necessitate a waiver from the requirements of subchapter I of chapter 35 of title 44 (commonly referred to as the Paperwork Reduction Act),

then the requirements of such subchapter I with respect to voluntary collection of information shall not be applicable during the immediate investigation of, and response to, such public health emergency during the period of such public health emergency or the period of time necessary to determine if a disease or disorder, including a novel and emerging public health threat, will become a public health emergency as provided for in this paragraph. The requirements of such subchapter I with respect to voluntary collection of information shall not be applicable during the immediate postresponse review regarding such public health emergency if such immediate postresponse review does not exceed a reasonable length of time.

(2) Transparency

If the Secretary determines that a waiver is necessary under paragraph (1), the Secretary shall promptly post on the Internet website of the Department of Health and Human Services a brief justification for such waiver, the anticipated period of time such waiver will be in effect, and the agencies and offices within the Department of Health and Human Services to which such waiver shall apply, and update such information posted on the Internet website of the Department of Health and Human Services, as applicable.

(3) Effectiveness of waiver

Any waiver under this subsection shall take effect on the date on which the Secretary posts information on the Internet website as provided for in this subsection.

(4) Termination of waiver

Upon determining that the circumstances necessitating a waiver under paragraph (1) no longer exist, the Secretary shall promptly update the Internet website of the Department of Health and Human Services to reflect the termination of such waiver.

(5) Limitations

(A) Period of waiver

The period of a waiver under paragraph (1) shall not exceed the period of time for the related public health emergency, including a public health emergency declared pursuant to subsection (a), and any immediate postresponse review regarding the public health emergency consistent with the requirements of this subsection.

(B) Subsequent compliance

An initiative subject to a waiver under paragraph (1) that is ongoing after the date on which the waiver expires, shall be subject to the requirements of subchapter I of chapter 35 of title 44 and the Secretary shall ensure that compliance with such requirements occurs in as timely a manner as possible based on the applicable circumstances, but not to exceed 30 calendar days after the expiration of the applicable waiver.

(g) Certain appointments to support public health emergency responses

(1) In general

In order to support the initial response to a public health emergency declared by the Secretary under this section, the Secretary may, subject to paragraph (2) and without regard to sections 3309 through 3318 of title 5, appoint individuals directly to positions in the Department of Health and Human Services for which the Secretary has provided public notice in order to—

(A) address a critical hiring need directly related to responding to a public health emergency declared by the Secretary under this section; or

(B) address a severe shortage of candidates that impacts the operational capacity of the Department of Health and Human Services to respond in the event of a public health emergency declared by the Secretary under this section.

(2) Number of appointments

Each fiscal year in which the Secretary makes a determination of a public health emergency under subsection (a) (not including a renewal), the Secretary may directly appoint not more than—

(A) 400 individuals under paragraph (1)(A); and

(B) 100 individuals under paragraph (1)(B).

(3) Compensation

The annual rate of basic pay of an individual appointed under this subsection shall be determined in accordance with chapter 51 and subchapter III of chapter 53 of title 5.

(4) Reporting

The Secretary shall establish and maintain records regarding the use of the authority under this subsection, including—

(A) the number of positions filled through such authority;

(B) the types of appointments of such positions;

(C) the titles, occupational series, and grades of such positions;

(D) the number of positions publicly noticed to be filled under such authority;

(E) the number of qualified applicants who apply for such positions;

(F) the qualification criteria for such positions; and

(G) the demographic information of individuals appointed to such positions.

(5) Notification to Congress

In the event the Secretary, within a single fiscal year, directly appoints more than 50 percent of the individuals allowable under either subparagraph (A) or (B) of paragraph (2), the Secretary shall, not later than 15 days after the date of such action, notify the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives. Such notification shall, in a manner that protects personal privacy, to the extent required by applicable Federal and State privacy law, at a minimum, include—

(A) information on each such appointment within such fiscal year;

(B) a description of how each such position relates to the requirements of subparagraph (A) or (B) of paragraph (1); and

(C) the additional number of personnel, if any, the Secretary anticipates to be necessary to adequately support a response to a public health emergency declared under this section using the authorities described in paragraph (1) within such fiscal year.

(6) Reports to Congress

Not later than September 30, 2023, and annually thereafter for each fiscal year in which the authority under this subsection is used, the Secretary shall submit to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives a report describing the total number of appointments filled under this subsection within the fiscal year and a description of how the positions relate to the requirements of subparagraph (A) or (B) of paragraph (1).

(7) Sunset

The authority under this subsection shall expire on September 30, 2028.

(h) Stockpile depletion reporting

The Secretary shall, not later than 30 days after the deployment of contents of the Strategic National Stockpile under section 247d–6b(a) of this title to respond to a public health emergency declared by the Secretary under this section or an emergency or major disaster declared by the President under the Robert T. Stafford Disaster Relief and Emergency Assistance Act [42 U.S.C. 5121 et seq.], and every 30 days thereafter until the expiration or termination of such public health emergency, emergency, or major disaster, submit a report to the Committee on Health, Education, Labor, and Pensions and the Committee on Appropriations of the Senate and the Committee on Energy and Commerce and the Committee on Appropriations of the House of Representatives on—

(1) the deployment of the contents of the stockpile in response to State, local, and Tribal requests;

(2) the amount of such products that remain within the stockpile following such deployment; and

(3) plans to replenish such products, as appropriate, including related timeframes and any barriers or limitations to replenishment.

(July 1, 1944, ch. 373, title III, §319, as added Pub. L. 106–505, title I, §102, Nov. 13, 2000, 114 Stat. 2315; amended Pub. L. 107–188, title I, §§141, 144(a), 158, June 12, 2002, 116 Stat. 626, 630, 633; Pub. L. 113–5, title II, §201, Mar. 13, 2013, 127 Stat. 170; Pub. L. 114–255, div. A, title III, §3087, Dec. 13, 2016, 130 Stat. 1147; Pub. L. 116–22, title II, §206, title VII, §701(c), June 24, 2019, 133 Stat. 925, 961; Pub. L. 117–328, div. FF, title II, §§2103(a), 2223(a), 2407, Dec. 29, 2022, 136 Stat. 5711, 5747, 5788; Pub. L. 118–15, div. B, title III, §2332, Sept. 30, 2023, 137 Stat. 96; Pub. L. 118–22, div. B, title II, §203(a), Nov. 17, 2023, 137 Stat. 120; Pub. L. 118–35, div. B, title I, §103(a), Jan. 19, 2024, 138 Stat. 5; Pub. L. 118–42, div. G, title I, §103(a), Mar. 9, 2024, 138 Stat. 398; Pub. L. 118–158, div. C, title I, §3103(a), Dec. 21, 2024, 138 Stat. 1763; Pub. L. 119–4, div. B, title I, §2103(a), Mar. 15, 2025, 139 Stat. 41; Pub. L. 119–37, div. F, title I, §6103(a), Nov. 12, 2025, 139 Stat. 630; Pub. L. 119–75, div. J, title IV, §6403(a), Feb. 3, 2026, 140 Stat. 688.)

EDITORIAL NOTES

REFERENCES IN TEXT

The Robert T. Stafford Disaster Relief and Emergency Assistance Act, referred to in subsec. (h), is Pub. L. 93–288, May 22, 1974, 88 Stat. 143, which is classified principally to chapter 68 (§5121 et seq.) of this title. For complete classification of this Act to the Code, see Short Title note set out under section 5121 of this title and Tables.

PRIOR PROVISIONS

A prior section 247d, act July 1, 1944, ch. 373, title III, §319, as added Pub. L. 98–49, July 13, 1983, 97 Stat. 245; amended Pub. L. 100–607, title II, §256(a), Nov. 4, 1988, 102 Stat. 3110; Pub. L. 102–321, title I, §163(b)(2), July 10, 1992, 106 Stat. 376; Pub. L. 102–531, title III, §312(d)(2), Oct. 27, 1992, 106 Stat. 3504, authorized the Secretary to take appropriate action relating to public health emergencies, prior to repeal by Pub. L. 106–505, title I, §102, Nov. 13, 2000, 114 Stat. 2315.

Another prior section 247d, act July 1, 1944, ch. 373, title III, §319, formerly §310, as added Sept. 25, 1962, Pub. L. 87–692, 76 Stat. 592, and amended and renumbered, which related to migrant health centers, was renumbered section 329 of act July 1, 1944, by Pub. L. 95–626, title I, §102(a), Nov. 10, 1978, 92 Stat. 3551, and transferred to section 254b of this title, prior to being omitted in the general amendment of subpart I (§254b et seq.) of part D of this subchapter by Pub. L. 104–299, §2.

AMENDMENTS

2026—Subsec. (e)(8). Pub. L. 119–75 substituted "December 31, 2026" for "January 30, 2026".

2025—Subsec. (e)(8). Pub. L. 119–37 substituted "January 30, 2026" for "September 30, 2025".

Pub. L. 119–4 substituted "September 30, 2025" for "March 31, 2025".

2024—Subsec. (e)(8). Pub. L. 118–158 substituted "March 31, 2025" for "December 31, 2024".

Pub. L. 118–42 substituted "December 31, 2024" for "March 8, 2024".

Pub. L. 118–35 substituted "March 8, 2024" for "January 19, 2024".

2023—Subsec. (e)(8). Pub. L. 118–22 substituted "January 19, 2024" for "November 17, 2023".

Pub. L. 118–15 substituted "November 17, 2023" for "September 30, 2023".

2022—Subsec. (b)(2)(F), (G). Pub. L. 117–328, §2103(a)(1), added subpar. (F) and redesignated former subpar. (F) as (G).

Subsec. (b)(3)(A). Pub. L. 117–328, §2103(a)(2), amended subpar. (A) generally. Prior to amendment, subpar. (A) read as follows: "the expenditures made from the Public Health Emergency Fund in such fiscal year; and".

Subsec. (g). Pub. L. 117–328, §2223(a), added subsec. (g).

Subsec. (h). Pub. L. 117–328, §2407, added subsec. (h).

2019—Subsec. (b)(1). Pub. L. 116–22, §206(1)(A), substituted "under such subsection or if the Secretary determines there is the significant potential for a public health emergency, to allow the Secretary to rapidly respond to the immediate needs resulting from such public health emergency or potential public health emergency. The Secretary shall plan for the expedited distribution of funds to appropriate agencies and entities." for "under such subsection."

Subsec. (b)(2), (3). Pub. L. 116–22, §206(1)(B), (C), added par. (2) and redesignated former par. (2) as (3).

Subsec. (b)(4), (5). Pub. L. 116–22, §206(1)(D), added pars. (4) and (5).

Subsec. (c). Pub. L. 116–22, §206(2), inserted "rapidly respond to public health emergencies or potential public health emergencies and" after "used to" and substituted "activities under this chapter or funds otherwise provided for emergency response." for "activities under this section."

Subsec. (e)(8). Pub. L. 116–22, §701(c), substituted "2023" for "2018".

2016—Subsec. (f). Pub. L. 114–255 added subsec. (f).

2013—Subsec. (e). Pub. L. 113–5 added subsec. (e).

2002—Subsec. (a). Pub. L. 107–188, §158, substituted "grants, providing awards for expenses, and" for "grants and" in concluding provisions.

Pub. L. 107–188, §144(a), inserted at end of concluding provisions "Any such determination of a public health emergency terminates upon the Secretary declaring that the emergency no longer exists, or upon the expiration of the 90-day period beginning on the date on which the determination is made by the Secretary, whichever occurs first. Determinations that terminate under the preceding sentence may be renewed by the Secretary (on the basis of the same or additional facts), and the preceding sentence applies to each such renewal. Not later than 48 hours after making a determination under this subsection of a public health emergency (including a renewal), the Secretary shall submit to the Congress written notification of the determination."

Subsec. (d). Pub. L. 107–188, §141, added subsec. (d).

STATUTORY NOTES AND RELATED SUBSIDIARIES

CHANGE OF NAME

Committee on Commerce of House of Representatives changed to Committee on Energy and Commerce of House of Representatives, and jurisdiction over matters relating to securities and exchanges and insurance generally transferred to Committee on Financial Services of House of Representatives by House Resolution No. 5, One Hundred Seventh Congress, Jan. 3, 2001.

EFFECTIVE DATE OF 2002 AMENDMENT

Pub. L. 107–188, title I, §144(b), June 12, 2002, 116 Stat. 630, provided that: "The amendment made by subsection (a) [amending this section] applies to any public health emergency under section 319(a) of the Public Health Service Act [42 U.S.C. 247d(a)], including any such emergency that was in effect as of the day before the date of the enactment of this Act [June 12, 2002]. In the case of such an emergency that was in effect as of such day, the 90-day period described in such section with respect to the termination of the emergency is deemed to begin on such date of enactment."

CONSIDERATION OF UNIQUE CHALLENGES IN NONCONTIGUOUS STATES AND TERRITORIES

Pub. L. 117–328, div. FF, title II, §2115, Dec. 29, 2022, 136 Stat. 5726, provided that: "During any public health emergency declared under section 319 of the Public Health Service Act (42 U.S.C. 247d), the Secretary of Health and Human Services shall conduct quarterly meetings or consultations, as applicable or appropriate, with noncontiguous States and territories with regard to addressing unique public health challenges in such States and territories associated with such public health emergency."

FUNDING FOR COVID–19 VACCINE ACTIVITIES AT THE CENTERS FOR DISEASE CONTROL

AND PREVENTION

Pub. L. 117–2, title II, §2301, Mar. 11, 2021, 135 Stat. 37, provided that:

"(a) IN GENERAL.—In addition to amounts otherwise available, there is appropriated to the Secretary of Health and Human Services (in this subtitle [subtitle D (§§2301–2305) of title II of Pub. L. 117–2, see Tables for classification] referred to as the 'Secretary') for fiscal year 2021, out of any money in the Treasury not otherwise appropriated, $7,500,000,000, to remain available until expended, to carry out activities to plan, prepare for, promote, distribute, administer, monitor, and track COVID–19 vaccines.

"(b) USE OF FUNDS.—The Secretary, acting through the Director of the Centers for Disease Control and Prevention, and in consultation with other agencies, as applicable, shall, in conducting activities referred to in subsection (a)—

"(1) conduct activities to enhance, expand, and improve nationwide COVID–19 vaccine distribution and administration, including activities related to distribution of ancillary medical products and supplies related to vaccines; and

"(2) provide technical assistance, guidance, and support to, and award grants or cooperative agreements to, State, local, Tribal, and territorial public health departments for enhancement of COVID–19 vaccine distribution and administration capabilities, including—

"(A) the distribution and administration of vaccines licensed under section 351 of the Public Health Service Act (42 U.S.C. 262) or authorized under section 564 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360bbb–3) and ancillary medical products and supplies related to vaccines;

"(B) the establishment and expansion, including staffing support, of community vaccination centers, particularly in underserved areas;

"(C) the deployment of mobile vaccination units, particularly in underserved areas;

"(D) information technology, standards-based data, and reporting enhancements, including improvements necessary to support standards-based sharing of data related to vaccine distribution and vaccinations and systems that enhance vaccine safety, effectiveness, and uptake, particularly among underserved populations;

"(E) facilities enhancements;

"(F) communication with the public regarding when, where, and how to receive COVID–19 vaccines; and

"(G) transportation of individuals to facilitate vaccinations, including at community vaccination centers and mobile vaccination units, particularly for underserved populations.

"(c) SUPPLEMENTAL FUNDING FOR STATE VACCINATION GRANTS.—

"(1) DEFINITIONS.—In this subsection:

"(A) BASE FORMULA.—The term 'base formula' means the allocation formula that applied to the Public Health Emergency Preparedness cooperative agreement in fiscal year 2020.

"(B) ALTERNATIVE ALLOCATION.—The term 'alternative allocation' means an allocation to each State, territory, or locality calculated using the percentage derived from the allocation received by such State, territory, or locality of the aggregate amount of fiscal year 2020 Public Health Emergency Preparedness cooperative agreement awards under section 319C–1 of the Public Health Service Act (42 U.S.C. 247d–3a).

"(2) SUPPLEMENTAL FUNDING.—

"(A) IN GENERAL.—Not later than 21 days after the date of enactment of this Act [Mar. 11, 2021], the Secretary shall, out of amounts described in subsection (a), provide supplemental funding to any State, locality, or territory that received less of the amounts that were appropriated under title III of division M of Public Law 116–260 [see Tables for classification] for vaccination grants to be issued by the Centers for Disease Control and Prevention than such State, locality, or territory would have received had such amounts been allocated using the alternative allocation.

"(B) AMOUNT.—The amount of supplemental funding provided under this subsection shall be equal to the difference between—

"(i) the amount the State, locality, or territory received, or would receive, under the base formula; and

"(ii) the amount the State, locality, or territory would receive under the alternative allocation."

FUNDING FOR COVID–19 TESTING, CONTACT TRACING, AND MITIGATION ACTIVITIES

Pub. L. 117–2, title II, §2401, Mar. 11, 2021, 135 Stat. 40, provided that:

"(a) IN GENERAL.—In addition to amounts otherwise available, there is appropriated to the Secretary of Health and Human Services (in this subtitle [subtitle E (§§2401–2404) of title II of Pub. L. 117–2, see Tables

for classification] referred to as the 'Secretary') for fiscal year 2021, out of any money in the Treasury not otherwise appropriated, $47,800,000,000, to remain available until expended, to carry out activities to detect, diagnose, trace, and monitor SARS–CoV–2 and COVID–19 infections and related strategies to mitigate the spread of COVID–19.

"(b) USE OF FUNDS.—From amounts appropriated by subsection (a), the Secretary shall—

"(1) implement a national, evidence-based strategy for testing, contact tracing, surveillance, and mitigation with respect to SARS–CoV–2 and COVID–19, including through activities authorized under section 319(a) of the Public Health Service Act [42 U.S.C. 247d(a)];

"(2) provide technical assistance, guidance, and support, and award grants or cooperative agreements to State, local, and territorial public health departments for activities to detect, diagnose, trace, and monitor SARS–CoV–2 and COVID–19 infections and related strategies and activities to mitigate the spread of COVID–19;

"(3) support the development, manufacturing, procurement, distribution, and administration of tests to detect or diagnose SARS–CoV–2 and COVID–19, including through—

"(A) support for the development, manufacture, procurement, and distribution of supplies necessary for administering tests, such as personal protective equipment; and

"(B) support for the acquisition, construction, alteration, or renovation of non-federally owned facilities for the production of diagnostics and ancillary medical products and supplies where the Secretary determines that such an investment is necessary to ensure the production of sufficient amounts of such supplies;

"(4) establish and expand Federal, State, local, and territorial testing and contact tracing capabilities, including—

"(A) through investments in laboratory capacity, such as—

"(i) academic and research laboratories, or other laboratories that could be used for processing of COVID–19 testing;

"(ii) community-based testing sites and community-based organizations; or

"(iii) mobile health units, particularly in medically underserved areas; and

"(B) with respect to quarantine and isolation of contacts;

"(5) enhance information technology, data modernization, and reporting, including improvements necessary to support sharing of data related to public health capabilities;

"(6) award grants to, or enter into cooperative agreements or contracts with, State, local, and territorial public health departments to establish, expand, and sustain a public health workforce; and

"(7) to cover administrative and program support costs necessary to conduct activities related to subparagraph (a)."

IMPORTANCE OF THE BLOOD SUPPLY

Pub. L. 116–136, div. A, title III, §3226, Mar. 27, 2020, 134 Stat. 383, provided that:

"(a) IN GENERAL.—The Secretary of Health and Human Services (referred to in this section as the 'Secretary') shall carry out a national campaign to improve awareness of, and support outreach to the public and health care providers about the importance and safety of blood donation and the need for donations for the blood supply during the public health emergency declared by the Secretary under section 319 of the Public Health Service Act (42 U.S.C. 247d) with respect to COVID–19.

"(b) AWARENESS CAMPAIGN.—In carrying out subsection (a), the Secretary may enter into contracts with one or more public or private nonprofit entities, to establish a national blood donation awareness campaign that may include television, radio, internet, and newspaper public service announcements, and other activities to provide for public and professional awareness and education.

"(c) CONSULTATION.—In carrying out subsection (a), the Secretary shall consult with the Commissioner of Food and Drugs, the Assistant Secretary for Health, the Director of the Centers for Disease Control and Prevention, the Director of the National Institutes of Health, and the heads of other relevant Federal agencies, and relevant accrediting bodies and representative organizations.

"(d) REPORT TO CONGRESS.—Not later than 2 years after the date of enactment of this Act [Mar. 27, 2020], the Secretary shall submit to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives, a report that shall include—

"(1) a description of the activities carried out under subsection (a);

"(2) a description of trends in blood supply donations; and

"(3) an evaluation of the impact of the public awareness campaign, including any geographic or population variations."

REPORTING BY LABORATORIES OF RESULTS OF TESTS TO DETECT SARS–COV–2 OR TO

DIAGNOSE COVID–19

Pub. L. 116–136, div. B, title VIII, §18115(a)–(c), Mar. 27, 2020, 134 Stat. 574, provided that:

"(a) IN GENERAL.—Every laboratory that performs or analyzes a test that is intended to detect SARS–CoV–2 or to diagnose a possible case of COVID–19 shall report the results from each such test, to the Secretary of Health and Human Services in such form and manner, and at such timing and frequency, as the Secretary may prescribe until the end of the Secretary's Public Health Emergency declaration with respect to COVID–19 or any extension of such declaration.

"(b) LABORATORIES COVERED.—The Secretary may prescribe which laboratories must submit reports pursuant to this section.

"(c) IMPLEMENTATION.—The Secretary may make prescriptions under this section by regulation, including by interim final rule, or by guidance, and may issue such regulations or guidance without regard to the procedures otherwise required by section 553 of title 5, United States Code."

EXECUTIVE DOCUMENTS

EXECUTIVE ORDER NO. 13987

Ex. Ord. No. 13987, Jan. 20, 2021, 86 F.R. 7019, organizing and mobilizing the United States government to provide a unified and effective response to combat COVID–19 and to provide United States leadership on global health and security, was revoked by Ex. Ord. No. 14148, §2(c), Jan. 20, 2025, 90 F.R. 8237, and Ex. Ord. No. 14155, §2(b), Jan. 20, 2025, 90 F.R. 8361. Positions of COVID–19 Response Coordinator and Deputy Coordinator of the COVID–19 Response, as established by section 2 of Ex. Ord. No. 13987 terminated, and responsibilities and duties transferred to Director of the Office of Pandemic Preparedness and Response Policy, by Ex. Ord. No. 14122, §3, Apr. 12, 2024, 89 F.R. 27355, set out in a note under section 300hh–3 of this title.

EXECUTIVE ORDER NO. 13991

Ex. Ord. No. 13991, Jan. 20, 2021, 86 F.R. 7045, which required compliance with CDC guidelines with respect to wearing masks, maintaining physical distance, and other public health measures by Federal employees and contractors and all persons in Federal buildings or on Federal lands, and HHS promotion of public health best practices identified by the CDC, was revoked by Ex. Ord. No. 14122, §2, Apr. 12, 2024, 89 F.R. 27355, set out in a note under section 300hh–3 of this title.

EXECUTIVE ORDER NO. 13994

Ex. Ord. No. 13994, Jan. 21, 2021, 86 F.R. 7189, which related to ensuring a data-driven response to COVID–19 and future high-consequence public health threats, was revoked by Ex. Ord. No. 14236, §2(a), Mar. 14, 2025, 90 F.R. 13037.

EXECUTIVE ORDER NO. 13995

Ex. Ord. No. 13995, Jan. 21, 2021, 86 F.R. 7193, which related to ensuring an equitable pandemic response and recovery, was revoked by Ex. Ord. No. 14148, §2(i), Jan. 20, 2025, 90 F.R. 8237.

EXECUTIVE ORDER NO. 13996

Ex. Ord. No. 13996, Jan. 21, 2021, 86 F.R. 7197, establishing the COVID–19 Pandemic Testing Board and ensuring a sustainable public health workforce for COVID–19 and other biological threats, was revoked by Ex. Ord. No. 14148 §2(j), Jan. 20, 2025, 90 F.R. 8237.

EXECUTIVE ORDER NO. 13997

Ex. Ord. No. 13997, Jan. 21, 2021, 86 F.R. 7201, improving and expanding access to care and treatments for COVID–19, was revoked by Ex. Ord. No. 14148, §2(k), Jan. 20, 2025, 90 F.R. 8237.

EXECUTIVE ORDER NO. 13998

Ex. Ord. No. 13998, Jan. 21, 2021, 86 F.R. 7205, which related to promoting COVID–19 safety in domestic and international travel, was revoked by Ex. Ord. No. 14122, §2, Apr. 12, 2024, 89 F.R. 27355, set out in a note under section 300hh–3 of this title.

EXECUTIVE ORDER NO. 13999

Ex. Ord. No. 13999, Jan. 21, 2021, 86 F.R. 7211, ensuring the health and safety of workers during the COVID–19 pandemic, was revoked by Ex. Ord. No. 14148, §2(l), Jan. 20, 2025, 90 F.R. 8238.

EXECUTIVE ORDER NO. 14000

Ex. Ord. No. 14000, Jan. 21, 2021, 86 F.R. 7215, supporting the reopening and continuing operation of schools and early childhood education providers, was revoked by Ex. Ord. No. 14148, §2(m), Jan. 20, 2025, 90 F.R. 8238.

ADDRESSING THE LONG-TERM EFFECTS OF COVID–19

Memorandum of President of the United States, Apr. 5, 2022, 87 F.R. 20995, provided:

Memorandum for the Heads of Executive Departments and Agencies

By the authority vested in me as President by the Constitution and the laws of the United States of America, it is hereby ordered as follows:

SECTION 1. *Policy*. My Administration has made combating the coronavirus disease 2019 (COVID–19) pandemic, and guiding the Nation through the worst public health crisis in more than a century, our top priority. When I came into office, COVID–19 was wreaking havoc on our country—closing our businesses, keeping our kids out of school, and forcing us into isolation. Today, America has the tools to protect against COVID–19 and to dramatically decrease its risks. We move towards a future in which COVID–19 does not disrupt our daily lives and is something we prevent, protect against, and treat.

As we chart the path forward, we remember the more than 950,000 people in the United States lost to COVID–19. They were beloved parents, grandparents, children, siblings, spouses, neighbors, and friends. More than 200,000 children in the United States have lost a parent or caregiver to the disease. Each soul is irreplaceable, and the families and communities left behind are still reeling from profound loss. Many families and communities have already received support from Federal programs that help with the loss they have experienced. As we move forward, we commit to ensuring that families and communities can access these support programs and connect to resources they may need to help with their healing, health, and well-being.

At the same time, many of our family members, neighbors, and friends continue to experience negative long-term effects of COVID–19. Many individuals report debilitating, long-lasting effects of having been infected with COVID–19, often called "long COVID." These symptoms can happen to anyone who has had COVID–19—including individuals across ages, races, genders, and ethnicities; individuals with or without disabilities; individuals with or without underlying health conditions; and individuals whether or not they had initial symptoms. Individuals experiencing long COVID report experiencing new or recurrent symptoms, which can include anxiety and depression, fatigue, shortness of breath, difficulty concentrating, heart palpitations, disordered sleep, chest and joint pain, headaches, and other symptoms. These symptoms can persist long after the acute COVID–19 infection has resolved. Even young people and otherwise healthy people have reported long COVID symptoms that last for many months. These symptoms may be affecting individuals' ability to work, conduct daily activities, engage in educational activities, and participate in their communities. Our world-class research and public health organizations have begun the difficult work of understanding these new conditions, their causes, and potential prevention and treatment options. Our health care and support programs are working to help meet the needs of individuals experiencing the lasting effects of COVID–19. To organize the Federal Government's response, executive departments and agencies (agencies) must work together to use the expertise, resources, and benefit programs of the Federal Government to ensure that we are accelerating scientific progress and providing individuals with the support and services they need.

In addition, the American public is grappling with a mental health crisis exacerbated by the pandemic. Too many have felt the effects of social isolation, sickness, economic insecurity, increased caregiver burdens, and grief. My Administration has made significant investments in mental health as well as substance use disorder prevention, treatment, and recovery support for the American public, including by expanding access to community-based behavioral health services. We are committed to advancing these behavioral health efforts in order to better identify the effects of the pandemic on mental health, substance use, and well-being, and to take steps to address these effects for the people we serve.

Our Nation can continue to protect the public—and spare countless families from the deepest pain imaginable—if everybody does their part. Today, we have numerous tools to protect ourselves and our loved ones from COVID–19—from vaccines to tests, treatments, masks, and more. My Administration recognizes the toll of this pandemic on the American public and commits to redoubling our efforts to support the American people in addressing the long-term effects of COVID–19 on their lives and on society.

SEC. 2. *Organizing the Government-Wide Response to the Long-Term Effects of COVID–19*. (a) The Secretary of Health and Human Services (Secretary) shall coordinate the Government-wide response to the long-term effects of COVID–19. My Administration will harness the full potential of the Federal Government,

in coordination with public- and private-sector partners, to mount a full and effective response. The Secretary shall report on the coordination efforts to the Coordinator of the COVID–19 Response and Counselor to the President and to the Assistant to the President for Domestic Policy.

(b) The heads of agencies shall assist and provide information to the Secretary, consistent with applicable law, as may be necessary to carry out the Secretary's duties described in subsection (a) of this section.

(c) In performing the duties described in subsection (a) of this section, the Secretary shall seek information from relevant nongovernmental experts, organizations, and stakeholders, including individuals affected directly by the long-term effects of COVID–19. The Secretary shall consider using all available legal authorities, as appropriate and consistent with applicable law, to assist in gathering relevant information, including a waiver under 42 U.S.C. 247d(f).

SEC. 3. *Report on the Long-Term Effects of COVID–19*. The Secretary, supported within the Department of Health and Human Services by the Assistant Secretary for Health and the Assistant Secretary for Mental Health and Substance Use, shall publish a public report within 120 days of the date of this memorandum [Apr. 5, 2022] outlining services and mechanisms of support across agencies to assist the American public in the face of the far-reaching and long-term effects of COVID–19. The report shall outline Federal Government services to support individuals experiencing long COVID, individuals and families experiencing a loss due to COVID–19, and all those grappling with mental health and substance use issues in the wake of this pandemic. The report shall also specifically address the long-term effects of COVID–19 on underserved communities and efforts to address disparities in availability and adoption of services and support for such communities.

SEC. 4. *National Research Action Plan on Long COVID*. (a) Coordinated efforts across the public and private sectors are needed to advance progress in prevention, diagnosis, treatment, and provision of services for individuals experiencing long COVID. The Secretary, supported by the Assistant Secretary for Health and in collaboration with the Secretary of Defense, the Secretary of Labor, the Secretary of Energy, and the Secretary of Veterans Affairs, shall coordinate a Government-wide effort to develop the first-ever interagency national research agenda on long COVID, to be reflected in a National Research Action Plan. The National Research Action Plan will build on ongoing efforts across the Federal Government, including the landmark RECOVER Initiative implemented by the National Institutes of Health. The Secretary shall release the jointly developed National Research Action Plan within 120 days of the date of this memorandum.

(b) The National Research Action Plan shall build upon existing research efforts and include strategies to:

(i) help measure and characterize long COVID in both children and adults, including with respect to its frequency, severity, duration, risk factors, and trends over time;

(ii) support the development of estimates on prevalence and incidence of long COVID disaggregated by demographic groups and symptoms;

(iii) better understand the epidemiology, course of illness, risk factors, and vaccine effectiveness in prevention of long COVID;

(iv) advance our understanding of the health and socioeconomic burdens on individuals affected by long COVID, including among different race and ethnicity groups, pregnant people, and those with underlying disabilities;

(v) foster development of new treatments and care models for long COVID based on a better understanding of the pathophysiological mechanisms of the SARS–CoV–2 virus;

(vi) inform decisions related to high-quality support, services, and interventions for long COVID;

(vii) improve data-sharing between agencies and academic and industry researchers about long COVID, to the extent permitted by law; and

(viii) specifically account for the pandemic's effect on underserved communities and rural populations.

SEC. 5. *General Provisions*. (a) Nothing in this memorandum shall be construed to impair or otherwise affect:

(i) the authority granted by law to an executive department or agency, or the head thereof; or

(ii) the functions of the Director of the Office of Management and Budget relating to budgetary, administrative, or legislative proposals.

(b) This memorandum shall be implemented consistent with applicable law and subject to the availability of appropriations.

(c) This memorandum is not intended to, and does not, create any right or benefit, substantive or procedural, enforceable at law or in equity by any party against the United States, its departments, agencies, or entities, its officers, employees, or agents, or any other person.

(d) The Secretary is authorized and directed to publish this memorandum in the Federal Register.

J.R. BIDEN, JR.

§247d–1. Vaccine tracking and distribution

(a) Tracking

The Secretary, together with relevant manufacturers, wholesalers, and distributors as may agree to cooperate, may track the initial distribution of federally purchased influenza vaccine in an influenza pandemic, or other federally purchased vaccine to address another pandemic. Such tracking information shall be used to inform Federal, State, local, and tribal decision makers during an influenza pandemic or other pandemic.

(b) Distribution

The Secretary shall promote communication between State, local, and tribal public health officials and such manufacturers, wholesalers, and distributors as agree to participate, regarding the effective distribution of seasonal influenza vaccine. Such communication shall include estimates of high priority populations, as determined by the Secretary, in State, local, and tribal jurisdictions in order to inform Federal, State, local, and tribal decision makers during vaccine shortages and supply disruptions.

(c) Confidentiality

The information submitted to the Secretary or its contractors, if any, under this section or under any other section of this chapter related to vaccine distribution information shall remain confidential in accordance with the exception from the public disclosure of trade secrets, commercial or financial information, and information obtained from an individual that is privileged and confidential, as provided for in section 552(b)(4) of title 5, and subject to the penalties and exceptions under sections 1832 and 1833 of title 18 relating to the protection and theft of trade secrets, and subject to privacy protections that are consistent with the regulations promulgated under section 264(c) of the Health Insurance Portability and Accountability Act of 1996. None of such information provided by a manufacturer, wholesaler, or distributor shall be disclosed without its consent to another manufacturer, wholesaler, or distributor, or shall be used in any manner to give a manufacturer, wholesaler, or distributor a proprietary advantage.

(d) Guidelines

The Secretary, in order to maintain the confidentiality of relevant information and ensure that none of the information contained in the systems involved may be used to provide proprietary advantage within the vaccine market, while allowing State, local, and tribal health officials access to such information to maximize the delivery and availability of vaccines to high priority populations, during times of influenza pandemics or other pandemics, vaccine shortages, and supply disruptions, in consultation with manufacturers, distributors, wholesalers and State, local, and tribal health departments, shall develop guidelines for subsections (a) and (b).

(e) Authorization of appropriations

There are authorized to be appropriated to carry out this section, $30,800,000 for each of fiscal years 2019 through 2023.

(f) Report to Congress

As part of the National Health Security Strategy described in section 300hh–1 of this title, the Secretary shall provide an update on the implementation of subsections (a) through (d).

(July 1, 1944, ch. 373, title III, §319A, as added Pub. L. 106–505, title I, §102, Nov. 13, 2000, 114 Stat. 2316; amended Pub. L. 107–188, title I, §111(1), June 12, 2002, 116 Stat. 611; Pub. L. 109–417, title II, §204(a), Dec. 19, 2006, 120 Stat. 2850; Pub. L. 113–5, title II, §202(b), Mar. 13, 2013, 127 Stat. 175; Pub. L. 116–22, title VII, §701(b), June 24, 2019, 133 Stat. 961; Pub. L. 117–328, div. FF, title II, §2232, Dec. 29, 2022, 136 Stat. 5754.)

EDITORIAL NOTES

REFERENCES IN TEXT

Section 264(c) of the Health Insurance Portability and Accountability Act of 1996, referred to in subsec. (c), is section 264(c) of Pub. L. 104–191, which is set out as a note under section 1320d–2 of this title.

AMENDMENTS

2022—Subsec. (a). Pub. L. 117–328, §2232(1), inserted ", or other federally purchased vaccine to address another pandemic" after "in an influenza pandemic" and "or other pandemic" after "during an influenza pandemic".

Subsec. (d). Pub. L. 117–328, §2232(2), inserted "or other pandemics" after "influenza pandemics".

2019—Subsec. (e). Pub. L. 116–22 substituted "2019 through 2023" for "2014 through 2018".

2013—Subsec. (e). Pub. L. 113–5 substituted "$30,800,000 for each of fiscal years 2014 through 2018" for "such sums for each of fiscal years 2007 through 2011".

2006—Pub. L. 109–417 amended section catchline and text generally, substituting provisions relating to vaccine tracking and distribution for provisions relating to establishment of capacities to combat threats to public health.

2002—Subsec. (a)(1). Pub. L. 107–188 substituted "five years" for "10 years".

§247d–2. Earlier development of diagnostic tests

The Secretary may contract with public and private entities, as appropriate, to increase capacity in the rapid development, validation, manufacture, and dissemination of diagnostic tests, as appropriate, to State, local, and Tribal health departments and other appropriate entities for immediate public health response activities to address an emerging infectious disease with respect to which a public health emergency is declared under section 247d of this title, or that has significant potential to cause such a public health emergency.

(July 1, 1944, ch. 373, title III, §319B, as added Pub. L. 117–328, div. FF, title II, §2303(b), Dec. 29, 2022, 136 Stat. 5758.)

EDITORIAL NOTES

PRIOR PROVISIONS

A prior section 247d–2, act July 1, 1944, ch. 373, title III, §319B, as added Pub. L. 106–505, title I, §102, Nov. 13, 2000, 114 Stat. 2317; amended Pub. L. 107–188, title I, §111(2), June 12, 2002, 116 Stat. 611, related to grants to States to assess public health needs, prior to repeal by Pub. L. 109–417, title II, §204(b)(1), Dec. 19, 2006, 120 Stat. 2851.

§247d–3. Repealed. Pub. L. 109–417, title II, §204(b)(1), Dec. 19, 2006, 120 Stat. 2851

Section, act July 1, 1944, ch. 373, title III, §319C, as added Pub. L. 106–505, title I, §102, Nov. 13, 2000, 114 Stat. 2317; amended Pub. L. 107–188, title I, §131(b), June 12, 2002, 116 Stat. 626, related to grants to improve State and local public health agencies.

§247d–3a. Improving State and local public health security

(a) In general

To enhance the security of the United States with respect to public health emergencies, the Secretary, acting through the Director of the Centers for Disease Control and Prevention, shall award cooperative agreements to eligible entities to enable such entities to conduct the activities described in subsection (d).

(b) Eligible entities

To be eligible to receive an award under subsection (a), an entity shall—

(1)(A) be a State;

(B) be a political subdivision determined by the Secretary to be eligible for an award under this section (based on criteria described in subsection (h)(4)); or

(C) be a consortium of States; and

(2) prepare and submit to the Secretary an application at such time, and in such manner, and containing such information as the Secretary may require, including—

(A) an All-Hazards Public Health Emergency Preparedness and Response Plan which shall include—

(i) a description of the activities such entity will carry out under the agreement to meet the goals identified under section 300hh–1 of this title, including with respect to chemical, biological, radiological, or nuclear threats, whether naturally occurring, unintentional, or deliberate;

(ii) a description of the activities such entity will carry out with respect to pandemic influenza, as a component of the activities carried out under clause (i), and consistent with the requirements of paragraphs (2) and (5) of subsection (g);

(iii) preparedness and response strategies and capabilities that take into account the medical and public health needs of at-risk individuals in the event of a public health emergency;

(iv) a description of the mechanism the entity will implement to utilize the Emergency Management Assistance Compact, or other mutual aid agreement, for medical and public health mutual aid, and, as appropriate, the activities such entity will implement pursuant to section 247d–7b of this title to improve enrollment and coordination of volunteer health care professionals seeking to provide medical services during a public health emergency, which may include—

(I) providing a public method of communication for purposes of volunteer coordination (such as a phone number);

(II) providing for optional registration to participate in volunteer services during processes related to State medical licensing, registration, or certification or renewal of such licensing, registration, or certification; or

(III) other mechanisms as the State determines appropriate;

(v) a description of how the entity will include the State Unit on Aging in public health emergency preparedness;

(vi) a description of how, as appropriate, the entity may partner with relevant public and private stakeholders, including public health agencies with specific expertise that may be relevant to public health security, such as environmental health agencies, in public health emergency preparedness and response;

(vii) a description of how, as applicable, such entity may integrate information to account for individuals with behavioral health needs during and following a public health emergency;

(viii) a description of how the entity, as applicable and appropriate, will coordinate with State emergency preparedness and response plans in public health emergency preparedness, including State education agencies [1] (as defined in section 7801 of title 20), State child care lead agencies (designated under section 9858b of this title), and other relevant State agencies [2]

(ix) in the case of entities that operate on the United States-Mexico border or the United States-Canada border, a description of the activities such entity will carry out under the agreement that are specific to the border area including disease detection, identification, investigation, and preparedness and response activities related to emerging diseases and infectious disease outbreaks whether naturally occurring or due to bioterrorism, consistent with the requirements of this section;

(x) a description of any activities that such entity will use to analyze real-time clinical specimens for pathogens of public health or bioterrorism significance, including any utilization of poison control centers;

(xi) a description of how the entity will partner with health care facilities, including

hospitals and nursing homes and other long-term care facilities, to promote and improve public health preparedness and response;

(xii) a description of how the entity will provide technical assistance to improve public health preparedness and response, as appropriate, to agencies or other entities that operate facilities within the entity's jurisdiction in which there is an increased risk of infectious disease outbreaks in the event of a public health emergency declared under section 247d of this title, such as residential care facilities, group homes, and other similar settings; and

(xiii) a description of how, as appropriate and practicable, the entity will include critical infrastructure partners, such as utility companies within the entity's jurisdiction, in planning pursuant to this subparagraph to help ensure that critical infrastructure will remain functioning during, or return to function as soon as practicable after, a public health emergency;

(B) an assurance that the entity will report to the Secretary on an annual basis (or more frequently as determined by the Secretary) on the evidence-based benchmarks and objective standards established by the Secretary to evaluate the preparedness and response capabilities of such entity under subsection (g);

(C) an assurance that the entity will conduct, on at least an annual basis, an exercise or drill that meets any criteria established by the Secretary to test the preparedness and response capabilities of such entity, including addressing the needs of at-risk individuals, and that the entity will report back to the Secretary within the application of the following year on the strengths and weaknesses identified through such exercise or drill, and corrective actions taken to address material weaknesses;

(D) an assurance that the entity will require relevant staff to complete relevant preparedness and response trainings, including trainings related to efficient and effective operation during an incident or event within an Incident Command System;

(E) an assurance that the entity will provide to the Secretary the data described under section 247d–4(c)(3) of this title as determined feasible by the Secretary;

(F) an assurance that the entity will conduct activities to inform and educate the hospitals within the jurisdiction of such entity on the role of such hospitals in the plan required under subparagraph (A);

(G) an assurance that the entity, with respect to the plan described under subparagraph (A), has developed and will implement an accountability system to ensure that such entity makes satisfactory annual improvement and describes such system in the plan under subparagraph (A);

(H) a description of the means by which to obtain public comment and input on the plan described in subparagraph (A) and on the implementation of such plan, that shall include an advisory committee or other similar mechanism for obtaining comment from the public and from other State, local, and tribal stakeholders; and

(I) as relevant, a description of the process used by the entity to consult with local departments of public health to reach consensus, approval, or concurrence on the relative distribution of amounts received under this section.

(c) Limitation

Beginning in fiscal year 2009, the Secretary may not award a cooperative agreement to a State unless such State is a participant in the Emergency System for Advance Registration of Volunteer Health Professionals described in section 247d–7b of this title.

(d) Use of funds

(1) In general

An award under subsection (a) shall be expended for activities to achieve the preparedness goals described under paragraphs (1), (2), (4), (5), and (6) of section 300hh–1(b) of this title.

(2) Effect of section

Nothing in this subsection may be construed as establishing new regulatory authority or as

modifying any existing regulatory authority.

(e) Coordination with local response capabilities

An entity shall, to the extent practicable, ensure that activities carried out under an award under subsection (a) are coordinated with activities of relevant Metropolitan Medical Response Systems, local public health departments, the Cities Readiness Initiative, local emergency plans, and any regional health care emergency preparedness and response system established pursuant to the applicable guidelines under section 247d–3c of this title.

(f) Consultation with Homeland Security

In making awards under subsection (a), the Secretary shall consult with the Secretary of Homeland Security to—

(1) ensure maximum coordination of public health and medical preparedness and response activities with the Metropolitan Medical Response System, and other relevant activities;

(2) minimize duplicative funding of programs and activities; and

(3) analyze activities, including exercises and drills, conducted under this section to develop recommendations and guidance on best practices for such activities.

(g) Achievement of measurable evidence-based benchmarks and objective standards

(1) In general

Not later than 180 days after December 19, 2006, the Secretary shall develop or where appropriate adopt, and require the application of, measurable evidence-based benchmarks and objective standards that measure levels of preparedness with respect to the activities described in this section and with respect to activities described in section 247d–3b of this title. In developing such benchmarks and standards, the Secretary shall consult with and seek comments from State, local, and tribal officials and private entities, as appropriate. Where appropriate, the Secretary shall incorporate existing objective standards. Such benchmarks and standards shall—

(A) include outcome goals representing operational achievements of the National Preparedness Goals developed under section 300hh–1(b) of this title with respect to all-hazards, including chemical, biological, radiological, or nuclear threats; and

(B) at a minimum, require entities to—

(i) measure progress toward achieving the outcome goals; and

(ii) at least annually, test, exercise, and rigorously evaluate the public health and medical emergency preparedness and response capabilities of the entity, and report to the Secretary on such measured and tested capabilities and measured and tested progress toward achieving outcome goals, based on criteria established by the Secretary.

(2) Criteria for pandemic influenza plans

(A) In general

Not later than 180 days after December 19, 2006, the Secretary shall develop and disseminate to the chief executive officer of each State criteria for an effective State plan for responding to pandemic influenza. The Secretary shall periodically update, as necessary and appropriate, such pandemic influenza plan criteria and shall require the integration of such criteria into the benchmarks and standards described in paragraph (1).

(B) Rule of construction

Nothing in this section shall be construed to require the duplication of Federal efforts with respect to the development of criteria or standards, without regard to whether such efforts were carried out prior to or after December 19, 2006.[3]

(3) Technical assistance

The Secretary shall, as determined appropriate by the Secretary, provide to a State, upon request, technical assistance in meeting the requirements of this section, including the provision of

advice by experts in the development of high-quality assessments, the setting of State objectives and assessment methods, the development of measures of satisfactory annual improvement that are valid and reliable, and other relevant areas.

(4) Notification of failures

The Secretary shall develop and implement a process to notify entities that are determined by the Secretary to have failed to meet the requirements of paragraph (1) or (2). Such process shall provide such entities with the opportunity to correct such noncompliance. An entity that fails to correct such noncompliance shall be subject to paragraph (5).

(5) Withholding of amounts from entities that fail to achieve benchmarks or submit influenza plan

Beginning with fiscal year 2019, and in each succeeding fiscal year, the Secretary shall—

(A) withhold from each entity that has failed substantially to meet the benchmarks and performance measures described in paragraph (1) for either of the 2 immediately preceding fiscal years (beginning with fiscal year 2018), pursuant to the process developed under paragraph (4), the amount described in paragraph (6); and

(B) withhold from each entity that has failed to submit to the Secretary a plan for responding to pandemic influenza that meets the criteria developed under paragraph (2), the amount described in paragraph (6).

(6) Amounts described

(A) In general

The amounts described in this paragraph are the following amounts that are payable to an entity for activities described in this section or section 247d–3b of this title:

(i) For no more than one of each of the first 2 fiscal years immediately following a fiscal year in which an entity experienced a failure described in subparagraph (A) or (B) of paragraph (5), an amount equal to 10 percent of the amount the entity was eligible to receive for the respective fiscal year.

(ii) For no more than one of the first 2 fiscal years immediately following the third consecutive fiscal year in which an entity experienced such a failure, in lieu of applying clause (i), an amount equal to 15 percent of the amount the entity was eligible to receive for the respective fiscal year.

(B) Separate accounting

Each failure described in subparagraph (A) or (B) of paragraph (5) shall be treated as a separate failure for purposes of calculating amounts withheld under subparagraph (A).

(7) Reallocation of amounts withheld

(A) In general

The Secretary shall make amounts withheld under paragraph (6) available for making awards under section 247d–3b of this title to entities described in subsection (b)(1) of such section.

(B) Preference in reallocation

In making awards under section 247d–3b of this title with amounts described in subparagraph (A), the Secretary shall give preference to eligible entities (as described in section 247d–3b(b)(1) of this title) that are located in whole or in part in States from which amounts have been withheld under paragraph (6).

(8) Waive or reduce withholding

The Secretary may waive or reduce the withholding described in paragraph (6), for a single entity or for all entities in a fiscal year, if the Secretary determines that mitigating conditions exist that justify the waiver or reduction.

(h) Funding

(1) Authorization of appropriations

(A) In general

For the purpose of carrying out this section, there is authorized to be appropriated $685,000,000 for each of fiscal years 2019 through 2023 for awards pursuant to paragraph (3) (subject to the authority of the Secretary to make awards pursuant to paragraphs (4) and (5)).

(B) Requirement for State matching funds

Beginning in fiscal year 2009, in the case of any State or consortium of two or more States, the Secretary may not award a cooperative agreement under this section unless the State or consortium of States agree that, with respect to the amount of the cooperative agreement awarded by the Secretary, the State or consortium of States will make available (directly or through donations from public or private entities) non-Federal contributions in an amount equal to—

(i) for the first fiscal year of the cooperative agreement, not less than 5 percent of such costs ($1 for each $20 of Federal funds provided in the cooperative agreement); and

(ii) for any second fiscal year of the cooperative agreement, and for any subsequent fiscal year of such cooperative agreement, not less than 10 percent of such costs ($1 for each $10 of Federal funds provided in the cooperative agreement).

(C) Determination of amount of non-Federal contributions

As determined by the Secretary, non-Federal contributions required in subparagraph (B) may be provided directly or through donations from public or private entities and may be in cash or in kind, fairly evaluated, including plant, equipment or services. Amounts provided by the Federal government, or services assisted or subsidized to any significant extent by the Federal government, may not be included in determining the amount of such non-Federal contributions.

(2) Maintaining State funding

(A) In general

An entity that receives an award under this section shall maintain expenditures for public health security at a level that is not less than the average level of such expenditures maintained by the entity for the preceding 2 year period.

(B) Rule of construction

Nothing in this section shall be construed to prohibit the use of awards under this section to pay salary and related expenses of public health and other professionals employed by State, local, or tribal public health agencies who are carrying out activities supported by such awards (regardless of whether the primary assignment of such personnel is to carry out such activities).

(3) Determination of amount

(A) In general

The Secretary shall award cooperative agreements under subsection (a) to each State or consortium of 2 or more States that submits to the Secretary an application that meets the criteria of the Secretary for the receipt of such an award and that meets other implementation conditions established by the Secretary for such awards.

(B) Base amount

In determining the amount of an award pursuant to subparagraph (A) for a State, the Secretary shall first determine an amount the Secretary considers appropriate for the State (referred to in this paragraph as the "base amount"), except that such amount may not be greater than the minimum amount determined under subparagraph (D).

(C) Increase on basis of population

After determining the base amount for a State under subparagraph (B), the Secretary shall increase the base amount by an amount equal to the product of—

(i) the amount appropriated under paragraph (1)(A) for the fiscal year, less an amount

equal to the sum of all base amounts determined for the States under subparagraph (B), and less the amount, if any, reserved by the Secretary under paragraphs (4) and (5); and

(ii) subject to paragraph (4)(C), the percentage constituted by the ratio of an amount equal to the population of the State over an amount equal to the total population of the States (as indicated by the most recent data collected by the Bureau of the Census).

(D) Minimum amount

Subject to the amount appropriated under paragraph (1)(A), an award pursuant to subparagraph (A) for a State shall be the greater of the base amount as increased under subparagraph (C), or the minimum amount under this subparagraph. The minimum amount under this subparagraph is—

(i) in the case of each of the several States, the District of Columbia, and the Commonwealth of Puerto Rico, an amount equal to the lesser of—

(I) $5,000,000; or

(II) if the amount appropriated under paragraph (1)(A) is less than $667,000,000, an amount equal to 0.75 percent of the amount appropriated under such paragraph, less the amount, if any, reserved by the Secretary under paragraphs (4) and (5); or

(ii) in the case of each of American Samoa, Guam, the Commonwealth of the Northern Mariana Islands, and the Virgin Islands, an amount determined by the Secretary to be appropriate, except that such amount may not exceed the amount determined under clause (i).

(4) Certain political subdivisions

(A) In general

For fiscal year 2007, the Secretary may, before making awards pursuant to paragraph (3) for such year, reserve from the amount appropriated under paragraph (1) for the year an amount determined necessary by the Secretary to make awards under subsection (a) to political subdivisions that have a substantial number of residents, have a substantial local infrastructure for responding to public health emergencies, and face a high degree of risk from bioterrorist attacks or other public health emergencies. Not more than three political subdivisions may receive awards pursuant to this subparagraph.

(B) Coordination with Statewide plans

An award pursuant to subparagraph (A) may not be made unless the application of the political subdivision involved is in coordination with, and consistent with, applicable Statewide plans described in subsection (b).

(C) Relationship to formula grants

In the case of a State that will receive an award pursuant to paragraph (3), and in which there is located a political subdivision that will receive an award pursuant to subparagraph (A), the Secretary shall, in determining the amount under paragraph (3)(C) for the State, subtract from the population of the State an amount equal to the population of such political subdivision.

(D) Continuity of funding

In determining whether to make an award pursuant to subparagraph (A) to a political subdivision, the Secretary may consider, as a factor indicating that the award should be made, that the political subdivision received public health funding from the Secretary for fiscal year 2006.

(5) Significant unmet needs; degree of risk

(A) In general

For fiscal year 2007, the Secretary may, before making awards pursuant to paragraph (3) for such year, reserve from the amount appropriated under paragraph (1) for the year an amount determined necessary by the Secretary to make awards under subsection (a) to eligible entities that—

(i) have a significant need for funds to build capacity to identify, detect, monitor, and respond to a bioterrorist or other threat to the public health, which need will not be met by awards pursuant to paragraph (3); and

(ii) face a particularly high degree of risk of such a threat.

(B) Recipients of grants

Awards pursuant to subparagraph (A) may be supplemental awards to States that receive awards pursuant to paragraph (3), or may be awards to eligible entities described in subsection (b)(1)(B) within such States.

(C) Finding with respect to District of Columbia

The Secretary shall consider the District of Columbia to have a significant unmet need for purposes of subparagraph (A), and to face a particularly high degree of risk for such purposes, on the basis of the concentration of entities of national significance located within the District.

(6) Funding of local entities

The Secretary shall, in making awards under this section, ensure that with respect to the cooperative agreement awarded, the entity make available appropriate portions of such award to political subdivisions and local departments of public health through a process involving the consensus, approval or concurrence with such local entities.

(7) Availability of cooperative agreement funds

(A) In general

Amounts provided to an eligible entity under a cooperative agreement under subsection (a) for a fiscal year and remaining unobligated at the end of such year shall remain available to such entity for the next fiscal year for the purposes for which such funds were provided.

(B) Funds contingent on achieving benchmarks

The continued availability of funds under subparagraph (A) with respect to an entity shall be contingent upon such entity achieving the benchmarks and submitting the pandemic influenza plan as described in subsection (g).

(i) Administrative and fiscal responsibility

(1) Annual reporting requirements

Each entity shall prepare and submit to the Secretary annual reports on its activities under this section and section 247d–3b of this title. Each such report shall be prepared by, or in consultation with, the health department. In order to properly evaluate and compare the performance of different entities assisted under this section and section 247d–3b of this title and to assure the proper expenditure of funds under this section and section 247d–3b of this title, such reports shall be in such standardized form and contain such information as the Secretary determines and describes within 180 days of December 19, 2006 (after consultation with the States) to be necessary to—

(A) secure an accurate description of those activities;

(B) secure a complete record of the purposes for which funds were spent, and of the recipients of such funds;

(C) describe the extent to which the entity has met the goals and objectives it set forth under this section or section 247d–3b of this title;

(D) determine the extent to which funds were expended consistent with the entity's application transmitted under this section or section 247d–3b of this title; and

(E) publish such information on a Federal Internet website consistent with subsection (j).

(2) Audits; implementation

(A) In general

Each entity receiving funds under this section or section 247d–3b of this title shall, not less often than once every 2 years, audit its expenditures from amounts received under this section

or section 247d–3b of this title. Such audits shall be conducted by an entity independent of the agency administering a program funded under this section or section 247d–3b of this title in accordance with the Comptroller General's standards for auditing governmental organizations, programs, activities, and functions and generally accepted auditing standards. Within 30 days following the completion of each audit report, the entity shall submit a copy of that audit report to the Secretary.

(B) Repayment

Each entity shall repay to the United States amounts found by the Secretary, after notice and opportunity for a hearing to the entity, not to have been expended in accordance with this section or section 247d–3b of this title and, if such repayment is not made, the Secretary may offset such amounts against the amount of any allotment to which the entity is or may become entitled under this section or section 247d–3b of this title or may otherwise recover such amounts.

(C) Withholding of payment

The Secretary may, after notice and opportunity for a hearing, withhold payment of funds to any entity which is not using its allotment under this section or section 247d–3b of this title in accordance with such section. The Secretary may withhold such funds until the Secretary finds that the reason for the withholding has been removed and there is reasonable assurance that it will not recur.

(j) Compilation and availability of data

The Secretary shall compile the data submitted under this section and make such data available in a timely manner on an appropriate Internet website in a format that is useful to the public and to other entities and that provides information on what activities are best contributing to the achievement of the outcome goals described in subsection (g).

(k) Evaluation

(1) In general

Not later than 2 years after June 24, 2019, and every 2 years thereafter, the Secretary shall conduct an evaluation of the evidence-based benchmarks and objective standards required under subsection (g). Such evaluation shall be submitted to the congressional committees of jurisdiction together with the National Health Security Strategy under section 300hh–1 of this title, at such time as such strategy is submitted.

(2) Content

The evaluation under this paragraph shall include—

(A) a review of evidence-based benchmarks and objective standards, and associated metrics and targets;

(B) a discussion of changes to any evidence-based benchmarks and objective standards, and the effect of such changes on the ability to track whether entities are meeting or making progress toward the goals under this section and, to the extent practicable, the applicable goals of the National Health Security Strategy under section 300hh–1 of this title;

(C) a description of amounts received by eligible entities described in subsection (b) and section 247d–3b(b) of this title, and amounts received by subrecipients and the effect of such funding on meeting evidence-based benchmarks and objective standards; and

(D) recommendations, as applicable and appropriate, to improve evidence-based benchmarks and objective standards to more accurately assess the ability of entities receiving awards under this section to better achieve the goals under this section and section 300hh–1 of this title.

(July 1, 1944, ch. 373, title III, §319C–1, as added Pub. L. 107–188, title I, §131(a), June 12, 2002, 116 Stat. 617; amended Pub. L. 109–417, title II, §201, Dec. 19, 2006, 120 Stat. 2837; Pub. L. 113–5, title II, §§202(a), (c)(1), 204(b), Mar. 13, 2013, 127 Stat. 173, 175, 179; Pub. L. 114–95, title

IX, §9215(kkk)(1), Dec. 10, 2015, 129 Stat. 2187; Pub. L. 116–22, title II, §§201(a), 202(a), (b)(1), (d), 203(e)(1), 207(b), title VII, §705(b), June 24, 2019, 133 Stat. 907–910, 914, 927, 964; Pub. L. 117–328, div. FF, title II, §2111(a), Dec. 29, 2022, 136 Stat. 5720.)

EDITORIAL NOTES

CODIFICATION

December 19, 2006, referred to in subsec. (g)(2)(B), was in the original "the date of enactment of this section", which was translated as meaning the date of enactment of Pub. L. 109–417, which enacted subsec. (g) of this section, to reflect the probable intent of Congress.

AMENDMENTS

2022—Subsec. (b)(2)(A)(vii). Pub. L. 117–328, §2111(a)(1)(A), inserted "during and" before "following a public health emergency".

Subsec. (b)(2)(A)(viii). Pub. L. 117–328, §2111(a)(1)(B), amended cl. (viii) generally. Prior to amendment, cl. (viii) read as follows: "a description of how the entity, as applicable and appropriate, will coordinate with State emergency preparedness and response plans in public health emergency preparedness, including State educational agencies (as defined in section 7801 of title 20) and State child care lead agencies (designated under section 9858b of this title);".

Subsec. (b)(2)(A)(xii), (xiii). Pub. L. 117–328, §2111(a)(1)(C)–(E), added cl. (xii) and redesignated former cl. (xii) as (xiii).

Subsec. (b)(2)(D) to (I). Pub. L. 117–328, §2111(a)(2), (3), added subpar. (D) and redesignated former subpars. (D) to (H) as (E) to (I), respectively.

2019—Subsec. (a). Pub. L. 116–22, §202(a)(1), inserted ", acting through the Director of the Centers for Disease Control and Prevention," after "the Secretary".

Subsec. (b)(2)(A)(iv). Pub. L. 116–22, §207(b), amended cl. (iv) generally. Prior to amendment, cl. (iv) read as follows: "a description of the mechanism the entity will implement to utilize the Emergency Management Assistance Compact or other mutual aid agreements for medical and public health mutual aid;".

Subsec. (b)(2)(A)(vi). Pub. L. 116–22, §202(a)(2)(A), inserted ", including public health agencies with specific expertise that may be relevant to public health security, such as environmental health agencies," after "stakeholders".

Subsec. (b)(2)(A)(vii) to (x). Pub. L. 116–22, §202(a)(2)(B), (C), added cl. (vii) and redesignated former cls. (vii) to (ix) as (viii) to (x), respectively.

Subsec. (b)(2)(A)(xi), (xii). Pub. L. 116–22, §202(a)(2)(D), (E), added cls. (xi) and (xii).

Subsec. (b)(2)(C). Pub. L. 116–22, §705(b)(1), substituted "individuals," for "individuals,,".

Subsec. (b)(2)(F). Pub. L. 116–22, §705(b)(2), substituted "makes satisfactory annual improvement and describes" for "make satisfactory annual improvement and describe".

Subsec. (e). Pub. L. 116–22, §203(e)(1), substituted ", local emergency plans, and any regional health care emergency preparedness and response system established pursuant to the applicable guidelines under section 247d–3c of this title." for ", and local emergency plans."

Subsec. (g)(5). Pub. L. 116–22, §202(b)(1)(A)(i), substituted "Beginning with fiscal year 2019" for "Beginning with fiscal year 2009" in introductory provisions.

Subsec. (g)(5)(A). Pub. L. 116–22, §202(b)(1)(A)(ii), substituted "for either of the 2 immediately preceding fiscal years" for "for the immediately preceding fiscal year" and "2018" for "2008".

Subsec. (g)(6)(A). Pub. L. 116–22, §202(b)(1)(B), amended subpar. (A) generally. Prior to amendment, subpar. (A) consisted of cls. (i) to (iv) describing amounts payable to an entity for the fiscal year immediately following one to four fiscal years in which the entity experienced a failure described in subsec. (g)(5)(A) or (B).

Subsec. (h)(1)(A). Pub. L. 116–22, §202(d), substituted "$685,000,000 for each of fiscal years 2019 through 2023 for awards pursuant to paragraph (3) (subject to the authority of the Secretary to make awards pursuant to paragraphs (4) and (5))." for "$641,900,000 for fiscal year 2014 for awards pursuant to paragraph (3) (subject to the authority of the Secretary to make awards pursuant to paragraphs (4) and (5)), and $641,900,000 for each of fiscal years 2015 through 2018."

Subsec. (k). Pub. L. 116–22, §201(a), added subsec. (k).

2015—Subsec. (b)(2)(A)(vii). Pub. L. 114–95 substituted "including State educational agencies (as defined in section 7801 of title 20)" for "including State educational agencies (as defined in section 7801(41) of title 20)".

2013—Subsec. (b)(1)(B). Pub. L. 113–5, §202(c)(1), substituted "subsection (h)(4)" for "subsection (i)(4)".

Subsec. (b)(1)(C). Pub. L. 113–5, §202(a)(1), substituted "consortium of States" for "consortium of entities described in subparagraph (A)".

Subsec. (b)(2)(A)(i), (ii). Pub. L. 113–5, §202(a)(2)(A)(i), added cls. (i) and (ii) and struck out former cls. (i) and (ii) which read as follows:

"(i) a description of the activities such entity will carry out under the agreement to meet the goals identified under section 300hh–1 of this title;

"(ii) a pandemic influenza plan consistent with the requirements of paragraphs (2) and (5) of subsection (g);".

Subsec. (b)(2)(A)(vi) to (ix). Pub. L. 113–5, §202(a)(2)(A)(ii), (iii), added cls. (vi) to (ix).

Subsec. (b)(2)(C). Pub. L. 113–5, §202(a)(2)(B), inserted ", including addressing the needs of at-risk individuals," after "capabilities of such entity".

Subsec. (b)(2)(D). Pub. L. 113–5, §204(b), substituted "section 247d–4(c)(3)" for "section 247d–4(d)(3)".

Subsec. (f)(2) to (4). Pub. L. 113–5, §202(a)(3), inserted "and" at end of par. (2), substituted period for "; and" at end of par. (3), and struck out par. (4) which read as follows: "disseminate such recommendations and guidance, including through expanding existing lessons learned information systems to create a single Internet-based point of access for sharing and distributing medical and public health best practices and lessons learned from drills, exercises, disasters, and other emergencies."

Subsec. (g)(1)(A). Pub. L. 113–5, §202(a)(4)(A), added subpar. (A) and struck out former subpar. (A) which read as follows: "include outcome goals representing operational achievement of the National Preparedness Goals developed under section 300hh–1(b) of this title; and".

Subsec. (g)(2)(A). Pub. L. 113–5, §202(a)(4)(B), inserted at end "The Secretary shall periodically update, as necessary and appropriate, such pandemic influenza plan criteria and shall require the integration of such criteria into the benchmarks and standards described in paragraph (1)."

Subsec. (h). Pub. L. 113–5, §202(a)(5), (6), redesignated subsec. (i) as (h) and struck out former subsec. (h) which related to grants for real-time disease detection improvement.

Subsec. (h)(1)(A). Pub. L. 113–5, §202(a)(7)(A)(i), substituted "$641,900,000 for fiscal year 2014" for "$824,000,000 for fiscal year 2007, of which $35,000,000 shall be used to carry out subsection (h)," and "$641,900,000 for each of fiscal years 2015 through 2018" for "such sums as may be necessary for each of fiscal years 2008 through 2011".

Subsec. (h)(1)(B) to (D). Pub. L. 113–5, §202(a)(7)(A)(ii)–(iv), redesignated subpars. (C) and (D) as (B) and (C), respectively, substituted "subparagraph (B)" for "subparagraph (C)" in subpar. (C), and struck out former subpar. (B). Prior to amendment, text of subpar. (B) read as follows: "There are authorized to be appropriated, $10,000,000 for fiscal year 2007 to carry out subsection (f)(4) of this section and section 300hh–16 of this title."

Subsec. (h)(3)(C), (D). Pub. L. 113–5, §202(a)(7)(B), substituted "paragraph (1)(A)" for "paragraph (1)(A)(i)(I)" wherever appearing.

Subsec. (h)(4)(B). Pub. L. 113–5, §202(a)(7)(C), substituted "subsection (b)" for "subsection (c)".

Subsec. (h)(7). Pub. L. 113–5, §202(a)(7)(D), added par. (7).

Subsec. (i). Pub. L. 113–5, §202(a)(6), redesignated subsec. (j) as (i). Former subsec. (i) redesignated (h).

Subsec. (i)(1)(E). Pub. L. 113–5, §202(a)(8)(A), substituted "subsection (j)" for "subsection (k)".

Subsec. (i)(3). Pub. L. 113–5, §202(a)(8)(B), struck out par. (3) which related to maximum amount of an award under this section that may be carried over to the succeeding fiscal year.

Subsecs. (j), (k). Pub. L. 113–5, §202(a)(6), redesignated subsec. (k) as (j). Former subsec. (j) redesignated (i).

2006—Pub. L. 109–417, §201(1), substituted "Improving State and local public health security" for "Grants to improve State, local, and hospital preparedness for and response to bioterrorism and other public health emergencies" in section catchline.

Subsecs. (a) to (h). Pub. L. 109–417, §201(2), added subsecs. (a) to (h) and struck out former subsecs. (a) to (h) which related to grants to improve State, local, and hospital preparedness for and response to bioterrorism and other public health emergencies.

Subsec. (i). Pub. L. 109–417, §201(3), redesignated subsec. (j) as (i).

Pub. L. 109–417, §201(2), struck out subsec. (i) which defined "eligible entity".

Subsec. (i)(1) to (3)(A). Pub. L. 109–417, §201(4)(A), added pars. (1) to (3)(A) and struck out former pars. (1) to (3)(A) which related to appropriations for fiscal years 2003 through 2006, use of amounts to supplement and not supplant other funds, and conditions for receipt of award in fiscal year 2003.

Subsec. (i)(4)(A). Pub. L. 109–417, §201(4)(B), substituted "fiscal year 2007" for "fiscal year 2003" and struck out "(A)(i)(I)" after "paragraph (1)".

Subsec. (i)(4)(D). Pub. L. 109–417, §201(4)(C), substituted "fiscal year 2006" for "fiscal year 2002".

Subsec. (i)(5)(A). Pub. L. 109–417, §201(4)(D), in introductory provisions, substituted "fiscal year 2007" for "fiscal year 2003" and struck out "(A)(i)(I)" after "paragraph (1)".

Subsec. (i)(6). Pub. L. 109–417, §201(4)(E), added par. (6) and struck out heading and text of former par. (6). Text read as follows: "For fiscal year 2003, the Secretary shall in making awards under this section ensure that appropriate portions of such awards are made available to political subdivisions, local departments of public health, hospitals (including children's hospitals), clinics, health centers, or primary care facilities, or consortia of such entities."

Subsec. (j). Pub. L. 109–417, §201(5), added subsec. (j).

Pub. L. 109–417, §201(3), redesignated subsec. (j) as (i).

Subsec. (k). Pub. L. 109–417, §201(5), added subsec. (k).

STATUTORY NOTES AND RELATED SUBSIDIARIES

EFFECTIVE DATE OF 2022 AMENDMENT

Pub. L. 117–328, div. FF, title II, §2111(b), Dec. 29, 2022, 136 Stat. 5721, provided that: "The amendments made by subsection (a) [amending this section] shall not apply with respect to any cooperative agreement entered into prior to the date of enactment of this Act [Dec. 29, 2022]."

EFFECTIVE DATE OF 2019 AMENDMENT

Pub. L. 116–22, title II, §202(b)(2), June 24, 2019, 133 Stat. 909, provided that: "The amendments made by paragraph (1) [amending this section] shall apply with respect to cooperative agreements awarded on or after the date of enactment of this Act [June 24, 2019]."

EFFECTIVE DATE OF 2015 AMENDMENT

Amendment by Pub. L. 114–95 effective Dec. 10, 2015, except with respect to certain noncompetitive programs and competitive programs, see section 5 of Pub. L. 114–95, set out as a note under section 6301 of Title 20, Education.

EMERGENCY MEDICAL AND PUBLIC HEALTH COMMUNICATIONS PILOT PROJECTS

Pub. L. 110–53, title XXII, §2201(d), Aug. 3, 2007, 121 Stat. 541, provided that:

"(1) IN GENERAL.—The Assistant Secretary of Commerce for Communications and Information may establish not more than 10 geographically dispersed project grants to emergency medical and public health care facilities to improve the capabilities of emergency communications systems in emergency medical care facilities.

"(2) MAXIMUM AMOUNT.—The Assistant Secretary may not provide more than $2,000,000 in Federal assistance under the pilot program to any applicant.

"(3) COST SHARING.—The Assistant Secretary may not provide more than 20 percent of the cost, incurred during the period of the grant, of any project under the pilot program.

"(4) MAXIMUM PERIOD OF GRANTS.—The Assistant Secretary may not fund any applicant under the pilot program for more than 3 years.

"(5) DEPLOYMENT AND DISTRIBUTION.—The Assistant Secretary shall seek to the maximum extent practicable to ensure a broad geographic distribution of project sites.

"(6) TRANSFER OF INFORMATION AND KNOWLEDGE.—The Assistant Secretary shall establish mechanisms to ensure that the information and knowledge gained by participants in the pilot program are transferred among the pilot program participants and to other interested parties, including other applicants that submitted applications."

[1] So in original. Section 7801 of title 20 defines "State educational agencies".

[2] So in original. Probably should be followed by a semicolon.

[3] See Codification note below.

§247d–3b. Partnerships for State and regional hospital preparedness to improve

surge capacity

(a) In general

The Secretary, acting through the Assistant Secretary for Preparedness and Response, shall award competitive grants or cooperative agreements to eligible entities to enable such entities to improve surge capacity and enhance community and hospital preparedness for, and response to, public health emergencies in accordance with subsection (c), including, as appropriate, capacity and preparedness to address the needs of children and other at-risk individuals.

(b) Eligibility

To be eligible for an award under subsection (a), an entity shall—

(1)(A) be a coalition that includes—

(i) one or more hospitals, at least one of which shall be a designated trauma center, consistent with section 300d–13(c) of this title;

(ii) one or more other local health care facilities, including clinics, health centers, community health centers, primary care facilities, mental health centers, mobile medical assets, or nursing homes;

(iii)(I) one or more political subdivisions;

(II) one or more States; or

(III) one or more States and one or more political subdivisions; and

(iv) one or more emergency medical service organizations or emergency management organizations; and

(B) prepare, in consultation with the Chief Executive Officer and the lead health officials of the State, District, or territory in which the hospital and health care facilities described in subparagraph (A) are located, and submit to the Secretary, an application at such time, in such manner, and containing such information as the Secretary may require; or

(2)(A) be an entity described in section 247d–3a(b)(1) of this title; and

(B) submit an application at such time, in such manner, and containing such information as the Secretary may require, including the information or assurances required under section 247d–3a(b)(2) of this title and an assurance that the State will adhere to any applicable guidelines established by the Secretary.

(c) Use of funds

An award under subsection (a) shall be expended for activities to achieve the preparedness goals described under paragraphs (1), (3), (4), (5), and (6) of section 300hh–1(b) of this title with respect to all-hazards, including chemical, biological, radiological, or nuclear threats.

(d) Preferences

(1) Regional coordination

In making awards under subsection (a), the Secretary shall give preference to eligible entities that submit applications that, in the determination of the Secretary—

(A) will enhance coordination—

(i) among the entities described in subsection (b)(1)(A)(i);

(ii) among one or more facilities in a regional health care emergency system under section 247d–3c of this title; and

(iii) between such entities and the entities described in subsection (b)(1)(A)(ii); and

(B) include, in the coalition described in subsection (b)(1)(A), a significant percentage of the hospitals and health care facilities within the geographic area served by such coalition.

(2) Other preferences

In making awards under subsection (a), the Secretary shall give preference to eligible entities that, in the determination of the Secretary—

(A) include one or more hospitals that are participants in the National Disaster Medical

System;

(B) are located in a geographic area that faces a high degree of risk, as determined by the Secretary in consultation with the Secretary of Homeland Security; or

(C) have a significant need for funds to achieve the preparedness and response goals described in section 300hh–1(b)(3) of this title.

(e) Consistency of planned activities

The Secretary may not award a cooperative agreement to an eligible entity described in subsection (b)(1) unless the application submitted by the entity is coordinated and consistent with an applicable State All-Hazards Public Health Emergency Preparedness and Response Plan and relevant local plans, as determined by the Secretary in consultation with relevant State health officials.

(f) Limitation on awards

A political subdivision shall not participate in more than one coalition described in subsection (b)(1).

(g) Coordination

(1) Local response capabilities

An eligible entity shall, to the extent practicable, ensure that activities carried out under an award under subsection (a) are coordinated with activities of relevant local Metropolitan Medical Response Systems, local Medical Reserve Corps, the local Cities Readiness Initiative, and local emergency plans.

(2) National collaboration

Coalitions consisting of one or more eligible entities under this section may, to the extent practicable, collaborate with other coalitions consisting of one or more eligible entities under this section for purposes of national coordination and collaboration with respect to activities to achieve the preparedness and response goals described under paragraphs (1), (3), (4), (5), and (6) of section 300hh–1(b) of this title.

(h) Maintenance of funding

(1) In general

An entity that receives an award under this section shall maintain expenditures for health care preparedness at a level that is not less than the average level of such expenditures maintained by the entity for the preceding 2 year period.

(2) Rule of construction

Nothing in this section shall be construed to prohibit the use of awards under this section to pay salary and related expenses of public health and other professionals employed by State, local, or tribal agencies who are carrying out activities supported by such awards (regardless of whether the primary assignment of such personnel is to carry out such activities).

(i) Performance and accountability

(1) In general

The requirements of section 247d–3a(g), (i), (j), and (k) of this title shall apply to entities receiving awards under this section (regardless of whether such entities are described under subsection (b)(1)(A) or (b)(2)(A)) in the same manner as such requirements apply to entities under section 247d–3a of this title. In submitting reports under this paragraph, a coalition shall include information on the progress that the coalition has made toward the implementation of section 247d–3c of this title (or barriers to progress, if any). A coalition described in subsection (b)(1)(A) shall make such reports available to the lead health official of the State in which such coalition is located.

(2) Meeting goals of National Health Security Strategy

The Secretary shall implement objective, evidence-based metrics to ensure that entities

receiving awards under this section are meeting, to the extent practicable, the applicable goals of the National Health Security Strategy under section 300hh–1 of this title.

(j) Authorization of appropriations

(1) In general

(A) Authorization of appropriations

For purposes of carrying out this section and section 247d–3c of this title, in accordance with subparagraph (B), there is authorized to be appropriated $385,000,000 for each of fiscal years 2019 through 2023.

(B) Reservation of amounts for regional systems

(i) In general

Subject to clause (ii), of the amount appropriated under subparagraph (A) for a fiscal year, the Secretary may reserve up to 5 percent for the purpose of carrying out section 247d–3c of this title.

(ii) Reservation contingent on continued appropriations for this section

If for fiscal year 2019 or a subsequent fiscal year, the amount appropriated under subparagraph (A) is such that, after application of clause (i), the amount remaining for the purpose of carrying out this section would be less than the amount available for such purpose for the previous fiscal year, the amount that may be reserved under clause (i) shall be reduced such that the amount remaining for the purpose of carrying out this section is not less than the amount available for such purpose for the previous fiscal year.

(iii) Sunset

The authority to reserve amounts under clause (i) shall expire on September 30, 2023.

(2) Reservation of amounts for partnerships

Prior to making awards described in paragraph (3), the Secretary may reserve from the amount appropriated under paragraph (1)(A) for a fiscal year and not reserved for the purpose described in paragraph (1)(B)(i), an amount determined appropriate by the Secretary for making awards to entities described in subsection (b)(1)(A).

(3) Awards to States and political subdivisions

(A) In general

From amounts appropriated for a fiscal year under paragraph (1)(A) and not reserved under paragraph (1)(B)(i) or (2), the Secretary shall make awards to entities described in subsection (b)(2)(A) that have completed an application as described in subsection (b)(2)(B).

(B) Amount

The Secretary shall determine the amount of an award to each entity described in subparagraph (A) in the same manner as such amounts are determined under section 247d–3a(h) of this title.

(4) Availability of cooperative agreement funds

(A) In general

Amounts provided to an eligible entity under a cooperative agreement under subsection (a) for a fiscal year and remaining unobligated at the end of such year shall remain available to such entity for the next fiscal year for the purposes for which such funds were provided.

(B) Funds contingent on achieving benchmarks

The continued availability of funds under subparagraph (A) with respect to an entity shall be contingent upon such entity achieving the benchmarks and submitting the pandemic influenza plan as required under subsection (i).

(July 1, 1944, ch. 373, title III, §319C–2, as added Pub. L. 107–188, title I, §131(a), June 12, 2002,

116 Stat. 624; amended Pub. L. 109–417, title III, §305, Dec. 19, 2006, 120 Stat. 2861; Pub. L. 110–85, title XI, §1104(1), Sept. 27, 2007, 121 Stat. 975; Pub. L. 113–5, title II, §§202(c)(2), 203(c), Mar. 13, 2013, 127 Stat. 175, 176; Pub. L. 116–22, title II, §§201(b), 202(c), (e), 203(c), (e)(2), June 24, 2019, 133 Stat. 908–910, 914.)

EDITORIAL NOTES

AMENDMENTS

2019—Subsec. (a). Pub. L. 116–22, §202(c)(1), inserted ", acting through the Assistant Secretary for Preparedness and Response," after "The Secretary" and substituted "preparedness for, and response to, public health emergencies in accordance with subsection (c)" for "preparedness for public health emergencies".

Subsec. (b)(1)(A). Pub. L. 116–22, §202(c)(2)(A), substituted "coalition that includes" for "partnership consisting of" in introductory provisions.

Subsec. (b)(1)(A)(iv). Pub. L. 116–22, §202(c)(2)(B), (C), added cl. (iv).

Subsec. (d)(1)(A)(ii), (iii). Pub. L. 116–22, §203(e)(2), added cl. (ii) and redesignated former cl. (ii) as (iii).

Subsec. (d)(1)(B). Pub. L. 116–22, §202(c)(3)(A), substituted "coalition" for "partnership" in two places.

Subsec. (d)(2)(C). Pub. L. 116–22, §202(c)(3)(B), substituted "preparedness and response" for "medical preparedness".

Subsec. (f). Pub. L. 116–22, §202(c)(4), substituted "coalition" for "partnership".

Subsec. (g)(2). Pub. L. 116–22, §202(c)(5), substituted "Coalitions" for "Partnerships" and "coalitions" for "partnerships" and inserted "and response" after "preparedness".

Subsec. (i)(1). Pub. L. 116–22, §203(c), inserted "In submitting reports under this paragraph, a coalition shall include information on the progress that the coalition has made toward the implementation of section 247d–3c of this title (or barriers to progress, if any)." after "under section 247d–3a of this title."

Pub. L. 116–22, §202(c)(6), substituted "A coalition" for "An entity" and "such coalition" for "such partnership".

Pub. L. 116–22, §201(b), substituted "section 247d–3a(g), (i), (j), and (k)" for "section 247d–3a(g), (i), and (j)".

Subsec. (j)(1). Pub. L. 116–22, §202(e)(1), amended par. (1) generally. Prior to amendment, text read as follows: "For purposes of carrying out this section, there is authorized to be appropriated $374,700,000 for each of fiscal years 2014 through 2018."

Subsec. (j)(2). Pub. L. 116–22, §202(e)(2), substituted "paragraph (1)(A) for a fiscal year and not reserved for the purpose described in paragraph (1)(B)(i)" for "paragraph (1) for a fiscal year".

Subsec. (j)(3)(A). Pub. L. 116–22, §202(e)(3), substituted "paragraph (1)(A) and not reserved under paragraph (1)(B)(i) or (2)" for "paragraph (1) and not reserved under paragraph (2)".

2013—Subsec. (a). Pub. L. 113–5, §203(c)(1), inserted ", including, as appropriate, capacity and preparedness to address the needs of children and other at-risk individuals" before period at end.

Subsec. (b)(1)(A)(ii). Pub. L. 113–5, §203(c)(2), substituted "centers, community health centers, primary" for "centers, primary".

Subsec. (c). Pub. L. 113–5, §203(c)(3), added subsec. (c) and struck out former subsec. (c). Prior to amendment, text read as follows: "An award under subsection (a) shall be expended for activities to achieve the preparedness goals described under paragraphs (1), (3), (4), (5), and (6) of section 300hh–1(b) of this title."

Subsec. (g). Pub. L. 113–5, §203(c)(4), added subsec. (g) and struck out former subsec. (g). Prior to amendment, text read as follows: "An eligible entity shall, to the extent practicable, ensure that activities carried out under an award under subsection (a) are coordinated with activities of relevant local Metropolitan Medical Response Systems, local Medical Reserve Corps, the Cities Readiness Initiative, and local emergency plans."

Subsec. (i). Pub. L. 113–5, §203(c)(5), designated existing provisions as par. (1), inserted heading, and added par. (2).

Pub. L. 113–5, §202(c)(2)(A), substituted "(i), and (j)" for "(j), and (k)".

Subsec. (j)(1). Pub. L. 113–5, §203(c)(6)(A), amended par. (1) generally. Prior to amendment, text read as follows: "For the purpose of carrying out this section, there is authorized to be appropriated $474,000,000 for fiscal year 2007, and such sums as may be necessary for each of fiscal years 2008 through 2011."

Subsec. (j)(3)(B). Pub. L. 113–5, §202(c)(2)(B), substituted "247d–3a(h)" for "247d–3a(i)".

Subsec. (j)(4). Pub. L. 113–5, §203(c)(6)(B), added par. (4).

2007—Subsec. (j)(3)(B). Pub. L. 110–85 substituted "section 247d–3a(i)" for "section 247d–3a(h)".

2006—Pub. L. 109–417 amended section catchline and text generally. Prior to amendment, section consisted of subsecs. (a) to (i) relating to partnerships for community and hospital preparedness.

§247d–3c. Guidelines for regional health care emergency preparedness and response systems

(a) Purpose

It is the purpose of this section to identify and provide guidelines for regional systems of hospitals, health care facilities, and other public and private sector entities, with varying levels of capability to treat patients and increase medical surge capacity during, in advance of, and immediately following a public health emergency, including threats posed by one or more chemical, biological, radiological, or nuclear agents, including emerging infectious diseases.

(b) Guidelines

The Assistant Secretary for Preparedness and Response, in consultation with the Director of the Centers for Disease Control and Prevention, the Administrator of the Centers for Medicare & Medicaid Services, the Administrator of the Health Resources and Services Administration, the Commissioner of Food and Drugs, the Assistant Secretary for Mental Health and Substance Use, the Assistant Secretary of Labor for Occupational Safety and Health, the Secretary of Veterans Affairs, the heads of such other Federal agencies as the Secretary determines to be appropriate, and State, local, Tribal, and territorial public health officials, shall, not later than 2 years after June 24, 2019—

(1) identify and develop a set of guidelines relating to practices and protocols for all-hazards public health emergency preparedness and response for hospitals and health care facilities to provide appropriate patient care during, in advance of, or immediately following, a public health emergency, resulting from one or more chemical, biological, radiological, or nuclear agents, including emerging infectious diseases (which may include existing practices, such as trauma care and medical surge capacity and capabilities), with respect to—

(A) a regional approach to identifying hospitals and health care facilities based on varying capabilities and capacity to treat patients affected by such emergency, including—

(i) the manner in which the system will coordinate with and integrate the partnerships and health care coalitions established under section 247d–3b(b) of this title; and

(ii) informing and educating appropriate first responders and health care supply chain partners of the regional emergency preparedness and response capabilities and medical surge capacity of such hospitals and health care facilities in the community;

(B) physical and technological infrastructure, laboratory capacity, staffing, blood supply, and other supply chain needs, taking into account resiliency, geographic considerations, and rural considerations;

(C) protocols or best practices for the safety and personal protection of workers who handle human remains and health care workers (including with respect to protective equipment and supplies, waste management processes, and decontamination), sharing of specialized experience among the health care workforce, behavioral health, psychological resilience, and training of the workforce, as applicable;

(D) in a manner that allows for disease containment (within the meaning of section 300hh–1(b)(2)(B) of this title), coordinated medical triage, treatment, and transportation of patients, based on patient medical need (including patients in rural areas), to the appropriate hospitals or health care facilities within the regional system or, as applicable and appropriate, between systems in different States or regions; and

(E) the needs of children and other at-risk individuals;

(2) make such guidelines available on the internet website of the Department of Health and Human Services in a manner that does not compromise national security; and

(3) update such guidelines as appropriate, including based on input received pursuant to

subsections (c) and (e) and information resulting from applicable reports required under the Pandemic and All-Hazards Preparedness and Advancing Innovation Act of 2019 (including any amendments made by such Act), to address new and emerging public health threats.

(c) Considerations

In identifying, developing, and updating guidelines under subsection (b), the Assistant Secretary for Preparedness and Response shall—

(1) include input from hospitals and health care facilities (including health care coalitions under section 247d–3b of this title), State, local, Tribal, and territorial public health departments, and health care or subject matter experts (including experts with relevant expertise in chemical, biological, radiological, or nuclear threats, including emerging infectious diseases), as the Assistant Secretary determines appropriate, to meet the goals under section 300hh–1(b)(3) of this title;

(2) consult and engage with appropriate health care providers and professionals, including physicians, nurses, first responders, health care facilities (including hospitals, primary care clinics, community health centers, mental health facilities, ambulatory care facilities, and dental health facilities), pharmacies, emergency medical providers, trauma care providers, environmental health agencies, public health laboratories, poison control centers, blood banks, tissue banks, and other experts that the Assistant Secretary determines appropriate, to meet the goals under section 300hh–1(b)(3) of this title;

(3) consider feedback related to financial implications for hospitals, health care facilities, public health agencies, laboratories, blood banks, tissue banks, and other entities engaged in regional preparedness planning to implement and follow such guidelines, as applicable; and

(4) consider financial requirements and potential incentives for entities to prepare for, and respond to, public health emergencies as part of the regional health care emergency preparedness and response system.

(d) Technical assistance

The Assistant Secretary for Preparedness and Response, in consultation with the Director of the Centers for Disease Control and Prevention and the Assistant Secretary of Labor for Occupational Safety and Health, may provide technical assistance and consultation toward meeting the guidelines described in subsection (b).

(e) Demonstration project for regional health care preparedness and response systems

(1) In general

The Assistant Secretary for Preparedness and Response may establish a demonstration project pursuant to the development and implementation of guidelines under subsection (b) to award grants to improve medical surge capacity for all hazards, build and integrate regional medical response capabilities, improve specialty care expertise for all-hazards response, and coordinate medical preparedness and response across State, local, Tribal, territorial, and regional jurisdictions.

(2) Sunset

The authority under this subsection shall expire on September 30, 2023.

(July 1, 1944, ch. 373, title III, §319C–3, as added Pub. L. 116–22, title II, §203(a), June 24, 2019, 133 Stat. 911.)

EDITORIAL NOTES

REFERENCES IN TEXT

The Pandemic and All-Hazards Preparedness and Advancing Innovation Act of 2019, referred to in subsec. (b)(3), is Pub. L. 116–22, June 24, 2019, 133 Stat. 905. For complete classfication of this Act to the Code, see Short Title of 2019 Amendment note set out under section 201 of this title and Tables.

§247d–4. Facilities and capacities of the Centers for Disease Control and Prevention

(a) In general

(1) Findings

Congress finds that the Centers for Disease Control and Prevention has an essential role in defending against and combatting public health threats domestically and abroad and requires secure and modern facilities, and expanded, improved, and appropriately maintained capabilities related to bioterrorism and other public health emergencies, sufficient to enable such Centers to conduct this important mission.

(2) Facilities

(A) In general

The Director of the Centers for Disease Control and Prevention may design, construct, and equip new facilities, renovate existing facilities (including laboratories, laboratory support buildings, scientific communication facilities, transshipment complexes, secured and isolated parking structures, office buildings, and other facilities and infrastructure), and upgrade security of such facilities, in order to better conduct the capacities described in section 247d–1 of this title, and for supporting public health activities.

(B) Multiyear contracting authority

For any project of designing, constructing, equipping, or renovating any facility under subparagraph (A), the Director of the Centers for Disease Control and Prevention may enter into a single contract or related contracts that collectively include the full scope of the project, and the solicitation and contract shall contain the clause "availability of funds" found at section 52.232–18 of title 48, Code of Federal Regulations.

(3) Improving the capacities of the Centers for Disease Control and Prevention

The Secretary shall expand, improve, enhance, and appropriately maintain the capabilities of the Centers for Disease Control and Prevention relating to preparedness for and responding effectively to bioterrorism and other public health emergencies, by—

(A) expanding or enhancing the training of personnel;

(B) improving communications facilities and networks, including delivery of necessary information to rural areas;

(C) improving capabilities for public health surveillance and reporting activities, taking into account the integrated system or systems of public health alert communications and surveillance networks under subsection (b); and

(D) improving laboratory facilities related to bioterrorism, infectious disease outbreaks, and other public health emergencies, including increasing the security of such facilities.

(4) Study of resources for facilities and capacities

Not later than June 1, 2022, the Comptroller General of the United States shall conduct a study on Federal spending in fiscal years 2013 through 2018 for activities authorized under this subsection. Such study shall include a review and assessment of obligations and expenditures directly related to each activity under paragraphs (2) and (3), including a specific accounting of, and delineation between, obligations and expenditures incurred for the construction, renovation, equipping, and security upgrades of facilities and associated contracts under this subsection, and the obligations and expenditures incurred to establish and improve the situational awareness and biosurveillance network under subsection (b), and shall identify the agency or agencies incurring such obligations and expenditures.

(b) Establishment of systems of public health communications and surveillance networks

(1) In general

The Secretary, directly or through awards of grants, contracts, or cooperative agreements, shall

provide for the establishment of an integrated system or systems of public health alert communications and surveillance networks between and among—

(A) Federal, State, local, and Tribal public health officials; and

(B) public and private health-related laboratories, hospitals, poison control centers, immunization information systems, and other health care facilities; [1]

(2) Requirements

The Secretary shall develop a plan to, and ensure that networks under paragraph (1) allow for the timely sharing and discussion, in a secure manner and in a form readily usable for analytical approaches, of essential, deidentified information concerning bioterrorism or another public health emergency, or recommended methods for responding to such an attack or emergency, allowing for coordination to maximize all-hazards medical and public health preparedness and response and to minimize duplication of effort. The Secretary shall ensure that the activities carried out pursuant to the previous sentence are conducted in a manner that protects personal privacy, to the extent required by applicable Federal and State information privacy or security law, at a minimum.

(3) Standards

(A) In general

Not later than 1 year after June 24, 2019, the Secretary, in cooperation with health care providers, State, local, Tribal, and territorial public health officials, and relevant Federal agencies (including the Office of the National Coordinator for Health Information Technology and the National Institute of Standards and Technology), shall, as necessary, adopt technical and reporting standards, including standards for interoperability as defined by section 300jj of this title, for networks under paragraph (1) and update such standards as necessary. Such standards shall be made available on the internet website of the Department of Health and Human Services, in a manner that does not compromise national security.

(B) Deference to standards development organizations

In adopting and implementing standards under this subsection and subsection (c), the Secretary shall give deference to standards published by standards development organizations and voluntary consensus-based standards entities.

(c) Modernizing public health situational awareness and biosurveillance

(1) In general

The Secretary, in collaboration with State, local, and Tribal public health officials, shall establish, modernize, and improve as applicable and appropriate, a near real-time electronic nationwide public health situational awareness capability through an interoperable network of systems to share data and information that is deidentified, as applicable, to enhance early detection of, rapid response to, and management of, potentially catastrophic infectious disease outbreaks, novel emerging threats, and other public health emergencies that originate domestically or abroad. Such network shall be built on existing State situational awareness systems or enhanced systems that enable such interoperability, to the extent practicable. The Secretary shall ensure that the activities carried out pursuant to this paragraph are conducted in a manner that protects personal privacy, to the extent required by applicable Federal and State information privacy or security law, at a minimum.

(2) Coordination and consultation

In establishing and improving the network under paragraph (1), the Secretary shall—

(A) facilitate coordination among agencies within the Department of Health and Human Services that provide, or have the potential to provide, information and data to, and analyses for, the situational awareness and biosurveillance network under paragraph (1), including coordination among relevant agencies related to health care services, the facilitation of health information exchange (including the Office of the National Coordinator for Health Information Technology), and public health emergency preparedness and response; and

(B) consult with the Secretary of Agriculture, the Secretary of Commerce (and the Director of the National Institute of Standards and Technology), the Secretary of Defense, the Secretary of Homeland Security, the Secretary of Veterans Affairs, and the heads of other Federal agencies, as the Secretary determines appropriate.

(3) Elements

(A) In general

The network described in paragraph (1) shall include data and information transmitted in a standardized format from—

(i) State, local, and Tribal public health entities, including public health laboratories;

(ii) Federal health agencies;

(iii) zoonotic disease monitoring systems; and

(iv) public and private sector health care entities, hospitals, pharmacies, poison control centers or professional organizations in the field of poison control, immunization information systems, community health centers, health centers, clinical laboratories, and public environmental health agencies, to the extent practicable and provided that such data are voluntarily provided simultaneously to the Secretary and appropriate State, local, and Tribal public health agencies.

(B) Review

Not later than 2 years after June 24, 2019, and every 6 years thereafter, the Secretary shall conduct a review of the elements described in subparagraph (A). Such review shall include a discussion of the addition of any elements pursuant to clause (v), including elements added to advancing new technologies, and identify any challenges in the incorporation of elements under subparagraph (A), and make recommendations to improve the quality of data collected pursuant to subparagraph (A) to ensure complete, accurate, and timely sharing of such data, as appropriate, across such elements as described in subparagraph (A). The Secretary shall provide such review to the congressional committees of jurisdiction.

(4) Rule of construction

Paragraph (3) shall not be construed as requiring separate reporting of data and information from each source listed.

(5) Required activities

(A) In general

In establishing, operating, and updating, as appropriate, the network described in paragraph (1), the Secretary shall—

(i) utilize applicable interoperability standards as adopted by the Secretary, and in consultation with the Office of the National Coordinator for Health Information Technology and the National Institute of Standards and Technology, through a joint public and private sector process;

(ii) define minimal data elements for such network;

(iii) in collaboration with State, local, and Tribal public health officials, integrate and build upon existing State, local, and Tribal capabilities, ensuring simultaneous sharing of data, information, and analyses that is deidentified, as applicable, from the network described in paragraph (1) with State, local, and Tribal public health agencies in accordance with applicable Federal and State privacy and security law;

(iv) in collaboration with State, local, and Tribal public health officials, develop procedures and standards for the collection, analysis, and interpretation of data that States, regions, or other entities collect and report to the network described in paragraph (1);

(v) pilot test standards and implementation specifications, consistent with the process described in section 300jj–12(b)(3)(C) of this title, which State, local, Tribal, and territorial public health entities may utilize, on a voluntary basis, as a part of the network; and

(vi) in collaboration with State, local, and Tribal public health officials, integrate and

update applicable existing public health data systems and networks of the Department of Health and Human Services to reflect technological advancements, consistent with section 300hh–33 of this title, as applicable.

(B) Public meeting

(i) In general

Not later than 180 days after June 24, 2019, and 180 days after December 29, 2022, the Secretary shall convene a public meeting for purposes of discussing and providing input on the potential goals, functions, and uses of the network described in paragraph (1) and incorporating the elements described in paragraph (3)(A).

(ii) Experts

The public meeting shall include representatives of relevant Federal agencies (including representatives from the Office of the National Coordinator for Health Information Technology and the National Institute of Standards and Technology); State, local, Tribal, and territorial public health officials; stakeholders with expertise in biosurveillance and situational awareness; stakeholders with expertise in capabilities relevant to biosurveillance and situational awareness, such as experts in informatics and data analytics (including experts in prediction, modeling, or forecasting); experts in State-based public health data systems; experts in standards and implementation specifications, including transaction standards; and experts in privacy and data security.

(iii) Topics

Such public meeting shall include a discussion of—

(I) data elements, including minimal or essential data elements, that are voluntarily provided for such network, which may include elements from public health and public and private health care entities, to the extent practicable;

(II) standards and implementation specifications that may improve the collection, analysis, and interpretation of data during a public health emergency;

(III) strategies to encourage the access, exchange, and use of information;

(IV) considerations for State, local, Tribal, and territorial capabilities and infrastructure related to data exchange and interoperability, including existing public health data systems;

(V) privacy and security protections provided at the Federal, State, local, Tribal, and territorial levels, and by nongovernmental stakeholders;

(VI) opportunities for the incorporation of innovative technologies to improve the network;

(VII) strategies to integrate laboratory and public health data systems and capabilities to support rapid and accurate reporting of laboratory test results and associated relevant data;

(VIII) strategies to improve the collection, reporting, and dissemination of relevant, aggregated, deidentified demographic data to inform responses to public health emergencies, including identification of at-risk populations and to address potential health disparities; and

(IX) strategies to improve the electronic exchange of health information, as appropriate, between State and local health departments and health care providers and facilities to improve the detection of, and responses to, potentially catastrophic infectious disease outbreaks.

(6) Strategy and implementation plan

(A) In general

Not later than 18 months after June 24, 2019, and every 5 years thereafter, the Secretary shall submit to the congressional committees of jurisdiction a coordinated strategy and an accompanying implementation plan that—

(i) is informed by the public meeting under paragraph (5)(B);

(ii) includes a review and assessment of existing capabilities of the network and related

infrastructure, including input provided by the public meeting under paragraph (5)(B);

(iii) identifies and demonstrates the measurable steps the Secretary will carry out to—

(I) develop, implement, and evaluate the network described in paragraph (1), utilizing elements described in paragraph (3)(A);

(II) modernize and enhance biosurveillance activities, including strategies to include innovative technologies and analytical approaches (including prediction and forecasting for pandemics and all-hazards) from public and private entities;

(III) improve information sharing, coordination, and communication among disparate biosurveillance systems supported by the Department of Health and Human Services, including the identification of methods to improve accountability, better utilize resources and workforce capabilities, and incorporate innovative technologies within and across agencies;

(IV) test and evaluate capabilities of the interoperable network of systems to improve situational awareness and biosurveillance capabilities;

(V) improve coordination and collaboration, as appropriate, with other Federal departments to improve the capabilities of the network and reduce administrative burden on State, local, and Tribal entities; and

(VI) implement applicable lessons learned from recent public health emergencies to address gaps in situational awareness and biosurveillance capabilities;

(iv) includes performance measures and the metrics by which performance measures will be assessed with respect to the measurable steps under clause (iii);

(v) establishes dates by which each measurable step under clause (iii) will be implemented, including a description of how such steps will further the goals of the network, consistent with paragraph (1); and

(vi) identifies and demonstrates measurable steps the Secretary will take to further develop and integrate infectious disease detection, support rapid, accurate, and secure sharing of laboratory test results, deidentified as appropriate, during a public health emergency, and improve coordination and collaboration with State, local, and Tribal public health officials, clinical laboratories, and other entities with expertise in public health surveillance.

(B) Annual budget plan

Not later than 2 years after June 24, 2019, and on an annual basis thereafter, in accordance with the strategy and implementation plan under this paragraph, the Secretary shall, taking into account recommendations provided by the National Biodefense Science Board, develop a budget plan based on the strategy and implementation plan under this section. Such budget plan shall include—

(i) a summary of resources previously expended to establish, improve, and utilize the nationwide public health situational awareness and biosurveillance network under paragraph (1);

(ii) estimates of costs and resources needed to establish and improve the network under paragraph (1) according to the strategy and implementation plan under subparagraph (A);

(iii) the identification of gaps and inefficiencies in nationwide public health situational awareness and biosurveillance capabilities, resources, and authorities needed to address such gaps; and

(iv) a strategy to minimize and address such gaps and improve inefficiencies.

(7) Consultation with the National Biodefense Science Board

In carrying out this section and consistent with section 247d–7g of this title, the National Biodefense Science Board shall provide expert advice and guidance, including recommendations, regarding the measurable steps the Secretary should take to modernize and enhance biosurveillance activities pursuant to the efforts of the Department of Health and Human Services to ensure comprehensive, real-time, all-hazards biosurveillance capabilities. In complying with the preceding sentence, the National Biodefense Science Board shall—

(A) identify the steps necessary to achieve a national biosurveillance system for human health (taking into account zoonotic disease, including gaps in scientific understanding of the interactions between human, animal, and environmental health), with international connectivity, where appropriate, that is predicated on State, regional, and community level capabilities and creates a networked system to allow for two-way information flow between and among Federal, State, and local government public health authorities and clinical health care providers;

(B) identify any duplicative surveillance programs and gaps in surveillance programs under the authority of the Secretary, or changes that are necessary to existing programs, in order to enhance and modernize such activities, minimize duplication, strengthen and streamline such activities under the authority of the Secretary, and achieve real-time and appropriate data that relate to disease activity, both human and zoonotic;

(C) coordinate with applicable existing advisory committees of the Director of the Centers for Disease Control and Prevention, including such advisory committees consisting of representatives from State, local, and Tribal public health authorities and appropriate public and private sector health care entities, animal health organizations related to zoonotic disease, and academic institutions, in order to provide guidance on public health surveillance activities; and

(D) provide recommendations to the Secretary on policies and procedures to complete the steps described in this paragraph in a manner that is consistent with section 300hh–1 of this title.

(8) Situational awareness and biosurveillance as a national security priority

The Secretary, on a periodic basis as applicable and appropriate, shall meet with the Director of National Intelligence to inform the development and capabilities of the nationwide public health situational awareness and biosurveillance network.

(9) Rules of construction

(A) Nothing in this subsection shall be construed to supplant, in whole or in part, State, local, or Tribal activities or responsibilities related to public health surveillance.

(B) Nothing in this subsection shall be construed to alter the authority of the Secretary with respect to the types of data the Secretary may receive through systems supported or established under this section.

(d) State and regional systems to enhance situational awareness in public health emergencies

(1) In general

To implement the network described in subsection (c), the Secretary may award grants to States or consortia of States to enhance the ability of such States or consortia of States to establish or operate a coordinated public health situational awareness system for regional or Statewide early detection of, rapid response to, and management of potentially catastrophic infectious disease outbreaks and public health emergencies, in collaboration with appropriate public health agencies, environmental health agencies, sentinel hospitals, clinical laboratories, pharmacies, poison control centers, immunization programs, other health care organizations, and animal health organizations within such States.

(2) Eligibility

To be eligible to receive a grant under paragraph (1), the State or consortium of States shall submit to the Secretary an application at such time, in such manner, and containing such information as the Secretary may require, including an assurance that the State or consortium of States will submit to the Secretary—

(A) reports of such deidentified data, information, and metrics as the Secretary may require, in consultation with such State or consortium of States;

(B) a report on the effectiveness of the systems funded under the grant;

(C) a description of the manner in which grant funds will be used to enhance the timelines and comprehensiveness of efforts to detect, respond to, and manage potentially catastrophic infectious disease outbreaks and public health emergencies, including any public-private

partnerships or other partnerships entered into to improve such capacity; and

(D) an implementation plan that may include measurable steps to achieve the purposes described in paragraph (1).

(3) Use of funds

A State or consortium of States that receives an award under this subsection—

(A) shall establish, enhance, or operate a coordinated public health situational awareness system for regional or Statewide early detection of, rapid response to, and management of potentially catastrophic infectious disease outbreaks and public health emergencies;

(B) may award grants or contracts to entities described in paragraph (1) within or serving such State to assist such entities in improving the operation of information technology systems, facilitating the secure exchange of data and information, and training personnel to enhance the operation of the system described in subparagraph (A); and

(C) may conduct a pilot program for the development of multi-State telehealth network test beds that build on, enhance, and securely link existing State and local telehealth programs to prepare for, monitor, respond to, and manage the events of public health emergencies, facilitate coordination and communication among medical, public health, and emergency response agencies, and provide medical services through telehealth initiatives within the States that are involved in such a multi-State telehealth network test bed.

(4) Limitation

Information technology systems acquired or implemented using grants awarded under this section must be compliant with—

(A) interoperability and other technological standards, as determined by the Secretary; and

(B) data collection and reporting requirements for the network described in subsection (c).

(5) Technical assistance

The Secretary may provide technical assistance to States, localities, Tribes, and territories or a consortium of States, localities, Tribes, and territories receiving an award under this subsection regarding interoperability and the technical standards set forth by the Secretary.

(6) Non-duplication of effort

The Secretary shall ensure that activities carried out under an award under this subsection do not unnecessarily duplicate efforts of other agencies and offices within the Department of Health and Human Services.

(e) Personnel authorities

(1) Specially qualified personnel

In addition to any other personnel authorities, to carry out subsections (b) and (c), the Secretary may—

(A) appoint highly qualified individuals to scientific or professional positions at the Centers for Disease Control and Prevention, not to exceed 30 such employees at any time (specific to positions authorized by this subsection), with expertise in capabilities relevant to biosurveillance and situational awareness, such as experts in informatics and data analytics (including experts in prediction, modeling, or forecasting), and other related scientific or technical fields; and

(B) compensate individuals appointed under subparagraph (A) in the same manner and subject to the same terms and conditions in which individuals appointed under 9903 [2] of title 5 are compensated, without regard to the provisions of chapter 51 and subchapter III of chapter 53 of such title relating to classification and General Schedule pay rates.

(2) Limitations

The Secretary shall exercise the authority under paragraph (1) in a manner that is consistent with the limitations described in section 247d–6a(e)(2) of this title.

(f) Timeline

The Secretary shall accomplish the purposes under subsections (b) and (c) no later than September 30, 2023, and shall provide a justification to the congressional committees of jurisdiction for any missed or delayed implementation of measurable steps identified under subsection (c)(6)(A)(iii).

(g) Independent evaluation

Not later than 3 years after June 24, 2019, the Comptroller General of the United States shall conduct an independent evaluation and submit to the Secretary and the congressional committees of jurisdiction a report concerning the activities conducted under subsections (b) and (c), and provide recommendations, as applicable and appropriate, on necessary improvements to the biosurveillance and situational awareness network.

(h) Authorization of appropriations

There are authorized to be appropriated—

(1) to carry out subsection (a), $25,000,000 for each of fiscal years 2022 and 2023; and

(2) to carry out subsections (b), (c), and (d), $136,800,000 for each of fiscal years 2022 and 2023.

(i) Definition

For purposes of this section the term "biosurveillance" means the process of gathering near real-time biological data that relates to human and zoonotic disease activity and threats to human or animal health, in order to achieve early warning and identification of such health threats, early detection and prompt ongoing tracking of health events, and overall situational awareness of disease activity.

(July 1, 1944, ch. 373, title III, §319D, as added Pub. L. 106–505, title I, §102, Nov. 13, 2000, 114 Stat. 2318; amended Pub. L. 107–188, title I, §103, June 12, 2002, 116 Stat. 603; Pub. L. 109–417, title II, §§202, 204(b)(2), Dec. 19, 2006, 120 Stat. 2845, 2851; Pub. L. 113–5, title II, §204(a), Mar. 13, 2013, 127 Stat. 177; Pub. L. 116–22, title II, §205(a), (b), June 24, 2019, 133 Stat. 918, 924; Pub. L. 117–328, div. FF, title II, §2211, Dec. 29, 2022, 136 Stat. 5729.)

EDITORIAL NOTES

AMENDMENTS

2022—Pub. L. 117–328, §2211(8), substituted "Tribal" for "tribal" wherever appearing.

Subsec. (a)(3). Pub. L. 117–328, §2211(1)(A), substituted "emergencies, by" for "emergencies. Activities that may be carried out under the preceding sentence include" in introductory provisions.

Subsec. (a)(3)(D). Pub. L. 117–328, §2211(1)(B), inserted ", infectious disease outbreaks," after "bioterrorism".

Subsec. (b)(1)(A). Pub. L. 117–328, §2211(2)(A)(i)(I), substituted ", local, and Tribal" for ", and local".

Subsec. (b)(1)(C). Pub. L. 117–328, §2211(2)(A)(i)(II)–(iii), struck out subpar. (C) which read as follows: "any other entities determined appropriate by the Secretary."

Subsec. (b)(2). Pub. L. 117–328, §2211(2)(B), inserted ", deidentified" before "information" and "The Secretary shall ensure that the activities carried out pursuant to the previous sentence are conducted in a manner that protects personal privacy, to the extent required by applicable Federal and State information privacy or security law, at a minimum." at end.

Subsec. (c)(1). Pub. L. 117–328, §2211(3)(A), inserted "modernize," after "establish,", "that is deidentified, as applicable," after "share data and information", ", to the extent practicable" after "interoperability", and "The Secretary shall ensure that the activities carried out pursuant to this paragraph are conducted in a manner that protects personal privacy, to the extent required by applicable Federal and State information privacy or security law, at a minimum." at end.

Subsec. (c)(3)(A)(v). Pub. L. 117–328, §2211(3)(B)(i), struck out cl. (v) which read as follows: "such other sources as the Secretary may deem appropriate."

Subsec. (c)(3)(B). Pub. L. 117–328, §2211(3)(B)(ii), inserted ", and make recommendations to improve the quality of data collected pursuant to subparagraph (A) to ensure complete, accurate, and timely sharing of such data, as appropriate, across such elements as described in subparagraph (A)" after "under subparagraph (A)".

Subsec. (c)(5)(A). Pub. L. 117–328, §2211(3)(C)(i)(I), substituted ", operating, and updating, as

appropriate," for "and operating" in introductory provisions.

Subsec. (c)(5)(A)(iii). Pub. L. 117–328, §2211(3)(C)(i)(II), inserted "that is deidentified, as applicable," after "analyses" and "in accordance with applicable Federal and State privacy and security law" after "agencies".

Subsec. (c)(5)(A)(vi). Pub. L. 117–328, §2211(3)(C)(i)(III)–(V), added cl. (vi).

Subsec. (c)(5)(B)(i). Pub. L. 117–328, §2211(3)(C)(ii)(I), inserted "and 180 days after December 29, 2022," after "June 24, 2019,".

Subsec. (c)(5)(B)(ii). Pub. L. 117–328, §2211(3)(C)(ii)(II), substituted "experts in State-based public health data systems; experts in standards and implementation specifications, including transaction standards; and experts in privacy and data security" for "and other representatives as the Secretary determines appropriate".

Subsec. (c)(5)(B)(iii)(IV). Pub. L. 117–328, §2211(3)(C)(ii)(III)(aa), inserted ", including existing public health data systems" after "interoperability".

Subsec. (c)(5)(B)(iii)(VII) to (IX). Pub. L. 117–328, §2211(3)(C)(ii)(III)(bb)–(dd), added subcls. (VII) to (IX).

Subsec. (c)(6)(A). Pub. L. 117–328, §2211(3)(D)(i), inserted "and every 5 years thereafter," after "June 24, 2019," in introductory provisions.

Subsec. (c)(6)(A)(iii)(V), (VI). Pub. L. 117–328, §2211(3)(D)(ii), added subcls. (V) and (VI).

Subsec. (c)(6)(A)(v). Pub. L. 117–328, §2211(3)(D)(iv), substituted ", including a description of how such steps will further the goals of the network, consistent with paragraph (1); and" for period at end.

Subsec. (c)(6)(A)(vi). Pub. L. 117–328, §2211(3)(D)(iii), (v), added cl. (vi).

Subsec. (c)(9). Pub. L. 117–328, §2211(3)(E), added par. (9).

Subsec. (d)(2)(A). Pub. L. 117–328, §2211(4)(A)(i), inserted "deidentified" before "data, information" and ", in consultation with such State or consortium of States" after "require".

Subsec. (d)(2)(C). Pub. L. 117–328, §2211(4)(A)(ii), inserted ", including any public-private partnerships or other partnerships entered into to improve such capacity" after "emergencies".

Subsec. (d)(6). Pub. L. 117–328, §2211(4)(B), added par. (6).

Subsecs. (e) to (g). Pub. L. 117–328, §2211(5), (6), redesignated subsecs. (f) to (h) as (e) to (g), respectively, and struck out former subsec. (e) which related to telehealth enhancements for emergency response.

Subsec. (h). Pub. L. 117–328, §2211(7), added subsec. (h) and struck out former subsec. (h). Prior to amendment, text read as follows: "There are authorized to be appropriated to carry out this section, $161,800,000 for each of fiscal years 2019 through 2023."

Pub. L. 117–328, §2211(6), redesignated subsec. (i) as (h).

Subsecs. (i), (j). Pub. L. 117–328, §2211(6), redesignated subsecs. (i) and (j) as (h) and (i), respectively.

2019—Pub. L. 116–22, §205(a)(1), substituted "Facilities and capacities of" for "Revitalizing" in section catchline.

Subsec. (a). Pub. L. 116–22, §205(a)(2)(A), substituted "In general" for "Facilities; capacities" in heading.

Subsec. (a)(1). Pub. L. 116–22, §205(a)(2)(B), substituted ", improved, and appropriately maintained" for "and improved".

Subsec. (a)(3). Pub. L. 116–22, §205(a)(2)(C), substituted "expand, improve, enhance, and appropriately maintain" for "expand, enhance, and improve" in introductory provisions.

Subsec. (a)(4). Pub. L. 116–22, §205(a)(2)(D), added par. (4).

Subsec. (b). Pub. L. 116–22, §205(a)(3)(A), substituted "Establishment of systems of public health" for "National" in heading.

Subsec. (b)(1)(B). Pub. L. 116–22, §205(a)(3)(B), inserted "immunization information systems," after "centers,".

Subsec. (b)(2). Pub. L. 116–22, §205(a)(3)(C), inserted "develop a plan to, and" after "The Secretary shall" and "and in a form readily usable for analytical approaches" after "in a secure manner".

Subsec. (b)(3). Pub. L. 116–22, §205(a)(3)(D), amended par. (3) generally. Prior to amendment, text read as follows: "Not later than one year after June 12, 2002, the Secretary, in cooperation with health care providers and State and local public health officials, shall establish any additional technical and reporting standards (including standards for interoperability) for networks under paragraph (1) and update such standards as necessary."

Subsec. (c)(1). Pub. L. 116–22, §205(a)(4)(A), substituted "The Secretary" for "Not later than 2 years after March 13, 2013, the Secretary" and "such interoperability" for "such connectivity" and inserted ", and improve as applicable and appropriate," after "shall establish" and a comma after "detection of".

Subsec. (c)(2). Pub. L. 116–22, §205(a)(4)(B), amended par. (2) generally. Prior to amendment, par. (2) related to a coordinated strategy and an accompanying implementation plan.

Subsec. (c)(3). Pub. L. 116–22, §205(a)(4)(C), designated existing provisions as subpar. (A) and inserted heading; redesignated former subpars. (A) to (E) as cls. (i) to (v), respectively, of subpar. (A) and realigned margins; in cl. (iv), inserted "immunization information systems," after "poison control," and substituted ", clinical laboratories, and public environmental health agencies" for "and clinical laboratories"; and added subpar. (B).

Subsec. (c)(5)(A). Pub. L. 116–22, §205(a)(4)(D)(i), (ii), designated existing provisions as subpar. (A), inserted heading, redesignated former subpars. (A) to (D) as (i) to (iv), respectively, of subpar. (A) and realigned margins.

Subsec. (c)(5)(A)(i). Pub. L. 116–22, §205(a)(4)(D)(iv)(I), substituted "as adopted" for "as determined" and inserted "and the National Institute of Standards and Technology" after "Office of the National Coordinator for Health Information Technology".

Subsec. (c)(5)(A)(v). Pub. L. 116–22, §205(a)(4)(D)(iv)(II)–(IV), added cl. (v).

Subsec. (c)(5)(B). Pub. L. 116–22, §205(a)(4)(D)(iii), added subpar. (B). Former subpar. (B) redesignated cl. (ii) of subpar. (A).

Subsec. (c)(6). Pub. L. 116–22, §205(a)(4)(F), added par. (6). Former par. (6) redesignated (7).

Subsec. (c)(7). Pub. L. 116–22, §205(a)(4)(E), redesignated par. (6) as (7).

Subsec. (c)(7)(A). Pub. L. 116–22, §205(a)(4)(G)(i), inserted "(taking into account zoonotic disease, including gaps in scientific understanding of the interactions between human, animal, and environmental health)" after "human health".

Subsec. (c)(7)(B). Pub. L. 116–22, §205(a)(4)(G)(ii), inserted "and gaps in surveillance programs" after "surveillance programs" and substituted "zoonotic;" for "zoonotic; and".

Subsec. (c)(7)(C). Pub. L. 116–22, §205(a)(4)(G)(iii), inserted ", animal health organizations related to zoonotic disease," after "health care entities" and substituted "activities; and" for "activities."

Subsec. (c)(7)(D). Pub. L. 116–22, §205(a)(4)(G)(iv), added subpar. (D).

Subsec. (c)(8). Pub. L. 116–22, §205(a)(4)(H), added par. (8).

Subsec. (d)(1). Pub. L. 116–22, §205(a)(5)(A), inserted "environmental health agencies," after "public health agencies," and "immunization programs," after "poison control centers,".

Subsec. (d)(2)(D). Pub. L. 116–22, §205(a)(5)(B), added subpar. (D).

Subsec. (d)(5). Pub. L. 116–22, §205(a)(5)(C), added par. (5) and struck out former par. (5) which required an independent evaluation and report from the Government Accountability Office no later than 3 years after Mar. 13, 2013.

Subsecs. (f) to (h). Pub. L. 116–22, §205(a)(7), added subsecs. (f) to (h). Former subsecs. (f) and (g) redesignated (i) and (j), respectively.

Subsec. (i). Pub. L. 116–22, §205(a)(6), (b), redesignated subsec. (f) as (i) and substituted "$161,800,000 for each of fiscal years 2019 through 2023" for "$138,300,000 for each of fiscal years 2014 through 2018".

Subsec. (j). Pub. L. 116–22, §205(a)(6), redesignated subsec. (g) as (j).

2013—Subsec. (b)(1)(B). Pub. L. 113–5, §204(a)(1)(A), inserted "poison control centers," after "hospitals,".

Subsec. (b)(2). Pub. L. 113–5, §204(a)(1)(B), inserted ", allowing for coordination to maximize all-hazards medical and public health preparedness and response and to minimize duplication of effort" before period at end.

Subsec. (b)(3). Pub. L. 113–5, §204(a)(1)(C), inserted "and update such standards as necessary" before period at end.

Subsec. (c). Pub. L. 113–5, §204(a)(4)(A), substituted "Modernizing public health situational awareness and biosurveillance" for "Public health situational awareness" in heading.

Pub. L. 113–5, §204(a)(2), (3), redesignated subsec. (d) as (c) and struck out former subsec. (c) which related to authorization of appropriations for fiscal years 2002 through 2006.

Subsec. (c)(1). Pub. L. 113–5, §204(a)(4)(B), substituted "March 13, 2013" for "December 19, 2006" and inserted ", novel emerging threats," after "disease outbreaks".

Subsec. (c)(2). Pub. L. 113–5, §204(a)(4)(C), added par. (2) and struck out former par. (2). Prior to amendment, text read as follows: "Not later than 180 days after December 19, 2006, the Secretary shall submit to the appropriate committees of Congress, a strategic plan that demonstrates the steps the Secretary will undertake to develop, implement, and evaluate the network described in paragraph (1), utilizing the elements described in paragraph (3)."

Subsec. (c)(3)(D). Pub. L. 113–5, §204(a)(4)(D), inserted "community health centers, health centers" after "of poison control,".

Subsec. (c)(5)(A). Pub. L. 113–5, §204(a)(4)(E), added subpar. (A) and struck out former subpar. (A) which read as follows: "utilize applicable interoperability standards as determined by the Secretary through a joint public and private sector process;".

Subsec. (c)(6). Pub. L. 113–5, §204(a)(4)(F), added par. (6).

Subsec. (d). Pub. L. 113–5, §204(a)(3), redesignated subsec. (e) as (d). Former subsec. (d) redesignated (c).

Subsec. (d)(1), (4)(B). Pub. L. 113–5, §204(a)(5)(A), (B), substituted "subsection (c)" for "subsection (d)".

Subsec. (d)(5). Pub. L. 113–5, §204(a)(5)(C), substituted "3 years after March 13, 2013" for "4 years after December 19, 2006" and "subsection (c)" for "subsection (d)".

Subsec. (e). Pub. L. 113–5, §204(a)(3), redesignated subsec. (f) as (e). Former subsec. (e) redesignated (d).

Subsec. (f). Pub. L. 113–5, §204(a)(3), (6), redesignated subsec. (g) as (f) and substituted "$138,300,000 for each of fiscal years 2014 through 2018" for "such sums as may be necessary in each of fiscal years 2007 through 2011". Former subsec. (f) redesignated (e).

Subsec. (g). Pub. L. 113–5, §204(a)(7), added subsec. (g). Former subsec. (g) redesignated (f).

2006—Subsec. (a)(1). Pub. L. 109–417, §202(1), inserted "domestically and abroad" after "public health threats".

Subsec. (a)(3). Pub. L. 109–417, §204(b)(2), struck out ", taking into account evaluations under section 247d–2(a) of this title," after "The Secretary" in introductory provisions.

Subsecs. (d) to (g). Pub. L. 109–417, §202(2), added subsecs. (d) to (g).

2002—Pub. L. 107–188 reenacted section catchline without change and amended text generally, substituting detailed provisions relating to facilities, capacities, and national communications and surveillance networks for provisions relating to findings of need for secure and modern facilities.

STATUTORY NOTES AND RELATED SUBSIDIARIES

WORKING CAPITAL FUND

Pub. L. 113–76, div. H, title II, Jan. 17, 2014, 128 Stat. 368, provided in part: "That to facilitate the implementation of the permanent Working Capital Fund ('WCF') authorized under this heading [CDC-WIDE ACTIVITIES AND PROGRAM SUPPORT] in division F of Public Law 112–74 [see note below], on or after enactment of this Act [Jan. 17, 2014], unobligated balances of amounts appropriated for business services for fiscal year 2013 shall be transferred to the WCF: *Provided further*, That on or after enactment of this Act, CDC shall transfer amounts available for business services to other CDC appropriations consistent with the benefit each appropriation received from the business services appropriation in fiscal year 2013: *Provided further*, That once the WCF is implemented in fiscal year 2014, assets purchased in any prior fiscal year with funds appropriated for or reimbursed to business services may be transferred to the WCF and customers billed for depreciation of those assets: *Provided further*, That CDC shall, consistent with the authorities provided in 42 U.S.C. 231, ensure that the WCF is used only for administrative support services and not for programmatic activities: *Provided further*, That CDC shall notify the Committees on Appropriations of the House of Representatives and the Senate not later than 15 days prior to any transfers made with funds provided under this heading."

Similar provisions were contained in the following prior appropriation act:

Pub. L. 113–6, div. F, title V, §1507, Mar. 26, 2013, 127 Stat. 423.

Pub. L. 112–74, div. F, title II, Dec. 23, 2011, 125 Stat. 1070, provided in part: "That CDC [Centers for Disease Control and Prevention] may establish a Working Capital Fund, with the authorities equivalent to those provided in 42 U.S.C. 231, to improve the provision of supplies and service."

[1] So in original.

[2] So in original. Probably should be preceded by "section".

§247d–4a. Infectious Diseases Rapid Response Reserve Fund

There is established in the Treasury a reserve fund to be known as the "Infectious Diseases Rapid Response Reserve Fund" (the "Reserve Fund"): *Provided*, That of the funds provided under the heading "CDC-Wide Activities and Program Support" [132 Stat. 3073], $50,000,000, to remain available until expended, shall be available to the Director of the CDC for deposit in the Reserve Fund: *Provided further*, That amounts in the Reserve Fund shall be for carrying out titles II, III, and XVII of the PHS Act [42 U.S.C. 201 et seq., 241 et seq., 300u et seq.] to prevent, prepare for, or respond to an infectious disease emergency, including, in connection with such activities, to purchase

or lease and provide for the insurance of passenger motor vehicles for official use in foreign countries: *Provided further*, That amounts in the Reserve Fund may only be provided for an infectious disease emergency if the infectious disease emergency (1) is declared by the Secretary of Health and Human Services under section 319 of the PHS Act [42 U.S.C. 247d] to be a public health emergency; or (2) as determined by the Secretary, has significant potential to imminently occur and potential, on occurrence, to affect national security or the health and security of United States citizens, domestically or internationally: *Provided further*, That amounts in the Reserve Fund may be transferred by the Director of the CDC to other accounts of the CDC, to accounts of the NIH, or to the Public Health and Social Services Emergency Fund, to be merged with such accounts or Fund for the purposes provided in this section: *Provided further*, That the Director shall provide to the Committees on Appropriations of the House of Representatives and the Senate, at least 7 days in advance of any transfer or obligation of funds made under the authority provided in this section, both a notification on the anticipated uses of funds by program, project, or activity; and a detailed spend plan of anticipated uses of funds, including estimated personnel and administrative costs, disaggregated by program, project, or activity: *Provided further*, That such spend plans shall be updated to include all applicable obligations to date and unobligated amounts and submitted quarterly to such Committees on Appropriations until such funds are fully expended: *Provided further*, That amounts in the Reserve Fund shall be in addition to amounts otherwise available to the Department of Health and Human Services for the purposes provided in this section: *Provided further*, That the transfer authorities in this section are in addition to any transfer authority otherwise available to the Department of Health and Human Services: *Provided further*, That products purchased using amounts in the Reserve Fund may, at the discretion of the Secretary of Health and Human Services, be deposited in the Strategic National Stockpile under section 319F–2 of the PHS Act [42 U.S.C. 247d–6b]: *Provided further*, That this section shall be in effect as of September 28, 2018, through each fiscal year hereafter.

(Pub. L. 115–245, div. B, title II, §231, Sept. 28, 2018, 132 Stat. 3095; Pub. L. 118–47, div. D, title II, §236, Mar. 23, 2024, 138 Stat. 680.)

EDITORIAL NOTES

REFERENCES IN TEXT

CDC and NIH, referred to in text, mean the Centers for Disease Control and Prevention and the National Institutes of Health, respectively.

The PHS Act, referred to in text, means the Public Health Service Act, act July 1, 1944, ch. 373, 58 Stat. 682. Titles II, III, and XVII of the Act are classified generally to subchapters I (§201 et seq.), II (§241 et seq.), and XV (§300u et seq.), respectively, of this chapter. For complete classification of this Act to the Code, see Short Title note set out under section 201 of this title and Tables.

CODIFICATION

Section was enacted as part of the Department of Health and Human Services Appropriations Act, 2019, and also as part of the Departments of Labor, Health and Human Services, and Education, and Related Agencies Appropriations Act, 2019, and the Department of Defense and Labor, Health and Human Services, and Education Appropriations Act, 2019 and Continuing Appropriations Act, 2019, and not as part of the Public Health Service Act which comprises this chapter.

AMENDMENTS

2024—Pub. L. 118–47 substituted "*Provided further*, That the Director shall provide to the Committees on Appropriations of the House of Representatives and the Senate, at least 7 days in advance of any transfer or obligation of funds made under the authority provided in this section, both a notification on the anticipated uses of funds by program, project, or activity; and a detailed spend plan of anticipated uses of funds, including estimated personnel and administrative costs, disaggregated by program, project, or activity: *Provided further*, That such spend plans shall be updated to include all applicable obligations to date and unobligated amounts and submitted quarterly to such Committees on Appropriations until such funds are fully expended:" for "*Provided further*, That the Committees on Appropriations of the House of Representatives and the Senate shall be notified in advance of any transfer or obligation made under the authority provided in this section,

including notification on the anticipated uses of such funds by program, project, or activity: *Provided further*, That not later than 15 days after notification of the planned use of the Reserve Fund, the Director shall provide a detailed spend plan of anticipated uses of funds, including estimated personnel and administrative costs, to the Committees on Appropriations of the House of Representatives and the Senate: *Provided further*, That such plans shall be updated and submitted every 90 days thereafter until funds have been fully expended which should include the unobligated balances in the Reserve Fund and all the actual obligations incurred to date:".

STATUTORY NOTES AND RELATED SUBSIDIARIES

REPORTS REQUIRED

Pub. L. 116–136, div. B, title VIII, Mar. 27, 2020, 134 Stat. 555, which provided in part that the Secretary of Health and Human Services, in consultation with the Director of the Centers for Disease Control and Prevention, would provide a report to the Committees on Appropriations of the House of Representatives and the Senate every 14 days, for one year from the date from any such declaration or determination described in the third proviso of section 247d–4a of this title, that detailed commitment and obligation information for the Infectious Diseases Rapid Response Reserve Fund during the prior two weeks, was repealed by Pub. L. 118–47, div. D, title II, §237, Mar. 23, 2024, 138 Stat. 681.

§247d–4b. Children's Preparedness Unit

(a) Enhancing emergency preparedness for children

The Secretary, acting through the Director of the Centers for Disease Control and Prevention (referred to in this subsection as the "Director"), shall maintain an internal team of experts, to be known as the Children's Preparedness Unit (referred to in this subsection as the "Unit"), to work collaboratively to provide guidance on the considerations for, and the specific needs of, children before, during, and after public health emergencies. The Unit shall inform the Director regarding emergency preparedness and response efforts pertaining to children at the Centers for Disease Control and Prevention.

(b) Expertise

The team described in subsection (a) shall include one or more pediatricians, which may be a developmental-behavioral pediatrician, and may also include behavioral scientists, child psychologists, epidemiologists, biostatisticians, health communications staff, and individuals with other areas of expertise, as the Secretary determines appropriate.

(c) Duties

The team described in subsection (a) may—

(1) assist State, local, Tribal, and territorial emergency planning and response activities related to children, which may include developing, identifying, and sharing best practices;

(2) provide technical assistance, training, and consultation to Federal, State, local, Tribal, and territorial public health officials to improve preparedness and response capabilities with respect to the needs of children, including providing such technical assistance, training, and consultation to eligible entities in order to support the achievement of measurable evidence-based benchmarks and objective standards applicable to sections 247d–3a and 247d–3b of this title;

(3) improve the utilization of methods to incorporate the needs of children in planning for and responding to a public health emergency, including public awareness of such methods;

(4) coordinate with, and improve, public-private partnerships, such as health care coalitions pursuant to sections 247d–3b and 247d–3c of this title, to address gaps and inefficiencies in emergency preparedness and response efforts for children;

(5) provide expertise and input during the development of guidance and clinical recommendations to address the needs of children when preparing for, and responding to, public health emergencies, including pursuant to section 247d–3c of this title; and

(6) carry out other duties related to preparedness and response activities for children, as the

Secretary determines appropriate.

(July 1, 1944, ch. 373, title III, §319D–1, as added Pub. L. 116–22, title III, §304, June 24, 2019, 133 Stat. 936.)

§247d–5. Combating antimicrobial resistance

(a) Task force

(1) In general

The Secretary shall establish an Antimicrobial Resistance Task Force to provide advice and recommendations to the Secretary and coordinate Federal programs relating to antimicrobial resistance. The Secretary may appoint or select a committee, or other organization in existence as of November 13, 2000, to serve as such a task force, if such committee, or other organization meets the requirements of this section.

(2) Members of task force

The task force described in paragraph (1) shall be composed of representatives from such Federal agencies, and shall seek input from public health constituencies, manufacturers, veterinary and medical professional societies and others, as determined to be necessary by the Secretary, to develop and implement a comprehensive plan to address the public health threat of antimicrobial resistance.

(3) Agenda

(A) In general

The task force described in paragraph (1) shall consider factors the Secretary considers appropriate, including—

(i) public health factors contributing to increasing antimicrobial resistance;

(ii) public health needs to detect and monitor antimicrobial resistance;

(iii) detection, prevention, and control strategies for resistant pathogens;

(iv) the need for improved information and data collection;

(v) the assessment of the risk imposed by pathogens presenting a threat to the public health; and

(vi) any other issues which the Secretary determines are relevant to antimicrobial resistance.

(B) Detection and control

The Secretary, in consultation with the task force described in paragraph (1) and State and local public health officials, shall—

(i) develop, improve, coordinate or enhance participation in a surveillance plan to detect and monitor emerging antimicrobial resistance; and

(ii) develop, improve, coordinate or enhance participation in an integrated information system to assimilate, analyze, and exchange antimicrobial resistance data between public health departments.

(4) Meetings

The task force described under paragraph (1) shall convene not less than twice a year, or more frequently as the Secretary determines to be appropriate.

(b) Research and development of new antimicrobial drugs and diagnostics

The Secretary and the Director of Agricultural Research Services, consistent with the recommendations of the task force established under subsection (a), shall directly or through awards of grants or cooperative agreements to public or private entities provide for the conduct of research, investigations, experiments, demonstrations, and studies in the health sciences that are related to—

(1) the development of new therapeutics, including vaccines and antimicrobials, against

resistant pathogens;

(2) the development or testing of medical diagnostics to detect pathogens resistant to antimicrobials;

(3) the epidemiology, mechanisms, and pathogenesis of antimicrobial resistance;

(4) the sequencing of the genomes, or other DNA analysis, or other comparative analysis, of priority pathogens (as determined by the Director of the National Institutes of Health in consultation with the task force established under subsection (a)), in collaboration and coordination with the activities of the Department of Defense and the Joint Genome Institute of the Department of Energy; and

(5) other relevant research areas.

(c) Education of medical and public health personnel

The Secretary, after consultation with the Assistant Secretary for Health, the Surgeon General, the Director of the Centers for Disease Control and Prevention, the Administrator of the Health Resources and Services Administration, the Director of the Agency for Healthcare Research and Quality, members of the task force described in subsection (a), professional organizations and societies, and such other public health officials as may be necessary, shall—

(1) develop and implement educational programs to increase the awareness of the general public with respect to the public health threat of antimicrobial resistance and the appropriate use of antibiotics;

(2) develop and implement educational programs to instruct health care professionals in the prudent use of antibiotics; and

(3) develop and implement programs to train laboratory personnel in the recognition or identification of resistance in pathogens.

(d) Grants

(1) In general

The Secretary shall award competitive grants to eligible entities to enable such entities to increase the capacity to detect, monitor, and combat antimicrobial resistance.

(2) Eligible entities

Eligible entities for grants under paragraph (1) shall be State or local public health agencies, Indian tribes or tribal organizations, or other public or private nonprofit entities.

(3) Use of funds

An eligible entity receiving a grant under paragraph (1) shall use funds from such grant for activities that are consistent with the factors identified by the task force under subsection (a)(3), which may include activities that—

(A) provide training to enable such entity to identify patterns of resistance rapidly and accurately;

(B) develop, improve, coordinate or enhance participation in information systems by which data on resistant infections can be shared rapidly among relevant national, State, and local health agencies and health care providers; and

(C) develop and implement policies to control the spread of antimicrobial resistance.

(e) Grants for demonstration programs

(1) In general

The Secretary shall award competitive grants to eligible entities to establish demonstration programs to promote judicious use of antimicrobial drugs or control the spread of antimicrobial-resistant pathogens.

(2) Eligible entities

Eligible entities for grants under paragraph (1) may include hospitals, clinics, institutions of long-term care, professional medical societies, schools or programs that train medical laboratory personnel, or other public or private nonprofit entities.

(3) Technical assistance

The Secretary shall provide appropriate technical assistance to eligible entities that receive grants under paragraph (1).

(f) Monitoring at Federal health care facilities

The Secretary shall encourage reporting on aggregate antimicrobial drug use and antimicrobial resistance to antimicrobial drugs and the implementation of antimicrobial stewardship programs by health care facilities of the Department of Defense, the Department of Veterans Affairs, and the Indian Health Service and shall provide technical assistance to the Secretary of Defense and the Secretary of Veterans Affairs, as appropriate and upon request.

(g) Report on antimicrobial resistance in humans and use of antimicrobial drugs

Not later than 1 year after December 13, 2016, and annually thereafter, the Secretary shall prepare and make publicly available data and information concerning—

(1) aggregate national and regional trends of antimicrobial resistance in humans to antimicrobial drugs, including such drugs approved under section 356(h) of title 21;

(2) antimicrobial stewardship, which may include summaries of State efforts to address antimicrobial resistance in humans to antimicrobial drugs and antimicrobial stewardship; and

(3) coordination between the Director of the Centers for Disease Control and Prevention and the Commissioner of Food and Drugs with respect to the monitoring of—

(A) any applicable resistance under paragraph (1); and

(B) drugs approved under section 356(h) of title 21.

(h) Information related to antimicrobial stewardship programs

The Secretary shall, as appropriate, disseminate guidance, educational materials, or other appropriate materials related to the development and implementation of evidence-based antimicrobial stewardship programs or practices at health care facilities, such as nursing homes and other long-term care facilities, ambulatory surgical centers, dialysis centers, outpatient clinics, and hospitals, including community and rural hospitals.

(i) Supporting State-based activities to combat antimicrobial resistance

The Secretary shall continue to work with State and local public health departments on statewide or regional programs related to antimicrobial resistance. Such efforts may include activities to related to—

(1) identifying patterns of bacterial and fungal resistance in humans to antimicrobial drugs;

(2) preventing the spread of bacterial and fungal infections that are resistant to antimicrobial drugs; and

(3) promoting antimicrobial stewardship.

(j) Antimicrobial resistance and stewardship activities

(1) In general

For the purposes of supporting stewardship activities, examining changes in antimicrobial resistance, and evaluating the effectiveness of section 356(h) of title 21, the Secretary shall—

(A) provide a mechanism for facilities to report data related to their antimicrobial stewardship activities (including analyzing the outcomes of such activities); and

(B) evaluate—

(i) antimicrobial resistance data using a standardized approach; and

(ii) trends in the utilization of drugs approved under such section 356(h) of title 21 with respect to patient populations.

(2) Use of systems

The Secretary shall use available systems, including the National Healthcare Safety Network or other systems identified by the Secretary, to fulfill the requirements or conduct activities under this section.

(k) Network of antibiotic resistance regional laboratories

(1) In general

The Secretary, acting through the Director of the Centers for Disease Control and Prevention, shall, as appropriate, maintain a network of antibiotic resistance laboratory sites to ensure the maintenance of appropriate capabilities, within existing laboratory capacity maintained or supported by the Centers for Disease Control and Prevention, to—

(A) identify and monitor the emergence and changes in the patterns of antimicrobial-resistant pathogens;

(B) detect, identify, confirm, and isolate such resistant pathogens, including, as appropriate, performing such activities upon the request of another laboratory and providing related technical assistance, and, as applicable, support efforts to respond to local or regional outbreaks of such resistant pathogens; and

(C) perform activities to support the diagnosis of such resistant pathogens and determine the susceptibility of relevant pathogen samples to applicable treatments.

(2) Geographic distribution

The Secretary shall ensure that such capacity and capabilities are appropriately distributed among the geographical regions of the United States.

(3) Partnerships and nonduplication of current domestic capacity

Activities supported under this subsection may be based in an academic center, a State health department, or other facility operated by a public or private entity that carries out relevant laboratory or public health surveillance activities.

(l) International collaboration

(1) In general

The Secretary, in coordination with heads of other relevant Federal departments and agencies, shall support activities related to addressing antimicrobial resistance internationally, including by—

(A) supporting basic, translational, epidemiological, and clinical research related to antimicrobial-resistant pathogens, including such pathogens that have not yet been detected in the United States, and improving related public health surveillance systems, and laboratory and other response capacity; and

(B) providing technical assistance related to antimicrobial resistant infection and control activities.

(2) Awards

In carrying out paragraph (1), the Secretary may award grants, contracts, or cooperative agreements to public and private entities, including nongovernmental organizations, with applicable expertise, for purposes of supporting new and innovative approaches to the prevention, detection, and mitigation of antimicrobial-resistant pathogens.

(m) Antimicrobial

For purposes of subsections (f) through (j), the term "antimicrobial" includes any antibacterial or antifungal drugs, and may include drugs that eliminate or inhibit the growth of other microorganisms, as appropriate.

(n) Supplement not supplant

Funds appropriated under this section shall be used to supplement and not supplant other Federal, State, and local public funds provided for activities under this section.

(o) Authorization of appropriations

There are authorized to be appropriated to carry out this section, $40,000,000 for fiscal year 2001, $25,000,000 for each of the fiscal years 2002 and 2003, and such sums as may be necessary for each of the fiscal years 2004 through 2006.

(July 1, 1944, ch. 373, title III, §319E, as added Pub. L. 106–505, title I, §102, Nov. 13, 2000, 114

Stat. 2318; amended Pub. L. 107–188, title I, §109, June 12, 2002, 116 Stat. 610; Pub. L. 114–255, div. A, title III, §3041(a), Dec. 13, 2016, 130 Stat. 1111; Pub. L. 117–328, div. FF, title II, §2234, Dec. 29, 2022, 136 Stat. 5754.)

EDITORIAL NOTES

AMENDMENTS

2022—Subsecs. (k) to (o). Pub. L. 117–328 added subsecs. (k) and (l) and redesignated former subsecs. (k) to (m) as (m) to (o), respectively.

2016—Subsecs. (f) to (m). Pub. L. 114–255 added subsecs. (f) to (k) and redesignated former subsecs. (f) and (g) as (l) and (m), respectively.

2002—Subsec. (b). Pub. L. 107–188, §109(1)(A), in introductory provisions, substituted "shall directly or through awards of grants or cooperative agreements to public or private entities provide for the conduct of" for "shall conduct and support".

Subsec. (b)(4). Pub. L. 107–188, §109(1)(B), amended par. (4) generally. Prior to amendment, par. (4) read as follows: "the sequencing of the genomes of priority pathogens as determined by the Director of the National Institutes of Health in consultation with the task force established under subsection (a) of this section; and".

Subsec. (e)(2). Pub. L. 107–188, §109(2), inserted "schools or programs that train medical laboratory personnel," after "professional medical societies,".

Subsec. (g). Pub. L. 107–188, §109(3), substituted "$25,000,000 for each of the fiscal years 2002 and 2003, and such sums as may be necessary for each of the fiscal years 2004 through 2006" for "and such sums as may be necessary for each subsequent fiscal year through 2006".

STATUTORY NOTES AND RELATED SUBSIDIARIES

CONSTRUCTION OF 2016 AMENDMENT

Nothing in amendment by Pub. L. 114–255 to be construed to restrict the prescribing of antimicrobial drugs or other products, including drugs approved under section 356(h) of Title 21, Food and Drugs, by health care professionals, or to limit the practice of health care, see section 3043 of Pub. L. 114–255, set out as a note under section 356 of Title 21.

ADDITIONAL STRATEGIES FOR COMBATING ANTIBIOTIC RESISTANCE

Pub. L. 116–22, title V, §505, June 24, 2019, 133 Stat. 951, provided that:

"(a) ADVISORY COUNCIL.—The Secretary of Health and Human Services (referred to in this section as the 'Secretary') may continue the Presidential Advisory Council on Combating Antibiotic-Resistant Bacteria, referred to in this section as the 'Advisory Council'.

"(b) DUTIES.—The Advisory Council shall advise and provide information and recommendations to the Secretary regarding programs and policies intended to reduce or combat antibiotic-resistant bacteria that may present a public health threat and improve capabilities to prevent, diagnose, mitigate, or treat such resistance. Such advice, information, and recommendations may be related to improving—

"(1) the effectiveness of antibiotics;

"(2) research and advanced research on, and the development of, improved and innovative methods for combating or reducing antibiotic resistance, including new treatments, rapid point-of-care diagnostics, alternatives to antibiotics, including alternatives to animal antibiotics, and antimicrobial stewardship activities;

"(3) surveillance of antibiotic-resistant bacterial infections, including publicly available and up-to-date information on resistance to antibiotics;

"(4) education for health care providers and the public with respect to up-to-date information on antibiotic resistance and ways to reduce or combat such resistance to antibiotics related to humans and animals;

"(5) methods to prevent or reduce the transmission of antibiotic-resistant bacterial infections, including stewardship programs; and

"(6) coordination with respect to international efforts in order to inform and advance United States capabilities to combat antibiotic resistance.

"(c) MEETINGS AND COORDINATION.—

"(1) MEETINGS.—The Advisory Council shall meet not less than biannually and, to the extent

practicable, in coordination with meetings of the Antimicrobial Resistance Task Force established in section 319E(a) of the Public Health Service Act [42 U.S.C. 247d–5(a)].

"(2) COORDINATION.—The Advisory Council shall, to the greatest extent practicable, coordinate activities carried out by the Council with the Antimicrobial Resistance Task Force established under section 319E(a) of the Public Health Service Act (42 U.S.C. 247d–5(a)).

"(d) FACA.—The Federal Advisory Committee Act ([former] 5 U.S.C. App.) [see 5 U.S.C. 1001 et seq.] shall apply to the activities and duties of the Advisory Council.

"(e) EXTENSION OF ADVISORY COUNCIL.—Not later than October 1, 2022, the Secretary shall submit to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives a recommendation on whether the Advisory Council should be extended, and in addition, identify whether there are other committees, councils, or task forces that have overlapping or similar duties to that of the Advisory Council, and whether such committees, councils, or task forces should be combined, including with respect to section 319E(a) of the Public Health Service Act (42 U.S.C. 247d–5(a))."

AVAILABILITY OF DATA

Pub. L. 114–255, div. A, title III, §3041(b), Dec. 13, 2016, 130 Stat. 1112, provided that: "The Secretary shall make the data collected pursuant to this subsection [probably refers to the amendments made to this section by section 3041(a) of Pub. L. 114–255] public. Nothing in this subsection shall be construed as authorizing the Secretary to disclose any information that is a trade secret or confidential information subject to section 552(b)(4) of title 5, United States Code, or section 1905 of title 18, United States Code."

EXECUTIVE DOCUMENTS

EX. ORD. NO. 13676. COMBATING ANTIBIOTIC-RESISTANT BACTERIA

Ex. Ord. No. 13676, Sept. 18, 2014, 79 F.R. 56931, provided:

By the authority vested in me as President by the Constitution and the laws of the United States of America, I hereby order as follows:

SECTION 1. *Policy*. The discovery of antibiotics in the early 20th century fundamentally transformed human and veterinary medicine. Antibiotics save millions of lives each year in the United States and around the world. The rise of antibiotic-resistant bacteria, however, represents a serious threat to public health and the economy. The Centers for Disease Control and Prevention (CDC) in the Department of Health and Human Services (HHS) estimates that annually at least two million illnesses and 23,000 deaths are caused by antibiotic-resistant bacteria in the United States alone.

Detecting, preventing, and controlling antibiotic resistance requires a strategic, coordinated, and sustained effort. It also depends on the engagement of governments, academia, industry, healthcare providers, the general public, and the agricultural community, as well as international partners. Success in this effort will require significant efforts to: minimize the emergence of antibiotic-resistant bacteria; preserve the efficacy of new and existing antibacterial drugs; advance research to develop improved methods for combating antibiotic resistance and conducting antibiotic stewardship; strengthen surveillance efforts in public health and agriculture; develop and promote the use of new, rapid diagnostic technologies; accelerate scientific research and facilitate the development of new antibacterial drugs, vaccines, diagnostics, and other novel therapeutics; maximize the dissemination of the most up-to-date information on the appropriate and proper use of antibiotics to the general public and healthcare providers; work with the pharmaceutical industry to include information on the proper use of over-the-counter and prescription antibiotic medications for humans and animals; and improve international collaboration and capabilities for prevention, surveillance, stewardship, basic research, and drug and diagnostics development.

The Federal Government will work domestically and internationally to detect, prevent, and control illness and death related to antibiotic-resistant infections by implementing measures that reduce the emergence and spread of antibiotic-resistant bacteria and help ensure the continued availability of effective therapeutics for the treatment of bacterial infections.

SEC. 2. *Oversight and Coordination*. Combating antibiotic-resistant bacteria is a national security priority. The National Security Council staff, in collaboration with the Office of Science and Technology Policy, the Domestic Policy Council, and the Office of Management and Budget, shall coordinate the development and implementation of Federal Government policies to combat antibiotic-resistant bacteria, including the activities, reports, and recommendations of the Task Force for Combating Antibiotic-Resistant Bacteria established in section 3 of this order.

SEC. 3. *Task Force for Combating Antibiotic-Resistant Bacteria*. There is hereby established the Task

Force for Combating Antibiotic-Resistant Bacteria (Task Force), to be co-chaired by the Secretaries of Defense, Agriculture, and HHS.

(a) Membership. In addition to the Co-Chairs, the Task Force shall consist of representatives from:

(i) the Department of State;

(ii) the Department of Justice;

(iii) the Department of Veterans Affairs;

(iv) the Department of Homeland Security;

(v) the Environmental Protection Agency;

(vi) the United States Agency for International Development;

(vii) the Office of Management and Budget;

(viii) the Domestic Policy Council;

(ix) the National Security Council staff;

(x) the Office of Science and Technology Policy;

(xi) the National Science Foundation; and

(xii) such executive departments, agencies, or offices as the Co-Chairs may designate.

Each executive department, agency, or office represented on the Task Force (Task Force agency) shall designate an employee of the Federal Government to perform the functions of the Task Force. In performing its functions, the Task Force may make use of existing interagency task forces on antibiotic resistance.

(b) *Mission.* The Task Force shall identify actions that will provide for the facilitation and monitoring of implementation of this order and the National Strategy for Combating Antibiotic-Resistant Bacteria (Strategy).

(c) *Functions.*

(i) By February 15, 2015, the Task Force shall submit a 5-year National Action Plan (Action Plan) to the President that outlines specific actions to be taken to implement the Strategy. The Action Plan shall include goals, milestones, and metrics for measuring progress, as well as associated timelines for implementation. The Action Plan shall address recommendations made by the President's Council of Advisors on Science and Technology regarding combating antibiotic resistance.

(ii) Within 180 days of the release of the Action Plan and each year thereafter, the Task Force shall provide the President with an update on Federal Government actions to combat antibiotic resistance consistent with this order, including progress made in implementing the Strategy and Action Plan, plans for addressing any barriers preventing full implementation of the Strategy and Action Plan, and recommendations for new or modified actions. Annual updates shall include specific goals, milestones, and metrics for all proposed actions and recommendations. The Task Force shall take Federal Government resources into consideration when developing these proposed actions and recommendations.

(iii) In performing its functions, the Task Force shall review relevant statutes, regulations, policies, and programs, and shall consult with relevant domestic and international organizations and experts, as necessary.

(iv) The Task Force shall conduct an assessment of progress made towards achieving the milestones and goals outlined in the Strategy in conjunction with the Advisory Council established pursuant to section 4 of this order.

SEC. 4. *Presidential Advisory Council on Combating Antibiotic-Resistant Bacteria*. (a) The Secretary of HHS (Secretary), in consultation with the Secretaries of Defense and Agriculture, shall establish the Presidential Advisory Council on Combating Antibiotic-Resistant Bacteria (Advisory Council). The Advisory Council shall be composed of not more than 30 members to be appointed or designated by the Secretary.

(b) The Secretary shall designate a chairperson from among the members of the Advisory Council.

(c) The Advisory Council shall provide advice, information, and recommendations to the Secretary regarding programs and policies intended to: preserve the effectiveness of antibiotics by optimizing their use; advance research to develop improved methods for combating antibiotic resistance and conducting antibiotic stewardship; strengthen surveillance of antibiotic-resistant bacterial infections; prevent the transmission of antibiotic-resistant bacterial infections; advance the development of rapid point-of-care and agricultural diagnostics; further research on new treatments for bacterial infections; develop alternatives to antibiotics for agricultural purposes; maximize the dissemination of up-to-date information on the appropriate and proper use of antibiotics to the general public and human and animal healthcare providers; and improve international coordination of efforts to combat antibiotic resistance. The Secretary shall provide the President with all written reports created by the Advisory Council.

(d) Task Force agencies shall, to the extent permitted by law, provide the Advisory Council with such information as it may require for purposes of carrying out its functions.

(e) To the extent permitted by law, and subject to the availability of appropriations, HHS shall provide the Advisory Council with such funds and support as may be necessary for the performance of its functions.

SEC. 5. *Improved Antibiotic Stewardship*. (a) By the end of calendar year 2016, HHS shall review existing regulations and propose new regulations or other actions, as appropriate, that require hospitals and other inpatient healthcare delivery facilities to implement robust antibiotic stewardship programs that adhere to best practices, such as those identified by the CDC. HHS shall also take steps to encourage other healthcare facilities, such as ambulatory surgery centers and dialysis facilities, to adopt antibiotic stewardship programs.

(b) Task Force agencies shall, as appropriate, define, promulgate, and implement stewardship programs in other healthcare settings, including office-based practices, outpatient settings, emergency departments, and institutional and long-term care facilities such as nursing homes, pharmacies, and correctional facilities.

(c) By the end of calendar year 2016, the Department of Defense (DoD) and the Department of Veterans Affairs (VA) shall review their existing regulations and, as appropriate, propose new regulations and other actions that require their hospitals and long-term care facilities to implement robust antibiotic stewardship programs that adhere to best practices, such as those defined by the CDC. DoD and the VA shall also take steps to encourage their other healthcare facilities, such as ambulatory surgery centers and outpatient clinics, to adopt antibiotic stewardship programs.

(d) Task Force agencies shall, as appropriate, monitor improvements in antibiotic use through the National Healthcare Safety Network and other systems.

(e) The Food and Drug Administration (FDA) in HHS, in coordination with the Department of Agriculture (USDA), shall continue taking steps to eliminate the use of medically important classes of antibiotics for growth promotion purposes in food-producing animals.

(f) USDA, the Environmental Protection Agency (EPA), and FDA shall strengthen coordination in common program areas, such as surveillance of antibiotic use and resistance patterns in food-producing animals, inter-species disease transmissibility, and research findings.

(g) DoD, HHS, and the VA shall review existing regulations and propose new regulations and other actions, as appropriate, to standardize the collection and sharing of antibiotic resistance data across all their healthcare settings.

SEC. 6. *Strengthening National Surveillance Efforts for Resistant Bacteria*. (a) The Task Force shall ensure that the Action Plan includes procedures for creating and integrating surveillance systems and laboratory networks to provide timely, high-quality data across healthcare and agricultural settings, including detailed genomic and other information, adequate to track resistant bacteria across diverse settings. The network-integrated surveillance systems and laboratory networks shall include common information requirements, repositories for bacteria isolates and other samples, a curated genomic database, rules for access to samples and scientific data, standards for electronic health record-based reporting, data transparency, budget coordination, and international coordination.

(b) Task Force agencies shall, as appropriate, link data from Federal Government sample isolate repositories for bacteria strains to an integrated surveillance system, and, where feasible, the repositories shall enhance their sample collections and further interoperable data systems with national surveillance efforts.

(c) USDA, EPA, and FDA shall work together with stakeholders to monitor and report on changes in antibiotic use in agriculture and their impact on the environment.

(d) Task Force agencies shall, as appropriate, monitor antibiotic resistance in healthcare settings through the National Healthcare Safety Network and related systems.

SEC. 7. *Preventing and Responding to Infections and Outbreaks with Antibiotic-Resistant Organisms*. (a) Task Force agencies shall, as appropriate, utilize the enhanced surveillance activities described in section 6 of this order to prevent antibiotic-resistant infections by: actively identifying and responding to antibiotic-resistant outbreaks; preventing outbreaks and transmission of antibiotic-resistant infections in healthcare, community, and agricultural settings through early detection and tracking of resistant organisms; and identifying and evaluating additional strategies in the healthcare and community settings for the effective prevention and control of antibiotic-resistant infections.

(b) Task Force agencies shall take steps to implement the measures and achieve the milestones outlined in the Strategy and Action Plan.

(c) DoD, HHS, and the VA shall review and, as appropriate, update their hospital and long-term care infectious disease protocols for identifying, isolating, and treating antibiotic-resistant bacterial infection cases.

SEC. 8. *Promoting New and Next Generation Antibiotics and Diagnostics*. (a) As part of the Action Plan, the Task Force shall describe steps that agencies can take to encourage the development of new and next-generation antibacterial drugs, diagnostics, vaccines, and novel therapeutics for both the public and agricultural sectors, including steps to develop infrastructure for clinical trials and options for attracting greater private investment in the development of new antibiotics and rapid point-of-care diagnostics. Task Force agency efforts shall focus on addressing areas of unmet medical need for individuals, including those antibiotic-resistant bacteria CDC has identified as public and agricultural health threats.

(b) Together with the countermeasures it develops for biodefense threats, the Biomedical Advanced Research Development Authority in HHS shall develop new and next-generation countermeasures that target antibiotic-resistant bacteria that present a serious or urgent threat to public health.

(c) The Public Health Emergency Medical Countermeasures Enterprise in HHS shall, as appropriate, coordinate with Task Force agencies' efforts to promote new and next-generation countermeasures to target antibiotic-resistant bacteria that present a serious or urgent threat to public health.

SEC. 9. *International Cooperation*. Within 30 days of the date of this order, the Secretaries of State, USDA, and HHS shall designate representatives to engage in international action to combat antibiotic-resistant bacteria, including the development of the World Health Organization (WHO) Global Action Plan for Antimicrobial Resistance with the WHO, Member States, and other relevant organizations. The Secretaries of State, USDA, and HHS shall conduct a review of international collaboration activities and partnerships, and identify and pursue opportunities for enhanced prevention, surveillance, research and development, and policy engagement. All Task Force agencies with research and development activities related to antibiotic resistance shall, as appropriate, expand existing bilateral and multilateral scientific cooperation and research pursuant to the Action Plan.

SEC. 10. *General Provisions*. (a) This order shall be implemented consistent with applicable law and subject to the availability of appropriations.

(b) Nothing in this order shall be construed to impair or otherwise affect:

(i) the authority granted by law to an executive department or agency, or the head thereof; or

(ii) the functions of the Director of the Office of Management and Budget relating to budgetary, administrative, or legislative proposals.

(c) This order is not intended to, and does not, create any right or benefit, substantive or procedural, enforceable at law or in equity by any party against the United States, its departments, agencies, or entities, its officers, employees, or agents, or any other person.

(d) Insofar as the Federal Advisory Committee Act, as amended ([former] 5 U.S.C. App.) [see 5 U.S.C. 1001 et seq.] (the "Act"), may apply to the Advisory Council, any functions of the President under the Act, except for that of reporting to the Congress, shall be performed by the Secretary in accordance with the guidelines issued by the Administrator of General Services.

BARACK OBAMA.

EXTENSION OF TERM OF PRESIDENTIAL ADVISORY COUNCIL ON COMBATING ANTIBIOTIC-RESISTANT BACTERIA

Term of Presidential Advisory Council on Combating Antibiotic-Resistant Bacteria extended until Sept. 30, 2019, by Ex. Ord. No. 13811, Sept. 29, 2017, 82 F.R. 46363, formerly set out as a note under section 1013 of Title 5, Government Organization and Employees.

Previous extension of term of Presidential Advisory Council on Combating Antibiotic-Resistant Bacteria was contained in the following prior Executive Order:

Ex. Ord. No. 13708, Sept. 30, 2015, 80 F.R. 60271, extended term until Sept. 30, 2017.

DELEGATION OF AUTHORITY TO RE-ESTABLISH THE PRESIDENTIAL ADVISORY COUNCIL ON COMBATING ANTIBIOTIC-RESISTANT BACTERIA

Memorandum of President of the United States, Mar. 3, 2020, 85 F.R. 13469, provided:

Memorandum for the Secretary of Health and Human Services

By the authority vested in me as President by the Constitution and the laws of the United States of America, including section 301 of title 3, United States Code, it is hereby ordered as follows:

SECTION 1. *Delegation of Re-establishment Authority*. The Secretary of Health and Human Services is delegated the authority under section 9(a)(1) of the Federal Advisory Committee Act, as amended ([former] 5 U.S.C. App.) [see 5 U.S.C. 1008(a)(1)], to re-establish the Presidential Advisory Council on Combating Antibiotic-Resistant Bacteria (Council). In exercising this authority, the Secretary may direct the Council to perform duties consistent with those assigned to the Council in section 505(b) of Public Law 116–22 [42 U.S.C. 247d–5 note], and may, at the Secretary's discretion, specify the membership of the Council, consistent with the requirements of the Federal Advisory Committee Act, as amended ([former] 5 U.S.C. App.) [see 5 U.S.C. 1001 et seq.].

SEC. 2. *General Provisions*. (a) Nothing in this memorandum shall be construed to impair or otherwise affect:

(i) the authority granted by law to an executive department or agency, or the head thereof; or

(ii) the functions of the Director of the Office of Management and Budget relating to budgetary, administrative, or legislative proposals.

(b) This memorandum shall be implemented consistent with applicable law and subject to the availability of appropriations.

(c) This memorandum is not intended to, and does not, create any right or benefit, substantive or procedural, enforceable at law or in equity by any party against the United States, its departments, agencies, or entities, its officers, employees, or agents, or any other person.

(d) You are hereby authorized and directed to publish this memorandum in the Federal Register.

DONALD J. TRUMP.

§247d–5a. Repealed. Pub. L. 114–255, div. A, title III, §3044(b)(1), Dec. 13, 2016, 130 Stat. 1121

Section, Pub. L. 110–85, title XI, §1111, Sept. 27, 2007, 121 Stat. 975, related to identification of clinically susceptible concentrations of antimicrobials. See section 360a–2 of Title 21, Food and Drugs.

§247d–6. Public health countermeasures to a bioterrorist attack

(a) All-hazards public health and medical response curricula and training

(1) In general

The Secretary, in collaboration with the Secretary of Defense, and in consultation with relevant public and private entities, shall develop core health and medical response curricula and trainings by adapting applicable existing curricula and training programs to improve responses to public health emergencies.

(2) Curriculum

The public health and medical response training program may include course work related to—

(A) medical management of casualties, taking into account the needs of at-risk individuals;

(B) public health aspects of public health emergencies;

(C) mental health aspects of public health emergencies;

(D) national incident management, including coordination among Federal, State, local, tribal, international agencies, and other entities; and

(E) protecting health care workers and health care first responders from workplace exposures during a public health emergency.

(3) Peer review

On a periodic basis, products prepared as part of the program shall be rigorously tested and peer-reviewed by experts in the relevant fields.

(4) Credit

The Secretary and the Secretary of Defense shall—

(A) take into account continuing professional education requirements of public health and healthcare professions; and

(B) cooperate with State, local, and tribal accrediting agencies and with professional associations in arranging for students enrolled in the program to obtain continuing professional education credit for program courses.

(5) Dissemination and training

(A) In general

The Secretary may provide for the dissemination and teaching of the materials described in paragraphs (1) and (2) by appropriate means, as determined by the Secretary.

(B) Certain entities

The education and training activities described in subparagraph (A) may be carried out by Federal public health, medical, or dental entities, appropriate educational entities, professional

organizations and societies, private accrediting organizations, and other nonprofit institutions or entities meeting criteria established by the Secretary.

(C) Grants and contracts

In carrying out this subsection, the Secretary may carry out activities directly or through the award of grants and contracts, and may enter into interagency agreements with other Federal agencies.

(b) Advice to the Federal Government

(1) Required advisory committees

In coordination with the working group under subsection (a), the Secretary shall establish advisory committees in accordance with paragraphs (2) and (3) to provide expert recommendations to assist such working groups in carrying out their respective responsibilities under subsections (a) and (b).

(2) National Advisory Committee on At-Risk Individuals and Public Health Emergencies

(A) In general

For purposes of paragraph (1), the Secretary shall establish an advisory committee to be known as the National Advisory Committee on At-Risk Individuals and Public Health Emergencies (referred to in this paragraph as the "Advisory Committee").

(B) Duties

The Advisory Committee shall provide recommendations regarding—

(i) the preparedness of the health care (including mental health care) system to respond to public health emergencies as they relate to at-risk individuals;

(ii) needed changes to the health care and emergency medical service systems and emergency medical services protocols to meet the special needs of at-risk individuals; and

(iii) changes, if necessary, to the national stockpile under section 300hh–12 of this title to meet the emergency health security of at-risk individuals.

(C) Composition

The Advisory Committee shall be composed of such Federal officials as may be appropriate to address the special needs of the diverse population groups of at-risk populations.

(D) Termination

The Advisory Committee terminates six years after June 12, 2002.

(3) Emergency Public Information and Communications Advisory Committee

(A) In general

For purposes of paragraph (1), the Secretary shall establish an advisory committee to be known as the Emergency Public Information and Communications Advisory Committee (referred to in this paragraph as the "EPIC Advisory Committee").

(B) Duties

The EPIC Advisory Committee shall make recommendations to the Secretary and report on appropriate ways to communicate public health information regarding bioterrorism and other public health emergencies to the public.

(C) Composition

The EPIC Advisory Committee shall be composed of individuals representing a diverse group of experts in public health, medicine, communications, behavioral psychology, and other areas determined appropriate by the Secretary.

(D) Dissemination

The Secretary shall review the recommendations of the EPIC Advisory Committee and ensure that appropriate information is disseminated to the public.

(E) Termination

The EPIC Advisory Committee terminates one year after June 12, 2002.

(c) Expansion of Epidemic Intelligence Service Program

The Secretary may establish 20 officer positions in the Epidemic Intelligence Service Program, in addition to the number of the officer positions offered under such Program in 2006, for individuals who agree to participate, for a period of not less than 2 years, in the Career Epidemiology Field Officer program in a State, local, or tribal health department that serves a health professional shortage area (as defined under section 254e(a) of this title), a medically underserved population (as defined under section 254b(b)(3) of this title), or a medically underserved area or area at high risk of a public health emergency as designated by the Secretary.

(d) Centers for Public Health Preparedness and Response

(1) In general

The Secretary, acting through the Director of the Centers for Disease Control and Prevention, may award grants, contracts, or cooperative agreements to institutions of higher education, including accredited schools of public health, or other nonprofit private entities to establish or maintain a network of Centers for Public Health Preparedness and Response (referred to in this subsection as "Centers").

(2) Eligibility

To be eligible to receive an award under this subsection, an entity shall submit to the Secretary an application containing such information as the Secretary may require, including a description of how the entity will—

(A) coordinate relevant activities with applicable State, local, and Tribal health departments and officials, health care facilities, and health care coalitions to improve public health preparedness and response, as informed by the public health preparedness and response needs of the community, or communities, involved;

(B) prioritize efforts to implement evidence-informed or evidence-based practices to improve public health preparedness and response, including by helping to reduce the transmission of emerging infectious diseases; and

(C) use funds awarded under this subsection, including by carrying out any activities described in paragraph (3).

(3) Use of funds

The Centers established or maintained under this subsection shall use funds awarded under this subsection to carry out activities to advance public health preparedness and response capabilities, which may include—

(A) identifying, translating, and disseminating promising research findings or strategies into evidence-informed or evidence-based practices to inform preparedness for, and responses to, chemical, biological, radiological, or nuclear threats, including emerging infectious diseases, and other public health emergencies, which may include conducting research related to public health preparedness and response systems;

(B) improving awareness of such evidence-informed or evidence-based practices and other relevant scientific or public health information among health care professionals, public health professionals, other stakeholders, and the public, including through the development, evaluation, and dissemination of trainings and training materials, consistent with section 300hh–1(b)(2) of this title, as applicable and appropriate, and with consideration given to existing training materials, to support preparedness for, and responses to, such threats;

(C) utilizing and expanding relevant technological and analytical capabilities to inform public health and medical preparedness and response efforts;

(D) expanding activities, including through public-private partnerships, related to public health preparedness and response, including participation in drills and exercises and training public health experts, as appropriate; and

(E) providing technical assistance and expertise that relies on evidence-based practices, as applicable, related to responses to public health emergencies, as appropriate, to State, local, and Tribal health departments and other entities pursuant to paragraph (2)(A).

(4) Distribution of awards

In awarding grants, contracts, or cooperative agreements under this subsection, the Secretary shall support not fewer than 10 Centers, subject to the availability of appropriations, and ensure that such awards are equitably distributed among the geographical regions of the United States.

(e) Accelerated research and development on priority pathogens and countermeasures

(1) In general

With respect to pathogens of potential use in a bioterrorist attack, and other agents that may cause a public health emergency, the Secretary, taking into consideration any recommendations of the working group under subsection (a), shall conduct, and award grants, contracts, or cooperative agreements for, research, investigations, experiments, demonstrations, and studies in the health sciences relating to—

(A) the epidemiology and pathogenesis of such pathogens;

(B) the sequencing of the genomes, or other DNA analysis, or other comparative analysis, of priority pathogens (as determined by the Director of the National Institutes of Health in consultation with the working group established in subsection (a)), in collaboration and coordination with the activities of the Department of Defense and the Joint Genome Institute of the Department of Energy;

(C) the development of priority countermeasures; and

(D) other relevant areas of research;

with consideration given to the needs of children and other vulnerable populations.

(2) Priority

The Secretary shall give priority under this section to the funding of research and other studies related to priority countermeasures.

(3) Role of Department of Veterans Affairs

In carrying out paragraph (1), the Secretary shall consider using the biomedical research and development capabilities of the Department of Veterans Affairs, in conjunction with that Department's affiliations with health-professions universities. When advantageous to the Government in furtherance of the purposes of such paragraph, the Secretary may enter into cooperative agreements with the Secretary of Veterans Affairs to achieve such purposes.

(4) Priority countermeasures

For purposes of this section, the term "priority countermeasure" means a drug, biological product, device, vaccine, vaccine adjuvant, antiviral, or diagnostic test that the Secretary determines to be—

(A) a priority to treat, identify, or prevent infection by a biological agent or toxin listed pursuant to section 262a(a)(1) of this title, or harm from any other agent that may cause a public health emergency; or

(B) a priority to treat, identify, or prevent conditions that may result in adverse health consequences or death and may be caused by the administering of a drug, biological product, device, vaccine, vaccine adjuvant, antiviral, or diagnostic test that is a priority under subparagraph (A).

(f) Authorization of appropriations

(1) Fiscal year 2007

There are authorized to be appropriated to carry out this section for fiscal year 2007—

(A) to carry out subsection (a)—

(i) $5,000,000 to carry out paragraphs (1) through (4); and

(ii) $7,000,000 to carry out paragraph (5);

(B) to carry out subsection (c), $3,000,000; and
(C) to carry out subsection (d), $31,000,000.

(2) Subsequent fiscal years

There are authorized to be appropriated such sums as may be necessary to carry out this section for fiscal year 2008 and each subsequent fiscal year.

(July 1, 1944, ch. 373, title III, §319F, as added Pub. L. 106–505, title I, §102, Nov. 13, 2000, 114 Stat. 2321; amended Pub. L. 107–188, title I, §§104(a) 105, 108, 111(3), 125, June 12, 2002, 116 Stat. 605, 606, 609, 611, 614; Pub. L. 108–276, §2(d), July 21, 2004, 118 Stat. 842; Pub. L. 109–417, title III, §§301(d), (e), 304, Dec. 19, 2006, 120 Stat. 2854, 2855, 2859; Pub. L. 113–5, title II, §203(a), Mar. 13, 2013, 127 Stat. 175; Pub. L. 117–328, div. FF, title II, §2231(a), Dec. 29, 2022, 136 Stat. 5752.)

EDITORIAL NOTES

AMENDMENTS

2022—Subsec. (d). Pub. L. 117–328, §2231(a)(1), added subsec. (d) and struck out former subsec. (d) which authorized Secretary to establish Centers for Public Health Preparedness at accredited schools of public health.

Subsec. (f)(1)(C). Pub. L. 117–328, §2231(a)(2), struck out ", of which $5,000,000 shall be used to carry out paragraphs (3) through (5) of such subsection" after "$31,000,000".

2013—Subsec. (a)(5)(B). Pub. L. 113–5 substituted "public health, medical, or dental" for "public health or medical".

2006—Subsec. (a). Pub. L. 109–417, §304(1), added subsec. (a) and struck out heading and text of former subsec. (a) which established a working group on bioterrorism and other public health emergencies.

Subsec. (b)(2). Pub. L. 109–417, §301(d)(1), substituted "At-Risk Individuals and Public Health Emergencies" for "Children and Terrorism" in heading.

Subsec. (b)(2)(A). Pub. L. 109–417, §301(d)(2), substituted "At-Risk Individuals and Public Health Emergencies" for "Children and Terrorism".

Subsec. (b)(2)(B)(i). Pub. L. 109–417, §301(d)(3)(A), substituted "public health emergencies as they relate to at-risk individuals" for "bioterrorism as it relates to children".

Subsec. (b)(2)(B)(ii), (iii). Pub. L. 109–417, §301(d)(3)(B), (C), substituted "at-risk individuals" for "children".

Subsec. (b)(2)(C). Pub. L. 109–417, §301(d)(4), substituted "at-risk populations" for "children, and child health experts on infectious disease, environmental health, toxicology, and other relevant professional disciplines".

Subsec. (b)(2)(D). Pub. L. 109–417, §301(d)(5), substituted "six years" for "one year".

Subsec. (b)(3)(B). Pub. L. 109–417, §301(e), struck out "and the working group under subsection (a) of this section" after "Secretary".

Subsecs. (c) to (h). Pub. L. 109–417, §304(2)–(4), added subsecs. (c), (d), and (f), redesignated subsec. (h) as (e), and struck out former subsecs. (c) to (g), which related to: in subsec. (c), development of communication strategy; in subsec. (d), Federal Internet site on bioterrorism; in subsec. (e), grants to increase capacity to detect, diagnose, and respond to acts of bioterrorism; in subsec. (f), assistance to State and local health agencies to enable effective response to attacks; and, in subsec. (g), education and training activities.

Subsecs. (i), (j). Pub. L. 109–417, §304(5), struck out subsecs. (i) and (j) which related to report to congressional committees on public health and medical consequences of a bioterrorist attack and the supplementary nature of funds appropriated under this section, respectively.

2004—Subsec. (a)(1). Pub. L. 108–276, §2(d)(1), inserted "the Secretary of Homeland Security," after "Management Agency," in introductory provisions.

Subsec. (h)(4)(B). Pub. L. 108–276, §2(d)(2), substituted "to treat, identify, or prevent conditions" for "to diagnose conditions".

2002—Subsec. (a). Pub. L. 107–188, §108, added subsec. (a) and struck out heading and text of former subsec. (a). Text read as follows: "The Secretary, in coordination with the Secretary of Defense, shall establish a joint interdepartmental working group on preparedness and readiness for the medical and public health

effects of a bioterrorist attack on the civilian population. Such joint working group shall—

"(1) coordinate research on pathogens likely to be used in a bioterrorist attack on the civilian population as well as therapies to treat such pathogens;

"(2) coordinate research and development into equipment to detect pathogens likely to be used in a bioterrorist attack on the civilian population and protect against infection from such pathogens;

"(3) develop shared standards for equipment to detect and to protect against infection from pathogens likely to be used in a bioterrorist attack on the civilian population; and

"(4) coordinate the development, maintenance, and procedures for the release of, strategic reserves of vaccines, drugs, and medical supplies which may be needed rapidly after a bioterrorist attack upon the civilian population."

Subsec. (b). Pub. L. 107–188, §104(a)(1), (3), added subsec. (b) and struck out former subsec. (b) which related to establishment, functions, membership, and coordination of a working group on the public health and medical consequences of bioterrorism.

Subsecs. (c), (d). Pub. L. 107–188, §104(a)(3), added subsecs. (c) and (d). Former subsecs. (c) and (d) redesignated (e) and (f), respectively.

Subsec. (e). Pub. L. 107–188, §104(a)(2), redesignated subsec. (c) as (e). Former subsec. (e) redesignated (g).

Subsec. (e)(2). Pub. L. 107–188, §111(3), which directed the amendment of section 391F(e)(2) of the Public Health Service Act by striking out "or" after "clinic," and inserting before period ", professional organization or society, school or program that trains medical laboratory personnel, private accrediting organization, or other nonprofit private institution or entity meeting criteria established by the Secretary", was executed to subsec. (e)(2) of this section, which is section 319F(e)(2) of the Act, to reflect the probable intent of Congress.

Subsec. (f). Pub. L. 107–188, §104(a)(2), redesignated subsec. (d) as (f). Former subsec. (f) redesignated (h).

Subsec. (g). Pub. L. 107–188, §105, amended heading and text of subsec. (g) generally. Prior to amendment, text read as follows: "The Secretary, in collaboration with members of the working group described in subsection (b) of this section, and professional organizations and societies, shall—

"(1) develop and implement educational programs to instruct public health officials, medical professionals, and other personnel working in health care facilities in the recognition and care of victims of a bioterrorist attack; and

"(2) develop and implement programs to train laboratory personnel in the recognition and identification of a potential bioweapon."

Pub. L. 107–188, §104(a)(2), redesignated subsec. (e) as (g). Former subsec. (g) redesignated (i).

Subsec. (h). Pub. L. 107–188, §125, amended heading and text of subsec. (h) generally. Prior to amendment, text read as follows: "The Secretary shall consult with the working group described in subsection (a) of this section, to develop priorities for and conduct research, investigations, experiments, demonstrations, and studies in the health sciences related to—

"(1) the epidemiology and pathogenesis of potential bioweapons;

"(2) the development of new vaccines or other therapeutics against pathogens likely to be used in a bioterrorist attack;

"(3) the development of medical diagnostics to detect potential bioweapons; and

"(4) other relevant research areas."

Pub. L. 107–188, §104(a)(2), redesignated subsec. (f) as (h). Former subsec. (h) redesignated (j).

Subsec. (i). Pub. L. 107–188, §104(a)(1), (2), redesignated subsec. (g) as (i) and struck out heading and text of former subsec. (i). Text read as follows: "There are authorized to be appropriated to carry out this section $215,000,000 for fiscal year 2001, and such sums as may be necessary for each subsequent fiscal year through 2006."

Subsec. (j). Pub. L. 107–188, §104(a)(2), redesignated subsec. (h) as (j).

STATUTORY NOTES AND RELATED SUBSIDIARIES

OTHER REPORTS

Pub. L. 107–188, title I, §101(b)(1), June 12, 2002, 116 Stat. 598, provided that:

"(1) IN GENERAL.—Not later than one year after the date of the enactment of this Act [June 12, 2002], the Secretary of Health and Human Services (referred to in this subsection as the 'Secretary') shall submit to the Committee on Energy and Commerce of the House of Representatives, and the Committee on Health, Education, Labor, and Pensions of the Senate, a report concerning—

"(A) the recommendations and findings of the National Advisory Committee on Children and Terrorism under section 319F(c)(2) of the Public Health Service Act [probably means section 319F(b)(2), 42 U.S.C. 247d–6(b)(2)];

"(B) the recommendations and findings of the EPIC Advisory Committee under section 319F(c)(3) of such Act [probably means section 319F(b)(3), 42 U.S.C. 247d–6(b)(3)];

"(C) the characteristics that may render a rural community uniquely vulnerable to a biological attack, including distance, lack of emergency transport, hospital or laboratory capacity, lack of integration of Federal or State public health networks, workforce deficits, or other relevant characteristics;

"(D) the characteristics that may render areas or populations designated as medically underserved populations (as defined in section 330 of such Act [42 U.S.C. 254b]) uniquely vulnerable to a biological attack, including significant numbers of low-income or uninsured individuals, lack of affordable and accessible health care services, insufficient public and primary health care resources, lack of integration of Federal or State public health networks, workforce deficits, or other relevant characteristics;

"(E) the recommendations of the Secretary with respect to additional legislative authority that the Secretary determines is necessary to effectively strengthen rural communities, or medically underserved populations (as defined in section 330 of such Act); and

"(F) the need for and benefits of a National Disaster Response Medical Volunteer Service that would be a private-sector, community-based rapid response corps of medical volunteers."

STUDY REGARDING COMMUNICATIONS ABILITIES OF PUBLIC HEALTH AGENCIES

Pub. L. 107–188, title I, §104(b), June 12, 2002, 116 Stat. 606, provided that: "The Secretary of Health and Human Services, in consultation with the Federal Communications Commission, the National Telecommunications and Information Administration, and other appropriate Federal agencies, shall conduct a study to determine whether local public health entities have the ability to maintain communications in the event of a bioterrorist attack or other public health emergency. The study shall examine whether redundancies are required in the telecommunications system, particularly with respect to mobile communications, for public health entities to maintain systems operability and connectivity during such emergencies. The study shall also include recommendations to industry and public health entities about how to implement such redundancies if necessary."

§247d–6a. Authority for use of certain procedures regarding qualified countermeasure research and development activities

(a) In general

(1) Authority

In conducting and supporting research and development activities regarding countermeasures under section 247d–6(e) of this title, the Secretary may conduct and support such activities in accordance with this section and, in consultation with the Director of the National Institutes of Health, as part of the program under section 285f of this title, if the activities concern qualified countermeasures.

(2) Definitions

In this section:

(A) Qualified countermeasure

The term "qualified countermeasure" means a drug (as that term is defined by section 321(g)(1) of title 21), biological product (as that term is defined by section 262(i) of this title), or device (as that term is defined by section 321(h) of title 21), that the Secretary determines to be a priority (consistent with sections 182(2) and 184(a) of title 6)—

(i) to diagnose, mitigate, prevent, or treat harm from any biological agent (including organisms that cause an infectious disease) or toxin, chemical, radiological, or nuclear agent that may cause a public health emergency affecting national security;

(ii) to diagnose, mitigate, prevent, or treat harm from a condition that may result in adverse health consequences or death and may be caused by administering a drug, biological product, or device that is used as described in this subparagraph; or

(iii) is a product or technology intended to enhance the use or effect of a drug, biological product, or device described in clause (i) or (ii).

(B) Infectious disease

The term "infectious disease" means a disease potentially caused by a pathogenic organism (including a bacteria, virus, fungus, or parasite) that is acquired by a person and that reproduces in that person.

(3) Interagency cooperation

(A) In general

In carrying out activities under this section, the Secretary is authorized, subject to subparagraph (B), to enter into interagency agreements and other collaborative undertakings with other agencies of the United States Government.

(B) Limitation

An agreement or undertaking under this paragraph shall not authorize another agency to exercise the authorities provided by this section.

(4) Availability of facilities to the Secretary

In any grant, contract, or cooperative agreement entered into under the authority provided in this section with respect to a biocontainment laboratory or other related or ancillary specialized research facility that the Secretary determines necessary for the purpose of performing, administering, or supporting qualified countermeasure research and development, the Secretary may provide that the facility that is the object of such grant, contract, or cooperative agreement shall be available as needed to the Secretary to respond to public health emergencies affecting national security.

(5) Transfers of qualified countermeasures

Each agreement for an award of a grant, contract, or cooperative agreement under section 247d–6(e) of this title for the development of a qualified countermeasure shall provide that the recipient of the award will comply with all applicable export-related controls with respect to such countermeasure.

(b) Expedited procurement authority

(1) Increased simplified acquisition threshold for qualified countermeasure procurements

(A) In general

For any procurement by the Secretary of property or services for use (as determined by the Secretary) in performing, administering, or supporting qualified countermeasure research or development activities under this section that the Secretary determines necessary to respond to pressing research and development needs under this section, the amount specified in section 134 of title 41, as applicable pursuant to section 3101(b)(1)(A) of title 41, shall be deemed to be $25,000,000 in the administration, with respect to such procurement, of—

(i) section 3305(a)(1) of title 41 and its implementing regulations; and

(ii) section 3101(b)(1)(B) of title 41 and its implementing regulations.

(B) Application of certain provisions

Notwithstanding subparagraph (A) and the provision of law and regulations referred to in such subparagraph, each of the following provisions shall apply to procurements described in this paragraph to the same extent that such provisions would apply to such procurements in the absence of subparagraph (A):

(i) Chapter 37 of title 40 (relating to contract work hours and safety standards).

(ii) Section 8703(a) of title 41.

(iii) Section 4706 of title 41 (relating to the examination of contractor records).

(iv) Section 3131 of title 40 (relating to bonds of contractors of public buildings or works).

(v) Section 3901 of title 41 (relating to contingent fees to middlemen).

(vi) Section 6962 of this title.

(vii) Section 1354 of title 31 (relating to the limitation on the use of appropriated funds for contracts with entities not meeting veterans employment reporting requirements).

(C) Internal controls to be instituted

The Secretary shall institute appropriate internal controls for procurements that are under this paragraph, including requirements with regard to documenting the justification for use of the authority in this paragraph with respect to the procurement involved.

(D) Authority to limit competition

In conducting a procurement under this paragraph, the Secretary may not use the authority provided for under subparagraph (A) to conduct a procurement on a basis other than full and open competition unless the Secretary determines that the mission of the BioShield Program under the Project BioShield Act of 2004 would be seriously impaired without such a limitation.

(2) Procedures other than full and open competition

(A) In general

In using the authority provided in section 3304(a)(1) of title 41 to use procedures other than competitive procedures in the case of a procurement described in paragraph (1) of this subsection, the phrase "available from only one responsible source" in such section 3304(a)(1) shall be deemed to mean "available from only one responsible source or only from a limited number of responsible sources".

(B) Relation to other authorities

The authority under subparagraph (A) is in addition to any other authority to use procedures other than competitive procedures.

(C) Applicable government-wide regulations

The Secretary shall implement this paragraph in accordance with government-wide regulations implementing such section 3304(a)(1) (including requirements that offers be solicited from as many potential sources as is practicable under the circumstances, that required notices be published, and that submitted offers be considered), as such regulations apply to procurements for which an agency has authority to use procedures other than competitive procedures when the property or services needed by the agency are available from only one responsible source or only from a limited number of responsible sources and no other type of property or services will satisfy the needs of the agency.

(3) Increased micropurchase threshold

(A) In general

For a procurement described by paragraph (1), the amount specified in subsections (a), (d), and (e) of section 1902 of title 41 shall be deemed to be $15,000 in the administration of that section with respect to such procurement.

(B) Internal controls to be instituted

The Secretary shall institute appropriate internal controls for purchases that are under this paragraph and that are greater than $2,500.

(C) Exception to preference for purchase card mechanism

No provision of law establishing a preference for using a Government purchase card method for purchases shall apply to purchases that are under this paragraph and that are greater than $2,500.

(4) Review

(A) Review allowed

Notwithstanding subsection (f), section 1491 of title 28, and section 3556 of title 31, review of a contracting agency decision relating to a procurement described in paragraph (1) may be

had only by filing a protest—

(i) with a contracting agency; or

(ii) with the Comptroller General under subchapter V of chapter 35 of title 31.

(B) Override of stay of contract award or performance committed to agency discretion

Notwithstanding section 1491 of title 28 and section 3553 of title 31, the following authorizations by the head of a procuring activity are committed to agency discretion:

(i) An authorization under section 3553(c)(2) of title 31 to award a contract for a procurement described in paragraph (1) of this subsection.

(ii) An authorization under section 3553(d)(3)(C) of such title to perform a contract for a procurement described in paragraph (1) of this subsection.

(c) Authority to expedite peer review

(1) In general

The Secretary may, as the Secretary determines necessary to respond to pressing qualified countermeasure research and development needs under this section, employ such expedited peer review procedures (including consultation with appropriate scientific experts) as the Secretary, in consultation with the Director of NIH, deems appropriate to obtain assessment of scientific and technical merit and likely contribution to the field of qualified countermeasure research, in place of the peer review and advisory council review procedures that would be required under sections 241(a)(3), 284(b)(1)(B), 284(b)(2), 284a(a)(3)(A), 289a, and 289c of this title, as applicable to a grant, contract, or cooperative agreement—

(A) that is for performing, administering, or supporting qualified countermeasure research and development activities; and

(B) the amount of which is not greater than $1,500,000.

(2) Subsequent phases of research

The Secretary's determination of whether to employ expedited peer review with respect to any subsequent phases of a research grant, contract, or cooperative agreement under this section shall be determined without regard to the peer review procedures used for any prior peer review of that same grant, contract, or cooperative agreement. Nothing in the preceding sentence may be construed to impose any requirement with respect to peer review not otherwise required under any other law or regulation.

(d) Authority for personal services contracts

(1) In general

For the purpose of performing, administering, or supporting qualified countermeasure research and development activities, the Secretary may, as the Secretary determines necessary to respond to pressing qualified countermeasure research and development needs under this section, obtain by contract (in accordance with section 3109 of title 5, but without regard to the limitations in such section on the period of service and on pay) the personal services of experts or consultants who have scientific or other professional qualifications, except that in no case shall the compensation provided to any such expert or consultant exceed the daily equivalent of the annual rate of compensation for the President.

(2) Federal Tort Claims Act coverage

(A) In general

A person carrying out a contract under paragraph (1), and an officer, employee, or governing board member of such person, shall, subject to a determination by the Secretary, be deemed to be an employee of the Department of Health and Human Services for purposes of claims under sections 1346(b) and 2672 of title 28 for money damages for personal injury, including death, resulting from performance of functions under such contract.

(B) Exclusivity of remedy

The remedy provided by subparagraph (A) shall be exclusive of any other civil action or proceeding by reason of the same subject matter against the entity involved (person, officer, employee, or governing board member) for any act or omission within the scope of the Federal Tort Claims Act.

(C) Recourse in case of gross misconduct or contract violation

(i) In general

Should payment be made by the United States to any claimant bringing a claim under this paragraph, either by way of administrative determination, settlement, or court judgment, the United States shall have, notwithstanding any provision of State law, the right to recover against any entity identified in subparagraph (B) for that portion of the damages so awarded or paid, as well as interest and any costs of litigation, resulting from the failure of any such entity to carry out any obligation or responsibility assumed by such entity under a contract with the United States or from any grossly negligent or reckless conduct or intentional or willful misconduct on the part of such entity.

(ii) Venue

The United States may maintain an action under this subparagraph against such entity in the district court of the United States in which such entity resides or has its principal place of business.

(3) Internal controls to be instituted

(A) In general

The Secretary shall institute appropriate internal controls for contracts under this subsection, including procedures for the Secretary to make a determination of whether a person, or an officer, employee, or governing board member of a person, is deemed to be an employee of the Department of Health and Human Services pursuant to paragraph (2).

(B) Determination of employee status to be final

A determination by the Secretary under subparagraph (A) that a person, or an officer, employee, or governing board member of a person, is or is not deemed to be an employee of the Department of Health and Human Services shall be final and binding on the Secretary and the Attorney General and other parties to any civil action or proceeding.

(4) Number of personal services contracts limited

The number of experts and consultants whose personal services are obtained under paragraph (1) shall not exceed 30 at any time.

(e) Streamlined personnel authority

(1) In general

In addition to any other personnel authorities, the Secretary may, as the Secretary determines necessary to respond to pressing qualified countermeasure research and development needs under this section, without regard to those provisions of title 5 governing appointments in the competitive service, and without regard to the provisions of chapter 51 and subchapter III of chapter 53 of such title relating to classification and General Schedule pay rates, appoint professional and technical employees, not to exceed 30 such employees at any time, to positions in the National Institutes of Health to perform, administer, or support qualified countermeasure research and development activities in carrying out this section.

(2) Limitations

The authority provided for under paragraph (1) shall be exercised in a manner that—

(A) recruits and appoints individuals based solely on their abilities, knowledge, and skills;

(B) does not discriminate for or against any applicant for employment on any basis described in section 2302(b)(1) of title 5;

(C) does not allow an official to appoint an individual who is a relative (as defined in section

3110(a)(3) of such title) of such official;

(D) does not discriminate for or against an individual because of the exercise of any activity described in paragraph (9) or (10) of section 2302(b) of such title; and

(E) accords a preference, among equally qualified persons, to persons who are preference eligibles (as defined in section 2108(3) of such title).

(3) Internal controls to be instituted

The Secretary shall institute appropriate internal controls for appointments under this subsection.

(f) Actions committed to agency discretion

Actions by the Secretary under the authority of this section are committed to agency discretion.

(July 1, 1944, ch. 373, title III, §319F–1, as added Pub. L. 108–276, §2(a), July 21, 2004, 118 Stat. 835; amended Pub. L. 109–417, title IV, §403(a), Dec. 19, 2006, 120 Stat. 2874; Pub. L. 113–5, title IV, §402(g)(1), Mar. 13, 2013, 127 Stat. 195; Pub. L. 116–22, title VII, §705(a)(1), June 24, 2019, 133 Stat. 964.)

EDITORIAL NOTES

REFERENCES IN TEXT

The Project BioShield Act of 2004, referred to in subsec. (b)(1)(D), is Pub. L. 108–276, July 21, 2004, 118 Stat. 835. For complete classification of this Act to the Code, see Short Title of 2004 Amendments note set out under section 201 of this title and Tables.

The Federal Tort Claims Act, referred to in subsec. (d)(2), is title IV of act Aug. 2, 1946, ch. 753, 60 Stat. 842, which was classified principally to chapter 20 (§§921, 922, 931–934, 941–946) of former Title 28, Judicial Code and Judiciary. Title IV of act Aug. 2, 1946, was substantially repealed and reenacted as sections 1346(b) and 2671 et seq. of Title 28, Judiciary and Judicial Procedure, by act June 25, 1948, ch. 646, 62 Stat. 992, the first section of which enacted Title 28. The Federal Tort Claims Act is also commonly used to refer to chapter 171 of Title 28, Judiciary and Judicial Procedure. For complete classification of title IV to the Code, see Tables. For distribution of former sections of Title 28 into the revised Title 28, see Table at the beginning of Title 28.

CODIFICATION

In subsec. (b)(1)(A), "section 134 of title 41" substituted for "section 4(11) of the Office of Federal Procurement Policy Act (41 U.S.C. 403(11))" and "section 3101(b)(1)(A) of title 41" substituted for "section 302A(a) of the Federal Property and Administrative Services Act of 1949 (41 U.S.C. 252a(a))" on authority of Pub. L. 111–350, §6(c), Jan. 4, 2011, 124 Stat. 3854, which Act enacted Title 41, Public Contracts.

In subsec. (b)(1)(A)(i), "section 3305(a)(1) of title 41" substituted for "section 303(g)(1)(A) of the Federal Property and Administrative Services Act of 1949 (41 U.S.C. 253(g)(1)(A))" on authority of Pub. L. 111–350, §6(c), Jan. 4, 2011, 124 Stat. 3854, which Act enacted Title 41, Public Contracts.

In subsec. (b)(1)(A)(ii), "section 3101(b)(1)(B) of title 41" substituted for "section 302A(b) of such Act (41 U.S.C. 252a(b))" on authority of Pub. L. 111–350, §6(c), Jan. 4, 2011, 124 Stat. 3854, which Act enacted Title 41, Public Contracts.

In subsec. (b)(1)(B)(ii), "Section 8703(a) of title 41" substituted for "Subsections (a) and (b) of section 7 of the Anti-Kickback Act of 1986 (41 U.S.C. 57(a) and (b))" on authority of Pub. L. 111–350, §6(c), Jan. 4, 2011, 124 Stat. 3854, which Act enacted Title 41, Public Contracts.

In subsec. (b)(1)(B)(iii), "Section 4706 of title 41" substituted for "Section 304C of the Federal Property and Administrative Services Act of 1949 (41 U.S.C. 254d)" on authority of Pub. L. 111–350, §6(c), Jan. 4, 2011, 124 Stat. 3854, which Act enacted Title 41, Public Contracts.

In subsec. (b)(1)(B)(v), "Section 3901 of title 41" substituted for "Subsection (a) of section 304 of the Federal Property and Administrative Services Act of 1949 (41 U.S.C. 254(a))" on authority of Pub. L. 111–350, §6(c), Jan. 4, 2011, 124 Stat. 3854, which Act enacted Title 41, Public Contracts.

In subsec. (b)(2)(A), "section 3304(a)(1) of title 41" substituted for "section 303(c)(1) of title III of the Federal Property and Administrative Services Act of 1949 (41 U.S.C. 253(c)(1))" and "such section 3304(a)(1)" substituted for "such section 303(c)(1)" on authority of Pub. L. 111–350, §6(c), Jan. 4, 2011, 124 Stat. 3854, which Act enacted Title 41, Public Contracts.

In subsec. (b)(2)(C), "such section 3304(a)(1)" substituted for "such section 303(c)(1)" on authority of Pub.

L. 111–350, §6(c), Jan. 4, 2011, 124 Stat. 3854, which Act enacted Title 41, Public Contracts.

In subsec. (b)(3)(A), "subsections (a), (d), and (e) of section 1902 of title 41" substituted for "subsections (c), (d), and (f) of section 32 of the Office of Federal Procurement Policy Act (41 U.S.C. 428)" on authority of Pub. L. 111–350, §6(c), Jan. 4, 2011, 124 Stat. 3854, which Act enacted Title 41, Public Contracts.

AMENDMENTS

2019—Subsec. (a)(1), (5). Pub. L. 116–22 substituted "section 247d–6(e) of this title" for "section 247d–6(h) of this title".

2013—Subsec. (a)(2)(A). Pub. L. 113–5 struck out "to" before dash at end of introductory provisions, inserted "to" before "diagnose" in cls. (i) and (ii), and added cl. (iii).

2006—Subsec. (a)(2). Pub. L. 109–417 added par. (2) and struck out heading and text of former par. (2). Text read as follows: "For purposes of this section, the term 'qualified countermeasure' means a drug (as that term is defined by section 321(g)(1) of title 21), biological product (as that term is defined by section 262(i) of this title), or device (as that term is defined by section 321(h) of title 21) that the Secretary determines to be a priority (consistent with sections 182(2) and 184(a) of title 6) to—

"(A) treat, identify, or prevent harm from any biological, chemical, radiological, or nuclear agent that may cause a public health emergency affecting national security; or

"(B) treat, identify, or prevent harm from a condition that may result in adverse health consequences or death and may be caused by administering a drug, biological product, or device that is used as described in subparagraph (A)."

STATUTORY NOTES AND RELATED SUBSIDIARIES

RULE OF CONSTRUCTION

Pub. L. 108–276, §2(e), July 21, 2004, 118 Stat. 842, provided that: "Nothing in this section [enacting this section and amending sections 247d–6, 287a–2, and 300aa–6 of this title] has any legal effect on sections 302(2), 302(4), 304(a), or 304(b) of the Homeland Security Act of 2002 [6 U.S.C. 182(2), (4), 184(a), (b)]."

COLLABORATION AND COORDINATION

Pub. L. 109–417, title IV, §405, Dec. 19, 2006, 120 Stat. 2875, as amended by Pub. L. 113–5, §402(e)(1), Mar. 13, 2013, 127 Stat. 195; Pub. L. 116–22, title VII, §701(e)(1)(A), (B), June 24, 2019, 133 Stat. 961, which authorized the Secretary of Health and Human Services, in coordination with the Attorney General and the Secretary of Homeland Security, to conduct meetings with persons engaged in the development of a security countermeasure, a qualified countermeasure, or a qualified pandemic or epidemic product, in such a manner to ensure that no national security, confidential commercial, or proprietary information is disclosed outside the meeting, and exempted from antitrust laws conduct pursuant to a written agreement executed at such a meeting approved by the Attorney General and the Chairman of the Federal Trade Commission, was redesignated as section 319L–1 of act July 1, 1944, ch. 373, known as the Public Health Service Act, by Pub. L. 116–22, title VII, §701(e)(1)(C), (D), June 24, 2019, 133 Stat. 961, and editorially reclassified as section 247d–7f of this title.

OUTREACH

Pub. L. 108–276, §6, July 21, 2004, 118 Stat. 862, provided that: "The Secretary of Health and Human Services shall develop outreach measures to ensure to the extent practicable that diverse institutions, including Historically Black Colleges and Universities and those serving large proportions of Black or African Americans, American Indians, Appalachian Americans, Alaska Natives, Asians, Native Hawaiians, other Pacific Islanders, Hispanics or Latinos, or other underrepresented populations, are meaningfully aware of available research and development grants, contracts, cooperative agreements, and procurements conducted under sections 2 and 3 of this Act [enacting this section and section 320 of Title 6, Domestic Security, amending sections 247d–6, 247d–6b, 287a–2, and 300aa–6 of this title and sections 312 and 313 of Title 6, renumbering section 300hh–12 of this title as section 247d–6b of this title, and enacting provisions set out as notes under this section and section 247d–6b of this title]."

RECOMMENDATION FOR EXPORT CONTROLS ON CERTAIN BIOMEDICAL COUNTERMEASURES

Pub. L. 108–276, §7, July 21, 2004, 118 Stat. 863, provided that: "Upon the award of any grant, contract, or cooperative agreement under section 2 or 3 of this Act [enacting this section and section 320 of Title 6, Domestic Security, amending sections 247d–6, 247d–6b, 287a–2, and 300aa–6 of this title and sections 312

and 313 of Title 6, renumbering section 300hh–12 of this title as section 247d–6b of this title, and enacting provisions set out as notes under this section and section 247d–6b of this title] for the research, development, or procurement of a qualified countermeasure or a security countermeasure (as those terms are defined in this Act [see Short Title of 2004 Amendments note set out under section 201 of this title]), the Secretary of Health and Human Services shall, in consultation with the heads of other appropriate Federal agencies, determine whether the countermeasure involved in such grant, contract, or cooperative agreement is subject to existing export-related controls and, if not, may make a recommendation to the appropriate Federal agency or agencies that such countermeasure should be included on the list of controlled items subject to such controls."

ENSURING COORDINATION, COOPERATION AND THE ELIMINATION OF UNNECESSARY DUPLICATION IN PROGRAMS DESIGNED TO PROTECT THE HOMELAND FROM BIOLOGICAL, CHEMICAL, RADIOLOGICAL, AND NUCLEAR AGENTS

Pub. L. 108–276, §8, July 21, 2004, 118 Stat. 863, provided that:

"(a) ENSURING COORDINATION OF PROGRAMS.—The Secretary of Health and Human Services, the Secretary of Homeland Security, and the Secretary of Defense shall ensure that the activities of their respective Departments coordinate, complement, and do not unnecessarily duplicate programs to identify potential domestic threats from biological, chemical, radiological or nuclear agents, detect domestic incidents involving such agents, analyze such incidents, and develop necessary countermeasures. The aforementioned Secretaries shall further ensure that information and technology possessed by the Departments relevant to these activities are shared with the other Departments.

"(b) DESIGNATION OF AGENCY COORDINATION OFFICER.—The Secretary of Health and Human Services, the Secretary of Homeland Security, and the Secretary of Defense shall each designate an officer or employee of their respective Departments who shall coordinate, through regular meetings and communications, with the other aforementioned Departments such programs and activities carried out by their Departments."

§247d–6b. Strategic National Stockpile and security countermeasure procurements

(a) Strategic National Stockpile

(1) In general

The Secretary, in collaboration with the Assistant Secretary for Preparedness and Response and the Director of the Centers for Disease Control and Prevention, and in coordination with the Secretary of Homeland Security (referred to in this section as the "Homeland Security Secretary"), shall maintain a stockpile or stockpiles of drugs, vaccines and other biological products, medical devices, and other supplies (including personal protective equipment, ancillary medical supplies, and other applicable supplies required for the administration of drugs, vaccines and other biological products, medical devices, and diagnostic tests in the stockpile) in such numbers, types, and amounts as are determined consistent with section 300hh–10 of this title by the Secretary to be appropriate and practicable, taking into account other available sources, to provide for and optimize the emergency health security of the United States, including the emergency health security of children and other vulnerable populations, in the event of a bioterrorist attack or other public health emergency and, as informed by existing recommendations of, or consultations with, the Public Health Emergency Medical Countermeasure Enterprise established under section 300hh–10a of this title, make necessary additions or modifications to the contents of such stockpile or stockpiles based on the review conducted under paragraph (2).

(2) Threat-based review

(A) In general

The Secretary shall conduct an annual threat-based review (taking into account at-risk individuals) of the contents of the stockpile under paragraph (1), including non-pharmaceutical supplies, and, in consultation with the Public Health Emergency Medical Countermeasures Enterprise established under section 300hh–10a of this title, review contents within the stockpile and assess whether such contents are consistent with the recommendations made

pursuant to section 300hh–10a(c)(1)(A) of this title. Such review shall be submitted on June 15, 2019, and on March 15 of each year thereafter, to the Committee on Health, Education, Labor, and Pensions and the Committee on Appropriations of the Senate and the Committee on Energy and Commerce and the Committee on Appropriations of the House of Representatives, in a manner that does not compromise national security.

(B) Additions, modifications, and replenishments

Each annual threat-based review under subparagraph (A) shall, for each new or modified countermeasure procurement or replenishment, provide—

(i) information regarding—

(I) the quantities of the additional or modified countermeasure procured for, or contracted to be procured for, the stockpile;

(II) planning considerations for appropriate manufacturing capacity and capability to meet the goals of such additions or modifications (without disclosing proprietary information), including—

(aa) consideration of the effect such additions or modifications may have on the availability of such products and ancillary medical supplies on the health care system; and

(bb) an assessment of the current supply chain for such products, including information on supply chain redundancies, any known domestic manufacturing capacity for such products, and any related vulnerabilities;

(III) the presence or lack of a commercial market for the countermeasure at the time of procurement;

(IV) the emergency health security threat or threats such countermeasure procurement is intended to address, including whether such procurement is consistent with meeting emergency health security needs associated with such threat or threats;

(V) an assessment of whether the emergency health security threat or threats described in subclause (IV) could be addressed in a manner that better utilizes the resources of the stockpile and permits the greatest possible increase in the level of emergency preparedness to address such threats;

(VI) whether such countermeasure is replenishing an expiring or expired countermeasure, is a different countermeasure with the same indication that is replacing an expiring or expired countermeasure, or is a new addition to the stockpile;

(VII) a description of how such additions or modifications align with projected investments under previous countermeasures budget plans under section 300hh–10(b)(7) of this title, including expected life-cycle costs, expenditures related to countermeasure procurement to address the threat or threats described in subclause (IV), replenishment dates (including the ability to extend the maximum shelf life of a countermeasure), and the manufacturing capacity required to replenish such countermeasure; and

(VIII) appropriate protocols and processes for the deployment, distribution, or dispensing of the countermeasure at the State and local level, including plans for relevant capabilities of State and local entities to dispense, distribute, and administer the countermeasure; and

(ii) an assurance, which need not be provided in advance of procurement, that for each countermeasure procured or replenished under this subsection, the Secretary completed a review addressing each item listed under this subsection in advance of such procurement or replenishment.

(3) Procedures

The Secretary, in managing the stockpile under paragraph (1), shall—

(A) consult with the working group under section 247d–6(a) of this title and the Public Health Emergency Medical Countermeasures Enterprise established under section 300hh–10a

of this title;

(B) ensure that adequate procedures are followed, regularly reviewed, and updated with respect to such stockpile for inventory management and accounting, and for the physical security of the stockpile;

(C) in consultation with Federal, State, local, and Tribal officials, take into consideration the timing and location of special events, and the availability, deployment, dispensing, and administration of countermeasures;

(D) review and revise, as appropriate, the contents of the stockpile on a regular basis to ensure that—

(i) emerging threats, advanced technologies, and new countermeasures are adequately considered;

(ii) the potential depletion of countermeasures currently in the stockpile is identified and appropriately addressed, including through necessary replenishment; and

(iii) such contents are in working condition or usable, as applicable, and are ready for deployment, which may include conducting maintenance services on such contents of the stockpile and disposing of such contents that are no longer in working condition, or usable, as applicable;

(E) devise plans for effective and timely supply-chain management of the stockpile, in consultation with the Director of the Centers for Disease Control and Prevention, the Assistant Secretary for Preparedness and Response, the Secretary of Transportation, the Secretary of Homeland Security, the Secretary of Veterans Affairs, and the heads of other appropriate Federal agencies; State, local, Tribal, and territorial agencies; and the public and private health care infrastructure, as applicable, taking into account the manufacturing capacity and other available sources of products and appropriate alternatives to supplies in the stockpile;

(F) deploy the stockpile at the discretion of the Secretary, in consultation with, or at the request of, the Secretary of Homeland Security, to respond to an actual or potential emergency;

(G) deploy the stockpile at the discretion of the Secretary to respond to an actual or potential public health emergency or other situation in which deployment is necessary to protect the public health or safety;

(H) ensure the adequate physical security of the stockpile;

(I) ensure that each countermeasure or product under consideration for procurement pursuant to this subsection receives the same consideration regardless of whether such countermeasure or product receives or had received funding under section 247d–7e of this title, including with respect to whether the countermeasure or product is most appropriate to meet the emergency health security needs of the United States;

(J) provide assistance, including technical assistance, to maintain and improve State [1] local, and Tribal public health preparedness capabilities to distribute and dispense medical countermeasures and products from the stockpile, as appropriate; and

(K) convene meetings, not less than once per year, with representatives from State, local, and Tribal health departments or officials, relevant industries, other Federal agencies, and other appropriate stakeholders, in a manner that does not compromise national security, to coordinate and share information related to maintenance and use of the stockpile, including a description of future countermeasure needs and additions, modifications, and replenishments of the contents of the stockpile, and considerations related to the manufacturing and procurement of products consistent with the requirements of the with the requirements of [2] chapter 83 of title 41 (commonly referred to as the "Buy American Act"), as appropriate.

(4) Utilization guidelines

The Secretary shall ensure timely and accurate recommended utilization guidelines for qualified countermeasures (as defined in section 247d–6a of this title), qualified pandemic and epidemic products (as defined in section 247d–6d of this title), and security countermeasures (as defined in subsection (c)), including for such products in the stockpile.

(5) Vendor-managed inventory and warm-base surge capacity

(A) In general

For the purposes of maintaining the stockpile under paragraph (1) and carrying out procedures under paragraph (3), the Secretary may enter into contracts or cooperative agreements with vendors, which may include manufacturers or distributors of medical products, with respect to medical products intended to be delivered to the ownership of the Federal Government. Each such contract or cooperative agreement shall be subject to such terms and conditions as the Secretary may specify, including terms and conditions with respect to—

(i) procurement, maintenance, storage, and delivery of products, in alignment with inventory management and other applicable best practices, under such contract or cooperative agreement, which may consider, as appropriate, costs of transporting and handling such products; or

(ii) maintenance of domestic manufacturing capacity and capabilities of such products to ensure additional reserved production capacity and capabilities are available, and that such capacity and capabilities are able to support the rapid manufacture, purchase, storage, and delivery of such products, as required by the Secretary to prepare for, or respond to, an existing or potential public health emergency.

(B) Report

Not later than 2 years after December 29, 2022, and annually thereafter, the Secretary shall submit to the Committee on Health, Education, Labor, and Pensions and the Committee on Appropriations of the Senate and the Committee on Energy and Commerce and the Committee on Appropriations of the House of Representatives a report on any contracts or cooperative agreements entered into under subparagraph (A) for purposes of establishing and maintaining vendor-managed inventory or reserve manufacturing capacity and capabilities for products intended for the stockpile, including a description of—

(i) the amount of each award;

(ii) the recipient of each award;

(iii) the product or products covered through each award; and

(iv) how the Secretary works with each recipient to ensure situational awareness related to the manufacturing capacity for, or inventory of, such products and coordinates the distribution and deployment of such products, as appropriate and applicable.

(6) GAO report

(A) In general

Not later than 3 years after June 24, 2019, and every 5 years thereafter, the Comptroller General of the United States shall conduct a review of any changes to the contents or management of the stockpile since January 1, 2015. Such review shall include—

(i) an assessment of the comprehensiveness and completeness of each annual threat-based review under paragraph (2), including whether all newly procured or replenished countermeasures within the stockpile were described in each annual review, and whether, consistent with paragraph (2)(B), the Secretary conducted the necessary internal review in advance of such procurement or replenishment;

(ii) an assessment of whether the Secretary established health security and science-based justifications, and a description of such justifications for procurement decisions related to health security needs with respect to the identified threat, for additions or modifications to the stockpile based on the information provided in such reviews under paragraph (2)(B), including whether such review was conducted prior to procurement, modification, or replenishment;

(iii) an assessment of the plans developed by the Secretary for the deployment, distribution, and dispensing of countermeasures procured, modified, or replenished under paragraph (1), including whether such plans were developed prior to procurement, modification, or replenishment;

(iv) an accounting of countermeasures procured, modified, or replenished under paragraph (1) that received advanced research and development funding from the Biomedical Advanced Research and Development Authority;

(v) an analysis of how such procurement decisions made progress toward meeting emergency health security needs related to the identified threats for countermeasures added, modified, or replenished under paragraph (1);

(vi) a description of the resources expended related to the procurement of countermeasures (including additions, modifications, and replenishments) in the stockpile, and how such expenditures relate to the ability of the stockpile to meet emergency health security needs;

(vii) an assessment of the extent to which additions, modifications, and replenishments reviewed under paragraph (2) align with previous relevant reports or reviews by the Secretary or the Comptroller General;

(viii) with respect to any change in the Federal organizational management of the stockpile, an assessment and comparison of the processes affected by such change, including planning for potential countermeasure deployment, distribution, or dispensing capabilities and processes related to procurement decisions, use of stockpiled countermeasures, and use of resources for such activities;

(ix) an assessment of whether the processes and procedures described by the Secretary pursuant to section 403(b) of the Pandemic and All-Hazards Preparedness and Advancing Innovation Act of 2019 are sufficient to ensure countermeasures and products under consideration for procurement pursuant to subsection (a) receive the same consideration regardless of whether such countermeasures and products receive or had received funding under section 247d–7e of this title, including with respect to whether such countermeasures and products are most appropriate to meet the emergency health security needs of the United States; and

(x) with respect to reports issued in 2027 or any subsequent year, an assessment of selected contracts or cooperative agreements entered into pursuant to paragraph (5).

(B) Submission

Not later than 6 months after completing a classified version of the review under subparagraph (A), the Comptroller General shall submit an unclassified version of the review to the congressional committees of jurisdiction.

(7) Reimbursement for certain supplies

(A) In general

The Secretary may, at appropriate intervals, make available for purchase excess contents procured for, and maintained within, the stockpile under paragraph (1) to any Federal agency or State, local, or Tribal government. The Secretary shall make such contents available for purchase only if—

(i) such contents are in excess of what is required for appropriate maintenance of such stockpile;

(ii) the Secretary determines that the costs for maintaining such excess contents are not appropriate to expend to meet the needs of the stockpile; and

(iii) the Secretary determines that such action does not compromise national security and is in the national interest.

(B) Reimbursement and collection

The Secretary may require reimbursement for contents that are made available under subparagraph (A), in an amount that reflects the cost of acquiring and maintaining such contents and the costs incurred to make available such contents in the time and manner specified by the Secretary. Amounts collected under this subsection shall be credited to the appropriations account or fund that incurred the costs to procure such contents, and shall remain available, without further appropriation, until expended, for the purposes of the appropriation account or fund so credited.

(C) Rule of construction

This paragraph shall not be construed to preclude transfers of contents in the stockpile under other authorities.

(D) Report

Not later than 2 years after December 29, 2022, and annually thereafter, the Secretary shall submit to the Committee on Health, Education, Labor, and Pensions and the Committee on Appropriations of the Senate and the Committee on Energy and Commerce and the Committee on Appropriations of the House of Representatives a report on the use of the authority provided under this paragraph, including details of each action taken pursuant to this paragraph, the account or fund to which any collected amounts have been credited, and how the Secretary has used such amounts.

(E) Sunset

The authority under this paragraph shall terminate on September 30, 2028.

(b) Smallpox vaccine development

(1) In general

The Secretary shall award contracts, enter into cooperative agreements, or carry out such other activities as may reasonably be required in order to ensure that the stockpile under subsection (a) includes an amount of vaccine against smallpox as determined by such Secretary to be sufficient to meet the health security needs of the United States.

(2) Rule of construction

Nothing in this section shall be construed to limit the private distribution, purchase, or sale of vaccines from sources other than the stockpile described in subsection (a).

(c) Additional authority regarding procurement of certain countermeasures; availability of special reserve fund

(1) In general

(A) Use of fund

A security countermeasure may, in accordance with this subsection, be procured with amounts in the special reserve fund as defined in subsection (h).

(B) Security countermeasure

For purposes of this subsection, the term "security countermeasure" means a drug (as that term is defined by section 201(g)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321(g)(1))), biological product (as that term is defined by section 262(i) of this title), or device (as that term is defined by section 201(h) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321(h))) that—

(i)(I) the Secretary determines to be a priority (consistent with sections 182(2) and 184(a) of title 6) to diagnose, mitigate, prevent, or treat harm from any biological, chemical, radiological, or nuclear agent identified as a material threat under paragraph (2)(A)(ii), or to diagnose, mitigate, prevent, or treat harm from a condition that may result in adverse health consequences or death and may be caused by administering a drug, biological product, or device against such an agent;

(II) the Secretary determines under paragraph (2)(B)(ii) to be a necessary countermeasure; and

(III)(aa) is approved or cleared under chapter V of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 351 et seq.] or licensed under section 262 of this title; or

(bb) is a countermeasure for which the Secretary determines that sufficient and satisfactory clinical experience or research data (including data, if available, from pre-clinical and clinical trials) support a reasonable conclusion that the countermeasure will qualify for approval or licensing within 10 years after the date of a determination under paragraph (5); or

(ii) is authorized for emergency use under section 564 of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 360bbb–3].

(2) Determination of material threats

(A) Material threat

The Homeland Security Secretary, in consultation with the Secretary and the heads of other agencies as appropriate, shall on an ongoing basis—

(i) assess current and emerging threats of chemical, biological, radiological, and nuclear agents; and

(ii) determine which of such agents present a material threat against the United States population sufficient to affect national security.

(B) Public health impact; necessary countermeasures

The Secretary shall on an ongoing basis—

(i) assess the potential public health consequences for the United States population of exposure to agents identified under subparagraph (A)(ii); and

(ii) determine, on the basis of such assessment, the agents identified under subparagraph (A)(ii) for which countermeasures are necessary to protect the public health.

(C) Notice to Congress

The Secretary and the Secretary of Homeland Security shall send to Congress, not later than March 15 of each year, all current material threat determinations and shall promptly notify the Committee on Health, Education, Labor, and Pensions and the Committee on Homeland Security and Governmental Affairs of the Senate and the Committee on Energy and Commerce and the Committee on Homeland Security of the House of Representatives that a determination has been made pursuant to subparagraph (A) or (B).

(D) Assuring access to threat information

In making the assessment and determination required under subparagraph (A), the Homeland Security Secretary shall use all relevant information to which such Secretary is entitled under section 122 of title 6, including but not limited to information, regardless of its level of classification, relating to current and emerging threats of chemical, biological, radiological, and nuclear agents.

(3) Assessment of availability and appropriateness of countermeasures

(A) In general

The Secretary, in consultation with the Homeland Security Secretary, shall assess on an ongoing basis the availability and appropriateness of specific countermeasures to address specific threats identified under paragraph (2).

(B) Information

The Secretary shall institute a process for making publicly available the results of assessments under subparagraph (A) while withholding such information as—

(i) would, in the judgment of the Secretary, tend to reveal public health vulnerabilities; or

(ii) would otherwise be exempt from disclosure under section 552 of title 5.

(4) Call for development of countermeasures; commitment for recommendation for procurement

(A) Proposal to the President

If, pursuant to an assessment under paragraph (3), the Homeland Security Secretary and the Secretary make a determination that a countermeasure would be appropriate but is either currently not developed or unavailable for procurement as a security countermeasure or is approved, licensed, or cleared only for alternative uses, such Secretaries may jointly submit to the President a proposal to—

(i) issue a call for the development of such countermeasure; and

(ii) make a commitment that, upon the first development of such countermeasure that meets the conditions for procurement under paragraph (5), the Secretaries will, based in part on information obtained pursuant to such call, and subject to the availability of appropriations, make available the special reserve fund as defined in subsection (h) for procurement of such countermeasure, as applicable.

(B) Countermeasure specifications

The Homeland Security Secretary and the Secretary shall, to the extent practicable, include in the proposal under subparagraph (A)—

(i) estimated quantity of purchase (in the form of number of doses or number of effective courses of treatments regardless of dosage form);

(ii) necessary measures of minimum safety and effectiveness;

(iii) estimated price for each dose or effective course of treatment regardless of dosage form; and

(iv) other information that may be necessary to encourage and facilitate research, development, and manufacture of the countermeasure or to provide specifications for the countermeasure.

(C) Presidential approval

If the President approves a proposal under subparagraph (A), the Homeland Security Secretary and the Secretary shall make known to persons who may respond to a call for the countermeasure involved—

(i) the call for the countermeasure;

(ii) specifications for the countermeasure under subparagraph (B); and

(iii) the commitment described in subparagraph (A)(ii).

(5) Secretary's determination of countermeasures appropriate for funding from special reserve fund

(A) In general

The Secretary, in accordance with the provisions of this paragraph, shall identify specific security countermeasures that the Secretary determines, in consultation with the Homeland Security Secretary, to be appropriate for inclusion in the stockpile under subsection (a) pursuant to procurements made with amounts in the special reserve fund as defined in subsection (h) (referred to in this subsection individually as a "procurement under this subsection").

(B) Requirements

In making a determination under subparagraph (A) with respect to a security countermeasure, the Secretary shall determine and consider the following:

(i) The quantities of the product that will be needed to meet the stockpile needs.

(ii) The feasibility of production and delivery within 10 years of sufficient quantities of the product.

(iii) Whether there is a lack of a significant commercial market for the product at the time of procurement, other than as a security countermeasure.

(6) Recommendations for procurement

(A) Notice to appropriate congressional committees

The Secretary shall notify the Committee on Appropriations and the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Appropriations and the Committee on Energy and Commerce of the House of Representatives of each decision to make available the special reserve fund as defined in subsection (h) for procurement of a security countermeasure, including, where available, the number of, the nature of, and other information concerning potential suppliers of such countermeasure, and whether other potential suppliers of the same or similar countermeasures were considered and rejected for procurement under this section and the reasons for each such rejection.

(B) Subsequent specific countermeasures

Procurement under this subsection of a security countermeasure for a particular purpose does not preclude the subsequent procurement under this subsection of any other security countermeasure for such purpose if the Secretary has determined under paragraph (5)(A) that such countermeasure is appropriate for inclusion in the stockpile and if, as determined by the Secretary, such countermeasure provides improved safety or effectiveness, or for other reasons enhances preparedness to respond to threats of use of a biological, chemical, radiological, or nuclear agent. Such a determination by the Secretary is committed to agency discretion.

(7) Procurement

(A) Payments from special reserve fund

The special reserve fund as defined in subsection (h) shall be available for payments made by the Secretary to a vendor for procurement of a security countermeasure in accordance with the provisions of this paragraph.

(B) Procurement

(i) In general

The Secretary shall be responsible for—

(I) arranging for procurement of a security countermeasure, including negotiating terms (including quantity, production schedule, and price) of, and entering into, contracts and cooperative agreements, and for carrying out such other activities as may reasonably be required, including advanced research and development, in accordance with the provisions of this subparagraph; and

(II) promulgating such regulations as the Secretary determines necessary to implement the provisions of this subsection.

(ii) Contract terms

A contract for procurements under this subsection shall (or, as specified below, may) include the following terms:

(I) Payment conditioned on delivery

The contract shall provide that no payment may be made until delivery of a portion, acceptable to the Secretary, of the total number of units contracted for, except that, notwithstanding any other provision of law, the contract may provide that, if the Secretary determines (in the Secretary's discretion) that an advance payment, partial payment for significant milestones, or payment to increase manufacturing capacity is necessary to ensure success of a project, the Secretary shall pay an amount, not to exceed 10 percent of the contract amount, in advance of delivery. The Secretary shall, to the extent practicable, make the determination of advance payment at the same time as the issuance of a solicitation. The contract shall provide that such advance payment is required to be repaid if there is a failure to perform by the vendor under the contract. The contract may also provide for additional advance payments of 5 percent each for meeting the milestones specified in such contract, except that such payments shall not exceed 50 percent of the total contract amount. If the specified milestones are reached, the advanced payments of 5 percent shall not be required to be repaid. Nothing in this subclause shall be construed as affecting the rights of vendors under provisions of law or regulation (including the Federal Acquisition Regulation) relating to the termination of contracts for the convenience of the Government.

(II) Discounted payment

The contract may provide for a discounted price per unit of a product that is not licensed, cleared, or approved as described in paragraph (1)(B)(i)(III)(aa) at the time of delivery, and may provide for payment of an additional amount per unit if the product becomes so licensed, cleared, or approved before the expiration date of the contract

(including an additional amount per unit of product delivered before the effective date of such licensing, clearance, or approval).

(III) Contract duration

The contract shall be for a period not to exceed five years, except that, in first awarding the contract, the Secretary may provide for a longer duration, not exceeding 10 years, if the Secretary determines that complexities or other difficulties in performance under the contract justify such a period. The contract shall be renewable for additional periods, none of which shall exceed five years. The Secretary shall notify the vendor within 90 days of a determination by the Secretary to renew, extend, or terminate such contract.

(IV) Storage by vendor

The contract may provide that the vendor will provide storage for stocks of a product delivered to the ownership of the Federal Government under the contract, for such period and under such terms and conditions as the Secretary may specify, and in such case amounts from the special reserve fund as defined in subsection (h) shall be available for costs of shipping, handling, storage, and related costs for such product.

(V) Product approval

The contract shall provide that the vendor seek approval, clearance, or licensing of the product from the Secretary; for a timetable for the development of data and other information to support such approval, clearance, or licensing; and that the Secretary may waive part or all of this contract term on request of the vendor or on the initiative of the Secretary.

(VI) Non-stockpile transfers of security countermeasures

The contract shall provide that the vendor will comply with all applicable export-related controls with respect to such countermeasure.

(VII) Sales exclusivity

The contract may provide that the vendor is the exclusive supplier of the product to the Federal Government for a specified period of time, not to exceed the term of the contract, on the condition that the vendor is able to satisfy the needs of the Government. During the agreed period of sales exclusivity, the vendor shall not assign its rights of sales exclusivity to another entity or entities without approval by the Secretary. Such a sales exclusivity provision in such a contract shall constitute a valid basis for a sole source procurement under section 3304(a)(1) of title 41.

(VIII) Warm based surge capacity

The contract may provide that the vendor establish domestic manufacturing capacity of the product to ensure that additional production of the product is available in the event that the Secretary determines that there is a need to quickly purchase additional quantities of the product. Such contract may provide a fee to the vendor for establishing and maintaining such capacity in excess of the initial requirement for the purchase of the product. Additionally, the cost of maintaining the domestic manufacturing capacity shall be an allowable and allocable direct cost of the contract.

(IX) Contract terms

The Secretary, in any contract for procurement under this section—

(aa) may specify—

(AA) the dosing and administration requirements for the countermeasure to be developed and procured;

(BB) the amount of funding that will be dedicated by the Secretary for advanced research, development, and procurement of the countermeasure; and

(CC) the specifications the countermeasure must meet to qualify for procurement under a contract under this section; and

(bb) shall provide a clear statement of defined Government purpose limited to uses related to a security countermeasure, as defined in paragraph (1)(B).

(iii) Availability of simplified acquisition procedures

(I) In general

If the Secretary determines that there is a pressing need for a procurement of a specific countermeasure, the amount of the procurement under this subsection shall be deemed to be below the threshold amount specified in section 134 of title 41, for purposes of application to such procurement, pursuant to section 3101(b)(1)(A) of title 41, of—

(aa) section 3305(a)(1) of title 41 and its implementing regulations; and

(bb) section 3101(b)(1)(B) of title 41 and its implementing regulations.

(II) Application of certain provisions

Notwithstanding subclause (I) and the provision of law and regulations referred to in such clause, each of the following provisions shall apply to procurements described in this clause to the same extent that such provisions would apply to such procurements in the absence of subclause (I):

(aa) Chapter 37 of title 40 (relating to contract work hours and safety standards).

(bb) Section 8703(a) of title 41.

(cc) Section 4706 of title 41 (relating to the examination of contractor records).

(dd) Section 3131 of title 40 (relating to bonds of contractors of public buildings or works).

(ee) Section 3901 of title 41 (relating to contingent fees to middlemen).

(ff) Section 6962 of this title.

(gg) Section 1354 of title 31 (relating to the limitation on the use of appropriated funds for contracts with entities not meeting veterans employment reporting requirements).

(III) Internal controls to be established

The Secretary shall establish appropriate internal controls for procurements made under this clause, including requirements with respect to documentation of the justification for the use of the authority provided under this paragraph with respect to the procurement involved.

(IV) Authority to limit competition

In conducting a procurement under this subparagraph, the Secretary may not use the authority provided for under subclause (I) to conduct a procurement on a basis other than full and open competition unless the Secretary determines that the mission of the BioShield Program under the Project BioShield Act of 2004 would be seriously impaired without such a limitation.

(iv) Procedures other than full and open competition

(I) In general

In using the authority provided in section 3304(a)(1) of title 41 to use procedures other than competitive procedures in the case of a procurement under this subsection, the phrase "available from only one responsible source" in such section 3304(a)(1) shall be deemed to mean "available from only one responsible source or only from a limited number of responsible sources".

(II) Relation to other authorities

The authority under subclause (I) is in addition to any other authority to use procedures other than competitive procedures.

(III) Applicable government-wide regulations

The Secretary shall implement this clause in accordance with government-wide regulations implementing such section 3304(a)(1) (including requirements that offers be solicited from as many potential sources as is practicable under the circumstances, that required notices be published, and that submitted offers be considered), as such regulations apply to procurements for which an agency has authority to use procedures other than competitive procedures when the property or services needed by the agency are available from only one responsible source or only from a limited number of responsible sources and no other type of property or services will satisfy the needs of the agency.

(v) Premium provision in multiple award contracts

(I) In general

If, under this subsection, the Secretary enters into contracts with more than one vendor to procure a security countermeasure, such Secretary may, notwithstanding any other provision of law, include in each of such contracts a provision that—

(aa) identifies an increment of the total quantity of security countermeasure required, whether by percentage or by numbers of units; and

(bb) promises to pay one or more specified premiums based on the priority of such vendors' production and delivery of the increment identified under item (aa), in accordance with the terms and conditions of the contract.

(II) Determination of Government's requirement not reviewable

If the Secretary includes in each of a set of contracts a provision as described in subclause (I), such Secretary's determination of the total quantity of security countermeasure required, and any amendment of such determination, is committed to agency discretion.

(vi) Extension of closing date for receipt of proposals not reviewable

A decision by the Secretary to extend the closing date for receipt of proposals for a procurement under this subsection is committed to agency discretion.

(vii) Limiting competition to sources responding to request for information

In conducting a procurement under this subsection, the Secretary may exclude a source that has not responded to a request for information under section 3306(a)(1)(B) of title 41 if such request has given notice that the Secretary may so exclude such a source.

(viii) Flexibility

In carrying out this section, the Secretary may, consistent with the applicable provisions of this section, enter into contracts and other agreements that are in the best interest of the Government in meeting identified security countermeasure needs, including with respect to reimbursement of the cost of advanced research and development as a reasonable, allowable, and allocable direct cost of the contract involved.

(8) Interagency cooperation

(A) In general

In carrying out activities under this section, the Homeland Security Secretary and the Secretary are authorized, subject to subparagraph (B), to enter into interagency agreements and other collaborative undertakings with other agencies of the United States Government. Such agreements may allow other executive agencies to order qualified and security countermeasures under procurement contracts or other agreements established by the Secretary. Such ordering process (including transfers of appropriated funds between an agency and the Department of Health and Human Services as reimbursements for such orders for countermeasures) may be conducted under the authority of section 1535 of title 31, except that all such orders shall be processed under the terms established under this subsection for the procurement of countermeasures.

(B) Limitation

An agreement or undertaking under this paragraph shall not authorize another agency to exercise the authorities provided by this section to the Homeland Security Secretary or to the Secretary.

(d) Disclosures

No Federal agency may disclose under section 552 of title 5 any information identifying the location at which materials in the stockpile described in subsection (a) are stored, or other information regarding the contents or deployment capability of the stockpile that could compromise national security.

(e) Definition

For purposes of subsection (a), the term "stockpile" includes—

(1) a physical accumulation (at one or more locations) of the supplies described in subsection (a); or

(2) a contractual agreement between the Secretary and a vendor or vendors under which such vendor or vendors agree to provide to such Secretary supplies described in subsection (a).

(f) Authorization of appropriations

(1) Strategic National Stockpile

For the purpose of carrying out subsection (a), there are authorized to be appropriated $610,000,000 for each of fiscal years 2019 through 2021, and $750,000,000 for each of fiscal years 2022 and 2023, to remain available until expended. Such authorization is in addition to amounts in the special reserve fund referred to in subsection (h).

(2) Smallpox vaccine development

For the purpose of carrying out subsection (b), there are authorized to be appropriated $509,000,000 for fiscal year 2002, and such sums as may be necessary for each of fiscal years 2003 through 2006.

(g) Special reserve fund

(1) Authorization of appropriations

In addition to amounts appropriated to the special reserve fund prior to March 13, 2013, there is authorized to be appropriated, for the procurement of security countermeasures under subsection (c) and for carrying out section 247d–7e of this title (relating to the Biomedical Advanced Research and Development Authority), $7,100,000,000 for the period of fiscal years 2019 through 2028, to remain available until expended.

(2) Use of special reserve fund for advanced research and development

The Secretary may utilize not more than 50 percent of the amounts authorized to be appropriated under paragraph (1) to carry out section 247d–7e of this title (related to the Biomedical Advanced Research and Development Authority). Amounts authorized to be appropriated under this subsection to carry out section 247d–7e of this title are in addition to amounts otherwise authorized to be appropriated to carry out such section.

(3) Restrictions on use of funds

Amounts in the special reserve fund shall not be used to pay costs other than payments made by the Secretary to a vendor for advanced development (under section 247d–7e of this title) or for procurement of a security countermeasure under subsection (c)(7).

(4) Report on security countermeasure procurement

Not later than March 1 of each year in which the Secretary determines that the amount of funds available for procurement of security countermeasures is less than $1,500,000,000, the Secretary shall submit to the Committee on Appropriations and the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Appropriations and the Committee on Energy

and Commerce of the House of Representatives a report detailing the amount of such funds available for procurement and the impact such amount of funding will have—

(A) in meeting the security countermeasure needs identified under this section; and

(B) on the annual Public Health Emergency Medical Countermeasures Enterprise and Strategy Implementation Plan (pursuant to section 300hh–10(d) of this title).

(5) Clarification on contracting authority

The Secretary, acting through the Director of the Biomedical Advanced Research and Development Authority, shall carry out the programs funded by the special reserve fund (for the procurement of security countermeasures under subsection (c) and for carrying out section 247d–7e of this title), including the execution of procurement contracts, grants, and cooperative agreements pursuant to this section and section 247d–7e of this title.

(h) Definitions

In this section:

(1) The term "advanced research and development" has the meaning given such term in section 247d–7e(a) of this title.

(2) The term "special reserve fund" means the "Biodefense Countermeasures" appropriations account, any appropriation made available pursuant to section 321j(a) of title 6, and any appropriation made available pursuant to subsection (g)(1).

(i) Pilot program to support State medical stockpiles

(1) In general

The Secretary, in consultation with the Assistant Secretary for Preparedness and Response and the Director of the Centers for Disease Control and Prevention, shall award grants or cooperative agreements to not fewer than 5 States, or consortia of States, with consideration given to distribution among the geographical regions of the United States, to establish, expand, or maintain a stockpile of appropriate drugs, vaccines and other biological products, medical devices, and other medical supplies determined by the State to be necessary to respond to a public health emergency declared by the Governor of a State or by the Secretary under section 247d of this title, or a major disaster or emergency declared by the President under section 5170 or 5191, respectively, of this title, in order to support the preparedness goals described in paragraphs (2) through (6) and (8) of section 300hh–1(b) of this title. A recipient of such an award may not use award funds to support the stockpiling of security countermeasures (as defined in subsection (c)(1),[3] unless the eligible entity provides justification for maintaining such countermeasures and the Secretary determines such justification is appropriate and applicable.

(2) Requirements

(A) Application

To be eligible to receive an award under paragraph (1), an entity shall prepare, in consultation with appropriate health care entities and health officials within the jurisdiction of such State or States, and submit to the Secretary an application that contains such information as the Secretary may require, including—

(i) a plan for such stockpile, consistent with paragraph (4), including—

(I) a description of the activities such entity will carry out under the agreement;

(II) an assurance that such entity will use funds under such award in alignment with the requirements of chapter 83 of title 41 (commonly referred to as the "Buy American Act"); and

(III) an outline of proposed expenses; and

(ii) a description of how such entity will coordinate with relevant entities in receipt of an award under section 247d–3a or 247d–3b of this title pursuant to paragraph (4), including

through promoting alignment between the stockpile plan established pursuant to clause (i) and applicable plans that are established by such entity pursuant to section 247d–3a or 247d–3b of this title.

(B) Matching funds

(i) Subject to clause (ii), the Secretary may not make an award under this subsection unless the applicant agrees, with respect to the costs to be incurred by the applicant in carrying out the purpose described in this subsection, to make available non-Federal contributions toward such costs in an amount equal to—

(I) for each of fiscal years 2023 and 2024, not less than $1 for each $20 of Federal funds provided in the award; and

(II) for fiscal year 2025 and each fiscal year thereafter, not less than $1 for each $10 of Federal funds provided in the award.

(ii) WAIVER.—The Secretary may, upon the request of a State, waive the requirement under clause (i), in whole or in part, if the Secretary determines that extraordinary economic conditions in the State in the fiscal year involved or in the previous fiscal year justify the waiver. A waiver provided by the Secretary under this subparagraph shall apply only to the fiscal year involved.

(C) Administrative expenses

Not more than 10 percent of amounts received by an entity pursuant to an award under this subsection may be used for administrative expenses.

(3) Lead entity

An entity in receipt of an award under paragraph (1) may designate a lead entity, which may be a public or private entity, as appropriate, to manage the stockpile at the direction of the State or consortium of States.

(4) Use of funds

An entity in receipt of an award under paragraph (1) shall use such funds to—

(A) purchase, store, and maintain a stockpile of appropriate drugs, vaccines and other biological products, medical devices, and other medical supplies to be used during a public health emergency, major disaster, or emergency described in paragraph (1), in such numbers, types, and amounts as the entity determines necessary, consistent with such entity's stockpile plan established pursuant to paragraph (2)(A)(i);

(B) deploy the stockpile as required by the entity to respond to an actual or potential public health emergency, major disaster, or other emergency described in paragraph (1);

(C) replenish and make necessary additions or modifications to the contents of such stockpile, including to address potential depletion;

(D) in consultation with Federal, State, and local officials, take into consideration the availability, deployment, dispensing, and administration requirements of medical products within the stockpile;

(E) ensure that procedures are followed for inventory management and accounting, and for the physical security of the stockpile, as appropriate;

(F) review and revise, as appropriate, the contents of the stockpile on a regular basis to ensure that, to the extent practicable, new technologies and medical products are considered;

(G) carry out exercises, drills, and other training for purposes of stockpile deployment, dispensing, and administration of medical products, and for purposes of assessing the capability of such stockpile to address the medical supply needs of public health emergencies, major disasters, or other emergencies described in paragraph (1) of varying types and scales, which may be conducted in accordance with requirements related to exercises, drills, and other training for recipients of awards under section 247d–3a or 247d–3b of this title, as applicable; and

(H) carry out other activities related to the State strategic stockpile as the entity determines

appropriate, to support State efforts to prepare for, and respond to, public health threats.

(5) Supplement not supplant

Awards under paragraph (1) shall supplement, not supplant, the maintenance and use of the Strategic National Stockpile by the Secretary under subsection (a).

(6) Guidance for States

Not later than 180 days after December 29, 2022, the Secretary, in consultation with States, health officials, and other relevant stakeholders, as appropriate, shall issue guidance, and update such guidance as appropriate, for States related to maintaining and replenishing a stockpile of medical products, which may include strategies and best practices related to—

(A) types of medical products and medical supplies that are critical to respond to public health emergencies, and may be appropriate for inclusion in a stockpile by States, with consideration of threats that require the large-scale and simultaneous deployment of stockpiles, including the stockpile maintained by the Secretary pursuant to subsection (a), and long-term public health and medical response needs;

(B) appropriate management of the contents of a stockpile, including management by vendors of reserve amounts of medical products and supplies intended to be delivered to the ownership of the State and appropriate disposition of excess products, as applicable; and

(C) the procurement of medical products and medical supplies consistent with the requirements of chapter 83 of title 41 (commonly referred to as the "Buy American Act").

(7) Technical assistance

The Secretary shall provide assistance to States, including technical assistance, as appropriate, in establishing, maintaining, improving, and utilizing a medical stockpile, including appropriate inventory management and disposition of products.

(8) Reporting

(A) State reports

Each entity receiving an award under paragraph (1) shall update, as appropriate, the plan established pursuant to paragraph (2)(A)(i) and submit to the Secretary an annual report on implementation of such plan, including any changes to the contents of the stockpile supported under such award. The Secretary shall use information obtained from such reports to inform the maintenance and management of the Strategic National Stockpile pursuant to subsection (a).

(B) Reports to Congress

Not later than 1 year after the initial issuance of awards pursuant to paragraph (1), and annually thereafter for the duration of the program established under this subsection, the Secretary shall submit to the Committee on Health, Education, Labor, and Pensions and the Committee on Appropriations of the Senate and the Committee on Energy and Commerce and the Committee on Appropriations of the House of Representatives a report on such program, including—

(i) Federal and State expenditures to support stockpiles under such program;

(ii) activities conducted pursuant to paragraph (4); and

(iii) any additional information from the States that the Secretary determines relevant.

(9) Authorization of appropriations

To carry out this subsection, there is authorized to be appropriated $3,500,000,000 for each of fiscal years 2023 and 2024, to remain available until expended.

(July 1, 1944, ch. 373, title III, §319F–2, formerly Pub. L. 107–188, title I, §121, June 12, 2002, 116 Stat. 611; Pub. L. 107–296, title XVII, §1705(a), Nov. 25, 2002, 116 Stat. 2316; renumbered §319F–2 of act July 1, 1944, and amended Pub. L. 108–276, §3(a), July 21, 2004, 118 Stat. 842; Pub. L. 109–417, title I, §102(c), title IV, §§403(b), 406, Dec. 19, 2006, 120 Stat. 2834, 2874, 2879; Pub. L. 113–5, title IV, §§401, 403, Mar. 13, 2013, 127 Stat. 192, 196; Pub. L. 114–255, div. A, title III, §§3081, 3082(a), 3085, Dec. 13, 2016, 130 Stat. 1140, 1144; Pub. L. 116–22, title IV, §403(a),

(c), title V, §§502, 504(a), title VII, §702, June 24, 2019, 133 Stat. 943, 947, 950, 951, 962; Pub. L. 116–136, div. A, title III, §3102, Mar. 27, 2020, 134 Stat. 361; Pub. L. 117–58, div. G, title IX, §70953(f)(3), Nov. 15, 2021, 135 Stat. 1316; Pub. L. 117–328, div. FF, title II, §§2402, 2403, 2404(b)–2406, 2408(a), 2409(a), Dec. 29, 2022, 136 Stat. 5785–5787, 5789.)

EDITORIAL NOTES

REFERENCES IN TEXT

Section 403(b) of the Pandemic and All-Hazards Preparedness and Advancing Innovation Act of 2019, referred to in subsec. (a)(6)(A)(ix), is section 403(b) of Pub. L. 116–22, title IV, June 24, 2019, 133 Stat. 947, which is not classified to the Code.

The Federal Food, Drug, and Cosmetic Act, referred to in subsec. (c)(1)(B)(i)(III)(aa), is act June 25, 1938, ch. 675, 52 Stat. 1040. Chapter V of the Act is classified generally to subchapter V (§351 et seq.) of chapter 9 of Title 21, Food and Drugs. For complete classification of this Act to the Code, see section 301 of Title 21 and Tables.

The Project BioShield Act of 2004, referred to in subsec. (c)(7)(B)(iii)(IV), is Pub. L. 108–276, July 21, 2004, 118 Stat. 835. For complete classification of this Act to the Code, see Short Title of 2004 Amendments note set out under section 201 of this title and Tables.

CODIFICATION

In subsec. (c)(7)(B)(ii)(VII), "section 3304(a)(1) of title 41" substituted for "section 303(c)(1) of the Federal Property and Administrative Services Act of 1949 (41 U.S.C. 253(c)(1))" on authority of Pub. L. 111–350, §6(c), Jan. 4, 2011, 124 Stat. 3854, which Act enacted Title 41, Public Contracts.

In subsec. (c)(7)(B)(iii)(I), "section 134 of title 41" substituted for "section 4(11) of the Office of Federal Procurement Policy Act (41 U.S.C. 403(11))" and "section 3101(b)(1)(A) of title 41" substituted for "section 302A(a) of the Federal Property and Administrative Services Act of 1949 (41 U.S.C. 252a(a))" on authority of Pub. L. 111–350, §6(c), Jan. 4, 2011, 124 Stat. 3854, which Act enacted Title 41, Public Contracts.

In subsec. (c)(7)(B)(iii)(I)(aa), "section 3305(a)(1) of title 41" substituted for "section 303(g)(1)(A) of the Federal Property and Administrative Services Act of 1949 (41 U.S.C. 253(g)(1)(A))" on authority of Pub. L. 111–350, §6(c), Jan. 4, 2011, 124 Stat. 3854, which Act enacted Title 41, Public Contracts.

In subsec. (c)(7)(B)(iii)(I)(bb), "section 3101(b)(1)(B) of title 41" substituted for "section 302A(b) of such Act (41 U.S.C. 252a(b))" on authority of Pub. L. 111–350, §6(c), Jan. 4, 2011, 124 Stat. 3854, which Act enacted Title 41, Public Contracts.

In subsec. (c)(7)(B)(iii)(II)(bb), "Section 8703(a) of title 41" substituted for "Subsections (a) and (b) of section 7 of the Anti-Kickback Act of 1986 (41 U.S.C. 57(a) and (b))" on authority of Pub. L. 111–350, §6(c), Jan. 4, 2011, 124 Stat. 3854, which Act enacted Title 41, Public Contracts.

In subsec. (c)(7)(B)(iii)(II)(cc), "Section 4706 of title 41" substituted for "Section 304C of the Federal Property and Administrative Services Act of 1949 (41 U.S.C. 254d)" on authority of Pub. L. 111–350, §6(c), Jan. 4, 2011, 124 Stat. 3854, which Act enacted Title 41, Public Contracts.

In subsec. (c)(7)(B)(iii)(II)(ee), "Section 3901 of title 41" substituted for "Subsection (a) of section 304 of the Federal Property and Administrative Services Act of 1949 (41 U.S.C. 254(a))" on authority of Pub. L. 111–350, §6(c), Jan. 4, 2011, 124 Stat. 3854, which Act enacted Title 41, Public Contracts.

In subsec. (c)(7)(B)(iv)(I), "section 3304(a)(1) of title 41" substituted for "section 303(c)(1) of title III of the Federal Property and Administrative Services Act of 1949 (41 U.S.C. 253(c)(1))" and "such section 3304(a)(1)" substituted for "such section 303(c)(1)" on authority of Pub. L. 111–350, §6(c), Jan. 4, 2011, 124 Stat. 3854, which Act enacted Title 41, Public Contracts.

In subsec. (c)(7)(B)(iv)(III), "such section 3304(a)(1)" substituted for "such section 303(c)(1)" on authority of Pub. L. 111–350, §6(c), Jan. 4, 2011, 124 Stat. 3854, which Act enacted Title 41, Public Contracts.

In subsec. (c)(7)(B)(vii), "section 3306(a)(1)(B) of title 41" substituted for "section 303A(a)(1)(B) of the Federal Property and Administrative Services Act of 1949 (41 U.S.C. 253a(a)(1)(B))" on authority of Pub. L. 111–350, §6(c), Jan. 4, 2011, 124 Stat. 3854, which Act enacted Title 41, Public Contracts.

Section was formerly classified to section 300hh–12 of this title prior to renumbering by Pub. L. 108–276.

AMENDMENTS

2022—Subsec. (a)(2)(B)(i)(II). Pub. L. 117–328, §2402, amended subcl. (II) generally. Prior to amendment, subcl. (II) read as follows: "planning considerations for appropriate manufacturing capacity and

capability to meet the goals of such additions or modifications (without disclosing proprietary information), including consideration of the effect such additions or modifications may have on the availability of such products and ancillary medical supplies in the health care system;".

Subsec. (a)(3)(B). Pub. L. 117–328, §2403(1), inserted ", regularly reviewed, and updated" after "followed".

Subsec. (a)(3)(C). Pub. L. 117–328, §2408(a)(1), substituted "local, and Tribal" for "and local".

Subsec. (a)(3)(D). Pub. L. 117–328, §2403(2), amended subpar. (D) generally. Prior to amendment, subpar. (D) read as follows: "review and revise, as appropriate, the contents of the stockpile on a regular basis to ensure that emerging threats, advanced technologies, and new countermeasures are adequately considered and that the potential depletion of countermeasures currently in the stockpile is identified and appropriately addressed, including through necessary replenishment;".

Subsec. (a)(3)(F). Pub. L. 117–328, §2405(a)(1)(A), substituted "at the discretion of the Secretary, in consultation with, or at the request of, the Secretary of Homeland Security," for "as required by the Secretary of Homeland Security".

Subsec. (a)(3)(J). Pub. L. 117–328, §2408(a)(2), substituted "local, and Tribal" for "and local".

Subsec. (a)(3)(K). Pub. L. 117–328, §2404(b), added subpar. (K).

Subsec. (a)(5). Pub. L. 117–328, §2405(a)(1)(C), added par. (5). Former par. (5) redesignated (6).

Subsec. (a)(6). Pub. L. 117–328, §2405(a)(1)(B), redesignated par. (5) as (6). Former par. (6) redesignated (7).

Subsec. (a)(6)(A)(x). Pub. L. 117–328, §2405(a)(1)(D), added cl. (x).

Subsec. (a)(7). Pub. L. 117–328, §2406, amended par. (7) generally. Prior to amendment, text read as follows: "The Secretary, in coordination with the Secretary of Homeland Security, may sell drugs, vaccines and other biological products, medical devices, or other supplies maintained in the stockpile under paragraph (1) to a Federal agency or private, nonprofit, State, local, tribal, or territorial entity for immediate use and distribution, provided that any such items being sold are—

"(A) within 1 year of their expiration date; or

"(B) determined by the Secretary to no longer be needed in the stockpile due to advances in medical or technical capabilities."

Pub. L. 117–328, §2405(a)(1)(B), redesignated par. (6) as (7).

Subsec. (c)(2)(C). Pub. L. 117–328, §2405(a)(2), substituted "not later than March 15 of each year" for "on an annual basis".

Subsec. (f)(1). Pub. L. 117–328, §2405(b), substituted "$610,000,000 for each of fiscal years 2019 through 2021, and $750,000,000 for each of fiscal years 2022 and 2023" for "$610,000,000 for each of fiscal years 2019 through 2023".

Subsec. (i). Pub. L. 117–328, §2409(a), added subsec. (i).

2021—Subsec. (a)(6). Pub. L. 117–58 added par. (6).

2020—Subsec. (a)(1). Pub. L. 116–136 inserted "(including personal protective equipment, ancillary medical supplies, and other applicable supplies required for the administration of drugs, vaccines and other biological products, medical devices, and diagnostic tests in the stockpile)" after "other supplies".

2019—Subsec. (a)(1). Pub. L. 116–22, §403(a)(2), inserted "the Assistant Secretary for Preparedness and Response and" after "collaboration with", "and optimize" after "provide for" and "and, as informed by existing recommendations of, or consultations with, the Public Health Emergency Medical Countermeasure Enterprise established under section 300hh–10a of this title, make necessary additions or modifications to the contents of such stockpile or stockpiles based on the review conducted under paragraph (2)" after "public health emergency", and struck out at end "The Secretary shall conduct an annual review (taking into account at-risk individuals) of the contents of the stockpile, including non-pharmaceutical supplies, and make necessary additions or modifications to the contents based on such review and shall submit such review annually to the appropriate congressional committees of jurisdiction to the extent that disclosure of such information does not compromise national security."

Subsec. (a)(2). Pub. L. 116–22, §403(a)(3), added par. (2). Former par. (2) redesignated (3).

Subsec. (a)(3). Pub. L. 116–22, §403(a)(1), redesignated par. (2) as (3). Former par. (3) redesignated (4).

Subsec. (a)(3)(A). Pub. L. 116–22, §403(a)(4)(A), inserted before semicolon at end "and the Public Health Emergency Medical Countermeasures Enterprise established under section 300hh–10a of this title".

Subsec. (a)(3)(C). Pub. L. 116–22, §403(a)(4)(B), inserted before semicolon at end ", and the availability, deployment, dispensing, and administration of countermeasures".

Subsec. (a)(3)(E). Pub. L. 116–22, §403(a)(4)(C), amended subpar. (E) generally. Prior to amendment, subpar. (E) read as follows: "devise plans for the effective and timely supply-chain management of the stockpile, in consultation with appropriate Federal, State and local agencies, and the public and private health care infrastructure;".

Subsec. (a)(3)(I), (J). Pub. L. 116–22, §403(a)(4)(D)–(F), added subpars. (I) and (J).

Subsec. (a)(4). Pub. L. 116–22, §403(a)(1), redesignated par. (3) as (4).

Subsec. (a)(5). Pub. L. 116–22, §403(a)(5), added par. (5).

Subsec. (c)(2)(C). Pub. L. 116–22, §502(a), substituted "The Secretary and the Secretary of Homeland Security shall send to Congress, on an annual basis, all current material threat determinations and shall promptly notify the Committee on Health, Education, Labor, and Pensions and the Committee on Homeland Security and Governmental Affairs of the Senate and the Committee on Energy and Commerce and the Committee on Homeland Security of the House of Representatives" for "The Secretary and the Homeland Security Secretary shall promptly notify the appropriate committees of Congress".

Subsec. (c)(7)(B)(ii)(III). Pub. L. 116–22, §502(b), inserted at end "The Secretary shall notify the vendor within 90 days of a determination by the Secretary to renew, extend, or terminate such contract."

Subsec. (d). Pub. L. 116–22, §702, amended subsec. (d) generally. Prior to amendment, text read as follows: "No Federal agency shall disclose under section 552 of title 5 any information identifying the location at which materials in the stockpile under subsection (a) are stored."

Subsec. (f)(1). Pub. L. 116–22, §403(c), substituted "$610,000,000 for each of fiscal years 2019 through 2023, to remain available until expended" for "$533,800,000 for each of fiscal years 2014 through 2018".

Subsec. (g)(1). Pub. L. 116–22, §504(a), substituted "$7,100,000,000 for the period of fiscal years 2019 through 2028, to remain available until expended" for "$2,800,000,000 for the period of fiscal years 2014 through 2018" and struck out at end "Amounts appropriated pursuant to the preceding sentence are authorized to remain available until September 30, 2019."

2016—Subsec. (a)(3). Pub. L. 114–255, §3081(1), added par. (3).

Subsec. (c)(4)(A)(ii). Pub. L. 114–255, §3085(1), substituted "and subject to the availability of appropriations, make available the special reserve fund as defined in subsection (h) for procurement of such countermeasure, as applicable" for "make a recommendation under paragraph (6) that the special reserve fund as defined in subsection (h) be made available for the procurement of such countermeasure".

Subsec. (c)(6). Pub. L. 114–255, §3085(2)(D), substituted "Recommendations for procurement" for "Recommendation for President's approval" in heading.

Subsec. (c)(6)(A). Pub. L. 114–255, §3085(2)(C), amended subpar. (A) generally. Prior to amendment, text read as follows: "The Secretary and the Homeland Security Secretary shall notify the appropriate congressional committees of each decision of the President to approve a recommendation under subparagraph (A). Such notice shall include an explanation of the decision to make available the special reserve fund as defined in subsection (h) for procurement of such a countermeasure, including, where available, the number of, nature of, and other information concerning potential suppliers of such countermeasure, and whether other potential suppliers of the same or similar countermeasures were considered and rejected for procurement under this section and the reasons therefor."

Pub. L. 114–255, §3085(2)(A), (B), redesignated subpar. (C) as (A) and struck out former subpar. (A). Text of former subpar. (A) read as follows: "In the case of a security countermeasure that the Secretary has, in accordance with paragraphs (3) and (5), determined to be appropriate for procurement under this subsection, the Homeland Security Secretary and the Secretary shall jointly submit to the President, in coordination with the Director of the Office of Management and Budget, a recommendation that the special reserve fund as defined in subsection (h) be made available for the procurement of such countermeasure."

Subsec. (c)(6)(B). Pub. L. 114–255, §3085(2)(A), (B), redesignated subpar. (D) as (B) and struck out former subpar. (B). Text of former subpar. (B) read as follows: "The special reserve fund as defined in subsection (h) is available for a procurement of a security countermeasure only if the President has approved a recommendation under subparagraph (A) regarding the countermeasure."

Subsec. (c)(6)(C), (D). Pub. L. 114–255, §3085(2)(B), redesignated subpars. (C) and (D) as (A) and (B), respectively.

Subsec. (c)(6)(E). Pub. L. 114–255, §3085(2)(A), struck out subpar. (E). Text read as follows: "Recommendations and approvals under this paragraph apply solely to determinations that the special reserve fund as defined in subsection (h) will be made available for a procurement of a security countermeasure, and not to the substance of contracts for such procurement or other matters relating to awards of such contracts."

Subsec. (c)(7)(A). Pub. L. 114–255, §3085(3)(A), added subpar. (A) and struck out former subpar. (A). Text of former subpar. (A) read as follows: "For purposes of a procurement under this subsection that is approved by the President under paragraph (6), the Homeland Security Secretary and the Secretary shall have responsibilities in accordance with subparagraphs (B) and (C)."

Subsec. (c)(7)(B), (C). Pub. L. 114–255, §3085(3), redesignated subpar. (C) as (B) and struck out former subpar. (B). Text of former subpar. (B) read as follows: "The Homeland Security Secretary shall enter into an agreement with the Secretary for procurement of a security countermeasure in accordance with the provisions

of this paragraph. The special reserve fund as defined in subsection (h) shall be available for payments made by the Secretary to a vendor for such procurement."

Subsec. (g)(4). Pub. L. 114–255, §3081(2), amended par. (4) generally. Prior to amendment, text read as follows: "Not later than 30 days after any date on which the Secretary determines that the amount of funds in the special reserve fund available for procurement is less than $1,500,000,000, the Secretary shall submit to the appropriate committees of Congress a report detailing the amount of such funds available for procurement and the impact such reduction in funding will have—

"(A) in meeting the security countermeasure needs identified under this section; and

"(B) on the annual Public Health Emergency Medical Countermeasures Enterprise and Strategy Implementation Plan (pursuant to section 300hh–10(d) of this title)."

Subsec. (g)(5). Pub. L. 114–255, §3082(a), added par. (5).

2013—Subsec. (a)(1). Pub. L. 113–5, §403(1)(A), inserted "consistent with section 300hh–10 of this title" after "amounts as are determined" and "and shall submit such review annually to the appropriate congressional committees of jurisdiction to the extent that disclosure of such information does not compromise national security" after "based on such review".

Subsec. (a)(2)(D). Pub. L. 113–5, §403(1)(B), inserted "and that the potential depletion of countermeasures currently in the stockpile is identified and appropriately addressed, including through necessary replenishment" before semicolon at end.

Subsec. (c). Pub. L. 113–5, §401(b)(1)(A), substituted "special reserve fund as defined in subsection (h)" for "special reserve fund under paragraph (10)" wherever appearing.

Subsec. (c)(1)(B)(i)(III)(bb). Pub. L. 113–5, §401(a)(1), substituted "10 years" for "eight years".

Subsec. (c)(2)(C). Pub. L. 113–5, §401(a)(2), substituted "the appropriate committees of Congress" for "the designated congressional committees (as defined in paragraph (10))".

Subsec. (c)(5)(B)(ii). Pub. L. 113–5, §401(a)(3), substituted "10 years" for "eight years".

Subsec. (c)(6)(C). Pub. L. 113–5, §401(a)(4), substituted "appropriate congressional committees" for "designated congressional committees" in heading and in text.

Subsec. (c)(7)(C)(i)(I). Pub. L. 113–5, §401(a)(5)(A), inserted "including advanced research and development," after "as may reasonably be required,".

Subsec. (c)(7)(C)(ii)(III). Pub. L. 113–5, §401(a)(5)(B)(i), substituted "10 years" for "eight years".

Subsec. (c)(7)(C)(ii)(IX). Pub. L. 113–5, §401(a)(5)(B)(ii), added subcl. (IX) and struck out former subcl. (IX). Prior to amendment, text read as follows: "The Secretary, in any contract for procurement under this section, may specify—

"(aa) the dosing and administration requirements for countermeasures to be developed and procured;

"(bb) the amount of funding that will be dedicated by the Secretary for development and acquisition of the countermeasure; and

"(cc) the specifications the countermeasure must meet to qualify for procurement under a contract under this section."

Subsec. (c)(7)(C)(viii). Pub. L. 113–5, §401(a)(5)(C), added cl. (viii).

Subsec. (c)(9), (10). Pub. L. 113–5, §401(b)(1)(B), struck out pars. (9) and (10) which described restrictions on the use of funds and defined "special reserve fund" and "designated congressional committees".

Subsec. (f)(1). Pub. L. 113–5, §403(2), substituted "$533,800,000 for each of fiscal years 2014 through 2018. Such authorization is in addition to amounts in the special reserve fund referred to in subsection (h)." for "$640,000,000 for fiscal year 2002, and such sums as may be necessary for each of fiscal years 2003 through 2006. Such authorization is in addition to amounts in the special reserve fund referred to in subsection (c)(10)(A) of this section."

Subsecs. (g), (h). Pub. L. 113–5, §401(b)(2), added subsecs. (g) and (h).

2006—Pub. L. 109–417, §406(1), inserted "and security countermeasure procurements" after "Stockpile" in section catchline.

Subsec. (a)(1). Pub. L. 109–417, §102(c), inserted "in collaboration with the Director of the Centers for Disease Control and Prevention, and" after "The Secretary," and inserted at end "The Secretary shall conduct an annual review (taking into account at-risk individuals) of the contents of the stockpile, including non-pharmaceutical supplies, and make necessary additions or modifications to the contents based on such review."

Subsec. (c). Pub. L. 109–417, §406(2)(A), struck out "biomedical" before "countermeasures" in heading.

Subsec. (c)(1)(B)(i)(I). Pub. L. 109–417, §403(b), which directed amendment of section 319F–2(c)(1)(B) by substituting "diagnose, mitigate, prevent, or treat" for "treat, identify, or prevent" wherever appearing, was executed by making the substitution in two places in subsec. (c)(1)(B)(i)(I) of this section, which is section 319F–2 of the Public Health Service Act, to reflect the probable intent of Congress.

Subsec. (c)(3). Pub. L. 109–417, §406(2)(B), designated existing provisions as subpar. (A), inserted heading, and added subpar. (B).

Subsec. (c)(4)(A). Pub. L. 109–417, §406(2)(C), inserted "not developed or" after "currently" in introductory provisions.

Subsec. (c)(5)(B)(i). Pub. L. 109–417, §406(2)(D), substituted "to meet the stockpile needs" for "to meet the needs of the stockpile".

Subsec. (c)(7)(B). Pub. L. 109–417, §406(2)(E), substituted "cost" for "costs" in subpar. heading, struck out cl. (i) designation and heading before "The Homeland", and struck out heading and text of cl. (ii). Text read as follows: "The actual costs to the Secretary under this section, other than the costs described in clause (i), shall be paid from the appropriation provided for under subsection (f)(1) of this section."

Subsec. (c)(7)(C)(ii)(I). Pub. L. 109–417, §406(2)(F)(i), amended heading and text of subcl. (I) generally. Prior to amendment, text read as follows: "The contract shall provide that no payment may be made until delivery has been made of a portion, acceptable to the Secretary, of the total number of units contracted for, except that, notwithstanding any other provision of law, the contract may provide that, if the Secretary determines (in the Secretary's discretion) that an advance payment is necessary to ensure success of a project, the Secretary may pay an amount, not to exceed 10 percent of the contract amount, in advance of delivery. The contract shall provide that such advance payment is required to be repaid if there is a failure to perform by the vendor under the contract. Nothing in this subclause may be construed as affecting rights of vendors under provisions of law or regulation (including the Federal Acquisition Regulation) relating to termination of contracts for the convenience of the Government."

Subsec. (c)(7)(C)(ii)(VII) to (IX). Pub. L. 109–417, §406(2)(F)(ii), added subcls. (VII) to (IX).

Subsec. (c)(8)(A). Pub. L. 109–417, §406(2)(G), inserted at end "Such agreements may allow other executive agencies to order qualified and security countermeasures under procurement contracts or other agreements established by the Secretary. Such ordering process (including transfers of appropriated funds between an agency and the Department of Health and Human Services as reimbursements for such orders for countermeasures) may be conducted under the authority of section 1535 of title 31, except that all such orders shall be processed under the terms established under this subsection for the procurement of countermeasures."

2004—Pub. L. 108–276, §3(a)(2), amended section generally. Prior to amendment, text related in subsec. (a) to Strategic National Stockpile, in subsec. (b) to smallpox vaccine development, in subsec. (c) to disclosures, in subsec. (d) to definition of "stockpile", and in subsec. (e) to authorization of appropriations.

2002—Subsec. (a)(1). Pub. L. 107–296, §1705(a)(1), substituted "The Secretary of Homeland Security" for "The Secretary of Health and Human Services" and inserted "the Secretary of Health and Human Services and" after "in coordination with" and "of Health and Human Services" after "as are determined by the Secretary".

Subsecs. (a)(2), (b)(1). Pub. L. 107–296, §1705(a)(2), inserted "of Health and Human Services" after "Secretary" wherever appearing.

STATUTORY NOTES AND RELATED SUBSIDIARIES

EFFECTIVE DATE OF 2002 AMENDMENT

Pub. L. 107–296, title XVII, §1705(b), Nov. 25, 2002, 116 Stat. 2316, provided that: "The amendments made by this section [amending this section] shall take effect on the date of transfer of the Strategic National Stockpile of the Department of Health and Human Services to the Department [of Homeland Security]."

IMPROVING TRANSPARENCY AND PREDICTABILITY OF PROCESSES OF THE STRATEGIC NATIONAL STOCKPILE

Pub. L. 117–328, div. FF, title II, §2404(a), Dec. 29, 2022, 136 Stat. 5785, provided that: "Not later than 60 days after the date of enactment of this Act [Dec. 29, 2022], the Secretary of Health and Human Services (referred to in this section as the 'Secretary') shall issue guidance describing the processes by which the Secretary deploys the contents of the Strategic National Stockpile under section 319F–2(a) of the Public Health Service Act (42 U.S.C. 247d–6b(a)), or otherwise distributes medical countermeasures, as applicable, to States, territories, Indian Tribes and Tribal organizations (as such terms are defined under section 4 of the Indian Self-Determination and Education Assistance Act [25 U.S.C. 5304]), and other applicable entities. Such guidance shall include information related to processes by which to request access to the contents of the Strategic National Stockpile, factors considered by the Secretary when making deployment or distribution decisions, and processes and points of contact through which entities may contact the Secretary to address any issues related to products requested or received by such entity from the stockpile, and on other relevant topics."

INCREASED MANUFACTURING CAPACITY FOR CERTAIN CRITICAL ANTIBIOTIC DRUGS

Pub. L. 117–328, div. FF, title II, §2411, Dec. 29, 2022, 136 Stat. 5793, provided that:

"(a) PROGRAM.—

"(1) IN GENERAL.—The Secretary, in consultation with the Assistant Secretary for Preparedness and Response and Commissioner of Food and Drugs, may award contracts to increase the domestic manufacturing capacity of certain antibiotic drugs with identified supply chain vulnerabilities, or the active pharmaceutical ingredient or key starting material of such antibiotic drugs.

"(2) ELIGIBLE ENTITIES.—To be eligible to receive an award under this subsection, an entity shall—

"(A) be a manufacturer that is in compliance with, or demonstrates capability to comply with, the relevant requirements of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.); and

"(B) prepare and submit to the Secretary an application at such time, and in such manner, and containing such information as the Secretary may require, including—

"(i) a description of proposed activities to be supported by an award under this subsection to increase manufacturing capacity for such antibiotic drug or drugs;

"(ii) the antibiotic drug or drugs, or related active pharmaceutical ingredients or key starting materials for such drug or drugs, that such entity intends to manufacture with any increased manufacturing capacity supported by an award under this subsection;

"(iii) any additional products such increased manufacturing capacity could be used to manufacture;

"(iv) a description of the current supply chain for such antibiotic drugs, including any existing and applicable manufacturing facilities, known vulnerabilities in the supply chain, known or potential supply limitations, such as foreign export restrictions, or subsidies from foreign governments, as applicable;

"(v) a description of how such entity may use advanced or flexible manufacturing in carrying out the terms of an award under this subsection; and

"(vi) a strategic plan regarding the maintenance, operation, and sustainment of such increased manufacturing capacity following the expiration of a contract under this subsection.

"(3) USE OF FUNDS.—A recipient of an award under this subsection shall use such funds to build, expand, upgrade, modify, or recommission a facility located in the United States, which may include the purchase or upgrade of equipment, as applicable, to support increased manufacturing capacity of certain antibiotic drugs for which supply chain vulnerabilities exist, or the active pharmaceutical ingredient or key starting material of such antibiotic drugs.

"(4) REPORTS.—An entity in receipt of an award under this subsection shall submit to the Secretary such reports as the Secretary may require related to increasing domestic manufacturing capacity of antibiotic drugs pursuant to a contract under this subsection, including actions taken to implement the strategic plan required under paragraph (2)(B)(vi).

"(5) CONTRACT TERMS.—The following shall apply to a contract to support increased domestic manufacturing capacity under this subsection:

"(A) MILESTONE-BASED PAYMENTS.—The Secretary may provide payment, including advance payment or partial payment for significant milestones, if the Secretary makes a determination that such payment is necessary and appropriate.

"(B) REPAYMENT.—The contract shall provide that such payment is required to be repaid if there is a failure to perform by the manufacturer under the contract; if the specified milestones are reached, an advance or partial payment shall not be required to be repaid.

"(C) CONTRACT DURATION.—

"(i) IN GENERAL.—Each contract shall be for a period not to exceed 5 years.

"(ii) NON-RENEWABILITY.—A contract shall not be renewable.

"(iii) NOTIFICATIONS OF EXTENSIONS AND TERMINATIONS.—If the Secretary decides to terminate a contract prior to its expiration, the Secretary shall notify the manufacturer within 90 days of such determination.

"(D) ADDITIONAL TERMS.—The Secretary, in any contract under this subsection—

"(i) may specify—

"(I) the amount of funding that will be dedicated by the Secretary for supporting increased manufacturing capacity under such contract; and

"(II) the amount of manufacturing capacity that such eligible entity must meet; and

"(ii) shall provide a clear statement of defined Federal Government purpose limited to uses related to increasing domestic manufacturing capacity for antibiotic drugs to address identified supply

chain vulnerabilities and challenges to establishing and maintaining domestic manufacturing capacity.

"(E) SUSTAINMENT.—Each contract shall provide for the eligible entity to update the strategic plan required under paragraph (2)(B)(vi) throughout the duration of such contract, as required by the Secretary.

"(b) REPORT.—Not later than 2 years after the date of enactment of this Act [Dec. 29, 2022] and every year thereafter until the termination or expiration of all such contracts, the Secretary shall submit to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives a report on any activities supported under subsection (a), including—

"(1) the antibiotic drugs for which the Secretary prioritized awards under subsection (a), including a description of how the Secretary consulted with stakeholders to inform such prioritization;

"(2) information regarding each contract awarded pursuant to subsection (a), including—

"(A) the recipient of each such contract, including any recipients of a subaward;

"(B) the milestone and performance requirements pursuant to each such contract;

"(C) the duration of each such contract;

"(D) the amount of funding provided by the Secretary pursuant to each such contract, including any advanced or partial payments;

"(E) the antibiotic drugs supported through each such contract, including a description of the medical necessity of each such antibiotic drug and any supply chain vulnerabilities, limitations, and related characteristics identified pursuant to subsection (a)(2)(B)(iv) for each such antibiotic drug; and

"(F) the amount of increased manufacturing capacity for such antibiotic drug that each such contract supports; and

"(3) a description of how such contracts address supply chain vulnerabilities, including increasing manufacturing capacity of antibiotic drugs in the United States; and

"(4) a description of the strategic plan submitted pursuant to subsection (a)(2)(B)(vi) by each recipient of an award under subsection (a).

"(c) RULE OF CONSTRUCTION.—Nothing in this section shall be construed—

"(1) to limit, directly or indirectly, or otherwise impact the private distribution, purchase, or sale of antibiotic drugs or active pharmaceutical ingredients or key starting materials; or

"(2) to authorize the Secretary to disclose any information that is a trade secret, or other privileged or confidential information subject to section 552(b)(4) of title 5, United States Code, or section 1905 of title 18, United States Code.

"(d) DEFINITIONS.—For purposes of this section:

"(1) ACTIVE PHARMACEUTICAL INGREDIENT.—The term 'active pharmaceutical ingredient' has the meaning given such term in section 744A of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379j–41).

"(2) ANTIBIOTIC DRUG.—The term 'antibiotic drug' means an antibacterial or antifungal drug approved by the Food and Drug Administration under section 505(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)) that is of significant priority to providing health care and is medically necessary to have available at all times in an amount adequate to serve patient needs.

"(3) KEY STARTING MATERIAL.—The term 'key starting material' means any component of a drug that the Secretary determines to be necessary to the safety and effectiveness of the drug.

"(4) SECRETARY.—The term 'Secretary' means the Secretary of Health and Human Services.

"(e) SUNSET.—The authority to enter into new contracts under this section shall cease to be effective 3 years after the date of enactment of this Act [Dec. 29, 2022], and, beginning on the date that is 8 years after the date of enactment of this Act, this section shall have no force or effect."

FIRST RESPONDER ANTHRAX PREPAREDNESS

Pub. L. 114–268, Dec. 14, 2016, 130 Stat. 1387, known as the First Responder Anthrax Preparedness Act, which required the Secretary of Homeland Security, in coordination with the Secretary of Health and Human Services, to carry out a pilot program to provide from the Strategic National Stockpile eligible anthrax vaccines nearing end of their labeled dates of use to consenting emergency response providers at high risk of exposure to anthrax if an attack should occur, expired on the date that is 5 years after Dec. 14, 2016.

STOCKPILE FUNCTIONS TRANSFERRED

Pub. L. 108–276, §3(c)(1), (2), July 21, 2004, 118 Stat. 853, provided that:

"(1) IN GENERAL.—Except as provided in paragraph (2), there shall be transferred to the Secretary of Health and Human Services the functions, personnel, assets, unexpended balances, and liabilities of the Strategic National Stockpile, including the functions of the Secretary of Homeland Security relating thereto.

"(2) EXCEPTIONS.—

"(A) FUNCTIONS.—The transfer of functions pursuant to paragraph (1) shall not include such functions as are explicitly assigned to the Secretary of Homeland Security by this Act [see Short Title of 2004 Amendments note set out under section 201 of this title] (including the amendments made by this Act).

"(B) ASSETS AND UNEXPENDED BALANCES.—The transfer of assets and unexpended balances pursuant to paragraph (1) shall not include the funds appropriated under the heading 'BIODEFENSE COUNTERMEASURES' in the Department of Homeland Security Appropriations Act, 2004 (Public Law 108–90 [117 Stat. 1148])."

POTASSIUM IODIDE

Pub. L. 107–188, title I, §127, June 12, 2002, 116 Stat. 615, provided that:

"(a) IN GENERAL.—Through the national stockpile under section 121 [now section 319F–2 of act July 1, 1944, 42 U.S.C. 247d–6b], the President, subject to subsections (b) and (c), shall make available to State and local governments potassium iodide tablets for stockpiling and for distribution as appropriate to public facilities, such as schools and hospitals, in quantities sufficient to provide adequate protection for the population within 20 miles of a nuclear power plant.

"(b) STATE AND LOCAL PLANS.—

"(1) IN GENERAL.—Subsection (a) applies with respect to a State or local government, subject to paragraph (2), if the government involved meets the following conditions:

"(A) Such government submits to the President a plan for the stockpiling of potassium iodide tablets, and for the distribution and utilization of potassium iodide tablets in the event of a nuclear incident.

"(B) The plan is accompanied by certifications by such government that the government has not already received sufficient quantities of potassium iodide tablets from the Federal Government.

"(2) LOCAL GOVERNMENTS.—Subsection (a) applies with respect to a local government only if, in addition to the conditions described in paragraph (1), the following conditions are met:

"(A) The State in which the locality involved is located—

"(i) does not have a plan described in paragraph (1)(A); or

"(ii) has a plan described in such paragraph, but the plan does not address populations at a distance greater than 10 miles from the nuclear power plant involved.

"(B) The local government has petitioned the State to modify the State plan to address such populations, not exceeding 20 miles from such plant, and 60 days have elapsed without the State modifying the State plan to address populations at the full distance sought by the local government through the petition.

"(C) The local government has submitted its local plan under paragraph (1)(A) to the State, and the State has approved the plan and certified that the plan is not inconsistent with the State emergency plan.

"(c) GUIDELINES.—Not later than one year after the date of the enactment of this Act [June 12, 2002], the President, in consultation with individuals representing appropriate Federal, State, and local agencies, shall establish guidelines for the stockpiling of potassium iodide tablets, and for the distribution and utilization of potassium iodide tablets in the event of a nuclear incident. Such tablets may not be made available under subsection (a) until such guidelines have been established.

"(d) INFORMATION.—The President shall carry out activities to inform State and local governments of the program under this section.

"(e) REPORTS.—

"(1) PRESIDENT.—Not later than six months after the date on which the guidelines under subsection (c) are issued, the President shall submit to the Congress a report—

"(A) on whether potassium iodide tablets have been made available under subsection (a) or other Federal, State, or local programs, and the extent to which State and local governments have established stockpiles of such tablets; and

"(B) the measures taken by the President to implement this section.

"(2) NATIONAL ACADEMY OF SCIENCES.—

"(A) IN GENERAL.—The President shall request the National Academy of Sciences to enter into an agreement with the President under which the Academy conducts a study to determine what is the most effective and safe way to distribute and administer potassium iodide tablets on a mass scale. If the Academy declines to conduct the study, the President shall enter into an agreement with another appropriate public or nonprofit private entity to conduct the study.

"(B) REPORT.—The President shall ensure that, not later than six months after the date of the enactment of this Act [June 12, 2002], the study required in subparagraph (A) is completed and a report describing the findings made in the study is submitted to the Congress.

"(f) APPLICABILITY.—Subsections (a) and (d) cease to apply as requirements if the President determines that there is an alternative and more effective prophylaxis or preventive measures for adverse thyroid conditions that may result from the release of radionuclides from nuclear power plants."

[Memorandum of President of the United States, July 3, 2007, 72 F.R. 37627, provided:

[Memorandum for the Secretary of Health and Human Services[,] the Secretary of Energy[,] the Secretary of Homeland Security[,] the Chairman of the Nuclear Regulatory Commission[, and] the Director of the Office of Science and Technology Policy

[By the authority vested in me as President by the Constitution and the laws of the United States, including section 301 of title 3, United States Code, and section 204(b) of the National Science and Technology Policy, Organization, and Priorities Act of 1976, as amended (42 U.S.C. 6613(b)), the functions of the President under section 127 of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (Public Law 107–188) (42 U.S.C. 247d–6b note) are assigned as follows:

[(1) the function of making a determination under subsection 127(f) of Public Law 107–188 is assigned to the Director of the Office of Science and Technology Policy; and

[(2) the functions of the President under section 127 of Public Law 107–188 other than that assigned under subsection 127(f) are assigned to the Chairman of the Nuclear Regulatory Commission.

[In the performance of such functions the Chairman and the Director should consult each other and the Secretaries of Health and Human Services, Energy, and Homeland Security, as appropriate.

[The Director is authorized and directed to publish this memorandum in the Federal Register.]

EXECUTIVE DOCUMENTS

EX. ORD. NO. 13944. COMBATING PUBLIC HEALTH EMERGENCIES AND STRENGTHENING NATIONAL SECURITY BY ENSURING ESSENTIAL MEDICINES, MEDICAL COUNTERMEASURES, AND CRITICAL INPUTS ARE MADE IN THE UNITED STATES

Ex. Ord. No. 13944, Aug. 6, 2020, 85 F.R. 49929, provided:

By the authority vested in me as President by the Constitution and the laws of the United States of America, it is hereby ordered as follows:

SECTION 1. *Policy*. The United States must protect our citizens, critical infrastructure, military forces, and economy against outbreaks of emerging infectious diseases and chemical, biological, radiological, and nuclear (CBRN) threats. To achieve this, the United States must have a strong Public Health Industrial Base with resilient domestic supply chains for Essential Medicines, Medical Countermeasures, and Critical Inputs deemed necessary for the United States. These domestic supply chains must be capable of meeting national security requirements for responding to threats arising from CBRN threats and public health emergencies, including emerging infectious diseases such as COVID–19. It is critical that we reduce our dependence on foreign manufacturers for Essential Medicines, Medical Countermeasures, and Critical Inputs to ensure sufficient and reliable long-term domestic production of these products, to minimize potential shortages, and to mobilize our Nation's Public Health Industrial Base to respond to these threats. It is therefore the policy of the United States to:

(a) accelerate the development of cost-effective and efficient domestic production of Essential Medicines and Medical Countermeasures and have adequate redundancy built into the domestic supply chain for Essential Medicines, Medical Countermeasures, and Critical Inputs;

(b) ensure long-term demand for Essential Medicines, Medical Countermeasures, and Critical Inputs that are produced in the United States;

(c) create, maintain, and maximize domestic production capabilities for Critical Inputs, Finished Drug Products, and Finished Devices that are essential to protect public safety and human health and to provide for the national defense; and

(d) combat the trafficking of counterfeit Essential Medicines, Medical Countermeasures, and Critical Inputs over e-commerce platforms and from third-party online sellers involved in the government procurement process.

I am therefore directing each executive department and agency involved in the procurement of Essential Medicines, Medical Countermeasures, and Critical Inputs (agency) to consider a variety of actions to increase their domestic procurement of Essential Medicines, Medical Countermeasures, and Critical Inputs, and to identify vulnerabilities in our Nation's supply chains for these products. Under this order, agencies will have the necessary flexibility to increase their domestic procurement in appropriate and responsible ways, while

protecting our Nation's service members, veterans, and their families from increases in drug prices and without interfering with our Nation's ability to respond to the spread of COVID–19.

SEC. 2. *Maximizing Domestic Production in Procurement.* (a) Agencies shall, as appropriate, to the maximum extent permitted by applicable law, and in consultation with the Commissioner of Food and Drugs (FDA Commissioner) with respect to Critical Inputs, use their respective authorities under section 2304(c) of title 10, United States Code [now 10 U.S.C. 3204(a)]; section 3304(a) of title 41, United States Code; and subpart 6.3 of the Federal Acquisition Regulation, title 48, Code of Federal Regulations, to conduct the procurement of Essential Medicines, Medical Countermeasures, and Critical Inputs by:

(i) using procedures to limit competition to only those Essential Medicines, Medical Countermeasures, and Critical Inputs that are produced in the United States; and

(ii) dividing procurement requirements among two or more manufacturers located in the United States, as appropriate.

(b) Within 90 days of the date of this order [Aug. 6, 2020], the Director of the Office of Management and Budget (OMB), in consultation with appropriate agency heads, shall:

(i) review the authority of each agency to limit the online procurement of Essential Medicines and Medical Countermeasures to e-commerce platforms that have:

(A) adopted, and certified their compliance with, the applicable best practices published by the Department of Homeland Security in its Report to the President on "Combating Trafficking in Counterfeit and Pirated Goods," dated January 24, 2020; and

(B) agreed to permit the Department of Homeland Security's National Intellectual Property Rights Coordination Center to evaluate and confirm their compliance with such best practices; and

(ii) report its findings to the President.

(c) Within 90 days of the date of this order, the head of each agency shall, in consultation with the FDA Commissioner, develop and implement procurement strategies, including long-term contracts, consistent with law, to strengthen and mobilize the Public Health Industrial Base in order to increase the manufacture of Essential Medicines, Medical Countermeasures, and Critical Inputs in the United States.

(d) No later than 30 days after the FDA Commissioner has identified, pursuant to section 3(c) of this order, the initial list of Essential Medicines, Medical Countermeasures, and Critical Inputs, the United States Trade Representative shall, to the extent permitted by law, take all appropriate action to modify United States Federal procurement product coverage under all relevant Free Trade Agreements and the World Trade Organization Agreement on Government Procurement to exclude coverage of Essential Medicines, Medical Countermeasures, and Critical Inputs. The United States Trade Representative shall further modify United States Federal procurement product coverage, as appropriate, to reflect updates by the FDA Commissioner. After the modifications to United States Federal procurement coverage take effect, the United States Trade Representative shall make any necessary, corresponding modifications of existing waivers under section 301 of the Trade Agreements Act of 1979 [19 U.S.C. 2511]. The United States Trade Representative shall notify the President, through the Director of OMB, once it has taken the actions described in this subsection.

(e) No later than 60 days after the FDA Commissioner has identified, pursuant to section 3(c) of this order, the initial list of Essential Medicines, Medical Countermeasures, and Critical Inputs, and notwithstanding the public interest exception in subsection (f)(i)(1) of this section, the Secretary of Defense shall, to the maximum extent permitted by applicable law, use his authority under section 225.872–1(c) of the Defense Federal Acquisition Regulation Supplement to restrict the procurement of Essential Medicines, Medical Countermeasures, and Critical Inputs to domestic sources and to reject otherwise acceptable offers of such products from sources in Qualifying Countries in instances where considered necessary for national defense reasons.

(f) Subsections (a), (d), and (e) of this section shall not apply:

(i) where the head of the agency determines in writing, with respect to a specific contract or order, that (1) their application would be inconsistent with the public interest; (2) the relevant Essential Medicines, Medical Countermeasures, and Critical Inputs are not produced in the United States in sufficient and reasonably available commercial quantities and of a satisfactory quality; or (3) their application would cause the cost of the procurement to increase by more than 25 percent, unless applicable law requires a higher percentage, in which case such higher percentage shall apply;

(ii) with respect to the procurement of items that are necessary to respond to any public health emergency declared under section 319 of the Public Health Service Act (42 U.S.C. 247d), any major disaster or emergency declared under the Stafford Disaster Relief and Emergency Assistance Act (42 U.S.C. 5121 et seq.), or any national emergency declared under the National Emergencies Act (50 U.S.C. 1601 et seq.).

(g) To the maximum extent permitted by law, any public interest determination made pursuant to section 2(f)(i)(1) of this order shall be construed to maximize the procurement and use of Essential Medicines and

Medical Countermeasures produced in the United States.

(h) The head of an agency who makes any determination pursuant to section 2(f)(i) of this order shall submit an annual report to the President, through the Director of OMB and the Assistant to the President for Trade and Manufacturing Policy, describing the justification for each such determination.

SEC. 3. *Identifying Vulnerabilities in Supply Chains*. (a) Within 180 days of the date of this order, the Secretary of Health and Human Services, through the FDA Commissioner and in consultation with the Director of OMB, shall take all necessary and appropriate action, consistent with law, to identify vulnerabilities in the supply chain for Essential Medicines, Medical Countermeasures, and Critical Inputs and to mitigate those vulnerabilities, including by:

(i) considering proposing regulations or revising guidance on the collection of the following information from manufacturers of Essential Medicines and Medical Countermeasures as part of the application and regulatory approval process:

(A) the sources of Finished Drug Products, Finished Devices, and Critical Inputs;

(B) the use of any scarce Critical Inputs; and

(C) the date of the last FDA inspection of the manufacturer's regulated facilities and the results of such inspection;

(ii) entering into written agreements, pursuant to section 20.85 of title 21, Code of Federal Regulations, with the National Security Council, Department of State, Department of Defense, Department of Veterans Affairs, and other interested agencies, as appropriate, to disclose records regarding the security and vulnerabilities of the supply chains for Essential Medicines, Medical Countermeasures, and Critical Inputs;

(iii) recommending to the President any changes in applicable law that may be necessary to accomplish the objectives of this subsection; and

(iv) reviewing FDA regulations to determine whether any of those regulations may be a barrier to domestic production of Essential Medicines, Medical Countermeasures, and Critical Inputs, and by advising the President whether such regulations should be repealed or amended.

(b) The Secretary of Health and Human Services, through the FDA Commissioner, shall take all appropriate action, consistent with applicable law, to:

(i) accelerate FDA approval or clearance, as appropriate, for domestic producers of Essential Medicines, Medical Countermeasures, and Critical Inputs, including those needed for infectious disease and CBRN threat preparedness and response;

(ii) issue guidance with recommendations regarding the development of Advanced Manufacturing techniques;

(iii) negotiate with countries to increase site inspections and increase the number of unannounced inspections of regulated facilities manufacturing Essential Medicines, Medical Countermeasures, and Critical Inputs; and

(iv) refuse admission, as appropriate, to imports of Essential Medicines, Medical Countermeasures, and Critical Inputs if the facilities in which they are produced refuse or unreasonably delay an inspection.

(c) Within 90 days of the date of this order, and periodically updated as appropriate, the FDA Commissioner, in consultation with the Director of OMB, the Assistant Secretary for Preparedness and Response in the Department of Health and Human Services, the Assistant to the President for Economic Policy, and the Director of the Office of Trade and Manufacturing Policy, shall identify the list of Essential Medicines, Medical Countermeasures, and their Critical Inputs that are medically necessary to have available at all times in an amount adequate to serve patient needs and in the appropriate dosage forms.

(d) Within 180 days of the date of this order, the Secretary of Defense, in consultation with the Director of OMB, shall take all necessary and appropriate action, consistent with law, to identify vulnerabilities in the supply chain for Essential Medicines, Medical Countermeasures, and Critical Inputs necessary to meet the unique needs of the United States Armed Forces and to mitigate the vulnerabilities identified in subsection (a) of this section. The Secretary of Defense shall provide to the Secretary of Health and Human Services, the FDA Commissioner, the Director of OMB, and the Director of the Office of Trade and Manufacturing Policy a list of defense-specific Essential Medicines, Medical Countermeasures, and Critical Inputs that are medically necessary to have available for defense use in adequate amounts and in appropriate dosage forms. The Secretary of Defense shall, as appropriate, periodically update this list.

SEC. 4. *Streamlining Regulatory Requirements*. Consistent with law, the Administrator of the Environmental Protection Agency shall take all appropriate action to identify relevant requirements and guidance documents that can be streamlined to provide for the development of Advanced Manufacturing facilities and the expeditious domestic production of Critical Inputs, including by accelerating siting and permitting approvals.

SEC. 5. *Priorities and Allocation of Essential Medicines, Medical Countermeasures, and Critical Inputs*.

The Secretary of Health and Human Services shall, as appropriate and in accordance with the delegation of authority under Executive Order 13603 of March 16, 2012 (National Defense Resources Preparedness) [50 U.S.C. 4553 note], use the authority under section 101 of the Defense Production Act of 1950, as amended (50 U.S.C. 4511), to prioritize the performance of Federal Government contracts or orders for Essential Medicines, Medical Countermeasures, or Critical Inputs over performance of any other contracts or orders, and to allocate such materials, services, and facilities as the Secretary deems necessary or appropriate to promote the national defense.

SEC. 6. *Reporting*. (a) No later than December 15, 2021, and annually thereafter, the head of each agency shall submit a report to the President, through the Director of OMB and the Assistant to the President for Trade and Manufacturing Policy, detailing, for the preceding three fiscal years:

(i) the Essential Medicines, Medical Countermeasures, and Critical Inputs procured by the agency;

(ii) the agency's annual itemized and aggregated expenditures for all Essential Medicines, Medical Countermeasures, and Critical Inputs;

(iii) the sources of these products and inputs; and

(iv) the agency's plan to support domestic production of such products and inputs in the next fiscal year.

(b) Within 180 days of the date of this order, the Secretary of Commerce shall submit a report to the Director of OMB, the Assistant to the President for National Security Affairs, the Director of the National Economic Council, and the Director of the Office of Trade and Manufacturing Policy, describing any change in the status of the Public Health Industrial Base and recommending initiatives to strengthen the Public Health Industrial Base.

(c) To the maximum extent permitted by law, and with the redaction of any information protected by law from disclosure, each agency's report shall be published in the Federal Register and on each agency's official website.

SEC. 7. *Definitions*. As used in this order:

(a) "Active Pharmaceutical Ingredient" has the meaning set forth in section 207.1 of title 21, Code of Federal Regulations.

(b) "Advanced Manufacturing" means any new medical product manufacturing technology that can improve drug quality, address shortages of medicines, and speed time to market, including continuous manufacturing and 3D printing.

(c) "API Starting Material" means a raw or intermediate material that is used in the manufacturing of an API, that is incorporated as a significant structural fragment into the structure of the API, and that is determined by the FDA Commissioner to be relevant in assessing the safety and effectiveness of Essential Medicines and Medical Countermeasures.

(d) "Critical Inputs" means API, API Starting Material, and other ingredients of drugs and components of medical devices that the FDA Commissioner determines to be critical in assessing the safety and effectiveness of Essential Medicines and Medical Countermeasures.

(e) "Essential Medicines" are those Essential Medicines deemed necessary for the United States pursuant to section 3(c) of this order.

(f) "Finished Device" has the meaning set forth in section 820.3(l) of title 21, Code of Federal Regulations.

(g) "Finished Drug Product" has the meaning set forth in section 207.1 of title 21, Code of Federal Regulations.

(h) "Healthcare and Public Health Sector" means the critical infrastructure sector identified in Presidential Policy Directive 21 of February 12, 2013 (Critical Infrastructure Security and Resilience), and the National Infrastructure Protection Plan of 2013.

(i) An Essential Medicine or Medical Countermeasure is "produced in the United States" if the Critical Inputs used to produce the Essential Medicine or Medical Countermeasures are produced in the United States and if the Finished Drug Product or Finished Device, are manufactured, prepared, propagated, compounded, or processed, as those terms are defined in section 360(a)(1) of title 21, United States Code, in the United States.

(j) "Medical Countermeasures" means items that meet the definition of "qualified countermeasure" in section 247d–6a(a)(2)(A) of title 42, United States Code; "qualified pandemic or epidemic product" in section 247d–6d(i)(7) of title 42, United States Code; "security countermeasure" in section 247d–6b(c)(1)(B) of title 42, United States Code; or personal protective equipment described in part 1910 of title 29, Code of Federal Regulations.

(k) "Public Health Industrial Base" means the facilities and associated workforces within the United States, including research and development facilities, that help produce Essential Medicines, Medical Countermeasures, and Critical Inputs for the Healthcare and Public Health Sector.

(l) "Qualifying Countries" has the meaning set forth in section 225.003, Defense Federal Acquisition

Regulation Supplement.

SEC. 8. *Rule of Construction*. Nothing in this order shall be construed to impair or otherwise affect:

(a) the ability of State, local, tribal, or territorial governments to timely procure necessary resources to respond to any public health emergency declared under section 319 of the Public Health Service Act (42 U.S.C. 247d), any major disaster or emergency declared under the Stafford Act (42 U.S.C. 5121 et seq.), or any national emergency declared under the National Emergencies Act (50 U.S.C. 1601 et seq.);

(b) the ability or authority of any agency to respond to the spread of COVID–19; or

(c) the authority of the Secretary of Veterans Affairs to take all necessary steps, including those necessary to implement the policy set forth in section 1 of this order, to ensure that service members, veterans, and their families continue to have full access to Essential Medicines at reasonable and affordable prices.

SEC. 9. *Severability*. If any provision of this order, or the application of any provision to any person or circumstance, is held to be invalid, the remainder of this order and the application of any of its other provisions to any other persons or circumstances shall not be affected thereby.

SEC. 10. *General Provisions*. (a) Nothing in this order shall be construed to impair or otherwise affect:

(i) the authority granted by law to an executive department or agency, or the head thereof; or

(ii) the functions of the Director of OMB relating to budgetary, administrative, or legislative proposals.

(b) This order shall be implemented consistent with applicable law and subject to the availability of appropriations.

(c) This order is not intended to, and does not, create any right or benefit, substantive or procedural, enforceable at law or in equity by any party against the United States, its departments, agencies, or entities, its officers, employees, or agents, or any other person.

DONALD J. TRUMP.

EX. ORD. NO. 13962. ENSURING ACCESS TO UNITED STATES GOVERNMENT COVID–19 VACCINES

Ex. Ord. No. 13962, Dec. 8, 2020, 85 F.R. 79777, provided:

By the authority vested in me as President by the Constitution and the laws of the United States of America, it is hereby ordered as follows:

SECTION 1. *Purpose*. Through unprecedented collaboration across the United States Government, industry, and international partners, the United States expects to soon have safe and effective COVID–19 vaccines available for the American people. To ensure the health and safety of our citizens, to strengthen our economy, and to enhance the security of our Nation, we must ensure that Americans have priority access to COVID–19 vaccines developed in the United States or procured by the United States Government ("United States Government COVID–19 Vaccines").

SEC. 2. *Policy*. It is the policy of the United States to ensure Americans have priority access to free, safe, and effective COVID–19 vaccines. After ensuring the ability to meet the vaccination needs of the American people, it is in the interest of the United States to facilitate international access to United States Government COVID–19 Vaccines.

SEC. 3. *American Access to COVID–19 Vaccines*. (a) The Secretary of Health and Human Services, through Operation Warp Speed and with the support of the Secretary of Defense, shall ensure safe and effective COVID–19 vaccines are available to the American people, coordinating with public and private entities—including State, territorial, and tribal governments, where appropriate—to enable the timely distribution of such vaccines.

(b) The Secretary of Health and Human Services, in consultation with the Secretary of Defense and the heads of other executive departments and agencies (agencies), as appropriate, shall ensure that Americans have priority access to United States Government COVID–19 Vaccines, and shall ensure that the most vulnerable United States populations have first access to such vaccines.

(c) The Secretary of Health and Human Services shall ensure that a sufficient supply of COVID–19 vaccine doses is available for all Americans who choose to be vaccinated in order to safeguard America from COVID–19.

SEC. 4. *International Access to United States Government COVID–19 Vaccines*. After determining that there exists a sufficient supply of COVID–19 vaccine doses for all Americans who choose to be vaccinated, as required by section 3(b) of this order, the Secretary of Health and Human Services and the Secretary of State, in coordination with the Administrator of the United States Agency for International Development, the Chief Executive Officer of the United States International Development Finance Corporation, the Chairman and President of the Export-Import Bank of the United States, and the heads of other agencies, shall facilitate international access to United States Government COVID–19 Vaccines for allies, partners, and others, as appropriate and consistent with applicable law.

SEC. 5. *Coordination of International Access to United States Government COVID–19 Vaccines*. Within 30 days of the date of this order [Dec. 8, 2020], the Assistant to the President for National Security Affairs shall coordinate development of an interagency strategy for the implementation of section 4 of this order.

SEC. 6. *General Provisions*. (a) Nothing in this order shall be construed to impair or otherwise affect:

(i) the authority granted by law to an executive department or agency, or the head thereof; or

(ii) the functions of the Director of the Office of Management and Budget relating to budgetary, administrative, or legislative proposals.

(b) This order shall be implemented consistent with applicable law and subject to the availability of appropriations.

(c) This order is not intended to, and does not, create any right or benefit, substantive or procedural, enforceable at law or in equity by any party against the United States, its departments, agencies, or entities, its officers, employees, or agents, or any other person.

DONALD J. TRUMP.

EX. ORD. NO. 14001. A SUSTAINABLE PUBLIC HEALTH SUPPLY CHAIN

Ex. Ord. No. 14001, Jan. 21, 2021, 86 F.R. 7219, provided:

By the authority vested in me as President by the Constitution and the laws of the United States of America, including the Defense Production Act of 1950, as amended (50 U.S.C. 4501 *et seq*.), sections 319 and 361 of the Public Health Service Act (42 U.S.C. 247d and 264), sections 306 and 307 of the Robert T. Stafford Disaster Relief and Emergency Assistance Act (42 U.S.C. 5149 and 5150), and section 301 of title 3, United States Code, it is hereby ordered as follows:

SECTION 1. *Purpose*. The Federal Government must act urgently and effectively to combat the coronavirus disease 2019 (COVID–19) pandemic. To that end, this order directs immediate actions to secure supplies necessary for responding to the pandemic, so that those supplies are available, and remain available, to the Federal Government and State, local, Tribal, and territorial authorities, as well as to America's health care workers, health systems, and patients. These supplies are vital to the Nation's ability to reopen its schools and economy as soon and safely as possible.

SEC. 2. *Immediate Inventory of Response Supplies and Identification of Emergency Needs*. (a) The Secretary of State, the Secretary of Defense, the Secretary of Health and Human Services, the Secretary of Homeland Security, and the heads of appropriate executive departments and agencies (agencies), in coordination with the COVID–19 Response Coordinator, shall:

(i) immediately review the availability of critical materials, treatments, and supplies needed to combat COVID–19 (pandemic response supplies), including personal protective equipment (PPE) and the resources necessary to effectively produce and distribute tests and vaccines at scale; and

(ii) assess, including by reviewing prior such assessments, whether United States industry can be reasonably expected to provide such supplies in a timely manner.

(b) Where a review and assessment described in section 2(a)(i) of this order identifies shortfalls in the provision of pandemic response supplies, the head of the relevant agency shall:

(i) promptly revise its operational assumptions and planning factors being used to determine the scope and prioritization, acquisition, and distribution of such supplies; and

(ii) take appropriate action using all available legal authorities, including the Defense Production Act, to fill those shortfalls as soon as practicable by acquiring additional stockpiles, improving distribution systems, building market capacity, or expanding the industrial base.

(c) Upon completing the review and assessment described in section 2(a)(i) of this order, the Secretary of Health and Human Services shall provide to the President, through the COVID–19 Response Coordinator, a report on the status and inventory of the Strategic National Stockpile.

(d) The Secretary of State, the Secretary of Defense, the Secretary of Health and Human Services, the Secretary of Homeland Security, and the heads of any other agencies relevant to inventorying pandemic response supplies shall, as soon as practicable, provide to the President, through the COVID–19 Response Coordinator, a report consisting of:

(i) an assessment of the need for, and an inventory of current supplies of, key pandemic response supplies;

(ii) an analysis of their agency's capacity to produce, provide, and distribute pandemic response supplies;

(iii) an assessment of their agency's procurement of pandemic response supplies on the availability of such supplies on the open market;

(iv) an account of all existing or ongoing agency actions, contracts, and investment agreements regarding pandemic response supplies;

(v) a list of any gaps between the needs identified in section 2(a)(i) of this order and supply chain delivery, and recommendations on how to close such gaps; and

(vi) a compilation and summary of their agency's existing distribution and prioritization plans for pandemic response supplies, which shall include any assumptions or planning factors used to determine such needs and any recommendations for changes to such assumptions or factors.

(e) The COVID–19 Response Coordinator, in coordination with the heads of appropriate agencies, shall review the report described in section 2(d) of this order and submit recommendations to the President that address:

(i) whether additional use of the Defense Production Act, by the President or agencies exercising delegated authority under the Act, would be helpful; and

(ii) the extent to which liability risk, regulatory requirements, or other factors impede the development, production, and procurement of pandemic response supplies, and any actions that can be taken, consistent with law, to remove those impediments.

(f) The heads of agencies responsible for completing the requirements of this section, as appropriate and in coordination with the COVID–19 Response Coordinator, shall consult with State, local, Tribal, and territorial authorities, as well as with other entities critical to assessing the availability of and need for pandemic response supplies.

SEC. 3. *Pricing*. To take steps to address the pricing of pandemic response supplies:

(a) The Secretary of Health and Human Services shall promptly recommend to the President, through the COVID–19 Response Coordinator, whether any changes should be made to the authorities delegated to the Secretary by Executive Order 13910 of March 23, 2020 (Preventing Hoarding of Health and Medical Resources To Respond to the Spread of COVID–19) [50 U.S.C. 4512 note], with respect to scarce materials or materials the supply of which would be threatened by accumulation for the purpose of hoarding or price gouging.

(b) The Secretary of Defense, the Secretary of Health and Human Services, and the Secretary of Homeland Security shall promptly review and provide to the President, through the COVID–19 Response Coordinator, recommendations for how to address the pricing of pandemic response supplies, including whether and how to direct the use of reasonable pricing clauses in Federal contracts and investment agreements, or other related vehicles, and whether to use General Services Administration Schedules to facilitate State, local, Tribal, and territorial government buyers and compacts in purchasing pandemic response supplies using Federal supply schedules.

SEC. 4. *Pandemic Supply Chain Resilience Strategy*. Within 180 days of the date of this order [Jan. 21, 2021], the Secretary of Defense, the Secretary of Health and Human Services, and the Secretary of Homeland Security, in coordination with the Assistant to the President for National Security Affairs (APNSA), the Assistant to the President for Domestic Policy, the COVID–19 Response Coordinator, and the heads of any agencies or entities selected by the APNSA and COVID–19 Response Coordinator, shall provide to the President a strategy to design, build, and sustain a long-term capability in the United States to manufacture supplies for future pandemics and biological threats. This strategy shall include:

(a) mechanisms to respond to emergency supply needs of State, local, Tribal, and territorial authorities, which should include standards and processes to prioritize requests and delivery and to ensure equitable distribution based on public health criteria;

(b) an analysis of the role of foreign supply chains in America's pandemic supply chain, America's role in the international public health supply chain, and options for strengthening and better coordinating global supply chain systems in future pandemics;

(c) mechanisms to address points of failure in the supply chains and to ensure necessary redundancies;

(d) the roles of the Strategic National Stockpile and other Federal and military stockpiles in providing pandemic supplies on an ongoing or emergency basis, including their roles in allocating supplies across States, localities, tribes, and territories, sustaining supplies during a pandemic, and in contingency planning to ensure adequate preparedness for future pandemics and public health emergencies;

(e) approaches to assess and maximize the value and efficacy of public/private partnerships and the value of Federal investments in latent manufacturing capacity; and

(f) an approach to develop a multi-year implementation plan for domestic production of pandemic supplies.

SEC. 5. *Access to Strategic National Stockpile*. The Secretary of Health and Human Services shall consult with Tribal authorities and take steps, as appropriate and consistent with applicable law, to facilitate access to the Strategic National Stockpile for federally recognized Tribal governments, Indian Health Service healthcare providers, Tribal health authorities, and Urban Indian Organizations.

SEC. 6. *General Provisions*. (a) Nothing in this order shall be construed to impair or otherwise affect:

(i) the authority granted by law to an executive department or agency, or the head thereof; or

(ii) the functions of the Director of the Office of Management and Budget relating to budgetary, administrative, or legislative proposals.

(b) This order shall be implemented consistent with applicable law and subject to the availability of appropriations.

(c) This order is not intended to, and does not, create any right or benefit, substantive or procedural, enforceable at law or in equity by any party against the United States, its departments, agencies, or entities, its officers, employees, or agents, or any other person.

J.R. BIDEN, JR.

EX. ORD. NO. 14336. ENSURING AMERICAN PHARMACEUTICAL SUPPLY CHAIN RESILIENCE BY FILLING THE STRATEGIC ACTIVE PHARMACEUTICAL INGREDIENTS RESERVE

Ex. Ord. No. 14335, Aug. 13, 2025, 90 F.R. 40223, provided:

By the authority vested in me as President by the Constitution and the laws of the United States of America, it is hereby ordered:

SECTION 1. *Purpose*. During my first term, my Administration acted to protect the health and security of the American people by restoring capacity for domestic production of essential pharmaceutical products. Executive Order 13944 of August 6, 2020 (Combatting Public Health Emergencies and Strengthening National Security by Ensuring Essential Medicines, Medical Countermeasures, and Critical Inputs Are Made in the United States) [set out above], directed certain executive departments and agencies (agencies) to consider a variety of actions to increase their domestic procurement of Essential Medicines, Medical Countermeasures, and Critical Inputs, as defined in section 7 of that order, and to identify supply chain vulnerabilities. The Food and Drug Administration published a list of Essential Medicines, Medical Countermeasures, and Critical Inputs in October 2020. The Office of the Assistant Secretary for Preparedness and Response (ASPR) within the Department of Health and Human Services later reduced the list to 86 essential medicines.

Nearly two in five prescription finished drug products are made in the United States, including many of the essential medicines. However, when it comes to Active Pharmaceutical Ingredients (APIs), the biologically active components of finished drug products, only about 10 percent of the APIs by volume for the finished drug products used in the United States are made here.

During my first term, my first Administration created a Strategic Active Pharmaceutical Ingredients Reserve (SAPIR) to stockpile APIs. Stockpiling APIs is advantageous as APIs are generally lower-cost and have longer shelf lives than the finished drug products they make. Filling the SAPIR will also insulate the United States from the concentration of foreign, sometimes adversary, nations in the world-wide supply of the Key Starting Materials used to make APIs. Moreover, Government purchases of APIs to fill the SAPIR can encourage more domestic production of APIs.

Unfortunately, the Biden Administration failed to advance the goal of ensuring domestic sources for essential medicines and their precursors despite spending billions of dollars on efforts to secure supply chains. Domestic production and procurement did not increase and the SAPIR is nearly empty.

SEC. 2. *Filling the SAPIR with APIs for the Most Critical Medicines*. (a) Within 30 days of the date of this order [Aug. 13, 2025], the ASPR shall develop a list, in consultation with agencies with scientific expertise, the Assistant to the President for Economic Policy (APEP), and the Assistant to the President and Homeland Security Advisor (APHSA), of approximately 26 drugs that are especially critical to the health and security interests of the Nation (the critical drugs) and an accounting of existing, available funds that can be utilized, consistent with statutory authorities, to finance the preparation and opening of the SAPIR repository and to obtain and maintain the 6-month supply of APIs for the critical drugs referenced in subsection (c) of this section shall be provided to the Director of the Office of Management and Budget (OMB). The OMB shall provide assistance to the Secretary of Health and Human Services to facilitate the repurposing of available funds, consistent with law.

(b) Within 120 days of the date of this order and subject to the availability of funds identified pursuant to subsection (a) of this section, the ASPR shall, in coordination with such other agencies as are necessary, take all measures to ready the existing SAPIR repository so that it can begin receiving and maintaining APIs.

(c) Subject to the availability of funds identified pursuant to subsection (a) of this section, the ASPR shall obtain a 6-month supply of the APIs needed to make the critical drugs to fill the SAPIR, with a preference for obtaining domestically manufactured APIs if possible. The ASPR shall place such APIs within the SAPIR repository no later than 30 days after the repository is certified by the ASPR as ready to receive and maintain APIs.

SEC. 3. *Ensuring SAPIR Resilience*. (a) Within 90 days of the date of this order, the ASPR shall provide the APHSA, the APEP, and the OMB with an update to the ASPR's 2022 list of 86 essential medicines and medical countermeasures, along with a plan to:

(i) obtain from domestic manufacturers, where possible;
(ii) store; and
(iii) maintain a 6-month supply of APIs for drugs on the updated essential medicines list if they have not already been addressed in the list of critical drugs identified pursuant to section 2(a) of this order.
(b) The plan provided pursuant to subsection (a) of this section shall include a proposal and cost estimate for opening a second SAPIR repository in the United States within 1 year of the date of this order.
SEC. 4. *General Provisions*. (a) Nothing in this order shall be construed to impair or otherwise affect:
(i) the authority granted by law to an executive department or agency, or the head thereof; or
(ii) the functions of the Director of the Office of Management and Budget relating to budgetary, administrative, or legislative proposals.
(b) This order shall be implemented consistent with applicable law and subject to the availability of appropriations.
(c) This order is not intended to, and does not, create any right or benefit, substantive or procedural, enforceable at law or in equity by any party against the United States, its departments, agencies, or entities, its officers, employees, or agents, or any other person.
(d) The costs for publication of this order shall be borne by the Department of Health and Human Services.

DONALD J. TRUMP.

DESIGNATION AND AUTHORIZATION TO PERFORM FUNCTIONS UNDER SECTION 319F–2 OF THE PUBLIC HEALTH SERVICE ACT

Memorandum of President of the United States, Oct. 21, 2004, 69 F.R. 70349, provided:
Memorandum for the Director of the Office of Management and Budget
By the authority vested in me by the Constitution and the laws of the United States of America, including section 301 of title 3, United States Code, I hereby direct you to perform the functions vested in the President under section 319F–2(c)(6) of the Public Health Service Act, 42 U.S.C. 247d–6b(c)(6).
Any reference in this memorandum to the provision of any Act shall be deemed to include references to any hereafter-enacted provision of law that is the same or substantially the same as such provision.
You are authorized and directed to publish this memorandum in the Federal Register.

GEORGE W. BUSH.

[1] So in original. Probably should be followed by a comma.

[2] So in original.

[3] So in original. Another closing parenthesis probably should precede the comma.

§247d–6c. Repealed. Pub. L. 113–5, title II, §205, Mar. 13, 2013, 127 Stat. 179

Section, Pub. L. 108–276, §5, July 21, 2004, 118 Stat. 860, related to reports regarding authorities under the Project BioShield Act of 2004.

§247d–6d. Targeted liability protections for pandemic and epidemic products and security countermeasures

(a) Liability protections

(1) In general

Subject to the other provisions of this section, a covered person shall be immune from suit and liability under Federal and State law with respect to all claims for loss caused by, arising out of, relating to, or resulting from the administration to or the use by an individual of a covered countermeasure if a declaration under subsection (b) has been issued with respect to such countermeasure.

(2) Scope of claims for loss

(A) Loss

For purposes of this section, the term "loss" means any type of loss, including—

(i) death;

(ii) physical, mental, or emotional injury, illness, disability, or condition;

(iii) fear of physical, mental, or emotional injury, illness, disability, or condition, including any need for medical monitoring; and

(iv) loss of or damage to property, including business interruption loss.

Each of clauses (i) through (iv) applies without regard to the date of the occurrence, presentation, or discovery of the loss described in the clause.

(B) Scope

The immunity under paragraph (1) applies to any claim for loss that has a causal relationship with the administration to or use by an individual of a covered countermeasure, including a causal relationship with the design, development, clinical testing or investigation, manufacture, labeling, distribution, formulation, packaging, marketing, promotion, sale, purchase, donation, dispensing, prescribing, administration, licensing, or use of such countermeasure.

(3) Certain conditions

Subject to the other provisions of this section, immunity under paragraph (1) with respect to a covered countermeasure applies only if—

(A) the countermeasure was administered or used during the effective period of the declaration that was issued under subsection (b) with respect to the countermeasure;

(B) the countermeasure was administered or used for the category or categories of diseases, health conditions, or threats to health specified in the declaration; and

(C) in addition, in the case of a covered person who is a program planner or qualified person with respect to the administration or use of the countermeasure, the countermeasure was administered to or used by an individual who—

(i) was in a population specified by the declaration; and

(ii) was at the time of administration physically present in a geographic area specified by the declaration or had a connection to such area specified in the declaration.

(4) Applicability of certain conditions

With respect to immunity under paragraph (1) and subject to the other provisions of this section:

(A) In the case of a covered person who is a manufacturer or distributor of the covered countermeasure involved, the immunity applies without regard to whether such countermeasure was administered to or used by an individual in accordance with the conditions described in paragraph (3)(C).

(B) In the case of a covered person who is a program planner or qualified person with respect to the administration or use of the covered countermeasure, the scope of immunity includes circumstances in which the countermeasure was administered to or used by an individual in circumstances in which the covered person reasonably could have believed that the countermeasure was administered or used in accordance with the conditions described in paragraph (3)(C).

(5) Effect of distribution method

The provisions of this section apply to a covered countermeasure regardless of whether such countermeasure is obtained by donation, commercial sale, or any other means of distribution, except to the extent that, under paragraph (2)(E) of subsection (b), the declaration under such subsection provides that subsection (a) applies only to covered countermeasures obtained through a particular means of distribution.

(6) Rebuttable presumption

For purposes of paragraph (1), there shall be a rebuttable presumption that any administration or use, during the effective period of the emergency declaration by the Secretary under subsection

(b), of a covered countermeasure shall have been for the category or categories of diseases, health conditions, or threats to health with respect to which such declaration was issued.

(b) Declaration by Secretary

(1) Authority to issue declaration

Subject to paragraph (2), if the Secretary makes a determination that a disease or other health condition or other threat to health constitutes a public health emergency, or that there is a credible risk that the disease, condition, or threat may in the future constitute such an emergency, the Secretary may make a declaration, through publication in the Federal Register, recommending, under conditions as the Secretary may specify, the manufacture, testing, development, distribution, administration, or use of one or more covered countermeasures, and stating that subsection (a) is in effect with respect to the activities so recommended.

(2) Contents

In issuing a declaration under paragraph (1), the Secretary shall identify, for each covered countermeasure specified in the declaration—

(A) the category or categories of diseases, health conditions, or threats to health for which the Secretary recommends the administration or use of the countermeasure;

(B) the period or periods during which, including as modified by paragraph (3), subsection (a) is in effect, which period or periods may be designated by dates, or by milestones or other description of events, including factors specified in paragraph (6);

(C) the population or populations of individuals for which subsection (a) is in effect with respect to the administration or use of the countermeasure (which may be a specification that such subsection applies without geographic limitation to all individuals);

(D) the geographic area or areas for which subsection (a) is in effect with respect to the administration or use of the countermeasure (which may be a specification that such subsection applies without geographic limitation), including, with respect to individuals in the populations identified under subparagraph (C), a specification, as determined appropriate by the Secretary, of whether the declaration applies only to individuals physically present in such areas or whether in addition the declaration applies to individuals who have a connection to such areas, which connection is described in the declaration; and

(E) whether subsection (a) is effective only to a particular means of distribution as provided in subsection (a)(5) for obtaining the countermeasure, and if so, the particular means to which such subsection is effective.

(3) Effective period of declaration

(A) Flexibility of period

The Secretary may, in describing periods under paragraph (2)(B), have different periods for different covered persons to address different logistical, practical or other differences in responsibilities.

(B) Additional time to be specified

In each declaration under paragraph (1), the Secretary, after consulting, to the extent the Secretary deems appropriate, with the manufacturer of the covered countermeasure, shall also specify a date that is after the ending date specified under paragraph (2)(B) and that allows what the Secretary determines is—

(i) a reasonable period for the manufacturer to arrange for disposition of the covered countermeasure, including the return of such product to the manufacturer; and

(ii) a reasonable period for covered persons to take such other actions as may be appropriate to limit administration or use of the covered countermeasure.

(C) Additional period for certain strategic national stockpile countermeasures

With respect to a covered countermeasure that is in the stockpile under section 247d–6b of this title, if such countermeasure was the subject of a declaration under paragraph (1) at the time

that it was obtained for the stockpile, the effective period of such declaration shall include a period when the countermeasure is administered or used pursuant to a distribution or release from the stockpile.

(4) Amendments to declaration

The Secretary may through publication in the Federal Register amend any portion of a declaration under paragraph (1). Such an amendment shall not retroactively limit the applicability of subsection (a) with respect to the administration or use of the covered countermeasure involved.

(5) Certain disclosures

In publishing a declaration under paragraph (1) in the Federal Register, the Secretary is not required to disclose any matter described in section 552(b) of title 5.

(6) Factors to be considered

In deciding whether and under what circumstances or conditions to issue a declaration under paragraph (1) with respect to a covered countermeasure, the Secretary shall consider the desirability of encouraging the design, development, clinical testing or investigation, manufacture, labeling, distribution, formulation, packaging, marketing, promotion, sale, purchase, donation, dispensing, prescribing, administration, licensing, and use of such countermeasure.

(7) Judicial review

No court of the United States, or of any State, shall have subject matter jurisdiction to review, whether by mandamus or otherwise, any action by the Secretary under this subsection.

(8) Preemption of State law

During the effective period of a declaration under subsection (b), or at any time with respect to conduct undertaken in accordance with such declaration, no State or political subdivision of a State may establish, enforce, or continue in effect with respect to a covered countermeasure any provision of law or legal requirement that—

(A) is different from, or is in conflict with, any requirement applicable under this section; and

(B) relates to the design, development, clinical testing or investigation, formulation, manufacture, distribution, sale, donation, purchase, marketing, promotion, packaging, labeling, licensing, use, any other aspect of safety or efficacy, or the prescribing, dispensing, or administration by qualified persons of the covered countermeasure, or to any matter included in a requirement applicable to the covered countermeasure under this section or any other provision of this chapter, or under the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 301 et seq.].

(9) Report to Congress

Within 30 days after making a declaration under paragraph (1), the Secretary shall submit to the appropriate committees of the Congress a report that provides an explanation of the reasons for issuing the declaration and the reasons underlying the determinations of the Secretary with respect to paragraph (2). Within 30 days after making an amendment under paragraph (4), the Secretary shall submit to such committees a report that provides the reasons underlying the determination of the Secretary to make the amendment.

(c) Definition of willful misconduct

(1) Definition

(A) In general

Except as the meaning of such term is further restricted pursuant to paragraph (2), the term "willful misconduct" shall, for purposes of subsection (d), denote an act or omission that is taken—

(i) intentionally to achieve a wrongful purpose;

(ii) knowingly without legal or factual justification; and

(iii) in disregard of a known or obvious risk that is so great as to make it highly probable

that the harm will outweigh the benefit.

(B) Rule of construction

The criterion stated in subparagraph (A) shall be construed as establishing a standard for liability that is more stringent than a standard of negligence in any form or recklessness.

(2) Authority to promulgate regulatory definition

(A) In general

The Secretary, in consultation with the Attorney General, shall promulgate regulations, which may be promulgated through interim final rules, that further restrict the scope of actions or omissions by a covered person that may qualify as "willful misconduct" for purposes of subsection (d).

(B) Factors to be considered

In promulgating the regulations under this paragraph, the Secretary, in consultation with the Attorney General, shall consider the need to define the scope of permissible civil actions under subsection (d) in a way that will not adversely affect the public health.

(C) Temporal scope of regulations

The regulations under this paragraph may specify the temporal effect that they shall be given for purposes of subsection (d).

(D) Initial rulemaking

Within 180 days after December 30, 2005, the Secretary, in consultation with the Attorney General, shall commence and complete an initial rulemaking process under this paragraph.

(3) Proof of willful misconduct

In an action under subsection (d), the plaintiff shall have the burden of proving by clear and convincing evidence willful misconduct by each covered person sued and that such willful misconduct caused death or serious physical injury.

(4) Defense for acts or omissions taken pursuant to Secretary's declaration

Notwithstanding any other provision of law, a program planner or qualified person shall not have engaged in "willful misconduct" as a matter of law where such program planner or qualified person acted consistent with applicable directions, guidelines, or recommendations by the Secretary regarding the administration or use of a covered countermeasure that is specified in the declaration under subsection (b), provided either the Secretary, or a State or local health authority, was provided with notice of information regarding serious physical injury or death from the administration or use of a covered countermeasure that is material to the plaintiff's alleged loss within 7 days of the actual discovery of such information by such program planner or qualified person.

(5) Exclusion for regulated activity of manufacturer or distributor

(A) In general

If an act or omission by a manufacturer or distributor with respect to a covered countermeasure, which act or omission is alleged under subsection (e)(3)(A) to constitute willful misconduct, is subject to regulation by this chapter or by the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 301 et seq.], such act or omission shall not constitute "willful misconduct" for purposes of subsection (d) if—

(i) neither the Secretary nor the Attorney General has initiated an enforcement action with respect to such act or omission; or

(ii) such an enforcement action has been initiated and the action has been terminated or finally resolved without a covered remedy.

Any action or proceeding under subsection (d) shall be stayed during the pendency of such an enforcement action.

(B) Definitions

For purposes of this paragraph, the following terms have the following meanings:

(i) Enforcement action

The term "enforcement action" means a criminal prosecution, an action seeking an injunction, a seizure action, a civil monetary proceeding based on willful misconduct, a mandatory recall of a product because voluntary recall was refused, a proceeding to compel repair or replacement of a product, a termination of an exemption under section 505(i) or 520(g) of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 355(i), 360j(g)], a debarment proceeding, an investigator disqualification proceeding where an investigator is an employee or agent of the manufacturer, a revocation, based on willful misconduct, of an authorization under section 564 of such Act [21 U.S.C. 360bbb–3], or a suspension or withdrawal, based on willful misconduct, of an approval or clearance under chapter V of such Act [21 U.S.C. 351 et seq.] or of a licensure under section 262 of this title.

(ii) Covered remedy

The term "covered remedy" means an outcome—

(I) that is a criminal conviction, an injunction, or a condemnation, a civil monetary payment, a product recall, a repair or replacement of a product, a termination of an exemption under section 505(i) or 520(g) of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 355(i), 360j(g)], a debarment, an investigator disqualification, a revocation of an authorization under section 564 of such Act [21 U.S.C. 360bbb–3], or a suspension or withdrawal of an approval or clearance under chapter 5 [1] of such Act or of a licensure under section 262 of this title; and

(II) that results from a final determination by a court or from a final agency action.

(iii) Final

The terms "final" and "finally"—

(I) with respect to a court determination, or to a final resolution of an enforcement action that is a court determination, mean a judgment from which an appeal of right cannot be taken or a voluntary or stipulated dismissal; and

(II) with respect to an agency action, or to a final resolution of an enforcement action that is an agency action, mean an order that is not subject to further review within the agency and that has not been reversed, vacated, enjoined, or otherwise nullified by a final court determination or a voluntary or stipulated dismissal.

(C) Rules of construction

(i) In general

Nothing in this paragraph shall be construed—

(I) to affect the interpretation of any provision of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 301 et seq.], of this chapter, or of any other applicable statute or regulation; or

(II) to impair, delay, alter, or affect the authority, including the enforcement discretion, of the United States, of the Secretary, of the Attorney General, or of any other official with respect to any administrative or court proceeding under this chapter, under the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 301 et seq.], under title 18, or under any other applicable statute or regulation.

(ii) Mandatory recalls

A mandatory recall called for in the declaration is not a Food and Drug Administration enforcement action.

(d) Exception to immunity of covered persons

(1) In general

Subject to subsection (f), the sole exception to the immunity from suit and liability of covered persons set forth in subsection (a) shall be for an exclusive Federal cause of action against a covered person for death or serious physical injury proximately caused by willful misconduct, as defined pursuant to subsection (c), by such covered person. For purposes of section 2679(b)(2)(B) of title 28, such a cause of action is not an action brought for violation of a statute of the United States under which an action against an individual is otherwise authorized.

(2) Persons who can sue

An action under this subsection may be brought for wrongful death or serious physical injury by any person who suffers such injury or by any representative of such a person.

(e) Procedures for suit

(1) Exclusive Federal jurisdiction

Any action under subsection (d) shall be filed and maintained only in the United States District Court for the District of Columbia.

(2) Governing law

The substantive law for decision in an action under subsection (d) shall be derived from the law, including choice of law principles, of the State in which the alleged willful misconduct occurred, unless such law is inconsistent with or preempted by Federal law, including provisions of this section.

(3) Pleading with particularity

In an action under subsection (d), the complaint shall plead with particularity each element of the plaintiff's claim, including—

(A) each act or omission, by each covered person sued, that is alleged to constitute willful misconduct relating to the covered countermeasure administered to or used by the person on whose behalf the complaint was filed;

(B) facts supporting the allegation that such alleged willful misconduct proximately caused the injury claimed; and

(C) facts supporting the allegation that the person on whose behalf the complaint was filed suffered death or serious physical injury.

(4) Verification, certification, and medical records

(A) In general

In an action under subsection (d), the plaintiff shall verify the complaint in the manner stated in subparagraph (B) and shall file with the complaint the materials described in subparagraph (C). A complaint that does not substantially comply with subparagraphs (B) and (C) shall not be accepted for filing and shall not stop the running of the statute of limitations.

(B) Verification requirement

(i) In general

The complaint shall include a verification, made by affidavit of the plaintiff under oath, stating that the pleading is true to the knowledge of the deponent, except as to matters specifically identified as being alleged on information and belief, and that as to those matters the plaintiff believes it to be true.

(ii) Identification of matters alleged upon information and belief

Any matter that is not specifically identified as being alleged upon the information and belief of the plaintiff, shall be regarded for all purposes, including a criminal prosecution, as having been made upon the knowledge of the plaintiff.

(C) Materials required

In an action under subsection (d), the plaintiff shall file with the complaint—

(i) an affidavit, by a physician who did not treat the person on whose behalf the complaint

was filed, certifying, and explaining the basis for such physician's belief, that such person suffered the serious physical injury or death alleged in the complaint and that such injury or death was proximately caused by the administration or use of a covered countermeasure; and

(ii) certified medical records documenting such injury or death and such proximate causal connection.

(5) Three-judge court

Any action under subsection (d) shall be assigned initially to a panel of three judges. Such panel shall have jurisdiction over such action for purposes of considering motions to dismiss, motions for summary judgment, and matters related thereto. If such panel has denied such motions, or if the time for filing such motions has expired, such panel shall refer the action to the chief judge for assignment for further proceedings, including any trial. Section 1253 of title 28 and paragraph (3) of subsection (b) of section 2284 of title 28 shall not apply to actions under subsection (d).

(6) Civil discovery

(A) Timing

In an action under subsection (d), no discovery shall be allowed—

(i) before each covered person sued has had a reasonable opportunity to file a motion to dismiss;

(ii) in the event such a motion is filed, before the court has ruled on such motion; and

(iii) in the event a covered person files an interlocutory appeal from the denial of such a motion, before the court of appeals has ruled on such appeal.

(B) Standard

Notwithstanding any other provision of law, the court in an action under subsection (d) shall permit discovery only with respect to matters directly related to material issues contested in such action, and the court shall compel a response to a discovery request (including a request for admission, an interrogatory, a request for production of documents, or any other form of discovery request) under Rule 37, Federal Rules of Civil Procedure, only if the court finds that the requesting party needs the information sought to prove or defend as to a material issue contested in such action and that the likely benefits of a response to such request equal or exceed the burden or cost for the responding party of providing such response.

(7) Reduction in award of damages for collateral source benefits

(A) In general

In an action under subsection (d), the amount of an award of damages that would otherwise be made to a plaintiff shall be reduced by the amount of collateral source benefits to such plaintiff.

(B) Provider of collateral source benefits not to have lien or subrogation

No provider of collateral source benefits shall recover any amount against the plaintiff or receive any lien or credit against the plaintiff's recovery or be equitably or legally subrogated to the right of the plaintiff in an action under subsection (d).

(C) Collateral source benefit defined

For purposes of this paragraph, the term "collateral source benefit" means any amount paid or to be paid in the future to or on behalf of the plaintiff, or any service, product, or other benefit provided or to be provided in the future to or on behalf of the plaintiff, as a result of the injury or wrongful death, pursuant to—

(i) any State or Federal health, sickness, income-disability, accident, or workers' compensation law;

(ii) any health, sickness, income-disability, or accident insurance that provides health benefits or income-disability coverage;

(iii) any contract or agreement of any group, organization, partnership, or corporation to provide, pay for, or reimburse the cost of medical, hospital, dental, or income disability

benefits; or

(iv) any other publicly or privately funded program.

(8) Noneconomic damages

In an action under subsection (d), any noneconomic damages may be awarded only in an amount directly proportional to the percentage of responsibility of a defendant for the harm to the plaintiff. For purposes of this paragraph, the term "noneconomic damages" means damages for losses for physical and emotional pain, suffering, inconvenience, physical impairment, mental anguish, disfigurement, loss of enjoyment of life, loss of society and companionship, loss of consortium, hedonic damages, injury to reputation, and any other nonpecuniary losses.

(9) Rule 11 sanctions

Whenever a district court of the United States determines that there has been a violation of Rule 11 of the Federal Rules of Civil Procedure in an action under subsection (d), the court shall impose upon the attorney, law firm, or parties that have violated Rule 11 or are responsible for the violation, an appropriate sanction, which may include an order to pay the other party or parties for the reasonable expenses incurred as a direct result of the filing of the pleading, motion, or other paper that is the subject of the violation, including a reasonable attorney's fee. Such sanction shall be sufficient to deter repetition of such conduct or comparable conduct by others similarly situated, and to compensate the party or parties injured by such conduct.

(10) Interlocutory appeal

The United States Court of Appeals for the District of Columbia Circuit shall have jurisdiction of an interlocutory appeal by a covered person taken within 30 days of an order denying a motion to dismiss or a motion for summary judgment based on an assertion of the immunity from suit conferred by subsection (a) or based on an assertion of the exclusion under subsection (c)(5).

(f) Actions by and against the United States

Nothing in this section shall be construed to abrogate or limit any right, remedy, or authority that the United States or any agency thereof may possess under any other provision of law or to waive sovereign immunity or to abrogate or limit any defense or protection available to the United States or its agencies, instrumentalities, officers, or employees under any other law, including any provision of chapter 171 of title 28 (relating to tort claims procedure).

(g) Severability

If any provision of this section, or the application of such provision to any person or circumstance, is held to be unconstitutional, the remainder of this section and the application of such remainder to any person or circumstance shall not be affected thereby.

(h) Rule of construction concerning National Vaccine Injury Compensation Program

Nothing in this section, or any amendment made by the Public Readiness and Emergency Preparedness Act, shall be construed to affect the National Vaccine Injury Compensation Program under subchapter XIX of this chapter.

(i) Definitions

In this section:

(1) Covered countermeasure

The term "covered countermeasure" means—

(A) a qualified pandemic or epidemic product (as defined in paragraph (7));

(B) a security countermeasure (as defined in section 247d–6b(c)(1)(B) of this title);

(C) a drug (as such term is defined in section 201(g)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321(g)(1)), biological product (as such term is defined by section 262(i) of this title), or device (as such term is defined by section 201(h) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. 321(h)) that is authorized for emergency use in accordance with section 564, 564A, or 564B of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 360bbb–3, 360bbb–3a, 360bbb–3b]; or

(D) a respiratory protective device that is approved by the National Institute for Occupational Safety and Health under part 84 of title 42, Code of Federal Regulations (or any successor regulations), and that the Secretary determines to be a priority for use during a public health emergency declared under section 247d of this title.

(2) Covered person

The term "covered person", when used with respect to the administration or use of a covered countermeasure, means—

(A) the United States; or

(B) a person or entity that is—

(i) a manufacturer of such countermeasure;

(ii) a distributor of such countermeasure;

(iii) a program planner of such countermeasure;

(iv) a qualified person who prescribed, administered, or dispensed such countermeasure; or

(v) an official, agent, or employee of a person or entity described in clause (i), (ii), (iii), or (iv).

(3) Distributor

The term "distributor" means a person or entity engaged in the distribution of drugs, biologics, or devices, including but not limited to manufacturers; repackers; common carriers; contract carriers; air carriers; own-label distributors; private-label distributors; jobbers; brokers; warehouses, and wholesale drug warehouses; independent wholesale drug traders; and retail pharmacies.

(4) Manufacturer

The term "manufacturer" includes—

(A) a contractor or subcontractor of a manufacturer;

(B) a supplier or licenser of any product, intellectual property, service, research tool, or component or other article used in the design, development, clinical testing, investigation, or manufacturing of a covered countermeasure; and

(C) any or all of the parents, subsidiaries, affiliates, successors, and assigns of a manufacturer.

(5) Person

The term "person" includes an individual, partnership, corporation, association, entity, or public or private corporation, including a Federal, State, or local government agency or department.

(6) Program planner

The term "program planner" means a State or local government, including an Indian tribe, a person employed by the State or local government, or other person who supervised or administered a program with respect to the administration, dispensing, distribution, provision, or use of a security countermeasure or a qualified pandemic or epidemic product, including a person who has established requirements, provided policy guidance, or supplied technical or scientific advice or assistance or provides a facility to administer or use a covered countermeasure in accordance with a declaration under subsection (b).

(7) Qualified pandemic or epidemic product

The term "qualified pandemic or epidemic product" means a drug (as such term is defined in section 201(g)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321(g)(1)),[2] biological product (as such term is defined by section 262(i) of this title), or device (as such term is defined by section 201(h) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. 321(h)) [2] that is—

(A)(i) a product manufactured, used, designed, developed, modified, licensed, or procured—

(I) to diagnose, mitigate, prevent, treat, or cure a pandemic or epidemic; or

(II) to limit the harm such pandemic or epidemic might otherwise cause;

(ii) a product manufactured, used, designed, developed, modified, licensed, or procured to diagnose, mitigate, prevent, treat, or cure a serious or life-threatening disease or condition caused by a product described in clause (i); or

(iii) a product or technology intended to enhance the use or effect of a drug, biological product, or device described in clause (i) or (ii); and

(B)(i) approved or cleared under chapter V of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 351 et seq.] or licensed under section 262 of this title;

(ii) the object of research for possible use as described by subparagraph (A) and is the subject of an exemption under section 505(i) or 520(g) of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 355(i), 360j(g)]; or

(iii) authorized for emergency use in accordance with section 564, 564A, or 564B of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 360bbb–3, 360bbb–3a, 360bbb–3b].

(8) Qualified person

The term "qualified person", when used with respect to the administration or use of a covered countermeasure, means—

(A) a licensed health professional or other individual who is authorized to prescribe, administer, or dispense such countermeasures under the law of the State in which the countermeasure was prescribed, administered, or dispensed; or

(B) a person within a category of persons so identified in a declaration by the Secretary under subsection (b).

(9) Security countermeasure

The term "security countermeasure" has the meaning given such term in section 247d–6b(c)(1)(B) of this title.

(10) Serious physical injury

The term "serious physical injury" means an injury that—

(A) is life threatening;

(B) results in permanent impairment of a body function or permanent damage to a body structure; or

(C) necessitates medical or surgical intervention to preclude permanent impairment of a body function or permanent damage to a body structure.

(July 1, 1944, ch. 373, title III, §319F–3, as added Pub. L. 109–148, div. C, §2, Dec. 30, 2005, 119 Stat. 2818; amended Pub. L. 113–5, title IV, §402(g)(2), (3), Mar. 13, 2013, 127 Stat. 196; Pub. L. 116–127, div. F, §6005, Mar. 18, 2020, 134 Stat. 207; Pub. L. 116–136, div. A, title III, §3103, Mar. 27, 2020, 134 Stat. 361.)

EDITORIAL NOTES

REFERENCES IN TEXT

The Federal Food, Drug, and Cosmetic Act, referred to in subsecs. (b)(8)(B), (c)(5)(A), (B)(i), (ii)(I), (C)(i), and (i)(7)(B)(i), is act June 25, 1938, ch. 675, 52 Stat. 1040, which is classified generally to chapter 9 (§301 et seq.) of Title 21, Food and Drugs. Chapter V of the Act is classified generally to subchapter V (§351 et seq.) of chapter 9 of Title 21. For complete classification of this Act to the Code, see section 301 of Title 21 and Tables.

The Federal Rules of Civil Procedure, referred to in subsec. (e)(6)(B), (9), are set out in the Appendix to Title 28, Judiciary and Judicial Procedure.

The Public Readiness and Emergency Preparedness Act, referred to in subsec. (h), is div. C of Pub. L. 109–148, Dec. 30, 2005, 119 Stat. 2818, which enacted this section, section 247d–6e of this title, and provisions set out as a note under section 201 of this title. For complete classification of this Act to the Code, see Short Title of 2005 Amendment note set out under section 201 of this title and Tables.

AMENDMENTS

2020—Subsec. (i)(1)(D). Pub. L. 116–136 amended subpar. (D) generally. Prior to amendment, subpar. (D)

read as follows: "a personal respiratory protective device that is—

"(i) approved by the National Institute for Occupational Safety and Health under part 84 of title 42, Code of Federal Regulations (or successor regulations);

"(ii) subject to the emergency use authorization issued by the Secretary on March 2, 2020, or subsequent emergency use authorizations, pursuant to section 564 of the Federal Food, Drug, and Cosmetic Act (authorizing emergency use of personal respiratory protective devices during the COVID–19 outbreak); and

"(iii) used during the period beginning on January 27, 2020, and ending on October 1, 2024, in response to the public health emergency declared on January 31, 2020, pursuant to section 247d of this title as a result of confirmed cases of 2019 Novel Coronavirus (2019-nCoV)."

Pub. L. 116–127 added subpar. (D).

2013—Subsec. (i)(1)(C). Pub. L. 113–5, §402(g)(3)(A), inserted ", 564A, or 564B" after "564".

Subsec. (i)(7)(A)(iii). Pub. L. 113–5, §402(g)(2), added cl. (iii).

Subsec. (i)(7)(B)(iii). Pub. L. 113–5, §402(g)(3)(B), inserted ", 564A, or 564B" after "564".

[1] *So in original. Probably should be chapter "V".*

[2] *So in original. A third closing parenthesis probably should appear.*

§247d–6e. Covered countermeasure process

(a) Establishment of Fund

Upon the issuance by the Secretary of a declaration under section 247d–6d(b) of this title, there is hereby established in the Treasury an emergency fund designated as the "Covered Countermeasure Process Fund" for purposes of providing timely, uniform, and adequate compensation to eligible individuals for covered injuries directly caused by the administration or use of a covered countermeasure pursuant to such declaration, which Fund shall consist of such amounts designated as emergency appropriations under section 402 of H. Con. Res. 95 of the 109th Congress, this emergency designation shall remain in effect through October 1, 2006.

(b) Payment of compensation

(1) In general

If the Secretary issues a declaration under 247d–6d(b) of this title, the Secretary shall, after amounts have by law been provided for the Fund under subsection (a), provide compensation to an eligible individual for a covered injury directly caused by the administration or use of a covered countermeasure pursuant to such declaration.

(2) Elements of compensation

The compensation that shall be provided pursuant to paragraph (1) shall have the same elements, and be in the same amount, as is prescribed by sections 239c, 239d, and 239e of this title in the case of certain individuals injured as a result of administration of certain countermeasures against smallpox, except that section 239e(a)(2)(B) of this title shall not apply.

(3) Rule of construction

Neither reasonable and necessary medical benefits nor lifetime total benefits for lost employment income due to permanent and total disability shall be limited by section 239e of this title.

(4) Determination of eligibility and compensation

Except as provided in this section, the procedures for determining, and for reviewing a determination of, whether an individual is an eligible individual, whether such individual has sustained a covered injury, whether compensation may be available under this section, and the amount of such compensation shall be those stated in section 239a of this title (other than in subsection (d)(2) of such section), in regulations issued pursuant to that section, and in such

additional or alternate regulations as the Secretary may promulgate for purposes of this section. In making determinations under this section, other than those described in paragraph (5)(A) as to the direct causation of a covered injury, the Secretary may only make such determination based on compelling, reliable, valid, medical and scientific evidence.

(5) Covered countermeasure injury table

(A) In general

The Secretary shall by regulation establish a table identifying covered injuries that shall be presumed to be directly caused by the administration or use of a covered countermeasure and the time period in which the first symptom or manifestation of onset of each such adverse effect must manifest in order for such presumption to apply. The Secretary may only identify such covered injuries, for purpose of inclusion on the table, where the Secretary determines, based on compelling, reliable, valid, medical and scientific evidence that administration or use of the covered countermeasure directly caused such covered injury.

(B) Amendments

The provisions of section 239b of this title (other than a provision of subsection (a)(2) of such section that relates to accidental vaccinia inoculation) shall apply to the table established under this section.

(C) Judicial review

No court of the United States, or of any State, shall have subject matter jurisdiction to review, whether by mandamus or otherwise, any action by the Secretary under this paragraph.

(6) Meanings of terms

In applying sections 239a, 239b, 239c, 239d, and 239e of this title for purposes of this section—

(A) the terms "vaccine" and "smallpox vaccine" shall be deemed to mean a covered countermeasure;

(B) the terms "smallpox vaccine injury table" and "table established under section 239b of this title" shall be deemed to refer to the table established under paragraph (4); and

(C) other terms used in those sections shall have the meanings given to such terms by this section.

(c) Voluntary program

The Secretary shall ensure that a State, local, or Department of Health and Human Services plan to administer or use a covered countermeasure is consistent with any declaration under 247d–6d of this title and any applicable guidelines of the Centers for Disease Control and Prevention and that potential participants are educated with respect to contraindications, the voluntary nature of the program, and the availability of potential benefits and compensation under this part.

(d) Exhaustion; exclusivity; election

(1) Exhaustion

Subject to paragraph (5), a covered individual may not bring a civil action under section 247d–6d(d) of this title against a covered person (as such term is defined in section 247d–6d(i)(2) of this title) unless such individual has exhausted such remedies as are available under subsection (a), except that if amounts have not by law been provided for the Fund under subsection (a), or if the Secretary fails to make a final determination on a request for benefits or compensation filed in accordance with the requirements of this section within 240 days after such request was filed, the individual may seek any remedy that may be available under section 247d–6d(d) of this title.

(2) Tolling of statute of limitations

The time limit for filing a civil action under section 247d–6d(d) of this title for an injury or death shall be tolled during the pendency of a claim for compensation under subsection (a).

(3) Rule of construction

This section shall not be construed as superseding or otherwise affecting the application of a

requirement, under chapter 171 of title 28, to exhaust administrative remedies.

(4) Exclusivity

The remedy provided by subsection (a) shall be exclusive of any other civil action or proceeding for any claim or suit this section encompasses, except for a proceeding under section 247d–6d of this title.

(5) Election

If under subsection (a) the Secretary determines that a covered individual qualifies for compensation, the individual has an election to accept the compensation or to bring an action under section 247d–6d(d) of this title. If such individual elects to accept the compensation, the individual may not bring such an action.

(e) Definitions

For purposes of this section, the following terms shall have the following meanings:

(1) Covered countermeasure

The term "covered countermeasure" has the meaning given such term in section 247d–6d of this title.

(2) Covered individual

The term "covered individual", with respect to administration or use of a covered countermeasure pursuant to a declaration, means an individual—

(A) who is in a population specified in such declaration, and with respect to whom the administration or use of the covered countermeasure satisfies the other specifications of such declaration; or

(B) who uses the covered countermeasure, or to whom the covered countermeasure is administered, in a good faith belief that the individual is in the category described by subparagraph (A).

(3) Covered injury

The term "covered injury" means serious physical injury or death.

(4) Declaration

The term "declaration" means a declaration under section 247d–6d(b) of this title.

(5) Eligible individual

The term "eligible individual" means an individual who is determined, in accordance with subsection (b), to be a covered individual who sustains a covered injury.

(July 1, 1944, ch. 373, title III, §319F–4, as added Pub. L. 109–148, div. C, §3, Dec. 30, 2005, 119 Stat. 2829.)

EDITORIAL NOTES

REFERENCES IN TEXT

H. Con. Res. 95 of the 109th Congress, referred to in subsec. (a), is H. Con. Res. 95, Apr. 28, 2005, 119 Stat. 3633, which is not classified to the Code.

§247d–6f. Provision of medical countermeasures to Indian programs and facilities

In the event that the Secretary deploys the contents of the Strategic National Stockpile under section 247d–6b(a) of this title, or otherwise distributes medical countermeasures to States to respond to a public health emergency declared by the Secretary under section 247d of this title, the Secretary shall, in consultation with the applicable States, make such contents or countermeasures directly available to Indian Tribes and Tribal organizations (as such terms are defined in section

5304 of title 25), which may include through health programs or facilities operated by the Indian Health Service, that are affected by such public health emergency.

(July 1, 1944, ch. 373, title III, §319F–5, as added Pub. L. 117–328, div. FF, title II, §2408(b), Dec. 29, 2022, 136 Stat. 5789.)

§247d–7. Repealed. Pub. L. 117–328, div. FF, title II, §2231(b), Dec. 29, 2022, 136 Stat. 5753

Section, act July 1, 1944, ch. 373, title III, §319G, as added Pub. L. 106–505, title I, §102, Nov. 13, 2000, 114 Stat. 2323; amended Pub. L. 108–271, §8(b), July 7, 2004, 118 Stat. 814, related to demonstration programs to enhance bioterrorism training, coordination, and readiness.

§247d–7a. Grants regarding training and education of certain health professionals

(a) In general

The Secretary may make awards of grants and cooperative agreements to appropriate public and nonprofit private health or educational entities, including health professions schools and programs as defined in section 295p of this title, for the purpose of providing low-interest loans, partial scholarships, partial fellowships, revolving loan funds, or other cost-sharing forms of assistance for the education and training of individuals in any category of health professions for which there is a shortage that the Secretary determines should be alleviated in order to prepare for or respond effectively to bioterrorism and other public health emergencies.

(b) Authority regarding non-Federal contributions

The Secretary may require as a condition of an award under subsection (a) that a grantee under such subsection provide non-Federal contributions toward the purpose described in such subsection.

(c) Authorization of appropriations

For the purpose of carrying out this section, there are authorized to be appropriated such sums as may be necessary for each of the fiscal years 2002 through 2006.

(July 1, 1944, ch. 373, title III, §319H, as added Pub. L. 107–188, title I, §106, June 12, 2002, 116 Stat. 607.)

§247d–7b. Emergency system for advance registration of volunteer health professional

(a) In general

Not later than 12 months after December 19, 2006, the Secretary shall link existing State verification systems to maintain a single national interoperable network of systems, each system being maintained by a State or group of States, for the purpose of verifying the credentials and licenses of health care professionals who volunteer to provide health services during a public health emergency. Such health care professionals may include members of the National Disaster Medical System, members of the Medical Reserve Corps, and individual health care professionals.

(b) Requirements

The interoperable network of systems established under subsection (a) (referred to in this section as the "verification network") shall include—

(1) with respect to each volunteer health professional included in the verification network—

(A) information necessary for the rapid identification of, and communication with, such professionals; and

(B) the credentials, certifications, licenses, and relevant training of such individuals; and

(2) the name of each member of the Medical Reserve Corps, the National Disaster Medical System, and any other relevant federally-sponsored or administered programs determined necessary by the Secretary.

(c) Other assistance

The Secretary may make grants and provide technical assistance to States and other public or nonprofit private entities for activities relating to the verification network developed under subsection (a).

(d) Accessibility

The Secretary shall ensure that the verification network is electronically accessible by State, local, and tribal health departments and can be linked with the identification cards under section 300hh–15 of this title.

(e) Confidentiality

The Secretary shall establish and require the application of and compliance with measures to ensure the effective security of, integrity of, and access to the data included in the verification network.

(f) Coordination

The Secretary shall coordinate with the Secretary of Veterans Affairs and the Secretary of Homeland Security to assess the feasibility of integrating the verification network under this section with the VetPro system of the Department of Veterans Affairs and the National Emergency Responder Credentialing System of the Department of Homeland Security. The Secretary shall, if feasible, integrate the verification network under this section with such VetPro system and the National Emergency Responder Credentialing System.

(g) Updating of information

The States that are participants in the verification network shall, on at least a quarterly basis, work with the Director to provide for the updating of the information contained in the verification network.

(h) Clarification

Inclusion of a health professional in the verification network shall not constitute appointment of such individual as a Federal employee for any purpose, either under section 300hh–11(c) of this title or otherwise. Such appointment may only be made under section 300hh–11 or 300hh–15 of this title.

(i) Health care provider licenses

The Secretary shall encourage States to establish and implement mechanisms to waive the application of licensing requirements applicable to health professionals, who are seeking to provide medical services (within their scope of practice), during a national, State, local, or tribal public health emergency upon verification that such health professionals are licensed and in good standing in another State and have not been disciplined by any State health licensing or disciplinary board. In order to inform the development of such mechanisms by States, the Secretary shall make available information and material provided by States that have developed mechanisms to waive the application of licensing requirements to applicable health professionals seeking to provide medical services during a public health emergency. Such information shall be made publicly available in a manner that does not compromise national security.

(j) Rule of construction

This section may not be construed as authorizing the Secretary to issue requirements regarding the provision by the States of credentials, licenses, accreditations, or hospital privileges.

(k) Authorization of appropriations

For the purpose of carrying out this section, there are authorized to be appropriated $5,000,000 for

each of fiscal years 2019 through 2023.

(July 1, 1944, ch. 373, title III, §319I, as added Pub. L. 107–188, title I, §107, June 12, 2002, 116 Stat. 608; amended Pub. L. 109–417, title III, §303(b), Dec. 19, 2006, 120 Stat. 2857; Pub. L. 113–5, title II, §203(b)(1), Mar. 13, 2013, 127 Stat. 175; Pub. L. 116–22, title II, §207(a), June 24, 2019, 133 Stat. 926.)

EDITORIAL NOTES

AMENDMENTS

2019—Pub. L. 116–22, §207(a)(1), substituted "volunteer health professional" for "health professions volunteers" in section catchline.

Subsec. (a). Pub. L. 116–22, §207(a)(2), inserted at end "Such health care professionals may include members of the National Disaster Medical System, members of the Medical Reserve Corps, and individual health care professionals."

Subsec. (i). Pub. L. 116–22, §207(a)(3), inserted at end "In order to inform the development of such mechanisms by States, the Secretary shall make available information and material provided by States that have developed mechanisms to waive the application of licensing requirements to applicable health professionals seeking to provide medical services during a public health emergency. Such information shall be made publicly available in a manner that does not compromise national security."

Subsec. (k). Pub. L. 116–22, §207(a)(4), substituted "2019 through 2023" for "2014 through 2018".

2013—Subsec. (k). Pub. L. 113–5 substituted "$5,000,000 for each of fiscal years 2014 through 2018" for "$2,000,000 for fiscal year 2002, and such sums as may be necessary for each of the fiscal years 2003 through 2011".

2006—Subsecs. (a), (b). Pub. L. 109–417, §303(b)(2), added subsecs. (a) and (b) and struck out former subsecs. (a) and (b) which related to establishment of a verification system and provisions regarding its promptness and efficiency.

Subsec. (c). Pub. L. 109–417, §303(b)(3), substituted "network" for "system".

Subsecs. (d) to (k). Pub. L. 109–417, §303(b)(1), (4), (5), added subsecs. (d) to (i), redesignated former subsecs. (e) and (f) as (j) and (k), respectively, substituted "2011" for "2006" in subsec. (k), and struck out heading and text of former subsec. (d). Text read as follows: "The Secretary may encourage each State to provide legal authority during a public health emergency for health professionals authorized in another State to provide certain health services to provide such health services in the State."

§247d–7c. Supplies and services in lieu of award funds

(a) In general

Upon the request of a recipient of an award under any of sections 247d through 247d–7b of this title or section 247d–7d of this title, the Secretary may, subject to subsection (b), provide supplies, equipment, and services for the purpose of aiding the recipient in carrying out the purposes for which the award is made and, for such purposes, may detail to the recipient any officer or employee of the Department of Health and Human Services.

(b) Corresponding reduction in payments

With respect to a request described in subsection (a), the Secretary shall reduce the amount of payments under the award involved by an amount equal to the costs of detailing personnel and the fair market value of any supplies, equipment, or services provided by the Secretary. The Secretary shall, for the payment of expenses incurred in complying with such request, expend the amounts withheld.

(July 1, 1944, ch. 373, title III, §319J, as added Pub. L. 107–188, title I, §110, June 12, 2002, 116 Stat. 611.)

§247d–7d. Security for countermeasure development and production

(a) In general

The Secretary, in consultation with the Attorney General and the Secretary of Defense, may provide technical or other assistance to provide security to persons or facilities that conduct development, production, distribution, or storage of priority countermeasures (as defined in section 247d–6(e)(4) of this title).

(b) Guidelines

The Secretary may develop guidelines to enable entities eligible to receive assistance under subsection (a) to secure their facilities against potential terrorist attack.

(July 1, 1944, ch. 373, title III, §319K, as added Pub. L. 107–188, title I, §124, June 12, 2002, 116 Stat. 614; amended Pub. L. 116–22, title VII, §705(a)(2), June 24, 2019, 133 Stat. 964.)

EDITORIAL NOTES

AMENDMENTS

2019—Subsec. (a). Pub. L. 116–22 substituted "section 247d–6(e)(4)" for "section 247d–6(h)(4)".

§247d–7e. Biomedical Advanced Research and Development Authority

(a) Definitions

In this section:

(1) BARDA

The term "BARDA" means the Biomedical Advanced Research and Development Authority.

(2) Fund

The term "Fund" means the Biodefense Medical Countermeasure Development Fund established under subsection (d).

(3) Other transactions

The term "other transactions" means transactions, other than procurement contracts, grants, and cooperative agreements.

(4) Qualified countermeasure

The term "qualified countermeasure" has the meaning given such term in section 247d–6a of this title.

(5) Qualified pandemic or epidemic product

The term "qualified pandemic or epidemic product" has the meaning given the term in section 247d–6d of this title.

(6) Advanced research and development

(A) In general

The term "advanced research and development" means, with respect to a product that is or may become a qualified countermeasure or a qualified pandemic or epidemic product, activities that predominantly—

(i) are conducted after basic research and preclinical development of the product; and

(ii) are related to manufacturing the product on a commercial scale and in a form that satisfies the regulatory requirements under the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 301 et seq.] or under section 262 of this title.

(B) Activities included

The term under subparagraph (A) includes—

(i) testing of the product to determine whether the product may be approved, cleared, or licensed under the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 301 et seq.] or under

section 262 of this title for a use that is or may be the basis for such product becoming a qualified countermeasure or qualified pandemic or epidemic product, or to help obtain such approval, clearance, or license;

(ii) design and development of tests or models, including animal models, for such testing;

(iii) activities to facilitate manufacture of the product on a commercial scale with consistently high quality, as well as to improve and make available new technologies to increase manufacturing surge capacity;

(iv) activities to support, maintain, and improve domestic manufacturing surge capacity and capabilities, as appropriate, including through the utilization of advanced manufacturing and platform technologies, to increase the availability of products that are or may become qualified countermeasures or qualified pandemic or epidemic products;

(v) activities to improve the shelf-life of the product or technologies for administering the product; and

(vi) such other activities as are part of the advanced stages of testing, refinement, improvement, manufacturing, or preparation of the product for such use and as are specified by the Secretary.

(7) Security countermeasure

The term "security countermeasure" has the meaning given such term in section 247d–6b of this title.

(8) Research tool

The term "research tool" means a device, technology, biological material (including a cell line or an antibody), reagent, animal model, computer system, computer software, or analytical technique that is developed to assist in the discovery, development, or manufacture of qualified countermeasures or qualified pandemic or epidemic products.

(9) Program manager

The term "program manager" means an individual appointed to carry out functions under this section and authorized to provide project oversight and management of strategic initiatives.

(10) Person

The term "person" includes an individual, partnership, corporation, association, entity, or public or private corporation, and a Federal, State, or local government agency or department.

(b) Strategic plan for countermeasure research, development, and procurement

(1) In general

Not later than 6 months after December 19, 2006, the Secretary shall develop and make public a strategic plan to integrate biodefense and emerging infectious disease requirements with the advanced research and development, strategic initiatives for innovation, support for domestic manufacturing surge capacity and capabilities, and the procurement of qualified countermeasures and qualified pandemic or epidemic products. The Secretary shall carry out such activities as may be practicable to disseminate the information contained in such plan to persons who may have the capacity to substantially contribute to the activities described in such strategic plan. The Secretary shall update and incorporate such plan as part of the National Health Security Strategy described in section 300hh–1 of this title.

(2) Content

The strategic plan under paragraph (1) shall guide—

(A) research and development, conducted or supported by the Department of Health and Human Services, of qualified countermeasures and qualified pandemic or epidemic products against possible biological, chemical, radiological, and nuclear agents and to emerging infectious diseases;

(B) innovation in technologies that may assist advanced research and development of qualified countermeasures and qualified pandemic or epidemic products (such research and

development referred to in this section as "countermeasure and product advanced research and development");

(C) activities to support, maintain, and improve domestic manufacturing surge capacity and capabilities, as appropriate, including through the utilization of advanced manufacturing and platform technologies, to increase the availability of products that are or may become qualified countermeasures or qualified pandemic or epidemic products; and

(D) procurement of such qualified countermeasures and qualified pandemic or epidemic products by such Department.

(c) Biomedical Advanced Research and Development Authority

(1) Establishment

There is established within the Department of Health and Human Services the Biomedical Advanced Research and Development Authority.

(2) In general

Based upon the strategic plan described in subsection (b), the Secretary shall coordinate the acceleration of countermeasure and product advanced research and development by—

(A) facilitating collaboration between the Department of Health and Human Services and other Federal agencies, relevant industries, academia, and other persons, with respect to such advanced research and development;

(B) promoting countermeasure and product advanced research and development, including through the establishment and maintenance of domestic manufacturing surge capacity and capabilities, consistent with subsection (a)(6)(B)(iv);

(C) facilitating contacts between interested persons and the offices or employees authorized by the Secretary to advise such persons regarding requirements under the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 301 et seq.] and under section 262 of this title; and

(D) promoting innovation to reduce the time and cost of countermeasure and product advanced research and development.

(3) Director

The BARDA shall be headed by a Director (referred to in this section as the "Director") who shall be appointed by the Secretary and to whom the Secretary shall delegate such functions and authorities as necessary to implement this section, including the execution of procurement contracts, grants, and cooperative agreements pursuant to this section.

(4) Duties

(A) Collaboration

To carry out the purpose described in paragraph (2)(A), the Secretary shall—

(i) facilitate and increase the expeditious and direct communication between the Department of Health and Human Services and relevant persons with respect to countermeasure and product advanced research and development, including by—

(I) facilitating such communication regarding the processes for procuring such advanced research and development with respect to qualified countermeasures and qualified pandemic or epidemic products of interest;

(II) soliciting information about and data from research on potential qualified countermeasures and qualified pandemic or epidemic products and related technologies;

(III) facilitating such communication, as appropriate, regarding manufacturing surge capacity and capabilities with respect to qualified countermeasures and qualified pandemic or epidemic products to prepare for, or respond to, a public health emergency or potential public health emergency; and

(IV) facilitating such communication, as appropriate and in a manner that does not compromise national security, with respect to potential eligibility for the material threat medical countermeasure priority review voucher program under section 565A of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 360bbb–4a];

(ii) at least annually—

(I) convene meetings with representatives from relevant industries, academia, other Federal agencies, international agencies as appropriate, and other interested persons;

(II) sponsor opportunities to demonstrate the operation and effectiveness of relevant biodefense countermeasure technologies; and

(III) convene such working groups on countermeasure and product advanced research and development as the Secretary may determine are necessary to carry out this section;

(iii) communicate regularly with entities in receipt of an award pursuant to subparagraph (B)(v), and facilitate communication between such entities and other entities in receipt of an award pursuant to subparagraph (B)(iv), as appropriate, for purposes of planning and response regarding the availability of countermeasures and the maintenance of domestic manufacturing surge capacity and capabilities, including any planned uses of such capacity and capabilities in the near- and mid-term, and identification of any significant challenges related to the long-term maintenance of such capacity and capabilities; and

(iv) carry out the activities described in section 247d–7f of this title.

(B) Support advanced research and development

To carry out the purpose described in paragraph (2)(B), the Secretary shall—

(i) conduct ongoing searches for, and support calls for, potential qualified countermeasures and qualified pandemic or epidemic products;

(ii) direct and coordinate the countermeasure and product advanced research and development activities of the Department of Health and Human Services;

(iii) establish strategic initiatives to accelerate countermeasure and product advanced research and development (which may include advanced research and development for purposes of fulfilling requirements under the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 301 et seq.] or section 262 of this title) and innovation in such areas as the Secretary may identify as priority unmet need areas;

(iv) award contracts, grants, cooperative agreements, and enter into other transactions, for countermeasure and product advanced research and development; and

(v) award contracts, grants, and cooperative agreements and enter into other transactions to support, maintain, and improve domestic manufacturing surge capacity and capabilities, including through supporting flexible or advanced manufacturing, to ensure that additional capacity is available to rapidly manufacture products that are or may become qualified countermeasures or qualified pandemic or epidemic products in the event of a public health emergency declaration or significant potential for a public health emergency.

(C) Facilitating advice

To carry out the purpose described in paragraph (2)(C) the Secretary shall—

(i) connect interested persons with the offices or employees authorized by the Secretary to advise such persons regarding the regulatory requirements under the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 301 et seq.] and under section 262 of this title related to the approval, clearance, or licensure of qualified countermeasures or qualified pandemic or epidemic products;

(ii) with respect to persons performing countermeasure and product advanced research and development funded under this section, enable such offices or employees to provide to the extent practicable such advice in a manner that is ongoing and that is otherwise designed to facilitate expeditious development of qualified countermeasures and qualified pandemic or epidemic products that may achieve such approval, clearance, or licensure; and

(iii) consult with the Commissioner of Food and Drugs, pursuant to section 565(b)(2) of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 360bbb–4(b)(2)], to ensure that facilities performing manufacturing, pursuant to an award under subparagraph (B)(v), are in compliance with applicable requirements under such Act and this chapter, as appropriate,

including current good manufacturing practice pursuant to section 501(a)(2)(B) of the Food, Drug, and Cosmetic Act [21 U.S.C. 351(a)(2)(B)]; and

(D) Supporting innovation

To carry out the purpose described in paragraph (2)(D), the Secretary may award contracts, grants, and cooperative agreements, or enter into other transactions, such as prize payments, to promote—

(i) innovation in technologies that may assist countermeasure and product advanced research and development, including to improve manufacturing capacities and capabilities for medical countermeasures;

(ii) research on and development of research tools and other devices and technologies; and

(iii) research to promote strategic initiatives, such as rapid diagnostics, broad spectrum antimicrobials, vaccine-manufacturing technologies, dose-sparing technologies, efficacy-increasing technologies, platform technologies, technologies to administer countermeasures, and technologies to improve storage and transportation of countermeasures.

(E) Medical countermeasures innovation partner

(i) In general

To support the purposes described in paragraph (2), the Secretary, acting through the Director of BARDA, may enter into an agreement (including through the use of grants, contracts, cooperative agreements, or other transactions as described in paragraph (5)) with an independent, nonprofit entity to—

(I) foster and accelerate the development and innovation of medical countermeasures and technologies that may assist advanced research and the development of qualified countermeasures and qualified pandemic or epidemic products, including through the use of strategic venture capital practices and methods;

(II) promote the development of new and promising technologies that address urgent medical countermeasure needs, as identified by the Secretary;

(III) address unmet public health needs that are directly related to medical countermeasure requirements, such as novel antimicrobials for multidrug resistant organisms and multiuse platform technologies for diagnostics, prophylaxis, vaccines, and therapeutics; and

(IV) provide expert consultation and advice to foster viable medical countermeasure innovators, including helping qualified countermeasure innovators navigate unique industry challenges with respect to developing chemical, biological, radiological, and nuclear countermeasure products.

(ii) Eligibility

(I) In general

To be eligible to enter into an agreement under clause (i) an entity shall—

(aa) be an independent, nonprofit entity;

(bb) have a demonstrated record of being able to create linkages between innovators and investors and leverage such partnerships and resources for the purpose of addressing identified strategic needs of the Federal Government;

(cc) have experience in promoting novel technology innovation;

(dd) be problem-driven and solution-focused based on the needs, requirements, and problems identified by the Secretary under clause (iv);

(ee) demonstrate the ability, or the potential ability, to promote the development of medical countermeasure products;

(ff) demonstrate expertise, or the capacity to develop or acquire expertise, related to technical and regulatory considerations with respect to medical countermeasures; and

(gg) not be within the Department of Health and Human Services.

(II) Partnering experience

In selecting an entity with which to enter into an agreement under clause (i), the Secretary shall place a high value on the demonstrated experience of the entity in partnering with the Federal Government to meet identified strategic needs.

(iii) Not agency

An entity that enters into an agreement under clause (i) shall not be deemed to be a Federal agency for any purpose, including for any purpose under title 5.

(iv) Direction

Pursuant to an agreement entered into under this subparagraph, the Secretary, acting through the Director of BARDA, shall provide direction to the entity that enters into an agreement under clause (i). As part of this agreement the Director of BARDA shall—

(I) communicate the medical countermeasure needs, requirements, and problems to be addressed by the entity under the agreement;

(II) develop a description of work to be performed by the entity under the agreement;

(III) provide technical feedback and appropriate oversight over work carried out by the entity under the agreement, including subsequent development and partnerships consistent with the needs and requirements set forth in this subparagraph;

(IV) ensure fair consideration of products developed under the agreement in order to maintain competition to the maximum practical extent, as applicable and appropriate under applicable provisions of this section; and

(V) ensure, as a condition of the agreement that the entity—

(aa) has in place a comprehensive set of policies that demonstrate a commitment to transparency and accountability;

(bb) protects against conflicts of interest through a comprehensive set of policies that address potential conflicts of interest, ethics, disclosure, and reporting requirements;

(cc) provides monthly accounting on the use of funds provided under such agreement; and

(dd) provides on a quarterly basis, reports regarding the progress made toward meeting the identified needs set forth in the agreement.

(v) Supplement not supplant

Activities carried out under this subparagraph shall supplement, and not supplant, other activities carried out under this section.

(vi) No establishment of entity

To prevent unnecessary duplication and target resources effectively, nothing in this subparagraph shall be construed to authorize the Secretary to establish within the Department of Health and Human Services an entity for the purposes of carrying out this subparagraph.

(vii) Transparency and oversight

Upon request, the Secretary shall provide to Congress the information provided to the Secretary under clause (iv)(V)(dd).

(viii) Independent evaluation

Not later than 4 years after December 13, 2016, the Comptroller General of the United States shall conduct an independent evaluation, and submit to the Secretary and the appropriate committees of Congress a report, concerning the activities conducted under this subparagraph. Such report shall include recommendations with respect to any agreement or activities carried out pursuant to this subparagraph.

(ix) Sunset

This subparagraph shall have no force or effect after September 30, 2028.

(F) Strategic initiatives

The Secretary, acting through the Director of BARDA, may implement strategic initiatives, including by building on existing programs and by awarding contracts, grants, and cooperative

agreements, or entering into other transactions, to support innovative candidate products in preclinical and clinical development that address priority, naturally occurring and man-made threats that, as determined by the Secretary, pose a significant level of risk to national security based on the characteristics of a chemical, biological, radiological or nuclear threat, or existing capabilities to respond to such a threat (including medical response and treatment capabilities and manufacturing infrastructure). Such initiatives shall accelerate and support the advanced research, development, and procurement of countermeasures and products, as applicable, to address areas including—

(i) chemical, biological, radiological, or nuclear threats, including emerging infectious diseases, for which insufficient approved, licensed, or authorized countermeasures exist, or for which such threat, or the result of an exposure to such threat, may become resistant to countermeasures or existing countermeasures may be rendered ineffective;

(ii) threats that consistently exist or continually circulate and have a significant potential to become a pandemic, such as pandemic influenza, which may include the advanced research and development, manufacturing, and appropriate stockpiling of qualified pandemic or epidemic products, and products, technologies, or processes to support the advanced research and development of such countermeasures (including multiuse platform technologies for diagnostics, vaccines, and therapeutics; virus seeds; clinical trial lots; novel virus strains; and antigen and adjuvant material); and

(iii) threats that may result primarily or secondarily from a chemical, biological, radiological, or nuclear agent, or emerging infectious diseases, and which may present increased treatment complications such as the occurrence of resistance to available countermeasures or potential countermeasures, including antimicrobial resistant pathogens.

(G) Annual reports by award recipients

As a condition of receiving an award under subparagraph (B)(v), a recipient shall develop and submit to the Secretary annual reports related to the maintenance of such capacity and capabilities, including ensuring that such capacity and capabilities are able to support the rapid manufacture of countermeasures as required by the Secretary.

(5) Transaction authorities

(A) Other transactions

(i) In general

The Secretary shall have the authority to enter into other transactions (as defined in subsection (a)(3)) under this subsection.

(ii) Limitations on authority

(I) In general

To the maximum extent practicable, competitive procedures shall be used when entering into transactions to carry out projects under this subsection.

(II) Written determinations required

The authority of this subparagraph may be exercised for a project that is expected to cost the Department of Health and Human Services in excess of $100,000,000 only upon a written determination by the Assistant Secretary for Financial Resources, that the use of such authority is essential to promoting the success of the project. The authority of the Assistant Secretary for Financial Resources under this subclause may not be delegated.

(iii) Authority during a public health emergency

(I) In general

Notwithstanding clause (ii), the Secretary, shall, to the maximum extent practicable, use competitive procedures when entering into transactions to carry out projects under this subsection for purposes of a public health emergency declared by the Secretary under section 247d of this title. Any such transactions entered into during such public health

emergency shall not be terminated solely due to the expiration of such public health emergency, if such public health emergency ends before the completion of the terms of such agreement.

(II) Report

After the expiration of the public health emergency declared by the Secretary under section 247d of this title, the Secretary shall provide a report to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives regarding the use of any funds pursuant to the authority under subclause (I), including any outcomes, benefits, and risks associated with the use of such funds, and a description of the reasons for the use of such authority for the project or projects.

(iv) Guidelines

The Secretary shall establish guidelines regarding the use of the authority under clause (i). Such guidelines shall include auditing requirements.

(B) Expedited authorities

(i) In general

In awarding contracts, grants, and cooperative agreements, and in entering into other transactions under subparagraph (B) or (D) of paragraph (4), the Secretary shall have the expedited procurement authorities, the authority to expedite peer review, and the authority for personal services contracts, supplied by subsections (b), (c), and (d) of section 247d–6a of this title.

(ii) Application of provisions

Provisions in such section 247d–6a of this title that apply to such authorities and that require institution of internal controls, limit review, provide for Federal Tort Claims Act coverage of personal services contractors, and commit decisions to the discretion of the Secretary shall apply to the authorities as exercised pursuant to this paragraph.

(iii) Authority to limit competition

For purposes of applying section 247d–6a(b)(1)(D) of this title to this paragraph, the phrase "BioShield Program under the Project BioShield Act of 2004" shall be deemed to mean the countermeasure and product advanced research and development program under this section.

(iv) Availability of data

The Secretary shall require that, as a condition of being awarded a contract, grant, cooperative agreement, or other transaction under subparagraph (B) or (D) of paragraph (4), a person make available to the Secretary on an ongoing basis, and submit upon request to the Secretary, all data related to or resulting from countermeasure and product advanced research and development carried out pursuant to this section.

(C) Advance payments; advertising

The Secretary may waive the requirements of section 3324(a) of title 31 or section 6101 of title 41 upon the determination by the Secretary that such waiver is necessary to obtain countermeasures or products under this section.

(D) Milestone-based payments allowed

In awarding contracts, grants, and cooperative agreements, and in entering into other transactions, under this section, the Secretary may use milestone-based awards and payments.

(E) Foreign nationals eligible

The Secretary may under this section award contracts, grants, and cooperative agreements to, and may enter into other transactions with, highly qualified foreign national persons outside the United States, alone or in collaboration with American participants, when such transactions may

inure to the benefit of the American people.

(F) Establishment of research centers

The Secretary may assess the feasibility and appropriateness of establishing, through contract, grant, cooperative agreement, or other transaction, an arrangement with an existing research center in order to achieve the goals of this section. If such an agreement is not feasible and appropriate, the Secretary may establish one or more federally-funded research and development centers, or university-affiliated research centers, in accordance with section 3304(a)(3) of title 41.

(G) Government purpose

In awarding contracts, grants, and cooperative agreements under this section, the Secretary shall provide a clear statement of defined Government purpose related to activities included in subsection (a)(6)(B) for a qualified countermeasure or qualified pandemic or epidemic product.

(H) Supporting warm-base and surge capacity and capabilities

Pursuant to an award under subparagraph (B)(v),[1] the Secretary may make payments for activities necessary to maintain domestic manufacturing surge capacity and capabilities supported under such award to ensure that such capacity and capabilities are able to support the rapid manufacture of countermeasures as required by the Secretary to prepare for, or respond to, an existing or potential public health emergency or otherwise address threats that pose a significant level of risk to national security. The Secretary may support the utilization of such capacity and capabilities under awards for countermeasure and product advanced research and development, as appropriate, to provide for the maintenance of such capacity and capabilities.

(6) At-risk individuals

In carrying out the functions under this section, the Secretary may give priority to the advanced research and development of qualified countermeasures and qualified pandemic or epidemic products that are likely to be safe and effective with respect to children, pregnant women, older adults, and other at-risk individuals with relevant characteristics that warrant consideration during the process of researching and developing such countermeasures and products.

(7) Personnel authorities

(A) Specially qualified scientific and professional personnel

(i) In general

In addition to any other personnel authorities, the Secretary may—

(I) without regard to those provisions of title 5 governing appointments in the competitive service, appoint highly qualified individuals to scientific or professional positions in BARDA, such as program managers, to carry out this section; and

(II) compensate them in the same manner and subject to the same terms and conditions in which individuals appointed under section 9903 of such title are compensated, without regard to the provisions of chapter 51 and subchapter III of chapter 53 of such title relating to classification and General Schedule pay rates.

(ii) Manner of exercise of authority

The authority provided for in this subparagraph shall be exercised subject to the same limitations described in section 247d–6a(e)(2) of this title.

(iii) Term of appointment

The term limitations described in section 9903(c) of title 5 shall apply to appointments under this subparagraph, except that the references to the "Secretary" and to the "Department of Defense's national security missions" shall be deemed to be to the Secretary of Health and Human Services and to the mission of the Department of Health and Human Services under this section.

(B) Special consultants

In carrying out this section, the Secretary may appoint special consultants pursuant to section 209(f) of this title.

(C) Limitation

(i) In general

The Secretary may hire up to 100 highly qualified individuals, or up to 50 percent of the total number of employees, whichever is less, under the authorities provided for in subparagraphs (A) and (B).

(ii) Report

The Secretary shall report to Congress on a biennial basis on the implementation of this subparagraph.

(d) Fund

(1) Establishment

There is established the Biodefense Medical Countermeasure Development Fund, which shall be available to carry out this section in addition to such amounts as are otherwise available for this purpose.

(2) Funding

To carry out the purposes of this section, there is authorized to be appropriated to the Fund $611,700,000 for each of fiscal years 2019 through 2023, such amounts to remain available until expended.

(e) Inapplicability of certain provisions

(1) Disclosure

(A) Nondisclosure of information

(i) In general

Information described in clause (ii) shall be deemed to be information described in section 552(b)(3) of title 5.

(ii) Information described

The information described in this clause is information relevant to programs of the Department of Health and Human Services that could compromise national security and reveal significant and not otherwise publicly known vulnerabilities of existing medical or public health defenses against chemical, biological, radiological, or nuclear threats, and is comprised of—

(I) specific technical data or scientific information that is created or obtained during the countermeasure and product advanced research and development carried out under subsection (c);

(II) information pertaining to the location security, personnel, and research materials and methods of high-containment laboratories conducting research with select agents, toxins, or other agents with a material threat determination under section 247d–6b(c)(2) of this title; or

(III) security and vulnerability assessments.

(B) Review

Information subject to nondisclosure under subparagraph (A) shall be reviewed by the Secretary every 5 years, or more frequently as determined necessary by the Secretary, to determine the relevance or necessity of continued nondisclosure.

(C) Reporting

One year after June 24, 2019, and annually thereafter, the Secretary shall report to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on

Energy and Commerce of the House of Representatives on the number of instances in which the Secretary has used the authority under this subsection to withhold information from disclosure, as well as the nature of any request under section 552 of title 5 that was denied using such authority.

(D) Sunset

This paragraph shall cease to have force or effect after December 31, 2026.

(2) Review

Notwithstanding section 1013 of title 5, a working group of BARDA under this section and the National Biodefense Science Board under section 247d–7g of this title shall each terminate on the date that is 5 years after the date on which each such group or Board, as applicable, was established. Such 5-year period may be extended by the Secretary for one or more additional 5-year periods if the Secretary determines that any such extension is appropriate.

(f) Independent evaluation

(1) In general

Not later than 180 days after December 29, 2022, the Comptroller General of the United States shall conduct an independent evaluation of the activities carried out to facilitate flexible manufacturing capacity pursuant to this section.

(2) Report

Not later than 1 year after December 29, 2022, the Comptroller General of the United States shall submit to the appropriate committees of Congress a report concerning the results of the evaluation conducted under paragraph (1). Such report shall review and assess—

(A) the extent to which flexible manufacturing capacity under this section is dedicated to chemical, biological, radiological, and nuclear threats;

(B) the activities supported by flexible manufacturing initiatives;

(C) the ability of flexible manufacturing activities carried out under this section to—

(i) secure and leverage leading technical expertise with respect to countermeasure advanced research, development, and manufacturing processes; and

(ii) meet the surge manufacturing capacity needs presented by novel and emerging threats, including chemical, biological, radiological, and nuclear agents; and

(D) plans for the near-, mid-, and long-term sustainment of manufacturing activities carried out under this section, including such activities pursuant to subsection (c)(5)(H), specific actions to regularly assess the ability of recipients of an award under subsection (c)(4)(B)(v) to rapidly manufacture countermeasures as required by the Secretary, and recommendations to address challenges, if any, related to such activities.

(July 1, 1944, ch. 373, title III, §319L, as added Pub. L. 109–417, title IV, §401, Dec. 19, 2006, 120 Stat. 2865; amended Pub. L. 113–5, title IV, §402(a)–(d), (f), Mar. 13, 2013, 127 Stat. 194, 195; Pub. L. 114–255, div. A, title III, §§3082(b), 3084, Dec. 13, 2016, 130 Stat. 1141; Pub. L. 116–22, title III, §303(b), title IV, §404(a), title V, §504(b), title VI, §§601, 602, title VII, §701(d), (e)(2)(B), (f), June 24, 2019, 133 Stat. 935, 948, 951–953, 961; Pub. L. 116–136, div. A, title III, §3301, Mar. 27, 2020, 134 Stat. 383; Pub. L. 117–286, §4(a)(228), Dec. 27, 2022, 136 Stat. 4331; Pub. L. 117–328, div. FF, title II, §2401(a), Dec. 29, 2022, 136 Stat. 5782; Pub. L. 118–22, div. B, title II, §203(b), Nov. 17, 2023, 137 Stat. 120; Pub. L. 118–35, div. B, title I, §103(b), Jan. 19, 2024, 138 Stat. 5; Pub. L. 118–42, div. G, title I, §103(b), Mar. 9, 2024, 138 Stat. 398; Pub. L. 118–158, div. C, title I, §3103(b), Dec. 21, 2024, 138 Stat. 1763; Pub. L. 119–4, div. B, title I, §2103(b), Mar. 15, 2025, 139 Stat. 41; Pub. L. 119–37, div. F, title I, §6103(b), Nov. 12, 2025, 139 Stat. 630; Pub. L. 119–75, div. J, title IV, §6403(b), Feb. 3, 2026, 140 Stat. 688.)

EDITORIAL NOTES

REFERENCES IN TEXT

The Federal Food, Drug, and Cosmetic Act, referred to in subsecs. (a)(6)(A)(ii), (B)(i) and (c)(2)(C), (4)(B)(iii), (C)(i), (iii), is act June 25, 1938, ch. 675, 52 Stat. 1040, which is classified generally to chapter 9 (§301 et seq.) of Title 21, Food and Drugs. For complete classification of this Act to the Code, see section 301 of Title 21 and Tables.

The Federal Tort Claims Act, referred to in subsec. (c)(5)(B)(ii), is title IV of act Aug. 2, 1946, ch. 753, 60 Stat. 842, which was classified principally to chapter 20 (§§921, 922, 931–934, 941–946) of former Title 28, Judicial Code and Judiciary. Title IV of act Aug. 2, 1946, was substantially repealed and reenacted as sections 1346(b) and 2671 et seq. of Title 28, Judiciary and Judicial Procedure, by act June 25, 1948, ch. 646, 62 Stat. 992, the first section of which enacted Title 28. The Federal Tort Claims Act is also commonly used to refer to chapter 171 of Title 28, Judiciary and Judicial Procedure. For complete classification of title IV to the Code, see Tables. For distribution of former sections of Title 28 into the revised Title 28, see Table at the beginning of Title 28.

CODIFICATION

In subsec. (c)(5)(C), "section 6101 of title 41" substituted for "section 3709 of the Revised Statutes of the United States (41 U.S.C. 5)" on authority of Pub. L. 111–350, §6(c), Jan. 4, 2011, 124 Stat. 3854, which Act enacted Title 41, Public Contracts.

In subsec. (c)(5)(F), "section 3304(a)(3) of title 41" substituted for "section 303(c)(3) of the Federal Property and Administrative Services Act of 1949 (41 U.S.C. 253(c)(3))" on authority of Pub. L. 111–350, §6(c), Jan. 4, 2011, 124 Stat. 3854, which Act enacted Title 41, Public Contracts.

AMENDMENTS

2026—Subsec. (e)(1)(D). Pub. L. 119–75 substituted "December 31, 2026" for "January 30, 2026".

2025—Subsec. (e)(1)(D). Pub. L. 119–37 substituted "January 30, 2026" for "September 30, 2025".

Pub. L. 119–4 substituted "September 30, 2025" for "March 31, 2025".

2024—Subsec. (e)(1)(D). Pub. L. 118–158 substituted "March 31, 2025" for "December 31, 2024".

Pub. L. 118–42 substituted "December 31, 2024" for "March 8, 2024".

Pub. L. 118–35 substituted "March 8, 2024" for "January 19, 2024".

2023—Subsec. (e)(1)(D). Pub. L. 118–22 substituted "after January 19, 2024" for "on the date that is 17 years after December 19, 2006".

2022—Subsec. (a)(6)(B)(iv), (v). Pub. L. 117–328, §2401(a)(1)(A), (B), added cl. (iv) and redesignated former cl. (iv) as (v). Former cl. (v) redesignated (vi).

Subsec. (a)(6)(B)(vi). Pub. L. 117–328, §2401(a)(1)(A), (C), redesignated cl. (v) as (vi) and inserted "manufacturing," after "improvement,".

Subsec. (b)(1). Pub. L. 117–328, §2401(a)(2)(A), inserted "support for domestic manufacturing surge capacity and capabilities," after "initiatives for innovation,".

Subsec. (b)(2)(C), (D). Pub. L. 117–328, §2401(a)(2)(B), added subpar. (C) and redesignated former subpar. (C) as (D).

Subsec. (c)(2)(B). Pub. L. 117–328, §2401(a)(3)(A), inserted ", including through the establishment and maintenance of domestic manufacturing surge capacity and capabilities, consistent with subsection (a)(6)(B)(iv)" after "development".

Subsec. (c)(4)(A)(i)(III), (IV). Pub. L. 117–328, §2401(a)(3)(B)(i)(I), added subcls. (III) and (IV).

Subsec. (c)(4)(A)(iii), (iv). Pub. L. 117–328, §2401(a)(3)(B)(i)(II)–(IV), added cl. (iii) and redesignated former cl. (iii) as (iv).

Subsec. (c)(4)(B)(v). Pub. L. 117–328, §2401(a)(3)(B)(ii), added cl. (v).

Subsec. (c)(4)(C)(iii). Pub. L. 117–328, §2401(a)(3)(B)(iii), added cl. (iii).

Subsec. (c)(4)(D)(i). Pub. L. 117–328, §2401(a)(3)(B)(iv), inserted ", including to improve manufacturing capacities and capabilities for medical countermeasures" after "development".

Subsec. (c)(4)(E)(ix). Pub. L. 117–328, §2401(a)(3)(B)(v), substituted "2028" for "2023".

Subsec. (c)(4)(G). Pub. L. 117–328, §2401(a)(3)(B)(vi), added subpar. (G).

Subsec. (c)(5)(H). Pub. L. 117–328, §2401(a)(3)(C), added subpar. (H).

Subsec. (e)(2). Pub. L. 117–286 substituted "section 1013 of title 5," for "section 14 of the Federal Advisory Committee Act,".

Subsec. (f)(1). Pub. L. 117–328, §2401(a)(4)(A), substituted "Not later than 180 days after December 29, 2022" for "Not later than 180 days after March 13, 2013".

Subsec. (f)(2). Pub. L. 117–328, §2401(a)(4)(B)(i), substituted "December 29, 2022" for "March 13, 2013" in introductory provisions.

Subsec. (f)(2)(D). Pub. L. 117–328, §2401(a)(4)(B)(ii)–(C), added subpar. (D).

2020—Subsec. (c)(5)(A)(iii), (iv). Pub. L. 116–136 added cl. (iii) and redesignated former cl. (iii) as (iv).

2019—Subsec. (a)(3). Pub. L. 116–22, §602(1), struck out ", such as the Secretary of Defense may enter into under section 2371 of title 10" before period at end.

Subsec. (c)(4)(A)(iii). Pub. L. 116–22, §701(e)(2)(B), substituted "section 247d–7f of this title" for "section 405 of the Pandemic and All-Hazards Preparedness Act".

Subsec. (c)(4)(D)(iii). Pub. L. 116–22, §601, substituted "platform technologies, technologies to administer countermeasures, and technologies to improve storage and transportation of countermeasures" for "and platform technologies".

Subsec. (c)(4)(E)(ix). Pub. L. 116–22, §701(d), substituted "2023" for "2022".

Subsec. (c)(4)(F). Pub. L. 116–22, §404(a), added subpar. (F).

Subsec. (c)(5)(A)(i). Pub. L. 116–22, §602(2)(A), substituted "(as defined in subsection (a)(3)) under this subsection" for "under this subsection in the same manner as the Secretary of Defense enters into such transactions under section 2371 of title 10".

Subsec. (c)(5)(A)(ii)(I). Pub. L. 116–22, §602(2)(B)(i), amended subcl. (I) generally. Prior to amendment, text read as follows: "Subsections (b), (c), and (h) of section 845 of the National Defense Authorization Act for Fiscal Year 1994 (10 U.S.C. 2371 note) shall apply to other transactions under this subparagraph as if such transactions were for prototype projects described by subsection (a) of such section 845."

Subsec. (c)(5)(A)(ii)(II). Pub. L. 116–22, §602(2)(B)(ii), substituted "$100,000,000" for "$20,000,000", "Assistant Secretary for Financial Resources" for "senior procurement executive for the Department (as designated for purpose of section 16(c) of the Office of Federal Procurement Policy Act (41 U.S.C. 414(c)))", and "Assistant Secretary for Financial Resources under" for "senior procurement executive under".

Subsec. (c)(6). Pub. L. 116–22, §303(b), substituted "older adults" for "elderly" and inserted "with relevant characteristics that warrant consideration during the process of researching and developing such countermeasures and products" before period at end.

Subsec. (d)(2). Pub. L. 116–22, §504(b), substituted "$611,700,000 for each of fiscal years 2019 through 2023" for "$415,000,000 for each of fiscal years 2014 through 2018".

Subsec. (e)(1)(A). Pub. L. 116–22, §701(f)(1), amended subpar. (A) generally. Prior to amendment, text read as follows: "The Secretary shall withhold from disclosure under section 552 of title 5 specific technical data or scientific information that is created or obtained during the countermeasure and product advanced research and development carried out under subsection (c) that reveals significant and not otherwise publicly known vulnerabilities of existing medical or public health defenses against biological, chemical, nuclear, or radiological threats. Such information shall be deemed to be information described in section 552(b)(3) of title 5."

Subsec. (e)(1)(C). Pub. L. 116–22, §701(f)(3), added subpar. (C). Former subpar. (C) redesignated (D).

Subsec. (e)(1)(D). Pub. L. 116–22, §701(f)(2), (4), redesignated subpar. (C) as (D) and substituted "17" for "12".

2016—Subsec. (c)(3). Pub. L. 114–255, §3082(b), inserted ", including the execution of procurement contracts, grants, and cooperative agreements pursuant to this section" before period at end.

Subsec. (c)(4)(E). Pub. L. 114–255, §3084, added subpar. (E).

2013—Subsec. (c)(4)(B)(iii). Pub. L. 113–5, §402(a)(1), inserted "(which may include advanced research and development for purposes of fulfilling requirements under the Federal Food, Drug, and Cosmetic Act or section 262 of this title)" after "research and development".

Subsec. (c)(4)(D)(iii). Pub. L. 113–5, §402(a)(2), substituted "vaccine-manufacturing technologies, dose-sparing technologies, efficacy-increasing technologies, and platform technologies" for "and vaccine manufacturing technologies".

Subsec. (c)(5)(G). Pub. L. 113–5, §402(b), added subpar. (G).

Subsec. (d)(2). Pub. L. 113–5, §402(c), amended par. (2) generally. Prior to amendment, text read as follows: "To carry out the purposes of this section, there are authorized to be appropriated to the Fund—

"(A) $1,070,000,000 for fiscal years 2006 through 2008, the amounts to remain available until expended; and

"(B) such sums as may be necessary for subsequent fiscal years, the amounts to remain available until expended."

Subsec. (e)(1)(C). Pub. L. 113–5, §402(d), substituted "12 years" for "7 years".

Subsec. (f). Pub. L. 113–5, §402(f), added subsec. (f).

EXECUTIVE DOCUMENTS

EX. ORD. NO. 13887. MODERNIZING INFLUENZA VACCINES IN THE UNITED STATES TO PROMOTE NATIONAL SECURITY AND PUBLIC HEALTH

Ex. Ord. No. 13887, Sept. 19, 2019, 84 F.R. 49935, provided:

By the authority vested in me as President by the Constitution and the laws of the United States of America, including section 301 of title 3, United States Code, it is hereby ordered as follows:

SECTION 1. *Findings*. (a) Influenza viruses are constantly changing as they circulate globally in humans and animals. Relatively minor changes in these viruses cause annual seasonal influenza outbreaks, which result in millions of illnesses, hundreds of thousands of hospitalizations, and tens of thousands of deaths each year in the United States. Periodically, new influenza A viruses emerge from animals, including birds and pigs, that can spread efficiently and have sustained transmission among humans. This situation is called an influenza pandemic (pandemic). Unlike seasonal influenza, a pandemic has the potential to spread rapidly around the globe, infect higher numbers of people, and cause high rates of illness and death in populations that lack prior immunity. While it is not possible to predict when or how frequently a pandemic may occur, there have been 4 pandemics in the last 100 years. The most devastating pandemic occurred in 1918–1919 and is estimated to have killed more than 50 million people worldwide, including 675,000 Americans.

(b) Vaccination is the most effective defense against influenza. Despite recommendations by the Centers for Disease Control and Prevention (CDC) that nearly every American should receive the influenza vaccine annually, however, seasonal influenza vaccination levels in the United States have currently reached only about 45 percent of CDC goals.

(c) All influenza vaccines presently in use have been developed for circulating or anticipated influenza viruses. These vaccines must be reformulated for each influenza season as well as in the event of a pandemic. Additional research is needed to develop influenza vaccines that provide more effective and longer-lasting protection against many or all influenza viruses.

(d) The current domestic enterprise for manufacturing influenza vaccines has critical shortcomings. Most influenza vaccines are made in chicken eggs, using a 70-year-old process that requires months-long production timelines, limiting their utility for pandemic control; rely on a potentially vulnerable supply chain of eggs; require the use of vaccine viruses adapted for growth in eggs, which could introduce mutations of the influenza vaccine virus that may render the final product less effective; and are unsuitable for efficient and scalable continuous manufacturing platforms.

(e) The seasonal influenza vaccine market rewards manufacturers that deliver vaccines in time for the influenza season, without consideration of the speed or scale of these manufacturers' production processes. This approach is insufficient to meet the response needs in the event of a pandemic, which can emerge rapidly and with little warning. Because the market does not sufficiently reward speed, and because a pandemic has the potential to overwhelm or compromise essential government functions, including defense and homeland security, the Government must take action to promote faster and more scalable manufacturing platforms.

SEC. 2. *Policy*. It is the policy of the United States to modernize the domestic influenza vaccine enterprise to be highly responsive, flexible, scalable, and more effective at preventing the spread of influenza viruses. This is a public health and national security priority, as influenza has the potential to significantly harm the United States and our interests, including through large-scale illness and death, disruption to military operations, and damage to the economy. This order directs actions to reduce the United States' reliance on egg-based influenza vaccine production; to expand domestic capacity of alternative methods that allow more agile and rapid responses to emerging influenza viruses; to advance the development of new, broadly protective vaccine candidates that provide more effective and longer lasting immunities; and to support the promotion of increased influenza vaccine immunization across recommended populations.

SEC. 3. *National Influenza Vaccine Task Force*. (a) There is hereby established a National Influenza Vaccine Task Force (Task Force). The Task Force shall identify actions to achieve the objectives identified in section 2 of this order and monitor and report on the implementation and results of those actions. The Task Force shall be co-chaired by the Secretary of Defense and the Secretary of Health and Human Services, or their designees.

(b) In addition to the Co-Chairs, the Task Force shall consist of a senior official from the following executive branch departments, agencies, and offices:

(i) the Department of Defense (DOD);

(ii) the Department of Justice;

(iii) the Department of Agriculture;

(iv) the Department of Veterans Affairs (VA);

(v) the Department of Homeland Security;

(vi) the United States Food and Drug Administration;

(vii) the Centers for Disease Control and Prevention;

(viii) the National Institutes of Health (NIH);

(ix) the Centers for Medicare and Medicaid Services (CMS); and

(x) the Biomedical Advanced Research and Development Authority (BARDA).

(c) The Co-Chairs may jointly invite additional Federal Government representatives, with the consent of the applicable executive department, agency, or office head, to attend meetings of the Task Force or to become members of the Task Force, as appropriate.

(d) The staffs of the Department of State, the Office of Management and Budget (OMB), the National Security Council, the Council of Economic Advisers, the Domestic Policy Council, the National Economic Council, and the Office of Science and Technology Policy (OSTP) may attend and participate in any Task Force meetings or discussions.

(e) The Task Force may consult with State, local, tribal, and territorial government officials and private sector representatives, as appropriate and consistent with applicable law.

(f) Within 120 days of the date of this order [Sept. 19, 2019], the Task Force shall submit a report to the President, through the Assistant to the President for National Security Affairs, the Assistant to the President for Domestic Policy, the Director of the Office of Management and Budget, and the Director of the Office of Science and Technology Policy. The report shall include:

(i) a 5-year national plan (Plan) to promote the use of more agile and scalable vaccine manufacturing technologies and to accelerate development of vaccines that protect against many or all influenza viruses;

(ii) recommendations for encouraging non-profit, academic, and private-sector influenza vaccine innovation; and

(iii) recommendations for increasing influenza vaccination among the populations recommended by the CDC and for improving public understanding of influenza risk and informed influenza vaccine decision-making.

(g) Not later than June 1 of each of the 5 years following submission of the report described in subsection (f) of this section, the Task Force shall submit an update on implementation of the Plan and, as appropriate, new recommendations for achieving the policy objectives set forth in section 2 of this order.

SEC. 4. *Agency Implementation*. The heads of executive departments and agencies shall also implement the policy objectives defined in section 2 of this order, consistent with existing authorities and appropriations, as follows:

(a) The Secretary of HHS shall:

(i) through the Assistant Secretary for Preparedness and Response and BARDA:

(A) estimate the cost of expanding and diversifying domestic vaccine-manufacturing capacity to use innovative, faster, and more scalable technologies, including cell-based and recombinant vaccine manufacturing, through cost-sharing agreements with the private sector, which shall include an agreed-upon pricing strategy during a pandemic;

(B) estimate the cost of expanding domestic production capacity of adjuvants in order to combine such adjuvants with both seasonal and pandemic influenza vaccines;

(C) estimate the cost of expanding domestic fill-and-finish capacity to rapidly fulfill antigen and adjuvant needs for pandemic response;

(D) estimate the cost of developing, evaluating, and implementing delivery systems to augment limited supplies of needles and syringes and to enable the rapid and large-scale administration of pandemic influenza vaccines;

(E) evaluate incentives for the development and production of vaccines by private manufacturers and public-private partnerships, including, in emergency situations, the transfer of technology to public-private partnerships—such as the HHS Centers for Innovation and Advanced Development and Manufacturing or other domestic manufacturing facilities—in advance of a pandemic, in order to be able to ensure adequate domestic pandemic manufacturing capacity and capability;

(F) support, in coordination with the DOD, NIH, and VA, a suite of clinical studies featuring different adjuvants to support development of improved vaccines and further expand vaccine supply by reducing the dose of antigen required; and

(G) update, in coordination with other relevant public health agencies, the research agenda to dramatically improve the effectiveness, efficiency, and reliability of influenza vaccine production;

(ii) through the Director of NIH, provide to the Task Force estimated timelines for implementing NIH's strategic plan and research agenda for developing influenza vaccines that can protect individuals over many years against multiple types of influenza viruses;

(iii) through the Commissioner of Food and Drugs:

(A) further implement vaccine production process improvements to reduce the time required for vaccine production (e.g., through the use of novel technologies for vaccine seed virus development and

through implementation of improved potency and sterility assays);

(B) develop, in conjunction with the CDC, proposed alternatives for the timing of vaccine virus selection to account for potentially shorter timeframes associated with non-egg based manufacturing and to facilitate vaccines optimally matched to the circulating strains;

(C) further support the conduct, in collaboration with the DOD, BARDA, and CDC, of applied scientific research regarding developing cell lines and expression systems that markedly increase the yield of cell-based and recombinant influenza vaccine manufacturing processes; and

(D) assess, in coordination with BARDA and relevant vaccine manufacturers, the use and potential effects of using advanced manufacturing platforms for influenza vaccines;

(iv) through the Director of the CDC:

(A) expand vaccine effectiveness studies to more rapidly evaluate the effectiveness of cell-based and recombinant influenza vaccines relative to egg-based vaccines;

(B) explore options to expand the production capacity of cell-based vaccine candidates used by industry;

(C) develop a plan to expand domestic capacity for whole genome characterization of influenza viruses;

(D) increase influenza vaccine use through enhanced communication and by removing barriers to vaccination; and

(E) enhance communication to healthcare providers about the performance of influenza vaccines, in order to assist them in promoting the most effective vaccines for their patient populations; and

(v) through the Administrator of CMS, examine the current legal, regulatory, and policy framework surrounding payment for influenza vaccines and assess adoption of domestically manufactured vaccines that have positive attributes for pandemic response (such as scalability and speed of manufacturing).

(b) The Secretary of Defense shall:

(i) provide OMB with a cost estimate for transitioning DOD's annual procurement of influenza vaccines to vaccines manufactured both domestically and through faster, more scalable, and innovative technologies;

(ii) direct, in coordination with the VA, CDC, and other components of HHS, the conduct of epidemiological studies of vaccine effectiveness to improve knowledge of the clinical effect of the currently licensed influenza vaccines;

(iii) use DOD's network of clinical research sites to evaluate the effectiveness of licensed influenza vaccines, including methods of boosting their effectiveness;

(iv) identify opportunities to use DOD's vaccine research and development enterprise, in collaboration with HHS, to include both early discovery and design of influenza vaccines as well as later-stage evaluation of candidate influenza vaccines;

(v) investigate, in collaboration with HHS, alternative correlates of immune protection that could facilitate development of next-generation influenza vaccines;

(vi) direct the conduct of a study to assess the feasibility of using DOD's advanced manufacturing facility for manufacturing cell-based or recombinant influenza vaccines during a pandemic; and

(vii) accelerate, in collaboration with HHS, research regarding rapidly scalable prophylactic influenza antibody approaches to complement a universal vaccine initiative and address gaps in current vaccine coverage.

(c) The Secretary of VA shall provide OMB with a cost estimate for transitioning its annual procurement of influenza vaccines to vaccines manufactured both domestically and with faster, more scalable, and innovative technologies.

SEC. 5. *Termination*. The Task Force shall terminate upon direction from the President or, with the approval of the President, upon direction from the Task Force Co-Chairs.

SEC. 6. *General Provisions*. (a) Nothing in this order shall be construed to impair or otherwise affect:

(i) the authority granted by law to an executive department or agency, or the head thereof; or

(ii) the functions of the Director of the Office of Management and Budget relating to budgetary, administrative, or legislative proposals.

(b) This order shall be implemented consistent with applicable law and subject to the availability of appropriations.

(c) This order is not intended to, and does not, create any right or benefit, substantive or procedural, enforceable at law or in equity by any party against the United States, its departments, agencies, or entities, its officers, employees, or agents, or any other person.

DONALD J. TRUMP.

[1] *So in original. Probably should be "paragraph (4)(B)(v),".*

§247d–7f. Collaboration and coordination

(a) Limited antitrust exemption

(1) Meetings and consultations to discuss security countermeasures, qualified countermeasures, or qualified pandemic or epidemic product development

(A) Authority to conduct meetings and consultations

The Secretary, in coordination with the Attorney General and the Secretary of Homeland Security, may conduct meetings and consultations with persons engaged in the development of a security countermeasure (as defined in section 247d–6b of this title), a qualified countermeasure (as defined in section 247d–6a of this title), or a qualified pandemic or epidemic product (as defined in section 247d–6d of this title) for the purpose of the development, manufacture, distribution, purchase, or storage of a countermeasure or product. The Secretary may convene such meeting or consultation at the request of the Secretary of Homeland Security, the Attorney General, the Chairman of the Federal Trade Commission (referred to in this section as the "Chairman"), or any interested person, or upon initiation by the Secretary. The Secretary shall give prior notice of any such meeting or consultation, and the topics to be discussed, to the Attorney General, the Chairman, and the Secretary of Homeland Security.

(B) Meeting and consultation conditions

A meeting or consultation conducted under subparagraph (A) shall—

(i) be chaired or, in the case of a consultation, facilitated by the Secretary;

(ii) be open to persons involved in the development, manufacture, distribution, purchase, or storage of a countermeasure or product, as determined by the Secretary;

(iii) be open to the Attorney General, the Secretary of Homeland Security, and the Chairman;

(iv) be limited to discussions involving covered activities; and

(v) be conducted in such manner as to ensure that no national security, confidential commercial, or proprietary information is disclosed outside the meeting or consultation.

(C) Limitation

The Secretary may not require participants to disclose confidential commercial or proprietary information.

(D) Transcript

The Secretary shall maintain a complete verbatim transcript of each meeting or consultation conducted under this subsection. Such transcript (or a portion thereof) shall not be disclosed under section 552 of title 5 to the extent that the Secretary, in consultation with the Attorney General and the Secretary of Homeland Security, determines that disclosure of such transcript (or portion thereof) would pose a threat to national security. The transcript (or portion thereof) with respect to which the Secretary has made such a determination shall be deemed to be information described in subsection (b)(3) of such section 552.

(E) Exemption

(i) In general

Subject to clause (ii), it shall not be a violation of the antitrust laws for any person to participate in a meeting or consultation conducted in accordance with this paragraph.

(ii) Limitation

Clause (i) shall not apply to any agreement or conduct that results from a meeting or consultation and that is not covered by an exemption granted under paragraph (4).

(2) Submission of written agreements

The Secretary shall submit each written agreement regarding covered activities that is made pursuant to meetings or consultations conducted under paragraph (1) to the Attorney General and the Chairman for consideration. In addition to the proposed agreement itself, any submission shall include—

(A) an explanation of the intended purpose of the agreement;

(B) a specific statement of the substance of the agreement;

(C) a description of the methods that will be utilized to achieve the objectives of the agreement;

(D) an explanation of the necessity for a cooperative effort among the particular participating persons to achieve the objectives of the agreement; and

(E) any other relevant information determined necessary by the Attorney General, in consultation with the Chairman and the Secretary.

(3) Exemption for conduct under approved agreement

It shall not be a violation of the antitrust laws for a person to engage in conduct in accordance with a written agreement to the extent that such agreement has been granted an exemption under paragraph (4), during the period for which the exemption is in effect.

(4) Action on written agreements

(A) In general

The Attorney General, in consultation with the Chairman, shall grant, deny, grant in part and deny in part, or propose modifications to an exemption request regarding a written agreement submitted under paragraph (2), in a written statement to the Secretary, within 15 business days of the receipt of such request. An exemption granted under this paragraph shall take effect immediately.

(B) Extension

The Attorney General may extend the 15-day period referred to in subparagraph (A) for an additional period of not to exceed 10 business days.

(C) Determination

An exemption shall be granted regarding a written agreement submitted in accordance with paragraph (2) only to the extent that the Attorney General, in consultation with the Chairman and the Secretary, finds that the conduct that will be exempted will not have any substantial anticompetitive effect that is not reasonably necessary for ensuring the availability of the countermeasure or product involved.

(5) Limitation on and renewal of exemptions

An exemption granted under paragraph (4) shall be limited to covered activities, and such exemption shall be renewed (with modifications, as appropriate, consistent with the finding described in paragraph (4)(C)), on the date that is 3 years after the date on which the exemption is granted unless the Attorney General in consultation with the Chairman determines that the exemption should not be renewed (with modifications, as appropriate) considering the factors described in paragraph (4).

(6) Authority to obtain information

Consideration by the Attorney General for granting or renewing an exemption submitted under this section shall be considered an antitrust investigation for purposes of the Antitrust Civil Process Act (15 U.S.C. 1311 et seq.).

(7) Limitation on parties

The use of any information acquired under an agreement for which an exemption has been granted under paragraph (4), for any purpose other than specified in the exemption, shall be subject to the antitrust laws and any other applicable laws.

(8) Report

Not later than one year after the date of enactment of this Act [1] and biannually thereafter, the Attorney General and the Chairman shall report to Congress on the use of the exemption from the antitrust laws provided by this subsection.

(b) Sunset

The applicability of this section shall expire after December 31, 2026.

(c) Definitions

In this section:

(1) Antitrust laws

The term "antitrust laws"—

(A) has the meaning given such term in subsection (a) of section 12 of title 15, except that such term includes section 45 of title 15 to the extent such section 45 of title 15 applies to unfair methods of competition; and

(B) includes any State law similar to the laws referred to in subparagraph (A).

(2) Countermeasure or product

The term "countermeasure or product" refers to a security countermeasure, qualified countermeasure, or qualified pandemic or epidemic product (as those terms are defined in subsection (a)(1)).

(3) Covered activities

(A) In general

Except as provided in subparagraph (B), the term "covered activities" includes any activity relating to the development, manufacture, distribution, purchase, or storage of a countermeasure or product.

(B) Exception

The term "covered activities" shall not include, with respect to a meeting or consultation conducted under subsection (a)(1) or an agreement for which an exemption has been granted under subsection (a)(4), the following activities involving 2 or more persons:

(i) Exchanging information among competitors relating to costs, profitability, or distribution of any product, process, or service if such information is not reasonably necessary to carry out covered activities—

(I) with respect to a countermeasure or product regarding which such meeting or consultation is being conducted; or

(II) that are described in the agreement as exempted.

(ii) Entering into any agreement or engaging in any other conduct—

(I) to restrict or require the sale, licensing, or sharing of inventions, developments, products, processes, or services not developed through, produced by, or distributed or sold through such covered activities; or

(II) to restrict or require participation, by any person participating in such covered activities, in other research and development activities, except as reasonably necessary to prevent the misappropriation of proprietary information contributed by any person participating in such covered activities or of the results of such covered activities.

(iii) Entering into any agreement or engaging in any other conduct allocating a market with a competitor that is not expressly exempted from the antitrust laws under subsection (a)(4).

(iv) Exchanging information among competitors relating to production (other than production by such covered activities) of a product, process, or service if such information is not reasonably necessary to carry out such covered activities.

(v) Entering into any agreement or engaging in any other conduct restricting, requiring, or otherwise involving the production of a product, process, or service that is not expressly

exempted from the antitrust laws under subsection (a)(4).

(vi) Except as otherwise provided in this subsection, entering into any agreement or engaging in any other conduct to restrict or require participation by any person participating in such covered activities, in any unilateral or joint activity that is not reasonably necessary to carry out such covered activities.

(vii) Entering into any agreement or engaging in any other conduct restricting or setting the price at which a countermeasure or product is offered for sale, whether by bid or otherwise.

(July 1, 1944, ch. 373, title III, §319L–1, formerly Pub. L. 109–417, title IV, §405, Dec. 19, 2006, 120 Stat. 2875, as amended Pub. L. 113–5, §402(e)(1), Mar. 13, 2013, 127 Stat. 195; renumbered §319L–1 of act July 1, 1944, and amended Pub. L. 116–22, title VII, §701(e)(1), June 24, 2019, 133 Stat. 961; Pub. L. 118–22, div. B, title II, §203(c), Nov. 17, 2023, 137 Stat. 120; Pub. L. 118–35, div. B, title I, §103(c), Jan. 19, 2024, 138 Stat. 5; Pub. L. 118–42, div. G, title I, §103(c), Mar. 9, 2024, 138 Stat. 398; Pub. L. 118–158, div. C, title I, §3103(c), Dec. 21, 2024, 138 Stat. 1763; Pub. L. 119–4, div. B, title I, §2103(c), Mar. 15, 2025, 139 Stat. 41; Pub. L. 119–37, div. F, title I, §6103(c), Nov. 12, 2025, 139 Stat. 630; Pub. L. 119–75, div. J, title IV, §6403(c), Feb. 3, 2026, 140 Stat. 688.)

EDITORIAL NOTES

REFERENCES IN TEXT

The Antitrust Civil Process Act, referred to in subsec. (a)(6), is Pub. L. 87–664, Sept. 19, 1962, 76 Stat. 548, which is classified principally to chapter 34 (§1311 et seq.) of Title 15, Commerce and Trade. For complete classification of this Act to the Code, see Short Title note set out under section 1311 of Title 15 and Tables.

The date of enactment of this Act, referred to in subsec. (a)(8), probably means the date of enactment of Pub. L. 109–417, which was approved Dec. 19, 2006. This section was originally enacted as section 405 of Pub. L. 109–417, prior to renumbering as section 319L–1 of act July 1, 1944, ch. 373.

CODIFICATION

Section was formerly set out as a note under section 247d–6a of this title prior to renumbering by Pub. L. 116–22.

PRIOR PROVISIONS

A prior section 247d–7f, act July 1, 1944, ch. 373, title III, §319M, as added Pub. L. 109–417, title IV, §402, Dec. 19, 2006, 120 Stat. 2872; amended Pub. L. 113–5, title IV, §404, Mar. 13, 2013, 127 Stat. 197, which related to National Biodefense Science Board and working groups, was transferred to section 247d–7g of this title.

AMENDMENTS

2026—Subsec. (b). Pub. L. 119–75 substituted "December 31, 2026" for "January 30, 2026".

2025—Subsec. (b). Pub. L. 119–37 substituted "January 30, 2026" for "September 30, 2025".

Pub. L. 119–4 substituted "September 30, 2025" for "March 31, 2025".

2024—Subsec. (b). Pub. L. 118–158 substituted "March 31, 2025" for "December 31, 2024".

Pub. L. 118–42 substituted "December 31, 2024" for "March 8, 2024".

Pub. L. 118–35 substituted "March 8, 2024" for "January 19, 2024".

2023—Subsec. (b). Pub. L. 118–22 substituted "after January 19, 2024" for "at the end of the 17-year period that begins on the date of enactment of this Act".

2019—Subsec. (a)(1)(A). Pub. L. 116–22, §701(e)(1)(A), substituted "The Secretary, in coordination" for "The Secretary of Health and Human Services (referred to in this subsection as the 'Secretary'), in coordination" and made technical amendments to references in original act which appear in text as references to sections 247d–6b, 247d–6a, and 247d–6d of this title.

Subsec. (b). Pub. L. 116–22, §701(e)(1)(B), substituted "17-year" for "12-year".

2013—Subsec. (b). Pub. L. 113–5 substituted "12-year" for "6-year".

STATUTORY NOTES AND RELATED SUBSIDIARIES

EFFECTIVE DATE OF 2013 AMENDMENT

Pub. L. 113–5, title IV, §402(e)(2), Mar. 13, 2013, 127 Stat. 195, provided that: "This subsection [amending this section] shall take effect as if enacted on December 17, 2012."

[1] *See References in Text note below.*

§247d–7g. National Biodefense Science Board and working groups

(a) In general

(1) Establishment and function

The Secretary shall establish the National Biodefense Science Board (referred to in this section as the "Board") to provide expert advice and guidance to the Secretary on scientific, technical and other matters of special interest to the Department of Health and Human Services regarding current and future chemical, biological, nuclear, and radiological agents, whether naturally occurring, accidental, or deliberate.

(2) Membership

The membership of the Board shall be comprised of individuals who represent the Nation's preeminent scientific, public health, and medical experts, as follows—

(A) such Federal officials as the Secretary may determine are necessary to support the functions of the Board;

(B) four individuals representing the pharmaceutical, biotechnology, and device industries;

(C) four individuals representing academia; and

(D) five other members as determined appropriate by the Secretary, of whom—

(i) one such member shall be a practicing healthcare professional;

(ii) one such member shall be an individual from an organization representing healthcare consumers;

(iii) one such member shall be an individual with pediatric subject matter expertise; and

(iv) one such member shall be a State, tribal, territorial, or local public health official.

Nothing in this paragraph shall preclude a member of the Board from satisfying two or more of the requirements described in subparagraph (D).

(3) Term of appointment

A member of the Board described in subparagraph (B), (C), or (D) of paragraph (2) shall serve for a term of 3 years, except that the Secretary may adjust the terms of the initial Board appointees in order to provide for a staggered term of appointment for all members.

(4) Consecutive appointments; maximum terms

A member may be appointed to serve not more than 3 terms on the Board and may serve not more than 2 consecutive terms.

(5) Duties

The Board shall—

(A) advise the Secretary on current and future trends, challenges, and opportunities presented by advances in biological and life sciences, biotechnology, and genetic engineering with respect to threats posed by naturally occurring infectious diseases and chemical, biological, radiological, and nuclear agents;

(B) at the request of the Secretary, review and consider any information and findings received from the working groups established under subsection (b);

(C) at the request of the Secretary, provide recommendations and findings for expanded, intensified, and coordinated biodefense research and development activities; and

(D) provide any recommendation, finding, or report provided to the Secretary under this paragraph to the appropriate committees of Congress.

(6) Meetings

(A) Initial meeting

Not later than one year after December 19, 2006, the Secretary shall hold the first meeting of the Board.

(B) Subsequent meetings

The Board shall meet at the call of the Secretary, but in no case less than twice annually.

(7) Vacancies

Any vacancy in the Board shall not affect its powers, but shall be filled in the same manner as the original appointment.

(8) Chairperson

The Secretary shall appoint a chairperson from among the members of the Board.

(9) Powers

(A) Hearings

The Board may hold such hearings, sit and act at such times and places, take such testimony, and receive such evidence as the Board considers advisable to carry out this subsection.

(B) Postal services

The Board may use the United States mails in the same manner and under the same conditions as other departments and agencies of the Federal Government.

(10) Personnel

(A) Employees of the Federal Government

A member of the Board that is an employee of the Federal Government may not receive additional pay, allowances, or benefits by reason of the member's service on the Board.

(B) Other members

A member of the Board that is not an employee of the Federal Government may be compensated at a rate not to exceed the daily equivalent of the annual rate of basic pay prescribed for level IV of the Executive Schedule under section 5315 of title 5 for each day (including travel time) during which the member is engaged in the actual performance of duties as a member of the Board.

(C) Travel expenses

Each member of the Board shall receive travel expenses, including per diem in lieu of subsistence, in accordance with applicable provisions under subchapter I of chapter 57 of title 5.

(D) Detail of Government employees

Any Federal Government employee may be detailed to the Board with the approval for the contributing agency without reimbursement, and such detail shall be without interruption or loss of civil service status or privilege.

(b) Other working groups

The Secretary may establish a working group of experts, or may use an existing working group or advisory committee, to—

(1) identify innovative research with the potential to be developed as a qualified countermeasure or a qualified pandemic or epidemic product;

(2) identify accepted animal models for particular diseases and conditions associated with any biological, chemical, radiological, or nuclear agent, any toxin, or any potential pandemic infectious disease, and identify strategies to accelerate animal model and research tool development and validation; and

(3) obtain advice regarding supporting and facilitating advanced research and development related to qualified countermeasures and qualified pandemic or epidemic products that are likely

to be safe and effective with respect to children, pregnant women, and other vulnerable populations, and other issues regarding activities under this section that affect such populations.

(c) Definitions

Any term that is defined in section 247d–7e of this title and that is used in this section shall have the same meaning in this section as such term is given in section 247d–7e of this title.

(d) Authorization of appropriations

There are authorized to be appropriated $1,000,000 to carry out this section for fiscal year 2007 and each fiscal year thereafter.

(July 1, 1944, ch. 373, title III, §319M, as added Pub. L. 109–417, title IV, §402, Dec. 19, 2006, 120 Stat. 2872; amended Pub. L. 113–5, title IV, §404, Mar. 13, 2013, 127 Stat. 197.)

EDITORIAL NOTES

CODIFICATION

Section was formerly classified to section 247d–7f of this title.

AMENDMENTS

2013—Subsec. (a)(2). Pub. L. 113–5, §404(1)(B), inserted concluding provisions.
Subsec. (a)(2)(D)(iii), (iv). Pub. L. 113–5, §404(1)(A), added cls. (iii) and (iv).
Subsec. (a)(5)(D). Pub. L. 113–5, §404(2), added subpar. (D).

§247d–8. Coordinated program to improve pediatric oral health

(a) In general

The Secretary, acting through the Administrator of the Health Resources and Services Administration, shall establish a program to fund innovative oral health activities that improve the oral health of children under 6 years of age who are eligible for services provided under a Federal health program, to increase the utilization of dental services by such children, and to decrease the incidence of early childhood and baby bottle tooth decay.

(b) Grants

The Secretary shall award grants to or enter into contracts with public or private nonprofit schools of dentistry or accredited dental training institutions or programs, community dental programs, and programs operated by the Indian Health Service (including federally recognized Indian tribes that receive medical services from the Indian Health Service, urban Indian health programs funded under title V of the Indian Health Care Improvement Act [25 U.S.C. 1651 et seq.], and tribes that contract with the Indian Health Service pursuant to the Indian Self-Determination and Education Assistance Act [25 U.S.C. 5301 et seq.]) to enable such schools, institutions, and programs to develop programs of oral health promotion, to increase training of oral health services providers in accordance with State practice laws, or to increase the utilization of dental services by eligible children.

(c) Distribution

In awarding grants under this section, the Secretary shall, to the extent practicable, ensure an equitable national geographic distribution of the grants, including areas of the United States where the incidence of early childhood caries is highest.

(d) Authorization of appropriations

There is authorized to be appropriated to carry out this section $10,000,000 for each [1] the fiscal years 2001 through 2005.

(July 1, 1944, ch. 373, title III, §320A, as added Pub. L. 106–310, div. A, title XVI, §1603, Oct. 17, 2000, 114 Stat. 1151.)

EDITORIAL NOTES

REFERENCES IN TEXT

The Indian Health Care Improvement Act, referred to in subsec. (b), is Pub. L. 94–437, Sept. 30, 1976, 90 Stat. 1400. Title V of the Act is classified generally to subchapter IV (§1651 et seq.) of chapter 18 of Title 25, Indians. For complete classification of this Act to the Code, see Short Title note set out under section 1601 of Title 25 and Tables.

The Indian Self-Determination and Education Assistance Act, referred to in subsec. (b), is Pub. L. 93–638, Jan. 4, 1975, 88 Stat. 2203, which is classified principally to chapter 46 (§5301 et seq.) of Title 25, Indians. For complete classification of this Act to the Code, see Short Title note set out under section 5301 of Title 25 and Tables.

CODIFICATION

Section 1603 of Pub. L. 106–310, which directed that section 320A (this section) be added at the end of part B of the Public Health Service Act, was executed by adding section 320A at the end of part B of title III of the Public Health Service Act, to reflect the probable intent of Congress, notwithstanding that section 320 of the Public Health Service Act (section 247e of this title) appears in part C of title III of the Public Health Service Act.

[1] *So in original. Probably should be followed by "of".*

§247d–9. Dental education for parents of newborns

The Secretary shall develop and implement, through entities that fund or provide perinatal care services to targeted low-income children under a State child health plan under title XXI of the Social Security Act [42 U.S.C. 1397aa et seq.], a program to deliver oral health educational materials that inform new parents about risks for, and prevention of, early childhood caries and the need for a dental visit within their newborn's first year of life.

(Pub. L. 111–3, title V, §501(c), Feb. 4, 2009, 123 Stat. 87.)

EDITORIAL NOTES

REFERENCES IN TEXT

The Social Security Act, referred to in text, is act Aug. 14, 1935, ch. 531, 49 Stat. 620. Title XXI of the Act is classified generally to subchapter XXI (§1397aa et seq.) of chapter 7 of this title. For complete classification of this Act to the Code, see section 1305 of this title and Tables.

CODIFICATION

Section was enacted as part of the Children's Health Insurance Program Reauthorization Act of 2009, and not as part of the Public Health Service Act which comprises this chapter.

STATUTORY NOTES AND RELATED SUBSIDIARIES

EFFECTIVE DATE

Section effective Apr. 1, 2009, and applicable to child health assistance and medical assistance provided on or after that date, with certain exceptions, see section 3 of Pub. L. 111–3, set out as a note under section 1396 of this title.

DEFINITION OF "SECRETARY"

"Secretary" means the Secretary of Health and Human Services, see section 1(c)(3) of Pub. L. 111–3, set out as a note under section 1396 of this title.

§247d–10. Pilot program for public health laboratories to detect fentanyl and

other synthetic opioids

(a) Grants

The Secretary of Health and Human Services (referred to in this section as the "Secretary") shall award grants to, or enter into cooperative agreements with, Federal, State, and local agencies to improve coordination between public health laboratories and laboratories operated by law enforcement agencies, such as Customs and Border Protection and the Drug Enforcement Administration, to improve detection of synthetic opioids, including fentanyl and its analogues, as described in subsection (b).

(b) Detection activities

The Secretary, in consultation with the Director of the National Institute of Standards and Technology, the Director of the Centers for Disease Control and Prevention, the Attorney General of the United States, and the Administrator of the Drug Enforcement Administration, shall, for purposes of this section, develop or identify—

(1) best practices for safely handling and testing synthetic opioids, including fentanyl and its analogues, including with respect to reference materials, instrument calibration, and quality control protocols;

(2) reference materials and quality control standards related to synthetic opioids, including fentanyl and its analogues, to enhance—

(A) clinical diagnostics;

(B) postmortem data collection; and

(C) portable testing equipment utilized by law enforcement and public health officials; and

(3) procedures for the identification of new and emerging synthetic opioid formulations and procedures for reporting those findings to appropriate law enforcement agencies and Federal, State, and local public health laboratories and health departments, as appropriate.

(c) Laboratories

The Secretary shall require recipients of grants or cooperative agreements under subsection (a) to—

(1) follow the best practices established under subsection (b) and have the appropriate capabilities to provide laboratory testing of controlled substances, such as synthetic fentanyl, and biospecimens for the purposes of aggregating and reporting public health information to Federal, State, and local public health officials, laboratories, and other entities the Secretary deems appropriate;

(2) work with law enforcement agencies and public health authorities, as practicable;

(3) provide early warning information to Federal, State, and local law enforcement agencies and public health authorities regarding trends or other data related to the supply of synthetic opioids, including fentanyl and its analogues;

(4) provide biosurveillance capabilities with respect to identifying trends in adverse health outcomes associated with non-fatal exposures; and

(5) provide diagnostic testing, as appropriate and practicable, for non-fatal exposures of emergency personnel, first responders, and other individuals.

(d) Authorization of appropriations

To carry out this section, there is authorized to be appropriated $15,000,000 for each of fiscal years 2019 through 2023.

(Pub. L. 115–271, title VII, §7011, Oct. 24, 2018, 132 Stat. 4008.)

EDITORIAL NOTES

CODIFICATION

Section was enacted as part of the Substance Use–Disorder Prevention that Promotes Opioid Recovery and

Treatment for Patients and Communities Act, also known as the SUPPORT for Patients and Communities Act, and not as part of the Public Health Service Act which comprises this chapter.

§247d–11. State All Payer Claims Databases

(a) In general

The Secretary shall make one-time grants to eligible States for the purposes described in subsection (b).

(b) Uses

A State may use a grant received under subsection (a) for one of the following purposes:

(1) To establish a State All Payer Claims Database.

(2) To improve an [1] existing State All Payer Claims Databases.[1]

(c) Eligibility

To be eligible to receive a grant under subsection (a), a State shall submit to the Secretary an application at such time, in such manner, and containing such information as the Secretary specifies, including, with respect to a State All Payer Claims Database, at least specifics on how the State will ensure uniform data collection and the privacy and security of such data.

(d) Grant period and amount

Grants awarded under this section shall be for a period of 3-years,[2] and in an amount of $2,500,000, of which $1,000,000 shall be made available to the State for each of the first 2 years of the grant period, and $500,000 shall be made available to the State for the third year of the grant period.

(e) Authorized users

(1) Application

An entity desiring authorization for access to a State All Payer Claims Database that has received a grant under this section shall submit to the State All Payer Claims Database an application for such access, which shall include—

(A) in the case of an entity requesting access for research purposes—

(i) a description of the uses and methodologies for evaluating health system performance using such data; and

(ii) documentation of approval of the research by an institutional review board, if applicable for a particular plan of research; or

(B) in the case of an entity such as an employer, health insurance issuer, third-party administrator, or health care provider, requesting access for the purpose of quality improvement or cost-containment, a description of the intended uses for such data.

(2) Requirements

(A) Access for research purposes

Upon approval of an application for research purposes under paragraph (1)(A), the authorized user shall enter into a data use and confidentiality agreement with the State All Payer Claims Database that has received a grant under this subsection, which shall include a prohibition on attempts to reidentify and disclose individually identifiable health information and proprietary financial information.

(B) Customized reports

Employers and employer organizations may request customized reports from a State All Payer Claims Database that has received a grant under this section, at cost, subject to the requirements of this section with respect to privacy, security, and proprietary financial information.

(C) Non-customized reports

A State All Payer Claims Database that has received a grant under this section shall make available to all authorized users aggregate data sets available through the State All Payer Claims Database, free of charge.

(3) Waivers

The Secretary may waive the requirements of this subsection of a State All Payer Claims Database to provide access of entities to such database if such State All Payer Claims Database is substantially in compliance with this subsection.

(f) Expanded access

(1) Multi-State applications

The Secretary may prioritize applications submitted by a State whose application demonstrates that the State will work with other State All Payer Claims Databases to establish a single application for access to data by authorized users across multiple States.

(2) Expansion of data sets

The Secretary may prioritize applications submitted by a State whose application demonstrates that the State will implement the reporting format for self-insured group health plans described in section 1191d of title 29.

(g) Definitions

In this section—

(1) the term "individually identifiable health information" has the meaning given such term in section 1320d(6) of this title;

(2) the term "proprietary financial information" means data that would disclose the terms of a specific contract between an individual health care provider or facility and a specific group health plan, managed care entity (as defined in section 1396u–2(a)(1)(B) of this title) or other managed care organization, or health insurance issuer offering group or individual health insurance coverage; and

(3) the term "State All Payer Claims Database" means, with respect to a State, a database that may include medical claims, pharmacy claims, dental claims, and eligibility and provider files, which are collected from private and public payers.

(h) Authorization of appropriations

To carry out this section, there is authorized to be appropriated $50,000,000 for each of fiscal years 2022 and 2023, and $25,000,000 for fiscal year 2024, to remain available until expended.

(July 1, 1944, ch. 373, title III, §320B, as added Pub. L. 116–260, div. BB, title I, §115(a), Dec. 27, 2020, 134 Stat. 2875.)

EDITORIAL NOTES

CODIFICATION

Section 115(a) of div. BB of Pub. L. 116–260, which directed that section 320B (this section) be added at the end of part B of title III of the Public Health Service Act, was executed as directed, notwithstanding that section 320 of the Public Health Service Act (section 247e of this title) appears in part C of title III of the Act, resulting in section 320B of the Act preceding section 320.

[1] So in original.

[2] So in original. Probably should be "3 years,".

§247d–12. Coordination and collaboration regarding blood supply

The Secretary of Health and Human Services, or the Secretary's designee, shall—

(1) ensure coordination and collaboration between relevant Federal departments and agencies related to the safety and availability of the blood supply, including—

(A) the Department of Health and Human Services, including the Office of the Assistant Secretary for Health, the Centers for Disease Control and Prevention, the Food and Drug Administration, the Office of the Assistant Secretary for Preparedness and Response, the National Institutes of Health, the Centers for Medicare & Medicaid Services, and the Health Resources and Services Administration;

(B) the Department of Defense; and

(C) the Department of Veterans Affairs; and

(2) consult and communicate with private stakeholders, including blood collection establishments, health care providers, accreditation organizations, researchers, and patients, regarding issues related to the safety and availability of the blood supply.

(Pub. L. 117–328, div. FF, title II, §2233, Dec. 29, 2022, 136 Stat. 5754.)

EDITORIAL NOTES

CODIFICATION

Section was enacted as part of the Prepare for and Respond to Existing Viruses, Emerging New Threats, and Pandemics Act, also known as the PREVENT Pandemics Act, and also as part of the Health Extenders, Improving Access to Medicare, Medicaid, and CHIP, and Strengthening Public Health Act of 2022, and not as part of the Public Health Service Act which comprises this chapter.

STATUTORY NOTES AND RELATED SUBSIDIARIES

STREAMLINING BLOOD DONOR INPUT

Pub. L. 117–328, div. FF, title III, §3631, Dec. 29, 2022, 136 Stat. 5895, provided that: "Chapter 35 of title 44, United States Code, shall not apply to the collection of information to which a response is voluntary and that is initiated by the Secretary [of Health and Human Services] to solicit information from blood donors or potential blood donors to support the development of recommendations by the Secretary, acting through the Commissioner of Food and Drugs, concerning blood donation."

PART C—HOSPITALS, MEDICAL EXAMINATIONS, AND MEDICAL CARE

EDITORIAL NOTES

CODIFICATION

Pub. L. 95–626, title I, §113(a)(1), Nov. 10, 1978, 92 Stat. 3562, struck out heading "Subpart I—General Provisions".

Pub. L. 94–484, title IV, §407(a), Oct. 12, 1976, 90 Stat. 2268, added heading "Subpart I—General Provisions".

§247e. National Hansen's Disease Programs Center

(a) Care and treatment

(1) At or through the National Hansen's Disease Programs Center (located in the State of Louisiana), the Secretary shall without charge provide short-term care and treatment, including outpatient care, for Hansen's disease and related complications to any person determined by the

Secretary to be in need of such care and treatment. The Secretary may not at or through such Center provide long-term care for any such disease or complication.

(2) The Center referred to in paragraph (1) shall conduct training in the diagnosis and management of Hansen's disease and related complications, and shall conduct and promote the coordination of research (including clinical research), investigations, demonstrations, and studies relating to the causes, diagnosis, treatment, control, and prevention of Hansen's disease and other mycobacterial diseases and complications related to such diseases.

(3) Paragraph (1) is subject to section 211 of the Department of Health and Human Services Appropriations Act, 1998.

(b) Additional sites authorized

In addition to the Center referred to in subsection (a), the Secretary may establish sites regarding persons with Hansen's disease. Each such site shall provide for the outpatient care and treatment for Hansen's disease and related complications to any person determined by the Secretary to be in need of such care and treatment.

(c) Agency designated by Secretary

The Secretary shall carry out subsections (a) and (b) acting through an agency of the Service. For purposes of the preceding sentence, the agency designated by the Secretary shall carry out both activities relating to the provision of health services and activities relating to the conduct of research.

(d) Payments to Board of Health of Hawaii

The Secretary shall make payments to the Board of Health of the State of Hawaii for the care and treatment (including outpatient care) in its facilities of persons suffering from Hansen's disease at a rate determined by the Secretary. The rate shall be approximately equal to the operating cost per patient of such facilities, except that the rate may not exceed the comparable costs per patient with Hansen's disease for care and treatment provided by the Center referred to in subsection (a). Payments under this subsection are subject to the availability of appropriations for such purpose.

(July 1, 1944, ch. 373, title III, §320, formerly §331, 58 Stat. 698; June 25, 1948, ch. 654, §4, 62 Stat. 1018; June 25, 1952, ch. 460, 66 Stat. 157; Pub. L. 86–624, §29(b), July 12, 1960, 74 Stat. 419; renumbered §339, Pub. L. 94–484, title IV, §407(b)(2), Oct. 12, 1976, 90 Stat. 2268; renumbered §320, and amended Pub. L. 95–626, title I, §105(a), Nov. 10, 1978, 92 Stat. 3560; Pub. L. 96–32, §7(b), July 10, 1979, 93 Stat. 84; Pub. L. 99–117, §2(a), Oct. 7, 1985, 99 Stat. 491; Pub. L. 105–78, title II, §211(h), Nov. 13, 1997, 111 Stat. 1494; Pub. L. 107–220, §1(a), Aug. 21, 2002, 116 Stat. 1332.)

EDITORIAL NOTES

REFERENCES IN TEXT

Section 211 of the Department of Health and Human Services Appropriations Act, 1998, referred to in subsec. (a)(3), is section 211 of Pub. L. 105–78, which enacted this section and provisions set out as notes below.

CODIFICATION

Section was classified to section 255 of this title prior to its renumbering by Pub. L. 95–626.

AMENDMENTS

2002—Subsec. (a)(1). Pub. L. 107–220 substituted "National Hansen's Disease Programs Center" for "Gillis W. Long Hansen's Disease Center".

1997—Pub. L. 105–78 amended section catchline and text generally, substituting present provisions for former provisions which related to: in subsec. (a), care and treatment; and in subsec. (b), payments to Board of Health of Hawaii.

1985—Pub. L. 99–117 substituted "Hansen's disease program" for "Receipt, apprehension, detention, treatment, and release of lepers" in section catchline.

Subsec. (a). Pub. L. 99–117 amended subsec. (a) generally. Prior to amendment, subsec. (a) read as follows: "The Service shall, in accordance with regulations, receive into any hospital of the Service suitable for his

accommodation any person afflicted with leprosy who presents himself for care, detention, or treatment, or who may be apprehended under subsection (b) of this section or section 264 of this title, and any person afflicted with leprosy duly consigned to the care of the Service by the proper health authority of any State. The Surgeon General is authorized, upon the request of any health authority, to send for any person within the jurisdiction of such authority who is afflicted with leprosy and to convey such person to the appropriate hospital for detention and treatment. When the transportation of any such person is undertaken for the protection of the public health the expense of such removal shall be met from funds available for the maintenance of hospitals of the Service. Such funds shall also be available, subject to regulations, for transportation of recovered indigent leper patients to their homes, including subsistence allowance while traveling. When so provided in appropriations available for any fiscal year for the maintenance of hospitals of the Service, the Surgeon General is authorized and directed to make payments to the Board of Health of Hawaii for the care and treatment in its facilities of persons afflicted with leprosy at a per diem rate, determined from time to time by the Surgeon General, which shall, subject to the availability of appropriations, be approximately equal to the per diem operating cost per patient of such facilities, except that such per diem rate shall not be greater than the comparable per diem operating cost per patient at the National Leprosarium, Carville, Louisiana."

Subsec. (b). Pub. L. 99–117 amended subsec. (b) generally. Prior to amendment, subsec. (b) read as follows: "The Surgeon General may provide by regulation for the apprehension, detention, treatment, and release of persons being treated by the Service for leprosy."

1979—Subsec. (a). Pub. L. 96–32 substituted "apprehended under subsection (b) of this section or section 264 of this title" for "apprehended under section 256 or 264 of this title".

1978—Pub. L. 95–626 designated existing provisions as subsec. (a) and added subsec. (b).

1960—Pub. L. 86–624 struck out ", Territory, or the District of Columbia" after "proper health authority of any State", and substituted "Board of Health of Hawaii" for "Board of Health of the Territory of Hawaii".

1952—Act June 25, 1952, provided for payments to Hawaiian Board of Health for expenditures made by them in care and treatment of patients.

1948—Act June 25, 1948, authorized payment of travel expenses of indigent leper patients.

STATUTORY NOTES AND RELATED SUBSIDIARIES

CHANGE OF NAME

Pub. L. 107–220, §§1(b), 2, Aug. 21, 2002, 116 Stat. 1332, provided that:

"(b) PUBLIC LAW 105–78.—References in section 211 of Public Law 105–78 [amending this section and enacting provisions set out as a note under this section], and in deeds, agreements, or other documents under such section, to the Gillis W. Long Hansen's Disease Center shall be deemed to be references to the National Hansen's Disease Programs Center.

"SEC. 2. OTHER REFERENCES.

"Any reference in a law, map, regulation, document, paper, or other record of the United States to the Gillis W. Long Hansen's Disease Center shall be deemed to be a reference to the 'National Hansen's Disease Programs Center' ".

EFFECTIVE DATE OF 1960 AMENDMENT

Amendment by Pub. L. 86–624 effective Aug. 21, 1959, see section 47(f) of Pub. L. 86–624, set out as a note under section 201 of this title.

RELOCATION OF NATIONAL HANSEN'S DISEASE PROGRAMS CENTER

Pub. L. 105–78, title II, §211(a)–(g), Nov. 13, 1997, 111 Stat. 1489, as amended by Pub. L. 107–220, §1(b), Aug. 21, 2002, 116 Stat. 1332, provided that:

"(a) The Secretary of Health and Human Services may in accordance with this section provide for the relocation of the Federal facility known as the National Hansen's Disease Programs Center (located in the vicinity of Carville, in the State of Louisiana), including the relocation of the patients of the Center.

"(b)(1) Subject to paragraph (2), in relocating the Center the Secretary may on behalf of the United States transfer to the State of Louisiana, without charge, title to the real property and improvements that as of the date of the enactment of this Act [Nov. 13, 1997] constitute the Center. Such real property is a parcel consisting of approximately 330 acres. The exact acreage and legal description used for purposes of the transfer shall be in accordance with a survey satisfactory to the Secretary.

"(2) Any conveyance under paragraph (1) is not effective unless the deed or other instrument of conveyance

contains the conditions specified in subsection (d); the instrument specifies that the United States and the State of Louisiana agree to such conditions; and the instrument specifies that, if the State engages in a material breach of the conditions, title to the real property and improvements involved reverts to the United States at the election of the Secretary.

"(c)(1) With respect to Federal equipment and other items of Federal personal property that are in use at the Center as of the date of the enactment of this Act [Nov. 13, 1997], the Secretary may, subject to paragraph (2), transfer to the State such items as the Secretary determines to be appropriate, if the Secretary makes the transfer under subsection (b).

"(2) A transfer of equipment or other items may be made under paragraph (1) only if the State agrees that, during the 30-year period beginning on the date on which the transfer under subsection (b) is made, the items will be used exclusively for purposes that promote the health or education of the public, except that the Secretary may authorize such exceptions as the Secretary determines to be appropriate.

"(d) For purposes of subsection (b)(2), the conditions specified in this subsection with respect to a transfer of title are the following:

"(1) During the 30-year period beginning on the date on which the transfer is made, the real property and improvements referred to in subsection (b)(1) (referred to in this subsection as the 'transferred property') will be used exclusively for purposes that promote the health or education of the public, with such incidental exceptions as the Secretary may approve.

"(2) For purposes of monitoring the extent to which the transferred property is being used in accordance with paragraph (1), the Secretary will have access to such documents as the Secretary determines to be necessary, and the Secretary may require the advance approval of the Secretary for such contracts, conveyances of real or personal property, or other transactions as the Secretary determines to be necessary.

"(3) The relocation of patients from the transferred property will be completed not later than 3 years after the date on which the transfer is made, except to the extent the Secretary determines that relocating particular patients is not feasible. During the period of relocation, the Secretary will have unrestricted access to the transferred property, and after such period will have such access as may be necessary with respect to the patients who pursuant to the preceding sentence are not relocated.

"(4)(A) With respect to projects to make repairs and energy-related improvements at the transferred property, the Secretary will provide for the completion of all such projects for which contracts have been awarded and appropriations have been made as of the date on which the transfer is made.

"(B) If upon completion of the projects referred to in subparagraph (A) there are any unobligated balances of amounts appropriated for the projects, and the sum of such balances is in excess of $100,000—

"(i) the Secretary will transfer the amount of such excess to the State; and

"(ii) the State will expend such amount for the purposes referred to in paragraph (1), which may include the renovation of facilities at the transferred property.

"(5)(A) The State will maintain the cemetery located on the transferred property, will permit individuals who were long-term-care patients of the Center to be buried at the cemetery, and will permit members of the public to visit the cemetery.

"(B) The State will permit the Center to maintain a museum on the transferred property, and will permit members of the public to visit the museum.

"(C) In the case of any waste products stored at the transferred property as of the date of the transfer, the Federal Government will after the transfer retain title to and responsibility for the products, and the State will not require that the Federal Government remove the products from the transferred property.

"(6) In the case of each individual who as of the date of the enactment of this Act [Nov. 13, 1997] is a Federal employee at the transferred property with facilities management or dietary duties:

"(A) The State will offer the individual an employment position with the State, the position with the State will have duties similar to the duties the individual performed in his or her most recent position at the transferred property, and the position with the State will provide compensation and benefits that are similar to the compensation and benefits provided for such most recent position, subject to the concurrence of the Governor of the State.

"(B) If the individual becomes an employee of the State pursuant to subparagraph (A), the State will make payments in accordance with subsection (e)(2)(B) (relating to disability), as applicable with respect to the individual.

"(7) The Federal Government may, consistent with the intended uses by the State of the transferred property, carry out at such property activities regarding at-risk youth.

"(8) Such additional conditions as the Secretary determines to be necessary to protect the interests of the United States.

"(e)(1) This subsection applies if the transfer under subsection (b) is made.

"(2) In the case of each individual who as of the date of the enactment of this Act [Nov. 13, 1997] is a Federal employee at the Center with facilities management or dietary duties, and who becomes an employee of the State pursuant to subsection (d)(6)(A):

"(A) The provisions of subchapter III of chapter 83 of title 5, United States Code, or of chapter 84 of such title, whichever are applicable, that relate to disability shall be considered to remain in effect with respect to the individual (subject to subparagraph (C)) until the earlier of—

"(i) the expiration of the 2-year period beginning on the date on which the transfer under subsection (b) is made; or

"(ii) the date on which the individual first meets all conditions for coverage under a State program for payments during retirement by reason of disability.

"(B) The payments to be made by the State pursuant to subsection (d)(6)(B) with respect to the individual are payments to the Civil Service Retirement and Disability Fund, if the individual is receiving Federal disability coverage pursuant to subparagraph (A). Such payments are to be made in a total amount equal to that portion of the normal-cost percentage (determined through the use of dynamic assumptions) of the basic pay of the individual that is allocable to such coverage and is paid for service performed during the period for which such coverage is in effect. Such amount is to be determined in accordance with chapter 84 of such title 5, is to be paid at such time and in such manner as mutually agreed by the State and the Office of Personnel Management, and is in lieu of individual or agency contributions otherwise required.

"(C) In the determination pursuant to subparagraph (A) of whether the individual is eligible for Federal disability coverage (during the applicable period of time under such subparagraph), service as an employee of the State after the date of the transfer under subsection (b) shall be counted toward the service requirement specified in the first sentence of section 8337(a) or 8451(a)(1)(A) of such title 5 (whichever is applicable).

"(3) In the case of each individual who as of the date of the enactment of this Act is a Federal employee with a position at the Center and is, for duty at the Center, receiving the pay differential under section 208(e) of the Public Health Service Act [42 U.S.C. 210(e)] or under section 5545(d) of title 5, United States Code:

"(A) If as of the date of the transfer under subsection (b) the individual is eligible for an annuity under section 8336 or 8412 of title 5, United States Code, then once the individual separates from the service and thereby becomes entitled to receive the annuity, the pay differential shall be included in the computation of the annuity if the individual separated from the service not later than the expiration of the 90-day period beginning on the date of the transfer.

"(B) If the individual is not eligible for such an annuity as of the date of the transfer under subsection (b) but subsequently does become eligible, then once the individual separates from the service and thereby becomes entitled to receive the annuity, the pay differential shall be included in the computation of the annuity if the individual separated from the service not later than the expiration of the 90-day period beginning on the date on which the individual first became eligible for the annuity.

"(C) For purposes of this paragraph, the individual is eligible for the annuity if the individual meets all conditions under such section 8336 or 8412 to be entitled to the annuity, except the condition that the individual be separated from the service.

"(4) With respect to individuals who as of the date of the enactment of this Act are Federal employees with positions at the Center and are not, for duty at the center, receiving the pay differential under section 208(e) of the Public Health Service Act [42 U.S.C. 210(e)] or under section 5545(d) of title 5, United States Code:

"(A) During the calendar years 1997 and 1998, the Secretary may in accordance with this paragraph provide to any such individual a voluntary separation incentive payment. The purpose of such payments is to avoid or minimize the need for involuntary separations under a reduction in force with respect to the Center.

"(B) During calendar year 1997, any payment under subparagraph (A) shall be made under section 663 of the Treasury, Postal Service, and General Government Appropriations Act, 1997 (as contained in section 101(f) of division A of Public Law 104–208) [5 U.S.C. 5597 note], except that, for purposes of this subparagraph, subsection (b) of such section 663 does not apply.

"(C) During calendar year 1998, such section 663 applies with respect to payments under subparagraph (A) to the same extent and in the same manner as such section applied with respect to the payments during fiscal year 1997, and for purposes of this subparagraph, the reference in subsection (c)(2)(D) of such section 663 to December 31, 1997, is deemed to be a reference to December 31, 1998.

"(f) The following provisions apply if under subsection (a) the Secretary makes the decision to relocate the Center:

"(1) The site to which the Center is relocated shall be in the vicinity of Baton Rouge, in the State of

Louisiana.

"(2) The facility involved shall continue to be designated as the National Hansen's Disease Programs Center.

"(3) The Secretary shall make reasonable efforts to inform the patients of the Center with respect to the planning and carrying out of the relocation.

"(4) In the case of each individual who as of October 1, 1996, was a patient of the Center and is considered by the Director of the Center to be a long-term-care patient (referred to in this subsection as an 'eligible patient'), the Secretary shall continue to provide for the long-term care of the eligible patient, without charge, for the remainder of the life of the patient.

"(5)(A) For purposes of paragraph (4), an eligible patient who is legally competent has the following options with respect to support and maintenance and other nonmedical expenses:

"(i) For the remainder of his or her life, the patient may reside at the Center.

"(ii) For the remainder of his or her life, the patient may receive payments each year at an annual rate of $33,000 (adjusted in accordance with subparagraphs (C) and (D)), and may not reside at the Center. Payments under this clause are in complete discharge of the obligation of the Federal Government under paragraph (4) for support and maintenance and other nonmedical expenses of the patient.

"(B) The choice by an eligible patient of the option under clause (i) of subparagraph (A) may at any time be revoked by the patient, and the patient may instead choose the option under clause (ii) of such subparagraph. The choice by an eligible patient of the option under such clause (ii) is irrevocable.

"(C) Payments under subparagraph (A)(ii) shall be made on a monthly basis, and shall be pro rated as applicable. In 1999 and each subsequent year, the monthly amount of such payments shall be increased by a percentage equal to any percentage increase taking effect under section 215(i) of the Social Security Act [42 U.S.C. 415(i)] (relating to a cost-of-living increase) for benefits under title II of such Act [42 U.S.C. 401 et seq.] (relating to Federal old-age, survivors, and disability insurance benefits). Any such percentage increase in monthly payments under subparagraph (A)(ii) shall take effect in the same month as the percentage increase under such section 215(i) takes effect.

"(D) With respect to the provision of outpatient and inpatient medical care for Hansen's disease and related complications to an eligible patient:

"(i) The choice the patient makes under subparagraph (A) does not affect the responsibility of the Secretary for providing to the patient such care at or through the Center.

"(ii) If the patient chooses the option under subparagraph (A)(ii) and receives inpatient care at or through the Center, the Secretary may reduce the amount of payments under such subparagraph, except to the extent that reimbursement for the expenses of such care is available to the provider of the care through the program under title XVIII of the Social Security Act [42 U.S.C. 1395 et seq.] or the program under title XIX of such Act [42 U.S.C. 1396 et seq.]. Any such reduction shall be made on the basis of the number of days for which the patient received the inpatient care.

"(6) The Secretary shall provide to each eligible patient such information and time as may be necessary for the patient to make an informed decision regarding the options under paragraph (5)(A).

"(7) After the date of the enactment of this Act [Nov. 13, 1997], the Center may not provide long-term care for any individual who as of such date was not receiving such care as a patient of the Center.

"(8) If upon completion of the projects referred to in subsection (d)(4)(A) there are unobligated balances of amounts appropriated for the projects, such balances are available to the Secretary for expenses relating to the relocation of the Center, except that, if the sum of such balances is in excess of $100,000, such excess is available to the State in accordance with subsection (d)(4)(B). The amounts available to the Secretary pursuant to the preceding sentence are available until expended.

"(g) For purposes of this section:

"(1) The term 'Center' means the National Hansen's Disease Programs Center.

"(2) The term 'Secretary' means the Secretary of Health and Human Services.

"(3) The term 'State' means the State of Louisiana."

§248. Control and management of hospitals; furnishing prosthetic and orthopedic devices; transfer of patients; disposal of articles produced by patients; disposal of money and effects of deceased patients; payment of burial expenses

The Surgeon General, pursuant to regulations, shall—

(a) Control, manage, and operate all institutions, hospitals, and stations of the Service, including minor repairs and maintenance, and provide for the care, treatment, and hospitalization of patients, including the furnishing of prosthetic and orthopedic devices; and from time to time, with the approval of the President, select suitable sites for and establish such additional institutions, hospitals, and stations in the States and possessions of the United States as in his judgment are necessary to enable the Service to discharge its functions and duties;

(b) Provide for the transfer of Public Health Service patients, in the care of attendants where necessary, between hospitals and stations operated by the Service or between such hospitals and stations and other hospitals and stations in which Public Health Service patients may be received, and the payment of expenses of such transfer;

(c) Provide for the disposal of articles produced by patients in the course of their curative treatment, either by allowing the patient to retain such articles or by selling them and depositing the money received therefor to the credit of the appropriation from which the materials for making the articles were purchased;

(d) Provide for the disposal of money and effects, in the custody of the hospitals or stations, of deceased patients; and

(e) Provide, to the extent the Surgeon General determines that other public or private funds are not available therefor, for the payment of expenses of preparing and transporting the remains of, or the payment of reasonable burial expenses for, any patient dying in a hospital or station.

(July 1, 1944, ch. 373, title III, §321, 58 Stat. 695; June 25, 1948, ch. 654, §2, 62 Stat. 1017; Pub. L. 95–622, title II, §266, Nov. 9, 1978, 92 Stat. 3437.)

EDITORIAL NOTES

AMENDMENTS

1978—Subsec. (a). Pub. L. 95–622 struck out ", and tobacco" after "orthopedic devices".

1948—Subsec. (a). Act June 25, 1948, §2(a), amended subsec. (a) generally, continuing authority of Service to furnish tobacco to patients being treated by it.

Subsec. (e). Act June 25, 1948, §2(b), added subsec. (e).

STATUTORY NOTES AND RELATED SUBSIDIARIES

CHANGE OF NAME

"Secretary of Health and Human Services" substituted for "Secretary of Health, Education, and Welfare" pursuant to section 509(b) of Pub. L. 96–88, which is classified to section 3508(b) of Title 20, Education.

EXECUTIVE DOCUMENTS

TRANSFER OF FUNCTIONS

Functions of Public Health Service, Surgeon General of Public Health Service, and all other officers and employees of Public Health Service, and functions of all agencies of or in Public Health Service transferred to Secretary of Health, Education, and Welfare by Reorg. Plan No. 3 of 1966, eff. June 25, 1966, 31 F.R. 8855, 80 Stat. 1610, set out as a note under section 202 of this title.

DELEGATION OF FUNCTIONS

Functions of President delegated to Secretary of Health and Human Services, see Ex. Ord. No. 11140, Jan. 30, 1964, 29 F.R. 1637, as amended, set out as a note under section 202 of this title.

§248a. Closing or transfer of hospitals; reduction of services; Congressional authorization required

(a) Except as provided in subsection (b), the Secretary of Health and Human Services shall take

such action as may be necessary to assure that the hospitals of the Public Health Service, located in Seattle, Washington, Boston, Massachusetts, San Francisco, California, Galveston, Texas, New Orleans, Louisiana, Baltimore, Maryland, Staten Island, New York, and Norfolk, Virginia, shall continue—

(1) in operation as hospitals of the Public Health Service,

(2) to provide for all categories of individuals entitled or authorized to receive care and treatment at hospitals or other stations of the Public Health Service inpatient, outpatient, and other health care services in like manner as such services were provided on January 1, 1973, to such categories of individuals at the hospitals of the Public Health Service referred to in the matter preceding paragraph (1) and at a level and range at least as great as the level and range of such services which were provided (or authorized to be provided) by such hospitals on such date, and

(3) to conduct at such hospitals a level and range of other health-related activities (including training and research activities) which is not less than the level and range of such activities which were being conducted on January 1, 1973, at such hospitals.

(b)(1) The Secretary may—

(A) close or transfer control of a hospital of the Public Health Service to which subsection (a) applies,

(B) reduce the level and range of health care services provided at such a hospital from the level and range required by subsection (a)(2) or change the manner in which such services are provided at such a hospital from the manner required by such subsection, or

(C) reduce the level and range of the other health-related activities conducted at such hospital from the level and range required by subsection (a)(3),

if Congress by law (enacted after November 16, 1973) specifically authorizes such action.

(2) Any recommendation submitted to the Congress for legislation to authorize an action described in paragraph (1) with respect to a hospital of the Public Health Service shall be accompanied by a copy of the written, unqualified approval of the proposed action submitted to the Secretary by each (A) section 314(a) State health planning agency whose section 314(a) plan covers (in whole or in part) the area in which such hospital is located or which is served by such hospital, and (B) section 314(b) areawide health planning agency whose section 314(b) plan covers (in whole or in part) such area.

(3) For purposes of this subsection, the term "section 314(a) State health planning agency" means the agency of a State which administers or supervises the administration of a State's health planning functions under a State plan approved under section 314(a) of the Public Health Service Act (referred to in paragraph (2) as a "section 314(a) plan"); and the term "section 314(b) areawide health planning agency" means a public or nonprofit private agency or organization which has developed a comprehensive regional, metropolitan, or other local area plan or plans referred to in section 314(b) of that Act (referred to in paragraph (2) as a "section 314(b) plan").

(Pub. L. 93–155, title VIII, §818(a), (b), Nov. 16, 1973, 87 Stat. 622; Pub. L. 96–88, title V, §509(b), Oct. 17, 1979, 93 Stat. 695.)

EDITORIAL NOTES

REFERENCES IN TEXT

Section 314 of the Public Health Service Act, referred to in subsec. (b)(2), (3), is classified to section 246 of this title.

CODIFICATION

Section was enacted as part of the Department of Defense Appropriation Authorization Act, 1974, and not as part of the Public Health Service Act which comprises this chapter.

PRIOR PROVISIONS

Provisions similar to those comprising this section were contained in Pub. L. 92–585, §3, Oct. 27, 1972, 86

Stat. 1292, setting out procedure to be followed in closing or transferring control of hospitals or other health care delivery facilities of Public Health Service, prior to repeal by Pub. L. 93–155, §818(c).

STATUTORY NOTES AND RELATED SUBSIDIARIES

CHANGE OF NAME

"Secretary of Health and Human Services" substituted for "Secretary of Health, Education, and Welfare" in subsec. (a) pursuant to section 509(b) of Pub. L. 96–88, which is classified to section 3508(b) of Title 20, Education.

§248b. Transfer or financial self-sufficiency of public health service hospitals and clinics

(a) Deadline for closure, transfer, or financial self-sufficiency

The Secretary of Health and Human Services (hereinafter in this subtitle referred to as the "Secretary") shall, in accordance with this section and notwithstanding section 248a of this title, provide for the closure, transfer, or financial self-sufficiency of all hospitals and other stations of the Public Health Service (hereinafter in this subtitle referred to as the "Service") not later than September 30, 1982.

(b) Proposals for transfer or financial self-sufficiency

Not later than July 1, 1981, the Secretary shall notify each Service hospital and other station, and the chief executive officer of each State and of each locality in which such a hospital or other station is located, that the Secretary will accept proposals for the transfer of each such hospital and station from the Service to a public (including Federal) or nonprofit private entity or for the achievement of financial self-sufficiency of each such hospital and station not later than September 30, 1982. No such proposal shall be considered by the Secretary if it is submitted later than September 1, 1981.

(c) Evaluation of proposals

The Secretary shall evaluate promptly each proposal submitted under subsection (b) with respect to a hospital or other station and determine, not later than September 30, 1981, whether or not under such proposal the hospital or station—

(1) will be maintained as a general health care facility providing a range of services to the population within its service area,

(2) will continue to make services available to existing patient populations, and

(3) has a reasonable expectation of financial viability and, in the case of a hospital or station that is not proposed to be transferred, of financial self-sufficiency.

Paragraph (1) shall not apply in the case of a proposal for the transfer of a discrete, minor, freestanding part of a hospital or station to a local public entity for the purpose of continuing the provision of services to refugees.

(d) Rejection or approval of proposal

(1) If the Secretary determines that a proposal for a hospital or other station does not meet the standards of subsection (c) or if there is no proposal submitted under subsection (b) with respect to a hospital or other station, the Secretary shall provide for the closure of the hospital or station by not later than October 31, 1981.

(2) If the Secretary determines that a proposal for a hospital or other station meets the standards of subsection (c), the Secretary shall take such steps, within the amounts available through appropriations, as may be necessary and proper—

(A) to operate (or participate or assist in the operation of) the hospital or station by the Service until the transfer is accomplished or financial self-sufficiency is achieved,

(B) to bring the hospital or station into compliance with applicable licensure, accreditation, and local medical practice standards, and

(C) to provide for such other legal, administrative, personnel, and financial arrangements (including allowing payments made with respect to services provided by the hospital or station to be made directly to that hospital or station) as may be necessary to effect a timely and orderly transfer of such hospital or station (including the land, building, and equipment thereof) from the Service, or for the financial self-sufficiency of the hospital or station, not later than September 30, 1982.

(e) Establishment of identifiable administrative unit

There is established, within the Office of the Assistant Secretary for Health of the Department of Health and Human Services, an identifiable administrative unit which shall have direct responsibility and authority for overseeing the activities under this section.

(f) Finding of financial self-sufficiency

For purposes of this section, a hospital or station cannot be found to be financially self-sufficient if the hospital or station is relying, in whole or in part, on direct appropriated funds for its continued operations.

(Pub. L. 97–35, title IX, §987, Aug. 13, 1981, 95 Stat. 603.)

EDITORIAL NOTES

REFERENCES IN TEXT

This subtitle, referred to in subsec. (a), is subtitle J of title IX of Pub. L. 97–35, §§985 to 988, Aug. 13, 1981, 95 Stat. 602, which enacted this section, amended sections 201, 249, and 254e of this title, and enacted provisions set out as notes under this section and section 249 of this title. For complete classification of this subtitle to the Code, see Tables.

Section 248a of this title, referred to in subsec. (a), was in the original "section 818 of Public Law 93–155", meaning section 818 of Pub. L. 93–155, title VIII, Nov. 16, 1973, 87 Stat. 622, which enacted section 248a of this title and repealed section 3 of Pub. L. 92–585, Oct. 27, 1972, 86 Stat. 1292.

CODIFICATION

Section was enacted as part of the Omnibus Budget Reconciliation Act of 1981, and not as part of the Public Health Service Act which comprises this chapter.

STATUTORY NOTES AND RELATED SUBSIDIARIES

CONGRESSIONAL FINDINGS AND DECLARATION OF PURPOSE

Pub. L. 97–35, title IX, §985, Aug. 13, 1981, 95 Stat. 602, provided that:

"(a) Congress finds that—

"(1) because of national budgetary considerations, it has become necessary to terminate Federal appropriations for Public Health Service hospitals and clinics,

"(2) with proper planning and coordination, some of these hospitals and clinics could be transferred to State, local, or private control or become financially self-sufficient and continue to provide effective and efficient health care to individuals in the areas in which they are located,

"(3) a precipitous closure of these hospitals and clinics will preclude the possibility of such orderly transfer to entities which are willing and able to take over operations at such facilities and will cause unnecessary and costly hardships on the patients and staffs at such facilities and on the communities in which the facilities are located, and

"(4) it is in the national interest, consistent with sound budgetary considerations, to assist in the orderly and prompt transfer of such operations to State, local, or private operation or in the achievement of financial self-sufficiency where feasible.

"(b) The purposes of this subtitle [enacting this section, amending sections 201, 249, and 254e of this title, and enacting provisions set out as notes under section 249 of this title] are—

"(1) to provide for the prompt and orderly closure by October 31, 1981, of Public Health Service hospitals and clinics which cannot reasonably be transferred to State, local, or private operation or become

financially self-sufficient and for the transfer or achievement of financial self-sufficiency by September 30, 1982, of those hospitals and clinics which can be so transferred or which can achieve such financial self-sufficiency, and

"(2) to provide for transitional assistance for merchant seamen whose entitlement to receive free care through Public Health Service hospitals and clinics is repealed and who are hospitalized at the end of fiscal year 1981 and require continuing hospitalization."

§§248c, 248d. Repealed. Pub. L. 104–201, div. A, title VII, §727(a)(1), (2), Sept. 23, 1996, 110 Stat. 2596

Section 248c, Pub. L. 97–99, title IX, §911, Dec. 23, 1981, 95 Stat. 1386; Pub. L. 98–94, title XII, §1252(g), formerly §1252(f), Sept. 24, 1983, 97 Stat. 699, renumbered §1252(g), Pub. L. 101–510, div. A, title VII, §718(b)(1), Nov. 5, 1990, 104 Stat. 1586; Pub. L. 98–557, §17(f)(1), Oct. 30, 1984, 98 Stat. 2868, related to continued use of former Public Health Service facilities.

Section 248d, Pub. L. 98–94, title XII, §1252, Sept. 24, 1983, 97 Stat. 698; Pub. L. 98–557, §17(f)(2), Oct. 30, 1984, 98 Stat. 2868; Pub. L. 99–661, div. A, title VII, §706, Nov. 14, 1986, 100 Stat. 3905; Pub. L. 100–456, div. A, title VI, §645, Sept. 29, 1988, 102 Stat. 1988; Pub. L. 101–510, div. A, title VII, §718(a), (b), Nov. 5, 1990, 104 Stat. 1586, 1587; Pub. L. 102–25, title VII, §705(h), Apr. 6, 1991, 105 Stat. 121; Pub. L. 103–160, div. A, title VII, §717(a), Nov. 30, 1993, 107 Stat. 1693; Pub. L. 104–106, div. A, title VII, §§721, 722, 727, title XV, §1502(c)(8), Feb. 10, 1996, 110 Stat. 377, 380, 508, related to Public Health Service facilities providing medical care for dependents, members, and former members of uniformed services.

STATUTORY NOTES AND RELATED SUBSIDIARIES

EFFECTIVE DATE OF REPEAL

Repeal effective Oct. 1, 1997, see section 727(b) of Pub. L. 104–201, set out in an Inclusion of Certain Designated Providers in Uniformed Services Health Care Delivery System note under section 1073 of Title 10, Armed Forces.

EQUITABLE IMPLEMENTATION OF UNIFORM COST SHARING REQUIREMENTS FOR UNIFORMED SERVICES TREATMENT FACILITIES

Pub. L. 104–106, div. A, title VII, §726, Feb. 10, 1996, 110 Stat. 379, provided that the uniform managed care benefit fee and copayment schedule developed by Secretary of Defense for use in all managed care initiatives of military health service system be extended to managed care program of Uniformed Services Treatment Facility only after the later of the implementation of the TRICARE regional program covering service area of Facility or Oct. 1, 1996, and provided for evaluation of such extension by Comptroller General, prior to repeal by Pub. L. 104–201, div. A, title VII, §727(a)(4), Sept. 23, 1996, 110 Stat. 2596.

MANAGED-CARE DELIVERY AND REIMBURSEMENT MODEL FOR THE UNIFORMED SERVICES TREATMENT FACILITIES

Pub. L. 101–510, div. A, title VII, §718(c), Nov. 5, 1990, 104 Stat. 1587, as amended by Pub. L. 102–484, div. A, title VII, §716, Oct. 23, 1992, 106 Stat. 2438; Pub. L. 103–160, div. A, title VII, §718, Nov. 30, 1993, 107 Stat. 1694; Pub. L. 104–106, div. A, title VII, §§724(a), 725, Feb. 10, 1996, 110 Stat. 378, provided that not later than Nov. 5, 1990, the Secretary of Defense was to begin operation of a managed-care delivery and reimbursement model to continue to use Uniformed Services Treatment Facilities in the military health services system, prior to repeal by Pub. L. 104–201, div. A, title VII, §727(a)(3), Sept. 23, 1996, 110 Stat. 2596.

§249. Medical care and treatment of quarantined and detained persons

(a) Persons entitled to treatment

Any person when detained in accordance with quarantine laws, or, at the request of the Immigration and Naturalization Service, any person detained by that Service, may be treated and cared for by the Public Health Service.

(b) Temporary treatment in emergency cases

Persons not entitled to treatment and care at institutions, hospitals, and stations of the Service may, in accordance with regulations of the Surgeon General, be admitted thereto for temporary treatment and care in case of emergency.

(c) Authorization for outside treatment

Persons whose care and treatment is authorized by subsection (a) may, in accordance with regulations, receive such care and treatment at the expense of the Service from public or private medical or hospital facilities other than those of the Service, when authorized by the officer in charge of the station at which the application is made.

(July 1, 1944, ch. 373, title III, §322, 58 Stat. 696; June 25, 1948, ch. 654, §3, 62 Stat. 1018; Aug. 8, 1956, ch. 1036, §3, 70 Stat. 1120; Pub. L. 88–424, Aug. 13, 1964, 78 Stat. 398; Pub. L. 90–174, §10(c), Dec. 5, 1967, 81 Stat. 541; Pub. L. 97–35, title IX, §986(a), (b)(1), (2), Aug. 13, 1981, 95 Stat. 603.)

EDITORIAL NOTES

AMENDMENTS

1981—Subsec. (a). Pub. L. 97–35, §986(a), (b)(2), redesignated subsec. (c) as (a). Former subsec. (a), which related to persons entitled to medical, etc., treatment and hospitalization, was struck out.

Subsec. (b). Pub. L. 97–35, §986(a), (b)(2), redesignated subsec. (d) as (b). Former subsec. (b), which related to treatment for seamen on foreign-flag vessels, was struck out.

Subsec. (c). Pub. L. 97–35, §986(b)(1), (2), redesignated subsec. (e) as (c), substituted "subsection (a)" for "subsection (c)", and struck out "entitled to care and treatment under subsection (a) of this section and persons" after "Persons". Former subsec. (c) redesignated (a).

Subsecs. (d), (e). Pub. L. 97–35, §986(b)(2), redesignated subsecs. (d) and (e) as (b) and (c), respectively.

1967—Subsec. (a)(7). Pub. L. 90–174 substituted provision for entitlement to treatment and hospitalization of seamen-trainees, while participating in maritime training programs to develop or enhance their employability in maritime industry, for provision for such entitlement of employees and noncommissioned officers in field service of Public Health Service when injured or taken sick in line of duty.

1964—Subsec. (a)(8). Pub. L. 88–424 added par. (8).

1948—Subsec. (e). Act June 25, 1948, permitted Service to provide for care and treatment of individuals detained in accordance with our quarantine laws.

STATUTORY NOTES AND RELATED SUBSIDIARIES

CHANGE OF NAME

"Secretary of Health and Human Services" substituted for "Secretary of Health, Education, and Welfare" pursuant to section 509(b) of Pub. L. 96–88, which is classified to section 3508(b) of Title 20, Education.

EFFECTIVE DATE OF 1981 AMENDMENT

Pub. L. 97–35, title IX, §986(c), Aug. 13, 1981, 95 Stat. 603, provided that: "The amendments and repeals made by this section [amending this section and sections 201 and 254e of this title] shall take effect on October 1, 1981."

ABOLITION OF IMMIGRATION AND NATURALIZATION SERVICE AND TRANSFER OF FUNCTIONS

For abolition of Immigration and Naturalization Service, transfer of functions, and treatment of related references, see note set out under section 1551 of Title 8, Aliens and Nationality.

CONTINUED CARE FOR MERCHANT SEAMEN HOSPITALIZED IN PUBLIC HEALTH SERVICE HOSPITALS

Pub. L. 97–35, title IX, §988, Aug. 13, 1981, 95 Stat. 604, provided that:

"(a) The Secretary shall provide, by contract or other arrangement with a Federal entity and without charge but subject to subsection (b), for the continuation of inpatient hospital services (and outpatient services related to the condition of hospitalization) to any individual who—

"(1) on September 30, 1981, is receiving inpatient hospital services at a Public Health Service hospital on the basis of the entitlement contained in section 322(a) of the Public Health Service Act (42 U.S.C. 249(a)), as such section was in effect on such date, for treatment of a condition,

"(2) requires continued hospitalization after such date for treatment of that condition (or requires outpatient services related to such condition), and

"(3) the Secretary determines has no other source of inpatient hospital services available for continued treatment of that condition.

"(b) Services may not be provided under subsection (a) to an individual after the earlier of—

"(1) September 30, 1982,

"(2) the end of the first 60-day consecutive period (beginning after September 30, 1981) during the entire period of which the individual is not an inpatient of a hospital.

"(c) Notwithstanding any other provision of law, the head of any Federal department or agency which provides, under other authority of law and through federal facilities, inpatient hospital services or outpatient services, or both, is authorized to provide inpatient hospital services (and related outpatient services) to individuals under contract or other arrangement with the Secretary pursuant to this section."

FOREIGN SEAMEN

Section 810(c), formerly §710(c), of act July 1, 1944, as renumbered by acts Aug. 13, 1946, ch. 958, §5, 60 Stat. 1049; July 30, 1956, ch. 779, §3(b), 70 Stat. 721, which gave foreign seamen the same benefits as accorded seamen employed on United States vessels under subsec. (a)(1) of this section, was repealed effective Jan. 25, 1948, by Joint Res. July 25, 1947, ch. 327, §2(b), 61 Stat. 451.

EXECUTIVE DOCUMENTS

TRANSFER OF FUNCTIONS

Functions of Public Health Service, Surgeon General of Public Health Service, and all other officers and employees of Public Health Service, and functions of all agencies of or in Public Health Service transferred to Secretary of Health, Education, and Welfare by Reorg. Plan No. 3 of 1966, eff. June 25, 1966, 31 F.R. 8855, 80 Stat. 1610, set out as a note under section 202 of this title.

Functions of all other officers of Department of Justice and functions of all agencies and employees of such Department transferred, with a few exceptions, to Attorney General, with power vested in him to authorize their performance or the performance of any of his functions by any of such officers, agencies, and employees, by sections 1 and 2 of Reorg. Plan No. 2 of 1950, eff. May 24, 1950, 15 F.R. 3173, 64 Stat. 1261, which were repealed by Pub. L. 89–554, §8(a), Sept. 6, 1966, 80 Stat. 662. Immigration and Naturalization Service, referred to in this section, was a bureau in Department of Justice.

§250. Medical care and treatment of Federal prisoners

The Service shall supervise and furnish medical treatment and other necessary medical, psychiatric, and related technical and scientific services, authorized by section 4005 of title 18, in penal and correctional institutions of the United States.

(July 1, 1944, ch. 373, title III, §323, 58 Stat. 697.)

EDITORIAL NOTES

CODIFICATION

"Section 4005 of title 18" substituted in text for "the Act of May 13, 1930, as amended (U.S.C., 1940 edition, title 18, secs. 751, 752)" on authority of act June 25, 1948, ch. 645, 62 Stat. 684, the first section of which enacted Title 18, Crimes and Criminal Procedure.

STATUTORY NOTES AND RELATED SUBSIDIARIES

CHANGE OF NAME

"Secretary of Health and Human Services" substituted for "Secretary of Health, Education, and Welfare" pursuant to section 509(b) of Pub. L. 96–88, which is classified to section 3508(b) of Title 20, Education.

EXECUTIVE DOCUMENTS

TRANSFER OF FUNCTIONS

Functions of Public Health Service, Surgeon General of Public Health Service, and all other officers and employees of Public Health Service, and functions of all agencies of or in Public Health Service transferred to Secretary of Health, Education, and Welfare by Reorg. Plan No. 3 of 1966, eff. June 25, 1966, 31 F.R. 8855, 80 Stat. 1610, set out as a note under section 202 of this title.

§250a. Transfer of appropriations

The Attorney General may transfer to the Department of Health and Human Services such amounts as may be necessary for direct expenditures by that Department for medical relief for inmates of Federal penal and correctional institutions.

(Pub. L. 119–74, div. A, title II, Jan. 23, 2026, 140 Stat. 24.)

EDITORIAL NOTES

CODIFICATION

Section was enacted as part of the appropriation act cited as the credit to this section, and not as part of the Public Health Service Act which comprises this chapter.

Section was formerly classified to section 341h of title 5 prior to the general revision and enactment of Title 5, Government Organization and Employees, by Pub. L. 89–554, §1, Sept. 6, 1966, 80 Stat. 378.

PRIOR PROVISIONS

Provisions similar to those in this section were contained in the following prior appropriation acts:

Pub. L. 118–42, div. C, title II, Mar. 9, 2024, 138 Stat. 139.
Pub. L. 117–328, div. B, title II, Dec. 29, 2022, 136 Stat. 4528.
Pub. L. 117–103, div. B, title II, Mar. 15, 2022, 136 Stat. 119.
Pub. L. 116–260, div. B, title II, Dec. 27, 2020, 134 Stat. 1252.
Pub. L. 116–93, div. B, title II, Dec. 20, 2019, 133 Stat. 2402.
Pub. L. 116–6, div. C, title II, Feb. 15, 2019, 133 Stat. 107.
Pub. L. 115–141, div. B, title II, Mar. 23, 2018, 132 Stat. 415.
Pub. L. 115–31, div. B, title II, May 5, 2017, 131 Stat. 198.
Pub. L. 114–113, div. B, title II, Dec. 18, 2015, 129 Stat. 2302.
Pub. L. 113–235, div. B, title II, Dec. 16, 2014, 128 Stat. 2188.
Pub. L. 113–76, div. B, title II, Jan. 17, 2014, 128 Stat. 57.
Pub. L. 113–6, div. B, title II, Mar. 26, 2013, 127 Stat. 248.
Pub. L. 112–55, div. B, title II, Nov. 18, 2011, 125 Stat. 610.
Pub. L. 111–117, div. B, title II, Dec. 16, 2009, 123 Stat. 3129.
Pub. L. 111–8, div. B, title II, Mar. 11, 2009, 123 Stat. 576.
Pub. L. 110–161, div. B, title II, Dec. 26, 2007, 121 Stat. 1905.
Pub. L. 109–108, title I, Nov. 22, 2005, 119 Stat. 2297.
Pub. L. 108–447, div. B, title I, Dec. 8, 2004, 118 Stat. 2860.
Pub. L. 108–199, div. B, title I, Jan. 23, 2004, 118 Stat. 53.
Pub. L. 108–7, div. B, title I, Feb. 20, 2003, 117 Stat. 58.
Pub. L. 107–77, title I, Nov. 28, 2001, 115 Stat. 757.
Pub. L. 106–553, §1(a)(2) [title I], Dec. 21, 2000, 114 Stat. 2762, 2762A–60.
Pub. L. 106–113, div. B, §1000(a)(1) [title I], Nov. 29, 1999, 113 Stat. 1535, 1501A–13.
Pub. L. 105–277, div. A, §101(b) [title I], Oct. 21, 1998, 112 Stat. 2681–50, 2681–60.
Pub. L. 105–119, title I, Nov. 26, 1997, 111 Stat. 2449.
Pub. L. 104–208, div. A, title I, §101(a) [title I], Sept. 30, 1996, 110 Stat. 3009, 3009–11.
Pub. L. 104–134, title I, §101[(a)] [title I], Apr. 26, 1996, 110 Stat. 1321, 1321–9; renumbered title I, Pub. L. 104–140, §1(a), May 2, 1996, 110 Stat. 1327.
Pub. L. 103–317, title I, Aug. 26, 1994, 108 Stat. 1732.
Pub. L. 103–121, title I, Oct. 27, 1993, 107 Stat. 1161.

Pub. L. 102–395, title I, Oct. 6, 1992, 106 Stat. 1836.
Pub. L. 102–140, title I, Oct. 28, 1991, 105 Stat. 790.
Pub. L. 101–515, title II, Nov. 5, 1990, 104 Stat. 2114.
Pub. L. 101–162, title II, Nov. 21, 1989, 103 Stat. 1000.
Pub. L. 100–459, title II, Oct. 1, 1988, 102 Stat. 2196.
Pub. L. 100–202, §101(a) [title II], Dec. 22, 1987, 101 Stat. 1329, 1329–13.
Pub. L. 99–500, §101(b) [title II], Oct. 18, 1986, 100 Stat. 1783–39, 1783–49, and Pub. L. 99–591, §101(b) [title II], Oct. 30, 1986, 100 Stat. 3341–39, 3341–49.
Pub. L. 99–180, title II, Dec. 13, 1985, 99 Stat. 1144.
Pub. L. 98–411, title II, Aug. 30, 1984, 98 Stat. 1556.
Pub. L. 98–166, title II, Nov. 28, 1983, 97 Stat. 1084.
Pub. L. 97–377, §101(d) [S. 2956, title II], Dec. 21, 1982, 96 Stat. 1866.
Pub. L. 97–92, §101(h) [incorporating Pub. L. 96–536, §101o; H.R. 7584, title II], Dec. 15, 1981, 95 Stat. 1190.
Pub. L. 96–536, §101o [H.R. 7584, title II], Dec. 16, 1980, 94 Stat. 3169.
Pub. L. 96–68, title II, Sept. 24, 1979, 93 Stat. 421.
Pub. L. 95–431, title II, Oct. 10, 1978, 92 Stat. 1028.
Pub. L. 95–86, title II, Aug. 2, 1977, 91 Stat. 427.
Pub. L. 94–362, title II, July 14, 1976, 90 Stat. 945.
Pub. L. 94–121, title II, Oct. 21, 1975, 89 Stat. 620.
Pub. L. 93–433, title II, Oct. 5, 1974, 88 Stat. 1194.
Pub. L. 93–162, title II, Nov. 27, 1973, 87 Stat. 643.
Pub. L. 92–544, title II, Oct. 25, 1972, 86 Stat. 1116.
Pub. L. 92–77, title II, Aug. 10, 1971, 85 Stat. 253.
Pub. L. 91–472, title II, Oct. 21, 1970, 84 Stat. 1047.
Pub. L. 91–153, title II, Dec. 24, 1969, 83 Stat. 410.
Pub. L. 90–470, title II, Aug. 9, 1968, 82 Stat. 675.
Pub. L. 90–133, title II, Nov. 8, 1967, 81 Stat. 418.
Pub. L. 89–797, title II, Nov. 8, 1966, 80 Stat. 1487.
Pub. L. 89–164, title II, Sept. 2, 1965, 79 Stat. 628.
Pub. L. 88–527, title II, Aug. 31, 1964, 78 Stat. 719.
Pub. L. 88–245, title II, Dec. 30, 1963, 77 Stat. 783.
Pub. L. 87–843, title II, Oct. 18, 1962, 76 Stat. 1088.
Pub. L. 87–264, title II, Sept. 21, 1961, 75 Stat. 553.
Pub. L. 86–678, title II, Aug. 31, 1960, 74 Stat. 563.
Pub. L. 86–84, title II, July 13, 1959, 73 Stat. 189.
Pub. L. 85–474, title II, June 30, 1958, 72 Stat. 252.
Pub. L. 85–49, title II, June 11, 1957, 71 Stat. 62.
June 20, 1956, ch. 414, title II, 70 Stat. 307.
July 7, 1955, ch. 279, title II, 69 Stat. 273.

§251. Medical examination and treatment of Federal employees; medical care at remote stations

(a) The Surgeon General is authorized to provide at institutions, hospitals, and station of the Service medical, surgical, and hospital services and supplies for persons entitled to treatment under subchapter I of Chapter 81 of title 5 and extensions thereof. The Surgeon General may also provide for making medical examinations of—

(1) employees of the Federal Government for retirement purposes;

(2) employees in the Federal classified service, and applicants for appointment, as requested by the Director of the Office of Personnel Management for the purpose of promoting health and efficiency;

(3) seamen for purposes of qualifying for certificates of service; and

(4) employees eligible for benefits under the Longshore and Harbor Workers' Compensation Act, as amended [33 U.S.C. 901 et seq.], as requested by any deputy commissioner thereunder.

(b) The Secretary is authorized to provide medical, surgical, and dental treatment and hospitalization and optometric care for Federal employees (as defined in section 8901(1) of title 5) and their dependents at remote medical facilities of the Public Health Service where such care and treatment are not otherwise available. Such employees and their dependents who are not entitled to this care and treatment under any other provision of law shall be charged for it at rates established by the Secretary to reflect the reasonable cost of providing the care and treatment. Any payments pursuant to the preceding sentence shall be credited to the applicable appropriation to the Public Health Service for the year in which such payments are received.

(July 1, 1944, ch. 373, title III, §324, 58 Stat. 697; Pub. L. 90–174, §10(a), (b), Dec. 5, 1967, 81 Stat. 540; 1978 Reorg. Plan No. 2, §102, eff. Jan. 1, 1979, 43 F.R. 36037, 92 Stat. 3783; Pub. L. 97–468, title VI, §615(b)(4), Jan. 14, 1983, 96 Stat. 2578; Pub. L. 98–426, §27(d)(2), Sept. 28, 1984, 98 Stat. 1654.)

EDITORIAL NOTES

REFERENCES IN TEXT

The Longshore and Harbor Workers' Compensation Act, as amended, referred to in subsec. (a)(4), is act Mar. 4, 1927, ch. 509, 44 Stat. 1424, which is classified generally to chapter 18 (§901 et seq.) of Title 33, Navigation and Navigable Waters. For complete classification of this Act to the Code, see section 901 of Title 33 and Tables.

CODIFICATION

In subsec. (a), "subchapter I of chapter 81 of title 5" substituted for "United States Employees' Compensation Act" on authority of Pub. L. 89–554, §7(b), Sept. 6, 1966, 80 Stat. 631, the first section of which enacted Title 5, Government Organization and Employees.

AMENDMENTS

1984—Subsec. (a)(4). Pub. L. 98–426 substituted "Longshore and Harbor Workers' Compensation Act" for "Longshoremen's and Harbor Workers' Compensation Act".

1983—Subsec. (a)(1). Pub. L. 97–468 struck out "employees of the Alaska Railroad and" before "employees of the Federal Government".

1967—Subsec. (a). Pub. L. 90–174, §10(a), designated existing provisions as subsec. (a) and redesignated cls. (a) to (d) as cls. (1) to (4), respectively.

Subsec. (b). Pub. L. 90–174, §10(b), added subsec. (b).

STATUTORY NOTES AND RELATED SUBSIDIARIES

CHANGE OF NAME

"Secretary of Health and Human Services" substituted for "Secretary of Health, Education, and Welfare" in subsec. (b) pursuant to section 509(b) of Pub. L. 96–88, which is classified to section 3508(b) of Title 20, Education.

EFFECTIVE DATE OF 1984 AMENDMENT

Amendment by Pub. L. 98–426 effective Sept. 28, 1984, see section 28(e)(1) of Pub. L. 98–426, set out as a note under section 901 of Title 33, Navigation and Navigable Waters.

EFFECTIVE DATE OF 1983 AMENDMENT

Amendment by Pub. L. 97–468 effective on date of transfer of Alaska Railroad to the State [Jan. 5, 1985], pursuant to section 1203 of Title 45, Railroads, see section 615(b) of Pub. L. 97–468.

EXECUTIVE DOCUMENTS

TRANSFER OF FUNCTIONS

"Director of the Office of Personnel Management" substituted for "Civil Service Commission" in subsec. (a)(2), pursuant to Reorg. Plan No. 2 of 1978, §102, 43 F.R. 36037, 92 Stat. 3783, set out under section 1101 of Title 5, Government Organization and Employees, which transferred all functions vested by statute in

United States Civil Service Commission to Director of Office of Personnel Management (except as otherwise specified), effective Jan. 1, 1979, as provided by section 1–102 of Ex. Ord. No. 12107, Dec. 28, 1978, 44 F.R. 1055, set out under section 1101 of Title 5.

Functions of Public Health Service, Surgeon General of Public Health Service, and all other officers and employees of Public Health Service, and functions of all agencies of or in Public Health Service transferred to Secretary of Health, Education, and Welfare by Reorg. Plan No. 3 of 1966, eff. June 25, 1966, 31 F.R. 8855, 80 Stat. 1610, set out as a note under section 202 of this title.

§252. Medical examination of aliens

The Surgeon General shall provide for making, at places within the United States or in other countries, such physical and mental examinations of aliens as are required by the immigration laws, subject to administrative regulations prescribed by the Attorney General and medical regulations prescribed by the Surgeon General with the approval of the Secretary.

(July 1, 1944, ch. 373, title III, §325, 58 Stat. 697; 1953 Reorg. Plan No. 1, §§5, 8, eff. Apr. 11, 1953, 18 F.R. 2053, 67 Stat. 631.)

STATUTORY NOTES AND RELATED SUBSIDIARIES

CHANGE OF NAME

"Secretary of Health and Human Services" substituted in text for "Secretary of Health, Education, and Welfare" pursuant to section 509(b) of Pub. L. 96–88, which is classified to section 3508(b) of Title 20, Education.

ABOLITION OF IMMIGRATION AND NATURALIZATION SERVICE AND TRANSFER OF FUNCTIONS

For abolition of Immigration and Naturalization Service, transfer of functions, and treatment of related references, see note set out under section 1551 of Title 8, Aliens and Nationality.

EXECUTIVE DOCUMENTS

TRANSFER OF FUNCTIONS

Office of Surgeon General abolished by section 3 of Reorg. Plan No. 3 of 1966, eff. June 25, 1966, 31 F.R. 8855, 80 Stat. 1610, and functions thereof transferred to Secretary of Health, Education, and Welfare by section 1 of Reorg. Plan No. 3 of 1966, set out as a note under section 202 of this title. Office of Surgeon General reestablished within the Office of the Assistant Secretary for Health, see Notice of Department of Health and Human Services, Office of the Assistant Secretary for Health, Mar. 30, 1987, 52 F.R. 11754.

Functions of Federal Security Administrator transferred to Secretary of Health, Education, and Welfare and all agencies of Federal Security Agency transferred to Department of Health, Education, and Welfare by section 5 of Reorg. Plan No. 1 of 1953, set out as a note under section 3501 of this title. Federal Security Agency and office of Administrator abolished by section 8 of Reorg. Plan No. 1 of 1953.

§253. Medical services to Coast Guard, National Oceanic and Atmospheric Administration, and Public Health Service

(a) Persons entitled to medical services

Subject to regulations of the President—

(1) commissioned officers, chief warrant officers, warrant officers, cadets, and enlisted personnel of the Regular Coast Guard on active duty, including those on shore duty and those on detached duty; and Regular, and temporary members of the United States Coast Guard Reserve when on active duty;

(2) commissioned officers, ships' officers, and members of the crews of vessels of the National Oceanic and Atmospheric Administration on active duty, including those on shore duty and those

on detached duty; and

(3) commissioned officers of the Regular or Reserve Corps [1] of the Public Health Service on active duty;

shall be entitled to medical, surgical, and dental treatment and hospitalization by the Service. The Surgeon General may detail commissioned officers for duty aboard vessels of the Coast Guard or the National Oceanic and Atmospheric Administration.

(b) Health care for involuntarily separated officers and dependents

(1) The Secretary may provide health care for an officer of the Regular or Reserve Corps [1] involuntarily separated from the Service, and for any dependent of such officer, if—

(A) the officer or dependent was receiving health care at the expense of the Service at the time of separation; and

(B) the Secretary finds that the officer or dependent is unable to obtain appropriate insurance for the conditions for which the officer or dependent was receiving health care.

(2) Health care may be provided under paragraph (1) for a period of not more than one year from the date of separation of the officer from the Service.

(c) Examination of personnel of Service assigned to Coast Guard or National Oceanic and Atmospheric Administration

The Service shall provide all services referred to in subsection (a) required by the Coast Guard or National Oceanic and Atmospheric Administration and shall perform all duties prescribed by statute in connection with the examinations to determine physical or mental condition for purposes of appointment, enlistment, and reenlistment, promotion and retirement, and officers of the Service assigned to duty on Coast Guard or National Oceanic and Atmospheric Administration vessels may extend aid to the crews of American vessels engaged in deep-sea fishing.

(July 1, 1944, ch. 373, title III, §326, 58 Stat. 697; June 7, 1956, ch. 374, §306(3), 70 Stat. 254; Pub. L. 86–415, §5(d), Apr. 8, 1960, 74 Stat. 34; Pub. L. 88–71, §2, July 19, 1963, 77 Stat. 83; 1965 Reorg. Plan No. 2, eff. July 13, 1965, 30 F.R. 8819, 79 Stat. 1318; 1970 Reorg. Plan No. 4, eff. Oct. 3, 1970, 35 F.R. 15627, 84 Stat. 2090; Pub. L. 99–117, §5, Oct. 7, 1985, 99 Stat. 492.)

EDITORIAL NOTES

AMENDMENTS

1985—Subsec. (b). Pub. L. 99–117 added subsec. (b).

1963—Subsec. (b). Pub. L. 88–71, §2(a), repealed subsec. (b) which provided for treatment of dependents of personnel. See section 253a(b) of this title.

Subsec. (c). Pub. L. 88–71, §2(b), inserted "or Coast and Geodetic Survey" after "Coast Guard" in two places.

1960—Subsec. (a). Pub. L. 86–415 struck out provisions which authorized medical, surgical, and dental care and hospitalization for retired personnel of Coast Guard, Coast and Geodetic Survey, and Public Health Service.

1956—Subsec. (b). Act June 7, 1956, repealed subsec. (b) except insofar as it related to dependent members of families of ships' officers and members of crews of vessels of Coast and Geodetic Survey.

STATUTORY NOTES AND RELATED SUBSIDIARIES

CHANGE OF NAME

Reference to Reserve Corps of the Public Health Service deemed to be a reference to the Ready Reserve Corps, see section 204(c)(3) of this title.

"Secretary of Health and Human Services" substituted for "Secretary of Health, Education, and Welfare" in subsec. (b) pursuant to section 509(b) of Pub. L. 96–88, which is classified to section 3508(b) of Title 20, Education.

EFFECTIVE DATE OF 1956 AMENDMENT

Amendment by act June 7, 1956, effective six months after June 7, 1956, see section 307 of act June 7, 1956.

TRANSFER OF FUNCTIONS

For transfer of authorities, functions, personnel, and assets of the Coast Guard, including the authorities and functions of the Secretary of Transportation relating thereto, to the Department of Homeland Security, and for treatment of related references, see sections 468(b), 551(d), 552(d), and 557 of Title 6, Domestic Security, and the Department of Homeland Security Reorganization Plan of November 25, 2002, as modified, set out as a note under section 542 of Title 6.

EXECUTIVE DOCUMENTS

CHANGE OF NAME

Coast and Geodetic Survey consolidated with Weather Bureau to form a new agency in Department of Commerce to be known as Environmental Science Services Administration, and commissioned officers of Survey transferred to ESSA, by Reorg. Plan No. 2 of 1965, eff. July 13, 1965, 30 F.R. 8819, 79 Stat. 1318, set out in the Appendix to Title 5, Government Organization and Employees. Reorg. Plan No. 4 of 1970, eff. Oct. 3, 1970, 35 F.R. 15627, 84 Stat. 2090, abolished Environmental Science Services Administration, established National Oceanic and Atmospheric Administration, and redesignated Commissioned Officer Corps of ESSA as Commissioned Officer Corps of NOAA. For further details, see Transfer of Functions note set out under section 851 of Title 33, Navigation and Navigable Waters.

TRANSFER OF FUNCTIONS

Functions of Public Health Service, Surgeon General of Public Health Service, and all other officers and employees of Public Health Service, and functions of all agencies of or in Public Health Service transferred to Secretary of Health, Education, and Welfare by Reorg. Plan No. 3 of 1966, eff. June 25, 1966, 31 F.R. 8855 80 Stat. 1610, set out as a note under section 202 of this title.

[1] *See Change of Name note below.*

§253a. Medical services to retired personnel of National Oceanic and Atmospheric Administration

(a) Eligibility

Subject to regulations of the President, retired ships' officers and retired members of the crews of vessels of the National Oceanic and Atmospheric Administration shall be entitled to medical, surgical, and dental treatment and hospitalization by the Public Health Service if the ships' officer or crew member, (1) was on active duty as a vessel employee of the National Oceanic and Atmospheric Administration on July 1, 1963, or on July 19, 1963, whichever is later, and his employment as a vessel employee was continuous from that date until retirement, or (2) was retired as a vessel employee of the National Oceanic and Atmospheric Administration on or before July 1, 1963, or on July 19, 1963, whichever is later.

(b) Treatment of dependents of personnel

Subject to regulations of the President, dependent members of families (as defined in such regulations) of ships' officers and members of crews of vessels of the National Oceanic and Atmospheric Administration, whether such, ships' officers and members of crew are on active duty or retired, shall be furnished medical advice and outpatient treatment by the Public Health Service and, if suitable accommodations are available, they shall also be furnished hospitalization by the Public Health Service if the ships' officer or crew member (1) was on active duty as a vessel employee of the National Oceanic and Atmospheric Administration on July 1, 1963, or on July 19, 1963, whichever is later, and his employment as a vessel employee has been continuous from that time, or (2) was on active duty as a vessel employee of the National Oceanic and Atmospheric

Administration on July 1, 1963, or on July 19, 1963, whichever is later, and his employment as a vessel employee was continuous from that time until retirement, or (3) was retired as a vessel employee of the National Oceanic and Atmospheric Administration on or before July 1, 1963, or on July 19, 1963, whichever is later. When dependent members of families are hospitalized, a per diem charge, at such uniform rate as may be prescribed from time to time for the hospitalization of dependents of members of the uniformed services at hospitals of the uniformed services pursuant to section 1078(a) of title 10 shall be made.

(c) Identification

The National Oceanic and Atmospheric Administration shall furnish proper identification to those persons entitled to medical treatment under the provisions of this section.

(Pub. L. 88–71, §1, July 19, 1963, 77 Stat. 83; 1965 Reorg. Plan No. 2, eff. July 13, 1965, 30 F.R. 8819, 79 Stat. 1318; 1970 Reorg. Plan No. 4, eff. Oct. 3, 1970, 35 F.R. 15627, 84 Stat. 2090; Pub. L. 98–498, title III, §310(b), (c), Oct. 19, 1984, 98 Stat. 2306, 2307.)

EDITORIAL NOTES

CODIFICATION

Section was not enacted as part of the Public Health Service Act which comprises this chapter.

AMENDMENTS

1984—Subsec. (a). Pub. L. 98–498, §310(b), substituted "by the Public Health Service if" for "at facilities of the Public Health Service: *Provided*, That".

Subsec. (b). Pub. L. 98–498, §310(c), struck out "at its hospitals and relief stations" before "and, if suitable accommodations" and substituted "by the Public Health Service if" for "at hospitals of the Public Health Service: *Provided*, That".

STATUTORY NOTES AND RELATED SUBSIDIARIES

CHANGE OF NAME

"Secretary of Health and Human Services" substituted for "Secretary of Health, Education, and Welfare" pursuant to section 509(b) of Pub. L. 96–88, which is classified to section 3508(b) of Title 20, Education.

EXECUTIVE DOCUMENTS

CHANGE OF NAME

Coast and Geodetic Survey consolidated with Weather Bureau to form a new agency in Department of Commerce to be known as Environmental Science Services Administration, and commissioned officers of Survey transferred to ESSA, by Reorg. Plan No. 2 of 1965, eff. July 13, 1965, 30 F.R. 8819, 79 Stat. 1318, set out in the Appendix to Title 5, Government Organization and Employees. Reorg. Plan No. 4 of 1970, eff. Oct. 3, 1970, 35 F.R. 15627, 84 Stat. 2090, abolished Environmental Science Services Administration, established National Oceanic and Atmospheric Administration, and redesignated Commissioned Officer Corps of ESSA as Commissioned Officer Corps of NOAA. For further details, see Transfer of Functions note set out under section 851 of Title 33, Navigation and Navigable Waters.

TRANSFER OF FUNCTIONS

Functions of Public Health Service, Surgeon General of Public Health Service, and all other officers and employees of Public Health Service, and functions of all agencies of or in Public Health Service transferred to Secretary of Health, Education, and Welfare by Reorg. Plan No. 3 of 1966, eff. June 25, 1966, 31 F.R. 8855, 80 Stat. 1610, set out as a note under section 202 of this title.

EX. ORD. NO. 11160. REGULATIONS RELATING TO MEDICAL CARE FOR RETIRED PERSONNEL OF COAST AND GEODETIC SURVEY [NOW NATIONAL OCEANIC AND ATMOSPHERIC ADMINISTRATION] AND THEIR DEPENDENTS

Ex. Ord. No. 11160, July 6, 1964, 29 F.R. 9315, provided:

By virtue of the authority vested in me by the first section of the Act of July 19, 1963 (Public Law 88–71,

77 Stat. 83, 42 U.S.C. 253a), and as President of the United States, I hereby prescribe the following regulations relating to the medical care of certain retired personnel of the Coast and Geodetic Survey [now National Oceanic and Atmospheric Administration] and dependents of Coast and Geodetic Survey [now National Oceanic and Atmospheric Administration] ships' officers and crew members, both active and retired.

SECTION 1. *Definitions*. As used in these regulations, the term:

(1) "Retired ships' officer and retired crew member" means a noncommissioned ships' officer or crew member of a vessel of the Coast and Geodetic Survey [now National Oceanic and Atmospheric Administration] who either was on active duty as a vessel employee on July 19, 1963, and whose employment as such vessel employee was continuous from that date until the date of his retirement, or who had retired as a vessel employee on or before July 19, 1963.

(2) "Active duty ships' officer and active duty crew member" means a noncommissioned ships' officer or crew member on active duty as a vessel employee of the Coast and Geodetic Survey [now National Oceanic and Atmospheric Administration] on July 19, 1963, and whose employment as such vessel employee has been continuous from that time.

(3) "Dependent members of families", with respect to active duty or retired ships' officers or crew members, means:

(A) the lawful wife;

(B) the unmarried legitimate child, including an adopted child or stepchild, who has not passed his twenty-first birthday; and

(C) the father or mother, if in fact dependent upon such active duty or retired ships' officer or crew member for over one-half of his or her support.

(4) "Relief stations" means Public Health Service outpatient clinics and outpatient offices.

(5) "Outpatient clinic" means a full-time outpatient medical facility, operated in Federally owned or leased space under the supervision of a commissioned medical officer or a full-time civil service medical officer (formerly known as a Second-Class Relief Station).

(6) "Outpatient office" means a part-time outpatient facility serving all classes of legal beneficiaries, located in other than Federal space, and in the charge of a local private physician under contract to the Service to provide medical care on an annual or fee basis (formerly known as a Third-Class Relief Station).

SEC. 2. *Persons entitled to treatment*. The following persons shall be entitled to medical care under these regulations:

(1) Retired ships' officers and retired crew members of the Coast and Geodetic Survey [now National Oceanic and Atmospheric Administration];

(2) Dependent members of families of persons described in paragraph (1) of this section;

(3) Dependent members of families of active duty ships' officers and crew members of the Coast and Geodetic Survey [now National Oceanic and Atmospheric Administration].

SEC. 3. *Application for treatment; evidence of eligibility*. Persons entitled to medical care under Section 2 of these regulations, when applying to Public Health Service medical care facilities for medical care, shall produce proper identification, as issued to them by the Coast and Geodetic Survey [now National Oceanic and Atmospheric Administration], and such identification shall be accepted as evidence of eligibility for such medical care by the Service.

SEC. 4. *Extent of treatment; retired ships' officers and crew members*. Subject to the limitation imposed by paragraph (2) of this section, retired ships' officers and crew members entitled to medical care under these regulations shall be furnished:

(1) Medical, surgical, and dental treatment at hospitals, outpatient clinics, and outpatient offices of the Service, and hospitalization at hospitals of the Service. The Service will not be responsible for defraying the cost of hospitalization, medical services, and supplies procured elsewhere.

(2) Dental treatment shall be furnished to the extent that facilities and services at hospitals and outpatient clinics of the Service having full-time dental officers on duty are available to provide such treatment. At other Service facilities, dental treatment shall be limited to emergency measures necessary to relieve pain.

SEC. 5. *Extent of treatment; dependent members of families; charges*. (a) Dependent members of families shall be furnished medical advice and outpatient treatment at hospitals, outpatient clinics, and outpatient offices of the Service and, if suitable accommodations are available, shall be furnished hospitalization at hospitals of the Service. The Service will not be responsible for defraying the cost of hospitalization, medical services, and supplies procured elsewhere.

(b) For the purpose of this section—

(1) Medical advice and outpatient treatment may include such services and supplies as the Medical Officer in Charge may deem to be necessary for reasonable and adequate treatment.

(2) Hospitalization shall be furnished when, in the opinion of the Medical Officer in Charge, suitable

accommodations are available and the condition of the patient is such as to require hospitalization. When hospitalization is authorized, it may include such services and supplies as the Medical Officer in Charge may deem to be necessary for reasonable and adequate treatment.

(c) Charges shall be made for hospitalization of dependent members of families at the same per diem rate as is prescribed for dependents of members of the uniformed services pursuant to section 1078(a) of Title 10 of the United States Code.

(d) Dental treatment may be furnished to the extent that facilities and services at hospitals and outpatient clinics of the Service having full-time dental officers are available to provide such treatment. Dental care will not be furnished under any circumstances in private facilities at the expense of the Service.

SEC. 6. *Prior orders*. Executive Order No. 9703 of March 12, 1946, prescribing regulations relating to medical care of certain personnel of the Coast Guard, Coast and Geodetic Survey [now National Oceanic and Atmospheric Administration], Public Health Service, and former Lighthouse Service, is hereby amended to the extent necessary to conform it to the provisions of this order.

LYNDON B. JOHNSON.

§253b. Former Lighthouse Service employees; medical service eligibility

Subject to regulations of the President, lightkeepers, assistant lightkeepers, and officers and crews of vessels of the former Lighthouse Service, including any such persons who subsequent to June 30, 1939, were involuntarily assigned to other civilian duty in the Coast Guard, who were entitled to medical relief at hospitals and other stations of the Public Health Service prior to July 1, 1944, and who retired under the provisions of section 763 of title 33, shall be entitled to medical, surgical, and dental treatment and hospitalization at hospitals and other stations of the Public Health Service.

(Pub. L. 93–353, title I, §108(a), July 23, 1974, 88 Stat. 371.)

EDITORIAL NOTES

CODIFICATION

Section was enacted as a part of Health Services Research, Health Statistics, and Medical Libraries Act of 1974, and also as a part of Health Services Research and Evaluation and Health Statistics Act of 1974, and not as a part of the Public Health Service Act which comprises this chapter.

STATUTORY NOTES AND RELATED SUBSIDIARIES

EFFECTIVE DATE

Pub. L. 93–353, title I, §108(b), July 23, 1974, 88 Stat. 371, provided that: "Subsection (a) [enacting this section] shall be effective from December 28, 1973."

TRANSFER OF FUNCTIONS

For transfer of authorities, functions, personnel, and assets of the Coast Guard, including the authorities and functions of the Secretary of Transportation relating thereto, to the Department of Homeland Security, and for treatment of related references, see sections 468(b), 551(d), 552(d), and 557 of Title 6, Domestic Security, and the Department of Homeland Security Reorganization Plan of November 25, 2002, as modified, set out as a note under section 542 of Title 6.

§254. Interdepartmental work

Nothing contained in this part shall affect the authority of the Service to furnish any materials, supplies, or equipment, or perform any work of services, requested in accordance with sections 1535 and 1536 of title 31, or the authority of any other executive department to furnish any materials, supplies, or equipment, or perform any work or services, requested by the Department of Health and Human Services for the Service in accordance with that section.

(July 1, 1944, ch. 373, title III, §327, 58 Stat. 697; 1953 Reorg. Plan No. 1, §§5, 8, eff. Apr. 11,

1953, 18 F.R. 2053, 67 Stat. 631; Pub. L. 96–88, title V, §509(b), Oct. 17, 1979, 93 Stat. 695.)

EDITORIAL NOTES

CODIFICATION

"Sections 1535 and 1536 of title 31" substituted in text for "section 7 of the Act of May 21, 1920, as amended (U.S.C., 1940 edition, title 31, sec. 686)" on authority of Pub. L. 97–258, §4(b), Sept. 13, 1982, 96 Stat. 1067, the first section of which enacted Title 31, Money and Finance.

STATUTORY NOTES AND RELATED SUBSIDIARIES

CHANGE OF NAME

"Department of Health and Human Services" substituted in text for "Department of Health, Education, and Welfare" pursuant to section 509(b) of Pub. L. 96–88, which is classified to section 3508(b) of Title 20, Education.

EXECUTIVE DOCUMENTS

TRANSFER OF FUNCTIONS

Functions of Public Health Service, Surgeon General of Public Health Service, and all other officers and employees of Public Health Service, and functions of all agencies of or in Public Health Service transferred to Secretary of Health, Education, and Welfare by Reorg. Plan No. 3 of 1966, eff. June 25, 1966, 31 F.R. 8855, 80 Stat. 1610, set out as a note under section 202 of this title.

Functions of Federal Security Administrator transferred to Secretary of Health, Education, and Welfare and all agencies of Federal Security Agency transferred to Department of Health, Education, and Welfare by section 5 of Reorg. Plan No. 1 of 1953, set out as a note under section 3501 of this title. Federal Security Agency and office of Administrator abolished by section 8 of Reorg. Plan No. 1 of 1953.

§254a. Sharing of medical care facilities and resources

(a) Definitions

For purposes of this section—

(1) the term "specialized health resources" means health care resources (whether equipment, space, or personnel) which, because of cost, limited availability, or unusual nature, are either unique in the health care community or are subject to maximum utilization only through mutual use;

(2) the term "hospital", unless otherwise specified, includes (in addition to other hospitals) any Federal hospital.

(b) Statement of purpose; agreements or arrangements; reciprocity; reimbursement; credits

For the purpose of maintaining or improving the quality of care in Public Health Service facilities and to provide a professional environment therein which will help to attract and retain highly qualified and talented health personnel, to encourage mutually beneficial relationships between Public Health Service facilities and hospitals and other health facilities in the health care community, and to promote the full utilization of hospitals and other health facilities and resources, the Secretary may—

(1) enter into agreements or arrangements with schools of medicine, schools of osteopathic medicine, and with other health professions schools, agencies, or institutions, for such interchange or cooperative use of facilities and services on a reciprocal or reimbursable basis, as will be of benefit to the training or research programs of the participating agencies; and

(2) enter into agreements or arrangements with hospitals and other health care facilities for the mutual use or the exchange of use of specialized health resources, and providing for reciprocal reimbursement.

Any reimbursement pursuant to any such agreement or arrangement shall be based on charges covering the reasonable cost of such utilization, including normal depreciation and amortization costs of equipment. Any proceeds to the Government under this subsection shall be credited to the applicable appropriation of the Public Health Service for the year in which such proceeds are received.

(July 1, 1944, ch. 373, title III, §327A, formerly §328, as added Pub. L. 90–174, §7, Dec. 5, 1967, 81 Stat. 539; renumbered §327A, Pub. L. 95–626, title I, §113(a)(2), Nov. 10, 1978, 92 Stat. 3562; amended Pub. L. 100–607, title VI, §629(a)(1), Nov. 4, 1988, 102 Stat. 3146.)

EDITORIAL NOTES

AMENDMENTS

1988—Subsec. (b)(1). Pub. L. 100–607 inserted "schools of osteopathic medicine," after "schools of medicine," and "professions" after "health".

STATUTORY NOTES AND RELATED SUBSIDIARIES

AVAILABILITY OF APPROPRIATIONS FOR EXPENSES OF SHARING MEDICAL CARE FACILITIES AND RESOURCES

Pub. L. 102–394, title II, §204, Oct. 6, 1992, 106 Stat. 1811, provided that: "Funds advanced to the National Institutes of Health Management Fund from appropriations in this Act or subsequent Departments of Labor, Health and Human Services, and Education, and Related Agencies Appropriations Acts shall be available for the expenses of sharing medical care facilities and resources pursuant to section 327A of the Public Health Service Act [42 U.S.C. 254a]."

Similar provisions were contained in the following prior appropriation acts:

Pub. L. 102–170, title II, §204, Nov. 26, 1991, 105 Stat. 1126.

Pub. L. 101–517, title II, §204, Nov. 5, 1990, 104 Stat. 2208.

Pub. L. 101–166, title II, §205, Nov. 21, 1989, 103 Stat. 1177.

Pub. L. 100–202, §101(h) [title II, §205], Dec. 22, 1987, 101 Stat. 1329–256, 1329–274.

Pub. L. 99–500, §101(i) [H.R. 5233, title II, §205], Oct. 18, 1986, 100 Stat. 1783–287, and Pub. L. 99–591, §101(i) [H.R. 5233, title II, §205], Oct. 30, 1986, 100 Stat. 3341–287.

Pub. L. 99–178, title II, §205, Dec. 12, 1985, 99 Stat. 1119.

Pub. L. 98–619, title II, §205, Nov. 8, 1984, 98 Stat. 3321.

Pub. L. 98–139, title II, §205, Oct. 31, 1983, 97 Stat. 887.

Pub. L. 97–377, title I, §101(e)(1) [title II, §205], Dec. 21, 1982, 96 Stat. 1878, 1894.

PART D—PRIMARY HEALTH CARE

EDITORIAL NOTES

CODIFICATION

Pub. L. 95–626, title I, §113(a)(3), Nov. 10, 1978, 92 Stat. 3562, added heading "Part D—Primary Health Care".

SUBPART I—HEALTH CENTERS

EDITORIAL NOTES

CODIFICATION

Pub. L. 104–299, §2, Oct. 11, 1996, 110 Stat. 3626, substituted "Health Centers" for "Primary Health Centers" in subpart heading.

Pub. L. 95–626, title I, §113(a)(3), Nov. 10, 1978, 92 Stat. 3562, added heading "Subpart I—Primary Health Centers".

§254b. Health centers

(a) "Health center" defined

(1) In general

For purposes of this section, the term "health center" means an entity that serves a population that is medically underserved, or a special medically underserved population comprised of migratory and seasonal agricultural workers, the homeless, and residents of public housing, by providing, either through the staff and supporting resources of the center or through contracts or cooperative arrangements—

(A) required primary health services (as defined in subsection (b)(1)); and

(B) as may be appropriate for particular centers, additional health services (as defined in subsection (b)(2)) necessary for the adequate support of the primary health services required under subparagraph (A);

for all residents of the area served by the center (hereafter referred to in this section as the "catchment area").

(2) Limitation

The requirement in paragraph (1) to provide services for all residents within a catchment area shall not apply in the case of a health center receiving a grant only under subsection (g), (h), or (i).

(b) Definitions

For purposes of this section:

(1) Required primary health services

(A) In general

The term "required primary health services" means—

(i) basic health services which, for purposes of this section, shall consist of—

(I) health services related to family medicine, internal medicine, pediatrics, obstetrics, or gynecology that are furnished by physicians and where appropriate, physician assistants, nurse practitioners, and nurse midwives;

(II) diagnostic laboratory and radiologic services;

(III) preventive health services, including—

(aa) prenatal and perinatal services;

(bb) appropriate cancer screening;

(cc) well-child services;

(dd) immunizations against vaccine-preventable diseases;

(ee) screenings for elevated blood lead levels, communicable diseases, and cholesterol;

(ff) pediatric eye, ear, and dental screenings to determine the need for vision and hearing correction and dental care;

(gg) voluntary family planning services; and

(hh) preventive dental services;

(IV) emergency medical services; and

(V) pharmaceutical services as may be appropriate for particular centers;

(ii) referrals to providers of medical services (including specialty referral when medically

indicated) and other health-related services (including substance use disorder and mental health services);

(iii) patient case management services (including counseling, referral, and follow-up services) and other services designed to assist health center patients in establishing eligibility for and gaining access to Federal, State, and local programs that provide or financially support the provision of medical, social, housing, educational, or other related services;

(iv) services that enable individuals to use the services of the health center (including outreach and transportation services and, if a substantial number of the individuals in the population served by a center are of limited English-speaking ability, the services of appropriate personnel fluent in the language spoken by a predominant number of such individuals); and

(v) education of patients and the general population served by the health center regarding the availability and proper use of health services.

(B) Exception

With respect to a health center that receives a grant only under subsection (g), the Secretary, upon a showing of good cause, shall—

(i) waive the requirement that the center provide all required primary health services under this paragraph; and

(ii) approve, as appropriate, the provision of certain required primary health services only during certain periods of the year.

(2) Additional health services

The term "additional health services" means services that are not included as required primary health services and that are appropriate to meet the health needs of the population served by the health center involved. Such term may include—

(A) behavioral and mental health and substance use disorder services;

(B) recuperative care services;

(C) environmental health services, including—

(i) the detection and alleviation of unhealthful conditions associated with—

(I) water supply;

(II) chemical and pesticide exposures;

(III) air quality; or

(IV) exposure to lead;

(ii) sewage treatment;

(iii) solid waste disposal;

(iv) rodent and parasitic infestation;

(v) field sanitation;

(vi) housing; and

(vii) other environmental factors related to health; and

(D) in the case of health centers receiving grants under subsection (g), special occupation-related health services for migratory and seasonal agricultural workers, including—

(i) screening for and control of infectious diseases, including parasitic diseases; and

(ii) injury prevention programs, including prevention of exposure to unsafe levels of agricultural chemicals including pesticides.

(3) Medically underserved populations

(A) In general

The term "medically underserved population" means the population of an urban or rural area designated by the Secretary as an area with a shortage of personal health services or a population group designated by the Secretary as having a shortage of such services.

(B) Criteria

In carrying out subparagraph (A), the Secretary shall prescribe criteria for determining the specific shortages of personal health services of an area or population group. Such criteria shall—

(i) take into account comments received by the Secretary from the chief executive officer of a State and local officials in a State; and

(ii) include factors indicative of the health status of a population group or residents of an area, the ability of the residents of an area or of a population group to pay for health services and their accessibility to them, and the availability of health professionals to residents of an area or to a population group.

(C) Limitation

The Secretary may not designate a medically underserved population in a State or terminate the designation of such a population unless, prior to such designation or termination, the Secretary provides reasonable notice and opportunity for comment and consults with—

(i) the chief executive officer of such State;

(ii) local officials in such State; and

(iii) the organization, if any, which represents a majority of health centers in such State.

(D) Permissible designation

The Secretary may designate a medically underserved population that does not meet the criteria established under subparagraph (B) if the chief executive officer of the State in which such population is located and local officials of such State recommend the designation of such population based on unusual local conditions which are a barrier to access to or the availability of personal health services.

(c) Planning grants

(1) Centers

The Secretary may make grants to public and nonprofit private entities for projects to plan and develop health centers which will serve medically underserved populations. A project for which a grant may be made under this subsection may include the cost of the acquisition and lease of buildings and equipment (including the costs of amortizing the principal of, and paying the interest on, loans) and shall include—

(A) an assessment of the need that the population proposed to be served by the health center for which the project is undertaken has for required primary health services and additional health services;

(B) the design of a health center program for such population based on such assessment;

(C) efforts to secure, within the proposed catchment area of such center, financial and professional assistance and support for the project;

(D) initiation and encouragement of continuing community involvement in the development and operation of the project; and

(E) proposed linkages between the center and other appropriate provider entities, such as health departments, local hospitals, and rural health clinics, to provide better coordinated, higher quality, and more cost-effective health care services.

(2) Limitation

Not more than two grants may be made under this subsection for the same project, except that upon a showing of good cause, the Secretary may make additional grant awards.

(3) Recognition of high poverty

(A) In general

In making grants under this subsection, the Secretary may recognize the unique needs of high poverty areas.

(B) High poverty area defined

For purposes of subparagraph (A), the term "high poverty area" means a catchment area

which is established in a manner that is consistent with the factors in subsection (k)(3)(J), and the poverty rate of which is greater than the national average poverty rate as determined by the Bureau of the Census.

(d) Improving quality of care

(1) Supplemental awards

The Secretary may award supplemental grant funds to health centers funded under this section to implement evidence-based models for increasing access to high-quality primary care services, which may include models related to—

(A) improving the delivery of care for individuals with multiple chronic conditions;

(B) workforce configuration;

(C) reducing the cost of care;

(D) enhancing care coordination;

(E) expanding the use of telehealth and technology-enabled collaborative learning and capacity building models;

(F) care integration, including integration of behavioral health, mental health, or substance use disorder services;

(G) addressing emerging public health or substance use disorder issues to meet the health needs of the population served by the health center; and

(H) improving access to recommended immunizations.

(2) Sustainability

In making supplemental awards under this subsection, the Secretary may consider whether the health center involved has submitted a plan for continuing the activities funded under this subsection after supplemental funding is expended.

(3) Special consideration

The Secretary may give special consideration to applications for supplemental funding under this subsection that seek to address significant barriers to access to care in areas with a greater shortage of health care providers and health services relative to the national average.

(e) Operating grants

(1) Authority

(A) In general

The Secretary may make grants for the costs of the operation of public and nonprofit private health centers that provide health services to medically underserved populations.

(B) Entities that fail to meet certain requirements

The Secretary may make grants, for a period of not to exceed 1 year, for the costs of the operation of public and nonprofit private entities which provide health services to medically underserved populations but with respect to which the Secretary is unable to make each of the determinations required by subsection (k)(3). The Secretary shall not make a grant under this paragraph unless the applicant provides assurances to the Secretary that within 120 days of receiving grant funding for the operation of the health center, the applicant will submit, for approval by the Secretary, an implementation plan to meet the requirements of subsection (k)(3). The Secretary may extend such 120-day period for achieving compliance upon a demonstration of good cause by the health center.

(C) Operation of networks

The Secretary may make grants to health centers that receive assistance under this section, or at the request of the health centers, directly to a network that is at least majority controlled and, as applicable, at least majority owned by such health centers receiving assistance under this section, for the costs associated with the operation of such network including—

(i) the purchase or lease of equipment, which may include data and information systems

(including the costs of amortizing the principal of, and paying the interest on, loans for equipment);

(ii) the provision of training and technical assistance; and

(iii) other activities that—

(I) reduce costs associated with the provision of health services;

(II) improve access to, and availability of, health services provided to individuals served by the centers;

(III) enhance the quality and coordination of health services; or

(IV) improve the health status of communities.

(2) Use of funds

The costs for which a grant may be made under subparagraph (A) or (B) of paragraph (1) may include the costs of acquiring and leasing buildings and equipment (including the costs of amortizing the principal of, and paying interest on, loans), and the costs of providing training related to the provision of required primary health services and additional health services and to the management of health center programs.

(3) Construction

The Secretary may award grants which may be used to pay the costs associated with expanding and modernizing existing buildings or constructing new buildings (including the costs of amortizing the principal of, and paying the interest on, loans) for projects approved prior to October 1, 1996.

(4) Limitation

Not more than two grants may be made under subparagraph (B) of paragraph (1) for the same entity.

(5) Amount

(A) In general

The amount of any grant made in any fiscal year under subparagraphs (A) and (B) of paragraph (1) to a health center shall be determined by the Secretary, but may not exceed the amount by which the costs of operation of the center in such fiscal year exceed the total of—

(i) State, local, and other operational funding provided to the center; and

(ii) the fees, premiums, and third-party reimbursements, which the center may reasonably be expected to receive for its operations in such fiscal year.

(B) Networks

The total amount of grant funds made available for any fiscal year under paragraph (1)(C) to a health center or to a network shall be determined by the Secretary, but may not exceed 2 percent of the total amount appropriated under this section for such fiscal year.

(C) Payments

Payments under grants under subparagraph (A) or (B) of paragraph (1) shall be made in advance or by way of reimbursement and in such installments as the Secretary finds necessary and adjustments may be made for overpayments or underpayments.

(D) Use of nongrant funds

Nongrant funds described in clauses (i) and (ii) of subparagraph (A), including any such funds in excess of those originally expected, shall be used as permitted under this section, and may be used for such other purposes as are not specifically prohibited under this section if such use furthers the objectives of the project.

(6) New access points and expanded services

(A) Approval of new access points

(i) In general

The Secretary may approve applications for grants under subparagraph (A) or (B) of paragraph (1) to establish new delivery sites.

(ii) Special consideration

In carrying out clause (i), the Secretary may give special consideration to applicants that have demonstrated the new delivery site will be located within a sparsely populated area, or an area which has a level of unmet need that is higher relative to other applicants.

(iii) Consideration of applications

In carrying out clause (i), the Secretary shall approve applications for grants in such a manner that the ratio of the medically underserved populations in rural areas which may be expected to use the services provided by the applicants involved to the medically underserved populations in urban areas which may be expected to use the services provided by the applicants is not less than two to three or greater than three to two.

(iv) Service area overlap

If in carrying out clause (i) the applicant proposes to serve an area that is currently served by another health center funded under this section, the Secretary may consider whether the award of funding to an additional health center in the area can be justified based on the unmet need for additional services within the catchment area.

(v) Mobile units

An existing health center may be awarded funds under clause (i) to establish a new delivery site that is a mobile unit, regardless of whether the applicant additionally proposes to establish a permanent, full-time site. In the case of a health center that is not currently receiving funds under this section, such health center may be awarded funds under clause (i) to establish a new delivery site that is a mobile unit only if such health center uses a portion of such funds to also establish a permanent, full-time site.

(B) Approval of expanded service applications

(i) In general

The Secretary may approve applications for grants under subparagraph (A) or (B) of paragraph (1) to expand the capacity of the applicant to provide required primary health services described in subsection (b)(1) or additional health services described in subsection (b)(2).

(ii) Priority expansion projects

In carrying out clause (i), the Secretary may give special consideration to expanded service applications that seek to address emerging public health or behavioral health, mental health, or substance abuse issues through increasing the availability of additional health services described in subsection (b)(2) in an area in which there are significant barriers to accessing care.

(iii) Consideration of applications

In carrying out clause (i), the Secretary shall approve applications for grants in such a manner that the ratio of the medically underserved populations in rural areas which may be expected to use the services provided by the applicants involved to the medically underserved populations in urban areas which may be expected to use the services provided by such applicants is not less than two to three or greater than three to two.

(f) Infant mortality grants

(1) In general

The Secretary may make grants to health centers for the purpose of assisting such centers in—

(A) providing comprehensive health care and support services for the reduction of—

(i) the incidence of infant mortality; and

(ii) morbidity among children who are less than 3 years of age; and

(B) developing and coordinating service and referral arrangements between health centers and other entities for the health management of pregnant women and children described in subparagraph (A).

(2) Priority

In making grants under this subsection the Secretary shall give priority to health centers providing services to any medically underserved population among which there is a substantial incidence of infant mortality or among which there is a significant increase in the incidence of infant mortality.

(3) Requirements

The Secretary may make a grant under this subsection only if the health center involved agrees that—

(A) the center will coordinate the provision of services under the grant to each of the recipients of the services;

(B) such services will be continuous for each such recipient;

(C) the center will provide follow-up services for individuals who are referred by the center for services described in paragraph (1);

(D) the grant will be expended to supplement, and not supplant, the expenditures of the center for primary health services (including prenatal care) with respect to the purpose described in this subsection; and

(E) the center will coordinate the provision of services with other maternal and child health providers operating in the catchment area.

(g) Migratory and seasonal agricultural workers

(1) In general

The Secretary may award grants for the purposes described in subsections (c), (e), and (f) for the planning and delivery of services to a special medically underserved population comprised of—

(A) migratory agricultural workers, seasonal agricultural workers, and members of the families of such migratory and seasonal agricultural workers who are within a designated catchment area; and

(B) individuals who have previously been migratory agricultural workers but who no longer meet the requirements of subparagraph (A) of paragraph (3) because of age or disability and members of the families of such individuals who are within such catchment area.

(2) Environmental concerns

The Secretary may enter into grants or contracts under this subsection with public and private entities to—

(A) assist the States in the implementation and enforcement of acceptable environmental health standards, including enforcement of standards for sanitation in migratory agricultural worker and seasonal agricultural worker labor camps, and applicable Federal and State pesticide control standards; and

(B) conduct projects and studies to assist the several States and entities which have received grants or contracts under this section in the assessment of problems related to camp and field sanitation, exposure to unsafe levels of agricultural chemicals including pesticides, and other environmental health hazards to which migratory agricultural workers and seasonal agricultural workers, and members of their families, are exposed.

(3) Definitions

For purposes of this subsection:

(A) Migratory agricultural worker

The term "migratory agricultural worker" means an individual whose principal employment

is in agriculture, who has been so employed within the last 24 months, and who establishes for the purposes of such employment a temporary abode.

(B) Seasonal agricultural worker

The term "seasonal agricultural worker" means an individual whose principal employment is in agriculture on a seasonal basis and who is not a migratory agricultural worker.

(C) Agriculture

The term "agriculture" means farming in all its branches, including—

(i) cultivation and tillage of the soil;

(ii) the production, cultivation, growing, and harvesting of any commodity grown on, in, or as an adjunct to or part of a commodity grown in or on, the land; and

(iii) any practice (including preparation and processing for market and delivery to storage or to market or to carriers for transportation to market) performed by a farmer or on a farm incident to or in conjunction with an activity described in clause (ii).

(h) Homeless population

(1) In general

The Secretary may award grants for the purposes described in subsections (c), (e), and (f) for the planning and delivery of services to a special medically underserved population comprised of homeless individuals, including grants for innovative programs that provide outreach and comprehensive primary health services to homeless children and youth, children and youth at risk of homelessness, homeless veterans, and veterans at risk of homelessness.

(2) Required services

In addition to required primary health services (as defined in subsection (b)(1)), an entity that receives a grant under this subsection shall be required to provide substance abuse services as a condition of such grant.

(3) Supplement not supplant requirement

A grant awarded under this subsection shall be expended to supplement, and not supplant, the expenditures of the health center and the value of in kind contributions for the delivery of services to the population described in paragraph (1).

(4) Temporary continued provision of services to certain former homeless individuals

If any grantee under this subsection has provided services described in this section under the grant to a homeless individual, such grantee may, notwithstanding that the individual is no longer homeless as a result of becoming a resident in permanent housing, expend the grant to continue to provide such services to the individual for not more than 12 months.

(5) Definitions

For purposes of this section:

(A) Homeless individual

The term "homeless individual" means an individual who lacks housing (without regard to whether the individual is a member of a family), including an individual whose primary residence during the night is a supervised public or private facility that provides temporary living accommodations and an individual who is a resident in transitional housing.

(B) Substance use disorder services

The term "substance use disorder services" includes detoxification, risk reduction, outpatient treatment, residential treatment, and rehabilitation for substance abuse provided in settings other than hospitals.

(i) Residents of public housing

(1) In general

The Secretary may award grants for the purposes described in subsections (c), (e), and (f) for the planning and delivery of services to a special medically underserved population comprised of residents of public housing (such term, for purposes of this subsection, shall have the same meaning given such term in section 1437a(b)(1) of this title) and individuals living in areas immediately accessible to such public housing.

(2) Supplement not supplant

A grant awarded under this subsection shall be expended to supplement, and not supplant, the expenditures of the health center and the value of in kind contributions for the delivery of services to the population described in paragraph (1).

(3) Consultation with residents

The Secretary may not make a grant under paragraph (1) unless, with respect to the residents of the public housing involved, the applicant for the grant—

(A) has consulted with the residents in the preparation of the application for the grant; and

(B) agrees to provide for ongoing consultation with the residents regarding the planning and administration of the program carried out with the grant.

(j) Access grants

(1) In general

The Secretary may award grants to eligible health centers with a substantial number of clients with limited English speaking proficiency to provide translation, interpretation, and other such services for such clients with limited English speaking proficiency.

(2) Eligible health center

In this subsection, the term "eligible health center" means an entity that—

(A) is a health center as defined under subsection (a);

(B) provides health care services for clients for whom English is a second language; and

(C) has exceptional needs with respect to linguistic access or faces exceptional challenges with respect to linguistic access.

(3) Grant amount

The amount of a grant awarded to a center under this subsection shall be determined by the Administrator. Such determination of such amount shall be based on the number of clients for whom English is a second language that is served by such center, and larger grant amounts shall be awarded to centers serving larger numbers of such clients.

(4) Use of funds

An eligible health center that receives a grant under this subsection may use funds received through such grant to—

(A) provide translation, interpretation, and other such services for clients for whom English is a second language, including hiring professional translation and interpretation services; and

(B) compensate bilingual or multilingual staff for language assistance services provided by the staff for such clients.

(5) Application

An eligible health center desiring a grant under this subsection shall submit an application to the Secretary at such time, in such manner, and containing such information as the Secretary may reasonably require, including—

(A) an estimate of the number of clients that the center serves for whom English is a second language;

(B) the ratio of the number of clients for whom English is a second language to the total number of clients served by the center;

(C) a description of any language assistance services that the center proposes to provide to aid clients for whom English is a second language; and

(D) a description of the exceptional needs of such center with respect to linguistic access or a

description of the exceptional challenges faced by such center with respect to linguistic access.

(6) Authorization of appropriations

There are authorized to be appropriated to carry out this subsection, in addition to any funds authorized to be appropriated or appropriated for health centers under any other subsection of this section, such sums as may be necessary for each of fiscal years 2002 through 2006.

(k) Applications

(1) Submission

No grant may be made under this section unless an application therefore is submitted to, and approved by, the Secretary. Such an application shall be submitted in such form and manner and shall contain such information as the Secretary shall prescribe.

(2) Description of unmet need

An application for a grant under subparagraph (A) or (B) of subsection (e)(1) or subsection (e)(6) for a health center shall include—

(A) a description of the unmet need for health services in the catchment area of the center;

(B) a demonstration by the applicant that the area or the population group to be served by the applicant has a shortage of personal health services;

(C) a demonstration that the center will be located so that it will provide services to the greatest number of individuals residing in the catchment area or included in such population group; and

(D) in the case of an application for a grant pursuant to subsection (e)(6), a demonstration that the applicant has consulted with appropriate State and local government agencies, and health care providers regarding the need for the health services to be provided at the proposed delivery site.

Such a demonstration shall be made on the basis of the criteria prescribed by the Secretary under subsection (b)(3) or on any other criteria which the Secretary may prescribe to determine if the area or population group to be served by the applicant has a shortage of personal health services. In considering an application for a grant under subparagraph (A) or (B) of subsection (e)(1), the Secretary may require as a condition to the approval of such application an assurance that the applicant will provide any health service defined under paragraphs (1) and (2) of subsection (b) that the Secretary finds is needed to meet specific health needs of the area to be served by the applicant. Such a finding shall be made in writing and a copy shall be provided to the applicant.

(3) Requirements

Except as provided in subsection (e)(1)(B) or subsection (e)(6), the Secretary may not approve an application for a grant under subparagraph (A) or (B) of subsection (e)(1) unless the Secretary determines that the entity for which the application is submitted is a health center (within the meaning of subsection (a)) and that—

(A) the required primary health services of the center will be available and accessible in the catchment area of the center promptly, as appropriate, and in a manner which assures continuity;

(B) the center has made and will continue to make every reasonable effort to establish and maintain collaborative relationships with other health care providers, including other health care providers that provide care within the catchment area, local hospitals, and specialty providers in the catchment area of the center, to provide access to services not available through the health center and to reduce the non-urgent use of hospital emergency departments;

(C) the center will have an ongoing quality improvement system that includes clinical services and management, and that maintains the confidentiality of patient records;

(D) the center will demonstrate its financial responsibility by the use of such accounting procedures and other requirements as may be prescribed by the Secretary;

(E) the center—

(i)(I) has or will have a contractual or other arrangement with the agency of the State, in which it provides services, which administers or supervises the administration of a State plan approved under title XIX of the Social Security Act [42 U.S.C. 1396 et seq.] for the payment of all or a part of the center's costs in providing health services to persons who are eligible for medical assistance under such a State plan; and

(II) has or will have a contractual or other arrangement with the State agency administering the program under title XXI of such Act (42 U.S.C. 1397aa et seq.) with respect to individuals who are State children's health insurance program beneficiaries; or

(ii) has made or will make every reasonable effort to enter into arrangements described in subclauses (I) and (II) of clause (i);

(F) the center has made or will make and will continue to make every reasonable effort to collect appropriate reimbursement for its costs in providing health services to persons who are entitled to insurance benefits under title XVIII of the Social Security Act [42 U.S.C. 1395 et seq.], to medical assistance under a State plan approved under title XIX of such Act [42 U.S.C. 1396 et seq.], or to assistance for medical expenses under any other public assistance program or private health insurance program;

(G) the center—

(i) has prepared a schedule of fees or payments for the provision of its services consistent with locally prevailing rates or charges and designed to cover its reasonable costs of operation and has prepared a corresponding schedule of discounts to be applied to the payment of such fees or payments, which discounts are adjusted on the basis of the patient's ability to pay;

(ii) has made and will continue to make every reasonable effort—

(I) to secure from patients payment for services in accordance with such schedules; and

(II) to collect reimbursement for health services to persons described in subparagraph (F) on the basis of the full amount of fees and payments for such services without application of any discount;

(iii)(I) will assure that no patient will be denied health care services due to an individual's inability to pay for such services; and

(II) will assure that any fees or payments required by the center for such services will be reduced or waived to enable the center to fulfill the assurance described in subclause (I); and

(iv) has submitted to the Secretary such reports as the Secretary may require to determine compliance with this subparagraph;

(H) the center has established a governing board which except in the case of an entity operated by an Indian tribe or tribal or Indian organization under the Indian Self-Determination Act [25 U.S.C. 5321 et seq.] or an urban Indian organization under the Indian Health Care Improvement Act (25 U.S.C. 1651 et seq.)—

(i) is composed of individuals, a majority of whom are being served by the center and who, as a group, represent the individuals being served by the center;

(ii) meets at least once a month, selects the services to be provided by the center, schedules the hours during which such services will be provided, approves the center's annual budget, approves the selection of a director for the center who shall be directly employed by the center, and, except in the case of a governing board of a public center (as defined in the second sentence of this paragraph), establishes general policies for the center; and

(iii) in the case of an application for a second or subsequent grant for a public center, has approved the application or if the governing body has not approved the application, the failure of the governing body to approve the application was unreasonable;

except that, upon a showing of good cause the Secretary shall waive, for the length of the project period, all or part of the requirements of this subparagraph in the case of a health center

that receives a grant pursuant to subsection (g), (h), (i), or (p);

(I) the center has developed—

(i) an overall plan and budget that meets the requirements of the Secretary; and

(ii) an effective procedure for compiling and reporting to the Secretary such statistics and other information as the Secretary may require relating to—

(I) the costs of its operations;

(II) the patterns of use of its services;

(III) the availability, accessibility, and acceptability of its services; and

(IV) such other matters relating to operations of the applicant as the Secretary may require;

(J) the center will review periodically its catchment area to—

(i) ensure that the size of such area is such that the services to be provided through the center (including any satellite) are available and accessible to the residents of the area promptly and as appropriate;

(ii) ensure that the boundaries of such area conform, to the extent practicable, to relevant boundaries of political subdivisions, school districts, and Federal and State health and social service programs; and

(iii) ensure that the boundaries of such area eliminate, to the extent possible, barriers to access to the services of the center, including barriers resulting from the area's physical characteristics, its residential patterns, its economic and social grouping, and available transportation;

(K) in the case of a center which serves a population including a substantial proportion of individuals of limited English-speaking ability, the center has—

(i) developed a plan and made arrangements responsive to the needs of such population for providing services to the extent practicable in the language and cultural context most appropriate to such individuals; and

(ii) identified an individual on its staff who is fluent in both that language and in English and whose responsibilities shall include providing guidance to such individuals and to appropriate staff members with respect to cultural sensitivities and bridging linguistic and cultural differences;

(L) the center, has developed an ongoing referral relationship with one or more hospitals;

(M) the center encourages persons receiving or seeking health services from the center to participate in any public or private (including employer-offered) health programs or plans for which the persons are eligible, so long as the center, in complying with this subparagraph, does not violate the requirements of subparagraph (G)(iii)(I); and

(N) the center has written policies and procedures in place to ensure the appropriate use of Federal funds in compliance with applicable Federal statutes, regulations, and the terms and conditions of the Federal award.

For purposes of subparagraph (H), the term "public center" means a health center funded (or to be funded) through a grant under this section to a public agency.

(l) Technical assistance

The Secretary shall establish a program through which the Secretary shall provide (either through the Department of Health and Human Services or by grant or contract) technical and other assistance to eligible entities to assist such entities to meet the requirements of subsection (k)(3). Services provided through the program may include necessary technical and nonfinancial assistance, including fiscal and program management assistance, training in fiscal and program management, operational and administrative support, and the provision of information to the entities of the variety of resources available under this subchapter and how those resources can be best used to meet the health needs of the communities served by the entities. Funds expended to carry out activities under

this subsection and operational support activities under subsection (m) shall not exceed 3 percent of the amount appropriated for this section for the fiscal year involved.

(m) Memorandum of agreement

In carrying out this section, the Secretary may enter into a memorandum of agreement with a State. Such memorandum may include, where appropriate, provisions permitting such State to—

(1) analyze the need for primary health services for medically underserved populations within such State;

(2) assist in the planning and development of new health centers;

(3) review and comment upon annual program plans and budgets of health centers, including comments upon allocations of health care resources in the State;

(4) assist health centers in the development of clinical practices and fiscal and administrative systems through a technical assistance plan which is responsive to the requests of health centers; and

(5) share information and data relevant to the operation of new and existing health centers.

(n) Records

(1) In general

Each entity which receives a grant under subsection (e) shall establish and maintain such records as the Secretary shall require.

(2) Availability

Each entity which is required to establish and maintain records under this subsection shall make such books, documents, papers, and records available to the Secretary or the Comptroller General of the United States, or any of their duly authorized representatives, for examination, copying or mechanical reproduction on or off the premises of such entity upon a reasonable request therefore. The Secretary and the Comptroller General of the United States, or any of their duly authorized representatives, shall have the authority to conduct such examination, copying, and reproduction.

(o) Delegation of authority

The Secretary may delegate the authority to administer the programs authorized by this section to any office, except that the authority to enter into, modify, or issue approvals with respect to grants or contracts may be delegated only within the central office of the Health Resources and Services Administration.

(p) Special consideration

In making grants under this section, the Secretary shall give special consideration to the unique needs of sparsely populated rural areas, including giving priority in the awarding of grants for new health centers under subsections (c) and (e), and the granting of waivers as appropriate and permitted under subsections (b)(1)(B)(i) and (k)(3)(G).

(q) Audits

(1) In general

Each entity which receives a grant under this section shall provide for an independent annual financial audit of any books, accounts, financial records, files, and other papers and property which relate to the disposition or use of the funds received under such grant and such other funds received by or allocated to the project for which such grant was made. For purposes of assuring accurate, current, and complete disclosure of the disposition or use of the funds received, each such audit shall be conducted in accordance with generally accepted accounting principles. Each audit shall evaluate—

(A) the entity's implementation of the guidelines established by the Secretary respecting cost accounting,

(B) the processes used by the entity to meet the financial and program reporting requirements of the Secretary, and

(C) the billing and collection procedures of the entity and the relation of the procedures to its

fee schedule and schedule of discounts and to the availability of health insurance and public programs to pay for the health services it provides.

A report of each such audit shall be filed with the Secretary at such time and in such manner as the Secretary may require.

(2) Records

Each entity which receives a grant under this section shall establish and maintain such records as the Secretary shall by regulation require to facilitate the audit required by paragraph (1). The Secretary may specify by regulation the form and manner in which such records shall be established and maintained.

(3) Availability of records

Each entity which is required to establish and maintain records or to provide for and [1] audit under this subsection shall make such books, documents, papers, and records available to the Secretary or the Comptroller General of the United States, or any of their duly authorized representatives, for examination, copying or mechanical reproduction on or off the premises of such entity upon a reasonable request therefore. The Secretary and the Comptroller General of the United States, or any of their duly authorized representatives, shall have the authority to conduct such examination, copying, and reproduction.

(4) Waiver

The Secretary may, under appropriate circumstances, waive the application of all or part of the requirements of this subsection with respect to an entity. A waiver provided by the Secretary under this paragraph may not remain in effect for more than 1 year and may not be extended after such period. An entity may not receive more than one waiver under this paragraph in consecutive years.

(r) Authorization of appropriations

(1) General amounts for grants

For the purpose of carrying out this section, in addition to the amounts authorized to be appropriated under subsection (d), there is authorized to be appropriated the following:

(A) For fiscal year 2010, $2,988,821,592.
(B) For fiscal year 2011, $3,862,107,440.
(C) For fiscal year 2012, $4,990,553,440.
(D) For fiscal year 2013, $6,448,713,307.
(E) For fiscal year 2014, $7,332,924,155.
(F) For fiscal year 2015, $8,332,924,155.
(G) For fiscal year 2016, and each subsequent fiscal year, the amount appropriated for the preceding fiscal year adjusted by the product of—
(i) one plus the average percentage increase in costs incurred per patient served; and
(ii) one plus the average percentage increase in the total number of patients served.

(2) Special provisions

(A) Public centers

The Secretary may not expend in any fiscal year, for grants under this section to public centers (as defined in the second sentence of subsection (k)(3)) the governing boards of which (as described in subsection (k)(3)(H)) do not establish general policies for such centers, an amount which exceeds 5 percent of the amounts appropriated under this section for that fiscal year. For purposes of applying the preceding sentence, the term "public centers" shall not include health centers that receive grants pursuant to subsection (h) or (i).

(B) Distribution of grants

For fiscal year 2002 and each of the following fiscal years, the Secretary, in awarding grants under this section, shall ensure that the proportion of the amount made available under each of

subsections (g), (h), and (i), relative to the total amount appropriated to carry out this section for that fiscal year, is equal to the proportion of the amount made available under that subsection for fiscal year 2001, relative to the total amount appropriated to carry out this section for fiscal year 2001.

(3) Funding report

The Secretary shall annually prepare and submit to the Committee on Health, Education, Labor, and Pensions of the Senate, and the Committee on Energy and Commerce of the House of Representatives, a report including, at a minimum—

(A) the distribution of funds for carrying out this section that are provided to meet the health care needs of medically underserved populations, including the homeless, residents of public housing, and migratory and seasonal agricultural workers, and the appropriateness of the delivery systems involved in responding to the needs of the particular populations;

(B) an assessment of the relative health care access needs of the targeted populations;

(C) the distribution of awards and funding for new or expanded services in each of rural areas and urban areas;

(D) the distribution of awards and funding for establishing new access points, and the number of new access points created;

(E) the amount of unexpended funding for loan guarantees and loan guarantee authority under subchapter XIV;

(F) the rationale for any substantial changes in the distribution of funds;

(G) the rate of closures for health centers and access points;

(H) the number and reason for any grants awarded pursuant to subsection (e)(1)(B); and

(I) the number and reason for any waivers provided pursuant to subsection (q)(4).

(4) Rule of construction with respect to rural health clinics

(A) In general

Nothing in this section shall be construed to prevent a community health center from contracting with a Federally certified rural health clinic (as defined in section 1861(aa)(2) of the Social Security Act [42 U.S.C. 1395x(aa)(2)]), a low-volume hospital (as defined for purposes of section 1886 of such Act [42 U.S.C. 1395ww]), a critical access hospital, a sole community hospital (as defined for purposes of section 1886(d)(5)(D)(iii) of such Act), or a medicare-dependent share hospital (as defined for purposes of section 1886(d)(5)(G)(iv) of such Act) for the delivery of primary health care services that are available at the clinic or hospital to individuals who would otherwise be eligible for free or reduced cost care if that individual were able to obtain that care at the community health center. Such services may be limited in scope to those primary health care services available in that clinic or hospitals.[2]

(B) Assurances

In order for a clinic or hospital to receive funds under this section through a contract with a community health center under subparagraph (A), such clinic or hospital shall establish policies to ensure—

(i) nondiscrimination based on the ability of a patient to pay; and

(ii) the establishment of a sliding fee scale for low-income patients.

(5) Funding for participation of health centers in All of Us Research Program

In addition to any amounts made available pursuant to paragraph (1) of this subsection, section 282a of this title, or section 254b–2 of this title, there is authorized to be appropriated, and there is appropriated, out of any monies in the Treasury not otherwise appropriated, to the Secretary $25,000,000 for fiscal year 2018 to support the participation of health centers in the All of Us Research Program under the Precision Medicine Initiative under section 289g–5 of this title.

(6) Additional amounts for supplemental awards

In addition to any amounts made available pursuant to this subsection, section 282a of this title, or section 254b—2 of this title, there is authorized to be appropriated, and there is appropriated,

out of any monies in the Treasury not otherwise appropriated, $1,320,000,000 for fiscal year 2020 for supplemental awards under subsection (d) for the detection of SARS–CoV–2 or the prevention, diagnosis, and treatment of COVID–19.

(July 1, 1944, ch. 373, title III, §330, as added Pub. L. 104–299, §2, Oct. 11, 1996, 110 Stat. 3626; amended Pub. L. 107–251, title I, §101, Oct. 26, 2002, 116 Stat. 1622; Pub. L. 108–163, §2(a), Dec. 6, 2003, 117 Stat. 2020; Pub. L. 110–355, §2(a), (c)(1), Oct. 8, 2008, 122 Stat. 3988, 3992; Pub. L. 111–148, title IV, §4206, title V, §5601, Mar. 23, 2010, 124 Stat. 576, 676; Pub. L. 115–123, div. E, title IX, §50901(b), Feb. 9, 2018, 132 Stat. 283; Pub. L. 116–136, div. A, title III, §3211(a), Mar. 27, 2020, 134 Stat. 368; Pub. L. 116–260, div. BB, title III, §311(c), Dec. 27, 2020, 134 Stat. 2925; Pub. L. 117–204, §2(a), Oct. 17, 2022, 136 Stat. 2231.)

EDITORIAL NOTES

REFERENCES IN TEXT

The Social Security Act, referred to in subsec. (k)(3)(E)(i), (F), is act Aug. 14, 1935, ch. 531, 49 Stat. 620. Titles XVIII, XIX, and XXI of the Act are classified generally to subchapters XVIII (§1395 et seq.), XIX (§1396 et seq.), and XXI (§1397aa et seq.), respectively, of chapter 7 of this title. For complete classification of this Act to the Code, see section 1305 of this title and Tables.

The Indian Self-Determination Act, referred to in subsec. (k)(3)(H), is title I of Pub. L. 93–638, Jan. 4, 1975, 88 Stat. 2206, which is classified principally to subchapter I (§5321 et seq.) of chapter 46 of Title 25, Indians. For complete classification of this Act to the Code, see Short Title note set out under section 5301 of Title 25 and Tables.

The Indian Health Care Improvement Act, referred to in subsec. (k)(3)(H), is Pub. L. 94–437, Sept. 30, 1976, 90 Stat. 1400, which is classified principally to chapter 18 (§1601 et seq.) of Title 25. For complete classification of this Act to the Code, see Short Title note set out under section 1601 of Title 25 and Tables.

PRIOR PROVISIONS

A prior section 254a–1, act July 1, 1944, ch. 373, title III, §328, as added Nov. 10, 1978, Pub. L. 95–626, title I, §114, 92 Stat. 3563; amended Pub. L. 96–88, title V, §509(b), Oct. 17, 1979, 93 Stat. 695, related to hospital-affiliated primary care centers, prior to repeal by Pub. L. 99–117, §12(c), Oct. 7, 1985, 99 Stat. 495.

A prior section 254b, act July 1, 1944, ch. 373, title III, §329, formerly §310, as added Sept. 25, 1962, Pub. L. 87–692, 76 Stat. 592; amended Aug. 5, 1965, Pub. L. 89–109, §3, 79 Stat. 436; Oct. 15, 1968, Pub. L. 90–574, title II, §201, 82 Stat. 1006; Mar. 12, 1970, Pub. L. 91–209, 84 Stat. 52; June 18, 1973, Pub. L. 93–45, title I, §105, 87 Stat. 91; renumbered §319, July 23, 1974, Pub. L. 93–353, title I, §102(d), 88 Stat. 362; amended July 29, 1975, Pub. L. 94–63, title IV, §401(a), title VII, §701(c), 89 Stat. 334, 352; Apr. 22, 1976, Pub. L. 94–278, title VIII, §801(a), 90 Stat. 414; Aug. 1, 1977, Pub. L. 95–83, title III, §303, 91 Stat. 388; renumbered §329 and amended Nov. 10, 1978, Pub. L. 95–626, title I, §§102(a), 103(a)–(g)(1)(B), (2), (h), (i), 92 Stat. 3551–3555; July 10, 1979, Pub. L. 96–32, §6(a), 93 Stat. 83; Oct. 17, 1979, Pub. L. 96–88, title V, §509(b), 93 Stat. 695; Aug. 13, 1981, Pub. L. 97–35, title IX, §930, 95 Stat. 569; Dec. 21, 1982, Pub. L. 97–375, title I, §107(b), 96 Stat. 1820; Apr. 24, 1986, Pub. L. 99–280, §§6, 7, 100 Stat. 400, 401; Aug. 10, 1988, Pub. L. 100–386, §2, 102 Stat. 919; Nov. 6, 1990, Pub. L. 101–527, §9(b), 104 Stat. 2333; Oct. 27, 1992, Pub. L. 102–531, title III, §309(a), 106 Stat. 3499, related to migrant health centers, prior to the general amendment of this subpart by Pub. L. 104–299, §2.

Another prior section 254b, act July 1, 1944, ch. 373, title III, §329, as added Dec. 31, 1970, Pub. L. 91–623, §2, 84 Stat. 1868; amended Nov. 18, 1971, Pub. L. 92–157, title II, §203, 85 Stat. 462; Oct. 27, 1972, Pub. L. 92–585, §2, 86 Stat. 1290; July 29, 1975, Pub. L. 94–63, title VIII, §§801–803, 89 Stat. 353, 354; Oct. 12, 1976, Pub. L. 94–484, title I, §101(b), 90 Stat. 2244, related to establishment of National Health Service Corps, assignment of personnel and statement of purpose, prior to repeal by Pub. L. 94–484, title IV, §407(b)(1), Oct. 12, 1976, 90 Stat. 2268. See section 254d et seq. of this title.

A prior section 330 of act July 1, 1944, was classified to section 254c of this title prior to the general amendment of this subpart by Pub. L. 104–299.

AMENDMENTS

2022—Subsec. (e)(6)(A)(v). Pub. L. 117–204 added cl. (v).

2020—Subsec. (d)(1)(H). Pub. L. 116–260 added subpar. (H).

Subsec. (r)(6). Pub. L. 116–136 added par. (6).

2018—Subsec. (b)(1)(A)(ii), (2)(A). Pub. L. 115–123, §50901(b)(1), (2), substituted "use disorder" for

"abuse".

Subsec. (c)(1). Pub. L. 115–123, §50901(b)(3), substituted "Centers" for "In general" in heading, struck out subpar. (A) designation and heading, redesignated cls. (i) to (v) of former subpar. (A) as subpars. (A) to (E), respectively, realigned margins, and struck out former subpars. (B) to (D) which related to managed care networks and plans, practice management networks, and use of funds, respectively.

Subsec. (d). Pub. L. 115–123, §50901(b)(4), added subsec. (d) and struck out former subsec. (d) which related to loan guarantee program.

Subsec. (e)(1)(B). Pub. L. 115–123, §50901(b)(5)(A), substituted "1 year" for "2 years" and inserted at end "The Secretary shall not make a grant under this paragraph unless the applicant provides assurances to the Secretary that within 120 days of receiving grant funding for the operation of the health center, the applicant will submit, for approval by the Secretary, an implementation plan to meet the requirements of subsection (k)(3). The Secretary may extend such 120-day period for achieving compliance upon a demonstration of good cause by the health center."

Subsec. (e)(1)(C). Pub. L. 115–123, §50901(b)(5)(B), in heading, struck out "and plans" after "networks", and in text, struck out "or plan (as described in subparagraphs (B) and (C) of subsection (c)(1))" after "to a network", substituted "including—" for "or plan, including", inserted cl. (i) designation before "the purchase" and ", which may include data and information systems" after "of equipment", and added cls. (ii) and (iii).

Subsec. (e)(5)(B). Pub. L. 115–123, §50901(b)(6), in heading, struck out "and plans" after "Networks" and in text, substituted "to a health center or to a network" for "and subparagraphs (B) and (C) of subsection (c)(1) to a health center or to a network or plan".

Subsec. (e)(6). Pub. L. 115–123, §50901(b)(7), added par. (6).

Subsec. (h)(1). Pub. L. 115–123, §50901(b)(8)(A), substituted ", children and youth at risk of homelessness, homeless veterans, and veterans at risk of homelessness" for "and children and youth at risk of homelessness".

Subsec. (h)(5)(B). Pub. L. 115–123, §50901(b)(8)(B)(iii)(II), which directed substitution of "use disorder" for "abuse", was executed by making the substitution the first place it appeared, to reflect the probable intent of Congress.

Pub. L. 115–123, §50901(b)(8)(B)(iii)(I), substituted "use disorder" for "abuse" in heading.

Pub. L. 115–123, §50901(b)(8)(B)(i), (ii), redesignated subpar. (C) as (B) and struck out former subpar. (B). Prior to amendment, text of subpar. (B) read as follows: "The term 'substance abuse' has the same meaning given such term in section 290cc–34(4) of this title."

Subsec. (h)(5)(C). Pub. L. 115–123, §50901(b)(8)(B)(ii), redesignated subpar. (C) as (B).

Subsec. (k)(2). Pub. L. 115–123, §50901(b)(9)(A)(i), (ii), in heading, inserted "unmet" before "need", and in introductory provisions, inserted "or subsection (e)(6)" after "subsection (e)(1)".

Subsec. (k)(2)(A). Pub. L. 115–123, §50901(b)(9)(A)(iii), inserted "unmet" before "need for health services".

Subsec. (k)(2)(D). Pub. L. 115–123, §50901(b)(9)(A)(iv)–(vi), added subpar. (D).

Subsec. (k)(3). Pub. L. 115–123, §50901(b)(9)(B)(i), inserted "or subsection (e)(6)" after "subsection (e)(1)(B)" in introductory provisions.

Subsec. (k)(3)(B). Pub. L. 115–123, §50901(b)(9)(B)(ii), substituted ", including other health care providers that provide care within the catchment area, local hospitals, and specialty providers in the catchment area of the center, to provide access to services not available through the health center and to reduce the non-urgent use of hospital emergency departments" for "in the catchment area of the center".

Subsec. (k)(3)(H)(ii). Pub. L. 115–123, §50901(b)(9)(B)(iii), inserted "who shall be directly employed by the center" after "approves the selection of a director for the center".

Subsec. (k)(3)(N). Pub. L. 115–123, §50901(b)(9)(B)(iv)–(vi), added subpar. (N).

Subsec. (k)(4). Pub. L. 115–123, §50901(b)(9)(C), struck out par. (4) which related to approval of new or expanded service applications.

Subsec. (l). Pub. L. 115–123, §50901(b)(10), inserted at end "Funds expended to carry out activities under this subsection and operational support activities under subsection (m) shall not exceed 3 percent of the amount appropriated for this section for the fiscal year involved."

Subsec. (q)(4). Pub. L. 115–123, §50901(b)(11), inserted at end "A waiver provided by the Secretary under this paragraph may not remain in effect for more than 1 year and may not be extended after such period. An entity may not receive more than one waiver under this paragraph in consecutive years."

Subsec. (r)(3). Pub. L. 115–123, §50901(b)(12), substituted "Committee on Health, Education, Labor, and Pensions of the Senate, and the Committee on Energy and Commerce of the House of Representatives, a report including, at a minimum—" for "appropriate committees of Congress a report concerning the distribution of funds under this section", inserted "(A) the distribution of funds for carrying out this section" before "that are provided", substituted "particular populations;" for "particular populations. Such report shall

include", inserted subsec. (B) designation before "an assessment", substituted "targeted populations;" for "targeted populations and the rationale for any substantial changes in the distribution of funds.", and added subpars. (C) to (I).

Subsec. (r)(5). Pub. L. 115–123, §50901(b)(13), added par. (5).

Subsec. (s). Pub. L. 115–123, §50901(b)(14), struck out subsec. (s) which related to demonstration program for individualized wellness plans.

2010—Subsec. (r)(1). Pub. L. 111–148, §5601(a), added par. (1) and struck out former par. (1). Prior to amendment, text read as follows: "For the purpose of carrying out this section, in addition to the amounts authorized to be appropriated under subsection (d), there are authorized to be appropriated—

"(A) $2,065,000,000 for fiscal year 2008;

"(B) $2,313,000,000 for fiscal year 2009;

"(C) $2,602,000,000 for fiscal year 2010;

"(D) $2,940,000,000 for fiscal year 2011; and

"(E) $3,337,000,000 for fiscal year 2012."

Subsec. (r)(4). Pub. L. 111–148, §5601(b), added par. (4).

Subsec. (s). Pub. L. 111–148, §4206, added subsec. (s).

2008—Subsec. (c)(3). Pub. L. 110–355, §2(c)(1), added par. (3).

Subsec. (r)(1). Pub. L. 110–355, §2(a), amended par. (1) generally. Prior to amendment, text read as follows: "For the purpose of carrying out this section, in addition to the amounts authorized to be appropriated under subsection (d) of this section, there are authorized to be appropriated $1,340,000,000 for fiscal year 2002 and such sums as may be necessary for each of the fiscal years 2003 through 2006."

2003—Subsec. (c)(1)(B). Pub. L. 108–163, §2(a)(2)(A), substituted "plan." for "plan.." in introductory provisions.

Subsec. (d)(1)(B)(iii)(I). Pub. L. 108–163, §2(a)(2)(B), inserted "or" at end.

Subsec. (e)(3) to (5). Pub. L. 108–163, §2(a)(1)(A), amended pars. (3) to (5) to read as if subpar. (C) of the second par. (4) of section 101 of Pub. L. 107–251 had not been enacted. See 2002 Amendment notes below.

Subsec. (j). Pub. L. 108–163, §2(a)(2)(E), added subsec. (j) identical to the subsec. (j) appearing in the amendment by section 101(8)(C) of Pub. L. 107–251. See 2002 Amendment notes below. Former subsec. (j) redesignated (k).

Pub. L. 108–163, §2(a)(1)(C), amended subsec. (j) to read as if pars. (8) through (11) of section 101 of Pub. L. 107–251 had not been enacted. See 2002 Amendment notes below.

Subsec. (j)(3)(H). Pub. L. 108–163, §2(a)(1)(B), amended subpar. (H) to read as if subpar. (C) of par. (7) of section 101 of Pub. L. 107–251 had not been enacted. See 2002 Amendment note below.

Subsec. (k). Pub. L. 108–163, §2(a)(2)(C), (D), redesignated subsec. (j) as (k) and struck out heading and text of former subsec. (k). Text read as follows: "The Secretary may provide (either through the Department of Health and Human Services or by grant or contract) all necessary technical and other nonfinancial assistance (including fiscal and program management assistance and training in such management) to any public or private nonprofit entity to assist entities in developing plans for, or operating as, health centers, and in meeting the requirements of subsection (j)(2) of this section."

Pub. L. 108–163, §2(a)(1)(C), amended subsec. (k) to read as if pars. (8) through (11) of section 101 of Pub. L. 107–251 had not been enacted. See 2002 Amendment notes below.

Subsec. (l). Pub. L. 108–163, §2(a)(2)(H), inserted "(either through the Department of Health and Human Services or by grant or contract)" after "shall provide" and substituted "(k)(3)" for "(l)(3)".

Pub. L. 108–163, §2(a)(2)(G), added subsec. (l) identical to the subsec. (m) appearing in the amendment by section 101(9) of Pub. L. 107–251. See 2002 Amendment notes below. Former subsec. (l) redesignated (r).

Pub. L. 108–163, §2(a)(1)(C), amended subsec. (l) to read as if pars. (8) through (11) of section 101 of Pub. L. 107–251 had not been enacted. See 2002 Amendment note below.

Subsecs. (m) to (o). Pub. L. 108–163, §2(a)(1)(C), amended subsecs. (m) to (o) to read as if pars. (8) through (11) of section 101 of Pub. L. 107–251 had not been enacted. See 2002 Amendment notes below.

Subsec. (p). Pub. L. 108–163, §2(a)(2)(I), substituted "(k)(3)(G)" for "(j)(3)(G)".

Pub. L. 108–163, §2(a)(1)(C), amended subsec. (p) to read as if pars. (8) through (11) of section 101 of Pub. L. 107–251 had not been enacted. See 2002 Amendment note below.

Subsec. (q). Pub. L. 108–163, §2(a)(1)(C), amended subsec. (q) to read as if pars. (8) through (11) of section 101 of Pub. L. 107–251 had not been enacted. See 2002 Amendment note below.

Subsec. (r). Pub. L. 108–163, §2(a)(2)(F), redesignated subsec. (l) as (r).

Pub. L. 108–163, §2(a)(1)(C), amended subsec. (r) to read as if pars. (8) through (11) of section 101 of Pub. L. 107–251 had not been enacted. See 2002 Amendment note below.

Subsec. (r)(1). Pub. L. 108–163, §2(a)(2)(J)(i), substituted "$1,340,000,000 for fiscal year 2002 and such

sums as may be necessary for each of the fiscal years 2003 through 2006" for "$802,124,000 for fiscal year 1997, and such sums as may be necessary for each of the fiscal years 1998 through 2001".

Subsec. (r)(2)(A). Pub. L. 108–163, §2(a)(2)(J)(ii), substituted "(k)(3)" for "(j)(3)" and "(k)(3)(H)" for "(j)(3)(G)(ii)".

Subsec. (r)(2)(B). Pub. L. 108–163, §2(a)(2)(J)(iii), added subpar. (B) identical to the subpar. (B) appearing in the amendment by section 101(11)(B)(ii) of Pub. L. 107–251 and struck out heading and text of former subpar. (B) relating to distribution of grants for fiscal years 1997 through 1999. See 2002 Amendment note below.

Subsec. (s). Pub. L. 108–163, §2(a)(1)(C), amended subsec. (s) to read as if pars. (8) through (11) of section 101 of Pub. L. 107–251 had not been enacted. See 2002 Amendment notes below.

2002—Subsec. (b)(1)(A)(i)(III)(bb). Pub. L. 107–251, §101(1)(A), substituted "appropriate cancer screening" for "screening for breast and cervical cancer".

Subsec. (b)(1)(A)(ii). Pub. L. 107–251, §101(1)(B), inserted "(including specialty referral when medically indicated)" after "medical services".

Subsec. (b)(1)(A)(iii). Pub. L. 107–251, §101(1)(C), inserted "housing," after "social,".

Subsec. (b)(2)(A). Pub. L. 107–251, §101(2)(C), added subpar. (A). Former subpar. (A) redesignated (C).

Subsec. (b)(2)(A)(i). Pub. L. 107–251, §101(2)(A), substituted "associated with—" and subcls. (I) to (IV) for "associated with water supply;".

Subsec. (b)(2)(B) to (D). Pub. L. 107–251, §101(2)(B), (C), added subpar. (B) and redesignated former subpars. (A) and (B) as (C) and (D), respectively.

Subsec. (c)(1)(B). Pub. L. 107–251, §101(3)(A)(iii), struck out concluding provisions which read as follows: "Any such grant may include the acquisition and lease of buildings and equipment which may include data and information systems (including the costs of amortizing the principal of, and paying the interest on, loans), and providing training and technical assistance related to the provision of health services on a prepaid basis or under another managed care arrangement, and for other purposes that promote the development of managed care networks and plans."

Pub. L. 107–251, §101(3)(A)(ii), in introductory provisions, substituted "managed care network or plan." for "network or plan for the provision of health services, which may include the provision of health services on a prepaid basis or through another managed care arrangement, to some or to all of the individuals which the centers serve".

Pub. L. 107–251, §101(3)(A)(i), substituted "Managed care" for "Comprehensive service delivery" in heading.

Subsec. (c)(1)(C), (D). Pub. L. 107–251, §101(3)(B), added subpars. (C) and (D).

Subsec. (d). Pub. L. 107–251, §101(4)(A), substituted "Loan guarantee program" for "Managed care loan guarantee program" in heading.

Subsec. (d)(1)(A). Pub. L. 107–251, §101(4)(B)(i), substituted "up to 90 percent of the principal and interest on loans made by non-Federal lenders to health centers, funded under this section, for the costs of developing and operating managed care networks or plans described in subsection (c)(1)(B), or practice management networks described in subsection (c)(1)(C)" for "the principal and interest on loans made by non-Federal lenders to health centers funded under this section for the costs of developing and operating managed care networks or plans".

Subsec. (d)(1)(B)(iii). Pub. L. 107–251, §101(4)(B)(ii), added cl. (iii).

Subsec. (d)(1)(D), (E). Pub. L. 107–251, §101(4)(B)(iii), added subpars. (D) and (E).

Subsec. (d)(6) to (8). Pub. L. 107–251, §101(4)(C), redesignated par. (8) as (6) and struck out headings and text of former pars. (6) and (7) which related to annual reports and program evaluation, respectively.

Subsec. (e)(1)(B). Pub. L. 107–251, §101(4)(A)(i), substituted "subsection (k)(3)" for "subsection (j)(3)".

Subsec. (e)(1)(C). Pub. L. 107–251, §101(4)(A)(ii), added subpar. (C).

Subsec. (e)(3). Pub. L. 107–251, §101(4)(C), redesignated par. (4), relating to limitation, as (3).

Subsec. (e)(4). Pub. L. 107–251, §101(4)(C), redesignated par. (5) as (4). Former par. (4) redesignated (3).

Subsec. (e)(5). Pub. L. 107–251, §101(4)(B), (C), redesignated par. (5) as (4), inserted "subparagraphs (A) and (B) of" after "any fiscal year under" in subpar. (A), added subpar. (B), and redesignated former subpars. (B) and (C) as (C) and (D), respectively.

Subsec. (g)(2)(A). Pub. L. 107–251, §101(5)(A)(i), inserted "and seasonal agricultural worker" after "migratory agricultural worker".

Subsec. (g)(2)(B). Pub. L. 107–251, §101(5)(A)(ii), substituted "and seasonal agricultural workers, and members of their families," for "and members of their families".

Subsec. (g)(3)(A). Pub. L. 107–251, §101(5)(B), struck out "on a seasonal basis" after "in agriculture".

Subsec. (h)(1). Pub. L. 107–251, §101(6)(A), substituted "homeless children and youth and children and

youth at risk of homelessness" for "homeless children and children at risk of homelessness".

Subsec. (h)(4). Pub. L. 107–251, §101(6)(B)(ii), added par. (4). Former par. (4) redesignated (5).

Subsec. (h)(5). Pub. L. 107–251, §101(6)(B)(i), (C), redesignated par. (4) as (5) and substituted ", risk reduction, outpatient treatment, residential treatment, and rehabilitation" for "and residential treatment" in subpar. (C).

Subsec. (j). Pub. L. 107–251, §101(8)(C), added subsec. (j) relating to access grants.

Pub. L. 107–251, §101(8)(B), which directed the redesignation of subsecs. (j), (k), and (m) through (q) as subsecs. (n), (o), and (p) through (s), respectively, could not be executed.

Subsec. (j)(3)(E)(i). Pub. L. 107–251, §101(7)(A)(i), designated existing provisions as subcl. (I) and added subcl. (II).

Subsec. (j)(3)(E)(ii). Pub. L. 107–251, §101(7)(A)(ii), substituted "arrangements described in subclauses (I) and (II) of clause (i)" for "such an arrangement".

Subsec. (j)(3)(G)(iii), (iv). Pub. L. 107–251, §101(7)(B), added cl. (iii) and redesignated former cl. (iii) as (iv).

Subsec. (j)(3)(H). Pub. L. 107–251, §101(7)(C), substituted "or (q)" for "or (p)" in concluding provisions.

Subsec. (j)(3)(M). Pub. L. 107–251, §101(7)(D)–(F), added subpar. (M).

Subsec. (k). Pub. L. 107–251, §101(8)(B), which directed the redesignation of subsecs. (j), (k), and (m) through (q) as subsecs. (n), (o), and (p) through (s), respectively, could not be executed.

Subsec. (l). Pub. L. 107–251, §101(8)(A), redesignated subsec. (l) as (s).

Subsec. (m). Pub. L. 107–251, §101(9), which directed striking subsec. (m) (as redesignated by paragraph (9)(B)) and adding a new subsec. (m), could not be executed. The new subsec. (m) to be added read as follows: "(m) TECHNICAL ASSISTANCE.—The Secretary shall establish a program through which the Secretary shall provide technical and other assistance to eligible entities to assist such entities to meet the requirements of subsection (l)(3). Services provided through the program may include necessary technical and nonfinancial assistance, including fiscal and program management assistance, training in fiscal and program management, operational and administrative support, and the provision of information to the entities of the variety of resources available under this subchapter and how those resources can be best used to meet the health needs of the communities served by the entities."

Pub. L. 107–251, §101(8)(B), which directed the redesignation of subsecs. (j), (k), and (m) through (q) as subsecs. (n), (o), and (p) through (s), respectively, could not be executed.

Subsecs. (n) to (p). Pub. L. 107–251, §101(8)(B), which directed the redesignation of subsecs. (j), (k), and (m) through (q) as subsecs. (n), (o), and (p) through (s), respectively, could not be executed.

Subsec. (q). Pub. L. 107–251, §101(10), which directed the substitution of "(l)(3)(G)" for "(j)(3)(G)" in subsec. (q) "(as redesignated by paragraph (9)(B))", could not be executed.

Pub. L. 107–251, §101(8)(B), which directed the redesignation of subsecs. (j), (k), and (m) through (q) as subsecs. (n), (o), and (p) through (s), respectively, could not be executed.

Subsec. (r). Pub. L. 107–251, §101(8)(B), which directed the redesignation of subsecs. (j), (k), and (m) through (q) as subsecs. (n), (o), and (p) through (s), respectively, could not be executed.

Subsec. (s). Pub. L. 107–251, §101(8)(B), which directed the redesignation of subsecs. (j), (k), and (m) through (q) as subsecs. (n), (o), and (p) through (s), respectively, could not be executed.

Subsec. (s)(1). Pub. L. 107–251, §101(11)(A), substituted "$1,340,000,000 for fiscal year 2002 and such sums as may be necessary for each of the fiscal years 2003 through 2006" for "$802,124,000 for fiscal year 1997, and such sums as may be necessary for each of the fiscal years 1998 through 2001".

Subsec. (s)(2)(A). Pub. L. 107–251, §101(11)(B)(i), substituted "(l)(3)" for "(j)(3)" and "(l)(3)(H)" for "(j)(3)(G)(ii)".

Subsec. (s)(2)(B). Pub. L. 107–251, §101(11)(B)(ii), added subpar. (B) and struck out heading and text of former subpar. (B) relating to distribution of grants for fiscal years 1997 through 1999.

STATUTORY NOTES AND RELATED SUBSIDIARIES

EFFECTIVE DATE OF 2022 AMENDMENT

Pub. L. 117–204, §2(b), Oct. 17, 2022, 136 Stat. 2231, provided that: "The amendment made by subsection (a) [amending this section] shall take effect on January 1, 2024."

EFFECTIVE DATE OF 2008 AMENDMENT

Pub. L. 110–355, §2(c)(2), Oct. 8, 2008, 122 Stat. 3992, provided that: "The amendment made by paragraph (1) [amending this section] shall apply to grants made on or after January 1, 2009."

EFFECTIVE DATE OF 2003 AMENDMENT

Amendments by Pub. L. 108–163 deemed to have taken effect immediately after the enactment of Pub. L. 107–251, see section 3 of Pub. L. 108–163, set out as a note under section 233 of this title.

EFFECTIVE DATE

Section effective Oct. 1, 1996, see section 5 of Pub. L. 104–299, as amended, set out as an Effective Date of 1996 Amendment note under section 233 of this title.

SAVINGS PROVISION FOR CURRENT GRANTS, CONTRACTS, AND COOPERATIVE AGREEMENTS

Pub. L. 104–299, §3(b), Oct. 11, 1996, 110 Stat. 3644, provided that: "The Secretary of Health and Human Services shall ensure the continued funding of grants made, or contracts or cooperative agreements entered into, under subpart I of part D of title III of the Public Health Service Act (42 U.S.C. 254b et seq.) (as such subpart existed on the day prior to the date of enactment of this Act [Oct. 11, 1996]), until the expiration of the grant period or the term of the contract or cooperative agreement. Such funding shall be continued under the same terms and conditions as were in effect on the date on which the grant, contract or cooperative agreement was awarded, subject to the availability of appropriations."

NEGOTIATED RULEMAKING FOR DEVELOPMENT OF METHODOLOGY AND CRITERIA FOR DESIGNATING MEDICALLY UNDERSERVED POPULATIONS AND HEALTH PROFESSIONS SHORTAGE AREAS

Pub. L. 111–148, title V, §5602, Mar. 23, 2010, 124 Stat. 677, provided that:

"(a) ESTABLISHMENT.—

"(1) IN GENERAL.—The Secretary of Health and Human Services (in this section referred to as the 'Secretary') shall establish, through a negotiated rulemaking process under subchapter 3 [III] of chapter 5 of title 5, United States Code, a comprehensive methodology and criteria for designation of—

"(A) medically underserved populations in accordance with section 330(b)(3) of the Public Health Service Act (42 U.S.C. 254b(b)(3));

"(B) health professions shortage areas under section 332 of the Public Health Service Act (42 U.S.C. 254e).

"(2) FACTORS TO CONSIDER.—In establishing the methodology and criteria under paragraph (1), the Secretary—

"(A) shall consult with relevant stakeholders who will be significantly affected by a rule (such as national, State and regional organizations representing affected entities), State health offices, community organizations, health centers and other affected entities, and other interested parties; and

"(B) shall take into account—

"(i) the timely availability and appropriateness of data used to determine a designation to potential applicants for such designations;

"(ii) the impact of the methodology and criteria on communities of various types and on health centers and other safety net providers;

"(iii) the degree of ease or difficulty that will face potential applicants for such designations in securing the necessary data; and

"(iv) the extent to which the methodology accurately measures various barriers that confront individuals and population groups in seeking health care services.

"(b) PUBLICATION OF NOTICE.—In carrying out the rulemaking process under this subsection, the Secretary shall publish the notice provided for under section 564(a) of title 5, United States Code, by not later than 45 days after the date of the enactment of this Act [Mar. 23, 2010].

"(c) TARGET DATE FOR PUBLICATION OF RULE.—As part of the notice under subsection (b), and for purposes of this subsection, the 'target date for publication', as referred to in section 564(a)(5) of title 5, United Sates [sic] Code, shall be July 1, 2010.

"(d) APPOINTMENT OF NEGOTIATED RULEMAKING COMMITTEE AND FACILITATOR.—The Secretary shall provide for—

"(1) the appointment of a negotiated rulemaking committee under section 565(a) of title 5, United States Code, by not later than 30 days after the end of the comment period provided for under section 564(c) of such title; and

"(2) the nomination of a facilitator under section 566(c) of such title 5 by not later than 10 days after the date of appointment of the committee.

"(e) PRELIMINARY COMMITTEE REPORT.—The negotiated rulemaking committee appointed under

subsection (d) shall report to the Secretary, by not later than April 1, 2010, regarding the committee's progress on achieving a consensus with regard to the rulemaking proceeding and whether such consensus is likely to occur before one month before the target date for publication of the rule. If the committee reports that the committee has failed to make significant progress toward such consensus or is unlikely to reach such consensus by the target date, the Secretary may terminate such process and provide for the publication of a rule under this section through such other methods as the Secretary may provide.

"(f) FINAL COMMITTEE REPORT.—If the committee is not terminated under subsection (e), the rulemaking committee shall submit a report containing a proposed rule by not later than one month before the target publication date.

"(g) INTERIM FINAL EFFECT.—The Secretary shall publish a rule under this section in the Federal Register by not later than the target publication date. Such rule shall be effective and final immediately on an interim basis, but is subject to change and revision after public notice and opportunity for a period (of not less than 90 days) for public comment. In connection with such rule, the Secretary shall specify the process for the timely review and approval of applications for such designations pursuant to such rules and consistent with this section.

"(h) PUBLICATION OF RULE AFTER PUBLIC COMMENT.—The Secretary shall provide for consideration of such comments and republication of such rule by not later than 1 year after the target publication date."

FUNDING FOR COMMUNITY HEALTH CENTERS AND COMMUNITY CARE

Pub. L. 117–2, title II, §2601, Mar. 11, 2021, 135 Stat. 43, provided that:

"(a) IN GENERAL.—In addition to amounts otherwise available, there is appropriated to the Secretary of Health and Human Services (in this subtitle [subtitle G (§§2601–2605) of title II of Pub. L 117–2, see Tables for classification] referred to as the 'Secretary') for fiscal year 2021, out of any money in the Treasury not otherwise appropriated, $7,600,000,000, to remain available until expended, for necessary expenses for awarding grants and cooperative agreements under section 330 of the Public Health Service Act (42 U.S.C. 254b) to be awarded without regard to the time limitation in subsection (e)(3) and subsections (e)(6)(A)(iii), (e)(6)(B)(iii), and (r)(2)(B) of such section 330, and for necessary expenses for awarding grants to Federally qualified health centers, as described in section 1861(aa)(4)(B) of the Social Security Act (42 U.S.C. 1395x(aa)(4)(B)), and for awarding grants or contracts to Papa Ola Lokahi and to qualified entities under sections 4 and 6 of the Native Hawaiian Health Care Improvement Act (42 U.S.C. 11703, 11705). Of the total amount appropriated by the preceding sentence, not less than $20,000,000 shall be for grants or contracts to Papa Ola Lokahi and to qualified entities under sections 4 and 6 of the Native Hawaiian Health Care Improvement Act (42 U.S.C. 11703, 11705).

"(b) USE OF FUNDS.—Amounts made available to an awardee pursuant to subsection (a) shall be used—

"(1) to plan, prepare for, promote, distribute, administer, and track COVID–19 vaccines, and to carry out other vaccine-related activities;

"(2) to detect, diagnose, trace, and monitor COVID–19 infections and related activities necessary to mitigate the spread of COVID–19, including activities related to, and equipment or supplies purchased for, testing, contact tracing, surveillance, mitigation, and treatment of COVID–19;

"(3) to purchase equipment and supplies to conduct mobile testing or vaccinations for COVID–19, to purchase and maintain mobile vehicles and equipment to conduct such testing or vaccinations, and to hire and train laboratory personnel and other staff to conduct such mobile testing or vaccinations, particularly in medically underserved areas;

"(4) to establish, expand, and sustain the health care workforce to prevent, prepare for, and respond to COVID–19, and to carry out other health workforce-related activities;

"(5) to modify, enhance, and expand health care services and infrastructure; and

"(6) to conduct community outreach and education activities related to COVID–19.

"(c) PAST EXPENDITURES.—An awardee may use amounts awarded pursuant to subsection (a) to cover the costs of the awardee carrying out any of the activities described in subsection (b) during the period beginning on the date of the declaration of a public health emergency by the Secretary under section 319 of the Public Health Service Act (42 U.S.C. 247d) on January 31, 2020, with respect to COVID–19 and ending on the date of such award."

STUDIES RELATING TO COMMUNITY HEALTH CENTERS

Pub. L. 110–355, §2(b)(1)–(3), Oct. 8, 2008, 122 Stat. 3988, 3989, provided that:

"(1) DEFINITIONS.—For purposes of this subsection—

"(A) the term 'community health center' means a health center receiving assistance under section 330 of the Public Health Service Act (42 U.S.C. 254b); and

"(B) the term 'medically underserved population' has the meaning given that term in such section 330.

"(2) SCHOOL-BASED HEALTH CENTER STUDY.—

"(A) IN GENERAL.—Not later than 2 years after the date of enactment of this Act [Oct. 8, 2008], the Comptroller General of the United States shall issue a study of the economic costs and benefits of school-based health centers and the impact on the health of students of these centers.

"(B) CONTENT.—In conducting the study under subparagraph (A), the Comptroller General of the United States shall analyze—

"(i) the impact that Federal funding could have on the operation of school-based health centers;

"(ii) any cost savings to other Federal programs derived from providing health services in school-based health centers;

"(iii) the effect on the Federal Budget and the health of students of providing Federal funds to school-based health centers and clinics, including the result of providing disease prevention and nutrition information;

"(iv) the impact of access to health care from school-based health centers in rural or underserved areas; and

"(v) other sources of Federal funding for school-based health centers.

"(3) HEALTH CARE QUALITY STUDY.—

"(A) IN GENERAL.—Not later than 1 year after the date of enactment of this Act [Oct. 8, 2008], the Secretary of Health and Human Services (referred to in this Act [see Short Title of 2008 Amendment note set out under section 201 of this title] as the 'Secretary'), acting through the Administrator of the Health Resources and Services Administration, and in collaboration with the Agency for Healthcare Research and Quality, shall prepare and submit to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives a report that describes agency efforts to expand and accelerate quality improvement activities in community health centers.

"(B) CONTENT.—The report under subparagraph (A) shall focus on—

"(i) Federal efforts, as of the date of enactment of this Act, regarding health care quality in community health centers, including quality data collection, analysis, and reporting requirements;

"(ii) identification of effective models for quality improvement in community health centers, which may include models that—

"(I) incorporate care coordination, disease management, and other services demonstrated to improve care;

"(II) are designed to address multiple, co-occurring diseases and conditions;

"(III) improve access to providers through non-traditional means, such as the use of remote monitoring equipment;

"(IV) target various medically underserved populations, including uninsured patient populations;

"(V) increase access to specialty care, including referrals and diagnostic testing; and

"(VI) enhance the use of electronic health records to improve quality;

"(iii) efforts to determine how effective quality improvement models may be adapted for implementation by community health centers that vary by size, budget, staffing, services offered, populations served, and other characteristics determined appropriate by the Secretary;

"(iv) types of technical assistance and resources provided to community health centers that may facilitate the implementation of quality improvement interventions;

"(v) proposed or adopted methodologies for community health center evaluations of quality improvement interventions, including any development of new measures that are tailored to safety-net, community-based providers;

"(vi) successful strategies for sustaining quality improvement interventions in the long-term; and

"(vii) partnerships with other Federal agencies and private organizations or networks as appropriate, to enhance health care quality in community health centers.

"(C) DISSEMINATION.—The Administrator of the Health Resources and Services Administration shall establish a formal mechanism or mechanisms for the ongoing dissemination of agency initiatives, best practices, and other information that may assist health care quality improvement efforts in community health centers."

GUARANTEE STUDY

Pub. L. 107–251, title V, §501, Oct. 26, 2002, 116 Stat. 1664, as amended by Pub. L. 108–163, §2(n)(2), Dec. 6, 2003, 117 Stat. 2023, required the Secretary of Health and Human Services to conduct a study regarding the ability of the Department of Health and Human Services to provide for guarantees of solvency

for managed care networks or plans involving health centers receiving funding under this section and to prepare and submit a report to Congress regarding such ability by 2 years after Oct. 26, 2002.

REFERENCE TO COMMUNITY, MIGRANT, PUBLIC HOUSING, OR HOMELESS HEALTH CENTER CONSIDERED REFERENCE TO HEALTH CENTER

Pub. L. 104–299, §4(c), Oct. 11, 1996, 110 Stat. 3645, provided that: "Whenever any reference is made in any provision of law, regulation, rule, record, or document to a community health center, migrant health center, public housing health center, or homeless health center, such reference shall be considered a reference to a health center."

LEGISLATIVE PROPOSAL FOR CHANGES CONFORMING TO PUB. L. 104–299

Pub. L. 104–299, §4(e), Oct. 11, 1996, 110 Stat. 3645, provided that: "After consultation with the appropriate committees of the Congress, the Secretary of Health and Human Services shall prepare and submit to the Congress a legislative proposal in the form of an implementing bill containing technical and conforming amendments to reflect the changes made by this Act [see Short Title of 1996 Amendments note set out under section 201 of this title]."

EXECUTIVE DOCUMENTS

EX. ORD. NO. 13937. ACCESS TO AFFORDABLE LIFE-SAVING MEDICATIONS

Ex. Ord. No. 13937, July 24, 2020, 85 F.R. 45755, provided:

By the authority vested in me as President by the Constitution and the laws of the United States of America, it is hereby ordered as follows:

SECTION 1. *Purpose*. Insulin is a critical and life-saving medication that approximately 8 million Americans rely on to manage diabetes. Likewise, injectable epinephrine is a life-saving medication used to stop severe allergic reactions.

The price of insulin in the United States has risen dramatically over the past decade. The list price for a single vial of insulin today is often more than $250 and most patients use at least two vials per month. As for injectable epinephrine, recent increased competition is helping to drive prices down. Nevertheless, the price for some types of injectable epinephrine remains more than $600 per kit. While Americans with diabetes and severe allergic reactions may have access to affordable insulin and injectable epinephrine through commercial insurance or Federal programs such as Medicare and Medicaid, many Americans still struggle to purchase these products.

Federally Qualified Health Centers (FQHCs), as defined in section 1905(l)(2)(B)(i) and (ii) of the Social Security Act, as amended, 42 U.S.C. 1396d(l)(2)(B)(i) and (ii), receive discounted prices through the 340B Prescription Drug Program on prescription drugs. Due to the sharp increases in list prices for many insulins and some types of injectable epinephrine in recent years, many of these products may be subject to the "penny pricing" policy when distributed to FQHCs, meaning FQHCs may purchase the drug at a price of one penny per unit of measure. These steep discounts, however, are not always passed through to low-income Americans at the point of sale. Those with low-incomes can be exposed to high insulin and injectable epinephrine prices, as they often do not benefit from discounts negotiated by insurers or the Federal or State governments.

SEC. 2. *Policy*. It is the policy of the United States to enable Americans without access to affordable insulin and injectable epinephrine through commercial insurance or Federal programs, such as Medicare and Medicaid, to purchase these pharmaceuticals from an FQHC at a price that aligns with the cost at which the FQHC acquired the medication.

SEC. 3. *Improving the Availability of Insulin and Injectable Epinephrine for the Uninsured*. To the extent permitted by law, the Secretary of Health and Human Services shall take action to ensure future grants available under section 330(e) of the Public Health Service Act, as amended, 42 U.S.C. 254b(e), are conditioned upon FQHCs' having established practices to make insulin and injectable epinephrine available at the discounted price paid by the FQHC grantee or sub-grantee under the 340B Prescription Drug Program (plus a minimal administration fee) to individuals with low incomes, as determined by the Secretary, who:

(a) have a high cost sharing requirement for either insulin or injectable epinephrine;

(b) have a high unmet deductible; or

(c) have no health care insurance.

SEC. 4. *General Provisions*. (a) Nothing in this order shall be construed to impair or otherwise affect:

(i) the authority granted by law to an executive department or agency, or the head thereof;

(ii) the functions of the Director of the Office of Management and Budget relating to budgetary, administrative, or legislative proposals.

(b) This order shall be implemented consistent with applicable law and subject to the availability of appropriations.

(c) This order is not intended to, and does not, create any right or benefit, substantive or procedural, enforceable at law or in equity by any party against the United States, its departments, agencies, or entities, its officers, employees, or agents, or any other person.

DONALD J. TRUMP.

MEDICARE DEMONSTRATION TO TEST MEDICAL HOMES IN FEDERALLY QUALIFIED HEALTH CENTERS

Memorandum of President of the United States, Dec. 9, 2009, 74 F.R. 66207, provided:

Memorandum for the Secretary of Health And Human Services

My Administration is committed to building a high-quality, efficient health care system and improving access to health care for all Americans. Health centers are a vital part of the health care delivery system. For more than 40 years, health centers have served populations with limited access to health care, treating all patients regardless of ability to pay. These include low-income populations, the uninsured, individuals with limited English proficiency, migrant and seasonal farm workers, individuals and families experiencing homelessness, and individuals living in public housing. There are over 1,100 health centers across the country, delivering care at over 7,500 sites. These centers served more than 17 million patients in 2008 and are estimated to serve more than 20 million patients in 2010.

The American Recovery and Reinvestment Act of 2009 (Recovery Act) provided $2 billion for health centers, including $500 million to expand health centers' services to over 2 million new patients by opening new health center sites, adding new providers, and improving hours of operations. An additional $1.5 billion is supporting much-needed capital improvements, including funding to buy equipment, modernize clinic facilities, expand into new facilities, and adopt or expand the use of health information technology and electronic health records.

One of the key benefits health centers provide to the communities they serve is quality primary health care services. Health centers use interdisciplinary teams to treat the "whole patient" and focus on chronic disease management to reduce the use of costlier providers of care, such as emergency rooms and hospitals.

Federally qualified health centers provide an excellent environment to demonstrate the further improvements to health care that may be offered by the medical homes approach. In general, this approach emphasizes the patient's relationship with a primary care provider who coordinates the patient's care and serves as the patient's principal point of contact for care. The medical homes approach also emphasizes activities related to quality improvement, access to care, communication with patients, and care management and coordination. These activities are expected to improve the quality and efficiency of care and to help avoid preventable emergency and inpatient hospital care. Demonstration programs establishing the medical homes approach have been recommended by the Medicare Payment Advisory Commission, an independent advisory body to the Congress.

Therefore, I direct you to implement a Medicare Federally Qualified Health Center Advanced Primary Care Practice demonstration, pursuant to your statutory authority to conduct experiments and demonstrations on changes in payments and services that may improve the quality and efficiency of services to beneficiaries. Health centers participating in this demonstration must have shown their ability to provide comprehensive, coordinated, integrated, and accessible health care.

This memorandum is not intended to, and does not, create any right or benefit, substantive or procedural, enforceable at law or in equity by any party against the United States, its departments, agencies, or entities, its officers, employees, or agents, or any other person.

You are authorized and directed to publish this memorandum in the Federal Register.

BARACK OBAMA.

[1] So in original. Probably should be "an".

[2] So in original. Probably should be "hospital".

§254b–1. State grants to health care providers who provide services to a high percentage of medically underserved populations or other special populations

(a) In general

A State may award grants to health care providers who treat a high percentage, as determined by such State, of medically underserved populations or other special populations in such State.

(b) Source of funds

A grant program established by a State under subsection (a) may not be established within a department, agency, or other entity of such State that administers the Medicaid program under title XIX of the Social Security Act (42 U.S.C. 1396 et seq.), and no Federal or State funds allocated to such Medicaid program, the Medicare program under title XVIII of the Social Security Act (42 U.S.C. 1395 et seq.), or the TRICARE program under chapter 55 of title 10 may be used to award grants or to pay administrative costs associated with a grant program established under subsection (a).

(Pub. L. 111–148, title V, §5606, as added Pub. L. 111–148, title X, §10501(k), Mar. 23, 2010, 124 Stat. 999.)

EDITORIAL NOTES

REFERENCES IN TEXT

The Social Security Act, referred to in subsec. (b), is act Aug. 14, 1935, ch. 531, 49 Stat. 620. Titles XVIII and XIX of the Act are classified generally to subchapters XVIII (§1395 et seq.) and XIX (§1396 et seq.), respectively, of chapter 7 of this title. For complete classification of this Act to the Code, see section 1305 of this title and Tables.

CODIFICATION

Section was enacted as part of the Patient Protection and Affordable Care Act, and not as part of the Public Health Service Act which comprises this chapter.

§254b–2. Community health centers and the National Health Service Corps Fund

(a) Purpose

It is the purpose of this section to establish a Community Health Center Fund (referred to in this section as the "CHC Fund"), to be administered through the Office of the Secretary of the Department of Health and Human Services to provide for expanded and sustained national investment in community health centers under section 254b of this title and the National Health Service Corps.

(b) Funding

There is authorized to be appropriated, and there is appropriated, out of any monies in the Treasury not otherwise appropriated, to the CHC Fund—

(1) to be transferred to the Secretary of Health and Human Services to provide enhanced funding for the community health center program under section 254b of this title—

(A) $1,000,000,000 for fiscal year 2011;
(B) $1,200,000,000 for fiscal year 2012;
(C) $1,500,000,000 for fiscal year 2013;
(D) $2,200,000,000 for fiscal year 2014;
(E) $3,600,000,000 for each of fiscal years 2015 through 2017;
(F) $3,800,000,000 for fiscal year 2018;
(G) $4,000,000,000 for each of fiscal years 2019 through 2023;
(H) $4,236,712,328 for fiscal year 2024;
(I) $4,295,287,671 for fiscal year 2025;
(J) $4,600,000,000 for fiscal year 2026; and
(K) $1,159,452,055 for the period beginning on October 1, 2026, and ending on December 31, 2026; and

(2) to be transferred to the Secretary of Health and Human Services to provide enhanced funding for the National Health Service Corps—

(A) $290,000,000 for fiscal year 2011;
(B) $295,000,000 for fiscal year 2012;
(C) $300,000,000 for fiscal year 2013;
(D) $305,000,000 for fiscal year 2014;
(E) $310,000,000 for each of fiscal years 2015 through 2017;
(F) $310,000,000 for each of fiscal years 2018 and 2019;
(G) $310,000,000 for fiscal year 2020;
(H) $310,000,000 for each of fiscal years 2021 through 2023;
(I) $341,208,605 for fiscal year 2024;
(J) $349,736,600 for fiscal year 2025;
(K) $350,000,000 for fiscal year 2026; and
(L) $88,219,178 for the period beginning on October 1, 2026, and ending on December 31, 2026.

(c) Construction

There is authorized to be appropriated, and there is appropriated, out of any monies in the Treasury not otherwise appropriated, $1,500,000,000 to be available for fiscal years 2011 through 2015 to be used by the Secretary of Health and Human Services for the construction and renovation of community health centers.

(d) Use of fund

The Secretary of Health and Human Services shall transfer amounts in the CHC Fund to accounts within the Department of Health and Human Services to increase funding, over the fiscal year 2008 level, for community health centers and the National Health Service Corps.

(e) Availability

Amounts appropriated under subsections (b) and (c) shall remain available until expended.

(Pub. L. 111–148, title X, §10503, Mar. 23, 2010, 124 Stat. 1004; Pub. L. 111–152, title II, §2303, Mar. 30, 2010, 124 Stat. 1083; Pub. L. 114–10, title II, §221(a), Apr. 16, 2015, 129 Stat. 154; Pub. L. 115–96, div. C, title I, §3101(a), (b), Dec. 22, 2017, 131 Stat. 2048; Pub. L. 115–123, div. E, title IX, §50901(a), (c), Feb. 9, 2018, 132 Stat. 282, 287; Pub. L. 116–59, div. B, title I, §1101(a), (b), Sept. 27, 2019, 133 Stat. 1102; Pub. L. 116–69, div. B, title I, §1101(a), (b), Nov. 21, 2019, 133 Stat. 1136; Pub. L. 116–94, div. N, title I, §401(a), (b), Dec. 20, 2019, 133 Stat. 3113; Pub. L. 116–136, div. A, title III, §3831(a), (b), Mar. 27, 2020, 134 Stat. 433; Pub. L. 116–159, div. C, title I, §2101(a), (b), Oct. 1, 2020, 134 Stat. 728; Pub. L. 116–215, div. B, title II, §1201(a), (b), Dec. 11, 2020, 134 Stat. 1044; Pub. L. 116–260, div. BB, title III, §301(a), (b), Dec. 27, 2020, 134 Stat. 2922; Pub. L. 118–15, div. B, title III, §2321(b), (c), Sept. 30, 2023, 137 Stat. 94, 95; Pub. L. 118–22, div. B, title II, §201(b), (c), Nov. 17, 2023, 137 Stat. 119, 120; Pub. L. 118–35, div. B, title I, §101(b), (c), Jan. 19, 2024, 138 Stat. 4; Pub. L. 118–42, div. G, title I, §101(a), (b), Mar. 9, 2024, 138 Stat. 397; Pub. L. 118–158, div. C, title I, §3101(a), (b), Dec. 21, 2024, 138 Stat. 1762; Pub. L. 119–4, div. B, title I, §2101(a), (b), Mar. 15, 2025, 139 Stat. 40; Pub. L. 119–37, div. F, title I, §6101(a), (b), Nov. 12, 2025, 139 Stat. 629; Pub. L. 119–75, div. J, title IV, §6401, Feb. 3, 2026, 140 Stat. 686.)

EDITORIAL NOTES

CODIFICATION

Section was enacted as part of the Patient Protection and Affordable Care Act, and not as part of the Public Health Service Act which comprises this chapter.

AMENDMENTS

2026—Subsec. (b)(1)(H) to (K). Pub. L. 119–75, §6401(a), added subpars. (H) to (K) and struck out former subpars. (H) to (K) whcih read as follows: "

(H) $526,027,397 for the period beginning on October 1, 2023, and ending on November 17, 2023, $690,410,959 for the period beginning on November 18, 2023, and ending on January 19, 2024, $536,986,301 for the period beginning on January 20, 2024, and ending on March 8, 2024, and $3,592,328,767 for the period beginning on October 1, 2023, and ending on December 31, 2024;

"(I) $1,050,410,959 for the period beginning on January 1, 2025, and ending on March 31, 2025;

"(J) $2,135,835,616 for the period beginning on April 1, 2025, and ending on September 30, 2025; and

"(K) $1,423,890,411 for the period beginning on October 1, 2025, and ending on January 30, 2026; and".

Subsec. (b)(2)(I) to (L). Pub. L. 119–75, §6401(b), added subpars. (I) to (L) and struck out former subpars. (I) to (L) which read as follows:

"(I) $40,767,123 for the period beginning on October 1, 2023, and ending on November 17, 2023, $53,506,849 for the period beginning on November 18, 2023, and ending on January 19, 2024, $41,616,438 for the period beginning on January 20, 2024, and ending on March 8, 2024, and $297,013,699 for the period beginning on October 1, 2023, and ending on December 31, 2024;

"(J) $85,068,493 for the period beginning on January 1, 2025, and ending on March 31, 2025;

"(K) $172,972,603 for the period beginning on April 1, 2025, and ending on September 30, 2025; and

"(L) $115,315,068 for the period beginning on October 1, 2025, and ending on January 30, 2026."

2025—Subsec. (b)(1)(J). Pub. L. 119–4, §2101(a), added subpar. (J).

Subsec. (b)(1)(K). Pub. L. 119–37, §6101(a), added subpar. (K).

Subsec. (b)(2)(K). Pub. L. 119–4, §2101(b), added subpar. (K).

Subsec. (b)(2)(L). Pub. L. 119–37, §6101(b), added subpar. (L).

2024—Subsec. (b)(1)(F). Pub. L. 118–158, §3101(a)(2), substituted semicolon for ", $4,000,000,000 for each of fiscal years 2019 through 2023, $526,027,397 for the period beginning on October 1, 2023, and ending on November 17, 2023, $690,410,959 for the period beginning on November 18, 2023, and ending on January 19, 2024, $536,986,301 for the period beginning on January 20, 2024, and ending on March 8, 2024, and $3,592,328,767 for the period beginning on October 1, 2023, and ending on December 31, 2024; and".

Pub. L. 118–42, §101(a), substituted "$536,986,301 for the period beginning on January 20, 2024, and ending on March 8, 2024, and $3,592,328,767 for the period beginning on October 1, 2023, and ending on December 31, 2024" for "and $536,986,301 for the period beginning on January 20, 2024, and ending on March 8, 2024".

Pub. L. 118–35, §101(b), substituted "$690,410,959 for the period beginning on November 18, 2023, and ending on January 19, 2024, and $536,986,301 for the period beginning on January 20, 2024, and ending on March 8, 2024" for "and $690,410,959 for the period beginning on November 18, 2023, and ending on January 19, 2024".

Subsec. (b)(1)(G) to (I). Pub. L. 118–158, §3101(a)(1), (3), added subpars. (G) to (I).

Subsec. (b)(2)(I). Pub. L. 118–42, §101(b), substituted "$41,616,438 for the period beginning on January 20, 2024, and ending on March 8, 2024, and $297,013,699 for the period beginning on October 1, 2023, and ending on December 31, 2024" for "and $41,616,438 for the period beginning on January 20, 2024, and ending on March 8, 2024".

Pub. L. 118–35, §101(c), substituted "$53,506,849 for the period beginning on November 18, 2023, and ending on January 19, 2024, and $41,616,438 for the period beginning on January 20, 2024, and ending on March 8, 2024" for "and $53,506,849 for the period beginning on November 18, 2023, and ending on January 19, 2024".

Subsec. (b)(2)(J). Pub. L. 118–158, §3101(b), added subpar. (J).

2023—Subsec. (b)(1)(F). Pub. L. 118–22, §201(b), substituted "$526,027,397 for the period beginning on October 1, 2023, and ending on November 17, 2023, and $690,410,959 for the period beginning on November 18, 2023, and ending on January 19, 2024" for "and $526,027,397 for the period beginning on October 1, 2023, and ending on November 17, 2023".

Pub. L. 118–15, §2321(b), substituted ", $4,000,000,000" for "and $4,000,000,000" and inserted ", and $526,027,397 for the period beginning on October 1, 2023, and ending on November 17, 2023" before the semicolon.

Subsec. (b)(2)(I). Pub. L. 118–22, §201(c), substituted "$40,767,123 for the period beginning on October 1, 2023, and ending on November 17, 2023, and $53,506,849 for the period beginning on November 18, 2023, and ending on January 19, 2024" for "$40,767,123 for the period beginning on October 1, 2023, and ending on November 17, 2023".

Pub. L. 118–15, §2321(c), added subpar. (I).

2020—Subsec. (b)(1)(F). Pub. L. 116–260, §301(a), substituted "and $4,000,000,000 for each of fiscal years 2019 through 2023" for ", $4,000,000,000 for fiscal year 2019, $4,000,000,000 for fiscal year 2020, and $865,753,425 for the period beginning on October 1, 2020, and ending on December 18, 2020".

Pub. L. 116–215, §1201(a), substituted "$865,753,425" for "$789,041,096" and "December 18, 2020" for "December 11, 2020".

Pub. L. 116–159, §2101(a), substituted "$789,041,096" for "$668,493,151" and "December 11, 2020" for "November 30, 2020".

Pub. L. 116–136, §3831(a), substituted "$4,000,000,000 for fiscal year 2020, and $668,493,151 for the period beginning on October 1, 2020, and ending on November 30, 2020" for "and $2,575,342,466 for the period beginning on October 1, 2019, and ending on May 22, 2020".

Subsec. (b)(2)(G). Pub. L. 116–136, §3831(b), added subpar. (G) and struck out former subpar. (G) which read as follows: "$199,589,041 for the period beginning on October 1, 2019, and ending on May 22, 2020."

Subsec. (b)(2)(H). Pub. L. 116–260, §301(b), substituted "$310,000,000 for each of fiscal years 2021 through 2023" for "$67,095,890 for the period beginning on October 1, 2020, and ending on December 18, 2020".

Pub. L. 116–215, §1201(b), substituted "$67,095,890" for '$61,150,685" and "December 18, 2020" for "December 11, 2020".

Pub. L. 116–159, §2101(b), substituted "$61,150,685" for "$51,808,219" and "December 11, 2020" for "November 30, 2020".

Pub. L. 116–136, §3831(b), added subpar. (H).

2019—Subsec. (b)(1)(F). Pub. L. 116–94, §401(a), substituted "$2,575,342,466" for "$887,671,223" and "May 22, 2020" for "December 20, 2019".

Pub. L. 116–69, §1101(a), substituted "$887,671,223" for "$569,863,014" and "December 20, 2019" for "November 21, 2019".

Pub. L. 116–59, §1101(a), substituted "2018, $4,000,000,000 for fiscal year 2019, and $569,863,014 for the period beginning on October 1, 2019, and ending on November 21, 2019; and" for "2018 and $4,000,000,000 for fiscal year 2019."

Subsec. (b)(2)(G). Pub. L. 116–94, §401(b), substituted "$199,589,041" for "$68,794,521" and "May 22, 2020" for "December 20, 2019".

Pub. L. 116–69, §1101(a), substituted "$887,671,223" for "$569,863,014" and "December 20, 2019" for "November 21, 2019".

Pub. L. 116–59, §1101(b), added subpar. (G).

2018—Subsec. (b)(1)(F). Pub. L. 115–123, §50901(a), amended subpar. (F) generally. Prior to amendment, subpar. (F) read as follows: "$550,000,000 for the period of the first and second quarters of fiscal year 2018;".

Subsec. (b)(2)(F). Pub. L. 115–123, §50901(c), amended subpar. (F) generally. Prior to amendment, subpar. (F) read as follows: "$65,000,000 for period of the first and second quarters of fiscal year 2018."

2017—Subsec. (b)(1)(F). Pub. L. 115–96, §3101(a), added subpar. (F).

Subsec. (b)(2)(F). Pub. L. 115–96, §3101(b), added subpar. (F).

2015—Subsec. (b)(1)(E), (2)(E). Pub. L. 114–10 substituted "for each of fiscal years 2015 through 2017" for "for fiscal year 2015".

2010—Subsec. (b)(1)(A). Pub. L. 111–152, §2303(1), substituted "1,000,000,000" for "700,000,000".

Subsec. (b)(1)(B). Pub. L. 111–152, §2303(2), substituted "1,200,000,000" for "800,000,000".

Subsec. (b)(1)(C). Pub. L. 111–152, §2303(3), substituted "1,500,000,000" for "1,000,000,000".

Subsec. (b)(1)(D). Pub. L. 111–152, §2303(4), substituted "2,200,000,000" for "1,600,000,000".

Subsec. (b)(1)(E). Pub. L. 111–152, §2303(5), substituted "3,600,000,000" for "2,900,000,000".

§254c. Rural health care services outreach, rural health network development, and small health care provider quality improvement grant programs

(a) Purpose

The purpose of this section is to provide grants for expanded delivery of health care services in rural areas, for the planning and implementation of integrated health care networks in rural areas, and for the planning and implementation of small health care provider quality improvement activities.

(b) Definitions

(1) Director

The term "Director" means the Director specified in subsection (d).

(2) Federally qualified health center; rural health clinic

The terms "Federally qualified health center" and "rural health clinic" have the meanings given the terms in section 1395x(aa) of this title.

(3) Health professional shortage area

The term "health professional shortage area" means a health professional shortage area designated under section 254e of this title.

(4) Medically underserved community

The term "medically underserved community" has the meaning given the term in section 295p(6) of this title.

(5) Medically underserved population

The term "medically underserved population" has the meaning given the term in section 254b(b)(3) of this title.

(c) Program

The Secretary shall establish, under section 241 of this title, a small health care provider quality improvement grant program.

(d) Administration

(1) Programs

The rural health care services outreach, rural health network development, and small health care provider quality improvement grant programs established under section 241 of this title shall be administered by the Director of the Office of Rural Health Policy of the Health Resources and Services Administration, in consultation with State offices of rural health or other appropriate State government entities.

(2) Grants

(A) In general

In carrying out the programs described in paragraph (1), the Director may award grants under subsections (e), (f), and (g) to expand access to, coordinate, and improve the quality of basic health care services, and enhance the delivery of health care, in rural areas.

(B) Types of grants

The Director may award the grants to—

(i) promote expanded delivery of health care services in rural areas under subsection (e);

(ii) provide for the planning and implementation of integrated health care networks in rural areas under subsection (f); and

(iii) provide for the planning and implementation of small health care provider quality improvement activities under subsection (g).

(e) Rural health care services outreach grants

(1) Grants

The Director may award grants to eligible entities to promote rural health care services outreach by improving and expanding the delivery of health care services to include new and enhanced services in rural areas, through community engagement and evidence-based or innovative, evidence-informed models. The Director may award the grants for periods of not more than 5 years.

(2) Eligibility

To be eligible to receive a grant under this subsection for a project, an entity shall—

(A) be an entity with demonstrated experience serving, or the capacity to serve, rural underserved populations;

(B) represent a consortium composed of members that—

(i) include 3 or more health care providers; and

(ii) may be nonprofit or for-profit entities; and

(C) not previously have received a grant under this subsection for the same or a similar project, unless the entity is proposing to expand the scope of the project or the area that will be served through the project.

(3) Applications

To be eligible to receive a grant under this subsection, an eligible entity, in consultation with the appropriate State office of rural health or another appropriate State entity, shall prepare and submit to the Secretary an application, at such time, in such manner, and containing such information as the Secretary may require, including—

(A) a description of the project that the eligible entity will carry out using the funds provided under the grant;

(B) a description of the manner in which the project funded under the grant will meet the health care needs of rural underserved populations in the local community or region to be served;

(C) a description of how the rural underserved populations in the local community or region to be served will be involved in the development and ongoing operations of the project;

(D) a plan for sustaining the project after Federal support for the project has ended;

(E) a description of how the project will be evaluated; and

(F) other such information as the Secretary determines to be appropriate.

(f) Rural health network development grants

(1) Grants

(A) In general

The Director may award rural health network development grants to eligible entities to plan, develop, and implement integrated health care networks that collaborate in order to—

(i) achieve efficiencies;

(ii) expand access to, coordinate, and improve the quality of basic health care services and associated health outcomes; and

(iii) strengthen the rural health care system as a whole.

(B) Grant periods

The Director may award grants under this subsection for periods of not more than 5 years.

(2) Eligibility

To be eligible to receive a grant under this subsection, an entity shall—

(A) be an entity with demonstrated experience serving, or the capacity to serve, rural underserved populations;

(B) represent a network composed of participants that—

(i) include 3 or more health care providers; and

(ii) may be nonprofit or for-profit entities; and

(C) not previously have received a grant under this subsection (other than a grant for planning activities) for the same or a similar project.

(3) Applications

To be eligible to receive a grant under this subsection, an eligible entity, in consultation with the appropriate State office of rural health or another appropriate State entity, shall prepare and submit to the Secretary an application, at such time, in such manner, and containing such information as the Secretary may require, including—

(A) a description of the project that the eligible entity will carry out using the funds provided under the grant;

(B) an explanation of the reasons why Federal assistance is required to carry out the project;

(C) a description of—

(i) the history of collaborative activities carried out by the participants in the network;

(ii) the degree to which the participants are ready to integrate their functions; and

(iii) how the rural underserved populations in the local community or region to be served will benefit from and be involved in the development and ongoing operations of the network;

(D) a description of how the rural underserved populations in the local community or region to be served will experience increased access to quality health care services across the continuum of care as a result of the integration activities carried out by the network;

(E) a plan for sustaining the project after Federal support for the project has ended;

(F) a description of how the project will be evaluated; and

(G) other such information as the Secretary determines to be appropriate.

(g) Small health care provider quality improvement grants

(1) Grants

The Director may award grants to provide for the planning and implementation of small health care provider quality improvement activities, including activities related to increasing care coordination, enhancing chronic disease management, and improving patient health outcomes. The Director may award the grants for periods of 1 to 5 years.

(2) Eligibility

To be eligible for a grant under this subsection, an entity shall—

(A)(i) be a rural public or rural nonprofit private health care provider or provider of health care services, such as a critical access hospital or a rural health clinic; or

(ii) be another rural provider or network of small rural providers identified by the Secretary as a key source of local or regional care; and

(B) not previously have received a grant under this subsection for the same or a similar project.

(3) Applications

To be eligible to receive a grant under this subsection, an eligible entity, in consultation with the appropriate State office of rural health or another appropriate State entity shall prepare and submit to the Secretary an application, at such time, in such manner, and containing such information as the Secretary may require, including—

(A) a description of the project that the eligible entity will carry out using the funds provided under the grant;

(B) an explanation of the reasons why Federal assistance is required to carry out the project;

(C) a description of the manner in which the project funded under the grant will assure continuous quality improvement in the provision of services by the entity;

(D) a description of how the rural underserved populations in the local community or region to be served will experience increased access to quality health care services across the continuum of care as a result of the activities carried out by the entity;

(E) a plan for sustaining the project after Federal support for the project has ended;

(F) a description of how the project will be evaluated; and

(G) other such information as the Secretary determines to be appropriate.

(4) Expenditures for small health care provider quality improvement grants

In awarding a grant under this subsection, the Director shall ensure that the funds made available through the grant will be used to provide services to residents of rural areas. The Director shall award not less than 50 percent of the funds made available under this subsection to providers located in and serving rural areas.

(h) General requirements

(1) Prohibited uses of funds

An entity that receives a grant under this section may not use funds provided through the

grant—

(A) to build or acquire real property; or

(B) for construction.

(2) Coordination with other agencies

The Secretary shall coordinate activities carried out under grant programs described in this section, to the extent practicable, with Federal and State agencies and nonprofit organizations that are operating similar grant programs, to maximize the effect of public dollars in funding meritorious proposals.

(3) Preference

In awarding grants under this section, the Secretary, as appropriate, shall give preference to entities that—

(A) are located in health professional shortage areas or medically underserved communities, or serve medically underserved populations; or

(B) propose to develop projects with a focus on primary care, and wellness and prevention strategies.

(i) Report

Not later than 4 years after March 27, 2020, and every 5 years thereafter, the Secretary shall prepare and submit to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives a report on the activities and outcomes of the grant programs under subsections (e), (f), and (g), including the impact of projects funded under such programs on the health status of rural residents with chronic conditions.

(j) Authorization of appropriations

There are authorized to be appropriated to carry out this section $79,500,000 for each of fiscal years 2021 through 2025.

(July 1, 1944, ch. 373, title III, §330A, as added Pub. L. 104–299, §3(a), Oct. 11, 1996, 110 Stat. 3642; amended Pub. L. 107–251, title II, §201, Oct. 26, 2002, 116 Stat. 1628; Pub. L. 108–163, §2(b), Dec. 6, 2003, 117 Stat. 2021; Pub. L. 110–355, §4, Oct. 8, 2008, 122 Stat. 3994; Pub. L. 116–136, div. A, title III, §3213, Mar. 27, 2020, 134 Stat. 370.)

EDITORIAL NOTES

PRIOR PROVISIONS

A prior section 254c, act July 1, 1944, ch. 373, title III, §330, as added July 29, 1975, Pub. L. 94–63, title V, §501(a), 89 Stat. 342; amended Apr. 22, 1976, Pub. L. 94–278, title VIII, §801(b), 90 Stat. 415; Aug. 1, 1977, Pub. L. 95–83, title III, §304, 91 Stat. 388; Nov. 10, 1978, Pub. L. 95–626, title I, §104(a)–(d)(3)(B), (4), (5), (e), (f), 92 Stat. 3556–3559; July 10, 1979, Pub. L. 96–32, §§6(b)–(d), 7(c), 93 Stat. 83, 84; Oct. 17, 1979, Pub. L. 96–88, title V, §509(b), 93 Stat. 695; Oct. 19, 1980, Pub. L. 96–470, title I, §106(e), 94 Stat. 2238; Aug. 13, 1981, Pub. L. 97–35, title IX, §§903(a), 905, 906, 95 Stat. 561, 562; Jan. 4, 1983, Pub. L. 97–414, §8(e), 96 Stat. 2060; Apr. 24, 1986, Pub. L. 99–280, §§2–4, 100 Stat. 399, 400; Aug. 10, 1988, Pub. L. 100–386, §§3, 4, 102 Stat. 921, 923; Nov. 4, 1988, Pub. L. 100–607, title I, §163(3), 102 Stat. 3062; Dec. 19, 1989, Pub. L. 101–239, title VI, §6103(e)(5), 103 Stat. 2207; Nov. 6, 1990, Pub. L. 101–527, §9(a), 104 Stat. 2332; Oct. 27, 1992, Pub. L. 102–531, title III, §309(b), 106 Stat. 3500, related to community health centers, prior to the general amendment of this subpart by Pub. L. 104–299, §2.

AMENDMENTS

2020—Subsec. (d)(2)(A). Pub. L. 116–136, §3213(1)(A), substituted "basic" for "essential".

Subsec. (d)(2)(B). Pub. L. 116–136, §3213(1)(B), inserted "to" after "grants" in introductory provisions and struck out "to" at beginning of cls. (i) to (iii).

Subsec. (e)(1). Pub. L. 116–136, §3213(2)(A), inserted "improving and" after "outreach by" and ", through community engagement and evidence-based or innovative, evidence-informed models" after "rural areas" and substituted "5 years" for "3 years".

Subsec. (e)(2). Pub. L. 116–136, §3213(2)(B)(i), inserted "shall" after "entity" in introductory provisions.

Subsec. (e)(2)(A). Pub. L. 116–136, §3213(2)(B)(ii), substituted "be an entity with demonstrated experience serving, or the capacity to serve, rural underserved populations" for "shall be a rural public or rural nonprofit private entity".

Subsec. (e)(2)(B). Pub. L. 116–136, §3213(2)(B)(iii), (iv), struck out "shall" before "represent" and inserted "that" after "members" in introductory provisions and struck out "that" at beginning of cls. (i) and (ii).

Subsec. (e)(2)(C). Pub. L. 116–136, §3213(2)(B)(iii), struck out "shall" before "not previously".

Subsec. (e)(3)(C). Pub. L. 116–136, §3213(2)(C), substituted "the rural underserved populations in the local community or region" for "the local community or region".

Subsec. (f)(1)(A). Pub. L. 116–136, §3213(3)(A)(i)(I), substituted "plan, develop, and implement integrated health care networks that collaborate" for "promote, through planning and implementation, the development of integrated health care networks that have combined the functions of the entities participating in the networks" in introductory provisions.

Subsec. (f)(1)(A)(ii). Pub. L. 116–136, §3213(3)(A)(i)(II), substituted "basic health care services and associated health outcomes" for "essential health care services".

Subsec. (f)(1)(B). Pub. L. 116–136, §3213(3)(A)(ii), amended subpar. (B) generally. Prior to amendment, text read as follows: "The Director may award such a rural health network development grant for implementation activities for a period of 3 years. The Director may also award such a rural health network development grant for planning activities for a period of 1 year, to assist in the development of an integrated health care network, if the proposed participants in the network do not have a history of collaborative efforts and a 3-year grant would be inappropriate."

Subsec. (f)(2). Pub. L. 116–136, §3213(3)(B)(i), inserted "shall" after "entity" in introductory provisions.

Subsec. (f)(2)(A). Pub. L. 116–136, §(3)(B)(ii), substituted "be an entity with demonstrated experience serving, or the capacity to serve, rural underserved populations" for "shall be a rural public or rural nonprofit private entity".

Subsec. (f)(2)(B). Pub. L. 116–136, §3213(3)(B)(iii), struck out "shall" before "represent" and inserted "that" after "participants" in introductory provisions and struck out "that" at beginning of cls. (i) and (ii).

Subsec. (f)(2)(C). Pub. L. 116–136, §3213(3)(B)(iv), struck out "shall" before "not previously".

Subsec. (f)(3)(C)(iii). Pub. L. 116–136, §3213(3)(C)(i), amended cl. (iii) generally. Prior to amendment, cl. (iii) read as follows: "how the local community or region to be served will benefit from and be involved in the activities carried out by the network;".

Subsec. (f)(3)(D). Pub. L. 116–136, §3213(3)(C)(ii), substituted "the rural underserved populations in the local community or region" for "the local community or region".

Subsec. (g)(1). Pub. L. 116–136, §3213(4)(A), inserted ", including activities related to increasing care coordination, enhancing chronic disease management, and improving patient health outcomes" after "quality improvement activities" and substituted "5 years" for "3 years".

Subsec. (g)(2). Pub. L. 116–136, §3213(4)(B)(i), inserted "shall" after "entity" in introductory provisions.

Subsec. (g)(2)(A). Pub. L. 116–136, §3213(4)(B)(ii), (iii), struck out "shall" at beginning of cls. (i) and (ii), and inserted "or regional" after "local" in cl. (ii).

Subsec. (g)(2)(B). Pub. L. 116–136, §3213(4)(B)(ii), struck out "shall" before "not previously".

Subsec. (g)(3)(D). Pub. L. 116–136, §3213(4)(C), substituted "the rural underserved populations in the local community or region" for "the local community or region".

Subsec. (h)(3). Pub. L. 116–136, §3213(5), inserted ", as appropriate," after "the Secretary" in introductory provisions.

Subsec. (i). Pub. L. 116–136, §3213(6), amended subsec. (i) generally. Prior to amendment, text read as follows: "Not later than September 30, 2005, the Secretary shall prepare and submit to the appropriate committees of Congress a report on the progress and accomplishments of the grant programs described in subsections (e), (f), and (g)."

Subsec. (j). Pub. L. 116–136, §3213(7), substituted "$79,500,000 for each of fiscal years 2021 through 2025" for "$45,000,000 for each of fiscal years 2008 through 2012".

2008—Subsec. (j). Pub. L. 110–355 substituted "$45,000,000 for each of fiscal years 2008 through 2012." for "$40,000,000 for fiscal year 2002, and such sums as may be necessary for each of fiscal years 2003 through 2006."

2003—Subsec. (b)(4). Pub. L. 108–163 substituted "section 295p(6)" for "section 295p".

2002—Pub. L. 107–251 amended section generally. Prior to amendment, section related to a rural health outreach, network development, and telemedicine grant program, and in subsec. (a), provided for administration by the Office of Rural Health Policy; in subsec. (b), set out the objectives of grants; in subsec.

(c), set out eligibility requirements; in subsec. (d), described preferred characteristics of applicant networks; in subsec. (e), specified permitted uses of grant funds; in subsec. (f), limited the duration of grants; and in subsec. (g), authorized appropriations.

STATUTORY NOTES AND RELATED SUBSIDIARIES

EFFECTIVE DATE OF 2003 AMENDMENT

Amendment by Pub. L. 108–163 deemed to have taken effect immediately after the enactment of Pub. L. 107–251, see section 3 of Pub. L. 108–163, set out as a note under section 233 of this title.

EFFECTIVE DATE

Section effective Oct. 1, 1996, see section 5 of Pub. L. 104–299, as amended, set out as an Effective Date of 1996 Amendment note under section 233 of this title.

RURAL ACCESS TO EMERGENCY DEVICES

Pub. L. 106–505, title IV, subtitle B, Nov. 13, 2000, 114 Stat. 2340, provided that:

"SEC. 411. SHORT TITLE.

"This subtitle may be cited as the 'Rural Access to Emergency Devices Act' or the 'Rural AED Act'.

"SEC. 412. FINDINGS.

"Congress makes the following findings:

"(1) Heart disease is the leading cause of death in the United States.

"(2) The American Heart Association estimates that 250,000 Americans die from sudden cardiac arrest each year.

"(3) A cardiac arrest victim's chance of survival drops 10 percent for every minute that passes before his or her heart is returned to normal rhythm.

"(4) Because most cardiac arrest victims are initially in ventricular fibrillation, and the only treatment for ventricular fibrillation is defibrillation, prompt access to defibrillation to return the heart to normal rhythm is essential.

"(5) Lifesaving technology, the automated external defibrillator, has been developed to allow trained lay rescuers to respond to cardiac arrest by using this simple device to shock the heart into normal rhythm.

"(6) Those people who are likely to be first on the scene of a cardiac arrest situation in many communities, particularly smaller and rural communities, lack sufficient numbers of automated external defibrillators to respond to cardiac arrest in a timely manner.

"(7) The American Heart Association estimates that more than 50,000 deaths could be prevented each year if defibrillators were more widely available to designated responders.

"(8) Legislation should be enacted to encourage greater public access to automated external defibrillators in communities across the United States.

"SEC. 413. GRANTS.

"(a) IN GENERAL.—The Secretary of Health and Human Services, acting through the Rural Health Outreach Office of the Health Resources and Services Administration, shall award grants to community partnerships that meet the requirements of subsection (b) to enable such partnerships to purchase equipment and provide training as provided for in subsection (c).

"(b) COMMUNITY PARTNERSHIPS.—A community partnership meets the requirements of this subsection if such partnership—

"(1) is composed of local emergency response entities such as community training facilities, local emergency responders, fire and rescue departments, police, community hospitals, and local non-profit entities and for-profit entities concerned about cardiac arrest survival rates;

"(2) evaluates the local community emergency response times to assess whether they meet the standards established by national public health organizations such as the American Heart Association and the American Red Cross; and

"(3) submits to the Secretary of Health and Human Services an application at such time, in such manner, and containing such information as the Secretary may require.

"(c) USE OF FUNDS.—Amounts provided under a grant under this section shall be used—

"(1) to purchase automated external defibrillators that have been approved, or cleared for marketing, by the Food and Drug Administration; and

"(2) to provide defibrillator and basic life support training in automated external defibrillator usage

through the American Heart Association, the American Red Cross, or other nationally recognized training courses.

"(d) REPORT.—Not later than 4 years after the date of the enactment of this Act [Nov. 13, 2000], the Secretary of Health and Human Services shall prepare and submit to the appropriate committees of Congress a report containing data relating to whether the increased availability of defibrillators has affected survival rates in the communities in which grantees under this section operated. The procedures under which the Secretary obtains data and prepares the report under this subsection shall not impose an undue burden on program participants under this section.

"(e) AUTHORIZATION OF APPROPRIATIONS.—There is authorized to be appropriated $25,000,000 for fiscal years 2001 through 2003 to carry out this section."

REPORT ON TELEMEDICINE

Pub. L. 106–129, §6, Dec. 6, 1999, 113 Stat. 1675, provided that: "Not later than January 10, 2001, the Secretary of Health and Human Services shall submit to the Congress a report that—

"(1) identifies any factors that inhibit the expansion and accessibility of telemedicine services, including factors relating to telemedicine networks;

"(2) identifies any factors that, in addition to geographical isolation, should be used to determine which patients need or require access to telemedicine care;

"(3) determines the extent to which—

"(A) patients receiving telemedicine service have benefited from the services, and are satisfied with the treatment received pursuant to the services; and

"(B) the medical outcomes for such patients would have differed if telemedicine services had not been available to the patients;

"(4) determines the extent to which physicians involved with telemedicine services have been satisfied with the medical aspects of the services;

"(5) determines the extent to which primary care physicians are enhancing their medical knowledge and experience through the interaction with specialists provided by telemedicine consultations; and

"(6) identifies legal and medical issues relating to State licensing of health professionals that are presented by telemedicine services, and provides any recommendations of the Secretary for responding to such issues."

EXECUTIVE DOCUMENTS

EX. ORD. NO. 13941. IMPROVING RURAL HEALTH AND TELEHEALTH ACCESS

Ex. Ord. No. 13941, Aug. 3, 2020, 85 F.R. 47881, provided:

By the authority vested in me as President by the Constitution and the laws of the United States of America, it is hereby ordered as follows:

SECTION 1. *Purpose*. My Administration is committed to improving the health of all Americans by improving access to better care, including for the approximately 57 million Americans living in rural communities. Americans living in rural communities face unique challenges when seeking healthcare services, such as limited transportation opportunities, shortages of healthcare workers, and an inability to fully benefit from technological and care-delivery innovations. These factors have contributed to financial insecurity and impaired health outcomes for rural Americans, who are more likely to die from five leading causes, many of which are preventable, than their urban counterparts. That gap widened from 2010 to 2017 for cancer, heart disease, and chronic lower respiratory disease.

Since 2010, the year the [Patient Protection and] Affordable Care Act [Pub. L. 111–148] was passed, 129 rural hospitals in the United States have closed. Predictably, financial distress is the strongest driver for risk of closure, and many rural hospitals lack sufficient patient volume to be sustainable under traditional healthcare-reimbursement mechanisms. From 2015 to 2017, the average occupancy rate of a hospital that closed was only 22 percent. When hospitals close, the patient population around them carries an increased risk of mortality due to increased travel time and decreased access.

During the COVID–19 public health emergency (PHE), hospitals curtailed elective medical procedures and access to in-person clinical care was limited. To help patients better access healthcare providers, my Administration implemented new flexibility regarding what services may be provided via telehealth, who may provide them, and in what circumstances, and the use of telehealth increased dramatically across the Nation. Internal analysis by the Centers for Medicare and Medicaid Services (CMS) of the Department of Health and Human Services (HHS) showed a weekly jump in virtual visits for CMS beneficiaries, from approximately 14,000 pre-PHE to almost 1.7 million in the last week of April. Additionally, a recent report by HHS shows

that nearly half (43.5 percent) of Medicare fee-for-service primary care visits were provided through telehealth in April, compared with far less than one percent (0.1 percent) in February before the PHE. Importantly, the report finds that telehealth visits continued to be frequent even after in-person primary care visits resumed in May, indicating that the expansion of telehealth services is likely to be a more permanent feature of the healthcare delivery system.

Rural healthcare providers, in particular, need these types of flexibilities to provide continuous care to patients in their communities. It is the purpose of this order to increase access to, improve the quality of, and improve the financial economics of rural healthcare, including by increasing access to high-quality care through telehealth.

SEC. 2. *Launching an Innovative Payment Model to Enable Rural Healthcare Transformation*. Within 30 days of the date of this order [Aug. 3, 2020], the Secretary of HHS (Secretary) will announce a new model, pursuant to section 1115A of the Social Security Act (42 U.S.C. 1315a), to test innovative payment mechanisms in order to ensure that rural healthcare providers are able to provide the necessary level and quality of care. This model should give rural providers flexibilities from existing Medicare rules, establish predictable financial payments, and encourage the movement into high-quality, value-based care.

SEC. 3. *Investments in Physical and Communications Infrastructure*. Within 30 days of the date of this order, the Secretary and the Secretary of Agriculture shall, consistent with applicable law and subject to the availability of appropriations, and in coordination with the Federal Communications Commission and other executive departments and agencies, as appropriate, develop and implement a strategy to improve rural health by improving the physical and communications healthcare infrastructure available to rural Americans.

SEC. 4. *Improving the Health of Rural Americans*. Within 30 days of the date of this order, the Secretary shall submit a report to the President, through the Assistant to the President for Domestic Policy and the Assistant to the President for Economic Policy, regarding existing and upcoming policy initiatives to:

(a) increase rural access to healthcare by eliminating regulatory burdens that limit the availability of clinical professionals;

(b) prevent disease and mortality by developing rural-specific efforts to drive improved health outcomes;

(c) reduce maternal mortality and morbidity; and

(d) improve mental health in rural communities.

SEC. 5. *Expanding Flexibilities Beyond the Public Health Emergency*. Within 60 days of the date of this order, the Secretary shall review the following temporary measures put in place during the PHE, and shall propose a regulation to extend these measures, as appropriate, beyond the duration of the PHE:

(a) the additional telehealth services offered to Medicare beneficiaries; and

(b) the services, reporting, staffing, and supervision flexibilities offered to Medicare providers in rural areas.

SEC. 6. *General Provisions*. (a) Nothing in this order shall be construed to impair or otherwise affect:

(i) the authority granted by law to an executive department or agency, or the head thereof; or

(ii) the functions of the Director of the Office of Management and Budget relating to budgetary, administrative, or legislative proposals.

(b) This order shall be implemented consistent with applicable law and subject to the availability of appropriations.

(c) This order is not intended to, and does not, create any right or benefit, substantive or procedural, enforceable at law or in equity by any party against the United States, its departments, agencies, or entities, its officers, employees, or agents, or any other person.

DONALD J. TRUMP.

§254c–1. Grants for health services for Pacific Islanders

(a) Grants

The Secretary of Health and Human Services (hereafter in this section referred to as the "Secretary") shall provide grants to, or enter into contracts with, public or private nonprofit agencies that have demonstrated experience in serving the health needs of Pacific Islanders living in the Territory of American Samoa, the Commonwealth of Northern Mariana Islands, the Territory of Guam, the Republic of the Marshall Islands, the Republic of Palau, and the Federated States of Micronesia.

(b) Use of grants or contracts

Grants or contracts made or entered into under subsection (a) shall be used, among other items—

(1) to continue, as a priority, the medical officer training program in Pohnpei, Federated States of Micronesia;

(2) to improve the quality and availability of health and mental health services and systems, with an emphasis therein on preventive health services and health promotion programs and projects, including improved health data systems;

(3) to improve the quality and availability of health manpower, including programs and projects to train new and upgrade the skills of existing health professionals by—

(A) establishing dental officer, dental assistant, nurse practitioner, or nurse clinical specialist training programs;

(B) providing technical training of new auxiliary health workers;

(C) upgrading the training of currently employed health personnel in special areas of need;

(D) developing long-term plans for meeting health profession needs;

(E) developing or improving programs for faculty enhancement or post-doctoral training; and

(F) providing innovative health professions training initiatives (including scholarships) targeted toward ensuring that residents of the Pacific Basin attend and graduate from recognized health professional programs;

(4) to improve the quality of health services, including laboratory, x-ray, and pharmacy, provided in ambulatory and inpatient settings through quality assurance, standard setting, and other culturally appropriate means;

(5) to improve facility and equipment repair and maintenance systems;

(6) to improve alcohol, drug abuse, and mental health prevention and treatment services and systems;

(7) to improve local and regional health planning systems; and

(8) to improve basic local public health systems, with particular attention to primary care and services to those most in need.

No funds under subsection (b) shall be used for capital construction.

(c) Advisory Council

The Secretary of Health and Human Services shall establish a "Pacific Health Advisory Council" which shall consist of 12 members and shall include—

(1) the Directors of the Health Departments for the entities identified in subsection (a); and

(2) 6 members, including a representative of the Rehabilitation Hospital of the Pacific, representing organizations in the State of Hawaii actively involved in the provision of health services or technical assistance to the entities identified in subsection (a). The Secretary shall solicit the advice of the Governor of the State of Hawaii in appointing the 5 Council members in addition to the representative of the Rehabilitation Hospital of the Pacific from the State of Hawaii.

The Secretary shall be responsible for providing sufficient staff support to the Council.

(d) Advisory Council functions

The Council shall meet at least annually to—

(1) recommend priority areas of need for funding by the Public Health Service under this section; and

(2) review progress in addressing priority areas and make recommendations to the Secretary for needed program modifications.

(e) Omitted

(f) Authorization of appropriation

There is authorized to be appropriated to carry out this section $10,000,000 for each of the fiscal years 1991 through 1993.

(Pub. L. 101–527, §10, Nov. 6, 1990, 104 Stat. 2333.)

EDITORIAL NOTES

CODIFICATION

Section was enacted as part of the Disadvantaged Minority Health Improvement Act of 1990, and not as part of the Public Health Service Act which comprises this chapter.

Subsec. (e) of this section, which required the Secretary, in consultation with the Council, to annually prepare and submit to appropriate committees of Congress a report describing the expenditure of funds authorized to be appropriated under this section, with any recommendations of the Secretary, terminated, effective May 15, 2000, pursuant to section 3003 of Pub. L. 104–66, as amended, set out as a note under section 1113 of Title 31, Money and Finance. See, also, page 95 of House Document No. 103–7.

STATUTORY NOTES AND RELATED SUBSIDIARIES

TERMINATION OF ADVISORY COUNCILS

Advisory councils established after Jan. 5, 1973, to terminate not later than the expiration of the 2-year period beginning on the date of their establishment, unless, in the case of a council established by the President or an officer of the Federal Government, such council is renewed by appropriate action prior to the expiration of such 2-year period, or in the case of a council established by Congress, its duration is otherwise provided by law. See sections 1001(2) and 1013 of Title 5, Government Organization and Employees.

§254c–1a. Grants to nurse-managed health clinics

(a) Definitions

(1) Comprehensive primary health care services

In this section, the term "comprehensive primary health care services" means the primary health services described in section 254b(b)(1) of this title.

(2) Nurse-managed health clinic

The term "nurse-managed health clinic" means a nurse-practice arrangement, managed by advanced practice nurses, that provides primary care or wellness services to underserved or vulnerable populations and that is associated with a school, college, university or department of nursing, federally qualified health center, or independent nonprofit health or social services agency.

(b) Authority to award grants

The Secretary shall award grants for the cost of the operation of nurse-managed health clinics that meet the requirements of this section.

(c) Applications

To be eligible to receive a grant under this section, an entity shall—

(1) be an NMHC; and

(2) submit to the Secretary an application at such time, in such manner, and containing—

(A) assurances that nurses are the major providers of services at the NMHC and that at least 1 advanced practice nurse holds an executive management position within the organizational structure of the NMHC;

(B) an assurance that the NMHC will continue providing comprehensive primary health care services or wellness services without regard to income or insurance status of the patient for the duration of the grant period; and

(C) an assurance that, not later than 90 days of receiving a grant under this section, the NMHC will establish a community advisory committee, for which a majority of the members shall be individuals who are served by the NMHC.

(d) Grant amount

The amount of any grant made under this section for any fiscal year shall be determined by the Secretary, taking into account—

(1) the financial need of the NMHC, considering State, local, and other operational funding provided to the NMHC; and

(2) other factors, as the Secretary determines appropriate.

(e) Authorization of appropriations

For the purposes of carrying out this section, there are authorized to be appropriated $50,000,000 for the fiscal year 2010 and such sums as may be necessary for each of the fiscal years 2011 through 2014.

(July 1, 1944, ch. 373, title III, §330A–1, as added Pub. L. 111–148, title V, §5208(b), Mar. 23, 2010, 124 Stat. 613.)

STATUTORY NOTES AND RELATED SUBSIDIARIES

PURPOSE

Pub. L. 111–148, title V, §5208(a), Mar. 23, 2010, 124 Stat. 612, provided that: "The purpose of this section [enacting this section] is to fund the development and operation of nurse-managed health clinics."

§254c–1b. Rural obstetric network grants

(a) Program established

The Secretary shall award grants or cooperative agreements to eligible entities to establish collaborative improvement and innovation networks (referred to in this section as "rural obstetric networks") to improve maternal and infant health outcomes and reduce preventable maternal mortality and severe maternal morbidity by improving maternity care and access to care in rural areas, frontier areas, maternity care health professional target areas, or jurisdictions of Indian Tribes and Tribal organizations.

(b) Use of funds

Grants or cooperative agreements awarded pursuant to this section shall be used for the establishment or continuation of collaborative improvement and innovation networks to improve maternal and infant health outcomes and reduce preventable maternal mortality and severe maternal morbidity by improving prenatal care, labor care, birthing, and postpartum care services in rural areas. Rural obstetric networks established in accordance with this section may—

(1) develop a network to improve coordination and increase access to maternal health care and assist pregnant women in the areas described in subsection (a) with accessing and utilizing prenatal care, labor care, birthing, and postpartum care services to improve outcomes in birth and maternal mortality and morbidity;

(2) identify and implement evidence-based and sustainable delivery models for providing prenatal care, labor care, birthing, and postpartum care services, including home visiting programs and culturally appropriate care models that reduce health disparities;

(3) develop a model for maternal health care collaboration between health care settings to improve access to care in areas described in subsection (a), which may include the use of telehealth;

(4) provide training for professionals in health care settings that do not have specialty maternity care;

(5) collaborate with academic institutions that can provide regional expertise and help identify barriers to providing maternal health care, including strategies for addressing such barriers; and

(6) assess and address disparities in infant and maternal health outcomes, including among racial and ethnic minority populations and underserved populations in such areas described in subsection (a).

(c) Definitions

In this section:

(1) Eligible entities

The term "eligible entities" means entities providing prenatal care, labor care, birthing, and postpartum care services in rural areas, frontier areas, or medically underserved areas, or to medically underserved populations or Indian Tribes or Tribal organizations.

(2) Frontier area

The term "frontier area" means a frontier county, as defined in section 1395ww(d)(3)(E)(iii)(III) of this title.

(3) Indian Tribes; Tribal organization

The terms "Indian Tribe" and "Tribal organization" have the meanings given the terms "Indian tribe" and "tribal organization" in section 5304 of title 25.

(4) Maternity care health professional target area

The term "maternity care health professional target area" has the meaning described in section 254e(k)(2) of this title.

(d) Report to Congress

Not later than September 30, 2026, the Secretary shall submit to Congress a report on activities supported by grants awarded under this section, including—

(1) a description of activities conducted pursuant to paragraphs (1) through (6) of subsection (b); and

(2) an analysis of the effects of rural obstetric networks on improving maternal and infant health outcomes.

(e) Authorization of appropriations

There are authorized to be appropriated to carry out this section $3,000,000 for each of fiscal years 2023 through 2027.

(July 1, 1944, ch. 373, title III, §330A–2, as added Pub. L. 117–103, div. P, title I, §142, Mar. 15, 2022, 136 Stat. 798.)

§254c–2. Special diabetes programs for type I diabetes

(a) In general

The Secretary, directly or through grants, shall provide for research into the prevention and cure of Type [1] I diabetes.

(b) Funding

(1) Transferred funds

Notwithstanding section 1397dd(a) of this title, from the amounts appropriated in such section for each of fiscal years 1998 through 2002, $30,000,000 is hereby transferred and made available in such fiscal year for grants under this section.

(2) Appropriations

For the purpose of making grants under this section, there is appropriated, out of any funds in the Treasury not otherwise appropriated—

(A) $70,000,000 for each of fiscal years 2001 and 2002 (which shall be combined with amounts transferred under paragraph (1) for each such fiscal years);

(B) $100,000,000 for fiscal year 2003;

(C) $150,000,000 for each of fiscal years 2004 through 2017;

(D) $150,000,000 for each of fiscal years 2018 through 2023, to remain available until

expended;

(E) $155,619,196 for fiscal year 2024, to remain available until expended;

(F) $159,228,188 for fiscal year 2025, to remain available until expended;

(G) $200,000,000 for fiscal year 2026, to remain available until expended; and

(H) $50,410,959 for the period beginning on October 1, 2026, and ending on December 31, 2026, to remain available until expended.

(July 1, 1944, ch. 373, title III, §330B, as added Pub. L. 105–33, title IV, §4921, Aug. 5, 1997, 111 Stat. 574; amended Pub. L. 105–34, title XVI, §1604(f)(1)(B), (C), Aug. 5, 1997, 111 Stat. 1098; Pub. L. 106–554, §1(a)(6) [title IX, §931(a)], Dec. 21, 2000, 114 Stat. 2763, 2763A–585; Pub. L. 107–360, §1(a), Dec. 17, 2002, 116 Stat. 3019; Pub. L. 110–173, title III, §302(a), Dec. 29, 2007, 121 Stat. 2514; Pub. L. 110–275, title III, §303(a), July 15, 2008, 122 Stat. 2594; Pub. L. 111–309, title I, §112(1), Dec. 15, 2010, 124 Stat. 3289; Pub. L. 112–240, title VI, §625(a), Jan. 2, 2013, 126 Stat. 2352; Pub. L. 113–93, title II, §204(a), Apr. 1, 2014, 128 Stat. 1046; Pub. L. 114–10, title II, §213(a), Apr. 16, 2015, 129 Stat. 152; Pub. L. 115–96, div. C, title I, §3102(a), Dec. 22, 2017, 131 Stat. 2049; Pub. L. 115–123, div. E, title IX, §50902(a), Feb. 9, 2018, 132 Stat. 289; Pub. L. 116–59, div. B, title I, §1102(a), Sept. 27, 2019, 133 Stat. 1103; Pub. L. 116–69, div. B, title I, §1102(a), Nov. 21, 2019, 133 Stat. 1136; Pub. L. 116–94, div. N, title I, §402(a), Dec. 20, 2019, 133 Stat. 3114; Pub. L. 116–136, div. A, title III, §3832(a), Mar. 27, 2020, 134 Stat. 434; Pub. L. 116–159, div. C, title I, §2102(a), Oct. 1, 2020, 134 Stat. 729; Pub. L. 116–215, div. B, title II, §1202(a), Dec. 11, 2020, 134 Stat. 1044; Pub. L. 116–260, div. BB, title III, §302(a), Dec. 27, 2020, 134 Stat. 2923; Pub. L. 118–15, div. B, title III, §2322(a), Sept. 30, 2023, 137 Stat. 95; Pub. L. 118–22, div. B, title II, §202(a), Nov. 17, 2023, 137 Stat. 120; Pub. L. 118–35, div. B, title I, §102(a), Jan. 19, 2024, 138 Stat. 5; Pub. L. 118–42, div. G, title I, §102(a), Mar. 9, 2024, 138 Stat. 398; Pub. L. 118–158, div. C, title I, §3102(a), Dec. 21, 2024, 138 Stat. 1763; Pub. L. 119–4, div. B, title I, §2102(a), Mar. 15, 2025, 139 Stat. 41; Pub. L. 119–37, div. F, title I, §6102(a), Nov. 12, 2025, 139 Stat. 630; Pub. L. 119–75, div. J, title IV, §6402(a), Feb. 3, 2026, 140 Stat. 687.)

EDITORIAL NOTES

AMENDMENTS

2026—Subsec. (b)(2)(E) to (H). Pub. L. 119–75 added subpars. (E) to (H) and struck out former subpars. (E) to (H) which read as follows:

"(E) $19,726,027 for the period beginning on October 1, 2023, and ending on November 17, 2023, $25,890,411 for the period beginning on November 18, 2023, and ending on January 19, 2024, $20,136,986 for the period beginning on January 20, 2024, and ending on March 8, 2024, and $130,000,000 for the period beginning on March 9, 2024, and ending on December 31, 2024, to remain available until expended;

"(F) $39,261,745 for the period beginning on January 1, 2025, and ending on March 31, 2025, to remain available until expended;

"(G) $79,832,215 for the period beginning on April 1, 2025, and ending on September 30, 2025, to remain available until expended; and

"(H) $53,145,205 for the period beginning on October 1, 2025, and ending on January 30, 2026, to remain available until expended."

2025—Subsec. (b)(2)(G). Pub. L. 119–4 added subpar. (G).

Subsec. (b)(2)(H). Pub. L. 119–37 added subpar. (H).

2024—Subsec. (b)(2)(E). Pub. L. 118–42 substituted "$20,136,986 for the period beginning on January 20, 2024, and ending on March 8, 2024, and $130,000,000 for the period beginning on March 9, 2024, and ending on December 31, 2024" for "and $20,136,986 for the period beginning on January 20, 2024, and ending on March 8, 2024".

Pub. L. 118–35 substituted "$25,890,411 for the period beginning on November 18, 2023, and ending on January 19, 2024, and $20,136,986 for the period beginning on January 20, 2024, and ending on March 8, 2024" for "and $25,890,411 for the period beginning on November 18, 2023, and ending on January 19, 2024".

Subsec. (b)(2)(F). Pub. L. 118–158 added subpar. (F).

2023—Subsec. (b)(2)(E). Pub. L. 118–22 substituted "$19,726,027 for the period beginning on October 1, 2023, and ending on November 17, 2023, and $25,890,411 for the period beginning on November 18, 2023,

and ending on January 19, 2024" for "$19,726,027 for the period beginning on October 1, 2023, and ending on November 17, 2023".

Pub. L. 118–15 added subpar. (E).

2020—Subsec. (b)(2)(D). Pub. L. 116–260 substituted "2023" for "2020, and $32,465,753 for the period beginning on October 1, 2020, and ending on December 18, 2020".

Pub. L. 116–215 substituted "$32,465,753" for "$29,589,042" and "December 18, 2020" for "December 11, 2020".

Pub. L. 116–159 substituted "$29,589,042" for "$25,068,493" and "December 11, 2020" for "November 30, 2020".

Pub. L. 116–136 substituted "through 2020, and $25,068,493 for the period beginning on October 1, 2020, and ending on November 30, 2020" for "and 2019, and $96,575,342 for the period beginning on October 1, 2019, and ending on May 22, 2020".

2019—Subsec. (b)(2)(D). Pub. L. 116–94 substituted "$96,575,342" for "$33,287,671" and "May 22, 2020" for "December 20, 2019".

Pub. L. 116–69 substituted "$33,287,671" for "$21,369,863" and "December 20, 2019" for "November 21, 2019".

Pub. L. 116–59 inserted "and $21,369,863 for the period beginning on October 1, 2019, and ending on November 21, 2019," before "to remain available".

2018—Subsec. (b)(2)(D). Pub. L. 115–123 amended subpar. (D) generally. Prior to amendment, subpar. (D) read as follows: "$37,500,000 for the period of the first and second quarters of fiscal year 2018, to remain available until expended."

2017—Subsec. (b)(2)(D). Pub. L. 115–96 added subpar. (D).

2015—Subsec. (b)(2)(C). Pub. L. 114–10 substituted "2017" for "2015".

2014—Subsec. (b)(2)(C). Pub. L. 113–93 substituted "2015" for "2014".

2013—Subsec. (b)(2)(C). Pub. L. 112–240 substituted "2014" for "2013".

2010—Subsec. (b)(2)(C). Pub. L. 111–309 substituted "2013" for "2011".

2008—Subsec. (b)(2)(C). Pub. L. 110–275 substituted "2011" for "2009".

2007—Subsec. (b)(2)(C). Pub. L. 110–173 substituted "2009" for "2008".

2002—Subsec. (b)(2)(C). Pub. L. 107–360 added subpar. (C).

2000—Subsec. (b). Pub. L. 106–554 designated existing provisions as par. (1), inserted par. heading, and added par. (2).

1997—Pub. L. 105–34, §1604(f)(1)(B), amended directory language of Pub. L. 105–33, §4921, which enacted this section.

Pub. L. 105–34, §1604(f)(1)(C)(i), struck out "children with" before "type I diabetes" in section catchline.

Subsec. (a). Pub. L. 105–34, §1604(f)(1)(C)(ii), amended heading and text of subsec. (a) generally. Prior to amendment, text read as follows: "The Secretary shall make grants for services for the prevention and treatment of type I diabetes in children, and for research in innovative approaches to such services. Such grants may be made to children's hospitals; grantees under section 254b of this title and other federally qualified health centers; State and local health departments; and other appropriate public or nonprofit private entities."

STATUTORY NOTES AND RELATED SUBSIDIARIES

EFFECTIVE DATE OF 1997 AMENDMENT

Pub. L. 105–34, title XVI, §1604(f)(4), Aug. 5, 1997, 111 Stat. 1099, provided that: "The provisions of, and amendments made by, this subsection [amending this section and provisions set out as a note under section 5701 of Title 26, Internal Revenue Code] shall take effect immediately after the sections referred to in this subsection [sections 4921, 9302, 11104, and 11201 of Pub. L. 105–33] take effect."

REPORT ON DIABETES GRANT PROGRAMS

Pub. L. 105–33, title IV, §4923, Aug. 5, 1997, 111 Stat. 574, as amended by Pub. L. 106–554, §1(a)(6) [title IX, §931(c)], Dec. 21, 2000, 114 Stat. 2763, 2763A–585; Pub. L. 107–360, §1(c), Dec. 17, 2002, 116 Stat. 3019; Pub. L. 109–482, title I, §104(b)(3)(C), Jan. 15, 2007, 120 Stat. 3694; Pub. L. 110–275, title III, §303(c), July 15, 2008, 122 Stat. 2594, provided that:

"(a) EVALUATION.—The Secretary of Health and Human Services shall conduct an evaluation of the diabetes grant programs established under the amendments made by this chapter [chapter 3 (§§4921–4923) of subtitle J of title IV of Pub. L. 105–33, enacting this section and section 254c–3 of this title].

"[(b) Repealed. Pub. L. 109–482, title I, §104(b)(3)(C), Jan. 15, 2007, 120 Stat. 3694.]"

[Pub. L. 110–275, §303(c), which directed amendment of section 4923(b) of Pub. L. 105–33 by substituting "a second interim report" for "a final report" in par. (2) and by adding par. (3) at end to read "a report on such evaluation not later than January 1, 2011.", could not be executed because of prior repeal.]

[1] *So in original. Probably should not be capitalized.*

§254c–3. Special diabetes programs for Indians

(a) In general

The Secretary shall make grants for providing services for the prevention and treatment of diabetes in accordance with subsection (b).

(b) Services through Indian health facilities

For purposes of subsection (a), services under such subsection are provided in accordance with this subsection if the services are provided through any of the following entities:

(1) The Indian Health Service.

(2) An Indian health program operated by an Indian tribe or tribal organization pursuant to a contract, grant, cooperative agreement, or compact with the Indian Health Service pursuant to the Indian Self-Determination Act [25 U.S.C. 5321 et seq.].

(3) An urban Indian health program operated by an urban Indian organization pursuant to a grant or contract with the Indian Health Service pursuant to title V of the Indian Health Care Improvement Act [25 U.S.C. 1651 et seq.].

(c) Funding

(1) Transferred funds

Notwithstanding section 1397dd(a) of this title, from the amounts appropriated in such section for each of fiscal years 1998 through 2002, $30,000,000, to remain available until expended, is hereby transferred and made available in such fiscal year for grants under this section.

(2) Appropriations

For the purpose of making grants under this section, there is appropriated, out of any money in the Treasury not otherwise appropriated—

(A) $70,000,000 for each of fiscal years 2001 and 2002 (which shall be combined with amounts transferred under paragraph (1) for each such fiscal years);

(B) $100,000,000 for fiscal year 2003;

(C) $150,000,000 for each of fiscal years 2004 through 2017;

(D) $150,000,000 for each of fiscal years 2018 through 2023, to remain available until expended;

(E) $155,619,196 for fiscal year 2024, to remain available until expended;

(F) $159,228,188 for fiscal year 2025, to remain available until expended;

(G) $200,000,000 for fiscal year 2026, to remain available until expended; and

(H) $50,410,959 for the period beginning on October 1, 2026, and ending on December 31, 2026, to remain available until expended.

(July 1, 1944, ch. 373, title III, §330C, as added Pub. L. 105–33, title IV, §4922, Aug. 5, 1997, 111 Stat. 574; amended Pub. L. 105–174, title III, §3001, May 1, 1998, 112 Stat. 82; Pub. L. 106–554, §1(a)(6) [title IX, §931(b)], Dec. 21, 2000, 114 Stat. 2763, 2763A–585; Pub. L. 107–360, §1(b), Dec. 17, 2002, 116 Stat. 3019; Pub. L. 110–173, title III, §302(b), Dec. 29, 2007, 121 Stat. 2515; Pub. L. 110–275, title III, §303(b), July 15, 2008, 122 Stat. 2594; Pub. L. 111–309, title I, §112(2), Dec. 15, 2010, 124 Stat. 3289; Pub. L. 112–240, title VI, §625(b), Jan. 2, 2013, 126 Stat. 2353; Pub. L. 113–93, title II, §204(b), Apr. 1, 2014, 128 Stat. 1046; Pub. L. 114–10, title II, §213(b), Apr. 16, 2015, 129 Stat. 152; Pub. L. 115–63, title III, §301(b), Sept. 29, 2017, 131 Stat. 1172; Pub. L. 115–96, div. C, title I, §3102(b), Dec. 22, 2017, 131 Stat. 2049; Pub. L. 115–123, div. E, title IX,

§50902(b), Feb. 9, 2018, 132 Stat. 289; Pub. L. 116–59, div. B, title I, §1102(b), Sept. 27, 2019, 133 Stat. 1103; Pub. L. 116–69, div. B, title I, §1102(b), Nov. 21, 2019, 133 Stat. 1136; Pub. L. 116–94, div. N, title I, §402(b), Dec. 20, 2019, 133 Stat. 3114; Pub. L. 116–136, div. A, title III, §3832(b), Mar. 27, 2020, 134 Stat. 434; Pub. L. 116–159, div. C, title I, §2102(b), Oct. 1, 2020, 134 Stat. 729; Pub. L. 116–215, div. B, title II, §1202(b), Dec. 11, 2020, 134 Stat. 1045; Pub. L. 116–260, div. BB, title III, §302(b), Dec. 27, 2020, 134 Stat. 2923; Pub. L. 118–15, div. B, title III, §2322(b), Sept. 30, 2023, 137 Stat. 95; Pub. L. 118–22, div. B, title II, §202(b), Nov. 17, 2023, 137 Stat. 120; Pub. L. 118–35, div. B, title I, §102(b), Jan. 19, 2024, 138 Stat. 5; Pub. L. 118–42, div. G, title I, §102(b), Mar. 9, 2024, 138 Stat. 398; Pub. L. 118–158, div. C, title I, §3102(b), Dec. 21, 2024, 138 Stat. 1763; Pub. L. 119–4, div. B, title I, §2102(b), Mar. 15, 2025, 139 Stat. 41; Pub. L. 119–37, div. F, title I, §6102(b), Nov. 12, 2025, 139 Stat. 630; Pub. L. 119–75, div. J, title IV, §6402(b), Feb. 3, 2026, 140 Stat. 687.)

EDITORIAL NOTES

REFERENCES IN TEXT

The Indian Self-Determination Act, referred to in subsec. (b)(2), is title I of Pub. L. 93–638, Jan. 4, 1975, 88 Stat. 2206, which is classified principally to subchapter I (§5321 et seq.) of chapter 46 of Title 25, Indians. For complete classification of this Act to the Code, see Short Title note set out under section 5301 of Title 25 and Tables.

The Indian Health Care Improvement Act, referred to in subsec. (b)(3), is Pub. L. 94–437, Sept. 30, 1976, 90 Stat. 1400. Title V of the Act is classified generally to subchapter IV (§1651 et seq.) of chapter 18 of Title 25, Indians. For complete classification of this Act to the Code, see Short Title note set out under section 1601 of Title 25 and Tables.

AMENDMENTS

2026—Subsec. (c)(2)(E) to (H). Pub. L. 119–75 added subpars. (E) to (H) and struck out former subpars. (E) to (H) which read as follows:

"(E) $19,726,027 for the period beginning on October 1, 2023, and ending on November 17, 2023, $25,890,411 for the period beginning on November 18, 2023, and ending on January 19, 2024, $20,136,986 for the period beginning on January 20, 2024, and ending on March 8, 2024, and $130,000,000 for the period beginning on March 9, 2024, and ending on December 31, 2024, to remain available until expended;

"(F) $39,261,745 for the period beginning on January 1, 2025, and ending on March 31, 2025, to remain available until expended;

"(G) $79,832,215 for the period beginning on April 1, 2025, and ending on September 30, 2025, to remain available until expended; and

"(H) $53,145,205 for the period beginning on October 1, 2025, and ending on January 30, 2026, to remain available until expended."

2025—Subsec. (c)(2)(G). Pub. L. 119–4 added subpar. (G).

Subsec. (c)(2)(H). Pub. L. 119–37 added subpar. (H).

2024—Subsec. (c)(2)(E). Pub. L. 118–42 substituted "$20,136,986 for the period beginning on January 20, 2024, and ending on March 8, 2024, and $130,000,000 for the period beginning on March 9, 2024, and ending on December 31, 2024" for "and $20,136,986 for the period beginning on January 20, 2024, and ending on March 8, 2024".

Pub. L. 118–35 substituted "$25,890,411 for the period beginning on November 18, 2023, and ending on January 19, 2024, and $20,136,986 for the period beginning on January 20, 2024, and ending on March 8, 2024" for "and $25,890,411 for the period beginning on November 18, 2023, and ending on January 19, 2024".

Subsec. (c)(2)(F). Pub. L. 118–158 added subpar. (F).

2023—Subsec. (c)(2)(E). Pub. L. 118–22 substituted "$19,726,027 for the period beginning on October 1, 2023, and ending on November 17, 2023, and $25,890,411 for the period beginning on November 18, 2023, and ending on January 19, 2024" for "$19,726,027 for the period beginning on October 1, 2023, and ending on November 17, 2023".

Pub. L. 118–15 added subpar. (E).

2020—Subsec. (c)(2)(D). Pub. L. 116–260 substituted "2023" for "2020, and $32,465,753 for the period beginning on October 1, 2020, and ending on December 18, 2020".

Pub. L. 116–215 substituted "$32,465,753" for "$29,589,042" and "December 18, 2020" for "December 11,

2020".

Pub. L. 116–159 substituted "$29,589,042" for "$25,068,493" and "December 11, 2020" for "November 30, 2020".

Pub. L. 116–136 substituted "through 2020, and $25,068,493 for the period beginning on October 1, 2020, and ending on November 30, 2020" for "and 2019, and $96,575,342 for the period beginning on October 1, 2019, and ending on May 22, 2020".

2019—Subsec. (c)(2)(D). Pub. L. 116–94 substituted "$96,575,342" for "$33,287,671" and "May 22, 2020" for "December 20, 2019".

Pub. L. 116–69 substituted "$33,287,671" for "$21,369,863" and "December 20, 2019" for "November 21, 2019".

Pub. L. 116–59 inserted "and $21,369,863 for the period beginning on October 1, 2019, and ending on November 21, 2019," before "to remain available".

2018—Subsec. (c)(2)(D). Pub. L. 115–123 amended subpar. (D) generally. Prior to amendment, subpar. (D) read as follows: "$37,500,000 for the first quarter of fiscal year 2018 and $37,500,000 for the second quarter of fiscal year 2018."

2017—Subsec. (c)(2)(D). Pub. L. 115–96 inserted "and $37,500,000 for the second quarter of fiscal year 2018" before period at end.

Pub. L. 115–63 added subpar. (D).

2015—Subsec. (c)(2)(C). Pub. L. 114–10 substituted "2017" for "2015".

2014—Subsec. (c)(2)(C). Pub. L. 113–93 substituted "2015" for "2014".

2013—Subsec. (c)(2)(C). Pub. L. 112–240 substituted "2014" for "2013".

2010—Subsec. (c)(2)(C). Pub. L. 111–309 substituted "2013" for "2011".

2008—Subsec. (c)(2)(C). Pub. L. 110–275 substituted "2011" for "2009".

2007—Subsec. (c)(2)(C). Pub. L. 110–173 substituted "2009" for "2008".

2002—Subsec. (c)(2)(C). Pub. L. 107–360 added subpar. (C).

2000—Subsec. (c). Pub. L. 106–554 designated existing provisions as par. (1), inserted par. heading, and added par. (2).

1998—Subsec. (c). Pub. L. 105–174 inserted ", to remain available until expended," after "fiscal years 1998 through 2002, $30,000,000".

STATUTORY NOTES AND RELATED SUBSIDIARIES

FUNDS AVAILABLE UNTIL EXPENDED

Pub. L. 108–7, div. F, title II, Feb. 20, 2003, 117 Stat. 261, provided in part "That funds appropriated under the Special Diabetes Program for Indians (42 U.S.C. 254c–3(c)) for fiscal year 2003 and thereafter for the purpose of making grants shall remain available until expended".

§254c–4. Repealed. Pub. L. 117–328, div. FF, title II, §2201(a)(2), Dec. 29, 2022, 136 Stat. 5729

Section, act July 1, 1944, ch. 373, title III, §330D, as added Pub. L. 106–129, §3, Dec. 6, 1999, 113 Stat. 1670, authorized grants for establishment and operation of regional centers to develop, evaluate, and disseminate effective strategies on facilitating utilization of preventive health services among various populations.

EDITORIAL NOTES

CODIFICATION

Pub. L. 117–328, which directed amendment of Part B of title III of the Public Health Service Act by striking section 330D, was executed by striking section 330D (this section) of Part D of title III of the Public Health Service Act, to reflect the probable intent of Congress.

§254c–5. Epilepsy; seizure disorder

(a) National public health campaign

(1) In general

The Secretary shall develop and implement public health surveillance, education, research, and intervention strategies to improve the lives of persons with epilepsy, with a particular emphasis on children. Such projects may be carried out by the Secretary directly and through awards of grants or contracts to public or nonprofit private entities. The Secretary may directly or through such awards provide technical assistance with respect to the planning, development, and operation of such projects.

(2) Certain activities

Activities under paragraph (1) shall include—

(A) expanding current surveillance activities through existing monitoring systems and improving registries that maintain data on individuals with epilepsy, including children;

(B) enhancing research activities on the diagnosis, treatment, and management of epilepsy;

(C) implementing public and professional information and education programs regarding epilepsy, including initiatives which promote effective management of the disease through children's programs which are targeted to parents, schools, daycare providers, patients;

(D) undertaking educational efforts with the media, providers of health care, schools and others regarding stigmas and secondary disabilities related to epilepsy and seizures, and its effects on youth;

(E) utilizing and expanding partnerships with organizations with experience addressing the health and related needs of people with disabilities; and

(F) other activities the Secretary deems appropriate.

(3) Coordination of activities

The Secretary shall ensure that activities under this subsection are coordinated as appropriate with other agencies of the Public Health Service that carry out activities regarding epilepsy and seizure.

(b) Seizure disorder; demonstration projects in medically underserved areas

(1) In general

The Secretary, acting through the Administrator of the Health Resources and Services Administration, may make grants for the purpose of carrying out demonstration projects to improve access to health and other services regarding seizures to encourage early detection and treatment in children and others residing in medically underserved areas.

(2) Application for grant

A grant may not be awarded under paragraph (1) unless an application therefore is submitted to the Secretary and the Secretary approves such application. Such application shall be submitted in such form and manner and shall contain such information as the Secretary may prescribe.

(c) Definitions

For purposes of this section:

(1) The term "epilepsy" refers to a chronic and serious neurological condition characterized by excessive electrical discharges in the brain causing recurring seizures affecting all life activities. The Secretary may revise the definition of such term to the extent the Secretary determines necessary.

(2) The term "medically underserved" has the meaning applicable under section 295p(6) of this title.

(d) Authorization of appropriations

For the purpose of carrying out this section, there are authorized to be appropriated such sums as may be necessary for each of the fiscal years 2001 through 2005.

(July 1, 1944, ch. 373, title III, §330E, as added Pub. L. 106–310, div. A, title VIII, §801, Oct. 17,

2000, 114 Stat. 1124.)

§254c–6. Certain services for pregnant women

(a) Infant adoption awareness

(1) In general

The Secretary shall make grants to national, regional, or local adoption organizations for the purpose of developing and implementing programs to train the designated staff of eligible health centers in providing adoption information and referrals to pregnant women on an equal basis with all other courses of action included in nondirective counseling to pregnant women.

(2) Best-practices guidelines

(A) In general

A condition for the receipt of a grant under paragraph (1) is that the adoption organization involved agree that, in providing training under such paragraph, the organization will follow the guidelines developed under subparagraph (B).

(B) Process for development of guidelines

(i) In general

The Secretary shall establish and supervise a process described in clause (ii) in which the participants are—

(I) an appropriate number and variety of adoption organizations that, as a group, have expertise in all models of adoption practice and that represent all members of the adoption triad (birth mother, infant, and adoptive parent); and

(II) affected public health entities.

(ii) Description of process

The process referred to in clause (i) is a process in which the participants described in such clause collaborate to develop best-practices guidelines on the provision of adoption information and referrals to pregnant women on an equal basis with all other courses of action included in nondirective counseling to pregnant women.

(iii) Date certain for development

The Secretary shall ensure that the guidelines described in clause (ii) are developed not later than 180 days after October 17, 2000.

(C) Relation to authority for grants

The Secretary may not make any grant under paragraph (1) before the date on which the guidelines under subparagraph (B) are developed.

(3) Use of grant

(A) In general

With respect to a grant under paragraph (1)—

(i) an adoption organization may expend the grant to carry out the programs directly or through grants to or contracts with other adoption organizations;

(ii) the purposes for which the adoption organization expends the grant may include the development of a training curriculum, consistent with the guidelines developed under paragraph (2)(B); and

(iii) a condition for the receipt of the grant is that the adoption organization agree that, in providing training for the designated staff of eligible health centers, such organization will make reasonable efforts to ensure that the individuals who provide the training are individuals who are knowledgeable in all elements of the adoption process and are experienced in providing adoption information and referrals in the geographic areas in which

the eligible health centers are located, and that the designated staff receive the training in such areas.

(B) Rule of construction regarding training of trainers

With respect to individuals who under a grant under paragraph (1) provide training for the designated staff of eligible health centers (referred to in this subparagraph as "trainers"), subparagraph (A)(iii) may not be construed as establishing any limitation regarding the geographic area in which the trainers receive instruction in being such trainers. A trainer may receive such instruction in a different geographic area than the area in which the trainer trains (or will train) the designated staff of eligible health centers.

(4) Adoption organizations; eligible health centers; other definitions

For purposes of this section:

(A) The term "adoption organization" means a national, regional, or local organization—

(i) among whose primary purposes are adoption;

(ii) that is knowledgeable in all elements of the adoption process and on providing adoption information and referrals to pregnant women; and

(iii) that is a nonprofit private entity.

(B) The term "designated staff", with respect to an eligible health center, means staff of the center who provide pregnancy or adoption information and referrals (or will provide such information and referrals after receiving training under a grant under paragraph (1)).

(C) The term "eligible health centers" means public and nonprofit private entities that provide health services to pregnant women.

(5) Training for certain eligible health centers

A condition for the receipt of a grant under paragraph (1) is that the adoption organization involved agree to make reasonable efforts to ensure that the eligible health centers with respect to which training under the grant is provided include—

(A) eligible health centers that receive grants under section 300 of this title (relating to voluntary family planning projects);

(B) eligible health centers that receive grants under section 254b of this title (relating to community health centers, migrant health centers, and centers regarding homeless individuals and residents of public housing); and

(C) eligible health centers that receive grants under this chapter for the provision of services in schools.

(6) Participation of certain eligible health clinics

In the case of eligible health centers that receive grants under section 254b or 300 of this title:

(A) Within a reasonable period after the Secretary begins making grants under paragraph (1), the Secretary shall provide eligible health centers with complete information about the training available from organizations receiving grants under such paragraph. The Secretary shall make reasonable efforts to encourage eligible health centers to arrange for designated staff to participate in such training. Such efforts shall affirm Federal requirements, if any, that the eligible health center provide nondirective counseling to pregnant women.

(B) All costs of such centers in obtaining the training shall be reimbursed by the organization that provides the training, using grants under paragraph (1).

(C) Not later than 1 year after October 17, 2000, the Secretary shall submit to the appropriate committees of the Congress a report evaluating the extent to which adoption information and referral, upon request, are provided by eligible health centers. Within a reasonable time after training under this section is initiated, the Secretary shall submit to the appropriate committees of the Congress a report evaluating the extent to which adoption information and referral, upon request, are provided by eligible health centers in order to determine the effectiveness of such training and the extent to which such training complies with subsection (a)(1). In preparing the reports required by this subparagraph, the Secretary shall in no respect interpret the provisions

of this section to allow any interference in the provider-patient relationship, any breach of patient confidentiality, or any monitoring or auditing of the counseling process or patient records which breaches patient confidentiality or reveals patient identity. The reports required by this subparagraph shall be conducted by the Secretary acting through the Administrator of the Health Resources and Services Administration and in collaboration with the Director of the Agency for Healthcare Research and Quality.

(b) Application for grant

The Secretary may make a grant under subsection (a) only if an application for the grant is submitted to the Secretary and the application is in such form, is made in such manner, and contains such agreements, assurances, and information as the Secretary determines to be necessary to carry out this section.

(c) Authorization of appropriations

For the purpose of carrying out this section, there are authorized to be appropriated such sums as may be necessary for each of the fiscal years 2001 through 2005.

(July 1, 1944, ch. 373, title III, §330F, as added Pub. L. 106–310, div. A, title XII, §1201, Oct. 17, 2000, 114 Stat. 1132.)

§254c–7. Special needs adoption programs; public awareness campaign and other activities

(a) Special needs adoption awareness campaign

(1) In general

The Secretary shall, through making grants to nonprofit private entities, provide for the planning, development, and carrying out of a national campaign to provide information to the public regarding the adoption of children with special needs.

(2) Input on planning and development

In providing for the planning and development of the national campaign under paragraph (1), the Secretary shall provide for input from a number and variety of adoption organizations throughout the States in order that the full national diversity of interests among adoption organizations is represented in the planning and development of the campaign.

(3) Certain features

With respect to the national campaign under paragraph (1):

(A) The campaign shall be directed at various populations, taking into account as appropriate differences among geographic regions, and shall be carried out in the language and cultural context that is most appropriate to the population involved.

(B) The means through which the campaign may be carried out include—

(i) placing public service announcements on television, radio, and billboards; and

(ii) providing information through means that the Secretary determines will reach individuals who are most likely to adopt children with special needs.

(C) The campaign shall provide information on the subsidies and supports that are available to individuals regarding the adoption of children with special needs.

(D) The Secretary may provide that the placement of public service announcements, and the dissemination of brochures and other materials, is subject to review by the Secretary.

(4) Matching requirement

(A) In general

With respect to the costs of the activities to be carried out by an entity pursuant to paragraph (1), a condition for the receipt of a grant under such paragraph is that the entity agree to make

available (directly or through donations from public or private entities) non-Federal contributions toward such costs in an amount that is not less than 25 percent of such costs.

(B) Determination of amount contributed

Non-Federal contributions under subparagraph (A) may be in cash or in kind, fairly evaluated, including plant, equipment, or services. Amounts provided by the Federal Government, or services assisted or subsidized to any significant extent by the Federal Government, may not be included in determining the amount of such contributions.

(b) National resources program

The Secretary shall (directly or through grant or contract) carry out a program that, through toll-free telecommunications, makes available to the public information regarding the adoption of children with special needs. Such information shall include the following:

(1) A list of national, State, and regional organizations that provide services regarding such adoptions, including exchanges and other information on communicating with the organizations. The list shall represent the full national diversity of adoption organizations.

(2) Information beneficial to individuals who adopt such children, including lists of support groups for adoptive parents and other postadoptive services.

(c) Other programs

With respect to the adoption of children with special needs, the Secretary shall make grants—

(1) to provide assistance to support groups for adoptive parents, adopted children, and siblings of adopted children; and

(2) to carry out studies to identify—

(A) the barriers to completion of the adoption process; and

(B) those components that lead to favorable long-term outcomes for families that adopt children with special needs.

(d) Application for grant

The Secretary may make an award of a grant or contract under this section only if an application for the award is submitted to the Secretary and the application is in such form, is made in such manner, and contains such agreements, assurances, and information as the Secretary determines to be necessary to carry out this section.

(e) Funding

For the purpose of carrying out this section, there are authorized to be appropriated such sums as may be necessary for each of the fiscal years 2001 through 2005.

(July 1, 1944, ch. 373, title III, §330G, as added Pub. L. 106–310, div. A, title XII, §1211, Oct. 17, 2000, 114 Stat. 1135.)

§254c–8. Healthy start for infants

(a) In general

(1) Continuation and expansion of program

The Secretary, acting through the Administrator of the Health Resources and Services Administration, Maternal and Child Health Bureau, shall under authority of this section continue in effect the Healthy Start Initiative and may carry out such program on a national basis.

(2) Definition

For purposes of paragraph (1), the term "Healthy Start Initiative" is a reference to the program that, as an initiative to reduce the rate of infant mortality and improve perinatal outcomes, makes grants for project areas with high or increasing above the national average annual rates of infant mortality and that, prior to the effective date of this section, was a demonstration program carried out under section 241 of this title.

(b) Considerations in making grants

(1) Requirements

In making grants under subsection (a), the Secretary shall require that applicants (in addition to meeting all eligibility criteria established by the Secretary) establish, for project areas under such subsection, community-based consortia of individuals and organizations (including agencies responsible for administering block grant programs under title V of the Social Security Act [42 U.S.C. 701 et seq.], participants and former participants of project services, public health departments, hospitals, health centers under section 254b of this title, State substance abuse agencies, and other significant sources of health care services) that are appropriate for participation in projects under subsection (a).

(2) Other considerations

In making grants under subsection (a), the Secretary shall take into consideration the following:

(A) Factors that contribute to infant mortality, including poor birth outcomes (such as low birthweight and preterm birth) and social determinants of health.

(B) Communities with—

(i) high rates of infant mortality or poor perinatal outcomes; or

(ii) high rates of infant mortality or poor perinatal outcomes in specific subpopulations within the community.

(C) The extent to which applicants for such grants facilitate—

(i) collaboration with the local community in the development of the project;

(ii) a community-based approach to the delivery of services;

(iii) a comprehensive approach to women's health care to improve perinatal outcomes; and

(iv) the use and collection of data demonstrating the effectiveness of such program in decreasing infant mortality rates and improving perinatal outcomes, as applicable, or the process by which new applicants plan to collect this data.

(3) Special projects

Nothing in paragraph (2) shall be construed to prevent the Secretary from awarding grants under subsection (a) for special projects that are intended to address significant disparities in perinatal health indicators in communities along the United States-Mexico border or in Alaska or Hawaii.

(c) Coordination

(1) In general

Recipients of grants under subsection (a) shall coordinate their services and activities with the State agency or agencies that administer block grant programs under title V of the Social Security Act [42 U.S.C. 701 et seq.] in order to promote cooperation, integration, and dissemination of information with Statewide systems and with other community services funded under the Maternal and Child Health Block Grant.

(2) Other programs

The Secretary shall ensure coordination of the program carried out pursuant to this section with other programs and activities related to the reduction of the rate of infant mortality and improved perinatal and infant health outcomes supported by the Department.

(d) Rule of construction

Except to the extent inconsistent with this section, this section may not be construed as affecting the authority of the Secretary to make modifications in the program carried out under subsection (a).

(e) Funding

(1) Authorization of appropriations

For the purpose of carrying out this section, there are authorized to be appropriated

$125,500,000 for each of fiscal years 2021 through 2025.

(2) Allocation

(A) Program administration

Of the amounts appropriated under paragraph (1) for a fiscal year, the Secretary may reserve up to 5 percent for coordination, dissemination, technical assistance, and data activities that are determined by the Secretary to be appropriate for carrying out the program under this section.

(B) Evaluation

Of the amounts appropriated under paragraph (1) for a fiscal year, the Secretary may reserve up to 1 percent for evaluations of projects carried out under subsection (a). Each such evaluation shall include a determination of whether such projects have been effective in reducing the disparity in health status between the general population and individuals who are members of racial or ethnic minority groups. Evaluations may also include, to the extent practicable, information related to—

(i) progress toward achieving any grant metrics or outcomes related to reducing infant mortality rates, improving perinatal outcomes, or reducing the disparity in health status;

(ii) recommendations on potential improvements that may assist with addressing gaps, as applicable and appropriate; and

(iii) the extent to which the grantee coordinated with the community in which the grantee is located in the development of the project and delivery of services, including with respect to technical assistance and mentorship programs.

(f) GAO report

(1) In general

Not later than 4 years after March 27, 2020, the Comptroller General of the United States shall conduct an independent evaluation, and submit to the appropriate Committees of Congress a report, concerning the Healthy Start program under this section.

(2) Evaluation

In conducting the evaluation under paragraph (1), the Comptroller General shall consider, as applicable and appropriate, information from the evaluations under subsection (e)(2)(B).

(3) Report

The report described in paragraph (1) shall review, assess, and provide recommendations, as appropriate, on the following:

(A) The allocation of Healthy Start program grants by the Health Resources and Services Administration, including considerations made by such Administration regarding disparities in infant mortality or perinatal outcomes among urban and rural areas in making such awards.

(B) Trends in the progress made toward meeting the evaluation criteria pursuant to subsection (e)(2)(B), including programs which decrease infant mortality rates and improve perinatal outcomes, programs that have not decreased infant mortality rates or improved perinatal outcomes, and programs that have made an impact on disparities in infant mortality or perinatal outcomes.

(C) The ability of grantees to improve health outcomes for project participants, promote the awareness of the Healthy Start program services, incorporate and promote family participation, facilitate coordination with the community in which the grantee is located, and increase grantee accountability through quality improvement, performance monitoring, evaluation, and the effect such metrics may have toward decreasing the rate of infant mortality and improving perinatal outcomes.

(D) The extent to which such Federal programs are coordinated across agencies and the identification of opportunities for improved coordination in such Federal programs and activities.

(July 1, 1944, ch. 373, title III, §330H, as added Pub. L. 106–310, div. A, title XV, §1501, Oct. 17,

2000, 114 Stat. 1146; amended Pub. L. 108–271, §8(b), July 7, 2004, 118 Stat. 814; Pub. L. 110–339, §2, Oct. 3, 2008, 122 Stat. 3733; Pub. L. 116–136, div. A, title III, §3225, Mar. 27, 2020, 134 Stat. 381.)

EDITORIAL NOTES

REFERENCES IN TEXT

The effective date of this section, referred to in subsec. (a)(2), is the date of enactment of Pub. L. 106–310, which was approved Oct. 17, 2000.

The Social Security Act, referred to in subsecs. (b)(1) and (c)(1), is act Aug. 14, 1935, ch. 531, 49 Stat. 620. Title V of the Act is classified generally to subchapter V (§701 et seq.) of chapter 7 of this title. For complete classification of this Act to the Code, see section 1305 of this title and Tables.

AMENDMENTS

2020—Subsec. (a)(1). Pub. L. 116–136, §3225(1)(A), struck out ", during fiscal year 2001 and subsequent years," after "and may".

Subsec. (a)(2). Pub. L. 116–136, §3225(1)(B), inserted "or increasing above the national average" after "areas with high".

Subsec. (b)(1). Pub. L. 116–136, §3225(2)(A), substituted "participants and former participants of project services, public health departments, hospitals, health centers under section 254b of this title, State substance abuse agencies" for "consumers of project services, public health departments, hospitals, health centers under section 254b of this title".

Subsec. (b)(2)(A). Pub. L. 116–136, §3225(2)(B)(i), substituted "including poor birth outcomes (such as low birthweight and preterm birth) and social determinants of health" for "such as low birthweight".

Subsec. (b)(2)(B). Pub. L. 116–136, §3225(2)(B)(iii), added subpar. (B). Former subpar. (B) redesignated (C).

Subsec. (b)(2)(C). Pub. L. 116–136, §3225(2)(B)(iv), added cl. (i) and (iv) and redesignated former cls. (i) and (ii) as (ii) and (iii), respectively.

Pub. L. 116–136, §3225(2)(B)(ii), redesignated subpar. (B) as (C).

Subsec. (c). Pub. L. 116–136, §3225(3), designated existing provisions as par. (1), inserted heading, and added par. (2).

Subsec. (e)(1). Pub. L. 116–136, §3225(4)(A), substituted "appropriated $125,500,000 for each of fiscal years 2021 through 2025." for "appropriated—

"(A) $120,000,000 for fiscal year 2008; and

"(B) for each of fiscal years 2009 through 2013, the amount authorized for the preceding fiscal year increased by the percentage increase in the Consumer Price Index for all urban consumers for such year."

Subsec. (e)(2)(B). Pub. L. 116–136, §3225(4)(B), inserted at end "Evaluations may also include, to the extent practicable, information related to—" and added cls. (i) to (iii).

Subsec. (f). Pub. L. 116–136, §3225(5), added subsec. (f).

2008—Subsec. (a)(3). Pub. L. 110–339, §2(b)(1), struck out par. (3). Text read as follows: "Effective upon increased funding beyond fiscal year 1999 for such Initiative, additional grants may be made to States to assist communities with technical assistance, replication of successful projects, and State policy formation to reduce infant and maternal mortality and morbidity."

Subsec. (b). Pub. L. 110–339, §2(a), substituted "Considerations in making grants" for "Requirements for making grants" in heading, designated existing provisions as par. (1), inserted par. heading, and added pars. (2) and (3).

Subsec. (e). Pub. L. 110–339, §2(b)(2), (c), added subsec. (e) and struck out former subsec. (e) which related to additional services for at-risk pregnant women and infants.

Subsec. (f). Pub. L. 110–339, §2(b)(2), struck out subsec. (f) which related to funding of program and additional services for at-risk pregnant women and infants.

2004—Subsec. (e)(3). Pub. L. 108–271 substituted "Government Accountability Office" for "General Accounting Office" in heading.

§254c–9. Establishment of program of grants

(a) In general

The Secretary of Health and Human Services shall in accordance with sections 254c–9 to 254c–13 of this title make grants to provide for projects for the establishment, operation, and coordination of effective and cost-efficient systems for the delivery of essential services to individuals with lupus and their families.

(b) Recipients of grants

A grant under subsection (a) may be made to an entity only if the entity is a public or nonprofit private entity, which may include a State or local government; a public or nonprofit private hospital, community-based organization, hospice, ambulatory care facility, community health center, migrant health center, or homeless health center; or other appropriate public or nonprofit private entity.

(c) Certain activities

To the extent practicable and appropriate, the Secretary shall ensure that projects under subsection (a) provide services for the diagnosis and disease management of lupus. Activities that the Secretary may authorize for such projects may also include the following:

(1) Delivering or enhancing outpatient, ambulatory, and home-based health and support services, including case management and comprehensive treatment services, for individuals with lupus; and delivering or enhancing support services for their families.

(2) Delivering or enhancing inpatient care management services that prevent unnecessary hospitalization or that expedite discharge, as medically appropriate, from inpatient facilities of individuals with lupus.

(3) Improving the quality, availability, and organization of health care and support services (including transportation services, attendant care, homemaker services, day or respite care, and providing counseling on financial assistance and insurance) for individuals with lupus and support services for their families.

(d) Integration with other programs

To the extent practicable and appropriate, the Secretary shall integrate the program under sections 254c–9 to 254c–13 of this title with other grant programs carried out by the Secretary, including the program under section 254b of this title.

(Pub. L. 106–505, title V, §521, Nov. 13, 2000, 114 Stat. 2343.)

EDITORIAL NOTES

CODIFICATION

Section was enacted as part of the Lupus Research and Care Amendments of 2000, and also as part of the Public Health Improvement Act, and not as part of the Public Health Service Act which comprises this chapter.

§254c–10. Certain requirements

A grant may be made under section 254c–9 of this title only if the applicant involved makes the following agreements:

(1) Not more than 5 percent of the grant will be used for administration, accounting, reporting, and program oversight functions.

(2) The grant will be used to supplement and not supplant funds from other sources related to the treatment of lupus.

(3) The applicant will abide by any limitations deemed appropriate by the Secretary on any charges to individuals receiving services pursuant to the grant. As deemed appropriate by the Secretary, such limitations on charges may vary based on the financial circumstances of the individual receiving services.

(4) The grant will not be expended to make payment for services authorized under section 254c–9(a) of this title to the extent that payment has been made, or can reasonably be expected to be made, with respect to such services—

(A) under any State compensation program, under an insurance policy, or under any Federal or State health benefits program; or

(B) by an entity that provides health services on a prepaid basis.

(5) The applicant will, at each site at which the applicant provides services under section 254c–9(a) of this title, post a conspicuous notice informing individuals who receive the services of any Federal policies that apply to the applicant with respect to the imposition of charges on such individuals.

(Pub. L. 106–505, title V, §522, Nov. 13, 2000, 114 Stat. 2344.)

EDITORIAL NOTES

CODIFICATION

Section was enacted as part of the Lupus Research and Care Amendments of 2000, and also as part of the Public Health Improvement Act, and not as part of the Public Health Service Act which comprises this chapter.

§254c–11. Technical assistance

The Secretary may provide technical assistance to assist entities in complying with the requirements of sections 254c–9 to 254c–13 of this title in order to make such entities eligible to receive grants under section 254c–9 of this title.

(Pub. L. 106–505, title V, §523, Nov. 13, 2000, 114 Stat. 2344.)

EDITORIAL NOTES

CODIFICATION

Section was enacted as part of the Lupus Research and Care Amendments of 2000, and also as part of the Public Health Improvement Act, and not as part of the Public Health Service Act which comprises this chapter.

§254c–12. Definitions

For purposes of sections 254c–9 to 254c–13 of this title:

(1) Official poverty line

The term "official poverty line" means the poverty line established by the Director of the Office of Management and Budget and revised by the Secretary in accordance with section 9902(2) of this title.

(2) Secretary

The term "Secretary" means the Secretary of Health and Human Services.

(Pub. L. 106–505, title V, §524, Nov. 13, 2000, 114 Stat. 2344.)

EDITORIAL NOTES

CODIFICATION

Section was enacted as part of the Lupus Research and Care Amendments of 2000, and also as part of the Public Health Improvement Act, and not as part of the Public Health Service Act which comprises this chapter.

§254c–13. Authorization of appropriations

For the purpose of carrying out sections 254c–9 to 254c–13 of this title, there are authorized to be appropriated such sums as may be necessary for each of the fiscal years 2001 through 2003.

(Pub. L. 106–505, title V, §525, Nov. 13, 2000, 114 Stat. 2345.)

EDITORIAL NOTES

CODIFICATION

Section was enacted as part of the Lupus Research and Care Amendments of 2000, and also as part of the Public Health Improvement Act, and not as part of the Public Health Service Act which comprises this chapter.

§254c–14. Telehealth network and telehealth resource centers grant programs

(a) Definitions

In this section:

(1) Director; Office

The terms "Director" and "Office" mean the Director and Office specified in subsection (c).

(2) Federally qualified health center and rural health clinic

The term "Federally qualified health center" and "rural health clinic" have the meanings given the terms in section 1395x(aa) of this title.

(3) Frontier community

The term "frontier community" shall have the meaning given the term in regulations issued under subsection (r).

(4) Medically underserved area

The term "medically underserved area" has the meaning given the term "medically underserved community" in section 295p(6) of this title.

(5) Medically underserved population

The term "medically underserved population" has the meaning given the term in section 254b(b)(3) of this title.

(6) Telehealth services

The term "telehealth services" means services provided through telehealth technologies.

(7) Telehealth technologies

The term "telehealth technologies" means technologies relating to the use of electronic information, and telecommunications technologies, to support and promote, at a distance, health care, patient and professional health-related education, health administration, and public health.

(b) Programs

The Secretary shall establish, under section 241 of this title, telehealth network and telehealth resource centers grant programs.

(c) Administration

(1) Establishment

There is established in the Health Resources and Services Administration an Office for the Advancement of Telehealth. The Office shall be headed by a Director.

(2) Duties

The telehealth network and telehealth resource centers grant programs established under section

241 of this title shall be administered by the Director, in consultation with the State offices of rural health, State offices concerning primary care, or other appropriate State government entities.

(d) Grants

(1) Telehealth network grants

The Director may, in carrying out the telehealth network grant program referred to in subsection (b), award grants to eligible entities for evidence-based projects that utilize telehealth technologies through telehealth networks in rural areas, frontier communities, and medically underserved areas, and for medically underserved populations, to—

(A) expand access to, coordinate, and improve access to, and the quality of, health care services; and

(B) expand and improve the quality of health information available to health care providers,,[1] patients, and their families.

(2) Telehealth resource centers grants

The Director may, in carrying out the telehealth resource centers grant program referred to in subsection (b), award grants to eligible entities for projects to support initiatives that utilize telehealth technologies in the areas and communities, and for the populations, described in paragraph (1).

(e) Grant periods

The Director may award grants under this section for periods of not more than 5 years.

(f) Eligible entities

(1) In general

To be eligible to receive a grant under subsection (d)(1), an entity shall demonstrate that the entity will provide services through a telehealth network.

(2) Nature of entities

Each entity participating in the telehealth network may be a nonprofit or for-profit entity.

(3) Composition of network

The telehealth network shall include at least 2 of the following entities (at least 1 of which shall be a community-based health care provider):

(A) Community or migrant health centers or other Federally qualified health centers.
(B) Health care providers, including pharmacists, in private practice.
(C) Entities operating clinics, including rural health clinics.
(D) Local health departments.
(E) Nonprofit hospitals, including community access hospitals.
(F) Other publicly funded health or social service agencies.
(G) Long-term care providers.
(H) Providers of health care services in the home.
(I) Providers of outpatient mental health and substance use disorder services and entities operating outpatient mental health and substance use disorder facilities.
(J) Local or regional emergency health care providers.
(K) Institutions of higher education.
(L) Entities operating dental clinics.
(M) Providers of prenatal, labor care, birthing, and postpartum care services, including hospitals that operate obstetric care units.

(g) Applications

To be eligible to receive a grant under subsection (d), an eligible entity, in consultation with the appropriate State office of rural health or another appropriate State entity, shall prepare and submit to the Secretary an application, at such time, in such manner, and containing such information as the Secretary may require, including—

(1) a description of the project that the eligible entity will carry out using the funds provided under the grant;

(2) a description of the manner in which the project funded under the grant will meet the health care needs of rural or other populations to be served through the project, and improve the access to services of, and the quality of the services received by, those populations;

(3) evidence of local support for the project, and a description of how the areas, communities, or populations to be served will be involved in the development and ongoing operations of the project;

(4) a plan for sustaining the project after Federal support for the project has ended;

(5) information on the source and amount of non-Federal funds that the entity will provide for the project;

(6) information demonstrating the long-term viability of the project, and other evidence of institutional commitment of the entity to the project;

(7) in the case of an application for a project involving a telehealth network, information demonstrating how the project will promote the integration of telehealth technologies into the operations of health care providers, to avoid redundancy, and improve access to and the quality of care; and

(8) other such information as the Secretary determines to be appropriate.

(h) Preferences

(1) Telehealth networks

In awarding grants under subsection (d)(1) for projects involving telehealth networks, the Secretary shall give preference to an eligible entity that meets at least 1 of the following requirements:

(A) Organization

The eligible entity is a rural community-based organization or another community-based organization.

(B) Services

The eligible entity proposes to use Federal funds made available through such a grant to develop plans for, or to establish, telehealth networks that provide mental health care, public health services, long-term care, home care, preventive care, case management services, prenatal care, labor care, birthing care, or postpartum care.

(C) Coordination

The eligible entity demonstrates how the project to be carried out under the grant will be coordinated with other relevant federally funded projects in the areas, communities, and populations to be served through the grant.

(D) Network

The eligible entity demonstrates that the project involves a telehealth network that includes an entity that—

(i) provides clinical health care services, or educational services for health care providers and for patients or their families; and

(ii) is—

(I) a public library;

(II) an institution of higher education; or

(III) a local government entity.

(E) Connectivity

The eligible entity proposes a project that promotes local and regional connectivity within areas, communities, or populations to be served through the project.

(2) Telehealth resource centers

In awarding grants under subsection (d)(2) for projects involving telehealth resource centers, the

Secretary shall give preference to an eligible entity that meets at least 1 of the following requirements:

(A) Provision of services

The eligible entity has a record of success in the provision of telehealth services to rural areas, medically underserved areas, or medically underserved populations.

(B) Collaboration and sharing of expertise

The eligible entity has a demonstrated record of collaborating and sharing expertise with providers of telehealth services at the national, regional, State, and local levels.

(C) Broad range of telehealth services

The eligible entity has a record of providing a broad range of telehealth services, which may include—

(i) a variety of clinical specialty services;
(ii) patient or family education;
(iii) health care professional education; and
(iv) rural residency support programs.

(i) Distribution of funds

(1) In general

In awarding grants under this section, the Director shall ensure, to the greatest extent possible, that such grants are equitably distributed among the geographical regions of the United States.

(2) Telehealth networks

In awarding grants under subsection (d)(1) for a fiscal year, the Director shall ensure that not less than 50 percent of the funds awarded shall be awarded for projects in rural areas.

(j) Use of funds

(1) Telehealth network program

The recipient of a grant under subsection (d)(1) may use funds received through such grant for salaries, equipment, and operating or other costs, including the cost of—

(A) developing and delivering clinical telehealth services that enhance access to community-based health care services in rural areas, frontier communities, or medically underserved areas, or for medically underserved populations;

(B) developing and acquiring, through lease or purchase, equipment that furthers the objectives of the telehealth network grant program;

(C)(i) developing and providing distance education, in a manner that enhances access to care in rural areas, frontier communities, or medically underserved areas, or for medically underserved populations; or

(ii) mentoring, precepting, or supervising health care providers and students seeking to become health care providers, in a manner that enhances access to care in the areas and communities, or for the populations, described in clause (i);

(D) developing and acquiring instructional programming;

(E)(i) providing for transmission of medical data, and maintenance of equipment; and

(ii) providing for compensation (including travel expenses) of specialists, and referring health care providers, who are providing telehealth services through the telehealth network, if no third party payment is available for the telehealth services delivered through the telehealth network;

(F) developing projects to use telehealth technology to facilitate collaboration between health care providers;

(G) collecting and analyzing usage statistics and data to document the cost-effectiveness of the telehealth services; and

(H) carrying out such other activities as are consistent with achieving the objectives of this section, as determined by the Secretary.

(2) Telehealth resource centers

The recipient of a grant under subsection (d)(2) may use funds received through such grant for salaries, equipment, and operating or other costs for—

(A) providing technical assistance, training, and support, and providing for travel expenses, for health care providers and a range of health care entities that provide or will provide telehealth services;

(B) disseminating information and research findings related to telehealth services;

(C) promoting effective collaboration among telehealth resource centers and the Office;

(D) conducting evaluations to determine the best utilization of telehealth technologies to meet health care needs;

(E) promoting the integration of the technologies used in clinical information systems with other telehealth technologies;

(F) fostering the use of telehealth technologies to provide health care information and education for consumers in a more effective manner; and

(G) implementing special projects or studies under the direction of the Office.

(k) Prohibited uses of funds

An entity that receives a grant under this section may not use funds made available through the grant—

(1) to acquire real property;

(2) for expenditures to purchase or lease equipment, to the extent that the expenditures would exceed 20 percent of the total grant funds;

(3) in the case of a project involving a telehealth network, to purchase or install transmission equipment;

(4) to pay for any equipment or transmission costs not directly related to the purposes for which the grant is awarded;

(5) to purchase or install general purpose voice telephone systems;

(6) for construction; or

(7) for expenditures for indirect costs (as determined by the Secretary), to the extent that the expenditures would exceed 15 percent of the total grant funds.

(l) Collaboration

In providing services under this section, an eligible entity shall collaborate, if feasible, with entities that—

(1)(A) are private or public organizations, that receive Federal or State assistance; or

(B) are public or private entities that operate centers, or carry out programs, that receive Federal or State assistance; and

(2) provide telehealth services or related activities.

(m) Coordination with other agencies

The Secretary shall coordinate activities carried out under grant programs described in subsection (b), to the extent practicable, with Federal and State agencies and nonprofit organizations that are operating similar programs, to maximize the effect of public dollars in funding meritorious proposals.

(n) Outreach activities

The Secretary shall establish and implement procedures to carry out outreach activities to advise potential end users of telehealth services in rural areas, frontier communities, medically underserved areas, and medically underserved populations in each State about the grant programs described in subsection (b).

(o) Telehealth

It is the sense of Congress that, for purposes of this section, States should develop reciprocity agreements so that a provider of services under this section who is a licensed or otherwise authorized health care provider under the law of 1 or more States, and who, through telehealth technology,

consults with a licensed or otherwise authorized health care provider in another State, is exempt, with respect to such consultation, from any State law of the other State that prohibits such consultation on the basis that the first health care provider is not a licensed or authorized health care provider under the law of that State.

(p) Report

Not later than 4 years after March 27, 2020, and every 5 years thereafter, the Secretary shall prepare and submit to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives a report on the activities and outcomes of the grant programs under subsection (b).

(q) Authorization of appropriations

There are authorized to be appropriated to carry out this section $29,000,000 for each of fiscal years 2021 through 2025.

(July 1, 1944, ch. 373, title III, §330I, as added Pub. L. 107–251, title II, §212, Oct. 26, 2002, 116 Stat. 1632; amended Pub. L. 108–163, §2(c), Dec. 6, 2003, 117 Stat. 2021; Pub. L. 113–55, title I, §103(a), Nov. 27, 2013, 127 Stat. 642; Pub. L. 116–136, div. A, title III, §3212, Mar. 27, 2020, 134 Stat. 368; Pub. L. 117–103, div. P, title I, §143, Mar. 15, 2022, 136 Stat. 799.)

EDITORIAL NOTES

AMENDMENTS

2022—Subsec. (f)(3)(M). Pub. L. 117–103, §143(1), added subpar. (M).

Subsec. (h)(1)(B). Pub. L. 117–103, §143(2), substituted "prenatal care, labor care, birthing care, or postpartum care" for "or prenatal care for high-risk pregnancies".

2020—Subsec. (d)(1). Pub. L. 116–136, §3212(1)(A)(i), substituted "evidence-based projects that utilize telehealth technologies through telehealth networks" for "projects to demonstrate how telehealth technologies can be used through telehealth networks" in introductory provisions.

Subsec. (d)(1)(A). Pub. L. 116–136, §3212(1)(A)(ii), substituted "access to, and the quality of," for "the quality of" and inserted "and" after semicolon.

Subsec. (d)(1)(B), (C). Pub. L. 116–136, §3212(1)(A)(iii)–(v), redesignated subpar. (C) as (B), substituted ", patients, and their families" for "and patients and their families, for decisionmaking", and struck out former subpar. (B) which read as follows: "improve and expand the training of health care providers; and".

Subsec. (d)(2). Pub. L. 116–136, §3212(1)(B), substituted "support initiatives that utilize telehealth technologies" for "demonstrate how telehealth technologies can be used" and struck out ", to establish telehealth resource centers" before period at end.

Subsec. (e). Pub. L. 116–136, §3212(2), substituted "5 years" for "4 years".

Subsec. (f). Pub. L. 116–136, §3212(3)(B), redesignated cls. (i) to (iii) of par. (1)(B) as pars. (1) to (3), respectively, and realigned margins; in par. (3), redesignated subcls. (I) to (XII) as subpars. (A) to (L), respectively, and realigned margins; and struck out heading of former par. (1), headings of former subpars. (A) and (B) of former par. (1), and text of former subpar. (A) which read as follows: "To be eligible to receive a grant under subsection (d)(1), an entity shall be a nonprofit entity."

Subsec. (f)(2). Pub. L. 116–136, §3212(3)(A), struck out par. (2). Text read as follows: "To be eligible to receive a grant under subsection (d)(2), an entity shall be a nonprofit entity."

Subsec. (f)(3)(I). Pub. L. 116–136, §3212(3)(C), inserted "and substance use disorder" after "mental health" in two places.

Subsec. (g)(2). Pub. L. 116–136, §3212(4), substituted "and improve" for "or improve".

Subsec. (h). Pub. L. 116–136, §3212(5), (6), redesignated subsec. (i) as (h) and struck out former subsec. (h). Prior to amendment, text of subsec. (h) read as follows: "The Secretary shall establish the terms and conditions of each grant program described in subsection (b) and the maximum amount of a grant to be awarded to an individual recipient for each fiscal year under this section. The Secretary shall publish, in a publication of the Health Resources and Services Administration, notice of the application requirements for each grant program described in subsection (b) for each fiscal year."

Subsec. (h)(1)(B). Pub. L. 116–136, §3212(7)(A)(i), substituted "mental health care, public health services, long-term care, home care, preventive care" for "mental health, public health, long-term care, home care, preventive".

Subsec. (h)(1)(E). Pub. L. 116–136, §3212(7)(A)(ii), inserted "and regional" after "local".

Subsec. (h)(1)(F). Pub. L. 116–136, §3212(7)(A)(iii), struck out subpar. (F). Text read as follows: "The eligible entity demonstrates that health care information has been integrated into the project."

Subsec. (h)(2)(A). Pub. L. 116–136, §3212(7)(B), substituted "rural areas, medically underserved areas, or" for "medically underserved areas or".

Subsec. (i). Pub. L. 116–136, §3212(6), redesignated subsec. (j) as (i). Former subsec. (i) redesignated (h).

Subsec. (i)(2). Pub. L. 116–136, §3212(8), substituted "ensure that not less than 50 percent of the funds awarded shall be awarded for projects in rural areas." for "ensure that—

"(A) not less than 50 percent of the funds awarded shall be awarded for projects in rural areas; and

"(B) the total amount of funds awarded for such projects for that fiscal year shall be not less than the total amount of funds awarded for such projects for fiscal year 2001 under section 254c of this title (as in effect on the day before October 26, 2002)."

Subsec. (j). Pub. L. 116–136, §3212(6), redesignated subsec. (k) as (j). Former subsec. (j) redesignated (i).

Subsec. (j)(1)(B). Pub. L. 116–136, §3212(9)(A), struck out "computer hardware and software, audio and video equipment, computer network equipment, interactive equipment, data terminal equipment, and other" before "equipment that furthers the objectives".

Subsec. (j)(2)(F). Pub. L. 116–136, §3212(9)(B), struck out "health care providers and" before "consumers".

Subsec. (k). Pub. L. 116–136, §3212(6), redesignated subsec. (l) as (k). Former subsec. (k) redesignated (j).

Subsec. (k)(2). Pub. L. 116–136, §3212(10)(A), substituted "20 percent" for "40 percent".

Subsec. (k)(3). Pub. L. 116–136, §3212(10)(B), struck out "(such as laying cable or telephone lines, or purchasing or installing microwave towers, satellite dishes, amplifiers, or digital switching equipment)" before semicolon at end.

Subsecs. (l) to (o). Pub. L. 116–136, §3212(6), redesignated subsecs. (m) to (p) as (l) to (o), respectively. Former subsec. (l) redesignated (k).

Subsec. (p). Pub. L. 116–136, §3212(11), added subsec. (p).

Subsec. (q). Pub. L. 116–136, §3212(13), substituted "this section $29,000,000 for each of fiscal years 2021 through 2025." for "this section—

"(1) for grants under subsection (d)(1), $40,000,000 for fiscal year 2002, and such sums as may be necessary for each of fiscal years 2003 through 2006; and

"(2) for grants under subsection (d)(2), $20,000,000 for fiscal year 2002, and such sums as may be necessary for each of fiscal years 2003 through 2006."

Pub. L. 116–136, §3212(11), (12), redesignated subsec. (s) as (q) and struck out former subsec. (q). Prior to amendment, text of subsec. (q) read as follows: "Not later than September 30, 2005, the Secretary shall prepare and submit to the appropriate committees of Congress a report on the progress and accomplishments of the grant programs described in subsection (b)."

Subsec. (r). Pub. L. 116–136, §3212(11), struck out subsec. (r). Text read as follows: "The Secretary shall issue regulations specifying, for purposes of this section, a definition of the term "frontier area". The definition shall be based on factors that include population density, travel distance in miles to the nearest medical facility, travel time in minutes to the nearest medical facility, and such other factors as the Secretary determines to be appropriate. The Secretary shall develop the definition in consultation with the Director of the Bureau of the Census and the Administrator of the Economic Research Service of the Department of Agriculture."

Subsec. (s). Pub. L. 116–136, §3212(12), redesignated subsec. (s) as (q).

2013—Subsec. (i)(1)(B). Pub. L. 113–55 substituted "case management services, or prenatal care for high-risk pregnancies" for "or case management services".

2003—Subsec. (a)(4). Pub. L. 108–163, §2(c)(1), substituted "section 295p(6)" for "section 295p".

Subsec. (c)(1). Pub. L. 108–163, §2(c)(2), substituted "Health Resources and Services Administration" for "Health and Resources and Services Administration".

STATUTORY NOTES AND RELATED SUBSIDIARIES

EFFECTIVE DATE OF 2003 AMENDMENT

Amendments by Pub. L. 108–163 deemed to have taken effect immediately after the enactment of Pub. L. 107–251, see section 3 of Pub. L. 108–163, set out as a note under section 233 of this title.

GUIDANCE ON FURNISHING SERVICES VIA TELEHEALTH TO INDIVIDUALS WITH LIMITED ENGLISH PROFICIENCY

Pub. L. 119–75, div. J, title II, §6213, Feb. 3, 2026, 140 Stat. 653, provided that:

"(a) IN GENERAL.—Not later than 1 year after the date of enactment of this section [Feb. 3, 2026], the

Secretary of Health and Human Services, in consultation with 1 or more entities from each of the categories described in paragraphs (1) through (7) of subsection (b), shall issue and disseminate, or update and revise as applicable, guidance for the entities described in such subsection on the following:

"(1) Best practices on facilitating and integrating use of interpreters during a telemedicine appointment.

"(2) Best practices on providing accessible instructions on how to access telecommunications systems (as such term is used for purposes of section 1834(m) of the Social Security Act (42 U.S.C. 1395m(m)) for individuals with limited English proficiency.

"(3) Best practices on improving access to digital patient portals for individuals with limited English proficiency.

"(4) Best practices on integrating the use of video platforms that enable multi-person video calls furnished via a telecommunications system for purposes of providing interpretation during a telemedicine appointment for an individual with limited English proficiency.

"(5) Best practices for providing patient materials, communications, and instructions in multiple languages, including text message appointment reminders and prescription information.

"(b) ENTITIES DESCRIBED.—For purposes of subsection (a), an entity described in this subsection is an entity in 1 or more of the following categories:

"(1) Health information technology service providers, including—

"(A) electronic medical record companies;

"(B) remote patient monitoring companies; and

"(C) telehealth or mobile health vendors and companies.

"(2) Health care providers, including—

"(A) physicians; and

"(B) hospitals.

"(3) Health insurers.

"(4) Language service companies.

"(5) Interpreter or translator professional associations.

"(6) Health and language services quality certification organizations.

"(7) Patient and consumer advocates, including such advocates that work with individuals with limited English proficiency."

[1] *So in original.*

§254c–15. Transferred

EDITORIAL NOTES

CODIFICATION

Section, act July 1, 1944, ch. 373, title III, §330J, as added Pub. L. 107–251, title II, §221, Oct. 26, 2002, 116 Stat. 1638; amended Pub. L. 115–334, title XII, §12608, Dec. 20, 2018, 132 Stat. 5008; Pub. L. 118–84, §2(1)–(5), Sept. 26, 2024, 138 Stat. 1544, which related to rural emergency medical service training and equipment assistance program, was renumbered section 553 of title V of act July 1, 1944, by Pub. L. 118–84, §2(6), (7), Sept. 26, 2024, 138 Stat. 1544, 1545, and transferred to section 290ee–10 of this title.

§254c–16. Mental health services delivered via telehealth

(a) Definitions

In this section:

(1) Eligible entity

The term "eligible entity" means a public or nonprofit private telehealth provider network that offers services that include mental health services provided by qualified mental health providers.

(2) Qualified mental health professionals

The term "qualified mental health professionals" refers to providers of mental health services reimbursed under the medicare program carried out under title XVIII of the Social Security Act (42 U.S.C. 1395 et seq.) who have additional training in the treatment of mental illness in children and adolescents or who have additional training in the treatment of mental illness in the elderly.

(3) Special populations

The term "special populations" refers to the following 2 distinct groups:

(A) Children and adolescents in mental health underserved rural areas or in mental health underserved urban areas.

(B) Elderly individuals located in long-term care facilities in mental health underserved rural or urban areas.

(4) Telehealth

The term "telehealth" means the use of electronic information and telecommunications technologies to support long distance clinical health care, patient and professional health-related education, public health, and health administration.

(b) Program authorized

(1) In general

The Secretary, acting through the Director of the Office for the Advancement of Telehealth of the Health Resources and Services Administration, shall award grants to eligible entities to establish demonstration projects for the provision of mental health services to special populations as delivered remotely by qualified mental health professionals using telehealth and for the provision of education regarding mental illness as delivered remotely by qualified mental health professionals using telehealth.

(2) Populations served

The Secretary shall award the grants under paragraph (1) in a manner that distributes the grants so as to serve equitably the populations described in subparagraphs (A) and (B) of subsection (a)(3).

(c) Use of funds

(1) In general

An eligible entity that receives a grant under this section shall use the grant funds—

(A) for the populations described in subsection (a)(3)(A)—

(i) to provide mental health services, including diagnosis and treatment of mental illness, as delivered remotely by qualified mental health professionals using telehealth; and

(ii) to collaborate with local public health entities to provide the mental health services; and

(B) for the populations described in subsection (a)(3)(B)—

(i) to provide mental health services, including diagnosis and treatment of mental illness, in long-term care facilities as delivered remotely by qualified mental health professionals using telehealth; and

(ii) to collaborate with local public health entities to provide the mental health services.

(2) Other uses

An eligible entity that receives a grant under this section may also use the grant funds to—

(A) pay telecommunications costs; and

(B) pay qualified mental health professionals on a reasonable cost basis as determined by the Secretary for services rendered.

(3) Prohibited uses

An eligible entity that receives a grant under this section shall not use the grant funds to—

(A) purchase or install transmission equipment (other than such equipment used by qualified

mental health professionals to deliver mental health services using telehealth under the project involved); or

(B) build upon or acquire real property.

(d) Equitable distribution

In awarding grants under this section, the Secretary shall ensure, to the greatest extent possible, that such grants are equitably distributed among geographical regions of the United States.

(e) Application

An entity that desires a grant under this section shall submit an application to the Secretary at such time, in such manner, and containing such information as the Secretary determines to be reasonable.

(f) Report

Not later than 4 years after October 26, 2002, the Secretary shall prepare and submit to the appropriate committees of Congress a report that shall evaluate activities funded with grants under this section.

(g) Authorization of appropriations

There are authorized to be appropriated to carry out this section, $20,000,000 for fiscal year 2002 and such sums as may be necessary for fiscal years 2003 through 2006.

(July 1, 1944, ch. 373, title III, §330K, as added Pub. L. 107–251, title II, §221, Oct. 26, 2002, 116 Stat. 1640; amended Pub. L. 108–163, §2(d), Dec. 6, 2003, 117 Stat. 2021.)

EDITORIAL NOTES

REFERENCES IN TEXT

The Social Security Act, referred to in subsec. (a)(2), is act Aug. 14, 1935, ch. 531, 49 Stat. 620. Title XVIII of the Act is classified generally to subchapter XVIII (§1395 et seq.) of chapter 7 of this title. For complete classification of this Act to the Code, see section 1305 of this title and Tables.

AMENDMENTS

2003—Subsec. (b)(2). Pub. L. 108–163, §2(d)(1), substituted "subsection (a)(3)" for "subsection (a)(4)".

Subsec. (c)(1)(A). Pub. L. 108–163, §2(d)(2)(A), substituted "subsection (a)(3)(A)" for "subsection (a)(4)(A)".

Subsec. (c)(1)(B). Pub. L. 108–163, §2(d)(2)(B), substituted "subsection (a)(3)(B)" for "subsection (a)(4)(B)".

STATUTORY NOTES AND RELATED SUBSIDIARIES

EFFECTIVE DATE OF 2003 AMENDMENT

Amendments by Pub. L. 108–163 deemed to have taken effect immediately after the enactment of Pub. L. 107–251, see section 3 of Pub. L. 108–163, set out as a note under section 233 of this title.

§254c–17. Repealed. Pub. L. 108–163, §2(e)(2), Dec. 6, 2003, 117 Stat. 2021

Section, Pub. L. 107–251, title I, §102, Oct. 26, 2002, 116 Stat. 1627, provided for grants to State professional licensing boards to develop and implement State policies to promote telemedicine.

STATUTORY NOTES AND RELATED SUBSIDIARIES

EFFECTIVE DATE OF REPEAL

Repeal deemed to have taken effect immediately after the enactment of Pub. L. 107–251, see section 3 of Pub. L. 108–163, set out as an Effective Date of 2003 Amendments note under section 233 of this title.

§254c–18. Telemedicine; incentive grants regarding coordination among States

(a) In general

The Secretary may make grants to State professional licensing boards to carry out programs under which such licensing boards of various States cooperate to develop and implement State policies that will reduce statutory and regulatory barriers to telemedicine.

(b) Authorization of appropriations

For the purpose of carrying out subsection (a), there are authorized to be appropriated such sums as may be necessary for each of the fiscal years 2002 through 2006.

(July 1, 1944, ch. 373, title III, §330L, as added Pub. L. 108–163, §2(e)(1), Dec. 6, 2003, 117 Stat. 2021.)

STATUTORY NOTES AND RELATED SUBSIDIARIES

EFFECTIVE DATE

Section deemed to have taken effect immediately after the enactment of Pub. L. 107–251, see section 3 of Pub. L. 108–163, set out as an Effective Date of 2003 Amendments note under section 233 of this title.

§254c–19. Pediatric mental health care access grants

(a) In general

The Secretary, acting through the Administrator of the Health Resources and Services Administration and in coordination with other relevant Federal agencies, shall award grants or cooperative agreements to States, political subdivisions of States, and Indian Tribes and Tribal organizations (for purposes of this section, as such terms are defined in section 5304 of title 25) to promote behavioral health integration in pediatric primary care by—

(1) supporting the development of statewide or regional pediatric mental health care telehealth access programs; and

(2) supporting the improvement of existing statewide or regional pediatric mental health care telehealth access programs.

(b) Program requirements

(1) In general

A pediatric mental health care telehealth access program referred to in subsection (a), with respect to which an award under such subsection may be used, shall—

(A) be a statewide or regional network of pediatric mental health teams that provide support to pediatric primary care sites as an integrated team;

(B) support and further develop organized State or regional networks of pediatric mental health teams to provide consultative support to pediatric primary care sites;

(C) conduct an assessment of critical behavioral consultation needs among pediatric providers and such providers' preferred mechanisms for receiving consultation, training, and technical assistance;

(D) develop an online database and communication mechanisms, including telehealth, to facilitate consultation support to pediatric practices;

(E) provide rapid statewide or regional clinical telephone or telehealth consultations when requested between the pediatric mental health teams and pediatric primary care providers;

(F) conduct training and provide technical assistance to pediatric primary care providers to support the early identification, diagnosis, treatment, and referral of children with behavioral health conditions;

(G) provide information to pediatric providers about, and assist pediatric providers in accessing, pediatric mental health care providers, including child and adolescent psychiatrists, developmental-behavioral pediatricians, and licensed mental health professionals, such as

psychologists, social workers, or mental health counselors and in scheduling and conducting technical assistance;

(H) provide information to pediatric health care providers about available mental health services for children in the community and assist with referrals to specialty care and community or behavioral health resources; and

(I) establish mechanisms for measuring and monitoring increased access to pediatric mental health care services by pediatric primary care providers and expanded capacity of pediatric primary care providers to identify, treat, and refer children with mental health conditions.

(2) Support to schools and emergency departments

(A) In general

In addition to the activities required under paragraph (1), a pediatric mental health care access program referred to in subsection (a), with respect to which an award under such subsection may be used, may provide information, consultative support, training, and technical assistance to—

(i) emergency departments; and

(ii) State educational agencies, local educational agencies, Tribal educational agencies, and elementary and secondary schools.

(B) Requirements for certain recipients

An entity receiving information, consultative support, training, and technical assistance under subparagraph (A)(ii) shall operate in a manner consistent with, and shall ensure consistency with, the requirements of subsections (a) and (c) of section 7101 of title 20 [1] with respect to such information, consultative support, training, and technical assistance.

(3) Pediatric mental health teams

In this subsection, the term "pediatric mental health team" means a team consisting of at least one case coordinator, at least one child and adolescent psychiatrist, and at least one licensed clinical mental health professional, such as a psychologist, social worker, or mental health counselor, and which may include a developmental-behavioral pediatrician. Such a team may be regionally based.

(c) Application

A State, political subdivision of a State, Indian Tribe, or Tribal organization seeking an award under this section shall submit an application to the Secretary at such time, in such manner, and containing such information as the Secretary may require, including a plan for the comprehensive evaluation of activities that are carried out with funds received under such award.

(d) Evaluation

A State, political subdivision of a State, Indian Tribe, or Tribal organization that receives an award under this section shall prepare and submit an evaluation of activities that are carried out with funds received under such award to the Secretary at such time, in such manner, and containing such information as the Secretary may reasonably require, including a process and outcome evaluation.

(e) Access to broadband

In administering awards under this section, the Secretary may coordinate with other agencies to ensure that funding opportunities are available to support access to reliable, high-speed Internet for providers.

(f) Matching requirement

The Secretary may not make an award under this section unless the State, political subdivision of a State, Indian Tribe, or Tribal organization involved agrees, with respect to the costs to be incurred by the State, political subdivision of a State, Indian Tribe, or Tribal organization in carrying out the

purpose described in this section, to make available non-Federal contributions (in cash or in kind) toward such costs in an amount that is not less than 20 percent of Federal funds provided in the award.

(g) Technical assistance

The Secretary may—

(1) provide, or continue to provide, technical assistance to recipients of awards under subsection (a); and

(2) award a grant or contract to an eligible public or nonprofit private entity (as determined by the Secretary) for the purpose of providing such technical assistance pursuant to this subsection.

(h) Authorization of appropriations

To carry out this section, there are authorized to be appropriated, $31,000,000 for each of fiscal years 2023 through 2027.

(July 1, 1944, ch. 373, title III, §330M, as added Pub. L. 114–255, div. B, title X, §10002, Dec. 13, 2016, 130 Stat. 1262; amended Pub. L. 117–159, div. A, title I, §11005, June 25, 2022, 136 Stat. 1321.)

EDITORIAL NOTES

REFERENCES IN TEXT

Section 7101 of title 20, referred to in subsec. (b)(2), was in the original "section 4001 of the Elementary and Secondary Education Act" and was translated as if it had read "section 4001 of the Elementary and Secondary Education Act of 1965" to reflect the probable intent of Congress.

AMENDMENTS

2022—Pub. L. 117–159, §11005(1), made technical amendment to section designation in original Act as added by Pub. L. 114–255, §10002, resulting in no change in text.

Subsec. (a). Pub. L. 117–159, §11005(2), inserted "or cooperative agreements" after "award grants" and substituted "Indian Tribes and Tribal organizations" for "Indian tribes and tribal organizations" in introductory provisions.

Subsec. (b)(1). Pub. L. 117–159, §11005(3)(A)(i), substituted "an award" for "a grant" in introductory provisions.

Subsec. (b)(1)(G). Pub. L. 117–159, §11005(3)(A)(ii), inserted "developmental-behavioral pediatricians," after "psychiatrists,".

Subsec. (b)(1)(H). Pub. L. 117–159, §11005(3)(A)(iii), inserted "provide information to pediatric health care providers about available mental health services for children in the community and" before "assist".

Subsec. (b)(1)(I). Pub. L. 117–159, §11005(3)(A)(iv), substituted "conditions" for "problems".

Subsec. (b)(2). Pub. L. 117–159, §11005(3)(C), added par. (2). Former par. (2) redesignated (3).

Subsec. (b)(3). Pub. L. 117–159, §11005(3)(B), (D), redesignated par. (2) as (3) and inserted ", and which may include a developmental-behavioral pediatrician" after "or mental health counselor".

Subsecs. (c), (d). Pub. L. 117–159, §11005(4), (5), substituted "Indian Tribe, or Tribal organization" for "Indian tribe, or tribal organization", "an award" for "a grant", and "such award" for "such grant".

Subsec. (e). Pub. L. 117–159, §11005(6), substituted "awards" for "grants".

Subsec. (f). Pub. L. 117–159, §11005(4), (7), substituted "make an award" for "award a grant", "Indian Tribe, or Tribal organization" for "Indian tribe, or tribal organization" in two places, and "the award" for "the grant".

Subsec. (g). Pub. L. 117–159, §11005(9), added subsec. (g). Former subsec. (g) redesignated (h).

Subsec. (h). Pub. L. 117–159, §11005(8), (10), redesignated subsec. (g) as (h) and substituted "$31,000,000 for each of fiscal years 2023 through 2027" for "$9,000,000 for the period of fiscal years 2018 through 2022".

[1] *See References in Text note below.*

§254c–20. Expanding capacity for health outcomes

(a) Definitions

In this section:

(1) Eligible entity

The term "eligible entity" means an entity that provides, or supports the provision of, health care services in rural areas, frontier areas, health professional shortage areas, or medically underserved areas, or to medically underserved populations or Native Americans, including Indian Tribes, Tribal organizations, and urban Indian organizations, and which may include entities leading, or capable of leading, a technology-enabled collaborative learning and capacity building model or engaging in technology-enabled collaborative training of participants in such model.

(2) Health professional shortage area

The term "health professional shortage area" means a health professional shortage area designated under section 254e of this title.

(3) Indian Tribe

The terms "Indian Tribe" and "Tribal organization" have the meanings given the terms "Indian tribe" and "tribal organization" in section 5304 of title 25.

(4) Medically underserved population

The term "medically underserved population" has the meaning given the term in section 254b(b)(3) of this title.

(5) Native Americans

The term "Native Americans" has the meaning given the term in section 293 of this title and includes Indian Tribes and Tribal organizations.

(6) Technology-enabled collaborative learning and capacity building model

The term "technology-enabled collaborative learning and capacity building model" means a distance health education model that connects health care professionals, and particularly specialists, with multiple other health care professionals through simultaneous interactive videoconferencing for the purpose of facilitating case-based learning, disseminating best practices, and evaluating outcomes.

(7) Urban Indian organization

The term "urban Indian organization" has the meaning given the term in section 1603 of title 25.

(b) Program established

The Secretary shall, as appropriate, award grants to evaluate, develop, and, as appropriate, expand the use of technology-enabled collaborative learning and capacity building models, to improve retention of health care providers and increase access to health care services, such as those to address chronic diseases and conditions, infectious diseases, mental health, substance use disorders, prenatal and maternal health, pediatric care, pain management, palliative care, and other specialty care in rural areas, frontier areas, health professional shortage areas, or medically underserved areas and for medically underserved populations or Native Americans.

(c) Use of funds

(1) In general

Grants awarded under subsection (b) shall be used for—

(A) the development and acquisition of instructional programming, and the training of health care providers and other professionals that provide or assist in the provision of services through models described in subsection (b), such as training on best practices for data collection and leading or participating in such technology-enabled activities consistent with technology-enabled collaborative learning and capacity-building models;

(B) information collection and evaluation activities to study the impact of such models on patient outcomes and health care providers, and to identify best practices for the expansion and

use of such models; or

(C) other activities consistent with achieving the objectives of the grants awarded under this section, as determined by the Secretary.

(2) Other uses

In addition to any of the uses under paragraph (1), grants awarded under subsection (b) may be used for—

(A) equipment to support the use and expansion of technology-enabled collaborative learning and capacity building models, including for hardware and software that enables distance learning, health care provider support, and the secure exchange of electronic health information; or

(B) support for health care providers and other professionals that provide or assist in the provision of services through such models.

(d) Length of grants

Grants awarded under subsection (b) shall be for a period of up to 5 years.

(e) Grant requirements

The Secretary may require entities awarded a grant under this section to collect information on the effect of the use of technology-enabled collaborative learning and capacity building models, such as on health outcomes, access to health care services, quality of care, and provider retention in areas and populations described in subsection (b). The Secretary may award a grant or contract to assist in the coordination of such models, including to assess outcomes associated with the use of such models in grants awarded under subsection (b), including for the purpose described in subsection (c)(1)(B).

(f) Application

An eligible entity that seeks to receive a grant under subsection (b) shall submit to the Secretary an application, at such time, in such manner, and containing such information as the Secretary may require. Such application shall include plans to assess the effect of technology-enabled collaborative learning and capacity building models on patient outcomes and health care providers.

(g) Access to broadband

In administering grants under this section, the Secretary may coordinate with other agencies to ensure that funding opportunities are available to support access to reliable, high-speed internet for grantees.

(h) Technical assistance

The Secretary shall provide (either directly through the Department of Health and Human Services or by contract) technical assistance to eligible entities, including recipients of grants under subsection (b), on the development, use, and evaluation of technology-enabled collaborative learning and capacity building models in order to expand access to health care services provided by such entities, including for medically underserved areas and to medically underserved populations or Native Americans.

(i) Research and evaluation

The Secretary, in consultation with stakeholders with appropriate expertise in such models, shall develop a strategic plan to research and evaluate the evidence for such models. The Secretary shall use such plan to inform the activities carried out under this section.

(j) Report by Secretary

Not later than 4 years after December 27, 2020, the Secretary shall prepare and submit to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives, and post on the internet website of the Department of Health and Human Services, a report including, at minimum—

(1) a description of any new and continuing grants awarded to entities under subsection (b) and the specific purpose and amounts of such grants;

(2) an overview of—
(A) the evaluations conducted under subsections (b);
(B) technical assistance provided under subsection (h); and
(C) activities conducted by entities awarded grants under subsection (b); and

(3) a description of any significant findings or developments related to patient outcomes or health care providers and best practices for eligible entities expanding, using, or evaluating technology-enabled collaborative learning and capacity building models, including through the activities described in subsection (h).

(k) Authorization of appropriations

There are authorized to be appropriated to carry out this section $10,000,000 for each of fiscal years 2022 through 2026.

(July 1, 1944, ch. 373, title III, §330N, as added Pub. L. 116–260, div. BB, title III, §313, Dec. 27, 2020, 134 Stat. 2927.)

§254c–21. Innovation for maternal health

(a) In general

The Secretary, in consultation with experts representing a variety of clinical specialties, State, Tribal, or local public health officials, researchers, epidemiologists, statisticians, and community organizations, shall establish or continue a program to award competitive grants to eligible entities for the purpose of—

(1) identifying, developing, or disseminating best practices to improve maternal health care quality and outcomes, improve maternal and infant health, and eliminate preventable maternal mortality and severe maternal morbidity, which may include—
(A) information on evidence-based practices to improve the quality and safety of maternal health care in hospitals and other health care settings of a State or health care system by addressing topics commonly associated with health complications or risks related to prenatal care, labor care, birthing, and postpartum care;
(B) best practices for improving maternal health care based on data findings and reviews conducted by a State maternal mortality review committee that address topics of relevance to common complications or health risks related to prenatal care, labor care, birthing, and postpartum care; and
(C) information on addressing determinants of health that impact maternal health outcomes for women before, during, and after pregnancy;

(2) collaborating with State maternal mortality review committees to identify issues for the development and implementation of evidence-based practices to improve maternal health outcomes and reduce preventable maternal mortality and severe maternal morbidity, consistent with section 247b–12 of this title;
(3) providing technical assistance and supporting the implementation of best practices identified in paragraph (1) to entities providing health care services to pregnant and postpartum women; and
(4) identifying, developing, and evaluating new models of care that improve maternal and infant health outcomes, which may include the integration of community-based services and clinical care.

(b) Eligible entities

To be eligible for a grant under subsection (a), an entity shall—
(1) submit to the Secretary an application at such time, in such manner, and containing such information as the Secretary may require; and
(2) demonstrate in such application that the entity is capable of carrying out data-driven maternal safety and quality improvement initiatives in the areas of obstetrics and gynecology or

maternal health.

(c) Report

Not later than September 30, 2025, and every 2 years thereafter, the Secretary shall submit a report to Congress on the practices described in paragraphs (1) and (2) of subsection (a). Such report shall include a description of the extent to which such practices reduced preventable maternal mortality and severe maternal morbidity, and whether such practices improved maternal and infant health. The Secretary shall disseminate information on such practices, as appropriate.

(d) Authorization of appropriations

To carry out this section, there are authorized to be appropriated $9,000,000 for each of fiscal years 2023 through 2027.

(July 1, 1944, ch. 373, title III, §330O, as added Pub. L. 117–103, div. P, title I, §131, Mar. 15, 2022, 136 Stat. 794.)

§254c–22. Integrated services for pregnant and postpartum women

(a) In general

The Secretary may award grants for the purpose of establishing or operating evidence-based or innovative, evidence-informed programs to deliver integrated health care services to pregnant and postpartum women to optimize the health of women and their infants, including to reduce adverse maternal health outcomes, pregnancy-related deaths, and related health disparities (including such disparities associated with racial and ethnic minority populations), and, as appropriate, by addressing issues researched under subsection (b)(2) of section 247b–12 of this title.

(b) Integrated services for pregnant and postpartum women

(1) Eligibility

To be eligible to receive a grant under subsection (a), a State, Indian Tribe, or Tribal organization (as such terms are defined in section 5304 of title 25) shall work with relevant stakeholders that coordinate care to develop and carry out the program, including—

(A) State, Tribal, and local agencies responsible for Medicaid, public health, social services, mental health, and substance use disorder treatment and services;

(B) health care providers who serve pregnant and postpartum women; and

(C) community-based health organizations and health workers, including providers of home visiting services and individuals representing communities with disproportionately high rates of maternal mortality and severe maternal morbidity, and including those representing racial and ethnic minority populations.

(2) Terms

(A) Period

A grant awarded under subsection (a) shall be made for a period of 5 years. Any supplemental award made to a grantee under subsection (a) may be made for a period of less than 5 years.

(B) Priorities

In awarding grants under subsection (a), the Secretary shall—

(i) give priority to States, Indian Tribes, and Tribal organizations that have the highest rates of maternal mortality and severe maternal morbidity relative to other such States, Indian Tribes, or Tribal organizations, respectively; and

(ii) shall consider health disparities related to maternal mortality and severe maternal morbidity, including such disparities associated with racial and ethnic minority populations.

(C) Evaluation

The Secretary shall require grantees to evaluate the outcomes of the programs supported

under the grant.

(c) Authorization of appropriations

There are authorized to be appropriated to carry out this section $10,000,000 for each of fiscal years 2023 through 2027.

(July 1, 1944, ch. 373, title III, §330P, as added Pub. L. 117–103, div. P, title I, §134(a), Mar. 15, 2022, 136 Stat. 796.)

STATUTORY NOTES AND RELATED SUBSIDIARIES

DISSEMINATION OF BEST PRACTICES

Pub. L. 117–103, div. P, title I, §134(b)(2), Mar. 15, 2022, 136 Stat. 797, provided that: "Not later than August 1, 2027, the Secretary of Health and Human Services shall disseminate information on best practices and models of care used by recipients of grants under the amendments made by this section [enacting this section] (including best practices and models of care relating to the reduction of health disparities, including such disparities associated with racial and ethnic minority populations, in rates of maternal mortality and severe maternal morbidity) to relevant stakeholders, which may include health providers, medical schools, nursing schools, relevant State, Tribal, and local agencies, and the general public."

SUBPART II—NATIONAL HEALTH SERVICE CORPS PROGRAM

EDITORIAL NOTES

CODIFICATION

Pub. L. 94–484, title IV, §407(b)(3), Oct. 12, 1976, 90 Stat. 2268, added heading "Subpart II—National Health Service Corps Program".

§254d. National Health Service Corps

(a) Establishment; composition; purpose; definitions

(1) For the purpose of eliminating health manpower shortages in health professional shortage areas, there is established, within the Service, the National Health Service Corps, which shall consist of—

(A) such officers of the Regular and Reserve Corps [1] of the Service as the Secretary may designate,

(B) such civilian employees of the United States as the Secretary may appoint, and

(C) such other individuals who are not employees of the United States.

(2) The Corps shall be utilized by the Secretary to provide primary health services in health professional shortage areas.

(3) For purposes of this subpart and subpart III:

(A) The term "Corps" means the National Health Service Corps.

(B) The term "Corps member" means each of the officers, employees, and individuals of which the Corps consists pursuant to paragraph (1).

(C) The term "health professional shortage area" has the meaning given such term in section 254e(a) of this title.

(D) The term "primary health services" means health services regarding family medicine, internal medicine, pediatrics, obstetrics and gynecology, dentistry, or mental health, that are provided by physicians or other health professionals.

(E)(i) The term "behavioral and mental health professionals" means health service

psychologists, licensed clinical social workers, licensed professional counselors, marriage and family therapists, psychiatric nurse specialists, and psychiatrists.

(ii) The term "graduate program of behavioral and mental health" means a program that trains behavioral and mental health professionals.

(b) Recruitment and fellowship programs

(1) The Secretary may conduct at schools of medicine, osteopathic medicine, dentistry, and, as appropriate, nursing and other schools of the health professions, including schools at which graduate programs of behavioral and mental health are offered, and at entities which train allied health personnel, recruiting programs for the Corps, the Scholarship Program, and the Loan Repayment Program. Such recruiting programs shall include efforts to recruit individuals who will serve in the Corps other than pursuant to obligated service under the Scholarship or Loan Repayment Program.

(2) In the case of physicians, dentists, behavioral and mental health professionals, certified nurse midwives, certified nurse practitioners, and physician assistants who have an interest and a commitment to providing primary health care, the Secretary may establish fellowship programs to enable such health professionals to gain exposure to and expertise in the delivery of primary health services in health professional shortage areas. To the maximum extent practicable, the Secretary shall ensure that any such programs are established in conjunction with accredited residency programs, and other training programs, regarding such health professions.

(c) Travel and moving expenses; persons entitled; reimbursement; limitation

(1) The Secretary may reimburse an applicant for a position in the Corps (including an individual considering entering into a written agreement pursuant to section 254n of this title) for the actual and reasonable expenses incurred in traveling to and from the applicant's place of residence to an eligible site to which the applicant may be assigned under section 254f of this title for the purpose of evaluating such site with regard to being assigned at such site. The Secretary may establish a maximum total amount that may be paid to an individual as reimbursement for such expenses.

(2) The Secretary may also reimburse the applicant for the actual and reasonable expenses incurred for the travel of 1 family member to accompany the applicant to such site. The Secretary may establish a maximum total amount that may be paid to an individual as reimbursement for such expenses.

(3) In the case of an individual who has entered into a contract for obligated service under the Scholarship Program or under the Loan Repayment Program, the Secretary may reimburse such individual for all or part of the actual and reasonable expenses incurred in transporting the individual, the individual's family, and the family's possessions to the site of the individual's assignment under section 254f of this title. The Secretary may establish a maximum total amount that may be paid to an individual as reimbursement for such expenses.

(d) Monthly pay adjustments of members directly engaged in delivery of health services in health professional shortage area; "monthly pay" defined; monthly pay adjustment of member with service obligation incurred under Scholarship Program or Loan Repayment Program; personnel system applicable

(1) The Secretary may, under regulations promulgated by the Secretary, adjust the monthly pay of each member of the Corps (other than a member described in subsection (a)(1)(C)) who is directly engaged in the delivery of health services in a health professional shortage area as follows:

(A) During the first 36 months in which such a member is so engaged in the delivery of health services, his monthly pay may be increased by an amount which when added to the member's monthly pay and allowances will provide a monthly income competitive with the average monthly income from a practice of an individual who is a member of the profession of the Corps member, who has equivalent training, and who has been in practice for a period equivalent to the period during which the Corps member has been in practice.

(B) During the period beginning upon the expiration of the 36 months referred to in subparagraph (A) and ending with the month in which the member's monthly pay and allowances are equal to or exceed the monthly income he received for the last of such 36 months, the member

may receive in addition to his monthly pay and allowances an amount which when added to such monthly pay and allowances equals the monthly income he received for such last month.

(C) For each month in which a member is directly engaged in the delivery of health services in a health professional shortage area in accordance with an agreement with the Secretary entered into under section 294n(f)(1)(C) [2] of this title, under which the Secretary is obligated to make payments in accordance with section 294n(f)(2) [2] of this title, the amount of any monthly increase under subparagraph (A) or (B) with respect to such member shall be decreased by an amount equal to one-twelfth of the amount which the Secretary is obligated to pay upon the completion of the year of practice in which such month occurs.

For purposes of subparagraphs (A) and (B), the term "monthly pay" includes special pay received under chapter 5 of title 37.

(2) In the case of a member of the Corps who is directly engaged in the delivery of health services in a health professional shortage area in accordance with a service obligation incurred under the Scholarship Program or the Loan Repayment Program, the adjustment in pay authorized by paragraph (1) may be made for such a member only upon satisfactory completion of such service obligation, and the first 36 months of such member's being so engaged in the delivery of health services shall, for purposes of paragraph (1)(A), be deemed to begin upon such satisfactory completion.

(3) A member of the Corps described in subparagraph (C) of subsection (a)(1) shall when assigned to an entity under section 254f of this title be subject to the personnel system of such entity, except that such member shall receive during the period of assignment the income that the member would receive if the member was a member of the Corps described in subparagraph (B) of such subsection.

(e) Employment ceiling of Department not affected by Corps members

Corps members assigned under section 254f of this title to provide health services in health professional shortage areas shall not be counted against any employment ceiling affecting the Department.

(f) Assignment of personnel provisions inapplicable to members whose service obligation incurred under Scholarship Program or Loan Repayment Program

Sections 215 and 217 of this title shall not apply to members of the National Health Service Corps during their period of obligated service under the Scholarship Program or the Loan Repayment Program, except when such members are Commissioned Corps officers who entered into a contract with [3] Secretary under section 254l or 254l–1 of this title after December 31, 2006 and when the Secretary determines that exercising the authority provided under section 215 or 217 of this title with respect to any such officer to [4] would not cause unreasonable disruption to health care services provided in the community in which such officer is providing health care services.

(g) Conversion from Corps member to commissioned officer; retirement credits

(1) The Secretary shall, by rule, prescribe conversion provisions applicable to any individual who, within a year after completion of service as a member of the Corps described in subsection (a)(1)(C), becomes a commissioned officer in the Regular or Reserve Corps [1] of the Service.

(2) The rules prescribed under paragraph (1) shall provide that in applying the appropriate provisions of this chapter which relate to retirement, any individual who becomes such an officer shall be entitled to have credit for any period of service as a member of the Corps described in subsection (a)(1)(C).

(h) Effective administration of program

The Secretary shall ensure that adequate staff is provided to the Service with respect to effectively administering the program for the Corps.

(i) Demonstration projects; waivers

(1) In carrying out subpart III, the Secretary may, in accordance with this subsection, issue

waivers to individuals who have entered into a contract for obligated service under the Scholarship Program or the Loan Repayment Program under which the individuals are authorized to satisfy the requirement of obligated service through providing clinical practice that is half time.

(2) A waiver described in paragraph (1) may be provided by the Secretary only if—

(A) the entity for which the service is to be performed—

(i) has been approved under section 254f–1 of this title for assignment of a Corps member; and

(ii) has requested in writing assignment of a health professional who would serve half time;

(B) the Secretary has determined that assignment of a health professional who would serve half time would be appropriate for the area where the entity is located;

(C) a Corps member who is required to perform obligated service has agreed in writing to be assigned for half-time service to an entity described in subparagraph (A);

(D) the entity and the Corps member agree in writing that the Corps member will perform half-time clinical practice;

(E) the Corps member agrees in writing to fulfill all of the service obligations under section 254m of this title through half-time clinical practice and either—

(i) double the period of obligated service that would otherwise be required; or

(ii) in the case of contracts entered into under section 254l–1 of this title, accept a minimum service obligation of 2 years with an award amount equal to 50 percent of the amount that would otherwise be payable for full-time service; and

(F) the Corps member agrees in writing that if the Corps member begins providing half-time service but fails to begin or complete the period of obligated service, the method stated in 254o(c) of this title for determining the damages for breach of the individual's written contract will be used after converting periods of obligated service or of service performed into their full-time equivalents.

(3) In evaluating waivers issued under paragraph (1), the Secretary shall examine the effect of multidisciplinary teams.

(j) Definitions

For the purposes of this subpart and subpart III:

(1) The term "Department" means the Department of Health and Human Services.

(2) The term "Loan Repayment Program" means the National Health Service Corps Loan Repayment Program established under section 254l–1 of this title.

(3) The term "Scholarship Program" means the National Health Service Corps Scholarship Program established under section 254l of this title.

(4) The term "State" includes, in addition to the several States, only the District of Columbia, the Commonwealth of Puerto Rico, the Commonwealth of the Northern Mariana Islands, the Virgin Islands, Guam, American Samoa, and the Trust Territory of the Pacific Islands.

(5) The terms "full time" and "full-time" mean a minimum of 40 hours per week in a clinical practice, for a minimum of 45 weeks per year.

(6) The terms "half time" and "half-time" mean a minimum of 20 hours per week (not to exceed 39 hours per week) in a clinical practice, for a minimum of 45 weeks per year.

(July 1, 1944, ch. 373, title III, §331, as added Pub. L. 94–484, title IV, §407(b)(3), Oct. 12, 1976, 90 Stat. 2268; amended Pub. L. 97–35, title XXVII, §2701, Aug. 13, 1981, 95 Stat. 902; Pub. L. 100–177, title II, §202(b), title III, §301, Dec. 1, 1987, 101 Stat. 996, 1003; Pub. L. 100–607, title VI, §629(a)(2), Nov. 4, 1988, 102 Stat. 3146; Pub. L. 101–597, title I, §101, title IV, §401(b)[(a)], Nov. 16, 1990, 104 Stat. 3013, 3035; Pub. L. 107–251, title III, §301, Oct. 26, 2002, 116 Stat. 1642; Pub. L. 109–417, title II, §206(c)(2), Dec. 19, 2006, 120 Stat. 2853; Pub. L. 111–148, title X, §10501(n)(1), (2), Mar. 23, 2010, 124 Stat. 1002, 1003.)

EDITORIAL NOTES

REFERENCES IN TEXT

Section 294n of this title, referred to in subsec. (d)(1)(C), was in the original a reference to section 741 of act July 1, 1944. Section 741 of that Act was omitted in the general revision of subchapter V of this chapter by Pub. L. 102–408, title I, §102, Oct. 13, 1992, 106 Stat. 1994. Pub. L. 102–408 enacted a new section 776 of act July 1, 1944, relating to acquired immune deficiency syndrome, which was classified to section 294n of this title, and subsequently renumbered section 2692 and transferred to section 300ff–111 of this title.

AMENDMENTS

2010—Subsec. (i)(1). Pub. L. 111–148, §10501(n)(1)(A), substituted "issue waivers to individuals who have entered into a contract for obligated service under the Scholarship Program or the Loan Repayment Program under which the individuals are authorized to satisfy the requirement of obligated service through providing clinical practice that is half time" for "carry out demonstration projects in which individuals who have entered into a contract for obligated service under the Loan Repayment Program receive waivers under which the individuals are authorized to satisfy the requirement of obligated service through providing clinical service that is not full-time".

Subsec. (i)(2)(A)(ii), (B). Pub. L. 111–148, §10501(n)(1)(B)(i), substituted "half time" for "less than full time".

Subsec. (i)(2)(C). Pub. L. 111–148, §10501(n)(1)(B)(ii), substituted "half-time service" for "less than full-time service".

Subsec. (i)(2)(D), (E). Pub. L. 111–148, §10501(n)(1)(B)(iii), amended subpars. (D) and (E) generally. Prior to amendment, subpars. (D) and (E) read as follows:

"(D) the entity and the Corps member agree in writing that the less than full-time service provided by the Corps member will not be less than 16 hours of clinical service per week;

"(E) the Corps member agrees in writing that the period of obligated service pursuant to section 254l–1 of this title will be extended so that the aggregate amount of less than full-time service performed will equal the amount of service that would be performed through full-time service under section 254m of this title; and".

Subsec. (i)(2)(F). Pub. L. 111–148, §10501(n)(1)(B)(ii), substituted "half-time service" for "less than full-time service".

Subsec. (i)(3). Pub. L. 111–148, §10501(n)(1)(C), substituted "In evaluating waivers issued under paragraph (1)" for "In evaluating a demonstration project described in paragraph (1)".

Subsec. (j)(5), (6). Pub. L. 111–148, §10501(n)(2), added pars. (5) and (6).

2006—Subsec. (f). Pub. L. 109–417 inserted before period at end ", except when such members are Commissioned Corps officers who entered into a contract with Secretary under section 254l or 254l–1 of this title after December 31, 2006 and when the Secretary determines that exercising the authority provided under section 215 or 217 of this title with respect to any such officer to would not cause unreasonable disruption to health care services provided in the community in which such officer is providing health care services".

2002—Subsec. (a)(3)(E). Pub. L. 107–251, §301(a)(1), added subpar. (E).

Subsec. (b)(1). Pub. L. 107–251, §301(a)(2)(A), substituted "health professions, including schools at which graduate programs of behavioral and mental health are offered," for "health professions".

Subsec. (b)(2). Pub. L. 107–251, §301(a)(2)(B), inserted "behavioral and mental health professionals," after "dentists,".

Subsec. (c). Pub. L. 107–251, §301(a)(3), added subsec. (c) and struck out former subsec. (c) which read as follows: "The Secretary may reimburse applicants for positions in the Corps (including individuals considering entering into a written agreement pursuant to section 254n of this title) for actual and reasonable expenses incurred in traveling to and from their places of residence to a health professional shortage area (designated under section 254e of this title) in which they may be assigned for the purpose of evaluating such area with regard to being assigned in such area. The Secretary shall not reimburse an applicant for more than one such trip."

Subsecs. (i), (j). Pub. L. 107–251, §301(b), added subsec. (i) and redesignated former subsec. (i) as (j).

1990—Subsec. (a). Pub. L. 101–597, §401(b)[(a)], substituted reference to health professional shortage area for reference to health manpower shortage area in pars. (1), (2), and (3)(C).

Pub. L. 101–597, §101(a), designated existing provisions as par. (1), substituted "For the purpose of eliminating health manpower shortages in health manpower shortage areas, there is established, within the Service, the National Health Service Corps, which shall consist of—" for "There is established, within the Service, the National Health Service Corps (hereinafter in this subpart referred to as the 'Corps') which (1) shall consist of—", substituted "States." for "States," at end of subpar. (C), struck out closing provisions which

read "(such officers, employees, and individuals hereinafter in this subpart referred to as 'Corps members'), and (2) shall be utilized by the Secretary to improve the delivery of health services in health manpower shortage areas as defined in section 254e(a) of this title.", and added pars. (2) and (3).

Subsec. (b). Pub. L. 101–597, §401(b)[(a)], substituted reference to health professional shortage area for reference to health manpower shortage area in par. (2).

Pub. L. 101–597, §101(b), designated existing provision as par. (1), inserted at end "Such recruiting programs shall include efforts to recruit individuals who will serve in the Corps other than pursuant to obligated service under the Scholarship or Loan Repayment Program.", and added par. (2).

Subsec. (c). Pub. L. 101–597, §401(b)[(a)], substituted reference to health professional shortage area for reference to health manpower shortage area.

Subsec. (d)(1). Pub. L. 101–597, §401(b)[(a)], substituted reference to health professional shortage area for reference to health manpower shortage area in introductory provisions and in subpar. (C).

Subsec. (d)(1)(A). Pub. L. 101–597, §101(c), struck out "(not to exceed $1,000)" after "by an amount".

Subsecs. (d)(2), (e). Pub. L. 101–597, §401(b)[(a)], substituted reference to health professional shortage area for reference to health manpower shortage area.

Subsec. (h). Pub. L. 101–597, §101(d), added subsec. (h) and struck out former subsec. (h) which read as follows: "In assigning members of the Corps to health manpower shortage areas, to the extent practicable, the Secretary shall—

"(1) give priority to meeting the needs of the Indian Health Service and the needs of health programs or facilities operated by tribes or tribal organizations under the Indian Self-Determination Act (25 U.S.C. 450f et seq.); and

"(2) provide special consideration to the homeless populations who do not have access to primary health care services."

Subsec. (i). Pub. L. 101–597, §101(e), substituted "of this subpart and subpart III" for "of this subpart".

1988—Subsec. (b). Pub. L. 100–607 substituted "osteopathic medicine" for "osteopathy".

1987—Subsec. (b). Pub. L. 100–177, §202(b)(1), inserted reference to Loan Repayment Program.

Subsec. (c). Pub. L. 100–177, §202(b)(2), made technical amendment to reference to section 254n of this title to reflect renumbering of corresponding section of original act.

Subsecs. (d)(2), (f). Pub. L. 100–177, §202(b)(3), (4), inserted reference to Loan Repayment Program.

Subsec. (h). Pub. L. 100–177, §301(2), added subsec. (h). Former subsec. (h) redesignated (i).

Subsec. (i). Pub. L. 100–177, §§202(b)(5), 301(1), redesignated subsec. (h) as (i), added par. (2), and redesignated former pars. (2) and (3) as (3) and (4), respectively.

1981—Subsec. (a)(1). Pub. L. 97–35, §2701(a), revised provisions and, as so revised, set out existing provisions in cls. (A) and (B), and added cl. (C).

Subsec. (b). Pub. L. 97–35, §2701(b), substituted "may" for "shall".

Subsec. (c). Pub. L. 97–35, §2701(c), inserted provisions respecting a written agreement under section 254n of this title.

Subsec. (d). Pub. L. 97–35, §2701(d), in par. (1) inserted reference to member described in subsec. (a)(1)(C) of this section, in subpars. (1)(A) and (B) substituted "may" for "shall", and added par. (3).

Subsec. (g). Pub. L. 97–35, §2701(e), substituted provisions relating to conversion from Corps member to commissioned officer and retirement credits, for provisions relating to school participation in development of administrative guidelines.

Subsec. (h). Pub. L. 97–35, §2701(f), in par. (1) substituted "Health and Human Services" for "Health, Education, and Welfare", in par. (2) substituted "254l" for "294t", and in par. (3) inserted reference to Commonwealth with respect to the Northern Mariana Islands.

STATUTORY NOTES AND RELATED SUBSIDIARIES

CHANGE OF NAME

Reference to Reserve Corps of the Public Health Service deemed to be a reference to the Ready Reserve Corps, see section 204(c)(3) of this title.

EFFECTIVE DATE OF 1990 AMENDMENT

Pub. L. 101–597, title V, §501, Nov. 16, 1990, 104 Stat. 3036, provided that: "This Act and the amendments made by this Act [enacting sections 254f–1, 254o–1, and 254r of this title, amending this section, sections 242a, 254e to 254i, 254k, 254l to 254q–1, 254s, 294h, 294n, 294aa, 295g–1, 296m, 1320c–5, 1395l,

1395u, 1395x, 3505d, and 9840 of this title, and section 2123 of Title 10, Armed Forces, and enacting provisions set out as notes under sections 201, 254l–1, and 254o of this title] shall take effect October 1, 1990, or upon the date of the enactment of this Act [Nov. 16, 1990], whichever occurs later."

SPECIAL REPORT ON PRESENT AND FUTURE DIRECTION OF NATIONAL HEALTH SERVICE CORPS; SUBMISSION TO CONGRESS NOT LATER THAN FEBRUARY 1, 1979

Pub. L. 95–626, title I, §116(c), Nov. 10, 1978, 92 Stat. 3569, directed Secretary, not later than Feb. 1, 1979, in consultation with National Advisory Council of National Health Service Corps and National Advisory Council on Health Professions Education, to submit to Congress a report on the direction of the National Health Service Corps, particularly its role as a health manpower program and as a health services delivery program, the use of members of the Corps in health manpower shortage areas to meet urban and rural health needs, the types of health professions needed to meet urban and rural health needs, and the projected size, composition, and use of the Corps through 1985.

EFFECTIVE DATE; OTHER PROVISIONS: HEALTH MANPOWER SHORTAGE AREA; APPROVAL OF APPLICATIONS FOR ASSIGNMENT OF CORPS PERSONNEL; ASSIGNMENT PERIOD, COMMENCEMENT; CREDIT FOR MONTHS OF PRIOR HEALTH CARE AND SERVICES FOR ADDITIONAL PAY BENEFIT; NATIONAL ADVISORY COUNCIL ON THE NATIONAL HEALTH SERVICE CORPS, CONTINUATION OF COUNCIL AND APPOINTMENT OF MEMBERS

Pub. L. 94–484, title IV, §407(c), Oct. 12, 1976, 90 Stat. 2278, provided that:

"(1) The amendment made by subsections (a) and (b) [enacting this subpart and repealing section 254b of this title] shall apply only with respect to fiscal years beginning after September 30, 1977, except that the Secretary of Health, Education, and Welfare [now Health and Human Services] shall carry out the activities described in section 332 of the Public Health Service Act (as added by such amendment) [42 U.S.C. 254e] after the date of enactment of this Act [Oct. 12, 1976].

"(2)(A) Any area for which a designation under section 329(b) of the Public Health Service Act (as in effect on September 30, 1977) [former 42 U.S.C. 254b(b)] was in effect on such date and in which National Health Service Corps personnel were, on such date, providing, under an assignment made under such section (as so in effect), health care and services for persons residing in such area shall, effective October 1, 1977, be considered under subpart II of part C of title III of such Act (as added by subsection (b) of this section) [42 U.S.C. 254d et seq.] to (i) be designated a health manpower shortage area (as defined by section 332 of such Act (as so added)) [42 U.S.C. 254e], and (ii) have had an application approved under section 333 of such Act (as so added)) [42 U.S.C. 254f] for the assignment of Corps personnel unless, as determined under subparagraph (B) of this paragraph, the assignment period applicable to such area (within the meaning of section 334 (as so added)) [former 42 U.S.C. 254g] has expired.

"(B) The assignment period (within the meaning of such section 334) [former 42 U.S.C. 254g] applicable to an area described in subparagraph (A) of this paragraph shall be considered to have begun on the date Corps personnel were first assigned to such area under section 329 of such Act (as in effect on September 30, 1977) [former 42 U.S.C. 254b].

"(C) In the case of any physician or dentist member of the Corps who was providing health care and services on September 30, 1977, under an assignment made under section 329(b) of such Act (as in effect on September 30, 1977) [former 42 U.S.C. 254b(b)], the number of the months during which such member provided such care and services before October 1, 1977, shall be counted in determining the application of the additional pay provisions of section 331(d) of such Act (as added by subsection (b) of this section) [42 U.S.C. 254d(d)] to such number.

"(3) The amendment made by subsection (b) which established an Advisory Council previously established under section 329 of the Public Health Service Act [former 42 U.S.C. 254b] shall not be construed as requiring the establishment of a new Advisory Council under such section 337 [42 U.S.C. 254j], and the amendment made by such subsection with respect to the composition of such Advisory Council shall apply with respect to appointments made to the Advisory Council after October 1, 1977, and the Secretary of Health, Education, and Welfare [now Health and Human Services] shall make appointments to the Advisory Council after such date in a manner which will bring about, at the earliest feasible time, the Advisory Council composition prescribed by the amendment."

EXECUTIVE DOCUMENTS

TERMINATION OF TRUST TERRITORY OF THE PACIFIC ISLANDS

For termination of Trust Territory of the Pacific Islands, see note set out preceding section 1681 of Title 48, Territories and Insular Possessions.

[1] *See Change of Name note below.*

[2] *See References in Text note below.*

[3] *So in original. The word "the" probably should appear.*

[4] *So in original.*

§254e. Health professional shortage areas

(a) Designation by Secretary; removal from areas designated; "medical facility" defined

(1) For purposes of this subpart the term "health professional shortage area" means (A) an area in an urban or rural area (which need not conform to the geographic boundaries of a political subdivision and which is a rational area for the delivery of health services) which the Secretary determines has a health manpower shortage and which is not reasonably accessible to an adequately served area, (B) a population group which the Secretary determines has such a shortage, or (C) a public or nonprofit private medical facility or other public facility which the Secretary determines has such a shortage. All Federally qualified health centers and rural health clinics, as defined in section 1861(aa) of the Social Security Act (42 U.S.C. 1395x(aa)), that meet the requirements of section 254g of this title shall be automatically designated as having such a shortage. The Secretary shall not remove an area from the areas determined to be health professional shortage areas under subparagraph (A) of the preceding sentence until the Secretary has afforded interested persons and groups in such area an opportunity to provide data and information in support of the designation as a health professional shortage area or a population group described in subparagraph (B) of such sentence or a facility described in subparagraph (C) of such sentence, and has made a determination on the basis of the data and information submitted by such persons and groups and other data and information available to the Secretary.

(2) For purposes of this subsection, the term "medical facility" means a facility for the delivery of health services and includes—

(A) a hospital, State mental hospital, public health center, outpatient medical facility, rehabilitation facility, facility for long-term care, community mental health center, migrant health center, facility operated by a city or county health department, and community health center;

(B) such a facility of a State correctional institution or of the Indian Health Service, and a health program or facility operated by a tribe or tribal organization under the Indian Self-Determination Act [25 U.S.C. 5321 et seq.];

(C) such a facility used in connection with the delivery of health services under section 248 of this title (relating to hospitals), 249 of this title (relating to care and treatment of persons under quarantine and others), 250 of this title (relating to care and treatment of Federal prisoners), 251 of this title (relating to examination and treatment of certain Federal employees), 252 of this title (relating to examination of aliens), 253 of this title (relating to services to certain Federal employees), 247e of this title (relating to services for persons with Hansen's disease), or 254b(h) of this title (relating to the provision of health services to homeless individuals); and

(D) a Federal medical facility.

(3) Homeless individuals (as defined in section 254b(h)(5) of this title), seasonal agricultural workers (as defined in section 254b(g)(3) of this title) and migratory agricultural workers (as so defined)), and residents of public housing (as defined in section 1437a(b)(1) of this title) may be population groups under paragraph (1).

(b) Criteria for designation of health professional shortage areas; promulgation of regulations

The Secretary shall establish by regulation criteria for the designation of areas, population groups, medical facilities, and other public facilities, in the States, as health professional shortage areas. In establishing such criteria, the Secretary shall take into consideration the following:

(1) The ratio of available health manpower to the number of individuals in an area or population group, or served by a medical facility or other public facility under consideration for designation.

(2) Indicators of a need, notwithstanding the supply of health manpower, for health services for the individuals in an area or population group or served by a medical facility or other public facility under consideration for designation.

(3) The percentage of physicians serving an area, population group, medical facility, or other public facility under consideration for designation who are employed by hospitals and who are graduates of foreign medical schools.

(c) Considerations in determination of designation

In determining whether to make a designation, the Secretary shall take into consideration the following:

(1) The recommendations of the Governor of each State in which the area, population group, medical facility, or other public facility under consideration for designation is in whole or part located.

(2) The extent to which individuals who are (A) residents of the area, members of the population group, or patients in the medical facility or other public facility under consideration for designation, and (B) entitled to have payment made for medical services under title XVIII, XIX, or XXI of the Social Security Act [42 U.S.C. 1395 et seq., 1396 et seq., 1397aa et seq.], cannot obtain such services because of suspension of physicians from the programs under such titles.

(d) Designation; publication of descriptive lists

(1) In accordance with the criteria established under subsection (b) and the considerations listed in subsection (c), the Secretary shall designate health professional shortage areas in the States, publish a descriptive list of the areas, population groups, medical facilities, and other public facilities so designated, and at least annually review and, as necessary, revise such designations.

(2) For purposes of paragraph (1), a complete descriptive list shall be published in the Federal Register not later than July 1 of 1991 and each subsequent year.

(e) Notice of proposed designation of areas and facilities; time for comment

(1) Prior to the designation of a public facility, including a Federal medical facility, as a health professional shortage area, the Secretary shall give written notice of such proposed designation to the chief administrative officer of such facility and request comments within 30 days with respect to such designation.

(2) Prior to the designation of a health professional shortage area under this section, the Secretary shall, to the extent practicable, give written notice of the proposed designation of such area to appropriate public or private nonprofit entities which are located or have a demonstrated interest in such area and request comments from such entities with respect to the proposed designation of such area.

(f) Notice of designation

The Secretary shall give written notice of the designation of a health professional shortage area, not later than 60 days from the date of such designation, to—

(1) the Governor of each State in which the area, population group, medical facility, or other public facility so designated is in whole or part located; and

(2) appropriate public or nonprofit private entities which are located or which have a demonstrated interest in the area so designated.

(g) Recommendations to Secretary

Any person may recommend to the Secretary the designation of an area, population group, medical facility, or other public facility as a health professional shortage area.

(h) Public information programs in designated areas

The Secretary may conduct such information programs in areas, among population groups, and in medical facilities and other public facilities designated under this section as health professional shortage areas as may be necessary to inform public and nonprofit private entities which are located or have a demonstrated interest in such areas of the assistance available under this subchapter by virtue of the designation of such areas.

(i) Dissemination

The Administrator of the Health Resources and Services Administration shall disseminate information concerning the designation criteria described in subsection (b) to—

(1) the Governor of each State;

(2) the representative of any area, population group, or facility selected by any such Governor to receive such information;

(3) the representative of any area, population group, or facility that requests such information; and

(4) the representative of any area, population group, or facility determined by the Administrator to be likely to meet the criteria described in subsection (b).

(j) Regulations and report

(1) The Secretary shall submit the report described in paragraph (2) if the Secretary, acting through the Administrator of the Health Resources and Services Administration, issues—

(A) a regulation that revises the definition of a health professional shortage area for purposes of this section; or

(B) a regulation that revises the standards concerning priority of such an area under section 254f–1 of this title.

(2) On issuing a regulation described in paragraph (1), the Secretary shall prepare and submit to the Committee on Energy and Commerce of the House of Representatives and the Committee on Health, Education, Labor, and Pensions of the Senate a report that describes the regulation.

(3) Each regulation described in paragraph (1) shall take effect 180 days after the committees described in paragraph (2) receive a report referred to in such paragraph describing the regulation.

(k) Maternity care health professional target areas

(1) The Secretary, acting through the Administrator of the Health Resources and Services Administration, shall identify, based on the data collected under paragraph (3), maternity care health professional target areas that satisfy the criteria described in paragraph (2) for purposes of, in connection with receipt of assistance under this subchapter, assigning to such identified areas maternity care health professionals who, without application of this subsection, would otherwise be eligible for such assistance. The Secretary shall distribute maternity care health professionals within health professional shortage areas using the maternity care health professional target areas so identified.

(2) For purposes of paragraph (1), the Secretary shall establish criteria for maternity care health professional target areas that identify geographic areas within health professional shortage areas that have a shortage of maternity care health professionals.

(3) For purposes of this subsection, the Secretary shall collect and publish in the Federal Register data comparing the availability and need of maternity care health services in health professional shortage areas and in areas within such health professional shortage areas.

(4) In carrying out paragraph (1), the Secretary shall seek input from relevant provider organizations, including medical societies, organizations representing medical facilities, and other organizations with expertise in maternity care.

(5) For purposes of this subsection, the term 'full scope maternity care health services' includes during labor care, birthing, prenatal care, and postpartum care.

(6) Nothing in this subsection shall be construed as—

(A) requiring the identification of a maternity care health professional target area in an area not

otherwise already designated as a health professional shortage area; or

(B) affecting the types of health professionals, without application of this subsection, otherwise eligible for assistance, including a loan repayment or scholarship, pursuant to the application of this section.

(July 1, 1944, ch. 373, title III, §332, as added Pub. L. 94–484, title IV, §407(b)(3), Oct. 12, 1976, 90 Stat. 2270; amended Pub. L. 95–142, §7(d), Oct. 25, 1977, 91 Stat. 1193; Pub. L. 96–32, §7(d), July 10, 1979, 93 Stat. 84; Pub. L. 97–35, title IX, §986(b)(4), title XXVII, §2702(a), (b), (c), Aug. 13, 1981, 95 Stat. 603, 903, 904; Pub. L. 100–77, title VI, §602, July 22, 1987, 101 Stat. 515; Pub. L. 100–177, title III, §302, Dec. 1, 1987, 101 Stat. 1003; Pub. L. 100–607, title VIII, §802(b)(2), Nov. 4, 1988, 102 Stat. 3169; Pub. L. 100–628, title VI, §602(b)(2), Nov. 7, 1988, 102 Stat. 3242; Pub. L. 101–597, title I, §102, title IV, §401(b)[(a)], Nov. 16, 1990, 104 Stat. 3014, 3035; Pub. L. 107–251, title III, §302(a), (d)(2), title VI, §601(a), Oct. 26, 2002, 116 Stat. 1643, 1645, 1664; Pub. L. 108–163, §2(f)(1), Dec. 6, 2003, 117 Stat. 2021; Pub. L. 110–355, §3(b), Oct. 8, 2008, 122 Stat. 3993; Pub. L. 115–320, §2, Dec. 17, 2018, 132 Stat. 4437.)

EDITORIAL NOTES

REFERENCES IN TEXT

The Indian Self-Determination Act, referred to in subsec. (a)(2)(B), is title I of Pub. L. 93–638, Jan. 4, 1975, 88 Stat. 2206, which is classified principally to subchapter I (§5321 et seq.) of chapter 46 of Title 25, Indians. For complete classification of this Act to the Code, see Short Title note set out under section 5301 of Title 25 and Tables.

The Social Security Act, referred to in subsec. (c)(2), is act Aug. 14, 1935, ch. 531, 49 Stat. 620. Titles XVIII, XIX, and XXI of the Act are classified generally to subchapters XVIII (§1395 et seq.), XIX (§1396 et seq.), and XXI (§1397aa et seq.), respectively, of chapter 7 of this title. For complete classification of this Act to the Code, see section 1305 of this title and Tables.

PRIOR PROVISIONS

A prior section 332 of act July 1, 1944, was renumbered section 340, and was classified to section 256 of this title prior to repeal by Pub. L. 95–626.

AMENDMENTS

2018—Subsec. (k). Pub. L. 115–320 added subsec. (k).

2008—Subsec. (a)(1). Pub. L. 110–355 struck out "Not earlier than 6 years after such date of designation, and every 6 years thereafter, each such center or clinic shall demonstrate that the center or clinic meets the applicable requirements of the Federal regulations regarding the definition of a health professional shortage area for purposes of this section." before "The Secretary shall not".

2003—Subsec. (a)(1). Pub. L. 108–163, §2(f)(1)(A), substituted "such date of designation" for "such date of enactment" and "regarding" for ", issued after the date of enactment of this Act, that revise".

Subsec. (a)(3). Pub. L. 108–163, §2(f)(1)(B), substituted "254b(h)(5)" for "254b(h)(4)".

Subsec. (b)(2). Pub. L. 108–163, §2(f)(1)(C), struck out comma before period at end.

Subsec. (j). Pub. L. 108–163, §2(f)(1)(D), added subsec. (j).

2002—Subsec. (a)(1). Pub. L. 107–251, §302(a)(1)(A), inserted after first sentence "All Federally qualified health centers and rural health clinics, as defined in section 1861(aa) of the Social Security Act (42 U.S.C. 1395x(aa)), that meet the requirements of section 254g of this title shall be automatically designated as having such a shortage. Not earlier than 6 years after such date of enactment, and every 6 years thereafter, each such center or clinic shall demonstrate that the center or clinic meets the applicable requirements of the Federal regulations, issued after the date of enactment of this Act, that revise the definition of a health professional shortage area for purposes of this section."

Subsec. (a)(2)(C). Pub. L. 107–251, §601(a), substituted "254b(h)" for "256".

Subsec. (a)(3). Pub. L. 107–251, §302(a)(1)(B), substituted "254b(h)(4) of this title), seasonal agricultural workers (as defined in section 254b(g)(3) of this title) and migratory agricultural workers (as so defined)), and residents of public housing (as defined in section 1437a(b)(1) of this title) may be population groups" for "256(r) of this title) may be a population group".

Subsec. (b)(2). Pub. L. 107–251, §302(a)(2), struck out after "designation," the following: "with special consideration to indicators of—

"(A) infant mortality,
"(B) access to health services,
"(C) health status, and
"(D) ability to pay for health services".

Subsec. (c)(2)(B). Pub. L. 107–251, §302(a)(3), substituted "XVIII, XIX, or XXI of the Social Security Act" for "XVIII or XIX of the Social Security Act".

Subsec. (i). Pub. L. 107–251, §302(d)(2), added subsec. (i).

1990—Subsec. (a)(1). Pub. L. 101–597, §401(b)[(a)], substituted reference to health professional shortage area for reference to health manpower shortage area wherever appearing.

Subsec. (a)(2)(A). Pub. L. 101–597, §102(b)(1), inserted "facility operated by a city or county health department," before "and community health center".

Subsec. (a)(2)(B). Pub. L. 101–597, §102(b)(2), inserted before semicolon ", and a health program or facility operated by a tribe or tribal organization under the Indian Self-Determination Act".

Subsec. (a)(2)(C). Pub. L. 101–597, §102(b)(3), substituted "section" for "sections" before "248", struck out "or" before "253" and "or section" before "247e", and inserted before semicolon ", or 256 of this title (relating to the provision of health services to homeless individuals)".

Subsec. (b). Pub. L. 101–597, §401(b)[(a)], substituted reference to health professional shortage area for reference to health manpower shortage area.

Pub. L. 101–597, §102(c)(1), struck out ", promulgated not later than May 1, 1977," after "establish by regulation".

Subsec. (c). Pub. L. 101–597, §102(c)(2), redesignated pars. (2) and (3) as (1) and (2), respectively, and struck out former par. (1) which read as follows:

"(A) The recommendations of each health systems agency (designated under section 300l–4 of this title) for a health service area which includes all or any part of the area, population group, medical facility, or other public facility under consideration for designation.

"(B) The recommendations of the State health planning and development agency (designated under section 300m of this title) if such area, population group, medical facility, or other public facility is within a health service area for which no health systems agency has been designated."

Subsec. (d). Pub. L. 101–597, §401(b)[(a)], substituted reference to health professional shortage area for reference to health manpower shortage area in par. (1).

Pub. L. 101–597, §102(a), (c)(3), designated existing provision as par. (1), struck out ", not later than November 1, 1977," after "Secretary shall designate", and added par. (2).

Subsec. (e). Pub. L. 101–597, §401(b)[(a)], substituted reference to health professional shortage area for reference to health manpower shortage area wherever appearing.

Subsec. (f). Pub. L. 101–597, §401(b)[(a)], substituted reference to health professional shortage area for reference to health manpower shortage area.

Pub. L. 101–597, §102(c)(4), redesignated par. (3) as (2) and struck out former par. (2) which read as follows:

"(A) each health systems agency (designated under section 300l–4 of this title) for a health service area which includes all or any part of the area, population group, medical facility, or other public facility so designated; or

"(B) the State health planning and development agency of the State (designated under section 300m of this title) if there is a part of such area, population group, medical facility, or other public facility within a health service area for which no health systems agency has been designated; and".

Subsecs. (g), (h). Pub. L. 101–597, §401(b)[(a)], substituted reference to health professional shortage area for reference to health manpower shortage area.

1988—Subsec. (a)(3). Pub. L. 100–607 and Pub. L. 100–628 made identical amendments, substituting "section 256(r)" for "section 256(q)(2)".

1987—Subsec. (a)(1). Pub. L. 100–177, §302(1), inserted sentence at end relating to removal of an area from areas determined to be health manpower shortage areas.

Subsec. (a)(3). Pub. L. 100–77 added par. (3).

Subsec. (b)(2)(D). Pub. L. 100–177, §302(2), added subpar. (D).

1981—Subsec. (a)(1)(A). Pub. L. 97–35, §2702(a), inserted provisions respecting reasonable accessibility to adequately served area.

Subsec. (a)(2)(C). Pub. L. 97–35, §986(b)(4), substituted "persons under quarantine" for "seamen".

Subsec. (e). Pub. L. 97–35, §2702(c), designated existing provisions as par. (1) and added par. (2).

Subsec. (h). Pub. L. 97–35, §2702(b), substituted "may" for "shall".

1979—Subsec. (a)(2)(C). Pub. L. 96–32 substituted "section 247e of this title" for "part D of subchapter II

of this chapter".

1977—Subsec. (c)(3). Pub. L. 95–142 added par. (3).

STATUTORY NOTES AND RELATED SUBSIDIARIES

EFFECTIVE DATE OF 2003 AMENDMENT

Amendments by Pub. L. 108–163 deemed to have taken effect immediately after the enactment of Pub. L. 107–251, see section 3 of Pub. L. 108–163, set out as a note under section 233 of this title.

EFFECTIVE DATE OF 1988 AMENDMENTS

Pub. L. 100–628, title VI, §631, Nov. 7, 1988, 102 Stat. 3244, provided that: "The amendments made by subsection (a) of section 601 [amending section 256 of this title] shall take effect in accordance with subsection (b) of such section [formerly set out as a note under section 256 of this title]. The amendments otherwise made by this title [amending this section and sections 256, 290bb–2, 290cc–21, 290cc–28, 290cc–29, 290cc–35, 290cc–36, 290dd, 290ee, and 290ee–1 of this title and amending provisions set out as a note under section 290aa–3 of this title] shall take effect October 1, 1988, or upon the date of the enactment of this Act [Nov. 7, 1988], whichever occurs later."

Pub. L. 100–607, title VIII, §831, Nov. 4, 1988, 102 Stat. 3171, provided that: "The amendments made by subsection (a) of section 801 [amending section 256 of this title] shall take effect in accordance with subsection (b) of such section [formerly set out as a note under section 256 of this title]. The amendments otherwise made by this title [amending this section and sections 256, 290bb–2, 290cc–21, 290cc–28, 290cc–29, 290cc–35, 290cc–36, 290dd, 290ee, and 290ee–1 of this title and amending provisions set out as a note under section 290aa–3 of this title] shall take effect October 1, 1988, or upon the date of the enactment of this Act [Nov. 4, 1988], whichever occurs later."

EFFECTIVE DATE OF 1981 AMENDMENT

Amendment by section 986(b)(4) of Pub. L. 97–35 effective Oct. 1, 1981, see section 986(c) of Pub. L. 97–35, set out as a note under section 249 of this title.

EFFECTIVE DATE OF 1977 AMENDMENT

Pub. L. 95–142, §7(e)(1), Oct. 25, 1977, 91 Stat. 1194, provided that: "The amendment made by subsection (d) [amending this section] shall apply with respect to determinations and designations made on and after the date of the enactment of this Act [Oct. 25, 1977]."

REGULATIONS

Pub. L. 107–251, title III, §302(b), Oct. 26, 2002, 116 Stat. 1644, which required the Secretary to submit a report to Congress, if the Secretary issued regulations revising the definition of a health professional shortage area under this section and standards concerning priority of such an area under section 254f–1 of this title, was repealed by Pub. L. 108–163, §2(f)(2), Dec. 6, 2003, 117 Stat. 2022.

IMPROVEMENT OF SITE DESIGNATION PROCESS

Pub. L. 107–251, title III, §302(d)(1), Oct. 26, 2002, 116 Stat. 1644, provided that: "The Administrator of the Health Resources and Services Administration, in consultation with the Association of State and Territorial Dental Directors, dental societies, and other interested parties, shall revise the criteria on which the designations of dental health professional shortage areas are based so that such criteria provide a more accurate reflection of oral health care need, particularly in rural areas."

GAO STUDY

Pub. L. 107–251, title III, §302(e), Oct. 26, 2002, 116 Stat. 1645, required the Comptroller General, no later than Feb. 1, 2005, to submit to Congress a report on the appropriateness of certain criteria established by the Secretary of Health and Human Services for the designation of health professional shortage areas and whether federally qualified health centers and rural health clinics should be deemed as such areas.

REFERENCE TO COMMUNITY, MIGRANT, PUBLIC HOUSING, OR HOMELESS HEALTH CENTER CONSIDERED REFERENCE TO HEALTH CENTER

Reference to community health center, migrant health center, public housing health center, or homeless health center, considered reference to health center, see section 4(c) of Pub. L. 104–299, set out as a note under section 254b of this title.

EVALUATION OF CRITERIA USED TO DESIGNATE HEALTH MANPOWER SHORTAGE AREAS; REPORT TO CONGRESS

Pub. L. 97–35, title XXVII, §2702(c), Aug. 13, 1981, 95 Stat. 903, directed the Secretary of Health and Human Services, effective Oct. 1, 1981, to evaluate the criteria used under section 254e(b) of this title to determine if the use of the criteria resulted in areas which did not have a shortage of health professions personnel being designated as health manpower shortage areas, and to consider different criteria (including the actual use of health professions personnel in an area by the residents, taking into account their health status and indicators of unmet demand and likelihood that such demand would not be met in two years) which might be used to designate health manpower shortage areas. The Secretary was to report the results of his activities to Congress not later than Nov. 30, 1982.

§254f. Corps personnel

(a) Conditions necessary for assignment of Corps personnel to area; contents of application for assignment; assignment to particular facility; approval of applications

(1) The Secretary may assign members of the Corps to provide, under regulations promulgated by the Secretary, health services in or to a health professional shortage area during the assignment period only if—

(A) a public or private entity, which is located or has a demonstrated interest in such area makes application to the Secretary for such assignment;

(B) such application has been approved by the Secretary;

(C) the entity agrees to comply with the requirements of section 254g of this title; and

(D) the Secretary has (i) conducted an evaluation of the need and demand for health manpower for the area, the intended use of Corps members to be assigned to the area, community support for the assignment of Corps members to the area, the area's efforts to secure health manpower for the area, and the fiscal management capability of the entity to which Corps members would be assigned and (ii) on the basis of such evaluation has determined that—

(I) there is a need and demand for health manpower for the area;

(II) there has been appropriate and efficient use of any Corps members assigned to the entity for the area;

(III) there is general community support for the assignment of Corps members to the entity;

(IV) the area has made unsuccessful efforts to secure health manpower for the area;

(V) there is a reasonable prospect of sound fiscal management, including efficient collection of fee-for-service, third-party, and other appropriate funds, by the entity with respect to Corps members assigned to such entity; and

(VI) the entity demonstrates willingness to support or facilitate mentorship, professional development, and training opportunities for Corps members.

An application for assignment of a Corps member to a health professional shortage area shall include a demonstration by the applicant that the area or population group to be served by the applicant has a shortage of personal health services and that the Corps member will be located so that the member will provide services to the greatest number of persons residing in such area or included in such population group. Such a demonstration shall be made on the basis of the criteria prescribed by the Secretary under section 254e(b) of this title and on additional criteria which the Secretary shall prescribe to determine if the area or population group to be served by the applicant has a shortage of personal health services.

(2) Corps members may be assigned to a Federal health care facility, but only upon the request of the head of the department or agency of which such facility is a part.

(3) In approving applications for assignment of members of the Corps the Secretary shall not discriminate against applications from entities which are not receiving Federal financial assistance under this chapter. In approving such applications, the Secretary shall give preference to applications in which a nonprofit entity or public entity shall provide a site to which Corps members may be assigned.

(b) Corps member income assurances; grants respecting sufficiency of financial resources

(1) The Secretary may not approve an application for the assignment of a member of the Corps described in subparagraph (C) of section 254d(a)(1) of this title to an entity unless the application of the entity contains assurances satisfactory to the Secretary that the entity (A) has sufficient financial resources to provide the member of the Corps with an income of not less than the income to which the member would be entitled if the member was a member described in subparagraph (B) of section 254d(a)(1) of this title, or (B) would have such financial resources if a grant was made to the entity under paragraph (2).

(2)(A) If in approving an application of an entity for the assignment of a member of the Corps described in subparagraph (C) of section 254d(a)(1) of this title the Secretary determines that the entity does not have sufficient financial resources to provide the member of the Corps with an income of not less than the income to which the member would be entitled if the member was a member described in subparagraph (B) of section 254d(a)(1) of this title, the Secretary may make a grant to the entity to assure that the member of the Corps assigned to it will receive during the period of assignment to the entity such an income.

(B) The amount of any grant under subparagraph (A) shall be determined by the Secretary. Payments under such a grant may be made in advance or by way of reimbursement, and at such intervals and on such conditions, as the Secretary finds necessary. No grant may be made unless an application therefor is submitted to and approved by the Secretary. Such an application shall be in such form, submitted in such manner, and contain such information, as the Secretary shall by regulation prescribe.

(c) Assignment of members without regard to ability of area to pay for services

The Secretary shall assign Corps members to entities in health professional shortage areas without regard to the ability of the individuals in such areas, population groups, medical facilities, or other public facilities to pay for such services.

(d) Entities entitled to aid; forms of assistance; coordination of efforts; agreements for assignment of Corps members; qualified entity

(1) The Secretary may provide technical assistance to a public or private entity which is located in a health professional shortage area and which desires to make an application under this section for assignment of a Corps member to such area. Assistance provided under this paragraph may include assistance to an entity in (A) analyzing the potential use of health professions personnel in defined health services delivery areas by the residents of such areas, (B) determining the need for such personnel in such areas, (C) determining the extent to which such areas will have a financial base to support the practice of such personnel and the extent to which additional financial resources are needed to adequately support the practice, (D) determining the types of inpatient and other health services that should be provided by such personnel in such areas, and (E) developing long-term plans for addressing health professional shortages and improving access to health care. The Secretary shall encourage entities that receive technical assistance under this paragraph to communicate with other communities, State Offices of Rural Health, State Primary Care Associations and Offices, and other entities concerned with site development and community needs assessment.

(2) The Secretary may provide, to public and private entities which are located in a health professional shortage area to which area a Corps member has been assigned, technical assistance to assist in the retention of such member in such area after the completion of such member's assignment to the area.

(3) The Secretary may provide, to health professional shortage areas to which no Corps member has been assigned, (A) technical assistance to assist in the recruitment of health manpower for such areas, and (B) current information on public and private programs which provide assistance in the securing of health manpower.

(4)(A) The Secretary shall undertake to demonstrate the improvements that can be made in the assignment of members of the Corps to health professional shortage areas and in the delivery of health care by Corps members in such areas through coordination with States, political subdivisions of States, agencies of States and political subdivisions, and other public and private entities which

have expertise in the planning, development, and operation of centers for the delivery of primary health care. In carrying out this subparagraph, the Secretary shall enter into agreements with qualified entities which provide that if—

(i) the entity places in effect a program for the planning, development, and operation of centers for the delivery of primary health care in health professional shortage areas which reasonably addresses the need for such care in such areas, and

(ii) under the program the entity will perform the functions described in subparagraph (B),

the Secretary will assign under this section members of the Corps in accordance with the program.

(B) For purposes of subparagraph (A), the term "qualified entity" means a State, political subdivision of a State, an agency of a State or political subdivision, or other public or private entity operating solely within one State, which the Secretary determines is able—

(i) to analyze the potential use of health professions personnel in defined health services delivery areas by the residents of such areas;

(ii) to determine the need for such personnel in such areas and to recruit, select, and retain health professions personnel (including members of the National Health Service Corps) to meet such need;

(iii) to determine the extent to which such areas will have a financial base to support the practice of such personnel and the extent to which additional financial resources are needed to adequately support the practice;

(iv) to determine the types of inpatient and other health services that should be provided by such personnel in such areas;

(v) to assist such personnel in the development of their clinical practice and fee schedules and in the management of their practice;

(vi) to assist in the planning and development of facilities for the delivery of primary health care; and

(vii) to assist in establishing the governing bodies of centers for the delivery of such care and to assist such bodies in defining and carrying out their responsibilities.

(e) Practice within State by Corps member

Notwithstanding any other law, any member of the Corps licensed to practice medicine, osteopathic medicine, dentistry, or any other health profession in any State shall, while serving in the Corps, be allowed to practice such profession in any State.

(July 1, 1944, ch. 373, title III, §333, as added Pub. L. 94–484, title IV, §407(b)(3), Oct. 12, 1976, 90 Stat. 2272; amended Pub. L. 97–35, title XXVII, §2703, Aug. 13, 1981, 95 Stat. 904; Pub. L. 100–177, title III, §§303, 304, Dec. 1, 1987, 101 Stat. 1004; Pub. L. 100–607, title VI, §629(a)(2), Nov. 4, 1988, 102 Stat. 3146; Pub. L. 101–597, title I, §103, title IV, §401(b)[(a)], Nov. 16, 1990, 104 Stat. 3015, 3035; Pub. L. 107–251, title III, §303, Oct. 26, 2002, 116 Stat. 1645; Pub. L. 108–163, §2(g), Dec. 6, 2003, 117 Stat. 2022; Pub. L. 110–355, §3(c), Oct. 8, 2008, 122 Stat. 3993.)

EDITORIAL NOTES

AMENDMENTS

2008—Subsec. (a)(1)(D)(ii)(VI). Pub. L. 110–355 added subcl. (VI).

2003—Subsec. (a)(1)(C). Pub. L. 108–163 realigned margin.

2002—Subsec. (a)(1). Pub. L. 107–251, §303(1)(A)(i), struck out "(specified in the agreement described in section 254g of this title)" after "assignment period" in introductory provisions.

Subsec. (a)(1)(A). Pub. L. 107–251, §303(1)(A)(ii), struck out "nonprofit" before "private entity".

Subsec. (a)(1)(C). Pub. L. 107–251, §303(1)(A)(iii), added subpar. (C) and struck out former subpar. (C) which read as follows: "an agreement has been entered into between the entity which has applied and the Secretary, in accordance with section 254g of this title; and".

Subsec. (a)(3). Pub. L. 107–251, §303(1)(B), inserted at end "In approving such applications, the Secretary shall give preference to applications in which a nonprofit entity or public entity shall provide a site to which Corps members may be assigned."

Subsec. (d)(1). Pub. L. 107–251, §303(2), struck out "nonprofit" before "private entity" in first sentence, added cl. (E), and inserted at end "The Secretary shall encourage entities that receive technical assistance under this paragraph to communicate with other communities, State Offices of Rural Health, State Primary Care Associations and Offices, and other entities concerned with site development and community needs assessment."

Subsec. (d)(2). Pub. L. 107–251, §303(2)(A), struck out "nonprofit" before "private entities".

Subsec. (d)(4). Pub. L. 107–251, §303(2)(A), struck out "nonprofit" before "private entities" in introductory provisions of subpar. (A) and before "private entity" in introductory provisions of subpar. (B).

1990—Subsec. (a)(1). Pub. L. 101–597, §401(b)[(a)], substituted reference to health professional shortage area for reference to health manpower shortage area in introductory and closing provisions.

Subsec. (a)(1)(D)(ii)(II). Pub. L. 101–597, §103(a), substituted "has been" and "any Corps" for "will be" and "Corps", respectively.

Subsec. (b). Pub. L. 101–597, §103(b), redesignated subsec. (d) as (b) and struck out former subsec. (b) which related to approval of application for assignment of Corps personnel subject to review and comment on application by health service agencies in designated area.

Subsec. (c). Pub. L. 101–597, §401(b)[(a)], substituted reference to health professional shortage area for reference to health manpower shortage area.

Pub. L. 101–597, §103(b), redesignated subsec. (e) as (c) and struck out former subsec. (c) which related to applications, consideration and approval by Secretary, priorities, cooperation with Corps members, and comments by health professionals and societies in designated areas.

Subsec. (d). Pub. L. 101–597, §401(b)[(a)], substituted reference to health professional shortage area for reference to health manpower shortage area wherever appearing in pars. (1) to (4)(A)(i).

Pub. L. 101–597, §103(b)(2), redesignated subsec. (g) as (d). Former subsec. (d) redesignated (b).

Subsec. (e). Pub. L. 101–597, §103(b)(2), redesignated subsec. (i) as (e). Former subsec. (e) redesignated (c).

Subsec. (f). Pub. L. 101–597, §103(b)(1), struck out subsec. (f) which provided for selection of Corps members for assignment upon basis of characteristics.

Subsec. (g). Pub. L. 101–597, §103(b)(2), redesignated subsec. (g) as (d).

Subsec. (h). Pub. L. 101–597, §103(b)(1), struck out subsec. (h) which related to study and contracts for study of methods of assignments of Corps members.

Subsec. (i). Pub. L. 101–597, §103(b)(2), redesignated subsec. (i) as (e).

Subsecs. (j), (k). Pub. L. 101–597, §103(b)(1), struck out subsecs. (j) and (k) which provided for placement of physicians in medically underserved areas and assignment of family physicians, respectively.

1988—Subsec. (i). Pub. L. 100–607 substituted "osteopathic medicine" for "osteopathy".

1987—Subsec. (j). Pub. L. 100–177, §303, added subsec. (j).

Subsec. (k). Pub. L. 100–177, §304, added subsec. (k).

1981—Subsec. (a). Pub. L. 97–35, §2703(a), (b), amended par. (1)(D) generally and, among changes, made numerous changes in nomenclature, inserted at end of par. (1) provisions respecting application, and added par. (3).

Subsec. (c). Pub. L. 97–35, §2703(c), struck out par. (2) which related to special considerations, and redesignated pars. (3) and (4) as (2) and (3), respectively.

Subsecs. (d) to (f). Pub. L. 97–35, §2703(d), added subsec. (d) and redesignated former subsecs. (d), (e), and (f) as (e), (f), and (g), respectively.

Subsec. (g). Pub. L. 97–35, §2703(d), (e), redesignated former subsec. (f) as (g) and substituted "may" for "shall" in pars. (1) to (3), inserted provisions respecting health professions personnel in par. (1), added par. (4), and struck out requirement respecting demonstrated interest in pars. (1) and (2). Former subsec. (g) redesignated (h).

Subsec. (h). Pub. L. 97–35, §2703(d), (f), redesignated former subsec. (g) as (h) and directed that "may" be substituted for "shall" which was executed by substituting "may" for "shall" in two places preceding par. (1). Former subsec. (h) redesignated (i).

Subsec. (i). Pub. L. 97–35, §2703(d), (g), redesignated former subsec. (h) as (i) and inserted reference to other health profession.

STATUTORY NOTES AND RELATED SUBSIDIARIES

EFFECTIVE DATE OF 2003 AMENDMENT

Amendment by Pub. L. 108–163 deemed to have taken effect immediately after the enactment of Pub. L. 107–251, see section 3 of Pub. L. 108–163, set out as a note under section 233 of this title.

EFFECTIVE DATE OF 1981 AMENDMENT

Pub. L. 97–35, title XXVII, §2703(d), Aug. 13, 1981, 95 Stat. 905, provided that the amendment made by that section is effective Oct. 1, 1981.

FLEXIBILITY FOR MEMBERS OF NATIONAL HEALTH SERVICE CORPS DURING EMERGENCY PERIOD

Pub. L. 116–136, div. A, title III, §3216, Mar. 27, 2020, 134 Stat. 375, provided that: "During the public health emergency declared by the Secretary of Health and Human Services under section 319 of the Public Health Service Act (42 U.S.C. 247d) on January 31, 2020, with respect to COVID–19, the Secretary may, notwithstanding section 333 of the Public Health Service Act (42 U.S.C. 254f), assign members of the National Health Service Corps, with the voluntary agreement of such corps members, to provide such health services at such places, and for such number of hours, as the Secretary determines necessary to respond to such emergency, provided that such places are within a reasonable distance of the site to which such members were originally assigned, and the total number of hours required are the same as were required of such members prior to the date of enactment of this Act [Mar. 27, 2020]."

§254f–1. Priorities in assignment of Corps personnel

(a) In general

In approving applications made under section 254f of this title for the assignment of Corps members, the Secretary shall—

(1) give priority to any such application that—

(A) is made regarding the provision of primary health services to a health professional shortage area with the greatest such shortage; and

(B) is made by an entity that—

(i) serves a health professional shortage area described in subparagraph (A);

(ii) coordinates the delivery of primary health services with related health and social services;

(iii) has a documented record of sound fiscal management; and

(iv) will experience a negative impact on its capacity to provide primary health services if a Corps member is not assigned to the entity;

(2) with respect to the geographic area in which the health professional shortage area is located, take into consideration the willingness of individuals in the geographic area, and of the appropriate governmental agencies or health entities in the area, to assist and cooperate with the Corps in providing effective primary health services; and

(3) take into consideration comments of medical, osteopathic, dental, or other health professional societies whose members deliver services to the health professional shortage area, or if no such societies exist, comments of physicians, dentists, or other health professionals delivering services to the area.

(b) Establishment of criteria for determining priorities

(1) In general

The Secretary shall establish criteria specifying the manner in which the Secretary makes a determination under subsection (a)(1)(A) of the health professional shortage areas with the greatest such shortages.

(2) Publication of criteria

The criteria required in paragraph (1) shall be published in the Federal Register not later than July 1, 1991. Any revisions made in the criteria by the Secretary shall be effective upon publication in the Federal Register.

(c) Notifications regarding priorities

(1) Proposed list

The Secretary shall prepare and publish a proposed list of health professional shortage areas and entities that would receive priority under subsection (a)(1) in the assignment of Corps members. The list shall contain the information described in paragraph (2), and the relative scores and relative priorities of the entities submitting applications under section 254f of this title, in a proposed format. All such entities shall have 30 days after the date of publication of the list to provide additional data and information in support of inclusion on the list or in support of a higher priority determination and the Secretary shall reasonably consider such data and information in preparing the final list under paragraph (2).

(2) Preparation of list for applicable period

For the purpose of carrying out paragraph (3), the Secretary shall prepare and, as appropriate, update a list of health professional shortage areas and entities that are receiving priority under subsection (a)(1) in the assignment of Corps members. Such list—

(A) shall include a specification, for each such health professional shortage area, of the entities for which the Secretary has provided an authorization to receive assignments of Corps members in the event that Corps members are available for the assignments; and

(B) shall, of the entities for which an authorization described in subparagraph (A) has been provided, specify—

(i) the entities provided such an authorization for the assignment of Corps members who are participating in the Scholarship Program;

(ii) the entities provided such an authorization for the assignment of Corps members who are participating in the Loan Repayment Program; and

(iii) the entities provided such an authorization for the assignment of Corps members who have become Corps members other than pursuant to contractual obligations under the Scholarship or Loan Repayment Programs.

The Secretary may set forth such specifications by medical specialty.

(3) Notification of affected parties

(A) Entities

Not later than 30 days after the Secretary has added to a list under paragraph (2) an entity specified as described in subparagraph (A) of such paragraph, the Secretary shall notify such entity that the entity has been provided an authorization to receive assignments of Corps members in the event that Corps members are available for the assignments.

(B) Individuals

In the case of an individual obligated to provide service under the Scholarship Program, not later than 3 months before the date described in section 254m(b)(5) of this title, the Secretary shall provide to such individual the names of each of the entities specified as described in paragraph (2)(B)(i) that is appropriate for the individual's medical specialty and discipline.

(4) Revisions

If the Secretary proposes to make a revision in the list under paragraph (2), and the revision would adversely alter the status of an entity with respect to the list, the Secretary shall notify the entity of the revision. Any entity adversely affected by such a revision shall be notified in writing by the Secretary of the reasons for the revision and shall have 30 days from such notification to file a written appeal of the determination involved which shall be reasonably considered by the Secretary before the revision to the list becomes final. The revision to the list shall be effective with respect to assignment of Corps members beginning on the date that the revision becomes final.

(d) Limitation on number of entities offered as assignment choices in Scholarship Program

(1) Determination of available Corps members

By April 1 of each calendar year, the Secretary shall determine the number of participants in the

Scholarship Program who will be available for assignments under section 254f of this title during the program year beginning on July 1 of that calendar year.

(2) Determination of number of entities

At all times during a program year, the number of entities specified under subsection (c)(2)(B)(i) shall be—

(A) not less than the number of participants determined with respect to that program year under paragraph (1); and

(B) not greater than twice the number of participants determined with respect to that program year under paragraph (1).

(July 1, 1944, ch. 373, title III, §333A, as added and amended Pub. L. 101–597, title I, §104, title IV, §401(b)[(a)], Nov. 16, 1990, 104 Stat. 3015, 3035; Pub. L. 107–251, title III, §304, Oct. 26, 2002, 116 Stat. 1646; Pub. L. 108–163, §2(h), Dec. 6, 2003, 117 Stat. 2022.)

EDITORIAL NOTES

AMENDMENTS

2003—Subsec. (c)(4). Pub. L. 108–163 substituted "30 days from such notification" for "30 days".

2002—Subsec. (a)(1)(A). Pub. L. 107–251, §304(1), struck out ", as determined in accordance with subsection (b) of this section" after "such shortage".

Subsec. (b). Pub. L. 107–251, §304(2), (7), redesignated subsec. (c) as (b) and struck out heading and text of former subsec. (b). Text read as follows: "In making a determination under subsection (a)(1)(A) of this section of the health professional shortage areas with the greatest such shortages, the Secretary may consider only the following factors:

"(1) The ratio of available health manpower to the number of individuals in the area or population group involved, or served by the medical facility or other public facility involved.

"(2) Indicators of need as follows:

"(A) The rate of low birthweight births.

"(B) The rate of infant mortality.

"(C) The rate of poverty.

"(D) Access to primary health services, taking into account the distance to such services."

Subsec. (c). Pub. L. 107–251, §304(7), redesignated subsec. (d) as (c). Former subsec. (c) redesignated (b).

Subsec. (c)(1). Pub. L. 107–251, §304(3), struck out second sentence, which read as follows: "Such criteria shall specify the manner in which the factors described in subsection (b) of this section are implemented regarding such a determination."

Subsec. (d). Pub. L. 107–251, §304(7), redesignated subsec. (e) as (d). Former subsec. (d) redesignated (c).

Subsec. (d)(1). Pub. L. 107–251, §304(4)(B), added par. (1). Former par. (1) redesignated (2).

Subsec. (d)(2). Pub. L. 107–251, §304(4)(C), in introductory provisions, substituted "paragraph (3)" for "paragraph (2)" and "prepare and, as appropriate, update a list of health professional shortage areas and entities" for "prepare a list of health professional shortage areas" and struck out "for the period applicable under subsection (f) of this section" after "Corps members".

Pub. L. 107–251, §304(4)(A), redesignated par. (1) as (2). Former par. (2) redesignated (3).

Subsec. (d)(3). Pub. L. 107–251, §304(4)(D), added par. (3) and struck out heading and text of former par. (3). Text read as follows:

"(A) Not later than 30 days after the preparation of each list under paragraph (1), the Secretary shall notify entities specified for purposes of subparagraph (A) of such paragraph of the fact that the entities have been provided an authorization to receive assignments of Corps members in the event that Corps members are available for the assignments.

"(B) In the case of individuals with respect to whom a period of obligated service under the Scholarship Program will begin during the period under subsection (f) of this section for which a list under paragraph (1) is prepared, the Secretary shall, not later than 30 days after the preparation of each such list, provide to such individuals the names of each of the entities specified for purposes of paragraph (1)(B)(i) that is appropriate to the medical specialty of the individuals."

Pub. L. 107–251, §304(4)(A), redesignated par. (2) as (3). Former par. (3) redesignated (4).

Subsec. (d)(4). Pub. L. 107–251, §304(4)(E), added par. (4) and struck out heading and text of former par. (4). Text read as follows: "If the Secretary makes a revision in a list under paragraph (1) during the period under subsection (f) of this section to which the list is applicable, and the revision alters the status of an entity

with respect to the list, the Secretary shall notify the entity of the effect on the entity of the revision. Such notification shall be provided not later than 30 days after the date on which the revision is made."

Pub. L. 107–251, §304(4)(A), redesignated par. (3) as (4).

Subsec. (e). Pub. L. 107–251, §304(7), redesignated subsec. (e) as (d).

Pub. L. 107–251, §304(5), added subsec. (e) and struck out heading and text of former subsec. (e). Text related to limitation on the number of entities offered as assignment choices in the Scholarship Program based on the number of participants available for assignments.

Subsec. (f). Pub. L. 107–251, §304(6), struck out heading and text of subsec. (f), which related to applicable period regarding priorities in assignment of Corps members.

1990—Pub. L. 101–597, §401(b)[(a)], substituted reference to health professional shortage area for reference to health manpower shortage area wherever appearing in subsecs. (a) to (c)(1), (d)(1), and (e)(3).

STATUTORY NOTES AND RELATED SUBSIDIARIES

EFFECTIVE DATE OF 2003 AMENDMENT

Amendment by Pub. L. 108–163 deemed to have taken effect immediately after the enactment of Pub. L. 107–251, see section 3 of Pub. L. 108–163, set out as a note under section 233 of this title.

§254g. Charges for services by entities using Corps members

(a) Availability of services regardless of ability to pay or payment source

An entity to which a Corps member is assigned shall not deny requested health care services, and shall not discriminate in the provision of services to an individual—

(1) because the individual is unable to pay for the services; or

(2) because payment for the services would be made under—

(A) the medicare program under title XVIII of the Social Security Act (42 U.S.C. 1395 et seq.);

(B) the medicaid program under title XIX of such Act (42 U.S.C. 1396 et seq.); or

(C) the State children's health insurance program under title XXI of such Act (42 U.S.C. 1397aa et seq.).

(b) Charges for services

The following rules shall apply to charges for health care services provided by an entity to which a Corps member is assigned:

(1) In general

(A) Schedule of fees or payments

Except as provided in paragraph (2), the entity shall prepare a schedule of fees or payments for the entity's services, consistent with locally prevailing rates or charges and designed to cover the entity's reasonable cost of operation.

(B) Schedule of discounts

Except as provided in paragraph (2), the entity shall prepare a corresponding schedule of discounts (including, in appropriate cases, waivers) to be applied to the payment of such fees or payments. In preparing the schedule, the entity shall adjust the discounts on the basis of a patient's ability to pay.

(C) Use of schedules

The entity shall make every reasonable effort to secure from patients fees and payments for services in accordance with such schedules, and fees or payments shall be sufficiently discounted in accordance with the schedule described in subparagraph (B).

(2) Services to beneficiaries of Federal and federally assisted programs

In the case of health care services furnished to an individual who is a beneficiary of a program listed in subsection (a)(2), the entity—

(A) shall accept an assignment pursuant to section 1842(b)(3)(B)(ii) of the Social Security Act (42 U.S.C. 1395u(b)(3)(B)(ii)) with respect to an individual who is a beneficiary under the medicare program; and

(B) shall enter into an appropriate agreement with—

(i) the State agency administering the program under title XIX of such Act [42 U.S.C. 1396 et seq.] with respect to an individual who is a beneficiary under the medicaid program; and

(ii) the State agency administering the program under title XXI of such Act [42 U.S.C. 1397aa et seq.] with respect to an individual who is a beneficiary under the State children's health insurance program.

(3) Collection of payments

The entity shall take reasonable and appropriate steps to collect all payments due for health care services provided by the entity, including payments from any third party (including a Federal, State, or local government agency and any other third party) that is responsible for part or all of the charge for such services.

(July 1, 1944, ch. 373, title III, §334, as added Pub. L. 107–251, title III, §305, Oct. 26, 2002, 116 Stat. 1647; amended Pub. L. 108–163, §2(i), Dec. 6, 2003, 117 Stat. 2022.)

EDITORIAL NOTES

REFERENCES IN TEXT

The Social Security Act, referred to in subsecs. (a)(2) and (b)(2)(B), is act Aug. 14, 1935, ch. 531, 49 Stat. 620. Titles XVIII, XIX, and XXI of the Act are classified generally to subchapters XVIII (§1395 et seq.), XIX (§1396 et seq.), and XXI (§1397aa et seq.), respectively, of chapter 7 of this title. For complete classification of this Act to the Code, see section 1305 of this title and Tables.

PRIOR PROVISIONS

A prior section 254g, act July 1, 1944, ch. 373, title III, §334, as added Pub. L. 94–484, title IV, §407(b)(3), Oct. 12, 1976, 90 Stat. 2274; amended Pub. L. 97–35, title XXVII, §2704, Aug. 13, 1981, 95 Stat. 906; Pub. L. 98–194, §3, Dec. 1, 1983, 97 Stat. 1345; Pub. L. 100–177, title II, §202(c), Dec. 1, 1987, 101 Stat. 996; Pub. L. 101–597, title I, §105, title IV, §401(b)[(a)], Nov. 16, 1990, 104 Stat. 3018, 3035, related to shared responsibility for costs of Corps personnel providing health services in or to a health professional shortage area during the assignment period, prior to repeal by Pub. L. 107–251, title III, §305, Oct. 26, 2002, 116 Stat. 1647.

AMENDMENTS

2003—Subsec. (b)(1)(B). Pub. L. 108–163 inserted "the payment of" after "applied to".

STATUTORY NOTES AND RELATED SUBSIDIARIES

EFFECTIVE DATE OF 2003 AMENDMENT

Amendment by Pub. L. 108–163 deemed to have taken effect immediately after the enactment of Pub. L. 107–251, see section 3 of Pub. L. 108–163, set out as a note under section 233 of this title.

§254h. Provision of health services by Corps members

(a) Means of delivery of services; cooperation with other health care providers

In providing health services in a health professional shortage area, Corps members shall utilize the techniques, facilities, and organizational forms most appropriate for the area, population group, medical facility, or other public facility, and shall, to the maximum extent feasible, provide such services (1) to all individuals in, or served by, such health professional shortage area regardless of their ability to pay for the services, and (2) in a manner which is cooperative with other health care providers serving such health professional shortage area.

(b) Utilization of existing health facilities; lease, acquisition, and use of equipment and supplies; permanent and temporary professional services

(1) Notwithstanding any other provision of law, the Secretary may (A) to the maximum extent feasible make such arrangements as he determines necessary to enable Corps members to utilize the health facilities in or serving the health professional shortage area in providing health services; (B) make such arrangements as he determines are necessary for the use of equipment and supplies of the Service and for the lease or acquisition of other equipment and supplies; and (C) secure the permanent or temporary services of physicians, dentists, nurses, administrators, and other health personnel. If there are no health facilities in or serving such area, the Secretary may arrange to have Corps members provide health services in the nearest health facilities of the Service or may lease or otherwise provide facilities in or serving such area for the provision of health services.

(2) If the individuals in or served by a health professional shortage area are being served (as determined under regulations of the Secretary) by a hospital or other health care delivery facility of the Service, the Secretary may, in addition to such other arrangements as he may make under paragraph (1), arrange for the utilization of such hospital or facility by Corps members in providing health services, but only to the extent that such utilization will not impair the delivery of health services and treatment through such hospital or facility to individuals who are entitled to health services and treatment through such hospital or facility.

(c) Loan; purposes; limitations

The Secretary may make one loan to any entity with an approved application under section 254f of this title to assist such entity in meeting the costs of (1) establishing medical, dental, or other health profession practices, including the development of medical practice management systems; (2) acquiring equipment for use in providing health services; and (3) renovating buildings to establish health facilities. No loan may be made under this subsection unless an application therefor is submitted to, and approved by, the Secretary. The amount of any such loan shall be determined by the Secretary, except that no such loan may exceed $50,000.

(d) Property and equipment disposal; fair market value; sale at less than full market value

Upon the expiration of the assignment of all Corps members to a health professional shortage area, the Secretary may (notwithstanding any other provision of law) sell, to any appropriate local entity, equipment and other property of the United States utilized by such members in providing health services. Sales made under this subsection shall be made at the fair market value (as determined by the Secretary) of the equipment or such other property; except that the Secretary may make such sales for a lesser value to an appropriate local entity, if he determines that the entity is financially unable to pay the full market value.

(e) Admitting privileges denied to Corps member by hospital; notice and hearing; denial of Federal funds for violation; "hospital" defined

(1)(A) It shall be unlawful for any hospital to deny an authorized Corps member admitting privileges when such Corps member otherwise meets the professional qualifications established by the hospital for granting such privileges and agrees to abide by the published bylaws of the hospital and the published bylaws, rules, and regulations of its medical staff.

(B) Any hospital which is found by the Secretary, after notice and an opportunity for a hearing on the record, to have violated this subsection shall upon such finding cease, for a period to be determined by the Secretary, to receive and to be eligible to receive any Federal funds under this chapter or under titles XVIII, XIX, or XXI of the Social Security Act [42 U.S.C. 1395 et seq., 1396 et seq., 1397aa et seq.].

(2) For purposes of this subsection, the term "hospital" includes a State or local public hospital, a private profit hospital, a private nonprofit hospital, a general or special hospital, and any other type of hospital (excluding a hospital owned or operated by an agency of the Federal Government), and any related facilities.

(July 1, 1944, ch. 373, title III, §335, as added Pub. L. 94–484, title IV, §407(b)(3), Oct. 12, 1976, 90 Stat. 2275; amended Pub. L. 97–35, title XXVII, §2705, Aug. 13, 1981, 95 Stat. 907; Pub. L.

101–597, title I, §106, title IV, §401(b)[(a)], Nov. 16, 1990, 104 Stat. 3018, 3035; Pub. L. 107–251, title III, §306, Oct. 26, 2002, 116 Stat. 1648.)

EDITORIAL NOTES

REFERENCES IN TEXT

The Social Security Act, referred to in subsec. (e)(1)(B), is act Aug. 14, 1935, ch. 531, 49 Stat. 620. Titles XVIII, XIX, and XXI of the Act are classified generally to subchapters XVIII (§1395 et seq.), XIX (§1396 et seq.), and XXI (§1397aa et seq.), respectively, of chapter 7 of this title. For complete classification of this Act to the Code, see section 1305 of this title and Tables.

AMENDMENTS

2002—Subsec. (e)(1)(B). Pub. L. 107–251 substituted "titles XVIII, XIX, or XXI of the Social Security Act" for "titles XVIII or XIX of the Social Security Act".

1990—Subsecs. (a), (b)(1)(A), (2), (d). Pub. L. 101–597, §401(b)[(a)], substituted reference to health professional shortage area for reference to health manpower shortage area wherever appearing.

Subsec. (e)(1)(A). Pub. L. 101–597, §106, substituted "authorized Corps member admitting privileges" for "authorized physician or dentist member of the Corps admitting privileges".

1981—Subsec. (a)(2). Pub. L. 97–35, §2705(a), substituted provisions respecting cooperation with other health care providers, for provisions respecting direct health services programs.

Subsec. (c)(4). Pub. L. 97–35, §2705(b), struck out cl. (4) relating to appropriate continuing education programs.

§254h–1. Facilitation of effective provision of Corps services

(a) Consideration of individual characteristics of members in making assignments

In making an assignment of a Corps member to an entity that has had an application approved under section 254f of this title, the Secretary shall, subject to making the assignment in accordance with section 254f–1 of this title, seek to assign to the entity a Corps member who has (and whose spouse, if any, has) characteristics that increase the probability that the member will remain in the health professional shortage area involved after the completion of the period of service in the Corps.

(b) Counseling on service in Corps

(1) In general

The Secretary shall, subject to paragraph (3), offer appropriate counseling on service in the Corps to individuals during the period of membership in the Corps, particularly during the initial period of each assignment.

(2) Career advisor regarding obligated service

(A) In the case of individuals who have entered into contracts for obligated service under the Scholarship or Loan Repayment Program, counseling under paragraph (1) shall include appropriate counseling on matters particular to such obligated service. The Secretary shall ensure that career advisors for providing such counseling are available to such individuals throughout the period of participation in the Scholarship or Loan Repayment Program.

(B) With respect to the Scholarship Program, counseling under paragraph (1) shall include counseling individuals during the period in which the individuals are pursuing an educational degree in the health profession involved, including counseling to prepare the individual for service in the Corps.

(3) Extent of counseling services

With respect to individuals who have entered into contracts for obligated service under the Scholarship or Loan Repayment Program, this subsection shall be carried out regarding such

individuals throughout the period of obligated service (and, additionally, throughout the period specified in paragraph (2)(B), in the case of the Scholarship Program). With respect to Corps members generally, this subsection shall be carried out to the extent practicable.

(c) Grants regarding preparation of students for practice

With respect to individuals who have entered into contracts for obligated service under the Scholarship or Loan Repayment Program, the Secretary may make grants to, and enter into contracts with, public and nonprofit private entities (including health professions schools) for the conduct of programs designed to prepare such individuals for the effective provision of primary health services in the health professional shortage areas to which the individuals are assigned.

(d) Professional development and training

(1) In general

The Secretary shall assist Corps members in establishing and maintaining professional relationships and development opportunities, including by—

(A) establishing appropriate professional relationships between the Corps member involved and the health professions community of the geographic area with respect to which the member is assigned;

(B) establishing professional development, training, and mentorship linkages between the Corps member involved and the larger health professions community, including through distance learning, direct mentorship, and development and implementation of training modules designed to meet the educational needs of offsite Corps members;

(C) establishing professional networks among Corps members; or

(D) engaging in other professional development, mentorship, and training activities for Corps members, at the discretion of the Secretary.

(2) Assistance in establishing professional relationships

In providing such assistance under paragraph (1), the Secretary shall focus on establishing relationships with hospitals, with academic medical centers and health professions schools, with area health education centers under section 294a of this title, with health education and training centers under section 294b [1] of this title, and with border health education and training centers under such section 294b [1] of this title. Such assistance shall include assistance in obtaining faculty appointments at health professions schools.

(3) Supplement not supplant

Such efforts under this subsection shall supplement, not supplant, non-government efforts by professional health provider societies to establish and maintain professional relationships and development opportunities.

(e) Temporary relief from Corps duties

(1) In general

The Secretary shall, subject to paragraph (4), provide assistance to Corps members in establishing arrangements through which Corps members may, as appropriate, be provided temporary relief from duties in the Corps in order to pursue continuing education in the health professions, to participate in exchange programs with teaching centers, to attend professional conferences, or to pursue other interests, including vacations.

(2) Assumption of duties of member

(A) Temporary relief under paragraph (1) may be provided only if the duties of the Corps member involved are assumed by another health professional. With respect to such temporary relief, the duties may be assumed by Corps members or by health professionals who are not Corps members, if the Secretary approves the professionals for such purpose. Any health professional so

approved by the Secretary shall, during the period of providing such temporary relief, be deemed to be a Corps member for purposes of section 233 of this title (including for purposes of the remedy described in such section), section 254f(f) of this title, and section 254h(e) of this title.

(B) In carrying out paragraph (1), the Secretary shall provide for the formation and continued existence of a group of health professionals to provide temporary relief under such paragraph.

(3) Recruitment from general health professions community

In carrying out paragraph (1), the Secretary shall—

(A) encourage health professionals who are not Corps members to enter into arrangements under which the health professionals temporarily assume the duties of Corps members for purposes of paragraph (1); and

(B) with respect to the entities to which Corps members have been assigned under section 254f of this title, encourage the entities to facilitate the development of arrangements described in subparagraph (A).

(4) Limitation

In carrying out paragraph (1), the Secretary may not, except as provided in paragraph (5), obligate any amounts (other than for incidental expenses) for the purpose of—

(A) compensating a health professional who is not a Corps member for assuming the duties of a Corps member; or

(B) paying the costs of a vacation, or other interests that a Corps member may pursue during the period of temporary relief under such paragraph.

(5) Sole providers of health services

In the case of any Corps member who is the sole provider of health services in the geographic area involved, the Secretary may, from amounts appropriated under section 254k of this title, obligate on behalf of the member such sums as the Secretary determines to be necessary for purposes of providing temporary relief under paragraph (1).

(f) Determinations regarding effective service

In carrying out subsection (a) and sections 254l(d) and 254l–1(d) of this title, the Secretary shall carry out activities to determine—

(1) the characteristics of physicians, dentists, and other health professionals who are more likely to remain in practice in health professional shortage areas after the completion of the period of service in the Corps;

(2) the characteristics of health manpower shortage areas, and of entities seeking assignments of Corps members, that are more likely to retain Corps members after the members have completed the period of service in the Corps; and

(3) the appropriate conditions for the assignment and utilization in health manpower shortage areas of certified nurse practitioners, certified nurse midwives, and physician assistants.

(July 1, 1944, ch. 373, title III, §336, as added Pub. L. 97–35, title XXVII, §2706(b), Aug. 13, 1981, 95 Stat. 907; amended Pub. L. 100–177, title II, §202(d), Dec. 1, 1987, 101 Stat. 997; Pub. L. 101–597, title I, §107, title IV, §401(b)[(a)], Nov. 16, 1990, 104 Stat. 3018, 3035; Pub. L. 107–251, title III, §307(a), Oct. 26, 2002, 116 Stat. 1649; Pub. L. 110–355, §3(d), Oct. 8, 2008, 122 Stat. 3993.)

EDITORIAL NOTES

REFERENCES IN TEXT

Section 294b of this title, referred to in subsec. (d)(2), was repealed and a new section 294b enacted by Pub. L. 111–148, title V, §5403(b), Mar. 23, 2010, 124 Stat. 648, and, as so enacted, no longer relates to health education and training centers.

PRIOR PROVISIONS

A prior section 336 of act July 1, 1944, was renumbered section 336A by Pub. L. 97–35, §2706(a), and is

classified to section 254i of this title.

AMENDMENTS

2008—Subsec. (d). Pub. L. 110–355 amended subsec. (d) generally. Prior to amendment, text read as follows: "The Secretary shall assist Corps members in establishing appropriate professional relationships between the Corps member involved and the health professions community of the geographic area with respect to which the member is assigned, including such relationships with hospitals, with health professions schools, with area health education centers under section 295g–1 of this title, with health education and training centers under such section, and with border health education and training centers under such section. Such assistance shall include assistance in obtaining faculty appointments at health professions schools."

2002—Subsecs. (c), (f)(1). Pub. L. 107–251 substituted "health professional shortage areas" for "health manpower shortage areas".

1990—Pub. L. 101–597, §107, amended section generally. Prior to amendment, section read as follows:

"(a) The Secretary may make grants to and enter into contracts with public and private nonprofit entities for the conduct of programs which are designed to prepare individuals subject to a service obligation under the National Health Service Corps Scholarship Program or Loan Repayment Program to effectively provide health services in the health manpower shortage area to which they are assigned.

"(b) No grant may be made or contract entered into under subsection (a) of this section unless an application therefor is submitted to and approved by the Secretary. Such an application shall be in such form, submitted in such manner, and contain such information, as the Secretary shall by regulation prescribe."

Subsec. (a). Pub. L. 101–597, §401(b)[(a)], substituted "health professional shortage area" for "health manpower shortage area".

1987—Subsec. (a). Pub. L. 100–177 substituted "Scholarship Program or Loan Repayment Program" for "scholarship program".

[1] *See References in Text note below.*

§254i. Annual report to Congress; contents

The Secretary shall submit an annual report to Congress, and shall include in such report with respect to the previous calendar year—

(1) the number, identity, and priority of all health professional shortage areas designated in such year and the number of health professional shortage areas which the Secretary estimates will be designated in the subsequent year;

(2) the number of applications filed under section 254f of this title in such year for assignment of Corps members and the action taken on each such application;

(3) the number and types of Corps members assigned in such year to health professional shortage areas, the number and types of additional Corps members which the Secretary estimates will be assigned to such areas in the subsequent year, and the need for additional members for the Corps;

(4) the recruitment efforts engaged in for the Corps in such year and the number of qualified individuals who applied for service in the Corps in such year;

(5) the number of patients seen and the number of patient visits recorded during such year with respect to each health professional shortage area to which a Corps member was assigned during such year;

(6) the number of Corps members who elected, and the number of Corps members who did not elect, to continue to provide health services in health professional shortage areas after termination of their service in the Corps and the reasons (as reported to the Secretary) of members who did not elect for not making such election;

(7) the results of evaluations and determinations made under section 254f(a)(1)(D) of this title during such year; and

(8) the amount charged during such year for health services provided by Corps members, the amount which was collected in such year by entities in accordance with section 254g of this title, and the amount which was paid to the Secretary in such year under such agreements.

(July 1, 1944, ch. 373, title III, §336A, formerly §336, as added Pub. L. 94–484, title IV, §407(b)(3), Oct. 12, 1976, 90 Stat. 2277, renumbered §336A, Pub. L. 97–35, title XXVII, §2706(a), Aug. 13, 1981, 95 Stat. 907; amended Pub. L. 97–375, title II, §206(a), Dec. 21, 1982, 96 Stat. 1823; Pub. L. 101–597, title IV, §401(b)[(a)], Nov. 16, 1990, 104 Stat. 3035; Pub. L. 107–251, title III, §307(b), Oct. 26, 2002, 116 Stat. 1649.)

EDITORIAL NOTES

AMENDMENTS

2002—Par. (8). Pub. L. 107–251 struck out "agreements under" after "in accordance with".

1990—Pars. (1), (3), (5), (6). Pub. L. 101–597 substituted reference to health professional shortage area for reference to health manpower shortage area wherever appearing.

1982—Pub. L. 97–375 struck out "on May 1 of each year" after "report to Congress".

§254j. National Advisory Council on National Health Service Corps

(a) Establishment; appointment of members

There is established a council to be known as the National Advisory Council on the National Health Service Corps (hereinafter in this section referred to as the "Council"). The Council shall be composed of not more than 15 members appointed by the Secretary. The Council shall consult with, advise, and make recommendations to, the Secretary with respect to his responsibilities in carrying out this subpart (other than section 254r [1] of this title), and shall review and comment upon regulations promulgated by the Secretary under this subpart.

(b) Term of members; compensation; expenses

(1) Members of the Council shall be appointed for a term of three years, except that any member appointed to fill a vacancy occurring prior to the expiration of the term for which the member's predecessor was appointed shall be appointed for the remainder of such term. No member shall be removed, except for cause.

(2) Members of the Council (other than members who are officers or employees of the United States), while attending meetings or conferences thereof or otherwise serving on the business of the Council, shall be entitled to receive for each day (including traveltime) in which they are so serving compensation at a rate fixed by the Secretary (but not to exceed the daily equivalent of the annual rate of basic pay in effect for grade GS–18 of the General Schedule); and while so serving away from their homes or regular places of business all members may be allowed travel expenses, including per diem in lieu of subsistence, as authorized by section 5703 of title 5 for persons in the Government Service employed intermittently.

(c) Termination

Section 1013 of title 5 shall not apply with respect to the Council.

(July 1, 1944, ch. 373, title III, §337, as added Pub. L. 94–484, title IV, §407(b)(3), Oct. 12, 1976, 90 Stat. 2277; amended Pub. L. 96–32, §7(g), July 10, 1979, 93 Stat. 84; Pub. L. 97–35, title XXVII, §2707, Aug. 13, 1981, 95 Stat. 907; Pub. L. 97–414, §8(f), Jan. 4, 1983, 96 Stat. 2061; Pub. L. 103–183, title VII, §706(b), Dec. 14, 1993, 107 Stat. 2241; Pub. L. 111–148, title X, §10501(n)(3), Mar. 23, 2010, 124 Stat. 1003; Pub. L. 117–286, §4(a)(229), Dec. 27, 2022, 136 Stat. 4331.)

EDITORIAL NOTES

REFERENCES IN TEXT

Section 254r of this title, referred to in subsec. (a), was in the original a reference to section 338G of act July 1, 1944, which was renumbered section 338I by Pub. L. 100–177, title II, §201(1), Dec. 1, 1987, 101 Stat. 992, and repealed by Pub. L. 100–713, title I, §104(b)(1), Nov. 23, 1988, 102 Stat. 4787.

AMENDMENTS

2022—Subsec. (c). Pub. L. 117–286 substituted "Section 1013 of title 5" for "Section 14 of the Federal Advisory Committee Act".

2010—Subsec. (b)(1). Pub. L. 111–148 struck out at end "Members may not be reappointed to the Council."

1993—Subsec. (b)(2). Pub. L. 103–183 inserted "compensation at a rate fixed by the Secretary (but not to exceed" before "the daily equivalent" and substituted "Schedule);" for "Schedule;".

1983—Subsec. (a). Pub. L. 97–414 inserted "(other than section 254r of this title)" after "carrying out this subpart".

1981—Subsec. (a). Pub. L. 97–35, §2707(a), amended subsec. (a) generally, striking out pars. (1) to (5) respecting required status and background of members appointed by the Secretary.

Subsec. (b)(1). Pub. L. 97–35, §2707(b), inserted "not" before "be reappointed".

1979—Subsec. (b)(2). Pub. L. 96–32 substituted "section 5703 of title 5" for "section 5703(b) of title 5".

STATUTORY NOTES AND RELATED SUBSIDIARIES

TERMINATION OF ADVISORY COMMITTEES

Pub. L. 93–641, §6, Jan. 4, 1975, 88 Stat. 2275, set out as a note under section 217a of this title, provided that an advisory committee established pursuant to the Public Health Service Act shall terminate at such time as may be specifically prescribed by an Act of Congress enacted after Jan. 4, 1975.

REFERENCES IN OTHER LAWS TO GS–16, 17, OR 18 PAY RATES

References in laws to the rates of pay for GS–16, 17, or 18, or to maximum rates of pay under the General Schedule, to be considered references to rates payable under specified sections of Title 5, Government Organization and Employees, see section 529 [title I, §101(c)(1)] of Pub. L. 101–509, set out in a note under section 5376 of Title 5.

[1] *See References in Text note below.*

§254k. Authorization of appropriations

(a) For the purpose of carrying out this subpart, there are authorized to be appropriated such sums as may be necessary for each of the fiscal years 2008 through 2012.

(b) An appropriation under an authorization under subsection (a) for any fiscal year may be made at any time before that fiscal year and may be included in an Act making an appropriation under an authorization under subsection (a) for another fiscal year; but no funds may be made available from any appropriation under such authorization for obligation under sections 254d through 254h, section 254i, and section 254j of this title before the fiscal year for which such appropriation is authorized.

(July 1, 1944, ch. 373, title III, §338, as added Pub. L. 94–484, title IV, §407(b)(3), Oct. 12, 1976, 90 Stat. 2278; amended Pub. L. 95–626, title I, §122, Nov. 10, 1978, 92 Stat. 3570; Pub. L. 96–76, title II, §202(c), Sept. 29, 1979, 93 Stat. 582; Pub. L. 97–35, title XXVII, §2708, Aug. 13, 1981, 95 Stat. 908; Pub. L. 100–177, title III, §305, Dec. 1, 1987, 101 Stat. 1004; Pub. L. 101–597, title I, §108, Nov. 16, 1990, 104 Stat. 3021; Pub. L. 107–251, title III, §308, Oct. 26, 2002, 116 Stat. 1649; Pub. L. 110–355, §3(a)(1), Oct. 8, 2008, 122 Stat. 3993.)

EDITORIAL NOTES

AMENDMENTS

2008—Subsec. (a). Pub. L. 110–355 substituted "2008 through 2012" for "2002 through 2006".

2002—Subsec. (a). Pub. L. 107–251 struck out par. (1) designation before "For the purpose", substituted "2002 through 2006" for "1991 through 2000", and struck out par. (2) which read as follows: "In the case of individuals who serve in the Corps other than pursuant to obligated service under the Scholarship or Loan

Repayment Program, the Secretary each fiscal year shall, to the extent practicable, make assignments under section 254f of this title of such individuals who are certified nurse midwives, certified nurse practitioners, or physician assistants."

1990—Subsec. (a). Pub. L. 101–597 added subsec. (a) and struck out former subsec. (a) which read as follows: "To carry out this subpart, there are authorized to be appropriated $65,000,000 for fiscal year 1988, $65,000,000 for fiscal year 1989, and $65,000,000 for fiscal year 1990."

1987—Subsec. (a). Pub. L. 100–177 amended subsec. (a) generally. Prior to amendment, subsec. (a) read as follows: "To carry out the purposes of this subpart, there are authorized to be appropriated $47,000,000 for the fiscal year ending September 30, 1978; $64,000,000 for the fiscal year ending September 30, 1979; $82,000,000 for the fiscal year ending September 30, 1980; $110,000,000 for the fiscal year ending September 30, 1982; $120,000,000 for the fiscal year ending September 30, 1983; and $130,000,000 for the fiscal year ending September 30, 1984."

1981—Subsec. (a). Pub. L. 97–35, §2708(a), inserted provisions authorizing appropriations for fiscal years ending Sept. 30, 1982, 1983, and 1984.

Subsec. (b). Pub. L. 97–35, §2708(b), substituted reference to sections 254d to 254h, 254i, and 254j of this title for reference to this subpart.

1979—Subsec. (a). Pub. L. 96–76 substituted "$82,000,000" for "$70,000,000".

1978—Subsec. (a). Pub. L. 95–626 substituted "$64,000,000" for "$57,000,000" as amount authorized to be appropriated for fiscal year ending Sept. 30, 1979.

SUBPART III—SCHOLARSHIP PROGRAM AND LOAN REPAYMENT PROGRAM

EDITORIAL NOTES

CODIFICATION

Pub. L. 100–177, title II, §202(f), Dec. 1, 1987, 101 Stat. 999, inserted subpart III heading and redesignated former subpart III as IV.

§254*l*. National Health Service Corps Scholarship Program

(a) Establishment

The Secretary shall establish the National Health Service Corps Scholarship Program to assure, with respect to the provision of primary health services pursuant to section 254d(a)(2) of this title—

(1) an adequate supply of physicians, dentists, behavioral and mental health professionals, certified nurse midwives, certified nurse practitioners, and physician assistants; and

(2) if needed by the Corps, an adequate supply of other health professionals.

(b) Eligibility; application; written contract

To be eligible to participate in the Scholarship Program, an individual must—

(1) be accepted for enrollment, or be enrolled, as a full-time student (A) in an accredited (as determined by the Secretary) educational institution in a State and (B) in a course of study or program, offered by such institution and approved by the Secretary, leading to a degree in medicine, osteopathic medicine, dentistry, or other health profession, or an appropriate degree from a graduate program of behavioral and mental health;

(2) be eligible for, or hold, an appointment as a commissioned officer in the Regular or Reserve Corps [1] of the Service or be eligible for selection for civilian service in the Corps;

(3) submit an application to participate in the Scholarship Program; and

(4) sign and submit to the Secretary, at the time of submittal of such application, a written contract (described in subsection (f)) to accept payment of a scholarship and to serve (in accordance with this subpart) for the applicable period of obligated service in a health professional shortage area.

(c) Review and evaluation of information and forms by prospective applicant

(1) In disseminating application forms and contract forms to individuals desiring to participate in the Scholarship Program, the Secretary shall include with such forms—

(A) a fair summary of the rights and liabilities of an individual whose application is approved (and whose contract is accepted) by the Secretary, including in the summary a clear explanation of the damages to which the United States is entitled under section 254o of this title in the case of the individual's breach of the contract; and

(B) information respecting meeting a service obligation through private practice under an agreement under section 254n of this title and such other information as may be necessary for the individual to understand the individual's prospective participation in the Scholarship Program and service in the Corps, including a statement of all factors considered in approving applications for participation in the Program and in making assignments for participants in the Program.

(2) The application form, contract form, and all other information furnished by the Secretary under this subpart shall be written in a manner calculated to be understood by the average individual applying to participate in the Scholarship Program. The Secretary shall make such application forms, contract forms, and other information available to individuals desiring to participate in the Scholarship Program on a date sufficiently early to insure that such individuals have adequate time to carefully review and evaluate such forms and information.

(3)(A) The Secretary shall distribute to health professions schools materials providing information on the Scholarship Program and shall encourage the schools to disseminate the materials to the students of the schools.

(B)(i) In the case of any health professional whose period of obligated service under the Scholarship Program is nearing completion, the Secretary shall encourage the individual to remain in a health professional shortage area and to continue providing primary health services.

(ii) During the period in which a health professional is planning and making the transition to private practice from obligated service under the Scholarship Program, the Secretary may provide assistance to the professional regarding such transition if the professional is remaining in a health professional shortage area and is continuing to provide primary health services.

(C) In the case of entities to which participants in the Scholarship Program are assigned under section 254f of this title, the Secretary shall encourage the entities to provide options with respect to assisting the participants in remaining in the health professional shortage areas involved, and in continuing to provide primary health services, after the period of obligated service under the Scholarship Program is completed. The options with respect to which the Secretary provides such encouragement may include options regarding the sharing of a single employment position in the health professions by 2 or more health professionals, and options regarding the recruitment of couples where both of the individuals are health professionals.

(d) Factors considered in providing contracts; priorities

(1) Subject to section 254f–1 of this title, in providing contracts under the Scholarship Program—

(A) the Secretary shall consider the extent of the demonstrated interest of the applicants for the contracts in providing primary health services;

(B) the Secretary, in considering applications from individuals accepted for enrollment or enrolled in dental school, shall consider applications from all individuals accepted for enrollment or enrolled in any accredited dental school in a State; and

(C) may [2] consider such other factors regarding the applicants as the Secretary determines to be relevant to selecting qualified individuals to participate in such Program.

(2) In providing contracts under the Scholarship Program, the Secretary shall give priority—

(A) first, to any application for such a contract submitted by an individual who has previously received a scholarship under this section or under section 294z [3] of this title;

(B) second, to any application for such a contract submitted by an individual who has characteristics that increase the probability that the individual will continue to serve in a health

professional shortage area after the period of obligated service pursuant to subsection (f) is completed; and

(C) third, subject to subparagraph (B), to any application for such a contract submitted by an individual who is from a disadvantaged background.

(e) Commencement of participation in Scholarship Program; notice

(1) An individual becomes a participant in the Scholarship Program only upon the Secretary's approval of the individual's application submitted under subsection (b)(3) and the Secretary's acceptance of the contract submitted by the individual under subsection (b)(4).

(2) The Secretary shall provide written notice to an individual promptly upon the Secretary's approving, under paragraph (1), of the individual's participation in the Scholarship Program.

(f) Written contract; contents

The written contract (referred to in this subpart) between the Secretary and an individual shall contain—

(1) an agreement that—

(A) subject to paragraph (2), the Secretary agrees (i) to provide the individual with a scholarship (described in subsection (g)) in each such school year or years for a period of years (not to exceed four school years) determined by the individual, during which period the individual is pursuing a course of study described in subsection (b)(1)(B), and (ii) to accept (subject to the availability of appropriated funds for carrying out sections 254d through 254h and section 254j of this title) the individual into the Corps (or for equivalent service as otherwise provided in this subpart); and

(B) subject to paragraph (2), the individual agrees—

(i) to accept provision of such a scholarship to the individual;

(ii) to maintain enrollment in a course of study described in subsection (b)(1)(B) until the individual completes the course of study;

(iii) while enrolled in such course of study, to maintain an acceptable level of academic standing (as determined under regulations of the Secretary by the educational institution offering such course of study);

(iv) if pursuing a degree from a school of medicine or osteopathic medicine, to complete a residency in a specialty that the Secretary determines is consistent with the needs of the Corps; and

(v) to serve for a time period (hereinafter in the subpart referred to as the "period of obligated service") equal to—

(I) one year for each school year for which the individual was provided a scholarship under the Scholarship Program, or

(II) two years,

whichever is greater, as a provider of primary health services in a health professional shortage area (designated under section 254e of this title) to which he is assigned by the Secretary as a member of the Corps, or as otherwise provided in this subpart;

(2) a provision that any financial obligation of the United States arising out of a contract entered into under this subpart and any obligation of the individual which is conditioned thereon, is contingent upon funds being appropriated for scholarships under this subpart and to carry out the purposes of sections 254d through 254h and sections 254j and 254k of this title;

(3) a statement of the damages to which the United States is entitled, under section 254o of this title, for the individual's breach of the contract; and

(4) such other statements of the rights and liabilities of the Secretary and of the individual, not inconsistent with the provisions of this subpart.

(g) Scholarship provisions; contract with educational institution; increase in monthly stipend

(1) A scholarship provided to a student for a school year under a written contract under the

Scholarship Program shall consist of—

(A) payment to, or (in accordance with paragraph (2)) on behalf of, the student of the amount (except as provided in section 292k [3] of this title) of—

(i) the tuition of the student in such school year; and

(ii) all other reasonable educational expenses, including fees, books, and laboratory expenses, incurred by the student in such school year; and

(B) payment to the student of a stipend of $400 per month (adjusted in accordance with paragraph (3)) for each of the 12 consecutive months beginning with the first month of such school year.

(2) The Secretary may contract with an educational institution, in which a participant in the Scholarship Program is enrolled, for the payment to the educational institution of the amounts of tuition and other reasonable educational expenses described in paragraph (1)(A). Payment to such an educational institution may be made without regard to section 3324(a) and (b) of title 31.

(3) The amount of the monthly stipend, specified in paragraph (1)(B) and as previously adjusted (if at all) in accordance with this paragraph, shall be increased by the Secretary for each school year ending in a fiscal year beginning after September 30, 1978, by an amount (rounded to the next highest multiple of $1) equal to the amount of such stipend multiplied by the overall percentage (under section 5303 of title 5) of the adjustment (if such adjustment is an increase) in the rates of pay under the General Schedule made effective in the fiscal year in which such school year ends.

(h) Employment ceiling of Department unaffected

Notwithstanding any other provision of law, individuals who have entered into written contracts with the Secretary under this section, while undergoing academic training, shall not be counted against any employment ceiling affecting the Department.

(July 1, 1944, ch. 373, title III, §338A, formerly title VII, §751, as added Pub. L. 94–484, title IV, §408(b)(1), Oct. 12, 1976, 90 Stat. 2281; amended Pub. L. 95–215, §5, Dec. 19, 1977, 91 Stat. 1506; Pub. L. 95–623, §12(c), Nov. 9, 1978, 92 Stat. 3457; Pub. L. 95–626, title I, §113(b), Nov. 10, 1978, 92 Stat. 3563; Pub. L. 96–32, §7(i), July 10, 1979, 93 Stat. 84; renumbered §338A and amended Pub. L. 97–35, title XXVII, §2709(a), (b), Aug. 13, 1981, 95 Stat. 908; Pub. L. 99–129, title II, §210(b), Oct. 22, 1985, 99 Stat. 537; Pub. L. 100–607, title VI, §629(a)(2), Nov. 4, 1988, 102 Stat. 3146; Pub. L. 101–509, title V, §529 [title I, §101(b)(4)(K)], Nov. 5, 1990, 104 Stat. 1427, 1440; Pub. L. 101–597, title II, §201, title IV, §401(b)[(a)], Nov. 16, 1990, 104 Stat. 3021, 3035; Pub. L. 107–251, title III, §309, Oct. 26, 2002, 116 Stat. 1649; Pub. L. 108–163, §2(j), Dec. 6, 2003, 117 Stat. 2022.)

EDITORIAL NOTES

REFERENCES IN TEXT

Section 294z of this title, referred to in subsec. (d)(2)(A), was omitted in the general revision of subchapter V of this chapter by Pub. L. 102–408, title I, §102, Oct. 13, 1992, 106 Stat. 1994.

Section 292k of this title, referred to in subsec. (g)(1)(A), was in the original a reference to section 711 of act July 1, 1944. Section 711 of that Act was renumbered as section 710 by Pub. L. 97–35, title XXVII, §2720(b), Aug. 13, 1981, 95 Stat. 915, and subsequently omitted in the general revision of subchapter V of this chapter by Pub. L. 102–408, title I, §102, Oct. 13, 1992, 106 Stat. 1994. Pub. L. 102–408 enacted a new section 710 of act July 1, 1944, relating to insurance accounts, a new section 711, relating to powers and responsibilities of the Secretary, and a new section 712, relating to participation by Federal credit unions, which are classified to sections 292i, 292j, and 292k, respectively, of this title.

The General Schedule, referred to in subsec. (g)(3), is set out under section 5332 of Title 5, Government Organization and Employees.

CODIFICATION

In subsec. (g)(2), "section 3324(a) and (b) of title 31" substituted for "section 3648 of the Revised Statutes (31 U.S.C. 529)" on authority of Pub. L. 97–258, §4(b), Sept. 13, 1982, 96 Stat. 1067, the first section of which enacted Title 31, Money and Finance.

Section was formerly classified to section 294t of this title prior to its renumbering by Pub. L. 97–35.

AMENDMENTS

2003—Subsec. (d)(1)(B). Pub. L. 108–163 realigned margin.

2002—Subsec. (a)(1). Pub. L. 107–251, §309(1), inserted "behavioral and mental health professionals," after "dentists,".

Subsec. (b)(1)(B). Pub. L. 107–251, §309(2), inserted ", or an appropriate degree from a graduate program of behavioral and mental health" after "other health profession".

Subsec. (c)(1). Pub. L. 107–251, §309(3), made technical amendment to references in original act which appear in subpar. (A) as reference to section 254o of this title and in subpar. (B) as reference to section 254n of this title.

Subsec. (d)(1)(B), (C). Pub. L. 107–251, §309(4), added subpar. (B) and redesignated former subpar. (B) as (C).

Subsec. (f)(1)(B)(iv), (v). Pub. L. 107–251, §309(5)(A), added cl. (iv) and redesignated former cl. (iv) as (v).

Subsec. (f)(3). Pub. L. 107–251, §309(5)(B), made technical amendment to reference in original act which appears in text as reference to section 254o of this title.

Subsec. (i). Pub. L. 107–251, §309(6), struck out subsec. (i), which required an annual report to Congress on the Scholarship Program.

1990—Subsec. (a). Pub. L. 101–597, §201(a)(1), substituted "Corps Scholarship Program to assure, with respect to the provision of primary health services pursuant to section 254d(a)(2) of this title—" and pars. (1) and (2) for "Corps Scholarship Program (hereinafter in this subpart referred to as the 'Scholarship Program') to assure an adequate supply of trained physicians, dentists, and nurses for the National Health Service Corps (hereinafter in this subpart referred to as the 'Corps') and, if needed by the Corps, podiatrists, optometrists, pharmacists, clinical psychologists, graduates of schools of veterinary medicine, graduates of schools of public health, graduates of programs in health administration, graduates of programs for the training of physician assistants, expanded function dental auxiliaries, and nurse practitioners (as defined in section 296m of this title), and other health professionals."

Subsec. (b)(4). Pub. L. 101–597, §401(b)[(a)], substituted reference to health professional shortage area for reference to health manpower shortage area.

Subsec. (c). Pub. L. 101–597, §401(b)[(a)], substituted reference to health professional shortage area for reference to health manpower shortage area in par. (3)(B), (C).

Pub. L. 101–597, §201(b), inserted par. (1) designation, redesignated former pars. (1) and (2) as subpars. (A) and (B), inserted before period at end of subpar. (B) ", including a statement of all factors considered in approving applications for participation in the Program and in making assignments for participants in the Program", inserted par. (2) designation, and added par. (3).

Subsec. (d). Pub. L. 101–597, §401(b)[(a)], substituted reference to health professional shortage area for reference to health manpower shortage area in par. (2)(B).

Pub. L. 101–597, §201(c), amended subsec. (d) generally. Prior to amendment, subsec. (d) read as follows: "In determining which applications under the Scholarship Program to approve (and which contracts to accept), the Secretary shall give priority—

"(1) first, to applications made (and contracts submitted) by individuals who have previously received scholarships under the Scholarship Program or under section 294z of this title; and

"(2) second, to applications made (and contracts submitted)—

"(A) for the school year beginning in calendar year 1978, by individuals who are entering their first, second, or third year of study in a course of study or program described in subsection (b)(1)(B) of this section in such school year;

"(B) for the school year beginning in calendar year 1979, by individuals who are entering their first or second year of study in a course of study or program described in subsection (b)(1)(B) of this section in such school year; and

"(C) for each school year thereafter, by individuals who are entering their first year of study in a course of study or program described in subsection (b)(1)(B) of this section in such school year."

Subsec. (f)(1)(B)(iv). Pub. L. 101–597, §401(b)[(a)], substituted reference to health professional shortage area for reference to health manpower shortage area in closing provisions.

Pub. L. 101–597, §201(a)(2), substituted "as a provider of primary health services" after "whichever is greater,".

Subsec. (g)(3). Pub. L. 101–509 substituted "(under section 5303 of title 5)" for "(as set forth in the report transmitted to the Congress under section 5305 of title 5)".

Subsec. (i). Pub. L. 101–597, §201(d)(1), amended introductory provisions generally. Prior to amendment, introductory provisions read as follows: "The Secretary shall report to Congress on March 1 of each year—".

Subsec. (i)(4), (5). Pub. L. 101–597, §201(d)(2), added pars. (4) and (5) and struck out former par. (4) which read as follows: "the amount of tuition paid in the aggregate and at each educational institution for the school year beginning in such year and for prior school years."

Subsec. (i)(6). Pub. L. 101–597, §401(b)[(a)], substituted reference to health professional shortage area for reference to health manpower shortage area.

Pub. L. 101–597, §201(d)(2)(C), added par. (6).

1988—Subsec. (b)(1). Pub. L. 100–607 substituted "osteopathic medicine" for "osteopathy".

1985—Subsec. (g)(1). Pub. L. 99–129 struck out "or under section 294z of this title (relating to scholarships for first-year students of exceptional financial need)," after "Scholarship Program".

1981—Subsec. (a). Pub. L. 97–35, §2709(b)(1), inserted reference to clinical psychologists.

Subsec. (c). Pub. L. 97–35, §2709(b)(2), (3), substituted "254o" for "294w" in par. (1), and inserted provisions relating to information concerning meeting the service obligation in par. (2).

Subsec. (f). Pub. L. 97–35, §2709(b)(4)–(6), in par. (1) substituted reference to sections 254d to 254h and 254j of this title, for reference to subpart II of part D of subchapter II of this chapter, in par. (2) substituted reference to sections 254d to 254h, 254j and 254k of this title, for reference to subpart II of part D of subchapter II of this chapter, and in par. (3) substituted "254o" for "294w".

Subsec. (j). Pub. L. 97–35, §2709(b)(7), struck out subsec. (j) which related to consultation and participation of schools.

1979—Subsec. (g)(3). Pub. L. 96–32 substituted "section 5305 of title 5" for "section 5303 of title 5".

1978—Subsec. (f). Pub. L. 95–626 substituted "subpart II of part D" for "subpart II of part C" in pars. (1)(A) and (2).

Subsec. (i). Pub. L. 95–623 substituted March 1 for December 1 as the date for Secretary's annual report to Congress.

1977—Subsec. (d)(2). Pub. L. 95–215 substituted provisions relating to the school years beginning in calendar years 1978 and 1979 for provisions relating to the school year ending in the fiscal year beginning Oct. 1, 1977.

STATUTORY NOTES AND RELATED SUBSIDIARIES

CHANGE OF NAME

Reference to Reserve Corps of the Public Health Service deemed to be a reference to the Ready Reserve Corps, see section 204(c)(3) of this title.

EFFECTIVE DATE OF 2003 AMENDMENT

Amendment by Pub. L. 108–163 deemed to have taken effect immediately after the enactment of Pub. L. 107–251, see section 3 of Pub. L. 108–163, set out as a note under section 233 of this title.

EFFECTIVE DATE OF 1990 AMENDMENT

Amendment by Pub. L. 101–509 effective on such date as the President shall determine, but not earlier than 90 days, and not later than 180 days, after Nov. 5, 1990, see section 529 [title III, §305] of Pub. L. 101–509, set out as a note under section 5301 of Title 5, Government Organization and Employees.

EFFECTIVE DATE OF 1985 AMENDMENT

Pub. L. 99–129, title II, §228, Oct. 22, 1985, 99 Stat. 548, provided that:

"(a) Except as provided in subsection (b), this Act and the amendments and repeals made by this Act [enacting sections 294q–1 to 294q–3 of this title, amending this section and sections 292a, 292b, 292h, 292j, 293c, 294a, 294b, 294d, 294e, 294g, 294j, 294m to 294p, 294z, 295f to 295f–2, 295g, 295g–1, 295g–3, 295g–4, 295g–6 to 295g–8, 295g–8b, 295h, 295h–1a to 295h–1c, 296k, 296l, 296m, 297a, 298b–5, and 300aa–14 of this title, repealing sections 292c, 295 to 295e–5, 295g–2, 295g–5, 295g–8a, and 295g–9 of this title, enacting provisions set out as notes under sections 201, 292h, 293c, 294d, 294n, and 300aa–14 of this title and section 3811 of Title 50, War and National Defense, and amending provisions set out as a note under section 298b–5 of this title] shall take effect on the date of enactment of this Act [Oct. 22, 1985].

"(b)(1) The amendments made by section 101(a) of this Act [amending section 294a of this title] shall take effect as of October 1, 1985.

"(2) The amendments made by section 208(e) of this Act [amending section 294e of this title] shall take effect nine months after the date of enactment of this Act [Oct. 22, 1985].

"(3) The amendment made by section 208(h) of this Act [amending section 294a of this title] shall take effect as of October 1, 1983.

"(4) The provisions of section 746 of the Public Health Service Act (as added by the amendment made by section 209(h)(2) of this Act) [former 42 U.S.C. 294q–2] shall take effect as of June 30, 1984.

"(5) The amendments made by section 209(j) of this Act [amending sections 294m and 297a of this title] shall take effect as of June 30, 1984.

"(6) The amendments made by section 213(a) of this Act [amending section 295g–1 of this title] shall take effect as of October 1, 1985."

EFFECTIVE DATE OF 1977 AMENDMENT

Pub. L. 95–215, §5, Dec. 19, 1977, 91 Stat. 1506, provided that the amendment made by that section is effective Oct. 1, 1977.

EFFECTIVE DATE

Pub. L. 94–484, title IV, §408(b)(1), Oct. 12, 1976, 90 Stat. 2281, provided that the enactment of sections 254l to 254r of this title and repeal of section 234 of this title by Pub. L. 94–484 is effective Oct. 1, 1977.

EFFECTIVE DATE; SAVINGS PROVISION; CREDIT FOR PERIOD OF INTERNSHIP OR RESIDENCY BEFORE SEPTEMBER 30, 1977, TOWARDS SERVICE OBLIGATION

Pub. L. 94–484, title IV, §408(b)(2), Oct. 12, 1976, 90 Stat. 2288, as amended, eff. Oct. 12, 1976, by Pub. L. 95–83, title III, §307(p), Aug. 1, 1977, 91 Stat. 394, provided that:

"(A) Except as provided in subparagraphs (B) and (C), the amendment made by paragraph (1) of this subsection [enacting this section and sections 254l–1 to 254r of this title and repealing section 234 of this title] shall apply with respect to scholarships awarded under the National Health Service Corps Scholarship Program from appropriations for such Program for fiscal years beginning after September 30, 1977.

"(B) The provisions of section 225(f)(1) of the Public Health Service Act (as in effect on September 30, 1977) [former 42 U.S.C. 234(f)(1)] prescribing the financial obligation of a participant in the Public Health and National Health Service Corps Scholarship Program who fails to complete an active duty service obligation incurred under that Program shall apply to any individual who received a scholarship under such Program from appropriations for such Program for any fiscal year ending before October 1, 1977.

"(C) If an individual received a scholarship under the Public Health and National Health Service Corps Scholarship Program for any school year beginning before the date of the enactment of this Act [Oct. 12, 1976], periods of internship or residency served by such individual in a facility of the National Health Service Corps or other facility of the Public Health Service shall be creditable in satisfying such individual's service obligation incurred under that Program for such scholarship or for any scholarship received under the National Health Service Corps Scholarship Program for any subsequent school year. If an individual received a scholarship under the Public Health and National Health Service Corps Program for the first time from appropriations for such Program for the fiscal year ending September 30, 1977, periods of internship or residency served by such individual in such a facility shall be creditable in satisfying such individual's service obligation incurred under that Program for such scholarship."

SCHOLARSHIP AND LOAN REPAYMENT PROGRAMS

Pub. L. 107–251, title III, §302(c), Oct. 26, 2002, 116 Stat. 1644, provided that: "The Secretary of Health and Human Services, in consultation with organizations representing individuals in the dental field and organizations representing publicly funded health care providers, shall develop and implement a plan for increasing the participation of dentists and dental hygienists in the National Health Service Corps Scholarship Program under section 338A of the Public Health Service Act (42 U.S.C. 254l) and the Loan Repayment Program under section 338B of such Act (42 U.S.C. 254l–1)."

[1] See Change of Name note below.

[2] So in original.

[3] See References in Text note below.

§254*l*–1. National Health Service Corps Loan Repayment Program

(a) Establishment

The Secretary shall establish a program to be known as the National Health Service Corps Loan Repayment Program to assure, with respect to the provision of primary health services pursuant to section 254d(a)(2) of this title—

(1) an adequate supply of physicians, dentists, behavioral and mental health professionals, certified nurse midwives, certified nurse practitioners, and physician assistants; and

(2) if needed by the Corps, an adequate supply of other health professionals.

(b) Eligibility

To be eligible to participate in the Loan Repayment Program, an individual must—

(1)(A) have a degree in medicine, osteopathic medicine, dentistry, or another health profession, or an appropriate degree from a graduate program of behavioral and mental health, or be certified as a nurse midwife, nurse practitioner, or physician assistant;

(B) be enrolled in an approved graduate training program in medicine, osteopathic medicine, dentistry, behavioral and mental health, or other health profession; or

(C) be enrolled as a full-time student—

(i) in an accredited (as determined by the Secretary) educational institution in a State; and

(ii) in the final year of a course of a study or program, offered by such institution and approved by the Secretary, leading to a degree in medicine, osteopathic medicine, dentistry, or other health profession;

(2) be eligible for, or hold, an appointment as a commissioned officer in the Regular or Reserve Corps [1] of the Service or be eligible for selection for civilian service in the Corps; and

(3) submit to the Secretary an application for a contract described in subsection (f) (relating to the payment by the Secretary of the educational loans of the individual in consideration of the individual serving for a period of obligated service).

(c) Information to be included with application and contract forms; understandability; availability

(1) Summary and information

In disseminating application forms and contract forms to individuals desiring to participate in the Loan Repayment Program, the Secretary shall include with such forms—

(A) a fair summary of the rights and liabilities of an individual whose application is approved (and whose contract is accepted) by the Secretary, including in the summary a clear explanation of the damages to which the United States is entitled under section 254o of this title in the case of the individual's breach of the contract; and

(B) information respecting meeting a service obligation through private practice under an agreement under section 254n of this title and such other information as may be necessary for the individual to understand the individual's prospective participation in the Loan Repayment Program and service in the Corps.

(2) Understandability

The application form, contract form, and all other information furnished by the Secretary under this subpart shall be written in a manner calculated to be understood by the average individual applying to participate in the Loan Repayment Program.

(3) Availability

The Secretary shall make such application forms, contract forms, and other information available to individuals desiring to participate in the Loan Repayment Program on a date sufficiently early to ensure that such individuals have adequate time to carefully review and evaluate such forms and information.

(4) Recruitment and retention

(A) The Secretary shall distribute to health professions schools materials providing information

on the Loan Repayment Program and shall encourage the schools to disseminate the materials to the students of the schools.

(B)(i) In the case of any health professional whose period of obligated service under the Loan Repayment Program is nearing completion, the Secretary shall encourage the individual to remain in a health professional shortage area and to continue providing primary health services.

(ii) During the period in which a health professional is planning and making the transition to private practice from obligated service under the Loan Repayment Program, the Secretary may provide assistance to the professional regarding such transition if the professional is remaining in a health professional shortage area and is continuing to provide primary health services.

(C) In the case of entities to which participants in the Loan Repayment Program are assigned under section 254f of this title, the Secretary shall encourage the entities to provide options with respect to assisting the participants in remaining in the health professional shortage areas involved, and in continuing to provide primary health services, after the period of obligated service under the Loan Repayment Program is completed. The options with respect to which the Secretary provides such encouragement may include options regarding the sharing of a single employment position in the health professions by 2 or more health professionals, and options regarding the recruitment of couples where both of the individuals are health professionals.

(d) Factors considered in providing contracts; priorities

(1) Subject to section 254f–1 of this title, in providing contracts under the Loan Repayment Program—

(A) the Secretary shall consider the extent of the demonstrated interest of the applicants for the contracts in providing primary health services; and

(B) may consider such other factors regarding the applicants as the Secretary determines to be relevant to selecting qualified individuals to participate in such Program.

(2) In providing contracts under the Loan Repayment Program, the Secretary shall give priority—

(A) to any application for such a contract submitted by an individual whose training is in a health profession or specialty determined by the Secretary to be needed by the Corps;

(B) to any application for such a contract submitted by an individual who has (and whose spouse, if any, has) characteristics that increase the probability that the individual will continue to serve in a health professional shortage area after the period of obligated service pursuant to subsection (f) is completed; and

(C) subject to subparagraph (B), to any application for such a contract submitted by an individual who is from a disadvantaged background.

(e) Approval required for participation

An individual becomes a participant in the Loan Repayment Program only upon the Secretary and the individual entering into a written contract described in subsection (f).

(f) Contents of contracts

The written contract (referred to in this subpart) between the Secretary and an individual shall contain—

(1) an agreement that—

(A) subject to paragraph (3), the Secretary agrees—

(i) to pay on behalf of the individual loans in accordance with subsection (g); and

(ii) to accept (subject to the availability of appropriated funds for carrying out sections 254d through 254h of this title and section 254j of this title) the individual into the Corps (or for equivalent service as otherwise provided in this subpart); and

(B) subject to paragraph (3), the individual agrees—

(i) to accept loan payments on behalf of the individual;

(ii) in the case of an individual described in subsection (b)(1)(C), to maintain enrollment in a course of study or training described in such subsection until the individual completes the

course of study or training;

(iii) in the case of an individual described in subsection (b)(1)(C), while enrolled in such course of study or training, to maintain an acceptable level of academic standing (as determined under regulations of the Secretary by the educational institution offering such course of study or training); and

(iv) to serve for a time period (hereinafter in this subpart referred to as the "period of obligated service") equal to 2 years or such longer period as the individual may agree to, as a provider of primary health services in a health professional shortage area (designated under section 254e of this title) to which such individual is assigned by the Secretary as a member of the Corps or released under section 254n of this title;

(2) a provision permitting the Secretary to extend for such longer additional periods, as the individual may agree to, the period of obligated service agreed to by the individual under paragraph (1)(B)(iv), including extensions resulting in an aggregate period of obligated service in excess of 4 years;

(3) a provision that any financial obligation of the United States arising out of a contract entered into under this subpart and any obligation of the individual that is conditioned thereon, is contingent on funds being appropriated for loan repayments under this subpart and to carry out the purposes of sections 254d through 254h of this title and sections 254j and 254k of this title;

(4) a statement of the damages to which the United States is entitled, under section 254o of this title for the individual's breach of the contract; and

(5) such other statements of the rights and liabilities of the Secretary and of the individual, not inconsistent with this subpart.

(g) Payments

(1) In general

A loan repayment provided for an individual under a written contract under the Loan Repayment Program shall consist of payment, in accordance with paragraph (2), on behalf of the individual of the principal, interest, and related expenses on government and commercial loans received by the individual regarding the undergraduate or graduate education of the individual (or both), which loans were made for—

(A) tuition expenses;

(B) all other reasonable educational expenses, including fees, books, and laboratory expenses, incurred by the individual; or

(C) reasonable living expenses as determined by the Secretary.

(2) Payments for years served

(A) In general

For each year of obligated service that an individual contracts to serve under subsection (f) the Secretary may pay up to $50,000, plus, beginning with fiscal year 2012, an amount determined by the Secretary on an annual basis to reflect inflation, on behalf of the individual for loans described in paragraph (1). In making a determination of the amount to pay for a year of such service by an individual, the Secretary shall consider the extent to which each such determination—

(i) affects the ability of the Secretary to maximize the number of contracts that can be provided under the Loan Repayment Program from the amounts appropriated for such contracts;

(ii) provides an incentive to serve in health professional shortage areas with the greatest such shortages; and

(iii) provides an incentive with respect to the health professional involved remaining in a health professional shortage area, and continuing to provide primary health services, after the completion of the period of obligated service under the Loan Repayment Program.

(B) Repayment schedule

Any arrangement made by the Secretary for the making of loan repayments in accordance with this subsection shall provide that any repayments for a year of obligated service shall be made no later than the end of the fiscal year in which the individual completes such year of service.

(3) Tax liability

For the purpose of providing reimbursements for tax liability resulting from payments under paragraph (2) on behalf of an individual—

(A) the Secretary shall, in addition to such payments, make payments to the individual in an amount equal to 39 percent of the total amount of loan repayments made for the taxable year involved; and

(B) may make such additional payments as the Secretary determines to be appropriate with respect to such purpose.

(4) Payment schedule

The Secretary may enter into an agreement with the holder of any loan for which payments are made under the Loan Repayment Program to establish a schedule for the making of such payments.

(h) Employment ceiling

Notwithstanding any other provision of law, individuals who have entered into written contracts with the Secretary under this section, while undergoing academic or other training, shall not be counted against any employment ceiling affecting the Department.

(July 1, 1944, ch. 373, title III, §338B, as added Pub. L. 100–177, title II, §201(3), Dec. 1, 1987, 101 Stat. 992; amended Pub. L. 100–607, title VI, §629(a)(2), Nov. 4, 1988, 102 Stat. 3146; Pub. L. 101–597, title II, §202(a)–(g)(1), (h), title IV, §401(b)[(a)], Nov. 16, 1990, 104 Stat. 3023–3026, 3035; Pub. L. 105–392, title I, §109, Nov. 13, 1998, 112 Stat. 3562; Pub. L. 107–251, title III, §310, Oct. 26, 2002, 116 Stat. 1650; Pub. L. 108–163, §2(k), Dec. 6, 2003, 117 Stat. 2022; Pub. L. 111–148, title X, §10501(n)(4), Mar. 23, 2010, 124 Stat. 1003.)

EDITORIAL NOTES

PRIOR PROVISIONS

A prior section 338B of act July 1, 1944, was renumbered section 338C by section 201(2) of Pub. L. 100–177 and is classified to section 254m of this title.

AMENDMENTS

2010—Subsec. (g)(2)(A). Pub. L. 111–148 substituted "$50,000, plus, beginning with fiscal year 2012, an amount determined by the Secretary on an annual basis to reflect inflation," for "$35,000" in introductory provisions.

2003—Subsec. (e). Pub. L. 108–163 made technical amendment.

2002—Subsec. (a)(1). Pub. L. 107–251, §310(1)(A), inserted "behavioral and mental health professionals," after "dentists,".

Subsec. (a)(2). Pub. L. 107–251, §310(1)(B), struck out "(including mental health professionals)" before period at end.

Subsec. (b)(1)(A). Pub. L. 107–251, §310(2), added subpar. (A) and struck out former subpar. (A) which read as follows: "must have a degree in medicine, osteopathic medicine, dentistry, or other health profession, or be certified as a nurse midwife, nurse practioner, or physician assistant;".

Subsec. (e)(1). Pub. L. 107–251, §310(3), struck out par. (1) designation and heading.

Subsec. (i). Pub. L. 107–251, §310(4), struck out subsec. (i), which required an annual report to Congress about the Loan Repayment Program.

1998—Subsec. (b)(1)(B). Pub. L. 105–392 substituted "behavioral and mental health, or other health profession" for "or other health profession".

1990—Subsec. (a). Pub. L. 101–597, §202(a)(1), substituted "Corps Loan Repayment Program to assure, with respect to the provision of primary health services pursuant to section 254d(a)(2) of this title—" and pars. (1) and (2) for "Corps Loan Repayment Program (hereinafter in this subpart referred to as the 'Loan

Repayment Program') in order to assure—

"(1) an adequate supply of trained physicians, dentists, and nurses for the Corps; and

"(2) if needed by the Corps, an adequate supply of podiatrists, optometrists, pharmacists, clinical psychologists, graduates of schools of veterinary medicine, graduates of schools of public health, graduates of programs in health administration, graduates of programs for the training of physician assistants, expanded function dental auxiliaries, and nurse practitioners (as defined in section 296m of this title), and other health professionals."

Subsec. (b)(1). Pub. L. 101–597, §202(b)(1)(A), amended par. (1) generally. Prior to amendment, par. (1) read as follows:

"(A) be enrolled—

"(i) as a full-time student—

"(I) in an accredited (as determined by the Secretary) educational institution in a State; and

"(II) in the final year of a course of study or program, offered by such institution and approved by the Secretary, leading to a degree in medicine, osteopathic medicine, dentistry, or other health profession; or

"(ii) in an approved graduate training program in medicine, osteopathic medicine, dentistry, or other health profession; or

"(B) have—

"(i) a degree in medicine, osteopathic medicine, dentistry, or other health profession;

"(ii) completed an approved graduate training program in medicine, osteopathic medicine, dentistry, or other health profession in a State, except that the Secretary may waive the completion requirement of this clause for good cause; and

"(iii) a license to practice medicine, osteopathic medicine, dentistry, or other health profession in a State;".

Subsec. (b)(2) to (4). Pub. L. 101–597, §202(b)(2)(A), inserted "and" at end of par. (2), added par. (3), and struck out former pars. (3) and (4) which read as follows:

"(3) submit an application to participate in the Loan Repayment Program; and

"(4) sign and submit to the Secretary, at the time of the submission of such application, a written contract (described in subsection (f) of this section) to accept repayment of educational loans and to serve (in accordance with this subpart) for the applicable period of obligated service in a health manpower shortage area."

Subsec. (c)(4). Pub. L. 101–597, §401(b)[(a)], substituted reference to health professional shortage area for reference to health manpower shortage area in subpars. (B) and (C).

Pub. L. 101–597, §202(c), added par. (4).

Subsec. (d). Pub. L. 101–597, §401(b)[(a)], substituted reference to health professional shortage area for reference to health manpower shortage area in par. (2)(B).

Pub. L. 101–597, §202(d), amended subsec. (d) generally. Prior to amendment, subsec. (d) read as follows: "In determining which applications under the Loan Repayment Program to approve (and which contracts to accept), the Secretary shall give priority to applications made by—

"(1) individuals whose training is in a health profession or specialty determined by the Secretary to be needed by the Corps; and

"(2) individuals who are committed to service in medically underserved areas."

Subsec. (e). Pub. L. 101–597, §202(b)(2)(B), substituted "only upon the Secretary and the individual entering into a written contract described in subsection (f)." for "only on the Secretary's approval of the individual's application submitted under subsection (b)(3) of this section and the Secretary's acceptance of the contract submitted by the individual under subsection (b)(4) of this section." in par. (1) and struck out par. (2) which read as follows: "The Secretary shall provide written notice to an individual promptly on—

"(A) the Secretary's approving, under paragraph (1), of the individual's participation in the Loan Repayment Program; or

"(B) the Secretary's disapproving an individual's participation in such Program."

Subsec. (f)(1)(B)(ii), (iii). Pub. L. 101–597, §202(b)(1)(B), substituted "subsection (b)(1)(C)" for "subsection (b)(1)(A)".

Subsec. (f)(1)(B)(iv). Pub. L. 101–597, §401(b)[(a)], substituted reference to health professional shortage area for reference to health manpower shortage area.

Pub. L. 101–597, §202(a)(2), inserted "as a provider of primary health services" before "in a health".

Subsec. (f)(2). Pub. L. 101–597, §202(e), inserted before semicolon at end ", including extensions resulting in an aggregate period of obligated service in excess of 4 years".

Subsec. (g)(1). Pub. L. 101–597, §202(f)(1), inserted "regarding the undergraduate or graduate education of

the individual (or both), which loans were made" after "loans received by the individual".

Subsec. (g)(2)(A). Pub. L. 101–597, §401(b)[(a)], substituted reference to health professional shortage area for reference to health manpower shortage area in cls. (ii) and (iii).

Pub. L. 101–597, §202(f)(2)(A), substituted "For each year" for "Except as provided in subparagraph (B) and paragraph (3), for each year" and "$35,000" for "$20,000", inserted at end "In making a determination of the amount to pay for a year of such service by an individual, the Secretary shall consider the extent to which each such determination—", and added immediately thereafter cls. (i) to (iii).

Subsec. (g)(2)(B), (C). Pub. L. 101–597, §202(f)(2)(B), redesignated subpar. (C) as (B) and struck out former subpar. (B) which read as follows: "For each year of obligated service that an individual contracts under subsection (f) of this section to serve in the Indian Health Service, or to serve in a health program or facility operated by a tribe or tribal organization under the Indian Self-Determination Act (25 U.S.C. 450f et seq.), the Secretary may pay up to $25,000 on behalf of the individual for loans described in paragraph (1)."

Subsec. (g)(3). Pub. L. 101–597, §202(g)(1), amended par. (3) generally. Prior to amendment, par. (3) read as follows: "In addition to payments made under paragraph (2), in any case in which payments on behalf of an individual under the Loan Repayment Program result in an increase in Federal, State, or local income tax liability for such individual, the Secretary may, on the request of such individual, make payments to such individual in a reasonable amount, as determined by the Secretary, to reimburse such individual for all or part of the increased tax liability of the individual."

Subsec. (i). Pub. L. 101–597, §401(b)[(a)], substituted reference to health professional shortage area for reference to health manpower shortage area in par. (8).

Pub. L. 101–597, §202(h), amended subsec. (i) generally. Prior to amendment, subsec. (i) read as follows: "The Secretary shall, not later than March 1 of each year, submit to the Congress a report specifying—

"(1) the number, and type of health profession training, of individuals receiving loan payments under the Loan Repayment Program;

"(2) the educational institution at which such individuals are receiving their training;

"(3) the number of applications filed under this section in the school year beginning in such year and in prior school years; and

"(4) the amount of loan payments made in the year reported on."

1988—Subsec. (b)(1). Pub. L. 100–607 substituted "osteopathic medicine" for "osteopathy" wherever appearing.

STATUTORY NOTES AND RELATED SUBSIDIARIES

CHANGE OF NAME

Reference to Reserve Corps of the Public Health Service deemed to be a reference to the Ready Reserve Corps, see section 204(c)(3) of this title.

EFFECTIVE DATE OF 2003 AMENDMENT

Amendment by Pub. L. 108–163 deemed to have taken effect immediately after the enactment of Pub. L. 107–251, see section 3 of Pub. L. 108–163, set out as a note under section 233 of this title.

EFFECTIVE DATE OF 1990 AMENDMENT

Pub. L. 101–597, title II, §202(g)(2), Nov. 16, 1990, 104 Stat. 3026, provided that: "The amendment made by paragraph (1) [amending this section] shall apply only with respect to contracts under section 338B of the Public Health Service Act [42 U.S.C. 254l–1] (relating to service in the National Health Service Corps) that are entered into on or after the effective date of this Act [Nov. 16, 1990]."

REGULATIONS

Pub. L. 100–177, title II, §205, Dec. 1, 1987, 101 Stat. 1003, provided that: "Not later than 180 days after the effective date of the amendments made by this title [Dec. 21, 1987], the Secretary of Health and Human Services shall issue regulations for the loan repayment programs established by the amendments [enacting this section and sections 254q and 254q–1 of this title, amending sections 242a, 254d, 254g, 254h–1, and 254o of this title, and repealing former section 254q of this title]."

CLARIFICATION ON CURRENT ELIGIBILITY FOR LOAN REPAYMENT PROGRAMS

Pub. L. 114–255, div. B, title IX, §9023, Dec. 13, 2016, 130 Stat. 1253, provided that: "The Administrator of the Health Resources and Services Administration shall clarify the eligibility pursuant to section 338B(b)(1)(B) of the Public Health Service Act (42 U.S.C. 254l–1(b)(1)(B)) of child and adolescent

psychiatrists for the National Health Service Corps Loan Repayment Program under subpart III of part D of title III of such Act (42 U.S.C. 254l et seq.)."

[1] *See Change of Name note below.*

§254m. Obligated service under contract

(a) Service in full-time clinical practice

Except as provided in section 254n of this title, each individual who has entered into a written contract with the Secretary under section 254l or 254l–1 of this title shall provide service in the full-time clinical practice of such individual's profession as a member of the Corps for the period of obligated service provided in such contract. The Secretary may treat teaching as clinical practice for up to 20 percent of such period of obligated service. Notwithstanding the preceding sentence, with respect to a member of the Corps participating in the teaching health centers graduate medical education program under section 256h of this title, for the purpose of calculating time spent in full-time clinical practice under this section, up to 50 percent of time spent teaching by such member may be counted toward his or her service obligation.

(b) Notice to individual; information for informed decision; eligibility; notice to Secretary; qualification and appointment as commissioned officer; appointment as civilian member; designation of non-United States employee as member; deferment of obligated service

(1) If an individual is required under subsection (a) to provide service as specified in section 254l(f)(1)(B)(v) or 254l–1(f)(1)(B)(iv) of this title (hereinafter in this subsection referred to as "obligated service"), the Secretary shall, not later than ninety days before the date described in paragraph (5), determine if the individual shall provide such service—

(A) as a member of the Corps who is a commissioned officer in the Regular or Reserve Corps [1] of the Service or who is a civilian employee of the United States, or

(B) as a member of the Corps who is not such an officer or employee,

and shall notify such individual of such determination.

(2) If the Secretary determines that an individual shall provide obligated service as a member of the Corps who is a commissioned officer in the Service or a civilian employee of the United States, the Secretary shall, not later than sixty days before the date described in paragraph (5), provide such individual with sufficient information regarding the advantages and disadvantages of service as such a commissioned officer or civilian employee to enable the individual to make a decision on an informed basis. To be eligible to provide obligated service as a commissioned officer in the Service, an individual shall notify the Secretary, not later than thirty days before the date described in paragraph (5), of the individual's desire to provide such service as such an officer. If an individual qualifies for an appointment as such an officer, the Secretary shall, as soon as possible after the date described in paragraph (5), appoint the individual as a commissioned officer of the Regular or Reserve Corps [1] of the Service and shall designate the individual as a member of the Corps.

(3) If an individual provided notice by the Secretary under paragraph (2) does not qualify for appointment as a commissioned officer in the Service, the Secretary shall, as soon as possible after the date described in paragraph (5), appoint such individual as a civilian employee of the United States and designate the individual as a member of the Corps.

(4) If the Secretary determines that an individual shall provide obligated service as a member of the Corps who is not an employee of the United States, the Secretary shall, as soon as possible after the date described in paragraph (5), designate such individual as a member of the Corps to provide such service.

(5)(A) In the case of the Scholarship Program, the date referred to in paragraphs (1) through (4) shall be the date on which the individual completes the training required for the degree for which the individual receives the scholarship, except that—

(i) for an individual receiving such a degree after September 30, 2000, from a school of medicine or osteopathic medicine, such date shall be the date the individual completes a residency in a specialty that the Secretary determines is consistent with the needs of the Corps; and

(ii) at the request of an individual, the Secretary may, consistent with the needs of the Corps, defer such date until the end of a period of time required for the individual to complete advanced training (including an internship or residency).

(B) No period of internship, residency, or other advanced clinical training shall be counted toward satisfying a period of obligated service under this subpart.

(C) In the case of the Loan Repayment Program, if an individual is required to provide obligated service under such Program, the date referred to in paragraphs (1) through (4)—

(i) shall be the date determined under subparagraph (A) in the case of an individual who is enrolled in the final year of a course of study;

(ii) shall, in the case of an individual who is enrolled in an approved graduate training program in medicine, osteopathic medicine, dentistry, or other health profession, be the date the individual completes such training program; and

(iii) shall, in the case of an individual who has a degree in medicine, osteopathic medicine, dentistry, or other health profession and who has completed graduate training, be the date the individual enters into an agreement with the Secretary under section 254l–1 of this title.

(c) Obligated service period; commencement

An individual shall be considered to have begun serving a period of obligated service—

(1) on the date such individual is appointed as an officer in a Regular or Reserve Corps [1] of the Service or is designated as a member of the Corps under subsection (b)(3) or (b)(4), or

(2) in the case of an individual who has entered into an agreement with the Secretary under section 254n of this title, on the date specified in such agreement,

whichever is earlier.

(d) Assignment of personnel

The Secretary shall assign individuals performing obligated service in accordance with a written contract under the Scholarship Program to health professional shortage areas in accordance with sections 254d through 254h and sections 254j and 254k of this title. If the Secretary determines that there is no need in a health professional shortage area (designated under section 254e of this title) for a member of the profession in which an individual is obligated to provide service under a written contract and if such individual is an officer in the Service or a civilian employee of the United States, the Secretary may detail such individual to serve his period of obligated service as a full-time member of such profession in such unit of the Department as the Secretary may determine.

(July 1, 1944, ch. 373, title III, §338C, formerly title VII, §752, as added Pub. L. 94–484, title IV, §408(b)(1), Oct. 12, 1976, 90 Stat. 2284; amended Pub. L. 95–626, title I, §113(b), Nov. 10, 1978, 92 Stat. 3563; Pub. L. 96–76, title II, §202(a), (b), Sept. 29, 1979, 93 Stat. 582; renumbered §338B and amended Pub. L. 97–35, title XXVII, §2709(a), (c), Aug. 13, 1981, 95 Stat. 908, 909; Pub. L. 97–414, §8(g)(1), Jan. 4, 1983, 96 Stat. 2061; renumbered §338C and amended Pub. L. 100–177, title II, §201(2), title III, §306, Dec. 1, 1987, 101 Stat. 992, 1004; Pub. L. 100–607, title VI, §629(a)(2), Nov. 4, 1988, 102 Stat. 3146; Pub. L. 101–597, title IV, §401(b)[(a)], Nov. 16, 1990, 104 Stat. 3035; Pub. L. 107–251, title III, §311, Oct. 26, 2002, 116 Stat. 1650; Pub. L. 111–148, title V, §5508(b), title X, §10501(n)(5), Mar. 23, 2010, 124 Stat. 670, 1003.)

EDITORIAL NOTES

CODIFICATION

Section was formerly classified to section 294u of this title prior to its renumbering by Pub. L. 97–35.

PRIOR PROVISIONS

A prior section 338C of act July 1, 1944, was renumbered section 338D by section 201(2) of Pub. L. 100–177 and is classified to section 254n of this title.

AMENDMENTS

2010—Subsec. (a). Pub. L. 111–148, §10501(n)(5), in second sentence, substituted "The Secretary may treat teaching as clinical practice for up to 20 percent of such period of obligated service" for "For the purpose of calculating time spent in full-time clinical practice under this subsection, up to 50 percent of time spent teaching by a member of the Corps may be counted toward his or her service obligation" and inserted at end "Notwithstanding the preceding sentence, with respect to a member of the Corps participating in the teaching health centers graduate medical education program under section 256h of this title, for the purpose of calculating time spent in full-time clinical practice under this section, up to 50 percent of time spent teaching by such member may be counted toward his or her service obligation."

Pub. L. 111–148, §5508(b), amended subsec. (a) generally. Prior to amendment, text read as follows: "Except as provided in section 254n of this title, each individual who has entered into a written contract with the Secretary under section 254l or 254l–1 of this title shall provide service in the full-time clinical practice of such individual's profession as a member of the Corps for the period of obligated service provided in such contract."

2002—Subsec. (b)(1). Pub. L. 107–251, §311(1)(A), substituted "section 254l(f)(1)(B)(v)" for "254l(f)(1)(B)(iv)" in introductory provisions.

Subsec. (b)(5)(A). Pub. L. 107–251, §311(1)(B)(i), added subpar. (A) and struck out former subpar. (A) which read as follows: "In the case of the Scholarship Program, with respect to an individual receiving a degree from a school of medicine, osteopathic medicine, dentistry, veterinary medicine, optometry, podiatry, or pharmacy, the date referred to in paragraphs (1) through (4) shall be the date on which the individual completes the training required for such degree, except that—

"(i) at the request of such an individual with whom the Secretary has entered into a contract under section 254l of this title prior to October 1, 1985, the Secretary shall defer such date until the end of the period of time (not to exceed the number of years specified in subparagraph (B) or such greater period as the Secretary, consistent with the needs of the Corps, may authorize) required for the individual to complete an internship, residency, or other advanced clinical training; and

"(ii) at the request of such an individual with whom the Secretary has entered into a contract under section 254l of this title on or after October 1, 1985, the Secretary may defer such date in accordance with clause (i)."

Subsec. (b)(5)(B). Pub. L. 107–251, §311(1)(B)(i), (iii), redesignated subpar. (C) as (B) and struck out former subpar. (B) which read as follows:

"(B)(i) In the case of the Scholarship Program, with respect to an individual receiving a degree from a school of medicine, osteopathic medicine, or dentistry, the number of years referred to in subparagraph (A)(i) shall be 3 years.

"(ii) In the case of the Scholarship Program, with respect to an individual receiving a degree from a school of veterinary medicine, optometry, podiatry, or pharmacy, the number of years referred to in subparagraph (A)(i) shall be 1 year."

Subsec. (b)(5)(C). Pub. L. 107–251, §311(1)(B)(iii), redesignated subpar. (E) as (C). Former subpar. (C) redesignated (B).

Subsec. (b)(5)(C)(i). Pub. L. 107–251, §311(1)(B)(iv), substituted "subparagraph (A)" for "subparagraph (A), (B), or (D)".

Subsec. (b)(5)(D). Pub. L. 107–251, §311(1)(B)(ii), struck out subpar. (D) which read as follows: "In the case of the Scholarship Program, with respect to an individual receiving a degree from an institution other than a school referred to in subparagraph (A), the date referred to in paragraphs (1) through (4) shall be the date on which the individual completes the academic training of the individual leading to such degree."

Subsec. (b)(5)(E). Pub. L. 107–251, §311(1)(B)(iii), redesignated subpar. (E) as (C).

Subsec. (e). Pub. L. 107–251, §311(2), struck out subsec. (e) which related to service under National Research Service Award program as credit against obligated service time.

1990—Subsec. (d). Pub. L. 101–597 substituted reference to health professional shortage area for reference to health manpower shortage area wherever appearing.

1988—Subsec. (b)(5). Pub. L. 100–607 substituted "osteopathic medicine" for "osteopathy" wherever appearing.

1987—Subsec. (a). Pub. L. 100–177, §306(1), inserted "or 254l–1", and made technical amendment to reference to section 254n of this title to reflect renumbering of corresponding section of original act.

Subsec. (b)(1). Pub. L. 100–177, §306(2), inserted reference to section 254l–l(f)(1)(B)(iv).

Subsec. (b)(5). Pub. L. 100–177, §306(3), substituted par. (5) consisting of subpars. (A) to (E) for former par. (5) consisting of subpars. (A) and (B).

Subsec. (c)(2). Pub. L. 100–177, §306(4), made technical amendment to reference to section 254n of this title to reflect renumbering of corresponding section of original act.

1983—Subsec. (e). Pub. L. 97–414 inserted "or under section 234 of this title as in effect on September 30, 1977" after "Scholarship Program".

1981—Subsec. (a). Pub. L. 97–35, §2709(c)(1), substituted "254n" for "294v" and "254l" for "294t".

Subsec. (b). Pub. L. 97–35, §2709(c)(2), substituted provisions relating to notice, information, etc., for individuals required to give obligated service, for provisions relating to notice, information, etc., for individuals required to provide service under the Scholarship Program.

Subsec. (c). Pub. L. 97–35, §2709(c)(3), (4), in par. (1) inserted reference to designation under subsec. (b)(3) or (4) of this section, and in par. (2) substituted "254n" for "294v".

Subsec. (d). Pub. L. 97–35, §2709(c)(5), inserted provision relating to individuals who are officers in the Service or civilian employees of the United States, and substituted reference to sections 254d to 254h, 254j, and 254k of this title, for reference to subpart II of part D of subchapter II of this chapter.

Subsec. (e). Pub. L. 97–35, §2709(c)(6), substituted provisions respecting mandatory determination of service requirement, for provisions respecting discretionary determination of service requirement.

1979—Subsec. (b)(5)(A). Pub. L. 96–76, §202(a), (b)(1), (2), inserted provisions authorizing a greater period than three years for individuals receiving degrees from schools of medicine, osteopathy, and dentistry, and provisions respecting individuals receiving degrees from schools of veterinary medicine, optometry, podiatry, and pharmacy, and substituted "No period" for "No such period".

Subsec. (b)(5)(B). Pub. L. 96–76, §202(b)(3), substituted "referred to in subparagraph (A)" for "of medicine, osteopathy, or dentistry".

1978—Subsec. (d). Pub. L. 95–626 substituted "subpart II of part D" for "subpart II of part C".

STATUTORY NOTES AND RELATED SUBSIDIARIES

CHANGE OF NAME

Reference to Reserve Corps of the Public Health Service deemed to be a reference to the Ready Reserve Corps, see section 204(c)(3) of this title.

EFFECTIVE DATE OF 1981 AMENDMENT

Pub. L. 97–35, title XXVII, §2709(h), Aug. 13, 1981, 95 Stat. 912, provided that: "The amendments made by paragraphs (2), (3), and (5)(B) of subsection (c) [amending this section] shall apply with respect to contracts entered into under the National Health Service Corps scholarship program under subpart III of part C of title VII of the Public Health Service Act [42 U.S.C. 294r et seq.] after the date of the enactment of this Act [Aug. 13, 1981]. An individual who before such date has entered into such a contract and who has not begun the period of obligated service required under such contract shall be given the opportunity to revise such contract to permit the individual to serve such period as a member of the National Health Service Corps who is not an employee of the United States."

EFFECTIVE DATE

Section effective Oct. 1, 1977, see section 408(b)(1) of Pub. L. 94–484, set out in part as a note under section 254l of this title.

EFFECTIVE DATE; SAVINGS PROVISION; CREDIT FOR PERIOD OF INTERNSHIP OR RESIDENCY BEFORE SEPTEMBER 30, 1977, TOWARDS SERVICE OBLIGATION

See section 408(b)(2) of Pub. L. 94–484, set out as a note under section 254l of this title.

SPECIAL RETENTION PAY FOR REGULAR OR RESERVE OFFICERS FOR PERIOD OFFICER IS OBLIGATED UNDER THIS SECTION

Pub. L. 100–446, title II, Sept. 27, 1988, 102 Stat. 1816, provided that: "the Secretary of Health and Human Services may authorize special retention pay under paragraph (4) of 37 U.S.C. 302(a) to any regular or reserve officer for the period during which the officer is obligated under section 338B [now 338C] of the Public Health Service Act [42 U.S.C. 254m] and assigned and providing direct health services or serving the officer's obligation as a specialist".

Similar provisions were contained in the following prior appropriation acts:

Pub. L. 100–202, §101(g) [title II], Dec. 22, 1987, 101 Stat. 1329–213, 1329–246.

Pub. L. 99–500, §101(h) [title II], Oct. 18, 1986, 100 Stat. 1783–242, 1783–277, and Pub. L. 99–591, §101(h) [title II], Oct. 30, 1986, 100 Stat. 3341–242, 3341–277.

[1] *See Change of Name note below.*

§254n. Private practice

(a) Application for release of obligations; conditions

The Secretary shall, to the extent permitted by, and consistent with, the requirements of applicable State law, release an individual from all or part of his service obligation under section 254m(a) of this title or under section 234 [1] of this title (as in effect on September 30, 1977) if the individual applies for such a release under this section and enters into a written agreement with the Secretary under which the individual agrees to engage for a period equal to the remaining period of his service obligation in the full-time private clinical practice (including service as a salaried employee in an entity directly providing health services) of his health profession—

(1) in the case of an individual who received a scholarship under the Scholarship Program or a loan repayment under the Loan Repayment Program and who is performing obligated service as a member of the Corps in a health professional shortage area on the date of his application for such a release, in the health professional shortage area in which such individual is serving on such date or in the case of an individual for whom a loan payment was made under the Loan Repayment Program and who is performing obligated service as a member of the Corps in a health professional shortage area on the date of the application of the individual for such a release, in the health professional shortage area selected by the Secretary; or

(2) in the case of any other individual, in a health professional shortage area (designated under section 254e of this title) selected by the Secretary.

(b) Written agreement; actions to ensure compliance

(1) The written agreement described in subsection (a) shall—

(A) provide that, during the period of private practice by an individual pursuant to the agreement, the individual shall comply with the requirements of section 254g of this title that apply to entities; and

(B) contain such additional provisions as the Secretary may require to carry out the objectives of this section.

(2) The Secretary shall take such action as may be appropriate to ensure that the conditions of the written agreement prescribed by this subsection are adhered to.

(c) Breach of service contract

If an individual breaches the contract entered into under section 254l or 254l–1 of this title by failing (for any reason) to begin his service obligation in accordance with an agreement entered into under subsection (a) or to complete such service obligation, the Secretary may permit such individual to perform such service obligation as a member of the Corps.

(d) Travel expenses

The Secretary may pay an individual who has entered into an agreement with the Secretary under subsection (a) an amount to cover all or part of the individual's expenses reasonably incurred in transporting himself, his family, and his possessions to the location of his private clinical practice.

(e) Sale of equipment and supplies

Upon the expiration of the written agreement under subsection (a), the Secretary may (notwithstanding any other provision of law) sell to the individual who has entered into an agreement with the Secretary under subsection (a), equipment and other property of the United States utilized by such individual in providing health services. Sales made under this subsection shall be made at the fair market value (as determined by the Secretary) of the equipment or such other property,

except that the Secretary may make such sales for a lesser value to the individual if he determines that the individual is financially unable to pay the full market value.

(f) Malpractice insurance

The Secretary may, out of appropriations authorized under section 254k of this title, pay to individuals participating in private practice under this section the cost of such individual's malpractice insurance and the lesser of—

(1)(A) $10,000 in the first year of obligated service;
(B) $7,500 in the second year of obligated service;
(C) $5,000 in the third year of obligated service; and
(D) $2,500 in the fourth year of obligated service; or
(2) an amount determined by subtracting such individual's net income before taxes from the income the individual would have received as a member of the Corps for each such year of obligated service.

(g) Technical assistance

The Secretary shall, upon request, provide to each individual released from service obligation under this section technical assistance to assist such individual in fulfilling his or her agreement under this section.

(July 1, 1944, ch. 373, title III, §338D, formerly title VII, §753, as added Pub. L. 94–484, title IV, §408(b)(1), Oct. 12, 1976, 90 Stat. 2285; amended Pub. L. 96–538, title IV, §403, Dec. 17, 1980, 94 Stat. 3192; renumbered §338C and amended Pub. L. 97–35, title XXVII, §2709(a), (d), Aug. 13, 1981, 95 Stat. 908, 910; renumbered §338D and amended Pub. L. 100–177, title II, §201(2), title III, §307, Dec. 1, 1987, 101 Stat. 992, 1005; Pub. L. 101–597, title IV, §401(b)[(a)], Nov. 16, 1990, 104 Stat. 3035; Pub. L. 107–251, title III, §312, Oct. 26, 2002, 116 Stat. 1650.)

EDITORIAL NOTES

REFERENCES IN TEXT

Section 234 of this title, referred to in subsec. (a), was repealed by Pub. L. 94–484, title IV, §408(b)(1), Oct. 12, 1976, 90 Stat. 2281, effective Oct. 1, 1977.

CODIFICATION

Section was formerly classified to section 294v of this title prior to its renumbering by Pub. L. 97–35.

PRIOR PROVISIONS

A prior section 338D of act July 1, 1944, was renumbered section 338E by section 201(2) of Pub. L. 100–177 and is classified to section 254o of this title.

AMENDMENTS

2002—Subsec. (b). Pub. L. 107–251 added subsec. (b) and struck out former subsec. (b) which related to written agreements, regulations, and actions to ensure compliance.

1990—Subsec. (a)(1), (2). Pub. L. 101–597 substituted reference to health professional shortage area for reference to health manpower shortage area wherever appearing.

1987—Subsec. (a). Pub. L. 100–177, §307(1)–(3), made technical amendment to reference to section 254m of this title to reflect renumbering of corresponding section of original act, in introductory provisions, in par. (1) inserted "who received a scholarship under the Scholarship Program or a loan repayment under the Loan Repayment Program and" after "individual" the first time it appeared as the probable intent of Congress, and inserted "or in the case of an individual for whom a loan payment was made under the Loan Repayment Program and who is performing obligated service as a member of the Corps in a health manpower shortage area on the date of the application of the individual for such a release, in the health manpower shortage area selected by the Secretary", and in par. (2) inserted "selected by the Secretary".

Subsec. (b). Pub. L. 100–177, §307(4), inserted at end "The Secretary shall take such action as may be appropriate to ensure that the conditions of the written agreement prescribed by this subsection are adhered to."

Subsec. (c). Pub. L. 100–177, §307(5), inserted reference to section 254l–1.

Subsec. (e). Pub. L. 100–177, §307(b), designated par. (2) as entire subsection and struck out par. (1) which read as follows: "The Secretary may make such arrangements as he determines are necessary for the individual for the use of equipment and supplies and for the lease or acquisition of other equipment and supplies."

1981—Subsec. (a). Pub. L. 97–35, §2709(d)(1), inserted provision respecting requirements of applicable State law, substituted references to sections 254m(a) and 234 of this title, for reference to section 294u(a) of this title, and in cl. (2) struck out priority requirement under section 254f(c) of this title.

Subsec. (b)(1)(B). Pub. L. 97–35, §2709(d)(2), inserted "(i)" before "shall not" and added cl. (ii).

Subsecs. (c) to (g). Pub. L. 97–35, §2709(d)(3), added subsecs. (c) to (g).

1980—Subsec. (a). Pub. L. 96–538 substituted in par. (2) "which has" for "which (A) has" and struck out subpar. (B) which referred to a health manpower shortage area which has a sufficient financial base to substain private practice and provide the individual with income of not less than the income of members of the Corps, and struck out provision following par. (2) which provided that in the case of an individual described in par. (1), the Secretary release the individual from his service obligation under this subsection only if the Secretary determines that the area in which the individual is serving met the requirements of cl. (B) of par. (2).

STATUTORY NOTES AND RELATED SUBSIDIARIES

EFFECTIVE DATE

Section effective Oct. 1, 1977, see section 408(b)(1) of Pub. L. 94–484, set out in part as a note under section 254l of this title.

EFFECTIVE DATE; SAVINGS PROVISION; CREDIT FOR PERIOD OF INTERNSHIP OR RESIDENCY BEFORE SEPTEMBER 30, 1977, TOWARDS SERVICE OBLIGATION

See section 408(b)(2) of Pub. L. 94–484, set out as a note under section 254l of this title.

[1] *See References in Text note below.*

§254*o*. Breach of scholarship contract or loan repayment contract

(a) Failure to maintain academic standing; dismissal from institution; voluntary termination; liability; failure to accept payment

(1) An individual who has entered into a written contract with the Secretary under section 254l of this title and who—

(A) fails to maintain an acceptable level of academic standing in the educational institution in which he is enrolled (such level determined by the educational institution under regulations of the Secretary);

(B) is dismissed from such educational institution for disciplinary reasons; or

(C) voluntarily terminates the training in such an educational institution for which he is provided a scholarship under such contract, before the completion of such training,

in lieu of any service obligation arising under such contract, shall be liable to the United States for the amount which has been paid to him, or on his behalf, under the contract.

(2) An individual who has entered into a written contract with the Secretary under section 254l–1 of this title and who—

(A) in the case of an individual who is enrolled in the final year of a course of study, fails to maintain an acceptable level of academic standing in the educational institution in which such individual is enrolled (such level determined by the educational institution under regulations of the Secretary) or voluntarily terminates such enrollment or is dismissed from such educational institution before completion of such course of study; or

(B) in the case of an individual who is enrolled in a graduate training program, fails to complete such training program and does not receive a waiver from the Secretary under section 254l–1(b)(1)(B)(ii) of this title,

in lieu of any service obligation arising under such contract shall be liable to the United States for the amount that has been paid on behalf of the individual under the contract.

(b) Failure to commence or complete service obligations; formula to determine liability; payment to United States; recovery of delinquent damages; disclosure to credit reporting agencies

(1)(A) Except as provided in paragraph (2), if an individual breaches his written contract by failing (for any reason not specified in subsection (a) or section 254p(d) of this title) to begin such individual's service obligation under section 254l of this title in accordance with section 254m or 254n of this title, to complete such service obligation, or to complete a required residency as specified in section 254l(f)(1)(B)(iv) of this title, the United States shall be entitled to recover from the individual an amount determined in accordance with the formula

$$A = 3\left(\frac{ts}{t}\right)$$

in which "A" is the amount the United States is entitled to recover, "" is the sum of the amounts paid under this subpart to or on behalf of the individual and the interest on such amounts which would be payable if at the time the amounts were paid they were loans bearing interest at the maximum legal prevailing rate, as determined by the Treasurer of the United States; "t" is the total number of months in the individual's period of obligated service; and "s" is the number of months of such period served by him in accordance with section 254m of this title or a written agreement under section 254n of this title.

(B)(i) Any amount of damages that the United States is entitled to recover under this subsection or under subsection (c) shall, within the 1-year period beginning on the date of the breach of the written contract (or such longer period beginning on such date as specified by the Secretary), be paid to the United States. Amounts not paid within such period shall be subject to collection through deductions in Medicare payments pursuant to section 1395ccc of this title.

(ii) If damages described in clause (i) are delinquent for 3 months, the Secretary shall, for the purpose of recovering such damages—

(I) utilize collection agencies contracted with by the Administrator of the General Services Administration; or

(II) enter into contracts for the recovery of such damages with collection agencies selected by the Secretary.

(iii) Each contract for recovering damages pursuant to this subsection shall provide that the contractor will, not less than once each 6 months, submit to the Secretary a status report on the success of the contractor in collecting such damages. Section 3718 of title 31 shall apply to any such contract to the extent not inconsistent with this subsection.

(iv) To the extent not otherwise prohibited by law, the Secretary shall disclose to all appropriate credit reporting agencies information relating to damages of more than $100 that are entitled to be recovered by the United States under this subsection and that are delinquent by more than 60 days or such longer period as is determined by the Secretary.

(2) If an individual is released under section 254n [1] of this title from a service obligation under section 234 [1] of this title (as in effect on September 30, 1977) and if the individual does not meet the service obligation incurred under section 254n [1] of this title, subsection (f) of such section 234 [1] of this title shall apply to such individual in lieu of paragraph (1) of this subsection.

(3) The Secretary may terminate a contract with an individual under section 254l of this title if, not later than 30 days before the end of the school year to which the contract pertains, the individual—

(A) submits a written request for such termination; and

(B) repays all amounts paid to, or on behalf of, the individual under section 254l(g) of this title.

(c) Failure to commence or complete service obligations for other reasons; determination of liability; payment to United States; waiver of recovery for extreme hardship or good cause shown

(1) If (for any reason not specified in subsection (a) or section 254p(d) of this title) an individual breaches the written contract of the individual under section 254l–1 of this title by failing either to begin such individual's service obligation in accordance with section 254m or 254n of this title or to complete such service obligation, the United States shall be entitled to recover from the individual an amount equal to the sum of—

(A) the total of the amounts paid by the United States under section 254l–1(g) of this title on behalf of the individual for any period of obligated service not served;

(B) an amount equal to the product of the number of months of obligated service that were not completed by the individual, multiplied by $7,500; and

(C) the interest on the amounts described in subparagraphs (A) and (B), at the maximum legal prevailing rate, as determined by the Treasurer of the United States, from the date of the breach;

except that the amount the United States is entitled to recover under this paragraph shall not be less than $31,000.

(2) The Secretary may terminate a contract with an individual under section 254l–1 of this title if, not later than 45 days before the end of the fiscal year in which the contract was entered into, the individual—

(A) submits a written request for such termination; and

(B) repays all amounts paid on behalf of the individual under section 254l–1(g) of this title.

(3) Damages that the United States is entitled to recover shall be paid in accordance with subsection (b)(1)(B).

(d) Cancellation of obligation upon death of individual; waiver or suspension of obligation for impossibility, hardship, or unconscionability; release of debt by discharge in bankruptcy, time limitations

(1) Any obligation of an individual under the Scholarship Program (or a contract thereunder) or the Loan Repayment Program (or a contract thereunder) for service or payment of damages shall be canceled upon the death of the individual.

(2) The Secretary shall by regulation provide for the partial or total waiver or suspension of any obligation of service or payment by an individual under the Scholarship Program (or a contract thereunder) or the Loan Repayment Program (or a contract thereunder) whenever compliance by the individual is impossible or would involve extreme hardship to the individual and if enforcement of such obligation with respect to any individual would be unconscionable.

(3)(A) Any obligation of an individual under the Scholarship Program (or a contract thereunder) or the Loan Repayment Program (or a contract thereunder) for payment of damages may be released by a discharge in bankruptcy under title 11 only if such discharge is granted after the expiration of the 7-year period beginning on the first date that payment of such damages is required, and only if the bankruptcy court finds that nondischarge of the obligation would be unconscionable.

(B)(i) Subparagraph (A) shall apply to any financial obligation of an individual under the provision of law specified in clause (ii) to the same extent and in the same manner as such subparagraph applies to any obligation of an individual under the Scholarship or Loan Repayment Program (or contract thereunder) for payment of damages.

(ii) The provision of law referred to in clause (i) is subsection (f) of section 234 [1] of this title, as in effect prior to the repeal of such section by section 408(b)(1) of Public Law 94–484.

(e) Inapplicability of Federal and State statute of limitations on actions for collection

Notwithstanding any other provision of Federal or State law, there shall be no limitation on the period within which suit may be filed, a judgment may be enforced, or an action relating to an offset

or garnishment, or other action, may be initiated or taken by the Secretary, the Attorney General, or the head of another Federal agency, as the case may be, for the repayment of the amount due from an individual under this section.

(f) Effective date

The amendment made by section 313(a)(4) of the Health Care Safety Net Amendments of 2002 (Public Law 107–251) shall apply to any obligation for which a discharge in bankruptcy has not been granted before the date that is 31 days after October 26, 2002.

(July 1, 1944, ch. 373, title III, §338E, formerly title VII, §754, as added Pub. L. 94–484, title IV, §408(b)(1), Oct. 12, 1976, 90 Stat. 2286; amended Pub. L. 95–83, title III, §307(g), Aug. 1, 1977, 91 Stat. 391; renumbered §338D and amended Pub. L. 97–35, title XXVII, §2709(a), (e)(1)–(4)(A), Aug. 13, 1981, 95 Stat. 908, 911; Pub. L. 97–414, §8(g)(2), Jan. 4, 1983, 96 Stat. 2061; renumbered §338E and amended Pub. L. 100–177, title II, §§201(2), 202(e), title III, §308(a), Dec. 1, 1987, 101 Stat. 992, 997, 1006; Pub. L. 100–203, title IV, §4052(b), Dec. 22, 1987, 101 Stat. 1330–97; Pub. L. 100–360, title IV, §411(f)(10)(B), July 1, 1988, 102 Stat. 780; Pub. L. 101–597, title II, §203(a), Nov. 16, 1990, 104 Stat. 3027; Pub. L. 107–251, title III, §313(a), Oct. 26, 2002, 116 Stat. 1651; Pub. L. 108–163, §2(l)(1), Dec. 6, 2003, 117 Stat. 2022.)

EDITORIAL NOTES

REFERENCES IN TEXT

Section 234 of this title, referred to in subsecs. (b)(2) and (d)(3)(B)(ii), was repealed by Pub. L. 94–484, title IV, §408(b)(1), Oct. 12, 1976, 90 Stat. 2281, effective Oct. 1, 1977.

Section 254n of this title, referred to in subsec. (b)(2), in the original referred to section 753, meaning section 753 of the Public Health Service Act, which was classified to section 294v of this title. Section 753 was redesignated section 338C of the Public Health Service Act by Pub. L. 97–35, title XXVII, §2709(a), Aug. 13, 1981, 95 Stat. 908, and was transferred to section 254n of this title. Section 338C of the Public Health Service Act was renumbered section 338D by Pub. L. 100–177, title II, §201(2), Dec. 1, 1987, 101 Stat. 992.

Section 313(a)(4) of the Health Care Safety Net Amendments of 2002, referred to in subsec. (f), is section 313(a)(4) of Pub. L. 107–251, which amended subsec. (d)(3)(A) of this section. See 2002 Amendment note below.

CODIFICATION

Section was formerly classified to section 294w of this title prior to its renumbering by Pub. L. 97–35.

PRIOR PROVISIONS

A prior section 338E of act July 1, 1944, was renumbered section 338F by Pub. L. 100–177 and classified to section 254p of this title, and subsequently renumbered 338G by Pub. L. 101–597.

AMENDMENTS

2003—Subsec. (c)(1). Pub. L. 108–163, §2(l)(1)(A), realigned margins.

Subsec. (f). Pub. L. 108–163, §2(l)(1)(B), added subsec. (f).

2002—Subsec. (a)(1). Pub. L. 107–251, §313(a)(1), substituted semicolon for comma at end of subpar. (A) and "; or" for comma at end of subpar. (B), struck out "or" at end of subpar. (C), and struck out subpar. (D) which read as follows: "fails to accept payment, or instructs the educational institution in which he is enrolled not to accept payment, in whole or in part, of a scholarship under such contract,".

Subsec. (b)(1)(A). Pub. L. 107–251, §313(a)(2)(A)(ii)–(iv), struck out "either" before "to begin", substituted "254n of this title," for "254n of this title or", and inserted "or to complete a required residency as specified in section 254l(f)(1)(B)(iv) of this title," before "the United States" the first time appearing.

Pub. L. 107–251, §313(a)(2)(A)(i), made technical amendment to reference in original act which appears in text as reference to section 254p of this title.

Subsec. (b)(3). Pub. L. 107–251, §313(a)(2)(B), added par. (3).

Subsec. (c)(1). Pub. L. 107–251, §313(a)(3)(A)(ii), added subpars. (A) to (C) and concluding provisions and struck out former subpars. (A) to (C) which related, respectively, to amounts to be recovered in the case of a contract for a 2-year period of obligated service, in the case of a contract for a period of obligated service of greater than 2 years where the breach occurred before the end of the first 2 years of such period, and in the

case of a contract for a period of obligated service of greater than 2 years, where the breach occurred after the first 2 years of such period.

Pub. L. 107–251, §313(a)(3)(A)(i), in introductory provisions, made technical amendment to reference in original act which appears in text as reference to section 254p(d) of this title.

Subsec. (c)(2). Pub. L. 107–251, §313(a)(3)(B), added par. (2) and struck out former par. (2) which read as follows: "For purposes of paragraph (1), the term 'unserved obligation penalty' means the amount equal to the product of the number of months of obligated service that were not completed by an individual, multiplied by $1,000, except that in any case in which the individual fails to serve 1 year, the unserved obligation penalty shall be equal to the full period of obligated service multiplied by $1,000."

Subsec. (c)(3), (4). Pub. L. 107–251, §313(a)(3)(B), (C), redesignated par. (4) as (3) and struck out former par. (3) which read as follows: "The Secretary may waive, in whole or in part, the rights of the United States to recover amounts under this section in any case of extreme hardship or other good cause shown, as determined by the Secretary."

Subsec. (d)(3)(A). Pub. L. 107–251, §313(a)(4), substituted "7-year period" for "five-year period".

Subsec. (e). Pub. L. 107–251, §313(a)(5), added subsec. (e).

1990—Subsec. (d)(3). Pub. L. 101–597 designated existing provision as subpar. (A) and added subpar. (B).

1988—Subsec. (b)(1)(B)(i). Pub. L. 100–360 made technical amendment to directory language of Pub. L. 100–203, see 1987 Amendment note below.

1987—Pub. L. 100–177, §202(e)(6), inserted "or loan repayment contract" in section catchline.

Subsec. (a). Pub. L. 100–177, §202(e)(1), designated existing provisions as par. (1), and former pars. (1) to (4) as subpars. (A) to (D), respectively, and added par. (2).

Subsec. (b)(1). Pub. L. 100–177, §202(e)(2), designated existing provisions as subpar. (A), made technical amendments to references to sections 254m, 254n, and 254p of this title wherever appearing to reflect renumbering of corresponding sections of original act, inserted "under section 254l of this title" after first reference to "service obligation" as the probable intent of Congress, struck out at end "Any amount of damages which the United States is entitled to recover under this subsection shall, within the one year period beginning on the date of the breach of the written contract (or such longer period beginning on such date as specified by the Secretary for good cause shown), be paid to the United States.", and added subpar. (B).

Subsec. (b)(1)(B)(i). Pub. L. 100–203, as amended by Pub. L. 100–360, inserted at end "Amounts not paid within such period shall be subject to collection through deductions in Medicare payments pursuant to section 1395ccc of this title."

Subsec. (c). Pub. L. 100–177, §202(e)(4), added subsec. (c). Former subsec. (c) redesignated (d).

Subsec. (d). Pub. L. 100–177, §§202(e)(3), (5), 308(a), redesignated subsec. (c) as (d), in pars. (1), (2), and (3), inserted "or the Loan Repayment Program (or a contract thereunder", and in par. (3) inserted ", and only if the bankruptcy court finds that nondischarge of the obligation would be unconscionable".

1983—Subsec. (b)(1). Pub. L. 97–414 substituted "section 254p(d)" for "section 254q(b)".

1981—Subsec. (a). Pub. L. 97–35, §2709(e)(1), (2), redesignated subsec. (b) as (a) and, as so redesignated, in introductory text substituted "254l" for "294t" and added par. (4). Former subsec. (a), which related to liability of individual upon failure to accept payment, was struck out.

Subsec. (b). Pub. L. 97–35, §2709(e)(1), (3), redesignated subsec. (c) as (b) and, as so redesignated, designated existing provisions as par. (1) and made numerous changes to reflect renumbering of subpart sections, and added par. (2). Former subsec. (b) redesignated (a).

Subsecs. (c), (d). Pub. L. 97–35, §2709(e)(1), (4)(A), redesignated subsec. (d) as (c) and, as so redesignated, in par. (2) inserted reference to partial or total waiver. Former subsec. (c) redesignated (b).

1977—Subsec. (c). Pub. L. 95–83 substituted " " is the sum of the amounts paid under this subpart to or on behalf of the individual and the interest on such amounts which would be payable if at the time the amounts were paid they were loans" for " " is the sum of the amount paid under this subpart to or on behalf of the individual and the interest on such amount which would be payable if at the time it was paid it was a loan".

STATUTORY NOTES AND RELATED SUBSIDIARIES

EFFECTIVE DATE OF 2003 AMENDMENT

Amendments by Pub. L. 108–163 deemed to have taken effect immediately after the enactment of Pub. L. 107–251, see section 3 of Pub. L. 108–163, set out as a note under section 233 of this title.

EFFECTIVE DATE OF 2002 AMENDMENT

Pub. L. 107–251, title III, §313(b), Oct. 26, 2002, 116 Stat. 1652, which provided that the amendment to this section made by section 313(a)(4) of Pub. L. 107–251 was applicable to any obligation for which a

discharge in bankruptcy had not been granted before the date that was 31 days after Oct. 26, 2002, was repealed by Pub. L. 108–163, §§2(l)(2), 3, Dec. 6, 2003, 117 Stat. 2023, effective immediately after enactment of Pub. L. 107–251.

EFFECTIVE DATE OF 1990 AMENDMENT

Pub. L. 101–597, title II, §203(b), Nov. 16, 1990, 104 Stat. 3027, provided that: "With respect to any financial obligation of an individual under subsection (f) of section 225 of the Public Health Service Act [former 42 U.S.C. 234], as in effect prior to the repeal of such section by section 408(b)(1) of Public Law 94–484, the amendment made by subsection (a) of this section [amending this section] applies to any backruptcy [sic] proceeding in which discharge of such an obligation has not been granted before the date that is 31 days after the date of the enactment of this Act [Nov. 16, 1990]."

EFFECTIVE DATE OF 1988 AMENDMENT

Except as specifically provided in section 411 of Pub. L. 100–360, amendment by Pub. L. 100–360, as it relates to a provision in the Omnibus Budget Reconciliation Act of 1987, Pub. L. 100–203, effective as if included in the enactment of that provision in Pub. L. 100–203, see section 411(a) of Pub. L. 100–360, set out as a Reference to OBRA; Effective Date note under section 106 of Title 1, General Provisions.

EFFECTIVE DATE

Section effective Oct. 1, 1977, see section 408(b)(1) of Pub. L. 94–484, set out in part as a note under section 254l of this title.

EFFECTIVE DATE; SAVINGS PROVISION; CREDIT FOR PERIOD OF INTERNSHIP OR RESIDENCY BEFORE SEPTEMBER 30, 1977, TOWARDS SERVICE OBLIGATION

See section 408(b)(2) of Pub. L. 94–484, set out as a note under section 254l of this title.

SPECIAL REPAYMENT PROVISIONS

Pub. L. 100–177, title II, §204, Dec. 1, 1987, 101 Stat. 1000, provided that an individual who breached a written contract entered into under section 254l of this title by failing either to begin such individual's service obligation in accordance with section 254m of this title or to complete such service obligation; or otherwise breached such a contract; and, as of Nov. 1, 1987, was liable to United States under subsec. (b) of this section was to be relieved of liability to United States under such section if the individual provided notice to Secretary and service in accordance with a written contract with the Secretary that obligated the individual to provide service in accordance with section and authorized Secretary to exclude an individual from relief from liability under this section for reasons related to the individual's professional competence or conduct.

EXISTING PROCEEDINGS

Pub. L. 100–177, title III, §308(b), Dec. 1, 1987, 101 Stat. 1006, provided that: "The amendment made by subsection (a) [amending this section] applies to any bankruptcy proceeding in which discharge of an obligation under section 338E(d)(3) of the Public Health Service Act [42 U.S.C. 254o(d)(3)] (as redesignated by sections 201(2) and 202(e)(3) of this Act) has not been granted before the date that is 31 days after the date of enactment of this Act [Dec. 1, 1987]."

[1] *See References in Text note below.*

§254*o*–1. Fund regarding use of amounts recovered for contract breach to replace services lost as result of breach

(a) Establishment of Fund

There is established in the Treasury of the United States a fund to be known as the National Health Service Corps Member Replacement Fund (hereafter in this section referred to as the "Fund"). The Fund shall consist of such amounts as may be appropriated under subsection (b) to the Fund. Amounts appropriated for the Fund shall remain available until expended.

(b) Authorization of appropriations to Fund

For each fiscal year, there is authorized to be appropriated to the Fund an amount equal to the sum of—

(1) the amount collected during the preceding fiscal year by the Federal Government pursuant to the liability of individuals under section 254o of this title for the breach of contracts entered into under section 254l or 254l–1 of this title;

(2) the amount by which grants under section 254q–1 of this title have, for such preceding fiscal year, been reduced under subsection (g)(2)(B) of such section; and

(3) the aggregate of the amount of interest accruing during the preceding fiscal year on obligations held in the Fund pursuant to subsection (d) and the amount of proceeds from the sale or redemption of such obligations during such fiscal year.

(c) Use of Fund

(1) Payments to certain health facilities

Amounts in the Fund and available pursuant to appropriations Act may, subject to paragraph (2), be expended by the Secretary to make payments to any entity—

(A) to which a Corps member has been assigned under section 254f of this title; and

(B) that has a need for a health professional to provide primary health services as a result of the Corps member having breached the contract entered into under section 254l or 254l–1 of this title by the individual.

(2) Purpose of payments

An entity receiving payments pursuant to paragraph (1) may expend the payments to recruit and employ a health professional to provide primary health services to patients of the entity, or to enter into a contract with such a professional to provide the services to the patients.

(d) Investment

(1) In general

The Secretary of the Treasury shall invest such amounts of the Fund as such Secretary determines are not required to meet current withdrawals from the Fund. Such investments may be made only in interest-bearing obligations of the United States. For such purpose, such obligations may be acquired on original issue at the issue price, or by purchase of outstanding obligations at the market price.

(2) Sale of obligations

Any obligation acquired by the Fund may be sold by the Secretary of the Treasury at the market price.

(July 1, 1944, ch. 373, title III, §338F, as added Pub. L. 101–597, title II, §204, Nov. 16, 1990, 104 Stat. 3027.)

EDITORIAL NOTES

PRIOR PROVISIONS

A prior section 338F of act July 1, 1944, was renumbered section 338G by Pub. L. 101–597 and is classified to section 254p of this title.

Another prior section 338F of act July 1, 1944, was renumbered section 338G by section 201(2) of Pub. L. 100–177 and classified to section 254q of this title, prior to repeal by Pub. L. 100–177, title II, §203, Dec. 1, 1987, 101 Stat. 999.

§254p. Special loans for former Corps members to enter private practice

(a) Persons entitled; conditions

The Secretary may, out of appropriations authorized under section 254k of this title, make one loan to a Corps member who has agreed in writing—

(1) to engage in the private full-time clinical practice of the profession of the member in a health professional shortage area (designated under section 254e of this title) for a period of not

less than 2 years which—

(A) in the case of a Corps member who is required to complete a period of obligated service under this subpart, begins not later than 1 year after the date on which such individual completes such period of obligated service; and

(B) in the case of an individual who is not required to complete a period of obligated service under this subpart, begins at such time as the Secretary considers appropriate;

(2) to conduct such practice in accordance with section 254n(b)(1) of this title; and

(3) to such additional conditions as the Secretary may require to carry out this section.

Such a loan shall be used to assist such individual in meeting the costs of beginning the practice of such individual's profession in accordance with such agreement, including the costs of acquiring equipment and renovating facilities for use in providing health services, and of hiring nurses and other personnel to assist in providing health services. Such loan may not be used for the purchase or construction of any building.

(b) Amount of loan; maximum interest rate

(1) The amount of a loan under subsection (a) to an individual shall not exceed $25,000.

(2) The interest rate for any such loan shall not exceed an annual rate of 5 percent.

(c) Application for loan; submission and approval; interest rates and repayment terms

The Secretary may not make a loan under this section unless an application therefor has been submitted to, and approved by, the Secretary. The Secretary shall, by regulation, set interest rates and repayment terms for loans under this section.

(d) Breach of agreement; notice; determination of liability

If the Secretary determines that an individual has breached a written agreement entered into under subsection (a), he shall, as soon as practicable after making such determination, notify the individual of such determination. If within 60 days after the date of giving such notice, such individual is not practicing his profession in accordance with the agreement under such subsection and has not provided assurances satisfactory to the Secretary that he will not knowingly violate such agreement again, the United States shall be entitled to recover from such individual—

(1) in the case of an individual who has received a grant under this section (as in effect prior to October 1, 1984), an amount determined under section 254o(b) of this title, except that in applying the formula contained in such section "" shall be the sum of the amount of the grant made under subsection (a) to such individual and the interest on such amount which would be payable if at the time it was paid it was a loan bearing interest at the maximum legal prevailing rate, "t" shall be the number of months that such individual agreed to practice his profession under such agreement, and "s" shall be the number of months that such individual practices his profession in accordance with such agreement; and

(2) in the case of an individual who has received a loan under this section, the full amount of the principal and interest owed by such individual under this section.

(July 1, 1944, ch. 373, title III, §338G, formerly title VII, §755, as added Pub. L. 94–484, title IV, §408(b)(1), Oct. 12, 1976, 90 Stat. 2287; renumbered §338E and amended Pub. L. 97–35, title XXVII, §2709(a), (f), Aug. 13, 1981, 95 Stat. 908, 911; Pub. L. 97–414, §8(g)(3), Jan. 4, 1983, 96 Stat. 2061; renumbered §338F and amended Pub. L. 100–177, title II, §201(2), title III, §309, Dec. 1, 1987, 101 Stat. 992, 1006; renumbered §338G and amended Pub. L. 101–597, title II, §204, title IV, §401(b)[(a)], Nov. 16, 1990, 104 Stat. 3027, 3035.)

EDITORIAL NOTES

CODIFICATION

Section was formerly classified to section 294x of this title prior to renumbering by Pub. L. 97–35.

PRIOR PROVISIONS

A prior section 338G of act July 1, 1944, was renumbered section 338H by Pub. L. 101–597 and is classified to section 254q of this title.

Another prior section 338G of act July 1, 1944, was renumbered section 338I by section 201(1) of Pub. L. 100–177 and classified to section 254r of this title, prior to repeal by Pub. L. 100–713, title I, §104(b)(1), Nov. 23, 1988, 102 Stat. 4787.

Another prior section 338G of act July 1, 1944, was classified to section 254q of this title prior to repeal by Pub. L. 100–177, title II, §203, Dec. 1, 1987, 101 Stat. 999.

AMENDMENTS

1990—Subsec. (a)(1). Pub. L. 101–597, §401(b)[(a)], substituted reference to health professional shortage area for reference to health manpower shortage area.

1987—Subsec. (a). Pub. L. 100–177, §309(1), substituted subsec. (a) consisting of pars. (1) to (3) for former subsec. (a) consisting of pars. (1) and (2).

Subsec. (b). Pub. L. 100–177, §309(1), added subsec. (b) and struck out former subsec. (b) which read as follows: "The amount of the grant or loan under subsection (a) of this section to an individual shall be—

"(1) $12,500 if the individual agrees to practice his profession in accordance with the agreement for a period of at least one year, but less than two years; or

"(2) $25,000 if the individual agrees to practice his profession in accordance with the agreement for a period of at least two years."

Subsec. (c). Pub. L. 100–177, §309(2), struck out "grant or" before "loan" in first sentence.

Subsec. (d)(1). Pub. L. 100–177, §309(3), substituted "under this section (as in effect prior to October 1, 1984)" for "under this section", and made technical amendment to reference to section 254o(b) of this title to reflect renumbering of corresponding section of original act.

1983—Subsec. (d)(1). Pub. L. 97–414 substituted "section 254o(b)" for "section 254o(c)".

1981—Subsec. (a). Pub. L. 97–35, §2709(f)(2)–(4), made numerous changes to reflect renumbering of subpart sections, among them inserting references to section 254k of this title and striking out references to section 294v of this title, and added applicability to loans.

Subsec. (b). Pub. L. 97–35, §2709(f)(5), inserted applicability to loans.

Subsec. (c). Pub. L. 97–35, §2709(f)(6), inserted provisions relating to loans and interest rates, etc.

Subsec. (d). Pub. L. 97–35, §2709(f)(7), restructured and revised criteria determining amount of liability of individual within 60 days after the date of notice instead of within 120 days after the date of notice.

STATUTORY NOTES AND RELATED SUBSIDIARIES

EFFECTIVE DATE

Section effective Oct. 1, 1977, see section 408(b)(1) of Pub. L. 94–484, set out in part as a note under section 254l of this title.

EFFECTIVE DATE; SAVINGS PROVISION; CREDIT FOR PERIOD OF INTERNSHIP OR RESIDENCY BEFORE SEPTEMBER 30, 1977, TOWARDS SERVICE OBLIGATION

See section 408(b)(2) of Pub. L. 94–484, set out as a note under section 254l of this title.

§254q. Authorization of appropriations

(a) Authorization of appropriations

For the purpose of carrying out this section,[1] there is authorized to be appropriated, out of any funds in the Treasury not otherwise appropriated, the following:

(1) For fiscal year 2010, $320,461,632.

(2) For fiscal year 2011, $414,095,394.

(3) For fiscal year 2012, $535,087,442.

(4) For fiscal year 2013, $691,431,432.

(5) For fiscal year 2014, $893,456,433.

(6) For fiscal year 2015, $1,154,510,336.

(7) For fiscal year 2016, and each subsequent fiscal year, the amount appropriated for the preceding fiscal year adjusted by the product of—

(A) one plus the average percentage increase in the costs of health professions education during the prior fiscal year; and

(B) one plus the average percentage change in the number of individuals residing in health professions shortage areas designated under section 254f of this title during the prior fiscal year, relative to the number of individuals residing in such areas during the previous fiscal year.

(b) Scholarships for new participants

Of the amounts appropriated under subsection (a) for a fiscal year, the Secretary shall obligate not less than 10 percent for the purpose of providing contracts for—

(1) scholarships under this subpart to individuals who have not previously received such scholarships; or

(2) scholarships or loan repayments under the Loan Repayment Program under section 254l–1 of this title to individuals from disadvantaged backgrounds.

(c) Scholarships and loan repayments

With respect to certification as a nurse practitioner, nurse midwife, or physician assistant, the Secretary shall, from amounts appropriated under subsection (a) for a fiscal year, obligate not less than a total of 10 percent for contracts for both scholarships under the Scholarship Program under section 254l of this title and loan repayments under the Loan Repayment Program under section 254l–1 of this title to individuals who are entering the first year of a course of study or program described in section 254l(b)(1)(B) of this title that leads to such a certification or individuals who are eligible for the loan repayment program as specified in section 254l–1(b) of this title for a loan related to such certification.

(July 1, 1944, ch. 373, title III, §338H, formerly §338G, as added Pub. L. 100–177, title II, §203, Dec. 1, 1987, 101 Stat. 999; renumbered §338H and amended Pub. L. 101–597, title II, §§204, 205, Nov. 16, 1990, 104 Stat. 3027, 3028; Pub. L. 107–251, title III, §314, Oct. 26, 2002, 116 Stat. 1652; Pub. L. 110–355, §3(a)(2), Oct. 8, 2008, 122 Stat. 3993; Pub. L. 111–148, title V, §5207, Mar. 23, 2010, 124 Stat. 612.)

EDITORIAL NOTES

PRIOR PROVISIONS

A prior section 254q, act July 1, 1944, ch. 373, title III, §338G, formerly title VII, §756, as added Oct. 12, 1976, Pub. L. 94–484, title IV, §408(b)(1), 90 Stat. 2288; renumbered §338F and amended Aug. 13, 1981, Pub. L. 97–35, title XXVII, §2709(a), (g), 95 Stat. 908, 912; renumbered §338G, Dec. 1, 1987, Pub. L. 100–177, title II, §201(2), 101 Stat. 992, authorized appropriations for fiscal years 1978 to 1987, prior to repeal by Pub. L. 100–177, §203.

A prior section 338H of act July 1, 1944, was renumbered section 338I by Pub. L. 101–597 and is classified to section 254q–1 of this title.

AMENDMENTS

2010—Subsec. (a). Pub. L. 111–148 amended subsec. (a) generally. Prior to amendment, subsec. (a) related to authorization of appropriations for the purposes of carrying out this subpart as follows: for fiscal year 2008, $131,500,000; for fiscal year 2009, $143,335,000; for fiscal year 2010, $156,235,150; for fiscal year 2011, $170,296,310; and for fiscal year 2012, $185,622,980.

2008—Subsec. (a). Pub. L. 110–355 substituted "appropriated—" for "appropriated $146,250,000 for fiscal year 2002, and such sums as may be necessary for each of fiscal years 2003 through 2006." and added pars. (1) to (5).

2002—Pub. L. 107–251 amended section generally. Prior to amendment, section related to annual report to Congress, authorization of appropriations for fiscal years 1991 through 2000, and reservation of percentage of appropriated amounts for scholarships for new participants and for first-year study in certain fields.

1990—Subsec. (a). Pub. L. 101–597, §205(a), substituted "March 1" for "January 20" and "5 fiscal years" for "3 fiscal years" wherever appearing.

Subsec. (b). Pub. L. 101–597, §205(b), amended subsec. (b) generally. Prior to amendment, subsec. (b) read as follows: "There are authorized to be appropriated such sums as may be necessary for scholarships and loan repayments under this subpart."

[1] *So in original. Probably should be "subpart,".*

§254q–1. Grants to States for loan repayment programs

(a) In general

(1) Authority for grants

The Secretary, acting through the Administrator of the Health Resources and Services Administration, may make grants to States for the purpose of assisting the States in operating programs described in paragraph (2) in order to provide for the increased availability of primary health care services in health professional shortage areas. The National Advisory Council established under section 254j of this title shall advise the Administrator regarding the program under this section.

(2) Loan repayment programs

The programs referred to in paragraph (1) are, subject to subsection (c), programs of entering into contracts under which the State involved agrees to pay all or part of the principal, interest, and related expenses of the educational loans of health professionals in consideration of the professionals agreeing to provide primary health services in health professional shortage areas.

(3) Direct administration by State agency

The Secretary may not make a grant under paragraph (1) unless the State involved agrees that the program operated with the grant will be administered directly by a State agency.

(b) Requirement of matching funds

(1) In general

The Secretary may not make a grant under subsection (a) unless the State agrees that, with respect to the costs of making payments on behalf of individuals under contracts made pursuant to paragraph (2) of such subsection, the State will make available (directly or through donations from public or private entities) non-Federal contributions in cash toward such costs in an amount equal to not less than $1 for each $1 of Federal funds provided in the grant.

(2) Determination of amount of non-Federal contribution

In determining the amount of non-Federal contributions in cash that a State has provided pursuant to paragraph (1), the Secretary may not include any amounts provided to the State by the Federal Government.

(c) Coordination with Federal program

(1) Assignments for health professional shortage areas under Federal program

The Secretary may not make a grant under subsection (a) unless the State involved agrees that, in carrying out the program operated with the grant, the State will assign health professionals participating in the program only to public and nonprofit private entities located in and providing health services in health professional shortage areas.

(2) Remedies for breach of contracts

The Secretary may not make a grant under subsection (a) unless the State involved agrees that the contracts provided by the State pursuant to paragraph (2) of such subsection will provide remedies for any breach of the contracts by the health professionals involved.

(3) Limitation regarding contract inducements

(A) Except as provided in subparagraph (B), the Secretary may not make a grant under subsection (a) unless the State involved agrees that the contracts provided by the State pursuant to paragraph (2) of such subsection will not be provided on terms that are more favorable to health professionals than the most favorable terms that the Secretary is authorized to provide for

contracts under the Loan Repayment Program under section 254l–1 of this title, including terms regarding—

(i) the annual amount of payments provided on behalf of the professionals regarding educational loans; and

(ii) the availability of remedies for any breach of the contracts by the health professionals involved.

(B) With respect to the limitation established in subparagraph (A) regarding the annual amount of payments that may be provided to a health professional under a contract provided by a State pursuant to subsection (a)(2), such limitation shall not apply with respect to a contract if—

(i) the excess of such annual payments above the maximum amount authorized in section 254l–1(g)(2)(A) of this title for annual payments regarding contracts is paid solely from non-Federal contributions under subsection (b); and

(ii) the contract provides that the health professional involved will satisfy the requirement of obligated service under the contract solely through the provision of primary health services in a health professional shortage area that is receiving priority for purposes of section 254f–1(a)(1) of this title and that is authorized to receive assignments under section 254f of this title of individuals who are participating in the Scholarship Program under section 254l of this title.

(d) Restrictions on use of funds

The Secretary may not make a grant under subsection (a) unless the State involved agrees that the grant will not be expended—

(1) to conduct activities for which Federal funds are expended—

(A) within the State to provide technical or other nonfinancial assistance under subsection (f) of section 254c [1] of this title;

(B) under a memorandum of agreement entered into with the State under subsection (h) of such section; or

(C) under a grant under section 254r of this title; or

(2) for any purpose other than making payments on behalf of health professionals under contracts entered into pursuant to subsection (a)(2).

(e) Reports

The Secretary may not make a grant under subsection (a) unless the State involved agrees—

(1) to submit to the Secretary such reports regarding the States loan repayment program, as are determined to be appropriate by the Secretary; and

(2) to submit such a report not later than January 10 of each fiscal year immediately following any fiscal year for which the State has received such a grant.

(f) Requirement of application

The Secretary may not make a grant under subsection (a) unless an application for the grant is submitted to the Secretary and the application is in such form, is made in such manner, and contains such agreements, assurances, and information as the Secretary determines to be necessary to carry out such subsection.

(g) Noncompliance

(1) In general

The Secretary may not make payments under subsection (a) to a State for any fiscal year subsequent to the first fiscal year of such payments unless the Secretary determines that, for the immediately preceding fiscal year, the State has complied with each of the agreements made by the State under this section.

(2) Reduction in grant relative to number of breached contracts

(A) Before making a grant under subsection (a) to a State for a fiscal year, the Secretary shall determine the number of contracts provided by the State under paragraph (2) of such subsection

with respect to which there has been an initial breach by the health professionals involved during the fiscal year preceding the fiscal year for which the State is applying to receive the grant.

(B) Subject to paragraph (3), in the case of a State with 1 or more initial breaches for purposes of subparagraph (A), the Secretary shall reduce the amount of a grant under subsection (a) to the State for the fiscal year involved by an amount equal to the sum of the expenditures of Federal funds made regarding the contracts involved and an amount representing interest on the amount of such expenditures, determined with respect to each contract on the basis of the maximum legal rate prevailing for loans made during the time amounts were paid under the contract, as determined by the Treasurer of the United States.

(3) Waiver regarding reduction in grant

The Secretary may waive the requirement established in paragraph (2)(B) with respect to the initial breach of a contract if the Secretary determines that such breach by the health professional involved was attributable solely to the professional having a serious illness.

(h) "State" defined

For purposes of this section, the term "State" means each of the 50 States, the District of Columbia, the Commonwealth of Puerto Rico, the United States Virgin Islands, Guam, American Samoa, Palau, the Marshall Islands, and the Commonwealth of the Northern Mariana Islands.

(i) Authorization of appropriations

(1) In general

For the purpose of making grants under subsection (a), there are authorized to be appropriated $12,000,000 for fiscal year 2008, and such sums as may be necessary for each of fiscal years 2009 through 2012.

(2) Availability

Amounts appropriated under paragraph (1) shall remain available until expended.

(j) Public health loan repayment

(1) In general

The Secretary may award grants to States for the purpose of assisting such States in operating loan repayment programs under which such States enter into contracts to repay all or part of the eligible loans borrowed by, or on behalf of, individuals who agree to serve in State, local, or tribal health departments that serve health professional shortage areas or other areas at risk of a public health emergency, as designated by the Secretary.

(2) Loans eligible for repayment

To be eligible for repayment under this subsection, a loan shall be a loan made, insured, or guaranteed by the Federal Government that is borrowed by, or on behalf of, an individual to pay the cost of attendance for a program of education leading to a degree appropriate for serving in a State, local, or tribal health department as determined by the Secretary and the chief executive officer of the State in which the grant is administered, at an institution of higher education (as defined in section 1002 of title 20), including principal, interest, and related expenses on such loan.

(3) Applicability of existing requirements

With respect to awards made under paragraph (1)—

(A) the requirements of subsections (b), (f), and (g) shall apply to such awards; and

(B) the requirements of subsection (c) shall apply to such awards except that with respect to paragraph (1) of such subsection, the State involved may assign an individual only to public and nonprofit private entities that serve health professional shortage areas or areas at risk of a public health emergency, as determined by the Secretary.

(4) Authorization of appropriations

There are authorized to be appropriated to carry out this subsection, such sums as may be

necessary for each of fiscal years 2007 through 2010.

(July 1, 1944, ch. 373, title III, §338I, formerly §338H, as added Pub. L. 100–177, title II, §203, Dec. 1, 1987, 101 Stat. 999; renumbered §338I and amended Pub. L. 101–597, title II, §204, title III, §301, title IV, §401(b)[(a)], Nov. 16, 1990, 104 Stat. 3027, 3029, 3035; Pub. L. 105–392, title IV, §408, Nov. 13, 1998, 112 Stat. 3589; Pub. L. 107–251, title III, §315, Oct. 26, 2002, 116 Stat. 1653; Pub. L. 109–417, title II, §203(b), Dec. 19, 2006, 120 Stat. 2849; Pub. L. 110–355, §3(e), Oct. 8, 2008, 122 Stat. 3994.)

EDITORIAL NOTES

REFERENCES IN TEXT

Section 254c of this title, referred to in subsec. (d)(1)(A), was in the original a reference to section 330, meaning section 330 of act July 1, 1944, which was omitted in the general amendment of subpart I (§254b et seq.) of this part by Pub. L. 104–299, §2, Oct. 11, 1996, 110 Stat. 3626. Sections 2 and 3(a) of Pub. L. 104–299 enacted new sections 330 and 330A of act July 1, 1944, which are classified, respectively, to sections 254b and 254c of this title.

PRIOR PROVISIONS

A prior section 338I of act July 1, 1944, was classified to section 254r of this title prior to repeal by Pub. L. 100–713, title I, §104(b)(1), Nov. 23, 1988, 102 Stat. 4787.

AMENDMENTS

2008—Subsec. (h). Pub. L. 110–355, §3(e)(1), substituted "50 States, the District of Columbia, the Commonwealth of Puerto Rico, the United States Virgin Islands, Guam, American Samoa, Palau, the Marshall Islands, and the Commonwealth of the Northern Mariana Islands" for "several States".

Subsec. (i)(1). Pub. L. 110–355, §3(e)(2), substituted "2008, and such sums as may be necessary for each of fiscal years 2009 through 2012." for "2002 and such sums as may be necessary for each of fiscal years 2003 through 2006."

2006—Subsec. (j). Pub. L. 109–417 added subsec. (j).

2002—Subsec. (a)(1). Pub. L. 107–251, §315(1), added par. (1) and struck out heading and text of former par. (1). Text read as follows: "The Secretary, acting through the Administrator of the Health Resources and Services Administration, may make grants to States for the purpose of assisting the States in operating programs described in paragraph (2) in order to provide for the increased availability of primary health services in health professional shortage areas."

Subsec. (e)(1). Pub. L. 107–251, §315(2), added par. (1) and struck out former par. (1) which read as follows: "to submit to the Secretary reports providing the same types of information regarding the program operated pursuant to such subsection as reports submitted pursuant to subsection (i) of section 254l–1 of this title provide regarding the Loan Repayment Program under such section; and".

Subsec. (i)(1). Pub. L. 107–251, §315(3), added par. (1) and struck out heading and text of former par. (1). Text read as follows: "For the purpose of making grants under subsection (a) of this section, there is authorized to be appropriated $10,000,000 for each of the fiscal years 1991 through 1995, and such sums as may be necessary for each of the fiscal years 1998 through 2002."

1998—Subsec. (i)(1). Pub. L. 105–392 inserted ", and such sums as may be necessary for each of the fiscal years 1998 through 2002" before period at end.

1990—Pub. L. 101–597, §401(b)[(a)], substituted reference to health professional shortage area for reference to health manpower shortage area wherever appearing in subsecs. (a)(1), (2) and (c)(1), (3)(B)(ii).

Pub. L. 101–597, §301, amended section generally, substituting present provisions for provisions which related to: in subsec. (a), grants; in subsec. (b), applications; in subsec. (c), Federal share; and in subsec. (d), authorization of appropriations.

[1] *See References in Text note below.*

§254r. Grants to State Offices of Rural Health

(a) In general

The Secretary, acting through the Director of the Federal Office of Rural Health Policy (established under section 912 of this title), shall make grants to each State Office of Rural Health for the purpose of improving health care in rural areas.

(b) Requirement of matching funds

(1) In general

Subject to paragraph (2), the Secretary may not make a grant under subsection (a) unless the State office of rural health involved agrees, with respect to the costs to be incurred in carrying out the purpose described in such subsection, to provide non-Federal contributions toward such costs in an amount equal to $3 for each $1 of Federal funds provided in the grant.

(2) Waiver or reduction

The Secretary may waive or reduce the non-Federal contribution if the Secretary determines that requiring matching funds would limit the State office of rural health's ability to carry out the purpose described in subsection (a).

(3) Determination of amount of non-Federal contribution

Non-Federal contributions required in paragraph (1) may be in cash or in kind, fairly evaluated, including plant, equipment, or services. Amounts provided by the Federal Government, or services assisted or subsidized to any significant extent by the Federal Government, may not be included in determining the amount of such non-Federal contributions.

(c) Certain required activities

Recipients of a grant under subsection (a) shall use the grant funds for purposes of—

(1) maintaining within the State office of rural health a clearinghouse for collecting and disseminating information on—

(A) rural health care issues;

(B) research findings relating to rural health care; and

(C) innovative approaches to the delivery of health care in rural areas;

(2) coordinating the activities carried out in the State that relate to rural health care, including providing coordination for the purpose of avoiding redundancy in such activities; and

(3) identifying Federal and State programs regarding rural health, and providing technical assistance to public and nonprofit private entities regarding participation in such programs.

(d) Requirement regarding annual budget for office

The Secretary may not make a grant under subsection (a) unless the State involved agrees that, for any fiscal year for which the State office of rural health receives such a grant, the office operated pursuant to subsection (a) of this section will be provided with an annual budget of not less than $150,000.

(e) Certain uses of funds

(1) Restrictions

The Secretary may not make a grant under subsection (a) unless the State office of rural health involved agrees that the grant will not be expended—

(A) to provide health care (including providing cash payments regarding such care);

(B) to conduct activities for which Federal funds are expended—

(i) within the State to provide technical and other nonfinancial assistance under section 254c(f) of this title;

(ii) under a memorandum of agreement entered into with the State office of rural health under section 254c(h) of this title; or

(iii) under a grant under section 254q–1 of this title;

(C) to purchase medical equipment, to purchase ambulances, aircraft, or other vehicles, or to purchase major communications equipment;

(D) to purchase or improve real property; or

(E) to carry out any activity regarding a certificate of need.

(2) Authorities

Activities for which a State office of rural health may expend a grant under subsection (a) include—

(A) paying the costs of maintaining an office of rural health for purposes of subsection (a);

(B) subject to paragraph (1)(B)(iii), paying the costs of any activity carried out with respect to recruiting and retaining health professionals to serve in rural areas of the State; and

(C) providing grants and contracts to public and nonprofit private entities to carry out activities authorized in this section.

(3) Limit on indirect costs

The Secretary may impose a limit of no more than 15 percent on indirect costs claimed by the recipient of the grant.

(f) Reports

The Secretary may not make a grant under subsection (a) unless the State office of rural health involved agrees—

(1) to submit to the Secretary reports or performance data containing such information as the Secretary may require regarding activities carried out under this section; and

(2) to submit such a report or performance data not later than September 30 of each fiscal year immediately following any fiscal year for which the State office of rural health has received such a grant.

(g) Requirement of application

The Secretary may not make a grant under subsection (a) unless an application for the grant is submitted to the Secretary and the application is in such form, is made in such manner, and contains such agreements, assurances, and information as the Secretary determines to be necessary to carry out such subsection.

(h) Noncompliance

The Secretary may not make payments under subsection (a) to a State office of rural health for any fiscal year subsequent to the first fiscal year of such payments unless the Secretary determines that, for the immediately preceding fiscal year, the State office of rural health has complied with each of the agreements made by the State office of rural health under this section.

(i) Authorization of appropriations

(1) In general

For the purpose of making grants under subsection (a), there are authorized to be appropriated $12,500,000 for each of fiscal years 2023 through 2027.

(2) Availability

Amounts appropriated under paragraph (1) shall remain available until expended.

(July 1, 1944, ch. 373, title III, §338J, as added Pub. L. 101–597, title III, §302, Nov. 16, 1990, 104 Stat. 3032; amended Pub. L. 105–392, title III, §301, Nov. 13, 1998, 112 Stat. 3585; Pub. L. 115–408, §2, Dec. 31, 2018, 132 Stat. 5384; Pub. L. 117–356, §2, Jan. 5, 2023, 136 Stat. 6282.)

EDITORIAL NOTES

PRIOR PROVISIONS

A prior section 254r, act July 1, 1944, ch. 373, title III, §338I, formerly title VII, §757, as added Aug. 1, 1977, Pub. L. 95–83, title III, §307(n)(1), 91 Stat. 392; amended Dec. 17, 1980, Pub. L. 96–537, §3(d), 94 Stat. 3174; renumbered §338G, Aug. 13, 1981, Pub. L. 97–35, title XXVII, §2709(a), 95 Stat. 908; Oct. 30, 1984, Pub. L. 98–551, §3, 98 Stat. 2817; renumbered §338I, Dec. 1, 1987, Pub. L. 100–177, title II, §201(1), 101 Stat. 992; Nov. 4, 1988, Pub. L. 100–607, title VI, §629(a)(3), 102 Stat. 3146, which related to Indian

Health Scholarships and was classified to section 294y–1 of this title prior to renumbering by Pub. L. 97–35, was repealed by Pub. L. 100–713, title I, §104(b)(1), Nov. 23, 1988, 102 Stat. 4787. For provisions continuing scholarships provided on or before Nov. 23, 1988, see section 104(b)(2) of Pub. L. 100–713.

A prior section 338J of act July 1, 1944, was renumbered section 338K by Pub. L. 101–597 and is classified to section 254s of this title.

AMENDMENTS

2023—Subsec. (i)(1). Pub. L. 117–356 substituted "fiscal years 2023 through 2027" for "fiscal years 2018 through 2022".

2018—Pub. L. 115–408 amended section generally. Prior to amendment, section related to grants to States for operation of offices of rural health.

1998—Subsec. (b)(1). Pub. L. 105–392, §301(1), struck out "in cash" after "contributions" in introductory provisions.

Subsec. (j)(1). Pub. L. 105–392, §301(2), struck out "and" after "1992," and inserted before period at end ", and such sums as may be necessary for each of the fiscal years 1998 through 2002".

Subsec. (k). Pub. L. 105–392, §301(3), substituted "$36,000,000" for "$10,000,000".

STATUTORY NOTES AND RELATED SUBSIDIARIES

COMMUNICATIONS FOR RURAL HEALTH PROVIDERS

Pub. L. 102–538, title I, §154, formerly §134, Oct. 27, 1992, 106 Stat. 3541, renumbered §154 by Pub. L. 103–66, title VI, §6001(a)(2), Aug. 10, 1993, 107 Stat. 379, directed Secretary of Commerce, in conjunction with Secretary of Health and Human Services, to establish an advisory panel to develop recommendations for the improvement of rural health care through the collection of information needed by providers and the improvement in the use of communications to disseminate such information and, not later than 1 year after establishment of Panel to prepare and submit to Congress a report summarizing the recommendations made by the Panel.

Similar provisions were contained in Pub. L. 101–555, §3, Nov. 15, 1990, 104 Stat. 2760.

§254s. Native Hawaiian Health Scholarships

(a) Eligibility

Subject to the availability of funds appropriated under the authority of subsection (d), the Secretary shall provide funds to Papa Ola Lokahi for the purpose of providing scholarship assistance to students who—

(1) meet the requirements of section 254l(b) of this title, and

(2) are Native Hawaiians.

(b) Terms and conditions

(1) The scholarship assistance provided under subsection (a) shall be provided under the same terms and subject to the same conditions, regulations, and rules that apply to scholarship assistance provided under section 254l of this title.

(2) The Native Hawaiian Health Scholarship program shall not be administered by or through the Indian Health Service.

(c) "Native Hawaiian" defined

For purposes of this section, the term "Native Hawaiian" means any individual who is—

(1) a citizen of the United States,

(2) a resident of the State of Hawaii, and

(3) a descendant of the aboriginal people, who prior to 1778, occupied and exercised sovereignty in the area that now constitutes the State of Hawaii, as evidenced by—

(A) genealogical records,

(B) Kupuna (elders) or Kama'aina (long-term community residents) verification, or

(C) birth records of the State of Hawaii.

(d) Authorization of appropriations

There are authorized to be appropriated $1,800,000 for each of the fiscal years 1990, 1991, and 1992 for the purpose of funding the scholarship assistance provided under subsection (a).

(July 1, 1944, ch. 373, title III, §338K, formerly §338J, as added Pub. L. 100–713, title I, §106, Nov. 23, 1988, 102 Stat. 4787; renumbered §338K, Pub. L. 101–597, title III, §302, Nov. 16, 1990, 104 Stat. 3032; amended Pub. L. 101–644, title IV, §401, Nov. 29, 1990, 104 Stat. 4668; Pub. L. 107–116, title V, §514(b), Jan. 10, 2002, 115 Stat. 2220.)

EDITORIAL NOTES

AMENDMENTS

2002—Subsec. (a). Pub. L. 107–116, which directed the amendment of subsec. (a) by substituting "Papa Ola Lokahi" for "Kamehameha School/Bishop Estate", was executed by making the substitution for "Kamehameha Schools/Bishop Estate" to reflect the probable intent of Congress.

1990—Subsec. (a). Pub. L. 101–644, which directed the general amendment of subsec. (a) of section 338J of the Public Health Service Act, was executed to subsec. (a) of this section, to reflect the probable intent of Congress and the intervening renumbering of section 338J as 338K by Pub. L. 101–597. Prior to amendment, subsec. (a) read as follows: "Subject to the availability of funds appropriated under the authority of subsection (d) of this section, the Secretary shall provide scholarship assistance, pursuant to a contract with the Kamehameha Schools/Bishop Estate, to students who—

"(1) meet the requirements of section 254l(b) of this title, and

"(2) are Native Hawaiians."

§254t. Demonstration project

(a) Program authorized

The Secretary shall establish a demonstration project to provide for the participation of individuals who are chiropractic doctors or pharmacists in the Loan Repayment Program described in section 254l–1 of this title.

(b) Procedure

An individual that receives assistance under this section with regard to the program described in section 254l–1 of this title shall comply with all rules and requirements described in such section (other than subparagraphs (A) and (B) of section 254l–1(b)(1) of this title) in order to receive assistance under this section.

(c) Limitations

(1) In general

The demonstration project described in this section shall provide for the participation of individuals who shall provide services in rural and urban areas.

(2) Availability of other health professionals

The Secretary may not assign an individual receiving assistance under this section to provide obligated service at a site unless—

(A) the Secretary has assigned a physician (as defined in section 1395x(r) of this title) or other health professional licensed to prescribe drugs to provide obligated service at such site under section 254m or 254n of this title; and

(B) such physician or other health professional will provide obligated service at such site concurrently with the individual receiving assistance under this section.

(3) Rules of construction

(A) Supervision of individuals

Nothing in this section shall be construed to require or imply that a physician or other health professional licensed to prescribe drugs must supervise an individual receiving assistance under

the demonstration project under this section, with respect to such project.

(B) Licensure of health professionals

Nothing in this section shall be construed to supersede State law regarding licensure of health professionals.

(d) Designations

The demonstration project described in this section, and any providers who are selected to participate in such project, shall not be considered by the Secretary in the designation of a health professional shortage area under section 254e of this title during fiscal years 2002 through 2004.

(e) Rule of construction

This section shall not be construed to require any State to participate in the project described in this section.

(f) Report

(1) In general

The Secretary shall evaluate the participation of individuals in the demonstration projects under this section and prepare and submit a report containing the information described in paragraph (2) to—

(A) the Committee on Health, Education, Labor, and Pensions of the Senate;

(B) the Subcommittee on Labor, Health and Human Services, and Education of the Committee on Appropriations of the Senate;

(C) the Committee on Energy and Commerce of the House of Representatives; and

(D) the Subcommittee on Labor, Health and Human Services, and Education of the Committee on Appropriations of the House of Representatives.

(2) Content

The report described in paragraph (1) shall detail—

(A) the manner in which the demonstration project described in this section has affected access to primary care services, patient satisfaction, quality of care, and health care services provided for traditionally underserved populations;

(B) how the participation of chiropractic doctors and pharmacists in the Loan Repayment Program might affect the designation of health professional shortage areas; and

(C) whether adding chiropractic doctors and pharmacists as permanent members of the National Health Service Corps would be feasible and would enhance the effectiveness of the National Health Service Corps.

(g) Authorization of appropriations

(1) In general

There are authorized to be appropriated to carry out this section, such sums as may be necessary for fiscal years 2002 through 2004.

(2) Fiscal year 2005

If the Secretary determines and certifies to Congress by not later than September 30, 2004, that the number of individuals participating in the demonstration project established under this section is insufficient for purposes of performing the evaluation described in subsection (f)(1), the authorization of appropriations under paragraph (1) shall be extended to include fiscal year 2005.

(July 1, 1944, ch. 373, title III, §338L, as added Pub. L. 107–251, title III, §317, Oct. 26, 2002, 116 Stat. 1653.)

EDITORIAL NOTES

PRIOR PROVISIONS

A prior section 254t, act July 1, 1944, ch. 373, title III, §338L, as added Pub. L. 101–527, §8, Nov. 6, 1990,

104 Stat. 2328, related to demonstration grants to States for community scholarship programs, prior to repeal by Pub. L. 107–251, title III, §316, Oct. 26, 2002, 116 Stat. 1653.

§254u. Public health departments

(a) In general

To the extent that funds are appropriated under subsection (e), the Secretary shall establish a demonstration project to provide for the participation of individuals who are eligible for the Loan Repayment Program described in section 254l–1 of this title and who agree to complete their service obligation in a State health department that provides a significant amount of service to health professional shortage areas or areas at risk of a public health emergency, as determined by the Secretary, or in a local or tribal health department that serves a health professional shortage area or an area at risk of a public health emergency.

(b) Procedure

To be eligible to receive assistance under subsection (a), with respect to the program described in section 254l–1 of this title, an individual shall—

(1) comply with all rules and requirements described in such section (other than section 254l–1(f)(1)(B)(iv) of this title); and

(2) agree to serve for a time period equal to 2 years, or such longer period as the individual may agree to, in a State, local, or tribal health department, described in subsection (a).

(c) Designations

The demonstration project described in subsection (a), and any healthcare providers who are selected to participate in such project, shall not be considered by the Secretary in the designation of health professional shortage areas under section 254e of this title during fiscal years 2007 through 2010.

(d) Report

Not later than 3 years after December 19, 2006, the Secretary shall submit a report to the relevant committees of Congress that evaluates the participation of individuals in the demonstration project under subsection (a), the impact of such participation on State, local, and tribal health departments, and the benefit and feasibility of permanently allowing such placements in the Loan Repayment Program.

(e) Authorization of appropriations

There are authorized to be appropriated to carry out this section, such sums as may be necessary for each of fiscal years 2007 through 2010.

(July 1, 1944, ch. 373, title III, §338M, as added Pub. L. 109–417, title II, §203(a), Dec. 19, 2006, 120 Stat. 2848.)

§254v. Clarification regarding service in schools and other community-based settings

(a) Schools and community-based settings

An entity to which a participant in the Scholarship Program or the Loan Repayment Program (referred to in this section as a "participant") is assigned under section 254f of this title may direct such participant to provide service as a behavioral or mental health professional at a school or other community-based setting located in a health professional shortage area.

(b) Obligated service

(1) In general

Any service described in subsection (a) that a participant provides may count towards such

participant's completion of any obligated service requirements under the Scholarship Program or the Loan Repayment Program, subject to any limitation imposed under paragraph (2).

(2) Limitation

The Secretary may impose a limitation on the number of hours of service described in subsection (a) that a participant may credit towards completing obligated service requirements, provided that the limitation allows a member to credit service described in subsection (a) for not less than 50 percent of the total hours required to complete such obligated service requirements.

(c) Rule of construction

The authorization under subsection (a) shall be notwithstanding any other provision of this subpart or subpart II.

(July 1, 1944, ch. 373, title III, §338N, as added Pub. L. 115–271, title VII, §7072, Oct. 24, 2018, 132 Stat. 4030.)

SUBPART IV—HOME HEALTH SERVICES

EDITORIAL NOTES

CODIFICATION

Pub. L. 100–177, title II, §202(f)(1), Dec. 1, 1987, 101 Stat. 999, substituted "IV" for "III" as subpart designation.

Pub. L. 97–414, §6(a), Jan. 4, 1983, 96 Stat. 2057, added heading "Subpart III—Home Health Services".

Pub. L. 95–626, title I, §105(b), title II, §207(a), Nov. 10, 1978, 92 Stat. 3560, 3585, struck out heading "Part D—Lepers" and added heading "Subpart III—Home Health Services".

§255. Home health services

(a) Purpose; authorization of grants and loans; considerations; conditions on loans; appropriations

(1) For the purpose of encouraging the establishment and initial operation of home health programs to provide home health services in areas in which such services are inadequate or not readily accessible, the Secretary may, in accordance with the provisions of this section, make grants to public and nonprofit private entities and loans to proprietary entities to meet the initial costs of establishing and operating such home health programs. Such grants and loans may include funds to provide training for paraprofessionals (including homemaker home health aides) to provide home health services.

(2) In making grants and loans under this subsection, the Secretary shall—

(A) consider the relative needs of the several States for home health services;

(B) give preference to areas in which a high percentage of the population proposed to be served is composed of individuals who are elderly, medically indigent, or disabled; and

(C) give special consideration to areas with inadequate means of transportation to obtain necessary health services.

(3)(A) No loan may be made to a proprietary entity under this section unless the application of such entity for such loan contains assurances satisfactory to the Secretary that—

(i) at the time the application is made the entity is fiscally sound;

(ii) the entity is unable to secure a loan for the project for which the application is submitted from non-Federal lenders at the rate of interest prevailing in the area in which the entity is located; and

(iii) during the period of the loan, such entity will remain fiscally sound.

(B) Loans under this section shall be made at an interest rate comparable to the rate of interest prevailing on the date the loan is made with respect to the marketable obligations of the United States of comparable maturities, adjusted to provide for administrative costs.

(4) Applications for grants and loans under this subsection shall be in such form and contain such information as the Secretary shall prescribe.

(5) There are authorized to be appropriated for grants and loans under this subsection $5,000,000 for each of the fiscal years ending on September 30, 1983, September 30, 1984, September 30, 1985, September 30, 1986, and September 30, 1987.

(b) Grants and contracts for training programs for paraprofessionals; considerations; applications; appropriations

(1) The Secretary may make grants to and enter into contracts with public and private entities to assist them in developing appropriate training programs for paraprofessionals (including homemaker home health aides) to provide home health services.

(2) Any program established with a grant or contract under this subsection to train homemaker home health aides shall—

(A) extend for at least forty hours, and consist of classroom instruction and at least twenty hours (in the aggregate) of supervised clinical instruction directed toward preparing students to deliver home health services;

(B) be carried out under appropriate professional supervision and be designed to train students to maintain or enhance the personal care of an individual in his home in a manner which promotes the functional independence of the individual; and

(C) include training in—

(i) personal care services designed to assist an individual in the activities of daily living such as bathing, exercising, personal grooming, and getting in and out of bed; and

(ii) household care services such as maintaining a safe living environment, light housekeeping, and assisting in providing good nutrition (by the purchasing and preparation of food).

(3) In making grants and entering into contracts under this subsection, special consideration shall be given to entities which establish or will establish programs to provide training for persons fifty years of age and older who wish to become paraprofessionals (including homemaker home health aides) to provide home health services.

(4) Applications for grants and contracts under this subsection shall be in such form and contain such information as the Secretary shall prescribe.

(5) There are authorized to be appropriated for grants and contracts under this subsection $2,000,000 for each of the fiscal years ending September 30, 1983, September 30, 1984, September 30, 1985, September 30, 1986, and September 30, 1987.

(c) Report to Congress with respect to grants and loans and training of personnel

The Secretary shall report to the Committee on Labor and Human Resources of the Senate and the Committee on Energy and Commerce of the House of Representatives on or before January 1, 1984, with respect to—

(1) the impact of grants made and contracts entered into under subsections (a) and (b) (as such subsections were in effect prior to October 1, 1981);

(2) the need to continue grants and loans under subsections (a) and (b) (as such subsections are in effect on the day after January 4, 1983); and

(3) the extent to which standards have been applied to the training of personnel who provide home health services.

(d) "Home health services" defined

For purposes of this section, the term "home health services" has the meaning prescribed for the term by section 1395x(m) of this title.

(July 1, 1944, ch. 373, title III, §339, as added Pub. L. 97–414, §6(a), Jan. 4, 1983, 96 Stat. 2057; amended Pub. L. 98–555, §6, Oct. 30, 1984, 98 Stat. 2856.)

EDITORIAL NOTES

REFERENCES IN TEXT

Subsections (a) and (b) (as such subsections were in effect prior to October 1, 1981), referred to in subsec. (c)(1), mean subsections (a) and (b) of section 255 of this title prior to repeal of section 255 by Pub. L. 97–35, title IX, §902(b), Aug. 13, 1981, 95 Stat. 559, effective Oct. 1, 1981.

PRIOR PROVISIONS

A prior section 255, act July 1, 1944, ch. 373, title III, §339, as added Nov. 10, 1978, Pub. L. 95–626, title II, §207(a), 92 Stat. 3585, related to grant authority, etc., for home health services, prior to repeal by Pub. L. 97–35, title IX, §902(b), (h), Aug. 13, 1981, 95 Stat. 559, 561, eff. Oct. 1, 1981.

Another prior section 339 of act July 1, 1944, ch. 373, title III, formerly §331, 58 Stat. 698; June 25, 1948, ch. 654, §4, 62 Stat. 1018; June 25, 1952, ch. 460, 66 Stat. 157; July 12, 1960, Pub. L. 86–624, §29(b), 74 Stat. 419; renumbered §339, Oct. 12, 1976, Pub. L. 94–484, title IV, §407(b)(2), 90 Stat. 2268, which related to reception of persons suffering from leprosy in any hospital, was renumbered section 320 of act July 1, 1944, and transferred to section 247e of this title.

AMENDMENTS

1984—Subsecs. (a)(5), (b)(5). Pub. L. 98–555 inserted provisions authorizing appropriations for fiscal years ending Sept. 30, 1985, 1986, and 1987.

STATUTORY NOTES AND RELATED SUBSIDIARIES

CHANGE OF NAME

Committee on Labor and Human Resources of Senate changed to Committee on Health, Education, Labor, and Pensions of Senate by Senate Resolution No. 20, One Hundred Sixth Congress, Jan. 19, 1999.

Committee on Energy and Commerce of House of Representatives treated as referring to Committee on Commerce of House of Representatives by section 1(a) of Pub. L. 104–14, set out as a note preceding section 21 of Title 2, The Congress. Committee on Commerce of House of Representatives changed to Committee on Energy and Commerce of House of Representatives, and jurisdiction over matters relating to securities and exchanges and insurance generally transferred to Committee on Financial Services of House of Representatives by House Resolution No. 5, One Hundred Seventh Congress, Jan. 3, 2001.

REPORT TO CONGRESS CONCERNING RESULTS OF STUDIES EVALUATING HOME AND COMMUNITY BASED HEALTH SERVICES; STUDIES OF REIMBURSEMENT METHODOLOGIES; INVESTIGATION OF FRAUD; DEMONSTRATION PROJECTS; HOME HEALTH SERVICES, DEFINED

Pub. L. 97–414, §6(b)–(f), Jan. 4, 1983, 96 Stat. 2058, 2059, directed Secretary of Health and Human Services to report results of studies evaluating home and community based health services, and any recommendations for legislative action which might improve the provision of such services, to Congress prior to Jan. 1, 1985, to compile and analyze results of significant public or private studies relating to reimbursement methodologies for home health services and to report recommendations to Congress within 180 days after Jan. 4, 1983, to investigate methods available to stem medicare and medicaid fraud and abuse and extent to which such methods are applied and to report results to Congress within 18 months of Jan. 4, 1983, and to develop and carry out demonstration projects commencing no later than Jan. 1, 1984, to test methods for identifying patients at risk of institutionalization who could be treated more cost-effectively with home health services, and to test alternative reimbursement methodologies for home health agencies in order to determine most cost-effective way of providing home health services, and to report to Congress with regard to the demonstrations no later than Jan. 1, 1985; and defined "home health services" for purposes of this section.

SUBPART V—HEALTHY COMMUNITIES ACCESS PROGRAM

EDITORIAL NOTES

PRIOR PROVISIONS

A prior subpart VI, consisting of section 256a, related to health services for residents of public housing, prior to repeal by Pub. L. 104–299, §4(a)(3), Oct. 11, 1996, 110 Stat. 3645.

§256. Grants to strengthen the effectiveness, efficiency, and coordination of services for the uninsured and underinsured

(a) In general

The Secretary may award grants to eligible entities to assist in the development of integrated health care delivery systems to serve communities of individuals who are uninsured and individuals who are underinsured—

(1) to improve the efficiency of, and coordination among, the providers providing services through such systems;

(2) to assist communities in developing programs targeted toward preventing and managing chronic diseases; and

(3) to expand and enhance the services provided through such systems.

(b) Eligible entities

To be eligible to receive a grant under this section, an entity shall be an entity that—

(1) represents a consortium—

(A) whose principal purpose is to provide a broad range of coordinated health care services for a community defined in the entity's grant application as described in paragraph (2); and

(B) that includes at least one of each of the following providers that serve the community (unless such provider does not exist within the community, declines or refuses to participate, or places unreasonable conditions on their participation)—

(i) a Federally qualified health center (as defined in section 1395x(aa) of this title);

(ii) a hospital with a low-income utilization rate (as defined in section 1396r–4(b)(3) of this title), that is greater than 25 percent;

(iii) a public health department; and

(iv) an interested public or private sector health care provider or an organization that has traditionally served the medically uninsured and underserved; and

(2) submits to the Secretary an application, in such form and manner as the Secretary shall prescribe, that—

(A) defines a community or geographic area of uninsured and underinsured individuals;

(B) identifies the providers who will participate in the consortium's program under the grant, and specifies each provider's contribution to the care of uninsured and underinsured individuals in the community, including the volume of care the provider provides to beneficiaries under the medicare, medicaid, and State child health insurance programs and to patients who pay privately for services;

(C) describes the activities that the applicant and the consortium propose to perform under the grant to further the objectives of this section;

(D) demonstrates the consortium's ability to build on the current system (as of the date of submission of the application) for serving a community or geographic area of uninsured and underinsured individuals by involving providers who have traditionally provided a significant volume of care for that community;

(E) demonstrates the consortium's ability to develop coordinated systems of care that either directly provide or ensure the prompt provision of a broad range of high-quality, accessible

services, including, as appropriate, primary, secondary, and tertiary services, as well as substance abuse treatment and mental health services in a manner that assures continuity of care in the community or geographic area;

(F) provides evidence of community involvement in the development, implementation, and direction of the program that the entity proposes to operate;

(G) demonstrates the consortium's ability to ensure that individuals participating in the program are enrolled in public insurance programs for which the individuals are eligible or know of private insurance programs where available;

(H) presents a plan for leveraging other sources of revenue, which may include State and local sources and private grant funds, and integrating current and proposed new funding sources in a way to assure long-term sustainability of the program;

(I) describes a plan for evaluation of the activities carried out under the grant, including measurement of progress toward the goals and objectives of the program and the use of evaluation findings to improve program performance;

(J) demonstrates fiscal responsibility through the use of appropriate accounting procedures and appropriate management systems;

(K) demonstrates the consortium's commitment to serve the community without regard to the ability of an individual or family to pay by arranging for or providing free or reduced charge care for the poor; and

(L) includes such other information as the Secretary may prescribe.

(c) Limitations

(1) Number of awards

(A) In general

For each of fiscal years 2003, 2004, 2005, and 2006, the Secretary may not make more than 35 new awards under subsection (a) (excluding renewals of such awards).

(B) Rule of construction

This paragraph shall not be construed to affect awards made before fiscal year 2003.

(2) In general

An eligible entity may not receive a grant under this section (including with respect to any such grant made before fiscal year 2003) for more than 3 consecutive fiscal years, except that such entity may receive such a grant award for not more than 1 additional fiscal year if—

(A) the eligible entity submits to the Secretary a request for a grant for such an additional fiscal year;

(B) the Secretary determines that extraordinary circumstances (as defined in paragraph (3)) justify the granting of such request; and

(C) the Secretary determines that granting such request is necessary to further the objectives described in subsection (a).

(3) Extraordinary circumstances

(A) In general

In paragraph (2), the term "extraordinary circumstances" means an event (or events) that is outside of the control of the eligible entity that has prevented the eligible entity from fulfilling the objectives described by such entity in the application submitted under subsection (b)(2).

(B) Examples

Extraordinary circumstances include—

(i) natural disasters or other major disruptions to the security or health of the community or geographic area served by the eligible entity; or

(ii) a significant economic deterioration in the community or geographic area served by such eligible entity, that directly and adversely affects the entity receiving an award under subsection (a).

(d) Priorities

In awarding grants under this section, the Secretary—

(1) shall accord priority to applicants that demonstrate the extent of unmet need in the community involved for a more coordinated system of care; and

(2) may accord priority to applicants that best promote the objectives of this section, taking into consideration the extent to which the application involved—

(A) identifies a community whose geographical area has a high or increasing percentage of individuals who are uninsured;

(B) demonstrates that the applicant has included in its consortium providers, support systems, and programs that have a tradition of serving uninsured individuals and underinsured individuals in the community;

(C) shows evidence that the program would expand utilization of preventive and primary care services for uninsured and underinsured individuals and families in the community, including behavioral and mental health services, oral health services, or substance abuse services;

(D) proposes a program that would improve coordination between health care providers and appropriate social service providers;

(E) demonstrates collaboration with State and local governments;

(F) demonstrates that the applicant makes use of non-Federal contributions to the greatest extent possible; or

(G) demonstrates a likelihood that the proposed program will continue after support under this section ceases.

(e) Use of funds

(1) Use by grantees

(A) In general

Except as provided in paragraphs (2) and (3), a grantee may use amounts provided under this section only for—

(i) direct expenses associated with achieving the greater integration of a health care delivery system so that the system either directly provides or ensures the provision of a broad range of culturally competent services, as appropriate, including primary, secondary, and tertiary services, as well as substance abuse treatment and mental health services; and

(ii) direct patient care and service expansions to fill identified or documented gaps within an integrated delivery system.

(B) Specific uses

The following are examples of purposes for which a grantee may use grant funds under this section, when such use meets the conditions stated in subparagraph (A):

(i) Increases in outreach activities and closing gaps in health care service.

(ii) Improvements to case management.

(iii) Improvements to coordination of transportation to health care facilities.

(iv) Development of provider networks and other innovative models to engage physicians in voluntary efforts to serve the medically underserved within a community.

(v) Recruitment, training, and compensation of necessary personnel.

(vi) Acquisition of technology for the purpose of coordinating care.

(vii) Improvements to provider communication, including implementation of shared information systems or shared clinical systems.

(viii) Development of common processes for determining eligibility for the programs provided through the system, including creating common identification cards and single sliding scale discounts.

(ix) Development of specific prevention and disease management tools and processes.

(x) Translation services.

(xi) Carrying out other activities that may be appropriate to a community and that would increase access by the uninsured to health care, such as access initiatives for which private

entities provide non-Federal contributions to supplement the Federal funds provided through the grants for the initiatives.

(2) Direct patient care limitation

Not more than 15 percent of the funds provided under a grant awarded under this section may be used for providing direct patient care and services.

(3) Reservation of funds for national program purposes

The Secretary may use not more than 3 percent of funds appropriated to carry out this section for providing technical assistance to grantees, obtaining assistance of experts and consultants, holding meetings, developing of tools, disseminating of information, evaluation, and carrying out activities that will extend the benefits of programs funded under this section to communities other than the community served by the program funded.

(f) Grantee requirements

(1) Evaluation of effectiveness

A grantee under this section shall—

(A) report to the Secretary annually regarding—

(i) progress in meeting the goals and measurable objectives set forth in the grant application submitted by the grantee under subsection (b); and

(ii) the extent to which activities conducted by such grantee have—

(I) improved the effectiveness, efficiency, and coordination of services for uninsured and underinsured individuals in the communities or geographic areas served by such grantee;

(II) resulted in the provision of better quality health care for such individuals; and

(III) resulted in the provision of health care to such individuals at lower cost than would have been possible in the absence of the activities conducted by such grantee; and

(B) provide for an independent annual financial audit of all records that relate to the disposition of funds received through the grant.

(2) Progress

The Secretary may not renew an annual grant under this section for an entity for a fiscal year unless the Secretary is satisfied that the consortium represented by the entity has made reasonable and demonstrable progress in meeting the goals and measurable objectives set forth in the entity's grant application for the preceding fiscal year.

(g) Maintenance of effort

With respect to activities for which a grant under this section is authorized, the Secretary may award such a grant only if the applicant for the grant, and each of the participating providers, agree that the grantee and each such provider will maintain its expenditures of non-Federal funds for such activities at a level that is not less than the level of such expenditures during the fiscal year immediately preceding the fiscal year for which the applicant is applying to receive such grant.

(h) Technical assistance

The Secretary may, either directly or by grant or contract, provide any entity that receives a grant under this section with technical and other nonfinancial assistance necessary to meet the requirements of this section.

(i) Evaluation of program

Not later than September 30, 2005, the Secretary shall prepare and submit to the appropriate committees of Congress a report that describes the extent to which projects funded under this section have been successful in improving the effectiveness, efficiency, and coordination of services for uninsured and underinsured individuals in the communities or geographic areas served by such

projects, including whether the projects resulted in the provision of better quality health care for such individuals, and whether such care was provided at lower costs, than would have been provided in the absence of such projects.

(j) Demonstration authority

The Secretary may make demonstration awards under this section to historically black health professions schools for the purposes of—

(1) developing patient-based research infrastructure at historically black health professions schools, which have an affiliation, or affiliations, with any of the providers identified in subsection (b)(1)(B);

(2) establishment of joint and collaborative programs of medical research and data collection between historically black health professions schools and such providers, whose goal is to improve the health status of medically underserved populations; or

(3) supporting the research-related costs of patient care, data collection, and academic training resulting from such affiliations.

(k) Authorization of appropriations

There are authorized to be appropriated to carry out this section such sums as may be necessary for each of fiscal years 2002 through 2006.

(l) Date certain for termination of program

Funds may not be appropriated to carry out this section after September 30, 2006.

(July 1, 1944, ch. 373, title III, §340, as added Pub. L. 107–251, title IV, §402, Oct. 26, 2002, 116 Stat. 1655.)

EDITORIAL NOTES

PRIOR PROVISIONS

A prior section 256, act July 1, 1944, ch. 373, title III, §340, as added July 22, 1987, Pub. L. 100–77, title VI, §601, 101 Stat. 511; amended Nov. 4, 1988, Pub. L. 100–607, title VIII, §§801(a), (c), 802(a), (b)(1), 803, 804, 102 Stat. 3168, 3169; Nov. 7, 1988, Pub. L. 100–628, title VI, §§601(a), (c), 602(a), (b)(1), 603, 604, 102 Stat. 3241, 3242; Aug. 16, 1989, Pub. L. 101–93, §5(t)(1), (3), 103 Stat. 615; Nov. 29, 1990, Pub. L. 101–645, title V, §§501–503, 104 Stat. 4724; Oct. 27, 1992, Pub. L. 102–531, title III, §309(c), 106 Stat. 3501, related to grant program for certain health services for the homeless, prior to repeal by Pub. L. 104–299, §4(a)(3), Oct. 11, 1996, 110 Stat. 3645, eff. Oct. 1, 1996.

Another prior section 256, act July 1, 1944, ch. 373, title III, §340, as added Nov. 10, 1978, Pub. L. 95–626, title I, §115(2), 92 Stat. 3567; amended Dec. 12, 1979, Pub. L. 96–142, title III, §301(a), 93 Stat. 1073; Aug. 13, 1981, Pub. L. 97–35, title IX, §903(b)(1), 95 Stat. 561; Jan. 4, 1983, Pub. L. 97–414, §8(h), 96 Stat. 2061, related to primary care research and demonstration projects to serve medically underserved population, prior to repeal by Pub. L. 97–35, title IX, §903(c), Aug. 13, 1981, 95 Stat. 561, eff. Oct. 1, 1982.

Another prior section 256, act July 1, 1944, ch. 373, title III, §340, formerly §332, 58 Stat. 698; renumbered §340, Oct. 12, 1976, Pub. L. 94–484, title IV, §407(b)(2), 90 Stat. 2268, related to apprehension, detention, treatment, and release of persons being treated for leprosy, prior to repeal by Pub. L. 95–626, title I, §105(b), Nov. 10, 1978, 92 Stat. 3560.

STATUTORY NOTES AND RELATED SUBSIDIARIES

DEMONSTRATION PROJECT TO PROVIDE ACCESS TO AFFORDABLE CARE

Pub. L. 111–148, title X, §10504, Mar. 23, 2010, 124 Stat. 1004, provided that:

"(a) IN GENERAL.—Not later than 6 months after the date of enactment of this Act [Mar. 23, 2010], the Secretary of Health and Human Services (referred to in this section as the 'Secretary'), acting through the Health Resources and Services Administration, shall establish a 3 year demonstration project in up to 10 States to provide access to comprehensive health care services to the uninsured at reduced fees. The Secretary shall evaluate the feasibility of expanding the project to additional States.

"(b) ELIGIBILITY.—To be eligible to participate in the demonstration project, an entity shall be a State-based, nonprofit, public-private partnership that provides access to comprehensive health care services

to the uninsured at reduced fees. Each State in which a participant selected by the Secretary is located shall receive not more than $2,000,000 to establish and carry out the project for the 3-year demonstration period.

"(c) AUTHORIZATION.—There is authorized to be appropriated such sums as may be necessary to carry out this section."

PURPOSE

Pub. L. 107–251, title IV, §401, Oct. 26, 2002, 116 Stat. 1655, provided that: "The purpose of this title [enacting this subpart and subpart X (§256f et seq.) of this part and provisions set out as a note under section 1396a of this title] is to provide assistance to communities and consortia of health care providers and others, to develop or strengthen integrated community health care delivery systems that coordinate health care services for individuals who are uninsured or underinsured and to develop or strengthen activities related to providing coordinated care for individuals with chronic conditions who are uninsured or underinsured, through the—

"(1) coordination of services to allow individuals to receive efficient and higher quality care and to gain entry into and receive services from a comprehensive system of care;

"(2) development of the infrastructure for a health care delivery system characterized by effective collaboration, information sharing, and clinical and financial coordination among all providers of care in the community; and

"(3) provision of new Federal resources that do not supplant funding for existing Federal categorical programs that support entities providing services to low-income populations."

§256a. Patient navigator grants

(a) Grants

The Secretary, acting through the Administrator of the Health Resources and Services Administration, may make grants to eligible entities for the development and operation of demonstration programs to provide patient navigator services to improve health care outcomes. The Secretary shall coordinate with, and ensure the participation of, the Indian Health Service, the National Cancer Institute, the Office of Rural Health Policy, and such other offices and agencies as deemed appropriate by the Secretary, regarding the design and evaluation of the demonstration programs.

(b) Use of funds

The Secretary shall require each recipient of a grant under this section to use the grant to recruit, assign, train, and employ patient navigators who have direct knowledge of the communities they serve to facilitate the care of individuals, including by performing each of the following duties:

(1) Acting as contacts, including by assisting in the coordination of health care services and provider referrals, for individuals who are seeking prevention or early detection services for, or who following a screening or early detection service are found to have a symptom, abnormal finding, or diagnosis of, cancer or other chronic disease.

(2) Facilitating the involvement of community organizations in assisting individuals who are at risk for or who have cancer or other chronic diseases to receive better access to high-quality health care services (such as by creating partnerships with patient advocacy groups, charities, health care centers, community hospice centers, other health care providers, or other organizations in the targeted community).

(3) Notifying individuals of clinical trials and, on request, facilitating enrollment of eligible individuals in these trials.

(4) Anticipating, identifying, and helping patients to overcome barriers within the health care system to ensure prompt diagnostic and treatment resolution of an abnormal finding of cancer or other chronic disease.

(5) Coordinating with the relevant health insurance ombudsman programs to provide information to individuals who are at risk for or who have cancer or other chronic diseases about health coverage, including private insurance, health care savings accounts, and other publicly funded programs (such as Medicare, Medicaid, health programs operated by the Department of Veterans Affairs or the Department of Defense, the State children's health insurance program, and any private or governmental prescription assistance programs).

(6) Conducting ongoing outreach to health disparity populations, including the uninsured, rural populations, and other medically underserved populations, in addition to assisting other individuals who are at risk for or who have cancer or other chronic diseases to seek preventative care.

(c) Prohibitions

(1) Referral fees

The Secretary shall require each recipient of a grant under this section to prohibit any patient navigator providing services under the grant from accepting any referral fee, kickback, or other thing of value in return for referring an individual to a particular health care provider.

(2) Legal fees and costs

The Secretary shall prohibit the use of any grant funds received under this section to pay any fees or costs resulting from any litigation, arbitration, mediation, or other proceeding to resolve a legal dispute.

(d) Grant period

(1) In general

Subject to paragraphs (2) and (3), the Secretary may award grants under this section for periods of not more than 3 years.

(2) Extensions

Subject to paragraph (3), the Secretary may extend the period of a grant under this section. Each such extension shall be for a period of not more than 1 year.

(3) Limitations on grant period

In carrying out this section, the Secretary shall ensure that the total period of a grant does not exceed 4 years.

(e) Application

(1) In general

To seek a grant under this section, an eligible entity shall submit an application to the Secretary in such form, in such manner, and containing such information as the Secretary may require.

(2) Contents

At a minimum, the Secretary shall require each such application to outline how the eligible entity will establish baseline measures and benchmarks that meet the Secretary's requirements to evaluate program outcomes.

(3) Minimum core proficiencies

The Secretary shall not award a grant to an entity under this section unless such entity provides assurances that patient navigators recruited, assigned, trained, or employed using grant funds meet minimum core proficiencies, as defined by the entity that submits the application, that are tailored for the main focus or intervention of the navigator involved.

(f) Uniform baseline measures

The Secretary shall establish uniform baseline measures in order to properly evaluate the impact of the demonstration projects under this section.

(g) Preference

In making grants under this section, the Secretary shall give preference to eligible entities that demonstrate in their applications plans to utilize patient navigator services to overcome significant barriers in order to improve health care outcomes in their respective communities.

(h) Duplication of services

An eligible entity that is receiving Federal funds for activities described in subsection (b) on the

date on which the entity submits an application under subsection (e) may not receive a grant under this section unless the entity can demonstrate that amounts received under the grant will be utilized to expand services or provide new services to individuals who would not otherwise be served.

(i) Coordination with other programs

The Secretary shall ensure coordination of the demonstration grant program under this section with existing authorized programs in order to facilitate access to high-quality health care services.

(j) Study; reports

(1) Final report by Secretary

Not later than 6 months after the completion of the demonstration grant program under this section, the Secretary shall conduct a study of the results of the program and submit to the Congress a report on such results that includes the following:

(A) An evaluation of the program outcomes, including—

(i) quantitative analysis of baseline and benchmark measures; and

(ii) aggregate information about the patients served and program activities.

(B) Recommendations on whether patient navigator programs could be used to improve patient outcomes in other public health areas.

(2) Interim reports by Secretary

The Secretary may provide interim reports to the Congress on the demonstration grant program under this section at such intervals as the Secretary determines to be appropriate.

(3) Reports by grantees

The Secretary may require grant recipients under this section to submit interim and final reports on grant program outcomes.

(k) Rule of construction

This section shall not be construed to authorize funding for the delivery of health care services (other than the patient navigator duties listed in subsection (b)).

(l) Definitions

In this section:

(1) The term "eligible entity" means a public or nonprofit private health center (including a Federally qualified health center (as that term is defined in section 1395x(aa)(4) of this title)), a health facility operated by or pursuant to a contract with the Indian Health Service, a hospital, a cancer center, a rural health clinic, an academic health center, or a nonprofit entity that enters into a partnership or coordinates referrals with such a center, clinic, facility, or hospital to provide patient navigator services.

(2) The term "health disparity population" means a population that, as determined by the Secretary, has a significant disparity in the overall rate of disease incidence, prevalence, morbidity, mortality, or survival rates as compared to the health status of the general population.

(3) The term "patient navigator" means an individual who has completed a training program approved by the Secretary to perform the duties listed in subsection (b).

(m) Authorization of appropriations

(1) In general

To carry out this section, there are authorized to be appropriated $2,000,000 for fiscal year 2006, $5,000,000 for fiscal year 2007, $8,000,000 for fiscal year 2008, $6,500,000 for fiscal year 2009, $3,500,000 for fiscal year 2010, and such sums as may be necessary for each of fiscal years 2011 through 2015.

(2) Availability

The amounts appropriated pursuant to paragraph (1) shall remain available for obligation through the end of fiscal year 2015.

(July 1, 1944, ch. 373, title III, §340A, as added Pub. L. 109–18, §2, June 29, 2005, 119 Stat. 340; amended Pub. L. 111–148, title III, §3510, Mar. 23, 2010, 124 Stat. 537.)

EDITORIAL NOTES

PRIOR PROVISIONS

A prior section 256a, act July 1, 1944, ch. 373, title III, §340A, as added Nov. 6, 1990, Pub. L. 101–527, §3, 104 Stat. 2314; amended Oct. 27, 1992, Pub. L. 102–531, title III, §309(d), 106 Stat. 3502, related to health services for residents of public housing, prior to repeal by Pub. L. 104–299, §§4(a)(3), 5, Oct. 11, 1996, 110 Stat. 3645, effective Oct. 1, 1996.

Another prior section 256a, act July 1, 1944, ch. 373, title III, §340A, as added Nov. 10, 1978, Pub. L. 95–626, title I, §106(a), 92 Stat. 3560, related to technical assistance demonstration grants and contracts, prior to repeal by Pub. L. 100–77, title VI, §601, July 22, 1987, 101 Stat. 511.

AMENDMENTS

2010—Subsec. (d)(3). Pub. L. 111–148, §3510(1), added par. (3) and struck out former par. (3). Prior to amendment, text read as follows: "In carrying out this section, the Secretary—

"(A) shall ensure that the total period of a grant does not exceed 4 years; and

"(B) may not authorize any grant period ending after September 30, 2010."

Subsec. (e)(3). Pub. L. 111–148, §3510(2), added par. (3).

Subsec. (m)(1). Pub. L. 111–148, §3510(3)(A), substituted "$3,500,000 for fiscal year 2010, and such sums as may be necessary for each of fiscal years 2011 through 2015" for "and $3,500,000 for fiscal year 2010".

Subsec. (m)(2). Pub. L. 111–148, §3510(3)(B), substituted "2015" for "2010".

§256a–1. Establishing community health teams to support the patient-centered medical home

(a) In general

The Secretary of Health and Human Services (referred to in this section as the "Secretary") shall establish a program to provide grants to or enter into contracts with eligible entities to establish community-based interdisciplinary, interprofessional teams (referred to in this section as "health teams") to support primary care practices, including obstetrics and gynecology practices, within the hospital service areas served by the eligible entities. Grants or contracts shall be used to—

(1) establish health teams to provide support services to primary care providers; and

(2) provide capitated payments to primary care providers as determined by the Secretary.

(b) Eligible entities

To be eligible to receive a grant or contract under subsection (a), an entity shall—

(1)(A) be a State or State-designated entity; or

(B) be an Indian tribe or tribal organization, as defined in section 1603 of title 25;

(2) submit a plan for achieving long-term financial sustainability within 3 years;

(3) submit a plan for incorporating prevention initiatives and patient education and care management resources into the delivery of health care that is integrated with community-based prevention and treatment resources, where available;

(4) ensure that the health team established by the entity includes an interdisciplinary, interprofessional team of health care providers, as determined by the Secretary; such team may include medical specialists, nurses, pharmacists, nutritionists, dieticians, social workers, behavioral and mental health providers (including substance use disorder prevention and treatment providers), doctors of chiropractic, licensed complementary and alternative medicine practitioners, and physicians' assistants;

(5) agree to provide services to eligible individuals with chronic conditions, as described in section 1396w–4 of this title (as added by section 2703), in accordance with the payment methodology established under subsection (c) of such section; and

(6) submit to the Secretary an application at such time, in such manner, and containing such

information as the Secretary may require.

(c) Requirements for health teams

A health team established pursuant to a grant or contract under subsection (a) shall—

(1) establish contractual agreements with primary care providers to provide support services;

(2) support patient-centered medical homes, defined as a mode of care that includes—

(A) personal physicians or other primary care providers;

(B) whole person orientation;

(C) coordinated and integrated care;

(D) safe and high-quality care through evidence-informed medicine, appropriate use of health information technology, and continuous quality improvements;

(E) expanded access to care; and

(F) payment that recognizes added value from additional components of patient-centered care;

(3) collaborate with local primary care providers and existing State and community based resources to coordinate disease prevention, chronic disease management, transitioning between health care providers and settings and case management for patients, including children, with priority given to those amenable to prevention and with chronic diseases or conditions identified by the Secretary;

(4) in collaboration with local health care providers, develop and implement interdisciplinary, interprofessional care plans that integrate clinical and community preventive and health promotion services for patients, including children, with a priority given to those amenable to prevention and with chronic diseases or conditions identified by the Secretary;

(5) incorporate health care providers, patients, caregivers, and authorized representatives in program design and oversight;

(6) provide support necessary for local primary care providers to—

(A) coordinate and provide access to high-quality health care services;

(B) coordinate and provide access to preventive and health promotion services;

(C) provide access to appropriate specialty care and inpatient services;

(D) provide quality-driven, cost-effective, culturally appropriate, and patient- and family-centered health care;

(E) provide access to pharmacist-delivered medication management services, including medication reconciliation;

(F) provide coordination of the appropriate use of complementary and alternative (CAM) services to those who request such services;

(G) promote effective strategies for treatment planning, monitoring health outcomes and resource use, sharing information, treatment decision support, and organizing care to avoid duplication of service and other medical management approaches intended to improve quality and value of health care services;

(H) provide local access to the continuum of health care services in the most appropriate setting, including access to individuals that implement the care plans of patients and coordinate care, such as integrative health care practitioners;

(I) collect and report data that permits evaluation of the success of the collaborative effort on patient outcomes, including collection of data on patient experience of care, and identification of areas for improvement; and

(J) establish a coordinated system of early identification and referral for children at risk for developmental or behavioral problems such as through the use of infolines, health information technology, or other means as determined by the Secretary;

(7) provide 24-hour care management and support during transitions in care settings including—

(A) a transitional care program that provides onsite visits from the care coordinator,[1] assists

with the development of discharge plans and medication reconciliation upon admission to and discharge from the hospitals,[2] nursing home, or other institution setting;

(B) discharge planning and counseling support to providers, patients, caregivers, and authorized representatives;

(C) assuring that post-discharge care plans include medication management, as appropriate;

(D) referrals for mental and behavioral health services, which may include the use of infolines; and

(E) transitional health care needs from adolescence to adulthood;

(8) serve as a liaison to community prevention and treatment programs;

(9) demonstrate a capacity to implement and maintain health information technology that meets the requirements of certified EHR technology (as defined in section 300jj of this title) to facilitate coordination among members of the applicable care team and affiliated primary care practices; and

(10) where applicable, report to the Secretary information on quality measures used under section 280j–2 of this title.

(d) Requirement for primary care providers

A provider who contracts with a care team shall—

(1) provide a care plan to the care team for each patient participant;

(2) provide access to participant health records; and

(3) meet regularly with the care team to ensure integration of care.

(e) Reporting to Secretary

An entity that receives a grant or contract under subsection (a) shall submit to the Secretary a report that describes and evaluates, as requested by the Secretary, the activities carried out by the entity under subsection (c).

(f) Definition of primary care

In this section, the term "primary care" means the provision of integrated, accessible health care services by clinicians who are accountable for addressing a large majority of personal health care needs, developing a sustained partnership with patients, and practicing in the context of family and community.

(Pub. L. 111–148, title III, §3502, title X, §10321, Mar. 23, 2010, 124 Stat. 513, 952.)

EDITORIAL NOTES

REFERENCES IN TEXT

Section 2703, referred to in subsec. (b)(5), means section 2703 of Pub. L. 111–148.

CODIFICATION

Section was enacted as part of the Patient Protection and Affordable Care Act, and not as part of the Public Health Service Act which comprises this chapter.

AMENDMENTS

2010—Subsec. (c)(2)(A). Pub. L. 111–148, §10321, inserted "or other primary care providers" after "physicians".

[1] So in original. The comma probably should be "and".

[2] So in original. Probably should be "hospital,".

SUBPART VII—DRUG PRICING AGREEMENTS

§256b. Limitation on prices of drugs purchased by covered entities

(a) Requirements for agreement with Secretary

(1) In general

The Secretary shall enter into an agreement with each manufacturer of covered outpatient drugs under which the amount required to be paid (taking into account any rebate or discount, as provided by the Secretary) to the manufacturer for covered outpatient drugs (other than drugs described in paragraph (3)) purchased by a covered entity on or after the first day of the first month that begins after November 4, 1992, does not exceed an amount equal to the average manufacturer price for the drug under title XIX of the Social Security Act [42 U.S.C. 1396 et seq.] in the preceding calendar quarter, reduced by the rebate percentage described in paragraph (2). Each such agreement shall require that the manufacturer furnish the Secretary with reports, on a quarterly basis, of the price for each covered outpatient drug subject to the agreement that, according to the manufacturer, represents the maximum price that covered entities may permissibly be required to pay for the drug (referred to in this section as the "ceiling price"), and shall require that the manufacturer offer each covered entity covered outpatient drugs for purchase at or below the applicable ceiling price if such drug is made available to any other purchaser at any price.

(2) "Rebate percentage" defined

(A) In general

For a covered outpatient drug purchased in a calendar quarter, the "rebate percentage" is the amount (expressed as a percentage) equal to—

(i) the average total rebate required under section 1927(c) of the Social Security Act [42 U.S.C. 1396r–8(c)] with respect to the drug (for a unit of the dosage form and strength involved) during the preceding calendar quarter; divided by

(ii) the average manufacturer price for such a unit of the drug during such quarter.

(B) Over the counter drugs

(i) In general

For purposes of subparagraph (A), in the case of over the counter drugs, the "rebate percentage" shall be determined as if the rebate required under section 1927(c) of the Social Security Act [42 U.S.C. 1396r–8(c)] is based on the applicable percentage provided under section 1927(c)(3) of such Act.

(ii) "Over the counter drug" defined

The term "over the counter drug" means a drug that may be sold without a prescription and which is prescribed by a physician (or other persons authorized to prescribe such drug under State law).

(3) Drugs provided under State medicaid plans

Drugs described in this paragraph are drugs purchased by the entity for which payment is made by the State under the State plan for medical assistance under title XIX of the Social Security Act [42 U.S.C. 1396 et seq.].

(4) "Covered entity" defined

In this section, the term "covered entity" means an entity that meets the requirements described in paragraph (5) and is one of the following:

(A) A Federally-qualified health center (as defined in section 1905(l)(2)(B) of the Social Security Act [42 U.S.C. 1396d(l)(2)(B)]).

(B) An entity receiving a grant under section 256a [1] of this title.

(C) A family planning project receiving a grant or contract under section 300 of this title.

(D) An entity receiving a grant under subpart II [1] of part C of subchapter XXIV (relating to categorical grants for outpatient early intervention services for HIV disease).

(E) A State-operated AIDS drug purchasing assistance program receiving financial assistance under subchapter XXIV.

(F) A black lung clinic receiving funds under section 937(a) of title 30.

(G) A comprehensive hemophilia diagnostic treatment center receiving a grant under section 501(a)(2) of the Social Security Act [42 U.S.C. 701(a)(2)].

(H) A Native Hawaiian Health Center receiving funds under the Native Hawaiian Health Care Act of 1988.

(I) An urban Indian organization receiving funds under title V of the Indian Health Care Improvement Act [25 U.S.C. 1651 et seq.].

(J) Any entity receiving assistance under subchapter XXIV (other than a State or unit of local government or an entity described in subparagraph (D)), but only if the entity is certified by the Secretary pursuant to paragraph (7).

(K) An entity receiving funds under section 247c of this title (relating to treatment of sexually transmitted diseases) or section 247b(j)(2) [1] of this title (relating to treatment of tuberculosis) through a State or unit of local government, but only if the entity is certified by the Secretary pursuant to paragraph (7).

(L) A subsection (d) hospital (as defined in section 1886(d)(1)(B) of the Social Security Act [42 U.S.C. 1395ww(d)(1)(B)]) that—

(i) is owned or operated by a unit of State or local government, is a public or private non-profit corporation which is formally granted governmental powers by a unit of State or local government, or is a private non-profit hospital which has a contract with a State or local government to provide health care services to low income individuals who are not entitled to benefits under title XVIII of the Social Security Act [42 U.S.C. 1395 et seq.] or eligible for assistance under the State plan under this subchapter;

(ii) for the most recent cost reporting period that ended before the calendar quarter involved, had a disproportionate share adjustment percentage (as determined under section 1886(d)(5)(F) of the Social Security Act [42 U.S.C. 1395ww(d)(5)(F)]) greater than 11.75 percent or was described in section 1886(d)(5)(F)(i)(II) of such Act [42 U.S.C. 1395ww(d)(5)(F)(i)(II)]; and

(iii) does not obtain covered outpatient drugs through a group purchasing organization or other group purchasing arrangement.

(M) A children's hospital excluded from the Medicare prospective payment system pursuant to section 1886(d)(1)(B)(iii) of the Social Security Act [42 U.S.C. 1395ww(d)(1)(B)(iii)], or a free-standing cancer hospital excluded from the Medicare prospective payment system pursuant to section 1886(d)(1)(B)(v) of the Social Security Act, that would meet the requirements of subparagraph (L), including the disproportionate share adjustment percentage requirement under clause (ii) of such subparagraph, if the hospital were a subsection (d) hospital as defined by section 1886(d)(1)(B) of the Social Security Act.

(N) An entity that is a critical access hospital (as determined under section 1820(c)(2) of the Social Security Act [42 U.S.C. 1395i–4(c)(2)]), and that meets the requirements of subparagraph (L)(i).

(O) An entity that is a rural referral center, as defined by section 1886(d)(5)(C)(i) of the Social Security Act [42 U.S.C. 1395ww(d)(5)(C)(i)], or a sole community hospital, as defined by section 1886(d)(5)(C)(iii) of such Act, and that both meets the requirements of subparagraph (L)(i) and has a disproportionate share adjustment percentage equal to or greater than 8 percent.

(5) Requirements for covered entities

(A) Prohibiting duplicate discounts or rebates

(i) In general

A covered entity shall not request payment under title XIX of the Social Security Act [42 U.S.C. 1396 et seq.] for medical assistance described in section 1905(a)(12) of such Act [42 U.S.C. 1396d(a)(12)] with respect to a drug that is subject to an agreement under this section if the drug is subject to the payment of a rebate to the State under section 1927 of such Act [42 U.S.C. 1396r–8].

(ii) Establishment of mechanism

The Secretary shall establish a mechanism to ensure that covered entities comply with clause (i). If the Secretary does not establish a mechanism within 12 months under the previous sentence, the requirements of section 1927(a)(5)(C) of the Social Security Act [42 U.S.C. 1396r–8(a)(5)(C)] shall apply.

(B) Prohibiting resale of drugs

With respect to any covered outpatient drug that is subject to an agreement under this subsection, a covered entity shall not resell or otherwise transfer the drug to a person who is not a patient of the entity.

(C) Auditing

A covered entity shall permit the Secretary and the manufacturer of a covered outpatient drug that is subject to an agreement under this subsection with the entity (acting in accordance with procedures established by the Secretary relating to the number, duration, and scope of audits) to audit at the Secretary's or the manufacturer's expense the records of the entity that directly pertain to the entity's compliance with the requirements described in subparagraphs [2] (A) or (B) with respect to drugs of the manufacturer.

(D) Additional sanction for noncompliance

If the Secretary finds, after audit as described in subparagraph (C) and after notice and hearing, that a covered entity is in violation of a requirement described in subparagraphs [2] (A) or (B), the covered entity shall be liable to the manufacturer of the covered outpatient drug that is the subject of the violation in an amount equal to the reduction in the price of the drug (as described in subparagraph (A)) provided under the agreement between the entity and the manufacturer under this paragraph.

(6) Treatment of distinct units of hospitals

In the case of a covered entity that is a distinct part of a hospital, the hospital shall not be considered a covered entity under this paragraph unless the hospital is otherwise a covered entity under this subsection.

(7) Certification of certain covered entities

(A) Development of process

Not later than 60 days after November 4, 1992, the Secretary shall develop and implement a process for the certification of entities described in subparagraphs (J) and (K) of paragraph (4).

(B) Inclusion of purchase information

The process developed under subparagraph (A) shall include a requirement that an entity applying for certification under this paragraph submit information to the Secretary concerning the amount such entity expended for covered outpatient drugs in the preceding year so as to assist the Secretary in evaluating the validity of the entity's subsequent purchases of covered outpatient drugs at discounted prices.

(C) Criteria

The Secretary shall make available to all manufacturers of covered outpatient drugs a description of the criteria for certification under this paragraph.

(D) List of purchasers and dispensers

The certification process developed by the Secretary under subparagraph (A) shall include

procedures under which each State shall, not later than 30 days after the submission of the descriptions under subparagraph (C), prepare and submit a report to the Secretary that contains a list of entities described in subparagraphs (J) and (K) of paragraph (4) that are located in the State.

(E) Recertification

The Secretary shall require the recertification of entities certified pursuant to this paragraph on a not more frequent than annual basis, and shall require that such entities submit information to the Secretary to permit the Secretary to evaluate the validity of subsequent purchases by such entities in the same manner as that required under subparagraph (B).

(8) Development of prime vendor program

The Secretary shall establish a prime vendor program under which covered entities may enter into contracts with prime vendors for the distribution of covered outpatient drugs. If a covered entity obtains drugs directly from a manufacturer, the manufacturer shall be responsible for the costs of distribution.

(9) Notice to manufacturers

The Secretary shall notify manufacturers of covered outpatient drugs and single State agencies under section 1902(a)(5) of the Social Security Act [42 U.S.C. 1396a(a)(5)] of the identities of covered entities under this paragraph, and of entities that no longer meet the requirements of paragraph (5) or that are no longer certified pursuant to paragraph (7).

(10) No prohibition on larger discount

Nothing in this subsection shall prohibit a manufacturer from charging a price for a drug that is lower than the maximum price that may be charged under paragraph (1).

(b) Other definitions

(1) In general

In this section, the terms "average manufacturer price", "covered outpatient drug", and "manufacturer" have the meaning given such terms in section 1927(k) of the Social Security Act [42 U.S.C. 1396r–8(k)].

(2) Covered drug

In this section, the term "covered drug"—

(A) means a covered outpatient drug (as defined in section 1927(k)(2) of the Social Security Act [42 U.S.C. 1396r–8(k)(2)]); and

(B) includes, notwithstanding paragraph (3)(A) of section 1927(k) of such Act [42 U.S.C. 1396r–8(k)(3)(A)], a drug used in connection with an inpatient or outpatient service provided by a hospital described in subparagraph (L), (M), (N), or (O) of subsection (a)(4) that is enrolled to participate in the drug discount program under this section.

(c) Repealed. Pub. L. 111–152, title II, §2302(2), Mar. 30, 2010, 124 Stat. 1083

(d) Improvements in program integrity

(1) Manufacturer compliance

(A) In general

From amounts appropriated under paragraph (4), the Secretary shall provide for improvements in compliance by manufacturers with the requirements of this section in order to prevent overcharges and other violations of the discounted pricing requirements specified in this section.

(B) Improvements

The improvements described in subparagraph (A) shall include the following:

(i) The development of a system to enable the Secretary to verify the accuracy of ceiling prices calculated by manufacturers under subsection (a)(1) and charged to covered entities,

which shall include the following:

(I) Developing and publishing through an appropriate policy or regulatory issuance, precisely defined standards and methodology for the calculation of ceiling prices under such subsection.

(II) Comparing regularly the ceiling prices calculated by the Secretary with the quarterly pricing data that is reported by manufacturers to the Secretary.

(III) Performing spot checks of sales transactions by covered entities.

(IV) Inquiring into the cause of any pricing discrepancies that may be identified and either taking, or requiring manufacturers to take, such corrective action as is appropriate in response to such price discrepancies.

(ii) The establishment of procedures for manufacturers to issue refunds to covered entities in the event that there is an overcharge by the manufacturers, including the following:

(I) Providing the Secretary with an explanation of why and how the overcharge occurred, how the refunds will be calculated, and to whom the refunds will be issued.

(II) Oversight by the Secretary to ensure that the refunds are issued accurately and within a reasonable period of time, both in routine instances of retroactive adjustment to relevant pricing data and exceptional circumstances such as erroneous or intentional overcharging for covered outpatient drugs.

(iii) The provision of access through the Internet website of the Department of Health and Human Services to the applicable ceiling prices for covered outpatient drugs as calculated and verified by the Secretary in accordance with this section, in a manner (such as through the use of password protection) that limits such access to covered entities and adequately assures security and protection of privileged pricing data from unauthorized re-disclosure.

(iv) The development of a mechanism by which—

(I) rebates and other discounts provided by manufacturers to other purchasers subsequent to the sale of covered outpatient drugs to covered entities are reported to the Secretary; and

(II) appropriate credits and refunds are issued to covered entities if such discounts or rebates have the effect of lowering the applicable ceiling price for the relevant quarter for the drugs involved.

(v) Selective auditing of manufacturers and wholesalers to ensure the integrity of the drug discount program under this section.

(vi) The imposition of sanctions in the form of civil monetary penalties, which—

(I) shall be assessed according to standards established in regulations to be promulgated by the Secretary not later than 180 days after March 23, 2010;

(II) shall not exceed $5,000 for each instance of overcharging a covered entity that may have occurred; and

(III) shall apply to any manufacturer with an agreement under this section that knowingly and intentionally charges a covered entity a price for purchase of a drug that exceeds the maximum applicable price under subsection (a)(1).

(2) Covered entity compliance

(A) In general

From amounts appropriated under paragraph (4), the Secretary shall provide for improvements in compliance by covered entities with the requirements of this section in order to prevent diversion and violations of the duplicate discount provision and other requirements specified under subsection (a)(5).

(B) Improvements

The improvements described in subparagraph (A) shall include the following:

(i) The development of procedures to enable and require covered entities to regularly

update (at least annually) the information on the Internet website of the Department of Health and Human Services relating to this section.

(ii) The development of a system for the Secretary to verify the accuracy of information regarding covered entities that is listed on the website described in clause (i).

(iii) The development of more detailed guidance describing methodologies and options available to covered entities for billing covered outpatient drugs to State Medicaid agencies in a manner that avoids duplicate discounts pursuant to subsection (a)(5)(A).

(iv) The establishment of a single, universal, and standardized identification system by which each covered entity site can be identified by manufacturers, distributors, covered entities, and the Secretary for purposes of facilitating the ordering, purchasing, and delivery of covered outpatient drugs under this section, including the processing of chargebacks for such drugs.

(v) The imposition of sanctions, in appropriate cases as determined by the Secretary, additional to those to which covered entities are subject under subsection (a)(5)(D), through one or more of the following actions:

(I) Where a covered entity knowingly and intentionally violates subsection (a)(5)(B), the covered entity shall be required to pay a monetary penalty to a manufacturer or manufacturers in the form of interest on sums for which the covered entity is found liable under subsection (a)(5)(D), such interest to be compounded monthly and equal to the current short term interest rate as determined by the Federal Reserve for the time period for which the covered entity is liable.

(II) Where the Secretary determines a violation of subsection (a)(5)(B) was systematic and egregious as well as knowing and intentional, removing the covered entity from the drug discount program under this section and disqualifying the entity from re-entry into such program for a reasonable period of time to be determined by the Secretary.

(III) Referring matters to appropriate Federal authorities within the Food and Drug Administration, the Office of Inspector General of Department of Health and Human Services, or other Federal agencies for consideration of appropriate action under other Federal statutes, such as the Prescription Drug Marketing Act (21 U.S.C. 353).[1]

(3) Administrative dispute resolution process

(A) In general

Not later than 180 days after March 23, 2010, the Secretary shall promulgate regulations to establish and implement an administrative process for the resolution of claims by covered entities that they have been overcharged for drugs purchased under this section, and claims by manufacturers, after the conduct of audits as authorized by subsection (a)(5)(C), of violations of subsections [3] (a)(5)(A) or (a)(5)(B), including appropriate procedures for the provision of remedies and enforcement of determinations made pursuant to such process through mechanisms and sanctions described in paragraphs (1)(B) and (2)(B).

(B) Deadlines and procedures

Regulations promulgated by the Secretary under subparagraph (A) shall—

(i) designate or establish a decision-making official or decision-making body within the Department of Health and Human Services to be responsible for reviewing and finally resolving claims by covered entities that they have been charged prices for covered outpatient drugs in excess of the ceiling price described in subsection (a)(1), and claims by manufacturers that violations of subsection (a)(5)(A) or (a)(5)(B) have occurred;

(ii) establish such deadlines and procedures as may be necessary to ensure that claims shall be resolved fairly, efficiently, and expeditiously;

(iii) establish procedures by which a covered entity may discover and obtain such information and documents from manufacturers and third parties as may be relevant to

demonstrate the merits of a claim that charges for a manufacturer's product have exceeded the applicable ceiling price under this section, and may submit such documents and information to the administrative official or body responsible for adjudicating such claim;

(iv) require that a manufacturer conduct an audit of a covered entity pursuant to subsection (a)(5)(C) as a prerequisite to initiating administrative dispute resolution proceedings against a covered entity;

(v) permit the official or body designated under clause (i), at the request of a manufacturer or manufacturers, to consolidate claims brought by more than one manufacturer against the same covered entity where, in the judgment of such official or body, consolidation is appropriate and consistent with the goals of fairness and economy of resources; and

(vi) include provisions and procedures to permit multiple covered entities to jointly assert claims of overcharges by the same manufacturer for the same drug or drugs in one administrative proceeding, and permit such claims to be asserted on behalf of covered entities by associations or organizations representing the interests of such covered entities and of which the covered entities are members.

(C) Finality of administrative resolution

The administrative resolution of a claim or claims under the regulations promulgated under subparagraph (A) shall be a final agency decision and shall be binding upon the parties involved, unless invalidated by an order of a court of competent jurisdiction.

(4) Authorization of appropriations

There are authorized to be appropriated to carry out this subsection, such sums as may be necessary for fiscal year 2010 and each succeeding fiscal year.

(e) Exclusion of orphan drugs for certain covered entities

For covered entities described in subparagraph (M) (other than a children's hospital described in subparagraph (M)), (N), or (O) of subsection (a)(4), the term "covered outpatient drug" shall not include a drug designated by the Secretary under section 360bb of title 21 for a rare disease or condition.

(July 1, 1944, ch. 373, title III, §340B, as added Pub. L. 102–585, title VI, §602(a), Nov. 4, 1992, 106 Stat. 4967; amended Pub. L. 103–43, title XX, §2008(i)(1)(A), June 10, 1993, 107 Stat. 212; Pub. L. 111–148, title II, §2501(f)(1), title VII, §§7101(a)–(d), 7102, Mar. 23, 2010, 124 Stat. 309, 821–823; Pub. L. 111–152, title II, §2302, Mar. 30, 2010, 124 Stat. 1082; Pub. L. 111–309, title II, §204(a)(1), Dec. 15, 2010, 124 Stat. 3289.)

EDITORIAL NOTES

REFERENCES IN TEXT

The Social Security Act, referred to in subsec. (a)(1), (3), (4)(L)(i), (5)(A)(i), is act Aug. 14, 1935, ch. 531, 49 Stat. 620, which is classified generally to chapter 7 (§301 et seq.) of this title. Titles XVIII and XIX of the Act are classified generally to subchapters XVIII (§1395 et seq.) and XIX (§1396 et seq.) of chapter 7 of this title, respectively. For complete classification of this Act to the Code, see section 1305 of this title and Tables.

Section 256a of this title, referred to in subsec. (a)(4)(B), was in the original a reference to section 340A of act July 1, 1944, which was repealed by Pub. L. 104–299, §4(a)(3), Oct. 11, 1996, 110 Stat. 3645. Subsequently, a new section 340A was added to the act of July 1, 1944, by Pub. L. 109–18, §2, June 29, 2005, 119 Stat. 340, which is also classified to section 256a of this title.

Subpart II of part C of subchapter XXIV, referred to in subsec. (a)(4)(D), was redesignated subpart I of part C of subchapter XXIV of this chapter by Pub. L. 106–345, title III, §301(b)(1), Oct. 20, 2000, 114 Stat. 1345, and is classified to section 300ff–51 et seq. of this title.

The Native Hawaiian Health Care Act of 1988, referred to in subsec. (a)(4)(H), was Pub. L. 100–579, Oct. 31, 1988, 102 Stat. 2916, and subtitle D of title II of Pub. L. 100–690, Nov. 18, 1988, 102 Stat. 4222, which were classified generally to chapter 122 (§11701 et seq.) of this title prior to being amended generally and renamed the Native Hawaiian Health Care Improvement Act by Pub. L. 102–396. For complete classification of this Act to the Code, see Tables.

The Indian Health Care Improvement Act, referred to in subsec. (a)(4)(I), is Pub. L. 94–437, Sept. 30, 1976, 90 Stat. 1400. Title V of the Act is classified generally to subchapter IV (§1651 et seq.) of chapter 18 of Title 25, Indians. For complete classification of this Act to the Code, see Short Title note set out under section 1601 of Title 25 and Tables.

Section 247b(j)(2) of this title, referred to in subsec. (a)(4)(K), was repealed and section 247b(j)(1)(B) was redesignated section 247b(j)(2) by Pub. L. 103–183, title III, §301(b)(1)(A), (C), Dec. 14, 1993, 107 Stat. 2235.

The Prescription Drug Marketing Act, referred to in subsec. (d)(2)(B)(v)(III), probably means the Prescription Drug Marketing Act of 1987, Pub. L. 100–293, Apr. 22, 1988, 102 Stat. 95, which amended sections 331, 333, 353, and 381 of Title 21, Food and Drugs, and enacted provisions set out as notes under sections 301 and 353 of Title 21. For complete classification of this Act to the Code, see Short Title of 1988 Amendments note set out under section 301 of Title 21 and Tables.

CODIFICATION

Another section 340B of act July 1, 1944, was renumbered section 340C and is classified to section 256c of this title.

AMENDMENTS

2010—Subsec. (a)(1). Pub. L. 111–152, §2302(1)(A), substituted "covered outpatient drug" for "covered drug" and "covered outpatient drugs" for "covered drugs" wherever appearing.

Pub. L. 111–148, §7102(b)(1), inserted at end "Each such agreement shall require that the manufacturer furnish the Secretary with reports, on a quarterly basis, of the price for each covered drug subject to the agreement that, according to the manufacturer, represents the maximum price that covered entities may permissibly be required to pay for the drug (referred to in this section as the 'ceiling price'), and shall require that the manufacturer offer each covered entity covered drugs for purchase at or below the applicable ceiling price if such drug is made available to any other purchaser at any price."

Subsec. (a)(2)(A). Pub. L. 111–152, §2302(1)(A), substituted "covered outpatient drug" for "covered drug" in introductory provisions.

Pub. L. 111–148, §7101(b)(1), substituted "covered drug" for "covered outpatient drug" in introductory provisions.

Subsec. (a)(2)(B)(i). Pub. L. 111–148, §2501(f)(1)(A), substituted "1927(c)(3)" for "1927(c)(4)".

Subsec. (a)(4)(L). Pub. L. 111–152, §2302(1)(B), struck out "and" at end of cl. (i), substituted "; and" for period at end of cl. (ii), and added cl. (iii).

Pub. L. 111–148, §7101(c)(1), in cl. (i), inserted "and" at end, in cl. (ii), substituted period for "; and" at end, and struck out cl. (iii) which read as follows: "does not obtain covered outpatient drugs through a group purchasing organization or other group purchasing arrangement."

Subsec. (a)(4)(M) to (O). Pub. L. 111–148, §7101(a), added subpars. (M) to (O).

Subsec. (a)(5)(B). Pub. L. 111–152, §2302(1)(A), substituted "covered outpatient drug" for "covered drug".

Pub. L. 111–148, §7101(b)(1), substituted "covered drug" for "covered outpatient drug".

Subsec. (a)(5)(C). Pub. L. 111–152, §2302(1)(C)(i), (ii), redesignated subpar. (D) as (C) and struck out former subpar. (C). Prior to amendment, text of subpar. (C) read as follows:

"(i) IN GENERAL.—A hospital described in subparagraph (L), (M), (N), or (O) of paragraph (4) shall not obtain covered outpatient drugs through a group purchasing organization or other group purchasing arrangement, except as permitted or provided for pursuant to clauses (ii) or (iii).

"(ii) INPATIENT DRUGS.—Clause (i) shall not apply to drugs purchased for inpatient use.

"(iii) EXCEPTIONS.—The Secretary shall establish reasonable exceptions to clause (i)—

"(I) with respect to a covered outpatient drug that is unavailable to be purchased through the program under this section due to a drug shortage problem, manufacturer noncompliance, or any other circumstance beyond the hospital's control;

"(II) to facilitate generic substitution when a generic covered outpatient drug is available at a lower price; or

"(III) to reduce in other ways the administrative burdens of managing both inventories of drugs subject to this section and inventories of drugs that are not subject to this section, so long as the exceptions do not create a duplicate discount problem in violation of subparagraph (A) or a diversion problem in violation of subparagraph (B).

"(iv) PURCHASING ARRANGEMENTS FOR INPATIENT DRUGS.—The Secretary shall ensure that a hospital described in subparagraph (L), (M), (N), or (O) of subsection (a)(4) that is enrolled to participate in the drug discount program under this section shall have multiple options for purchasing covered outpatient drugs for inpatients, including by utilizing a group purchasing organization or other group purchasing

arrangement, establishing and utilizing its own group purchasing program, purchasing directly from a manufacturer, and any other purchasing arrangements that the Secretary determines is appropriate to ensure access to drug discount pricing under this section for inpatient drugs taking into account the particular needs of small and rural hospitals."

Pub. L. 111–148, §7101(c)(2)(B), added subpar. (C). Former subpar. (C) redesignated (D).

Pub. L. 111–148, §7101(b)(1), substituted "covered drug" for "covered outpatient drug".

Subsec. (a)(5)(C)(iv). Pub. L. 111–152, §2302(1)(A), substituted "covered outpatient drugs" for "covered drugs".

Subsec. (a)(5)(D). Pub. L. 111–152, §2302(1)(C)(ii), (iii), redesignated subpar. (E) as (D) and substituted "subparagraph (C)" for "subparagraph (D)". Former subpar. (D) redesignated (C).

Pub. L. 111–152, §2302(1)(A), substituted "covered outpatient drug" for "covered drug".

Pub. L. 111–148, §7101(c)(2)(A), redesignated subpar. (C) as (D). Former subpar. (D) redesignated (E).

Pub. L. 111–148, §7101(b)(1), substituted "covered drug" for "covered outpatient drug".

Subsec. (a)(5)(E). Pub. L. 111–152, §2302(1)(C)(ii), redesignated subpar. (E) as (D).

Pub. L. 111–152, §2302(1)(A), substituted "covered outpatient drug" for "covered drug".

Pub. L. 111–148, §§7101(c)(2)(A), 7102(b)(2), redesignated subpar. (D) as (E) and inserted "after audit as described in subparagraph (D) and" after "finds,".

Subsec. (a)(7). Pub. L. 111–152, §2302(1)(A), substituted "covered outpatient drugs" for "covered drugs" wherever appearing.

Pub. L. 111–148, §7101(b)(1), substituted "covered drugs" for "covered outpatient drugs" wherever appearing.

Subsec. (a)(9). Pub. L. 111–152, §2302(1)(A), substituted "covered outpatient drugs" for "covered drugs".

Pub. L. 111–148, §7101(b)(1), substituted "covered drugs" for "covered outpatient drugs".

Subsec. (b). Pub. L. 111–148, §7101(b)(2)(A), which directed substitution of "Other definitions" for "Other definition" in subsec. heading, designation of existing provisions as par. (1), and insertion of par. (1) heading, was executed by reenacting subsec. heading without change, designating existing provisions as par. (1), and inserting par. (1) heading, to reflect the probable intent of Congress.

Subsec. (b)(2). Pub. L. 111–148, §7101(b)(2)(B), added par. (2).

Subsec. (c). Pub. L. 111–152, §2302(2), struck out subsec. (c). Text read as follows: "Not later than 90 days after the date of filing of the hospital's most recently filed Medicare cost report, the hospital shall issue a credit as determined by the Secretary to the State Medicaid program for inpatient covered drugs provided to Medicaid recipients."

Pub. L. 111–148, §7101(d), added subsec. (c) and struck out former subsec. (c). Prior to amendment, text read as follows: "A manufacturer is deemed to meet the requirements of subsection (a) of this section if the manufacturer establishes to the satisfaction of the Secretary that the manufacturer would comply (and has offered to comply) with the provisions of this section (as in effect immediately after November 4, 1992), as applied by the Secretary, and would have entered into an agreement under this section (as such section was in effect at such time), but for a legislative change in this section (or the application of this section) after November 4, 1992."

Pub. L. 111–148, §2501(f)(1)(B), (C), redesignated subsec. (d) as (c) and struck out former subsec. (c). Text of former subsec. (c) read as follows: "Any reference in this section to a provision of the Social Security Act shall be deemed to be a reference to the provision as in effect on November 4, 1992."

Subsec. (d). Pub. L. 111–152, §2302(3), substituted "covered outpatient drugs" for "covered drugs" wherever appearing and substituted "(a)(5)(C)" for "(a)(5)(D)" and "(a)(5)(D)" for "(a)(5)(E)" in two places.

Pub. L. 111–148, §7102(a), which directed general amendment of subsec. (d), was executed by adding subsec. (d) after subsec. (c) to reflect the probable intent of Congress, because no subsec. (d) appeared subsequent to amendment by Pub. L. 111–148, §2501(f)(1)(C). See below.

Pub. L. 111–148, §2501(f)(1)(C), redesignated subsec. (d) as (c).

Subsec. (e). Pub. L. 111–309 substituted "covered entities described in subparagraph (M) (other than a children's hospital described in subparagraph (M))" for "covered entities described in subparagraph (M)".

Pub. L. 111–152, §2302(4), added subsec. (e).

1993—Pub. L. 103–43 made technical amendment to directory language of Pub. L. 102–585, §602(a), which enacted this section.

STATUTORY NOTES AND RELATED SUBSIDIARIES

EFFECTIVE DATE OF 2010 AMENDMENT

Pub. L. 111–309, title II, §204(a)(2), Dec. 15, 2010, 124 Stat. 3289, provided that: "The amendment made

by paragraph (1) [amending this section] shall take effect as if included in the enactment of section 2302 of the Health Care and Education Reconciliation Act of 2010 (Public Law 111–152)."

Pub. L. 111–148, title II, §2501(f)(2), Mar. 23, 2010, 124 Stat. 310, provided that: "The amendments made by this subsection [amending this section] take effect on January 1, 2010."

Pub. L. 111–148, title VII, §7101(e), Mar. 23, 2010, 124 Stat. 823, provided that:

"(1) IN GENERAL.—The amendments made by this section [amending this section] and section 7102 [amending this section] shall take effect on January 1, 2010, and shall apply to drugs purchased on or after January 1, 2010.

"(2) EFFECTIVENESS.—The amendments made by this section and section 7102 shall be effective and shall be taken into account in determining whether a manufacturer is deemed to meet the requirements of section 340B(a) of the Public Health Service Act (42 U.S.C. 256b(a)), notwithstanding any other provision of law."

ELIGIBILITY EXCEPTION FOR THE DRUG DISCOUNT PROGRAM DUE TO THE COVID–19 PUBLIC HEALTH EMERGENCY

Pub. L. 117–103, div. P, title I, §121, Mar. 15, 2022, 136 Stat. 792, provided that:

"(a) IN GENERAL.—Notwithstanding any other provision of law, in the case of a hospital described in subsection (b) that, with respect to cost reporting periods that begin during fiscal year 2020 or a subsequent fiscal year, but do not end after December 31, 2022, does not meet the applicable requirement for the disproportionate share adjustment percentage described in subsection (c) by reason of the COVID–19 public health emergency, but otherwise meets the requirements for being a covered entity under subparagraph (L), (M), or (O) of subsection (a)(4) of section 340B of the Public Health Service Act (42 U.S.C. 256b) and is in compliance with all other requirements of the program under such section, shall be deemed a covered entity for purposes of such section for the period—

"(1) beginning on the date of the enactment of this Act [Mar. 15, 2022] (or, if later, with the first of such cost reporting periods for which the hospital does not so meet such applicable requirement for the disproportionate share adjustment percentage, but otherwise meets all other such requirements for being such a covered entity and of such program); and

"(2) ending with the last of such cost reporting periods (ending not later than December 31, 2022) for which the hospital does not so meet such applicable requirement for the disproportionate share adjustment percentage, but otherwise meets all other such requirements for being such a covered entity and of such program.

"(b) HOSPITALS.—A hospital described in this subsection is an entity that, on the day before the first day of the COVID–19 public health emergency, was a covered entity described in subparagraph (L), (M), or (O) of subsection (a)(4) of section 340B of the Public Health Service Act participating in the drug discount program under such section.

"(c) APPLICABLE REQUIREMENT FOR DISPROPORTIONATE SHARE ADJUSTMENT PERCENTAGE.—The applicable requirement for the disproportionate share adjustment percentage described in this subsection is—

"(1) in the case of a hospital described in subsection (a) that otherwise meets the requirements under subparagraph (L) or (M) of section 340B(a)(4) of the Public Health Service Act, the requirement under subparagraph (L)(ii) of such section; and

"(2) in the case of a hospital described in subsection (a) that otherwise meets the requirements under subparagraph (O) of such section 340B(a)(4), the requirement with respect to the disproportionate share adjustment percentage described in such subparagraph (O).

"(d) SELF-ATTESTATION.—

"(1) IN GENERAL.—A hospital described in subsection (a) that fails to meet the applicable requirement for the disproportionate share adjustment percentage described in subsection (c) shall, within 30 days of such failure, or in the case of a hospital where such failure occurred prior to the date of enactment of this Act but after the start of the COVID-19 public health emergency, within 30 days of the date of enactment, provide to the Secretary of Health and Human Services an attestation that contains information on any actions taken by or other impact on such hospital in response to or as a result of the COVID-19 public health emergency that may have impacted the ability to meet the applicable requirement for the disproportionate share adjustment percentage described in subsection (c).

"(2) PAPERWORK REDUCTION ACT.—Chapter 35 of title 44, United States Code, shall not apply to the collection of information provided pursuant to this subsection.

"(e) DEFINITIONS.—In this section:

"(1) COVERED ENTITY.—The term 'covered entity' has the meaning given such term in section

340B(a)(4) of the Public Health Service Act (42 U.S.C. 256b(a)(4)).

"(2) COVID–19 PUBLIC HEALTH EMERGENCY.—The term 'COVID–19 public health emergency' means the public health emergency declared by the Secretary of Health and Human Services under section 319 of the Public Health Service Act (42 U.S.C. 247d) on January 31, 2020, with respect to COVID–19 (or any renewal of such declaration)."

PRICING OF DIAGNOSTIC TESTING

Pub. L. 116–136, div. A, title III, §3202, Mar. 27, 2020, 134 Stat. 367, provided that:

"(a) REIMBURSEMENT RATES.—A group health plan or a health insurance issuer providing coverage of items and services described in section 6001(a) of division F of the Families First Coronavirus Response Act (Public Law 116–127) [42 U.S.C. 1320b–5 note] with respect to an enrollee shall reimburse the provider of the diagnostic testing as follows:

"(1) If the health plan or issuer has a negotiated rate with such provider in effect before the public health emergency declared under section 319 of the Public Health Service Act (42 U.S.C. 247d), such negotiated rate shall apply throughout the period of such declaration.

"(2) If the health plan or issuer does not have a negotiated rate with such provider, such plan or issuer shall reimburse the provider in an amount that equals the cash price for such service as listed by the provider on a public internet website, or such plan or issuer may negotiate a rate with such provider for less than such cash price.

"(b) REQUIREMENT TO PUBLICIZE CASH PRICE FOR DIAGNOSTIC TESTING FOR COVID–19.—

"(1) IN GENERAL.—During the emergency period declared under section 319 of the Public Health Service Act (42 U.S.C. 247d), each provider of a diagnostic test for COVID–19 shall make public the cash price for such test on a public internet website of such provider.

"(2) CIVIL MONETARY PENALTIES.—The Secretary of Health and Human Services may impose a civil monetary penalty on any provider of a diagnostic test for COVID–19 that is not in compliance with paragraph (1) and has not completed a corrective action plan to comply with the requirements of such paragraph, in an amount not to exceed $300 per day that the violation is ongoing."

STUDY OF TREATMENT OF CERTAIN CLINICS AS COVERED ENTITIES ELIGIBLE FOR PRESCRIPTION DRUG DISCOUNTS

Pub. L. 102–585, title VI, §602(b), Nov. 4, 1992, 106 Stat. 4970, directed Secretary of Health and Human Services to conduct a study of feasibility and desirability of including specified entities receiving funds from a State as covered entities eligible for limitations on prices of covered outpatient drugs under 42 U.S.C. 256b(a) and, not later than 1 year after Nov. 4, 1992, to submit a report to Congress on the study, including in the report a description of the entities that were the subject of the study, an analysis of the extent to which such entities procured prescription drugs, and an analysis of the impact of the inclusion of such entities as covered entities on the quality of care provided to and the health status of the patients of such entities.

[1] See References in Text note below.

[2] So in original. Probably should be "subparagraph".

[3] So in original. Probably should be "subsection".

SUBPART VIII—BULK PURCHASES OF VACCINES FOR CERTAIN PROGRAMS

EDITORIAL NOTES

CODIFICATION

Pub. L. 103–43, title XX, §2008(i)(2)(A)(i), June 10, 1993, 107 Stat. 213, made technical amendment relating to placement of subpart VIII within part D of this subchapter.

§256c. Bulk purchases of vaccines for certain programs

(a) Agreements for purchases

(1) In general

Not later than 180 days after October 27, 1992, the Secretary, acting through the Director of the Centers for Disease Control and Prevention and in consultation with the Administrator of the Health Resources and Services Administration, shall enter into negotiations with manufacturers of vaccines for the purpose of establishing and maintaining agreements under which entities described in paragraph (2) may purchase vaccines from the manufacturers at the prices specified in the agreements.

(2) Relevant entities

The entities referred to in paragraph (1) are entities that provide immunizations against vaccine-preventable diseases with assistance provided under section 254b of this title.

(b) Negotiation of prices

In carrying out subsection (a), the Secretary shall, to the extent practicable, ensure that the prices provided for in agreements under such subsection are comparable to the prices provided for in agreements negotiated by the Secretary on behalf of grantees under section 247b(j)(1) of this title.

(c) Authority of Secretary

In carrying out subsection (a), the Secretary, in the discretion of the Secretary, may enter into the agreements described in such subsection (and may decline to enter into such agreements), may modify such agreements, may extend such agreements, and may terminate such agreements.

(d) Rule of construction

This section may not be construed as requiring any State to reduce or terminate the supply of vaccines provided by the State to any of the entities described in subsection (a)(2).

(July 1, 1944, ch. 373, title III, §340C, formerly §340B, as added Pub. L. 102–531, title III, §305, Oct. 27, 1992, 106 Stat. 3494; renumbered §340C, Pub. L. 103–43, title XX, §2008(i)(2)(A)(ii), June 10, 1993, 107 Stat. 213; amended Pub. L. 104–299, §4(a)(2), Oct. 11, 1996, 110 Stat. 3645.)

EDITORIAL NOTES

AMENDMENTS

1996—Subsec. (a)(2). Pub. L. 104–299 substituted "with assistance provided under section 254b of this title" for "under the programs established in sections 254b, 254c, 256, and 256a of this title."

STATUTORY NOTES AND RELATED SUBSIDIARIES

EFFECTIVE DATE OF 1996 AMENDMENT

Amendment by Pub. L. 104–299 effective Oct. 1, 1996, see section 5 of Pub. L. 104–299, as amended, set out as a note under section 233 of this title.

§256d. Breast and cervical cancer information

(a) In general

As a condition of receiving grants, cooperative agreements, or contracts under this chapter, each of the entities specified in subsection (c) shall, to the extent determined to be appropriate by the Secretary, make available information concerning breast and cervical cancer.

(b) Certain authorities

In carrying out subsection (a), an entity specified in subsection (c)—

(1) may make the information involved available to such individuals as the entity determines

appropriate;

(2) may, as appropriate, provide information under subsection (a) on the need for self-examination of the breasts and on the skills for such self-examinations;

(3) shall provide information under subsection (a) in the language and cultural context most appropriate to the individuals to whom the information is provided; and

(4) shall refer such clients as the entities determine appropriate for breast and cervical cancer screening, treatment, or other appropriate services.

(c) Relevant entities

The entities specified in this subsection are the following:

(1) Entities receiving assistance under section 247b–7 [1] of this title (relating to tuberculosis).

(2) Entities receiving assistance under section 247c of this title (relating to sexually transmitted diseases).

(3) Migrant health centers receiving assistance under section 254b [1] of this title.

(4) Community health centers receiving assistance under section 254c [1] of this title.

(5) Entities receiving assistance under section 254b(h) of this title (relating to homeless individuals).

(6) Entities receiving assistance under section 256a [1] of this title (relating to health services for residents of public housing).

(7) Entities providing services with assistance under subchapter III–A or subchapter XVII.

(8) Entities receiving assistance under section 300 of this title (relating to family planning).

(9) Entities receiving assistance under subchapter XXIV (relating to services with respect to acquired immune deficiency syndrome).

(10) Non-Federal entities authorized under the Indian Self-Determination Act [25 U.S.C. 5321 et seq.].

(July 1, 1944, ch. 373, title III, §340D, as added Pub. L. 103–183, title I, §104, Dec. 14, 1993, 107 Stat. 2230; amended Pub. L. 106–310, div. A, title XXV, §2502(b), Oct. 17, 2000, 114 Stat. 1163; Pub. L. 107–251, title VI, §601(a), Oct. 26, 2002, 116 Stat. 1664.)

EDITORIAL NOTES

REFERENCES IN TEXT

Section 247b–7 of this title, referred to in subsec. (c)(1), relates to loan repayment program and not to assistance relating to tuberculosis.

Sections 254b and 254c of this title, referred to in subsec. (c)(3), (4), were in the original references to sections 329 and 330, meaning sections 329 and 330 of act July 1, 1944, which were omitted in the general amendment of subpart I (§254b et seq.) of this part by Pub. L. 104–299, §2, Oct. 11, 1996, 110 Stat. 3626. Sections 2 and 3(a) of Pub. L. 104–299 enacted new sections 330 and 330A of act July 1, 1944, which are classified, respectively, to sections 254b and 254c of this title.

Section 256a of this title, referred to in subsec. (c)(6), was repealed by Pub. L. 104–299, §4(a)(3), Oct. 11, 1996, 110 Stat. 3645.

The Indian Self-Determination Act, referred to in subsec. (c)(10), is title I of Pub. L. 93–638, Jan. 4, 1975, 88 Stat. 2206, which is classified principally to subchapter I (§5321 et seq.) of chapter 46 of Title 25, Indians. For complete classification of this Act to the Code, see Short Title note set out under section 5301 of Title 25 and Tables.

AMENDMENTS

2002—Subsec. (c)(5). Pub. L. 107–251 substituted "254b(h)" for "256".

2000—Subsec. (c)(1). Pub. L. 106–310 substituted "section 247b–7 of this title" for "section 247b–6 of this title".

STATUTORY NOTES AND RELATED SUBSIDIARIES

REFERENCE TO COMMUNITY, MIGRANT, PUBLIC HOUSING, OR HOMELESS HEALTH

CENTER CONSIDERED REFERENCE TO HEALTH CENTER

Reference to community health center, migrant health center, public housing health center, or homeless health center, considered reference to health center, see section 4(c) of Pub. L. 104–299, set out as a note under section 254b of this title.

[1] *See References in Text note below.*

SUBPART IX—SUPPORT OF GRADUATE MEDICAL EDUCATION PROGRAMS IN CHILDREN'S HOSPITALS

§256e. Program of payments to children's hospitals that operate graduate medical education programs

(a) Payments

The Secretary shall make two payments under this section to each children's hospital for each of fiscal years 2000 through 2005, each of fiscal years 2007 through 2011, each of fiscal years 2014 through 2018, and each of fiscal years 2019 through 2023, one for the direct expenses and the other for indirect expenses associated with operating approved graduate medical residency training programs. The Secretary shall promulgate regulations pursuant to the rulemaking requirements of title 5 which shall govern payments made under this subpart.

(b) Amount of payments

(1) In general

Subject to paragraphs (2) and (3), the amounts payable under this section to a children's hospital for an approved graduate medical residency training program for a fiscal year are each of the following amounts:

(A) Direct expense amount

The amount determined under subsection (c) for direct expenses associated with operating approved graduate medical residency training programs.

(B) Indirect expense amount

The amount determined under subsection (d) for indirect expenses associated with the treatment of more severely ill patients and the additional costs relating to teaching residents in such programs.

(2) Capped amount

(A) In general

The total of the payments made to children's hospitals under paragraph (1)(A) or paragraph (1)(B) in a fiscal year shall not exceed the funds appropriated under paragraph (1) or (2), respectively, of subsection (f) for such payments for that fiscal year.

(B) Pro rata reductions of payments for direct expenses

If the Secretary determines that the amount of funds appropriated under subsection (f)(1) for a fiscal year is insufficient to provide the total amount of payments otherwise due for such periods under paragraph (1)(A), the Secretary shall reduce the amounts so payable on a pro rata basis to reflect such shortfall.

(3) Annual reporting required

(A) Reduction in payment for failure to report

(i) In general

The amount payable under this section to a children's hospital for a fiscal year (beginning with fiscal year 2008 and after taking into account paragraph (2)) shall be reduced by 25 percent if the Secretary determines that—

(I) the hospital has failed to provide the Secretary, as an addendum to the hospital's application under this section for such fiscal year, the report required under subparagraph (B) for the previous fiscal year; or

(II) such report fails to provide the information required under any clause of such subparagraph.

(ii) Notice and opportunity to provide missing information

Before imposing a reduction under clause (i) on the basis of a hospital's failure to provide information described in clause (i)(II), the Secretary shall provide notice to the hospital of such failure and the Secretary's intention to impose such reduction and shall provide the hospital with the opportunity to provide the required information within a period of 30 days beginning on the date of such notice. If the hospital provides such information within such period, no reduction shall be made under clause (i) on the basis of the previous failure to provide such information.

(B) Annual report

The report required under this subparagraph for a children's hospital for a fiscal year is a report that includes (in a form and manner specified by the Secretary) the following information for the residency academic year completed immediately prior to such fiscal year:

(i) The types of resident training programs that the hospital provided for residents described in subparagraph (C), such as general pediatrics, internal medicine/pediatrics, and pediatric subspecialties, including both medical subspecialties certified by the American Board of Pediatrics (such as pediatric gastroenterology) and non-medical subspecialties approved by other medical certification boards (such as pediatric surgery).

(ii) The number of training positions for residents described in subparagraph (C), the number of such positions recruited to fill, and the number of such positions filled.

(iii) The types of training that the hospital provided for residents described in subparagraph (C) related to the health care needs of different populations, such as children who are underserved for reasons of family income or geographic location, including rural and urban areas.

(iv) The changes in residency training for residents described in subparagraph (C) which the hospital has made during such residency academic year (except that the first report submitted by the hospital under this subparagraph shall be for such changes since the first year in which the hospital received payment under this section), including—

(I) changes in curricula, training experiences, and types of training programs, and benefits that have resulted from such changes; and

(II) changes for purposes of training the residents in the measurement and improvement of the quality and safety of patient care.

(v) The numbers of residents described in subparagraph (C) who completed their residency training at the end of such residency academic year and care for children within the borders of the service area of the hospital or within the borders of the State in which the hospital is located. Such numbers shall be disaggregated with respect to residents who completed residencies in general pediatrics or internal medicine/pediatrics, subspecialty residencies, and dental residencies.

(C) Residents

The residents described in this subparagraph are those who—

(i) are in full-time equivalent resident training positions in any training program sponsored by the hospital; or

(ii) are in a training program sponsored by an entity other than the hospital, but who spend

more than 75 percent of their training time at the hospital.

(D) Report to Congress

Not later than the end of fiscal year 2018, and the end of fiscal year 2022, the Secretary, acting through the Administrator of the Health Resources and Services Administration, shall submit a report to the Congress—

(i) summarizing the information submitted in reports to the Secretary under subparagraph (B);

(ii) describing the results of the program carried out under this section; and

(iii) making recommendations for improvements to the program.

(c) Amount of payment for direct graduate medical education

(1) In general

The amount determined under this subsection for payments to a children's hospital for direct graduate expenses relating to approved graduate medical residency training programs for a fiscal year is equal to the product of—

(A) the updated per resident amount for direct graduate medical education, as determined under paragraph (2); and

(B) the average number of full-time equivalent residents in the hospital's graduate approved medical residency training programs (as determined under section 1395ww(h)(4) of this title during the fiscal year.

(2) Updated per resident amount for direct graduate medical education

The updated per resident amount for direct graduate medical education for a hospital for a fiscal year is an amount determined as follows:

(A) Determination of hospital single per resident amount

The Secretary shall compute for each hospital operating an approved graduate medical education program (regardless of whether or not it is a children's hospital) a single per resident amount equal to the average (weighted by number of full-time equivalent residents) of the primary care per resident amount and the non-primary care per resident amount computed under section 1395ww(h)(2) of this title for cost reporting periods ending during fiscal year 1997.

(B) Determination of wage and non-wage-related proportion of the single per resident amount

The Secretary shall estimate the average proportion of the single per resident amounts computed under subparagraph (A) that is attributable to wages and wage-related costs.

(C) Standardizing per resident amounts

The Secretary shall establish a standardized per resident amount for each such hospital—

(i) by dividing the single per resident amount computed under subparagraph (A) into a wage-related portion and a non-wage-related portion by applying the proportion determined under subparagraph (B);

(ii) by dividing the wage-related portion by the factor applied under section 1395ww(d)(3)(E) of this title for discharges occurring during fiscal year 1999 for the hospital's area; and

(iii) by adding the non-wage-related portion to the amount computed under clause (ii).

(D) Determination of national average

The Secretary shall compute a national average per resident amount equal to the average of the standardized per resident amounts computed under subparagraph (C) for such hospitals, with the amount for each hospital weighted by the average number of full-time equivalent residents at such hospital.

(E) Application to individual hospitals

The Secretary shall compute for each such hospital that is a children's hospital a per resident

amount—

(i) by dividing the national average per resident amount computed under subparagraph (D) into a wage-related portion and a non-wage-related portion by applying the proportion determined under subparagraph (B);

(ii) by multiplying the wage-related portion by the factor applied under section 1395ww(d)(3)(E) of this title for discharges occurring during the preceding fiscal year for the hospital's area; and

(iii) by adding the non-wage-related portion to the amount computed under clause (ii).

(F) Updating rate

The Secretary shall update such per resident amount for each such children's hospital by the estimated percentage increase in the consumer price index for all urban consumers during the period beginning October 1997 and ending with the midpoint of the Federal fiscal year for which payments are made.

(d) Amount of payment for indirect medical education

(1) In general

The amount determined under this subsection for payments to a children's hospital for indirect expenses associated with the treatment of more severely ill patients and the additional costs associated with the teaching of residents for a fiscal year is equal to an amount determined appropriate by the Secretary.

(2) Factors

In determining the amount under paragraph (1), the Secretary shall—

(A) take into account variations in case mix among children's hospitals and the ratio of the number of full-time equivalent residents in the hospitals' approved graduate medical residency training programs to beds (but excluding beds or bassinets assigned to healthy newborn infants); and

(B) assure that the aggregate of the payments for indirect expenses associated with the treatment of more severely ill patients and the additional costs related to the teaching of residents under this section in a fiscal year are equal to the amount appropriated for such expenses for the fiscal year involved under subsection (f)(2).

(e) Making of payments

(1) Interim payments

The Secretary shall determine, before the beginning of each fiscal year involved for which payments may be made for a hospital under this section, the amounts of the payments for direct graduate medical education and indirect medical education for such fiscal year and shall (subject to paragraph (2)) make the payments of such amounts in 12 equal interim installments during such period. Such interim payments to each individual hospital shall be based on the number of residents reported in the hospital's most recently filed Medicare cost report prior to the application date for the Federal fiscal year for which the interim payment amounts are established. In the case of a hospital that does not report residents on a Medicare cost report, such interim payments shall be based on the number of residents trained during the hospital's most recently completed Medicare cost report filing period.

(2) Withholding

The Secretary shall withhold up to 25 percent from each interim installment for direct and indirect graduate medical education paid under paragraph (1) as necessary to ensure a hospital will not be overpaid on an interim basis.

(3) Reconciliation

Prior to the end of each fiscal year, the Secretary shall determine any changes to the number of residents reported by a hospital in the application of the hospital for the current fiscal year to determine the final amount payable to the hospital for the current fiscal year for both direct

expense and indirect expense amounts. Based on such determination, the Secretary shall recoup any overpayments made and pay any balance due to the extent possible. The final amount so determined shall be considered a final intermediary determination for the purposes of section 1395oo of this title and shall be subject to administrative and judicial review under that section in the same manner as the amount of payment under section 1395ww(d) [1] of this title is subject to review under such section.

(f) Authorization of appropriations

(1) Direct graduate medical education

(A) In general

There are hereby authorized to be appropriated, out of any money in the Treasury not otherwise appropriated, for payments under subsection (b)(1)(A)—

(i) for fiscal year 2000, $90,000,000;
(ii) for fiscal year 2001, $95,000,000;
(iii) for each of the fiscal years 2002 through 2005, such sums as may be necessary;
(iv) for each of fiscal years 2007 through 2011, $110,000,000;
(v) for each of fiscal years 2014 through 2018, $100,000,000; and
(vi) for each of fiscal years 2019 through 2023, $105,000,000.

(B) Carryover of excess

The amounts appropriated under subparagraph (A) for fiscal year 2000 shall remain available for obligation through the end of fiscal year 2001.

(2) Indirect medical education

There are hereby authorized to be appropriated, out of any money in the Treasury not otherwise appropriated, for payments under subsection (b)(1)(B)—

(A) for fiscal year 2000, $190,000,000;
(B) for fiscal year 2001, $190,000,000;
(C) for each of the fiscal years 2002 through 2005, such sums as may be necessary;
(D) for each of fiscal years 2007 through 2011, $220,000,000;
(E) for each of fiscal years 2014 through 2018, $200,000,000; and
(F) for each of fiscal years 2019 through 2023, $220,000,000.

(g) Definitions

In this section:

(1) Approved graduate medical residency training program

The term "approved graduate medical residency training program" has the meaning given the term "approved medical residency training program" in section 1395ww(h)(5)(A) of this title.

(2) Children's hospital

The term "children's hospital" means a hospital with a Medicare payment agreement and which is excluded from the Medicare inpatient prospective payment system pursuant to section 1395ww(d)(1)(B)(iii) of this title and its accompanying regulations.

(3) Direct graduate medical education costs

The term "direct graduate medical education costs" has the meaning given such term in section 1395ww(h)(5)(C) of this title.

(h) Additional provisions

(1) In general

The Secretary is authorized to make available up to 25 percent of the total amounts in excess of $245,000,000 appropriated under paragraphs (1) and (2) of subsection (f), but not to exceed

$7,000,000, for payments to hospitals qualified as described in paragraph (2), for the direct and indirect expenses associated with operating approved graduate medical residency training programs, as described in subsection (a).

(2) Qualified hospitals

(A) In general

To qualify to receive payments under paragraph (1), a hospital shall be a free-standing hospital—

(i) with a Medicare payment agreement and that is excluded from the Medicare inpatient hospital prospective payment system pursuant to section 1395ww(d)(1)(B) of this title and its accompanying regulations;

(ii) whose inpatients are predominantly individuals under 18 years of age;

(iii) that has an approved medical residency training program as defined in section 1395ww(h)(5)(A) of this title; and

(iv) that is not otherwise qualified to receive payments under this section or section 1395ww(h) of this title.

(B) Establishment of residency cap

In the case of a freestanding children's hospital that, on April 7, 2014, meets the requirements of subparagraph (A) but for which the Secretary has not determined an average number of full-time equivalent residents under section 1395ww(h)(4) of this title, the Secretary may establish such number of full-time equivalent residents for the purposes of calculating payments under this subsection.

(3) Payments

Payments to hospitals made under this subsection shall be made in the same manner as payments are made to children's hospitals, as described in subsections (b) through (e).

(4) Payment amounts

The direct and indirect payment amounts under this subsection shall be determined using per resident amounts that are no greater than the per resident amounts used for determining direct and indirect payment amounts under subsection (a).

(5) Reporting

A hospital receiving payments under this subsection shall be subject to the reporting requirements under subsection (b)(3).

(6) Remaining funds

(A) In general

If the payments to qualified hospitals under paragraph (1) for a fiscal year are less than the total amount made available under such paragraph for that fiscal year, any remaining amounts for such fiscal year may be made available to all hospitals participating in the program under this subsection or subsection (a).

(B) Quality bonus system

For purposes of distributing the remaining amounts described in subparagraph (A), the Secretary may establish a quality bonus system, whereby the Secretary distributes bonus payments to hospitals participating in the program under this subsection or subsection (a) that meet standards specified by the Secretary, which may include a focus on quality measurement and improvement, interpersonal and communications skills, delivering patient-centered care, and practicing in integrated health systems, including training in community-based settings. In developing such standards, the Secretary shall collaborate with relevant stakeholders, including program accrediting bodies, certifying boards, training programs, health care organizations, health care purchasers, and patient and consumer groups.

(July 1, 1944, ch. 373, title III, §340E, as added Pub. L. 106–129, §4, Dec. 6, 1999, 113 Stat. 1671;

amended Pub. L. 106–310, div. A, title XX, §2001, Oct. 17, 2000, 114 Stat. 1155; Pub. L. 108–490, §1(a), Dec. 23, 2004, 118 Stat. 3972; Pub. L. 109–307, §2, Oct. 6, 2006, 120 Stat. 1721; Pub. L. 113–98, §§2, 3, Apr. 7, 2014, 128 Stat. 1140; Pub. L. 115–241, §2, Sept. 18, 2018, 132 Stat. 2892.)

EDITORIAL NOTES

REFERENCES IN TEXT

Section 1395ww(d) of this title, referred to in subsec. (e)(3), was in the original "section 1186(d) of such Act" and was translated as reading "section 1886(d) of such Act", meaning section 1886(d) of the Social Security Act, to reflect the probable intent of Congress, because the Social Security Act does not contain a section 1186 and section 1395ww(d) of this title relates to review of inpatient hospital service payments.

AMENDMENTS

2018—Subsec. (a). Pub. L. 115–241, §2(1), substituted "each of fiscal years 2014 through 2018, and each of fiscal years 2019 through 2023," for "and each of fiscal years 2014 through 2018,".

Subsec. (b)(3)(D). Pub. L. 115–241, §2(2), inserted "and the end of fiscal year 2022," after "fiscal year 2018," in introductory provisions.

Subsec. (f)(1)(A)(vi). Pub. L. 115–241, §2(3)(A), added cl. (vi).

Subsec. (f)(2)(F). Pub. L. 115–241, §2(3)(B), added subpar. (F).

2014—Subsec. (a). Pub. L. 113–98, §2(a)(1), substituted "through 2005, each of fiscal years 2007 through 2011, and each of fiscal years 2014 through 2018" for "through 2005 and each of fiscal years 2007 through 2011".

Subsec. (b)(3)(D). Pub. L. 113–98, §2(b), substituted "Not later than the end of fiscal year 2018" for "Not later than the end of fiscal year 2011" in introductory provisions.

Subsec. (f)(1)(A)(v). Pub. L. 113–98, §2(a)(2)(A), added cl. (v).

Subsec. (f)(2)(E). Pub. L. 113–98, §2(a)(2)(B), added subpar. (E).

Subsec. (h). Pub. L. 113–98, §3, added subsec. (h).

2006—Subsec. (a). Pub. L. 109–307, §2(a)(1), inserted "and each of fiscal years 2007 through 2011" after "for each of fiscal years 2000 through 2005".

Subsec. (b)(1). Pub. L. 109–307, §2(b)(1), substituted "paragraphs (2) and (3)" for "paragraph (2)" in introductory provisions.

Subsec. (b)(3). Pub. L. 109–307, §2(b)(2), added par. (3).

Subsec. (c)(2)(E)(ii). Pub. L. 109–307, §2(c)(1), substituted "applied under section 1395ww(d)(3)(E) of this title for discharges occurring during the preceding fiscal year" for "described in subparagraph (C)(ii)".

Subsec. (e)(1). Pub. L. 109–307, §2(a)(2), substituted "12" for "26".

Subsec. (e)(2). Pub. L. 109–307, §2(c)(2), struck out first sentence which read as follows: "The Secretary shall withhold up to 25 percent from each interim installment for direct and indirect graduate medical education paid under paragraph (1)."

Subsec. (e)(3). Pub. L. 109–307, §2(c)(3), substituted "made and pay" for "made to pay".

Subsec. (f)(1)(A)(iv). Pub. L. 109–307, §2(a)(3), added cl. (iv).

Subsec. (f)(2). Pub. L. 109–307, §2(a)(4)(A), substituted "subsection (b)(1)(B)" for "subsection (b)(1)(A)" in introductory provisions.

Subsec. (f)(2)(D). Pub. L. 109–307, §2(a)(4)(B)–(D), added subpar. (D).

2004—Subsec. (d)(1). Pub. L. 108–490, §1(a)(1), substituted "costs associated with" for "costs related to".

Subsec. (d)(2)(A). Pub. L. 108–490, §1(a)(2), inserted "ratio of the" after "hospitals and the" and "to beds (but excluding beds or bassinets assigned to healthy newborn infants)" before semicolon.

2000—Subsec. (a). Pub. L. 106–310, §2001(a), substituted "2000 through 2005" for "2000 and 2001" and inserted at end "The Secretary shall promulgate regulations pursuant to the rulemaking requirements of title 5 which shall govern payments made under this subpart."

Subsec. (c)(2)(F). Pub. L. 106–310, §2001(b), substituted "Federal fiscal year for which payments are made" for "hospital's cost reporting period that begins during fiscal year 2000".

Subsec. (e)(1). Pub. L. 106–310, §2001(c), inserted at end "Such interim payments to each individual hospital shall be based on the number of residents reported in the hospital's most recently filed Medicare cost report prior to the application date for the Federal fiscal year for which the interim payment amounts are established. In the case of a hospital that does not report residents on a Medicare cost report, such interim payments shall be based on the number of residents trained during the hospital's most recently completed Medicare cost report filing period."

Subsec. (e)(2). Pub. L. 106–310, §2001(d), inserted "and indirect" after "interim installment for direct" and inserted at end "The Secretary shall withhold up to 25 percent from each interim installment for direct and indirect graduate medical education paid under paragraph (1) as necessary to ensure a hospital will not be overpaid on an interim basis."

Subsec. (e)(3). Pub. L. 106–310, §2001(e), reenacted heading without change and amended text generally. Prior to amendment, text read as follows: "At the end of each fiscal year for which payments may be made under this section, the hospital shall submit to the Secretary such information as the Secretary determines to be necessary to determine the percent (if any) of the total amount withheld under paragraph (2) that is due under this section for the hospital for the fiscal year. Based on such determination, the Secretary shall recoup any overpayments made, or pay any balance due. The amount so determined shall be considered a final intermediary determination for purposes of applying section 1395oo of this title and shall be subject to review under that section in the same manner as the amount of payment under section 1395ww(d) of this title is subject to review under such section."

Subsec. (f)(1)(A)(iii). Pub. L. 106–310, §2001(f)(1), added cl. (iii).

Subsec. (f)(2)(C). Pub. L. 106–310, §2001(f)(2), added subpar. (C).

Subsec. (g)(2). Pub. L. 106–310, §2001(g), substituted "with a Medicare payment agreement and which is excluded from the Medicare inpatient prospective payment system pursuant to section 1395ww(d)(1)(B)(iii) of this title and its accompanying regulations" for "described in section 1395ww(d)(1)(B)(iii) of this title".

STATUTORY NOTES AND RELATED SUBSIDIARIES

EFFECTIVE DATE OF 2004 AMENDMENT

Pub. L. 108–490, §1(b), Dec. 23, 2004, 118 Stat. 3972, provided that: "The amendments made by subsection (a) [amending this section] shall apply to payments for periods beginning with fiscal year 2005."

[1] *See References in Text note below.*

SUBPART X—PRIMARY DENTAL PROGRAMS

§256f. Designated dental health professional shortage area

In this subpart, the term "designated dental health professional shortage area" means an area, population group, or facility that is designated by the Secretary as a dental health professional shortage area under section 254e of this title or designated by the applicable State as having a dental health professional shortage.

(July 1, 1944, ch. 373, title III, §340F, as added Pub. L. 107–251, title IV, §403, Oct. 26, 2002, 116 Stat. 1660.)

§256g. Grants for innovative programs

(a) Grant program authorized

The Secretary, acting through the Administrator of the Health Resources and Services Administration, is authorized to award grants to States for the purpose of helping States develop and implement innovative programs to address the dental workforce needs of designated dental health professional shortage areas in a manner that is appropriate to the States' individual needs.

(b) State activities

A State receiving a grant under subsection (a) may use funds received under the grant for—

(1) loan forgiveness and repayment programs for dentists who—

(A) agree to practice in designated dental health professional shortage areas;

(B) are dental school graduates who agree to serve as public health dentists for the Federal,

State, or local government; and

(C) agree to—

(i) provide services to patients regardless of such patients' ability to pay; and

(ii) use a sliding payment scale for patients who are unable to pay the total cost of services;

(2) dental recruitment and retention efforts;

(3) grants and low-interest or no-interest loans to help dentists who participate in the medicaid program under title XIX of the Social Security Act (42 U.S.C. 1396 et seq.) to establish or expand practices in designated dental health professional shortage areas by equipping dental offices or sharing in the overhead costs of such practices;

(4) the establishment or expansion of dental residency programs in coordination with accredited dental training institutions in States without dental schools;

(5) programs developed in consultation with State and local dental societies to expand or establish oral health services and facilities in designated dental health professional shortage areas, including services and facilities for children with special needs, such as—

(A) the expansion or establishment of a community-based dental facility, free-standing dental clinic, consolidated health center dental facility, school-linked dental facility, or United States dental school-based facility;

(B) the establishment of a mobile or portable dental clinic;

(C) the establishment or expansion of private dental services to enhance capacity through additional equipment or additional hours of operation;

(D) the establishment or development of models for the provision of dental services to children and adults, such as dental homes, including for the elderly, blind, individuals with disabilities, and individuals living in long-term care facilities; and

(E) the establishment of initiatives to reduce the use of emergency departments by individuals who seek dental services more appropriately delivered in a dental primary care setting;

(6) placement and support of dental students, dental residents, and advanced dentistry trainees;

(7) continuing dental education, including distance-based education;

(8) practice support through teledentistry conducted in accordance with State laws;

(9) community-based prevention services such as water fluoridation and dental sealant programs;

(10) coordination with local educational agencies within the State to foster programs that promote children going into oral health or science professions;

(11) the establishment of faculty recruitment programs at accredited dental training institutions whose mission includes community outreach and service and that have a demonstrated record of serving underserved States;

(12) the development of a State dental officer position or the augmentation of a State dental office to coordinate oral health and access issues in the State; and

(13) any other activities determined to be appropriate by the Secretary.

(c) Application

(1) In general

Each State desiring a grant under this section shall submit an application to the Secretary at such time, in such manner, and containing such information as the Secretary may reasonably require.

(2) Assurances

The application shall include assurances that the State will meet the requirements of subsection (d) and that the State possesses sufficient infrastructure to manage the activities to be funded through the grant and to evaluate and report on the outcomes resulting from such activities.

(d) Matching requirement

The Secretary may not make a grant to a State under this section unless that State agrees that, with

respect to the costs to be incurred by the State in carrying out the activities for which the grant was awarded, the State will provide non-Federal contributions in an amount equal to not less than 40 percent of Federal funds provided under the grant. The State may provide the contributions in cash or in kind, fairly evaluated, including plant, equipment, and services and may provide the contributions from State, local, or private sources.

(e) Report

Not later than 5 years after October 26, 2002, the Secretary shall prepare and submit to the appropriate committees of Congress a report containing data relating to whether grants provided under this section have increased access to dental services in designated dental health professional shortage areas.

(f) Authorization of appropriations

There is authorized to be appropriated to carry out this section, $13,903,000 for each of fiscal years 2019 through 2023.

(July 1, 1944, ch. 373, title III, §340G, as added Pub. L. 107–251, title IV, §403, Oct. 26, 2002, 116 Stat. 1661; amended Pub. L. 110–355, §5, Oct. 8, 2008, 122 Stat. 3994; Pub. L. 115–302, §3, Dec. 11, 2018, 132 Stat. 4397.)

EDITORIAL NOTES

REFERENCES IN TEXT

The Social Security Act, referred to in subsec. (b)(3), is act Aug. 14, 1935, ch. 531, 49 Stat. 620. Title XIX of the Act is classified generally to subchapter XIX (§1396 et seq.) of chapter 7 of this title. For complete classification of this Act to the Code, see section 1305 of this title and Tables.

AMENDMENTS

2018—Subsec. (b)(5)(D), (E). Pub. L. 115–302, §3(1), added subpars. (D) and (E).

Subsec. (f). Pub. L. 115–302, §3(2), substituted "$13,903,000 for each of fiscal years 2019 through 2023" for "$25,000,000 for the 5-fiscal year period beginning with fiscal year 2008".

2008—Subsec. (f). Pub. L. 110–355 substituted "$25,000,000" for "$50,000,000" and "2008" for "2002".

§256g–1. Demonstration program to increase access to dental health care services

(a) In general

(1) Authorization

The Secretary is authorized to award grants to 15 eligible entities to enable such entities to establish a demonstration program to establish training programs to train, or to employ, alternative dental health care providers in order to increase access to dental health care services in rural and other underserved communities.

(2) Definition

The term "alternative dental health care providers" includes community dental health coordinators, advance practice dental hygienists, independent dental hygienists, supervised dental hygienists, primary care physicians, dental therapists, dental health aides, and any other health professional that the Secretary determines appropriate.

(b) Timeframe

The demonstration projects funded under this section shall begin not later than 2 years after March 23, 2010, and shall conclude not later than 7 years after March 23, 2010.

(c) Eligible entities

To be eligible to receive a grant under subsection (a), an entity shall—

(1) be—

(A) an institution of higher education, including a community college;
(B) a public-private partnership;
(C) a federally qualified health center;
(D) an Indian Health Service facility or a tribe or tribal organization (as such terms are defined in section 5304 of title 25);
(E) a State or county public health clinic, a health facility operated by an Indian tribe or tribal organization, or urban Indian organization providing dental services; or
(F) a public hospital or health system;

(2) be within a program accredited by the Commission on Dental Accreditation or within a dental education program in an accredited institution; and
(3) shall submit an application to the Secretary at such time, in such manner, and containing such information as the Secretary may require.

(d) Administrative provisions

(1) Amount of grant

Each grant under this section shall be in an amount that is not less than $4,000,000 for the 5-year period during which the demonstration project [1] being conducted.

(2) Disbursement of funds

(A) Preliminary disbursements

Beginning 1 year after March 23, 2010, the Secretary may disperse to any entity receiving a grant under this section not more than 20 percent of the total funding awarded to such entity under such grant, for the purpose of enabling the entity to plan the demonstration project to be conducted under such grant.

(B) Subsequent disbursements

The remaining amount of grant funds not dispersed under subparagraph (A) shall be dispersed such that not less than 15 percent of such remaining amount is dispersed each subsequent year.

(e) Compliance with State requirements

Each entity receiving a grant under this section shall certify that it is in compliance with all applicable State licensing requirements.

(f) Evaluation

The Secretary shall contract with the Director of the Institute of Medicine to conduct a study of the demonstration programs conducted under this section that shall provide analysis, based upon quantitative and qualitative data, regarding access to dental health care in the United States.

(g) Clarification regarding dental health aide program

Nothing in this section shall prohibit a dental health aide training program approved by the Indian Health Service from being eligible for a grant under this section.

(h) Authorization of appropriations

There is authorized to be appropriated such sums as may be necessary to carry out this section.

(July 1, 1944, ch. 373, title III, §340G–1, as added Pub. L. 111–148, title V, §5304, Mar. 23, 2010, 124 Stat. 621.)

[1] So in original. The word "is" probably should appear.

SUBPART XI—SUPPORT OF GRADUATE MEDICAL EDUCATION IN

QUALIFIED TEACHING HEALTH CENTERS

EDITORIAL NOTES

CODIFICATION

Subpart is comprised of subpart XI of part D of title III of act July 1, 1944. Another subpart XI of part D of title III of the Act was redesignated subpart XII by Pub. L. 115–63, title III, §301(c)(1), Sept. 29, 2017, 131 Stat. 1172, and is classified to subpart XII (§256i) of this part.

§256h. Program of payments to teaching health centers that operate graduate medical education programs

(a) Payments

(1) In general

Subject to subsection (h)(2), the Secretary shall make payments under this section for direct expenses and indirect expenses to qualified teaching health centers that are listed as sponsoring institutions by the relevant accrediting body for, as appropriate—

(A) maintenance of filled positions at existing approved graduate medical residency training programs;

(B) expansion of existing approved graduate medical residency training programs; and

(C) establishment of new approved graduate medical residency training programs.

(2) Per resident amount

In making payments under paragraph (1), the Secretary shall consider the cost of training residents at teaching health centers and the implications of the per resident amount on approved graduate medical residency training programs at teaching health centers.

(3) Priority

In making payments under paragraph (1)(C), the Secretary shall give priority to qualified teaching health centers that—

(A) serve a health professional shortage area with a designation in effect under section 254e of this title or a medically underserved community (as defined in section 295p of this title); or

(B) are located in a rural area (as defined in section 1395ww(d)(2)(D) of this title).

(b) Amount of payments

(1) In general

Subject to paragraph (2), the amounts payable under this section to qualified teaching health centers for an approved graduate medical residency training program for a fiscal year are each of the following amounts:

(A) Direct expense amount

The amount determined under subsection (c) for direct expenses associated with sponsoring approved graduate medical residency training programs.

(B) Indirect expense amount

The amount determined under subsection (d) for indirect expenses associated with the additional costs relating to teaching residents in such programs.

(2) Capped amount

(A) In general

The total of the payments made to qualified teaching health centers under paragraph (1)(A) or paragraph (1)(B) in a fiscal year shall not exceed the amount of funds appropriated under subsection (g) for such payments for that fiscal year.

(B) Limitation

The Secretary shall limit the funding of full-time equivalent residents in order to ensure the direct and indirect payments as determined under subsection [1] (c) and (d) do not exceed the total amount of funds appropriated in a fiscal year under subsection (g).

(C) Addition

Notwithstanding any provision of this section, for the period beginning on October 1, 2023, and ending on December 31, 2024, the Secretary may use any amounts made available in any fiscal year to carry out this section (including amounts recouped under subsection (f)) to make payments described in paragraphs (1)(A) and (1)(B), in addition to the total amount of funds appropriated under subsection (g).

(c) Amount of payment for direct graduate medical education

(1) In general

The amount determined under this subsection for payments to qualified teaching health centers for direct graduate expenses relating to approved graduate medical residency training programs for a fiscal year is equal to the product of—

(A) the updated national per resident amount for direct graduate medical education, as determined under paragraph (2); and

(B) the average number of full-time equivalent residents in the teaching health center's graduate approved medical residency training programs as determined under section 1395ww(h)(4) of this title (without regard to the limitation under subparagraph (F) of such section) during the fiscal year.

(2) Updated national per resident amount for direct graduate medical education

The updated per resident amount for direct graduate medical education for a qualified teaching health center for a fiscal year is an amount determined as follows:

(A) Determination of qualified teaching health center per resident amount

The Secretary shall compute for each individual qualified teaching health center a per resident amount—

(i) by dividing the national average per resident amount computed under section 256e(c)(2)(D) of this title into a wage-related portion and a non-wage related portion by applying the proportion determined under subparagraph (B);

(ii) by multiplying the wage-related portion by the factor applied under section 1395ww(d)(3)(E) of this title (but without application of section 4410 of the Balanced Budget Act of 1997 (42 U.S.C. 1395ww note)) during the preceding fiscal year for the teaching health center's area; and

(iii) by adding the non-wage-related portion to the amount computed under clause (ii).

(B) Updating rate

The Secretary shall update such per resident amount for each such qualified teaching health center as determined appropriate by the Secretary.

(d) Amount of payment for indirect medical education

(1) In general

The amount determined under this subsection for payments to qualified teaching health centers for indirect expenses associated with the additional costs of teaching residents for a fiscal year is equal to an amount determined appropriate by the Secretary.

(2) Factors

In determining the amount under paragraph (1), the Secretary shall—

(A) evaluate indirect training costs relative to supporting a primary care residency program in qualified teaching health centers; and

(B) based on this evaluation, assure that the aggregate of the payments for indirect expenses

under this section and the payments for direct graduate medical education as determined under subsection (c) in a fiscal year do not exceed the amount appropriated for such expenses as determined in subsection (g).

(3) Interim payment

Before the Secretary makes a payment under this subsection pursuant to a determination of indirect expenses under paragraph (1), the Secretary may provide to qualified teaching health centers a payment, in addition to any payment made under subsection (c), for expected indirect expenses associated with the additional costs of teaching residents for a fiscal year, based on an estimate by the Secretary.

(e) Clarification regarding relationship to other payments for graduate medical education

Payments under this section—

(1) shall be in addition to any payments—

(A) for the indirect costs of medical education under section 1395ww(d)(5)(B) of this title;

(B) for direct graduate medical education costs under section 1395ww(h) of this title; and

(C) for direct costs of medical education under section 1395ww(k) of this title;

(2) shall not be taken into account in applying the limitation on the number of total full-time equivalent residents under subparagraphs (F) and (G) of section 1395ww(h)(4) of this title and clauses (v), (vi)(I), and (vi)(II) of section 1395ww(d)(5)(B) of this title for the portion of time that a resident rotates to a hospital; and

(3) shall not include the time in which a resident is counted toward full-time equivalency by a hospital under paragraph (2) or under section 1395ww(d)(5)(B)(iv) of this title, section 1395ww(h)(4)(E) of this title, or section 256e of this title.

(f) Reconciliation

The Secretary shall determine any changes to the number of residents reported by a teaching health center in the application of the teaching health center for the current fiscal year to determine the final amount payable to the teaching health center for the current fiscal year for both direct expense and indirect expense amounts. Based on such determination, the Secretary shall recoup any overpayments made to pay any balance due to the extent possible. The final amount so determined shall be considered a final intermediary determination for the purposes of section 1395oo of this title and shall be subject to administrative and judicial review under that section in the same manner as the amount of payment under section 1395ww(d) [2] of this title is subject to review under such section.

(g) Funding

(1) In general

To carry out this section, there are appropriated such sums as may be necessary, to remain available until expended, not to exceed—

(A) $230,000,000, for the period of fiscal years 2011 through 2015;

(B) $60,000,000 for each of fiscal years 2016 and 2017;

(C) $126,500,000 for each of fiscal years 2018 through 2023;

(D) $168,915,878 for fiscal year 2024;

(E) $181,563,574 for fiscal year 2025;

(F) $225,000,000 for fiscal year 2026;

(G) $250,000,000 for fiscal year 2027;

(H) $275,000,000 for fiscal year 2028; and

(I) $300,000,000 for fiscal year 2029.

(2) Administrative expenses

Of the amount made available to carry out this section for any fiscal year, the Secretary may not use more than 5 percent of such amount for the expenses of administering this section.

(h) Annual reporting required

(1) Annual report

The report required under this paragraph for a qualified teaching health center for a fiscal year is a report that includes (in a form and manner specified by the Secretary) the following information for the residency academic year completed immediately prior to such fiscal year:

(A) The types of primary care resident approved training programs that the qualified teaching health center provided for residents.

(B) The number of approved training positions for residents described in paragraph (4).

(C) The number of residents described in paragraph (4) who completed their residency training at the end of such residency academic year and care for vulnerable populations living in underserved areas.

(D) The number of patients treated by residents described in paragraph (4).

(E) The number of visits by patients treated by residents described in paragraph (4).

(F) Of the number of residents described in paragraph (4) who completed their residency training at the end of such residency academic year, the number and percentage of such residents entering primary care practice (meaning any of the areas of practice listed in the definition of a primary care residency program in section 293l–1 of this title).

(G) Of the number of residents described in paragraph (4) who completed their residency training at the end of such residency academic year, the number and percentage of such residents who entered practice at a health care facility—

(i) primarily serving a health professional shortage area with a designation in effect under section 254e of this title or a medically underserved community (as defined in section 295p of this title); or

(ii) located in a rural area (as defined in section 1395ww(d)(2)(D) of this title).

(H) Other information as deemed appropriate by the Secretary.

(2) Audit authority; limitation on payment

(A) Audit authority

The Secretary may audit a qualified teaching health center to ensure the accuracy and completeness of the information submitted in a report under paragraph (1).

(B) Limitation on payment

A teaching health center may only receive payment in a cost reporting period for a number of such resident positions that is greater than the base level of primary care resident positions, as determined by the Secretary. For purposes of this subparagraph, the "base level of primary care residents" for a teaching health center is the level of such residents as of a base period.

(3) Reduction in payment for failure to report

(A) In general

The amount payable under this section to a qualified teaching health center for a fiscal year shall be reduced by at least 25 percent if the Secretary determines that—

(i) the qualified teaching health center has failed to provide the Secretary, as an addendum to the qualified teaching health center's application under this section for such fiscal year, the report required under paragraph (1) for the previous fiscal year; or

(ii) such report fails to provide complete and accurate information required under any subparagraph of such paragraph.

(B) Notice and opportunity to provide accurate and missing information

Before imposing a reduction under subparagraph (A) on the basis of a qualified teaching health center's failure to provide complete and accurate information described in subparagraph (A)(ii), the Secretary shall provide notice to the teaching health center of such failure and the Secretary's intention to impose such reduction and shall provide the teaching health center with

the opportunity to provide the required information within the period of 30 days beginning on the date of such notice. If the teaching health center provides such information within such period, no reduction shall be made under subparagraph (A) on the basis of the previous failure to provide such information.

(4) Residents

The residents described in this paragraph are those who are in part-time or full-time equivalent resident training positions at a qualified teaching health center in any approved graduate medical residency training program.

(i) Regulations

The Secretary shall promulgate regulations to carry out this section.

(j) Definitions

In this section:

(1) Approved graduate medical residency training program

The term "approved graduate medical residency training program" means a residency or other postgraduate medical training program—

(A) participation in which may be counted toward certification in a specialty or subspecialty and includes formal postgraduate training programs in geriatric medicine approved by the Secretary; and

(B) that meets criteria for accreditation (as established by the Accreditation Council for Graduate Medical Education, the American Osteopathic Association, or the American Dental Association).

(2) New approved graduate medical residency training program

The term "new approved graduate medical residency training program" means an approved graduate medical residency training program for which the sponsoring qualified teaching health center has not received a payment under this section for a previous fiscal year (other than pursuant to subsection (a)(1)(C)).

(3) Primary care residency program

The term "primary care residency program" has the meaning given that term in section 293l–1 of this title.

(4) Qualified teaching health center

The term "qualified teaching health center" has the meaning given the term "teaching health center" in section 293l–1 of this title.

(July 1, 1944, ch. 373, title III, §340H, as added Pub. L. 111–148, title V, §5508(c), Mar. 23, 2010, 124 Stat. 670; amended Pub. L. 114–10, title II, §221(b), Apr. 16, 2015, 129 Stat. 154; Pub. L. 115–63, title III, §301(a), Sept. 29, 2017, 131 Stat. 1171; Pub. L. 115–96, div. C, title I, §3101(c), Dec. 22, 2017, 131 Stat. 2048; Pub. L. 115–123, div. E, title IX, §50901(d)(1)–(3), (5), (6), Feb. 9, 2018, 132 Stat. 287–289; Pub. L. 116–59, div. B, title I, §1101(c), Sept. 27, 2019, 133 Stat. 1102; Pub. L. 116–69, div. B, title I, §1101(c), Nov. 21, 2019, 133 Stat. 1136; Pub. L. 116–94, div. N, title I, §401(c), Dec. 20, 2019, 133 Stat. 3113; Pub. L. 116–136, div. A, title III, §3831(c), Mar. 27, 2020, 134 Stat. 434; Pub. L. 116–159, div. C, title I, §2101(c), Oct. 1, 2020, 134 Stat. 728; Pub. L. 116–215, div. B, title II, §1201(c), Dec. 11, 2020, 134 Stat. 1044; Pub. L. 116–260, div. BB, title III, §301(c), Dec. 27, 2020, 134 Stat. 2922; Pub. L. 118–15, div. B, title III, §2321(a), Sept. 30, 2023, 137 Stat. 94; Pub. L. 118–22, div. B, title II, §201(a), Nov. 17, 2023, 137 Stat. 119; Pub. L. 118–35, div. B, title I, §101(a), Jan. 19, 2024, 138 Stat. 4; Pub. L. 118–42, div. G, title I, §101(c)(1), (2), Mar. 9, 2024, 138 Stat. 397; Pub. L. 118–158, div. C, title I, §3101(c), Dec. 21, 2024, 138 Stat. 1762; Pub. L. 119–4, div. B, title I, §2101(c), Mar. 15, 2025, 139 Stat. 40; Pub. L. 119–37, div. F, title I, §6101(c), Nov. 12, 2025, 139 Stat. 629; Pub. L. 119–75, div. J, title IV, §6401(c), Feb. 3, 2026, 140 Stat. 687.)

EDITORIAL NOTES

REFERENCES IN TEXT

Section 4410 of the Balanced Budget Act of 1997, referred to in subsec. (c)(2)(A)(ii), is section 4410 of Pub. L. 105–33, which is set out as a note under section 1395ww of this title.

Section 1395ww(d) of this title, referred to in subsec. (f), was in the original "section 1186(d) of such Act", and was translated as meaning section 1886(d) of act Aug. 14, 1935, ch. 531, known as the Social Security Act, to reflect the probable intent of Congress. The Social Security Act does not contain a section 1186.

CODIFICATION

Another section 340H of act July 1, 1944, was renumbered section 340I and is classified to section 256i of this title.

AMENDMENTS

2026—Subsec. (g)(1)(D) to (I). Pub. L. 119–75 added subpars. (D) to (I) and struck out former subpars. (D) to (G) which read as follows:

"(D) $16,635,616 for the period beginning on October 1, 2023, and ending on November 17, 2023, $21,834,247 for the period beginning on November 18, 2023, and ending on January 19, 2024, $16,982,192 for the period beginning on January 20, 2024, and ending on March 8, 2024, and $164,136,986 for the period beginning on October 1, 2023, and ending on December 31, 2024;

"(E) $43,150,685 for the period beginning on January 1, 2025, and ending on March 31, 2025;

"(F) $87,739,726 for the period beginning on April 1, 2025, and ending on September 30, 2025; and

"(G) $58,493,151 for the period beginning on October 1, 2025, and ending on January 30, 2026."

2025—Subsec. (g)(1)(F). Pub. L. 119–4 added subpar. (F).

Subsec. (g)(1)(G). Pub. L. 119–37 added subpar. (G).

2024—Subsec. (b)(2)(C). Pub. L. 118–42, §101(c)(2), added subpar. (C).

Subsec. (g)(1). Pub. L. 118–158, §3101(c)(2), substituted ", not to exceed—" and subpars. (A) to (E) for period at end.

Pub. L. 118–158, §3101(c)(1), struck out "not to exceed $230,000,000, for the period of fiscal years 2011 through 2015, $60,000,000 for each of fiscal years 2016 and 2017, $126,500,000 for each of fiscal years 2018 through 2023, $16,635,616 for the period beginning on October 1, 2023, and ending on November 17, 2023, $21,834,247 for the period beginning on November 18, 2023, and ending on January 19, 2024, $16,982,192 for the period beginning on January 20, 2024, and ending on March 8, 2024, and $164,136,986 for the period beginning on October 1, 2023, and ending on December 31, 2024," after "as may be necessary,".

Pub. L. 118–42, §101(c)(1), substituted "$16,982,192 for the period beginning on January 20, 2024, and ending on March 8, 2024, and $164,136,986 for the period beginning on October 1, 2023, and ending on December 31, 2024" for "and $16,982,192 for the period beginning on January 20, 2024, and ending on March 8, 2024".

Pub. L. 118–35 substituted "$21,834,247 for the period beginning on November 18, 2023, and ending on January 19, 2024, and $16,982,192 for the period beginning on January 20, 2024, and ending on March 8, 2024" for "and $21,834,247 for the period beginning on November 18, 2023, and ending on January 19, 2024".

2023—Subsec. (g)(1). Pub. L. 118–22 substituted "$16,635,616 for the period beginning on October 1, 2023, and ending on November 17, 2023, and $21,834,247 for the period beginning on November 18, 2023, and ending on January 19, 2024" for "and $16,635,616 for the period beginning on October 1, 2023, and ending on November 17, 2023".

Pub. L. 118–15 struck out "and" before "$126,500,000" and inserted "and $16,635,616 for the period beginning on October 1, 2023, and ending on November 17, 2023," before "to remain available".

2020—Subsec. (g)(1). Pub. L. 116–260 inserted "and" after "2017," and substituted "2023" for "fiscal year 2020, and $27,379,452 for the period beginning on October 1, 2020, and ending on December 18, 2020".

Pub. L. 116–215 substituted "$27,379,452" for "$24,953,425" and "December 18, 2020" for "December 11, 2020".

Pub. L. 116–159 substituted "$24,953,425" for "$21,141,096" and "December 11, 2020" for "November 30, 2020".

Pub. L. 116–136 substituted "through fiscal year 2020, and $21,141,096 for the period beginning on October 1, 2020, and ending on November 30, 2020" for "and 2019, and $81,445,205 for the period beginning on October 1, 2019, and ending on May 22, 2020".

2019—Subsec. (g)(1). Pub. L. 116–94 substituted "$81,445,205" for "$28,072,603" and "May 22, 2020" for

"December 20, 2019".

Pub. L. 116–69 substituted "$28,072,603" for "$18,021,918" and "December 20, 2019" for "November 21, 2019".

Pub. L. 116–59 struck out "and" before "$126,500,000" and inserted "and $18,021,918 for the period beginning on October 1, 2019, and ending on November 21, 2019," before "to remain available".

2018—Subsec. (a). Pub. L. 115–123, §50901(d)(1), amended subsec. (a) generally. Prior to amendment, text read as follows: "Subject to subsection (h)(2), the Secretary shall make payments under this section for direct expenses and for indirect expenses to qualified teaching health centers that are listed as sponsoring institutions by the relevant accrediting body for expansion of existing or establishment of new approved graduate medical residency training programs."

Subsec. (f). Pub. L. 115–123, §50901(d)(6), substituted "teaching health center" for "hospital" wherever appearing.

Subsec. (g)(1). Pub. L. 115–123, §50901(d)(2), substituted "and $126,500,000 for each of fiscal years 2018 and 2019," for "and $30,000,000 for the period of the first and second quarters of fiscal year 2018,".

Subsec. (h)(1)(D) to (H). Pub. L. 115–123, §50901(d)(3), added subpars. (D) to (G) and redesignated former subpar. (D) as (H).

Subsec. (j)(2) to (4). Pub. L. 115–123, §50901(d)(5), added par. (2) and redesignated former pars. (2) and (3) as (3) and (4), respectively.

2017—Subsec. (g). Pub. L. 115–96 designated existing provisions as par. (1), inserted heading, substituted "and $30,000,000 for the period of the first and second quarters of fiscal year 2018, to remain available until expended" for "and $15,000,000 for the first quarter of fiscal year 2018", and added par. (2).

Pub. L. 115–63 substituted "2015, $60,000,000" for "2015 and $60,000,000" and inserted ", and $15,000,000 for the first quarter of fiscal year 2018" before period at end.

2015—Subsec. (g). Pub. L. 114–10 inserted "and $60,000,000 for each of fiscal years 2016 and 2017" before period at end.

STATUTORY NOTES AND RELATED SUBSIDIARIES

FUNDING FOR TEACHING HEALTH CENTERS THAT OPERATE GRADUATE MEDICAL EDUCATION

Pub. L. 117–2, title II, §2604, Mar. 11, 2021, 135 Stat. 44, provided that:

"(a) IN GENERAL.—In addition to amounts otherwise available, and notwithstanding the capped amount referenced in sections 340H(b)(2) and 340H(d)(2) of the Public Health Service Act (42 U.S.C. 256h(b)(2) and (d)(2)), there is appropriated to the Secretary [of Health and Human Services] for fiscal year 2021, out of any money in the Treasury not otherwise appropriated, $330,000,000, to remain available until September 30, 2023, for the program of payments to teaching health centers that operate graduate medical education under section 340H of the Public Health Service Act (42 U.S.C. 256h) and for teaching health center development grants authorized under section 749A of the Public Health Service Act (42 U.S.C. 293l–1).

"(b) USE OF FUNDS.—Amounts made available pursuant to subsection (a) shall be used for the following activities:

"(1) For making payments to establish new approved graduate medical residency training programs pursuant to section 340H(a)(1)(C) of the Public Health Service Act (42 U.S.C. 256h(a)(1)(C)).

"(2) To provide an increase to the per resident amount described in section 340H(a)(2) of the Public Health Service Act (42 U.S.C. 256h(a)(2)) of $10,000.

"(3) For making payments under section 340H(a)(1)(A) of the Public Health Service Act (42 U.S.C. 256h(a)(1)(A))) [sic] to qualified teaching health centers for maintenance of filled positions at existing approved graduate medical residency training programs.

"(4) For making payments under section 340H(a)(1)(B) of the Public Health Service Act (42 U.S.C. 256h(a)(1)(B)) for the expansion of existing approved graduate medical residency training programs.

"(5) For making awards under section 749A of the Public Health Service Act (42 U.S.C. 293l–1) to teaching health centers for the purpose of establishing new accredited or expanded primary care residency programs.

"(6) To cover administrative costs and activities necessary for qualified teaching health centers receiving payments under section 340H of the Public Health Service Act (42 U.S.C. 256h) to carry out activities under such section."

PAYMENTS FOR PREVIOUS FISCAL YEARS

Pub. L. 115–123, div. E, title IX, §50901(d)(7), Feb. 9, 2018, 132 Stat. 289, provided that: "The provisions

of section 340H of the Public Health Service Act (42 U.S.C. 256h), as in effect on the day before the date of enactment of Public Law 115–96 [Dec. 22, 2017], shall continue to apply with respect to payments under such section for fiscal years before fiscal year 2018."

[1] *So in original. Probably should be "subsections".*

[2] *See References in Text note below.*

SUBPART XII—COMMUNITY-BASED COLLABORATIVE CARE NETWORK PROGRAM

EDITORIAL NOTES

CODIFICATION

Pub. L. 115–63, title III, §301(c)(1), Sept. 29, 2017, 131 Stat. 1172, redesignated this subpart, which was formerly subpart XI of part D of title III of act July 1, 1944, as subpart XII. Another subpart XI of part D of title III of the Act is classified to subpart XI (§256h) of this part.

§256i. Community-based collaborative care network program

(a) In general

The Secretary may award grants to eligible entities to support community-based collaborative care networks that meet the requirements of subsection (b).

(b) Community-based collaborative care networks

(1) Description

A community-based collaborative care network (referred to in this section as a "network") shall be a consortium of health care providers with a joint governance structure (including providers within a single entity) that provides comprehensive coordinated and integrated health care services (as defined by the Secretary) for low-income populations.

(2) Required inclusion

A network shall include the following providers (unless such provider does not exist within the community, declines or refuses to participate, or places unreasonable conditions on their participation):

(A) A hospital that meets the criteria in section 1396r–4(b)(1) of this title; and

(B) All Federally qualified health centers (as defined in section 1395x(aa) of this title [1] located in the community.

(3) Priority

In awarding grants, the Secretary shall give priority to networks that include—

(A) the capability to provide the broadest range of services to low-income individuals;

(B) the broadest range of providers that currently serve a high volume of low-income individuals; and

(C) a county or municipal department of health.

(c) Application

(1) Application

A network described in subsection (b) shall submit an application to the Secretary.

(2) Renewal

In subsequent years, based on the performance of grantees, the Secretary may provide renewal grants to prior year grant recipients.

(d) Use of funds

(1) Use by grantees

Grant funds may be used for the following activities:

(A) Assist low-income individuals to—

(i) access and appropriately use health services;

(ii) enroll in health coverage programs; and

(iii) obtain a regular primary care provider or a medical home.

(B) Provide case management and care management.

(C) Perform health outreach using neighborhood health workers or through other means.

(D) Provide transportation.

(E) Expand capacity, including through telehealth, after-hours services or urgent care.

(F) Provide direct patient care services.

(2) Grant funds to HRSA grantees

The Secretary may limit the percent of grant funding that may be spent on direct care services provided by grantees of programs administered by the Health Resources and Services Administration or impose other requirements on such grantees deemed necessary.

(e) Authorization of appropriations

There are authorized to be appropriated to carry out this section such sums as may be necessary for each of fiscal years 2011 through 2015.

(July 1, 1944, ch. 373, title III, §340I, formerly §340H, as added Pub. L. 111–148, title X, §10333, Mar. 23, 2010, 124 Stat. 970; renumbered §340I, Pub. L. 115–63, title III, §301(c)(2), Sept. 29, 2017, 131 Stat. 1172.)

[1] So in original. A closing parenthesis probably should appear.

PART E—NARCOTIC ADDICTS AND OTHER DRUG ABUSERS

§257. Repealed. Pub. L. 106–310, div. B, title XXXIV, §3405(a), Oct. 17, 2000, 114 Stat. 1221, as amended by Pub. L. 114–198, title I, §110(b), July 22, 2016, 130 Stat. 710

Section, acts July 1, 1944, ch. 373, title III, §341, 58 Stat. 698; May 8, 1954, ch. 195, §3, 68 Stat. 80; July 24, 1956, ch. 676, title III, §302(a), 70 Stat. 622; Pub. L. 89–793, title VI, §601, Nov. 8, 1966, 80 Stat. 1449; 1967 Reorg. Plan No. 3, §401, eff. Nov. 3, 1967 (in part), 32 F.R. 11669, 81 Stat. 951; Pub. L. 91–513, title I, §2(a)(1), Oct. 27, 1970, 84 Stat. 1240; Pub. L. 92–255, title IV, §402, Mar. 21, 1972, 86 Stat. 77; Pub. L. 93–198, title IV, §421, Dec. 24, 1973, 87 Stat. 789; Pub. L. 98–473, title II, §232(a), Oct. 12, 1984, 98 Stat. 2031; Pub. L. 99–646, §22(a), Nov. 10, 1986, 100 Stat. 3597; Pub. L. 102–54, §13(q)(1)(B)(i), June 13, 1991, 105 Stat. 278, related to care and treatment of narcotic addicts.

STATUTORY NOTES AND RELATED SUBSIDIARIES

EFFECTIVE DATE OF 2016 AMENDMENT

Pub. L. 114–198, title I, §110(b), July 22, 2016, 130 Stat. 710, provided that the amendment made by section 110(b) (amending directory language of section 3405(a) of Pub. L. 106–310, which repealed this section) is effective as if included in the enactment of Pub. L. 106–310.

§257a. Transferred

EDITORIAL NOTES

CODIFICATION

Section, Pub. L. 91–513, title I, §4, Oct. 27, 1970, 84 Stat. 1241; Pub. L. 96–88, title V, §509(b), Oct. 17, 1979, 93 Stat. 695, which related to medical treatment of narcotics addiction, was transferred to section 290bb–2a of this title.

§258. Repealed. Pub. L. 106–310, div. B, title XXXIV, §3405(a), Oct. 17, 2000, 114 Stat. 1221, as amended by Pub. L. 114–198, title I, §110(b), July 22, 2016, 130 Stat. 710

Section, acts July 1, 1944, ch. 373, title III, §342, 58 Stat. 699; 1953 Reorg. Plan No. 1, §§5, 8, eff. Apr. 11, 1953, 18 F.R. 2053, 67 Stat. 631; Pub. L. 91–513, title I, §2(a)(2)(A), Oct. 27, 1970, 84 Stat. 1240; Pub. L. 96–88, title V, §509(b), Oct. 17, 1979, 93 Stat. 695, related to employment, establishment of industries, plants, etc., sale of commodities, and disposition of proceeds.

STATUTORY NOTES AND RELATED SUBSIDIARIES

EFFECTIVE DATE OF 2016 AMENDMENT

Pub. L. 114–198, title I, §110(b), July 22, 2016, 130 Stat. 710, provided that the amendment made by section 110(b) (amending directory language of section 3405(a) of Pub. L. 106–310, which repealed this section) is effective as if included in the enactment of Pub. L. 106–310.

§258a. Transferred

EDITORIAL NOTES

CODIFICATION

Section, act July 8, 1947, ch. 210, title II, §201, 61 Stat. 269, which related to transfer of balances in working capital fund, narcotic hospitals, to surplus fund, was transferred and is set out as a note under section 290aa of this title.

§§259 to 261a. Repealed. Pub. L. 106–310, div. B, title XXXIV, §3405(a), Oct. 17, 2000, 114 Stat. 1221, as amended by Pub. L. 114–198, title I, §110(b), July 22, 2016, 130 Stat. 710

Section 259, acts July 1, 1944, ch. 373, title III, §343, 58 Stat. 699; Pub. L. 91–513, title I, §2(a)(2)(A), (3), (4), Oct. 27, 1970, 84 Stat. 1240; Pub. L. 92–293, §3, May 11, 1972, 86 Stat. 136; Pub. L. 98–473, title II, §232(b), Oct. 12, 1984, 98 Stat. 2031, related to convict addicts or other persons with drug abuse or drug dependence problems.

Section 260, acts July 1, 1944, ch. 373, title III, §344, 58 Stat. 701; June 25, 1948, ch. 654, §5, 62 Stat. 1018; July 24, 1956, ch. 676, title III, §302(b), 70 Stat. 622; Pub. L. 91–513, title I, §2(a)(2)(A), (3), (4), Oct. 27, 1970, 84 Stat. 1240, related to addicts and persons with drug abuse or drug dependence problems.

Section 260a, act July 1, 1944, ch. 373, title III, §345, as added May 8, 1954, ch. 195, §2, 68 Stat. 79; amended July 24, 1956, ch. 676, title III, §302(c), 70 Stat. 622; Pub. L. 91–358, title I, §155(c)(32), July 29, 1970, 84 Stat. 572, related to admission of addicts committed from District of Columbia.

Section 261, acts July 1, 1944, ch. 373, title III, §346, formerly §345, 58 Stat. 701; renumbered §346, May 8, 1954, ch. 195, §2, 68 Stat. 79; amended Pub. L. 91–513, title I, §2(a)(2)(A), (5), Oct. 27, 1970, 84 Stat.

1240, related to penalties for introducing prohibited articles and substances into hospitals and escaping from, or aiding and abetting escape from hospitals.

Section 261a, act July 1, 1944, ch. 373, title III, §347, as added May 8, 1954, ch. 195, §4, 68 Stat. 80; amended Pub. L. 91–513, title I, §2(a)(4), Oct. 27, 1970, 84 Stat. 1240, related to release of patients and determination by Surgeon General.

STATUTORY NOTES AND RELATED SUBSIDIARIES

EFFECTIVE DATE OF 2016 AMENDMENT

Pub. L. 114–198, title I, §110(b), July 22, 2016, 130 Stat. 710, provided that the amendment made by section 110(b) (amending directory language of section 3405(a) of Pub. L. 106–310, which repealed sections 259 to 261a of this title) is effective as if included in the enactment of Pub. L. 106–310.

PART F—LICENSING OF BIOLOGICAL PRODUCTS AND CLINICAL LABORATORIES

SUBPART 1—BIOLOGICAL PRODUCTS

§262. Regulation of biological products

(a) Biologics license

(1) No person shall introduce or deliver for introduction into interstate commerce any biological product unless—

(A) a biologics license under this subsection or subsection (k) is in effect for the biological product; and

(B) each package of the biological product is plainly marked with—

(i) the proper name of the biological product contained in the package;

(ii) the name, address, and applicable license number of the manufacturer of the biological product; and

(iii) the expiration date of the biological product.

(2)(A) The Secretary shall establish, by regulation, requirements for the approval, suspension, and revocation of biologics licenses.

(B) PEDIATRIC STUDIES.—A person that submits an application for a license under this paragraph shall submit to the Secretary as part of the application any assessments required under section 505B of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 355c].

(C) The Secretary shall approve a biologics license application—

(i) on the basis of a demonstration that—

(I) the biological product that is the subject of the application is safe, pure, and potent; and

(II) the facility in which the biological product is manufactured, processed, packed, or held meets standards designed to assure that the biological product continues to be safe, pure, and potent; and

(ii) if the applicant (or other appropriate person) consents to the inspection of the facility that is the subject of the application, in accordance with subsection (c).

(D) POSTMARKET STUDIES AND CLINICAL TRIALS; LABELING; RISK EVALUATION AND MITIGATION STRATEGY.—A person that submits an application for a license under this paragraph is subject to sections 505(o), 505(p), and 505–1 of the Federal Food, Drug, and Cosmetic

Act [21 U.S.C. 355(o), (p), 355–1].

(E)(i) The Secretary may rely upon qualified data summaries to support the approval of a supplemental application, with respect to a qualified indication for a drug, submitted under this subsection, if such supplemental application complies with the requirements of subparagraph (B) of section 505(c)(5) of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 355(c)(5)].

(ii) In this subparagraph, the terms "qualified indication" and "qualified data summary" have the meanings given such terms in section 505(c)(5) of the Federal Food, Drug, and Cosmetic Act.

(3) The Secretary shall prescribe requirements under which a biological product undergoing investigation shall be exempt from the requirements of paragraph (1).

(b) Falsely labeling or marking package or container; altering label or mark

No person shall falsely label or mark any package or container of any biological product or alter any label or mark on the package or container of the biological product so as to falsify the label or mark.

(c) Inspection of establishment for propagation and preparation

Any officer, agent, or employee of the Department of Health and Human Services, authorized by the Secretary for the purpose, may during all reasonable hours enter and inspect any establishment for the propagation or manufacture and preparation of any biological product.

(d) Recall of product presenting imminent hazard; violations

(1) Upon a determination that a batch, lot, or other quantity of a product licensed under this section presents an imminent or substantial hazard to the public health, the Secretary shall issue an order immediately ordering the recall of such batch, lot, or other quantity of such product. An order under this paragraph shall be issued in accordance with section 554 of title 5.

(2) Any violation of paragraph (1) shall subject the violator to a civil penalty of up to $100,000 per day of violation. The amount of a civil penalty under this paragraph shall, effective December 1 of each year beginning 1 year after the effective date of this paragraph, be increased by the percent change in the Consumer Price Index for the base quarter of such year over the Consumer Price Index for the base quarter of the preceding year, adjusted to the nearest 1/10 of 1 percent. For purposes of this paragraph, the term "base quarter", as used with respect to a year, means the calendar quarter ending on September 30 of such year and the price index for a base quarter is the arithmetical mean of such index for the 3 months comprising such quarter.

(e) Interference with officers

No person shall interfere with any officer, agent, or employee of the Service in the performance of any duty imposed upon him by this section or by regulations made by authority thereof.

(f) Penalties for offenses

Any person who shall violate, or aid or abet in violating, any of the provisions of this section shall be punished upon conviction by a fine not exceeding $500 or by imprisonment not exceeding one year, or by both such fine and imprisonment, in the discretion of the court.

(g) Construction with other laws

Nothing contained in this chapter shall be construed as in any way affecting, modifying, repealing, or superseding the provisions of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 301 et seq.].

(h) Exportation of partially processed biological products

A partially processed biological product which—

(1) is not in a form applicable to the prevention, treatment, or cure of diseases or injuries of man;

(2) is not intended for sale in the United States; and

(3) is intended for further manufacture into final dosage form outside the United States,

shall be subject to no restriction on the export of the product under this chapter or the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 301 et seq.] if the product is manufactured, processed,

packaged, and held in conformity with current good manufacturing practice requirements or meets international manufacturing standards as certified by an international standards organization recognized by the Secretary and meets the requirements of section 801(e)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 381(e)).

(i) "Biological product" defined

In this section:

(1) The term "biological product" means a virus, therapeutic serum, toxin, antitoxin, vaccine, blood, blood component or derivative, allergenic product, protein, or analogous product, or arsphenamine or derivative of arsphenamine (or any other trivalent organic arsenic compound), applicable to the prevention, treatment, or cure of a disease or condition of human beings.

(2) The term "biosimilar" or "biosimilarity", in reference to a biological product that is the subject of an application under subsection (k), means—

(A) that the biological product is highly similar to the reference product notwithstanding minor differences in clinically inactive components; and

(B) there are no clinically meaningful differences between the biological product and the reference product in terms of the safety, purity, and potency of the product.

(3) The term "interchangeable" or "interchangeability", in reference to a biological product that is shown to meet the standards described in subsection (k)(4), means that the biological product may be substituted for the reference product without the intervention of the health care provider who prescribed the reference product.

(4) The term "reference product" means the single biological product licensed under subsection (a) against which a biological product is evaluated in an application submitted under subsection (k).

(j) Application of Federal Food, Drug, and Cosmetic Act

The Federal Food, Drug, and Cosmetic Act [21 U.S.C. 301 et seq.], including the requirements under sections 505(o), 505(p), and 505–1 of such Act [21 U.S.C. 355(o), (p), 355–1], applies to a biological product subject to regulation under this section, except that a product for which a license has been approved under subsection (a) shall not be required to have an approved application under section 505 of such Act.

(k) Licensure of biological products as biosimilar or interchangeable

(1) In general

Any person may submit an application for licensure of a biological product under this subsection.

(2) Content

(A) In general

(i) Required information

An application submitted under this subsection shall include information demonstrating that—

(I) the biological product is biosimilar to a reference product based upon data derived from—

(aa) analytical studies that demonstrate that the biological product is highly similar to the reference product notwithstanding minor differences in clinically inactive components;

(bb) an assessment of toxicity (which may rely on, or consist of, a study or studies described in item (aa) or (cc)); and

(cc) a clinical study or studies (including the assessment of immunogenicity and pharmacokinetics or pharmacodynamics) that are sufficient to demonstrate safety,

purity, and potency in 1 or more appropriate conditions of use for which the reference product is licensed and intended to be used and for which licensure is sought for the biological product;

(II) the biological product and reference product utilize the same mechanism or mechanisms of action for the condition or conditions of use prescribed, recommended, or suggested in the proposed labeling, but only to the extent the mechanism or mechanisms of action are known for the reference product;

(III) the condition or conditions of use prescribed, recommended, or suggested in the labeling proposed for the biological product have been previously approved for the reference product;

(IV) the route of administration, the dosage form, and the strength of the biological product are the same as those of the reference product; and

(V) the facility in which the biological product is manufactured, processed, packed, or held meets standards designed to assure that the biological product continues to be safe, pure, and potent.

(ii) Determination by Secretary

The Secretary may determine, in the Secretary's discretion, that an element described in clause (i)(I) is unnecessary in an application submitted under this subsection.

(iii) Additional information

An application submitted under this subsection—

(I) shall include publicly-available information regarding the Secretary's previous determination that the reference product is safe, pure, and potent;

(II) may include any additional information in support of the application, including publicly-available information with respect to the reference product or another biological product; and

(III) may include information to show that the conditions of use prescribed, recommended, or suggested in the labeling proposed for the biological product have been previously approved for the reference product.

(B) Interchangeability

An application (or a supplement to an application) submitted under this subsection may include information demonstrating that the biological product meets the standards described in paragraph (4).

(3) Evaluation by Secretary

Upon review of an application (or a supplement to an application) submitted under this subsection, the Secretary shall license the biological product under this subsection if—

(A) the Secretary determines that the information submitted in the application (or the supplement) is sufficient to show that the biological product—

(i) is biosimilar to the reference product; or

(ii) meets the standards described in paragraph (4), and therefore is interchangeable with the reference product; and

(B) the applicant (or other appropriate person) consents to the inspection of the facility that is the subject of the application, in accordance with subsection (c).

(4) Safety standards for determining interchangeability

Upon review of an application submitted under this subsection or any supplement to such application, the Secretary shall determine the biological product to be interchangeable with the reference product if the Secretary determines that the information submitted in the application (or a supplement to such application) is sufficient to show that—

(A) the biological product—

(i) is biosimilar to the reference product; and

(ii) can be expected to produce the same clinical result as the reference product in any given patient; and

(B) for a biological product that is administered more than once to an individual, the risk in terms of safety or diminished efficacy of alternating or switching between use of the biological product and the reference product is not greater than the risk of using the reference product without such alternation or switch.

(5) General rules

(A) One reference product per application

A biological product, in an application submitted under this subsection, may not be evaluated against more than 1 reference product.

(B) Review

An application submitted under this subsection shall be reviewed by the division within the Food and Drug Administration that is responsible for the review and approval of the application under which the reference product is licensed.

(C) Risk evaluation and mitigation strategies

The authority of the Secretary with respect to risk evaluation and mitigation strategies under the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 301 et seq.] shall apply to biological products licensed under this subsection in the same manner as such authority applies to biological products licensed under subsection (a).

(6) Exclusivity for first interchangeable biological product

The Secretary shall not make approval as an interchangeable biological product effective with respect to an application submitted under this subsection that relies on the same reference product for which a prior biological product has received a determination of interchangeability for any condition of use, until the earlier of—

(A) 1 year after the first commercial marketing of the first interchangeable biosimilar biological product to be approved as interchangeable for that reference product;

(B) 18 months after—

(i) a final court decision on all patents in suit in an action instituted under subsection (l)(6) against the applicant that submitted the application for the first approved interchangeable biosimilar biological product; or

(ii) the dismissal with or without prejudice of an action instituted under subsection (l)(6) against the applicant that submitted the application for the first approved interchangeable biosimilar biological product; or

(C)(i) 42 months after approval of the first interchangeable biosimilar biological product if the applicant that submitted such application has been sued under subsection (l)(6) and such litigation is still ongoing within such 42-month period; or

(ii) 18 months after approval of the first interchangeable biosimilar biological product if the applicant that submitted such application has not been sued under subsection (l)(6).

For purposes of this paragraph, the term "final court decision" means a final decision of a court from which no appeal (other than a petition to the United States Supreme Court for a writ of certiorari) has been or can be taken, and the term "first interchangeable biosimilar biological product" means any interchangeable biosimilar biological product that is approved on the first day on which such a product is approved as interchangeable with the reference product.

(7) Exclusivity for reference product

(A) Effective date of biosimilar application approval

Approval of an application under this subsection may not be made effective by the Secretary until the date that is 12 years after the date on which the reference product was first licensed under subsection (a).

(B) Filing period

An application under this subsection may not be submitted to the Secretary until the date that is 4 years after the date on which the reference product was first licensed under subsection (a).

(C) First licensure

Subparagraphs (A) and (B) shall not apply to a license for or approval of—

(i) a supplement for the biological product that is the reference product; or

(ii) a subsequent application filed by the same sponsor or manufacturer of the biological product that is the reference product (or a licensor, predecessor in interest, or other related entity) for—

(I) a change (not including a modification to the structure of the biological product) that results in a new indication, route of administration, dosing schedule, dosage form, delivery system, delivery device, or strength; or

(II) a modification to the structure of the biological product that does not result in a change in safety, purity, or potency.

(D) Deemed licenses

(i) No additional exclusivity through deeming

An approved application that is deemed to be a license for a biological product under this section pursuant to section 7002(e)(4) of the Biologics Price Competition and Innovation Act of 2009 shall not be treated as having been first licensed under subsection (a) for purposes of subparagraphs (A) and (B).

(ii) Application of limitations on exclusivity

Subparagraph (C) shall apply with respect to a reference product referred to in such subparagraph that was the subject of an approved application that was deemed to be a license pursuant to section 7002(e)(4) of the Biologics Price Competition and Innovation Act of 2009.

(iii) Applicability

The exclusivity periods described in section 527, section 505A(b)(1)(A)(ii), and section 505A(c)(1)(A)(ii) of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 360cc and 355a(b)(1)(A)(ii), (c)(1)(A)(ii)] shall continue to apply to a biological product after an approved application for the biological product is deemed to be a license for the biological product under subsection (a) pursuant to section 7002(e)(4) of the Biologics Price Competition and Innovation Act of 2009.

(8) Guidance documents

(A) In general

The Secretary may, after opportunity for public comment, issue guidance in accordance, except as provided in subparagraph (B)(i), with section 701(h) of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 371(h)] with respect to the licensure of a biological product under this subsection. Any such guidance may be general or specific.

(B) Public comment

(i) In general

The Secretary shall provide the public an opportunity to comment on any proposed guidance issued under subparagraph (A) before issuing final guidance.

(ii) Input regarding most valuable guidance

The Secretary shall establish a process through which the public may provide the Secretary

with input regarding priorities for issuing guidance.

(C) No requirement for application consideration

The issuance (or non-issuance) of guidance under subparagraph (A) shall not preclude the review of, or action on, an application submitted under this subsection.

(D) Requirement for product class-specific guidance

If the Secretary issues product class-specific guidance under subparagraph (A), such guidance shall include a description of—

(i) the criteria that the Secretary will use to determine whether a biological product is highly similar to a reference product in such product class; and

(ii) the criteria, if available, that the Secretary will use to determine whether a biological product meets the standards described in paragraph (4).

(E) Certain product classes

(i) Guidance

The Secretary may indicate in a guidance document that the science and experience, as of the date of such guidance, with respect to a product or product class (not including any recombinant protein) does not allow approval of an application for a license as provided under this subsection for such product or product class.

(ii) Modification or reversal

The Secretary may issue a subsequent guidance document under subparagraph (A) to modify or reverse a guidance document under clause (i).

(iii) No effect on ability to deny license

Clause (i) shall not be construed to require the Secretary to approve a product with respect to which the Secretary has not indicated in a guidance document that the science and experience, as described in clause (i), does not allow approval of such an application.

(9) Public listing

(A) In general

(i) Initial publication

Not later than 180 days after December 27, 2020, the Secretary shall publish and make available to the public in a searchable, electronic format—

(I) a list of each biological product, by nonproprietary name (proper name), for which, as of December 27, 2020, a biologics license under subsection (a) or this subsection is in effect, or that, as of such date of enactment, is deemed to be licensed under this section pursuant to section 7002(e)(4) of the Biologics Price Competition and Innovation Act of 2009;

(II) the date of licensure of the marketing application and the application number; and

(III) with respect to each biological product described in subclause (I), the licensure status, and, as available, the marketing status.

(ii) Revisions

Every 30 days after the publication of the first list under clause (i), the Secretary shall revise the list to include each biological product which has been licensed under subsection (a) or this subsection during the 30-day period or deemed licensed under this section pursuant to section 7002(e)(4) of the Biologics Price Competition and Innovation Act of 2009.

(iii) Patent information

Not later than 30 days after a list of patents under subsection (l)(3)(A), or a supplement to such list under subsection (l)(7), has been provided by the reference product sponsor to the subsection (k) applicant respecting a biological product included on the list published under this subparagraph, the reference product sponsor shall provide such list of patents (or

supplement thereto) and their corresponding expiry dates to the Secretary, and the Secretary shall, in revisions made under clause (ii), include such information for such biological product. Within 30 days of providing any subsequent or supplemental list of patents to any subsequent subsection (k) applicant under subsection (l)(3)(A) or (l)(7), the reference product sponsor shall update the information provided to the Secretary under this clause with any additional patents from such subsequent or supplemental list and their corresponding expiry dates.

(iv) Listing of exclusivities

For each biological product included on the list published under this subparagraph, the Secretary shall specify each exclusivity period under paragraph (6) or paragraph (7) for which the Secretary has determined such biological product to be eligible and that has not concluded.

(B) Revocation or suspension of license

If the license of a biological product is determined by the Secretary to have been revoked or suspended for safety, purity, or potency reasons, it may not be published in the list under subparagraph (A). If such revocation or suspension occurred after inclusion of such biological product in the list published under subparagraph (A), the reference product sponsor shall notify the Secretary that—

(i) the biological product shall be immediately removed from such list for the same period as the revocation or suspension; and

(ii) a notice of the removal shall be published in the Federal Register.

(l) Patents

(1) Confidential access to subsection (k) application

(A) Application of paragraph

Unless otherwise agreed to by a person that submits an application under subsection (k) (referred to in this subsection as the "subsection (k) applicant") and the sponsor of the application for the reference product (referred to in this subsection as the "reference product sponsor"), the provisions of this paragraph shall apply to the exchange of information described in this subsection.

(B) In general

(i) Provision of confidential information

When a subsection (k) applicant submits an application under subsection (k), such applicant shall provide to the persons described in clause (ii), subject to the terms of this paragraph, confidential access to the information required to be produced pursuant to paragraph (2) and any other information that the subsection (k) applicant determines, in its sole discretion, to be appropriate (referred to in this subsection as the "confidential information").

(ii) Recipients of information

The persons described in this clause are the following:

(I) Outside counsel

One or more attorneys designated by the reference product sponsor who are employees of an entity other than the reference product sponsor (referred to in this paragraph as the "outside counsel"), provided that such attorneys do not engage, formally or informally, in patent prosecution relevant or related to the reference product.

(II) In-house counsel

One attorney that represents the reference product sponsor who is an employee of the reference product sponsor, provided that such attorney does not engage, formally or informally, in patent prosecution relevant or related to the reference product.

(iii) Patent owner access

A representative of the owner of a patent exclusively licensed to a reference product sponsor with respect to the reference product and who has retained a right to assert the patent or participate in litigation concerning the patent may be provided the confidential information, provided that the representative informs the reference product sponsor and the subsection (k) applicant of his or her agreement to be subject to the confidentiality provisions set forth in this paragraph, including those under clause (ii).

(C) Limitation on disclosure

No person that receives confidential information pursuant to subparagraph (B) shall disclose any confidential information to any other person or entity, including the reference product sponsor employees, outside scientific consultants, or other outside counsel retained by the reference product sponsor, without the prior written consent of the subsection (k) applicant, which shall not be unreasonably withheld.

(D) Use of confidential information

Confidential information shall be used for the sole and exclusive purpose of determining, with respect to each patent assigned to or exclusively licensed by the reference product sponsor, whether a claim of patent infringement could reasonably be asserted if the subsection (k) applicant engaged in the manufacture, use, offering for sale, sale, or importation into the United States of the biological product that is the subject of the application under subsection (k).

(E) Ownership of confidential information

The confidential information disclosed under this paragraph is, and shall remain, the property of the subsection (k) applicant. By providing the confidential information pursuant to this paragraph, the subsection (k) applicant does not provide the reference product sponsor or the outside counsel any interest in or license to use the confidential information, for purposes other than those specified in subparagraph (D).

(F) Effect of infringement action

In the event that the reference product sponsor files a patent infringement suit, the use of confidential information shall continue to be governed by the terms of this paragraph until such time as a court enters a protective order regarding the information. Upon entry of such order, the subsection (k) applicant may redesignate confidential information in accordance with the terms of that order. No confidential information shall be included in any publicly-available complaint or other pleading. In the event that the reference product sponsor does not file an infringement action by the date specified in paragraph (6), the reference product sponsor shall return or destroy all confidential information received under this paragraph, provided that if the reference product sponsor opts to destroy such information, it will confirm destruction in writing to the subsection (k) applicant.

(G) Rule of construction

Nothing in this paragraph shall be construed—

(i) as an admission by the subsection (k) applicant regarding the validity, enforceability, or infringement of any patent; or

(ii) as an agreement or admission by the subsection (k) applicant with respect to the competency, relevance, or materiality of any confidential information.

(H) Effect of violation

The disclosure of any confidential information in violation of this paragraph shall be deemed to cause the subsection (k) applicant to suffer irreparable harm for which there is no adequate legal remedy and the court shall consider immediate injunctive relief to be an appropriate and necessary remedy for any violation or threatened violation of this paragraph.

(2) Subsection (k) application information

Not later than 20 days after the Secretary notifies the subsection (k) applicant that the

application has been accepted for review, the subsection (k) applicant—

(A) shall provide to the reference product sponsor a copy of the application submitted to the Secretary under subsection (k), and such other information that describes the process or processes used to manufacture the biological product that is the subject of such application; and

(B) may provide to the reference product sponsor additional information requested by or on behalf of the reference product sponsor.

(3) List and description of patents

(A) List by reference product sponsor

Not later than 60 days after the receipt of the application and information under paragraph (2), the reference product sponsor shall provide to the subsection (k) applicant—

(i) a list of patents for which the reference product sponsor believes a claim of patent infringement could reasonably be asserted by the reference product sponsor, or by a patent owner that has granted an exclusive license to the reference product sponsor with respect to the reference product, if a person not licensed by the reference product sponsor engaged in the making, using, offering to sell, selling, or importing into the United States of the biological product that is the subject of the subsection (k) application; and

(ii) an identification of the patents on such list that the reference product sponsor would be prepared to license to the subsection (k) applicant.

(B) List and description by subsection (k) applicant

Not later than 60 days after receipt of the list under subparagraph (A), the subsection (k) applicant—

(i) may provide to the reference product sponsor a list of patents to which the subsection (k) applicant believes a claim of patent infringement could reasonably be asserted by the reference product sponsor if a person not licensed by the reference product sponsor engaged in the making, using, offering to sell, selling, or importing into the United States of the biological product that is the subject of the subsection (k) application;

(ii) shall provide to the reference product sponsor, with respect to each patent listed by the reference product sponsor under subparagraph (A) or listed by the subsection (k) applicant under clause (i)—

(I) a detailed statement that describes, on a claim by claim basis, the factual and legal basis of the opinion of the subsection (k) applicant that such patent is invalid, unenforceable, or will not be infringed by the commercial marketing of the biological product that is the subject of the subsection (k) application; or

(II) a statement that the subsection (k) applicant does not intend to begin commercial marketing of the biological product before the date that such patent expires; and

(iii) shall provide to the reference product sponsor a response regarding each patent identified by the reference product sponsor under subparagraph (A)(ii).

(C) Description by reference product sponsor

Not later than 60 days after receipt of the list and statement under subparagraph (B), the reference product sponsor shall provide to the subsection (k) applicant a detailed statement that describes, with respect to each patent described in subparagraph (B)(ii)(I), on a claim by claim basis, the factual and legal basis of the opinion of the reference product sponsor that such patent will be infringed by the commercial marketing of the biological product that is the subject of the subsection (k) application and a response to the statement concerning validity and enforceability provided under subparagraph (B)(ii)(I).

(4) Patent resolution negotiations

(A) In general

After receipt by the subsection (k) applicant of the statement under paragraph (3)(C), the reference product sponsor and the subsection (k) applicant shall engage in good faith

negotiations to agree on which, if any, patents listed under paragraph (3) by the subsection (k) applicant or the reference product sponsor shall be the subject of an action for patent infringement under paragraph (6).

(B) Failure to reach agreement

If, within 15 days of beginning negotiations under subparagraph (A), the subsection (k) applicant and the reference product sponsor fail to agree on a final and complete list of which, if any, patents listed under paragraph (3) by the subsection (k) applicant or the reference product sponsor shall be the subject of an action for patent infringement under paragraph (6), the provisions of paragraph (5) shall apply to the parties.

(5) Patent resolution if no agreement

(A) Number of patents

The subsection (k) applicant shall notify the reference product sponsor of the number of patents that such applicant will provide to the reference product sponsor under subparagraph (B)(i)(I).

(B) Exchange of patent lists

(i) In general

On a date agreed to by the subsection (k) applicant and the reference product sponsor, but in no case later than 5 days after the subsection (k) applicant notifies the reference product sponsor under subparagraph (A), the subsection (k) applicant and the reference product sponsor shall simultaneously exchange—

(I) the list of patents that the subsection (k) applicant believes should be the subject of an action for patent infringement under paragraph (6); and

(II) the list of patents, in accordance with clause (ii), that the reference product sponsor believes should be the subject of an action for patent infringement under paragraph (6).

(ii) Number of patents listed by reference product sponsor

(I) In general

Subject to subclause (II), the number of patents listed by the reference product sponsor under clause (i)(II) may not exceed the number of patents listed by the subsection (k) applicant under clause (i)(I).

(II) Exception

If a subsection (k) applicant does not list any patent under clause (i)(I), the reference product sponsor may list 1 patent under clause (i)(II).

(6) Immediate patent infringement action

(A) Action if agreement on patent list

If the subsection (k) applicant and the reference product sponsor agree on patents as described in paragraph (4), not later than 30 days after such agreement, the reference product sponsor shall bring an action for patent infringement with respect to each such patent.

(B) Action if no agreement on patent list

If the provisions of paragraph (5) apply to the parties as described in paragraph (4)(B), not later than 30 days after the exchange of lists under paragraph (5)(B), the reference product sponsor shall bring an action for patent infringement with respect to each patent that is included on such lists.

(C) Notification and publication of complaint

(i) Notification to Secretary

Not later than 30 days after a complaint is served to a subsection (k) applicant in an action for patent infringement described under this paragraph, the subsection (k) applicant shall

provide the Secretary with notice and a copy of such complaint.

(ii) Publication by Secretary

The Secretary shall publish in the Federal Register notice of a complaint received under clause (i).

(7) Newly issued or licensed patents

In the case of a patent that—

(A) is issued to, or exclusively licensed by, the reference product sponsor after the date that the reference product sponsor provided the list to the subsection (k) applicant under paragraph (3)(A); and

(B) the reference product sponsor reasonably believes that, due to the issuance of such patent, a claim of patent infringement could reasonably be asserted by the reference product sponsor if a person not licensed by the reference product sponsor engaged in the making, using, offering to sell, selling, or importing into the United States of the biological product that is the subject of the subsection (k) application,

not later than 30 days after such issuance or licensing, the reference product sponsor shall provide to the subsection (k) applicant a supplement to the list provided by the reference product sponsor under paragraph (3)(A) that includes such patent, not later than 30 days after such supplement is provided, the subsection (k) applicant shall provide a statement to the reference product sponsor in accordance with paragraph (3)(B), and such patent shall be subject to paragraph (8).

(8) Notice of commercial marketing and preliminary injunction

(A) Notice of commercial marketing

The subsection (k) applicant shall provide notice to the reference product sponsor not later than 180 days before the date of the first commercial marketing of the biological product licensed under subsection (k).

(B) Preliminary injunction

After receiving the notice under subparagraph (A) and before such date of the first commercial marketing of such biological product, the reference product sponsor may seek a preliminary injunction prohibiting the subsection (k) applicant from engaging in the commercial manufacture or sale of such biological product until the court decides the issue of patent validity, enforcement, and infringement with respect to any patent that is—

(i) included in the list provided by the reference product sponsor under paragraph (3)(A) or in the list provided by the subsection (k) applicant under paragraph (3)(B); and

(ii) not included, as applicable, on—

(I) the list of patents described in paragraph (4); or

(II) the lists of patents described in paragraph (5)(B).

(C) Reasonable cooperation

If the reference product sponsor has sought a preliminary injunction under subparagraph (B), the reference product sponsor and the subsection (k) applicant shall reasonably cooperate to expedite such further discovery as is needed in connection with the preliminary injunction motion.

(9) Limitation on declaratory judgment action

(A) Subsection (k) application provided

If a subsection (k) applicant provides the application and information required under paragraph (2)(A), neither the reference product sponsor nor the subsection (k) applicant may, prior to the date notice is received under paragraph (8)(A), bring any action under section 2201 of title 28 for a declaration of infringement, validity, or enforceability of any patent that is described in clauses (i) and (ii) of paragraph (8)(B).

(B) Subsequent failure to act by subsection (k) applicant

If a subsection (k) applicant fails to complete an action required of the subsection (k) applicant under paragraph (3)(B)(ii), paragraph (5), paragraph (6)(C)(i), paragraph (7), or paragraph (8)(A), the reference product sponsor, but not the subsection (k) applicant, may bring an action under section 2201 of title 28 for a declaration of infringement, validity, or enforceability of any patent included in the list described in paragraph (3)(A), including as provided under paragraph (7).

(C) Subsection (k) application not provided

If a subsection (k) applicant fails to provide the application and information required under paragraph (2)(A), the reference product sponsor, but not the subsection (k) applicant, may bring an action under section 2201 of title 28 for a declaration of infringement, validity, or enforceability of any patent that claims the biological product or a use of the biological product.

(m) Pediatric studies

(1) Application of certain provisions

The provisions of subsections (a), (d), (e), (f), (h), (i), (j), (k), (l), (n), and (p) of section 505A of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 355a(a), (d), (e), (f), (h), (i), (j), (k), (l), (n), (p)] shall apply with respect to the extension of a period under paragraphs (2) and (3) to the same extent and in the same manner as such provisions apply with respect to the extension of a period under subsection (b) or (c) of section 505A of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 355a(b), (c)].

(2) Market exclusivity for new biological products

If, prior to approval of an application that is submitted under subsection (a), the Secretary determines that information relating to the use of a new biological product in the pediatric population may produce health benefits in that population, the Secretary makes a written request for pediatric studies (which shall include a timeframe for completing such studies), the applicant agrees to the request, such studies are completed using appropriate formulations for each age group for which the study is requested within any such timeframe, and the reports thereof are submitted and accepted in accordance with section 505A(d)(4) of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 355a(d)(4)]—

(A) the periods for such biological product referred to in subsection (k)(7) are deemed to be 4 years and 6 months rather than 4 years and 12 years and 6 months rather than 12 years; and

(B) if the biological product is designated under section 526 [1] [21 U.S.C. 360bb] for a rare disease or condition, the period for such biological product referred to in section 527(a) [1] [21 U.S.C. 360cc(a)] is deemed to be 7 years and 6 months rather than 7 years.

(3) Market exclusivity for already-marketed biological products

If the Secretary determines that information relating to the use of a licensed biological product in the pediatric population may produce health benefits in that population and makes a written request to the holder of an approved application under subsection (a) for pediatric studies (which shall include a timeframe for completing such studies), the holder agrees to the request, such studies are completed using appropriate formulations for each age group for which the study is requested within any such timeframe, and the reports thereof are submitted and accepted in accordance with section 505A(d)(4) of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 355a(d)(4)]—

(A) the periods for such biological product referred to in subsection (k)(7) are deemed to be 4 years and 6 months rather than 4 years and 12 years and 6 months rather than 12 years; and

(B) if the biological product is designated under section 526 [1] [21 U.S.C. 360bb] for a rare disease or condition, the period for such biological product referred to in section 527(a) [1] [21 U.S.C. 360cc(a)] is deemed to be 7 years and 6 months rather than 7 years.

(4) Exception

The Secretary shall not extend a period referred to in paragraph (2)(A), (2)(B), (3)(A), or (3)(B) if the determination under section 505A(d)(4) [1] [21 U.S.C. 355a(d)(4)] is made later than 9 months prior to the expiration of such period.

(n) Date of approval in the case of recommended controls under the CSA

(1) In general

In the case of an application under subsection (a) with respect to a biological product for which the Secretary provides notice to the sponsor that the Secretary intends to issue a scientific and medical evaluation and recommend controls under the Controlled Substances Act [21 U.S.C. 801 et seq.], approval of such application shall not take effect until the interim final rule controlling the biological product is issued in accordance with section 201(j) of the Controlled Substances Act [21 U.S.C. 811(j)].

(2) Date of approval

For purposes of this section, with respect to an application described in paragraph (1), references to the date of approval of such application, or licensure of the product subject to such application, shall mean the later of—

(A) the date an application is approved under subsection (a); or

(B) the date of issuance of the interim final rule controlling the biological product.

(July 1, 1944, ch. 373, title III, §351, 58 Stat. 702; 1953 Reorg. Plan No. 1, §§5, 8, eff. Apr. 11, 1953, 18 F.R. 2053, 67 Stat. 631; Pub. L. 85–881, §2, Sept. 2, 1958, 72 Stat. 1704; Pub. L. 91–515, title II, §291, Oct. 30, 1970, 84 Stat. 1308; Pub. L. 96–88, title V, §509(b), Oct. 17, 1979, 93 Stat. 695; Pub. L. 99–660, title I, §105(a), title III, §315, Nov. 14, 1986, 100 Stat. 3751, 3783; Pub. L. 102–300, §6(b)(1), June 16, 1992, 106 Stat. 240; Pub. L. 104–134, title II, §§2102(d)(2), 2104, Apr. 26, 1996, 110 Stat. 1321–319, 1321–320; Pub. L. 105–115, title I, §123(a)–(d), (g), Nov. 21, 1997, 111 Stat. 2323, 2324; Pub. L. 108–155, §2(b)(3), Dec. 3, 2003, 117 Stat. 1941; Pub. L. 110–85, title IX, §901(c), Sept. 27, 2007, 121 Stat. 939; Pub. L. 111–148, title VII, §7002(a), (b), (g)(1), Mar. 23, 2010, 124 Stat. 804, 814, 819; Pub. L. 112–144, title V, §502(a)(2), July 9, 2012, 126 Stat. 1040; Pub. L. 114–89, §2(a)(2), Nov. 25, 2015, 129 Stat. 698; Pub. L. 114–255, div. A, title III, §3031(b), Dec. 13, 2016, 130 Stat. 1100; Pub. L. 115–52, title V, §505(b)(2)(B), Aug. 18, 2017, 131 Stat. 1046; Pub. L. 116–94, div. N, title I, §§605, 606, Dec. 20, 2019, 133 Stat. 3127; Pub. L. 116–260, div. BB, title III, §§322, 325(a), Dec. 27, 2020, 134 Stat. 2933, 2936; Pub. L. 117–328, div. FF, title III, §§3206, 3209(b), Dec. 29, 2022, 136 Stat. 5820, 5822.)

EDITORIAL NOTES

REFERENCES IN TEXT

The effective date of this paragraph, referred to in subsec. (d)(2), is the effective date of section 315 of Pub. L. 99–660 which added subsec. (d)(2). See Effective Date of 1986 Amendment note set out below.

The Federal Food, Drug, and Cosmetic Act, referred to in subsecs. (g), (h), (j), and (k)(5)(C), is act June 25, 1938, ch. 675, 52 Stat. 1040, which is classified generally to chapter 9 (§301 et seq.) of Title 21, Food and Drugs. For complete classification of this Act to the Code, see section 301 of Title 21 and Tables.

Section 7002(e)(4) of the Biologics Price Competition and Innovation Act of 2009, referred to in subsec. (k)(7)(D), (9)(A)(i)(I), (ii), is section 7002(e)(4) of Pub. L. 111–148, which is set out in a note under this section.

Sections 526, 527(a), and 505A(d)(4), referred to in subsec. (m)(2)(B), (3)(B), (4), probably mean sections 526, 527(a), and 505A(d)(4) of the Federal Food, Drug, and Cosmetic Act, act June 25, 1938, ch. 675, which are classified to sections 360bb, 360cc(a), and 355a(d)(4), respectively, of Title 21, Food and Drugs.

The Controlled Substances Act, referred to in subsec. (n)(1), is title II of Pub. L. 91–513, Oct. 27, 1970, 84 Stat. 1242, which is classified principally to subchapter I (§801 et seq.) of chapter 13 of Title 21, Food and Drugs. For complete classification of this Act to the Code, see Short Title note set out under section 801 of Title 21 and Tables.

AMENDMENTS

2022—Subsec. (k)(2)(A)(i)(I)(bb). Pub. L. 117–328, §3209(b), amended item (bb) generally. Prior to

amendment, item (bb) read as follows: "animal studies (including the assessment of toxicity); and".

Subsec. (k)(6). Pub. L. 117–328, §3206(2), substituted "taken, and the term 'first interchangeable biosimilar biological product' means any interchangeable biosimilar biological product that is approved on the first day on which such a product is approved as interchangeable with the reference product." for "taken." in concluding provisions.

Pub. L. 117–328, §3206(1), substituted "The Secretary shall not make approval as an interchangeable biological product effective with respect to" for "Upon review of" and "that relies on" for "relying on" and struck out "the Secretary shall not make a determination under paragraph (4) that the second or subsequent biological product is interchangeable for any condition of use" before "until the earlier of" in introductory provisions.

2020—Subsec. (k)(2)(A)(iii)(III). Pub. L. 116–260, §322, added subcl. (III).

Subsec. (k)(9). Pub. L. 116–260, §325(a), added par. (9).

2019—Subsec. (i)(1). Pub. L. 116–94, §605, struck out "(except any chemically synthesized polypeptide)" after "protein".

Subsec. (k)(7)(D). Pub. L. 116–94, §606, added subpar. (D).

2017—Subsec. (m)(2) to (4). Pub. L. 115–52 substituted "section 505A(d)(4)" for "section 505A(d)(3)".

2016—Subsec. (a)(2)(E). Pub. L. 114–255 added subpar. (E).

2015—Subsec. (n). Pub. L. 114–89 added subsec. (n).

2012—Subsec. (m)(1). Pub. L. 112–144 substituted "(f), (h), (i), (j), (k), (l), (n), and (p)" for "(f), (i), (j), (k), (l), (p), and (q)".

2010—Subsec. (a)(1)(A). Pub. L. 111–148, §7002(a)(1), inserted "under this subsection or subsection (k)" after "biologics license".

Subsec. (i). Pub. L. 111–148, §7002(b), substituted "In this section:" for "In this section,", designated remainder of existing provisions as par. (1), substituted "The term" for "the term", inserted "protein (except any chemically synthesized polypeptide)," after "allergenic product,", and added pars. (2) to (4).

Subsecs. (k), (l). Pub. L. 111–148, §7002(a)(2), added subsecs. (k) and (l).

Subsec. (m). Pub. L. 111–148, §7002(g)(1), added subsec. (m).

2007—Subsec. (a)(2)(D). Pub. L. 110–85, §901(c)(1), added subpar. (D).

Subsec. (j). Pub. L. 110–85, §901(c)(2), inserted ", including the requirements under sections 505(o), 505(p), and 505–1 of such Act," after "and Cosmetic Act".

2003—Subsec. (a)(2)(B), (C). Pub. L. 108–155 added subpar. (B) and redesignated former subpar. (B) as (C).

1997—Subsec. (a). Pub. L. 105–115, §123(a)(1), amended subsec. (a) generally. Prior to amendment, subsec. (a) related to intrastate and interstate traffic in biological products and suspension or revocation of licenses as affecting prior sales.

Subsec. (b). Pub. L. 105–115, §123(b), amended subsec. (b) generally. Prior to amendment, subsec. (b) read as follows: "No person shall falsely label or mark any package or container of any virus, serum, toxin, antitoxin, vaccine, blood, blood component or derivative, allergenic product, or other product aforesaid; nor alter any label or mark on any package or container of any virus, serum, toxin, antitoxin, vaccine, blood, blood component or derivative, allergenic product, or other product aforesaid so as to falsify such label or mark."

Subsec. (c). Pub. L. 105–115, §123(c), substituted "biological product." for "virus, serum, toxin, antitoxin, vaccine, blood, blood component or derivative, allergenic product, or other product aforesaid for sale, barter, or exchange in the District of Columbia, or to be sent, carried, or brought from any State or possession into any other State or possession or into any foreign country, or from any foreign country into any State or possession."

Subsec. (d). Pub. L. 105–115, §123(a)(2), designated par. (2) as subsec. (d), redesignated subpars. (A) and (B) of par. (2) as pars. (1) and (2), respectively, in par. (2), substituted "Any violation of paragraph (1)" for "Any violation of subparagraph (A)" and substituted "this paragraph" for "this subparagraph" wherever appearing, and struck out former par. (1) which read as follows: "Licenses for the maintenance of establishments for the propagation or manufacture and preparation of products described in subsection (a) of this section may be issued only upon a showing that the establishment and the products for which a license is desired meet standards, designed to insure the continued safety, purity, and potency of such products, prescribed in regulations, and licenses for new products may be issued only upon a showing that they meet such standards. All such licenses shall be issued, suspended, and revoked as prescribed by regulations and all licenses issued for the maintenance of establishments for the propagation or manufacture and preparation, in any foreign country, of any such products for sale, barter, or exchange in any State or possession shall be issued upon condition that the licensees will permit the inspection of their establishments in accordance with subsection (c) of this section."

Subsec. (i). Pub. L. 105–115, §123(d), added subsec. (i).

Subsec. (j). Pub. L. 105–115, §123(g), added subsec. (j).

1996—Subsec. (h). Pub. L. 104–134, §2104, amended subsec. (h) generally, revising and restating former provisions, which also related to exportation of partially processed biological products.

Subsec. (h)(1)(A). Pub. L. 104–134, §2102(d)(2), substituted "in a country listed under section 802(b)(1)" for "in a country listed under section 802(b)(A)" and "to a country listed under section 802(b)(1)" for "to a country listed under section 802(b)(4)".

1992—Subsec. (c). Pub. L. 102–300, which directed substitution of "Health and Human Services" for "Health, Education, and Welfare", could not be executed because the words "Health, Education, and Welfare" did not appear in original statutory text. Previously, references to Department and Secretary of Health and Human Services were substituted for references to Federal Security Agency and its Administrator pursuant to provisions cited in Transfer of Functions note below.

1986—Subsec. (d). Pub. L. 99–660, §315, designated existing provisions as par. (1) and added par. (2).

Subsec. (h). Pub. L. 99–660, §105(a), added subsec. (h).

1970—Subsecs. (a) to (c). Pub. L. 91–515 inserted "vaccine, blood, blood component or derivative, allergenic product," after "antitoxin" wherever appearing.

1958—Subsec. (d). Pub. L. 85–881 struck out "made jointly by the Surgeon General, the Surgeon General of the Army, and the Surgeon General of the Navy, and approved by the Secretary" after "regulations" in first sentence.

STATUTORY NOTES AND RELATED SUBSIDIARIES

CHANGE OF NAME

"Secretary of Health and Human Services" substituted for "Secretary of Health, Education, and Welfare" in subsecs. (a), (c), (d), (h), and (k) to (n), and "Department of Health and Human Services" substituted for "Department of Health, Education, and Welfare" in subsec. (c), pursuant to section 509(b) of Pub. L. 96–88, which is classified to section 3508(b) of Title 20, Education.

EFFECTIVE DATE OF 2007 AMENDMENT

Amendment by Pub. L. 110–85 effective 180 days after Sept. 27, 2007, see section 909 of Pub. L. 110–85, set out as a note under section 331 of Title 21, Food and Drugs.

EFFECTIVE DATE OF 2003 AMENDMENT

Amendment by Pub. L. 108–155 effective Dec. 3, 2003, except as otherwise provided, see section 4 of Pub. L. 108–155, set out as an Effective Date note under section 355c of Title 21, Food and Drugs.

EFFECTIVE DATE OF 1997 AMENDMENT

Amendment by Pub. L. 105–115 effective 90 days after Nov. 21, 1997, except as otherwise provided, see section 501 of Pub. L. 105–115, set out as a note under section 321 of Title 21, Food and Drugs.

EFFECTIVE DATE OF 1986 AMENDMENT

Pub. L. 99–660, title I, §105(b), Nov. 14, 1986, 100 Stat. 3752, provided that: "Paragraph (1) of section 351(h) of the Public Health Service Act [former 42 U.S.C. 262(h)(1)] as added by subsection (a) shall take effect upon the expiration of 90 days after the date of the enactment of this Act [Nov. 14, 1986]."

Amendment by section 315 of Pub. L. 99–660 effective Dec. 22, 1987, see section 323 of Pub. L. 99–660, as amended, set out as an Effective Date note under section 300aa–1 of this title.

PRODUCTS PREVIOUSLY APPROVED UNDER THE FEDERAL FOOD, DRUG, AND COSMETIC ACT

Pub. L. 111–148, title VII, §7002(e), Mar. 23, 2010, 124 Stat. 817, as amended by Pub. L. 116–94, div. N, title I, §607, Dec. 20, 2019, 133 Stat. 3127, provided that:

"(1) REQUIREMENT TO FOLLOW SECTION 351.—Except as provided in paragraph (2), an application for a biological product shall be submitted under section 351 of the Public Health Service Act (42 U.S.C. 262) (as amended by this Act).

"(2) EXCEPTION.—An application for a biological product may be submitted under section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355) if—

"(A) such biological product is in a product class for which a biological product in such product class is the subject of an application approved under such section 505 not later than the date of enactment of this

Act [Mar. 23, 2010]; and

"(B) such application—

"(i) has been submitted to the Secretary of Health and Human Services (referred to in this subtitle [subtitle A (§§7001–7003) of title VII of Pub. L. 111–148, see Short Title of 2010 Amendment note under section 201 of this title] as the 'Secretary') before the date of enactment of this Act; or

"(ii) is submitted to the Secretary not later than the date that is 10 years after the date of enactment of this Act.

"(3) LIMITATION.—Notwithstanding paragraph (2), an application for a biological product may not be submitted under section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355) if there is another biological product approved under subsection (a) of section 351 of the Public Health Service Act [42 U.S.C. 262] that could be a reference product with respect to such application (within the meaning of such section 351) if such application were submitted under subsection (k) of such section 351.

"(4) DEEMED APPROVED UNDER SECTION 351.—

"(A) IN GENERAL.—An approved application for a biological product under section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355) shall be deemed to be a license for the biological product under such section 351 on the date that is 10 years after the date of enactment of this Act.

"(B) TREATMENT OF CERTAIN APPLICATIONS.—

"(i) IN GENERAL.—With respect to an application for a biological product submitted under subsection (b) or (j) of section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355) that is filed not later than March 23, 2019, and is not approved as of March 23, 2020, the Secretary shall continue to review such application under such section 505 after March 23, 2020.

"(ii) EFFECT ON LISTED DRUGS.—Only for purposes of carrying out clause (i), with respect to any applicable listed drug with respect to such application, the following shall apply:

"(I) Any drug that is a biological product that has been deemed licensed under section 351 of the Public Health Service Act (42 U.S.C. 262) pursuant to subparagraph (A) and that is referenced in an application described in clause (i), shall continue to be identified as a listed drug on the list published pursuant to section 505(j)(7) of the Federal Food, Drug, and Cosmetic Act, and the information for such drug on such list shall not be revised after March 20, 2020, until—

"(aa) such drug is removed from such list in accordance with subclause (III) or subparagraph (C) of such section 505(j)(7); or

"(bb) this subparagraph no longer has force or effect.

"(II) Any drug that is a biological product that has been deemed licensed under section 351 of the Public Health Service Act (42 U.S.C. 262) pursuant to subparagraph (A) and that is referenced in an application described in clause (i) shall be subject only to requirements applicable to biological products licensed under such section.

"(III) Upon approval under subsection (c) or (j) of section 505 of the Federal Food, Drug, and Cosmetic Act of an application described in clause (i), the Secretary shall remove from the list published pursuant to section 505(j)(7) of the Federal Food, Drug, and Cosmetic Act any listed drug that is a biological product that has been deemed licensed under section 351 of the Public Health Service Act pursuant to subparagraph (A) and that is referenced in such approved application, unless such listed drug is referenced in one or more additional applications described in clause (i).

"(iii) DEEMED LICENSURE.—Upon approval of an application described in clause (i), such approved application shall be deemed to be a license for the biological product under section 351 of the Public Health Service Act.

"(iv) RULE OF CONSTRUCTION.—

"(I) APPLICATION OF CERTAIN PROVISIONS.—

"(aa) PATENT CERTIFICATION OR STATEMENT.—An application described in clause (i) shall contain a patent certification or statement described in, as applicable, section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act or clauses (vii) and (viii) of section 505(j)(2)(A) of such Act and, with respect to any listed drug referenced in such application, comply with related requirements concerning any timely filed patent information listed pursuant to section 505(j)(7) of such Act.

"(bb) DATE OF APPROVAL.—The earliest possible date on which any pending application described in clause (i) may be approved shall be determined based on—

"(AA) the last expiration date of any applicable period of exclusivity that would prevent such approval and that is described in section 505(c)(3)(E), 505(j)(5)(B)(iv), 505(j)(5)(F), 505A [21 U.S.C. 355a], 505E [21 U.S.C. 355f], or 527 [21 U.S.C. 360cc] of the Federal Food, Drug, and Cosmetic Act; and

"(BB) if the application was submitted pursuant to section 505(b)(2) of the Federal Food,

Drug, and Cosmetic Act and references any listed drug, the last applicable date determined under subparagraph (A), (B), or (C) of section 505(c)(3) of such Act, or, if the application was submitted under section 505(j) of such Act, the last applicable date determined under clause (i), (ii), or (iii) of section 505(j)(5)(B) of such Act.

"(II) EXCLUSIVITY.—Nothing in this subparagraph shall be construed to affect section 351(k)(7)(D) of the Public Health Service Act.

"(v) LISTING.—The Secretary may continue to review an application after March 23, 2020, pursuant to clause (i), and continue to identify any applicable listed drug pursuant to clause (ii) on the list published pursuant to section 505(j)(7) of the Federal Food, Drug, and Cosmetic Act, even if such review or listing may reveal the existence of such application and the identity of any listed drug for which the investigations described in section 505(b)(1)(A) of the Federal Food, Drug, and Cosmetic Act are relied upon by the applicant for approval of the pending application. Nothing in this subparagraph shall be construed as authorizing the Secretary to disclose any other information that is a trade secret or confidential information described in section 552(b)(4) of title 5, United States Code.

"(vi) SUNSET.—Beginning on October 1, 2022, this subparagraph shall have no force or effect and any applications described in clause (i) that have not been approved shall be deemed withdrawn.

"(5) DEFINITIONS.—For purposes of this subsection, the term 'biological product' has the meaning given such term under section 351 of the Public Health Service Act (42 U.S.C. 262) (as amended by this Act)."

COSTS OF REVIEWING BIOSIMILAR BIOLOGICAL PRODUCT APPLICATIONS

Pub. L. 111–148, title VII, §7002(f)(3)(B), (C), Mar. 23, 2010, 124 Stat. 818, 819, provided that:

"(B) EVALUATION OF COSTS OF REVIEWING BIOSIMILAR BIOLOGICAL PRODUCT APPLICATIONS.—During the period beginning on the date of enactment of this Act [Mar. 23, 2010] and ending on October 1, 2010, the Secretary [of Health and Human Services] shall collect and evaluate data regarding the costs of reviewing applications for biological products submitted under section 351(k) of the Public Health Service Act [42 U.S.C. 262(k)] (as added by this Act) during such period.

"(C) AUDIT.—

"(i) IN GENERAL.—On the date that is 2 years after first receiving a user fee applicable to an application for a biological product under section 351(k) of the Public Health Service Act [42 U.S.C. 262(k)] (as added by this Act), and on a biennial basis thereafter until October 1, 2013, the Secretary shall perform an audit of the costs of reviewing such applications under such section 351(k). Such an audit shall compare—

"(I) the costs of reviewing such applications under such section 351(k) to the amount of the user fee applicable to such applications; and

"(II)(aa) such ratio determined under subclause (I); to

"(bb) the ratio of the costs of reviewing applications for biological products under section 351(a) of such Act [42 U.S.C. 262(a)] (as amended by this Act) to the amount of the user fee applicable to such applications under such section 351(a).

"(ii) ALTERATION OF USER FEE.—If the audit performed under clause (i) indicates that the ratios compared under subclause (II) of such clause differ by more than 5 percent, then the Secretary shall alter the user fee applicable to applications submitted under such section 351(k) [42 U.S.C. 262(k)] to more appropriately account for the costs of reviewing such applications.

"(iii) ACCOUNTING STANDARDS.—The Secretary shall perform an audit under clause (i) in conformance with the accounting principles, standards, and requirements prescribed by the Comptroller General of the United States under section 3511 of title 31, United State Code, to ensure the validity of any potential variability."

LICENSING OF ORPHAN PRODUCTS

Pub. L. 111–148, title VII, §7002(h), Mar. 23, 2010, 124 Stat. 821, provided that: "If a reference product, as defined in section 351 of the Public Health Service Act (42 U.S.C. 262) (as amended by this Act) has been designated under section 526 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360bb) for a rare disease or condition, a biological product seeking approval for such disease or condition under subsection (k) of such section 351 as biosimilar to, or interchangeable with, such reference product may be licensed by the Secretary [of Health and Human Services] only after the expiration for such reference product of the later of—

"(1) the 7-year period described in section 527(a) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360cc(a)); and

"(2) the 12-year period described in subsection (k)(7) of such section 351."

SAVINGS GENERATED BY 2010 AMENDMENT

Pub. L. 111–148, title VII, §7003, Mar. 23, 2010, 124 Stat. 821, provided that:

"(a) DETERMINATION.—The Secretary of the Treasury, in consultation with the Secretary of Health and Human Services, shall for each fiscal year determine the amount of savings to the Federal Government as a result of the enactment of this subtitle [subtitle A (§§7001–7003) of title VII of Pub. L. 111–148, see Short Title of 2010 Amendment note under section 201 of this title].

"(b) USE.—Notwithstanding any other provision of this subtitle (or an amendment made by this subtitle), the savings to the Federal Government generated as a result of the enactment of this subtitle shall be used for deficit reduction."

ENHANCED PENALTIES AND CONTROL OF BIOLOGICAL AGENTS

Pub. L. 104–132, title V, §511, Apr. 24, 1996, 110 Stat. 1284, as amended by Pub. L. 107–188, title II, §204, June 12, 2002, 116 Stat. 647, provided that:

"(a) FINDINGS.—The Congress finds that—

"(1) certain biological agents have the potential to pose a severe threat to public health and safety;

"(2) such biological agents can be used as weapons by individuals or organizations for the purpose of domestic or international terrorism or for other criminal purposes;

"(3) the transfer and possession of potentially hazardous biological agents should be regulated to protect public health and safety; and

"(4) efforts to protect the public from exposure to such agents should ensure that individuals and groups with legitimate objectives continue to have access to such agents for clinical and research purposes.

"(b) CRIMINAL ENFORCEMENT.—[Amended sections 175, 177, and 178 of Title 18, Crimes and Criminal Procedure.]

"(c) TERRORISM.—[Amended section 2332a of Title 18.]"

EXECUTIVE DOCUMENTS

TRANSFER OF FUNCTIONS

Functions of Public Health Service, Surgeon General of Public Health Service, and all other officers and employees of Public Health Service, and functions of all agencies of or in Public Health Service transferred to Secretary of Health, Education, and Welfare by Reorg. Plan No. 3 of 1966, eff. June 25, 1966, 31 F.R. 8855, 80 Stat. 1610, set out as a note under section 202 of this title.

References to Secretary and Department of Health, Education, and Welfare substituted for references to Federal Security Administrator and Federal Security Agency, respectively, pursuant to Reorg. Plan No. 1 of 1953, §5, set out as a note under section 3501 of this title, which transferred all functions of Federal Security Administrator to Secretary of Health, Education, and Welfare and all agencies of Federal Security Agency to Department of Health, Education, and Welfare. Federal Security Agency and office of Administrator abolished by section 8 of Reorg. Plan No. 1 of 1953.

[1] *See References in Text note below.*

§262a. Enhanced control of dangerous biological agents and toxins

(a) Regulatory control of certain biological agents and toxins

(1) List of biological agents and toxins

(A) In general

The Secretary shall by regulation establish and maintain a list of each biological agent and each toxin that has the potential to pose a severe threat to public health and safety.

(B) Criteria

In determining whether to include an agent or toxin on the list under subparagraph (A), the Secretary shall—

(i) consider—

(I) the effect on human health of exposure to the agent or toxin;

(II) the degree of contagiousness of the agent or toxin and the methods by which the

agent or toxin is transferred to humans;

(III) the availability and effectiveness of pharmacotherapies and immunizations to treat and prevent any illness resulting from infection by the agent or toxin; and

(IV) any other criteria, including the needs of children and other vulnerable populations, that the Secretary considers appropriate; and

(ii) consult with appropriate Federal departments and agencies and with scientific experts representing appropriate professional groups, including groups with pediatric expertise.

(2) Biennial review

The Secretary shall review and republish the list under paragraph (1) biennially, or more often as needed, and shall by regulation revise the list as necessary in accordance with such paragraph.

(b) Regulation of transfers of listed agents and toxins

The Secretary shall by regulation provide for—

(1) the establishment and enforcement of safety procedures for the transfer of listed agents and toxins, including measures to ensure—

(A) proper training, including with respect to notification requirements under this section, of—

(i) individuals who are involved in the handling and use of such agents and toxins, including appropriate skills to handle such agents and toxins;

(ii) individuals whose responsibilities routinely place them in close proximity to laboratory facilities in which such agents and toxins are being transferred, possessed, or used; and

(iii) individuals who perform administrative or oversight functions of the facility related to the transfer, possession, or use of such agents and toxins on behalf of registered persons;

(B) proper laboratory facilities to contain and dispose of such agents and toxins;

(2) the establishment and enforcement of safeguard and security measures to prevent access to such agents and toxins for use in domestic or international terrorism or for any other criminal purpose;

(3) the establishment of procedures to protect the public safety in the event of a transfer or potential transfer of such an agent or toxin in violation of the safety procedures established under paragraph (1) or the safeguard and security measures established under paragraph (2); and

(4) appropriate availability of biological agents and toxins for research, education, and other legitimate purposes.

(c) Possession and use of listed agents and toxins

The Secretary shall by regulation provide for the establishment and enforcement of standards and procedures governing the possession and use of listed agents and toxins, including the provisions described in paragraphs (1) through (4) of subsection (b), in order to protect the public health and safety.

(d) Registration; identification; database

(1) Registration

Regulations under subsections (b) and (c) shall require registration with the Secretary of the possession, use, and transfer of listed agents and toxins, and shall include provisions to ensure that persons seeking to register under such regulations have a lawful purpose to possess, use, or transfer such agents and toxins, including provisions in accordance with subsection (e)(6).

(2) Identification; database

Regulations under subsections (b) and (c) shall require that registration include (if available to the person registering) information regarding the characterization of listed agents and toxins to facilitate their identification, including their source. The Secretary shall maintain a national database that includes the names and locations of registered persons, the listed agents and toxins

such persons are possessing, using, or transferring, and information regarding the characterization of such agents and toxins.

(e) Safeguard and security requirements for registered persons

(1) In general

Regulations under subsections (b) and (c) shall include appropriate safeguard and security requirements for persons possessing, using, or transferring a listed agent or toxin commensurate with the risk such agent or toxin poses to public health and safety (including risks posed by the release, theft, or loss of such agent or toxin, or use in domestic or international terrorism). The Secretary shall establish such requirements in collaboration with the Secretary of Homeland Security and the Attorney General, and shall ensure compliance with such requirements as part of the registration system under such regulations.

(2) Limiting access to listed agents and toxins

Requirements under paragraph (1) shall include provisions to ensure that registered persons—

(A) provide access to listed agents and toxins to only those individuals whom the registered person involved determines have a legitimate need to handle or use such agents and toxins;

(B) submit the names and other identifying information for such individuals to the Secretary and the Attorney General, promptly after first determining that the individuals need access under subparagraph (A), and periodically thereafter while the individuals have such access, not less frequently than once every five years;

(C) deny access to such agents and toxins by individuals whom the Attorney General has identified as restricted persons; and

(D) limit or deny access to such agents and toxins by individuals whom the Attorney General has identified as within any category under paragraph (3)(B)(ii), if limiting or denying such access by the individuals involved is determined appropriate by the Secretary, in consultation with the Attorney General.

(3) Submitted names; use of databases by attorney general

(A) In general

Upon the receipt of names and other identifying information under paragraph (2)(B), the Attorney General shall, for the sole purpose of identifying whether the individuals involved are within any of the categories specified in subparagraph (B), promptly use criminal, immigration, national security, and other electronic databases that are available to the Federal Government and are appropriate for such purpose.

(B) Certain individuals

For purposes of subparagraph (A), the categories specified in this subparagraph regarding an individual are that—

(i) the individual is a restricted person; or

(ii) the individual is reasonably suspected by any Federal law enforcement or intelligence agency of—

(I) committing a crime set forth in section 2332b(g)(5) of title 18;

(II) knowing involvement with an organization that engages in domestic or international terrorism (as defined in section 2331 of such title 18) or with any other organization that engages in intentional crimes of violence; or

(III) being an agent of a foreign power (as defined in section 1801 of title 50).

(C) Notification by Attorney General regarding submitted names

After the receipt of a name and other identifying information under paragraph (2)(B), the Attorney General shall promptly notify the Secretary whether the individual is within any of the categories specified in subparagraph (B).

(4) Notifications by Secretary

The Secretary, after receiving notice under paragraph (3) regarding an individual, shall

promptly notify the registered person involved of whether the individual is granted or denied access under paragraph (2). If the individual is denied such access, the Secretary shall promptly notify the individual of the denial.

(5) Expedited review

Regulations under subsections (b) and (c) shall provide for a procedure through which, upon request to the Secretary by a registered person who submits names and other identifying information under paragraph (2)(B) and who demonstrates good cause, the Secretary may, as determined appropriate by the Secretary—

(A) request the Attorney General to expedite the process of identification under paragraph (3)(A) and notification of the Secretary under paragraph (3)(C); and

(B) expedite the notification of the registered person by the Secretary under paragraph (4).

(6) Process regarding persons seeking to register

(A) Individuals

Regulations under subsections (b) and (c) shall provide that an individual who seeks to register under either of such subsections is subject to the same processes described in paragraphs (2) through (4) as apply to names and other identifying information submitted to the Attorney General under paragraph (2)(B). Paragraph (5) does not apply for purposes of this subparagraph.

(B) Other persons

Regulations under subsections (b) and (c) shall provide that, in determining whether to deny or revoke registration by a person other than an individual, the Secretary shall submit the name of such person to the Attorney General, who shall use criminal, immigration, national security, and other electronic databases available to the Federal Government, as appropriate for the purpose of promptly notifying the Secretary whether the person, or, where relevant, the individual who owns or controls such person, is a restricted person or is reasonably suspected by any Federal law enforcement or intelligence agency of being within any category specified in paragraph (3)(B)(ii) (as applied to persons, including individuals). Such regulations shall provide that a person who seeks to register under either of such subsections is subject to the same processes described in paragraphs (2) and (4) as apply to names and other identifying information submitted to the Attorney General under paragraph (2)(B). Paragraph (5) does not apply for purposes of this subparagraph. The Secretary may exempt Federal, State, or local governmental agencies from the requirements of this subparagraph.

(7) Review

(A) Administrative review

(i) In general

Regulations under subsections (b) and (c) shall provide for an opportunity for a review by the Secretary—

(I) when requested by the individual involved, of a determination under paragraph (2) to deny the individual access to listed agents and toxins; and

(II) when requested by the person involved, of a determination under paragraph (6) to deny or revoke registration for such person.

(ii) Ex parte review

During a review under clause (i), the Secretary may consider information relevant to the review ex parte to the extent that disclosure of the information could compromise national security or an investigation by any law enforcement agency.

(iii) Final agency action

The decision of the Secretary in a review under clause (i) constitutes final agency action for purposes of section 702 of title 5.

(B) Certain procedures

(i) Submission of ex parte materials in judicial proceedings

When reviewing a decision of the Secretary under subparagraph (A), and upon request made ex parte and in writing by the United States, a court, upon a sufficient showing, may review and consider ex parte documents containing information the disclosure of which could compromise national security or an investigation by any law enforcement agency. If the court determines that portions of the documents considered ex parte should be disclosed to the person involved to allow a response, the court shall authorize the United States to delete from such documents specified items of information the disclosure of which could compromise national security or an investigation by any law enforcement agency, or to substitute a summary of the information to which the person may respond. Any order by the court authorizing the disclosure of information that the United States believes could compromise national security or an investigation by any law enforcement agency shall be subject to the processes set forth in subparagraphs (A) and (B)(i) of section 2339B(f)(5) of title 18 (relating to interlocutory appeal and expedited consideration).

(ii) Disclosure of information

In a review under subparagraph (A), and in any judical [1] proceeding conducted pursuant to such review, neither the Secretary nor the Attorney General may be required to disclose to the public any information that under subsection (h) shall not be disclosed under section 552 of title 5.

(8) Notifications regarding theft or loss of agents

Requirements under paragraph (1) shall include the prompt notification of the Secretary, and appropriate Federal, State, and local law enforcement agencies, of the theft or loss of listed agents and toxins.

(9) Technical assistance for registered persons

The Secretary, in consultation with the Attorney General, may provide technical assistance to registered persons to improve security of the facilities of such persons.

(f) Inspections

The Secretary shall have the authority to inspect persons subject to regulations under subsection (b) or (c) to ensure their compliance with such regulations, including prohibitions on restricted persons and other provisions of subsection (e).

(g) Exemptions

(1) Clinical or diagnostic laboratories

Regulations under subsections (b) and (c) shall exempt clinical or diagnostic laboratories and other persons who possess, use, or transfer listed agents or toxins that are contained in specimens presented for diagnosis, verification, or proficiency testing, provided that—

(A) the identification of such agents or toxins is reported to the Secretary, and when required under Federal, State, or local law, to other appropriate authorities; and

(B) such agents or toxins are transferred or destroyed in a manner set forth by the Secretary by regulation.

(2) Products

(A) In general

Regulations under subsections (b) and (c) shall exempt products that are, bear, or contain listed agents or toxins and are cleared, approved, licensed, or registered under any of the Acts specified in subparagraph (B), unless the Secretary by order determines that applying additional regulation under subsection (b) or (c) to a specific product is necessary to protect public health and safety.

(B) Relevant laws

For purposes of subparagraph (A), the Acts specified in this subparagraph are the following:

(i) The Federal Food, Drug, and Cosmetic Act [21 U.S.C. 301 et seq.].

(ii) Section 262 of this title.

(iii) The Act commonly known as the Virus-Serum-Toxin Act (the eighth paragraph under the heading "Bureau of Animal Industry" in the Act of March 4, 1913; 21 U.S.C. 151–159).

(iv) The Federal Insecticide, Fungicide, and Rodenticide Act [7 U.S.C. 136 et seq.].

(C) Investigational use

(i) In general

The Secretary may exempt an investigational product that is, bears, or contains a listed agent or toxin from the applicability of provisions of regulations under subsection (b) or (c) when such product is being used in an investigation authorized under any Federal Act and the Secretary determines that applying additional regulation under subsection (b) or (c) to such product is not necessary to protect public health and safety.

(ii) Certain processes

Regulations under subsections (b) and (c) shall set forth the procedures for applying for an exemption under clause (i). In the case of investigational products authorized under any of the Acts specified in subparagraph (B), the Secretary shall make a determination regarding a request for an exemption not later than 14 days after the first date on which both of the following conditions have been met by the person requesting the exemption:

(I) The person has submitted to the Secretary an application for the exemption meeting the requirements established by the Secretary.

(II) The person has notified the Secretary that the investigation has been authorized under such an Act.

(3) Public health emergencies

The Secretary may temporarily exempt a person from the applicability of the requirements of this section, in whole or in part, if the Secretary determines that such exemption is necessary to provide for the timely participation of the person in a response to a domestic or foreign public health emergency (whether determined under section 247d(a) of this title or otherwise) that involves a listed agent or toxin. With respect to the emergency involved, such exemption for a person may not exceed 30 days, except that the Secretary, after review of whether such exemption remains necessary, may provide one extension of an additional 30 days.

(4) Agricultural emergencies

Upon request of the Secretary of Agriculture, after the granting by such Secretary of an exemption under section 8401(g)(1)(D) of title 7 pursuant to a finding that there is an agricultural emergency, the Secretary of Health and Human Services may temporarily exempt a person from the applicability of the requirements of this section, in whole or in part, to provide for the timely participation of the person in a response to the agricultural emergency. With respect to the emergency involved, the exemption under this paragraph for a person may not exceed 30 days, except that upon request of the Secretary of Agriculture, the Secretary of Health and Human Services may, after review of whether such exemption remains necessary, provide one extension of an additional 30 days.

(h) Disclosure of information

(1) Nondisclosure of certain information

No Federal agency specified in paragraph (2) shall disclose under section 552 of title 5 any of the following:

(A) Any registration or transfer documentation submitted under subsections (b) and (c) for the possession, use, or transfer of a listed agent or toxin; or information derived therefrom to the extent that it identifies the listed agent or toxin possessed, used, or transferred by a specific registered person or discloses the identity or location of a specific registered person.

(B) The national database developed pursuant to subsection (d), or any other compilation of the registration or transfer information submitted under subsections (b) and (c) to the extent that such compilation discloses site-specific registration or transfer information.

(C) Any portion of a record that discloses the site-specific or transfer-specific safeguard and security measures used by a registered person to prevent unauthorized access to listed agents and toxins.

(D) Any notification of a release of a listed agent or toxin submitted under subsections (b) and (c), or any notification of theft or loss submitted under such subsections.

(E) Any portion of an evaluation or report of an inspection of a specific registered person conducted under subsection (f) that identifies the listed agent or toxin possessed by a specific registered person or that discloses the identity or location of a specific registered person if the agency determines that public disclosure of the information would endanger public health or safety.

(2) Covered agencies

For purposes of paragraph (1) only, the Federal agencies specified in this paragraph are the following:

(A) The Department of Health and Human Services, the Department of Justice, the Department of Agriculture, and the Department of Transportation.

(B) Any Federal agency to which information specified in paragraph (1) is transferred by any agency specified in subparagraph (A) of this paragraph.

(C) Any Federal agency that is a registered person, or has a sub-agency component that is a registered person.

(D) Any Federal agency that awards grants or enters into contracts or cooperative agreements involving listed agents and toxins to or with a registered person, and to which information specified in paragraph (1) is transferred by any such registered person.

(3) Other exemptions

This subsection may not be construed as altering the application of any exemptions to public disclosure under section 552 of title 5, except as to subsection [2] 552(b)(3) of such title, to any of the information specified in paragraph (1).

(4) Rule of construction

Except as specifically provided in paragraph (1), this subsection may not be construed as altering the authority of any Federal agency to withhold under section 552 of title 5, or the obligation of any Federal agency to disclose under section 552 of title 5, any information, including information relating to—

(A) listed agents and toxins, or individuals seeking access to such agents and toxins;

(B) registered persons, or persons seeking to register their possession, use, or transfer of such agents and toxins;

(C) general safeguard and security policies and requirements under regulations under subsections (b) and (c); or

(D) summary or statistical information concerning registrations, registrants, denials or revocations of registrations, listed agents and toxins, inspection evaluations and reports, or individuals seeking access to such agents and toxins.

(5) Disclosures to Congress; other disclosures

This subsection may not be construed as providing any authority—

(A) to withhold information from the Congress or any committee or subcommittee thereof; or

(B) to withhold information from any person under any other Federal law or treaty.

(i) Civil money penalty

(1) In general

In addition to any other penalties that may apply under law, any person who violates any provision of regulations under subsection (b) or (c) shall be subject to the United States for a civil

money penalty in an amount not exceeding $250,000 in the case of an individual and $500,000 in the case of any other person.

(2) Applicability of certain provisions

The provisions of section 1320a–7a of this title (other than subsections (a), (b), (h), and (i), the first sentence of subsection (c), and paragraphs (1) and (2) of subsection (f)) shall apply to a civil money penalty under paragraph (1) in the same manner as such provisions apply to a penalty or proceeding under section 1320a–7a(a) of this title. The Secretary may delegate authority under this subsection in the same manner as provided in section 1320a–7a(j)(2) of this title, and such authority shall include all powers as contained in section 406 of title 5.

(j) Notification in event of release

Regulations under subsections (b) and (c) shall require the prompt notification of the Secretary by a registered person whenever a release, meeting criteria established by the Secretary, of a listed agent or toxin has occurred outside of the biocontainment area of a facility of the registered person. Upon receipt of such notification and a finding by the Secretary that the release poses a threat to public health or safety, the Secretary shall take appropriate action to notify relevant State and local public health authorities, other relevant Federal authorities, and, if necessary, other appropriate persons (including the public). If the released listed agent or toxin is an overlap agent or toxin (as defined in subsection (l)), the Secretary shall promptly notify the Secretary of Agriculture upon notification by the registered person.

(k) Reports

(1) Notification with respect to Federal facilities

In the event of the release, loss, or theft of an agent or toxin listed by the Secretary pursuant to subsection (a)(1), or by the Secretary of Agriculture pursuant to section 8401(a)(1) of title 7, from or within a laboratory facility owned or operated by the Department of Health and Human Services, or other Federal laboratory facility subject to the requirements of this section, the Secretary, in a manner that does not compromise national security, shall—

(A) not later than 72 hours after such event is reported to the Secretary, notify the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives of such event, including—

(i) the Federal laboratory facility in which such release, loss, or theft occurred; and

(ii) the circumstances of such release, loss, or theft; and

(B) not later than 14 days after such notification, update such Committees on—

(i) any actions taken or planned by the Secretary to mitigate any potential threat such release, loss, or theft may pose to public health and safety; and

(ii) any actions taken or planned by the Secretary to review the circumstances of such release, loss, or theft, and prevent similar events.

(2) Annual report

The Secretary shall submit to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives on an annual basis a report—

(A) summarizing the number and nature of notifications received under subsection (e)(8) (relating to theft or loss) and subsection (j) (relating to releases), during the preceding fiscal year;

(B) describing actions taken by the Secretary to address such incidents, such as any corrective action plans required and steps taken to promote adherence to, and compliance with, safety and security best practices, standards, and regulations; and

(C) describing any gaps, challenges, or limitations with respect to ensuring that such safety and security practices are consistently applied and adhered to, and actions taken to address such gaps, challenges, or limitations.

(3) Implementation of recommendations of the Federal Experts Security Advisory Panel and the fast track action committee on select agent regulations

(A) In general

Not later than 1 year after June 24, 2019, the Secretary shall report to the congressional committees of jurisdiction on the implementation of recommendations of the Federal Experts Security Advisory Panel concerning the select agent program.

(B) Continued updates

The Secretary shall report to the congressional committees of jurisdiction annually following the submission of the report under subparagraph (A) until the recommendations described in such subparagraph are fully implemented, or a justification is provided for the delay in, or lack of, implementation.

(l) Definitions

For purposes of this section:

(1) The terms "biological agent" and "toxin" have the meanings given such terms in section 178 of title 18.

(2) The term "listed agents and toxins" means biological agents and toxins listed pursuant to subsection (a)(1).

(3) The term "listed agents or toxins" means biological agents or toxins listed pursuant to subsection (a)(1).

(4) The term "overlap agents and toxins" means biological agents and toxins that—

(A) are listed pursuant to subsection (a)(1); and

(B) are listed pursuant to section 8401(a)(1) of title 7.

(5) The term "overlap agent or toxin" means a biological agent or toxin that—

(A) is listed pursuant to subsection (a)(1); and

(B) is listed pursuant to section 8401(a)(1) of title 7.

(6) The term "person" includes Federal, State, and local governmental entities.

(7) The term "registered person" means a person registered under regulations under subsection (b) or (c).

(8) The term "restricted person" has the meaning given such term in section 175b of title 18.

(m) Authorization of appropriations

For the purpose of carrying out this section, there are authorized to be appropriated such sums as may be necessary for each of the fiscal years 2023 through 2027.

(July 1, 1944, ch. 373, title III, §351A, as added Pub. L. 107–188, title II, §201(a), June 12, 2002, 116 Stat. 637; amended Pub. L. 107–296, title XVII, §1709(a), Nov. 25, 2002, 116 Stat. 2318; Pub. L. 116–22, title IV, §405, June 24, 2019, 133 Stat. 949; Pub. L. 117–286, §4(b)(75), Dec. 27, 2022, 136 Stat. 4351; Pub. L. 117–328, div. FF, title II, §2311, Dec. 29, 2022, 136 Stat. 5759.)

EDITORIAL NOTES

REFERENCES IN TEXT

The Federal Food, Drug, and Cosmetic Act, referred to in subsec.(g)(2)(B)(i), is act June 25, 1938, ch. 675, 52 Stat. 1040, which is classified generally to chapter 9 (§301 et seq.) of Title 21, Food and Drugs. For complete classification of this Act to the Code, see section 301 of Title 21 and Tables.

The Act commonly known as the Virus-Serum-Toxin Act, referred to in subsec. (g)(2)(B)(iii), is the eighth paragraph under the heading "Bureau of Animal Industry" of act Mar. 4, 1913, ch. 145, 37 Stat. 832, which is classified generally to chapter 5 (§151 et seq.) of Title 21, Food and Drugs. For complete classification of this Act to the Code, see Short Title note set out under section 151 of Title 21 and Tables.

The Federal Insecticide, Fungicide, and Rodenticide Act, referred to in subsec. (g)(2)(B)(iv), is act June 25, 1947, ch. 125, as amended generally by Pub. L. 92–516, Oct. 21, 1972, 86 Stat. 973, which is classified

generally to subchapter II (§136 et seq.) of chapter 6 of Title 7, Agriculture. For complete classification of this Act to the Code, see Short Title note set out under section 136 of Title 7 and Tables.

AMENDMENTS

2022—Subsec. (b)(1)(A). Pub. L. 117–328, §2311(1), amended subpar. (A) generally. Prior to amendment, text read as follows: "proper training and appropriate skills to handle such agents and toxins; and".

Subsec. (e)(1). Pub. L. 117–328, §2311(2), substituted "(including risks posed by the release, theft, or loss of such agent or toxin, or use in domestic or international terrorism)" for "(including the risk of use in domestic or international terrorism)".

Subsec. (i)(2). Pub. L. 117–286 substituted "section 406 of title 5." for "section 6 of the Inspector General Act of 1978 (5 U.S.C. App.)."

Subsec. (k)(1). Pub. L. 117–328, §2311(3)(B), added par. (1). Former par. (1) redesignated (2).

Subsec. (k)(2). Pub. L. 117–328, §2311(3)(A), (C), redesignated par. (1) as (2) and amended it generally. Prior to amendment, text read as follows: "The Secretary shall report to the Congress annually on the number and nature of notifications received under subsection (e)(8) (relating to theft or loss) and subsection (j) (relating to releases)." Former par. (2) redesignated (3).

Subsec. (k)(3). Pub. L. 117–328, §2311(3)(A), redesignated par. (2) as (3).

Subsec. (m). Pub. L. 117–328, §2311(4), substituted "fiscal years 2023 through 2027" for "fiscal years 2002 through 2007".

2019—Subsec. (k). Pub. L. 116–22 designated existing provisions as par. (1), inserted heading, and added par. (2).

2002—Subsec. (e)(1). Pub. L. 107–296 substituted "collaboration with the Secretary of Homeland Security and" for "consultation with".

STATUTORY NOTES AND RELATED SUBSIDIARIES

EFFECTIVE DATE OF 2002 AMENDMENT

Amendment by Pub. L. 107–296 effective 60 days after Nov. 25, 2002, see section 4 of Pub. L. 107–296, set out as an Effective Date note under section 101 of Title 6, Domestic Security.

EFFECTIVE DATE

Pub. L. 107–188, title II, §203(b), June 12, 2002, 116 Stat. 647, provided that: "Subsection (h) of section 351A of the Public Health Service Act [42 U.S.C. 262a(h)], as added by section 201 of this Act, is deemed to have taken effect on the effective date of the Antiterrorism and Effective Death Penalty Act of 1996 [Pub. L. 104–132, Apr. 24, 1996, 110 Stat. 1214]."

REGULATIONS

Pub. L. 107–188, title II, §203(a), June 12, 2002, 116 Stat. 647, provided that: "Regulations promulgated by the Secretary of Health and Human Services under section 511 of the Antiterrorism and Effective Death Penalty Act of 1996 [Pub. L. 104–132, 42 U.S.C. 262 note] are deemed to have been promulgated under section 351A of the Public Health Service Act [42 U.S.C. 262a], as added by section 201 of this Act. Such regulations, including the list under [former] subsection (d)(1) of such section 511, that were in effect on the day before the date of the enactment of this Act [June 12, 2002] remain in effect until modified by the Secretary in accordance with such section 351A and with section 202 of this Act [set out as a note below]."

IMPROVING RESEARCH AND DEVELOPMENT OF MEDICAL COUNTERMEASURES FOR NOVEL PATHOGENS

Pub. L. 117–328, div. FF, title II, §2303(a), Dec. 29, 2022, 136 Stat. 5758, provided that:

"(1) SAMPLE ACCESS.—Not later than 1 year after the date of enactment of this Act [Dec. 29, 2022], the Secretary of Health and Human Services (referred to in this subsection as the 'Secretary') shall make publicly available policies and procedures related to public and private entities accessing specimens of, or specimens containing, pathogens or suitable surrogates for, or alternatives to, such pathogens as the Secretary determines appropriate to support public health preparedness and response activities or biomedical research for purposes of the development and validation, as applicable, of medical products to address emerging infectious diseases and for use to otherwise respond to emerging infectious diseases. Such policies and procedures shall take into account, as appropriate, any applicable existing Federal resources.

"(2) GUIDANCE.—The Secretary shall issue guidance regarding the procedures for carrying out paragraph (1), including—

"(A) the method for requesting such samples;

"(B) considerations for sample availability and use of suitable surrogates or alternatives to such pathogens, as appropriate, including applicable safeguard and security measures; and

"(C) information required to be provided in order to receive such samples or suitable surrogates or alternatives."

STRATEGY FOR FEDERAL HIGH-CONTAINMENT LABORATORIES

Pub. L. 117–328, div. FF, title II, §2312, Dec. 29, 2022, 136 Stat. 5761, provided that:

"(a) STRATEGY FOR FEDERAL HIGH-CONTAINMENT LABORATORIES.—Not later than 1 year after the date of enactment of this Act [Dec. 29, 2022], the Director of the Office of Science and Technology Policy, in consultation with relevant Federal departments and agencies, shall establish a strategy for the management, maintenance, and oversight of federally-owned laboratory facilities operating at Biosafety Level 3 or 4, including equivalent classification levels and facilities with Biosafety Level 4 capabilities. Such strategy shall include—

"(1) a description of the roles and responsibilities of relevant Federal departments and agencies with respect to the management, maintenance, and oversight of Biosafety Level 3 or 4 laboratory facilities;

"(2) an assessment of the needs of the Federal Government with respect to Biosafety Level 3 or 4 laboratory facilities;

"(3) a summary of existing federally-owned Biosafety Level 3 or 4 laboratory facility capacity;

"(4) a summary of other Biosafety Level 3 or 4 laboratory facility capacity established through Federal funds;

"(5) a description of how the capacity described in paragraphs (3) and (4) addresses the needs of the Federal Government, including—

"(A) how relevant Federal departments and agencies coordinate to provide access to appropriate laboratory facilities to reduce unnecessary duplication; and

"(B) any gaps in such capacity related to such needs;

"(6) a summary of plans that are in place for the maintenance of such capacity within each relevant Federal department or agency, as applicable and appropriate, including processes for determining whether to maintain or expand such capacity, and a description of how the Federal Government will address rapid changes in the need for such capacity within each relevant Federal department or agency during a public health emergency; and

"(7) a description of how the heads of relevant Federal departments and agencies will coordinate to ensure appropriate oversight of federally-owned laboratory facility capacity and leverage such capacity within each relevant Federal department, as appropriate, to fulfill the needs of each Federal department and agency in order to reduce unnecessary duplication and improve collaboration within the Federal Government.

"(b) CLARIFICATION.—The strategy under subsection (a) shall not be construed to supersede the authorities of each relevant Federal department or agency with respect to the management, maintenance, and oversight of the Federally-owned laboratory facilities operated by any such Federal department or agency."

RESEARCH TO IMPROVE BIOSAFETY

Pub. L. 117–328, div. FF, title II, §2314, Dec. 29, 2022, 136 Stat. 5763, provided that:

"(a) IN GENERAL.—The Secretary of Health and Human Services (referred to in this section as the 'Secretary') shall, as appropriate, conduct or support research to improve the safe conduct of biomedical research activities involving pathogens of pandemic potential or biological agents or toxins listed pursuant to section 351A(a)(1) of the Public Health Service Act (42 U.S.C. 262a(a)(1)).

"(b) REPORT.—Not later than 5 years after the date of enactment of this Act [Dec. 29, 2022], the Secretary shall prepare and submit a report to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives regarding an overview of any research conducted or supported under this section, any relevant findings, and steps the Secretary is taking to disseminate any such findings to support the reduction of risks associated with biomedical research involving pathogens of pandemic potential or biological agents or toxins listed pursuant to section 351A(a)(1) of the Public Health Service Act (42 U.S.C. 262a(a)(1))."

NATIONAL SCIENCE ADVISORY BOARD FOR BIOSECURITY

Pub. L. 109–417, title II, §205, Dec. 19, 2006, 120 Stat. 2851, formerly set out as a note under this section, was transferred and is set out as a National Science Advisory Board for Biosecurity: Provision of Advice, Guidance, or Recommendations note under section 283r of this title.

REPORT TO CONGRESS

Pub. L. 107–188, title II, §201(b), June 12, 2002, 116 Stat. 646, required the Secretary of Health and Human Services to report to Congress not later than one year after June 12, 2002, on the implementation, compliance, and future plans under this section.

IMPLEMENTATION BY DEPARTMENT OF HEALTH AND HUMAN SERVICES

Pub. L. 107–188, title II, §202, June 12, 2002, 116 Stat. 646, provided that:

"(a) DATE CERTAIN FOR NOTICE OF POSSESSION.—Not later than 90 days after the date of the enactment of this Act [June 12, 2002], all persons (unless exempt under subsection (g) of section 351A of the Public Health Service Act [42 U.S.C. 262a(g)], as added by section 201 of this Act) in possession of biological agents or toxins listed under such section 351A of the Public Health Service Act [42 U.S.C. 262a] shall notify the Secretary of Health and Human Services of such possession. Not later than 30 days after such date of enactment, the Secretary shall provide written guidance on how such notice is to be provided to the Secretary.

"(b) DATE CERTAIN FOR PROMULGATION; EFFECTIVE DATE REGARDING CRIMINAL AND CIVIL PENALTIES.—Not later than 180 days after the date of the enactment of this Act [June 12, 2002], the Secretary of Health and Human Services shall promulgate an interim final rule for carrying out section 351A of the Public Health Service Act [42 U.S.C. 262a], subject to subsection (c). Such interim final rule shall take effect 60 days after the date on which such rule is promulgated, including for purposes of—

"(1) section 175b(c) of title 18, United States Code (relating to criminal penalties), as added by section 231(a)(5) of this Act; and

"(2) section 351A(i) of the Public Health Service Act [42 U.S.C. 262a(i)] (relating to civil penalties).

"(c) TRANSITIONAL PROVISION REGARDING CURRENT RESEARCH AND EDUCATION.—The interim final rule under subsection (b) shall include time frames for the applicability of the rule that minimize disruption of research or educational projects that involve biological agents and toxins listed pursuant to section 351A(a)(1) of the Public Health Service Act [42 U.S.C. 262a(a)(1)] and that were underway as of the effective date of such rule."

EXECUTIVE DOCUMENTS

EX. ORD. NO. 13546. OPTIMIZING THE SECURITY OF BIOLOGICAL SELECT AGENTS AND TOXINS IN THE UNITED STATES

Ex. Ord. No. 13546, July 2, 2010, 75 F.R. 39439, provided:

By the authority vested in me as President by the Constitution and the laws of the United States of America, it is hereby ordered as follows:

SECTION 1. *Policy*. It is the policy of the United States that:

(a) A robust and productive scientific enterprise that utilizes biological select agents and toxins (BSAT) is essential to national security;

(b) BSAT shall be secured in a manner appropriate to their risk of misuse, theft, loss, and accidental release; and

(c) Security measures shall be taken in a coordinated manner that balances their efficacy with the need to minimize the adverse impact on the legitimate use of BSAT.

SEC. 2. *Definitions*. (a) "Select Agent Program" (SAP) means the regulatory oversight and administrative activities conducted by the Secretaries of Health and Human Services and Agriculture and the Attorney General to implement the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 and the Agricultural Bioterrorism Protection Act of 2002.

(b) "Select Agent Regulations" (SAR) means the Federal regulations found in Part 73 of Title 42 of the Code of Federal Regulations, Part 331 of Title 7 of the Code of Federal Regulations, and Part 121 of Title 9 of the Code of Federal Regulations.

(c) "Biological Select Agents and Toxins" means biological agents and toxins with the potential to pose a severe threat to public health and safety, animal and plant health, or animal and plant products and whose possession, use, and transfer are regulated by the Department of Health and Human Services and the Department of Agriculture under the SAR.

SEC. 3. *Findings*. (a) The use of BSAT presents the risk that BSAT might be lost, stolen, or diverted for malicious purpose. The SAP exists to provide effective regulatory oversight of the possession, use, and transfer of BSAT that reduces the risk of their misuse or mishandling. The absence of clearly defined, risk-based security measures in the SAR/SAP has raised concern about the need for optimized security and for risk management.

(b) In addition, variations in, and limited coordination of, individual executive departments' and agencies' oversight, security practices, and inspections have raised concerns that the cost and complexity of compliance for those who are registered to work with BSAT could discourage research or other legitimate activities.

(c) Understanding that research and laboratory work on BSAT is essential to both public health and national security, it is in the interest of the United States to address these issues.

SEC. 4. *Risk-based Tiering of the Select Agent List*. To help ensure that BSAT are secured according to level of risk, the Secretaries of Health and Human Services and Agriculture shall, through their ongoing review of the biological Select Agents and Toxins List ("Select Agent List") contained in regulations, and no later than 18 months from the date of this order:

(a) designate a subset of the Select Agent List (Tier 1) that presents the greatest risk of deliberate misuse with most significant potential for mass casualties or devastating effects to the economy, critical infrastructure, or public confidence;

(b) explore options for graded protection of Tier 1 agents and toxins as described in subsection (a) of this section to permit tailored risk management practices based upon relevant contextual factors; and

(c) consider reducing the overall number of agents and toxins on the Select Agent List.

SEC. 5. *Revision of Regulations, Rules, and Guidance to Accommodate a Tiered Select Agent List*. Consistent with section 4 of this order, I request that:

(a) The Secretaries of Health and Human Services and Agriculture, no later than 15 months from the date of this order, propose amendments to their respective parts of the SAR that would establish security standards specific to Tier 1 agents and toxins.

(b) The Secretaries of Health and Human Services and Agriculture each, no later than 27 months from the date of this order, promulgate final rules and guidance that clearly articulate security actions for registrants who possess, use, or transfer Tier 1 agents and toxins.

SEC. 6. *Coordination of Federal Oversight for BSAT Security*. To ensure that the policies and practices used to secure BSAT are harmonized and that the related oversight activities of the Federal Government are coordinated, the heads of executive departments and agencies identified in section 7(a)(ii) of this order shall:

(a) no later than 6 months from the date of this order, develop and implement a plan for the coordination of BSAT security oversight that:

(i) articulates a mechanism for coordinated and reciprocal inspection of and harmonized administrative practices for facilities registered with the SAP;

(ii) ensures consistent and timely identification and resolution of BSAT security and compliance issues;

(iii) facilitates information sharing among departments and agencies regarding ongoing oversight and inspection activities; and

(iv) provides for comprehensive and effective Federal oversight of BSAT security; and

(b) no later than 6 months from the issuance of final rules and guidance as described in section 5 of this order, and annually thereafter, review for inconsistent requirements and revise or rescind, as appropriate, any regulations, directives, guidance, or policies regarding BSAT security within their department or agency that exceed those in the updated SAR and guidance as described in section 5 of this order.

SEC. 7. *Implementation*. (a) Establishment, Operation, and Functions of the Federal Experts Security Advisory Panel.

(i) There is hereby established, within the Department of Health and Human Services for administrative purposes only, the Federal Experts Security Advisory Panel (Panel), which shall make technical and substantive recommendations on BSAT security concerning the SAP.

(ii) The Panel shall consist of representatives from the following, who may consult with additional experts from their department or agency as required:

1. the Department of State;
2. the Department of Defense;
3. the Department of Justice;
4. the Department of Agriculture (Co-Chair);
5. the Department of Commerce;
6. the Department of Health and Human Services (Co-Chair);
7. the Department of Transportation;
8. the Department of Labor;
9. the Department of Energy;
10. the Department of Veterans Affairs;
11. the Department of Homeland Security;
12. the Environmental Protection Agency;
13. the Office of the Director of National Intelligence;

14. the Office of Science and Technology Policy;
15. the Joint Chiefs of Staff; and
16. any other department or agency designated by the Co-Chairs.

(iii) To assist the Secretaries of Health and Human Services and Agriculture and the Attorney General in implementing the policies set forth in sections 1, 4, 5, and 6 of this order, the Panel shall, no later than 4 months from the date of this order, provide consensus recommendations concerning the SAP on:

1. the designation of Tier 1 agents and toxins;
2. reduction in the number of agents on the Select Agent List;
3. the establishment of appropriate practices to ensure reliability of personnel with access to Tier 1 agents and toxins at registered facilities;
4. the establishment of appropriate practices for physical security and cyber security for facilities that possess Tier 1 agents. The Department of Homeland Security shall Chair a Working Group of the Panel that develops recommended laboratory critical infrastructure security standards in these areas; and
5. other emerging policy issues relevant to the security of BSAT.

Thereafter, the Panel shall continue to provide technical advice concerning the SAP on request.

(iv) If the Panel is unable to reach consensus on recommendations for an issue within its charge, the matter shall be resolved through the interagency policy committee process led by the National Security Staff.

(v) The Secretaries of Health and Human Services and Agriculture and the Attorney General shall report to the Assistant to the President for Homeland Security and Counterterrorism on the consideration and implementation of Panel recommendations concerning the SAP, including a rationale for failure to implement any recommendations.

(vi) The Panel shall be chartered for a period of 4 years subject to renewal through the interagency policy committee process led by the National Security Staff.

(b) To further assist the Secretaries of Health and Human Services and Agriculture and the Attorney General in implementing the policy set forth in sections 1, 4, 5, and 6 of this order, the National Science Advisory Board for Biosecurity shall provide technical advice and serve as a conduit for public consultation, as needed, on topics of relevance to the SAP.

SEC. 8. *Sharing of Select Agent Program Information*. (a) Consistent with applicable laws and regulations, the Secretaries of Health and Human Services and Agriculture and the Attorney General shall, no later than 6 months from the date of this order, develop a process and the criteria for making SAP information available to executive departments and agencies when such information is necessary for furthering a public health, safety, security, law enforcement, or national security mission.

(b) SAP information shall continue to be safeguarded properly and handled securely to minimize the risk of disclosing sensitive, personal, and other information protected by the Privacy Act, 5 U.S.C. 552a.

SEC. 9. *General Provisions*. (a) The National Security Staff shall, on a biennial basis, review the implementation and effectiveness of this order and refer to the interagency policy committee process any issues that require further deliberation or adjudication.

(b) Nothing in this order shall be construed to impair or otherwise affect the authority granted by law to a department or agency, or the head thereof, or functions of the Director of the Office of Management and Budget relating to budgetary, administrative, or legislative proposals.

(c) This order shall be implemented consistent with applicable law and subject to the availability of appropriations.

(d) This order is not intended to, and does not, create any right or benefit, substantive or procedural, enforceable at law or in equity by any party against the United States, its departments, agencies, or entities, its officers, employees, or agents, or any other person.

BARACK OBAMA.

[Reference to the National Security Staff deemed to be a reference to the National Security Council Staff, see Ex. Ord. No. 13657, set out as a note under section 3021 of Title 50, War and National Defense.]

[1] So in original. Probably should be "judicial".

[2] So in original. Probably should be "section".

§263. Preparation of biological products by Service

(a) The Service may prepare for its own use any product described in section 262 of this title and any product necessary to carrying out any of the purposes of section 241 of this title.

(b) The Service may prepare any product described in section 262 of this title for the use of other Federal departments or agencies, and public or private agencies and individuals engaged in work in the field of medicine when such product is not available from establishments licensed under such section.

(July 1, 1944, ch. 373, title III, §352, 58 Stat. 703.)

STATUTORY NOTES AND RELATED SUBSIDIARIES

CHANGE OF NAME

"Secretary of Health and Human Services" substituted for "Secretary of Health, Education, and Welfare" pursuant to section 509(b) of Pub. L. 96–88, which is classified to section 3508(b) of Title 20, Education.

EXECUTIVE DOCUMENTS

TRANSFER OF FUNCTIONS

Functions of Public Health Service, Surgeon General of Public Health Service, and all other officers and employees of Public Health Service, and functions of all agencies of or in Public Health Service transferred to Secretary of Health, Education, and Welfare by Reorg. Plan No. 3 of 1966, eff. June 25, 1966, 31 F.R. 8855, 80 Stat. 1610, set out as a note under section 202 of this title.

§263–1. Education on biological products

(a) Internet website

(1) In general

The Secretary may maintain and operate an internet website to provide educational materials for health care providers, patients, and caregivers, regarding the meaning of the terms, and the standards for review and licensing of, biological products, including biosimilar biological products and interchangeable biosimilar biological products.

(2) Content

Educational materials provided under paragraph (1) may include—

(A) explanations of key statutory and regulatory terms, including "biosimilar" and "interchangeable", and clarification regarding the use of interchangeable biosimilar biological products;

(B) information related to development programs for biological products, including biosimilar biological products and interchangeable biosimilar biological products and relevant clinical considerations for prescribers, which may include, as appropriate and applicable, information related to the comparability of such biological products;

(C) an explanation of the process for reporting adverse events for biological products, including biosimilar biological products and interchangeable biosimilar biological products; and

(D) an explanation of the relationship between biosimilar biological products and interchangeable biosimilar biological products licensed under section 262(k) of this title and reference products (as defined in section 262(i) of this title), including the standards for review and licensing of each such type of biological product.

(3) Format

The educational materials provided under paragraph (1) may be—

(A) in formats such as webinars, continuing education modules, videos, fact sheets, infographics, stakeholder toolkits, or other formats as appropriate and applicable; and

(B) tailored for the unique needs of health care providers, patients, caregivers, and other audiences, as the Secretary determines appropriate.

(4) Other information

In addition to the information described in paragraph (2), the Secretary shall continue to publish—

(A) the action package of each biological product licensed under subsection (a) or (k) of section 262 of this title; or

(B) the summary review of each biological product licensed under subsection (a) or (k) of section 262 of this title.

(5) Confidential and trade secret information

This subsection does not authorize the disclosure of any trade secret, confidential commercial or financial information, or other matter described in section 552(b) of title 5.

(b) Continuing education

The Secretary shall advance education and awareness among health care providers regarding biological products, including biosimilar biological products and interchangeable biosimilar biological products, as appropriate, including by developing or improving continuing education programs that advance the education of such providers on the prescribing of, and relevant clinical considerations with respect to, biological products, including biosimilar biological products and interchangeable biosimilar biological products.

(July 1, 1944, ch. 373, title III, §352A, as added Pub. L. 117–8, §2, Apr. 23, 2021, 135 Stat. 254.)

SUBPART 2—CLINICAL LABORATORIES

§263a. Certification of laboratories

(a) "Laboratory" or "clinical laboratory" defined

As used in this section, the term "laboratory" or "clinical laboratory" means a facility for the biological, microbiological, serological, chemical, immuno-hematological, hematological, biophysical, cytological, pathological, or other examination of materials derived from the human body for the purpose of providing information for the diagnosis, prevention, or treatment of any disease or impairment of, or the assessment of the health of, human beings.

(b) Certificate requirement

No person may solicit or accept materials derived from the human body for laboratory examination or other procedure unless there is in effect for the laboratory a certificate issued by the Secretary under this section applicable to the category of examinations or procedures which includes such examination or procedure.

(c) Issuance and renewal of certificates

(1) In general

The Secretary may issue or renew a certificate for a laboratory only if the laboratory meets the requirements of subsection (d).

(2) Term

A certificate issued under this section shall be valid for a period of 2 years or such shorter period as the Secretary may establish.

(d) Requirements for certificates

(1) In general

A laboratory may be issued a certificate or have its certificate renewed if—

(A) the laboratory submits (or if the laboratory is accredited under subsection (e), the

accreditation body which accredited the laboratory submits), an application—

(i) in such form and manner as the Secretary shall prescribe,

(ii) that describes the characteristics of the laboratory examinations and other procedures performed by the laboratory including—

(I) the number and types of laboratory examinations and other procedures performed,

(II) the methodologies for laboratory examinations and other procedures employed, and

(III) the qualifications (educational background, training, and experience) of the personnel directing and supervising the laboratory and performing the laboratory examinations and other procedures, and

(iii) that contains such other information as the Secretary may require to determine compliance with this section, and

the laboratory agrees to provide to the Secretary (or if the laboratory is accredited, to the accreditation body which accredited it) a description of any change in the information submitted under clause (ii) not later than 6 months after the change was put into effect,

(B) the laboratory provides the Secretary—

(i) with satisfactory assurances that the laboratory will be operated in accordance with standards issued by the Secretary under subsection (f), or

(ii) with proof of accreditation under subsection (e),

(C) the laboratory agrees to permit inspections by the Secretary under subsection (g),

(D) the laboratory agrees to make records available and submit reports to the Secretary as the Secretary may reasonably require, and

(E) the laboratory agrees to treat proficiency testing samples in the same manner as it treats materials derived from the human body referred to it for laboratory examinations or other procedures in the ordinary course of business, except that no proficiency testing sample shall be referred to another laboratory for analysis as prohibited under subsection (i)(4).

(2) Requirements for certificates of waiver

(A) In general

A laboratory which only performs laboratory examinations and procedures described in paragraph (3) shall be issued a certificate of waiver or have its certificate of waiver renewed if—

(i) the laboratory submits an application—

(I) in such form and manner as the Secretary shall prescribe,

(II) that describes the characteristics of the laboratory examinations and other procedures performed by the laboratory, including the number and types of laboratory examinations and other procedures performed, the methodologies for laboratory examinations and other procedures employed, and the qualifications (educational background, training, and experience) of the personnel directing and supervising the laboratory and performing the laboratory examinations and other procedures, and

(III) that contains such other information as the Secretary may reasonably require to determine compliance with this section, and

(ii) the laboratory agrees to make records available and submit reports to the Secretary as the Secretary may require.

(B) Changes

If a laboratory makes changes in the examinations and other procedures performed by it only with respect to examinations and procedures which are described in paragraph (3), the laboratory shall report such changes to the Secretary not later than 6 months after the change has been put into effect. If a laboratory proposes to make changes in the examinations and procedures performed by it such that the laboratory will perform an examination or procedure

not described in paragraph (3), the laboratory shall report such change to the Secretary before the change takes effect.

(C) Effect

Subsections (f) and (g) shall not apply to a laboratory to which has been issued a certificate of waiver.

(3) Examinations and procedures

The examinations and procedures identified in paragraph (2) are laboratory examinations and procedures that have been approved by the Food and Drug Administration for home use or that, as determined by the Secretary, are simple laboratory examinations and procedures that have an insignificant risk of an erroneous result, including those that—

(A) employ methodologies that are so simple and accurate as to render the likelihood of erroneous results by the user negligible, or

(B) the Secretary has determined pose no unreasonable risk of harm to the patient if performed incorrectly.

(4) "Certificate" defined

As used in this section, the term "certificate" includes a certificate of waiver issued under paragraph (2).

(e) Accreditation

(1) In general

A laboratory may be accredited for purposes of obtaining a certificate if the laboratory—

(A) meets the standards of an approved accreditation body, and

(B) authorizes the accreditation body to submit to the Secretary (or such State agency as the Secretary may designate) such records or other information as the Secretary may require.

(2) Approval of accreditation bodies

(A) In general

The Secretary may approve a private nonprofit organization to be an accreditation body for the accreditation of laboratories if—

(i) using inspectors qualified to evaluate the methodologies used by the laboratories in performing laboratory examinations and other procedures, the accreditation body agrees to inspect a laboratory for purposes of accreditation with such frequency as determined by [1] Secretary,

(ii) the standards applied by the body in determining whether or not to accredit a laboratory are equal to or more stringent than the standards issued by the Secretary under subsection (f),

(iii) there is adequate provision for assuring that the standards of the accreditation body continue to be met by the laboratory,

(iv) in the case of any laboratory accredited by the body which has had its accreditation denied, suspended, withdrawn, or revoked or which has had any other action taken against it by the accrediting body, the accrediting body agrees to submit to the Secretary the name of such laboratory within 30 days of the action taken,

(v) the accreditation body agrees to notify the Secretary at least 30 days before it changes its standards, and

(vi) if the accreditation body has its approval withdrawn by the Secretary, the body agrees to notify each laboratory accredited by the body of the withdrawal within 10 days of the withdrawal.

(B) Criteria and procedures

The Secretary shall promulgate criteria and procedures for approving an accreditation body and for withdrawing such approval if the Secretary determines that the accreditation body does not meet the requirements of subparagraph (A).

(C) Effect of withdrawal of approval

If the Secretary withdraws the approval of an accreditation body under subparagraph (B), the certificate of any laboratory accredited by the body shall continue in effect for 60 days after the laboratory receives notification of the withdrawal of the approval, except that the Secretary may extend such period for a laboratory if it determines that the laboratory submitted an application for accreditation or a certificate in a timely manner after receipt of the notification of the withdrawal of approval. If an accreditation body withdraws or revokes the accreditation of a laboratory, the certificate of the laboratory shall continue in effect—

(i) for 45 days after the laboratory receives notice of the withdrawal or revocation of the accreditation, or

(ii) until the effective date of any action taken by the Secretary under subsection (i).

(D) Evaluations

The Secretary shall evaluate annually the performance of each approved accreditation body by—

(i) inspecting under subsection (g) a sufficient number of the laboratories accredited by such body to allow a reasonable estimate of the performance of such body, and

(ii) such other means as the Secretary determines appropriate.

(3) Omitted

(f) Standards

(1) In general

The Secretary shall issue standards to assure consistent performance by laboratories issued a certificate under this section of valid and reliable laboratory examinations and other procedures. Such standards shall require each laboratory issued a certificate under this section—

(A) to maintain a quality assurance and quality control program adequate and appropriate for the validity and reliability of the laboratory examinations and other procedures of the laboratory and to meet requirements relating to the proper collection, transportation, and storage of specimens and the reporting of results,

(B) to maintain records, equipment, and facilities necessary for the proper and effective operation of the laboratory,

(C) in performing and carrying out its laboratory examinations and other procedures, to use only personnel meeting such qualifications as the Secretary may establish for the direction, supervision, and performance of examinations and procedures within the laboratory, which qualifications shall take into consideration competency, training, experience, job performance, and education and which qualifications shall, as appropriate, be different on the basis of the type of examinations and procedures being performed by the laboratory and the risks and consequences of erroneous results associated with such examinations and procedures,

(D) to qualify under a proficiency testing program meeting the standards established by the Secretary under paragraph (3), and

(E) to meet such other requirements as the Secretary determines necessary to assure consistent performance by such laboratories of accurate and reliable laboratory examinations and procedures.

(2) Considerations

In developing the standards to be issued under paragraph (1), the Secretary shall, within the flexibility provided under subparagraphs (A) through (E) of paragraph (1), take into consideration—

(A) the examinations and procedures performed and the methodologies employed,

(B) the degree of independent judgment involved,

(C) the amount of interpretation involved,

(D) the difficulty of the calculations involved,

(E) the calibration and quality control requirements of the instruments used,

(F) the type of training required to operate the instruments used in the methodology, and
(G) such other factors as the Secretary considers relevant.

(3) Proficiency testing program

(A) In general

The Secretary shall establish standards for the proficiency testing programs for laboratories issued a certificate under this section which are conducted by the Secretary, conducted by an organization approved under subparagraph (C), or conducted by an approved accrediting body. The standards shall require that a laboratory issued a certificate under this section be tested for each examination and procedure conducted within a category of examinations or procedures for which it has received a certificate, except for examinations and procedures for which the Secretary has determined that a proficiency test cannot reasonably be developed. The testing shall be conducted on a quarterly basis, except where the Secretary determines for technical and scientific reasons that a particular examination or procedure may be tested less frequently (but not less often than twice per year).

(B) Criteria

The standards established under subparagraph (A) shall include uniform criteria for acceptable performance under a proficiency testing program, based on the available technology and the clinical relevance of the laboratory examination or other procedure subject to such program. The criteria shall be established for all examinations and procedures and shall be uniform for each examination and procedure. The standards shall also include a system for grading proficiency testing performance to determine whether a laboratory has performed acceptably for a particular quarter and acceptably for a particular examination or procedure or category of examination or procedure over a period of successive quarters.

(C) Approved proficiency testing programs

For the purpose of administering proficiency testing programs which meet the standards established under subparagraph (A), the Secretary shall approve a proficiency testing program offered by a private nonprofit organization or a State if the program meets the standards established under subparagraph (A) and the organization or State provides technical assistance to laboratories seeking to qualify under the program. The Secretary shall evaluate each program approved under this subparagraph annually to determine if the program continues to meet the standards established under subparagraph (A) and shall withdraw the approval of any program that no longer meets such standards.

(D) Onsite testing

The Secretary shall perform, or shall direct a program approved under subparagraph (C) to perform, onsite proficiency testing to assure compliance with the requirements of subsection (d)(5). The Secretary shall perform, on an onsite or other basis, proficiency testing to evaluate the performance of a proficiency testing program approved under subparagraph (C) and to assure quality performance by a laboratory.

(E) Training, technical assistance, and enhanced proficiency testing

The Secretary may, in lieu of or in addition to actions authorized under subsection (h), (i), or (j), require any laboratory which fails to perform acceptably on an individual examination and procedure or a category of examination and procedures—

(i) to undertake training and to obtain the necessary technical assistance to meet the requirements of the proficency [2] testing program,
(ii) to enroll in a program of enhanced proficiency testing, or
(iii) to undertake any combination of the training, technical assistance, or testing described in clauses (i) and (ii).

(F) Testing results

The Secretary shall establish a system to make the results of the proficiency testing programs

subject to the standards established by the Secretary under subparagraph (A) available, on a reasonable basis, upon request of any person. The Secretary shall include with results made available under this subparagraph such explanatory information as may be appropriate to assist in the interpretation of such results.

(4) National standards for quality assurance in cytology services

(A) Establishment

The Secretary shall establish national standards for quality assurance in cytology services designed to assure consistent performance by laboratories of valid and reliable cytological services.

(B) Standards

The standards established under subparagraph (A) shall include—

(i) the maximum number of cytology slides that any individual may screen in a 24-hour period,

(ii) requirements that a clinical laboratory maintain a record of (I) the number of cytology slides screened during each 24-hour period by each individual who examines cytology slides for the laboratory, and (II) the number of hours devoted during each 24-hour period to screening cytology slides by such individual,

(iii) criteria for requiring rescreening of cytological preparations, such as (I) random rescreening of cytology specimens determined to be in the benign category, (II) focused rescreening of such preparations in high risk groups, and (III) for each abnormal cytological result, rescreening of all prior cytological specimens for the patient, if available,

(iv) periodic confirmation and evaluation of the proficiency of individuals involved in screening or interpreting cytological preparations, including announced and unannounced on-site proficiency testing of such individuals, with such testing to take place, to the extent practicable, under normal working conditions,

(v) procedures for detecting inadequately prepared slides, for assuring that no cytological diagnosis is rendered on such slides, and for notifying referring physicians of such slides,

(vi) requirements that all cytological screening be done on the premises of a laboratory that is certified under this section,

(vii) requirements for the retention of cytology slides by laboratories for such periods of time as the Secretary considers appropriate, and

(viii) standards requiring periodic inspection of cytology services by persons capable of evaluating the quality of cytology services.

(g) Inspections

(1) In general

The Secretary may, on an announced or unannounced basis, enter and inspect, during regular hours of operation, laboratories which have been issued a certificate under this section. In conducting such inspections the Secretary shall have access to all facilities, equipment, materials, records, and information that the Secretary determines have a bearing on whether the laboratory is being operated in accordance with this section. As part of such an inspection the Secretary may copy any such material or require to it [3] be submitted to the Secretary. An inspection under this paragraph may be made only upon presenting identification to the owner, operator, or agent in charge of the laboratory being inspected.

(2) Compliance with requirements and standards

The Secretary shall conduct inspections of laboratories under paragraph (1) to determine their compliance with the requirements of subsection (d) and the standards issued under subsection (f). Inspections of laboratories not accredited under subsection (e) shall be conducted on a biennial basis or with such other frequency as the Secretary determines to be necessary to assure

compliance with such requirements and standards. Inspections of laboratories accredited under subsection (e) shall be conducted on such basis as the Secretary determines is necessary to assure compliance with such requirements and standards.

(h) Intermediate sanctions

(1) In general

If the Secretary determines that a laboratory which has been issued a certificate under this section no longer substantially meets the requirements for the issuance of a certificate, the Secretary may impose intermediate sanctions in lieu of the actions authorized by subsection (i).

(2) Types of sanctions

The intermediate sanctions which may be imposed under paragraph (1) shall consist of—

(A) directed plans of correction,

(B) civil money penalties in an amount not to exceed $10,000 for each violation listed in subsection (i)(1) or for each day of substantial noncompliance with the requirements of this section,

(C) payment for the costs of onsite monitoring, or

(D) any combination of the actions described in subparagraphs (A), (B), and (C).

(3) Procedures

The Secretary shall develop and implement procedures with respect to when and how each of the intermediate sanctions is to be imposed under paragraph (1). Such procedures shall provide for notice to the laboratory and a reasonable opportunity to respond to the proposed sanction and appropriate procedures for appealing determinations relating to the imposition of intermediate sanctions [4]

(i) Suspension, revocation, and limitation

(1) In general

Except as provided in paragraph (2), the certificate of a laboratory issued under this section may be suspended, revoked, or limited if the Secretary finds, after reasonable notice and opportunity for hearing to the owner or operator of the laboratory, that such owner or operator or any employee of the laboratory—

(A) has been guilty of misrepresentation in obtaining the certificate,

(B) has performed or represented the laboratory as entitled to perform a laboratory examination or other procedure which is not within a category of laboratory examinations or other procedures authorized in the certificate,

(C) has failed to comply with the requirements of subsection (d) or the standards prescribed by the Secretary under subsection (f),

(D) has failed to comply with reasonable requests of the Secretary for—

(i) any information or materials, or

(ii) work on materials,

that the Secretary concludes is necessary to determine the laboratory's continued eligibility for its certificate or continued compliance with the Secretary's standards under subsection (f),

(E) has refused a reasonable request of the Secretary, or any Federal officer or employee duly designated by the Secretary, for permission to inspect the laboratory and its operations and pertinent records during the hours the laboratory is in operation,

(F) has violated or aided and abetted in the violation of any provisions of this section or of any regulation promulgated thereunder, or

(G) has not complied with an intermediate sanction imposed under subsection (h).

(2) Action before a hearing

If the Secretary determines that—

(A) the failure of a laboratory to comply with the standards of the Secretary under subsection

(f) presents an imminent and serious risk to human health, or

(B) a laboratory has engaged in an action described in subparagraph (D) or (E) of paragraph (1),

the Secretary may suspend or limit the certificate of the laboratory before holding a hearing under paragraph (1) regarding such failure or refusal. The opportunity for a hearing shall be provided no later than 60 days from the effective date of the suspension or limitation. A suspension or limitation under this paragraph shall stay in effect until the decision of the Secretary made after the hearing under paragraph (1).

(3) Ineligibility to own or operate laboratories after revocation

No person who has owned or operated a laboratory which has had its certificate revoked may, within 2 years of the revocation of the certificate, own or operate a laboratory for which a certificate has been issued under this section, except that if the revocation occurs pursuant to paragraph (4) the Secretary may substitute intermediate sanctions under subsection (h) instead of the 2-year prohibition against ownership or operation which would otherwise apply under this paragraph. The certificate of a laboratory which has been excluded from participation under the medicare program under title XVIII of the Social Security Act [42 U.S.C. 1395 et seq.] because of actions relating to the quality of the laboratory shall be suspended for the period the laboratory is so excluded.

(4) Improper referrals

Any laboratory that the Secretary determines intentionally refers its proficiency testing samples to another laboratory for analysis may have its certificate revoked for at least one year and shall be subject to appropriate fines and penalties as provided for in subsection (h).

(j) Injunctions

Whenever the Secretary has reason to believe that continuation of any activity by a laboratory would constitute a significant hazard to the public health the Secretary may bring suit in the district court of the United States for the district in which such laboratory is situated to enjoin continuation of such activity. Upon proper showing, a temporary injunction or restraining order against continuation of such activity pending issuance of a final order under this subsection shall be granted without bond by such court.

(k) Judicial review

(1) Petition

Any laboratory which has had an intermediate sanction imposed under subsection (h) or has had its certificate suspended, revoked, or limited under subsection (i) may, at any time within 60 days after the date the action of the Secretary under subsection (i) or (h) becomes final, file a petition with the United States court of appeals for the circuit wherein the laboratory has its principal place of business for judicial review of such action. As soon as practicable after receipt of the petition, the clerk of the court shall transmit a copy of the petition to the Secretary or other officer designated by the Secretary for that purpose. As soon as practicable after receipt of the copy, the Secretary shall file in the court the record on which the action of the Secretary is based, as provided in section 2112 of title 28.

(2) Additional evidence

If the petitioner applies to the court for leave to adduce additional evidence, and shows to the satisfaction of the court that such additional evidence is material and that there were reasonable grounds for the failure to adduce such evidence in the proceeding before the Secretary, the court may order such additional evidence (and evidence in rebuttal of such additional evidence) to be taken before the Secretary, and to be adduced upon the hearing in such manner and upon such terms and conditions as the court may deem proper. The Secretary may modify the findings of the Secretary as to the facts, or make new findings, by reason of the additional evidence so taken, and the Secretary shall file such modified or new findings, and the recommendations of the Secretary,

if any, for the modification or setting aside of his original action, with the return of such additional evidence.

(3) Judgment of court

Upon the filing of the petition referred to in paragraph (1), the court shall have jurisdiction to affirm the action, or to set it aside in whole or in part, temporarily or permanently. The findings of the Secretary as to the facts, if supported by substantial evidence, shall be conclusive.

(4) Finality of judgment

The judgment of the court affirming or setting aside, in whole or in part, any such action of the Secretary shall be final, subject to review by the Supreme Court of the United States upon certiorari or certification as provided in section 1254 of title 28.

(l) Sanctions

Any person who intentionally violates any requirement of this section or any regulation promulgated thereunder shall be imprisoned for not more than one year or fined under title 18, or both, except that if the conviction is for a second or subsequent violation of such a requirement such person shall be imprisoned for not more than 3 years or fined in accordance with title 18, or both.

(m) Fees

(1) Certificate fees

The Secretary shall require payment of fees for the issuance and renewal of certificates, except that the Secretary shall only require a nominal fee for the issuance and renewal of certificates of waiver.

(2) Additional fees

The Secretary shall require the payment of fees for inspections of laboratories which are not accredited and for the cost of performing proficiency testing on laboratories which do not participate in proficiency testing programs approved under subsection (f)(3)(C).

(3) Criteria

(A) Fees under paragraph (1)

Fees imposed under paragraph (1) shall be sufficient to cover the general costs of administering this section, including evaluating and monitoring proficiency testing programs approved under subsection (f) and accrediting bodies and implementing and monitoring compliance with the requirements of this section.

(B) Fees under paragraph (2)

Fees imposed under paragraph (2) shall be sufficient to cover the cost of the Secretary in carrying out the inspections and proficiency testing described in paragraph (2).

(C) Fees imposed under paragraphs (1) and (2)

Fees imposed under paragraphs (1) and (2) shall vary by group or classification of laboratory, based on such considerations as the Secretary determines are relevant, which may include the dollar volume and scope of the testing being performed by the laboratories.

(n) Information

On April 1, 1990 and annually thereafter, the Secretary shall compile and make available to physicians and the general public information, based on the previous calendar year, which the Secretary determines is useful in evaluating the performance of a laboratory, including—

(1) a list of laboratories which have been convicted under Federal or State laws relating to fraud and abuse, false billings, or kickbacks,

(2) a list of laboratories—

(A) which have had their certificates revoked, suspended, or limited under subsection (i), or

(B) which have been the subject of a sanction under subsection (l),

together with a statement of the reasons for the revocation, suspension, limitation, or sanction,

(3) a list of laboratories subject to intermediate sanctions under subsection (h) together with a statement of the reasons for the sanctions,

(4) a list of laboratories whose accreditation has been withdrawn or revoked together with a statement of the reasons for the withdrawal or revocation,

(5) a list of laboratories against which the Secretary has taken action under subsection (j) together with a statement of the reasons for such action, and

(6) a list of laboratories which have been excluded from participation under title XVIII or XIX of the Social Security Act [42 U.S.C. 1395 et seq., 1396 et seq.].

The information to be compiled under paragraphs (1) through (6) shall be information for the calendar year preceding the date the information is to be made available to the public and shall be accompanied by such explanatory information as may be appropriate to assist in the interpretation of the information compiled under such paragraphs.

(o) Delegation

In carrying out this section, the Secretary may, pursuant to agreement, use the services or facilities of any Federal or State or local public agency or nonprofit private organization, and may pay therefor in advance or by way of reimbursement, and in such installments, as the Secretary may determine.

(p) State laws

(1) Except as provided in paragraph (2), nothing in this section shall be construed as affecting the power of any State to enact and enforce laws relating to the matters covered by this section to the extent that such laws are not inconsistent with this section or with the regulations issued under this section.

(2) If a State enacts laws relating to matters covered by this section which provide for requirements equal to or more stringent than the requirements of this section or than the regulations issued under this section, the Secretary may exempt clinical laboratories in that State from compliance with this section.

(q) Consultations

In carrying out this section, the Secretary shall consult with appropriate private organizations and public agencies.

(July 1, 1944, ch. 373, title III, §353, as added Pub. L. 90–174, §5(a), Dec. 5, 1967, 81 Stat. 536; amended Pub. L. 100–578, §2, Oct. 31, 1988, 102 Stat. 2903; Pub. L. 105–115, title I, §123(h), Nov. 21, 1997, 111 Stat. 2324; Pub. L. 112–202, §2, Dec. 4, 2012, 126 Stat. 1483.)

EDITORIAL NOTES

REFERENCES IN TEXT

The Social Security Act, referred to in subsecs. (i)(3) and (n)(6), is act Aug. 14, 1935, ch. 531, 49 Stat. 620. Titles XVIII and XIX of the Social Security Act are classified generally to subchapters XVIII (§1395 et seq.) and XIX (§1396 et seq.), respectively, of chapter 7 of this title. For complete classification of this Act to the Code, see section 1305 of this title and Tables.

CODIFICATION

Subsec. (e)(3) of this section, which required the Secretary to annually prepare and submit to certain committees of Congress a report describing the results of the evaluation conducted under subsec. (e)(2)(D) of this section, terminated, effective May 15, 2000, pursuant to section 3003 of Pub. L. 104–66, as amended, set out as a note under section 1113 of Title 31, Money and Finance. See, also, page 96 of House Document No. 103–7.

AMENDMENTS

2012—Subsec. (d)(1)(E). Pub. L. 112–202, §2(1), inserted ", except that no proficiency testing sample shall be referred to another laboratory for analysis as prohibited under subsection (i)(4)" before period at end.

Subsec. (i)(3). Pub. L. 112–202, §2(2)(A), inserted ", except that if the revocation occurs pursuant to

paragraph (4) the Secretary may substitute intermediate sanctions under subsection (h) instead of the 2-year prohibition against ownership or operation which would otherwise apply under this paragraph" after "issued under this section".

Subsec. (i)(4). Pub. L. 112–202, §2(2)(B), substituted "may have its certificate revoked" for "shall have its certificate revoked".

1997—Subsec. (d)(3). Pub. L. 105–115 amended heading and text of par. (3) generally. Prior to amendment, text read as follows: "The examinations and procedures identified in paragraph (2) are simple laboratory examinations and procedures which, as determined by the Secretary, have an insignificant risk of an erroneous result, including those which—

"(A) have been approved by the Food and Drug Administration for home use,

"(B) employ methodologies that are so simple and accurate as to render the likelihood of erroneous results negligible, or

"(C) the Secretary has determined pose no reasonable risk of harm to the patient if performed incorrectly."

1988—Pub. L. 100–578 substituted "Certification of laboratories" for "Licensing of laboratories" in section catchline, and amended text generally, revising and restating as subsecs. (a) to (q) provisions of former subsecs. (a) to (l).

STATUTORY NOTES AND RELATED SUBSIDIARIES

EFFECTIVE DATE OF 1997 AMENDMENT

Amendment by Pub. L. 105–115 effective 90 days after Nov. 21, 1997, except as otherwise provided, see section 501 of Pub. L. 105–115, set out as a note under section 321 of Title 21, Food and Drugs.

EFFECTIVE DATE OF 1988 AMENDMENT; EXCEPTIONS; CONTINUING APPLICABILITY

Pub. L. 100–578, §3, Oct. 31, 1988, 102 Stat. 2914, provided that: "Subsections (g)(1), (h), (i), (j), (k), (l), and (m) of section 353 of the Public Health Service Act [42 U.S.C. 263a], as amended by section 101 [probably means section 2 of Pub. L. 100–578], shall take effect January 1, 1989, except that any reference in such subsections to the standards established under subsection (f) shall be considered a reference to the standards established under subsection (d) of such section 353, as in effect on December 31, 1988. During the period beginning January 1, 1989, and ending December 31, 1989, subsections (a) through (d) and subsection (i) through (l) of such section 353 as in effect on December 31, 1988, shall continue to apply to clinical laboratories. The remaining subsections of such section 353, as so amended, shall take effect January 1, 1990, except that subsections (f)(1)(C) and (g)(2) shall take effect July 1, 1991, with respect to laboratories which were not subject to the requirements of such section 353 as in effect on December 31, 1988."

EFFECTIVE DATE

Pub. L. 90–174, §5(b), Dec. 5, 1967, 81 Stat. 539, provided that: "The amendment made by subsection (a) [enacting this section] shall become effective on the first day of the thirteenth month after the month [December 1967] in which it is enacted, except that the Secretary of Health, Education, and Welfare may postpone such effective date for such additional period as he finds necessary, but not beyond the first day of the 19th month after such month [December 1967] in which the amendment is enacted."

CLIA WAIVER IMPROVEMENTS

Pub. L. 114–255, div. A, title III, §3057, Dec. 13, 2016, 130 Stat. 1128, provided that:

"(a) DRAFT REVISED GUIDANCE.—Not later than 1 year after the date of the enactment of this Act [Dec. 13, 2016], the Secretary of Health and Human Services, acting through the Commissioner of Food and Drugs, shall publish a draft guidance that—

"(1) revises 'Section V. Demonstrating Insignificant Risk of an Erroneous Result – Accuracy' of the guidance entitled 'Recommendations for Clinical Laboratory Improvement Amendments of 1988 (CLIA) Waiver Applications for Manufacturers of In Vitro Diagnostic Devices' and dated January 30, 2008; and

"(2) includes the appropriate use of comparable performance between a waived user and a moderately complex laboratory user to demonstrate accuracy.

"(b) FINAL REVISED GUIDANCE.—The Secretary of Health and Human Services, acting through the Commissioner of Food and Drugs, shall finalize the draft guidance published under subsection (a) not later than 1 year after the comment period for such draft guidance closes."

STUDIES

Pub. L. 100–578, §4, Oct. 31, 1988, 102 Stat. 2914, directed Secretary to conduct studies and submit report to Congress, not later than May 1, 1990, relating to the reliability and quality control procedures of clinical laboratory testing programs and the effect of errors in the testing procedures and results on the diagnosis and treatment of patients.

[1] So in original. Probably should be "by the".

[2] So in original. Probably should be "proficiency".

[3] So in original. Probably should be "require it to".

[4] So in original. Probably should be followed by a period.

§263a–1. Assisted reproductive technology programs

(a) In general

Effective 2 years after October 24, 1992, each assisted reproductive technology (as defined in section 263a–7 [1] of this title) program shall annually report to the Secretary through the Centers for Disease Control—

(1) pregnancy success rates achieved by such program through each assisted reproductive technology, and

(2) the identity of each embryo laboratory (as defined in section 263a–7 [1] of this title) used by such program and whether the laboratory is certified under section 263a–2 of this title or has applied for such certification.

(b) Pregnancy success rates

(1) In general

For purposes of subsection (a)(1), the Secretary shall, in consultation with the organizations referenced in subsection (c), define pregnancy success rates and shall make public any proposed definition in such manner as to facilitate comment from any person (including any Federal or other public agency) during its development.

(2) Definition

In developing the definition of pregnancy success rates, the Secretary shall take into account the effect on success rates of age, diagnosis, and other significant factors and shall include in such rates—

(A) the basic live birth rate calculated for each assisted reproductive technology performed by an assisted reproductive technology program by dividing the number of pregnancies which result in live births by the number of ovarian stimulation procedures attempted by such program, and

(B) the live birth rate per successful oocyte retrieval procedure calculated for each assisted reproductive technology performed by an assisted reproductive technology program by dividing the number of pregnancies which result in live births by the number of successful oocyte retrieval procedures performed by such program.

(c) Consultation

In developing the definition under subsection (b), the Secretary shall consult with appropriate consumer and professional organizations with expertise in using, providing, and evaluating professional services and embryo laboratories associated with assisted reproductive technologies.

(Pub. L. 102–493, §2, Oct. 24, 1992, 106 Stat. 3146.)

EDITORIAL NOTES

REFERENCES IN TEXT

Section 263a–7 of this title, referred to in subsec. (a), was in the original "section 7" meaning section 7 of Pub. L. 102–493, which was translated as reading section 8 to reflect the probable intent of Congress, because definitions are contained in section 8 instead of section 7.

CODIFICATION

Section was enacted as part of the Fertility Clinic Success Rate and Certification Act of 1992, and not as part of the Public Health Service Act which comprises this chapter.

STATUTORY NOTES AND RELATED SUBSIDIARIES

CHANGE OF NAME

Centers for Disease Control changed to Centers for Disease Control and Prevention by Pub. L. 102–531, title III, §312, Oct. 27, 1992, 106 Stat. 3504.

EFFECTIVE DATE

Pub. L. 102–493, §9, Oct. 24, 1992, 106 Stat. 3152, provided that: "This Act [enacting this section, sections 263a–2 to 263a–7 of this title, and provisions set out as a note under section 201 of this title] shall take effect upon the expiration of 2 years after the date of the enactment of this Act [Oct. 24, 1992]."

[1] *See References in Text note below.*

§263a–2. Certification of embryo laboratories

(a) In general

(1) Development

Not later than 2 years after October 24, 1992, the Secretary, through the Centers for Disease Control, shall develop a model program for the certification of embryo laboratories (referred to in this section as a "certification program") to be carried out by the States.

(2) Consultation

In developing the certification program under paragraph (1), the Secretary shall consult with appropriate consumer and professional organizations with expertise in using, providing, and evaluating professional services and embryo laboratories associated with the assisted reproductive technology programs.

(b) Distribution

The Secretary shall distribute a description of the certification program to—

(1) the Governor of each State,

(2) the presiding officers of each State legislature,

(3) the public health official of each State, and

(4) the official responsible in each State for the operation of the State's contract with the Secretary under section 1395aa of this title,

and shall encourage such officials to assist in the State adopting such program.

(c) Requirements

The certification program shall include the following requirements:

(1) Administration

The certification program shall be administered by the State and shall provide for the inspection and certification of embryo laboratories in the State by the State or by approved accreditation organizations.

(2) Application requirements

The certification program shall provide for the submission of an application to a State by an embryo laboratory for certification, in such form as may be specified by the State. Such an application shall include—

(A) assurances satisfactory to the State that the embryo laboratory will be operated in accordance with the standards under subsection (d),

(B) a report to the State identifying the assisted reproductive technology programs with which the laboratory is associated, and

(C) such other information as the State finds necessary.

An embryo laboratory which meets the requirements of section 263a of this title shall, for the purposes of subparagraph (A) be considered in compliance with the standards referred to in such subparagraph which are the same as the standards in effect under section 263a of this title.

(d) Standards

The certification program shall include the following standards developed by the Secretary:

(1) A standard to assure consistent performance of procedures by each embryo laboratory certified under the certification program or by an approved accreditation organization in a State which has not adopted the certification program.

(2) A standard for a quality assurance and a quality control program to assure valid, reliable, and reproduceable [1] procedures in the laboratory.

(3) A standard for the maintenance of records (on a program by program basis) on laboratory tests and procedures performed, including the scientific basis of, and the methodology used for, the tests, procedures, and preparation of any standards or controls, criteria for acceptable and unacceptable outcomes, criteria for sample rejection, and procedures for safe sample disposal.

(4) A standard for the maintenance of written records on personnel and facilities necessary for proper and effective operation of the laboratory, schedules of preventive maintenance, function verification for equipment, and the release of such records to the State upon demand.

(5) A standard for the use of such personnel who meet such qualifications as the Secretary may develop.

(e) Certification under State programs

A State may qualify to adopt the certification program if the State has submitted an application to the Secretary to adopt such program and the Secretary has approved the application. Such an application shall include—

(1) assurances by the State satisfactory to the Secretary that the certification program within the State meets the requirements of this section,

(2) an agreement to make such reports as the Secretary may require, and

(3) information about any proposed use of accreditation organizations under subsection (g).[2]

(f) Use of accreditation organizations

A State which has adopted the certification program may use accreditation organizations approved under section 263a–3 of this title to inspect and certify embryo laboratories.

(g) Inspections

(1) In general

A State which qualifies to adopt the certification program within the State shall conduct inspections in accordance with paragraph (2) to determine if laboratories in the State meet the requirements of such program. Such inspections shall be carried out by the State or by accreditation organizations used by the State under subsection (g).[2]

(2) Requirements

Inspections carried out under paragraph (1) shall—

(A) be periodic and unannounced, or

(B) be announced in such circumstances as the Secretary determines will not diminish the likelihood of discovering deficiencies in the operations of a laboratory.

Before making a determination under subparagraph (B), the Secretary shall make public, in such manner as to facilitate comment from any person (including any Federal or other public agency), a proposal indicating the circumstances under which announced inspections would be permitted.

(3) Results

The specific findings, including deficiencies, identified in an inspection carried out under paragraph (1) and any subsequent corrections to those deficiencies shall be announced and made available to the public upon request beginning no later than 60 days after the date of the inspection.

(h) Validation inspections

(1) In general

The Secretary may enter and inspect, during regular hours of operation, embryo laboratories—

(A) which have been certified by a State under the certification program, or

(B) which have been certified by an accreditation organization approved by the Secretary under section 263a–3 of this title,

for the purpose of determining whether the laboratory is being operated in accordance with the standards in subsection (d).

(2) Access to facilities and records

In conducting an inspection of an embryo laboratory under paragraph (1), the Secretary shall have access to all facilities, equipment, materials, records, and information which the Secretary determines is necessary to determine if such laboratory is being operated in accordance with the standards in subsection (d). As part of such an inspection, the Secretary may copy any material, record, or information inspected or require it to be submitted to the Secretary. Such an inspection may be made only upon the presentation of identification to the owner, operator, or agent in charge of the laboratory being inspected.

(3) Failure to comply

If the Secretary determines as a result of an inspection under paragraph (1) that the embryo laboratory is not in compliance with the standards in subsection (d), the Secretary shall—

(A) notify the State in which the laboratory is located and, if appropriate, the accreditation organization which certified the laboratory,

(B) make available to the public the results of the inspection,

(C) conduct additional inspections of other embryo laboratories under paragraph (1) to determine if—

(i) such State in carrying out the certification program is reliably identifying the deficiencies of such laboratory, or

(ii) the accreditation organization which certified such laboratories is reliably identifying such deficencies,[3] and

(D) if the Secretary determines—

(i) that such State in carrying out the certification program has not met the requirements applicable to such program, or

(ii) the accreditation organization which certified such laboratory has not met the requirements of section 263a–3 of this title,

the Secretary may revoke the approval of the State certification program or revoke the approval of such accreditation organization.

(i) Limitation

(1) Secretary

In developing the certification program, the Secretary may not establish any regulation, standard, or requirement which has the effect of exercising supervision or control over the practice of medicine in assisted reproductive technology programs.

(2) State

In adopting the certification program, a State may not establish any regulation, standard, or requirement which has the effect of exercising supervision or control over the practice of medicine in assisted reproductive technology programs.

(j) Term

The term of a certification issued by a State or an accreditation organization in a State shall be prescribed by the Secretary in the certification program and shall be valid for a period of time to be defined by the Secretary through the public comment process described in subsection (h)(2).[4] The Secretary shall provide an application for recertification to be submitted at the time of changes in the ownership of a certified laboratory or changes in the administration of such a laboratory.

(Pub. L. 102–493, §3, Oct. 24, 1992, 106 Stat. 3146.)

EDITORIAL NOTES

CODIFICATION

Section was enacted as part of the Fertility Clinic Success Rate and Certification Act of 1992, and not as part of the Public Health Service Act which comprises this chapter.

STATUTORY NOTES AND RELATED SUBSIDIARIES

CHANGE OF NAME

Centers for Disease Control changed to Centers for Disease Control and Prevention by Pub. L. 102–531, title III, §312, Oct. 27, 1992, 106 Stat. 3504.

EFFECTIVE DATE

Section effective upon expiration of 2 years after Oct. 24, 1992, see section 9 of Pub. L. 102–493, set out as a note under section 263a–1 of this title.

[1] So in original. Probably should be "reproducible".

[2] So in original. Probably should be subsection "(f)".

[3] So in original. Probably should be "deficiencies,".

[4] So in original. Probably should be subsection "(g)(2)".

§263a–3. Accreditation organizations

(a) Approval of accreditation organizations

Not later than 2 years after October 24, 1992, the Secretary, through the Centers for Disease Control, shall promulgate criteria and procedures for the approval of accreditation organizations to inspect and certify embryo laboratories. The procedures shall require an application to the Secretary by an accreditation organization for approval. An accreditation organization which has received such an approval—

(1) may be used by States in the certification program under section 263a–2 of this title to inspect and certify embryo laboratories, or

(2) may certify embryo laboratories in States which have not adopted such a certification program.

(b) Criteria and procedures

The criteria and procedures promulgated under subsection (a) shall include—

(1) requirements for submission of such reports and the maintenance of such records as the Secretary or a State may require, and

(2) requirements for the conduct of inspections under section 263a–2(h) [1] of this title.

(c) Evaluations

The Secretary shall evaluate annually the performance of each accreditation organization approved by the Secretary by—

(1) inspecting under section 263a–2(i) [2] of this title a sufficient number of embryo laboratories accredited by such an organization to allow a reasonable estimate of the performance of such organization, and

(2) such other means as the Secretary determines to be appropriate.

(d) Transition

If the Secretary revokes approval under section 263a–2(i)(3)(D) [3] of this title of an accreditation organization after an evaluation under subsection (c), the certification of any embryo laboratory accredited by the organization shall continue in effect for 60 days after the laboratory is notified by the Secretary of the withdrawal of approval, except that the Secretary may extend the period during which the certification shall remain in effect if the Secretary determines that the laboratory submitted an application to another approved accreditation organization for certification after receipt of such notice in a timely manner.

(Pub. L. 102–493, §4, Oct. 24, 1992, 106 Stat. 3150.)

EDITORIAL NOTES

CODIFICATION

Section was enacted as part of the Fertility Clinic Success Rate and Certification Act of 1992, and not as part of the Public Health Service Act which comprises this chapter.

STATUTORY NOTES AND RELATED SUBSIDIARIES

CHANGE OF NAME

Centers for Disease Control changed to Centers for Disease Control and Prevention by Pub. L. 102–531, title III, §312, Oct. 27, 1992, 106 Stat. 3504.

EFFECTIVE DATE

Section effective upon expiration of 2 years after Oct. 24, 1992, see section 9 of Pub. L. 102–493, set out as a note under section 263a–1 of this title.

[1] So in original. Probably should be section "263a–2(g)".

[2] So in original. Probably should be section "263a–2(h)".

[3] So in original. Probably should be section "263a–2(h)(3)(D)".

§263a–4. Certification revocation and suspension

(a) In general

A certification issued by a State or an accreditation organization for an embryo laboratory shall be

revoked or suspended if the State or organization finds, on the basis of inspections and after reasonable notice and opportunity for hearing to the owner or operator of the laboratory, that the owner or operator or any employee of the laboratory—

(1) has been guilty of misrepresentation in obtaining the certification,

(2) has failed to comply with any standards under section 263a–2 of this title applicable to the certification, or

(3) has refused a request of the State or accreditation organization for permission to inspect the laboratory, its operations, and records.

(b) Effect

If the certification of an embryo laboratory is revoked or suspended, the certification of the laboratory shall continue in effect for 60 days after the laboratory receives notice of the revocation or suspension. If the certification of an embryo laboratory is revoked or suspended, the laboratory may apply for recertification after one year after the date of the revocation or suspension.

(Pub. L. 102–493, §5, Oct. 24, 1992, 106 Stat. 3150.)

EDITORIAL NOTES

CODIFICATION

Section was enacted as part of the Fertility Clinic Success Rate and Certification Act of 1992, and not as part of the Public Health Service Act which comprises this chapter.

STATUTORY NOTES AND RELATED SUBSIDIARIES

EFFECTIVE DATE

Section effective upon expiration of 2 years after Oct. 24, 1992, see section 9 of Pub. L. 102–493, set out as a note under section 263a–1 of this title.

§263a–5. Publication

The Secretary, through the Centers for Disease Control, shall not later than 3 years after October 24, 1992, and annually thereafter publish and distribute to the States and the public—

(1)(A) [1] pregnancy success rates reported to the Secretary under section 263a–1(a)(1) of this title and, in the case of an assisted reproductive technology program which failed to report one or more success rates as required under such section, the name of each such program and each pregnancy success rate which the program failed to report, and

(B) from information reported under section 263a–1(a)(2) of this title—

(i) the identity of each embryo laboratory in a State which has adopted the certification program under such program and whether such laboratory is certified under section 263a–2 of this title,

(ii) the identity of each embryo laboratory in a State which has not adopted such certification program and which has been certified by an accreditation organization approved by the Secretary under section 263a–3 of this title, and

(iii) in the case of an embryo laboratory which is not certified under section 263a–2 of this title or certified by an accreditation organization approved by the Secretary under section 263a–3 of this title, whether the laboratory applied for certification.

(Pub. L. 102–493, §6, Oct. 24, 1992, 106 Stat. 3151.)

EDITORIAL NOTES

CODIFICATION

Section was enacted as part of the Fertility Clinic Success Rate and Certification Act of 1992, and not as

part of the Public Health Service Act which comprises this chapter.

STATUTORY NOTES AND RELATED SUBSIDIARIES

CHANGE OF NAME

Centers for Disease Control changed to Centers for Disease Control and Prevention by Pub. L. 102–531, title III, §312, Oct. 27, 1992, 106 Stat. 3504.

EFFECTIVE DATE

Section effective upon expiration of 2 years after Oct. 24, 1992, see section 9 of Pub. L. 102–493, set out as a note under section 263a–1 of this title.

[1] *So in original. No par. (2) has been enacted.*

§263a–6. Fees

The Secretary may require the payment of fees for the purpose of, and in an amount sufficient to cover the cost of, administering sections 263a–1 to 263a–7 of this title. A State operating a program under section 263a–2 of this title may require the payment of fees for the purpose of, and in an amount sufficient to cover the costs of, administering its program.

(Pub. L. 102–493, §7, Oct. 24, 1992, 106 Stat. 3151.)

EDITORIAL NOTES

REFERENCES IN TEXT

Sections 263a–1 to 263a–7 of this title, referred to in text, was in the original "this Act", meaning Pub. L. 102–493, Oct. 24, 1992, 106 Stat. 3146, known as the Fertility Clinic Success Rate and Certification Act of 1992, which enacted sections 263a–1 to 263a–7 of this title and provisions set out as notes under sections 201 and 263a–1 of this title. For complete classification of this Act to the Code, see Short Title note set out under section 201 of this title and Tables.

CODIFICATION

Section was enacted as part of the Fertility Clinic Success Rate and Certification Act of 1992, and not as part of the Public Health Service Act which comprises this chapter.

STATUTORY NOTES AND RELATED SUBSIDIARIES

EFFECTIVE DATE

Section effective upon expiration of 2 years after Oct. 24, 1992, see section 9 of Pub. L. 102–493, set out as a note under section 263a–1 of this title.

§263a–7. Definitions

For purposes of sections 263a–1 to 263a–7 of this title:

(1) Assisted reproductive technology

The term "assisted reproductive technology" means all treatments or procedures which include the handling of human oocytes or embryos, including in vitro fertilization, gamete intrafallopian transfer, zygote intrafallopian transfer, and such other specific technologies as the Secretary may include in this definition, after making public any proposed definition in such manner as to facilitate comment from any person (including any Federal or other public agency).

(2) Embryo laboratory

The term "embryo laboratory" means a facility in which human oocytes are subject to assisted

reproductive technology treatment or procedures based on manipulation of oocytes or embryos which are subject to implantation.

(3) Secretary

The term "Secretary" means the Secretary of Health and Human Services.

(Pub. L. 102–493, §8, Oct. 24, 1992, 106 Stat. 3151.)

EDITORIAL NOTES

REFERENCES IN TEXT

Sections 263a–1 to 263a–7 of this title, referred to in text, was in the original "this Act", meaning Pub. L. 102–493, Oct. 24, 1992, 106 Stat. 3146, known as the Fertility Clinic Success Rate and Certification Act of 1992, which enacted sections 263a–1 to 263a–7 of this title and provisions set out as notes under sections 201 and 263a–1 of this title. For complete classification of this Act to the Code, see Short Title note set out under section 201 of this title and Tables.

CODIFICATION

Section was enacted as part of the Fertility Clinic Success Rate and Certification Act of 1992, and not as part of the Public Health Service Act which comprises this chapter.

STATUTORY NOTES AND RELATED SUBSIDIARIES

EFFECTIVE DATE

Section effective upon expiration of 2 years after Oct. 24, 1992, see section 9 of Pub. L. 102–493, set out as a note under section 263a–1 of this title.

SUBPART 3—MAMMOGRAPHY FACILITIES

EDITORIAL NOTES

PRIOR PROVISIONS

A prior subpart 3 of part F of title III of the Public Health Service Act, comprising this subpart, was renumbered subchapter C of chapter V of the Federal Food, Drug, and Cosmetic Act, by Pub. L. 101–629, §19(a)(4), Nov. 28, 1990, 104 Stat. 4530, as amended by Pub. L. 103–80, §4(a)(2), Aug. 13, 1993, 107 Stat. 779, and is classified to part C (§360hh et seq.) of subchapter V of chapter 9 of Title 21, Food and Drugs.

§263b. Certification of mammography facilities

(a) Definitions

As used in this section:

(1) Accreditation body

The term "accreditation body" means a body that has been approved by the Secretary under subsection (e)(1)(A) to accredit mammography facilities.

(2) Certificate

The term "certificate" means the certificate described in subsection (b)(1).

(3) Facility

(A) In general

The term "facility" means a hospital, outpatient department, clinic, radiology practice, or mobile unit, an office of a physician, or other facility as determined by the Secretary, that

conducts breast cancer screening or diagnosis through mammography activities. Such term does not include a facility of the Department of Veterans Affairs.

(B) Activities

For the purposes of this section, the activities of a facility include the operation of equipment to produce the mammogram, the processing of the film, the initial interpretation of the mammogram and the viewing conditions for that interpretation. Where procedures such as the film processing, or the interpretation of the mammogram are performed in a location different from where the mammogram is performed, the facility performing the mammogram shall be responsible for meeting the quality standards described in subsection (f).

(4) Inspection

The term "inspection" means an onsite evaluation of the facility by the Secretary, or State or local agency on behalf of the Secretary.

(5) Mammogram

The term "mammogram" means a radiographic image produced through mammography.

(6) Mammography

The term "mammography" means radiography of the breast.

(7) Survey

The term "survey" means an onsite physics consultation and evaluation performed by a medical physicist as described in subsection (f)(1)(E).

(8) Review physician

The term "review physician" means a physician as prescribed by the Secretary under subsection (f)(1)(D) who meets such additional requirements as may be established by an accreditation body under subsection (e) and approved by the Secretary to review clinical images under subsection (e)(1)(B)(i) on behalf of the accreditation body.

(b) Certificate requirement

(1) Certificate

No facility may conduct an examination or procedure described in paragraph (2) involving mammography after October 1, 1994, unless the facility obtains—

(A) a certificate or a temporary renewal certificate—

(i) that is issued, and, if applicable, renewed, by the Secretary in accordance with paragraphs [1] (1) or (2) of subsection (c);

(ii) that is applicable to the examination or procedure to be conducted; and

(iii) that is displayed prominently in such facility; or

(B) a provisional certificate or a limited provisional certificate—

(i) that is issued by the Secretary in accordance with paragraphs (3) and (4) of subsection (c);

(ii) that is applicable to the examination or procedure to be conducted; and

(iii) that is displayed prominently in such facility.

The reference to a certificate in this section includes a temporary renewal certificate, provisional certificate, or a limited provisional certificate.

(2) Examination or procedure

A facility shall obtain a certificate in order to—

(A) operate radiological equipment that is used to image the breast;

(B) provide for the interpretation of a mammogram produced by such equipment at the facility or under arrangements with a qualified individual at a facility different from where the mammography examination is performed; and

(C) provide for the processing of film produced by such equipment at the facility or under arrangements with a qualified individual at a facility different from where the mammography examination is performed.

(c) Issuance and renewal of certificates

(1) In general

The Secretary may issue or renew a certificate for a facility if the person or agent described in subsection (d)(1)(A) meets the applicable requirements of subsection (d)(1) with respect to the facility. The Secretary may issue or renew a certificate under this paragraph for not more than 3 years.

(2) Temporary renewal certificate

The Secretary may issue a temporary renewal certificate, for a period of not to exceed 45 days, to a facility seeking reaccreditation if the accreditation body has issued an accreditation extension, for a period of not to exceed 45 days, for any of the following:

(A) The facility has submitted the required materials to the accreditation body within the established time frames for the submission of such materials but the accreditation body is unable to complete the reaccreditation process before the certification expires.

(B) The facility has acquired additional or replacement equipment, or has had significant personnel changes or other unforeseen situations that have caused the facility to be unable to meet reaccreditation timeframes, but in the opinion of the accreditation body have not compromised the quality of mammography.

(3) Limited provisional certificate

The Secretary may, upon the request of an accreditation body, issue a limited provisional certificate to an entity to enable the entity to conduct examinations for educational purposes while an onsite visit from an accreditation body is in progress. Such certificate shall be valid only during the time the site visit team from the accreditation body is physically in the facility, and in no case shall be valid for longer than 72 hours. The issuance of a certificate under this paragraph, shall not preclude the entity from qualifying for a provisional certificate under paragraph (4).

(4) Provisional certificate

The Secretary may issue a provisional certificate for an entity to enable the entity to qualify as a facility. The applicant for a provisional certificate shall meet the requirements of subsection (d)(1), except providing information required by clauses (iii) and (iv) of subsection (d)(1)(A). A provisional certificate may be in effect no longer than 6 months from the date it is issued, except that it may be extended once for a period of not more than 90 days if the owner, lessor, or agent of the facility demonstrates to the Secretary that without such extension access to mammography in the geographic area served by the facility would be significantly reduced and if the owner, lessor, or agent of the facility will describe in a report to the Secretary steps that will be taken to qualify the facility for certification under subsection (b)(1).

(d) Application for certificate

(1) Submission

The Secretary may issue or renew a certificate for a facility if—

(A) the person who owns or leases the facility or an authorized agent of the person, submits to the Secretary, in such form and manner as the Secretary shall prescribe, an application that contains at a minimum—

(i) a description of the manufacturer, model, and type of each x-ray machine, image receptor, and processor operated in the performance of mammography by the facility;

(ii) a description of the procedures currently used to provide mammography at the facility, including—

(I) the types of procedures performed and the number of such procedures performed in the prior 12 months;

(II) the methodologies for mammography; and

(III) the names and qualifications (educational background, training, and experience) of the personnel performing mammography and the physicians reading and interpreting the results from the procedures;

(iii) proof of on-site survey by a qualified medical physicist as described in subsection (f)(1)(E); and

(iv) proof of accreditation in such manner as the Secretary shall prescribe; and

(B) the person or agent submits to the Secretary—

(i) a satisfactory assurance that the facility will be operated in accordance with standards established by the Secretary under subsection (f) to assure the safety and accuracy of mammography;

(ii) a satisfactory assurance that the facility will—

(I) permit inspections under subsection (g);

(II) make such records and information available, and submit such reports, to the Secretary as the Secretary may require; and

(III) update the information submitted under subparagraph (A) or assurances submitted under this subparagraph on a timely basis as required by the Secretary; and

(iii) such other information as the Secretary may require.

An applicant shall not be required to provide in an application under subparagraph (A) any information which the applicant has supplied to the accreditation body which accredited the applicant, except as required by the Secretary.

(2) Appeal

If the Secretary denies an application for the certification of a facility submitted under paragraph (1)(A), the Secretary shall provide the owner or lessor of the facility or the agent of the owner or lessor who submitted such application—

(A) a statement of the grounds on which the denial is based, and

(B) an opportunity for an appeal in accordance with the procedures set forth in regulations of the Secretary published at part 498 of title 42, Code of Federal Regulations.

(3) Effect of denial

If the application for the certification of a facility is denied, the facility may not operate unless the denial of the application is overturned at the conclusion of the administrative appeals process provided in the regulations referred to in paragraph (2)(B).

(e) Accreditation

(1) Approval of accreditation bodies

(A) In general

The Secretary may approve a private nonprofit organization or State agency to accredit facilities for purposes of subsection (d)(1)(A)(iv) if the accreditation body meets the standards for accreditation established by the Secretary as described in subparagraph (B) and provides the assurances required by subparagraph (C).

(B) Standards

The Secretary shall establish standards for accreditation bodies, including—

(i) standards that require an accreditation body to perform—

(I) a review of clinical images from each facility accredited by such body not less often than every 3 years which review will be made by qualified review physicians; and

(II) a review of a random sample of clinical images from such facilities in each 3-year period beginning October 1, 1994, which review will be made by qualified review

physicians;

(ii) standards that prohibit individuals conducting the reviews described in clause (i) from maintaining any relationship to the facility undergoing review which would constitute a conflict of interest;

(iii) standards that limit the imposition of fees for accreditation to reasonable amounts;

(iv) standards that require as a condition of accreditation that each facility undergo a survey at least annually by a medical physicist as described in subsection (f)(1)(E) to ensure that the facility meets the standards described in subparagraphs (A) and (B) of subsection (f)(1);

(v) standards that require monitoring and evaluation of such survey, as prescribed by the Secretary;

(vi) standards that are equal to standards established under subsection (f) which are relevant to accreditation as determined by the Secretary; and

(vii) such additional standards as the Secretary may require.

(C) Assurances

The accrediting body shall provide the Secretary satisfactory assurances that the body will—

(i) comply with the standards as described in subparagraph (B);

(ii) comply with the requirements described in paragraph (4);

(iii) submit to the Secretary the name of any facility for which the accreditation body denies, suspends, or revokes accreditation;

(iv) notify the Secretary in a timely manner before the accreditation body changes the standards of the body;

(v) notify each facility accredited by the accreditation body if the Secretary withdraws approval of the accreditation body under paragraph (2) in a timely manner; and

(vi) provide such other additional information as the Secretary may require.

(D) Regulations

Not later than 9 months after October 27, 1992, the Secretary shall promulgate regulations under which the Secretary may approve an accreditation body.

(2) Withdrawal of approval

(A) In general

The Secretary shall promulgate regulations under which the Secretary may withdraw the approval of an accreditation body if the Secretary determines that the accreditation body does not meet the standards under subparagraph (B) of paragraph (1), the requirements of clauses (i) through (vi) of subparagraph (C) of paragraph (1), or the requirements of paragraph (4).

(B) Effect of withdrawal

If the Secretary withdraws the approval of an accreditation body under subparagraph (A), the certificate of any facility accredited by the body shall continue in effect until the expiration of a reasonable period, as determined by the Secretary, for such facility to obtain another accreditation.

(3) Accreditation

To be accredited by an approved accreditation body a facility shall meet—

(A) the standards described in paragraph (1)(B) which the Secretary determines are applicable to the facility, and

(B) such other standards which the accreditation body may require.

(4) Compliance

To ensure that facilities accredited by an accreditation body will continue to meet the standards of the accreditation body, the accreditation body shall—

(A) make onsite visits on an annual basis of a sufficient number of the facilities accredited by

the body to allow a reasonable estimate of the performance of the body; and

(B) take such additional measures as the Secretary determines to be appropriate.

Visits made under subparagraph (A) shall be made after providing such notice as the Secretary may require.

(5) Revocation of accreditation

If an accreditation body revokes the accreditation of a facility, the certificate of the facility shall continue in effect until such time as may be determined by the Secretary.

(6) Evaluation and report

(A) Evaluation

The Secretary shall evaluate annually the performance of each approved accreditation body by—

(i) inspecting under subsection (g)(2) a sufficient number of the facilities accredited by the body to allow a reasonable estimate of the performance of the body; and

(ii) such additional means as the Secretary determines to be appropriate.

(B) Report

The Secretary shall annually prepare and submit to the Committee on Labor and Human Resources of the Senate and the Committee on Energy and Commerce of the House of Representatives a report that describes the results of the evaluation conducted in accordance with subparagraph (A).

(f) Quality standards

(1) In general

The standards referred to in subsection (d)(1)(B)(i) are standards established by the Secretary which include—

(A) standards that require establishment and maintenance of a quality assurance and quality control program at each facility that is adequate and appropriate to ensure the reliability, clarity, and accuracy of interpretation of mammograms and standards for appropriate radiation dose;

(B) standards that require use of radiological equipment specifically designed for mammography, including radiologic standards and standards for other equipment and materials used in conjunction with such equipment;

(C) a requirement that personnel who perform mammography—

(i)(I) be licensed by a State to perform radiological procedures; or

(II) be certified as qualified to perform radiological procedures by an organization described in paragraph (2)(A); and

(ii) during the 2-year period beginning October 1, 1994, meet training standards for personnel who perform mammography or meet experience requirements which shall at a minimum include 1 year of experience in the performance of mammography; and

(iii) upon the expiration of such 2-year period meet minimum training standards for personnel who perform mammograms;

(D) a requirement that mammograms be interpreted by a physician who is certified as qualified to interpret radiological procedures, including mammography—

(i)(I) by a board described in paragraph (2)(B); or

(II) by a program that complies with the standards described in paragraph (2)(C); and

(ii) who meets training and continuing medical education requirements as established by the Secretary;

(E) a requirement that individuals who survey mammography facilities be medical physicists—

(i) licensed or approved by a State to perform such surveys, reviews, or inspections for

mammography facilities;

(ii) certified in diagnostic radiological physics or certified as qualified to perform such surveys by a board as described in paragraph (2)(D); or

(iii) in the first 5 years after October 27, 1992, who meet other criteria established by the Secretary which are comparable to the criteria described in clause (i) or (ii);

(F) a requirement that a medical physicist who is qualified in mammography as described in subparagraph (E) survey mammography equipment and oversee quality assurance practices at each facility;

(G) a requirement that—

(i) a facility that performs any mammogram—

(I) except as provided in subclause (II), maintain the mammogram in the permanent medical records of the patient for a period of not less than 5 years, or not less than 10 years if no subsequent mammograms of such patient are performed at the facility, or longer if mandated by State law; and

(II) upon the request of or on behalf of the patient, transfer the mammogram to a medical institution, to a physician of the patient, or to the patient directly; and

(ii)(I) a facility must assure the preparation of a written report of the results of any mammography examination signed by the interpreting physician;

(II) such written report shall be provided to the patient's physicians (if any);

(III) if such a physician is not available or if there is no such physician, the written report shall be sent directly to the patient; and

(IV) whether or not such a physician is available or there is no such physician, a summary of the written report shall be sent directly to the patient in terms easily understood by a lay person; and

(H) standards relating to special techniques for mammography of patients with breast implants.

Subparagraph (G) shall not be construed to limit a patient's access to the patient's medical records.

(2) Certification of personnel

The Secretary shall by regulation—

(A) specify organizations eligible to certify individuals to perform radiological procedures as required by paragraph (1)(C);

(B) specify boards eligible to certify physicians to interpret radiological procedures, including mammography, as required by paragraph (1)(D);

(C) establish standards for a program to certify physicians described in paragraph (1)(D); and

(D) specify boards eligible to certify medical physicists who are qualified to survey mammography equipment and to oversee quality assurance practices at mammography facilities.

(g) Inspections

(1) Annual inspections

(A) In general

The Secretary may enter and inspect facilities to determine compliance with the certification requirements under subsection (b) and the standards established under subsection (f). The Secretary shall, if feasible, delegate to a State or local agency the authority to make such inspections.

(B) Identification

The Secretary, or State or local agency acting on behalf of the Secretary, may conduct inspections only on presenting identification to the owner, operator, or agent in charge of the

facility to be inspected.

(C) Scope of inspection

In conducting inspections, the Secretary or State or local agency acting on behalf of the Secretary—

(i) shall have access to all equipment, materials, records, and information that the Secretary or State or local agency considers necessary to determine whether the facility is being operated in accordance with this section; and

(ii) may copy, or require the facility to submit to the Secretary or the State or local agency, any of the materials, records, or information.

(D) Qualifications of inspectors

Qualified individuals, as determined by the Secretary, shall conduct all inspections. The Secretary may request that a State or local agency acting on behalf of the Secretary designate a qualified officer or employee to conduct the inspections, or designate a qualified Federal officer or employee to conduct inspections. The Secretary shall establish minimum qualifications and appropriate training for inspectors and criteria for certification of inspectors in order to inspect facilities for compliance with subsection (f).

(E) Frequency

The Secretary or State or local agency acting on behalf of the Secretary shall conduct inspections under this paragraph of each facility not less often than annually, subject to paragraph (6).

(F) Records and annual reports

The Secretary or a State or local agency acting on behalf of the Secretary which is responsible for inspecting mammography facilities shall maintain records of annual inspections required under this paragraph for a period as prescribed by the Secretary. Such a State or local agency shall annually prepare and submit to the Secretary a report concerning the inspections carried out under this paragraph. Such reports shall include a description of the facilities inspected and the results of such inspections.

(2) Inspection of accredited facilities

The Secretary shall inspect annually a sufficient number of the facilities accredited by an accreditation body to provide the Secretary with a reasonable estimate of the performance of such body.

(3) Inspection of facilities inspected by State or local agencies

The Secretary shall inspect annually facilities inspected by State or local agencies acting on behalf of the Secretary to assure a reasonable performance by such State or local agencies.

(4) Timing

The Secretary, or State or local agency, may conduct inspections under paragraphs (1), (2), and (3), during regular business hours or at a mutually agreeable time and after providing such notice as the Secretary may prescribe, except that the Secretary may waive such requirements if the continued performance of mammography at such facility threatens the public health.

(5) Limited reinspection

Nothing in this section limits the authority of the Secretary to conduct limited reinspections of facilities found not to be in compliance with this section.

(6) Demonstration program

(A) In general

The Secretary may establish a demonstration program under which inspections under paragraph (1) of selected facilities are conducted less frequently by the Secretary (or as applicable, by State or local agencies acting on behalf of the Secretary) than the interval specified in subparagraph (E) of such paragraph.

(B) Requirements

Any demonstration program under subparagraph (A) shall be carried out in accordance with the following:

(i) The program may not be implemented before April 1, 2001. Preparations for the program may be carried out prior to such date.

(ii) In carrying out the program, the Secretary may not select a facility for inclusion in the program unless the facility is substantially free of incidents of noncompliance with the standards under subsection (f). The Secretary may at any time provide that a facility will no longer be included in the program.

(iii) The number of facilities selected for inclusion in the program shall be sufficient to provide a statistically significant sample, subject to compliance with clause (ii).

(iv) Facilities that are selected for inclusion in the program shall be inspected at such intervals as the Secretary determines will reasonably ensure that the facilities are maintaining compliance with such standards.

(h) Sanctions

(1) In general

In order to promote voluntary compliance with this section, the Secretary may, in lieu of taking the actions authorized by subsection (i), impose one or more of the following sanctions:

(A) Directed plans of correction which afford a facility an opportunity to correct violations in a timely manner.

(B) Payment for the cost of onsite monitoring.

(2) Patient information

If the Secretary determines that the quality of mammography performed by a facility (whether or not certified pursuant to subsection (c)) was so inconsistent with the quality standards established pursuant to subsection (f) as to present a significant risk to individual or public health, the Secretary may require such facility to notify patients who received mammograms at such facility, and their referring physicians, of the deficiencies presenting such risk, the potential harm resulting, appropriate remedial measures, and such other relevant information as the Secretary may require.

(3) Civil money penalties

The Secretary may assess civil money penalties in an amount not to exceed $10,000 for—

(A) failure to obtain a certificate as required by subsection (b),

(B) each failure by a facility to substantially comply with, or each day on which a facility fails to substantially comply with, the standards established under subsection (f) or the requirements described in subclauses (I) through (III) of subsection (d)(1)(B)(ii),

(C) each failure to notify a patient of risk as required by the Secretary pursuant to paragraph (2), and

(D) each violation, or for each aiding and abetting in a violation of, any provision of, or regulation promulgated under, this section by an owner, operator, or any employee of a facility required to have a certificate.

(4) Procedures

The Secretary shall develop and implement procedures with respect to when and how each of the sanctions is to be imposed under paragraphs (1) through (3). Such procedures shall provide for notice to the owner or operator of the facility and a reasonable opportunity for the owner or operator to respond to the proposed sanctions and appropriate procedures for appealing determinations relating to the imposition of sanctions.

(i) Suspension and revocation

(1) In general

The certificate of a facility issued under subsection (c) may be suspended or revoked if the

Secretary finds, after providing, except as provided in paragraph (2), reasonable notice and an opportunity for a hearing to the owner or operator of the facility, that the owner, operator, or any employee of the facility—

(A) has been guilty of misrepresentation in obtaining the certificate;

(B) has failed to comply with the requirements of subsection (d)(1)(B)(ii)(III) or the standards established by the Secretary under subsection (f);

(C) has failed to comply with reasonable requests of the Secretary (or of an accreditation body approved pursuant to subsection (e)) for any record, information, report, or material that the Secretary (or such accreditation body or State carrying out certification program requirements pursuant to subsection (q)) concludes is necessary to determine the continued eligibility of the facility for a certificate or continued compliance with the standards established under subsection (f);

(D) has refused a reasonable request of the Secretary, any Federal officer or employee duly designated by the Secretary, or any State or local officer or employee duly designated by the State or local agency, for permission to inspect the facility or the operations and pertinent records of the facility in accordance with subsection (g);

(E) has violated or aided and abetted in the violation of any provision of, or regulation promulgated under, this section; or

(F) has failed to comply with a sanction imposed under subsection (h).

(2) Action before a hearing

(A) In general

The Secretary may suspend the certificate of the facility before holding a hearing required by paragraph (1) if the Secretary has reason to believe that the circumstance of the case will support one or more of the findings described in paragraph (1) and that—

(i) the failure or violation was intentional; or

(ii) the failure or violation presents a serious risk to human health.

(B) Hearing

If the Secretary suspends a certificate under subparagraph (A), the Secretary shall provide an opportunity for a hearing to the owner or operator of the facility not later than 60 days from the effective date of the suspension. The suspension shall remain in effect until the decision of the Secretary made after the hearing.

(3) Ineligibility to own or operate facilities after revocation

If the Secretary revokes the certificate of a facility on the basis of an act described in paragraph (1), no person who owned or operated the facility at the time of the act may, within 2 years of the revocation of the certificate, own or operate a facility that requires a certificate under this section.

(j) Injunctions

If the Secretary determines that—

(1) continuation of any activity related to the provision of mammography by a facility would constitute a serious risk to human health, the Secretary may bring suit in the district court of the United States for the district in which the facility is situated to enjoin continuation of the activity; and

(2) a facility is operating without a certificate as required by subsection (b), the Secretary may bring suit in the district court of the United States for the district in which the facility is situated to enjoin the operation of the facility.

Upon a proper showing, the district court shall grant a temporary injunction or restraining order against continuation of the activity or against operation of a facility, as the case may be, without requiring the Secretary to post a bond, pending issuance of a final order under this subsection.

(k) Judicial review

(1) Petition

If the Secretary imposes a sanction on a facility under subsection (h) or suspends or revokes the certificate of a facility under subsection (i), the owner or operator of the facility may, not later than 60 days after the date the action of the Secretary becomes final, file a petition with the United States court of appeals for the circuit in which the facility is situated for judicial review of the action. As soon as practicable after receipt of the petition, the clerk of the court shall transmit a copy of the petition to the Secretary or other officer designated by the Secretary. As soon as practicable after receipt of the copy, the Secretary shall file in the court the record on which the action of the Secretary is based, as provided in section 2112 of title 28.

(2) Additional evidence

If the petitioner applies to the court for leave to adduce additional evidence, and shows to the satisfaction of the court that the additional evidence is material and that there were reasonable grounds for the failure to adduce such evidence in the proceeding before the Secretary, the court may order the additional evidence (and evidence in rebuttal of the additional evidence) to be taken before the Secretary, and to be adduced upon the hearing in such manner and upon such terms and conditions as the court may determine to be proper. The Secretary may modify the findings of the Secretary as to the facts, or make new findings, by reason of the additional evidence so taken, and the Secretary shall file the modified or new findings, and the recommendations of the Secretary, if any, for the modification or setting aside of the original action of the Secretary with the return of the additional evidence.

(3) Judgment of court

Upon the filing of the petition referred to in paragraph (1), the court shall have jurisdiction to affirm the action, or to set the action aside in whole or in part, temporarily or permanently. The findings of the Secretary as to the facts, if supported by substantial evidence, shall be conclusive.

(4) Finality of judgment

The judgment of the court affirming or setting aside, in whole or in part, any action of the Secretary shall be final, subject to review by the Supreme Court of the United States upon certiorari or certification, as provided in section 1254 of title 28.

(l) Information

(1) In general

Not later than October 1, 1996, and annually thereafter, the Secretary shall compile and make available to physicians and the general public information that the Secretary determines is useful in evaluating the performance of facilities, including a list of facilities—

(A) that have been convicted under Federal or State laws relating to fraud and abuse, false billings, or kickbacks;

(B) that have been subject to sanctions under subsection (h), together with a statement of the reasons for the sanctions;

(C) that have had certificates revoked or suspended under subsection (i), together with a statement of the reasons for the revocation or suspension;

(D) against which the Secretary has taken action under subsection (j), together with a statement of the reasons for the action;

(E) whose accreditation has been revoked, together with a statement of the reasons of the revocation;

(F) against which a State has taken adverse action; and

(G) that meets such other measures of performance as the Secretary may develop.

(2) Date

The information to be compiled under paragraph (1) shall be information for the calendar year preceding the date the information is to be made available to the public.

(3) Explanatory information

The information to be compiled under paragraph (1) shall be accompanied by such explanatory

information as may be appropriate to assist in the interpretation of the information compiled under such paragraph.

(m) State laws

Nothing in this section shall be construed to limit the authority of any State to enact and enforce laws relating to the matters covered by this section that are at least as stringent as this section or the regulations issued under this section.

(n) National Advisory Committee

(1) Establishment

In carrying out this section, the Secretary shall establish an advisory committee to be known as the National Mammography Quality Assurance Advisory Committee (hereafter in this subsection referred to as the "Advisory Committee").

(2) Composition

The Advisory Committee shall be composed of not fewer than 13, nor more than 19 individuals, who are not officers or employees of the Federal Government. The Secretary shall make appointments to the Advisory Committee from among—

(A) physicians,
(B) practitioners, and
(C) other health professionals,

whose clinical practice, research specialization, or professional expertise include a significant focus on mammography. The Secretary shall appoint at least 4 individuals from among national breast cancer or consumer health organizations with expertise in mammography, at least 2 industry representatives with expertise in mammography equipment, and at least 2 practicing physicians who provide mammography services.

(3) Functions and duties

The Advisory Committee shall—

(A) advise the Secretary on appropriate quality standards and regulations for mammography facilities;
(B) advise the Secretary on appropriate standards and regulations for accreditation bodies;
(C) advise the Secretary in the development of regulations with respect to sanctions;
(D) assist in developing procedures for monitoring compliance with standards under subsection (f);
(E) make recommendations and assist in the establishment of a mechanism to investigate consumer complaints;
(F) report on new developments concerning breast imaging that should be considered in the oversight of mammography facilities;
(G) determine whether there exists a shortage of mammography facilities in rural and health professional shortage areas and determine the effects of personnel or other requirements of subsection (f) on access to the services of such facilities in such areas;
(H) determine whether there will exist a sufficient number of medical physicists after October 1, 1999, to assure compliance with the requirements of subsection (f)(1)(E);
(I) determine the costs and benefits of compliance with the requirements of this section (including the requirements of regulations promulgated under this section); and
(J) perform other activities that the Secretary may require.

The Advisory Committee shall report the findings made under subparagraphs (G) and (I) to the Secretary and the Congress no later than October 1, 1993.

(4) Meetings

The Advisory Committee shall meet not less than quarterly for the first 3 years of the program and thereafter, at least annually.

(5) Chairperson

The Secretary shall appoint a chairperson of the Advisory Committee.

(o) Consultations

In carrying out this section, the Secretary shall consult with appropriate Federal agencies within the Department of Health and Human Services for the purposes of developing standards, regulations, evaluations, and procedures for compliance and oversight.

(p) Breast cancer screening surveillance research grants

(1) Research

(A) Grants

The Secretary shall award grants to such entities as the Secretary may determine to be appropriate to establish surveillance systems in selected geographic areas to provide data to evaluate the functioning and effectiveness of breast cancer screening programs in the United States, including assessments of participation rates in screening mammography, diagnostic procedures, incidence of breast cancer, mode of detection (mammography screening or other methods), outcome and follow up information, and such related epidemiologic analyses that may improve early cancer detection and contribute to reduction in breast cancer mortality. Grants may be awarded for further research on breast cancer surveillance systems upon the Secretary's review of the evaluation of the program.

(B) Use of funds

Grants awarded under subparagraph (A) may be used—

(i) to study—

(I) methods to link mammography and clinical breast examination records with population-based cancer registry data;

(II) methods to provide diagnostic outcome data, or facilitate the communication of diagnostic outcome data, to radiology facilities for purposes of evaluating patterns of mammography interpretation; and

(III) mechanisms for limiting access and maintaining confidentiality of all stored data; and

(ii) to conduct pilot testing of the methods and mechanisms described in subclauses (I), (II), and (III) of clause (i) on a limited basis.

(C) Grant application

To be eligible to receive funds under this paragraph, an entity shall submit an application to the Secretary at such time, in such manner, and containing such information as the Secretary may require.

(D) Report

A recipient of a grant under this paragraph shall submit a report to the Secretary containing the results of the study and testing conducted under clauses (i) and (ii) of subparagraph (B), along with recommendations for methods of establishing a breast cancer screening surveillance system.

(2) Establishment

The Secretary shall establish a breast cancer screening surveillance system based on the recommendations contained in the report described in paragraph (1)(D).

(3) Standards and procedures

The Secretary shall establish standards and procedures for the operation of the breast cancer screening surveillance system, including procedures to maintain confidentiality of patient records.

(4) Information

The Secretary shall recruit facilities to provide to the breast cancer screening surveillance system relevant data that could help in the research of the causes, characteristics, and prevalence of, and potential treatments for, breast cancer and benign breast conditions, if the information may be disclosed under section 552 of title 5.

(q) State program

(1) In general

The Secretary may, upon application, authorize a State—

(A) to carry out, subject to paragraph (2), the certification program requirements under subsections (b), (c), (d), (g)(1), (h), (i), and (j) (including the requirements under regulations promulgated pursuant to such subsections), and

(B) to implement the standards established by the Secretary under subsection (f),

with respect to mammography facilities operating within the State.

(2) Approval

The Secretary may approve an application under paragraph (1) if the Secretary determines that—

(A) the State has enacted laws and issued regulations relating to mammography facilities which are the requirements of this section (including the requirements under regulations promulgated pursuant to such subsections), and

(B) the State has provided satisfactory assurances that the State—

(i) has the legal authority and qualified personnel necessary to enforce the requirements of and the regulations promulgated pursuant to this section (including the requirements under regulations promulgated pursuant to such subsections),

(ii) will devote adequate funds to the administration and enforcement of such requirements, and

(iii) will provide the Secretary with such information and reports as the Secretary may require.

(3) Authority of Secretary

In a State with an approved application—

(A) the Secretary shall carry out the Secretary's functions under subsections (e) and (f);

(B) the Secretary may take action under subsections (h), (i), and (j); and

(C) the Secretary shall conduct oversight functions under subsections (g)(2) and (g)(3).

(4) Withdrawal of approval

(A) In general

The Secretary may, after providing notice and opportunity for corrective action, withdraw the approval of a State's authority under paragraph (1) if the Secretary determines that the State does not meet the requirements of such paragraph. The Secretary shall promulgate regulations for the implementation of this subparagraph.

(B) Effect of withdrawal

If the Secretary withdraws the approval of a State under subparagraph (A), the certificate of any facility certified by the State shall continue in effect until the expiration of a reasonable period, as determined by the Secretary, for such facility to obtain certification by the Secretary.

(r) Funding

(1) Fees

(A) In general

The Secretary shall, in accordance with this paragraph assess and collect fees from persons described in subsection (d)(1)(A) (other than persons who are governmental entities, as determined by the Secretary) to cover the costs of inspections conducted under subsection (g)(1)

by the Secretary or a State acting under a delegation under subparagraph (A) of such subsection. Fees may be assessed and collected under this paragraph only in such manner as would result in an aggregate amount of fees collected during any fiscal year which equals the aggregate amount of costs for such fiscal year for inspections of facilities of such persons under subsection (g)(1). A person's liability for fees shall be reasonably based on the proportion of the inspection costs which relate to such person.

(B) Deposit and appropriations

(i) Deposit and availability

Fees collected under subparagraph (A) shall be deposited as an offsetting collection to the appropriations for the Department of Health and Human Services as provided in appropriation Acts and shall remain available without fiscal year limitation.

(ii) Appropriations

Fees collected under subparagraph (A) shall be collected and available only to the extent provided in advance in appropriation Acts.

(2) Authorization of appropriations

There are authorized to be appropriated to carry out this section—

(A) to award research grants under subsection (p), such sums as may be necessary for each of the fiscal years 1993 through 2007; and

(B) for the Secretary to carry out other activities which are not supported by fees authorized and collected under paragraph (1), such sums as may be necessary for fiscal years 1993 through 2007.

(July 1, 1944, ch. 373, title III, §354, as added Pub. L. 102–539, §2, Oct. 27, 1992, 106 Stat. 3547; amended Pub. L. 105–248, §§2–13, Oct. 9, 1998, 112 Stat. 1864–1867; Pub. L. 108–365, §§2–4, Oct. 25, 2004, 118 Stat. 1738–1740.)

EDITORIAL NOTES

PRIOR PROVISIONS

A prior section 263b, act July 1, 1944, ch. 373, title III, §354, as added Oct. 18, 1968, Pub. L. 90–602, §2(3), 82 Stat. 1173; amended Nov. 28, 1990, Pub. L. 101–629, §19(a)(1)(B), 104 Stat. 4529; Aug. 13, 1993, Pub. L. 103–80, §4(a)(2), 107 Stat. 779, set forth Congressional declaration of purpose, prior to repeal by Pub. L. 101–629, §19(a)(3), Nov. 28, 1990, 104 Stat. 4530.

Sections 263c to 263n, act July 1, 1944, ch. 373, title III, §§355–360F, as added Oct. 18, 1968, Pub. L. 90–602, §2(3), 82 Stat. 1174, and amended, which related to electronic product radiation control, were renumbered sections 531 to 542, respectively, of the Federal Food, Drug, and Cosmetic Act by Pub. L. 101–629, §19(a)(4), Nov. 28, 1990, 104 Stat. 4530, and are classified to sections 360hh to 360ss, respectively, of Title 21, Food and Drugs.

AMENDMENTS

2004—Subsec. (b)(1). Pub. L. 108–365, §2(1)(C), substituted "temporary renewal certificate, provisional certificate, or a limited provisional certificate" for "provisional certificate" in concluding provisions.

Subsec. (b)(1)(A). Pub. L. 108–365, §2(1)(A), inserted "or a temporary renewal certificate" after "certificate" in introductory provisions and substituted "paragraphs (1) or (2) of subsection (c)" for "subsection (c)(1)" in cl. (i).

Subsec. (b)(1)(B). Pub. L. 108–365, §2(1)(B), inserted "or a limited provisional certificate" after "certificate" in introductory provisions and substituted "paragraphs (3) and (4) of subsection (c)" for "subsection (c)(2)" in cl. (i).

Subsec. (c)(2) to (4). Pub. L. 108–365, §2(2), added pars. (2) and (3) and redesignated former par. (2) as (4).

Subsec. (n)(2). Pub. L. 108–365, §3(1), reenacted subpar. (C) without change, added concluding provisions, and struck out former concluding provisions which read as follows: "whose clinical practice, research

specialization, or professional expertise include a significant focus on mammography. The Secretary shall appoint at least 4 individuals from among national breast cancer or consumer health organizations with expertise in mammography and at least 2 practicing physicians who provide mammography services."

Subsec. (n)(4). Pub. L. 108–365, §3(2), substituted "annually" for "biannually".

Subsec. (r)(2). Pub. L. 108–365, §4, substituted "2007" for "2002" in subpars. (A) and (B).

1998—Subsec. (a)(4). Pub. L. 105–248, §9(1), inserted "or local" after "State".

Subsec. (a)(8). Pub. L. 105–248, §4(b), added par. (8).

Subsec. (d)(2)(B). Pub. L. 105–248, §3, substituted "part 498 of title 42, Code of Federal Regulations" for "42 C.F.R. 498 and in effect on October 27, 1992".

Subsec. (e)(1)(B)(i)(I), (II). Pub. L. 105–248, §4(a)(1), substituted "review physicians" for "practicing physicians".

Subsec. (e)(1)(B)(ii). Pub. L. 105–248, §4(a)(2), substituted "relationship" for "financial relationship".

Subsec. (f)(1)(G)(i). Pub. L. 105–248, §5, added cl. (i) and struck out former cl. (i) which read as follows: "a facility that performs any mammogram maintain the mammogram in the permanent medical records of the patient—

"(I) for a period of not less than 5 years, or not less than 10 years if no additional mammograms of such patient are performed at the facility, or longer if mandated by State law; or

"(II) until such time as the patient should request that the patient's medical records be forwarded to a medical institution or a physician of the patient;

whichever is longer; and".

Subsec. (f)(1)(G)(ii)(IV). Pub. L. 105–248, §6, added subcl. (IV) and struck out former subcl. (IV) which read as follows: "if such report is sent to the patient, the report shall include a summary written in terms easily understood by a lay person; and".

Subsec. (g)(1). Pub. L. 105–248, §9(1), inserted "or local" after "State" wherever appearing.

Subsec. (g)(1)(A). Pub. L. 105–248, §7, in first sentence, struck out "certified" before "facilities" and inserted "the certification requirements under subsection (b) and" after "compliance with".

Subsec. (g)(1)(E). Pub. L. 105–248, §8(1), inserted ", subject to paragraph (6)" before period at end.

Subsec. (g)(3). Pub. L. 105–248, §9(1), (2), inserted "or local" after "State" in heading and in two places in text.

Subsec. (g)(4). Pub. L. 105–248, §9(1), inserted "or local" after "State".

Subsec. (g)(6). Pub. L. 105–248, §8(2), added par. (6).

Subsec. (h)(2). Pub. L. 105–248, §10(a), added par. (2) and redesignated former par. (2) as (3).

Subsec. (h)(3). Pub. L. 105–248, §10(a)(1), (b), redesignated par. (2) as (3), added subpar. (C), and redesignated former subpar. (C) as (D). Former par. (3) redesignated (4).

Subsec. (h)(4). Pub. L. 105–248, §10(a)(1), (c), redesignated par. (3) as (4) and substituted "paragraphs (1) through (3)" for "paragraphs (1) and (2)".

Subsec. (i)(1)(C). Pub. L. 105–248, §11, inserted "(or of an accreditation body approved pursuant to subsection (e))" after "of the Secretary" and inserted "(or such accreditation body or State carrying out certification program requirements pursuant to subsection (q))" after "that the Secretary".

Subsec. (i)(1)(D). Pub. L. 105–248, §9(3), inserted "or local" after "any State" and "or local agency" after "by the State".

Subsec. (i)(2)(A). Pub. L. 105–248, §12, substituted "has reason to believe that the circumstance of the case will support one or more of the findings described in paragraph (1) and that—" and cls. (i) and (ii) for "makes the finding described in paragraph (1) and determines that—

"(i) the failure of a facility to comply with the standards established by the Secretary under subsection (f) of this section presents a serious risk to human health; or

"(ii) a facility has engaged in an action described in subparagraph (D) or (E) of paragraph (1)."

Subsec. (q)(4)(B). Pub. L. 105–248, §13, substituted "certified" for "accredited".

Subsec. (r)(2)(A). Pub. L. 105–248, §2, substituted "subsection (p)" for "subsection (q)" and "2002" for "1997".

Subsec. (r)(2)(B). Pub. L. 105–248, §2, substituted "fiscal years" for "fiscal year" and "2002" for "1997".

STATUTORY NOTES AND RELATED SUBSIDIARIES

CHANGE OF NAME

Committee on Labor and Human Resources of Senate changed to Committee on Health, Education, Labor, and Pensions of Senate by Senate Resolution No. 20, One Hundred Sixth Congress, Jan. 19, 1999.

Committee on Energy and Commerce of House of Representatives treated as referring to Committee on

Commerce of House of Representatives by section 1(a) of Pub. L. 104–14, set out as a note preceding section 21 of Title 2, The Congress. Committee on Commerce of House of Representatives changed to Committee on Energy and Commerce of House of Representatives, and jurisdiction over matters relating to securities and exchanges and insurance generally transferred to Committee on Financial Services of House of Representatives by House Resolution No. 5, One Hundred Seventh Congress, Jan. 3, 2001.

TERMINATION OF ADVISORY COMMITTEES

Advisory committees established after Jan. 5, 1973, to terminate not later than the expiration of the 2-year period beginning on the date of their establishment, unless, in the case of a committee established by the President or an officer of the Federal Government, such committee is renewed by appropriate action prior to the expiration of such 2-year period, or in the case of a committee established by Congress, its duration is otherwise provided for by law. See section 1013 of Title 5, Government Organization and Employees.

Pub. L. 93–641, §6, Jan. 4, 1975, 88 Stat. 2275, set out as a note under section 217a of this title, provided that an advisory committee established pursuant to the Public Health Service Act shall terminate at such time as may be specifically prescribed by an Act of Congress enacted after Jan. 4, 1975.

REGULATIONS

Pub. L. 103–183, title VII, §707, Dec. 14, 1993, 107 Stat. 2241, provided that: "The Secretary of Health and Human Services is authorized to issue interim final regulations—

"(1) under which the Secretary may approve accreditation bodies under section 354(e) of the Public Health Service Act (42 U.S.C. 263b(e)); and

"(2) establishing quality standards under section 354(f) of the Public Health Service Act (42 U.S.C. 263b(f))."

STUDY

Section 3 of Pub. L. 102–539 directed Comptroller General of United States to conduct a study of the certification program authorized by this section to determine if the program has resulted in improvement of quality and accessibility of mammography services, and if the program has reduced the frequency of poor quality mammography and improved early detection of breast cancer, with Comptroller General, not later than 3 years from Oct. 27, 1992, submit to Congress an interim report of results of study and, not later than 5 years from such date to submit a final report.

[1] *So in original. Probably should be "paragraph".*

PART G—QUARANTINE AND INSPECTION

§264. Regulations to control communicable diseases

(a) Promulgation and enforcement by Surgeon General

The Surgeon General, with the approval of the Secretary, is authorized to make and enforce such regulations as in his judgment are necessary to prevent the introduction, transmission, or spread of communicable diseases from foreign countries into the States or possessions, or from one State or possession into any other State or possession. For purposes of carrying out and enforcing such regulations, the Surgeon General may provide for such inspection, fumigation, disinfection, sanitation, pest extermination, destruction of animals or articles found to be so infected or contaminated as to be sources of dangerous infection to human beings, and other measures, as in his judgment may be necessary.

(b) Apprehension, detention, or conditional release of individuals

Regulations prescribed under this section shall not provide for the apprehension, detention, or conditional release of individuals except for the purpose of preventing the introduction, transmission, or spread of such communicable diseases as may be specified from time to time in Executive orders of the President upon the recommendation of the Secretary, in consultation with the Surgeon General,[1].

(c) Application of regulations to persons entering from foreign countries

Except as provided in subsection (d), regulations prescribed under this section, insofar as they provide for the apprehension, detention, examination, or conditional release of individuals, shall be applicable only to individuals coming into a State or possession from a foreign country or a possession.

(d) Apprehension and examination of persons reasonably believed to be infected

(1) Regulations prescribed under this section may provide for the apprehension and examination of any individual reasonably believed to be infected with a communicable disease in a qualifying stage and (A) to be moving or about to move from a State to another State; or (B) to be a probable source of infection to individuals who, while infected with such disease in a qualifying stage, will be moving from a State to another State. Such regulations may provide that if upon examination any such individual is found to be infected, he may be detained for such time and in such manner as may be reasonably necessary. For purposes of this subsection, the term "State" includes, in addition to the several States, only the District of Columbia.

(2) For purposes of this subsection, the term "qualifying stage", with respect to a communicable disease, means that such disease—

(A) is in a communicable stage; or

(B) is in a precommunicable stage, if the disease would be likely to cause a public health emergency if transmitted to other individuals.

(e) Preemption

Nothing in this section or section 266 of this title, or the regulations promulgated under such sections, may be construed as superseding any provision under State law (including regulations and including provisions established by political subdivisions of States), except to the extent that such a provision conflicts with an exercise of Federal authority under this section or section 266 of this title.

(July 1, 1944, ch. 373, title III, §361, 58 Stat. 703; 1953 Reorg. Plan No. 1, §§5, 8, eff. Apr. 11, 1953, 18 F.R. 2053, 67 Stat. 631; Pub. L. 86–624, §29(c), July 12, 1960, 74 Stat. 419; Pub. L. 94–317, title III, §301(b)(1), June 23, 1976, 90 Stat. 707; Pub. L. 107–188, title I, §142(a)(1), (2), (b)(1), (c), June 12, 2002, 116 Stat. 626, 627.)

EDITORIAL NOTES

AMENDMENTS

2002—Pub. L. 107–188, §142(a)(1), (2), (b)(1), and (c), which directed certain amendments to section 361 of the Public Health Act, was executed by making the amendments to this section, which is section 361 of the Public Health Service Act, to reflect the probable intent of Congress. See below.

Subsec. (b). Pub. L. 107–188, §142(a)(1), substituted "Executive orders of the President upon the recommendation of the Secretary, in consultation with the Surgeon General," for "Executive orders of the President upon the recommendation of the National Advisory Health Council and the Surgeon General".

Subsec. (d). Pub. L. 107–188, §142(a)(2), (b)(1), substituted in first sentence "Regulations" for "On recommendation of the National Advisory Health Council, regulations", "in a qualifying stage" for "in a communicable stage" in two places, designated existing text as par. (1) and substituted "(A)" and "(B)" for "(1)" and "(2)", respectively, and added par. (2).

Subsec. (e). Pub. L. 107–188, §142(c), added subsec. (e).

1976—Subsec. (d). Pub. L. 94–317 inserted provision defining "State" to include, in addition to the several States, only the District of Columbia.

1960—Subsec. (c). Pub. L. 86–624 struck out reference to Territory of Hawaii.

STATUTORY NOTES AND RELATED SUBSIDIARIES

CHANGE OF NAME

"Secretary of Health and Human Services" substituted for "Secretary of Health, Education, and Welfare" in subsecs. (a) and (b) pursuant to section 509(b) of Pub. L. 96–88, which is classified to section 3508(b) of Title

20, Education.

EFFECTIVE DATE OF 1960 AMENDMENT

Amendment by Pub. L. 86–624 effective Aug. 21, 1959, see section 47(f) of Pub. L. 86–624, set out as a note under section 201 of this title.

EXTENSION OF EVICTION MORATORIUM

Pub. L. 116–260, div. N, title V, §502, Dec. 27, 2020, 134 Stat. 2078, provided that: "The order issued by the Centers for Disease Control and Prevention under section 361 of the Public Health Service Act (42 U.S.C. 264), entitled 'Temporary Halt in Residential Evictions To Prevent the Further Spread of COVID–19' (85 Fed. Reg. 55292 (September 4, 2020)[)] is extended through January 31, 2021, notwithstanding the effective dates specified in such Order."

EVALUATION OF PUBLIC HEALTH AUTHORITIES

Pub. L. 110–392, title I, §121, Oct. 13, 2008, 122 Stat. 4200, provided that:

"(a) IN GENERAL.—Not later than 180 days after the date of enactment of the Comprehensive Tuberculosis Elimination Act of 2008 [Oct. 13, 2008], the Secretary of Health and Human Services shall prepare and submit to the appropriate committees of Congress a report that evaluates and provides recommendations on changes needed to Federal and State public health authorities to address current disease containment challenges such as isolation and quarantine.

"(b) CONTENTS OF EVALUATION.—The report described in subsection (a) shall include—

"(1) an evaluation of the effectiveness of current policies to detain patients with active tuberculosis;

"(2) an evaluation of whether Federal laws should be strengthened to expressly address the movement of individuals with active tuberculosis; and

"(3) specific legislative recommendations for changes to Federal laws, if any.

"(c) UPDATE OF QUARANTINE REGULATIONS.—Not later than 240 days after the date of enactment of this Act [Oct. 13, 2008], the Secretary of Health and Human Services shall promulgate regulations to update the current interstate and foreign quarantine regulations found in parts 70 and 71 of title 42, Code of Federal Regulations."

EXECUTIVE DOCUMENTS

TRANSFER OF FUNCTIONS

Office of Surgeon General abolished by section 3 of Reorg. Plan No. 3 of 1966, eff. June 25, 1966, 31 F.R. 8855, 80 Stat. 1610, and functions thereof transferred to Secretary of Health, Education, and Welfare by section 1 of Reorg. Plan No. 3 of 1966, set out as a note under section 202 of this title. Office of Surgeon General reestablished within the Office of the Assistant Secretary for Health, see Notice of Department of Health and Human Services, Office of the Assistant Secretary for Health, Mar. 30, 1987, 52 F.R. 11754.

Functions of Federal Security Administrator transferred to Secretary of Health, Education, and Welfare and all agencies of Federal Security Agency transferred to Department of Health, Education, and Welfare by section 5 of Reorg. Plan No. 1 of 1953, set out as a note under section 3501 of this title. Federal Security Agency and office of Administrator abolished by section 8 of Reorg. Plan No. 1 of 1953.

EXECUTIVE ORDER NO. 12452

Ex. Ord. No. 12452, Dec. 22, 1983, 48 F.R. 56927, which specified certain communicable diseases for regulations providing for the apprehension, detention, or conditional release of individuals to prevent the introduction, transmission, or spread of such diseases, was revoked by Ex. Ord. No. 13295, §5, Apr. 4, 2003, 68 F.R. 17255, set out below.

EX. ORD. NO. 13295. REVISED LIST OF QUARANTINABLE COMMUNICABLE DISEASES

Ex. Ord. No. 13295, Apr. 4, 2003, 68 F.R. 17255, as amended by Ex. Ord. No. 13375, §1, Apr. 1, 2005, 70 F.R. 17299; Ex. Ord. No. 13674, §1, July 31, 2014, 79 F.R. 45671; Ex. Ord. No. 14047, Sept. 17, 2021, 86 F.R. 52591, provided:

By the authority vested in me as President by the Constitution and the laws of the United States of America, including section 361(b) of the Public Health Service Act (42 U.S.C. 264(b)), it is hereby ordered as follows:

SECTION 1. Based upon the recommendation of the Secretary of Health and Human Services (the "Secretary"), in consultation with the Surgeon General, and for the purpose of specifying certain communicable diseases for regulations providing for the apprehension, detention, or conditional release of individuals to prevent the introduction, transmission, or spread of suspected communicable diseases, the

following communicable diseases are hereby specified pursuant to section 361(b) of the Public Health Service Act:

(a) Cholera; Diphtheria; infectious Tuberculosis; Measles; Plague; Smallpox; Yellow Fever; and Viral Hemorrhagic Fevers (Lassa, Marburg, Ebola, Crimean-Congo, South American, and others not yet isolated or named).

(b) Severe acute respiratory syndromes, which are diseases that are associated with fever and signs and symptoms of pneumonia or other respiratory illness, are capable of being transmitted from person to person, and that either are causing, or have the potential to cause, a pandemic, or, upon infection, are highly likely to cause mortality or serious morbidity if not properly controlled. This subsection does not apply to influenza.

(c) Influenza caused by novel or reemergent influenza viruses that are causing, or have the potential to cause, a pandemic.

SEC. 2. The Secretary, in the Secretary's discretion, shall determine whether a particular condition constitutes a communicable disease of the type specified in section 1 of this order.

SEC. 3. The functions of the President under sections 362 and 364(a) of the Public Health Service Act (42 U.S.C. 265 and 267(a)) are assigned to the Secretary.

SEC. 4. This order is not intended to, and does not, create any right or benefit enforceable at law or equity by any party against the United States, its departments, agencies, entities, officers, employees or agents, or any other person.

SEC. 5. Executive Order 12452 of December 22, 1983, is hereby revoked.

[1] *So in original. The comma probably should not appear.*

§265. Suspension of entries and imports from designated places to prevent spread of communicable diseases

Whenever the Surgeon General determines that by reason of the existence of any communicable disease in a foreign country there is serious danger of the introduction of such disease into the United States, and that this danger is so increased by the introduction of persons or property from such country that a suspension of the right to introduce such persons and property is required in the interest of the public health, the Surgeon General, in accordance with regulations approved by the President, shall have the power to prohibit, in whole or in part, the introduction of persons and property from such countries or places as he shall designate in order to avert such danger, and for such period of time as he may deem necessary for such purpose.

(July 1, 1944, ch. 373, title III, §362, 58 Stat. 704.)

STATUTORY NOTES AND RELATED SUBSIDIARIES

CHANGE OF NAME

"Secretary of Health and Human Services" substituted for "Secretary of Health, Education, and Welfare" pursuant to section 509(b) of Pub. L. 96–88, which is classified to section 3508(b) of Title 20, Education.

EXECUTIVE DOCUMENTS

TRANSFER OF FUNCTIONS

Office of Surgeon General abolished by section 3 of Reorg. Plan No. 3 of 1966, eff. June 25, 1966, 31 F.R. 8855, 80 Stat. 1610, and functions thereof transferred to Secretary of Health, Education, and Welfare by section 1 of Reorg. Plan No. 3 of 1966, set out as a note under section 202 of this title. Office of Surgeon General reestablished within the Office of the Assistant Secretary for Health, see Notice of Department of Health and Human Services, Office of the Assistant Secretary for Health, Mar. 30, 1987, 52 F.R. 11754.

DELEGATION OF FUNCTIONS

For assignment of functions of President under this section, see section 3 of Ex. Ord. No. 13295, Apr. 4, 2003, 68 F.R. 17255, set out as a note under section 264 of this title.

§266. Special quarantine powers in time of war

To protect the military and naval forces and war workers of the United States, in time of war, against any communicable disease specified in Executive orders as provided in subsection (b) of section 264 of this title, the Secretary, in consultation with the Surgeon General, is authorized to provide by regulations for the apprehension and examination, in time of war, of any individual reasonably believed (1) to be infected with such disease and (2) to be a probable source of infection to members of the armed forces of the United States or to individuals engaged in the production or transportation of arms, munitions, ships, food, clothing, or other supplies for the armed forces. Such regulations may provide that if upon examination any such individual is found to be so infected, he may be detained for such time and in such manner as may be reasonably necessary.

(July 1, 1944, ch. 373, title III, §363, 58 Stat. 704; Pub. L. 107–188, title I, §142(a)(3), (b)(2), June 12, 2002, 116 Stat. 626, 627.)

EDITORIAL NOTES

AMENDMENTS

2002—Pub. L. 107–188, which directed substitution of "the Secretary, in consultation with the Surgeon General," for "the Surgeon General, on recommendation of the National Advisory Health Council," and striking out of "in a communicable stage" after "(1) to be infected with such disease", in section 363 of the Public Health Act, was executed to this section, which is section 363 of the Public Health Service Act, to reflect the probable intent of Congress.

STATUTORY NOTES AND RELATED SUBSIDIARIES

CHANGE OF NAME

"Secretary of Health and Human Services" substituted in text for "Secretary of Health, Education, and Welfare" pursuant to section 509(b) of Pub. L. 96–88, which is classified to section 3508(b) of Title 20, Education.

TERMINATION OF WAR AND EMERGENCIES

Joint Res. July 25, 1947, ch. 327, §3, 61 Stat. 451, provided that in the interpretation of this section, the date July 25, 1947, shall be deemed to be the date of termination of any state of war theretofore declared by Congress and of the national emergencies proclaimed by the President on Sept. 8, 1939, and May 27, 1941.

EXECUTIVE DOCUMENTS

TRANSFER OF FUNCTIONS

Office of Surgeon General abolished by section 3 of Reorg. Plan No. 3 of 1966, eff. June 25, 1966, 31 F.R. 8855, 80 Stat. 1610, and functions thereof transferred to Secretary of Health, Education, and Welfare by section 1 of Reorg. Plan No. 3 of 1966, set out as a note under section 202 of this title. Office of Surgeon General reestablished within the Office of the Assistant Secretary for Health, see Notice of Department of Health and Human Services, Office of the Assistant Secretary for Health, Mar. 30, 1987, 52 F.R. 11754.

§267. Quarantine stations, grounds, and anchorages

(a) Control and management

Except as provided in title II [1] of the Act of June 15, 1917, as amended, the Surgeon General shall control, direct, and manage all United States quarantine stations, grounds, and anchorages, designate their boundaries, and designate the quarantine officers to be in charge thereof. With the approval of the President he shall from time to time select suitable sites for and establish such additional stations,

grounds, and anchorages in the States and possessions of the United States as in his judgment are necessary to prevent the introduction of communicable diseases into the States and possessions of the United States.

(b) Hours of inspection

The Surgeon General shall establish the hours during which quarantine service shall be performed at each quarantine station, and, upon application by any interested party, may establish quarantine inspection during the twenty-four hours of the day, or any fraction thereof, at such quarantine stations as, in his opinion, require such extended service. He may restrict the performance of quarantine inspection to hours of daylight for such arriving vessels as cannot, in his opinion, be satisfactorily inspected during hours of darkness. No vessel shall be required to undergo quarantine inspection during the hours of darkness, unless the quarantine officer at such quarantine station shall deem an immediate inspection necessary to protect the public health. Uniformity shall not be required in the hours during which quarantine inspection may be obtained at the various ports of the United States.

(c) Overtime pay for employees of Service

The Surgeon General shall fix a reasonable rate of extra compensation for overtime services of employees of the United States Public Health Service, Foreign Quarantine Division, performing overtime duties including the operation of vessels, in connection with the inspection or quarantine treatment of persons (passengers and crews), conveyances, or goods arriving by land, water, or air in the United States or any place subject to the jurisdiction thereof, hereinafter referred to as "employees of the Public Health Service", when required to be on duty between the hours of 6 o'clock postmeridian and 6 o'clock antemeridian (or between the hours of 7 o'clock postmeridian and 7 o'clock antemeridian at stations which have a declared workday of from 7 o'clock antemeridian to 7 o'clock postmeridian), or on Sundays or holidays, such rate, in lieu of compensation under any other provision of law, to be fixed at two times the basic hourly rate for each hour that the overtime extends beyond 6 o'clock (or 7 o'clock as the case may be) postmeridian, and two times the basic hourly rate for each overtime hour worked on Sundays or holidays. As used in this subsection, the term "basic hourly rate" shall mean the regular basic rate of pay which is applicable to such employees for work performed within their regular scheduled tour of duty.

(d) Payment of extra compensation to United States; bond or deposit to assure payment; deposit of moneys to credit of appropriation

(1) The said extra compensation shall be paid to the United States by the owner, agent, consignee, operator, or master or other person in charge of any conveyance, for whom, at his request, services as described in this subsection (hereinafter referred to as overtime service) are performed. If such employees have been ordered to report for duty and have so reported, and the requested services are not performed by reason of circumstances beyond the control of the employees concerned, such extra compensation shall be paid on the same basis as though the overtime services had actually been performed during the period between the time the employees were ordered to report for duty and did so report, and the time they were notified that their services would not be required, and in any case as though their services had continued for not less than one hour. The Surgeon General with the approval of the Secretary of Health and Human Services may prescribe regulations requiring the owner, agent, consignee, operator, or master or other person for whom the overtime services are performed to file a bond in such amounts and containing such conditions and with such sureties, or in lieu of a bond, to deposit money or obligations of the United States in such amount, as will assure the payment of charges under this subsection, which bond or deposit may cover one or more transactions or all transactions during a specified period: *Provided*, That no charges shall be made for services performed in connection with the inspection of (1) persons arriving by international highways, ferries, bridges, or tunnels, or the conveyances in which they arrive, or (2) persons arriving by aircraft or railroad trains, the operations of which are covered by published schedules, or

the aircraft or trains in which they arrive, or (3) persons arriving by vessels operated between Canadian ports and ports on Puget Sound or operated on the Great Lakes and connecting waterways, the operations of which are covered by published schedules, or the vessels in which they arrive.

(2) Moneys collected under this subsection shall be deposited in the Treasury of the United States to the credit of the appropriation charged with the expense of the services, and the appropriations so credited shall be available for the payment of such compensation to the said employees for services so rendered.

(July 1, 1944, ch. 373, title III, §364, 58 Stat. 704; Pub. L. 85–58, ch. VII, §701, June 21, 1957, 71 Stat. 181; Pub. L. 85–580, title II, §201, Aug. 1, 1958, 72 Stat. 467; Pub. L. 96–88, title V, §509(b), Oct. 17, 1979, 93 Stat. 695.)

EDITORIAL NOTES

REFERENCES IN TEXT

Title II of the Act of June 15, 1917, referred to in subsec. (a), is act June 15, 1917, ch. 30, title II, 40 Stat. 220, which was formerly classified to sections 191, 192, 193 and 194 of Title 50, War and National Defense. Sections 191, 192, and 194 of Title 50 were redesignated and transferred to sections 70051 to 70053, respectively, of Title 46, Shipping, by Pub. L. 115–282, title IV, §407(b)(1), (5), (c)(1), (3), (d)(1), (3), Dec. 4, 2018, 132 Stat. 4267. Section 193 of Title 50 was repealed by act June 25, 1948, ch. 645, §21, 62 Stat. 862.

AMENDMENTS

1958—Subsec. (c). Pub. L. 85–580 increased rate of pay for each hour that overtime extends beyond 6 o'clock (or 7 o'clock as the case may be) postmeridian from one and one-half times the basic hourly rate to two times the basic hourly rate.

1957—Subsecs. (c), (d). Pub. L. 85–58 added subsecs. (c) and (d).

STATUTORY NOTES AND RELATED SUBSIDIARIES

CHANGE OF NAME

"Secretary of Health and Human Services" substituted for "Secretary of Health, Education, and Welfare" in subsec. (d) pursuant to section 509(b) of Pub. L. 96–88, which is classified to section 3508(b) of Title 20, Education.

EXECUTIVE DOCUMENTS

TRANSFER OF FUNCTIONS

Functions of Public Health Service, Surgeon General of Public Health Service, and all other officers and employees of Public Health Service, and functions of all agencies of or in Public Health Service transferred to Secretary of Health, Education, and Welfare by Reorg. Plan No. 3 of 1966, eff. June 25, 1966, 31 F.R. 8855, 80 Stat. 1610, set out as a note under section 202 of this title.

DELEGATION OF FUNCTIONS

Functions of President delegated to Secretary of Health Health and Human Services, see Ex. Ord. No. 11140, Jan. 30, 1964, 29 F.R. 1637, as amended, set out as a note under section 202 of this title.

For assignment of functions of President under subsec. (a) of this section, see section 3 of Ex. Ord. No. 13295, Apr. 4, 2003, 68 F.R. 17255, set out as a note under section 264 of this title.

[1] *See References in Text note below.*

§268. Quarantine duties of consular and other officers

(a) Any consular or medical officer of the United States, designated for such purpose by the Secretary, shall make reports to the Surgeon General, on such forms and at such intervals as the Surgeon General may prescribe, of the health conditions at the port or place at which such officer is

stationed.

(b) It shall be the duty of the customs officers and of Coast Guard officers to aid in the enforcement of quarantine rules and regulations; but no additional compensation, except actual and necessary traveling expenses, shall be allowed any such officer by reason of such services.

(July 1, 1944, ch. 373, title III, §365, 58 Stat. 705; 1953 Reorg. Plan No. 1, §§5, 8, eff. Apr. 11, 1953, 18 F.R. 2053, 67 Stat. 631.)

STATUTORY NOTES AND RELATED SUBSIDIARIES

CHANGE OF NAME

"Secretary of Health and Human Services" substituted for "Secretary of Health, Education, and Welfare" in subsec. (a) pursuant to section 509(b) of Pub. L. 96–88, which is classified to section 3508(b) of Title 20, Education.

TRANSFER OF FUNCTIONS

For transfer of authorities, functions, personnel, and assets of the Coast Guard, including the authorities and functions of the Secretary of Transportation relating thereto, to the Department of Homeland Security, and for treatment of related references, see sections 468(b), 551(d), 552(d), and 557 of Title 6, Domestic Security, and the Department of Homeland Security Reorganization Plan of November 25, 2002, as modified, set out as a note under section 542 of Title 6.

EXECUTIVE DOCUMENTS

TRANSFER OF FUNCTIONS

Office of Surgeon General abolished by section 3 of Reorg. Plan No. 3 of 1966, eff. June 25, 1966, 31 F.R. 8855, 80 Stat. 1610, and functions thereof transferred to Secretary of Health, Education, and Welfare by section 1 of Reorg. Plan No. 3 of 1966, set out as a note under section 202 of this title. Office of Surgeon General reestablished within the Office of the Assistant Secretary for Health, see Notice of Department of Health and Human Services, Office of the Assistant Secretary for Health, Mar. 30, 1987, 52 F.R. 11754.

Reference to Secretary of Health, Education, and Welfare substituted for reference to Federal Security Administrator pursuant to section 5 of Reorg. Plan No. 1, of 1953, set out as a note under section 3501 of this title, which transferred functions of Federal Security Administrator to Secretary of Health, Education, and Welfare and all agencies of Federal Security Agency to Department of Health, Education, and Welfare. Federal Security Agency and office of Administrator abolished by section 8 of Reorg. Plan No. 1 of 1953.

§269. Bills of health

(a) Detail of medical officer; conditions precedent to issuance; consular officer to receive fees

Except as otherwise prescribed in regulations, any vessel at any foreign port or place clearing or departing for any port or place in a State or possession shall be required to obtain from the consular officer of the United States or from the Public Health Service officer, or other medical officer of the United States designated by the Surgeon General, at the port or place of departure, a bill of health in duplicate, in the form prescribed by the Surgeon General. The President, from time to time, shall specify the ports at which a medical officer shall be stationed for this purpose. Such bill of health shall set forth the sanitary history and condition of said vessel, and shall state that it has in all respects complied with the regulations prescribed pursuant to subsection (c). Before granting such duplicate bill of health, such consular or medical officer shall be satisfied that the matters and things therein stated are true. The consular officer shall be entitled to demand and receive the fees for bills of health and such fees shall be established by regulation.

(b) Collectors of customs to receive originals; duplicate copies as part of ship's papers

Original bills of health shall be delivered to the collectors of customs at the port of entry. Duplicate copies of such bills of health shall be delivered at the time of inspection to quarantine officers at such port. The bills of health herein prescribed shall be considered as part of the ship's

papers, and when duly certified to by the proper consular or other officer of the United States, over his official signature and seal, shall be accepted as evidence of the statements therein contained in any court of the United States.

(c) Regulations to secure sanitary conditions of vessels

The Surgeon General shall from time to time prescribe regulations, applicable to vessels referred to in subsection (a) of this section for the purpose of preventing the introduction into the States or possessions of the United States of any communicable disease by securing the best sanitary condition of such vessels, their cargoes, passengers, and crews. Such regulations shall be observed by such vessels prior to departure, during the course of the voyage, and also during inspection, disinfection, or other quarantine procedure upon arrival at any United States quarantine station.

(d) Vessels from ports near frontier

The provisions of subsections (a) and (b) of this section shall not apply to vessels plying between such foreign ports on or near the frontiers of the United States and ports of the United States as are designated by treaty.

(e) Compliance with regulations

It shall be unlawful for any vessel to enter any port in any State or possession of the United States to discharge its cargo, or land its passengers, except upon a certificate of the quarantine officer that regulations prescribed under subsection (c) have in all respects been complied with by such officer, the vessel, and its master. The master of every such vessel shall deliver such certificate to the collector of customs at the port of entry, together with the original bill of health and other papers of the vessel. The certificate required by this subsection shall be procurable from the quarantine officer, upon arrival of the vessel at the quarantine station and satisfactory inspection thereof, at any time within which quarantine services are performed at such station.

(July 1, 1944, ch. 373, title III, §366, 58 Stat. 705.)

STATUTORY NOTES AND RELATED SUBSIDIARIES

CHANGE OF NAME

"Secretary of Health and Human Services" substituted for "Secretary of Health, Education, and Welfare" pursuant to section 509(b) of Pub. L. 96–88, which is classified to section 3508(b) of Title 20, Education.

EXECUTIVE DOCUMENTS

TRANSFER OF FUNCTIONS

Functions of Public Health Service, Surgeon General of Public Health Service, and all other officers and employees of Public Health Service, and functions of all agencies of or in Public Health Service transferred to Secretary of Health, Education, and Welfare by Reorg. Plan No. 3 of 1966, eff. June 25, 1966, 31 F.R. 8855, 80 Stat. 1610, set out as a note under section 202 of this title.

All offices of collector of customs, comptroller of customs, surveyor of customs, and appraiser of merchandise of Bureau of Customs of Department of the Treasury to which appointments were required to be made by the President with the advice and consent of the Senate ordered abolished, with such offices to be terminated not later than December 31, 1966, by Reorg. Plan No. 1, of 1965, eff. May 25, 1965, 30 F.R. 7035, 79 Stat. 1317, set out in the Appendix to Title 5, Government Organization and Employees. All functions of offices eliminated were already vested in Secretary of the Treasury by Reorg. Plan No. 26 of 1950, eff. July 31, 1950, 15 F.R. 4935, 64 Stat. 1280, set out in the Appendix to Title 5.

§270. Quarantine regulations governing civil air navigation and civil aircraft

The Surgeon General is authorized to provide by regulations for the application to air navigation and aircraft of any of the provisions of sections 267 to 269 of this title and regulations prescribed thereunder (including penalties and forfeitures for violations of such sections and regulations), to

such extent and upon such conditions as he deems necessary for the safeguarding of the public health.

(July 1, 1944, ch. 373, title III, §367, 58 Stat. 706.)

STATUTORY NOTES AND RELATED SUBSIDIARIES

CHANGE OF NAME

"Secretary of Health and Human Services" substituted for "Secretary of Health, Education, and Welfare" pursuant to section 509(b) of Pub. L. 96–88, which is classified to section 3508(b) of Title 20, Education.

EXECUTIVE DOCUMENTS

TRANSFER OF FUNCTIONS

Office of Surgeon General abolished by section 3 of Reorg. Plan No. 3 of 1966, eff. June 25, 1966, 31 F.R. 8855, 80 Stat. 1610, and functions thereof transferred to Secretary of Health, Education, and Welfare by section 1 of Reorg. Plan No. 3 of 1966, set out as a note under section 202 of this title. Office of Surgeon General reestablished within the Office of the Assistant Secretary for Health, see Notice of Department of Health and Human Services, Office of the Assistant Secretary for Health, Mar. 30, 1987, 52 F.R. 11754.

§271. Penalties for violation of quarantine laws

(a) Penalties for persons violating quarantine laws

Any person who violates any regulation prescribed under sections 264 to 266 of this title, or any provision of section 269 of this title or any regulation prescribed thereunder, or who enters or departs from the limits of any quarantine station, ground, or anchorage in disregard of quarantine rules and regulations or without permission of the quarantine officer in charge, shall be punished by a fine of not more than $1,000 or by imprisonment for not more than one year, or both.

(b) Penalties for vessels violating quarantine laws

Any vessel which violates section 269 of this title, or any regulations thereunder or under section 267 of this title, or which enters within or departs from the limits of any quarantine station, ground, or anchorage in disregard of the quarantine rules and regulations or without permission of the officer in charge, shall forfeit to the United States not more than $5,000, the amount to be determined by the court, which shall be a lien on such vessel, to be recovered by proceedings in the proper district court of the United States. In all such proceedings the United States attorney shall appear on behalf of the United States; and all such proceedings shall be conducted in accordance with the rules and laws governing cases of seizure of vessels for violation of the revenue laws of the United States.

(c) Remittance or mitigation of forfeitures

With the approval of the Secretary, the Surgeon General may, upon application therefor, remit or mitigate any forfeiture provided for under subsection (b) of this section, and he shall have authority to ascertain the facts upon all such applications.

(July 1, 1944, ch. 373, title III, §368, 58 Stat. 706; June 25, 1948, ch. 646, §1, 62 Stat. 909; 1953 Reorg. Plan No. 1, §§5, 8, eff. Apr. 11, 1953, 18 F.R. 2053, 67 Stat. 631.)

STATUTORY NOTES AND RELATED SUBSIDIARIES

CHANGE OF NAME

"Secretary of Health and Human Services" substituted for "Secretary of Health, Education, and Welfare" pursuant to section 509(b) of Pub. L. 96–88, which is classified to section 3508(b) of Title 20, Education.

Act June 25, 1948, eff. Sept. 1, 1948, substituted "United States attorney" for "United States district attorney". See section 541 of Title 28, Judiciary and Judicial Procedure, and Historical and Revision note thereunder.

EXECUTIVE DOCUMENTS

TRANSFER OF FUNCTIONS

Office of Surgeon General abolished by section 3 of Reorg. Plan No. 3 of 1966, eff. June 25, 1966, 31 F.R. 8855, 80 Stat. 1610, and functions thereof transferred to Secretary of Health, Education, and Welfare by section 1 of Reorg. Plan No. 3 of 1966, set out as a note under section 202 of this title. Office of Surgeon General reestablished within the Office of the Assistant Secretary for Health, see Notice of Department of Health and Human Services, Office of the Assistant Secretary for Health, Mar. 30, 1987, 52 F.R. 11754.

Functions of Federal Security Administrator transferred to Secretary of Health, Education, and Welfare and all agencies of Federal Security Agency transferred to Department of Health, Education, and Welfare by section 5 of Reorg. Plan No. 1 of 1953, set out as a note under section 3501 of this title. Federal Security Agency and office of Administrator abolished by section 8 of Reorg. Plan No. 1 of 1953.

§272. Administration of oaths by quarantine officers

Medical officers of the United States, when performing duties as quarantine officers at any port or place within the United States, are authorized to take declarations and administer oaths in matters pertaining to the administration of the quarantine laws and regulations of the United States.

(July 1, 1944, ch. 373, title III, §369, 58 Stat. 706.)

PART H—ORGAN TRANSPLANTS

EDITORIAL NOTES

PRIOR PROVISIONS

A prior part H related to grants to Alaska for mental health, prior to the general revision of part H by Pub. L. 98–507, title II, §201, Oct. 19, 1984, 98 Stat. 2342.

Another prior part H, entitled "National Library of Medicine", as added by act Aug. 3, 1956, ch. 907, 70 Stat. 960, was redesignated part I and classified to section 275 et seq. of this title, prior to repeal by Pub. L. 99–158.

§273. Organ procurement organizations

(a) Grant authority of Secretary

(1) The Secretary may make grants for the planning of qualified organ procurement organizations described in subsection (b).

(2) The Secretary may make grants for the establishment, initial operation, consolidation, and expansion of qualified organ procurement organizations described in subsection (b).

(b) Qualified organizations

(1) A qualified organ procurement organization for which grants may be made under subsection (a) is an organization which, as determined by the Secretary, will carry out the functions described in paragraph (2) [1] and—

(A) is a nonprofit entity,

(B) has accounting and other fiscal procedures (as specified by the Secretary) necessary to assure the fiscal stability of the organization,

(C) has an agreement with the Secretary to be reimbursed under title XVIII of the Social Security Act [42 U.S.C. 1395 et seq.] for the procurement of kidneys,

(D) notwithstanding any other provision of law, has met the other requirements of this section

and has been certified or recertified by the Secretary within the previous 4-year period as meeting the performance standards to be a qualified organ procurement organization through a process that either—

(i) granted certification or recertification within such 4-year period with such certification or recertification in effect as of January 1, 2000, and remaining in effect through the earlier of—

(I) January 1, 2002; or

(II) the completion of recertification under the requirements of clause (ii); or

(ii) is defined through regulations that are promulgated by the Secretary by not later than January 1, 2002, that—

(I) require recertifications of qualified organ procurement organizations not more frequently than once every 4 years;

(II) rely on outcome and process performance measures that are based on empirical evidence, obtained through reasonable efforts, of organ donor potential and other related factors in each service area of qualified organ procurement organizations;

(III) use multiple outcome measures as part of the certification process; and

(IV) provide for a qualified organ procurement organization to appeal a decertification to the Secretary on substantive and procedural grounds; [2]

(E) has procedures to obtain payment for non-renal organs provided to transplant centers,

(F) has a defined service area that is of sufficient size to assure maximum effectiveness in the procurement and equitable distribution of organs, and that either includes an entire metropolitan statistical area (as specified by the Director of the Office of Management and Budget) or does not include any part of the area,

(G) has a director and such other staff, including the organ donation coordinators and organ procurement specialists necessary to effectively obtain organs from donors in its service area, and

(H) has a board of directors or an advisory board which—

(i) is composed of—

(I) members who represent hospital administrators, intensive care or emergency room personnel, tissue banks, and voluntary health associations in its service area,

(II) members who represent the public residing in such area,

(III) a physician with knowledge, experience, or skill in the field of histocompatibility or an individual with a doctorate degree in a biological science with knowledge, experience, or skill in the field of histocompatibility,

(IV) a physician with knowledge or skill in the field of neurology, and

(V) from each transplant center in its service area which has arrangements described in paragraph (3)(G) with the organization, a member who is a surgeon who has practicing privileges in such center and who performs organ transplant surgery,

(ii) has the authority to recommend policies for the procurement of organs and the other functions described in paragraph (3), and

(iii) has no authority over any other activity of the organization.

(2)(A) Not later than 90 days after November 16, 1990, the Secretary shall publish in the Federal Register a notice of proposed rulemaking to establish criteria for determining whether an entity meets the requirement established in paragraph (1)(E).[1]

(B) Not later than 1 year after November 16, 1990, the Secretary shall publish in the Federal Register a final rule to establish the criteria described in subparagraph (A).

(3) An organ procurement organization shall—

(A) have effective agreements, to identify potential organ donors, with a substantial majority of the hospitals and other health care entities in its service area which have facilities for organ donations,

(B) conduct and participate in systematic efforts, including professional education, to acquire all

useable organs from potential donors,

(C) arrange for the acquisition and preservation of donated organs and provide quality standards for the acquisition of organs which are consistent with the standards adopted by the Organ Procurement and Transplantation Network under section 274(b)(2)(E) of this title, including arranging for testing with respect to identifying organs that are infected with human immunodeficiency virus (HIV),

(D) arrange for the appropriate tissue typing of donated organs,

(E) have a system to allocate donated organs equitably among transplant patients according to established medical criteria,

(F) provide or arrange for the transportation of donated organs to transplant centers,

(G) have arrangements to coordinate its activities with transplant centers in its service area,

(H) participate in the Organ Procurement Transplantation Network established under section 274 of this title,

(I) have arrangements to cooperate with tissue banks for the retrieval, processing, preservation, storage, and distribution of tissues as may be appropriate to assure that all useable tissues are obtained from potential donors,

(J) evaluate annually the effectiveness of the organization in acquiring potentially available organs, and

(K) assist hospitals in establishing and implementing protocols for making routine inquiries about organ donations by potential donors.

(c) Pancreata islet cell transplantation or research

Pancreata procured by an organ procurement organization and used for islet cell transplantation or research shall be counted for purposes of certification or recertification under subsection (b).

(July 1, 1944, ch. 373, title III, §371, as added Pub. L. 98–507, title II, §201, Oct. 19, 1984, 98 Stat. 2342; amended Pub. L. 100–607, title IV, §402(a), (c)(1), (2), (d), Nov. 4, 1988, 102 Stat. 3114, 3115; Pub. L. 101–616, title II, §§201(a)–(c)(1), (d), (e), 206(b), Nov. 16, 1990, 104 Stat. 3283, 3285; Pub. L. 106–505, title VII, §701(c), Nov. 13, 2000, 114 Stat. 2347; Pub. L. 106–554, §1(a)(1) [title II, §219(b)], Dec. 21, 2000, 114 Stat. 2763, 2763A–29; Pub. L. 108–216, §9, Apr. 5, 2004, 118 Stat. 590; Pub. L. 108–362, §2, Oct. 25, 2004, 118 Stat. 1703; Pub. L. 113–51, §2(a)(2), (3), Nov. 21, 2013, 127 Stat. 579, 580; Pub. L. 118–14, §3(1), Sept. 22, 2023, 137 Stat. 69.)

EDITORIAL NOTES

REFERENCES IN TEXT

Paragraph (2), referred to in subsec. (b)(1), meaning paragraph (2) of subsec. (b) of this section, was redesignated paragraph (3) by section 201(d)(1) of Pub. L. 101–616. See 1990 Amendment note below.

The Social Security Act, referred to in subsec. (b)(1)(C), is act Aug. 14, 1935, ch. 531, 49 Stat. 620. Title XVIII of the Social Security Act is classified generally to subchapter XVIII (§1395 et seq.) of chapter 7 of this title. For complete classification of this Act to the Code, see section 1305 of this title and Tables.

Paragraph (1)(E), referred to in subsec. (b)(2)(A), meaning par. (1)(E) of subsec. (b) of this section, probably should refer to par. (1)(F) of subsec. (b) after the redesignations by section 701(c)(1) of Pub. L. 106–505, section 1(a)(1) [title II, §219(b)(1)] of Pub. L. 106–554, and section 2(a)(3)(B) of Pub. L. 113–51, which successively redesignated such subpar. (E) as (F), (G), and (F). See 2000 and 2013 Amendment notes below.

PRIOR PROVISIONS

A prior section 273, act July 1, 1944, ch. 373, title III, §371, as added July 28, 1956, ch. 772, title II, §201, 70 Stat. 709, authorized grants to the Territory of Alaska for an integrated mental health program, prior to repeal by Pub. L. 86–70, §31(b)(1), June 25, 1959, 73 Stat. 148, effective July 1, 1959.

A prior section 371 of act July 1, 1944, added by act Aug. 3, 1956, ch. 907, §1, 70 Stat. 960, was renumbered section 381 and classified to section 275 of this title, prior to repeal by Pub. L. 99–158, §3(b), Nov. 20, 1985, 99 Stat. 879.

AMENDMENTS

2023—Subsec. (b)(1)(H)(i)(III). Pub. L. 118–14 substituted "histocompatibility or an individual" for "histocompatability or an individual".

2013—Subsec. (b)(1)(E), (F). Pub. L. 113–51, §2(a)(3)(A), (B), redesignated subpars. (F) and (G) as (E) and (F), respectively, and struck out former subpar. (E) which was identical to subpar. (D).

Subsec. (b)(1)(G). Pub. L. 113–51, §2(a)(3)(C), substituted "(G) has a director" for "(H) has a director". Former subpar. (G) redesignated (F).

Subsec. (b)(1)(H)(i)(V). Pub. L. 113–51, §2(a)(3)(D)(i), substituted "paragraph (3)(G)" for "paragraph (2)(G)".

Subsec. (b)(1)(H)(ii). Pub. L. 113–51, §2(a)(3)(D)(ii), substituted "paragraph (3)" for "paragraph (2)".

Subsec. (b)(3)(C). Pub. L. 113–51, §2(a)(2), substituted "including arranging for testing with respect to identifying organs that are infected with human immunodeficiency virus (HIV)" for "including arranging for testing with respect to preventing the acquisition of organs that are infected with the etiologic agent for acquired immune deficiency syndrome".

2004—Subsec. (a)(3). Pub. L. 108–216 struck out par. (3) which read as follows: "The Secretary may make grants to, and enter into contracts with, qualified organ procurement organizations described in subsection (b) of this section and other nonprofit private entities for the purpose of carrying out special projects designed to increase the number of organ donors."

Subsec. (c). Pub. L. 108–362 added subsec. (c).

2000—Subsec. (b)(1)(D) to (H). Pub. L. 106–554 added subpar. (D) identical to that added by Pub. L. 106–505 and redesignated former subpars. (D) to (G), respectively, as (E) to (G) and (H) relating to director and such other staff obtaining organs from donors in its service area. Additional amendment directing realignment of margin of subpar. (F) could not be executed after amendment by Pub. L. 106–505.

Pub. L. 106–505 added subpar. (D), redesignated former subpars. (D) to (G), respectively, as (E) to (G) and (H) relating to board of directors or advisory board, and realigned margin of subpar. (F).

1990—Pub. L. 101–616, §201(a), substituted "Organ procurement organizations" for "Assistance for organ procurement organizations" in section catchline.

Subsec. (a)(3). Pub. L. 101–616, §201(b)(1), substituted "may make grants to, and enter into contracts with, qualified organ procurement organizations described in subsection (b) of this section and other nonprofit private entities for the purpose of carrying out special projects" for "may make grants for special projects".

Subsec. (a)(4). Pub. L. 101–616, §201(b)(2), struck out par. (4) which set forth factors to consider in making grants.

Subsec. (b)(1)(E). Pub. L. 101–616, §201(c)(1), amended subpar. (E) generally. Prior to amendment, subpar. (E) read as follows: "has a defined service area which is a geographical area of sufficient size such that (unless the service area comprises an entire State) the organization can reasonably expect to procure organs from not less than 50 donors each year and which either includes an entire standard metropolitan statistical area (as specified by the Office of Management and Budget) or does not include any part of such an area,".

Subsec. (b)(1)(G)(i)(III). Pub. L. 101–616, §201(e), made technical correction to Pub. L. 100–607, §402(c)(2). See 1988 Amendment note below.

Subsec. (b)(2), (3). Pub. L. 101–616, §201(d), added par. (2) and redesignated former par. (2) as (3).

Subsec. (c). Pub. L. 101–616, §206(b), struck out subsec. (c) which authorized appropriations for subsec. (a) grants for fiscal years 1988 through 1990.

1988—Subsec. (a)(2). Pub. L. 100–607, §402(a)(1), inserted "consolidation," after "initial operation,".

Subsec. (a)(3). Pub. L. 100–607, §402(a)(2), added par. (3). Former par. (3) redesignated (4).

Subsec. (a)(4). Pub. L. 100–607, §402(a)(2), redesignated former par. (3) as (4).

Subsec. (a)(4)(C). Pub. L. 100–607, §402(a)(3), added subpar. (C).

Subsec. (b)(1)(E). Pub. L. 100–607, §402(c)(1)(A), substituted "size such that" for "size which", and "the organization can reasonably expect to procure organs from not less than 50 donors each year" for "will include at least fifty potential organ donors each year".

Subsec. (b)(1)(G)(i)(III). Pub. L. 100–607, §402(c)(2), as amended by Pub. L. 101–616, §201(e), inserted "or an individual with a doctorate degree in a biological science with knowledge, experience, or skill in the field of histocompatibility" before comma at end.

Subsec. (b)(2)(C). Pub. L. 100–607, §402(c)(1)(B), substituted "274(b)(2)(E) of this title, including arranging for testing with respect to preventing the acquisition of organs that are infected with the etiologic agent for acquired immune deficiency syndrome," for "274(b)(2)(D) of this title,".

Subsec. (b)(2)(E). Pub. L. 100–607, §402(c)(1)(C), substituted "organs equitably among transplant patients" for "organs among transplant centers and patients".

Subsec. (b)(2)(K). Pub. L. 100–607, §402(c)(1)(D), added subpar. (K).

Subsec. (c). Pub. L. 100–607, §402(d), amended subsec. (c) generally. Prior to amendment, subsec. (c) read as follows: "For grants under subsection (a) of this section there are authorized to be appropriated $5,000,000 for fiscal year 1985, $8,000,000 for fiscal year 1986, and $12,000,000 for fiscal year 1987."

STATUTORY NOTES AND RELATED SUBSIDIARIES

EFFECTIVE DATE OF 1990 AMENDMENT

Pub. L. 101–616, title II, §207, Nov. 16, 1990, 104 Stat. 3286, provided that: "Except as otherwise provided in this title, the amendments made by this title [enacting sections 274f and 274g of this title, amending this section and sections 274 and 274b to 274d of this title, and repealing provisions set out as a note below] shall become effective on October 1, 1990, or on the date of the enactment of this Act [Nov. 16, 1990], whichever occurs later."

EFFECTIVE DATE OF 1988 AMENDMENT

Pub. L. 100–607, title IV, §402(c)(3), Nov. 4, 1988, 102 Stat. 3115, as amended by Pub. L. 101–274, Apr. 23, 1990, 104 Stat. 139, which provided that the amendment made by section 402(c)(1)(A) of Pub. L. 100–607, amending this section, was not to apply to an organ procurement organization designated under section 1320b–8(b) of this title until Jan. 1, 1992, was repealed by Pub. L. 101–616, title II, §201(c)(2), Nov. 16, 1990, 104 Stat. 3283.

SHORT TITLE

For short title of Pub. L. 98–507, which enacted this part as the "National Organ Transplant Act", see section 1 of Pub. L. 98–507, set out as a Short Title of 1984 Amendments note under section 201 of this title.

SEVERABILITY

Pub. L. 101–616, title III, §301, Nov. 16, 1990, 104 Stat. 3286, provided that: "If any provision of this Act [enacting sections 274f, 274g, 274k, and 274l of this title, amending this section and sections 274 to 274d of this title, enacting provisions set out as notes under this section and sections 274 and 274k of this title, and repealing provisions set out as a note above], amendment made by this Act, or application of the provision or amendment to any person or circumstance is held to be unconstitutional, the remainder of this Act, the amendments made by this Act, and the application of the provisions or amendments to any person or circumstance shall not be affected."

CERTIFICATION OF ORGAN PROCUREMENT ORGANIZATIONS

Pub. L. 106–505, title VII, §701(b), Nov. 13, 2000, 114 Stat. 2346, and Pub. L. 106–554, §1(a)(1) [title II, §219(a)], Dec. 21, 2000, 114 Stat. 2763, 2763A–28, provided that: "Congress makes the following findings:

"(1) Organ procurement organizations play an important role in the effort to increase organ donation in the United States.

"(2) The current process for the certification and recertification of organ procurement organizations conducted by the Department of Health and Human Services has created a level of uncertainty that is interfering with the effectiveness of organ procurement organizations in raising the level of organ donation.

"(3) The General Accounting Office [now Government Accountability Office], the Institute of Medicine, and the Harvard School of Public Health have identified substantial limitations in the organ procurement organization certification and recertification process and have recommended changes in that process.

"(4) The limitations in the recertification process include:

"(A) An exclusive reliance on population-based measures of performance that do not account for the potential in the population for organ donation and do not permit consideration of other outcome and process standards that would more accurately reflect the relative capability and performance of each organ procurement organization.

"(B) A lack of due process to appeal to the Secretary of Health and Human Services for recertification on either substantive or procedural grounds.

"(5) The Secretary of Health and Human Services has the authority under section 1138(b)(1)(A)(i) of the Social Security Act (42 U.S.C. 1320b–8(b)(1)(A)(i)) to extend the period for recertification of an organ procurement organization from 2 to 4 years on the basis of its past practices in order to avoid the inappropriate disruption of the nation's organ system.

"(6) The Secretary of Health and Human Services can use the extended period described in paragraph (5) for recertification of all organ procurement organizations to—

"(A) develop improved performance measures that would reflect organ donor potential and interim outcomes, and to test these measures to ensure that they accurately measure performance differences among the organ procurement organizations; and

"(B) improve the overall certification process by incorporating process as well as outcome performance measures, and developing equitable processes for appeals."

STUDY REGARDING IMMUNOSUPPRESSIVE DRUGS

Pub. L. 106–310, div. A, title XXI, §2101(b), Oct. 17, 2000, 114 Stat. 1156, required the Secretary of Health and Human Services to provide for a study to determine the costs of immunosuppressive drugs provided to children pursuant to organ transplants and to determine the extent to which health plans and health insurance covered such costs, and related issues, and to submit the report to Congress by Dec. 31, 2001.

STUDY ON HOSPITAL AGREEMENTS WITH ORGAN PROCUREMENT AGENCIES

Pub. L. 103–432, title I, §155(b), Oct. 31, 1994, 108 Stat. 4439, directed Office of Technology Assessment to conduct study to determine efficacy and fairness of requiring a hospital to enter into agreement under subsec. (b)(3)(A) of this section with organ procurement agency for service area in which such hospital is located and impact of such requirement on efficacy and fairness of organ procurement and distribution, and to submit to Congress, not later than 2 years after Oct. 31, 1994, report containing findings of such study and implications of such findings with respect to policies affecting organ procurement and distribution.

TASK FORCE ON ORGAN PROCUREMENT AND TRANSPLANTATION

Pub. L. 98–507, title I, §§101–105, Oct. 19, 1984, 98 Stat. 2339–2342, directed Secretary of Health and Human Services, not later than 90 days after Oct. 19, 1984, to establish a Task Force on Organ Transplantation to conduct comprehensive examinations, prepare an assessment and report, and submit advice as to regulation of the medical, legal, ethical, economic, and social issues presented by human organ procurement and transplantation, with the final report due not later than 12 months after the Task Force is established and the Task Force to terminate 3 months thereafter.

BONE MARROW REGISTRY DEMONSTRATION AND STUDY

Pub. L. 98–507, title IV, §401, Oct. 19, 1984, 98 Stat. 3268, directed Secretary of Health and Human Services to hold a conference on the feasibility of establishing and the effectiveness of a national registry of voluntary bone marrow donors not later than 9 months after Oct. 19, 1984, and if the conference found that it was feasible to establish a national registry of voluntary donors of bone marrow and that such a registry was likely to be effective in matching donors with recipients, the Secretary was to establish a registry of voluntary donors of bone marrow not later than six months after the completion of the conference, and further directed the Secretary, acting through the Assistant Secretary for Health, to study the establishment and implementation of the registry to identify the issues presented by the establishment of such a registry, to evaluate participation of bone marrow donors, to assess the implementation of the informed consent and confidentiality requirements, and to determine if the establishment of a permanent bone marrow registry was needed and appropriate, and to report the results of the study to Congress not later than two years after the date the registry was established.

[1] See References in Text note below.

[2] So in original. The semicolon probably should be a comma.

§273a. National living donor mechanisms

The Secretary may establish and maintain mechanisms to evaluate the long-term effects associated with living organ donations by individuals who have served as living donors.

(July 1, 1944, ch. 373, title III, §371A, as added Pub. L. 108–216, §7, Apr. 5, 2004, 118 Stat. 589.)

§273b. Report on the long-term health effects of living organ donation

Not later than 1 year after December 21, 2007, and annually thereafter, the Secretary of Health and Human Services shall submit to the appropriate committees of Congress a report that details the

progress made towards understanding the long-term health effects of living organ donation.
(Pub. L. 110–144, §3, Dec. 21, 2007, 121 Stat. 1814.)

EDITORIAL NOTES

CODIFICATION

Section was enacted as part of the Charlie W. Norwood Living Organ Donation Act, and not as part of the Public Health Service Act which comprises this chapter.

§274. Organ procurement and transplantation network

(a) In general

The Secretary shall provide for the continued operation of an Organ Procurement and Transplantation Network which meets the requirements of subsection (b). The Secretary may award grants, contracts, or cooperative agreements, as the Secretary determines appropriate, for purposes of carrying out this section.

(b) Composition

(1) IN GENERAL.—The Organ Procurement and Transplantation Network shall—

(A) be operated through awards to public or private entities made by the Secretary that are distinct from the awards made to support the organization tasked with supporting the board of directors described in subparagraph (B); and

(B) have a board of directors—

(i) that includes representatives of organ procurement organizations (including organizations that have received grants under section 273 of this title), transplant centers, voluntary health associations, and the general public; and

(ii) that shall establish an executive committee and other committees, whose chairpersons shall be selected to ensure continuity of leadership for the board.

(2) The Organ Procurement and Transplantation Network shall—

(A) establish in one location or through regional centers—

(i) a national list of individuals who need organs; and

(ii) a national system, through the use of computers and in accordance with established medical criteria, to match organs and individuals included in the list, especially individuals whose immune system makes it difficult for them to receive organs;

(B) establish membership criteria and medical criteria for allocating organs and provide to members of the public an opportunity to comment with respect to such criteria;

(C) maintain a 24-hour telephone or information technology service to facilitate matching organs with individuals included in the list;

(D) assist organ procurement organizations in the nationwide distribution of organs equitably among transplant patients;

(E) adopt and use standards of quality for the acquisition and transportation of donated organs;

(F) prepare and distribute, on a regionalized basis (and, to the extent practicable, among regions or on a national basis), samples of blood sera from individuals who are included on the list and whose immune system makes it difficult for them to receive organs, in order to facilitate matching the compatibility of such individuals with organ donors;

(G) coordinate, as appropriate, the transportation of organs from organ procurement organizations to transplant centers;

(H) provide information to physicians and other health professionals regarding organ donation;

(I) collect, analyze, and publish data concerning organ donation and transplants;

(J) carry out studies and demonstration projects for the purpose of improving procedures for

organ procurement and allocation;

(K) work actively to increase the supply of donated organs;

(L) submit to the Secretary an annual report containing information on the comparative costs and patient outcomes at each transplant center affiliated with the organ procurement and transplantation network;

(M) recognize the differences in health and in organ transplantation issues between children and adults throughout the system and adopt criteria, polices, and procedures that address the unique health care needs of children;

(N) carry out studies and demonstration projects for the purpose of improving procedures for organ donation procurement and allocation, including but not limited to projects to examine and attempt to increase transplantation among populations with special needs, including children and individuals who are members of racial or ethnic minority groups, and among populations with limited access to transportation;

(O) provide that for purposes of this paragraph, the term "children" refers to individuals who are under the age of 18;

(P) encourage the integration of electronic health records systems through application programming interfaces (or successor technologies) among hospitals, organ procurement organizations, and transplant centers, including the use of automated electronic hospital referrals and the grant of remote, electronic access to hospital electronic health records of potential donors by organ procurement organizations, in a manner that complies with the privacy regulations promulgated under the Health Insurance Portability and Accountability Act of 1996, at part 160 of title 45, Code of Federal Regulations, and subparts A, C, and E of part 164 of such title (or any successor regulations); and

(Q) consider establishing a dashboard to display the number of transplants performed, the types of transplants performed, the number and types of organs that entered the Organ Procurement and Transplantation Network system and failed to be transplanted, and other appropriate statistics, which should be updated more frequently than annually.

(3) CLARIFICATION.—In adopting and using standards of quality under paragraph (2)(E), the Organ Procurement and Transplantation Network may adopt and use such standards with respect to organs infected with human immunodeficiency virus (in this paragraph referred to as "HIV"), provided that any such standards ensure that organs infected with HIV may be transplanted only into individuals who—

(A) are infected with HIV before receiving such organ; and

(B)(i) are participating in clinical research approved by an institutional review board under the criteria, standards, and regulations described in subsections (a) and (b) of section 274f–5 of this title; or

(ii) if the Secretary has determined under section 274f–5(c) of this title that participation in such clinical research, as a requirement for such transplants, is no longer warranted, are receiving a transplant under the standards and regulations under section 274f–5(c) of this title.

(c) Consideration of critical comments

The Secretary shall establish procedures for—

(1) receiving from interested persons critical comments relating to the manner in which the Organ Procurement and Transplantation Network is carrying out the duties of the Network under subsection (b); and

(2) the consideration by the Secretary of such critical comments.

(d) Registration fees

(1) In general

The Secretary may collect registration fees from any member of the Organ Procurement and Transplantation Network for each transplant candidate such member places on the list described in

subsection (b)(2)(A)(i). Such registration fees shall be collected and distributed only to support the operation of the Organ Procurement and Transplantation Network. Such registration fees are authorized to remain available until expended.

(2) Collection

The Secretary may collect the registration fees under paragraph (1) directly or through awards made under subsection (b)(1)(A).

(3) Distribution

Any amounts collected under this subsection shall—

(A) be credited to the currently applicable appropriation, account, or fund of the Department of Health and Human Services as discretionary offsetting collections; and

(B) be available, only to the extent and in the amounts provided in advance in appropriations Acts, to distribute such fees among awardees described in subsection (b)(1)(A).

(4) Transparency

The Secretary shall—

(A) promptly post on the website of the Organ Procurement and Transplantation Network—

(i) the amount of registration fees collected under this subsection from each member of the Organ Procurement and Transplantation Network; and

(ii) a list of activities such fees are used to support; and

(B) update the information posted pursuant to subparagraph (A), as applicable for each calendar quarter for which fees are collected under paragraph (1).

(5) GAO review

Not later than 2 years after February 3, 2026, the Comptroller General of the United States shall, to the extent data are available—

(A) conduct a review concerning the activities under this subsection; and

(B) submit to the Committee on Health, Education, Labor, and Pensions and the Committee on Finance of the Senate and the Committee on Energy and Commerce of the House of Representatives, a report on such review, including related recommendations, as applicable.

(6) Sunset

The authority to collect registration fees under paragraph (1) shall expire on the date that is 3 years after February 3, 2026.

(July 1, 1944, ch. 373, title III, §372, as added Pub. L. 98–507, title II, §201, Oct. 19, 1984, 98 Stat. 2344; amended Pub. L. 100–607, title IV, §403, Nov. 4, 1988, 102 Stat. 3115; Pub. L. 101–616, title II, §202(a)–(c), Nov. 16, 1990, 104 Stat. 3283, 3284; Pub. L. 106–310, div. A, title XXI, §2101(a), Oct. 17, 2000, 114 Stat. 1156; Pub. L. 110–426, §2, Oct. 15, 2008, 122 Stat. 4835; Pub. L. 113–51, §2(a)(1), Nov. 21, 2013, 127 Stat. 579; Pub. L. 118–14, §2, Sept. 22, 2023, 137 Stat. 69; Pub. L. 119–75, div. J, title V, §6502, Feb. 3, 2026, 140 Stat. 690.)

EDITORIAL NOTES

REFERENCES IN TEXT

The Health Insurance Portability and Accountability Act of 1996, referred to in subsec. (b)(2)(P), is Pub. L. 104–191, Aug. 21, 1996, 110 Stat. 1936. For complete classification of this Act to the Code, see Short Title of 1996 Amendments note set out under section 201 of this title and Tables.

PRIOR PROVISIONS

A prior section 274, act July 1, 1944, ch. 373, title III, §372, as added July 28, 1956, ch. 772, title II, §201, 70 Stat. 710; amended June 25, 1959, Pub. L. 86–70, §31(b)(2)–(4), 73 Stat. 148, related to grants to Alaska for a mental health program and payment for construction of hospital facilities, prior to the general revision of this part by section 201 of Pub. L. 98–507.

Another section 372 of act July 1, 1944, added by act Aug. 3, 1956, ch. 941, §1, 70 Stat. 960, which related

to functions of National Library of Medicine, was renumbered section 382 and classified to section 276 of this title, prior to repeal by Pub. L. 99–158, §3(b), Nov. 20, 1985, 99 Stat. 879.

AMENDMENTS

2026—Subsec. (b)(2)(A)(i). Pub. L. 119–75, §6502(1)(B)(i), substituted "; and" for ", and".

Subsec. (b)(2)(A)(ii). Pub. L. 119–75, §6502(1)(B)(ii), substituted semicolon for comma at end.

Subsec. (b)(2)(B). Pub. L. 119–75, §6502(1)(D), substituted semicolon for comma at end.

Subsec. (b)(2)(C). Pub. L. 119–75, §6502(1)(C), (D), substituted "24-hour telephone or information technology service" for "twenty-four-hour telephone service" and semicolon for comma at end.

Subsec. (b)(2)(D) to (L). Pub. L. 119–75, §6502(1)(D), substituted semicolon for comma at end.

Subsec. (b)(2)(M). Pub. L. 119–75, §6502(1)(A), (D), realigned margins and substituted semicolon for comma at end.

Subsec. (b)(2)(N). Pub. L. 119–75, §6502(1)(A), (E), realigned margins and substituted "transportation;" for "transportation, and".

Subsec. (b)(2)(O). Pub. L. 119–75, §6502(1)(A), (F), realigned margins and substituted semicolon for period at end.

Subsec. (b)(2)(P), (Q). Pub. L. 119–75, §6502(1)(G), added subpars. (P) and (Q).

Subsec. (d). Pub. L. 119–75, §6502(2), added subsec. (d).

2023—Subsec. (a). Pub. L. 118–14, §2(1), inserted heading, substituted "The Secretary shall" for "The Secretary shall by contract", "continued" for "establishment and", and "The Secretary may award grants, contracts, or cooperative agreements, as the Secretary determines appropriate, for purposes of carrying out this section." for "The amount provided under such contract in any fiscal year may not exceed $7,000,000. Funds for such contracts shall be made available from funds available to the Public Health Service from appropriations for fiscal years beginning after fiscal year 1984."

Subsec. (b). Pub. L. 118–14, §2(2), inserted subsec. and par. (1) headings and, in par. (1), substituted "The Organ Procurement and Transplantation Network shall—" and subpar. (A) for "The Organ Procurement and Transplantation Network shall carry out the functions described in paragraph (2) and shall—

"(A) be a private nonprofit entity that has an expertise in organ procurement and transplantation, and".

2013—Subsec. (b)(2)(E). Pub. L. 113–51, §2(a)(1)(A), struck out ", including standards for preventing the acquisition of organs that are infected with the etiologic agent for acquired immune deficiency syndrome" after "organs".

Subsec. (b)(3). Pub. L. 113–51, §2(a)(1)(B), added par. (3).

2008—Subsec. (a). Pub. L. 110–426 substituted "$7,000,000" for "$2,000,000".

2000—Subsec. (b)(2)(M) to(O). Pub. L. 106–310 added subpars. (M) to (O).

1990—Subsec. (b)(1)(A). Pub. L. 101–616, §202(a)(1), substituted "that has an expertise in organ procurement and transplantation" for "which is not engaged in any activity unrelated to organ procurement".

Subsec. (b)(1)(B). Pub. L. 101–616, §202(a)(2), amended subpar. (B) generally. Prior to amendment, subpar. (B) read as follows: "have a board of directors which includes representatives of organ procurement organizations (including organizations which have received grants under section 273 of this title), transplant centers, voluntary health associations, and the general public."

Subsec. (b)(2)(D). Pub. L. 101–616, §202(b)(1), inserted "nationwide" after "organizations in the" and "equitably among transplant patients" after "organs".

Subsec. (b)(2)(F). Pub. L. 101–616, §202(c), substituted "compatibility" for "compatability".

Subsec. (b)(2)(K), (L). Pub. L. 101–616, §202(b)(2)–(4), added subpars. (K) and (L).

1988—Subsec. (b)(2)(B), (C). Pub. L. 100–607, §403(a)(1), added subpar. (B) and redesignated former subpars. (B) and (C) as (C) and (D), respectively.

Subsec. (b)(2)(D). Pub. L. 100–607, §403(a)(1), (2), redesignated former subpar. (C) as (D) and substituted "organs" for "organs which cannot be placed within the service areas of the organizations". Former subpar. (D) redesignated (E).

Subsec. (b)(2)(E). Pub. L. 100–607, §403(a)(1), (3), redesignated former subpar. (D) as (E) and inserted "including standards for preventing the acquisition of organs that are infected with the etiologic agent for acquired immune deficiency syndrome," after "organs,". Former subpar. (E) redesignated (F).

Subsec. (b)(2)(F). Pub. L. 100–607, §403(a)(1), (4), redesignated former subpar. (E) as (F) and inserted "(and, to the extent practicable, among regions or on a national basis)" after "basis". Former subpar. (F) redesignated (G).

Subsec. (b)(2)(G) to (I). Pub. L. 100–607, §403(a)(1), redesignated former subpars. (F) to (H) as (G) to (I), respectively.

Subsec. (b)(2)(J). Pub. L. 100–607, §403(a)(5), added subpar. (J).

Subsec. (c). Pub. L. 100–607, §403(b), added subsec. (c).

STATUTORY NOTES AND RELATED SUBSIDIARIES

EFFECTIVE DATE OF 1990 AMENDMENT

Pub. L. 101–616, title II, §202(d), Nov. 16, 1990, 104 Stat. 3284, provided that: "The amendments made by subsection (a) [amending this section] shall become effective on December 31, 1990."

REPORT; LIMITATION ON AMENDMENT BY PUB. L. 110–426

Pub. L. 110–426, §3, Oct. 15, 2008, 122 Stat. 4835, provided that:

"(a) IN GENERAL.—The Secretary of Health and Human Services shall request that the Executive Director of the Organ Procurement and Transplantation Network submit to Congress, not later than 1 year after the date of enactment of this Act [Oct. 15, 2008], a report that shall include—

"(1) the identity of transplant programs that have become inactive or have closed since the heart allocation policy change of 2006;

"(2) the distance to the next closest operational heart transplant center from such inactivated or closed programs and an evaluation of whether or not access to care has been reduced to the population previously serviced by such inactive or closed program;

"(3) the number of patients with rural zip codes that received transplants after the heart allocation policy change of 2006 as compared with the number of such patients that received such transplants prior to such heart allocation policy change;

"(4) a comparison of the number of transplants performed, the mortality rate for individuals on the transplant waiting lists, and the post-transplant survival rate nationally and by region prior to and after the heart allocation policy change of 2006; and

"(5) specifically with respect to allosensitized patients, a comparison of the number of heart transplants performed, the mortality rate for individuals on the heart transplant waiting lists, and the post heart transplant survival rate nationally and by region prior to and after the heart allocation policy change of 2006.

"(b) LIMITATION ON FUNDING.—The increase provided for in the amendment made by section 2 [amending this section] shall not apply with respect to contracts entered into under section 372(a) of the Public Health Service Act (42 U.S.C. 274(a)) after the date that is 1 year after the date of enactment of this Act [Oct. 15, 2008] if the Executive Director of the Organ Procurement and Transplantation Network fails to submit the report under subsection (a)."

§274a. Scientific registry

The Secretary shall, by grant or contract, develop and maintain a scientific registry of the recipients of organ transplants. The registry shall include such information respecting patients and transplant procedures as the Secretary deems necessary to an ongoing evaluation of the scientific and clinical status of organ transplantation. The Secretary shall prepare for inclusion in the report under section 274d of this title an analysis of information derived from the registry.

(July 1, 1944, ch. 373, title III, §373, as added Pub. L. 98–507, title II, §201, Oct. 19, 1984, 98 Stat. 2345; amended Pub. L. 100–607, title IV, §404, Nov. 4, 1988, 102 Stat. 3116; Pub. L. 101–616, title I, §101(b), Nov. 16, 1990, 104 Stat. 3282.)

EDITORIAL NOTES

PRIOR PROVISIONS

A prior section 373 of act July 1, 1944, added by act Aug. 3, 1956, ch. 907, §1, 70 Stat. 960, which related to a Board of Regents of National Library of Medicine, was renumbered section 383 and classified to section 277 of this title, prior to repeal by Pub. L. 99–158, §3(b), Nov. 20, 1985, 99 Stat. 879.

AMENDMENTS

1990—Pub. L. 101–616 struck out "and bone marrow registry" after "Scientific registry" in section catchline and struck out subsec. (a) designation and subsec. (b) which directed establishment of bone marrow registry and authorized appropriations for fiscal years 1989 and 1990 for such purpose.

1988—Pub. L. 100–607 inserted "and bone marrow registry" in section catchline, designated existing text as subsec. (a), and added subsec. (b).

§274b. General provisions respecting grants and contracts

(a) Application requirement

No grant may be made under this part or contract entered into under section 274 or 274a of this title unless an application therefor has been submitted to, and approved by, the Secretary. Such an application shall be in such form and shall be submitted in such manner as the Secretary shall by regulation prescribe.

(b) Special considerations and priority; planning and establishment grants

(1) A grant for planning under section 273(a)(1) of this title may be made for one year with respect to any organ procurement organization and may not exceed $100,000.

(2) Grants under section 273(a)(2) of this title may be made for two years. No such grant may exceed $500,000 for any year and no organ procurement organization may receive more than $800,000 for initial operation or expansion.

(3) Grants or contracts under section 273(a)(3) of this title may be made for not more than 3 years.

(c) Determination of grant amount; terms of payment; recordkeeping; access for purposes of audits and examination of records

(1) The Secretary shall determine the amount of a grant or contract made under section 273 or 274a of this title. Payments under such grants and contracts may be made in advance on the basis of estimates or by the way of reimbursement, with necessary adjustments on account of underpayments or overpayments, and in such installments and on such terms and conditions as the Secretary finds necessary to carry out the purposes of such grants and contracts.

(2)(A) Each recipient of a grant or contract under section 273, 274, or 274a of this title shall keep such records as the Secretary shall prescribe, including records which fully disclose the amount and disposition by such recipient of the proceeds of such grant or contract, the total cost of the undertaking in connection with which such grant or contract was made, and the amount of that portion of the cost of the undertaking supplied by other sources, and such other records as will facilitate an effective audit.

(B) The Secretary and the Comptroller General of the United States, or any of their duly authorized representatives, shall have access for the purpose of audit and examination to any books, documents, papers, and records of the recipient of a grant or contract under section 273, 274, or 274a of this title that are pertinent to such grant or contract.

(d) "Transplant center" and "organ" defined

For purposes of this part:

(1) The term "transplant center" means a health care facility in which transplants of organs are performed.

(2) The term "organ" means the human kidney, liver, heart, lung, pancreas, and any other human organ (other than corneas and eyes) specified by the Secretary by regulation and for purposes of section 274a of this title, such term includes bone marrow.

(July 1, 1944, ch. 373, title III, §374, as added Pub. L. 98–507, title II, §201, Oct. 19, 1984, 98 Stat. 2345; amended Pub. L. 100–607, title IV, §402(b), Nov. 4, 1988, 102 Stat. 3114; Pub. L. 101–616, title II, §203, Nov. 16, 1990, 104 Stat. 3284; Pub. L. 118–14, §3(2), Sept. 22, 2023, 137 Stat. 69.)

EDITORIAL NOTES

PRIOR PROVISIONS

A prior section 374 of act July 1, 1944, added by act Aug. 3, 1956, ch. 907, §1, 70 Stat. 961, which related to acceptance and administration of gifts to National Library of Medicine and to establishment of memorials

to donors, was renumbered section 384 and classified to section 278 of this title, prior to repeal by Pub. L. 99–158, §3(b), Nov. 20, 1985, 99 Stat. 879.

AMENDMENTS

2023—Subsec. (c)(2). Pub. L. 118–14 substituted "section 273, 274, or 274a" for "section 273 or 274a" in subpars. (A) and (B).

1990—Subsec. (a). Pub. L. 101–616, §203(1), substituted "No grant may be made under this part" for "No grant may be made under section 273 or 274a of this title".

Subsec. (b). Pub. L. 101–616, §203(2), redesignated par. (2) as (1) and substituted "section 273(a)(1)" for "section 273", struck out former par. (1) which set forth factors in considering applications for section 273 grants, redesignated par. (3) as (2) and substituted "section 273(a)(2)" for "paragraphs (2) and (3) of section 273(a)", and added par. (3).

Subsec. (c). Pub. L. 101–616, §203(3), inserted "or contract" after "grant" wherever appearing and "and contracts" after "grants" wherever appearing.

1988—Subsec. (b)(3). Pub. L. 100–607 substituted "paragraphs (2) and (3) of section 273(a) of this title" for "section 273 of this title for the establishment, initial operation, or expansion of organ procurement organizations".

§274c. Administration

The Secretary shall designate and maintain an identifiable administrative unit in the Public Health Service to—

(1) administer this part and coordinate with the organ procurement activities under title XVIII of the Social Security Act [42 U.S.C. 1395 et seq.];

(2) conduct a program of public information to inform the public of the need for organ donations;

(3) provide technical assistance to organ procurement organizations, the Organ Procurement and Transplantation Network established under section 274 of this title, and other entities in the health care system involved in organ donations, procurement, and transplants; and

(4) provide information—

(A) to patients, their families, and their physicians about transplantation; and

(B) to patients and their families about the resources available nationally and in each State, and the comparative costs and patient outcomes at each transplant center affiliated with the organ procurement and transplantation network, in order to assist the patients and families with the costs associated with transplantation.

(July 1, 1944, ch. 373, title III, §375, as added Pub. L. 98–507, title II, §201, Oct. 19, 1984, 98 Stat. 2346; amended Pub. L. 100–607, title IV, §405, Nov. 4, 1988, 102 Stat. 3116; Pub. L. 101–616, title II, §204, Nov. 16, 1990, 104 Stat. 3285; Pub. L. 118–14, §3(3), Sept. 22, 2023, 137 Stat. 69.)

EDITORIAL NOTES

REFERENCES IN TEXT

The Social Security Act, referred to in par. (1), is act Aug. 14, 1935, ch. 531, 49 Stat. 620. Title XVIII of the Social Security Act is classified generally to subchapter XVIII (§1395 et seq.) of chapter 7 of this title. For complete classification of this Act to the Code, see section 1305 of this title and Tables.

PRIOR PROVISIONS

A prior section 375 of act July 1, 1944, added by act Aug. 3, 1956, ch. 907, §1, 70 Stat. 962, which related to definitions, was renumbered section 385 and classified to section 279 of this title, prior to repeal by Pub. L. 99–158, §3(b), Nov. 20, 1985, 99 Stat. 879.

AMENDMENTS

2023—Pars. (1), (2). Pub. L. 118–14, §3(3)(A), substituted semicolon for comma at end.

Par. (3). Pub. L. 118–14, §3(3)(B), substituted "transplants; and" for "transplants, and".

Par. (4). Pub. L. 118–14, §3(3)(C), redesignated cls. (i) and (ii) as subpars. (A) and (B), respectively.

1990—Pub. L. 101–616, §204(a), struck out ", during fiscal years 1985 through 1990," after "The Secretary shall".

Par. (3). Pub. L. 101–616, §204(b)(1), struck out "receiving funds under section 273 of this title" after "organ procurement organizations".

Par. (4). Pub. L. 101–616, §204(b)(2), amended par. (4) generally. Prior to amendment, par. (4) read as follows: "not later than April 1 of each of the years 1989 and 1990, submit to the Congress a report on the status of organ donation and coordination services and include in the report an analysis of the efficiency and effectiveness of the procurement and allocation of organs and a description of problems encountered in the procurement and allocation of organs."

1988—Pub. L. 100–607, in introductory provisions, substituted "1985 through 1990" for "1985, 1986, 1987, and 1988" and, in par. (4), substituted "not later than April 1 of each of the years 1989 and 1990, submit to the Congress a report" for "one year after the date on which the Task Force on Organ Transplantation transmits its final report under section 104(c) of the National Organ Transplant Act, and annually thereafter through fiscal year 1988, submit to Congress an annual report".

§274d. Report

Not later than 2 years after September 22, 2023, and every second year thereafter, the Secretary shall publish, and submit to the Committee on Energy and Commerce of the House of Representatives and the Committee on Health, Education, Labor, and Pensions of the Senate, a report on the scientific and clinical status of organ transplantation. The Secretary shall consult with the Director of the National Institutes of Health and the Commissioner of the Food and Drug Administration in the preparation of the report.

(July 1, 1944, ch. 373, title III, §376, as added Pub. L. 98–507, title II, §201, Oct. 19, 1984, 98 Stat. 2346; amended Pub. L. 100–607, title IV, §406, Nov. 4, 1988, 102 Stat. 3116; Pub. L. 101–616, title II, §205, Nov. 16, 1990, 104 Stat. 3285; Pub. L. 118–14, §3(4), Sept. 22, 2023, 137 Stat. 70.)

EDITORIAL NOTES

PRIOR PROVISIONS

A prior section 376 of act July 1, 1944, added by act Aug. 3, 1956, ch. 907, §1, 70 Stat. 962, which related to Library facilities, was renumbered section 386 and classified to section 280 of this title, prior to repeal by Pub. L. 99–158, §3(b), Nov. 20, 1985, 99 Stat. 879.

AMENDMENTS

2023—Pub. L. 118–14 substituted "2 years after September 22, 2023, and every second year thereafter" for "February 10 of 1991 and of each second year thereafter" and "Committee on Health, Education, Labor, and Pensions of the Senate," for "Committee on Labor and Human Resources of the Senate.".

1990—Pub. L. 101–616 substituted "Not later than February 10 of 1991 and of each second year thereafter, the Secretary shall publish, and submit to the Committee on Energy and Commerce of the House of Representatives and the Committee on Labor and Human Resources of the Senate." for "The Secretary shall, not later than October 1 of each year, publish".

1988—Pub. L. 100–607 substituted "shall, not later than October 1 of each year," for "shall annually".

STATUTORY NOTES AND RELATED SUBSIDIARIES

CHANGE OF NAME

Committee on Energy and Commerce of House of Representatives treated as referring to Committee on Commerce of House of Representatives by section 1(a) of Pub. L. 104–14, set out as a note preceding section 21 of Title 2, The Congress. Committee on Commerce of House of Representatives changed to Committee on Energy and Commerce of House of Representatives, and jurisdiction over matters relating to securities and exchanges and insurance generally transferred to Committee on Financial Services of House of Representatives by House Resolution No. 5, One Hundred Seventh Congress, Jan. 3, 2001.

§274e. Prohibition of organ purchases

(a) Prohibition

It shall be unlawful for any person to knowingly acquire, receive, or otherwise transfer any human organ for valuable consideration for use in human transplantation if the transfer affects interstate commerce. The preceding sentence does not apply with respect to human organ paired donation.

(b) Penalties

Any person who violates subsection (a) shall be fined not more than $50,000 or imprisoned not more than five years, or both.

(c) Definitions

For purposes of subsection (a):

(1) The term "human organ" means the human (including fetal) kidney, liver, heart, lung, pancreas, bone marrow, cornea, eye, bone, and skin or any subpart thereof and any other human organ (or any subpart thereof, including that derived from a fetus) specified by the Secretary of Health and Human Services by regulation.

(2) The term "valuable consideration" does not include the reasonable payments associated with the removal, transportation, implantation, processing, preservation, quality control, and storage of a human organ or the expenses of travel, housing, and lost wages incurred by the donor of a human organ in connection with the donation of the organ.

(3) The term "interstate commerce" has the meaning prescribed for it by section 321(b) of title 21.

(4) The term "human organ paired donation" means the donation and receipt of human organs under the following circumstances:

(A) An individual (referred to in this paragraph as the "first donor") desires to make a living donation of a human organ specifically to a particular patient (referred to in this paragraph as the "first patient"), but such donor is biologically incompatible as a donor for such patient.

(B) A second individual (referred to in this paragraph as the "second donor") desires to make a living donation of a human organ specifically to a second particular patient (referred to in this paragraph as the "second patient"), but such donor is biologically incompatible as a donor for such patient.

(C) Subject to subparagraph (D), the first donor is biologically compatible as a donor of a human organ for the second patient, and the second donor is biologically compatible as a donor of a human organ for the first patient.

(D) If there is any additional donor-patient pair as described in subparagraph (A) or (B), each donor in the group of donor-patient pairs is biologically compatible as a donor of a human organ for a patient in such group.

(E) All donors and patients in the group of donor-patient pairs (whether 2 pairs or more than 2 pairs) enter into a single agreement to donate and receive such human organs, respectively, according to such biological compatibility in the group.

(F) Other than as described in subparagraph (E), no valuable consideration is knowingly acquired, received, or otherwise transferred with respect to the human organs referred to in such subparagraph.

(Pub. L. 98–507, title III, §301, Oct. 19, 1984, 98 Stat. 2346; Pub. L. 100–607, title IV, §407, Nov. 4, 1988, 102 Stat. 3116; Pub. L. 110–144, §2, Dec. 21, 2007, 121 Stat. 1813.)

EDITORIAL NOTES

CODIFICATION

Section was enacted as part of the National Organ Transplant Act, and not as part of the Public Health Service Act which comprises this chapter.

AMENDMENTS

2007—Subsec. (a). Pub. L. 110–144, §2(1), inserted at end "The preceding sentence does not apply with respect to human organ paired donation."

Subsec. (c)(4). Pub. L. 110–144, §2(2), added par. (4).

1988—Subsec. (c)(1). Pub. L. 100–607 amended par. (1) generally. Prior to amendment, par. (1) read as follows: "The term 'human organ' means the human kidney, liver, heart, lung, pancreas, bone marrow, cornea, eye, bone, and skin, and any other human organ specified by the Secretary of Health and Human Services by regulation."

STATUTORY NOTES AND RELATED SUBSIDIARIES

DETERMINATION ON THE DEFINITION OF HUMAN ORGAN

Pub. L. 114–104, §4, Dec. 18, 2015, 129 Stat. 2218, provided that: "Not later than one year after the date of enactment of this Act [Dec. 18, 2015], the Secretary of Health and Human Services shall issue determinations with respect to the inclusion of peripheral blood stem cells and umbilical cord blood in the definition of human organ."

NO IMPACT ON SOCIAL SECURITY TRUST FUND

Pub. L. 110–144, §4, Dec. 21, 2007, 121 Stat. 1814, provided that: "Nothing in this Act [see Short Title of 2007 Amendment note set out under section 201 of this title] (or an amendment made by this Act) shall be construed to alter or amend the Social Security Act (42 U.S.C. 301 et seq.) (or any regulation promulgated under that Act)."

§274f. Reimbursement of travel and subsistence expenses incurred toward living organ donation

(a) In general

The Secretary may award grants to States, transplant centers, qualified organ procurement organizations under section 273 of this title, or other public or private entities for the purpose of—

(1) providing for the reimbursement of travel and subsistence expenses incurred by individuals toward making living donations of their organs (in this section referred to as "donating individuals"); and

(2) providing for the reimbursement of such incidental nonmedical expenses that are so incurred as the Secretary determines by regulation to be appropriate.

(b) Preference

The Secretary shall, in carrying out subsection (a), give preference to those individuals that the Secretary determines are more likely to be otherwise unable to meet such expenses.

(c) No consideration of income of organ recipient

The recipient of a grant under this section, in providing reimbursement to a donating individual through such grant, shall not give any consideration to the income of the organ recipient.

(d) Certain circumstances

The Secretary may, in carrying out subsection (a), consider—

(1) the term "donating individuals" as including individuals who in good faith incur qualifying expenses toward the intended donation of an organ but with respect to whom, for such reasons as the Secretary determines to be appropriate, no donation of the organ occurs; and

(2) the term "qualifying expenses" as including the expenses of having relatives or other individuals, not to exceed 2, accompany or assist the donating individual for purposes of subsection (a) (subject to making payment for only those types of expenses that are paid for a donating individual).

(e) Relationship to payments under other programs

An award may be made under subsection (a) only if the applicant involved agrees that the award will not be expended to pay the qualifying expenses of a donating individual to the extent that

payment has been made, or can reasonably be expected to be made, with respect to such expenses—

(1) under any State compensation program, under an insurance policy, or under any Federal or State health benefits program; or

(2) by an entity that provides health services on a prepaid basis.

(f) Definitions

For purposes of this section:

(1) The term "donating individuals" has the meaning indicated for such term in subsection (a)(1), subject to subsection (d)(1).

(2) The term "qualifying expenses" means the expenses authorized for purposes of subsection (a), subject to subsection (d)(2).

(g) Authorization of appropriations

For the purpose of carrying out this section, there is authorized to be appropriated $5,000,000 for each of the fiscal years 2005 through 2009.

(h) Annual report

Not later than December 31 of each year, beginning in fiscal year 2027, the Secretary shall—

(1) prepare, submit to the Congress, and make public a report on whether grants under this section provided adequate funding during the preceding fiscal year to reimburse all donating individuals participating in the grant program under this section for all qualifying expenses; and

(2) include in each such report—

(A) the estimated number of all donating individuals participating in the grant program under this section who did not receive reimbursement for all qualifying expenses during the preceding fiscal year; and

(B) the total amount of funding that is estimated to be necessary to fully reimburse all donating individuals participating in the grant program under this section for all qualifying expenses.

(July 1, 1944, ch. 373, title III, §377, as added Pub. L. 101–616, title II, §206(a), Nov. 16, 1990, 104 Stat. 3285; amended Pub. L. 108–216, §3, Apr. 5, 2004, 118 Stat. 584; Pub. L. 119–75, div. J, title V, §6503, Feb. 3, 2026, 140 Stat. 692.)

EDITORIAL NOTES

AMENDMENTS

2026—Subsecs. (c), (d). Pub. L. 119–75, §6503(a), added subsec. (c) and redesignated former subsec. (c) as (d). Former subsec. (d) redesignated (e).

Subsec. (e). Pub. L. 119–75, §6503(a)(1), redesignated subsec. (d) as (e). Former subsec. (e) redesignated (f).

Subsec. (e)(3). Pub. L. 119–75, §6503(b), struck out par. (3) which read as follows: "by the recipient of the organ."

Subsec. (f). Pub. L. 119–75, §6503(a)(1), redesignated subsec. (e) as subsec. (f). Former subsec. (f) redesignated (g).

Subsec. (f)(1). Pub. L. 119–75, §6503(a)(3)(A), substituted "subsection (d)(1)" for "subsection (c)(1)".

Subsec. (f)(2). Pub. L. 119–75, §6503(a)(3)(B), substituted "subsection (d)(2)" for "subsection (c)(2)".

Subsec. (g). Pub. L. 119–75, §6503(a)(1), redesignated subsec. (f) as (g).

Subsec. (h). Pub. L. 119–75, §6503(c), added subsec. (h).

2004—Pub. L. 108–216 amended section catchline and text generally, substituting provisions relating to reimbursement of travel and subsistence expenses incurred toward living organ donation for provisions requiring the Comptroller General to study and report on organ procurement and allocation.

§274f–1. Public awareness; studies and demonstrations

(a) Organ donation public awareness program

The Secretary shall, directly or through grants or contracts, establish a public education program in cooperation with existing national public awareness campaigns to increase awareness about organ donation and the need to provide for an adequate rate of such donations.

(b) Studies and demonstrations

The Secretary may make peer-reviewed grants to, or enter into peer-reviewed contracts with, public and nonprofit private entities for the purpose of carrying out studies and demonstration projects to increase organ donation and recovery rates, including living donation.

(c) Grants to States

(1) In general

The Secretary may make grants to States for the purpose of assisting States in carrying out organ donor awareness, public education, and outreach activities and programs designed to increase the number of organ donors within the State, including living donors.

(2) Eligibility

To be eligible to receive a grant under this subsection, a State shall—

(A) submit an application to the Department in the form prescribed;

(B) establish yearly benchmarks for improvement in organ donation rates in the State; and

(C) report to the Secretary on an annual basis a description and assessment of the State's use of funds received under this subsection, accompanied by an assessment of initiatives for potential replication in other States.

(3) Use of funds

Funds received under this subsection may be used by the State, or in partnership with other public agencies or private sector institutions, for education and awareness efforts, information dissemination, activities pertaining to the State donor registry, and other innovative donation specific initiatives, including living donation.

(d) Educational activities

The Secretary, in coordination with the Organ Procurement and Transplantation Network and other appropriate organizations, shall support the development and dissemination of educational materials to inform health care professionals and other appropriate professionals in issues surrounding organ, tissue, and eye donation including evidence-based proven methods to approach patients and their families, cultural sensitivities, and other relevant issues.

(e) Authorization of appropriations

For the purpose of carrying out this section, there are authorized to be appropriated $15,000,000 for fiscal year 2005, and such sums as may be necessary for each of the fiscal years 2006 through 2009. Such authorization of appropriations is in addition to any other authorizations of appropriations that are available for such purpose.

(July 1, 1944, ch. 373, title III, §377A, as added Pub. L. 108–216, §4, Apr. 5, 2004, 118 Stat. 585.)

§274f–2. Grants regarding hospital organ donation coordinators

(a) Authority

(1) In general

The Secretary may award grants to qualified organ procurement organizations and hospitals under section 273 of this title to establish programs coordinating organ donation activities of eligible hospitals and qualified organ procurement organizations under section 273 of this title. Such activities shall be coordinated to increase the rate of organ donations for such hospitals.

(2) Eligible hospital

For purposes of this section, the term "eligible hospital" means a hospital that performs

significant trauma care, or a hospital or consortium of hospitals that serves a population base of not fewer than 200,000 individuals.

(b) Administration of coordination program

A condition for the receipt of a grant under subsection (a) is that the applicant involved agree that the program under such subsection will be carried out jointly—

(1) by representatives from the eligible hospital and the qualified organ procurement organization with respect to which the grant is made; and

(2) by such other entities as the representatives referred to in paragraph (1) may designate.

(c) Requirements

Each entity receiving a grant under subsection (a) shall—

(1) establish joint organ procurement organization and hospital designated leadership responsibility and accountability for the project;

(2) develop mutually agreed upon overall project performance goals and outcome measures, including interim outcome targets; and

(3) collaboratively design and implement an appropriate data collection process to provide ongoing feedback to hospital and organ procurement organization leadership on project progress and results.

(d) Rule of construction

Nothing in this section shall be construed to interfere with regulations in force on April 5, 2004.

(e) Evaluations

Within 3 years after the award of grants under this section, the Secretary shall ensure an evaluation of programs carried out pursuant to subsection (a) in order to determine the extent to which the programs have increased the rate of organ donation for the eligible hospitals involved.

(f) Matching requirement

The Secretary may not award a grant to a qualifying organ donation entity under this section unless such entity agrees that, with respect to costs to be incurred by the entity in carrying out activities for which the grant was awarded, the entity shall contribute (directly or through donations from public or private entities) non-Federal contributions in cash or in kind, in an amount equal to not less than 30 percent of the amount of the grant awarded to such entity.

(g) Funding

For the purpose of carrying out this section, there are authorized to be appropriated $3,000,000 for fiscal year 2005, and such sums as may be necessary for each of fiscal years 2006 through 2009.

(July 1, 1944, ch. 373, title III, §377B, as added Pub. L. 108–216, §4, Apr. 5, 2004, 118 Stat. 586.)

§274f–3. Studies relating to organ donation and the recovery, preservation, and transportation of organs

(a) Development of supportive information

The Secretary, acting through the Director of the Agency for Healthcare Research and Quality, shall develop scientific evidence in support of efforts to increase organ donation and improve the recovery, preservation, and transportation of organs.

(b) Activities

In carrying out subsection (a), the Secretary shall—

(1) conduct or support evaluation research to determine whether interventions, technologies, or other activities improve the effectiveness, efficiency, or quality of existing organ donation practice;

(2) undertake or support periodic reviews of the scientific literature to assist efforts of professional societies to ensure that the clinical practice guidelines that they develop reflect the

latest scientific findings;

(3) ensure that scientific evidence of the research and other activities undertaken under this section is readily accessible by the organ procurement workforce; and

(4) work in coordination with the appropriate professional societies as well as the Organ Procurement and Transplantation Network and other organ procurement and transplantation organizations to develop evidence and promote the adoption of such proven practices.

(c) Research and dissemination

The Secretary, acting through the Director of the Agency for Healthcare Research and Quality, as appropriate, shall provide support for research and dissemination of findings, to—

(1) develop a uniform clinical vocabulary for organ recovery;

(2) apply information technology and telecommunications to support the clinical operations of organ procurement organizations;

(3) enhance the skill levels of the organ procurement workforce in undertaking quality improvement activities; and

(4) assess specific organ recovery, preservation, and transportation technologies.

(d) Authorization of appropriations

For the purpose of carrying out this section, there are authorized to be appropriated $2,000,000 for fiscal year 2005, and such sums as may be necessary for each of fiscal years 2006 through 2009.

(July 1, 1944, ch. 373, title III, §377C, as added Pub. L. 108–216, §5, Apr. 5, 2004, 118 Stat. 587.)

§274f–4. Report relating to organ donation and the recovery, preservation, and transportation of organs

(a) In general

Not later than December 31, 2005, and every 2 years thereafter, the Secretary shall report to the appropriate committees of Congress on the activities of the Department carried out pursuant to this part, including an evaluation describing the extent to which the activities have affected the rate of organ donation and recovery.

(b) Requirements

To the extent practicable, each report submitted under subsection (a) shall—

(1) evaluate the effectiveness of activities, identify effective activities, and disseminate such findings with respect to organ donation and recovery;

(2) assess organ donation and recovery activities that are recently completed, ongoing, or planned; and

(3) evaluate progress on the implementation of the plan required under subsection (c)(5).

(c) Initial report requirements

The initial report under subsection (a) shall include the following:

(1) An evaluation of the organ donation practices of organ procurement organizations, States, other countries, and other appropriate organizations including an examination across all populations, including those with low organ donation rates, of—

(A) existing barriers to organ donation; and

(B) the most effective donation and recovery practices.

(2) An evaluation of living donation practices and procedures. Such evaluation shall include an assessment of issues relating to informed consent and the health risks associated with living donation (including possible reduction of long-term effects).

(3) An evaluation of—

(A) federally supported or conducted organ donation efforts and policies, as well as federally supported or conducted basic, clinical, and health services research (including research on

preservation techniques and organ rejection and compatibility); and

(B) the coordination of such efforts across relevant agencies within the Department and throughout the Federal Government.

(4) An evaluation of the costs and benefits of State donor registries, including the status of existing State donor registries, the effect of State donor registries on organ donation rates, issues relating to consent, and recommendations regarding improving the effectiveness of State donor registries in increasing overall organ donation rates.

(5) A plan to improve federally supported or conducted organ donation and recovery activities, including, when appropriate, the establishment of baselines and benchmarks to measure overall outcomes of these programs. Such plan shall provide for the ongoing coordination of federally supported or conducted organ donation and research activities.

(July 1, 1944, ch. 373, title III, §377D, as added Pub. L. 108–216, §6, Apr. 5, 2004, 118 Stat. 588.)

§274f–5. Criteria, standards, and regulations with respect to organs infected with HIV

(a) In general

Not later than 2 years after November 21, 2013, the Secretary shall develop and publish criteria for the conduct of research relating to transplantation of organs from donors infected with human immunodeficiency virus (in this section referred to as "HIV") into individuals who are infected with HIV before receiving such organ.

(b) Corresponding changes to standards and regulations applicable to research

Not later than 2 years after November 21, 2013, to the extent determined by the Secretary to be necessary to allow the conduct of research in accordance with the criteria developed under subsection (a)—

(1) the Organ Procurement and Transplantation Network shall revise the standards of quality adopted under section 274(b)(2)(E) of this title; and

(2) the Secretary shall revise section 121.6 of title 42, Code of Federal Regulations (or any successor regulations).

(c) Revision of standards and regulations generally

Not later than 4 years after November 21, 2013, and annually thereafter, the Secretary,[1] shall—

(1) review the results of scientific research in conjunction with the Organ Procurement and Transplantation Network to determine whether the results warrant revision of the standards of quality adopted under section 274(b)(2)(E) of this title with respect to donated organs infected with HIV and with respect to the safety of transplanting an organ with a particular strain of HIV into a recipient with a different strain of HIV;

(2) if the Secretary determines under paragraph (1) that such results warrant revision of the standards of quality adopted under section 274(b)(2)(E) of this title with respect to donated organs infected with HIV and with respect to transplanting an organ with a particular strain of HIV into a recipient with a different strain of HIV, direct the Organ Procurement and Transplantation Network to revise such standards, consistent with section 274 of this title and in a way that ensures the changes will not reduce the safety of organ transplantation; and

(3) in conjunction with any revision of such standards under paragraph (2), revise section 121.6 of title 42, Code of Federal Regulations (or any successor regulations).

(July 1, 1944, ch. 373, title III, §377E, as added Pub. L. 113–51, §2(b), Nov. 21, 2013, 127 Stat. 580.)

[1] *So in original. The comma probably should not appear.*

§274g. Authorization of appropriations

For the purpose of carrying out this part, there are authorized to be appropriated $8,000,000 for fiscal year 1991, and such sums as may be necessary for each of the fiscal years 1992 and 1993.

(July 1, 1944, ch. 373, title III, §378, as added Pub. L. 101–616, title II, §206(a), Nov. 16, 1990, 104 Stat. 3285; amended Pub. L. 105–196, §4(1), July 16, 1998, 112 Stat. 636.)

EDITORIAL NOTES

AMENDMENTS

1998—Pub. L. 105–196 made technical amendment relating to placement of section within part H of this subchapter.

PART H–1—Stephanie Tubbs Jones Gift of Life Medal

EDITORIAL NOTES

CODIFICATION

Part was enacted as part of the Stephanie Tubbs Jones Gift of Life Medal Act of 2008, and not as part of the Public Health Service Act which comprises this chapter.

§274i. Eligibility requirements for Stephanie Tubbs Jones Gift of Life Medal

(a) In general

Subject to the provisions of this section and the availability of funds under this part, any organ donor, or the family of any organ donor, shall be eligible for a Stephanie Tubbs Jones Gift of Life Medal (hereafter in this part referred to as a "medal").

(b) Documentation

The Secretary of Health and Human Services shall direct the entity operating the Organ Procurement and Transplantation Network to—

(1) establish an application procedure requiring the relevant organ procurement organization through which an individual or family of the individual made an organ donation, to submit to such entity documentation supporting the eligibility of the individual or the family, respectively, to receive a medal;

(2) determine through the documentation provided and, if necessary, independent investigation whether the individual or family, respectively, is eligible to receive such a medal; and

(3) arrange for the presentation to the relevant organ procurement organization all medals struck pursuant to section 274i–2 of this title to individuals or families that are determined to be eligible to receive medals.

(c) Limitation

(1) In general

Except as provided in paragraph (2), only 1 medal may be presented to a family under subsection (b). Such medal shall be presented to the donating family member, or in the case of a deceased donor, the family member who signed the consent form authorizing, or who otherwise authorized, the donation of the organ involved.

(2) Exception

In the case of a family in which more than 1 member is an organ donor, a medal may be

presented for each such organ donor.

(Pub. L. 110–413, §2, Oct. 14, 2008, 122 Stat. 4338.)

§274i–1. Solicitation of donations; prohibition on use of Federal funds

(a) In general

The Organ Procurement and Transplantation Network may collect funds to offset expenditures relating to the issuance of medals authorized under this part.

(b) Payment of funds

(1) In general

Except as provided in paragraph (2), all funds received by the Organ Procurement and Transplantation Network under subsection (a) shall be promptly paid by the Organ Procurement and Transplantation Network to the Secretary of Health and Human Services for purposes of purchasing medals under this part for distribution and paying the administrative costs of the Secretary of Health and Human Services and the Secretary of the Treasury in carrying out this part.

(2) Limitation

Not more than 7 percent of any funds received under subsection (a) may be used to pay administrative costs, and fundraising costs to solicit funds under subsection (a), incurred by the Organ Procurement and Transplantation Network in carrying out this part.

(c) Prohibition on use of Federal funds

No Federal funds (including amounts appropriated for use by the Organ Procurement and Transplantation Network) may be used for purposes of carrying out this part, including purchasing medals under this part or paying the administrative costs of the Secretary of Health and Human Services or the Secretary of the Treasury in carrying out this part.

(Pub. L. 110–413, §3, Oct. 14, 2008, 122 Stat. 4339.)

§274i–2. Design and production of medal

(a) In general

Subject to the provisions of this section, the Secretary of the Treasury shall design and strike the Stephanie Tubbs Jones Gift of Life Medals, each of which shall—

(1) weigh 250 grams;

(2) have a diameter of 3 inches; and

(3) consist of bronze.

(b) Design

(1) In general

The design of the medals shall commemorate the compassion and courage manifested by and the sacrifices made by organ donors and their families, and the medals shall bear suitable emblems, devices, and inscriptions.

(2) Selection

The design of medals struck under this section shall be—

(A) selected by the Secretary of the Treasury, in consultation with the Secretary of Health and Human Services, the Organ Procurement and Transplantation Network, interested members of the family of Stephanie Tubbs Jones, Dr. William H. Frist, and the Commission of Fine Arts; and

(B) reviewed by the Citizens Coin Advisory Committee.

(c) National medals

The medals struck pursuant to this section are national medals for purposes of chapter 51 of title 31.

(d) Striking and delivery of minimum-sized lots

The Secretary of the Treasury shall strike and deliver to the Secretary of Health and Human Services no fewer than 100 medals at any time pursuant to an order by such Secretary.

(e) Cost of medals

Medals struck under this section and sold to the Secretary of Health and Human Services for distribution in accordance with this part shall be sold to the Secretary of Health and Human Services at a price sufficient to cover the cost of designing and striking the medals, including labor, materials, dies, use of machinery, and overhead expenses.

(f) No expenditures in advance of receipt of fund

(1) In general

The Secretary of the Treasury shall not strike or distribute any medals under this part until such time as the Secretary of Health and Human Services certifies that sufficient funds have been received by such Secretary to cover the cost of the medals ordered.

(2) Design in advance of order

Notwithstanding paragraph (1), the Secretary of the Treasury may begin designing the medal at any time after October 14, 2008, and take such other action as may be necessary to be prepared to strike such medals upon receiving the certification described in such paragraph, including preparing dies and striking test pieces.

(Pub. L. 110–413, §4, Oct. 14, 2008, 122 Stat. 4339.)

§274i–3. Medals not treated as valuable consideration

A medal under this part shall not be treated as valuable consideration for purposes of section 274e(a) of this title.

(Pub. L. 110–413, §5, Oct. 14, 2008, 122 Stat. 4340.)

§274i–4. Definitions

For purposes of this part:

(1) Organ

The term "organ" has the meaning given such term in section 121.2 of title 42, Code of Federal Regulations.

(2) Organ procurement organization

The term "organ procurement organization" means a qualified organ procurement organization described in section 273(b)(1) of this title.

(3) Organ Procurement and Transplantation Network

The term "Organ Procurementand [1] Transplantation Network" means the Organ Procurement and Transplantation Network established under section 274 of this title.

(Pub. L. 110–413, §6, Oct. 14, 2008, 122 Stat. 4340.)

[1] *So in original. Probably should be "Procurement and".*

PART I—C.W. BILL YOUNG CELL TRANSPLANTATION PROGRAM

EDITORIAL NOTES

CODIFICATION

Pub. L. 109–129, §3(e), Dec. 20, 2005, 119 Stat. 2562, substituted "C.W. Bill Young Cell Transplantation Program" for "National Bone Marrow Donor Registry" in part heading.

Pub. L. 101–616, title I, §101(a)(2), Nov. 16, 1990, 104 Stat. 3279, added part I "National Bone Marrow Donor Registry" and redesignated former part I "Biomedical Ethics" as J.

Pub. L. 99–158, §§3(b), 11, Nov. 20, 1985, 99 Stat. 879, 883, added part I "Biomedical Ethics", and repealed former part I "National Library of Medicine".

Pub. L. 91–212, §10(a)(2), Mar. 13, 1970, 84 Stat. 66, redesignated part H "National Library of Medicine", as I. Former part I "Assistance to Medical Libraries" redesignated J.

§274k. National Program

(a) Establishment

The Secretary, acting through the Administrator of the Health Resources and Services Administration, shall by one or more contracts establish and maintain a C.W. Bill Young Cell Transplantation Program (referred to in this section as the "Program"), successor to the National Bone Marrow Donor Registry, that has the purpose of increasing the number of transplants for recipients suitably matched to biologically unrelated donors of bone marrow and cord blood, and that meets the requirements of this section. The Secretary may award a separate contract to perform each of the major functions of the Program described in paragraphs (1) and (2) of subsection (d) if deemed necessary by the Secretary to operate an effective and efficient system that is in the best interest of patients. The Secretary shall conduct a separate competition for the initial establishment of the cord blood functions of the Program. The Program shall be under the general supervision of the Secretary. The Secretary shall establish an Advisory Council to advise, assist, consult with, and make recommendations to the Secretary on matters related to the activities carried out by the Program. The members of the Advisory Council shall be appointed in accordance with the following:

(1) Each member of the Advisory Council shall serve for a term of 2 years, and each such member may serve as many as 3 consecutive 2-year terms, except that—

(A) such limitations shall not apply to the Chair of the Advisory Council (or the Chair-elect) or to the member of the Advisory Council who most recently served as the Chair; and

(B) one additional consecutive 2-year term may be served by any member of the Advisory Council who has no employment, governance, or financial affiliation with any donor center, recruitment organization, transplant center, or cord blood bank.

(2) A member of the Advisory Council may continue to serve after the expiration of the term of such member until a successor is appointed.

(3) In order to ensure the continuity of the Advisory Council, the Advisory Council shall be appointed so that each year the terms of approximately one-third of the members of the Advisory Council expire.

(4) The membership of the Advisory Council—

(A) shall include as voting members a balanced number of representatives including representatives of marrow donor centers and marrow transplant centers, representatives of cord blood banks and participating birthing hospitals, recipients of a bone marrow transplant, recipients of a cord blood transplant, persons who require such transplants, family members of such a recipient or family members of a patient who has requested the assistance of the Program in searching for an unrelated donor of bone marrow or cord blood, persons with expertise in

bone marrow and cord blood transplantation, persons with expertise in typing, matching, and transplant outcome data analysis, persons with expertise in the social sciences, basic scientists with expertise in the biology of adult stem cells, and members of the general public; and

(B) shall include as nonvoting members representatives from the Department of Defense Marrow Donor Recruitment and Research Program operated by the Department of the Navy, the Division of Transplantation of the Health Resources and Services Administration, the Food and Drug Administration, and the National Institutes of Health.

(5) Members of the Advisory Council shall be chosen so as to ensure objectivity and balance and reduce the potential for conflicts of interest. The Secretary shall establish bylaws and procedures—

(A) to prohibit any member of the Advisory Council who has an employment, governance, or financial affiliation with a donor center, recruitment organization, transplant center, or cord blood bank from participating in any decision that materially affects the center, recruitment organization, transplant center, or cord blood bank; and

(B) to limit the number of members of the Advisory Council with any such affiliation.

(6) The Secretary, acting through the Administrator of the Health Resources and Services Administration, shall submit to Congress an annual report on the activities carried out under this section.

(7) The Secretary shall convene the Advisory Council at least two times each calendar year.

(b) Accreditation

The Secretary shall, through a public process, recognize one or more accreditation entities for the accreditation of cord blood banks.

(c) Informed consent

The Secretary shall, through a public process, examine issues of informed consent, including—

(1) the appropriate timing of such consent; and

(2) the information provided to the maternal donor regarding all of her medically appropriate cord blood options.

Based on such examination, the Secretary shall require that the standards used by the accreditation entities recognized under subsection (b) ensure that a cord blood unit is acquired with the informed consent of the maternal donor.

(d) Functions

(1) Bone marrow functions

With respect to bone marrow, the Program shall—

(A) operate a system for identifying, matching, and facilitating the distribution of bone marrow that is suitably matched to candidate patients;

(B) consistent with paragraph (3), permit transplant physicians, other appropriate health care professionals, and patients to search by means of electronic access all available bone marrow donors listed in the Program;

(C) carry out a program for the recruitment of bone marrow donors in accordance with subsection (e), including with respect to increasing the representation of racial and ethnic minority groups (including persons of mixed ancestry) in the enrollment of the Program;

(D) maintain and expand medical contingency response capabilities, in coordination with Federal programs, to prepare for and respond effectively to biological, chemical, or radiological attacks, and other public health emergencies that can damage marrow, so that the capability of supporting patients with marrow damage from disease can be used to support casualties with marrow damage;

(E) carry out informational and educational activities in accordance with subsection (e);

(F) at least annually update information to account for changes in the status of individuals as

potential donors of bone marrow;

(G) provide for a system of patient advocacy through the office established under subsection (h);

(H) provide case management services for any potential donor of bone marrow to whom the Program has provided a notice that the potential donor may be suitably matched to a particular patient through the office established under subsection (h);

(I) with respect to searches for unrelated donors of bone marrow that are conducted through the system under subparagraph (A), collect, analyze, and publish data in a standardized electronic format on the number and percentage of patients at each of the various stages of the search process, including data regarding the furthest stage reached, the number and percentage of patients who are unable to complete the search process, and the reasons underlying such circumstances;

(J) support studies and demonstration and outreach projects for the purpose of increasing the number of individuals who are willing to be marrow donors to ensure a genetically diverse donor pool; and

(K) facilitate research with the appropriate Federal agencies to improve the availability, efficiency, safety, and cost of transplants from unrelated donors and the effectiveness of Program operations.

(2) Cord blood functions

(A) In general

With respect to cord blood, the Program shall—

(i) operate a system for identifying, matching, and facilitating the distribution of donated cord blood units that are suitably matched to candidate patients and meet all applicable Federal and State regulations (including informed consent and Food and Drug Administration regulations) from a qualified cord blood bank;

(ii) consistent with paragraph (3), allow transplant physicians, other appropriate health care professionals, and patients to search by means of electronic access all available cord blood units made available through the Program;

(iii) allow transplant physicians and other appropriate health care professionals to reserve, as defined by the Secretary, a cord blood unit for transplantation;

(iv) support and expand new and existing studies and demonstration and outreach projects for the purpose of increasing cord blood unit donation and collection from a genetically diverse population and expanding the number of cord blood unit collection sites partnering with cord blood banks receiving a contract under the National Cord Blood Inventory program under section 2 of the Stem Cell Therapeutic and Research Act of 2005, including such studies and projects that focus on—

(I) remote collection of cord blood units, consistent with the requirements under the Program and the National Cord Blood Inventory program goal described in section 2(a) of the Stem Cell Therapeutic and Research Act of 2005; and

(II) exploring novel approaches or incentives to encourage innovative technological advances that could be used to collect cord blood units, consistent with the requirements under the Program and such National Cord Blood Inventory program goal;

(v) provide for a system of patient advocacy through the office established under subsection (h);

(vi) coordinate with the qualified cord blood banks to support informational and educational activities in accordance with subsection (g);

(vii) maintain and expand medical contingency response capabilities, in coordination with Federal programs, to prepare for and respond effectively to biological, chemical, or radiological attacks, and other public health emergencies that can damage marrow, so that the capability of supporting patients with marrow damage from disease can be used to support casualties with marrow damage; and

(viii) with respect to the system under subparagraph (A), collect, analyze, and publish data in a standardized electronic format, as required by the Secretary, on the number and percentage of patients at each of the various stages of the search process, including data regarding the furthest stage reached, the number and percentage of patients who are unable to complete the search process, and the reasons underlying such circumstances.

(B) Efforts to increase collection of high quality cord blood units

In carrying out subparagraph (A)(iv), not later than 1 year after October 8, 2010, and annually thereafter, the Secretary shall set an annual goal of increasing collections of high quality cord blood units, including remote collection, consistent with the inventory goal described in section 2(a) of the Stem Cell Therapeutic and Research Act of 2005 (referred to in this subparagraph as the "inventory goal"), and shall identify at least one project under subparagraph (A)(iv) to replicate and expand nationwide, as appropriate.

(C) Definition

In this paragraph, the term "remote collection" means the collection of cord blood units at locations that do not have written contracts with cord blood banks for collection support.

(3) Single point of access; standard data

(A) Single point of access

The Secretary shall ensure that health care professionals and patients are able to search electronically for and facilitate access to, in the manner and to the extent defined by the Secretary and consistent with the functions described in paragraphs (1)(A) and (2)(A)(i), cells from bone marrow donors and cord blood units through a single point of access.

(B) Standard data

The Secretary shall require all recipients of contracts under this section to make available a standard dataset for purposes of subparagraph (A) in a standardized electronic format that enables transplant physicians to compare among and between bone marrow donors and cord blood units to ensure the best possible match for the patient.

(4) Definition

The term "qualified cord blood bank" means a cord blood bank that—

(A) has obtained all applicable Federal and State licenses, certifications, registrations (including pursuant to the regulations of the Food and Drug Administration), and other authorizations required to operate and maintain a cord blood bank;

(B) has implemented donor screening, cord blood collection practices, and processing methods intended to protect the health and safety of donors and transplant recipients to improve transplant outcomes, including with respect to the transmission of potentially harmful infections and other diseases;

(C) is accredited by an accreditation entity recognized by the Secretary under subsection (b);

(D) has established a system of strict confidentiality to protect the identity and privacy of patients and donors in accordance with existing Federal and State law;

(E) has established a system for encouraging donation by a genetically diverse group of donors; and

(F) has established a system to confidentially maintain linkage between a cord blood unit and a maternal donor.

(e) Bone marrow recruitment; priorities; information and education

(1) Recruitment; priorities

The Program shall carry out activities for the recruitment of bone marrow donors. Such recruitment program shall identify populations that are underrepresented among potential donors enrolled with the Program. In the case of populations that are identified under the preceding sentence:

(A) The Program shall give priority to carrying out activities under this part to increase

representation for such populations in order to enable a member of such a population, to the extent practicable, to have a probability of finding a suitable unrelated donor that is comparable to the probability that an individual who is not a member of an underrepresented population would have.

(B) The Program shall consider racial and ethnic minority groups (including persons of mixed ancestry) to be populations that have been identified for purposes of this paragraph, and shall carry out subparagraph (A) with respect to such populations.

(2) Information and education regarding recruitment; testing and enrollment

(A) In general

The Program shall carry out informational and educational activities, in coordination with organ donation public awareness campaigns operated through the Department of Health and Human Services, for purposes of recruiting individuals to serve as donors of bone marrow, and shall test and enroll with the Program potential bone marrow donors. Such information and educational activities shall include the following:

(i) Making information available to the general public, including information describing the needs of patients with respect to donors of bone marrow.

(ii) Educating and providing information to individuals who are willing to serve as potential bone marrow donors.

(iii) Training individuals in requesting individuals to serve as potential bone marrow donors.

(B) Priorities

In carrying out informational and educational activities under subparagraph (A), the Program shall give priority to recruiting individuals to serve as donors of bone marrow for populations that are identified under paragraph (1).

(3) Transplantation as treatment option

In addition to activities regarding recruitment, the recruitment program under paragraph (1) shall provide information to physicians, other health care professionals, and the public regarding bone marrow transplants from unrelated donors as a treatment option.

(4) Implementation of subsection

The requirements of this subsection shall be carried out by the entity that has been awarded a contract by the Secretary under subsection (a) to carry out the functions described in subsection (d)(1).

(f) Bone marrow criteria, standards, and procedures

The Secretary shall enforce, for participating entities, including the Program, individual marrow donor centers, marrow donor registries, marrow collection centers, and marrow transplant centers—

(1) quality standards and standards for tissue typing, obtaining the informed consent of donors, and providing patient advocacy;

(2) donor selection criteria, based on established medical criteria, to protect both the donor and the recipient and to prevent the transmission of potentially harmful infectious diseases such as the viruses that cause hepatitis and the etiologic agent for Acquired Immune Deficiency Syndrome;

(3) procedures to ensure the proper collection and transportation of the marrow;

(4) standards for the system for patient advocacy operated under subsection (h), including standards requiring the provision of appropriate information (at the start of the search process and throughout the process) to patients and their families and physicians;

(5) standards that—

(A) require the establishment of a system of strict confidentiality to protect the identity and privacy of patients and donors in accordance with Federal and State law; and

(B) prescribe the purposes for which the records described in subparagraph (A) may be disclosed, and the circumstances and extent of the disclosure; and

(6) in the case of a marrow donor center or marrow donor registry participating in the program, procedures to ensure the establishment of a method for integrating donor files, searches, and general procedures of the center or registry with the Program.

(g) Cord blood recruitment; priorities; information and education

(1) Recruitment; priorities

The Program shall support activities, in cooperation with qualified cord blood banks, for the recruitment of cord blood donors. Such recruitment program shall identify populations that are underrepresented among cord blood donors. In the case of populations that are identified under the preceding sentence:

(A) The Program shall give priority to supporting activities under this part to increase representation for such populations in order to enable a member of such a population, to the extent practicable, to have a probability of finding a suitable cord blood unit that is comparable to the probability that an individual who is not a member of an underrepresented population would have.

(B) The Program shall consider racial and ethnic minority groups (including persons of mixed ancestry) to be populations that have been identified for purposes of this paragraph, and shall support activities under subparagraph (A) with respect to such populations.

(2) Information and education regarding recruitment; testing and donation

(A) In general

In carrying out the recruitment program under paragraph (1), the Program shall support informational and educational activities in coordination with qualified cord blood banks and organ donation public awareness campaigns operated through the Department of Health and Human Services, for purposes of recruiting pregnant women to serve as donors of cord blood. Such information and educational activities shall include the following:

(i) Making information available to the general public, including information describing the needs of patients with respect to cord blood units.

(ii) Educating and providing information to pregnant women who are willing to donate cord blood units.

(iii) Training individuals in requesting pregnant women to serve as cord blood donors.

(B) Priorities

In carrying out informational and educational activities under subparagraph (A), the Program shall give priority to supporting the recruitment of pregnant women to serve as donors of cord blood for populations that are identified under paragraph (1).

(3) Transplantation as treatment option

In addition to activities regarding recruitment, the recruitment program under paragraph (1) shall provide information to physicians, other health care professionals, and the public regarding cord blood transplants from donors as a treatment option.

(4) Implementation of subsection

The requirements of this subsection shall be carried out by the entity that has been awarded a contract by the Secretary under subsection (a) to carry out the functions described in subsection (d)(2).

(h) Patient advocacy and case management for bone marrow and cord blood

(1) In general

The Secretary shall establish and maintain, through a contract or other means determined appropriate by the Secretary, an office of patient advocacy (in this subsection referred to as the "Office").

(2) General functions

The Office shall meet the following requirements:

(A) The Office shall be headed by a director.

(B) The Office shall be staffed by individuals with expertise in bone marrow and cord blood therapy covered under the Program.

(C) The Office shall operate a system for patient advocacy, which shall be separate from mechanisms for donor advocacy, and which shall serve patients for whom the Program is conducting, or has been requested to conduct, a search for a bone marrow donor or cord blood unit.

(D) In the case of such a patient, the Office shall serve as an advocate for the patient by directly providing to the patient (or family members, physicians, or other individuals acting on behalf of the patient) individualized services with respect to efficiently utilizing the system under paragraphs (1) and (2) of subsection (d) to conduct an ongoing search for a bone marrow donor or cord blood unit and assist with information regarding third party payor matters.

(E) In carrying out subparagraph (D), the Office shall monitor the system under paragraphs (1) and (2) of subsection (d) to determine whether the search needs of the patient involved are being met, including with respect to the following:

(i) Periodically providing to the patient (or an individual acting on behalf of the patient) information regarding bone marrow donors or cord blood units that are suitably matched to the patient, and other information regarding the progress being made in the search.

(ii) Informing the patient (or such other individual) if the search has been interrupted or discontinued.

(iii) Identifying and resolving problems in the search, to the extent practicable.

(F) The Office shall ensure that the following data are made available to patients:

(i) The resources available through the Program.

(ii) A comparison of transplant centers regarding search and other costs that prior to transplantation are charged to patients by transplant centers.

(iii) The post-transplant outcomes for individual transplant centers.

(iv) Information concerning issues that patients may face after a transplant.

(v) Such other information as the Program determines to be appropriate.

(G) The Office shall conduct surveys of patients (or family members, physicians, or other individuals acting on behalf of patients) to determine the extent of satisfaction with the system for patient advocacy under this subsection, and to identify ways in which the system can be improved to best meet the needs of patients.

(3) Case management

(A) In general

In serving as an advocate for a patient under paragraph (2), the Office shall provide individualized case management services directly to the patient (or family members, physicians, or other individuals acting on behalf of the patient), including—

(i) individualized case assessment; and

(ii) the functions described in paragraph (2)(D) (relating to progress in the search process).

(B) Postsearch functions

In addition to the case management services described in paragraph (1) for patients, the Office shall, on behalf of patients who have completed the search for a bone marrow donor or cord blood unit, provide information and education on the process of receiving a transplant, including the post-transplant process.

(i) Comment procedures

The Secretary shall establish and provide information to the public on procedures under which the Secretary shall receive and consider comments from interested persons relating to the manner in which the Program is carrying out the duties of the Program. The Secretary may promulgate regulations under this section.

(j) Consultation

In developing policies affecting the Program, the Secretary shall consult with the Advisory Council, the Department of Defense Marrow Donor Recruitment and Research Program operated by the Department of the Navy, and the board of directors of each entity awarded a contract under this section.

(k) Contracts

(1) Application

To be eligible to enter into a contract under this section, an entity shall submit to the Secretary and obtain approval of an application at such time, in such manner, and containing such information as the Secretary shall by regulation prescribe.

(2) Considerations

In awarding contracts under this section, the Secretary shall give consideration to the continued safety of donors and patients and other factors deemed appropriate by the Secretary.

(l) Eligibility

Entities eligible to receive a contract under this section shall include private nonprofit entities.

(m) Records

(1) Recordkeeping

Each recipient of a contract or subcontract under subsection (a) shall keep such records as the Secretary shall prescribe, including records that fully disclose the amount and disposition by the recipient of the proceeds of the contract, the total cost of the undertaking in connection with which the contract was made, and the amount of the portion of the cost of the undertaking supplied by other sources, and such other records as will facilitate an effective audit.

(2) Examination of records

The Secretary and the Comptroller General of the United States shall have access to any books, documents, papers, and records of the recipient of a contract or subcontract entered into under this section that are pertinent to the contract, for the purpose of conducting audits and examinations.

(n) Penalties for disclosure

Any person who discloses the content of any record referred to in subsection (d)(4)(D) or (f)(5)(A) without the prior written consent of the donor or potential donor with respect to whom the record is maintained, or in violation of the standards described in subsection (f)(5)(B), shall be imprisoned for not more than 2 years or fined in accordance with title 18, or both.

(o) Periodic review of state of science

(1) Review

Not less frequently than every 2 years, the Secretary, in consultation with the Director of the National Institutes of Health, the Commissioner of Food and Drugs, the Administrator of the Health Resources and Services Administration, the Advisory Council, and other stakeholders, where appropriate given relevant expertise, shall conduct a review of the state of the science of using adult stem cells and birthing tissues to develop new types of therapies for patients, for the purpose of considering the potential inclusion of such new types of therapies in the Program.

(2) Recommendations

Not later than June 30, 2025, the Secretary shall—

(A) complete the second review required by paragraph (1); and

(B) informed by such review, submit to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives recommendations on the appropriateness of the inclusion of new types of therapies in the Program.

(July 1, 1944, ch. 373, title III, §379, as added Pub. L. 101–616, title I, §101(a)(2), Nov. 16, 1990,

104 Stat. 3279; amended Pub. L. 105–196, §2(a), (b)(1), (c)–(g), July 16, 1998, 112 Stat. 631–635; Pub. L. 109–129, §3(a), Dec. 20, 2005, 119 Stat. 2553; Pub. L. 111–264, §2(b), Oct. 8, 2010, 124 Stat. 2791; Pub. L. 114–104, §2(a), Dec. 18, 2015, 129 Stat. 2216; Pub. L. 117–15, §2(a)–(c), May 26, 2021, 135 Stat. 277.)

EDITORIAL NOTES

REFERENCES IN TEXT

Section 2 of the Stem Cell Therapeutic and Research Act of 2005, referred to in subsec. (d)(2)(A)(iv), (B), is section 2 of Pub. L. 109–129, Dec. 20, 2005, 119 Stat. 2550, which is set out as a note under this section.

AMENDMENTS

2021—Subsec. (a)(7). Pub. L. 117–15, §2(a), added par. (7).

Subsec. (d)(2)(B). Pub. L. 117–15, §2(b)(2), struck out at end "If the Secretary cannot identify a project as described in the preceding sentence, the Secretary shall submit a plan, not later than 180 days after the date on which the Secretary was required to identify such a project, to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives for expanding collection of high quality cord blood units, consistent with the requirements under the National Cord Blood Inventory program under section 2 of the Stem Cell Therapeutic and Research Act of 2005 and the inventory goal. Each such plan shall be made available to the public."

Pub. L. 117–15, §2(b)(1), made technical amendment to directory language of Pub. L. 114–104, §2(a)(2). See 2015 Amendment note below.

Subsec. (o). Pub. L. 117–15, §2(c), added subsec. (o).

2015—Subsec. (d)(2)(B). Pub. L. 114–104, §2(a)(2), as amended by Pub. L. 117–15, §2(b)(1), inserted "including remote collection," after "goal of increasing collections of high quality cord blood units,".

Pub. L. 114–104, §2(a)(1), substituted "expanding collection" for "expanding remote collection".

2010—Subsec. (a)(6). Pub. L. 111–264, §2(b)(1), added par. (6) and struck out former par. (6) which read as follows: "The Secretary, acting through the Advisory Council, shall submit to the Congress—

"(A) an annual report on the activities carried out under this section; and

"(B) not later than 6 months after December 20, 2005, a report of recommendations on the scientific factors necessary to define a cord blood unit as a high-quality unit."

Subsec. (d)(2). Pub. L. 111–264, §2(b)(2)(A), designated existing provisions as subpar. (A), inserted heading, redesignated former subpars. (A) to (H) as cls. (i) to (viii), respectively, of subpar. (A), added cl. (iv) and struck out former cl. (iv) which related to studies and demonstration and outreach projects for the purpose of increasing cord blood donation, and added subpars. (B) and (C).

Subsec. (d)(3)(A). Pub. L. 111–264, §2(b)(2)(B), substituted "(2)(A)(i)" for "(2)(A)".

Subsec. (f)(5)(A). Pub. L. 111–264, §2(b)(3), added subpar. (A) and struck out former subpar. (A) which read as follows: "require the establishment of a system of strict confidentiality of records relating to the identity, address, HLA type, and managing marrow donor center for marrow donors and potential marrow donors; and".

2005—Pub. L. 109–129 amended section generally, substituting provisions relating to the C.W. Bill Young Cell Transplantation Program for provisions relating to the National Bone Marrow Donor Registry.

1998—Subsec. (a). Pub. L. 105–196, §2(a), substituted "(referred to in this part as the 'Registry') that has the purpose of increasing the number of transplants for recipients suitably matched to biologically unrelated donors of bone marrow, and that meets" for "(referred to in this part as the 'Registry') that meets" and substituted "under the direction of a board of directors meeting the following requirements:" and pars. (1) to (4) for "under the direction of a board of directors that shall include representatives of marrow donor centers, marrow transplant centers, persons with expertise in the social science, and the general public."

Subsec. (b)(2) to (8). Pub. L. 105–196, §2(b)(1), added pars. (2) to (7), redesignated former par. (7) as (8), and struck out former pars. (2) to (6) which read as follows:

"(2) establish a system for patient advocacy, separate from mechanisms for donor advocacy, that directly assists patients, their families, and their physicians in the search for an unrelated marrow donor;

"(3) increase the representation of individuals from racial and ethnic minority groups in the pool of potential donors for the Registry in order to enable an individual in a minority group, to the extent practicable, to have a comparable chance of finding a suitable unrelated donor as would an individual not in a minority group;

"(4) provide information to physicians, other health care professionals, and the public regarding bone

marrow transplantation;

"(5) recruit potential bone marrow donors;

"(6) collect, analyze, and publish data concerning bone marrow donation and transplantation; and".

Subsecs. (c), (d). Pub. L. 105–196, §2(c), (d), added subsecs. (c) and (d). Former subsecs. (c) and (d) redesignated (e) and (f), respectively.

Subsec. (e). Pub. L. 105–196, §2(c), redesignated subsec. (c) as (e). Former subsec. (e) redesignated (g).

Subsec. (e)(4). Pub. L. 105–196, §2(e), added par. (4) and struck out former par. (4) which read as follows: "standards that require the provision of information to patients, their families, and their physicians at the start of the search process concerning—

"(A) the resources available through the Registry;

"(B) all other marrow donor registries meeting the standards described in this paragraph; and

"(C) in the case of the Registry—

"(i) the comparative costs of all charges by marrow transplant centers incurred by patients prior to transplantation; and

"(ii) the success rates of individual marrow transplant centers;".

Subsec. (f). Pub. L. 105–196, §2(c), (g)(1), redesignated subsec. (d) as (f) and substituted "subsection (e)" for "subsection (c)". Former subsec. (f) redesignated (h).

Subsecs. (g) to (i). Pub. L. 105–196, §2(c), redesignated subsecs. (e) to (g) as (g) to (i), respectively. Former subsecs. (h) and (i) redesignated (j) and (k), respectively.

Subsec. (j). Pub. L. 105–196, §2(c), redesignated subsec. (h) as (j) and struck out heading and text of former subsec. (j). Text read as follows: "There are authorized to be appropriated to carry out this section $15,000,000 for fiscal year 1991 and such sums as may be necessary for each of fiscal years 1992 and 1993."

Subsec. (k). Pub. L. 105–196, §2(c), (g)(2), redesignated subsec. (i) as (k) and substituted "subsection (e)(5)(A)" for "subsection (c)(5)(A)" and "subsection (e)(5)(B)" for "subsection (c)(5)(B)".

Subsec. (l). Pub. L. 105–196, §2(f), added subsec. (l).

STATUTORY NOTES AND RELATED SUBSIDIARIES

EFFECTIVE DATE OF 2021 AMENDMENT

Pub. L. 117–15, §2(b)(1), May 26, 2021, 135 Stat. 277, provided that the amendment made by section 2(b)(1) is effective as if included in the enactment of the Stem Cell Therapeutic and Research Reauthorization Act of 2015 (Pub. L. 114–104).

EFFECTIVE DATE OF 1998 AMENDMENT

Pub. L. 105–196, §7, July 16, 1998, 112 Stat. 637, provided that: "This Act [see Short Title of 1998 Amendment note set out under section 201 of this title] takes effect October 1, 1998, or upon the date of the enactment of this Act [July 16, 1998], whichever occurs later."

SAVINGS PROVISION

Pub. L. 101–616, title I, §102, Nov. 16, 1990, 104 Stat. 3282, provided that:

"(a) IN GENERAL.—This title [enacting this section and section 274l of this title and amending section 274a of this title], and the amendments made by this title, shall not affect any legal document, including any order, regulation, grant, or contract, in effect on the date of enactment of this Act [Nov. 16, 1990], or any administrative proceeding or lawsuit pending on the date, that relates to the bone marrow registry established under section 373(b) of the Public Health Service Act [42 U.S.C. 274a(b)] (as it existed before the amendment made by section 101(b) of this Act).

"(b) CONTINUED EFFECT.—A legal document described in subsection (a) or an order issued in a lawsuit described in subsection (a) shall continue in effect until modified, terminated, or revoked.

"(c) PROCEEDINGS.—In any administrative proceeding or lawsuit described in subsection (a), parties shall take appeals, and officials shall hold proceedings and render judgments, in the same manner and with the same effect as if this title had not been enacted."

CORD BLOOD INVENTORY

Pub. L. 109–129, §2, Dec. 20, 2005, 119 Stat. 2550, as amended by Pub. L. 111–264, §2(a), Oct. 8, 2010, 124 Stat. 2789; Pub. L. 114–104, §3, Dec. 18, 2015, 129 Stat. 2217; Pub. L. 117–15, §3, May 26, 2021, 135 Stat. 278, provided that:

"(a) IN GENERAL.—The Secretary of Health and Human Services shall enter into contracts with qualified cord blood banks to assist in the collection and maintenance of the inventory goal of at least 150,000 new

units of high-quality cord blood to be made available for transplantation through the C.W. Bill Young Cell Transplantation Program and to carry out the requirements of subsection (b).

"(b) REQUIREMENTS.—The Secretary shall require each recipient of a contract under this section—

"(1) to acquire, tissue-type, test, cryopreserve, and store donated units of cord blood acquired with the informed consent of the donor, as determined by the Secretary pursuant to section 379(c) of the Public Health Service Act [42 U.S.C. 274k(c)], in a manner that complies with applicable Federal and State regulations;

"(2) to encourage donation from a genetically diverse population;

"(3) to make cord blood units that are collected pursuant to this section or otherwise and meet all applicable Federal standards available to transplant centers for transplantation;

"(4) to make cord blood units that are collected, but not appropriate for clinical use, available for peer-reviewed research;

"(5) to make data available, as required by the Secretary and consistent with section 379(d)(3) of the Public Health Service Act (42 U.S.C. 274k(d)(3)), as amended by this Act, in a standardized electronic format, as determined by the Secretary, for the C.W. Bill Young Cell Transplantation Program; and

"(6) to submit data in a standardized electronic format for inclusion in the stem cell therapeutic outcomes database maintained under section 379A of the Public Health Service Act [42 U.S.C. 274l], as amended by this Act.

"(c) APPLICATION.—To seek to enter into a contract under this section, a qualified cord blood bank shall submit an application to the Secretary at such time, in such manner, and containing such information as the Secretary may reasonably require. At a minimum, an application for a contract under this section shall include a requirement that the applicant—

"(1) will participate in the C.W. Bill Young Cell Transplantation Program for a period of at least 10 years beginning on the last date on which the recipient of a contract under this section receives Federal funds under this section;

"(2) will make cord blood units collected pursuant to this section available through the C.W. Bill Young Cell Transplantation Program in perpetuity or for such time as determined viable by the Secretary;

"(3) will provide a plan to increase cord blood unit collections at collection sites that exist at the time of application, assist with the establishment of new collection sites, or contract with new collection sites;

"(4) will annually provide to the Secretary a plan for, and demonstrate, ongoing measurable progress toward achieving self-sufficiency of cord blood unit collection and banking operations; and

"(5) if the Secretary determines through an assessment, or through petition by the applicant, that a cord blood bank is no longer operational or does not meet the requirements of section 379(d)(4) of the Public Health Service Act [42 U.S.C. 274k(d)(4)] (as added by this Act) and as a result may not distribute the units, transfer the units collected pursuant to this section to another qualified cord blood bank approved by the Secretary to ensure continued availability of cord blood units.

"(d) DURATION OF CONTRACTS.—

"(1) IN GENERAL.—Except as provided in paragraph (2), the term of each contract entered into by the Secretary under this section shall be for a period of at least 10 years beginning on the last date on which the recipient of a contract under this section receives Federal funds under this section. The Secretary shall ensure that no Federal funds shall be obligated under any such contract after the date that is 5 years after the date on which the contract is entered into, except as provided in paragraphs (2), (3), and (4).

"(2) EXTENSIONS.—The Secretary may extend the period of funding under a contract under this section to exceed a period of 5 years if—

"(A) the Secretary finds that the inventory goal described in subsection (a) has not yet been met;

"(B) the Secretary does not receive an application for a contract under this section meeting the requirements under subsection (c) from any qualified cord blood bank that has not previously entered into a contract under this section; or

"(C) the Secretary determines that the outstanding inventory need cannot be met by the qualified cord blood banks under contract under this section.

"(3) EXTENSION ELIGIBILITY.—A qualified cord blood bank shall be eligible for a 5-year extension of a contract awarded under this section, as described in paragraph (2), provided that the qualified cord blood bank—

"(A) demonstrates a superior ability to satisfy the requirements described in subsection (b) and achieves the overall goals for which the contract was awarded;

"(B) provides a plan for how the qualified cord blood bank will increase cord blood unit collections at collection sites that exist at the time of consideration for such extension of a contract, assist with the establishment of new collection sites, or contract with new collection sites; and

"(C) annually provides to the Secretary a plan for, and demonstrates, ongoing measurable progress toward achieving self-sufficiency of cord blood unit collection and banking operations.

"(4) CONSIDERATION OF BEST SCIENCE.—The Secretary shall take into consideration the best scientific information available in order to maximize the number of cord blood units available for transplant when entering into contracts under this section, or when extending a period of funding under such a contract under paragraph (2).

"(5) CONSIDERATION OF BANKED UNITS OF CORD BLOOD.—In extending contracts pursuant to paragraph (3), and determining new allocation amounts for the next contract period or contract extension for such cord blood bank, the Secretary shall take into account the number of cord blood units banked in the National Cord Blood Inventory by a cord blood bank during the previous contract period, in addition to consideration of the ability of such cord blood bank to increase the collection and maintenance of additional, genetically diverse cord blood units.

"(e) REGULATIONS.—The Secretary may promulgate regulations to carry out this section.

"(f) DEFINITIONS.—In this section:

"(1) The term 'C.W. Bill Young Cell Transplantation Program' means the C.W. Bill Young Cell Transplantation Program under section 379 of the Public Health Service Act [42 U.S.C. 274k], as amended by this Act.

"(2) The term 'cord blood donor' means a mother who has delivered a baby and consents to donate the neonatal blood remaining in the placenta and umbilical cord after separation from the newborn baby.

"(3) The term 'cord blood unit' means the neonatal blood collected from the placenta and umbilical cord of a single newborn baby.

"(4) The term 'qualified cord blood bank' has the meaning given to that term in section 379(d)(4) of the Public Health Service Act [42 U.S.C. 274k(d)(4)], as amended by this Act.

"(5) The term 'Secretary' means the Secretary of Health and Human Services.

"(g) AUTHORIZATION OF APPROPRIATIONS.—To carry out this section, there is authorized to be appropriated $23,000,000 for each of fiscal years 2022 through 2026."

REPORT OF INSPECTOR GENERAL; PLAN REGARDING RELATIONSHIP BETWEEN REGISTRY AND DONOR CENTERS

Pub. L. 105–196, §2(b)(2), July 16, 1998, 112 Stat. 632, directed the Secretary of Health and Human Services to ensure that, not later than 1 year after July 16, 1998, the National Bone Marrow Donor Registry (under this section) developed, evaluated, and implemented a plan to effectuate efficiencies in the relationship between such Registry and donor centers.

STUDY BY GAO

Pub. L. 105–196, §5, July 16, 1998, 112 Stat. 636, provided that the Comptroller General was to conduct a study of the National Bone Marrow Donor Registry under this section to determine the extent to which the Registry had increased the representation of racial and ethnic minority groups among potential donors enrolled with the Registry and whether the extent of increase resulted in a level of representation that met the standard established in subsec. (c)(1)(A) of this section, the extent to which patients in need of a transplant of bone marrow from a biologically unrelated donor, and the physicians of such patients, had been utilizing the Registry, the number of patients for whom the Registry began a preliminary but not complete search process and the reasons underlying such circumstances, the extent to which the plan required in section 2(b)(2) of Pub. L. 105–196 (42 U.S.C. 274k note) had been implemented, and the extent to which the Registry, donor centers, donor registries, collection centers, transplant centers, and other appropriate entities had been complying with subsec. (e) of this section; and provided that a report describing the findings of this study was to be submitted to Congress not later than Oct. 1, 2001, and not before Jan. 1, 2001.

COMPLIANCE WITH NEW REQUIREMENTS FOR OFFICE OF PATIENT ADVOCACY

Pub. L. 105–196, §6, July 16, 1998, 112 Stat. 636, provided that with respect to requirements for the office of patient advocacy under subsec. (d) of this section, the Secretary of Health and Human Services was to ensure that, not later than 180 days after Oct. 1, 1998, such office was in compliance with all requirements that were additional to the requirements under this section in effect with respect to patient advocacy on the day before July 16, 1998.

§274*l*. Stem cell therapeutic outcomes database

(a) Establishment

The Secretary shall by contract establish and maintain a scientific database of information relating to patients who have been recipients of a stem cell therapeutics product (including bone marrow, cord blood, or other such product) from a donor.

(b) Information

The outcomes database shall include information in a standardized electronic format with respect to patients described in subsection (a), diagnosis, transplant procedures, results, long-term follow-up, and such other information as the Secretary determines to be appropriate, to conduct an ongoing evaluation of the scientific and clinical status of transplantation involving recipients of a stem cell therapeutics product from a donor.

(c) Annual report on patient outcomes

The Secretary shall require the entity awarded a contract under this section to submit to the Secretary an annual report concerning patient outcomes with respect to each transplant center, based on data collected and maintained by the entity pursuant to this section.

(d) Publicly available data

The outcomes database shall make relevant scientific information not containing individually identifiable information available to the public in the form of summaries and data sets to encourage medical research and to provide information to transplant programs, physicians, patients, entities awarded a contract under section 274k of this title [1] donor registries, and cord blood banks.

(July 1, 1944, ch. 373, title III, §379A, as added Pub. L. 105–196, §3, July 16, 1998, 112 Stat. 635; amended Pub. L. 109–129, §3(b), Dec. 20, 2005, 119 Stat. 2561.)

EDITORIAL NOTES

PRIOR PROVISIONS

A prior section 274l, act July 1, 1944, ch. 373, title III, §379A, as added Pub. L. 101–616, title I, §101(a)(2), Nov. 16, 1990, 104 Stat. 3282, related to study by General Accounting Office, prior to repeal by Pub. L. 105–196, §§3, 7, July 16, 1998, 112 Stat. 635, 637, effective Oct. 1, 1998.

AMENDMENTS

2005—Pub. L. 109–129, amended section generally, substituting provisions relating to the stem cell therapeutic outcomes database for provisions relating to the bone marrow scientific registry.

STATUTORY NOTES AND RELATED SUBSIDIARIES

EFFECTIVE DATE

Section effective Oct. 1, 1998, see section 7 of Pub. L. 105–196, set out as an Effective Date of 1998 Amendment note under section 274k of this title.

[1] So in original. Probably should be followed by a comma.

§274*l*–1. Definitions

In this part:

(1) The term "Advisory Council" means the advisory council established by the Secretary under section 274k(a)(1) of this title.

(2) The term "bone marrow" means the cells found in adult bone marrow and peripheral blood.

(3) The term "outcomes database" means the database established by the Secretary under section 274l of this title.

(4) The term "Program" means the C.W. Bill Young Cell Transplantation Program established

under section 274k of this title.

(July 1, 1944, ch. 373, title III, §379A–1, as added Pub. L. 109–129, §3(c), Dec. 20, 2005, 119 Stat. 2562.)

§274m. Authorization of appropriations

For the purpose of carrying out this part, there are authorized to be appropriated $31,009,000 for each of fiscal years 2022 through 2026.

(July 1, 1944, ch. 373, title III, §379B, as added Pub. L. 105–196, §4(2), July 16, 1998, 112 Stat. 636; amended Pub. L. 109–129, §3(d), Dec. 20, 2005, 119 Stat. 2562; Pub. L. 111–264, §2(d), Oct. 8, 2010, 124 Stat. 2792; Pub. L. 114–104, §2(b), Dec. 18, 2015, 129 Stat. 2216; Pub. L. 117–15, §2(d), May 26, 2021, 135 Stat. 278.)

EDITORIAL NOTES

AMENDMENTS

2021—Pub. L. 117–15 substituted "$31,009,000 for each of fiscal years 2022 through 2026" for "$33,000,000 for fiscal year 2015 and $30,000,000 for each of fiscal years 2016 through 2020".

2015—Pub. L. 114–104 struck out "$30,000,000 for each of fiscal years 2011 through 2014 and" after "to be appropriated" and inserted "and $30,000,000 for each of fiscal years 2016 through 2020" after "fiscal year 2015".

2010—Pub. L. 111–264 substituted "$30,000,000 for each of fiscal years 2011 through 2014 and $33,000,000 for fiscal year 2015." for "$34,000,000 for fiscal year 2006 and $38,000,000 for each of fiscal years 2007 through 2010."

2005—Pub. L. 109–129 amended section generally. Prior to amendment, section read as follows: "For the purpose of carrying out this part, there are authorized to be appropriated $18,000,000 for fiscal year 1999, and such sums as may be necessary for each of the fiscal years 2000 through 2003."

STATUTORY NOTES AND RELATED SUBSIDIARIES

EFFECTIVE DATE

Section effective Oct. 1, 1998, see section 7 of Pub. L. 105–196, set out as an Effective Date of 1998 Amendment note under section 274k of this title.

§275. Repealed. Pub. L. 103–43, title I, §121(a), June 10, 1993, 107 Stat. 133

Section, act July 1, 1944, ch. 373, title III, §381, as added Nov. 20, 1985, Pub. L. 99–158, §11, 99 Stat. 883; amended Nov. 4, 1988, Pub. L. 100–607, title I, §157(a), 102 Stat. 3059, established the Biomedical Ethics Board and provided for its membership, functions, reports to Congress, etc., and provided for appointment of a Biomedical Ethics Advisory Committee to assist the Biomedical Ethics Board.

A prior section 275, act July 1, 1944, ch. 373, title III, §381, formerly §371, as added Aug. 3, 1956, ch. 907, §1, 70 Stat. 960; renumbered §381, Mar. 13, 1970, Pub. L. 91–212, §10(a)(3), 84 Stat. 66, established a National Library of Medicine in the Public Health Service and stated the congressional purposes for such establishment, prior to repeal by Pub. L. 99–158, §3(b), Nov. 20, 1985, 99 Stat. 879.

§§276 to 280a–1. Repealed. Pub. L. 99–158, §3(b), Nov. 20, 1985, 99 Stat. 879

Section 276, act July 1, 1944, ch. 373, title III, §382, formerly §372, as added Aug. 3, 1956, ch. 907, §1, 70 Stat. 960; renumbered §382 and amended Mar. 13, 1970, Pub. L. 91–212, §10(a)(3), (b)(1), (d)(1), 84 Stat. 66, 67; Nov. 18, 1971, Pub. L. 92–157, title III, §301(d)(1), 85 Stat. 463, related to functions of Secretary with regard to acquisition, etc., of materials and rules for public access to materials.

Section 277, act July 1, 1944, ch. 373, title III, §383, formerly §373, as added Aug. 3, 1956, ch. 907, §1, 70 Stat. 960; amended Oct. 22, 1965, Pub. L. 89–291, §4, 79 Stat. 1067; renumbered §383 and amended Mar. 13,

1970, Pub. L. 91–212, §10(a)(3), (d)(1), 84 Stat. 66, 67; Oct. 30, 1970, Pub. L. 91–515, title VI, §601(b)(2), 84 Stat. 1311; Nov. 18, 1971, Pub. L. 92–157, title III, §301(d)(2), 85 Stat. 464; Nov. 9, 1978, Pub. L. 95–622, title II, §212, 92 Stat. 3421, related to establishment, etc., of Board of Regents.

Section 278, act July 1, 1944, ch. 373, title III, §384, formerly §374, as added Aug. 3, 1956, ch. 907, §1, 70 Stat. 961; renumbered §384 and amended Mar. 13, 1970, Pub. L. 91–212, §10(a)(3), (d)(1), 84 Stat. 66, 67; Oct. 17, 1979, Pub. L. 96–88, title V, §509(b), 93 Stat. 695; Apr. 26, 1983, Pub. L. 98–24, §2(a)(2), 97 Stat. 176, related to acceptance and administration of gifts and establishment of memorials to donors.

Section 279, act July 1, 1944, ch. 373, title III, §385, formerly §375, as added Aug. 3, 1956, ch. 907 §1, 70 Stat. 962; renumbered §385 and amended Mar. 13, 1970, Pub. L. 91–212, §10(a)(3), (b)(2), 84 Stat. 66, defined "medicine" and "medical".

Section 280, act July 1, 1944, ch. 373, title III, §386, formerly §376, as added Aug. 3, 1956, ch. 907, §1, 70 Stat. 962; renumbered §386 and amended Mar. 13, 1970, Pub. L. 91–212, §10(a)(3), (d)(1), 84 Stat. 66, 67; Nov. 18, 1971, Pub. L. 92–157, title III, §301(d)(3), 85 Stat. 464, authorized appropriations for erection and equipment of Library.

Section 280a, act July 1, 1944, ch. 373, title III, §387, formerly §377, as added Aug. 3, 1956, ch. 907, §1, 70 Stat. 962; amended 1970 Reorg. Plan No. 2 §102, eff. July 1, 1970, 35 F.R. 7959, 84 Stat. 2085; renumbered §387, Mar. 13, 1970, Pub. L. 91–212, §10(a)(3), 84 Stat. 66, related to transfer of Armed Forces Medical Library to Public Health Service for use in administration of part I.

Section 280a–1, act July 1, 1944, ch. 373, title III, §388, formerly §378, as added Oct. 22, 1965, Pub. L. 89–291, §3, 79 Stat. 1067; renumbered §388 and amended Mar. 13, 1970, Pub. L. 91–212, §10(a)(3), (d)(1), 84 Stat. 66, 67; Nov. 18, 1971, Pub. L. 92–157, title III, §301(d)(4), 85 Stat. 464, related to establishment of regional branches.

PART J—PREVENTION AND CONTROL OF INJURIES

EDITORIAL NOTES

CODIFICATION

Pub. L. 103–183, title II, §203(a)(1), Dec. 14, 1993, 107 Stat. 2232, substituted "Prevention and Control of Injuries" for "Injury Control" in part heading.

Pub. L. 103–43, title I, §121(a), title XX, §2008(i)(2)(B)(i), June 10, 1993, 107 Stat. 133, 213, redesignated part K "Injury Control" as J and repealed former part J "Biomedical Ethics".

Pub. L. 101–616, title I, §101(a)(1), Nov. 16, 1990, 104 Stat. 3279, redesignated part I "Biomedical Ethics" as J. Former part J "Injury Control" redesignated K.

Pub. L. 99–649, §3, Nov. 10, 1986, 100 Stat. 3633, added part J "Injury Control".

Pub. L. 99–158, §3(b), Nov. 20, 1985, 99 Stat. 879, repealed part J "Assistance to Medical Libraries".

Pub. L. 91–212, §10(a)(1), Mar. 13, 1970, 84 Stat. 66, redesignated part I "Assistance to Medical Libraries" as J.

§280b. Research

(a) The Secretary, through the Director of the Centers for Disease Control and Prevention, shall—

(1) conduct, and give assistance to public and nonprofit private entities, scientific institutions, and individuals engaged in the conduct of, research relating to the causes, mechanisms, prevention, diagnosis, treatment of injuries, and rehabilitation from injuries;

(2) make grants to, or enter into cooperative agreements or contracts with, public and nonprofit private entities (including academic institutions, hospitals, and laboratories) and individuals for the conduct of such research; and

(3) make grants to, or enter into cooperative agreements or contracts with, academic institutions for the purpose of providing training on the causes, mechanisms, prevention, diagnosis, treatment of injuries, and rehabilitation from injuries.

(b) The Secretary, through the Director of the Centers for Disease Control and Prevention, shall

collect and disseminate, through publications and other appropriate means, information concerning the practical applications of research conducted or assisted under subsection (a). In carrying out the preceding sentence, the Secretary shall disseminate such information to the public, including through elementary and secondary schools.

(July 1, 1944, ch. 373, title III, §391, as added Pub. L. 99–649, §3, Nov. 10, 1986, 100 Stat. 3633; amended Pub. L. 101–558, §2(a), Nov. 15, 1990, 104 Stat. 2772; Pub. L. 102–531, title III, §312(d)(3), Oct. 27, 1992, 106 Stat. 3504; Pub. L. 103–183, title II, §203(b)(2), Dec. 14, 1993, 107 Stat. 2232.)

EDITORIAL NOTES

PRIOR PROVISIONS

A prior section 280b, act July 1, 1944, ch. 373, title III, §390, as added Oct. 22, 1965, Pub. L. 89–291, §2, 79 Stat. 1059; amended Mar. 13, 1970, Pub. L. 91–212, §§4(b), 5(b), 6(b), 84 Stat. 64, 65; July 23, 1974, Pub. L. 93–353, title II, §§201(a), (b), 202(a), 88 Stat. 371, 372; Aug. 1, 1977, Pub. L. 95–83, title II, §202, 91 Stat. 386; Nov. 9, 1978, Pub. L. 95–622, title II, §211, 92 Stat. 3420; Aug. 13, 1981, Pub. L. 97–35, title IX, §925(a), 95 Stat. 569, set forth findings and declaration of policy and authorized appropriations with regard to assistance to medical libraries, prior to repeal by Pub. L. 99–158, §3(b), Nov. 20, 1985, 99 Stat. 879.

A prior section 391 of act July 1, 1944, ch. 373, title III, as added Oct. 22, 1965, Pub. L. 89–291, §2, 79 Stat. 1059; amended Mar. 13, 1970, Pub. L. 91–212, §10(b)(3), 84 Stat. 66; July 23, 1974, Pub. L. 93–353, title II, §202(b), 88 Stat. 372, which defined "sciences related to health", "National Medical Libraries Assistance Advisory Board", "Board", and "medical library", was classified to section 280b–1 of this title, prior to repeal by Pub. L. 99–158, §3(b), Nov. 20, 1985, 99 Stat. 879.

AMENDMENTS

1993—Subsec. (b). Pub. L. 103–183 inserted at end "In carrying out the preceding sentence, the Secretary shall disseminate such information to the public, including through elementary and secondary schools."

1992—Pub. L. 102–531 substituted "Centers for Disease Control and Prevention" for "Centers for Disease Control" in subsecs. (a) and (b).

1990—Subsec. (a)(2). Pub. L. 101–558, §2(a)(1), inserted ", or enter into cooperative agreements or contracts with," after "grants to".

Subsec. (a)(3). Pub. L. 101–558, §2(a)(2), added par. (3).

STATUTORY NOTES AND RELATED SUBSIDIARIES

FINDINGS AND PURPOSES

Pub. L. 99–649, §2, Nov. 10, 1986, 100 Stat. 3633, provided that:

"(a) The Congress finds and declares that:

"(1) Injury is one of the principal public health problems in America, and causes over 140,000 deaths per year.

"(2) Injury rates are particularly high for children and the elderly.

"(3) Injury causes 50 percent of all deaths for children over the age of one year and two-thirds of all deaths for children over the age of 15 years, and is the leading cause of death for individuals under the age of 44 years. Individuals over the age of 65 years have the highest fatality rates for many injuries.

"(4) Injury control has not been given high priority in the United States, and the research being conducted on injury control and the number of personnel involved in injury control activities are not adequate.

"(b) The purposes of this Act [enacting this part] are—

"(1) to promote research into the causes, diagnosis, treatment, prevention, and control of injuries and rehabilitation from injuries;

"(2) to promote cooperation between specialists in fields involved in injury research; and

"(3) to promote coordination between Federal, State, and local governments and public and private entities in order to achieve a reduction in deaths from injuries."

§280b–0. Prevention and control activities

(a) The Secretary, through the Director of the Centers for Disease Control and Prevention, shall—

(1) assist States and political subdivisions of States in activities for the prevention and control of injuries; and

(2) encourage regional activities between States designed to reduce injury rates.

(b) The Secretary, through the Director of the Centers for Disease Control and Prevention, may—

(1) enter into agreements between the Service and public and private community health agencies which provide for cooperative planning of activities to deal with problems relating to the prevention and control of injuries;

(2) work in cooperation with other Federal agencies, and with public and nonprofit private entities, to promote activities regarding the prevention and control of injuries; and

(3) make grants to States and, after consultation with State health agencies, to other public or nonprofit private entities for the purpose of carrying out demonstration projects for the prevention and control of injuries at sites that are not subject to the Occupational Safety and Health Act of 1970 [29 U.S.C. 651 et seq.], including homes, elementary and secondary schools, and public buildings.

(July 1, 1944, ch. 373, title III, §392, as added Pub. L. 99–649, §3, Nov. 10, 1986, 100 Stat. 3634; amended Pub. L. 101–558, §2(b), Nov. 15, 1990, 104 Stat. 2772; Pub. L. 102–531, title III, §§301, 312(d)(4), Oct. 27, 1992, 106 Stat. 3482, 3504; Pub. L. 103–183, title II, §203(a)(2), (b)(1), Dec. 14, 1993, 107 Stat. 2232.)

EDITORIAL NOTES

REFERENCES IN TEXT

The Occupational Safety and Health Act of 1970, referred to in subsec. (b)(3), is Pub. L. 91–596, Dec. 29, 1970, 84 Stat. 1590, which is classified principally to chapter 15 (§651 et seq.) of Title 29, Labor. For complete classification of this Act to the Code, see Short Title note set out under section 651 of Title 29 and Tables.

CODIFICATION

Section was formerly classified to section 280b–1 of this title.

PRIOR PROVISIONS

A prior section 392 of act July 1, 1944, ch. 373, title III, as added Oct. 22, 1965, Pub. L. 89–291, §2, 79 Stat. 1060; amended Mar. 13, 1970, Pub. L. 91–212, §10(b)(4), (d)(2)(A), 84 Stat. 66, 67; July 23, 1974, Pub. L. 93–353, title II, §202(c), 88 Stat. 372, which related to composition, functions, etc., of the National Medical Libraries Assistance Advisory Board, was classified to section 280b–2 of this title, prior to repeal by Pub. L. 99–158, §3(b), Nov. 20, 1985, 99 Stat. 879.

AMENDMENTS

1993—Pub. L. 103–183, §203(a)(2)(A), substituted "Prevention and control activities" for "Control activities" in section catchline.

Subsec. (a)(1). Pub. L. 103–183, §203(a)(2)(B), inserted "and control" after "prevention".

Subsec. (b)(1). Pub. L. 103–183, §203(a)(2)(C), substituted "the prevention and control of injuries" for "injuries and injury control".

Subsec. (b)(2). Pub. L. 103–183, §203(b)(1), substituted "to promote activities regarding the prevention and control of injuries; and" for "to promote injury control. In carrying out the preceding sentence, the Secretary shall disseminate such information to the public, including through elementary and secondary schools; and".

1992—Pub. L. 102–531, §312(d)(4), substituted "Centers for Disease Control and Prevention" for "Centers for Disease Control" in introductory provisions of subsecs. (a) and (b).

Subsec. (b)(1). Pub. L. 102–531, §301(1), struck out "and" after semicolon at end.

Subsec. (b)(2). Pub. L. 102–531, §301(2), inserted sentence requiring Secretary to disseminate information on injury control to the public, including through elementary and secondary schools and substituted "; and" for period at end.

Subsec. (b)(3). Pub. L. 102–531, §301(3), added par. (3).

1990—Subsec. (b)(2). Pub. L. 101–558 amended par. (2) generally. Prior to amendment, par. (2) read as follows: "work in cooperation with Federal, State, and local agencies to promote injury control."

§280b–1. Preventing overdoses of controlled substances

(a) Evidence-based prevention grants

(1) In general

The Director of the Centers for Disease Control and Prevention may—

(A) to the extent practicable, carry out and expand any evidence-based prevention activities described in paragraph (2);

(B) provide training and technical assistance to States, localities, and Indian Tribes for purposes of carrying out such activity; and

(C) award grants to States, localities, and Indian Tribes for purposes of carrying out such activity.

(2) Evidence-based prevention activities

An evidence-based prevention activity described in this paragraph is any of the following activities:

(A) Improving the efficiency and use of a new or currently operating prescription drug monitoring program, including by—

(i) encouraging all authorized users (as specified by the State or other entity) to register with and use the program;

(ii) enabling such users to access any updates to information collected by the program in as close to real-time as possible;

(iii) improving the ease of use of such program;

(iv) providing for a mechanism for the program to notify authorized users of any potential misuse or abuse of controlled substances and any detection of inappropriate prescribing or dispensing practices relating to such substances;

(v) encouraging the analysis of prescription drug monitoring data for purposes of providing de-identified, aggregate reports based on such analysis to State public health agencies, State substance abuse agencies, State licensing boards, and other appropriate State agencies, as permitted under applicable Federal and State law and the policies of the prescription drug monitoring program and not containing any protected health information, to prevent inappropriate prescribing, drug diversion, or abuse and misuse of controlled substances, and to facilitate better coordination among agencies;

(vi) enhancing interoperability between the program and any health information technology (including certified health information technology), including by integrating program data into such technology;

(vii) updating program capabilities to respond to technological innovation for purposes of appropriately addressing the occurrence and evolution of controlled substance overdoses;

(viii) facilitating and encouraging data exchange between the program and the prescription drug monitoring programs of other States;

(ix) enhancing data collection and quality, including improving patient matching and proactively monitoring data quality;

(x) providing prescriber and dispenser practice tools, including prescriber practice insight reports for practitioners to review their prescribing patterns in comparison to such patterns of other practitioners in the specialty; and

(xi) meeting the purpose of the program established under section 280g–3 of this title, as described in section 280g–3(a) of this title.

(B) Promoting community or health system interventions.

(C) Evaluating interventions to prevent controlled substance overdoses and associated risks.

(D) Implementing projects to advance an innovative prevention approach with respect to new and emerging public health crises and opportunities to address such crises, such as enhancing public education and awareness on the risks associated with substances causing overdose.

(3) Additional grants

The Director may award grants to States, localities, and Indian Tribes for the following purposes:

(A) To carry out innovative projects for grantees to detect, identify, and rapidly respond to controlled substance misuse, abuse, and overdoses, and associated risk factors, including changes in patterns of such controlled substance use. Such projects may include the use of innovative, evidence-based strategies for detecting such patterns, such as wastewater surveillance, if proven to support actionable prevention strategies, in a manner consistent with applicable Federal and State privacy laws.

(B) For any other evidence-based activity for preventing controlled substance misuse, abuse, and overdoses as the Director determines appropriate.

(4) Research

The Director, in coordination with the Assistant Secretary for Mental Health and Substance Use and the National Mental Health and Substance Use Policy Laboratory established under section 290aa–0 of this title, as appropriate and applicable, may conduct studies and evaluations to address substance use disorders, including preventing substance use disorders or other related topics the Director determines appropriate.

(b) Enhanced controlled substance overdose data collection, analysis, and dissemination grants

(1) In general

The Director of the Centers for Disease Control and Prevention may—

(A) to the extent practicable, carry out any controlled substance overdose data collection activities described in paragraph (2);

(B) provide training and technical assistance to States, localities, and Indian Tribes for purposes of carrying out such activity;

(C) award grants to States, localities, and Indian Tribes for purposes of carrying out such activity; and

(D) coordinate with the Assistant Secretary for Mental Health and Substance Use to collect data pursuant to section 290aa–4(d)(1)(A) of this title (relating to the number of individuals admitted to emergency departments as a result of the abuse of alcohol or other drugs).

(2) Controlled substance overdose data collection and analysis activities

A controlled substance overdose data collection, analysis, and dissemination activity described in this paragraph is any of the following activities:

(A) Improving the timeliness of reporting data to the public, including data on fatal and nonfatal overdoses of controlled substances.

(B) Enhancing the comprehensiveness of controlled substance overdose data by collecting information on such overdoses, and associated risk factors, from appropriate sources such as toxicology reports, autopsy reports, death scene investigations, and emergency departments.

(C) Modernizing the system for monitoring and identifying causes of death related to controlled substance overdoses to use an electronic-based system.

(D) Using data to help identify risk factors associated with controlled substance overdoses.

(E) Supporting entities involved in providing information on controlled substance overdoses, such as coroners, medical examiners, and public health laboratories, to improve accurate testing and standardized reporting of causes and contributing factors to controlled substances overdoses and analysis of various opioid analogues and other emerging substances related to controlled substance overdoses.

(F) Working to enable and encourage the access, exchange, and use of information regarding controlled substance overdoses and associated risk factors among data sources and entities.

(c) Priority

In awarding grants to States under subsections (a) and (b), the Director of the Centers for Disease Control and Prevention may give priority to jurisdictions with a disproportionately high rate of drug overdoses or drug overdose deaths, as applicable.

(d) Definitions

In this section:

(1) Controlled substance

The term "controlled substance" has the meaning given that term in section 802 of title 21.

(2) Indian tribe

The term "Indian tribe" has the meaning given that term in section 5304 of title 25.

(e) Authorization of appropriations

For purposes of carrying out this section, section 280g–3 of this title, and section 290bb–25g of this title, there is authorized to be appropriated $505,579,000 for each of fiscal years 2026 through 2030.

(July 1, 1944, ch. 373, title III, §392A, as added Pub. L. 115–271, title VII, §7161(a), Oct. 24, 2018, 132 Stat. 4059; amended Pub. L. 117–328, div. FF, title I, §1271(b), Dec. 29, 2022, 136 Stat. 5686; Pub. L. 119–44, title I, §103, Dec. 1, 2025, 139 Stat. 670.)

EDITORIAL NOTES

PRIOR PROVISIONS

A prior section 280b–1, act July 1, 1944, ch. 373, title III, §392, as added Pub. L. 99–649, §3, Nov. 10, 1986, 100 Stat. 3634; amended Pub. L. 101–558, §2(b), Nov. 15, 1990, 104 Stat. 2772; Pub. L. 102–531, title III, §§301, 312(d)(4), Oct. 27, 1992, 106 Stat. 3482, 3504; Pub. L. 103–183, title II, §203(a)(2), (b)(1), Dec. 14, 1993, 107 Stat. 2232, which related to prevention and control activities, was transferred to section 280b–0 of this title.

Another prior section 280b–1, act July 1, 1944, ch. 373, title III, §391, as added Oct. 22, 1965, Pub. L. 89–291, §2, 79 Stat. 1059; amended Mar. 13, 1970, Pub. L. 91–212, §10(b)(3), 84 Stat. 66; July 23, 1974, Pub. L. 93–353, title II, §202(b), 88 Stat. 372, defined "sciences related to health", "National Medical Libraries Assistance Advisory Board", "Board", and "medical library", prior to repeal by Pub. L. 99–158, §3(b), Nov. 20, 1985, 99 Stat. 879.

AMENDMENTS

2025—Subsec. (a)(2)(C). Pub. L. 119–44, §103(a)(1)(A), inserted "and associated risks" before period at end.

Subsec. (a)(2)(D). Pub. L. 119–44, §103(a)(1)(B), substituted "substances causing overdose" for "opioids".

Subsec. (a)(3). Pub. L. 119–44, §103(b)(1), substituted "and Indian Tribes for the following purposes:" for "and Indian Tribes—" in introductory provisions.

Subsec. (a)(3)(A). Pub. L. 119–44, §103(b)(2), amended subpar. (A) generally. Prior to amendment, subpar. (A) read as follows: "to carry out innovative projects for grantees to rapidly respond to controlled substance misuse, abuse, and overdoses, including changes in patterns of controlled substance use; and".

Subsec. (a)(3)(B). Pub. L. 119–44, §103(b)(3), substituted "For any" for "for any".

Subsec. (b)(2)(B). Pub. L. 119–44, §103(a)(2)(A), inserted ", and associated risk factors," after "such overdoses".

Subsec. (b)(2)(C). Pub. L. 119–44, §103(a)(2)(B), substituted "monitoring and identifying" for "coding".

Subsec. (b)(2)(E). Pub. L. 119–44, §103(a)(2)(C), inserted a comma after "public health laboratories" and "and other emerging substances related" after "analogues".

Subsec. (b)(2)(F). Pub. L. 119–44, §103(a)(2)(D), inserted "and associated risk factors" after "overdoses".

Subsec. (e). Pub. L. 119–44, §103(c), substituted "$505,579,000 for each of fiscal years 2026 through 2030" for "$496,000,000 for each of fiscal years 2019 through 2023".

2022—Subsecs. (a)(1)(B), (C), (b)(1)(B), (C). Pub. L. 117–328, §1271(b)(2), substituted "Indian Tribes" for "Indian tribes".

Subsecs. (c) to (e). Pub. L. 117–328, §1271(b)(1), added subsec. (c) and redesignated former subsecs. (c)

and (d) as (d) and (e), respectively.

§280b–1a. Interpersonal violence within families and among acquaintances

(a) With respect to activities that are authorized in sections 280b and 280b–0 of this title, the Secretary, acting through the Director of the Centers for Disease Control and Prevention, shall carry out such activities with respect to interpersonal violence within families and among acquaintances. Activities authorized in the preceding sentence include the following:

(1) Collecting data relating to the incidence of such violence.

(2) Making grants to public and nonprofit private entities for the evaluation of programs whose purpose is to prevent such violence, including the evaluation of demonstration projects under paragraph (6).

(3) Making grants to public and nonprofit private entities for the conduct of research on identifying effective strategies for preventing such violence.

(4) Providing to the public information and education on such violence, including information and education to increase awareness of the public health consequences of such violence.

(5) Training health care providers as follows:

(A) To identify individuals whose medical conditions or statements indicate that the individuals are victims of such violence.

(B) To routinely determine, in examining patients, whether the medical conditions or statements of the patients so indicate.

(C) To refer individuals so identified to entities that provide services regarding such violence, including referrals for counseling, housing, legal services, and services of community organizations.

(6) Making grants to public and nonprofit private entities for demonstration projects with respect to such violence, including with respect to prevention.

(b) For purposes of this part, the term "interpersonal violence within families and among acquaintances" includes behavior commonly referred to as domestic violence, sexual assault, spousal abuse, woman battering, partner abuse, elder abuse, and acquaintance rape.

(July 1, 1944, ch. 373, title III, §393, as added Pub. L. 103–183, title II, §201(2), Dec. 14, 1993, 107 Stat. 2231.)

EDITORIAL NOTES

PRIOR PROVISIONS

A prior section 393 of act July 1, 1944, was renumbered section 394 and is classified to section 280b–2 of this title.

Another prior section 393 of act July 1, 1944, was renumbered section 394 and was classified to section 280b–4 of this title.

§280b–1b. Use of allotments for rape prevention education

(a) Permitted use

The Secretary, acting through the National Center for Injury Prevention and Control at the Centers for Disease Control and Prevention, shall award targeted grants to States to be used for rape prevention and education programs conducted by rape crisis centers, State, territorial or tribal sexual assault coalitions, and other public and private nonprofit entities for—

(1) educational seminars;

(2) the operation of hotlines or utilization of other communication technologies for purposes related to such a hotline;

(3) training programs for professionals, including school-based professionals, to identify and refer students who may have experienced or are at risk of experiencing sexual violence;

(4) the preparation of informational material;

(5) education and training programs for students and campus personnel designed to reduce the incidence of sexual assault at colleges and universities;

(6) education to increase awareness about drugs and alcohol used to facilitate rapes or sexual assaults; and

(7) other efforts to increase awareness of the facts about, or to help prevent, sexual violence, sexual assault, and sexual harassment, including efforts to increase awareness in underserved communities and awareness among individuals with disabilities (as defined in section 12102 of this title) and Deaf individuals.

(b) Collection and dissemination of information on sexual assault

The Secretary shall, through the National Resource Center on Sexual Assault established under the National Center for Injury Prevention and Control at the Centers for Disease Control and Prevention, provide resource information, policy, training, and technical assistance to Federal, State, local, and Indian Tribal agencies, as well as to State sexual assault coalitions and local sexual assault programs and to other professionals and interested parties on issues relating to sexual assault, including maintenance of a central resource library in order to collect, prepare, analyze, and disseminate information and statistics and analyses thereof relating to the incidence and prevention of sexual assault.

(c) Meaningful involvement of State sexual assault coalitions, culturally specific organizations, and underserved communities

In awarding funds to States under this section, the Secretary shall set forth procedures designed to ensure meaningful involvement of sexual assault coalitions, culturally specific organizations, and representatives from underserved communities of the State or territory in the application for, and implementation of, funding.

(d) Authorization of appropriations

(1) In general

There is authorized to be appropriated to carry out this section $100,000,000 for each of fiscal years 2023 through 2027.

(2) National sexual violence resource center allotment

Of the total amount made available under this subsection in each fiscal year, not less than $1,500,000 shall be available for allotment under subsection (b).

(3) Baseline funding for States, the District of Columbia, and Puerto Rico

A minimum allocation of $150,000 shall be awarded in each fiscal year for each of the States, the District of Columbia, and Puerto Rico. A minimum allocation of $35,000 shall be awarded in each fiscal year for each Territory. Any unused or remaining funds shall be allotted to each State, the District of Columbia, and Puerto Rico on the basis of population. Not less than 80 percent of the total amount made available under this subsection in each fiscal year shall be awarded in accordance with this paragraph.

(4) State, territorial, and Tribal sexual assault coalition allotment

(A) In general

Of the total amount appropriated under this subsection for a fiscal year, not less than 15 percent shall be allocated to State, territorial, and Tribal sexual assault coalitions for the purposes of coordinating and providing prevention activities, providing assistance to prevention programs, and collaborating and coordinating with applicable Federal, State, Tribal, and local entities engaged in sexual violence prevention, in accordance with this paragraph.

(B) Allocations

Of the total amount appropriated under this subsection and allocated to making awards to sexual assault coalitions, as described in subparagraph (A), for a fiscal year—

(i) not less than 10 percent shall be made available to Tribal sexual assault coalitions; and

(ii) any remaining amounts shall be made available, in equal amounts, to each State coalition and each territorial coalition.

(C) Clarification

Receipt of an award under this subsection by a sexual assault coalition shall not preclude the coalition from receiving additional grants or administering funds to carry out the purposes described in subsection (a).

(e) Limitations

(1) Supplement not supplant

Amounts provided to States under this section shall be used to supplement and not supplant other Federal, State, and local public funds expended to provide services of the type described in subsection (a).

(2) Studies

A State may not use more than 2 percent of the amount received by the State under this section for each fiscal year for surveillance studies or prevalence studies.

(3) Administration

A State may not use more than 5 percent of the amount received by the State under this section for each fiscal year for administrative expenses.

(f) Report

Not later than 1 year after March 15, 2022, the Secretary, acting through the Director of the Centers for Disease Control and Prevention, shall submit to the Committee on Appropriations, the Committee on Energy and Commerce, and the Committee on the Judiciary of the House of Representatives and the Committee on Appropriations, the Committee on Health, Education, Labor, and Pensions, and the Committee on the Judiciary of the Senate a report on the activities funded by grants awarded under this section and best practices relating to rape prevention and education.

(July 1, 1944, ch. 373, title III, §393A, formerly §393B, as added Pub. L. 106–386, div. B, title IV, §1401(a), Oct. 28, 2000, 114 Stat. 1512; amended Pub. L. 109–162, title III, §302, Jan. 5, 2006, 119 Stat. 3004; renumbered §393C, Pub. L. 110–202, §2(1), Apr. 23, 2008, 122 Stat. 697; renumbered §393A, Pub. L. 110–206, §2(1), Apr. 28, 2008, 122 Stat. 714; Pub. L. 113–4, title III, §301, Mar. 7, 2013, 127 Stat. 84; Pub. L. 117–103, div. W, title III, §301, Mar. 15, 2022, 136 Stat. 863.)

EDITORIAL NOTES

CODIFICATION

Section was formerly classified to section 280b–1c of this title. Pub. L. 110–206, which directed the renumbering of "the section 393B (42 U.S.C. 280b–1c)" of act July 1, 1944, "relating to the use of allotments for rape prevention education" as section 393A and the transfer of that section so as to appear after section 393 of that Act, was executed by renumbering section 393C of that Act as 393A and transferring the renumbered provisions to this section, to reflect the probable intent of Congress and the renumbering of section 393B as 393C by section 2(1) of Pub. L. 110–202.

PRIOR PROVISIONS

A prior section 393A of act July 1, 1944, was renumbered section 393B and is classified to section 280b–1c of this title.

AMENDMENTS

2022—Subsec. (a)(2). Pub. L. 117–103, §301(1)(A), inserted before semicolon at end "or utilization of other communication technologies for purposes related to such a hotline".

Subsec. (a)(3). Pub. L. 117–103, §301(1)(B), substituted "professionals, including school-based

professionals, to identify and refer students who may have experienced or are at risk of experiencing sexual violence" for "professionals".

Subsec. (a)(7). Pub. L. 117–103, §301(1)(C), substituted "sexual violence, sexual assault, and sexual harassment" for "sexual assault" and inserted "and Deaf individuals" before period at end.

Subsec. (b). Pub. L. 117–103, §301(2), substituted "Indian Tribal" for "Indian tribal".

Subsec. (c). Pub. L. 117–103, §301(4), added subsec. (c). Former subsec. (c) redesignated (d).

Subsec. (d). Pub. L. 117–103, §301(3), redesignated subsec. (c) as (d). Former subsec. (d) redesignated (e).

Subsec. (d)(1). Pub. L. 117–103, §301(5)(A), substituted "$100,000,000 for each of fiscal years 2023 through 2027" for "$50,000,000 for each of fiscal years 2014 through 2018".

Subsec. (d)(3). Pub. L. 117–103, §301(5)(B), inserted at end "Not less than 80 percent of the total amount made available under this subsection in each fiscal year shall be awarded in accordance with this paragraph."

Subsec. (d)(4). Pub. L. 117–103, §301(5)(C), added par. (4).

Subsec. (e). Pub. L. 117–103, §301(3), redesignated subsec. (d) as (e).

Subsec. (f). Pub. L. 117–103, §301(6), added subsec. (f).

2013—Subsec. (a). Pub. L. 113–4, §301(1)(A), inserted ", territorial or tribal" after "crisis centers, State" in introductory provisions.

Subsec. (a)(6). Pub. L. 113–4, §301(1)(B), inserted "and alcohol" after "about drugs".

Subsec. (c)(1). Pub. L. 113–4, §301(2)(A), substituted "$50,000,000 for each of fiscal years 2014 through 2018" for "$80,000,000 for each of fiscal years 2007 through 2011".

Subsec. (c)(3). Pub. L. 113–4, §301(2)(B), added par. (3).

2006—Subsec. (c). Pub. L. 109–162 reenacted heading without change and amended text generally. Prior to amendment, text contained provisions in par. (1) authorizing appropriations for fiscal years 2001 through 2005 and in par. (2) directing an allotment under subsec. (b) of this section.

STATUTORY NOTES AND RELATED SUBSIDIARIES

EFFECTIVE DATE OF 2022 AMENDMENT

Amendment by Pub. L. 117–103 not effective until Oct. 1 of the first fiscal year beginning after Mar. 15, 2022, see section 4(a) of div. W of Pub. L. 117–103, set out as an Effective Date note under section 6851 of Title 15, Commerce and Trade.

EFFECTIVE DATE OF 2013 AMENDMENT

Amendment by Pub. L. 113–4 not effective until the beginning of the fiscal year following Mar. 7, 2013, see section 4 of Pub. L. 113–4, set out as a note under section 2261 of Title 18, Crimes and Criminal Procedure.

§280b–1c. Prevention of traumatic brain injury

(a) In general

The Secretary, acting through the Director of the Centers for Disease Control and Prevention, may carry out projects to reduce the incidence of traumatic brain injury. Such projects may be carried out by the Secretary directly or through awards of grants or contracts to public or nonprofit private entities. The Secretary may directly or through such awards provide technical assistance with respect to the planning, development, and operation of such projects.

(b) Certain activities

Activities under subsection (a) may include—

(1) the conduct of research into identifying effective strategies for the prevention of traumatic brain injury;

(2) the implementation of public information and education programs for the prevention of such injury and for broadening the awareness of the public concerning the public health consequences of such injury; and

(3) the implementation of a national education and awareness campaign regarding such injury (in conjunction with the program of the Secretary regarding health-status goals for 2020, commonly referred to as Healthy People 2020), including—

(A) the national dissemination of information on—
(i) incidence and prevalence; and
(ii) information relating to traumatic brain injury and the sequelae of secondary conditions arising from traumatic brain injury upon discharge from hospitals and emergency departments; and

(B) the provision of information in primary care settings, including emergency rooms and trauma centers, concerning the availability of State level services and resources.

(c) Coordination of activities

The Secretary shall ensure that activities under this section are coordinated as appropriate with other agencies of the Public Health Service that carry out activities regarding traumatic brain injury.

(d) "Traumatic brain injury" defined

For purposes of this section, the term "traumatic brain injury" means an acquired injury to the brain. Such term does not include brain dysfunction caused by congenital or degenerative disorders, nor birth trauma, but may include brain injuries caused by anoxia due to trauma. The Secretary may revise the definition of such term as the Secretary determines necessary, after consultation with States and other appropriate public or nonprofit private entities.

(July 1, 1944, ch. 373, title III, §393B, formerly §393A, as added Pub. L. 104–166, §1, July 29, 1996, 110 Stat. 1445; amended Pub. L. 106–310, div. A, title XIII, §1301(a), Oct. 17, 2000, 114 Stat. 1137; renumbered §393B and amended Pub. L. 110–206, §§2(2), 3(a), Apr. 28, 2008, 122 Stat. 714; Pub. L. 113–196, §2(a), Nov. 26, 2014, 128 Stat. 2052.)

EDITORIAL NOTES

CODIFICATION

Section was formerly classified to section 280b–1b of this title.

PRIOR PROVISIONS

Prior sections 393B of act July 1, 1944, were renumbered sections 393A and 393C and are classified to sections 280b–1b and 280b–1d, respectively, of this title.

AMENDMENTS

2014—Subsec. (b)(3). Pub. L. 113–196 substituted "2020, commonly referred to as Healthy People 2020" for "2010, commonly referred to as Healthy People 2010" in introductory provisions.

2008—Subsec. (b)(3)(A)(ii). Pub. L. 110–206, §3(a), substituted "from hospitals and emergency departments" for "from hospitals and trauma centers".

2000—Subsec. (b)(3). Pub. L. 106–310, §1301(a)(1), added par. (3).

Subsec. (d). Pub. L. 106–310, §1301(a)(2), substituted "anoxia due to trauma" for "anoxia due to near drowning" and inserted ", after consultation with States and other appropriate public or nonprofit private entities" after "Secretary determines necessary".

§280b–1d. National program for traumatic brain injury surveillance and registries

(a) In general

The Secretary, acting through the Director of the Centers for Disease Control and Prevention, may make grants to States or their designees to develop or operate the State's traumatic brain injury surveillance system or registry to determine the incidence and prevalence of traumatic brain injury and related disability, to ensure the uniformity of reporting under such system or registry, to link individuals with traumatic brain injury to services and supports, and to link such individuals with

academic institutions to conduct applied research that will support the development of such surveillance systems and registries as may be necessary. A surveillance system or registry under this section shall provide for the collection of data concerning—

(1) demographic information about each traumatic brain injury;

(2) information about the circumstances surrounding the injury event associated with each traumatic brain injury;

(3) administrative information about the source of the collected information, dates of hospitalization and treatment, and the date of injury; and

(4) information characterizing the clinical aspects of the traumatic brain injury, including the severity of the injury, outcomes of the injury, the types of treatments received, and the types of services utilized.

(b) Report

Not later than 18 months after April 28, 2008, the Secretary, acting through the Director of the Centers for Disease Control and Prevention and the Director of the National Institutes of Health and in consultation with the Secretary of Defense and the Secretary of Veterans Affairs, shall submit to the relevant committees of Congress a report that contains the findings derived from an evaluation concerning activities and procedures that can be implemented by the Centers for Disease Control and Prevention to improve the collection and dissemination of compatible epidemiological studies on the incidence and prevalence of traumatic brain injury in individuals who were formerly in the military. The report shall include recommendations on the manner in which such agencies can further collaborate on the development and improvement of traumatic brain injury diagnostic tools and treatments.

(c) National concussion data collection and analysis

The Secretary, acting through the Director of the Centers for Disease Control and Prevention, may implement concussion data collection and analysis to determine the prevalence and incidence of concussion.

(July 1, 1944, ch. 373, title III, §393C, formerly §393B, as added Pub. L. 106–310, div. A, title XIII, §1301(b), Oct. 17, 2000, 114 Stat. 1137; renumbered §393C and amended Pub. L. 110–206, §§2(3), 3(b), (c), Apr. 28, 2008, 122 Stat. 714, 715; Pub. L. 115–377, §2(1), Dec. 21, 2018, 132 Stat. 5114.)

EDITORIAL NOTES

PRIOR PROVISIONS

A prior section 393C of act July 1, 1944, was renumbered section 393A and is classified to section 280b–1b of this title.

AMENDMENTS

2018—Subsec. (c). Pub. L. 115–377 added subsec. (c).

2008—Pub. L. 110–206, §3(b)(1), inserted "surveillance and" after "National program for traumatic brain injury" in section catchline.

Subsec. (a). Pub. L. 110–206, §3(b)(2), in introductory provisions, substituted "may make grants to States or their designees to develop or operate the State's traumatic brain injury surveillance system or registry to determine the incidence and prevalence of traumatic brain injury and related disability, to ensure the uniformity of reporting under such system or registry, to link individuals with traumatic brain injury to services and supports, and to link such individuals with academic institutions to conduct applied research that will support the development of such surveillance systems and registries as may be necessary. A surveillance system or registry under this section shall provide for the collection of data concerning—" for "may make grants to States or their designees to operate the State's traumatic brain injury registry, and to academic institutions to conduct applied research that will support the development of such registries, to collect data concerning—".

Subsec. (b). Pub. L. 110–206, §3(c), added subsec. (b).

§280b–1e. Repealed. Pub. L. 115–377, §2(3), Dec. 21, 2018, 132 Stat. 5114

Section, July 1, 1944, ch. 373, title III, §393C–1, as added Pub. L. 110–206, §4, Apr. 28, 2008, 122 Stat. 715, provided that the Secretary, acting with appropriate health officials, could conduct a study on traumatic brain injury.

§280b–1f. Prevention of falls among older adults

(a) Public education

The Secretary may—

(1) oversee and support a national education campaign to be carried out by a nonprofit organization with experience in designing and implementing national injury prevention programs, that is directed principally to older adults, their families, and health care providers, and that focuses on reducing falls among older adults and preventing repeat falls; and

(2) award grants, contracts, or cooperative agreements to qualified organizations, institutions, or consortia of qualified organizations and institutions, specializing, or demonstrating expertise, in falls or fall prevention, for the purpose of organizing State-level coalitions of appropriate State and local agencies, safety, health, senior citizen, and other organizations to design and carry out local education campaigns, focusing on reducing falls among older adults and preventing repeat falls.

(b) Research

(1) In general

The Secretary may—

(A) conduct and support research to—

(i) improve the identification of older adults who have a high risk of falling;

(ii) improve data collection and analysis to identify fall risk and protective factors;

(iii) design, implement, and evaluate the most effective fall prevention interventions;

(iv) improve strategies that are proven to be effective in reducing falls by tailoring these strategies to specific populations of older adults;

(v) conduct research in order to maximize the dissemination of proven, effective fall prevention interventions;

(vi) intensify proven interventions to prevent falls among older adults;

(vii) improve the diagnosis, treatment, and rehabilitation of elderly fall victims and older adults at high risk for falls; and

(viii) assess the risk of falls occurring in various settings;

(B) conduct research concerning barriers to the adoption of proven interventions with respect to the prevention of falls among older adults;

(C) conduct research to develop, implement, and evaluate the most effective approaches to reducing falls among high-risk older adults living in communities and long-term care and assisted living facilities; and

(D) evaluate the effectiveness of community programs designed to prevent falls among older adults.

(2) Educational support

The Secretary, either directly or through awarding grants, contracts, or cooperative agreements to qualified organizations, institutions, or consortia of qualified organizations and institutions, specializing, or demonstrating expertise, in falls or fall prevention, may provide professional education for physicians and allied health professionals, and aging service providers in fall prevention, evaluation, and management.

(c) Demonstration projects

The Secretary may carry out the following:

(1) Oversee and support demonstration and research projects to be carried out by qualified

organizations, institutions, or consortia of qualified organizations and institutions, specializing, or demonstrating expertise, in falls or fall prevention, in the following areas:

(A) A multistate demonstration project assessing the utility of targeted fall risk screening and referral programs.

(B) Programs designed for community-dwelling older adults that utilize multicomponent fall intervention approaches, including physical activity, medication assessment and reduction when possible, vision enhancement, and home modification strategies.

(C) Programs that are targeted to new fall victims who are at a high risk for second falls and which are designed to maximize independence and quality of life for older adults, particularly those older adults with functional limitations.

(D) Private sector and public-private partnerships to develop technologies to prevent falls among older adults and prevent or reduce injuries if falls occur.

(2)(A) Award grants, contracts, or cooperative agreements to qualified organizations, institutions, or consortia of qualified organizations and institutions, specializing, or demonstrating expertise, in falls or fall prevention, to design, implement, and evaluate fall prevention programs using proven intervention strategies in residential and institutional settings.

(B) Award 1 or more grants, contracts, or cooperative agreements to 1 or more qualified organizations, institutions, or consortia of qualified organizations and institutions, specializing, or demonstrating expertise, in falls or fall prevention, in order to carry out a multistate demonstration project to implement and evaluate fall prevention programs using proven intervention strategies designed for single and multifamily residential settings with high concentrations of older adults, including—

(i) identifying high-risk populations;

(ii) evaluating residential facilities;

(iii) conducting screening to identify high-risk individuals;

(iv) providing fall assessment and risk reduction interventions and counseling;

(v) coordinating services with health care and social service providers; and

(vi) coordinating post-fall treatment and rehabilitation.

(3) Award 1 or more grants, contracts, or cooperative agreements to qualified organizations, institutions, or consortia of qualified organizations and institutions, specializing, or demonstrating expertise, in falls or fall prevention, to conduct evaluations of the effectiveness of the demonstration projects described in this subsection.

(d) Priority

In awarding grants, contracts, or cooperative agreements under this section, the Secretary may give priority to entities that explore the use of cost-sharing with respect to activities funded under the grant, contract, or agreement to ensure the institutional commitment of the recipients of such assistance to the projects funded under the grant, contract, or agreement. Such non-Federal cost sharing contributions may be provided directly or through donations from public or private entities and may be in cash or in-kind, fairly evaluated, including plant, equipment, or services.

(e) Study of effects of falls on health care costs

(1) In general

The Secretary may conduct a review of the effects of falls on health care costs, the potential for reducing falls, and the most effective strategies for reducing health care costs associated with falls.

(2) Report

If the Secretary conducts the review under paragraph (1), the Secretary shall, not later than 36 months after April 23, 2008, submit to Congress a report describing the findings of the Secretary in conducting such review.

(July 1, 1944, ch. 373, title III, §393D, as added Pub. L. 110–202, §2(2), Apr. 23, 2008, 122 Stat. 697.)

§280b–2. General provisions

(a) Advisory committee

The Secretary, acting through the Director of the Centers for Disease Control and Prevention, shall establish an advisory committee to advise the Secretary and such Director with respect to the prevention and control of injuries.

(b) Technical assistance

The Secretary, acting through the Director of the Centers for Disease Control and Prevention, may provide technical assistance to public and nonprofit private entities with respect to the planning, development, and operation of any program or service carried out pursuant to this part. The Secretary may provide such technical assistance directly or through grants or contracts.

(c) Biennial report

Not later than February 1 of 1995 and of every second year thereafter, the Secretary, acting through the Director of the Centers for Disease Control and Prevention, shall submit to the Committee on Energy and Commerce of the House of Representatives, and to the Committee on Labor and Human Resources of the Senate, a report describing the activities carried out under this part during the preceding 2 fiscal years. Such report shall include a description of such activities that were carried out with respect to interpersonal violence within families and among acquaintances and with respect to rural areas.

(July 1, 1944, ch. 373, title III, §394, formerly §393, as added Pub. L. 99–649, §3, Nov. 10, 1986, 100 Stat. 3634; amended Pub. L. 101–558, §2(c), Nov. 15, 1990, 104 Stat. 2772; Pub. L. 102–531, title III, §312(d)(5), Oct. 27, 1992, 106 Stat. 3504; renumbered §394 and amended Pub. L. 103–183, title II, §§201(1), 202, Dec. 14, 1993, 107 Stat. 2231, 2232.)

EDITORIAL NOTES

PRIOR PROVISIONS

A prior section 280b–2, act July 1, 1944, ch. 373, title III, §392, as added Oct. 22, 1965, Pub. L. 89–291, §2, 79 Stat. 1060; amended Mar. 13, 1970, Pub. L. 91–212, §10(b)(4), (d)(2)(A), 84 Stat. 66, 67; July 23, 1974, Pub. L. 93–353, title II, §202(c), 88 Stat. 372, related to composition, functions, etc., of National Medical Libraries Assistance Advisory Board, prior to repeal by Pub. L. 99–158, §3(b), Nov. 20, 1985, 99 Stat. 879.

A prior section 394 of act July 1, 1944, was renumbered section 394A and is classified to section 280b–3 of this title.

AMENDMENTS

1993—Pub. L. 103–183, §202, amended section generally. Prior to amendment, section read as follows: "By not later than September 30, 1992, the Secretary, through the Director of the Centers for Disease Control and Prevention, shall prepare and submit to the Committee on Energy and Commerce of the House of Representatives, and to the Committee on Labor and Human Resources of the Senate, a report describing the activities conducted or supported under this part. The report shall include—

"(1) information regarding the practical applications of research conducted pursuant to subsection (a) of section 280b of this title, including information that has not been disseminated under subsection (b) of such section; and

"(2) information on such activities regarding the prevention and control of injuries in rural areas, including information regarding injuries that are particular to rural areas."

1992—Pub. L. 102–531 substituted "Centers for Disease Control and Prevention" for "Centers for Disease Control" in introductory provisions.

1990—Pub. L. 101–558 amended section generally. Prior to amendment, section read as follows: "By January 1, 1989, the Secretary, through the Director of the Centers for Disease Control, shall prepare and

transmit to the Congress a report analyzing the incidence and causes of childhood injuries in the United States and containing recommendations for such legislation with respect to injury control as the Secretary considers appropriate."

STATUTORY NOTES AND RELATED SUBSIDIARIES

CHANGE OF NAME

Committee on Labor and Human Resources of Senate changed to Committee on Health, Education, Labor, and Pensions of Senate by Senate Resolution No. 20, One Hundred Sixth Congress, Jan. 19, 1999.

Committee on Energy and Commerce of House of Representatives treated as referring to Committee on Commerce of House of Representatives by section 1(a) of Pub. L. 104–14, set out as a note preceding section 21 of Title 2, The Congress. Committee on Commerce of House of Representatives changed to Committee on Energy and Commerce of House of Representatives, and jurisdiction over matters relating to securities and exchanges and insurance generally transferred to Committee on Financial Services of House of Representatives by House Resolution No. 5, One Hundred Seventh Congress, Jan. 3, 2001.

TERMINATION OF ADVISORY COMMITTEES

Advisory committees established after Jan. 5, 1973, to terminate not later than the expiration of the 2-year period beginning on the date of their establishment, unless, in the case of a committee established by the President or an officer of the Federal Government, such committee is renewed by appropriate action prior to the expiration of such 2-year period, or in the case of a committee established by Congress, its duration is otherwise provided by law. See section 1013 of Title 5, Government Organization and Employees.

Pub. L. 93–641, §6, Jan. 4, 1975, 88 Stat. 2275, set out as a note under section 217a of this title, provided that an advisory committee established pursuant to the Public Health Service Act shall terminate at such time as may be specifically prescribed by an Act of Congress enacted after Jan. 4, 1975.

§280b–3. Authorization of appropriations

(a) In general

For the purpose of carrying out this part, there are authorized to be appropriated $50,000,000 for fiscal year 1994, such sums as may be necessary for each of the fiscal years 1995 through 1998, and such sums as may be necessary for each of the fiscal years 2001 through 2005.

(b) Traumatic brain injury

To carry out sections 280b–1c and 280b–1d of this title, there are authorized to be appropriated $11,750,000 for each of fiscal years 2020 through 2024.

(July 1, 1944, ch. 373, title III, §394A, formerly §394, as added Pub. L. 99–649, §3, Nov. 10, 1986, 100 Stat. 3634; amended Pub. L. 101–558, §2(d), Nov. 15, 1990, 104 Stat. 2773; renumbered §394A and amended Pub. L. 103–183, title II, §§201(1), 204, Dec. 14, 1993, 107 Stat. 2231, 2233; Pub. L. 106–310, div. A, title XIII, §1306, Oct. 17, 2000, 114 Stat. 1143; Pub. L. 113–196, §2(b), Nov. 26, 2014, 128 Stat. 2052; Pub. L. 115–377, §2(2), Dec. 21, 2018, 132 Stat. 5114.)

EDITORIAL NOTES

PRIOR PROVISIONS

A prior section 280b–3, act July 1, 1944, ch. 373, title III, §393, as added Oct. 22, 1965, Pub. L. 89–291, §2, 79 Stat. 1060; amended Mar. 13, 1970, Pub. L. 91–212, §§2(a), 3, 10(d)(2), 84 Stat. 63, 64, 67, related to grants for construction of medical library facilities, prior to repeal by Pub. L. 93–353, title II, §202(d), July 23, 1974, 88 Stat. 372.

AMENDMENTS

2018—Subsec. (b). Pub. L. 115–377 substituted "$11,750,000 for each of fiscal years 2020 through 2024" for "$6,564,000 for each of fiscal years 2015 through 2019".

2014—Pub. L. 113–196 substituted "Authorization of appropriations" for "Authorizations of appropriations" in section catchline; designated existing provisions as subsec. (a), inserted heading, and struck

out second period at end; and added subsec. (b).

2000—Pub. L. 106–310, which directed the amendment of this section by striking out "and" after "1994", was executed by striking "and" after "1994," to reflect the probable intent of Congress.

Pub. L. 106–310 inserted before period at end ", and such sums as may be necessary for each of the fiscal years 2001 through 2005."

1993—Pub. L. 103–183, §204, amended section generally. Prior to amendment, section read as follows: "To carry out sections 280b and 280b–1 of this title, there are authorized to be appropriated $10,000,000 for each of the fiscal years 1988, 1989, and 1990, $30,000,000 for fiscal year 1991, and such sums as may be necessary for each of the fiscal years 1992 and 1993."

1990—Pub. L. 101–558 struck out subsec. (a) designation, inserted before period at end of first sentence ", $30,000,000 for fiscal year 1991, and such sums as may be necessary for each of the fiscal years 1992 and 1993", and struck out at end "Of the amounts appropriated under this section for any fiscal year, not more than 20 percent may be used for Federal administrative expenses to carry out such section for such fiscal year."

§280b–4. Study conducted by the Centers for Disease Control and Prevention

(a) Purposes

The Secretary of Health and Human Services acting through the National Center for Injury Prevention and Control at the Centers for Disease Control [1] Prevention shall make grants to entities, including domestic and sexual assault coalitions and programs, research organizations, tribal organizations, and academic institutions to support research to examine prevention and intervention programs to further the understanding of sexual and domestic violence by and against adults, youth, and children.

(b) Use of funds

The research conducted under this section shall include evaluation and study of best practices for reducing and preventing violence against adults, youth, and children addressed by the strategies included in Department of Health and Human Services-related provisions [2] this title,[3] including strategies addressing underserved communities.

(c) Authorization of appropriations

There shall be authorized to be appropriated to carry out this title [3] $1,000,000 for each of fiscal years 2023 through 2027.

(Pub. L. 109–162, title IV, §402, Jan. 5, 2006, 119 Stat. 3023; Pub. L. 113–4, title IV, §401, Mar. 7, 2013, 127 Stat. 92; Pub. L. 117–103, div. W, title IV, §401, Mar. 15, 2022, 136 Stat. 869.)

EDITORIAL NOTES

REFERENCES IN TEXT

This title, referred to in subsecs. (b) and (c), is title IV of Pub. L. 109–162, Jan. 5, 2006, 119 Stat. 3017, which enacted this section and part L (§14043d et seq.) of subchapter III of chapter 136 and section 14045c of this title. For complete classification of title IV to the Code, see Tables.

CODIFICATION

Section was enacted as part of the Violence Against Women and Department of Justice Reauthorization Act of 2005, and not as part of the Public Health Service Act which comprises this chapter.

PRIOR PROVISIONS

Prior sections 280b–4 to 280b–11 were repealed by Pub. L. 99–158, §3(b), Nov. 20, 1985, 99 Stat. 879.

Section 280b–4, act July 1, 1944, ch. 373, title III, §393, formerly §394, as added Oct. 22, 1965, Pub. L. 89–291, §2, 79 Stat. 1062; amended Mar. 13, 1970, Pub. L. 91–212, §§2(b), 10(d)(2)(A), 84 Stat. 63, 67; June 18, 1973, Pub. L. 93–45, title I, §107(a), 87 Stat. 92; renumbered §393 and amended July 23, 1974, Pub. L. 93–353, title II, §§203(a), 204, 88 Stat. 372, 373, related to grants for training in medical library sciences.

Section 280b–5, act July 1, 1944, ch. 373, title III, §394, formerly §395, as added Oct. 22, 1965, Pub. L. 89–291, §2, 79 Stat. 1062; amended Mar. 13, 1970, Pub. L. 91–212, §§2(c), (d), 4(a), 5(a), 10(c)(1)(A), (B),

(2)(A)–(C), (d)(2)(A), 84 Stat. 63, 64, 66, 67; June 18, 1973, Pub. L. 93–45, title I, §107(b), (c), 87 Stat. 92; renumbered §394 and amended July 23, 1974, Pub. L. 93–353, title II, §§203(b), 204, 88 Stat. 372, 373, related to assistance for special scientific projects; research and development in medical library science and related fields.

Section 280b–6, act July 1, 1944, ch. 373, title III, §396, as added Oct. 22, 1965, Pub. L. 89–291, §2, 79 Stat. 1063, was redesignated as subsecs. (b) and (c) of section 280b–5 of this title by Pub. L. 91–212, §10(c)(2), Mar. 13, 1970, 84 Stat. 66.

Section 280b–7, act July 1, 1944, ch. 373, title III, §395, formerly §397, as added Oct. 22, 1965, Pub. L. 89–291, §2, 79 Stat. 1063; renumbered §396 and amended Mar. 13, 1970, Pub. L. 91–212, §§2(e), 6(a)(1), (2), 10(c)(3), (d)(2)(A), 84 Stat. 63, 64, 67; June 18, 1973, Pub. L. 93–45, title I, §107(d), 87 Stat. 92; renumbered §395 and amended July 23, 1974, Pub. L. 93–353, title II, §§203(c), 204, 88 Stat. 372, 373, related to grants for establishing, expanding, and improving basic medical library or related resources.

Section 280b–8, act July 1, 1944, ch. 373, title III, §396, formerly §398, as added Oct. 22, 1965, Pub. L. 89–291, §2, 79 Stat. 1065; renumbered §397 and amended Mar. 13, 1970, Pub. L. 91–212, §§2(f), 7, 10(c)(3), (d)(2)(A), 84 Stat. 63, 65, 67; June 18, 1973, Pub. L. 93–45, title I, §107(e), 87 Stat. 92; renumbered §396 and amended July 23, 1974, Pub. L. 93–353, title II, §§202(e), (f), 203(d), 204, 88 Stat. 372, 373, related to grants for establishment of regional medical libraries.

Section 280b–9, act July 1, 1944, ch. 373, title III, §397, formerly §399, as added Oct. 22, 1965, Pub. L. 89–291, §2, 79 Stat. 1066; renumbered §398 and amended Mar. 13, 1970, Pub. L. 91–212, §§2(g), 8, 10(c)(3), (d)(2)(A), 84 Stat. 63, 65, 67; June 18, 1973, Pub. L. 93–45, title I, §107(f), 87 Stat. 92; renumbered §397 and amended July 23, 1974, Pub. L. 93–353, title II, §§203(e), 204, 88 Stat. 372, 373, related to grants to provide support for biomedical scientific publications.

Section 280b–10, act July 1, 1944, ch. 373, title III, §398, formerly §399a, as added Oct. 22, 1965, Pub. L. 89–291, §2, 79 Stat. 1066; renumbered §399, Mar. 13, 1970, Pub. L. 91–212, §10(c)(3), 84 Stat. 67; renumbered §398, July 23, 1974, Pub. L. 93–353, title II, §204, 88 Stat. 373, related to the continuing availability of appropriated funds.

Section 280b–11, act July 1, 1944, ch. 373, title III, §399, formerly §399b, as added Oct. 22, 1965, Pub. L. 89–291, §2, 79 Stat. 1066; renumbered §399a and amended Mar. 13, 1970, Pub. L. 91–212, §10(c)(3), (d)(2)(A), 84 Stat. 67; renumbered §399, July 23, 1974, Pub. L. 93–353, title II, §204, 88 Stat. 373; Oct. 17, 1979, Pub. L. 96–88, title V, §509(b), 93 Stat. 695, related to the maintenance of records by recipients of grants and audits thereof by the Secretary of Health and Human Services and the Comptroller General of the United States.

A prior section 280b–12, act July 1, 1944, ch. 373, title III, §399b, as added Mar. 13, 1970, Pub. L. 91–212, §9, 84 Stat. 65, related to transfer of funds, prior to repeal by Pub. L. 93–353, title II, §204, July 23, 1974, 88 Stat. 373, applicable with respect to fiscal years beginning after June 30, 1974.

AMENDMENTS

2022—Subsec. (b). Pub. L. 117–103, §401(1), substituted "violence against adults, youth," for "violence against women".

Subsec. (c). Pub. L. 117–103, §401(2), substituted "fiscal years 2023 through 2027" for "the fiscal years 2014 through 2018".

2013—Subsec. (c). Pub. L. 113–4 substituted "$1,000,000 for each of the fiscal years 2014 through 2018" for "$2,000,000 for each of the fiscal years 2007 through 2011".

STATUTORY NOTES AND RELATED SUBSIDIARIES

EFFECTIVE DATE OF 2022 AMENDMENT

Amendment by Pub. L. 117–103 not effective until Oct. 1 of the first fiscal year beginning after Mar. 15, 2022, see section 4(a) of div. W of Pub. L. 117–103, set out as an Effective Date note under section 6851 of Title 15, Commerce and Trade.

EFFECTIVE DATE OF 2013 AMENDMENT

Amendment by Pub. L. 113–4 not effective until the beginning of the fiscal year following Mar. 7, 2013, see section 4 of Pub. L. 113–4, set out as a note under section 2261 of Title 18, Crimes and Criminal Procedure.

[1] *So in original. Probably should be followed by "and".*

[2] *So in original. Probably should be followed by "of".*

[3] *See References in Text note below.*

PART K—HEALTH CARE SERVICES IN THE HOME AND PUBLIC HEALTH PROGRAMS FOR DEMENTIA

EDITORIAL NOTES

CODIFICATION

Pub. L. 115–406, §2(1), Dec. 31, 2018, 132 Stat. 5362, inserted "and Public Health Programs for Dementia" after "Home" in part heading.

Pub. L. 103–43, title XX, §2008(i)(2)(B)(i), June 10, 1993, 107 Stat. 213, redesignated part L "Health Care Services in the Home" as K. Former part K "Injury Control" redesignated J.

Pub. L. 101–616, title I, §101(a)(1), Nov. 16, 1990, 104 Stat. 3279, redesignated part J "Injury Control" as K. Former part K "Health Care Services in the Home" redesignated L.

PRIOR PROVISIONS

A prior part K, added Pub. L. 93–222, §3, Dec. 29, 1973, 87 Stat. 934, related to quality assurance, prior to repeal by Pub. L. 95–623, §11(b), Nov. 9, 1978, 92 Stat. 3455.

SUBPART I—GRANTS FOR DEMONSTRATION PROJECTS

§280c. Establishment of program

(a) In general

The Secretary, acting through the Administrator of the Health Resources and Services Administration, shall make not less than 5, and not more than 20, grants to States for the purpose of assisting grantees in carrying out demonstration projects—

(1) to identify low-income individuals who can avoid institutionalization or prolonged hospitalization if skilled medical services, skilled nursing care services, homemaker or home health aide services, or personal care services are provided in the homes of the individuals;

(2) to pay the costs of the provision of such services in the homes of such individuals; and

(3) to coordinate the provision by public and private entities of such services, and other long-term care services, in the homes of such individuals.

(b) Requirement with respect to age of recipients of services

The Secretary may not make a grant under subsection (a) to a State unless the State agrees to ensure that—

(1) not less than 25 percent of the grant is expended to provide services under such subsection to individuals who are not less than 65 years of age; and

(2) of the portion of the grant reserved by the State for purposes of complying with paragraph (1), not less than 10 percent is expended to provide such services to individuals who are not less than 85 years of age.

(c) Relationship to items and services under other programs

A State may not make payments from a grant under subsection (a) for any item or service to the extent that payment has been made, or can reasonably be expected to be made, with respect to such item or service—

(1) under any State compensation program, under an insurance policy, or under any Federal or State health benefits program; or

(2) by an entity that provides health services on a prepaid basis.

(July 1, 1944, ch. 373, title III, §395, as added Pub. L. 100–175, title VI, §602, Nov. 29, 1987, 101 Stat. 979; amended Pub. L. 101–557, title I, §101(a)–(c), Nov. 15, 1990, 104 Stat. 2766; Pub. L. 102–108, §2(f), Aug. 17, 1991, 105 Stat. 550.)

EDITORIAL NOTES

PRIOR PROVISIONS

A prior section 280C, act July 1, 1944, ch. 373, title III, §399A, formerly §399c, as added Dec. 29, 1973, Pub. L. 93–222, §3, 87 Stat. 934; renumbered §399A, July 29, 1975, Pub. L. 94–63, title VI, §607(a), (c), 89 Stat. 351, provided for programs designed to assure the quality of health care, prior to repeal by Pub. L. 95–623, §11(b), Nov. 9, 1978, 92 Stat. 3455.

A prior section 395 of act July 1, 1944, ch. 373, title III, formerly §397, as added Oct. 22, 1965, Pub. L. 89–291, §2, 79 Stat. 1063; renumbered §396 and amended Mar. 13, 1970, Pub. L. 91–212, §§2(e), 6(a)(1), (2), 10(c)(3), (d)(2)(A), 84 Stat. 63, 64, 67; June 18, 1973, Pub. L. 93–45, title I, §107(d), 87 Stat. 92; renumbered §395 and amended July 23, 1974, Pub. L. 93–353, title II, §§203(c), 204, 88 Stat. 372, 373, which related to grants for establishing, expanding, and improving basic medical library or related resources, was classified to section 280b–7 of this title, prior to repeal by Pub. L. 99–158, §3(b), Nov. 20, 1985, 99 Stat. 879.

AMENDMENTS

1991—Subsec. (a)(1). Pub. L. 102–108 inserted "skilled medical services," after "if".

1990—Subsec. (a). Pub. L. 101–557, §101(a), substituted "shall make not less than 5, and not more than 20, grants" for "shall make not less than 3, and not more than 5, grants".

Subsec. (a)(1). Pub. L. 101–557, §101(b), substituted "skilled nursing care services, homemaker or home health aide services, or personal care services are provided in the homes of the individuals" for "skilled medical services or related health services (or both) are provided in the homes of the individuals".

Subsec. (b). Pub. L. 101–557, §101(c), substituted "to ensure that—" and pars. (1) and (2) for "to ensure that not less than 25 percent of individuals receiving services pursuant to subsection (a) of this section are individuals who are not less than 65 years of age".

STATUTORY NOTES AND RELATED SUBSIDIARIES

EFFECTIVE DATE

Section effective Oct. 1, 1987, see section 701(a) of Pub. L. 100–175, set out as an Effective Date of 1987 Amendment note under section 3001 of this title.

SHORT TITLE

For short title of title VI of Pub. L. 100–175, which enacted this part as the "Health Care Services in the Home Act of 1987", see section 601 of Pub. L. 100–175, set out as a Short Title of 1987 Amendments note under section 201 of this title.

§280c–1. Limitation on duration of grant and requirement of matching funds

(a) Limitation on duration of grant

The period during which payments are made to a State from a grant under section 280c(a) of this title may not exceed 3 years. Such payments shall be subject to annual evaluation by the Secretary.

(b) Requirement of matching funds

(1)(A) For the first year of payments to a State from a grant under section 280c(a) of this title, the Secretary may not make such payments in an amount exceeding 75 percent of the costs of services to be provided by the State pursuant to such section.

(B) For the second year of such payments to a State, the Secretary may not make such payments in an amount exceeding 65 percent of the costs of such services.

(C) For the third year of such payments to a State, the Secretary may not make such payments in an amount exceeding 55 percent of the costs of such services.

(2) The Secretary may not make a grant under section 280c(a) of this title to a State unless the State agrees to make available, directly or through donations from public or private entities, non-Federal contributions toward the costs of services to be provided pursuant to such section in an amount equal to—

(A) for the first year of payments to the State from the grant, not less than $25 (in cash or in kind under subsection (c)) for each $75 of Federal funds provided in the grant;

(B) for the second year of such payments to the State, not less than $35 (in cash or in kind under subsection (c)) for each $65 of such Federal funds; and

(C) for the third year of such payments to the State, not less than $45 (in cash or in kind under subsection (c)) for each $55 of such Federal funds.

(c) Determination of amount of non-Federal contribution

Non-Federal contributions required in subsection (b) may be in cash or in kind, fairly evaluated, including plant, equipment, or services. Amounts provided by the Federal Government, or services assisted or subsidized to any significant extent by the Federal Government, may not be included in determining the amount of such non-Federal contributions.

(July 1, 1944, ch. 373, title III, §396, as added Pub. L. 100–175, title VI, §602, Nov. 29, 1987, 101 Stat. 979.)

EDITORIAL NOTES

PRIOR PROVISIONS

A prior section 396 of act July 1, 1944, ch. 373, title III, formerly §398, as added Oct. 22, 1965, Pub. L. 89–291, §2, 79 Stat. 1065; renumbered §397 and amended Mar. 13, 1970, Pub. L. 91–212, §§2(f), 7, 10(c)(3), (d)(2)(A), 84 Stat. 63, 65, 67; June 18, 1973, Pub. L. 93–45, title I, §107(e), 87 Stat. 92; renumbered §396 and amended July 23, 1974, Pub. L. 93–353, title II, §§202(e), (f), 203(d), 204, 88 Stat. 372, 373, which related to grants for establishment of regional medical libraries, was classified to section 280b–8 of this title, prior to repeal by Pub. L. 99–158, §3(b), Nov. 20, 1985, 99 Stat. 879.

STATUTORY NOTES AND RELATED SUBSIDIARIES

EFFECTIVE DATE

Section effective Oct. 1, 1987, see section 701(a) of Pub. L. 100–175, set out as an Effective Date of 1987 Amendment note under section 3001 of this title.

§280c–2. General provisions

(a) Limitation on administrative expenses

The Secretary may not make a grant under section 280c(a) of this title to a State unless the State agrees that not more than 10 percent of the grant will be expended for administrative expenses with respect to the grant.

(b) Description of intended use of grant

The Secretary may not make a grant under section 280c(a) of this title to a State unless—

(1) the State submits to the Secretary a description of the purposes for which the State intends to expend the grant; and

(2) such description provides information relating to the programs and activities to be supported and services to be provided, including—

(A) the number of individuals who will receive services pursuant to section 280c(a) of this title and the average costs of providing such services to each such individual; and

(B) a description of the manner in which such programs and activities will be coordinated

with any similar programs and activities of public and private entities.

(c) Requirement of application

The Secretary may not make a grant under section 280c(a) of this title to a State unless the State has submitted to the Secretary an application for the grant. The application shall—

(1) contain the description of intended expenditures required in subsection (b);

(2) with respect to carrying out the purpose for which the grant is to be made, provide assurances of compliance satisfactory to the Secretary; and

(3) otherwise be in such form, be made in such manner, and contain such information and agreements as the Secretary determines to be necessary to carry out this subpart.

(d) Evaluations and report by Secretary

The Secretary shall—

(1) provide for an evaluation of each demonstration project for which a grant is made under section 280c(a) of this title; and

(2) not later than 6 months after the completion of such evaluations, submit to the Congress a report describing the findings made as a result of the evaluations.

(e) Authorizations of appropriations

For the purpose of carrying out this subpart, there are authorized to be appropriated $5,000,000 for each of the fiscal years 1988 through 1990, $7,500,000 for fiscal year 1991, and such sums as may be necessary for each of the fiscal years 1992 and 1993.

(July 1, 1944, ch. 373, title III, §397, as added Pub. L. 100–175, title VI, §602, Nov. 29, 1987, 101 Stat. 980; amended Pub. L. 101–557, title I, §101(d), Nov. 15, 1990, 104 Stat. 2766.)

EDITORIAL NOTES

PRIOR PROVISIONS

A prior section 397 of act July 1, 1944, ch. 373, title III, formerly §399, as added Oct. 22, 1965, Pub. L. 89–291, §2, 79 Stat. 1066; renumbered §398 and amended Mar. 13, 1970, Pub. L. 91–212, §§2(g), 8, 10(c)(3), (d)(2)(A), 84 Stat. 63, 65, 67; June 18, 1973, Pub. L. 93–45, title I, §107(f), 87 Stat. 92; renumbered §397 and amended July 23, 1974, Pub. L. 93–353, title II, §§203(e), 204, 88 Stat. 372, 373, which related to grants to provide support for biomedical scientific publications, was classified to section 280b–9 of this title, prior to repeal by Pub. L. 99–158, §3(b), Nov. 20, 1985, 99 Stat. 879.

AMENDMENTS

1990—Subsec. (e). Pub. L. 101–557 substituted "there are" for "there is" and inserted before period at end ", $7,500,000 for fiscal year 1991, and such sums as may be necessary for each of the fiscal years 1992 and 1993".

STATUTORY NOTES AND RELATED SUBSIDIARIES

EFFECTIVE DATE

Section effective Oct. 1, 1987, see section 701(a) of Pub. L. 100–175, set out as an Effective Date of 1987 Amendment note under section 3001 of this title.

SUBPART II—PROGRAMS WITH RESPECT TO ALZHEIMER'S DISEASE AND RELATED DEMENTIAS

EDITORIAL NOTES

CODIFICATION

Pub. L. 115–406, §2(2)(A), Dec. 31, 2018, 132 Stat. 5362, substituted "PROGRAMS WITH RESPECT TO

ALZHEIMER'S DISEASE AND RELATED DEMENTIAS" for "GRANTS FOR DEMONSTRATION PROJECTS WITH RESPECT TO ALZHEIMER'S DISEASE" in subpart heading.

§280c–3. Cooperative agreements to States and public health departments for Alzheimer's disease and related dementias

(a) In general

The Secretary, in coordination with the Director of the Centers for Disease Control and Prevention and the heads of other agencies, as appropriate, shall award cooperative agreements to health departments of States, political subdivisions of States, and Indian tribes and tribal organizations, to address Alzheimer's disease and related dementias, including by reducing cognitive decline, helping meet the needs of caregivers, and addressing unique aspects of Alzheimer's disease and related dementias to support the development and implementation of evidence-based interventions with respect to—

(1) educating and informing the public, based on evidence-based public health research and data, about Alzheimer's disease and related dementias;

(2) supporting early detection and diagnosis;

(3) reducing the risk of potentially avoidable hospitalizations for individuals with Alzheimer's disease and related dementias;

(4) reducing the risk of cognitive decline and cognitive impairment associated with Alzheimer's disease and related dementias;

(5) improving support to meet the needs of caregivers of individuals with Alzheimer's disease and related dementias;

(6) supporting care planning and management for individuals with Alzheimer's disease and related dementias.[1]

(7) supporting other relevant activities identified by the Secretary or the Director of the Centers for Disease Control and Prevention, as appropriate [2]

(b) Preference

In awarding cooperative agreements under this section, the Secretary shall give preference to applications that focus on addressing health disparities, including populations and geographic areas that have the highest prevalence of Alzheimer's disease and related dementias.

(c) Eligibility

To be eligible to receive a cooperative agreement under this section, an eligible entity (pursuant to subsection (a)) shall prepare and submit to the Secretary an application at such time, in such manner, and containing such information as the Secretary may require, including a plan that describes—

(1) how the applicant proposes to develop or expand, programs to educate individuals through partnership engagement, workforce development, guidance and support for programmatic efforts, and evaluation with respect to Alzheimer's disease and related dementias, and in the case of a cooperative agreement under this section, how the applicant proposes to support other relevant activities identified by the Secretary or Director of the Centers for Disease Control and Prevention, as appropriate.

(2) the manner in which the applicant will coordinate with Federal, tribal, and State programs related to Alzheimer's disease and related dementias, and appropriate State, tribal, and local agencies, as well as other relevant public and private organizations or agencies; and

(3) the manner in which the applicant will evaluate the effectiveness of any program carried out under the cooperative agreement.

(d) Matching requirement

Each health department that is awarded a cooperative agreement under subsection (a) shall provide, from non-Federal sources, an amount equal to 30 percent of the amount provided under such agreement (which may be provided in cash or in-kind) to carry out the activities supported by

the cooperative agreement.

(e) Waiver authority

The Secretary may waive all or part of the matching requirement described in subsection (d) for any fiscal year for a health department of a State, political subdivision of a State, or Indian tribe and tribal organization (including those located in a rural area or frontier area), if the Secretary determines that applying such matching requirement would result in serious hardship or an inability to carry out the purposes of the cooperative agreement awarded to such health department of a State, political subdivision of a State, or Indian tribe and tribal organization.

(f) Non-duplication of effort

The Secretary shall ensure that activities under any cooperative agreement awarded under this subpart do not unnecessarily duplicate efforts of other agencies and offices within the Department of Health and Human Services related to—

(1) activities of centers of excellence with respect to Alzheimer's disease and related dementias described in section 280c–4 of this title; and

(2) activities of public health departments with respect to Alzheimer's disease and related dementias described in this section.

(g) Relationship to items and services under other programs

A State may not make payments from a cooperative agreement under subsection (a) for any item or service to the extent that payment has been made, or can reasonably be expected to be made, with respect to such item or service—

(1) under any State compensation program, under an insurance policy, or under any Federal or State health benefits program; or

(2) by an entity that provides health services on a prepaid basis.

(July 1, 1944, ch. 373, title III, §398, as added Pub. L. 100–175, title VI, §602, Nov. 29, 1987, 101 Stat. 981; amended Pub. L. 101–557, title I, §102(a), (b), Nov. 15, 1990, 104 Stat. 2767; Pub. L. 105–392, title III, §302(a), Nov. 13, 1998, 112 Stat. 3586; Pub. L. 115–406, §3, Dec. 31, 2018, 132 Stat. 5365.)

EDITORIAL NOTES

PRIOR PROVISIONS

A prior section 398 of act July 1, 1944, ch. 373, title III, formerly §399a, as added Oct. 22, 1965, Pub. L. 89–291, §2, 79 Stat. 1066; renumbered §399, Mar. 13, 1970, Pub. L. 91–212, §10(c)(3), 84 Stat. 67; renumbered §398, July 23, 1974, Pub. L. 93–353, title II, §204, 88 Stat. 373, which related to the continuing availability of appropriated funds, was classified to section 280b–10 of this title, prior to repeal by Pub. L. 99–158, §3(b), Nov. 20, 1985, 99 Stat. 879.

AMENDMENTS

2018—Pub. L. 115–406, §3(1), substituted "Cooperative agreements to States and public health departments for Alzheimer's disease and related dementias" for "Establishment of program" in section catchline.

Subsec. (a). Pub. L. 115–406, §3(2), added subsec. (a) and struck out former subsec. (a) which provided that the Secretary would make grants to States for planning, establishing, and operating programs to provide care to Alzheimer's patients.

Subsecs. (b) to (e). Pub. L. 115–406, §3(3), (5), added subsecs. (b) to (e) and struck out former subsec. (b). Prior to amendment, text of subsec. (b) read as follows: "The Secretary may not make a grant under subsection (a) to a State unless the State agrees to expend not less than 50 percent of the grant for the provision of services described in subsection (a)(2)." Former subsec. (c) redesignated (g).

Subsec. (f). Pub. L. 115–406, §3(7), which directed adding subsec. (f) at the end of the section, was executed by adding subsec. (f) before subsec. (g) as redesignated by Pub. L. 115–406, §3(4), to reflect the probable intent of Congress.

Subsec. (g). Pub. L. 115–406, §3(6), which directed amendment of "subsection (f) (as so redesignated)" by substituting "cooperative agreement" for "grant", was executed by making the substitution in introductory

provisions of subsec. (g) as redesignated, to reflect the probable intent of Congress. See below.

Pub. L. 115–406, §3(4), redesignated subsec. (c) as (g).

1998—Subsec. (a). Pub. L. 105–392, §302(a)(1), struck out "not less than 5, and not more than 15," after "shall make" in introductory provisions.

Subsec. (a)(2). Pub. L. 105–392, §302(a)(2), inserted "who are living in single family homes or in congregate settings" after "disorders" and struck out "and" at end.

Subsec. (a)(3), (4). Pub. L. 105–392, §302(a)(3), (4), added par. (3) and redesignated former par. (3) as (4).

1990—Subsec. (a). Pub. L. 101–557, §102(a), substituted "shall make not less than 5, and not more than 15, grants" for "shall make not less than 3, and not more than 5, grants".

Subsec. (a)(1). Pub. L. 101–557, §102(b), substituted "with public and private organizations" for "by public and private organizations".

STATUTORY NOTES AND RELATED SUBSIDIARIES

EFFECTIVE DATE

Section effective Oct. 1, 1987, see section 701(a) of Pub. L. 100–175, set out as an Effective Date of 1987 Amendment note under section 3001 of this title.

[1] So in original. The period probably should be "; and".

[2] So in original. Probably should be followed by a period.

§280c–4. Promotion of public health knowledge and awareness of Alzheimer's disease and related dementias

(a) Alzheimer's disease and related dementias public health centers of excellence

(1) In general

The Secretary, in coordination with the Director of the Centers for Disease Control and Prevention and the heads of other agencies as appropriate, shall award grants, contracts, or cooperative agreements to eligible entities, such as institutions of higher education, State, tribal, and local health departments, Indian tribes, tribal organizations, associations, or other appropriate entities for the establishment or support of regional centers to address Alzheimer's disease and related dementias by—

(A) advancing the awareness of public health officials, health care professionals, and the public, on the most current information and research related to Alzheimer's disease and related dementias, including cognitive decline, brain health, and associated health disparities;

(B) identifying and translating promising research findings, such as findings from research and activities conducted or supported by the National Institutes of Health, including Alzheimer's Disease Research Centers authorized by section 285e–2 of this title, into evidence-based programmatic interventions for populations with Alzheimer's disease and related dementias and caregivers for such populations; and

(C) expanding activities, including through public-private partnerships related to Alzheimer's disease and related dementias and associated health disparities.

(2) Requirements

To be eligible to receive a grant, contract, or cooperative agreement under this subsection, an entity shall submit to the Secretary an application containing such agreements and information as the Secretary may require, including a description of how the entity will—

(A) coordinate, as applicable, with existing Federal, State, and tribal programs related to Alzheimer's disease and related dementias;

(B) examine, evaluate, and promote evidence-based interventions for individuals with Alzheimer's disease and related dementias, including underserved populations with such

conditions, and those who provide care for such individuals; and

(C) prioritize activities relating to—

(i) expanding efforts, as appropriate, to implement evidence-based practices to address Alzheimer's disease and related dementias, including through the training of State, local, and tribal public health officials and other health professionals on such practices;

(ii) supporting early detection and diagnosis of Alzheimer's disease and related dementias;

(iii) reducing the risk of potentially avoidable hospitalizations of individuals with Alzheimer's disease and related dementias;

(iv) reducing the risk of cognitive decline and cognitive impairment associated with Alzheimer's disease and related dementias;

(v) enhancing support to meet the needs of caregivers of individuals with Alzheimer's disease and related dementias;

(vi) reducing health disparities related to the care and support of individuals with Alzheimer's disease and related dementias;

(vii) supporting care planning and management for individuals with Alzheimer's disease and related dementias; and

(viii) supporting other relevant activities identified by the Secretary or the Director of the Centers for Disease Control and Prevention, as appropriate.

(3) Considerations

In awarding grants, contracts, and cooperative agreements under this subsection, the Secretary shall consider, among other factors, whether the entity—

(A) provides services to rural areas or other underserved populations;

(B) is able to build on an existing infrastructure of services and public health research; and

(C) has experience with providing care or caregiver support, or has experience conducting research related to Alzheimer's disease and related dementias.

(4) Distribution of awards

In awarding grants, contracts, or cooperative agreements under this subsection, the Secretary, to the extent practicable, shall ensure equitable distribution of awards based on geographic area, including consideration of rural areas, and the burden of the disease within sub-populations.

(5) Data reporting and program oversight

With respect to a grant, contract, or cooperative agreement awarded under this subsection, not later than 90 days after the end of the first year of the period of assistance, and annually thereafter for the duration of the grant, contract, or agreement (including the duration of any renewal period as provided for under paragraph (5)), the entity shall submit data, as appropriate, to the Secretary regarding—

(A) the programs and activities funded under the grant, contract, or agreement; and

(B) outcomes related to such programs and activities.

(b) Improving data on State and national prevalence of Alzheimer's disease and related dementias

(1) In general

The Secretary shall, as appropriate, improve the analysis and timely reporting of data on the incidence and prevalence of Alzheimer's disease and related dementias. Such data may include, as appropriate, information on cognitive decline, caregiving, and health disparities experienced by individuals with cognitive decline and their caregivers. The Secretary may award grants, contracts, or cooperative agreements to eligible entities for activities under this paragraph.

(2) Eligibility

To be eligible to receive a grant, contract, or cooperative agreement under this subsection, an entity shall be a public or nonprofit private entity, including institutions of higher education, State,

local, and tribal health departments, and Indian tribes and tribal organizations, and submit to the Secretary an application at such time, in such manner, and containing such information as the Secretary may require.

(3) Data sources

The analysis, timely public reporting, and dissemination of data under this subsection may be carried out using data sources such as the following:

(A) The Behavioral Risk Factor Surveillance System.

(B) The National Health and Nutrition Examination Survey.

(C) The National Health Interview Survey.

(c) Improved coordination

The Secretary shall ensure that activities and programs related to dementia under this section do not unnecessarily duplicate activities and programs of other agencies and offices within the Department of Health and Human Services.

(July 1, 1944, ch. 373, title III, §398A, as added Pub. L. 115–406, §2(2)(B), Dec. 31, 2018, 132 Stat. 5362.)

EDITORIAL NOTES

PRIOR PROVISIONS

A prior section 280c–4, act July 1, 1944, ch. 373, title III, §398A, formerly §399, as added Pub. L. 100–175, title VI, §602, Nov. 29, 1987, 101 Stat. 982; renumbered §398A, Pub. L. 102–321, title V, §502(1), July 10, 1992, 106 Stat. 427; amended Pub. L. 105–392, title III, §302(b), Nov. 13, 1998, 112 Stat. 3586, related to the requirement of matching funds, prior to repeal by Pub. L. 115–406, §2(2)(B), Dec. 31, 2018, 132 Stat. 5362.

§280c–5. General provisions

(a) Limitation on administrative expenses

The Secretary may not make a grant or cooperative agreement under sections [1] 280c–3 or 280c–4 of this title to an entity unless the entity agrees that not more than 5 percent of the grant or cooperative agreement will be expended for administrative expenses with respect to the grant or cooperative agreement.

(b) Requirement of application

The Secretary may not make a grant under sections [1] 280c–3 or 280c–4 of this title to an entity unless the entity has submitted to the Secretary an application for the grant. The application shall—

(1) contain the description of intended expenditures;

(2) with respect to carrying out the purpose for which the grant is to be made, provide assurances of compliance satisfactory to the Secretary; and

(3) otherwise be in such form, be made in such manner, and contain such information and agreements as the Secretary determines to be necessary to carry out this subpart.

(c) Evaluations and report by Secretary

The Secretary shall—

(1) provide for an evaluation of the activities for which an award is made under sections [1] 280c–3 or 280c–4 of this title; and

(2) not later than 1 year after the completion of such evaluations, submit to the Congress a report describing the findings made as a result of the evaluations.

(d) Definition

In this subpart, the terms "Indian tribe" and "tribal organization" have the meanings given such terms in section 1603 of title 25.

(e) Authorizations of appropriations

For the purpose of carrying out this subpart, there are authorized to be appropriated $20,000,000 for each of fiscal years 2020 through 2024 and $33,000,000 for each of fiscal years 2025 through 2029.

(July 1, 1944, ch. 373, title III, §398B, formerly §399A, as added Pub. L. 100–175, title VI, §602, Nov. 29, 1987, 101 Stat. 982; amended Pub. L. 101–557, title I, §102(c), Nov. 15, 1990, 104 Stat. 2767; renumbered §398B, Pub. L. 102–321, title V, §502(1), July 10, 1992, 106 Stat. 427; Pub. L. 105–392, title III, §302(c), Nov. 13, 1998, 112 Stat. 3586; Pub. L. 115–406, §4, Dec. 31, 2018, 132 Stat. 5366; Pub. L. 118–142, §2, Dec. 11, 2024, 138 Stat. 1662.)

EDITORIAL NOTES

AMENDMENTS

2024—Subsec. (e). Pub. L. 118–142 inserted "and $33,000,000 for each of fiscal years 2025 through 2029" before period at end.

2018—Subsec. (a). Pub. L. 115–406, §4(1), inserted "or cooperative agreement" after "grant" wherever appearing and substituted "sections 280c–3 or 280c–4 of this title to an entity unless the entity" for "section 280c–3(a) of this title to a State unless the State" and "5 percent" for "10 percent".

Subsec. (b). Pub. L. 115–406, §4(4)(A), substituted "sections 280c–3 or 280c–4 of this title to an entity unless the entity" for "section 280c–3(a) of this title to a State unless the State" in introductory provisions.

Pub. L. 115–406, §4(2), (3), redesignated subsec. (c) as (b) and struck out former subsec. (b) which required a State to submit a description of the purposes for which the State intended to expend a grant.

Subsec. (b)(1). Pub. L. 115–406, §4(4)(B), substituted "expenditures;" for "expenditures required in subsection (b);".

Subsec. (c). Pub. L. 115–406, §4(3), redesignated subsec. (d) as (c). Former subsec. (c) redesignated (b).

Subsec. (c)(1). Pub. L. 115–406, §4(5)(A), substituted "the activities for which an award" for "each demonstration project for which a grant" and "sections 280c–3 or 280c–4 of this title" for "section 280c–3(a) of this title".

Subsec. (c)(2). Pub. L. 115–406, §4(5)(B), substituted "1 year" for "6 months".

Subsec. (d). Pub. L. 115–406, §4(3), (6), added subsec. (d) and redesignated former subsec. (d) as (c).

Subsec. (e). Pub. L. 115–406, §4(7), substituted "$20,000,000 for each of fiscal years 2020 through 2024" for "$5,000,000 for each of the fiscal years 1988 through 1990, $7,500,000 for fiscal year 1991, such sums as may be necessary for each of the fiscal years 1992 and 1993, $8,000,000 for fiscal year 1998, and such sums as may be necessary for each of the fiscal years 1999 through 2002".

1998—Subsec. (e). Pub. L. 105–392 substituted "1991, such sums" for "1991, and such sums" and inserted before period at end ", $8,000,000 for fiscal year 1998, and such sums as may be necessary for each of the fiscal years 1999 through 2002".

1990—Subsec. (e). Pub. L. 101–557 substituted "there are" for "there is" and inserted before period at end ", $7,500,000 for fiscal year 1991, and such sums as may be necessary for each of the fiscal years 1992 and 1993".

STATUTORY NOTES AND RELATED SUBSIDIARIES

EFFECTIVE DATE

Section effective Oct. 1, 1987, see section 701(a) of Pub. L. 100–175, set out as an Effective Date of 1987 Amendment note under section 3001 of this title.

[1] So in original. Probably should be "section".

SUBPART III—GRANTS FOR HOME VISITING SERVICES FOR AT-RISK FAMILIES

§280c–6. Projects to improve maternal, infant, and child health

(a) In general

(1) Establishment of program

The Secretary, acting through the Administrator of the Health Resources and Services Administration, shall make grants to eligible entities to pay the Federal share of the cost of providing the services specified in subsection (b) to families in which a member is—

(A) a pregnant woman at risk of delivering an infant with a health or developmental complication; or

(B) a child less than 3 years of age—

(i) who is experiencing or is at risk of a health or developmental complication, or of child abuse or neglect; or

(ii) who has been prenatally exposed to maternal substance abuse.

(2) Minimum period of awards; administrative consultations

(A) The Secretary shall award grants under paragraph (1) for periods of at least three years.

(B) The Administrator of the Administration for Children, Youth, and Families and the Director of the National Commission to Prevent Infant Mortality shall be consulted regarding the promulgation of program guidelines and funding priorities under this section.

(3) Requirement of status as medicaid provider

(A) Subject to subparagraph (B), the Secretary may make a grant under paragraph (1) only if, in the case of any service under such paragraph that is covered in the State plan approved under title XIX of the Social Security Act [42 U.S.C. 1396 et seq.] for the State involved—

(i) the entity involved will provide the service directly, and the entity has entered into a participation agreement under the State plan and is qualified to receive payments under such plan; or

(ii) the entity will enter into an agreement with an organization under which the organization will provide the service, and the organization has entered into such a participation agreement and is qualified to receive such payments.

(B)(i) In the case of an organization making an agreement under subparagraph (A)(ii) regarding the provision of services under paragraph (1), the requirement established in such subparagraph regarding a participation agreement shall be waived by the Secretary if the organization does not, in providing health or mental health services, impose a charge or accept reimbursement available from any third-party payor, including reimbursement under any insurance policy or under any Federal or State health benefits program.

(ii) A determination by the Secretary of whether an organization referred to in clause (i) meets the criteria for a waiver under such clause shall be made without regard to whether the organization accepts voluntary donations regarding the provision of services to the public.

(b) Home visiting services for eligible families

With respect to an eligible family, each of the following services shall, directly or through arrangement with other public or nonprofit private entities, be available (as applicable to the family member involved) in each project operated with a grant under subsection (a):

(1) Prenatal and postnatal health care.

(2) Primary health care for the children, including developmental assessments.

(3) Education for the parents concerning infant care and child development, including the development and utilization of parent and teacher resource networks and other family resource and support networks where such networks are available.

(4) Upon the request of a parent, providing the education described in paragraph (3) to other individuals who have responsibility for caring for the children.

(5) Education for the parents concerning behaviors that adversely affect health.

(6) Assistance in obtaining necessary health, mental health, developmental, social, housing, and

nutrition services and other assistance, including services and other assistance under maternal and child health programs; the special supplemental nutrition program for women, infants, and children; section 1786 of this title; title V of the Social Security Act [42 U.S.C. 701 et seq.]; title XIX of such Act [42 U.S.C. 1396 et seq.] (including the program for early and periodic screening, diagnostic, and treatment services described in section 1905(r) of such Act [42 U.S.C. 1396d(r)]); titles IV and XIX of the Social Security Act [42 U.S.C. 601 et seq., 1396 et seq.]; housing programs; other food assistance programs; and appropriate alcohol and drug dependency treatment programs, according to need.

(c) Considerations in making grants

In awarding grants under subsection (a), the Secretary shall take into consideration—

(1) the ability of the entity involved to provide, either directly or through linkages, a broad range of preventive and primary health care services and related social, family support, and developmental services;

(2) different combinations of professional and lay home visitors utilized within programs that are reflective of the identified service needs and characteristics of target populations;

(3) the extent to which the population to be targeted has limited access to health care, and related social, family support, and developmental services; and

(4) whether such grants are equitably distributed among urban and rural settings and whether entities serving Native American communities are represented among the grantees.

(d) Federal share

With respect to the costs of carrying out a project under subsection (a), a grant under such subsection for the project may not exceed 90 percent of such costs. To be eligible to receive such a grant, an applicant must provide assurances that the applicant will obtain at least 10 percent of such costs from non-Federal funds (and such contributions to such costs may be in cash or in-kind, including facilities and personnel).

(e) Rule of construction regarding at-risk births

For purposes of subsection (a)(1), a pregnant woman shall be considered to be at risk of delivering an infant with a health or developmental complication if during the pregnancy the woman—

(1) lacks appropriate access to, or information concerning, early and routine prenatal care;

(2) lacks the transportation necessary to gain access to the services described in subsection (b);

(3) lacks appropriate child care assistance, which results in impeding the ability of such woman to utilize health and related social services;

(4) is fearful of accessing substance abuse services or child and family support services; or

(5) is a minor with a low income.

(f) Delivery of services and case management

(1) Case management model

Home visiting services provided under this section shall be delivered according to a case management model, and a registered nurse, licensed social worker, or other licensed health care professional with experience and expertise in providing health and related social services in home and community settings shall be assigned as the case manager for individual cases under such model.

(2) Case manager

A case manager assigned under paragraph (1) shall have primary responsibility for coordinating and overseeing the development of a plan for each family that is to receive home visiting services under this section, and for coordinating the delivery of such services provided through appropriate personnel.

(3) Appropriate personnel

In determining which personnel shall be utilized in the delivery of services, the case manager shall consider—

(A) the stated objective of the project to be operated with the grant, as determined after considering identified gaps in the current service delivery system; and

(B) the nature of the needs of the family to be served, as determined at the initial assessment of the family that is conducted by the case manager, and through follow-up contacts by other providers of home visiting services.

(4) Family service plan

A case manager, in consultation with a team established in accordance with paragraph (5) for the family involved, shall develop a plan for the family following the initial visit to the home of the family. Such plan shall reflect—

(A) an assessment of the health and related social service needs of the family;

(B) a structured plan for the delivery of home visiting services to meet the identified needs of the family;

(C) the frequency with which such services are to be provided to the family;

(D) ongoing revisions made as the needs of family members change; and

(E) the continuing voluntary participation of the family in the plan.

(5) Home visiting services team

The team to be consulted under paragraph (4) on behalf of a family shall include, as appropriate, other nursing professionals, physician assistants, social workers, child welfare professionals, infant and early childhood specialists, nutritionists, and laypersons trained as home visitors. The case manager shall ensure that the plan is coordinated with those physician services that may be required by the mother or child.

(g) Outreach

Each grantee under subsection (a) shall provide outreach and casefinding services to inform eligible families of the availability of home visiting services from the project.

(h) Confidentiality

In accordance with applicable State law, an entity receiving a grant under subsection (a) shall maintain confidentiality with respect to services provided to families under this section.

(i) Certain assurances

The Secretary may award a grant under subsection (a) only if the entity involved provides assurances satisfactory to the Secretary that—

(1) the entity will provide home visiting services with reasonable frequency—

(A) to families with pregnant women, as early in the pregnancy as is practicable, and until the infant reaches at least 2 years of age; and

(B) to other eligible families, for at least 2 years; and

(2) the entity will coordinate with public health and related social service agencies to prevent duplication of effort and improve the delivery of comprehensive health and related social services.

(j) Submission to Secretary of certain information

The Secretary may award a grant under subsection (a) only if the entity involved submits to the Secretary—

(1) a description of the population to be targeted for home visiting services and methods of outreach and casefinding for identifying eligible families, including the use of lay home visitors where appropriate;

(2) a description of the types and qualifications of home visitors used by the entity and the process by which the entity will provide continuing training and sufficient support to the home visitors; and

(3) such other information as the Secretary determines to be appropriate.

(k) Limitation regarding administrative expenses

Not more than 10 percent of a grant under subsection (a) may be expended for administrative

expenses with respect to the grant. The costs of training individuals to serve in the project involved are not subject to the preceding sentence.

(l) Restrictions on use of grant

To be eligible to receive a grant under this section, an entity must agree that the grant will not be expended—

(1) to provide inpatient hospital services;

(2) to make cash payments to intended recipients of services;

(3) to purchase or improve land, purchase, construct, or permanently improve (other than minor remodeling) any building or other facility, or purchase major medical equipment;

(4) to satisfy any requirement for the expenditure of non-Federal funds as a condition for the receipt of Federal funds; or

(5) to provide financial assistance to any entity other than a public or nonprofit private entity.

(m) Reports to Secretary

To be eligible to receive a grant under this section, an entity must agree to submit an annual report on the services provided under this section to the Secretary in such manner and containing such information as the Secretary by regulation requires. At a minimum, the entity shall report information concerning eligible families, including—

(1) the characteristics of the families and children receiving services under this section;

(2) the usage, nature, and location of the provider, of preventive health services, including prenatal, primary infant, and child health care;

(3) the incidence of low birthweight and premature infants;

(4) the length of hospital stays for pre- and post-partum women and their children;

(5) the incidence of substantiated child abuse and neglect for all children within participating families;

(6) the number of emergency room visits for routine health care;

(7) the source of payment for health care services and the extent to which the utilization of health care services, other than routine screening and medical care, available to the individuals under the program established under title XIX of the Social Security Act [42 U.S.C. 1396 et seq.], and under other Federal, State, and local programs, is reduced;

(8) the number and type of referrals made for health and related social services, including alcohol and drug treatment services, and the utilization of such services provided by the grantee; and

(9) the incidence of developmental disabilities.

(n) Requirement of application

The Secretary may make a grant under subsection (a) only if—

(1) an application for the grant is submitted to the Secretary;

(2) the application contains the agreements and assurances required in this section, and the information required in subsection (j);

(3) the application contains evidence that the preparation of the application has been coordinated with the State agencies responsible for maternal and child health and child welfare, and coordinated with services provided under part C of the Individuals with Disabilities Education Act [20 U.S.C. 1431 et seq.]; and

(4) the application is in such form, is made in such manner, and contains such agreements, assurances, and information as the Secretary determines to be necessary to carry out this section.

(o) Peer review

(1) Requirement

In making determinations for awarding grants under subsection (a), the Secretary shall rely on the recommendations of the peer review panel established under paragraph (2).

(2) Composition

The Secretary shall establish a review panel to make recommendations under paragraph (1) that

shall be composed of—

(A) national experts in the fields of maternal and child health, child abuse and neglect, and the provision of community-based primary health services; and

(B) representatives of relevant Federal agencies, including the Health Resources and Services Administration, the Substance Abuse and Mental Health Services Administration, the Administration for Children, Youth, and Families, the U.S. Advisory Board on Child Abuse and Neglect, and the National Commission to Prevent Infant Mortality.

(p) Evaluations

(1) In general

The Secretary shall, directly or through contracts with public or private entities—

(A) conduct evaluations to determine the effectiveness of projects under subsection (a) in reducing the incidence of children born with health or developmental complications, the incidence among children less than 3 years of age of such complications, and the incidence of child abuse and neglect; and

(B) not less than once during each 3-year period, prepare and submit to the appropriate committees of Congress a report concerning the results of such evaluations.

(2) Contents

The evaluations conducted under paragraph (1) shall—

(A) include a summary of the data contained in the annual reports submitted under subsection (m);

(B) assess the relative effectiveness of projects under subsection (a) in urban and rural areas, and among programs utilizing differing combinations of professionals and trained home visitors recruited from the community to meet the needs of defined target service populations; and

(C) make further recommendations necessary or desirable to increase the effectiveness of such projects.

(q) Definitions

For purposes of this section:

(1) The term "eligible entity" includes public and nonprofit private entities that provide health or related social services, including community-based organizations, visiting nurse organizations, hospitals, local health departments, community health centers, Native Hawaiian health centers, nurse managed clinics, family service agencies, child welfare agencies, developmental service providers, family resource and support programs, and resource mothers projects.

(2) The term "eligible family" means a family described in subsection (a).

(3) The term "health or developmental complication", with respect to a child, means—

(A) being born in an unhealthy or potentially unhealthy condition, including premature birth, low birthweight, and prenatal exposure to maternal substance abuse;

(B) a condition arising from a condition described in subparagraph (A);

(C) a physical disability or delay; and

(D) a developmental disability or delay.

(4) The term "home visiting services" means the services specified in subsection (b), provided at the residence of the eligible family involved or provided pursuant to arrangements made for the family (including arrangements for services in community settings).

(5) The term "home visitors" means providers of home visiting services.

(r) Authorization of appropriations

For the purpose of carrying out this section, there is authorized to be appropriated $30,000,000 for each of the fiscal years 1993 and 1994.

(July 1, 1944, ch. 373, title III, §399, as added Pub. L. 102–321, title V, §502(2), July 10, 1992, 106 Stat. 427; amended Pub. L. 103–448, title II, §204(w)(2)(D), Nov. 2, 1994, 108 Stat. 4746; Pub. L. 108–446, title III, §305(i)(2), Dec. 3, 2004, 118 Stat. 2806.)

EDITORIAL NOTES

REFERENCES IN TEXT

The Social Security Act, referred to in subsecs. (a)(3)(A), (b)(6), and (m)(7), is act Aug. 14, 1935, ch. 531, 49 Stat. 620. Titles IV, V, and XIX of the Act are classified generally to subchapters IV (§601 et seq.), V (§701 et seq.), and XIX (§1396 et seq.), respectively, of chapter 7 of this title. For complete classification of this Act to the Code, see section 1305 of this title and Tables.

The Individuals with Disabilities Education Act, referred to in subsec. (n)(3), is title VI of Pub. L. 91–230, Apr. 13, 1970, 84 Stat. 175. Part C of the Act is classified generally to subchapter III (§1431 et seq.) of chapter 33 of Title 20, Education. For complete classification of this Act to the Code, see section 1400 of Title 20 and Tables.

PRIOR PROVISIONS

A prior section 399 of act July 1, 1944, was renumbered section 398A by section 502(1) of Pub. L. 102–321 and is classified to section 280c–4 of this title.

Another prior section 399 of act July 1, 1944, ch. 373, title III, formerly §399b, as added Oct. 22, 1965, Pub. L. 89–291, §2, 79 Stat. 1066; renumbered §399a and amended Mar. 13, 1970, Pub. L. 91–212, §10(c)(3), (d)(2)(A), 84 Stat. 67; renumbered §399, July 23, 1974, Pub. L. 93–353, title II, §204, 88 Stat. 373; Oct. 17, 1979, Pub. L. 96–88, title V, §509(b), 93 Stat. 695, which related to the maintenance of records by recipients of grants and audits thereof by the Secretary of Health and Human Services and the Comptroller General of the United States, was classified to section 280b–11 of this title, prior to repeal by Pub. L. 99–158, §3(b), Nov. 20, 1985, 99 Stat. 879.

AMENDMENTS

2004—Subsec. (n)(3). Pub. L. 108–446 substituted "part C" for "part H".

1994—Subsec. (b)(6). Pub. L. 103–448 substituted "special supplemental nutrition program" for "special supplemental food program".

STATUTORY NOTES AND RELATED SUBSIDIARIES

EFFECTIVE DATE OF 1994 AMENDMENT

Amendment by Pub. L. 103–448 effective Oct. 1, 1994, see section 401 of Pub. L. 103–448, set out as a note under section 1755 of this title.

EFFECTIVE DATE

Section effective July 10, 1992, with programs making awards providing financial assistance in fiscal year 1993 and subsequent years effective for awards made on or after Oct. 1, 1992, see section 801(b), (d)(1) of Pub. L. 102–321, set out as an Effective Date of 1992 Amendment note under section 236 of this title.

REFERENCE TO COMMUNITY, MIGRANT, PUBLIC HOUSING, OR HOMELESS HEALTH CENTER CONSIDERED REFERENCE TO HEALTH CENTER

Reference to community health center, migrant health center, public housing health center, or homeless health center considered reference to health center, see section 4(c) of Pub. L. 104–299, set out as a note under section 254b of this title.

PURPOSE

Pub. L. 102–321, title V, §501, July 10, 1992, 106 Stat. 426, provided that: "The purpose of this title [enacting this section] is—

"(1) to increase the use of, and to provide information on the availability of early, continuous and comprehensive prenatal care;

"(2) to reduce the incidence of infant mortality and of infants born prematurely, with low birthweight, or with other impairments including those associated with maternal substance abuse;

"(3) for pregnant women and mothers of children below the age of 3 whose children have experienced or are at risk of experiencing a health or developmental complication, to provide assistance in obtaining health and related social services necessary to meet the special needs of the women and their children;

"(4) to assist, when requested, women who are pregnant and at-risk for poor birth outcomes, or who have young children and are abusing alcohol or other drugs, in obtaining appropriate treatment; and

"(5) to reduce the incidence of child abuse and neglect."

PART L—[REPEALED]

EDITORIAL NOTES

CODIFICATION

Pub. L. 106–310, div. B, title XXXI, §3106(n), Oct. 17, 2000, 114 Stat. 1179, struck out heading for part L "Services for Children of Substance Abusers".

Pub. L. 103–43, title XX, §2008(i)(2)(B)(ii), June 10, 1993, 107 Stat. 213, redesignated part M "Services for Children of Substance Abusers" as L. Former part L "Health Care Services in the Home" redesignated K.

Pub. L. 101–616, title I, §101(a)(1), Nov. 16, 1990, 104 Stat. 3279, redesignated part K "Health Care Services in the Home" as L.

§280d. Transferred

EDITORIAL NOTES

CODIFICATION

Section, act July 1, 1944, ch. 373, title III, §399D, as added Pub. L. 102–321, title IV, §401(a), July 10, 1992, 106 Stat. 419, and amended, which related to grants for services for children of substance abusers, was renumbered section 399A of title III of act July 1, 1944 by Pub. L. 106–310, div. A, title V, §502(1), Oct. 17, 2000, 114 Stat. 1115. Subsequently, section 399D was renumbered section 519 of title V of act July 1, 1944, without reference to its prior renumbering as 399A, by Pub. L. 106–310, div. B, title XXXI, §3106(m), Oct. 17, 2000, 114 Stat. 1179. Section was transferred to section 290bb–25 of this title.

§280d–11. Transferred

EDITORIAL NOTES

CODIFICATION

Section, act July 1, 1944, ch. 373, title III, §399F, as added Pub. L. 102–531, title II, §201, Oct. 27, 1992, 106 Stat. 3474, which comprised part N in its entirety and which related to establishment and duties of National Foundation for the Centers for Disease Control and Prevention, was renumbered section 399G of act July 1, 1944, by Pub. L. 106–310, div. A, title V, §502(3), Oct. 17, 2000, 114 Stat. 1115, and transferred to section 280e–11 of this title.

PART M—NATIONAL PROGRAM OF CANCER REGISTRIES

§280e. National program of cancer registries

(a) In general

(1) Statewide cancer registries

The Secretary, acting through the Director of the Centers for Disease Control, may make grants to States, or may make grants or enter into contracts with academic or nonprofit organizations designated by the State to operate the State's cancer registry in lieu of making a grant directly to

the State, to support the operation of population-based, statewide registries to collect, for each condition specified in paragraph (2)(A), data concerning—

(A) demographic information about each case of cancer;

(B) information on the industrial or occupational history of the individuals with the cancers, to the extent such information is available from the same record;

(C) administrative information, including date of diagnosis and source of information;

(D) pathological data characterizing the cancer, including the cancer site, stage of disease (pursuant to Staging Guide), incidence, and type of treatment; and

(E) other elements determined appropriate by the Secretary.

(2) Cancer; benign brain-related tumors

(A) In general

For purposes of paragraph (1), the conditions referred to in this paragraph are the following:

(i) Each form of in-situ and invasive cancer (with the exception of basal cell and squamous cell carcinoma of the skin), including malignant brain-related tumors.

(ii) Benign brain-related tumors.

(B) Brain-related tumor

For purposes of subparagraph (A):

(i) The term "brain-related tumor" means a listed primary tumor (whether malignant or benign) occurring in any of the following sites:

(I) The brain, meninges, spinal cord, cauda equina, a cranial nerve or nerves, or any other part of the central nervous system.

(II) The pituitary gland, pineal gland, or craniopharyngeal duct.

(ii) The term "listed", with respect to a primary tumor, means a primary tumor that is listed in the International Classification of Diseases for Oncology (commonly referred to as the ICD–O).

(iii) The term "International Classification of Diseases for Oncology" means a classification system that includes topography (site) information and histology (cell type information) developed by the World Health Organization, in collaboration with international centers, to promote international comparability in the collection, classification, processing, and presentation of cancer statistics. The ICD–O system is a supplement to the International Statistical Classification of Diseases and Related Health Problems (commonly known as the ICD) and is the standard coding system used by cancer registries worldwide. Such term includes any modification made to such system for purposes of the United States. Such term further includes any published classification system that is internationally recognized as a successor to the classification system referred to in the first sentence of this clause.

(C) Statewide cancer registry

References in this section to cancer registries shall be considered to be references to registries described in this subsection.

(b) Matching funds

(1) In general

The Secretary may make a grant under subsection (a) only if the State, or the academic or nonprofit private organization designated by the State to operate the cancer registry of the State, involved agrees, with respect to the costs of the program, to make available (directly or through donations from public or private entities) non-Federal contributions toward such costs in an amount that is not less than 25 percent of such costs or $1 for every $3 of Federal funds provided in the grant.

(2) Determination of amount of non-Federal contribution; maintenance of effort

(A) Non-Federal contributions required in paragraph (1) may be in cash or in kind, fairly

evaluated, including plant, equipment, or services. Amounts provided by the Federal Government, or services assisted or subsidized to any significant extent by the Federal Government, may not be included in determining the amount of such non-Federal contributions.

(B) With respect to a State in which the purpose described in subsection (a) is to be carried out, the Secretary, in making a determination of the amount of non-Federal contributions provided under paragraph (1), may include only such contributions as are in excess of the amount of such contributions made by the State toward the collection of data on cancer for the fiscal year preceding the first year for which a grant under subsection (a) is made with respect to the State. The Secretary may decrease the amount of non-Federal contributions that otherwise would have been required by this subsection in those cases in which the State can demonstrate that decreasing such amount is appropriate because of financial hardship.

(c) Eligibility for grants

(1) In general

No grant shall be made by the Secretary under subsection (a) unless an application has been submitted to, and approved by, the Secretary. Such application shall be in such form, submitted in such a manner, and be accompanied by such information, as the Secretary may specify. No such application may be approved unless it contains assurances that the applicant will use the funds provided only for the purposes specified in the approved application and in accordance with the requirements of this section, that the application will establish such fiscal control and fund accounting procedures as may be necessary to assure proper disbursement and accounting of Federal funds paid to the applicant under subsection (a), and that the applicant will comply with the peer review requirements under sections 289 and 289a of this title.

(2) Assurances

Each applicant, prior to receiving Federal funds under subsection (a), shall provide assurances satisfactory to the Secretary that the applicant will—

(A) provide for the establishment of a registry in accordance with subsection (a);

(B) comply with appropriate standards of completeness, timeliness, and quality of population-based cancer registry data;

(C) provide for the annual publication of reports of cancer data under subsection (a); and

(D) provide for the authorization under State law of the statewide cancer registry, including promulgation of regulations providing—

(i) a means to assure complete reporting of cancer cases (as described in subsection (a)) to the statewide cancer registry by hospitals or other facilities providing screening, diagnostic or therapeutic services to patients with respect to cancer;

(ii) a means to assure the complete reporting of cancer cases (as defined in subsection (a)) to the statewide cancer registry by physicians, surgeons, and all other health care practitioners diagnosing or providing treatment for cancer patients, except for cases directly referred to or previously admitted to a hospital or other facility providing screening, diagnostic or therapeutic services to patients in that State and reported by those facilities;

(iii) a means for the statewide cancer registry to access all records of physicians and surgeons, hospitals, outpatient clinics, nursing homes, and all other facilities, individuals, or agencies providing such services to patients which would identify cases of cancer or would establish characteristics of the cancer, treatment of the cancer, or medical status of any identified patient;

(iv) for the reporting of cancer case data to the statewide cancer registry in such a format, with such data elements, and in accordance with such standards of quality timeliness and completeness, as may be established by the Secretary;

(v) for the protection of the confidentiality of all cancer case data reported to the statewide cancer registry, including a prohibition on disclosure to any person of information reported to the statewide cancer registry that identifies, or could lead to the identification of, an individual cancer patient, except for disclosure to other State cancer registries and local and State health officers;

(vi) for a means by which confidential case data may in accordance with State law be disclosed to cancer researchers for the purposes of cancer prevention, control and research;

(vii) for the authorization or the conduct, by the statewide cancer registry or other persons and organizations, of studies utilizing statewide cancer registry data, including studies of the sources and causes of cancer, evaluations of the cost, quality, efficacy, and appropriateness of diagnostic, therapeutic, rehabilitative, and preventative services and programs relating to cancer, and any other clinical, epidemiological, or other cancer research; and

(viii) for protection for individuals complying with the law, including provisions specifying that no person shall be held liable in any civil action with respect to a cancer case report provided to the statewide cancer registry, or with respect to access to cancer case information provided to the statewide cancer registry.

(d) Relationship to certain programs

(1) In general

This section may not be construed to act as a replacement for or diminishment of the program carried out by the Director of the National Cancer Institute and designated by such Director as the Surveillance, Epidemiology, and End Results Program (SEER).

(2) Supplanting of activities

In areas where both such programs exist, the Secretary shall ensure that SEER support is not supplanted and that any additional activities are consistent with the guidelines provided for in subsection (c)(2)(C) and (D) and are appropriately coordinated with the existing SEER program.

(3) Transfer of responsibility

The Secretary may not transfer administration responsibility for such SEER program from such Director.

(4) Coordination

To encourage the greatest possible efficiency and effectiveness of Federally supported efforts with respect to the activities described in this subsection, the Secretary shall take steps to assure the appropriate coordination of programs supported under this part with existing Federally supported cancer registry programs.

(e) Requirement regarding certain study on breast cancer

In the case of a grant under subsection (a) to any State specified in subsection (b) of section 280e–3 of this title, the Secretary may establish such conditions regarding the receipt of the grant as the Secretary determines are necessary to facilitate the collection of data for the study carried out under such section.

(July 1, 1944, ch. 373, title III, §399B, formerly §399H, as added Pub. L. 102–515, §3, Oct. 24, 1992, 106 Stat. 3372; renumbered §399B and amended Pub. L. 106–310, div. A, title V, §502(2)(A), (B), Oct. 17, 2000, 114 Stat. 1115; Pub. L. 107–260, §2(a), Oct. 29, 2002, 116 Stat. 1743.)

EDITORIAL NOTES

AMENDMENTS

2002—Subsec. (a). Pub. L. 107–260 designated existing provisions as par. (1), inserted par. (1) heading, substituted "population-based, statewide registries to collect, for each condition specified in paragraph (2)(A), data" for "population-based, statewide cancer registries in order to collect, for each form of in-situ and invasive cancer (with the exception of basal cell and squamous cell carcinoma of the skin), data", redesignated former pars. (1) to (5) as subpars. (A) to (E) of par. (1), respectively, and added par. (2).

2000—Subsec. (e). Pub. L. 106–310, §502(2)(B), substituted "subsection (b) of section 280e–3 of this title" for "section 280e–3(b) of this title" and "such section" for "section 399C".

STATUTORY NOTES AND RELATED SUBSIDIARIES

CHANGE OF NAME

Centers for Disease Control changed to Centers for Disease Control and Prevention by Pub. L. 102–531, title III, §312, Oct. 27, 1992, 106 Stat. 3504.

EFFECTIVE DATE OF 2002 AMENDMENT

Pub. L. 107–260, §2(b), Oct. 29, 2002, 116 Stat. 1744, provided that: "The amendments made by subsection (a) [amending this section] apply to grants under section 399B of the Public Health Service Act [42 U.S.C. 280e] for fiscal year 2002 and subsequent fiscal years, except that, in the case of a State that received such a grant for fiscal year 2000, the Secretary of Health and Human Services may delay the applicability of such amendments to the State for not more than 12 months if the Secretary determines that compliance with such amendments requires the enactment of a statute by the State or the issuance of State regulations."

CONGRESSIONAL FINDINGS AND PURPOSE

Pub. L. 102–515, §2, Oct. 24, 1992, 106 Stat. 3372, provided that:

"(a) FINDINGS.—Congress finds that—

"(1) cancer control efforts, including prevention and early detection, are best addressed locally by State health departments that can identify unique needs;

"(2) cancer control programs and existing statewide population-based cancer registries have identified cancer incidence and cancer mortality rates that indicate the burden of cancer for Americans is substantial and varies widely by geographic location and by ethnicity;

"(3) statewide cancer incidence and cancer mortality data, can be used to identify cancer trends, patterns, and variation for directing cancer control intervention;

"(4) the American Association of Central Cancer Registries (AACCR) cites that of the 50 States, approximately 38 have established cancer registries, many are not statewide and 10 have no cancer registry; and

"(5) AACCR also cites that of the 50 States, 39 collect data on less than 100 percent of their population, and less than half have adequate resources for insuring minimum standards for quality and for completeness of case information.

"(b) PURPOSE.—It is the purpose of this Act [enacting this part and provisions set out as a note under section 201 of this title] to establish a national program of cancer registries."

§280e–1. Planning grants regarding registries

(a) In general

(1) States

The Secretary, acting through the Director of the Centers for Disease Control, may make grants to States for the purpose of developing plans that meet the assurances required by the Secretary under section 280e(c)(2) of this title.

(2) Other entities

For the purpose described in paragraph (1), the Secretary may make grants to public entities other than States and to nonprofit private entities. Such a grant may be made to an entity only if the State in which the purpose is to be carried out has certified that the State approves the entity as qualified to carry out the purpose.

(b) Application

The Secretary may make a grant under subsection (a) only if an application for the grant is submitted to the Secretary, the application contains the certification required in subsection (a)(2) (if the application is for a grant under such subsection), and the application is in such form, is made in such manner, and contains such agreements, assurances, and information as the Secretary determines to be necessary to carry out this section.

(July 1, 1944, ch. 373, title III, §399C, formerly §399I, as added Pub. L. 102–515, §3, Oct. 24, 1992, 106 Stat. 3375; renumbered §399C, Pub. L. 106–310, div. A, title V, §502(2)(A), Oct. 17, 2000, 114 Stat. 1115.)

STATUTORY NOTES AND RELATED SUBSIDIARIES

CHANGE OF NAME

Centers for Disease Control changed to Centers for Disease Control and Prevention by Pub. L. 102–531, title III, §312, Oct. 27, 1992, 106 Stat. 3504.

§280e–2. Technical assistance in operations of statewide cancer registries

The Secretary, acting through the Director of the Centers for Disease Control, may, directly or through grants and contracts, or both, provide technical assistance to the States in the establishment and operation of statewide registries, including assistance in the development of model legislation for statewide cancer registries and assistance in establishing a computerized reporting and data processing system.

(July 1, 1944, ch. 373, title III, §399D, formerly §399J, as added Pub. L. 102–515, §3, Oct. 24, 1992, 106 Stat. 3376; renumbered §399D, Pub. L. 106–310, div. A, title V, §502(2)(A), Oct. 17, 2000, 114 Stat. 1115.)

EDITORIAL NOTES

PRIOR PROVISIONS

A prior section 399D of act July 1, 1944, was renumbered section 519, and is classified to section 290bb–25 of this title.

STATUTORY NOTES AND RELATED SUBSIDIARIES

CHANGE OF NAME

Centers for Disease Control changed to Centers for Disease Control and Prevention by Pub. L. 102–531, title III, §312, Oct. 27, 1992, 106 Stat. 3504.

§280e–3. Study in certain States to determine factors contributing to elevated breast cancer mortality rates

(a) In general

Subject to subsections (c) and (d), the Secretary, acting through the Director of the National Cancer Institute, shall conduct a study for the purpose of determining the factors contributing to the fact that breast cancer mortality rates in the States specified in subsection (b) are elevated compared to rates in other States.

(b) Relevant States

The States referred to in subsection (a) are Connecticut, Delaware, Maryland, Massachusetts, New Hampshire, New Jersey, New York, Rhode Island, Vermont, and the District of Columbia.

(c) Cooperation of State

The Secretary may conduct the study required in subsection (a) in a State only if the State agrees to cooperate with the Secretary in the conduct of the study, including providing information from any registry operated by the State pursuant to section 280e(a) of this title.

(d) Planning, commencement, and duration

The Secretary shall, during each of the fiscal years 1993 and 1994, develop a plan for conducting the study required in subsection (a). The study shall be initiated by the Secretary not later than fiscal year 1994, and the collection of data under the study may continue through fiscal year 1998.

(July 1, 1944, ch. 373, title III, §399E, formerly §399K, as added Pub. L. 102–515, §3, Oct. 24, 1992, 106 Stat. 3376; renumbered §399E and amended Pub. L. 106–310, div. A, title V, §502(2)(A),

(C), Oct. 17, 2000, 114 Stat. 1115; Pub. L. 109–482, title I, §104(b)(2)(A), Jan. 15, 2007, 120 Stat. 3693.)

EDITORIAL NOTES

AMENDMENTS

2007—Subsec. (e). Pub. L. 109–482 struck out heading and text of subsec. (e). Text read as follows: "Not later than September 30, 1999, the Secretary shall complete the study required in subsection (a) of this section and submit to the Committee on Energy and Commerce of the House of Representatives, and to the Committee on Labor and Human Resources of the Senate, a report describing the findings and recommendations made as a result of the study."

2000—Subsec. (c). Pub. L. 106–310, §502(2)(C), made technical amendment to reference in original act which appears in text as reference to section 280e(a) of this title.

STATUTORY NOTES AND RELATED SUBSIDIARIES

EFFECTIVE DATE OF 2007 AMENDMENT

Amendment by Pub. L. 109–482 applicable only with respect to amounts appropriated for fiscal year 2007 or subsequent fiscal years, see section 109 of Pub. L. 109–482, set out as a note under section 281 of this title.

POTENTIAL ENVIRONMENTAL AND OTHER RISKS CONTRIBUTING TO INCIDENCE OF BREAST CANCER

Pub. L. 103–43, title XIX, §1911, June 10, 1993, 107 Stat. 205, provided that Director of the National Cancer Institute, in collaboration with Director of the National Institute of Environmental Health Sciences, was to conduct case-control study to assess biological markers of environmental and other potential risk factors contributing to incidence of breast cancer in specified counties in State of New York and northeastern United States that had highest age-adjusted mortality rate of such cancer, and to report results of such study to Congress not later than 30 months after June 10, 1993.

§280e–3a. National childhood cancer registry

(a) In general

The Secretary, acting through the Director of the Centers for Disease Control and Prevention, may make awards to State cancer registries to enhance and expand infrastructure to collect information to better understand the epidemiology of cancer in children, adolescents, and young adults. Such registries may be updated to include each occurrence of such cancers within a period of time designated by the Secretary.

(b) Activities

The grants described in subsection (a) may be used for—

(1) identifying, recruiting, and training potential sources for reporting childhood, adolescent, and young adult cancer cases;

(2) developing practices to ensure early inclusion of childhood, adolescent, and young adult cancer cases in State cancer registries through the use of electronic reporting;

(3) collecting and submitting deidentified data to the Centers for Disease Control and Prevention for inclusion in a national database that includes information on childhood, adolescent, and young adult cancers; and

(4) improving State cancer registries and the database described in paragraph (3), as appropriate, including to support the early inclusion of childhood, adolescent, and young adult cancer cases.

(c) Coordination

To encourage the greatest possible efficiency and effectiveness of federally supported efforts with respect to the activities described in this section, the Secretary shall ensure the appropriate

coordination of programs supported under this section with other federally supported cancer registry programs and the activities under section 285a–11(a) of this title, as appropriate.

(d) Informed consent and privacy requirements and coordination with existing programs

The activities described in this section shall be subject to section 552a of title 5, the regulations promulgated under section 264(c) of the Health Insurance Portability and Accountability Act of 1996, applicable Federal and State informed consent regulations, any other applicable Federal and State laws relating to the privacy of patient information, and section 280e(d)(4) of this title.

(July 1, 1944, ch. 373, title III, §399E–1, as added Pub. L. 110–285, §4(b)(1), July 29, 2008, 122 Stat. 2630; amended Pub. L. 115–180, title I, §102(a), June 5, 2018, 132 Stat. 1385.)

EDITORIAL NOTES

REFERENCES IN TEXT

Section 264(c) of the Health Insurance Portability and Accountability Act of 1996, referred to in subsec. (d), is section 264(c) of Pub. L. 104–191, which is set out as a note under section 1320d–2 of this title.

AMENDMENTS

2018—Subsec. (a). Pub. L. 115–180, §102(a)(1), substituted "may make awards to State cancer registries" for "shall award a grant", "collect information to better understand the epidemiology of cancer in children, adolescents, and young adults" for "track the epidemiology of pediatric cancer into a comprehensive nationwide registry of actual occurrences of pediatric cancer", and "Such registries may be updated to include each occurrence of such cancers within a period of time designated by the Secretary." for "Such registry shall be updated to include an actual occurrence within weeks of the date of such occurrence."

Subsecs. (b), (c). Pub. L. 115–180, §102(a)(3), added subsecs. (b) and (c). Former subsec. (b) redesignated (d).

Subsec. (d). Pub. L. 115–180, §102(a)(2), (4), redesignated subsec. (b) as (d) and substituted "activities described in this section" for "registry established pursuant to subsection (a)".

STATUTORY NOTES AND RELATED SUBSIDIARIES

FINDINGS AND PURPOSES

Pub. L. 110–285, §§2, 3, July 29, 2008, 122 Stat. 2628, provided that:

"SEC. 2. FINDINGS

"Congress makes the following findings:

"(1) Cancer kills more children than any other disease.

"(2) Each year cancer kills more children between 1 and 20 years of age than asthma, diabetes, cystic fibrosis, and AIDS, combined.

"(3) Every year, over 12,500 young people are diagnosed with cancer.

"(4) Each year about 2,300 children and teenagers die from cancer.

"(5) One in every 330 Americans develops cancer before age 20.

"(6) Some forms of childhood cancer have proven to be so resistant that even in spite of the great research strides made, most of those children die. Up to 75 percent of the children with cancer can now be cured.

"(7) The causes of most childhood cancers are not yet known.

"(8) Childhood cancers are mostly those of the white blood cells (leukemias), brain, bone, the lymphatic system, and tumors of the muscles, kidneys, and nervous system. Each of these behaves differently, but all are characterized by an uncontrolled proliferation of abnormal cells.

"(9) Eighty percent of the children who are diagnosed with cancer have disease which has already spread to distant sites in the body.

"(10) Ninety percent of children with a form of pediatric cancer are treated at one of the more than 200 Children's Oncology Group member institutions throughout the United States.

"SEC. 3. PURPOSES

"It is the purpose of this Act [see Short Title of 2008 Amendment note set out under section 201 of this title] to authorize appropriations to—

"(1) encourage the support for pediatric cancer research and other activities related to pediatric cancer;
"(2) establish a comprehensive national childhood cancer registry; and
"(3) provide informational services to patients and families affected by childhood cancer."

§280e–4. Authorization of appropriations

(a) Registries

For the purpose of carrying out this part (other than section 280e–3a of this title), there are authorized to be appropriated $30,000,000 for fiscal year 1994, and such sums as may be necessary for each of the fiscal years 1995 through 2003. Of the amounts appropriated under the preceding sentence for any such fiscal year, the Secretary may obligate not more than 25 percent for carrying out section 280e–1 of this title, and not more than 10 percent may be expended for assessing the accuracy, completeness and quality of data collected, and not more than 10 percent of which is to be expended under section 280e–2 of this title.

(b) Breast cancer study

Of the amounts appropriated for the National Cancer Institute under subpart 1 of part C of subchapter III for any fiscal year in which the study required in section 280e–3 of this title is being carried out, the Secretary shall expend not less than $1,000,000 for the study.

(July 1, 1944, ch. 373, title III, §399F, formerly §399L, as added Pub. L. 102–515, §3, Oct. 24, 1992, 106 Stat. 3376; amended Pub. L. 103–43, title XX, §2003, June 10, 1993, 107 Stat. 208; Pub. L. 103–183, title VII, §705(c), Dec. 14, 1993, 107 Stat. 2241; Pub. L. 105–340, title II, §202, Oct. 31, 1998, 112 Stat. 3194; renumbered §399F and amended Pub. L. 106–310, div. A, title V, §502(2)(A), (D), Oct. 17, 2000, 114 Stat. 1115; Pub. L. 110–285, §4(b)(2), July 29, 2008, 122 Stat. 2631.)

EDITORIAL NOTES

PRIOR PROVISIONS

A prior section 399F of act July 1, 1944, was renumbered section 399G and is classified to section 280e–11 of this title.

AMENDMENTS

2008—Subsec. (a). Pub. L. 110–285 inserted "(other than section 280e–3a of this title)" after "this part".

2000—Subsec. (a). Pub. L. 106–310, §502(2)(D)(ii), substituted "section 280e–2 of this title" for "subsection 280e–2 of this title".

Pub. L. 106–310, §502(2)(D)(i), made technical amendment to reference in original act which appears in text as reference to section 280e–1 of this title.

Subsec. (b). Pub. L. 106–310, §502(2)(D)(iii), made technical amendment to reference in original act which appears in text as reference to section 280e–3 of this title.

1998—Subsec. (a). Pub. L. 105–340 substituted "2003" for "1998".

1993—Subsec. (a). Pub. L. 103–183 substituted "through 1998" for "through 1996".

Pub. L. 103–43 substituted "there are authorized to be appropriated $30,000,000 for fiscal year 1994, and such sums as may be necessary for each of the fiscal years 1995 through 1996" for "the Secretary may use $30,000,000 for each of the fiscal years 1993 through 1997" in first sentence and "Of the amounts appropriated under the preceding sentence" for "Out of any amounts used" in second sentence.

§280e–5. Voluntary registry for firefighter cancer incidence

(a) In general

The Secretary of Health and Human Services (referred to in this section as the Secretary), acting through the Director of the Centers for Disease Control and Prevention and in coordination with other agencies as the Secretary determines appropriate, shall develop and maintain, directly or through a grant or cooperative agreement, a voluntary registry of firefighters (referred to in this

section as the Firefighter Registry) to collect relevant health and occupational information of such firefighters for purposes of determining cancer incidence.

(b) Use of Firefighter Registry

The Firefighter Registry may be used for the following purposes:

(1) To improve data collection and data coordination activities related to the nationwide monitoring of the incidence of cancer among firefighters.

(2) To collect, consolidate, and maintain, consistent with subsection (g), epidemiological information and analyses related to cancer incidence and trends among firefighters [1]

(c) Relevant data

(1) Data collection

In carrying out the voluntary data collection for purposes of inclusion under the Firefighter Registry, the Secretary may collect the following:

(A) Information, as determined by the Secretary under subsection (d)(1), of volunteer, paid-on-call, and career firefighters, independent of cancer status or diagnosis.

(B) Individual risk factors and occupational history of firefighters.

(C) Information, if available, related to—

(i) basic demographic information, including—

(I) the age of the firefighter involved during the relevant dates of occupation as a firefighter; and

(II) the age of cancer diagnosis;

(ii) the status of the firefighter as either volunteer, paid-on-call, or career firefighter;

(iii) the total number of years of occupation as a firefighter and a detailing of additional employment experience, whether concurrent, before, or anytime thereafter;

(iv)(I) the approximate number of fire incidents attended, including information related to the type of fire incidents and the role of the firefighter in responding to the incident; or

(II) in the case of a firefighter for whom information on such number and type is unavailable, an estimate of such number and type based on the method developed under subsection (d)(1)(D); and

(v) other medical information and health history, including additional risk factors, as appropriate, and other information relevant to a cancer incidence study of firefighters.

(2) Information on diagnoses and treatment

In carrying out paragraph (1), with respect to diagnoses and treatment of firefighters with cancer, the Secretary shall, as appropriate, enable the Firefighter Registry to electronically connect to State-based cancer registries, for a purpose described by clause (vi) or (vii) of section 280e(c)(2)(D) of this title, to obtain—

(A) date of diagnoses and source of information; and

(B) pathological data characterizing the cancer, including cancer site, state of disease (pursuant to Staging Guide), incidence, and type of treatment.

(d) Firefighter Registry coordination strategy

(1) Required strategy

The Secretary shall, in consultation with the relevant stakeholders identified in subsection (e), including epidemiologists and pathologists, develop a strategy to coordinate data collection activities, including within existing State registries, for inclusion in the Firefighter Registry established under this Act. The strategy may include the following:

(A) Increasing awareness of the Firefighter Registry and encouraging participation among volunteer, paid-on-call, and career firefighters.

(B) Consideration of unique data collection needs that may arise to generate a statistically reliable representation of minority, female, and volunteer firefighters, including methods, as needed, to encourage participation from such populations.

(C) Information on how the Secretary will store data described in subsection (c)(1) and provide electronic access to relevant health information described in subsection (c)(2).

(D) Working in consultation with the experts described in subsection (e), a reliable and standardized method for estimating the number of fire incidents attended by a firefighter as well as the type of fire incident so attended in the case such firefighter is unable to provide such information.

(2) Report to Congress

The Secretary shall submit the strategy described in paragraph (1) to the Committee on Energy and Commerce of the House of Representatives and the Committee on Health, Education, Labor, and Pensions of the Senate not later than 30 days after the date of the completion of the strategy.

(3) Guidance for inclusion and maintenance of data on firefighters

The Secretary shall develop, in consultation with the stakeholders identified in subsection (e), State health agencies, State departments of homeland security, and volunteer, paid-on-call, combination, and career firefighting agencies, a strategy for inclusion of firefighters in the registry that are representative of the general population of firefighters, that outlines the following:

(A) How new information about firefighters will be submitted to the Firefighter Registry for inclusion.

(B) How information about firefighters will be maintained and updated in the Firefighter Registry over time.

(C) A method for estimating the number of fire incidents attended by a firefighter as well as the type of fire incident so attended in the case such firefighter is unable to provide such information.

(D) Further information, as deemed necessary by the Secretary.

(e) Consultation and report

The Secretary shall consult with non-Federal experts on the Firefighter Registry established under this section, and shall submit to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives a report that includes, as appropriate, information on goals achieved and improvements needed to strengthen the Firefighter Registry. Such non-Federal experts shall include the following:

(1) Public health experts with experience in developing and maintaining cancer registries.

(2) Epidemiologists with experience in studying cancer incidence.

(3) Clinicians with experience in diagnosing and treating cancer incidence.

(4) Active and retired volunteer, paid-on-call, and career firefighters as well as relevant national fire and emergency response organizations.

(f) Research availability

Subject to subsection (g), the Secretary shall ensure that information and analysis in the Firefighter Registry are available, as appropriate, to the public, including researchers, firefighters, and national fire service organizations.

(g) Privacy

In carrying out this Act, the Secretary shall ensure that information in and analysis of the Firefighter Registry are made available in a manner that, at a minimum, protects personal privacy to the extent required by applicable Federal and State privacy law.

(h) Authorization of funds

To carry out this section, there are authorized to be appropriated $5,500,000 for each of fiscal years 2024 through 2028.

(Pub. L. 115–194, §2, July 7, 2018, 132 Stat. 1506; Pub. L. 118–147, §2, Dec. 12, 2024, 138 Stat. 1674.)

EDITORIAL NOTES

REFERENCES IN TEXT

This Act, referred to in subsecs. (d)(1) and (g), is Pub. L. 115–194, July 7, 2018, 132 Stat. 1506, known as the Firefighter Cancer Registry Act of 2018, which enacted this section and provisions set out as a note under section 201 of this title. For complete classification of this Act to the Code, see Short Title of 2018 Amendment note set out under section 201 of this title and Tables.

CODIFICATION

Section was enacted as part of the Firefighter Cancer Registry Act of 2018, and not as part of the Public Health Service Act which comprises this chapter.

AMENDMENTS

2024—Subsec. (h). Pub. L. 118–147 substituted "$5,500,000 for each of fiscal years 2024 through 2028" for "$2,500,000 for each of the fiscal years 2018 through 2022".

[1] *So in original. Probably should be followed by a period.*

PART N—NATIONAL FOUNDATION FOR THE CENTERS FOR DISEASE CONTROL AND PREVENTION

EDITORIAL NOTES

CODIFICATION

This part was formerly set out preceding part M of this subchapter.

§280e–11. Establishment and duties of Foundation

(a) In general

There shall be established in accordance with this section a nonprofit private corporation to be known as the National Foundation for the Centers for Disease Control and Prevention (in this part referred to as the "Foundation"). The Foundation shall not be an agency or instrumentality of the Federal Government, and officers, employees, and members of the board of the Foundation shall not be officers or employees of the Federal Government.

(b) Purpose of Foundation

The purpose of the Foundation shall be to support and carry out activities for the prevention and control of diseases, disorders, injuries, and disabilities, and for promotion of public health.

(c) Endowment fund

(1) In general

In carrying out subsection (b), the Foundation shall establish a fund for providing endowments for positions that are associated with the Centers for Disease Control and Prevention and dedicated to the purpose described in such subsection. Subject to subsection (f)(1)(B), the fund shall consist of such donations as may be provided by non-Federal entities and such non-Federal assets of the Foundation (including earnings of the Foundation and the fund) as the Foundation may elect to transfer to the fund.

(2) Authorized expenditures of fund

The provision of endowments under paragraph (1) shall be the exclusive function of the fund established under such paragraph. Such endowments may be expended only for the compensation of individuals holding the positions, for staff, equipment, quarters, travel, and other expenditures that are appropriate in supporting the positions, and for recruiting individuals to hold the positions endowed by the fund.

(d) Certain activities of Foundation

In carrying out subsection (b), the Foundation may provide for the following with respect to the purpose described in such subsection:

(1) Programs of fellowships for State and local public health officials to work and study in association with the Centers for Disease Control and Prevention.

(2) Programs of international arrangements to provide opportunities for public health officials of other countries to serve in public health capacities in the United States in association with the Centers for Disease Control and Prevention or elsewhere, or opportunities for employees of such Centers (or other public health officials in the United States) to serve in such capacities in other countries, or both.

(3) Studies, projects, and research (which may include applied research on the effectiveness of prevention activities, demonstration projects, and programs and projects involving international, Federal, State, and local governments).

(4) Forums for government officials and appropriate private entities to exchange information. Participants in such forums may include institutions of higher education and appropriate international organizations.

(5) Meetings, conferences, courses, and training workshops.

(6) Programs to improve the collection and analysis of data on the health status of various populations.

(7) Programs for writing, editing, printing, and publishing of books and other materials.

(8) Other activities to carry out the purpose described in subsection (b).

(e) General structure of Foundation; nonprofit status

(1) Board of directors

The Foundation shall have a board of directors (in this part referred to as the "Board"), which shall be established and conducted in accordance with subsection (f). The Board shall establish the general policies of the Foundation for carrying out subsection (b), including the establishment of the bylaws of the Foundation.

(2) Executive director

The Foundation shall have an executive director (in this part referred to as the "Director"), who shall be appointed by the Board, who shall serve at the pleasure of the Board, and for whom the Board shall establish the rate of compensation. Subject to compliance with the policies and bylaws established by the Board pursuant to paragraph (1), the Director shall be responsible for the daily operations of the Foundation in carrying out subsection (b).

(3) Nonprofit status

In carrying out subsection (b), the Board shall establish such policies and bylaws under paragraph (1), and the Director shall carry out such activities under paragraph (2), as may be necessary to ensure that the Foundation maintains status as an organization that—

(A) is described in subsection (c)(3) of section 501 of title 26; and

(B) is, under subsection (a) of such section, exempt from taxation.

(f) Board of directors

(1) Certain bylaws

(A) In establishing bylaws under subsection (e)(1), the Board shall ensure that the bylaws of the Foundation include bylaws for the following:

(i) Policies for the selection of the officers, employees, agents, and contractors of the Foundation.

(ii) Policies, including ethical standards, for the acceptance and disposition of donations to the Foundation and for the disposition of the assets of the Foundation.

(iii) Policies for the conduct of the general operations of the Foundation.

(iv) Policies for writing, editing, printing, and publishing of books and other materials, and the acquisition of patents and licenses for devices and procedures developed by the Foundation.

(B) In establishing bylaws under subsection (e)(1), the Board shall ensure that the bylaws of the Foundation (and activities carried out under the bylaws) do not—

(i) reflect unfavorably upon the ability of the Foundation, or the Centers for Disease Control and Prevention, to carry out its responsibilities or official duties in a fair and objective manner; or

(ii) compromise, or appear to compromise, the integrity of any governmental program or any officer or employee involved in such program.

(2) Composition

(A) Subject to subparagraph (B), the Board shall be composed of 7 individuals, appointed in accordance with paragraph (4), who collectively possess education or experience appropriate for representing the general field of public health, the general field of international health, and the general public. Each such individual shall be a voting member of the Board.

(B) The Board may, through amendments to the bylaws of the Foundation, provide that the number of members of the Board shall be a greater number than the number specified in subparagraph (A).

(3) Chair

The Board shall, from among the members of the Board, designate an individual to serve as the chair of the Board (in this subsection referred to as the "Chair").

(4) Appointments, vacancies, and terms

Subject to subsection (j) (regarding the initial membership of the Board), the following shall apply to the Board:

(A) Any vacancy in the membership of the Board shall be filled by appointment by the Board, after consideration of suggestions made by the Chair and the Director regarding the appointments. Any such vacancy shall be filled not later than the expiration of the 180-day period beginning on the date on which the vacancy occurs.

(B) The term of office of each member of the Board appointed under subparagraph (A) shall be 5 years. A member of the Board may continue to serve after the expiration of the term of the member until the expiration of the 180-day period beginning on the date on which the term of the member expires.

(C) A vacancy in the membership of the Board shall not affect the power of the Board to carry out the duties of the Board. If a member of the Board does not serve the full term applicable under subparagraph (B), the individual appointed to fill the resulting vacancy shall be appointed for the remainder of the term of the predecessor of the individual.

(5) Compensation

Members of the Board may not receive compensation for service on the Board. The members may be reimbursed for travel, subsistence, and other necessary expenses incurred in carrying out the duties of the Board.

(g) Certain responsibilities of executive director

In carrying out subsection (e)(2), the Director shall carry out the following functions:

(1) Hire, promote, compensate, and discharge officers and employees of the Foundation, and define the duties of the officers and employees.

(2) Accept and administer donations to the Foundation, and administer the assets of the Foundation.

(3) Establish a process for the selection of candidates for holding endowed positions under subsection (c).

(4) Enter into such financial agreements as are appropriate in carrying out the activities of the Foundation.

(5) Take such action as may be necessary to acquire patents and licenses for devices and procedures developed by the Foundation and the employees of the Foundation.

(6) Adopt, alter, and use a corporate seal, which shall be judicially noticed.
(7) Commence and respond to judicial proceedings in the name of the Foundation.
(8) Other functions that are appropriate in the determination of the Director.

(h) General provisions

(1) Authority for accepting funds

The Director of the Centers for Disease Control and Prevention may accept and utilize, on behalf of the Federal Government, any gift, donation, bequest, or devise of real or personal property from the Foundation for the purpose of aiding or facilitating the work of such Centers. Funds may be accepted and utilized by such Director under the preceding sentence without regard to whether the funds are designated as general-purpose funds or special-purpose funds.

(2) Authority for acceptance of voluntary services

(A) The Director of the Centers for Disease Control and Prevention may accept, on behalf of the Federal Government, any voluntary services provided to such Centers by the Foundation for the purpose of aiding or facilitating the work of such Centers. In the case of an individual, such Director may accept the services provided under the preceding sentence by the individual until such time as the private funding for such individual ends.

(B) The limitation established in subparagraph (A) regarding the period of time in which services may be accepted applies to each individual who is not an employee of the Federal Government and who serves in association with the Centers for Disease Control and Prevention pursuant to financial support from the Foundation.

(3) Administrative control

No officer, employee, or member of the Board of the Foundation may exercise any administrative or managerial control over any Federal employee.

(4) Applicability of certain standards to non-Federal employees

In the case of any individual who is not an employee of the Federal Government and who serves in association with the Centers for Disease Control and Prevention pursuant to financial support from the Foundation, the Foundation shall negotiate a memorandum of understanding with the individual and the Director of the Centers for Disease Control and Prevention specifying that the individual—

(A) shall be subject to the ethical and procedural standards regulating Federal employment, scientific investigation, and research findings (including publications and patents) that are required of individuals employed by the Centers for Disease Control and Prevention, including standards under this chapter, chapter 131 of title 5, and the Technology Transfer Act; [1] and

(B) shall be subject to such ethical and procedural standards under chapter 11 of title 18 (relating to conflicts of interest), as the Director of such Centers determines is appropriate, except such memorandum may not provide that the individual shall be subject to the standards of section 209 of title 18.

(5) Financial conflicts of interest

Any individual who is an officer, employee, or member of the Board of the Foundation may not directly or indirectly participate in the consideration or determination by the Foundation of any question affecting—

(A) any direct or indirect financial interest of the individual; or

(B) any direct or indirect financial interest of any business organization or other entity of which the individual is an officer or employee or in which the individual has a direct or indirect financial interest.

(6) Audits; availability of records

The Foundation shall—

(A) provide for biennial audits of the financial condition of the Foundation; and

(B) make such audits, and all other records, documents, and other papers of the Foundation,

available to the Secretary and the Comptroller General of the United States for examination or audit.

(7) Reports

(A) Not later than February 1 of each fiscal year, the Foundation shall publish a report describing the activities of the Foundation during the preceding fiscal year. Each such report shall include for the fiscal year involved a comprehensive statement of the operations, activities, financial condition, and accomplishments of the Foundation, including an accounting of the use of amounts provided for under subsection (i).

(B) With respect to the financial condition of the Foundation, each report under subparagraph (A) shall include the source, and a description of, all gifts to the Foundation of real or personal property, and the source and amount of all gifts to the Foundation of money. Each such report shall include a specification of any restrictions on the purposes for which gifts to the Foundation may be used.

(C) The Foundation shall make copies of each report submitted under subparagraph (A) available—

(i) for public inspection, and shall upon request provide a copy of the report to any individual for a charge not to exceed the cost of providing the copy; and

(ii) to the appropriate committees of Congress.

(8) Liaison from Centers for Disease Control and Prevention

The Director of the Centers for Disease Control and Prevention shall serve as the liaison representative of such Centers to the Board and the Foundation.

(i) Federal funding

(1) Authority for annual grants

(A) The Secretary, acting through the Director of the Centers for Disease Control and Prevention, shall—

(i) for fiscal year 1993, make a grant to an entity described in subsection (j)(9) (relating to the establishment of a committee to establish the Foundation);

(ii) for fiscal year 1994, make a grant to the committee established under such subsection, or if the Foundation has been established, to the Foundation; and

(iii) for fiscal year 1995 and each subsequent fiscal year, make a grant to the Foundation.

(B) A grant under subparagraph (A) may be expended—

(i) in the case of an entity receiving the grant under subparagraph (A)(i), only for the purpose of carrying out the duties established in subsection (j)(9) for the entity;

(ii) in the case of the committee established under such subsection, only for the purpose of carrying out the duties established in subsection (j) for the committee; and

(iii) in the case of the Foundation, only for the purpose of the administrative expenses of the Foundation.

(C) A grant under subparagraph (A) may not be expended to provide amounts for the fund established under subsection (c).

(D) For the purposes described in subparagraph (B)—

(i) any portion of the grant made under subparagraph (A)(i) for fiscal year 1993 that remains unobligated after the entity receiving the grant completes the duties established in subsection (j)(9) for the entity shall be available to the committee established under such subsection; and

(ii) any portion of a grant under subparagraph (A) made for fiscal year 1993 or 1994 that remains unobligated after such committee completes the duties established in such subsection for the committee shall be available to the Foundation.

(2) Funding for grants

(A) For the purpose of grants under paragraph (1), there is authorized to be appropriated

$1,250,000 for each fiscal year.

(B) For the purpose of grants under paragraph (1), the Secretary may for each fiscal year make available not less than $500,000, and not more than $1,250,000 from the amounts appropriated for the fiscal year for the programs of the Department of Health and Human Services. Such amounts may be made available without regard to whether amounts have been appropriated under subparagraph (A).

(3) Certain restriction

If the Foundation receives Federal funds for the purpose of serving as a fiscal intermediary between Federal agencies, the Foundation may not receive such funds for the indirect costs of carrying out such purpose in an amount exceeding 10 percent of the direct costs of carrying out such purpose. The preceding sentence may not be construed as authorizing the expenditure of any grant under paragraph (1) for such purpose.

(4) Support services

The Director of the Centers for Disease Control and Prevention may provide facilities, utilities, and support services to the Foundation if it is determined by the Director to be advantageous to the programs of such Centers.

(j) Committee for establishment of Foundation

(1) In general

There shall be established in accordance with this subsection a committee to carry out the functions described in paragraph (2) (which committee is referred to in this subsection as the "Committee").

(2) Functions

The functions referred to in paragraph (1) for the Committee are as follows:

(A) To carry out such activities as may be necessary to incorporate the Foundation under the laws of the State involved, including serving as incorporators for the Foundation. Such activities shall include ensuring that the articles of incorporation for the Foundation require that the Foundation be established and operated in accordance with the applicable provisions of this part (or any successor to this part), including such provisions as may be in effect pursuant to amendments enacted after October 27, 1992.

(B) To ensure that the Foundation qualifies for and maintains the status described in subsection (e)(3) (regarding taxation).

(C) To establish the general policies and initial bylaws of the Foundation, which bylaws shall include the bylaws described in subsections (e)(3) and (f)(1).

(D) To provide for the initial operation of the Foundation, including providing for quarters, equipment, and staff.

(E) To appoint the initial members of the Board in accordance with the requirements established in subsection (f)(2)(A) for the composition of the Board, and in accordance with such other qualifications as the Committee may determine to be appropriate regarding such composition. Of the members so appointed—

(i) 2 shall be appointed to serve for a term of 3 years;

(ii) 2 shall be appointed to serve for a term of 4 years; and

(iii) 3 shall be appointed to serve for a term of 5 years.

(3) Completion of functions of Committee; initial meeting of Board

(A) The Committee shall complete the functions required in paragraph (1) not later than September 30, 1994. The Committee shall terminate upon the expiration of the 30-day period beginning on the date on which the Secretary determines that the functions have been completed.

(B) The initial meeting of the Board shall be held not later than November 1, 1994.

(4) Composition

The Committee shall be composed of 5 members, each of whom shall be a voting member. Of

the members of the Committee—

(A) no fewer than 2 shall have broad, general experience in public health; and

(B) no fewer than 2 shall have broad, general experience in nonprofit private organizations (without regard to whether the individuals have experience in public health).

(5) Chair

The Committee shall, from among the members of the Committee, designate an individual to serve as the chair of the Committee.

(6) Terms; vacancies

The term of members of the Committee shall be for the duration of the Committee. A vacancy in the membership of the Committee shall not affect the power of the Committee to carry out the duties of the Committee. If a member of the Committee does not serve the full term, the individual appointed to fill the resulting vacancy shall be appointed for the remainder of the term of the predecessor of the individual.

(7) Compensation

Members of the Committee may not receive compensation for service on the Committee. Members of the Committee may be reimbursed for travel, subsistence, and other necessary expenses incurred in carrying out the duties of the Committee.

(8) Committee support

The Director of the Centers for Disease Control and Prevention may, from amounts available to the Director for the general administration of such Centers, provide staff and financial support to assist the Committee with carrying out the functions described in paragraph (2). In providing such staff and support, the Director may both detail employees and contract for assistance.

(9) Grant for establishment of Committee

(A) With respect to a grant under paragraph (1)(A)(i) of subsection (i) for fiscal year 1993, an entity described in this paragraph is a private nonprofit entity with significant experience in domestic and international issues of public health. Not later than 180 days after October 27, 1992, the Secretary shall make the grant to such an entity (subject to the availability of funds under paragraph (2) of such subsection).

(B) The grant referred to in subparagraph (A) may be made to an entity only if the entity agrees that—

(i) the entity will establish a committee that is composed in accordance with paragraph (4); and

(ii) the entity will not select an individual for membership on the Committee unless the individual agrees that the Committee will operate in accordance with each of the provisions of this subsection that relate to the operation of the Committee.

(C) The Secretary may make a grant referred to in subparagraph (A) only if the applicant for the grant makes an agreement that the grant will not be expended for any purpose other than carrying out subparagraph (B). Such a grant may be made only if an application for the grant is submitted to the Secretary containing such agreement, and the application is in such form, is made in such manner, and contains such other agreements and such assurances and information as the Secretary determines to be necessary to carry out this paragraph.

(July 1, 1944, ch. 373, title III, §399G, formerly §399F, as added Pub. L. 102–531, title II, §201, Oct. 27, 1992, 106 Stat. 3474; renumbered §399G, Pub. L. 106–310, div. A, title V, §502(3), Oct. 17, 2000, 114 Stat. 1115; amended Pub. L. 109–245, §1, July 26, 2006, 120 Stat. 575; Pub. L. 117–286, §4(c)(38), Dec. 27, 2022, 136 Stat. 4358.)

EDITORIAL NOTES

REFERENCES IN TEXT

The Technology Transfer Act, referred to in subsec. (h)(4)(A), may mean the Federal Technology Transfer Act of 1986, Pub. L. 99–502, Oct. 20, 1986, 100 Stat. 1785, or the National Competitiveness Technology Transfer Act of 1989, part C (§§3131–3133) of title XXXI of div. C of Pub. L. 101–189, Nov. 29, 1989, 103 Stat. 1674. For complete classification of these Acts to the Code, see Short Title of 1986 Amendment note and Short Title of 1989 Amendment note both set out under section 3701 of Title 15, Commerce and Trade, and Tables.

CODIFICATION

Section was formerly classified to section 280d–11 of this title prior to renumbering by Pub. L. 106–310.

PRIOR PROVISIONS

A prior section 399G of act July 1, 1944, was renumbered section 399H and was classified to section 280f of this title, prior to being omitted from the Code.

AMENDMENTS

2022—Subsec. (h)(4)(A). Pub. L. 117–286 substituted "chapter 131 of title 5," for "the Ethics in Government Act,".

2006—Subsec. (h)(2)(A). Pub. L. 109–245, §1(a), substituted "In the case of an individual, such Director may accept the services provided under the preceding sentence by the individual until such time as the private funding for such individual ends." for "In the case of an individual, such Director may accept the services provided under the preceding sentence by the individual for not more than 2 years."

Subsec. (h)(7)(A). Pub. L. 109–245, §1(b)(1), inserted ", including an accounting of the use of amounts provided for under subsection (i)" before period at end of second sentence.

Subsec. (h)(7)(C). Pub. L. 109–245, §1(b)(2), added subpar. (C) and struck out former subpar. (C) which read as follows: "The Foundation shall make copies of each report submitted under subparagraph (A) available for public inspection, and shall upon request provide a copy of the report to any individual for a charge not exceeding the cost of providing the copy."

Subsec. (i)(2)(A). Pub. L. 109–245, §1(c)(1)(A), substituted "$1,250,000" for "$500,000".

Subsec. (i)(2)(B). Pub. L. 109–245, §1(c)(1)(B), substituted "not less than $500,000, and not more than $1,250,000" for "not more than $500,000".

Subsec. (i)(4). Pub. L. 109–245, §1(c)(2), added par. (4).

[1] *See References in Text note below.*

PART O—FETAL ALCOHOL SPECTRUM DISORDER PREVENTION AND SERVICES PROGRAM

EDITORIAL NOTES

CODIFICATION

Part O of title III of the Public Health Service Act, comprising this part, was originally added to act July 1, 1944, ch. 373, title III, by Pub. L. 105–392, title IV, §419(d), Nov. 13, 1998, 112 Stat. 3593, and amended by Pub. L. 106–310, div. A, title V, §502(4), Oct. 17, 2000, 114 Stat. 1115. Part O, consisting of sections 280f to 280f–3 of this title, had been omitted from the Code pursuant to former section 280f–3, which provided that this part would no longer apply on the date that was 7 years after the date on which all members of the National Task Force on Fetal Alcohol Syndrome and Fetal Alcohol Effect established under former section 280f(d)(1) were appointed, which occurred May 17, 2000. Part O is shown herein, however, as having been added by Pub. L. 119–44, title I, §104(a), Dec. 1, 2025, 139 Stat. 671, without reference to those intervening amendments because of the extensive revision of Part O by Pub. L. 119–44.

§280f. Fetal alcohol spectrum disorders prevention, intervention, and services delivery program

(a) In general

The Secretary shall establish or continue activities to support a comprehensive fetal alcohol spectrum disorders (referred to in this section as "FASD") education, prevention, identification, intervention, and services delivery program, which may include—

(1) an education and public awareness program to support, conduct, and evaluate the effectiveness of—

(A) educational programs targeting health professions schools, social and other supportive services, educators and counselors and other service providers in all phases of childhood development, and other relevant service providers, concerning the prevention, identification, and provision of services for infants, children, adolescents, and adults with FASD;

(B) strategies to educate school-age children, including pregnant and high-risk youth, concerning FASD;

(C) public and community awareness programs concerning FASD; and

(D) strategies to coordinate information and services across affected community agencies, including agencies providing social services such as foster care, adoption, and social work, agencies providing health services, and agencies involved in education, vocational training, and civil and criminal justice;

(2) supporting and conducting research on FASD, as appropriate, including to—

(A) develop appropriate medical diagnostic methods for identifying FASD; and

(B) develop effective culturally and linguistically appropriate evidence-based or evidence-informed interventions and appropriate supports for preventing prenatal alcohol exposure, which may co-occur with exposure to other substances;

(3) building State and Tribal capacity for the identification, treatment, and support of individuals with FASD and their families, which may include—

(A) utilizing and adapting existing Federal, State, or Tribal programs to include FASD identification and FASD-informed support;

(B) developing and expanding screening and diagnostic capacity for FASD;

(C) developing, implementing, and evaluating targeted FASD-informed intervention programs for FASD;

(D) providing training with respect to FASD for professionals across relevant sectors; and

(E) disseminating information about FASD and support services to affected individuals and their families; and

(4) an applied research program concerning intervention and prevention to support and conduct service demonstration projects, clinical studies and other research models providing advocacy, educational and vocational training, counseling, medical and mental health, and other supportive services, as well as models that integrate and coordinate such services, that are aimed at the unique challenges facing individuals with fetal alcohol spectrum disorder or fetal alcohol effect and their families.

(b) Grants and technical assistance

(1) In general

The Secretary may award grants, cooperative agreements and contracts and provide technical assistance to eligible entities to carry out subsection (a).

(2) Eligible entities

To be eligible to receive a grant, or enter into a cooperative agreement or contract, under this section, an entity shall—

(A) be a State, Indian Tribe or Tribal organization, local government, scientific or academic institution, or nonprofit organization; and

(B) prepare and submit to the Secretary an application at such time, in such manner, and

containing such information as the Secretary may require, including a description of the activities that the entity intends to carry out using amounts received under this section.

(3) Additional application contents

The Secretary may require that an eligible entity include in the application submitted under paragraph (2)(B)—

(A) a designation of an individual to serve as a FASD State or Tribal coordinator of activities such eligible entity proposes to carry out through a grant, cooperative agreement, or contract under this section; and

(B) a description of an advisory committee the entity will establish to provide guidance for the entity on developing and implementing a statewide or Tribal strategic plan to prevent FASD and provide for the identification, treatment, and support of individuals with FASD and their families.

(c) Definition of FASD-informed

For purposes of this section, the term "FASD-informed", with respect to support or an intervention program, means that such support or intervention program uses culturally and linguistically informed evidence-based or practice-based interventions and appropriate resources to support an improved quality of life for an individual with FASD and the family of such individual.

(July 1, 1944, ch. 373, title III, §399H, as added Pub. L. 119–44, title I, §104(a), Dec. 1, 2025, 139 Stat. 671.)

EDITORIAL NOTES

PRIOR PROVISIONS

A prior section 280f, act July 1, 1944, ch. 373, title III, §399H, formerly §399G, as added Pub. L. 105–392, title IV, §419(d), Nov. 13, 1998, 112 Stat. 3593; renumbered §399H and amended Pub. L. 106–310, div. A, title V, §502(4)(A), (B), Oct. 17, 2000, 114 Stat. 1115, required the Secretary of Health and Human Services to establish a comprehensive Fetal Alcohol Syndrome and Fetal Alcohol Effect prevention, intervention and services delivery program and to establish the National Task Force on Fetal Alcohol Syndrome and Fetal Alcohol Effect, prior to the general amendment of this part by Pub. L. 119–44.

STATUTORY NOTES AND RELATED SUBSIDIARIES

REPORT

Pub. L. 119–44, title I, §104(b), Dec. 1, 2025, 139 Stat. 673, provided that: "Not later than 4 years after the date of enactment of this Act [Dec. 1, 2025], and every year thereafter, the Secretary of Health and Human Services shall prepare and submit to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives a report containing—

"(1) a review of the activities carried out pursuant to sections 399H and 399I of the Public Health Service Act [42 U.S.C. 280f, 280f–1], as amended, to advance public education and awareness of fetal alcohol spectrum disorders (referred to in this section as 'FASD');

"(2) a description of—

"(A) the activities carried out pursuant to such sections 399H and 399I [42 U.S.C. 280f, 280f–1] to identify, prevent, and treat FASD; and

"(B) methods used to evaluate the outcomes of such activities; and

"(3) an assessment of activities carried out pursuant to such sections 399H and 399I [42 U.S.C. 280f, 280f–1] to support individuals with FASD."

§280f–1. Strengthening capacity and education for fetal alcohol spectrum disorders

(a) In general

The Secretary shall award grants, contracts, or cooperative agreements, as the Secretary

determines appropriate, to public or nonprofit private entities with demonstrated expertise in the field of fetal alcohol spectrum disorders (referred to in this section as "FASD"). Such awards shall be for the purposes of building local, Tribal, State, and nationwide capacities to prevent the occurrence of FASD by carrying out the programs described in subsection (b).

(b) Programs

An entity receiving an award under subsection (a) may use such award for the following purposes:

(1) Developing and supporting public education and outreach activities to raise public awareness of the risks associated with alcohol consumption during pregnancy.

(2) Acting as a clearinghouse for evidence-based resources on FASD prevention, identification, and culturally and linguistically appropriate best practices to help inform systems of care for individuals with FASD across their lifespan.

(3) Increasing awareness and understanding of efficacious, evidence-based screening tools and culturally and linguistically appropriate evidence-based intervention services and best practices, which may include improving the capacity for State, Tribal, and local affiliates.

(4) Providing technical assistance to recipients of grants, cooperative agreements, or contracts under section 280f of this title, as appropriate.

(c) Application

To be eligible for a grant, contract, or cooperative agreement under this section, an entity shall submit to the Secretary an application at such time, in such manner, and containing such information as the Secretary may require.

(d) Subcontracting

A public or private nonprofit entity may carry out the following activities required under this section through contracts or cooperative agreements with other public and private nonprofit entities with demonstrated expertise in FASD:

(1) Resource development and dissemination.

(2) Intervention services.

(3) Training and technical assistance.

(July 1, 1944, ch. 373, title III, §399I, as added Pub. L. 119–44, title I, §104(a), Dec. 1, 2025, 139 Stat. 673.)

EDITORIAL NOTES

PRIOR PROVISIONS

A prior section 280f–1, act July 1, 1944, ch. 373, title III, §399I, formerly §399H, as added Pub. L. 105–392, title IV, §419(d), Nov. 13, 1998, 112 Stat. 3594; renumbered §399I, Pub. L. 106–310, div. A, title V, §502(4)(A), Oct. 17, 2000, 114 Stat. 1115, provided eligibility criteria for receiving a grant or entering into a cooperative agreement or contract under this part, prior to the general amendment of this part by Pub. L. 119–44.

§280f–2. Authorization of appropriations

There are authorized to be appropriated to carry out this part $12,500,000 for each of fiscal years 2026 through 2030.

(July 1, 1944, ch. 373, title III, §399J, as added Pub. L. 119–44, title I, §104(a), Dec. 1, 2025, 139 Stat. 673.)

EDITORIAL NOTES

PRIOR PROVISIONS

A prior section 280f–2, act July 1, 1944, ch. 373, title III, §399J, formerly §399I, as added Pub. L. 105–392, title IV, §419(d), Nov. 13, 1998, 112 Stat. 3595; renumbered §399J and amended Pub. L. 106–310, div. A,

title V, §502(4)(A), (C), Oct. 17, 2000, 114 Stat. 1115, authorized appropriations to carry out this part, prior to the general amendment of this part by Pub. L. 119–44.

A prior section 280f–3, act July 1, 1944, ch. 373, title III, §399K, formerly §399J, as added Pub. L. 105–392, title IV, §419(d), Nov. 13, 1998, 112 Stat. 3595; renumbered §399K and amended Pub. L. 106–310, div. A, title V, §502(4)(A), (D), Oct. 17, 2000, 114 Stat. 1115, provided for the expiration of this part 7 years after the date on which all members of the National Task Force had been appointed, prior to the general amendment of this part by Pub. L. 119–44.

PART P—ADDITIONAL PROGRAMS

§280g. Children's asthma treatment grants program

(a) Authority to make grants

(1) In general

In addition to any other payments made under this chapter or title V of the Social Security Act [42 U.S.C. 701 et seq.], the Secretary shall award grants to eligible entities to carry out the following purposes:

(A) To provide access to quality medical care for children who live in areas that have a high prevalence of asthma and who lack access to medical care.

(B) To provide on-site education to parents, children, health care providers, and medical teams to recognize the signs and symptoms of asthma, and to train them in the use of medications to treat asthma and prevent its exacerbations.

(C) To decrease preventable trips to the emergency room by making medication available to individuals who have not previously had access to treatment or education in the management of asthma.

(D) To provide other services, such as smoking cessation programs, home modification, and other direct and support services that ameliorate conditions that exacerbate or induce asthma.

(2) [1] Certain projects

In making grants under paragraph (1), the Secretary may make grants designed to develop and expand the following projects:

(A) Projects to provide comprehensive asthma services to children in accordance with the guidelines of the National Asthma Education and Prevention Program (through the National Heart, Lung and Blood Institute), including access to care and treatment for asthma in a community-based setting.

(B) Projects to fully equip mobile health care clinics that provide preventive asthma care including diagnosis, physical examinations, pharmacological therapy, skin testing, peak flow meter testing, and other asthma-related health care services.

(C) Projects to conduct validated asthma management education programs for patients with asthma and their families, including patient education regarding asthma management, family education on asthma management, and the distribution of materials, including displays and videos, to reinforce concepts presented by medical teams.

(2) [1] Award of grants

(A) Application

(i) In general

An eligible entity shall submit an application to the Secretary for a grant under this section in such form and manner as the Secretary may require.

(ii) Required information

An application submitted under this subparagraph shall include a plan for the use of funds awarded under the grant and such other information as the Secretary may require.

(B) Requirement

In awarding grants under this section, the Secretary shall give preference to eligible entities that demonstrate that the activities to be carried out under this section shall be in localities within areas of known or suspected high prevalence of childhood asthma or high asthma-related mortality or high rate of hospitalization or emergency room visits for asthma (relative to the average asthma prevalence rates and associated mortality rates in the United States). Acceptable data sets to demonstrate a high prevalence of childhood asthma or high asthma-related mortality may include data from Federal, State, or local vital statistics, claims data under title XIX or XXI of the Social Security Act [42 U.S.C. 1396 et seq., 1397aa et seq.], other public health statistics or surveys, or other data that the Secretary, in consultation with the Director of the Centers for Disease Control and Prevention, deems appropriate.

(3) Definition of eligible entity

For purposes of this section, the term "eligible entity" means a public or nonprofit private entity (including a State or political subdivision of a State), or a consortium of any of such entities.

(b) Coordination with other children's programs

An eligible entity shall identify in the plan submitted as part of an application for a grant under this section how the entity will coordinate operations and activities under the grant with—

(1) other programs operated in the State that serve children with asthma, including any such programs operated under title V, XIX, or XXI of the Social Security Act [42 U.S.C. 701 et seq., 1396 et seq., 1397aa et seq.]; and

(2) one or more of the following—

(A) the child welfare and foster care and adoption assistance programs under parts B and E of title IV of such Act [42 U.S.C. 620 et seq., 670 et seq.];

(B) the head start program established under the Head Start Act (42 U.S.C. 9831 et seq.);

(C) the program of assistance under the special supplemental nutrition program for women, infants and children (WIC) under section 1786 of this title;

(D) local public and private elementary or secondary schools; or

(E) public housing agencies, as defined in section 1437a of this title.

(c) Evaluation

An eligible entity that receives a grant under this section shall submit to the Secretary an evaluation of the operations and activities carried out under the grant that includes—

(1) a description of the health status outcomes of children assisted under the grant;

(2) an assessment of the utilization of asthma-related health care services as a result of activities carried out under the grant;

(3) the collection, analysis, and reporting of asthma data according to guidelines prescribed by the Director of the Centers for Disease Control and Prevention; and

(4) such other information as the Secretary may require.

(d) Preference for States that allow students to self-administer medication to treat asthma and anaphylaxis

(1) Preference

The Secretary, in making any grant under this section or any other grant that is asthma-related (as determined by the Secretary) to a State, shall give preference to any State that satisfies the following:

(A) In general

The State must require that each public elementary school and secondary school in that State will grant to any student in the school an authorization for the self-administration of medication to treat that student's asthma or anaphylaxis, if—

(i) a health care practitioner prescribed the medication for use by the student during school hours and instructed the student in the correct and responsible use of the medication;

(ii) the student has demonstrated to the health care practitioner (or such practitioner's designee) and the school nurse (if available) the skill level necessary to use the medication and any device that is necessary to administer such medication as prescribed;

(iii) the health care practitioner formulates a written treatment plan for managing asthma or anaphylaxis episodes of the student and for medication use by the student during school hours; and

(iv) the student's parent or guardian has completed and submitted to the school any written documentation required by the school, including the treatment plan formulated under clause (iii) and other documents related to liability.

(B) Scope

An authorization granted under subparagraph (A) must allow the student involved to possess and use his or her medication—

(i) while in school;

(ii) while at a school-sponsored activity, such as a sporting event; and

(iii) in transit to or from school or school-sponsored activities.

(C) Duration of authorization

An authorization granted under subparagraph (A)—

(i) must be effective only for the same school and school year for which it is granted; and

(ii) must be renewed by the parent or guardian each subsequent school year in accordance with this subsection.

(D) Backup medication

The State must require that backup medication, if provided by a student's parent or guardian, be kept at a student's school in a location to which the student has immediate access in the event of an asthma or anaphylaxis emergency.

(E) Maintenance of information

The State must require that information described in subparagraphs (A)(iii) and (A)(iv) be kept on file at the student's school in a location easily accessible in the event of an asthma or anaphylaxis emergency.

(F) School personnel administration of epinephrine or school comprehensive allergies and asthma management program

(i) In general

In determining the preference (if any) to be given to a State under this subsection, the Secretary shall give additional preference to a State that provides to the Secretary the certification described in subparagraph (G) and that requires that each public elementary school and secondary school in the State satisfy the criteria described in clause (ii) or clause (iii).

(ii) Criteria for school personnel administration of epinephrine

For purposes of clause (i), the criteria described in this clause, with respect to each public elementary school and secondary school in the State, are that each such school—

(I) permits trained personnel of the school to administer epinephrine to any student of the school reasonably believed to be having an anaphylactic reaction;

(II) maintains a supply of epinephrine in a secure location that is easily accessible to trained personnel of the school for the purpose of administration to any student of the school reasonably believed to be having an anaphylactic reaction; and

(III) has in place a plan for having on the premises of the school during all operating hours of the school one or more individuals who are trained personnel of the school.

(iii) Criteria for school comprehensive allergies and asthma management program

For purposes of clause (i), the criteria described in this clause, with respect to each public elementary school and secondary school in the State, are that each such school—

(I) has in place a plan for having on the premises of the school during all operating hours of the school a school nurse or one or more other individuals who are designated by the principal (or other appropriate administrative staff) of the school to direct and apply the program described in subclause (II) on a voluntary basis outside their scope of employment; and

(II) has in place, under the direction of a school nurse or other individual designated under subclause (I), a comprehensive school-based allergies and asthma management program that includes—

(aa) a method to identify all students of such school with a diagnosis of allergies and asthma;

(bb) an individual student allergies and asthma action plan for each student of such school with a diagnosis of allergies and asthma;

(cc) allergies and asthma education for school staff who are directly responsible for students who have been identified as having allergies or asthma, such as education regarding basics, management, trigger management, and comprehensive emergency responses with respect to allergies and asthma;

(dd) efforts to reduce the presence of environmental triggers of allergies and asthma; and

(ee) a system to support students with a diagnosis of allergies or asthma through coordination with family members of such students, primary care providers of such students, primary asthma or allergy care providers of such students, and others as necessary.

(G) Civil liability protection law

The certification required in subparagraph (F) shall be a certification made by the State attorney general that the State has reviewed any applicable civil liability protection law to determine the application of such law with regard to elementary and secondary school trained personnel who may administer epinephrine to a student reasonably believed to be having an anaphylactic reaction and has concluded that such law provides adequate civil liability protection applicable to such trained personnel. For purposes of the previous sentence, the term "civil liability protection law" means a State law offering legal protection to individuals who give aid on a voluntary basis in an emergency to an individual who is ill, in peril, or otherwise incapacitated.

(2) Rule of construction

Nothing in this subsection creates a cause of action or in any other way increases or diminishes the liability of any person under any other law.

(3) Definitions

For purposes of this subsection:

(A) The terms "elementary school" and "secondary school" have the meaning given to those terms in section 7801 of title 20.

(B) The term "health care practitioner" means a person authorized under law to prescribe drugs subject to section 353(b) of title 21.

(C) The term "medication" means a drug as that term is defined in section 321 of title 21 and includes inhaled bronchodilators and auto-injectable epinephrine.

(D) The term "self-administration" means a student's discretionary use of his or her prescribed asthma or anaphylaxis medication, pursuant to a prescription or written direction from a health care practitioner.

(E) The term "trained personnel" means, with respect to an elementary or secondary school, an individual, such as the school nurse—

(i) who has been designated by the school nurse or principal (or other appropriate

administrative staff) of the school to administer epinephrine on a voluntary basis outside their scope of employment;

(ii) who has received training in the administration of epinephrine; and

(iii) whose training in the administration of epinephrine meets appropriate medical standards and has been documented by appropriate administrative staff of the school.

(e) Authorization of appropriations

For the purpose of carrying out this section, there are authorized to be appropriated such sums as may be necessary for each of the fiscal years 2001 through 2005.

(July 1, 1944, ch. 373, title III, §399L, as added Pub. L. 106–310, div. A, title V, §501, Oct. 17, 2000, 114 Stat. 1113; amended Pub. L. 108–377, §3(a), Oct. 30, 2004, 118 Stat. 2203; Pub. L. 113–48, §2, Nov. 13, 2013, 127 Stat. 575; Pub. L. 114–95, title IX, §9215(kkk)(2), Dec. 10, 2015, 129 Stat. 2187; Pub. L. 116–292, §2, Jan. 5, 2021, 134 Stat. 4896.)

EDITORIAL NOTES

REFERENCES IN TEXT

The Social Security Act, referred to in subsecs. (a)(1), (2)(B) and (b)(1), (2)(A), is act Aug. 14, 1935, ch. 531, 49 Stat. 620. Parts B and E of title IV of the Act are classified generally to parts B (§620 et seq.) and E (§670 et seq.), respectively, of subchapter IV of chapter 7 of this title. Titles V, XIX, and XXI of the Act are classified generally to subchapters V (§701 et seq.), XIX (§1396 et seq.), and XXI (§1397aa et seq.), respectively, of chapter 7 of this title. For complete classification of this Act to the Code, see section 1305 of this title and Tables.

The Head Start Act, referred to in subsec. (b)(2)(B), is subchapter B (§§635–657) of chapter 8 of subtitle A of title VI of Pub. L. 97–35, Aug. 13, 1981, 95 Stat. 499, which is classified generally to subchapter II (§9831 et seq.) of chapter 105 of this title. For complete classification of this Act to the Code, see Short Title note set out under section 9801 of this title and Tables.

PRIOR PROVISIONS

A prior section 399L of act July 1, 1944, was renumbered section 399F and is classified to section 280e–4 of this title.

AMENDMENTS

2021—Subsec. (d)(1)(F). Pub. L. 116–292, §2(1)(B), inserted "or school comprehensive allergies and asthma management program" after "epinephrine" in heading; designated introductory provisions as cl. (i), inserted heading, and substituted "in the State satisfy the criteria described in clause (ii) or clause (iii)." for "in the State—"; inserted cl. (ii) heading and introductory provisions; redesignated former cls. (i) to (iii) as subcls. (I) to (III), respectively, of cl. (ii); added cl. (iii); and realigned margins.

Subsec. (d)(3)(E). Pub. L. 116–292, §2(2)(A), inserted ", such as the school nurse" after "individual" in introductory provisions.

Subsec. (d)(3)(E)(i). Pub. L. 116–292, §2(2)(B), inserted "school nurse or" before "principal".

2015—Subsec. (d)(3)(A). Pub. L. 114–95 made technical amendment to reference in original act which appears in text as reference to section 7801 of title 20.

2013—Subsec. (d)(1)(F), (G). Pub. L. 113–48, §2(1), added subpars. (F) and (G).

Subsec. (d)(3)(E). Pub. L. 113–48, §2(2), added subpar. (E).

2004—Subsecs. (d), (e). Pub. L. 108–377 added subsec. (d) and redesignated former subsec. (d) as (e).

STATUTORY NOTES AND RELATED SUBSIDIARIES

EFFECTIVE DATE OF 2015 AMENDMENT

Amendment by Pub. L. 114–95 effective Dec. 10, 2015, except with respect to certain noncompetitive programs and competitive programs, see section 5 of Pub. L. 114–95, set out as a note under section 6301 of Title 20, Education.

EFFECTIVE DATE OF 2004 AMENDMENT

Pub. L. 108–377, §3(b), Oct. 30, 2004, 118 Stat. 2204, provided that: "The amendments made by this

section [amending this section] shall apply only with respect to grants made on or after the date that is 9 months after the date of the enactment of this Act [Oct. 30, 2004]."

FINDINGS OF 2004 AMENDMENT

Pub. L. 108–377, §2, Oct. 30, 2004, 118 Stat. 2202, provided that: "The Congress finds the following:

"(1) Asthma is a chronic condition requiring lifetime, ongoing medical intervention.

"(2) In 1980, 6,700,000 Americans had asthma.

"(3) In 2001, 20,300,000 Americans had asthma; 6,300,000 children under age 18 had asthma.

"(4) The prevalence of asthma among African-American children was 40 percent greater than among Caucasian children, and more than 26 percent of all asthma deaths are in the African-American population.

"(5) In 2000, there were 1,800,000 asthma-related visits to emergency departments (more than 728,000 of these involved children under 18 years of age).

"(6) In 2000, there were 465,000 asthma-related hospitalizations (214,000 of these involved children under 18 years of age).

"(7) In 2000, 4,487 people died from asthma, and of these 223 were children.

"(8) According to the Centers for Disease Control and Prevention, asthma is a common cause of missed school days, accounting for approximately 14,000,000 missed school days annually.

"(9) According to the New England Journal of Medicine, working parents of children with asthma lose an estimated $1,000,000,000 a year in productivity.

"(10) At least 30 States have legislation protecting the rights of children to carry and self-administer asthma metered-dose inhalers, and at least 18 States expand this protection to epinephrine auto-injectors.

"(11) Tragic refusals of schools to permit students to carry their inhalers and auto-injectable epinephrine have occurred, some resulting in death and spawning litigation.

"(12) School district medication policies must be developed with the safety of all students in mind. The immediate and correct use of asthma inhalers and auto-injectable epinephrine are necessary to avoid serious respiratory complications and improve health care outcomes.

"(13) No school should interfere with the patient-physician relationship.

"(14) Anaphylaxis, or anaphylactic shock, is a systemic allergic reaction that can kill within minutes. Anaphylaxis occurs in some asthma patients. According to the American Academy of Allergy, Asthma, and Immunology, people who have experienced symptoms of anaphylaxis previously are at risk for subsequent reactions and should carry an epinephrine auto-injector with them at all times, if prescribed.

"(15) An increasing number of students and school staff have life-threatening allergies. Exposure to the affecting allergen can trigger anaphylaxis. Anaphylaxis requires prompt medical intervention with an injection of epinephrine."

[1] *So in original. Two pars. (2) have been enacted.*

§280g–1. Early detection, diagnosis, and treatment regarding deaf and hard-of-hearing newborns, infants, and young children

(a) Statewide newborn, infant, and young child hearing screening, evaluation and intervention programs and systems

The Secretary, acting through the Administrator of the Health Resources and Services Administration, shall make awards of grants or cooperative agreements to develop statewide newborn, infant, and young child hearing screening, evaluation, diagnosis, and intervention programs and systems, and to assist in the recruitment, retention, education, and training of qualified personnel and health care providers (including, as appropriate, education and training of family members), for the following purposes:

(1) To develop and monitor the efficacy of statewide programs and systems for hearing screening of newborns, infants, and young children (referred to in this section as "children"); prompt evaluation and diagnosis of children referred from screening programs; and appropriate educational, audiological, medical, and communication (or language acquisition) interventions (including family support), for children identified as deaf or hard-of-hearing, consistent with the following:

(A) Early intervention includes referral to, and delivery of, information and services by

organizations such as schools and agencies (including community, consumer, and family-based agencies), in health care settings (including medical homes for children), and in programs mandated by part C of the Individuals with Disabilities Education Act [20 U.S.C. 1431 et seq.], which offer programs specifically designed to meet the unique language and communication needs of deaf and hard-of-hearing children.

(B) Information provided to families should be accurate, comprehensive, up-to-date, and evidence-based, as appropriate, to allow families to make important decisions for their children in a timely manner, including decisions with respect to the full range of assistive hearing technologies and communications modalities, as appropriate.

(C) Programs and systems under this paragraph shall offer mechanisms that foster family-to-family and deaf and hard-of-hearing consumer-to-family supports.

(2) To continue to provide technical support to States, through one or more technical resource centers, to assist in further developing and enhancing State early hearing detection and intervention programs.

(3) To identify or develop efficient models (educational and medical) to ensure that children who are identified as deaf or hard-of-hearing through screening receive follow-up by qualified early intervention providers or qualified health care providers (including those at medical homes for children), and referrals, as appropriate, including to early intervention services under part C of the Individuals with Disabilities Education Act [20 U.S.C. 1431 et seq.]. State agencies shall be encouraged to effectively increase the rate of such follow-up and referral.

(b) Technical assistance, data management, and applied research

(1) Centers for Disease Control and Prevention

(A) In general

The Secretary, acting through the Director of the Centers for Disease Control and Prevention, shall make awards of grants or cooperative agreements to provide technical assistance to State agencies or designated entities of States—

(i) to develop, maintain, and improve data collection systems related to newborn, infant, and young child hearing screening, evaluation (including audiologic, medical, and language acquisition evaluations), diagnosis, and intervention services;

(ii) to conduct applied research related to newborn, infant, and young child hearing screening, evaluation, and intervention programs and outcomes;

(iii) to ensure quality monitoring of hearing screening, evaluation, and intervention programs and systems for newborns, infants, and young children; and

(iv) to support newborn, infant, and young child hearing screening, evaluation, and intervention programs, and information systems.

(B) Use of awards

The awards made under subparagraph (A) may be used—

(i) to provide technical assistance on data collection and management, including to coordinate and develop standardized procedures for data management;

(ii) to assess and report on the cost and program effectiveness of newborn, infant, and young child hearing screening, evaluation, and intervention programs and systems;

(iii) to collect data and report on newborn, infant, and young child hearing screening, evaluation, diagnosis, and intervention programs and systems for applied research, program evaluation, and policy improvement;

(iv) to identify the causes and risk factors for congenital hearing loss;

(v) to study the effectiveness of newborn, infant, and young child hearing screening, audiologic and medical evaluations and intervention programs and systems by assessing the health, intellectual and social developmental, cognitive, and hearing status of these children at school age; and

(vi) to promote the integration and interoperability of data regarding early hearing loss

across multiple sources to increase the flow of information between clinical care and public health settings, including the ability of States and territories to exchange and share data.

(2) National Institutes of Health

The Director of the National Institutes of Health, acting through the Director of the National Institute on Deafness and Other Communication Disorders, shall for purposes of this section, continue a program of research and development on the efficacy of new screening techniques and technology, including clinical studies of screening methods, studies on efficacy of intervention, and related research.

(c) Coordination and collaboration

(1) In general

In carrying out programs under this section, the Administrator of the Health Resources and Services Administration, the Director of the Centers for Disease Control and Prevention, and the Director of the National Institutes of Health shall collaborate and consult with—

(A) other Federal agencies;

(B) State and local agencies, including agencies responsible for early intervention services pursuant to title XIX of the Social Security Act [42 U.S.C. 1396 et seq.] (Medicaid Early and Periodic Screening, Diagnosis and Treatment Program); title XXI of the Social Security Act [42 U.S.C. 1397aa et seq.] (State Children's Health Insurance Program); title V of the Social Security Act [42 U.S.C. 701 et seq.] (Maternal and Child Health Block Grant Program); and part C of the Individuals with Disabilities Education Act [20 U.S.C. 1431 et seq.];

(C) consumer groups of, and that serve, individuals who are deaf and hard-of-hearing and their families;

(D) appropriate national medical and other health and education specialty organizations;

(E) individuals who are deaf or hard-of-hearing and their families;

(F) other qualified professional personnel who are proficient in deaf or hard-of-hearing children's language and who possess the specialized knowledge, skills, and attributes needed to serve deaf and hard-of-hearing children, and their families;

(G) third-party payers and managed care organizations; and

(H) related commercial industries.

(2) Policy development

The Administrator of the Health Resources and Services Administration, the Director of the Centers for Disease Control and Prevention, and the Director of the National Institutes of Health shall coordinate and collaborate on recommendations for policy development at the Federal and State levels and with the private sector, including consumer, medical and other health and education professional-based organizations, with respect to newborn and infant hearing screening, evaluation, diagnosis, and intervention programs and systems.

(3) State early detection, diagnosis, and intervention programs and systems; data collection

The Administrator of the Health Resources and Services Administration and the Director of the Centers for Disease Control and Prevention shall coordinate and collaborate in assisting States—

(A) to establish newborn, infant, and young child hearing screening, evaluation, diagnosis, and intervention programs and systems under subsection (a); and

(B) to develop a data collection system under subsection (b).

(d) Rule of construction; religious accommodation

Nothing in this section shall be construed to preempt or prohibit any State law, including State laws that do not require the screening for hearing loss of children of parents who object to the screening on the grounds that such screening conflicts with the parent's religious beliefs.

(e) Definitions

For purposes of this section:

(1) The term "audiologic", when used in connection with evaluation, means procedures—

(A) to assess the status of the auditory system;

(B) to establish the site of the auditory disorder, the type and degree of hearing loss, and the potential effects of hearing loss on communication; and

(C) to identify appropriate treatment and referral options, including—

(i) linkage to State coordinating agencies under part C of the Individuals with Disabilities Education Act [20 U.S.C. 1431 et seq.] or other appropriate agencies;

(ii) medical evaluation;

(iii) assessment for the full range of assistive hearing technologies appropriate for newborns, infants, and young children;

(iv) audiologic rehabilitation treatment; and

(v) referral to national and local consumer, self-help, parent, family, and education organizations, and other family-centered services.

(2) The term "early intervention" means—

(A) providing appropriate services for the child who is deaf or hard-of-hearing, including nonmedical services; and

(B) ensuring that the family of the child is—

(i) provided comprehensive, consumer-oriented information about the full range of family support, training, information services, and language acquisition in oral and visual modalities; and

(ii) given the opportunity to consider and obtain the full range of such appropriate services, educational and program placements, and other options for the child from highly qualified providers.

(3) The term "medical evaluation" means key components performed by a physician including history, examination, and medical decisionmaking focused on symptomatic and related body systems for the purpose of diagnosing the etiology of hearing loss and related physical conditions, and for identifying appropriate treatment and referral options.

(4) The term "medical intervention" means the process by which a physician provides medical diagnosis and direction for medical or surgical treatment options for hearing loss or other medical disorders associated with hearing loss.

(5) The term "newborn, infant, and young child hearing screening" means objective physiologic procedures to detect possible hearing loss and to identify newborns, infants, and young children under 3 years of age who require further audiologic and medical evaluations.

(f) Authorization of appropriations

(1) Statewide newborn and infant hearing screening, evaluation and intervention programs and systems

For the purpose of carrying out subsection (a), there are authorized to be appropriated to the Health Resources and Services Administration $17,818,000 for each of fiscal years 2023 through 2027.

(2) Technical assistance, data management, and applied research; Centers for Disease Control and Prevention

For the purpose of carrying out subsection (b)(1), there are authorized to be appropriated to the Centers for Disease Control and Prevention $10,760,000 for each of fiscal years 2023 through 2027.

(3) Technical assistance, data management, and applied research; National Institute on Deafness and Other Communication Disorders

For the purpose of carrying out subsection (b)(2), there are authorized to be appropriated to the National Institute on Deafness and Other Communication Disorders such sums as may be necessary for fiscal years 2011 through 2015.

(July 1, 1944, ch. 373, title III, §399M, as added Pub. L. 106–310, div. A, title VII, §702, Oct. 17,

2000, 114 Stat. 1121; amended Pub. L. 111–337, §2, Dec. 22, 2010, 124 Stat. 3588; Pub. L. 115–71, §2, Oct. 18, 2017, 131 Stat. 1218; Pub. L. 117–241, §2, Dec. 20, 2022, 136 Stat. 2332.)

EDITORIAL NOTES

REFERENCES IN TEXT

The Individuals with Disabilities Education Act, referred to in subsecs. (a)(1)(A), (3), (c)(1)(B), and (e)(1)(C)(i), is title VI of Pub. L. 91–230, Apr. 13, 1970, 84 Stat. 175. Part C of the Act is classified generally to subchapter III (§1431 et seq.) of chapter 33 of Title 20, Education. For complete classification of this Act to the Code, see section 1400 of Title 20 and Tables.

The Social Security Act, referred to in subsec. (c)(1)(B), is act Aug. 14, 1935, ch. 531, 49 Stat. 620. Titles V, XIX, and XXI of the Act are classified generally to subchapters V (§701 et seq.), XIX (§1396 et seq.), and XXI (§1397aa et seq.), respectively, of chapter 7 of this title. For complete classification of this Act to the Code, see section 1305 of this title and Tables.

AMENDMENTS

2022—Subsec. (e)(3). Pub. L. 117–241, §2(1), inserted par. (3) designation before "The term 'medical evaluation' ".

Subsec. (f)(1). Pub. L. 117–241, §2(2)(A), substituted "$17,818,000 for each of fiscal years 2023 through 2027" for "$17,818,000 for fiscal year 2018, $18,173,800 for fiscal year 2019, $18,628,145 for fiscal year 2020, $19,056,592 for fiscal year 2021, and $19,522,758 for fiscal year 2022".

Subsec. (f)(2). Pub. L. 117–241, §2(2)(B), substituted "$10,760,000 for each of fiscal years 2023 through 2027" for "$10,800,000 for fiscal year 2018, $11,026,800 for fiscal year 2019, $11,302,470 for fiscal year 2020, $11,562,427 for fiscal year 2021, and $11,851,488 for fiscal year 2022".

2017—Pub. L. 115–71, §2(a), substituted "Early detection, diagnosis, and treatment regarding deaf and hard-of-hearing newborns, infants, and young children" for "Early detection, diagnosis, and treatment regarding hearing loss in newborns and infants" in section catchline.

Subsec. (a). Pub. L. 115–71, §2(b)(2), substituted "newborn, infant, and young child" for "newborn and infant" and "providers (including, as appropriate, education and training of family members)," for "providers," in introductory provisions.

Pub. L. 115–71, §2(b)(1), substituted "newborn, infant, and young child" for "newborn and infant" in heading.

Subsec. (a)(1). Pub. L. 115–71, §2(b)(3), in first sentence, substituted "newborns, infants, and young children (referred to in this section as 'children')" for "newborns and infants" and "medical, and communication (or language acquisition) interventions (including family support), for children identified as deaf or hard-of-hearing, consistent with the following:" for "and medical interventions for children identified with hearing loss."; designated second sentence as subpar. (A) and substituted ", and delivery of," for "and delivery of", "by organizations such as schools and agencies (including community, consumer, and family-based agencies), in health care settings (including medical homes for children), and in programs mandated" for "by schools and agencies, including community, consumer, and parent-based agencies and organizations and other programs mandated", and "hard-of-hearing children." for "hard of hearing newborns, infants, toddlers, and children."; struck out third sentence which read "Programs and systems under this paragraph shall establish and foster family-to-family support mechanisms that are critical in the first months after a child is identified with hearing loss."; and added subpars. (B) and (C).

Subsec. (a)(2). Pub. L. 115–71, §2(b)(4), substituted "To continue to provide technical support to States, through one or more technical resource centers, to assist in further developing and enhancing State early hearing detection and intervention programs." for "To collect data on statewide newborn and infant hearing screening, evaluation and intervention programs and systems that can be used for applied research, program evaluation and policy development."

Subsec. (a)(3). Pub. L. 115–71, §2(b)(5), added par. (3) and struck out former par. (3) which read as follows: "Other activities may include developing efficient models to ensure that newborns and infants who are identified with a hearing loss through screening receive follow-up by a qualified health care provider, and State agencies shall be encouraged to adopt models that effectively increase the rate of occurrence of such follow-up."

Subsec. (b)(1). Pub. L. 115–71, §2(c), made extensive amendments to text and structure of par. (1). Prior to amendments, text of par. (1) read as follows: "The Secretary, acting through the Director of the Centers for Disease Control and Prevention, shall make awards of grants or cooperative agreements to provide technical assistance to State agencies to complement an intramural program and to conduct applied research related to

newborn and infant hearing screening, evaluation and intervention programs and systems. The program shall develop standardized procedures for data management and program effectiveness and costs, such as—

"(A) to ensure quality monitoring of newborn and infant hearing loss screening, evaluation, diagnosis, and intervention programs and systems;

"(B) to provide technical assistance on data collection and management;

"(C) to study the costs and effectiveness of newborn and infant hearing screening, evaluation and intervention programs and systems conducted by State-based programs in order to answer issues of importance to State and national policymakers;

"(D) to identify the causes and risk factors for congenital hearing loss;

"(E) to study the effectiveness of newborn and infant hearing screening, audiologic and medical evaluations and intervention programs and systems by assessing the health, intellectual and social developmental, cognitive, and language status of these children at school age; and

"(F) to promote the sharing of data regarding early hearing loss with State-based birth defects and developmental disabilities monitoring programs for the purpose of identifying previously unknown causes of hearing loss."

Subsec. (c)(1). Pub. L. 115–71, §2(d)(1), substituted "consult with—" for "consult with", "(A) other Federal" for "other Federal", "(B) State and local agencies, including agencies" for "State and local agencies, including those", "(C) consumer groups of, and that serve," for "consumer groups of and that serve", "(D) appropriate national" for "appropriate national", "(E) individuals who are deaf or" for "persons who are deaf and", "(F) other qualified" for "other qualified", "children," for "newborns, infants, toddlers, children,", "(G) third-party" for "third-party", and "(H) related commercial" for "related commercial".

Subsec. (c)(3). Pub. L. 115–71, §2(d)(2), substituted "States—" for "States", "(A) to establish newborn, infant, and young child" for "to establish newborn and infant", "subsection (a); and" for "subsection (a) and", and "(B) to develop" for "to develop".

Subsec. (d). Pub. L. 115–71, §2(e), substituted "that do not" for "which do not" and "parent's" for "parents' " and struck out "newborn infants or young" after "hearing loss of".

Subsec. (e)(1). Pub. L. 115–71, §2(f)(1), made extensive amendments to text and structure of par. (1). Prior to amendments, par. (1) read as follows: "The term 'audiologic evaluation' refers to procedures to assess the status of the auditory system; to establish the site of the auditory disorder; the type and degree of hearing loss, and the potential effects of hearing loss on communication; and to identify appropriate treatment and referral options. Referral options should include linkage to State coordinating agencies under part C of the Individuals with Disabilities Education Act or other appropriate agencies, medical evaluation, hearing aid/sensory aid assessment, audiologic rehabilitation treatment, national and local consumer, self-help, parent, and education organizations, and other family-centered services."

Subsec. (e)(2). Pub. L. 115–71, §2(f)(4), made extensive amendments to text and structure of par. (2). Prior to amendments, par. (2) read as follows: "The term 'early intervention' refers to providing appropriate services for the child with hearing loss, including nonmedical services, and ensuring that families of the child are provided comprehensive, consumer-oriented information about the full range of family support, training, information services, and language and communication options and are given the opportunity to consider and obtain the full range of such appropriate services, educational and program placements, and other options for their child from highly qualified providers."

Pub. L. 115–71, §2(f)(2), (3), redesignated par. (3) as (2) and struck out former par. (2) which read as follows: "The terms 'audiologic rehabilitation' and 'audiologic intervention' refer to procedures, techniques, and technologies to facilitate the receptive and expressive communication abilities of a child with hearing loss."

Subsec. (e)(3). Pub. L. 115–71, §2(f)(5), substituted "The term 'medical evaluation' means key components performed by a physician including history, examination, and medical decisionmaking" for "(3) The term 'medical evaluation by a physician' refers to key components including history, examination, and medical decision making".

Pub. L. 115–71, §2(f)(3), redesignated par. (4) as (3). Former par. (3) redesignated (2).

Subsec. (e)(4). Pub. L. 115–71, §2(f)(6), substituted "means" for "refers to", "or surgical" for "and/or surgical", and "for hearing loss or other medical disorders" for "of hearing loss and/or related medical disorder".

Pub. L. 115–71, §2(f)(3), redesignated par. (5) as (4). Former par. (4) redesignated (3).

Subsec. (e)(5). Pub. L. 115–71, §2(f)(7), substituted "The term 'newborn, infant, and young child hearing screening' means" for "The term 'newborn and infant hearing screening' refers to" and ", infants, and young children under 3 years of age" for "and infants".

Pub. L. 115–71, §2(f)(3), redesignated par. (6) as (5). Former par. (5) redesignated (4).

Subsec. (e)(6). Pub. L. 115–71, §2(f)(3), redesignated par. (6) as (5).

Subsec. (f)(1). Pub. L. 115–71, §2(g)(1), substituted "$17,818,000 for fiscal year 2018, $18,173,800 for fiscal year 2019, $18,628,145 for fiscal year 2020, $19,056,592 for fiscal year 2021, and $19,522,758 for fiscal year 2022." for "such sums as may be necessary for fiscal years 2011 through 2015."

Subsec. (f)(2). Pub. L. 115–71, §2(g)(2), substituted "$10,800,000 for fiscal year 2018, $11,026,800 for fiscal year 2019, $11,302,470 for fiscal year 2020, $11,562,427 for fiscal year 2021, and $11,851,488 for fiscal year 2022." for "such sums as may be necessary for fiscal years 2011 through 2015."

2010—Pub. L. 111–337, §2(1), substituted "newborns and infants" for "infants" in section catchline.

Subsec. (a). Pub. L. 111–337, §2(2)(A), substituted "screening, evaluation, diagnosis, and intervention programs and systems, and to assist in the recruitment, retention, education, and training of qualified personnel and health care providers," for "screening, evaluation and intervention programs and systems" in introductory provisions.

Subsec. (a)(1). Pub. L. 111–337, §2(2)(B), amended par. (1) generally. Prior to amendment, par. (1) read as follows: "To develop and monitor the efficacy of state-wide newborn and infant hearing screening, evaluation and intervention programs and systems. Early intervention includes referral to schools and agencies, including community, consumer, and parent-based agencies and organizations and other programs mandated by part C of the Individuals with Disabilities Education Act, which offer programs specifically designed to meet the unique language and communication needs of deaf and hard of hearing newborns, infants, toddlers, and children."

Subsec. (a)(3). Pub. L. 111–337, §2(2)(C), added par. (3).

Subsec. (b)(1)(A). Pub. L. 111–337, §2(3), substituted "hearing loss screening, evaluation, diagnosis, and intervention programs" for "hearing loss screening, evaluation, and intervention programs".

Subsec. (c)(2), (3). Pub. L. 111–337, §2(4), substituted "hearing screening, evaluation, diagnosis, and intervention programs" for "hearing screening, evaluation and intervention programs".

Subsec. (e)(3). Pub. L. 111–337, §2(5)(A), substituted "ensuring that families of the child are provided comprehensive, consumer-oriented information about the full range of family support, training, information services, and language and communication options and are given the opportunity to consider and obtain the full range of such appropriate services, educational and program placements, and other options for their child from highly qualified providers." for "ensuring that families of the child are provided comprehensive, consumer-oriented information about the full range of family support, training, information services, communication options and are given the opportunity to consider the full range of educational and program placements and options for their child."

Subsec. (e)(6). Pub. L. 111–337, §2(5)(B), struck out ", after rescreening," after "infants who".

Subsec. (f). Pub. L. 111–337, §2(6), substituted "fiscal years 2011 through 2015" for "fiscal year 2002" in pars. (1) to (3).

STATUTORY NOTES AND RELATED SUBSIDIARIES

JAMES T. WALSH UNIVERSAL NEWBORN HEARING SCREENING PROGRAM

Pub. L. 111–8, div. F, title II, §224, Mar. 11, 2009, 123 Stat. 784, provided that: "Hereafter, the activities authorized under section 399M of the Public Health Service Act [42 U.S.C. 280g–1] shall be known as the 'James T. Walsh Universal Newborn Hearing Screening Program.' "

PURPOSES

Pub. L. 106–310, div. A, title VII, §701, Oct. 17, 2000, 114 Stat. 1120, provided that: "The purposes of this title [enacting this section] are to clarify the authority within the Public Health Service Act [42 U.S.C. 201 et seq.] to authorize statewide newborn and infant hearing screening, evaluation and intervention programs and systems, technical assistance, a national applied research program, and interagency and private sector collaboration for policy development, in order to assist the States in making progress toward the following goals:

"(1) All babies born in hospitals in the United States and its territories should have a hearing screening before leaving the birthing facility. Babies born in other countries and residing in the United States via immigration or adoption should have a hearing screening as early as possible.

"(2) All babies who are not born in hospitals in the United States and its territories should have a hearing screening within the first 3 months of life.

"(3) Appropriate audiologic and medical evaluations should be conducted by 3 months for all newborns and infants suspected of having hearing loss to allow appropriate referral and provisions for audiologic rehabilitation, medical and early intervention before the age of 6 months.

"(4) All newborn and infant hearing screening programs and systems should include a component for audiologic rehabilitation, medical and early intervention options that ensures linkage to any new and existing state-wide systems of intervention and rehabilitative services for newborns and infants with hearing loss.

"(5) Public policy in regard to newborn and infant hearing screening and intervention should be based on applied research and the recognition that newborns, infants, toddlers, and children who are deaf or hard-of-hearing have unique language, learning, and communication needs, and should be the result of consultation with pertinent public and private sectors."

§280g–2. Childhood malignancies

(a) In general

The Secretary, acting as appropriate through the Director of the Centers for Disease Control and Prevention and the Director of the National Institutes of Health, shall study environmental and other risk factors for childhood cancers (including skeletal malignancies, leukemias, malignant tumors of the central nervous system, lymphomas, soft tissue sarcomas, and other malignant neoplasms) and carry out projects to improve outcomes among children with childhood cancers and resultant secondary conditions, including limb loss, anemia, rehabilitation, and palliative care. Such projects shall be carried out by the Secretary directly and through awards of grants or contracts.

(b) Certain activities

Activities under subsection (a) include—

(1) the expansion of current demographic data collection and population surveillance efforts to include childhood cancers nationally;

(2) the development of a uniform reporting system under which treating physicians, hospitals, clinics, and States report the diagnosis of childhood cancers, including relevant associated epidemiological data; and

(3) support for the National Limb Loss Information Center to address, in part, the primary and secondary needs of persons who experience childhood cancers in order to prevent or minimize the disabling nature of these cancers.

(c) Coordination of activities

The Secretary shall assure that activities under this section are coordinated as appropriate with other agencies of the Public Health Service that carry out activities focused on childhood cancers and limb loss.

(d) Definition

For purposes of this section, the term "childhood cancer" refers to a spectrum of different malignancies that vary by histology, site of disease, origin, race, sex, and age. The Secretary may for purposes of this section revise the definition of such term to the extent determined by the Secretary to be appropriate.

(e) Authorization of appropriations

For the purpose of carrying out this section, there are authorized to be appropriated such sums as may be necessary for each of the fiscal years 2001 through 2005.

(July 1, 1944, ch. 373, title III, §399N, as added Pub. L. 106–310, div. A, title XI, §1101, Oct. 17, 2000, 114 Stat. 1131.)

§280g–3. Prescription drug monitoring program

(a) Program

(1) In general

Each fiscal year, the Secretary, acting through the Director of the Centers for Disease Control

and Prevention, in coordination with the heads of other departments and agencies as appropriate, shall support States or localities for the purpose of improving the efficiency and use of PDMPs, including—

(A) establishment and implementation of a PDMP;

(B) maintenance of a PDMP;

(C) improvements to a PDMP by—

(i) enhancing functional components to work toward—

(I) universal use of PDMPs among providers and their delegates, to the extent that State laws allow;

(II) more timely inclusion of data within a PDMP;

(III) active management of the PDMP, in part by sending proactive or unsolicited reports to providers to inform prescribing; and

(IV) ensuring the highest level of ease in use of and access to PDMPs by providers and their delegates, to the extent that State laws allow;

(ii) in consultation with the Office of the National Coordinator for Health Information Technology, improving the intrastate interoperability of PDMPs by—

(I) making PDMPs more actionable by integrating PDMPs within electronic health records and health information technology infrastructure; and

(II) linking PDMP data to other data systems within the State, including—

(aa) the data of pharmacy benefit managers, medical examiners and coroners, and the State's Medicaid program;

(bb) worker's compensation data; and

(cc) prescribing data of providers of the Department of Veterans Affairs and the Indian Health Service within the State;

(iii) in consultation with the Office of the National Coordinator for Health Information Technology, improving the interstate interoperability of PDMPs through—

(I) sharing of dispensing data in near-real time across State lines; and

(II) integration of automated queries for multistate PDMP data and analytics into clinical workflow to improve the use of such data and analytics by practitioners and dispensers; or

(iv) improving the ability to include treatment availability resources and referral capabilities within the PDMP.

(2) Legislation

As a condition on the receipt of support under this section, the Secretary shall require a State or locality to demonstrate that it has enacted legislation or regulations—

(A) to provide for the implementation of the PDMP; and

(B) to permit the imposition of appropriate penalties for the unauthorized use and disclosure of information maintained by the PDMP.

(b) PDMP strategies

The Secretary shall encourage a State or locality, in establishing, improving, or maintaining a PDMP, to implement strategies that improve—

(1) the reporting of dispensing in the State or locality of a controlled substance to an ultimate user so the reporting occurs not later than 24 hours after the dispensing event;

(2) the consultation of the PDMP by each prescribing practitioner, or their designee, in the State or locality before initiating treatment with a controlled substance, or any substance as required by the State to be reported to the PDMP, and over the course of ongoing treatment for each prescribing event;

(3) the consultation of the PDMP before dispensing a controlled substance, or any substance as required by the State to be reported to the PDMP;

(4) the proactive notification to a practitioner when patterns indicative of controlled substance

misuse by a patient, including opioid misuse, are detected;

(5) the availability of data in the PDMP to other States, as allowable under State law; and

(6) the availability of nonidentifiable information to the Centers for Disease Control and Prevention for surveillance, epidemiology, statistical research, or educational purposes.

(c) Drug misuse and abuse

In consultation with practitioners, dispensers, and other relevant and interested stakeholders, a State receiving support under this section—

(1) shall establish a program to notify practitioners and dispensers of information that will help to identify and prevent the unlawful diversion or misuse of controlled substances;

(2) may, to the extent permitted under State law, notify the appropriate authorities responsible for carrying out drug diversion investigations if the State determines that information in the PDMP maintained by the State indicates an unlawful diversion or abuse of a controlled substance;

(3) may conduct analyses of controlled substance program data for purposes of providing appropriate State agencies with aggregate reports based on such analyses in as close to real-time as practicable, regarding prescription patterns flagged as potentially presenting a risk of misuse, abuse, addiction, overdose, and other aggregate information, as appropriate and in compliance with applicable Federal and State laws and provided that such reports shall not include protected health information; and

(4) may access information about prescriptions, such as claims data, to ensure that such prescribing and dispensing history is updated in as close to real-time as practicable, in compliance with applicable Federal and State laws and provided that such information shall not include protected health information.

(d) Evaluation and reporting

As a condition on receipt of support under this section, the State shall report on interoperability with PDMPs of other States and Federal agencies, where appropriate, intrastate interoperability with health information technology systems such as electronic health records, health information exchanges, and e-prescribing, where appropriate, and whether or not the State provides automatic, up-to-date, or daily information about a patient when a practitioner (or the designee of a practitioner, where permitted) requests information about such patient.

(e) Evaluation and reporting

A State receiving support under this section shall provide the Secretary with aggregate nonidentifiable information, as permitted by State law, to enable the Secretary—

(1) to evaluate the success of the State's program in achieving the purpose described in subsection (a); or

(2) to prepare and submit to the Congress the report required by subsection (i)(2).

(f) Education and access to the monitoring system

A State receiving support under this section shall take steps to—

(1) facilitate prescribers and dispensers, and their delegates, as permitted by State law, to use the PDMP, to the extent practicable; and

(2) educate prescribers and dispensers, and their delegates on the benefits of the use of PDMPs.

(g) Electronic format

The Secretary may issue guidelines specifying a uniform electronic format for the reporting, sharing, and disclosure of information pursuant to PDMPs. To the extent possible, such guidelines shall be consistent with standards recognized by the Office of the National Coordinator for Health Information Technology.

(h) Rules of construction

(1) Functions otherwise authorized by law

Nothing in this section shall be construed to restrict the ability of any authority, including any local, State, or Federal law enforcement, narcotics control, licensure, disciplinary, or program

authority, to perform functions otherwise authorized by law.

(2) Additional privacy protections

Nothing in this section shall be construed as preempting any State from imposing any additional privacy protections.

(3) Federal privacy requirements

Nothing in this section shall be construed to supersede any Federal privacy or confidentiality requirement, including the regulations promulgated under section 264(c) of the Health Insurance Portability and Accountability Act of 1996 (Public Law 104–191; 110 Stat. 2033) and section 290dd–2 of this title.

(4) No Federal private cause of action

Nothing in this section shall be construed to create a Federal private cause of action.

(5) Promoting State choice

Nothing in this section shall be construed to authorize the Secretary to require States to use a specific vendor or a specific interoperability connection other than to align with nationally recognized, consensus-based open standards, such as in accordance with sections 300jj–11 and 300jj–14 of this title.

(i) Progress report

Not later than 3 years after October 24, 2018, the Secretary shall—

(1) complete a study that—

(A) determines the progress of grantees in establishing and implementing PDMPs consistent with this section;

(B) provides an analysis of the extent to which the operation of PDMPs has—

(i) reduced inappropriate use, abuse, diversion of, and overdose with, controlled substances;

(ii) established or strengthened initiatives to ensure linkages to substance use disorder treatment services; or

(iii) affected patient access to appropriate care in States operating PDMPs;

(C) determine [1] the progress of grantees in achieving interstate interoperability and intrastate interoperability of PDMPs, including an assessment of technical, legal, and financial barriers to such progress and recommendations for addressing these barriers;

(D) determines the progress of grantees in implementing near real-time electronic PDMPs;

(E) provides an analysis of the privacy protections in place for the information reported to the PDMP in each State or locality receiving support under this section and any recommendations of the Secretary for additional Federal or State requirements for protection of this information;

(F) determines the progress of States or localities in implementing technological alternatives to centralized data storage, such as peer-to-peer file sharing or data pointer systems, in PDMPs and the potential for such alternatives to enhance the privacy and security of individually identifiable data; and

(G) evaluates the penalties that States or localities have enacted for the unauthorized use and disclosure of information maintained in PDMPs, and the criteria used by the Secretary to determine whether such penalties qualify as appropriate for purposes of subsection (a)(2); and

(2) submit a report to the Congress on the results of the study.

(j) Advisory Council

(1) Establishment

A State or locality may establish an advisory council to assist in the establishment, improvement, or maintenance of a PDMP consistent with this section.

(2) Limitation

A State or locality may not use Federal funds for the operations of an advisory council to assist in the establishment, improvement, or maintenance of a PDMP.

(3) Sense of Congress

It is the sense of the Congress that, in establishing an advisory council to assist in the establishment, improvement, or maintenance of a PDMP, a State or locality should consult with appropriate professional boards and other interested parties.

(k) Definitions

For purposes of this section:

(1) The term "controlled substance" means a controlled substance (as defined in section 802 of title 21) in schedule II, III, or IV of section 812 of such title.

(2) The term "dispense" means to deliver a controlled substance to an ultimate user by, or pursuant to the lawful order of, a practitioner, irrespective of whether the dispenser uses the Internet or other means to effect such delivery.

(3) The term "dispenser" means a physician, pharmacist, or other person that dispenses a controlled substance to an ultimate user.

(4) The term "interstate interoperability" with respect to a PDMP means the ability of the PDMP to electronically share reported information with another State if the information concerns either the dispensing of a controlled substance to an ultimate user who resides in such other State, or the dispensing of a controlled substance prescribed by a practitioner whose principal place of business is located in such other State.

(5) The term "intrastate interoperability" with respect to a PDMP means the integration of PDMP data within electronic health records and health information technology infrastructure or linking of a PDMP to other data systems within the State, including the State's Medicaid program, workers' compensation programs, and medical examiners or coroners.

(6) The term "nonidentifiable information" means information that does not identify a practitioner, dispenser, or an ultimate user and with respect to which there is no reasonable basis to believe that the information can be used to identify a practitioner, dispenser, or an ultimate user.

(7) The term "PDMP" means a prescription drug monitoring program that is State-controlled.

(8) The term "practitioner" means a physician, dentist, veterinarian, scientific investigator, pharmacy, hospital, or other person licensed, registered, or otherwise permitted, by the United States or the jurisdiction in which the individual practices or does research, to distribute, dispense, conduct research with respect to, administer, or use in teaching or chemical analysis, a controlled substance in the course of professional practice or research.

(9) The term "State" means each of the 50 States, the District of Columbia, and any commonwealth or territory of the United States.

(10) The term "ultimate user" means a person who has obtained from a dispenser, and who possesses, a controlled substance for the person's own use, for the use of a member of the person's household, or for the use of an animal owned by the person or by a member of the person's household.

(11) The term "clinical workflow" means the integration of automated queries for prescription drug monitoring programs data and analytics into health information technologies such as electronic health record systems, health information exchanges, and/or pharmacy dispensing software systems, thus streamlining provider access through automated queries.

(July 1, 1944, ch. 373, title III, §399O, as added Pub. L. 109–60, §3, Aug. 11, 2005, 119 Stat. 1979; amended Pub. L. 114–198, title I, §109(b), July 22, 2016, 130 Stat. 706; Pub. L. 115–271, title VII, §7162, Oct. 24, 2018, 132 Stat. 4062; Pub. L. 119–44, title I, §105, Dec. 1, 2025, 139 Stat. 674.)

EDITORIAL NOTES

REFERENCES IN TEXT

Section 264(c) of the Health Insurance Portability and Accountability Act of 1996, referred to in subsec. (h)(3), is section 264(c) of Pub. L. 104–191, which is set out as a note under section 1320d–2 of this title.

CODIFICATION

Another section 399O of act July 1, 1944, was renumbered section 399P and is classified to section 280g–4 of this title.

AMENDMENTS

2025—Subsec. (h)(5). Pub. L. 119–44 added par. (5).

2018—Pub. L. 115–271 amended section generally. Prior to amendment, section related to grants for State controlled substance monitoring programs.

2016—Subsec. (a)(1). Pub. L. 114–198, §109(b)(1)(A), inserted ", in consultation with the Administrator of the Substance Abuse and Mental Health Services Administration and Director of the Centers for Disease Control and Prevention," after "the Secretary" in introductory provisions.

Subsec. (a)(1)(C). Pub. L. 114–198, §109(b)(1)(B)–(D), added subpar. (C).

Subsec. (b). Pub. L. 114–198, §109(b)(2), amended subsec. (b) generally. Prior to amendment, text read as follows: "Prior to awarding a grant under this section, and not later than 6 months after the date on which funds are first appropriated to carry out this section, after seeking consultation with States and other interested parties, the Secretary shall, after publishing in the Federal Register proposed minimum requirements and receiving public comments, establish minimum requirements for criteria to be used by States for purposes of clauses (ii), (v), (vi), and (vii) of subsection (c)(1)(A) of this section."

Subsec. (c)(1)(A)(iv). Pub. L. 114–198, §109(b)(9), substituted "subsection (i)" for "subsection (h)".

Subsec. (c)(1)(B). Pub. L. 114–198, §109(b)(3)(A)(i), substituted "(a)(1)(B) or (a)(1)(C)" for "(a)(1)(B)" in introductory provisions.

Subsec. (c)(1)(B)(i). Pub. L. 114–198, §109(b)(3)(A)(ii), substituted "program to be improved or maintained" for "program to be improved".

Subsec. (c)(1)(B)(iii). Pub. L. 114–198, §109(b)(3)(A)(iv), added cl. (iii). Former cl. (iii) redesignated (iv).

Subsec. (c)(1)(B)(iv). Pub. L. 114–198, §109(b)(3)(A)(iii), (v), redesignated cl. (iii) as (iv) and substituted "and at least one health information technology system such as electronic health records, health information exchanges, or e-prescribing systems;" for "; and". Former cl. (iv) redesignated (v).

Subsec. (c)(1)(B)(v). Pub. L. 114–198, §109(b)(3)(A)(iii), (vi), redesignated cl. (iv) as (v) and substituted "public health or safety in such State; and" for "public health in such State."

Subsec. (c)(1)(B)(vi). Pub. L. 114–198, §109(b)(3)(A)(vii), added cl. (vi).

Subsec. (c)(3). Pub. L. 114–198, §109(b)(3)(B), designated existing provisions as subpar. (A) and inserted heading, inserted before period at end "and include timelines for full implementation of such interoperability. The State shall also describe the manner in which it will achieve interoperability between its monitoring program and health information technology systems, as allowable under State law, and include timelines for the implementation of such interoperability", and added subpar. (B).

Subsec. (c)(5). Pub. L. 114–198, §109(b)(3)(C), substituted "establish, improve, or maintain" for "implement or improve" and inserted at end "The Secretary shall redistribute any funds that are so returned among the remaining grantees under this section in accordance with the formula described in subsection (a)(2)(B)."

Subsec. (d). Pub. L. 114–198, §109(b)(4)(A), in introductory provisions, substituted "In establishing, improving, or maintaining a controlled substance monitoring program under this section, a State shall comply, or with respect to a State that applies for a grant under subparagraph (B) or (C) of subsection (a)(1)" for "In implementing or improving a controlled substance monitoring program under this section, a State shall comply, or with respect to a State that applies for a grant under subsection (a)(1)(B)" and "public health or safety" for "public health".

Subsec. (d)(4). Pub. L. 114–198, §109(b)(9), substituted "subsection (i)" for "subsection (h)".

Subsec. (d)(5). Pub. L. 114–198, §109(b)(4)(B), added par. (5).

Subsecs. (e), (f)(1). Pub. L. 114–198, §109(b)(5), substituted "establishing, improving, or maintaining" for "implementing or improving" in introductory provisions.

Subsec. (f)(1)(B). Pub. L. 114–198, §109(b)(6)(A)(i), substituted "misuse of a controlled substance included in schedule II, III, or IV of section 812(c) of title 21" for "misuse of a schedule II, III, or IV substance".

Subsec. (f)(1)(D). Pub. L. 114–198, §109(b)(6)(A)(ii), inserted "a State substance abuse agency," after "State health department," and substituted "such department, program, agency, or administration" for "such department, program, or administration" in two places.

Subsec. (f)(3), (4). Pub. L. 114–198, §109(b)(6)(B), added pars. (3) and (4).

Subsec. (g). Pub. L. 114–198, §109(b)(5), substituted "establishing, improving, or maintaining" for "implementing or improving" in introductory provisions.

Subsecs. (h) to (j). Pub. L. 114–198, §109(b)(8), (10), added subsec. (h) and redesignated former subsecs. (h) and (i) as (i) and (j), respectively. Former subsec. (j) redesignated (k).

Subsec. (k). Pub. L. 114–198, §109(b)(7), (8), redesignated subsec. (j) as (k) and struck out former subsec. (k). Prior to amendment, text of subsec. (k) read as follows: "Beginning 3 years after the date on which funds are first appropriated to carry out this section, the Secretary, in awarding any competitive grant that is related to drug abuse (as determined by the Secretary) and for which only States are eligible to apply, shall give preference to any State with an application approved under this section. The Secretary shall have the discretion to apply such preference to States with existing controlled substance monitoring programs that meet minimum requirements under this section or to States that put forth a good faith effort to meet those requirements (as determined by the Secretary)."

Subsec. (k)(2)(A)(ii). Pub. L. 114–198, §109(b)(11)(A), substituted ", established or strengthened initiatives to ensure linkages to substance use disorder services, or affected" for "or affected".

Subsec. (k)(2)(A)(iii). Pub. L. 114–198, §109(b)(11)(B), substituted "and between controlled substance monitoring programs and health information technology systems, including an assessment" for "including an assessment".

Subsec. (l)(1). Pub. L. 114–198, §109(b)(12), substituted "establishment, improvement, or maintenance" for "establishment, implementation, or improvement".

Subsec. (m)(8). Pub. L. 114–198, §109(b)(13), substituted ", the District of Columbia, and any commonwealth or territory of the United States" for "and the District of Columbia".

Subsec. (n). Pub. L. 114–198, §109(b)(14), amended subsec. (n) generally. Prior to amendment, subsec. (n) authorized appropriations for fiscal years 2006 to 2010.

STATUTORY NOTES AND RELATED SUBSIDIARIES

PURPOSE

Pub. L. 109–60, §2, Aug. 11, 2005, 119 Stat. 1979, as amended by Pub. L. 114–198, title I, §109(a), July 22, 2016, 130 Stat. 706, provided that: "It is the purpose of this Act [enacting this section and provisions set out as a note under section 201 of this title] to—

> "(1) foster the establishment of State-administered controlled substance monitoring systems in order to ensure that health care providers have access to the accurate, timely prescription history information that they may use as a tool for the early identification of patients at risk for addiction in order to initiate appropriate medical interventions and avert the tragic personal, family, and community consequences of untreated addiction; and
>
> "(2) establish, based on the experiences of existing State controlled substance monitoring programs, a set of best practices to guide the establishment of new State programs and the improvement of existing programs."

[1] *So in original. Probably should be "determines".*

§280g–4. Grants to strengthen the healthcare system's response to domestic violence, dating violence, sexual assault, and stalking

(a) In general

The Secretary shall award grants for—

(1) the development or enhancement and implementation of interdisciplinary training for health professionals, public health staff, community health workers, violence prevention advocates working with health providers, and allied health professionals;

(2) the development or enhancement and implementation of education programs for medical, psychology, dental, social work, nursing, and other health profession students, interns, residents, fellows, or current health care providers (including midwives and doulas);

(3) the development or enhancement and implementation of comprehensive statewide strategies to improve the capacity of clinics, public health facilities, hospitals, and other health settings (including behavioral and mental health programs) to prevent and respond to domestic violence, dating violence, sexual assault, and stalking;

(4) the development or enhancement and implementation of training programs to improve the capacity of early childhood programs to address domestic violence, dating violence, sexual assault, and stalking among families they serve; and

(5) the development or enhancement and implementation of comprehensive statewide strategies for health and violence prevention programs to work together to promote primary prevention of domestic violence, dating violence, sexual assault, and stalking.

(b) Use of funds

(1) Required uses

Amounts provided under a grant under this section shall be used to—

(A) fund interdisciplinary training and education programs under paragraphs (1) and (2) of subsection (a) that—

(i) are designed to train medical, psychology, dental, social work, nursing, and other health profession students, interns, residents, fellows, or current health care providers to provide universal education on healthy relationships and provide trauma-informed health care services (including mental or behavioral health care services and referrals to appropriate community services) to individuals who are or who have been victims of domestic violence, dating violence, sexual assault, or stalking;

(ii) plan and develop training components that center the experiences of, and are developed in collaboration with, culturally specific individuals and American Indians and Alaska Natives, and include community-defined practices such as the use of doulas, midwives, and traditional healers, for integration into approved internship, residency, and fellowship training or continuing medical or other health education training that address physical, mental, and behavioral health issues, including protective factors, related to domestic violence, dating violence, sexual assault, stalking, and other forms of violence and abuse (including labor and sex trafficking), focus on reducing health inequities and preventing violence and abuse, and include the primacy of victim safety and confidentiality;

(iii) are designed to be inclusive of the experiences of all individuals, including LGBT individuals, and include training on improving equity and reducing disparities in access to health care services and prevention resources; and

(iv) include training on the use of a universal prevention education approach to both prevent and respond to domestic violence, dating violence, sexual assault, or stalking in health care settings;

(B) design and implement comprehensive strategies to improve the capacity of the health care system to prevent and respond to domestic or sexual violence in clinical and public health settings, hospitals, clinics, and other health settings (including behavioral and mental health), under subsection (a)(3) through—

(i) the implementation, dissemination, and evaluation of policies and procedures to guide health professionals and public health staff in identifying, responding to, and promoting prevention of domestic violence, dating violence, sexual assault, and stalking during in-person or virtual visits, including strategies to ensure that health information is maintained in a manner that protects the patient's privacy and safety, and safely uses health information technology to improve documentation, identification, assessment, treatment, and follow-up care and to maximize victim choice on the use and sharing of their health information;

(ii) the development of services to address the safety, medical, and mental health needs of patients by—

(I) increasing the capacity of existing health care professionals (including professionals who specialize in trauma or in substance use disorders) in behavioral and mental health care, community health workers, and public health staff to address domestic violence, dating violence, sexual assault, stalking, and children exposed to violence;

(II) contracting with or hiring advocates for victims of domestic violence or sexual assault to provide such services; or

(III) providing funding to State domestic and sexual violence coalitions to improve the capacity of such coalitions to coordinate and support health advocates and other health system partnerships;

(iii) the development of measures and methods for the evaluation of the practice of prevention, intervention, and documentation regarding victims of domestic violence, dating violence, sexual assault, and stalking during in-person or virtual visits, including the development and testing of quality improvement measurements, in accordance with the multi-stakeholder and quality measurement processes established under paragraphs (7) and (8) of section 1395aaa(b) of this title and section 1395aaa–1 of this title;

(iv) the provision of training and follow-up technical assistance to health care professionals, and public health staff, and allied health professionals to identify, assess, treat, and refer clients who are victims of domestic violence, dating violence, sexual assault, or stalking, and promote prevention during in-person or virtual visits, including using tools and training materials already developed;

(v) the development, implementation, dissemination, and evaluation of best practices, tools, and training materials, including culturally relevant tools, for mental health, behavioral health, and substance use disorder professionals to identify and respond to domestic violence, sexual violence, stalking, and dating violence; and

(vi) the development and provision of culturally relevant training and follow-up technical assistance to health care professionals, and public health staff, and allied health professionals to identify, assess, treat, and refer clients who are victims of domestic violence, dating violence, sexual assault, or stalking from culturally specific communities and promote prevention, using tools and training materials, developed by and for culturally specific communities, with priority given to trainings provided by culturally specific organizations; and

(C) design and implement comprehensive strategies to prevent domestic or sexual violence including through the use of universal education in clinical and public health settings, hospitals, clinics and other health settings.

(2) Permissible uses

(A) Child abuse and abuse in later life

To the extent consistent with the purpose of this section, a grantee may use amounts received under this section to address, as part of a comprehensive programmatic approach implemented under the grant, issues relating to child abuse or abuse in later life.

(B) Rural areas

Grants funded under paragraphs (1) and (2) of subsection (a) may be used to offer to rural areas community-based training opportunities, which may include the use of distance learning networks and other available technologies needed to reach isolated rural areas, for medical, nursing, and other health profession students and residents on domestic violence, dating violence, sexual assault, stalking, and, as appropriate, other forms of violence and abuse.

(C) Other uses

Grants funded under subsection (a)(3) may be used for—

(i) the development of training modules and policies that address the overlap of child abuse, domestic violence, dating violence, sexual assault, and stalking and abuse in later life, as well as childhood exposure to domestic and sexual violence;

(ii) the development, expansion, and implementation of programs that promote the prevention of sexual assault as well as sexual assault forensic medical examination or sexual assault nurse examiner programs;

(iii) the inclusion of the health effects of lifetime exposure to violence and abuse and exposure to violence across generations as well as related protective factors and behavioral

risk factors in health professional training schools including medical, dental, nursing, social work, and mental and behavioral health curricula, and allied health service training courses;

(iv) the integration of knowledge of domestic violence, dating violence, sexual assault, and stalking into health care accreditation and professional licensing examinations, such as medical, dental, mental health, social work, and nursing boards, and where appropriate, other allied health exams and certifications;

(v) providing funding to culturally specific organizations to improve the capacity of such organizations to engage and partner with health care providers to support victims and meet increased referrals from health systems;

(vi) developing a State-level pilot program to—

(I) improve the response of substance use disorder treatment programs, harm reduction programs for people who use substances, and systems to domestic violence, dating violence, sexual assault, and stalking;

(II) improve the capacity of substance use disorder treatment programs, harm reduction programs for people who use substances, and systems to serve survivors of domestic violence, dating violence, sexual assault, and stalking dealing with substance use disorder; and

(III) improve the capacity of domestic violence, dating violence, sexual assault, and stalking programs to serve survivors who have substance use history; or

(vii) developing and utilizing existing technical assistance and training resources to improve the capacity of substance use disorder treatment programs and harm reduction programs for people who use substances to address domestic violence, dating violence, sexual assault, and stalking among patients the programs serve.

(c) Requirements for grantees

(1) Confidentiality and safety

(A) In general

Grantees under this section shall ensure that all programs developed with grant funds address issues of confidentiality and patient safety and comply with applicable confidentiality and nondisclosure requirements under section 12291(b)(2) of title 34 and the Family Violence Prevention and Services Act [42 U.S.C. 10401 et seq.], and that faculty and staff associated with delivering educational components are fully trained in procedures that will protect the immediate and ongoing security and confidentiality of the patients, patient records, and staff. Such grantees shall consult entities with demonstrated expertise in the confidentiality and safety needs of victims of domestic violence, dating violence, sexual assault, and stalking on the development and adequacy of confidentially and security procedures, and provide documentation of such consultation.

(B) Advance notice of information disclosure

Grantees under this section shall provide to patients advance notice about any circumstances under which information may be disclosed, such as mandatory reporting laws, and shall give patients the option to receive information and referrals without affirmatively disclosing abuse.

(2) Limitation on administrative expenses

A grantee shall use not more than 10 percent of the amounts received under a grant under this section for administrative expenses.

(3) Application

(A) Preference

In selecting grant recipients under this section, the Secretary shall give preference to applicants based on the strength of their evaluation strategies, with priority given to—

(i) outcome based evaluations;

(ii) culturally specific and population specific organizations; and

(iii) programs developing and implementing community-driven solutions to address domestic violence, dating violence, sexual assault, or stalking.

(B) Subsection (a)(1) and (2) grantees

Applications for grants under paragraphs (1) and (2) of subsection (a) shall include—

(i) documentation that the applicant represents a team of entities working collaboratively to strengthen the response of the health care system to domestic violence, dating violence, sexual assault, or stalking, and which includes at least one of each of—

(I) an accredited school of allopathic or osteopathic medicine, psychology, nursing, dentistry, social work, or other health field;

(II) a health care facility or system; or

(III) a government or nonprofit entity, including a culturally specific organization or community-based organization working to address the social determinants of health, with a history of effective work in the fields of domestic violence, dating violence, sexual assault, or stalking; and

(ii) strategies for the dissemination and sharing of curricula and other educational materials developed under the grant, if any, with other interested health professions schools and national resource repositories for materials on domestic violence, dating violence, sexual assault, and stalking.

(C) Subsection (a)(3) grantees

An entity desiring a grant under subsection (a)(3) shall submit an application to the Secretary at such time, in such a manner, and containing such information and assurances as the Secretary may require, including—

(i) documentation that all training, education, screening, assessment, services, treatment, and any other approach to patient care will be informed by an understanding of violence and abuse victimization and trauma-specific approaches that will be integrated into prevention, intervention, and treatment activities;

(ii) strategies—

(I) for the development and implementation of policies to prevent and address domestic violence, dating violence, sexual assault, and stalking over the lifespan and generations in health care settings; and

(II) to address primary prevention of domestic violence, dating violence, sexual assault, and stalking over the lifespan and generations, including strategies that address related social determinants of health, economic justice, and equity issues, and that are inclusive of LGBT individuals;

(iii) a plan for consulting with State and tribal domestic violence or sexual assault coalitions, national nonprofit victim advocacy organizations, culturally specific organizations, and population specific organizations with demonstrated expertise in domestic violence, dating violence, sexual assault, or stalking;

(iv) with respect to an application for a grant under which the grantee will have contact with patients, a plan, developed in collaboration with local victim service providers (including culturally specific organizations), to respond appropriately to and make correct referrals for individuals who disclose that they are victims of domestic violence, dating violence, sexual assault, stalking, or other types of violence, and documentation provided by the grantee of an ongoing collaborative relationship with a local victim service provider; and

(v) with respect to an application for a grant proposing to fund a program described in subsection (b)(2)(C)(ii), a certification that any sexual assault forensic medical examination and sexual assault nurse examiner programs supported with such grant funds will adhere to the guidelines set forth by the Attorney General.

(d) Eligible entities

(1) In general

To be eligible to receive funding under paragraph (1) or (2) of subsection (a), an entity shall be—

(A) a nonprofit organization with a history of effective work in the field of training health professionals with an understanding of, and clinical skills pertinent to, domestic violence, dating violence, sexual assault, or stalking, and lifetime exposure to violence and abuse;

(B) an accredited school of allopathic or osteopathic medicine, psychology, nursing, dentistry, social work, or allied health;

(C) a health care provider membership or professional organization, or a health care system; or

(D) a State, tribal, territorial, or local entity.

(2) Subsection (a)(3) grantees

To be eligible to receive funding under subsection (a)(3), an entity shall be—

(A) a State department (or other division) of health (including mental health or substance abuse agencies), a State, tribal, or territorial domestic violence or sexual assault coalition or victim service provider, or any other nonprofit, nongovernmental organization with a history of effective work in the fields of domestic violence, dating violence, sexual assault, or stalking, and health care, including physical or behavioral health care and substance use disorder prevention and treatment; or

(B) a local victim service provider, a local department (or other division) of health, a local health clinic, hospital, behavioral health treatment system, or health system, a community-based organization with a history of effective work in the field of domestic violence, dating violence, sexual assault, or stalking and health care, including physical or mental health care or substance use disorder prevention and treatment, or a community-based organization with a history of partnership with programs in the field of domestic violence, dating violence, sexual assault, or stalking and health care, including physical or mental health care or substance use disorder prevention and treatment.

(e) Technical assistance

(1) In general

Of the funds made available to carry out this section for any fiscal year, the Secretary may make grants or enter into contracts to provide technical assistance with respect to the planning, development, and operation of any program, activity or service carried out pursuant to this section. Not more than 8 percent of the funds appropriated under this section in each fiscal year may be used to fund technical assistance under this subsection.

(2) Availability of materials

The Secretary shall make publicly available materials developed by grantees under this section, including materials on training, best practices, and research and evaluation.

(3) Reporting

The Secretary shall publish a biennial report on—

(A) the distribution of funds under this section; and

(B) the programs and activities supported by such funds.

(f) Research and evaluation

(1) In general

Of the funds made available to carry out this section for any fiscal year, the Secretary may use not more than 20 percent to make a grant or enter into a contract for research and evaluation of—

(A) grants awarded under this section; and

(B) other training for health professionals and effective interventions in the health care setting that prevent domestic violence, dating violence, and sexual assault across the lifespan, prevent the health effects of such violence, and improve the safety and health of individuals who are

currently being victimized.

(2) Research

Research authorized in paragraph (1) may include—

(A) research on the effects of domestic violence, dating violence, sexual assault, and childhood exposure to domestic, dating or sexual violence on health behaviors, health conditions, and health status of individuals, families, and populations, including underserved populations;

(B) research to determine effective health care interventions to respond to and prevent domestic violence, dating violence, sexual assault, and stalking;

(C) research on the impact of domestic, dating and sexual violence, childhood exposure to such violence, and stalking on the health care system, health care utilization, health care costs, and health status; and

(D) research on the impact of adverse childhood experiences on adult experience with domestic violence, dating violence, sexual assault, stalking, and adult health outcomes, including how to reduce or prevent the impact of adverse childhood experiences through the health care setting.

(g) Authorization of appropriations

There is authorized to be appropriated to carry out this section, $20,000,000 for each of fiscal years 2023 through 2027.

(h) Definitions

Except as otherwise provided, the definitions in section 12291 of title 34 shall apply to this section.

(July 1, 1944, ch. 373, title III, §399P, formerly §399O, as added Pub. L. 109–162, title V, §504, Jan. 5, 2006, 119 Stat. 3026; renumbered §399P, Pub. L. 109–450, §4(1), Dec. 22, 2006, 120 Stat. 3342; amended Pub. L. 113–4, title V, §501(a), Mar. 7, 2013, 127 Stat. 96; Pub. L. 117–103, div. W, title V, §501, Mar. 15, 2022, 136 Stat. 869.)

EDITORIAL NOTES

REFERENCES IN TEXT

The Family Violence Prevention and Services Act, referred to in subsec. (c)(1)(A), is title III of Pub. L. 98–457, Oct. 9, 1984, 98 Stat. 1757, which is classified generally to chapter 110 (§10401 et seq.) of this title. For complete classification of this Act to the Code, see Short Title note set out under section 10401 of this title and Tables.

AMENDMENTS

2022—Subsec. (a)(1). Pub. L. 117–103, §501(1)(A), inserted "community health workers, violence prevention advocates working with health providers," after "health staff,".

Subsec. (a)(2). Pub. L. 117–103, §501(1)(B), substituted "for medical, psychology, dental, social work, nursing, and other health profession students, interns, residents, fellows, or current health care providers (including midwives and doulas);" for "for medical, nursing, dental, and other health profession students and residents to prevent and respond to domestic violence, dating violence, sexual assault, and stalking; and".

Subsec. (a)(3). Pub. L. 117–103, §501(1)(C)(i), (ii), substituted "capacity" for "response" and inserted "prevent and respond to" after "(including behavioral and mental health programs) to".

Subsec. (a)(4), (5). Pub. L. 117–103, §501(1)(C)(iii), (D), added pars. (4) and (5).

Subsec. (b)(1)(A)(i). Pub. L. 117–103, §501(2)(A)(i), substituted "to provide universal education on healthy relationships and provide trauma-informed" for "to identify and provide".

Subsec. (b)(1)(A)(ii). Pub. L. 117–103, §501(2)(B), substituted "training components that center the experiences of, and are developed in collaboration with, culturally specific individuals and American Indians and Alaska Natives, and include community-defined practices such as the use of doulas, midwives, and traditional healers," for "culturally competent clinical training components" and "inequities" for "disparities" and inserted "(including labor and sex trafficking)" after "other forms of violence and abuse".

Subsec. (b)(1)(A)(iii), (iv). Pub. L. 117–103, §501(2)(A)(ii), (C), added cls. (iii) and (iv).

Subsec. (b)(1)(B). Pub. L. 117–103, §501(2)(D), substituted "capacity of the health care system to prevent and respond" for "response of the health care system" in introductory provisions.

Subsec. (b)(1)(B)(i). Pub. L. 117–103, §501(2)(E), substituted "identifying, responding to, and promoting prevention of" for "identifying and responding to" and inserted "during in-person or virtual visits" after "and stalking" and "and to maximize victim choice on the use and sharing of their health information" before semicolon at end.

Subsec. (b)(1)(B)(ii). Pub. L. 117–103, §501(2)(F), substituted "services to address the safety, medical, and mental health needs of patients by—" and subcls. (I) to (III) for "on-site access to services to address the safety, medical, and mental health needs of patients by increasing the capacity of existing health care professionals and public health staff to address domestic violence, dating violence, sexual assault, and stalking, or by contracting with or hiring domestic or sexual assault advocates to provide such services or to model other services appropriate to the geographic and cultural needs of a site;".

Subsec. (b)(1)(B)(iii). Pub. L. 117–103, §501(2)(G)(i), (ii), substituted "of prevention" for "of identification" and inserted "during in-person or virtual visits" after "and stalking".

Subsec. (b)(1)(B)(iv). Pub. L. 117–103, §501(2)(H)(i), inserted "and promote prevention during in-person or virtual visits," after "or stalking,".

Subsec. (b)(1)(B)(v), (vi). Pub. L. 117–103, §501(2)(G)(iii), (H)(ii), (I), added cls. (v) and (vi).

Subsec. (b)(1)(C). Pub. L. 117–103, §501(2)(J), added subpar. (C).

Subsec. (b)(2)(A). Pub. L. 117–103, §501(3), substituted "Child abuse and abuse in later life" for "Child and elder abuse" in heading and "child abuse or abuse in later life" for "child or elder abuse" in text.

Subsec. (b)(2)(C)(i). Pub. L. 117–103, §501(4), substituted "abuse in later life" for "elder abuse".

Subsec. (b)(2)(C)(ii). Pub. L. 117–103, §501(5), inserted "programs that promote the prevention of sexual assault as well as" after "implementation of".

Subsec. (b)(2)(C)(iii). Pub. L. 117–103, §501(6)(A), inserted "and exposure to violence across generations" after "abuse".

Subsec. (b)(2)(C)(iv). Pub. L. 117–103, §501(7), inserted "mental health," after "dental," and substituted "exams and certifications;" for "exams."

Subsec. (b)(2)(C)(v) to (vii). Pub. L. 117–103, §501(6)(B), (8), added cls. (v) to (vii).

Subsec. (c)(3)(A). Pub. L. 117–103, §501(9), substituted "given to—" and cls. (i) to (iii) for "given to outcome based evaluations."

Subsec. (c)(3)(B)(i)(III). Pub. L. 117–103, §501(10), inserted ", including a culturally specific organization or community-based organization working to address the social determinants of health," after "nonprofit entity".

Subsec. (c)(3)(C)(ii). Pub. L. 117–103, §501(11), substituted "strategies—" for "strategies", inserted subcl. (I) designation before "for the development", inserted "and generations" after "lifespan" and added subcl. (II).

Subsec. (c)(3)(C)(iii). Pub. L. 117–103, §501(12), substituted "culturally specific organizations" for "State or tribal law enforcement task forces (where appropriate)".

Subsec. (c)(3)(C)(iv). Pub. L. 117–103, §501(13), inserted "(including culturally specific organizations)" after "service providers".

Subsec. (d)(2)(A). Pub. L. 117–103, §501(14)(C), which directed insertion of "and substance use disorder prevention and treatment" before "the semicolon at the end", was executed by making the insertion before "; or", to reflect the probable intent of Congress.

Pub. L. 117–103, §501(14)(A), (B), inserted "(including mental health or substance abuse agencies)" after "of health" and substituted "or behavioral" for "or mental".

Subsec. (d)(2)(B). Pub. L. 117–103, §501(15), substituted "hospital, behavioral health treatment system, or health system, a community-based" for "hospital, or health system, or any other community-based" and inserted "or substance use disorder prevention and treatment, or a community-based organization with a history of partnership with programs in the field of domestic violence, dating violence, sexual assault, or stalking and health care, including physical or mental health care or substance use disorder prevention and treatment" after "mental health care".

Subsec. (g). Pub. L. 117–103, §501(16), substituted "$20,000,000" for "$10,000,000" and "2023 through 2027" for "2014 through 2018".

Subsec. (h). Pub. L. 117–103, §501(17), struck out "herein" after "otherwise provided" and "provided for" after "definitions".

2013—Pub. L. 113–4 amended section generally. Prior to amendment, section related to grants to foster public health responses to domestic violence, dating violence, sexual assault, and stalking.

STATUTORY NOTES AND RELATED SUBSIDIARIES

EFFECTIVE DATE OF 2022 AMENDMENT

Amendment by Pub. L. 117–103 not effective until Oct. 1 of the first fiscal year beginning after Mar. 15, 2022, see section 4(a) of div. W of Pub. L. 117–103, set out as an Effective Date note under section 6851 of Title 15, Commerce and Trade.

FINDINGS

Pub. L. 109–162, title V, §501, Jan. 5, 2006, 119 Stat. 3023, provided that: "Congress makes the following findings:

"(1) The health-related costs of intimate partner violence in the United States exceed $5,800,000,000 annually.

"(2) Thirty-seven percent of all women who sought care in hospital emergency rooms for violence-related injuries were injured by a current or former spouse, boyfriend, or girlfriend.

"(3) In addition to injuries sustained during violent episodes, physical and psychological abuse is linked to a number of adverse physical and mental health effects. Women who have been abused are much more likely to suffer from chronic pain, diabetes, depression, unintended pregnancies, substance abuse and sexually transmitted infections, including HIV/AIDS.

"(4) Health plans spend an average of $1,775 more a year on abused women than on general enrollees.

"(5) Each year about 324,000 pregnant women in the United States are battered by the men in their lives. This battering leads to complications of pregnancy, including low weight gain, anemia, infections, and first and second trimester bleeding.

"(6) Pregnant and recently pregnant women are more likely to be victims of homicide than to die of any other pregnancy-related cause, and evidence exists that a significant proportion of all female homicide victims are killed by their intimate partners.

"(7) Children who witness domestic violence are more likely to exhibit behavioral and physical health problems including depression, anxiety, and violence towards peers. They are also more likely to attempt suicide, abuse drugs and alcohol, run away from home, engage in teenage prostitution, and commit sexual assault crimes.

"(8) Recent research suggests that women experiencing domestic violence significantly increase their safety-promoting behaviors over the short- and long-term when health care providers screen for, identify, and provide followup care and information to address the violence.

"(9) Currently, only about 10 percent of primary care physicians routinely screen for intimate partner abuse during new patient visits and 9 percent routinely screen for intimate partner abuse during periodic checkups.

"(10) Recent clinical studies have proven the effectiveness of a 2-minute screening for early detection of abuse of pregnant women. Additional longitudinal studies have tested a 10-minute intervention that was proven highly effective in increasing the safety of pregnant abused women. Comparable research does not yet exist to support the effectiveness of screening men.

"(11) Seventy to 81 percent of the patients studied reported that they would like their healthcare providers to ask them privately about intimate partner violence."

PURPOSE

Pub. L. 109–162, title V, §502, Jan. 5, 2006, 119 Stat. 3024, provided that: "It is the purpose of this title [enacting this section, sections 294h and 13973 of this title, and provisions set out as a note above] to improve the health care system's response to domestic violence, dating violence, sexual assault, and stalking through the training and education of health care providers, developing comprehensive public health responses to violence against women and children, increasing the number of women properly screened, identified, and treated for lifetime exposure to violence, and expanding research on effective interventions in the health care setting."

§280g–4a. Understanding sexual assault care in health systems

(a) Purpose

It is the purpose of this section to identify areas for improvement in health care delivery systems providing forensic examinations to survivors of sexual assault.

(b) Grants

The Secretary of Health and Human Services (referred to in this section as "the Secretary") shall award grants to States and Indian Tribes to develop and implement State and Tribal surveys to identify—

(1) the availability of, and patient access to, medical forensic examinations;

(2) the training level of the health care providers who perform medical forensic examinations;

(3) the hospitals or clinics that offer medical forensic examinations and whether each hospital or clinic has full-time, part-time, or on-call coverage;

(4) barriers to medical forensic examinations provided through sexual assault care and services;

(5) billing and reimbursement practices for medical forensic examinations;

(6) State and Tribal requirements, minimum standards, and protocols for training sexual assault examiners for sexual assault forensic examiners and for other personnel involved in medical forensic examinations;

(7) the availability of sexual assault forensic examiner training, the frequency of such training, the providers of such training, the State's or Indian Tribe's role in such training, and the processes or procedures in place for continuing education of such examiners; and

(8) the dedicated Federal and State funding available to support sexual assault forensic examiner training.

(c) Eligibility

To be eligible to receive a grant under this section, a State or Indian Tribe shall submit to the Secretary an application through a competitive process to be determined by the Secretary.

(d) Public dissemination and campaign

(1) Public availability

The results of the surveys conducted under grants awarded under this section shall be published by the Secretary on the website of the Department of Health and Human Services on a biennial basis.

(2) Campaigns

A State or Indian Tribe that receives a grant under this section shall carry out the following activities:

(A) Make the findings of the survey conducted using amounts received under the grant public, including a map showing health care providers who perform medical forensic examinations, based on the findings from the State and Tribal surveys under subsection (b)(3).

(B) Use the findings to develop a strategic action plan to increase the number of trained medical forensic examiners available in the State or Tribal community and create policies to increase survivor access to trained examiners.

(C) Use the findings to develop and implement a public awareness campaign that includes the following:

(i) An online toolkit describing how and where sexual assault survivors can obtain assistance and care, including medical forensic examinations, in the State or Tribal community.

(ii) A model standard response protocol for health care providers to implement upon arrival of a patient seeking care for sexual assault.

(iii) A model sexual assault response team protocol incorporating interdisciplinary community coordination between hospitals, emergency departments, hospital administration, local rape crisis programs, law enforcement, prosecuting attorneys, and other health and human service agencies and stakeholders with respect to delivering survivor-centered sexual assault care and medical forensic examinations.

(iv) A notice of applicable laws prohibiting charging or billing survivors of sexual assault for care and services related to sexual assault.

(e) Authorization of appropriations

There is authorized to be appropriated to carry out this section $7,000,000 for each of fiscal years

2023 through 2027.

(Pub. L. 117–103, div. W, title V, §503, Mar. 15, 2022, 136 Stat. 874.)

EDITORIAL NOTES

CODIFICATION

Section was enacted as part of the Violence Against Women Act Reauthorization Act of 2022, and also as part of the Consolidated Appropriations Act, 2022, and not as part of the Public Health Service Act which comprises this chapter.

STATUTORY NOTES AND RELATED SUBSIDIARIES

EFFECTIVE DATE

Section not effective until Oct. 1 of the first fiscal year beginning after Mar. 15, 2022, see section 4(a) of div. W of Pub. L. 117–103, set out as a note under section 6851 of Title 15, Commerce and Trade.

NATIONAL REPORT ON SEXUAL ASSAULT SERVICES IN NATION'S HEALTH SYSTEM

Pub. L. 117–103, div. W, title V, §504, Mar. 15, 2022, 136 Stat. 876, provided that:

"(a) IN GENERAL.—Not later than 1 year after the date of enactment of this Act [Mar. 15, 2022], and annually thereafter, the Agency for Healthcare Research and Quality, in consultation with the Centers for Medicare & Medicaid Services, the Centers for Disease Control and Prevention, the Health Resources and Services Administration, the Indian Health Service, the Office for Victims of Crime of the Department of Justice, the Office on Women's Health of the Department of Health and Human Services, and the Office of Violence Against Women of the Department of Justice (collectively referred to in this section as the 'Agencies'), shall submit to the Secretary of Health and Human Services (referred to in this section as 'the Secretary') a report of existing Federal, Indian Tribe, and State practices relating to medical forensic examinations which may include the findings of the surveys developed under section 503 [42 U.S.C. 280g–4a].

"(b) CORE COMPETENCIES.—In conducting activities under this section, the Agencies shall address sexual assault forensic examination competencies, including—

"(1) providing medical care to sexual assault patients;

"(2) demonstrating the ability to conduct a medical forensic examination, including an evaluation for evidence collection;

"(3) showing compassion and sensitivity towards survivors of sexual assault;

"(4) testifying in Federal, State, local, and Tribal courts; and

"(5) other competencies, as the Agencies determine appropriate.

"(c) PUBLICATION.—The Agency for Healthcare Research and Quality shall establish, maintain, and publish on the website of the Department of Health and Human Services an online public map of availability of sexual assault forensic examinations. Such maps shall clarify if there is full-time, part-time, or on-call coverage.

"(d) REPORT TO CONGRESS.—Not later than 60 days after receiving the report described in subsection (a), the Secretary shall submit to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce and the Committee on Education and Labor [now Committee on Education and the Workforce] of the House of Representatives recommendations for improving sexual assault forensic examination competencies based on the report described in subsection (a)."

[For definition of terms used in section 504 of div. W of Pub. L. 117–103, set out above, see section 12291 Title 34, Crime Control and Law Enforcement, as made applicable by section 2(b) of div. W of Pub. L. 117–103, which is set out as a note under section 12291 of Title 34].

DEFINITIONS

For definitions of terms used in this section, see section 12291 of Title 34, Crime Control and Law Enforcement, as made applicable by section 2(b) of div. W of Pub. L. 117–103, which is set out as a note under section 12291 of Title 34.

§280g–4b. Expanding access to unified care

(a) Establishment of program

The Secretary of Health and Human Services (referred to in this section as the "Secretary") shall establish a program (referred to in this section as the "program") to award grants to eligible entities for the clinical training of sexual assault forensic examiners (including registered nurses, nurse practitioners, nurse midwives, clinical nurse specialists, physician assistants, and physicians) to administer medical forensic examinations and treatments to survivors of sexual assault.

(b) Purpose

The purpose of the program is to enable each grant recipient to expand access to medical forensic examination services by providing new providers with the clinical training necessary to establish and maintain competency in such services and to test the provisions of such services at new facilities in expanded health care settings.

(c) Grants

Under the program, the Secretary shall award 3-year grants to eligible entities that meet the requirements established by the Secretary.

(d) Eligible entities

To be eligible to receive a grant under this section, an entity shall—

(1) be—

(A) a safety net clinic acting in partnership with a high-volume emergency services provider or a hospital currently providing sexual assault medical forensic examinations performed by sexual assault forensic examiners, that will use grant funds to—

(i) assign rural health care service providers to the high-volume hospitals for clinical practicum hours to qualify such providers as sexual assault forensic examiners; or

(ii) assign practitioners at high-volume hospitals to rural health care services providers to instruct, oversee, and approve clinical practicum hours in the community to be served;

(B) an organization described in section 501(c)(3) of title 26 and exempt from taxation under 501(a) of such title, that provides legal training and technical assistance to Tribal communities and to organizations and agencies serving Indians; or

(C) an Indian Tribe (as defined in section 5304 of title 25); and

(2) submit to the Secretary an application at such time, in such manner, and containing such information as the Secretary may require, including a description of whether the applicant will provide services described in subparagraph (A) or (B) of paragraph (1).

(e) Grant amount

Each grant awarded under this section shall be in an amount not to exceed $400,000 per year. A grant recipient may carry over funds from one fiscal year to the next without obtaining approval from the Secretary.

(f) Authorization of appropriations

(1) In general

There is authorized to be appropriated to carry out this section $10,000,000 for each of fiscal years 2023 through 2027.

(2) Set-aside

Of the amount appropriated under this subsection for a fiscal year, the Secretary shall reserve 15 percent of such amount for purposes of making grants to entities that are affiliated with Indian Tribes or Tribal organizations (as defined in section 5304 of title 25), or Urban Indian organizations (as defined in section 1603 of title 25). Amounts reserved may be used to support referrals and the delivery of emergency first aid, culturally competent support, and forensic evidence collection training.

(Pub. L. 117–103, div. W, title V, §506, Mar. 15, 2022, 136 Stat. 878.)

EDITORIAL NOTES

CODIFICATION

Section was enacted as part of the Violence Against Women Act Reauthorization Act of 2022, and also as part of the Consolidated Appropriations Act, 2022, and not as part of the Public Health Service Act which comprises this chapter.

STATUTORY NOTES AND RELATED SUBSIDIARIES

EFFECTIVE DATE

Section not effective until Oct. 1 of the first fiscal year beginning after Mar. 15, 2022, see section 4(a) of div. W of Pub. L. 117–103, set out as a note under section 6851 of Title 15, Commerce and Trade.

IMPROVING AND STRENGTHENING THE SEXUAL ASSAULT EXAMINER WORKFORCE CLINICAL AND CONTINUING EDUCATION PILOT PROGRAM

Pub. L. 117–103, div. W, title V, §505, Mar. 15, 2022, 136 Stat. 876, provided that:

"(a) PURPOSE.—It is the purpose of this section to establish a pilot program to develop, test, and implement training and continuing education that expands and supports the availability of medical forensic examination services for survivors of sexual assault.

"(b) ESTABLISHMENT.—

"(1) IN GENERAL.—Not later than 1 year after the date of enactment of this Act [Mar. 15, 2022], the Secretary of Health and Human Services (referred to in this section as 'the Secretary') shall establish a National Continuing and Clinical Education Pilot Program for sexual assault forensic examiners, sexual assault nurse examiners, and other individuals who perform medical forensic examinations.

"(2) CONSULTATION.—In establishing such program, the Secretary shall consult with the Centers for Medicare & Medicaid Services, the Centers for Disease Control and Prevention, the Health Resources and Services Administration, the Indian Health Service, the Office for Victims of Crime of the Department of Justice, the Office on Violence Against Women of the Department of Justice, and the Office on Women's Health of the Department of Health and Human Services, and shall solicit input from regional, national, and Tribal organizations with expertise in forensic nursing, rape trauma or crisis counseling, investigating rape and gender violence cases, survivors' advocacy and support, sexual assault prevention education, rural health, and responding to sexual violence in Tribal communities.

"(c) FUNCTIONS.—The pilot program established under subsection (b) shall develop, pilot, implement, and update, as appropriate, continuing and clinical education program modules, webinars, and programs for all hospitals and providers to increase access to medical forensic examination services and address ongoing competency issues in medical forensic examination services, including—

"(1) training and continuing education to help support sexual assault forensic examiners practicing in rural or underserved areas;

"(2) training to help connect sexual assault survivors who are Indian with sexual assault forensic examiners, including through emergency first aid, referrals, culturally competent support, and forensic evidence collection in rural communities;

"(3) replication of successful sexual assault forensic examination programs to help develop and improve the evidence base for medical forensic examinations; and

"(4) training to increase the number of medical professionals who are considered sexual assault forensic examiners based on the recommendations of the National Sexual Assault Forensic Examination Training Standards issued by the Office on Violence Against Women of the Department of Justice.

"(d) ELIGIBILITY TO PARTICIPATE IN PILOT PROGRAMS.—The Secretary shall ensure that medical forensic examination services provided under the pilot program established under subsection (b), and other medical forensic examiner services under the pilot program are provided by health care providers who are also one of the following:

"(1) A physician, including a resident physician.

"(2) A nurse practitioner.

"(3) A nurse midwife.

"(4) A physician assistant.

"(5) A certified nurse specialist.

"(6) A registered nurse.

"(7) A community health practitioner or a community health aide who has completed level III or level IV certification and training requirements.

"(e) NATURE OF TRAINING.—The continuing education program established under this section shall incorporate and reflect current best practices and standards on medical forensic examination services consistent with the purpose of this section.

"(f) AVAILABILITY.—After termination of the pilot program established under subsection (b)(1), the training and continuing education program established under such program shall be available to all sexual assault forensic examiners and other providers employed by, or any individual providing services through, facilities that receive Federal funding.

"(g) EFFECTIVE DATE.—The pilot program established under this section shall terminate on the date that is 2 years after the date of such establishment.

"(h) AUTHORIZATION.—There are authorized to be appropriated to carry out this section $5,000,000 for each of fiscal years 2023 through 2025."

[For definition of terms used in section 505 of div. W of Pub. L. 117–103, set out above, see section 12291 of Title 34, Crime Control and Law Enforcement, as made applicable by section 2(b) of div. W of Pub. L. 117–103, which is set out as a note under section 12291 of Title 34].

DEFINITIONS

For definitions of terms used in this section, see section 12291 of Title 34, Crime Control and Law Enforcement, as made applicable by section 2(b) of div. W of Pub. L. 117–103, which is set out as a note under section 12291 of Title 34.

§280g–4c. Expanding access to forensics for victims of interpersonal violence

(a) Definitions

In this section:

(1) Community health aide; community health practitioner

The terms "community health aide" and "community health practitioner" have the meanings given such terms for purposes of section 1616l of title 25.

(2) Health care provider

The term "health care provider" has the meaning given such term by the Secretary, and includes registered nurses, nurse practitioners, nurse midwives, clinical nurse specialists, physician assistants, and physicians.

(3) Indian tribe; Tribal organization

The terms "Indian Tribe" and "Tribal organization" shall have the meanings given such terms in section 5304 of title 25.

(4) Institution of higher education

The term "institution of higher education" has the meaning given such term in section 1001 of title 20.

(5) Interpersonal violence

The term "interpersonal violence" means any form of violence that is emotional and trauma-inducing for victims, families of victims, perpetrators, and communities.

(6) Native Hawaiian organization

The term "Native Hawaiian organization" has the meaning given such term in section 11711 of this title.

(7) Secretary

The term "Secretary" means the Secretary of Health and Human Services.

(8) Trauma-informed care

The term "trauma-informed care" means care received by trauma survivors that is culturally competent in accordance with professional standards of practice and accounting for patients'

experiences and preferences in order to eliminate or mitigate triggers that may cause re-traumatization of the patient.

(9) Urban Indian organization

The term "Urban Indian organization" has the meaning given such term in section 1603 of title 25.

(b) Demonstration grants for comprehensive forensic training

(1) Establishment of program

The Secretary shall establish a demonstration program to award grants to eligible entities for the clinical training of health care providers to provide generalist forensic services and trauma-informed care to survivors of interpersonal violence of all ages.

(2) Purpose

The purpose of the demonstration program under this subsection is to develop training and curriculum to provide health care providers with the skills to support the provision of forensic assessment and trauma-informed care to individuals, families, and communities that have experienced violence or trauma and to be available to collaborate with members of an inter-professional forensic team.

(3) Term

Grants under this subsection shall be for a term of 5 years.

(4) Eligible entities

To be eligible to receive a grant under this subsection, an entity shall—

(A) be an institute of higher education, including a minority serving institution as described in section 1067q of title 20; and

(B) submit to the Secretary an application at such time, in such manner, and containing such information as the Secretary may require.

(5) Grant amount

Each grant awarded under this subsection shall be in an amount that does not exceed $400,000 per year. A grant recipient may carry over funds from one fiscal year to the next without obtaining approval from the Secretary.

(6) Authorization of appropriations

(A) In general

There is authorized to be appropriated to carry out this subsection $5,000,000 for each of fiscal years 2023 through 2027.

(B) Set-aside

Of the amount appropriated under this paragraph for a fiscal year, the Secretary shall reserve 10 percent for purposes of making grants to support training and curricula that addresses the unique needs of Indian Tribes, Tribal organizations, Urban Indian organizations, and Native Hawaiian organizations. Amounts so reserved may be used to support training, referrals, and the delivery of emergency first aid, culturally competent support, and forensic evidence collection training.

(c) Technical assistance grants and learning collectives

(1) In general

The Secretary shall establish a State and Tribal forensic provider technical resource center to provide technical assistance and support collaboration and best practices for health care providers, community health aides, and community health practitioners to improve the quality of, and increase access to, forensic services for all survivors of interpersonal violence. The Secretary may enter into contracts with national experts for purposes of carrying out this subsection.

(2) Authorization of appropriations

There is authorized to be appropriated to carry out this subsection, $2,000,000 for each of fiscal years 2023 through 2027.

(d) National report

Not later than 1 year after March 15, 2022, and annually thereafter, the Office for Victims of Crime of the Department of Justice, the Centers for Disease Control and Prevention, the Health Resources and Services Administration, the Indian Health Service, the Office on Women's Health of the Department of Health and Human Services, and the Office on Violence Against Women of the Department of Justice shall jointly submit to the Secretary a report on the need for, throughout the States, Indian Tribes, and territories—

(1) access to generalist medical forensic services, evidence collection, and documentation that aids in meeting the needs of health care patients and improves future law enforcement investigation and prosecution; and

(2) data for research to support the response to and prevention of interpersonal violence, improved ability of health care providers to adequately respond to patients who exhibit signs of victimization, and address the unique needs of Tribal communities.

(Pub. L. 117–103, div. W, title V, §507, Mar. 15, 2022, 136 Stat. 879.)

EDITORIAL NOTES

CODIFICATION

Section was enacted as part of the Violence Against Women Act Reauthorization Act of 2022, and also as part of the Consolidated Appropriations Act, 2022, and not as part of the Public Health Service Act which comprises this chapter.

STATUTORY NOTES AND RELATED SUBSIDIARIES

EFFECTIVE DATE

Section not effective until Oct. 1 of the first fiscal year beginning after Mar. 15, 2022, see section 4(a) of div. W of Pub. L. 117–103, set out as a note under section 6851 of Title 15, Commerce and Trade.

DEFINITIONS

For definition of "law enforcement" and "State" as used in this section, see section 12291 of Title 34, Crime Control and Law Enforcement, as made applicable by section 2(b) of div. W of Pub. L. 117–103, which is set out as a note under section 12291 of Title 34.

§280g–5. Public and health care provider education and support services

(a) In general

The Secretary, directly or through the awarding of grants to public or private nonprofit entities, may conduct activities, which may include demonstration projects for the purpose of improving the provision of information on prematurity to health professionals and other health care providers and the public and improving the treatment and outcomes mothers [1] of infants born preterm, and infants born preterm, as appropriate.

(b) Activities

Activities to be carried out under subsection (a) may include the establishment of—

(1) programs, including those to test and evaluate strategies, which, in collaboration with States, localities, tribes, and community organizations, support the provision of information and education to health professionals, other health care providers, and the public concerning—

(A) the core risk factors for preterm labor and delivery;

(B) evidence-based strategies to prevent preterm birth and associated outcomes;

(C) medically indicated deliveries before full term, and the risks of non-medically indicated deliveries before full term;

(D) the importance of preconception and prenatal care, including—

(i) smoking cessation;

(ii) weight maintenance and good nutrition, including folic acid intake;

(iii) the screening for and the treatment of infections;

(iv) screening for and treatment of substance use disorders;

(v) screening for and treatment of maternal depression;

(vi) maternal immunization; and

(vii) stress management;

(E) treatments and outcomes for premature infants, including late preterm infants; and

(F) the informational needs of families during the stay of an infant in a neonatal intensive care unit.

(2) programs to increase the availability, awareness, and use of pregnancy and post-term information services that provide evidence-based, clinical information through counselors, community outreach efforts, electronic or telephonic communication, or other appropriate means regarding causes associated with prematurity, birth defects, or health risks to a post-term infant, as well as prevention of a future preterm birth;

(3) programs to respond to the informational needs of families during the stay of an infant in a neonatal intensive care unit, during the transition of the infant to the home, and in the event of a newborn death; and

(4) such other programs as the Secretary determines appropriate to achieve the purpose specified in subsection (a).

(c) Authorization of appropriations

There is authorized to be appropriated to carry out this section $1,900,000 for each of fiscal years 2014 through 2018.

(July 1, 1944, ch. 373, title III, §399Q, as added Pub. L. 109–450, §4(2), Dec. 22, 2006, 120 Stat. 3342; amended Pub. L. 113–55, title I, §103(b), Nov. 27, 2013, 127 Stat. 642; Pub. L. 115–328, §3, Dec. 18, 2018, 132 Stat. 4472.)

EDITORIAL NOTES

AMENDMENTS

2018—Subsec. (a). Pub. L. 115–328, §3(1), substituted "conduct activities, which may include demonstration projects" for "conduct demonstration projects" and "mothers of infants born preterm, and infants born preterm, as appropriate" for "for babies born preterm".

Subsec. (b). Pub. L. 115–328, §3(2)(A), struck out "under the demonstration project" after "to be carried out" in introductory provisions.

Subsec. (b)(1). Pub. L. 115–328, §3(2)(B)(i), substituted "programs, including those to test and evaluate strategies, which, in collaboration with States, localities, tribes, and community organizations, support the provision of" for "programs to test and evaluate various strategies to provide" in introductory provisions.

Subsec. (b)(1)(B). Pub. L. 115–328, §3(2)(B)(iii), added subpar. (B). Former subpar. (B) redesignated (C).

Subsec. (b)(1)(C). Pub. L. 115–328, §3(2)(B)(ii), (iv), redesignated subpar. (B) as (C) and inserted ", and the risks of non-medically indicated deliveries before full term" before semicolon at end. Former subpar. (C) redesignated (D).

Subsec. (b)(1)(D). Pub. L. 115–328, §3(2)(B)(ii), redesignated subpar. (C) as (D). Former subpar. (D) redesignated (E).

Subsec. (b)(1)(D)(ii). Pub. L. 115–328, §3(2)(B)(v)(I), inserted "intake" after "folic acid".

Subsec. (b)(1)(D)(iv) to (vii). Pub. L. 115–328, §3(2)(B)(v)(II)–(IV), added cls. (iv) to (vi) and redesignated former cl. (iv) as (vii).

Subsec. (b)(1)(E) to (G). Pub. L. 115–328, §3(2)(B)(ii), (vi)–(viii), redesignated subpars. (D) to (F) as (E) to (G), respectively, and struck out subpar. (G), as redesignated, which read as follows: "utilization of

evidence-based strategies to prevent birth injuries;".

Subsec. (b)(2). Pub. L. 115–328, §3(2)(C), inserted ", as well as prevention of a future preterm birth" before semicolon at end.

2013—Subsec. (b)(1). Pub. L. 113–55, §103(b)(1)(A), added subpars. (A) to (F) and struck out former subpars. (A) to (F) which read as follows:

"(A) the signs of preterm labor, updated as new research results become available;

"(B) the screening for and the treating of infections;

"(c) counseling on optimal weight and good nutrition, including folic acid;

"(D) smoking cessation education and counseling;

"(E) stress management; and

"(F) appropriate prenatal care;".

Subsec. (b)(2). Pub. L. 113–55, §103(b)(1)(B), added par. (2) and struck out former par. (2) which read as follows: "programs to improve the treatment and outcomes for babies born premature, including the use of evidence-based standards of care by health care professionals for pregnant women at risk of preterm labor or other serious complications and for infants born preterm and at a low birthweight;".

Subsec. (c). Pub. L. 113–55, §103(b)(2), substituted "$1,900,000 for each of fiscal years 2014 through 2018." for "$5,000,000 for each of fiscal years 2007 through 2011."

[1] *So in original. Probably should be preceded by "for".*

§280g–6. Chronic kidney disease initiatives

(a) In general

The Secretary shall establish pilot projects to—

(1) increase public and medical community awareness (particularly of those who treat patients with diabetes and hypertension) regarding chronic kidney disease, focusing on prevention;

(2) increase screening for chronic kidney disease, focusing on Medicare beneficiaries at risk of chronic kidney disease; and

(3) enhance surveillance systems to better assess the prevalence and incidence of chronic kidney disease.

(b) Scope and duration

(1) Scope

The Secretary shall select at least 3 States in which to conduct pilot projects under this section.

(2) Duration

The pilot projects under this section shall be conducted for a period that is not longer than 5 years and shall begin on January 1, 2009.

(c) Evaluation and report

The Comptroller General of the United States shall conduct an evaluation of the pilot projects conducted under this section. Not later than 12 months after the date on which the pilot projects are completed, the Comptroller General shall submit to Congress a report on the evaluation.

(d) Authorization of appropriations

There are authorized to be appropriated such sums as may be necessary for the purpose of carrying out this section.

(July 1, 1944, ch. 373, title III, §399R, as added Pub. L. 110–275, title I, §152(a), July 15, 2008, 122 Stat. 2551.)

EDITORIAL NOTES

CODIFICATION

Another section 399R of act July 1, 1944, ch. 373, as added by Pub. L. 110–373, §2, Oct. 8, 2008, 122 Stat.

4047, was renumbered section 399S and is classified to section 280g–7 of this title.

Another section 399R of act July 1, 1944, ch. 373, as added by Pub. L. 110–374, §3, Oct. 8, 2008, 122 Stat. 4051, was renumbered section 399T and is classified to section 280g–8 of this title.

EXECUTIVE DOCUMENTS

EX. ORD. NO. 13879. ADVANCING AMERICAN KIDNEY HEALTH

Ex. Ord. No. 13879, July 10, 2019, 84 F.R. 33817, provided:

By the authority vested in me as President by the Constitution and the laws of the United States of America, it is hereby ordered as follows:

SECTION 1. *Purpose*. My Administration is dedicated to advancing American kidney health. The state of care for patients with chronic kidney disease and end-stage renal disease (ESRD) is unacceptable: too many at-risk patients progress to late-stage kidney failure; the mortality rate is too high; current treatment options are expensive and do not produce an acceptable quality of life; and there are not enough kidneys donated to meet the current demand for transplants.

Kidney disease was the ninth-leading cause of death in the United States in 2017. Approximately 37 million Americans have chronic kidney disease and more than 726,000 have ESRD. More than 100,000 Americans begin dialysis each year to treat ESRD. Twenty percent die within a year; fifty percent die within 5 years. Currently, nearly 100,000 Americans are on the waiting list to receive a kidney transplant.

SEC. 2. *Policy*. It is the policy of the United States to:

(a) prevent kidney failure whenever possible through better diagnosis, treatment, and incentives for preventive care;

(b) increase patient choice through affordable alternative treatments for ESRD by encouraging higher value care, educating patients on treatment alternatives, and encouraging the development of artificial kidneys; and

(c) increase access to kidney transplants by modernizing the organ recovery and transplantation systems and updating outmoded and counterproductive regulations.

SEC. 3. *Announcing an Awareness Initiative on Kidney and Related Diseases*. Within 120 days of the date of this order [July 10, 2019], the Secretary of Health and Human Services (Secretary) shall launch an awareness initiative at the Department of Health and Human Services (Department) to aid the Secretary's efforts to educate patients and support programs that promote kidney disease awareness. The initiative shall develop proposals for the Secretary to support research regarding preventing, treating, and slowing progression of kidney disease; to improve kidney transplantation; and to share information with patients and providers to enhance awareness of the causes and consequences of kidney disease.

SEC. 4. *Payment Model to Identify and Treat At-Risk Populations Earlier in Disease Development*. Within 30 days of the date of this order, the Secretary shall select a payment model to test innovations in compensation for providers of kidney care services based on kidney patient cost and quality outcomes. The model should broaden the range of care and Medicare payment options available to potential participants with a focus on delaying or preventing the onset of kidney failure, preventing unnecessary hospitalizations, and increasing the rate of transplants. It should aim at achieving these outcomes by creating incentives to provide care for Medicare beneficiaries who have advanced stages of kidney disease but who are not yet on dialysis. The selected model shall include options for flexible advance payments for nephrologists to better support their management and coordination of care for patients with kidney disease.

SEC. 5. *Payment Model to Increase Home Dialysis and Kidney Transplants*. Within 30 days of the date of this order, the Secretary shall select a payment model to evaluate the effects of creating payment incentives for greater use of home dialysis and kidney transplants for Medicare beneficiaries on dialysis. The model should adjust payments based on the percentage of a participating provider's attributed patients who either are on home dialysis or have received a kidney transplant and should include a learning system to help participants improve performance. Greater rates of home dialysis and transplantation will improve quality of life and care for patients who require dialysis and may eliminate the need for dialysis altogether for many patients.

SEC. 6. *Encouraging the Development of an Artificial Kidney*. Within 120 days of the date of this order, in order to increase breakthrough technologies to provide patients suffering from kidney disease with better options for care than those that are currently available, the Secretary shall:

(a) announce that the Department will consider requests for premarket approval of wearable or implantable artificial kidneys in order to encourage their development and to enhance cooperation between developers and the Food and Drug Administration; and

(b) produce a strategy for encouraging innovation in new therapies through the Kidney Innovation Accelerator (KidneyX), a public-private partnership between the Department and the American Society of Nephrology.

SEC. 7. *Increasing Utilization of Available Organs*. (a) Within 90 days of the date of this order, the Secretary shall propose a regulation to enhance the procurement and utilization of organs available through deceased donation by revising Organ Procurement Organization (OPO) rules and evaluation metrics to establish more transparent, reliable, and enforceable objective metrics for evaluating an OPO's performance.

(b) Within 180 days of the date of this order, the Secretary shall streamline and expedite the process of kidney matching and delivery to reduce the discard rate. Removing process inefficiencies in matching and delivery that result in delayed acceptance by transplant centers will reduce the detrimental effects on organ quality of prolonged time with reduced or cut-off blood supply.

SEC. 8. *Supporting Living Organ Donors*. Within 90 days of the date of this order, the Secretary shall propose a regulation to remove financial barriers to living organ donation. The regulation should expand the definition of allowable costs that can be reimbursed under the Reimbursement of Travel and Subsistence Expenses Incurred Toward Living Organ Donation program, raise the limit on the income of donors eligible for reimbursement under the program, allow reimbursement for lost-wage expenses, and provide for reimbursement of child-care and elder-care expenses.

SEC. 9. *General Provisions*. (a) Nothing in this order shall be construed to impair or otherwise affect:

(i) the authority granted by law to an executive department or agency, or the head thereof; or

(ii) the functions of the Director of the Office of Management and Budget relating to budgetary, administrative, or legislative proposals.

(b) This order shall be implemented consistent with applicable law and subject to the availability of appropriations.

(c) This order is not intended to, and does not, create any right or benefit, substantive or procedural, enforceable at law or in equity by any party against the United States, its departments, agencies, or entities, its officers, employees, or agents, or any other person.

DONALD J. TRUMP.

§280g–7. Amyotrophic lateral sclerosis registry

(a) Establishment

(1) In general

Not later than 1 year after the receipt of the report described in subsection (b)(2)(A), the Secretary, acting through the Director of the Centers for Disease Control and Prevention, may, if scientifically advisable—

(A) develop a system to collect data on amyotrophic lateral sclerosis (referred to in this section as "ALS") and other motor neuron disorders that can be confused with ALS, misdiagnosed as ALS, and in some cases progress to ALS, including information with respect to the incidence and prevalence of the disease in the United States; and

(B) establish a national registry for the collection and storage of such data to develop a population-based registry of cases in the United States of ALS and other motor neuron disorders that can be confused with ALS, misdiagnosed as ALS, and in some cases progress to ALS.

(2) Purpose

It is the purpose of the registry established under paragraph (1)(B) to—

(A) better describe the incidence and prevalence of ALS in the United States;

(B) examine appropriate factors, such as environmental and occupational, that may be associated with the disease;

(C) better outline key demographic factors (such as age, race or ethnicity, gender, and family history of individuals who are diagnosed with the disease) associated with the disease;

(D) better examine the connection between ALS and other motor neuron disorders that can be confused with ALS, misdiagnosed as ALS, and in some cases progress to ALS; and

(E) other matters as recommended by the Advisory Committee established under subsection (b).

(b) Advisory Committee

(1) Establishment

Not later than 180 days after October 8, 2008, the Secretary, acting through the Director of the Centers for Disease Control and Prevention, may establish a committee to be known as the Advisory Committee on the National ALS Registry (referred to in this section as the "Advisory Committee"). The Advisory Committee shall be composed of not more than 27 members to be appointed by the Secretary, acting through the Centers for Disease Control and Prevention, of which—

(A) two-thirds of such members shall represent governmental agencies—

(i) including at least one member representing—

(I) the National Institutes of Health, to include, upon the recommendation of the Director of the National Institutes of Health, representatives from the National Institute of Neurological Disorders and Stroke and the National Institute of Environmental Health Sciences;

(II) the Department of Veterans Affairs;

(III) the Agency for Toxic Substances and Disease Registry; and

(IV) the Centers for Disease Control and Prevention; and

(ii) of which at least one such member shall be a clinician with expertise on ALS and related diseases, an epidemiologist with experience in data registries, a statistician, an ethicist, and a privacy expert (relating to the privacy regulations under the Health Insurance Portability and Accountability Act of 1996); and

(B) one-third of such members shall be public members, including at least one member representing—

(i) national and voluntary health associations; [1]

(ii) patients with ALS or their family members;

(iii) clinicians with expertise on ALS and related diseases;

(iv) epidemiologists with experience in data registries;

(v) geneticists or experts in genetics who have experience with the genetics of ALS or other neurological diseases [2] and

(vi) other individuals with an interest in developing and maintaining the National ALS Registry.

(2) Duties

The Advisory Committee may review information and make recommendations to the Secretary concerning—

(A) the development and maintenance of the National ALS Registry;

(B) the type of information to be collected and stored in the Registry;

(C) the manner in which such data is to be collected;

(D) the use and availability of such data including guidelines for such use; and

(E) the collection of information about diseases and disorders that primarily affect motor neurons that are considered essential to furthering the study and cure of ALS.

(3) Report

Not later than 270 days after the date on which the Advisory Committee is established, the Advisory Committee may submit a report to the Secretary concerning the review conducted under paragraph (2) that contains the recommendations of the Advisory Committee with respect to the results of such review.

(c) Grants

The Secretary, acting through the Director of the Centers for Disease Control and Prevention, may award grants to, and enter into contracts and cooperative agreements with, public or private nonprofit entities for the collection, analysis, and reporting of data on ALS and other motor neuron disorders that can be confused with ALS, misdiagnosed as ALS, and in some cases progress to ALS after receiving the report under subsection (b)(3).

(d) Coordination with State, local, and Federal registries

(1) [3] In general

In establishing the National ALS Registry under subsection (a), the Secretary, acting through the Director of the Centers for Disease Control and Prevention, may—

(A) identify, build upon, expand, and coordinate among existing data and surveillance systems, surveys, registries, and other Federal public health and environmental infrastructure wherever possible, which may include—

(i) any registry pilot projects previously supported by the Centers for Disease Control and Prevention;

(ii) the Department of Veterans Affairs ALS Registry;

(iii) the DNA and Cell Line Repository of the National Institute of Neurological Disorders and Stroke Human Genetics Resource Center at the National Institutes of Health;

(iv) Agency for Toxic Substances and Disease Registry studies, including studies conducted in Illinois, Missouri, El Paso and San Antonio, Texas, and Massachusetts;

(v) State-based ALS registries;

(vi) the National Vital Statistics System; and

(vii) any other existing or relevant databases that collect or maintain information on those motor neuron diseases recommended by the Advisory Committee established in subsection (b); and

(B) provide for research access to ALS data as recommended by the Advisory Committee established in subsection (b) to the extent permitted by applicable statutes and regulations and in a manner that protects personal privacy consistent with applicable privacy statutes and regulations.

(C) COORDINATION WITH NIH AND DEPARTMENT OF VETERANS AFFAIRS .—Consistent with applicable privacy statutes and regulations, the Secretary may ensure that epidemiological and other types of information obtained under subsection (a) is made available to the National Institutes of Health and the Department of Veterans Affairs.

(e) Definition

For the purposes of this section, the term "national voluntary health association" means a national non-profit organization with chapters or other affiliated organizations in States throughout the United States with experience serving the population of individuals with ALS and have demonstrated experience in ALS research, care, and patient services.

(July 1, 1944, ch. 373, title III, §399S, formerly §399R, as added Pub. L. 110–373, §2, Oct. 8, 2008, 122 Stat. 4047; renumbered §399S, Pub. L. 111–148, title IV, §4003(b)(2)(A), Mar. 23, 2010, 124 Stat. 544.)

EDITORIAL NOTES

REFERENCES IN TEXT

The Health Insurance Portability and Accountability Act of 1996, referred to in subsec. (b)(1)(A)(ii), is Pub. L. 104–191, Aug. 21, 1996, 110 Stat. 1936. For complete classification of this Act to the Code, see Short Title of 1996 Amendments note set out under section 201 of this title and Tables.

[1] So in original. Probably should be "national voluntary health associations;".

[2] So in original. Probably should be followed by a semicolon.

[3] So in original. No par. (2) has been enacted.

§280g–7a. Surveillance of neurological diseases

(a) In general

The Secretary, acting through the Director of the Centers for Disease Control and Prevention and in coordination with other agencies as the Secretary determines, shall, as appropriate—

(1) enhance and expand infrastructure and activities to track the epidemiology of neurological diseases; and

(2) incorporate information obtained through such activities into an integrated surveillance system, which may consist of or include a registry, to be known as the National Neurological Conditions Surveillance System.

(b) Research

The Secretary shall ensure that the National Neurological Conditions Surveillance System is designed in a manner that facilitates further research on neurological diseases.

(c) Content

In carrying out subsection (a), the Secretary—

(1) shall provide for the collection and storage of information on the incidence and prevalence of neurological diseases in the United States;

(2) to the extent practicable, shall provide for the collection and storage of other available information on neurological diseases, including information related to persons living with neurological diseases who choose to participate, such as—

(A) demographics, such as age, race, ethnicity, sex, geographic location, family history, and other information, as appropriate;

(B) risk factors that may be associated with neurological diseases, such as genetic and environmental risk factors and other information, as appropriate; and

(C) diagnosis and progression markers;

(3) may provide for the collection and storage of information relevant to analysis on neurological diseases, such as information concerning—

(A) the natural history of the diseases;

(B) the prevention of the diseases;

(C) the detection, management, and treatment approaches for the diseases; and

(D) the development of outcomes measures;

(4) may address issues identified during the consultation process under subsection (d); and

(5) initially may address a limited number of neurological diseases.

(d) Consultation

In carrying out this section, the Secretary shall consult with individuals with appropriate expertise, which may include—

(1) epidemiologists with experience in disease surveillance or registries;

(2) representatives of national voluntary health associations that—

(A) focus on neurological diseases; and

(B) have demonstrated experience in research, care, or patient services;

(3) health information technology experts or other information management specialists;

(4) clinicians with expertise in neurological diseases; and

(5) research scientists with experience conducting translational research or utilizing surveillance systems for scientific research purposes.

(e) Grants

The Secretary may award grants to, or enter into contracts or cooperative agreements with, public or private nonprofit entities to carry out activities under this section.

(f) Coordination with other Federal, State, and local agencies

Subject to subsection (h), the Secretary shall—

(1) make information and analysis in the National Neurological Conditions Surveillance System available, as appropriate—

(A) to Federal departments and agencies, such as the National Institutes of Health and the Department of Veterans Affairs; and

(B) to State and local agencies; and

(2) identify, build upon, leverage, and coordinate among existing data and surveillance systems, surveys, registries, and other Federal public health infrastructure, wherever practicable.

(g) Public access

Subject to subsection (h), the Secretary shall ensure that information and analysis in the National Neurological Conditions Surveillance System are available, as appropriate, to the public, including researchers.

(h) Privacy

The Secretary shall ensure that information and analysis in the National Neurological Conditions Surveillance System are made available only to the extent permitted by applicable Federal and State law, and in a manner that protects personal privacy, to the extent required by applicable Federal and State privacy law, at a minimum.

(i) Reports

(1) Report on information and analyses

Not later than 1 year after the date on which any system is established under this section, the Secretary shall submit an interim report to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives regarding aggregate information collected pursuant to this section and epidemiological analyses, as appropriate. Such report shall be posted on the Internet website of the Department of Health and Human Services and shall be updated biennially.

(2) Implementation report

Not later than 4 years after December 13, 2016, the Secretary shall submit a report to the Congress concerning the implementation of this section. Such report shall include information on—

(A) the development and maintenance of the National Neurological Conditions Surveillance System;

(B) the type of information collected and stored in the surveillance system;

(C) the use and availability of such information, including guidelines for such use; and

(D) the use and coordination of databases that collect or maintain information on neurological diseases.

(j) Definition

In this section, the term "national voluntary health association" means a national nonprofit organization with chapters, other affiliated organizations, or networks in States throughout the United States with experience serving the population of individuals with neurological disease and have demonstrated experience in neurological disease research, care, and patient services.

(k) Authorization of appropriations

To carry out this section, there is authorized to be appropriated $5,000,000 for each of fiscal years 2018 through 2022.

(July 1, 1944, ch. 373, title III, §399S–1, as added Pub. L. 114–255, div. A, title II, §2061, Dec. 13, 2016, 130 Stat. 1076.)

§280g–7b. HHS public-private partnership for rare neurodegenerative diseases

(a) Establishment

Not later than one year after December 23, 2021, the Secretary of Health and Human Services (referred to in this section as the "Secretary") shall establish and implement a Public-Private Partnership for Neurodegenerative Diseases between the National Institutes of Health, the Food and Drug Administration, and one or more eligible entities (to be known and referred to in this section as the "Partnership") through cooperative agreements, contracts, or other appropriate mechanisms with such eligible entities, for the purpose of advancing the understanding of neurodegenerative diseases and fostering the development of treatments for amytrophic lateral sclerosis and other rare neurodegenerative diseases. The Partnership shall—

(1) establish partnerships and consortia with other public and private entities and individuals with expertise in amyotrophic lateral sclerosis and other rare neurodegenerative diseases for the purposes described in this subsection;

(2) focus on advancing regulatory science and scientific research that will support and accelerate the development and review of drugs for patients with amyotrophic lateral sclerosis and other rare neurodegenerative diseases; and

(3) foster the development of effective drugs that improve the lives of people that suffer from amyotrophic lateral sclerosis and other rare neurodegenerative diseases.

(b) Eligible entity

In this section, the term "eligible entity" means an entity that—

(1) is—

(A) an institution of higher education (as such term is defined in section 1001 [1] of title 20) or a consortium of such institutions; or

(B) an organization described in section 501(c)(3) of title 26 and exempt from tax under subsection (a) of such section;

(2) has experienced personnel with clinical and other technical expertise in the field of biomedical sciences and demonstrated connection to the patient population;

(3) demonstrates to the Secretary's satisfaction that the entity is capable of identifying and establishing collaborations between public and private entities and individuals with expertise in neurodegenerative diseases, including patients, in order to facilitate—

(A) development and critical evaluation of tools, methods, and processes—

(i) to characterize neurodegenerative diseases and their natural history;

(ii) to identify molecular targets for neurodegenerative diseases; and

(iii) to increase efficiency, predictability, and productivity of clinical development of therapies, including advancement of rational therapeutic development and establishment of clinical trial networks; and

(B) securing funding for the Partnership from Federal and non-Federal governmental sources, foundations, and private individuals; and

(4) provides an assurance that the entity will not accept funding for a Partnership project from any organization that manufactures or distributes products regulated by the Food and Drug Administration unless the entity provides assurances in its agreement with the Secretary that the results of the project will not be influenced by any source of funding.

(c) Gifts

(1) In general

The Partnership may solicit and accept gifts, grants, and other donations, establish accounts, and invest and expend funds in support of basic research and research associated with phase 3 clinical trials conducted with respect to investigational drugs that are the subjects of expanded access requests under section 360bbb of title 21.

(2) Use

In addition to any amounts appropriated for purposes of carrying out this section, the Partnership may use, without further appropriation, any funds derived from a gift, grant, or other donation accepted pursuant to paragraph (1).

(Pub. L. 117–79, §3, Dec. 23, 2021, 135 Stat. 1535.)

EDITORIAL NOTES

REFERENCES IN TEXT

Section 1001 of title 20, referred to in subsec. (b)(1)(A), was in the original "section 1001 of the Higher Education Act of 1965" and was translated as if it had read "section 101 of the Higher Education Act of 1965" to reflect the probable intent of Congress. Section 101 of the Higher Education Act of 1965 is classified to section 1001 of Title 20, Education, and defines "institution of higher education".

CODIFICATION

Section was enacted as part of the Accelerating Access to Critical Therapies for ALS Act, and not as part of the Public Health Service Act which comprises this chapter.

[1] *See References in Text note below.*

§280g–8. Support for patients receiving a positive diagnosis of Down syndrome or other prenatally or postnatally diagnosed conditions

(a) Definitions

In this section:

(1) Down syndrome

The term "Down syndrome" refers to a chromosomal disorder caused by an error in cell division that results in the presence of an extra whole or partial copy of chromosome 21.

(2) Health care provider

The term "health care provider" means any person or entity required by State or Federal law or regulation to be licensed, registered, or certified to provide health care services, and who is so licensed, registered, or certified.

(3) Postnatally diagnosed condition

The term "postnatally diagnosed condition" means any health condition identified during the 12-month period beginning at birth.

(4) Prenatally diagnosed condition

The term "prenatally diagnosed condition" means any fetal health condition identified by prenatal genetic testing or prenatal screening procedures.

(5) Prenatal test

The term "prenatal test" means diagnostic or screening tests offered to pregnant women seeking routine prenatal care that are administered on a required or recommended basis by a health care provider based on medical history, family background, ethnic background, previous test results, or other risk factors.

(b) Information and support services

(1) In general

The Secretary, acting through the Director of the National Institutes of Health, the Director of the Centers for Disease Control and Prevention, or the Administrator of the Health Resources and Services Administration, may authorize and oversee certain activities, including the awarding of grants, contracts or cooperative agreements to eligible entities, to—

(A) collect, synthesize, and disseminate current evidence-based information relating to Down syndrome or other prenatally or postnatally diagnosed conditions; and

(B) coordinate the provision of, and access to, new or existing supportive services for patients receiving a positive diagnosis for Down syndrome or other prenatally or postnatally diagnosed conditions, including—

(i) the establishment of a resource telephone hotline accessible to patients receiving a positive test result or to the parents of newly diagnosed infants with Down syndrome and other diagnosed conditions;

(ii) the expansion and further development of the National Dissemination Center for Children with Disabilities, so that such Center can more effectively conduct outreach to new and expecting parents and provide them with up-to-date information on the range of outcomes for individuals living with the diagnosed condition, including physical, developmental, educational, and psychosocial outcomes;

(iii) the expansion and further development of national and local peer-support programs, so that such programs can more effectively serve women who receive a positive diagnosis for Down syndrome or other prenatal conditions or parents of infants with a postnatally diagnosed condition;

(iv) the establishment of a national registry, or network of local registries, of families willing to adopt newborns with Down syndrome or other prenatally or postnatally diagnosed conditions, and links to adoption agencies willing to place babies with Down syndrome or other prenatally or postnatally diagnosed conditions, with families willing to adopt; and

(v) the establishment of awareness and education programs for health care providers who provide, interpret, or inform parents of the results of prenatal tests for Down syndrome or other prenatally or postnatally diagnosed conditions, to patients, consistent with the purpose described in section 2(b)(1) [1] of the Prenatally and Postnatally Diagnosed Conditions Awareness Act.

(2) Eligible entity

In this subsection, the term "eligible entity" means—

(A) a State or a political subdivision of a State;

(B) a consortium of 2 or more States or political subdivisions of States;

(C) a territory;

(D) a health facility or program operated by or pursuant to a contract with or grant from the Indian Health Service; or

(E) any other entity with appropriate expertise in prenatally and postnatally diagnosed conditions (including nationally recognized disability groups), as determined by the Secretary.

(3) Distribution

In distributing funds under this subsection, the Secretary shall place an emphasis on funding partnerships between health care professional groups and disability advocacy organizations.

(c) Provision of information to providers

(1) In general

A grantee under this section shall make available to health care providers of parents who receive a prenatal or postnatal diagnosis the following:

(A) Up-to-date, evidence-based, written information concerning the range of outcomes for individuals living with the diagnosed condition, including physical, developmental, educational, and psychosocial outcomes.

(B) Contact information regarding support services, including information hotlines specific to Down syndrome or other prenatally or postnatally diagnosed conditions, resource centers or clearinghouses, national and local peer support groups, and other education and support programs as described in subsection (b)(2).

(2) Informational requirements

Information provided under this subsection shall be—

(A) culturally and linguistically appropriate as needed by women receiving a positive prenatal diagnosis or the family of infants receiving a postnatal diagnosis; and

(B) approved by the Secretary.

(d) Report

Not later than 2 years after October 8, 2008, the Government Accountability Office shall submit a report to Congress concerning the effectiveness of current healthcare and family support programs serving as resources for the families of children with disabilities.

(July 1, 1944, ch. 373, title III, §399T, formerly §399R, as added Pub. L. 110–374, §3, Oct. 8, 2008, 122 Stat. 4051; renumbered §399T, Pub. L. 111–148, title IV, §4003(b)(2)(B), Mar. 23, 2010, 124 Stat. 544.)

EDITORIAL NOTES

REFERENCES IN TEXT

Section 2(b)(1) of the Prenatally and Postnatally Diagnosed Conditions Awareness Act, referred to in subsec. (b)(1)(B)(v), probably means section 2(1) of that Act, Pub. L. 110–374, which is set out as a note under this section.

STATUTORY NOTES AND RELATED SUBSIDIARIES

PURPOSES

Pub. L. 110–374, §2, Oct. 8, 2008, 122 Stat. 4051, provided that: "It is the purpose of this Act [enacting this section and provisions set out as a note under section 201 of this title] to—

"(1) increase patient referrals to providers of key support services for women who have received a positive diagnosis for Down syndrome, or other prenatally or postnatally diagnosed conditions, as well as to provide up-to-date information on the range of outcomes for individuals living with the diagnosed condition, including physical, developmental, educational, and psychosocial outcomes;

"(2) strengthen existing networks of support through the Centers for Disease Control and Prevention, the Health Resources and Services Administration, and other patient and provider outreach programs; and

"(3) ensure that patients receive up-to-date, evidence-based information about the accuracy of the test."

[1] *See References in Text note below.*

§280g–9. Programs to improve quality of life for persons with paralysis and other physical disabilities

(a) In general

The Secretary of Health and Human Services (in this section referred to as the "Secretary") may study the unique health challenges associated with paralysis and other physical disabilities and carry out projects and interventions to improve the quality of life and long-term health status of persons with paralysis and other physical disabilities. The Secretary may carry out such projects directly and through awards of grants or contracts.

(b) Certain activities

Activities under subsection (a) may include—

(1) the development of a national paralysis and physical disability quality of life action plan, to promote health and wellness in order to enhance full participation, independent living, self-sufficiency, and equality of opportunity in partnership with voluntary health agencies focused on paralysis and other physical disabilities, to be carried out in coordination with the State-based Disability and Health Program of the Centers for Disease Control and Prevention;

(2) support for programs to disseminate information involving care and rehabilitation options

and quality of life grant programs supportive of community-based programs and support systems for persons with paralysis and other physical disabilities;

(3) in collaboration with other centers and national voluntary health agencies, the establishment of a population-based database that may be used for longitudinal and other research on paralysis and other disabling conditions; and

(4) the replication and translation of best practices and the sharing of information across States, as well as the development of comprehensive, unique, and innovative programs, services, and demonstrations within existing State-based disability and health programs of the Centers for Disease Control and Prevention which are designed to support and advance quality of life programs for persons living with paralysis and other physical disabilities focusing on—

(A) caregiver education;

(B) promoting proper nutrition, increasing physical activity, and reducing tobacco use;

(C) education and awareness programs for health care providers;

(D) prevention of secondary complications;

(E) home- and community-based interventions;

(F) coordinating services and removing barriers that prevent full participation and integration into the community; and

(G) recognizing the unique needs of underserved populations.

(c) Grants

The Secretary may award grants in accordance with the following:

(1) To State and local health and disability agencies for the purpose of—

(A) establishing a population-based database that may be used for longitudinal and other research on paralysis and other disabling conditions;

(B) developing comprehensive paralysis and other physical disability action plans and activities focused on the items listed in subsection (b)(4);

(C) assisting State-based programs in establishing and implementing partnerships and collaborations that maximize the input and support of people with paralysis and other physical disabilities and their constituent organizations;

(D) coordinating paralysis and physical disability activities with existing State-based disability and health programs;

(E) providing education and training opportunities and programs for health professionals and allied caregivers; and

(F) developing, testing, evaluating, and replicating effective intervention programs to maintain or improve health and quality of life.

(2) To private health and disability organizations for the purpose of—

(A) disseminating information to the public;

(B) improving access to services for persons living with paralysis and other physical disabilities and their caregivers;

(C) testing model intervention programs to improve health and quality of life; and

(D) coordinating existing services with State-based disability and health programs.

(d) Coordination of activities

The Secretary shall ensure that activities under this section are coordinated as appropriate by the agencies of the Department of Health and Human Services.

(e) Authorization of appropriations

For the purpose of carrying out this section, there is authorized to be appropriated $25,000,000 for each of fiscal years 2008 through 2011.

(Pub. L. 111–11, title XIV, §14301, Mar. 30, 2009, 123 Stat. 1454.)

EDITORIAL NOTES

CODIFICATION

Section was enacted as part of the Christopher and Dana Reeve Paralysis Act, and also as part of the Omnibus Public Land Management Act of 2009, and not as part of the Public Health Service Act which comprises this chapter.

§280g–10. Community Preventive Services Task Force

(a) Establishment and purpose

The Director of the Centers for Disease Control and Prevention shall convene an independent Community Preventive Services Task Force (referred to in this subsection as the "Task Force") to be composed of individuals with appropriate expertise. Such Task Force shall review the scientific evidence related to the effectiveness, appropriateness, and cost-effectiveness of community preventive interventions for the purpose of developing recommendations, to be published in the Guide to Community Preventive Services (referred to in this section as the "Guide"), for individuals and organizations delivering population-based services, including primary care professionals, health care systems, professional societies, employers, community organizations, non-profit organizations, schools, governmental public health agencies, Indian tribes, tribal organizations and urban Indian organizations, medical groups, Congress and other policy-makers. Community preventive services include any policies, programs, processes or activities designed to affect or otherwise affecting health at the population level.

(b) Duties

The duties of the Task Force shall include—

(1) the development of additional topic areas for new recommendations and interventions related to those topic areas, including those related to specific populations and age groups, as well as the social, economic and physical environments that can have broad effects on the health and disease of populations and health disparities among sub-populations and age groups;

(2) at least once during every 5-year period, review [1] interventions and update [1] recommendations related to existing topic areas, including new or improved techniques to assess the health effects of interventions, including health impact assessment and population health modeling;

(3) improved integration with Federal Government health objectives and related target setting for health improvement;

(4) the enhanced dissemination of recommendations;

(5) the provision of technical assistance to those health care professionals, agencies, and organizations that request help in implementing the Guide recommendations; and

(6) providing yearly reports to Congress and related agencies identifying gaps in research and recommending priority areas that deserve further examination, including areas related to populations and age groups not adequately addressed by current recommendations.

(c) Role of agency

The Director shall provide ongoing administrative, research, and technical support for the operations of the Task Force, including coordinating and supporting the dissemination of the recommendations of the Task Force, ensuring adequate staff resources, and assistance to those organizations requesting it for implementation of Guide recommendations.

(d) Coordination with Preventive Services Task Force

The Task Force shall take appropriate steps to coordinate its work with the U.S. Preventive Services Task Force and the Advisory Committee on Immunization Practices, including the examination of how each task force's recommendations interact at the nexus of clinic and community.

(e) Operation

In carrying out the duties under subsection (b), the Task Force shall not be subject to the

provisions of chapter 10 of title 5.

(f) Authorization of appropriations

There are authorized to be appropriated such sums as may be necessary for each fiscal year to carry out the activities of the Task Force.

(July 1, 1944, ch. 373, title III, §399U, as added Pub. L. 111–148, title IV, §4003(b)(1), Mar. 23, 2010, 124 Stat. 543; amended Pub. L. 117–286, §4(a)(230), Dec. 27, 2022, 136 Stat. 4331.)

EDITORIAL NOTES

AMENDMENTS

2022—Subsec. (e). Pub. L. 117–286 substituted "chapter 10 of title 5." for "Appendix 2 of title 5."

[1] *So in original. Probably should be followed by "of".*

§280g–11. Awards to support community health workers and community health

(a) In general

The Secretary shall award grants, contracts, or cooperative agreements to eligible entities to promote positive health behaviors and outcomes for populations in medically underserved communities by leveraging community health workers, including by addressing ongoing and longer-term community health needs, and by building the capacity of the community health worker workforce. Such grants, contracts, and cooperative agreements shall be awarded in alignment and coordination with existing funding arrangements supporting community health workers.

(b) Use of funds

Subject to any requirements for the scope of licensure, registration, or certification of a community health worker under applicable State law, grants, contracts, and cooperative agreements awarded under subsection (a) shall be used to—

(1) recruit, hire, train, and retain community health workers that reflect the needs of the community;

(2) support community health workers in providing education and outreach, in a community setting, regarding—

(A) health conditions prevalent in—

(i) medically underserved communities (as defined in section 295p of this title), particularly racial and ethnic minority populations; and

(ii) other such at-risk populations or geographic areas that may require additional support during public health emergencies, which may include counties identified by the Secretary using applicable measures developed by the Centers for Disease Control and Prevention or other Federal agencies; and

(B) addressing health disparities, including by—

(i) promoting awareness of services and resources to increase access to health care, mental health and substance use disorder services, child services, technology, housing services, educational services, nutrition services, employment services, and other services; and

(ii) assisting in conducting individual and community needs assessments;

(3) educate community members, including regarding effective strategies to promote healthy behaviors;

(4) educate and provide outreach regarding enrollment in health insurance including the Children's Health Insurance Program under title XXI of the Social Security Act [42 U.S.C. 1397aa et seq.], Medicare under title XVIII of such Act [42 U.S.C. 1395 et seq.] and Medicaid under title

XIX of such Act [42 U.S.C. 1396 et seq.];

(5) identify and refer underserved populations to appropriate health care agencies and community-based programs and organizations in order to increase access to quality health care services and to streamline care, including serving as a liaison between communities and health care agencies; and

(6) support community health workers in educating, guiding, or providing home visitation services regarding chronic diseases, maternal health, prenatal, and postpartum care in order to improve maternal and infant health outcomes.

(c) Application

To be eligible to receive an award under subsection (a), an entity shall prepare and submit to the Secretary an application at such time, in such manner, and containing such information as the Secretary may require.

(d) Priority

In making awards under subsection (a), the Secretary shall give priority to applicants that—

(1) propose to serve—

(A) areas with populations that have a high rate of chronic disease, infant mortality, or maternal morbidity and mortality;

(B) low-income populations, including medically underserved populations (as defined in section 254b(b)(3) of this title);

(C) populations residing in health professional shortage areas (as defined in section 254e(a) of this title);

(D) populations residing in maternity care health professional target areas identified under section 254e(k) of this title; or

(E) rural or traditionally underserved populations, including racial and ethnic minority populations or low-income populations;

(2) have experience in providing health or health-related social services to individuals who are underserved with respect to such services, including rural populations and racial and ethnic minority populations;

(3) have documented community activity and experience and established relationships with community health workers in the communities expected to be served by the program;

(4) develop a plan for providing services to the extent practicable, in the language and cultural context most appropriate to individuals expected to be served by the program; and

(5) propose to use evidence-informed or evidence-based practices, as applicable and appropriate.

(e) Collaboration with academic institutions and the one-stop delivery system

The Secretary shall encourage eligible entities receiving funds under this section to collaborate with academic institutions, health professions schools, minority-serving institutions (defined, for purposes of this subsection, as institutions and programs described in section 1063b(e)(1) of title 20 and institutions described in section 1067q(a) of title 20), area health education centers under section 294a of this title, and one-stop delivery systems under section 3151 of title 29. Nothing in this section shall be construed to require such collaboration.

(f) Technical assistance

The Secretary may provide to eligible entities that receive awards under subsection (a) technical assistance with respect to planning, development, and operation of community health worker programs authorized or supported under this section.

(g) Dissemination of best practices

Not later than 4 years after December 29, 2022, the Secretary shall, based on activities carried out under this section and in consultation with relevant stakeholders, identify and disseminate evidence-based or evidence-informed practices regarding recruitment and retention of community

health workers and paraprofessionals to address ongoing public health and community health needs, and to prepare for, and respond to, future public health emergencies.

(h) Report to Congress

Not later than 4 years after December 29, 2022, the Secretary shall submit to the Committee on Health, Education, Labor, and Pensions and the Committee on Appropriations of the Senate and the Committee on Energy and Commerce and the Committee on Appropriations of the House of Representatives a report concerning the effectiveness of the program under this section in addressing ongoing public health and community health needs. Such report shall include recommendations regarding any improvements to such program, including recommendations for how to improve recruitment, training, and retention of the community health workforce.

(i) Authorization of appropriations

For purposes of carrying out this section, there are authorized to be appropriated $50,000,000 for each of fiscal years 2023 through 2027.

(j) Definitions

In this section:

(1) Eligible entity

The term "eligible entity" means a public or nonprofit private entity, including a State or political subdivision of a State, an Indian Tribe or Tribal organization, an urban Indian organization, a community-based organization, a public health department, a free health clinic, a hospital, or a Federally-qualified health center ((as [1] defined in section 1861(aa)(4) of the Social Security Act [42 U.S.C. 1395x(aa)(4)]), or a consortium of any such entities.

(2) Indian Tribe; Tribal organization

The terms "Indian Tribe" and "Tribal organization" have the meanings given the terms "Indian tribe" and "tribal organization", respectively, in section 5304 of title 25.

(3) Urban Indian organization

The term "urban Indian organization" has the meaning given such term in section 1603 of title 25.

(July 1, 1944, ch. 373, title III, §399V, as added and amended Pub. L. 111–148, title V, §5313(a), title X, §10501(c), Mar. 23, 2010, 124 Stat. 633, 994; Pub. L. 113–128, title V, §512(z)(1), July 22, 2014, 128 Stat. 1716; Pub. L. 117–328, div. FF, title II, §2222(a), Dec. 29, 2022, 136 Stat. 5744.)

EDITORIAL NOTES

REFERENCES IN TEXT

The Social Security Act, referred to in subsec. (b)(4), is act Aug. 14, 1935, ch. 531, 49 Stat. 620. Titles XVIII, XIX, and XXI of the Act are classified generally to subchapters XVIII (§1395 et seq.), XIX (§1396 et seq.), and XXI (§1397aa et seq.), respectively, of chapter 7 of this title. For complete classification of this Act to the Code, see section 1305 of this title and Tables.

AMENDMENTS

2022—Pub. L. 117–328, §2222(a)(1), amended section catchline generally. Prior to amendment, section catchline read as follows: "Grants to promote positive health behaviors and outcomes".

Subsec. (a). Pub. L. 117–328, §2222(a)(2), amended subsec. (a) generally. Prior to amendment, text read as follows: "The Director of the Centers for Disease Control and Prevention, in collaboration with the Secretary, shall award grants to eligible entities to promote positive health behaviors and outcomes for populations in medically underserved communities through the use of community health workers."

Subsec. (b). Pub. L. 117–328, §2222(a)(3)(A), substituted "Subject to any requirements for the scope of licensure, registration, or certification of a community health worker under applicable State law, grants, contracts, and cooperative agreements awarded" for "Grants awarded" and struck out "support community health workers" after "used to" in introductory provisions.

Subsec. (b)(1) to (3). Pub. L. 117–328, §2222(a)(3)(C), added pars. (1) to (3) and struck out former pars. (1)

and (2). Former par. (3) redesignated (4). Prior to amendment, pars. (1) and (2) read as follows:

"(1) to educate, guide, and provide outreach in a community setting regarding health problems prevalent in medically underserved communities, particularly racial and ethnic minority populations;

"(2) to educate and provide guidance regarding effective strategies to promote positive health behaviors and discourage risky health behaviors;".

Subsec. (b)(4). Pub. L. 117–328, §2222(a)(3)(D), substituted "educate" for "to educate".

Pub. L. 117–328, §2222(a)(3)(B), redesignated par. (3) as (4). Former par. (4) redesignated (5).

Subsec. (b)(5). Pub. L. 117–328, §2222(a)(3)(E), substituted "identify" for "to identify", "health care agencies" for "healthcare agencies", and "health care services and to streamline care, including serving as a liaison between communities and health care agencies; and" for "healthcare services and to eliminate duplicative care; or".

Pub. L. 117–328, §2222(a)(3)(B), redesignated par. (4) as (5). Former par. (5) redesignated (6).

Subsec. (b)(6). Pub. L. 117–328, §2222(a)(3)(F), substituted "support community health workers in educating, guiding, or providing" for "to educate, guide, and provide" and "chronic diseases, maternal health, prenatal, and postpartum care in order to improve maternal and infant health outcomes" for "maternal health and prenatal care".

Pub. L. 117–328, §2222(a)(3)(B), redesignated par. (5) as (6).

Subsec. (c). Pub. L. 117–328, §2222(a)(4), substituted "To be eligible to receive an award under subsection (a), an entity shall prepare and submit to the Secretary an application at such time, in such manner, and containing" for "Each eligible entity that desires to receive a grant under subsection (a) shall submit an application to the Secretary, at such time, in such manner, and accompanied by".

Subsec. (d). Pub. L. 117–328, §2222(a)(5)(A), substituted "making awards" for "awarding grants" in introductory provisions.

Subsec. (d)(1). Pub. L. 117–328, §2222(a)(5)(B), amended par. (1) generally. Prior to amendment, par. (1) read as follows: "propose to target geographic areas—

"(A) with a high percentage of residents who are eligible for health insurance but are uninsured or underinsured;

"(B) with a high percentage of residents who suffer from chronic diseases; or

"(C) with a high infant mortality rate;".

Subsec. (d)(2). Pub. L. 117–328, §2222(a)(5)(C), substituted ", including rural populations and racial and ethnic minority populations;" for "; and".

Subsec. (d)(3). Pub. L. 117–328, §2222(a)(5)(D), substituted "and established relationships with community health workers in the communities expected to be served by the program;" for "with community health workers."

Subsec. (d)(4), (5). Pub. L. 117–328, §2222(a)(5)(E), added pars. (4) and (5).

Subsec. (e). Pub. L. 117–328, §2222(a)(6), substituted "eligible entities" for "community health worker programs" and ", health professions schools, minority-serving institutions (defined, for purposes of this subsection, as institutions and programs described in section 1063b(e)(1) of title 20 and institutions described in section 1067q(a) of such title), area health education centers under section 294a of this title, and one-stop delivery systems under section 3151" for "and one-stop delivery systems under section 3151(e)".

Subsecs. (f) to (i). Pub. L. 117–328, §2222(a)(7), added subsecs. (f) to (i) and struck out former subsecs. (f) to (i) which read as follows:

"(f) EVIDENCE-BASED INTERVENTIONS.—The Secretary shall encourage community health worker programs receiving funding under this section to implement a process or an outcome-based payment system that rewards community health workers for connecting underserved populations with the most appropriate services at the most appropriate time. Nothing in this section shall be construed to require such a payment.

"(g) QUALITY ASSURANCE AND COST EFFECTIVENESS.—The Secretary shall establish guidelines for assuring the quality of the training and supervision of community health workers under the programs funded under this section and for assuring the cost-effectiveness of such programs.

"(h) MONITORING.—The Secretary shall monitor community health worker programs identified in approved applications under this section and shall determine whether such programs are in compliance with the guidelines established under subsection (g).

"(i) TECHNICAL ASSISTANCE.—The Secretary may provide technical assistance to community health worker programs identified in approved applications under this section with respect to planning, developing, and operating programs under the grant."

Subsec. (j). Pub. L. 117–328, §2222(a)(7), (8), redesignated subsec. (k) as (j) and struck out former subsec. (j). Prior to amendment, text of subsec. (j) read as follows: "There are authorized to be appropriated, such sums as may be necessary to carry out this section for each of fiscal years 2010 through 2014."

Subsec. (j)(1). Pub. L. 117–328, §2222(a)(9)(C), substituted "entity, including a State or political subdivision of a State, an Indian Tribe or Tribal organization, an urban Indian organization, a community-based organization" for "entity (including a State or public subdivision of a State" and "(as defined in section 1861(aa)(4) of the Social Security Act)" for "as defined in section 1861(aa) of the Social Security Act))".

Pub. L. 117–328, §2222(a)(9)(A), (B), redesignated par. (3) as (1) and struck out former par. (1) which defined "community health worker".

Subsec. (j)(2) to (4). Pub. L. 117–328, §2222(a)(9)(A), (D), added pars. (2) and (3) and struck out former pars. (2) and (4) which defined "community setting" and "medically underserved community", respectively. Former par. (3) redesignated (1).

Subsec. (k). Pub. L. 117–328, §2222(a)(8), redesignated subsec. (k) as (j).

2014—Subsec. (e). Pub. L. 113–128 substituted "one-stop delivery systems under section 3151(e) of title 29" for "one-stop delivery systems under section 2864(c) of title 29".

2010—Subsec. (b)(4). Pub. L. 111–148, §10501(c)(1), substituted "identify and refer" for "identify, educate, refer, and enroll".

Subsec. (k)(1). Pub. L. 111–148, §10501(c)(2), struck out ", as defined by the Department of Labor as Standard Occupational Classification [21–1094]" before "means" in introductory provisions.

STATUTORY NOTES AND RELATED SUBSIDIARIES

EFFECTIVE DATE OF 2014 AMENDMENT

Amendment by Pub. L. 113–128 effective on the first day of the first full program year after July 22, 2014 (July 1, 2015), see section 506 of Pub. L. 113–128, set out as an Effective Date note under section 3101 of Title 29, Labor.

[1] *So in original.*

§280g–12. Primary Care Extension Program

(a) Establishment, purpose and definition

(1) In general

The Secretary, acting through the Director of the Agency for Healthcare Research and Quality, shall establish a Primary Care Extension Program.

(2) Purpose

The Primary Care Extension Program shall provide support and assistance to primary care providers to educate providers about preventive medicine, health promotion, chronic disease management, mental and behavioral health services (including substance abuse prevention and treatment services), and evidence-based and evidence-informed therapies and techniques, in order to enable providers to incorporate such matters into their practice and to improve community health by working with community-based health connectors (referred to in this section as "Health Extension Agents").

(3) Definitions

In this section:

(A) Health Extension Agent

The term "Health Extension Agent" means any local, community-based health worker who facilitates and provides assistance to primary care practices by implementing quality improvement or system redesign, incorporating the principles of the patient-centered medical home to provide high-quality, effective, efficient, and safe primary care and to provide guidance to patients in culturally and linguistically appropriate ways, and linking practices to diverse health system resources.

(B) Primary care provider

The term "primary care provider" means a clinician who provides integrated, accessible health care services and who is accountable for addressing a large majority of personal health care needs, including providing preventive and health promotion services for men, women, and children of all ages, developing a sustained partnership with patients, and practicing in the context of family and community, as recognized by a State licensing or regulatory authority, unless otherwise specified in this section.

(b) Grants to establish State Hubs and local Primary Care Extension Agencies

(1) Grants

The Secretary shall award competitive grants to States for the establishment of State- or multistate-level primary care Primary Care Extension Program State Hubs (referred to in this section as "Hubs").

(2) Composition of Hubs

A Hub established by a State pursuant to paragraph (1)—

(A) shall consist of, at a minimum, the State health department, the entity responsible for administering the State Medicaid program (if other than the State health department), the State-level entity administering the Medicare program, and the departments that train providers in primary care in 1 or more health professions schools in the State; and

(B) may include entities such as hospital associations, primary care practice-based research networks, health professional societies, State primary care associations, State licensing boards, organizations with a contract with the Secretary under section 1320c–2 of this title, consumer groups, and other appropriate entities.

(c) State and local activities

(1) Hub activities

Hubs established under a grant under subsection (b) shall—

(A) submit to the Secretary a plan to coordinate functions with quality improvement organizations and area health education centers if such entities are members of the Hub not described in subsection (b)(2)(A);

(B) contract with a county- or local-level entity that shall serve as the Primary Care Extension Agency to administer the services described in paragraph (2);

(C) organize and administer grant funds to county- or local-level Primary Care Extension Agencies that serve a catchment area, as determined by the State; and

(D) organize State-wide or multistate networks of local-level Primary Care Extension Agencies to share and disseminate information and practices.

(2) Local Primary Care Extension Agency activities

(A) Required activities

Primary Care Extension Agencies established by a Hub under paragraph (1) shall—

(i) assist primary care providers to implement a patient-centered medical home to improve the accessibility, quality, and efficiency of primary care services, including health homes;

(ii) develop and support primary care learning communities to enhance the dissemination of research findings for evidence-based practice, assess implementation of practice improvement, share best practices, and involve community clinicians in the generation of new knowledge and identification of important questions for research;

(iii) participate in a national network of Primary Care Extension Hubs and propose how the Primary Care Extension Agency will share and disseminate lessons learned and best practices; and

(iv) develop a plan for financial sustainability involving State, local, and private contributions, to provide for the reduction in Federal funds that is expected after an initial 6-year period of program establishment, infrastructure development, and planning.

(B) Discretionary activities

Primary Care Extension Agencies established by a Hub under paragraph (1) may—

(i) provide technical assistance, training, and organizational support for community health teams established under section 256a–1 [1] of this title;

(ii) collect data and provision of primary care provider feedback from standardized measurements of processes and outcomes to aid in continuous performance improvement;

(iii) collaborate with local health departments, community health centers, tribes and tribal entities, and other community agencies to identify community health priorities and local health workforce needs, and participate in community-based efforts to address the social and primary determinants of health, strengthen the local primary care workforce, and eliminate health disparities;

(iv) develop measures to monitor the impact of the proposed program on the health of practice enrollees and of the wider community served; and

(v) participate in other activities, as determined appropriate by the Secretary.

(d) Federal program administration

(1) Grants; types

Grants awarded under subsection (b) shall be—

(A) program grants, that are awarded to State or multistate entities that submit fully-developed plans for the implementation of a Hub, for a period of 6 years; or

(B) planning grants, that are awarded to State or multistate entities with the goal of developing a plan for a Hub, for a period of 2 years.

(2) Applications

To be eligible for a grant under subsection (b), a State or multistate entity shall submit to the Secretary an application, at such time, in such manner, and containing such information as the Secretary may require.

(3) Evaluation

A State that receives a grant under subsection (b) shall be evaluated at the end of the grant period by an evaluation panel appointed by the Secretary.

(4) Continuing support

After the sixth year in which assistance is provided to a State under a grant awarded under subsection (b), the State may receive additional support under this section if the State program has received satisfactory evaluations with respect to program performance and the merits of the State sustainability plan, as determined by the Secretary.

(5) Limitation

A State shall not use in excess of 10 percent of the amount received under a grant to carry out administrative activities under this section. Funds awarded pursuant to this section shall not be used for funding direct patient care.

(e) Requirements on the Secretary

In carrying out this section, the Secretary shall consult with the heads of other Federal agencies with demonstrated experience and expertise in health care and preventive medicine, such as the Centers for Disease Control and Prevention, the Substance Abuse and Mental Health Administration, the Health Resources and Services Administration, the National Institutes of Health, the Office of the National Coordinator for Health Information Technology, the Indian Health Service, the Agricultural Cooperative Extension Service of the Department of Agriculture, and other entities, as the Secretary determines appropriate.

(f) Authorization of appropriations

To awards grants as provided in subsection (d), there are authorized to be appropriated $120,000,000 for each of fiscal years 2011 and 2012, and such sums as may be necessary to carry out this section for each of fiscal years 2013 through 2014.

(July 1, 1944, ch. 373, title III, §399V–1, formerly §399W, as added, amended, and renumbered §399V–1, Pub. L. 111–148, title V, §5405, title X, §10501(f)(1), (2), Mar. 23, 2010, 124 Stat. 649, 996.)

EDITORIAL NOTES

REFERENCES IN TEXT

Section 256a–1 of this title, referred to in subsec. (c)(2)(B)(i), was in the original "section 3602 of the Patient Protection and Affordable Care Act", and was translated as meaning section 3502 of the Patient Protection and Affordable Care Act, Pub. L. 111–148, to reflect the probable intent of Congress.

AMENDMENTS

2010—Subsec. (b)(2)(A). Pub. L. 111–148, §10501(f)(2), substituted "and the departments that train providers in primary care in 1 or more health professions schools in the State" for "and the departments of 1 or more health professions schools in the State that train providers in primary care".

[1] *See References in Text note below.*

§280g–13. National congenital heart disease research, surveillance, and awareness

(a) In general

The Secretary shall, as appropriate—

(1) enhance and expand research and data collection efforts related to congenital heart disease, including to study and track the epidemiology of congenital heart disease to understand health outcomes for individuals with congenital heart disease across all ages;

(2) conduct activities to improve public awareness of, and education related to, congenital heart disease, including care of individuals with such disease; and

(3) award grants to entities to undertake the activities described in this section.

(b) Activities

(1) In general

The Secretary shall carry out activities, including, as appropriate, through a national cohort study and a nationally-representative, population-based surveillance system, to improve the understanding of the epidemiology of congenital heart disease in all age groups, with particular attention to—

(A) the incidence and prevalence of congenital heart disease in the United States;

(B) causation and risk factors associated with, and natural history of, congenital heart disease;

(C) health care utilization by individuals with congenital heart disease;

(D) demographic factors associated with congenital heart disease, such as age, race, ethnicity, sex, and family history of individuals who are diagnosed with the disease; and

(E) evidence-based practices related to care and treatment for individuals with congenital heart disease.

(2) Permissible considerations

In carrying out the activities under this section, the Secretary may, as appropriate—

(A) collect data on the health outcomes, including behavioral and mental health outcomes, of a diverse population of individuals of all ages with congenital heart disease, such that analysis of the outcomes will inform evidence-based practices for individuals with congenital heart disease; and

(B) consider health disparities among individuals with congenital heart disease, which may include the consideration of prenatal exposures.

(c) Awareness campaign

The Secretary may carry out awareness and educational activities related to congenital heart disease in individuals of all ages, which may include information for patients, family members, and health care providers, on topics such as the prevalence of such disease, the effect of such disease on individuals of all ages, and the importance of long-term, specialized care for individuals with such disease.

(d) Public access

The Secretary shall ensure that, subject to subsection (e), information collected under this section is made available, as appropriate, to the public, including researchers.

(e) Patient privacy

The Secretary shall ensure that the data and information collected under this section are made available in a manner that, at a minimum, protects personal privacy to the extent required by applicable Federal and State law.

(f) Report and strategy

(1) Report

Not later than 2 years after November 21, 2024, the Secretary shall issue a report to the Committee on Energy and Commerce of the House of Representatives and the Committee on Health, Education, Labor, and Pensions of the Senate including the following:

(A) A description of past and present activities of the Department of Health and Human Services to increase awareness and knowledge of the public with respect to congenital heart disease, including efforts to address the lifelong needs of congenital heart disease patients.

(B) An assessment of past and present activities of the Department of Health and Human Services to increase education and training of health care providers with respect to congenital heart disease, including efforts to address the lifelong needs of congenital heart disease patients.

(C) A description of the current workforce capacity in the United States of health care providers who treat adult patients living with congenital heart disease.

(2) Strategy

(A) Development; submission to Congress

Not later than 1 year after submitting the report required by paragraph (1), the Secretary shall develop and submit to Congress a strategy for improving efforts to increase awareness and knowledge of the public and education and training of health care providers with respect to congenital heart disease. Such strategy shall include findings and recommendations to—

(i) address any public awareness and research gaps and opportunities related to the lifelong needs of congenital heart disease patients, including long-term health outcomes, quality of life, mental health, and health care utilization;

(ii) address any shortages in the current workforce of health care providers who treat adult patients living with congenital heart disease, which may include strategies to enhance fellowship training programs or other continuing education programs; and

(iii) foster collaboration and dissemination of information across Federal agencies, health care providers, researchers, and patient organizations.

(B) Consultation

In developing the strategy under subparagraph (A), the Secretary shall, as appropriate, consult with qualified stakeholder groups, including patient organizations, health care professionals, research entities, health insurance providers, accrediting organizations, and relevant Federal agencies, including the Centers for Disease Control and Prevention, the National Institutes of Health, and the Health Resources and Services Administration.

(g) Eligibility for grants

To be eligible to receive a grant under subsection (a)(3), an entity shall—

(1) be a public or private nonprofit entity with specialized experience in congenital heart

disease; and

(2) submit to the Secretary an application at such time, in such manner, and containing such information as the Secretary may require.

(h) Authorization of appropriations

To carry out this section, there are authorized to be appropriated $10,000,000 for each of fiscal years 2025 through 2029.

(July 1, 1944, ch. 373, title III, §399V–2, as added Pub. L. 111–148, title X, §10411(b)(1), Mar. 23, 2010, 124 Stat. 988; amended Pub. L. 115–342, §2, Dec. 21, 2018, 132 Stat. 5040; Pub. L. 118–107, §2, Nov. 21, 2024, 138 Stat. 1594.)

EDITORIAL NOTES

AMENDMENTS

2024—Subsecs. (f), (g). Pub. L. 118–107, §2(1), (2), added subsec. (f) and redesignated former subsec. (f) as (g). Former subsec. (g) redesignated (h).

Subsec. (h). Pub. L. 118–107, §2(1), (3), redesignated subsec. (g) as (h) and substituted "2025 through 2029" for "2020 through 2024".

2018—Pub. L. 115–342 amended section generally. Prior to amendment, section related to National Congenital Heart Disease Surveillance System.

§280g–14. National diabetes prevention program

(a) In general

The Secretary, acting through the Director of the Centers for Disease Control and Prevention, shall establish a national diabetes prevention program (referred to in this section as the "program") targeted at adults at high risk for diabetes in order to eliminate the preventable burden of diabetes.

(b) Program activities

The program described in subsection (a) shall include—

(1) a grant program for community-based diabetes prevention program model sites;

(2) a program within the Centers for Disease Control and Prevention to determine eligibility of entities to deliver community-based diabetes prevention services;

(3) a training and outreach program for lifestyle intervention instructors; and

(4) evaluation, monitoring and technical assistance, and applied research carried out by the Centers for Disease Control and Prevention.

(c) Eligible entities

To be eligible for a grant under subsection (b)(1), an entity shall be a State or local health department, a tribal organization, a national network of community-based non-profits focused on health and wellbeing, an academic institution, or other entity, as the Secretary determines.

(d) Authorization of appropriations

For the purpose of carrying out this section, there are authorized to be appropriated such sums as may be necessary for each of fiscal years 2010 through 2014.

(July 1, 1944, ch. 373, title III, §399V–3, as added Pub. L. 111–148, title X, §10501(g), Mar. 23, 2010, 124 Stat. 996.)

§280g–15. State demonstration programs to evaluate alternatives to current medical tort litigation

(a) In general

The Secretary is authorized to award demonstration grants to States for the development,

implementation, and evaluation of alternatives to current tort litigation for resolving disputes over injuries allegedly caused by health care providers or health care organizations. In awarding such grants, the Secretary shall ensure the diversity of the alternatives so funded.

(b) Duration

The Secretary may award grants under subsection (a) for a period not to exceed 5 years.

(c) Conditions for demonstration grants

(1) Requirements

Each State desiring a grant under subsection (a) shall develop an alternative to current tort litigation that—

(A) allows for the resolution of disputes over injuries allegedly caused by health care providers or health care organizations; and

(B) promotes a reduction of health care errors by encouraging the collection and analysis of patient safety data related to disputes resolved under subparagraph (A) by organizations that engage in efforts to improve patient safety and the quality of health care.

(2) Alternative to current tort litigation

Each State desiring a grant under subsection (a) shall demonstrate how the proposed alternative described in paragraph (1)(A)—

(A) makes the medical liability system more reliable by increasing the availability of prompt and fair resolution of disputes;

(B) encourages the efficient resolution of disputes;

(C) encourages the disclosure of health care errors;

(D) enhances patient safety by detecting, analyzing, and helping to reduce medical errors and adverse events;

(E) improves access to liability insurance;

(F) fully informs patients about the differences in the alternative and current tort litigation;

(G) provides patients the ability to opt out of or voluntarily withdraw from participating in the alternative at any time and to pursue other options, including litigation, outside the alternative;

(H) would not conflict with State law at the time of the application in a way that would prohibit the adoption of an alternative to current tort litigation; and

(I) would not limit or curtail a patient's existing legal rights, ability to file a claim in or access a State's legal system, or otherwise abrogate a patient's ability to file a medical malpractice claim.

(3) Sources of compensation

Each State desiring a grant under subsection (a) shall identify the sources from and methods by which compensation would be paid for claims resolved under the proposed alternative to current tort litigation, which may include public or private funding sources, or a combination of such sources. Funding methods shall to the extent practicable provide financial incentives for activities that improve patient safety.

(4) Scope

(A) In general

Each State desiring a grant under subsection (a) shall establish a scope of jurisdiction (such as Statewide, designated geographic region, a designated area of health care practice, or a designated group of health care providers or health care organizations) for the proposed alternative to current tort litigation that is sufficient to evaluate the effects of the alternative. No scope of jurisdiction shall be established under this paragraph that is based on a health care payer or patient population.

(B) Notification of patients

A State shall demonstrate how patients would be notified that they are receiving health care

services that fall within such scope, and the process by which they may opt out of or voluntarily withdraw from participating in the alternative. The decision of the patient whether to participate or continue participating in the alternative process shall be made at any time and shall not be limited in any way.

(5) Preference in awarding demonstration grants

In awarding grants under subsection (a), the Secretary shall give preference to States—

(A) that have developed the proposed alternative through substantive consultation with relevant stakeholders, including patient advocates, health care providers and health care organizations, attorneys with expertise in representing patients and health care providers, medical malpractice insurers, and patient safety experts;

(B) that make proposals that are likely to enhance patient safety by detecting, analyzing, and helping to reduce medical errors and adverse events; and

(C) that make proposals that are likely to improve access to liability insurance.

(d) Application

(1) In general

Each State desiring a grant under subsection (a) shall submit to the Secretary an application, at such time, in such manner, and containing such information as the Secretary may require.

(2) Review panel

(A) In general

In reviewing applications under paragraph (1), the Secretary shall consult with a review panel composed of relevant experts appointed by the Comptroller General.

(B) Composition

(i) Nominations

The Comptroller General shall solicit nominations from the public for individuals to serve on the review panel.

(ii) Appointment

The Comptroller General shall appoint, at least 9 but not more than 13, highly qualified and knowledgeable individuals to serve on the review panel and shall ensure that the following entities receive fair representation on such panel:

(I) Patient advocates.

(II) Health care providers and health care organizations.

(III) Attorneys with expertise in representing patients and health care providers.

(IV) Medical malpractice insurers.

(V) State officials.

(VI) Patient safety experts.

(C) Chairperson

The Comptroller General shall designate a member of the review panel to be the chairperson of the review panel.

(D) Availability of information

The Secretary shall make available to the review panel such information, personnel, and administrative services and assistance as the review panel may reasonably require to carry out its duties.

(E) Information from agencies

The review panel may request directly from any department or agency of the United States any information that such panel considers necessary to carry out its duties. To the extent consistent with applicable laws and regulations, the head of such department or agency shall furnish the requested information to the review panel.

(e) Reports

(1) By State

Each State receiving a grant under subsection (a) shall submit to the Secretary an annual report evaluating the effectiveness of activities funded with grants awarded under such subsection. Such report shall, at a minimum, include the impact of the activities funded on patient safety and on the availability and price of medical liability insurance.

(2) By Secretary

The Secretary shall submit to Congress an annual compendium of the reports submitted under paragraph (1) and an analysis of the activities funded under subsection (a) that examines any differences that result from such activities in terms of the quality of care, number and nature of medical errors, medical resources used, length of time for dispute resolution, and the availability and price of liability insurance.

(f) Technical assistance

(1) In general

The Secretary shall provide technical assistance to the States applying for or awarded grants under subsection (a).

(2) Requirements

Technical assistance under paragraph (1) shall include—

(A) guidance on non-economic damages, including the consideration of individual facts and circumstances in determining appropriate payment, guidance on identifying avoidable injuries, and guidance on disclosure to patients of health care errors and adverse events; and

(B) the development, in consultation with States, of common definitions, formats, and data collection infrastructure for States receiving grants under this section to use in reporting to facilitate aggregation and analysis of data both within and between States.

(3) Use of common definitions, formats, and data collection infrastructure

States not receiving grants under this section may also use the common definitions, formats, and data collection infrastructure developed under paragraph (2)(B).

(g) Evaluation

(1) In general

The Secretary, in consultation with the review panel established under subsection (d)(2), shall enter into a contract with an appropriate research organization to conduct an overall evaluation of the effectiveness of grants awarded under subsection (a) and to annually prepare and submit a report to Congress. Such an evaluation shall begin not later than 18 months following the date of implementation of the first program funded by a grant under subsection (a).

(2) Contents

The evaluation under paragraph (1) shall include—

(A) an analysis of the effects of the grants awarded under subsection (a) with regard to the measures described in paragraph (3);

(B) for each State, an analysis of the extent to which the alternative developed under subsection (c)(1) is effective in meeting the elements described in subsection (c)(2);

(C) a comparison among the States receiving grants under subsection (a) of the effectiveness of the various alternatives developed by such States under subsection (c)(1);

(D) a comparison, considering the measures described in paragraph (3), of States receiving grants approved under subsection (a) and similar States not receiving such grants; and

(E) a comparison, with regard to the measures described in paragraph (3), of—

(i) States receiving grants under subsection (a);

(ii) States that enacted, prior to March 23, 2010, any cap on non-economic damages; and

(iii) States that have enacted, prior to March 23, 2010, a requirement that the complainant

obtain an opinion regarding the merit of the claim, although the substance of such opinion may have no bearing on whether the complainant may proceed with a case.

(3) Measures

The evaluations under paragraph (2) shall analyze and make comparisons on the basis of—

(A) the nature and number of disputes over injuries allegedly caused by health care providers or health care organizations;

(B) the nature and number of claims in which tort litigation was pursued despite the existence of an alternative under subsection (a);

(C) the disposition of disputes and claims, including the length of time and estimated costs to all parties;

(D) the medical liability environment;

(E) health care quality;

(F) patient safety in terms of detecting, analyzing, and helping to reduce medical errors and adverse events;

(G) patient and health care provider and organization satisfaction with the alternative under subsection (a) and with the medical liability environment; and

(H) impact on utilization of medical services, appropriately adjusted for risk.

(4) Funding

The Secretary shall reserve 5 percent of the amount appropriated in each fiscal year under subsection (k) to carry out this subsection.

(h) MedPAC and MACPAC reports

(1) MedPAC

The Medicare Payment Advisory Commission shall conduct an independent review of the alternatives to current tort litigation that are implemented under grants under subsection (a) to determine the impact of such alternatives on the Medicare program under title XVIII of the Social Security Act [42 U.S.C. 1395 et seq.], and its beneficiaries.

(2) MACPAC

The Medicaid and CHIP Payment and Access Commission shall conduct an independent review of the alternatives to current tort litigation that are implemented under grants under subsection (a) to determine the impact of such alternatives on the Medicaid or CHIP programs under titles XIX and XXI of the Social Security Act [42 U.S.C. 1396 et seq., 1397aa et seq.], and their beneficiaries.

(3) Reports

Not later than December 31, 2016, the Medicare Payment Advisory Commission and the Medicaid and CHIP Payment and Access Commission shall each submit to Congress a report that includes the findings and recommendations of each respective Commission based on independent reviews conducted under paragraphs (1) and (2), including an analysis of the impact of the alternatives reviewed on the efficiency and effectiveness of the respective programs.

(i) Option to provide for initial planning grants

Of the funds appropriated pursuant to subsection (k), the Secretary may use a portion not to exceed $500,000 per State to provide planning grants to such States for the development of demonstration project applications meeting the criteria described in subsection (c). In selecting States to receive such planning grants, the Secretary shall give preference to those States in which State law at the time of the application would not prohibit the adoption of an alternative to current tort litigation.

(j) Definitions

In this section:

(1) Health care services

The term "health care services" means any services provided by a health care provider, or by any individual working under the supervision of a health care provider, that relate to—

(A) the diagnosis, prevention, or treatment of any human disease or impairment; or

(B) the assessment of the health of human beings.

(2) Health care organization

The term "health care organization" means any individual or entity which is obligated to provide, pay for, or administer health benefits under any health plan.

(3) Health care provider

The term "health care provider" means any individual or entity—

(A) licensed, registered, or certified under Federal or State laws or regulations to provide health care services; or

(B) required to be so licensed, registered, or certified but that is exempted by other statute or regulation.

(k) Authorization of appropriations

There are authorized to be appropriated to carry out this section, $50,000,000 for the 5-fiscal year period beginning with fiscal year 2011.

(l) Current State efforts to establish alternative to tort litigation

Nothing in this section shall be construed to limit any prior, current, or future efforts of any State to establish any alternative to tort litigation.

(m) Rule of construction

Nothing in this section shall be construed as limiting states' [1] authority over or responsibility for their state [1] justice systems.

(July 1, 1944, ch. 373, title III, §399V–4, as added Pub. L. 111–148, title X, §10607, Mar. 23, 2010, 124 Stat. 1009; amended Pub. L. 114–301, §3(d), Dec. 16, 2016, 130 Stat. 1515.)

EDITORIAL NOTES

REFERENCES IN TEXT

The Social Security Act, referred to in subsec. (h)(1), (2), is act Aug. 14, 1935, ch. 531, 49 Stat. 620. Titles XVIII, XIX, and XXI of the Act are classified generally to subchapters XVIII (§1395 et seq.), XIX (§1396 et seq.), and XXI (§1397aa et seq.), respectively, of chapter 7 of this title. For complete classification of this Act to the Code, see section 1305 of this title and Tables.

AMENDMENTS

2016—Subsec. (d)(2)(C). Pub. L. 114–301, §3(d)(1), substituted "shall designate a member of the review panel to" for ", or an individual within the Government Accountability Office designated by the Comptroller General, shall".

Subsec. (d)(2)(D). Pub. L. 114–301, §3(d)(2), substituted "Secretary" for "Comptroller General".

[1] So in original. Probably should be capitalized.

§280g–16. Food Safety Integrated Centers of Excellence

(a) In general

Not later than 1 year after January 4, 2011, the Secretary, acting through the Director of the Centers for Disease Control and Prevention and in consultation with the working group described in subsection (b)(2), shall designate 5 Integrated Food Safety Centers of Excellence (referred to in this

section as the "Centers of Excellence") to serve as resources for Federal, State, and local public health professionals to respond to foodborne illness outbreaks. The Centers of Excellence shall be headquartered at selected State health departments.

(b) Selection of Centers of Excellence

(1) Eligible entities

To be eligible to be designated as a Center of Excellence under subsection (a), an entity shall—

(A) be a State health department;

(B) partner with 1 or more institutions of higher education that have demonstrated knowledge, expertise, and meaningful experience with regional or national food production, processing, and distribution, as well as leadership in the laboratory, epidemiological, and environmental detection and investigation of foodborne illness; and

(C) provide to the Secretary such information, at such time, and in such manner, as the Secretary may require.

(2) Working group

Not later than 180 days after January 4, 2011, the Secretary shall establish a diverse working group of experts and stakeholders from Federal, State, and local food safety and health agencies, the food industry, including food retailers and food manufacturers, consumer organizations, and academia to make recommendations to the Secretary regarding designations of the Centers of Excellence.

(3) Additional Centers of Excellence

The Secretary may designate eligible entities to be regional Food Safety Centers of Excellence, in addition to the 5 Centers designated under subsection (a).

(c) Activities

Under the leadership of the Director of the Centers for Disease Control and Prevention, each Center of Excellence shall be based out of a selected State health department, which shall provide assistance to other regional, State, and local departments of health through activities that include—

(1) providing resources, including timely information concerning symptoms and tests, for frontline health professionals interviewing individuals as part of routine surveillance and outbreak investigations;

(2) providing analysis of the timeliness and effectiveness of foodborne disease surveillance and outbreak response activities;

(3) providing training for epidemiological and environmental investigation of foodborne illness, including suggestions for streamlining and standardizing the investigation process;

(4) establishing fellowships, stipends, and scholarships to train future epidemiological and food-safety leaders and to address critical workforce shortages;

(5) training and coordinating State and local personnel;

(6) strengthening capacity to participate in existing or new foodborne illness surveillance and environmental assessment information systems; and

(7) conducting research and outreach activities focused on increasing prevention, communication, and education regarding food safety.

(d) Report to Congress

Not later than 2 years after January 4, 2011, the Secretary shall submit to Congress a report that—

(1) describes the effectiveness of the Centers of Excellence; and

(2) provides legislative recommendations or describes additional resources required by the Centers of Excellence.

(e) Authorization of appropriations

There is authorized to be appropriated such sums as may be necessary to carry out this section.

(f) No duplication of effort

In carrying out activities of the Centers of Excellence or other programs under this section, the

Secretary shall not duplicate other Federal foodborne illness response efforts.

(July 1, 1944, ch. 373, title III, §399V–5, as added Pub. L. 111–353, title II, §210(b), Jan. 4, 2011, 124 Stat. 3950.)

§280g–17. Designation and investigation of potential cancer clusters

(a) Definitions

In this section:

(1) Cancer cluster

The term "cancer cluster" means the incidence of a particular cancer within a population group, a geographical area, and a period of time that is greater than expected for such group, area, and period.

(2) Particular cancer

The term "particular cancer" means one specific type of cancer or a type of cancers scientifically proven to have the same cause.

(3) Population group

The term "population group" means a group, for purposes of calculating cancer rates, defined by factors such as race, ethnicity, age, or gender.

(b) Criteria for designation of potential cancer clusters

(1) Development of criteria

The Secretary shall develop criteria for the designation of potential cancer clusters.

(2) Requirements

The criteria developed under paragraph (1) shall consider, as appropriate—

(A) a standard for cancer cluster identification and reporting protocols used to determine when cancer incidence is greater than would be typically observed;

(B) scientific screening standards that ensure that a cluster of a particular cancer involves the same type of cancer, or types of cancers;

(C) the population in which the cluster of a particular cancer occurs by factors such as race, ethnicity, age, and gender, for purposes of calculating cancer rates;

(D) the boundaries of a geographic area in which a cluster of a particular cancer occurs so as not to create or obscure a potential cluster by selection of a specific area; and

(E) the time period over which the number of cases of a particular cancer, or the calculation of an expected number of cases, occurs.

(c) Guidelines for investigation of potential cancer clusters

The Secretary, in consultation with the Council of State and Territorial Epidemiologists and representatives of State and local health departments, shall develop, publish, and periodically update guidelines for investigating potential cancer clusters. The guidelines shall—

(1) recommend that investigations of cancer clusters—

(A) use the criteria developed under subsection (b);

(B) use the best available science; and

(C) rely on a weight of the scientific evidence;

(2) provide standardized methods of reviewing and categorizing data, including from health surveillance systems and reports of potential cancer clusters; and

(3) provide guidance for using appropriate epidemiological and other approaches for investigations.

(d) Investigation of cancer clusters

(1) Secretary discretion

The Secretary—

(A) in consultation with representatives of the relevant State and local health departments, shall consider whether it is appropriate to conduct an investigation of a potential cancer cluster; and

(B) in conducting investigations shall have the discretion to prioritize certain potential cancer clusters, based on the availability of resources.

(2) Coordination

In investigating potential cancer clusters, the Secretary shall coordinate with agencies within the Department of Health and Human Services and other Federal agencies, such as the Environmental Protection Agency.

(3) Biomonitoring

In investigating potential cancer clusters, the Secretary shall rely on all appropriate biomonitoring information collected under other Federal programs, such as the National Health and Nutrition Examination Survey. The Secretary may provide technical assistance for relevant biomonitoring studies of other Federal agencies.

(e) Duties

The Secretary shall—

(1) ensure that appropriate staff of agencies within the Department of Health and Human Services are prepared to provide timely assistance, to the extent practicable, upon receiving a request to investigate a potential cancer cluster from a State or local health authority;

(2) maintain staff expertise in epidemiology, toxicology, data analysis, environmental health and cancer surveillance, exposure assessment, pediatric health, pollution control, community outreach, health education, laboratory sampling and analysis, spatial mapping, and informatics;

(3) consult with community members as investigations into potential cancer clusters are conducted, as the Secretary determines appropriate;

(4) collect, store, and disseminate reports on investigations of potential cancer clusters, the possible causes of such clusters, and the actions taken to address such clusters; and

(5) provide technical assistance for investigating cancer clusters to State and local health departments through existing programs, such as the Epi-Aids program of the Centers for Disease Control and Prevention and the Assessments of Chemical Exposures Program of the Agency for Toxic Substances and Disease Registry.

(July 1, 1944, ch. 373, title III, §399V–6, as added Pub. L. 114–182, title I, §21(b), June 22, 2016, 130 Stat. 510.)

STATUTORY NOTES AND RELATED SUBSIDIARIES

PURPOSES OF TREVOR'S LAW

Pub. L. 114–182, title I, §21(a), June 22, 2016, 130 Stat. 510, provided that: "The purposes of this section [enacting this section] are—

"(1) to provide the appropriate Federal agencies with the authority to help conduct investigations into potential cancer clusters;

"(2) to ensure that Federal agencies have the authority to undertake actions to help address cancer clusters and factors that may contribute to the creation of potential cancer clusters; and

"(3) to enable Federal agencies to coordinate with other Federal, State, and local agencies, institutes of higher education, and the public in investigating and addressing cancer clusters."

§280g–18. Maternal mental health hotline

(a) In general

The Secretary shall maintain, by grant or contract, a national maternal mental health hotline to

provide emotional support, information, brief intervention, and mental health and substance use disorder resources to pregnant and postpartum women at risk of, or affected by, maternal mental health and substance use disorders, and to their families or household members.

(b) Requirements for hotline

The hotline under subsection (a) shall—

(1) be a 24/7 real-time hotline;

(2) provide voice and text support;

(3) be staffed by certified peer specialists, licensed health care professionals, or licensed mental health professionals who are trained on—

(A) maternal mental health and substance use disorder prevention, identification, and intervention; and

(B) providing culturally and linguistically appropriate support; and

(4) provide maternal mental health and substance use disorder assistance and referral services to meet the needs of underserved populations, individuals with disabilities, and family and household members of pregnant or postpartum women at risk of experiencing maternal mental health and substance use disorders.

(c) Additional requirements

In maintaining the hotline under subsection (a), the Secretary shall—

(1) consult with the Domestic Violence Hotline, National Suicide Prevention Lifeline, and Veterans Crisis Line to ensure that pregnant and postpartum women are connected in real-time to the appropriate specialized hotline service, when applicable;

(2) conduct a public awareness campaign for the hotline;

(3) consult with Federal departments and agencies, including the Substance Abuse and Mental Health Services Administration and the Department of Veterans Affairs, to increase awareness regarding the hotline; and

(4) consult with appropriate State, local, and Tribal public health officials, including officials who administer programs that serve low-income pregnant and postpartum individuals.

(d) Annual report

The Secretary shall submit an annual report to the Congress on the hotline under subsection (a) and implementation of this section, including—

(1) an evaluation of the effectiveness of activities conducted or supported under subsection (a);

(2) a directory of entities or organizations to which staff maintaining the hotline funded under this section may make referrals; and

(3) such additional information as the Secretary determines appropriate.

(e) Authorization of appropriations

To carry out this section, there are authorized to be appropriated $10,000,000 for each of fiscal years 2023 through 2027.

(July 1, 1944, ch. 373, title III, §399V–7, as added Pub. L. 117–328, div. FF, title I, §1112, Dec. 29, 2022, 136 Stat. 5643.)

PART Q—PROGRAMS TO IMPROVE THE HEALTH OF CHILDREN

EXECUTIVE DOCUMENTS

EX. ORD. NO. 14187. PROTECTING CHILDREN FROM CHEMICAL AND SURGICAL MUTILATION

Ex. Ord. No. 14187, Jan. 28, 2025, 90 F.R. 8771, provided:

By the authority vested in me as President by the Constitution and the laws of the United States of America, it is hereby ordered:

SECTION 1. *Policy and Purpose*. Across the country today, medical professionals are maiming and sterilizing a growing number of impressionable children under the radical and false claim that adults can change a child's sex through a series of irreversible medical interventions. This dangerous trend will be a stain on our Nation's history, and it must end.

Countless children soon regret that they have been mutilated and begin to grasp the horrifying tragedy that they will never be able to conceive children of their own or nurture their children through breastfeeding. Moreover, these vulnerable youths' medical bills may rise throughout their lifetimes, as they are often trapped with lifelong medical complications, a losing war with their own bodies, and, tragically, sterilization.

Accordingly, it is the policy of the United States that it will not fund, sponsor, promote, assist, or support the so-called "transition" of a child from one sex to another, and it will rigorously enforce all laws that prohibit or limit these destructive and life-altering procedures.

SEC. 2. *Definitions*. For the purposes of this order:

(a) The term "child" or "children" means an individual or individuals under 19 years of age.

(b) The term "pediatric" means relating to the medical care of a child.

(c) The phrase "chemical and surgical mutilation" means the use of puberty blockers, including GnRH agonists and other interventions, to delay the onset or progression of normally timed puberty in an individual who does not identify as his or her sex; the use of sex hormones, such as androgen blockers, estrogen, progesterone, or testosterone, to align an individual's physical appearance with an identity that differs from his or her sex; and surgical procedures that attempt to transform an individual's physical appearance to align with an identity that differs from his or her sex or that attempt to alter or remove an individual's sexual organs to minimize or destroy their natural biological functions. This phrase sometimes is referred to as "gender affirming care."

SEC. 3. *Ending Reliance on Junk Science*. (a) The blatant harm done to children by chemical and surgical mutilation cloaks itself in medical necessity, spurred by guidance from the World Professional Association for Transgender Health (WPATH), which lacks scientific integrity. In light of the scientific concerns with the WPATH guidance:

(i) agencies shall rescind or amend all policies that rely on WPATH guidance, including WPATH's "Standards of Care Version 8"; and

(ii) within 90 days of the date of this order [Jan. 28, 2025], the Secretary of Health and Human Services (HHS) shall publish a review of the existing literature on best practices for promoting the health of children who assert gender dysphoria, rapid-onset gender dysphoria, or other identity-based confusion.

(b) The Secretary of HHS, as appropriate and consistent with applicable law, shall use all available methods to increase the quality of data to guide practices for improving the health of minors with gender dysphoria, rapid-onset gender dysphoria, or other identity-based confusion, or who otherwise seek chemical or surgical mutilation.

SEC. 4. *Defunding Chemical and Surgical Mutilation*. The head of each executive department or agency (agency) that provides research or education grants to medical institutions, including medical schools and hospitals, shall, consistent with applicable law and in coordination with the Director of the Office of Management and Budget, immediately take appropriate steps to ensure that institutions receiving Federal research or education grants end the chemical and surgical mutilation of children.

SEC. 5. *Additional Directives to the Secretary of HHS*. (a) The Secretary of HHS shall, consistent with applicable law, take all appropriate actions to end the chemical and surgical mutilation of children, including regulatory and sub-regulatory actions, which may involve the following laws, programs, issues, or documents:

(i) Medicare or Medicaid conditions of participation or conditions for coverage;

(ii) clinical-abuse or inappropriate-use assessments relevant to State Medicaid programs;

(iii) mandatory drug use reviews;

(iv) section 1557 of the Patient Protection and Affordable Care Act [42 U.S.C. 18116];

(v) quality, safety, and oversight memoranda;

(vi) essential health benefits requirements; and

(vii) the Eleventh Revision of the International Classification of Diseases and other federally funded manuals, including the Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition.

(b) The Secretary of HHS shall promptly withdraw HHS's March 2, 2022, guidance document titled "HHS Notice and Guidance on Gender Affirming Care, Civil Rights and Patient Privacy" and, in consultation with the Attorney General, issue new guidance protecting whistleblowers who take action related to ensuring compliance with this order.

SEC. 6. *TRICARE*. The Department of Defense provides health insurance, through TRICARE, to nearly 2

million individuals under the age of 18. As appropriate and consistent with applicable law, the Secretary of Defense shall commence a rulemaking or sub-regulatory action to exclude chemical and surgical mutilation of children from TRICARE coverage and amend the TRICARE provider handbook to exclude chemical and surgical mutilation of children.

SEC. 7. *Requirements for Insurance Carriers*. The Director of the Office of Personnel Management, as appropriate and consistent with applicable law, shall:

(a) include provisions in the Federal Employee Health Benefits (FEHB) and Postal Service Health Benefits (PSHB) programs call letter for the 2026 Plan Year specifying that eligible carriers, including the Foreign Service Benefit Plan, will exclude coverage for pediatric transgender surgeries or hormone treatments; and

(b) negotiate to obtain appropriate corresponding reductions in FEHB and PSHB premiums.

SEC. 8. *Directives to the Department of Justice*. The Attorney General shall:

(a) review Department of Justice enforcement of section 116 of title 18, United States Code, and prioritize enforcement of protections against female genital mutilation;

(b) convene States' Attorneys General and other law enforcement officers to coordinate the enforcement of laws against female genital mutilation across all American States and Territories;

(c) prioritize investigations and take appropriate action to end deception of consumers, fraud, and violations of the [Federal] Food, Drug, and Cosmetic Act [21 U.S.C. 301 et seq.] by any entity that may be misleading the public about long-term side effects of chemical and surgical mutilation;

(d) in consultation with the Congress, work to draft, propose, and promote legislation to enact a private right of action for children and the parents of children whose healthy body parts have been damaged by medical professionals practicing chemical and surgical mutilation, which should include a lengthy statute of limitations; and

(e) prioritize investigations and take appropriate action to end child-abusive practices by so-called sanctuary States that facilitate stripping custody from parents who support the healthy development of their own children, including by considering the application of the Parental Kidnaping Prevention Act [of 1980, Pub. L. 96–611, see Tables for classification] and recognized constitutional rights.

SEC. 9. *Enforcing Adequate Progress*. Within 60 days of the date of this order, the heads of agencies with responsibilities under this order shall submit a single, combined report to the Assistant to the President for Domestic Policy, detailing progress in implementing this order and a timeline for future action. The Assistant to the President for Domestic Policy shall regularly convene the heads of agencies with responsibilities under this order (or their designees) to coordinate and prepare for this submission.

SEC. 10. *Severability*. If any provision of this order, or the application of any provision to any person or circumstances, is held to be invalid, the remainder of this order and the application of any of its other provisions to any other persons or circumstances shall not be affected thereby.

SEC. 11. *General Provisions*. (a) Nothing in this order shall be construed to impair or otherwise affect:

(i) the authority granted by law to an executive department or agency, or the head thereof; or

(ii) the functions of the Director of the Office of Management and Budget relating to budgetary, administrative, or legislative proposals.

(b) This order shall be implemented consistent with applicable law and subject to the availability of appropriations.

(c) This order is not intended to, and does not, create any right or benefit, substantive or procedural, enforceable at law or in equity by any party against the United States, its departments, agencies, or entities, its officers, employees, or agents, or any other person.

DONALD J. TRUMP.

§280h. Grants to promote childhood nutrition and physical activity

(a) In general

The Secretary, acting though the Director of the Centers for Disease Control and Prevention, shall award competitive grants to States and political subdivisions of States for the development and implementation of State and community-based intervention programs to promote good nutrition and physical activity in children and adolescents.

(b) Eligibility

To be eligible to receive a grant under this section a State or political subdivision of a State shall prepare and submit to the Secretary an application at such time, in such manner, and containing such

information as the Secretary may require, including a plan that describes—

(1) how the applicant proposes to develop a comprehensive program of school- and community-based approaches to encourage and promote good nutrition and appropriate levels of physical activity with respect to children or adolescents in local communities;

(2) the manner in which the applicant shall coordinate with appropriate State and local authorities, such as State and local school departments, State departments of health, chronic disease directors, State directors of programs under section 1786 of this title, 5-a-day coordinators, governors councils for physical activity and good nutrition, and State and local parks and recreation departments; and

(3) the manner in which the applicant will evaluate the effectiveness of the program carried out under this section.

(c) Use of funds

A State or political subdivision of a State shall use amount received under a grant under this section to—

(1) develop, implement, disseminate, and evaluate school- and community-based strategies in States to reduce inactivity and improve dietary choices among children and adolescents;

(2) expand opportunities for physical activity programs in school- and community-based settings; and

(3) develop, implement, and evaluate programs that promote good eating habits and physical activity including opportunities for children with cognitive and physical disabilities.

(d) Technical assistance

The Secretary may set-aside an amount not to exceed 10 percent of the amount appropriated for a fiscal year under subsection (h) to permit the Director of the Centers for Disease Control and Prevention to—

(1) provide States and political subdivisions of States with technical support in the development and implementation of programs under this section; and

(2) disseminate information about effective strategies and interventions in preventing and treating obesity through the promotion of good nutrition and physical activity.

(e) Limitation on administrative costs

Not to exceed 10 percent of the amount of a grant awarded to the State or political subdivision under subsection (a) for a fiscal year may be used by the State or political subdivision for administrative expenses.

(f) Term

A grant awarded under subsection (a) shall be for a term of 3 years.

(g) Definition

In this section, the term "children and adolescents" means individuals who do not exceed 18 years of age.

(h) Authorization of appropriations

There are authorized to be appropriated to carry out this section such sums as may be necessary for each of the fiscal years 2001 through 2005.

(July 1, 1944, ch. 373, title III, §399W, as added Pub. L. 106–310, div. A, title XXIV, §2401, Oct. 17, 2000, 114 Stat. 1158.)

EDITORIAL NOTES

CODIFICATION

Another section 399W of act July 1, 1944, was renumbered section 399V–1 and is classified to section 280g–12 of this title.

§280h–1. Applied research program

(a) In general

The Secretary, acting through the Centers for Disease Control and Prevention and in consultation with the Director of the National Institutes of Health, shall—

(1) conduct research to better understand the relationship between physical activity, diet, and health and factors that influence health-related behaviors;

(2) develop and evaluate strategies for the prevention and treatment of obesity to be used in community-based interventions and by health professionals;

(3) develop and evaluate strategies for the prevention and treatment of eating disorders, such as anorexia and bulimia;

(4) conduct research to establish the prevalence, consequences, and costs of childhood obesity and its effects in adulthood;

(5) identify behaviors and risk factors that contribute to obesity;

(6) evaluate materials and programs to provide nutrition education to parents and teachers of children in child care or pre-school and the food service staff of such child care and pre-school entities; and

(7) evaluate materials and programs that are designed to educate and encourage physical activity in child care and pre-school facilities.

(b) Authorization of appropriations

There are authorized to be appropriated to carry out this section such sums as may be necessary for each of the fiscal years 2001 through 2005.

(July 1, 1944, ch. 373, title III, §399X, as added Pub. L. 106–310, div. A, title XXIV, §2401, Oct. 17, 2000, 114 Stat. 1159.)

§280h–2. Education campaign

(a) In general

The Secretary, acting through the Director of the Centers for Disease Control and Prevention, and in collaboration with national, State, and local partners, physical activity organizations, nutrition experts, and health professional organizations, shall develop a national public campaign to promote and educate children and their parents concerning—

(1) the health risks associated with obesity, inactivity, and poor nutrition;

(2) ways in which to incorporate physical activity into daily living; and

(3) the benefits of good nutrition and strategies to improve eating habits.

(b) Authorization of appropriations

There are authorized to be appropriated to carry out this section such sums as may be necessary for each of the fiscal years 2001 through 2005.

(July 1, 1944, ch. 373, title III, §399Y, as added Pub. L. 106–310, div. A, title XXIV, §2401, Oct. 17, 2000, 114 Stat. 1160.)

§280h–3. Health professional education and training

(a) In general

The Secretary, acting through the Director of the Centers for Disease Control and Prevention, in collaboration with the Administrator of the Health Resources and Services Administration and the heads of other agencies, and in consultation with appropriate health professional associations, shall develop and carry out a program to educate and train health professionals in effective strategies to—

(1) better identify and assess patients with obesity or an eating disorder or patients at-risk of becoming obese or developing an eating disorder;

(2) counsel, refer, or treat patients with obesity or an eating disorder; and

(3) educate patients and their families about effective strategies to improve dietary habits and establish appropriate levels of physical activity.

(b) Authorization of appropriations

There are authorized to be appropriated to carry out this section such sums as may be necessary for each of the fiscal years 2001 through 2005.

(July 1, 1944, ch. 373, title III, §399Z, as added Pub. L. 106–310, div. A, title XXIV, §2401, Oct. 17, 2000, 114 Stat. 1160.)

STATUTORY NOTES AND RELATED SUBSIDIARIES

GUIDE ON EVIDENCE-BASED STRATEGIES FOR PUBLIC HEALTH DEPARTMENT OBESITY PREVENTION PROGRAMS

Pub. L. 116–260, div. BB, title III, §312, Dec. 27, 2020, 134 Stat. 2925, provided that:

"(a) DEVELOPMENT AND DISSEMINATION OF AN EVIDENCE-BASED STRATEGIES GUIDE .—The Secretary of Health and Human Services (referred to in this section as the 'Secretary'), acting through the Director of the Centers for Disease Control and Prevention, not later than 2 years after the date of enactment of this Act [Dec. 27, 2020], may—

"(1) develop a guide on evidence-based strategies for State, territorial, and local health departments to use to build and maintain effective obesity prevention and reduction programs, and, in consultation with Indian Tribes, Tribal organizations, and urban Indian organizations, a guide on such evidence-based strategies with respect to Indian Tribes and Tribal organizations for such Indian Tribes and Tribal organizations to use for such purpose, both of which guides shall—

"(A) describe an integrated program structure for implementing interventions proven to be effective in preventing and reducing the incidence of obesity; and

"(B) recommend—

"(i) optimal resources, including staffing and infrastructure, for promoting nutrition and obesity prevention and reduction; and

"(ii) strategies for effective obesity prevention programs for State, territorial, and local health departments, Indian Tribes, and Tribal organizations, including strategies related to—

"(I) the application of evidence-based and evidence-informed practices to prevent and reduce obesity rates;

"(II) the development, implementation, and evaluation of obesity prevention and reduction strategies for specific communities and populations;

"(III) demonstrated knowledge of obesity prevention practices that reduce associated preventable diseases, health conditions, death, and health care costs;

"(IV) best practices for the coordination of efforts to prevent and reduce obesity and related chronic diseases;

"(V) addressing the underlying risk factors and social determinants of health that impact obesity rates; and

"(VI) interdisciplinary coordination between relevant public health officials specializing in fields such as nutrition, physical activity, epidemiology, communications, and policy implementation, and collaboration between public health officials, community-based organizations, and others, as appropriate; and

"(2) disseminate the guides and current research, evidence-based practices, tools, and educational materials related to obesity prevention, consistent with the guides, to State, territorial, and local health departments, Indian Tribes, and Tribal organizations.

"(b) TECHNICAL ASSISTANCE.—The Secretary, acting through the Director of the Centers for Disease Control and Prevention, shall provide technical assistance to State, territorial, and local health departments, Indian Tribes, and Tribal organizations to support such health departments in implementing the guide developed under subsection (a)(1).

"(c) INDIAN TRIBES; TRIBAL ORGANIZATIONS; URBAN INDIAN ORGANIZATIONS.—In this section—

"(1) the terms 'Indian Tribe' and 'Tribal organization' have the meanings given the terms 'Indian tribe' and 'tribal organization', respectively, in section 4 of the Indian Self-Determination and Education Assistance Act (25 U.S.C. 5304); and

"(2) the term 'urban Indian organization' has the meaning given such term in section 4 of the Indian Health Care Improvement Act (25 U.S.C. 1603)."

EDUCATION AND TRAINING ON EATING DISORDERS

Pub. L. 114–255, div. B, title XIII, §13006, Dec. 13, 2016, 130 Stat. 1287, provided that: "The Secretary of Health and Human Services may facilitate the identification of model programs and materials for educating and training health professionals in effective strategies to—

"(1) identify individuals with eating disorders;

"(2) provide early intervention services for individuals with eating disorders;

"(3) refer patients with eating disorders for appropriate treatment;

"(4) prevent the development of eating disorders; and

"(5) provide appropriate treatment services for individuals with eating disorders."

§280h–4. Grants for the establishment of school-based health centers

(1) Program

The Secretary of Health and Human Services (in this section referred to as the "Secretary") shall establish a program to award grants to eligible entities to support the operation of school-based health centers.

(2) Eligibility

To be eligible for a grant under this section, an entity shall—

(A) be a school-based health center or a sponsoring facility of a school-based health center; and

(B) submit an application at such time, in such manner, and containing such information as the Secretary may require, including at a minimum an assurance that funds awarded under the grant shall not be used to provide any service that is not authorized or allowed by Federal, State, or local law.

(3) Preference

In awarding grants under this section,[1] the Secretary shall give preference to awarding grants for school-based health centers that serve a large population of children eligible for medical assistance under the State Medicaid plan under title XIX of the Social Security Act [42 U.S.C. 1396 et seq.] or under a waiver of such plan or children eligible for child health assistance under the State child health plan under title XXI of that Act (42 U.S.C. 1397aa et seq.).

(4) Limitation on use of funds

An eligible entity shall use funds provided under a grant awarded under this section only for expenditures for facilities (including the acquisition or improvement of land, or the acquisition, construction, expansion, replacement, or other improvement of any building or other facility), equipment, or similar expenditures, as specified by the Secretary. No funds provided under a grant awarded under this section [1] shall be used for expenditures for personnel or to provide health services.

(5) Appropriations

Out of any funds in the Treasury not otherwise appropriated, there is appropriated for each of fiscal years 2010 through 2013, $50,000,000 for the purpose of carrying out this section. Funds appropriated under this paragraph shall remain available until expended.

(6) Definitions

In this section, the terms "school-based health center" and "sponsoring facility" have the meanings given those terms in section 2110(c)(9) of the Social Security Act (42 U.S.C. 1397jj(c)(9)).

(Pub. L. 111–148, title IV, §4101(a), Mar. 23, 2010, 124 Stat. 546.)

EDITORIAL NOTES

REFERENCES IN TEXT

This section, referred to in par. (3) and in par. (4) the second place it appears, was in the original "this

section", meaning section 4101 of Pub. L. 111–148, which enacted this section and section 280h–5 of this title.

The Social Security Act, referred to in par. (3), is act Aug. 14, 1935, ch. 531, 49 Stat. 620. Titles XIX and XXI of the Act are classified generally to subchapters XIX (§1396 et seq.) and XXI (§1397aa et seq.), respectively, of chapter 7 of this title. For complete classification of this Act to the Code, see section 1305 of this title and Tables.

CODIFICATION

Section was enacted as part of the Patient Protection and Affordable Care Act, and not as part of the Public Health Service Act which comprises this chapter.

[1] See References in Text note below.

§280h–5. School-based health centers

(a) Definitions; establishment of criteria

In this section:

(1) Comprehensive primary health services

The term "comprehensive primary health services" means the core services offered by school-based health centers, which shall include the following:

(A) Physical

Comprehensive health assessments, diagnosis, and treatment of minor, acute, and chronic medical conditions, and referrals to, and follow-up for, specialty care and oral and vision health services.

(B) Mental health

Mental health and substance use disorder assessments, crisis intervention, counseling, treatment, and referral to a continuum of services including emergency psychiatric care, community support programs, inpatient care, and outpatient programs.

(2) Medically underserved children and adolescents

(A) In general

The term "medically underserved children and adolescents" means a population of children and adolescents who are residents of an area designated as a medically underserved area or a health professional shortage area by the Secretary.

(B) Criteria

The Secretary shall prescribe criteria for determining the specific shortages of personal health services for medically underserved children and adolescents under subparagraph (A) that shall—

(i) take into account any comments received by the Secretary from the chief executive officer of a State and local officials in a State; and

(ii) include factors indicative of the health status of such children and adolescents of an area, including the ability of the residents of such area to pay for health services, the accessibility of such services, the availability of health professionals to such children and adolescents, and other factors as determined appropriate by the Secretary.

(3) School-based health center

The term "school-based health center" means a health clinic that—

(A) meets the definition of a school-based health center under section 1397jj(c)(9)(A) of this title and is administered by a sponsoring facility (as defined in section 1397jj(c)(9)(B) of this title);

(B) provides, at a minimum, comprehensive primary health services during school hours to

children and adolescents by health professionals in accordance with established standards, community practice, reporting laws, and other State laws, including parental consent and notification laws that are not inconsistent with Federal law; and

(C) does not perform abortion services.

(b) Authority to award grants

The Secretary shall award grants for the costs of the operation of school-based health centers (referred to in this section as "SBHCs") that meet the requirements of this section.

(c) Applications

To be eligible to receive a grant under this section, an entity shall—

(1) be an SBHC (as defined in subsection (a)(3)); and

(2) submit to the Secretary an application at such time, in such manner, and containing—

(A) evidence that the applicant meets all criteria necessary to be designated an SBHC;

(B) evidence of local need for the services to be provided by the SBHC;

(C) an assurance that—

(i) SBHC services will be provided to those children and adolescents for whom parental or guardian consent has been obtained in cooperation with Federal, State, and local laws governing health care service provision to children and adolescents;

(ii) the SBHC has made and will continue to make every reasonable effort to establish and maintain collaborative relationships with other health care providers in the catchment area of the SBHC;

(iii) the SBHC will provide on-site access during the academic day when school is in session and 24-hour coverage through an on-call system and through its backup health providers to ensure access to services on a year-round basis when the school or the SBHC is closed;

(iv) the SBHC will be integrated into the school environment and will coordinate health services with school personnel, such as administrators, teachers, nurses, counselors, and support personnel, as well as with other community providers co-located at the school;

(v) the SBHC sponsoring facility assumes all responsibility for the SBHC administration, operations, and oversight; and

(vi) the SBHC will comply with Federal, State, and local laws concerning patient privacy and student records, including regulations promulgated under the Health Insurance Portability and Accountability Act of 1996 and section 1232g of title 20; and

(D) such other information as the Secretary may require.

(d) Preferences and consideration

In reviewing applications:

(1) The Secretary may give preference to applicants who demonstrate an ability to serve the following:

(A) Communities that have evidenced barriers to primary health care and mental health and substance use disorder prevention services for children and adolescents.

(B) Communities with high per capita numbers of children and adolescents who are uninsured, underinsured, or enrolled in public health insurance programs.

(C) Populations of children and adolescents that have historically demonstrated difficulty in accessing health and mental health and substance use disorder prevention services.

(2) The Secretary may give consideration to whether an applicant has received a grant under section 280h–4 of this title.

(e) Waiver of requirements

The Secretary may—

(1) under appropriate circumstances, waive the application of all or part of the requirements of this subsection with respect to an SBHC for not to exceed 2 years; and

(2) upon a showing of good cause, waive the requirement that the SBHC provide all required comprehensive primary health services for a designated period of time to be determined by the Secretary.

(f) Use of funds

(1) Funds

Funds awarded under a grant under this section—

(A) may be used for—

(i) acquiring and leasing equipment (including the costs of amortizing the principle of, and paying interest on, loans for such equipment);

(ii) providing training related to the provision of required comprehensive primary health services and additional health services;

(iii) the management and operation of health center programs;

(iv) the payment of salaries for physicians, nurses, and other personnel of the SBHC; and

(B) may not be used to provide abortions.

(2) Construction

The Secretary may award grants which may be used to pay the costs associated with expanding and modernizing existing buildings for use as an SBHC, including the purchase of trailers or manufactured buildings to install on the school property.

(3) Limitations

(A) In general

Any provider of services that is determined by a State to be in violation of a State law described in subsection (a)(3)(B) with respect to activities carried out at a [1] SBHC shall not be eligible to receive additional funding under this section.

(B) No overlapping grant period

No entity that has received funding under section 254b of this title for a grant period shall be eligible for a grant under this section for with respect to [1] the same grant period.

(g) Matching requirement

(1) In general

Each eligible entity that receives a grant under this section shall provide, from non-Federal sources, an amount equal to 20 percent of the amount of the grant (which may be provided in cash or in-kind) to carry out the activities supported by the grant.

(2) Waiver

The Secretary may waive all or part of the matching requirement described in paragraph (1) for any fiscal year for the SBHC if the Secretary determines that applying the matching requirement to the SBHC would result in serious hardship or an inability to carry out the purposes of this section.

(h) Supplement, not supplant

Grant funds provided under this section shall be used to supplement, not supplant, other Federal or State funds.

(i) Evaluation

The Secretary shall develop and implement a plan for evaluating SBHCs and monitoring quality performance under the awards made under this section.

(j) Age appropriate services

An eligible entity receiving funds under this section shall only provide age appropriate services through a [1] SBHC funded under this section to an individual.

(k) Parental consent

An eligible entity receiving funds under this section shall not provide services through a [1] SBHC funded under this section to an individual without the consent of the parent or guardian of such individual if such individual is considered a minor under applicable State law.

(l) Technical assistance

The Secretary shall provide technical assistance by grants or contracts awarded to private, nonprofit entities with demonstrated expertise related to school-based health centers. Such technical assistance, taking into account local and regional differences among school based [1] health centers, shall support such entities in providing services described in subsection (a)(1) pursuant to this section, including mental health and substance use disorder services, and may include technical assistance relating to program operations and support for the implementation of evidence-based or evidence-informed best practices related to the provision of high quality health care services to children and adolescents.

(m) Authorization of appropriations

For purposes of carrying out this section, there are authorized to be appropriated such sums as may be necessary for each of the fiscal years 2022 through 2026.

(July 1, 1944, ch. 373, title III, §399Z–1, as added and amended Pub. L. 111–148, title IV, §4101(b), title X, §10402(a), Mar. 23, 2010, 124 Stat. 547, 975; Pub. L. 116–260, div. BB, title III, §317, Dec. 27, 2020, 134 Stat. 2932; Pub. L. 117–328, div. FF, title I, §1401, Dec. 29, 2022, 136 Stat. 5699.)

EDITORIAL NOTES

REFERENCES IN TEXT

The Health Insurance Portability and Accountability Act of 1996, referred to in subsec. (c)(2)(C)(vi), is Pub. L. 104–191, Aug. 21, 1996, 110 Stat. 1936. For complete classification of this Act to the Code, see Short Title of 1996 Amendments note set out under section 201 of this title and Tables.

AMENDMENTS

2022—Subsecs. (l), (m). Pub. L. 117–328 added subsec. (l) and redesignated former subsec. (l) as (m).
2020—Subsec. (l). Pub. L. 116–260 substituted "2022 through 2026" for "2010 through 2014".
2010—Subsec. (a)(1)(A). Pub. L. 111–148, §10402(a), inserted "and vision" after "oral".

[1] So in original.

§280h–6. Infant and early childhood mental health promotion, intervention, and treatment

(a) Grants

The Secretary shall—

(1) award grants to eligible entities to develop, maintain, or enhance infant and early childhood mental health promotion, intervention, and treatment programs, including—

(A) programs for infants and children at significant risk of developing, showing early signs of, or having been diagnosed with mental illness, including a serious emotional disturbance; and

(B) multigenerational therapy and other services that support the caregiving relationship; and

(2) ensure that programs funded through grants under this section are evidence-informed or evidence-based models, practices, and methods that are, as appropriate, culturally and linguistically appropriate, and can be replicated in other appropriate settings.

(b) Eligible children and entities

In this section:

(1) Eligible child

The term "eligible child" means a child from birth to not more than 12 years of age who—

(A) is at risk for, shows early signs of, or has been diagnosed with a mental illness, including a serious emotional disturbance; and

(B) may benefit from infant and early childhood intervention or treatment programs or specialized preschool or elementary school programs that are evidence-based or that have been scientifically demonstrated to show promise but would benefit from further applied development.

(2) Eligible entity

The term "eligible entity" means a human services agency or nonprofit institution that—

(A) employs licensed mental health professionals who have specialized training and experience in infant and early childhood mental health assessment, diagnosis, and treatment, or is accredited or approved by the appropriate State agency, as applicable, to provide for children from infancy to 12 years of age mental health promotion, intervention, or treatment services; and

(B) provides services or programs described in subsection (a) that are evidence-based or that have been scientifically demonstrated to show promise but would benefit from further applied development.

(c) Application

An eligible entity seeking a grant under subsection (a) shall submit to the Secretary an application at such time, in such manner, and containing such information as the Secretary may require.

(d) Use of funds for early intervention and treatment programs

An eligible entity may use amounts awarded under a grant under subsection (a)(1) to carry out the following:

(1) Provide age-appropriate mental health promotion and early intervention services or mental illness treatment services, which may include specialized programs, for eligible children at significant risk of developing, showing early signs of, or having been diagnosed with a mental illness, including a serious emotional disturbance. Such services may include social and behavioral services as well as multigenerational therapy and other services that support the caregiving relationship.

(2) Provide training for health care professionals with expertise in infant and early childhood mental health care with respect to appropriate and relevant integration with other disciplines such as primary care clinicians, early intervention specialists, child welfare staff, home visitors, early care and education providers, and others who work with young children and families.

(3) Provide mental health consultation to personnel of early care and education programs (including licensed or regulated center-based and home-based child care, home visiting, preschool special education, and early intervention programs) who work with children and families.

(4) Provide training for mental health clinicians in infant and early childhood in promising and evidence-based practices and models for infant and early childhood mental health treatment and early intervention, including with regard to practices for identifying and treating mental illness and behavioral disorders of infants and children resulting from exposure or repeated exposure to adverse childhood experiences or childhood trauma.

(5) Provide age-appropriate assessment, diagnostic, and intervention services for eligible children, including early mental health promotion, intervention, and treatment services.

(e) Matching funds

The Secretary may not award a grant under this section to an eligible entity unless the eligible entity agrees, with respect to the costs to be incurred by the eligible entity in carrying out the activities described in subsection (d), to make available non-Federal contributions (in cash or in kind) toward such costs in an amount that is not less than 10 percent of the total amount of Federal funds provided in the grant.

(f) Technical assistance

The Secretary may, directly or by awarding grants or contracts to public and private nonprofit entities, provide training and technical assistance to eligible entities to carry out activities described in subsection (d).

(g) Authorization of appropriations

To carry out this section, there are authorized to be appropriated $50,000,000 for the period of fiscal years 2023 through 2027.

(July 1, 1944, ch. 373, title III, §399Z–2, as added Pub. L. 114–255, div. B, title X, §10006, Dec. 13, 2016, 130 Stat. 1267; amended Pub. L. 117–328, div. FF, title I, §1402, Dec. 29, 2022, 136 Stat. 5699.)

EDITORIAL NOTES

AMENDMENTS

2022—Subsec. (f). Pub. L. 117–328, §1402(2), added subsec. (f). Former subsec. (f) redesignated (g).

Subsec. (g). Pub. L. 117–328, §1402(1), (3), redesignated subsec. (f) as (g) and substituted "$50,000,000 for the period of fiscal years 2023 through 2027" for "$20,000,000 for the period of fiscal years 2018 through 2022".

§280h–7. Grants to improve trauma support services and mental health care for children and youth in educational settings

(a) Grants, contracts, and cooperative agreements authorized

The Secretary, in coordination with the Assistant Secretary for Mental Health and Substance Use, is authorized to award grants to, or enter into contracts or cooperative agreements with, State educational agencies, local educational agencies, Indian Tribes (as defined in section 5304 of title 25) or their tribal educational agencies, a school operated by the Bureau of Indian Education, a Regional Corporation, or a Native Hawaiian educational organization, for the purpose of increasing student access to evidence-based trauma support services and mental health care by developing innovative initiatives, activities, or programs to link local school systems with local trauma-informed support and mental health systems, including those under the Indian Health Service.

(b) Duration

With respect to a grant, contract, or cooperative agreement awarded or entered into under this section, the period during which payments under such grant, contract or agreement are made to the recipient may not exceed 4 years.

(c) Use of funds

An entity that receives a grant, contract, or cooperative agreement under this section shall use amounts made available through such grant, contract, or cooperative agreement for evidence-based activities, which shall include any of the following:

(1) Collaborative efforts between school-based service systems and trauma-informed support and mental health service systems to provide, develop, or improve prevention, screening, referral, and treatment and support services to students, such as providing trauma screenings to identify students in need of specialized support.

(2) To implement schoolwide positive behavioral interventions and supports, or other trauma-informed models of support.

(3) To provide professional development to teachers, teacher assistants, school leaders, specialized instructional support personnel, and mental health professionals that—

(A) fosters safe and stable learning environments that prevent and mitigate the effects of trauma, including through social and emotional learning;

(B) improves school capacity to identify, refer, and provide services to students in need of

trauma support or behavioral health services; or

(C) reflects the best practices for trauma-informed identification, referral, and support developed by the Task Force under section 7132.

(4) Services at a full-service community school that focuses on trauma-informed supports, which may include a full-time site coordinator, or other activities consistent with section 7275 of title 20.

(5) Engaging families and communities in efforts to increase awareness of child and youth trauma, which may include sharing best practices with law enforcement regarding trauma-informed care and working with mental health professionals to provide interventions, as well as longer term coordinated care within the community for children and youth who have experienced trauma and their families.

(6) To provide technical assistance to school systems and mental health agencies.

(7) To evaluate the effectiveness of the program carried out under this section in increasing student access to evidence-based trauma support services and mental health care.

(8) To establish partnerships with or provide subgrants to Head Start agencies (including Early Head Start agencies), public and private preschool programs, child care programs (including home-based providers), or other entities described in subsection (a), to include such entities described in this paragraph in the evidence-based trauma initiatives, activities, support services, and mental health systems established under this section in order to provide, develop, or improve prevention, screening, referral, and treatment and support services to young children and their families.

(d) Applications

To be eligible to receive a grant, contract, or cooperative agreement under this section, an entity described in subsection (a) shall submit an application to the Secretary at such time, in such manner, and containing such information as the Secretary may reasonably require, which shall include the following:

(1) A description of the innovative initiatives, activities, or programs to be funded under the grant, contract, or cooperative agreement, including how such program will increase access to evidence-based trauma support services and mental health care for students, and, as applicable, the families of such students.

(2) A description of how the program will provide linguistically appropriate and culturally competent services.

(3) A description of how the program will support students and the school in improving the school climate in order to support an environment conducive to learning.

(4) An assurance that—

(A) persons providing services under the grant, contract, or cooperative agreement are adequately trained to provide such services; and

(B) teachers, school leaders, administrators, specialized instructional support personnel, representatives of local Indian Tribes or tribal organizations as appropriate, other school personnel, and parents or guardians of students participating in services under this section will be engaged and involved in the design and implementation of the services.

(5) A description of how the applicant will support and integrate existing school-based services with the program in order to provide mental health services for students, as appropriate.

(6) A description of the entities in the community with which the applicant will partner or to which the applicant will provide subgrants in accordance with subsection (c)(8).

(e) Interagency agreements

(1) Local interagency agreements

To ensure the provision of the services described in subsection (c), a recipient of a grant, contract, or cooperative agreement under this section, or their designee, shall establish a local interagency agreement among local educational agencies, agencies responsible for early childhood

education programs, Head Start agencies (including Early Head Start agencies), juvenile justice authorities, mental health agencies, child welfare agencies, and other relevant agencies, authorities, or entities in the community that will be involved in the provision of such services.

(2) Contents

In ensuring the provision of the services described in subsection (c), the local interagency agreement shall specify with respect to each agency, authority, or entity that is a party to such agreement—

(A) the financial responsibility for the services;

(B) the conditions and terms of responsibility for the services, including quality, accountability, and coordination of the services; and

(C) the conditions and terms of reimbursement among such agencies, authorities, or entities, including procedures for dispute resolution.

(f) Evaluation

The Secretary shall reserve not more than 3 percent of the funds made available under subsection (l) for each fiscal year to—

(1) conduct a rigorous, independent evaluation of the activities funded under this section; and

(2) disseminate and promote the utilization of evidence-based practices regarding trauma support services and mental health care.

(g) Distribution of awards

The Secretary shall ensure that grants, contracts, and cooperative agreements awarded or entered into under this section are equitably distributed among the geographical regions of the United States and among tribal, urban, suburban, and rural populations.

(h) Rule of construction

Nothing in this section shall be construed—

(1) to prohibit an entity involved with a program carried out under this section from reporting a crime that is committed by a student to appropriate authorities; or

(2) to prevent Federal, State, and tribal law enforcement and judicial authorities from exercising their responsibilities with regard to the application of Federal, tribal, and State law to crimes committed by a student.

(i) Supplement, not supplant

Any services provided through programs carried out under this section shall supplement, and not supplant, existing mental health services, including any special education and related services provided under the Individuals with Disabilities Education Act (20 U.S.C. 1400 et seq.).

(j) Consultation with Indian Tribes

In carrying out subsection (a), the Secretary shall, in a timely manner, meaningfully consult with Indian Tribes and their representatives to ensure notice of eligibility.

(k) Definitions

In this section:

(1) Elementary school

The term "elementary school" has the meaning given such term in section 7801 of title 20.

(2) Evidence-based

The term "evidence-based" has the meaning given such term in section 7801(21)(A)(i) of title 20.

(3) Native Hawaiian educational organization

The term "Native Hawaiian educational organization" has the meaning given such term in section 7517 of title 20.

(4) Local educational agency

The term "local educational agency" has the meaning given such term in section 7801 of title 20.

(5) Regional Corporation

The term "Regional Corporation" has the meaning given the term in section 1602 of title 43).[1]

(6) School

The term "school" means a public elementary school or public secondary school.

(7) School leader

The term "school leader" has the meaning given such term in section 7801 of title 20.

(8) Secondary school

The term "secondary school" has the meaning given such term in section 7801 of title 20.

(9) Secretary

The term "Secretary" means the Secretary of Education.

(10) Specialized instructional support personnel

The term "specialized instructional support personnel" has the meaning given such term in section 7801 of title 20.

(11) State educational agency

The term "State educational agency" has the meaning given such term in section 7801 of title 20.

(l) Authorization of appropriations

There is authorized to be appropriated to carry out this section, $50,000,000 for each of fiscal years 2019 through 2023.

(Pub. L. 115–271, title VII, §7134, Oct. 24, 2018, 132 Stat. 4051.)

EDITORIAL NOTES

REFERENCES IN TEXT

Section 7132, referred to in subsec. (c)(3)(C), is section 7132 of Pub. L. 115–271, title VII, Oct. 24, 2018, 132 Stat. 4046, which is not classified to the Code.

The Individuals with Disabilities Education Act, referred to in subsec. (i), is title VI of Pub. L. 91–230, Apr. 13, 1970, 84 Stat. 175, which is classified generally to chapter 33 (§1400 et seq.) of Title 20, Education. For complete classification of this Act to the Code, see section 1400 of Title 20 and Tables.

CODIFICATION

Section was enacted as part of the Substance Use–Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act, also known as the SUPPORT for Patients and Communities Act, and not as part of the Public Health Service Act which comprises this chapter.

[1] *So in original.*

§280h–8. Recognizing early childhood trauma related to substance abuse

(a) Dissemination of information

The Secretary of Health and Human Services shall disseminate information, resources, and, if requested, technical assistance to early childhood care and education providers and professionals working with young children on—

(1) ways to properly recognize children who may be impacted by trauma, including trauma related to substance use by a family member or other adult; and

(2) how to respond appropriately in order to provide for the safety and well-being of young

children and their families.

(b) Goals

The information, resources, and technical assistance provided under subsection (a) shall—

(1) educate early childhood care and education providers and professionals working with young children on understanding and identifying the early signs and risk factors of children who might be impacted by trauma, including trauma due to exposure to substance use;

(2) suggest age-appropriate communication tools, procedures, and practices for trauma-informed care, including ways to prevent or mitigate the effects of trauma;

(3) provide options for responding to children impacted by trauma, including due to exposure to substance use, that consider the needs of the child and family, including recommending resources and referrals for evidence-based services to support such family; and

(4) promote whole-family and multi-generational approaches to keep families safely together when it is in the best interest of the child.

(c) Coordination

The Secretary of Health and Human Services shall coordinate with the task force to develop best practices for trauma-informed identification, referral, and support authorized under section 7132 in disseminating the information, resources, and technical assistance described under subsection (b).

(d) Rule of construction

Such information, resources, and if applicable, technical assistance, shall not be construed to amend the requirements under—

(1) the Child Care and Development Block Grant Act of 1990 (42 U.S.C. 9858 et seq.);

(2) the Head Start Act (42 U.S.C. 9831 et seq.); or

(3) the Individuals with Disabilities Education Act (20 U.S.C. 1400 et seq.).

(Pub. L. 115–271, title VII, §7135, Oct. 24, 2018, 132 Stat. 4055.)

EDITORIAL NOTES

REFERENCES IN TEXT

Section 7132, referred to in subsec. (c), is section 7132 of Pub. L. 115–271, title VII, Oct. 24, 2018, 132 Stat. 4046, which is not classified to the Code.

The Child Care and Development Block Grant Act of 1990, referred to in subsec. (d)(1), is subchapter C (§658A et seq.) of chapter 8 of subtitle A of title VI of Pub. L. 97–35, as added by Pub. L. 101–508, title V, §5082(2), Nov. 5, 1990, 104 Stat. 1388–236, which is classified generally to subchapter II–B (§9857 et seq.) of chapter 105 of this title. For complete classification of this Act to the Code, see section 9857(a) of this title and Tables.

The Head Start Act, referred to in subsec. (d)(2), is subchapter B (§635 et seq.) of chapter 8 of subtitle A of title VI of Pub. L. 97–35, Aug. 13, 1981, 95 Stat. 499, which is classified generally to subchapter II (§9831 et seq.) of chapter 105 of this title. For complete classification of this Act to the Code, see Short Title note set out under section 9801 of this title and Tables.

The Individuals with Disabilities Education Act, referred to in subsec. (d)(3), is title VI of Pub. L. 91–230, Apr. 13, 1970, 84 Stat. 175, which is classified generally to chapter 33 (§1400 et seq.) of Title 20, Education. For complete classification of this Act to the Code, see section 1400 of Title 20 and Tables.

CODIFICATION

Section was enacted as part of the Substance Use–Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act, also known as the SUPPORT for Patients and Communities Act, and not as part of the Public Health Service Act which comprises this chapter.

PART R—PROGRAMS RELATING TO AUTISM

§280i. Developmental disabilities surveillance and research program

(a) Autism spectrum disorder and other developmental disabilities

(1) In general

The Secretary, acting through the Director of the Centers for Disease Control and Prevention, may award grants or cooperative agreements to eligible entities for the collection, analysis, and reporting of State epidemiological data for children and adults with autism spectrum disorder and other developmental disabilities. An eligible entity shall assist with the development and coordination of State autism spectrum disorder and other developmental disability surveillance efforts within a region. In making such awards, the Secretary may provide direct technical assistance in lieu of cash.

(2) Data standards

In submitting epidemiological data to the Secretary pursuant to paragraph (1), an eligible entity shall report data according to guidelines prescribed by the Director of the Centers for Disease Control and Prevention, after consultation with relevant State, local, and Tribal public health officials, private sector developmental disability researchers, and advocates for individuals with autism spectrum disorder and other developmental disabilities.

(3) Eligibility

To be eligible to receive an award under paragraph (1), an entity shall be a public or nonprofit private entity (including a health department of a State or a political subdivision of a State, a university, any other educational institution, an Indian Tribe, or a Tribal organization), and submit to the Secretary an application at such time, in such manner, and containing such information as the Secretary may require.

(b) Centers of excellence in autism spectrum disorder epidemiology

(1) In general

The Secretary, acting through the Director of the Centers for Disease Control and Prevention, shall, subject to the availability of appropriations, award grants or cooperative agreements for the establishment or support of regional centers of excellence in autism spectrum disorder and other developmental disabilities epidemiology for the purpose of collecting and analyzing information on the number, incidence, correlates, and causes of autism spectrum disorder and other developmental disabilities for children and adults across the lifespan.

(2) Requirements

To be eligible to receive a grant or cooperative agreement under paragraph (1), an entity shall submit to the Secretary an application containing such agreements and information as the Secretary may require, including an agreement that the center to be established or supported under the grant or cooperative agreement shall operate in accordance with the following:

(A) The center will collect, analyze, and report autism spectrum disorder and other developmental disability data according to guidelines prescribed by the Director of the Centers for Disease Control and Prevention, after consultation with State, local, and Tribal public health officials, private sector developmental disability researchers, advocates for individuals with autism spectrum disorder, and advocates for individuals with other developmental disabilities.

(B) The center will develop or extend an area of special research expertise (including genetics, epigenetics, and epidemiological research related to environmental exposures), immunology, and other relevant research specialty areas.

(C) The center will identify eligible cases and controls through its surveillance system and conduct research into factors which may cause or increase the risk of autism spectrum disorder and other developmental disabilities.

(c) Federal response

The Secretary shall coordinate the Federal response to requests for assistance from State health, mental health, and education department officials regarding potential or alleged autism spectrum

disorder or developmental disability clusters.

(d) Definitions

In this part:

(1) Indian Tribe; Tribal organization

The terms "Indian Tribe" and "Tribal organization" have the meanings given such terms in section 1603 of title 25.

(2) Other developmental disabilities

The term "other developmental disabilities" has the meaning given the term "developmental disability" in section 15002(8) of this title.

(3) State

The term "State" means each of the several States, the District of Columbia, the Commonwealth of Puerto Rico, American Samoa, Guam, the Commonwealth of the Northern Mariana Islands, the Virgin Islands, and the Trust Territory of the Pacific Islands.

(e) Sunset

This section shall not apply after September 30, 2029.

(July 1, 1944, ch. 373, title III, §399AA, as added Pub. L. 109–416, §3(a), Dec. 19, 2006, 120 Stat. 2822; amended Pub. L. 112–32, §2(1), Sept. 30, 2011, 125 Stat. 361; Pub. L. 113–157, §3, Aug. 8, 2014, 128 Stat. 1831; Pub. L. 116–60, §3(a), Sept. 30, 2019, 133 Stat. 1111; Pub. L. 118–83, div. B, title II, §201(a), Sept. 26, 2024, 138 Stat. 1537; Pub. L. 118–180, §3(a), Dec. 23, 2024, 138 Stat. 2615.)

EDITORIAL NOTES

AMENDMENTS

2024—Subsec. (a)(3). Pub. L. 118–180, §3(a)(1), substituted "an Indian Tribe, or a Tribal organization" for "an Indian tribe, or a tribal organization".

Subsec. (b)(1). Pub. L. 118–180, §3(a)(2), inserted "across the lifespan" before period at end.

Subsec. (d)(1). Pub. L. 118–180, §3(a)(3), substituted "TRIBE; TRIBAL" for "TRIBE; TRIBAL" in heading of original Act which appears in heading as "Tribe; Tribal" and substituted "Tribe" for "tribe" and "Tribal" for "tribal" in text.

Subsec. (e). Pub. L. 118–180, §3(a)(4), substituted "September 30, 2029" for "December 20, 2024".

Pub. L. 118–83 substituted "December 20, 2024" for "September 30, 2024".

2019—Subsec. (a)(1). Pub. L. 116–60, §3(a)(1), substituted "adults with autism spectrum disorder" for "adults on autism spectrum disorder".

Subsec. (a)(2). Pub. L. 116–60, §3(a)(2), substituted "State, local, and Tribal public health officials" for "State and local public health officials" and "and other developmental disabilities" for "or other developmental disabilities".

Subsec. (a)(3). Pub. L. 116–60, §3(a)(3), substituted "a university, any other educational institution, an Indian tribe, or a tribal organization" for "a university, or any other educational institution".

Subsec. (b)(2)(A). Pub. L. 116–60, §3(a)(4), substituted "State, local, and Tribal public health officials, private sector developmental disability researchers, advocates for individuals with autism spectrum disorder, and advocates for individuals with other developmental disabilities" for "relevant State and local public health officials, private sector developmental disability researchers, and advocates for individuals with developmental disabilities".

Subsec. (d). Pub. L. 116–60, §3(a)(5), added par. (1) and redesignated former pars. (1) and (2) as (2) and (3), respectively.

Subsec. (e). Pub. L. 116–60, §3(a)(6), substituted "2024" for "2019".

2014—Subsec. (a)(1). Pub. L. 113–157, §3(1), inserted "for children and adults" after "reporting of State epidemiological data".

Subsec. (b)(1). Pub. L. 113–157, §3(2), substituted "establishment or support of regional centers of excellence" for "establishment of regional centers of excellence" and inserted "for children and adults" before period at end.

Subsec. (b)(2). Pub. L. 113–157, §3(3), substituted "center to be established or supported" for "center to be established" in introductory provisions.

Subsec. (e). Pub. L. 113–157, §3(4), substituted "2019" for "2014".

2011—Subsec. (e). Pub. L. 112–32 substituted "2014" for "2011".

STATUTORY NOTES AND RELATED SUBSIDIARIES

TECHNICAL ASSISTANCE TO IMPROVE ACCESS TO COMMUNICATION TOOLS

Pub. L. 118–180, §4, Dec. 23, 2024, 138 Stat. 2619, provided that:

"(a) IN GENERAL.—The Secretary of Health and Human Services (referred to in this section as the 'Secretary') may, at the request of a State, Indian Tribe, Tribal organization, locality, or territory, provide training and technical assistance to such jurisdiction on the manner in which Federal funding administered by the Secretary may be used to provide individuals with autism spectrum disorder and other developmental disabilities with access to evidence-based services, tools, and technologies that support communication needs.

"(b) ANNUAL REPORT.—The Secretary shall annually prepare and submit to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives a report summarizing any technical assistance provided by the Secretary in the preceding fiscal year under subsection (a) and any advancements in the development or evaluation of such evidence-based services, tools, and technologies."

NATIONAL AUTISM SPECTRUM DISORDER INITIATIVE

Pub. L. 113–157, §2, Aug. 8, 2014, 128 Stat. 1831, provided that:

"(a) IN GENERAL.—The Secretary of Health and Human Services shall designate an existing official within the Department of Health and Human Services to oversee, in consultation with the Secretaries of Defense and Education, national autism spectrum disorder research, services, and support activities.

"(b) DUTIES.—The official designated under subsection (a) shall—

"(1) implement autism spectrum disorder activities, taking into account the strategic plan developed by the Interagency Autism Coordinating Committee under section 399CC(b) of the Public Health Service Act (42 U.S.C. 280i–2(b)); and

"(2) ensure that autism spectrum disorder activities of the Department of Health and Human Services and of other Federal departments and agencies are not unnecessarily duplicative."

EXECUTIVE DOCUMENTS

TERMINATION OF TRUST TERRITORY OF THE PACIFIC ISLANDS

For termination of Trust Territory of the Pacific Islands, see note set out preceding section 1681 of Title 48, Territories and Insular Possessions.

§280i–1. Autism education, early detection, and intervention

(a) Purpose

It is the purpose of this section—

(1) to increase awareness, reduce barriers to screening and diagnosis, promote evidence-based interventions for individuals with autism spectrum disorder and other developmental disabilities, and train professionals to utilize valid and reliable screening tools to diagnose or rule out and provide evidence-based interventions for individuals with autism spectrum disorder and other developmental disabilities across their lifespan; and

(2) to conduct activities under this section with a focus on an interdisciplinary approach (as defined in programs developed under section 501(a)(2) of the Social Security Act [42 U.S.C. 701(a)(2)]) that will also focus on specific issues for children who are not receiving an early diagnosis and subsequent interventions.

(b) In general

The Secretary shall, subject to the availability of appropriations, establish and evaluate activities to—

(1) provide culturally and linguistically appropriate information and education on autism spectrum disorder and other developmental disabilities to increase public awareness of developmental milestones;

(2) promote research, which may include research that takes a community-based approach, into the development and validation of reliable screening and diagnostic tools for individuals with autism spectrum disorder and other developmental disabilities and disseminate information regarding those screening and diagnostic tools;

(3) promote early screening of individuals at increased likelihood for autism spectrum disorder and other developmental disabilities as early as practicable, given evidence-based screening techniques and interventions;

(4) promote evidence-based screening techniques and interventions for individuals with autism spectrum disorder and other developmental disabilities across their lifespan, which may give consideration to the perspectives of parents and guardians;

(5) increase the number of individuals who are able to confirm or rule out a diagnosis of autism spectrum disorder and other developmental disabilities;

(6) increase the number of individuals able to provide evidence-based interventions for individuals diagnosed with autism spectrum disorder or other developmental disabilities; and

(7) promote the use of evidence-based interventions for individuals at increased likelihood for autism spectrum disorder and other developmental disabilities as early as practicable.

(c) Information and education

(1) In general

In carrying out subsection (b)(1), the Secretary, in collaboration with the Secretary of Education and the Secretary of Agriculture, shall, subject to the availability of appropriations, provide culturally and linguistically appropriate information regarding autism spectrum disorder and other developmental disabilities, risk factors, characteristics, identification, diagnosis or rule out, and evidence-based interventions to meet the needs of individuals with autism spectrum disorder and other developmental disabilities across their lifespan and the needs of their families through—

(A) Federal programs, including—

(i) the Head Start program;

(ii) the Early Start program;

(iii) the Healthy Start program;

(iv) programs under the Child Care and Development Block Grant Act of 1990 [42 U.S.C. 9857 et seq.];

(v) programs under title XIX of the Social Security Act [42 U.S.C. 1396 et seq.] (particularly the Medicaid Early and Periodic Screening, Diagnosis and Treatment Program);

(vi) the program under title XXI of the Social Security Act [42 U.S.C. 1397aa et seq.] (the State Children's Health Insurance Program);

(vii) the program under title V of the Social Security Act [42 U.S.C. 701 et seq.] (the Maternal and Child Health Block Grant Program);

(viii) the program under parts B and C of the Individuals with Disabilities Education Act [20 U.S.C. 1411 et seq., 1431 et seq.];

(ix) the special supplemental nutrition program for women, infants, and children established under section 1786 of this title; and

(x) the State grant program under the Rehabilitation Act of 1973 [29 U.S.C. 701 et seq.].

(B) State licensed child care facilities; and

(C) other community-based organizations or points of entry for individuals with autism spectrum disorder and other developmental disabilities to receive services.

(2) Lead agency

(A) Designation

As a condition on the provision of assistance or the conduct of activities under this section

with respect to a State, the Secretary may require the Governor of the State—

(i) to designate a public agency as a lead agency to coordinate the activities provided for under paragraph (1) in the State at the State level; and

(ii) acting through such lead agency, to make available to individuals and their family members, guardians, advocates, or authorized representatives; providers; and other appropriate individuals in the State, comprehensive culturally and linguistically appropriate information about State and local resources regarding autism spectrum disorder and other developmental disabilities, risk factors, characteristics, identification, diagnosis or rule out, available services and supports (which may include respite care for caregivers of individuals with autism spectrum disorder or other developmental disabilities), and evidence-based interventions.

(B) Requirements of agency

In designating the lead agency under subparagraph (A)(i), the Governor shall—

(i) select an agency that has demonstrated experience and expertise in—

(I) autism spectrum disorder and other developmental disability issues; and

(II) developing, implementing, conducting, and administering programs and delivering education, information, and referral services (including technology-based curriculum-development services) to individuals with autism spectrum disorder and developmental disabilities and their family members, guardians, advocates or authorized representatives, providers, and other appropriate individuals locally and across the State; and

(ii) consider input from individuals with autism spectrum disorder and developmental disabilities and their family members, guardians, advocates or authorized representatives, providers, and other appropriate individuals.

(C) Information

Information under subparagraph (A)(ii) shall be provided through—

(i) toll-free telephone numbers;

(ii) Internet websites;

(iii) mailings; or

(iv) such other means as the Governor may require.

(d) Tools

(1) In general

To promote the use of valid and reliable screening tools for autism spectrum disorder and other developmental disabilities, the Secretary shall develop a curriculum for continuing education to assist individuals in recognizing the need for valid and reliable screening tools and the use of such tools.

(2) Collection, storage, coordination, and availability

The Secretary, in collaboration with the Secretary of Education, shall provide for the collection, storage, coordination, and public availability of tools described in paragraph (1), educational materials and other products that are used by the Federal programs referred to in subsection (c)(1)(A), as well as—

(A) programs authorized under the Developmental Disabilities Assistance and Bill of Rights Act of 2000 [42 U.S.C. 15001 et seq.];

(B) early intervention programs or interagency coordinating councils authorized under part C of the Individuals with Disabilities Education Act [20 U.S.C. 1431 et seq.]; and

(C) children with special health care needs programs authorized under title V of the Social Security Act [42 U.S.C. 701 et seq.].

(3) Required sharing

In establishing mechanisms and entities under this subsection, the Secretary, and the Secretary

of Education, shall ensure the sharing of tools, materials, and products developed under this subsection among entities receiving funding under this section.

(e) Diagnosis

(1) Training

The Secretary, in coordination with activities conducted under title V of the Social Security Act [42 U.S.C. 701 et seq.], shall, subject to the availability of appropriations, expand, and strengthen the capacity of, existing interdisciplinary training opportunities or opportunities to increase the number of sites able to diagnose or rule out individuals with autism spectrum disorder or other developmental disabilities across their lifespan and ensure that—

(A) competitive grants or cooperative agreements are awarded to public or nonprofit agencies, including institutions of higher education, to expand and strengthen the capacity of existing, or, in States that do not have such a program, develop new, maternal and child health interdisciplinary leadership education in neurodevelopmental and related disabilities programs (similar to the programs developed under section 501(a)(2) of the Social Security Act [42 U.S.C. 701(a)(2)]);

(B) trainees under such training programs—

(i) receive an appropriate balance of academic, clinical, and community opportunities;

(ii) are culturally competent;

(iii) are ethnically diverse;

(iv) demonstrate a capacity to evaluate, diagnose or rule out, develop, and provide evidence-based interventions to individuals with autism spectrum disorder and other developmental disabilities across their lifespan; and

(v) demonstrate an ability to use a family-centered approach, which may include collaborating with research centers or networks to provide training for providers of respite care (as defined in section 300ii of this title) or other providers, as applicable; and

(C) program sites—

(i) provide culturally and linguistically appropriate services;

(ii) take a multidisciplinary approach and have experience working with underserved populations; and

(iii) identify opportunities to partner with community-based organizations to expand the capacity of communities to serve individuals with autism spectrum disorder or other developmental disabilities.

(2) Developmental-behavioral pediatrician training programs

(A) In general

In making awards under this subsection, the Secretary may prioritize awards to applicants that are developmental-behavioral pediatrician training programs located in rural or underserved areas.

(B) Definition of underserved area

In this paragraph, the term "underserved area" means—

(i) a health professional shortage area (as defined in section 254e(a)(1)(A) of this title); and

(ii) an urban or rural area designated by the Secretary as an area with a shortage of personal health services (as described in section 254b(b)(3)(A) of this title).

(C) Report

Not later than 2 years after December 23, 2024, the Secretary shall submit to the Committee on Energy and Commerce of the House of Representatives and the Committee on Health, Education, Labor, and Pensions of the Senate a report that examines the need for, and feasibility of, expanding the developmental-behavioral pediatrician training programs described in subparagraph (A).

(3) Technical assistance

The Secretary may award one or more grants under this section to provide technical assistance to the network of interdisciplinary training programs.

(4) Best practices

The Secretary shall promote research into additional valid and reliable tools for shortening the time required to confirm or rule out a diagnosis of autism spectrum disorder or other developmental disabilities and detecting individuals with autism spectrum disorder or other developmental disabilities at an earlier age.

(f) Intervention

The Secretary shall promote research through grants or contracts, which may include grants or contracts to research centers or networks, to—

(1) develop and evaluate evidence-based practices and interventions to improve outcomes for individuals with autism spectrum disorder or other developmental disabilities by addressing physical and behavioral health and communication needs of such individuals across the lifespan;

(2) develop guidelines for such evidence-based practices and interventions; and

(3) disseminate information related to such evidence-based practices and interventions and guidelines.

(g) Sunset

This section shall not apply after September 30, 2029.

(July 1, 1944, ch. 373, title III, §399BB, as added Pub. L. 109–416, §3(a), Dec. 19, 2006, 120 Stat. 2823; amended Pub. L. 112–32, §2(2), Sept. 30, 2011, 125 Stat. 361; Pub. L. 113–157, §4, Aug. 8, 2014, 128 Stat. 1831; Pub. L. 116–60, §3(b), Sept. 30, 2019, 133 Stat. 1111; Pub. L. 118–83, div. B, title II, §201(b), Sept. 26, 2024, 138 Stat. 1537; Pub. L. 118–180, §3(b), Dec. 23, 2024, 138 Stat. 2616.)

EDITORIAL NOTES

REFERENCES IN TEXT

The Child Care and Development Block Grant Act of 1990, referred to in subsec. (c)(1)(A)(iv), is subchapter C (§658A et seq.) of chapter 8 of subtitle A of title VI of Pub. L. 97–35, as added by Pub. L. 101–508, title V, §5082(2), Nov. 5, 1990, 104 Stat. 1388–236, which is classified generally to subchapter II–B (§9857 et seq.) of chapter 105 of this title. For complete classification of this Act to the Code, see section 9857(a) of this title and Tables.

The Social Security Act, referred to in subsecs. (c)(1)(A)(v)–(vii), (d)(2)(C), and (e)(1), is act Aug. 14, 1935, ch. 531, 49 Stat. 620. Titles V, XIX, and XXI of the Act are classified generally to subchapters V (§701 et seq.), XIX (§1396 et seq.), and XXI (§1397aa et seq.), respectively, of chapter 7 of this title. For complete classification of this Act to the Code, see section 1305 of this title and Tables.

The Individuals with Disabilities Education Act, referred to in subsecs. (c)(1)(A)(viii) and (d)(2)(B), is title VI of Pub. L. 91–230, Apr. 13, 1970, 84 Stat. 175. Parts B and C of the Act are classified generally to subchapters II (§1411 et seq.) and III (§1431 et seq.), respectively, of chapter 33 of Title 20, Education. For complete classification of this Act to the Code, see section 1400 of Title 20 and Tables.

The Rehabilitation Act of 1973, referred to in subsec. (c)(1)(A)(x), is Pub. L. 93–112, Sept. 26, 1973, 87 Stat. 355, which is classified principally to chapter 16 (§701 et seq.) of Title 29, Labor. For complete classification of this Act to the Code, see Short Title note set out under section 701 of Title 29 and Tables.

The Developmental Disabilities Assistance and Bill of Rights Act of 2000, referred to in subsec. (d)(2)(A), is Pub. L. 106–402, Oct. 30, 2000, 114 Stat. 1677, which is classified principally to chapter 144 (§15001 et seq.) of this title. For complete classification of this Act to the Code, see Short Title note set out under section 15001 of this title and Tables.

AMENDMENTS

2024—Subsec. (b)(1). Pub. L. 118–180, §3(b)(1), substituted "culturally and linguistically appropriate information" for "culturally competent information".

Subsec. (b)(2). Pub. L. 118–180, §3(b)(2), substituted "promote research, which may include research that takes a community-based approach," for "promote research" and, in two places, "screening and diagnostic

tools" for "screening tools".

Subsec. (b)(3). Pub. L. 118–180, §3(b)(3), substituted "at increased likelihood" for "at higher risk".

Subsec. (b)(4). Pub. L. 118–180, §3(b)(4), inserted ", which may give consideration to the perspectives of parents and guardians" before semicolon at end.

Subsec. (b)(7). Pub. L. 118–180, §3(b)(5), substituted "at increased likelihood" for "at higher risk".

Subsec. (c)(1). Pub. L. 118–180, §3(b)(6), substituted "culturally and linguistically appropriate information" for "culturally competent information" in introductory provisions.

Subsec. (c)(2)(A)(ii). Pub. L. 118–180, §3(b)(7), substituted "culturally and linguistically appropriate information" for "culturally competent information".

Subsec. (e)(1). Pub. L. 118–180, §3(b)(9)(A), inserted ", and strengthen the capacity of," after "expand" in introductory provisions.

Pub. L. 118–180, §3(b)(8), which directed the amendment of subsec. (e)(1) "to read as follows" but was not followed by any text, was not given effect, to reflect the probable intent of Congress.

Subsec. (e)(1)(A). Pub. L. 118–180, §3(b)(9)(B), substituted "expand and strengthen the capacity of existing, or, in States that do not have such a program, develop new," for "expand existing or develop new" and struck out "in States that do not have such a program" before semicolon at end.

Subsec. (e)(1)(B)(v). Pub. L. 118–180, §3(b)(9)(C), inserted "or other providers, as applicable" before "; and".

Subsec. (e)(1)(C). Pub. L. 118–180, §3(b)(9)(D), amended subpar. (C) generally. Prior to amendment, subpar. (C) read as follows: "program sites provide culturally competent services."

Subsec. (e)(2)(C). Pub. L. 118–180, §3(b)(10), added subpar. (C).

Subsec. (f). Pub. L. 118–180, §3(b)(11), amended subsec. (f) generally. Prior to amendment, text read as follows: "The Secretary shall promote research, through grants or contracts, which may include grants or contracts to research centers or networks, to determine the evidence-based practices for interventions to improve the physical and behavioral health of individuals with autism spectrum disorder or other developmental disabilities across the lifespan of such individuals, develop guidelines for those interventions, and disseminate information related to such research and guidelines."

Subsec. (g). Pub. L. 118–180, §3(b)(12), substituted "September 30, 2029" for "December 20, 2024".

Pub. L. 118–83 substituted "December 20, 2024" for "September 30, 2024".

2019—Subsec. (a)(1). Pub. L. 116–60, §3(b)(1), substituted "individuals with autism spectrum disorder and other developmental disabilities" for "individuals with autism spectrum disorder or other developmental disabilities" and "individuals with autism spectrum disorder and other developmental disabilities across their lifespan;" for "children with autism spectrum disorder and other developmental disabilities;".

Subsec. (b)(2). Pub. L. 116–60, §3(b)(2)(A), inserted "individuals with" before "autism spectrum disorder".

Subsec. (b)(4) to (7). Pub. L. 116–60, §3(b)(2)(B), (C), added par. (4) and redesignated former pars. (4) to (6) as (5) to (7), respectively.

Subsec. (c)(1). Pub. L. 116–60, §3(b)(3)(A), substituted "the needs of individuals with autism spectrum disorder and other developmental disabilities across their lifespan and the needs of their families" for "the needs of individuals with autism spectrum disorder or other developmental disabilities and their families" in introductory provisions.

Subsec. (c)(2)(A)(ii). Pub. L. 116–60, §3(b)(3)(B)(i), substituted "caregivers of individuals with autism spectrum disorder or other developmental disabilities" for "caregivers of individuals with an autism spectrum disorder".

Subsec. (c)(2)(B)(i)(II). Pub. L. 116–60, §3(b)(3)(B)(ii), inserted "autism spectrum disorder and" after "individuals with".

Subsec. (c)(2)(B)(ii). Pub. L. 116–60, §3(b)(3)(B)(iii), inserted "autism spectrum disorder and" after "individuals with".

Subsec. (e)(1). Pub. L. 116–60, §3(b)(4)(A)(i), inserted "across their lifespan" before "and ensure" in introductory provisions.

Subsec. (e)(1)(B)(iv). Pub. L. 116–60, §3(b)(4)(A)(ii), inserted "across their lifespan" after "other developmental disabilities".

Subsec. (e)(2) to (4). Pub. L. 116–60, §3(b)(4)(B), (C), added par. (2) and redesignated former pars. (2) and (3) as (3) and (4), respectively.

Subsec. (f). Pub. L. 116–60, §3(b)(5), inserted "across the lifespan of such individuals" after "other developmental disabilities".

Subsec. (g). Pub. L. 116–60, §3(b)(6), substituted "2024" for "2019".

2014—Subsec. (b)(1). Pub. L. 113–157, §4(1), inserted "culturally competent" after "provide".

Subsec. (c)(2)(A)(ii). Pub. L. 113–157, §4(2), inserted "(which may include respite care for caregivers of

individuals with an autism spectrum disorder)" after "services and supports".

Subsec. (e)(1)(B)(v). Pub. L. 113–157, §4(3), inserted before semicolon ", which may include collaborating with research centers or networks to provide training for providers of respite care (as defined in section 300ii of this title)".

Subsec. (f). Pub. L. 113–157, §4(4), substituted "grants or contracts, which may include grants or contracts to research centers or networks, to determine the evidence-based practices for interventions to improve the physical and behavioral health of individuals with" for "grants or contracts, to determine the evidence-based practices for interventions for individuals with".

Subsec. (g). Pub. L. 113–157, §4(5), substituted "2019" for "2014".

2011—Subsec. (g). Pub. L. 112–32 substituted "2014" for "2011".

§280i–2. Interagency Autism Coordinating Committee

(a) Establishment

The Secretary shall establish a committee, to be known as the "Interagency Autism Coordinating Committee" (in this section referred to as the "Committee"), to coordinate all efforts within the Department of Health and Human Services concerning autism spectrum disorder.

(b) Responsibilities

In carrying out its duties under this section, the Committee shall, on a regular basis—

(1) monitor autism spectrum disorder research, and to the extent practicable services and support activities, across all relevant Federal departments and agencies, including coordination of Federal activities with respect to autism spectrum disorder;

(2) summarize of [1] advances in autism spectrum disorder research related to causes, prevention, treatment, early screening, diagnosis or rule out, interventions, including school and community-based interventions, and access to services and supports for individuals with autism spectrum disorder across the lifespan of such individuals;

(3) make recommendations to the Secretary regarding any appropriate changes to such activities, including with [2] respect to the strategic plan developed under paragraph (5);

(4) make recommendations to the Secretary regarding public participation in decisions relating to autism spectrum disorder, and the process by which public feedback can be better integrated into such decisions;

(5) develop a strategic plan for the conduct of, and support for, autism spectrum disorder research, as described in section 284g(a)(1) of this title, which shall include—

(A) proposed budgetary requirements; and

(B) recommendations to ensure that autism spectrum disorder research, and services and support activities to the extent practicable, of the Department of Health and Human Services and of other Federal departments and agencies are not unnecessarily duplicative; and

(6) submit to the Congress and the President—

(A) an annual update on the summary of advances described in paragraph (2); and

(B) a biennial update on the strategic plan described in paragraph (5), including progress made in achieving the goals outlined in such strategic plan and any specific measures taken pursuant to such strategic plan.

(c) Membership

(1) Federal membership

The Committee shall be composed of the following Federal members—

(A) the Director of the Centers for Disease Control and Prevention;

(B) the Director of the National Institutes of Health, and the Directors of such national research institutes of the National Institutes of Health as the Secretary determines appropriate;

(C) the heads of such other agencies as the Secretary determines appropriate, such as the Administration for Community Living, Administration for Children and Families, the Centers

for Medicare & Medicaid Services, the Food and Drug Administration, and the Health Resources and Services Administration; and

(D) representatives of other Federal Governmental agencies that serve individuals with autism spectrum disorder such as the Department of Education, the Department of Labor, the Department of Justice, the Department of Veterans Affairs, the Department of Housing and Urban Development, and the Department of Defense.

(2) Non-Federal members

Not more than ½, but not fewer than 1/3, of the total membership of the Committee,[3] shall be composed of non-Federal public members to be appointed by the Secretary, of which—

(A) at least three such members shall be individuals with a diagnosis of autism spectrum disorder;

(B) at least three such members shall be parents or legal guardians of an individual with an autism spectrum disorder; and

(C) at least three such members shall be representatives of leading research, advocacy, and service organizations for individuals with autism spectrum disorder.

(3) Period of appointment; vacancies

(A) Period of appointment for non-Federal members

Non-Federal members shall serve for a term of 4 years, and may be reappointed for one additional 4-year term.

(B) Vacancies

A vacancy on the Committee shall be filled in the manner in which the original appointment was made and shall not affect the powers or duties of the Committee. Any member appointed to fill a vacancy for an unexpired term shall be appointed for the remainder of such term. A member may serve after the expiration of the member's term until a successor has been appointed.

(d) Administrative support; terms of service; other provisions

The following provisions shall apply with respect to the Committee:

(1) The Committee shall receive necessary and appropriate administrative support from the Secretary.

(2) The Committee shall meet at the call of the chairperson or upon the request of the Secretary. The Committee shall meet not fewer than 2 times each year.

(3) All meetings of the Committee shall be public and shall include appropriate time periods for questions and presentations by the public.

(e) Subcommittees; establishment and membership

In carrying out its functions, the Committee may establish subcommittees and convene workshops and conferences. Such subcommittees shall be composed of Committee members and may hold such meetings as are necessary to enable the subcommittees to carry out their duties.

(f) Sunset

This section shall not apply after September 30, 2029, and the Committee shall be terminated on such date.

(July 1, 1944, ch. 373, title III, §399CC, as added Pub. L. 109–416, §3(a), Dec. 19, 2006, 120 Stat. 2827; amended Pub. L. 112–32, §2(3), Sept. 30, 2011, 125 Stat. 361; Pub. L. 113–157, §5, Aug. 8, 2014, 128 Stat. 1832; Pub. L. 116–60, §3(c), Sept. 30, 2019, 133 Stat. 1112; Pub. L. 118–83, div. B, title II, §201(c), Sept. 26, 2024, 138 Stat. 1537; Pub. L. 118–180, §3(c), Dec. 23, 2024, 138 Stat. 2617.)

EDITORIAL NOTES

AMENDMENTS

2024—Subsec. (b). Pub. L. 118–180, §3(c)(1)(A), inserted ", on a regular basis" after "shall" in introductory provisions.

Subsec. (b)(2). Pub. L. 118–180, §3(c)(1)(B), substituted "summarize" for "develop a summary".

Subsec. (b)(5), (6). Pub. L. 118–180, §3(c)(1)(C), added pars. (5) and (6) and struck out former pars (5) and (6) which related, respectively, to development of a strategic plan and annual updates to Congress and the President.

Subsec. (f). Pub. L. 118–180, §3(c)(2), substituted "September 30, 2029" for "December 20, 2024".

Pub. L. 118–83 substituted "December 20, 2024" for "September 30, 2024".

2019—Subsec. (b)(2). Pub. L. 116–60, §3(c)(1)(A), inserted "across the lifespan of such individuals" before semicolon at end.

Subsec. (b)(5). Pub. L. 116–60, §3(c)(1)(B), inserted "across the lifespan of such individuals" before "and the families" in introductory provisions.

Subsec. (c)(1)(D). Pub. L. 116–60, §3(c)(2)(A), inserted ", the Department of Labor, the Department of Justice, the Department of Veterans Affairs, the Department of Housing and Urban Development," after "Department of Education".

Subsec. (c)(2). Pub. L. 116–60, §3(c)(2)(B), substituted "at least three such members" for "at least two such members" in subpars. (A) to (C).

Subsec. (c)(3)(A). Pub. L. 116–60, §3(c)(2)(C), substituted "one additional 4-year term" for "one or more additional 4-year terms".

Subsec. (f). Pub. L. 116–60, §3(c)(3), substituted "2024" for "2019".

2014—Subsec. (b)(1). Pub. L. 113–157, §5(1)(C), added par. (1). Former par. (1) redesignated (2).

Pub. L. 113–157, §5(1)(A), struck out "and annually update" after "develop" and substituted "interventions, including school and community-based interventions" for "intervention".

Subsec. (b)(2). Pub. L. 113–157, §5(1)(B), (C), redesignated par. (1) as (2) and struck out former par. (2) which read as follows: "monitor Federal activities with respect to autism spectrum disorder;".

Subsec. (b)(3). Pub. L. 113–157, §5(1)(D), struck out "recommendations to the Director of NIH" after "including".

Subsec. (b)(4). Pub. L. 113–157, §5(1)(E), inserted before semicolon ", and the process by which public feedback can be better integrated into such decisions".

Subsec. (b)(5), (6). Pub. L. 113–157, §5(1)(F), added pars. (5) and (6) and struck out former pars. (5) and (6) which read as follows:

"(5) develop and annually update a strategic plan for the conduct of, and support for, autism spectrum disorder research, including proposed budgetary requirements; and

"(6) submit to the Congress such strategic plan and any updates to such plan."

Subsec. (c)(1). Pub. L. 113–157, §5(2)(A)(i), substituted "Federal membership" for "In general" in heading and "The Committee shall be composed of the following Federal members—" for "The Committee shall be composed of—" in introductory provisions.

Subsec. (c)(1)(C). Pub. L. 113–157, §5(2)(A)(ii), inserted ", such as the Administration for Community Living, Administration for Children and Families, the Centers for Medicare & Medicaid Services, the Food and Drug Administration, and the Health Resources and Services Administration" before semicolon and inserted "and" at end.

Subsec. (c)(1)(D). Pub. L. 113–157, §5(2)(A)(iii), inserted "and the Department of Defense" after "Department of Education" and substituted period at end for "; and".

Subsec. (c)(1)(E). Pub. L. 113–157, §5(2)(A)(iv), struck out subpar. (E) which read as follows: "the additional members appointed under paragraph (2)."

Subsec. (c)(2). Pub. L. 113–157, §5(2)(B)(i), (ii), substituted "Non-Federal" for "Additional" in heading and "Not more than ½, but not fewer than 1/3, of the total membership of the Committee" for "Not fewer than 6 members of the Committee, or 1/3 of the total membership of the Committee, whichever is greater" in introductory provisions. Substitution in text was executed as the probable intent of Congress, notwithstanding directory language that struck out "1/3" instead of "1/3" as it appeared in the original.

Subsec. (c)(2)(A). Pub. L. 113–157, §5(2)(B)(iii), substituted "two such members shall be individuals" for "one such member shall be an individual".

Subsec. (c)(2)(B). Pub. L. 113–157, §5(2)(B)(iv), substituted "two such members shall be parents or legal guardians" for "one such member shall be a parent or legal guardian".

Subsec. (c)(2)(C). Pub. L. 113–157, §5(2)(B)(v), substituted "two such members shall be representatives" for "one such member shall be a representative".

Subsec. (c)(3). Pub. L. 113–157, §5(2)(C), added par. (3).

Subsec. (d)(2) to (4). Pub. L. 113–157, §5(3), redesignated pars. (3) and (4) as (2) and (3), respectively, and

struck out former par. (2) which read as follows: "Members of the Committee appointed under subsection (c)(2) shall serve for a term of 4 years, and may be reappointed for one or more additional 4 year term. Any member appointed to fill a vacancy for an unexpired term shall be appointed for the remainder of such term. A member may serve after the expiration of the member's term until a successor has taken office."

Subsec. (f). Pub. L. 113–157, §5(4), substituted "2019" for "2014".

2011—Subsec. (f). Pub. L. 112–32 substituted "2014" for "2011".

[1] So in original. The word "of" probably should not appear.

[2] So in original. Probably should be preceded by "recommendations".

[3] So in original. The comma probably should not appear.

§280i–3. Reports to Congress

(a) Progress report

(1) In general

Not later than 4 years after September 30, 2024, the Secretary, in consultation with other relevant Federal departments and agencies, shall prepare and submit to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives, and make publicly available, including through posting on the website of the Department of Health and Human Services, a progress report on activities related to autism spectrum disorder and other developmental disabilities. Such report shall include activities and research related to the entire population of individuals with autism spectrum disorder, including those individuals with co-occurring conditions and the full range of needs for supports and services, including such supports and services to ensure the safety, and promote the well-being, of such individuals.

(2) Contents

The report submitted under subsection (a) shall contain—

(A) a description of the progress made in implementing the provisions of the Autism CARES Act of 2024;

(B) a description of the amounts expended on the implementation of the amendments made by the Autism CARES Act of 2024;

(C) information on the incidence and prevalence of autism spectrum disorder, including available information on the prevalence of autism spectrum disorder among children and adults, and identification of any changes over time with respect to the incidence and prevalence of autism spectrum disorder;

(D) information on the average age of diagnosis for children with autism spectrum disorder and other disabilities, including how that age may have changed over the 4-year period beginning on December 23, 2024, and, as appropriate, how this age varies across population subgroups;

(E) information on the average age for intervention for individuals diagnosed with autism spectrum disorder and other developmental disabilities, including how that age may have changed over the 4-year period beginning on December 23, 2024, and, as appropriate, how this age varies across population subgroups;

(F) information on the average time between initial screening and then diagnosis or rule out for individuals with autism spectrum disorder or other developmental disabilities, as well as information on the average time between diagnosis and evidence-based intervention for individuals with autism spectrum disorder or other developmental disabilities and, as appropriate, on how such average time varies across population subgroups;

(G) information on the effectiveness and outcomes of interventions for individuals diagnosed

with autism spectrum disorder, including by severity level as practicable, and other developmental disabilities and how the age of the individual or other factors, such as demographic characteristics, may affect such effectiveness;

(H) information on the effectiveness and outcomes of innovative and newly developed intervention strategies for individuals with autism spectrum disorder or other developmental disabilities;

(I) a description of the actions taken to implement and the progress made on implementation of the strategic plan developed by the Interagency Autism Coordinating Committee under section 280i–2(b) of this title; and

(J) information on how States use home- and community-based services and other supports to ensure that individuals with autism spectrum disorder and other developmental disabilities are living, working, and participating in their community.

(b) Report on the mental health needs of individuals with autism spectrum disorder across their lifespan

(1) In general

Not later than 2 years after December 23, 2024, the Secretary shall prepare and submit, to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives, a report concerning the mental health needs of individuals with autism spectrum disorder.

(2) Contents

The report submitted under paragraph (1) shall contain—

(A) an overview of policies and programs relevant to the mental health of individuals with autism spectrum disorder across their lifespan, including an identification of existing Federal laws, regulations, policies, research, and programs; and

(B) recommendations to improve mental health outcomes and address related disparities in mental health care for individuals with autism spectrum disorder, including prevention, care coordination, and community-based services.

(c) Update on young adults and youth transitioning to adulthood

Not later than 2 years after December 23, 2024, the Secretary, in coordination with other relevant Federal departments and agencies, as appropriate, shall prepare and submit to the Committee on Energy and Commerce of the House of Representatives and the Committee on Health, Education, Labor, and Pensions of the Senate an update to the report required pursuant to subsection (b) of this section, as added by section 6 of the Autism Cares Act of 2014 (Public Law 113–157), and in effect before September 30, 2019, concerning young adults with autism spectrum disorder and the challenges related to the transition from existing school-based services to those services available during adulthood.

(July 1, 1944, ch. 373, title III, §399DD, as added Pub. L. 109–416, §3(a), Dec. 19, 2006, 120 Stat. 2828; amended Pub. L. 112–32, §2(4), Sept. 30, 2011, 125 Stat. 361; Pub. L. 113–157, §6, Aug. 8, 2014, 128 Stat. 1834; Pub. L. 116–60, §3(d), Sept. 30, 2019, 133 Stat. 1113; Pub. L. 118–180, §3(d), Dec. 23, 2024, 138 Stat. 2617.)

EDITORIAL NOTES

REFERENCES IN TEXT

The Autism CARES Act of 2024, referred to in subsec. (a)(2)(A), (B), is Pub. L. 118–180, Dec. 23, 2024, 138 Stat. 2614, also known as the Autism Collaboration, Accountability, Research, Education, and Support Act of 2024, which amended this part and section 284g of this title and enacted provisions set out as notes under sections 201 and 280i of this title. For complete classification of this Act to the Code, see Short Title of 2024 Amendment note set out under section 201 of this title and Tables.

AMENDMENTS

2024—Subsec. (a)(1). Pub. L. 118–180, §3(d)(2), amended par. (1) generally. Prior to amendment, text read as follows: "Not later than 4 years after September 30, 2019, the Secretary, in coordination with the Secretary of Education and the Secretary of Defense, shall prepare and submit to the Health, Education, Labor, and Pensions Committee of the Senate and the Energy and Commerce Committee of the House of Representatives, and make publicly available, including through posting on the Internet Web site of the Department of Health and Human Services, a progress report on activities related to autism spectrum disorder and other developmental disabilities."

Subsec. (a)(2)(A), (B). Pub. L. 118–180, §3(d)(1), substituted "Autism CARES Act of 2024" for "Autism CARES Act of 2019".

Subsec. (a)(2)(D), (E). Pub. L. 118–180, §3(d)(1), substituted "December 23, 2024" for "September 30, 2019".

Subsec. (b). Pub. L. 118–180, §3(d)(3)(A), substituted "mental health needs" for "health and well-being" in heading.

Subsec. (b)(1). Pub. L. 118–180, §3(d)(3)(B), substituted "mental health needs" for "health and well-being".

Pub. L. 118–180, §3(d)(1), substituted "December 23, 2024" for "September 30, 2019".

Subsec. (b)(2). Pub. L. 118–180, §3(d)(3)(C), amended par. (2) generally. Prior to amendment, par. (2) related to the content of reports submitted under par. (1).

Subsec. (c). Pub. L. 118–180, §3(d)(4), added subsec. (c).

2019—Subsec. (a)(1). Pub. L. 116–60, §3(d)(1)(A), substituted "September 30, 2019" for "August 8, 2014".

Subsec. (a)(2)(A), (B). Pub. L. 116–60, §3(d)(1)(B)(i), substituted "Autism CARES Act of 2019" for "Autism CARES Act of 2014".

Subsec. (a)(2)(D), (E). Pub. L. 116–60, §3(d)(1)(B)(i), substituted "September 30, 2019" for "August 8, 2014".

Subsec. (a)(2)(G). Pub. L. 116–60, §3(d)(1)(B)(ii), substituted "age of the individual" for "age of the child".

Subsec. (a)(2)(J). Pub. L. 116–60, §3(d)(1)(B)(iii)–(v), added subsec. (J).

Subsec. (b). Pub. L. 116–60, §3(d)(2)(A), substituted "the health and well-being of individuals with autism spectrum disorder across their lifespan" for "young adults and transitioning youth" in heading.

Subsec. (b)(1). Pub. L. 116–60, §3(d)(2)(B), amended par. (1) generally. Prior to amendment, text read as follows: "Not later than 2 years after August 8, 2014, the Secretary of Health and Human Services, in coordination with the Secretary of Education and in collaboration with the Secretary of Transportation, the Secretary of Labor, the Secretary of Housing and Urban Development, and the Attorney General, shall prepare and submit to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives, a report concerning young adults with autism spectrum disorder and the challenges related to the transition from existing school-based services to those services available during adulthood."

Subsec. (b)(2)(A). Pub. L. 116–60, §3(d)(2)(C)(i), amended subpar. (A) generally. Prior to amendment, subpar. (A) read as follows: "demographic characteristics of youth transitioning from school-based to community-based supports;".

Subsec. (b)(2)(B). Pub. L. 116–60, §3(d)(2)(C)(ii), substituted "the health and well-being of individuals with autism spectrum disorder, including an identification of existing Federal laws, regulations, policies, research, and programs;" for "young adults with autism spectrum disorder relating to post-secondary school transitional services, including an identification of existing Federal laws, regulations, policies, research, and programs;".

Subsec. (b)(2)(C) to (E). Pub. L. 116–60, §3(d)(2)(C)(iii), amended subpars. (C) to (E) generally. Prior to amendment, subpars. (C) to (E) related, respectively, to proposals on establishing certain best practices guidelines, comprehensive approaches to transitioning from existing school-based services to those services available during adulthood, and proposals that seek to improve outcomes for adults with autism spectrum disorder making the transition from a school-based support system to adulthood.

2014—Pub. L. 113–157, §6(1), substituted "Reports" for "Report" in section catchline.

Subsec. (a). Pub. L. 113–157, §6(2)–(4), designated existing provisions of entire section as subsec. (a), inserted heading, redesignated former subsecs. (a) and (b) as pars. (1) and (2), respectively, of subsec. (a), redesignated pars. (1) to (9) of former subsec. (b) as subpars. (A) to (I), respectively, of par. (2) of subsec. (a), and realigned margins.

Subsec. (a)(1). Pub. L. 113–157, §6(5), substituted "4 years after August 8, 2014" for "2 years after September 30, 2011" and inserted "and the Secretary of Defense" after "the Secretary of Education" and ", and make publicly available, including through posting on the Internet Web site of the Department of Health and Human Services," after "Representatives".

Subsec. (a)(2)(A). Pub. L. 113–157, §6(6)(A), substituted "Autism CARES Act of 2014" for "Combating

Autism Act of 2006".

Subsec. (a)(2)(B). Pub. L. 113–157, §6(6)(B), substituted "amendments made by the Autism CARES Act of 2014" for "particular provisions of Combating Autism Act of 2006".

Subsec. (a)(2)(C). Pub. L. 113–157, §6(6)(C), added subpar. (C) and struck out former subpar. (C) which read as follows: "information on the incidence of autism spectrum disorder and trend data of such incidence since December 19, 2006;".

Subsec. (a)(2)(D), (E). Pub. L. 113–157, §6(6)(D), (E), substituted "4-year period beginning on August 8, 2014, and, as appropriate, how this age varies across population subgroups" for "6-year period beginning on December 19, 2006".

Subsec. (a)(2)(F). Pub. L. 113–157, §6(6)(F), inserted "and, as appropriate, on how such average time varies across population subgroups" before semicolon at end.

Subsec. (a)(2)(G). Pub. L. 113–157, §6(6)(G), substituted "including by severity level as practicable," for "including by various subtypes," and "child or other factors, such as demographic characteristics, may" for "child may".

Subsec. (a)(2)(I). Pub. L. 113–157, §6(6)(H), added subpar. (I) and struck out former subpar. (I) which read as follows: "information on services and supports provided to individuals with autism spectrum disorder and other developmental disabilities who have reached the age of majority (as defined for purposes of section 1415(m) of title 20)."

Subsec. (b). Pub. L. 113–157, §6(7), added subsec. (b). Former subsec. (b) redesignated par. (2) of subsec. (a).

2011—Subsec. (a). Pub. L. 112–32, §2(4)(A), substituted "Not later than 2 years after September 30, 2011" for "Not later than 4 years after December 19, 2006".

Subsec. (b)(4), (5). Pub. L. 112–32, §2(4)(B), substituted "the 6-year period beginning on December 19, 2006" for "the 4-year period beginning on the date of enactment of this Act", which for purposes of codification was translated as "the 4-year period beginning on December 19, 2006".

§280i–4. Authorization of appropriations

(a) Developmental disabilities surveillance and research program

To carry out section 280i of this title, there is authorized to be appropriated 28,100,000 for each of fiscal years 2025 through 2029.

(b) Autism education, early detection, and intervention

To carry out section 280i–1 of this title, there is authorized to be appropriated $56,344,000 for each of fiscal years 2025 through 2029.

(c) Interagency Autism Coordinating Committee; certain other programs

To carry out sections 280i–2 and 284g of this title, there is authorized to be appropriated $306,000,000 for each of fiscal years 2025 through 2029.

(July 1, 1944, ch. 373, title III, §399EE, as added Pub. L. 109–416, §4(a), Dec. 19, 2006, 120 Stat. 2829; amended Pub. L. 112–32, §3, Sept. 30, 2011, 125 Stat. 361; Pub. L. 113–157, §7, Aug. 8, 2014, 128 Stat. 1836; Pub. L. 114–255, div. A, title II, §2042(f)(2), Dec. 13, 2016, 130 Stat. 1073; Pub. L. 116–60, §3(e), Sept. 30, 2019, 133 Stat. 1114; Pub. L. 118–180, §3(e), Dec. 23, 2024, 138 Stat. 2618.)

EDITORIAL NOTES

AMENDMENTS

2024—Subsec. (a). Pub. L. 118–180, §3(e)(1), substituted "$28,100,000 for each of fiscal years 2025 through 2029" for "$23,100,000 for each of fiscal years 2020 through 2024".

Subsec. (b). Pub. L. 118–180, §3(e)(2), substituted "$56,344,000 for each of fiscal years 2025 through 2029" for "$50,599,000 for each of fiscal years 2020 through 2024".

Subsec. (c). Pub. L. 118–180, §3(e)(3), substituted "there is authorized to be appropriated $306,000,000 for each of fiscal years 2025 through 2029" for "there are authorized to be appropriated $296,000,000 for each of fiscal years 2020 through 2024".

2019—Subsec. (a). Pub. L. 116–60, §3(e)(1), substituted "$23,100,000 for each of fiscal years 2020 through 2024" for "$22,000,000 for each of fiscal years 2015 through 2019".

Subsec. (b). Pub. L. 116–60, §3(e)(2), substituted "$50,599,000 for each of fiscal years 2020 through 2024" for "$48,000,000 for each of fiscal years 2015 through 2019".

Subsec. (c). Pub. L. 116–60, §3(e)(3), substituted "there are authorized to be appropriated $296,000,000 for each of fiscal years 2020 through 2024" for "there is authorized to be appropriated $190,000,000 for each of fiscal years 2015 through 2019".

2016—Subsec. (c). Pub. L. 114–255 substituted "280i–2" for "280i–2, 283j,".

2014—Subsec. (a). Pub. L. 113–157, §7(1), substituted "fiscal years 2015 through 2019" for "fiscal years 2012 through 2014".

Subsec. (b). Pub. L. 113–157, §7(2), substituted "fiscal years 2015 through 2019" for "fiscal years 2011 through 2014".

Subsec. (c). Pub. L. 113–157, §7(3), substituted "$190,000,000 for each of fiscal years 2015 through 2019" for "$161,000,000 for each of fiscal years 2011 through 2014".

2011—Pub. L. 112–32 amended section generally. Prior to amendment, section authorized appropriations for fiscal years 2007 to 2011.

PART S—HEALTH CARE QUALITY PROGRAMS

SUBPART I—NATIONAL STRATEGY FOR QUALITY IMPROVEMENT IN HEALTH CARE

EDITORIAL NOTES

CODIFICATION

Subpart is based on subpart I of part S of title III of act July 1, 1944, as added by Pub. L. 111–148, title III, §3011, Mar. 23, 2010, 124 Stat. 378. No subpart II has been enacted.

§280j. National strategy for quality improvement in health care

(a) Establishment of national strategy and priorities

(1) National strategy

The Secretary, through a transparent collaborative process, shall establish a national strategy to improve the delivery of health care services, patient health outcomes, and population health.

(2) Identification of priorities

(A) In general

The Secretary shall identify national priorities for improvement in developing the strategy under paragraph (1).

(B) Requirements

The Secretary shall ensure that priorities identified under subparagraph (A) will—

(i) have the greatest potential for improving the health outcomes, efficiency, and patient-centeredness of health care for all populations, including children and vulnerable populations;

(ii) identify areas in the delivery of health care services that have the potential for rapid improvement in the quality and efficiency of patient care;

(iii) address gaps in quality, efficiency, comparative effectiveness information (taking into consideration the limitations set forth in subsections (c) and (d) of section 1182 of the Social

Security Act [42 U.S.C. 1320e–1(c), (d)]), and health outcomes measures and data aggregation techniques;

(iv) improve Federal payment policy to emphasize quality and efficiency;

(v) enhance the use of health care data to improve quality, efficiency, transparency, and outcomes;

(vi) address the health care provided to patients with high-cost chronic diseases;

(vii) improve research and dissemination of strategies and best practices to improve patient safety and reduce medical errors, preventable admissions and readmissions, and health care-associated infections;

(viii) reduce health disparities across health disparity populations (as defined in section 285t [1] of this title) and geographic areas; and

(ix) address other areas as determined appropriate by the Secretary.

(C) Considerations

In identifying priorities under subparagraph (A), the Secretary shall take into consideration the recommendations submitted by the entity with a contract under section 1890(a) of the Social Security Act [42 U.S.C. 1395aaa(a)] and other stakeholders.

(D) Coordination with State agencies

The Secretary shall collaborate, coordinate, and consult with State agencies responsible for administering the Medicaid program under title XIX of the Social Security Act [42 U.S.C. 1396 et seq.] and the Children's Health Insurance Program under title XXI of such Act [42 U.S.C. 1397aa et seq.] with respect to developing and disseminating strategies, goals, models, and timetables that are consistent with the national priorities identified under subparagraph (A).

(b) Strategic plan

(1) In general

The national strategy shall include a comprehensive strategic plan to achieve the priorities described in subsection (a).

(2) Requirements

The strategic plan shall include provisions for addressing, at a minimum, the following:

(A) Coordination among agencies within the Department, which shall include steps to minimize duplication of efforts and utilization of common quality measures, where available. Such common quality measures shall be measures identified by the Secretary under section 1139A or 1139B of the Social Security Act [42 U.S.C. 1320b–9a, 1320b–9b] or endorsed under section 1890 of such Act [42 U.S.C. 1395aaa].

(B) Agency-specific strategic plans to achieve national priorities.

(C) Establishment of annual benchmarks for each relevant agency to achieve national priorities.

(D) A process for regular reporting by the agencies to the Secretary on the implementation of the strategic plan.

(E) Strategies to align public and private payers with regard to quality and patient safety efforts.

(F) Incorporating quality improvement and measurement in the strategic plan for health information technology required by the American Recovery and Reinvestment Act of 2009 (Public Law 111–5).

(c) Periodic update of national strategy

The Secretary shall update the national strategy not less than annually. Any such update shall include a review of short- and long-term goals.

(d) Submission and availability of national strategy and updates

(1) Deadline for initial submission of national strategy

Not later than January 1, 2011, the Secretary shall submit to the relevant committees of

Congress the national strategy described in subsection (a).

(2) Updates

(A) In general

The Secretary shall submit to the relevant committees of Congress an annual update to the strategy described in paragraph (1).

(B) Information submitted

Each update submitted under subparagraph (A) shall include—

(i) a review of the short- and long-term goals of the national strategy and any gaps in such strategy;

(ii) an analysis of the progress, or lack of progress, in meeting such goals and any barriers to such progress;

(iii) the information reported under section 1139A of the Social Security Act [42 U.S.C. 1320b–9a], consistent with the reporting requirements of such section; and

(iv) in the case of an update required to be submitted on or after January 1, 2014, the information reported under section 1139B(b)(4) of the Social Security Act [42 U.S.C. 1320b–9b(b)(4)], consistent with the reporting requirements of such section.

(C) Satisfaction of other reporting requirements

Compliance with the requirements of clauses (iii) and (iv) of subparagraph (B) shall satisfy the reporting requirements under sections 1139A(a)(6) and 1139B(b)(4), respectively, of the Social Security Act [42 U.S.C. 1320b–9a(a)(6), 1320b–9b(b)(4)].

(e) Health care quality Internet website

Not later than January 1, 2011, the Secretary shall create an Internet website to make public information regarding—

(1) the national priorities for health care quality improvement established under subsection (a)(2);

(2) the agency-specific strategic plans for health care quality described in subsection (b)(2)(B); and

(3) other information, as the Secretary determines to be appropriate.

(July 1, 1944, ch. 373, title III, §399HH, as added and amended Pub. L. 111–148, title III, §3011, title X, §10302, Mar. 23, 2010, 124 Stat. 378, 937.)

EDITORIAL NOTES

REFERENCES IN TEXT

Section 285t of this title, referred to in subsec. (a)(2)(B)(viii), was in the original "section 485E", meaning section 485E of act July 1, 1944, ch. 373, as added by section 101(a) of Pub. L. 106–525, which was classified to section 287c–31 of this title. Section 485E of act July 1, 1944, was renumbered section 464z–3 by Pub. L. 111–148, title X, §10334(c)(1)(D)(i), Mar. 23, 2010, 124 Stat. 973, and transferred to section 285t of this title. The act July 1, 1944, no longer contains a section 485E.

The Social Security Act, referred to in subsec. (a)(2)(D), is act Aug. 14, 1935, ch. 531, 49 Stat. 620. Titles XIX and XXI of the Act are classified generally to subchapters XIX (§1396 et seq.) and XXI (§1397aa et seq.), respectively, of chapter 7 of this title. For complete classification of this Act to the Code, see section 1305 of this title and Tables.

The American Recovery and Reinvestment Act of 2009, referred to in subsec. (b)(2)(F), is Pub. L. 111–5, Feb. 17, 2009, 123 Stat. 115. For complete classification of this Act to the Code, see Short Title of 2009 Amendment note set out under section 1 of Title 26, Internal Revenue Code, and Tables.

AMENDMENTS

2010—Subsec. (a)(2)(B)(iii). Pub. L. 111–148, §10302, inserted "(taking into consideration the limitations set forth in subsections (c) and (d) of section 1182 of the Social Security Act)" after "information".

STATUTORY NOTES AND RELATED SUBSIDIARIES

INTERAGENCY WORKING GROUP ON HEALTH CARE QUALITY

Pub. L. 111–148, title III, §3012, Mar. 23, 2010, 124 Stat. 380, provided that:

"(a) IN GENERAL.—The President shall convene a working group to be known as the Interagency Working Group on Health Care Quality (referred to in this section as the 'Working Group').

"(b) GOALS.—The goals of the Working Group shall be to achieve the following:

"(1) Collaboration, cooperation, and consultation between Federal departments and agencies with respect to developing and disseminating strategies, goals, models, and timetables that are consistent with the national priorities identified under section 399HH(a)(2) of the Public Health Service Act [42 U.S.C. 280j(a)(2)] (as added by section 3011 [of Pub. L. 111–148]).

"(2) Avoidance of inefficient duplication of quality improvement efforts and resources, where practicable, and a streamlined process for quality reporting and compliance requirements.

"(3) Assess alignment of quality efforts in the public sector with private sector initiatives.

"(c) COMPOSITION.—

"(1) IN GENERAL.—The Working Group shall be composed of senior level representatives of—

"(A) the Department of Health and Human Services;
"(B) the Centers for Medicare & Medicaid Services;
"(C) the National Institutes of Health;
"(D) the Centers for Disease Control and Prevention;
"(E) the Food and Drug Administration;
"(F) the Health Resources and Services Administration;
"(G) the Agency for Healthcare Research and Quality;
"(H) the Office of the National Coordinator for Health Information Technology;
"(I) the Substance Abuse and Mental Health Services Administration;
"(J) the Administration for Children and Families;
"(K) the Department of Commerce;
"(L) the Office of Management and Budget;
"(M) the United States Coast Guard;
"(N) the Federal Bureau of Prisons;
"(O) the National Highway Traffic Safety Administration;
"(P) the Federal Trade Commission;
"(Q) the Social Security Administration;
"(R) the Department of Labor;
"(S) the United States Office of Personnel Management;
"(T) the Department of Defense;
"(U) the Department of Education;
"(V) the Department of Veterans Affairs;
"(W) the Veterans Health Administration; and
"(X) any other Federal agencies and departments with activities relating to improving health care quality and safety, as determined by the President.

"(2) CHAIR AND VICE-CHAIR.—

"(A) CHAIR.—The Working Group shall be chaired by the Secretary of Health and Human Services.

"(B) VICE CHAIR.—Members of the Working Group, other than the Secretary of Health and Human Services, shall serve as Vice Chair of the Group on a rotating basis, as determined by the Group.

"(d) REPORT TO CONGRESS.—Not later than December 31, 2010, and annually thereafter, the Working Group shall submit to the relevant Committees of Congress, and make public on an Internet website, a report describing the progress and recommendations of the Working Group in meeting the goals described in subsection (b)."

[1] *See References in Text note below.*

§280j–1. Collection and analysis of data for quality and resource use measures

(a) In general

(1) Establishment of strategic framework

The Secretary shall establish and implement an overall strategic framework to carry out the public reporting of performance information, as described in section 280j–2 of this title. Such strategic framework may include methods and related timelines for implementing nationally consistent data collection, data aggregation, and analysis methods.

(2) Collection and aggregation of data

The Secretary shall collect and aggregate consistent data on quality and resource use measures from information systems used to support health care delivery, and may award grants or contracts for this purpose. The Secretary shall align such collection and aggregation efforts with the requirements and assistance regarding the expansion of health information technology systems, the interoperability of such technology systems, and related standards that are in effect on March 23, 2010.

(3) Scope

The Secretary shall ensure that the data collection, data aggregation, and analysis systems described in paragraph (1) involve an increasingly broad range of patient populations, providers, and geographic areas over time.

(b) Grants or contracts for data collection

(1) In general

The Secretary may award grants or contracts to eligible entities to support new, or improve existing, efforts to collect and aggregate quality and resource use measures described under subsection (c).

(2) Eligible entities

To be eligible for a grant or contract under this subsection, an entity shall—

(A) be—

(i) a multi-stakeholder entity that coordinates the development of methods and implementation plans for the consistent reporting of summary quality and cost information;

(ii) an entity capable of submitting such summary data for a particular population and providers, such as a disease registry, regional collaboration, health plan collaboration, or other population-wide source; or

(iii) a Federal Indian Health Service program or a health program operated by an Indian tribe (as defined in section 1603 of title 25);

(B) promote the use of the systems that provide data to improve and coordinate patient care;

(C) support the provision of timely, consistent quality and resource use information to health care providers, and other groups and organizations as appropriate, with an opportunity for providers to correct inaccurate measures; and

(D) agree to report, as determined by the Secretary, measures on quality and resource use to the public in accordance with the public reporting process established under section 280j–2 of this title.

(c) Consistent data aggregation

The Secretary may award grants or contracts under this section only to entities that enable summary data that can be integrated and compared across multiple sources. The Secretary shall provide standards for the protection of the security and privacy of patient data.

(d) Matching funds

The Secretary may not award a grant or contract under this section to an entity unless the entity agrees that it will make available (directly or through contributions from other public or private entities) non-Federal contributions toward the activities to be carried out under the grant or contract

in an amount equal to $1 for each $5 of Federal funds provided under the grant or contract. Such non-Federal matching funds may be provided directly or through donations from public or private entities and may be in cash or in-kind, fairly evaluated, including plant, equipment, or services.

(e) Authorization of appropriations

To carry out this section, there are authorized to be appropriated such sums as may be necessary for fiscal years 2010 through 2014.

(July 1, 1944, ch. 373, title III, §399II, as added and amended Pub. L. 111–148, title III, §3015, title X, §10305, Mar. 23, 2010, 124 Stat. 387, 938.)

EDITORIAL NOTES

AMENDMENTS

2010—Subsec. (a). Pub. L. 111–148, §10305, amended subsec. (a) generally. Prior to amendment, text read as follows: "The Secretary shall collect and aggregate consistent data on quality and resource use measures from information systems used to support health care delivery to implement the public reporting of performance information, as described in section 280j–2 of this title, and may award grants or contracts for this purpose. The Secretary shall ensure that such collection, aggregation, and analysis systems span an increasingly broad range of patient populations, providers, and geographic areas over time."

§280j–2. Public reporting of performance information

(a) Development of performance websites

The Secretary shall make available to the public, through standardized Internet websites, performance information summarizing data on quality measures. Such information shall be tailored to respond to the differing needs of hospitals and other institutional health care providers, physicians and other clinicians, patients, consumers, researchers, policymakers, States, and other stakeholders, as the Secretary may specify.

(b) Information on conditions

The performance information made publicly available on an Internet website, as described in subsection (a), shall include information regarding clinical conditions to the extent such information is available, and the information shall, where appropriate, be provider-specific and sufficiently disaggregated and specific to meet the needs of patients with different clinical conditions.

(c) Consultation

(1) In general

In carrying out this section, the Secretary shall consult with the entity with a contract under section 1890(a) of the Social Security Act [42 U.S.C. 1395aaa(a)], and other entities, as appropriate, to determine the type of information that is useful to stakeholders and the format that best facilitates use of the reports and of performance reporting Internet websites.

(2) Consultation with stakeholders

The entity with a contract under section 1890(a) of the Social Security Act [42 U.S.C. 1395aaa(a)] shall convene multi-stakeholder groups, as described in such section, to review the design and format of each Internet website made available under subsection (a) and shall transmit to the Secretary the views of such multi-stakeholder groups with respect to each such design and format.

(d) Coordination

Where appropriate, the Secretary shall coordinate the manner in which data are presented through Internet websites described in subsection (a) and for public reporting of other quality measures by the Secretary, including such quality measures under title XVIII of the Social Security Act [42 U.S.C. 1395 et seq.].

(e) Authorization of appropriations

To carry out this section, there are authorized to be appropriated such sums as may be necessary for fiscal years 2010 through 2014.

(July 1, 1944, ch. 373, title III, §399JJ, as added Pub. L. 111–148, title III, §3015, Mar. 23, 2010, 124 Stat. 388.)

EDITORIAL NOTES

REFERENCES IN TEXT

The Social Security Act, referred to in subsec. (d), is act Aug. 14, 1935, ch. 531, 49 Stat. 620. Title XVIII of the Act is classified generally to subchapter XVIII (§1395 et seq.) of chapter 7 of this title. For complete classification of this Act to the Code, see section 1305 of this title and Tables.

§280j–3. Quality improvement program for hospitals with a high severity adjusted readmission rate

(a) Establishment

(1) In general

Not later than 2 years after March 23, 2010, the Secretary shall make available a program for eligible hospitals to improve their readmission rates through the use of patient safety organizations (as defined in section 299b–21(4) of this title).

(2) Eligible hospital defined

In this subsection, the term "eligible hospital" means a hospital that the Secretary determines has a high rate of risk adjusted readmissions for the conditions described in section 1395ww(q)(8)(A) of this title and has not taken appropriate steps to reduce such readmissions and improve patient safety as evidenced through historically high rates of readmissions, as determined by the Secretary.

(3) Risk adjustment

The Secretary shall utilize appropriate risk adjustment measures to determine eligible hospitals.

(b) Report to the Secretary

As determined appropriate by the Secretary, eligible hospitals and patient safety organizations working with those hospitals shall report to the Secretary on the processes employed by the hospital to improve readmission rates and the impact of such processes on readmission rates.

(July 1, 1944, ch. 373, title III, §399KK, as added Pub. L. 111–148, title III, §3025(b), Mar. 23, 2010, 124 Stat. 412.)

PART T—ORAL HEALTHCARE PREVENTION ACTIVITIES

§280k. Oral healthcare prevention education campaign

(a) Establishment of Oral Health Education Campaign

The Secretary, acting through the Director of the Centers for Disease Control and Prevention and in consultation with professional oral health organizations, shall, subject to the availability of appropriations, establish a 5-year national, public education campaign (referred to in this section as the "campaign") that is focused on oral health education, including prevention of oral disease such as early childhood and other caries, periodontal disease, and oral cancer.

(b) Requirements

In establishing the campaign under subsection (a), the Secretary shall—

(1) ensure that activities are targeted towards specific populations such as children, pregnant women, parents, the elderly, individuals with disabilities, and ethnic and racial minority populations, including Indians, Alaska Natives and Native Hawaiians (as defined in section 1603(c) [1] of title 25) in a culturally and linguistically appropriate manner; and

(2) utilize science-based strategies to convey oral health prevention messages that include, but are not limited to, community water fluoridation and dental sealants.

(c) Action for dental health program

(1) In general

The Secretary, in consultation with the Director of the Centers for Disease Control and Prevention and the Administrator of the Health Resources and Services Administration, may award grants, contracts, or cooperative agreements to eligible entities to collaborate with State or local public health officials, tribal health officials, oral health professional organizations, and others, as appropriate, to develop and implement initiatives to improve oral health, including activities to prevent dental disease and reduce barriers to the provision of dental services, including—

(A) through community-wide dental disease prevention programs; and

(B) by increasing public awareness and education related to oral health and dental disease prevention.

(2) Eligible entities

To be eligible to receive a grant, contract, or cooperative agreement under this subsection, an entity shall be—

(A) a dental association;

(B) a State or tribal health department or State or tribal oral health program;

(C) an accredited dental education, dental hygiene, or postdoctoral dental education program; or

(D) a non-profit community-based organization that partners with public and private non-profit entities, such as an academic institution, to facilitate the provision of dental services to underserved populations.

(July 1, 1944, ch. 373, title III, §399LL, as added Pub. L. 111–148, title IV, §4102(a), Mar. 23, 2010, 124 Stat. 550; amended Pub. L. 115–302, §2(a), Dec. 11, 2018, 132 Stat. 4396.)

EDITORIAL NOTES

REFERENCES IN TEXT

Section 1603(c) of title 25, referred to in subsec. (b)(1), which defines "Indians", was redesignated section 1603(13) of title 25 by Pub. L. 111–148, title X, §10221(a), Mar. 23, 2010, 124 Stat. 935.

AMENDMENTS

2018—Subsec. (a). Pub. L. 115–302, §2(a)(1), inserted "of Oral Health Education Campaign" after "Establishment" in heading and substituted "focused on oral health education" for "focused on oral healthcare prevention and education" in text.

Subsec. (b). Pub. L. 115–302, §2(a)(2), substituted "campaign under subsection (a)" for "campaign" in introductory provisions.

Subsec. (c). Pub. L. 115–302, §2(a)(3), added subsec. (c) and struck out former subsec. (c). Prior to amendment, text read as follows: "Not later than 2 years after March 23, 2010, the Secretary shall begin implementing the 5-year campaign. During the 2-year period referred to in the previous sentence, the Secretary shall conduct planning activities with respect to the campaign."

[1] *See References in Text note below.*

§280k–1. Research-based dental caries disease management

(a) In general

The Secretary, acting through the Director of the Centers for Disease Control and Prevention, shall award demonstration grants to eligible entities to demonstrate the effectiveness of research-based dental caries disease management activities.

(b) Eligibility

To be eligible for a grant under this section, an entity shall—

(1) be a community-based provider of dental services (as defined by the Secretary), including a Federally-qualified health center, a clinic of a hospital owned or operated by a State (or by an instrumentality or a unit of government within a State), a State or local department of health, a dental program of the Indian Health Service, an Indian tribe or tribal organization, or an urban Indian organization (as such terms are defined in section 1603 of title 25), a health system provider, a private provider of dental services, medical, dental, public health, nursing, nutrition educational institutions, or national organizations involved in improving children's oral health; and

(2) submit to the Secretary an application at such time, in such manner, and containing such information as the Secretary may require.

(c) Use of funds

A grantee shall use amounts received under a grant under this section to demonstrate the effectiveness of research-based dental caries disease management activities.

(d) Use of information

The Secretary shall, as practicable and appropriate, utilize information generated from grantees under this section in planning and implementing the oral health education campaign and action for dental health program under section 280k of this title.

(July 1, 1944, ch. 373, title III, §399LL–1, as added Pub. L. 111–148, title IV, §4102(a), Mar. 23, 2010, 124 Stat. 551; amended Pub. L. 115–302, §2(b), Dec. 11, 2018, 132 Stat. 4397.)

EDITORIAL NOTES

AMENDMENTS

2018—Subsec. (d). Pub. L. 115–302 substituted "shall, as practicable and appropriate," for "shall" and "oral health education campaign and action for dental health program" for "public education campaign".

§280k–2. Authorization of appropriations

There is authorized to be appropriated to carry out this part, such sums as may be necessary.

(July 1, 1944, ch. 373, title III, §399LL–2, as added Pub. L. 111–148, title IV, §4102(a), Mar. 23, 2010, 124 Stat. 551.)

§280k–3. Updating national oral healthcare surveillance activities

(1) PRAMS

(A) In general

The Secretary of Health and Human Services (referred to in this section as the "Secretary") shall carry out activities to update and improve the Pregnancy Risk Assessment Monitoring System (referred to in this section as "PRAMS") as it relates to oral healthcare.

(B) State reports and mandatory measurements

(i) In general

Not later than 5 years after March 23, 2010, and every 5 years thereafter, a State shall submit to the Secretary a report concerning activities conducted within the State under PRAMS.

(ii) Measurements

The oral healthcare measurements developed by the Secretary for use under PRAMS shall be mandatory with respect to States for purposes of the State reports under clause (i).

(C) Funding

There is authorized to be appropriated to carry out this paragraph, such sums as may be necessary.

(2) National Health and Nutrition Examination Survey

The Secretary shall develop oral healthcare components that shall include tooth-level surveillance for inclusion in the National Health and Nutrition Examination Survey. Such components shall be updated by the Secretary at least every 6 years. For purposes of this paragraph, the term "tooth-level surveillance" means a clinical examination where an examiner looks at each dental surface, on each tooth in the mouth and as expanded by the Division of Oral Health of the Centers for Disease Control and Prevention.

(3) Medical Expenditures Panel Survey

The Secretary shall ensure that the Medical Expenditures Panel Survey by the Agency for Healthcare Research and Quality includes the verification of dental utilization, expenditure, and coverage findings through conduct of a look-back analysis.

(4) National Oral Health Surveillance System

(A) Appropriations

There is authorized to be appropriated, such sums as may be necessary for each of fiscal years 2010 through 2014 to increase the participation of States in the National Oral Health Surveillance System from 16 States to all 50 States, territories, and District of Columbia.

(B) Requirements

The Secretary shall ensure that the National Oral Health Surveillance System include the measurement of early childhood caries.

(Pub. L. 111–148, title IV, §4102(d), Mar. 23, 2010, 124 Stat. 552.)

EDITORIAL NOTES

CODIFICATION

Section was enacted as part of the Patient Protection and Affordable Care Act, and not as part of the Public Health Service Act which comprises this chapter.

PART U—EMPLOYER-BASED WELLNESS PROGRAM

§280*l*. Technical assistance for employer-based wellness programs

In order to expand the utilization of evidence-based prevention and health promotion approaches in the workplace, the Director shall—

(1) provide employers (including small, medium, and large employers, as determined by the Director) with technical assistance, consultation, tools, and other resources in evaluating such employers' employer-based wellness programs, including—

(A) measuring the participation and methods to increase participation of employees in such

programs;

(B) developing standardized measures that assess policy, environmental and systems changes necessary to have a positive health impact on employees' health behaviors, health outcomes, and health care expenditures; and

(C) evaluating such programs as they relate to changes in the health status of employees, the absenteeism of employees, the productivity of employees, the rate of workplace injury, and the medical costs incurred by employees; and

(2) build evaluation capacity among workplace staff by training employers on how to evaluate employer-based wellness programs and ensuring evaluation resources, technical assistance, and consultation are available to workplace staff as needed through such mechanisms as web portals, call centers, or other means.

(July 1, 1944, ch. 373, title III, §399MM, as added and amended Pub. L. 111–148, title IV, §4303, title X, §10404, Mar. 23, 2010, 124 Stat. 583, 975.)

EDITORIAL NOTES

AMENDMENTS

2010—Par. (2). Pub. L. 111–148, §10404, substituted "and ensuring" for "by ensuring".

STATUTORY NOTES AND RELATED SUBSIDIARIES

GRANTS FOR SMALL BUSINESSES TO PROVIDE COMPREHENSIVE WORKPLACE WELLNESS PROGRAMS

Pub. L. 111–148, title X, §10408, Mar. 23, 2010, 124 Stat. 977, provided that:

"(a) ESTABLISHMENT.—The Secretary shall award grants to eligible employers to provide their employees with access to comprehensive workplace wellness programs (as described under subsection (c)).

"(b) SCOPE.—

"(1) DURATION.—The grant program established under this section shall be conducted for a 5-year period.

"(2) ELIGIBLE EMPLOYER.—The term 'eligible employer' means an employer (including a non-profit employer) that—

"(A) employs less than 100 employees who work 25 hours or greater per week; and

"(B) does not provide a workplace wellness program as of the date of enactment of this Act [Mar. 23, 2010].

"(c) COMPREHENSIVE WORKPLACE WELLNESS PROGRAMS.—

"(1) CRITERIA.—The Secretary shall develop program criteria for comprehensive workplace wellness programs under this section that are based on and consistent with evidence-based research and best practices, including research and practices as provided in the Guide to Community Preventive Services, the Guide to Clinical Preventive Services, and the National Registry for Effective Programs.

"(2) REQUIREMENTS.—A comprehensive workplace wellness program shall be made available by an eligible employer to all employees and include the following components:

"(A) Health awareness initiatives (including health education, preventive screenings, and health risk assessments).

"(B) Efforts to maximize employee engagement (including mechanisms to encourage employee participation).

"(C) Initiatives to change unhealthy behaviors and lifestyle choices (including counseling, seminars, online programs, and self-help materials).

"(D) Supportive environment efforts (including workplace policies to encourage healthy lifestyles, healthy eating, increased physical activity, and improved mental health).

"(d) APPLICATION.—An eligible employer desiring to participate in the grant program under this section shall submit an application to the Secretary, in such manner and containing such information as the Secretary may require, which shall include a proposal for a comprehensive workplace wellness program that meet [sic] the criteria and requirements described under subsection (c).

"(e) AUTHORIZATION OF APPROPRIATION.—For purposes of carrying out the grant program under

this section, there is authorized to be appropriated $200,000,000 for the period of fiscal years 2011 through 2015. Amounts appropriated pursuant to this subsection shall remain available until expended."

§280*l*–1. National worksite health policies and programs study

(a) In general

In order to assess, analyze, and monitor over time data about workplace policies and programs, and to develop instruments to assess and evaluate comprehensive workplace chronic disease prevention and health promotion programs, policies and practices, not later than 2 years after March 23, 2010, and at regular intervals (to be determined by the Director) thereafter, the Director shall conduct a national worksite health policies and programs survey to assess employer-based health policies and programs.

(b) Report

Upon the completion of each study under subsection (a), the Director shall submit to Congress a report that includes the recommendations of the Director for the implementation of effective employer-based health policies and programs.

(July 1, 1944, ch. 373, title III, §399MM–1, as added Pub. L. 111–148, title IV, §4303, Mar. 23, 2010, 124 Stat. 583.)

§280*l*–2. Prioritization of evaluation by Secretary

The Secretary shall evaluate, in accordance with this part, all programs funded through the Centers for Disease Control and Prevention before conducting such an evaluation of privately funded programs unless an entity with a privately funded wellness program requests such an evaluation.

(July 1, 1944, ch. 373, title III, §399MM–2, as added Pub. L. 111–148, title IV, §4303, Mar. 23, 2010, 124 Stat. 583.)

§280*l*–3. Prohibition of Federal workplace wellness requirements

Notwithstanding any other provision of this part, any recommendations, data, or assessments carried out under this part shall not be used to mandate requirements for workplace wellness programs.

(July 1, 1944, ch. 373, title III, §399MM–3, as added Pub. L. 111–148, title IV, §4303, Mar. 23, 2010, 124 Stat. 583.)

PART V—PROGRAMS RELATING TO BREAST HEALTH AND CANCER

§280m. Young women's breast health awareness and support of young women diagnosed with breast cancer

(a) Public education campaign

(1) In general

The Secretary, acting through the Director of the Centers for Disease Control and Prevention, shall conduct a national evidence-based education campaign to increase awareness of young women's knowledge regarding—

(A) breast health in young women of all racial, ethnic, and cultural backgrounds;

(B) breast awareness and good breast health habits;

(C) the occurrence of breast cancer and the general and specific risk factors in women who may be at high risk for breast cancer based on familial, racial, ethnic, and cultural backgrounds such as Ashkenazi Jewish populations;

(D) evidence-based information that would encourage young women and their health care professional to increase early detection of breast cancers; and

(E) the availability of health information and other resources for young women diagnosed with breast cancer.

(2) Evidence-based, age appropriate messages

The campaign shall provide evidence-based, age-appropriate messages and materials as developed by the Centers for Disease Control and Prevention and the Advisory Committee established under paragraph (4).

(3) Media campaign

In conducting the education campaign under paragraph (1), the Secretary shall award grants to entities to establish national multimedia campaigns oriented to young women that may include advertising through television, radio, print media, billboards, posters, all forms of existing and especially emerging social networking media, other Internet media, and any other medium determined appropriate by the Secretary.

(4) Advisory committee

(A) Establishment

Not later than 60 days after March 23, 2010, the Secretary, acting through the Director of the Centers for Disease Control and Prevention, shall establish an advisory committee to assist in creating and conducting the education campaigns under paragraph (1) and subsection (b)(1).

(B) Membership

The Secretary, acting through the Director of the Centers for Disease Control and Prevention, shall appoint to the advisory committee under subparagraph (A) such members as deemed necessary to properly advise the Secretary, and shall include organizations and individuals with expertise in breast cancer, disease prevention, early detection, diagnosis, public health, social marketing, genetic screening and counseling, treatment, rehabilitation, palliative care, and survivorship in young women.

(b) Health care professional education campaign

The Secretary, acting through the Director of the Centers for Disease Control and Prevention, and in consultation with the Administrator of the Health Resources and Services Administration, shall conduct an education campaign among physicians and other health care professionals to increase awareness—

(1) of breast health, symptoms, and early diagnosis and treatment of breast cancer in young women, including specific risk factors such as family history of cancer and women that may be at high risk for breast cancer, such as Ashkenazi Jewish population;

(2) on how to provide counseling to young women about their breast health, including knowledge of their family cancer history and importance of providing regular clinical breast examinations;

(3) concerning the importance of discussing healthy behaviors, and increasing awareness of services and programs available to address overall health and wellness, and making patient referrals to address tobacco cessation, good nutrition, and physical activity;

(4) on when to refer patients to a health care provider with genetics expertise;

(5) on how to provide counseling that addresses long-term survivorship and health concerns of young women diagnosed with breast cancer; and

(6) on when to provide referrals to organizations and institutions that provide credible health information and substantive assistance and support to young women diagnosed with breast cancer.

(c) Prevention research activities

The Secretary, acting through—

(1) the Director of the Centers for Disease Control and Prevention, shall conduct prevention research on breast cancer in younger women, including—

(A) behavioral, survivorship studies, and other research on the impact of breast cancer diagnosis on young women;

(B) formative research to assist with the development of educational messages and information for the public, targeted populations, and their families about breast health, breast cancer, and healthy lifestyles;

(C) testing and evaluating existing and new social marketing strategies targeted at young women; and

(D) surveys of health care providers and the public regarding knowledge, attitudes, and practices related to breast health and breast cancer prevention and control in high-risk populations; and

(2) the Director of the National Institutes of Health, shall conduct research to develop and validate new screening tests and methods for prevention and early detection of breast cancer in young women.

(d) Support for young women diagnosed with breast cancer

(1) In general

The Secretary shall award grants to organizations and institutions to provide health information from credible sources and substantive assistance directed to young women diagnosed with breast cancer and pre-neoplastic breast diseases.

(2) Priority

In making grants under paragraph (1), the Secretary shall give priority to applicants that deal specifically with young women diagnosed with breast cancer and pre-neoplastic breast disease.

(e) No duplication of effort

In conducting an education campaign or other program under subsections (a), (b), (c), or (d), the Secretary shall avoid duplicating other existing Federal breast cancer education efforts.

(f) Measurement; reporting

The Secretary, acting through the Director of the Centers for Disease Control and Prevention, shall—

(1) measure—

(A) young women's awareness regarding breast health, including knowledge of family cancer history, specific risk factors and early warning signs, and young women's proactive efforts at early detection;

(B) the number or percentage of young women utilizing information regarding lifestyle interventions that foster healthy behaviors;

(C) the number or percentage of young women receiving regular clinical breast exams; and

(D) the number or percentage of young women who perform breast self exams, and the frequency of such exams, before the implementation of this section;

(2) not less than every 3 years, measure the impact of such activities; and

(3) submit reports to the Congress on the results of such measurements.

(g) Definition

In this section, the term "young women" means women 15 to 44 years of age.

(h) Authorization of appropriations

To carry out subsections (a), (b), (c)(1), and (d), there are authorized to be appropriated $9,000,000 for each of fiscal years 2022 through 2026.

(July 1, 1944, ch. 373, title III, §399NN, as added Pub. L. 111–148, title X, §10413(b), Mar. 23, 2010, 124 Stat. 991; amended Pub. L. 113–265, §2, Dec. 18, 2014, 128 Stat. 2942; Pub. L. 116–260, div. BB, title III, §316, Dec. 27, 2020, 134 Stat. 2932.)

EDITORIAL NOTES

AMENDMENTS

2020—Subsec. (h). Pub. L. 116–260 substituted "$9,000,000 for each of fiscal years 2022 through 2026" for "$4,900,000 for each of fiscal years 2015 through 2019".

2014—Subsec. (h). Pub. L. 113–265 substituted "$4,900,000 for each of fiscal years 2015 through 2019" for "$9,000,000 for each of the fiscal years 2010 through 2014".

PART W—PARKINSON'S AND RELATED DISORDERS

§280n. National Parkinson's Project

(a) Definition of Parkinson's

In this section, the term "Parkinson's" means—

(1) Parkinson's disease; and

(2) all other neurodegenerative Parkinsonisms, including multiple system atrophy, corticobasal degeneration, progressive supranuclear palsy, and Parkinson's-related dementia.

(b) Establishment

The Secretary shall carry out a national project, to be known as the National Parkinson's Project (referred to in this section as the "Project"), to prevent, diagnose, treat, and cure Parkinson's.

(c) Activities carried out through Project

In carrying out the Project, the Secretary shall—

(1) create, maintain, and periodically update an integrated national plan to prevent, diagnose, treat, and cure Parkinson's, ameliorate symptoms, and slow or stop progression;

(2) carry out the annual assessment under subsection (d);

(3) provide information, including—

(A) an estimate of the level of current Federal investment in preventing, diagnosing, treating, and curing Parkinson's, ameliorating symptoms, and slowing or stopping progression; and

(B) if applicable, an estimate of the investment necessary to prevent, diagnose, treat, and cure Parkinson's, ameliorate symptoms, and slow or stop progression;

(4) coordinate research and services across all Federal agencies related to Parkinson's;

(5) encourage the development of safe and effective treatments, strategies, and other approaches to prevent, diagnose, treat, and cure Parkinson's, ameliorate symptoms, and slow or stop progression;

(6) improve the—

(A) early diagnosis of Parkinson's; and

(B) coordination of the care and treatment of individuals with Parkinson's;

(7) review the impact of Parkinson's on the physical, mental, and social health of individuals living with Parkinson's and their caregivers and families;

(8) coordinate with international bodies, to the extent possible, to integrate and inform the mission to prevent, diagnose, treat, and cure Parkinson's, ameliorate symptoms, and slow or stop progression globally; and

(9) to the extent practicable, collaborate with other entities to prevent duplication of existing

research activities for related disorders.

(d) Annual assessment

Not later than 24 months after July 2, 2024, and annually thereafter, the Secretary shall carry out an assessment of the Nation's progress in preparing for, and responding to, the escalating burden of Parkinson's, including—

(1) recommendations for priority actions based on the assessment;

(2) a description of any steps that are planned or have already been taken to implement such recommendations, including whether such recommendations can be implemented under existing law; and

(3) such other items as the Secretary determines appropriate.

(e) Advisory Council

(1) In general

The Secretary shall establish and maintain an Advisory Council on Parkinson's Research, Care, and Services (referred to in this section as the "Advisory Council") to advise the Secretary on Parkinson's-related issues.

(2) Membership

(A) Federal members

The Advisory Council shall be comprised of experts, to be appointed by the Secretary, who collectively are from various backgrounds and perspectives, including at least one member from each of—

(i) the Centers for Disease Control and Prevention;
(ii) the Administration on Community Living;
(iii) the Centers for Medicare & Medicaid Services;
(iv) the National Institutes of Health;
(v) the Agency for Healthcare Research and Quality;
(vi) the Department of Veterans Affairs;
(vii) the Food and Drug Administration;
(viii) the National Science Foundation;
(ix) the Department of Defense;
(x) the Environmental Protection Agency;
(xi) the Office of Minority Health;
(xii) the Indian Health Service;
(xiii) the Office of the Surgeon General of the Public Health Service; and
(xiv) other relevant Federal departments and agencies as determined by the Secretary.

(B) Non-federal members

In addition to the members listed in subparagraph (A), the Advisory Council shall include 10 expert members, to be appointed by the Secretary, who shall include representatives of minority communities, communities disproportionately affected by Parkinson's, and communities underrepresented in Parkinson's research, who shall each be from outside the Federal Government, and who shall include—

(i) 2 Parkinson's patient advocates, at least 1 of whom is living with young-onset Parkinson's;

(ii) 1 Parkinson's family caregiver;

(iii) 1 health care provider;

(iv) 2 biomedical researchers with Parkinson's-related expertise in basic, translational, clinical, or drug development science;

(v) 1 movement disorder specialist who treats Parkinson's patients;

(vi) 1 dementia specialist who treats Parkinson's patients; and

(vii) 2 representatives from nonprofit organizations that have demonstrated experience in Parkinson's-related research or Parkinson's-related patient care and other services.

(C) Representation

The Secretary shall ensure that the members of the Advisory Council are collectively representative of agencies, professions, individuals, and entities concerned with, or affected by, activities under this section.

(3) Meetings

(A) Frequency

The Advisory Council shall meet—

(i) at least once each quarter during the 2-year period beginning on the date on which the Advisory Council is established; and

(ii) at the Secretary's discretion after such period.

(B) Annual research meeting

Not later than 24 months after July 2, 2024, and every year thereafter, the Advisory Council shall convene a meeting of Federal and non-Federal organizations to discuss Parkinson's research.

(C) Open meetings

The meetings under subparagraphs (A) and (B) shall be open to the public.

(4) Annual report

Not later than 18 months after July 2, 2024, and every year thereafter, the Advisory Council shall provide to the Secretary and Congress a report containing—

(A) a list of all federally-funded efforts in Parkinson's research, prevention, diagnosis, treatment, clinical care, and institutional-, home-, and community-based programs and the outcomes of such efforts;

(B) recommendations for priority actions to expand, eliminate, coordinate, refocus, streamline, or condense Federal programs based on each program's performance, mission, scope, and purpose;

(C) recommendations to—

(i) reduce the financial impact of Parkinson's on families living with Parkinson's;

(ii) improve health outcomes for, and the quality of life of, individuals living with Parkinson's;

(iii) prevent Parkinson's, ameliorate symptoms, and slow or stop progression;

(iv) improve the quality of care provided to beneficiaries with Parkinson's who receive coverage through a federally-funded health care program, such as the Medicare program under title XVIII of the Social Security Act [42 U.S.C. 1395 et seq.] or the Medicaid program under title XIX of such Act [42 U.S.C. 1396 et seq.];

(v) research the association between environmental triggers and Parkinson's to help reduce exposure to potential triggers; and

(vi) research and better understand the underlying factors contributing to Parkinson's;

(D) priority actions to improve all federally-funded efforts in Parkinson's research, prevention, diagnosis, treatment, clinical care, and institutional-, home-, and community-based programs;

(E) an evaluation of the implementation, including outcomes, of the national plan under subsection (c)(1); and

(F) implementation steps to address the recommendations and priority actions under subparagraphs (B), (C), and (D), based in part on the evaluation under subparagraph (E).

(5) Termination

The Advisory Council shall terminate at the end of calendar year 2035.

(f) Information sharing

Each Federal department and agency that has information relating to Parkinson's shall share such

information with the Secretary consistent with the statutory obligations of such department or agency regarding disclosure of information, as necessary to enable the Secretary to complete a report under subsection (e)(4).

(g) Sunset

The section shall cease to be effective at the end of calendar year 2035.

(July 1, 1944, ch. 373, title III, §399OO, as added Pub. L. 118–66, §2, July 2, 2024, 138 Stat. 1443.)

EDITORIAL NOTES

REFERENCES IN TEXT

The Social Security Act, referred to in subsec. (e)(4)(C)(iv), is act Aug. 14, 1935, ch. 531, 49 Stat. 620. Titles XVIII and XIX of the Act are classified generally to subchapters XVIII (§1395 et seq.) and XIX (§1396 et seq.), respectively, of chapter 7 of this title. For complete classification of this Act to the Code, see section 1305 of this title and Tables.

SUBCHAPTER III—NATIONAL RESEARCH INSTITUTES

EDITORIAL NOTES

CODIFICATION

Title IV of the Public Health Service Act, comprising this subchapter, was originally enacted by act July 1, 1944, ch. 373, 58 Stat. 707, at which time title IV related solely to the National Cancer Institute. Because of the extensive amendments, reorganization of the subject matter, and expansion of title IV by the acts listed below, title IV is shown herein as having been added by Pub. L. 99–158, without reference to intervening amendments.

The provisions of title IV as originally enacted were subsequently redesignated as part A of title IV and amended, and parts B to I of title IV were added and amended by the following acts: June 16, 1948, ch. 481, 62 Stat. 464; June 24, 1948, ch. 621, 62 Stat. 598; Aug. 15, 1950, ch. 714, 64 Stat. 443; Oct. 5, 1961, Pub. L. 87–395, 75 Stat. 824; Oct. 17, 1962, Pub. L. 87–838, 76 Stat. 1072; Aug. 16, 1968, Pub. L. 90–489, 82 Stat. 771; Oct. 30, 1970, Pub. L. 91–515, 84 Stat. 1297; Dec. 23, 1971, Pub. L. 92–218, 85 Stat. 778; May 19, 1972, Pub. L. 92–305, 86 Stat. 162; Sept. 19, 1972, Pub. L. 92–423, 86 Stat. 679; Apr. 22, 1974, Pub. L. 93–270, 88 Stat. 90; May 14, 1974, Pub. L. 93–282, 88 Stat. 126; May 31, 1974, Pub. L. 93–296, 88 Stat. 184; July 12, 1974, Pub. L. 93–348, 88 Stat. 342; July 23, 1974, Pub. L. 93–352, 88 Stat. 358; July 23, 1974, Pub. L. 93–354, 88 Stat. 373; Jan. 4, 1975, Pub. L. 93–640, 88 Stat. 2217; July 29, 1975, Pub. L. 94–63, 89 Stat. 304; Nov. 28, 1975, Pub. L. 94–135, 89 Stat. 713; Apr. 21, 1976, Pub. L. 94–273, 90 Stat. 375; Apr. 22, 1976, Pub. L. 94–278, 90 Stat. 401; Oct. 19, 1976, Pub. L. 94–562, 90 Stat. 2645; Aug. 1, 1977, Pub. L. 95–83, 91 Stat. 383; Nov. 9, 1978, Pub. L. 95–622, 92 Stat. 3412; Nov. 9, 1978, Pub. L. 95–623, 92 Stat. 3443; July 10, 1979, Pub. L. 96–32, 93 Stat. 82; Oct. 7, 1980, Pub. L. 96–398, 94 Stat. 1564; Dec. 17, 1980, Pub. L. 96–538, 94 Stat. 3183; Aug. 13, 1981, Pub. L. 97–35, 95 Stat. 358; Apr. 26, 1984, Pub. L. 98–24, 97 Stat. 175.

Title IV was subsequently amended generally and completely reorganized by Pub. L. 99–158, §2, Nov. 20, 1985, 99 Stat. 822.

PART A—NATIONAL INSTITUTES OF HEALTH

§281. Organization of National Institutes of Health

(a) Relation to Public Health Service

The National Institutes of Health is an agency of the Service.

(b) National research institutes and national centers

The following agencies of the National Institutes of Health are national research institutes or national centers:

(1) The National Cancer Institute.
(2) The National Heart, Lung, and Blood Institute.
(3) The National Institute of Diabetes and Digestive and Kidney Diseases.
(4) The National Institute of Arthritis and Musculoskeletal and Skin Diseases.
(5) The National Institute on Aging.
(6) The National Institute of Allergy and Infectious Diseases.
(7) The Eunice Kennedy Shriver National Institute of Child Health and Human Development.
(8) The National Institute of Dental and Craniofacial Research.
(9) The National Eye Institute.
(10) The National Institute of Neurological Disorders and Stroke.
(11) The National Institute on Deafness and Other Communication Disorders.
(12) The National Institute on Alcohol Abuse and Alcoholism.
(13) The National Institute on Drug Abuse.
(14) The National Institute of Mental Health.
(15) The National Institute of General Medical Sciences.
(16) The National Institute of Environmental Health Sciences.
(17) The National Institute of Nursing Research.
(18) The National Institute of Biomedical Imaging and Bioengineering.
(19) The National Human Genome Research Institute.
(20) The National Library of Medicine.
(21) The National Center for Advancing Translational Sciences.
(22) The John E. Fogarty International Center for Advanced Study in the Health Sciences.
(23) The National Center for Complementary and Integrative Health.
(24) The National Institute on Minority Health and Health Disparities.
(25) Any other national center that, as an agency separate from any national research institute, was established within the National Institutes of Health as of the day before January 15, 2007.

(c) Division of Program Coordination, Planning, and Strategic Initiatives

(1) In general

Within the Office of the Director of the National Institutes of Health, there shall be a Division of Program Coordination, Planning, and Strategic Initiatives (referred to in this subsection as the "Division").

(2) Offices within Division

(A) Offices

The following offices are within the Division: The Office of AIDS Research, the Office of Research on Women's Health, the Office of Behavioral and Social Sciences Research, the Office of Disease Prevention, the Office of Dietary Supplements, and any other office located within the Office of the Director of NIH as of the day before January 15, 2007. In addition to such offices, the Director of NIH may establish within the Division such additional offices or other administrative units as the Director determines to be appropriate.

(B) Authorities

Each office in the Division—

(i) shall continue to carry out the authorities that were in effect for the office before January 15, 2007; and

(ii) shall, as determined appropriate by the Director of NIH, support the Division with respect to the authorities described in section 282(b)(7) of this title.

(d) Organization

(1) Number of institutes and centers

In the National Institutes of Health, the number of national research institutes and national

centers may not exceed a total of 27, including any such institutes or centers established under authority of paragraph (2) or under authority of this subchapter as in effect on the day before January 15, 2007.

(2) Reorganization of institutes

(A) In general

The Secretary may establish in the National Institutes of Health one or more additional national research institutes to conduct and support research, training, health information, and other programs with respect to any particular disease or groups of diseases or any other aspect of human health if—

(i) the Secretary determines that an additional institute is necessary to carry out such activities; and

(ii) the additional institute is not established before the expiration of 180 days after the Secretary has provided the Committee on Energy and Commerce of the House of Representatives and the Committee on Health, Education, Labor, and Pensions of the Senate written notice of the determination made under clause (i) with respect to the institute.

(B) Additional authority

The Secretary may reorganize the functions of any national research institute and may abolish any national research institute if the Secretary determines that the institute is no longer required. A reorganization or abolition may not take effect under this paragraph before the expiration of 180 days after the Secretary has provided the Committee on Energy and Commerce of the House of Representatives and the Committee on Health, Education, Labor, and Pensions of the Senate written notice of the reorganization or abolition.

(3) Reorganization of Office of Director

Notwithstanding subsection (c), the Director of NIH may, after a series of public hearings, and with the approval of the Secretary, reorganize the offices within the Office of the Director, including the addition, removal, or transfer of functions of such offices, and the establishment or termination of such offices, if the Director determines that the overall management and operation of programs and activities conducted or supported by such offices would be more efficiently carried out under such a reorganization.

(4) Internal reorganization of institutes and centers

Notwithstanding any conflicting provisions of this subchapter, the director of a national research institute or a national center may, after a series of public hearings and with the approval of the Director of NIH, reorganize the divisions, centers, or other administrative units within such institute or center, including the addition, removal, or transfer of functions of such units, and the establishment or termination of such units, if the director of such institute or center determines that the overall management and operation of programs and activities conducted or supported by such divisions, centers, or other units would be more efficiently carried out under such a reorganization.

(e) Scientific Management Review Board for periodic organizational reviews

(1) In general

Not later than 60 days after January 15, 2007, the Secretary shall establish an advisory council within the National Institutes of Health to be known as the Scientific Management Review Board (referred to in this subsection as the "Board").

(2) Duties

(A) Reports on organizational issues

The Board shall provide advice to the appropriate officials under subsection (d) regarding the use of the authorities established in paragraphs (2), (3), and (4) of such subsection to reorganize the National Institutes of Health (referred to in this subsection as "organizational authorities"). Not less frequently than once each 7 years, the Board shall—

(i) determine whether and to what extent the organizational authorities should be used; and

(ii) issue a report providing the recommendations of the Board regarding the use of the authorities and the reasons underlying the recommendations.

(B) Certain responsibilities regarding reports

The activities of the Board with respect to a report under subparagraph (A) shall include the following:

(i) Reviewing the research portfolio of the National Institutes of Health (referred to in this subsection as "NIH") in order to determine the progress and effectiveness and value of the portfolio and the allocation among the portfolio activities of the resources of NIH.

(ii) Determining pending scientific opportunities, and public health needs, with respect to research within the jurisdiction of NIH.

(iii) For any proposal for organizational changes to which the Board gives significant consideration as a possible recommendation in such report—

(I) analyzing the budgetary and operational consequences of the proposed changes;

(II) taking into account historical funding and support for research activities at national research institutes and centers that have been established recently relative to national research institutes and centers that have been in existence for more than two decades;

(III) estimating the level of resources needed to implement the proposed changes;

(IV) assuming the proposed changes will be made and making a recommendation for the allocation of the resources of NIH among the national research institutes and national centers; and

(V) analyzing the consequences for the progress of research in the areas affected by the proposed changes.

(C) Consultation

In carrying out subparagraph (A), the Board shall consult with—

(i) the heads of national research institutes and national centers whose directors are not members of the Board;

(ii) other scientific leaders who are officers or employees of NIH and are not members of the Board;

(iii) advisory councils of the national research institutes and national centers;

(iv) organizations representing the scientific community; and

(v) organizations representing patients.

(3) Composition of Board

The Board shall consist of the Director of NIH, who shall be a permanent nonvoting member on an ex officio basis, and an odd number of additional members, not to exceed 21, all of whom shall be voting members. The voting members of the Board shall be the following:

(A) Not fewer than 9 officials who are directors of national research institutes or national centers. The Secretary shall designate such officials for membership and shall ensure that the group of officials so designated includes directors of—

(i) national research institutes whose budgets are substantial relative to a majority of the other institutes;

(ii) national research institutes whose budgets are small relative to a majority of the other institutes;

(iii) national research institutes that have been in existence for a substantial period of time without significant organizational change under subsection (d);

(iv) as applicable, national research institutes that have undergone significant organization changes under such subsection, or that have been established under such subsection, other than national research institutes for which such changes have been in place for a substantial period of time; and

(v) national centers.

(B) Members appointed by the Secretary from among individuals who are not officers or employees of the United States. Such members shall include—

(i) individuals representing the interests of public or private institutions of higher education that have historically received funds from NIH to conduct research; and

(ii) individuals representing the interests of private entities that have received funds from NIH to conduct research or that have broad expertise regarding how the National Institutes of Health functions, exclusive of private entities to which clause (i) applies.

(4) Chair

The Chair of the Board shall be selected by the Secretary from among the members of the Board appointed under paragraph (3)(B). The term of office of the Chair shall be 2 years.

(5) Meetings

(A) In general

The Board shall meet at the call of the Chair or upon the request of the Director of NIH, but not fewer than 5 times with respect to issuing any particular report under paragraph (2)(A). The location of the meetings of the Board is subject to the approval of the Director of NIH.

(B) Particular forums

Of the meetings held under subparagraph (A) with respect to a report under paragraph (2)(A)—

(i) one or more shall be directed toward the scientific community to address scientific needs and opportunities related to proposals for organizational changes under subsection (d), or as the case may be, related to a proposal that no such changes be made; and

(ii) one or more shall be directed toward consumer organizations to address the needs and opportunities of patients and their families with respect to proposals referred to in clause (i).

(C) Availability of information from forums

For each meeting under subparagraph (B), the Director of NIH shall post on the Internet site of the National Institutes of Health a summary of the proceedings.

(6) Compensation; term of office

The provisions of subsections (b)(4) and (c) of section 284a of this title apply with respect to the Board to the same extent and in the same manner as such provisions apply with respect to an advisory council referred to in such subsections, except that the reference in such subsection (c) to 4 years regarding the term of an appointed member is deemed to be a reference to 5 years.

(7) Reports

(A) Recommendations for changes

Each report under paragraph (2)(A) shall be submitted to—

(i) the Committee on Energy and Commerce and the Committee on Appropriations of the House of Representatives;

(ii) the Committee on Health, Education, Labor, and Pensions and the Committee on Appropriations of the Senate;

(iii) the Secretary; and

(iv) officials with organizational authorities, other than any such official who served as a member of the Board with respect to the report involved.

(B) Availability to public

The Director of NIH shall post each report under paragraph (2) on the Internet site of the National Institutes of Health.

(C) Report on Board activities

Not later than 18 months after January 15, 2007, the Board shall submit to the committees specified in subparagraph (A) a report describing the activities of the Board.

(f) Organizational changes per recommendation of Scientific Management Review Board

(1) In general

With respect to an official who has organizational authorities within the meaning of subsection (e)(2)(A), if a recommendation to the official for an organizational change is made in a report under such subsection, the official shall, except as provided in paragraphs (2), (3), and (4) of this subsection, make the change in accordance with the following:

(A) Not later than 100 days after the report is submitted under subsection (e)(7)(A), the official shall initiate the applicable public process required in subsection (d) toward making the change.

(B) The change shall be fully implemented not later than the expiration of the 3-year period beginning on the date on which such process is initiated.

(2) Inapplicability to certain reorganizations

Paragraph (1) does not apply to a recommendation made in a report under subsection (e)(2)(A) if the recommendation is for—

(A) an organizational change under subsection (d)(2) that constitutes the establishment, termination, or consolidation of one or more national research institutes or national centers; or

(B) an organizational change under subsection (d)(3).

(3) Objection by Director of NIH

(A) In general

Paragraph (1) does not apply to a recommendation for an organizational change made in a report under subsection (e)(2)(A) if, not later than 90 days after the report is submitted under subsection (e)(7)(A), the Director of NIH submits to the committees specified in such subsection a report providing that the Director objects to the change, which report includes the reasons underlying the objection.

(B) Scope of objection

For purposes of subparagraph (A), an objection by the Director of NIH may be made to the entirety of a recommended organizational change or to 1 or more aspects of the change. Any aspect of a change not objected to by the Director in a report under subparagraph (A) shall be implemented in accordance with paragraph (1).

(4) Congressional review

An organizational change under subsection (d)(2) that is initiated pursuant to paragraph (1) shall be carried out by regulation in accordance with the procedures for substantive rules under section 553 of title 5. A rule under the preceding sentence shall be considered a major rule for purposes of chapter 8 of such title (relating to congressional review of agency rulemaking).

(g) Definitions

For purposes of this subchapter:

(1) The term "Director of NIH" means the Director of the National Institutes of Health.

(2) The terms "national research institute" and "national center" mean an agency of the National Institutes of Health that is—

(A) listed in subsection (b) and not terminated under subsection (d)(2)(A); or

(B) established by the Director of NIH under such subsection.

(h) References to NIH

For purposes of this subchapter, a reference to the National Institutes of Health includes its agencies.

(July 1, 1944, ch. 373, title IV, §401, as added Pub. L. 99–158, §2, Nov. 20, 1985, 99 Stat. 822; amended Pub. L. 100–553, §2(1), Oct. 28, 1988, 102 Stat. 2769; Pub. L. 100–607, title I, §101(1), Nov. 4, 1988, 102 Stat. 3048; Pub. L. 100–690, title II, §2613(b)(2), Nov. 18, 1988, 102 Stat. 4238; Pub. L. 102–321, title I, §121(a), July 10, 1992, 106 Stat. 358; Pub. L. 103–43, title XV, §§1501(1),

1511(b)(1), 1521(1), June 10, 1993, 107 Stat. 172, 179, 180; Pub. L. 103–417, §13(b), Oct. 25, 1994, 108 Stat. 4335; Pub. L. 105–277, div. A, §101(f) [title II, §212, title VI, §601(k)], Oct. 21, 1998, 112 Stat. 2681–337, 2681–359, 2681–388; Pub. L. 106–525, title I, §101(b)(1), Nov. 22, 2000, 114 Stat. 2501; Pub. L. 106–580, §3(e), Dec. 29, 2000, 114 Stat. 3091; Pub. L. 109–482, title I, §§101(a), (b), 108(a), Jan. 15, 2007, 120 Stat. 3675, 3676, 3697; Pub. L. 110–154, §1(b)(1), Dec. 21, 2007, 121 Stat. 1827; Pub. L. 111–148, title X, §10334(c)(3)(A), Mar. 23, 2010, 124 Stat. 974; Pub. L. 112–74, div. F, title II, §221(a)(2), (c)(2)(B), Dec. 23, 2011, 125 Stat. 1087, 1089; Pub. L. 113–235, div. G, title II, §224(1), Dec. 16, 2014, 128 Stat. 2490.)

EDITORIAL NOTES

AMENDMENTS

2014—Subsec. (b)(23). Pub. L. 113–235 substituted "National Center for Complementary and Integrative Health" for "National Center for Complementary and Alternative Medicine".

2011—Subsec. (b)(21). Pub. L. 112–74, §221(a)(2), substituted "National Center for Advancing Translational Sciences" for "National Center for Research Resources".

Subsec. (c)(2)(A). Pub. L. 112–74, §221(c)(2)(B), struck out "the Office of Rare Diseases," after "the Office of Dietary Supplements,".

2010—Subsec. (b)(24). Pub. L. 111–148 substituted "Institute" for "Center".

2007—Subsec. (b)(7). Pub. L. 110–154 substituted "Eunice Kennedy Shriver National Institute of Child Health and Human Development" for "National Institute of Child Health and Human Development".

Pub. L. 109–482, §101(a), reenacted section catchline without change and amended text generally, substituting provisions consisting of subsecs. (a) to (d)(1) for former subsecs. (a) to (d) which related to: in subsec. (a), relationship to Public Health Service; in subsec. (b), list of national research institutes that were agencies; in subsec. (c), establishment of additional institutes and reorganization or abolition of institutes; and, in subsec. (d), definition of "national research institute". See below.

Subsec. (d)(2). Pub. L. 109–482, §108(a), added after subsec. (d)(1) provisions identical to text of subsec. (c) prior to amendment by Pub. L. 109–482, §101(a), redesignated such provisions as par. (2), added par. heading, redesignated former pars. (1) and (2) as subpars. (A) and (B), respectively, added subpar. headings, in subpar. (A), redesignated former subpars. (A) and (B) as cls. (i) and (ii), respectively, in cl. (ii), substituted "Health, Education, Labor, and Pensions" for "Labor and Human Resources" and "clause (i)" for "subparagraph (A)", and, in subpar. (B), substituted "Health, Education, Labor, and Pensions" for "Labor and Human Resources".

Subsec. (d)(3), (4). Pub. L. 109–482, §101(b)(1), added pars. (3) and (4).

Subsecs. (e) to (h). Pub. L. 109–482, §101(b)(2), added subsecs. (e) to (h).

2000—Subsec. (b)(1)(R). Pub. L. 106–580 added subpar. (R).

Subsec. (b)(2)(F). Pub. L. 106–525, §101(b)(1)(A), realigned margins.

Subsec. (b)(2)(G). Pub. L. 106–525, §101(b)(1)(B), added subpar. (G).

1998—Subsec. (b)(1)(H). Pub. L. 105–277, §101(f) [title II, §212], substituted "National Institute of Dental and Craniofacial Research" for "National Institute of Dental Research".

Subsec. (b)(2)(F). Pub. L. 105–277, §101(f) [title VI, §601(k)], added subpar. (F).

1994—Subsec. (b)(2)(E). Pub. L. 103–417 added subpar. (E).

1993—Subsec. (b)(1)(Q). Pub. L. 103–43, §1511(b)(1)(A), added subpar. (Q).

Subsec. (b)(2)(B). Pub. L. 103–43, §1501(1), amended subpar. (B) generally, substituting "National Center for Research Resources" for "Division of Research Resources".

Subsec. (b)(2)(D). Pub. L. 103–43, §§1511(b)(1)(B), 1521(1), added subpar. (D) and struck out former subpar. (D) which read as follows: "The National Center for Nursing Research."

1992—Subsec. (b)(1)(N) to (P). Pub. L. 102–321 added subpars. (N) to (P).

1988—Subsec. (b)(1)(J), (M). Pub. L. 100–553 and Pub. L. 100–607 made identical amendments, striking out "and Communicative" after "Neurological" in subpar. (J), and adding subpar. (M). Pub. L. 100–690 amended subsec. (b)(1) to read as if the amendments by Pub. L. 100–607 had not been enacted.

STATUTORY NOTES AND RELATED SUBSIDIARIES

EFFECTIVE DATE OF 2007 AMENDMENT

Pub. L. 109–482, title I, §109, Jan. 15, 2007, 120 Stat. 3697, provided that: "This title [see Tables for

classification] and the amendments made by this title apply only with respect to amounts appropriated for fiscal year 2007 or subsequent fiscal years."

EFFECTIVE DATE OF 2000 AMENDMENT

Pub. L. 106–525, title VI, §603, Nov. 22, 2000, 114 Stat. 2511, provided that: "This Act [enacting subpart 6 (§287c–31 et seq.) of part E of this subchapter and sections 293e, 296e–1, and 299a–1 of this title, amending sections 281, 296f, 299a, 299c–6, and 300u–6 of this title, repealing section 283b of this title, and enacting provisions set out as notes under sections 201, 287c–31, 293e, and 3501 of this title] and the amendments made by this Act take effect October 1, 2000, or upon the date of the enactment of this Act [Nov. 22, 2000], whichever occurs later."

EFFECTIVE DATE OF 1992 AMENDMENT

Amendment by Pub. L. 102–321 effective Oct. 1, 1992, with provision for programs providing financial assistance, see section 801(c), (d) of Pub. L. 102–321, set out as a note under section 236 of this title.

EFFECTIVE DATE OF 1988 AMENDMENT

For effective date of amendment by Pub. L. 100–690, see section 2613(b)(1) of Pub. L. 100–690, set out as an Effect of Enactment of Similar Provisions note under section 285m of this title.

CONSTRUCTION OF 2007 AMENDMENT

Pub. L. 109–482, title I, §102(g), Jan. 15, 2007, 120 Stat. 3685, provided that: "This Act [see Tables for classification] and the amendments made by this Act may not be construed as affecting the authorities of the national research institutes and national centers that were in effect under the Public Health Service Act [42 U.S.C. 201 et seq.] on the day before the date of the enactment of this Act [Jan. 15, 2007], subject to the authorities of the Secretary of Health and Human Services and the Director of NIH under section 401 of the Public Health Service Act [42 U.S.C. 281] (as amended by section 101 of this Act). For purposes of the preceding sentence, the terms 'national research institute', 'national center', and 'Director of NIH' have the meanings given such terms in such section 401."

STUDY OF THE USE OF CENTERS OF EXCELLENCE AT THE NATIONAL INSTITUTES OF HEALTH

Pub. L. 107–84, §7, Dec. 18, 2001, 115 Stat. 829, required the Secretary of Health and Human Services to contract, not later than 60 days after Dec. 18, 2001, with the Institute of Medicine to conduct a study on the impact of, need for, and other issues associated with Centers of Excellence at the National Institutes of Health and complete the study and submit a report not later than one year after the date of the contract.

REPORT ON MEDICAL USES OF BIOLOGICAL AGENTS IN DEVELOPMENT OF DEFENSES AGAINST BIOLOGICAL WARFARE

Pub. L. 103–43, title XIX, §1904, June 10, 1993, 107 Stat. 203, directed Secretary of Health and Human Services, in consultation with Secretary of Defense and with heads of other appropriate executive agencies, to report to Congress, not later than 12 months after June 10, 1993, on the appropriateness and impact of the National Institutes of Health assuming responsibility for the conduct of all Federal research, development, testing, and evaluation functions relating to medical countermeasures against biowarfare threat agents.

RESEARCH ON LUPUS ERYTHEMATOSUS

Pub. L. 99–158, §5, Nov. 20, 1985, 99 Stat. 880, as amended by Pub. L. 102–531, title III, §312(f), Oct. 27, 1992, 106 Stat. 3506, directed Secretary of Health and Human Resources to establish a Lupus Erythematosus Coordinating Committee to plan, develop, coordinate, and implement comprehensive Federal initiatives in research on Lupus Erythematosus, provided for composition of committee and meetings, and directed Committee to prepare a report for Congress on its activities, to be submitted not later than 18 months after Nov. 20, 1985, with Committee to terminate one month after the report was submitted.

INTERAGENCY COMMITTEE ON LEARNING DISABILITIES

Pub. L. 99–158, §9, Nov. 20, 1985, 99 Stat. 882, directed Director of the National Institutes of Health, not later than 90 days after Nov. 20, 1985, to establish an Interagency Committee on Learning Disabilities to review and assess Federal research priorities, activities, and findings regarding learning disabilities (including central nervous system dysfunction in children), provided for composition of the Committee, directed Committee to report to Congress on its activities not later than 18 months after Nov. 20, 1985, and provided that the Committee terminate 90 days after submission of the report.

§282. Director of National Institutes of Health

(a) Appointment

The National Institutes of Health shall be headed by the Director of NIH who shall be appointed by the President by and with the advice and consent of the Senate. The Director of NIH shall perform functions as provided under subsection (b) and as the Secretary may otherwise prescribe.

(b) Duties and authority

In carrying out the purposes of section 241 of this title, the Secretary, acting through the Director of NIH—

(1) shall carry out this subchapter, including being responsible for the overall direction of the National Institutes of Health and for the establishment and implementation of general policies respecting the management and operation of programs and activities within the National Institutes of Health;

(2) shall coordinate and oversee the operation of the national research institutes, national centers, and administrative entities within the National Institutes of Health;

(3) shall, in consultation with the heads of the national research institutes and national centers, be responsible for program coordination across the national research institutes and national centers, including conducting priority-setting reviews, to ensure that the research portfolio of the National Institutes of Health is balanced and free of unnecessary duplication, and takes advantage of collaborative, cross-cutting research;

(4) shall assemble accurate data to be used to assess research priorities, including—

(A) information to better evaluate scientific opportunity, public health burdens, and progress in reducing health disparities; and

(B) data on study populations of clinical research, funded by or conducted at each national research institute and national center, which—

(i) specifies the inclusion of—

(I) women;

(II) members of minority groups;

(III) relevant age categories, including pediatric subgroups; and

(IV) other demographic variables as the Director of the National Institutes of Health determines appropriate;

(ii) is disaggregated by research area, condition, and disease categories; and

(iii) is to be made publicly available on the Internet website of the National Institutes of Health;

(5) shall ensure that scientifically based strategic planning is implemented in support of research priorities as determined by the agencies of the National Institutes of Health, and through the development, implementation, and updating of the strategic plan developed under subsection (m);

(6) shall ensure that the resources of the National Institutes of Health are sufficiently allocated for research projects identified in strategic plans;

(7)(A) shall, through the Division of Program Coordination, Planning, and Strategic Initiatives—

(i) identify research that represents important areas of emerging scientific opportunities, rising public health challenges, or knowledge gaps that deserve special emphasis and would benefit from conducting or supporting additional research that involves collaboration between 2 or more national research institutes or national centers, or would otherwise benefit from strategic coordination and planning;

(ii) include information on such research in reports under section 283 of this title; and

(iii) in the case of such research supported with funds referred to in subparagraph (B)—

(I) require as appropriate that proposals include milestones and goals for the research;

(II) require that the proposals include timeframes for funding of the research; and

(III) ensure appropriate consideration of proposals for which the principal investigator is an individual who has not previously served as the principal investigator of research conducted or supported by the National Institutes of Health;

(B)(i) may, with respect to funds reserved under section 282a(c)(1) of this title for the Common Fund, allocate such funds to the national research institutes and national centers for conducting and supporting research that is identified under subparagraph (A); and

(ii) shall, with respect to funds appropriated to the Division of Program Coordination, Planning, and Strategic Initiatives pursuant to section 282a(a)(2) of this title, allocate such funds to the national research institutes and national centers for making grants for pediatric research that is identified under subparagraph (A) and shall prioritize, as appropriate, such pediatric research that does not duplicate existing research activities of the National Institutes of Health; and

(C) may assign additional functions to the Division in support of responsibilities identified in subparagraph (A), as determined appropriate by the Director;

(8) shall, in coordination with the heads of the national research institutes and national centers, ensure that such institutes and centers—

(A) preserve an emphasis on investigator-initiated research project grants, including with respect to research involving collaboration between 2 or more such institutes or centers;

(B) when appropriate, maximize investigator-initiated research project grants in their annual research portfolios;

(C) foster collaboration between clinical research projects funded by the respective national research institutes and national centers that—

(i) conduct research involving human subjects; and

(ii) collect similar data; and

(D) encourage the collaboration described in subparagraph (C) to—

(i) allow for an increase in the number of subjects studied; and

(ii) utilize diverse study populations, with special consideration to biological, social, and other determinants of health that contribute to health disparities;

(9) shall ensure that research conducted or supported by the National Institutes of Health is subject to review in accordance with section 289a of this title and that, after such review, the research is reviewed in accordance with section 289a–1(a)(2) of this title by the appropriate advisory council under section 284a of this title before the research proposals are approved for funding;

(10) shall have authority to review and approve the establishment of all centers of excellence recommended by the national research institutes;

(11)(A) shall oversee research training for all of the national research institutes and National Research Service Awards in accordance with section 288 of this title; and

(B) may conduct and support research training—

(i) for which fellowship support is not provided under section 288 of this title; and

(ii) that does not consist of residency training of physicians or other health professionals;

(12) may, from funds appropriated under section 282a(b) of this title, reserve funds to provide for research on matters that have not received significant funding relative to other matters, to respond to new issues and scientific emergencies, and to act on research opportunities of high priority;

(13) may, subject to appropriations Acts, collect and retain registration fees obtained from third parties to defray expenses for scientific, educational, and research-related conferences;

(14) for the national research institutes and administrative entities within the National Institutes of Health—

(A) may acquire, construct, improve, repair, operate, and maintain, at the site of such institutes and entities, laboratories, and other research facilities, other facilities, equipment, and

other real or personal property, and

(B) may acquire, without regard to section 8141 of title 40, by lease or otherwise through the Administrator of General Services, buildings or parts of buildings in the District of Columbia or communities located adjacent to the District of Columbia for use for a period not to exceed ten years;

(15) may secure resources for research conducted by or through the National Institutes of Health;

(16) may, without regard to the provisions of title 5 governing appointments in the competitive service, and without regard to the provisions of chapter 51 and subchapter III of chapter 53 of such title relating to classification and General Schedule pay rates, establish such technical and scientific peer review groups and scientific program advisory committees as are needed to carry out the requirements of this subchapter and appoint and pay the members of such groups, except that officers and employees of the United States shall not receive additional compensation for service as members of such groups;

(17) may secure for the National Institutes of Health consultation services and advice of persons from the United States or abroad;

(18) may use, with their consent, the services, equipment, personnel, information, and facilities of other Federal, State, or local public agencies, with or without reimbursement therefor;

(19) may, for purposes of study, admit and treat at facilities of the National Institutes of Health individuals not otherwise eligible for such treatment;

(20) may accept voluntary and uncompensated services;

(21) may perform such other administrative functions as the Secretary determines are needed to effectively carry out this subchapter;

(22) may appoint physicians, dentists, and other health care professionals, subject to the provisions of title 5 relating to appointments and classifications in the competitive service, and may compensate such professionals subject to the provisions of chapter 74 of title 38;

(23) shall designate a contact point or office to help innovators and physicians identify sources of funding available for pediatric medical device development;

(24) implement the Cures Acceleration Network described in section 287a of this title;

(25) may require recipients of National Institutes of Health awards to share scientific data, to the extent feasible, generated from such National Institutes of Health awards in a manner that is consistent with all applicable Federal laws and regulations, including such laws and regulations for the protection of—

(A) human research participants, including with respect to privacy, security, informed consent, and protected health information; and

(B) proprietary interests, confidential commercial information, and the intellectual property rights of the funding recipient;

(26) shall consult with the Assistant Secretary for Preparedness and Response, the Director of the Biomedical Advanced Research and Development Authority, the Director of the Centers for Disease Control and Prevention, and the heads of other Federal agencies and offices, as appropriate, regarding research needs to advance medical countermeasures to diagnose, mitigate, prevent, or treat harm from any biological agent or toxin, including emerging infectious diseases, chemical, radiological, or nuclear agent that may cause a public health emergency or other research needs related to emerging public health threats;

(27) shall consult with the Director of the Office of National Security within the Department of Health and Human Services, the Assistant Secretary for Preparedness and Response, the Director of National Intelligence, the Director of the Federal Bureau of Investigation, and the heads of other appropriate agencies on a regular basis, regarding biomedical research conducted or supported by the National Institutes of Health that may affect or be affected by matters of national security;

(28) shall ensure that recipients of awards from the National Institutes of Health, and, as

appropriate and practicable, entities collaborating with such recipients, have in place and are adhering to appropriate technology practices and policies for the security of identifiable, sensitive information, including information collected, stored, managed, or analyzed by domestic and non-domestic entities; and

(29) shall ensure that recipients of awards from the National Institutes of Health are in compliance with the terms and conditions of such award, which may include activities to support awareness of, and compliance with, such terms and conditions by any subrecipients of the award.

Chapter 10 of title 5 shall not apply to the duration of a peer review group appointed under paragraph (16). The members of such a group shall be individuals who by virtue of their training or experience are eminently qualified to perform the review functions of such group. Not more than one-fourth of the members of any such group shall be officers or employees of the United States.

(c) Availability of substances and organisms for research

The Director of NIH may make available to individuals and entities, for biomedical and behavioral research, substances and living organisms. Such substances and organisms shall be made available under such terms and conditions (including payment for them) as the Secretary determines appropriate.

(d) Services of experts or consultants; number; payment of expenses, conditions, recovery

(1) The Director of NIH may obtain (in accordance with section 3109 of title 5, but without regard to the limitation in such section on the period of service) the services of not more than 220 experts or consultants, with scientific or other professional qualifications, for the National Institutes of Health.

(2)(A) Except as provided in subparagraph (B), experts and consultants whose services are obtained under paragraph (1) shall be paid or reimbursed, in accordance with title 5, for their travel to and from their place of service and for other expenses associated with their assignment.

(B) Expenses specified in subparagraph (A) shall not be allowed in connection with the assignment of an expert or consultant whose services are obtained under paragraph (1) unless the expert or consultant has agreed in writing to complete the entire period of the assignment or one year of the assignment, whichever is shorter, unless separated or reassigned for reasons which are beyond the control of the expert or consultant and which are acceptable to the Secretary. If the expert or consultant violates the agreement, the money spent by the United States for such expenses is recoverable from the expert or consultant as a debt due the United States. The Secretary may waive in whole or in part a right of recovery under this subparagraph.

(e) Dissemination of research information

The Director of NIH shall—

(1) advise the agencies of the National Institutes of Health on medical applications of research;

(2) coordinate, review, and facilitate the systematic identification and evaluation of, clinically relevant information from research conducted by or through the national research institutes;

(3) promote the effective transfer of the information described in paragraph (2) to the health care community and to entities that require such information;

(4) monitor the effectiveness of the activities described in paragraph (3); and

(5) ensure that, after January 1, 1994, all new or revised health education and promotion materials developed or funded by the National Institutes of Health and intended for the general public are in a form that does not exceed a level of functional literacy, as defined in the National Literacy Act of 1991 (Public Law 102–73).

(f) Associate Director for Prevention; functions

There shall be in the National Institutes of Health an Associate Director for Prevention. The Director of NIH shall delegate to the Associate Director for Prevention the functions of the Director relating to the promotion of the disease prevention research programs of the national research institutes and the coordination of such programs among the national research institutes and between the national research institutes and other public and private entities, including elementary, secondary, and post-secondary schools. The Associate Director shall—

(1) annually review the efficacy of existing policies and techniques used by the national research institutes to disseminate the results of disease prevention and behavioral research programs; and

(2) recommend, coordinate, and oversee the modification or reconstruction of such policies and techniques to ensure maximum dissemination, using advanced technologies to the maximum extent practicable, of research results to such entities.

(g) Transferred

(h) Increased participation of women and disadvantaged individuals in biomedical and behavioral research

The Secretary, acting through the Director of NIH and the Directors of the agencies of the National Institutes of Health, shall, in conducting and supporting programs for research, research training, recruitment, and other activities, provide for an increase in the number of women and individuals from disadvantaged backgrounds (including racial and ethnic minorities) in the fields of biomedical and behavioral research.

(i) Data bank of information on clinical trials for drugs for serious or life-threatening diseases and conditions

(1)(A) The Secretary, acting through the Director of NIH, shall establish, maintain, and operate a data bank of information on clinical trials for drugs for serious or life-threatening diseases and conditions (in this subsection referred to as the "data bank"). The activities of the data bank shall be integrated and coordinated with related activities of other agencies of the Department of Health and Human Services, and to the extent practicable, coordinated with other data banks containing similar information.

(B) The Secretary shall establish the data bank after consultation with the Commissioner of Food and Drugs, the directors of the appropriate agencies of the National Institutes of Health (including the National Library of Medicine), and the Director of the Centers for Disease Control and Prevention.

(2) In carrying out paragraph (1), the Secretary shall collect, catalog, store, and disseminate the information described in such paragraph. The Secretary shall disseminate such information through information systems, which shall include toll-free telephone communications, available to individuals with serious or life-threatening diseases and conditions, to other members of the public, to health care providers, and to researchers.

(3) The data bank shall include the following:

(A) A registry of clinical trials (whether federally or privately funded) of experimental treatments for serious or life-threatening diseases and conditions under regulations promulgated pursuant to section 355(i) of title 21, which provides a description of the purpose of each experimental drug, either with the consent of the protocol sponsor, or when a trial to test effectiveness begins. Information provided shall consist of eligibility criteria for participation in the clinical trials, a description of the location of trial sites, a point of contact for those wanting to enroll in the trial, and a description of whether, and through what procedure, the manufacturer or sponsor of the investigation of a new drug will respond to requests for protocol exception, with appropriate safeguards, for single-patient and expanded protocol use of the new drug, particularly in children, and shall be in a form that can be readily understood by members of the public. Such information shall be forwarded to the data bank by the sponsor of the trial not later than 21 days after the approval of the protocol.

(B) Information pertaining to experimental treatments for serious or life-threatening diseases and conditions that may be available—

(i) under a treatment investigational new drug application that has been submitted to the Secretary under section 360bbb(c) of title 21; or

(ii) as a Group C cancer drug (as defined by the National Cancer Institute).

The data bank may also include information pertaining to the results of clinical trials of such treatments, with the consent of the sponsor, including information concerning potential toxicities

or adverse effects associated with the use or administration of such experimental treatments.

(4) The data bank shall not include information relating to an investigation if the sponsor has provided a detailed certification to the Secretary that disclosure of such information would substantially interfere with the timely enrollment of subjects in the investigation, unless the Secretary, after the receipt of the certification, provides the sponsor with a detailed written determination that such disclosure would not substantially interfere with such enrollment.

(5) Fees collected under section 379h of title 21 shall not be used in carrying out this subsection.

(j) Expanded clinical trial registry data bank

(1) Definitions; requirement

(A) Definitions

In this subsection:

(i) Applicable clinical trial

The term "applicable clinical trial" means an applicable device clinical trial or an applicable drug clinical trial.

(ii) Applicable device clinical trial

The term "applicable device clinical trial" means—

(I) a prospective clinical study of health outcomes comparing an intervention with a device subject to section 360(k), 360e, or 360j(m) of title 21 against a control in human subjects (other than a small clinical trial to determine the feasibility of a device, or a clinical trial to test prototype devices where the primary outcome measure relates to feasibility and not to health outcomes); and

(II) a pediatric postmarket surveillance as required under section 360l of title 21.

(iii) Applicable drug clinical trial

(I) In general

The term "applicable drug clinical trial" means a controlled clinical investigation, other than a phase I clinical investigation, of a drug subject to section 355 of title 21 or to section 262 of this title.

(II) Clinical investigation

For purposes of subclause (I), the term "clinical investigation" has the meaning given that term in section 312.3 of title 21, Code of Federal Regulations (or any successor regulation).

(III) Phase I

For purposes of subclause (I), the term "phase I" has the meaning given that term in section 312.21 of title 21, Code of Federal Regulations (or any successor regulation).

(iv) Clinical trial information

The term "clinical trial information" means, with respect to an applicable clinical trial, those data elements that the responsible party is required to submit under paragraph (2) or under paragraph (3).

(v) Completion date

The term "completion date" means, with respect to an applicable clinical trial, the date that the final subject was examined or received an intervention for the purposes of final collection of data for the primary outcome, whether the clinical trial concluded according to the prespecified protocol or was terminated.

(vi) Device

The term "device" means a device as defined in section 321(h) of title 21.

(vii) Drug

The term "drug" means a drug as defined in section 321(g) of title 21 or a biological product as defined in section 262 of this title.

(viii) Ongoing

The term "ongoing" means, with respect to a clinical trial of a drug or a device and to a date, that—

(I) 1 or more patients is enrolled in the clinical trial; and

(II) the date is before the completion date of the clinical trial.

(ix) Responsible party

The term "responsible party", with respect to a clinical trial of a drug or device, means—

(I) the sponsor of the clinical trial (as defined in section 50.3 of title 21, Code of Federal Regulations (or any successor regulation)); or

(II) the principal investigator of such clinical trial if so designated by a sponsor, grantee, contractor, or awardee, so long as the principal investigator is responsible for conducting the trial, has access to and control over the data from the clinical trial, has the right to publish the results of the trial, and has the ability to meet all of the requirements under this subsection for the submission of clinical trial information.

(B) Requirement

The Secretary shall develop a mechanism by which the responsible party for each applicable clinical trial shall submit the identity and contact information of such responsible party to the Secretary at the time of submission of clinical trial information under paragraph (2).

(2) Expansion of clinical trial registry data bank with respect to clinical trial information

(A) In general

(i) Expansion of data bank

To enhance patient enrollment and provide a mechanism to track subsequent progress of clinical trials, the Secretary, acting through the Director of NIH, shall expand, in accordance with this subsection, the clinical trials registry of the data bank described under subsection (i)(1) (referred to in this subsection as the "registry data bank"). The Director of NIH shall ensure that the registry data bank is made publicly available through the Internet.

(ii) Content

The clinical trial information required to be submitted under this paragraph for an applicable clinical trial shall include—

(I) descriptive information, including—

(aa) a brief title, intended for the lay public;

(bb) a brief summary, intended for the lay public;

(cc) the primary purpose;

(dd) the study design;

(ee) for an applicable drug clinical trial, the study phase;

(ff) study type;

(gg) the primary disease or condition being studied, or the focus of the study;

(hh) the intervention name and intervention type;

(ii) the study start date;

(jj) the expected completion date;

(kk) the target number of subjects; and

(ll) outcomes, including primary and secondary outcome measures;

(II) recruitment information, including—

(aa) eligibility criteria;

(bb) gender;

(cc) age limits;
(dd) whether the trial accepts healthy volunteers;
(ee) overall recruitment status;
(ff) individual site status; and
(gg) in the case of an applicable drug clinical trial, if the drug is not approved under section 355 of title 21 or licensed under section 262 of this title, specify whether or not there is expanded access to the drug under section 360bbb of title 21 for those who do not qualify for enrollment in the clinical trial and how to obtain information about such access;

(III) location and contact information, including—
(aa) the name of the sponsor;
(bb) the responsible party, by official title; and
(cc) the facility name and facility contact information (including the city, State, and zip code for each clinical trial location, or a toll-free number through which such location information may be accessed); and

(IV) administrative data (which the Secretary may make publicly available as necessary), including—
(aa) the unique protocol identification number;
(bb) other protocol identification numbers, if any; and
(cc) the Food and Drug Administration IND/IDE protocol number and the record verification date.

(iii) Modifications

The Secretary may by regulation modify the requirements for clinical trial information under this paragraph, if the Secretary provides a rationale for why such a modification improves and does not reduce such clinical trial information.

(B) Format and structure

(i) Searchable categories

The Director of NIH shall ensure that the public may, in addition to keyword searching, search the entries in the registry data bank by 1 or more of the following criteria:
(I) The disease or condition being studied in the clinical trial, using Medical Subject Headers (MeSH) descriptors.
(II) The name of the intervention, including any drug or device being studied in the clinical trial.
(III) The location of the clinical trial.
(IV) The age group studied in the clinical trial, including pediatric subpopulations.
(V) The study phase of the clinical trial.
(VI) The sponsor of the clinical trial, which may be the National Institutes of Health or another Federal agency, a private industry source, or a university or other organization.
(VII) The recruitment status of the clinical trial.
(VIII) The National Clinical Trial number or other study identification for the clinical trial.

(ii) Additional searchable category

Not later than 18 months after September 27, 2007, the Director of NIH shall ensure that the public may search the entries of the registry data bank by the safety issue, if any, being studied in the clinical trial as a primary or secondary outcome.

(iii) Other elements

The Director of NIH shall also ensure that the public may search the entries of the registry data bank by such other elements as the Director deems necessary on an ongoing basis.

(iv) Format

The Director of the NIH shall ensure that the registry data bank is easily used by the public, and that entries are easily compared.

(C) Data submission

The responsible party for an applicable clinical trial, including an applicable drug clinical trial for a serious or life-threatening disease or condition, that is initiated after, or is ongoing on the date that is 90 days after, September 27, 2007, shall submit to the Director of NIH for inclusion in the registry data bank the clinical trial information described in of [1] subparagraph (A)(ii) not later than the later of—

(i) 90 days after September 27, 2007;

(ii) 21 days after the first patient is enrolled in such clinical trial; or

(iii) in the case of a clinical trial that is not for a serious or life-threatening disease or condition and that is ongoing on September 27, 2007, 1 year after September 27, 2007.

(D) Posting of data

(i) Applicable drug clinical trial

The Director of NIH shall ensure that clinical trial information for an applicable drug clinical trial submitted in accordance with this paragraph is posted in the registry data bank not later than 30 days after such submission.

(ii) Applicable device clinical trial

The Director of NIH shall ensure that clinical trial information for an applicable device clinical trial submitted in accordance with this paragraph is posted publicly in the registry data bank—

(I) not earlier than the date of clearance under section 360(k) of title 21, or approval under section 360e or 360j(m) of title 21, as applicable, for a device that was not previously cleared or approved, and not later than 30 days after such date, unless the responsible party affirmatively requests that the Director of the National Institutes of Health publicly post such clinical trial information for an applicable device clinical trial prior to such date of clearance or approval; or

(II) for a device that was previously cleared or approved, not later than 30 days after the clinical trial information under paragraph (3)(C) is required to be posted by the Secretary.

(iii) Option to make certain clinical trial information available earlier

The Director of the National Institutes of Health shall inform responsible parties of the option to request that clinical trial information for an applicable device clinical trial be publicly posted prior to the date of clearance or approval, in accordance with clause (ii)(I).

(iv) Combination products

An applicable clinical trial for a product that is a combination of drug, device, or biological product shall be considered—

(I) an applicable drug clinical trial, if the Secretary determines under section 353(g) of title 21 that the primary mode of action of such product is that of a drug or biological product; or

(II) an applicable device clinical trial, if the Secretary determines under such section that the primary mode of action of such product is that of a device.

(3) Expansion of registry data bank to include results of clinical trials

(A) Linking registry data bank to existing results

(i) In general

Beginning not later than 90 days after September 27, 2007, for those clinical trials that form the primary basis of an efficacy claim or are conducted after the drug involved is approved or after the device involved is cleared or approved, the Secretary shall ensure that

the registry data bank includes links to results information as described in clause (ii) for such clinical trial—

(I) not earlier than 30 days after the date of the approval of the drug involved or clearance or approval of the device involved; or

(II) not later than 30 days after the results information described in clause (ii) becomes publicly available.

(ii) Required information

(I) FDA information

The Secretary shall ensure that the registry data bank includes links to the following information:

(aa) If an advisory committee considered at a meeting an applicable clinical trial, any posted Food and Drug Administration summary document regarding such applicable clinical trial.

(bb) If an applicable drug clinical trial was conducted under section 355a or 355c of title 21, a link to the posted Food and Drug Administration assessment of the results of such trial.

(cc) Food and Drug Administration public health advisories regarding the drug or device that is the subject of the applicable clinical trial, if any.

(dd) For an applicable drug clinical trial, the Food and Drug Administration action package for approval document required under section 355(l)(2) of title 21.

(ee) For an applicable device clinical trial, in the case of a premarket application under section 360e of title 21, the detailed summary of information respecting the safety and effectiveness of the device required under section 360j(h)(1) of title 21, or, in the case of a report under section 360(k) of title 21, the section 360(k) summary of the safety and effectiveness data required under section 807.95(d) of title 21, Code of Federal Regulations (or any successor regulation).

(II) NIH information

The Secretary shall ensure that the registry data bank includes links to the following information:

(aa) Medline citations to any publications focused on the results of an applicable clinical trial.

(bb) The entry for the drug that is the subject of an applicable drug clinical trial in the National Library of Medicine database of structured product labels, if available.

(iii) Results for existing data bank entries

The Secretary may include the links described in clause (ii) for data bank entries for clinical trials submitted to the data bank prior to September 27, 2007, as available.

(B) Inclusion of results

The Secretary, acting through the Director of NIH, shall—

(i) expand the registry data bank to include the results of applicable clinical trials (referred to in this subsection as the "registry and results data bank");

(ii) ensure that such results are made publicly available through the Internet;

(iii) post publicly a glossary for the lay public explaining technical terms related to the results of clinical trials; and

(iv) in consultation with experts on risk communication, provide information with the information included under subparagraph (C) in the registry and results data bank to help ensure that such information does not mislead the patients or the public.

(C) Basic results

Not later than 1 year after September 27, 2007, the Secretary shall include in the registry and results data bank for each applicable clinical trial for a drug that is approved under section 355 of title 21 or licensed under section 262 of this title or a device that is cleared under section

360(k) of title 21 or approved under section 360e or 360j(m) of title 21, the following elements:

(i) Demographic and baseline characteristics of patient sample

A table of the demographic and baseline data collected overall and for each arm of the clinical trial to describe the patients who participated in the clinical trial, including the number of patients who dropped out of the clinical trial and the number of patients excluded from the analysis, if any.

(ii) Primary and secondary outcomes

The primary and secondary outcome measures as submitted under paragraph (2)(A)(ii)(I)(ll), and a table of values for each of the primary and secondary outcome measures for each arm of the clinical trial, including the results of scientifically appropriate tests of the statistical significance of such outcome measures.

(iii) Point of contact

A point of contact for scientific information about the clinical trial results.

(iv) Certain agreements

Whether there exists an agreement (other than an agreement solely to comply with applicable provisions of law protecting the privacy of participants) between the sponsor or its agent and the principal investigator (unless the sponsor is an employer of the principal investigator) that restricts in any manner the ability of the principal investigator, after the completion date of the trial, to discuss the results of the trial at a scientific meeting or any other public or private forum, or to publish in a scientific or academic journal information concerning the results of the trial.

(D) Expanded registry and results data bank

(i) Expansion by rulemaking

To provide more complete results information and to enhance patient access to and understanding of the results of clinical trials, not later than 3 years after September 27, 2007, the Secretary shall by regulation expand the registry and results data bank as provided under this subparagraph.

(ii) Clinical trials

(I) Approved products

The regulations under this subparagraph shall require the inclusion of the results information described in clause (iii) for—

(aa) each applicable drug clinical trial for a drug that is approved under section 355 of title 21 or licensed under section 262 of this title; and

(bb) each applicable device clinical trial for a device that is cleared under section 360(k) of title 21 or approved under section 360e or 360j(m) of title 21.

(II) Unapproved products

The regulations under this subparagraph shall establish whether or not the results information described in clause (iii) shall be required for—

(aa) an applicable drug clinical trial for a drug that is not approved under section 355 of title 21 and not licensed under section 262 of this title (whether approval or licensure was sought or not); and

(bb) an applicable device clinical trial for a device that is not cleared under section 360(k) of title 21 and not approved under section 360e or section 360j(m) of title 21 (whether clearance or approval was sought or not).

(iii) Required elements

The regulations under this subparagraph shall require, in addition to the elements described in subparagraph (C), information within each of the following categories:

(I) A summary of the clinical trial and its results that is written in non-technical,

understandable language for patients, if the Secretary determines that such types of summary can be included without being misleading or promotional.

(II) A summary of the clinical trial and its results that is technical in nature, if the Secretary determines that such types of summary can be included without being misleading or promotional.

(III) The full protocol or such information on the protocol for the trial as may be necessary to help to evaluate the results of the trial.

(IV) Such other categories as the Secretary determines appropriate.

(iv) Results submission

The results information described in clause (iii) shall be submitted to the Director of NIH for inclusion in the registry and results data bank as provided by subparagraph (E), except that the Secretary shall by regulation determine—

(I) whether the 1-year period for submission of clinical trial information described in subparagraph (E)(i) should be increased from 1 year to a period not to exceed 18 months;

(II) whether the clinical trial information described in clause (iii) should be required to be submitted for an applicable clinical trial for which the clinical trial information described in subparagraph (C) is submitted to the registry and results data bank before the effective date of the regulations issued under this subparagraph; and

(III) in the case when the clinical trial information described in clause (iii) is required to be submitted for the applicable clinical trials described in clause (ii)(II), the date by which such clinical trial information shall be required to be submitted, taking into account—

(aa) the certification process under subparagraph (E)(iii) when approval, licensure, or clearance is sought; and

(bb) whether there should be a delay of submission when approval, licensure, or clearance will not be sought.

(v) Additional provisions

The regulations under this subparagraph shall also establish—

(I) a standard format for the submission of clinical trial information under this paragraph to the registry and results data bank;

(II) additional information on clinical trials and results that is written in nontechnical, understandable language for patients;

(III) considering the experience under the pilot quality control project described in paragraph (5)(C), procedures for quality control, including using representative samples, with respect to completeness and content of clinical trial information under this subsection, to help ensure that data elements are not false or misleading and are non-promotional;

(IV) the appropriate timing and requirements for updates of clinical trial information, and whether and, if so, how such updates should be tracked;

(V) a statement to accompany the entry for an applicable clinical trial when the primary and secondary outcome measures for such clinical trial are submitted under paragraph (4)(A) after the date specified for the submission of such information in paragraph (2)(C); and

(VI) additions or modifications to the manner of reporting of the data elements established under subparagraph (C).

(vi) Consideration of World Health Organization data set

The Secretary shall consider the status of the consensus data elements set for reporting clinical trial results of the World Health Organization when issuing the regulations under this subparagraph.

(vii) Public meeting

The Secretary shall hold a public meeting no later than 18 months after September 27, 2007, to provide an opportunity for input from interested parties with regard to the regulations to be issued under this subparagraph.

(E) Submission of results information

(i) In general

Except as provided in clauses (iii), (iv), (v), and (vi) the responsible party for an applicable clinical trial that is described in clause (ii) shall submit to the Director of NIH for inclusion in the registry and results data bank the clinical trial information described in subparagraph (C) not later than 1 year, or such other period as may be provided by regulation under subparagraph (D), after the earlier of—

(I) the estimated completion date of the trial as described in paragraph (2)(A)(ii)(I)(jj)); [2] or

(II) the actual date of completion.

(ii) Clinical trials described

An applicable clinical trial described in this clause is an applicable clinical trial subject to—

(I) paragraph (2)(C); and

(II)(aa) subparagraph (C); or

(bb) the regulations issued under subparagraph (D).

(iii) Delayed submission of results with certification

If the responsible party for an applicable clinical trial submits a certification that clause (iv) or (v) applies to such clinical trial, the responsible party shall submit to the Director of NIH for inclusion in the registry and results data bank the clinical trial information described in subparagraphs (C) and (D) as required under the applicable clause.

(iv) Seeking initial approval of a drug or device

With respect to an applicable clinical trial that is completed before the drug is initially approved under section 355 of title 21 or initially licensed under section 262 of this title, or the device is initially cleared under section 360(k) or initially approved under section 360e or 360j(m) of title 21, the responsible party shall submit to the Director of NIH for inclusion in the registry and results data bank the clinical trial information described in subparagraphs (C) and (D) not later than 30 days after the drug or device is approved under such section 355, licensed under such section 262, cleared under such section 360(k), or approved under such section 360e or 360j(m), as applicable.

(v) Seeking approval of a new use for the drug or device

(I) In general

With respect to an applicable clinical trial where the manufacturer of the drug or device is the sponsor of an applicable clinical trial, and such manufacturer has filed, or will file within 1 year, an application seeking approval under section 355 of title 21, licensing under section 262 of this title, or clearance under section 360(k), or approval under section 360e or 360j(m) of title 21 for the use studied in such clinical trial (which use is not included in the labeling of the approved drug or device), then the responsible party shall submit to the Director of NIH for inclusion in the registry and results data bank the clinical trial information described in subparagraphs (C) and (D) on the earlier of the date that is 30 days after the date—

(aa) the new use of the drug or device is approved under such section 355, licensed under such section 262, cleared under such section 360(k), or approved under such section 360e or 360j(m);

(bb) the Secretary issues a letter, such as a complete response letter, not approving the submission or not clearing the submission, a not approvable letter, or a not substantially equivalent letter for the new use of the drug or device under such section 355, 262, 360(k), 360e, or 360j(m); or

(cc) except as provided in subclause (III), the application or premarket notification under such section 355, 262, 360(k), 360e, or 360j(m) is withdrawn without

resubmission for no less than 210 days.

(II) Requirement that each clinical trial in application be treated the same

If a manufacturer makes a certification under clause (iii) that this clause applies with respect to a clinical trial, the manufacturer shall make such a certification with respect to each applicable clinical trial that is required to be submitted in an application or report for licensure, approval, or clearance (under section 262 of this title or section 355, 360(k), 360e, or 360j(m) of title 21, as applicable) of the use studied in the clinical trial.

(III) Two-year limitation

The responsible party shall submit to the Director of NIH for inclusion in the registry and results data bank the clinical trial information subject to subclause (I) on the date that is 2 years after the date a certification under clause (iii) was made to the Director of NIH, if an action referred to in item (aa), (bb), or (cc) of subclause (I) has not occurred by such date.

(vi) Extensions

The Director of NIH may provide an extension of the deadline for submission of clinical trial information under clause (i) if the responsible party for the trial submits to the Director a written request that demonstrates good cause for the extension and provides an estimate of the date on which the information will be submitted. The Director of NIH may grant more than one such extension for a clinical trial.

(F) Notice to Director of NIH

The Commissioner of Food and Drugs shall notify the Director of NIH when there is an action described in subparagraph (E)(iv) or item (aa), (bb), or (cc) of subparagraph (E)(v)(I) with respect to an application or a report that includes a certification required under paragraph (5)(B) of such action not later than 30 days after such action.

(G) Posting of data

The Director of NIH shall ensure that the clinical trial information described in subparagraphs (C) and (D) for an applicable clinical trial submitted in accordance with this paragraph is posted publicly in the registry and results database not later than 30 days after such submission.

(H) Waivers regarding certain clinical trial results

The Secretary may waive any applicable requirements of this paragraph for an applicable clinical trial, upon a written request from the responsible party, if the Secretary determines that extraordinary circumstances justify the waiver and that providing the waiver is consistent with the protection of public health, or in the interest of national security. Not later than 30 days after any part of a waiver is granted, the Secretary shall notify, in writing, the appropriate committees of Congress of the waiver and provide an explanation for why the waiver was granted.

(I) Adverse events

(i) Regulations

Not later than 18 months after September 27, 2007, the Secretary shall by regulation determine the best method for including in the registry and results data bank appropriate results information on serious adverse and frequent adverse events for applicable clinical trials described in subparagraph (C) in a manner and form that is useful and not misleading to patients, physicians, and scientists.

(ii) Default

If the Secretary fails to issue the regulation required by clause (i) by the date that is 24 months after September 27, 2007, clause (iii) shall take effect.

(iii) Additional elements

Upon the application of clause (ii), the Secretary shall include in the registry and results

data bank for applicable clinical trials described in subparagraph (C), in addition to the clinical trial information described in subparagraph (C), the following elements:

(I) Serious adverse events

A table of anticipated and unanticipated serious adverse events grouped by organ system, with number and frequency of such event in each arm of the clinical trial.

(II) Frequent adverse events

A table of anticipated and unanticipated adverse events that are not included in the table described in subclause (I) that exceed a frequency of 5 percent within any arm of the clinical trial, grouped by organ system, with number and frequency of such event in each arm of the clinical trial.

(iv) Posting of other information

In carrying out clause (iii), the Secretary shall, in consultation with experts in risk communication, post with the tables information to enhance patient understanding and to ensure such tables do not mislead patients or the lay public.

(v) Relation to subparagraph (C)

Clinical trial information included in the registry and results data bank pursuant to this subparagraph is deemed to be clinical trial information included in such data bank pursuant to subparagraph (C).

(4) Additional submissions of clinical trial information

(A) Voluntary submissions

A responsible party for a clinical trial that is not an applicable clinical trial, or that is an applicable clinical trial that is not subject to paragraph (2)(C), may submit complete clinical trial information described in paragraph (2) or paragraph (3) provided the responsible party submits clinical trial information for each applicable clinical trial that is required to be submitted under section 262 of this title or under section 355, 360(k), 360e, or 360j(m) of title 21 in an application or report for licensure, approval, or clearance of the drug or device for the use studied in the clinical trial.

(B) Required submissions

(i) In general

Notwithstanding paragraphs (2) and (3) and subparagraph (A), in any case in which the Secretary determines for a specific clinical trial described in clause (ii) that posting in the registry and results data bank of clinical trial information for such clinical trial is necessary to protect the public health—

(I) the Secretary may require by notification that such information be submitted to the Secretary in accordance with paragraphs (2) and (3) except with regard to timing of submission;

(II) unless the responsible party submits a certification under paragraph (3)(E)(iii), such information shall be submitted not later than 30 days after the date specified by the Secretary in the notification; and

(III) failure to comply with the requirements under subclauses (I) and (II) shall be treated as a violation of the corresponding requirement of such paragraphs.

(ii) Clinical trials described

A clinical trial described in this clause is—

(I) an applicable clinical trial for a drug that is approved under section 355 of title 21 or licensed under section 262 of this title or for a device that is cleared under section 360(k) of title 21 or approved under section 360e or section 360j(m) of title 21, whose completion date is on or after the date 10 years before September 27, 2007; or

(II) an applicable clinical trial that is described by both by [3] paragraph (2)(C) and

paragraph (3)(D)(ii)(II)).[4]

(C) Updates to clinical trial data bank

(i) Submission of updates

The responsible party for an applicable clinical trial shall submit to the Director of NIH for inclusion in the registry and results data bank updates to reflect changes to the clinical trial information submitted under paragraph (2). Such updates—

(I) shall be provided not less than once every 12 months, unless there were no changes to the clinical trial information during the preceding 12-month period;

(II) shall include identification of the dates of any such changes;

(III) not later than 30 days after the recruitment status of such clinical trial changes, shall include an update of the recruitment status; and

(IV) not later than 30 days after the completion date of the clinical trial, shall include notification to the Director that such clinical trial is complete.

(ii) Public availability of updates

The Director of NIH shall make updates submitted under clause (i) publicly available in the registry data bank. Except with regard to overall recruitment status, individual site status, location, and contact information, the Director of NIH shall ensure that updates to elements required under subclauses (I) to (V) of paragraph (2)(A)(ii) do not result in the removal of any information from the original submissions or any preceding updates, and information in such databases is presented in a manner that enables users to readily access each original element submission and to track the changes made by the updates. The Director of NIH shall provide a link from the table of primary and secondary outcomes required under paragraph (3)(C)(ii) to the tracked history required under this clause of the primary and secondary outcome measures submitted under paragraph (2)(A)(ii)(I)(ll).

(5) Coordination and compliance

(A) Clinical trials supported by grants from Federal agencies

(i) Grants from certain Federal agencies

If an applicable clinical trial is funded in whole or in part by a grant from any agency of the Department of Health and Human Services, including the Food and Drug Administration, the National Institutes of Health, or the Agency for Healthcare Research and Quality, any grant or progress report forms required under such grant shall include a certification that the responsible party has made all required submissions to the Director of NIH under paragraphs (2) and (3).

(ii) Verification by Federal agencies

The heads of the agencies referred to in clause (i), as applicable, shall verify that the clinical trial information for each applicable clinical trial for which a grantee is the responsible party has been submitted under paragraphs (2) and (3) before releasing any remaining funding for a grant or funding for a future grant to such grantee.

(iii) Notice and opportunity to remedy

If the head of an agency referred to in clause (i), as applicable, verifies that a grantee has not submitted clinical trial information as described in clause (ii), such agency head shall provide notice to such grantee of such non-compliance and allow such grantee 30 days to correct such non-compliance and submit the required clinical trial information.

(iv) Consultation with other Federal agencies

The Secretary shall—

(I) consult with other agencies that conduct research involving human subjects in accordance with any section of part 46 of title 45, Code of Federal Regulations (or any successor regulations), to determine if any such research is an applicable clinical trial; and

(II) develop with such agencies procedures comparable to those described in clauses (i), (ii), and (iii) to ensure that clinical trial information for such applicable clinical trial is submitted under paragraphs (2) and (3).

(B) Certification to accompany drug, biological product, and device submissions

At the time of submission of an application under section 355 of title 21, section 360e of title 21, section 360j(m) of title 21, or section 262 of this title, or submission of a report under section 360(k) of title 21, such application or submission shall be accompanied by a certification that all applicable requirements of this subsection have been met. Where available, such certification shall include the appropriate National Clinical Trial control numbers.

(C) Quality control

(i) Pilot quality control project

Until the effective date of the regulations issued under paragraph (3)(D), the Secretary, acting through the Director of NIH and the Commissioner of Food and Drugs, shall conduct a pilot project to determine the optimal method of verification to help to ensure that the clinical trial information submitted under paragraph (3)(C) is non-promotional and is not false or misleading in any particular under subparagraph (D). The Secretary shall use the publicly available information described in paragraph (3)(A) and any other information available to the Secretary about applicable clinical trials to verify the accuracy of the clinical trial information submitted under paragraph (3)(C).

(ii) Notice of compliance

If the Secretary determines that any clinical trial information was not submitted as required under this subsection, or was submitted but is false or misleading in any particular, the Secretary shall notify the responsible party and give such party an opportunity to remedy such noncompliance by submitting the required revised clinical trial information not later than 30 days after such notification.

(D) Truthful clinical trial information

(i) In general

The clinical trial information submitted by a responsible party under this subsection shall not be false or misleading in any particular.

(ii) Effect

Clause (i) shall not have the effect of—

(I) requiring clinical trial information with respect to an applicable clinical trial to include information from any source other than such clinical trial involved; or

(II) requiring clinical trial information described in paragraph (3)(D) to be submitted for purposes of paragraph (3)(C).

(E) Public notices

(i) Notice of violations

If the responsible party for an applicable clinical trial fails to submit clinical trial information for such clinical trial as required under paragraphs (2) or (3), the Director of NIH shall include in the registry and results data bank entry for such clinical trial a notice—

(I) that the responsible party is not in compliance with this chapter by—

(aa) failing to submit required clinical trial information; or

(bb) submitting false or misleading clinical trial information;

(II) of the penalties imposed for the violation, if any; and

(III) whether the responsible party has corrected the clinical trial information in the registry and results data bank.

(ii) Notice of failure to submit primary and secondary outcomes

If the responsible party for an applicable clinical trial fails to submit the primary and secondary outcomes as required under section 2(A)(ii)(I)(ll),[5] the Director of NIH shall include in the registry and results data bank entry for such clinical trial a notice that the responsible party is not in compliance by failing to register the primary and secondary outcomes in accordance with this chapter, and that the primary and secondary outcomes were not publicly disclosed in the database before conducting the clinical trial.

(iii) Failure to submit statement

The notice under clause (i) for a violation described in clause (i)(I)(aa) shall include the following statement: "The entry for this clinical trial was not complete at the time of submission, as required by law. This may or may not have any bearing on the accuracy of the information in the entry.".

(iv) Submission of false information statement

The notice under clause (i) for a violation described in clause (i)(I)(bb) shall include the following statement: "The entry for this clinical trial was found to be false or misleading and therefore not in compliance with the law.".

(v) Non-submission of statement

The notice under clause (ii) for a violation described in clause (ii) shall include the following statement: "The entry for this clinical trial did not contain information on the primary and secondary outcomes at the time of submission, as required by law. This may or may not have any bearing on the accuracy of the information in the entry.".

(vi) Compliance searches

The Director of NIH shall provide that the public may easily search the registry and results data bank for entries that include notices required under this subparagraph.

(6) Limitation on disclosure of clinical trial information

(A) In general

Nothing in this subsection (or under section 552 of title 5) shall require the Secretary to publicly disclose, by any means other than the registry and results data bank, information described in subparagraph (B).

(B) Information described

Information described in this subparagraph is—

(i) information submitted to the Director of NIH under this subsection, or information of the same general nature as (or integrally associated with) the information so submitted; and

(ii) information not otherwise publicly available, including because it is protected from disclosure under section 552 of title 5.

(7) Authorization of appropriations

There are authorized to be appropriated to carry out this subsection $10,000,000 for each fiscal year.

(k) Day care for children of employees

(1) The Director of NIH may establish a program to provide day care services for the employees of the National Institutes of Health similar to those services provided by other Federal agencies (including the availability of day care service on a 24-hour-a-day basis).

(2) Any day care provider at the National Institutes of Health shall establish a sliding scale of fees that takes into consideration the income and needs of the employee.

(3) For purposes regarding the provision of day care services, the Director of NIH may enter into rental or lease purchase agreements.

(l) Council of Councils

(1) Establishment

Not later than 90 days after January 15, 2007, the Director of NIH shall establish within the Office of the Director an advisory council to be known as the "Council of Councils" (referred to in this subsection as the "Council") for the purpose of advising the Director on matters related to the policies and activities of the Division of Program Coordination, Planning, and Strategic Initiatives, including making recommendations with respect to the conduct and support of research described in subsection (b)(7).

(2) Membership

(A) In general

The Council shall be composed of 27 members selected by the Director of NIH with approval from the Secretary from among the list of nominees under subparagraph (C).

(B) Certain requirements

In selecting the members of the Council, the Director of NIH shall ensure—

(i) the representation of a broad range of disciplines and perspectives; and

(ii) the ongoing inclusion of at least 1 representative from each national research institute whose budget is substantial relative to a majority of the other institutes.

(C) Nomination

The Director of NIH shall maintain an updated list of individuals who have been nominated to serve on the Council, which list shall consist of the following:

(i) For each national research institute and national center, 3 individuals nominated by the head of such institute or center from among the members of the advisory council of the institute or center, of which—

(I) two shall be scientists; and

(II) one shall be from the general public or shall be a leader in the field of public policy, law, health policy, economics, or management.

(ii) For each office within the Division of Program Coordination, Planning, and Strategic Initiatives, 1 individual nominated by the head of such office.

(iii) Members of the Council of Public Representatives.

(3) Terms

(A) In general

The term of service for a member of the Council shall be 6 years, except as provided in subparagraphs (B) and (C).

(B) Terms of initial appointees

Of the initial members selected for the Council, the Director of NIH shall designate—

(i) nine for a term of 6 years;

(ii) nine for a term of 4 years; and

(iii) nine for a term of 2 years.

(C) Vacancies

Any member appointed to fill a vacancy occurring before the expiration of the term for which the member's predecessor was appointed shall be appointed only for the remainder of that term. A member may serve after the expiration of that member's term until a successor has taken office.

(m) National Institutes of Health Strategic Plan

(1) In general

Not later than 2 years after December 13, 2016, and at least every 6 years thereafter, the Director of the National Institutes of Health shall develop and submit to the appropriate committees of Congress and post on the Internet website of the National Institutes of Health, a coordinated strategy (to be known as the "National Institutes of Health Strategic Plan") to provide

direction to the biomedical research investments made by the National Institutes of Health, to facilitate collaboration across the institutes and centers, to leverage scientific opportunity, and to advance biomedicine.

(2) Requirements

The strategy under paragraph (1) shall—

(A) identify strategic research priorities and objectives across biomedical research, including—

(i) an assessment of the state of biomedical and behavioral research, including areas of opportunity with respect to basic, clinical, and translational research;

(ii) priorities and objectives to advance the treatment, cure, and prevention of health conditions;

(iii) emerging scientific opportunities, rising public health challenges, and scientific knowledge gaps; and

(iv) the identification of near-, mid-, and long-term scientific needs;

(B) consider, in carrying out subparagraph (A)—

(i) disease burden in the United States and the potential for return on investment to the United States;

(ii) rare diseases and conditions;

(iii) biological, social, and other determinants of health that contribute to health disparities; and

(iv) other factors the Director of National Institutes of Health determines appropriate;

(C) include multi-institute priorities, including coordination of research among institutes and centers;

(D) include strategic priorities for funding research through the Common Fund, in accordance with section 282a(c)(1)(C) of this title;

(E) address the National Institutes of Health's proposed and ongoing activities related to training and the biomedical workforce; and

(F) describe opportunities for collaboration with other agencies and departments, as appropriate.

(3) Use of plans

Strategic plans developed and updated by the national research institutes and national centers of the National Institutes of Health shall be prepared regularly and in such a manner that such plans will be informed by the strategic plans developed and updated under this subsection. Such plans developed by and updated by the national research institutes and national centers shall have a common template.

(4) Consultation

The Director of National Institutes of Health shall develop the strategic plan under paragraph (1) in consultation with the directors of the national research institutes and national centers, researchers, patient advocacy groups, and industry leaders.

(n) Unique research initiatives

(1) In general

The Director of NIH may approve, after consideration of a proposal under paragraph (2)(A), requests by the national research institutes and centers, or program officers within the Office of the Director to engage in transactions other than a contract, grant, or cooperative agreement with respect to projects that carry out—

(A) the Precision Medicine Initiative under section 289g–5 of this title;

(B) subsection (b)(7), except that not more than 50 percent of the funds available for a fiscal year through the Common Fund under section 282a(c)(1) of this title for purposes of carrying

out such subsection (b)(7) may be used to engage in such other transactions; or

(C) high impact cutting-edge research that fosters scientific creativity and increases fundamental biological understanding leading to the prevention, diagnosis, or treatment of diseases and disorders, or research urgently required to respond to a public health threat.

(2) Requirements

The authority provided under this subsection may be used to conduct or support high impact cutting-edge research described in paragraph (1) using the other transactions authority described in such paragraph if the institute, center, or office—

(A) submits a proposal to the Director of NIH for the use of such authority before conducting or supporting the research, including why the use of such authority is essential to promoting the success of the project;

(B) receives approval for the use of such authority from the Director of NIH; and

(C) for each year in which the institute, center, or office has used such authority in accordance with this subsection, submits a report to the Director of NIH on the activities of the institute, center, or office relating to such research.

(o) Regenerative medicine

The Director of NIH shall, as appropriate, continue to consult with the directors of relevant institutes and centers of the National Institutes of Health, other relevant experts from such institutes and centers, and relevant experts within the Food and Drug Administration, to further the field of regenerative medicine using adult stem cells, including autologous stem cells, therapeutic tissue engineering products, human cell and tissue products, human gene therapies, and genetically modified cells.

(July 1, 1944, ch. 373, title IV, §402, as added Pub. L. 99–158, §2, Nov. 20, 1985, 99 Stat. 823; amended Pub. L. 100–607, title I, §111, Nov. 4, 1988, 102 Stat. 3052; Pub. L. 102–321, title I, §163(b)(3), July 10, 1992, 106 Stat. 376; Pub. L. 103–43, title I, §141(b), title II, §§201, 202, 206, 208, 210(b), (c), title III, §303(b), June 10, 1993, 107 Stat. 139, 144, 148–150, 153; Pub. L. 105–115, title I, §113(a), Nov. 21, 1997, 111 Stat. 2310; Pub. L. 105–362, title VI, §601(a)(1)(A), Nov. 10, 1998, 112 Stat. 3285; Pub. L. 105–392, title IV, §409, Nov. 13, 1998, 112 Stat. 3589; Pub. L. 107–109, §15(c)(2), Jan. 4, 2002, 115 Stat. 1420; Pub. L. 109–482, title I, §§102(a)–(d), (f)(1)(A), 103(b)(1), Jan. 15, 2007, 120 Stat. 3681, 3683, 3684, 3687; Pub. L. 110–85, title III, §304(a), title VIII, §801(a), title XI, §1104(2), Sept. 27, 2007, 121 Stat. 863, 904, 975; Pub. L. 110–316, title III, §302, Aug. 14, 2008, 122 Stat. 3524; Pub. L. 111–148, title X, §10409(b), Mar. 23, 2010, 124 Stat. 978; Pub. L. 112–74, div. F, title II, §221(b)(5)(B), (d)(1), Dec. 23, 2011, 125 Stat. 1089, 1090; Pub. L. 113–94, §3(a), Apr. 3, 2014, 128 Stat. 1086; Pub. L. 114–255, div. A, title II, §§2014(a), 2031(a), 2036(a), 2038(a), 2051, Dec. 13, 2016, 130 Stat. 1051, 1054, 1062, 1064, 1074; Pub. L. 115–271, title VII, §7041, Oct. 24, 2018, 132 Stat. 4016; Pub. L. 117–15, §4, May 26, 2021, 135 Stat. 278; Pub. L. 117–286, §4(a)(231), Dec. 27, 2022, 136 Stat. 4331; Pub. L. 117–328, div. FF, title II, §§2302, 2323, Dec. 29, 2022, 136 Stat. 5757, 5767; Pub. L. 118–228, §§2(3), 3(b), Jan. 4, 2025, 138 Stat. 2822.)

EDITORIAL NOTES

REFERENCES IN TEXT

The General Schedule, referred to in subsec. (b)(16), is set out under section 5332 of Title 5, Government Organization and Employees.

The National Literacy Act of 1991, referred to in subsec. (e)(5), is Pub. L. 102–73, July 25, 1991, 105 Stat. 333, which was repealed by Pub. L. 105–220, title II, §251(a)(2), Aug. 7, 1998, 112 Stat. 1079. For complete classification of this Act to the Code, see Tables.

CODIFICATION

In subsec. (b)(14)(B), "section 8141 of title 40" substituted for "the Act of March 3, 1877 (40 U.S.C. 34)" on authority of Pub. L. 107–217, §5(c), Aug. 21, 2002, 116 Stat. 1303, the first section of which enacted Title 40, Public Buildings, Property, and Works.

AMENDMENTS

2025—Subsec. (b)(7)(B)(ii). Pub. L. 118–228, §3(b), inserted "and shall prioritize, as appropriate, such pediatric research that does not duplicate existing research activities of the National Institutes of Health" before "; and".

Pub. L. 118–228, §2(3), substituted "the Division of Program Coordination, Planning, and Strategic Initiatives" for "the Common Fund".

2022—Subsec. (b). Pub. L. 117–286 substituted "Chapter 10 of title 5" for "The Federal Advisory Committee Act" in concluding provisions.

Subsec. (b)(26). Pub. L. 117–328, §2302, added par. (26).

Subsec. (b)(27) to (29). Pub. L. 117–328, §2323, added pars. (27) to (29).

2021—Subsec. (o). Pub. L. 117–15 added subsec. (o).

2018—Subsec. (n)(1)(C). Pub. L. 115–271 added subpar. (C).

2016—Subsec. (b)(4). Pub. L. 114–255, §2038(a)(1), amended par. (4) generally. Prior to amendment, text read as follows: "shall assemble accurate data to be used to assess research priorities, including information to better evaluate scientific opportunity, public health burdens, and progress in reducing minority and other health disparities;".

Subsec. (b)(5). Pub. L. 114–255, §2031(a)(1), inserted ", and through the development, implementation, and updating of the strategic plan developed under subsection (m)" before semicolon.

Subsec. (b)(8)(C), (D). Pub. L. 114–255, §2038(a)(2), added subpars. (C) and (D).

Subsec. (b)(25). Pub. L. 114–255, §2014(a), added par. (25).

Subsec. (j)(2)(D)(ii)(I). Pub. L. 114–255, §2051(1), inserted ", unless the responsible party affirmatively requests that the Director of the National Institutes of Health publicly post such clinical trial information for an applicable device clinical trial prior to such date of clearance or approval" before semicolon.

Subsec. (j)(2)(D)(iii), (iv). Pub. L. 114–255, §2051(2), added cls. (iii) and (iv).

Subsec. (m). Pub. L. 114–255, §2031(a)(2), added subsec. (m).

Subsec. (n). Pub. L. 114–255, §2036(a), added subsec. (n).

2014—Subsec. (b)(7). Pub. L. 113–94 amended par. (7) generally, enacting similar provisions and adding provisions relating to allocating funds appropriated pursuant to section 282a(a)(2) of this title for making grants for pediatric research.

2011—Subsec. (b)(24). Pub. L. 112–74, §221(d)(1), substituted "287a" for "282d".

Subsec. (g). Pub. L. 112–74, §221(b)(5)(B), redesignated and transferred subsec. (g) of this section to subsec. (b) of section 285k of this title.

2010—Subsec. (b)(24). Pub. L. 111–148 added par. (24).

2008—Subsec. (j)(3)(C). Pub. L. 110–316, §302(1), in introductory provisions, substituted "for each applicable clinical trial for a drug that is approved under section 355 of title 21 or licensed under section 262 of this title or a device that is cleared under section 360(k) of title 21 or approved under section 360e or 360j(m) of title 21, the following elements:" for "the following elements for drugs that are approved under section 355 of title 21 or licensed under section 262 of this title and devices that are cleared under section 360(k) of title 21 or approved under section 360e or 360j(m) of title 21:".

Subsec. (j)(3)(I)(i), (iii). Pub. L. 110–316, §302(2), substituted "applicable clinical trials described in subparagraph (C)" for "drugs described in subparagraph (C)".

2007—Subsec. (a). Pub. L. 109–482, §102(f)(1)(A), substituted "Director of NIH who shall" for "Director of the National Institutes of Health (hereafter in this subchapter referred to as the 'Director of NIH') who shall".

Subsec. (b). Pub. L. 109–482, §102(a)(5), substituted "paragraph (16)" for "paragraph (6)" in concluding provisions.

Subsec. (b)(1). Pub. L. 109–482, §102(a)(6), added par. (1) and struck out former par. (1) which read as follows: "shall be responsible for the overall direction of the National Institutes of Health and for the establishment and implementation of general policies respecting the management and operation of programs and activities within the National Institutes of Health;".

Subsec. (b)(2), (3). Pub. L. 109–482, §102(b), added pars. (2) and (3) and struck out former pars. (2) and (3) which read as follows:

"(2) shall coordinate and oversee the operation of the national research institutes and administrative entities within the National Institutes of Health;

"(3) shall assure that research at or supported by the National Institutes of Health is subject to review in accordance with section 289a of this title;".

Subsec. (b)(4). Pub. L. 110–85, §1104(2), inserted "minority and other" after "reducing".

Pub. L. 109–482, §102(b), added par. (4). Former par. (4) redesignated (14).

Subsec. (b)(5) to (22). Pub. L. 109–482, §102(a)(1)–(4), (b), added pars. (5) to (13), redesignated former pars. (4) to (11) and (14) as (14) to (22), respectively, in par. (21) inserted "and" at end, and struck out former pars. (12) and (13) which read as follows:

"(12) after consultation with the Director of the Office of Research on Women's Health, shall ensure that resources of the National Institutes of Health are sufficiently allocated for projects of research on women's health that are identified under section 287d(b) of this title;

"(13) may conduct and support research training—

"(A) for which fellowship support is not provided under section 288 of this title; and

"(B) which does not consist of residency training of physicians or other health professionals; and".

Subsec. (b)(23). Pub. L. 110–85, §304(a), added par. (23).

Subsec. (i). Pub. L. 109–482, §102(c), redesignated subsec. (j) as (i) and struck out former subsec. (i) which related to discretionary fund for use by the Director of NIH to carry out activities authorized in this chapter.

Subsec. (i)(5). Pub. L. 109–482, §103(b)(1), struck out first sentence which read as follows: "For the purpose of carrying out this subsection, there are authorized to be appropriated such sums as may be necessary."

Subsecs. (j), (k). Pub. L. 110–85, §801(a), added subsec. (j) and redesignated former subsec. (j) as (k). Former subsec. (k) redesignated (l).

Pub. L. 109–482, §102(c)(2), (d), added subsec. (k) and redesignated former subsec. (k) as (j).

Subsec. (l). Pub. L. 110–85, §801(a)(1), redesignated subsec. (k) as (l).

Pub. L. 109–482, §102(c)(1), struck out subsec. (l) which read as follows: "The Director of NIH shall carry out the program established in part F of subchapter X of this chapter (relating to interagency research on trauma)."

2002—Subsec. (j)(3)(A). Pub. L. 107–109, which directed the amendment of the first sentence of subsec. (j)(3)(A) by substituting "trial sites," for "trial sites, and" and "in the trial, and a description of whether, and through what procedure, the manufacturer or sponsor of the investigation of a new drug will respond to requests for protocol exception, with appropriate safeguards, for single-patient and expanded protocol use of the new drug, particularly in children," for "in the trial,", was executed by making the substitutions in the second sentence, to reflect the probable intent of Congress.

1998—Subsec. (b)(13), (14). Pub. L. 105–392 added pars. (13) and (14).

Subsec. (f). Pub. L. 105–362 inserted "and" at end of par. (1), substituted a period for "; and" at end of par. (2), and struck out par. (3) which read as follows: "annually prepare and submit to the Director of NIH a report concerning the prevention and dissemination activities undertaken by the Associate Director, including—

"(A) a summary of the Associate Director's review of existing dissemination policies and techniques together with a detailed statement concerning any modification or restructuring, or recommendations for modification or restructuring, of such policies and techniques; and

"(B) a detailed statement of the expenditures made for the prevention and dissemination activities reported on and the personnel used in connection with such activities."

1997—Subsecs. (j) to (l). Pub. L. 105–115 added subsec. (j) and redesignated former subsecs. (j) and (k) as (k) and (l), respectively.

1993—Subsec. (b)(12). Pub. L. 103–43, §141(b), added par. (12).

Subsec. (e)(5). Pub. L. 103–43, §210(b), added par. (5).

Subsec. (f). Pub. L. 103–43, §201, substituted "other public and private entities, including elementary, secondary, and post-secondary schools. The Associate Director shall—" and pars. (1) to (3) for "other public and private entities. The Associate Director shall annually report to the Director of NIH on the prevention activities undertaken by the Associate Director. The report shall include a detailed statement of the expenditures made for the activities reported on and the personnel used in connection with such activities".

Subsec. (g). Pub. L. 103–43, §202, added subsec. (g).

Subsec. (h). Pub. L. 103–43, §206, added subsec. (h).

Subsec. (i). Pub. L. 103–43, §208, added subsec. (i).

Subsec. (j). Pub. L. 103–43, §210(c), added subsec. (j).

Subsec. (k). Pub. L. 103–43, §303(b), added subsec. (k).

1992—Subsec. (d)(1). Pub. L. 102–321 substituted "220" for "two hundred".

1988—Subsec. (b)(6). Pub. L. 100–607 inserted "and scientific program advisory committees" after "peer review groups".

STATUTORY NOTES AND RELATED SUBSIDIARIES

EFFECTIVE DATE OF 2007 AMENDMENT

Amendment by Pub. L. 109–482 applicable only with respect to amounts appropriated for fiscal year 2007 or subsequent fiscal years, see section 109 of Pub. L. 109–482, set out as a note under section 281 of this title.

EFFECTIVE DATE OF 1997 AMENDMENT

Amendment by Pub. L. 105–115 effective 90 days after Nov. 21, 1997, except as otherwise provided, see section 501 of Pub. L. 105–115, set out as a note under section 321 of Title 21, Food and Drugs.

EFFECTIVE DATE OF 1992 AMENDMENT

Amendment by Pub. L. 102–321 effective Oct. 1, 1992, with provision for programs providing financial assistance, see section 801(c), (d) of Pub. L. 102–321, set out as a note under section 236 of this title.

RULE OF CONSTRUCTION REGARDING CONTINUATION OF PROGRAMS

Pub. L. 109–482, title I, §103(c), Jan. 15, 2007, 120 Stat. 3689, provided that: "The amendment of a program by a provision of subsection (b) [amending this section and sections 283a, 283d, 283g to 283i, 284e to 284j, 284l, 284m, 285a–9, 285a–10, 285b–7a, 285b–7b, 285c–9, 285d–6a, 285d–8, 285e–10, 285e–10a, 285f–2, 285f–3, 285g–5, 285g–9, 285g–10, 285n, 285o, 285o–2, 285o–4, 285p, 285r, 286a–1, 287a–2, 287a–3, 287a–4, 287c–11, 287c–31 to 287c–33, 288, 288–1, and former 288–5a of this title and repealing sections 285a–8, 285b–8, 285e–11, and 286a–2 of this title] may not be construed as terminating the authority of the Federal agency involved to carry out the program."

CONFIDENTIALITY

Pub. L. 114–255, div. A, title II, §2014(b), Dec. 13, 2016, 130 Stat. 1051, provided that: "Nothing in the amendments made by subsection (a) [amending this section] authorizes the Secretary of Health and Human Services to disclose any information that is a trade secret, or other privileged or confidential information, described in section 552(b)(4) of title 5, United States Code, or section 1905 of title 18, United States Code, or [shall] be construed to require recipients of grants or cooperative agreements through the National Institutes of Health to share such information."

APPROPRIATE AGE GROUPINGS IN CLINICAL RESEARCH

Pub. L. 114–255, div. A, title II, §2038(i), Dec. 13, 2016, 130 Stat. 1067, provided that:

"(1) INPUT FROM EXPERTS.—Not later than 180 days after the date of enactment of this Act [Dec. 13, 2016], the Director of the National Institutes of Health shall convene a workshop of experts on pediatric and older populations to provide input on—

"(A) appropriate age groups to be included in research studies involving human subjects; and

"(B) acceptable justifications for excluding participants from a range of age groups from human subjects research studies.

"(2) POLICY UPDATES.—Not later than 180 days after the conclusion of the workshop under paragraph (1), the Director of the National Institutes of Health shall make a determination with respect to whether the policies of the National Institutes of Health on the inclusion of relevant age groups in clinical studies need to be updated, and shall update such policies as appropriate. In making the determination, the Director of the National Institutes of Health shall take into consideration whether such policies—

"(A) address the consideration of age as an inclusion variable in research involving human subjects; and

"(B) identify the criteria for justification for any age-related exclusions in such research.

"(3) PUBLIC AVAILABILITY OF FINDINGS AND CONCLUSIONS.—The Director of the National Institutes of Health shall—

"(A) make the findings and conclusions resulting from the workshop under paragraph (1) and updates to policies in accordance with paragraph (2), as applicable, available to the public on the Internet website of the National Institutes of Health; and

"(B) ensure that age-related data reported in the triennial report under section 403 of the Public Health Service Act (42 U.S.C. 283) (as amended by section 2032 [of Pub. L. 114–255]) are made available to the public on the Internet website of the National Institutes of Health."

ENHANCING THE RIGOR AND REPRODUCIBILITY OF SCIENTIFIC RESEARCH

Pub. L. 114–255, div. A, title II, §2039, Dec. 13, 2016, 130 Stat. 1068, provided that:

"(a) ESTABLISHMENT.—Not later than 1 year after the date of enactment of this Act [Dec. 13, 2016], the

Secretary of Health and Human Services, acting through the Director of the National Institutes of Health, shall convene a working group under the Advisory Committee to the Director of the National Institutes of Health (referred to in this section as the 'Advisory Committee'), appointed under section 222 of the Public Health Service Act (42 U.S.C. 217a), to develop and issue recommendations through the Advisory Committee for a formal policy, which may incorporate or be informed by relevant existing and ongoing activities, to enhance rigor and reproducibility of scientific research funded by the National Institutes of Health.

"(b) CONSIDERATIONS.—In developing and issuing recommendations through the Advisory Committee under subsection (a), the working group established under such subsection shall consider, as appropriate—

"(1) preclinical experiment design, including analysis of sex as a biological variable;

"(2) clinical experiment design, including—

"(A) the diversity of populations studied for clinical research, with respect to biological, social, and other determinants of health that contribute to health disparities;

"(B) the circumstances under which summary information regarding biological, social, and other factors that contribute to health disparities should be reported; and

"(C) the circumstances under which clinical studies, including clinical trials, should conduct an analysis of the data collected during the study on the basis of biological, social, and other factors that contribute to health disparities;

"(3) applicable levels of rigor in statistical methods, methodology, and analysis;

"(4) data and information sharing in accordance with applicable privacy laws and regulations; and

"(5) any other matter the working group determines relevant.

"(c) POLICIES.—Not later than 18 months after the date of enactment of this Act, the Director of the National Institutes of Health shall consider the recommendations developed by the working group and issued by the Advisory Committee under subsection (a) and develop or update policies as appropriate.

"(d) REPORT.—Not later than 2 years after the date of enactment of this Act, the Director of the National Institutes of Health shall issue a report to the Secretary of Health and Human Services, the Committee on Health, Education, Labor, and Pensions of the Senate, and the Committee on Energy and Commerce of the House of Representatives regarding recommendations developed under subsection (a) and any subsequent policy changes implemented, to enhance rigor and reproducibility in scientific research funded by the National Institutes of Health.

"(e) CONFIDENTIALITY.—Nothing in this section authorizes the Secretary of Health and Human Services to disclose any information that is a trade secret, or other privileged or confidential information, described in section 552(b)(4) of title 5, United States Code, or section 1905 of title 18, United States Code."

DEMONSTRATION GRANTS FOR IMPROVING PEDIATRIC DEVICE AVAILABILITY

Pub. L. 110–85, title III, §305, Sept. 27, 2007, 121 Stat. 863, as amended by Pub. L. 112–144, title VI, §620(a), July 9, 2012, 126 Stat. 1064; Pub. L. 115–52, title V, §502(c), Aug. 18, 2017, 131 Stat. 1037; Pub. L. 117–180, div. F, title V, §5003, Sept. 30, 2022, 136 Stat. 2167; Pub. L. 117–229, div. C, title III, §304, Dec. 16, 2022, 136 Stat. 2312; Pub. L. 117–328, div. FF, title III, §3104, Dec. 29, 2022, 136 Stat. 5807, provided that:

"(a) IN GENERAL.—

"(1) REQUEST FOR PROPOSALS.—Not later than 90 days after the date of the enactment of this Act [Sept. 27, 2007], the Secretary of Health and Human Services shall issue a request for proposals for 1 or more grants or contracts to nonprofit consortia for demonstration projects to promote pediatric device development.

"(2) DETERMINATION ON GRANTS OR CONTRACTS.—Not later than 180 days after the date the Secretary of Health and Human Services issues a request for proposals under paragraph (1), the Secretary shall make a determination on the grants or contracts under this section.

"(b) APPLICATION.—A nonprofit consortium that desires to receive a grant or contract under this section shall submit an application to the Secretary of Health and Human Services at such time, in such manner, and containing such information as the Secretary may require.

"(c) USE OF FUNDS.—A nonprofit consortium that receives a grant or contract under this section shall facilitate the development, production, and distribution of pediatric medical devices by—

"(1) encouraging innovation and connecting qualified individuals with pediatric device ideas with potential manufacturers;

"(2) mentoring and managing pediatric device projects through the development process, including product identification, prototype design, device development, and marketing;

"(3) connecting innovators and physicians to existing Federal and non-Federal resources, including resources from the Food and Drug Administration, the National Institutes of Health, the Small Business

Administration, the Department of Energy, the Department of Education, the National Science Foundation, the Department of Veterans Affairs, the Agency for Healthcare Research and Quality, and the National Institute of Standards and Technology;

"(4) assessing the scientific and medical merit of proposed pediatric device projects;

"(5) providing assistance and advice as needed on business development, personnel training, prototype development, postmarket needs, and other activities consistent with the purposes of this section; and

"(6) providing regulatory consultation to device sponsors in support of the submission of an application for a pediatric device, where appropriate.

"(d) COORDINATION.—

"(1) NATIONAL INSTITUTES OF HEALTH.—Each consortium that receives a grant or contract under this section shall—

"(A) coordinate with the National Institutes of Health's pediatric device contact point or office, designated under section 402(b)(23) of the Public Health Service Act [42 U.S.C. 282(b)(23)], as added by section 304(a) of this Act; and

"(B) provide to the National Institutes of Health any identified pediatric device needs that the consortium lacks sufficient capacity to address or those needs in which the consortium has been unable to stimulate manufacturer interest.

"(2) FOOD AND DRUG ADMINISTRATION.—Each consortium that receives a grant or contract under this section shall coordinate with the Commissioner of Food and Drugs and device companies to facilitate the application for approval or clearance of devices labeled for pediatric use.

"(3) EFFECTIVENESS AND OUTCOMES.—Each consortium that receives a grant or contract under this section shall annually report to the Secretary of Health and Human Services on the status of pediatric device development, production, and distribution that has been facilitated by the consortium.

"(e) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated to carry out this section $1,610,959 for the period beginning on October 1, 2022 and ending on December 23, 2022."

[Pub. L. 117–328, div. FF, title III, §3104, Dec. 29, 2022, 136 Stat. 5807, which directed amendment of section 305(e) of Pub. L. 110–85, set out above, by substituting "$7,000,000 for each of fiscal years 2023 through 2027" for "$1,107,534 for the period beginning on October 1, 2022, and ending on December 23, 2022", could not be executed because "$1,107,534" did not appear after the intervening amendment by section 304 of Pub. L. 117–229.]

SURVEILLANCES

Pub. L. 110–85, title VIII, §801(c), Sept. 27, 2007, 121 Stat. 921, provided that: "Not later than 12 months after the date of the enactment of this Act [Sept. 27, 2007], the Secretary of Health and Human Services shall issue guidance on how the requirements of section 402(j) of the Public Health Service Act [42 U.S.C. 282(j)], as added by this section, apply to a pediatric postmarket surveillance described in paragraph (1)(A)(ii)(II) of such section 402(j) that is not a clinical trial."

PREEMPTION

Pub. L. 110–85, title VIII, §801(d), Sept. 27, 2007, 121 Stat. 922, provided that:

"(1) IN GENERAL.—Upon the expansion of the registry and results data bank under section 402(j)(3)(D) of the Public Health Service Act [42 U.S.C. 282(j)(3)(D)], as added by this section, no State or political subdivision of a State may establish or continue in effect any requirement for the registration of clinical trials or for the inclusion of information relating to the results of clinical trials in a database.

"(2) RULE OF CONSTRUCTION.—The fact of submission of clinical trial information, if submitted in compliance with subsection (j) of section 402 of the Public Health Service Act (as amended by this section), that relates to a use of a drug or device not included in the official labeling of the approved drug or device shall not be construed by the Secretary of Health and Human Services or in any administrative or judicial proceeding, as evidence of a new intended use of the drug or device that is different from the intended use of the drug or device set forth in the official labeling of the drug or device. The availability of clinical trial information through the registry and results data bank under such subsection (j), if submitted in compliance with such subsection, shall not be considered as labeling, adulteration, or misbranding of the drug or device under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.)."

COLLABORATION AND REPORT

Pub. L. 105–115, title I, §113(b), Nov. 21, 1997, 111 Stat. 2312, directed the Secretary of Health and Human Services, the Director of the National Institutes of Health, and the Commissioner of Food and Drugs to collaborate to determine the feasibility of including device investigations within the scope of the data bank under subsec. (j) of this section, with the Secretary to report to Congress, not later than two years after Nov.

21, 1997, on the public health need, if any, for inclusion of device investigations within the scope of the data bank under subsec. (j), and on the adverse impact, if any, on device innovation and research in the United States if information relating to such device investigations was required to be publicly disclosed.

CHRONIC FATIGUE SYNDROME; EXPERTS AND RESEARCH REPRESENTATIVES ON ADVISORY COMMITTEES AND BOARDS

Pub. L. 103–43, title IX, §902(c), June 10, 1993, 107 Stat. 164, provided that: "The Secretary of Health and Human Services, acting through the Director of the National Institutes of Health, shall ensure that appropriate individuals with expertise in chronic fatigue syndrome or neuromuscular diseases and representative of a variety of disciplines and fields within the research community are appointed to appropriate National Institutes of Health advisory committees and boards."

THIRD-PARTY PAYMENTS REGARDING CERTAIN CLINICAL TRIALS AND CERTAIN LIFE-THREATENING ILLNESSES

Pub. L. 103–43, title XIX, §1901(a), June 10, 1993, 107 Stat. 200, provided that: "The Secretary of Health and Human Services, acting through the Director of the National Institutes of Health, shall conduct a study for the purpose of—

"(1) determining the policies of third-party payors regarding the payment of the costs of appropriate health services that are provided incident to the participation of individuals as subjects in clinical trials conducted in the development of drugs with respect to acquired immune deficiency syndrome, cancer, and other life-threatening illnesses; and

"(2) developing recommendations regarding such policies."

PERSONNEL STUDY OF RECRUITMENT, RETENTION AND TURNOVER

Pub. L. 103–43, title XIX, §1905, June 10, 1993, 107 Stat. 203, directed Secretary of Health and Human Services, acting through Director of National Institutes of Health, to conduct a study to review the retention, recruitment, vacancy and turnover rates of support staff, including firefighters, law enforcement, procurement officers, technicians, nurses and clerical employees, to ensure that National Institutes of Health is adequately supporting conduct of efficient, effective and high quality research for the American public, and to submit a report to Congress on results of such study not later than 1 year after June 10, 1993.

CHRONIC PAIN CONDITIONS

Pub. L. 103–43, title XIX, §1907, June 10, 1993, 107 Stat. 204, directed Director of the National Institutes of Health to submit to Congress, not later than 2 years after June 10, 1993, a report and study on the incidence in the United States of cases of chronic pain, including chronic pain resulting from back injuries, reflex sympathetic dystrophy syndrome, temporomandibular joint disorder, post-herpetic neuropathy, painful diabetic neuropathy, phantom pain, and post-stroke pain, and the effect of such cases on the costs of health care in the United States.

SUPPORT FOR BIOENGINEERING RESEARCH

Pub. L. 103–43, title XIX, §1912, June 10, 1993, 107 Stat. 206, directed Secretary of Health and Human Services, acting through Director of the National Institutes of Health, to conduct a study for the purpose of determining the sources and amounts of public and private funding devoted to basic research in bioengineering, including biomaterials sciences, cellular bioprocessing, tissue and rehabilitation engineering, evaluating whether that commitment is sufficient to maintain the innovative edge that the United States has in these technologies, evaluating the role of the National Institutes of Health or any other Federal agency to achieve a greater commitment to innovation in bioengineering, and evaluating the need for better coordination and collaboration among Federal agencies and between the public and private sectors, and, not later than 1 year after June 10, 1993, to prepare and submit to Committee on Labor and Human Resources of Senate, and Committee on Energy and Commerce of House of Representatives, a report containing the findings of the study together with recommendations concerning the enactment of legislation to implement the results of such study.

MASTER PLAN FOR PHYSICAL INFRASTRUCTURE FOR RESEARCH

Pub. L. 103–43, title XX, §2002, June 10, 1993, 107 Stat. 208, directed Secretary of Health and Human Services, acting through Director of the National Institutes of Health, not later than June 1, 1994, to present to Congress a master plan to provide for replacement or refurbishment of less than adequate buildings, utility equipment and distribution systems (including the resources that provide electrical and other utilities, chilled water, air handling, and other services that the Secretary, acting through the Director, deemed necessary),

roads, walkways, parking areas, and grounds that underpin the laboratory and clinical facilities of the National Institutes of Health, and provided that the plan could make recommendations for the undertaking of new projects that are consistent with the objectives of this section, such as encircling the National Institutes of Health Federal enclave with an adequate chilled water conduit.

[1] *So in original. The word "of" probably should not appear.*

[2] *So in original. The second closing parenthesis probably should not appear.*

[3] *So in original.*

[4] *So in original. The second closing parenthesis probably should not appear.*

[5] *So in original. Probably should be "paragraph (2)(A)(ii)(I)(ll),".*

§282a. Authorization of appropriations

(a) In general

(1) This subchapter

For purposes of carrying out this subchapter, there are authorized to be appropriated—
(A) $30,331,309,000 for fiscal year 2007;
(B) $32,831,309,000 for fiscal year 2008;
(C) such sums as may be necessary for fiscal year 2009;
(D) $34,851,000,000 for fiscal year 2018;
(E) $35,585,871,000 for fiscal year 2019; and
(F) $36,472,442,775 for fiscal year 2020.

(2) Funding for pediatric research initiative

For the purpose of carrying out section 282(b)(7)(B)(ii) of this title, there is authorized to be appropriated to the Division of Program Coordination, Planning, and Strategic Initiatives, out of the Pediatric Research Initiative Fund described in section 9008 of title 26, and in addition to amounts otherwise made available under paragraph (1) of this subsection, $12,600,000 for each of fiscal years 2024 through 2028.

(b) Office of the Director

Of the amount authorized to be appropriated under subsection (a) for a fiscal year, there are authorized to be appropriated for programs and activities under this subchapter carried out through the Office of the Director of NIH such sums as may be necessary for each of the fiscal years 2007 through 2009.

(c) Trans-NIH research

(1) Common Fund

(A) Account

For the purpose of allocations under section 282(b)(7)(B)(i) of this title (relating to research identified by the Division of Program Coordination, Planning, and Strategic Initiatives), there is established an account to be known as the Common Fund.

(B) Reservation

(i) In general

Of the total amount appropriated under subsection (a)(1) for fiscal year 2007 or any subsequent fiscal year, the Director of NIH shall reserve an amount for the Common Fund, subject to any applicable provisions in appropriations Acts.

(ii) Minimum amount

For each fiscal year, the percentage constituted by the amount reserved under clause (i) relative to the total amount appropriated under subsection (a)(1) for such year may not be less than the percentage constituted by the amount so reserved for the preceding fiscal year relative to the total amount appropriated under subsection (a)(1) for such preceding fiscal year, subject to any applicable provisions in appropriations Acts.

(C) Common Fund strategic planning report

As part of the National Institutes of Health Strategic Plan required under section 282(m) of this title, the Secretary, acting through the Director of NIH, shall submit a report to the Congress containing a strategic plan for funding research described in section 282(b)(7)(A)(i) of this title (including personnel needs) through the Common Fund. Each such plan shall include the following:

(i) An estimate of the amounts determined by the Director of NIH to be appropriate for maximizing the potential of such research.

(ii) An estimate of the amounts determined by the Director of NIH to be sufficient only for continuing to fund research activities previously identified by the Division of Program Coordination, Planning, and Strategic Initiatives.

(iii) An estimate of the amounts determined by the Director of NIH to be necessary to fund research described in section 282(b)(7)(A)(i) of this title—

(I) that is in addition to the research activities described in clause (ii); and

(II) for which there is the most substantial need.

(D) Evaluation

During the 6-month period following the end of the first fiscal year for which the total amount reserved under subparagraph (B) is equal to 5 percent of the total amount appropriated under subsection (a)(1) for such fiscal year, the Secretary, acting through the Director of NIH, in consultation with the advisory council established under section 282(k) of this title, shall submit recommendations to the Congress for changes regarding amounts for the Common Fund.

(2) Trans-NIH research reporting

(A) Limitation

With respect to the total amount appropriated under subsection (a) for fiscal year 2008 or any subsequent fiscal year, if the head of a national research institute or national center fails to submit the report required by subparagraph (B) for the preceding fiscal year, the amount made available for the institute or center for the fiscal year involved may not exceed the amount made available for the institute or center for fiscal year 2006.

(B) Reporting

Not later than 2 years after December 13, 2016, the head of each national research institute or national center shall submit to the Director of the National Institutes of Health a report, to be included in the triennial report under section 283 of this title, on the amount made available by the institute or center for conducting or supporting research that involves collaboration between the institute or center and 1 or more other national research institutes or national centers.

(C) Determination

For purposes of determining the amount or percentage of funds to be reported under subparagraph (B), any amounts made available to an institute or center under section 282(b)(7)(B)(i) of this title shall be included.

(D) Verification of amounts

Upon receipt of each report submitted under subparagraph (B), the Director of NIH shall review and, in cases of discrepancy, verify the accuracy of the amounts specified in the report.

(E) Waiver

At the request of any national research institute or national center, the Director of NIH may waive the application of this paragraph to such institute or center if the Director finds that the conduct or support of research described in subparagraph (B) is inconsistent with the mission of such institute or center.

(d) Transfer authority

Of the total amount appropriated under subsection (a)(1) for a fiscal year, the Director of NIH may (in addition to the reservation under subsection (c)(1) for such year) transfer not more than 1 percent for programs or activities that are authorized in this subchapter and identified by the Director to receive funds pursuant to this subsection. In making such transfers, the Director may not decrease any appropriation account under subsection (a)(1) by more than 1 percent.

(e) Rule of construction

This section may not be construed as affecting the authorities of the Director of NIH under section 281 of this title.

(July 1, 1944, ch. 373, title IV, §402A, as added Pub. L. 109–482, title I, §103(a), Jan. 15, 2007, 120 Stat. 3685; amended Pub. L. 113–94, §3(b), Apr. 3, 2014, 128 Stat. 1087; Pub. L. 114–255, div. A, title II, §§2001, 2031(b), 2042(a), Dec. 13, 2016, 130 Stat. 1047, 1056, 1073; Pub. L. 118–228, §2(1), (2), Jan. 4, 2025, 138 Stat. 2822.)

EDITORIAL NOTES

AMENDMENTS

2025—Subsec. (a)(2). Pub. L. 118–228, §2(1), struck out "10-year" before "pediatric" and "through Common Fund" after "initiative" in heading, and in text substituted "to the Division of Program Coordination, Planning, and Strategic Initiatives" for "to the Common Fund" and "2024 through 2028" for "2014 through 2023", and struck out "10-Year" before "Pediatric Research Initiative Fund" and "and reserved under subsection (c)(1)(B)(i) of this section" after "paragraph (1) of this subsection".

Subsec. (c)(1)(A), (2)(C). Pub. L. 118–228, §2(2), substituted "section 282(b)(7)(B)(i)" for "section 282(b)(7)(B)".

2016—Subsec. (a)(1)(D) to (F). Pub. L. 114–255, §2001, added subpars. (D) to (F).

Subsec. (c)(1)(C). Pub. L. 114–255, §2031(b), substituted "As part of the National Institutes of Health Strategic Plan required under section 282(m) of this title," for "Not later than June 1, 2007, and every 2 years thereafter,".

Subsec. (c)(2)(B). Pub. L. 114–255, §2042(a)(1), amended subpar. (B) generally. Prior to amendment, text read as follows: "Not later than January 1, 2008, and each January 1st thereafter—

"(i) the head of each national research institute or national center shall submit to the Director of NIH a report on the amount made available by the institute or center for conducting or supporting research that involves collaboration between the institute or center and 1 or more other national research institutes or national centers; and

"(ii) the Secretary shall submit a report to the Congress identifying the percentage of funds made available by each national research institute and national center with respect to such fiscal year for conducting or supporting research described in clause (i)."

Subsec. (c)(2)(D), (E). Pub. L. 114–255, §2042(a)(2), substituted "(B)" for "(B)(i)".

2014—Subsec. (a). Pub. L. 113–94, §3(b)(1)(B), which directed amendment of subsec. (a) by striking "For purposes of carrying out this subchapter" and inserting par. (1) designation, heading, and "For purposes of carrying out this subchapter", was executed by striking "For the purpose of carrying out this subchapter" and making the insertions as directed, to reflect the probable intent of Congress.

Pub. L. 113–94, §3(b)(1)(A), redesignated pars. (1) to (3) as subpars. (A) to (C), respectively, and realigned margins.

Subsec. (a)(2). Pub. L. 113–94, §3(b)(1)(C), added par. (2). Former par. (2) redesignated subpar. (B) of par. (1).

Subsecs. (c)(1)(B), (D), (d). Pub. L. 113–94, §3(b)(2), substituted "subsection (a)(1)" for "subsection (a)" wherever appearing.

STATUTORY NOTES AND RELATED SUBSIDIARIES

EFFECTIVE DATE

Section applicable only with respect to amounts appropriated for fiscal year 2007 or subsequent fiscal years, see section 109 of Pub. L. 109–482, set out as an Effective Date of 2007 Amendment note under section 281 of this title.

SUPPLEMENT, NOT SUPPLANT; PROHIBITION AGAINST TRANSFER

Pub. L. 113–94, §3(c), Apr. 3, 2014, 128 Stat. 1087, provided that: "Funds appropriated pursuant to section 402A(a)(2) of the Public Health Service Act [42 U.S.C. 282a(a)(2)], as added by subsection (b)—

"(1) shall be used to supplement, not supplant, the funds otherwise allocated by the National Institutes of Health for pediatric research; and

"(2) notwithstanding any transfer authority in any appropriation Act, shall not be used for any purpose other than allocating funds for making grants as described in section 402(b)(7)(B)(ii) of the Public Health Service Act [42 U.S.C. 282(b)(7)(B)(ii)], as added by subsection (a)."

§282b. Electronic coding of grants and activities

The Secretary, acting through the Director of NIH, shall establish an electronic system to uniformly code research grants and activities of the Office of the Director and of all the national research institutes and national centers. The electronic system shall be searchable by a variety of codes, such as the type of research grant, the research entity managing the grant, and the public health area of interest. When permissible, the Secretary, acting through the Director of NIH, shall provide information on relevant literature and patents that are associated with research activities of the National Institutes of Health.

(July 1, 1944, ch. 373, title IV, §402B, as added Pub. L. 109–482, title I, §104(a)(3), Jan. 15, 2007, 120 Stat. 3689.)

STATUTORY NOTES AND RELATED SUBSIDIARIES

EFFECTIVE DATE

Section applicable only with respect to amounts appropriated for fiscal year 2007 or subsequent fiscal years, see section 109 of Pub. L. 109–482, set out as an Effective Date of 2007 Amendment note under section 281 of this title.

§282c. Public access to funded investigators' final manuscripts

The Director of the National Institutes of Health ("NIH") shall require in the current fiscal year and thereafter that all investigators funded by the NIH submit or have submitted for them to the National Library of Medicine's PubMed Central an electronic version of their final, peer-reviewed manuscripts upon acceptance for publication, to be made publicly available no later than 12 months after the official date of publication: *Provided,* That the NIH shall implement the public access policy in a manner consistent with copyright law.

(Pub. L. 111–8, div. F, title II, §217, Mar. 11, 2009, 123 Stat. 782.)

EDITORIAL NOTES

CODIFICATION

Section was enacted as part of the Department of Health and Human Services Appropriations Act, 2009, and also as part of the Departments of Labor, Health and Human Services, and Education, and Related Agencies Appropriations Act, 2009, and the Omnibus Appropriations Act, 2009, and not as part of the Public Health Service Act which comprises this chapter.

§282d. Transferred

EDITORIAL NOTES

CODIFICATION

Section, act July 1, 1944, ch. 373, title IV, §402C, as added Pub. L. 111–148, title X, §10409(d), Mar. 23, 2010, 124 Stat. 978, which related to the Cures Acceleration Network, was renumbered section 480 of act July 1, 1944, by Pub. L. 112–74, div. F, title II, §221(c)(1)(A), Dec. 23, 2011, 125 Stat. 1089, and transferred to section 287a of this title.

§283. Triennial reports of Director of NIH

(a) In general

The Director of NIH shall submit to the Congress on a triennial basis a report in accordance with this section. The first report shall be submitted not later than 1 year after January 15, 2007. Each such report shall include the following information:

(1) An assessment of the state of biomedical and behavioral research.

(2) A description of the activities conducted or supported by the agencies of the National Institutes of Health and policies respecting the programs of such agencies.

(3) A description of intra-National Institutes of Health activities, including—

(A) identification of the percentage of funds made available by each national research institute and national center with respect to each applicable fiscal year for conducting or supporting research that involves collaboration between the institute or center and 1 or more other national research institutes or national centers; and

(B) recommendations for promoting coordination of information among the centers of excellence.

(4) A catalog of all the research activities of the agencies, prepared in accordance with the following:

(A) The catalog shall, for each such activity—

(i) identify the agency or agencies involved;

(ii) state whether the activity was carried out directly by the agencies or was supported by the agencies and describe to what extent the agency was involved; and

(iii) identify whether the activity was carried out through a center of excellence.

(B) In the case of clinical research, the catalog shall, as appropriate, identify study populations by demographic variables, including biological and social variables and relevant age categories (such as pediatric subgroups), and determinants of health, that contribute to research on minority health and health disparities.

(C) Research activities listed in the catalog shall include, where applicable, the following:

(i) Epidemiological studies and longitudinal studies.

(ii) Disease registries, information clearinghouses, and other data systems.

(iii) Public education and information campaigns.

(iv) Training activities, including—

(I) National Research Service Awards and Clinical Transformation Science Awards;

(II) graduate medical education programs, including information on the number and type of graduate degrees awarded during the period in which the programs received funding under this subchapter;

(III) investigator-initiated awards for postdoctoral training and postdoctoral training funded through research grants;

(IV) a breakdown by demographic variables and other appropriate categories; and

(V) an evaluation and comparison of outcomes and effectiveness of various training

programs.

(v) Clinical trials, including a breakdown of participation by study populations and demographic variables, including relevant age categories (such as pediatric subgroups), information submitted by each national research institute and national center to the Director of National Institutes of Health under section 289a–2(f) of this title, and such other information as may be necessary to demonstrate compliance with section 289a–2 of this title and other applicable requirements regarding inclusion of demographic groups.

(vi) Translational research activities with other agencies of the Public Health Service.

(5) A summary of the research activities throughout the agencies, which summary shall be organized by the following categories, where applicable:

(A) Cancer.
(B) Neurosciences.
(C) Life stages, human development, and rehabilitation.
(D) Organ systems.
(E) Autoimmune diseases.
(F) Genomics.
(G) Molecular biology and basic science.
(H) Technology development.
(I) Chronic diseases, including pain and palliative care.
(J) Infectious diseases and bioterrorism.
(K) Minority health and health disparities.
(L) Such additional categories as the Director determines to be appropriate.

(6) A review of each entity receiving funding under this subchapter in its capacity as a center of excellence (in this paragraph referred to as a "center of excellence"), including the following—

(A) an evaluation of the performance and research outcomes of each center of excellence; and

(B) recommendations for improving the effectiveness, efficiency, and outcomes of the centers of excellence.

(b) Requirement regarding disease-specific research activities

In a report under subsection (a), the Director of NIH, when reporting on research activities relating to a specific disease, disorder, or other adverse health condition, shall—

(1) present information in a standardized format;

(2) identify the actual dollar amounts obligated for such activities; and

(3) include a plan for research on the specific disease, disorder, or other adverse health condition, including a statement of objectives regarding the research, the means for achieving the objectives, a date by which the objectives are expected to be achieved, and justifications for revisions to the plan.

(c) Additional reports

In addition to reports required by subsections (a) and (b), the Director of NIH or the head of a national research institute or national center may submit to the Congress such additional reports as the Director or the head of such institute or center determines to be appropriate.

(July 1, 1944, ch. 373, title IV, §403, as added Pub. L. 109–482, title I, §104(a)(3), Jan. 15, 2007, 120 Stat. 3689; amended Pub. L. 110–85, title XI, §1104(3), Sept. 27, 2007, 121 Stat. 975; Pub. L. 114–255, div. A, title II, §2032, Dec. 13, 2016, 130 Stat. 1056.)

EDITORIAL NOTES

PRIOR PROVISIONS

A prior section 283, act July 1, 1944, ch. 373, title IV, §403, as added Pub. L. 99–158, §2, Nov. 20, 1985, 99 Stat. 826; amended Pub. L. 100–607, title I, §112, Nov. 4, 1988, 102 Stat. 3052, required a biennial report

by the Director to the President and Congress, prior to repeal by Pub. L. 109–482, title I, §104(a)(3), Jan. 15, 2007, 120 Stat. 3689.

AMENDMENTS

2016—Pub. L. 114–255, §2032(1), substituted "Triennial" for "Biennial" in section catchline.

Subsec. (a). Pub. L. 114–255, §2032(2)(A), substituted "triennial" for "biennial" in introductory provisions.

Subsec. (a)(3). Pub. L. 114–255, §2032(2)(B), amended par. (3) generally. Prior to amendment, par. (3) read as follows: "Classification and justification for the priorities established by the agencies, including a strategic plan and recommendations for future research initiatives to be carried out under section 282(b)(7) of this title through the Division of Program Coordination, Planning, and Strategic Initiatives."

Subsec. (a)(4)(B). Pub. L. 114–255, §2032(2)(C)(i), substituted "demographic variables, including biological and social variables and relevant age categories (such as pediatric subgroups), and determinants of health," for "demographic variables and other variables".

Subsec. (a)(4)(C)(v). Pub. L. 114–255, §2032(2)(C)(ii), substituted "demographic variables, including relevant age categories (such as pediatric subgroups), information submitted by each national research institute and national center to the Director of National Institutes of Health under section 289a–2(f) of this title, and such" for "demographic variables and such" and "and other applicable requirements regarding inclusion of demographic groups" for "(regarding inclusion of women and minorities in clinical research)".

Subsec. (a)(6). Pub. L. 114–255, §2032(2)(D), substituted "the following—" for "the following:" in introductory provisions, "an evaluation" for "An evaluation" and "; and" for the period in subpar. (A), redesignated subpar. (C) as (B) and substituted "recommendations" for "Recommendations", and struck out former subpars. (B) and (D), which read as follows:

"(B) Recommendations for promoting coordination of information among the centers of excellence.

"(D) If no additional centers of excellence have been funded under this subchapter since the previous report under this section, an explanation of the reasons for not funding any additional centers."

2007—Subsec. (a)(4)(C)(iv)(III). Pub. L. 110–85 inserted "and postdoctoral training funded through research grants" before semicolon at end.

STATUTORY NOTES AND RELATED SUBSIDIARIES

EFFECTIVE DATE

Section applicable only with respect to amounts appropriated for fiscal year 2007 or subsequent fiscal years, see section 109 of Pub. L. 109–482, set out as an Effective Date of 2007 Amendment note under section 281 of this title.

§283a. Annual reporting to increase interagency collaboration and coordination

(a) Collaboration with other HHS agencies

On an annual basis, the Director of NIH shall submit to the Secretary a report on the activities of the National Institutes of Health involving collaboration with other agencies of the Department of Health and Human Services.

(b) Clinical trials

Each calendar year, the Director of NIH shall submit to the Commissioner of Food and Drugs a report that identifies each clinical trial that is registered during such calendar year in the databank of information established under section 282(i) of this title.

(c) Human tissue samples

On an annual basis, the Director of NIH shall submit to the Congress a report that describes how the National Institutes of Health and its agencies store and track human tissue samples.

(d) First report

The first report under subsections (a), (b), and (c) shall be submitted not later than 1 year after January 15, 2007.

(July 1, 1944, ch. 373, title IV, §403A, as added Pub. L. 109–482, title I, §104(a)(3), Jan. 15, 2007, 120 Stat. 3691.)

EDITORIAL NOTES

PRIOR PROVISIONS

A prior section 403A of act July 1, 1944, was renumbered section 403D and is classified to section 283a–3 of this title.

STATUTORY NOTES AND RELATED SUBSIDIARIES

EFFECTIVE DATE

Section applicable only with respect to amounts appropriated for fiscal year 2007 or subsequent fiscal years, see section 109 of Pub. L. 109–482, set out as an Effective Date of 2007 Amendment note under section 281 of this title.

§283a–1. Annual reporting to prevent fraud and abuse

(a) Whistleblower complaints

(1) In general

On an annual basis, the Director of NIH shall submit to the Inspector General of the Department of Health and Human Services, the Secretary, the Committee on Energy and Commerce and the Committee on Appropriations of the House of Representatives, and the Committee on Health, Education, Labor, and Pensions and the Committee on Appropriations of the Senate a report summarizing the activities of the National Institutes of Health relating to whistleblower complaints.

(2) Contents

For each whistleblower complaint pending during the year for which a report is submitted under this subsection, the report shall identify the following:

(A) Each agency of the National Institutes of Health involved.

(B) The status of the complaint.

(C) The resolution of the complaint to date.

(b) First report

The first report under subsection (a) shall be submitted not later than 1 year after January 15, 2007.

(July 1, 1944, ch. 373, title IV, §403B, as added Pub. L. 109–482, title I, §104(a)(3), Jan. 15, 2007, 120 Stat. 3691; amended Pub. L. 114–255, div. A, title II, §2042(b), Dec. 13, 2016, 130 Stat. 1073.)

EDITORIAL NOTES

AMENDMENTS

2016—Subsecs. (b), (c). Pub. L. 114–255 redesignated subsec. (c) as (b), substituted "subsection (a)" for "subsections (a) and (b)", and struck out former subsec. (b), which related to annual report by the Director of NIH on experts and consultants whose services were obtained by the National Institutes of Health or its agencies.

STATUTORY NOTES AND RELATED SUBSIDIARIES

EFFECTIVE DATE

Section applicable only with respect to amounts appropriated for fiscal year 2007 or subsequent fiscal years, see section 109 of Pub. L. 109–482, set out as an Effective Date of 2007 Amendment note under section 281 of this title.

§283a–2. Annual reporting regarding training of graduate students for doctoral degrees

(a) In general

Each institution receiving an award under this subchapter for the training of graduate students for doctoral degrees shall annually report to the Director of NIH, with respect to graduate students supported by the National Institutes of Health at such institution—

(1) the percentage of such students admitted for study who successfully attain a doctoral degree; and

(2) for students described in paragraph (1), the average time between the beginning of graduate study and the receipt of a doctoral degree.

(3) [1] Provision of information to applicants

Each institution described in subsection (a) shall provide to each student submitting an application for a program of graduate study at such institution the information described in paragraphs (1) and (2) of such subsection with respect to the program or programs to which such student has applied.

(July 1, 1944, ch. 373, title IV, §403C, as added Pub. L. 109–482, title I, §104(a)(3), Jan. 15, 2007, 120 Stat. 3692; amended Pub. L. 110–85, title XI, §1104(5), Sept. 27, 2007, 121 Stat. 975; Pub. L. 114–255, div. A, title II, §2042(c), Dec. 13, 2016, 130 Stat. 1073.)

EDITORIAL NOTES

PRIOR PROVISIONS

A prior section 403C of act July 1, 1944, was renumbered section 403D and is classified to section 283a–3 of this title.

AMENDMENTS

2016—Subsec. (a)(2). Pub. L. 114–255 struck out "(not including any leaves of absence)" after "time".

2007—Subsec. (a). Pub. L. 110–85, §1104(5)(A), substituted "graduate students supported by the National Institutes of Health" for "each degree-granting program" in introductory provisions.

Subsec. (a)(1). Pub. L. 110–85, §1104(5)(B), inserted "such" after "percentage of".

Subsec. (a)(2). Pub. L. 110–85, §1104(5)(C), inserted "(not including any leaves of absence)" after "average time".

STATUTORY NOTES AND RELATED SUBSIDIARIES

EFFECTIVE DATE

Section applicable only with respect to amounts appropriated for fiscal year 2007 or subsequent fiscal years, see section 109 of Pub. L. 109–482, set out as an Effective Date of 2007 Amendment note under section 281 of this title.

[1] So in original. Probably should be "(b)".

§283a–3. Establishment of program regarding DES

(a) In general

The Director of NIH shall establish a program for the conduct and support of research and training, the dissemination of health information, and other programs with respect to the diagnosis and treatment of conditions associated with exposure to the drug diethylstilbestrol (in this section referred to as "DES").

(b) Education programs

In carrying out subsection (a), the Director of NIH, after consultation with nonprofit private entities representing individuals who have been exposed to DES, shall conduct or support programs to educate health professionals and the public on the drug, including the importance of identifying and treating individuals who have been exposed to the drug.

(c) Longitudinal studies

After consultation with the Office of Research on Women's Health, the Director of NIH, acting through the appropriate national research institutes, shall in carrying out subsection (a) conduct or support one or more longitudinal studies to determine the incidence of the following diseases or disorders in the indicated populations and the relationship of DES to the diseases or disorders:

(1) In the case of women to whom (on or after January 1, 1938) DES was administered while the women were pregnant, the incidence of all diseases and disorders (including breast cancer, gynecological cancers, and impairments of the immune system, including autoimmune disease).

(2) In the case of women exposed to DES in utero, the incidence of clear cell cancer (including recurrences), the long-term health effects of such cancer, and the effects of treatments for such cancer.

(3) In the case of men and women exposed to DES in utero, the incidence of all diseases and disorders (including impairments of the reproductive and autoimmune systems).

(4) In the case of children of men or women exposed to DES in utero, the incidence of all diseases and disorders.

(d) Exposure to DES in utero

For purposes of this section, an individual shall be considered to have been exposed to DES in utero if, during the pregnancy that resulted in the birth of such individual, DES was (on or after January 1, 1938) administered to the biological mother of the individual.

(July 1, 1944, ch. 373, title IV, §403D, formerly §403A, as added Pub. L. 102–409, §2, Oct. 13, 1992, 106 Stat. 2092; amended Pub. L. 105–340, title I, §101(a), Oct. 31, 1998, 112 Stat. 3191; renumbered §403C and amended Pub. L. 109–482, title I, §§103(b)(2), 104(a)(1), Jan. 15, 2007, 120 Stat. 3687, 3689; renumbered §403D, Pub. L. 110–85, title XI, §1104(4), Sept. 27, 2007, 121 Stat. 975.)

EDITORIAL NOTES

CODIFICATION

Section was formerly classified to section 283a of this title prior to renumbering by Pub. L. 109–482.

AMENDMENTS

2007—Subsec. (e). Pub. L. 109–482, §103(b)(2), struck out subsec. (e) which read as follows: "In addition to any other authorization of appropriations available for the purpose of carrying out this section, there are authorized to be appropriated for such purpose such sums as may be necessary for each of the fiscal years 1993 through 2003."

1998—Subsec. (e). Pub. L. 105–340 substituted "2003" for "1996".

STATUTORY NOTES AND RELATED SUBSIDIARIES

EFFECTIVE DATE OF 2007 AMENDMENT

Amendment by Pub. L. 109–482 applicable only with respect to amounts appropriated for fiscal year 2007 or subsequent fiscal years, see section 109 of Pub. L. 109–482, set out as a note under section 281 of this title.

§283a–4. Notification to Director of personnel removed or disciplined for harassment, bullying, retaliation, or hostile working conditions

The Director of the National Institutes of Health shall hereafter require institutions that receive funds through a grant or cooperative agreement during fiscal year 2022 and in future years to notify

the Director when individuals identified as a principal investigator or as key personnel in an NIH notice of award are removed from their position or are otherwise disciplined due to concerns about harassment, bullying, retaliation, or hostile working conditions. The Director may issue regulations consistent with this section.

(Pub. L. 117–103, div. H, title II, §239, Mar. 15, 2022, 136 Stat. 474.)

EDITORIAL NOTES

CODIFICATION

Section was enacted as part of the Department of Health and Human Services Appropriations Act, 2022, and also as part of the Departments of Labor, Health and Human Services, and Education, and Related Agencies Appropriations Act, 2022, and the Consolidated Appropriations Act, 2022, and not as part of the Public Health Service Act which comprises this chapter.

§283a–5. Grant recipient requirements regarding harassment investigation and reporting

The Director of the NIH shall hereafter require institutions that receive funds through a grant or cooperative agreement or other form of extramural award during fiscal year 2026 and in future years to complete any investigation undertaken due to concerns about harassment, bullying retaliation, or hostile working conditions regarding any individual identified as a principal investigator or key personnel in an NIH notice of award or progress report even if during the course of the investigation the individual under investigation leaves their current position and is no longer employed by the institution. The Director may hereafter decline transfer of an ongoing extramural award to a different institution if concerns about harassment, bullying, hostile work environment, or other professional misconduct on the part of a principal investigator or key personnel named in the Notice of Award or progress report have not been resolved to the NIH's satisfaction. The Director of the NIH shall hereafter have the authority to share investigation reports, conclusions, and results of any investigation of individuals identified as a principal investigator or as key personnel in an NIH notice of award or progress report due to concerns about harassment, bullying, retaliation, or hostile working conditions on an as needed basis with any institution that receives funds through a grant or cooperative agreement or other form of extramural award during fiscal year 2026 or any subsequent fiscal year. The Director may issue regulations consistent with this section.

(Pub. L. 119–75, div. B, title II, §238, Feb. 3, 2026, 140 Stat. 291.)

EDITORIAL NOTES

CODIFICATION

Section was enacted as part of the Department of Health and Human Services Appropriations Act, 2026, and also as part of the Departments of Labor, Health and Human Services, and Education, and Related Agencies Appropriations Act, 2026, and the Consolidated Appropriations Act, 2026, and not as part of the Public Health Service Act which comprises this chapter.

§283b. Repealed. Pub. L. 106–525, title I, §101(b)(2), Nov. 22, 2000, 114 Stat. 2501

Section, act July 1, 1944, ch. 373, title IV, §404, as added Pub. L. 103–43, title I, §151, June 10, 1993, 107 Stat. 139, related to the establishment and purpose of the Office of Research on Minority Health.

§283c. Office of Behavioral and Social Sciences Research

(a) There is established within the Office of the Director of NIH an office to be known as the Office of Behavioral and Social Sciences Research (in this section referred to as the "Office"). The Office shall be headed by a director, who shall be appointed by the Director of NIH.

(b)(1) With respect to research on the relationship between human behavior and the development, treatment, and prevention of medical conditions, the Director of the Office shall—

(A) coordinate research conducted or supported by the agencies of the National Institutes of Health; and

(B) identify projects of behavioral and social sciences research that should be conducted or supported by the national research institutes, and develop such projects in cooperation with such institutes.

(2) Research authorized under paragraph (1) includes research on teen pregnancy, infant mortality, violent behavior, suicide, and homelessness. Such research does not include neurobiological research, or research in which the behavior of an organism is observed for the purpose of determining activity at the cellular or molecular level.

(July 1, 1944, ch. 373, title IV, §404A, as added Pub. L. 103–43, title II, §203(a), June 10, 1993, 107 Stat. 145.)

STATUTORY NOTES AND RELATED SUBSIDIARIES

EFFECTIVE DATE

Pub. L. 103–43, title II, §203(c), June 10, 1993, 107 Stat. 146, provided that: "The amendment described in subsection (a) [enacting this section] is made upon the date of the enactment of this Act [June 10, 1993] and takes effect July 1, 1993. Subsection (b) [107 Stat. 145] takes effect on such date."

§283d. Children's Vaccine Initiative

The Secretary, in consultation with the Director of the National Vaccine Program under subchapter XIX and acting through the Directors of the National Institute for Allergy and Infectious Diseases, the Eunice Kennedy Shriver National Institute of Child Health and Human Development, the National Institute for Aging, and other public and private programs, shall carry out activities, which shall be consistent with the global Children's Vaccine Initiative, to develop affordable new and improved vaccines to be used in the United States and in the developing world that will increase the efficacy and efficiency of the prevention of infectious diseases. In carrying out such activities, the Secretary shall, to the extent practicable, develop and make available vaccines that require fewer contacts to deliver, that can be given early in life, that provide long lasting protection, that obviate refrigeration, needles and syringes, and that protect against a larger number of diseases.

(July 1, 1944, ch. 373, title IV, §404B, as added Pub. L. 103–43, title II, §204, June 10, 1993, 107 Stat. 146; amended Pub. L. 109–482, title I, §103(b)(3), Jan. 15, 2007, 120 Stat. 3687; Pub. L. 110–154, §1(b)(2), Dec. 21, 2007, 121 Stat. 1827; Pub. L. 114–255, div. A, title II, §2042(d), Dec. 13, 2016, 130 Stat. 1073.)

EDITORIAL NOTES

AMENDMENTS

2016—Pub. L. 114–255 struck out subsec. (a) designation and heading "Development of New Vaccines" and subsec. (b). Prior to amendment, text of subsec. (b) read as follows: "In the report required in section 300aa–4 of this title, the Secretary, acting through the Director of the National Vaccine Program under subchapter XIX, shall include information with respect to activities and the progress made in implementing the provisions of this section and achieving its goals."

2007—Subsec. (a). Pub. L. 110–154 substituted "Eunice Kennedy Shriver National Institute of Child Health and Human Development" for "National Institute for Child Health and Human Development".

Subsec. (c). Pub. L. 109–482 struck out heading and text of subsec. (c). Text read as follows: "In addition to

any other amounts authorized to be appropriated for activities of the type described in this section, there are authorized to be appropriated to carry out this section $20,000,000 for fiscal year 1994, and such sums as may be necessary for each of the fiscal years 1995 and 1996."

STATUTORY NOTES AND RELATED SUBSIDIARIES

EFFECTIVE DATE OF 2007 AMENDMENT

Amendment by Pub. L. 109–482 applicable only with respect to amounts appropriated for fiscal year 2007 or subsequent fiscal years, see section 109 of Pub. L. 109–482, set out as a note under section 281 of this title.

§283e. Plan for use of animals in research

(a) Preparation

The Director of NIH, after consultation with the committee established under subsection (e), shall prepare a plan—

(1) for the National Institutes of Health to conduct or support research into—

(A) methods of biomedical research and experimentation that do not require the use of animals;

(B) methods of such research and experimentation that reduce the number of animals used in such research;

(C) methods of such research and experimentation that produce less pain and distress in such animals; and

(D) methods of such research and experimentation that involve the use of marine life (other than marine mammals);

(2) for establishing the validity and reliability of the methods described in paragraph (1);

(3) for encouraging the acceptance by the scientific community of such methods that have been found to be valid and reliable; and

(4) for training scientists in the use of such methods that have been found to be valid and reliable.

(b) Submission to Congressional committees

Not later than October 1, 1993, the Director of NIH shall submit to the Committee on Energy and Commerce of the House of Representatives, and to the Committee on Labor and Human Resources of the Senate, the plan required in subsection (a) and shall begin implementation of the plan.

(c) Periodic review and revision

The Director of NIH shall periodically review, and as appropriate, make revisions in the plan required under subsection (a). A description of any revision made in the plan shall be included in the first biennial report under section 283 of this title that is submitted after the revision is made.

(d) Dissemination of information

The Director of NIH shall take such actions as may be appropriate to convey to scientists and others who use animals in biomedical or behavioral research or experimentation information respecting the methods found to be valid and reliable under subsection (a)(2).

(e) Interagency Coordinating Committee on the Use of Animals in Research

(1) The Director of NIH shall establish within the National Institutes of Health a committee to be known as the Interagency Coordinating Committee on the Use of Animals in Research (in this subsection referred to as the "Committee").

(2) The Committee shall provide advice to the Director of NIH on the preparation of the plan required in subsection (a).

(3) The Committee shall be composed of—

(A) the Directors of each of the national research institutes (or the designees of such Directors);

and

(B) representatives of the Environmental Protection Agency, the Food and Drug Administration, the Consumer Product Safety Commission, the National Science Foundation, and such additional agencies as the Director of NIH determines to be appropriate, which representatives shall include not less than one veterinarian with expertise in laboratory-animal medicine.

(July 1, 1944, ch. 373, title IV, §404C, as added Pub. L. 103–43, title II, §205(a), June 10, 1993, 107 Stat. 146; amended Pub. L. 112–74, div. F, title II, §221(d)(2), Dec. 23, 2011, 125 Stat. 1090.)

EDITORIAL NOTES

AMENDMENTS

2011—Subsec. (e)(3)(A). Pub. L. 112–74 struck out "and the Director of the Center for Research Resources" after "institutes".

STATUTORY NOTES AND RELATED SUBSIDIARIES

CHANGE OF NAME

Committee on Labor and Human Resources of Senate changed to Committee on Health, Education, Labor, and Pensions of Senate by Senate Resolution No. 20, One Hundred Sixth Congress, Jan. 19, 1999.

Committee on Energy and Commerce of House of Representatives treated as referring to Committee on Commerce of House of Representatives by section 1(a) of Pub. L. 104–14, set out as a note preceding section 21 of Title 2, The Congress. Committee on Commerce of House of Representatives changed to Committee on Energy and Commerce of House of Representatives, and jurisdiction over matters relating to securities and exchanges and insurance generally transferred to Committee on Financial Services of House of Representatives by House Resolution No. 5, One Hundred Seventh Congress, Jan. 3, 2001.

§283f. Requirements regarding surveys of sexual behavior

With respect to any survey of human sexual behavior proposed to be conducted or supported through the National Institutes of Health, the survey may not be carried out unless—

(1) the proposal has undergone review in accordance with any applicable requirements of sections 289 and 289a of this title; and

(2) the Secretary, in accordance with section 289a–1 of this title, makes a determination that the information expected to be obtained through the survey will assist—

(A) in reducing the incidence of sexually transmitted diseases, the incidence of infection with the human immunodeficiency virus, or the incidence of any other infectious disease; or

(B) in improving reproductive health or other conditions of health.

(July 1, 1944, ch. 373, title IV, §404D, as added Pub. L. 103–43, title II, §207, June 10, 1993, 107 Stat. 148.)

STATUTORY NOTES AND RELATED SUBSIDIARIES

PROHIBITION AGAINST SHARP ADULT SEX SURVEY AND AMERICAN TEENAGE SEX SURVEY

Pub. L. 103–43, title XX, §2015, June 10, 1993, 107 Stat. 217, provided that: "The Secretary of Health and Human Services may not during fiscal year 1993 or any subsequent fiscal year conduct or support the SHARP survey of adult sexual behavior or the American Teenage Study of adolescent sexual behavior. This section becomes effective on the date of the enactment of this Act [June 10, 1993]."

§283g. Muscular dystrophy; initiative through Director of National Institutes of

Health

(a) Expansion, intensification, and coordination of activities

(1) In general

The Director of NIH, in coordination with the Directors of the National Institute of Neurological Disorders and Stroke, the National Institute of Arthritis and Musculoskeletal and Skin Diseases, the Eunice Kennedy Shriver National Institute of Child Health and Human Development, the National Heart, Lung, and Blood Institute, and the other national research institutes as appropriate, shall expand and intensify programs of such Institutes with respect to research and related activities concerning various forms of muscular dystrophy, including Duchenne, Becker, congenital muscular dystrophy, limb-girdle muscular dystrophy, myotonic, facioscapulohumeral muscular dystrophy (referred to in this section as "FSHD") and other forms of muscular dystrophy.

(2) Coordination

The Directors referred to in paragraph (1) shall jointly coordinate the programs referred to in such paragraph and consult with the Muscular Dystrophy Interagency Coordinating Committee established under section 6 of the MD–CARE Act.[1]

(3) Allocations by Director of NIH

The Director of NIH shall allocate the amounts appropriated to carry out this section for each fiscal year among the national research institutes referred to in paragraph (1).

(b) Centers of excellence

(1) In general

The Director of NIH shall award grants and contracts under subsection (a)(1) to public or nonprofit private entities to pay all or part of the cost of planning, establishing, improving, and providing basic operating support for centers of excellence regarding research on various forms of muscular dystrophy. Such centers of excellence shall be known as the "Paul D. Wellstone Muscular Dystrophy Cooperative Research Centers".

(2) Research

Each center under paragraph (1) shall supplement but not replace the establishment of a comprehensive research portfolio in all the muscular dystrophies. As a whole, the centers shall conduct basic and clinical research in all forms of muscular dystrophy including early detection, diagnosis, prevention, and treatment, including the fields of muscle biology, genetics, noninvasive imaging, cardiac and pulmonary function, and pharmacological and other therapies.

(3) Coordination of centers

The Director of NIH shall, as appropriate, provide for the coordination of information among centers under paragraph (1) and ensure regular communication and sharing of data between such centers.

(4) Organization of centers

Each center under paragraph (1) shall use the facilities of a single institution, or be formed from a consortium of cooperating institutions, meeting such requirements as may be prescribed by the Director of NIH.

(5) Duration of support

Support for a center established under paragraph (1) may be provided under this section for a period of not to exceed 5 years. Such period may be extended for 1 or more additional periods not exceeding 5 years if the operations of such center have been reviewed by an appropriate technical and scientific peer review group established by the Director of NIH and if such group has recommended to the Director that such period should be extended.

(c) Facilitation of research

The Director of NIH shall provide for a program under subsection (a)(1) under which samples of tissues and genetic materials that are of use in research on muscular dystrophy are donated, collected, preserved, and made available for such research. The program shall be carried out in accordance with accepted scientific and medical standards for the donation, collection, and preservation of such samples.

(d) Coordinating Committee

(1) In general

The Secretary shall establish the Muscular Dystrophy Coordinating Committee (referred to in this section as the "Coordinating Committee") to coordinate activities across the National Institutes and with other Federal health programs and activities relating to the various forms of muscular dystrophy.

(2) Composition

The Coordinating Committee shall consist of not more than 18 members to be appointed by the Secretary, of which—

(A) 2/3 of such members shall represent governmental agencies, including the directors or their designees of each of the national research institutes involved in research with respect to muscular dystrophy and representatives of all other Federal departments and agencies whose programs involve health functions or responsibilities relevant to such diseases, including the Centers for Disease Control and Prevention, the Health Resources and Services Administration, the Food and Drug Administration, and the Administration for Community Living and representatives of other governmental agencies that serve children and adults with muscular dystrophy, including the Department of Education and the Social Security Administration; and

(B) 1/3 of such members shall be public members, including a broad cross section of persons affected with muscular dystrophies including parents or legal guardians, affected individuals, researchers, and clinicians.

Members appointed under subparagraph (B) shall serve for a term of 3 years, and may serve for an unlimited number of terms if reappointed.

(3) Chair

(A) In general

With respect to muscular dystrophy, the Chair of the Coordinating Committee shall serve as the principal advisor to the Secretary, the Assistant Secretary for Health, and the Director of NIH, and shall provide advice to the Director of the Centers for Disease Control and Prevention, the Commissioner of Food and Drugs, and to the heads of other relevant agencies. The Coordinating Committee shall select the Chair for a term not to exceed 2 years.

(B) Appointment

The Chair of the Committee shall be appointed by and be directly responsible to the Secretary.

(4) Administrative support; terms of service; other provisions

The following shall apply with respect to the Coordinating Committee:

(A) The Coordinating Committee shall receive necessary and appropriate administrative support from the Department of Health and Human Services.

(B) The Coordinating Committee shall meet as appropriate as determined by the Secretary, in consultation with the chair,[2] but shall meet no fewer than two times per calendar year.

(e) Plan for HHS activities

(1) In general

Not later than 1 year after December 18, 2001, the Coordinating Committee shall develop a plan for conducting and supporting research and education on muscular dystrophy through the agencies

represented on the Coordinating Committee pursuant to subsection (d)(2)(A) and shall periodically review and revise the plan. The plan shall—

(A) provide for a broad range of research and education activities relating to biomedical, epidemiological, psychosocial, public services, and rehabilitative issues, including studies of the impact of such diseases in rural and underserved communities, studies to demonstrate the cost-effectiveness of providing independent living resources and support to patients with various forms of muscular dystrophy, and studies to determine optimal clinical care interventions for adults with various forms of muscular dystrophy;

(B) identify priorities among the programs and activities of the National Institutes of Health regarding such diseases; and

(C) reflect input from a broad range of scientists, patients, and advocacy groups.

(2) Certain elements of plan

The plan under paragraph (1) shall, with respect to each form of muscular dystrophy, provide for the following as appropriate:

(A) Research to determine the reasons underlying the incidence and prevalence of various forms of muscular dystrophy.

(B) Basic research concerning the etiology and genetic links of the disease and potential causes of mutations.

(C) The development of improved screening techniques.

(D) Basic and clinical research for the development and evaluation of new treatments, including new biological agents and new clinical interventions to improve the health of those with muscular dystrophy.

(E) Information and education programs for health care professionals and the public.

(f) Public input

The Secretary shall, under subsection (a)(1), provide for a means through which the public can obtain information on the existing and planned programs and activities of the Department of Health and Human Services with respect to various forms of muscular dystrophy and through which the Secretary can receive comments from the public regarding such programs and activities.

(g) Clinical research

The Coordinating Committee may evaluate the potential need to enhance the clinical research infrastructure required to test emerging therapies for the various forms of muscular dystrophy by prioritizing the achievement of the goals related to this topic in the plan under subsection (e)(1).

(July 1, 1944, ch. 373, title IV, §404E, as added Pub. L. 107–84, §3, Dec. 18, 2001, 115 Stat. 824; amended Pub. L. 109–482, title I, §§103(b)(4), 104(b)(1)(A), Jan. 15, 2007, 120 Stat. 3687, 3692; Pub. L. 110–154, §1(b)(3), Dec. 21, 2007, 121 Stat. 1827; Pub. L. 110–361, §2, Oct. 8, 2008, 122 Stat. 4010; Pub. L. 113–166, §2, Sept. 26, 2014, 128 Stat. 1879.)

EDITORIAL NOTES

REFERENCES IN TEXT

Section 6 of the MD–CARE Act, referred to in subsec. (a)(2), is section 6 of Pub. L. 107–84, which was formerly set out as a note under section 247b–18 of this title and does not relate to establishment of a coordinating committee. However, subsec. (d) of this section contains provisions relating to the establishment of the Muscular Dystrophy Coordinating Committee.

PRIOR PROVISIONS

A prior section 283g, act July 1, 1944, ch. 373, title IV, §404E, as added Pub. L. 103–43, title II, §209, June 10, 1993, 107 Stat. 149, related to Office of Alternative Medicine, prior to repeal by Pub. L. 105–277, div. A, §101(f) [title VI, §601(1)], Oct. 21, 1998, 112 Stat. 2681–337, 2681–387.

AMENDMENTS

2014—Subsec. (a)(1). Pub. L. 113–166, §2(1), substituted "Musculoskeletal" for "Muscoskeletal" and

inserted "Becker, congenital muscular dystrophy, limb-girdle muscular dystrophy," after "Duchenne,".

Subsec. (b)(2). Pub. L. 113–166, §2(2)(A), substituted "cardiac and pulmonary function, and pharmacological" for "genetics, pharmacological".

Subsec. (b)(3). Pub. L. 113–166, §2(2)(B), inserted "and sharing of data" after "regular communication".

Subsec. (d)(2). Pub. L. 113–166, §2(3)(A)(i), substituted "18" for "15" in introductory provisions.

Subsec. (d)(2)(A). Pub. L. 113–166, §2(3)(A)(ii), substituted ", the Food and Drug Administration, and the Administration for Community Living" for "and the Food and Drug Administration" and "including the Department of Education and the Social Security Administration" for "such as the Department of Education" and inserted "and adults" after "children".

Subsec. (d)(4)(B). Pub. L. 113–166, §2(3)(B), inserted ", but shall meet no fewer than two times per calendar year" before period at end.

Subsec. (e)(1). Pub. L. 113–166, §2(4)(A)(i), substituted "through the agencies represented on the Coordinating Committee pursuant to subsection (d)(2)(A)" for "through the national research institutes" in introductory provisions.

Subsec. (e)(1)(A). Pub. L. 113–166, §2(4)(A)(ii), inserted "public services," after "psychosocial," and ", studies to demonstrate the cost-effectiveness of providing independent living resources and support to patients with various forms of muscular dystrophy, and studies to determine optimal clinical care interventions for adults with various forms of muscular dystrophy" after "including studies of the impact of such diseases in rural and underserved communities".

Subsec. (e)(2)(D). Pub. L. 113–166, §2(4)(B), inserted "and new clinical interventions to improve the health of those with muscular dystrophy" after "including new biological agents".

2008—Subsec. (a)(1). Pub. L. 110–361, §2(b)(1), inserted "the National Heart, Lung, and Blood Institute," after "the Eunice Kennedy Shriver National Institute of Child Health and Human Development,".

Subsec. (b)(1). Pub. L. 110–361, §2(b)(2), inserted at end "Such centers of excellence shall be known as the 'Paul D. Wellstone Muscular Dystrophy Cooperative Research Centers'."

Subsec. (f). Pub. L. 110–361, §2(a), redesignated subsec. (g) as (f) and struck out former subsec. (f) which related to reports.

Subsec. (g). Pub. L. 110–361, §2(a), (b)(3), added subsec. (g) and redesignated former subsec. (g) as (f).

2007—Pub. L. 109–482, §104(b)(1)(A)(ii), which directed amendment of subsec. (b) by striking subsec. (f) and redesignating subsec. (g) as (f), could not literally be executed and was not executed in view of amendments by Pub. L. 110–361. See 2008 Amendment notes above.

Subsec. (a)(1). Pub. L. 110–154 substituted "Eunice Kennedy Shriver National Institute of Child Health and Human Development" for "National Institute of Child Health and Human Development".

Subsec. (b)(3). Pub. L. 109–482, §104(b)(1)(A)(i), amended heading and text of par. (3) generally. Text read as follows: "The Director of NIH—

"(A) shall, as appropriate, provide for the coordination of information among centers under paragraph (1) and ensure regular communication between such centers; and

"(B) shall require the periodic preparation of reports on the activities of the centers and the submission of the reports to the Director."

Subsec. (h). Pub. L. 109–482, §103(b)(4), struck out heading and text of subsec. (h). Text read as follows: "For the purpose of carrying out this section, there are authorized to be appropriated such sums as may be necessary for each of fiscal years 2002 through 2006. The authorization of appropriations established in the preceding sentence is in addition to any other authorization of appropriations that is available for conducting or supporting through the National Institutes of Health research and other activities with respect to muscular dystrophy."

STATUTORY NOTES AND RELATED SUBSIDIARIES

EFFECTIVE DATE OF 2007 AMENDMENT

Amendment by Pub. L. 109–482 applicable only with respect to amounts appropriated for fiscal year 2007 or subsequent fiscal years, see section 109 of Pub. L. 109–482, set out as a note under section 281 of this title.

[1] See References in Text note below.

[2] So in original. Probably should be capitalized.

§§283h, 283i. Transferred

EDITORIAL NOTES

CODIFICATION

Section 283h, act July 1, 1944, ch. 373, title IV, §404F, as added Pub. L. 107–280, §3, Nov. 6, 2002, 116 Stat. 1989; amended Pub. L. 109–482, title I, §§103(b)(5), 104(b)(1)(B), Jan. 15, 2007, 120 Stat. 3687, 3693, which related to the Office of Rare Diseases, was renumbered section 481 of act July 1, 1944, by Pub. L. 112–74, div. F, title II, §221(c)(2)(A)(i), Dec. 23, 2011, 125 Stat. 1089, and transferred to section 287a–1 of this title.

Section 283i, act July 1, 1944, ch. 373, title IV, §404G, as added Pub. L. 107–280, §4, Nov. 6, 2002, 116 Stat. 1990; amended Pub. L. 109–482, title I, §103(b)(6), Jan. 15, 2007, 120 Stat. 3687, which related to rare disease regional centers of excellence, was renumbered section 481A of act July 1, 1944, by Pub. L. 112–74, div. F, title II, §221(c)(3), Dec. 23, 2011, 125 Stat. 1089, and transferred to section 287a–2 of this title.

§283j. Repealed. Pub. L. 114–255, div. A, title II, §2042(f)(1), Dec. 13, 2016, 130 Stat. 1073

Section, July 1, 1944, ch. 373, title IV, §404H, as added Pub. L. 109–416, §2(b), Dec. 19, 2006, 120 Stat. 2821, required review and report on centers of excellence funded under this subchapter.

§283k. Biomedical and behavioral research facilities

(a) Modernization and construction of facilities

(1) In general

The Director of NIH, acting through the Office of the Director of NIH or the Director of the National Institute of Allergy and Infectious Diseases, may make grants or contracts to public and nonprofit private entities to expand, remodel, renovate, or alter existing research facilities or construct new research facilities, subject to the provisions of this section.

(2) Construction and cost of construction

For purposes of this section, the terms "construction" and "cost of construction" include the construction of new buildings and the expansion, renovation, remodeling, and alteration of existing buildings, including architects' fees, but do not include the cost of acquisition of land or off-site improvements.

(b) Scientific and technical review boards for merit-based review of proposals

(1) In general: approval as precondition to grants

(A) Establishment

There is established a Scientific and Technical Review Board on Biomedical and Behavioral Research Facilities (referred to in this section as the "Board").

(B) Requirement

The Director of NIH, acting through the Office of the Director of NIH, may approve an application for a grant under subsection (a) only if the Board has under paragraph (2) recommended the application for approval.

(2) Duties

(A) Advice

The Board shall provide advice to the Director of NIH and the Council of Councils established under section 282(l) of this title (in this section referred to as the "Council") in carrying out this section.

(B) Determination of merit

In carrying out subparagraph (A), the Board shall make a determination of the merit of each application submitted for a grant under subsection (a), after consideration of the requirements established in subsection (c), and shall report the results of the determination to the Director of NIH and the Council. Such determinations shall be conducted in a manner consistent with procedures established under section 289a of this title.

(C) Amount

In carrying out subparagraph (A), the Board shall, in the case of applications recommended for approval, make recommendations to the Director and the Council on the amount that should be provided under the grant.

(D) Annual report

In carrying out subparagraph (A), the Board shall prepare an annual report for the Director of NIH and the Council describing the activities of the Board in the fiscal year for which the report is made. Each such report shall be available to the public, and shall—

(i) summarize and analyze expenditures made under this section;

(ii) provide a summary of the types, numbers, and amounts of applications that were recommended for grants under subsection (a) but that were not approved by the Director of NIH; and

(iii) contain the recommendations of the Board for any changes in the administration of this section.

(3) Membership

(A) In general

Subject to subparagraph (B), the Board shall be composed of 15 members to be appointed by the Director of NIH, acting through the Office of the Director of NIH, and such ad-hoc or temporary members as the Director of NIH, acting through the Office of the Director of NIH, determines to be appropriate. All members of the Board, including temporary and ad-hoc members, shall be voting members.

(B) Limitation

Not more than three individuals who are officers or employees of the Federal Government may serve as members of the Board.

(4) Certain requirements regarding membership

In selecting individuals for membership on the Board, the Director of NIH, acting through the Office of the Director of NIH, shall ensure that the members are individuals who, by virtue of their training or experience, are eminently qualified to perform peer review functions. In selecting such individuals for such membership, the Director of NIH, acting through the Office of the Director of NIH, shall ensure that the members of the Board collectively—

(A) are experienced in the planning, construction, financing, and administration of entities that conduct biomedical or behavioral research sciences;

(B) are knowledgeable in making determinations of the need of entities for biomedical or behavioral research facilities, including such facilities for the dentistry, nursing, pharmacy, and allied health professions;

(C) are knowledgeable in evaluating the relative priorities for applications for grants under subsection (a) in view of the overall research needs of the United States; and

(D) are experienced with emerging centers of excellence, as described in subsection (c)(2).

(5) Certain authorities

(A) Workshops and conferences

In carrying out paragraph (2), the Board may convene workshops and conferences, and collect data as the Board considers appropriate.

(B) Subcommittees

In carrying out paragraph (2), the Board may establish subcommittees within the Board. Such subcommittees may hold meetings as determined necessary to enable the subcommittee to carry out its duties.

(6) Terms

(A) In general

Except as provided in subparagraph (B), each appointed member of the Board shall hold office for a term of 4 years. Any member appointed to fill a vacancy occurring prior to the expiration of the term for which such member's predecessor was appointed shall be appointed for the remainder of the term of the predecessor.

(B) Staggered terms

Members appointed to the Board shall serve staggered terms as specified by the Director of NIH, acting through the Office of the Director of NIH, when making the appointments.

(C) Reappointment

No member of the Board shall be eligible for reappointment to the Board until 1 year has elapsed after the end of the most recent term of the member.

(7) Compensation

Members of the Board who are not officers or employees of the United States shall receive for each day the members are engaged in the performance of the functions of the Board compensation at the same rate received by members of other national advisory councils established under this subchapter.

(c) Requirements for grants

(1) In general

The Director of NIH, acting through the Office of the Director of NIH or the National Institute of Allergy and Infectious Diseases, may make a grant under subsection (a) only if the applicant for the grant meets the following conditions:

(A) The applicant is determined by such Director to be competent to engage in the type of research for which the proposed facility is to be constructed.

(B) The applicant provides assurances satisfactory to the Director that—

(i) for not less than 20 years after completion of the construction involved, the facility will be used for the purposes of the research for which it is to be constructed;

(ii) sufficient funds will be available to meet the non-Federal share of the cost of constructing the facility;

(iii) sufficient funds will be available, when construction is completed, for the effective use of the facility for the research for which it is being constructed; and

(iv) the proposed construction will expand the applicant's capacity for research, or is necessary to improve or maintain the quality of the applicant's research.

(C) The applicant meets reasonable qualifications established by the Director with respect to—

(i) the relative scientific and technical merit of the applications, and the relative effectiveness of the proposed facilities, in expanding the capacity for biomedical or behavioral research and in improving the quality of such research;

(ii) the quality of the research or training, or both, to be carried out in the facilities involved;

(iii) the congruence of the research activities to be carried out within the facility with the research and investigator manpower needs of the United States; and

(iv) the age and condition of existing research facilities.

(D) The applicant has demonstrated a commitment to enhancing and expanding the research productivity of the applicant.

(2) Institutions of emerging excellence

From the amount appropriated to carry out this section for a fiscal year up to $50,000,000, the Director of NIH, acting through the Office of the Director of NIH, shall make available 25 percent of such amount, and from the amount appropriated to carry out this section for a fiscal year that is over $50,000,000, the Director of NIH, acting through the Office of the Director of NIH, shall make available up to 25 percent of such amount, for grants under subsection (a) to applicants that in addition to meeting the requirements established in paragraph (1), have demonstrated emerging excellence in biomedical or behavioral research, as follows:

(A) The applicant has a plan for research or training advancement and possesses the ability to carry out the plan.

(B) The applicant carries out research and research training programs that have a special relevance to a problem, concern, or unmet health need of the United States.

(C) The applicant has been productive in research or research development and training.

(D) The applicant—

(i) has been designated as a center of excellence under section 293c [1] of this title;

(ii) is located in a geographic area whose population includes a significant number of individuals with health status deficit, and the applicant provides health services to such individuals; or

(iii) is located in a geographic area in which a deficit in health care technology, services, or research resources may adversely affect the health status of the population of the area in the future, and the applicant is carrying out activities with respect to protecting the health status of such population.

(d) Requirement of application

The Director of NIH, acting through the Office of the Director of NIH or the National Institute of Allergy and Infectious Diseases, may make a grant under subsection (a) only if an application for the grant is submitted to the Director and the application is in such form, is made in such manner, and contains such agreements, assurances, and information as the Director determines to be necessary to carry out this section.

(e) Amount of grant; payments

(1) Amount

The amount of any grant awarded under subsection (a) shall be determined by the Director of NIH, acting through the Office of the Director of NIH or the National Institute of Allergy and Infectious Diseases,,[2] except that such amount shall not exceed—

(A) 50 percent (or, in the case of the Institute, 75 percent) of the necessary cost of the construction of a proposed facility as determined by the Director; or

(B) in the case of a multipurpose facility, 40 percent (or, in the case of the Institute, 75 percent) of that part of the necessary cost of construction that the Director determines to be proportionate to the contemplated use of the facility.

(2) Reservation of amounts

On the approval of any application for a grant under subsection (a), the Director of NIH, acting through the Office of the Director of NIH or the National Institute of Allergy and Infectious Diseases, shall reserve, from any appropriation available for such grants, the amount of such grant, and shall pay such amount, in advance or by way of reimbursement, and in such installments consistent with the construction progress, as the Director may determine appropriate. The reservation of any amount by the Director under this paragraph may be amended by the Director, either on the approval of an amendment of the application or on the revision of the estimated cost of construction of the facility.

(3) Exclusion of certain costs

In determining the amount of any grant under subsection (a), there shall be excluded from the cost of construction an amount equal to the sum of—

(A) the amount of any other Federal grant that the applicant has obtained, or is assured of obtaining, with respect to construction that is to be financed in part by a grant authorized under this section; and

(B) the amount of any non-Federal funds required to be expended as a condition of such other Federal grant.

(4) Waiver of limitations

The limitations imposed under paragraph (1) may be waived at the discretion of the Director of NIH, acting through the Office of the Director of NIH or the National Institute of Allergy and Infectious Diseases, for applicants meeting the conditions described in subsection (c).

(f) Recapture of payments

If, not later than 20 years after the completion of construction for which a grant has been awarded under subsection (a)—

(1) in the case of an award by the Director of NIH, acting through the Office of the Director of NIH, the applicant or other owner of the facility shall cease to be a public or non profit [3] private entity; or

(2) the facility shall cease to be used for the research purposes for which it was constructed (unless the Director of NIH, acting through the Office of the Director of NIH or the National Institute of Allergy and Infectious Diseases, determines, in accordance with regulations, that there is good cause for releasing the applicant or other owner from obligation to do so),

the United States shall be entitled to recover from the applicant or other owner of the facility the amount bearing the same ratio to the current value (as determined by an agreement between the parties or by action brought in the United States District Court for the district in which such facility is situated) of the facility as the amount of the Federal participation bore to the cost of the construction of such facility.

(g) Guidelines

Not later than 6 months after June 10, 1993, the Director of NIH, acting through the Office of the Director of NIH, after consultation with the Council, shall issue guidelines with respect to grants under subsection (a).

(July 1, 1944, ch. 373, title IV, §404I, formerly §481A, as added Pub. L. 103–43, title XV, §1502, June 10, 1993, 107 Stat. 173; amended Pub. L. 105–392, title I, §101(c), Nov. 13, 1998, 112 Stat. 3537; Pub. L. 106–505, title III, §303, Nov. 13, 2000, 114 Stat. 2330; Pub. L. 108–276, §2(b), July 21, 2004, 118 Stat. 841; Pub. L. 109–482, title I, §§103(b)(40), 104(b)(1)(M), Jan. 15, 2007, 120 Stat. 3688, 3693; renumbered §404I and amended Pub. L. 112–74, div. F, title II, §221(b)(1), Dec. 23, 2011, 125 Stat. 1087.)

EDITORIAL NOTES

REFERENCES IN TEXT

Section 293c of this title, referred to in subsec. (c)(2)(D)(i), does not contain provisions relating to designation as a center of excellence. See section 293 of this title.

CODIFICATION

Section was formerly classified to section 287a–2 of this title.

AMENDMENTS

2011—Subsec. (a)(1). Pub. L. 112–74, §221(b)(1)(B)(i), substituted "acting through the Office of the Director of NIH or the Director of the National Institute of Allergy and Infectious Diseases" for "acting through the Director of the Center or the Director of the National Institute of Allergy and Infectious Diseases".

Subsec. (b)(1)(A). Pub. L. 112–74, §221(b)(1)(B)(vi)(I), struck out "within the Center" after "established".

Subsec. (b)(1)(B). Pub. L. 112–74, §221(b)(1)(B)(v), substituted "Director of NIH, acting through the Office of the Director of NIH," for "Director of the Center".

Subsec. (b)(2)(A). Pub. L. 112–74, §221(b)(1)(B)(vi)(II)(aa), substituted "and the Council of Councils established under section 282(l) of this title (in this section referred to as the 'Council')" for "and the advisory council established under section 287a of this title (in this section referred to as the 'Advisory Council')".

Pub. L. 112–74, §221(b)(1)(B)(iii), substituted "Director of NIH" for "Director of the Center".

Subsec. (b)(2)(B). Pub. L. 112–74, §221(b)(1)(B)(vi)(II)(bb), struck out "Advisory" before "Council".

Pub. L. 112–74, §221(b)(1)(B)(iii), substituted "Director of NIH" for "Director of the Center".

Subsec. (b)(2)(C). Pub. L. 112–74, §221(b)(1)(B)(vi)(II)(bb), struck out "Advisory" before "Council".

Subsec. (b)(2)(D). Pub. L. 112–74, §221(b)(1)(B)(vi)(II)(bb), struck out "Advisory" before "Council".

Pub. L. 112–74, §221(b)(1)(B)(iii), substituted "Director of NIH" for "Director of the Center" in introductory provisions and cl. (ii).

Subsec. (b)(3)(A). Pub. L. 112–74, §221(b)(1)(B)(v), substituted "Director of NIH, acting through the Office of the Director of NIH," for "Director of the Center" in two places.

Pub. L. 112–74, §221(b)(1)(B)(iv), struck out comma after "Director of the Center" the first place appearing.

Subsec. (b)(4). Pub. L. 112–74, §221(b)(1)(B)(v), substituted "Director of NIH, acting through the Office of the Director of NIH," for "Director of the Center" in two places in introductory provisions.

Subsec. (b)(6)(B). Pub. L. 112–74, §221(b)(1)(B)(v), substituted "Director of NIH, acting through the Office of the Director of NIH," for "Director of the Center".

Subsec. (c)(1). Pub. L. 112–74, §221(b)(1)(B)(ii), substituted "Director of NIH, acting through the Office of the Director of NIH or the National Institute of Allergy and Infectious Diseases," for "Director of the Center or the Director of the National Institute of Allergy and Infectious Diseases" in introductory provisions.

Subsec. (c)(2). Pub. L. 112–74, §221(b)(1)(B)(v), substituted "Director of NIH, acting through the Office of the Director of NIH," for "Director of the Center" in two places in introductory provisions.

Subsec. (d). Pub. L. 112–74, §221(b)(1)(B)(ii), substituted "Director of NIH, acting through the Office of the Director of NIH or the National Institute of Allergy and Infectious Diseases," for "Director of the Center or the Director of the National Institute of Allergy and Infectious Diseases".

Subsec. (e). Pub. L. 112–74, §221(b)(1)(B)(ii), substituted "Director of NIH, acting through the Office of the Director of NIH or the National Institute of Allergy and Infectious Diseases," for "Director of the Center or the Director of the National Institute of Allergy and Infectious Diseases" wherever appearing.

Subsec. (f)(1). Pub. L. 112–74, §221(b)(1)(B)(v), substituted "Director of NIH, acting through the Office of the Director of NIH," for "Director of the Center".

Pub. L. 112–74, §221(b)(1)(B)(iv), struck out comma after "Director of the Center".

Subsec. (f)(2). Pub. L. 112–74, §221(b)(1)(B)(ii), substituted "Director of NIH, acting through the Office of the Director of NIH or the National Institute of Allergy and Infectious Diseases," for "Director of the Center or the Director of the National Institute of Allergy and Infectious Diseases".

Subsec. (g). Pub. L. 112–74, §221(b)(1)(B)(vii), substituted "after consultation with the Council" for "after consultation with the Advisory Council".

Pub. L. 112–74, §221(b)(1)(B)(v), substituted "Director of NIH, acting through the Office of the Director of NIH," for "Director of the Center".

Pub. L. 112–74, §221(b)(1)(B)(iv), struck out comma after "Director of the Center".

2007—Subsec. (c)(2). Pub. L. 109–482, §103(b)(40)(A), in introductory provisions, substituted "to carry out this section for a fiscal year up to" for "under subsection (i)(1) of this section for a fiscal year up to" and "to carry out this section for a fiscal year that" for "under such subsection for a fiscal year that".

Subsec. (h). Pub. L. 109–482, §104(b)(1)(M), struck out subsec. (h) which required biennial report concerning the status of biomedical and behavioral research facilities and the availability and condition of laboratory equipment.

Subsec. (i). Pub. L. 109–482, §103(b)(40)(B), struck out subsec. (i) which authorized appropriations for the National Center for Research Resources and the National Institute of Allergy and Infectious Diseases.

2004—Subsec. (a)(1). Pub. L. 108–276, §2(b)(1), inserted "or the Director of the National Institute of Allergy and Infectious Diseases" after "Director of the Center".

Subsec. (c)(1). Pub. L. 108–276, §2(b)(2)(A), inserted "or the Director of the National Institute of Allergy and Infectious Diseases" after "Director of the Center".

Subsec. (c)(2). Pub. L. 108–276, §2(b)(2)(B), substituted "subsection (i)(1)" for "subsection (i)" in introductory provisions.

Subsec. (d). Pub. L. 108–276, §2(b)(3), inserted "or the Director of the National Institute of Allergy and Infectious Diseases" after "Director of the Center".

Subsec. (e)(1). Pub. L. 108–276, §2(b)(4)(A)(i), inserted "or the Director of the National Institute of Allergy and Infectious Diseases" after "Director of the Center" in introductory provisions.

Subsec. (e)(1)(A). Pub. L. 108–276, §2(b)(4)(A)(ii), inserted "(or, in the case of the Institute, 75 percent)" after "50 percent".

Subsec. (e)(1)(B). Pub. L. 108–276, §2(b)(4)(A)(iii), inserted "(or, in the case of the Institute, 75 percent)" after "40 percent".

Subsec. (e)(2). Pub. L. 108–276, §2(b)(4)(B), inserted "or the Director of the National Institute of Allergy and Infectious Diseases" after "Director of the Center".

Subsec. (e)(4). Pub. L.108–276, §2(b)(4)(C), inserted "of the Center or the Director of the National Institute of Allergy and Infectious Diseases" after "Director".

Subsec. (f)(1). Pub. L. 108–276, §2(b)(5)(A), inserted "in the case of an award by the Director of the Center," before "the applicant".

Subsec. (f)(2). Pub. L. 108–276, §2(b)(5)(B), inserted "of the Center or the Director of the National Institute of Allergy and Infectious Diseases" after "Director".

Subsec. (i). Pub. L. 108–276, §2(b)(6), designated existing provisions as par. (1), inserted heading, substituted "For the purpose of carrying out this section with respect to the Center," for "For the purpose of carrying out this section,", and added par. (2).

2000—Pub. L. 106–505 amended section generally, adding provisions requiring the Director to provide Congress with biennial status reports.

1998—Subsec. (c)(3)(D)(i). Pub. L. 105–392 substituted "part B of subchapter V of this chapter" for "section 293c of this title".

STATUTORY NOTES AND RELATED SUBSIDIARIES

EFFECTIVE DATE OF 2007 AMENDMENT

Amendment by Pub. L. 109–482 applicable only with respect to amounts appropriated for fiscal year 2007 or subsequent fiscal years, see section 109 of Pub. L. 109–482, set out as a note under section 281 of this title.

FINDINGS

Pub. L. 106–505, title III, §302, Nov. 13, 2000, 114 Stat. 2330, provided that: "Congress finds that—

"(1) the National Institutes of Health is the principal source of Federal funding for medical research at universities and other research institutions in the United States;

"(2) the National Institutes of Health has received a substantial increase in research funding from Congress for the purpose of expanding the national investment of the United States in behavioral and biomedical research;

"(3) the infrastructure of our research institutions is central to the continued leadership of the United States in medical research;

"(4) as Congress increases the investment in cutting-edge basic and clinical research, it is critical that Congress also examine the current quality of the laboratories and buildings where research is being conducted, as well as the quality of laboratory equipment used in research;

"(5) many of the research facilities and laboratories in the United States are outdated and inadequate;

"(6) the National Science Foundation found, in a 1998 report on the status of biomedical research facilities, that over 60 percent of research-performing institutions indicated that they had an inadequate amount of medical research space;

"(7) the National Science Foundation reports that academic institutions have deferred nearly $11,000,000,000 in renovation and construction projects because of a lack of funds; and

"(8) future increases in Federal funding for the National Institutes of Health must include increased support for the renovation and construction of extramural research facilities in the United States and the purchase of state-of-the-art laboratory instrumentation."

[1] See References in Text note below.

[2] So in original.

[3] So in original. Probably should be "nonprofit".

§283*l*. Construction of regional centers for research on primates

(a) With respect to activities carried out by the Director of NIH, acting through the Office of the Director of NIH, to support regional centers for research on primates, the Director of NIH may, for each of the fiscal years 2000 through 2002, reserve from the amounts appropriated to carry out section 283k of this title such sums as necessary for the purpose of making awards of grants and contracts to public or nonprofit private entities to construct, renovate, or otherwise improve such regional centers. The reservation of such amounts for any fiscal year is subject to the availability of qualified applicants for such awards.

(b) The Director of NIH may not make a grant or enter into a contract under subsection (a) unless the applicant for such assistance agrees, with respect to the costs to be incurred by the applicant in carrying out the purpose described in such subsection, to make available (directly or through donations from public or private entities) non-Federal contributions in cash toward such costs in an amount equal to not less than $1 for each $4 of Federal funds provided in such assistance.

(July 1, 1944, ch. 373, title IV, §404J, formerly §481B, as added Pub. L. 103–43, title XV, §1503, June 10, 1993, 107 Stat. 178; amended Pub. L. 105–392, title IV, §411, Nov. 13, 1998, 112 Stat. 3590; Pub. L. 106–505, title III, §304, Nov. 13, 2000, 114 Stat. 2335; Pub. L. 109–482, title I, §103(b)(41), Jan. 15, 2007, 120 Stat. 3688; renumbered §404J and amended Pub. L. 112–74, div. F, title II, §221(b)(2), Dec. 23, 2011, 125 Stat. 1088.)

EDITORIAL NOTES

CODIFICATION

Section was formerly classified to section 287a–3 of this title.

AMENDMENTS

2011—Subsec. (a). Pub. L. 112–74, §221(b)(2)(B), substituted "by the Director of NIH, acting through the Office of the Director of NIH," for "by the National Center for Research Resources" and "283k" for "287a–2".

2007—Subsec. (a). Pub. L. 109–482, which directed the substitution of "to carry out section 287a–2" for "under section 287a–2(h)", was executed by making substitution for "under section 287a–2(i)", to reflect the probable intent of Congress.

2000—Subsec. (a). Pub. L. 106–505, which directed the amendment of subsec. (a) by substituting "2000 through 2002, reserve from the amounts appropriated under section 287a–2(i) of this title such sums as necessary" for " '1994' and all that follows through '$5,000,000' ", was executed by making the substitution for "1994 through 1996, reserve from the amounts appropriated under section 287a–2(h) of this title up to $2,500,000", to reflect the probable intent of Congress and the amendment by Pub. L. 105–392. See 1998 Amendment note below.

1998—Subsec. (a). Pub. L. 105–392, in first sentence, substituted "may" for "shall" and "up to $2,500,000" for "$5,000,000".

STATUTORY NOTES AND RELATED SUBSIDIARIES

EFFECTIVE DATE OF 2007 AMENDMENT

Amendment by Pub. L. 109–482 applicable only with respect to amounts appropriated for fiscal year 2007 or subsequent fiscal years, see section 109 of Pub. L. 109–482, set out as a note under section 281 of this title.

§283m. Sanctuary system for surplus chimpanzees

(a) In general

The Secretary shall provide for the establishment and operation in accordance with this section of a system to provide for the lifetime care of chimpanzees that have been used, or were bred or purchased for use, in research conducted or supported by the National Institutes of Health, the Food

and Drug Administration, or other agencies of the Federal Government, and with respect to which it has been determined by the Secretary that the chimpanzees are not needed for such research (in this section referred to as "surplus chimpanzees").

(b) Administration of sanctuary system

The Secretary shall carry out this section, including the establishment of regulations under subsection (d), in consultation with the board of directors of the nonprofit private entity that receives the contract under subsection (e) (relating to the operation of the sanctuary system).

(c) Acceptance of chimpanzees into system

All surplus chimpanzees owned by the Federal Government shall be accepted into the sanctuary system. Subject to standards under subsection (d)(4), any chimpanzee that is not owned by the Federal Government can be accepted into the system if the owner transfers to the sanctuary system title to the chimpanzee.

(d) Standards for permanent retirement of surplus chimpanzees

(1) In general

Not later than 180 days after December 20, 2000, the Secretary shall by regulation establish standards for operating the sanctuary system to provide for the permanent retirement of surplus chimpanzees. In establishing the standards, the Secretary shall consider the recommendations of the board of directors of the nonprofit private entity that receives the contract under subsection (e), and shall consider the recommendations of the National Research Council applicable to surplus chimpanzees that are made in the report published in 1997 and entitled "Chimpanzees in Research—Strategies for Their Ethical Care, Management, and Use".

(2) Chimpanzees accepted into system

With respect to chimpanzees that are accepted into the sanctuary system, standards under paragraph (1) shall include the following:

(A) A prohibition that the chimpanzees may not be used for research, except as authorized under paragraph (3).

(B) Provisions regarding the housing of the chimpanzees.

(C) Provisions regarding the behavioral well-being of the chimpanzees.

(D) A requirement that the chimpanzees be cared for in accordance with the Animal Welfare Act [7 U.S.C. 2131 et seq.].

(E) A requirement that the chimpanzees be prevented from breeding.

(F) A requirement that complete histories be maintained on the health and use in research of the chimpanzees.

(G) A requirement that the chimpanzees be monitored for the purpose of promptly detecting the presence in the chimpanzees of any condition that may be a threat to the public health or the health of other chimpanzees.

(H) A requirement that chimpanzees posing such a threat be contained in accordance with applicable recommendations of the Director of the Centers for Disease Control and Prevention.

(I) A prohibition that none of the chimpanzees may be subjected to euthanasia, except as in the best interests of the chimpanzee involved, as determined by the system and an attending veterinarian.

(J) A prohibition that the chimpanzees may not be discharged from the system.

(K) A provision that the Secretary may, in the discretion of the Secretary, accept into the system chimpanzees that are not surplus chimpanzees.

(L) Such additional standards as the Secretary determines to be appropriate.

(3) Restrictions regarding research

(A) In general

For purposes of paragraph (2)(A), standards under paragraph (1) shall provide that a chimpanzee accepted into the sanctuary system may not be used for studies or research, except

that the chimpanzee may be used for noninvasive behavioral studies or medical studies based on information collected during the course of normal veterinary care that is provided for the benefit of the chimpanzee, provided that any such study involves minimal physical and mental harm, pain, distress, and disturbance to the chimpanzee and the social group in which the chimpanzee lives.

(B) Additional restriction

For purposes of paragraph (2)(A), a condition for the use in studies or research of a chimpanzee accepted into the sanctuary system is (in addition to conditions under subparagraph (A) of this paragraph) that the applicant for such use has not been fined for, or signed a consent decree for, any violation of the Animal Welfare Act [7 U.S.C. 2131 et seq.].

(4) Non-Federal chimpanzees offered for acceptance into system

With respect to a chimpanzee that is not owned by the Federal Government and is offered for acceptance into the sanctuary system, standards under paragraph (1) shall include the following:

(A) A provision that the Secretary may authorize the imposition of a fee for accepting such chimpanzee into the system, except as follows:

(i) Such a fee may not be imposed for accepting the chimpanzee if, on the day before December 20, 2000, the chimpanzee was owned by the nonprofit private entity that receives the contract under subsection (e) or by any individual sanctuary facility receiving a subcontract or grant under subsection (e)(1).

(ii) Such a fee may not be imposed for accepting the chimpanzee if the chimpanzee is owned by an entity that operates a primate center, and if the chimpanzee is housed in the primate center pursuant to the program for regional centers for research on primates that is carried out by the Director of NIH, acting through the Office of the Director of NIH,.[1]

Any fees collected under this subparagraph are available to the Secretary for the costs of operating the system. Any other fees received by the Secretary for the long-term care of chimpanzees (including any Federal fees that are collected for such purpose and are identified in the report under section 3 of the Chimpanzee Health Improvement, Maintenance, and Protection Act) are available for operating the system, in addition to availability for such other purposes as may be authorized for the use of the fees.

(B) A provision that the Secretary may deny such chimpanzee acceptance into the system if the capacity of the system is not sufficient to accept the chimpanzee, taking into account the physical capacity of the system; the financial resources of the system; the number of individuals serving as the staff of the system, including the number of professional staff; the necessity of providing for the safety of the staff and of the public; the necessity of caring for accepted chimpanzees in accordance with the standards under paragraph (1); and such other factors as may be appropriate.

(C) A provision that the Secretary may deny such chimpanzee acceptance into the system if a complete history of the health and use in research of the chimpanzee is not available to the Secretary.

(D) Such additional standards as the Secretary determines to be appropriate.

(e) Award of contract for operation of system

(1) In general

Subject to the availability of funds pursuant to subsection (g), the Secretary shall make an award of a contract to a nonprofit private entity under which the entity has the responsibility of operating (and establishing, as applicable) the sanctuary system and awarding subcontracts or grants to individual sanctuary facilities that meet the standards under subsection (d).

(2) Requirements

The Secretary may make an award under paragraph (1) to a nonprofit private entity only if the entity meets the following requirements:

(A) The entity has a governing board of directors that is composed and appointed in accordance with paragraph (3) and is satisfactory to the Secretary.

(B) The terms of service for members of such board are in accordance with paragraph (3).

(C) The members of the board serve without compensation. The members may be reimbursed for travel, subsistence, and other necessary expenses incurred in carrying out the duties of the board.

(D) The entity has an executive director meeting such requirements as the Secretary determines to be appropriate.

(E) The entity makes the agreement described in paragraph (4) (relating to non-Federal contributions).

(F) The entity agrees to comply with standards under subsection (d).

(G) The entity agrees to make necropsy reports on chimpanzees in the sanctuary system available on a reasonable basis to persons who conduct biomedical or behavioral research, with priority given to such persons who are Federal employees or who receive financial support from the Federal Government for research.

(H) Such other requirements as the Secretary determines to be appropriate.

(3) Board of directors

For purposes of subparagraphs (A) and (B) of paragraph (2):

(A) The governing board of directors of the nonprofit private entity involved is composed and appointed in accordance with this paragraph if the following conditions are met:

(i) Such board is composed of not more than 13 voting members.

(ii) Such members include individuals with expertise and experience in the science of managing captive chimpanzees (including primate veterinary care), appointed from among individuals endorsed by organizations that represent individuals in such field.

(iii) Such members include individuals with expertise and experience in the field of animal protection, appointed from among individuals endorsed by organizations that represent individuals in such field.

(iv) Such members include individuals with expertise and experience in the zoological field (including behavioral primatology), appointed from among individuals endorsed by organizations that represent individuals in such field.

(v) Such members include individuals with expertise and experience in the field of the business and management of nonprofit organizations, appointed from among individuals endorsed by organizations that represent individuals in such field.

(vi) Such members include representatives from entities that provide accreditation in the field of laboratory animal medicine.

(vii) Such members include individuals with expertise and experience in the field of containing biohazards.

(viii) Such members include an additional member who serves as the chair of the board, appointed from among individuals who have been endorsed for purposes of clause (ii), (iii), (iv), or (v).

(ix) None of the members of the board has been fined for, or signed a consent decree for, any violation of the Animal Welfare Act [7 U.S.C. 2131 et seq.].

(B) The terms of service for members of the board of directors are in accordance with this paragraph if the following conditions are met:

(i) The term of the chair of the board is 3 years.

(ii) The initial members of the board select, by a random method, one member from each of the six fields specified in subparagraph (A) to serve a term of 2 years and (in addition to the chair) one member from each of such fields to serve a term of 3 years.

(iii) After the initial terms under clause (ii) expire, each member of the board (other than the chair) is appointed to serve a term of 2 years.

(iv) An individual whose term of service expires may be reappointed to the board.

(v) A vacancy in the membership of the board is filled in the manner in which the original

appointment was made.

(vi) If a member of the board does not serve the full term applicable to the member, the individual appointed to fill the resulting vacancy is appointed for the remainder of the term of the predecessor member.

(4) Requirement of matching funds

The agreement required in paragraph (2)(E) for a nonprofit private entity (relating to the award of the contract under paragraph (1)) is an agreement that, with respect to the costs to be incurred by the entity in establishing and operating the sanctuary system, the entity will make available (directly or through donations from public or private entities) non-Federal contributions toward such costs, in cash or in kind, in an amount not less than the following, as applicable:

(A) For expenses associated with establishing the sanctuary system (as determined by the Secretary), 10 percent of such costs ($1 for each $9 of Federal funds provided under the contract under paragraph (1)).

(B) For expenses associated with operating the sanctuary system (as determined by the Secretary), 25 percent of such costs ($1 for each $3 of Federal funds provided under such contract).

(5) Establishment of contract entity

If the Secretary determines that an entity meeting the requirements of paragraph (2) does not exist, not later than 60 days after December 20, 2000, the Secretary shall, for purposes of paragraph (1), make a grant for the establishment of such an entity, including paying the cost of incorporating the entity under the law of one of the States.

(f) Definitions

For purposes of this section:

(1) Permanent retirement

The term "permanent retirement", with respect to a chimpanzee that has been accepted into the sanctuary system, means that under subsection (a) the system provides for the lifetime care of the chimpanzee, that under subsection (d)(2) the system does not permit the chimpanzee to be used in research (except as authorized under subsection (d)(3)) or to be euthanized (except as provided in subsection (d)(2)(I)), that under subsection (d)(2) the system will not discharge the chimpanzee from the system, and that under such subsection the system otherwise cares for the chimpanzee.

(2) Sanctuary system

The term "sanctuary system" means the system described in subsection (a).

(3) Secretary

The term "Secretary" means the Secretary of Health and Human Services.

(4) Surplus chimpanzees

The term "surplus chimpanzees" has the meaning given that term in subsection (a).

(g) Funding

(1) In general

Of the amount appropriated for the National Institutes of Health, there are authorized to be appropriated to carry out this section and for the care, maintenance, and transportation of all chimpanzees otherwise under the ownership or control of the National Institutes of Health, and to enable the National Institutes of Health to operate more efficiently and economically by decreasing the overall Federal cost of providing for the care, maintenance, and transportation of chimpanzees—

(A) for fiscal year 2014, $12,400,000;

(B) for fiscal year 2015, $11,650,000;

(C) for fiscal year 2016, $10,900,000;

(D) for fiscal year 2017, $10,150,000; and

(E) for fiscal year 2018, $9,400,000.

(2) Use of funds for other compliant facilities

With respect to amounts authorized to be appropriated by paragraph (1) for a fiscal year, the Secretary may use a portion of such amounts to make awards of grants or contracts to public or private entities operating facilities that, as determined by the Secretary in consultation with the board of directors of the nonprofit private entity that receives the contract under subsection (e), provide for the retirement of chimpanzees in accordance with the same standards that apply to the sanctuary system pursuant to regulations under subsection (d). Such an award may be expended for the expenses of operating the facilities involved.

(3) Biennial report

Not later than 180 days after November 27, 2013, the Director of the National Institutes of Health shall submit to the Committee on Health, Education, Labor, and Pensions and the Committee on Appropriations of the Senate and the Committee on Energy and Commerce and the Committee on Appropriations in the House of Representatives a report, to be updated biennially, regarding—

(A) the care, maintenance, and transportation of the chimpanzees under the ownership or control of the National Institutes of Health;

(B) costs related to such care, maintenance, and transportation, and any other related costs; and

(C) the research status of such chimpanzees.

(July 1, 1944, ch. 373, title IV, §404K, formerly §481C, as added Pub. L. 106–551, §2, Dec. 20, 2000, 114 Stat. 2752; amended Pub. L. 110–170, §2(a), Dec. 26, 2007, 121 Stat. 2465; renumbered §404K and amended Pub. L. 112–74, div. F, title II, §221(b)(3), Dec. 23, 2011, 125 Stat. 1088; Pub. L. 113–55, title III, §302(a), (c), Nov. 27, 2013, 127 Stat. 646, 647.)

EDITORIAL NOTES

REFERENCES IN TEXT

The Animal Welfare Act, referred to in subsecs. (d)(2)(D), (3)(B) and (e)(3)(A)(ix), is Pub. L. 89–544, Aug. 24, 1966, 80 Stat. 350, which is classified generally to chapter 54 (§2131 et seq.) of Title 7, Agriculture. For complete classification of this Act to the Code, see Short Title note set out under section 2131 of Title 7 and Tables.

Section 3 of the Chimpanzee Health Improvement, Maintenance, and Protection Act, referred to in subsec. (d)(4)(A), is section 3 of Pub. L. 106–551, which is set out as a note below.

CODIFICATION

Section was formerly classified to section 287a–3a of this title.

November 27, 2013, referred to in subsec. (g)(3), was in the original "the date enactment of this Act" (sic), which was translated as meaning the date of enactment of Pub. L. 113–55, which enacted par. (3), to reflect the probable intent of Congress.

AMENDMENTS

2013—Subsec. (g)(1). Pub. L. 113–55, §302(a)(1), amended par. (1) generally. Prior to amendment, text read as follows: "Of the amount appropriated under this chapter for fiscal year 2001 and each subsequent fiscal year, the Secretary, subject to paragraph (2), shall reserve a portion for purposes of the operation (and establishment, as applicable) of the sanctuary system and for purposes of paragraph (3), except that the Secretary may not for such purposes reserve any further funds from such amount after the aggregate total of the funds so reserved for such fiscal years reaches $30,000,000. The purposes for which funds reserved under the preceding sentence may be expended include the construction and renovation of facilities for the sanctuary system."

Subsec. (g)(2). Pub. L. 113–55, §302(a)(4), substituted "With respect to amounts authorized to be appropriated by paragraph (1)" for "With respect to amounts reserved under paragraph (1)" and "Secretary in consultation with the board of directors" for "board of directors".

Pub. L. 113–55, §302(a)(2), (3), redesignated par. (3) as (2) and struck out former par. (2). Prior to

amendment, text of par. (2) read as follows: "Funds may not be reserved for a fiscal year under paragraph (1) unless the amount appropriated under this chapter for such year equals or exceeds the amount appropriated under this chapter for fiscal year 1999."

Subsec. (g)(3). Pub. L. 113–55, §302(c), added par. (3). Former par. (3) redesignated (2).

Pub. L. 113–55, §302(a)(3), redesignated par. (3) as (2).

2011—Subsec. (d)(4)(A)(ii). Pub. L. 112–74, §221(b)(3)(B), substituted "that is carried out by the Director of NIH, acting through the Office of the Director of NIH," for "that is carried out by the National Center for Research Resources".

2007—Subsec. (d)(2)(J). Pub. L. 110–170, §2(a)(1), struck out at end "If any chimpanzee is removed from a sanctuary facility for purposes of research authorized under paragraph (3)(A)(ii), the chimpanzee shall be returned immediately upon the completion of that research. All costs associated with the removal of the chimpanzee from the facility, with the care of the chimpanzee during such absence from the facility, and with the return of the chimpanzee to the facility shall be the responsibility of the entity that obtains approval under such paragraph regarding use of the chimpanzee and removes the chimpanzee from the sanctuary facility."

Subsec. (d)(3)(A). Pub. L. 110–170, §2(a)(2)(A), substituted "except that the chimpanzee may be used for noninvasive behavioral studies" for "except as provided in clause (i) or (ii), as follows:

"(i) The chimpanzee may be used for noninvasive behavioral studies"

and struck out cl. (ii) which related to findings necessary before a chimpanzee may be used in research.

Subsec. (d)(3)(B), (C). Pub. L. 110–170, §2(a)(2)(B)–(D), redesignated subpar. (C) as (B), substituted "under subparagraph (A)" for "under subparagraphs (A) and (B)", and struck out former subpar. (B) which related to approval of research design.

STATUTORY NOTES AND RELATED SUBSIDIARIES

REPORT TO CONGRESS REGARDING NUMBER OF CHIMPANZEES AND FUNDING FOR CARE OF CHIMPANZEES

Pub. L. 106–551, §3, Dec. 20, 2000, 114 Stat. 2759, required the Secretary of Health and Human Services to submit a report to Congress, not later than 365 days after Dec. 20, 2000, about the chimpanzees that had been used, or bred or purchased for use, in research conducted or supported by the National Institutes of Health, the Food and Drug Administration, or other agencies of the Federal Government.

[1] *So in original. Comma probably should not appear.*

§283n. Shared Instrumentation Grant Program

(a) Requirements for grants

In determining whether to award a grant to an applicant under the Shared Instrumentation Grant Program, the Director of NIH, acting through the Office of the Director of NIH, shall consider—

(1) the extent to which an award for the specific instrument involved would meet the scientific needs and enhance the planned research endeavors of the major users by providing an instrument that is unavailable or to which availability is highly limited;

(2) with respect to the instrument involved, the availability and commitment of the appropriate technical expertise within the major user group or the applicant institution for use of the instrumentation;

(3) the adequacy of the organizational plan for the use of the instrument involved and the internal advisory committee for oversight of the applicant, including sharing arrangements if any;

(4) the applicant's commitment for continued support of the utilization and maintenance of the instrument; and

(5) the extent to which the specified instrument will be shared and the benefit of the proposed instrument to the overall research community to be served.

(b) Peer review

In awarding grants under the program described in subsection (a), the Director of NIH, acting through the Office of the Director of NIH, shall comply with the peer review requirements in section

289a of this title.

(July 1, 1944, ch. 373, title IV, §404L, formerly Pub. L. 106–505, title III, §305, Nov. 13, 2000, 114 Stat. 2335; renumbered July 1, 1944, ch. 373, title IV, §404L, and amended Pub. L. 112–74, div. F, title II, §221(b)(4), Dec. 23, 2011, 125 Stat. 1088.)

EDITORIAL NOTES

CODIFICATION

Section was formerly set out as a note under section 287 of this title, prior to renumbering by Pub. L. 112–74.

AMENDMENTS

2011—Pub. L. 112–74, §221(b)(4)(B)(iii), substituted "Director of NIH, acting through the Office of the Director of NIH," for "Director of the National Center for Research Resources" in subsecs. (a) and (b).

Subsec. (a). Pub. L. 112–74, §221(b)(4)(B)(ii), substituted "under the Shared Instrumentation Grant Program" for "under the program described in subsection (a)" in introductory provisions.

Pub. L. 112–74, §221(b)(4)(B)(i), redesignated subsec. (b) as (a) and struck out former subsec. (a). Prior to amendment, text of subsec. (a) read as follows: "There is authorized to be appropriated $100,000,000 for fiscal year 2000, and such sums as may be necessary for each subsequent fiscal year, to enable the Secretary of Health and Human Services, acting through the Director of the National Center for Research Resources, to provide for the continued operation of the Shared Instrumentation Grant Program (initiated in fiscal year 1992 under the authority of section 287 of this title)."

Subsec. (b). Pub. L. 112–74, §221(b)(4)(B)(iv), substituted "in subsection (a), the" for "in subsection (a)" and made technical amendment to reference in original act which appears in text as reference to section 289a of this title.

Pub. L. 112–74, §221(b)(4)(B)(i), redesignated subsec. (c) as (b). Former subsec. (b) redesignated (a).

Subsec. (c). Pub. L. 112–74, §221(b)(4)(B)(i), redesignated subsec. (c) as (b).

§283*o*. Next generation of researchers

(a) Next generation of researchers initiative

There shall be established within the Office of the Director of the National Institutes of Health, the Next Generation of Researchers Initiative (referred to in this section as the "Initiative"), through which the Director shall coordinate all policies and programs within the National Institutes of Health that are focused on promoting and providing opportunities for new researchers and earlier research independence.

(b) Activities

The Director of the National Institutes of Health, through the Initiative shall—

(1) promote policies and programs within the National Institutes of Health that are focused on improving opportunities for new researchers and promoting earlier research independence, including existing policies and programs, as appropriate;

(2) develop, modify, or prioritize policies, as needed, within the National Institutes of Health to promote opportunities for new researchers and earlier research independence, such as policies to increase opportunities for new researchers to receive funding, enhance training and mentorship programs for researchers, and enhance workforce diversity;

(3) coordinate, as appropriate, with relevant agencies, professional and academic associations, academic institutions, and others, to improve and update existing information on the biomedical research workforce in order to inform programs related to the training, recruitment, and retention of biomedical researchers; and

(4) carry out other activities, including evaluation and oversight of existing programs, as appropriate, to promote the development of the next generation of researchers and earlier research independence.

(July 1, 1944, ch. 373, title IV, §404M, as added Pub. L. 114–255, div. A, title II, §2021(a), Dec. 13,

2016, 130 Stat. 1051.)

§283p. Population focused research

The Director of the National Institutes of Health shall, as appropriate, encourage efforts to improve research related to the health of sexual and gender minority populations, including by—

(1) facilitating increased participation of sexual and gender minority populations in clinical research supported by the National Institutes of Health, and reporting on such participation, as applicable;

(2) facilitating the development of valid and reliable methods for research relevant to sexual and gender minority populations; and

(3) addressing methodological challenges.

(July 1, 1944, ch. 373, title IV, §404N, as added Pub. L. 114–255, div. A, title II, §2038(d), Dec. 13, 2016, 130 Stat. 1065.)

STATUTORY NOTES AND RELATED SUBSIDIARIES

REPORTING

Pub. L. 114–255, div. A, title II, §2038(e), Dec. 13, 2016, 130 Stat. 1065, provided that:

"(1) IN GENERAL.—The Secretary, in collaboration with the Director of the National Institutes of Health, shall as appropriate—

"(A) continue to support research for the development of appropriate measures related to reporting health information about sexual and gender minority populations; and

"(B) not later than 2 years after the date of enactment of this Act [Dec. 13, 2016], disseminate and make public such measures.

"(2) NATIONAL ACADEMY OF MEDICINE RECOMMENDATIONS.—In developing the measures described in paragraph (1)(A), the Secretary shall take into account recommendations made by the National Academy of Medicine."

§283q. Eureka prize competitions

(a) In general

Pursuant to the authorities and processes established under section 3719 of title 15, the Director of the National Institutes of Health shall support prize competitions for one or both of the following goals:

(1) Identifying and funding areas of biomedical science that could realize significant advancements through a prize competition.

(2) Improving health outcomes, particularly with respect to human diseases and conditions—

(A) for which public and private investment in research is disproportionately small relative to Federal Government expenditures on prevention and treatment activities with respect to such diseases and conditions, such that Federal expenditures on health programs would be reduced;

(B) that are serious and represent a significant disease burden in the United States; or

(C) for which there is potential for significant return on investment to the United States.

(b) Tracking; reporting

The Director of the National Institutes of Health shall—

(1) collect information on—

(A) the effect of innovations funded through the prize competitions under this section in advancing biomedical science or improving health outcomes pursuant to subsection (a); and

(B) the effect of the innovations on Federal expenditures; and

(2) include the information collected under paragraph (1) in the triennial report under section 283 of this title (as amended by section 2032).

(Pub. L. 114–255, div. A, title II, §2002, Dec. 13, 2016, 130 Stat. 1047.)

EDITORIAL NOTES

REFERENCES IN TEXT

Section 2032, referred to in subsec. (b)(2), means section 2032 of Pub. L. 114–255.

CODIFICATION

Section was enacted as part of the 21st Century Cures Act, and not as part of the Public Health Service Act which comprises this chapter.

§283r. National Science Advisory Board for Biosecurity

(a) Establishment

The Secretary, acting through the Director of NIH, shall establish an advisory committee, to be known as the "National Science Advisory Board for Biosecurity" (referred to in this section as the "Board").

(b) Duties

(1) [1] In general

The National Science Advisory Board for Biosecurity referred to in section 205 of the Pandemic and All-Hazards Preparedness Act (Public Law 109–417) (referred to in this section as the "Board") shall provide technical advice, guidance, or recommendations, to relevant Federal departments and agencies related to biosafety and biosecurity oversight of biomedical research, including—

(A) oversight of federally-conducted or federally-supported dual use biomedical research, such as the review of policies or frameworks used to assess and appropriately manage safety and security risks associated with such research, taking into consideration national security concerns, the potential benefits of such research, considerations related to the research community, transparency, and public availability of information, and international research collaboration; and

(B) continuing to carry out the activities required under section 205 of the Pandemic and All-Hazards Preparedness Act (Public Law 109–417).

(c) Considerations

In carrying out the duties under subsection (b), the Board may consider strategies to improve the safety and security of biomedical research, including through—

(1) leveraging or using new technologies and scientific advancements to reduce safety and security risks associated with such research and improve containment of pathogens; and

(2) outreach to, and education and training of, researchers, laboratory personnel, and other appropriate individuals with respect to safety and security risks associated with such research and mitigation of such risks.

(d) Membership

The Board shall be composed of the following:

(1) Non-voting, ex officio members, including the following:

(A) At least one representative of each of the following:

(i) The Department of Health and Human Services.

(ii) The Department of Defense.

(iii) The Department of Agriculture.

(iv) The Department of Homeland Security.

(v) The Department of Energy.

(vi) The Department of State.

(vii) The Office of Science and Technology Policy.
(viii) The Office of the Director of National Intelligence.

(B) Representatives of such other Federal departments or agencies as the Secretary determines appropriate to carry out the requirements of this section.

(2) Individuals, appointed by the Secretary, with expertise in biology, infectious diseases, public health, ethics, national security, and other fields, as the Secretary determines appropriate, who shall serve as voting members.

(July 1, 1944, ch. 373, title IV, §404O, as added Pub. L. 117–328, div. FF, title II, §2313(a), Dec. 29, 2022, 136 Stat. 5761.)

EDITORIAL NOTES

REFERENCES IN TEXT

Section 205 of the Pandemic and All-Hazards Preparedness Act, referred to in subsec. (b)(1), is section 205 of Pub. L. 109–417, which is set out as a note below.

STATUTORY NOTES AND RELATED SUBSIDIARIES

ORDERLY TRANSITION

Pub. L. 117–328, div. FF, title II, §2313(b), Dec. 29, 2022, 136 Stat. 5762, provided that: "The Secretary of Health and Human Services shall take such steps as are necessary to provide for the orderly transition to the authority of the National Science Advisory Board for Biosecurity established under section 404O of the Public Health Service Act [42 U.S.C. 283r], as added by subsection (a), from any authority of the Board described in section 205 of the Pandemic and All-Hazards Preparedness Act (Public Law 109–417) [set out below], as in effect on the day before the date of enactment of this Act [Dec. 29, 2022]."

APPLICATION

Pub. L. 117–328, div. FF, title II, §2313(c), Dec. 29, 2022, 136 Stat. 5763, provided that: "The requirements under section 404O of the Public Health Service Act [42 U.S.C. 283r], as added by subsection (a), related to the mission, activities, or functions of the National Science Advisory Board for Biosecurity shall not apply until the completion of any work undertaken by such Board before the date of enactment of this Act [Dec. 29, 2022]."

NATIONAL SCIENCE ADVISORY BOARD FOR BIOSECURITY: PROVISION OF ADVICE, GUIDANCE, OR RECOMMENDATIONS

Pub. L. 109–417, title II, §205, Dec. 19, 2006, 120 Stat. 2851, provided that: "The National Science Advisory Board for Biosecurity shall, when requested by the Secretary of Health and Human Services, provide to relevant Federal departments and agencies, advice, guidance, or recommendations concerning—

"(1) a core curriculum and training requirements for workers in maximum containment biological laboratories; and

"(2) periodic evaluations of maximum containment biological laboratory capacity nationwide and assessments of the future need for increased laboratory capacity."

[1] *So in original. No par. (2) has been enacted.*

PART B—GENERAL PROVISIONS RESPECTING NATIONAL RESEARCH INSTITUTES

§284. Directors of national research institutes

(a) Appointment

(1) In general

The Director of the National Cancer Institute shall be appointed by the President, and the Directors of the other national research institutes and national centers shall be appointed by the Secretary, acting through the Director of National Institutes of Health. Each Director of a national research institute or national center shall report directly to the Director of National Institutes of Health.

(2) Appointment

(A) Term

A Director of a national research institute or national center who is appointed by the Secretary, acting through the Director of National Institutes of Health, shall be appointed for 5 years.

(B) Reappointment

At the end of the term of a Director of a national research institute or national center, the Director may be reappointed in accordance with standards applicable to the relevant appointment mechanism. There shall be no limit on the number of terms that a Director may serve.

(C) Vacancies

If the office of a Director of a national research institute or national center becomes vacant before the end of such Director's term, the Director appointed to fill the vacancy shall be appointed for a 5-year term starting on the date of such appointment.

(D) Current directors

Each Director of a national research institute or national center who is serving on December 13, 2016, shall be deemed to be appointed for a 5-year term under this subsection beginning on such date.

(E) Rule of construction

Nothing in this subsection shall be construed to limit the authority of the Secretary or the Director of National Institutes of Health to terminate the appointment of a director referred to in subparagraph (A) before the expiration of such director's 5-year term.

(F) Nature of appointment

Appointments and reappointments under this subsection shall be made on the basis of ability and experience as it relates to the mission of the National Institutes of Health and its components, including compliance with any legal requirement that the Secretary or Director of National Institutes of Health determines relevant.

(3) Nonapplication of certain provision

The restrictions contained in section 202 of the Departments of Labor, Health and Human Services, and Education, and Related Agencies Appropriations Act, 1993 (Public Law 102–394; 42 U.S.C. 238f note) related to consultants and individual scientists appointed for limited periods of time shall not apply to Directors appointed under this subsection.

(b) Duties and authority; grants, contracts, and cooperative agreements

(1) In carrying out the purposes of section 241 of this title with respect to human diseases or disorders or other aspects of human health for which the national research institutes were established, the Secretary, acting through the Director of each national research institute—

(A) shall encourage and support research, investigations, experiments, demonstrations, and studies in the health sciences related to—

(i) the maintenance of health,

(ii) the detection, diagnosis, treatment, and prevention of human diseases and disorders,

(iii) the rehabilitation of individuals with human diseases, disorders, and disabilities, and

(iv) the expansion of knowledge of the processes underlying human diseases, disorders, and disabilities, the processes underlying the normal and pathological functioning of the body and its organ systems, and the processes underlying the interactions between the human organism and the environment;

(B) may, subject to the peer review prescribed under section 289a(b) of this title and any advisory council review under section 284a(a)(3)(A)(i) of this title, conduct the research, investigations, experiments, demonstrations, and studies referred to in subparagraph (A);

(C) shall, as appropriate, conduct and support research that has the potential to transform the scientific field, has inherently higher risk, and that seeks to address major current challenges;

(D) may conduct and support research training (i) for which fellowship support is not provided under section 288 of this title, and (ii) which is not residency training of physicians or other health professionals;

(E) may develop, implement, and support demonstrations and programs for the application of the results of the activities of the institute to clinical practice and disease prevention activities;

(F) may develop, conduct, and support public and professional education and information programs;

(G) may secure, develop and maintain, distribute, and support the development and maintenance of resources needed for research;

(H) may make available the facilities of the institute to appropriate entities and individuals engaged in research activities and cooperate with and assist Federal and State agencies charged with protecting the public health;

(I) may accept unconditional gifts made to the institute for its activities, and, in the case of gifts of a value in excess of $50,000, establish suitable memorials to the donor;

(J) may secure for the institute consultation services and advice of persons from the United States or abroad;

(K) may use, with their consent, the services, equipment, personnel, information, and facilities of other Federal, State, or local public agencies, with or without reimbursement therefor;

(L) may accept voluntary and uncompensated services; and

(M) may perform such other functions as the Secretary determines are needed to carry out effectively the purposes of the institute.

The indemnification provisions of section 3861 of title 10 shall apply with respect to contracts entered into under this subsection and section 282(b) of this title.

(2) Support for an activity or program under this subsection may be provided through grants, contracts, and cooperative agreements. The Secretary, acting through the Director of each national research institute—

(A) may enter into a contract for research, training, or demonstrations only if the contract has been recommended after technical and scientific peer review required by regulations under section 289a of this title;

(B) may make grants and cooperative agreements under paragraph (1) for research, training, or demonstrations, except that—

(i) if the direct cost of the grant or cooperative agreement to be made does not exceed $50,000, such grant or cooperative agreement may be made only if such grant or cooperative agreement has been recommended after technical and scientific peer review required by regulations under section 289a of this title, and

(ii) if the direct cost of the grant or cooperative agreement to be made exceeds $50,000, such grant or cooperative agreement may be made only if such grant or cooperative agreement has been recommended after technical and scientific peer review required by regulations under section 289a of this title and is recommended under section 284a(a)(3)(A)(ii) of this title by the advisory council for the national research institute involved; and

(C) shall, subject to section 300cc–40c(d)(2) of this title, receive from the President and the Office of Management and Budget directly all funds appropriated by the Congress for obligation and expenditure by the Institute.

(3) Before an award is made by a national research institute or by a national center for a grant for a research program or project (commonly referred to as an "R-series grant"), other than an award constituting a noncompetitive renewal of such a grant, or a noncompetitive administrative supplement to such a grant, the Director of such national research institute or national center shall, consistent with the peer review process—

(A) review and make the final decision with respect to making the award; and

(B) take into consideration, as appropriate—

(i) the mission of the national research institute or national center and the scientific priorities identified in the strategic plan under section 282(m) of this title;

(ii) programs or projects funded by other agencies on similar research topics; and

(iii) advice by staff and the advisory council or board of such national research institute or national center.

(c) Coordination with other public and private entities; cooperation with other national research institutes; appointment of additional peer review groups

In carrying out subsection (b), each Director of a national research institute—

(1) shall coordinate, as appropriate, the activities of the institute with similar programs of other public and private entities;

(2) shall cooperate with the Directors of the other national research institutes in the development and support of multidisciplinary research and research that involves more than one institute;

(3) may, in consultation with the advisory council for the Institute and with the approval of the Director of NIH—

(A) establish technical and scientific peer review groups in addition to those appointed under section 282(b)(16) of this title; and

(B) appoint the members of peer review groups established under subparagraph (A); and

(4) may publish, or arrange for the publication of, information with respect to the purpose of the Institute without regard to section 501 of title 44.

Chapter 10 of title 5 shall not apply to the duration of a peer review group appointed under paragraph (3).

(July 1, 1944, ch. 373, title IV, §405, as added Pub. L. 99–158, §2, Nov. 20, 1985, 99 Stat. 826; amended Pub. L. 100–607, title I, §116, Nov. 4, 1988, 102 Stat. 3053; Pub. L. 100–690, title II, §2613(c), Nov. 18, 1988, 102 Stat. 4239; Pub. L. 103–43, title III, §301(a)(1), (b), June 10, 1993, 107 Stat. 150; Pub. L. 109–482, title I, §102(f)(1)(B), Jan. 15, 2007, 120 Stat. 3685; Pub. L. 114–255, div. A, title II, §§2033(a), (b), 2036(c), Dec. 13, 2016, 130 Stat. 1057, 1058, 1063; Pub. L. 117–81, div. A, title XVII, §1702(j)(1)(B), Dec. 27, 2021, 135 Stat. 2159; Pub. L. 117–286, §4(a)(232), Dec. 27, 2022, 136 Stat. 4331.)

EDITORIAL NOTES

AMENDMENTS

2022—Subsec. (c). Pub. L. 117–286 substituted "Chapter 10 of title 5" for "The Federal Advisory Committee Act" in concluding provisions.

2021—Subsec. (b)(1). Pub. L. 117–81 substituted "section 3861" for "section 2354" in concluding provisions.

2016—Subsec. (a). Pub. L. 114–255, §2033(a), amended subsec. (a) generally. Prior to amendment, text read as follows: "The Director of the National Cancer Institute shall be appointed by the President and the Directors of the other national research institutes shall be appointed by the Secretary. Each Director of a

national research institute shall report directly to the Director of NIH."

Subsec. (b)(1)(C) to (M). Pub. L. 114–255, §2036(c), added par. (C) and redesignated former pars. (C) to (L) as (D) to (M), respectively.

Subsec. (b)(3). Pub. L. 114–255, §2033(b), added par. (3).

2007—Subsec. (c)(3)(A). Pub. L. 109–482 substituted "section 282(b)(16)" for "section 282(b)(6)".

1993—Subsec. (b)(2)(C). Pub. L. 103–43, §301(a)(1), added subpar. (C).

Subsec. (c). Pub. L. 103–43, §301(b)(2), inserted concluding provisions relating to Federal Advisory Committee Act.

Subsec. (c)(3). Pub. L. 103–43, §301(b)(1), amended par. (3) generally. Prior to amendment, par. (3) read as follows: "may, in consultation with the advisory council for the Institute and the approval of the Director of NIH, establish and appoint technical and scientific peer review groups in addition to those established and appointed under section 282(b)(6) of this title; and".

1988—Subsec. (b)(1). Pub. L. 100–607, §116(1), struck out "the" after "with respect to" in introductory provisions.

Subsec. (c)(3). Pub. L. 100–690 substituted "establish and appoint" and "established and appointed" for "establish" and "established", respectively.

Pub. L. 100–607, §116(2)(A), amended par. (3) generally. Prior to amendment, par. (3) read as follows: "may, with the approval of the advisory council for the institute and the Director of NIH, appoint technical and scientific peer review groups in addition to those appointed under section 282(b)(6) of this title."

Subsec. (c)(4). Pub. L. 100–607, §116(2)(C), added par. (4).

STATUTORY NOTES AND RELATED SUBSIDIARIES

EFFECTIVE DATE OF 2007 AMENDMENT

Amendment by Pub. L. 109–482 applicable only with respect to amounts appropriated for fiscal year 2007 or subsequent fiscal years, see section 109 of Pub. L. 109–482, set out as a note under section 281 of this title.

EFFECTIVE DATE OF 1988 AMENDMENT

Amendment by Pub. L. 100–690 effective immediately after enactment of Pub. L. 100–607, which was approved Nov. 4, 1988, see section 2600 of Pub. L. 100–690, set out as a note under section 242m of this title.

FEDERAL RESEARCH

Pub. L. 117–215, title IV, §401, Dec. 2, 2022, 136 Stat. 2265, provided that:

"(a) IN GENERAL.—Not later than 1 year after the date of enactment of this Act [Dec. 2, 2022], the Secretary of Health and Human Services, in coordination with the Director of the National Institutes of Health and the heads of other relevant Federal agencies, shall submit to the Caucus on International Narcotics Control, the Committee on the Judiciary, and the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce and the Committee on the Judiciary of the House of Representatives a report on—

"(1) the potential therapeutic effects of cannabidiol or marijuana on serious medical conditions, including intractable epilepsy;

"(2) the potential effects of marijuana, including—

"(A) the effect of increasing delta-9-tetrahydrocannabinol levels on the human body and developing adolescent brains; and

"(B) the effect of various delta-9-tetrahydrocannabinol levels on cognitive abilities, such as those that are required to operate motor vehicles or other heavy equipment; and

"(3) the barriers associated with researching marijuana or cannabidiol in States that have legalized the use of such substances, which shall include—

"(A) recommendations as to how such barriers might be overcome, including whether public-private partnerships or Federal-State research partnerships may or should be implemented to provide researchers with access to additional strains of marijuana and cannabidiol; and

"(B) recommendations as to what safeguards must be in place to verify—

"(i) the levels of tetrahydrocannabinol, cannabidiol, or other cannabinoids contained in products obtained from such States is accurate; and

"(ii) that such products do not contain harmful or toxic components.

"(b) ACTIVITIES.—To the extent practicable, the Secretary of Health and Human Services, either directly or through awarding grants, contacts, or cooperative agreements, shall expand and coordinate the activities of the National Institutes of Health and other relevant Federal agencies to better determine the effects of

cannabidiol and marijuana, as outlined in the report submitted under paragraphs (1) and (2) of subsection (a)."

[For definitions of terms as used in section 401 of Pub. L. 117–215, set out above, see section 2(a) of Pub. L. 117–215, set out as a note under section 801 of Title 21, Food and Drugs.]

ENHANCING THE CLINICAL AND TRANSLATIONAL SCIENCE AWARD

Pub. L. 109–482, title I, §106, Jan. 15, 2007, 120 Stat. 3696, provided that:

"(a) IN GENERAL.—In administering the Clinical and Translational Science Award, the Director of NIH shall establish a mechanism to preserve independent funding and infrastructure for pediatric clinical research centers by—

"(1) allowing the appointment of a secondary principal investigator under a single Clinical and Translational Science Award, such that a pediatric principal investigator may be appointed with direct authority over a separate budget and infrastructure for pediatric clinical research; or

"(2) otherwise securing institutional independence of pediatric clinical research centers with respect to finances, infrastructure, resources, and research agenda.

"(b) REPORT.—As part of the biennial report under section 403 of the Public Health Service Act [42 U.S.C. 283], the Director of NIH shall provide an evaluation and comparison of outcomes and effectiveness of training programs under subsection (a).

"(c) DEFINITION.—For purposes of this section, the term 'Director of NIH' has the meaning given such term in section 401 of the Public Health Service Act [42 U.S.C. 281]."

§284a. Advisory councils

(a) Establishment; acceptance of conditional gifts; functions

(1) Except as provided in subsection (h), the Secretary shall appoint an advisory council for each national research institute which (A) shall advise, assist, consult with, and make recommendations to the Secretary and the Director of such institute on matters related to the activities carried out by and through the institute and the policies respecting such activities, and (B) shall carry out the special functions prescribed by part C.

(2) Each advisory council for a national research institute may recommend to the Secretary acceptance, in accordance with section 238 of this title, of conditional gifts for study, investigation, or research respecting the diseases, disorders, or other aspect of human health with respect to which the institute was established, for the acquisition of grounds, or for the construction, equipping, or maintenance of facilities for the institute.

(3) Each advisory council for a national research institute—

(A)(i) may on the basis of the materials provided under section 289a(b)(2) of this title respecting research conducted at the institute, make recommendations to the Director of the institute respecting such research,

(ii) may review applications for grants and cooperative agreements for research or training and for which advisory council approval is required under section 284(b)(2) of this title and recommend for approval applications for projects which show promise of making valuable contributions to human knowledge, and

(iii) may review any grant, contract, or cooperative agreement proposed to be made or entered into by the institute;

(B) may collect, by correspondence or by personal investigation, information as to studies which are being carried on in the United States or any other country as to the diseases, disorders, or other aspect of human health with respect to which the institute was established and with the approval of the Director of the institute make available such information through appropriate publications for the benefit of public and private health entities and health professions personnel and scientists and for the information of the general public; and

(C) may appoint subcommittees and convene workshops and conferences.

(b) Membership; compensation

(1) Each advisory council shall consist of ex officio members and not more than eighteen members appointed by the Secretary. The ex officio members shall be nonvoting members.

(2) The ex officio members of an advisory council shall consist of—

(A) the Secretary, the Director of NIH, the Director of the national research institute for which the council is established, the Under Secretary for Health of the Department of Veterans Affairs or the Chief Dental Director of the Department of Veterans Affairs, and the Assistant Secretary of Defense for Health Affairs (or the designees of such officers), and

(B) such additional officers or employees of the United States as the Secretary determines necessary for the advisory council to effectively carry out its functions.

(3) The members of an advisory council who are not ex officio members shall be appointed as follows:

(A) Two-thirds of the members shall be appointed by the Secretary from among the leading representatives of the health and scientific disciplines (including not less than two individuals who are leaders in the fields of public health and the behavioral or social sciences) relevant to the activities of the national research institute for which the advisory council is established.

(B) One-third of the members shall be appointed by the Secretary from the general public and shall include leaders in fields of public policy, law, health policy, economics, and management.

(4) Members of an advisory council who are officers or employees of the United States shall not receive any compensation for service on the advisory council. The other members of an advisory council shall receive, for each day (including traveltime) they are engaged in the performance of the functions of the advisory council, compensation at rates not to exceed the daily equivalent of the annual rate in effect for grade GS–18 of the General Schedule.

(c) Term of office; reappointment; vacancy

The term of office of an appointed member of an advisory council is four years, except that any member appointed to fill a vacancy for an unexpired term shall be appointed for the remainder of such term and the Secretary shall make appointments to an advisory council in such a manner as to ensure that the terms of the members do not all expire in the same year. A member may serve after the expiration of the member's term for 180 days after the date of such expiration. A member who has been appointed for a term of four years may not be reappointed to an advisory council before two years from the date of expiration of such term of office. If a vacancy occurs in the advisory council among the appointed members, the Secretary shall make an appointment to fill the vacancy within 90 days from the date the vacancy occurs.

(d) Chairman; term of office

The chairman of an advisory council shall be selected by the Secretary from among the appointed members, except that the Secretary may select the Director of the national research institute for which the advisory council is established to be the chairman of the advisory council. The term of office of the chairman shall be two years.

(e) Meetings

The advisory council shall meet at the call of the chairman or upon the request of the Director of the national research institute for which it was established, but at least three times each fiscal year. The location of the meetings of each advisory council is subject to the approval of the Director of the national research institute for which the advisory council was established.

(f) Appointment of executive secretary; training and orientation for new members

The Director of the national research institute for which an advisory council is established shall designate a member of the staff of the institute to serve as the executive secretary of the advisory council. The Director of such institute shall make available to the advisory council such staff, information, and other assistance as it may require to carry out its functions. The Director of such institute shall provide orientation and training for new members of the advisory council to provide them with such information and training as may be appropriate for their effective participation in the functions of the advisory council.

(g) Comments and recommendations for inclusion in biennial report; additional reports

Each advisory council may prepare, for inclusion in the biennial report made under section 284b [1] of this title, (1) comments respecting the activities of the advisory council in the fiscal years respecting which the report is prepared, (2) comments on the progress of the national research institute for which it was established in meeting its objectives, and (3) recommendations respecting the future directions and program and policy emphasis of the institute. Each advisory council may prepare such additional reports as it may determine appropriate.

(h) Advisory councils in existence; application of section to National Cancer Advisory Board and advisory council to National Heart, Lung, and Blood Institute

(1) Except as provided in paragraph (2), this section does not terminate the membership of any advisory council for a national research institute which was in existence on November 20, 1985. After November 20, 1985—

(A) the Secretary shall make appointments to each such advisory council in such a manner as to bring about as soon as practicable the composition for such council prescribed by this section;

(B) each advisory council shall organize itself in accordance with this section and exercise the functions prescribed by this section; and

(C) the Director of each national research institute shall perform for such advisory council the functions prescribed by this section.

(2)(A) The National Cancer Advisory Board shall be the advisory council for the National Cancer Institute. This section applies to the National Cancer Advisory Board, except that—

(i) appointments to such Board shall be made by the President;

(ii) the term of office of an appointed member shall be 6 years;

(iii) of the members appointed to the Board—

(I) not less than 5 members shall be individuals knowledgeable in environmental carcinogenesis (including carcinogenesis involving occupational and dietary factors); and

(II) not less than one member shall be an individual knowledgeable in pediatric oncology;

(iv) the chairman of the Board shall be selected by the President from the appointed members and shall serve as chairman for a term of two years;

(v) the ex officio members of the Board shall be nonvoting members and shall be the Secretary, the Director of the Office of Science and Technology Policy, the Director of NIH, the Under Secretary for Health of the Department of Veterans Affairs, the Director of the National Institute for Occupational Safety and Health, the Director of the National Institute of Environmental Health Sciences, the Secretary of Labor, the Commissioner of the Food and Drug Administration, the Administrator of the Environmental Protection Agency, the Chairman of the Consumer Product Safety Commission, the Assistant Secretary of Defense for Health Affairs, and the Director of the Office of Science of the Department of Energy (or the designees of such officers); and

(vi) the Board shall meet at least four times each fiscal year.

(B) This section applies to the advisory council to the National Heart, Lung, and Blood Institute, except that the advisory council shall meet at least four times each fiscal year.

(July 1, 1944, ch. 373, title IV, §406, as added Pub. L. 99–158, §2, Nov. 20, 1985, 99 Stat. 828; amended Pub. L. 100–607, title I, §117, Nov. 4, 1988, 102 Stat. 3053; Pub. L. 101–381, title I, §102(1), Aug. 18, 1990, 104 Stat. 585; Pub. L. 102–405, title III, §302(e)(1), Oct. 9, 1992, 106 Stat. 1985; Pub. L. 103–43, title II, §210(a), title XX, §§2008(b)(1), 2010(b)(2), June 10, 1993, 107 Stat. 149, 210, 214; Pub. L. 105–245, title III, §309(b)(2)(C), Oct. 7, 1998, 112 Stat. 1853; Pub. L. 115–180, title I, §111, June 5, 2018, 132 Stat. 1386.)

EDITORIAL NOTES

REFERENCES IN TEXT

Section 284b of this title, referred to in subsec. (g), was repealed by Pub. L. 109–482, title I, §104(b)(1)(C),

Jan. 15, 2007, 120 Stat. 3693.

AMENDMENTS

2018—Subsec. (h)(2)(A)(iii). Pub. L. 115–180 substituted "appointed to the Board—" for "appointed to the Board", inserted subcl. (I) designation before "not less than", substituted "5 members" for "five members", inserted "and" at end, and added subcl. (II).

1998—Subsec. (h)(2)(A)(v). Pub. L. 105–245 substituted "Science of the Department of Energy" for "Energy Research of the Department of Energy".

1993—Subsec. (a)(2). Pub. L. 103–43, §2010(b)(2), substituted "section 238" for "section 300aaa".

Subsec. (b)(2)(A). Pub. L. 103–43, §2008(b)(1)(A), substituted "Department of Veterans Affairs" for "Veterans' Administration" in two places.

Subsec. (c). Pub. L. 103–43, §210(a), substituted "for 180 days after the date of such expiration" for "until a successor has taken office".

Subsec. (h)(2)(A)(v). Pub. L. 103–43, §2008(b)(1)(B), substituted "Department of Veterans Affairs" for "Veterans' Administration".

1992—Subsecs. (b)(2)(A), (h)(2)(A)(v). Pub. L. 102–405 substituted "Under Secretary for Health" for "Chief Medical Director".

1990—Subsec. (a)(2). Pub. L. 101–381 made technical amendment to reference to section 300aaa of this title to reflect renumbering of corresponding section of original act.

1988—Subsec. (b)(1). Pub. L. 100–607, §117(a), inserted at end "The ex officio members shall be nonvoting members."

Subsec. (b)(3)(A). Pub. L. 100–607, §117(b), inserted "not less than two individuals who are leaders in the fields of" after "(including".

Subsec. (h)(2)(A)(v). Pub. L. 100–607, §117(c), inserted "shall be nonvoting members and" after "Board" and substituted "the Assistant Secretary of Defense for Health Affairs, and the Director of the Office of Energy Research of the Department of Energy" for "and the Assistant Secretary of Defense for Health Affairs".

STATUTORY NOTES AND RELATED SUBSIDIARIES

TERMINATION OF ADVISORY COUNCILS

Advisory councils established after Jan. 5, 1973, to terminate not later than the expiration of the 2-year period beginning on the date of their establishment, unless, in the case of a council established by the President or an officer of the Federal Government, such council is renewed by appropriate action prior to the expiration of such 2-year period, or in the case of a council established by the Congress, its duration is otherwise provided by law. See sections 1001(2) and 1013 of Title 5, Government Organization and Employees.

Pub. L. 93–641, §6, Jan. 4, 1975, 88 Stat. 2275, set out as a note under section 217a of this title, provided that an advisory committee established pursuant to the Public Health Service Act shall terminate at such time as may be specifically prescribed by an Act of Congress enacted after Jan. 4, 1975.

REFERENCES IN OTHER LAWS TO GS–16, 17, OR 18 PAY RATES

References in laws to the rates of pay for GS–16, 17, or 18, or to maximum rates of pay under the General Schedule, to be considered references to rates payable under specified sections of Title 5, Government Organization and Employees, see section 529 [title I, §101(c)(1)] of Pub. L. 101–509, set out in a note under section 5376 of Title 5.

[1] *See References in Text note below.*

§284b. Repealed. Pub. L. 109–482, title I, §104(b)(1)(C), Jan. 15, 2007, 120 Stat. 3693

Section, act July 1, 1944, ch. 373, title IV, §407, as added Pub. L. 99–158, §2, Nov. 20, 1985, 99 Stat. 831, related to biennial report and its contents.

STATUTORY NOTES AND RELATED SUBSIDIARIES

EFFECTIVE DATE OF REPEAL

Repeal applicable only with respect to amounts appropriated for fiscal year 2007 or subsequent fiscal years, see section 109 of Pub. L. 109–482, set out as an Effective Date of 2007 Amendment note under section 281 of this title.

§284c. Certain uses of funds

(a)(1) Except as provided in paragraph (2), the sum of the amounts obligated in any fiscal year for administrative expenses of the National Institutes of Health may not exceed an amount which is 5.5 percent of the total amount appropriated for such fiscal year for the National Institutes of Health.

(2) Paragraph (1) does not apply to the National Library of Medicine, the National Center for Nursing Research, the John E. Fogarty International Center for Advanced Study in the Health Sciences, the Warren G. Magnuson Clinical Center, and the Office of Medical Applications of Research.

(3) For purposes of paragraph (1), the term "administrative expenses" means expenses incurred for the support of activities relevant to the award of grants, contracts, and cooperative agreements and expenses incurred for general administration of the scientific programs and activities of the National Institutes of Health.

(b) For fiscal year 1989 and subsequent fiscal years, amounts made available to the National Institutes of Health shall be available for payment of nurses and allied health professionals in accordance with payment authorities, scheduling options, benefits, and other authorities provided under chapter 73 of title 38 for nurses of the Department of Veterans Affairs.

(July 1, 1944, ch. 373, title IV, §408, as added Pub. L. 99–158, §2, Nov. 20, 1985, 99 Stat. 831; amended Pub. L. 100–607, title I, §118, Nov. 4, 1988, 102 Stat. 3053; Pub. L. 100–690, title II, §2613(d), Nov. 18, 1988, 102 Stat. 4239; Pub. L. 103–43, title IV, §403(b)(1), title XX, §2008(b)(2), June 10, 1993, 107 Stat. 158, 211; Pub. L. 104–316, title I, §122(a), Oct. 19, 1996, 110 Stat. 3836; Pub. L. 105–362, title VI, §601(a)(1)(B), Nov. 10, 1998, 112 Stat. 3285.)

EDITORIAL NOTES

AMENDMENTS

1998—Subsec. (a)(4). Pub. L. 105–362 struck out par. (4) which read as follows: "Not later than December 31, 1987, and December 31 of each succeeding year, the Secretary shall report to the Congress the amount obligated in the fiscal year preceding such date for administrative expenses of the National Institutes of Health and the total amount appropriated for the National Institutes of Health for such fiscal year. The Secretary shall consult with the Comptroller General of the United States in preparing each report."

1996—Subsec. (a)(3). Pub. L. 104–316 struck out at end "In identifying expenses incurred for such support and administration the Secretary shall consult with the Comptroller General of the United States."

1993—Pub. L. 103–43 amended section catchline generally, redesignated subsec. (b) as (a) and par. (5) of subsec. (a) as (b), struck out former subsec. (a) which authorized appropriations in addition to amounts otherwise appropriated under this subchapter for the National Cancer Institute for programs other than under section 285a–1 of this title and for its program under section 285a–1 of this title and for the National Heart, Lung, and Blood Institute for programs other than under section 285b–1 of this title and for its program under section 285b–1 of this title, and substituted "Department of Veterans Affairs" for "Veterans' Administration" in subsec. (b).

1988—Subsec. (a)(1), (2). Pub. L. 100–607, §118(a), amended pars. (1) and (2) generally. Prior to amendment, pars. (1) and (2) read as follows:

"(1)(A) For the National Cancer Institute (other than its programs under section 285a–1 of this title), there are authorized to be appropriated $1,194,000,000 for fiscal year 1986, $1,270,000,000 for fiscal year 1987, and $1,344,000,000 for fiscal year 1988.

"(B) For the programs under section 285a–1 of this title, there are authorized to be appropriated $68,000,000 for fiscal year 1986, $74,000,000 for fiscal year 1987, and $80,000,000 for fiscal year 1988.

"(2)(A) For the National Heart, Lung, and Blood Institute (other than its programs under section 285b–1 of

this title), there are authorized to be appropriated $809,000,000 for fiscal year 1986, $871,000,000 for fiscal year 1987, and $927,000,000 for fiscal year 1988. Of the amount appropriated under this subsection for such fiscal year, not less than 15 percent of such amount shall be reserved for programs respecting diseases of the lung and not less than 15 percent of such amount shall be reserved for programs respecting blood diseases and blood resources.

"(B) For the programs under section 285b–1 of this title, there are authorized to be appropriated $82,000,000 for fiscal year 1986, $90,000,000 for fiscal year 1987, and $98,000,000 for fiscal year 1988."

Subsec. (a)(2)(B). Pub. L. 100–690 inserted a comma after "section 285b–1 of this title".

Subsec. (b)(5). Pub. L. 100–607, §118(b), added par. (5).

STATUTORY NOTES AND RELATED SUBSIDIARIES

CHANGE OF NAME

National Center for Nursing Research changed to National Institute of Nursing Research by Pub. L. 103–43, title XV, §1511, June 10, 1993, 107 Stat. 178.

EFFECTIVE DATE OF 1988 AMENDMENT

Amendment by Pub. L. 100–690 effective immediately after enactment of Pub. L. 100–607, which was approved Nov. 4, 1988, see section 2600 of Pub. L. 100–690, set out as a note under section 242m of this title.

WARREN G. MAGNUSON CLINICAL CENTER; AVAILABILITY OF FUNDS FOR PAYMENT OF NURSES; RATE OF PAY AND OPTIONS AND BENEFITS

Pub. L. 99–349, title I, July 2, 1986, 100 Stat. 738, provided that: "Funds made available for fiscal year 1986 and hereafter to the Warren G. Magnuson Clinical Center of the National Institutes of Health shall be available for payment of nurses at the rates of pay and with schedule options and benefits authorized for the Veterans Administration pursuant to 38 U.S.C. 4107."

§284d. Definitions

(a) Health service research

For purposes of this subchapter, the term "health services research" means research endeavors that study the impact of the organization, financing and management of health services on the quality, cost, access to and outcomes of care. Such term does not include research on the efficacy of services to prevent, diagnose, or treat medical conditions.

(b) Clinical research

As used in this subchapter, the term "clinical research" means patient oriented clinical research conducted with human subjects, or research on the causes and consequences of disease in human populations involving material of human origin (such as tissue specimens and cognitive phenomena) for which an investigator or colleague directly interacts with human subjects in an outpatient or inpatient setting to clarify a problem in human physiology, pathophysiology or disease, or epidemiologic or behavioral studies, outcomes research or health services research, or developing new technologies, therapeutic interventions, or clinical trials.

(July 1, 1944, ch. 373, title IV, §409, as added Pub. L. 102–321, title I, §121(b), July 10, 1992, 106 Stat. 358; amended Pub. L. 103–43, title XX, §2016(a), June 10, 1993, 107 Stat. 218; Pub. L. 106–505, title II, §206, Nov. 13, 2000, 114 Stat. 2329.)

EDITORIAL NOTES

AMENDMENTS

2000—Pub. L. 106–505 designated existing provisions as subsec. (a), inserted heading, and added subsec. (b).

1993—Pub. L. 103–43 inserted at end "Such term does not include research on the efficacy of services to prevent, diagnose, or treat medical conditions."

STATUTORY NOTES AND RELATED SUBSIDIARIES

EFFECTIVE DATE

Section effective Oct. 1, 1992, with provision for programs providing financial assistance, see section 801(c), (d) of Pub. L. 102–321, set out as an Effective Date of 1992 Amendment note under section 236 of this title.

§284e. Research on osteoporosis, Paget's disease, and related bone disorders

(a) Establishment

The Directors of the National Institute of Arthritis and Musculoskeletal and Skin Diseases, the National Institute on Aging, the National Institute of Dental Research, and the National Institute of Diabetes and Digestive and Kidney Diseases, shall expand and intensify the programs of such Institutes with respect to research and related activities concerning osteoporosis, Paget's disease, and related bone disorders.

(b) Coordination

The Directors referred to in subsection (a) shall jointly coordinate the programs referred to in such subsection and consult with the Arthritis and Musculoskeletal Diseases Interagency Coordinating Committee and the Interagency Task Force on Aging Research.

(c) Information clearinghouse

(1) In general

In order to assist in carrying out the purpose described in subsection (a), the Director of NIH shall provide for the establishment of an information clearinghouse on osteoporosis and related bone disorders to facilitate and enhance knowledge and understanding on the part of health professionals, patients, and the public through the effective dissemination of information.

(2) Establishment through grant or contract

For the purpose of carrying out paragraph (1), the Director of NIH shall enter into a grant, cooperative agreement, or contract with a nonprofit private entity involved in activities regarding the prevention and control of osteoporosis and related bone disorders.

(July 1, 1944, ch. 373, title IV, §409A, as added Pub. L. 103–43, title III, §302, June 10, 1993, 107 Stat. 151; amended Pub. L. 105–340, title I, §102, Oct. 31, 1998, 112 Stat. 3192; Pub. L. 109–482, title I, §103(b)(7), Jan. 15, 2007, 120 Stat. 3687.)

EDITORIAL NOTES

AMENDMENTS

2007—Subsec. (d). Pub. L. 109–482 struck out heading and text of subsec. (d). Text read as follows: "For the purpose of carrying out this section, there are authorized to be appropriated $40,000,000 for fiscal year 1994, and such sums as may be necessary for each of the fiscal years 1995 through 2003."

1998—Subsec. (d). Pub. L. 105–340 substituted "through 2003" for "and 1996".

STATUTORY NOTES AND RELATED SUBSIDIARIES

EFFECTIVE DATE OF 2007 AMENDMENT

Amendment by Pub. L. 109–482 applicable only with respect to amounts appropriated for fiscal year 2007 or subsequent fiscal years, see section 109 of Pub. L. 109–482, set out as a note under section 281 of this title.

§284f. Parkinson's disease

(a) In general

The Director of NIH shall establish a program for the conduct and support of research and training with respect to Parkinson's disease (subject to the extent of amounts appropriated to carry out this section).

(b) Inter-institute coordination

(1) In general

The Director of NIH shall provide for the coordination of the program established under subsection (a) among all of the national research institutes conducting Parkinson's disease research.

(2) Conference

Coordination under paragraph (1) shall include the convening of a research planning conference not less frequently than once every 2 years. Each such conference shall prepare and submit to the Committee on Appropriations and the Committee on Labor and Human Resources of the Senate and the Committee on Appropriations and the Committee on Commerce of the House of Representatives a report concerning the conference.

(c) Morris K. Udall research centers

(1) In general

The Director of NIH is authorized to award Core Center Grants to encourage the development of innovative multidisciplinary research and provide training concerning Parkinson's disease. The Director is authorized to award not more than 10 Core Center Grants and designate each center funded under such grants as a Morris K. Udall Center for Research on Parkinson's Disease.

(2) Requirements

(A) In general

With respect to Parkinson's disease, each center assisted under this subsection shall—

(i) use the facilities of a single institution or a consortium of cooperating institutions, and meet such qualifications as may be prescribed by the Director of the NIH; and

(ii) conduct basic and clinical research.

(B) Discretionary requirements

With respect to Parkinson's disease, each center assisted under this subsection may—

(i) conduct training programs for scientists and health professionals;

(ii) conduct programs to provide information and continuing education to health professionals;

(iii) conduct programs for the dissemination of information to the public;

(iv) separately or in collaboration with other centers, establish a nationwide data system derived from patient populations with Parkinson's disease, and where possible, comparing relevant data involving general populations;

(v) separately or in collaboration with other centers, establish a Parkinson's Disease Information Clearinghouse to facilitate and enhance knowledge and understanding of Parkinson's disease; and

(vi) separately or in collaboration with other centers, establish a national education program that fosters a national focus on Parkinson's disease and the care of those with Parkinson's disease.

(3) Stipends regarding training programs

A center may use funds provided under paragraph (1) to provide stipends for scientists and health professionals enrolled in training programs under paragraph (2)(B).

(4) Duration of support

Support of a center under this subsection may be for a period not exceeding five years. Such period may be extended by the Director of NIH for one or more additional periods of not more

than five years if the operations of such center have been reviewed by an appropriate technical and scientific peer review group established by the Director and if such group has recommended to the Director that such period should be extended.

(d) Morris K. Udall Awards for Excellence in Parkinson's Disease Research

The Director of NIH is authorized to establish a grant program to support investigators with a proven record of excellence and innovation in Parkinson's disease research and who demonstrate potential for significant future breakthroughs in the understanding of the pathogensis,[1] diagnosis, and treatment of Parkinson's disease. Grants under this subsection shall be available for a period of not to exceed 5 years.

(July 1, 1944, ch. 373, title IV, §409B, as added Pub. L. 105–78, title VI, §603(c), Nov. 13, 1997, 111 Stat. 1520; amended Pub. L. 109–482, title I, §103(b)(8), Jan. 15, 2007, 120 Stat. 3687.)

EDITORIAL NOTES

AMENDMENTS

2007—Subsec. (a). Pub. L. 109–482, §103(b)(8)(A), substituted "to carry out this section" for "under subsection (e) of this section".

Subsec. (e). Pub. L. 109–482, §103(b)(8)(B), struck out heading and text of subsec. (e). Text read as follows: "For the purpose of carrying out this section and section 241 of this title and this subchapter with respect to research focused on Parkinson's disease, there are authorized to be appropriated up to $100,000,000 for fiscal year 1998, and such sums as may be necessary for each of the fiscal years 1999 and 2000."

STATUTORY NOTES AND RELATED SUBSIDIARIES

CHANGE OF NAME

Committee on Commerce of House of Representatives changed to Committee on Energy and Commerce of House of Representatives, and jurisdiction over matters relating to securities and exchanges and insurance generally transferred to Committee on Financial Services of House of Representatives by House Resolution No. 5, One Hundred Seventh Congress, Jan. 3, 2001.

Committee on Labor and Human Resources of Senate changed to Committee on Health, Education, Labor, and Pensions of Senate by Senate Resolution No. 20, One Hundred Sixth Congress, Jan. 19, 1999.

EFFECTIVE DATE OF 2007 AMENDMENT

Amendment by Pub. L. 109–482 applicable only with respect to amounts appropriated for fiscal year 2007 or subsequent fiscal years, see section 109 of Pub. L. 109–482, set out as a note under section 281 of this title.

ADDITIONAL GRANTS

Pub. L. 108–199, div. E, title II, §217, Jan. 23, 2004, 118 Stat. 255, provided that: "Notwithstanding section 409B(c) of the Public Health Service Act [42 U.S.C. 284f(c)] regarding a limitation on the number of such grants, funds appropriated in this Act [div. E of Pub. L. 108–199, see Tables for classification] and Acts in fiscal years thereafter may be expended by the Director of the National Institutes of Health to award Core Center Grants to encourage the development of innovative multidisciplinary research and provide training concerning Parkinson's disease. Each center funded under such grants shall be designated as a Morris K. Udall Center for Research on Parkinson's Disease."

Similar provisions were contained in Pub. L. 108–7, div. G, title II, §218, Feb. 20, 2003, 117 Stat. 326.

FINDING AND PURPOSE

Pub. L. 105–78, title VI, §603(b), Nov. 13, 1997, 111 Stat. 1519, provided that:

"(1) FINDING.—Congress finds that to take full advantage of the tremendous potential for finding a cure or effective treatment, the Federal investment in Parkinson's disease must be expanded, as well as the coordination strengthened among the National Institutes of Health research institutes.

"(2) PURPOSE.—It is the purpose of this section [enacting this section] to provide for the expansion and coordination of research regarding Parkinson's disease, and to improve care and assistance for afflicted individuals and their family caregivers."

[1] *So in original. Probably should be "pathogenesis,".*

§284g. Expansion, intensification, and coordination of activities of National Institutes of Health with respect to research on autism spectrum disorder

(a) In general

(1) Expansion of activities

The Director of NIH (in this section referred to as the "Director"), in consultation with relevant Federal departments and agencies, as appropriate, shall—

(A) subject to the availability of appropriations, expand, intensify, and coordinate the activities of the National Institutes of Health with respect to research on autism spectrum disorder, including basic and clinical research—

(i) in fields, such as pathology, developmental neurobiology, genetics, epigenetics, pharmacology, nutrition, immunology, neuroimmunology, neurobehavioral development, endocrinology, gastroenterology, toxicology, psychiatry, psychology, developmental behavioral pediatrics, audiology, and gerontology; and

(ii) on interventions to maximize outcomes for individuals with autism spectrum disorder; and

(B) ensure that research referred to in subparagraph (A)—

(i) investigates the causes (including possible environmental causes), diagnosis or ruling out, early and ongoing detection, prevention, services and supports across the lifespan, intervention, and treatment of autism spectrum disorder and co-occurring conditions, including dissemination and implementation of clinical care, supports, interventions, and treatments;

(ii) examines supports for caregivers; and

(iii) reflects the entire population of individuals with autism spectrum disorder, including those individuals with co-occurring conditions and the full range of needs for supports and services, including such supports and services to ensure the safety, and promote the well-being, of such individuals.

(2) Consolidation

The Director may consolidate program activities under this section if such consolidation would improve program efficiencies and outcomes.

(3) Administration of program; collaboration among agencies

The Director shall carry out this section acting through the Director of the National Institute of Mental Health and in collaboration with any other agencies that the Director determines appropriate.

(b) Centers of excellence

(1) In general

The Director shall under subsection (a)(1) make awards of grants and contracts to public or nonprofit private entities to pay all or part of the cost of planning, establishing, improving, and providing basic operating support for centers of excellence regarding research on autism spectrum disorder.

(2) Research

Each center under paragraph (1) shall conduct basic and clinical research into autism spectrum disorder. Such research should include investigations into the causes, diagnosis, early and ongoing detection, prevention, and treatment of autism spectrum disorder across the lifespan. The centers, as a group, shall conduct research in fields such as developmental neurobiology, genetics,

genomics, psychopharmacology, developmental psychology, behavioral psychology, clinical psychology, and gerontology.

(3) Services for patients

(A) In general

A center under paragraph (1) may expend amounts provided under such paragraph to carry out a program to make individuals aware of opportunities to participate as subjects in research conducted by the centers.

(B) Referrals and costs

A program under subparagraph (A) may, in accordance with such criteria as the Director may establish, provide to the subjects described in such subparagraph, referrals for health and other services, and such patient care costs as are required for research.

(C) Availability and access

The extent to which a center can demonstrate availability and access to clinical services shall be considered by the Director in decisions about awarding grants to applicants which meet the scientific criteria for funding under this section.

(D) Reducing disparities

The Director may consider, as appropriate, the extent to which a center can demonstrate availability and access to clinical services for youth and adults from diverse racial, ethnic, geographic, or linguistic backgrounds in decisions about awarding grants to applicants which meet the scientific criteria for funding under this section.

(4) Organization of centers

Each center under paragraph (1) shall use the facilities of a single institution, or be formed from a consortium of cooperating institutions, meeting such requirements as may be prescribed by the Director.

(5) Number of centers; duration of support

(A) In general

The Director shall provide for the establishment of not less than seven centers under paragraph (1).

(B) Duration

Support for a center established under paragraph (1) may be provided under this section for a period not to exceed 5 years. Such period may be extended for one or more additional periods not exceeding 5 years if the operations of such center have been reviewed by an appropriate technical and scientific peer review group established by the Director and if such group has recommended to the Director that such period should be extended.

(c) Facilitation of research

The Director shall under subsection (a)(1) provide for a program under which samples of tissues and genetic materials that are of use in research on autism spectrum disorder are donated, collected, preserved, and made available for such research. The program shall be carried out in accordance with accepted scientific and medical standards for the donation, collection, and preservation of such samples.

(d) Public input

(1) In general

The Director shall under subsection (a)(1) provide for means through which the public can obtain information on the existing and planned programs and activities of the National Institutes of Health with respect to autism spectrum disorder and through which the Director can receive comments from the public regarding such programs and activities.

(2) Guidance

The Director may provide guidance to centers under subsection (b)(1) on strategies, activities, and opportunities to promote engagement with, and solicit input from, individuals with autism spectrum disorder and their family members, guardians, advocates or authorized representatives, providers, or other appropriate individuals to inform the activities of the center. Such strategies, activities, and opportunities should consider including, as appropriate, individuals, family members, and caregivers of individuals with autism spectrum disorder who represent the entire population of individuals with autism spectrum disorder, including those individuals with co-occurring conditions and the full range of needs for supports and services, including such supports and services to ensure the safety, and promote the well-being, of such individuals, to inform the activities of the center.

(e) Budget estimate

For each of fiscal years 2026 through 2029, the Director shall prepare and submit, directly to the President for review and transmittal to Congress, an annual budget estimate for the initiatives of the National Institutes of Health pursuant to the strategic plan developed under section 280i–2(b)(5) of this title and updated under section 280i–2(b)(6)(B) of this title, after reasonable opportunity for comment (but without change) by the Secretary and the Interagency Autism Coordinating Committee established under section 280i–2 of this title.

(July 1, 1944, ch. 373, title IV, §409C, as added Pub. L. 106–310, div. A, title I, §101, Oct. 17, 2000, 114 Stat. 1105; amended Pub. L. 109–416, §§2(a), 4(b), Dec. 19, 2006, 120 Stat. 2821, 2830; Pub. L. 109–482, title I, §§103(b)(9), 104(b)(1)(D), Jan. 15, 2007, 120 Stat. 3687, 3693; Pub. L. 116–60, §2, Sept. 30, 2019, 133 Stat. 1110; Pub. L. 118–180, §2, Dec. 23, 2024, 138 Stat. 2614.)

EDITORIAL NOTES

CODIFICATION

Another section 409C of act July 1, 1944, was renumbered section 409G and is classified to section 284k of this title.

AMENDMENTS

2024—Subsec. (a)(1). Pub. L. 118–180, §2(a), made numerous amendments to text and structure of par. (1). Prior to amendment, text read as follows: "The Director of NIH (in this section referred to as the "Director") shall, subject to the availability of appropriations, expand, intensify, and coordinate the activities of the National Institutes of Health with respect to research on autism spectrum disorder, including basic and clinical research in fields including pathology, developmental neurobiology, genetics, epigenetics, pharmacology, nutrition, immunology, neuroimmunology, neurobehavioral development, endocrinology, gastroenterology, toxicology, and interventions to maximize outcomes for individuals with autism spectrum disorder. Such research shall investigate the causes (including possible environmental causes), diagnosis or ruling out, early and ongoing detection, prevention, services across the lifespan, supports, intervention, and treatment of autism spectrum disorder, including dissemination and implementation of clinical care, supports, interventions, and treatments."

Subsec. (b)(2). Pub. L. 118–180, §2(b)(1), substituted "in fields such as" for "including the fields of" and "behavioral psychology, clinical psychology, and gerontology" for "behavioral psychology, and clinical psychology".

Subsec. (b)(5)(A). Pub. L. 118–180, §2(b)(2), substituted "seven centers" for "five centers".

Subsec. (b)(5)(B). Pub. L. 118–180, §2(b)(3), substituted "period not to exceed" for "period of not to exceed".

Subsec. (d). Pub. L. 118–180, §2(c), amended subsec. (d) generally. Prior to amendment, text read as follows: "The Director shall under subsection (a)(1) provide for means through which the public can obtain information on the existing and planned programs and activities of the National Institutes of Health with respect to autism spectrum disorder and through which the Director can receive comments from the public regarding such programs and activities."

Subsec. (e). Pub. L. 118–180, §2(d), added subsec. (e).

2019—Subsec. (a)(1). Pub. L. 116–60, §2(1), substituted "toxicology, and interventions to maximize outcomes for individuals with autism spectrum disorder" for "and toxicology" and "Such research shall

investigate the causes (including possible environmental causes), diagnosis or ruling out, early and ongoing detection, prevention, services across the lifespan, supports, intervention, and treatment of autism spectrum disorder, including dissemination and implementation of clinical care, supports, interventions, and treatments." for "Such research shall investigate the cause (including possible environmental causes), diagnosis or rule out, early detection, prevention, services, supports, intervention, and treatment of autism spectrum disorder."

Subsec. (b)(2). Pub. L. 116–60, §2(2)(A), substituted "causes, diagnosis, early and ongoing detection, prevention, and treatment of autism spectrum disorder across the lifespan" for "cause, diagnosis, early detection, prevention, control, and treatment of autism spectrum disorder" and "neurobiology, genetics, genomics, psychopharmacology, developmental psychology, behavioral psychology, and clinical psychology." for "neurobiology, genetics, and psychopharmacology."

Subsec. (b)(3)(D). Pub. L. 116–60, §2(2)(B), added subpar. (D).

2007—Subsec. (b)(4) to (6). Pub. L. 109–482, §104(b)(1)(D), redesignated pars. (5) and (6) as (4) and (5), respectively, and struck out heading and text of former par. (4). Text read as follows: "The Director shall, as appropriate, provide for the coordination of information among centers under paragraph (1) and ensure regular communication between such centers, and may require the periodic preparation of reports on the activities of the centers and the submission of the reports to the Director."

Subsec. (e). Pub. L. 109–482, §103(b)(9), which directed the striking of subsec. (e), could not be executed because of prior amendment by Pub. L. 109–416. See 2006 Amendment note below.

2006—Pub. L. 109–416, §2(a)(1), substituted "autism spectrum disorder" for "autism" in section catchline.

Subsec. (a). Pub. L. 109–416, §2(a)(3), added pars. (1) and (2), redesignated former par. (2) as (3), and struck out heading and text of former par. (1). Text read as follows: "The Director of NIH (in this section referred to as the 'Director') shall expand, intensify, and coordinate the activities of the National Institutes of Health with respect to research on autism."

Subsec. (b)(1), (2). Pub. L. 109–416, §2(a)(2), substituted "autism spectrum disorder" for "autism" in par. (1) and in two places in par. (2).

Subsecs. (c), (d). Pub. L. 109–416, §2(a)(2), substituted "autism spectrum disorder" for "autism".

Subsec. (e). Pub. L. 109–416, §4(b), struck out heading and text of subsec. (e). Text read as follows: "There are authorized to be appropriated such sums as may be necessary to carry out this section. Amounts appropriated under this subsection are in addition to any other amounts appropriated for such purpose."

STATUTORY NOTES AND RELATED SUBSIDIARIES

EFFECTIVE DATE OF 2007 AMENDMENT

Amendment by Pub. L. 109–482 applicable only with respect to amounts appropriated for fiscal year 2007 or subsequent fiscal years, see section 109 of Pub. L. 109–482, set out as a note under section 281 of this title.

§284h. Pediatric Research Initiative

(a) Establishment

The Secretary shall establish within the Office of the Director of NIH a Pediatric Research Initiative (referred to in this section as the "Initiative") to conduct and support research that is directly related to diseases, disorders, and other conditions in children. The Initiative shall be headed by the Director of NIH.

(b) Purpose

The purpose of the Initiative is to provide funds to enable the Director of NIH—

(1) to increase support for pediatric biomedical research within the National Institutes of Health to realize the expanding opportunities for advancement in scientific investigations and care for children;

(2) to enhance collaborative efforts among the Institutes to conduct and support multidisciplinary research in the areas that the Director deems most promising; and

(3) in coordination with the Food and Drug Administration, to increase the development of adequate pediatric clinical trials and pediatric use information to promote the safer and more effective use of prescription drugs in the pediatric population.

(c) Duties

In carrying out subsection (b), the Director of NIH shall—

(1) consult with the Director of the Eunice Kennedy Shriver National Institute of Child Health and Human Development and the other national research institutes, in considering their requests for new or expanded pediatric research efforts, and consult with the Administrator of the Health Resources and Services Administration and other advisors as the Director determines to be appropriate;

(2) have broad discretion in the allocation of any Initiative assistance among the Institutes, among types of grants, and between basic and clinical research so long as the assistance is directly related to the illnesses and conditions of children; and

(3) be responsible for the oversight of any newly appropriated Initiative funds and annually report to Congress and the public on the extent of the total funds obligated to conduct or support pediatric research across the National Institutes of Health, including the specific support and research awards allocated through the Initiative.

(d) National Pediatric Research Network

(1) Network

In carrying out the Initiative, the Director of NIH, in collaboration with the national research institutes and national centers that carry out activities involving pediatric research, shall support a National Pediatric Research Network in order to more effectively support pediatric research and optimize the use of Federal resources. Such National Pediatric Research Network may be comprised of, as appropriate—

(A) the pediatric research consortia receiving awards under paragraph (2); or

(B) other consortia, centers, or networks focused on pediatric research that are recognized by the Director of NIH and established pursuant to the authorities vested in the National Institutes of Health by other sections of this chapter.

(2) Pediatric research consortia

(A) In general

The Director of NIH shall award funding, including through grants, contracts, or other mechanisms, to public or private nonprofit entities for providing support for pediatric research consortia, including with respect to—

(i) basic, clinical, behavioral, or translational research to meet unmet needs for pediatric research; and

(ii) training researchers in pediatric research techniques in order to address unmet pediatric research needs.

(B) Research

The Director of NIH shall, as appropriate, ensure that—

(i) each consortium receiving an award under subparagraph (A) conducts or supports at least one category of research described in subparagraph (A)(i) and collectively such consortia conduct or support such categories of research; and

(ii) one or more such consortia provide training described in subparagraph (A)(ii).

(C) Organization of consortium

Each consortium receiving an award under subparagraph (A) shall—

(i) be formed from a collaboration of cooperating institutions;

(ii) be coordinated by a lead institution or institutions;

(iii) agree to disseminate scientific findings, including from clinical trials, rapidly and efficiently, as appropriate, to—

(I) other consortia;

(II) the National Institutes of Health;

(III) the Food and Drug Administration;

(IV) and [1] other relevant agencies; and

(iv) meet such requirements as may be prescribed by the Director of NIH.

(D) Supplement, not supplant

Any support received by a consortium under subparagraph (A) shall be used to supplement, and not supplant, other public or private support for activities authorized to be supported under this paragraph.

(E) Duration of support

Support of a consortium under subparagraph (A) shall be for a period of not to exceed 5 years. Such period may be extended at the discretion of the Director of NIH.

(3) Coordination of consortia activities

The Director of NIH shall, as appropriate—

(A) provide for the coordination of activities (including the exchange of information and regular communication) among the consortia established pursuant to paragraph (2); and

(B) require the periodic preparation and submission to the Director of reports on the activities of each such consortium.

(4) Assistance with registries

Each consortium receiving an award under paragraph (2)(A) may provide assistance, as appropriate, to the Centers for Disease Control and Prevention for activities related to patient registries and other surveillance systems upon request by the Director of the Centers for Disease Control and Prevention.

(e) Research on pediatric rare diseases or conditions

In making awards under subsection (d)(2) for pediatric research consortia, the Director of NIH shall ensure that an appropriate number of such awards are awarded to such consortia that agree to—

(1) consider pediatric rare diseases or conditions, or those related to birth defects; and

(2) conduct or coordinate one or more multisite clinical trials of therapies for, or approaches to, the prevention, diagnosis, or treatment of one or more pediatric rare diseases or conditions.

(f) Transfer of funds

The Director of NIH may transfer amounts appropriated under this section to any of the Institutes for a fiscal year to carry out the purposes of the Initiative under this section.

(July 1, 1944, ch. 373, title IV, §409D, as added Pub. L. 106–310, div. A, title X, §1001, Oct. 17, 2000, 114 Stat. 1127; amended Pub. L. 109–482, title I, §103(b)(10), Jan. 15, 2007, 120 Stat. 3687; Pub. L. 110–154, §1(b)(4), Dec. 21, 2007, 121 Stat. 1827; Pub. L. 113–55, title II, §202, Nov. 27, 2013, 127 Stat. 644; Pub. L. 114–255, div. A, title II, §2071, Dec. 13, 2016, 130 Stat. 1083.)

EDITORIAL NOTES

CODIFICATION

Another section 409D of act July 1, 1944, was renumbered section 409H and is classified to section 284l of this title.

AMENDMENTS

2016—Subsec. (d)(1). Pub. L. 114–255, §2071(1), substituted "in collaboration with the national research institutes and national centers that carry out activities involving pediatric research, shall support" for "in consultation with the Director of the Eunice Kennedy Shriver National Institute of Child Health and Human Development and in collaboration with other appropriate national research institutes and national centers that carry out activities involving pediatric research, may provide for the establishment of" in introductory provisions.

Subsec. (d)(2)(A), (E). Pub. L. 114–255, §2071(2), substituted "shall" for "may" in introductory provisions of par. (2)(A) and in first sentence of par. (2)(E).

2013—Subsecs. (d) to (f). Pub. L. 113–55 added subsecs. (d) and (e) and redesignated former subsec. (d) as (f).

2007—Subsec. (c)(1). Pub. L. 110–154 substituted "Eunice Kennedy Shriver National Institute of Child Health and Human Development" for "National Institute of Child Health and Human Development".

Subsecs. (d), (e). Pub. L. 109–482 redesignated subsec. (e) as (d) and struck out heading and text of former subsec. (d). Text read as follows: "For the purpose of carrying out this section, there are authorized to be appropriated $50,000,000 for fiscal year 2001, and such sums as may be necessary for each of the fiscal years 2002 through 2005."

STATUTORY NOTES AND RELATED SUBSIDIARIES

EFFECTIVE DATE OF 2007 AMENDMENT

Amendment by Pub. L. 109–482 applicable only with respect to amounts appropriated for fiscal year 2007 or subsequent fiscal years, see section 109 of Pub. L. 109–482, set out as a note under section 281 of this title.

[1] So in original. The word "and" probably should appear at end of subcl. (III).

§284i. Autoimmune diseases

(a) Expansion, intensification, and coordination of activities

(1) In general

The Director of NIH shall expand, intensify, and coordinate research and other activities of the National Institutes of Health with respect to autoimmune diseases.

(2) Allocations by Director of NIH

With respect to amounts appropriated to carry out this section for a fiscal year, the Director of NIH shall allocate the amounts among the national research institutes that are carrying out paragraph (1).

(3) Definition

The term "autoimmune disease" includes, for purposes of this section such diseases or disorders with evidence of autoimmune pathogensis [1] as the Secretary determines to be appropriate.

(b) Coordinating Committee

(1) In general

The Secretary shall ensure that the Autoimmune Diseases Coordinating Committee (referred to in this section as the "Coordinating Committee") coordinates activities across the National Institutes and with other Federal health programs and activities relating to such diseases.

(2) Composition

The Coordinating Committee shall be composed of the directors or their designees of each of the national research institutes involved in research with respect to autoimmune diseases and representatives of all other Federal departments and agencies whose programs involve health functions or responsibilities relevant to such diseases, including the Centers for Disease Control and Prevention and the Food and Drug Administration.

(3) Chair

(A) In general

With respect to autoimmune diseases, the Chair of the Committee shall serve as the principal advisor to the Secretary, the Assistant Secretary for Health, and the Director of NIH, and shall provide advice to the Director of the Centers for Disease Control and Prevention, the Commissioner of Food and Drugs, and other relevant agencies.

(B) Director of NIH

The Chair of the Committee shall be directly responsible to the Director of NIH.

(c) Plan for NIH activities

(1) In general

Not later than 1 year after October 17, 2000, the Coordinating Committee shall develop a plan for conducting and supporting research and education on autoimmune diseases through the national research institutes and shall periodically review and revise the plan. The plan shall—

(A) provide for a broad range of research and education activities relating to biomedical, psychosocial, and rehabilitative issues, including studies of the disproportionate impact of such diseases on women;

(B) identify priorities among the programs and activities of the National Institutes of Health regarding such diseases; and

(C) reflect input from a broad range of scientists, patients, and advocacy groups.

(2) Certain elements of plan

The plan under paragraph (1) shall, with respect to autoimmune diseases, provide for the following as appropriate:

(A) Research to determine the reasons underlying the incidence and prevalence of the diseases.

(B) Basic research concerning the etiology and causes of the diseases.

(C) Epidemiological studies to address the frequency and natural history of the diseases, including any differences among the sexes and among racial and ethnic groups.

(D) The development of improved screening techniques.

(E) Clinical research for the development and evaluation of new treatments, including new biological agents.

(F) Information and education programs for health care professionals and the public.

(3) Implementation of plan

The Director of NIH shall ensure that programs and activities of the National Institutes of Health regarding autoimmune diseases are implemented in accordance with the plan under paragraph (1).

(July 1, 1944, ch. 373, title IV, §409E, as added Pub. L. 106–310, div. A, title XIX, §1901, Oct. 17, 2000, 114 Stat. 1153; amended Pub. L. 109–482, title I, §§103(b)(11), 104(b)(1)(E), Jan. 15, 2007, 120 Stat. 3687, 3693.)

EDITORIAL NOTES

AMENDMENTS

2007—Subsec. (d). Pub. L. 109–482, §104(b)(1)(E), struck out heading and text of subsec. (d). Text read as follows: "The Coordinating Committee under subsection (b)(1) of this section shall biennially submit to the Committee on Commerce of the House of Representatives, and the Committee on Health, Education, Labor and Pensions of the Senate, a report that describes the research, education, and other activities on autoimmune diseases being conducted or supported through the national research institutes, and that in addition includes the following:

"(1) The plan under subsection (c)(1) of this section (or revisions to the plan, as the case may be).

"(2) Provisions specifying the amounts expended by the National Institutes of Health with respect to each of the autoimmune diseases included in the plan.

"(3) Provisions identifying particular projects or types of projects that should in the future be considered by the national research institutes or other entities in the field of research on autoimmune diseases."

Subsec. (e). Pub. L. 109–482, §103(b)(11), struck out heading and text of subsec. (e). Text read as follows: "For the purpose of carrying out this section, there are authorized to be appropriated such sums as may be necessary for each of the fiscal years 2001 through 2005. The authorization of appropriations established in the preceding sentence is in addition to any other authorization of appropriations that is available for conducting or supporting through the National Institutes of Health research and other activities with respect to autoimmune diseases."

STATUTORY NOTES AND RELATED SUBSIDIARIES

EFFECTIVE DATE OF 2007 AMENDMENT

Amendment by Pub. L. 109–482 applicable only with respect to amounts appropriated for fiscal year 2007 or subsequent fiscal years, see section 109 of Pub. L. 109–482, set out as a note under section 281 of this title.

[1] So in original. Probably should be "pathogenesis".

§284j. Muscular dystrophy research

(a) Coordination of activities

The Director of NIH shall expand and increase coordination in the activities of the National Institutes of Health with respect to research on muscular dystrophies, including Duchenne muscular dystrophy.

(b) Administration of program; collaboration among agencies

The Director of NIH shall carry out this section through the appropriate institutes, including the National Institute of Neurological Disorders and Stroke and in collaboration with any other agencies that the Director determines appropriate.

(July 1, 1944, ch. 373, title IV, §409F, as added Pub. L. 106–310, div. A, title XXII, §2201, Oct. 17, 2000, 114 Stat. 1157; amended Pub. L. 109–482, title I, §103(b)(12), Jan. 15, 2007, 120 Stat. 3687.)

EDITORIAL NOTES

AMENDMENTS

2007—Subsec. (c). Pub. L. 109–482 struck out heading and text of subsec. (c). Text read as follows: "There are authorized to be appropriated such sums as may be necessary to carry out this section for each of the fiscal years 2001 through 2005. Amounts appropriated under this subsection shall be in addition to any other amounts appropriated for such purpose."

STATUTORY NOTES AND RELATED SUBSIDIARIES

EFFECTIVE DATE OF 2007 AMENDMENT

Amendment by Pub. L. 109–482 applicable only with respect to amounts appropriated for fiscal year 2007 or subsequent fiscal years, see section 109 of Pub. L. 109–482, set out as a note under section 281 of this title.

§284k. Clinical research

(a) In general

The Director of National Institutes of Health shall undertake activities to support and expand the involvement of the National Institutes of Health in clinical research.

(b) Requirements

In carrying out subsection (a), the Director of National Institutes of Health shall—

(1) consider the recommendations of the Division of Research Grants Clinical Research Study Group and other recommendations for enhancing clinical research; and

(2) establish intramural and extramural clinical research fellowship programs directed specifically at medical and dental students and a continuing education clinical research training program at the National Institutes of Health.

(c) Support for the diverse needs of clinical research

The Director of National Institutes of Health, in cooperation with the Directors of the Institutes, Centers, and Divisions of the National Institutes of Health, shall support and expand the resources available for the diverse needs of the clinical research community, including inpatient, outpatient, and critical care clinical research.

(d) Peer review

The Director of National Institutes of Health shall establish peer review mechanisms to evaluate applications for the awards and fellowships provided for in subsection (b)(2) and section 284l of this title. Such review mechanisms shall include individuals who are exceptionally qualified to appraise the merits of potential clinical research training and research grant proposals.

(July 1, 1944, ch. 373, title IV, §409G, formerly §409C, as added Pub. L. 106–505, title II, §203, Nov. 13, 2000, 114 Stat. 2326; renumbered §409G, Pub. L. 107–109, §3(1), Jan. 4, 2002, 115 Stat. 1408.)

EDITORIAL NOTES

REFERENCES IN TEXT

Section 284l of this title, referred to in subsec. (d), was in the original "section 409D", and was translated as meaning section 409D of act July 1, 1944, ch. 373, as added by section 204(b) of Pub. L. 106–505. Such section 409D was renumbered section 409H of act July 1, 1944, ch. 373, by Pub. L. 107–109, §3(2), Jan. 4, 2002, 115 Stat. 1408. Another section 409D of act July 1, 1944, ch. 373, as added by section 1001 of Pub. L. 106–310, is classified to section 284h of this title.

STATUTORY NOTES AND RELATED SUBSIDIARIES

FINDINGS AND PURPOSE

Pub. L. 106–505, title II, §202, Nov. 13, 2000, 114 Stat. 2325, provided that:

"(a) FINDINGS.—Congress makes the following findings:

"(1) Clinical research is critical to the advancement of scientific knowledge and to the development of cures and improved treatment for disease.

"(2) Tremendous advances in biology are opening doors to new insights into human physiology, pathophysiology and disease, creating extraordinary opportunities for clinical research.

"(3) Clinical research includes translational research which is an integral part of the research process leading to general human applications. It is the bridge between the laboratory and new methods of diagnosis, treatment, and prevention and is thus essential to progress against cancer and other diseases.

"(4) The United States will spend more than $1,200,000,000,000 on health care in 1999, but the Federal budget for health research at the National Institutes of Health was $15,600,000,000 only 1 percent of that total.

"(5) Studies at the Institute of Medicine, the National Research Council, and the National Academy of Sciences have all addressed the current problems in clinical research.

"(6) The Director of the National Institutes of Health has recognized the current problems in clinical research and appointed a special panel, which recommended expanded support for existing National Institutes of Health clinical research programs and the creation of new initiatives to recruit and retain clinical investigators.

"(7) The current level of training and support for health professionals in clinical research is fragmented, undervalued, and underfunded.

"(8) Young investigators are not only apprentices for future positions but a crucial source of energy, enthusiasm, and ideas in the day-to-day research that constitutes the scientific enterprise. Serious questions about the future of life-science research are raised by the following:

"(A) The number of young investigators applying for grants dropped by 54 percent between 1985 and 1993.

"(B) The number of physicians applying for first-time National Institutes of Health research project grants fell from 1226 in 1994 to 963 in 1998, a 21 percent reduction.

"(C) Newly independent life-scientists are expected to raise funds to support their new research programs and a substantial proportion of their own salaries.

"(9) The following have been cited as reasons for the decline in the number of active clinical

researchers, and those choosing this career path:

"(A) A medical school graduate incurs an average debt of $85,619, as reported in the Medical School Graduation Questionnaire by the Association of American Medical Colleges (AAMC).

"(B) The prolonged period of clinical training required increases the accumulated debt burden.

"(C) The decreasing number of mentors and role models.

"(D) The perceived instability of funding from the National Institutes of Health and other Federal agencies.

"(E) The almost complete absence of clinical research training in the curriculum of training grant awardees.

"(F) Academic Medical Centers are experiencing difficulties in maintaining a proper environment for research in a highly competitive health care marketplace, which are compounded by the decreased willingness of third party payers to cover health care costs for patients engaged in research studies and research procedures.

"(10) In 1960, general clinical research centers were established under the Office of the Director of the National Institutes of Health with an initial appropriation of $3,000,000.

"(11) Appropriations for general clinical research centers in fiscal year 1999 equaled $200,500,000.

"(12) Since the late 1960s, spending for general clinical research centers has declined from approximately 3 percent to 1 percent of the National Institutes of Health budget.

"(13) In fiscal year 1999, there were 77 general clinical research centers in operation, supplying patients in the areas in which such centers operate with access to the most modern clinical research and clinical research facilities and technologies.

"(b) PURPOSE.—It is the purpose of this title [see Short Title of 2000 Amendments note set out under section 201 of this title] to provide additional support for and to expand clinical research programs."

OVERSIGHT BY GAO

Pub. L. 106–505, title II, §207, Nov. 13, 2000, 114 Stat. 2330, provided that, not later than 18 months after Nov. 13, 2000, the Comptroller General was to submit to Congress a report describing the extent to which the National Institutes of Health had complied with the amendments made by title II of Pub. L. 106–505.

§284*l*. Enhancement awards

(a) Mentored Patient-Oriented Research Career Development Awards

(1) Grants

(A) In general

The Director of the National Institutes of Health shall make grants (to be referred to as "Mentored Patient-Oriented Research Career Development Awards") to support individual careers in clinical research at general clinical research centers or at other institutions that have the infrastructure and resources deemed appropriate for conducting patient-oriented clinical research.

(B) Use

Grants under subparagraph (A) shall be used to support clinical investigators in the early phases of their independent careers by providing salary and such other support for a period of supervised study.

(2) Applications

An application for a grant under this subsection shall be submitted by an individual scientist at such time as the Director may require.

(b) Mid-Career Investigator Awards in Patient-Oriented Research

(1) Grants

(A) In general

The Director of the National Institutes of Health shall make grants (to be referred to as "Mid-Career Investigator Awards in Patient-Oriented Research") to support individual clinical

research projects at general clinical research centers or at other institutions that have the infrastructure and resources deemed appropriate for conducting patient-oriented clinical research.

(B) Use

Grants under subparagraph (A) shall be used to provide support for mid-career level clinicians to allow such clinicians to devote time to clinical research and to act as mentors for beginning clinical investigators.

(2) Applications

An application for a grant under this subsection shall be submitted by an individual scientist at such time as the Director requires.

(c) Graduate Training in Clinical Investigation Award

(1) In general

The Director of the National Institutes of Health shall make grants (to be referred to as "Graduate Training in Clinical Investigation Awards") to support individuals pursuing master's or doctoral degrees in clinical investigation.

(2) Applications

An application for a grant under this subsection shall be submitted by an individual scientist at such time as the Director may require.

(3) Limitations

Grants under this subsection shall be for terms of 2 years or more and shall provide stipend, tuition, and institutional support for individual advanced degree programs in clinical investigation.

(4) Definition

As used in this subsection, the term "advanced degree programs in clinical investigation" means programs that award a master's or Ph.D. degree in clinical investigation after 2 or more years of training in areas such as the following:

(A) Analytical methods, biostatistics, and study design.
(B) Principles of clinical pharmacology and pharmacokinetics.
(C) Clinical epidemiology.
(D) Computer data management and medical informatics.
(E) Ethical and regulatory issues.
(F) Biomedical writing.

(d) Clinical Research Curriculum Awards

(1) In general

The Director of the National Institutes of Health shall make grants (to be referred to as "Clinical Research Curriculum Awards") to institutions for the development and support of programs of core curricula for training clinical investigators, including medical students. Such core curricula may include training in areas such as the following:

(A) Analytical methods, biostatistics, and study design.
(B) Principles of clinical pharmacology and pharmacokinetics.
(C) Clinical epidemiology.
(D) Computer data management and medical informatics.
(E) Ethical and regulatory issues.
(F) Biomedical writing.

(2) Applications

An application for a grant under this subsection shall be submitted by an individual institution or a consortium of institutions at such time as the Director may require. An institution may submit only one such application.

(3) Limitations

Grants under this subsection shall be for terms of up to 5 years and may be renewable.

(July 1, 1944, ch. 373, title IV, §409H, formerly §409D, as added Pub. L. 106–505, title II, §204(b), Nov. 13, 2000, 114 Stat. 2327; renumbered §409H, Pub. L. 107–109, §3(2), Jan. 4, 2002, 115 Stat. 1408; amended Pub. L. 109–482, title I, §103(b)(13), Jan. 15, 2007, 120 Stat. 3687.)

EDITORIAL NOTES

AMENDMENTS

2007—Subsec. (a)(3). Pub. L. 109–482, §103(b)(13)(A), struck out heading and text of par. (3). Text read as follows: "For the purpose of carrying out this subsection, there are authorized to be appropriated such sums as may be necessary for each fiscal year."

Subsec. (b)(3). Pub. L. 109–482, §103(b)(13)(B), struck out heading and text of par. (3). Text read as follows: "For the purpose of carrying out this subsection, there are authorized to be appropriated such sums as may be necessary for each fiscal year."

Subsec. (c)(5). Pub. L. 109–482, §103(b)(13)(C), struck out heading and text of par. (5). Text read as follows: "For the purpose of carrying out this subsection, there are authorized to be appropriated such sums as may be necessary for each fiscal year."

Subsec. (d)(4). Pub. L. 109–482, §103(b)(13)(D), struck out heading and text of par. (4). Text read as follows: "For the purpose of carrying out this subsection, there are authorized to be appropriated such sums as may be necessary for each fiscal year."

STATUTORY NOTES AND RELATED SUBSIDIARIES

EFFECTIVE DATE OF 2007 AMENDMENT

Amendment by Pub. L. 109–482 applicable only with respect to amounts appropriated for fiscal year 2007 or subsequent fiscal years, see section 109 of Pub. L. 109–482, set out as a note under section 281 of this title.

§284m. Program for pediatric studies of drugs

(a) List of priority issues in pediatric therapeutics

(1) In general

Not later than one year after September 27, 2007, the Secretary, acting through the Director of the National Institutes of Health and in consultation with the Commissioner of Food and Drugs and experts in pediatric research, shall develop and publish a priority list of needs in pediatric therapeutics, including drugs, biological products, or indications that require study. The list shall be revised every three years.

(2) Consideration of available information

In developing and prioritizing the list under paragraph (1), the Secretary—

(A) shall consider—

(i) therapeutic gaps in pediatrics that may include developmental pharmacology, pharmacogenetic determinants of drug response, metabolism of drugs and biologics in children, and pediatric clinical trials;

(ii) particular pediatric diseases, disorders or conditions where more complete knowledge and testing of therapeutics, including drugs and biologics, and identification of biomarkers for such diseases, disorders, or conditions, may be beneficial in pediatric populations; and

(iii) the adequacy of necessary infrastructure to conduct pediatric pharmacological research, including research networks and trained pediatric investigators; and

(B) may consider the availability of qualified countermeasures (as defined in section 247d–6a of this title), security countermeasures (as defined in section 247d–6b of this title), and qualified pandemic or epidemic products (as defined in section 247d–6d of this title) to address the needs

of pediatric populations, in consultation with the Assistant Secretary for Preparedness and Response, consistent with the purposes of this section.

(b) Pediatric studies and research

The Secretary, acting through the National Institutes of Health, shall award funds to entities that have the expertise to conduct pediatric clinical trials or other research (including qualified universities, hospitals, laboratories, contract research organizations, practice groups, federally funded programs such as pediatric pharmacology research units, other public or private institutions, or individuals) to enable the entities to conduct the drug studies or other research on the issues described in paragraphs (1) and (2)(A) of subsection (a). The Secretary may use contracts, grants, or other appropriate funding mechanisms to award funds under this subsection.

(c) Process for proposed pediatric study requests and labeling changes

(1) Submission of proposed pediatric study request

The Director of the National Institutes of Health shall, as appropriate, submit proposed pediatric study requests for consideration by the Commissioner of Food and Drugs for pediatric studies of a specific pediatric indication identified under subsection (a). Such a proposed pediatric study request shall be made in a manner equivalent to a written request made under subsection (b) or (c) of section 505A of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 355a], or section 262(m) of this title, including with respect to the information provided on the pediatric studies to be conducted pursuant to the request. The Director of the National Institutes of Health may submit a proposed pediatric study request for a drug for which—

(A)(i) there is an approved application under section 505(j) of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 355(j)] or section 262(k) of this title; or

(ii) there is a submitted application that could be approved under the criteria of such section; and

(B) there remains no patent listed pursuant to section 505(b)(1) of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 355(b)(1)], and every three-year and five-year period referred to in subsection (c)(3)(E)(ii), (c)(3)(E)(iii), (c)(3)(E)(iv), (j)(5)(F)(ii), (j)(5)(F)(iii), or (j)(5)(F)(iv) of section 505 of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 355], or applicable twelve-year period referred to in section 262(k)(7) of this title, and any seven-year period referred to in section 527 of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 360cc] has ended for at least one form of the drug; and

(C) additional studies are needed to assess the safety and effectiveness of the use of the drug in the pediatric population.

(2) Written request to holders of approved applications

The Commissioner of Food and Drugs, in consultation with the Director of the National Institutes of Health, may issue a written request based on the proposed pediatric study request for the indication or indications submitted pursuant to paragraph (1) (which shall include a timeframe for negotiations for an agreement) for pediatric studies concerning a drug identified under subsection (a) to all holders of an approved application for the drug. Such a written request shall be made in a manner equivalent to the manner in which a written request is made under subsection (b) or (c) of section 505A of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 355a] or section 262(m) of this title, including with respect to information provided on the pediatric studies to be conducted pursuant to the request and using appropriate formulations for each age group for which the study is requested.

(3) Requests for proposals

If the Commissioner of Food and Drugs does not receive a response to a written request issued under paragraph (2) not later than 30 days after the date on which a request was issued, the Secretary, acting through the Director of the National Institutes of Health and in consultation with the Commissioner of Food and Drugs, shall publish a request for proposals to conduct the pediatric studies described in the written request in accordance with subsection (b).

(4) Disqualification

A holder that receives a first right of refusal shall not be entitled to respond to a request for proposals under paragraph (3).

(5) Contracts, grants, or other funding mechanisms

A contract, grant, or other funding may be awarded under this section only if a proposal is submitted to the Secretary in such form and manner, and containing such agreements, assurances, and information as the Secretary determines to be necessary to carry out this section.

(6) Reporting of studies

(A) In general

On completion of a pediatric study in accordance with an award under this section, a report concerning the study shall be submitted to the Director of the National Institutes of Health and the Commissioner of Food and Drugs. The report shall include all data generated in connection with the study, including a written request if issued.

(B) Availability of reports

(i) In general

Each report submitted under subparagraph (A) shall be considered to be in the public domain (subject to section 505A(d)(4) of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 355a(d)(4)]) and not later than 90 days after submission of such report, shall be—

(I) posted on the internet website of the National Institutes of Health in a manner that is accessible and consistent with all applicable Federal laws and regulations, including such laws and regulations for the protection of—

(aa) human research participants, including with respect to privacy, security, informed consent, and protected health information; and

(bb) proprietary interests, confidential commercial information, and intellectual property rights; and

(II) assigned a docket number by the Commissioner of Food and Drugs and made available for the submission of public comments.

(ii) Submission of comments

An interested person may submit written comments concerning such pediatric studies to the Commissioner of Food and Drugs, and the submitted comments shall become part of the docket file with respect to each of the drugs.

(C) Action by Commissioner

The Commissioner of Food and Drugs shall take action in a timely and appropriate manner in response to the reports submitted under subparagraph (A), and shall begin such action upon receipt of the report under subparagraph (A), in accordance with paragraph (7).

(7) Requests for labeling change

Within the 180-day period after the date on which a report is submitted under paragraph (6)(A), the Commissioner of Food and Drugs shall—

(A) review the report and such other data as are available concerning the safe and effective use in the pediatric population of the drug studied;

(B) negotiate with the holders of approved applications for the drug studied for any labeling changes that the Commissioner of Food and Drugs determines to be appropriate and requests the holders to make; and

(C)(i) include in the public docket file a reference to the location of the report on the internet website of the National Institutes of Health and a copy of any requested labeling changes; and

(ii) publish through a posting on the Web site of the Food and Drug Administration a summary of the report and a copy of any requested labeling changes.

(8) Dispute resolution

(A) Referral to Pediatric Advisory Committee

If, not later than the end of the 180-day period specified in paragraph (7), the holder of an approved application for the drug involved does not agree to any labeling change requested by the Commissioner of Food and Drugs under that paragraph, the Commissioner of Food and Drugs shall refer the request to the Pediatric Advisory Committee.

(B) Action by the Pediatric Advisory Committee

Not later than 90 days after receiving a referral under subparagraph (A), the Pediatric Advisory Committee shall—

(i) review the available information on the safe and effective use of the drug in the pediatric population, including study reports submitted under this section; and

(ii) make a recommendation to the Commissioner of Food and Drugs as to appropriate labeling changes, if any.

(9) FDA determination

Not later than 30 days after receiving a recommendation from the Pediatric Advisory Committee under paragraph (8)(B)(ii) with respect to a drug, the Commissioner of Food and Drugs shall consider the recommendation and, if appropriate, make a request to the holders of approved applications for the drug to make any labeling change that the Commissioner of Food and Drugs determines to be appropriate.

(10) Failure to agree

If a holder of an approved application for a drug, within 30 days after receiving a request to make a labeling change under paragraph (9), does not agree to make a requested labeling change, the Commissioner of Food and Drugs may deem the drug to be misbranded under the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 301 et seq.].

(11) No effect on authority

Nothing in this subsection limits the authority of the United States to bring an enforcement action under the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 301 et seq.] when a drug lacks appropriate pediatric labeling. Neither course of action (the Pediatric Advisory Committee process or an enforcement action referred to in the preceding sentence) shall preclude, delay, or serve as the basis to stay the other course of action.

(d) Authorization of appropriations

(1) In general

There are authorized to be appropriated to carry out this section, $25,000,000 for each of fiscal years 2026 through 2028.

(2) Availability

Any amount appropriated under paragraph (1) shall remain available to carry out this section until expended.

(July 1, 1944, ch. 373, title IV, §409I, as added Pub. L. 107–109, §3(3), Jan. 4, 2002, 115 Stat. 1408; amended Pub. L. 108–155, §3(b)(6), Dec. 3, 2003, 117 Stat. 1942; Pub. L. 109–482, title I, §103(b)(14), Jan. 15, 2007, 120 Stat. 3687; Pub. L. 110–85, title V, §502(b), Sept. 27, 2007, 121 Stat. 886; Pub. L. 111–148, title VII, §7002(g)(2)(A), Mar. 23, 2010, 124 Stat. 820; Pub. L. 112–144, title V, §§507(d), 509(d), July 9, 2012, 126 Stat. 1045, 1049; Pub. L. 113–5, title III, §307(b), Mar. 13, 2013, 127 Stat. 192; Pub. L. 115–52, title V, §501, Aug. 18, 2017, 131 Stat. 1036; Pub. L. 117–180, div. F, title V, §5001, Sept. 30, 2022, 136 Stat. 2167; Pub. L. 117–229, div. C, title III, §302, Dec. 16, 2022, 136 Stat. 2312; Pub. L. 117–328, div. FF, title III, §3102, Dec. 29, 2022, 136 Stat. 5807; Pub. L. 119–75, div. J, title V, §6504, Feb. 3, 2026, 140 Stat. 692.)

EDITORIAL NOTES

REFERENCES IN TEXT

The Federal Food, Drug, and Cosmetic Act, referred to in subsec. (c)(10), (11), is act June 25, 1938, ch. 675, 52 Stat. 1040, which is classified generally to chapter 9 (§301 et seq.) of Title 21, Food and Drugs. For complete classification of this Act to the Code, see section 301 of Title 21 and Tables.

AMENDMENTS

2026—Subsec. (d)(1). Pub. L. 119–75 substituted "section, $25,000,000 for each of fiscal years 2026 through 2028." for "section, $5,753,425 for the period beginning on October 1, 2022 and ending on December 23, 2022."

2022—Subsec. (d)(1). Pub. L. 117–328, which directed the substitution of "$25,000,000 for each of fiscal years 2023 through 2027" for "$5,273,973 for the period beginning on October 1, 2022 and ending on December 23, 2022", could not be executed because "$5,273,973" did not appear after the intervening amendment by Pub. L. 117–229. See below.

Pub. L. 117–229 substituted "$5,753,425 for the period beginning on October 1, 2022 and ending on December 23, 2022" for "$5,273,973 for the period beginning on October 1, 2022 and ending on December 16, 2022".

Pub. L. 117–180 substituted "$5,273,973 for the period beginning on October 1, 2022 and ending on December 16, 2022" for "$25,000,000 for each of fiscal years 2018 through 2022".

2017—Subsec. (a)(2)(A)(ii). Pub. L. 115–52, §501(1), inserted "and identification of biomarkers for such diseases, disorders, or conditions," after "biologics,".

Subsec. (c)(6)(B). Pub. L. 115–52, §501(2)(A)(i), amended subpar. (B) generally. Prior to amendment, text read as follows: "Each report submitted under subparagraph (A) shall be considered to be in the public domain (subject to section 505A(d)(4) of the Federal Food, Drug, and Cosmetic Act) and shall be assigned a docket number by the Commissioner of Food and Drugs. An interested person may submit written comments concerning such pediatric studies to the Commissioner of Food and Drugs, and the written comments shall become part of the docket file with respect to each of the drugs."

Subsec. (c)(6)(C). Pub. L. 115–52, §501(2)(A)(ii), substituted "action in a timely and appropriate manner in response to the reports submitted under subparagraph (A), and shall begin such action upon receipt of the report under subparagraph (A), in accordance with paragraph (7)." for "appropriate action in response to the reports submitted under subparagraph (A) in accordance with paragraph (7)."

Subsec. (c)(7). Pub. L. 115–52, §501(2)(B)(i), substituted "Within" for "During" in introductory provisions.

Subsec. (c)(7)(C)(i). Pub. L. 115–52, §501(2)(B)(ii), substituted "include in the public docket file a reference to the location of the report on the internet website of the National Institutes of Health and a copy of" for "place in the public docket file a copy of the report and of".

Subsec. (c)(7)(C)(ii). Pub. L. 115–52, §501(2)(B)(iii), struck out "in the Federal Register and" after "publish".

Subsec. (d). Pub. L. 115–52, §501(3), (4), redesignated subsec. (e) as (d) and struck out former subsec. (d). Prior to amendment, text of subsec. (d) read as follows: "Not later than one year after September 27, 2007, the Secretary, acting through the Director of the National Institutes of Health, shall study the feasibility of establishing a compilation of information on pediatric drug use and report the findings to Congress."

Subsec. (d)(1). Pub. L. 115–52, §501(5), substituted "2018 through 2022" for "2013 through 2017".

Subsec. (e). Pub. L. 115–52, §501(4), redesignated subsec. (e) as (d).

2013—Subsec. (a)(2). Pub. L. 113–5, §307(b)(1), added par. (2) and struck out former par. (2). Prior to amendment, text read as follows: "In developing and prioritizing the list under paragraph (1), the Secretary shall consider—

"(A) therapeutic gaps in pediatrics that may include developmental pharmacology, pharmacogenetic determinants of drug response, metabolism of drugs and biologics in children, and pediatric clinical trials;

"(B) particular pediatric diseases, disorders or conditions where more complete knowledge and testing of therapeutics, including drugs and biologics, may be beneficial in pediatric populations; and

"(C) the adequacy of necessary infrastructure to conduct pediatric pharmacological research, including research networks and trained pediatric investigators."

Subsec. (b). Pub. L. 113–5, §307(b)(2), substituted "paragraphs (1) and (2)(A) of subsection (a)" for "subsection (a)".

2012—Subsec. (c)(1). Pub. L. 112–144, §509(d)(1)(A), inserted "or section 262(m) of this title," after "Cosmetic Act,".

Subsec. (c)(1)(A)(i). Pub. L. 112–144, §509(d)(1)(B), inserted "or section 262(k) of this title" after "Cosmetic Act".

Subsec. (c)(1)(B). Pub. L. 112–144, §509(d)(1)(C), amended subpar. (B) generally. Prior to amendment,

subpar. (B) read as follows: "there is no patent protection or market exclusivity protection for at least one form of the drug under the Federal Food, Drug, and Cosmetic Act; and".

Subsec. (c)(2). Pub. L. 112–144, §509(d)(2), struck out "for drugs lacking exclusivity" after "applications" in heading, and in text struck out "under section 505 of the Federal Food, Drug, and Cosmetic Act" after "for the drug" and substituted "505A of the Federal Food, Drug, and Cosmetic Act or section 262(m) of this title" for "505A of such Act".

Subsec. (e)(1). Pub. L. 112–144, §507(d), substituted "to carry out this section, $25,000,000 for each of fiscal years 2013 through 2017." for "to carry out this section—

"(A) $200,000,000 for fiscal year 2008; and

"(B) such sums as are necessary for each of the four succeeding fiscal years."

2010—Subsec. (a)(1). Pub. L. 111–148 inserted ", biological products," after "including drugs".

2007—Pub. L. 110–85 amended section generally. Prior to amendment, section related to development of list of drugs for which pediatric studies are needed, award of contracts for pediatric studies, process for requesting contract proposals to conduct certain pediatric studies, reporting of completed studies, requests for labeling changes and dispute resolution, and recommendation by the Secretary for formulation changes.

Subsec. (d). Pub. L. 109–482 struck out subsec. (d) which related to authorization and availability of appropriations.

2003—Subsec. (c)(8), (9), (11). Pub. L. 108–155 struck out "Advisory Subcommittee of the Anti-Infective Drugs" before "Advisory Committee" wherever appearing.

STATUTORY NOTES AND RELATED SUBSIDIARIES

EFFECTIVE DATE OF 2007 AMENDMENT

Amendment by Pub. L. 109–482 applicable only with respect to amounts appropriated for fiscal year 2007 or subsequent fiscal years, see section 109 of Pub. L. 109–482, set out as a note under section 281 of this title.

EFFECTIVE DATE OF 2003 AMENDMENT

Amendment by Pub. L. 108–155 effective Dec. 3, 2003, except as otherwise provided, see section 4 of Pub. L. 108–155, set out as an Effective Date note under section 355c of Title 21, Food and Drugs.

§284m–1. Pediatric Advisory Committee

(a) In general

The Secretary of Health and Human Services shall, under section 217a of this title or other appropriate authority, convene and consult an advisory committee on pediatric therapeutics (including drugs and biological products) and medical devices (referred to in this section as the "advisory committee").

(b) Purpose

(1) In general

The advisory committee shall advise and make recommendations to the Secretary, through the Commissioner of Food and Drugs, on matters relating to pediatric therapeutics (including drugs and biological products) and medical devices.

(2) Matters included

The matters referred to in paragraph (1) include—

(A) pediatric research conducted under sections 262, 284m, and 290b of this title and sections 351, 352, 355, 355a, 355c, 360(k), 360e, and 360j(m) of title 21;

(B) identification of research priorities related to therapeutics (including drugs and biological products) and medical devices for pediatric populations and the need for additional diagnostics and treatments for specific pediatric diseases or conditions;

(C) the ethics, design, and analysis of clinical trials related to pediatric therapeutics (including drugs and biological products) and medical devices; and

(D) the development of countermeasures (as defined in section 360bbb–4(a) of title 21) for pediatric populations.

(c) Composition

The advisory committee shall include representatives of pediatric health organizations, pediatric researchers, relevant patient and patient-family organizations, and other experts selected by the Secretary.

(d) Continuation of Operation of Committee

Notwithstanding section 1013 of title 5, the advisory committee shall continue to operate to carry out the advisory committee's responsibilities under sections 355a, 355c, and 360j(m) of title 21.

(Pub. L. 107–109, §14, Jan. 4, 2002, 115 Stat. 1419, as amended by Pub. L. 108–155, §3(b)(2), Dec. 3, 2003, 117 Stat. 1941; Pub. L. 110–85, title III, §306(b), title V, §502(d), Sept. 27, 2007, 121 Stat. 865, 889; Pub. L. 112–144, title V, §507(a), July 9, 2012, 126 Stat. 1045; Pub. L. 113–5, title III, §307(c), Mar. 13, 2013, 127 Stat. 192; Pub. L. 117–286, §4(a)(233), Dec. 27, 2022, 136 Stat. 4331.)

EDITORIAL NOTES

CODIFICATION

Section was formerly set out as a note under section 284m of this title.

Section was enacted as part of the Best Pharmaceuticals for Children Act, and not as part of the Public Health Service Act which comprises this chapter.

AMENDMENTS

2022—Subsec. (d). Pub. L. 117–286 substituted "section 1013 of title 5," for "section 14 of the Federal Advisory Committee Act,".

2013—Subsec. (b)(2)(D). Pub. L. 113–5 added subpar. (D).

2012—Subsec. (d). Pub. L. 112–144 substituted "to carry out the advisory committee's responsibilities under sections 355a, 355c, and 360j(m) of title 21" for "during the five-year period beginning on September 27, 2007".

2007—Subsec. (a). Pub. L. 110–85, §306(b)(1), inserted "(including drugs and biological products) and medical devices" after "therapeutics".

Subsec. (b)(1). Pub. L. 110–85, §306(b)(2)(A), inserted "(including drugs and biological products) and medical devices" after "therapeutics".

Subsec. (b)(2)(A). Pub. L. 110–85, §306(b)(2)(B)(i), substituted "355c, 360(k), 360e, and 360j(m)" for "and 355c".

Subsec. (b)(2)(B). Pub. L. 110–85, §306(b)(2)(B)(ii), added subpar. (B) and struck out former subpar. (B) which read as follows: "identification of research priorities related to pediatric therapeutics and the need for additional treatments of specific pediatric diseases or conditions; and".

Subsec. (b)(2)(C). Pub. L. 110–85, §306(b)(2)(B)(iii), inserted "(including drugs and biological products) and medical devices" after "therapeutics".

Subsec. (d). Pub. L. 110–85, §502(d), added subsec. (d).

2003—Pub. L. 108–155, §3(b)(2)(A), struck out "Pharmacology" after "Pediatric" in section catchline.

Subsec. (a). Pub. L. 108–155, §3(b)(2)(D), substituted "therapeutics" for "pharmacology".

Pub. L. 108–155, §3(b)(2)(B), inserted "or other appropriate authority" after "217a of this title".

Subsec. (b)(1). Pub. L. 108–155, §3(b)(2)(D), substituted "therapeutics" for "pharmacology".

Pub. L. 108–155, §3(b)(2)(C)(i), struck out "and in consultation with the Director of the National Institutes of Health" after "Commissioner of Food and Drugs".

Subsec. (b)(2). Pub. L. 108–155, §3(b)(2)(C)(ii), substituted "355a, and 355c" for "and 355a".

Subsec. (b)(2)(B), (C). Pub. L. 108–155, §3(b)(2)(D), substituted "therapeutics" for "pharmacology".

STATUTORY NOTES AND RELATED SUBSIDIARIES

EFFECTIVE DATE OF 2003 AMENDMENT

Amendment by Pub. L. 108–155 effective Dec. 3, 2003, except as otherwise provided, see section 4 of Pub. L. 108–155, set out as an Effective Date note under section 355c of Title 21, Food and Drugs.

§284n. Certain demonstration projects

(a) Bridging the sciences

(1) In general

From amounts to be appropriated under section 282a(b) of this title, the Secretary of Health and Human Services, acting through the Director of NIH, (in this subsection referred to as the "Secretary") in consultation with the Director of the National Science Foundation, the Secretary of Energy, and other agency heads when necessary, may allocate funds for the national research institutes and national centers to make grants for the purpose of improving the public health through demonstration projects for biomedical research at the interface between the biological, behavioral, and social sciences and the physical, chemical, mathematical, and computational sciences.

(2) Goals, priorities, and methods; interagency collaboration

The Secretary shall establish goals, priorities, and methods of evaluation for research under paragraph (1), and shall provide for interagency collaboration with respect to such research. In developing such goals, priorities, and methods, the Secretary shall ensure that—

(A) the research reflects the vision of innovation and higher risk with long-term payoffs; and

(B) the research includes a wide spectrum of projects, funded at various levels, with varying timeframes.

(3) Peer review

A grant may be made under paragraph (1) only if the application for the grant has undergone technical and scientific peer review under section 289a of this title and has been reviewed by the advisory council under section 282(k) of this title or has been reviewed by an advisory council composed of representatives from appropriate scientific disciplines who can fully evaluate the applicant.

(b) High-risk, high-reward research

(1) In general

From amounts to be appropriated under section 282a(b) of this title, the Secretary, acting through the Director of NIH, may allocate funds for the national research institutes and national centers to make awards of grants or contracts or to engage in other transactions for demonstration projects for high-impact, cutting-edge research that fosters scientific creativity and increases fundamental biological understanding leading to the prevention, diagnosis, and treatment of diseases and disorders. The head of a national research institute or national center may conduct or support such high-impact, cutting-edge research (with funds allocated under the preceding sentence or otherwise available for such purpose) if the institute or center gives notice to the Director of NIH beforehand and submits a report to the Director of NIH on an annual basis on the activities of the institute or center relating to such research.

(2) Special consideration

In carrying out the program under paragraph (1), the Director of NIH shall give special consideration to coordinating activities with national research institutes whose budgets are substantial relative to a majority of the other institutes.

(3) Administration of program

Activities relating to research described in paragraph (1) shall be designed by the Director of NIH or the head of a national research institute or national center, as applicable, to enable such research to be carried out with maximum flexibility and speed.

(4) Public-private partnerships

In providing for research described in paragraph (1), the Director of NIH or the head of a national research institute or national center, as applicable, shall seek to facilitate partnerships between public and private entities and shall coordinate when appropriate with the Foundation for

the National Institutes of Health.

(5) Peer review

A grant for research described in paragraph (1) may be made only if the application for the grant has undergone technical and scientific peer review under section 289a of this title and has been reviewed by the advisory council under section 282(k) of this title.

(c) Report to Congress

Not later than the end of fiscal year 2009, the Secretary, acting through the Director of NIH, shall conduct an evaluation of the activities under this section and submit a report to the Congress on the results of such evaluation.

(d) Definitions

For purposes of this section, the terms "Director of NIH", "national research institute", and "national center" have the meanings given such terms in section 281 of this title.

(Pub. L. 109–482, title I, §105, Jan. 15, 2007, 120 Stat. 3694.)

EDITORIAL NOTES

CODIFICATION

Section was enacted as part of the National Institutes of Health Reform Act of 2006, and not as part of the Public Health Service Act which comprises this chapter.

STATUTORY NOTES AND RELATED SUBSIDIARIES

EFFECTIVE DATE

Section applicable only with respect to amounts appropriated for fiscal year 2007 or subsequent fiscal years, see section 109 of Pub. L. 109–482, set out as an Effective Date of 2007 Amendment note under section 281 of this title.

§284*o*. Activities of the National Institutes of Health with respect to research on paralysis

(a) Coordination

The Director of the National Institutes of Health (referred to in this section and sections 280g–9 and 284p of this title as the "Director"), pursuant to the general authority of the Director, may develop mechanisms to coordinate the paralysis research and rehabilitation activities of the Institutes and Centers of the National Institutes of Health in order to further advance such activities and avoid duplication of activities.

(b) Christopher and Dana Reeve Paralysis Research Consortia

(1) In general

The Director may make awards of grants to public or private entities to pay all or part of the cost of planning, establishing, improving, and providing basic operating support for consortia in paralysis research. The Director shall designate each consortium funded through such grants as a Christopher and Dana Reeve Paralysis Research Consortium.

(2) Research

Each consortium under paragraph (1)—

(A) may conduct basic, translational, and clinical paralysis research;

(B) may focus on advancing treatments and developing therapies in paralysis research;

(C) may focus on one or more forms of paralysis that result from central nervous system trauma or stroke;

(D) may facilitate and enhance the dissemination of clinical and scientific findings; and

(E) may replicate the findings of consortia members or other researchers for scientific and translational purposes.

(3) Coordination of consortia; reports

The Director may, as appropriate, provide for the coordination of information among consortia under paragraph (1) and ensure regular communication among members of the consortia, and may require the periodic preparation of reports on the activities of the consortia and the submission of the reports to the Director.

(4) Organization of consortia

Each consortium under paragraph (1) may use the facilities of a single lead institution, or be formed from several cooperating institutions, meeting such requirements as may be prescribed by the Director.

(c) Public input

The Director may provide for a mechanism to educate and disseminate information on the existing and planned programs and research activities of the National Institutes of Health with respect to paralysis and through which the Director can receive comments from the public regarding such programs and activities.

(Pub. L. 111–11, title XIV, §14101, Mar. 30, 2009, 123 Stat. 1452.)

EDITORIAL NOTES

CODIFICATION

Section was enacted as part of the Christopher and Dana Reeve Paralysis Act, and also as part of the Omnibus Public Land Management Act of 2009, and not as part of the Public Health Service Act which comprises this chapter.

§284p. Activities of the National Institutes of Health with respect to research with implications for enhancing daily function for persons with paralysis

(a) In general

The Director, pursuant to the general authority of the Director, may make awards of grants to public or private entities to pay all or part of the costs of planning, establishing, improving, and providing basic operating support to multicenter networks of clinical sites that will collaborate to design clinical rehabilitation intervention protocols and measures of outcomes on one or more forms of paralysis that result from central nervous system trauma, disorders, or stroke, or any combination of such conditions.

(b) Research

A multicenter network of clinical sites funded through this section may—

(1) focus on areas of key scientific concern, including—

(A) improving functional mobility;

(B) promoting behavioral adaptation to functional losses, especially to prevent secondary complications;

(C) assessing the efficacy and outcomes of medical rehabilitation therapies and practices and assisting technologies;

(D) developing improved assistive technology to improve function and independence; and

(E) understanding whole body system responses to physical impairments, disabilities, and societal and functional limitations; and

(2) replicate the findings of network members or other researchers for scientific and translation purposes.

(c) Coordination of clinical trials networks; reports

The Director may, as appropriate, provide for the coordination of information among networks funded through this section and ensure regular communication among members of the networks, and may require the periodic preparation of reports on the activities of the networks and submission of reports to the Director.

(Pub. L. 111–11, title XIV, §14201, Mar. 30, 2009, 123 Stat. 1453.)

EDITORIAL NOTES

CODIFICATION

Section was enacted as part of the Christopher and Dana Reeve Paralysis Act, and also as part of the Omnibus Public Land Management Act of 2009, and not as part of the Public Health Service Act which comprises this chapter.

STATUTORY NOTES AND RELATED SUBSIDIARIES

DEFINITION OF "DIRECTOR"

"Director" as meaning the Director of the National Institutes of Health, see section 284o(a) of this title.

§284q. Pain research

(a) Research initiatives

(1) In general

The Director of NIH is encouraged to continue and expand, through the Pain Consortium, an aggressive program of basic and clinical research on the causes of and potential treatments for pain.

(2) Annual recommendations

Not less than annually, the Pain Consortium, in consultation with the Division of Program Coordination, Planning, and Strategic Initiatives, shall develop and submit to the Director of NIH recommendations on appropriate pain research initiatives that could be undertaken with funds reserved under section 282a(c)(1) of this title for the Common Fund or otherwise available for such initiatives.

(3) Definition

In this subsection, the term "Pain Consortium" means the Pain Consortium of the National Institutes of Health or a similar trans-National Institutes of Health coordinating entity designated by the Secretary for purposes of this subsection.

(b) Interagency Pain Research Coordinating Committee

(1) Establishment

The Secretary shall establish not later than 1 year after March 23, 2010, and as necessary maintain a committee, to be known as the Interagency Pain Research Coordinating Committee (in this section referred to as the "Committee"), to coordinate all efforts within the Department of Health and Human Services and other Federal agencies that relate to pain research.

(2) Membership

(A) In general

The Committee shall be composed of the following voting members:

(i) Not more than 7 voting Federal representatives appoint [1] by the Secretary from agencies that conduct pain care research and treatment.

(ii) 12 additional voting members appointed under subparagraph (B).

(B) Additional members

The Committee shall include additional voting members appointed by the Secretary as follows:

(i) 6 non-Federal members shall be appointed from among scientists, physicians, and other health professionals.

(ii) 6 members shall be appointed from members of the general public, who are representatives of leading research, advocacy, and service organizations for individuals with pain-related conditions.

(C) Nonvoting members

The Committee shall include such nonvoting members as the Secretary determines to be appropriate.

(3) Chairperson

The voting members of the Committee shall select a chairperson from among such members. The selection of a chairperson shall be subject to the approval of the Director of NIH.

(4) Meetings

The Committee shall meet at the call of the chairperson of the Committee or upon the request of the Director of NIH, but in no case less often than once each year.

(5) Duties

The Committee shall—

(A) develop a summary of advances in pain care research supported or conducted by the Federal agencies relevant to the diagnosis, prevention, treatment, and management of pain and diseases and disorders associated with pain, including information on best practices for the utilization of non-pharmacologic treatments, non-addictive medical products, and other drugs or devices approved or cleared by the Food and Drug Administration;

(B) identify critical gaps in basic and clinical research on—

(i) the symptoms and causes of pain, including the identification of relevant biomarkers and screening models and the epidemiology of acute and chronic pain;

(ii) the diagnosis, prevention, treatment, and management of acute and chronic pain, including with respect to non-pharmacologic treatments, non-addictive medical products, and other drugs or devices approved or cleared by the Food and Drug Administration; and

(iii) risk factors for, and early warning signs of, substance use disorders in populations with acute and chronic pain; and

(C) make recommendations to the Director of NIH—

(i) to ensure that the activities of the National Institutes of Health and other Federal agencies are free of unnecessary duplication of effort;

(ii) on how best to disseminate information on pain care and epidemiological data related to acute and chronic pain; and

(iii) on how to expand partnerships between public entities and private entities to expand collaborative, cross-cutting research.

(6) Report

The Secretary shall ensure that recommendations and actions taken by the Director with respect to the topics discussed at the meetings described in paragraph (4) are included in appropriate reports to Congress.

(7) Review

The Secretary shall review the necessity of the Committee at least once every 2 years.

(July 1, 1944, ch. 373, title IV, §409J, as added Pub. L. 111–148, title IV, §4305(b), Mar. 23, 2010, 124 Stat. 585; amended Pub. L. 115–271, title VII, §7042, Oct. 24, 2018, 132 Stat. 4016.)

EDITORIAL NOTES

AMENDMENTS

2018—Subsec. (b)(5)(A). Pub. L. 115–271, §7042(1)(A), substituted "treatment, and management of pain and diseases and disorders associated with pain, including information on best practices for the utilization of non-pharmacologic treatments, non-addictive medical products, and other drugs or devices approved or cleared by the Food and Drug Administration" for "and treatment of pain and diseases and disorders associated with pain".

Subsec. (b)(5)(B). Pub. L. 115–271, §7042(1)(B), substituted "on—" and cls. (i) to (iii) for "on the symptoms and causes of pain;".

Subsec. (b)(5)(C) to (E). Pub. L. 115–271, §7042(1)(C), added subpar. (C) and struck out former subpars. (C) to (E) which read as follows:

"(C) make recommendations to ensure that the activities of the National Institutes of Health and other Federal agencies are free of unnecessary duplication of effort;

"(D) make recommendations on how best to disseminate information on pain care; and

"(E) make recommendations on how to expand partnerships between public entities and private entities to expand collaborative, cross-cutting research."

Subsec. (b)(6), (7). Pub. L. 115–271, §7042(2), (3), added par. (6) and redesignated former par. (6) as (7).

[1] *So in original. Probably should be "appointed".*

§284q–1. NIH opioid research

(a) In general

The Director of the National Institutes of Health (referred to in this section as the "NIH") may intensify and coordinate fundamental, translational, and clinical research of the NIH with respect to—

(1) the understanding of pain;

(2) the discovery and development of therapies for chronic pain; and

(3) the development of alternatives to opioids for effective pain treatments.

(b) Priority and direction

The prioritization and direction of the Federally funded portfolio of pain research studies shall consider recommendations made by the Interagency Pain Research Coordinating Committee in concert with the Pain Management Best Practices Inter-Agency Task Force, and in accordance with the National Pain Strategy, the Federal Pain Research Strategy, and the NIH-Wide Strategic Plan for Fiscal Years 2016–2020, the latter of which calls for the relative burdens of individual diseases and medical disorders to be regarded as crucial considerations in balancing the priorities of the Federal research portfolio.

(Pub. L. 114–198, title I, §108, July 22, 2016, 130 Stat. 705.)

EDITORIAL NOTES

CODIFICATION

Section was enacted as part of the Comprehensive Addiction and Recovery Act of 2016, and not as part of the Public Health Service Act which comprises this chapter.

§284r. Basic research

(1) Developing policies

Not later than 2 years after December 13, 2016, the Director of the National Institutes of Health (referred to in this section as the "Director of the National Institutes of Health"), taking into consideration the recommendations developed under section 2039,[1] shall develop policies for

projects of basic research funded by National Institutes of Health to assess—

(A) relevant biological variables including sex, as appropriate; and

(B) how differences between male and female cells, tissues, or animals may be examined and analyzed.

(2) Revising policies

The Director of the National Institutes of Health may update or revise the policies developed under paragraph (1) as appropriate.

(3) Consultation and outreach

In developing, updating, or revising the policies under this section, the Director of the National Institutes of Health shall—

(A) consult with—

(i) the Office of Research on Women's Health;

(ii) the Office of Laboratory Animal Welfare; and

(iii) appropriate members of the scientific and academic communities; and

(B) conduct outreach to solicit feedback from members of the scientific and academic communities on the influence of sex as a variable in basic research, including feedback on when it is appropriate for projects of basic research involving cells, tissues, or animals to include both male and female cells, tissues, or animals.

(4) Additional requirements

The Director of the National Institutes of Health shall—

(A) ensure that projects of basic research funded by the National Institutes of Health are conducted in accordance with the policies developed, updated, or revised under this section, as applicable; and

(B) encourage that the results of such research, when published or reported, be disaggregated as appropriate with respect to the analysis of any sex differences.

(Pub. L. 114–255, div. A, title II, §2038(g), Dec. 13, 2016, 130 Stat. 1066.)

EDITORIAL NOTES

REFERENCES IN TEXT

Section 2039, referred to in par. (1), is section 2039 of Pub. L. 114–255, which is set out as a note under section 282 of this title.

CODIFICATION

Section was enacted as part of the 21st Century Cures Act, and not as part of the Public Health Service Act which comprises this chapter.

[1] *See References in Text note below.*

§284s. Tick-borne diseases

(a) In general

The Secretary of Health and Human Services (referred to in this section as "the Secretary") shall continue to conduct or support epidemiological, basic, translational, and clinical research related to vector-borne diseases, including tick-borne diseases.

(b) Reports

The Secretary shall ensure that each triennial report under section 283 of this title (as amended by section 2032) includes information on actions undertaken by the National Institutes of Health to carry out subsection (a) with respect to tick-borne diseases.

(c) Tick-Borne Diseases Working Group

(1) Establishment

The Secretary shall establish a working group, to be known as the Tick-Borne Disease Working Group (referred to in this section as the "Working Group"), comprised of representatives of appropriate Federal agencies and other non-Federal entities, to provide expertise and to review all efforts within the Department of Health and Human Services related to all tick-borne diseases, to help ensure interagency coordination and minimize overlap, and to examine research priorities.

(2) Responsibilities

The working group shall—

(A) not later than 2 years after December 13, 2016, develop or update a summary of—

(i) ongoing tick-borne disease research, including research related to causes, prevention, treatment, surveillance, diagnosis, diagnostics, duration of illness, and intervention for individuals with tick-borne diseases;

(ii) advances made pursuant to such research;

(iii) Federal activities related to tick-borne diseases, including—

(I) epidemiological activities related to tick-borne diseases; and

(II) basic, clinical, and translational tick-borne disease research related to the pathogenesis, prevention, diagnosis, and treatment of tick-borne diseases;

(iv) gaps in tick-borne disease research described in clause (iii)(II);

(v) the Working Group's meetings required under paragraph (4); and

(vi) the comments received by the Working Group;

(B) make recommendations to the Secretary regarding any appropriate changes or improvements to such activities and research; and

(C) solicit input from States, localities, and nongovernmental entities, including organizations representing patients, health care providers, researchers, and industry regarding scientific advances, research questions, surveillance activities, and emerging strains in species of pathogenic organisms.

(3) Membership

The members of the working group shall represent a diversity of scientific disciplines and views and shall be composed of the following members:

(A) Federal members

Seven Federal members, consisting of one or more representatives of each of the following:

(i) The Office of the Assistant Secretary for Health.

(ii) The Food and Drug Administration.

(iii) The Centers for Disease Control and Prevention.

(iv) The National Institutes of Health.

(v) Such other agencies and offices of the Department of Health and Human Services as the Secretary determines appropriate.

(B) Non–Federal public members

Seven non–Federal public members, consisting of representatives of the following categories:

(i) Physicians and other medical providers with experience in diagnosing and treating tick-borne diseases.

(ii) Scientists or researchers with expertise.

(iii) Patients and their family members.

(iv) Nonprofit organizations that advocate for patients with respect to tick-borne diseases.

(v) Other individuals whose expertise is determined by the Secretary to be beneficial to the functioning of the Working Group.

(4) Meetings

The Working Group shall meet not less than twice each year.

(5) Reporting

Not later than 2 years after December 13, 2016, and every 2 years thereafter until termination of the Working Group pursuant to paragraph (7), the Working Group shall—

(A) submit a report on its activities under paragraph (2)(A) and any recommendations under paragraph (2)(B) to the Secretary, the Committee on Energy and Commerce of the House of Representatives, and the Committee on Health, Education, Labor, and Pensions of the Senate; and

(B) make such report publicly available on the Internet website of the Department of Health and Human Services.

(6) Applicability of FACA

The Working Group shall be treated as an advisory committee subject to the Federal Advisory Committee Act (5 U.S.C. App.).[1]

(7) Sunset

The Working Group under this section shall terminate 6 years after December 13, 2016.

(Pub. L. 114–255, div. A, title II, §2062, Dec. 13, 2016, 130 Stat. 1079.)

EDITORIAL NOTES

REFERENCES IN TEXT

Section 2032, referred to in subsec. (b), means section 2032 of Pub. L. 114–255.

The Federal Advisory Committee Act, referred to in subsec. (c)(6), is Pub. L. 92–463, Oct. 6, 1972, 86 Stat. 770, which was set out in the Appendix to Title 5, Government Organization and Employees, and was substantially repealed and restated in chapter 10 (§1001 et seq.) of Title 5 by Pub. L. 117–286, §§3(a), 7, Dec. 27, 2022, 136 Stat. 4197, 4361. For disposition of sections of the Act into chapter 10 of Title 5, see Disposition Table preceding section 101 of Title 5.

CODIFICATION

Section was enacted as part of the 21st Century Cures Act, and not as part of the Public Health Service Act which comprises this chapter.

[1] *See References in Text note below.*

PART C—SPECIFIC PROVISIONS RESPECTING NATIONAL RESEARCH INSTITUTES

SUBPART 1—NATIONAL CANCER INSTITUTE

§285. Purpose of Institute

The general purpose of the National Cancer Institute (hereafter in this subpart referred to as the "Institute") is the conduct and support of research, training, health information dissemination, and other programs with respect to the cause, diagnosis, prevention, and treatment of cancer, rehabilitation from cancer, and the continuing care of cancer patients and the families of cancer patients.

(July 1, 1944, ch. 373, title IV, §410, as added Pub. L. 99–158, §2, Nov. 20, 1985, 99 Stat. 832; amended Pub. L. 100–607, title I, §121, Nov. 4, 1988, 102 Stat. 3054.)

EDITORIAL NOTES

AMENDMENTS

1988—Pub. L. 100–607 inserted ", rehabilitation from cancer," after "treatment of cancer".

EXECUTIVE DOCUMENTS

WHITE HOUSE CANCER MOONSHOT TASK FORCE

Memorandum of President of the United States, Jan. 28, 2016, 81 F.R. 5361, provided:

Memorandum for the Heads of Executive Departments and Agencies

Cancer is a leading cause of death, and cancer incidence is expected to increase worldwide in the coming decades. But today, cancer research is on the cusp of major breakthroughs. It is of critical national importance that we accelerate progress towards prevention, treatment, and a cure—to double the rate of progress in the fight against cancer—and put ourselves on a path to achieve in just 5 years research and treatment gains that otherwise might take a decade or more. To that end, I hereby direct the following:

SECTION 1. *White House Cancer Moonshot Task Force*. There is established, within the Office of the Vice President, a White House Cancer Moonshot Task Force (Task Force), which will focus on making the most of Federal investments, targeted incentives, private sector efforts from industry and philanthropy, patient engagement initiatives, and other mechanisms to support cancer research and enable progress in treatment and care. The Vice President shall serve as Chair of the Task Force.

(a) Membership of the Task Force. In addition to the Vice President, the Task Force shall consist of the heads of the executive branch departments, agencies, and offices listed below:

(i) the Department of Defense;

(ii) the Department of Commerce;

(iii) the Department of Health and Human Services;

(iv) the Department of Energy;

(v) the Department of Veterans Affairs;

(vi) the Office of Management and Budget;

(vii) the National Economic Council;

(viii) the Domestic Policy Council;

(ix) the Office of Science and Technology Policy;

(x) the Food and Drug Administration;

(xi) the National Cancer Institute (NCI);

(xii) the National Institutes of Health (NIH);

(xiii) the National Science Foundation; and

(xiv) such other executive branch departments, agencies, or offices as the President may designate.

A member of the Task Force may designate, to perform the Task Force functions of the member, any person who is a part of the member's department, agency, or office, and who is a full time officer or employee of the Federal Government. At the direction of the Chair, the Task Force may establish subgroups consisting exclusively of Task Force members or their designees under this section, as appropriate.

(b) Administration of the Task Force. The NIH shall provide funding and administrative support for the Task Force to the extent permitted by law and within existing appropriations. The Vice President shall designate an officer or employee of the executive branch as the Executive Director of the Task Force, who shall coordinate the work of the Task Force.

SEC. 2. *Mission and Functions of the Task Force*. The Task Force shall work with a wide array of executive departments and agencies that have responsibility for key issues related to basic, translational, and clinical research, therapy development, regulation of medical products, and medical care related to cancer. Consistent with applicable law, the Task Force also will consult with external experts from relevant scientific sectors, including the Presidentially appointed National Cancer Advisory Board (NCAB). The NCAB shall advise the Director of NCI on its recommendations respecting the future direction and program and policy emphasis of NCI as it relates to the work of the Task Force. To assist the NCAB in providing this advice, the NCAB is strongly encouraged to establish a working group consisting of a Blue Ribbon Panel of scientific experts. The Director shall relay the advice of the NCAB to the Task Force, as appropriate. The functions of the Task Force are advisory only and shall include, but shall not be limited to, producing a detailed set of findings and recommendations to:

(a) accelerate our understanding of cancer, and its prevention, early detection, treatment, and cure;

(b) improve patient access and care;
(c) support greater access to new research, data, and computational capabilities;
(d) encourage development of cancer treatments;
(e) identify and address any unnecessary regulatory barriers and consider ways to expedite administrative reforms;
(f) ensure optimal investment of Federal resources; and
(g) identify opportunities to develop public-private partnerships and increase coordination of the Federal Government's efforts with the private sector, as appropriate.

SEC. 3. *Outreach*. Consistent with the objectives set out in section 2 of this memorandum, the Task Force, in accordance with applicable law, in addition to regular meetings, shall conduct outreach with representatives of the cancer patient community, academia, business, nonprofit organizations, State and local government agencies, the research community, and other interested persons that will assist with the Task Force's development of a detailed set of recommendations.

SEC. 4. *Transparency and Reports*. The Task Force shall facilitate the posting on the Internet of reports and engage in an open, reciprocal dialogue with the American people. The Task Force shall present to the President a report before December 31, 2016, on its findings and recommendations, which shall be made available to the public and posted on the Internet.

SEC. 5. *General Provisions*. (a) The heads of executive departments and agencies shall assist and provide information to the Task Force, consistent with applicable law, as may be necessary to carry out the functions of the Task Force. Each executive department and agency shall bear its own expense for participating in the Task Force.

(b) Nothing in this memorandum shall be construed to impair or otherwise affect:
(i) authority granted by law to an executive department, agency, or the head thereof; or
(ii) functions of the Director of the Office of Management and Budget relating to budgetary, administrative, or legislative proposals.

(c) This memorandum shall be implemented consistent with applicable law and subject to the availability of appropriations.

(d) This memorandum is not intended to, and does not, create any right or benefit, substantive or procedural, enforceable at law or in equity by any party against the United States, its departments, agencies, or entities, its officers, employees, or agents, or any other person.

SEC. 6. *Publication*. The Secretary of Health and Human Services is authorized and directed to publish this memorandum in the Federal Register.

BARACK OBAMA.

§285a. National Cancer Program

The National Cancer Program shall consist of (1) an expanded, intensified, and coordinated cancer research program encompassing the research programs conducted and supported by the Institute and the related research programs of the other national research institutes, including an expanded and intensified research program for the prevention of cancer caused by occupational or environmental exposure to carcinogens, and (2) the other programs and activities of the Institute.

(July 1, 1944, ch. 373, title IV, §411, as added Pub. L. 99–158, §2, Nov. 20, 1985, 99 Stat. 832.)

§285a–1. Cancer control programs

The Director of the Institute shall establish and support demonstration, education, and other programs for the detection, diagnosis, prevention, and treatment of cancer and for rehabilitation and counseling respecting cancer. Programs established and supported under this section shall include—

(1) locally initiated education and demonstration programs (and regional networks of such programs) to transmit research results and to disseminate information respecting—
(A) the detection, diagnosis, prevention, and treatment of cancer,
(B) the continuing care of cancer patients and the families of cancer patients, and
(C) rehabilitation and counseling respecting cancer,

to physicians and other health professionals who provide care to individuals who have cancer;

(2) the demonstration of and the education of students of the health professions and health professionals in—

(A) effective methods for the prevention and early detection of cancer and the identification of individuals with a high risk of developing cancer, and

(B) improved methods of patient referral to appropriate centers for early diagnosis and treatment of cancer; and

(3) the demonstration of new methods for the dissemination of information to the general public concerning the prevention, early detection, diagnosis, and treatment and control of cancer and information concerning unapproved and ineffective methods, drugs, and devices for the diagnosis, prevention, treatment, and control of cancer.

(July 1, 1944, ch. 373, title IV, §412, as added Pub. L. 99–158, §2, Nov. 20, 1985, 99 Stat. 832.)

§285a–2. Special authorities of Director

(a) Information and education program

(1) The Director of the Institute shall establish an information and education program to collect, identify, analyze, and disseminate on a timely basis, through publications and other appropriate means, to cancer patients and their families, physicians and other health professionals, and the general public, information on cancer research, diagnosis, prevention, and treatment (including information respecting nutrition programs for cancer patients and the relationship between nutrition and cancer). The Director of the Institute may take such action as may be necessary to insure that all channels for the dissemination and exchange of scientific knowledge and information are maintained between the Institute and the public and between the Institute and other scientific, medical, and biomedical disciplines and organizations nationally and internationally.

(2) In carrying out paragraph (1), the Director of the Institute shall—

(A) provide public and patient information and education programs, providing information that will help individuals take personal steps to reduce their risk of cancer, to make them aware of early detection techniques and to motivate appropriate utilization of those techniques, to help individuals deal with cancer if it strikes, and to provide information to improve long-term survival;

(B) continue and expand programs to provide physicians and the public with state-of-the-art information on the treatment of particular forms of cancers, and to identify those clinical trials that might benefit patients while advancing knowledge of cancer treatment;

(C) assess the incorporation of state-of-the-art cancer treatments into clinical practice and the extent to which cancer patients receive such treatments and include the results of such assessments in the biennial reports required under section 284b [1] of this title;

(D) maintain and operate the International Cancer Research Data Bank, which shall collect, catalog, store, and disseminate insofar as feasible the results of cancer research and treatment undertaken in any country for the use of any person involved in cancer research and treatment in any country; and

(E) to the extent practicable, in disseminating the results of such cancer research and treatment, utilize information systems available to the public.

(b) National Cancer Program

The Director of the Institute in carrying out the National Cancer Program—

(1) shall establish or support the large-scale production or distribution of specialized biological materials and other therapeutic substances for cancer research and set standards of safety and care for persons using such materials;

(2) shall, in consultation with the advisory council for the Institute, support (A) research in the cancer field outside the United States by highly qualified foreign nationals which can be expected to benefit the American people, (B) collaborative research involving American and foreign

participants, and (C) the training of American scientists abroad and foreign scientists in the United States;

(3) shall, in consultation with the advisory council for the Institute, support appropriate programs of education and training (including continuing education and laboratory and clinical research training);

(4) shall encourage and coordinate cancer research by industrial concerns where such concerns evidence a particular capability for such research;

(5) may obtain (after consultation with the advisory council for the Institute and in accordance with section 3109 of title 5, but without regard to the limitation in such section on the period of service) the services of not more than one hundred and fifty-one experts or consultants who have scientific or professional qualifications;

(6)(A) may, in consultation with the advisory council for the Institute, acquire, construct, improve, repair, operate, and maintain laboratories, other research facilities, equipment, and such other real or personal property as the Director determines necessary;

(B) may, in consultation with the advisory council for the Institute, make grants for construction or renovation of facilities; and

(C) may, in consultation with the advisory council for the Institute, acquire, without regard to section 8141 of title 40, by lease or otherwise through the Administrator of General Services, buildings or parts of buildings in the District of Columbia or communities located adjacent to the District of Columbia for the use of the Institute for a period not to exceed ten years;

(7) may, in consultation with the advisory council for the Institute, appoint one or more advisory committees composed of such private citizens and officials of Federal, State, and local governments to advise the Director with respect to the Director's functions;

(8) may, subject to section 284(b)(2) of this title and without regard to section 3324 of title 31 and section 6101 of title 41, enter into such contracts, leases, cooperative agreements, as may be necessary in the conduct of functions of the Director, with any public agency, or with any person, firm, association, corporation, or educational institution; and

(9) shall, notwithstanding section 284(a) of this title, prepare and submit, directly to the President for review and transmittal to Congress, an annual budget estimate (including an estimate of the number and type of personnel needs for the Institute) for the National Cancer Program, after reasonable opportunity for comment (but without change) by the Secretary, the Director of NIH, and the Institute's advisory council.

Except as otherwise provided, experts and consultants whose services are obtained under paragraph (5) shall be paid or reimbursed, in accordance with title 5 for their travel to and from their place of service and for other expenses associated with their assignment. Such expenses shall not be allowed in connection with the assignment of an expert or consultant whose services are obtained under paragraph (5) unless the expert or consultant has agreed in writing to complete the entire period of the assignment or one year of the assignment, whichever is shorter, unless separated or reassigned for reasons which are beyond the control of the expert or consultant and which are acceptable to the Director of the Institute. If the expert or consultant violates the agreement, the money spent by the United States for such expenses is recoverable from the expert or consultant as a debt due the United States. The Secretary may waive in whole or in part a right of recovery under the preceding sentence.

(c) Pre-clinical models to evaluate promising pediatric cancer therapies

(1) Expansion and coordination of activities

The Director of the National Cancer Institute shall expand, intensify, and coordinate the activities of the Institute with respect to research on the development of preclinical models to evaluate which therapies are likely to be effective for treating pediatric cancer.

(2) Coordination with other institutes

The Director of the Institute shall coordinate the activities under paragraph (1) with similar activities conducted by other national research institutes and agencies of the National Institutes of

Health to the extent that those Institutes and agencies have responsibilities that are related to pediatric cancer.

(July 1, 1944, ch. 373, title IV, §413, as added Pub. L. 99–158, §2, Nov. 20, 1985, 99 Stat. 833; amended Pub. L. 100–607, title I, §122, Nov. 4, 1988, 102 Stat. 3054; Pub. L. 101–93, §5(c), Aug. 16, 1989, 103 Stat. 611; Pub. L. 103–43, title III, §301(a)(2), June 10, 1993, 107 Stat. 150; Pub. L. 107–109, §15(b), Jan. 4, 2002, 115 Stat. 1420.)

EDITORIAL NOTES

REFERENCES IN TEXT

Section 284b of this title, referred to in subsec. (a)(2)(C), was repealed by Pub. L. 109–482, title I, §104(b)(1)(C), Jan. 15, 2007, 120 Stat. 3693.

CODIFICATION

In subsec. (b)(6)(C), "section 8141 of title 40" substituted for "the Act of March 3, 1877 (40 U.S.C. 34)" on authority of Pub. L. 107–217, §5(c), Aug. 21, 2002, 116 Stat. 1303, the first section of which enacted Title 40, Public Buildings, Property, and Works.

In subsec. (b)(8), "section 6101 of title 41" substituted for "section 3709 of the Revised Statutes (41 U.S.C. 5)" on authority of Pub. L. 111–350, §6(c), Jan. 4, 2011, 124 Stat. 3854, which Act enacted Title 41, Public Contracts.

AMENDMENTS

2002—Subsec. (c). Pub. L. 107–109 added subsec. (c).

1993—Subsec. (b)(9). Pub. L. 103–43 struck out subpar. (A) designation and subpar. (B) which permitted Director to receive from President and Office of Management and Budget directly all funds appropriated by Congress for obligation and expenditure by Institute.

1989—Subsec. (a)(1). Pub. L. 101–93 substituted "Institute and" for "Institute and and".

1988—Subsec. (a). Pub. L. 100–607, §122(1), designated existing provisions as par. (1), substituted "education program" for "education center", inserted "and the public and between the Institute and" after "between the Institute", and added par. (2).

Subsec. (b)(5). Pub. L. 100–607, §122(2)(A), substituted "after consultation with" for "with the approval of".

Subsec. (b)(8) to (10). Pub. L. 100–607, §122(2)(B), inserted "and" after "or educational institution;" in par. (8), redesignated par. (10) as (9), and struck out former par. (9) which related to International Cancer Research Data Bank.

[1] *See References in Text note below.*

§285a–3. National cancer research and demonstration centers

(a) Cooperative agreements and grants for establishing and supporting

(1) The Director of the Institute may enter into cooperative agreements with and make grants to public or private nonprofit entities to pay all or part of the cost of planning, establishing, or strengthening, and providing basic operating support for centers for basic and clinical research into, training in, and demonstration of advanced diagnostic, prevention, control, and treatment methods for cancer.

(2) A cooperative agreement or grant under paragraph (1) shall be entered into in accordance with policies established by the Director of NIH and after consultation with the Institute's advisory council.

(b) Uses for Federal payments under cooperative agreements or grants

Federal payments made under a cooperative agreement or grant under subsection (a) may be used for—

(1) construction (notwithstanding any limitation under section 289e of this title);

(2) staffing and other basic operating costs, including such patient care costs as are required for research;

(3) clinical training, including training for allied health professionals, continuing education for health professionals and allied health professions personnel, and information programs for the public respecting cancer; and

(4) demonstration purposes.

As used in this paragraph, the term "construction" does not include the acquisition of land, and the term "training" does not include research training for which Ruth L. Kirschstein National Research Service Awards may be provided under section 288 of this title.

(c) Period of support; additional periods

Support of a center under subsection (a) may be for a period of not to exceed five years. Such period may be extended by the Director for additional periods of not more than five years each if the operations of such center have been reviewed by an appropriate technical and scientific peer review group established by the Director and if such group has recommended to the Director that such period should be extended.

(d) Construction

Research centers under this section may not be considered centers of excellence for purposes of section 282(b)(10) of this title.

(July 1, 1944, ch. 373, title IV, §414, as added Pub. L. 99–158, §2, Nov. 20, 1985, 99 Stat. 835; amended Pub. L. 100–607, title I, §123, Nov. 4, 1988, 102 Stat. 3055; Pub. L. 107–206, title I, §804(c), Aug. 2, 2002, 116 Stat. 874; Pub. L. 109–482, title I, §108(b), Jan. 15, 2007, 120 Stat. 3697.)

EDITORIAL NOTES

AMENDMENTS

2007—Subsec. (d). Pub. L. 109–482 added subsec. (d).

2002—Subsec. (b). Pub. L. 107–206 substituted "Ruth L. Kirschstein National Research Service Awards" for "National Research Service Awards" in concluding provisions.

1988—Subsec. (a)(1). Pub. L. 100–607 inserted "control," after "prevention,".

STATUTORY NOTES AND RELATED SUBSIDIARIES

EFFECTIVE DATE OF 2007 AMENDMENT

Amendment by Pub. L. 109–482 applicable only with respect to amounts appropriated for fiscal year 2007 or subsequent fiscal years, see section 109 of Pub. L. 109–482, set out as a note under section 281 of this title.

§285a–4. President's Cancer Panel; establishment, membership, etc., functions

(a)(1) The President's Cancer Panel (hereafter in this section referred to as the "Panel") shall be composed of three persons appointed by the President who by virtue of their training, experience, and background are exceptionally qualified to appraise the National Cancer Program. At least two members of the Panel shall be distinguished scientists or physicians.

(2)(A) Members of the Panel shall be appointed for three-year terms, except that (i) any member appointed to fill a vacancy occurring prior to the expiration of the term for which the member's predecessor was appointed shall be appointed only for the remainder of such term, and (ii) a member may serve until the member's successor has taken office. If a vacancy occurs in the Panel, the President shall make an appointment to fill the vacancy not later than 90 days after the date the vacancy occurred.

(B) The President shall designate one of the members to serve as the chairman of the Panel for a

term of one year.

(C) Members of the Panel shall each be entitled to receive the daily equivalent of the annual rate of basic pay in effect for grade GS–18 of the General Schedule for each day (including traveltime) during which they are engaged in the actual performance of duties as members of the Panel and shall be paid or reimbursed, in accordance with title 5, for their travel to and from their place of service and for other expenses associated with their assignment.

(3) The Panel shall meet at the call of the chairman, but not less often than four times a year. A transcript shall be kept of the proceedings of each meeting of the Panel, and the chairman shall make such transcript available to the public.

(b) The Panel shall monitor the development and execution of the activities of the National Cancer Program, and shall report directly to the President. Any delays or blockages in rapid execution of the Program shall immediately be brought to the attention of the President. The Panel shall submit to the President periodic progress reports on the National Cancer Program and shall submit to the President, the Secretary, and the Congress an annual evaluation of the efficacy of the Program and suggestions for improvements, and shall submit such other reports as the President shall direct.

(July 1, 1944, ch. 373, title IV, §415, as added Pub. L. 99–158, §2, Nov. 20, 1985, 99 Stat. 835.)

STATUTORY NOTES AND RELATED SUBSIDIARIES

TERMINATION OF REPORTING REQUIREMENTS

For termination, effective May 15, 2000, of provisions in subsec. (b) of this section relating to the requirement that the Panel submit to Congress an annual evaluation of the efficacy of the Program and suggestions for improvements, see section 3003 of Pub. L. 104–66, as amended, set out as a note under section 1113 of Title 31, Money and Finance, and page 189 of House Document No. 103–7.

TERMINATION OF ADVISORY PANELS

Advisory panels established after Jan. 5, 1973, to terminate not later than the expiration of the 2-year period beginning on the date of their establishment, unless, in the case of a panel established by the President or an officer of the Federal Government, such panel is renewed by appropriate action prior to the expiration of such 2-year period, or in the case of a panel established by the Congress, its duration is otherwise provided by law. See sections 1001(2) and 1013 of Title 5, Government Organization and Employees.

Pub. L. 93–641, §6, Jan. 4, 1975, 88 Stat. 2275, set out as a note under section 217a of this title, provided that an advisory committee established pursuant to the Public Health Service Act shall terminate at such time as may be specifically prescribed by an Act of Congress enacted after Jan. 4, 1975.

REFERENCES IN OTHER LAWS TO GS–16, 17, OR 18 PAY RATES

References in laws to the rates of pay for GS–16, 17, or 18, or to maximum rates of pay under the General Schedule, to be considered references to rates payable under specified sections of Title 5, Government Organization and Employees, see section 529 [title I, §101(c)(1)] of Pub. L. 101–509, set out in a note under section 5376 of Title 5.

§285a–5. Associate Director for Prevention; appointment; function

(a) There shall be in the Institute an Associate Director for Prevention to coordinate and promote the programs in the Institute concerning the prevention of cancer. The Associate Director shall be appointed by the Director of the Institute from individuals who because of their professional training or experience are experts in public health or preventive medicine.

(b) The Associate Director for Prevention shall prepare for inclusion in the biennial report made under section 284b [1] of this title a description of the prevention activities of the Institute, including a description of the staff and resources allocated to those activities.

(July 1, 1944, ch. 373, title IV, §416, as added Pub. L. 99–158, §2, Nov. 20, 1985, 99 Stat. 836.)

EDITORIAL NOTES

REFERENCES IN TEXT

Section 284b of this title, referred to in subsec. (b), was repealed by Pub. L. 109–482, title I, §104(b)(1)(C), Jan. 15, 2007, 120 Stat. 3693.

[1] *See References in Text note below.*

§285a–6. Breast and gynecological cancers

(a) Expansion and coordination of activities

The Director of the Institute, in consultation with the National Cancer Advisory Board, shall expand, intensify, and coordinate the activities of the Institute with respect to research on breast cancer, ovarian cancer, and other cancers of the reproductive system of women.

(b) Coordination with other institutes

The Director of the Institute shall coordinate the activities of the Director under subsection (a) with similar activities conducted by other national research institutes and agencies of the National Institutes of Health to the extent that such Institutes [1] and agencies have responsibilities that are related to breast cancer and other cancers of the reproductive system of women.

(c) Programs for breast cancer

(1) In general

In carrying out subsection (a), the Director of the Institute shall conduct or support research to expand the understanding of the cause of, and to find a cure for, breast cancer. Activities under such subsection shall provide for an expansion and intensification of the conduct and support of—

(A) basic research concerning the etiology and causes of breast cancer;

(B) clinical research and related activities concerning the causes, prevention, detection and treatment of breast cancer;

(C) control programs with respect to breast cancer in accordance with section 285a–1 of this title, including community-based programs designed to assist women who are members of medically underserved populations, low-income populations, or minority groups;

(D) information and education programs with respect to breast cancer in accordance with section 285a–2 of this title; and

(E) research and demonstration centers with respect to breast cancer in accordance with section 285a–3 of this title, including the development and operation of centers for breast cancer research to bring together basic and clinical, biomedical and behavioral scientists to conduct basic, clinical, epidemiological, psychosocial, prevention and treatment research and related activities on breast cancer.

Not less than six centers shall be operated under subparagraph (E). Activities of such centers should include supporting new and innovative research and training programs for new researchers. Such centers shall give priority to expediting the transfer of research advances to clinical applications.

(2) Implementation of plan for programs

(A) The Director of the Institute shall ensure that the research programs described in paragraph (1) are implemented in accordance with a plan for the programs. Such plan shall include comments and recommendations that the Director of the Institute considers appropriate, with due consideration provided to the professional judgment needs of the Institute as expressed in the annual budget estimate prepared in accordance with section 285a–2(9) [2] of this title. The Director of the Institute, in consultation with the National Cancer Advisory Board, shall periodically review and revise such plan.

(B) Not later than October 1, 1993, the Director of the Institute shall submit a copy of the plan

to the President's Cancer Panel, the Secretary and the Director of NIH.

(C) The Director of the Institute shall submit any revisions of the plan to the President's Cancer Panel, the Secretary, and the Director of NIH.

(D) The Secretary shall provide a copy of the plan submitted under subparagraph (A), and any revisions submitted under subparagraph (C), to the Committee on Energy and Commerce of the House of Representatives and the Committee on Labor and Human Resources of the Senate.

(d) Other cancers

In carrying out subsection (a), the Director of the Institute shall conduct or support research on ovarian cancer and other cancers of the reproductive system of women. Activities under such subsection shall provide for the conduct and support of—

(1) basic research concerning the etiology and causes of ovarian cancer and other cancers of the reproductive system of women;

(2) clinical research and related activities into the causes, prevention, detection and treatment of ovarian cancer and other cancers of the reproductive system of women;

(3) control programs with respect to ovarian cancer and other cancers of the reproductive system of women in accordance with section 285a–1 of this title;

(4) information and education programs with respect to ovarian cancer and other cancers of the reproductive system of women in accordance with section 285a–2 of this title; and

(5) research and demonstration centers with respect to ovarian cancer and cancers of the reproductive system in accordance with section 285a–3 of this title.

(e) Report

The Director of the Institute shall prepare, for inclusion in the biennial report submitted under section 284b [3] of this title, a report that describes the activities of the National Cancer Institute under the research programs referred to in subsection (a), that shall include—

(1) a description of the research plan with respect to breast cancer prepared under subsection (c);

(2) an assessment of the development, revision, and implementation of such plan;

(3) a description and evaluation of the progress made, during the period for which such report is prepared, in the research programs on breast cancer and cancers of the reproductive system of women;

(4) a summary and analysis of expenditures made, during the period for which such report is made, for activities with respect to breast cancer and cancers of the reproductive system of women conducted and supported by the National Institutes of Health; and

(5) such comments and recommendations as the Director considers appropriate.

(July 1, 1944, ch. 373, title IV, §417, as added Pub. L. 103–43, title IV, §401, June 10, 1993, 107 Stat. 153.)

EDITORIAL NOTES

REFERENCES IN TEXT

Section 284b of this title, referred to in subsec. (e), was repealed by Pub. L. 109–482, title I, §104(b)(1)(C), Jan. 15, 2007, 120 Stat. 3693.

STATUTORY NOTES AND RELATED SUBSIDIARIES

CHANGE OF NAME

Committee on Labor and Human Resources of Senate changed to Committee on Health, Education, Labor, and Pensions of Senate by Senate Resolution No. 20, One Hundred Sixth Congress, Jan. 19, 1999.

Committee on Energy and Commerce of House of Representatives treated as referring to Committee on Commerce of House of Representatives by section 1(a) of Pub. L. 104–14, set out as a note preceding section 21 of Title 2, The Congress. Committee on Commerce of House of Representatives changed to Committee on Energy and Commerce of House of Representatives, and jurisdiction over matters relating to securities and

exchanges and insurance generally transferred to Committee on Financial Services of House of Representatives by House Resolution No. 5, One Hundred Seventh Congress, Jan. 3, 2001.

[1] So in original. Probably should not be capitalized.

[2] So in original. Probably should be section "285a–2(b)(9)".

[3] See References in Text note below.

§285a–7. Prostate cancer

(a) Expansion and coordination of activities

The Director of the Institute, in consultation with the National Cancer Advisory Board, shall expand, intensify, and coordinate the activities of the Institute with respect to research on prostate cancer.

(b) Coordination with other institutes

The Director of the Institute shall coordinate the activities of the Director under subsection (a) with similar activities conducted by other national research institutes and agencies of the National Institutes of Health to the extent that such Institutes [1] and agencies have responsibilities that are related to prostate cancer.

(c) Programs

(1) In general

In carrying out subsection (a), the Director of the Institute shall conduct or support research to expand the understanding of the cause of, and to find a cure for, prostate cancer. Activities under such subsection shall provide for an expansion and intensification of the conduct and support of—

(A) basic research concerning the etiology and causes of prostate cancer;

(B) clinical research and related activities concerning the causes, prevention, detection and treatment of prostate cancer;

(C) prevention and control and early detection programs with respect to prostate cancer in accordance with section 285a–1 of this title, particularly as it relates to intensifying research on the role of prostate specific antigen for the screening and early detection of prostate cancer;

(D) an Inter-Institute Task Force, under the direction of the Director of the Institute, to provide coordination between relevant National Institutes of Health components of research efforts on prostate cancer;

(E) control programs with respect to prostate cancer in accordance with section 285a–1 of this title;

(F) information and education programs with respect to prostate cancer in accordance with section 285a–2 of this title; and

(G) research and demonstration centers with respect to prostate cancer in accordance with section 285a–3 of this title, including the development and operation of centers for prostate cancer research to bring together basic and clinical, biomedical and behavioral scientists to conduct basic, clinical, epidemiological, psychosocial, prevention and control, treatment, research, and related activities on prostate cancer.

Not less than six centers shall be operated under subparagraph (G). Activities of such centers should include supporting new and innovative research and training programs for new researchers. Such centers shall give priority to expediting the transfer of research advances to clinical applications.

(2) Implementation of plan for programs

(A) The Director of the Institute shall ensure that the research programs described in paragraph

(1) are implemented in accordance with a plan for the programs. Such plan shall include comments and recommendations that the Director of the Institute considers appropriate, with due consideration provided to the professional judgment needs of the Institute as expressed in the annual budget estimate prepared in accordance with section 285a–2(9) [2] of this title. The Director of the Institute, in consultation with the National Cancer Advisory Board, shall periodically review and revise such plan.

(B) Not later than October 1, 1993, the Director of the Institute shall submit a copy of the plan to the President's Cancer Panel, the Secretary, and the Director of NIH.

(C) The Director of the Institute shall submit any revisions of the plan to the President's Cancer Panel, the Secretary, and the Director of NIH.

(D) The Secretary shall provide a copy of the plan submitted under subparagraph (A), and any revisions submitted under subparagraph (C), to the Committee on Energy and Commerce of the House of Representatives and the Committee on Labor and Human Resources of the Senate.

(July 1, 1944, ch. 373, title IV, §417A, as added Pub. L. 103–43, title IV, §402, June 10, 1993, 107 Stat. 155.)

STATUTORY NOTES AND RELATED SUBSIDIARIES

CHANGE OF NAME

Committee on Labor and Human Resources of Senate changed to Committee on Health, Education, Labor, and Pensions of Senate by Senate Resolution No. 20, One Hundred Sixth Congress, Jan. 19, 1999.

Committee on Energy and Commerce of House of Representatives treated as referring to Committee on Commerce of House of Representatives by section 1(a) of Pub. L. 104–14, set out as a note preceding section 21 of Title 2, The Congress. Committee on Commerce of House of Representatives changed to Committee on Energy and Commerce of House of Representatives, and jurisdiction over matters relating to securities and exchanges and insurance generally transferred to Committee on Financial Services of House of Representatives by House Resolution No. 5, One Hundred Seventh Congress, Jan. 3, 2001.

[1] So in original. Probably should not be capitalized.

[2] So in original. Probably should be section "285a–2(b)(9)".

§285a–8. Repealed. Pub. L. 109–482, title I, §103(b)(15), Jan. 15, 2007, 120 Stat. 3687

Section, act July 1, 1944, ch. 373, title IV, §417B, as added Pub. L. 103–43, title IV, §403(a), June 10, 1993, 107 Stat. 157; amended Pub. L. 105–340, title I, §103, Oct. 31, 1998, 112 Stat. 3192; Pub. L. 106–505, title VI, §602(b), Nov. 13, 2000, 114 Stat. 2346, related to authorization of appropriations.

STATUTORY NOTES AND RELATED SUBSIDIARIES

EFFECTIVE DATE OF REPEAL

Repeal applicable only with respect to amounts appropriated for fiscal year 2007 or subsequent fiscal years, see section 109 of Pub. L. 109–482, set out as an Effective Date of 2007 Amendment note under section 281 of this title.

§285a–9. Grants for education, prevention, and early detection of radiogenic cancers and diseases

(a) Definition

In this section the term "entity" means any—

(1) National Cancer Institute-designated cancer center;
(2) Department of Veterans Affairs hospital or medical center;
(3) Federally Qualified Health Center, community health center, or hospital;
(4) agency of any State or local government, including any State department of health; or
(5) nonprofit organization.

(b) In general

The Secretary, acting through the Administrator of the Health Resources and Services Administration in consultation with the Director of the National Institutes of Health and the Director of the Indian Health Service, may make competitive grants to any entity for the purpose of carrying out programs to—

(1) screen individuals described under section 4(a)(1)(A)(i) or 5(a)(1)(A) of the Radiation Exposure Compensation Act (42 U.S.C. 2210 note) for cancer as a preventative health measure;

(2) provide appropriate referrals for medical treatment of individuals screened under paragraph (1) and to ensure, to the extent practicable, the provision of appropriate follow-up services;

(3) develop and disseminate public information and education programs for the detection, prevention, and treatment of radiogenic cancers and diseases; and

(4) facilitate putative applicants in the documentation of claims as described in section 5(a) of the Radiation Exposure Compensation Act (42 U.S.C. 2210 note).

(c) Indian Health Service

The programs under subsection (a) shall include programs provided through the Indian Health Service or through tribal contracts, compacts, grants, or cooperative agreements with the Indian Health Service and which are determined appropriate to raising the health status of Indians.

(d) Grant and contract authority

Entities receiving a grant under subsection (b) may expend the grant to carry out the purpose described in such subsection.

(e) Health coverage unaffected

Nothing in this section shall be construed to affect any coverage obligation of a governmental or private health plan or program relating to an individual referred to under subsection (b)(1).

(July 1, 1944, ch. 373, title IV, §417C, as added Pub. L. 106–245, §4, July 10, 2000, 114 Stat. 508; amended Pub. L. 109–482, title I, §§103(b)(16), 104(b)(1)(F), Jan. 15, 2007, 120 Stat. 3687, 3693.)

EDITORIAL NOTES

REFERENCES IN TEXT

Sections 4 and 5 of the Radiation Exposure Compensation Act, referred to in subsec. (b)(1) and (4), are sections 4 and 5 of Pub. L. 101–426, which are set out as a note under section 2210 of this title.

AMENDMENTS

2007—Subsec. (f). Pub. L. 109–482, §104(b)(1)(F), struck out heading and text of subsec. (f). Text read as follows: "Beginning on October 1 of the year following the date on which amounts are first appropriated to carry out this section and annually on each October 1 thereafter, the Secretary shall submit a report to the Committee on the Judiciary and the Committee on Health, Education, Labor, and Pensions of the Senate and to the Committee on the Judiciary and the Committee on Commerce of the House of Representatives. Each report shall summarize the expenditures and programs funded under this section as the Secretary determines to be appropriate."

Subsec. (g). Pub. L. 109–482, §103(b)(16), struck out heading and text of subsec. (g). Text read as follows: "There are authorized to be appropriated for the purpose of carrying out this section $20,000,000 for fiscal year 1999 and such sums as may be necessary for each of the fiscal years 2000 through 2009."

STATUTORY NOTES AND RELATED SUBSIDIARIES

EFFECTIVE DATE OF 2007 AMENDMENT

Amendment by Pub. L. 109–482 applicable only with respect to amounts appropriated for fiscal year 2007 or subsequent fiscal years, see section 109 of Pub. L. 109–482, set out as a note under section 281 of this title.

§285a–10. Research, information, and education with respect to blood cancer

(a) Joe Moakley Research Excellence Program

(1) In general

The Director of NIH shall expand, intensify, and coordinate programs for the conduct and support of research with respect to blood cancer, and particularly with respect to leukemia, lymphoma, and multiple myeloma.

(2) Administration

The Director of NIH shall carry out this subsection through the Director of the National Cancer Institute and in collaboration with any other agencies that the Director determines to be appropriate.

(b) Geraldine Ferraro Cancer Education Program

(1) In general

The Secretary shall direct the appropriate agency within the Department of Health and Human Services, in collaboration with the Director of NIH, to establish and carry out a program to provide information and education for patients and the general public with respect to blood cancer, and particularly with respect to the treatment of leukemia, lymphoma, and multiple myeloma.

(2) Administration

The Agency determined by the Secretary under paragraph (1) shall carry out this subsection in collaboration with private health organizations that have national education and patient assistance programs on blood-related cancers.

(July 1, 1944, ch. 373, title IV, §417D, as added Pub. L. 107–172, §3, May 14, 2002, 116 Stat. 541; amended Pub. L. 109–482, title I, §103(b)(17), Jan. 15, 2007, 120 Stat. 3688; Pub. L. 115–180, title II, §204(a), June 5, 2018, 132 Stat. 1390.)

EDITORIAL NOTES

AMENDMENTS

2018—Pub. L. 115–180 made technical correction to directory language of Pub. L. 107–172, §3, which enacted this section.

2007—Subsec. (a)(3). Pub. L. 109–482, §103(b)(17)(A), struck out heading and text of par. (3). Text read as follows: "For the purpose of carrying out this subsection, there is authorized to be appropriated such sums as may be necessary for fiscal year 2002 and each subsequent fiscal year. Such authorizations of appropriations are in addition to other authorizations of appropriations that are available for such purpose."

Subsec. (b)(3). Pub. L. 109–482, §103(b)(17)(B), struck out heading and text of par. (3). Text read as follows: "For the purpose of carrying out this subsection, there is authorized to be appropriated such sums as may be necessary for fiscal year 2002 and each subsequent fiscal year. Such authorizations of appropriations are in addition to other authorizations of appropriations that are available for such purpose."

STATUTORY NOTES AND RELATED SUBSIDIARIES

EFFECTIVE DATE OF 2018 AMENDMENT

Pub. L. 115–180, title II, §204(b), June 5, 2018, 132 Stat. 1390, provided that: "The amendment made by subsection (a) [amending section 3 of Pub. L. 107–172] shall take effect as if included in section 3 of the Hematological Cancer Research Investment and Education Act of 2002 (Public Law 107–172; 116 Stat. 541) [enacting this section]."

EFFECTIVE DATE OF 2007 AMENDMENT

Amendment by Pub. L. 109–482 applicable only with respect to amounts appropriated for fiscal year 2007 or subsequent fiscal years, see section 109 of Pub. L. 109–482, set out as a note under section 281 of this title.

CONGRESSIONAL FINDINGS

Pub. L. 107–172, §2, May 14, 2002, 116 Stat. 541, provided that: "Congress finds that:

"(1) An estimated 109,500 people in the United States will be diagnosed with leukemia, lymphoma, and multiple myeloma in 2001.

"(2) New cases of the blood cancers described in paragraph (1) account for 8.6 percent of new cancer cases.

"(3) Those devastating blood cancers will cause the deaths of an estimated 60,300 persons in the United States in 2001. Every 9 minutes, a person in the United States dies from leukemia, lymphoma, or multiple myeloma.

"(4) While less than 5 percent of Federal funds for cancer research are spent on those blood cancers, those blood cancers cause 11 percent of all cancer deaths in the United States.

"(5) Increased Federal support of research into leukemia, lymphoma, and multiple myeloma has resulted and will continue to result in significant advances in the treatment, and ultimately the cure, of those blood cancers as well as other cancers."

§285a–11. Pediatric cancer research, awareness, and survivorship

(a) Children's cancer biorepositories

(1) Award

The Secretary, acting through the Director of NIH, may make awards to an entity or entities described in paragraph (4) to build upon existing research efforts to collect biospecimens and clinical and demographic information of children, adolescents, and young adults with selected cancer subtypes (and their recurrences) for which current treatments are least effective, in order to achieve a better understanding of the causes of such cancer subtypes (and their recurrences), and the effects and outcomes of treatments for such cancers.

(2) Use of funds

Amounts received under an award under paragraph (1) may be used to carry out the following:

(A) Collect and store high-quality, donated biospecimens and associated clinical and demographic information on children, adolescents, and young adults diagnosed with cancer in the United States, focusing on children, adolescents, and young adults with cancer enrolled in clinical trials for whom current treatments are least effective. Activities under this subparagraph may include storage of biospecimens and associated clinical and demographic data at existing biorepositories supported by the National Cancer Institute, such as collected samples of both solid tumor cancer and paired samples.

(B) Maintain an interoperable, secure, and searchable database on stored biospecimens and associated clinical and demographic data from children, adolescents, and young adults with cancer for the purposes of research by scientists and qualified health care professionals.

(C) Establish and implement procedures for evaluating applications for access to such biospecimens and clinical and demographic data from researchers and other qualified health care professionals.

(D) Provide access to biospecimens and clinical and demographic data from children, adolescents, and young adults with cancer to researchers and qualified health care professionals for peer-reviewed research—

(i) consistent with the procedures established pursuant to subparagraph (C);

(ii) only to the extent permitted by applicable Federal and State law; and

(iii) in a manner that protects personal privacy to the extent required by applicable Federal and State privacy law, at minimum.

(3) No requirement

No child, adolescent, or young adult with cancer shall be required under this subsection to

contribute a specimen to a biorepository or share clinical or demographic data.

(4) Application; considerations

(A) Application

To be eligible to receive an award under paragraph (1) an entity shall submit an application to the Secretary at such a time, in such manner, and containing such information as the Secretary may reasonably require.

(B) Considerations

In evaluating applications submitted under subparagraph (A), the Secretary shall consider the existing infrastructure of the entity that would allow for the timely capture of biospecimens and related clinical and demographic information for children, adolescents, and young adults with cancer for whom current treatments are least effective.

(5) Privacy protections and informed consent

(A) In general

The Secretary may not make an award under paragraph (1) to an entity unless the Secretary ensures that such entity—

(i) collects biospecimens and associated clinical and demographic information only from participants who have given their informed consent in accordance with Federal and State law; and

(ii) protects personal privacy to the extent required by applicable Federal and State law, at minimum.

(B) Informed consent

The Secretary shall ensure biospecimens and associated clinical and demographic information are collected with informed consent, as described in subparagraph (A)(i).

(6) Guidelines and oversight

The Secretary shall develop and disseminate appropriate guidelines for the development and maintenance of the biorepositories supported under this subsection, including appropriate oversight, to facilitate further research on select cancer subtypes (and their recurrences) in children, adolescents, and young adults with such cancers (and their recurrences).

(7) Coordination

To encourage the greatest possible efficiency and effectiveness of federally supported efforts with respect to the activities described in this subsection, the Secretary shall ensure the appropriate coordination of programs supported under this section with existing federally supported cancer registry programs and the activities under section 280e–3a of this title, as appropriate.

(8) Supplement not supplant

Funds provided under this subsection shall be used to supplement, and not supplant, Federal and non-Federal funds available for carrying out the activities described in this subsection.

(9) Report

Not later than 4 years after January 5, 2023, the Secretary shall submit to Congress a report on—

(A) the number of biospecimens and corresponding clinical demographic data collected through the biospecimen research efforts supported under paragraph (1);

(B) the number of biospecimens and corresponding clinical demographic data requested for use by researchers;

(C) barriers to the collection of biospecimens and corresponding clinical demographic data;

(D) barriers experienced by researchers or health care professionals in accessing the biospecimens and corresponding clinical demographic data necessary for use in research; and

(E) recommendations with respect to improving the biospecimen and biorepository research efforts under this subsection.

(10) Report on researcher access to children's cancer biorepository samples

Not later than 2 years after January 5, 2023, the Director of NIH shall—

(A) conduct a review of the procedures established under paragraph (2)(C) and other policies or procedures related to researcher access to such biospecimens to identify any opportunities to reduce administrative burden, consistent with paragraph (2)(D), in a manner that protects personal privacy to the extent required by applicable Federal and State privacy law, at a minimum; and

(B) submit to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives a report on the findings of the review under subparagraph (A) and whether the Director of NIH plans to make any changes to the policies or procedures considered in such review, based on such findings.

(11) Definitions

For purposes of this subsection:

(A) Award

The term "award" includes a grant, contract, or cooperative agreement determined by the Secretary.

(B) Biospecimen

The term "biospecimen" includes—

(i) solid tumor tissue or bone marrow;
(ii) normal or control tissue;
(iii) blood and plasma;
(iv) DNA and RNA extractions;
(v) familial DNA; and
(vi) any other sample relevant to cancer research, as required by the Secretary.

(C) Clinical and demographic information

The term "clinical and demographic information" includes—

(i) date of diagnosis;
(ii) age at diagnosis;
(iii) the patient's sex, race, ethnicity, and environmental exposures;
(iv) extent of disease at enrollment;
(v) site of metastases;
(vi) location of primary tumor coded;
(vii) histologic diagnosis;
(viii) tumor marker data when available;
(ix) treatment and outcome data;
(x) information related to specimen quality; and
(xi) any other applicable information required by the Secretary.

(b) Improving care for pediatric cancer survivors

(1) Research on pediatric cancer survivorship

The Director of NIH, in coordination with ongoing research activities, may continue to conduct or support pediatric cancer survivorship research including in any of the following areas:

(A) Outcomes of pediatric cancer survivors, including within minority or other medically underserved populations and with respect to health disparities of such outcomes.

(B) Barriers to follow-up care for pediatric cancer survivors, including within minority or other medically underserved populations.

(C) The impact of relevant factors, which may include familial, socioeconomic, and other environmental factors, on treatment outcomes and survivorship.

(D) The development of indicators used for long-term follow-up and analysis of the late effects of cancer treatment for pediatric cancer survivors.

(E) The identification of, as applicable—
(i) risk factors associated with the late effects of cancer treatment;
(ii) predictors of adverse neurocognitive and psychosocial outcomes; and
(iii) the molecular basis of long-term complications.

(F) The development of targeted interventions to reduce the burden of morbidity borne by cancer survivors in order to protect such cancer survivors from the late effects of cancer.

(2) Balanced approach

In conducting or supporting research under paragraph (1)(A)(i) on pediatric cancer survivors within minority or other medically underserved populations, the Director of NIH shall ensure that such research addresses both the physical and the psychological needs of such survivors, as appropriate.

(c) Rule of construction

Nothing in this section shall be construed as being inconsistent with the goals and purposes of the Minority Health and Health Disparities Research and Education Act of 2000.

(d) Authorization of appropriations

For purposes of carrying out this section and section 280e–3a of this title, there are authorized to be appropriated $30,000,000 for each of fiscal years 2024 through 2028. Funds appropriated under this subsection shall remain available until expended.

(July 1, 1944, ch. 373, title IV, §417E, as added Pub. L. 110–285, §4(a), July 29, 2008, 122 Stat. 2629; amended Pub. L. 115–180, title I, §§101, 102(b), title II, §202, June 5, 2018, 132 Stat. 1383, 1386, 1389; Pub. L. 117–350, §2(a), Jan. 5, 2023, 136 Stat. 6262.)

EDITORIAL NOTES

REFERENCES IN TEXT

The Minority Health and Health Disparities Research and Education Act of 2000, referred to in subsec. (c), is Pub. L. 106–525, Nov. 22, 2000, 114 Stat. 2495. For complete classification of this Act to the Code, see Short Title of 2000 Amendments note set out under section 201 of this title and Tables.

AMENDMENTS

2023—Subsec. (a)(2)(A). Pub. L. 117–350, §2(a)(1)(A), inserted ", such as collected samples of both solid tumor cancer and paired samples" after "National Cancer Institute".

Subsec. (a)(9). Pub. L. 117–350, §2(a)(1)(B), substituted "January 5, 2023" for "June 5, 2018" in introductory provisions.

Subsec. (a)(10), (11). Pub. L. 117–350, §2(a)(1)(C), (D), added par. (10) and redesignated former par. (10) as (11).

Subsec. (d). Pub. L. 117–350, §2(a)(2), substituted "2024 through 2028" for "2019 through 2023".

2018—Pub. L. 115–180, §101(1), substituted "research, awareness, and survivorship" for "research and awareness" in section catchline.

Subsec. (a). Pub. L. 115–180, §101(2), added subsec. (a) and struck out former subsec. (a). Prior to amendment, text read as follows:

"(1) PROGRAMS OF RESEARCH EXCELLENCE IN PEDIATRIC CANCER.—The Secretary, in collaboration with the Director of NIH and other Federal agencies with interest in prevention and treatment of pediatric cancer, shall continue to enhance, expand, and intensify pediatric cancer research and other activities related to pediatric cancer, including therapeutically applicable research to generate effective treatments, pediatric preclinical testing, and pediatric clinical trials through National Cancer Institute-supported pediatric cancer clinical trial groups and their member institutions. In enhancing, expanding, and intensifying such research and other activities, the Secretary is encouraged to take into consideration the application of such research and other activities for minority, health disparity, and medically underserved communities. For purposes of this section, the term 'pediatric cancer research' means research on the causes, prevention, diagnosis, recognition, treatment, and long-term effects of pediatric cancer.

"(2) PEER REVIEW REQUIREMENTS.—All grants awarded under this subsection shall be awarded in

accordance with section 289a of this title."

Subsec. (b). Pub. L. 115–180, §202, added subsec. (b) and struck out former subsec. (b) which related to public awareness of pediatric cancers and available treatments and research.

Subsec. (c). Pub. L. 115–180, §101(3), struck out "(42 U.S.C. 202 note)" before period at end.

Subsec. (d). Pub. L. 115–180, §102(b), substituted "2019 through 2023" for "2009 through 2013" and struck out "Such authorization of appropriations is in addition to the authorization of appropriations established in section 282a of this title with respect to such purpose." before "Funds appropriated".

STATUTORY NOTES AND RELATED SUBSIDIARIES

REPORTING ON CHILDHOOD CANCER RESEARCH PROJECTS

Pub. L. 115–180, title I, §121, June 5, 2018, 132 Stat. 1387, provided that: "The Director of the National Institutes of Health shall ensure that childhood cancer research projects conducted or supported by the National Institutes of Health are included in appropriate reports to Congress, which may include the Pediatric Research Initiative report."

EXECUTIVE DOCUMENTS

EX. ORD. NO. 14355. UNLOCKING CURES FOR PEDIATRIC CANCER WITH ARTIFICIAL INTELLIGENCE

Ex. Ord. No. 14355, Sept. 30, 2025, 90 F.R. 48153, provided:

By the authority vested in me as President by the Constitution and the laws of the United States of America, it is hereby ordered:

SECTION 1. *Purpose and Policy*. My Administration is committed to driving innovation to prevent and treat childhood diseases, including through the use of artificial intelligence (AI). Pediatric cancer remains the leading cause of disease-related death for children in the United States aged 1–19 years, and its incidence has increased by more than 40 percent since 1975.

As outlined in my joint address to the Congress in March, reversing this trend is one of the top priorities for the Make America Healthy Again (MAHA) Commission established in Executive Order 14212 of February 13, 2025 (Establishing the President's Make America Healthy Again Commission) [42 U.S.C. 201 note]. AI presents an opportunity to more quickly achieve this aim.

In 2019, my Administration created the Childhood Cancer Data Initiative (CCDI), a Federal investment in childhood cancer research of $50 million in funding every year for 10 years to address the critical need to collect, generate, and analyze childhood cancer data. The CCDI is building a foundational data infrastructure, aggregating and generating new data, and using this data to make new discoveries.

AI can be used to build upon this data initiative to produce meaningful solutions to pediatric, adolescent, and young adulthood cancer. This application of AI has the potential to transform the Nation's current care and research approach for pediatric cancer—as well as our healthcare and research infrastructure more broadly—through use of the rich and multimodal data, secured with appropriate individual privacy protections, to develop early and superior diagnostics, identify cures and optimize treatments, and advance medicine that will save lives.

For too long, we have watched our children and their families battle cancer and its long-term chronic effects while healthcare systems often rely on outdated technologies and can be slow to adopt certain innovations. We must prioritize investment in AI-enabled science, build world-class scientific datasets, and empower researchers and clinicians with the tools needed to translate data and AI capabilities into improved care.

SEC. 2. *Harnessing American AI Innovation*. The MAHA Commission, in coordination with the Secretary of Health and Human Services (Secretary), the Assistant to the President for Science and Technology (APST), and the Special Advisor for AI and Crypto, and in alignment with the implementation of America's AI Action Plan, shall work to develop innovative ways to utilize advanced technologies such as AI to unlock improved diagnoses, treatments, cures, and prevention strategies for pediatric cancer. The initial focus shall be on identifying opportunities to accelerate the progress of AI-driven solutions at the CCDI, including by making data platforms and tools available as part of the CCDI Data Ecosystem and funding research projects at National Cancer Institute-Designated Cancer Centers that prioritize:

(a) improving data infrastructure by consolidating data from multiple sources for AI-ready analysis and utilizing AI to better select participants for clinical trials;

(b) enhancing data analysis of complex biologic systems with AI tools to radically improve predictive modeling of patient response, disease progression, and treatment toxicity and to turn multi-omics data and

imaging data into novel diagnostic, prognostic, and therapeutic biomarkers; and

(c) improving clinical trial design, access, and outcomes for patients by incorporating multimodal data and using AI approaches to maximize utilization of the information from clinical trials and improve accessibility, recruitment, administration, conduct, and interpretation of clinical trial results.

SEC. 3. *Increasing Investment and Engagement in Pediatric Cancer Research and Care Infrastructure*. The MAHA Commission, in coordination with the Secretary, the Director of the Office of Management and Budget, the Director of the National Institutes of Health, and the APST, shall prioritize expanding pediatric cancer research and advancements in care by identifying and implementing strategies for:

(a) increasing investment from existing Federal funds for the CCDI and other Federal Government initiatives that address pediatric cancer; and

(b) encouraging the private sector to make use of the most advanced technologies to unlock cures for pediatric cancer, including those based on AI, to the maximum possible extent.

SEC. 4. *Improving Data Sharing and Empowering Patients*. The Secretary, in consultation with the APST, shall work to ensure that AI innovation is appropriately integrated into current work on interoperability to maximize the potential for electronic health record and claims data to inform private sector and academic research and clinical trial design, while ensuring that patients and parents control their health information. In addition, the Secretary shall work to finalize interoperability standards for patient data to be used with AI that appropriately account for structured and unstructured data and enable safe and privacy-compliant exchanges of data.

SEC. 5. *Definition*. For the purposes of this order, "artificial intelligence" or "AI" has the meaning set forth in 15 U.S.C. 9401(3).

SEC. 6. *General Provisions*. (a) Nothing in this order shall be construed to impair or otherwise affect:

(i) the authority granted by law to an executive department or agency, or the head thereof; or

(ii) the functions of the Director of the Office of Management and Budget relating to budgetary, administrative, or legislative proposals.

(b) This order shall be implemented consistent with applicable law and subject to the availability of appropriations.

(c) This order is not intended to, and does not, create any right or benefit, substantive or procedural, enforceable at law or in equity by any party against the United States, its departments, agencies, or entities, its officers, employees, or agents, or any other person.

(d) The costs for publication of this order shall be borne by the Department of Health and Human Services.

DONALD J. TRUMP.

§285a–11a. Cancer survivorship programs

(a) Research to evaluate model systems of care for pediatric cancer survivors

(1) In general

The Secretary of Health and Human Services (referred to in this section as the "Secretary") shall, as appropriate, make awards to eligible entities to conduct or support research to develop, study, or evaluate approaches for monitoring and caring for childhood and adolescent cancer survivors throughout their lifespan, including transition to adult care and care coordination.

(2) Awards

(A) Types of entities

In making awards under this subsection, the Secretary shall, to the extent practicable, within the existing peer review process, include—

(i) small, medium, and large-sized eligible entities; and

(ii) sites located in different geographic areas, including rural and urban areas.

(B) Eligible entities

In this subsection, the term "eligible entity" means—

(i) a medical school;

(ii) a children's hospital;

(iii) a cancer center;

(iv) a community-based medical facility; or

(v) any other entity with significant experience and expertise in carrying out the activities described in paragraph (1).

(3) Use of funds

Funds awarded under this subsection may be used—

(A) to develop, study, or evaluate one or more models for monitoring and caring for cancer survivors; and

(B) in developing, studying, and evaluating such models, to give special emphasis to—

(i) design of models of follow-up care, monitoring, and other survivorship programs (including peer support and mentoring programs);

(ii) development of models for providing multidisciplinary care;

(iii) dissemination of information to health care providers about culturally and linguistically appropriate follow-up care for cancer survivors and their families, as appropriate and practicable;

(iv) development of psychosocial and support programs to improve the quality of life of cancer survivors and their families, which may include peer support and mentoring programs;

(v) design tools to support the secure electronic transfer of treatment information and care summaries between health care providers or, as applicable and appropriate, longitudinal childhood cancer survivorship cohorts (including risk factors and a plan for recommended follow-up care);

(vi) dissemination of the information and programs described in clauses (i) through (v) to other health care providers (including primary care physicians and internists) and to cancer survivors and their families, where appropriate and in accordance with Federal and State law; and

(vii) development of initiatives that promote the coordination and effective transition of care between cancer care providers, primary care physicians, mental health professionals, and other health care professionals, as appropriate, including models that use a team-based or multi-disciplinary approach to care.

(b) Workforce development for health care providers on medical and psychosocial care for childhood cancer survivors

(1) In general

The Secretary shall, not later than 1 year after January 5, 2023, conduct a review of the activities of the Department of Health and Human Services related to workforce development for health care providers who treat pediatric cancer patients and survivors. Such review shall include—

(A) identification of existing models relevant to providing medical and psychosocial services to individuals surviving pediatric cancers, and programs related to training for health professionals who provide such services to individuals surviving pediatric cancers; and

(B) recommendations for enhancing or promoting activities of the Department of Health and Human Services related to workforce development for health care providers who provide psychosocial care to pediatric cancer patients and survivors.

(2) Report

Not later than 2 years after January 5, 2023, the Secretary shall submit to the Committee on Health, Education, Labor, and Pensions of the Senate and Committee on Energy and Commerce of the House of Representatives, a report concerning the findings and recommendations from the review conducted under paragraph (1).

(Pub. L. 115–180, title II, §201, June 5, 2018, 132 Stat. 1387; Pub. L. 117–350, §2(b), Jan. 5, 2023, 136 Stat. 6263.)

EDITORIAL NOTES

CODIFICATION

Section was enacted as part of the Childhood Cancer Survivorship, Treatment, Access, and Research Act of 2018, also known as the Childhood Cancer STAR Act, and not as part of the Public Health Service Act which comprises this chapter.

AMENDMENTS

2023—Subsec. (a). Pub. L. 117–350, §2(b)(1)(A), substituted "Research to evaluate" for "Pilot programs to explore" in heading.

Subsec. (a)(1). Pub. L. 117–350, §2(b)(1)(B), substituted "shall, as appropriate, make awards to eligible entities to conduct or support research" for "may make awards to eligible entities to establish pilot programs" and "approaches" for "model systems", inserted "and adolescent" after "childhood", and struck out "evaluation of models for" before "transition".

Subsec. (a)(2)(A). Pub. L. 117–350, §2(b)(1)(C)(i), inserted "within the existing peer review process," after "practicable," in introductory provisions.

Subsec. (a)(2)(B)(v). Pub. L. 117–350, §2(b)(1)(C)(ii), substituted "in carrying out the activities described in paragraph (1)" for "in treating survivors of childhood cancers".

Subsec. (a)(3)(B)(v). Pub. L. 117–350, §2(b)(1)(D), substituted "design tools to support the secure electronic transfer of treatment information and care summaries between health care providers or, as applicable and appropriate, longitudinal childhood cancer survivorship cohorts" for "design of systems for the effective transfer of treatment information and care summaries from cancer care providers to other health care providers".

Subsec. (b)(1). Pub. L. 117–350, §2(b)(2)(A), substituted "January 5, 2023" for "June 5, 2018" in introductory provisions.

Subsec. (b)(1)(A) to (C). Pub. L. 117–350, §2(b)(2)(B), added subpar. (B), redesignated former subpar. (B) as (A), and struck out former subpars. (A) and (C) which read as follows:

"(A) an assessment of the effectiveness of supportive psychosocial care services for pediatric cancer patients and survivors, including pediatric cancer survivorship care patient navigators and peer support programs;

"(C) recommendations for improving the provision of psychosocial care for pediatric cancer survivors and patients."

Subsec. (b)(2). Pub. L. 117–350, §2(b)(2)(A), substituted "January 5, 2023" for "June 5, 2018".

§285a–11b. Best practices for long-term follow-up services for pediatric cancer survivors

The Secretary of Health and Human Services may facilitate the identification of best practices for childhood and adolescent cancer survivorship care, and, as appropriate, may consult with individuals who have expertise in late effects of disease and treatment of childhood and adolescent cancers, which may include—

(1) oncologists, which may include pediatric oncologists;

(2) primary care providers engaged in survivorship care;

(3) survivors of childhood and adolescent cancer;

(4) parents of children and adolescents who have been diagnosed with and treated for cancer and parents of long-term survivors;

(5) nurses and social workers;

(6) mental health professionals;

(7) allied health professionals, including physical therapists and occupational therapists; and

(8) others, as the Secretary determines appropriate.

(Pub. L. 115–180, title II, §203, June 5, 2018, 132 Stat. 1389.)

EDITORIAL NOTES

CODIFICATION

Section was enacted as part of the Childhood Cancer Survivorship, Treatment, Access, and Research Act of 2018, also known as the Childhood Cancer STAR Act, and not as part of the Public Health Service Act which comprises this chapter.

§285a–12. Interagency Breast Cancer and Environmental Research Coordinating Committee

(a) Interagency Breast Cancer and Environmental Research Coordinating Committee

(1) Establishment

Not later than 6 months after October 8, 2008, the Secretary shall establish a committee, to be known as the Interagency Breast Cancer and Environmental Research Coordinating Committee (in this section referred to as the "Committee").

(2) Duties

The Committee shall—

(A) share and coordinate information on existing research activities, and make recommendations to the National Institutes of Health and other Federal agencies regarding how to improve existing research programs, that are related to breast cancer research;

(B) develop a comprehensive strategy and advise the National Institutes of Health and other Federal agencies in the solicitation of proposals for collaborative, multidisciplinary research, including proposals to evaluate environmental and genomic factors that may be related to the etiology of breast cancer that would—

(i) result in innovative approaches to study emerging scientific opportunities or eliminate knowledge gaps in research to improve the research portfolio;

(ii) outline key research questions, methodologies, and knowledge gaps;

(iii) expand the number of research proposals that involve collaboration between 2 or more national research institutes or national centers, including proposals for Common Fund research described in section 282(b)(7) of this title to improve the research portfolio; and

(iv) expand the number of collaborative, multidisciplinary, and multi-institutional research grants;

(C) develop a summary of advances in breast cancer research supported or conducted by Federal agencies relevant to the diagnosis, prevention, and treatment of cancer and other diseases and disorders; and

(D) not later than 2 years after the date of the establishment of the Committee, make recommendations to the Secretary—

(i) regarding any appropriate changes to research activities, including recommendations to improve the research portfolio of the National Institutes of Health to ensure that scientifically-based strategic planning is implemented in support of research priorities that impact breast cancer research activities;

(ii) to ensure that the activities of the National Institutes of Health and other Federal agencies, including the Department of Defense, are free of unnecessary duplication of effort;

(iii) regarding public participation in decisions relating to breast cancer research to increase the involvement of patient advocacy and community organizations representing a broad geographical area;

(iv) on how best to disseminate information on breast cancer research progress; and

(v) on how to expand partnerships between public entities, including Federal agencies, and private entities to expand collaborative, cross-cutting research.

(3) Rule of construction

For the purposes of the Committee, when focusing on research to evaluate environmental and genomic factors that may be related to the etiology of breast cancer, nothing in this section shall be construed to restrict the Secretary from including other forms of cancer, as appropriate, when doing so may advance research in breast cancer or advance research in other forms of cancer.

(4) Membership

(A) In general

The Committee shall be composed of the following voting members:

(i) Not more than 7 voting Federal representatives as follows:

(I) The Director of the Centers for Disease Control and Prevention.

(II) The Director of the National Institutes of Health and the directors of such national research institutes and national centers (which may include the National Institute of Environmental Health Sciences) as the Secretary determines appropriate.

(III) One representative from the National Cancer Institute Board of Scientific Advisors, appointed by the Director of the National Cancer Institute.

(IV) The heads of such other agencies of the Department of Health and Human Services as the Secretary determines appropriate.

(V) Representatives of other Federal agencies that conduct or support cancer research, including the Department of Defense.

(ii) 12 additional voting members appointed under subparagraph (B).

(B) Additional members

The Committee shall include additional voting members appointed by the Secretary as follows:

(i) 6 members shall be appointed from among scientists, physicians, and other health professionals, who—

(I) are not officers or employees of the United States;

(II) represent multiple disciplines, including clinical, basic, and public health sciences;

(III) represent different geographical regions of the United States;

(IV) are from practice settings, academia, or other research settings; and

(V) are experienced in scientific peer review process.

(ii) 6 members shall be appointed from members of the general public, who represent individuals with breast cancer.

(C) Nonvoting members

The Committee shall include such nonvoting members as the Secretary determines to be appropriate.

(5) Chairperson

The voting members of the Committee shall select a chairperson from among such members. The selection of a chairperson shall be subject to the approval of the Director of NIH.

(6) Meetings

The Committee shall meet at the call of the chairperson of the Committee or upon the request of the Director of NIH, but in no case less often than once each year.

(b) Review

The Secretary shall review the necessity of the Committee in calendar year 2011 and, thereafter, at least once every 2 years.

(July 1, 1944, ch. 373, title IV, §417F, as added Pub. L. 110–354, §2(a), Oct. 8, 2008, 122 Stat. 3984.)

§285a–13. Scientific framework for recalcitrant cancers

(a) Development of scientific framework

(1) In general

For each recalcitrant cancer identified under subsection (b), the Director of the Institute shall

develop (in accordance with subsection (c)) a scientific framework for the conduct or support of research on such cancer.

(2) Contents

The scientific framework with respect to a recalcitrant cancer shall include the following:

(A) Current status

(i) Review of literature

A summary of findings from the current literature in the areas of—

(I) the prevention, diagnosis, and treatment of such cancer;

(II) the fundamental biologic processes that regulate such cancer (including similarities and differences of such processes from the biological processes that regulate other cancers); and

(III) the epidemiology of such cancer.

(ii) Scientific advances

The identification of relevant emerging scientific areas and promising scientific advances in basic, translational, and clinical science relating to the areas described in subclauses (I) and (II) of clause (i).

(iii) Researchers

A description of the availability of qualified individuals to conduct scientific research in the areas described in clause (i).

(iv) Coordinated research initiatives

The identification of the types of initiatives and partnerships for the coordination of intramural and extramural research of the Institute in the areas described in clause (i) with research of the relevant national research institutes, Federal agencies, and non-Federal public and private entities in such areas.

(v) Research resources

The identification of public and private resources, such as patient registries and tissue banks, that are available to facilitate research relating to each of the areas described in clause (i).

(B) Identification of research questions

The identification of research questions relating to basic, translational, and clinical science in the areas described in subclauses (I) and (II) of subparagraph (A)(i) that have not been adequately addressed with respect to such recalcitrant cancer.

(C) Recommendations

Recommendations for appropriate actions that should be taken to advance research in the areas described in subparagraph (A)(i) and to address the research questions identified in subparagraph (B), as well as for appropriate benchmarks to measure progress on achieving such actions, including the following:

(i) Researchers

Ensuring adequate availability of qualified individuals described in subparagraph (A)(iii).

(ii) Coordinated research initiatives

Promoting and developing initiatives and partnerships described in subparagraph (A)(iv).

(iii) Research resources

Developing additional public and private resources described in subparagraph (A)(v) and strengthening existing resources.

(3) Timing

(A) Initial development and subsequent update

For each recalcitrant cancer identified under subsection (b)(1), the Director of the Institute shall—

(i) develop a scientific framework under this subsection not later than 18 months after January 2, 2013; and

(ii) review and update the scientific framework not later than 5 years after its initial development.

(B) Other updates

The Director of the Institute may review and update each scientific framework developed under this subsection as necessary.

(4) Public notice

With respect to each scientific framework developed under subsection (a), not later than 30 days after the date of completion of the framework, the Director of the Institute shall—

(A) submit such framework to the Committee on Energy and Commerce and Committee on Appropriations of the House of Representatives, and the Committee on Health, Education, Labor, and Pensions and Committee on Appropriations of the Senate; and

(B) make such framework publically available on the Internet website of the Department of Health and Human Services.

(b) Identification of recalcitrant cancer

(1) In general

Not later than 6 months after January 2, 2013, the Director of the Institute shall identify two or more recalcitrant cancers that each—

(A) have a 5-year relative survival rate of less than 20 percent; and

(B) are estimated to cause the death of at least 30,000 individuals in the United States per year.

(2) Additional cancers

The Director of the Institute may, at any time, identify other recalcitrant cancers for purposes of this section. In identifying a recalcitrant cancer pursuant to the previous sentence, the Director may consider additional metrics of progress (such as incidence and mortality rates) against such type of cancer.

(c) Working groups

For each recalcitrant cancer identified under subsection (b), the Director of the Institute shall convene a working group comprised of representatives of appropriate Federal agencies and other non-Federal entities to provide expertise on, and assist in developing, a scientific framework under subsection (a). The Director of the Institute (or the Director's designee) shall participate in the meetings of each such working group.

(d) Reporting

(1) Biennial reports

The Director of NIH shall ensure that each biennial report under section 283 of this title includes information on actions undertaken to carry out each scientific framework developed under subsection (a) with respect to a recalcitrant cancer, including the following:

(A) Information on research grants awarded by the National Institutes of Health for research relating to such cancer.

(B) An assessment of the progress made in improving outcomes (including relative survival rates) for individuals diagnosed with such cancer.

(C) An update on activities pertaining to such cancer under the authority of section 285a–2(b)(7) of this title.

(2) Additional one-time report for certain frameworks

For each recalcitrant cancer identified under subsection (b)(1), the Director of the Institute shall, not later than 6 years after the initial development of a scientific framework under subsection (a), submit a report to the Congress on the effectiveness of the framework (including the update required by subsection (a)(3)(A)(ii)) in improving the prevention, detection, diagnosis, and treatment of such cancer.

(e) Recommendations for exception funding

The Director of the Institute shall consider each relevant scientific framework developed under subsection (a) when making recommendations for exception funding for grant applications.

(f) Definition

In this section, the term "recalcitrant cancer" means a cancer for which the five-year relative survival rate is below 50 percent.

(July 1, 1944, ch. 373, title IV, §417G, as added Pub. L. 112–239, div. A, title X, §1083, Jan. 2, 2013, 126 Stat. 1960.)

SUBPART 2—NATIONAL HEART, LUNG, AND BLOOD INSTITUTE

§285b. Purpose of Institute

The general purpose of the National Heart, Lung, and Blood Institute (hereafter in this subpart referred to as the "Institute") is the conduct and support of research, training, health information dissemination, and other programs with respect to heart, blood vessel, lung, and blood diseases and with respect to the use of blood and blood products and the management of blood resources.

(July 1, 1944, ch. 373, title IV, §418, as added Pub. L. 99–158, §2, Nov. 20, 1985, 99 Stat. 836.)

§285b–1. Heart, blood vessel, lung, and blood disease prevention and control programs

(a) The Director of the Institute shall conduct and support programs for the prevention and control of heart, blood vessel, lung, and blood diseases. Such programs shall include community-based and population-based programs carried out in cooperation with other Federal agencies, with public health agencies of State or local governments, with nonprofit private entities that are community-based health agencies, or with other appropriate public or nonprofit private entities.

(b) In carrying out programs under subsection (a), the Director of the Institute shall give special consideration to the prevention and control of heart, blood vessel, lung, and blood diseases in children, and in populations that are at increased risk with respect to such diseases.

(July 1, 1944, ch. 373, title IV, §419, as added Pub. L. 99–158, §2, Nov. 20, 1985, 99 Stat. 836; amended Pub. L. 103–43, title V, §505, June 10, 1993, 107 Stat. 160.)

EDITORIAL NOTES

AMENDMENTS

1993—Pub. L. 103–43 substituted subsecs. (a) and (b) for former section which read as follows: "The Director of the Institute, under policies established by the Director of NIH and after consultation with the advisory council for the Institute, shall establish programs as necessary for cooperation with other Federal health agencies, State, local, and regional public health agencies, and nonprofit private health agencies in the diagnosis, prevention, and treatment (including the provision of emergency medical services) of heart, blood vessel, lung, and blood diseases, appropriately emphasizing the prevention, diagnosis, and treatment of such diseases of children."

§285b–2. Information and education

The Director of the Institute shall collect, identify, analyze, and disseminate on a timely basis, through publications and other appropriate means, to patients, families of patients, physicians and other health professionals, and the general public, information on research, prevention, diagnosis, and treatment of heart, blood vessel, lung, and blood diseases, the maintenance of health to reduce the incidence of such diseases, and on the use of blood and blood products and the management of blood resources. In carrying out this section, the Director of the Institute shall place special emphasis upon the utilization of collaborative efforts with both the public and private sectors to—

(1) increase the awareness and knowledge of health care professionals and the public regarding the prevention of heart and blood vessel, lung, and blood diseases and the utilization of blood resources; and

(2) develop and disseminate to health professionals, patients and patient families, and the public information designed to encourage adults and children to adopt healthful practices concerning the prevention of such diseases.

(July 1, 1944, ch. 373, title IV, §420, as added Pub. L. 99–158, §2, Nov. 20, 1985, 99 Stat. 837; amended Pub. L. 100–607, title I, §126, Nov. 4, 1988, 102 Stat. 3055.)

EDITORIAL NOTES

AMENDMENTS

1988—Pub. L. 100–607 amended second sentence generally. Prior to amendment, second sentence read as follows: "In carrying out this section the Director of the Institute shall place special emphasis upon—

"(1) the dissemination of information regarding diet and nutrition, environmental pollutants, exercise, stress, hypertension, cigarette smoking, weight control, and other factors affecting the prevention of arteriosclerosis and other cardiovascular diseases and of pulmonary and blood diseases; and

"(2) the dissemination of information designed to encourage children to adopt healthful habits respecting the risk factors related to the prevention of such diseases."

§285b–3. National Heart, Blood Vessel, Lung, and Blood Diseases and Blood Resources Program; administrative provisions

(a)(1) The National Heart, Blood Vessel, Lung, and Blood Diseases and Blood Resources Program (hereafter in this subpart referred to as the "Program") may provide for—

(A) investigation into the epidemiology, etiology, and prevention of all forms and aspects of heart, blood vessel, lung, and blood diseases, including investigations into the social, environmental, behavioral, nutritional, biological, and genetic determinants and influences involved in the epidemiology, etiology, and prevention of such diseases;

(B) studies and research into the basic biological processes and mechanisms involved in the underlying normal and abnormal heart, blood vessel, lung, and blood phenomena;

(C) research into the development, trial, and evaluation of techniques, drugs, and devices (including computers) used in, and approaches to, the diagnosis, treatment (including the provision of emergency medical services), and prevention of heart, blood vessel, lung, and blood diseases and the rehabilitation of patients suffering from such diseases;

(D) establishment of programs that will focus and apply scientific and technological efforts involving the biological, physical, and engineering sciences to all facets of heart, blood vessel, lung, and blood diseases with emphasis on the refinement, development, and evaluation of technological devices that will assist, replace, or monitor vital organs and improve instrumentation for detection, diagnosis, and treatment of and rehabilitation from such diseases;

(E) establishment of programs for the conduct and direction of field studies, large-scale testing and evaluation, and demonstration of preventive, diagnostic, therapeutic, and rehabilitative approaches to, and emergency medical services for, such diseases;

(F) studies and research into blood diseases and blood, and into the use of blood for clinical purposes and all aspects of the management of blood resources in the United States, including the collection, preservation, fractionation, and distribution of blood and blood products;

(G) the education (including continuing education) and training of scientists, clinical investigators, and educators, in fields and specialties (including computer sciences) requisite to the conduct of clinical programs respecting heart, blood vessel, lung, and blood diseases and blood resources;

(H) public and professional education relating to all aspects of such diseases, including the prevention of such diseases, and the use of blood and blood products and the management of blood resources;

(I) establishment of programs for study and research into heart, blood vessel, lung, and blood diseases of children (including cystic fibrosis, hyaline membrane, hemolytic diseases such as sickle cell anemia and Cooley's anemia, and hemophilic diseases) and for the development and demonstration of diagnostic, treatment, and preventive approaches to such diseases; and

(J) establishment of programs for study, research, development, demonstrations and evaluation of emergency medical services for people who become critically ill in connection with heart, blood vessel, lung, or blood diseases.

(2) The Program shall be coordinated with other national research institutes to the extent that they have responsibilities respecting such diseases and shall give special emphasis to the continued development in the Institute of programs related to the causes of stroke and to effective coordination of such programs with related stroke programs in the National Institute of Neurological and Communicative Disorders and Stroke. The Director of the Institute, with the advice of the advisory council for the Institute, shall revise annually the plan for the Program and shall carry out the Program in accordance with such plan.

(b) In carrying out the Program, the Director of the Institute, under policies established by the Director of NIH—

(1) may, after consultation with the advisory council for the Institute, obtain (in accordance with section 3109 of title 5, but without regard to the limitation in such section on the period of such service) the services of not more than one hundred experts or consultants who have scientific or professional qualifications;

(2)(A) may, in consultation with the advisory council for the Institute, acquire and construct, improve, repair, operate, alter, renovate, and maintain, heart, blood vessel, lung, and blood disease and blood resource laboratories, research, training, and other facilities, equipment, and such other real or personal property as the Director determines necessary;

(B) may, in consultation with the advisory council for the Institute, make grants for construction or renovation of facilities; and

(C) may, in consultation with the advisory council for the Institute, acquire, without regard to section 8141 of title 40, by lease or otherwise, through the Administrator of General Services, buildings or parts of buildings in the District of Columbia or communities located adjacent to the District of Columbia for the use of the Institute for a period not to exceed ten years;

(3) subject to section 284(b)(2) of this title and without regard to section 3324 of title 31 and section 6101 of title 41, may enter into such contracts, leases, cooperative agreements, or other transactions, as may be necessary in the conduct of the Director's functions, with any public agency, or with any person, firm, association, corporation, or educational institutions;

(4) may make grants to public and nonprofit private entities to assist in meeting the cost of the care of patients in hospitals, clinics, and related facilities who are participating in research projects; and

(5) shall, in consultation with the advisory council for the Institute, conduct appropriate intramural training and education programs, including continuing education and laboratory and clinical research training programs.

Except as otherwise provided, experts and consultants whose services are obtained under

paragraph (1) shall be paid or reimbursed, in accordance with title 5, for their travel to and from their place of service and for other expenses associated with their assignment. Such expenses shall not be allowed in connection with the assignment of an expert or consultant whose services are obtained under paragraph (1) unless the expert or consultant has agreed in writing to complete the entire period of the assignment or one year of the assignment, whichever is shorter, unless separated or reassigned for reasons which are beyond the control of the expert or consultant and which are acceptable to the Director of the Institute. If the expert or consultant violates the agreement, the money spent by the United States for such expenses is recoverable from the expert or consultant as a debt due the United States. The Secretary may waive in whole or in part a right of recovery under the preceding sentence.

(July 1, 1944, ch. 373, title IV, §421, as added Pub. L. 99–158, §2, Nov. 20, 1985, 99 Stat. 837; amended Pub. L. 100–607, title I, §127, Nov. 4, 1988, 102 Stat. 3055; Pub. L. 103–43, title V, §501, title XX, §2008(b)(3), June 10, 1993, 107 Stat. 158, 211.)

EDITORIAL NOTES

CODIFICATION

In subsec. (b)(2)(C), "section 8141 of title 40" substituted for "the Act of March 3, 1877 (40 U.S.C. 34)" on authority of Pub. L. 107–217, §5(c), Aug. 21, 2002, 116 Stat. 1303, the first section of which enacted Title 40, Public Buildings, Property, and Works.

In subsec. (b)(3), "section 6101 of title 41" substituted for "section 3709 of the Revised Statutes (41 U.S.C. 5)" on authority of Pub. L. 111–350, §6(c), Jan. 4, 2011, 124 Stat. 3854, which Act enacted Title 41, Public Contracts.

AMENDMENTS

1993—Subsec. (b)(1). Pub. L. 103–43, §2008(b)(3), inserted comma after "may".

Subsec. (b)(5). Pub. L. 103–43, §501, added par. (5).

1988—Subsec. (a)(1)(D). Pub. L. 100–607, §127(1), inserted "and rehabilitation from" after "and treatment of".

Subsec. (b)(1). Pub. L. 100–607, §127(2), substituted "after consultation with" for ", after approval of".

§285b–4. National research and demonstration centers

(a) Heart, blood vessel, lung, blood diseases, and blood resources; utilization of centers for prevention programs

(1) The Director of the Institute may provide, in accordance with subsection (c), for the development of—

(A) ten centers for basic and clinical research into, training in, and demonstration of, advanced diagnostic, prevention, and treatment and rehabilitation methods (including methods of providing emergency medical services) for heart and blood vessel diseases;

(B) ten centers for basic and clinical research into, training in, and demonstration of, advanced diagnostic, prevention, and treatment and rehabilitation methods (including methods of providing emergency medical services) for lung diseases (including bronchitis, emphysema, asthma, cystic fibrosis, and other lung diseases of children);

(C) ten centers for basic and clinical research into, training in, and demonstration of, advanced diagnostic, prevention, and treatment methods (including methods of providing emergency medical services) for blood diseases and research into blood, in the use of blood products and in the management of blood resources; and

(D) three centers for basic and clinical research into, training in, and demonstration of, advanced diagnostic, prevention, and treatment (including genetic studies, intrauterine environment studies, postnatal studies, heart arrhythmias, and acquired heart disease and preventive cardiology) for cardiovascular diseases in children.

(2) The centers developed under paragraph (1) shall, in addition to being utilized for research, training, and demonstrations, be utilized for the following prevention programs for cardiovascular, pulmonary, and blood diseases:

(A) Programs to develop improved methods of detecting individuals with a high risk of developing cardiovascular, pulmonary, and blood diseases.

(B) Programs to develop improved methods of intervention against those factors which cause individuals to have a high risk of developing such diseases.

(C) Programs to develop health professions and allied health professions personnel highly skilled in the prevention of such diseases.

(D) Programs to develop improved methods of providing emergency medical services for persons with such diseases.

(E) Programs of continuing education for health and allied health professionals in the diagnosis, prevention, and treatment of such diseases and the maintenance of health to reduce the incidence of such diseases and information programs for the public respecting the prevention and early diagnosis and treatment of such diseases and the maintenance of health.

(3) The research, training, and demonstration activities carried out through any such center may relate to any one or more of the diseases referred to in paragraph (1) of this subsection.

(b) Sickle cell anemia

The Director of the Institute shall provide, in accordance with subsection (c), for the development of ten centers for basic and clinical research into the diagnosis, treatment, and control of sickle cell anemia.

(c) Cooperative agreements and grants for establishing and supporting; uses for Federal payments; period of support, additional periods

(1) The Director of the Institute may enter into cooperative agreements with and make grants to public or private nonprofit entities to pay all or part of the cost of planning, establishing, or strengthening, and providing basic operating support for centers for basic and clinical research into, training in, and demonstration of the management of blood resources and advanced diagnostic, prevention, and treatment methods for heart, blood vessel, lung, or blood diseases.

(2) A cooperative agreement or grant under paragraph (1) shall be entered into in accordance with policies established by the Director of NIH and after consultation with the Institute's advisory council.

(3) Federal payments made under a cooperative agreement or grant under paragraph (1) may be used for—

(A) construction (notwithstanding any limitation under section 289e of this title);

(B) staffing and other basic operating costs, including such patient care costs as are required for research;

(C) training, including training for allied health professionals; and

(D) demonstration purposes.

As used in this subsection, the term "construction" does not include the acquisition of land, and the term "training" does not include research training for which Ruth L. Kirschstein National Research Service Awards may be provided under section 288 of this title.

(4) Support of a center under paragraph (1) may be for a period of not to exceed five years. Such period may be extended by the Director for additional periods of not more than five years each if the operations of such center have been reviewed by an appropriate technical and scientific peer review group established by the Director and if such group has recommended to the Director that such period should be extended.

(July 1, 1944, ch. 373, title IV, §422, as added Pub. L. 99–158, §2, Nov. 20, 1985, 99 Stat. 839; amended Pub. L. 100–607, title I, §128, Nov. 4, 1988, 102 Stat. 3055; Pub. L. 103–43, title V, §502, June 10, 1993, 107 Stat. 158; Pub. L. 107–206, title I, §804(c), Aug. 2, 2002, 116 Stat. 874.)

EDITORIAL NOTES

AMENDMENTS

2002—Subsec. (c)(3). Pub. L. 107–206 substituted "Ruth L. Kirschstein National Research Service Awards" for "National Research Service Awards" in concluding provisions.

1993—Subsec. (a)(1)(D). Pub. L. 103–43 added subpar. (D).

1988—Subsec. (a)(1)(A), (B). Pub. L. 100–607 inserted "and rehabilitation" after "prevention, and treatment".

§285b–5. Repealed. Pub. L. 100–607, title I, §129, Nov. 4, 1988, 102 Stat. 3055

Section, act July 1, 1944, ch. 373, title IV, §423, as added Nov. 20, 1985, Pub. L. 99–158, §2, 99 Stat. 841, directed Secretary to establish an Interagency Technical Committee on Heart, Blood Vessel, Lung, and Blood Diseases and Blood Resources.

§285b–6. Associate Director for Prevention; appointment; function

(a) There shall be in the Institute an Associate Director for Prevention to coordinate and promote the programs in the Institute concerning the prevention of heart, blood vessel, lung, and blood diseases. The Associate Director shall be appointed by the Director of the Institute from individuals who because of their professional training or experience are experts in public health or preventive medicine.

(b) The Associate Director for Prevention shall prepare for inclusion in the biennial report made under section 284b [1] of this title a description of the prevention activities of the Institute, including a description of the staff and resources allocated to those activities.

(July 1, 1944, ch. 373, title IV, §423, formerly §424, as added Pub. L. 99–158, §2, Nov. 20, 1985, 99 Stat. 841; renumbered §423, Pub. L. 100–607, title I, §129, Nov. 4, 1988, 102 Stat. 3055.)

EDITORIAL NOTES

REFERENCES IN TEXT

Section 284b of this title, referred to in subsec. (b), was repealed by Pub. L. 109–482, title I, §104(b)(1)(C), Jan. 15, 2007, 120 Stat. 3693.

PRIOR PROVISIONS

A prior section 423 of act July 1, 1944, was classified to section 285b–5 of this title prior to repeal by Pub. L. 100–607.

[1] *See References in Text note below.*

§285b–7. National Center on Sleep Disorders Research

(a) Establishment

Not later than 1 year after June 10, 1993, the Director of the Institute shall establish the National Center on Sleep Disorders Research (in this section referred to as the "Center"). The Center shall be headed by a director, who shall be appointed by the Director of the Institute.

(b) Purpose

The general purpose of the Center is—

(1) the conduct and support of research, training, health information dissemination, and other activities with respect to sleep disorders, including biological and circadian rhythm research, basic understanding of sleep, chronobiological and other sleep related research; and

(2) to coordinate the activities of the Center with similar activities of other Federal agencies, including the other agencies of the National Institutes of Health, and similar activities of other public entities and nonprofit entities.

(c) Sleep Disorders Research Advisory Board

(1) The Director of the National Institutes of Health shall establish a board to be known as the Sleep Disorders Research Advisory Board (in this section referred to as the "Advisory Board").

(2) The Advisory Board shall advise, assist, consult with, and make recommendations to the Director of the National Institutes of Health, through the Director of the Institute, and the Director of the Center concerning matters relating to the scientific activities carried out by and through the Center and the policies respecting such activities, including recommendations with respect to the plan required in subsection (c).[1]

(3)(A) The Director of the National Institutes of Health shall appoint to the Advisory Board 12 appropriately qualified representatives of the public who are not officers or employees of the Federal Government. Of such members, eight shall be representatives of health and scientific disciplines with respect to sleep disorders and four shall be individuals representing the interests of individuals with or undergoing treatment for sleep disorders.

(B) The following officials shall serve as ex officio members of the Advisory Board:

(i) The Director of the National Institutes of Health.

(ii) The Director of the Center.

(iii) The Director of the National Heart, Lung and Blood Institute.

(iv) The Director of the National Institute of Mental Health.

(v) The Director of the National Institute on Aging.

(vi) The Director of the Eunice Kennedy Shriver National Institute of Child Health and Human Development.

(vii) The Director of the National Institute of Neurological Disorders and Stroke.

(viii) The Assistant Secretary for Health.

(ix) The Assistant Secretary of Defense (Health Affairs).

(x) The Chief Medical Director of the Veterans' Administration.

(4) The members of the Advisory Board shall, from among the members of the Advisory Board, designate an individual to serve as the chair of the Advisory Board.

(5) Except as inconsistent with, or inapplicable to, this section, the provisions of section 284a of this title shall apply to the advisory board [2] established under this section in the same manner as such provisions apply to any advisory council established under such section.

(d) Development of comprehensive research plan; revision

(1) After consultation with the Director of the Center and the advisory board [2] established under subsection (c), the Director of the National Institutes of Health shall develop a comprehensive plan for the conduct and support of sleep disorders research.

(2) The plan developed under paragraph (1) shall identify priorities with respect to such research and shall provide for the coordination of such research conducted or supported by the agencies of the National Institutes of Health.

(3) The Director of the National Institutes of Health (after consultation with the Director of the Center and the advisory board [2] established under subsection (c)) shall revise the plan developed under paragraph (1) as appropriate.

(e) Collection and dissemination of information

The Director of the Center, in cooperation with the Centers for Disease Control and Prevention, is authorized to coordinate activities with the Department of Transportation, the Department of Defense, the Department of Education, the Department of Labor, and the Department of Commerce to collect data, conduct studies, and disseminate public information concerning the impact of sleep disorders and sleep deprivation.

(July 1, 1944, ch. 373, title IV, §424, as added Pub. L. 103–43, title V, §503, June 10, 1993, 107 Stat. 159; amended Pub. L. 110–154, §1(b)(5), Dec. 21, 2007, 121 Stat. 1827.)

EDITORIAL NOTES

AMENDMENTS

2007—Subsec. (c)(3)(B)(vi). Pub. L. 110–154 substituted "Eunice Kennedy Shriver National Institute of Child Health and Human Development" for "National Institute of Child Health and Human Development".

STATUTORY NOTES AND RELATED SUBSIDIARIES

CHANGE OF NAME

Reference to Chief Medical Director of Department of Veterans Affairs deemed to refer to Under Secretary for Health of Department of Veterans Affairs pursuant to section 302(e) of Pub. L. 102–405, set out as a note under section 305 of Title 38, Veterans' Benefits.

Reference to Chief Medical Director of Veterans' Administration deemed to refer to Chief Medical Director of Department of Veterans Affairs pursuant to section 10 of Pub. L. 100–527, set out as a Department of Veterans Affairs Act note under section 201 of Title 38.

TERMINATION OF ADVISORY BOARDS

Advisory boards established after Jan. 5, 1973, to terminate not later than the expiration of the 2-year period beginning on the date of their establishment, unless, in the case of a board established by the President or an officer of the Federal Government, such board is renewed by appropriate action prior to the expiration of such 2-year period, or in the case of a board established by Congress, its duration is otherwise provided by law. See sections 1001(2) and 1013 of Title 5, Government Organization and Employees.

Pub. L. 93–641, §6, Jan. 4, 1975, 88 Stat. 2275, set out as a note under section 217a of this title, provided that an advisory committee established pursuant to the Public Health Service Act shall terminate at such time as may be specifically prescribed by an Act of Congress enacted after Jan. 4, 1975.

[1] So in original. Probably should be subsection "(d)".

[2] So in original. Probably should be capitalized.

§285b–7a. Heart attack, stroke, and other cardiovascular diseases in women

(a) In general

The Director of the Institute shall expand, intensify, and coordinate research and related activities of the Institute with respect to heart attack, stroke, and other cardiovascular diseases in women.

(b) Coordination with other institutes

The Director of the Institute shall coordinate activities under subsection (a) with similar activities conducted by the other national research institutes and agencies of the National Institutes of Health to the extent that such Institutes and agencies have responsibilities that are related to heart attack, stroke, and other cardiovascular diseases in women.

(c) Certain programs

In carrying out subsection (a), the Director of the Institute shall conduct or support research to expand the understanding of the causes of, and to develop methods for preventing, cardiovascular diseases in women. Activities under such subsection shall include conducting and supporting the following:

(1) Research to determine the reasons underlying the prevalence of heart attack, stroke, and other cardiovascular diseases in women, including African-American women and other women who are members of racial or ethnic minority groups.

(2) Basic research concerning the etiology and causes of cardiovascular diseases in women.

(3) Epidemiological studies to address the frequency and natural history of such diseases and the differences among men and women, and among racial and ethnic groups, with respect to such diseases.

(4) The development of safe, efficient, and cost-effective diagnostic approaches to evaluating women with suspected ischemic heart disease.

(5) Clinical research for the development and evaluation of new treatments for women, including rehabilitation.

(6) Studies to gain a better understanding of methods of preventing cardiovascular diseases in women, including applications of effective methods for the control of blood pressure, lipids, and obesity.

(7) Information and education programs for patients and health care providers on risk factors associated with heart attack, stroke, and other cardiovascular diseases in women, and on the importance of the prevention or control of such risk factors and timely referral with appropriate diagnosis and treatment. Such programs shall include information and education on health-related behaviors that can improve such important risk factors as smoking, obesity, high blood cholesterol, and lack of exercise.

(July 1, 1944, ch. 373, title IV, §424A, as added Pub. L. 105–340, title I, §104, Oct. 31, 1998, 112 Stat. 3192; amended Pub. L. 109–482, title I, §103(b)(18), Jan. 15, 2007, 120 Stat. 3688.)

EDITORIAL NOTES

AMENDMENTS

2007—Subsec. (d). Pub. L. 109–482 struck out heading and text of subsec. (d). Text read as follows: "For the purpose of carrying out this section, there are authorized to be appropriated such sums as may be necessary for each of the fiscal years 1999 through 2003. The authorization of appropriations established in the preceding sentence is in addition to any other authorization of appropriation that is available for such purpose."

STATUTORY NOTES AND RELATED SUBSIDIARIES

EFFECTIVE DATE OF 2007 AMENDMENT

Amendment by Pub. L. 109–482 applicable only with respect to amounts appropriated for fiscal year 2007 or subsequent fiscal years, see section 109 of Pub. L. 109–482, set out as a note under section 281 of this title.

§285b–7b. Coordination of Federal asthma activities

(a) In general

The Director of [1] Institute shall, through the National Asthma Education Prevention Program Coordinating Committee—

(1) identify all Federal programs that carry out asthma-related activities; and

(2) develop, in consultation with appropriate Federal agencies and professional and voluntary health organizations, a Federal plan for responding to asthma.

(b) Representation of the Department of Housing and Urban Development

A representative of the Department of Housing and Urban Development shall be included on the National Asthma Education Prevention Program Coordinating Committee for the purpose of performing the tasks described in subsection (a).

(July 1, 1944, ch. 373, title IV, §424B, as added Pub. L. 106–310, div. A, title V, §521, Oct. 17, 2000, 114 Stat. 1116; amended Pub. L. 109–482, title I, §§103(b)(19), 104(b)(1)(G), Jan. 15, 2007, 120 Stat. 3688, 3693.)

EDITORIAL NOTES

AMENDMENTS

2007—Subsec. (a). Pub. L. 109–482, §104(b)(1)(G), inserted "and" at end of par. (1), substituted a period for "; and" at end of par. (2), and struck out par. (3) which read as follows: "not later than 12 months after October 17, 2000, submit recommendations to the appropriate committees of the Congress on ways to strengthen and improve the coordination of asthma-related activities of the Federal Government."

Subsec. (c). Pub. L. 109–482, §103(b)(19), struck out heading and text of subsec. (c). Text read as follows: "For the purpose of carrying out this section, there are authorized to be appropriated such sums as may be necessary for each of the fiscal years 2001 through 2005."

STATUTORY NOTES AND RELATED SUBSIDIARIES

EFFECTIVE DATE OF 2007 AMENDMENT

Amendment by Pub. L. 109–482 applicable only with respect to amounts appropriated for fiscal year 2007 or subsequent fiscal years, see section 109 of Pub. L. 109–482, set out as a note under section 281 of this title.

[1] *So in original. Probably should be followed by "the".*

§285b–7c. Tuberculosis

(a) In general

The Director of the National Institutes of Health may expand, intensify, and coordinate research and development and related activities of the Institutes with respect to tuberculosis including activities toward the goal of eliminating such disease.

(b) Certain activities

Activities under subsection (a) may include—

(1) enhancing basic and clinical research on tuberculosis, including drug resistant tuberculosis;

(2) expanding research on the relationship between such disease and the human immunodeficiency virus; and

(3) developing new tools for the elimination of tuberculosis, including public health interventions and methods to enhance detection and response to outbreaks of tuberculosis, including multidrug resistant tuberculosis.

(July 1, 1944, ch. 373, title IV, §424C, as added Pub. L. 110–392, title II, §201, Oct. 13, 2008, 122 Stat. 4201.)

§285b–8. Congenital heart disease

(a) In general

The Director of the Institute may expand, intensify, and coordinate research and related activities of the Institute with respect to congenital heart disease, which may include congenital heart disease research with respect to—

(1) causation of congenital heart disease, including genetic causes;

(2) long-term outcomes in individuals with congenital heart disease, including infants, children, teenagers, adults, and elderly individuals;

(3) diagnosis, treatment, and prevention;

(4) studies using longitudinal data and retrospective analysis to identify effective treatments and outcomes for individuals with congenital heart disease; and

(5) identifying barriers to life-long care for individuals with congenital heart disease.

(b) Coordination of research activities

The Director of the Institute may coordinate research efforts related to congenital heart disease among multiple research institutions and may develop research networks.

(c) Minority and medically underserved communities

In carrying out the activities described in this section, the Director of the Institute shall consider the application of such research and other activities to minority and medically underserved communities.

(July 1, 1944, ch. 373, title IV, §425, as added Pub. L. 111–148, title X, §10411(b)(2), Mar. 23, 2010, 124 Stat. 989.)

EDITORIAL NOTES

PRIOR PROVISIONS

A prior section 285b–8, act July 1, 1944, ch. 373, title IV, §425, as added Pub. L. 103–43, title V, §504, June 10, 1993, 107 Stat. 160, authorized appropriations to carry out this subpart, prior to repeal by Pub. L. 109–482, title I, §§103(b)(20), 109, Jan. 15, 2007, 120 Stat. 3688, 3697, applicable only with respect to amounts appropriated for fiscal year 2007 or subsequent fiscal years.

§285b–9. HHS valvular heart disease activities

(a) In general

The Secretary of Health and Human Services (referred to in this section as the "Secretary") shall, as appropriate, continue activities related to research, education, and awareness of valvular heart diseases.

(b) NIH research related to valvular heart diseases

(1) In general

The Director of the National Institutes of Health, in consultation with the Director of the National Heart, Lung, and Blood Institute, may support or conduct research regarding valvular heart diseases.

(2) Support further research

In order to improve information on, and understanding of, causation and risk factors for valvular heart diseases, research conducted or supported under this subsection for such diseases may include the following:

(A) Use of advanced technological imaging and other relevant methods to generate data related to valvular heart diseases.

(B) Assessing potential risk factors for sudden cardiac arrest or sudden cardiac death from valvular heart diseases.

(C) Other activities, as appropriate, in order to improve the availability of information on, and advance research related to, valvular heart diseases.

(3) Mitral valve prolapse workshop

Not later than 2 years after December 20, 2022, the Director of the National Heart, Lung, and Blood Institute shall, as appropriate, convene a workshop composed of subject matter experts and stakeholders to identify research needs and opportunities to develop recommendations for the identification and treatment of individuals with mitral valve prolapse, including such individuals who may be at risk for sudden cardiac arrest or sudden cardiac death.

(c) Prevention activities to improve awareness of sudden cardiac death as a result of valvular heart diseases

(1) In general

The Secretary may carry out activities to increase education and awareness of valvular heart diseases in order to reduce the incidence of sudden cardiac death caused by such diseases. The Secretary may—

(A) award grants or contracts to public or nonprofit private entities to carry out activities under this subsection; and

(B) directly, or through grants or contracts, provide technical assistance with respect to such activities.

(2) Certain activities

Upon availability of applicable data, projects carried out under paragraph (1) may include—

(A) continuing activities at the Centers for Disease Control and Prevention related to valvular heart diseases;

(B) improving the awareness of the public concerning any risk factors for, the symptoms of, and the public health impact of, valvular heart diseases; and

(C) enhancing public health data collection and improving the quality of such data, as appropriate, regarding cardiac arrests, including cardiac arrests that occur outside of the hospital.

(3) Grant prioritization

The Secretary may, in awarding grants or entering into contracts pursuant to paragraph (1), give priority to entities seeking to carry out projects for populations most impacted by valvular heart diseases.

(4) Coordination of activities

The Secretary shall, as appropriate, ensure that activities under this section are coordinated with other agencies and offices of the Department of Health and Human Services that carry out activities regarding valvular heart diseases.

(5) Best practices

The Secretary shall, as applicable and appropriate, identify and disseminate best practices for relevant health care providers related to valvular heart diseases.

(d) Authorization of appropriations

For purposes of carrying out this section, there are authorized to be appropriated $28,000,000 for each of fiscal years 2023 through 2027.

(Pub. L. 117–244, §2, Dec. 20, 2022, 136 Stat. 2340.)

EDITORIAL NOTES

CODIFICATION

Section was enacted as part of the Cardiovascular Advances in Research and Opportunities Legacy Act, and not as part of the Public Health Service Act which comprises this chapter.

SUBPART 3—NATIONAL INSTITUTE OF DIABETES AND DIGESTIVE AND KIDNEY DISEASES

§285c. Purpose of Institute

The general purpose of the National Institute of Diabetes and Digestive and Kidney Diseases (hereafter in this subpart referred to as the "Institute") is the conduct and support of research, training, health information dissemination, and other programs with respect to diabetes mellitus and endocrine and metabolic diseases, digestive diseases and nutritional disorders, and kidney, urologic, and hematologic diseases.

(July 1, 1944, ch. 373, title IV, §426, as added Pub. L. 99–158, §2, Nov. 20, 1985, 99 Stat. 841.)

STATUTORY NOTES AND RELATED SUBSIDIARIES

STUDY ON METABOLIC DISORDERS

Pub. L. 106–310, div. A, title XXVIII, §2802, Oct. 17, 2000, 114 Stat. 1167, provided that:

"(a) IN GENERAL.—The Secretary of Health and Human Services (in this section referred to as the 'Secretary') shall, in consultation with relevant experts or through the Institute of Medicine, study issues related to treatment of PKU and other metabolic disorders for children, adolescents, and adults, and mechanisms to assure access to effective treatment, including special diets, for children and others with PKU and other metabolic disorders. Such mechanisms shall be evidence-based and reflect the best scientific knowledge regarding effective treatment and prevention of disease progression.

"(b) DISSEMINATION OF RESULTS.—Upon completion of the study referred to in subsection (a), the Secretary shall disseminate and otherwise make available the results of the study to interested groups and organizations, including insurance commissioners, employers, private insurers, health care professionals, State and local public health agencies, and State agencies that carry out the Medicaid program under title XIX of the Social Security Act [42 U.S.C. 1396 et seq.] or the State children's health insurance program under title XXI of such Act [42 U.S.C. 1397aa et seq.].

"(c) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated to carry out this section such sums as may be necessary for each of the fiscal years 2001 through 2003."

REVIEW OF DISEASE RESEARCH PROGRAMS OF THE NATIONAL INSTITUTE OF DIABETES AND DIGESTIVE AND KIDNEY DISEASES

Pub. L. 99–158, §10, Nov. 20, 1985, 99 Stat. 883, required the Secretary of Health and Human Services to review the efficiency of the disease research programs of the National Institute of Diabetes and Digestive and Kidney Diseases, to be completed within one year of Nov. 20, 1985.

§285c–1. Data systems and information clearinghouses

(a) National Diabetes Data System and National Diabetes Clearinghouse

The Director of the Institute shall (1) establish the National Diabetes Data System for the collection, storage, analysis, retrieval, and dissemination of data derived from patient populations with diabetes, including, where possible, data involving general populations for the purpose of detection of individuals with a risk of developing diabetes, and (2) establish the National Diabetes Information Clearinghouse to facilitate and enhance knowledge and understanding of diabetes on the part of health professionals, patients, and the public through the effective dissemination of information.

(b) National Digestive Diseases Data System and National Digestive Diseases Information Clearinghouse

The Director of the Institute shall (1) establish the National Digestive Diseases Data System for the collection, storage, analysis, retrieval, and dissemination of data derived from patient populations with digestive diseases, including, where possible, data involving general populations for the purpose of detection of individuals with a risk of developing digestive diseases, and (2) establish the National Digestive Diseases Information Clearinghouse to facilitate and enhance knowledge and understanding of digestive diseases on the part of health professionals, patients, and the public through the effective dissemination of information.

(c) National Kidney and Urologic Diseases Data System and National Kidney and Urologic Diseases Information Clearinghouse

The Director of the Institute shall (1) establish the National Kidney and Urologic Diseases Data System for the collection, storage, analysis, retrieval, and dissemination of data derived from patient populations with kidney and urologic diseases, including, where possible, data involving general populations for the purpose of detection of individuals with a risk of developing kidney and urologic diseases, and (2) establish the National Kidney and Urologic Diseases Information Clearinghouse to facilitate and enhance knowledge and understanding of kidney and urologic diseases on the part of health professionals, patients, and the public through the effective dissemination of information.

(July 1, 1944, ch. 373, title IV, §427, as added Pub. L. 99–158, §2, Nov. 20, 1985, 99 Stat. 841.)

§285c–2. Division Directors for Diabetes, Endocrinology, and Metabolic Diseases, Digestive Diseases and Nutrition, and Kidney, Urologic, and Hematologic Diseases; functions

(a)(1) In the Institute there shall be a Division Director for Diabetes, Endocrinology, and Metabolic Diseases, a Division Director for Digestive Diseases and Nutrition, and a Division Director for Kidney, Urologic, and Hematologic Diseases. Such Division Directors, under the supervision of the Director of the Institute, shall be responsible for—

(A) developing a coordinated plan (including recommendations for expenditures) for each of the national research institutes within the National Institutes of Health with respect to research and training concerning diabetes, endocrine and metabolic diseases, digestive diseases and nutrition, and kidney, urologic, and hematologic diseases;

(B) assessing the adequacy of management approaches for the activities within such institutes concerning such diseases and nutrition and developing improved approaches if needed;

(C) monitoring and reviewing expenditures by such institutes concerning such diseases and nutrition; and

(D) identifying research opportunities concerning such diseases and nutrition and recommending ways to utilize such opportunities.

(2) The Director of the Institute shall transmit to the Director of NIH the plans, recommendations, and reviews of the Division Directors under subparagraphs (A) through (D) of paragraph (1) together with such comments and recommendations as the Director of the Institute determines appropriate.

(b) The Director of the Institute, acting through the Division Director for Diabetes, Endocrinology, and Metabolic Diseases, the Division Director for Digestive Diseases and Nutrition, and the Division Director for Kidney, Urologic, and Hematologic Diseases, shall—

(1) carry out programs of support for research and training (other than training for which Ruth L. Kirschstein National Research Service Awards may be made under section 288 of this title) in the diagnosis, prevention, and treatment of diabetes mellitus and endocrine and metabolic diseases, digestive diseases and nutritional disorders, and kidney, urologic, and hematologic diseases, including support for training in medical schools, graduate clinical training, graduate training in epidemiology, epidemiology studies, clinical trials, and interdisciplinary research programs; and

(2) establish programs of evaluation, planning, and dissemination of knowledge related to such research and training.

(July 1, 1944, ch. 373, title IV, §428, as added Pub. L. 99–158, §2, Nov. 20, 1985, 99 Stat. 842; amended Pub. L. 103–43, title XX, §2008(b)(4), June 10, 1993, 107 Stat. 211; Pub. L. 107–206, title I, §804(c), Aug. 2, 2002, 116 Stat. 874.)

EDITORIAL NOTES

AMENDMENTS

2002—Subsec. (b)(1). Pub. L. 107–206 substituted "Ruth L. Kirschstein National Research Service Awards" for "National Research Service Awards".

1993—Subsec. (b). Pub. L. 103–43 substituted "the" for "the the" before "Division Director for Diabetes" in introductory provisions.

§285c–3. Interagency coordinating committees

(a) Establishment and purpose

For the purpose of—

(1) better coordination of the research activities of all the national research institutes relating to diabetes mellitus, digestive diseases, and kidney, urologic, and hematologic diseases; and

(2) coordinating those aspects of all Federal health programs and activities relating to such diseases to assure the adequacy and technical soundness of such programs and activities and to provide for the full communication and exchange of information necessary to maintain adequate coordination of such programs and activities;

the Secretary shall establish a Diabetes Mellitus Interagency Coordinating Committee, a Digestive Diseases Interagency Coordinating Committee, and a Kidney, Urologic, and Hematologic Diseases Coordinating Committee (hereafter in this section individually referred to as a "Committee").

(b) Membership; chairman; meetings

Each Committee shall be composed of the Directors of each of the national research institutes and divisions involved in research with respect to the diseases for which the Committee is established, the Division Director of the Institute for the diseases for which the Committee is established, the Under Secretary for Health of the Department of Veterans Affairs, and the Assistant Secretary of Defense for Health Affairs (or the designees of such officers) and shall include representation from all other Federal departments and agencies whose programs involve health functions or responsibilities relevant to such diseases, as determined by the Secretary. Each Committee shall be chaired by the Director of NIH (or the designee of the Director). Each Committee shall meet at the call of the chairman, but not less often than four times a year.

(July 1, 1944, ch. 373, title IV, §429, as added Pub. L. 99–158, §2, Nov. 20, 1985, 99 Stat. 843; amended Pub. L. 100–527, §10(4), Oct. 25, 1988, 102 Stat. 2641; Pub. L. 102–405, title III, §302(e)(1), Oct. 9, 1992, 106 Stat. 1985; Pub. L. 108–362, §3, Oct. 25, 2004, 118 Stat. 1703; Pub. L. 109–482, title I, §104(b)(1)(H), Jan. 15, 2007, 120 Stat. 3693.)

EDITORIAL NOTES

AMENDMENTS

2007—Subsecs. (c), (d). Pub. L. 109–482 struck out subsecs. (c) and (d) which required an annual report detailing the work of the Committee in carrying out subsec. (a) and an annual assessment on Federal pancreatic islet cell transplantation, respectively.

2004—Subsec. (d). Pub. L. 108–362 added subsec. (d).

1992—Subsec. (b). Pub. L. 102–405 substituted "Under Secretary for Health of the Department of Veterans Affairs" for "Chief Medical Director of the Department of Veterans Affairs".

1988—Subsec. (b). Pub. L. 100–527 substituted "Chief Medical Director of the Department of Veterans Affairs" for "Chief Medical Director of the Veterans' Administration".

STATUTORY NOTES AND RELATED SUBSIDIARIES

EFFECTIVE DATE OF 2007 AMENDMENT

Amendment by Pub. L. 109–482 applicable only with respect to amounts appropriated for fiscal year 2007 or subsequent fiscal years, see section 109 of Pub. L. 109–482, set out as a note under section 281 of this title.

EFFECTIVE DATE OF 1988 AMENDMENT

Amendment by Pub. L. 100–527 effective Mar. 15, 1989, see section 18(a) of Pub. L. 100–527, set out as a Department of Veterans Affairs Act note under section 301 of Title 38, Veterans' Benefits.

§285c–4. Advisory boards

(a) Establishment

The Secretary shall establish in the Institute the National Diabetes Advisory Board, the National

Digestive Diseases Advisory Board, and the National Kidney and Urologic Diseases Advisory Board (hereafter in this section individually referred to as an "Advisory Board").

(b) Membership; ex officio members

Each Advisory Board shall be composed of eighteen appointed members and nonvoting ex officio members as follows:

(1) The Secretary shall appoint—

(A) twelve members from individuals who are scientists, physicians, and other health professionals, who are not officers or employees of the United States, and who represent the specialties and disciplines relevant to the diseases with respect to which the Advisory Board is established; and

(B) six members from the general public who are knowledgeable with respect to such diseases, including at least one member who is a person who has such a disease and one member who is a parent of a person who has such a disease.

Of the appointed members at least five shall by virtue of training or experience be knowledgeable in the fields of health education, nursing, data systems, public information, and community program development.

(2)(A) The following shall be ex officio members of each Advisory Board:

(i) The Assistant Secretary for Health, the Director of NIH, the Director of the National Institute of Diabetes and Digestive and Kidney Diseases, the Director of the Centers for Disease Control and Prevention, the Under Secretary for Health of the Department of Veterans Affairs, the Assistant Secretary of Defense for Health Affairs, and the Division Director of the National Institute of Diabetes and Digestive and Kidney Diseases for the diseases for which the Board is established (or the designees of such officers).

(ii) Such other officers and employees of the United States as the Secretary determines necessary for the Advisory Board to carry out its functions.

(B) In the case of the National Diabetes Advisory Board, the following shall also be ex officio members: The Director of the National Heart, Lung, and Blood Institute, the Director of the National Eye Institute, the Director of the Eunice Kennedy Shriver National Institute of Child Health and Human Development, and the Administrator of the Health Resources and Services Administration (or the designees of such officers).

(c) Compensation

Members of an Advisory Board who are officers or employees of the Federal Government shall serve as members of the Advisory Board without compensation in addition to that received in their regular public employment. Other members of the Board shall receive compensation at rates not to exceed the daily equivalent of the annual rate in effect for grade GS–18 of the General Schedule for each day (including traveltime) they are engaged in the performance of their duties as members of the Board.

(d) Term of office; vacancy

The term of office of an appointed member of an Advisory Board is four years, except that no term of office may extend beyond the expiration of the Advisory Board. Any member appointed to fill a vacancy for an unexpired term shall be appointed for the remainder of such term. A member may serve after the expiration of the member's term until a successor has taken office. If a vacancy occurs in an Advisory Board, the Secretary shall make an appointment to fill the vacancy not later than 90 days from the date the vacancy occurred.

(e) Chairman

The members of each Advisory Board shall select a chairman from among the appointed members.

(f) Executive director; professional and clerical staff; administrative support services and

facilities

The Secretary shall, after consultation with and consideration of the recommendations of an Advisory Board, provide the Advisory Board with an executive director and one other professional staff member. In addition, the Secretary shall, after consultation with and consideration of the recommendations of the Advisory Board, provide the Advisory Board with such additional professional staff members, such clerical staff members, such services of consultants, such information, and (through contracts or other arrangements) such administrative support services and facilities, as the Secretary determines are necessary for the Advisory Board to carry out its functions.

(g) Meetings

Each Advisory Board shall meet at the call of the chairman or upon request of the Director of the Institute, but not less often than four times a year.

(h) Functions of National Diabetes Advisory Board and National Digestive Diseases Advisory Board

The National Diabetes Advisory Board and the National Digestive Diseases Advisory Board shall—

(1) review and evaluate the implementation of the plan (referred to in section 285c–7 of this title) respecting the diseases with respect to which the Advisory Board was established and periodically update the plan to ensure its continuing relevance;

(2) for the purpose of assuring the most effective use and organization of resources respecting such diseases, advise and make recommendations to the Congress, the Secretary, the Director of NIH, the Director of the Institute, and the heads of other appropriate Federal agencies for the implementation and revision of such plan; and

(3) maintain liaison with other advisory bodies related to Federal agencies involved in the implementation of such plan, the coordinating committee for such diseases, and with key non-Federal entities involved in activities affecting the control of such diseases.

(i) Subcommittees; establishment and membership

In carrying out its functions, each Advisory Board may establish subcommittees, convene workshops and conferences, and collect data. Such subcommittees may be composed of Advisory Board members and nonmember consultants with expertise in the particular area addressed by such subcommittees. The subcommittees may hold such meetings as are necessary to enable them to carry out their activities.

(j) Termination of predecessor boards; time within which to appoint members

The National Diabetes Advisory Board and the National Digestive Diseases Advisory Board in existence on November 20, 1985, shall terminate upon the appointment of a successor Board under subsection (a). The Secretary shall make appointments to the Advisory Boards established under subsection (a) before the expiration of 90 days after November 20, 1985. The members of the Boards in existence on November 20, 1985, may be appointed, in accordance with subsections (b) and (d), to the Boards established under subsection (a) for diabetes and digestive diseases, except that at least one-half of the members of the National Diabetes Advisory Board in existence on November 20, 1985, shall be appointed to the National Diabetes Advisory Board first established under subsection (a).

(July 1, 1944, ch. 373, title IV, §430, as added Pub. L. 99–158, §2, Nov. 20, 1985, 99 Stat. 844; amended Pub. L. 100–607, title I, §131, Nov. 4, 1988, 102 Stat. 3056; Pub. L. 102–405, title III, §302(e)(1), Oct. 9, 1992, 106 Stat. 1985; Pub. L. 102–531, title III, §312(d)(6), Oct. 27, 1992, 106 Stat. 3504; Pub. L. 103–43, title XX, §2008(b)(5), June 10, 1993, 107 Stat. 211; Pub. L. 105–362, title VI, §601(a)(1)(C), Nov. 10, 1998, 112 Stat. 3285; Pub. L. 110–154, §1(b)(6), Dec. 21, 2007, 121 Stat. 1827.)

EDITORIAL NOTES

AMENDMENTS

2007—Subsec. (b)(2)(B). Pub. L. 110–154 substituted "Eunice Kennedy Shriver National Institute of Child Health and Human Development" for "National Institute of Child Health and Human Development".

1998—Subsecs. (j), (k). Pub. L. 105–362 redesignated subsec. (k) as (j) and struck out former subsec. (j) which read as follows: "Each Advisory Board shall prepare an annual report for the Secretary which—

"(1) describes the Advisory Board's activities in the fiscal year for which the report is made;

"(2) describes and evaluates the progress made in such fiscal year in research, treatment, education, and training with respect to the diseases with respect to which the Advisory Board was established;

"(3) summarizes and analyzes expenditures made by the Federal Government for activities respecting such diseases in such fiscal year; and

"(4) contains the Advisory Board's recommendations (if any) for changes in the plan referred to in section 285c–7 of this title."

1993—Subsec. (b)(2)(A)(i). Pub. L. 103–43 substituted "Department of Veterans Affairs" for "Veterans' Administration".

1992—Subsec. (b)(2)(A)(i). Pub. L. 102–531 substituted "Centers for Disease Control and Prevention" for "Centers for Disease Control".

Pub. L. 102–405 substituted "Under Secretary for Health" for "Chief Medical Director".

1988—Subsecs. (k), (l). Pub. L. 100–607 redesignated subsec. (l) as (k) and struck out former subsec. (k) which read as follows: "Each Advisory Board shall expire on September 30, 1988."

STATUTORY NOTES AND RELATED SUBSIDIARIES

TERMINATION OF ADVISORY BOARDS

Advisory boards established after Jan. 5, 1973, to terminate not later than the expiration of the 2-year period beginning on the date of their establishment, unless, in the case of a board established by the President or an officer of the Federal Government, such board is renewed by appropriate action prior to the expiration of such 2-year period, or in the case of a board established by the Congress, its duration is otherwise provided by law. See sections 1001(2) and 1013 of Title 5, Government Organization and Employees.

Pub. L. 93–641, §6, Jan. 4, 1975, 88 Stat. 2275, set out as a note under section 217a of this title, provided that an advisory committee established pursuant to the Public Health Service Act shall terminate at such time as may be specifically prescribed by an Act of Congress enacted after Jan. 4, 1975.

REFERENCES IN OTHER LAWS TO GS–16, 17, OR 18 PAY RATES

References in laws to the rates of pay for GS–16, 17, or 18, or to maximum rates of pay under the General Schedule, to be considered references to rates payable under specified sections of Title 5, Government Organization and Employees, see section 529 [title I, §101(c)(1)] of Pub. L. 101–509, set out in a note under section 5376 of Title 5.

§285c–5. Research and training centers; development or expansion

(a) Diabetes mellitus and related endocrine and metabolic diseases

(1) Consistent with applicable recommendations of the National Commission on Diabetes, the Director of the Institute shall provide for the development or substantial expansion of centers for research and training in diabetes mellitus and related endocrine and metabolic diseases. Each center developed or expanded under this subsection shall—

(A) utilize the facilities of a single institution, or be formed from a consortium of cooperating institutions, meeting such research and training qualifications as may be prescribed by the Secretary; and

(B) conduct—

(i) research in the diagnosis and treatment of diabetes mellitus and related endocrine and metabolic diseases and the complications resulting from such diseases;

(ii) training programs for physicians and allied health personnel in current methods of diagnosis and treatment of such diseases and complications, and in research in diabetes; and

(iii) information programs for physicians and allied health personnel who provide primary care for patients with such diseases or complications.

(2) A center may use funds provided under paragraph (1) to provide stipends for nurses and allied health professionals enrolled in research training programs described in paragraph (1)(B)(ii).

(b) Digestive diseases and related functional, congenital, metabolic disorders, and normal development of digestive tract

Consistent with applicable recommendations of the National Digestive Diseases Advisory Board, the Director shall provide for the development or substantial expansion of centers for research in digestive diseases and related functional, congenital, metabolic disorders, and normal development of the digestive tract. Each center developed or expanded under this subsection—

(1) shall utilize the facilities of a single institution, or be formed from a consortium of cooperating institutions, meeting such research qualifications as may be prescribed by the Secretary;

(2) shall develop and conduct basic and clinical research into the cause, diagnosis, early detection, prevention, control, and treatment of digestive diseases and nutritional disorders and related functional, congenital, or metabolic complications resulting from such diseases or disorders;

(3) shall encourage research into and programs for—

(A) providing information for patients with such diseases and the families of such patients, physicians and others who care for such patients, and the general public;

(B) model programs for cost effective and preventive patient care; and

(C) training physicians and scientists in research on such diseases, disorders, and complications; and

(4) may perform research and participate in epidemiological studies and data collection relevant to digestive diseases and disorders and disseminate such research, studies, and data to the health care profession and to the public.

(c) Kidney and urologic diseases

The Director shall provide for the development or substantial expansion of centers for research in kidney and urologic diseases. Each center developed or expanded under this subsection—

(1) shall utilize the facilities of a single institution, or be formed from a consortium of cooperating institutions, meeting such research qualifications as may be prescribed by the Secretary;

(2) shall develop and conduct basic and clinical research into the cause, diagnosis, early detection, prevention, control, and treatment of kidney and urologic diseases;

(3) shall encourage research into and programs for—

(A) providing information for patients with such diseases, disorders, and complications and the families of such patients, physicians and others who care for such patients, and the general public;

(B) model programs for cost effective and preventive patient care; and

(C) training physicians and scientists in research on such diseases; and

(4) may perform research and participate in epidemiological studies and data collection relevant to kidney and urologic diseases in order to disseminate such research, studies, and data to the health care profession and to the public.

(d) Nutritional disorders

(1) The Director of the Institute shall, subject to the extent of amounts made available in appropriations Acts, provide for the development or substantial expansion of centers for research and training regarding nutritional disorders, including obesity.

(2) The Director of the Institute shall carry out paragraph (1) in collaboration with the Director of the National Cancer Institute and with the Directors of such other agencies of the National Institutes of Health as the Director of NIH determines to be appropriate.

(3) Each center developed or expanded under paragraph (1) shall—

(A) utilize the facilities of a single institution, or be formed from a consortium of cooperating institutions, meeting such research and training qualifications as may be prescribed by the Director;

(B) conduct basic and clinical research into the cause, diagnosis, early detection, prevention, control and treatment of nutritional disorders, including obesity and the impact of nutrition and diet on child development;

(C) conduct training programs for physicians and allied health professionals in current methods of diagnosis and treatment of such diseases and complications, and in research in such disorders; and

(D) conduct information programs for physicians and allied health professionals who provide primary care for patients with such disorders or complications.

(e) Geographic distribution; period of support, additional periods

Insofar as practicable, centers developed or expanded under this section should be geographically dispersed throughout the United States and in environments with proven research capabilities. Support of a center under this section may be for a period of not to exceed five years and such period may be extended by the Director of the Institute for additional periods of not more than five years each if the operations of such center have been reviewed by an appropriate technical and scientific peer review group established by the Director and if such group has recommended to the Director that such period should be extended.

(July 1, 1944, ch. 373, title IV, §431, as added Pub. L. 99–158, §2, Nov. 20, 1985, 99 Stat. 846; amended Pub. L. 103–43, title VI, §601(b), June 10, 1993, 107 Stat. 161.)

EDITORIAL NOTES

AMENDMENTS

1993—Subsecs. (d), (e). Pub. L. 103–43 added subsec. (d) and redesignated former subsec. (d) as (e).

§285c–6. Advisory council subcommittees

There are established within the advisory council for the Institute appointed under section 284a of this title a subcommittee on diabetes and endocrine and metabolic diseases, a subcommittee on digestive diseases and nutrition, and a subcommittee on kidney, urologic, and hematologic diseases. The subcommittees shall be composed of members of the advisory council who are outstanding in the diagnosis, prevention, and treatment of the diseases for which the subcommittees are established and members of the advisory council who are leaders in the fields of education and public affairs. The subcommittees are authorized to review applications made to the Director of the Institute for grants for research and training projects relating to the diagnosis, prevention, and treatment of the diseases for which the subcommittees are established and shall recommend to the advisory council those applications and contracts that the subcommittees determine will best carry out the purposes of the Institute. The subcommittees shall also review and evaluate the diabetes and endocrine and metabolic diseases, digestive diseases and nutrition, and kidney, urologic, and hematologic diseases programs of the Institute and recommend to the advisory council such changes in the administration of such programs as the subcommittees determine are necessary.

(July 1, 1944, ch. 373, title IV, §432, as added Pub. L. 99–158, §2, Nov. 20, 1985, 99 Stat. 847.)

§285c–7. Biennial report

The Director of the Institute shall prepare for inclusion in the biennial report made under section 284b [1] of this title a description of the Institute's activities—

(1) under the current diabetes plan under the National Diabetes Mellitus Research and

Education Act; and

(2) under the current digestive diseases plan formulated under the Arthritis, Diabetes, and Digestive Diseases Amendments of 1976.

The description submitted by the Director shall include an evaluation of the activities of the centers supported under section 285c–5 of this title.

(July 1, 1944, ch. 373, title IV, §433, as added Pub. L. 99–158, §2, Nov. 20, 1985, 99 Stat. 848.)

EDITORIAL NOTES

REFERENCES IN TEXT

Section 284b of this title, referred to in text, was repealed by Pub. L. 109–482, title I, §104(b)(1)(C), Jan. 15, 2007, 120 Stat. 3693.

The National Diabetes Mellitus Research and Education Act, referred to in par. (1), is Pub. L. 93–354, July 23, 1974, 88 Stat. 373, which enacted former sections 289c–1a, 289c–2, and 289c–3 of this title, amended section 247b and former section 289c–1 of this title, and enacted provisions formerly set out as notes under section 289c–2 of this title. For complete classification of this Act to the Code, see Short Title of 1974 Amendments note set out under section 201 of this title and Tables.

The Arthritis, Diabetes, and Digestive Diseases Amendments of 1976, referred to in par. (2), is Pub. L. 94–562, Oct. 19, 1976, 90 Stat. 2645, which enacted former sections 289c–3a, 289c–7, and 289c–8 of this title, amended former sections 289c–2, 289c–5, and 289c–6 of this title, and enacted provisions formerly set out as notes under sections 289a, 289c–3a, and 289c–7 of this title. For complete classification of this Act to the Code, see Short Title of 1976 Amendments note set out under section 201 of this title and Tables.

[1] *See References in Text note below.*

§285c–8. Nutritional disorders program

(a) Establishment

The Director of the Institute, in consultation with the Director of NIH, shall establish a program of conducting and supporting research, training, health information dissemination, and other activities with respect to nutritional disorders, including obesity.

(b) Support of activities

In carrying out the program established under subsection (a), the Director of the Institute shall conduct and support each of the activities described in such subsection.

(c) Dissemination of information

In carrying out the program established under subsection (a), the Director of the Institute shall carry out activities to facilitate and enhance knowledge and understanding of nutritional disorders, including obesity, on the part of health professionals, patients, and the public through the effective dissemination of information.

(July 1, 1944, ch. 373, title IV, §434, as added Pub. L. 103–43, title VI, §601[(a)], June 10, 1993, 107 Stat. 161.)

§285c–9. Juvenile diabetes

(a) Long-term epidemiology studies

The Director of the Institute shall conduct or support long-term epidemiology studies in which individuals with or at risk for type 1, or juvenile, diabetes are followed for 10 years or more. Such studies shall investigate the causes and characteristics of the disease and its complications.

(b) Clinical trial infrastructure/innovative treatments for juvenile diabetes

The Secretary, acting through the Director of the National Institutes of Health, shall support regional clinical research centers for the prevention, detection, treatment, and cure of juvenile diabetes.

(c) Prevention of type 1 diabetes

The Secretary, acting through the appropriate agencies, shall provide for a national effort to prevent type 1 diabetes. Such effort shall provide for a combination of increased efforts in research and development of prevention strategies, including consideration of vaccine development, coupled with appropriate ability to test the effectiveness of such strategies in large clinical trials of children and young adults.

(July 1, 1944, ch. 373, title IV, §434A, as added Pub. L. 106–310, div. A, title IV, §402, Oct. 17, 2000, 114 Stat. 1112; amended Pub. L. 109–482, title I, §103(b)(21), Jan. 15, 2007, 120 Stat. 3688.)

EDITORIAL NOTES

AMENDMENTS

2007—Subsec. (d). Pub. L. 109–482 struck out heading and text of subsec. (d). Text read as follows: "For the purpose of carrying out this section, there are authorized to be appropriated such sums as may be necessary for each of the fiscal years 2001 through 2005."

STATUTORY NOTES AND RELATED SUBSIDIARIES

EFFECTIVE DATE OF 2007 AMENDMENT

Amendment by Pub. L. 109–482 applicable only with respect to amounts appropriated for fiscal year 2007 or subsequent fiscal years, see section 109 of Pub. L. 109–482, set out as a note under section 281 of this title.

SUBPART 4—NATIONAL INSTITUTE OF ARTHRITIS AND MUSCULOSKELETAL AND SKIN DISEASES

§285d. Purpose of Institute

The general purpose of the National Institute of Arthritis and Musculoskeletal and Skin Diseases (hereafter in this subpart referred to as the "Institute") is the conduct and support of research and training, the dissemination of health information, and other programs with respect to arthritis and musculoskeletal and skin diseases (including sports-related disorders), with particular attention to the effect of these diseases on children.

(July 1, 1944, ch. 373, title IV, §435, as added Pub. L. 99–158, §2, Nov. 20, 1985, 99 Stat. 848; amended Pub. L. 103–43, title VII, §701(a), June 10, 1993, 107 Stat. 162.)

EDITORIAL NOTES

AMENDMENTS

1993—Pub. L. 103–43 substituted "(including sports-related disorders), with particular attention to the effect of these diseases on children" for ", including sports-related disorders".

§285d–1. National arthritis and musculoskeletal and skin diseases program

(a) Plan to expand, intensify, and coordinate activities; submission; periodic review and revision

The Director of the Institute, with the advice of the Institute's advisory council, shall prepare and transmit to the Director of NIH a plan for a national arthritis and musculoskeletal and skin diseases program to expand, intensify, and coordinate the activities of the Institute respecting arthritis and musculoskeletal and skin diseases. The plan shall include such comments and recommendations as the Director of the Institute determines appropriate. The plan shall place particular emphasis upon expanding research into better understanding the causes and the development of effective treatments for arthritis affecting children. The Director of the Institute shall periodically review and revise such plan and shall transmit any revisions of such plan to the Director of NIH.

(b) Coordination of activities with other national research institutes; minimum activities under program

Activities under the national arthritis and musculoskeletal and skin diseases program shall be coordinated with the other national research institutes to the extent that such institutes have responsibilities respecting arthritis and musculoskeletal and skin diseases, and shall, at least, provide for—

(1) investigation into the epidemiology, etiology, and prevention of all forms of arthritis and musculoskeletal and skin diseases, including sports-related disorders, primarily through the support of basic research in such areas as immunology, genetics, biochemistry, microbiology, physiology, bioengineering, and any other scientific discipline which can contribute important knowledge to the treatment and understanding of arthritis and musculoskeletal and skin diseases;

(2) research into the development, trial, and evaluation of techniques, drugs, and devices used in the diagnosis, treatment, including medical rehabilitation, and prevention of arthritis and musculoskeletal and skin diseases;

(3) research on the refinement, development, and evaluation of technological devices that will replace or be a substitute for damaged bone, muscle, and joints and other supporting structures;

(4) the establishment of mechanisms to monitor the causes of athletic injuries and identify ways of preventing such injuries on scholastic athletic fields; and

(5) research into the causes of arthritis affecting children and the development, trial, and evaluation of techniques, drugs and devices used in the diagnosis, treatment (including medical rehabilitation), and prevention of arthritis in children.

(c) Program to be carried out in accordance with plan

The Director of the Institute shall carry out the national arthritis and musculoskeletal and skin diseases program in accordance with the plan prepared under subsection (a) and any revisions of such plan made under such subsection.

(July 1, 1944, ch. 373, title IV, §436, as added Pub. L. 99–158, §2, Nov. 20, 1985, 99 Stat. 848; amended Pub. L. 100–607, title I, §136, Nov. 4, 1988, 102 Stat. 3056; Pub. L. 103–43, title VII, §701(b), June 10, 1993, 107 Stat. 162.)

EDITORIAL NOTES

AMENDMENTS

1993—Subsec. (a). Pub. L. 103–43, §701(b)(1), inserted after second sentence "The plan shall place particular emphasis upon expanding research into better understanding the causes and the development of effective treatments for arthritis affecting children."

Subsec. (b)(5). Pub. L. 103–43, §701(b)(2), added par. (5).

1988—Pub. L. 100–607 inserted "and skin" after "musculoskeletal" in section catchline and wherever appearing in text.

§285d–2. Research and training

The Director of the Institute shall—

(1) carry out programs of support for research and training (other than training for which Ruth L. Kirschstein National Research Service Awards may be made under section 288 of this title) in

the diagnosis, prevention, and treatment of arthritis and musculoskeletal and skin diseases, including support for training in medical schools, graduate clinical training, graduate training in epidemiology, epidemiology studies, clinical trials, and interdisciplinary research programs; and

(2) establish programs of evaluation, planning, and dissemination of knowledge related to such research and training.

(July 1, 1944, ch. 373, title IV, §437, as added Pub. L. 99–158, §2, Nov. 20, 1985, 99 Stat. 849; amended Pub. L. 107–206, title I, §804(c), Aug. 2, 2002, 116 Stat. 874.)

EDITORIAL NOTES

AMENDMENTS

2002—Par. (1). Pub. L. 107–206 substituted "Ruth L. Kirschstein National Research Service Awards" for "National Research Service Awards".

§285d–3. Data system and information clearinghouse

(a) The Director of the Institute shall establish the National Arthritis and Musculoskeletal and Skin Diseases Data System for the collection, storage, analysis, retrieval, and dissemination of data derived from patient populations with arthritis and musculoskeletal and skin diseases, including where possible, data involving general populations for the purpose of detection of individuals with a risk of developing arthritis and musculoskeletal and skin diseases.

(b) The Director of the Institute shall establish the National Arthritis and Musculoskeletal and Skin Diseases Information Clearinghouse to facilitate and enhance, through the effective dissemination of information, knowledge and understanding of arthritis and musculoskeletal and skin diseases, including juvenile arthritis and related conditions, by health professionals, patients, and the public.

(July 1, 1944, ch. 373, title IV, §438, as added Pub. L. 99–158, §2, Nov. 20, 1985, 99 Stat. 849; amended Pub. L. 106–310, div. A, title III, §302, Oct. 17, 2000, 114 Stat. 1111.)

EDITORIAL NOTES

AMENDMENTS

2000—Subsec. (b). Pub. L. 106–310 inserted ", including juvenile arthritis and related conditions," after "skin diseases".

§285d–4. Interagency coordinating committees

(a) Establishment and purpose

For the purpose of—

(1) better coordination of the research activities of all the national research institutes relating to arthritis, musculoskeletal diseases, and skin diseases, including sports-related disorders; and

(2) coordinating the aspects of all Federal health programs and activities relating to arthritis, musculoskeletal diseases, and skin diseases in order to assure the adequacy and technical soundness of such programs and activities and in order to provide for the full communication and exchange of information necessary to maintain adequate coordination of such programs and activities,

the Secretary shall establish an Arthritis and Musculoskeletal Diseases Interagency Coordinating Committee and a Skin Diseases Interagency Coordinating Committee (hereafter in this section individually referred to as a "Committee").

(b) Membership; chairman; meetings

Each Committee shall be composed of the Directors of each of the national research institutes and divisions involved in research regarding the diseases with respect to which the Committee is established, the Under Secretary for Health of the Department of Veterans Affairs, and the Assistant Secretary of Defense for Health Affairs (or the designees of such officers), and representatives of all other Federal departments and agencies (as determined by the Secretary) whose programs involve health functions or responsibilities relevant to arthritis and musculoskeletal diseases or skin diseases, as the case may be. Each Committee shall be chaired by the Director of NIH (or the designee of the Director). Each Committee shall meet at the call of the chairman, but not less often than four times a year.

(July 1, 1944, ch. 373, title IV, §439, as added Pub. L. 99–158, §2, Nov. 20, 1985, 99 Stat. 849; amended Pub. L. 102–405, title III, §302(e)(1), Oct. 9, 1992, 106 Stat. 1985; Pub. L. 103–43, title XX, §2008(b)(6), June 10, 1993, 107 Stat. 211; Pub. L. 105–362, title VI, §601(a)(1)(D), Nov. 10, 1998, 112 Stat. 3285.)

EDITORIAL NOTES

AMENDMENTS

1998—Subsec. (c). Pub. L. 105–362 struck out subsec. (c) which read as follows: "Not later than 120 days after the end of each fiscal year, each Committee shall prepare and transmit to the Secretary, the Director of NIH, the Director of the Institute, and the advisory council for the Institute a report detailing the activities of the Committee in such fiscal year in carrying out paragraphs (1) and (2) of subsection (a) of this section."

1993—Subsec. (b). Pub. L. 103–43 substituted "Department of Veterans Affairs" for "Veterans' Administration".

1992—Subsec. (b). Pub. L. 102–405 substituted "Under Secretary for Health" for "Chief Medical Director".

§285d–5. Arthritis and musculoskeletal diseases demonstration projects

(a) Grants for establishment and support

The Director of the Institute may make grants to public and private nonprofit entities to establish and support projects for the development and demonstration of methods for screening, detection, and referral for treatment of arthritis and musculoskeletal diseases and for the dissemination of information on such methods to the health and allied health professions. Activities under such projects shall be coordinated with Federal, State, local, and regional health agencies, centers assisted under section 285d–6 of this title, and the data system established under subsection (c).

(b) Programs included

Projects supported under this section shall include—

(1) programs which emphasize the development and demonstration of new and improved methods of screening and early detection, referral for treatment, and diagnosis of individuals with a risk of developing arthritis and musculoskeletal diseases;

(2) programs which emphasize the development and demonstration of new and improved methods for patient referral from local hospitals and physicians to appropriate centers for early diagnosis and treatment;

(3) programs which emphasize the development and demonstration of new and improved means of standardizing patient data and recordkeeping;

(4) programs which emphasize the development and demonstration of new and improved methods of dissemination of knowledge about the programs, methods, and means referred to in paragraphs (1), (2), and (3) of this subsection to health and allied health professionals;

(5) programs which emphasize the development and demonstration of new and improved methods for the dissemination to the general public of information—

(A) on the importance of early detection of arthritis and musculoskeletal diseases, of seeking prompt treatment, and of following an appropriate regimen; and

(B) to discourage the promotion and use of unapproved and ineffective diagnostic, preventive

treatment, and control methods for arthritis and unapproved and ineffective drugs and devices for arthritis and musculoskeletal diseases; and

(6) projects for investigation into the epidemiology of all forms and aspects of arthritis and musculoskeletal diseases, including investigations into the social, environmental, behavioral, nutritional, and genetic determinants and influences involved in the epidemiology of arthritis and musculoskeletal diseases.

(c) Standardization of patient data and recordkeeping

The Director shall provide for the standardization of patient data and recordkeeping for the collection, storage, analysis, retrieval, and dissemination of such data in cooperation with projects assisted under this section, centers assisted under section 285d–6 of this title, and other persons engaged in arthritis and musculoskeletal disease programs.

(July 1, 1944, ch. 373, title IV, §440, as added Pub. L. 99–158, §2, Nov. 20, 1985, 99 Stat. 850.)

§285d–6. Multipurpose arthritis and musculoskeletal diseases centers

(a) Development, modernization, and operation

The Director of the Institute shall, after consultation with the advisory council for the Institute, provide for the development, modernization, and operation (including staffing and other operating costs such as the costs of patient care required for research) of new and existing centers for arthritis and musculoskeletal diseases. For purposes of this section, the term "modernization" means the alteration, remodeling, improvement, expansion, and repair of existing buildings and the provision of equipment for such buildings to the extent necessary to make them suitable for use as centers described in the preceding sentence.

(b) Duties and functions

Each center assisted under this section shall—

(1)(A) use the facilities of a single institution or a consortium of cooperating institutions, and (B) meet such qualifications as may be prescribed by the Secretary; and

(2) conduct—

(A) basic and clinical research into the cause, diagnosis, early detection, prevention, control, and treatment of and rehabilitation from arthritis and musculoskeletal diseases and complications resulting from arthritis and musculoskeletal diseases, including research into implantable biomaterials and biomechanical and other orthopedic procedures;

(B) training programs for physicians, scientists, and other health and allied health professionals;

(C) information and continuing education programs for physicians and other health and allied health professionals who provide care for patients with arthritis and musculoskeletal diseases; and

(D) programs for the dissemination to the general public of information—

(i) on the importance of early detection of arthritis and musculoskeletal diseases, of seeking prompt treatment, and of following an appropriate regimen; and

(ii) to discourage the promotion and use of unapproved and ineffective diagnostic, preventive, treatment, and control methods and unapproved and ineffective drugs and devices.

A center may use funds provided under subsection (a) to provide stipends for health professionals enrolled in training programs described in paragraph (2)(B).

(c) Optional programs

Each center assisted under this section may conduct programs to—

(1) establish the effectiveness of new and improved methods of detection, referral, and

diagnosis of individuals with a risk of developing arthritis and musculoskeletal diseases;

(2) disseminate the results of research, screening, and other activities, and develop means of standardizing patient data and recordkeeping; and

(3) develop community consultative services to facilitate the referral of patients to centers for treatment.

(d) Geographical distribution

The Director of the Institute shall, insofar as practicable, provide for an equitable geographical distribution of centers assisted under this section. The Director shall give appropriate consideration to the need for centers especially suited to meeting the needs of children affected by arthritis and musculoskeletal diseases.

(e) Period of support; additional periods

Support of a center under this section may be for a period of not to exceed five years. Such period may be extended by the Director of the Institute for one or more additional periods of not more than five years if the operations of such center have been reviewed by an appropriate technical and scientific peer review group established by the Director and if such group has recommended to the Director that such period should be extended.

(f) Treatment and rehabilitation of children

Not later than October 1, 1993, the Director shall establish a multipurpose arthritis and musculoskeletal disease center for the purpose of expanding the level of research into the cause, diagnosis, early detection, prevention, control, and treatment of, and rehabilitation of children with arthritis and musculoskeletal diseases.

(July 1, 1944, ch. 373, title IV, §441, as added Pub. L. 99–158, §2, Nov. 20, 1985, 99 Stat. 851; amended Pub. L. 100–607, title I, §137, Nov. 4, 1988, 102 Stat. 3056; Pub. L. 103–43, title VII, §701(c), June 10, 1993, 107 Stat. 162.)

EDITORIAL NOTES

AMENDMENTS

1993—Subsec. (f). Pub. L. 103–43 added subsec. (f).

1988—Subsec. (b)(2)(A). Pub. L. 100–607 inserted "and rehabilitation from" after "and treatment of".

§285d–6a. Lupus

(a) In general

The Director of the Institute shall expand and intensify research and related activities of the Institute with respect to lupus.

(b) Coordination with other institutes

The Director of the Institute shall coordinate the activities of the Director under subsection (a) with similar activities conducted by the other national research institutes and agencies of the National Institutes of Health to the extent that such Institutes and agencies have responsibilities that are related to lupus.

(c) Programs for lupus

In carrying out subsection (a), the Director of the Institute shall conduct or support research to expand the understanding of the causes of, and to find a cure for, lupus. Activities under such subsection shall include conducting and supporting the following:

(1) Research to determine the reasons underlying the elevated prevalence of lupus in women, including African-American women.

(2) Basic research concerning the etiology and causes of the disease.

(3) Epidemiological studies to address the frequency and natural history of the disease and the

differences among the sexes and among racial and ethnic groups with respect to the disease.

(4) The development of improved diagnostic techniques.

(5) Clinical research for the development and evaluation of new treatments, including new biological agents.

(6) Information and education programs for health care professionals and the public.

(July 1, 1944, ch. 373, title IV, §441A, as added Pub. L. 106–505, title V, §511, Nov. 13, 2000, 114 Stat. 2342; amended Pub. L. 109–482, title I, §103(b)(22), Jan. 15, 2007, 120 Stat. 3688.)

EDITORIAL NOTES

AMENDMENTS

2007—Subsec. (d). Pub. L. 109–482 struck out heading and text of subsec. (d). Text read as follows: "For the purpose of carrying out this section, there are authorized to be appropriated such sums as may be necessary for each of the fiscal years 2001 through 2003."

STATUTORY NOTES AND RELATED SUBSIDIARIES

EFFECTIVE DATE OF 2007 AMENDMENT

Amendment by Pub. L. 109–482 applicable only with respect to amounts appropriated for fiscal year 2007 or subsequent fiscal years, see section 109 of Pub. L. 109–482, set out as a note under section 281 of this title.

FINDINGS

Pub. L. 106–505, title V, §502, Nov. 13, 2000, 114 Stat. 2342, provided that: "The Congress finds that—

"(1) lupus is a serious, complex, inflammatory, autoimmune disease of particular concern to women;

"(2) lupus affects women nine times more often than men;

"(3) there are three main types of lupus: systemic lupus, a serious form of the disease that affects many parts of the body; discoid lupus, a form of the disease that affects mainly the skin; and drug-induced lupus caused by certain medications;

"(4) lupus can be fatal if not detected and treated early;

"(5) the disease can simultaneously affect various areas of the body, such as the skin, joints, kidneys, and brain, and can be difficult to diagnose because the symptoms of lupus are similar to those of many other diseases;

"(6) lupus disproportionately affects African-American women, as the prevalence of the disease among such women is three times the prevalence among white women, and an estimated 1 in 250 African-American women between the ages of 15 and 65 develops the disease;

"(7) it has been estimated that between 1,400,000 and 2,000,000 Americans have been diagnosed with the disease, and that many more have undiagnosed cases;

"(8) current treatments for the disease can be effective, but may lead to damaging side effects;

"(9) many victims of the disease suffer debilitating pain and fatigue, making it difficult to maintain employment and lead normal lives; and

"(10) in fiscal year 1996, the amount allocated by the National Institutes of Health for research on lupus was $33,000,000, which is less than one-half of 1 percent of the budget for such Institutes."

§285d–7. Advisory Board

(a) Establishment

The Secretary shall establish in the Institute the National Arthritis and Musculoskeletal and Skin Diseases Advisory Board (hereafter in this section referred to as the "Advisory Board").

(b) Membership; ex officio members

The Advisory Board shall be composed of twenty appointed members and nonvoting, ex officio members, as follows:

(1) The Secretary shall appoint—

(A) twelve members from individuals who are scientists, physicians, and other health professionals, who are not officers or employees of the United States, and who represent the

specialties and disciplines relevant to arthritis, musculoskeletal diseases, and skin diseases; and

(B) eight members from the general public who are knowledgeable with respect to such diseases, including one member who is a person who has such a disease, one person who is the parent of an adult with such a disease, and two members who are parents of children with arthritis.

Of the appointed members at least five shall by virtue of training or experience be knowledgeable in health education, nursing, data systems, public information, or community program development.

(2) The following shall be ex officio members of the Advisory Board:

(A) the Assistant Secretary for Health, the Director of NIH, the Director of the National Institute of Arthritis and Musculoskeletal and Skin Diseases, the Director of the Centers for Disease Control and Prevention, the Under Secretary for Health of the Department of Veterans Affairs, and the Assistant Secretary of Defense for Health Affairs (or the designees of such officers), and

(B) such other officers and employees of the United States as the Secretary determines necessary for the Advisory Board to carry out its functions.

(c) Compensation

Members of the Advisory Board who are officers or employees of the Federal Government shall serve as members of the Advisory Board without compensation in addition to that received in their regular public employment. Other members of the Advisory Board shall receive compensation at rates not to exceed the daily equivalent of the annual rate in effect for grade GS–18 of the General Schedule for each day (including traveltime) they are engaged in the performance of their duties as members of the Advisory Board.

(d) Term of office; vacancy

The term of office of an appointed member of the Advisory Board is four years. Any member appointed to fill a vacancy for an unexpired term shall be appointed for the remainder of such term. A member may serve after the expiration of the member's term until a successor has taken office. If a vacancy occurs in the Advisory Board, the Secretary shall make an appointment to fill the vacancy not later than 90 days after the date the vacancy occurred.

(e) Chairman

The members of the Advisory Board shall select a chairman from among the appointed members.

(f) Executive director, professional and clerical staff; administrative support services and facilities

The Secretary shall, after consultation with and consideration of the recommendations of the Advisory Board, provide the Advisory Board with an executive director and one other professional staff member. In addition, the Secretary shall, after consultation with and consideration of the recommendations of the Advisory Board, provide the Advisory Board with such additional professional staff members, such clerical staff members, and (through contracts or other arrangements) with such administrative support services and facilities, such information, and such services of consultants, as the Secretary determines are necessary for the Advisory Board to carry out its functions.

(g) Meetings

The Advisory Board shall meet at the call of the chairman or upon request of the Director of the Institute, but not less often than four times a year.

(h) Duties and functions

The Advisory Board shall—

(1) review and evaluate the implementation of the plan prepared under section 285d–1(a) of this title and periodically update the plan to ensure its continuing relevance;

(2) for the purpose of assuring the most effective use and organization of resources respecting

arthritis, musculoskeletal diseases and skin diseases, advise and make recommendations to the Congress, the Secretary, the Director of NIH, the Director of the Institute, and the heads of other appropriate Federal agencies for the implementation and revision of such plan; and

(3) maintain liaison with other advisory bodies for Federal agencies involved in the implementation of such plan, the interagency coordinating committees for such diseases established under section 285d–4 of this title, and with key non-Federal entities involved in activities affecting the control of such diseases.

(i) Subcommittees; establishment and membership

In carrying out its functions, the Advisory Board may establish subcommittees, convene workshops and conferences, and collect data. Such subcommittees may be composed of Advisory Board members and nonmember consultants with expertise in the particular area addressed by such subcommittees. The subcommittees may hold such meetings as are necessary to enable them to carry out their activities.

(j) Termination of predecessor board; time within which to appoint members

The National Arthritis Advisory Board in existence on November 20, 1985, shall terminate upon the appointment of a successor Board under subsection (a). The Secretary shall make appointments to the Advisory Board established under subsection (a) before the expiration of 90 days after November 20, 1985. The member of the Board in existence on November 20, 1985, may be appointed, in accordance with subsections (b) and (d), to the Advisory Board established under subsection (a).

(July 1, 1944, ch. 373, title IV, §442, as added Pub. L. 99–158, §2, Nov. 20, 1985, 99 Stat. 852; amended Pub. L. 102–405, title III, §302(e)(1), Oct. 9, 1992, 106 Stat. 1985; Pub. L. 102–531, title III, §312(d)(7), Oct. 27, 1992, 106 Stat. 3504; Pub. L. 103–43, title VII, §701(d), title XX, §2008(b)(7), June 10, 1993, 107 Stat. 162, 211; Pub. L. 109–482, title I, §104(b)(1)(I), Jan. 15, 2007, 120 Stat. 3693.)

EDITORIAL NOTES

AMENDMENTS

2007—Subsecs. (j), (k). Pub. L. 109–482 redesignated subsec. (k) as (j) and struck out former subsec. (j) which required the Advisory Board to prepare an annual report for the Secretary and set out the subjects for report.

1993—Subsec. (a). Pub. L. 103–43, §701(d)(1), inserted "and Musculoskeletal and Skin Diseases" after "Arthritis".

Subsec. (b). Pub. L. 103–43, §§701(d)(2), 2008(b)(7), substituted "twenty" for "eighteen" in introductory provisions, "eight" for "six" and "including one member who is a person who has such a disease, one person who is the parent of an adult with such a disease, and two members who are parents of children with arthritis" for "including at least one member who is a person who has such a disease and one member who is a parent of a person who has such a disease" in par. (1)(B), and "Department of Veterans Affairs" for "Veterans' Administration" in par. (2)(A).

Subsec. (j)(5). Pub. L. 103–43, §701(d)(3), added par. (5).

1992—Subsec. (b)(2)(A). Pub. L. 102–531 substituted "Centers for Disease Control and Prevention" for "Centers for Disease Control".

Pub. L. 102–405 substituted "Under Secretary for Health" for "Chief Medical Director".

STATUTORY NOTES AND RELATED SUBSIDIARIES

EFFECTIVE DATE OF 2007 AMENDMENT

Amendment by Pub. L. 109–482 applicable only with respect to amounts appropriated for fiscal year 2007 or subsequent fiscal years, see section 109 of Pub. L. 109–482, set out as a note under section 281 of this title.

TERMINATION OF ADVISORY BOARDS

Advisory boards established after Jan. 5, 1973, to terminate not later than the expiration of the 2-year period

beginning on the date of their establishment, unless, in the case of a board established by the President or an officer of the Federal Government, such board is renewed by appropriate action prior to the expiration of such 2-year period, or in the case of a board established by the Congress, its duration is otherwise provided by law. See sections 1001(2) and 1013 of Title 5, Government Organization and Employees.

Pub. L. 93–641, §6, Jan. 4, 1975, 88 Stat. 2275, set out as a note under section 217a of this title, provided that an advisory committee established pursuant to the Public Health Service Act shall terminate at such time as may be specifically prescribed by an Act of Congress enacted after Jan. 4, 1975.

REFERENCES IN OTHER LAWS TO GS–16, 17, OR 18 PAY RATES

References in laws to the rates of pay for GS–16, 17, or 18, or to maximum rates of pay under the General Schedule, to be considered references to rates payable under specified sections of Title 5, Government Organization and Employees, see section 529 [title I, §101(c)(1)] of Pub. L. 101–509, set out in a note under section 5376 of Title 5.

§285d–8. Juvenile arthritis and related conditions

(a) Expansion and coordination of activities

The Director of the Institute, in coordination with the Director of the National Institute of Allergy and Infectious Diseases, shall expand and intensify the programs of such Institutes with respect to research and related activities concerning juvenile arthritis and related conditions.

(b) Coordination

The Directors referred to in subsection (a) shall jointly coordinate the programs referred to in such subsection and consult with the Arthritis and Musculoskeletal Diseases Interagency Coordinating Committee.

(July 1, 1944, ch. 373, title IV, §442A, as added Pub. L. 106–310, div. A, title III, §301(a), Oct. 17, 2000, 114 Stat. 1111; amended Pub. L. 109–482, title I, §103(b)(23), Jan. 15, 2007, 120 Stat. 3688.)

EDITORIAL NOTES

AMENDMENTS

2007—Subsec. (c). Pub. L. 109–482 struck out heading and text of subsec. (c). Text read as follows: "For the purpose of carrying out this section, there are authorized to be appropriated such sums as may be necessary for each of the fiscal years 2001 through 2005."

STATUTORY NOTES AND RELATED SUBSIDIARIES

EFFECTIVE DATE OF 2007 AMENDMENT

Amendment by Pub. L. 109–482 applicable only with respect to amounts appropriated for fiscal year 2007 or subsequent fiscal years, see section 109 of Pub. L. 109–482, set out as a note under section 281 of this title.

SUBPART 5—NATIONAL INSTITUTE ON AGING

§285e. Purpose of Institute

The general purpose of the National Institute on Aging (hereafter in this subpart referred to as the "Institute") is the conduct and support of biomedical, social, and behavioral research, training, health information dissemination, and other programs with respect to the aging process and the diseases and other special problems and needs of the aged.

(July 1, 1944, ch. 373, title IV, §443, as added Pub. L. 99–158, §2, Nov. 20, 1985, 99 Stat. 854.)

STATUTORY NOTES AND RELATED SUBSIDIARIES

STUDY OF MALNUTRITION IN ELDERLY

Pub. L. 103–43, title XIX, §1902, June 10, 1993, 107 Stat. 201, directed Secretary of Health and Human Services, acting through National Institute on Aging, to conduct a 3-year study on health benefits and cost-effectiveness of nutrition screening and intervention activities of the elderly, and a 3-year study to determine extent of malnutrition in elderly individuals in hospitals and long-term care facilities and in elderly individuals who are living independently, provided for creation of advisory panel to oversee studies, provided for submission to Congress of reports containing findings of such studies, and provided for termination of advisory panel 3 years after June 10, 1993.

STUDY OF PERSONNEL FOR HEALTH NEEDS OF ELDERLY

Section 8 of Pub. L. 99–158 directed Secretary to conduct a study on the adequacy and availability of personnel to meet the current and projected health needs (including needs for home and community-based care) of elderly Americans through the year 2020, and report the results of the study, with recommendations, to Congress by Mar. 1, 1987.

§285e–1. Special functions

(a) Education and training of adequate numbers of personnel

In carrying out the training responsibilities under this chapter or any other Act for health and allied health professions personnel, the Secretary shall take appropriate steps to insure the education and training of adequate numbers of allied health, nursing, and paramedical personnel in the field of health care for the aged.

(b) Scientific studies

The Director of the Institute shall conduct scientific studies to measure the impact on the biological, medical, social, and psychological aspects of aging of programs and activities assisted or conducted by the Department of Health and Human Services.

(c) Public information and education programs

The Director of the Institute shall carry out public information and education programs designed to disseminate as widely as possible the findings of research sponsored by the Institute, other relevant aging research and studies, and other information about the process of aging which may assist elderly and near-elderly persons in dealing with, and all Americans in understanding, the problems and processes associated with growing older.

(d) Grants for research relating to Alzheimer's Disease

The Director of the Institute shall make grants to public and private nonprofit institutions to conduct research relating to Alzheimer's Disease.

(July 1, 1944, ch. 373, title IV, §444, as added Pub. L. 99–158, §2, Nov. 20, 1985, 99 Stat. 854.)

§285e–2. Alzheimer's Disease centers

(a) Cooperative agreements and grants for establishing and supporting

(1) The Director of the Institute may enter into cooperative agreements with and make grants to public or private nonprofit entities (including university medical centers) to pay all or part of the cost of planning, establishing, or strengthening, and providing basic operating support (including staffing) for centers for basic and clinical research (including multidisciplinary research) into, training in, and demonstration of advanced diagnostic, prevention, and treatment methods for Alzheimer's disease.

(2) A cooperative agreement or grant under paragraph (1) shall be entered into in accordance with policies established by the Director of NIH and after consultation with the Institute's advisory council.

(b) Use of Federal payments under cooperative agreement or grant

(1) Federal payments made under a cooperative agreement or grant under subsection (a) may, with respect to Alzheimer's disease, be used for—

(A) diagnostic examinations, patient assessments, patient care costs, and other costs necessary for conducting research;

(B) training, including training for allied health professionals;

(C) diagnostic and treatment clinics designed to meet the special needs of minority and rural populations and other underserved populations;

(D) activities to educate the public; and

(E) the dissemination of information.

(2) For purposes of paragraph (1), the term "training" does not include research training for which Ruth L. Kirschstein National Research Service Awards may be provided under section 288 of this title.

(c) Support period; additional periods

Support of a center under subsection (a) may be for a period of not to exceed five years. Such period may be extended by the Director for additional periods of not more than five years each if the operations of such center have been reviewed by an appropriate technical and scientific peer review group established by the Director and if such group has recommended to the Director that such period should be extended.

(July 1, 1944, ch. 373, title IV, §445, as added Pub. L. 99–158, §2, Nov. 20, 1985, 99 Stat. 855; amended Pub. L. 101–557, title II, §201, Nov. 15, 1990, 104 Stat. 2767; Pub. L. 107–206, title I, §804(c), Aug. 2, 2002, 116 Stat. 874.)

EDITORIAL NOTES

AMENDMENTS

2002—Subsec. (b)(2). Pub. L. 107–206 substituted "Ruth L. Kirschstein National Research Service Awards" for "National Research Service Awards".

1990—Subsec. (a)(1). Pub. L. 101–557, §201(1), inserted "(including university medical centers)" after "nonprofit entities", "(including staffing)" after "operating support", and "(including multidisciplinary research)" after "clinical research" and substituted "Alzheimer's disease" for "Alzheimer's Disease".

Subsec. (b). Pub. L. 101–557, §201(2), amended subsec. (b) generally. Prior to amendment, subsec. (b) read as follows: "Federal payments made under a cooperative agreement or grant under subsection (a) of this section may be used for—

"(1) construction (notwithstanding any limitation under section 289e of this title);

"(2) staffing and other basic operating costs, including such patient care costs as are required for research;

"(3) training, including training for allied health professionals; and

"(4) demonstration purposes.

As used in this subsection, the term 'construction' does not include the acquisition of land, and the term 'training' does not include research training for which National Research Service Awards may be provided under section 288 of this title."

STATUTORY NOTES AND RELATED SUBSIDIARIES

ALZHEIMER'S DISEASE RESEARCH

Pub. L. 100–175, title III, Nov. 29, 1987, 101 Stat. 972, provided that:

"SEC. 301. REQUIREMENT FOR CLINICAL TRIALS.

"(a) IN GENERAL.—The Director of the National Institute on Aging shall provide for the conduct of clinical trials on the efficacy of the use of such promising therapeutic agents as have been or may be

discovered and recommended for further scientific analysis by the National Institute on Aging and the Food and Drug Administration to treat individuals with Alzheimer's disease, to retard the progression of symptoms of Alzheimer's disease, or to improve the functioning of individuals with such disease.

"(b) RULE OF CONSTRUCTION.—Nothing in this title shall be construed to affect adversely any research being conducted as of the date of the enactment of this Act [Nov. 29, 1987].

"SEC. 302. AUTHORIZATION OF APPROPRIATIONS.

"For the purpose of carrying out section 301, there is authorized to be appropriated $2,000,000 for fiscal year 1988."

ALZHEIMER'S DISEASE REGISTRY

Section 12 of Pub. L. 99–158, which was formerly set out as a note under this section, was renumbered section 445G of the Public Health Service Act by Pub. L. 103–43, title VIII, §801(a), June 10, 1993, 107 Stat. 163, and is classified to section 285e–9 of this title.

§285e–3. Claude D. Pepper Older Americans Independence Centers

(a) Development and expansion of centers

The Director of the Institute shall enter into cooperative agreements with, and make grants to, public and private nonprofit entities for the development or expansion of not less than 10 centers of excellence in geriatric research and training of researchers. Each such center shall be known as a Claude D. Pepper Older Americans Independence Center.

(b) Functions of centers

Each center developed or expanded under this section shall—

(1) utilize the facilities of a single institution, or be formed from a consortium of cooperating institutions, meeting such research and training qualifications as may be prescribed by the Director; and

(2) conduct—

(A) research into the aging processes and into the diagnosis and treatment of diseases, disorders, and complications related to aging, including menopause, which research includes research on such treatments, and on medical devices and other medical interventions regarding such diseases, disorders, and complications, that can assist individuals in avoiding institutionalization and prolonged hospitalization and in otherwise increasing the independence of the individuals; and

(B) programs to develop individuals capable of conducting research described in subparagraph (A).

(c) Geographic distribution of centers

In making cooperative agreements and grants under this section for the development or expansion of centers, the Director of the Institute shall ensure that, to the extent practicable, any such centers are distributed equitably among the principal geographic regions of the United States.

(d) "Independence" defined

For purposes of this section, the term "independence", with respect to diseases, disorders, and complications of aging, means the functional ability of individuals to perform activities of daily living or instrumental activities of daily living without assistance or supervision.

(July 1, 1944, ch. 373, title IV, §445A, as added Pub. L. 100–607, title I, §141, Nov. 4, 1988, 102 Stat. 3056; amended Pub. L. 101–557, title II, §202, Nov. 15, 1990, 104 Stat. 2767.)

EDITORIAL NOTES

AMENDMENTS

1990—Pub. L. 101–557, §202(a)(1), substituted "Claude D. Pepper Older Americans Independence Centers" for "Centers of geriatric research and training" in section catchline.

Subsec. (a). Pub. L. 101–557, §202(a)(2), (b)(1)(A), inserted "not less than 10" before "centers of excellence" and inserted provision designating centers as Claude D. Pepper Older Americans Independence Centers.

Subsec. (b)(2)(A). Pub. L. 101–557, §202(b)(1)(B), inserted before semicolon at end ", including menopause, which research includes research on such treatments, and on medical devices and other medical interventions regarding such diseases, disorders, and complications, that can assist individuals in avoiding institutionalization and prolonged hospitalization and in otherwise increasing the independence of the individuals".

Subsec. (b)(2)(B). Pub. L. 101–557, §202(b)(2), substituted "research described in subparagraph (A)" for "research concerning aging and concerning such diseases, disorders, and complications."

Subsec. (d). Pub. L. 101–557, §202(c), added subsec. (d).

§285e–4. Awards for leadership and excellence in Alzheimer's disease and related dementias

(a) Senior researchers in biomedical research

The Director of the Institute shall make awards to senior researchers who have made distinguished achievements in biomedical research in areas relating to Alzheimer's disease and related dementias. Awards under this section shall be used by the recipients to support research in areas relating to such disease and dementias, and may be used by the recipients to train junior researchers who demonstrate exceptional promise to conduct research in such areas.

(b) Eligible centers

The Director of the Institute may make awards under this section to researchers at centers supported under section 285e–2 of this title and to researchers at other public and nonprofit private entities.

(c) Required recommendation

The Director of the Institute shall make awards under this section only to researchers who have been recommended for such awards by the National Advisory Council on Aging.

(d) Selection procedures

The Director of the Institute shall establish procedures for the selection of the recipients of awards under this section.

(e) Term of award; renewal

Awards under this section shall be made for a one-year period, and may be renewed for not more than six additional consecutive one-year periods.

(July 1, 1944, ch. 373, title IV, §445B, formerly Pub. L. 99–660, title IX, §931, Nov. 14, 1986, 100 Stat. 3807; renumbered §445B of act July 1, 1944, and amended Pub. L. 100–607, title I, §142(a), (d)(1), Nov. 4, 1988, 102 Stat. 3057.)

EDITORIAL NOTES

CODIFICATION

Section was formerly classified to section 11231 of this title prior to renumbering by Pub. L. 100–607.

AMENDMENTS

1988—Pub. L. 100–607, §142(a), renumbered section 11231 of this title as this section.

Subsec. (a). Pub. L. 100–607, §142(d)(1)(A), substituted "the Institute" for "the National Institute on Aging".

Subsec. (b). Pub. L. 100–607, §142(d)(1)(B), substituted "the Institute" for "the National Institute on Aging" and made technical amendment to reference to section 285e–2 of this title to correct reference to corresponding provision of original act.

Subsecs. (c), (d). Pub. L. 100–607, §142(d)(1)(C), substituted "the Institute" for "the National Institute on

Aging".

STATUTORY NOTES AND RELATED SUBSIDIARIES

AVAILABILITY OF APPROPRIATIONS

Pub. L. 100–607, title I, §142(b), Nov. 4, 1988, 102 Stat. 3057, provided that: "With respect to amounts made available in appropriation Acts for the purpose of carrying out the programs transferred by subsection (a) to the Public Health Service Act [sections 285e–4 to 285e–8 of this title], such subsection may not be construed to affect the availability of such funds for such purpose."

§285e–5. Research relevant to appropriate services for individuals with Alzheimer's disease and related dementias and their families

(a) Grants for research

The Director of the Institute shall conduct, or make grants for the conduct of, research relevant to appropriate services for individuals with Alzheimer's disease and related dementias and their families.

(b) Preparation of plan; contents; revision

(1) Within 6 months after November 14, 1986, the Director of the Institute shall prepare and transmit to the Chairman of the Council on Alzheimer's Disease (in this section referred to as the "Council") a plan for the research to be conducted under subsection (a). The plan shall—

(A) provide for research concerning—

(i) the epidemiology of, and the identification of risk factors for, Alzheimer's disease and related dementias; and

(ii) the development and evaluation of reliable and valid multidimensional diagnostic and assessment procedures and instruments; and

(B) ensure that research carried out under the plan is coordinated with, and uses, to the maximum extent feasible, resources of, other Federal programs relating to Alzheimer's disease and related dementias, including centers supported under section 285e–2 of this title, centers supported by the National Institute of Mental Health on the psychopathology of the elderly, relevant activities of the Administration on Aging, other programs and centers involved in research on Alzheimer's disease and related dementias supported by the Department, and other programs relating to Alzheimer's disease and related dementias which are planned or conducted by Federal agencies other than the Department, State or local agencies, community organizations, or private foundations.

(2) Within one year after transmitting the plan required under paragraph (1), and annually thereafter, the Director of the Institute shall prepare and transmit to the Chairman of the Council such revisions of such plan as the Director considers appropriate.

(c) Consultation for preparation and revision of plan

In preparing and revising the plan required by subsection (b), the Director of the Institute shall consult with the Chairman of the Council and the heads of agencies within the Department.

(d) Grants for promoting independence and preventing secondary disabilities

the [1] Director of the Institute may develop, or make grants to develop—

(1) model techniques to—

(A) promote greater independence, including enhanced independence in performing activities of daily living and instrumental activities of daily living, for persons with Alzheimer's disease and related disorders; and

(B) prevent or reduce the severity of secondary disabilities, including confusional episodes,

falls, bladder and bowel incontinence, and adverse effects of prescription and over-the-counter medications, in such persons; and

(2) model curricula for health care professionals, health care paraprofessionals, and family caregivers, for training and application in the use of such techniques.

(e) "Council on Alzheimer's Disease" defined

For purposes of this section, the term "Council on Alzheimer's Disease" means the council established in section 11211(a) [2] of this title.

(July 1, 1944, ch. 373, title IV, §445C, formerly Pub. L. 99–660, title IX, §941, Nov. 14, 1986, 100 Stat. 3808; renumbered §445C of act July 1, 1944, and amended Pub. L. 100–607, title I, §142(a), (d)(2), Nov. 4, 1988, 102 Stat. 3057, 3058; Pub. L. 102–507, §9, Oct. 24, 1992, 106 Stat. 3287; Pub. L. 103–43, title VIII, §804, June 10, 1993, 107 Stat. 164.)

EDITORIAL NOTES

REFERENCES IN TEXT

Section 11211 of this title, referred to in subsec. (e), was repealed by Pub. L. 105–362, title VI, §601(a)(2)(E), Nov. 10, 1998, 112 Stat. 3286.

CODIFICATION

Section was formerly classified to section 11241 of this title prior to renumbering by Pub. L. 100–607.

AMENDMENTS

1993—Subsec. (b)(1). Pub. L. 103–43, §804(1), inserted "on Alzheimer's Disease (in this section referred to as the 'Council')" after "Council".

Subsec. (e). Pub. L. 103–43, §804(2), added subsec. (e).

1992—Subsec. (d). Pub. L. 102–507 added subsec. (d).

1988—Pub. L. 100–607, §142(a), renumbered section 11241 of this title as this section.

Subsec. (a). Pub. L. 100–607, §142(d)(2)(A), substituted "the Institute" for "the National Institute on Aging".

Subsec. (b)(1). Pub. L. 100–607, §142(d)(2)(B)(i)(I), in introductory provisions, substituted "the date of enactment of the Alzheimer's Disease and Related Dementias Services Research Act of 1986" for "the date of enactment of this Act", which for purposes of codification was translated as "November 14, 1986", thus requiring no change in text.

Pub. L. 100–607, §142(d)(2)(B)(i)(II), in introductory provisions, substituted "the Institute" for "the National Institute on Aging".

Subsec. (b)(1)(B). Pub. L. 100–607, §142(d)(2)(B)(ii), made technical amendment to reference to section 285e–2 of this title to correct reference to corresponding provision of original act.

Subsecs. (b)(2), (c). Pub. L. 100–607, §142(d)(2)(B)(iii), (C), substituted "the Institute" for "the National Institute on Aging".

[1] So in original. Probably should be capitalized.

[2] See References in Text note below.

§285e–6. Dissemination of research results

The Director of the Institute shall disseminate the results of research conducted under section 285e–5 of this title and this section to appropriate professional entities and to the public.

(July 1, 1944, ch. 373, title IV, §445D, formerly Pub. L. 99–660, title IX, §942, Nov. 14, 1986, 100 Stat. 3809; renumbered §445D of act July 1, 1944, and amended Pub. L. 100–607, title I, §142(a), (d)(3), Nov. 4, 1988, 102 Stat. 3057, 3058.)

EDITORIAL NOTES

CODIFICATION

Section was formerly classified to section 11242 of this title prior to renumbering by Pub. L. 100–607.

AMENDMENTS

1988—Pub. L. 100–607, §142(a), renumbered section 11242 of this title as this section.

Pub. L. 100–607, §142(d)(3), substituted "the Institute" for "the National Institute on Aging" and "section 285e–5 of this title and this section" for "this part".

§285e–7. Clearinghouse on Alzheimer's Disease

(a) Establishment; purpose; duties; publication of summary

The Director of the Institute shall establish the Clearinghouse on Alzheimer's Disease (hereinafter referred to as the "Clearinghouse"). The purpose of the Clearinghouse is the dissemination of information concerning services available for individuals with Alzheimer's disease and related dementias and their families. The Clearinghouse shall—

(1) compile, archive, and disseminate information concerning research, demonstration, evaluation, and training programs and projects concerning Alzheimer's disease and related dementias; and

(2) annually publish a summary of the information compiled under paragraph (1) during the preceding 12-month period, and make such information available upon request to appropriate individuals and entities, including educational institutions, research entities, and Federal and public agencies.

(b) Fee for information

The Clearinghouse may charge an appropriate fee for information provided through the toll-free telephone line established under subsection (a)(3).[1]

(c) Summaries of research findings from other agencies

The Director of the Institute, the Director of the National Institute of Mental Health, and the Director of the National Center for Health Services Research and Health Care Technology Assessment shall provide to the Clearinghouse summaries of the findings of research conducted under part D.

(July 1, 1944, ch. 373, title IV, §445E, formerly Pub. L. 99–660, title IX, §951, Nov. 14, 1986, 100 Stat. 3813; renumbered §445E of act July 1, 1944, and amended Pub. L. 100–607, title I, §142(a), (d)(4), Nov. 4, 1988, 102 Stat. 3057, 3058.)

EDITORIAL NOTES

REFERENCES IN TEXT

Part D, referred to in subsec. (c), probably means part D of title IX of Pub. L. 99–660, Nov. 14, 1986, 100 Stat. 3808, which is classified to subchapter IV (§11251 et seq.) of chapter 118 of this title. Prior to renumbering by Pub. L. 100–607, this section was part of title IX of Pub. L. 99–660.

CODIFICATION

Section was formerly classified to section 11281 of this title prior to renumbering by Pub. L. 100–607.

AMENDMENTS

1988—Pub. L. 100–607, §142(a), renumbered section 11281 of this title as this section.

Subsec. (a). Pub. L. 100–607, §142(d)(4)(A), substituted "the Institute" for "the National Institute on Aging" in introductory provisions.

Subsec. (c). Pub. L. 100–607, §142(d)(4)(B), substituted "the Institute" for "the National Institute on Aging" and "part D" for "part E".

[1] *So in original. No subsec. (a)(3) has been enacted.*

§285e–8. Dissemination project

(a) Grant or contract for establishment

The Director of the Institute shall make a grant to, or enter into a contract with, a national organization representing individuals with Alzheimer's disease and related dementias for the conduct of the activities described in subsection (b).

(b) Project activities

The organization receiving a grant or contract under this section shall—

(1) establish a central computerized information system to—

(A) compile and disseminate information concerning initiatives by State and local governments and private entities to provide programs and services for individuals with Alzheimer's disease and related dementias; and

(B) translate scientific and technical information concerning such initiatives into information readily understandable by the general public, and make such information available upon request; and

(2) establish a national toll-free telephone line to make available the information described in paragraph (1), and information concerning Federal programs, services, and benefits for individuals with Alzheimer's disease and related dementias and their families.

(c) Fees for information; exception

The organization receiving a grant or contract under this section may charge appropriate fees for information provided through the toll-free telephone line established under subsection (b)(2), and may make exceptions to such fees for individuals and organizations who are not financially able to pay such fees.

(d) Application for grant or contract; contents

In order to receive a grant or contract under this section, an organization shall submit an application to the Director of the Institute. Such application shall contain—

(1) information demonstrating that such organization has a network of contacts which will enable such organization to receive information necessary to the operation of the central computerized information system described in subsection (b)(1);

(2) information demonstrating that, by the end of fiscal year 1991, such organization will be financially able to, and will, carry out the activities described in subsection (b) without a grant or contract from the Federal Government; and

(3) such other information as the Director may prescribe.

(July 1, 1944, ch. 373, title IV, §445F, formerly Pub. L. 99–660, title IX, §952, Nov. 14, 1986, 100 Stat. 3813; renumbered §445F of act July 1, 1944, and amended Pub. L. 100–607, title I, §142(a), (d)(5), Nov. 4, 1988, 102 Stat. 3057, 3058.)

EDITORIAL NOTES

CODIFICATION

Section was formerly classified to section 11282 of this title prior to renumbering by Pub. L. 100–607.

AMENDMENTS

1988—Pub. L. 100–607, §142(a), renumbered section 11282 of this title as this section.

Subsecs. (a), (d). Pub. L. 100–607, §142(d)(5), substituted "the Institute" for "the National Institute on Aging".

§285e–9. Alzheimer's disease registry

(a) In general

The Director of the Institute may make a grant to develop a registry for the collection of epidemiological data about Alzheimer's disease and its incidence in the United States, to train personnel in the collection of such data, and for other matters respecting such disease.

(b) Qualifications

To qualify for a grant under subsection (a) an applicant shall—

(1) be an accredited school of medicine or public health which has expertise in the collection of epidemiological data about individuals with Alzheimer's disease and in the development of disease registries, and

(2) have access to a large patient population, including a patient population representative of diverse ethnic backgrounds.

(July 1, 1944, ch. 373, title IV, §445G, formerly Pub. L. 99–158, §12, Nov. 20, 1985, 99 Stat. 885; renumbered §445G of act July 1, 1944, and amended Pub. L. 103–43, title VIII, §801, June 10, 1993, 107 Stat. 163.)

EDITORIAL NOTES

CODIFICATION

Section was formerly set out as a note under section 285e–2 of this title prior to renumbering by Pub. L. 103–43.

AMENDMENTS

1993—Pub. L. 103–43, §801(b)(1), reenacted section catchline without change.

Subsec. (a). Pub. L. 103–43, §801(b)(1), substituted in heading "In general" for "Grant authority" and in text substituted "Director of the Institute" for "Director of the National Institute on Aging".

Subsec. (c). Pub. L. 103–43, §801(b)(2), struck out subsec. (c) which authorized appropriations of $2,500,000 for grants to remain available until expended or through fiscal year 1989, whichever occurred first.

§285e–10. Aging processes regarding women

The Director of the Institute, in addition to other special functions specified in section 285e–1 of this title and in cooperation with the Directors of the other national research institutes and agencies of the National Institutes of Health, shall conduct research into the aging processes of women, with particular emphasis given to the effects of menopause and the physiological and behavioral changes occurring during the transition from pre- to post-menopause, and into the diagnosis, disorders, and complications related to aging and loss of ovarian hormones in women.

(July 1, 1944, ch. 373, title IV, §445H, as added Pub. L. 103–43, title VIII, §802, June 10, 1993, 107 Stat. 163; amended Pub. L. 105–340, title I, §105, Oct. 31, 1998, 112 Stat. 3193; Pub. L. 109–482, title I, §103(b)(24), Jan. 15, 2007, 120 Stat. 3688.)

EDITORIAL NOTES

AMENDMENTS

2007—Pub. L. 109–482 struck out subsec. (a) designation before "The Director" and subsec. (b) which read as follows: "For the purpose of carrying out this section, there are authorized to be appropriated such sums as may be necessary for each of the fiscal years 1999 through 2003. The authorization of appropriations established in the preceding sentence is in addition to any other authorization of appropriation that is available for such purpose."

1998—Pub. L. 105–340 designated existing provisions as subsec. (a) and added subsec. (b).

STATUTORY NOTES AND RELATED SUBSIDIARIES

EFFECTIVE DATE OF 2007 AMENDMENT

Amendment by Pub. L. 109–482 applicable only with respect to amounts appropriated for fiscal year 2007 or subsequent fiscal years, see section 109 of Pub. L. 109–482, set out as a note under section 281 of this title.

§285e–10a. Alzheimer's clinical research and training awards

(a) In general

The Director of the Institute is authorized to establish and maintain a program to enhance and promote the translation of new scientific knowledge into clinical practice related to the diagnosis, care and treatment of individuals with Alzheimer's disease.

(b) Support of promising clinicians

In order to foster the application of the most current developments in the etiology, pathogenesis, diagnosis, prevention and treatment of Alzheimer's disease, amounts made available under this section shall be directed to the support of promising clinicians through awards for research, study, and practice at centers of excellence in Alzheimer's disease research and treatment.

(c) Excellence in certain fields

Research shall be carried out under awards made under subsection (b) in environments of demonstrated excellence in neuroscience, neurobiology, geriatric medicine, and psychiatry and shall foster innovation and integration of such disciplines or other environments determined suitable by the Director of the Institute.

(July 1, 1944, ch. 373, title IV, §445I, as added Pub. L. 106–505, title VIII, §801(2), Nov. 13, 2000, 114 Stat. 2349; amended Pub. L. 109–482, title I, §103(b)(25), Jan. 15, 2007, 120 Stat. 3688.)

EDITORIAL NOTES

PRIOR PROVISIONS

A prior section 445I of act July 1, 1944, was renumbered section 445J and was classified to section 285e–11 of this title prior to repeal by Pub. L. 109–482.

AMENDMENTS

2007—Subsec. (d). Pub. L. 109–482 struck out heading and text of subsec. (d). Text read as follows: "For the purpose of carrying out this section, there are authorized to be appropriated $2,250,000 for fiscal year 2001, and such sums as may be necessary for each of fiscal years 2002 through 2005."

STATUTORY NOTES AND RELATED SUBSIDIARIES

EFFECTIVE DATE OF 2007 AMENDMENT

Amendment by Pub. L. 109–482 applicable only with respect to amounts appropriated for fiscal year 2007 or subsequent fiscal years, see section 109 of Pub. L. 109–482, set out as a note under section 281 of this title.

§285e–11. Repealed. Pub. L. 109–482, title I, §103(b)(26), Jan. 15, 2007, 120 Stat. 3688

Section, act July 1, 1944, ch. 373, title IV, §445J, formerly §445I, as added Pub. L. 103–43, title VIII, §803, June 10, 1993, 107 Stat. 163; renumbered §445J, Pub. L. 106–505, title VIII, §801(1), Nov. 13, 2000, 114 Stat. 2349, authorized appropriations to carry out this subpart.

STATUTORY NOTES AND RELATED SUBSIDIARIES

EFFECTIVE DATE OF REPEAL

Repeal applicable only with respect to amounts appropriated for fiscal year 2007 or subsequent fiscal years, see section 109 of Pub. L. 109–482, set out as an Effective Date of 2007 Amendment note under section 281 of this title.

SUBPART 6—NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES

§285f. Purpose of Institute

The general purpose of the National Institute of Allergy and Infectious Diseases is the conduct and support of research, training, health information dissemination, and other programs with respect to allergic and immunologic diseases and disorders and infectious diseases, including tropical diseases.

(July 1, 1944, ch. 373, title IV, §446, as added Pub. L. 99–158, §2, Nov. 20, 1985, 99 Stat. 855; amended Pub. L. 103–43, title IX, §901, June 10, 1993, 107 Stat. 164.)

EDITORIAL NOTES

AMENDMENTS

1993—Pub. L. 103–43 inserted before period at end ", including tropical diseases".

§285f–1. Research centers regarding chronic fatigue syndrome

(a) The Director of the Institute, after consultation with the advisory council for the Institute, may make grants to, or enter into contracts with, public or nonprofit private entities for the development and operation of centers to conduct basic and clinical research on chronic fatigue syndrome.

(b) Each center assisted under this section shall use the facilities of a single institution, or be formed from a consortium of cooperating institutions, meeting such requirements as may be prescribed by the Director of the Institute.

(July 1, 1944, ch. 373, title IV, §447, as added Pub. L. 103–43, title IX, §902(a), June 10, 1993, 107 Stat. 164.)

EDITORIAL NOTES

CODIFICATION

Another section 447 of act July 1, 1944, was renumbered section 447A and is classified to section 285f–2 of this title.

STATUTORY NOTES AND RELATED SUBSIDIARIES

EXTRAMURAL STUDY SECTION

Pub. L. 103–43, title IX, §902(b), June 10, 1993, 107 Stat. 164, provided that: "Not later than 6 months after the date of enactment of this Act [June 10, 1993], the Secretary of Health and Human Services shall establish an extramural study section for chronic fatigue syndrome research."

RESEARCH ACTIVITIES ON CHRONIC FATIGUE SYNDROME

Pub. L. 103–43, title XIX, §1903, June 10, 1993, 107 Stat. 203, directed Secretary of Health and Human Services to, not later than Oct. 1, 1993, and annually thereafter for next 3 years, prepare and submit to Congress a report that summarizes research activities conducted or supported by National Institutes of Health concerning chronic fatigue syndrome, with information concerning grants made, cooperative agreements or

contracts entered into, intramural activities, research priorities and needs, and plan to address such priorities and needs.

§285f–2. Research and research training regarding tuberculosis

In carrying out section 285f of this title, the Director of the Institute shall conduct or support research and research training regarding the cause, diagnosis, early detection, prevention and treatment of tuberculosis.

(July 1, 1944, ch. 373, title IV, §447A, formerly §447, as added Pub. L. 103–183, title III, §302(a), Dec. 14, 1993, 107 Stat. 2235; renumbered §447A, Pub. L. 105–392, title IV, §401(b)(3), Nov. 13, 1998, 112 Stat. 3587; amended Pub. L. 109–482, title I, §103(b)(27), Jan. 15, 2007, 120 Stat. 3688.)

EDITORIAL NOTES

AMENDMENTS

2007—Pub. L. 109–482 struck out subsec. (a) designation before "In carrying out" and subsec. (b) which read as follows: "For the purpose of carrying out subsection (a) of this section, there are authorized to be appropriated $50,000,000 for fiscal year 1994, and such sums as may be necessary for each of the fiscal years 1995 through 1998. Such authorization is in addition to any other authorization of appropriations that is available for such purpose."

STATUTORY NOTES AND RELATED SUBSIDIARIES

EFFECTIVE DATE OF 2007 AMENDMENT

Amendment by Pub. L. 109–482 applicable only with respect to amounts appropriated for fiscal year 2007 or subsequent fiscal years, see section 109 of Pub. L. 109–482, set out as a note under section 281 of this title.

RESEARCH THROUGH FOOD AND DRUG ADMINISTRATION

Pub. L. 103–183, title III, §303, Dec. 14, 1993, 107 Stat. 2235, provided that: "The Secretary of Health and Human Services, acting through the Commissioner of Food and Drugs, shall implement a tuberculosis drug and device research program under which the Commissioner may—

"(1) provide assistance to other Federal agencies for the development of tuberculosis protocols;

"(2) review and evaluate medical devices designed for the diagnosis and control of airborne tuberculosis; and

"(3) conduct research concerning drugs or devices to be used in diagnosing, controlling and preventing tuberculosis."

§285f–3. Sexually transmitted disease clinical research and training awards

(a) In general

The Director of the Institute is authorized to establish and maintain a program to enhance and promote the translation of new scientific knowledge into clinical practice related to the diagnosis, care and treatment of individuals with sexually transmitted diseases.

(b) Support of promising clinicians

In order to foster the application of the most current developments in the etiology, pathogenesis, diagnosis, prevention and treatment of sexually transmitted diseases, amounts made available under this section shall be directed to the support of promising clinicians through awards for research, study, and practice at centers of excellence in sexually transmitted disease research and treatment.

(c) Excellence in certain fields

Research shall be carried out under awards made under subsection (b) in environments of demonstrated excellence in the etiology and pathogenesis of sexually transmitted diseases and shall foster innovation and integration of such disciplines or other environments determined suitable by

the Director of the Institute.

(July 1, 1944, ch. 373, title IV, §447B, as added Pub. L. 106–505, title IX, §901, Nov. 13, 2000, 114 Stat. 2349; amended Pub. L. 109–482, title I, §103(b)(28), Jan. 15, 2007, 120 Stat. 3688.)

EDITORIAL NOTES

AMENDMENTS

2007—Subsec. (d). Pub. L. 109–482 struck out heading and text of subsec. (d). Text read as follows: "For the purpose of carrying out this section, there are authorized to be appropriated $2,250,000 for fiscal year 2001, and such sums as may be necessary for each of fiscal years 2002 through 2005."

STATUTORY NOTES AND RELATED SUBSIDIARIES

EFFECTIVE DATE OF 2007 AMENDMENT

Amendment by Pub. L. 109–482 applicable only with respect to amounts appropriated for fiscal year 2007 or subsequent fiscal years, see section 109 of Pub. L. 109–482, set out as a note under section 281 of this title.

§285f–4. Microbicide research and development

The Director of the Institute, acting through the head of the Division of AIDS, shall, consistent with the peer-review process of the National Institutes of Health, carry out research on, and development of, safe and effective methods for use by women to prevent the transmission of the human immunodeficiency virus, which may include microbicides.

(July 1, 1944, ch. 373, title IV, §447C, as added Pub. L. 110–293, title II, §203(c), July 30, 2008, 122 Stat. 2941.)

§285f–5. Research centers for pathogens of pandemic concern

(a) In general

The Director of the Institute, in collaboration, as appropriate, with the directors of applicable institutes, centers, and divisions of the National Institutes of Health, the Assistant Secretary for Preparedness and Response, and the Director of the Biomedical Advanced Research and Development Authority, shall establish or continue a multidisciplinary research program to advance the discovery and preclinical development of medical products for priority virus families and other viral pathogens with a significant potential to cause a pandemic, through support for research centers.

(b) Uses of funds

The Director of the Institute shall award funding through grants, contracts, or cooperative agreements to public or private entities to provide support for research centers described in subsection (a) for the purpose of—

(1) conducting basic research through preclinical development of new medical products or technologies, including platform technologies, to address pathogens of pandemic concern;

(2) identifying potential targets for therapeutic candidates, including antivirals, to treat such pathogens;

(3) identifying existing medical products with the potential to address such pathogens, including candidates that could be used in outpatient settings; and

(4) carrying out or supporting other research related to medical products to address such pathogens, as determined appropriate by the Director.

(c) Coordination

The Director of the Institute shall, as appropriate, provide for the coordination of activities among the centers described in subsection (a), including through—

(1) facilitating the exchange of information and regular communication among the centers, as appropriate; and

(2) requiring the periodic preparation and submission to the Director of reports on the activities of each center.

(d) Priority

In awarding funding through grants, contracts, or cooperative agreements under subsection (a), the Director of the Institute shall, as appropriate, give priority to applicants with existing frameworks and partnerships, as applicable, to support the advancement of such research.

(e) Collaboration

The Director of the Institute shall—

(1) collaborate with the heads of other appropriate Federal departments, agencies, and offices with respect to the identification of additional priority virus families and other viral pathogens with a significant potential to cause a pandemic; and

(2) collaborate with the Director of the Biomedical Advanced Research and Development Authority with respect to the research conducted by centers described in subsection (a), including, as appropriate, providing any updates on the research advancements made by such centers, identifying any advanced research and development needs for such countermeasures, consistent with section 247d–7e(a)(6) of this title, and taking into consideration existing manufacturing capacity and future capacity needs for such medical products or technologies, including platform technologies, supported by the centers described in subsection (a).

(f) Supplement, not supplant

Any support received by a center described in subsection (a) under this section shall be used to supplement, and not supplant, other public or private support for activities authorized to be supported.

(July 1, 1944, ch. 373, title IV, §447D, as added Pub. L. 117–328, div. FF, title II, §2301, Dec. 29, 2022, 136 Stat. 5756.)

SUBPART 7—EUNICE KENNEDY SHRIVER NATIONAL INSTITUTE OF CHILD HEALTH AND HUMAN DEVELOPMENT

EDITORIAL NOTES

CODIFICATION

Pub. L. 110–154, §1(b)(7), Dec. 21, 2007, 121 Stat. 1827, substituted "Eunice Kennedy Shriver National Institute of Child Health and Human Development" for "National Institute of Child Health and Human Development" in subpart heading.

§285g. Purpose of Institute

The general purpose of the Eunice Kennedy Shriver National Institute of Child Health and Human Development (hereafter in this subpart referred to as the "Institute") is the conduct and support of research, training, health information dissemination, and other programs with respect to gynecologic health, maternal health, child health, intellectual disabilities, human growth and development, including prenatal development, population research, and special health problems and requirements of mothers and children.

(July 1, 1944, ch. 373, title IV, §448, as added Pub. L. 99–158, §2, Nov. 20, 1985, 99 Stat. 856; amended Pub. L. 106–554, §1(a)(1) [title II, §215], Dec. 21, 2000, 114 Stat. 2763, 2763A–28; Pub. L. 110–154, §1(d), Dec. 21, 2007, 121 Stat. 1828; Pub. L. 111–256, §2(f)(2), Oct. 5, 2010, 124 Stat.

2644.)

EDITORIAL NOTES

AMENDMENTS

2010—Pub. L. 111–256 substituted "intellectual disabilities," for "mental retardation,".

2000—Pub. L. 106–554 inserted "gynecologic health," after "with respect to".

STATUTORY NOTES AND RELATED SUBSIDIARIES

CHANGE OF NAME

"Eunice Kennedy Shriver National Institute of Child Health and Human Development" substituted for "National Institute of Child Health and Human Development" in text, on authority of section 1(d) of Pub. L. 110–154, set out below.

Pub. L. 110–154, §1(d), Dec. 21, 2007, 121 Stat. 1828, provided that: "Any reference in any law, regulation, order, document, paper, or other record of the United States to the 'National Institute of Child Health and Human Development' shall be deemed to be a reference to the 'Eunice Kennedy Shriver National Institute of Child Health and Human Development'."

EUNICE KENNEDY SHRIVER NATIONAL INSTITUTE OF CHILD HEALTH AND HUMAN DEVELOPMENT; FINDINGS

Pub. L. 110–154, §1(a), Dec. 21, 2007, 121 Stat. 1826, as amended by Pub. L. 111–256, §2(h), Oct. 5, 2010, 124 Stat. 2644, provided that: "Congress makes the following findings:

"(1) Since it was established by Congress in 1962 at the request of President John F. Kennedy, the National Institute of Child Health and Human Development has achieved an outstanding record of achievement in catalyzing a concentrated attack on the unsolved health problems of children and of mother-infant relationships by fulfilling its mission to—

"(A) ensure that every individual is born healthy and wanted, that women suffer no harmful effects from reproductive processes, and that all children have the chance to achieve their full potential for healthy and productive lives, free from disease or disability; and

"(B) ensure the health, productivity, independence, and well-being of all individuals through optimal rehabilitation.

"(2) The National Institute of Child Health and Human Development has made unparalleled contributions to the advancement of child health and human development, including significant efforts to—

"(A) reduce dramatically the rates of Sudden Infant Death Syndrome, infant mortality, and maternal HIV transmission;

"(B) develop the Haemophilus Influenza B (Hib) vaccine, credited with nearly eliminating the incidence of intellectual disabilities; and

"(C) conduct intramural research, support extramural research, and train thousands of child health and human development researchers who have contributed greatly to dramatic gains in child health throughout the world.

"(3) The vision, drive, and tenacity of one woman, Eunice Kennedy Shriver, was instrumental in proposing, passing, and enacting legislation to establish the National Institute of Child Health and Human Development (Public Law 87–838) [see Tables for classification] on October 17, 1962.

"(4) It is befitting and appropriate to recognize the substantial achievements of Eunice Kennedy Shriver, a tireless advocate for children with special needs, whose foresight in creating the National Institute of Child Health and Human Development gave life to the words of President Kennedy, who wished to 'encourage imaginative research into the complex processes of human development from conception to old age.' "

[For definition of "intellectual disabilities" in section 1(a) of Pub. L. 110–154, set out above, see Definitions note below.]

LONG-TERM CHILD DEVELOPMENT STUDY

Pub. L. 106–310, div. A, title X, §1004, Oct. 17, 2000, 114 Stat. 1130, as amended by Pub. L. 108–446, title III, §301, Dec. 3, 2004, 118 Stat. 2803; Pub. L. 109–482, title I, §104(b)(3)(E), Jan. 15, 2007, 120 Stat. 3694; Pub. L. 110–154, §1(d), Dec. 21, 2007, 121 Stat. 1828, provided that:

"(a) PURPOSE.—It is the purpose of this section to authorize the Eunice Kennedy Shriver National

Institute of Child Health and Human Development to conduct a national longitudinal study of environmental influences (including physical, chemical, biological, and psychosocial) on children's health and development.

"(b) IN GENERAL.—The Director of the Eunice Kennedy Shriver National Institute of Child Health and Human Development shall establish a consortium of representatives from appropriate Federal agencies (including the Centers for Disease Control and Prevention, the Environmental Protection Agency, and the Department of Education) to—

"(1) plan, develop, and implement a prospective cohort study, from birth to adulthood, to evaluate the effects of both chronic and intermittent exposures on child health and human development; and

"(2) investigate basic mechanisms of developmental disorders and environmental factors, both risk and protective, that influence health and developmental processes.

"(c) REQUIREMENT.—The study under subsection (b) shall—

"(1) incorporate behavioral, emotional, educational, and contextual consequences to enable a complete assessment of the physical, chemical, biological and psychosocial environmental influences on children's well-being;

"(2) gather data on environmental influences and outcomes on diverse populations of children, which may include the consideration of prenatal exposures;

"(3) consider health disparities among children which may include the consideration of prenatal exposures; and

"(4) be conducted in compliance with section 444 of the General Education Provisions Act (20 U.S.C. 1232g), including the requirement of prior parental consent for the disclosure of any education records, except without the use of authority or exceptions granted to authorized representatives of the Secretary of Education for the evaluation of Federally-supported education programs or in connection with the enforcement of the Federal legal requirements that relate to such programs.

"[(d) Repealed. Pub. L. 109–482, title I, §104(b)(3)(E), Jan. 15, 2007, 120 Stat. 3694.]

"(e) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated to carry out this section $18,000,000 for fiscal year 2001, and such sums as may be necessary for each [sic] the fiscal years 2002 through 2005."

NATIONAL COMMISSION TO PREVENT INFANT MORTALITY; COMPOSITION; VOLUNTARY SERVICES; DURATION

Pub. L. 100–436, title IV, Sept. 20, 1988, 102 Stat. 1709, provided that the National Commission to Prevent Infant Mortality was to be composed of sixteen members, including seven at large members, and that it had power to accept voluntary and uncompensated services, notwithstanding section 1342 of title 31, and was to continue operating, notwithstanding sections 208 and 209 of Pub. L. 99–660 (formerly set out below).

NATIONAL COMMISSION TO PREVENT INFANT MORTALITY

Pub. L. 99–660, title II, Nov. 14, 1986, 100 Stat. 3752, known as the National Commission to Prevent Infant Mortality Act of 1986, established National Commission to Prevent Infant Mortality to examine and make recommendation on government and private resources, policies, and programs which impact on infant mortality, required Commission to submit recommendations to President and Congress no later than one year after Nov. 14, 1986, and terminated Commission 90 days after submission of recommendations.

DEFINITIONS

For meaning of references to an intellectual disability and to individuals with intellectual disabilities in provisions amended by section 2 of Pub. L. 111–256, see section 2(k) of Pub. L. 111–256, set out as a note under section 1400 of Title 20, Education.

§285g–1. Sudden infant death syndrome research

The Director of the Institute shall conduct and support research which specifically relates to sudden infant death syndrome.

(July 1, 1944, ch. 373, title IV, §449, as added Pub. L. 99–158, §2, Nov. 20, 1985, 99 Stat. 856.)

§285g–2. Research on intellectual disabilities

The Director of the Institute shall conduct and support research and related activities into the

causes, prevention, and treatment of intellectual disabilities.

(July 1, 1944, ch. 373, title IV, §450, as added Pub. L. 99–158, §2, Nov. 20, 1985, 99 Stat. 856; amended Pub. L. 111–256, §2(f)(3), Oct. 5, 2010, 124 Stat. 2644.)

EDITORIAL NOTES

AMENDMENTS

2010—Pub. L. 111–256 amended section generally. Prior to amendment, text read as follows: "The Director of the Institute shall conduct and support research and related activities into the causes, prevention, and treatment of mental retardation."

STATUTORY NOTES AND RELATED SUBSIDIARIES

DEFINITIONS

For meaning of references to an intellectual disability and to individuals with intellectual disabilities in provisions amended by section 2 of Pub. L. 111–256, see section 2(k) of Pub. L. 111–256, set out as a note under section 1400 of Title 20, Education.

§285g–3. Associate Director for Prevention; appointment; function

There shall be in the Institute an Associate Director for Prevention to coordinate and promote the programs in the Institute concerning the prevention of health problems of mothers and children. The Associate Director shall be appointed by the Director of the Institute from individuals who because of their professional training or experience are experts in public health or preventive medicine.

(July 1, 1944, ch. 373, title IV, §451, as added Pub. L. 99–158, §2, Nov. 20, 1985, 99 Stat. 856; amended Pub. L. 105–362, title VI, §601(a)(1)(E), Nov. 10, 1998, 112 Stat. 3285.)

EDITORIAL NOTES

AMENDMENTS

1998—Pub. L. 105–362 struck out subsec. (a) designation and struck out subsec. (b) which read as follows: "The Associate Director for Prevention shall prepare for inclusion in the biennial report made under section 284b of this title a description of the prevention activities of the Institute, including a description of the staff and resources allocated to those activities."

§285g–4. National Center for Medical Rehabilitation Research

(a) Establishment of Center

There shall be in the Institute an agency to be known as the National Center for Medical Rehabilitation Research (hereafter in this section referred to as the "Center"). The Director of the Institute shall appoint a qualified individual to serve as Director of the Center. The Director of the Center shall report directly to the Director of the Institute.

(b) Purpose

The general purpose of the Center is the conduct, support, and coordination of research and research training (including research on the development of orthotic and prosthetic devices), the dissemination of health information, and other programs with respect to the rehabilitation of individuals with physical disabilities resulting from diseases or disorders of the neurological, musculoskeletal, cardiovascular, pulmonary, or any other physiological system (hereafter in this section referred to as "medical rehabilitation").

(c) Authority of Director

(1) In carrying out the purpose described in subsection (b), the Director of the Center may—

(A) provide for clinical trials regarding medical rehabilitation;

(B) provide for research regarding model systems of medical rehabilitation;

(C) coordinate the activities within the Center with similar activities of other agencies of the Federal Government, including the other agencies of the National Institutes of Health, and with similar activities of other public entities and of private entities;

(D) support multidisciplinary medical rehabilitation research conducted or supported by more than one such agency;

(E) in consultation with the advisory council for the Institute and with the approval of the Director of NIH—

(i) establish technical and scientific peer review groups in addition to those appointed under section 282(b)(16) of this title; and

(ii) appoint the members of peer review groups established under subparagraph (A); and

(F) support medical rehabilitation research and training centers.

Chapter 10 of title 5 shall not apply to the duration of a peer review group appointed under subparagraph (E).

(2) In carrying out this section, the Director of the Center may make grants and enter into cooperative agreements and contracts.

(d) Research Plan

(1) The Director of the Center, in consultation with the Director of the Institute, the coordinating committee established under subsection (e), and the advisory board established under subsection (f), shall develop a comprehensive plan (referred to in this section as the "Research Plan") for the conduct, support, and coordination of medical rehabilitation research.

(2) The Research Plan shall—

(A) identify current medical rehabilitation research activities conducted or supported by the Federal Government, opportunities and needs for additional research, and priorities for such research;

(B) make recommendations for the coordination of such research conducted or supported by the National Institutes of Health and other agencies of the Federal Government; and

(C) include goals and objectives for conducting, supporting, and coordinating medical rehabilitation research, consistent with the purpose described in subsection (b).

(3)(A) Not later than 18 months after the date of the enactment of the National Institutes of Health Revitalization Amendments of 1990, the Director of the Institute shall transmit the Research Plan to the Director of NIH, who shall submit the Plan to the President and the Congress.

(B) Subparagraph (A) shall be carried out independently of the process of reporting that is required in sections 283 and 284b [1] of this title.

(4) The Director of the Center, in consultation with the Director of the Institute, the coordinating committee established under subsection (e), and the advisory board established under subsection (f), shall revise and update the Research Plan periodically, as appropriate, or not less than every 5 years. Not later than 30 days after the Research Plan is so revised and updated, the Director of the Center shall transmit the revised and updated Research Plan to the President, the Committee on Health, Education, Labor, and Pensions of the Senate, and the Committee on Energy and Commerce of the House of Representatives.

(5) The Director of the Center, in consultation with the Director of the Institute, shall, prior to revising and updating the Research Plan, prepare a report for the coordinating committee established under subsection (e) and the advisory board established under subsection (f) that describes and analyzes the progress during the preceding fiscal year in achieving the goals and objectives described in paragraph (2)(C) and includes expenditures for rehabilitation research at the National Institutes of Health. The report shall include recommendations for revising and updating the Research Plan, and

such initiatives as the Director of the Center and the Director of the Institute determine appropriate. In preparing the report, the Director of the Center and the Director of the Institute shall consult with the Director of the National Institutes of Health.

(e) Medical Rehabilitation Coordinating Committee

(1) The Director of NIH shall establish a committee to be known as the Medical Rehabilitation Coordinating Committee (hereafter in this section referred to as the "Coordinating Committee").

(2) The Coordinating Committee shall periodically host a scientific conference or workshop on medical rehabilitation research and make recommendations to the Director of the Institute and the Director of the Center with respect to the content of the Research Plan and with respect to the activities of the Center that are carried out in conjunction with other agencies of the National Institutes of Health and with other agencies of the Federal Government.

(3) The Coordinating Committee shall be composed of the Director of the Division of Program Coordination, Planning, and Strategic Initiatives within the Office of the Director of the National Institutes of Health, the Director of the Center, the Director of the Institute, and the Directors of the National Institute on Aging, the National Institute of Arthritis and Musculoskeletal and Skin Diseases, the National Heart, Lung, and Blood Institute, the National Institute of Neurological Disorders and Stroke, and such other national research institutes and such representatives of other agencies of the Federal Government as the Director of NIH determines to be appropriate.

(4) The Coordinating Committee shall be chaired by the Director of the Center.

(f) National Advisory Board on Medical Rehabilitation Research

(1) Not later than 90 days after the date of the enactment of the National Institutes of Health Revitalization Amendments of 1990, the Director of NIH shall establish a National Advisory Board on Medical Rehabilitation Research (hereafter in this section referred to as the "Advisory Board").

(2) The Advisory Board shall review and assess Federal research priorities, activities, and findings regarding medical rehabilitation research, and shall advise the Director of the Center and the Director of the Institute on the provisions of the Research Plan.

(3)(A) The Director of NIH shall appoint to the Advisory Board 18 qualified representatives of the public who are not officers or employees of the Federal Government. Of such members, 12 shall be representatives of health and scientific disciplines with respect to medical rehabilitation and 6 shall be individuals representing the interests of individuals undergoing, or in need of, medical rehabilitation.

(B) The following officials shall serve as ex officio members of the Advisory Board:

(i) The Director of the Center.
(ii) The Director of the Institute.
(iii) The Director of the National Institute on Aging.
(iv) The Director of the National Institute of Arthritis and Musculoskeletal and Skin Diseases.
(v) The Director of the National Institute on Deafness and Other Communication Disorders.
(vi) The Director of the National Heart, Lung, and Blood Institute.
(vii) The Director of the National Institute of Neurological Disorders and Stroke.
(viii) The Director of the National Institute on Disability and Rehabilitation Research.
(ix) The Director of the Division of Program Coordination, Planning, and Strategic Initiatives.
(x) The Commissioner for Rehabilitation Services Administration.
(xi) The Assistant Secretary of Defense (Health Affairs).
(xii) The Under Secretary for Health of the Department of Veterans Affairs.

(4) The members of the Advisory Board shall, from among the members appointed under paragraph (3)(A), designate an individual to serve as the chair of the Advisory Board.

(g) Review and coordination of medical rehabilitation research programs

(1) The Secretary and the heads of other Federal agencies shall jointly review the programs carried out (or proposed to be carried out) by each such official with respect to medical rehabilitation research and, as appropriate, enter into agreements preventing duplication among such programs.

(2) The Secretary shall, as appropriate, enter into interagency agreements relating to the coordination of medical rehabilitation research conducted by agencies of the National Institutes of Health and other agencies of the Federal Government.

(h) "Medical rehabilitation research" defined

For purposes of this section, the term "medical rehabilitation research" means the science of mechanisms and interventions that prevent, improve, restore, or replace lost, underdeveloped, or deteriorating function.

(July 1, 1944, ch. 373, title IV, §452, as added Pub. L. 101–613, §3(a), Nov. 16, 1990, 104 Stat. 3227; amended Pub. L. 102–405, title III, §302(e)(1), Oct. 9, 1992, 106 Stat. 1985; Pub. L. 109–482, title I, §102(f)(1)(B), Jan. 15, 2007, 120 Stat. 3685; Pub. L. 114–255, div. A, title II, §2040(a), (b)(1), Dec. 13, 2016, 130 Stat. 1069, 1070; Pub. L. 117–286, §4(a)(234), Dec. 27, 2022, 136 Stat. 4331.)

EDITORIAL NOTES

REFERENCES IN TEXT

The date of the enactment of the National Institutes of Health Revitalization Amendments of 1990, referred to in subsecs. (d)(3)(A) and (f)(1), probably means the date of enactment of the National Institutes of Health Amendments of 1990, Pub. L. 101–613, which was approved Nov. 16, 1990.

Section 284b of this title, referred to in subsec. (d)(3)(B), was repealed by Pub. L. 109–482, title I, §104(b)(1)(C), Jan. 15, 2007, 120 Stat. 3693.

AMENDMENTS

2022—Subsec. (c)(1). Pub. L. 117–286 substituted "Chapter 10 of title 5" for "The Federal Advisory Committee Act" in concluding provisions.

2016—Pub. L. 114–255, §2040(b)(1), made technical amendment to directory language of Pub. L. 101–613, §3(a), which enacted this section.

Subsec. (b). Pub. L. 114–255, §2040(a)(1), substituted "conduct, support, and coordination" for "conduct and support".

Subsec. (c)(1)(C). Pub. L. 114–255, §2040(a)(2), substituted "within the Center" for "of the Center".

Subsec. (d)(1). Pub. L. 114–255, §2040(a)(3)(A), added par. (1) and struck out former par. (1), which read as follows: "In consultation with the Director of the Center, the coordinating committee established under subsection (e), and the advisory board established under subsection (f), the Director of the Institute shall develop a comprehensive plan for the conduct and support of medical rehabilitation research (hereafter in this section referred to as the 'Research Plan')."

Subsec. (d)(2)(C). Pub. L. 114–255, §2040(a)(3)(B), added subpar. (C).

Subsec. (d)(4). Pub. L. 114–255, §2040(a)(3)(C), added par. (4) and struck out former par. (4) which read as follows: "The Director of the Institute shall periodically revise and update the Research Plan as appropriate, after consultation with the Director of the Center, the coordinating committee established under subsection (e), and the advisory board established under subsection (f). A description of any revisions in the Research Plan shall be contained in each report prepared under section 284b of this title by the Director of the Institute."

Subsec. (d)(5). Pub. L. 114–255, §2040(a)(3)(D), added par. (5).

Subsec. (e)(2). Pub. L. 114–255, §2040(a)(4)(A), inserted "periodically host a scientific conference or workshop on medical rehabilitation research and" after "The Coordinating Committee shall".

Subsec. (e)(3). Pub. L. 114–255, §2040(a)(4)(B), inserted "the Director of the Division of Program Coordination, Planning, and Strategic Initiatives within the Office of the Director of the National Institutes of Health," after "shall be composed of".

Subsec. (f)(3)(B)(ix) to (xii). Pub. L. 114–255, §2040(a)(5), added cl. (ix) and redesignated former cls. (ix) to (xi) as (x) to (xii), respectively.

Subsecs. (g), (h). Pub. L. 114–255, §2040(a)(6), added subsecs. (g) and (h).

2007—Subsec. (c)(1)(E)(i). Pub. L. 109–482 substituted "section 282(b)(16)" for "section 282(b)(6)".

1992—Subsec. (f)(3)(B)(xi). Pub. L. 102–405 substituted "Under Secretary for Health of the Department of Veterans Affairs" for "Chief Medical Director of the Department of Veterans Affairs".

STATUTORY NOTES AND RELATED SUBSIDIARIES

EFFECTIVE DATE OF 2007 AMENDMENT

Amendment by Pub. L. 109–482 applicable only with respect to amounts appropriated for fiscal year 2007 or subsequent fiscal years, see section 109 of Pub. L. 109–482, set out as a note under section 281 of this title.

TRANSFER OF FUNCTIONS

Functions which the Director of the National Institute on Disability and Rehabilitation Research exercised before July 22, 2014 (including all related functions of any officer or employee of the National Institute on Disability and Rehabilitation Research), transferred to the National Institute on Disability, Independent Living, and Rehabilitation Research, see subsection (n) of section 3515e of Title 42, The Public Health and Welfare.

PREVENTING DUPLICATIVE PROGRAMS OF MEDICAL REHABILITATION RESEARCH

Pub. L. 101–613, §3(b), Nov. 16, 1990, 104 Stat. 3230, which required the Secretary of Health and Human Services and the heads of other Federal agencies to jointly review medical rehabilitation research programs and enter into agreements for preventing duplication among such programs not later than one year after November 16, 1990, was repealed by Pub. L. 114–255, div. A, title II, §2040(b)(2), Dec. 13, 2016, 130 Stat. 1070. See subsecs. (g) and (h) of this section.

TERMINATION OF ADVISORY BOARDS

Advisory boards established after Jan. 5, 1973, to terminate not later than the expiration of the 2-year period beginning on the date of their establishment, unless, in the case of a board established by the President or an officer of the Federal Government, such board is renewed by appropriate action prior to the expiration of such 2-year period, or in the case of a board established by Congress, its duration is otherwise provided by law. See sections 1001(2) and 1013 of Title 5, Government Organization and Employees.

Pub. L. 93–641, §6, Jan. 4, 1975, 88 Stat. 2275, set out as a note under section 217a of this title, provided that an advisory committee established pursuant to the Public Health Service Act shall terminate at such time as may be specifically prescribed by an Act of Congress enacted after Jan. 4, 1975.

[1] *See References in Text note below.*

§285g–5. Research centers with respect to contraception and infertility

(a) Grants and contracts

The Director of the Institute, after consultation with the advisory council for the Institute, shall make grants to, or enter into contracts with, public or nonprofit private entities for the development and operation of centers to conduct activities for the purpose of improving methods of contraception and centers to conduct activities for the purpose of improving methods of diagnosis and treatment of infertility.

(b) Number of centers

In carrying out subsection (a), the Director of the Institute shall, subject to the extent of amounts made available in appropriations Acts, provide for the establishment of three centers with respect to contraception and for two centers with respect to infertility.

(c) Duties

(1) Each center assisted under this section shall, in carrying out the purpose of the center involved—

(A) conduct clinical and other applied research, including—

(i) for centers with respect to contraception, clinical trials of new or improved drugs and devices for use by males and females (including barrier methods); and

(ii) for centers with respect to infertility, clinical trials of new or improved drugs and devices for the diagnosis and treatment of infertility in males and females;

(B) develop protocols for training physicians, scientists, nurses, and other health and allied health professionals;

(C) conduct training programs for such individuals;
(D) develop model continuing education programs for such professionals; and
(E) disseminate information to such professionals and the public.

(2) A center may use funds provided under subsection (a) to provide stipends for health and allied health professionals enrolled in programs described in subparagraph (C) of paragraph (1), and to provide fees to individuals serving as subjects in clinical trials conducted under such paragraph.

(d) Coordination of information

The Director of the Institute shall, as appropriate, provide for the coordination of information among the centers assisted under this section.

(e) Facilities

Each center assisted under subsection (a) shall use the facilities of a single institution, or be formed from a consortium of cooperating institutions, meeting such requirements as may be prescribed by the Director of the Institute.

(f) Period of support

Support of a center under subsection (a) may be for a period not exceeding 5 years. Such period may be extended for one or more additional periods not exceeding 5 years if the operations of such center have been reviewed by an appropriate technical and scientific peer review group established by the Director and if such group has recommended to the Director that such period should be extended.

(July 1, 1944, ch. 373, title IV, §452A, as added Pub. L. 103–43, title X, §1001, June 10, 1993, 107 Stat. 165; amended Pub. L. 109–482, title I, §103(b)(29), Jan. 15, 2007, 120 Stat. 3688.)

EDITORIAL NOTES

AMENDMENTS

2007—Subsec. (g). Pub. L. 109–482 struck out subsec. (g) which read as follows: "For the purpose of carrying out this section, there are authorized to be appropriated $30,000,000 for fiscal year 1994, and such sums as may be necessary for each of the fiscal years 1995 and 1996."

STATUTORY NOTES AND RELATED SUBSIDIARIES

EFFECTIVE DATE OF 2007 AMENDMENT

Amendment by Pub. L. 109–482 applicable only with respect to amounts appropriated for fiscal year 2007 or subsequent fiscal years, see section 109 of Pub. L. 109–482, set out as a note under section 281 of this title.

§285g–6. Program regarding obstetrics and gynecology

The Director of the Institute shall establish and maintain within the Institute an intramural laboratory and clinical research program in obstetrics and gynecology.

(July 1, 1944, ch. 373, title IV, §452B, as added Pub. L. 103–43, title X, §1011, June 10, 1993, 107 Stat. 166.)

§285g–7. Child health research centers

The Director of the Institute shall develop and support centers for conducting research with respect to child health. Such centers shall give priority to the expeditious transfer of advances from basic science to clinical applications and improving the care of infants and children.

(July 1, 1944, ch. 373, title IV, §452C, as added Pub. L. 103–43, title X, §1021, June 10, 1993, 107 Stat. 167.)

§285g–8. Prospective longitudinal study on adolescent health

(a) In general

Not later than October 1, 1993, the Director of the Institute shall commence a study for the purpose of providing information on the general health and well-being of adolescents in the United States, including, with respect to such adolescents, information on—

(1) the behaviors that promote health and the behaviors that are detrimental to health; and

(2) the influence on health of factors particular to the communities in which the adolescents reside.

(b) Design of study

(1) In general

The study required in subsection (a) shall be a longitudinal study in which a substantial number of adolescents participate as subjects. With respect to the purpose described in such subsection, the study shall monitor the subjects throughout the period of the study to determine the health status of the subjects and any change in such status over time.

(2) Population-specific analyses

The study required in subsection (a) shall be conducted with respect to the population of adolescents who are female, the population of adolescents who are male, various socioeconomic populations of adolescents, and various racial and ethnic populations of adolescents. The study shall be designed and conducted in a manner sufficient to provide for a valid analysis of whether there are significant differences among such populations in health status and whether and to what extent any such differences are due to factors particular to the populations involved.

(c) Coordination with Women's Health Initiative

With respect to the national study of women being conducted by the Secretary and known as the Women's Health Initiative, the Secretary shall ensure that such study is coordinated with the component of the study required in subsection (a) that concerns adolescent females, including coordination in the design of the 2 studies.

(July 1, 1944, ch. 373, title IV, §452D, as added Pub. L. 103–43, title X, §1031, June 10, 1993, 107 Stat. 167.)

§285g–9. Fragile X

(a) Expansion and coordination of research activities

The Director of the Institute, after consultation with the advisory council for the Institute, shall expand, intensify, and coordinate the activities of the Institute with respect to research on the disease known as fragile X.

(b) Research centers

(1) In general

The Director of the Institute shall make grants or enter into contracts for the development and operation of centers to conduct research for the purposes of improving the diagnosis and treatment of, and finding the cure for, fragile X.

(2) Number of centers

(A) In general

In carrying out paragraph (1), the Director of the Institute shall, to the extent that amounts are appropriated, and subject to subparagraph (B), provide for the establishment of at least three fragile X research centers.

(B) Peer review requirement

The Director of the Institute shall make a grant to, or enter into a contract with, an entity for purposes of establishing a center under paragraph (1) only if the grant or contract has been recommended after technical and scientific peer review required by regulations under section 289a of this title.

(3) Activities

The Director of the Institute, with the assistance of centers established under paragraph (1), shall conduct and support basic and biomedical research into the detection and treatment of fragile X.

(4) Coordination among centers

The Director of the Institute shall, as appropriate, provide for the coordination of the activities of the centers assisted under this section, including providing for the exchange of information among the centers.

(5) Certain administrative requirements

Each center assisted under paragraph (1) shall use the facilities of a single institution, or be formed from a consortium of cooperating institutions, meeting such requirements as may be prescribed by the Director of the Institute.

(6) Duration of support

Support may be provided to a center under paragraph (1) for a period not exceeding 5 years. Such period may be extended for one or more additional periods, each of which may not exceed 5 years, if the operations of such center have been reviewed by an appropriate technical and scientific peer review group established by the Director and if such group has recommended to the Director that such period be extended.

(July 1, 1944, ch. 373, title IV, §452E, as added Pub. L. 106–310, div. A, title II, §201, Oct. 17, 2000, 114 Stat. 1109; amended Pub. L. 109–482, title I, §103(b)(30), Jan. 15, 2007, 120 Stat. 3688.)

EDITORIAL NOTES

AMENDMENTS

2007—Subsec. (b)(7). Pub. L. 109–482 struck out heading and text of par. (7). Text read as follows: "For the purpose of carrying out this subsection, there are authorized to be appropriated such sums as may be necessary for each of the fiscal years 2001 through 2005."

STATUTORY NOTES AND RELATED SUBSIDIARIES

EFFECTIVE DATE OF 2007 AMENDMENT

Amendment by Pub. L. 109–482 applicable only with respect to amounts appropriated for fiscal year 2007 or subsequent fiscal years, see section 109 of Pub. L. 109–482, set out as a note under section 281 of this title.

§285g–10. Investment in tomorrow's pediatric researchers

In order to ensure the future supply of researchers dedicated to the care and research needs of children, the Director of the Institute, after consultation with the Administrator of the Health Resources and Services Administration, shall support activities to provide for—

(1) an increase in the number and size of institutional training grants to institutions supporting pediatric training; and

(2) an increase in the number of career development awards for health professionals who intend to build careers in pediatric basic and clinical research, including pediatric pharmacological research.

(July 1, 1944, ch. 373, title IV, §452G, as added Pub. L. 106–310, div. A, title X, §1002(a), Oct. 17,

2000, 114 Stat. 1128; amended Pub. L. 109–482, title I, §103(b)(31), Jan. 15, 2007, 120 Stat. 3688; Pub. L. 110–85, title V, §503(a), Sept. 27, 2007, 121 Stat. 890.)

EDITORIAL NOTES

AMENDMENTS

2007—Pub. L. 109–482 struck out subsec. (a) designation and heading before "In order to" and struck out heading and text of subsec. (b). Text read as follows: "For the purpose of carrying out subsection (a) of this section, there are authorized to be appropriated such sums as may be necessary for each of the fiscal years 2001 through 2005."

Par. (2). Pub. L. 110–85 inserted ", including pediatric pharmacological research" before period at end.

STATUTORY NOTES AND RELATED SUBSIDIARIES

EFFECTIVE DATE OF 2007 AMENDMENT

Amendment by Pub. L. 109–482 applicable only with respect to amounts appropriated for fiscal year 2007 or subsequent fiscal years, see section 109 of Pub. L. 109–482, set out as a note under section 281 of this title.

§285g–11. Research on the health and development effects of media and related technology on infants, children, and adolescents

(a) In general

The Secretary of Health and Human Services (in this section referred to as the "Secretary") shall, as appropriate, conduct or support research related to the health and developmental effects, including long-term effects, of media and related technology use on infants, children, and adolescents, which may include the effects of exposure to, and use of, media and related technology, such as social media, applications, websites, television, motion pictures, artificial intelligence, mobile devices, computers, video games, virtual and augmented reality, and other content, networks, or platforms disseminated through the internet, broadcasted, or other media technologies, as applicable.

(b) Activities

In carrying out subsection (a), the Secretary, acting through the Director of the National Institutes of Health, shall, as appropriate, develop a research agenda to assess the effects of media and related technologies on infants, children, and adolescents, which may include consideration of the following, as appropriate:

(1) The cognitive development of infants, children, and adolescents, which may include effects related to language development, learning abilities, and other areas of cognitive development.

(2) The physical health of infants, children, and adolescents, which may include effects related to diet, exercise, sleeping and eating routines, and other areas of physical development.

(3) The mental health of infants, children, and adolescents, which may include effects related to self-awareness, social awareness, relationship skills, decision-making, violence, bullying, privacy, mental disorders, and other areas related to mental health.

(c) Consultation

In developing the research agenda under subsection (b), the Secretary may consult with appropriate national research institutes, academies, and centers, relevant consortia, and non-Federal experts, as appropriate. The Secretary may utilize scientific workshops, symposia, and other activities to assess current knowledge and identify relevant research opportunities and gaps in this area.

(d) Report to Congress

Not later than 2 years after December 29, 2022, the Director of the National Institutes of Health shall submit to the Committee on Energy and Commerce of the House of Representatives and the Committee on Health, Education, Labor, and Pensions of the Senate a report—

(1) on the progress made in improving data and expanding research on the health and developmental effects of media and related technology on infants, children, and adolescents in accordance with this section; and

(2) that summarizes the grants and research funded under this section for each of the years covered by the report.

(Pub. L. 117–328, div. FF, title I, §1432, Dec. 29, 2022, 136 Stat. 5705.)

EDITORIAL NOTES

CODIFICATION

Section was enacted as part of the Restoring Hope for Mental Health and Well-Being Act of 2022 and also as part of the Health Extenders, Improving Access to Medicare, Medicaid, and CHIP, and Strengthening Public Health Act of 2022, and not as part of the Public Health Service Act which comprises this chapter.

SUBPART 8—NATIONAL INSTITUTE OF DENTAL RESEARCH

§285h. Purpose of Institute

The general purpose of the National Institute of Dental Research is the conduct and support of research, training, health information dissemination, and other programs with respect to the cause, prevention, and methods of diagnosis and treatment of dental and oral diseases and conditions.

(July 1, 1944, ch. 373, title IV, §453, as added Pub. L. 99–158, §2, Nov. 20, 1985, 99 Stat. 856.)

SUBPART 9—NATIONAL EYE INSTITUTE

§285i. Purpose of Institute

The general purpose of the National Eye Institute (hereafter in this subpart referred to as the "Institute") is the conduct and support of research, training, health information dissemination, and other programs with respect to blinding eye diseases, visual disorders, mechanisms of visual function, preservation of sight, and the special health problems and requirements of the blind. Subject to section 285i–1 of this title, the Director of the Institute may carry out a program of grants for public and private nonprofit vision research facilities.

(July 1, 1944, ch. 373, title IV, §455, as added Pub. L. 99–158, §2, Nov. 20, 1985, 99 Stat. 856; amended Pub. L. 103–43, title XI, §1101(b), June 10, 1993, 107 Stat. 169.)

EDITORIAL NOTES

AMENDMENTS

1993—Pub. L. 103–43 substituted "Subject to section 285i–1 of this title, the Director" for "The Director" in second sentence.

§285i–1. Clinical research on eye care and diabetes

(a) Program of grants

The Director of the Institute, in consultation with the advisory council for the Institute, may award

research grants to one or more Diabetes Eye Research Institutions for the support of programs in clinical or health services aimed at—

(1) providing comprehensive eye care services for people with diabetes, including a full complement of preventive, diagnostic and treatment procedures;

(2) developing new and improved techniques of patient care through basic and clinical research;

(3) assisting in translation of the latest research advances into clinical practice; and

(4) expanding the knowledge of the eye and diabetes through further research.

(b) Use of funds

Amounts received under a grant awarded under this section shall be used for the following:

(1) Establishing the biochemical, cellular, and genetic mechanisms associated with diabetic eye disease and the earlier detection of pending eye abnormalities. The focus of work under this paragraph shall require that ophthalmologists have training in the most up-to-date molecular and cell biological methods.

(2) Establishing new frontiers in technology, such as video-based diagnostic and research resources, to—

(A) provide improved patient care;

(B) provide for the evaluation of retinal physiology and its affect on diabetes; and

(C) provide for the assessment of risks for the development and progression of diabetic eye disease and a more immediate evaluation of various therapies aimed at preventing diabetic eye disease.

Such technologies shall be designed to permit evaluations to be performed both in humans and in animal models.

(3) The translation of the results of vision research into the improved care of patients with diabetic eye disease. Such translation shall require the application of institutional resources that encompass patient care, clinical research and basic laboratory research.

(4) The conduct of research concerning the outcomes of eye care treatments and eye health education programs as they relate to patients with diabetic eye disease, including the evaluation of regional approaches to such research.

(c) Authorized expenditures

The purposes for which a grant under subsection (a) may be expended include equipment for the research described in such subsection.

(July 1, 1944, ch. 373, title IV, §456, as added Pub. L. 103–43, title XI, §1101(a), June 10, 1993, 107 Stat. 168.)

SUBPART 10—NATIONAL INSTITUTE OF NEUROLOGICAL DISORDERS AND STROKE

EDITORIAL NOTES

CODIFICATION

Pub. L. 100–553, §2(2), Oct. 28, 1988, 102 Stat. 2769, and Pub. L. 100–607, title I, §101(2), Nov. 4, 1988, 102 Stat. 3049, made identical amendments to subpart heading, substituting "Neurological Disorders" for "Neurological and Communicative Disorders". Pub. L. 100–690, title II, §2613(b)(2), Nov. 18, 1988, 102 Stat. 4238, amended subpart heading to read as if the amendment by Pub. L. 100–607 had not been enacted.

§285j. Purpose of Institute

The general purpose of the National Institute of Neurological Disorders and Stroke (hereafter in

this subpart referred to as the "Institute") is the conduct and support of research, training, health information dissemination, and other programs with respect to neurological disease and disorder and stroke.

(July 1, 1944, ch. 373, title IV, §457, as added Pub. L. 99–158, §2, Nov. 20, 1985, 99 Stat. 857; amended Pub. L. 100–553, §2(3), Oct. 28, 1988, 102 Stat. 2769; Pub. L. 100–607, title I, §101(3), Nov. 4, 1988, 102 Stat. 3049; Pub. L. 100–690, title II, §2613(b)(2), Nov. 18, 1988, 102 Stat. 4238; Pub. L. 101–93, §5(a), Aug. 16, 1989, 103 Stat. 611.)

EDITORIAL NOTES

AMENDMENTS

1989—Pub. L. 101–93 substituted "disease and" for "disease and and".

1988—Pub. L. 100–553 and Pub. L. 100–607 made identical amendments, substituting "Neurological Disorders" for "Neurological and Communicative Disorders" and "and disorder and stroke" for "disorder, stroke, and disorders of human communication". Pub. L. 100–690 amended this section to read as if the amendments by Pub. L. 100–607 had not been enacted.

STATUTORY NOTES AND RELATED SUBSIDIARIES

EFFECTIVE DATE OF 1988 AMENDMENT

For effective date of amendment by Pub. L. 100–690, see section 2613(b)(1) of Pub. L. 100–690, set out as an Effect of Enactment of Similar Provisions note under section 285m of this title.

§285j–1. Spinal cord regeneration research

The Director of the Institute shall conduct and support research into spinal cord regeneration.

(July 1, 1944, ch. 373, title IV, §458, as added Pub. L. 99–158, §2, Nov. 20, 1985, 99 Stat. 857.)

STATUTORY NOTES AND RELATED SUBSIDIARIES

INTERAGENCY COMMITTEE ON SPINAL CORD INJURY

Pub. L. 99–158, §7, Nov. 20, 1985, 99 Stat. 881, provided that:

"(a) ESTABLISHMENT.—Within 90 days after the date of enactment of this Act [Nov. 20, 1985], the Secretary of Health and Human Services shall establish in the National Institute of Neurological and Communicative Diseases and Stroke an Interagency Committee on Spinal Cord Injury (hereafter in this section referred to as the 'Interagency Committee'). The Interagency Committee shall plan, develop, coordinate, and implement comprehensive Federal initiatives in research on spinal cord injury and regeneration.

"(b) COMMITTEE COMPOSITION AND MEETINGS.—(1) The Interagency Committee shall consist of representatives from—

"(A) the National Institute on Neurological and Communicative Disorders and Stroke;

"(B) the Department of Defense;

"(C) the Department of Education;

"(D) the Veterans' Administration;

"(E) the Office of Science and Technology Policy; and

"(F) the National Science Foundation;

designated by the heads of such entities.

"(2) The Interagency Committee shall meet at least four times. The Secretary of Health and Human Services shall select the Chairman of the Interagency Committee from the members of the Interagency Committee.

"(c) REPORT.—Within the 18 months after the date of enactment of this Act [Nov. 20, 1985], the Interagency Committee shall prepare and transmit to the Congress a report concerning its activities under this section. The report shall include a description of research projects on spinal cord injury and regeneration conducted or supported by Federal agencies during such 18-month period, the nature and purpose of each such

project, the amounts expended for each such project, and an identification of the entity which conducted the research under each such project.

"(d) TERMINATION.—The Interagency Committee shall terminate 90 days after the date on which the Interagency Committee transmits the report required by subsection (c) to the Congress."

§285j–2. Bioengineering research

The Director of the Institute shall make grants or enter into contracts for research on the means to overcome paralysis of the extremities through electrical stimulation and the use of computers.

(July 1, 1944, ch. 373, title IV, §459, as added Pub. L. 99–158, §2, Nov. 20, 1985, 99 Stat. 857.)

§285j–3. Research on multiple sclerosis

The Director of the Institute shall conduct and support research on multiple sclerosis, especially research on effects of genetics and hormonal changes on the progress of the disease.

(July 1, 1944, ch. 373, title IV, §460, as added Pub. L. 103–43, title XII, §1201, June 10, 1993, 107 Stat. 169.)

SUBPART 11—NATIONAL INSTITUTE OF GENERAL MEDICAL SCIENCES

§285k. National Institute of General Medical Sciences

(a) General purpose

The general purpose of the National Institute of General Medical Sciences is the conduct and support of research, training, and, as appropriate, health information dissemination, and other programs with respect to general or basic medical sciences and related natural or behavioral sciences which have significance for two or more other national research institutes or are outside the general area of responsibility of any other national research institute.

(b) Institutional development award program

(1)(A) In the case of entities described in subparagraph (B), the Director of NIH, acting through the Director of the National Institute of General Medical Sciences, shall establish a program to enhance the competitiveness of such entities in obtaining funds from the national research institutes for conducting biomedical and behavioral research.

(B) The entities referred to in subparagraph (A) are entities that conduct biomedical and behavioral research and are located in a State in which the aggregate success rate for applications to the national research institutes for assistance for such research by the entities in the State has historically constituted a low success rate of obtaining such funds, relative to such aggregate rate for such entities in other States.

(C) With respect to enhancing competitiveness for purposes of subparagraph (A), the Director of NIH, in carrying out the program established under such subparagraph, may—

(i) provide technical assistance to the entities involved, including technical assistance in the preparation of applications for obtaining funds from the national research institutes;

(ii) assist the entities in developing a plan for biomedical or behavioral research proposals; and

(iii) assist the entities in implementing such plan.

(2) The Director of NIH shall establish a program of supporting projects of biomedical or behavioral research whose principal researchers are individuals who have not previously served as

the principal researchers of such projects supported by the Director.

(July 1, 1944, ch. 373, title IV, §461, as added Pub. L. 99–158, §2, Nov. 20, 1985, 99 Stat. 857; amended Pub. L. 112–74, div. F, title II, §221(b)(5), Dec. 23, 2011, 125 Stat. 1088.)

EDITORIAL NOTES

CODIFICATION

Section 282(g) of this title, which was transferred and redesignated as subsec. (b) of this section by Pub. L. 112–74, div. F, title II, §221(b)(5)(B), Dec. 23, 2011, 125 Stat. 1088, was based on act July 1, 1944, ch. 373, title IV, §402(g), as added Pub. L. 103–43, title II, §202, June 10, 1993, 107 Stat. 144.

AMENDMENTS

2011—Pub. L. 112–74, §221(b)(5)(A), substituted "National Institute of General Medical Sciences" for "Purpose of Institute" in section catchline, designated existing provisions as subsec. (a), and inserted subsec. heading.

Subsec. (b). Pub. L. 112–74, §221(b)(5)(C)(i), (ii), inserted heading and realigned margins.

Pub. L. 112–74, §221(b)(5)(B), transferred subsec. (g) of section 282 of this title and redesignated it as subsec. (b) of this section. See Codification note above.

Subsec. (b)(1)(A). Pub. L. 112–74, §221(b)(5)(C)(iii), substituted "acting through the Director of the National Institute of General Medical Sciences" for "acting through the Director of the National Center for Research Resources".

SUBPART 12—NATIONAL INSTITUTE OF ENVIRONMENTAL HEALTH SCIENCES

§285*l*. Purpose of Institute

The general purpose of the National Institute of Environmental Health Sciences (in this subpart referred to as the "Institute") is the conduct and support of research, training, health information dissemination, and other programs with respect to factors in the environment that affect human health, directly or indirectly.

(July 1, 1944, ch. 373, title IV, §463, as added Pub. L. 99–158, §2, Nov. 20, 1985, 99 Stat. 857; amended Pub. L. 103–43, title XIII, §1301(b), June 10, 1993, 107 Stat. 170.)

EDITORIAL NOTES

AMENDMENTS

1993—Pub. L. 103–43 inserted "(in this subpart referred to as the 'Institute')" after "Sciences".

§285*l*–1. Applied Toxicological Research and Testing Program

(a) There is established within the Institute a program for conducting applied research and testing regarding toxicology, which program shall be known as the Applied Toxicological Research and Testing Program.

(b) In carrying out the program established under subsection (a), the Director of the Institute shall, with respect to toxicology, carry out activities—

(1) to expand knowledge of the health effects of environmental agents;

(2) to broaden the spectrum of toxicology information that is obtained on selected chemicals;

(3) to develop and validate assays and protocols, including alternative methods that can reduce or eliminate the use of animals in acute or chronic safety testing;

(4) to establish criteria for the validation and regulatory acceptance of alternative testing and to recommend a process through which scientifically validated alternative methods can be accepted for regulatory use;

(5) to communicate the results of research to government agencies, to medical, scientific, and regulatory communities, and to the public; and

(6) to integrate related activities of the Department of Health and Human Services.

(July 1, 1944, ch. 373, title IV, §463A, as added Pub. L. 103–43, title XIII, §1301(a), June 10, 1993, 107 Stat. 169.)

§285*l*–2. Definitions

In sections 285l–2 to 285l–5 of this title:

(1) Alternative test method

The term "alternative test method" means a test method that—

(A) includes any new or revised test method; and

(B)(i) reduces the number of animals required;

(ii) refines procedures to lessen or eliminate pain or distress to animals, or enhances animal well-being; or

(iii) replaces animals with non-animal systems or one animal species with a phylogenetically lower animal species, such as replacing a mammal with an invertebrate.

(2) ICCVAM test recommendation

The term "ICCVAM test recommendation" means a summary report prepared by the ICCVAM characterizing the results of a scientific expert peer review of a test method.

(Pub. L. 106–545, §2, Dec. 19, 2000, 114 Stat. 2721.)

EDITORIAL NOTES

CODIFICATION

Section was enacted as part of the ICCVAM Authorization Act of 2000, and not as part of the Public Health Service Act which comprises this chapter.

§285*l*–3. Interagency Coordinating Committee on the Validation of Alternative Methods

(a) In general

With respect to the interagency coordinating committee that is known as the Interagency Coordinating Committee on the Validation of Alternative Methods (referred to in sections 285l–2 to 285l–5 of this title as "ICCVAM") and that was established by the Director of the National Institute of Environmental Health Sciences for purposes of section 285l–1(b) of this title, the Director of the Institute shall designate such committee as a permanent interagency coordinating committee of the Institute under the National Toxicology Program Interagency Center for the Evaluation of Alternative Toxicological Methods. Sections 285l–2 to 285l–5 of this title may not be construed as affecting the authorities of such Director regarding ICCVAM that were in effect on the day before December 19, 2000, except to the extent inconsistent with sections 285l–2 to 285l–5 of this title.

(b) Purposes

The purposes of the ICCVAM shall be to—

(1) increase the efficiency and effectiveness of Federal agency test method review;

(2) eliminate unnecessary duplicative efforts and share experiences between Federal regulatory agencies;

(3) optimize utilization of scientific expertise outside the Federal Government;

(4) ensure that new and revised test methods are validated to meet the needs of Federal agencies; and

(5) reduce, refine, or replace the use of animals in testing, where feasible.

(c) Composition

The ICCVAM shall be composed of the heads of the following Federal agencies (or their designees):

(1) Agency for Toxic Substances and Disease Registry.
(2) Consumer Product Safety Commission.
(3) Department of Agriculture.
(4) Department of Defense.
(5) Department of Energy.
(6) Department of the Interior.
(7) Department of Transportation.
(8) Environmental Protection Agency.
(9) Food and Drug Administration.
(10) National Institute for Occupational Safety and Health.
(11) National Institutes of Health.
(12) National Cancer Institute.
(13) National Institute of Environmental Health Sciences.
(14) National Library of Medicine.
(15) Occupational Safety and Health Administration.
(16) Any other agency that develops, or employs tests or test data using animals, or regulates on the basis of the use of animals in toxicity testing.

(d) Scientific Advisory Committee

(1) Establishment

The Director of the National Institute of Environmental Health Sciences shall establish a Scientific Advisory Committee (referred to in sections 285l–2 to 285l–5 of this title as the "SAC") to advise ICCVAM and the National Toxicology Program Interagency Center for the Evaluation of Alternative Toxicological Methods regarding ICCVAM activities. The activities of the SAC shall be subject to provisions of chapter 10 of title 5.

(2) Membership

(A) In general

The SAC shall be composed of the following voting members:

(i) At least one knowledgeable representative having a history of expertise, development, or evaluation of new or revised or alternative test methods from each of—

(I) the personal care, pharmaceutical, industrial chemicals, or agriculture industry;

(II) any other industry that is regulated by the Federal agencies specified in subsection (c); and

(III) a national animal protection organization established under section 501(c)(3) of title 26.

(ii) Representatives (selected by the Director of the National Institute of Environmental Health Sciences) from an academic institution, a State government agency, an international regulatory body, or any corporation developing or marketing new or revised or alternative test methodologies, including contract laboratories.

(B) Nonvoting ex officio members

The membership of the SAC shall, in addition to voting members under subparagraph (A), include as nonvoting ex officio members the agency heads specified in subsection (c) (or their designees).

(e) Duties

The ICCVAM shall, consistent with the purposes described in subsection (b), carry out the following functions:

(1) Review and evaluate new or revised or alternative test methods, including batteries of tests and test screens, that may be acceptable for specific regulatory uses, including the coordination of technical reviews of proposed new or revised or alternative test methods of interagency interest.

(2) Facilitate appropriate interagency and international harmonization of acute or chronic toxicological test protocols that encourage the reduction, refinement, or replacement of animal test methods.

(3) Facilitate and provide guidance on the development of validation criteria, validation studies and processes for new or revised or alternative test methods and help facilitate the acceptance of such scientifically valid test methods and awareness of accepted test methods by Federal agencies and other stakeholders.

(4) Submit ICCVAM test recommendations for the test method reviewed by the ICCVAM, through expeditious transmittal by the Secretary of Health and Human Services (or the designee of the Secretary), to each appropriate Federal agency, along with the identification of specific agency guidelines, recommendations, or regulations for a test method, including batteries of tests and test screens, for chemicals or class of chemicals within a regulatory framework that may be appropriate for scientific improvement, while seeking to reduce, refine, or replace animal test methods.

(5) Consider for review and evaluation, petitions received from the public that—

(A) identify a specific regulation, recommendation, or guideline regarding a regulatory mandate; and

(B) recommend new or revised or alternative test methods and provide valid scientific evidence of the potential of the test method.

(6) Make available to the public final ICCVAM test recommendations to appropriate Federal agencies and the responses from the agencies regarding such recommendations.

(7) Prepare reports to be made available to the public on its progress under sections 285l–2 to 285l–5 of this title. The first report shall be completed not later than 12 months after December 19, 2000, and subsequent reports shall be completed biennially thereafter.

(Pub. L. 106–545, §3, Dec. 19, 2000, 114 Stat. 2721; Pub. L. 117–286, §4(a)(235), Dec. 27, 2022, 136 Stat. 4331.)

EDITORIAL NOTES

CODIFICATION

Section was enacted as part of the ICCVAM Authorization Act of 2000, and not as part of the Public Health Service Act which comprises this chapter.

AMENDMENTS

2022—Subsec. (d)(1). Pub. L. 117–286 substituted "chapter 10 of title 5." for "the Federal Advisory Committee Act."

STATUTORY NOTES AND RELATED SUBSIDIARIES

TERMINATION OF ADVISORY COMMITTEES

Advisory committees established after Jan. 5, 1973, to terminate not later than the expiration of the 2-year period beginning on the date of their establishment, unless, in the case of a committee established by the President or an officer of the Federal Government, such committee is renewed by appropriate action prior to the expiration of such 2-year period, or in the case of a committee established by the Congress, its duration is otherwise provided by law. See section 1013 of Title 5, Government Organization and Employees.

Pub. L. 93–641, §6, Jan. 4, 1975, 88 Stat. 2275, set out as a note under section 217a of this title, provided that an advisory committee established pursuant to the Public Health Service Act shall terminate at such time

as may be specifically prescribed by an Act of Congress enacted after Jan. 4, 1975.

§285*l*–4. Federal agency action

(a) Identification of tests

With respect to each Federal agency carrying out a program that requires or recommends acute or chronic toxicological testing, such agency shall, not later than 180 days after receiving an ICCVAM test recommendation, identify and forward to the ICCVAM any relevant test method specified in a regulation or industry-wide guideline which specifically, or in practice requires, recommends, or encourages the use of an animal acute or chronic toxicological test method for which the ICCVAM test recommendation may be added or substituted.

(b) Alternatives

Each Federal agency carrying out a program described in subsection (a) shall promote and encourage the development and use of alternatives to animal test methods (including batteries of tests and test screens), where appropriate, for the purpose of complying with Federal statutes, regulations, guidelines, or recommendations (in each instance, and for each chemical class) if such test methods are found to be effective for generating data, in an amount and of a scientific value that is at least equivalent to the data generated from existing tests, for hazard identification, dose-response assessment, or risk assessment purposes.

(c) Test method validation

Each Federal agency carrying out a program described in subsection (a) shall ensure that any new or revised acute or chronic toxicity test method, including animal test methods and alternatives, is determined to be valid for its proposed use prior to requiring, recommending, or encouraging the application of such test method.

(d) Review

Not later than 180 days after receipt of an ICCVAM test recommendation, a Federal agency carrying out a program described in subsection (a) shall review such recommendation and notify the ICCVAM in writing of its findings.

(e) Recommendation adoption

Each Federal agency carrying out a program described in subsection (a), or its specific regulatory unit or units, shall adopt the ICCVAM test recommendation unless such Federal agency determines that—

(1) the ICCVAM test recommendation is not adequate in terms of biological relevance for the regulatory goal authorized by that agency, or mandated by Congress;

(2) the ICCVAM test recommendation does not generate data, in an amount and of a scientific value that is at least equivalent to the data generated prior to such recommendation, for the appropriate hazard identification, dose-response assessment, or risk assessment purposes as the current test method recommended or required by that agency;

(3) the agency does not employ, recommend, or require testing for that class of chemical or for the recommended test endpoint; or

(4) the ICCVAM test recommendation is unacceptable for satisfactorily fulfilling the test needs for that particular agency and its respective congressional mandate.

(Pub. L. 106–545, §4, Dec. 19, 2000, 114 Stat. 2723.)

EDITORIAL NOTES

CODIFICATION

Section was enacted as part of the ICCVAM Authorization Act of 2000, and not as part of the Public Health Service Act which comprises this chapter.

§285*l*–5. Application

(a) Application

Sections 285l–2 to 285l–5 of this title shall not apply to research, including research performed using biotechnology techniques, or research related to the causes, diagnosis, treatment, control, or prevention of physical or mental diseases or impairments of humans or animals.

(b) Use of test methods

Nothing in sections 285l–2 to 285l–5 of this title shall prevent a Federal agency from retaining final authority for incorporating the test methods recommended by the ICCVAM in the manner determined to be appropriate by such Federal agency or regulatory body.

(c) Limitation

Nothing in sections 285l–2 to 285l–5 of this title shall be construed to require a manufacturer that is currently not required to perform animal testing to perform such tests. Nothing in sections 285l–2 to 285l–5 of this title shall be construed to require a manufacturer to perform redundant endpoint specific testing.

(d) Submission of tests and data

Nothing in sections 285l–2 to 285l–5 of this title precludes a party from submitting a test method or scientific data directly to a Federal agency for use in a regulatory program.

(Pub. L. 106–545, §5, Dec. 19, 2000, 114 Stat. 2724.)

EDITORIAL NOTES

CODIFICATION

Section was enacted as part of the ICCVAM Authorization Act of 2000, and not as part of the Public Health Service Act which comprises this chapter.

§285*l*–6. Methods of controlling certain insect and vermin populations

The Director of the Institute shall conduct or support research to identify or develop methods of controlling insect and vermin populations that transmit to humans diseases that have significant adverse health consequences.

(July 1, 1944, ch. 373, title IV, §463B, as added Pub. L. 108–75, §3, Aug. 15, 2003, 117 Stat. 902.)

SUBPART 13—NATIONAL INSTITUTE ON DEAFNESS AND OTHER COMMUNICATION DISORDERS

§285m. Purpose of Institute

The general purpose of the National Institute on Deafness and Other Communication Disorders (hereafter referred to in this subpart as the "Institute") is the conduct and support of research and training, the dissemination of health information, and other programs with respect to disorders of hearing and other communication processes, including diseases affecting hearing, balance, voice, speech, language, taste, and smell.

(July 1, 1944, ch. 373, title IV, §464, as added Pub. L. 100–553, §2(4), Oct. 28, 1988, 102 Stat. 2769, and Pub. L. 100–607, title I, §101(4), Nov. 4, 1988, 102 Stat. 3049; amended Pub. L. 100–690, title II, §2613(b)(2), Nov. 18, 1988, 102 Stat. 4238.)

EDITORIAL NOTES

CODIFICATION

Pub. L. 100–553 and Pub. L. 100–607 contained identical provisions enacting this section. See 1988 Amendment note below.

AMENDMENTS

1988—Pub. L. 100–690 amended this section to read as if the amendments made by Pub. L. 100–607, which enacted this section, had not been enacted. See Codification note above.

STATUTORY NOTES AND RELATED SUBSIDIARIES

SHORT TITLE OF 1988 AMENDMENT

For short title of Pub. L. 100–553 which enacted this subpart and amended sections 281 and 285j of this title as the "National Deafness and Other Communication Disorders Act of 1988", see section 1 of Pub. L. 100–553, set out as a note under section 201 of this title.

EFFECT OF ENACTMENT OF SIMILAR PROVISIONS

Pub. L. 100–690, title II, §2613(b), Nov. 18, 1988, 102 Stat. 4238, provided that:

"(1) Paragraphs (2) and (3) shall take effect immediately after the enactment of both the bill, S. 1727, of the One Hundredth Congress [Pub. L. 100–553, approved Oct. 28, 1988], and the Health Omnibus Programs Extension of 1988 [Pub. L. 100–607, approved Nov. 4, 1988].

"(2)(A) The provisions of the Public Health Service Act referred to in subparagraph (B), as similarly amended by the enactment of the bill, S. 1727, of the One Hundredth Congress, by subtitle A of title I of the Health Omnibus Programs Extension of 1988, and by subsection (a)(1) of this section, are amended to read as if the amendments made by such subtitle A and such subsection (a)(1) had not been enacted.

"(B) The provisions of the Public Health Service Act referred to in subparagraph (A) are—

"(A) sections 401(b)(1) and 457 [42 U.S.C. 281(b)(1), 285j];

"(B) part C of title IV [42 U.S.C. 285 et seq.]; and

"(C) the heading for subpart 10 of such part C [42 U.S.C. prec. 285j].

"(3) Subsection (a)(2) of this section [formerly set out below] is repealed."

TRANSITIONAL AND SAVINGS PROVISIONS

Pub. L. 100–553, §3, Oct. 28, 1988, 102 Stat. 2774, provided that:

"(a) TRANSFER OF PERSONNEL, ASSETS, AND LIABILITIES.—Personnel employed by the National Institutes of Health in connection with the functions vested under section 2 [enacting this subpart and amending sections 281 and 285j of this title] in the Director of the National Institute on Deafness and Other Communication Disorders, and assets, property, contracts, liabilities, records, unexpended balances of appropriations, authorizations, allocations, and other funds of the National Institutes of Health, arising from or employed, held, used, available to, or to be made available, in connection with such functions shall be transferred to the Director for appropriate allocation. Unexpended funds transferred under this subsection shall be used only for the purposes for which the funds were originally authorized and appropriated.

"(b) SAVINGS PROVISIONS.—With respect to functions vested under section 1 [probably means section 2, enacting this subpart and amending sections 281 and 285j of this title] in the Director of the National Institute on Deafness and Other Communication Disorders, all orders, rules, regulations, grants, contracts, certificates, licenses, privileges, and other determinations, actions, or official documents, that have been issued, made, granted, or allowed to become effective, and that are effective on the date of the enactment of this Act [Oct. 28, 1988], shall continue in effect according to their terms unless changed pursuant to law."

Pub. L. 100–690, title II, §2613(a)(2), Nov. 18, 1988, 102 Stat. 4238, which enacted provisions that were substantially identical to the transitional and savings provisions above, was repealed by section 2613(b)(3) of Pub. L. 100–690.

§285m–1. National Deafness and Other Communication Disorders Program

(a) The Director of the Institute, with the advice of the Institute's advisory council, shall establish a National Deafness and Other Communication Disorders Program (hereafter in this section referred to as the "Program"). The Director or [1] the Institute shall, with respect to the Program, prepare and

transmit to the Director of NIH a plan to initiate, expand, intensify and coordinate activities of the Institute respecting disorders of hearing (including tinnitus) and other communication processes, including diseases affecting hearing, balance, voice, speech, language, taste, and smell. The plan shall include such comments and recommendations as the Director of the Institute determines appropriate. The Director of the Institute shall periodically review and revise the plan and shall transmit any revisions of the plan to the Director of NIH.

(b) Activities under the Program shall include—

(1) investigation into the etiology, pathology, detection, treatment, and prevention of all forms of disorders of hearing and other communication processes, primarily through the support of basic research in such areas as anatomy, audiology, biochemistry, bioengineering, epidemiology, genetics, immunology, microbiology, molecular biology, the neurosciences, otolaryngology, psychology, pharmacology, physiology, speech and language pathology, and any other scientific disciplines that can contribute important knowledge to the understanding and elimination of disorders of hearing and other communication processes;

(2) research into the evaluation of techniques (including surgical, medical, and behavioral approaches) and devices (including hearing aids, implanted auditory and nonauditory prosthetic devices and other communication aids) used in diagnosis, treatment, rehabilitation, and prevention of disorders of hearing and other communication processes;

(3) research into prevention, and early detection and diagnosis, of hearing loss and speech and language disturbances (including stuttering) and research into preventing the effects of such disorders on learning and learning disabilities with extension of programs for appropriate referral and rehabilitation;

(4) research into the detection, treatment, and prevention of disorders of hearing and other communication processes in the growing elderly population with extension of rehabilitative programs to ensure continued effective communication skills in such population;

(5) research to expand knowledge of the effects of environmental agents that influence hearing or other communication processes; and

(6) developing and facilitating intramural programs on clinical and fundamental aspects of disorders of hearing and all other communication processes.

(July 1, 1944, ch. 373, title IV, §464A, as added Pub. L. 100–553, §2(4), Oct. 28, 1988, 102 Stat. 2769, and Pub. L. 100–607, title I, §101(4), Nov. 4, 1988, 102 Stat. 3049; amended Pub. L. 100–690, title II, §2613(b)(2), Nov. 18, 1988, 102 Stat. 4238.)

EDITORIAL NOTES

CODIFICATION

Pub. L. 100–553 and Pub. L. 100–607 contained identical provisions enacting this section. See 1988 Amendment note below.

AMENDMENTS

1988—Pub. L. 100–690 amended this section to read as if the amendments made by Pub. L. 100–607, which enacted this section, had not been enacted. See Codification note above.

STATUTORY NOTES AND RELATED SUBSIDIARIES

EFFECTIVE DATE OF 1988 AMENDMENT

For effective date of amendment by Pub. L. 100–690, see section 2613(b)(1) of Pub. L. 100–690, set out as an Effect of Enactment of Similar Provisions note under section 285m of this title.

[1] So in original. Probably should be "of".

§285m–2. Data System and Information Clearinghouse

(a) The Director of the Institute shall establish a National Deafness and Other Communication Disorders Data System for the collection, storage, analysis, retrieval, and dissemination of data derived from patient populations with disorders of hearing or other communication processes, including where possible, data involving general populations for the purpose of identifying individuals at risk of developing such disorders.

(b) The Director of the Institute shall establish a National Deafness and Other Communication Disorders Information Clearinghouse to facilitate and enhance, through the effective dissemination of information, knowledge and understanding of disorders of hearing and other communication processes by health professionals, patients, industry, and the public.

(July 1, 1944, ch. 373, title IV, §464B, as added Pub. L. 100–553, §2(4), Oct. 28, 1988, 102 Stat. 2770, and Pub. L. 100–607, title I, §101(4), Nov. 4, 1988, 102 Stat. 3050; amended Pub. L. 100–690, title II, §2613(b)(2), Nov. 18, 1988, 102 Stat. 4238.)

EDITORIAL NOTES

CODIFICATION

Pub. L. 100–553 and Pub. L. 100–607 contained identical provisions enacting this section. See 1988 Amendment note below.

AMENDMENTS

1988—Pub. L. 100–690 amended this section to read as if the amendments made by Pub. L. 100–607, which enacted this section, had not been enacted. See Codification note above.

STATUTORY NOTES AND RELATED SUBSIDIARIES

EFFECTIVE DATE OF 1988 AMENDMENT

For effective date of amendment by Pub. L. 100–690, see section 2613(b)(1) of Pub. L. 100–690, set out as an Effect of Enactment of Similar Provisions note under section 285m of this title.

§285m–3. Multipurpose deafness and other communication disorders center

(a) Development, modernization and operation; "modernization" defined

The Director of the Institute shall, after consultation with the advisory council for the Institute, provide for the development, modernization, and operation (including care required for research) of new and existing centers for studies of disorders of hearing and other communication processes. For purposes of this section, the term "modernization" means the alteration, remodeling, improvement, expansion, and repair of existing buildings and the provision of equipment for such buildings to the extent necessary to make them suitable for use as centers described in the preceding sentence.

(b) Use of facilities; qualifications

Each center assisted under this section shall—

(1) use the facilities of a single institution or a consortium of cooperating institutions; and

(2) meet such qualifications as may be prescribed by the Secretary.

(c) Requisite programs

Each center assisted under this section shall, at least, conduct—

(1) basic and clinical research into the cause [1] diagnosis, early detection, prevention, control and treatment of disorders of hearing and other communication processes and complications resulting from such disorders, including research into rehabilitative aids, implantable biomaterials, auditory speech processors, speech production devices, and other otolaryngologic procedures;

(2) training programs for physicians, scientists, and other health and allied health professionals;

(3) information and continuing education programs for physicians and other health and allied health professionals who will provide care for patients with disorders of hearing or other

communication processes; and

(4) programs for the dissemination to the general public of information—

(A) on the importance of early detection of disorders of hearing and other communication processes, of seeking prompt treatment, rehabilitation, and of following an appropriate regimen; and

(B) on the importance of avoiding exposure to noise and other environmental toxic agents that may affect disorders of hearing or other communication processes.

(d) Stipends

A center may use funds provided under subsection (a) to provide stipends for health professionals enrolled in training programs described in subsection (c)(2).

(e) Discretionary programs

Each center assisted under this section may conduct programs—

(1) to establish the effectiveness of new and improved methods of detection, referral, and diagnosis of individuals at risk of developing disorders of hearing or other communication processes; and

(2) to disseminate the results of research, screening, and other activities, and develop means of standardizing patient data and recordkeeping.

(f) Equitable geographical distribution; needs of elderly and children

The Director of the Institute shall, to the extent practicable, provide for an equitable geographical distribution of centers assisted under this section. The Director shall give appropriate consideration to the need for centers especially suited to meeting the needs of the elderly, and of children (particularly with respect to their education and training), affected by disorders of hearing or other communication processes.

(g) Period of support; recommended extensions of peer review group

Support of a center under this section may be for a period not to exceed seven years. Such period may be extended by the Director of the Institute for one or more additional periods of not more than five years if the operations of such center have been reviewed by an appropriate technical and scientific peer review group established by the Director, with the advice of the Institute's advisory council, if such group has recommended to the Director that such period should be extended.

(July 1, 1944, ch. 373, title IV, §464C, as added Pub. L. 100–553, §2(4), Oct. 28, 1988, 102 Stat. 2771, and Pub. L. 100–607, title I, §101(4), Nov. 4, 1988, 102 Stat. 3050; amended Pub. L. 100–690, title II, §2613(b)(2), Nov. 18, 1988, 102 Stat. 4238.)

EDITORIAL NOTES

CODIFICATION

Pub. L. 100–553 and Pub. L. 100–607 contained identical provisions enacting this section. See 1988 Amendment note below.

AMENDMENTS

1988—Pub. L. 100–690 amended this section to read as if the amendments made by Pub. L. 100–607, which enacted this section, had not been enacted. See Codification note above.

STATUTORY NOTES AND RELATED SUBSIDIARIES

EFFECTIVE DATE OF 1988 AMENDMENT

For effective date of amendment by Pub. L. 100–690, see section 2613(b)(1) of Pub. L. 100–690, set out as an Effect of Enactment of Similar Provisions note under section 285m of this title.

[1] *So in original. Probably should be followed by a comma.*

§285m–4. National Institute on Deafness and Other Communication Disorders Advisory Board

(a) Establishment

The Secretary shall establish in the Institute the National Deafness and Other Communication Disorders Advisory Board (hereafter in this section referred to as the "Advisory Board").

(b) Composition; qualifications; appointed and ex officio members

The Advisory Board shall be composed of eighteen appointed members and nonvoting ex officio members as follows:

(1) The Secretary shall appoint—

(A) twelve members from individuals who are scientists, physicians, and other health and rehabilitation professionals, who are not officers or employees of the United States, and who represent the specialties and disciplines relevant to deafness and other communication disorders, including not less than two persons with a communication disorder; and

(B) six members from the general public who are knowledgeable with respect to such disorders, including not less than one person with a communication disorder and not less than one person who is a parent of an individual with such a disorder.

Of the appointed members, not less than five shall by virtue of training or experience be knowledgeable in diagnoses and rehabilitation of communication disorders, education of the hearing, speech, or language impaired, public health, public information, community program development, occupational hazards to communications senses, or the aging process.

(2) The following shall be ex officio members of each Advisory Board:

(A) The Assistant Secretary for Health, the Director of NIH, the Director of the National Institute on Deafness and Other Communication Disorders, the Director of the Centers for Disease Control and Prevention, the Under Secretary for Health of the Department of Veterans Affairs, and the Assistant Secretary of Defense for Health Affairs (or the designees of such officers).

(B) Such other officers and employees of the United States as the Secretary determines necessary for the Advisory Board to carry out its functions.

(c) Compensation

Members of an Advisory Board who are officers or employees of the Federal Government shall serve as members of the Advisory Board without compensation in addition to that received in their regular public employment. Other members of the Board shall receive compensation at rates not to exceed the daily equivalent of the annual rate in effect for grade GS–18 of the General Schedule for each day (including traveltime) they are engaged in the performance of their duties as members of the Board.

(d) Term of office; vacancies

The term of office of an appointed member of the Advisory Board is four years, except that no term of office may extend beyond the expiration of the Advisory Board. Any member appointed to fill a vacancy for an unexpired term shall be appointed for the remainder of such term. A member may serve after the expiration of the member's term until a successor has taken office. If a vacancy occurs in the Advisory Board, the Secretary shall make an appointment to fill the vacancy not later than 90 days from the date the vacancy occurred.

(e) Chairman

The members of the Advisory Board shall select a chairman from among the appointed members.

(f) Personnel; executive director; professional and clerical staff members; consultants; information and administrative support services and facilities

The Secretary shall, after consultation with and consideration of the recommendations of the

Advisory Board, provide the Advisory Board with an executive director and one other professional staff member. In addition, the Secretary shall, after consultation with and consideration of the recommendations of the Advisory Board, provide the Advisory Board with such additional professional staff members, such clerical staff members, such services of consultants, such information, and (through contracts or other arrangements) such administrative support services and facilities, as the Secretary determines are necessary for the Advisory Board to carry out its functions.

(g) Meetings

The Advisory Board shall meet at the call of the chairman or upon request of the Director of the Institute, but not less often than four times a year.

(h) Functions

The Advisory Board shall—

(1) review and evaluate the implementation of the plan prepared under section 285m–1(a) of this title and periodically update the plan to ensure its continuing relevance;

(2) for the purpose of assuring the most effective use and organization of resources respecting deafness and other communication disorders, advise and make recommendations to the Congress, the Secretary, the Director of NIH, the Director of the Institute, and the heads of other appropriate Federal agencies for the implementation and revision of such plan; and

(3) maintain liaison with other advisory bodies related to Federal agencies involved in the implementation of such plan and with key non-Federal entities involved in activities affecting the control of such disorders.

(i) Subcommittee activities; workshops and conferences; collection of data

In carrying out its functions, the Advisory Board may establish subcommittees, convene workshops and conferences, and collect data. Such subcommittees may be composed of Advisory Board members and nonmember consultants with expertise in the particular area addressed by such subcommittees. The subcommittees may hold such meetings as are necessary to enable them to carry out their activities.

(j) Repealed. Pub. L. 109–482, title I, §104(b)(1)(J), Jan. 15, 2007, 120 Stat. 3693

(k) Commencement of existence

The National Deafness and Other Communication Disorders Advisory Board shall be established not later than April 1, 1989.

(July 1, 1944, ch. 373, title IV, §464D, as added Pub. L. 100–553, §2(4), Oct. 28, 1988, 102 Stat. 2772, and Pub. L. 100–690, title II, §2613(a)(1), Nov. 18, 1988, 102 Stat. 4235; amended Pub. L. 100–690, title II, §2613(b)(2), Nov. 18, 1988, 102 Stat. 4238; Pub. L. 101–93, §5(b), Aug. 16, 1989, 103 Stat. 611; Pub. L. 102–405, title III, §302(e)(1), Oct. 9, 1992, 106 Stat. 1985; Pub. L. 102–531, title III, §312(d)(8), Oct. 27, 1992, 106 Stat. 3504; Pub. L. 103–43, title XX, §2008(b)(8), June 10, 1993, 107 Stat. 211; Pub. L. 109–482, title I, §104(b)(1)(J), Jan. 15, 2007, 120 Stat. 3693.)

EDITORIAL NOTES

CODIFICATION

Pub. L. 100–553 and section 2613(a)(1) of Pub. L. 100–690 contained identical provisions enacting this section. See 1988 Amendment note below.

AMENDMENTS

2007—Subsec. (j). Pub. L. 109–482 struck out subsec. (j) which read as follows: "The Advisory Board shall prepare an annual report for the Secretary which—

"(1) describes the Advisory Board's activities in the fiscal year for which the report is made;

"(2) describes and evaluates the progress made in such fiscal year in research, treatment, education, and training with respect to the deafness and other communication disorders;

"(3) summarizes and analyzes expenditures made by the Federal Government for activities respecting such disorders in such fiscal year; and

"(4) contains the Advisory Board's recommendations (if any) for changes in the plan prepared under section 285m–1(a) of this title."

1993—Subsec. (b)(2)(A). Pub. L. 103–43 substituted "Department of Veterans Affairs" for "Veterans' Administration".

1992—Subsec. (b)(2)(A). Pub. L. 102–531 substituted "Centers for Disease Control and Prevention" for "Centers for Disease Control".

Pub. L. 102–405 substituted "Under Secretary for Health" for "Chief Medical Director".

1989—Subsec. (k). Pub. L. 101–93 substituted "April 1, 1989" for "90 days after the date of the enactment of the National Institute on Deafness and Other Communication Disorders Act".

1988—Pub. L. 100–690, §2613(b)(2), amended this section to read as if the amendments made by Pub. L. 100–690, §2613(a)(1), which enacted this section, had not been enacted. See Codification note above.

STATUTORY NOTES AND RELATED SUBSIDIARIES

EFFECTIVE DATE OF 2007 AMENDMENT

Amendment by Pub. L. 109–482 applicable only with respect to amounts appropriated for fiscal year 2007 or subsequent fiscal years, see section 109 of Pub. L. 109–482, set out as a note under section 281 of this title.

EFFECTIVE DATE OF 1988 AMENDMENT

For effective date of amendment by section 2613(b)(2) of Pub. L. 100–690, see section 2613(b)(1) of Pub. L. 100–690, set out as an Effect of Enactment of Similar Provisions note under section 285m of this title.

TERMINATION OF ADVISORY BOARDS

Advisory boards established after Jan. 5, 1973, to terminate not later than the expiration of the 2-year period beginning on the date of their establishment, unless, in the case of a board established by the President or an officer of the Federal Government, such board is renewed by appropriate action prior to the expiration of such 2-year period, or in the case of a board established by the Congress, its duration is otherwise provided by law. See sections 1001(2) and 1013 of Title 5, Government Organization and Employees.

Pub. L. 93–641, §6, Jan. 4, 1975, 88 Stat. 2275, set out as a note under section 217a of this title, provided that an advisory committee established pursuant to the Public Health Service Act shall terminate at such time as may be specifically prescribed by an Act of Congress enacted after Jan. 4, 1975.

REFERENCES IN OTHER LAWS TO GS–16, 17, OR 18 PAY RATES

References in laws to the rates of pay for GS–16, 17, or 18, or to maximum rates of pay under the General Schedule, to be considered references to rates payable under specified sections of Title 5, Government Organization and Employees, see section 529 [title I, §101(c)(1)] of Pub. L. 101–509, set out in a note under section 5376 of Title 5.

§285m–5. Interagency Coordinating Committee

(a) Establishment

The Secretary may establish a committee to be known as the Deafness and Other Communication Disorders Interagency Coordinating Committee (hereafter in this section referred to as the "Coordinating Committee").

(b) Functions

The Coordinating Committee shall, with respect to deafness and other communication disorders—

(1) provide for the coordination of the activities of the national research institutes; and

(2) coordinate the aspects of all Federal health programs and activities relating to deafness and other communication disorders in order to assure the adequacy and technical soundness of such programs and activities and in order to provide for the full communication and exchange of information necessary to maintain adequate coordination of such programs and activities.

(c) Composition

The Coordinating Committee shall be composed of the directors of each of the national research institutes and divisions involved in research with respect to deafness and other communication

disorders and representatives of all other Federal departments and agencies whose programs involve health functions or responsibilities relevant to deafness and other communication disorders.

(d) Chairman; meetings

The Coordinating Committee shall be chaired by the Director of NIH (or the designee of the Director). The Committee shall meet at the call of the chair, but not less often than four times a year.

(July 1, 1944, ch. 373, title IV, §464E, as added Pub. L. 100–553, §2(4), Oct. 28, 1988, 102 Stat. 2774, and Pub. L. 100–690, title II, §2613(a)(1), Nov. 18, 1988, 102 Stat. 4237; amended Pub. L. 100–690, title II, §2613(b)(2), Nov. 18, 1988, 102 Stat. 4238; Pub. L. 103–43, title XX, §2008(b)(9), June 10, 1993, 107 Stat. 211; Pub. L. 109–482, title I, §104(b)(1)(K), Jan. 15, 2007, 120 Stat. 3693.)

EDITORIAL NOTES

CODIFICATION

Pub. L. 100–553 and section 2613(a)(1) of Pub. L. 100–690 contained identical provisions enacting this section. See 1988 Amendment note below.

AMENDMENTS

2007—Subsec. (e). Pub. L. 109–482 struck out subsec. (e) which read as follows: "Not later than 120 days after the end of each fiscal year, the Coordinating Committee shall prepare and transmit to the Secretary, the Director of NIH, the Director of the Institute, and the advisory council for the Institute a report detailing the activities of the Committee in such fiscal year in carrying out subsection (b) of this section."

1993—Subsecs. (d), (e). Pub. L. 103–43 inserted "Coordinating" before "Committee" in first sentence of subsec. (d) and before first reference to "Committee" in subsec. (e).

1988—Pub. L. 100–690, §2613(b)(2), amended this section to read as if the amendments made by Pub. L. 100–690, §2613(a)(1), which enacted this section, had not been enacted. See Codification note above.

STATUTORY NOTES AND RELATED SUBSIDIARIES

EFFECTIVE DATE OF 2007 AMENDMENT

Amendment by Pub. L. 109–482 applicable only with respect to amounts appropriated for fiscal year 2007 or subsequent fiscal years, see section 109 of Pub. L. 109–482, set out as a note under section 281 of this title.

EFFECTIVE DATE OF 1988 AMENDMENT

For effective date of amendment by section 2613(b)(2) of Pub. L. 100–690, see section 2613(b)(1) of Pub. L. 100–690, set out as an Effect of Enactment of Similar Provisions note under section 285m of this title.

§285m–6. Limitation on administrative expenses

With respect to amounts appropriated for a fiscal year for the National Institutes of Health, the limitation established in section 284c(a)(1) of this title on the expenditure of such amounts for administrative expenses shall apply to administrative expenses of the National Institute on Deafness and Other Communication Disorders.

(July 1, 1944, ch. 373, title IV, §464F, as added Pub. L. 100–553, §2(4), Oct. 28, 1988, 102 Stat. 2774, and Pub. L. 100–690, title II, §2613(a)(1), Nov. 18, 1988, 102 Stat. 4238; amended Pub. L. 100–690, title II, §2613(b)(2), Nov. 18, 1988, 102 Stat. 4238; Pub. L. 103–43, title IV, §403(b)(2), June 10, 1993, 107 Stat. 158.)

EDITORIAL NOTES

CODIFICATION

Pub. L. 100–553 and section 2613(a)(1) of Pub. L. 100–690 contained identical provisions enacting this section. See 1988 Amendment note below.

AMENDMENTS

1993—Pub. L. 103–43 substituted "section 284c(a)(1)" for "section 284c(b)(1)".

1988—Pub. L. 100–690, §2613(b)(2), amended this section to read as if the amendments made by Pub. L. 100–690, §2613(a)(1), which enacted this section, had not been enacted. See Codification note above.

STATUTORY NOTES AND RELATED SUBSIDIARIES

EFFECTIVE DATE OF 1988 AMENDMENT

For effective date of amendment by section 2613(b)(2) of Pub. L. 100–690, see section 2613(b)(1) of Pub. L. 100–690, set out as an Effect of Enactment of Similar Provisions note under section 285m of this title.

SUBPART 14—NATIONAL INSTITUTE ON ALCOHOL ABUSE AND ALCOHOLISM

§285n. Purpose of Institute

(a) In general

The general purpose of the National Institute on Alcohol Abuse and Alcoholism (hereafter in this subpart referred to as the "Institute") is the conduct and support of biomedical and behavioral research, health services research, research training, and health information dissemination with respect to the prevention of alcohol abuse and the treatment of alcoholism.

(b) Research program

The research program established under this subpart shall encompass the social, behavioral, and biomedical etiology, mental and physical health consequences, and social and economic consequences of alcohol abuse and alcoholism. In carrying out the program, the Director of the Institute is authorized to—

(1) collect and disseminate through publications and other appropriate means (including the development of curriculum materials), information as to, and the practical application of, the research and other activities under the program;

(2) make available research facilities of the Public Health Service to appropriate public authorities, and to health officials and scientists engaged in special study;

(3) make grants to universities, hospitals, laboratories, and other public or nonprofit institutions, and to individuals for such research projects as are recommended by the National Advisory Council on Alcohol Abuse and Alcoholism, giving special consideration to projects relating to—

(A) the relationship between alcohol abuse and domestic violence,

(B) the effects of alcohol use during pregnancy,

(C) the impact of alcoholism and alcohol abuse on the family, the workplace, and systems for the delivery of health services,

(D) the relationship between the abuse of alcohol and other drugs,

(E) the effect on the incidence of alcohol abuse and alcoholism of social pressures, legal requirements respecting the use of alcoholic beverages, the cost of such beverages, and the economic status and education of users of such beverages,

(F) the interrelationship between alcohol use and other health problems,

(G) the comparison of the cost and effectiveness of various treatment methods for alcoholism and alcohol abuse and the effectiveness of prevention and intervention programs for alcoholism and alcohol abuse,

(H) alcoholism and alcohol abuse among women;

(4) secure from time to time and for such periods as he deems advisable, the assistance and advice of experts, scholars, and consultants from the United States or abroad;

(5) promote the coordination of research programs conducted by the Institute, and similar programs conducted by the National Institute of Drug Abuse and by other departments, agencies, organizations, and individuals, including all National Institutes of Health research activities which are or may be related to the problems of individuals suffering from alcoholism or alcohol abuse or those of their families or the impact of alcohol abuse on other health problems;

(6) conduct an intramural program of biomedical, behavioral, epidemiological, and social research, including research into the most effective means of treatment and service delivery, and including research involving human subjects, which is—

(A) located in an institution capable of providing all necessary medical care for such human subjects, including complete 24-hour medical diagnostic services by or under the supervision of physicians, acute and intensive medical care, including 24-hour emergency care, psychiatric care, and such other care as is determined to be necessary for individuals suffering from alcoholism and alcohol abuse; and

(B) associated with an accredited medical or research training institution;

(7) for purposes of study, admit and treat at institutions, hospitals, and stations of the Public Health Service, persons not otherwise eligible for such treatment;

(8) provide to health officials, scientists, and appropriate public and other nonprofit institutions and organizations, technical advice and assistance on the application of statistical and other scientific research methods to experiments, studies, and surveys in health and medical fields;

(9) enter into contracts under this subchapter without regard to section 3324(a) and (b) of title 31 and section 6101 of title 41; and

(10) adopt, upon recommendation of the National Advisory Council on Alcohol Abuse and Alcoholism, such additional means as he deems necessary or appropriate to carry out the purposes of this section.

(c) Collaboration

The Director of the Institute shall collaborate with the Administrator of the Substance Abuse and Mental Health Services Administration in focusing the services research activities of the Institute and in disseminating the results of such research to health professionals and the general public.

(July 1, 1944, ch. 373, title IV, §464H, as added and amended Pub. L. 102–321, title I, §122(a), (b), July 10, 1992, 106 Stat. 358, 359; Pub. L. 102–352, §2(a)(1), Aug. 26, 1992, 106 Stat. 938; Pub. L. 109–482, title I, §103(b)(32), Jan. 15, 2007, 120 Stat. 3688.)

EDITORIAL NOTES

CODIFICATION

Section 290bb(b) of this title, which was transferred to subsec. (b) of this section and amended by Pub. L. 102–321, was based on act July 1, 1944, ch. 373, title V, §510, formerly Pub. L. 91–616, title V, §501(b), as added Pub. L. 94–371, §7, July 26, 1976, 90 Stat. 1038; amended Pub. L. 95–622, title II, §268(d), Nov. 9, 1978, 92 Stat. 3437; Pub. L. 96–180, §14(b), Jan. 2, 1980, 93 Stat. 1305; renumbered §510(b) of act July 1, 1944, and amended Apr. 26, 1983, Pub. L. 98–24, §2(b)(9), 97 Stat. 179; Oct. 19, 1984, Pub. L. 98–509, title II, §205(a)(1), 98 Stat. 2361.

In subsec. (b)(9), "section 3324(a) and (b) of title 31 and section 6101 of title 41" substituted for "sections 3648 and 3709 of the Revised Statutes (31 U.S.C. 529; 41 U.S.C. 5)" on authority of Pub. L. 97–258, §4(b), Sept. 13, 1982, 96 Stat. 1067, which Act enacted Title 31, Money and Finance, and Pub. L. 111–350, §6(c), Jan. 4, 2011, 124 Stat. 3854, which Act enacted Title 41, Public Contracts.

AMENDMENTS

2007—Subsec. (d). Pub. L. 109–482 struck out subsec. (d) which related to authorization of appropriations and allocation for health services research.

1992—Subsec. (a). Pub. L. 102–352 substituted "Institute on Alcohol" for "Institute of Alcohol".

Subsec. (b). Pub. L. 102–321, §122(b)(1), (2)(A), transferred subsec. (b) of section 290bb of this title to subsec. (b) of this section, substituted "(b) RESEARCH PROGRAM.—The research program established under this subpart shall encompass the social, behavioral, and biomedical etiology, mental and physical health

consequences, and social and economic consequences of alcohol abuse and alcoholism. In carrying out the program, the Director of the Institute is authorized" for "(b) In carrying out the program described in subsection (a) of this section, the Secretary, acting through the Institute, is authorized" in introductory provisions, and substituted a semicolon for period at end of par. (3)(H).

Subsecs. (c), (d). Pub. L. 102–321, §122(b)(2)(B), added subsecs. (c) and (d).

STATUTORY NOTES AND RELATED SUBSIDIARIES

EFFECTIVE DATE OF 2007 AMENDMENT

Amendment by Pub. L. 109–482 applicable only with respect to amounts appropriated for fiscal year 2007 or subsequent fiscal years, see section 109 of Pub. L. 109–482, set out as a note under section 281 of this title.

EFFECTIVE DATE OF 1992 AMENDMENT

Pub. L. 102–352, §3, Aug. 26, 1992, 106 Stat. 940, provided that: "The amendments made by—

"(1) subsection (a) of section 2 [amending this section and sections 285n–2, 285o, 285o–2, 285p, 290aa–1, 290aa–3, 300x–7, 300x–27, 300x–33, 300x–53, and 300y of this title], shall take effect immediately upon the effectuation of the amendments made by titles I and II of the ADAMHA Reorganization Act [Pub. L. 102–321, see Effective Date of 1992 Amendment note set out under section 236 of this title]; and

"(2) subsections (b) and (c) of section 2 [amending sections 290cc–21, 290cc–28, and 290cc–30 of this title and provisions set out as notes under sections 290aa and 300x of this title], shall take effect on the date of enactment of this Act [Aug. 26, 1992]."

EFFECTIVE DATE

Section effective Oct. 1, 1992, with provision for programs providing financial assistance, see section 801(c), (d) of Pub. L. 102–321, set out as an Effective Date of 1992 Amendment note under section 236 of this title.

REQUIRED ALLOCATIONS FOR HEALTH SERVICES RESEARCH

Pub. L. 103–43, title XX, §2016(b), June 10, 1993, 107 Stat. 218, provided that, with respect to the allocation for health services research required in former subsec. (d)(2) of this section and former sections 285o(d)(2) and 285p(f)(2) of this title, the term "15 percent" appearing in each of such provisions was deemed to be 12 percent in the case of allocations for fiscal year 1993.

STUDY ON FETAL ALCOHOL EFFECT AND FETAL ALCOHOL SYNDROME

Pub. L. 102–321, title VII, §705, July 10, 1992, 106 Stat. 438, directed Secretary of Health and Human Services to enter into a contract with a public or nonprofit private entity to conduct a study on the prevalence of fetal alcohol effect and fetal alcohol syndrome in the general population of the United States and on the adequacy of Federal efforts to reduce the incidence of such conditions (including efforts regarding appropriate training for health care providers in identifying such effect or syndrome), and to ensure that a report outlining this study be submitted to Congress not later than 18 months after July 10, 1992.

ALCOHOLISM AND ALCOHOL ABUSE TREATMENT STUDY

Pub. L. 99–570, title IV, §4022, Oct. 27, 1986, 100 Stat. 3207–124, directed Secretary of Health and Human Services, acting through Director of National Institute on Alcohol Abuse and Alcoholism, to conduct a study of alternative approaches for alcoholism and alcohol abuse treatment and rehabilitation and of financing alternatives including policies and experiences of third party insurers and State and municipal governments; to recommend policies and programs for research, planning, administration, and reimbursement for treatment and rehabilitation; to request National Academy of Sciences to conduct such study in consultation with Director of National Institute on Alcohol Abuse and Alcoholism under an arrangement entered into with consent of Academy that actual expenses of Academy will be paid by Secretary and that Academy would submit a final report to Secretary no later than 24 months after the arrangement was entered into; and to transmit a final report to Congress no later than 30 days after receiving Academy's report.

§285n–1. Associate Director for Prevention

(a) In general

There shall be in the Institute an Associate Director for Prevention who shall be responsible for the full-time coordination and promotion of the programs in the Institute concerning the prevention of alcohol abuse and alcoholism. The Associate Director shall be appointed by the Director of the Institute from individuals who because of their professional training or expertise are experts in alcohol abuse and alcoholism or the prevention of such.

(b) Biennial report

The Associate Director for Prevention shall prepare for inclusion in the biennial report made under section 284b [1] of this title a description of the prevention activities of the Institute, including a description of the staff and resources allocated to those activities.

(July 1, 1944, ch. 373, title IV, §464I, as added Pub. L. 102–321, title I, §122(c), July 10, 1992, 106 Stat. 359.)

EDITORIAL NOTES

REFERENCES IN TEXT

Section 284b of this title, referred to in subsec. (b), was repealed by Pub. L. 109–482, title I, §104(b)(1)(C), Jan. 15, 2007, 120 Stat. 3693.

STATUTORY NOTES AND RELATED SUBSIDIARIES

EFFECTIVE DATE

Section effective Oct. 1, 1992, with provision for programs providing financial assistance, see section 801(c), (d) of Pub. L. 102–321, set out as an Effective Date of 1992 Amendment note under section 236 of this title.

[1] *See References in Text note below.*

§285n–2. National Alcohol Research Centers; mandatory grant for research of effects of alcohol on elderly

(a) Designation; procedures applicable for approval of applications

The Secretary acting through the Institute may designate National Alcohol Research Centers for the purpose of interdisciplinary research relating to alcoholism and other biomedical, behavioral, and social issues related to alcoholism and alcohol abuse. No entity may be designated as a Center unless an application therefor has been submitted to, and approved by, the Secretary. Such an application shall be submitted in such manner and contain such information as the Secretary may reasonably require. The Secretary may not approve such an application unless—

(1) the application contains or is supported by reasonable assurances that—

(A) the applicant has the experience, or capability, to conduct, through biomedical, behavioral, social, and related disciplines, long-term research on alcoholism and other alcohol problems and to provide coordination of such research among such disciplines;

(B) the applicant has available to it sufficient facilities (including laboratory, reference, and data analysis facilities) to carry out the research plan contained in the application;

(C) the applicant has facilities and personnel to provide training in the prevention and treatment of alcoholism and other alcohol problems;

(D) the applicant has the capacity to train predoctoral and postdoctoral students for careers in research on alcoholism and other alcohol problems;

(E) the applicant has the capacity to conduct courses on alcohol problems and research on alcohol problems for undergraduate and graduate students, and for medical and osteopathic, nursing, social work, and other specialized graduate students; and

(F) the applicant has the capacity to conduct programs of continuing education in such

medical, legal, and social service fields as the Secretary may require.[1]

(2) the application contains a detailed five-year plan for research relating to alcoholism and other alcohol problems.

(b) Annual grants; amount; limitation on uses

The Secretary shall, under such conditions as the Secretary may reasonably require, make annual grants to Centers which have been designated under this section. No funds provided under a grant under this subsection may be used for the purchase of any land or the purchase, construction, preservation, or repair of any building. For the purposes of the preceding sentence, the term "construction" has the meaning given that term by section 292a(1) [2] of this title. The Secretary shall include in the grants made under this section for fiscal years beginning after September 30, 1981, a grant to a designated Center for research on the effects of alcohol on the elderly.

(July 1, 1944, ch. 373, title IV, §464J, formerly title V, §511, formerly Pub. L. 91–616, title V, §503, formerly §504, as added Pub. L. 94–371, §7, July 26, 1976, 90 Stat. 1039; amended Pub. L. 95–622, title I, §110(d), Nov. 9, 1978, 92 Stat. 3420; Pub. L. 96–180, §16, Jan. 2, 1980, 93 Stat. 1305; renumbered §503 of Pub. L. 91–616 and amended Pub. L. 97–35, title IX, §965(b), (c), Aug. 13, 1981, 95 Stat. 594; renumbered §511 of act July 1, 1944, and amended Pub. L. 98–24, §2(b)(9), Apr. 26, 1983, 97 Stat. 179; Pub. L. 99–570, title IV, §4008, Oct. 27, 1986, 100 Stat. 3207–115; renumbered title IV, §464J and amended Pub. L. 102–321, title I, §122(d), July 10, 1992, 106 Stat. 360; Pub. L. 102–352, §2(a)(2), Aug. 26, 1992, 106 Stat. 938.)

EDITORIAL NOTES

REFERENCES IN TEXT

Section 292a of this title, referred to in subsec. (b), was in the original a reference to section 701 of act July 1, 1944. Section 701 of that Act was omitted in the general revision of subchapter V of this chapter by Pub. L. 102–408, title I, §102, Oct. 13, 1992, 106 Stat. 1994. Pub. L. 102–408 enacted a new section 701 of act July 1, 1944, relating to statement of purpose, and a new section 702, relating to scope and duration of loan insurance program, which are classified to sections 292 and 292a, respectively, of this title. For provisions relating to definitions, see sections 292o and 295p of this title.

CODIFICATION

Section was formerly classified to section 290bb–1 of this title prior to renumbering by Pub. L. 102–321.
Section was formerly classified to section 4587 of this title prior to renumbering by Pub. L. 98–24.
Section was formerly classified to section 4588 of this title prior to renumbering by Pub. L. 97–35.

AMENDMENTS

1992—Subsec. (b). Pub. L. 102–352 substituted "292a(1)" for "292a(2)".

Pub. L. 102–321, §122(d)(2), struck "or rental" before "of any land".

1986—Subsec. (b). Pub. L. 99–570, §4008(1), which directed that subsec. (b) be amended by striking out "or rental" before "any land", could not be executed because "or rental" appeared before "of any land".

Pub. L. 99–570, §4008(2), struck out "rental," before "purchase".

1983—Subsec. (a). Pub. L. 98–24, §2(b)(9)(B)(i), struck out direction that, insofar as practicable, the Secretary approve applications under this subsection in a manner resulting in an equitable geographic distribution of Centers.

Subsec. (b). Pub. L. 98–24, §2(b)(9)(B)(ii), (iii), struck out provision that no annual grant to any Center might exceed $1,500,000, and made a technical amendment to reference to section 292a of this title to reflect the transfer of this section to the Public Health Service Act.

Subsec. (c). Pub. L. 98–24, §2(b)(9)(B)(iv), struck out subsec. (c) which authorized $6,000,000 for each of fiscal years ending Sept. 30, 1977, 1978, and 1979, $8,000,000 for fiscal year ending Sept. 30, 1980, and $9,000,000 for fiscal year ending Sept. 30, 1981.

1981—Subsec. (b). Pub. L. 97–35, §965(b), inserted provisions relating to grants made for fiscal years beginning after Sept. 30, 1981.

1980—Subsec. (a). Pub. L. 96–180, §16(a), substituted: in first sentence "biomedical, behavioral, and social issues related to alcoholism and alcohol abuse" for "alcohol problems"; in par. (1)(B) "facilities (including

laboratory, reference, and data analysis facilities) to carry out the research plan contained in the application" for "laboratory facilities and reference services (including reference services that will afford access to scientific alcohol literature)"; and in par. (1)(E) "medical and osteopathic, nursing, social work, and other specialized graduate students; and" for "medical and osteopathic students and physicians;", and added par. (1)(F).

Subsec. (b). Pub. L. 96–180, §16(b), increased annual grant limitation to $1,500,000 from $1,000,000.

Subsec. (c). Pub. L. 96–180, §16(c), authorized appropriation of $8,000,000 and $9,000,000 for fiscal years ending Sept. 30, 1980, and 1981.

1978—Subsec. (a). Pub. L. 95–622 inserted provision following par. (2) relating to approval of applications under this subsection by the Secretary in a manner which results in equitable geographic distribution of Centers.

STATUTORY NOTES AND RELATED SUBSIDIARIES

EFFECTIVE DATE OF 1992 AMENDMENTS

Amendment by Pub. L. 102–352 effective immediately upon effectuation of amendment made by Pub. L. 102–321, see section 3(1) of Pub. L. 102–352, set out as a note under section 285n of this title.

Amendment by Pub. L. 102–321 effective Oct. 1, 1992, with provision for programs providing financial assistance, see section 801(c), (d) of Pub. L. 102–321, set out as a note under section 236 of this title.

[1] So in original. The period probably should be "; and".

[2] See References in Text note below.

SUBPART 15—NATIONAL INSTITUTE ON DRUG ABUSE

§285*o*. Purpose of Institute

(a) In general

The general purpose of the National Institute on Drug Abuse (hereafter in this subpart referred to as the "Institute") is the conduct and support of biomedical and behavioral research, health services research, research training, and health information dissemination with respect to the prevention of drug abuse and the treatment of drug abusers.

(b) Research program

The research program established under this subpart shall encompass the social, behavioral, and biomedical etiology, mental and physical health consequences, and social and economic consequences of drug abuse. In carrying out the program, the Director of the Institute shall give special consideration to projects relating to drug abuse among women (particularly with respect to pregnant women).

(c) Collaboration

The Director of the Institute shall collaborate with the Substance Abuse and Mental Health Services Administration in focusing the services research activities of the Institute and in disseminating the results of such research to health professionals and the general public.

(July 1, 1944, ch. 373, title IV, §464L, as added Pub. L. 102–321, title I, §123(a), July 10, 1992, 106 Stat. 360; amended Pub. L. 102–352, §2(a)(3), Aug. 26, 1992, 106 Stat. 938; Pub. L. 109–482, title I, §103(b)(33), Jan. 15, 2007, 120 Stat. 3688.)

EDITORIAL NOTES

AMENDMENTS

2007—Subsec. (d). Pub. L. 109–482 struck out subsec. (d) which related to authorization of appropriations and allocation for health services research.

1992—Subsec. (d)(1). Pub. L. 102–352 inserted "other than section 285o–4 of this title," after "this subpart,".

STATUTORY NOTES AND RELATED SUBSIDIARIES

EFFECTIVE DATE OF 2007 AMENDMENT

Amendment by Pub. L. 109–482 applicable only with respect to amounts appropriated for fiscal year 2007 or subsequent fiscal years, see section 109 of Pub. L. 109–482, set out as a note under section 281 of this title.

EFFECTIVE DATE OF 1992 AMENDMENT

Amendment by Pub. L. 102–352 effective immediately upon effectuation of amendment made by Pub. L. 102–321, see section 3(1) of Pub. L. 102–352, set out as a note under section 285n of this title.

EFFECTIVE DATE

Section effective Oct. 1, 1992, with provision for programs providing financial assistance, see section 801(c), (d) of Pub. L. 102–321, set out as an Effective Date of 1992 Amendment note under section 236 of this title.

§285*o*–1. Associate Director for Prevention

(a) In general

There shall be in the Institute an Associate Director for Prevention who shall be responsible for the full-time coordination and promotion of the programs in the Institute concerning the prevention of drug abuse. The Associate Director shall be appointed by the Director of the Institute from individuals who because of their professional training or expertise are experts in drug abuse and the prevention of such abuse.

(b) Report

The Associate Director for Prevention shall prepare for inclusion in the biennial report made under section 284b [1] of this title a description of the prevention activities of the Institute, including a description of the staff and resources allocated to those activities.

(July 1, 1944, ch. 373, title IV, §464M, as added Pub. L. 102–321, title I, §123(b), July 10, 1992, 106 Stat. 361.)

EDITORIAL NOTES

REFERENCES IN TEXT

Section 284b of this title, referred to in subsec. (b), was repealed by Pub. L. 109–482, title I, §104(b)(1)(C), Jan. 15, 2007, 120 Stat. 3693.

STATUTORY NOTES AND RELATED SUBSIDIARIES

EFFECTIVE DATE

Section effective Oct. 1, 1992, with provision for programs providing financial assistance, see section 801(c), (d) of Pub. L. 102–321, set out as an Effective Date of 1992 Amendment note under section 236 of this title.

[1] *See References in Text note below.*

§285*o*–2. Drug Abuse Research Centers

(a) Authority

The Director of the Institute may designate National Drug Abuse Research Centers for the purpose of interdisciplinary research relating to drug abuse and other biomedical, behavioral, and social issues related to drug abuse. No entity may be designated as a Center unless an application therefore has been submitted to, and approved by, the Secretary. Such an application shall be submitted in such manner and contain such information as the Secretary may reasonably require. The Secretary may not approve such an application unless—

(1) the application contains or is supported by reasonable assurances that—

(A) the applicant has the experience, or capability, to conduct, through biomedical, behavioral, social, and related disciplines, long-term research on drug abuse and to provide coordination of such research among such disciplines;

(B) the applicant has available to it sufficient facilities (including laboratory, reference, and data analysis facilities) to carry out the research plan contained in the application;

(C) the applicant has facilities and personnel to provide training in the prevention and treatment of drug abuse;

(D) the applicant has the capacity to train predoctoral and postdoctoral students for careers in research on drug abuse;

(E) the applicant has the capacity to conduct courses on drug abuse problems and research on drug abuse for undergraduate and graduate students, and medical and osteopathic, nursing, social work, and other specialized graduate students; and

(F) the applicant has the capacity to conduct programs of continuing education in such medical, legal, and social service fields as the Secretary may require.[1]

(2) the application contains a detailed five-year plan for research relating to drug abuse.

(b) Grants

The Director of the Institute shall, under such conditions as the Secretary may reasonably require, make annual grants to Centers which have been designated under this section. No funds provided under a grant under this subsection may be used for the purchase of any land or the purchase, construction, preservation, or repair of any building. For the purposes of the preceding sentence, the term "construction" has the meaning given that term by section 292a(1) [2] of this title.

(c) Drug abuse and addiction research

(1) Grants or cooperative agreements

The Director of the Institute may make grants or enter into cooperative agreements to expand the current and ongoing interdisciplinary research and clinical trials with treatment centers of the National Drug Abuse Treatment Clinical Trials Network relating to drug abuse and addiction, including related biomedical, behavioral, and social issues.

(2) Use of funds

Amounts made available under a grant or cooperative agreement under paragraph (1) for drug abuse and addiction may be used for research and clinical trials relating to—

(A) the effects of drug abuse on the human body, including the brain;

(B) the addictive nature of drugs and how such effects differ with respect to different individuals;

(C) the connection between drug abuse and mental health;

(D) the identification and evaluation of the most effective methods of prevention of drug abuse and addiction;

(E) the identification and development of the most effective methods of treatment of drug addiction, including pharmacological treatments;

(F) risk factors for drug abuse;

(G) effects of drug abuse and addiction on pregnant women and their fetuses; and

(H) cultural, social, behavioral, neurological, and psychological reasons that individuals

abuse drugs, or refrain from abusing drugs.

(3) Research results

The Director shall promptly disseminate research results under this subsection to Federal, State, and local entities involved in combating drug abuse and addiction.

(July 1, 1944, ch. 373, title IV, §464N, as added Pub. L. 102–321, title I, §123(b), July 10, 1992, 106 Stat. 361; amended Pub. L. 102–352, §2(a)(4), Aug. 26, 1992, 106 Stat. 938; Pub. L. 106–310, div. B, title XXXVI, §3631, Oct. 17, 2000, 114 Stat. 1235; Pub. L. 107–273, div. B, title II, §2203, Nov. 2, 2002, 116 Stat. 1794; Pub. L. 109–482, title I, §103(b)(34), Jan. 15, 2007, 120 Stat. 3688.)

EDITORIAL NOTES

REFERENCES IN TEXT

Section 292a of this title, referred to in subsec. (b), was in the original a reference to section 701 of act July 1, 1944. Section 701 of that Act was omitted in the general revision of subchapter V of this chapter by Pub. L. 102–408, title I, §102, Oct. 13, 1992, 106 Stat. 1994. Pub. L. 102–408 enacted a new section 701 of act July 1, 1944, relating to statement of purpose, and a new section 702, relating to scope and duration of loan insurance program, which are classified to sections 292 and 292a, respectively, of this title. For provisions relating to definitions, see sections 292o and 295p of this title.

AMENDMENTS

2007—Subsec. (c)(4). Pub. L. 109–482 struck out par. (4) which authorized appropriations and provided they were supplemental to other funding of research on drug abuse.

2002—Subsec. (c). Pub. L. 107–273 amended heading and text of subsec. (c) generally, substituting provisions relating to grants or cooperative agreements for research and clinical trials relating to drug abuse and addiction for similar provisions relating to grants or cooperative agreements for research and clinical trials relating to methamphetamine abuse and addiction.

2000—Subsec. (c). Pub. L. 106–310 added subsec. (c).

1992—Subsec. (b). Pub. L. 102–352 substituted "292a(1)" for "292a(2)".

STATUTORY NOTES AND RELATED SUBSIDIARIES

EFFECTIVE DATE OF 2007 AMENDMENT

Amendment by Pub. L. 109–482 applicable only with respect to amounts appropriated for fiscal year 2007 or subsequent fiscal years, see section 109 of Pub. L. 109–482, set out as a note under section 281 of this title.

EFFECTIVE DATE OF 1992 AMENDMENT

Amendment by Pub. L. 102–352 effective immediately upon effectuation of amendment made by Pub. L. 102–321, see section 3(1) of Pub. L. 102–352, set out as a note under section 285n of this title.

EFFECTIVE DATE

Section effective Oct. 1, 1992, with provision for programs providing financial assistance, see section 801(c), (d) of Pub. L. 102–321, set out as an Effective Date of 1992 Amendment note under section 236 of this title.

[1] So in original. The period probably should be "; and".

[2] See References in Text note below.

§285*o*–3. Office on AIDS

The Director of the Institute shall establish within the Institute an Office on AIDS. The Office shall be responsible for the coordination of research and determining the direction of the Institute with respect to AIDS research related to—

(1) primary prevention of the spread of HIV, including transmission via drug abuse;

(2) drug abuse services research; and
(3) other matters determined appropriate by the Director.

(July 1, 1944, ch. 373, title IV, §464O, as added Pub. L. 102–321, title I, §123(b), July 10, 1992, 106 Stat. 362.)

STATUTORY NOTES AND RELATED SUBSIDIARIES

EFFECTIVE DATE

Section effective Oct. 1, 1992, with provision for programs providing financial assistance, see section 801(c), (d) of Pub. L. 102–321, set out as an Effective Date of 1992 Amendment note under section 236 of this title.

STUDY BY NATIONAL ACADEMY OF SCIENCES

Section 706 of Pub. L. 102–321 directed Secretary of Health and Human Services to contract for a study or studies relating to programs that provide both sterile hypodermic needles and bleach to individuals in order to reduce the risk of contracting acquired immune deficiency syndrome or related conditions, in order to determine extent to which such programs promote the abuse of drugs or otherwise altered any behaviors constituting a substantial risk of contracting AIDS or hepatitus, or of transmitting such conditions, and further directed Secretary to ensure that a report is submitted to Congress on the results of this study not later than 18 months after July 10, 1992.

§285*o*–4. Medication Development Program

(a) Establishment

There is established in the Institute a Medication Development Program through which the Director of such Institute shall—

(1) conduct periodic meetings with the Commissioner of Food and Drugs to discuss measures that may facilitate the approval process of drug abuse treatments;

(2) encourage and promote (through grants, contracts, international collaboration, or otherwise) expanded research programs, investigations, experiments, community trials, and studies, into the development and use of medications to treat drug addiction;

(3) establish or provide for the establishment of research facilities;

(4) report on the activities of other relevant agencies relating to the development and use of pharmacotherapeutic treatments for drug addiction;

(5) collect, analyze, and disseminate data useful in the development and use of pharmacotherapeutic treatments for drug addiction and collect, catalog, analyze, and disseminate through international channels, the results of such research;

(6) directly or through grants, contracts, or cooperative agreements, support training in the fundamental sciences and clinical disciplines related to the pharmacotherapeutic treatment of drug abuse, including the use of training stipends, fellowships, and awards where appropriate; and

(7) coordinate the activities conducted under this section with related activities conducted within the National Institute on Alcohol Abuse and Alcoholism, the National Institute of Mental Health, and other appropriate institutes and shall consult with the Directors of such Institutes.

(b) Duties

In carrying out the activities described in subsection (a), the Director of the Institute—

(1) shall collect and disseminate through publications and other appropriate means, information pertaining to the research and other activities under this section;

(2) shall make grants to or enter into contracts and cooperative agreements with individuals and public and private entities to further the goals of the program;

(3) may, in accordance with section 289e of this title, and in consultation with the National Advisory Council on Drug Abuse, acquire, construct, improve, repair, operate, and maintain pharmacotherapeutic research centers, laboratories, and other necessary facilities and equipment,

and such other real or personal property as the Director determines necessary, and may, in consultation with such Advisory Council, make grants for the construction or renovation of facilities to carry out the purposes of this section;

(4) may accept voluntary and uncompensated services;

(5) may accept gifts, or donations of services, money, or property, real, personal, or mixed, tangible or intangible; and

(6) shall take necessary action to ensure that all channels for the dissemination and exchange of scientific knowledge and information are maintained between the Institute and the other scientific, medical, and biomedical disciplines and organizations nationally and internationally.

(c) Report

(1) In general

Not later than December 31, 1992, and each December 31 thereafter, the Director of the Institute shall submit to the Office of National Drug Control Policy established under section 1501 [1] of title 21 a report, in accordance with paragraph (3), that describes the objectives and activities of the program assisted under this section.

(2) National Drug Control Strategy

The Director of National Drug Control Policy shall incorporate, by reference or otherwise, each report submitted under this subsection in the National Drug Control Strategy submitted the following February 1 under section 1504 [1] of title 21.

(d) "Pharmacotherapeutics" defined

For purposes of this section, the term "pharmacotherapeutics" means medications used to treat the symptoms and disease of drug abuse, including medications to—

(1) block the effects of abused drugs;

(2) reduce the craving for abused drugs;

(3) moderate or eliminate withdrawal symptoms;

(4) block or reverse the toxic effect of abused drugs; or

(5) prevent relapse in persons who have been detoxified from drugs of abuse.

(July 1, 1944, ch. 373, title IV, §464P, as added Pub. L. 102–321, title I, §123(b), July 10, 1992, 106 Stat. 362; amended Pub. L. 103–43, title XX, §2008(b)(10), June 10, 1993, 107 Stat. 211; Pub. L. 109–482, title I, §103(b)(35), Jan. 15, 2007, 120 Stat. 3688.)

EDITORIAL NOTES

REFERENCES IN TEXT

Sections 1501 and 1504 of title 21, referred to in subsec. (c), were repealed by Pub. L. 100–690, title I, §1009, Nov. 18, 1988, 102 Stat. 4188.

AMENDMENTS

2007—Subsec. (e). Pub. L. 109–482 struck out heading and text of subsec. (e). Text read as follows: "For the purpose of carrying out this section, there are authorized to be appropriated $85,000,000 for fiscal year 1993, and $95,000,000 for fiscal year 1994."

1993—Subsec. (b)(6). Pub. L. 103–43 substituted "Institute" for "Administration".

STATUTORY NOTES AND RELATED SUBSIDIARIES

EFFECTIVE DATE OF 2007 AMENDMENT

Amendment by Pub. L. 109–482 applicable only with respect to amounts appropriated for fiscal year 2007 or subsequent fiscal years, see section 109 of Pub. L. 109–482, set out as a note under section 281 of this title.

EFFECTIVE DATE

Section effective Oct. 1, 1992, with provision for programs providing financial assistance, see section

801(c), (d) of Pub. L. 102–321, set out as an Effective Date of 1992 Amendment note under section 236 of this title.

REPORT BY INSTITUTE ON MEDICINE

Pub. L. 102–321, title VII, §701, July 10, 1992, 106 Stat. 436, directed Secretary of Health and Human Services to enter into a contract with a public or nonprofit private entity to conduct a study concerning (1) role of the private sector in development of anti-addiction medications, including legislative proposals designed to encourage private sector development of such medications, (2) process by which anti-addiction medications receive marketing approval from Food and Drug Administration, including an assessment of feasibility of expediting marketing approval process in a manner consistent with maintaining safety and effectiveness of such medications, (3) with respect to pharmacotherapeutic treatments for drug addiction (A) recommendations with respect to a national strategy for developing such treatments and improvements in such strategy, (B) state of the scientific knowledge concerning such treatments, and (C) assessment of progress toward development of safe, effective pharmacological treatments for drug addiction, and (4) other related information determined appropriate by the authors of the study, and to submit to Congress a report of the results of such study not later than 18 months after July 10, 1992.

[1] *See References in Text note below.*

SUBPART 16—NATIONAL INSTITUTE OF MENTAL HEALTH

§285p. Purpose of Institute

(a) In general

The general purpose of the National Institute of Mental Health (hereafter in this subpart referred to as the "Institute") is the conduct and support of biomedical and behavioral research, health services research, research training, and health information dissemination with respect to the cause, diagnosis, treatment, control and prevention of mental illness.

(b) Research program

The research program established under this subpart shall include support for biomedical and behavioral neuroscience and shall be designed to further the treatment and prevention of mental illness, the promotion of mental health, and the study of the psychological, social and legal factors that influence behavior.

(c) Collaboration

The Director of the Institute shall collaborate with the Administrator of the Substance Abuse and Mental Health Services Administration in focusing the services research activities of the Institute and in disseminating the results of such research to health professionals and the general public.

(d) Information with respect to suicide

(1) In general

The Director of the Institute shall—

(A) develop and publish information with respect to the causes of suicide and the means of preventing suicide; and

(B) make such information generally available to the public and to health professionals.

(2) Youth suicide

Information described in paragraph (1) shall especially relate to suicide among individuals under 24 years of age.

(e) Associate Director for Special Populations

(1) In general

The Director of the Institute shall designate an Associate Director for Special Populations.

(2) Duties

The Associate Director for Special Populations shall—

(A) develop and coordinate research policies and programs to assure increased emphasis on the mental health needs of women and minority populations;

(B) support programs of basic and applied social and behavioral research on the mental health problems of women and minority populations;

(C) study the effects of discrimination on institutions and individuals, including majority institutions and individuals;

(D) support and develop research designed to eliminate institutional discrimination; and

(E) provide increased emphasis on the concerns of women and minority populations in training programs, service delivery programs, and research endeavors of the Institute.

(July 1, 1944, ch. 373, title IV, §464R, as added Pub. L. 102–321, title I, §124(a), July 10, 1992, 106 Stat. 364; amended Pub. L. 102–352, §2(a)(5), Aug. 26, 1992, 106 Stat. 938; Pub. L. 109–482, title I, §103(b)(36), Jan. 15, 2007, 120 Stat. 3688.)

EDITORIAL NOTES

AMENDMENTS

2007—Subsec. (f). Pub. L. 109–482 struck out subsec. (f) which authorized appropriations and provided that at least 15% of the appropriated amounts were to carry out health services research relating to mental health.

1992—Subsec. (f)(1). Pub. L. 102–352 struck out "other than section 285o–4 of this title" after "this subpart".

STATUTORY NOTES AND RELATED SUBSIDIARIES

EFFECTIVE DATE OF 2007 AMENDMENT

Amendment by Pub. L. 109–482 applicable only with respect to amounts appropriated for fiscal year 2007 or subsequent fiscal years, see section 109 of Pub. L. 109–482, set out as a note under section 281 of this title.

EFFECTIVE DATE OF 1992 AMENDMENT

Amendment by Pub. L. 102–352 effective immediately upon effectuation of amendment made by Pub. L. 102–321, see section 3(1) of Pub. L. 102–352, set out as a note under section 285n of this title.

EFFECTIVE DATE

Section effective Oct. 1, 1992, with provision for programs providing financial assistance, see section 801(c), (d) of Pub. L. 102–321, set out as an Effective Date of 1992 Amendment note under section 236 of this title.

STUDY OF BARRIERS TO INSURANCE COVERAGE OF TREATMENT FOR MENTAL ILLNESS AND SUBSTANCE ABUSE

Section 704 of Pub. L. 102–321 directed Secretary of Health and Human Services, acting through Director of the National Institute of Mental Health and in consultation with Administrator of Health Care Financing Administration, to conduct a study of the barriers to insurance coverage for the treatment of mental illness and substance abuse and to submit a report to Congress on the results of such study not later than Oct. 1, 1993.

§285p–1. Associate Director for Prevention

(a) In general

There shall be in the Institute an Associate Director for Prevention who shall be responsible for the full-time coordination and promotion of the programs in the Institute concerning the prevention of mental disorder. The Associate Director shall be appointed by the Director of the Institute from

individuals who because of their professional training or expertise are experts in mental disorder and the prevention of such.

(b) Report

The Associate Director for Prevention shall prepare for inclusion in the biennial report made under section 284b [1] of this title a description of the prevention activities of the Institute, including a description of the staff and resources allocated to those activities.

(July 1, 1944, ch. 373, title IV, §464S, as added Pub. L. 102–321, title I, §124(b), July 10, 1992, 106 Stat. 365.)

EDITORIAL NOTES

REFERENCES IN TEXT

Section 284b of this title, referred to in subsec. (b), was repealed by Pub. L. 109–482, title I, §104(b)(1)(C), Jan. 15, 2007, 120 Stat. 3693.

STATUTORY NOTES AND RELATED SUBSIDIARIES

EFFECTIVE DATE

Section effective Oct. 1, 1992, with provision for programs providing financial assistance, see section 801(c), (d) of Pub. L. 102–321, set out as an Effective Date of 1992 Amendment note under section 236 of this title.

[1] *See References in Text note below.*

§285p–2. Office of Rural Mental Health Research

(a) In general

There is established within the Institute an office to be known as the Office of Rural Mental Health Research (hereafter in this section referred to as the "Office"). The Office shall be headed by a director, who shall be appointed by the Director of such Institute from among individuals experienced or knowledgeable in the provision of mental health services in rural areas. The Secretary shall carry out the authorities established in this section acting through the Director of the Office.

(b) Coordination of activities

The Director of the Office, in consultation with the Director of the Institute and with the Director of the Office of Rural Health Policy, shall—

(1) coordinate the research activities of the Department of Health and Human Services as such activities relate to the mental health of residents of rural areas; and

(2) coordinate the activities of the Office with similar activities of public and nonprofit private entities.

(c) Research, demonstrations, evaluations, and dissemination

The Director of the Office may, with respect to the mental health of adults and children residing in rural areas—

(1) conduct research on conditions that are unique to the residents of rural areas, or more serious or prevalent in such residents;

(2) conduct research on improving the delivery of services in such areas; and

(3) disseminate information to appropriate public and nonprofit private entities.

(d) Authority regarding grants and contracts

The Director of the Office may carry out the authorities established in subsection (c) directly and through grants, cooperative agreements, or contracts with public or nonprofit private entities.

(July 1, 1944, ch. 373, title IV, §464T, as added Pub. L. 102–321, title I, §124(b), July 10, 1992, 106 Stat. 365; amended Pub. L. 109–482, title I, §104(b)(1)(L), Jan. 15, 2007, 120 Stat. 3693.)

EDITORIAL NOTES

AMENDMENTS

2007—Subsec. (e). Pub. L. 109–482 struck out heading and text of subsec. (e). Text read as follows: "Not later than February 1, 1993, and each fiscal year thereafter, the Director shall submit to the Subcommittee on Health and the Environment of the Committee on Energy and Commerce (of the House of Representatives), and to the Committee on Labor and Human Resources (of the Senate), a report describing the activities of the Office during the preceding fiscal year, including a summary of the activities of demonstration projects and a summary of evaluations of the projects."

STATUTORY NOTES AND RELATED SUBSIDIARIES

EFFECTIVE DATE OF 2007 AMENDMENT

Amendment by Pub. L. 109–482 applicable only with respect to amounts appropriated for fiscal year 2007 or subsequent fiscal years, see section 109 of Pub. L. 109–482, set out as a note under section 281 of this title.

EFFECTIVE DATE

Section effective Oct. 1, 1992, with provision for programs providing financial assistance, see section 801(c), (d) of Pub. L. 102–321, set out as an Effective Date of 1992 Amendment note under section 236 of this title.

§285p–3. Office on AIDS

The Director of the Institute shall establish within the Institute an Office on AIDS. The Office shall be responsible for the coordination of research and determining the direction of the Institute with respect to AIDS research related to—

(1) primary prevention of the spread of HIV, including transmission via sexual behavior;

(2) mental health services research; and

(3) other matters determined appropriate by the Director.

(July 1, 1944, ch. 373, title IV, §464U, as added Pub. L. 102–321, title I, §124(b), July 10, 1992, 106 Stat. 366.)

STATUTORY NOTES AND RELATED SUBSIDIARIES

EFFECTIVE DATE

Section effective Oct. 1, 1992, with provision for programs providing financial assistance, see section 801(c), (d) of Pub. L. 102–321, set out as an Effective Date of 1992 Amendment note under section 236 of this title.

SUBPART 17—NATIONAL INSTITUTE OF NURSING RESEARCH

§285q. Purpose of Institute

The general purpose of the National Institute of Nursing Research (in this subpart referred to as the "Institute") is the conduct and support of, and dissemination of information respecting, basic and clinical nursing research, training, and other programs in patient care research.

(July 1, 1944, ch. 373, title IV, §464V, formerly §483, as added Pub. L. 99–158, §2, Nov. 20, 1985, 99 Stat. 867; renumbered §464V and amended Pub. L. 103–43, title XV, §1511(a)(1), (b)(2), June

10, 1993, 107 Stat. 178, 179.)

EDITORIAL NOTES

CODIFICATION

Section was formerly classified to section 287c of this title prior to renumbering by Pub. L. 103–43.

AMENDMENTS

1993—Pub. L. 103–43, §1511(a)(1) substituted "Institute" for "Center" in section catchline and "National Institute of Nursing Research (in this subpart referred to as the 'Institute')" for "National Center for Nursing Research (hereafter in this subpart referred to as the 'Center')" in text.

STATUTORY NOTES AND RELATED SUBSIDIARIES

STUDY ON ADEQUACY OF NUMBER OF NURSES

Section 1512 of Pub. L. 103–43 directed Secretary of Health and Human Services, acting through Director of National Institute of Nursing Research, to enter into a contract with a public or nonprofit private entity to conduct a study for purpose of determining whether and to what extent there is a need for an increase in the number of nurses in hospitals and nursing homes in order to promote the quality of patient care and reduce the incidence among nurses of work-related injuries and stress and to complete such study and submit a report to Congress not later than 18 months after June 10, 1993.

§285q–1. Specific authorities

To carry out section 285q of this title, the Director of the Institute may provide research training and instruction and establish, in the Institute and other nonprofit institutions, research traineeships and fellowships in the study and investigation of the prevention of disease, health promotion, and the nursing care of individuals with and the families of individuals with acute and chronic illnesses. The Director of the Institute may provide individuals receiving such training and instruction or such traineeships or fellowships with such stipends and allowances (including amounts for travel and subsistence and dependency allowances) as the Director determines necessary. The Director may make grants to nonprofit institutions to provide such training and instruction and traineeships and fellowships.

(July 1, 1944, ch. 373, title IV, §464W, formerly §484, as added Pub. L. 99–158, §2, Nov. 20, 1985, 99 Stat. 867; renumbered §464W and amended Pub. L. 103–43, title XV, §1511(a)(2), (b)(2), (4)(A), June 10, 1993, 107 Stat. 178, 179.)

EDITORIAL NOTES

CODIFICATION

Section was formerly classified to section 287c–1 of this title prior to renumbering by Pub. L. 103–43.

AMENDMENTS

1993—Pub. L. 103–43, §1511(a)(2), (b)(4)(A), substituted "section 285q" for "section 287c" and "Institute" for "Center" wherever appearing.

§285q–2. Advisory council

(a) Appointment; functions and duties; acceptance of conditional gifts; subcommittees

(1) The Secretary shall appoint an advisory council for the Institute which shall advise, assist, consult with, and make recommendations to the Secretary and the Director of the Institute on matters related to the activities carried out by and through the Institute and the policies respecting such activities.

(2) The advisory council for the Institute may recommend to the Secretary acceptance, in accordance with section 238 of this title, of conditional gifts for study, investigations, and research and for the acquisition of grounds or construction, equipping, or maintenance of facilities for the Institute.

(3) The advisory council for the Institute—

(A)(i) may make recommendations to the Director of the Institute respecting research conducted at the Institute,

(ii) may review applications for grants and cooperative agreements for research or training and recommend for approval applications for projects which show promise of making valuable contributions to human knowledge, and

(iii) may review any grant, contract, or cooperative agreement proposed to be made or entered into by the Institute;

(B) may collect, by correspondence or by personal investigation, information as to studies which are being carried on in the United States or any other country as to the diseases, disorders, or other aspects of human health with respect to which the Institute is concerned and with the approval of the Director of the Institute make available such information through appropriate publications for the benefit of public and private health entities and health professions personnel and scientists and for the information of the general public; and

(C) may appoint subcommittees and convene workshops and conferences.

(b) Membership; ex officio members; compensation

(1) The advisory council shall consist of ex officio members and not more than eighteen members appointed by the Secretary.

(2) The ex officio members of the advisory council shall consist of—

(A) the Secretary, the Director of NIH, the Director of the Institute, the chief nursing officer of the Department of Veterans Affairs, the Assistant Secretary of Defense for Health Affairs, the Director of the Division of Nursing of the Health Resources and Services Administration (or the designees of such officers), and

(B) such additional officers or employees of the United States as the Secretary determines necessary for the advisory council to effectively carry out its functions.

(3) The members of the advisory council who are not ex officio members shall be appointed as follows:

(A) Two-thirds of the members shall be appointed by the Secretary from among the leading representatives of the health and scientific disciplines (including public health and the behavioral or social sciences) relevant to the activities of the Institute. Of the members appointed pursuant to this subparagraph, at least seven shall be professional nurses who are recognized experts in the area of clinical practice, education, or research.

(B) One-third of the members shall be appointed by the Secretary from the general public and shall include leaders in fields of public policy, law, health policy, economics, and management.

(4) Members of the advisory council who are officers or employees of the United States shall not receive any compensation for service on the advisory council. The other members of the advisory council shall receive, for each day (including traveltime) they are engaged in the performance of the functions of the advisory council, compensation at rates not to exceed the daily equivalent of the annual rate in effect for grade GS–18 of the General Schedule.

(c) Term of office; vacancy; reappointment

The term of office of an appointed member of the advisory council is four years, except that any member appointed to fill a vacancy for an unexpired term shall be appointed for the remainder of such term and the Secretary shall make appointments to an advisory council in such a manner as to ensure that the terms of the members do not all expire in the same year. A member may serve after the expiration of the member's term until a successor has taken office. A member who has been appointed for a term of four years may not be reappointed to an advisory council before two years

from the date of expiration of such term of office. If a vacancy occurs in the advisory council among the appointed members, the Secretary shall make an appointment to fill the vacancy within 90 days from the date the vacancy occurs.

(d) Chairman; selection; term of office

The chairman of the advisory council shall be selected by the Secretary from among the appointed members, except that the Secretary may select the Director of the Institute to be the chairman of the advisory council. The term of office of the chairman shall be two years.

(e) Meetings

The advisory council shall meet at the call of the chairman or upon the request of the Director of the Institute, but at least three times each fiscal year. The location of the meetings of the advisory council is subject to the approval of the Director of the Institute.

(f) Executive secretary; staff; orientation and training for new members

The Director of the Institute shall designate a member of the staff of the Institute to serve as the executive secretary of the advisory council. The Director of the Institute shall make available to the advisory council such staff, information, and other assistance as it may require to carry out its functions. The Director of the Institute shall provide orientation and training for new members of the advisory council to provide them with such information and training as may be appropriate for their effective participation in the functions of the advisory council.

(g) Material for inclusion in biennial report; additional reports

The advisory council may prepare, for inclusion in the triennial report made under section 283 of this title (1) comments respecting the activities of the advisory council in the fiscal years respecting which the report is prepared, (2) comments on the progress of the Institute in meeting its objectives, and (3) recommendations respecting the future directions and program and policy emphasis of the Institute. The advisory council may prepare such additional reports as it may determine appropriate.

(July 1, 1944, ch. 373, title IV, §464X, formerly §485, as added Pub. L. 99–158, §2, Nov. 20, 1985, 99 Stat. 867; amended Pub. L. 101–381, title I, §102(4), Aug. 18, 1990, 104 Stat. 586; Pub. L. 102–54, §13(q)(1)(E), June 13, 1991, 105 Stat. 279; renumbered §464X and amended Pub. L. 103–43, title XV, §1511(a)(3), (b)(2), (4)(B), title XX, §§2008(b)(13), 2010(b)(5), June 10, 1993, 107 Stat. 178, 179, 211, 214; Pub. L. 114–255, div. A, title II, §2042(h)(2), Dec. 13, 2016, 130 Stat. 1073.)

EDITORIAL NOTES

CODIFICATION

Section was formerly classified to section 285c–2 of this title prior to renumbering by Pub. L. 103–43.

AMENDMENTS

2016—Subsec. (g). Pub. L. 114–255 substituted "triennial report made under section 283 of this title" for "biennial report made under section 285q–3 of this title,".

1993—Subsec. (a). Pub. L. 103–43, §1511(a)(3)(A), substituted "Institute" for "Center" wherever appearing.

Subsec. (a)(2). Pub. L. 103–43, §2010(b)(5), which directed the substitution of "section 238" for "section 300aaa" in section 287c–2(a)(2) of this title, was executed to subsec. (a)(2) of this section to reflect the probable intent of Congress and the renumbering of this section. See Codification note above.

Subsec. (b)(2)(A). Pub. L. 103–43, §2008(b)(13), which directed the substitution of "Department of Veterans Affairs" for "Veterans' Administration" in section 287c–2(b)(2)(A) of this title could not be executed because the words "Veterans' Administration" do not appear in subsec. (b)(2)(A) of this section subsequent to amendment by Pub. L. 102–54 and because of the renumbering of this section. See Codification note above and 1991 Amendment note below.

Pub. L. 103–43, §§1511(a)(3)(B)(i), substituted "Institute" for "Center".

Subsec. (b)(3)(A). Pub. L. 103–43, §1511(a)(3)(B)(ii), substituted "Institute" for "Center".

Subsecs. (d) to (f). Pub. L. 103–43, §1511(a)(3)(C), substituted "Institute" for "Center" wherever appearing.

Subsec. (g). Pub. L. 103–43, §1511(a)(3)(C), (b)(4)(B), substituted "section 285q–3" for "section 287c–3" and "Institute" for "Center" in two places.

1991—Subsec. (b)(2)(A). Pub. L. 102–54 substituted "chief nursing officer of the Department of Veterans Affairs" for "Chief Nursing Officer of the Veterans' Administration".

1990—Subsec. (a)(2). Pub. L. 101–381 made technical amendment to reference to section 300aaa of this title to reflect renumbering of corresponding section of original act.

STATUTORY NOTES AND RELATED SUBSIDIARIES

TERMINATION OF ADVISORY COUNCILS

Advisory councils established after Jan. 5, 1973, to terminate not later than the expiration of the 2-year period beginning on the date of their establishment, unless, in the case of a council established by the President or an officer of the Federal Government, such council is renewed by appropriate action prior to the expiration of such 2-year period, or in the case of a council established by the Congress, its duration is otherwise provided by law. See sections 1001(2) and 1013 of Title 5, Government Organization and Employees.

Pub. L. 93–641, §6, Jan. 4, 1975, 88 Stat. 2275, set out as a note under section 217a of this title, provided that an advisory committee established pursuant to the Public Health Service Act shall terminate at such time as may be specifically prescribed by an Act of Congress enacted after Jan. 4, 1975.

REFERENCES IN OTHER LAWS TO GS–16, 17, OR 18 PAY RATES

References in laws to the rates of pay for GS–16, 17, or 18, or to maximum rates of pay under the General Schedule, to be considered references to rates payable under specified sections of Title 5, Government Organization and Employees, see section 529 [title I, §101(c)(1)] of Pub. L. 101–509, set out in a note under section 5376 of Title 5.

§285q–3. Repealed. Pub. L. 114–255, div. A, title II, §2042(h)(1), Dec. 13, 2016, 130 Stat. 1073

Section, July 1, 1944, ch. 373, title IV, §464Y, formerly §486, as added Pub. L. 99–158, §2, Nov. 20, 1985, 99 Stat. 869; renumbered §485A, renumbered §464Y, and amended Pub. L. 103–43, title I, §141(a)(1), title XV, §1511(a)(4), (b)(2), (4)(C), June 10, 1993, 107 Stat. 136, 179, related to biennial report of activities of the National Institute of Nursing Research.

SUBPART 18—NATIONAL INSTITUTE OF BIOMEDICAL IMAGING AND BIOENGINEERING

§285r. Purpose of the Institute

(a) In general

The general purpose of the National Institute of Biomedical Imaging and Bioengineering (in this section referred to as the "Institute") is the conduct and support of research, training, the dissemination of health information, and other programs with respect to biomedical imaging, biomedical engineering, and associated technologies and modalities with biomedical applications (in this section referred to as "biomedical imaging and bioengineering").

(b) National Biomedical Imaging and Bioengineering Program

(1) The Director of the Institute, with the advice of the Institute's advisory council, shall establish a National Biomedical Imaging and Bioengineering Program (in this section referred to as the "Program").

(2) Activities under the Program shall include the following with respect to biomedical imaging and bioengineering:

(A) Research into the development of new techniques and devices.

(B) Related research in physics, engineering, mathematics, computer science, and other disciplines.

(C) Technology assessments and outcomes studies to evaluate the effectiveness of biologics, materials, processes, devices, procedures, and informatics.

(D) Research in screening for diseases and disorders.

(E) The advancement of existing imaging and bioengineering modalities, including imaging, biomaterials, and informatics.

(F) The development of target-specific agents to enhance images and to identify and delineate disease.

(G) The development of advanced engineering and imaging technologies and techniques for research from the molecular and genetic to the whole organ and body levels.

(H) The development of new techniques and devices for more effective interventional procedures (such as image-guided interventions).

(3)(A) With respect to the Program, the Director of the Institute shall prepare and transmit to the Secretary and the Director of NIH a plan to initiate, expand, intensify, and coordinate activities of the Institute with respect to biomedical imaging and bioengineering. The plan shall include such comments and recommendations as the Director of the Institute determines appropriate. The Director of the Institute shall periodically review and revise the plan and shall transmit any revisions of the plan to the Secretary and the Director of NIH.

(B) The plan under subparagraph (A) shall include the recommendations of the Director of the Institute with respect to the following:

(i) Where appropriate, the consolidation of programs of the National Institutes of Health for the express purpose of enhancing support of activities regarding basic biomedical imaging and bioengineering research.

(ii) The coordination of the activities of the Institute with related activities of the other agencies of the National Institutes of Health and with related activities of other Federal agencies.

(c) Membership

The establishment under section 284a of this title of an advisory council for the Institute is subject to the following:

(1) The number of members appointed by the Secretary shall be 12.

(2) Of such members—

(A) six members shall be scientists, engineers, physicians, and other health professionals who represent disciplines in biomedical imaging and bioengineering and who are not officers or employees of the United States; and

(B) six members shall be scientists, engineers, physicians, and other health professionals who represent other disciplines and are knowledgeable about the applications of biomedical imaging and bioengineering in medicine, and who are not officers or employees of the United States.

(3) In addition to the ex officio members specified in section 284a(b)(2) of this title, the ex officio members of the advisory council shall include the Director of the Centers for Disease Control and Prevention, the Director of the National Science Foundation, and the Director of the National Institute of Standards and Technology (or the designees of such officers).

(July 1, 1944, ch. 373, title IV, §464z, as added Pub. L. 106–580, §3(a), Dec. 29, 2000, 114 Stat. 3089; amended Pub. L. 109–482, title I, §103(b)(37), Jan. 15, 2007, 120 Stat. 3688.)

EDITORIAL NOTES

AMENDMENTS

2007—Subsec. (d). Pub. L. 109–482 struck out subsec. (d) which related to appropriations for fiscal years 2001 to 2003.

STATUTORY NOTES AND RELATED SUBSIDIARIES

EFFECTIVE DATE OF 2007 AMENDMENT

Amendment by Pub. L. 109–482 applicable only with respect to amounts appropriated for fiscal year 2007 or subsequent fiscal years, see section 109 of Pub. L. 109–482, set out as a note under section 281 of this title.

EFFECTIVE DATE

Pub. L. 106–580, §4, Dec. 29, 2000, 114 Stat. 3092, provided that: "This Act [enacting this subpart, amending section 281 of this title, and enacting provisions set out as notes under this section and section 201 of this title] takes effect October 1, 2000, or upon the date of the enactment of this Act [Dec. 29, 2000], whichever occurs later."

FINDINGS

Pub. L. 106–580, §2, Dec. 29, 2000, 114 Stat. 3088, provided that: "The Congress makes the following findings:

"(1) Basic research in imaging, bioengineering, computer science, informatics, and related fields is critical to improving health care but is fundamentally different from the research in molecular biology on which the current national research institutes at the National Institutes of Health ('NIH') are based. To ensure the development of new techniques and technologies for the 21st century, these disciplines therefore require an identity and research home at the NIH that is independent of the existing institute structure.

"(2) Advances based on medical research promise new, more effective treatments for a wide variety of diseases, but the development of new, noninvasive imaging techniques for earlier detection and diagnosis of disease is essential to take full advantage of such new treatments and to promote the general improvement of health care.

"(3) The development of advanced genetic and molecular imaging techniques is necessary to continue the current rapid pace of discovery in molecular biology.

"(4) Advances in telemedicine, and teleradiology in particular, are increasingly important in the delivery of high quality, reliable medical care to rural citizens and other underserved populations. To fulfill the promise of telemedicine and related technologies fully, a structure is needed at the NIH to support basic research focused on the acquisition, transmission, processing, and optimal display of images.

"(5) A number of Federal departments and agencies support imaging and engineering research with potential medical applications, but a central coordinating body, preferably housed at the NIH, is needed to coordinate these disparate efforts and facilitate the transfer of technologies with medical applications.

"(6) Several breakthrough imaging technologies, including magnetic resonance imaging ('MRI') and computed tomography ('CT'), have been developed primarily abroad, in large part because of the absence of a home at the NIH for basic research in imaging and related fields. The establishment of a central focus for imaging and bioengineering research at the NIH would promote both scientific advance and United States economic development.

"(7) At a time when a consensus exists to add significant resources to the NIH in coming years, it is appropriate to modernize the structure of the NIH to ensure that research dollars are expended more effectively and efficiently and that the fields of medical science that have contributed the most to the detection, diagnosis, and treatment of disease in recent years receive appropriate emphasis.

"(8) The establishment of a National Institute of Biomedical Imaging and Bioengineering at the NIH would accelerate the development of new technologies with clinical and research applications, improve coordination and efficiency at the NIH and throughout the Federal Government, reduce duplication and waste, lay the foundation for a new medical information age, promote economic development, and provide a structure to train the young researchers who will make the pathbreaking discoveries of the next century."

ESTABLISHMENT OF INSTITUTE AND ADVISORY COUNCIL

Pub. L. 106–580, §3(b)–(d), Dec. 29, 2000, 114 Stat. 3091, provided that:

"(b) USE OF EXISTING RESOURCES.—In providing for the establishment of the National Institute of Biomedical Imaging and Bioengineering pursuant to the amendment made by subsection (a) [enacting this subpart], the Director of the National Institutes of Health (referred to in this subsection as 'NIH')—

"(1) may transfer to the National Institute of Biomedical Imaging and Bioengineering such personnel of NIH as the Director determines to be appropriate;

"(2) may, for quarters for such Institute, utilize such facilities of NIH as the Director determines to be appropriate; and

"(3) may obtain administrative support for the Institute from the other agencies of NIH, including the other national research institutes.

"(c) CONSTRUCTION OF FACILITIES.—None of the provisions of this Act [enacting this subpart, amending section 281 of this title, and enacting provisions set out as notes under this section and section 201 of this title] or the amendments made by the Act may be construed as authorizing the construction of facilities, or the acquisition of land, for purposes of the establishment or operation of the National Institute of Biomedical Imaging and Bioengineering.

"(d) DATE CERTAIN FOR ESTABLISHMENT OF ADVISORY COUNCIL.—Not later than 90 days after the effective date of this Act [Dec. 29, 2000] under section 4 [set out above], the Secretary of Health and Human Services shall complete the establishment of an advisory council for the National Institute of Biomedical Imaging and Bioengineering in accordance with section 406 of the Public Health Service Act [42 U.S.C. 284a] and in accordance with section 464z of such Act (as added by subsection (a) of this section) [42 U.S.C. 285r]."

SUBPART 19—NATIONAL HUMAN GENOME RESEARCH INSTITUTE

EDITORIAL NOTES

CODIFICATION

Pub. L. 109–482, title I, §101(c)(1)–(3), Jan. 15, 2007, 120 Stat. 3681, redesignated subpart 3 of part E of this subchapter as this subpart.

§285s. Purpose of Institute

(a) General purpose

The general purpose of the National Human Genome Research Institute (in this subpart referred to as the "Institute") is to characterize the structure and function of the human genome, including the mapping and sequencing of individual genes. Such purpose includes—

(1) planning and coordinating the research goal of the genome project;

(2) reviewing and funding research proposals;

(3) developing training programs;

(4) coordinating international genome research;

(5) communicating advances in genome science to the public; and

(6) reviewing and funding proposals to address the ethical and legal issues associated with the genome project (including legal issues regarding patents).

(b) Research training

The Director of the Institute may conduct and support research training—

(1) for which fellowship support is not provided under section 288 of this title; and

(2) that is not residency training of physicians or other health professionals.

(c) Amount available for ethical and legal issues

(1) Except as provided in paragraph (2), of the amounts appropriated to carry out subsection (a) for a fiscal year, the Director of the Institute shall make available not less than 5 percent for carrying out paragraph (6) of such subsection.

(2) With respect to providing funds under subsection (a)(6) for proposals to address the ethical issues associated with the genome project, paragraph (1) shall not apply for a fiscal year if the Director of the Institute certifies to the Committee on Energy and Commerce of the House of Representatives, and to the Committee on Labor and Human Resources of the Senate, that the Director has determined that an insufficient number of such proposals meet the applicable requirements of sections 289 and 289a of this title.

(July 1, 1944, ch. 373, title IV, §464z–1, formerly §485B, as added Pub. L. 103–43, title XV,

§1521(2), June 10, 1993, 107 Stat. 180; renumbered §464z–1 and amended Pub. L. 109–482, title I, §101(c)(4), Jan. 15, 2007, 120 Stat. 3681.)

EDITORIAL NOTES

CODIFICATION

Section was formerly classified to section 287c of this title prior to renumbering by Pub. L. 109–482.

AMENDMENTS

2007—Pub. L. 109–482, §101(c)(4)(C), substituted "Institute" for "Center" wherever appearing in section catchline and text.

Subsec. (a). Pub. L. 109–482, §101(c)(4)(B), substituted "National Human Genome Research Institute" for "National Center for Human Genome Research" in introductory provisions.

STATUTORY NOTES AND RELATED SUBSIDIARIES

CHANGE OF NAME

Committee on Labor and Human Resources of Senate changed to Committee on Health, Education, Labor, and Pensions of Senate by Senate Resolution No. 20, One Hundred Sixth Congress, Jan. 19, 1999.

Committee on Energy and Commerce of House of Representatives treated as referring to Committee on Commerce of House of Representatives by section 1(a) of Pub. L. 104–14, set out as a note preceding section 21 of Title 2, The Congress. Committee on Commerce of House of Representatives changed to Committee on Energy and Commerce of House of Representatives, and jurisdiction over matters relating to securities and exchanges and insurance generally transferred to Committee on Financial Services of House of Representatives by House Resolution No. 5, One Hundred Seventh Congress, Jan. 3, 2001.

EFFECTIVE DATE OF 2007 AMENDMENT

Amendment by Pub. L. 109–482 applicable only with respect to amounts appropriated for fiscal year 2007 or subsequent fiscal years, see section 109 of Pub. L. 109–482, set out as a note under section 281 of this title.

SUBPART 20—NATIONAL INSTITUTE ON MINORITY HEALTH AND HEALTH DISPARITIES

EDITORIAL NOTES

CODIFICATION

Pub. L. 111–148, title X, §10334(c)(1)(A)–(C), (D)(ii), Mar. 23, 2010, 124 Stat. 973, redesignated subpart 6 of part E of this subchapter as this subpart and substituted "National Institute on Minority Health and Health Disparities" for "National Center on Minority Health and Health Disparities" in heading.

§285t. Purpose of Institute

(a) In general

The general purpose of the National Institute on Minority Health and Health Disparities (in this subpart referred to as the "Institute") is the conduct and support of research, training, dissemination of information, and other programs with respect to minority health conditions and other populations with health disparities.

(b) Priorities

The Director of the Institute shall in expending amounts appropriated under this subpart give priority to conducting and supporting minority health disparities research.

(c) Minority health disparities research

For purposes of this subpart:

(1) The term "minority health disparities research" means basic, clinical, and behavioral research on minority health conditions (as defined in paragraph (2)), including research to prevent, diagnose, and treat such conditions.

(2) The term "minority health conditions", with respect to individuals who are members of minority groups, means all diseases, disorders, and conditions (including with respect to mental health and substance abuse)—

(A) unique to, more serious, or more prevalent in such individuals;

(B) for which the factors of medical risk or types of medical intervention may be different for such individuals, or for which it is unknown whether such factors or types are different for such individuals; or

(C) with respect to which there has been insufficient research involving such individuals as subjects or insufficient data on such individuals.

(3) The term "minority group" has the meaning given the term "racial and ethnic minority group" in section 300u–6 of this title.

(4) The terms "minority" and "minorities" refer to individuals from a minority group.

(d) Health disparity populations

For purposes of this subpart:

(1) A population is a health disparity population if, as determined by the Director of the Institute after consultation with the Director of the Agency for Healthcare Research and Quality, there is a significant disparity in the overall rate of disease incidence, prevalence, morbidity, mortality, or survival rates in the population as compared to the health status of the general population.

(2) The Director shall give priority consideration to determining whether minority groups qualify as health disparity populations under paragraph (1).

(3) The term "health disparities research" means basic, clinical, and behavioral research on health disparity populations (including individual members and communities of such populations) that relates to health disparities as defined under paragraph (1), including the causes of such disparities and methods to prevent, diagnose, and treat such disparities.

(e) Coordination of activities

The Director of the Institute shall act as the primary Federal official with responsibility for coordinating all minority health disparities research and other health disparities research conducted or supported by the National Institutes of Health, and—

(1) shall represent the health disparities research program of the National Institutes of Health, including the minority health disparities research program, at all relevant Executive branch task forces, committees and planning activities; and

(2) shall maintain communications with all relevant Public Health Service agencies, including the Indian Health Service, and various other departments of the Federal Government to ensure the timely transmission of information concerning advances in minority health disparities research and other health disparities research between these various agencies for dissemination to affected communities and health care providers.

(f) Collaborative comprehensive plan and budget

(1) In general

Subject to the provisions of this section and other applicable law, the Director of NIH, the Director of the Institute, and the directors of the other agencies of the National Institutes of Health in collaboration (and in consultation with the advisory council for the Institute) shall—

(A) establish a comprehensive plan and budget for the conduct and support of all minority health disparities research and other health disparities research activities of the agencies of the National Institutes of Health (which plan and budget shall be first established under this subsection not later than 12 months after November 22, 2000);

(B) ensure that the plan and budget establish priorities among the health disparities research

activities that such agencies are authorized to carry out;

(C) ensure that the plan and budget establish objectives regarding such activities, describes the means for achieving the objectives, and designates the date by which the objectives are expected to be achieved;

(D) ensure that, with respect to amounts appropriated for activities of the Institute, the plan and budget give priority in the expenditure of funds to conducting and supporting minority health disparities research;

(E) ensure that all amounts appropriated for such activities are expended in accordance with the plan and budget;

(F) review the plan and budget not less than annually, and revise the plan and budget as appropriate;

(G) ensure that the plan and budget serve as a broad, binding statement of policies regarding minority health disparities research and other health disparities research activities of the agencies, but do not remove the responsibility of the heads of the agencies for the approval of specific programs or projects, or for other details of the daily administration of such activities, in accordance with the plan and budget; and

(H) promote coordination and collaboration among the agencies conducting or supporting minority health or other health disparities research.

(2) Certain components of plan and budget

With respect to health disparities research activities of the agencies of the National Institutes of Health, the Director of the Institute shall ensure that the plan and budget under paragraph (1) provide for—

(A) basic research and applied research, including research and development with respect to products;

(B) research that is conducted by the agencies;

(C) research that is supported by the agencies;

(D) proposals developed pursuant to solicitations by the agencies and for proposals developed independently of such solicitations; and

(E) behavioral research and social sciences research, which may include cultural and linguistic research in each of the agencies.

(3) Minority health disparities research

The plan and budget under paragraph (1) shall include a separate statement of the plan and budget for minority health disparities research.

(g) Participation in clinical research

The Director of the Institute shall work with the Director of NIH and the directors of the agencies of the National Institutes of Health to carry out the provisions of section 289a–2 of this title that relate to minority groups.

(h) Research endowments

(1) In general

The Director of the Institute may carry out a program to facilitate minority health disparities research and other health disparities research by providing for research endowments—

(A) at current or former centers of excellence under section 293 of this title; and

(B) at current or former centers of excellence under section 285t–1 of this title.

(2) Eligibility

The Director of the Institute may provide for a research endowment under paragraph (1) only if the institution involved meets the following conditions:

(A) The institution does not have an endowment that is worth in excess of an amount equal to 50 percent of the national median of endowment funds at institutions that conduct similar biomedical research or training of health professionals.

(B) The application of the institution under paragraph (1) regarding a research endowment

has been recommended pursuant to technical and scientific peer review and has been approved by the advisory council under subsection (j).

(i) Certain activities

In carrying out subsection (a), the Director of the Institute—

(1) shall assist the Director of NIH in carrying out section 283k(c)(2) of this title and in committing resources for construction at Institutions of Emerging Excellence under such section;

(2) shall establish projects to promote cooperation among Federal agencies, State, local, tribal, and regional public health agencies, and private entities in health disparities research; and

(3) may utilize information from previous health initiatives concerning minorities and other health disparity populations.

(j) Advisory council

(1) In general

The Secretary shall, in accordance with section 284a of this title, establish an advisory council to advise, assist, consult with, and make recommendations to the Director of the Institute on matters relating to the activities described in subsection (a), and with respect to such activities to carry out any other functions described in section 284a of this title for advisory councils under such section. Functions under the preceding sentence shall include making recommendations on budgetary allocations made in the plan under subsection (f), and shall include reviewing reports under subsection (k) before the reports are submitted under such subsection.

(2) Membership

With respect to the membership of the advisory council under paragraph (1), a majority of the members shall be individuals with demonstrated expertise regarding minority health disparity and other health disparity issues; representatives of communities impacted by minority and other health disparities shall be included; and a diversity of health professionals shall be represented. The membership shall in addition include a representative of the Office of Behavioral and Social Sciences Research under section 283c of this title.

(k) Intra-National Institutes of Health coordination

The Director of the Institute, as the primary Federal official with responsibility for coordinating all research and activities conducted or supported by the National Institutes of Health on minority health and health disparities, shall plan, coordinate, review, and evaluate research and other activities conducted or supported by the national research institutes and national centers. The Director of the Institute may foster partnerships between the national research institutes and national centers and may encourage the funding of collaborative research projects to achieve the goals of the National Institutes of Health that are related to minority health and health disparities.

(July 1, 1944, ch. 373, title IV, §464z–3, formerly §485E, as added Pub. L. 106–525, title I, §101(a), Nov. 22, 2000, 114 Stat. 2497; amended Pub. L. 109–482, title I, §§103(b)(44), 104(b)(1)(N), Jan. 15, 2007, 120 Stat. 3688, 3693; renumbered §464z–3 and amended Pub. L. 111–148, title X, §10334(c)(1)(D), (2), Mar. 23, 2010, 124 Stat. 973; Pub. L. 112–74, div. F, title II, §221(d)(3), Dec. 23, 2011, 125 Stat. 1090; Pub. L. 114–255, div. A, title II, §2038(f), Dec. 13, 2016, 130 Stat. 1066; Pub. L. 117–104, §2, Mar. 18, 2022, 136 Stat. 1117.)

EDITORIAL NOTES

CODIFICATION

Section was formerly classified to section 287c–31 of this title prior to renumbering by Pub. L. 111–148.

AMENDMENTS

2022—Subsec. (h)(1). Pub. L. 117–104 amended par. (1) generally. Prior to amendment, text read as follows: "The Director of the Institute may carry out a program to facilitate minority health disparities research and other health disparities research by providing for research endowments—

"(1) at centers of excellence under section 293 of this title; and

"(2) at centers of excellence under section 285t–1 of this title."

2016—Subsec. (h). Pub. L. 114–255, §2038(f)(1), redesignated subsec. (h) relating to interagency coordination as (k).

Subsec. (k). Pub. L. 114–255 redesignated subsec. (h) relating to interagency coordination as (k), in heading substituted "Intra-National Institutes of Health" for "Interagency", in text substituted "as the primary Federal official" for "as the primary Federal officials" and "national research institutes and national centers" for "Institutes and Centers of the National Institutes of Health", inserted a comma after "review", and inserted at end "The Director of the Institute may foster partnerships between the national research institutes and national centers and may encourage the funding of collaborative research projects to achieve the goals of the National Institutes of Health that are related to minority health and health disparities."

2011—Subsec. (i)(1). Pub. L. 112–74 substituted "Director of NIH" for "Director of the National Institute for Research Resources" and "283k(c)(2)" for "287a–1(c)(3)" and inserted "under such section" after "Institutions of Emerging Excellence".

2010—Pub. L. 111–148, §10334(c)(1)(D)(iii), substituted "Institute" for "Center" in section catchline.

Subsec. (a). Pub. L. 111–148, §10334(c)(1)(D)(ii), (iii), substituted "National Institute on Minority Health and Health Disparities" for "National Center on Minority Health and Health Disparities" and "Institute" for "Center".

Subsecs. (b), (d) to (g). Pub. L. 111–148, §10334(c)(1)(D)(iii), substituted "Institute" for "Center" wherever appearing.

Subsec. (h). Pub. L. 111–148, §10334(c)(2)(C), added at end subsec. (h) relating to interagency coordination.

Subsec. (h)(1). Pub. L. 111–148, §10334(c)(2)(A), in par. (1) of subsec. (h) relating to research endowments, substituted "research endowments—

"(1) at centers of excellence under section 293 of this title; and

"(2) at centers of excellence under section 285t–1 of this title."

for "research endowments at centers of excellence under section 293 of this title."

Pub. L. 111–148, §10334(c)(1)(D)(iii), in par. (1) of subsec. (h) relating to research endowments, substituted "Institute" for "Center".

Subsec. (h)(2). Pub. L. 111–148, §10334(c)(1)(D)(iii), in par. (2) of subsec. (h) relating to research endowments, substituted "Institute" for "Center" in introductory provisions.

Subsec. (h)(2)(A). Pub. L. 111–148, §10334(c)(2)(B), in par. (2)(A) of subsec. (h) relating to research endowments, substituted "median" for "average".

Subsecs. (i), (j). Pub. L. 111–148, §10334(c)(1)(D)(iii), substituted "Institute" for "Center" wherever appearing.

2007—Subsec. (k). Pub. L. 109–482, §104(b)(1)(N), struck out heading and text of subsec. (k). Text read as follows: "The Director of the Center shall prepare an annual report on the activities carried out or to be carried out by the Center, and shall submit each such report to the Committee on Health, Education, Labor, and Pensions of the Senate, the Committee on Commerce of the House of Representatives, the Secretary, and the Director of NIH. With respect to the fiscal year involved, the report shall—

"(1) describe and evaluate the progress made in health disparities research conducted or supported by the national research institutes;

"(2) summarize and analyze expenditures made for activities with respect to health disparities research conducted or supported by the National Institutes of Health;

"(3) include a separate statement applying the requirements of paragraphs (1) and (2) specifically to minority health disparities research; and

"(4) contain such recommendations as the Director considers appropriate."

Subsec. (l). Pub. L. 109–482, §103(b)(44), struck out heading and text of subsec. (l). Text read as follows: "For the purpose of carrying out this subpart, there are authorized to be appropriated $100,000,000 for fiscal year 2001, and such sums as may be necessary for each of the fiscal years 2002 through 2005. Such authorization of appropriations is in addition to other authorizations of appropriations that are available for the conduct and support of minority health disparities research or other health disparities research by the agencies of the National Institutes of Health."

STATUTORY NOTES AND RELATED SUBSIDIARIES

EFFECTIVE DATE OF 2007 AMENDMENT

Amendment by Pub. L. 109–482 applicable only with respect to amounts appropriated for fiscal year 2007 or subsequent fiscal years, see section 109 of Pub. L. 109–482, set out as a note under section 281 of this title.

FINDINGS

Pub. L. 106–525, §2, Nov. 22, 2000, 114 Stat. 2495, provided that: "The Congress finds as follows:

"(1) Despite notable progress in the overall health of the Nation, there are continuing disparities in the burden of illness and death experienced by African Americans, Hispanics, Native Americans, Alaska Natives, and Asian Pacific Islanders, compared to the United States population as a whole.

"(2) The largest numbers of the medically underserved are white individuals, and many of them have the same health care access problems as do members of minority groups. Nearly 20,000,000 white individuals live below the poverty line with many living in nonmetropolitan, rural areas such as Appalachia, where the high percentage of counties designated as health professional shortage areas (47 percent) and the high rate of poverty contribute to disparity outcomes. However, there is a higher proportion of racial and ethnic minorities in the United States represented among the medically underserved.

"(3) There is a national need for minority scientists in the fields of biomedical, clinical, behavioral, and health services research. Ninety percent of minority physicians educated at Historically Black Medical Colleges live and serve in minority communities.

"(4) Demographic trends inspire concern about the Nation's ability to meet its future scientific, technological, and engineering workforce needs. Historically, non-Hispanic white males have made up the majority of the United States scientific, technological, and engineering workers.

"(5) The Hispanic and Black population will increase significantly in the next 50 years. The scientific, technological, and engineering workforce may decrease if participation by underrepresented minorities remains the same.

"(6) Increasing rates of Black and Hispanic workers can help ensure a strong scientific, technological, and engineering workforce.

"(7) Individuals such as underrepresented minorities and women in the scientific, technological, and engineering workforce enable society to address its diverse needs.

"(8) If there had not been a substantial increase in the number of science and engineering degrees awarded to women and underrepresented minorities over the past few decades, the United States would be facing even greater shortages in scientific, technological, and engineering workers.

"(9) In order to effectively promote a diverse and strong 21st century scientific, technological, and engineering workforce, Federal agencies should expand or add programs that effectively overcome barriers such as educational transition from one level to the next and student requirements for financial resources.

"(10) Federal agencies should work in concert with the private nonprofit sector to emphasize the recruitment and retention of qualified individuals from ethnic and gender groups that are currently underrepresented in the scientific, technological, and engineering workforce.

"(11) Behavioral and social sciences research has increased awareness and understanding of factors associated with health care utilization and access, patient attitudes toward health services, and risk and protective behaviors that affect health and illness. These factors have the potential to then be modified to help close the health disparities gap among ethnic minority populations. In addition, there is a shortage of minority behavioral science researchers and behavioral health care professionals. According to the National Science Foundation, only 15.5 percent of behavioral research-oriented psychology doctorate degrees were awarded to minority students in 1997. In addition, only 17.9 percent of practice-oriented psychology doctorate degrees were awarded to ethnic minorities."

PUBLIC AWARENESS AND DISSEMINATION OF INFORMATION ON HEALTH DISPARITIES

Pub. L. 106–525, title V, §501, Nov. 22, 2000, 114 Stat. 2510, provided that:

"(a) PUBLIC AWARENESS ON HEALTH DISPARITIES.—The Secretary of Health and Human Services (in this section referred to as the 'Secretary') shall conduct a national campaign to inform the public and health care professionals about health disparities in minority and other underserved populations by disseminating information and materials available on specific diseases affecting these populations and programs and activities to address these disparities. The campaign shall—

"(1) have a specific focus on minority and other underserved communities with health disparities; and

"(2) include an evaluation component to assess the impact of the national campaign in raising awareness of health disparities and information on available resources.

"(b) DISSEMINATION OF INFORMATION ON HEALTH DISPARITIES.—The Secretary shall develop and implement a plan for the dissemination of information and findings with respect to health disparities under titles I, II, III, and IV of this Act [see Tables for classification]. The plan shall—

"(1) include the participation of all agencies of the Department of Health and Human Services that are responsible for serving populations included in the health disparities research; and

"(2) have agency-specific strategies for disseminating relevant findings and information on health

disparities and improving health care services to affected communities."

TERMINATION OF ADVISORY COUNCILS

Advisory councils established after Jan. 5, 1973, to terminate not later than the expiration of the 2-year period beginning on the date of their establishment, unless, in the case of a council established by the President or an officer of the Federal Government, such council is renewed by appropriate action prior to the expiration of such 2-year period, or in the case of a council established by Congress, its duration is otherwise provided by law. See sections 1001(2) and 1013 of Title 5, Government Organization and Employees.

Pub. L. 93–641, §6, Jan. 4, 1975, 88 Stat. 2275, set out as a note under section 217a of this title, provided that an advisory committee established pursuant to the Public Health Service Act shall terminate at such time as may be specifically prescribed by an Act of Congress enacted after Jan. 4, 1975.

§285t–1. Centers of excellence for research education and training

(a) In general

The Director of the Institute shall make awards of grants or contracts to designated biomedical and behavioral research institutions under paragraph (1) of subsection (c), or to consortia under paragraph (2) of such subsection, for the purpose of assisting the institutions in supporting programs of excellence in biomedical and behavioral research training for individuals who are members of minority health disparity populations or other health disparity populations.

(b) Required use of funds

An award may be made under subsection (a) only if the applicant involved agrees that the grant will be expended—

(1) to train members of minority health disparity populations or other health disparity populations as professionals in the area of biomedical or behavioral research or both; or

(2) to expand, remodel, renovate, or alter existing research facilities or construct new research facilities for the purpose of conducting minority health disparities research and other health disparities research.

(c) Centers of excellence

(1) In general

For purposes of this section, a designated biomedical and behavioral research institution is a biomedical and behavioral research institution that—

(A) has a significant number of members of minority health disparity populations or other health disparity populations enrolled as students in the institution (including individuals accepted for enrollment in the institution);

(B) has been effective in assisting such students of the institution to complete the program of education or training and receive the degree involved;

(C) has made significant efforts to recruit minority students to enroll in and graduate from the institution, which may include providing means-tested scholarships and other financial assistance as appropriate; and

(D) has made significant recruitment efforts to increase the number of minority or other members of health disparity populations serving in faculty or administrative positions at the institution.

(2) Consortium

Any designated biomedical and behavioral research institution involved may, with other biomedical and behavioral institutions (designated or otherwise), including tribal health programs, form a consortium to receive an award under subsection (a).

(3) Application of criteria to other programs

In the case of any criteria established by the Director of the Institute for purposes of determining whether institutions meet the conditions described in paragraph (1), this section may not, with respect to minority health disparity populations or other health disparity populations, be

construed to authorize, require, or prohibit the use of such criteria in any program other than the program established in this section.

(d) Duration of grant

The period during which payments are made under a grant under subsection (a) may not exceed 5 years. Such payments shall be subject to annual approval by the Director of the Institute and to the availability of appropriations for the fiscal year involved to make the payments.

(e) Maintenance of effort

(1) In general

With respect to activities for which an award under subsection (a) is authorized to be expended, the Director of the Institute may not make such an award to a designated research institution or consortium for any fiscal year unless the institution, or institutions in the consortium, as the case may be, agree to maintain expenditures of non-Federal amounts for such activities at a level that is not less than the level of such expenditures maintained by the institutions involved for the fiscal year preceding the fiscal year for which such institutions receive such an award.

(2) Use of Federal funds

With respect to any Federal amounts received by a designated research institution or consortium and available for carrying out activities for which an award under subsection (a) is authorized to be expended, the Director of the Institute may make such an award only if the institutions involved agree that the institutions will, before expending the award, expend the Federal amounts obtained from sources other than the award.

(f) Certain expenditures

The Director of the Institute may authorize a designated biomedical and behavioral research institution to expend a portion of an award under subsection (a) for research endowments.

(g) Definitions

For purposes of this section:

(1) The term "designated biomedical and behavioral research institution" has the meaning indicated for such term in subsection (c)(1). Such term includes any health professions school receiving an award of a grant or contract under section 293 of this title.

(2) The term "program of excellence" means any program carried out by a designated biomedical and behavioral research institution with an award under subsection (a), if the program is for purposes for which the institution involved is authorized in subsection (b) to expend the grant.

(July 1, 1944, ch. 373, title IV, §464z–4, formerly §485F, as added Pub. L. 106–525, title I, §102, Nov. 22, 2000, 114 Stat. 2501; amended Pub. L. 109–482, title I, §103(b)(45), Jan. 15, 2007, 120 Stat. 3688; renumbered §464z–4 and amended Pub. L. 111–148, title X, §10334(c)(1)(D)(i), (iii), Mar. 23, 2010, 124 Stat. 973.)

EDITORIAL NOTES

CODIFICATION

Section was formerly classified to section 287c–32 of this title prior to renumbering by Pub. L. 111–148.

AMENDMENTS

2010—Subsecs. (a), (c)(3) to (f). Pub. L. 111–148, §10334(c)(1)(D)(iii), substituted "Institute" for "Center" wherever appearing.

2007—Subsec. (h). Pub. L. 109–482 struck out heading and text of subsec. (h). Text read as follows: "For the purpose of making grants under subsection (a) of this section, there are authorized to be appropriated such sums as may be necessary for each of the fiscal years 2001 through 2005."

STATUTORY NOTES AND RELATED SUBSIDIARIES

EFFECTIVE DATE OF 2007 AMENDMENT

Amendment by Pub. L. 109–482 applicable only with respect to amounts appropriated for fiscal year 2007 or subsequent fiscal years, see section 109 of Pub. L. 109–482, set out as a note under section 281 of this title.

§285t–2. Repealed. Pub. L. 114–255, div. A, title II, §2022(c)(1), Dec. 13, 2016, 130 Stat. 1054

Section, July 1, 1944, ch. 373, title IV, §464z–5, formerly §485G, as added Pub. L. 106–525, title I, §103, Nov. 22, 2000, 114 Stat. 2503; amended Pub. L. 109–482, title I, §103(b)(46), Jan. 15, 2007, 120 Stat. 3688; renumbered §464z–5 and amended Pub. L. 111–148, title X, §10334(c)(1)(D)(i), (iii), Mar. 23, 2010, 124 Stat. 973, related to loan repayment program for minority health disparities research.

§285t–3. General provisions regarding the Institute

The Secretary, acting through the Director of the National Institutes of Health, shall provide administrative support and support services to the Director of the Institute and shall ensure that such support takes maximum advantage of existing administrative structures at the agencies of the National Institutes of Health.

(July 1, 1944, ch. 373, title IV, §464z–6, formerly §485H, as added Pub. L. 106–525, title I, §104, Nov. 22, 2000, 114 Stat. 2503; amended Pub. L. 109–482, title I, §104(b)(1)(O), Jan. 15, 2007, 120 Stat. 3693; renumbered §464z–6 and amended Pub. L. 111–148, title X, §10334(c)(1)(D)(i), (iii), Mar. 23, 2010, 124 Stat. 973.)

EDITORIAL NOTES

CODIFICATION

Section was formerly classified to section 287c–34 of this title prior to renumbering by Pub. L. 111–148.

AMENDMENTS

2010—Pub. L. 111–148, §10334(c)(1)(D)(iii), substituted "Institute" for "Center" in section catchline and text.

2007—Pub. L. 109–482 struck out subsec. (a) designation and heading before "The Secretary" and struck out subsec. (b) which related to evaluation of this subpart not later than 5 years after Nov. 22, 2000, and report on such evaluation not later than 1 year after its commencement.

STATUTORY NOTES AND RELATED SUBSIDIARIES

EFFECTIVE DATE OF 2007 AMENDMENT

Amendment by Pub. L. 109–482 applicable only with respect to amounts appropriated for fiscal year 2007 or subsequent fiscal years, see section 109 of Pub. L. 109–482, set out as a note under section 281 of this title.

PART D—NATIONAL LIBRARY OF MEDICINE

SUBPART 1—GENERAL PROVISIONS

§286. National Library of Medicine

(a) Purpose and establishment

In order to assist the advancement of medical and related sciences and to aid the dissemination and exchange of scientific and other information important to the progress of medicine and to the public health, there is established the National Library of Medicine (hereafter in this part referred to as the "Library").

(b) Functions

The Secretary, through the Library and subject to subsection (d), shall—

(1) acquire and preserve books, periodicals, prints, films, recordings, and other library materials pertinent to medicine;

(2) organize the materials specified in paragraph (1) by appropriate cataloging, indexing, and bibliographical listings;

(3) publish and disseminate the catalogs, indexes, and bibliographies referred to in paragraph (2);

(4) make available, through loans, photographic or other copying procedures, or otherwise, such materials in the Library as the Secretary determines appropriate;

(5) provide reference and research assistance;

(6) publicize the availability from the Library of the products and services described in any of paragraphs (1) through (5);

(7) promote the use of computers and telecommunications by health professionals (including health professionals in rural areas) for the purpose of improving access to biomedical information for health care delivery and medical research; and

(8) engage in such other activities as the Secretary determines appropriate and as the Library's resources permit.

(c) Exchange, destruction, or disposal of materials not needed

The Secretary may exchange, destroy, or otherwise dispose of any books, periodicals, films, and other library materials not needed for the permanent use of the Library.

(d) Availability of publications, materials, facilities, or services; prescription of rules

(1) The Secretary may, after obtaining the advice and recommendations of the Board of Regents, prescribe rules under which the Library will—

(A) provide copies of its publications or materials,

(B) will make available its facilities for research, or

(C) will make available its bibliographic, reference, or other services,

to public and private entities and individuals.

(2) Rules prescribed under paragraph (1) may provide for making available such publications, materials, facilities, or services—

(A) without charge as a public service,

(B) upon a loan, exchange, or charge basis, or

(C) in appropriate circumstances, under contract arrangements made with a public or other nonprofit entity.

(e) Regional medical libraries; establishment

Whenever the Secretary, with the advice of the Board of Regents, determines that—

(1) in any geographic area of the United States there is no regional medical library adequate to serve such area;

(2) under criteria prescribed for the administration of section 286b–6 of this title, there is a need for a regional medical library to serve such area; and

(3) because there is no medical library located in such area which, with financial assistance under section 286b–6 of this title, can feasibly be developed into a regional medical library adequate to serve such area,

the Secretary may establish, as a branch of the Library, a regional medical library to serve the needs of such area.

(f) Acceptance and administration of gifts; memorials

Section 238 of this title shall be applicable to the acceptance and administration of gifts made for the benefit of the Library or for carrying out any of its functions, and the Board of Regents shall make recommendations to the Secretary relating to establishment within the Library of suitable memorials to the donors.

(g) "Medicine" and "medical" defined

For purposes of this part, the terms "medicine" and "medical", except when used in section 286a of this title, include preventive and therapeutic medicine, dentistry, pharmacy, hospitalization, nursing, public health, and the fundamental sciences related thereto, and other related fields of study, research, or activity.

(July 1, 1944, ch. 373, title IV, §465, as added Pub. L. 99–158, §2, Nov. 20, 1985, 99 Stat. 857; amended Pub. L. 99–660, title III, §311(b)(1), Nov. 14, 1986, 100 Stat. 3779; Pub. L. 100–202, §101(h) [title II, §215], Dec. 22, 1987, 101 Stat. 1329–256, 1329–275; Pub. L. 100–607, title II, §204(2), Nov. 4, 1988, 102 Stat. 3079; Pub. L. 100–690, title II, §2620(b)(1), Nov. 18, 1988, 102 Stat. 4244; Pub. L. 101–381, title I, §102(2), Aug. 18, 1990, 104 Stat. 585; Pub. L. 103–43, title XIV, §1401(a), (c)(1), title XX, §2010(b)(3), June 10, 1993, 107 Stat. 170, 214.)

EDITORIAL NOTES

AMENDMENTS

1993—Pub. L. 103–43, §1401(c)(1), repealed amendment by Pub. L. 100–202. See 1987 Amendment note below.

Subsec. (b)(6) to (8). Pub. L. 103–43, §1401(a), added pars. (6) and (7) and redesignated former par. (6) as (8).

Subsec. (f). Pub. L. 103–43, §2010(b)(3), substituted "Section 238" for "Section 300aaa".

1990—Subsec. (f). Pub. L. 101–381 made technical amendment to reference to section 300aaa of this title to reflect renumbering of corresponding section of original act.

1988—Subsec. (f). Pub. L. 100–690 made technical amendment to reference to section 300aaa of this title to reflect renumbering of corresponding section of original act.

Pub. L. 100–607 substituted "300aaa" for "300cc".

1987—Pub. L. 100–202, which directed the amendment of "Section 465(B) of 42 U.S.C. 286" by inserting "between (5) and (6) an additional charge to the Secretary to 'publicize the availability of the above products and services of the National Library of Medicine' ", was repealed by Pub. L. 103–43, §1401(c)(1).

1986—Subsec. (f). Pub. L. 99–660 substituted "section 300cc of this title" for "section 300aa of this title".

STATUTORY NOTES AND RELATED SUBSIDIARIES

EFFECTIVE DATE OF 1988 AMENDMENT

Amendment by Pub. L. 100–690 effective immediately after enactment of Pub. L. 100–607, which was approved Nov. 4, 1988, see section 2600 of Pub. L. 100–690, set out as a note under section 242m of this title.

EFFECTIVE DATE OF 1986 AMENDMENT

Amendment by Pub. L. 99–660 effective Dec. 22, 1987, see section 323 of Pub. L. 99–660, as amended, set out as an Effective Date note under section 300aa–1 of this title.

APPLICABILITY OF CERTAIN NEW AUTHORITY

Pub. L. 103–43, title XIV, §1401(c)(2), June 10, 1993, 107 Stat. 170, provided that: "With respect to the authority established for the National Library of Medicine in section 465(b)(6) of the Public Health Service Act, as added by subsection (a) of this section [42 U.S.C. 286(b)(6)], such authority shall be effective as if the authority had been established on December 22, 1987."

§286a. Board of Regents

(a) Membership; ex officio members

(1)(A) The Board of Regents of the National Library of Medicine consists of ex officio members and ten members appointed by the Secretary.

(B) The ex officio members are the Surgeons General of the Public Health Service, the Army, the Navy, and the Air Force, the Under Secretary for Health of the Department of Veterans Affairs, the Dean of the Uniformed Services University of the Health Sciences, the Assistant Director for Biological, Behavioral, and Social Sciences of the National Science Foundation, the Director of the National Agricultural Library, and the Librarian of Congress (or their designees).

(C) The appointed members shall be selected from among leaders in the various fields of the fundamental sciences, medicine, dentistry, public health, hospital administration, pharmacology, health communications technology, or scientific or medical library work, or in public affairs. At least six of the appointed members shall be selected from among leaders in the fields of medical, dental, or public health research or education.

(2) The Board shall annually elect one of the appointed members to serve as chairman until the next election. The Secretary shall designate a member of the Library staff to act as executive secretary of the Board.

(b) Recommendations on matters of policy; recommendations included in annual report; use of services of members by Secretary

The Board shall advise, consult with, and make recommendations to the Secretary on matters of policy in regard to the Library, including such matters as the acquisition of materials for the Library, the scope, content, and organization of the Library's services, and the rules under which its materials, publications, facilities, and services shall be made available to various kinds of users. The Secretary shall include in the annual report of the Secretary to the Congress a statement covering the recommendations made by the Board and the disposition thereof. The Secretary may use the services of any member of the Board in connection with matters related to the work of the Library, for such periods, in addition to conference periods, as the Secretary may determine.

(c) Term of office; vacancy; reappointment

Each appointed member of the Board shall hold office for a term of four years, except that any member appointed to fill a vacancy occurring prior to the expiration of the term for which the predecessor of such member was appointed shall be appointed for the remainder of such term. None of the appointed members shall be eligible for reappointment within one year after the end of the preceding term of such member.

(July 1, 1944, ch. 373, title IV, §466, as added Pub. L. 99–158, §2, Nov. 20, 1985, 99 Stat. 859; amended Pub. L. 102–405, title III, §302(e)(1), Oct. 9, 1992, 106 Stat. 1985; Pub. L. 103–43, title XX, §2008(b)(11), June 10, 1993, 107 Stat. 211.)

EDITORIAL NOTES

AMENDMENTS

1993—Subsec. (a)(1)(B). Pub. L. 103–43 substituted "Department of Veterans Affairs" for "Veterans' Administration".

1992—Subsec. (a)(1)(B). Pub. L. 102–405 substituted "Under Secretary for Health" for "Chief Medical Director".

§286a–1. Library facilities

The Administrator of General Services may acquire, by purchase, condemnation, donation, or otherwise, a suitable site or sites, selected by the Secretary in accordance with the direction of the Board, for suitable and adequate buildings and facilities for use of the Library and to erect thereon, furnish, and equip such buildings and facilities. Amounts appropriated to carry out this section may be used for the cost of preparation of drawings and specifications, supervision of construction, and

other administrative expenses incident to the work. The Administrator of General Services shall prepare the plans and specifications, make all necessary contracts, and supervise construction.

(July 1, 1944, ch. 373, title IV, §467, as added Pub. L. 99–158, §2, Nov. 20, 1985, 99 Stat. 859; amended Pub. L. 109–482, title I, §103(b)(38), Jan. 15, 2007, 120 Stat. 3688.)

EDITORIAL NOTES

AMENDMENTS

2007—Pub. L. 109–482 substituted "for suitable and adequate buildings and facilities for use of the Library" for "for such buildings and facilities" and "Amounts appropriated to carry out this section may be used for" for "The amounts authorized to be appropriated by this section include" and struck out first sentence which read as follows: "There are authorized to be appropriated amounts sufficient for the erection and equipment of suitable and adequate buildings and facilities for use of the Library."

STATUTORY NOTES AND RELATED SUBSIDIARIES

EFFECTIVE DATE OF 2007 AMENDMENT

Amendment by Pub. L. 109–482 applicable only with respect to amounts appropriated for fiscal year 2007 or subsequent fiscal years, see section 109 of Pub. L. 109–482, set out as a note under section 281 of this title.

§286a–2. Repealed. Pub. L. 109–482, title I, §103(b)(39), Jan. 15, 2007, 120 Stat. 3688

Section, act July 1, 1944, ch. 373, title IV, §468, as added Pub. L. 103–43, title XIV, §1402(a), June 10, 1993, 107 Stat. 170, authorized appropriations for this part.

STATUTORY NOTES AND RELATED SUBSIDIARIES

EFFECTIVE DATE OF REPEAL

Repeal applicable only with respect to amounts appropriated for fiscal year 2007 or subsequent fiscal years, see section 109 of Pub. L. 109–482, set out as an Effective Date of 2007 Amendment note under section 281 of this title.

SUBPART 2—FINANCIAL ASSISTANCE

§286b. Repealed. Pub. L. 103–43, title XIV, §1402(b), June 10, 1993, 107 Stat. 171

Section, act July 1, 1944, ch. 373, title IV, §469, as added Nov. 20, 1985, Pub. L. 99–158, §2, 99 Stat. 860; amended Nov. 4, 1988, Pub. L. 100–607, title I, §146(a), 102 Stat. 3058, authorized appropriations for grants and contracts under sections 286b–3 through 286b–7 of this title.

§286b–1. Definitions

As used in this subpart—

(1) the term "medical library" means a library related to the sciences related to health; and

(2) the term "sciences related to health" includes medicine, osteopathy, dentistry, and public health, and fundamental and applied sciences when related thereto.

(July 1, 1944, ch. 373, title IV, §470, as added Pub. L. 99–158, §2, Nov. 20, 1985, 99 Stat. 860.)

§286b–2. National Medical Libraries Assistance Advisory Board

(a) Board of Regents of National Library of Medicine to serve as

The Board of Regents of the National Library of Medicine shall also serve as the National Medical Libraries Assistance Advisory Board (hereafter in this subpart referred to as the "Board").

(b) Functions

The Board shall advise and assist the Secretary in the preparation of general regulations and with respect to policy matters arising in the administration of this subpart.

(c) Use of services of members by Secretary

The Secretary may use the services of any member of the Board, in connection with matters related to the administration of this part for such periods, in addition to conference periods, as the Secretary may determine.

(d) Compensation

Appointed members of the Board who are not otherwise in the employ of the United States, while attending conferences of the Board or otherwise serving at the request of the Secretary in connection with the administration of this subpart, shall be entitled to receive compensation, per diem in lieu of subsistence, and travel expenses in the same manner and under the same conditions as that prescribed under section 210(c) of this title when attending conferences, traveling, or serving at the request of the Secretary in connection with the Board's function under this section.

(July 1, 1944, ch. 373, title IV, §471, as added Pub. L. 99–158, §2, Nov. 20, 1985, 99 Stat. 860.)

STATUTORY NOTES AND RELATED SUBSIDIARIES

TERMINATION OF ADVISORY BOARDS

Advisory boards established after Jan. 5, 1973, to terminate not later than the expiration of the 2-year period beginning on the date of their establishment, unless, in the case of a board established by the President or an officer of the Federal Government, such board is renewed by appropriate action prior to the expiration of such 2-year period, or in the case of a board established by the Congress, its duration is otherwise provided by law. See sections 1001(2) and 1013 of Title 5, Government Organization and Employees.

Pub. L. 93–641, §6, Jan. 4, 1975, 88 Stat. 2275, set out as a note under section 217a of this title, provided that an advisory committee established pursuant to the Public Health Service Act shall terminate at such time as may be specifically prescribed by an Act of Congress enacted after Jan. 4, 1975.

§286b–3. Grants for training in medical library sciences

The Secretary shall make grants—

(1) to individuals to enable them to accept traineeships and fellowships leading to postbaccalaureate academic degrees in the field of medical library science, in related fields pertaining to sciences related to health, or in the field of the communication of information;

(2) to individuals who are librarians or specialists in information on sciences relating to health, to enable them to undergo intensive training or retraining so as to attain greater competence in their occupations (including competence in the fields of automatic data processing and retrieval);

(3) to assist appropriate public and private nonprofit institutions in developing, expanding, and improving training programs in library science and the field of communications of information pertaining to sciences relating to health; and

(4) to assist in the establishment of internship programs in established medical libraries meeting standards which the Secretary shall prescribe.

(July 1, 1944, ch. 373, title IV, §472, as added Pub. L. 99–158, §2, Nov. 20, 1985, 99 Stat. 860.)

§286b–4. Assistance for projects in sciences related to health, for research and

development in medical library science, and for development of education technologies

(a) Compilation of existing and original writings on health

The Secretary shall make grants to physicians and other practitioners in the sciences related to health, to scientists, and to public or nonprofit private institutions on behalf of such physicians, other practitioners, and scientists for the compilation of existing, or the writing of original, contributions relating to scientific, social, or cultural advancements in sciences related to health. In making such grants, the Secretary shall make appropriate arrangements under which the facilities of the Library and the facilities of libraries of public and private nonprofit institutions of higher learning may be made available in connection with the projects for which such grants are made.

(b) Medical library science and related activities

The Secretary shall make grants to appropriate public or private nonprofit institutions and enter into contracts with appropriate persons, for purposes of carrying out projects of research, investigations, and demonstrations in the field of medical library science and related activities and for the development of new techniques, systems, and equipment, for processing, storing, retrieving, and distributing information pertaining to sciences related to health.

(c) Development of education technologies

(1) The Secretary shall make grants to public or nonprofit private institutions for the purpose of carrying out projects of research on, and development and demonstration of, new education technologies.

(2) The purposes for which a grant under paragraph (1) may be made include projects concerning—

(A) computer-assisted teaching and testing of clinical competence at health professions and research institutions;

(B) the effective transfer of new information from research laboratories to appropriate clinical applications;

(C) the expansion of the laboratory and clinical uses of computer-stored research databases; and

(D) the testing of new technologies for training health care professionals.

(3) The Secretary may not make a grant under paragraph (1) unless the applicant for the grant agrees to make the projects available with respect to—

(A) assisting in the training of health professions students; and

(B) enhancing and improving the capabilities of health professionals regarding research and teaching.

(July 1, 1944, ch. 373, title IV, §473, as added Pub. L. 99–158, §2, Nov. 20, 1985, 99 Stat. 861; amended Pub. L. 103–43, title XIV, §1411, June 10, 1993, 107 Stat. 171.)

EDITORIAL NOTES

AMENDMENTS

1993—Subsec. (c). Pub. L. 103–43 added subsec. (c).

§286b–5. Grants for establishing, expanding, and improving basic resources of medical libraries and related instrumentalities

(a) The Secretary shall make grants of money, materials, or both, to public or private nonprofit medical libraries and related scientific communication instrumentalities for the purpose of establishing, expanding, and improving their basic medical library or related resources. A grant under this subsection may be used for—

(1) the acquisition of books, journals, photographs, motion picture and other films, and other

similar materials;

(2) cataloging, binding, and other services and procedures for processing library resource materials for use by those who are served by the library or related instrumentality;

(3) the acquisition of duplication devices, facsimile equipment, film projectors, recording equipment, and other equipment to facilitate the use of the resources of the library or related instrumentality by those who are served by it; and

(4) the introduction of new technologies in medical librarianship.

(b)(1) The amount of any grant under this section to any medical library or related instrumentality shall be determined by the Secretary on the basis of the scope of library or related services provided by such library or instrumentality in relation to the population and purposes served by it. In making a determination of the scope of services served by any medical library or related instrumentality, the Secretary shall take into account—

(A) the number of graduate and undergraduate students making use of the resources of such library or instrumentality;

(B) the number of physicians and other practitioners in the sciences related to health utilizing the resources of such library or instrumentality;

(C) the type of supportive staffs, if any, available to such library or instrumentality;

(D) the type, size, and qualifications of the faculty of any school with which such library or instrumentality is affiliated;

(E) the staff of any hospital or hospitals or of any clinic or clinics with which such library or instrumentality is affiliated; and

(F) the geographic area served by such library or instrumentality and the availability within such area of medical library or related services provided by other libraries or related instrumentalities.

(2) Grants to such medical libraries or related instrumentalities under this section shall be in such amounts as the Secretary may by regulation prescribe with a view to assuring adequate continuing financial support for such libraries or instrumentalities from other sources during and after the period for which grants are provided, except that in no case shall any grant under this section to a medical library or related instrumentality for any fiscal year exceed $1,000,000.

(July 1, 1944, ch. 373, title IV, §474, as added Pub. L. 99–158, §2, Nov. 20, 1985, 99 Stat. 861; amended Pub. L. 100–607, title I, §146(b), Nov. 4, 1988, 102 Stat. 3058; Pub. L. 103–43, title XIV, §1401(b), June 10, 1993, 107 Stat. 170.)

EDITORIAL NOTES

AMENDMENTS

1993—Subsec. (b)(2). Pub. L. 103–43 substituted "$1,000,000" for "$750,000".
1988—Subsec. (b)(2). Pub. L. 100–607 substituted "$750,000" for "$500,000".

§286b–6. Grants and contracts for establishment of regional medical libraries

(a) Existing public or private nonprofit medical libraries

The Secretary, with the advice of the Board, shall make grants to and enter into contracts with existing public or private nonprofit medical libraries so as to enable each of them to serve as the regional medical library for the geographical area in which it is located.

(b) Uses for grants and contracts

The uses for which grants and contracts under this section may be employed include the—

(1) acquisition of books, journals, and other similar materials;

(2) cataloging, binding, and other procedures for processing library resource materials for use

by those who are served by the library;

(3) acquisition of duplicating devices and other equipment to facilitate the use of the resources of the library by those who are served by it;

(4) acquisition of mechanisms and employment of personnel for the speedy transmission of materials from the regional library to local libraries in the geographic area served by the regional library; and

(5) planning for services and activities under this section.

(c) Conditions

(1) Grants and contracts under this section shall only be made to or entered into with medical libraries which agree—

(A) to modify and increase their library resources, and to supplement the resources of cooperating libraries in the region, so as to be able to provide adequate supportive services to all libraries in the region as well as to individual users of library services; and

(B) to provide free loan services to qualified users and make available photoduplicated or facsimile copies of biomedical materials which qualified requesters may retain.

(2) The Secretary, in awarding grants and contracts under this section, shall give priority to medical libraries having the greatest potential of fulfilling the needs for regional medical libraries. In determining the priority to be assigned to any medical library, the Secretary shall consider—

(A) the adequacy of the library (in terms of collections, personnel, equipment, and other facilities) as a basis for a regional medical library; and

(B) the size and nature of the population to be served in the region in which the library is located.

(d) Basic resources materials; limitation on grant or contract

Grants and contracts under this section for basic resource materials to a library may not exceed—

(1) 50 percent of the library's annual operating expense (exclusive of Federal financial assistance under this part) for the preceding year; or

(2) in case of the first year in which the library receives a grant under this section for basic resource materials, 50 percent of its average annual operating expenses over the past three years (or if it had been in operation for less than three years, its annual operating expenses determined by the Secretary in accordance with regulations).

(July 1, 1944, ch. 373, title IV, §475, as added Pub. L. 99–158, §2, Nov. 20, 1985, 99 Stat. 862.)

§286b–7. Financial support of biomedical scientific publications

(a) The Secretary, with the advice of the Board, shall make grants to, and enter into appropriate contracts with, public or private nonprofit institutions of higher education and individual scientists for the purpose of supporting biomedical scientific publications of a nonprofit nature and to procure the compilation, writing, editing, and publication of reviews, abstracts, indices, handbooks, bibliographies, and related matter pertaining to scientific works and scientific developments.

(b) Grants under subsection (a) in support of any single periodical publication may not be made for more than three years, except in those cases in which the Secretary determines that further support is necessary to carry out the purposes of subsection (a).

(July 1, 1944, ch. 373, title IV, §476, as added Pub. L. 99–158, §2, Nov. 20, 1985, 99 Stat. 863.)

§286b–8. Grant payments, records, and audit

(a) Payments under grants made under sections 286b–3, 286b–4, 286b–5, 286b–6, and 286b–7 of this title may be made in advance or by way of reimbursement and in such installments as the Secretary shall prescribe by regulation after consultation with the Board.

(b)(1) Each recipient of a grant under this subpart shall keep such records as the Secretary shall

prescribe, including records which fully disclose the amount and disposition by such recipient of the proceeds of such grant, the total cost of the project or undertaking in connection with which such grant is given or used, and the amount of that portion of the cost of the project or undertaking supplied by other sources, and such other records as will facilitate an effective audit.

(2) The Secretary and the Comptroller General of the United States, or any of their duly authorized representatives, shall have access for the purpose of audit and examination to any books, documents, papers, and records of such recipients that are pertinent to any grant received under this subpart.

(July 1, 1944, ch. 373, title IV, §477, as added Pub. L. 99–158, §2, Nov. 20, 1985, 99 Stat. 863.)

SUBPART 3—NATIONAL CENTER FOR BIOTECHNOLOGY INFORMATION

§286c. Purpose, establishment, functions, and funding of National Center for Biotechnology Information

(a) Establishment

In order to focus and expand the collection, storage, retrieval, and dissemination of the results of biotechnology research by information systems, and to support and enhance the development of new information technologies to aid in the understanding of the molecular processes that control health and disease, there is established the National Center for Biotechnology Information (hereinafter in this section referred to as the "Center") in the National Library of Medicine.

(b) Functions

The Secretary, through the Center and subject to section 286(d) of this title, shall—

(1) design, develop, implement, and manage automated systems for the collection, storage, retrieval, analysis, and dissemination of knowledge concerning human molecular biology, biochemistry, and genetics;

(2) perform research into advanced methods of computer-based information processing capable of representing and analyzing the vast number of biologically important molecules and compounds;

(3) enable persons engaged in biotechnology research and medical care to use systems developed under paragraph (1) and methods described in paragraph (2); and

(4) coordinate, as much as is practicable, efforts to gather biotechnology information on an international basis.

(July 1, 1944, ch. 373, title IV, §478, as added Pub. L. 100–607, title I, §105, Nov. 4, 1988, 102 Stat. 3052; amended Pub. L. 103–43, title XIV, §1402(b), June 10, 1993, 107 Stat. 171.)

EDITORIAL NOTES

AMENDMENTS

1993—Subsec. (c). Pub. L. 103–43 struck out subsec. (c) which read as follows: "For the purpose of performing the duties specified in subsection (b) of this section, there are authorized to be appropriated $8,000,000 for fiscal year 1989 and such sums as may be necessary for fiscal year 1990. Funds appropriated under this subsection shall remain available until expended."

SUBPART 4—NATIONAL INFORMATION CENTER ON HEALTH SERVICES RESEARCH AND HEALTH CARE TECHNOLOGY

§286d. National Information Center

(a) Establishment

There is established within the Library an entity to be known as the National Information Center on Health Services Research and Health Care Technology (in this section referred to as the "Center").

(b) Purpose

The purpose of the Center is the collection, storage, analysis, retrieval, and dissemination of information on health services research, clinical practice guidelines, and on health care technology, including the assessment of such technology. Such purpose includes developing and maintaining data bases and developing and implementing methods of carrying out such purpose.

(c) Electronic, convenient format; criteria for inclusion

The Director of the Center shall ensure that information under subsection (b) concerning clinical practice guidelines is collected and maintained electronically and in a convenient format. Such Director shall develop and publish criteria for the inclusion of practice guidelines and technology assessments in the information center database.

(d) Coordination with Director of the Agency for Healthcare Research and Quality

The Secretary, acting through the Center, shall coordinate the activities carried out under this section through the Center with related activities of the Director of the Agency for Healthcare Research and Quality.

(July 1, 1944, ch. 373, title IV, §478A, as added Pub. L. 103–43, title XIV, §1421, June 10, 1993, 107 Stat. 171; amended Pub. L. 106–129, §2(b)(2), Dec. 6, 1999, 113 Stat. 1670.)

EDITORIAL NOTES

AMENDMENTS

1999—Subsec. (d). Pub. L. 106–129 substituted "Director of the Agency for Healthcare Research and Quality" for "Administrator for Health Care Policy and Research".

STATUTORY NOTES AND RELATED SUBSIDIARIES

CONSTRUCTION

Pub. L. 103–43, §1422(b), June 10, 1993, 107 Stat. 172, provided that: "The amendments made by section 3 of Public Law 102–410 (106 Stat. 2094) [amending section 299a–1 of this title], by section 1421 of this Act [enacting this section], and by subsection (a) of this section [amending section 299a–1 of this title] may not be construed as terminating the information center on health care technologies and health care technology assessment established under section 904 of the Public Health Service Act [42 U.S.C. 299a–2], as in effect on the day before the date of the enactment of Public Law 102–410 [Oct. 13, 1992]. Such center shall be considered to be the center established in section 478A of the Public Health Service Act [42 U.S.C. 286d], as added by section 1421 of this Act, and shall be subject to the provisions of such section 478A."

PART E—OTHER AGENCIES OF NIH

SUBPART 1—NATIONAL CENTER FOR ADVANCING TRANSLATIONAL SCIENCES

EDITORIAL NOTES

CODIFICATION

Pub. L. 112–74, div. F, title II, §221(a)(1)(A), Dec. 23, 2011, 125 Stat. 1086, substituted "advancing translational sciences" for "research resources" in subpart heading.

§287. National Center for Advancing Translational Sciences

(a) Purpose

The purpose of the National Center for Advancing Translational Sciences (in this subpart referred to as the "Center") is to advance translational sciences, including by—

(1) coordinating and developing resources that leverage basic research in support of translational science; and

(2) developing partnerships and working cooperatively to foster synergy in ways that do not create duplication, redundancy, and competition with industry activities.

(b) Clinical trial activities

(1) In general

The Center may develop and provide infrastructure and resources for all phases of clinical trials research. Except as provided in paragraph (2), the Center may support clinical trials only through the end of phase IIB.

(2) Exception

The Center may support clinical trial activities through the end of phase III for a treatment for a rare disease or condition (as defined in section 360bb of title 21) so long as—

(A) the Center gives public notice for a period of at least 120 days of the Center's intention to support the clinical trial activities in phase III;

(B) no public or private organization provides credible written intent to the Center that the organization has timely plans to further the clinical trial activities or conduct clinical trials of a similar nature beyond phase IIB; and

(C) the Center ensures that support of the clinical trial activities in phase III will not increase the Federal Government's liability beyond the award value of the Center's support.

(c) Biennial report

The Center shall publish a report on a biennial basis that, with respect to all research supported by the Center, includes a complete list of—

(1) the molecules being studied;

(2) clinical trial activities being conducted;

(3) the methods and tools in development;

(4) ongoing partnerships, including—

(A) the rationale for each partnership;

(B) the status of each partnership;

(C) the funding provided by the Center to other entities pursuant to each partnership, and

(D) the activities which have been transferred to industry pursuant to each partnership;

(5) known research activity of other entities that is or will expand upon research activity of the Center;

(6) the methods and tools, if any, that have been developed since the last biennial report was prepared; and

(7) the methods and tools, if any, that have been developed and are being utilized by the Food and Drug Administration to support medical product reviews.

(d) Inclusion of list

The first biennial report submitted under this section after December 13, 2016, shall include a

complete list of all of the methods and tools, if any, which have been developed by research supported by the Center.

(e) Rule of construction

Nothing in this section shall be construed as authorizing the Secretary to disclose any information that is a trade secret, or other privileged or confidential information subject to section 552(b)(4) of title 5 or section 1905 of title 18.

(July 1, 1944, ch. 373, title IV, §479, as added Pub. L. 99–158, §2, Nov. 20, 1985, 99 Stat. 864; amended Pub. L. 103–43, title XV, §1501(2)(B), June 10, 1993, 107 Stat. 172; Pub. L. 112–74, div. F, title II, §221(a)(1)(C), Dec. 23, 2011, 125 Stat. 1086; Pub. L. 114–255, div. A, title II, §§2037, 2042(e), Dec. 13, 2016, 130 Stat. 1063, 1073.)

EDITORIAL NOTES

AMENDMENTS

2016—Subsec. (b)(1). Pub. L. 114–255, §2037(a)(1), substituted "phase IIB" for "phase IIA".

Subsec. (b)(2). Pub. L. 114–255, §2037(a)(2)(A), substituted "phase III" for "phase IIB" in introductory provisions.

Subsec. (b)(2)(A). Pub. L. 114–255, §2037(a)(2)(B), substituted "phase III" for "phase IIB".

Subsec. (b)(2)(B). Pub. L. 114–255, §2037(a)(2)(C), substituted "phase IIB" for "phase IIA".

Subsec. (b)(2)(C). Pub. L. 114–255, §2037(a)(2)(D), substituted "phase III" for "phase IIB".

Subsec. (c). Pub. L. 114–255, §2042(e), substituted "Biennial" for "Annual" in heading and "a report on a biennial basis" for "an annual report" in introductory provisions.

Subsec. (c)(6), (7). Pub. L. 114–255, §2037(b)(1), added pars. (6) and (7).

Subsecs. (d), (e). Pub. L. 114–255, §2037(b)(2), added subsecs. (d) and (e).

2011—Pub. L. 112–74 amended section generally. Prior to amendment, text read as follows: "The general purpose of the National Center for Research Resources (in this subpart referred to as the 'Center') is to strengthen and enhance the research environments of entities engaged in health-related research by developing and supporting essential research resources."

1993—Pub. L. 103–43 substituted "the National Center for Research Resources (in this subpart referred to as the 'Center')" for "the Division of Research Resources".

STATUTORY NOTES AND RELATED SUBSIDIARIES

SHARED INSTRUMENTATION GRANT PROGRAM

Pub. L. 106–505, title III, §305, Nov. 13, 2000, 114 Stat. 2335, which was formerly set out as a note under this section, was renumbered section 404L of act July 1, 1944, ch. 373, the Public Health Service Act, by Pub. L. 112–74, div. F, title II, §221(b)(4)(A), Dec. 23, 2011, 125 Stat. 1088, and is classified to section 283n of this title.

§287a. Cures Acceleration Network

(a) Definitions

In this section:

(1) Biological product

The term "biological product" has the meaning given such term in section 262 of this title.

(2) Drug; device

The terms "drug" and "device" have the meanings given such terms in section 321 of title 21.

(3) High need cure

The term "high need cure" means a drug (as that term is defined by section 321(g)(1) of title 21, [1] biological product (as that term is defined by section 262(i) [2] of this title), or device (as that term is defined by section 321(h) of title 21) that, in the determination of the Director of the Center—

(A) is a priority to diagnose, mitigate, prevent, or treat harm from any disease or condition; and

(B) for which the incentives of the commercial market are unlikely to result in its adequate or timely development.

(4) Medical product

The term "medical product" means a drug, device, biological product, or product that is a combination of drugs, devices, and biological products.

(b) Establishment of the Cures Acceleration Network

Subject to the appropriation of funds as described in subsection (g), there is established within the Center a program to be known as the Cures Acceleration Network (referred to in this section as "CAN"), which shall—

(1) be under the direction of the Director of the Center, taking into account the recommendations of a CAN Review Board (referred to in this section as the "Board"), described in subsection (d); and

(2) award grants and contracts to eligible entities, as described in subsection (e), to accelerate the development of high need cures, including through the development of medical products and behavioral therapies.

(c) Functions

The functions of the CAN are to—

(1) conduct and support revolutionary advances in basic research, translating scientific discoveries from bench to bedside;

(2) award grants and contracts to eligible entities to accelerate the development of high need cures;

(3) provide the resources necessary for government agencies, independent investigators, research organizations, biotechnology companies, academic research institutions, and other entities to develop high need cures;

(4) reduce the barriers between laboratory discoveries and clinical trials for new therapies; and

(5) facilitate review in the Food and Drug Administration for the high need cures funded by the CAN, through activities that may include—

(A) the facilitation of regular and ongoing communication with the Food and Drug Administration regarding the status of activities conducted under this section;

(B) ensuring that such activities are coordinated with the approval requirements of the Food and Drug Administration, with the goal of expediting the development and approval of countermeasures and products; and

(C) connecting interested persons with additional technical assistance made available under section 360bbb–4 of title 21.

(d) CAN Board

(1) Establishment

There is established a Cures Acceleration Network Review Board (referred to in this section as the "Board"), which shall advise the Director of the Center on the conduct of the activities of the Cures Acceleration Network.

(2) Membership

(A) In general

(i) Appointment

The Board shall be comprised of 24 members who are appointed by the Secretary and who serve at the pleasure of the Secretary.

(ii) Chairperson and Vice Chairperson

The Secretary shall designate, from among the 24 members appointed under clause (i), one

Chairperson of the Board (referred to in this section as the "Chairperson") and one Vice Chairperson.

(B) Terms

(i) In general

Each member shall be appointed to serve a 4-year term, except that any member appointed to fill a vacancy occurring prior to the expiration of the term for which the member's predecessor was appointed shall be appointed for the remainder of such term.

(ii) Consecutive appointments; maximum terms

A member may be appointed to serve not more than 3 terms on the Board, and may not serve more than 2 such terms consecutively.

(C) Qualifications

(i) In general

The Secretary shall appoint individuals to the Board based solely upon the individual's established record of distinguished service in one of the areas of expertise described in clause (ii). Each individual appointed to the Board shall be of distinguished achievement and have a broad range of disciplinary interests.

(ii) Expertise

The Secretary shall select individuals based upon the following requirements:

(I) For each of the fields of—

(aa) basic research;
(bb) medicine;
(cc) biopharmaceuticals;
(dd) discovery and delivery of medical products;
(ee) bioinformatics and gene therapy;
(ff) medical instrumentation; and
(gg) regulatory review and approval of medical products,

the Secretary shall select at least 1 individual who is eminent in such fields.

(II) At least 4 individuals shall be recognized leaders in professional venture capital or private equity organizations and have demonstrated experience in private equity investing.

(III) At least 8 individuals shall represent disease advocacy organizations.

(3) Ex-officio members

(A) Appointment

In addition to the 24 Board members described in paragraph (2), the Secretary shall appoint as ex-officio members of the Board—

(i) a representative of the National Institutes of Health, recommended by the Secretary of the Department of Health and Human Services;

(ii) a representative of the Office of the Assistant Secretary of Defense for Health Affairs, recommended by the Secretary of Defense;

(iii) a representative of the Office of the Under Secretary for Health for the Veterans Health Administration, recommended by the Secretary of Veterans Affairs;

(iv) a representative of the National Science Foundation, recommended by the Chair of the National Science Board; and

(v) a representative of the Food and Drug Administration, recommended by the Commissioner of Food and Drugs.

(B) Terms

Each ex-officio member shall serve a 3-year term on the Board, except that the Chairperson may adjust the terms of the initial ex-officio members in order to provide for a staggered term

of appointment for all such members.

(4) Responsibilities of the Board and the Director of the Center

(A) Responsibilities of the Board

(i) In general

The Board shall advise, and provide recommendations to, the Director of the Center with respect to—

(I) policies, programs, and procedures for carrying out the duties of the Director of the Center under this section; and

(II) significant barriers to successful translation of basic science into clinical application (including issues under the purview of other agencies and departments).

(ii) Report

In the case that the Board identifies a significant barrier, as described in clause (i)(II), the Board shall submit to the Secretary a report regarding such barrier.

(B) Responsibilities of the Director of the Center

With respect to each recommendation provided by the Board under subparagraph (A)(i), the Director of the Center shall respond in writing to the Board, indicating whether such Director will implement such recommendation. In the case that the Director of the Center indicates a recommendation of the Board will not be implemented, such Director shall provide an explanation of the reasons for not implementing such recommendation.

(5) Meetings

(A) In general

The Board shall meet 4 times per calendar year, at the call of the Chairperson.

(B) Quorum; requirements; limitations

(i) Quorum

A quorum shall consist of a total of 13 members of the Board, excluding ex-officio members, with diverse representation as described in clause (iii).

(ii) Chairperson or Vice Chairperson

Each meeting of the Board shall be attended by either the Chairperson or the Vice Chairperson.

(iii) Diverse representation

At each meeting of the Board, there shall be not less than one scientist, one representative of a disease advocacy organization, and one representative of a professional venture capital or private equity organization.

(6) Compensation and travel expenses

(A) Compensation

Members shall receive compensation at a rate to be fixed by the Chairperson but not to exceed a rate equal to the daily equivalent of the annual rate of basic pay prescribed for level IV of the Executive Schedule under section 5315 of title 5 for each day (including travel time) during which the member is engaged in the performance of the duties of the Board. All members of the Board who are officers or employees of the United States shall serve without compensation in addition to that received for their services as officers or employees of the United States.

(B) Travel expenses

Members of the Board shall be allowed travel expenses, including per diem in lieu of subsistence, at rates authorized for persons employed intermittently by the Federal Government under section 5703(b) [3] of title 5, while away from their homes or regular places of business in

the performance of services for the Board.

(e) Grant program

(1) Supporting innovation

To carry out the purposes described in this section, the Director of the Center shall award contracts, grants, or cooperative agreements to the entities described in paragraph (2), to—

(A) promote innovation in technologies supporting the advanced research and development and production of high need cures, including through the development of medical products and behavioral therapies.

(B) accelerate the development of high need cures, including through the development of medical products, behavioral therapies, and biomarkers that demonstrate the safety or effectiveness of medical products; or

(C) help the award recipient establish protocols that comply with Food and Drug Administration standards and otherwise permit the recipient to meet regulatory requirements at all stages of development, manufacturing, review, approval, and safety surveillance of a medical product.

(2) Eligible entities

To receive assistance under paragraph (1), an entity shall—

(A) be a public or private entity, which may include a private or public research institution, an institution of higher education, a medical center, a biotechnology company, a pharmaceutical company, a disease advocacy organization, a patient advocacy organization, or an academic research institution;

(B) submit an application containing—

(i) a detailed description of the project for which the entity seeks such grant or contract;

(ii) a timetable for such project;

(iii) an assurance that the entity will submit—

(I) interim reports describing the entity's—

(aa) progress in carrying out the project; and

(bb) compliance with all provisions of this section and conditions of receipt of such grant or contract; and

(II) a final report at the conclusion of the grant period, describing the outcomes of the project; and

(iv) a description of the protocols the entity will follow to comply with Food and Drug Administration standards and regulatory requirements at all stages of development, manufacturing, review, approval, and safety surveillance of a medical product; and

(C) provide such additional information as the Director of the Center may require.

(3) Awards

(A) The cures acceleration partnership awards

(i) Initial award amount

Each award under this subparagraph shall be not more than $15,000,000 per project for the first fiscal year for which the project is funded, which shall be payable in one payment.

(ii) Funding in subsequent fiscal years

An eligible entity receiving an award under clause (i) may apply for additional funding for such project by submitting to the Director of the Center the information required under subparagraphs (B) and (C) of paragraph (2). The Director may fund a project of such eligible entity in an amount not to exceed $15,000,000 for a fiscal year subsequent to the initial award under clause (i).

(iii) Matching funds

As a condition for receiving an award under this subsection, an eligible entity shall contribute to the project non-Federal funds in the amount of $1 for every $3 awarded under clauses (i) and (ii), except that the Director of the Center may waive or modify such matching requirement in any case where the Director determines that the goals and objectives of this section cannot adequately be carried out unless such requirement is waived.

(B) The cures acceleration grant awards

(i) Initial award amount

Each award under this subparagraph shall be not more than $15,000,000 per project for the first fiscal year for which the project is funded, which shall be payable in one payment.

(ii) Funding in subsequent fiscal years

An eligible entity receiving an award under clause (i) may apply for additional funding for such project by submitting to the Board the information required under subparagraphs (B) and (C) of paragraph (2). The Director of the Center may fund a project of such eligible entity in an amount not to exceed $15,000,000 for a fiscal year subsequent to the initial award under clause (i).

(C) The cures acceleration flexible research awards

If the Director of the Center determines that the goals and objectives of this section cannot adequately be carried out through a contract, grant, or cooperative agreement, the Director of the Center shall have flexible research authority to use other transactions to fund projects in accordance with the terms and conditions of this section. Awards made under such flexible research authority for a fiscal year shall not exceed 20 percent of the total funds appropriated under subsection (g)(1) for such fiscal year.

(4) Suspension of awards for defaults, noncompliance with provisions and plans, and diversion of funds; repayment of funds

The Director of the Center may suspend the award to any entity upon noncompliance by such entity with provisions and plans under this section or diversion of funds.

(5) Audits

The Director of the Center may enter into agreements with other entities to conduct periodic audits of the projects funded by grants or contracts awarded under this subsection.

(6) Closeout procedures

At the end of a grant or contract period, a recipient shall follow the closeout procedures under section 74.71 of title 45, Code of Federal Regulations (or any successor regulation).

(7) Review

A determination by the Director of the Center as to whether a drug, device, or biological product is a high need cure (for purposes of subsection (a)(3)) shall not be subject to judicial review.

(f) Competitive basis of awards

Any grant, cooperative agreement, or contract awarded under this section shall be awarded on a competitive basis.

(g) Authorization of appropriations

(1) In general

For purposes of carrying out this section, there are authorized to be appropriated $500,000,000 for fiscal year 2010, and such sums as may be necessary for subsequent fiscal years. Funds appropriated under this section shall be available until expended.

(2) Limitation on use of funds otherwise appropriated

No funds appropriated under this chapter, other than funds appropriated under paragraph (1), may be allocated to the Cures Acceleration Network.

(July 1, 1944, ch. 373, title IV, §480, formerly §402C, as added Pub. L. 111–148, title X, §10409(d), Mar. 23, 2010, 124 Stat. 978; renumbered §480 and amended Pub. L. 112–74, div. F, title II, §221(c)(1), Dec. 23, 2011, 125 Stat. 1089.)

EDITORIAL NOTES

REFERENCES IN TEXT

Section 262(i) of this title, referred to in subsec. (a)(3), was in the original "section 262(i)", and was translated as meaning section 351(i) of act July 1, 1944, ch. 373, to reflect the probable intent of Congress.

CODIFICATION

Section was formerly classified to section 282d of this title.

PRIOR PROVISIONS

A prior section 287a, July 1, 1944, ch. 373, title IV, §480, as added Pub. L. 99–158, §2, Nov. 20, 1985, 99 Stat. 864; amended Pub. L. 101–381, title I, §102(3), Aug. 18, 1990, 104 Stat. 586; Pub. L. 102–405, title III, §302(e)(1), Oct. 9, 1992, 106 Stat. 1985; Pub. L. 103–43, title XV, §1501(2)(C), (D), title XX, §§2008(b)(12), 2010(b)(4), June 10, 1993, 107 Stat. 172, 173, 211, 214, related to the advisory council for the National Center for Research Resources, prior to repeal by Pub. L. 112–74, div. F, title II, §221(a)(1)(B), Dec. 23, 2011, 125 Stat. 1086.

AMENDMENTS

2011—Pub. L. 112–74, §221(c)(1)(C), substituted "Director of the Center" for "Director of NIH" wherever appearing.

Subsec. (b). Pub. L. 112–74, §221(c)(1)(B), substituted "within the Center" for "within the Office of the Director of NIH" in introductory provisions.

Subsec. (d)(4). Pub. L. 112–74, §221(c)(1)(D), substituted "Director of the Center" for "Director of NIH" in heading.

Subsec. (d)(4)(B). Pub. L. 112–74, §221(c)(1)(D), substituted "Director of the Center" for "Director of NIH" in heading.

[1] So in original. A closing parenthesis probably should precede the comma.

[2] See References in Text note below.

[3] So in original. Section 5703 of title 5 does not contain a subsec. (b).

§287a–1. Office of Rare Diseases

(a) Establishment

There is established within the Center an office to be known as the Office of Rare Diseases (in this section referred to as the "Office"), which shall be headed by a Director (in this section referred to as the "Director"), appointed by the Director of the Center.

(b) Duties

(1) In general

The Director of the Office shall carry out the following:

(A) The Director shall recommend an agenda for conducting and supporting research on rare diseases through the national research institutes and centers. The agenda shall provide for a broad range of research and education activities, including scientific workshops and symposia to identify research opportunities for rare diseases.

(B) The Director shall, with respect to rare diseases, promote coordination and cooperation

among the national research institutes and centers and entities whose research is supported by such institutes.

(C) The Director, in collaboration with the directors of the other relevant institutes and centers of the National Institutes of Health, may enter into cooperative agreements with and make grants for regional centers of excellence on rare diseases in accordance with section 287a–2 of this title.

(D) The Director shall promote the sufficient allocation of the resources of the National Institutes of Health for conducting and supporting research on rare diseases.

(E) The Director shall promote and encourage the establishment of a centralized clearinghouse for rare and genetic disease information that will provide understandable information about these diseases to the public, medical professionals, patients and families.

(2) Principal advisor regarding orphan diseases

With respect to rare diseases, the Director shall serve as the principal advisor to the Director of NIH and shall provide advice to other relevant agencies. The Director shall provide liaison with national and international patient, health and scientific organizations concerned with rare diseases.

(c) Definition

For purposes of this section, the term "rare disease" means any disease or condition that affects less than 200,000 persons in the United States.

(July 1, 1944, ch. 373, title IV, §481, formerly §404F, as added Pub. L. 107–280, §3, Nov. 6, 2002, 116 Stat. 1989; amended Pub. L. 109–482, title I, §§103(b)(5), 104(b)(1)(B), Jan. 15, 2007, 120 Stat. 3687, 3693; renumbered §481 and amended Pub. L. 112–74, div. F, title II, §221(c)(2)(A), Dec. 23, 2011, 125 Stat. 1089.)

EDITORIAL NOTES

CODIFICATION

Section was formerly classified to section 283h of this title.

PRIOR PROVISIONS

A prior section 287a–1, act July 1, 1944, ch. 373, title IV, §481, as added Pub. L. 99–158, §2, Nov. 20, 1985, 99 Stat. 866; amended Pub. L. 103–43, title XV, §1501(2)(C), (D), June 10, 1993, 107 Stat. 172, 173, required biennial reports regarding the activities and policies of the National Center for Research Resources, prior to repeal by Pub. L. 112–74, div. F, title II, §221(a)(1)(B), Dec. 23, 2011, 125 Stat. 1086.

AMENDMENTS

2011—Subsec. (a). Pub. L. 112–74, §221(c)(2)(A)(ii), substituted "within the Center" for "within the Office of the Director of NIH" and "Director of the Center" for "Director of NIH".

Subsec. (b)(1)(C). Pub. L. 112–74, §221(c)(2)(A)(iii), substituted "287a–2" for "283i".

2007—Subsec. (b)(1)(F), (G). Pub. L. 109–482, §104(b)(1)(B), struck out subpars. (F) and (G) which read as follows:

"(F) The Director shall biennially prepare a report that describes the research and education activities on rare diseases being conducted or supported through the national research institutes and centers, and that identifies particular projects or types of projects that should in the future be conducted or supported by the national research institutes and centers or other entities in the field of research on rare diseases.

"(G) The Director shall prepare the NIH Director's annual report to Congress on rare disease research conducted by or supported through the national research institutes and centers."

Subsec. (d). Pub. L. 109–482, §103(b)(5), struck out heading and text of subsec. (d). Text read as follows: "For the purpose of carrying out this section, there are authorized to be appropriated such sums as already have been appropriated for fiscal year 2002, and $4,000,000 for each of the fiscal years 2003 through 2006."

STATUTORY NOTES AND RELATED SUBSIDIARIES

EFFECTIVE DATE OF 2007 AMENDMENT

Amendment by Pub. L. 109–482 applicable only with respect to amounts appropriated for fiscal year 2007

or subsequent fiscal years, see section 109 of Pub. L. 109–482, set out as a note under section 281 of this title.

FINDINGS AND PURPOSES

Pub. L. 107–280, §2, Nov. 6, 2002, 116 Stat. 1988, provided that:

"(a) FINDINGS.—Congress makes the following findings:

"(1) Rare diseases and disorders are those which affect small patient populations, typically populations smaller than 200,000 individuals in the United States. Such diseases and conditions include Huntington's disease, amyotrophic lateral sclerosis (Lou Gehrig's disease), Tourette syndrome, Crohn's disease, cystic fibrosis, cystinosis, and Duchenne muscular dystrophy.

"(2) For many years, the 25,000,000 Americans suffering from the over 6,000 rare diseases and disorders were denied access to effective medicines because prescription drug manufacturers could rarely make a profit from marketing drugs for such small groups of patients. The prescription drug industry did not adequately fund research into such treatments. Despite the urgent health need for these medicines, they came to be known as 'orphan drugs' because no companies would commercialize them.

"(3) During the 1970s, an organization called the National Organization for Rare Disorders (NORD) was founded to provide services and to lobby on behalf of patients with rare diseases and disorders. NORD was instrumental in pressing Congress for legislation to encourage the development of orphan drugs.

"(4) The Orphan Drug Act [Pub. L. 97–414, see Short Title of 1983 Amendments note set out under section 301 of Title 21, Food and Drugs] created financial incentives for the research and production of such orphan drugs. New Federal programs at the National Institutes of Health and the Food and Drug Administration encouraged clinical research and commercial product development for products that target rare diseases. An Orphan Products Board was established to promote the development of drugs and devices for rare diseases or disorders.

"(5) Before 1983, some 38 orphan drugs had been developed. Since the enactment of the Orphan Drug Act [Jan. 4, 1983], more than 220 new orphan drugs have been approved and marketed in the United States and more than 800 additional drugs are in the research pipeline.

"(6) Despite the tremendous success of the Orphan Drug Act, rare diseases and disorders deserve greater emphasis in the national biomedical research enterprise. The Office of Rare Diseases at the National Institutes of Health was created in 1993, but lacks a statutory authorization.

"(7) The National Institutes of Health has received a substantial increase in research funding from Congress for the purpose of expanding the national investment of the United States in behavioral and biomedical research.

"(8) Notwithstanding such increases, funding for rare diseases and disorders at the National Institutes of Health has not increased appreciably.

"(9) To redress this oversight, the Department of Health and Human Services has proposed the establishment of a network of regional centers of excellence for research on rare diseases.

"(b) PURPOSES.—The purposes of this Act [see Short Title of 2002 Amendments note set out under section 201 of this title] are to—

"(1) amend the Public Health Service Act [42 U.S.C. 201 et seq.] to establish an Office of Rare Diseases at the National Institutes of Health; and

"(2) increase the national investment in the development of diagnostics and treatments for patients with rare diseases and disorders."

§287a–2. Rare disease regional centers of excellence

(a) Cooperative agreements and grants

(1) In general

The Director of the Office of Rare Diseases (in this section referred to as the "Director"), in collaboration with the directors of the other relevant institutes and centers of the National Institutes of Health, may enter into cooperative agreements with and make grants to public or private nonprofit entities to pay all or part of the cost of planning, establishing, or strengthening, and providing basic operating support for regional centers of excellence for clinical research into, training in, and demonstration of diagnostic, prevention, control, and treatment methods for rare diseases.

(2) Policies

A cooperative agreement or grant under paragraph (1) shall be entered into in accordance with policies established by the Director of NIH.

(b) Coordination with other institutes

The Director shall coordinate the activities under this section with similar activities conducted by other national research institutes, centers and agencies of the National Institutes of Health and by the Food and Drug Administration to the extent that such institutes, centers and agencies have responsibilities that are related to rare diseases.

(c) Uses for Federal payments under cooperative agreements or grants

Federal payments made under a cooperative agreement or grant under subsection (a) may be used for—

(1) staffing, administrative, and other basic operating costs, including such patient care costs as are required for research;

(2) clinical training, including training for allied health professionals, continuing education for health professionals and allied health professions personnel, and information programs for the public with respect to rare diseases; and

(3) clinical research and demonstration programs.

(d) Period of support; additional periods

Support of a center under subsection (a) may be for a period of not to exceed 5 years. Such period may be extended by the Director for additional periods of not more than 5 years if the operations of such center have been reviewed by an appropriate technical and scientific peer review group established by the Director and if such group has recommended to the Director that such period should be extended.

(July 1, 1944, ch. 373, title IV, §481A, formerly §404G, as added Pub. L. 107–280, §4, Nov. 6, 2002, 116 Stat. 1990; amended Pub. L. 109–482, title I, §103(b)(6), Jan. 15, 2007, 120 Stat. 3687; renumbered §481A, Pub. L. 112–74, div. F, title II, §221(c)(3), Dec. 23, 2011, 125 Stat. 1089.)

EDITORIAL NOTES

CODIFICATION

Section was formerly classified to section 283i of this title.

PRIOR PROVISIONS

A prior section 481A of act July 1, 1944, was renumbered section 404I, and is classified to section 283k of this title.

AMENDMENTS

2007—Subsec. (e). Pub. L. 109–482 struck out heading and text of subsec. (e). Text read as follows: "For the purpose of carrying out this section, there are authorized to be appropriated such sums as already have been appropriated for fiscal year 2002, and $20,000,000 for each of the fiscal years 2003 through 2006."

STATUTORY NOTES AND RELATED SUBSIDIARIES

EFFECTIVE DATE OF 2007 AMENDMENT

Amendment by Pub. L. 109–482 applicable only with respect to amounts appropriated for fiscal year 2007 or subsequent fiscal years, see section 109 of Pub. L. 109–482, set out as a note under section 281 of this title.

§§287a–3, 287a–3a. Transferred

EDITORIAL NOTES

CODIFICATION

Section 287a–3, act July 1, 1944, ch. 373, title IV, §481B, as added Pub. L. 103–43, title XV, §1503, June 10, 1993, 107 Stat. 178; amended Pub. L. 105–392, title IV, §411, Nov. 13, 1998, 112 Stat. 3590; Pub. L. 106–505, title III, §304, Nov. 13, 2000, 114 Stat. 2335; Pub. L. 109–482, title I, §103(b)(41), Jan. 15, 2007, 120 Stat. 3688, which related to construction of regional centers for research on primates, was renumbered section 404J of act July 1, 1944, by Pub. L. 112–74, div. F, title II, §221(b)(2)(A), Dec. 23, 2011, 125 Stat. 1088, and transferred to section 283l of this title.

Section 287a–3a, July 1, 1944, ch. 373, title IV, §481C, as added Pub. L. 106–551, §2, Dec. 20, 2000, 114 Stat. 2752; amended Pub. L. 110–170, §2(a), Dec. 26, 2007, 121 Stat. 2465, which related to sanctuary system for surplus chimpanzees, was renumbered section 404K of act July 1, 1944, by Pub. L. 112–74, div. F, title II, §221(b)(3)(A), Dec. 23, 2011, 125 Stat. 1088, and transferred to section 283m of this title.

A prior section 481C of act July 1, 1944, was renumbered section 481B of act July 1, 1944, and is classified to section 287a–4 of this title.

§287a–4. General clinical research centers

(a) Grants

The Director of the Center shall award grants for the establishment of general clinical research centers to provide the infrastructure for clinical research including clinical research training and career enhancement. Such centers shall support clinical studies and career development in all settings of the hospital or academic medical center involved.

(b) Activities

In carrying out subsection (a), the Director of National Institutes of Health shall expand the activities of the general clinical research centers through the increased use of telecommunications and telemedicine initiatives.

(July 1, 1944, ch. 373, title IV, §481B, formerly §481C, as added Pub. L. 106–505, title II, §204(a), Nov. 13, 2000, 114 Stat. 2327; amended Pub. L. 109–482, title I, §103(b)(42), Jan. 15, 2007, 120 Stat. 3688; renumbered §481D, Pub. L. 110–170, §2(b), Dec. 26, 2007, 121 Stat. 2466; renumbered §481B and amended Pub. L. 112–74, div. F, title II, §221(c)(4), Dec. 23, 2011, 125 Stat. 1089.)

EDITORIAL NOTES

PRIOR PROVISIONS

A prior section 481B of act July 1, 1944, was renumbered section 404J, and is classified to section 283l of this title.

AMENDMENTS

2011—Subsec. (a). Pub. L. 112–74, §221(c)(4)(B), substituted "Director of the Center" for "Director of the National Center for Research Resources".

2007—Subsec. (c). Pub. L. 109–482 struck out heading and text of subsec. (c). Text read as follows: "For the purpose of carrying out this section, there are authorized to be appropriated such sums as may be necessary for each fiscal year."

STATUTORY NOTES AND RELATED SUBSIDIARIES

EFFECTIVE DATE OF 2007 AMENDMENT

Amendment by Pub. L. 109–482 applicable only with respect to amounts appropriated for fiscal year 2007 or subsequent fiscal years, see section 109 of Pub. L. 109–482, set out as a note under section 281 of this title.

SUBPART 2—JOHN E. FOGARTY INTERNATIONAL CENTER FOR ADVANCED STUDY IN HEALTH SCIENCES

§287b. General purpose

The general purpose of the John E. Fogarty International Center for Advanced Study in the Health Sciences is to—

(1) facilitate the assembly of scientists and others in the biomedical, behavioral, and related fields for discussion, study, and research relating to the development of health science internationally;

(2) provide research programs, conferences, and seminars to further international cooperation and collaboration in the life sciences;

(3) provide postdoctorate fellowships for research training in the United States and abroad and promote exchanges of senior scientists between the United States and other countries;

(4) coordinate the activities of the National Institutes of Health concerned with the health sciences internationally; and

(5) receive foreign visitors to the National Institutes of Health.

(July 1, 1944, ch. 373, title IV, §482, as added Pub. L. 99–158, §2, Nov. 20, 1985, 99 Stat. 866.)

SUBPART 3—NATIONAL CENTER FOR HUMAN GENOME RESEARCH

EDITORIAL NOTES

CODIFICATION

Subpart 3 of part E of title IV of act July 1, 1944, comprising this subpart, was renumbered subpart 19 of part C of title IV by Pub. L. 109–482, title I, §101(c)(1)–(3), Jan. 15, 2007, 120 Stat. 3681, and is classified to subpart 19 (§285s) of part C of this subchapter.

§287c. Transferred

EDITORIAL NOTES

CODIFICATION

Section, act July 1, 1944, ch. 373, title IV, §485B, as added Pub. L. 103–43, title XV, §1521(2), June 10, 1993, 107 Stat. 180, which set out the purpose of the National Center for Human Genome Research, was renumbered section 464z–1 of act July 1, 1944, by Pub. L. 109–482, title I, §101(c)(4)(A), Jan. 15, 2007, 120 Stat. 3681, and transferred to section 285s of this title.

PRIOR PROVISIONS

Another prior section 287c, act July 1, 1944, ch. 373, title IV, §483, as added Nov. 20, 1985, Pub. L. 99–158, §2, 99 Stat. 867, and amended, which related to purpose of National Center for Nursing Research, was renumbered section 464V of act July 1, 1944, by Pub. L. 103–43, title XV, §1511(b)(2), June 10, 1993, 107 Stat. 179, and transferred to section 285q of this title.

A prior section 287c–1, act July 1, 1944, ch. 373, title IV, §484, as added Nov. 20, 1985, Pub. L. 99–158, §2, 99 Stat. 867, and amended, which related to specific authorities of the Director of the Center, was renumbered section 464W of act July 1, 1944, by Pub. L. 103–43, title XV, §1511(b)(2), June 10, 1993, 107 Stat. 179, and transferred to section 285q–1 of this title.

A prior section 287c–2, act July 1, 1944, ch. 373, title IV, §485, as added Nov. 20, 1985, Pub. L. 99–158, §2, 99 Stat. 867, and amended, which related to the advisory council for the Center, was renumbered section 464X of act July 1, 1944, by Pub. L. 103–43, title XV, §1511(b)(2), June 10, 1993, 107 Stat. 179, and transferred to section 285q–2 of this title.

A prior section 287c–3, act July 1, 1944, ch. 373, title IV, §486, as added Nov. 20, 1985, Pub. L. 99–158, §2, 99 Stat. 869, and amended, which related to biennial report of activities of the Center, was renumbered section 464Y of act July 1, 1944, by Pub. L. 103–43, title XV, §1511(b)(2), June 10, 1993, 107 Stat. 179, and

transferred to section 285q–3 of this title. Section 285q–3 was subsequently repealed by Pub. L. 114–255, div. A, title II, §2042(h)(1), Dec. 13, 2016, 130 Stat. 1073.

SUBPART 4—OFFICE OF DIETARY SUPPLEMENTS

§287c–11. Dietary supplements

(a) Establishment

The Secretary shall establish an Office of Dietary Supplements within the National Institutes of Health.

(b) Purpose

The purposes of the Office are—

(1) to explore more fully the potential role of dietary supplements as a significant part of the efforts of the United States to improve health care; and

(2) to promote scientific study of the benefits of dietary supplements in maintaining health and preventing chronic disease and other health-related conditions.

(c) Duties

The Director of the Office of Dietary Supplements shall—

(1) conduct and coordinate scientific research within the National Institutes of Health relating to dietary supplements and the extent to which the use of dietary supplements can limit or reduce the risk of diseases such as heart disease, cancer, birth defects, osteoporosis, cataracts, or prostatism;

(2) collect and compile the results of scientific research relating to dietary supplements, including scientific data from foreign sources or the Office of Alternative Medicine; [1]

(3) serve as the principal advisor to the Secretary and to the Assistant Secretary for Health and provide advice to the Director of the National Institutes of Health, the Director of the Centers for Disease Control and Prevention, and the Commissioner of Food and Drugs on issues relating to dietary supplements including—

(A) dietary intake regulations;

(B) the safety of dietary supplements;

(C) claims characterizing the relationship between—

(i) dietary supplements; and

(ii)(I) prevention of disease or other health-related conditions; and

(II) maintenance of health; and

(D) scientific issues arising in connection with the labeling and composition of dietary supplements;

(4) compile a database of scientific research on dietary supplements and individual nutrients; and

(5) coordinate funding relating to dietary supplements for the National Institutes of Health.

(d) "Dietary supplement" defined

As used in this section, the term "dietary supplement" has the meaning given the term in section 321(ff) of title 21.

(July 1, 1944, ch. 373, title IV, §485C, as added Pub. L. 103–417, §13(a), Oct. 25, 1994, 108 Stat. 4334; amended Pub. L. 109–482, title I, §103(b)(43), Jan. 15, 2007, 120 Stat. 3688.)

EDITORIAL NOTES

REFERENCES IN TEXT

The Office of Alternative Medicine, referred to in subsec. (c)(2), probably should be a reference to the National Center for Complementary and Integrative Health. Establishment of the Office of Alternative Medicine was repealed and authority for the National Center for Complementary and Alternative Medicine was enacted by Pub. L. 105–277, div. A, §101(f) [title VI, §601], Oct. 21, 1998, 112 Stat. 2681–337, 2681–387. The National Center for Complementary and Alternative Medicine was renamed the National Center for Complementary and Integrative Health by Pub. L. 113–235, div. G, title II, §224(1), Dec. 16, 2014, 128 Stat. 2490. See section 287c–21 of this title and Prior Provisions note under section 283g of this title.

AMENDMENTS

2007—Subsec. (e). Pub. L. 109–482 struck out heading and text of subsec. (e). Text read as follows: "There are authorized to be appropriated to carry out this section $5,000,000 for fiscal year 1994 and such sums as may be necessary for each subsequent fiscal year."

STATUTORY NOTES AND RELATED SUBSIDIARIES

EFFECTIVE DATE OF 2007 AMENDMENT

Amendment by Pub. L. 109–482 applicable only with respect to amounts appropriated for fiscal year 2007 or subsequent fiscal years, see section 109 of Pub. L. 109–482, set out as a note under section 281 of this title.

[1] *See References in Text note below.*

SUBPART 5—NATIONAL CENTER FOR COMPLEMENTARY AND INTEGRATIVE HEALTH

EDITORIAL NOTES

CODIFICATION

Pub. L. 113–235, div. G, title II, §224(1), Dec. 16, 2014, 128 Stat. 2490, substituted "NATIONAL CENTER FOR COMPLEMENTARY AND INTEGRATIVE HEALTH" for "NATIONAL CENTER FOR COMPLEMENTARY AND ALTERNATIVE MEDICINE" in subpart heading.

§287c–21. Purpose of Center

(a) In general

The general purposes of the National Center for Complementary and Integrative Health (in this subpart referred to as the "Center") are the conduct and support of basic and applied research (including both intramural and extramural research), research training, the dissemination of health information, and other programs with respect to identifying, investigating, and validating complementary and integrative health, diagnostic and prevention modalities, disciplines and systems. The Center shall be headed by a director, who shall be appointed by the Secretary. The Director of the Center shall report directly to the Director of NIH.

(b) Advisory council

The Secretary shall establish an advisory council for the Center in accordance with section 284a of this title, except that at least half of the members of the advisory council who are not ex officio members shall include practitioners licensed in one or more of the major systems with which the Center is concerned, and at least 3 individuals representing the interests of individual consumers of complementary and integrative health.

(c) Integration of new and non-traditional approaches

In carrying out subsection (a), the Director of the Center shall, as appropriate, study the integration

of new and non-traditional approaches to health care treatment and consumption, including but not limited to non-traditional treatment, diagnostic and prevention systems, modalities, and disciplines.

(d) Appropriate scientific expertise and coordination with institutes and Federal agencies

The Director of the Center, after consultation with the advisory council for the Center and the division of research grants, shall ensure that scientists with appropriate expertise in research on complementary and integrative health are incorporated into the review, oversight, and management processes of all research projects and other activities funded by the Center. In carrying out this subsection, the Director of the Center, as necessary, may establish review groups with appropriate scientific expertise. The Director of the Center shall coordinate efforts with other Institutes and Federal agencies to ensure appropriate scientific input and management.

(e) Evaluation of various disciplines and systems

In carrying out subsection (a), the Director of the Center shall identify and evaluate complementary and integrative health, diagnostic and prevention modalities in each of the disciplines and systems with which the Center is concerned, including each discipline and system in which accreditation, national certification, or a State license is available.

(f) Ensuring high quality, rigorous scientific review

In order to ensure high quality, rigorous scientific review of complementary and alternative, diagnostic and prevention modalities, disciplines and systems, the Director of the Center shall conduct or support the following activities:

(1) Outcomes research and investigations.
(2) Epidemiological studies.
(3) Health services research.
(4) Basic science research.
(5) Clinical trials.
(6) Other appropriate research and investigational activities.

The Director of NIH, in coordination with the Director of the Center, shall designate specific personnel in each Institute to serve as full-time liaisons with the Center in facilitating appropriate coordination and scientific input.

(g) Data system; information clearinghouse

(1) Data system

The Director of the Center shall establish a bibliographic system for the collection, storage, and retrieval of worldwide research relating to complementary and integrative health, diagnostic and prevention modalities, disciplines and systems. Such a system shall be regularly updated and publicly accessible.

(2) Clearinghouse

The Director of the Center shall establish an information clearinghouse to facilitate and enhance, through the effective dissemination of information, knowledge and understanding of integrative health treatment, diagnostic and prevention practices by health professionals, patients, industry, and the public.

(h) Research centers

The Director of the Center, after consultation with the advisory council for the Center, shall provide support for the development and operation of multipurpose centers to conduct research and other activities described in subsection (a) with respect to complementary and integrative health, diagnostic and prevention modalities, disciplines and systems. The provision of support for the development and operation of such centers shall include accredited complementary and integrative health research and education facilities.

(i) Availability of resources

After consultation with the Director of the Center, the Director of NIH shall ensure that resources

of the National Institutes of Health, including laboratory and clinical facilities, fellowships (including research training fellowship and junior and senior clinical fellowships), and other resources are sufficiently available to enable the Center to appropriately and effectively carry out its duties as described in subsection (a). The Director of NIH, in coordination with the Director of the Center, shall designate specific personnel in each Institute to serve as full-time liaisons with the Center in facilitating appropriate coordination and scientific input.

(j) Availability of appropriations

Amounts appropriated to carry out this section for fiscal year 1999 are available for obligation through September 30, 2001. Amounts appropriated to carry out this section for fiscal year 2000 are available for obligation through September 30, 2001.

(July 1, 1944, ch. 373, title IV, §485D, as added Pub. L. 105–277, div. A, §101(f) [title VI, §601(2)], Oct. 21, 1998, 112 Stat. 2681–337, 2681–387; amended Pub. L. 113–235, div. G, title II, §224, Dec. 16, 2014, 128 Stat. 2490.)

EDITORIAL NOTES

AMENDMENTS

2014—Subsec. (a). Pub. L. 113–235, §224(1), (3), substituted "National Center for Complementary and Integrative Health" for "National Center for Complementary and Alternative Medicine" and "complementary and integrative health" for "complementary and alternative treatment".

Subsec. (b). Pub. L. 113–235, §224(2), substituted "integrative health" for "alternative medicine".

Subsec. (c). Pub. L. 113–235, §224(5), added subsec. (c) and struck out former subsec. (c). Prior to amendment, text read as follows: "In carrying out subsection (a) of this section, the Director of the Center shall, as appropriate, study the integration of alternative treatment, diagnostic and prevention systems, modalities, and disciplines with the practice of conventional medicine as a complement to such medicine and into health care delivery systems in the United States."

Subsec. (d). Pub. L. 113–235, §224(2), substituted "integrative health" for "alternative medicine".

Subsec. (e). Pub. L. 113–235, §224(3), substituted "complementary and integrative health" for "alternative and complementary medical treatment".

Subsec. (g)(1). Pub. L. 113–235, §224(3), substituted "complementary and integrative health" for "complementary and alternative treatment".

Subsec. (g)(2). Pub. L. 113–235, §224(4), substituted "integrative health treatment" for "alternative medical treatment".

Subsec. (h). Pub. L. 113–235, §224(2), (3), substituted "complementary and integrative health," for "complementary and alternative treatment," and "integrative health research" for "alternative medicine research".

STATUTORY NOTES AND RELATED SUBSIDIARIES

TERMINATION OF ADVISORY COUNCILS

Advisory councils established after Jan. 5, 1973, to terminate not later than the expiration of the 2-year period beginning on the date of their establishment, unless, in the case of a council established by the President or an officer of the Federal Government, such council is renewed by appropriate action prior to the expiration of such 2-year period, or in the case of a council established by Congress, its duration is otherwise provided by law. See sections 1001(2) and 1013 of Title 5, Government Organization and Employees.

Pub. L. 93–641, §6, Jan. 4, 1975, 88 Stat. 2275, set out as a note under section 217a of this title, provided that an advisory committee established pursuant to the Public Health Service Act shall terminate at such time as may be specifically prescribed by an Act of Congress enacted after Jan. 4, 1975.

EXECUTIVE DOCUMENTS

EXECUTIVE ORDER NO. 13147

Ex. Ord. No. 13147, Mar. 7, 2000, 65 F.R. 13233, as amended by Ex. Ord. No. 13167, Sept. 15, 2000, 65 F.R. 54079 [57079], 65 F.R. 57436, which established White House Commission on Complementary and

Alternative Medicine Policy, was revoked by Ex. Ord. No. 13316, §3(i), Sept. 17, 2003, 68 F.R. 55256, eff. Sept. 30, 2003.

SUBPART 6—TRANSFERRED

EDITORIAL NOTES

CODIFICATION

Subpart 6 of part E of title IV of act July 1, 1944, comprising this subpart, was renumbered subpart 20 of part C of title IV by Pub. L. 111–148, title X, §10334(c)(1)(A)–(C), Mar. 23, 2010, 124 Stat. 973, and is classified to subpart 20 (§285t et seq.) of part C of this subchapter.

§§287c–31 to 287c–34. Transferred

EDITORIAL NOTES

CODIFICATION

Section 287c–31, act July 1, 1944, ch. 373, title IV, §485E, as added Pub. L. 106–525, title I, §101(a), Nov. 22, 2000, 114 Stat. 2497; amended Pub. L. 109–482, title I, §§103(b)(44), 104(b)(1)(N), Jan. 15, 2007, 120 Stat. 3688, 3693, which set out the purpose of the National Center on Minority Health and Health Disparities, was renumbered section 464z–3 of act July 1, 1944, and transferred to section 285t of this title.

Section 287c–32, act July 1, 1944, ch. 373, title IV, §485F, as added Pub. L. 106–525, title I, §102, Nov. 22, 2000, 114 Stat. 2501; amended Pub. L. 109–482, title I, §103(b)(45), Jan. 15, 2007, 120 Stat. 3688, which related to centers of excellence for research education and training, was renumbered section 464z–4 of act July 1, 1944, and transferred to section 285t–1 of this title.

Section 287c–33, act July 1, 1944, ch. 373, title IV, §485G, as added Pub. L. 106–525, title I, §103, Nov. 22, 2000, 114 Stat. 2503; amended Pub. L. 109–482, title I, §103(b)(46), Jan. 15, 2007, 120 Stat. 3688, which related to loan repayment program for minority health disparities research, was renumbered section 464z–5 of act July 1, 1944, and transferred to section 285t–2 of this title, prior to repeal by Pub. L. 114–255, div. A, title II, §2022(c)(1), Dec. 13, 2016, 130 Stat. 1054.

Section 287c–34, act July 1, 1944, ch. 373, title IV, §485H, as added Pub. L. 106–525, title I, §104, Nov. 22, 2000, 114 Stat. 2503; amended Pub. L. 109–482, title I, §104(b)(1)(O), Jan. 15, 2007, 120 Stat. 3693, which related to administrative support and support services, was renumbered section 464z–6 of act July 1, 1944, and transferred to section 285t–3 of this title.

PART F—RESEARCH ON WOMEN'S HEALTH

§287d. Office of Research on Women's Health

(a) Establishment

There is established within the Office of the Director of NIH an office to be known as the Office of Research on Women's Health (in this part referred to as the "Office"). The Office shall be headed by a director, who shall be appointed by the Director of NIH and who shall report directly to the Director.

(b) Purpose

The Director of the Office shall—

(1) identify projects of research on women's health that should be conducted or supported by the national research institutes;

(2) identify multidisciplinary research relating to research on women's health that should be so conducted or supported;

(3) carry out paragraphs (1) and (2) with respect to the aging process in women, with priority given to menopause;

(4) promote coordination and collaboration among entities conducting research identified under any of paragraphs (1) through (3);

(5) encourage the conduct of such research by entities receiving funds from the national research institutes;

(6) recommend an agenda for conducting and supporting such research;

(7) promote the sufficient allocation of the resources of the national research institutes for conducting and supporting such research;

(8) assist in the administration of section 289a–2 of this title with respect to the inclusion of women as subjects in clinical research; and

(9) prepare the report required in section 287d–2 of this title.

(c) Coordinating Committee

(1) In carrying out subsection (b), the Director of the Office shall establish a committee to be known as the Coordinating Committee on Research on Women's Health (in this subsection referred to as the "Coordinating Committee").

(2) The Coordinating Committee shall be composed of the Directors of the national research institutes (or the senior-level staff designees of the Directors).

(3) The Director of the Office shall serve as the chair of the Coordinating Committee.

(4) With respect to research on women's health, the Coordinating Committee shall assist the Director of the Office in—

(A) identifying the need for such research, and making an estimate each fiscal year of the funds needed to adequately support the research;

(B) identifying needs regarding the coordination of research activities, including intramural and extramural multidisciplinary activities;

(C) supporting the development of methodologies to determine the circumstances in which obtaining data specific to women (including data relating to the age of women and the membership of women in ethnic or racial groups) is an appropriate function of clinical trials of treatments and therapies;

(D) supporting the development and expansion of clinical trials of treatments and therapies for which obtaining such data has been determined to be an appropriate function; and

(E) encouraging the national research institutes to conduct and support such research, including such clinical trials.

(d) Advisory Committee

(1) In carrying out subsection (b), the Director of the Office shall establish an advisory committee to be known as the Advisory Committee on Research on Women's Health (in this subsection referred to as the "Advisory Committee").

(2) The Advisory Committee shall be composed of no fewer than 12, and not more than 18 individuals, who are not officers or employees of the Federal Government. The Director of NIH shall make appointments to the Advisory Committee from among physicians, practitioners, scientists, and other health professionals, whose clinical practice, research specialization, or professional expertise includes a significant focus on research on women's health. A majority of the members of the Advisory Committee shall be women.

(3) The Director of the Office shall serve as the chair of the Advisory Committee.

(4) The Advisory Committee shall—

(A) advise the Director of the Office on appropriate research activities to be undertaken by the national research institutes with respect to—

(i) research on women's health;

(ii) research on gender differences in clinical drug trials, including responses to pharmacological drugs;

(iii) research on gender differences in disease etiology, course, and treatment;

(iv) research on obstetrical and gynecological health conditions, diseases, and treatments, including preventable maternal mortality and severe maternal morbidity; and

(v) research on women's health conditions which require a multidisciplinary approach;

(B) report to the Director of the Office on such research;

(C) provide recommendations to such Director regarding activities of the Office (including recommendations on the development of the methodologies described in subsection (c)(4)(C) and recommendations on priorities in carrying out research described in subparagraph (A)); and

(D) assist in monitoring compliance with section 289a–2 of this title regarding the inclusion of women in clinical research.

(5)(A) The Advisory Committee shall prepare a biennial report describing the activities of the Committee, including findings made by the Committee regarding—

(i) compliance with section 289a–2 of this title;

(ii) the extent of expenditures made for research on women's health by the agencies of the National Institutes of Health; and

(iii) the level of funding needed for such research.

(B) The report required in subparagraph (A) shall be submitted to the Director of NIH for inclusion in the report required in section 283 of this title.

(e) Representation of women among researchers

The Secretary, acting through the Assistant Secretary for Personnel and in collaboration with the Director of the Office, shall determine the extent to which women are represented among senior physicians and scientists of the national research institutes and among physicians and scientists conducting research with funds provided by such institutes, and as appropriate, carry out activities to increase the extent of such representation.

(f) Definitions

For purposes of this part:

(1) The term "women's health conditions", with respect to women of all age, ethnic, and racial groups, means all diseases, disorders, and conditions (including with respect to mental health)—

(A) unique to, more serious, or more prevalent in women;

(B) for which the factors of medical risk or types of medical intervention are different for women, or for which it is unknown whether such factors or types are different for women; or

(C) with respect to which there has been insufficient clinical research involving women as subjects or insufficient clinical data on women.

(2) The term "research on women's health" means research on women's health conditions, including research on preventing such conditions.

(July 1, 1944, ch. 373, title IV, §486, as added Pub. L. 103–43, title I, §141(a)(3), June 10, 1993, 107 Stat. 136; amended Pub. L. 105–340, title I, §106, Oct. 31, 1998, 112 Stat. 3193; Pub. L. 111–148, title III, §3509(c), Mar. 23, 2010, 124 Stat. 534; Pub. L. 114–255, div. A, title II, §2038(c), Dec. 13, 2016, 130 Stat. 1065; Pub. L. 117–103, div. P, title I, §141(d), Mar. 15, 2022, 136 Stat. 798.)

EDITORIAL NOTES

AMENDMENTS

2022—Subsec. (d)(4)(A)(iv). Pub. L. 117–103 inserted ", including preventable maternal mortality and severe maternal morbidity" before "; and".

2016—Subsec. (c)(2). Pub. L. 114–255 substituted "senior-level staff designees" for "designees".

2010—Subsec. (a). Pub. L. 111–148 inserted "and who shall report directly to the Director" before period at end.

1998—Subsec. (d)(2). Pub. L. 105–340 substituted "NIH" for "the Office".

STATUTORY NOTES AND RELATED SUBSIDIARIES

TERMINATION OF ADVISORY COMMITTEES

Advisory committees established after Jan. 5, 1973, to terminate not later than the expiration of the 2-year period beginning on the date of their establishment, unless, in the case of a committee established by the President or an officer of the Federal Government, such committee is renewed by appropriate action prior to the expiration of such 2-year period, or in the case of a committee established by Congress, its duration is otherwise provided for by law. See section 1013 of Title 5, Government Organization and Employees.

Pub. L. 93–641, §6, Jan. 4, 1975, 88 Stat. 2275, set out as a note under section 217a of this title, provided that an advisory committee established pursuant to the Public Health Service Act shall terminate at such time as may be specifically prescribed by an Act of Congress enacted after Jan. 4, 1975.

§287d–1. National data system and clearinghouse on research on women's health

(a) Data system

(1) The Director of NIH, in consultation with the Director of the Office and the Director of the National Library of Medicine, shall establish a data system for the collection, storage, analysis, retrieval, and dissemination of information regarding research on women's health that is conducted or supported by the national research institutes. Information from the data system shall be available through information systems available to health care professionals and providers, researchers, and members of the public.

(2) The data system established under paragraph (1) shall include a registry of clinical trials of experimental treatments that have been developed for research on women's health. Such registry shall include information on subject eligibility criteria, sex, age, ethnicity or race, and the location of the trial site or sites. Principal investigators of such clinical trials shall provide this information to the registry within 30 days after it is available. Once a trial has been completed, the principal investigator shall provide the registry with information pertaining to the results, including potential toxicities or adverse effects associated with the experimental treatment or treatments evaluated.

(b) Clearinghouse

The Director of NIH, in consultation with the Director of the Office and with the National Library of Medicine, shall establish, maintain, and operate a program to provide information on research and prevention activities of the national research institutes that relate to research on women's health.

(July 1, 1944, ch. 373, title IV, §486A, as added Pub. L. 103–43, title I, §141(a)(3), June 10, 1993, 107 Stat. 138.)

§287d–2. Biennial report

(a) In general

With respect to research on women's health, the Director of the Office shall, not later than February 1, 1994, and biennially thereafter, prepare a report—

(1) describing and evaluating the progress made during the preceding 2 fiscal years in research and treatment conducted or supported by the National Institutes of Health;

(2) describing and analyzing the professional status of women physicians and scientists of such Institutes, including the identification of problems and barriers regarding advancements;

(3) summarizing and analyzing expenditures made by the agencies of such Institutes (and by such Office) during the preceding 2 fiscal years; and

(4) making such recommendations for legislative and administrative initiatives as the Director of the Office determines to be appropriate.

(b) Inclusion in biennial report of Director of NIH

The Director of the Office shall submit each report prepared under subsection (a) to the Director of NIH for inclusion in the report submitted to the President and the Congress under section 283 of this title.

(July 1, 1944, ch. 373, title IV, §486B, as added Pub. L. 103–43, title I, §141(a)(3), June 10, 1993, 107 Stat. 139.)

PART G—AWARDS AND TRAINING

EDITORIAL NOTES

CODIFICATION

Pub. L. 103–43, title I, §141(a)(2), June 10, 1993, 107 Stat. 136, redesignated part F "Awards and Training" as G. Former part G "General Provisions" redesignated H.

§288. Ruth L. Kirschstein National Research Service Awards

(a) Biomedical and behavioral research and research training; programs and institutions included; restriction; special consideration

(1) The Secretary shall—

(A) provide Ruth L. Kirschstein National Research Service Awards for—

(i) biomedical and behavioral research at the National Institutes of Health in matters relating to the cause, diagnosis, prevention, and treatment of the diseases or other health problems to which the activities of the National Institutes of Health and Administration [1] are directed;

(ii) training at the National Institutes of Health and at the Administration [1] of individuals to undertake such research;

(iii) biomedical and behavioral research and health services research (including research in primary medical care) at public and nonprofit private entities; and

(iv) pre-doctoral and post-doctoral training at public and private institutions of individuals to undertake biomedical and behavioral research;

(B) make grants to public and nonprofit private institutions to enable such institutions to make Ruth L. Kirschstein National Research Service Awards for research (and training to undertake biomedical and behavioral research) in the matters described in subparagraph (A)(i) to individuals selected by such institutions; and

(C) provide contracts for scholarships and loan repayments in accordance with sections 288–4 and 288–5 [2] of this title, subject to providing not more than an aggregate 50 such contracts during the fiscal years 1994 through 1996.

A reference in this subsection to the National Institutes of Health shall be considered to include the institutes, agencies, divisions, and bureaus included in the National Institutes of Health or under the Administration,[1] as the case may be.

(2) Ruth L. Kirschstein National Research Service Awards may not be used to support residency training of physicians and other health professionals.

(3) In awarding Ruth L. Kirschstein National Research Service Awards under this section, the Secretary shall take account of the Nation's overall need for biomedical research personnel by giving special consideration to physicians who agree to undertake a minimum of two years of biomedical research.

(4) The Secretary shall carry out paragraph (1) in a manner that will result in the recruitment of women, and individuals from disadvantaged backgrounds (including racial and ethnic minorities),

into fields of biomedical or behavioral research and in the provision of research training to women and such individuals.

(b) Prerequisites for Award; review and approval by appropriate advisory councils; Award period; uses for Award; payments to non-Federal public or nonprofit private institutions

(1) No Ruth L. Kirschstein National Research Service Award may be made by the Secretary to any individual unless—

(A) the individual has submitted to the Secretary an application therefor and the Secretary has approved the application;

(B) the individual provides, in such form and manner as the Secretary shall by regulation prescribe, assurances satisfactory to the Secretary that the individual will meet the service requirement of subsection (c); and

(C) in the case of a Ruth L. Kirschstein National Research Service Award for a purpose described in subsection (a)(1)(A)(iii), the individual has been sponsored (in such manner as the Secretary may by regulation require) by the institution at which the research or training under the award will be conducted.

An application for an award shall be in such form, submitted in such manner, and contain such information, as the Secretary may by regulation prescribe.

(2) The making of grants under subsection (a)(1)(B) for Ruth L. Kirschstein National Research Service Awards shall be subject to review and approval by the appropriate advisory councils within the Department of Health and Human Services (A) whose activities relate to the research or training under the awards, or (B) for the entity at which such research or training will be conducted.

(3) No grant may be made under subsection (a)(1)(B) unless an application therefor has been submitted to and approved by the Secretary. Such application shall be in such form, submitted in such manner, and contain such information, as the Secretary may by regulation prescribe. Subject to the provisions of this section (other than paragraph (1)), Ruth L. Kirschstein National Research Service Awards made under a grant under subsection (a)(1)(B) shall be made in accordance with such regulations as the Secretary shall prescribe.

(4) The period of any Ruth L. Kirschstein National Research Service Award made to any individual under subsection (a) may not exceed—

(A) five years in the aggregate for pre-doctoral training; and

(B) three years in the aggregate for post-doctoral training;

unless the Secretary for good cause shown waives the application of such limit to such individual.

(5) Ruth L. Kirschstein National Research Service Awards shall provide for such stipends, tuition, fees, and allowances (including travel and subsistence expenses and dependency allowances), adjusted periodically to reflect increases in the cost of living, for the recipients of the awards as the Secretary may deem necessary. A Ruth L. Kirschstein National Research Service Award made to an individual for research or research training at a non-Federal public or nonprofit private institution shall also provide for payments to be made to the institution for the cost of support services (including the cost of faculty salaries, supplies, equipment, general research support, and related items) provided such individual by such institution. The amount of any such payments to any institution shall be determined by the Secretary and shall bear a direct relationship to the reasonable costs of the institution for establishing and maintaining the quality of its biomedical and behavioral research and training programs.

(c) Health research or teaching; service period; recovery upon noncompliance with service requirement, formula; cancellation or waiver of obligation

(1) Each individual who is awarded a Ruth L. Kirschstein National Research Service Award for postdoctoral research training shall, in accordance with paragraph (3), engage in research training, research, or teaching that is health-related (or any combination thereof) for the period specified in paragraph (2). Such period shall be served in accordance with the usual patterns of scientific employment.

(2)(A) The period referred to in paragraph (1) is 12 months, or one month for each month for which the individual involved receives a Ruth L. Kirschstein National Research Service Award for postdoctoral research training, whichever is less.

(B) With respect to postdoctoral research training, in any case in which an individual receives a Ruth L. Kirschstein National Research Service Award for more than 12 months, the 13th month and each subsequent month of performing activities under the Award shall be considered to be activities engaged in toward satisfaction of the requirement established in paragraph (1) regarding a period of service.

(3) The requirement of paragraph (1) shall be complied with by any individual to whom it applies within such reasonable period of time, after the completion of such individual's award, as the Secretary shall by regulation prescribe. The Secretary shall by regulation prescribe the type of research and teaching in which an individual may engage to comply with such requirement and such other requirements respecting research and teaching as the Secretary considers appropriate.

(4)(A) If any individual to whom the requirement of paragraph (1) is applicable fails, within the period prescribed by paragraph (3), to comply with such requirements, the United States shall be entitled to recover from such individual an amount determined in accordance with the formula—

$$A = \left(\frac{ts}{t}\right)$$

in which "A" is the amount the United States is entitled to recover; "" is the sum of the total amount paid under one or more Ruth L. Kirschstein National Research Service Awards to such individual; "t" is the total number of months in such individual's service obligation; and "s" is the number of months of such obligation served by such individual in accordance with paragraphs (1) and (2) of this subsection.

(B) Any amount which the United States is entitled to recover under subparagraph (A) shall, within the three-year period beginning on the date the United States becomes entitled to recover such amount, be paid to the United States. Until any amount due the United States under subparagraph (A) on account of any Ruth L. Kirschstein National Research Service Award is paid, there shall accrue to the United States interest on such amount at a rate fixed by the Secretary of the Treasury after taking into consideration private consumer rates of interest prevailing on the date the United States becomes entitled to such amount.

(5)(A) Any obligation of an individual under paragraph (1) shall be canceled upon the death of such individual.

(B) The Secretary shall by regulation provide for the waiver or suspension of any such obligation applicable to any individual whenever compliance by such individual is impossible or would involve substantial hardship to such individual or would be against equity and good conscience.

(July 1, 1944, ch. 373, title IV, §487, as added Pub. L. 99–158, §2, Nov. 20, 1985, 99 Stat. 869; amended Pub. L. 100–607, title I, §151, title VI, §635, Nov. 4, 1988, 102 Stat. 3058, 3148; Pub. L. 101–93, §5(d), Aug. 16, 1989, 103 Stat. 612; Pub. L. 101–239, title VI, §6103(e)(7), Dec. 19, 1989, 103 Stat. 2208; Pub. L. 102–321, title I, §163(b)(4), July 10, 1992, 106 Stat. 376; Pub. L. 103–43, title XVI, §§1601, 1602, 1632, 1641, title XX, §2008(b)(14), June 10, 1993, 107 Stat. 181, 186, 211; Pub. L. 106–129, §2(b)(2), Dec. 6, 1999, 113 Stat. 1670; Pub. L. 107–206, title I, §804(a), (b), Aug. 2, 2002, 116 Stat. 874; Pub. L. 109–482, title I, §103(b)(47), Jan. 15, 2007, 120 Stat. 3688.)

EDITORIAL NOTES

REFERENCES IN TEXT

Section 288–5 of this title, referred to in subsec. (a)(1)(C), was repealed by Pub. L. 114–255, div. A, title II, §2022(c)(3), Dec. 13, 2016, 130 Stat. 1054.

AMENDMENTS

2007—Subsec. (d). Pub. L. 109–482 struck out subsec. (d) which related to authorization and apportionment of appropriations.

2002—Pub. L. 107–206 inserted "Ruth L. Kirschstein" before "National Research Service Award" and "National Research Service Awards" wherever appearing in section catchline and text.

1999—Subsec. (d)(3). Pub. L. 106–129 substituted "Agency for Healthcare Research and Quality" for "Agency for Health Care Policy and Research".

1993—Subsec. (a)(1)(C). Pub. L. 103–43, §1632, added subpar. (C).

Subsec. (a)(4). Pub. L. 103–43, §1601, added par. (4).

Subsec. (c)(1), (2). Pub. L. 103–43, §1602, added pars. (1) and (2) and struck out former pars. (1) and (2) which read as follows:

"(1) Each individual who is awarded a National Research Service Award (other than an individual who is a pre-baccalaureate student who is awarded a National Research Service Award for research training) shall, in accordance with paragraph (3), engage in health research or teaching or any combination thereof which is in accordance with the usual patterns of academic employment, for a period computed in accordance with paragraph (2).

"(2) For each month for which an individual receives a National Research Service Award which is made for a period in excess of twelve months, such individual shall engage in one month of health research or teaching or any combination thereof which is in accordance with the usual patterns of academic employment."

Subsec. (d). Pub. L. 103–43, §1641(1), amended first sentence generally. Prior to amendment, first sentence read as follows: "For the purpose of making payments under National Research Service Awards and under grants for such Awards, there are authorized to be appropriated $300,000,000 for fiscal year 1989 and such sums as may be necessary for fiscal year 1990."

Subsec. (d)(3). Pub. L. 103–43, §§1641(2), 2008(b)(14), substituted "1 percent" for "one-half of one percent" in two places, "293k, 293l, or 293m" for "295g, 295g–4, or 295g–6", and "242b(a)" for "242b(a)(3)".

1992—Subsec. (a)(1). Pub. L. 102–321 struck out "and the Alcohol, Drug Abuse, and Mental Health Administration" before "in matters relating to" in subpar. (A)(i) and struck out "or the Alcohol, Drug Abuse, and Mental Health Administration" before "shall be considered" in last sentence.

1989—Subsec. (d)(3). Pub. L. 101–93 directed that par. (3), as similarly amended by sections 151(2) and 635 of Pub. L. 100–607, be amended to read as if the amendment made by such section 635 had not been enacted. See 1988 Amendment note below.

Subsec. (d)(3)(B). Pub. L. 101–239 substituted "Agency for Health Care Policy and Research" for "National Center for Health Services Research and Health Care Technology Assessment".

1988—Subsec. (d). Pub. L. 100–607, §151(1), amended first sentence generally. Prior to amendment, first sentence read as follows: "There are authorized to be appropriated to make payments under National Research Service Awards and under grants for such awards $244,000,000 for fiscal year 1986, $260,000,000 for fiscal year 1987, and $275,000,000 for fiscal year 1988."

Subsec. (d)(3). Pub. L. 100–607, §§151(2), 635, made identical amendments, inserting "to the Secretary, acting through the Administrator of the Health Resources and Services Administration," after first reference to "available".

STATUTORY NOTES AND RELATED SUBSIDIARIES

CHANGE OF NAME

Pub. L. 107–206, title I, §804(c), Aug. 2, 2002, 116 Stat. 874, provided that: "Any reference in any law (other than this Act [see Tables for classification]), regulation, document, record, map, or other paper of the United States to 'National Research Service Awards' shall be considered to be a reference to 'Ruth L. Kirschstein National Research Service Awards'."

EFFECTIVE DATE OF 2007 AMENDMENT

Amendment by Pub. L. 109–482 applicable only with respect to amounts appropriated for fiscal year 2007 or subsequent fiscal years, see section 109 of Pub. L. 109–482, set out as a note under section 281 of this title.

EFFECTIVE DATE OF 1992 AMENDMENT

Amendment by Pub. L. 102–321 effective Oct. 1, 1992, with provision for programs providing financial assistance, see section 801(c), (d) of Pub. L. 102–321, set out as a note under section 236 of this title.

[1] *So in original. Reference to Administration probably should not appear.*

[2] *See References in Text note below.*

§288–1. Intramural loan repayment program

(a) In general

The Director of the National Institutes of Health shall, as appropriate and based on workforce and scientific priorities, carry out a program through the subcategories listed in subsection (b)(1) (or modified subcategories as provided for in subsection (b)(2)) of entering into agreements with appropriately qualified health professionals under which such health professionals agree to conduct research, as employees of the National Institutes of Health, in consideration of the Federal Government agreeing to repay, for each year of such service, not more than $50,000 of the principal and interest of the educational loans of such health professionals.

(b) Subcategories of research

(1) In general

In carrying out the program under subsection (a), the Director of the National Institutes of Health—

(A) shall continue to focus on—

(i) general research;

(ii) research on acquired immune deficiency syndrome; and

(iii) clinical research conducted by appropriately qualified health professional [1] who are from disadvantaged backgrounds; and

(B) may focus on an area of emerging scientific or workforce need.

(2) Elimination or establishment of subcategories

The Director of the National Institutes of Health may eliminate one or more subcategories provided for in paragraph (1) due to changes in workforce or scientific needs related to biomedical research. The Director may establish other subcategory areas based on workforce and scientific priorities if the total number of subcategories does not exceed the number of subcategories listed in paragraph (1).

(c) Limitation

The Director of the National Institutes of Health may not enter into a contract with a health professional pursuant to subsection (a) unless such professional has a substantial amount of education loans relative to income (as determined pursuant to guidelines issued by the Director).

(d) Applicability of certain provisions

With respect to the National Health Service Corps Loan Repayment Program established in subpart III of part D of subchapter II, the provisions of such subpart shall, except as inconsistent with subsection (a) of this section, apply to the program established in such subsection (a) in the same manner and to the same extent as such provisions apply to the National Health Service Corps Loan Repayment Program established in such subpart.

(e) Availability of appropriations

Amounts available for carrying out this section shall remain available until the expiration of the second fiscal year beginning after the fiscal year for which such amounts are made available.

(July 1, 1944, ch. 373, title IV, §487A, as added Pub. L. 100–607, title VI, §634(a), Nov. 4, 1988, 102 Stat. 3148; amended Pub. L. 103–43, title XVI, §1611(a), June 10, 1993, 107 Stat. 181; Pub. L. 105–392, title IV, §410(a), Nov. 13, 1998, 112 Stat. 3589; Pub. L. 109–482, title I, §103(b)(48), Jan. 15, 2007, 120 Stat. 3688; Pub. L. 114–255, div. A, title II, §2022(a), Dec. 13, 2016, 130 Stat. 1052.)

EDITORIAL NOTES

AMENDMENTS

2016—Pub. L. 114–255, §2022(a)(1), amended section catchline generally. Prior to amendment, catchline read as follows: "Loan repayment program for research with respect to acquired immune deficiency syndrome".

Subsec. (a). Pub. L. 114–255, §2022(a)(2), substituted "The Director of the National Institutes of Health shall, as appropriate and based on workforce and scientific priorities, carry out a program through the subcategories listed in subsection (b)(1) (or modified subcategories as provided for in subsection (b)(2))" for "The Secretary shall carry out a program", "conduct research" for "conduct", and "$50,000" for "$35,000", and struck out "research with respect to acquired immune deficiency syndrome" after "National Institutes of Health,".

Subsecs. (b) to (d). Pub. L. 114–255, §2022(a)(3), (4), added subsecs. (b) and (c) and redesignated former subsec. (b) as (d).

Subsec. (e). Pub. L. 114–255, §2022(a)(5), added subsec. (e).

2007—Subsec. (c). Pub. L. 109–482 struck out heading and text of subsec. (c). Text read as follows: "For the purpose of carrying out this section, there are authorized to be appropriated such sums as may be necessary for each of the fiscal years 1994 through 2001."

1998—Subsec. (a). Pub. L. 105–392, §410(a)(1), substituted "$35,000" for "$20,000".

Subsec. (c). Pub. L. 105–392, §410(a)(2), substituted "2001" for "1996".

1993—Pub. L. 103–43 amended section generally, in subsec. (a) redesignating former par. (1) as entire subsec., striking out provisions setting a deadline for implementation of the program and former par. (2) containing a limitation that the health professional have a substantial amount of educational loans relative to income and not have been employed at the National Institutes of Health during the 1-year period preceding Nov. 4, 1988, reenacting subsec. (b) without change, and in subsec. (c) redesignating former par. (1) as entire subsec., substituting authorization of appropriations for fiscal years 1994 through 1996 for authorization of appropriations for fiscal years 1989 through 1991, and striking out former par. (2) relating to continued availability of appropriated amounts.

STATUTORY NOTES AND RELATED SUBSIDIARIES

EFFECTIVE DATE OF 2007 AMENDMENT

Amendment by Pub. L. 109–482 applicable only with respect to amounts appropriated for fiscal year 2007 or subsequent fiscal years, see section 109 of Pub. L. 109–482, set out as a note under section 281 of this title.

EFFECTIVE DATE OF 1993 AMENDMENT

Pub. L. 103–43, title XVI, §1611(b), June 10, 1993, 107 Stat. 182, provided that: "The amendment made by subsection (a) [amending this section] does not apply to any agreement entered into under section 487A of the Public Health Service Act [42 U.S.C. 288–1] before the date of the enactment of this Act [June 10, 1993]. Each such agreement continues to be subject to the terms of the agreement in effect on the day before such date."

[1] *So in original. Probably should be "professionals".*

§288–2. Extramural loan repayment program

(a) In general

The Director of the National Institutes of Health shall, as appropriate and based on workforce and scientific priorities, carry out a program through the subcategories listed in subsection (b)(1) (or modified subcategories as provided for in subsection (b)(2)), of entering into contracts with qualified health professionals under which such health professionals agree to conduct research in consideration of the Federal Government agreeing to repay, for each year of such research, not more than $50,000 of the principal and interest of the educational loans of such health professionals.

(b) Subcategories of research

(1) In general

In carrying out the program under subsection (a), the Director of the National Institutes of Health—

(A) shall continue to focus on—

(i) contraception or infertility research;

(ii) pediatric research, including pediatric pharmacological research;

(iii) minority health disparities research;

(iv) clinical research; and

(v) clinical research conducted by appropriately qualified health professional [1] who are from disadvantaged backgrounds; and

(B) may focus on an area of emerging scientific or workforce need.

(2) Elimination or establishment of subcategories

The Director of the National Institutes of Health may eliminate one or more subcategories provided for in paragraph (1) due to changes in workforce or scientific needs related to biomedical research. The Director may establish other subcategory areas based on workforce and scientific priorities if the total number of subcategories does not exceed the number of subcategories listed in paragraph (1).

(c) Limitation

The Director of the National Institutes of Health may not enter into a contract with a health professional pursuant to subsection (a) unless such professional has a substantial amount of education loans relative to income (as determined pursuant to guidelines issued by the Director).

(d) Applicability of certain provisions regarding obligated service

The provisions of sections 254l–1, 254m, and 254o of this title shall, except as inconsistent with subsection (a) of this section, apply to the program established in subsection (a) to the same extent and in the same manner as such provisions apply to the National Health Service Corps Loan Repayment Program established in subpart III of part D of subchapter II.

(e) Availability of appropriations

Amounts available for carrying out this section shall remain available until the expiration of the second fiscal year beginning after the fiscal year for which the amounts were made available.

(July 1, 1944, ch. 373, title IV, §487B, as added Pub. L. 103–43, title X, §1002, June 10, 1993, 107 Stat. 166; amended Pub. L. 105–392, title IV, §410(b), Nov. 13, 1998, 112 Stat. 3589; Pub. L. 110–154, §1(b)(8), Dec. 21, 2007, 121 Stat. 1827; Pub. L. 114–255, div. A, title II, §2022(b), Dec. 13, 2016, 130 Stat. 1053.)

EDITORIAL NOTES

AMENDMENTS

2016—Pub. L. 114–255, §2022(b)(1), amended section catchline generally. Prior to amendment, catchline read as follows: "Loan repayment program for research with respect to contraception and infertility".

Subsec. (a). Pub. L. 114–255, §2022(b)(2), inserted heading and, in text, substituted "The Director of the National Institutes of Health shall, as appropriate and based on workforce and scientific priorities, carry out a program through the subcategories listed in subsection (b)(1) (or modified subcategories as provided for in subsection (b)(2))," for "The Secretary, in consultation with the Director of the Eunice Kennedy Shriver National Institute of Child Health and Human Development, shall establish a program" and "research, not more than $50,000" for "service, not more than $35,000" and struck out "(including graduate students)" after "qualified health professionals" and "with respect to contraception, or with respect to infertility," after "conduct research".

Subsecs. (b), (c). Pub. L. 114–255, §2022(b)(4), added subsecs. (b) and (c). Former subsecs. (b) and (c) redesignated (d) and (e), respectively.

Subsec. (d). Pub. L. 114–255, §2022(3), (5), redesignated subsec. (b) as (d) and inserted heading.
Subsec. (e). Pub. L. 114–255, §2002(3), (6), redesignated subsec. (c) as (e) and inserted heading.
2007—Subsec. (a). Pub. L. 110–154, which directed substitution of "Eunice Kennedy Shriver National Institute of Child Health and Human Development" for "National Institute on Child Health and Human Development", was executed by making the substitution for "National Institute of Child Health and Human Development" to reflect the probable intent of Congress.
1998—Subsec. (a). Pub. L. 105–392 substituted "$35,000" for "$20,000".

[1] *So in original. Probably should be "professionals".*

§288–3. Repealed. Pub. L. 114–255, div. A, title II, §2022(c)(2), Dec. 13, 2016, 130 Stat. 1054

Section, July 1, 1944, ch. 373, title IV, §487C, as added Pub. L. 103–43, title XVI, §1621, June 10, 1993, 107 Stat. 182; amended Pub. L. 105–392, title IV, §410(c), Nov. 13, 1998, 112 Stat. 3589, related to loan repayment program for research generally.

§288–4. Undergraduate scholarship program regarding professions needed by National Research Institutes

(a) Establishment of program

(1) In general

Subject to section 288(a)(1)(C) of this title, the Secretary, acting through the Director of NIH, may carry out a program of entering into contracts with individuals described in paragraph (2) under which—

(A) the Director of NIH agrees to provide to the individuals scholarships for pursuing, as undergraduates at accredited institutions of higher education, academic programs appropriate for careers in professions needed by the National Institutes of Health; and

(B) the individuals agree to serve as employees of the National Institutes of Health, for the period described in subsection (c), in positions that are needed by the National Institutes of Health and for which the individuals are qualified.

(2) Individuals from disadvantaged backgrounds

The individuals referred to in paragraph (1) are individuals who—

(A) are enrolled or accepted for enrollment as full-time undergraduates at accredited institutions of higher education; and

(B) are from disadvantaged backgrounds.

(b) Facilitation of interest of students in careers at National Institutes of Health

In providing employment to individuals pursuant to contracts under subsection (a)(1), the Director of NIH shall carry out activities to facilitate the interest of the individuals in pursuing careers as employees of the National Institutes of Health.

(c) Period of obligated service

(1) Duration of service

For purposes of subparagraph (B) of subsection (a)(1), the period of service for which an individual is obligated to serve as an employee of the National Institutes of Health is, subject to paragraph (2)(A), 12 months for each academic year for which the scholarship under such subsection is provided.

(2) Schedule for service

(A) Subject to subparagraph (B), the Director of NIH may not provide a scholarship under subsection (a) unless the individual applying for the scholarship agrees that—

(i) the individual will serve as an employee of the National Institutes of Health full-time for not less than 10 consecutive weeks of each year during which the individual is attending the educational institution involved and receiving such a scholarship;

(ii) the period of service as such an employee that the individual is obligated to provide under clause (i) is in addition to the period of service as such an employee that the individual is obligated to provide under subsection (a)(1)(B); and

(iii) not later than 60 days after obtaining the educational degree involved, the individual will begin serving full-time as such an employee in satisfaction of the period of service that the individual is obligated to provide under subsection (a)(1)(B).

(B) The Director of NIH may defer the obligation of an individual to provide a period of service under subsection (a)(1)(B), if the Director determines that such a deferral is appropriate.

(3) Applicability of certain provisions relating to appointment and compensation

For any period in which an individual provides service as an employee of the National Institutes of Health in satisfaction of the obligation of the individual under subsection (a)(1)(B) or paragraph (2)(A)(i), the individual may be appointed as such an employee without regard to the provisions of title 5 relating to appointment and compensation.

(d) Provisions regarding scholarship

(1) Approval of academic program

The Director of NIH may not provide a scholarship under subsection (a) for an academic year unless—

(A) the individual applying for the scholarship has submitted to the Director a proposed academic program for the year and the Director has approved the program; and

(B) the individual agrees that the program will not be altered without the approval of the Director.

(2) Academic standing

The Director of NIH may not provide a scholarship under subsection (a) for an academic year unless the individual applying for the scholarship agrees to maintain an acceptable level of academic standing, as determined by the educational institution involved in accordance with regulations issued by the Secretary.

(3) Limitation on amount

The Director of NIH may not provide a scholarship under subsection (a) for an academic year in an amount exceeding $20,000.

(4) Authorized uses

A scholarship provided under subsection (a) may be expended only for tuition expenses, other reasonable educational expenses, and reasonable living expenses incurred in attending the school involved.

(5) Contract regarding direct payments to institution

In the case of an institution of higher education with respect to which a scholarship under subsection (a) is provided, the Director of NIH may enter into a contract with the institution under which the amounts provided in the scholarship for tuition and other educational expenses are paid directly to the institution.

(e) Penalties for breach of scholarship contract

The provisions of section 254o of this title shall apply to the program established in subsection (a) to the same extent and in the same manner as such provisions apply to the National Health Service Corps Loan Repayment Program established in section 254l–1 of this title.

(f) Requirement of application

The Director of NIH may not provide a scholarship under subsection (a) unless an application for

the scholarship is submitted to the Director and the application is in such form, is made in such manner, and contains such agreements, assurances, and information as the Director determines to be necessary to carry out this section.

(g) Availability of authorization of appropriations

Amounts appropriated for a fiscal year for scholarships under this section shall remain available until the expiration of the second fiscal year beginning after the fiscal year for which the amounts were appropriated.

(July 1, 1944, ch. 373, title IV, §487D, as added Pub. L. 103–43, title XVI, §1631, June 10, 1993, 107 Stat. 183.)

§§288–5 to 288–6. Repealed. Pub. L. 114–255, div. A, title II, §2022(c)(3)–(5), Dec. 13, 2016, 130 Stat. 1054

Section 288–5, July 1, 1944, ch. 373, title IV, §487E, as added Pub. L. 103–43, title XVI, §1631, June 10, 1993, 107 Stat. 185; amended Pub. L. 105–392, title IV, §410(d), Nov. 13, 1998, 112 Stat. 3589; Pub. L. 106–554, §1(a)(1) [title II, §223], Dec. 21, 2000, 114 Stat. 2763, 2763A–30, related to loan repayment program regarding clinical researchers from disadvantaged backgrounds.

Section 288–5a, July 1, 1944, ch. 373, title IV, §487F, as added Pub. L. 106–505, title II, §205, Nov. 13, 2000, 114 Stat. 2329; amended Pub. L. 109–482, title I, §103(b)(49), Jan. 15, 2007, 120 Stat. 3689, related to loan repayment program regarding clinical researchers. Another section 487F of act July 1, 1944, was classified to section 288–6 of this title, prior to repeal by Pub. L. 114–255.

Section 288–6, July 1, 1944, ch. 373, title IV, §487F, as added Pub. L. 106–310, div. A, title X, §1002(b), Oct. 17, 2000, 114 Stat. 1129; amended Pub. L. 110–85, title V, §503(b), Sept. 27, 2007, 121 Stat. 890, related to pediatric research loan repayment program. Another section 487F of act July 1, 1944, was classified to section 288–5a of this title, prior to repeal by Pub. L. 114–255.

§288a. Visiting Scientist Awards

(a) The Secretary may make awards (hereafter in this section referred to as "Visiting Scientist Awards") to outstanding scientists who agree to serve as visiting scientists at institutions of postsecondary education which have significant enrollments of disadvantaged students. Visiting Scientist Awards shall be made by the Secretary to enable the faculty and students of such institutions to draw upon the special talents of scientists from other institutions for the purpose of receiving guidance, advice, and instruction with regard to research, teaching, and curriculum development in the biomedical and behavioral sciences and such other aspects of these sciences as the Secretary shall deem appropriate.

(b) The amount of each Visiting Scientist Award shall include such sum as shall be commensurate with the salary or remuneration which the individual receiving the award would have been entitled to receive from the institution with which the individual has, or had, a permanent or immediately prior affiliation. Eligibility for and terms of Visiting Scientist Awards shall be determined in accordance with regulations the Secretary shall prescribe.

(July 1, 1944, ch. 373, title IV, §488, as added Pub. L. 99–158, §2, Nov. 20, 1985, 99 Stat. 872.)

§288b. Studies respecting biomedical and behavioral research personnel

(a) Scope of undertaking

The Secretary shall, in accordance with subsection (b), arrange for the conduct of a continuing study to—

(1) establish (A) the Nation's overall need for biomedical and behavioral research personnel, (B) the subject areas in which such personnel are needed and the number of such personnel needed in each such area, and (C) the kinds and extent of training which should be provided such personnel;

(2) assess (A) current training programs available for the training of biomedical and behavioral research personnel which are conducted under this chapter, at or through national research institutes under the National Institutes of Health, and (B) other current training programs available for the training of such personnel;

(3) identify the kinds of research positions available to and held by individuals completing such programs;

(4) determine, to the extent feasible, whether the programs referred to in clause (B) of paragraph (2) would be adequate to meet the needs established under paragraph (1) if the programs referred to in clause (A) of paragraph (2) were terminated; and

(5) determine what modifications in the programs referred to in paragraph (2) are required to meet the needs established under paragraph (1).

(b) Arrangement with National Academy of Sciences or other nonprofit private groups or associations

(1) The Secretary shall request the National Academy of Sciences to conduct the study required by subsection (a) under an arrangement under which the actual expenses incurred by such Academy in conducting such study will be paid by the Secretary. If the National Academy of Sciences is willing to do so, the Secretary shall enter into such an arrangement with such Academy for the conduct of such study.

(2) If the National Academy of Sciences is unwilling to conduct such study under such an arrangement, then the Secretary shall enter into a similar arrangement with other appropriate nonprofit private groups or associations under which such groups or associations will conduct such study and prepare and submit the reports thereon as provided in subsection (c).[1]

(3) The National Academy of Sciences or other group or association conducting the study required by subsection (a) shall conduct such study in consultation with the Director of NIH.

(July 1, 1944, ch. 373, title IV, §489, as added Pub. L. 99–158, §2, Nov. 20, 1985, 99 Stat. 872; amended Pub. L. 102–321, title I, §163(b)(5), July 10, 1992, 106 Stat. 376.)

EDITORIAL NOTES

REFERENCES IN TEXT

Subsection (c), referred to in subsec. (b)(2), was omitted from the Code. See Codification note below.

CODIFICATION

Subsec. (c) of this section, which required the Secretary to submit a report on results of the study required under subsec. (a) of this section to certain committees of Congress at least once every four years, terminated, effective May 15, 2000, pursuant to section 3003 of Pub. L. 104–66, as amended, set out as a note under section 1113 of Title 31, Money and Finance. See, also, page 96 of House Document No. 103–7.

AMENDMENTS

1992—Subsec. (a)(2). Pub. L. 102–321 struck out "and institutes under the Alcohol, Drug Abuse, and Mental Health Administration" after "National Institutes of Health".

STATUTORY NOTES AND RELATED SUBSIDIARIES

EFFECTIVE DATE OF 1992 AMENDMENT

Amendment by Pub. L. 102–321 effective Oct. 1, 1992, with provision for programs providing financial assistance, see section 801(c), (d) of Pub. L. 102–321, set out as a note under section 236 of this title.

[1] *See References in Text note below.*

PART H—GENERAL PROVISIONS

EDITORIAL NOTES

CODIFICATION

Pub. L. 103–43, title I, §141(a)(2), June 10, 1993, 107 Stat. 136, redesignated part G "General Provisions" as H. Former part H "National Foundation for Biomedical Research" redesignated I.

§289. Institutional review boards; ethics guidance program

(a) The Secretary shall by regulation require that each entity which applies for a grant, contract, or cooperative agreement under this chapter for any project or program which involves the conduct of biomedical or behavioral research involving human subjects submit in or with its application for such grant, contract, or cooperative agreement assurances satisfactory to the Secretary that it has established (in accordance with regulations which the Secretary shall prescribe) a board (to be known as an "Institutional Review Board") to review biomedical and behavioral research involving human subjects conducted at or supported by such entity in order to protect the rights of the human subjects of such research.

(b)(1) The Secretary shall establish a program within the Department of Health and Human Services under which requests for clarification and guidance with respect to ethical issues raised in connection with biomedical or behavioral research involving human subjects are responded to promptly and appropriately.

(2) The Secretary shall establish a process for the prompt and appropriate response to information provided to the Director of NIH respecting incidences of violations of the rights of human subjects of research for which funds have been made available under this chapter. The process shall include procedures for the receiving of reports of such information from recipients of funds under this chapter and taking appropriate action with respect to such violations.

(July 1, 1944, ch. 373, title IV, §491, as added Pub. L. 99–158, §2, Nov. 20, 1985, 99 Stat. 873.)

STATUTORY NOTES AND RELATED SUBSIDIARIES

PROTECTION OF HUMAN RESEARCH SUBJECTS

Pub. L. 114–255, div. A, title III, §3023, Dec. 13, 2016, 130 Stat. 1098, provided that:

"(a) IN GENERAL.—In order to simplify and facilitate compliance by researchers with applicable regulations for the protection of human subjects in research, the Secretary of Health and Human Services (referred to in this section as the 'Secretary') shall, to the extent practicable and consistent with other statutory provisions, harmonize differences between the HHS Human Subject Regulations and the FDA Human Subject Regulations in accordance with subsection (b).

"(b) AVOIDING REGULATORY DUPLICATION AND UNNECESSARY DELAYS.—The Secretary shall, as appropriate—

"(1) make such modifications to the provisions of the HHS Human Subject Regulations, the FDA Human Subject Regulations, and the vulnerable populations rules as may be necessary—

"(A) to reduce regulatory duplication and unnecessary delays;

"(B) to modernize such provisions in the context of multisite and cooperative research projects; and

"(C) to protect vulnerable populations, incorporate local considerations, and support community engagement through mechanisms such as consultation with local researchers and human research protection programs, in a manner consistent with subparagraph (B); and

"(2) ensure that human subject research that is subject to the HHS Human Subject Regulations and to the FDA Human Subject Regulations may—

"(A) use joint or shared review;

"(B) rely upon the review of—

"(i) an independent institutional review board; or

"(ii) an institutional review board of an entity other than the sponsor of the research; or

"(C) use similar arrangements to avoid duplication of effort.

"(c) CONSULTATION.—In harmonizing or modifying regulations or guidance under this section, the Secretary shall consult with stakeholders (including researchers, academic organizations, hospitals, institutional research boards, pharmaceutical, biotechnology, and medical device developers, clinical research organizations, patient groups, and others).

"(d) TIMING.—The Secretary shall complete the harmonization described in subsection (a) not later than 3 years after the date of enactment of this Act [Dec. 13, 2016].

"(e) PROGRESS REPORT.—Not later than 2 years after the date of enactment of this Act, the Secretary shall submit to Congress a report on the progress made toward completing such harmonization.

"(f) DEFINITIONS.—

"(1) HUMAN SUBJECT REGULATIONS.—In this section:

"(A) FDA HUMAN SUBJECT REGULATIONS.—The term 'FDA Human Subject Regulations' means the provisions of parts 50, 56, 312, and 812 of title 21, Code of Federal Regulations (or any successor regulations).

"(B) HHS HUMAN SUBJECT REGULATIONS.—The term 'HHS Human Subject Regulations' means the provisions of subpart A of part 46 of title 45, Code of Federal Regulations (or any successor regulations).

"(C) VULNERABLE POPULATION RULES.—The term 'vulnerable population rules' means—

"(i) except in the case of research described in clause (ii), the provisions of subparts B through D of part 46, Code of Federal Regulations (or any successor regulations); and

"(ii) in the case of research that is subject to FDA Human Subject Regulations, the provisions applicable to vulnerable populations under part 56 of title 21, Code of Federal Regulations (or any successor regulations) and subpart D of part 50 of such title 21 (or any successor regulations).

"(2) INSTITUTIONAL REVIEW BOARD DEFINED.—In this section, the term 'institutional review board' has the meaning that applies to the term 'institutional review board' under the HHS Human Subject Regulations."

INFORMED CONSENT FOR NEWBORN SCREENING RESEARCH

Pub. L. 113–240, §12, Dec. 18, 2014, 128 Stat. 2857, provided that:

"(a) IN GENERAL.—Research on newborn dried blood spots shall be considered research carried out on human subjects meeting the definition of section 46.102(f)(2) of title 45, Code of Federal Regulations, for purposes of Federally funded research conducted pursuant to the Public Health Service Act [42 U.S.C. 201 et seq.] until such time as updates to the Federal Policy for the Protection of Human Subjects (the Common Rule) are promulgated pursuant to subsection (c). For purposes of this subsection, sections 46.116(c) and 46.116(d) of title 45, Code of Federal Regulations, shall not apply.

"(b) EFFECTIVE DATE.—Subsection (a) shall apply only to newborn dried blood spots used for purposes of Federally funded research that were collected not earlier than 90 days after the date of enactment of this Act [Dec. 18, 2014].

"(c) REGULATIONS.—Not later than 6 months after the date of enactment of this Act, the Secretary of Health and Human Services shall promulgate proposed regulations related to the updating of the Federal Policy for the Protection of Human Subjects (the Common Rule), particularly with respect to informed consent. Not later than 2 years after such date of enactment, the Secretary shall promulgate final regulations based on such proposed regulations."

STUDY CONCERNING RESEARCH INVOLVING CHILDREN

Pub. L. 107–109, §12, Jan. 4, 2002, 115 Stat. 1416, provided that:

"(a) CONTRACT WITH INSTITUTE OF MEDICINE.—The Secretary of Health and Human Services shall enter into a contract with the Institute of Medicine for—

"(1) the conduct, in accordance with subsection (b), of a review of—

"(A) Federal regulations in effect on the date of the enactment of this Act [Jan. 4, 2002] relating to research involving children;

"(B) federally prepared or supported reports relating to research involving children; and

"(C) federally supported evidence-based research involving children; and

"(2) the submission to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives, not later than two years after the date of enactment of this Act, of a report concerning the review conducted under paragraph (1) that includes recommendations on best practices relating to research involving children.

"(b) AREAS OF REVIEW.—In conducting the review under subsection (a)(1), the Institute of Medicine shall consider the following:

"(1) The written and oral process of obtaining and defining 'assent', 'permission' and 'informed consent'

with respect to child clinical research participants and the parents, guardians, and the individuals who may serve as the legally authorized representatives of such children (as defined in subpart A of part 46 of title 45, Code of Federal Regulations).

"(2) The expectations and comprehension of child research participants and the parents, guardians, or legally authorized representatives of such children, for the direct benefits and risks of the child's research involvement, particularly in terms of research versus therapeutic treatment.

"(3) The definition of 'minimal risk' with respect to a healthy child or a child with an illness.

"(4) The appropriateness of the regulations applicable to children of differing ages and maturity levels, including regulations relating to legal status.

"(5) Whether payment (financial or otherwise) may be provided to a child or his or her parent, guardian, or legally authorized representative for the participation of the child in research, and if so, the amount and type of payment that may be made.

"(6) Compliance with the regulations referred to in subsection (a)(1)(A), the monitoring of such compliance (including the role of institutional review boards), and the enforcement actions taken for violations of such regulations.

"(7) The unique roles and responsibilities of institutional review boards in reviewing research involving children, including composition of membership on institutional review boards.

"(c) REQUIREMENTS OF EXPERTISE.—The Institute of Medicine shall conduct the review under subsection (a)(1) and make recommendations under subsection (a)(2) in conjunction with experts in pediatric medicine, pediatric research, and the ethical conduct of research involving children."

REQUIREMENT FOR ADDITIONAL PROTECTIONS FOR CHILDREN INVOLVED IN RESEARCH

Pub. L. 106–310, div. A, title XXVII, §2701, Oct. 17, 2000, 114 Stat. 1167, as amended by Pub. L. 106–505, title X, §1001(a), Nov. 13, 2000, 114 Stat. 2350, provided that: "Notwithstanding any other provision of law, not later than 6 months after the date of the enactment of this Act [Oct. 17, 2000], the Secretary of Health and Human Services shall require that all research involving children that is conducted, supported, or regulated by the Department of Health and Human Services be in compliance with subpart D of part 46 of title 45, Code of Federal Regulations."

[Pub. L. 106–505, title X, §1001(b), Nov. 13, 2000, 114 Stat. 2350, provided that: "The amendment made by subsection (a) [amending section 2701 of Pub. L. 106–310, set out above] takes effect on the date of the enactment of the Children's Health Act of 2000 [Oct. 17, 2000]."]

§289a. Peer review requirements

(a) Applications for biomedical and behavioral research grants, cooperative agreements, and contracts; regulations

(1) The Secretary, acting through the Director of NIH, shall by regulation require appropriate technical and scientific peer review of—

(A) applications made for grants and cooperative agreements under this chapter for biomedical and behavioral research; and

(B) applications made for biomedical and behavioral research and development contracts to be administered through the National Institutes of Health.

(2) Regulations promulgated under paragraph (1) shall require that the review of applications made for grants, contracts, and cooperative agreements required by the regulations be conducted—

(A) to the extent practical, in a manner consistent with the system for technical and scientific peer review applicable on November 20, 1985, to grants under this chapter for biomedical and behavioral research, and

(B) to the extent practical, by technical and scientific peer review groups performing such review on or before November 20, 1985,

and shall authorize such review to be conducted by groups appointed under sections 282(b)(16) and 284(c)(3) of this title.

(b) Periodic review of research at National Institutes of Health

The Director of NIH shall establish procedures for periodic technical and scientific peer review of research at the National Institutes of Health. Such procedures shall require that—

(1) the reviewing entity be provided a written description of the research to be reviewed, and

(2) the reviewing entity provide the advisory council of the national research institute involved with such description and the results of the review by the entity,

and shall authorize such review to be conducted by groups appointed under sections 282(b)(6) [1] and 284(c)(3) of this title.

(c) Compliance with requirements for inclusion of women and minorities in clinical research

(1) In technical and scientific peer review under this section of proposals for clinical research, the consideration of any such proposal (including the initial consideration) shall, except as provided in paragraph (2), include an evaluation of the technical and scientific merit of the proposal regarding compliance with section 289a–2 of this title.

(2) Paragraph (1) shall not apply to any proposal for clinical research that, pursuant to subsection (b) of section 289a–2 of this title, is not subject to the requirement of subsection (a) of such section regarding the inclusion of women and members of minority groups as subjects in clinical research.

(July 1, 1944, ch. 373, title IV, §492, as added Pub. L. 99–158, §2, Nov. 20, 1985, 99 Stat. 874; amended Pub. L. 103–43, title I, §132, June 10, 1993, 107 Stat. 135; Pub. L. 109–482, title I, §102(f)(1)(B), Jan. 15, 2007, 120 Stat. 3685.)

EDITORIAL NOTES

REFERENCES IN TEXT

Section 282(b)(6) of this title, referred to in subsec. (b), was redesignated section 282(b)(16) by Pub. L. 109–482, title I, §102(a)(3), Jan. 15, 2007, 120 Stat. 3681.

AMENDMENTS

2007—Subsec. (a)(2). Pub. L. 109–482 substituted "sections 282(b)(16)" for "sections 282(b)(6)" in concluding provisions.

1993—Subsec. (c). Pub. L. 103–43 added subsec. (c).

STATUTORY NOTES AND RELATED SUBSIDIARIES

EFFECTIVE DATE OF 2007 AMENDMENT

Amendment by Pub. L. 109–482 applicable only with respect to amounts appropriated for fiscal year 2007 or subsequent fiscal years, see section 109 of Pub. L. 109–482, set out as a note under section 281 of this title.

[1] *See References in Text note below.*

§289a–1. Certain provisions regarding review and approval of proposals for research

(a) Review as precondition to research

(1) Protection of human research subjects

(A) In the case of any application submitted to the Secretary for financial assistance to conduct research, the Secretary may not approve or fund any application that is subject to review under section 289(a) of this title by an Institutional Review Board unless the application has undergone review in accordance with such section and has been recommended for approval by a majority of the members of the Board conducting such review.

(B) In the case of research that is subject to review under procedures established by the Secretary for the protection of human subjects in clinical research conducted by the National

Institutes of Health, the Secretary may not authorize the conduct of the research unless the research has, pursuant to such procedures, been recommended for approval.

(2) Peer review

In the case of any proposal for the National Institutes of Health to conduct or support research, the Secretary may not approve or fund any proposal that is subject to technical and scientific peer review under section 289a of this title unless the proposal has undergone such review in accordance with such section and has been recommended for approval by a majority of the members of the entity conducting such review, and unless a majority of the voting members of the appropriate advisory council under section 284a of this title, or as applicable, of the advisory council under section 282(k) of this title, has recommended the proposal for approval.

(b) Ethical review of research

(1) Procedures regarding withholding of funds

If research has been recommended for approval for purposes of subsection (a), the Secretary may not withhold funds for the research because of ethical considerations unless—

(A) the Secretary convenes an advisory board in accordance with paragraph (5) to study such considerations; and

(B)(i) the majority of the advisory board recommends that, because of such considerations, the Secretary withhold funds for the research; or

(ii) the majority of such board recommends that the Secretary not withhold funds for the research because of such considerations, but the Secretary finds, on the basis of the report submitted under paragraph (5)(B)(ii), that the recommendation is arbitrary and capricious.

(2) Rules of construction

Paragraph (1) may not be construed as prohibiting the Secretary from withholding funds for research on the basis of—

(A) the inadequacy of the qualifications of the entities that would be involved with the conduct of the research (including the entity that would directly receive the funds from the Secretary), subject to the condition that, with respect to the process of review through which the research was recommended for approval for purposes of subsection (a), all findings regarding such qualifications made in such process are conclusive; or

(B) the priorities established by the Secretary for the allocation of funds among projects of research that have been so recommended.

(3) Applicability

The limitation established in paragraph (1) regarding the authority to withhold funds because of ethical considerations shall apply without regard to whether the withholding of funds on such basis is characterized as a disapproval, a moratorium, a prohibition, or other characterization.

(4) Preliminary matters regarding use of procedures

(A) If the Secretary makes a determination that an advisory board should be convened for purposes of paragraph (1), the Secretary shall, through a statement published in the Federal Register, announce the intention of the Secretary to convene such a board.

(B) A statement issued under subparagraph (A) shall include a request that interested individuals submit to the Secretary recommendations specifying the particular individuals who should be appointed to the advisory board involved. The Secretary shall consider such recommendations in making appointments to the board.

(C) The Secretary may not make appointments to an advisory board under paragraph (1) until the expiration of the 30-day period beginning on the date on which the statement required in subparagraph (A) is made with respect to the board.

(5) Ethics advisory boards

(A) Any advisory board convened for purposes of paragraph (1) shall be known as an ethics advisory board (in this paragraph referred to as an "ethics board").

(B)(i) An ethics board shall advise, consult with, and make recommendations to the Secretary regarding the ethics of the project of biomedical or behavioral research with respect to which the board has been convened.

(ii) Not later than 180 days after the date on which the statement required in paragraph (4)(A) is made with respect to an ethics board, the board shall submit to the Secretary, and to the Committee on Energy and Commerce of the House of Representatives and the Committee on Labor and Human Resources of the Senate, a report describing the findings of the board regarding the project of research involved and making a recommendation under clause (i) of whether the Secretary should or should not withhold funds for the project. The report shall include the information considered in making the findings.

(C) An ethics board shall be composed of no fewer than 14, and no more than 20, individuals who are not officers or employees of the United States. The Secretary shall make appointments to the board from among individuals with special qualifications and competence to provide advice and recommendations regarding ethical matters in biomedical and behavioral research. Of the members of the board—

(i) no fewer than 1 shall be an attorney;

(ii) no fewer than 1 shall be an ethicist;

(iii) no fewer than 1 shall be a practicing physician;

(iv) no fewer than 1 shall be a theologian; and

(v) no fewer than one-third, and no more than one-half, shall be scientists with substantial accomplishments in biomedical or behavioral research.

(D) The term of service as a member of an ethics board shall be for the life of the board. If such a member does not serve the full term of such service, the individual appointed to fill the resulting vacancy shall be appointed for the remainder of the term of the predecessor of the individual.

(E) A member of an ethics board shall be subject to removal from the board by the Secretary for neglect of duty or malfeasance or for other good cause shown.

(F) The Secretary shall designate an individual from among the members of an ethics board to serve as the chair of the board.

(G) In carrying out subparagraph (B)(i) with respect to a project of research, an ethics board shall conduct inquiries and hold public hearings.

(H) In carrying out subparagraph (B)(i) with respect to a project of research, an ethics board shall have access to all relevant information possessed by the Department of Health and Human Services, or available to the Secretary from other agencies.

(I) Members of an ethics board shall receive compensation for each day engaged in carrying out the duties of the board, including time engaged in traveling for purposes of such duties. Such compensation may not be provided in an amount in excess of the maximum rate of basic pay payable for GS–18 of the General Schedule.

(J) The Secretary, acting through the Director of the National Institutes of Health, shall provide to each ethics board reasonable staff and assistance to carry out the duties of the board.

(K) An ethics board shall terminate 30 days after the date on which the report required in subparagraph (B)(ii) is submitted to the Secretary and the congressional committees specified in such subparagraph.

(6) "Ethical considerations" defined

For purposes of this subsection, the term "ethical considerations" means considerations as to whether the nature of the research involved is such that it is unethical to conduct or support the research.

(July 1, 1944, ch. 373, title IV, §492A, as added Pub. L. 103–43, title I, §101, June 10, 1993, 107 Stat. 126; amended Pub. L. 109–482, title I, §102(e), Jan. 15, 2007, 120 Stat. 3684.)

EDITORIAL NOTES

AMENDMENTS

2007—Subsec. (a)(2). Pub. L. 109–482 inserted before period at end ", and unless a majority of the voting members of the appropriate advisory council under section 284a of this title, or as applicable, of the advisory council under section 282(k) of this title, has recommended the proposal for approval".

STATUTORY NOTES AND RELATED SUBSIDIARIES

CHANGE OF NAME

Committee on Labor and Human Resources of Senate changed to Committee on Health, Education, Labor, and Pensions of Senate by Senate Resolution No. 20, One Hundred Sixth Congress, Jan. 19, 1999.

Committee on Energy and Commerce of House of Representatives treated as referring to Committee on Commerce of House of Representatives by section 1(a) of Pub. L. 104–14, set out as a note preceding section 21 of Title 2, The Congress. Committee on Commerce of House of Representatives changed to Committee on Energy and Commerce of House of Representatives, and jurisdiction over matters relating to securities and exchanges and insurance generally transferred to Committee on Financial Services of House of Representatives by House Resolution No. 5, One Hundred Seventh Congress, Jan. 3, 2001.

EFFECTIVE DATE OF 2007 AMENDMENT

Amendment by Pub. L. 109–482 applicable only with respect to amounts appropriated for fiscal year 2007 or subsequent fiscal years, see section 109 of Pub. L. 109–482, set out as a note under section 281 of this title.

REFERENCES IN OTHER LAWS TO GS–16, 17, OR 18 PAY RATES

References in laws to the rates of pay for GS–16, 17, or 18, or to maximum rates of pay under the General Schedule, to be considered references to rates payable under specified sections of Title 5, Government Organization and Employees, see section 529 [title I, §101(c)(1)] of Pub. L. 101–509, set out in a note under section 5376 of Title 5.

§289a–2. Inclusion of women and minorities in clinical research

(a) Requirement of inclusion

(1) In general

In conducting or supporting clinical research for purposes of this subchapter, the Director of NIH shall, subject to subsection (b), ensure that—

(A) women are included as subjects in each project of such research; and

(B) members of minority groups are included as subjects in such research.

(2) Outreach regarding participation as subjects

The Director of NIH, in consultation with the Director of the Office of Research on Women's Health and the Director of the Office of Research on Minority Health, shall conduct or support outreach programs for the recruitment of women and members of minority groups as subjects in projects of clinical research.

(3) Strategic planning

(A) In general

The directors of the national institutes and national centers shall consult at least once annually with the Director of the National Institute on Minority Health and Health Disparities and the Director of the Office of Research on Women's Health regarding objectives of the national institutes and national centers to ensure that future activities by such institutes and centers take into account women and minorities and are focused on reducing health disparities.

(B) Strategic plans

Any strategic plan issued by a national institute or national center shall include details on the objectives described in subparagraph (A).

(b) Inapplicability of requirement

The requirement established in subsection (a) regarding women and members of minority groups shall not apply to a project of clinical research if the inclusion, as subjects in the project, of women and members of minority groups, respectively—

(1) is inappropriate with respect to the health of the subjects;

(2) is inappropriate with respect to the purpose of the research; or

(3) is inappropriate under such other circumstances as the Director of NIH may designate.

(c) Design of clinical trials

(1) In general

In the case of any clinical trial in which women or members of minority groups will under subsection (a) be included as subjects, the Director of NIH shall ensure that the trial is designed and carried out in a manner sufficient to provide for a valid analysis of whether the variables being studied in the trial affect women or members of minority groups, as the case may be, differently than other subjects in the trial.

(2) Reporting requirements

For any new and competing project of clinical research subject to the requirements under this section that receives a grant award 1 year after December 13, 2016, or any date thereafter, for which a valid analysis is provided under paragraph (1)—

(A) and which is an applicable clinical trial as defined in section 282(j) of this title, the entity conducting such clinical research shall submit the results of such valid analysis to the clinical trial registry data bank expanded under section 282(j)(3) of this title, and the Director of the National Institutes of Health shall, as appropriate, consider whether such entity has complied with the reporting requirement described in this subparagraph in awarding any future grant to such entity, including pursuant to section 282(j)(5)(A)(ii) of this title when applicable; and

(B) the Director of the National Institutes of Health shall encourage the reporting of the results of such valid analysis described in paragraph (1) through any additional means determined appropriate by the Director.

(d) Guidelines

(1) In general

Subject to paragraph (2), the Director of NIH, in consultation with the Director of the Office of Research on Women's Health and the Director of the Office of Research on Minority Health, shall establish guidelines regarding the requirements of this section. The guidelines shall include guidelines regarding—

(A) the circumstances under which the inclusion of women and minorities as subjects in projects of clinical research is inappropriate for purposes of subsection (b);

(B) the manner in which clinical trials are required to be designed and carried out for purposes of subsection (c); and

(C) the operation of outreach programs under subsection (a).

(2) Certain provisions

With respect to the circumstances under which the inclusion of women or members of minority groups (as the case may be) as subjects in a project of clinical research is inappropriate for purposes of subsection (b), the following applies to guidelines under paragraph (1):

(A)(i) In the case of a clinical trial, the guidelines shall provide that the costs of such inclusion in the trial is not a permissible consideration in determining whether such inclusion is inappropriate.

(ii) In the case of other projects of clinical research, the guidelines shall provide that the costs of such inclusion in the project is not a permissible consideration in determining whether such inclusion is inappropriate unless the data regarding women or members of minority groups, respectively, that would be obtained in such project (in the event that such inclusion were required) have been or are being obtained through other means that provide data of comparable quality.

(B) In the case of a clinical trial, the guidelines may provide that such inclusion in the trial is not required if there is substantial scientific data demonstrating that there is no significant difference between—

(i) the effects that the variables to be studied in the trial have on women or members of minority groups, respectively; and

(ii) the effects that the variables have on the individuals who would serve as subjects in the trial in the event that such inclusion were not required.

(e) Date certain for guidelines; applicability

(1) Date certain

The guidelines required in subsection (d) shall be established and published in the Federal Register not later than 180 days after June 10, 1993.

(2) Applicability

For fiscal year 1995 and subsequent fiscal years, the Director of NIH may not approve any proposal of clinical research to be conducted or supported by any agency of the National Institutes of Health unless the proposal specifies the manner in which the research will comply with this section.

(f) Reports by advisory councils

(1) In general

The advisory council of each national research institute shall prepare triennial reports describing the manner in which the institute has complied with this section. Each such report shall be submitted to the Director of the institute involved for inclusion in the triennial report under section 283 of this title.

(2) Contents

Each triennial report prepared by an advisory council of each national research institute as described in paragraph (1) shall include each of the following:

(A) The number of women included as subjects, and the proportion of subjects that are women, in any project of clinical research conducted during the applicable reporting period, disaggregated by categories of research area, condition, or disease, and accounting for single-sex studies.

(B) The number of members of minority groups included as subjects, and the proportion of subjects that are members of minority groups, in any project of clinical research conducted during the applicable reporting period, disaggregated by categories of research area, condition, or disease and accounting for single-race and single-ethnicity studies.

(C) For the applicable reporting period, the number of projects of clinical research that include women and members of minority groups and that—

(i) have been completed during such reporting period; and

(ii) are being carried out during such reporting period and have not been completed.

(D) The number of studies completed during the applicable reporting period for which reporting has been submitted in accordance with subsection (c)(2)(A).

(g) Definitions

For purposes of this section:

(1) The term "project of clinical research" includes a clinical trial.

(2) The term "minority group" includes subpopulations of minority groups. The Director of NIH shall, through the guidelines established under subsection (d), define the terms "minority group" and "subpopulation" for purposes of the preceding sentence.

(July 1, 1944, ch. 373, title IV, §492B, as added Pub. L. 103–43, title I, §131, June 10, 1993, 107 Stat. 133; amended Pub. L. 114–255, div. A, title II, §§2031(c), 2038(b), 2053, Dec. 13, 2016, 130 Stat. 1056, 1065, 1076.)

EDITORIAL NOTES

AMENDMENTS

2016—Subsec. (a)(3). Pub. L. 114–255, §2031(c), added par. (3).

Subsec. (c). Pub. L. 114–255, §2053, designated existing provisions as par. (1), inserted heading, and added par. (2).

Subsec. (f). Pub. L. 114–255, §2038(b), designated existing provisions as par. (1), inserted heading, substituted "triennial" for "biennial" in two places, and added par. (2).

STATUTORY NOTES AND RELATED SUBSIDIARIES

CLINICAL RESEARCH

Pub. L. 114–255, div. A, title II, §2038(h), Dec. 13, 2016, 130 Stat. 1067, provided that:

"(1) IN GENERAL.—Not later than 1 year after the date of enactment of this Act [Dec. 13, 2016], the Director of the National Institutes of Health, in consultation with the Director of the Office of Research on Women's Health and the Director of the National Institute on Minority Health and Health Disparities, shall update the guidelines established under section 492B(d) of [the] Public Health Service Act (42 U.S.C. 289a–2(d)) in accordance with paragraph (2).

"(2) REQUIREMENTS.—The updated guidelines described in paragraph (1) shall—

"(A) reflect the science regarding sex differences;

"(B) improve adherence to the requirements under section 492B of the Public Health Service Act (42 U.S.C. 289a–2), including the reporting requirements under subsection (f) of such section; and

"(C) clarify the circumstances under which studies should be designed to support the conduct of analyses to detect significant differences in the intervention effect due to demographic factors related to section 492B of the Public Health Service Act, including in the absence of prior studies that demonstrate a difference in study outcomes on the basis of such factors and considering the effects of the absence of such analyses on the availability of data related to demographic differences."

TASK FORCE ON RESEARCH SPECIFIC TO PREGNANT WOMEN AND LACTATING WOMEN

Pub. L. 114–255, div. A, title II, §2041, Dec. 13, 2016, 130 Stat. 1070, provided that:

"(a) TASK FORCE ON RESEARCH SPECIFIC TO PREGNANT WOMEN AND LACTATING WOMEN.—

"(1) ESTABLISHMENT.—Not later than 90 days after the date of enactment of this Act [Dec. 13, 2016], the Secretary of Health and Human Services (referred to in this section as the 'Secretary') shall establish a task force, in accordance with the Federal Advisory Committee Act ([former] 5 U.S.C. App.) [see 5 U.S.C. 1001 et seq.], to be known as the 'Task Force on Research Specific to Pregnant Women and Lactating Women' (in this section referred to as the 'Task Force').

"(2) DUTIES.—The Task Force shall provide advice and guidance to the Secretary regarding Federal activities related to identifying and addressing gaps in knowledge and research regarding safe and effective therapies for pregnant women and lactating women, including the development of such therapies and the collaboration on and coordination of such activities.

"(3) MEMBERSHIP.—

"(A) FEDERAL MEMBERS.—The Task Force shall be composed of each of the following Federal members, or the designees of such members:

"(i) The Director of the Centers for Disease Control and Prevention.

"(ii) The Director of the National Institutes of Health, the Director of the Eunice Kennedy Shriver National Institute of Child Health and Human Development, and the directors of such other appropriate national research institutes.

"(iii) The Commissioner of Food and Drugs.

"(iv) The Director of the Office on Women's Health.

"(v) The Director of the National Vaccine Program Office.

"(vi) The head of any other research-related agency or department not described in clauses (i) through (v) that the Secretary determines appropriate, which may include the Department of Veterans Affairs and the Department of Defense.

"(B) NON-FEDERAL MEMBERS.—The Task Force shall be composed of each of the following non-Federal members, including—

"(i) representatives from relevant medical societies with subject matter expertise on pregnant women, lactating women, or children;

"(ii) nonprofit organizations with expertise related to the health of women and children;

"(iii) relevant industry representatives; and

"(iv) other representatives, as appropriate.

"(C) LIMITATIONS.—The non-Federal members described in subparagraph (B) shall—

"(i) compose not more than one-half, and not less than one-third, of the total membership of the Task Force; and

"(ii) be appointed by the Secretary.

"(4) TERMINATION.—

"(A) IN GENERAL.—Subject to subparagraph (B), the Task Force shall terminate on the date that is 2 years after the date on which the Task Force is established under paragraph (1).

"(B) EXTENSION.—The Secretary may extend the operation of the Task Force for one additional 2-year period following the 2-year period described in subparagraph (A), if the Secretary determines that the extension is appropriate for carrying out the purpose of this section.

"(5) MEETINGS.—The Task Force shall meet not less than 2 times each year and shall convene public meetings, as appropriate, to fulfill its duties under paragraph (2).

"(6) TASK FORCE REPORT TO CONGRESS.—Not later than 18 months after the date on which the Task Force is established under paragraph (1), the Task Force shall prepare and submit to the Secretary, the Committee on Health, Education, Labor, and Pensions of the Senate, and the Committee on Energy and Commerce of the House of Representatives a report that includes each of the following:

"(A) A plan to identify and address gaps in knowledge and research regarding safe and effective therapies for pregnant women and lactating women, including the development of such therapies.

"(B) Ethical issues surrounding the inclusion of pregnant women and lactating women in clinical research.

"(C) Effective communication strategies with health care providers and the public on information relevant to pregnant women and lactating women.

"(D) Identification of Federal activities, including—

"(i) the state of research on pregnancy and lactation;

"(ii) recommendations for the coordination of, and collaboration on research related to pregnant women and lactating women;

"(iii) dissemination of research findings and information relevant to pregnant women and lactating women to providers and the public; and

"(iv) existing Federal efforts and programs to improve the scientific understanding of the health impacts on pregnant women, lactating women, and related birth and pediatric outcomes, including with respect to pharmacokinetics, pharmacodynamics, and toxicities.

"(E) Recommendations to improve the development of safe and effective therapies for pregnant women and lactating women.

"(b) CONFIDENTIALITY.—Nothing in this section shall authorize the Secretary of Health and Human Services to disclose any information that is a trade secret, or other privileged or confidential information, described in section 552(b)(4) of title 5, United States Code, or section 1905 of title 18, United States Code.

"(c) UPDATING PROTECTIONS FOR PREGNANT WOMEN AND LACTATING WOMEN IN RESEARCH.—

"(1) IN GENERAL.—Not later than 2 years after the date of enactment of this Act [Dec. 13, 2016], the Secretary, considering any recommendations of the Task Force available at such time and in consultation with the heads of relevant agencies of the Department of Health and Human Services, shall, as appropriate, update regulations and guidance, as applicable, regarding the inclusion of pregnant women and lactating women in clinical research.

"(2) CRITERIA FOR EXCLUDING PREGNANT OR LACTATING WOMEN.—In updating any regulations or guidance described in paragraph (1), the Secretary shall consider any appropriate criteria to be used by institutional review boards and individuals reviewing grant proposals for excluding pregnant women or lactating women as a study population requiring additional protections from participating in human subject research."

INAPPLICABILITY TO CURRENT PROJECTS

Pub. L. 103–43, title I, §133, June 10, 1993, 107 Stat. 135, provided that: "Section 492B of the Public Health Service Act, as added by section 131 of this Act [42 U.S.C. 289a–2], shall not apply with respect to projects of clinical research for which initial funding was provided prior to the date of the enactment of this

Act [June 10, 1993]. With respect to the inclusion of women and minorities as subjects in clinical research conducted or supported by the National Institutes of Health, any policies of the Secretary of Health and Human Services regarding such inclusion that are in effect on the day before the date of the enactment of this Act shall continue to apply to the projects referred to in the preceding sentence."

§289b. Office of Research Integrity

(a) In general

(1) Establishment of Office

Not later than 90 days after June 10, 1993, the Secretary shall establish an office to be known as the Office of Research Integrity (referred to in this section as the "Office"), which shall be established as an independent entity in the Department of Health and Human Services.

(2) Appointment of Director

The Office shall be headed by a Director, who shall be appointed by the Secretary, be experienced and specially trained in the conduct of research, and have experience in the conduct of investigations of research misconduct. The Secretary shall carry out this section acting through the Director of the Office. The Director shall report to the Secretary.

(3) Definitions

(A) The Secretary shall by regulation establish a definition for the term "research misconduct" for purposes of this section.

(B) For purposes of this section, the term "financial assistance" means a grant, contract, or cooperative agreement.

(b) Existence of administrative processes as condition of funding for research

The Secretary shall by regulation require that each entity that applies for financial assistance under this chapter for any project or program that involves the conduct of biomedical or behavioral research submit in or with its application for such assistance—

(1) assurances satisfactory to the Secretary that such entity has established and has in effect (in accordance with regulations which the Secretary shall prescribe) an administrative process to review reports of research misconduct in connection with biomedical and behavioral research conducted at or sponsored by such entity;

(2) an agreement that the entity will report to the Director any investigation of alleged research misconduct in connection with projects for which funds have been made available under this chapter that appears substantial; and

(3) an agreement that the entity will comply with regulations issued under this section.

(c) Process for response of Director

The Secretary shall by regulation establish a process to be followed by the Director for the prompt and appropriate—

(1) response to information provided to the Director respecting research misconduct in connection with projects for which funds have been made available under this chapter;

(2) receipt of reports by the Director of such information from recipients of funds under this chapter;

(3) conduct of investigations, when appropriate; and

(4) taking of other actions, including appropriate remedies, with respect to such misconduct.

(d) Monitoring by Director

The Secretary shall by regulation establish procedures for the Director to monitor administrative processes and investigations that have been established or carried out under this section.

(e) Protection of whistleblowers

(1) In general

In the case of any entity required to establish administrative processes under subsection (b), the Secretary shall by regulation establish standards for preventing, and for responding to the occurrence of retaliation by such entity, its officials or agents, against an employee in the terms and conditions of employment in response to the employee having in good faith—

(A) made an allegation that the entity, its officials or agents, has engaged in or failed to adequately respond to an allegation of research misconduct; or

(B) cooperated with an investigation of such an allegation.

(2) Monitoring by Secretary

The Secretary shall by regulation establish procedures for the Director to monitor the implementation of the standards established by an entity under paragraph (1) for the purpose of determining whether the procedures have been established, and are being utilized, in accordance with the standards established under such paragraph.

(3) Noncompliance

The Secretary shall by regulation establish remedies for noncompliance by an entity, its officials or agents, which has engaged in retaliation in violation of the standards established under paragraph (1). Such remedies may include termination of funding provided by the Secretary for such project or recovery of funding being provided by the Secretary for such project, or other actions as appropriate.

(July 1, 1944, ch. 373, title IV, §493, as added Pub. L. 99–158, §2, Nov. 20, 1985, 99 Stat. 874; amended Pub. L. 103–43, title I, §§161, 163, June 10, 1993, 107 Stat. 140, 142.)

EDITORIAL NOTES

CODIFICATION

June 10, 1993, referred to in subsec. (a)(1), was in the original "the date of enactment of this section" which was translated as meaning the date of enactment of Pub. L. 103–43, which amended this section generally, to reflect the probable intent of Congress.

AMENDMENTS

1993—Pub. L. 103–43, §161, amended section generally. Prior to amendment, section read as follows:

"(a) The Secretary shall by regulation require that each entity which applies for a grant, contract, or cooperative agreement under this chapter for any project or program which involves the conduct of biomedical or behavioral research submit in or with its application for such grant, contract, or cooperative agreement assurances satisfactory to the Secretary that such entity—

"(1) has established (in accordance with regulations which the Secretary shall prescribe) an administrative process to review reports of scientific fraud in connection with biomedical and behavioral research conducted at or sponsored by such entity; and

"(2) will report to the Secretary any investigation of alleged scientific fraud which appears substantial.

"(b) The Director of NIH shall establish a process for the prompt and appropriate response to information provided the Director of NIH respecting scientific fraud in connection with projects for which funds have been made available under this chapter. The process shall include procedures for the receiving of reports of such information from recipients of funds under this chapter and taking appropriate action with respect to such fraud."

Subsec. (e). Pub. L. 103–43, §163, added subsec. (e).

STATUTORY NOTES AND RELATED SUBSIDIARIES

REGULATIONS

Pub. L. 103–43, title I, §165, June 10, 1993, 107 Stat. 143, provided that:

"(a) ISSUANCE OF FINAL RULES.—

"(1) IN GENERAL.—Not later than 180 days after the date of the enactment of this Act [June 10, 1993], the Secretary shall, subject to paragraph (2), issue the final rule for each regulation required in section 493 or 493A of the Public Health Service Act [42 U.S.C. 289b, 289b–1].

"(2) DEFINITION OF RESEARCH MISCONDUCT.—Not later than 90 days after the date on which

the report required in section 162(e) [107 Stat. 142] is submitted to the Secretary, the Secretary shall issue the final rule for the regulations required in section 493 of the Public Health Service Act with respect to the definition of the term 'research misconduct'.

"(b) APPLICABILITY TO ONGOING INVESTIGATIONS.—The final rule issued pursuant to subsection (a) for investigations under section 493 of the Public Health Service Act [42 U.S.C. 289b] does not apply to investigations commenced before the date of the enactment of this Act [June 10, 1993] under authority of such section as in effect before such date.

"(c) DEFINITIONS.—For purposes of this section:

"(1) The term 'section 493 of the Public Health Service Act' means such section [42 U.S.C. 289b] as amended by sections 161 and 163 of this Act, except as indicated otherwise in subsection (b).

"(2) The term 'section 493A of the Public Health Service Act' means such section [42 U.S.C. 289b–1] as added by section 164 of this Act.

"(3) The term 'Secretary' means the Secretary of Health and Human Services."

§289b–1. Protection against financial conflicts of interest in certain projects of research

(a) Issuance of regulations

The Secretary shall by regulation define the specific circumstances that constitute the existence of a financial interest in a project on the part of an entity or individual that will, or may be reasonably expected to, create a bias in favor of obtaining results in such project that are consistent with such financial interest. Such definition shall apply uniformly to each entity or individual conducting a research project under this chapter. In the case of any entity or individual receiving assistance from the Secretary for a project of research described in subsection (b), the Secretary shall by regulation establish standards for responding to, including managing, reducing, or eliminating, the existence of such a financial interest. The entity may adopt individualized procedures for implementing the standards.

(b) Relevant projects

A project of research referred to in subsection (a) is a project of clinical research whose purpose is to evaluate the safety or effectiveness of a drug, medical device, or treatment and for which such entity is receiving assistance from the Secretary.

(c) Identifying and reporting to Secretary

The Secretary shall by regulation require that each entity described in subsection (a) that applies for assistance under this chapter for any project described in subsection (b) submit in or with its application for such assistance—

(1) assurances satisfactory to the Secretary that such entity has established and has in effect an administrative process under subsection (a) to identify financial interests (as defined under subsection (a)) that exist regarding the project; and

(2) an agreement that the entity will report to the Secretary such interests identified by the entity and how any such interests identified by the entity will be managed or eliminated in order that the project in question will be protected from bias that may stem from such interests; and

(3) an agreement that the entity will comply with regulations issued under this section.

(d) Monitoring of process

The Secretary shall monitor the establishment and conduct of the administrative process established by an entity pursuant to subsection (a).

(e) Response

In any case in which the Secretary determines that an entity has failed to comply with subsection (c) regarding a project of research described in subsection (b), the Secretary—

(1) shall require that, as a condition of receiving assistance, the entity disclose the existence of a financial interest (as defined under subsection (a)) in each public presentation of the results of such project; and

(2) may take such other actions as the Secretary determines to be appropriate.

(f) Definitions

For purposes of this section:

(1) The term "financial interest" includes the receipt of consulting fees or honoraria and the ownership of stock or equity.

(2) The term "assistance", with respect to conducting a project of research, means a grant, contract, or cooperative agreement.

(July 1, 1944, ch. 373, title IV, §493A, as added Pub. L. 103–43, title I, §164, June 10, 1993, 107 Stat. 142.)

STATUTORY NOTES AND RELATED SUBSIDIARIES

REGULATIONS

Final rule for regulations required in this section to be issued not later than 180 days after June 10, 1993, see section 165 of Pub. L. 103–43, set out as a note under section 289b of this title.

§289c. Research on public health emergencies

If the Secretary determines, after consultation with the Director of NIH, the Commissioner of the Food and Drug Administration, or the Director of the Centers for Disease Control and Prevention, that a disease or disorder constitutes a public health emergency, the Secretary, acting through the Director of NIH—

(1) shall expedite the review by advisory councils under section 284a of this title and by peer review groups under section 289a of this title of applications for grants for research on such disease or disorder or proposals for contracts for such research;

(2) shall exercise the authority in section 6101 of title 41 respecting public exigencies to waive the advertising requirements of such section in the case of proposals for contracts for such research;

(3) may provide administrative supplemental increases in existing grants and contracts to support new research relevant to such disease or disorder; and

(4) shall disseminate, to health professionals and the public, information on the cause, prevention, and treatment of such disease or disorder that has been developed in research assisted under this section.

The amount of an increase in a grant or contract provided under paragraph (3) may not exceed one-half the original amount of the grant or contract.

(July 1, 1944, ch. 373, title IV, §494, as added Pub. L. 99–158, §2, Nov. 20, 1985, 99 Stat. 875; amended Pub. L. 102–531, title III, §312(d)(9), Oct. 27, 1992, 106 Stat. 3504; Pub. L. 109–482, title I, §104(b)(1)(P), Jan. 15, 2007, 120 Stat. 3693.)

EDITORIAL NOTES

CODIFICATION

In par. (2), "section 6101 of title 41" substituted for "section 3709 of the Revised Statutes (41 U.S.C. 5)" on authority of Pub. L. 111–350, §6(c), Jan. 4, 2011, 124 Stat. 3854, which Act enacted Title 41, Public Contracts.

AMENDMENTS

2007—Pub. L. 109–482 struck out subsec. (a) designation before "If the Secretary" and subsec. (b) which read as follows: "Not later than 90 days after the end of a fiscal year, the Secretary shall report to the Committee on Energy and Commerce of the House of Representatives and the Committee on Labor and Human Resources of the Senate on actions taken under subsection (a) of this section in such fiscal year."

1992—Subsec. (a). Pub. L. 102–531 substituted "Centers for Disease Control and Prevention" for "Centers for Disease Control".

STATUTORY NOTES AND RELATED SUBSIDIARIES

EFFECTIVE DATE OF 2007 AMENDMENT

Amendment by Pub. L. 109–482 applicable only with respect to amounts appropriated for fiscal year 2007 or subsequent fiscal years, see section 109 of Pub. L. 109–482, set out as a note under section 281 of this title.

§289c–1. Collaborative use of certain health services research funds

The Secretary shall ensure that amounts made available under subparts 14, 15 and 16 of part C for health services research relating to alcohol abuse and alcoholism, drug abuse and mental health be used collaboratively, as appropriate, and in consultation with the Agency for Healthcare Research and Quality.

(July 1, 1944, ch. 373, title IV, §494A, as added Pub. L. 102–321, title I, §125, July 10, 1992, 106 Stat. 366; amended Pub. L. 103–43, title XX, §2016(c), June 10, 1993, 107 Stat. 218; Pub. L. 104–66, title I, §1062(b), Dec. 21, 1995, 109 Stat. 720; Pub. L. 105–362, title VI, §601(a)(1)(F), Nov. 10, 1998, 112 Stat. 3285; Pub. L. 106–129, §2(b)(2), Dec. 6, 1999, 113 Stat. 1670.)

EDITORIAL NOTES

REFERENCES IN TEXT

Subparts 14, 15 and 16 of part C, referred to in text, are classified to sections 285n et seq., 285o et seq., and 285p et seq., respectively, of this title.

AMENDMENTS

1999—Pub. L. 106–129, which directed the substitution of "Agency for Healthcare Research and Quality" for "Agency for Health Care Policy and Research", was executed by making the substitution for "Agency for Health Care Policy Research", to reflect the probable intent of Congress.

1998—Pub. L. 105–362 struck out heading and designation of subsec. (a) and heading and text of subsec. (b). Text of subsec. (b) read as follows: "Not later than December 30, 1993, and each December 30 thereafter, the Secretary shall prepare and submit to the Committee on Energy and Commerce of the House of Representatives and the Committee on Labor and Human Resources of the Senate, a report concerning the activities carried out with the amounts referred to in subsection (a) of this section."

1995—Subsec. (b). Pub. L. 104–66 substituted "December 30, 1993, and each December 30 thereafter" for "September 30, 1993, and annually thereafter".

1993—Subsec. (b). Pub. L. 103–43 substituted "September 30, 1993" for "May 3, 1993".

STATUTORY NOTES AND RELATED SUBSIDIARIES

EFFECTIVE DATE

Section effective Oct. 1, 1992, with provision for programs providing financial assistance, see section 801(c), (d) of Pub. L. 102–321, set out as an Effective Date of 1992 Amendment note under section 236 of this title.

§289d. Animals in research

(a) Establishment of guidelines

The Secretary, acting through the Director of NIH, shall establish guidelines for the following:

(1) The proper care of animals to be used in biomedical and behavioral research.

(2) The proper treatment of animals while being used in such research. Guidelines under this paragraph shall require—

(A) the appropriate use of tranquilizers, analgesics, anesthetics, paralytics, and euthanasia for animals in such research; and

(B) appropriate pre-surgical and post-surgical veterinary medical and nursing care for animals in such research.

Such guidelines shall not be construed to prescribe methods of research.

(3) The organization and operation of animal care committees in accordance with subsection (b).

(b) Animal care committees; establishment; membership; functions

(1) Guidelines of the Secretary under subsection (a)(3) shall require animal care committees at each entity which conducts biomedical and behavioral research with funds provided under this chapter (including the National Institutes of Health and the national research institutes) to assure compliance with the guidelines established under subsection (a).

(2) Each animal care committee shall be appointed by the chief executive officer of the entity for which the committee is established, shall be composed of not fewer than three members, and shall include at least one individual who has no association with such entity and at least one doctor of veterinary medicine.

(3) Each animal care committee of a research entity shall—

(A) review the care and treatment of animals in all animal study areas and facilities of the research entity at least semi-annually to evaluate compliance with applicable guidelines established under subsection (a) for appropriate animal care and treatment;

(B) keep appropriate records of reviews conducted under subparagraph (A); and

(C) for each review conducted under subparagraph (A), file with the Director of NIH at least annually (i) a certification that the review has been conducted, and (ii) reports of any violations of guidelines established under subsection (a) or assurances required under paragraph (1) which were observed in such review and which have continued after notice by the committee to the research entity involved of the violations.

Reports filed under subparagraph (C) shall include any minority views filed by members of the committee.

(c) Assurances required in application or contract proposal; reasons for use of animals; notice and comment requirements for promulgation of regulations

The Director of NIH shall require each applicant for a grant, contract, or cooperative agreement involving research on animals which is administered by the National Institutes of Health or any national research institute to include in its application or contract proposal, submitted after the expiration of the twelve-month period beginning on November 20, 1985—

(1) assurances satisfactory to the Director of NIH that—

(A) the applicant meets the requirements of the guidelines established under paragraphs (1) and (2) of subsection (a) and has an animal care committee which meets the requirements of subsection (b); and

(B) scientists, animal technicians, and other personnel involved with animal care, treatment, and use by the applicant have available to them instruction or training in the humane practice of animal maintenance and experimentation, and the concept, availability, and use of research or testing methods that limit the use of animals or limit animal distress; and

(2) a statement of the reasons for the use of animals in the research to be conducted with funds provided under such grant or contract.

Notwithstanding subsection (a)(2) of section 553 of title 5, regulations under this subsection shall be promulgated in accordance with the notice and comment requirements of such section.

(d) Failure to meet guidelines; suspension or revocation of grant or contract

If the Director of NIH determines that—

(1) the conditions of animal care, treatment, or use in an entity which is receiving a grant, contract, or cooperative agreement involving research on animals under this subchapter do not meet applicable guidelines established under subsection (a);

(2) the entity has been notified by the Director of NIH of such determination and has been given a reasonable opportunity to take corrective action; and

(3) no action has been taken by the entity to correct such conditions;

the Director of NIH shall suspend or revoke such grant or contract under such conditions as the Director determines appropriate.

(e) Disclosure of trade secrets or privileged or confidential information

No guideline or regulation promulgated under subsection (a) or (c) may require a research entity to disclose publicly trade secrets or commercial or financial information which is privileged or confidential.

(July 1, 1944, ch. 373, title IV, §495, as added Pub. L. 99–158, §2, Nov. 20, 1985, 99 Stat. 875.)

STATUTORY NOTES AND RELATED SUBSIDIARIES

PROHIBITION ON FUNDING OF PROJECTS INVOLVING USE OF CHIMPANZEES OBTAINED FROM THE WILD

Pub. L. 102–394, title II, §213, Oct. 6, 1992, 106 Stat. 1812, provided that: "No funds appropriated under this Act or subsequent Departments of Labor, Health and Human Services, and Education, and Related Agencies Appropriations Acts shall be used by the National Institutes of Health, or any other Federal agency, or recipient of Federal funds on any project that entails the capture or procurement of chimpanzees obtained from the wild. For purposes of this section, the term 'recipient of Federal funds' includes private citizens, corporations, or other research institutions located outside of the United States that are recipients of Federal funds."

Similar provisions were contained in the following prior appropriation acts:

Pub. L. 102–170, title II, §213, Nov. 26, 1991, 105 Stat. 1127.

Pub. L. 101–517, title II, §211, Nov. 5, 1990, 104 Stat. 2209.

Pub. L. 101–166, title II, §214, Nov. 21, 1989, 103 Stat. 1178.

PLAN FOR RESEARCH INVOLVING ANIMALS

Section 4 of Pub. L. 99–158 directed Director of National Institutes of Health to establish, not later than Oct. 1, 1986, a plan for research into methods of biomedical research and experimentation which reduces the use of animals in research or which produce less pain and distress in animals to develop methods found to be valid and reliable, to train scientists in use of such methods, to disseminate information on such methods and to establish an Interagency Coordinating Committee to assist in development of the plan, prior to repeal by Pub. L. 103–43, title II, §205(b), June 10, 1993, 107 Stat. 148. See section 283e of this title.

§289e. Use of appropriations

(a) Appropriations to carry out the purposes of this subchapter, unless otherwise expressly provided, may be expended in the District of Columbia for—

(1) personal services;

(2) stenographic recording and translating services;

(3) travel expenses (including the expenses of attendance at meetings when specifically authorized by the Secretary);

(4) rental;

(5) supplies and equipment;

(6) purchase and exchange of medical books, books of reference, directories, periodicals, newspapers, and press clippings;

(7) purchase, operation, and maintenance of passenger motor vehicles;

(8) printing and binding (in addition to that otherwise provided by law); and

(9) all other necessary expenses in carrying out this subchapter.

Such appropriations may be expended by contract if deemed necessary, without regard to section 6101 of title 41.

(b)(1) None of the amounts appropriated under this chapter for the purposes of this subchapter may be obligated for the construction of facilities (including the acquisition of land) unless a provision of this subchapter establishes express authority for such purpose and unless the Act making appropriations under such provision specifies that the amounts appropriated are available for such purpose.

(2) Any grants, cooperative agreements, or contracts authorized in this subchapter for the construction of facilities may be awarded only on a competitive basis.

(July 1, 1944, ch. 373, title IV, §496, as added Pub. L. 99–158, §2, Nov. 20, 1985, 99 Stat. 877; amended Pub. L. 101–190, §8, Nov. 29, 1989, 103 Stat. 1695; Pub. L. 103–43, title XX, §2008(b)(15), June 10, 1993, 107 Stat. 211.)

EDITORIAL NOTES

CODIFICATION

In subsec. (a), "section 6101 of title 41" substituted for "section 3709 of the Revised Statutes (41 U.S.C. 5)" on authority of Pub. L. 111–350, §6(c), Jan. 4, 2011, 124 Stat. 3854, which Act enacted Title 41, Public Contracts.

AMENDMENTS

1993—Subsec. (a). Pub. L. 103–43 substituted "Appropriations to carry out the purposes of this subchapter" for "Such appropriations".

1989—Subsec. (a). Pub. L. 101–190 designated existing provisions as subsec. (a), struck out first sentence which read as follows: "Appropriations to carry out the purposes of this subchapter shall be available for the acquisition of land or the erection of buildings only if so specified.", and added subsec. (b).

STATUTORY NOTES AND RELATED SUBSIDIARIES

CONSTRUCTION OF BIOMEDICAL FACILITIES FOR DEVELOPMENT AND BREEDING OF SPECIALIZED STRAINS OF MICE

Pub. L. 101–190, §§1–7, Nov. 29, 1989, 103 Stat. 1691–1695, as amended by Pub. L. 101–374, §4(a), (c)(1), Aug. 15, 1990, 104 Stat. 458, 459, authorized a reservation of funds for making a grant to construct facilities for development and breeding of specialized strains of mice for use in biomedical research, provided for a competitive grant award process, required applicant for the grant to agree to a twenty-year transferable obligation, restricted grant applicant to public or nonprofit private status, with assurances of sufficient financial resources, set forth other grant requirements, and specified consequences of failure to comply with agreements and violation of the twenty-year obligation.

§289f. Gifts and donations; memorials

The Secretary may, in accordance with section 238 of this title, accept conditional gifts for the National Institutes of Health or a national research institute or for the acquisition of grounds or for the erection, equipment, or maintenance of facilities for the National Institutes of Health or a national research institute. Donations of $50,000 or over for the National Institutes of Health or a national research institute for carrying out the purposes of this subchapter may be acknowledged by the establishment within the National Institutes of Health or a national research institute of suitable memorials to the donors.

(July 1, 1944, ch. 373, title IV, §497, as added Pub. L. 99–158, §2, Nov. 20, 1985, 99 Stat. 877; amended Pub. L. 99–660, title III, §311(b)(1), Nov. 14, 1986, 100 Stat. 3779; Pub. L. 100–607, title II, §204(3), Nov. 4, 1988, 102 Stat. 3079; Pub. L. 100–690, title II, §2620(b)(2), Nov. 18, 1988, 102

Stat. 4244; Pub. L. 101–381, title I, §102(5), Aug. 18, 1990, 104 Stat. 586; Pub. L. 103–43, title XX, §2010(b)(6), June 10, 1993, 107 Stat. 214.)

EDITORIAL NOTES

AMENDMENTS

1993—Pub. L. 103–43 substituted "section 238" for "section 300aaa".

1990—Pub. L. 101–381 made technical amendment to reference to section 300aaa of this title to reflect renumbering of corresponding section of original act.

1988—Pub. L. 100–690 made technical amendment to reference to section 300aaa of this title to reflect renumbering of corresponding section of original act.

Pub. L. 100–607 substituted "300aaa" for "300cc".

1986—Pub. L. 99–660 substituted "section 300cc of this title" for "section 300aa of this title".

STATUTORY NOTES AND RELATED SUBSIDIARIES

EFFECTIVE DATE OF 1988 AMENDMENT

Amendment by Pub. L. 100–690 effective immediately after enactment of Pub. L. 100–607, which was approved Nov. 4, 1988, see section 2600 of Pub. L. 100–690, set out as a note under section 242m of this title.

EFFECTIVE DATE OF 1986 AMENDMENT

Amendment by Pub. L. 99–660 effective Dec. 22, 1987, see section 323 of Pub. L. 99–660, as amended, set out as an Effective Date note under section 300aa–1 of this title.

§289g. Fetal research

(a) Conduct or support by Secretary; restrictions

The Secretary may not conduct or support any research or experimentation, in the United States or in any other country, on a nonviable living human fetus ex utero or a living human fetus ex utero for whom viability has not been ascertained unless the research or experimentation—

(1) may enhance the well-being or meet the health needs of the fetus or enhance the probability of its survival to viability; or

(2) will pose no added risk of suffering, injury, or death to the fetus and the purpose of the research or experimentation is the development of important biomedical knowledge which cannot be obtained by other means.

(b) Risk standard for fetuses intended to be aborted and fetuses intended to be carried to term to be same

In administering the regulations for the protection of human research subjects which—

(1) apply to research conducted or supported by the Secretary;

(2) involve living human fetuses in utero; and

(3) are published in section 46.208 of part 46 of title 45 of the Code of Federal Regulations;

or any successor to such regulations, the Secretary shall require that the risk standard (published in section 46.102(g) of such part 46 or any successor to such regulations) be the same for fetuses which are intended to be aborted and fetuses which are intended to be carried to term.

(July 1, 1944, ch. 373, title IV, §498, as added Pub. L. 99–158, §2, Nov. 20, 1985, 99 Stat. 877; amended Pub. L. 100–607, title I, §§156, 157(b), Nov. 4, 1988, 102 Stat. 3059; Pub. L. 103–43, title I, §121(b)(1), June 10, 1993, 107 Stat. 133.)

EDITORIAL NOTES

AMENDMENTS

1993—Subsec. (c). Pub. L. 103–43 struck out subsec. (c) which directed Biomedical Ethics Advisory Committee to conduct a study of the nature, advisability, and biomedical and ethical implications of exercising any waiver of the risk standard published in section 46.102(g) of part 46 of title 45 of the Code of Federal Regulations and to report its finding to the Biomedical Ethics Board not later than 24 months after Nov. 4, 1988, which report was to be then transmitted to specified Congressional committees.

1988—Subsec. (c)(1). Pub. L. 100–607, §157(b), substituted "24 months after November 4, 1988" for "thirty months after November 20, 1985".

Subsec. (c)(2). Pub. L. 100–607, §156(1), substituted "24-month period beginning on November 4, 1988" for "thirty-six month period beginning on November 20, 1985".

Subsec. (c)(3). Pub. L. 100–607, §156(2), substituted "1990" for "1988".

STATUTORY NOTES AND RELATED SUBSIDIARIES

NULLIFICATION OF CERTAIN PROVISIONS

Pub. L. 103–43, title I, §121(c), June 10, 1993, 107 Stat. 133, provided that: "The provisions of Executive Order 12806 (57 Fed. Reg. 21589 (May 21, 1992)) [formerly set out below] shall not have any legal effect. The provisions of section 204(d) of part 46 of title 45 of the Code of Federal Regulations (45 CFR 46.204(d)) shall not have any legal effect."

EXECUTIVE DOCUMENTS

EXECUTIVE ORDER NO. 12806. ESTABLISHMENT OF FETAL TISSUE BANK

Ex. Ord. No. 12806, May 19, 1992, 57 F.R. 21589, which established a human fetal tissue bank, was nullified by Pub. L. 103–43, title I, §121(c), June 10, 1993, 107 Stat. 133, set out above.

FEDERAL FUNDING OF FETAL TISSUE TRANSPLANTATION RESEARCH

Memorandum of President of the United States, Jan. 22, 1993, 58 F.R. 7457, provided:

Memorandum for the Secretary of Health and Human Services

On March 22, 1988, the Assistant Secretary for Health of Health and Human Services ("HHS") imposed a temporary moratorium on Federal funding of research involving transplantation of fetal tissue from induced abortions. Contrary to the recommendations of a National Institutes of Health advisory panel, on November 2, 1989, the Secretary of Health and Human Services extended the moratorium indefinitely. This moratorium has significantly hampered the development of possible treatments for individuals afflicted with serious diseases and disorders, such as Parkinson's disease, Alzheimer's disease, diabetes, and leukemia. Accordingly, I hereby direct that you immediately lift the moratorium.

You are hereby authorized and directed to publish this memorandum in the Federal Register.

WILLIAM J. CLINTON.

§289g–1. Research on transplantation of fetal tissue

(a) Establishment of program

(1) In general

The Secretary may conduct or support research on the transplantation of human fetal tissue for therapeutic purposes.

(2) Source of tissue

Human fetal tissue may be used in research carried out under paragraph (1) regardless of whether the tissue is obtained pursuant to a spontaneous or induced abortion or pursuant to a stillbirth.

(b) Informed consent of donor

(1) In general

In research carried out under subsection (a), human fetal tissue may be used only if the woman providing the tissue makes a statement, made in writing and signed by the woman, declaring

that—

(A) the woman donates the fetal tissue for use in research described in subsection (a);

(B) the donation is made without any restriction regarding the identity of individuals who may be the recipients of transplantations of the tissue; and

(C) the woman has not been informed of the identity of any such individuals.

(2) Additional statement

In research carried out under subsection (a), human fetal tissue may be used only if the attending physician with respect to obtaining the tissue from the woman involved makes a statement, made in writing and signed by the physician, declaring that—

(A) in the case of tissue obtained pursuant to an induced abortion—

(i) the consent of the woman for the abortion was obtained prior to requesting or obtaining consent for a donation of the tissue for use in such research;

(ii) no alteration of the timing, method, or procedures used to terminate the pregnancy was made solely for the purposes of obtaining the tissue; and

(iii) the abortion was performed in accordance with applicable State law;

(B) the tissue has been donated by the woman in accordance with paragraph (1); and

(C) full disclosure has been provided to the woman with regard to—

(i) such physician's interest, if any, in the research to be conducted with the tissue; and

(ii) any known medical risks to the woman or risks to her privacy that might be associated with the donation of the tissue and that are in addition to risks of such type that are associated with the woman's medical care.

(c) Informed consent of researcher and donee

In research carried out under subsection (a), human fetal tissue may be used only if the individual with the principal responsibility for conducting the research involved makes a statement, made in writing and signed by the individual, declaring that the individual—

(1) is aware that—

(A) the tissue is human fetal tissue;

(B) the tissue may have been obtained pursuant to a spontaneous or induced abortion or pursuant to a stillbirth; and

(C) the tissue was donated for research purposes;

(2) has provided such information to other individuals with responsibilities regarding the research;

(3) will require, prior to obtaining the consent of an individual to be a recipient of a transplantation of the tissue, written acknowledgment of receipt of such information by such recipient; and

(4) has had no part in any decisions as to the timing, method, or procedures used to terminate the pregnancy made solely for the purposes of the research.

(d) Availability of statements for audit

(1) In general

In research carried out under subsection (a), human fetal tissue may be used only if the head of the agency or other entity conducting the research involved certifies to the Secretary that the statements required under subsections (b)(2) and (c) will be available for audit by the Secretary.

(2) Confidentiality of audit

Any audit conducted by the Secretary pursuant to paragraph (1) shall be conducted in a confidential manner to protect the privacy rights of the individuals and entities involved in such research, including such individuals and entities involved in the donation, transfer, receipt, or transplantation of human fetal tissue. With respect to any material or information obtained pursuant to such audit, the Secretary shall—

(A) use such material or information only for the purposes of verifying compliance with the requirements of this section;

(B) not disclose or publish such material or information, except where required by Federal law, in which case such material or information shall be coded in a manner such that the identities of such individuals and entities are protected; and

(C) not maintain such material or information after completion of such audit, except where necessary for the purposes of such audit.

(e) Applicability of State and local law

(1) Research conducted by recipients of assistance

The Secretary may not provide support for research under subsection (a) unless the applicant for the financial assistance involved agrees to conduct the research in accordance with applicable State law.

(2) Research conducted by Secretary

The Secretary may conduct research under subsection (a) only in accordance with applicable State and local law.

(f) Report

The Secretary shall annually submit to the Committee on Energy and Commerce of the House of Representatives, and to the Committee on Labor and Human Resources of the Senate, a report describing the activities carried out under this section during the preceding fiscal year, including a description of whether and to what extent research under subsection (a) has been conducted in accordance with this section.

(g) "Human fetal tissue" defined

For purposes of this section, the term "human fetal tissue" means tissue or cells obtained from a dead human embryo or fetus after a spontaneous or induced abortion, or after a stillbirth.

(July 1, 1944, ch. 373, title IV, §498A, as added Pub. L. 103–43, title I, §111, June 10, 1993, 107 Stat. 129.)

STATUTORY NOTES AND RELATED SUBSIDIARIES

CHANGE OF NAME

Committee on Labor and Human Resources of Senate changed to Committee on Health, Education, Labor, and Pensions of Senate by Senate Resolution No. 20, One Hundred Sixth Congress, Jan. 19, 1999.

Committee on Energy and Commerce of House of Representatives treated as referring to Committee on Commerce of House of Representatives by section 1(a) of Pub. L. 104–14, set out as a note preceding section 21 of Title 2, The Congress. Committee on Commerce of House of Representatives changed to Committee on Energy and Commerce of House of Representatives, and jurisdiction over matters relating to securities and exchanges and insurance generally transferred to Committee on Financial Services of House of Representatives by House Resolution No. 5, One Hundred Seventh Congress, Jan. 3, 2001.

NULLIFICATION OF MORATORIUM

Pub. L. 103–43, title I, §113, June 10, 1993, 107 Stat. 132, provided that:

"(a) IN GENERAL.—Except as provided in subsection (c), no official of the executive branch may impose a policy that the Department of Health and Human Services is prohibited from conducting or supporting any research on the transplantation of human fetal tissue for therapeutic purposes. Such research shall be carried out in accordance with section 498A of the Public Health Service Act [42 U.S.C. 289g–1] (as added by section 111 of this Act), without regard to any such policy that may have been in effect prior to the date of the enactment of this Act [June 10, 1993].

"(b) PROHIBITION AGAINST WITHHOLDING OF FUNDS IN CASES OF TECHNICAL AND SCIENTIFIC MERIT.—

"(1) IN GENERAL.—Subject to subsection (b)(2) of section 492A of the Public Health Service Act [42 U.S.C. 289a–1(b)(2)] (as added by section 101 of this Act), in the case of any proposal for research on the transplantation of human fetal tissue for therapeutic purposes, the Secretary of Health and Human

Services may not withhold funds for the research if—

"(A) the research has been approved for purposes of subsection (a) of such section 492A;

"(B) the research will be carried out in accordance with section 498A of such Act [42 U.S.C. 289g–1] (as added by section 111 of this Act); and

"(C) there are reasonable assurances that the research will not utilize any human fetal tissue that has been obtained in violation of section 498B(a) of such Act [42 U.S.C. 289g–2(a)] (as added by section 112 of this Act).

"(2) STANDING APPROVAL REGARDING ETHICAL STATUS.—In the case of any proposal for research on the transplantation of human fetal tissue for therapeutic purposes, the issuance in December 1988 of the Report of the Human Fetal Tissue Transplantation Research Panel shall be deemed to be a report—

"(A) issued by an ethics advisory board pursuant to section 492A(b)(5)(B)(ii) of the Public Health Service Act [42 U.S.C. 289a–1(b)(5)(B)(ii)] (as added by section 101 of this Act); and

"(B) finding, on a basis that is neither arbitrary nor capricious, that the nature of the research is such that it is not unethical to conduct or support the research.

"(c) AUTHORITY FOR WITHHOLDING FUNDS FROM RESEARCH.—In the case of any research on the transplantation of human fetal tissue for therapeutic purposes, the Secretary of Health and Human Services may withhold funds for the research if any of the conditions specified in any of subparagraphs (A) through (C) of subsection (b)(1) are not met with respect to the research.

"(d) DEFINITION.—For purposes of this section, the term 'human fetal tissue' has the meaning given such term in section 498A(f) of the Public Health Service Act [42 U.S.C. 289g–1(f)] (as added by section 111 of this Act)."

REPORT BY GENERAL ACCOUNTING OFFICE ON ADEQUACY OF REQUIREMENTS

Pub. L. 103–43, title I, §114, June 10, 1993, 107 Stat. 132, provided that, with respect to research on the transplantation of human fetal tissue for therapeutic purposes, the Comptroller General of the United States was to conduct an audit for the purpose of determining whether and to what extent such research conducted or supported by Secretary of Health and Human Services had been conducted in accordance with this section and whether and to what extent there have been violations of section 289g–2 of this title and directed the Comptroller General to complete the audit and report the findings to Congress, not later than May 19, 1995.

§289g–2. Prohibitions regarding human fetal tissue

(a) Purchase of tissue

It shall be unlawful for any person to knowingly acquire, receive, or otherwise transfer any human fetal tissue for valuable consideration if the transfer affects interstate commerce.

(b) Solicitation or acceptance of tissue as directed donation for use in transplantation

It shall be unlawful for any person to solicit or knowingly acquire, receive, or accept a donation of human fetal tissue for the purpose of transplantation of such tissue into another person if the donation affects interstate commerce, the tissue will be or is obtained pursuant to an induced abortion, and—

(1) the donation will be or is made pursuant to a promise to the donating individual that the donated tissue will be transplanted into a recipient specified by such individual;

(2) the donated tissue will be transplanted into a relative of the donating individual; or

(3) the person who solicits or knowingly acquires, receives, or accepts the donation has provided valuable consideration for the costs associated with such abortion.

(c) Solicitation or acceptance of tissue from fetuses gestated for research purposes

It shall be unlawful for any person or entity involved or engaged in interstate commerce to—

(1) solicit or knowingly acquire, receive, or accept a donation of human fetal tissue knowing that a human pregnancy was deliberately initiated to provide such tissue; or

(2) knowingly acquire, receive, or accept tissue or cells obtained from a human embryo or fetus that was gestated in the uterus of a nonhuman animal.

(d) Criminal penalties for violations

(1) In general

Any person who violates subsection (a), (b), or (c) shall be fined in accordance with title 18, subject to paragraph (2), or imprisoned for not more than 10 years, or both.

(2) Penalties applicable to persons receiving consideration

With respect to the imposition of a fine under paragraph (1), if the person involved violates subsection (a) or (b)(3), a fine shall be imposed in an amount not less than twice the amount of the valuable consideration received.

(e) Definitions

For purposes of this section:

(1) The term "human fetal tissue" has the meaning given such term in section 289g–1(g) of this title.

(2) The term "interstate commerce" has the meaning given such term in section 321(b) of title 21.

(3) The term "valuable consideration" does not include reasonable payments associated with the transportation, implantation, processing, preservation, quality control, or storage of human fetal tissue.

(July 1, 1944, ch. 373, title IV, §498B, as added Pub. L. 103–43, title I, §112, June 10, 1993, 107 Stat. 131; amended Pub. L. 109–242, §2, July 19, 2006, 120 Stat. 570.)

EDITORIAL NOTES

AMENDMENTS

2006—Subsec. (c). Pub. L. 109–242, §2(2), added subsec. (c). Former subsec. (c) redesignated (d).

Subsec. (d). Pub. L. 109–242, §2(1), (3), redesignated subsec. (c) as (d) and substituted "(a), (b), or (c)" for "(a) or (b)" in par. (1). Former subsec. (d) redesignated (e).

Subsec. (e). Pub. L. 109–242, §2(1), (4), redesignated subsec. (d) as (e) and substituted "section 289g–1(g)" for "section 289g–1(f)" in par. (1).

§289g–3. Breast implant research

(a) In general

The Director of NIH may conduct or support research to examine the long-term health implications of silicone breast implants, both gel and saline filled. Such research studies may include the following:

(1) Developing and examining techniques to measure concentrations of silicone in body fluids and tissues.

(2) Surveillance of recipients of silicone breast implants, including long-term outcomes and local complications.

(b) Definition

For purposes of this section, the term "breast implant" means a breast prosthesis that is implanted to augment or reconstruct the female breast.

(July 1, 1944, ch. 373, title IV, §498C, as added Pub. L. 107–250, title II, §215(b), Oct. 26, 2002, 116 Stat. 1615.)

STATUTORY NOTES AND RELATED SUBSIDIARIES

BREAST IMPLANTS; STUDY BY COMPTROLLER GENERAL

Pub. L. 107–250, title II, §214, Oct. 26, 2002, 116 Stat. 1615, which provided that the Comptroller General was to conduct a study of information typically provided by health professionals to women on breast implant surgery and to report the findings of the study to Congress, was repealed by Pub. L. 111–8, div. G, title I,

§1301(g), Mar. 11, 2009, 123 Stat. 829.

§289g–4. Support for emergency medicine research

(a) Emergency medical research

The Secretary shall support Federal programs administered by the National Institutes of Health, the Agency for Healthcare Research and Quality, the Health Resources and Services Administration, the Centers for Disease Control and Prevention, and other agencies involved in improving the emergency care system to expand and accelerate research in emergency medical care systems and emergency medicine, including—

(1) the basic science of emergency medicine;

(2) the model of service delivery and the components of such models that contribute to enhanced patient health outcomes;

(3) the translation of basic scientific research into improved practice; and

(4) the development of timely and efficient delivery of health services.

(b) Pediatric emergency medical research

The Secretary shall support Federal programs administered by the National Institutes of Health, the Agency for Healthcare Research and Quality, the Health Resources and Services Administration, the Centers for Disease Control and Prevention, and other agencies to coordinate and expand research in pediatric emergency medical care systems and pediatric emergency medicine, including—

(1) an examination of the gaps and opportunities in pediatric emergency care research and a strategy for the optimal organization and funding of such research;

(2) the role of pediatric emergency services as an integrated component of the overall health system;

(3) system-wide pediatric emergency care planning, preparedness, coordination, and funding;

(4) pediatric training in professional education; and

(5) research in pediatric emergency care, specifically on the efficacy, safety, and health outcomes of medications used for infants, children, and adolescents in emergency care settings in order to improve patient safety.

(c) Impact research

The Secretary shall support research to determine the estimated economic impact of, and savings that result from, the implementation of coordinated emergency care systems.

(d) Authorization of appropriations

There are authorized to be appropriated to carry out this section such sums as may be necessary for each of fiscal years 2010 through 2014.

(July 1, 1944, ch. 373, title IV, §498D, as added Pub. L. 111–148, title III, §3504(b), Mar. 23, 2010, 124 Stat. 521.)

§289g–5. Precision medicine initiative

(a) In general

The Secretary is encouraged to establish and carry out an initiative, to be known as the "Precision Medicine Initiative" (in this section referred to as the "Initiative"), to augment efforts to address disease prevention, diagnosis, and treatment.

(b) Components

The Initiative described under subsection (a) may include—

(1) developing a network of scientists to assist in carrying out the purposes of the Initiative;

(2) developing new approaches for addressing scientific, medical, public health, and regulatory

science issues;

(3) applying genomic technologies, such as whole genomic sequencing, to provide data on the molecular basis of disease;

(4) collecting information voluntarily provided by a diverse cohort of individuals that can be used to better understand health and disease; and

(5) other activities to advance the goals of the Initiative, as the Secretary determines appropriate.

(c) Authority of the Secretary

In carrying out this section, the Secretary may—

(1) coordinate with the Secretary of Energy, private industry, and others, as the Secretary determines appropriate, to identify and address the advanced supercomputing and other advanced technology needs for the Initiative;

(2) develop and utilize public-private partnerships; and

(3) leverage existing data sources.

(d) Requirements

In the implementation of the Initiative under subsection (a), the Secretary shall—

(1) ensure the collaboration of the National Institutes of Health, the Food and Drug Administration, the Office of the National Coordinator for Health Information Technology, and the Office for Civil Rights of the Department of Health and Human Services;

(2) comply with existing laws and regulations for the protection of human subjects involved in research, including the protection of participant privacy;

(3) implement policies and mechanisms for appropriate secure data sharing across systems that include protections for privacy and security of data;

(4) consider the diversity of the cohort to ensure inclusion of a broad range of participants, including consideration of biological, social, and other determinants of health that contribute to health disparities;

(5) ensure that only authorized individuals may access controlled or sensitive, identifiable biological material and associated information collected or stored in connection with the Initiative; and

(6) on the appropriate Internet website of the Department of Health and Human Services, identify any entities with access to such information and provide information with respect to the purpose of such access, a summary of the research project for which such access is granted, as applicable, and a description of the biological material and associated information to which the entity has access.

(e) Report

Not later than 1 year after December 13, 2016, the Secretary shall submit a report on the relevant data access policies and procedures to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives. Such report shall include steps the Secretary has taken to consult with experts or other heads of departments or agencies of the Federal Government in the development of such policies.

(July 1, 1944, ch. 373, title IV, §498E, as added Pub. L. 114–255, div. A, title II, §2011, Dec. 13, 2016, 130 Stat. 1047.)

STATUTORY NOTES AND RELATED SUBSIDIARIES

FUNDING FOR SARS–COV–2 GENOMIC SEQUENCING AND SURVEILLANCE

Pub. L. 117–2, title II, §2402, Mar. 11, 2021, 135 Stat. 41, provided that:

"(a) IN GENERAL.—In addition to amounts otherwise available, there is appropriated to the Secretary [of Health and Human Services] for fiscal year 2021 out of any money in the Treasury not otherwise appropriated, $1,750,000,000, to remain available until expended, to strengthen and expand activities and workforce related to genomic sequencing, analytics, and disease surveillance.

"(b) USE OF FUNDS.—From amounts appropriated by subsection (a), the Secretary, acting through the

Director of the Centers for Disease Control and Prevention, shall—

"(1) conduct, expand, and improve activities to sequence genomes, identify mutations, and survey the circulation and transmission of viruses and other organisms, including strains of SARS–CoV–2;

"(2) award grants or cooperative agreements to State, local, Tribal, or territorial public health departments or public health laboratories—

"(A) to increase their capacity to sequence genomes of circulating strains of viruses and other organisms, including SARS–CoV–2;

"(B) to identify mutations in viruses and other organisms, including SARS–CoV–2;

"(C) to use genomic sequencing to identify outbreaks and clusters of diseases or infections, including COVID–19; and

"(D) to develop effective disease response strategies based on genomic sequencing and surveillance data;

"(3) enhance and expand the informatics capabilities of the public health workforce; and

"(4) award grants for the construction, alteration, or renovation of facilities to improve genomic sequencing and surveillance capabilities at the State and local level."

§289h. Repealed. Pub. L. 103–43, title I, §121(b)(2), June 10, 1993, 107 Stat. 133

Section, act July 1, 1944, ch. 373, title IV, §499, as added Nov. 20, 1985, Pub. L. 99–158, §2, 99 Stat. 878, related to construction of subchapter.

§290. National Institutes of Health Management Fund; establishment; advancements; availability; final adjustments of advances

For the purpose of facilitating the economical and efficient conduct of operations in the National Institutes of Health which are financed by two or more appropriations where the costs of operation are not readily susceptible of distribution as charges to such appropriations, there is established the National Institutes of Health Management Fund. Such amounts as the Director of the National Institutes of Health may determine to represent a reasonable distribution of estimated costs among the various appropriations involved may be advanced each year to this fund and shall be available for expenditure for such costs under such regulations as may be prescribed by said Director, including the operation of facilities for the sale of meals to employees and others at rates to be determined by said Director to be sufficient to cover the reasonable value of the meals served and the proceeds thereof shall be deposited to the credit of this fund: *Provided*, That funds advanced to this fund shall be available only in the fiscal year in which they are advanced: *Provided further*, That final adjustments of advances in accordance with actual costs shall be effected wherever practicable with the appropriations from which such funds are advanced.

(Pub. L. 85–67, title II, §201, June 29, 1957, 71 Stat. 220; Pub. L. 87–290, title II, §201, Sept. 22, 1961, 75 Stat. 603.)

EDITORIAL NOTES

CODIFICATION

Section was enacted as a part of the Department of Health, Education, and Welfare Appropriation Act, 1958, and not as a part of the Public Health Service Act which comprises this chapter.

AMENDMENTS

1961—Pub. L. 87–290 substituted "reasonable value of the meals served" for "cost of such operation".

§290a. Victims of fire

(a) Research on burns, burn injuries, and rehabilitation

The Secretary of Health and Human Services shall establish, within the National Institutes of

Health and in cooperation with the Administrator of FEMA, an expanded program of research on burns, treatment of burn injuries, and rehabilitation of victims of fires. The National Institutes of Health shall—

(1) sponsor and encourage the establishment throughout the Nation of twenty-five additional burn centers, which shall comprise separate hospital facilities providing specialized burn treatment and including research and teaching programs and twenty-five additional burn units, which shall comprise specialized facilities in general hospitals used only for burn victims;

(2) provide training and continuing support of specialists to staff the new burn centers and burn units;

(3) sponsor and encourage the establishment of ninety burn programs in general hospitals which comprise staffs of burn injury specialists;

(4) provide special training in emergency care for burn victims;

(5) augment sponsorship of research on burns and burn treatment;

(6) administer and support a systematic program of research concerning smoke inhalation injuries; and

(7) sponsor and support other research and training programs in the treatment and rehabilitation of burn injury victims.

(b) Authorization of appropriations

For purposes of this section, there are authorized to be appropriated not to exceed $5,000,000 for the fiscal year ending June 30, 1975 and not to exceed $8,000,000 for the fiscal year ending June 30, 1976.

(Pub. L. 93–498, §19, Oct. 29, 1974, 88 Stat. 1547; Pub. L. 96–88, title V, §509(b), Oct. 17, 1979, 93 Stat. 695; Pub. L. 106–503, title I, §110(a)(2)(B)(vii), Nov. 13, 2000, 114 Stat. 2302; Pub. L. 112–239, div. A, title XVIII, §1802(b)(1), Jan. 2, 2013, 126 Stat. 2100.)

EDITORIAL NOTES

CODIFICATION

Section was enacted as part of the Federal Fire Prevention and Control Act of 1974 (which is classified principally to chapter 49 (§2201 et seq.) of Title 15), and not as a part of the Public Health Service Act which comprises this chapter.

AMENDMENTS

2013—Subsec. (a). Pub. L. 112–239 substituted "Administrator of FEMA" for "Director" in introductory provisions.

2000—Subsec. (a). Pub. L. 106–503 substituted "in cooperation with the Director" for "in cooperation with the Secretary".

STATUTORY NOTES AND RELATED SUBSIDIARIES

CHANGE OF NAME

"Secretary of Health and Human Services" substituted for "Secretary of Health, Education, and Welfare" in subsec. (a) pursuant to section 509(b) of Pub. L. 96–88, which is classified to section 3508(b) of Title 20, Education.

TRANSFER OF FUNCTIONS

For transfer of all functions, personnel, assets, components, authorities, grant programs, and liabilities of the Federal Emergency Management Agency, including the functions of the Under Secretary for Federal Emergency Management relating thereto, to the Federal Emergency Management Agency, see section 315(a)(1) of Title 6, Domestic Security.

For transfer of functions, personnel, assets, and liabilities of the Federal Emergency Management Agency, including the functions of the Director of the Federal Emergency Management Agency relating thereto, to the

Secretary of Homeland Security, and for treatment of related references, see former section 313(1) and sections 551(d), 552(d), and 557 of Title 6, Domestic Security, and the Department of Homeland Security Reorganization Plan of November 25, 2002, as modified, set out as a note under section 542 of Title 6.

DEFINITIONS

For definition of terms used in this section, see section 2203 of Title 15, Commerce and Trade.

PART I—FOUNDATION FOR THE NATIONAL INSTITUTES OF HEALTH

EDITORIAL NOTES

CODIFICATION

Pub. L. 105–392, title IV, §418(1), Nov. 13, 1998, 112 Stat. 3591, substituted "Foundation for the National Institutes of Health" for "National Foundation for Biomedical Research" in part heading.

Pub. L. 103–43, title I, §141(a)(2), June 10, 1993, 107 Stat. 136, redesignated part H "National Foundation for Biomedical Research" as I.

§290b. Establishment and duties of Foundation

(a) In general

The Secretary shall, acting through the Director of NIH, establish a nonprofit corporation to be known as the Foundation for the National Institutes of Health (hereafter in this section referred to as the "Foundation"). The Foundation shall not be an agency or instrumentality of the United States Government.

(b) Purpose of Foundation

The purpose of the Foundation shall be to support the National Institutes of Health in its mission (including collection of funds for pediatric pharmacologic research), and to advance collaboration with biomedical researchers from universities, industry, and nonprofit organizations.

(c) Certain activities of Foundation

(1) In general

In carrying out subsection (b), the Foundation may solicit and accept gifts, grants, and other donations, establish accounts, and invest and expend funds in support of the following activities with respect to the purpose described in such subsection:

(A) A program to provide and administer endowed positions that are associated with the research program of the National Institutes of Health. Such endowments may be expended for the compensation of individuals holding the positions, for staff, equipment, quarters, travel, and other expenditures that are appropriate in supporting the endowed positions.

(B) A program to provide and administer fellowships and grants to research personnel in order to work and study in association with the National Institutes of Health. Such fellowships and grants may include stipends, travel, health insurance benefits and other appropriate expenses. The recipients of fellowships shall be selected by the donors and the Foundation upon the recommendation of the National Institutes of Health employees in the laboratory where the fellow would serve, and shall be subject to the agreement of the Director of the National Institutes of Health and the Executive Director of the Foundation.

(C) A program to collect funds for pediatric pharmacologic research and studies.

(D) Supplementary programs to provide for—

(i) scientists of other countries to serve in research capacities in the United States in association with the National Institutes of Health or elsewhere, or opportunities for employees of the National Institutes of Health or other public health officials in the United

States to serve in such capacities in other countries, or both;

(ii) the conduct and support of studies, projects, and research, which may include stipends, travel and other support for personnel in collaboration with national and international non-profit and for-profit organizations;

(iii) the conduct and support of forums, meetings, conferences, courses, and training workshops that may include undergraduate, graduate, post-graduate, and post-doctoral accredited courses and the maintenance of accreditation of such courses by the Foundation at the State and national level for college or continuing education credits or for degrees;

(iv) programs to support and encourage teachers and students of science at all levels of education and programs for the general public which promote the understanding of science;

(v) programs for writing, editing, printing, publishing, and vending of books and other materials; and

(vi) the conduct of other activities to carry out and support the purpose described in subsection (b).

(E) The Cures Acceleration Network described in section 287a of this title.

(2) Fees

The Foundation may assess fees for the provision of professional, administrative and management services by the Foundation in amounts determined reasonable and appropriate by the Executive Director.

(3) Authority of Foundation

The Foundation shall be the sole entity responsible for carrying out the activities described in this subsection.

(d) Board of Directors

(1) Composition

(A) The Foundation shall have a Board of Directors (hereafter referred to in this section as the "Board"), which shall be composed of ex officio and appointed members in accordance with this subsection. All appointed members of the Board shall be voting members.

(B) The ex officio members of the Board shall be—

(i) the Chairman and ranking minority member of the Subcommittee on Health and the Environment (Committee on Energy and Commerce) or their designees, in the case of the House of Representatives;

(ii) the Chairman and ranking minority member of the Committee on Labor and Human Resources or their designees, in the case of the Senate;

(iii) the Director of the National Institutes of Health; and

(iv) the Commissioner of Food and Drugs.

(C) The ex officio members of the Board under subparagraph (B) shall appoint to the Board individuals from among a list of candidates to be provided by the National Academy of Science. Such appointed members shall include—

(i) representatives of the general biomedical field;

(ii) representatives of experts in pediatric medicine and research;

(iii) representatives of the general biobehavioral field, which may include experts in biomedical ethics; and

(iv) representatives of the general public, which may include representatives of affected industries.

(D)(i) Not later than 30 days after June 10, 1993, the Director of the National Institutes of Health shall convene a meeting of the ex officio members of the Board to—

(I) incorporate the Foundation and establish the general policies of the Foundation for carrying out the purposes of subsection (b), including the establishment of the bylaws of the

Foundation; and

(II) appoint the members of the Board in accordance with subparagraph (C).

(ii) Upon the appointment of the appointed members of the Board under clause (i)(II), the terms of service as members of the Board of the ex officio members of the Board described in clauses (i) and (ii) of subparagraph (B) shall terminate. The ex officio members of the Board described in clauses (iii) and (iv) of subparagraph (B) shall continue to serve as ex officio members of the Board.

(E) The agreement of not less than three-fifths of the members of the ex officio members of the Board shall be required for the appointment of each member to the initial Board.

(F) No employee of the National Institutes of Health shall be appointed as a member of the Board.

(G) The Board may, through amendments to the bylaws of the Foundation, provide that the number of appointed members of the Board shall be greater than the number specified in subparagraph (C).

(2) Chair

(A) The ex officio members of the Board under paragraph (1)(B) shall designate an individual to serve as the initial Chair of the Board.

(B) Upon the termination of the term of service of the initial Chair of the Board, the appointed members of the Board shall elect a member of the Board to serve as the Chair of the Board.

(3) Terms and vacancies

(A) The term of office of each member of the Board appointed under paragraph (1)(C) shall be 5 years, except that the terms of offices for the initial appointed members of the Board shall expire as determined by the ex officio members and the Chair.

(B) Any vacancy in the membership of the appointed members of the Board shall be filled in accordance with the bylaws of the Foundation established in accordance with paragraph (6), and shall not affect the power of the remaining appointed members to execute the duties of the Board.

(C) If a member of the Board does not serve the full term applicable under subparagraph (A), the individual appointed to fill the resulting vacancy shall be appointed for the remainder of the term of the predecessor of the individual.

(D) A member of the Board may continue to serve after the expiration of the term of the member until a successor is appointed.

(4) Compensation

Members of the Board may not receive compensation for service on the Board. Such members may be reimbursed for travel, subsistence, and other necessary expenses incurred in carrying out the duties of the Board, as set forth in the bylaws issued by the Board.

(5) Meetings and quorum

A majority of the appointed members of the Board shall constitute a quorum for purposes of conducting the business of the Board.

(6) Certain bylaws

(A) In establishing bylaws under this subsection, the Board shall ensure that the following are provided for:

(i) Policies for the selection of the officers, employees, agents, and contractors of the Foundation.

(ii) Policies, including ethical standards, for the acceptance, solicitation, and disposition of donations and grants to the Foundation and for the disposition of the assets of the Foundation. Policies with respect to ethical standards shall ensure that officers, employees and agents of the Foundation (including members of the Board) avoid encumbrances that would result in a conflict of interest, including a financial conflict of interest or a divided allegiance. Such policies shall include requirements for the provision of information concerning any ownership

or controlling interest in entities related to the activities of the Foundation by such officers, employees and agents and their spouses and relatives.

(iii) Policies for the conduct of the general operations of the Foundation.

(iv) Policies for writing, editing, printing, publishing, and vending of books and other materials.

(B) In establishing bylaws under this subsection, the Board shall ensure that such bylaws (and activities carried out under the bylaws) do not—

(i) reflect unfavorably upon the ability of the Foundation or the National Institutes of Health to carry out its responsibilities or official duties in a fair and objective manner; or

(ii) compromise, or appear to compromise, the integrity of any governmental agency or program, or any officer or employee involved in such program.

(e) Incorporation

The initial members of the Board shall serve as incorporators and shall take whatever actions necessary to incorporate the Foundation.

(f) Nonprofit status

The Foundation shall be considered to be a corporation under section 501(c) of title 26, and shall be subject to the provisions of such section.

(g) Executive Director

(1) In general

The Foundation shall have an Executive Director who shall be appointed by the Board and shall serve at the pleasure of the Board. The Executive Director shall be responsible for the day-to-day operations of the Foundation and shall have such specific duties and responsibilities as the Board shall prescribe.

(2) Compensation

The rate of compensation of the Executive Director shall be fixed by the Board.

(h) Powers

In carrying out subsection (b), the Foundation may—

(1) operate under the direction of its Board;

(2) adopt, alter, and use a corporate seal, which shall be judicially noticed;

(3) provide for 1 or more officers, employees, and agents, as may be necessary, define their duties, and require surety bonds or make other provisions against losses occasioned by acts of such persons;

(4) hire, promote, compensate, and discharge officers and employees of the Foundation, and define the duties of the officers and employees;

(5) with the consent of any executive department or independent agency, use the information, services, staff, and facilities of such in carrying out this section;

(6) sue and be sued in its corporate name, and complain and defend in courts of competent jurisdiction;

(7) modify or consent to the modification of any contract or agreement to which it is a party or in which it has an interest under this part;

(8) establish a process for the selection of candidates for positions under subsection (c);

(9) enter into contracts with public and private organizations for the writing, editing, printing, and publishing of books and other material;

(10) take such action as may be necessary to obtain patents and licenses for devices and procedures developed by the Foundation and its employees;

(11) solicit, accept, hold, administer, invest, and spend any gift, devise, or bequest of real or personal property made to the Foundation;

(12) enter into such other contracts, leases, cooperative agreements, and other transactions as the Executive Director considers appropriate to conduct the activities of the Foundation;

(13) appoint other groups of advisors as may be determined necessary from time to time to carry out the functions of the Foundation;

(14) enter into such other contracts, leases, cooperative agreements, and other transactions as the Executive Director considers appropriate to conduct the activities of the Foundation; and

(15) exercise other powers as set forth in this section, and such other incidental powers as are necessary to carry out its powers, duties, and functions in accordance with this part.

(i) Administrative control

No participant in the program established under this part shall exercise any administrative control over any Federal employee.

(j) General provisions

(1) Foundation integrity

The members of the Board shall be accountable for the integrity of the operations of the Foundation and shall ensure such integrity through the development and enforcement of criteria and procedures relating to standards of conduct, financial disclosure statements, conflict of interest rules, recusal and waiver rules, audits and other matter determined appropriate by the Board.

(2) Financial conflicts of interest

Any individual who is an officer, employee, or member of the Board of the Foundation may not (in accordance with policies and requirements developed under subsection (d)(6)) personally or substantially participate in the consideration or determination by the Foundation of any matter that would directly or predictably affect any financial interest of the individual or a relative (as such term is defined in section 13101(16) of title 5) of the individual, of any business organization or other entity, or of which the individual is an officer or employee, or is negotiating for employment, or in which the individual has any other financial interest.

(3) Audits; availability of records

The Foundation shall—

(A) provide for annual audits of the financial condition of the Foundation; and

(B) make such audits, and all other records, documents, and other papers of the Foundation, available to the Secretary and the Comptroller General of the United States for examination or audit.

(4) Reports

(A) Not later than 5 months following the end of each fiscal year, the Foundation shall publish a report describing the activities of the Foundation during the preceding fiscal year. Each such report shall include for the fiscal year involved a comprehensive statement of the operations, activities, financial condition, and accomplishments of the Foundation, including an accounting of the use of amounts transferred under subsection (l).

(B) With respect to the financial condition of the Foundation, each report under subparagraph (A) shall include the source, and a description of, all gifts or grants to the Foundation of real or personal property, and the source and amount of all gifts or grants to the Foundation of money. Each such report shall include a specification of any restrictions on the purposes for which gifts or grants to the Foundation may be used.

(C) The Foundation shall make copies of each report submitted under subparagraph (A) available—

(i) for public inspection, and shall upon request provide a copy of the report to any individual for a charge that shall not exceed the cost of providing the copy; and

(ii) to the appropriate committees of Congress.

(D) The Board shall annually hold a public meeting to summarize the activities of the Foundation and distribute written reports concerning such activities and the scientific results derived from such activities.

(5) Service of Federal employees

Federal employees may serve on committees advisory to the Foundation and otherwise cooperate with and assist the Foundation in carrying out its function, so long as the employees do not direct or control Foundation activities.

(6) Relationship with existing entities

The Foundation may, pursuant to appropriate agreements, merge with, acquire, or use the resources of existing nonprofit private corporations with missions similar to the purposes of the Foundation, such as the Foundation for Advanced Education in the Sciences.

(7) Intellectual property rights

The Board shall adopt written standards with respect to the ownership of any intellectual property rights derived from the collaborative efforts of the Foundation prior to the commencement of such efforts.

(8) National Institutes of Health Amendments of 1990

The activities conducted in support of the National Institutes of Health Amendments of 1990 (Public Law 101–613), and the amendments made by such Act, shall not be nullified by the enactment of this section.[1]

(9) Limitation of activities

(A) In general

The Foundation shall exist solely as an entity to work in collaboration with the research programs of the National Institutes of Health. The Foundation may not undertake activities (such as the operation of independent laboratories or competing for Federal research funds) that are independent of those of the National Institutes of Health research programs.

(B) Gifts, grants, and other donations

(i) In general

Gifts, grants, and other donations to the Foundation may be designated for pediatric research and studies on drugs, and funds so designated shall be used solely for grants for research and studies under subsection (c)(1)(C).

(ii) Other gifts

Other gifts, grants, or donations received by the Foundation and not described in clause (i) may also be used to support such pediatric research and studies.

(iii) Report

The recipient of a grant for research and studies shall agree to provide the Director of the National Institutes of Health and the Commissioner of Food and Drugs, at the conclusion of the research and studies—

(I) a report describing the results of the research and studies; and

(II) all data generated in connection with the research and studies.

(iv) Action by the Commissioner of Food and Drugs

The Commissioner of Food and Drugs shall take appropriate action in response to a report received under clause (iii) in accordance with paragraphs (7) through (12) [2] of section 284m(c) of this title, including negotiating with the holders of approved applications for the drugs studied for any labeling changes that the Commissioner determines to be appropriate and requests the holders to make.

(C) Applicability

Subparagraph (A) does not apply to the program described in subsection (c)(1)(C).

(10) Transfer of funds

The Foundation may transfer funds to the National Institutes of Health and the National

Institutes of Health may accept transfers of funds from the Foundation. Any funds transferred under this paragraph shall be subject to all Federal limitations relating to federally-funded research.

(k) Duties of Director

(1) Applicability of certain standards to non-Federal employees

In the case of any individual who is not an employee of the Federal Government and who serves in association with the National Institutes of Health, with respect to financial assistance received from the Foundation, the Foundation may not provide the assistance of, or otherwise permit the work at the National Institutes of Health to begin until a memorandum of understanding between the individual and the Director of the National Institutes of Health, or the designee of such Director, has been executed specifying that the individual shall be subject to such ethical and procedural standards of conduct relating to duties performed at the National Institutes of Health, as the Director of the National Institutes of Health determines is appropriate.

(2) Support services

The Director of the National Institutes of Health may provide facilities, utilities and support services to the Foundation if it is determined by the Director to be advantageous to the research programs of the National Institutes of Health.

(l) Funding

From amounts appropriated to the National Institutes of Health, for each fiscal year, the Director of NIH shall transfer not less than $1,250,000 and not more than $5,000,000 to the Foundation.

(July 1, 1944, ch. 373, title IV, §499, formerly §499A, as added Pub. L. 101–613, §2, Nov. 16, 1990, 104 Stat. 3224; amended Pub. L. 102–170, title II, §216, Nov. 26, 1991, 105 Stat. 1128; Pub. L. 102–321, title I, §163(b)(6), July 10, 1992, 106 Stat. 376; renumbered §499 and amended Pub. L. 103–43, title I, §121(b)(3), title XVII, §1701, June 10, 1993, 107 Stat. 133, 186; Pub. L. 104–316, title I, §122(b), Oct. 19, 1996, 110 Stat. 3836; Pub. L. 105–392, title IV, §418(2), Nov. 13, 1998, 112 Stat. 3591; Pub. L. 107–109, §13, Jan. 4, 2002, 115 Stat. 1417; Pub. L. 109–482, title I, §107, Jan. 15, 2007, 120 Stat. 3696; Pub. L. 110–85, title V, §502(c), Sept. 27, 2007, 121 Stat. 889; Pub. L. 111–148, title X, §10409(c), Mar. 23, 2010, 124 Stat. 978; Pub. L. 112–74, div. F, title II, §221(d)(4), Dec. 23, 2011, 125 Stat. 1090; Pub. L. 112–144, title V, §509(f), July 9, 2012, 126 Stat. 1050; Pub. L. 117–101, §2(b), Mar. 15, 2022, 136 Stat. 47; Pub. L. 117–286, §4(c)(39), Dec. 27, 2022, 136 Stat. 4358.)

EDITORIAL NOTES

REFERENCES IN TEXT

The National Institutes of Health Amendments of 1990, referred to in subsec. (j)(8), is Pub. L. 101–613, Nov. 16, 1990, 104 Stat. 3224, which enacted this section, section 285g–4 of this title, and provisions set out as notes under section 201 and 285g–4 of this title. For complete classification of this Act to the Code, see Short Title of 1990 Amendments note set out under section 201 of this title and Tables.

Section 284m of this title, referred to in subsec. (j)(9)(B)(iv), was amended generally by Pub. L. 110–85, title V, §502(b), Sept. 27, 2007, 121 Stat. 886, and, as so amended, does not contain a par. (12) in subsec. (c).

PRIOR PROVISIONS

A prior section 499 of act July 1, 1944, was classified to section 289h of this title prior to repeal by Pub. L. 103–43.

AMENDMENTS

2022—Subsec. (j)(2). Pub. L. 117–286 substituted "section 13101(16) of title 5)" for "section 109(16) of the Ethics in Government Act of 1978)".

Subsec. (l). Pub. L. 117–101 substituted "$1,250,000 and not more than $5,000,000" for "$500,000 and not more than $1,250,000".

2012—Subsec. (c)(1)(C). Pub. L. 112–144 struck out "for which the Secretary issues a certification in the

affirmative under section 355a(n)(1)(A) of title 21" before period at end.

2011—Subsec. (c)(1)(E). Pub. L. 112–74 substituted "section 287a" for "section 282d".

2010—Subsec. (c)(1)(E). Pub. L. 111–148 added subpar. (E).

2007—Subsec. (c)(1)(C). Pub. L. 110–85 substituted "and studies for which the Secretary issues a certification in the affirmative under section 355a(n)(1)(A) of title 21" for "and studies listed by the Secretary pursuant to section 284m(a)(1)(A) of this title and referred under section 355a(d)(4)(C) of title 21". Amendment, which directed striking out language ending with "section 505A(d)(4)(C) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. 355(a)(d)(4)(C)' " in the original, was executed by striking out language ending with "section 505A(d)(4)(C) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355a(d)(4)(C))" in the original to reflect the probable intent of Congress. That language had been translated as "section 355a(d)(4)(C) of title 21" for purposes of codification.

Subsec. (d)(1)(D)(ii). Pub. L. 109–482, §107(1)(A)(i), amended cl. (ii) generally. Prior to amendment, cl. (ii) read as follows: "Upon the appointment of the members of the Board under clause (i)(II), the terms of service of the ex officio members of the Board as members of the Board shall terminate."

Subsec. (d)(1)(G). Pub. L. 109–482, §107(1)(A)(ii), inserted "appointed" after "that the number of".

Subsec. (d)(3)(B). Pub. L. 109–482, §107(1)(B), amended subpar. (B) generally. Prior to amendment, subpar. (B) read as follows: "Any vacancy in the membership of the Board shall be filled in the manner in which the original position was made and shall not affect the power of the remaining members to execute the duties of the Board."

Subsec. (d)(5). Pub. L. 109–482, §107(1)(C), inserted "appointed" after "majority of the".

Subsec. (j)(2). Pub. L. 109–482, §107(2)(A), substituted "subsection (d)(6)" for "subsection (d)(2)(B)(i)(II)".

Subsec. (j)(4)(A). Pub. L. 109–482, §107(2)(B)(i), inserted ", including an accounting of the use of amounts transferred under subsection (l)" before period at end.

Subsec. (j)(4)(C). Pub. L. 109–482, §107(2)(B)(ii), added subpar. (C) and struck out former subpar. (C) which read as follows: "The Foundation shall make copies of each report submitted under subparagraph (A) available for public inspection, and shall upon request provide a copy of the report to any individual for a charge not exceeding the cost of providing the copy."

Subsec. (j)(10). Pub. L. 109–482, §107(2)(C), substituted "of Health and the National Institutes of Health may accept transfers of funds from the Foundation" for "of Health".

Subsec. (l). Pub. L. 109–482, §107(3), added subsec. (l) and struck out former subsec. (l) which related to authorization of appropriations and limitation regarding other funds.

2002—Subsec. (b). Pub. L. 107–109, §13(1), inserted "(including collection of funds for pediatric pharmacologic research)" after "mission".

Subsec. (c)(1)(C), (D). Pub. L. 107–109, §13(2), added subpar. (C) and redesignated former subpar. (C) as (D).

Subsec. (d)(1)(B)(iv). Pub. L. 107–109, §13(3)(A)(i), added cl. (iv).

Subsec. (d)(1)(C). Pub. L. 107–109, §13(3)(A)(ii), added subpar. (C) and struck out former subpar. (C) which read as follows: "The ex officio members of the Board under subparagraph (B) shall appoint to the Board 11 individuals from among a list of candidates to be provided by the National Academy of Science. Of such appointed members—

"(i) 4 shall be representative of the general biomedical field;

"(ii) 2 shall be representatives of the general biobehavorial field; and

"(iii) 5 shall be representatives of the general public."

Subsec. (d)(2)(B). Pub. L. 107–109, §13(3)(B), realigned margin.

Subsec. (e) to (g). Pub. L. 107–109, §13(5), redesignated subsecs. (f) to (h) as (e) to (g), respectively.

Subsec. (h). Pub. L. 107–109, §13(5), (6), redesignated subsec. (i) as (h) and substituted "solicit," for "solicit" in par. (11). Former subsec. (h) redesignated (g).

Subsec. (i). Pub. L. 107–109, §13(5), redesignated subsec. (j) as (i). Former subsec. (i) redesignated (h).

Subsec. (j). Pub. L. 107–109, §13(5), redesignated subsec. (k) as (j). Former subsec. (j) redesignated (i).

Subsec. (j)(1). Pub. L. 107–109, §13(7), struck out "(including those developed under subsection (d)(2)(B)(i)(II))" after "procedures relating to standards of conduct".

Subsec. (j)(2). Pub. L. 107–109, §13(7), which directed striking out "(including those developed under subsection (d)(2)(B)(i)(II))" in par. (2), could not be executed because those words do not appear in par. (2).

Subsec. (k). Pub. L. 107–109, §13(5), redesignated subsec. (l) as (k). Former subsec. (k) redesignated (j).

Subsec. (k)(9). Pub. L. 107–109, §13(4), designated existing provisions as subpar. (A), inserted subpar. heading, and added subpars. (B) and (C).

Subsecs. (l), (m). Pub. L. 107–109, §13(5), redesignated subsec. (m) as (l). Former subsec. (l) redesignated

(k).

1998—Subsec. (a). Pub. L. 105–392, §418(2)(A), substituted "Foundation for the National Institutes of Health" for "National Foundation for Biomedical Research".

Subsec. (k)(10). Pub. L. 105–392, §418(2)(B), struck out "not" after "may" and inserted at end "Any funds transferred under this paragraph shall be subject to all Federal limitations relating to federally-funded research."

Subsec. (m)(1). Pub. L. 105–392, §418(2)(C), substituted "$500,000 for each fiscal year" for "$200,000 for the fiscal years 1994 and 1995".

1996—Subsec. (n). Pub. L. 104–316 struck out subsec. (n) which required Comptroller General to conduct audit and prepare report to Congress on adequacy of compliance of the Foundation with guidelines established under this section.

1993—Subsec. (a). Pub. L. 103–43, §1701(1), inserted ", acting through the Director of NIH," after "Secretary shall" and struck out ", except for the purposes of the Ethics in Government Act and the Technology Transfer Act," after "shall not".

Subsec. (b). Pub. L. 103–43, §1701(3), added subsec. (b) and struck out heading and text of former subsec. (b). Text related to duties of Foundation.

Subsec. (c). Pub. L. 103–43, §1701(3), added subsec. (c). Former subsec. (c) redesignated (d).

Subsec. (d). Pub. L. 103–43, §1701(2), redesignated subsec. (c) as (d). Former subsec. (d) redesignated (f).

Subsec. (d)(1). Pub. L. 103–43, §1701(4)(A), substituted "appointed members of the Board" for "members of the Foundation" in subpar. (A), "Board" for "Council" in subpar. (B), and "appoint to the Board" for "appoint to the Council" in subpar. (C), and added subpars. (D) to (G).

Subsec. (d)(2). Pub. L. 103–43, §1701(4)(B), designated existing provisions as subpar. (A), substituted "an individual to serve as the initial Chair" for "an appointed member of the Board to serve as the Chair", and added subpar. (B).

Subsec. (d)(3)(A). Pub. L. 103–43, §1701(4)(C), substituted "(1)(C)" for "(2)(C)".

Subsec. (d)(5), (6). Pub. L. 103–43, §1701(4)(D), added pars. (5) and (6).

Subsec. (e). Pub. L. 103–43, §1701(2), redesignated subsec. (e) as (g).

Subsecs. (f) to (h). Pub. L. 103–43, §1701(2), redesignated subsecs. (d) to (f) as (f) to (h), respectively. Former subsecs. (g) and (h) redesignated (i) and (j), respectively.

Subsec. (i). Pub. L. 103–43, §1701(2), redesignated subsec. (g) as (i). Former subsec. (i) redesignated (m).

Subsec. (i)(4). Pub. L. 103–43, §1701(5)(A), inserted before period at end ", and define the duties of the officers and employees".

Subsec. (i)(5), (6). Pub. L. 103–43, §1701(5)(B), (C), redesignated par. (6) as (5) and struck out former par. (5) which read as follows: "prescribe by its Board its bylaws, that shall be consistent with law, and that shall provide for the manner in which—

"(A) its officers, employees, and agents are selected;

"(B) its property is acquired, held, and transferred;

"(C) its general operations are to be conducted; and

"(D) the privileges granted by law are exercised and enjoyed;".

Subsec. (i)(7). Pub. L. 103–43, §1701(5)(C), (D), redesignated par. (8) as (7) and substituted "part" for "subtitle". Former par. (7) redesignated (6).

Subsec. (i)(8). Pub. L. 103–43, §1701(5)(C), (E), redesignated par. (9) as (8) and substituted "establish a process for the selection of candidates for positions under subsection (c)" for "establish a mechanism for the selection of candidates, subject to the approval of the Director of the National Institutes of Health, for the endowed scientific positions within the organizational structure of the intramural research programs of the National Institutes of Health and candidates for participation in the National Institutes of Health Scholars program".

Subsec. (i)(9), (10). Pub. L. 103–43, §1701(5)(C), redesignated pars. (10) and (11) as (9) and (10), respectively. Former par. (9) redesignated (8).

Subsec. (i)(11). Pub. L. 103–43, §1701(5)(C), (F), redesignated par. (12) as (11) and inserted "solicit" before "accept". Former par. (11) redesignated (10).

Subsec. (i)(12), (13). Pub. L. 103–43, §1701(5)(C), redesignated pars. (13) and (14) as (12) and (13), respectively. Former par. (12) redesignated (11).

Subsec. (i)(14). Pub. L. 103–43, §1701(5)(G), (H), added par. (14). Former par. (14) redesignated (13).

Subsec. (i)(15). Pub. L. 103–43, §1701(5)(I), substituted "part" for "subtitle".

Subsec. (j). Pub. L. 103–43, §1701(2), redesignated subsec. (h) as (j).

Subsecs. (k), (l). Pub. L. 103–43, §1701(6), added subsecs. (k) and (l).

Subsec. (m). Pub. L. 103–43, §1701(7), amended heading and text of subsec. (m) generally. Prior to

amendment, text read as follows:

"(1) AUTHORIZATION OF APPROPRIATIONS.—Subject to paragraph (2), for the purpose of carrying out this part, there are authorized to be appropriated such sums as may be necessary for each of the fiscal years 1991 through 1995.

"(2) LIMITATIONS.—

"(A) Amounts appropriated under paragraph (1) or made available under subparagraph (C) may not be provided to the fund established under subsection (b)(1)(A) of this section.

"(B) For the first fiscal year for which amounts are appropriated under paragraph (1), $200,000 is authorized to be appropriated.

"(C) With respect to the first fiscal year for which amounts are appropriated under paragraph (1), the Secretary may, from amounts appropriated for such fiscal year for the programs of the Department of Health and Human Services, make available not more than $200,000 for carrying out this part, subject to subparagraph (A)."

Pub. L. 103–43, §1701(2), redesignated subsec. (i) as (m).

Subsec. (n). Pub. L. 103–43, §1701(8), added subsec. (n).

1992—Subsec. (g)(9). Pub. L. 102–321 struck out "or the Administrator of the Alcohol, Drug Abuse, and Mental Health Administration" after "Director of the National Institutes of Health" and "and the Alcohol, Drug Abuse, and Mental Health Administration" after "research programs of the National Institutes of Health".

1991—Subsec. (c)(1)(C). Pub. L. 102–170, §216(1), substituted "11" for "9".

Subsec. (c)(1)(C)(iii). Pub. L. 102–170, §216(2), substituted "5" for "3".

STATUTORY NOTES AND RELATED SUBSIDIARIES

CHANGE OF NAME

Committee on Labor and Human Resources of Senate changed to Committee on Health, Education, Labor, and Pensions of Senate by Senate Resolution No. 20, One Hundred Sixth Congress, Jan. 19, 1999.

Committee on Energy and Commerce of House of Representatives treated as referring to Committee on Commerce of House of Representatives by section 1(a) of Pub. L. 104–14, set out as a note preceding section 21 of Title 2, The Congress. Committee on Commerce of House of Representatives changed to Committee on Energy and Commerce of House of Representatives, and jurisdiction over matters relating to securities and exchanges and insurance generally transferred to Committee on Financial Services of House of Representatives by House Resolution No. 5, One Hundred Seventh Congress, Jan. 3, 2001.

EFFECTIVE DATE OF 2007 AMENDMENT

Amendment by Pub. L. 109–482 applicable only with respect to amounts appropriated for fiscal year 2007 or subsequent fiscal years, see section 109 of Pub. L. 109–482, set out as a note under section 281 of this title.

EFFECTIVE DATE OF 1992 AMENDMENT

Amendment by Pub. L. 102–321 effective Oct. 1, 1992, with provision for programs providing financial assistance, see section 801(c), (d) of Pub. L. 102–321, set out as a note under section 236 of this title.

[1] So in original. Probably should be "subsection".

[2] See References in Text note below.

PART J—ADVANCED RESEARCH PROJECTS AGENCY–HEALTH

§290c. Advanced Research Projects Agency–Health

(a) Establishment

(1) In general

There is established within the National Institutes of Health the Advanced Research Projects

Agency–Health (referred to in this section as "ARPA–H"). Not later than 180 days after December 29, 2022, the Secretary shall transfer all functions, personnel, missions, activities, authorities, and funds of the Advanced Research Projects Agency for Health as in existence on December 29, 2022, to ARPA–H established by the preceding sentence.

(2) Organization

(A) In general

There shall be within ARPA–H—

(i) an Office of the Director;

(ii) not more than 8 program offices; and

(iii) such special project offices as the Director may establish.

(B) Requirement

Not fewer than two-thirds of the program offices of ARPA–H shall be exclusively dedicated to supporting research and development activities, consistent with the goals and functions described in subsection (b).

(C) Notification

The Director shall submit a notification to the Committee on Health, Education, Labor, and Pensions and the Committee on Appropriations of the Senate and the Committee on Energy and Commerce and the Committee on Appropriations of the House of Representatives if the Director determines that additional program offices are required to carry out this section.

(3) Exemption from certain policies of NIH

(A) In general

Except as otherwise provided for in this section, and subject to subparagraph (B), in establishing ARPA–H pursuant to paragraph (1), the Secretary may exempt ARPA–H from policies and requirements of the National Institutes of Health that are in effect on the day before December 29, 2022, as necessary and appropriate to ensure ARPA–H can most effectively achieve the goals described in subsection (b)(1).

(B) Notice

Not later than 90 days after December 29, 2022, the Secretary shall publish a notice in the Federal Register describing the specific policies and requirements of the National Institutes of Health from which the Secretary intends to exempt ARPA–H, including a rationale for such exemptions.

(b) Goals and functions

(1) Goals

The goals of ARPA–H shall be to—

(A) foster the development of novel, breakthrough, and broadly applicable capabilities and technologies to accelerate transformative innovation in biomedical science and medicine in a manner that cannot be readily accomplished through traditional Federal biomedical research and development programs or commercial activity;

(B) revolutionize the detection, diagnosis, mitigation, prevention, treatment, and cure of diseases and health conditions by overcoming long-term and significant technological and scientific barriers to developing transformative health technologies;

(C) promote high-risk, high-reward innovation to enable the advancement of transformative health technologies; and

(D) contribute to ensuring the United States—

(i) pursues initiatives that aim to maintain global leadership in science and innovation; and

(ii) improves the health and wellbeing of its citizens by supporting the advancement of biomedical science and innovation.

(2) Functions

ARPA–H shall achieve the goals specified in paragraph (1) by addressing specific scientific or technical questions by involving high-impact transformative, translational, applied, and advanced research in relevant areas of science, by supporting—

(A) discovery, identification, and promotion of revolutionary advancements in science;

(B) translation of scientific discoveries into transformative health technologies with potential application for biomedical science and medicine;

(C) creation of platform capabilities that draw on multiple disciplines;

(D) delivery of proofs of concept that demonstrate meaningful advances with potential clinical application;

(E) development of new capabilities and methods to identify potential targets and technological strategies for early disease detection and intervention, such as advanced computational tools and predictive models; and

(F) acceleration of transformational health technological advances in areas with limited technical certainty.

(c) Director

(1) In general

The President shall appoint a director of ARPA–H (in this section referred to as the "Director").

(2) Qualifications

The Director shall be an individual who, by reason of professional background and experience—

(A) is especially qualified to advise the Secretary on, and manage—

(i) research and development programs; and

(ii) large-scale, high-risk initiatives with respect to health research and technology development across multiple sectors, including identifying and supporting potentially transformative health technologies; and

(B) has a demonstrated ability to identify and develop partnerships to address strategic needs in meeting the goals described in subsection (b)(1).

(3) Reporting

The Director shall report to the Secretary of Health and Human Services.

(4) Duties

The duties of the Director shall include the following:

(A) Establish strategic goals, objectives, and priorities for ARPA–H to advance the goals described in subsection (b)(1).

(B) Approve the projects and programs of ARPA–H and restructure, expand, or terminate any project or program within ARPA–H that is not achieving its goals.

(C) Develop funding criteria and assess the success of programs through the establishment of technical milestones.

(D) Request that applications for funding disclose current and previous research and development efforts related to such applications, as appropriate, and identify any challenges associated with such efforts, including any scientific or technical barriers encountered in the course of such efforts or challenges in securing sources of funding, as applicable.

(E) Coordinate with the heads of relevant Federal departments and agencies to facilitate sharing of data and information, as applicable and appropriate, and ensure that research supported by ARPA–H is informed by and supplements, not supplants, the activities of such departments and agencies and is free of unnecessary duplication of effort.

(F) Ensure ARPA–H does not provide funding for a project unless the program manager determines that the project aligns with the goals described in subsection (b)(1).

(G) Prioritize investments based on considerations such as—

(i) scientific opportunity and potential impact, especially in areas that fit within the

strategies and operating practices of ARPA–H and require public-private partnerships to effectively advance research and development activities; and

(ii) the potential applications that an innovation may have to address areas of currently unmet need in medicine and health, including health disparities and the potential to prevent progression to serious disease.

(H) Encourage strategic collaboration and partnerships with a broad range of entities, which may include institutions of higher education, minority-serving institutions (defined, for the purposes of this section, as institutions and programs described in section 1063b(e)(1) of title 20 and institutions described in section 1067q(a) of title 20), industry, nonprofit organizations, Federally funded research and development centers, or consortia of such entities.

(5) Term

Notwithstanding section 284(a)(2) of this title, the Director—

(A) shall be appointed for a 4-year term; and

(B) may be reappointed for 1 consecutive 4-year term.

(6) Autonomy of Agency regarding recommendations and testimony

No office or agency of the United States shall have authority to require the Director to submit legislative recommendations, or testimony or comments on legislation, to any officer or agency of the United States for approval, comments, or review prior to the submission of such recommendations, testimony or comments to Congress, if such recommendations, testimony, or comments to Congress include a statement indicating that the views expressed therein are those of the Director and do not necessarily reflect the views of the President or another Federal department, agency, or office.

(7) Deputy Director

The Director shall appoint a Deputy Director to serve as the principal assistant to the Director.

(8) Nonapplication of certain provision

The restrictions contained in section 202 of the Departments of Labor, Health and Human Services, and Education, and Related Agencies Appropriations Act, 1993 (Public Law 102–394; 42 U.S.C. 238f note) related to consultants and individual scientists appointed for limited periods of time shall not apply to the Director appointed under this subsection.

(d) Application of certain flexibilities

The flexibilities provided to the National Institutes of Health under section 241(g) of this title shall apply to ARPA–H with respect to the functions described in subsection (b)(2).

(e) Protection of information

(1) No authorization for disclosure

Nothing in this section shall be construed as authorizing the Director to disclose any information that is a trade secret or other privileged or confidential information subject to section 552(b)(4) of title 5 or section 1905 of title 18.

(2) Reporting

If there have been requests under section 522 [1] of title 5 or the Secretary has used such authority to withhold information within the preceding year, not later than 1 year after December 29, 2022, and annually thereafter, the Director shall report to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives on—

(A) the number of instances in which the Secretary has used the authority under this subsection to withhold information from disclosure; and

(B) the nature of any request under section 552 of title 5 or section 1905 of title 18 that was denied using such authority.

(3) Clarification

The protections for trade secrets or other privileged or confidential information described in paragraph (1) shall not be construed to limit the availability or disclosure of information necessary to inform and facilitate the evaluation required under subsection (k)(2). Any such information made available to members of the National Academies of Sciences, Engineering, and Medicine (referred to in this section as the "National Academies") for such evaluation shall be kept confidential by such members and shall not be used for any purposes other than informing and facilitating the evaluation required under subsection (k)(2).

(f) Cooperation with the Food and Drug Administration

(1) In general

In order to facilitate the enhanced collaboration and communication with respect to the most current priorities of ARPA–H, the Food and Drug Administration may meet with ARPA–H and any other Federal partners at appropriate intervals to discuss the development status, and actions that may be taken to facilitate the development, of medical products and projects that are the highest priorities to ARPA–H.

(2) Reimbursement

Utilizing interagency agreements or other appropriate resource allocation mechanisms available, the Director shall reimburse, using funds made available to ARPA–H, the Food and Drug Administration, as appropriate, for activities identified by the Commissioner of Food and Drugs and the Director as being conducted by the Food and Drug Administration under the authority of this subsection.

(g) Awards

(1) In general

In carrying out this section, the Director may—

(A) award grants and cooperative agreements, which shall include requirements to publicly report indirect facilities and administrative costs, broken out by fixed capital costs, administrative overhead, and labor costs;

(B) award contracts, which may include multi-year contracts subject to section 3903 of title 41;

(C) award cash prizes, utilizing the authorities and processes established under section 3719 of title 15; and

(D) enter into other transactions, as defined by section 247d–7e(a)(3) of this title, subject to paragraph (2).

(2) Limitations on entering into other transactions

(A) Use of competitive procedures

To the maximum extent practicable, competitive procedures shall be used when entering into other transactions under this section.

(B) Written determination required

The authority of paragraph (1)(D) may be exercised for a project if the program manager—

(i) submits a request to the Director for each individual use of such authority before conducting or supporting a program, including an explanation of why the use of such authority is essential to promoting the success of the project;

(ii) receives approval for the use of such authority from the Director; and

(iii) for each year in which the program manager has used such authority in accordance with this paragraph, submits a report to the Director on the activities of the program related to such project.

(3) Exemptions from certain requirements

Research funded by ARPA–H shall not be subject to the requirements of section

284a(a)(3)(A)(ii) of this title or section 289a of this title.

(h) Facilities authority

(1) In general

The Director is authorized, for administrative purposes, to—

(A) acquire (by purchase, lease, condemnation or otherwise), construct, improve, repair, operate, and maintain such real and personal property as are necessary to carry out this section; and

(B) lease an interest in property for not more than 20 years, notwithstanding section 1341(a)(1) of title 31.

(2) Locations

(A) In general

ARPA–H, including its headquarters, shall not be located on any part of the existing National Institutes of Health campuses.

(B) Number of locations

ARPA–H shall have offices or facilities in not less than 3 geographic areas.

(C) Considerations

In determining the location of each office or facility, the Director shall make a fair and open consideration of—

(i) the characteristics of the intended location; and

(ii) the extent to which such location will facilitate advancement of the goals and functions specified in subsection (b).

(i) Personnel

(1) In general

The Director may—

(A) appoint and remove scientific, engineering, medical, and professional personnel, which may include temporary or term-limited appointments as determined by the Director to fulfill the mission of ARPA–H, without regard to any provision in title 5 governing appointments and removals under the civil service laws;

(B) notwithstanding any other provision of law, including any requirement with respect to General Schedule pay rates under subchapter III of chapter 53 of title 5, fix the base pay compensation of such personnel at a rate to be determined by the Director, up to the amount of annual compensation (excluding expenses) specified in section 102 of title 3; and

(C) contract with private recruiting firms for assistance in identifying highly qualified candidates for technical positions needed to carry out this section.

(2) Support staff

The Director may use authorities in existence on December 29, 2022, that are provided to the Secretary to hire administrative, financial, clerical, and other staff necessary to carry out functions that support the goals and functions described in subsection (b).

(3) Number of personnel

The Director may appoint not more than 210 personnel under this section. The Director shall submit a notification to the Committee on Health, Education, Labor, and Pensions and the Committee on Appropriations of the Senate and the Committee on Energy and Commerce and the Committee on Appropriations of the House of Representatives if the Director determines that additional personnel are required to carry out this section.

(4) Clarification on previous positions

(A) In general

Except as provided in subparagraph (B), the Director shall ensure that the personnel who are

appointed to staff or support ARPA–H are individuals who, at the time of appointment and for 3 years prior to such appointment, were not employed by the National Institutes of Health. The Director may grant an exemption only for individuals who are uniquely qualified, by way of professional background and expertise, to advance the goals and functions specified in subsection (b).

(B) Nonapplication of provision

The restriction provided under subparagraph (A) shall not apply to any individuals who are employed by ARPA–H on December 29, 2022.

(5) Additional considerations

In appointing personnel under this subsection, the Director—

(A) may contract with private entities for the purposes of recruitment services;

(B) shall make efforts to recruit a diverse workforce, including individuals underrepresented in science, engineering, and medicine, including racial and ethnic minorities, provided such efforts do not conflict with applicable Federal civil rights law, and individuals with a variety of professional experiences or backgrounds; and

(C) shall recruit program managers with demonstrated expertise in a wide range of scientific disciplines and management skills.

(6) Use of Intergovernmental Personnel Act

To the extent needed to carry out the authorities under paragraph (1) and the goals and functions specified in subsection (b), the Director may utilize hiring authorities under sections 3371 through 3376 of title 5.

(7) Authority to accept Federal detailees

The Director may accept officers or employees of the United States or members of the uniformed service on a detail from an element of the Federal Government, on a reimbursable or a nonreimbursable basis, as jointly agreed to by the heads of the receiving and detailing elements, for a period not to exceed 3 years.

(j) Program managers

(1) In general

The Director shall appoint program managers for 3-year terms (and may reappoint such program managers for 1 additional consecutive 3-year term) for the programs carried out by ARPA–H.

(2) Duties

A program manager shall—

(A) establish, in consultation with the Director, research and development goals for programs, including timelines and milestones, and make such goals available to the public;

(B) manage applications and proposals, through the appropriate officials, for making awards as described in subsection (g) for activities consistent with the goals and functions described in subsection (b);

(C) issue funding opportunity announcements, using uniform administrative processes, as appropriate;

(D) select, on the basis of merit, each of the projects to be supported under a program carried out by ARPA–H, and taking into consideration—

(i) the scientific, technical merit, and novelty of the proposed project;

(ii) the ability of the applicant to successfully carry out the proposed project;

(iii) the potential future commercial applications of the project proposed by the applicant, including whether such applications may have the potential to address areas of currently unmet need within biomedicine and improve health outcomes;

(iv) the degree to which the proposed project has the potential to transform biomedicine and addresses a scientific or technical question pursuant to subsection (b);

(v) the potential for the project to take an interdisciplinary approach; and
(vi) such other criteria as established by the Director;

(E) provide project oversight and management of strategic initiatives to advance the program, including by conducting project reviews not later than 18 months after the date of funding awards to identify and monitor progress of milestones with respect to each project and prior to disbursement of additional funds;

(F) provide recommendations to the Director with respect to advancing the goals and functions specified in subsection (b);

(G) encourage research collaborations and cultivate opportunities for the application or utilization of successful projects, including through identifying and supporting applicable public-private partnerships or partnerships between or among award recipients;

(H) provide recommendations to the Director to establish, expand, restructure, or terminate partnerships or projects; and

(I) communicate and collaborate with leaders and experts within the health care and biomedical research and development fields, including from both the public and private sectors and, as necessary, through the convening of workshops and meetings, to identify research and development gaps and opportunities and solicit stakeholder input on programs and goals.

(k) Reports and evaluation

(1) Annual report

(A) In general

Beginning not later than 1 year after December 29, 2022, as part of the annual budget request submitted for each fiscal year, the Director shall submit a report on the actions undertaken, and the results generated, by ARPA–H, including—

(i) a description of projects supported by ARPA–H in the previous fiscal year and whether such projects are meeting the goals developed by the Director pursuant to subsection (c)(4)(A);

(ii) a description of projects terminated in the previous fiscal year, and the reason for such termination;

(iii) a description of planned programs starting in the next fiscal year, pending the availability of funding;

(iv) activities conducted in coordination with other Federal departments and agencies;

(v) a description of any successes with, or barriers to, coordinating with other Federal departments and agencies to achieve the goals and functions under subsection (b);

(vi) aggregated demographic information, if available, of direct recipients and performers in funded projects and of the ARPA–H workforce (consistent with the reporting requirements under paragraph (3)); and

(vii) a summary of award recipient compliance with section 242v of this title.

(B) Submission to Congress

The report under subparagraph (A) shall be submitted to—

(i) the Committee on Energy and Commerce and the Committee on Appropriations of the House of Representatives; and

(ii) the Committee on Health, Education, Labor, and Pensions and the Committee on Appropriations of the Senate.

(2) Evaluation

(A) In general

Not later than 5 years after December 29, 2022, the Director shall seek to enter into an agreement with the National Academies under which the National Academies conducts an evaluation of whether ARPA–H is meeting the goals and functions specified in subsection (b).

(B) Submission of results

The agreement entered into under subparagraph (A) shall require the National Academies to submit the evaluation conducted under such agreement to the Director, the Committee on Health, Education, Labor, and Pensions of the Senate, and the Committee on Energy and Commerce of the House of Representatives, and make the report publicly available.

(3) Reporting related to ARPA–H personnel

(A) In general

The Director shall establish and maintain records regarding the use of the authority under subsection (i)(1)(A), including—

(i) the number of positions filled through such authority;
(ii) the types of appointments of such positions;
(iii) the titles, occupational series, and grades of such positions;
(iv) the number of positions publicly noticed to be filled under such authority;
(v) the number of qualified applicants who apply for such positions;
(vi) the qualification criteria for such positions; and
(vii) the demographic information of individuals appointed to such positions.

(B) Reports to Congress

Not later than 2 years after December 29, 2022, and annually thereafter for each fiscal year in which such authority is used, the Director shall submit to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives a report describing the total number of appointments filled under subsection (i) within the fiscal year and how the positions relate to the goals and functions of ARPA–H.

(C) GAO report

Not later than 2 years after December 29, 2022, the Comptroller General of the United States shall submit to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives a report on the use of the authority provided under subsection (i)(1)(A). Such report shall, in a manner that protects personal privacy, to the extent required by applicable Federal and State privacy law, at a minimum, include information on—

(i) the number of positions publicly noticed and filled under the authority under subsection (i);
(ii) the occupational series, grades, and types of appointments of such positions;
(iii) how such positions related to advancing the goals and functions of ARPA–H;
(iv) how the Director made appointment decisions under subsection (i);
(v) a summary of sources used to identify candidates for filling such positions, as applicable;
(vi) the number of individuals appointed;
(vii) aggregated demographic information related to individuals appointed; and
(viii) any challenges, limitations, or gaps related to the use of the authority under subsection (i) and any related recommendations to address such challenges, limitations, or gaps.

(l) Strategic plan

Not later than 1 year after December 29, 2022, and every 3 years thereafter, the Director shall provide to the Committee on Health, Education, Labor, and Pensions and the Committee on Appropriations of the Senate and the Committee on Energy and Commerce and the Committee on Appropriations of the House of Representatives a strategic plan describing how ARPA–H will carry out investments each fiscal year in the following 3-year period. The requirements regarding individual institute and center strategic plans under section 282(m) of this title, including paragraph (3) of such subsection, shall not apply to ARPA–H.

(m) Independent review

Not later than 1 year after December 29, 2022, and every 4 years thereafter, the Comptroller

General of the United States shall conduct, and submit to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives, an independent review of the biomedical research and development portfolio of the Department of Health and Human Services, including ARPA–H, the National Institutes of Health, the Food and Drug Administration, and the Biomedical Advanced Research and Development Authority—

(1) to assess the degree of any potential duplication of existing Federal programs and projects; and

(2) to make any recommendations regarding any potential reorganization, consolidation, or termination of such programs and projects.

(n) Prioritization

(1) In general

The Director shall—

(A) prioritize awarding grants, cooperative agreements, contracts, prizes, and other transaction awards to entities that will conduct funded work in the United States;

(B) as appropriate and practicable, encourage nondomestic recipients of any grants, cooperative agreements, contracts, prizes, and other transactions under this section to collaborate with a domestic entity;

(C) not make awards under this section to nondomestic entities organized under the laws of a covered foreign country (as defined in section 3059 of title 50); and

(D) in accordance with the requirements of chapter 33 of title 41 and the Federal Acquisition Regulation, not make awards under this section to entities that have more than 3 ongoing concurrent awards under this section.

(2) Clarification

In making an award under this section, the Director may waive the requirements of subparagraphs (A), (B), and (D) of paragraph (1) if such requirements cannot reasonably be met, and the proposed project has the potential to advance the goals described in subsection (b)(1). The Director shall provide notice to Congress not later than 30 days after waiving such requirements.

(o) Additional consultation

In carrying out this section, the Director may consult with—

(1) the President's Council of Advisors on Science and Technology;

(2) representatives of professional or scientific organizations, including academia and industry, with expertise in specific technologies under consideration or development by ARPA–H;

(3) an existing advisory committee providing advice to the Secretary or the head of any operating or staff division of the Department;

(4) the advisory committee established under subsection (p); and

(5) any other entity the Director may deem appropriate.

(p) Advisory Committee

(1) In general

There is established an ARPA–H Interagency Advisory Committee (referred to in this subsection as the "Advisory Committee") to coordinate efforts and provide advice and assistance on specific program or project tasks and the overall direction of ARPA–H.

(2) Members

The Advisory Committee established under paragraph (1) shall consist of the heads of the following agencies or their designees:

(A) The National Institutes of Health.

(B) The Centers for Disease Control and Prevention.

(C) The Food and Drug Administration.

(D) The Office of the Assistant Secretary for Preparedness and Response.

(E) The Office of the Assistant Secretary of Health.
(F) The Defense Advanced Research Projects Agency.
(G) The Office of Science of the Department of Energy.
(H) The National Science Foundation.
(I) Any other agency or office with subject matter expertise that the Director of ARPA–H determines appropriate to advance programs or projects under this section.

(3) Nonapplicability of FACA

The Federal Advisory Committee Act (5 U.S.C. App.) [2] shall not apply to the Advisory Committee.

(4) Advisory nature

The functions of the Advisory Committee shall be advisory in nature, and nothing in this subsection shall be construed as granting such Committee authority over the activities authorized under this section.

(5) Performance measures framework

(A) In general

The Director, in consultation with the Advisory Committee, shall develop a performance measures framework for programs or projects supported by ARPA–H in order to inform and facilitate the evaluation required under subsection (k)(2), including identification of any data needed to perform such evaluation,

(B) Availability of performance measures

The Director shall provide to the National Academies such performance measures and data necessary to perform the evaluation required under subsection (k)(2).

(q) Rule of construction

The authorities under this section, with respect to the Director, are additional authorities that do not supersede or modify any existing authorities.

(r) Transformative health technology defined

In this section, the term "transformative health technology" means a novel, broadly applicable capability or technology—
(1) that has potential to revolutionize the detection, diagnosis, mitigation, prevention, cure, or treatment of a disease or health condition that can cause severe health outcomes and which is an area of currently unmet need; and
(2) for which—
(A) significant scientific or technical challenges exist; or
(B) incentives in the commercial market are unlikely to result in the adequate or timely development of such capability or technology.

(s) Authorization of appropriations

To carry out this section, there is authorized to be appropriated $500,000,000 for each of the fiscal years 2024 through 2028, to remain available until expended.

(t) Additional budget clarification

Any budget request for ARPA–H shall propose a separate appropriation from the other accounts of the National Institutes of Health.

(July 1, 1944, ch. 373, title IV, §499A, as added Pub. L. 117–328, div. FF, title II, §2331(a), Dec. 29, 2022, 136 Stat. 5770.)

EDITORIAL NOTES

REFERENCES IN TEXT

The Federal Advisory Committee Act, referred to in subsec. (p)(3), is Pub. L. 92–463, Oct. 6, 1972, 86 Stat.

770, which was set out in the Appendix to Title 5, Government Organization and Employees, and was substantially repealed and restated in chapter 10 (§1001 et seq.) of Title 5 by Pub. L. 117–286, §§3(a), 7, Dec. 27, 2022, 136 Stat. 4197, 4361. For disposition of sections of the Act into chapter 10 of Title 5, see Disposition Table preceding section 101 of Title 5.

PRIOR PROVISIONS

A prior section 499A of act July 1, 1944, was renumbered section 499 by Pub. L. 103–43 and is classified to section 290b of this title.

[1] *So in original. Probably should be "section 552".*

[2] *See References in Text note below.*

SUBCHAPTER III–A—SUBSTANCE ABUSE AND MENTAL HEALTH SERVICES ADMINISTRATION

PART A—ORGANIZATION AND GENERAL AUTHORITIES

§290aa. Substance Abuse and Mental Health Services Administration

(a) Establishment

The Substance Abuse and Mental Health Services Administration (hereafter referred to in this subchapter as the "Administration") is an agency of the Service.

(b) Centers

The following Centers are agencies of the Administration:

(1) The Center for Substance Abuse Treatment.

(2) The Center for Substance Abuse Prevention.

(3) The Center for Mental Health Services.

(c) Assistant Secretary and Deputy Assistant Secretary

(1) Assistant Secretary

The Administration shall be headed by an official to be known as the Assistant Secretary for Mental Health and Substance Use (hereinafter in this subchapter referred to as the "Assistant Secretary") who shall be appointed by the President, by and with the advice and consent of the Senate.

(2) Deputy Assistant Secretary

The Assistant Secretary, with the approval of the Secretary, may appoint a Deputy Assistant Secretary and may employ and prescribe the functions of such officers and employees, including attorneys, as are necessary to administer the activities to be carried out through the Administration.

(d) Authorities

The Secretary, acting through the Assistant Secretary, shall—

(1) supervise the functions of the Centers of the Administration in order to assure that the programs carried out through each such Center receive appropriate and equitable support and that there is cooperation among the Centers in the implementation of such programs;

(2) establish and implement, through the respective Centers, a comprehensive program to improve the provision of treatment and related services to individuals with respect to substance

use disorders and mental illness and to improve prevention services, promote mental health and protect the legal rights of individuals with mental illnesses and individuals with substance use disorders;

(3) carry out the administrative and financial management, policy development and planning, evaluation, knowledge dissemination, and public information functions that are required for the implementation of this subchapter;

(4) assure that the Administration conduct and coordinate demonstration projects, evaluations, and service system assessments and other activities necessary to improve the availability and quality of treatment, prevention and related services;

(5) support activities that will improve the provision of treatment, prevention and related services, including the development of national mental health and substance use disorder goals and model programs;

(6) in cooperation with the National Institutes of Health, the Centers for Disease Control and Prevention, and the Health Resources and Services Administration, develop educational materials and intervention strategies to reduce the risks of HIV, hepatitis, tuberculosis, and other communicable diseases among individuals with mental or substance use disorders, and to develop appropriate mental health services for individuals with such diseases or disorders;

(7) coordinate Federal policy with respect to the provision of treatment services for substance use disorders, including services that utilize drugs or devices approved or cleared by the Food and Drug Administration for the treatment of substance use disorders;

(8) conduct programs, and assure the coordination of such programs with activities of the National Institutes of Health and the Agency for Healthcare Research and Quality, as appropriate, to evaluate the process, outcomes and community impact of prevention and treatment services and systems of care in order to identify the manner in which such services can most effectively be provided;

(9) collaborate with the Director of the National Institutes of Health in the development and maintenance of a system by which the relevant research findings of the National Institute on Drug Abuse, the National Institute on Alcohol Abuse and Alcoholism, the National Institute of Mental Health, and, as appropriate, the Agency for Healthcare Research and Quality are disseminated to service providers in a manner designed to improve the delivery and effectiveness of prevention, treatment, and recovery support services and are appropriately incorporated into programs carried out by the Administration;

(10) encourage public and private entities that provide health insurance to provide benefits for substance use disorder and mental health services;

(11) work with relevant agencies of the Department of Health and Human Services on integrating mental health promotion and substance use disorder prevention with general health promotion and disease prevention and integrating mental and substance use disorders treatment services with physical health treatment services;

(12) monitor compliance by hospitals and other facilities with the requirements of sections 290dd–1 and 290dd–2 of this title;

(13) with respect to grant programs authorized under this subchapter or part B of subchapter XVII, or grant programs otherwise funded by the Administration—

(A) require that all grants that are awarded for the provision of services are subject to performance and outcome evaluations;

(B) ensure that the director of each Center of the Administration consistently documents the application of criteria when awarding grants and the ongoing oversight of grantees after such grants are awarded;

(C) require that all grants that are awarded to entities other than States are awarded only after the State in which the entity intends to provide services—

(i) is notified of the pendency of the grant application; and

(ii) is afforded an opportunity to comment on the merits of the application; and

(D) inform a State when any funds are awarded through such a grant to any entity within such

State;

(14) assure that services provided with amounts appropriated under this subchapter are provided bilingually, if appropriate;

(15) improve coordination among prevention programs, treatment facilities and nonhealth care systems such as employers, labor unions, and schools, and encourage the adoption of employee assistance programs and student assistance programs;

(16) maintain a clearinghouse for substance use disorder information, including evidence-based and promising best practices for prevention, treatment, and recovery support services for individuals with mental and substance use disorders, to assure the widespread dissemination of such information to States, political subdivisions, educational agencies and institutions, treatment providers, and the general public;

(17) in collaboration with the National Institute on Aging, and in consultation with the National Institute on Drug Abuse, the National Institute on Alcohol Abuse and Alcoholism and the National Institute of Mental Health, as appropriate, promote and evaluate substance use disorder services for older Americans in need of such services, and mental health services for older Americans who are seriously mentally ill;

(18) promote the coordination of service programs conducted by other departments, agencies, organizations and individuals that are or may be related to the problems of individuals suffering from mental illness or substance abuse, including liaisons with the Social Security Administration, Centers for Medicare & Medicaid Services, and other programs of the Department, as well as liaisons with the Department of Education, Department of Justice, and other Federal Departments and offices, as appropriate;

(19) consult with State, local, and tribal governments, nongovernmental entities, and individuals with mental illness, particularly adults with a serious mental illness, children with a serious emotional disturbance, and the family members of such adults and children, with respect to improving community-based and other mental health services;

(20) collaborate with the Secretary of Defense and the Secretary of Veterans Affairs to improve the provision of mental and substance use disorder services provided by the Department of Defense and the Department of Veterans Affairs to members of the Armed Forces, veterans, and the family members of such members and veterans, including through the provision of services using the telehealth capabilities of the Department of Defense and the Department of Veterans Affairs;

(21) collaborate with the heads of relevant Federal agencies and departments, States, communities, and nongovernmental experts to improve mental and substance use disorders services for chronically homeless individuals, including by designing strategies to provide such services in supportive housing;

(22) work with States and other stakeholders to develop and support activities to recruit and retain a workforce addressing mental and substance use disorders;

(23) collaborate with the Attorney General and representatives of the criminal justice system to improve mental and substance use disorders services for individuals who have been arrested or incarcerated;

(24) support the continued access to, or availability of, mental health and substance use disorder services during, or in response to, a public health emergency declared under section 247d of this title, including in consultation with, as appropriate, the Assistant Secretary for Preparedness and Response, the Director of the Centers for Disease Control and Prevention, and the heads of other relevant agencies, in preparing for, and responding to, a public health emergency;

(25) after providing an opportunity for public input, set standards for grant programs under this subchapter for mental and substance use disorders services and prevention programs, which standards may address—

(A) the capacity of the grantee to implement the award;

(B) requirements for the description of the program implementation approach;

(C) the extent to which the grant plan submitted by the grantee as part of its application must

explain how the grantee will reach the population of focus and provide a statement of need, which may include information on how the grantee will increase access to services and a description of measurable objectives for improving outcomes;

(D) the extent to which the grantee must collect and report on required performance measures; and

(E) the extent to which the grantee is proposing to use evidence-based practices;

(26) [1] advance, through existing programs, the use of performance metrics, including those based on the recommendations on performance metrics from the Assistant Secretary for Planning and Evaluation under section 6021(d) of the Helping Families in Mental Health Crisis Reform Act of 2016; and

(26) [1] collaborate with national accrediting entities, recovery housing providers, organizations or individuals with established expertise in delivery of recovery housing services, States, Federal agencies (including the Department of Health and Human Services, the Department of Housing and Urban Development, and the agencies listed in section 290ee–5(e)(2)(B) of this title), and other relevant stakeholders, to promote the availability of high-quality recovery housing and services for individuals with a substance use disorder.

(e) Associate Administrator for Alcohol Prevention and Treatment Policy

(1) In general

There may be in the Administration an Associate Administrator for Alcohol Prevention and Treatment Policy to whom the Assistant Secretary may delegate the functions of promoting, monitoring, and evaluating service programs for the prevention and treatment of alcoholism and alcohol abuse within the Center for Substance Abuse Prevention, the Center for Substance Abuse Treatment and the Center for Mental Health Services, and coordinating such programs among the Centers, and among the Centers and other public and private entities. The Associate Administrator also may ensure that alcohol prevention, education, and policy strategies are integrated into all programs of the Centers that address substance abuse prevention, education, and policy, and that the Center for Substance Abuse Prevention addresses the Healthy People 2010 goals and the National Dietary Guidelines of the Department of Health and Human Services and the Department of Agriculture related to alcohol consumption.

(2) Plan

(A) The Assistant Secretary, acting through the Associate Administrator for Alcohol Prevention and Treatment Policy, shall develop, and periodically review and as appropriate revise, a plan for programs and policies to treat and prevent alcoholism and alcohol abuse. The plan shall be developed (and reviewed and revised) in collaboration with the Directors of the Centers of the Administration and in consultation with members of other Federal agencies and public and private entities.

(B) Not later than 1 year after July 10, 1992, the Assistant Secretary shall submit to the Congress the first plan developed under subparagraph (A).

(3) Report

(A) Not less than once during each 2 years, the Assistant Secretary, acting through the Associate Administrator for Alcohol Prevention and Treatment Policy, shall prepare a report describing the alcoholism and alcohol abuse prevention and treatment programs undertaken by the Administration and its agencies, and the report shall include a detailed statement of the expenditures made for the activities reported on and the personnel used in connection with such activities.

(B) Each report under subparagraph (A) shall include a description of any revisions in the plan under paragraph (2) made during the preceding 2 years.

(C) Each report under subparagraph (A) shall be submitted to the Assistant Secretary for inclusion in the biennial report under subsection (m).

(f) Associate Administrator for Women's Services

(1) Appointment

The Assistant Secretary, with the approval of the Secretary, shall appoint an Associate Administrator for Women's Services who shall report directly to the Assistant Secretary.

(2) Duties

The Associate Administrator appointed under paragraph (1) shall—

(A) establish a committee to be known as the Coordinating Committee for Women's Services (hereafter in this subparagraph referred to as the "Coordinating Committee"), which shall be composed of the Directors of the agencies of the Administration (or the designees of the Directors);

(B) acting through the Coordinating Committee, with respect to women's substance abuse and mental health services—

(i) identify the need for such services, and make an estimate each fiscal year of the funds needed to adequately support the services;

(ii) identify needs regarding the coordination of services;

(iii) encourage the agencies of the Administration to support such services; and

(iv) assure that the unique needs of minority women, including Native American, Hispanic, African-American and Asian women, are recognized and addressed within the activities of the Administration; and

(C) establish an advisory committee to be known as the Advisory Committee for Women's Services, which shall be composed of not more than 10 individuals, a majority of whom shall be women, who are not officers or employees of the Federal Government, to be appointed by the Assistant Secretary from among physicians, practitioners, treatment providers, and other health professionals, whose clinical practice, specialization, or professional expertise includes a significant focus on women's substance abuse and mental health conditions, that shall—

(i) advise the Associate Administrator on appropriate activities to be undertaken by the agencies of the Administration with respect to women's substance abuse and mental health services, including services which require a multidisciplinary approach;

(ii) collect and review data, including information provided by the Secretary (including the material referred to in paragraph (3)), and report biannually to the Assistant Secretary regarding the extent to which women are represented among senior personnel, and make recommendations regarding improvement in the participation of women in the workforce of the Administration; and

(iii) prepare, for inclusion in the biennial report required pursuant to subsection (m), a description of activities of the Committee, including findings made by the Committee regarding—

(I) the extent of expenditures made for women's substance abuse and mental health services by the agencies of the Administration; and

(II) the estimated level of funding needed for substance abuse and mental health services to meet the needs of women;

(D) improve the collection of data on women's health by—

(i) reviewing the current data at the Administration to determine its uniformity and applicability;

(ii) developing standards for all programs funded by the Administration so that data are, to the extent practicable, collected and reported using common reporting formats, linkages and definitions; and

(iii) reporting to the Assistant Secretary a plan for incorporating the standards developed under clause (ii) in all Administration programs and a plan to assure that the data so collected are accessible to health professionals, providers, researchers, and members of the public; and

(E) shall establish, maintain, and operate a program to provide information on women's substance abuse and mental health services.

(3) Study

(A) The Secretary, acting through the Assistant Secretary for Personnel, shall conduct a study to evaluate the extent to which women are represented among senior personnel at the Administration.

(B) Not later than 90 days after July 10, 1992, the Assistant Secretary for Personnel shall provide the Advisory Committee for Women's Services with a study plan, including the methodology of the study and any sampling frames. Not later than 180 days after July 10, 1992, the Assistant Secretary shall prepare and submit directly to the Advisory Committee a report concerning the results of the study conducted under subparagraph (A).

(C) The Secretary shall prepare and provide to the Advisory Committee for Women's Services any additional data as requested.

(4) Office

Nothing in this subsection shall be construed to preclude the Secretary from establishing within the Substance Abuse and Mental Health Administration an Office of Women's Health.

(5) Definition

For purposes of this subsection, the term "women's substance abuse and mental health conditions", with respect to women of all age, ethnic, and racial groups, means all aspects of substance abuse and mental illness—

(A) unique to or more prevalent among women; or

(B) with respect to which there have been insufficient services involving women or insufficient data.

(g) Chief Medical Officer

(1) In general

The Assistant Secretary, with the approval of the Secretary, shall appoint a Chief Medical Officer to serve within the Administration.

(2) Eligible candidates

The Assistant Secretary shall select the Chief Medical Officer from among individuals who—

(A) have a doctoral degree in medicine or osteopathic medicine;

(B) have experience in the provision of mental or substance use disorder services;

(C) have experience working with mental or substance use disorder programs;

(D) have an understanding of biological, psychosocial, and pharmaceutical treatments of mental or substance use disorders; and

(E) are licensed to practice medicine in one or more States.

(3) Duties

The Chief Medical Officer shall—

(A) serve as a liaison between the Administration and providers of mental and substance use disorders prevention, treatment, and recovery services;

(B) assist the Assistant Secretary in the evaluation, organization, integration, and coordination of programs operated by the Administration;

(C) promote evidence-based and promising best practices, including culturally and linguistically appropriate practices, as appropriate, for the prevention and treatment of, and recovery from, mental and substance use disorders, including serious mental illness and serious emotional disturbances;

(D) participate in regular strategic planning with the Administration;

(E) coordinate with the Assistant Secretary for Planning and Evaluation to assess the use of performance metrics to evaluate activities within the Administration related to mental and substance use disorders; and

(F) coordinate with the Assistant Secretary to ensure mental and substance use disorders

grant programs within the Administration consistently utilize appropriate performance metrics and evaluation designs.

(h) Services of experts

(1) In general

The Assistant Secretary may obtain (in accordance with section 3109 of title 5, but without regard to the limitation in such section on the number of days or the period of service) the services of not more than 20 experts or consultants who have professional qualifications. Such experts and consultants shall be obtained for the Administration and for each of its agencies.

(2) Compensation and expenses

(A) Experts and consultants whose services are obtained under paragraph (1) shall be paid or reimbursed for their expenses associated with traveling to and from their assignment location in accordance with sections 5724, 5724a(a), 5724a(c), and 5726(c) of title 5.

(B) Expenses specified in subparagraph (A) may not be allowed in connection with the assignment of an expert or consultant whose services are obtained under paragraph (1), unless and until the expert or consultant agrees in writing to complete the entire period of assignment or one year, whichever is shorter, unless separated or reassigned for reasons beyond the control of the expert or consultant that are acceptable to the Secretary. If the expert or consultant violates the agreement, the money spent by the United States for the expenses specified in subparagraph (A) is recoverable from the expert or consultant as a debt of the United States. The Secretary may waive in whole or in part a right of recovery under this subparagraph.

(i) Peer review groups

The Assistant Secretary shall, without regard to the provisions of title 5 governing appointments in the competitive service, and without regard to the provisions of chapter 51 and subchapter III of chapter 53 of such title, relating to classification and General Schedule pay rates, establish such peer review groups and program advisory committees as are needed to carry out the requirements of this subchapter and appoint and pay members of such groups, except that officers and employees of the United States shall not receive additional compensation for services as members of such groups. Chapter 10 of title 5 shall not apply to the duration of a peer review group appointed under this subsection.

(j) Voluntary services

The Assistant Secretary may accept voluntary and uncompensated services.

(k) Administration

The Assistant Secretary shall ensure that programs and activities assigned under this subchapter to the Administration are fully administered by the respective Centers to which such programs and activities are assigned.

(l) Strategic plan

(1) In general

Not later than September 30, 2018, and every 4 years thereafter, the Assistant Secretary shall develop and carry out a strategic plan in accordance with this subsection for the planning and operation of activities carried out by the Administration, including evidence-based programs.

(2) Coordination

In developing and carrying out the strategic plan under this subsection, the Assistant Secretary shall take into consideration the findings and recommendations of the Assistant Secretary for Planning and Evaluation under section 6021(d) of the Helping Families in Mental Health Crisis Reform Act of 2016 and the report of the Interdepartmental Serious Mental Illness Coordinating Committee under section 290aa–0b of this title.

(3) Publication of plan

Not later than September 30, 2018, and every 4 years thereafter, the Assistant Secretary shall—

(A) submit the strategic plan developed under paragraph (1) to the Committee on Energy and Commerce and the Committee on Appropriations of the House of Representatives and the Committee on Health, Education, Labor, and Pensions and the Committee on Appropriations of the Senate; and

(B) post such plan on the Internet website of the Administration.

(4) Contents

The strategic plan developed under paragraph (1) shall—

(A) identify strategic priorities, goals, and measurable objectives for mental and substance use disorders activities and programs operated and supported by the Administration, including priorities to prevent or eliminate the burden of mental and substance use disorders;

(B) identify ways to improve the quality of services for individuals with mental and substance use disorders, and to reduce homelessness, arrest, incarceration, violence, including self-directed violence, and unnecessary hospitalization of individuals with a mental or substance use disorder, including adults with a serious mental illness or children with a serious emotional disturbance;

(C) ensure that programs provide, as appropriate, access to effective and evidence-based prevention, diagnosis, intervention, treatment, and recovery services, including culturally and linguistically appropriate services, as appropriate, for individuals with a mental or substance use disorder;

(D) identify opportunities to collaborate with the Health Resources and Services Administration to develop or improve—

(i) initiatives to encourage individuals to pursue careers (especially in rural and underserved areas and with rural and underserved populations) as psychiatrists, including child and adolescent psychiatrists, psychologists, psychiatric nurse practitioners, physician assistants, clinical social workers, certified peer support specialists, licensed professional counselors, or other licensed or certified mental health or substance use disorder professionals, including such professionals specializing in the diagnosis, evaluation, or treatment of adults with a serious mental illness or children with a serious emotional disturbance; and

(ii) a strategy to improve the recruitment, training, and retention of a workforce for the treatment of individuals with mental or substance use disorders, or co-occurring disorders;

(E) identify opportunities to improve collaboration with States, local governments, communities, and Indian tribes and tribal organizations (as such terms are defined in section 5304 of title 25);

(F) specify a strategy to disseminate evidence-based and promising best practices related to prevention, diagnosis, early intervention, treatment, and recovery services related to mental illness, particularly for adults with a serious mental illness and children with a serious emotional disturbance, and for individuals with a substance use disorder; and

(G) specify a strategy to support the continued access to, or availability of, mental health and substance use disorder services, including to at-risk individuals (as defined in section 300hh–1(b)(4) of this title), during, or in response to, public health emergencies declared pursuant to section 247d of this title.

(m) Biennial report concerning activities and progress

Not later than September 30, 2020, and every 2 years thereafter, the Assistant Secretary shall prepare and submit to the Committee on Energy and Commerce and the Committee on Appropriations of the House of Representatives and the Committee on Health, Education, Labor, and Pensions and the Committee on Appropriations of the Senate, and post on the Internet website of the Administration, a report containing at a minimum—

(1) a review of activities conducted or supported by the Administration, including progress toward strategic priorities, goals, and objectives identified in the strategic plan developed under subsection (l);

(2) an assessment of programs and activities carried out by the Assistant Secretary, including the extent to which programs and activities under this subchapter and part B of subchapter XVII meet identified goals and performance measures developed for the respective programs and activities;

(3) a description of the progress made in addressing gaps in mental and substance use disorders prevention, treatment, and recovery services and improving outcomes by the Administration, including with respect to serious mental illnesses, serious emotional disturbances, and co-occurring disorders;

(4) a description of the Administration's activities to support the continued provision of mental health and substance use disorder services, as applicable, in response to public health emergencies declared pursuant to section 247d of this title;

(5) a description of the manner in which the Administration coordinates and partners with other Federal agencies and departments related to mental and substance use disorders, including activities related to—

(A) the implementation and dissemination of research findings into improved programs, including with respect to how advances in serious mental illness and serious emotional disturbance research have been incorporated into programs;

(B) the recruitment, training, and retention of a mental and substance use disorders workforce;

(C) the integration of mental disorder services, substance use disorder services, and physical health services;

(D) relevant preparedness and response activities;

(E) homelessness; and

(F) veterans;

(6) a description of the manner in which the Administration promotes coordination by grantees under this subchapter, and part B of subchapter XVII, with State or local agencies; and

(7) a description of the activities carried out under section 290aa–0(e) of this title, with respect to mental and substance use disorders, including—

(A) the number and a description of grants awarded;

(B) the total amount of funding for grants awarded;

(C) a description of the activities supported through such grants, including outcomes of programs supported; and

(D) information on how the National Mental Health and Substance Use Policy Laboratory is consulting with the Assistant Secretary for Planning and Evaluation and collaborating with the Center for Substance Abuse Treatment, the Center for Substance Abuse Prevention, the Center for Behavioral Health Statistics and Quality, and the Center for Mental Health Services to carry out such activities; and

(8) recommendations made by the Assistant Secretary for Planning and Evaluation under section 6021 of the Helping Families in Mental Health Crisis Reform Act of 2016 to improve programs within the Administration, and actions taken in response to such recommendations to improve programs within the Administration.

The Assistant Secretary may meet reporting requirements established under this subchapter by providing the contents of such reports as an addendum to the biennial report established under this subsection, notwithstanding the timeline of other reporting requirements in this subchapter. Nothing in this subsection shall be construed to alter the content requirements of such reports or authorize the Assistant Secretary to alter the timeline of any such reports to be less frequent than biennially, unless as specified in this subchapter.

(n) Applications for grants and contracts

With respect to awards of grants, cooperative agreements, and contracts under this subchapter, the Assistant Secretary, or the Director of the Center involved, as the case may be, may not make such

an award unless—

(1) an application for the award is submitted to the official involved;

(2) with respect to carrying out the purpose for which the award is to be provided, the application provides assurances of compliance satisfactory to such official; and

(3) the application is otherwise in such form, is made in such manner, and contains such agreements, assurances, and information as the official determines to be necessary to carry out the purpose for which the award is to be provided.

(o) Emergency response

(1) In general

Notwithstanding section 290aa–3 of this title and except as provided in paragraph (2), the Secretary may use not to exceed 2.5 percent of all amounts appropriated under this subchapter for a fiscal year to make noncompetitive grants, contracts or cooperative agreements to public entities to enable such entities to address emergency substance abuse or mental health needs in local communities.

(2) Exceptions

Amounts appropriated under part C shall not be subject to paragraph (1).

(3) Emergencies

The Secretary shall establish criteria for determining that a substance abuse or mental health emergency exists and publish such criteria in the Federal Register prior to providing funds under this subsection.

(4) Emergency response

Amounts made available for carrying out this subsection shall remain available through the end of the fiscal year following the fiscal year for which such amounts are appropriated.

(p) Limitation on the use of certain information

No information, if an establishment or person supplying the information or described in it is identifiable, obtained in the course of activities undertaken or supported under section 290aa–4 of this title may be used for any purpose other than the purpose for which it was supplied unless such establishment or person has consented (as determined under regulations of the Secretary) to its use for such other purpose. Such information may not be published or released in other form if the person who supplied the information or who is described in it is identifiable unless such person has consented (as determined under regulations of the Secretary) to its publication or release in other form.

(q) Authorization of appropriations

For the purpose of providing grants, cooperative agreements, and contracts under this section, there are authorized to be appropriated $25,000,000 for fiscal year 2001, and such sums as may be necessary for each of the fiscal years 2002 and 2003.

(July 1, 1944, ch. 373, title V, §501, formerly Pub. L. 93–282, title II, §201, May 14, 1974, 88 Stat. 134, as amended Pub. L. 94–371, §8, July 26, 1976, 90 Stat. 1040; renumbered §501 of act July 1, 1944, and amended Pub. L. 98–24, §2(b)(2), Apr. 26, 1983, 97 Stat. 176; Pub. L. 98–509, title II, §201, title III, §301(c)(1), Oct. 19, 1984, 98 Stat. 2359, 2364; Pub. L. 99–570, title IV, §4003, Oct. 27, 1986, 100 Stat. 3207–106; Pub. L. 100–690, title II, §2058(a)(2), Nov. 18, 1988, 102 Stat. 4213; Pub. L. 101–93, §3(f), Aug. 16, 1989, 103 Stat. 611; Pub. L. 102–321, title I, §101(a), July 10, 1992, 106 Stat. 324; Pub. L. 104–201, div. A, title XVII, §1723(a)(3)(A), Sept. 23, 1996, 110 Stat. 2759; Pub. L. 106–129, §2(b)(2), Dec. 6, 1999, 113 Stat. 1670; Pub. L. 106–310, div. B, title XXXI, §3102, title XXXIV, §3401(a), Oct. 17, 2000, 114 Stat. 1170, 1218; Pub. L. 108–173, title IX, §900(e)(2)(A), Dec. 8, 2003, 117 Stat. 2372; Pub. L. 111–148, title III, §3509(d), Mar. 23, 2010, 124 Stat. 534; Pub. L. 114–255, div. B, title VI, §§6001(a), (c)(2), 6002, 6003, 6005, 6006(a), Dec. 13,

2016, 130 Stat. 1202–1206, 1209, 1210; Pub. L. 117–286, §4(a)(236), Dec. 27, 2022, 136 Stat. 4331; Pub. L. 117–328, div. FF, title I, §§1121(c)(2)(A), 1231, title II, §2112(a)–(c), Dec. 29, 2022, 136 Stat. 5650, 5673, 5721.)

EDITORIAL NOTES

REFERENCES IN TEXT

Section 6021 of the Helping Families in Mental Health Crisis Reform Act of 2016, referred to in subsecs. (d)(26), (l)(2), and (m)(8), is section 6021 of Pub. L. 114–255, which is set out as a note below.

CODIFICATION

Section was formerly classified to section 3511 of this title prior to renumbering by Pub. L. 98–24.

PRIOR PROVISIONS

A prior section 501 of act July 1, 1944, which was classified to section 219 of this title, was successively renumbered by subsequent acts and transferred, see section 238 of this title.

AMENDMENTS

2022—Subsec. (d)(24), (25). Pub. L. 117–328, §2112(a), added par. (24) and redesignated former par. (24) as (25). Former par. (25) redesignated (26).

Subsec. (d)(26). Pub. L. 117–328, §2112(a)(1), redesignated par. (25) as (26) relating to performance metrics.

Pub. L. 117–328, §1231, added par. (26) relating to recovery housing and services.

Subsec. (i). Pub. L. 117–286, which directed amendment of subsec. (h) by substituting "Chapter 10 of title 5" for "The Federal Advisory Committee Act", was executed by making the substitution in subsec. (i) to reflect the probable intent of Congress and the redesignation of subsec. (h) as (i) by Pub. L. 114–255, §6003(1). See 2016 Amendment note below.

Subsec. (l)(2). Pub. L. 117–328, §1121(c)(2)(A), substituted "section 290aa–0b of this title" for "section 6031 of such Act".

Subsec. (l)(4)(G). Pub. L. 117–328, §2112(b), added subpar. (G).

Subsec. (m)(4). Pub. L. 117–328, §2112(c)(2), added par. (4). Former par. (4) redesignated (5).

Subsec. (m)(5). Pub. L. 117–328, §2112(c)(1), redesignated par. (4) as (5). Former par. (5) redesignated (6).

Subsec. (m)(5)(D) to (F). Pub. L. 117–328, §2112(c)(3), added subpar. (D) and redesignated former subpars. (D) and (E) as (E) and (F), respectively.

Subsec. (m)(6) to (8). Pub. L. 117–328, §2112(c)(1), redesignated pars. (5) to (7) as (6) to (8), respectively.

2016—Subsec. (b). Pub. L. 114–255, §6002(1), substituted "Centers" for "Agencies" in heading and "Centers" for "entities" in introductory provisions.

Subsec. (c). Pub. L. 114–255, §6001(a), amended subsec. (c) generally, substituting references to the Assistant Secretary and Deputy Assistant Secretary for references to the Administrator and Deputy Administrator.

Subsec. (d). Pub. L. 114–255, §6001(c)(2), substituted "Assistant Secretary" for "Administrator" in introductory provisions.

Subsec. (d)(1). Pub. L. 114–255, §6002(2)(A), substituted "Centers" for "agencies" in two places and "such Center" for "such agency".

Subsec. (d)(2). Pub. L. 114–255, §6002(2)(B), substituted "Centers" for "agencies", "with respect to substance use disorders" for "with respect to substance abuse", and "and individuals with substance use disorders" for "and individuals who are substance abusers".

Subsec. (d)(5). Pub. L. 114–255, §6002(2)(C), substituted "substance use disorder" for "substance abuse".

Subsec. (d)(6). Pub. L. 114–255, §6002(2)(D), substituted "the Centers for Disease Control and Prevention," for "the Centers for Disease Control", "Administration, develop" for "Administration develop", "HIV, hepatitis, tuberculosis, and other communicable diseases among individuals with mental or substance use disorders," for "HIV or tuberculosis among substance abusers and individuals with mental illness", and "diseases or disorders" for "illnesses".

Subsec. (d)(7). Pub. L. 114–255, §6002(2)(E), substituted "use disorders, including services that utilize drugs or devices approved or cleared by the Food and Drug Administration for the treatment of substance use disorders" for "abuse utilizing anti-addiction medications, including methadone".

Subsec. (d)(8). Pub. L. 114–255, §6002(2)(F), substituted "Agency for Healthcare Research and Quality" for "Agency for Health Care Policy Research" and "prevention and treatment" for "treatment and prevention".

Subsec. (d)(9). Pub. L. 114–255, §6002(2)(G), inserted "and maintenance" after "development" and substituted "Agency for Healthcare Research and Quality" for "Agency for Health Care Policy Research" and "prevention, treatment, and recovery support services and are appropriately incorporated into programs carried out by the Administration" for "treatment and prevention services".

Subsec. (d)(10). Pub. L. 114–255, §6002(2)(H), substituted "use disorder" for "abuse".

Subsec. (d)(11). Pub. L. 114–255, §6002(2)(I), added par. (11) and struck out former par. (11) which read as follows: "promote the integration of substance abuse and mental health services into the mainstream of the health care delivery system of the United States;".

Subsec. (d)(13). Pub. L. 114–255, §6002(2)(J)(i), substituted "this subchapter or part B of subchapter XVII, or grant programs otherwise funded by the Administration" for "this subchapter, assure that" in introductory provisions.

Subsec. (d)(13)(A) to (D). Pub. L. 114–255, §6002(2)(J)(ii)–(vi), added subpar. (B), redesignated former subpar. (B) as (C), inserted "require that" before "all grants" in subpars. (A) and (C), and added subpar. (D).

Subsec. (d)(16). Pub. L. 114–255, §6002(2)(K), substituted "use disorder information, including evidence-based and promising best practices for prevention, treatment, and recovery support services for individuals with mental and substance use disorders," for "abuse and mental health information".

Subsec. (d)(17), (19) to (25). Pub. L. 114–255, §6002(2)(L)–(N), substituted "substance use disorder" for "substance abuse" in par. (17) and added pars. (19) to (25).

Subsec. (e)(1). Pub. L. 114–255, §6001(c)(2), substituted "Assistant Secretary may delegate" for "Administrator may delegate".

Subsec. (e)(2). Pub. L. 114–255, §6001(c)(2), substituted "Assistant Secretary, acting through" for "Administrator, acting through" in subpar. (A) and "Assistant Secretary" for "Administrator" in subpar. (B).

Subsec. (e)(3)(A). Pub. L. 114–255, §6001(c)(2), substituted "Assistant Secretary, acting through" for "Administrator, acting through".

Subsec. (e)(3)(C). Pub. L. 114–255, §6003(2), substituted "subsection (m)" for "subsection (k)".

Pub. L. 114–255, §6001(c)(2), substituted "Assistant Secretary" for "Administrator".

Subsec. (f)(1). Pub. L. 114–255, §6001(c)(2), substituted "The Assistant Secretary," for "The Administrator," and "the Assistant Secretary" for "the Administrator".

Subsec. (f)(2)(C). Pub. L. 114–255, §6001(c)(2), substituted "Assistant Secretary" for "Administrator" in introductory provisions.

Subsec. (f)(2)(C)(ii). Pub. L. 114–255, §6001(c)(2), substituted "Assistant Secretary" for "Administrator".

Subsec. (f)(2)(C)(iii). Pub. L. 114–255, §6003(3), substituted "subsection (m)" for "subsection (k)" in introductory provisions.

Subsec. (f)(2)(D)(iii). Pub. L. 114–255, §6001(c)(2), substituted "Assistant Secretary" for "Administrator".

Subsec. (g). Pub. L. 114–255, §6003(4), added subsec. (g). Former subsec. (g) redesignated (h).

Subsec. (g)(1). Pub. L. 114–255, §6001(c)(2), substituted "Assistant Secretary" for "Administrator".

Subsec. (h). Pub. L. 114–255, §6003(1), redesignated subsec. (g) as (h). Former subsec. (h) redesignated (i).

Pub. L. 114–255, §6001(c)(2), substituted "Assistant Secretary" for "Administrator".

Subsec. (i). Pub. L. 114–255, §6003(1), redesignated subsec. (h) as (i). Former subsec. (i) redesignated (j).

Pub. L. 114–255, §6001(c)(2), substituted "Assistant Secretary" for "Administrator".

Subsec. (j). Pub. L. 114–255, §6003(1), redesignated subsec. (i) as (j). Former subsec. (j) redesignated (k).

Pub. L. 114–255, §6001(c)(2), substituted "Assistant Secretary" for "Administrator".

Subsec. (k). Pub. L. 114–255, §6003(1), redesignated subsec. (j) as (k). Former subsec. (k) redesignated (m).

Pub. L. 114–255, §6001(c)(2), substituted "Assistant Secretary" for "Administrator" in introductory provisions.

Subsec. (l). Pub. L. 114–255, §6005, added subsec. (l). Former subsec. (l) redesignated (n).

Pub. L. 114–255, §6001(c)(2), substituted "Assistant Secretary" for "Administrator" in introductory provisions.

Subsec. (m). Pub. L. 114–255, §6006(a), amended subsec. (m) generally, substituting requirements for biennial reports beginning no later than September 30, 2020, for requirements for biennial reports beginning no later than February 10, 1994.

Pub. L. 114–255, §6003(1), redesignated subsec. (k) as (m). Former subsec. (m) redesignated (o).

Subsec. (m)(4). Pub. L. 114–255, §6002(3), added par. (4).

Subsecs. (n) to (q). Pub. L. 114–255, §6003(1), redesignated subsecs. (l) to (o) as (n) to (q), respectively.

2010—Subsec. (f)(1). Pub. L. 111–148, §3509(d)(1), inserted "who shall report directly to the Administrator" before period at end.

Subsec. (f)(4), (5). Pub. L. 111–148, §3509(d)(2), (3), added par. (4) and redesignated former par. (4) as (5).

2003—Subsec. (d)(18). Pub. L. 108–173 substituted "Centers for Medicare & Medicaid Services" for "Health Care Financing Administration".

2000—Subsec. (e)(1). Pub. L. 106–310, §3401(a), reenacted heading without change and amended text generally. Prior to amendment, text read as follows: "There shall be in the Administration an Associate Administrator for Alcohol Prevention and Treatment Policy to whom the Administrator shall delegate the functions of promoting, monitoring, and evaluating service programs for the prevention and treatment of alcoholism and alcohol abuse within the Center for Substance Abuse Prevention, the Center for Substance Abuse Treatment, and the Center for Mental Health Services, and coordinating such programs among the Centers, and among the Centers and other public and private entities. The Associate Administrator also shall ensure that alcohol prevention, education, and policy strategies are integrated into all programs of the Centers that address substance abuse prevention, education, and policy, and that the Center for Substance Abuse Prevention addresses the Healthy People 2000 goals and the National Dietary Guidelines of the Department of Health and Human Services and the Department of Agriculture related to alcohol consumption."

Subsecs. (m) to (o). Pub. L. 106–310, §3102, added subsecs. (m) and (n), redesignated former subsec. (m) as (o), and substituted "2001, and such sums as may be necessary for each of the fiscal years 2002 and 2003" for "1993, and such sums as may be necessary for fiscal year 1994" before period at end.

1999—Subsec. (d)(8), (9). Pub. L. 106–129, which directed the substitution of "Agency for Healthcare Research and Quality" for "Agency for Health Care Policy and Research", was not executed because the term "Agency for Health Care Policy and Research" did not appear in text and because of the amendment by Pub. L. 114–255, §6002(2)(G)(ii), which presumed that the substitution did not take place. See 2016 Amendment note above.

1996—Subsec. (g)(2)(A). Pub. L. 104–201 substituted "5724a(a), 5724a(c)" for "5724a(a)(1), 5724a(a)(3)".

1992—Pub. L. 102–321 amended section generally, substituting provisions relating to the Substance Abuse and Mental Health Services Administration for provisions relating to the Alcohol, Drug Abuse, and Mental Health Administration.

1989—Subsec. (b)(4). Pub. L. 101–93, §3(f)(1), substituted "for" for "of".

Subsec. (j). Pub. L. 101–93, §3(f)(2), substituted "section 290aa–5 of this title, establish program advisory committees, and pay members of such groups and committees" for "section 290aa–5 of this title and appoint and pay members of such groups" and "as members of such groups or committees" for "as members of such groups".

1988—Subsec. (b)(4). Pub. L. 100–690, §2058(a)(2)(A), added par. (4).

Subsec. (e)(2). Pub. L. 100–690, §2058(a)(2)(B), substituted "Not less than once each three years, the Administrator" for "The Administrator" and "shall submit" for "shall annually submit".

Subsec. (f). Pub. L. 100–690, §2058(a)(2)(C), substituted "misconduct" for "fraud" in heading and two places in text.

Subsecs. (k) to (m). Pub. L. 100–690, §2058(a)(2)(D), (E), added subsecs. (k) to (m) and struck out former subsec. (k), which related to Alcohol, Drug Abuse, and Mental Health Advisory Board, including its duties, membership, terms of office, compensation, personnel, chairman, meetings, and reports to Congress.

1986—Pub. L. 99–570 amended section generally, revising and restating former subsecs. (a), (b), (c), (d), (e), (f), (g), and (h) as (c), (d), (k), (h), (e), (f), (g), and (i), respectively, and adding new subsecs. (a), (b), and (j).

1984—Pub. L. 98–509, §301(c)(1), amended directory language of Pub. L. 98–24, §2(b)(2). See 1983 Amendment note below.

Subsec. (c). Pub. L. 98–509, §201(a), substituted provisions relating to the Alcohol, Drug Abuse, and Mental Health Advisory Board for provisions relating to the National Panel on Alcohol, Drug Abuse, and Mental Health.

Subsecs. (g), (h). Pub. L. 98–509, §201(b), added subsecs. (g) and (h).

1983—Pub. L. 98–24, §2(b)(2), as amended by Pub. L. 98–509, §301(c)(1), renumbered section 3511 of this title as this section.

Subsec. (a). Pub. L. 98–24, §2(b)(2)(A), struck out "of Health, Education, and Welfare" after "The Secretary" and "Department".

Subsec. (c). Pub. L. 98–24, §2(b)(2)(A), (B), struck out "of Health, Education, and Welfare" after "The Secretary", and made a technical amendment to reference to section 218 of this title to reflect the transfer of this section to the Public Health Service Act.

Subsec. (d). Pub. L. 98–24, §2(b)(2)(C), substituted provisions directing the Administrator to distribute information on the hazards of alcoholism and the abuse of alcohol and drugs for provisions directing the

Secretary, through the Administration, to evaluate and make recommendations regarding improved, coordinated activities, where appropriate, for public education and other prevention programs with respect to the abuse of alcohol and other substances.

Subsecs. (e), (f). Pub. L. 98–24, §2(b)(2)(D), added subsecs. (e) and (f).

1976—Subsec. (d). Pub. L. 94–371 added subsec. (d).

STATUTORY NOTES AND RELATED SUBSIDIARIES

CHANGE OF NAME; REFERENCES

Committee on Labor and Human Resources of Senate changed to Committee on Health, Education, Labor, and Pensions of Senate by Senate Resolution No. 20, One Hundred Sixth Congress, Jan. 19, 1999.

Committee on Energy and Commerce of House of Representatives treated as referring to Committee on Commerce of House of Representatives by section 1(a) of Pub. L. 104–14, set out as a note preceding section 21 of Title 2, The Congress. Committee on Commerce of House of Representatives changed to Committee on Energy and Commerce of House of Representatives, and jurisdiction over matters relating to securities and exchanges and insurance generally transferred to Committee on Financial Services of House of Representatives by House Resolution No. 5, One Hundred Seventh Congress, Jan. 3, 2001.

Pub. L. 114–255, div. B, title VI, §6001(d), Dec. 13, 2016, 130 Stat. 1203, provided that: "After executing subsections (a), (b), and (c) [see Tables for classification], any reference in statute, regulation, or guidance to the Administrator of the Substance Abuse and Mental Health Services Administration shall be construed to be a reference to the Assistant Secretary for Mental Health and Substance Use."

Centers for Disease Control changed to Centers for Disease Control and Prevention by Pub. L. 102–531, title III, §312, Oct. 27, 1992, 106 Stat. 3504.

Pub. L. 102–321, title I, §161, July 10, 1992, 106 Stat. 375, provided that: "Reference in any other Federal law, Executive order, rule, regulation, or delegation of authority, or any document of or pertaining to the Alcohol, Drug Abuse and Mental Health Administration or to the Administrator of the Alcohol, Drug Abuse and Mental Health Administration shall be deemed to refer to the Substance Abuse and Mental Health Services Administration or to the Administrator of the Substance Abuse and Mental Health Services Administration."

EFFECTIVE DATE OF 1996 AMENDMENT

Amendment by Pub. L. 104–201 effective 180 days after Sept. 23, 1996, see section 1725(a) of Pub. L. 104–201, set out as a note under section 5722 of Title 5, Government Organization and Employees.

EFFECTIVE DATE OF 1992 AMENDMENT

Amendment by Pub. L. 102–321 effective Oct. 1, 1992, with provision for programs providing financial assistance, see section 801(c), (d) of Pub. L. 102–321, set out as a note under section 236 of this title.

TRANSFER OF AUTHORITIES

Pub. L. 114–255, div. B, title VI, §6001(b), Dec. 13, 2016, 130 Stat. 1203, provided that: "The Secretary of Health and Human Services shall delegate to the Assistant Secretary for Mental Health and Substance Use all duties and authorities that—

"(1) as of the day before the date of enactment of this Act [Dec. 13, 2016], were vested in the Administrator of the Substance Abuse and Mental Health Services Administration; and

"(2) are not terminated by this Act [division B of Pub. L. 114–255, see Tables for classification]."

TRANSFER PROVISIONS

Pub. L. 102–321, title I, subtitle D, July 10, 1992, 106 Stat. 370, as amended by Pub. L. 102–352, §2(b)(1), Aug. 26, 1992, 106 Stat. 939, provided that:

"SEC. 141. TRANSFERS.

"(a) SUBSTANCE ABUSE AND MENTAL HEALTH SERVICES ADMINISTRATION.—Except as specifically provided otherwise in this Act [see Tables for classification] or an amendment made by this Act, there are transferred to the Administrator of the Substance Abuse and Mental Health Services Administration all service related functions which the Administrator of the Alcohol, Drug Abuse and Mental Health Administration, or the Director of any entity within the Alcohol, Drug Abuse and Mental Health Administration, exercised before the date of the enactment of this Act [July 10, 1992] and all related functions of any officer or employee of the Alcohol, Drug Abuse and Mental Health Administration.

"(b) NATIONAL INSTITUTES.—Except as specifically provided otherwise in this Act or an amendment

made by this Act, there are transferred to the appropriate Directors of the National Institute on Alcohol Abuse and Alcoholism, the National Institute on Drug Abuse and the National Institute of Mental Health, through the Director of the National Institutes of Health, all research related functions which the Administrator of the Alcohol, Drug Abuse and Mental Health Administration exercised before the date of the enactment of this Act and all related functions of any officer or employee of the Alcohol, Drug Abuse, and Mental Health Administration.

"(c) ADEQUATE PERSONNEL AND RESOURCES.—The transfers required under this subtitle shall be effectuated in a manner that ensures that the Substance Abuse and Mental Health Services Administration has adequate personnel and resources to carry out its statutory responsibilities and that the National Institute on Alcohol Abuse and Alcoholism, the National Institute on Drug Abuse and the National Institute of Mental Health have adequate personnel and resources to enable such institutes to carry out their respective statutory responsibilities.

"SEC. 142. TRANSFER AND ALLOCATIONS OF APPROPRIATIONS AND PERSONNEL.

"(a) SUBSTANCE ABUSE AND MENTAL HEALTH SERVICES ADMINISTRATION.—Except as otherwise provided in the Public Health Service Act [42 U.S.C. 201 et seq.], all personnel employed in connection with, and all assets, liabilities, contracts, property, records, and unexpended balances of appropriations, authorizations, allocations, and other funds employed, used, held, arising from, available to, or to be made available in connection with the functions transferred to the Administrator of the Substance Abuse and Mental Health Services Administration by this subtitle, subject to section 1531 of title 31, United States Code, shall be transferred to the Substance Abuse and Mental Health Services Administration. Unexpended funds transferred pursuant to this subsection shall be used only for the purposes for which the funds were originally authorized and appropriated.

"(b) NATIONAL INSTITUTES.—Except as otherwise provided in the Public Health Service Act, all personnel employed in connection with, and all assets, liabilities, contracts, property, records, and unexpended balances of appropriations, authorizations, allocations, and other funds employed, used, held, arising from, available to, or to be made available in connection with the functions transferred to the Directors of the National Institute on Alcohol Abuse and Alcoholism, the National Institute on Drug Abuse and the National Institute of Mental Health by this subtitle, subject to section 1531 of title 31, United States Code, shall be transferred to the National Institute on Alcohol Abuse and Alcoholism, the National Institute on Drug Abuse and the National Institute of Mental Health. Unexpended funds transferred pursuant to this subsection shall be used only for the purposes for which the funds were originally authorized and appropriated.

"(c) CUSTODY OF BALANCES.—The actual transfer of custody of obligation balances is not required in order to implement this section.

"SEC. 143. INCIDENTAL TRANSFERS.

"Prior to October 1, 1992, the Secretary of Health and Human Services is authorized to make such determinations as may be necessary with regard to the functions transferred by this subtitle, and to make such additional incidental dispositions of personnel, assets, liabilities, grants, contracts, property, records, and unexpended balances of appropriations, authorizations, allocations, and other funds held, used, arising from, available to, or to be made available in connection with such functions, as may be necessary to carry out the provisions of this subtitle and the Public Health Service Act [42 U.S.C. 201 et seq.]. Such Secretary shall provide for the termination of the affairs of all entities terminated by this subtitle and for such further measures and dispositions as may be necessary to effectuate the purposes of this subtitle.

"SEC. 144. EFFECT ON PERSONNEL.

"(a) IN GENERAL.—Except as otherwise provided by this subtitle and the Public Health Service Act [42 U.S.C. 201 et seq.], the transfer pursuant to this subtitle of full-time personnel (except special Government employees) and part-time personnel holding permanent positions shall not cause any such employee to be separated or reduced in grade or compensation for one year after the date of transfer of such employee under this subtitle.

"(b) EXECUTIVE SCHEDULE POSITIONS.—Any person who, on the day preceding the effective date of this Act [see Effective Date of 1992 Amendment note set out under section 236 of this title], held a position compensated in accordance with the Executive Schedule prescribed in chapter 53 of title 5, United States Code, and who, without a break in service, is appointed in the Substance Abuse and Mental Health Services Administration to a position having duties comparable to the duties performed immediately preceding such appointment shall continue to be compensated in such new position at not less than the rate provided for such previous position, for the duration of the service of such person in such new position.

"SEC. 145. SAVINGS PROVISIONS.

"(a) EFFECT ON PREVIOUS DETERMINATIONS.—All orders, determinations, rules, regulations, permits, contracts, certificates, licenses, and privileges that—

"(1) have been issued, made, granted, or allowed to become effective by the President, any Federal agency or official thereof, or by a court of competent jurisdiction, in the performance of functions which are transferred by this subtitle; and

"(2) are in effect on the date of enactment of this Act [July 10, 1992];

shall continue in effect according to their terms until modified, terminated, superseded, set aside, or revoked in accordance with law by the President, the Director of the National Institutes of Health, or the Administrator of the Substance Abuse and Mental Health Services Administration, as appropriate, a court of competent jurisdiction, or by operation of law.

"(b) CONTINUATION OF PROCEEDINGS.—

"(1) IN GENERAL.—The provisions of this subtitle shall not affect any proceedings, including notices of proposed rule making, or any application for any license, permit, certificate, or financial assistance pending on the date of enactment of this Act before the Department of Health and Human Services, which relates to the Alcohol, Drug Abuse and Mental Health Administration or the National Institute on Alcohol Abuse and Alcoholism, the National Institute on Drug Abuse, or the National Institute of Mental Health, or any office thereof with respect to functions transferred by this subtitle. Such proceedings or applications, to the extent that they relate to functions transferred, shall be continued. Orders shall be issued in such proceedings, appeals shall be taken therefrom, and payments shall be made under such orders, as if this Act [see Tables for classification] had not been enacted, and orders issued in any such proceedings shall continue in effect until modified, terminated, superseded, or revoked by the Administrator of the Substance Abuse and Mental Health Services Administration or the Directors of the National Institute on Alcohol Abuse and Alcoholism, the National Institute on Drug Abuse and the National Institute of Mental Health by a court of competent jurisdiction, or by operation of law. Nothing in this subsection prohibits the discontinuance or modification of any such proceeding under the same terms and conditions and to the same extent that such proceeding could have been discontinued or modified if this subtitle had not been enacted.

"(2) REGULATIONS.—The Secretary of Health and Human Services is authorized to issue regulations providing for the orderly transfer of proceedings continued under paragraph (1).

"(c) EFFECT ON LEGAL ACTIONS.—Except as provided in subsection (e)—

"(1) the provisions of this subtitle do not affect actions commenced prior to the date of enactment of this Act [July 10, 1992]; and

"(2) in all such actions, proceedings shall be had, appeals taken, and judgments rendered in the same manner and effect as if this Act had not been enacted.

"(d) NO ABATEMENT OF ACTIONS OR PROCEEDINGS.—No action or other proceeding commenced by or against any officer in his official capacity as an officer of the Department of Health and Human Services with respect to functions transferred by this subtitle shall abate by reason of the enactment of this Act [see Tables for classification]. No cause of action by or against the Department of Health and Human Services with respect to functions transferred by this subtitle, or by or against any officer thereof in his official capacity, shall abate by reason of the enactment of this Act. Causes of action and actions with respect to a function transferred by this subtitle, or other proceedings may be asserted by or against the United States or the Administrator of the Alcohol, Drug Abuse and Mental Health Administration or the Directors of the National Institute on Alcohol Abuse and Alcoholism, the National Institute on Drug Abuse, and the National Institute of Mental Health, as may be appropriate, and, in an action pending when this Act takes effect [see Effective Date of 1992 Amendment note set out under section 236 of this title], the court may at any time, on its own motion or that of any party, enter an order which will give effect to the provisions of this subsection.

"(e) SUBSTITUTION.—If, before the date of enactment of this Act [July 10, 1992], the Department of Health and Human Services, or any officer thereof in the official capacity of such officer, is a party to an action, and under this subtitle any function of such Department, Office, or officer is transferred to the Administrator of the Substance Abuse and Mental Health Services Administration or the Directors of the National Institute on Alcohol Abuse and Alcoholism, the National Institute on Drug Abuse and the National Institute of Mental Health, then such action shall be continued with the Administrator of the Substance Abuse and Mental Health Services Administration or the Directors of the National Institute on Alcohol Abuse and Alcoholism, the National Institute on Drug Abuse and the National Institute of Mental Health, as the case may be, substituted or added as a party.

"(f) JUDICIAL REVIEW.—Orders and actions of the Administrator of the Substance Abuse and Mental Health Services Administration or the Directors of the National Institute on Alcohol Abuse and Alcoholism, the National Institute on Drug Abuse and the National Institute of Mental Health in the exercise of functions

transferred to the Directors by this subtitle shall be subject to judicial review to the same extent and in the same manner as if such orders and actions had been by the Administrator of the Alcohol, Drug Abuse and Mental Health Administration or the Directors of the National Institute on Alcohol Abuse and Alcoholism, the National Institute on Drug Abuse, and the National Institute of Mental Health, or any office or officer thereof, in the exercise of such functions immediately preceding their transfer. Any statutory requirements relating to notice, hearings, action upon the record, or administrative review that apply to any function transferred by this subtitle shall apply to the exercise of such function by the Administrator of the Substance Abuse and Mental Health Services Administration or the Directors.

"SEC. 146. TRANSITION.

"With the consent of the Secretary of Health and Human Services, the Administrator of the Substance Abuse and Mental Health Services Administration and the Directors of the National Institute on Alcohol Abuse and Alcoholism, the National Institute on Drug Abuse and the National Institute of Mental Health are authorized to utilize—

"(1) the services of such officers, employees, and other personnel of the Department with respect to functions transferred to the Administrator of the Substance Abuse and Mental Health Services Administration and the Director of the National Institute on Alcohol Abuse and Alcoholism, the National Institute on Drug Abuse and the National Institute of Mental Health by this subtitle; and

"(2) funds appropriated to such functions for such period of time as may reasonably be needed to facilitate the orderly implementation of this subtitle.

"SEC. 147. PEER REVIEW.

"With respect to fiscal years 1993 through 1996, the peer review systems, advisory councils and scientific advisory committees utilized, or approved for utilization, by the National Institute on Alcohol Abuse and Alcoholism, the National Institute on Drug Abuse and the National Institute of Mental Health prior to the transfer of such Institutes to the National Institute of Health shall be utilized by such Institutes.

"SEC. 148. MERGERS.

"Notwithstanding the provisions of section 401(c)(2) of the Public Health Service Act (42 U.S.C. 281(c)(2)), the Secretary of Health and Human Services may not merge the National Institute on Alcohol Abuse and Alcoholism, the National Institute on Drug Abuse or the National Institute of Mental Health with any other institute or entity (or with each other) within the national research institutes for a 5-year period beginning on the date of enactment of this Act [July 10, 1992].

"SEC. 149. CONDUCT OF MULTI-YEAR RESEARCH PROJECTS.

"With respect to multi-year grants awarded prior to fiscal year 1993 by the National Institute on Alcohol Abuse and Alcoholism, the National Institute on Drug Abuse, and the National Institute of Mental Health with amounts received under section 1911(b) [former 42 U.S.C. 300x(b)], as such section existed one day prior to the date of enactment of this Act [July 10, 1992], such grants shall be continued for the entire period of the grant through the utilization of funds made available pursuant to sections 464H, 464L, and 464R [42 U.S.C. 285n, 285o, 285p], as appropriate, subject to satisfactory performance.

"SEC. 150. SEPARABILITY.

"If a provision of this subtitle or its application to any person or circumstance is held invalid, neither the remainder of this Act [see Tables for classification] nor the application of the provision to other persons or circumstances shall be affected.

"SEC. 151. BUDGETARY AUTHORITY.

"With respect to fiscal years 1994 and 1995, the Directors of the National Institute on Alcohol Abuse and Alcoholism, the National Institute on Drug Abuse, and the National Institute of Mental Health shall notwithstanding section 405(a) [42 U.S.C. 284(a)], prepare and submit, directly to the President for review and transmittal to Congress, an annual budget estimate (including an estimate of the number and type of personnel needs for the Institute) for their respective Institutes, after reasonable opportunity for comment (but without change) by the Secretary of Health and Human Services, the Director of the National Institutes of Health, and the Institute's advisory council."

WEBSITE IMPROVEMENTS

Pub. L. 119–44, title III, §307(c), Dec. 1, 2025, 139 Stat. 689, provided that: "The Secretary shall implement improvements to Grants.gov related to SAMHSA funding opportunities based on stakeholder feedback received at the public meeting under subsection (a) [not classified to the Code], as appropriate, to the maximum extent feasible."

FUNDING FOR COMMUNITY-BASED FUNDING FOR LOCAL BEHAVIORAL HEALTH NEEDS

Pub. L. 117–2, title II, §2707, Mar. 11, 2021, 135 Stat. 47, provided that:

"(a) IN GENERAL.—In addition to amounts otherwise available, there is appropriated to the Secretary [of Health and Human Services] for fiscal year 2021, out of any money in the Treasury not otherwise appropriated, $50,000,000, to remain available until expended, to carry out the purpose described in subsection (b).

"(b) USE OF FUNDS.—

"(1) IN GENERAL.—The Secretary, acting through the Assistant Secretary for Mental Health and Substance Use, shall award grants to State, local, Tribal, and territorial governments, Tribal organizations, nonprofit community-based entities, and primary care and behavioral health organizations to address increased community behavioral health needs worsened by the COVID–19 public health emergency.

"(2) USE OF GRANT FUNDS.—Grant funds awarded under this section to eligible entities shall be used for promoting care coordination among local entities; training the mental and behavioral health workforce, relevant stakeholders, and community members; expanding evidence-based integrated models of care; addressing surge capacity for mental and behavioral health needs; providing mental and behavioral health services to individuals with mental health needs (including co-occurring substance use disorders) as delivered by behavioral and mental health professionals utilizing telehealth services; and supporting, enhancing, or expanding mental and behavioral health preventive and crisis intervention services."

INTERDEPARTMENTAL SUBSTANCE USE DISORDERS COORDINATING COMMITTEE

Pub. L. 115–271, title VII, §7022, Oct. 24, 2018, 132 Stat. 4010, as amended by Pub. L. 119–44, title I, §110(b), Dec. 1, 2025, 139 Stat. 677, provided that:

"(a) ESTABLISHMENT.—Not later than 3 months after the date of the enactment of this Act [Oct. 24, 2018], the Secretary of Health and Human Services (in this section referred to as the 'Secretary') shall, in coordination with the Director of National Drug Control Policy, establish a committee, to be known as the Interdepartmental Substance Use Disorders Coordinating Committee (in this section referred to as the 'Committee'), to coordinate Federal activities related to substance use disorders.

"(b) MEMBERSHIP.—

"(1) FEDERAL MEMBERS.—The Committee shall be composed of the following Federal representatives, or the designees of such representatives:

"(A) The Secretary, who shall serve as the Chair of the Committee.

"(B) The Attorney General of the United States.

"(C) The Secretary of Labor.

"(D) The Secretary of Housing and Urban Development.

"(E) The Secretary of Education.

"(F) The Secretary of Veterans Affairs.

"(G) The Commissioner of Social Security.

"(H) The Assistant Secretary for Mental Health and Substance Use.

"(I) The Director of National Drug Control Policy.

"(J) Representatives of other Federal agencies that support or conduct activities or programs related to substance use disorders, as determined appropriate by the Secretary.

"(2) NON-FEDERAL MEMBERS.—The Committee shall include a minimum of 15 non-Federal members appointed by the Secretary, of which—

"(A) at least two such members shall be an individual who has received treatment for a diagnosis of a substance use disorder;

"(B) at least two such members shall be a director of a State substance abuse agency;

"(C) at least two such members shall be a representative of a leading research, advocacy, or service organization for adults with substance use disorder;

"(D) at least two such members shall—

"(i) be a physician, licensed mental health professional, advance practice registered nurse, or physician assistant; and

"(ii) have experience in treating individuals with substance use disorders;

"(E) at least one such member shall be a substance use disorder treatment professional who provides treatment services at a certified opioid treatment program;

"(F) at least one such member shall be a substance use disorder treatment professional who has research or clinical experience in working with racial and ethnic minority populations;

"(G) at least one such member shall be a substance use disorder treatment professional who has research or clinical mental health experience in working with medically underserved populations;

"(H) at least one such member shall be a State-certified substance use disorder peer support specialist;

"(I) at least one such member shall be a drug court judge or a judge with experience in adjudicating cases related to substance use disorder;

"(J) at least one such member shall be a public safety officer with extensive experience in interacting with adults with a substance use disorder; and

"(K) at least one such member shall be an individual with experience providing services for homeless individuals with a substance use disorder.

"(c) TERMS.—

"(1) IN GENERAL.—A member of the Committee appointed under subsection (b)(2) shall be appointed for a term of 3 years and may be reappointed for one or more 3-year terms.

"(2) VACANCIES.—A vacancy on the Committee shall be filled in the same manner in which the original appointment was made. Any individual appointed to fill a vacancy for an unexpired term shall be appointed for the remainder of such term and may serve after the expiration of such term until a successor has been appointed.

"(d) MEETINGS.—The Committee shall meet not fewer than two times each year.

"(e) DUTIES.—The Committee shall—

"(1) identify areas for improved coordination of activities, if any, related to substance use disorders, including research, services, supports, and prevention activities across all relevant Federal agencies;

"(2) identify and provide to the Secretary recommendations for improving Federal programs for the prevention and treatment of, and recovery from, substance use disorders, including by expanding access to prevention, treatment, and recovery services;

"(3) analyze substance use disorder prevention and treatment strategies in different regions of and populations in the United States and evaluate the extent to which Federal substance use disorder prevention and treatment strategies are aligned with State and local substance use disorder prevention and treatment strategies;

"(4) make recommendations to the Secretary regarding any appropriate changes with respect to the activities and strategies described in paragraphs (1) through (3);

"(5) make recommendations to the Secretary regarding public participation in decisions relating to substance use disorders and the process by which public feedback can be better integrated into such decisions; and

"(6) make recommendations to ensure that substance use disorder research, services, supports, and prevention activities of the Department of Health and Human Services and other Federal agencies are not unnecessarily duplicative.

"(f) ANNUAL REPORT.—Not later than 1 year after the date of the enactment of this Act [Oct. 24, 2018], and annually thereafter for the life of the Committee, the Committee shall publish on the Internet website of the Department of Health and Human Services, which may include the public information dashboard established under section 1711 of the Public Health Service Act [42 U.S.C. 300u–16], as added by section 7021, a report summarizing the activities carried out by the Committee pursuant to subsection (e), including any findings resulting from such activities.

"(g) WORKING GROUPS.—

"(1) IN GENERAL.—The Committee may establish working groups for purposes of carrying out the duties described in subsection (e). Any such working group shall be composed of members of the Committee (or the designees of such members) and may hold such meetings as are necessary to carry out the duties delegated to the working group.

"(2) ADDITIONAL FEDERAL INTERAGENCY WORK GROUP ON FENTANYL CONTAMINATION OF ILLEGAL DRUGS.—

"(A) ESTABLISHMENT.—The Secretary, acting through the Committee, shall establish a Federal Interagency Work Group on Fentanyl Contamination of Illegal Drugs (referred to in this paragraph as the 'Work Group') consisting of representatives from relevant Federal departments and agencies on the Committee.

"(B) CONSULTATION.—The Work Group shall consult with relevant stakeholders and subject matter experts, including—

"(i) State, Tribal, and local subject matter experts in reducing, preventing, and responding to drug overdose caused by fentanyl contamination of illicit drugs; and

"(ii) family members of both adults and youth who have overdosed by fentanyl contaminated illicit drugs.

"(C) DUTIES.—The Work Group shall—

"(i) examine Federal efforts to reduce and prevent drug overdose by fentanyl-contaminated illicit drugs;

"(ii) identify strategies to improve State, Tribal, and local responses to overdose by fentanyl-contaminated illicit drugs;

"(iii) coordinate with the Secretary, as appropriate, in carrying out activities to raise public awareness of synthetic opioids and other emerging drug use and misuse issues;

"(iv) make recommendations to Congress for improving Federal programs, including with respect to the coordination of efforts across such programs; and

"(v) make recommendations for educating youth on the potency and dangers of drugs contaminated by fentanyl.

"(D) ANNUAL REPORT TO SECRETARY.—The Work Group shall annually prepare and submit to the Secretary, the Committee on Health, Education, Labor, and Pensions of the Senate, and the Committee on Energy and Commerce and the Committee on Education and Workforce of the House of Representatives, a report on the activities carried out by the Work Group under subparagraph (C), including recommendations to reduce and prevent drug overdose by fentanyl contamination of illegal drugs, in all populations, and specifically among youth at risk for substance misuse.

"(h) FEDERAL ADVISORY COMMITTEE ACT.—The Federal Advisory Committee Act ([former] 5 U.S.C. App.) [see 5 U.S.C. 1001 et seq.] shall apply to the Committee only to the extent that the provisions of such Act do not conflict with the requirements of this section.

"(i) SUNSET.—The Committee shall terminate on September 30, 2030."

IMPROVING OVERSIGHT OF MENTAL AND SUBSTANCE USE DISORDERS PROGRAMS THROUGH THE ASSISTANT SECRETARY FOR PLANNING AND EVALUATION

Pub. L. 114–255, div. B, title VI, §6021, Dec. 13, 2016, 130 Stat. 1215, provided that:

"(a) IN GENERAL.—The Secretary of Health and Human Services, acting through the Assistant Secretary for Planning and Evaluation, shall ensure efficient and effective planning and evaluation of mental and substance use disorders prevention and treatment programs and related activities.

"(b) EVALUATION STRATEGY.—In carrying out subsection (a), the Assistant Secretary for Planning and Evaluation shall, not later than 180 days after the date of enactment of this Act [Dec. 13, 2016], develop a strategy for conducting ongoing evaluations that identifies priority programs to be evaluated by the Assistant Secretary for Planning and Evaluation and priority programs to be evaluated by other relevant offices and agencies within the Department of Health and Human Services. The strategy shall—

"(1) include a plan for evaluating programs related to mental and substance use disorders, including co-occurring disorders, across agencies, as appropriate, including programs related to—

"(A) prevention, intervention, treatment, and recovery support services, including such services for adults with a serious mental illness or children with a serious emotional disturbance;

"(B) the reduction of homelessness and incarceration among individuals with a mental or substance use disorder; and

"(C) public health and health services; and

"(2) include a plan for assessing the use of performance metrics to evaluate activities carried out by entities receiving grants, contracts, or cooperative agreements related to mental and substance use disorders prevention and treatment services under title V or title XIX of the Public Health Service Act (42 U.S.C. 290aa et seq.; 42 U.S.C. 300w et seq.).

"(c) CONSULTATION.—In carrying out this section, the Assistant Secretary for Planning and Evaluation shall consult, as appropriate, with the Assistant Secretary for Mental Health and Substance Use, the Chief Medical Officer of the Substance Abuse and Mental Health Services Administration appointed under section 501(g) of the Public Health Service Act (42 U.S.C. 290aa(g)), as amended by section 6003, the Behavioral Health Coordinating Council of the Department of Health and Human Services, other agencies within the Department of Health and Human Services, and other relevant Federal departments and agencies.

"(d) RECOMMENDATIONS.—In carrying out this section, the Assistant Secretary for Planning and Evaluation shall provide recommendations to the Secretary of Health and Human Services, the Assistant Secretary for Mental Health and Substance Use, and the Congress on improving the quality of prevention and treatment programs and activities related to mental and substance use disorders, including recommendations for the use of performance metrics. The Assistant Secretary for Mental Health and Substance Use shall include such recommendations in the biennial report required by subsection 501(m) of the Public Health Service Act [42 U.S.C. 290aa(m)], as redesignated by section 6003 of this Act."

ASSISTED OUTPATIENT TREATMENT GRANT PROGRAM FOR INDIVIDUALS WITH SERIOUS MENTAL ILLNESS

Pub. L. 113–93, title II, §224, Apr. 1, 2014, 128 Stat. 1083, as amended by Pub. L. 114–255, div. B, title IX, §9014, Dec. 13, 2016, 130 Stat. 1245, which related to assisted outpatient treatment grant program for individuals with serious mental illness, was editorially reclassified as section 290aa–17 of this title.

REPORT BY SUBSTANCE ABUSE AND MENTAL HEALTH SERVICES ADMINISTRATION

Pub. L. 102–321, title VII, §708, July 10, 1992, 106 Stat. 440, directed Administrator of Substance Abuse and Mental Health Services Administration to submit to Congress an interim report, not later than 6 months after July 10, 1992, and a final report, not later than Oct. 1, 1993, concerning current policies and barriers to provision of substance abuse and mental health services, with emphasis on barriers to health insurance and Medicaid coverage of such services, and further directed Secretary of Health and Human Services to initiate, not later than Jan. 1, 1994, research and demonstration projects which, consistent with information from reports submitted by the Administrator, explore alternative mechanisms of providing health insurance and treatment services for substance abuse and mental illness.

RELATIONSHIP BETWEEN MENTAL ILLNESS AND SUBSTANCE ABUSE

Pub. L. 100–690, title II, §2071, Nov. 18, 1988, 102 Stat. 4214, directed Secretary of Health and Human Services to conduct a study for the purpose of determining the relationship between mental illness and substance abuse, and developing recommendations on the most effective methods of treatment for individuals with both mental illness and substance abuse problems, and, not later than 12 months after Nov. 18, 1988, to complete the study and submit to Congress the findings made as a result of the study.

REPORT WITH RESPECT TO ADMINISTRATION OF CERTAIN RESEARCH PROGRAMS

Pub. L. 100–690, title II, §2073, Nov. 18, 1988, 102 Stat. 4215, directed Secretary of Health and Human Services to request National Academy of Sciences to conduct a review of research activities of National Institutes of Health and the Alcohol, Drug Abuse, and Mental Health Administration and, not later than 12 months after the date on which any contract requested is entered into, provide for the completion of the review and submit to Congress a report describing the findings made as a result of the review, with Secretary of Health and Human Services authorized to enter into a contract with National Academy of Sciences to carry out the review.

CONGRESSIONAL STATEMENT OF POLICY FOR ALCOHOL AND DRUG ABUSE AMENDMENTS OF 1983

Pub. L. 98–24, §1(b), Apr. 26, 1983, 97 Stat. 175, provided that: "It is the policy of the United States and the purpose of this Act [see Short Title of 1983 Amendment note set out under section 201 of this title] to provide leadership in the national effort to reduce the incidence of alcoholism and alcohol-related problems and drug abuse through—

"(1) a continued Federal commitment to research into the behavioral and biomedical etiology, the treatment, and the mental and physical health and social and economic consequences of alcohol abuse and alcoholism and drug abuse;

"(2) a commitment to—

"(A) extensive dissemination to States, units of local government, community organizations, and private groups of the most recent information and research findings with respect to alcohol abuse and alcoholism and drug abuse, including information with respect to the application of research findings; and

"(B) the accomplishment of such dissemination through up-to-date publications, demonstrations, educational programs, and other appropriate means;

"(3) the provision of technical assistance to research personnel; services personnel, and prevention personnel in the field of alcohol abuse and alcoholism and drug abuse;

"(4) the development and encouragement of prevention programs designed to combat the spread of alcoholism, alcohol abuse, drug abuse, and the abuse of other legal and illegal substances;

"(5) the development and encouragement of effective occupational prevention and treatment programs within Government and in cooperation with the private sector; and

"(6) the provision of a Federal response to alcohol abuse and alcoholism and drug abuse which encourages the greatest participation by the private sector, both financially and otherwise, and concentrates on carrying out functions relating to alcohol abuse and alcoholism and drug abuse which are truly national in scope."

ALCOHOL AND DRUG ABUSE AND MENTAL HEALTH REPORTS BY THE SECRETARY

Pub. L. 98–24, §3, Apr. 26, 1983, 97 Stat. 182, directed Secretary of Health and Human Services to submit

to Congress, on or before Jan. 15, 1984, a report describing the extent to which Federal and State programs, departments, and agencies are concerned and are dealing effectively with problems of alcohol abuse and alcoholism, problems of drug abuse, and mental illness.

TRANSFER OF BALANCES IN WORKING CAPITAL FUND, NARCOTIC HOSPITALS, TO SURPLUS FUND

Act July 8, 1947, ch. 210, title II, §201, 61 Stat. 269, provided: "That as of June 30, 1947, and the end of each fiscal year thereafter any balances in the 'Working capital fund, narcotic hospitals,' in excess of $150,000 shall be transferred to the surplus fund of the Treasury."

[Section 201 of act July 8, 1947, set out above, was formerly classified to section 258a of this title.]

EXECUTIVE DOCUMENTS

EX. ORD. NO. 13954. SAVING LIVES THROUGH INCREASED SUPPORT FOR MENTAL- AND BEHAVIORAL-HEALTH NEEDS

Ex. Ord. No. 13954, Oct. 3, 2020, 85 F.R. 63977, provided:

By the authority vested in me as President by the Constitution and the laws of the United States of America, it is hereby ordered as follows:

SECTION 1. *Purpose*. My Administration is committed to preventing the tragedy of suicide, ending the opioid crisis, and improving mental and behavioral health. Before the COVID–19 pandemic, these urgent issues were prioritized through significant initiatives, including the President's Roadmap to Empower Veterans and End a National Tragedy of Suicide (PREVENTS), expanded access to medication-assisted treatment and life-saving naloxone, and budget requests for significant investments in the funding of evidence-based treatment for mental- and behavioral-health needs.

During the COVID–19 pandemic, the Federal Government has dedicated billions of dollars and thousands of hours in resources to help Americans, including approximately $425 million in emergency funds to address mental and substance use disorders through the Substance Abuse and Mental Health Services Administration. The pandemic has also exacerbated mental- and behavioral-health conditions as a result of stress from prolonged lockdown orders, lost employment, and social isolation. Survey data from the Centers for Disease Control and Prevention show that during the last week of June, 40.9 percent of Americans struggled with mental-health or substance-abuse issues and 10.7 percent reported seriously considering suicide. We must enhance the ability of the Federal Government, as well as its State, local, and Tribal partners, to appropriately address these ongoing mental- and behavioral-health concerns.

SEC. 2. *Policy*. It is the policy of the United States to prevent suicides, drug-related deaths, and poor behavioral-health outcomes, particularly those that are induced or made worse by prolonged State and local COVID–19 shutdown orders. I am therefore issuing a national call to action to:

(a) Engage the resources of the Federal Government to address the mental- and behavioral-health needs of vulnerable Americans, including by:

(i) providing crisis-intervention services to treat those in immediate life-threatening situations; and

(ii) increasing the availability of and access to quality continuing care following initial crisis resolution to improve behavioral-health outcomes;

(b) Permit and encourage safe in-person mentorship programs; support-group participation; and attendance at communal facilities, including schools, civic centers, and houses of worship;

(c) Increase the availability of telehealth and online mental-health and substance-use tools and services; and

(d) Marshal public and private resources to address deteriorating mental health, such as factors that contribute to prolonged unemployment and social isolation.

SEC. 3. *Establishment of a Coronavirus Mental Health Working Group*. The Coronavirus Mental Health Working Group (Working Group) is hereby established to facilitate an "all-of-government" response to the mental-health conditions induced or exacerbated by the pandemic, including issues related to suicide prevention. The Working Group will be co-chaired by the Secretary of Health and Human Services, or his designee, and the Assistant to the President for Domestic Policy, or her designee. The Working Group shall be composed of representatives from the Department of Defense, the Department of Justice, the Department of Agriculture, the Department of Labor, the Department of Housing and Urban Development, the Department of Education, the Department of Veterans Affairs, the Small Business Administration, the Office of National Drug Control Policy, the Office of Management and Budget (OMB), and such representatives of other executive departments, agencies, and offices as the Co-Chairs may, from time to time, designate with the concurrence of the head of the department, agency, or office concerned. All members of the Working Group shall be full-time, or permanent part-time, officers or employees of the Federal Government.

SEC. 4. *Responsibilities of the Coronavirus Mental Health Working Group*. (a) As part of the Working Group's efforts, it shall consider the mental- and behavioral-health conditions of those vulnerable populations affected by the pandemic, including: minorities, seniors, veterans, small business owners, children, and individuals potentially affected by domestic violence or physical abuse; those living with disabilities; and those with a substance use disorder. The Working Group shall examine existing protocols and evidence-based programs that may serve as models to better support these at-risk groups, including implementation and broader application of the PREVENTS, and the Department of Labor's Employer Assistance and Resource Network on Disability Inclusion's Mental Health Toolkit and Centralized Accommodation Programs.

(b) Within 45 days of the date of this order [Oct. 3, 2020], the Working Group shall develop and submit to the President a report that outlines a plan for improved service coordination between all relevant public and private stakeholders and executive departments and agencies (agencies) to assist individuals in crisis so that they receive effective treatment and recovery services.

SEC. 5. *Grant Funding for States and Organizations that Permit In-Person Treatment and Recovery Support Activities for Mental and Behavioral Health*. The heads of agencies, in consultation with the Director of OMB, shall:

(a) Examine their existing grant programs that fund mental-health, medical, or related services and, consistent with applicable law, take steps to encourage grantees to consider adopting policies, where appropriate, that have been shown to improve mental health and reduce suicide risk, including the following:

(i) Safe in-person and telehealth participation in support groups for people in recovery from substance use disorders, mental-health issues, or other ailments that benefit from communal support; and peer-to-peer services that support underserved communities;

(ii) Safe face-to-face therapeutic services, including group therapy, to remediate poor behavioral health; and

(iii) Safe participation in communal support—both faith-based and secular—including educational programs, civic activities, and in-person religious services.

(b) Maximize use of existing agency authorities to award contracts or grants to community organizations or other local entities to enhance mental-health and suicide-prevention services, such as outreach, education, and case management, to vulnerable Americans.

SEC. 6. *General Provisions*. (a) Nothing in this order shall be construed to impair or otherwise affect:

(i) the authority granted by law to an executive department or agency, or the head thereof; or

(ii) the functions of the Director of the Office of Management and Budget relating to budgetary, administrative, or legislative proposals.

(b) This order shall be implemented consistent with applicable law and subject to the availability of appropriations.

(c) This order is not intended to, and does not, create any right or benefit, substantive or procedural, enforceable at law or in equity by any party against the United States, its departments, agencies, or entities, its officers, employees, or agents, or any other person.

DONALD J. TRUMP.

EX. ORD. NO. 14379. ADDRESSING ADDICTION THROUGH THE GREAT AMERICAN RECOVERY INITIATIVE

Ex. Ord. No. 14379, Jan. 29, 2026, 91 F.R. 5081, provided:

By the authority vested in me as President by the Constitution and the laws of the United States of America, it is hereby ordered:

SECTION 1. *Purpose and Policy*. The disease of addiction, also known as substance use disorder, is a crisis that touches families in every community and neighborhood in our Nation. 48.4 million Americans, or 16.8 percent of our Nation's population, suffer from addiction, and my Administration will continue to respond to a crisis of this scale with the attention it deserves. Over the past year, we have made incredible progress in stopping the inflow of illegal drugs that threaten American communities. We must now supplement that work by furthering a national effort to prioritize addiction treatment and recovery.

Addiction is a chronic, treatable disease with relapse rates similar to other chronic diseases. Unfortunately, very few Americans who need treatment ever receive it or believe they need it. Among the 40.7 million adults who had a substance use disorder in 2024 and did not receive substance use treatment, 95.6 percent (or 38.1 million people) did not perceive that they needed treatment. Despite significant investment of resources, addiction recovery efforts remain fragmented and do not keep pace with scientific advancements.

The costs of these failures are devastating, not only in lives lost, but also in the ripple effects across our economy, workforce, and national strength. Addiction contributes to declining workforce participation, increased healthcare costs, homelessness, family instability, and lost productivity that together cost the United States hundreds of billions of dollars each year.

The framework for addiction treatment should parallel that of other chronic diseases—utilizing evidence-based care, scientific advancement, continuous support, and community connection. My Administration will drive a new national response to the disease of addiction that will create stronger coordination across government, the healthcare sector, faith communities, and the private sector in order to save lives, restore families, strengthen our communities, and build the Great American Recovery.

SEC. 2. *Launching the Great American Recovery Initiative*. (a) There is hereby established the White House Great American Recovery Initiative (Initiative) co-chaired by the Secretary of Health and Human Services and the Senior Advisor for Addiction Recovery. There shall be an Executive Director who shall administer and execute the day to day operations of the Initiative, and who shall report to the Assistant to the President for Domestic Policy.

(b) In addition to the Co-Chairs and the Executive Director, the Initiative shall consist of the following officials, or their designees:

(i) the Attorney General;

(ii) the Secretary of the Interior;

(iii) the Secretary of Education;

(iv) the Secretary of Labor;

(v) the Secretary of Housing and Urban Development;

(vi) the Secretary of Veterans Affairs;

(vii) the Assistant to the President and Chief of Staff;

(viii) the Assistant to the President and Special Envoy for Peace Missions;

(ix) the Assistant to the President and Cabinet Secretary;

(x) the Director of National Drug Control Policy;

(xi) the Administrator of the Centers for Medicare and Medicaid Services;

(xii) the Commissioner of Food and Drugs;

(xiii) the Director of the National Institutes of Health;

(xiv) the Assistant Secretary for Mental Health and Substance Use, Department of Health and Human Services; and

(xv) the heads of such other executive departments, agencies, and offices that the Co-Chairs and the Executive Director may from time to time designate or invite to participate.

(c) The Co-Chairs may hold public hearings, meetings, roundtables, and similar events, as appropriate, and may receive expert input from leaders in public health, addiction and recovery treatment, and other relevant subject matter areas.

SEC. 3. *Addressing the Disease of Addiction*. The Co-Chairs and the Executive Director, along with the other members of the Initiative, shall:

(i) recommend all necessary steps to coordinate the Federal Government's response to the addiction crisis, including by better aligning relevant Federal programs, setting clear objectives, and providing data-driven updates to the public on progress towards meeting these objectives;

(ii) take appropriate actions to increase awareness of the disease of addiction, help Americans receive the treatment they need, and foster a culture that celebrates recovery;

(iii) advise heads of executive departments and agencies (agency heads) on how to implement programs that integrate prevention, early intervention, treatment, recovery support, and re-entry into all relevant public health, healthcare, criminal justice, workforce, education, housing and social services systems, and remove outdated silos between agencies, programs, or systems, in each case as deemed appropriate by the agency head and consistent with applicable law;

(iv) advise agency heads on directing appropriate grants to support addiction recovery, with a focus on prevention, treatment, and long-term resilience; and

(v) consult with States, tribal nations, local jurisdictions, community-based organizations, faith-based organizations, the private sector, and philanthropic entities on the best strategies to ensure more Americans receive the treatment they need and celebrate individuals going through the recovery process.

SEC. 4. *General Provisions*. (a) Nothing in this order shall be construed to impair or otherwise affect:

(i) the authority granted by law to an executive department or agency, or the head thereof; or

(ii) the functions of the Director of the Office of Management and Budget relating to budgetary, administrative, or legislative proposals.

(b) This order shall be implemented consistent with applicable law and subject to the availability of appropriations.

(c) This order is not intended to, and does not, create any right or benefit, substantive or procedural, enforceable at law or in equity by any party against the United States, its departments, agencies, or entities, its officers, employees, or agents, or any other person.

(d) The costs for publication of this order shall be borne by the Department of Health and Human Services.

DONALD J. TRUMP.

[1] *So in original. Two pars. (26) have been enacted.*

§290aa–0. National Mental Health and Substance Use Policy Laboratory

(a) In general

There shall be established within the Administration a National Mental Health and Substance Use Policy Laboratory (referred to in this section as the "Laboratory").

(b) Responsibilities

The Laboratory shall—

(1) continue to carry out the authorities and activities that were in effect for the Office of Policy, Planning, and Innovation as such Office existed prior to December 13, 2016;

(2) identify, coordinate, and facilitate the implementation of policy changes likely to have a significant effect on mental health, mental illness, recovery supports, and the prevention and treatment of substance use disorder services;

(3) work with the Center for Behavioral Health Statistics and Quality to collect, as appropriate, information from grantees under programs operated by the Administration in order to evaluate and disseminate information on evidence-based practices, including culturally and linguistically appropriate services, as appropriate, and service delivery models;

(4) provide leadership in identifying and coordinating policies and programs, including evidence-based programs, related to mental and substance use disorders;

(5) periodically review programs and activities operated by the Administration relating to the diagnosis or prevention of, treatment for, and recovery from, mental and substance use disorders to—

(A) identify any such programs or activities that are duplicative;

(B) identify any such programs or activities that are not evidence-based, effective, or efficient; and

(C) formulate recommendations for coordinating, eliminating, or improving programs or activities identified under subparagraph (A) or (B) and merging such programs or activities into other successful programs or activities;

(6) issue and periodically update information for entities applying for grants or cooperative agreements from the Substance Abuse and Mental Health Services Administration in order to—

(A) encourage the implementation and replication of evidence-based practices; and

(B) provide technical assistance to applicants for funding, including with respect to justifications for such programs and activities; and

(7) carry out other activities as deemed necessary to continue to encourage innovation and disseminate evidence-based programs and practices.

(c) Evidence-based practices and service delivery models

(1) In general

In carrying out subsection (b)(3), the Laboratory—

(A) may give preference to models that improve—

(i) the coordination between mental health and physical health providers;

(ii) the coordination among such providers and the justice and corrections system; and

(iii) the cost effectiveness, quality, effectiveness, and efficiency of health care services furnished to adults with a serious mental illness, children with a serious emotional disturbance, or individuals in a mental health crisis; and

(B) may include clinical protocols and practices that address the needs of individuals with early serious mental illness.

(2) Consultation

In carrying out this section, the Laboratory shall consult with—

(A) the Chief Medical Officer appointed under section 290aa(g) of this title;

(B) representatives of the National Institute of Mental Health, the National Institute on Drug Abuse, and the National Institute on Alcohol Abuse and Alcoholism, on an ongoing basis;

(C) other appropriate Federal agencies;

(D) clinical and analytical experts with expertise in psychiatric medical care and clinical psychological care, health care management, education, corrections health care, and mental health court systems, as appropriate; and

(E) other individuals and agencies as determined appropriate by the Assistant Secretary.

(d) Deadline for beginning implementation

The Laboratory shall begin implementation of this section not later than January 1, 2018.

(e) Promoting innovation

(1) In general

The Assistant Secretary, in coordination with the Laboratory, may award grants to States, local governments, Indian Tribes or Tribal organizations (as such terms are defined in section 5304 of title 25), educational institutions, and nonprofit organizations to develop evidence-based interventions, including culturally and linguistically appropriate services, as appropriate, for—

(A) evaluating a model that has been scientifically demonstrated to show promise, but would benefit from further applied development, for—

(i) enhancing the prevention, diagnosis, intervention, and treatment of, and recovery from, mental illness, serious emotional disturbances, substance use disorders, and co-occurring illness or disorders; or

(ii) integrating or coordinating physical health services and mental and substance use disorders services; and

(B) expanding, replicating, or scaling evidence-based programs across a wider area to enhance effective screening, early diagnosis, intervention, and treatment with respect to mental illness, serious mental illness, serious emotional disturbances, and substance use disorders, primarily by—

(i) applying such evidence-based programs to the delivery of care, including by training staff in effective evidence-based treatments; or

(ii) integrating such evidence-based programs into models of care across specialties and jurisdictions.

(2) Consultation

In awarding grants under this subsection, the Assistant Secretary shall, as appropriate, consult with the Chief Medical Officer, appointed under section 290aa(g) of this title, the advisory councils described in section 290aa–1 of this title, the National Institute of Mental Health, the National Institute on Drug Abuse, and the National Institute on Alcohol Abuse and Alcoholism, as appropriate.

(f) Authorization of appropriations

To carry out this section, there is authorized to be appropriated $10,000,000 for each of fiscal years 2023 through 2027.

(July 1, 1944, ch. 373, title V, §501A, as added Pub. L. 114–255, div. B, title VII, §7001, Dec. 13, 2016, 130 Stat. 1220; amended Pub. L. 115–271, title VII, §7111, Oct. 24, 2018, 132 Stat. 4042; Pub. L. 117–328, div. FF, title I, §1121(a), Dec. 29, 2022, 136 Stat. 5647.)

EDITORIAL NOTES

AMENDMENTS

2022—Subsec. (e)(1). Pub. L. 117–328, §1121(a)(1), substituted "Indian Tribes or Tribal organizations" for "Indian tribes or tribal organizations" in introductory provisions.

Subsec. (e)(3). Pub. L. 117–328, §1121(a)(2), struck out par. (3) which authorized appropriations for grants for fiscal years 2018 through 2020.

Subsec. (f). Pub. L. 117–328, §1121(a)(3), added subsec. (f).

2018—Subsec. (b)(6), (7). Pub. L. 115–271 added par. (6) and redesignated former par. (6) as (7).

§290aa–0a. Behavioral health crisis coordinating office

(a) In general

The Secretary shall establish, within the Substance Abuse and Mental Health Services Administration, an office to coordinate work relating to behavioral health crisis care across the operating divisions and agencies of the Department of Health and Human Services, including the Substance Abuse and Mental Health Services Administration, the Centers for Medicare & Medicaid Services, and the Health Resources and Services Administration, and external stakeholders.

(b) Duty

The office established under subsection (a) shall—

(1) convene Federal, State, Tribal, local, and private partners;

(2) launch and manage Federal workgroups charged with making recommendations regarding issues related to mental health and substance use disorder crises, including with respect to health care best practices, workforce development, health disparities, data collection, technology, program oversight, public awareness, and engagement; and

(3) support technical assistance, data analysis, and evaluation functions in order to assist States, localities, Territories, Indian Tribes, and Tribal organizations in developing crisis care systems and identifying best practices with the objective of expanding the capacity of, and access to, local crisis call centers, mobile crisis care, crisis stabilization, psychiatric emergency services, and rapid post-crisis follow-up care provided by—

(A) the National Suicide Prevention and Mental Health Crisis Hotline and Response System;

(B) the Veterans Crisis Line;

(C) community mental health centers (as defined in section 1395x(ff)(3)(B) of this title);

(D) certified community behavioral health clinics, as described in section 223 of the Protecting Access to Medicare Act of 2014; and

(E) other community mental health and substance use disorder providers.

(c) Authorization of appropriations

There is authorized to be appropriated to carry out this section $5,000,000 for each of fiscal years 2023 through 2027.

(July 1, 1944, ch. 373, title V, §501B, as added Pub. L. 117–328, div. FF, title I, §1101, Dec. 29, 2022, 136 Stat. 5635.)

EDITORIAL NOTES

REFERENCES IN TEXT

Section 223 of the Protecting Access to Medicare Act of 2014, referred to in subsec. (b)(3)(D), is section 223 of Pub. L. 113–93, which is set out as a note under section 1396a of this title.

STATUTORY NOTES AND RELATED SUBSIDIARIES

CRISIS RESPONSE CONTINUUM OF CARE

Pub. L. 117–328, div. FF, title I, §1102, Dec. 29, 2022, 136 Stat. 5635, provided that:

"(a) IN GENERAL.—The Secretary, acting through the Assistant Secretary for Mental Health and Substance Use, shall facilitate the identification and publication of best practices for a crisis response continuum of care related to mental health and substance use disorders for use by health care providers, crisis services administrators, and crisis services providers in responding to individuals (including children and adolescents) experiencing mental health crises, substance-related crises, and crises arising from co-occurring disorders.

"(b) BEST PRACTICES.—

"(1) IN GENERAL.—The best practices published under subsection (a) shall, as appropriate, address best practices related to crisis response services for the range of entities that furnish such services, taking into consideration such services that—

"(A) do not require prior authorization from an insurance provider or group health plan nor a referral from a health care provider prior to the delivery of services;

"(B) provide for serving all individuals regardless of age or ability to pay;

"(C) provide for operating 24 hours a day, 7 days a week;

"(D) provide for care and support through resources described in paragraph (2)(A) until the individual has been stabilized or transferred to the next level of crisis care; and

"(E) address psychiatric stabilization, including for—

"(i) individuals screened over the phone, text, and chat; and

"(ii) individuals stabilized on the scene by mobile teams.

"(2) IDENTIFICATION OF FUNCTIONS.—The best practices published under subsection (a) shall consider the functions of the range of services in the crisis response continuum, including the following:

"(A) Identification of resources for referral and enrollment in continuing mental health, substance use, or other human services relevant for the individual in crisis where necessary.

"(B) A description of access and entry points to services within the crisis response continuum.

"(C) Identification, as appropriate and consistent with State laws, of any protocols and agreements for the transfer and receipt of individuals to and from other segments of the crisis response continuum segments as needed, and from outside referrals, including health care providers, first responders (including law enforcement, paramedics, and firefighters), education institutions, and community-based organizations.

"(D) Description of the qualifications of the range of crisis services staff, including roles for physicians, licensed clinicians, case managers, and peers (in accordance with State licensing requirements or requirements applicable to Tribal health professionals).

"(E) The convening of collaborative meetings of relevant crisis response system partners, such as crisis response service providers, first responders (including law enforcement, paramedics, and firefighters), and community partners (including the National Suicide Prevention Lifeline or 9–8–8 call centers, 9–1–1 public service answering points, and local mental health and substance use disorder treatment providers), operating in a common region for the discussion of case management, best practices, and general performance improvement.

"(3) SERVICE CAPACITY AND QUALITY BEST PRACTICES.—The best practices under subsection (a) may include recommendations on—

"(A) the volume of services to meet population need;

"(B) appropriate timely response; and

"(C) capacity to meet the needs of different patient populations that may experience a mental health or substance use crisis, including children, families, and all age groups, racial and ethnic minorities, veterans, individuals with co-occurring mental health and substance use disorders, individuals with disabilities, and individuals with chronic illness.

"(4) IMPLEMENTATION TIMEFRAME.—The Secretary shall—

"(A) not later than 1 year after the date of enactment of this section [Dec. 29, 2022], publish and maintain the best practices required by subsection (a); and

"(B) after 3 years, facilitate the identification of any updates to such best practices, as appropriate.

"(5) EVALUATIONS.—Not later than 3 years after the date of enactment of this Act, the Comptroller General of the United States shall submit to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives, an assessment of relevant programs related to mental health and substance use disorder crises authorized under title V of the Public Health Service Act (42 U.S.C. 290aa et seq.) in order to assess the extent to which such programs meet objectives and performance metrics, as determined by the Secretary. Such evaluation may, as appropriate, include data on—

"(A) the type and variety of services provided when responding to mental health and substance use-related crises;

"(B) the impact on emergency department facility use and length of stay, including for patients who require further psychiatric care;

"(C) the impact on access to crisis care centers and crisis bed services;

"(D) the impact on linkage to appropriate post-crisis care; and

"(E) the use of best practices and recommendations identified under this section."

§290aa–0b. Interdepartmental Serious Mental Illness Coordinating Committee

(a) Establishment

(1) In general

The Secretary, or the designee of the Secretary, shall establish a committee to be known as the Interdepartmental Serious Mental Illness Coordinating Committee (in this section referred to as the "Committee").

(2) Federal Advisory Committee Act

Except as provided in this section, the provisions of the Federal Advisory Committee Act (5 U.S.C. App.) [1] shall apply to the Committee.

(b) Meetings

The Committee shall meet not fewer than 2 times each year.

(c) Responsibilities

Not later than each of 1 year and 5 years after December 29, 2022, the Committee shall submit to Congress and any other relevant Federal department or agency a report including—

(1) a summary of advances in serious mental illness and serious emotional disturbance research related to the prevention of, diagnosis of, intervention in, and treatment and recovery of serious mental illnesses, serious emotional disturbances, and advances in access to services and support for adults with a serious mental illness or children with a serious emotional disturbance;

(2) an evaluation of the effect Federal programs related to serious mental illness have on public health, including outcomes such as—

(A) rates of suicide, suicide attempts, incidence and prevalence of serious mental illnesses, serious emotional disturbances, and substance use disorders, overdose, overdose deaths, emergency hospitalizations, emergency department boarding, preventable emergency department visits, interaction with the criminal justice system, homelessness, and unemployment;

(B) increased rates of employment and enrollment in educational and vocational programs;

(C) quality of mental and substance use disorders treatment services; or

(D) any other criteria as may be determined by the Secretary; and

(3) specific recommendations for actions that agencies can take to better coordinate the administration of mental health services for adults with a serious mental illness or children with a serious emotional disturbance.

(d) Membership

(1) Federal members

The Committee shall be composed of the following Federal representatives, or the designees of such representatives—

(A) the Secretary of Health and Human Services, who shall serve as the Chair of the Committee;

(B) the Assistant Secretary for Mental Health and Substance Use;

(C) the Attorney General;

(D) the Secretary of Veterans Affairs;

(E) the Secretary of Defense;
(F) the Secretary of Housing and Urban Development;
(G) the Secretary of Education;
(H) the Secretary of Labor;
(I) the Administrator of the Centers for Medicare & Medicaid Services;
(J) the Administrator of the Administration for Community Living; and
(K) the Commissioner of Social Security.

(2) Non-Federal members

The Committee shall also include not less than 14 non-Federal public members appointed by the Secretary of Health and Human Services, of which—

(A) at least 2 members shall be an individual who has received treatment for a diagnosis of a serious mental illness;

(B) at least 1 member shall be a parent or legal guardian of an adult with a history of a serious mental illness or a child with a history of a serious emotional disturbance;

(C) at least 1 member shall be a representative of a leading research, advocacy, or service organization for adults with a serious mental illness;

(D) at least 2 members shall be—

(i) a licensed psychiatrist with experience in treating serious mental illnesses;

(ii) a licensed psychologist with experience in treating serious mental illnesses or serious emotional disturbances;

(iii) a licensed clinical social worker with experience treating serious mental illnesses or serious emotional disturbances; or

(iv) a licensed psychiatric nurse, nurse practitioner, or physician assistant with experience in treating serious mental illnesses or serious emotional disturbances;

(E) at least 1 member shall be a licensed mental health professional with a specialty in treating children and adolescents with a serious emotional disturbance;

(F) at least 1 member shall be a mental health professional who has research or clinical mental health experience in working with minorities;

(G) at least 1 member shall be a mental health professional who has research or clinical mental health experience in working with medically underserved populations;

(H) at least 1 member shall be a State certified mental health peer support specialist;

(I) at least 1 member shall be a judge with experience in adjudicating cases related to criminal justice or serious mental illness;

(J) at least 1 member shall be a law enforcement officer or corrections officer with extensive experience in interfacing with adults with a serious mental illness, children with a serious emotional disturbance, or individuals in a mental health crisis; and

(K) at least 1 member shall have experience providing services for homeless individuals and working with adults with a serious mental illness, children with a serious emotional disturbance, or individuals in a mental health crisis.

(3) Terms

A member of the Committee appointed under paragraph (2) shall serve for a term of 3 years, and may be reappointed for 1 or more additional 3-year terms. Any member appointed to fill a vacancy for an unexpired term shall be appointed for the remainder of such term. A member may serve after the expiration of the member's term until a successor has been appointed.

(e) Working groups

In carrying out its functions, the Committee may establish working groups. Such working groups shall be composed of Committee members, or their designees, and may hold such meetings as are necessary.

(f) Sunset

The Committee shall terminate on September 30, 2027.

(July 1, 1944, ch. 373, title V, §501C, as added Pub. L. 117–328, div. FF, title I, §1121(c)(1), Dec. 29, 2022, 136 Stat. 5648.)

EDITORIAL NOTES

REFERENCES IN TEXT

The Federal Advisory Committee Act, referred to in subsec. (a)(2), is Pub. L. 92–463, Oct. 6, 1972, 86 Stat. 770, which was set out in the Appendix to Title 5, Government Organization and Employees, and was substantially repealed and restated in chapter 10 (§1001 et seq.) of Title 5 by Pub. L. 117–286, §§3(a), 7, Dec. 27, 2022, 136 Stat. 4197, 4361. For disposition of sections of the Act into chapter 10 of Title 5, see Disposition Table preceding section 101 of Title 5.

[1] See References in Text note below.

§290aa–1. Advisory councils

(a) Appointment

(1) In general

The Secretary shall appoint an advisory council for—

(A) the Substance Abuse and Mental Health Services Administration;

(B) the Center for Substance Abuse Treatment;

(C) the Center for Substance Abuse Prevention; and

(D) the Center for Mental Health Services.

Each such advisory council shall advise, consult with, and make recommendations to the Secretary and the Assistant Secretary or Director of the Administration or Center for which the advisory council is established concerning matters relating to the activities carried out by and through the Administration or Center and the policies respecting such activities.

(2) Function and activities

An advisory council—

(A)(i) may on the basis of the materials provided by the organization respecting activities conducted at the organization, make recommendations to the Assistant Secretary or Director of the Administration or Center for which it was established respecting such activities;

(ii) shall review applications submitted for grants and cooperative agreements for activities for which advisory council approval is required under section 290aa–3(d)(2) of this title and recommend for approval applications for projects that show promise of making valuable contributions to the Administration's mission; and

(iii) may review any grant, contract, or cooperative agreement proposed to be made or entered into by the organization;

(B) may collect, by correspondence or by personal investigation, information as to studies and services that are being carried on in the United States or any other country as to the diseases, disorders, or other aspects of human health with respect to which the organization was established and with the approval of the Assistant Secretary or Director, whichever is appropriate, make such information available through appropriate publications for the benefit of public and private health entities and health professions personnel and for the information of the general public; and

(C) may appoint subcommittees and convene workshops and conferences.

(b) Membership

(1) In general

Each advisory council shall consist of nonvoting ex officio members and not more than 12

members to be appointed by the Secretary under paragraph (3).

(2) Ex officio members

The ex officio members of an advisory council shall consist of—

(A) the Secretary;

(B) the Assistant Secretary;

(C) the Director of the Center for which the council is established;

(D) the Under Secretary for Health of the Department of Veterans Affairs;

(E) the Assistant Secretary for Defense for Health Affairs (or the designates of such officers);

(F) the Chief Medical Officer, appointed under section 290aa(g) of this title;

(G) the Director of the National Institute of Mental Health for the advisory councils appointed under subsections (a)(1)(A) and (a)(1)(D);

(H) the Director of the National Institute on Drug Abuse for the advisory councils appointed under subsections (a)(1)(A), (a)(1)(B), and (a)(1)(C);

(I) the Director of the National Institute on Alcohol Abuse and Alcoholism for the advisory councils appointed under subsections (a)(1)(A), (a)(1)(B), and (a)(1)(C); and

(J) such additional officers or employees of the United States as the Secretary determines necessary for the advisory council to effectively carry out its functions.

(3) Appointed members

Individuals shall be appointed to an advisory council under paragraph (1) as follows:

(A) Nine of the members shall be appointed by the Secretary from among the leading representatives of the health disciplines (including public health and behavioral and social sciences) relevant to the activities of the Administration or Center for which the advisory council is established.

(B) Three of the members shall be appointed by the Secretary from the general public and shall include leaders in fields of public policy, public relations, law, health policy economics, or management.

(C) Not less than half of the members of the advisory council appointed under subsection (a)(1)(D)—

(i) shall—

(I) have a medical degree;

(II) have a doctoral degree in psychology; or

(III) have an advanced degree in nursing or social work from an accredited graduate school or be a certified physician assistant; and

(ii) shall specialize in the mental health field.

(D) Not less than half of the members of the advisory councils appointed under subsections (a)(1)(B) and (a)(1)(C)—

(i) shall—

(I) have a medical degree;

(II) have a doctoral degree; or

(III) have an advanced degree in nursing, public health, behavioral or social sciences, or social work from an accredited graduate school or be a certified physician assistant; and

(ii) shall have experience in the provision of substance use disorder services or the development and implementation of programs to prevent substance misuse.

(4) Compensation

Members of an advisory council who are officers or employees of the United States shall not receive any compensation for service on the advisory council. The remaining members of an

advisory council shall receive, for each day (including travel time) they are engaged in the performance of the functions of the advisory council, compensation at rates not to exceed the daily equivalent to the annual rate in effect for grade GS–18 of the General Schedule.

(c) Terms of office

(1) In general

The term of office of a member of an advisory council appointed under subsection (b) shall be 4 years, except that any member appointed to fill a vacancy for an unexpired term shall serve for the remainder of such term. The Secretary shall make appointments to an advisory council in such a manner as to ensure that the terms of the members not all expire in the same year. A member of an advisory council may serve after the expiration of such member's term until a successor has been appointed and taken office.

(2) Reappointments

A member who has been appointed to an advisory council for a term of 4 years may not be reappointed to an advisory council during the 2-year period beginning on the date on which such 4-year term expired.

(3) Time for appointment

If a vacancy occurs in an advisory council among the members under subsection (b), the Secretary shall make an appointment to fill such vacancy within 90 days from the date the vacancy occurs.

(d) Chair

The Secretary shall select a member of an advisory council to serve as the chair of the council. The Secretary may so select an individual from among the appointed members, or may select the Assistant Secretary or the Director of the Center involved. The term of office of the chair shall be 2 years.

(e) Meetings

An advisory council shall meet at the call of the chairperson or upon the request of the Assistant Secretary or Director of the Administration or Center for which the advisory council is established, but in no event less than 2 times during each fiscal year. The location of the meetings of each advisory council shall be subject to the approval of the Assistant Secretary or Director of Administration or Center for which the council was established.

(f) Executive Secretary and staff

The Assistant Secretary or Director of the Administration or Center for which the advisory council is established shall designate a member of the staff of the Administration or Center for which the advisory council is established to serve as the Executive Secretary of the advisory council. The Assistant Secretary or Director shall make available to the advisory council such staff, information, and other assistance as it may require to carry out its functions. The Assistant Secretary or Director shall provide orientation and training for new members of the advisory council to provide for their effective participation in the functions of the advisory council.

(July 1, 1944, ch. 373, title V, §502, formerly §505, as added Pub. L. 99–570, title IV, §4004(a), Oct. 27, 1986, 100 Stat. 3207–109; amended Pub. L. 100–527, §10(4), Oct. 25, 1988, 102 Stat. 2641; Pub. L. 101–381, title I, §102(6), Aug. 18, 1990, 104 Stat. 586; renumbered §502 and amended Pub. L. 102–321, title I, §102, July 10, 1992, 106 Stat. 331; Pub. L. 102–352, §2(a)(6), Aug. 26, 1992, 106 Stat. 938; Pub. L. 103–446, title XII, §1203(a)(1), Nov. 2, 1994, 108 Stat. 4689; Pub. L. 106–310, div. B, title XXXIV, §3402, Oct. 17, 2000, 114 Stat. 1219; Pub. L. 114–255, div. B, title VI, §§6001(c)(2), 6008, Dec. 13, 2016, 130 Stat. 1203, 1214.)

EDITORIAL NOTES

CODIFICATION

Section was formerly classified to section 290aa–3a of this title prior to renumbering by Pub. L. 102–321.

PRIOR PROVISIONS

A prior section 290aa–1, act July 1, 1944, ch. 373, title V, §502, formerly Pub. L. 91–616, title I, §101, Dec. 31, 1970, 84 Stat. 1848, as amended Pub. L. 93–282, title II, §203(a), May 14, 1974, 88 Stat. 135; Pub. L. 96–180, §3, Jan. 2, 1980, 93 Stat. 1302; Pub. L. 97–35, title IX, §966(a), Aug. 13, 1981, 95 Stat. 595; renumbered §502 of act July 1, 1944, and amended Apr. 26, 1983, Pub. L. 98–24, §2(b)(3), 97 Stat. 177; Oct. 19, 1984, Pub. L. 98–509, title II, §205(b)(2), 98 Stat. 2361; Oct. 27, 1986, Pub. L. 99–570, title IV, §4005(b)(1), 100 Stat. 3207–114, related to National Institute on Alcohol Abuse and Alcoholism, prior to repeal by Pub. L. 102–321, title I, §101(b), July 10, 1992, 106 Stat. 331. See section 285n of this title.

A prior section 502 of act July 1, 1944, which was classified to section 220 of this title, was successively renumbered by subsequent acts and transferred, see section 238a of this title.

AMENDMENTS

2016—Subsec. (a)(1). Pub. L. 114–255, §6001(c)(2), substituted "Assistant Secretary" for "Administrator" in concluding provisions.

Subsec. (a)(2)(A)(i), (B). Pub. L. 114–255, §6001(c)(2), substituted "Assistant Secretary" for "Administrator".

Subsec. (b)(2)(B). Pub. L. 114–255, §6001(c)(2), substituted "Assistant Secretary" for "Administrator".

Subsec. (b)(2)(F) to (J). Pub. L. 114–255, §6008(1), added subpars. (F) to (I) and redesignated former subpar. (F) as (J).

Subsec. (b)(3)(C), (D). Pub. L. 114–255, §6008(2), added subpars. (C) and (D).

Subsecs. (d) to (f). Pub. L. 114–255, §6001(c)(2), substituted "Assistant Secretary" for "Administrator" wherever appearing.

2000—Subsec. (e). Pub. L. 106–310 substituted "2 times during each fiscal year" for "3 times during each fiscal year".

1994—Subsec. (b)(2)(D). Pub. L. 103–446 amended subpar. (D) generally. Prior to amendment, subpar. (D) read as follows: "the Chief Medical Director of the Veterans Administration; and".

1992—Pub. L. 102–352 substituted "or management" for "and management" in subsec. (b)(3)(B).

Pub. L. 102–321 amended section generally, substituting provisions relating to appointment of advisory councils to Substance Abuse and Mental Health Services Administration, Center for Substance Abuse Treatment, Center for Substance Abuse Prevention, and Center for Mental Health Services for provisions appointing advisory councils for National Institute on Alcohol Abuse and Alcoholism, National Institute on Drug Abuse, and National Institute of Mental Health.

1990—Subsec. (a)(2). Pub. L. 101–381 made technical amendment to reference to section 300aaa of this title to reflect renumbering of corresponding section of original act.

1988—Subsec. (b)(2)(A). Pub. L. 100–527 substituted "Chief Medical Director of the Department of Veterans Affairs" for "Chief Medical Director of the Veterans' Administration".

STATUTORY NOTES AND RELATED SUBSIDIARIES

EFFECTIVE DATE OF 1992 AMENDMENTS

Amendment by Pub. L. 102–352 effective immediately upon effectuation of amendment made by Pub. L. 102–321, see section 3(1) of Pub. L. 102–352, set out as a note under section 285n of this title.

Amendment by Pub. L. 102–321 effective Oct. 1, 1992, with provision for programs providing financial assistance, see section 801(c), (d) of Pub. L. 102–321, set out as a note under section 236 of this title.

EFFECTIVE DATE OF 1988 AMENDMENT

Amendment by Pub. L. 100–527 effective Mar. 15, 1989, see section 18(a) of Pub. L. 100–527, set out as a Department of Veterans Affairs Act note under section 301 of Title 38, Veterans' Benefits.

TERMINATION OF ADVISORY COUNCILS

Advisory councils established after Jan. 5, 1973, to terminate not later than the expiration of the 2-year period beginning on the date of their establishment, unless, in the case of a council established by the President or an officer of the Federal Government, such council is renewed by appropriate action prior to the expiration of such 2-year period, or in the case of a council established by Congress, its duration is otherwise provided by law. See sections 1001(2) and 1013 of Title 5, Government Organization and Employees.

Pub. L. 93–641, §6, Jan. 4, 1975, 88 Stat. 2275, set out as a note under section 217a of this title, provided

that an advisory committee established pursuant to the Public Health Service Act shall terminate at such time as may be specifically prescribed by an Act of Congress enacted after Jan. 4, 1975.

REFERENCES IN OTHER LAWS TO GS–16, 17, OR 18 PAY RATES

References in laws to the rates of pay for GS–16, 17, or 18, or to maximum rates of pay under the General Schedule, to be considered references to rates payable under specified sections of Title 5, Government Organization and Employees, see section 529 [title I, §101(c)(1)] of Pub. L. 101–509, set out in a note under section 5376 of Title 5.

CONTINUATION OF EXISTING ADVISORY COUNCILS

Pub. L. 99–570, title IV, §4004(b), Oct. 27, 1986, 100 Stat. 3207–111, provided that: "The amendment made by subsection (a) [enacting this section and renumbering this section and section 290aa–5 of this title] does not terminate the membership of any advisory council for the National Institute on Alcohol Abuse and Alcoholism, the National Institute on Drug Abuse, or the National Institute of Mental Health which was in existence on the date of enactment of this Act [Oct. 27, 1986]. After such date—

"(1) the Secretary of Health and Human Services shall make appointments to each such advisory council in such a manner as to bring about as soon as practicable the composition for such council prescribed by section 505 [now 502] of the Public Health Service Act [42 U.S.C. 290aa–1];

"(2) each advisory council shall organize itself in accordance with such section and exercise the functions prescribed by such section; and

"(3) the Director of each such institute shall perform for such advisory council the functions prescribed by such section."

§290aa–2. Omitted

EDITORIAL NOTES

CODIFICATION

Section, act July 1, 1944, ch. 373, title V, §503, formerly §505, as added Pub. L. 98–24, §2(b)(7), Apr. 26, 1983, 97 Stat. 178; renumbered §506, Pub. L. 99–570, title IV, §4004(a), Oct. 27, 1986, 100 Stat. 3207–109; renumbered §503, Pub. L. 102–321, title I, §103, July 10, 1992, 106 Stat. 333, which required the Secretary of Health and Human Services to submit triennial reports to Congress on the health consequences of using alcoholic beverages, the health consequences and extent of drug abuse in the United States, and current research findings made with respect to drug abuse, including current findings on the health effects of marihuana and the addictive property of tobacco, terminated, effective May 15, 2000, pursuant to section 3003 of Pub. L. 104–66, as amended, set out as a note under section 1113 of Title 31, Money and Finance. See, also, pages 92 and 93 of House Document No. 103–7.

Section was formerly classified to section 290aa–4 of this title prior to renumbering by Pub. L. 102–321.

A prior section 290aa–2, act July 1, 1944, ch. 373, title V, §503, formerly Pub. L. 92–255, title IV, §406(a), title V, §501, Mar. 21, 1972, 86 Stat. 78, 85; amended Pub. L. 93–282, title II, §204, May 14, 1974, 88 Stat. 136; Pub. L. 94–237, §12(a), Mar. 19, 1976, 90 Stat. 247; Pub. L. 96–181, §10, Jan. 2, 1980, 93 Stat. 1314; Pub. L. 97–35, title IX, §§968(a), 973(f), Aug. 13, 1981, 95 Stat. 595, 598; renumbered §503 of act July 1, 1944, and amended Apr. 26, 1983, Pub. L. 98–24, §2(b)(4), (5), 97 Stat. 177; Oct. 19, 1984, Pub. L. 98–509, title II, §§202, 205(b)(1), 98 Stat. 2360, 2361; Oct. 27, 1986, Pub. L. 99–570, title IV, §4005(b)(2), 100 Stat. 3207–114, related to National Institute on Drug Abuse, prior to repeal by Pub. L. 102–321, title I, §101(b), July 10, 1992, 106 Stat. 331. See section 285o of this title.

A prior section 503 of act July 1, 1944, which was classified to section 221 of this title, was successively renumbered by subsequent acts and transferred, see section 238b of this title.

§290aa–2a. Report on individuals with co-occurring mental illness and substance abuse disorders

(a) In general

Not later than 2 years after October 17, 2000, the Secretary shall, after consultation with

organizations representing States, mental health and substance abuse treatment providers, prevention specialists, individuals receiving treatment services, and family members of such individuals, prepare and submit to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Commerce of the House of Representatives, a report on prevention and treatment services for individuals who have co-occurring mental illness and substance abuse disorders.

(b) Report content

The report under subsection (a) shall be based on data collected from existing Federal and State surveys regarding the treatment of co-occurring mental illness and substance abuse disorders and shall include—

(1) a summary of the manner in which individuals with co-occurring disorders are receiving treatment, including the most up-to-date information available regarding the number of children and adults with co-occurring mental illness and substance abuse disorders and the manner in which funds provided under sections 300x and 300x–21 of this title are being utilized, including the number of such children and adults served with such funds;

(2) a summary of improvements necessary to ensure that individuals with co-occurring mental illness and substance abuse disorders receive the services they need;

(3) a summary of practices for preventing substance abuse among individuals who have a mental illness and are at risk of having or acquiring a substance abuse disorder; and

(4) a summary of evidenced-based practices for treating individuals with co-occurring mental illness and substance abuse disorders and recommendations for implementing such practices.

(c) Funds for report

The Secretary may obligate funds to carry out this section with such appropriations as are available.

(July 1, 1944, ch. 373, title V, §503A, as added Pub. L. 106–310, div. B, title XXXIV, §3406, Oct. 17, 2000, 114 Stat. 1221.)

STATUTORY NOTES AND RELATED SUBSIDIARIES

CHANGE OF NAME

Committee on Commerce of House of Representatives changed to Committee on Energy and Commerce of House of Representatives, and jurisdiction over matters relating to securities and exchanges and insurance generally transferred to Committee on Financial Services of House of Representatives by House Resolution No. 5, One Hundred Seventh Congress, Jan. 3, 2001.

§290aa–3. Peer review

(a) In general

The Secretary, after consultation with the Assistant Secretary, shall require appropriate peer review of grants, cooperative agreements, and contracts to be administered through the agency which exceed the simple acquisition threshold as defined in section 134 of title 41.

(b) Members

The members of any peer review group established under subsection (a) shall be individuals who by virtue of their training or experience are eminently qualified to perform the review functions of the group. Not more than one-fourth of the members of any such peer review group shall be officers or employees of the United States. In the case of any such peer review group that is reviewing a grant, cooperative agreement, or contract related to mental illness treatment, not less than half of the members of such peer review group shall be licensed and experienced professionals in the prevention, diagnosis, or treatment of, or recovery from, mental illness or co-occurring mental illness and substance use disorders and have a medical degree, a doctoral degree in psychology, or an advanced degree in nursing or social work from an accredited program, and the Secretary, in

consultation with the Assistant Secretary, shall, to the extent possible, ensure such peer review groups include broad geographic representation, including both urban and rural representatives.

(c) Advisory council review

If the direct cost of a grant or cooperative agreement (described in subsection (a)) exceeds the simple acquisition threshold as defined by section 134 of title 41, the Secretary may make such a grant or cooperative agreement only if such grant or cooperative agreement is recommended—

(1) after peer review required under subsection (a); and

(2) by the appropriate advisory council.

(d) Conditions

The Secretary may establish limited exceptions to the limitations contained in this section regarding participation of Federal employees and advisory council approval. The circumstances under which the Secretary may make such an exception shall be made public.

(July 1, 1944, ch. 373, title V, §504, formerly §506, as added Pub. L. 98–24, §2(b)(7), Apr. 26, 1983, 97 Stat. 178; amended Pub. L. 99–158, §3(c), Nov. 20, 1985, 99 Stat. 879; renumbered §507 and amended Pub. L. 99–570, title IV, §§4004(a), 4007, Oct. 27, 1986, 100 Stat. 3207–109, 3207–115; renumbered §504 and amended Pub. L. 102–321, title I, §104, July 10, 1992, 106 Stat. 333; Pub. L. 102–352, §2(a)(7), Aug. 26, 1992, 106 Stat. 938; Pub. L. 105–392, title IV, §412, Nov. 13, 1998, 112 Stat. 3590; Pub. L. 106–310, div. B, title XXXIV, §3401(b), Oct. 17, 2000, 114 Stat. 1218; Pub. L. 114–255, div. B, title VI, §§6001(c)(2), 6009, Dec. 13, 2016, 130 Stat. 1203, 1215.)

EDITORIAL NOTES

CODIFICATION

In subsecs. (a) and (c), "section 134 of title 41" substituted for "section 4(11) of the Office of Federal Procurement Policy Act" on authority of Pub. L. 111–350, §6(c), Jan. 4, 2011, 124 Stat. 3854, which Act enacted Title 41, Public Contracts.

Section was formerly classified to section 290aa–5 of this title prior to renumbering by Pub. L. 102–321.

PRIOR PROVISIONS

A prior section 290aa–3, act July 1, 1944, ch. 373, title V, §504, formerly title IV, §455, as added May 14, 1974, Pub. L. 93–282, title II, §202, 88 Stat. 135; amended Oct. 7, 1980, Pub. L. 96–398, title III, §325, title IV, §401(a), title VIII, §804(a), 94 Stat. 1596, 1597, 1608; Aug. 13, 1981, Pub. L. 97–35, title IX, §902(g)(1), 95 Stat. 560; renumbered title V, §504, Apr. 26, 1983, Pub. L. 98–24, §2(b)(6), 97 Stat. 177; Oct. 19, 1984, Pub. L. 98–509, title II, §§203, 204, 98 Stat. 2360, 2361; Oct. 7, 1985, Pub. L. 99–117, §11(b), 99 Stat. 495; Oct. 27, 1986, Pub. L. 99–570, title IV, §§4011(a), 4012, 4013, 4021(a), (b)(1), 100 Stat. 3207–115, 3207–116, 3207–124; Nov. 14, 1986, Pub. L. 99–660, title V, §504, 100 Stat. 3797; Nov. 18, 1988, Pub. L. 100–690, title II, §2057(1), (2), 102 Stat. 4211, related to National Institute of Mental Health, prior to repeal by Pub. L. 102–321, title I, §101(b), July 10, 1992, 106 Stat. 331. See section 285p of this title.

A prior section 504 of act July 1, 1944, which was classified to section 222 of this title, was renumbered section 2104 of act July 1, 1944, by Pub. L. 98–24 and transferred to section 300aa–3 of this title, renumbered section 2304 of act July 1, 1944, by Pub. L. 99–660 and transferred to section 300cc–3 of this title, prior to repeal by Pub. L. 98–621, §10(s), Nov. 8, 1984, 98 Stat. 3381.

AMENDMENTS

2016—Subsec. (a). Pub. L. 114–255, §6001(c)(2), substituted "Assistant Secretary" for "Administrator".

Subsec. (b). Pub. L. 114–255, §6009, inserted at end: "In the case of any such peer review group that is reviewing a grant, cooperative agreement, or contract related to mental illness treatment, not less than half of the members of such peer review group shall be licensed and experienced professionals in the prevention, diagnosis, or treatment of, or recovery from, mental illness or co-occurring mental illness and substance use disorders and have a medical degree, a doctoral degree in psychology, or an advanced degree in nursing or social work from an accredited program, and the Secretary, in consultation with the Assistant Secretary, shall, to the extent possible, ensure such peer review groups include broad geographic representation, including both urban and rural representatives."

2000—Pub. L. 106–310 reenacted section catchline without change and amended text generally, substituting, in subsec. (a), provisions requiring, after consultation with the Administrator of the Substance

Abuse and Mental Health Services Administration, appropriate peer review of grants, cooperative agreements, and contracts to be administered through the agency that exceed the simple acquisition threshold as defined in section 403 of title 41 for provisions requiring such peer review after consultation with the Directors of the Center for Substance Abuse Treatment, the Center for Substance Abuse Prevention, and the Center for Mental Health Services, in subsec. (b), provisions relating to members of peer groups qualified to perform review functions under subsec. (a) for similar provisions in former subsec. (b) but which included reference to regulatory establishment of such groups, in subsec. (c), provisions relating to advisory council review for provisions relating to requirements and specification of regulations promulgated under subsec. (a), and in subsec. (d), provisions relating to Secretary's authority to establish exceptions to the limitations in section regarding participation of Federal employees and advisory council approval for provisions relating to recommendations.

1998—Subsec. (d)(2). Pub. L. 105–392 substituted "or cooperative agreement" for "cooperative agreement, or contract" wherever appearing in introductory provisions.

1992—Pub. L. 102–352 struck out "by regulation" after "Center for Mental Health Services, shall" in subsec. (a).

Pub. L. 102–321 amended section generally, substituting provisions relating to peer review of grants, cooperative agreements, and contracts administered through the Centers for Substance Abuse Treatment, Substance Abuse Prevention, and Mental Health Services for provisions relating to peer review of biomedical and behavioral research and development grants, cooperative agreements, and contracts administered through the National Institutes of Mental Health, Alcohol Abuse and Alcoholism, and Drug Abuse.

1986—Subsec. (b). Pub. L. 99–570, §4007, inserted "applications made for" before "grants, cooperative" in introductory text.

1985—Subsec. (e). Pub. L. 99–158 added subsec. (e).

STATUTORY NOTES AND RELATED SUBSIDIARIES

EFFECTIVE DATE OF 1992 AMENDMENTS

Amendment by Pub. L. 102–352 effective immediately upon effectuation of amendment made by Pub. L. 102–321, see section 3(1) of Pub. L. 102–352, set out as a note under section 285n of this title.

Amendment by Pub. L. 102–321 effective Oct. 1, 1992, with provision for programs providing financial assistance, see section 801(c), (d) of Pub. L. 102–321, set out as a note under section 236 of this title.

§290aa–3a. Transferred

EDITORIAL NOTES

CODIFICATION

Section, act July 1, 1944, ch. 373, title V, §505, as added Oct. 27, 1986, Pub. L. 99–570, title IV, §4004(a), 100 Stat. 3207–109, and amended, which related to advisory councils for the National Institute on Alcohol Abuse and Alcoholism, the National Institute on Drug Abuse, and the National Institute of Mental Health, was renumbered section 502 of act July 1, 1944, by Pub. L. 102–321, title I, §102(1), July 10, 1992, 106 Stat. 331, and transferred to section 290aa–1 of this title.

§290aa–4. Center for behavioral health statistics and quality

(a) In general

The Assistant Secretary shall maintain within the Administration a Center for Behavioral Health Statistics and Quality (in this section referred to as the "Center"). The Center shall be headed by a Director (in this section referred to as the "Director") appointed by the Secretary from among individuals with extensive experience and academic qualifications in research and analysis in behavioral health care or related fields.

(b) Requirement of annual collection of data on mental illness and substance abuse

The Director shall—

(1) coordinate the Administration's integrated data strategy, including by collecting data each year on—

(A) the national incidence and prevalence of the various forms of mental illness and substance abuse; and

(B) the incidence and prevalence of such various forms in major metropolitan areas selected by the Director.

(2) provide statistical and analytical support for activities of the Administration;

(3) recommend a core set of performance metrics to evaluate activities supported by the Administration; and

(4) coordinate with the Assistant Secretary, the Assistant Secretary for Planning and Evaluation, and the Chief Medical Officer appointed under section 290aa(g) of this title, as appropriate, to improve the quality of services provided by programs of the Administration and the evaluation of activities carried out by the Administration.

(c) Mental health

With respect to the activities of the Director under subsection (b)(1) relating to mental health, the Director shall ensure that such activities include, at a minimum, the collection of data on—

(1) the number and variety of public and nonprofit private treatment programs;

(2) the number and demographic characteristics of individuals receiving treatment through such programs;

(3) the type of care received by such individuals; and

(4) such other data as may be appropriate.

(d) Substance abuse

(1) In general

With respect to the activities of the Director under subsection (b)(1) relating to substance abuse, the Director shall ensure that such activities include, at a minimum, the collection of data on—

(A) the number of individuals admitted to the emergency rooms of hospitals as a result of the abuse of alcohol or other drugs;

(B) the number of deaths occurring as a result of substance abuse, as indicated in reports by coroners in coordination with the Centers for Disease Control and Prevention;

(C) the number and variety of public and private nonprofit treatment programs, including the number and type of patient slots available;

(D) the number of individuals seeking treatment through such programs, the number and demographic characteristics of individuals receiving such treatment, the percentage of individuals who complete such programs, and, with respect to individuals receiving such treatment, the length of time between an individual's request for treatment and the commencement of treatment;

(E) the number of such individuals who return for treatment after the completion of a prior treatment in such programs and the method of treatment utilized during the prior treatment;

(F) the number of individuals receiving public assistance for such treatment programs;

(G) the costs of the different types of treatment modalities for drug and alcohol abuse and the aggregate relative costs of each such treatment modality provided within a State in each fiscal year;

(H) to the extent of available information, the number of individuals receiving treatment for alcohol or drug abuse who have private insurance coverage for the costs of such treatment;

(I) the extent of alcohol and drug abuse among high school students and among the general population; and

(J) the number of alcohol and drug abuse counselors and other substance abuse treatment personnel employed in public and private treatment facilities.

(2) Annual surveys; public availability of data

Annual surveys shall be carried out in the collection of data under this subsection. Summaries and analyses of the data collected shall be made available to the public.

(e) Consultation

After consultation with the States and with appropriate national organizations, the Assistant Secretary shall use existing standards and best practices to develop uniform criteria for the collection of data, using the best available technology, pursuant to this section.

(July 1, 1944, ch. 373, title V, §505, formerly §509D, as added Pub. L. 100–690, title II, §2052(a), Nov. 18, 1988, 102 Stat. 4207; amended Pub. L. 101–93, §3(b), Aug. 16, 1989, 103 Stat. 609; renumbered §505, Pub. L. 102–321, title I, §105, July 10, 1992, 106 Stat. 334; Pub. L. 103–43, title XX, §2010(b)(7), June 10, 1993, 107 Stat. 214; Pub. L. 114–255, div. B, title VI, §§6001(c)(2), 6004, Dec. 13, 2016, 130 Stat. 1203, 1207.)

EDITORIAL NOTES

CODIFICATION

Section was formerly classified to section 290aa–11 of this title prior to renumbering by Pub. L. 102–321.

PRIOR PROVISIONS

A prior section 290aa–4, act July 1, 1944, ch. 373, title V, §506, formerly §505, as added Apr. 26, 1983, Pub. L. 98–24, §2(b)(7), 97 Stat. 178; renumbered §506, Oct. 27, 1986, Pub. L. 99–570, title IV, §4004(a), 100 Stat. 3207–109, which related to reports on alcoholism and alcohol and drug abuse, was renumbered section 503 of act July 1, 1944, by Pub. L. 102–321 and transferred to section 290aa–2 of this title.

A prior section 505 of act July 1, 1944, was renumbered section 502 by section 102 of Pub. L. 102–321 and is classified to section 290aa–1 of this title.

Another prior section 505 of act July 1, 1944, which was classified to section 223 of this title, was renumbered section 2105 of act July 1, 1944, by Pub. L. 98–24 and transferred to section 300aa–4 of this title, renumbered section 2305 of act July 1, 1944, by Pub. L. 99–660 and transferred to section 300cc–4 of this title, prior to repeal by Pub. L. 99–117, §12(f), Oct. 7, 1985, 99 Stat. 495.

AMENDMENTS

2016—Pub. L. 114–255, §6004(1), substituted "Center for behavioral health statistics and quality" for "Data collection" in section catchline.

Subsec. (a). Pub. L. 114–255, §6004(3), added subsec. (a). Former subsec. (a) redesignated (b).

Pub. L. 114–255, §6001(c)(2), substituted "Assistant Secretary" for "Administrator" in introductory provisions and in par. (2).

Subsec. (b). Pub. L. 114–255, §6004(4), substituted "The Director shall—" for "The Secretary, acting through the Assistant Secretary, shall collect data each year on—", added par. (1), redesignated former pars. (1) and (2) as subpars. (A) and (B) of par. (1), respectively, substituted "Director" for "Assistant Secretary" in subpar. (B), and added pars. (2) to (4).

Pub. L. 114–255, §6004(2), redesignated subsec. (a) as (b). Former subsec. (b) redesignated (c).

Pub. L. 114–255, §6001(c)(2), substituted "Assistant Secretary" for "Administrator" in two places in introductory provisions.

Subsec. (c). Pub. L. 114–255, §6004(5), inserted heading and in introductory provisions substituted "subsection (b)(1)" for "subsection (a)" and "Director" for "Assistant Secretary" in two places.

Pub. L. 114–255, §6004(2), redesignated subsec. (b) as (c). Former subsec. (c) redesignated (d).

Subsec. (c)(1). Pub. L. 114–255, §6001(c)(2), substituted "Assistant Secretary" for "Administrator" in two places in introductory provisions.

Subsec. (d). Pub. L. 114–255, §6004(6), inserted heading, in par. (1) inserted heading and in introductory provisions substituted "subsection (b)(1)" for "subsection (a)" and "Director" for "Assistant Secretary" in two places, in par. (1)(B) inserted "in coordination with the Centers for Disease Control and Prevention" before semicolon at end, and in par. (2) inserted heading.

Pub. L. 114–255, §6004(2), redesignated subsec. (c) as (d). Former subsec. (d) redesignated (e)

Pub. L. 114–255, §6001(c)(2), substituted "Assistant Secretary" for "Administrator".

Subsec. (e). Pub. L. 114–255, §6004(7), inserted heading and substituted "Assistant Secretary shall use existing standards and best practices to develop" for "Assistant Secretary shall develop".

Pub. L. 114–255, §6004(2), redesignated subsec. (d) as (e).

1993—Pub. L. 103–43, §2010(b)(7), which directed the substitution of "section 238 of this title" for "section 300aaa of this title" in section 505(a)(2) of act July 1, 1944 (this section), could not be executed because the language did not appear. Amendment was probably intended for prior section 505 which was renumbered section 502 and amended generally by Pub. L. 102–321, §102, which is classified to section 290aa–1 of this title.

1989—Subsec. (c)(1)(A). Pub. L. 101–93, §3(b)(1), substituted "alcohol or" for "alcohol and".

Subsec. (c)(2). Pub. L. 101–93, §3(b)(2), substituted "this subsection" for "this section".

STATUTORY NOTES AND RELATED SUBSIDIARIES

NATIONAL SURVEY ON DRUG USE AND HEALTH

Pub. L. 108–358, §5, Oct. 22, 2004, 118 Stat. 1664, provided that:

"(a) IN GENERAL.—The Secretary of Health and Human Services shall ensure that the National Survey on Drug Use and Health includes questions concerning the use of anabolic steroids.

"(b) AUTHORIZATION OF APPROPRIATIONS.—There is authorized to be appropriated to carry out this section, $1,000,000 for each of fiscal years 2005 through 2010."

REPORTS ON CONSUMPTION OF METHAMPHETAMINE AND OTHER ILLICIT DRUGS

Pub. L. 106–310, div. B, title XXXVI, §3641, Oct. 17, 2000, 114 Stat. 1237, provided that: "The Secretary of Health and Human Services shall include in each National Household Survey on Drug Abuse appropriate prevalence data and information on the consumption of methamphetamine and other illicit drugs in rural areas, metropolitan areas, and consolidated metropolitan areas."

PUBLIC HEALTH MONITORING OF METHAMPHETAMINE ABUSE

Pub. L. 104–237, title V, §502, Oct. 3, 1996, 110 Stat. 3112, provided that: "The Secretary of Health and Human Services shall develop a public health monitoring program to monitor methamphetamine abuse in the United States. The program shall include the collection and dissemination of data related to methamphetamine abuse which can be used by public health officials in policy development."

§290aa–5. Grants for the benefit of homeless individuals

(a) In general

The Secretary shall award grants, contracts and cooperative agreements to community-based public and private nonprofit entities for the purposes of providing mental health and substance use disorder services for homeless individuals. In carrying out this section, the Secretary shall consult with the Interagency Council on the Homeless [1], established under section 11311 of this title.

(b) Preferences

In awarding grants, contracts, and cooperative agreements under subsection (a), the Secretary shall give a preference to—

(1) entities that provide integrated primary health, substance use disorder, and mental health services to homeless individuals;

(2) entities that demonstrate effectiveness in serving runaway, homeless, and street youth;

(3) entities that have experience in providing substance use disorder and mental health services to homeless individuals;

(4) entities that demonstrate experience in providing housing for individuals in treatment for or in recovery from mental illness or a substance use disorder; and

(5) entities that demonstrate effectiveness in serving homeless veterans.

(c) Services for certain individuals

In awarding grants, contracts, and cooperative agreements under subsection (a), the Secretary shall not—

(1) prohibit the provision of services under such subsection to homeless individuals who are suffering from a substance use disorder and are not suffering from a mental health disorder; and

(2) make payments under subsection (a) to any entity that has a policy of—

(A) excluding individuals from mental health services due to the existence or suspicion of a substance use disorder; or

(B) has a policy of excluding individuals from substance use disorder services due to the existence or suspicion of mental illness.

(d) Term of the awards

No entity may receive a grant, contract, or cooperative agreement under subsection (a) for more than 5 years.

(e) Authorization of appropriations

There is authorized to be appropriated to carry out this section $41,304,000 for each of fiscal years 2023 through 2027.

(July 1, 1944, ch. 373, title V, §506, formerly §512, as added Pub. L. 98–509, title II, §206(a), Oct. 19, 1984, 98 Stat. 2361; amended Pub. L. 100–77, title VI, §613(a), (b), July 22, 1987, 101 Stat. 524; renumbered §506 and amended Pub. L. 102–321, title I, §106, July 10, 1992, 106 Stat. 334; Pub. L. 106–310, div. B, title XXXII, §3202, Oct. 17, 2000, 114 Stat. 1190; Pub. L. 106–400, §2, Oct. 30, 2000, 114 Stat. 1675; Pub. L. 114–255, div. B, title IX, §9001, Dec. 13, 2016, 130 Stat. 1234; Pub. L. 117–328, div. FF, title I, §1211, Dec. 29, 2022, 136 Stat. 5661.)

EDITORIAL NOTES

CODIFICATION

Section was formerly classified to section 290bb–1a of this title prior to renumbering by Pub. L. 102–321.

PRIOR PROVISIONS

A prior section 290aa–5, act July 1, 1944, ch. 373, title V, §507, formerly §506, as added Apr. 26, 1983, Pub. L. 98–24, §2(b)(7), 97 Stat. 178; amended Nov. 20, 1985, Pub. L. 99–158, §3(c), 99 Stat. 879; renumbered §507 and amended Oct. 27, 1986, Pub. L. 99–570, title IV, §§4004(a), 4007, 100 Stat. 3207–109, 3207–115, which related to peer review of biomedical and behavioral research and development grants, was renumbered section 504 of act July 1, 1944, by Pub. L. 102–321 and transferred to section 290aa–3 of this title.

A prior section 506 of act July 1, 1944, which was classified to section 224 of this title, was successively renumbered by subsequent acts, and transferred, see section 238c of this title.

AMENDMENTS

2022—Subsec. (e). Pub. L. 117–328 substituted "2023 through 2027" for "2018 through 2022".

2016—Subsec. (a). Pub. L. 114–255, §9001(1), substituted "substance use disorder" for "substance abuse".

Subsec. (b)(1), (3). Pub. L. 114–255, §9001(2)(A), substituted "substance use disorder" for "substance abuse".

Subsec. (b)(4). Pub. L. 114–255, §9001(2)(B), substituted "a substance use disorder" for "substance abuse".

Subsec. (c)(1). Pub. L. 114–255, §9001(3)(A), substituted "substance use disorder" for "substance abuse disorder".

Subsec. (c)(2)(A). Pub. L. 114–255, §9001(3)(B)(i), substituted "a substance use disorder" for "substance abuse".

Subsec. (c)(2)(B). Pub. L. 114–255, §9001(3)(B)(ii), substituted "substance use disorder" for "substance abuse".

Subsec. (e). Pub. L. 114–255, §9001(4), substituted "$41,304,000 for each of fiscal years 2018 through 2022" for ", $50,000,000 for fiscal year 2001, and such sums as may be necessary for each of the fiscal years 2002 and 2003".

2000—Pub. L. 106–310 amended section catchline and text generally, substituting present provisions for provisions, in subsec. (a), authorizing Secretary to make grants for benefit of homeless individuals through the Administrator of Substance Abuse and Mental Health Services Administration, in subsec. (b), relating to preferences for grants to entities providing integrated primary health, substance abuse, and mental health services, in subsec. (c), relating to services for certain individuals, in subsec. (d), relating to 5-year grants with renewals, and in subsec. (e), authorizing appropriations for fiscal years 1993 and 1994.

Subsec. (a). Pub. L. 106–400 made technical amendment to reference in original act which appears in text as reference to section 11311 of this title.

1992—Pub. L. 102–321 amended section generally, substituting provisions relating to grants for benefit of homeless individuals for provisions relating to alcohol abuse and alcoholism demonstration projects.

1987—Subsecs. (c), (d). Pub. L. 100–77 added subsec. (c), redesignated former subsec. (c) as (d), and substituted "subsection (a) or (c)" for "subsection (a)".

STATUTORY NOTES AND RELATED SUBSIDIARIES

CHANGE OF NAME

Interagency Council on the Homeless changed to United States Interagency Council on Homelessness by Pub. L. 108–199, div. G, title II, §216, Jan. 23, 2004, 118 Stat. 394.

EFFECTIVE DATE OF 1992 AMENDMENT

Amendment by Pub. L. 102–321 effective Oct. 1, 1992, with provision for programs providing financial assistance, see section 801(c), (d) of Pub. L. 102–321, set out as a note under section 236 of this title.

[1] *See Change of Name note below.*

§290aa–5a. Behavioral health and substance use disorder resources for Native Americans

(a) Definitions

In this section:

(1) The term "eligible entity" means any health program administered directly by the Indian Health Service, a Tribal health program, an Indian Tribe, a Tribal organization, an Urban Indian organization, and a Native Hawaiian health organization.

(2) The terms "Indian Tribe", "Tribal health program", "Tribal organization", and "Urban Indian organization" have the meanings given to the terms "Indian tribe", "Tribal [1] health program", "tribal organization", and "Urban Indian organization" in section 1603 of title 25.

(3) The term "health program administered directly by the Indian Health Service" means a "health program administered by the Service" [2] as such term is used in section 1603(12)(A) of title 25.

(4) The term "Native Hawaiian health organization" means "Papa Ola Lokahi" as defined in section 11711 of this title.

(b) Grant program

(1) In general

The Secretary, acting through the Assistant Secretary for Mental Health and Substance Use, and in consultation with the Director of the Indian Health Service, as appropriate, shall award funds to eligible entities, in amounts developed in accordance with paragraph (2), to be used by the eligible entity to provide services for the prevention of, treatment of, and recovery from mental health and substance use disorders among American Indians, Alaska Natives, and Native Hawaiians.

(2) Formula

The Secretary, in consultation with the Director of the Indian Health Service, using the process described in subsection (d), shall develop a formula to determine the amount of an award under paragraph (1).

(3) Delivery of funds

On request from an Indian Tribe or Tribal organization, the Secretary, acting through the Assistant Secretary for Mental Health and Substance Use and in coordination with the Director of the Indian Health Service, may award funds under this section through a contract or compact under, as applicable, title I or V of the Indian Self-Determination and Education Assistance Act.

(c) Technical assistance and program evaluation

(1) In general

The Secretary shall—

(A) provide technical assistance to applicants and awardees under this section; and

(B) in consultation with Indian Tribes and Tribal organizations, conference with Urban Indian organizations, and engagement with a Native Hawaiian health organization, identify and establish appropriate mechanisms for Indian Tribes and Tribal organizations, Urban Indian organizations, and a Native Hawaiian health organization to demonstrate outcomes and report data as required for participation in the program under this section.

(2) Data submission and reporting

As a condition of receipt of funds under this section, an applicant shall agree to submit program evaluation data and reports consistent with the data submission and reporting requirements developed under this subsection.

(d) Consultation

The Secretary shall, using an accountable process, consult with Indian Tribes and Tribal organizations, confer with Urban Indian organizations, and engage with a Native Hawaiian health organization regarding the development of funding allocations pursuant to subsection (b)(2) and program evaluation and reporting requirements pursuant to subsection (c). In establishing such requirements, the Secretary shall seek to minimize administrative burden for eligible entities, as practicable.

(e) Application

An entity desiring an award under subsection (b) shall submit an application to the Secretary at such time, in such manner, and accompanied by such information as the Secretary may reasonably require.

(f) Report

Not later than 3 years after December 29, 2022, the Secretary shall prepare and submit, to the Committee on Health, Education, Labor, and Pensions of the Senate, and the Committee on Energy and Commerce of the House of Representatives, a report describing the services provided pursuant to this section.

(g) Authorization of appropriations

There are authorized to be appropriated to carry out this section, $80,000,000 for each of fiscal years 2023 through 2027.

(July 1, 1944, ch. 373, title V, §506A, as added Pub. L. 106–310, div. B, title XXXIII, §3306, Oct. 17, 2000, 114 Stat. 1215; amended Pub. L. 117–328, div. FF, title I, §1201, Dec. 29, 2022, 136 Stat. 5659.)

EDITORIAL NOTES

REFERENCES IN TEXT

The Indian Self-Determination and Education Assistance Act, referred to in subsec. (b)(3), is Pub. L. 93–638, Jan. 4, 1975, 88 Stat. 2203. Title I of the Act, also known as the Indian Self-Determination Act, is classified principally to subchapter I (§5321 et seq.) of chapter 46 of Title 25, Indians. Title V of the Act is classified generally to subchapter V (§5381 et seq.) of such chapter. For complete classification of this Act to the Code, see section 1 of Pub. L. 93–638, set out as a Short Title note under section 5301 of Title 25 and Tables.

AMENDMENTS

2022—Pub. L. 117–328 amended section generally. Prior to amendment, section related to alcohol and drug prevention or treatment services for Indians and Native Alaskans.

[1] *So in original. Probably should be "tribal".*

[2] *So in original. Probably should be " 'health program administered directly by the Service' ".*

§290aa–5b. Repealed. Pub. L. 114–255, div. B, title IX, §9017, Dec. 13, 2016, 130 Stat. 1248

Section, act July 1, 1944, ch. 373, title V, §506B, as added Pub. L. 106–310, div. B, title XXXVI, §3665(a), Oct. 17, 2000, 114 Stat. 1244, related to grants for ecstasy and other club drugs abuse prevention.

§§290aa–6 to 290aa–8. Transferred

EDITORIAL NOTES

CODIFICATION

Section 290aa–6, act July 1, 1944, ch. 373, title V, §508, as added Oct. 27, 1986, Pub. L. 99–570, title IV, §4005(a), 100 Stat. 3207–111, and amended, which related to the Office of Substance Abuse Prevention, was renumbered section 515 of act July 1, 1944, by Pub. L. 102–321, title I, §113(b), July 10, 1992, 106 Stat. 345, and transferred to section 290bb–21 of this title.

Section 290aa–7, act July 1, 1944, ch. 373, title V, §509, as added Oct. 27, 1986, Pub. L. 99–570, title IV, §4005(a), 100 Stat. 3207–112, which related to Alcohol and Drug Abuse Information Clearinghouse, was renumbered section 516 of act July 1, 1944, by Pub. L. 102–321, title I, §113(f)(1)–(3), July 10, 1992, 106 Stat. 345, and transferred to section 290bb–22 of this title.

Section 290aa–8, act July 1, 1944, ch. 373, title V, §509A, as added Oct. 27, 1986, Pub. L. 99–570, title IV, §4005(a), 100 Stat. 3207–113, and amended, which related to alcohol and drug abuse prevention, treatment, and rehabilitation model projects for high risk youth, was renumbered section 517 of act July 1, 1944, by Pub. L. 102–321, title I, §114(a), July 10, 1992, 106 Stat. 346, transferred to section 290bb–23 of this title, and repealed by Pub. L. 114–255, div. B, title IX, §9017, Dec. 13, 2016, 130 Stat. 1248.

§§290aa–9, 290aa–10. Repealed. Pub. L. 102–321, title I, §120(a), July 10, 1992, 106 Stat. 358

Section 290aa–9, act July 1, 1944, ch. 373, title V, §509B, as added Oct. 27, 1986, Pub. L. 99–570, title IV, §4006, 100 Stat. 3207–114; amended Oct. 27, 1992, Pub. L. 102–531, title III, §312(d)(11), 106 Stat. 3505, related to research on public health emergencies.

Section 290aa–10, act July 1, 1944, ch. 373, title V, §509C, as added Oct. 27, 1986, Pub. L. 99–570, title IV, §420 [4020], 100 Stat. 3207–122, related to guidelines for use of animals in research.

STATUTORY NOTES AND RELATED SUBSIDIARIES

EFFECTIVE DATE OF REPEAL

Repeal effective Oct. 1, 1992, with provision for programs providing financial assistance, see section 801(c), (d) of Pub. L. 102–321, set out as an Effective Date of 1992 Amendment note under section 236 of this title.

§290aa–11. Transferred

EDITORIAL NOTES

CODIFICATION

Section, act July 1, 1944, ch. 373, title V, §509D, as added Nov. 18, 1988, Pub. L. 100–690, title II, §2052(a), 102 Stat. 4207, and amended, which related to the collection of data on mental illness and substance abuse, was renumbered section 505 of act July 1, 1944, by Pub. L. 102–321, title I, §105, July 10, 1992, 106 Stat. 334, and transferred to section 290aa–4 of this title.

§§290aa–12 to 290aa–14. Repealed. Pub. L. 102–321, title I, §120(a), July 10, 1992, 106 Stat. 358

Section 290aa–12, act July 1, 1944, ch. 373, title V, §509E, as added Nov. 18, 1988, Pub. L. 100–690, title II, §2053, 102 Stat. 4208; amended Aug. 16, 1989, Pub. L. 101–93, §3(c), 103 Stat. 610; Aug. 15, 1990, Pub. L. 101–374, §2(a)–(c)(2), 104 Stat. 456, related to reduction of waiting periods for drug abuse treatment.

Section 290aa–13, act July 1, 1944, ch. 373, title V, §509F, as added Nov. 18, 1988, Pub. L. 100–690, title II, §2054, 102 Stat. 4209, related to model projects for pregnant and post partum women and their infants.

Section 290aa–14, act July 1, 1944, ch. 373, title V, §509G, as added Nov. 18, 1988, Pub. L. 100–690, title II, §2055, 102 Stat. 4210; amended Aug. 16, 1989, Pub. L. 101–93, §3(d), 103 Stat. 610, related to drug abuse demonstration projects of national significance.

STATUTORY NOTES AND RELATED SUBSIDIARIES

EFFECTIVE DATE OF REPEAL

Repeal effective Oct. 1, 1992, with provision for programs providing financial assistance, see section 801(c), (d) of Pub. L. 102–321, set out as an Effective Date of 1992 Amendment note under section 236 of this title.

§290aa–15. Department of Health and Human Services grant accountability

(1) Definitions

In this section:

(A) Applicable committees

The term "applicable committees" means—

(i) the Committee on Health, Education, Labor and Pensions of the Senate; and

(ii) the Committee on Energy and Commerce of the House of Representatives.

(B) Covered grant

The term "covered grant" means a grant awarded by the Secretary under a program established under this Act (or an amendment made by this Act, other than sections 703 through 707), including any grant administered by the Administrator of the Substance Abuse and Mental Health Services Administration under section 1536 of title 21.

(C) Grantee

The term "grantee" means the recipient of a covered grant.

(D) Secretary

The term "Secretary" means the Secretary of Health and Human Services.

(2) Accountability measures

Each covered grant shall be subject to the following accountability requirements:

(A) Effectiveness report

The Secretary shall require grantees to report on the effectiveness of the activities carried out with amounts made available to carry out the program under which the covered grant is awarded,

including the number of persons served by such grant, if applicable, the number of persons seeking services who could not be served by such grant, and such other information as the Secretary may prescribe.

(B) Report on prevention of fraud, waste, and abuse

(i) In general

Not later than 1 year after July 22, 2016, the Secretary, in coordination with the Inspector General of the Department of Health and Human Services, shall submit to the applicable committees a report on the policies and procedures the Department has in place to prevent waste, fraud, and abuse in the administration of covered grants.

(ii) Contents

The policies and procedures referred to in clause (i) shall include policies and procedures that are designed to—

(I) prevent grantees from utilizing funds awarded through a covered grant for unauthorized expenditures or otherwise unallowable costs; and

(II) ensure grantees will not receive unwarranted duplicate grants for the same purpose.

(C) Conference expenditures

(i) In general

No amounts made available to the Secretary under this Act (or in a provision of law amended by this Act, other than sections 703 through 707) may be used by the Secretary, or by any individual or entity awarded discretionary funds through a cooperative agreement under a program established under this Act (or in a provision of law amended by this Act), to host or support any expenditure for conferences that uses more than $20,000 in funds made available by the Secretary, unless the head of the relevant operating division or program office provides prior written authorization that the funds may be expended to host or support the conference. Such written authorization shall include a written estimate of all costs associated with the conference, including the cost of all food, beverages, audio-visual equipment, honoraria for speakers, and entertainment.

(ii) Report

The Secretary (or the Secretary's designee) shall submit to the applicable committees an annual report on all conference expenditures approved by the Secretary under this subparagraph.

(Pub. L. 114–198, title VII, §701(c), July 22, 2016, 130 Stat. 738.)

EDITORIAL NOTES

REFERENCES IN TEXT

This Act, referred to in pars. (1)(B) and (2)(C)(i), is Pub. L. 114–198, July 22, 2016, 130 Stat. 695, known as the Comprehensive Addiction and Recovery Act of 2016. Section 703 of the Act is not classified to the Code, and sections 704 to 707 of the Act enacted section 1320a–7n of this title, amended sections 1395w–101, 1395w–104, 1395w–152, 1395ddd, 1395iii, 1396a, 1396r–8, 1396w–1, and 1397bb of this title, and enacted provisions set out as notes under sections 1395w–101 and 1396r–8 of this title. For complete classification of this Act to the Code, see Short Title of 2016 Amendment note set out under section 201 of this title and Tables.

CODIFICATION

Section was enacted as part of the Comprehensive Addiction and Recovery Act of 2016, and not as part of the Public Health Service Act which comprises this chapter.

STATUTORY NOTES AND RELATED SUBSIDIARIES

ADDITIONAL REPORT

Pub. L. 114–198, title VII, §701(e), July 22, 2016, 130 Stat. 740, provided that: "In the case of a report submitted under subsection (c) [enacting this section] to the applicable committees, if such report pertains to a grant under section 103 [21 U.S.C. 1536], that report shall also be submitted, in the same manner and at the same time, to the Committee on Oversight and Government Reform [now Committee on Oversight and Accountability] of the House of Representatives and to the Committee on the Judiciary of the Senate."

§290aa–16. Evaluation of performance of Department of Health and Human Services programs

(1) Evaluations

(A) In general

Not later than 5 years after July 22, 2016, except as otherwise provided in this section,[1] the Secretary of Health and Human Services (in this section referred to as the "Secretary") shall complete an evaluation of any program administered by the Secretary included in this Act (or an amendment made by this Act, excluding sections 703 through 707), including any grant administered by the Administrator of the Substance Abuse and Mental Health Services Administration under section 1536 of title 21, that provides grants for the primary purpose of providing assistance in addressing problems pertaining to opioid abuse based upon the outcomes and metrics identified under paragraph (2).

(B) Publication

With respect to each evaluation completed under subparagraph (A), the Secretary shall, not later than 90 days after the date on which such evaluation is completed, publish the results of such evaluation and issue a report on such evaluation to the appropriate committees. Such report shall also be published along with the data used to make such evaluation.

(2) Metrics and outcomes

(A) In general

Not later than 180 days after July 22, 2016, the Secretary shall identify—

(i) outcomes that are to be achieved by activities funded by the programs described in paragraph (1)(A); and

(ii) the metrics by which the achievement of such outcomes shall be determined.

(B) Publication

The Secretary shall, not later than 30 days after completion of the requirement under subparagraph (A), publish the outcomes and metrics identified under such subparagraph.

(3) Metrics data collection

The Secretary shall require grantees under the programs described in paragraph (1)(A) to collect, and annually report to the Secretary, data based upon the metrics identified under paragraph (2)(A).

(4) Independent evaluation

For purposes of paragraph (1), the Secretary shall—

(A) enter into an arrangement with the National Academy of Sciences; or

(B) enter into a contract or cooperative agreement with an entity that—

(i) is not an agency of the Federal Government; and

(ii) is qualified to conduct and evaluate research pertaining to opioid use and abuse and draw conclusions about overall opioid use and abuse on the basis of that research.

(5) Exception

If a program described in paragraph (1)(A) is subject to an evaluation similar to the evaluation required under such paragraph pursuant to another provision of Federal law, the Secretary may opt not to conduct an evaluation under such paragraph with respect to such program.

(Pub. L. 114–198, title VII, §701(d), July 22, 2016, 130 Stat. 739.)

EDITORIAL NOTES

REFERENCES IN TEXT

This section, the first time appearing in par. (1)(A), is section 701 of Pub. L. 114–198, July 22, 2016, 130 Stat. 739, which enacted this section, section 290aa–15 of this title, sections 10706 and 10707 of Title 34, Crime Control and Law Enforcement, and provisions set out as a note under section 290aa–15 of this title.

This Act, referred to in par. (1)(A), is Pub. L. 114–198, July 22, 2016, 130 Stat. 695, known as the Comprehensive Addiction and Recovery Act of 2016. Section 703 of the Act is not classified to the Code, and sections 704 to 707 of the Act enacted section 1320a–7n of this title, amended sections 1395w–101, 1395w–104, 1395w–152, 1395ddd, 1395iii, 1396a, 1396r–8, 1396w–1, and 1397bb of this title, and enacted provisions set out as notes under sections 1395w–101 and 1396r–8 of this title. For complete classification of this Act to the Code, see Short Title of 2016 Amendment note set out under section 201 of this title and Tables.

CODIFICATION

Section was enacted as part of the Comprehensive Addiction and Recovery Act of 2016, and not as part of the Public Health Service Act which comprises this chapter.

[1] *See References in Text note below.*

§290aa–17. Assisted outpatient treatment grant program for individuals with serious mental illness

(a) In general

The Secretary shall establish a program to award not more than 50 grants each year to eligible entities for assisted outpatient treatment programs for individuals with serious mental illness.

(b) Consultation

The Secretary shall carry out this section in consultation with the Director of the National Institute of Mental Health, the Attorney General of the United States, the Administrator of the Administration for Community Living, and the Administrator of the Substance Abuse and Mental Health Services Administration.

(c) Selecting among applicants

The Secretary—

(1) may only award grants under this section to applicants that have not previously implemented an assisted outpatient treatment program; and

(2) shall evaluate applicants based on their potential to reduce hospitalization, homelessness, incarceration, and interaction with the criminal justice system while improving the health and social outcomes of the patient.

(d) Use of grant

An assisted outpatient treatment program funded with a grant awarded under this section shall include—

(1) evaluating the medical and social needs of the patients who are participating in the program;

(2) preparing and executing treatment plans for such patients that—

(A) include criteria for completion of court-ordered treatment; and

(B) provide for monitoring of the patient's compliance with the treatment plan, including compliance with medication and other treatment regimens;

(3) providing for such patients case management services that support the treatment plan;

(4) ensuring appropriate referrals to medical and social service providers;

(5) evaluating the process for implementing the program to ensure consistency with the patient's

needs and State law; and

(6) measuring treatment outcomes, including health and social outcomes such as rates of incarceration, health care utilization, and homelessness.

(e) Report

Not later than the end of fiscal year 2023, and biennially thereafter, the Secretary shall submit a report to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives on the grant program under this section. Each such report shall include an evaluation of the following:

(1) Cost savings and public health outcomes such as mortality, suicide, substance abuse, hospitalization, and use of services.

(2) Rates of incarceration by patients.

(3) Rates of homelessness among patients.

(4) Patient and family satisfaction with program participation.

(5) Demographic information regarding participation of those served by the grant compared to demographic information in the population of the grant recipient.

(f) Definitions

In this section:

(1) The term "assisted outpatient treatment" means medically prescribed mental health treatment that a patient receives while living in a community under the terms of a law authorizing a State or local court to order such treatment.

(2) The term "eligible entity" means a county, city, mental health system, mental health court, or any other entity with authority under the law of the State in which the grantee is located to implement, monitor, and oversee assisted outpatient treatment programs.

(3) The term "Secretary" means the Secretary of Health and Human Services.

(g) Funding

(1) Amount of grants

A grant under this section shall be in an amount that is not more than $1,000,000 for each of fiscal years 2023 through 2027. Subject to the preceding sentence, the Secretary shall determine the amount of each grant based on the population of the area, including estimated patients, to be served under the grant.

(2) Authorization of appropriations

There is authorized to be appropriated to carry out this section $22,000,000 for each of fiscal years 2023 through 2027.

(Pub. L. 113–93, title II, §224, Apr. 1, 2014, 128 Stat. 1083; Pub. L. 114–255, div. B, title IX, §9014, Dec. 13, 2016, 130 Stat. 1245; Pub. L. 117–328, div. FF, title I, §1123(b)(1), Dec. 29, 2022, 136 Stat. 5653.)

EDITORIAL NOTES

CODIFICATION

Section was formerly classified as a note under section 290aa of this title prior to editorial reclassification and renumbering as this section.

Section was enacted as part of the Protecting Access to Medicare Act of 2014, and not as part of the Public Health Service Act which comprises this chapter.

AMENDMENTS

2022—Subsec. (a). Pub. L. 117–328, §1123(b)(1)(A), struck out "4-year pilot" before "program".

Subsec. (e). Pub. L. 117–328, §1123(b)(1)(B), in introductory provisions, substituted "fiscal year 2023, and biennially thereafter" for "each of fiscal years 2016, 2017, 2018, 2019, 2020, 2021, and 2022" and "Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives" for "appropriate congressional committees".

Subsec. (e)(5). Pub. L. 117–328, §1123(b)(1)(C), added par. (5).

Subsec. (g)(1). Pub. L. 117–328, §1123(b)(1)(D)(i), substituted "2023 through 2027" for "2015 through 2022".

Subsec. (g)(2). Pub. L. 117–328, §1123(b)(1)(D)(ii), amended par. (2) generally. Prior to amendment, text read as follows: "There are authorized to be appropriated to carry out this section $15,000,000 for each of fiscal years 2015 through 2017, $20,000,000 for fiscal year 2018, $19,000,000 for each of fiscal years 2019 and 2020, and $18,000,000 for each of fiscal years 2021 and 2022."

2016—Subsec. (e). Pub. L. 114–255, §9014(1), substituted "2018, 2019, 2020, 2021, and 2022," for "and 2018," in introductory provisions.

Subsec. (g)(1). Pub. L. 114–255, §9014(2)(A), substituted "2022" for "2018".

Subsec. (g)(2). Pub. L. 114–255, §9014(2)(B), substituted "are authorized to be appropriated to carry out this section $15,000,000 for each of fiscal years 2015 through 2017, $20,000,000 for fiscal year 2018, $19,000,000 for each of fiscal years 2019 and 2020, and $18,000,000 for each of fiscal years 2021 and 2022" for "is authorized to be appropriated to carry out this section $15,000,000 for each of fiscal years 2015 through 2018".

§290aa–18. Limitations on authority

In carrying out any program of the Substance Abuse and Mental Health Services Administration whose statutory authorization is enacted or amended by this title, the Secretary of Health and Human Services shall not allocate funding, or require award recipients to prioritize, dedicate, or allocate funding, without consideration of the incidence, prevalence, or determinants of mental health or substance use issues, unless such allocation or requirement is consistent with statute, regulation, or other Federal law.

(Pub. L. 117–328, div. FF, title I, §1501, Dec. 29, 2022, 136 Stat. 5706.)

EDITORIAL NOTES

REFERENCES IN TEXT

This title, referred to in text, is title I of div. FF of Pub. L. 117–328, Dec. 29, 2022, 136 Stat. 5634. For complete classification of title I to the Code, see Tables.

CODIFICATION

Section was enacted as part of the Restoring Hope for Mental Health and Well-Being Act of 2022 and also as part of the Health Extenders, Improving Access to Medicare, Medicaid, and CHIP, and Strengthening Public Health Act of 2022, and not as part of the Public Health Service Act which comprises this chapter.

PART B—CENTERS AND PROGRAMS

SUBPART 1—CENTER FOR SUBSTANCE ABUSE TREATMENT

§290bb. Center for Substance Abuse Treatment

(a) Establishment

There is established in the Administration a Center for Substance Abuse Treatment (hereafter in this section referred to as the "Center"). The Center shall be headed by a Director (hereafter in this section referred to as the "Director") appointed by the Secretary from among individuals with extensive experience or academic qualifications in the treatment of substance use disorders or in the evaluation of substance use disorder treatment systems.

(b) Duties

The Director of the Center shall—

(1) administer the substance use disorder treatment block grant program authorized in section 300x–21 of this title;

(2) ensure that emphasis is placed on children and adolescents in the development of treatment programs;

(3) collaborate with the Attorney General to develop programs to provide substance use disorder treatment services to individuals who have had contact with the Justice system, especially adolescents;

(4) collaborate with the Director of the Center for Substance Abuse Prevention in order to provide outreach services to identify individuals in need of treatment services, with emphasis on the provision of such services to pregnant and postpartum women and their infants and to individuals who illicitly use drugs intravenously;

(5) collaborate with the Director of the National Institute on Drug Abuse, with the Director of the National Institute on Alcohol Abuse and Alcoholism, and with the States to promote the study, dissemination, and implementation of research findings that will improve the delivery and effectiveness of treatment services;

(6) collaborate with the Administrator of the Health Resources and Services Administration and the Administrator of the Centers for Medicare & Medicaid Services to promote the increased integration into the mainstream of the health care system of the United States of programs for providing treatment services;

(7) evaluate plans submitted by the States pursuant to section 300x–32(a)(6) of this title in order to determine whether the plans adequately provide for the availability, allocation, and effectiveness of treatment services;

(8) sponsor regional workshops on improving the quality and availability of treatment services;

(9) provide technical assistance to public and nonprofit private entities that provide treatment services, including technical assistance with respect to the process of submitting to the Director applications for any program of grants or contracts;

(10) carry out activities to educate individuals on the need for establishing treatment facilities within their communities;

(11) encourage public and private entities that provide health insurance to provide benefits for outpatient treatment services and other nonhospital-based treatment services;

(12) evaluate treatment programs to determine the quality and appropriateness of various forms of treatment, which shall be carried out through grants, contracts, or cooperative agreements provided to public or nonprofit private entities;

(13) ensure the consistent documentation of the application of criteria when awarding grants and the ongoing oversight of grantees after such grants are awarded;

(14) work with States, providers, and individuals in recovery, and their families, to promote the expansion of recovery support services and systems of care oriented toward recovery;

(15) in cooperation with the Secretary, implement and disseminate, as appropriate, the recommendations in the report entitled "Protecting Our Infants Act: Final Strategy" issued by the Department of Health and Human Services in 2017; and

(16) in cooperation with relevant stakeholders, and through public-private partnerships, encourage education about substance use disorders for pregnant women and health care providers who treat pregnant women and babies.

(c) Grants and contracts

In carrying out the duties established in subsection (b), the Director may make grants to and enter into contracts and cooperative agreements with public and nonprofit private entities.

(July 1, 1944, ch. 373, title V, §507, as added Pub. L. 102–321, title I, §107(2), July 10, 1992, 106 Stat. 335; amended Pub. L. 106–310, div. B, title XXXI, §3112(a), Oct. 17, 2000, 114 Stat. 1188;

Pub. L. 108–173, title IX, §900(e)(2)(B), Dec. 8, 2003, 117 Stat. 2372; Pub. L. 114–255, div. B, title VI, §6007(c), Dec. 13, 2016, 130 Stat. 1214; Pub. L. 115–271, title VII, §7063(b), (c), Oct. 24, 2018, 132 Stat. 4020.)

EDITORIAL NOTES

PRIOR PROVISIONS

A prior section 290bb, act July 1, 1944, ch. 373, title V, §510, formerly Pub. L. 91–616, title V, §501, as added Pub. L. 94–371, §7, July 26, 1976, 90 Stat. 1038; amended Pub. L. 95–622, title II, §268(c), (d), Nov. 9, 1978, 92 Stat. 3437; Pub. L. 96–180, §14, Jan. 2, 1980, 93 Stat. 1305; renumbered §510 of act July 1, 1944, and amended Apr. 26, 1983, Pub. L. 98–24, §2(b)(9), 97 Stat. 179; Oct. 19, 1984, Pub. L. 98–509, title II, §§205(a)(1), 206(c)(1), 98 Stat. 2361, 2362, related to encouragement of alcohol abuse and alcoholism research, prior to repeal by Pub. L. 102–321, §122(b)(1). Prior to repeal, section 510(b) of act July 1, 1944, was renumbered section 464H(b) by Pub. L. 102–321 and transferred to section 285n(b) of this title.

A prior section 507 of act July 1, 1944, which was classified to section 290aa–5 of this title, was renumbered section 504 of act July 1, 1944, by Pub. L. 102–321 and transferred to section 290aa–3 of this title.

AMENDMENTS

2018—Subsec. (b)(15). Pub. L. 115–271, §7063(b), added subsec. (b)(15).

Subsec. (b)(16). Pub. L. 115–271, §7063(c), added par. (16).

2016—Subsec. (a). Pub. L. 114–255, §6007(c)(1), substituted "treatment of substance use disorders" for "treatment of substance abuse" and "use disorder treatment systems" for "abuse treatment systems".

Subsec. (b)(1). Pub. L. 114–255, §6007(c)(2)(A), substituted "use disorder" for "abuse".

Subsec. (b)(3). Pub. L. 114–255, §6007(c)(2)(B), substituted "use disorder" for "abuse".

Subsec. (b)(4). Pub. L. 114–255, §6007(c)(2)(C), substituted "individuals who illicitly use drugs" for "individuals who abuse drugs".

Subsec. (b)(9). Pub. L. 114–255, §6007(c)(2)(D), struck out "carried out by the Director" before semicolon at end.

Subsec. (b)(10) to (14). Pub. L. 114–255, §6007(c)(2)E–(H), added pars. (13) and (14), redesignated pars. (11) to (14) as (10) to (13), respectively, struck out former par. (10), which related to encouraging the States to expand the availability (relative to fiscal year 1992) of programs providing treatment services, and struck out par. (13), as redesignated, which related to assessing the quality, appropriateness, and costs of various treatment forms.

2003—Subsec. (b)(6). Pub. L. 108–173 substituted "Centers for Medicare & Medicaid Services" for "Health Care Financing Administration".

2000—Subsec. (b)(2) to (6). Pub. L. 106–310, §3112(a)(1), (2), added pars. (2) and (3) and redesignated former pars. (2) to (4) as (4) to (6), respectively. Former pars. (5) and (6) redesignated (7) and (8), respectively.

Subsec. (b)(7). Pub. L. 106–310, §3112(a)(1), (3), redesignated par. (5) as (7) and substituted "services" for "services, and monitor the use of revolving loan funds pursuant to section 300x–25 of this title". Former par. (7) redesignated (9).

Subsec. (b)(8) to (12). Pub. L. 106–310, §3112(a)(1), redesignated pars. (6) to (10) as (8) to (12), respectively. Former pars. (11) and (12) redesignated (13) and (14), respectively.

Subsec. (b)(13). Pub. L. 106–310, §3112(a)(1), (4), redesignated par. (11) as (13) and substituted "treatment, which shall" for "treatment, including the effect of living in housing provided by programs established under section 300x–25 of this title, which shall".

Subsec. (b)(14). Pub. L. 106–310, §3112(a)(1), (5), redesignated par. (12) as (14) and substituted "paragraph (13)" for "paragraph (11)".

STATUTORY NOTES AND RELATED SUBSIDIARIES

EFFECTIVE DATE

Section effective Oct. 1, 1992, with provision for programs providing financial assistance, see section 801(c), (d) of Pub. L. 102–321, set out as an Effective Date of 1992 Amendment note under section 236 of this title.

§290bb–1. Residential treatment programs for pregnant and postpartum women

(a) In general

The Director of the Center for Substance Abuse Treatment (referred to in this section as the "Director") shall provide awards of grants, including the grants under subsection (r), cooperative agreements or contracts to public and nonprofit private entities for the purpose of providing to pregnant and postpartum women treatment for substance use disorders through programs in which, during the course of receiving treatment—

(1) the women reside in or receive outpatient treatment services from facilities provided by the programs;

(2) the minor children of the women reside with the women in such facilities, if the women so request; and

(3) the services described in subsection (d) are available to or on behalf of the women.

(b) Availability of services for each participant

A funding agreement for an award under subsection (a) for an applicant is that, in the program operated pursuant to such subsection—

(1) treatment services and each supplemental service will be available through the applicant, either directly or through agreements with other public or nonprofit private entities; and

(2) the services will be made available to each woman admitted to the program and her children.

(c) Individualized plan of services

A funding agreement for an award under subsection (a) for an applicant is that—

(1) in providing authorized services for an eligible woman pursuant to such subsection, the applicant will, in consultation with the women, prepare an individualized plan for the provision of services for the woman and her children; and

(2) treatment services under the plan will include—

(A) individual, group, and family counseling, as appropriate, regarding substance use disorders; and

(B) follow-up services to assist the woman in preventing a relapse into such a disorder.

(d) Required supplemental services

In the case of an eligible woman, the services referred to in subsection (a)(3) are as follows:

(1) Prenatal and postpartum health care.

(2) Referrals for necessary hospital services.

(3) For the infants and children of the woman—

(A) pediatric health care, including treatment for any perinatal effects of a maternal substance use disorder and including screenings regarding the physical and mental development of the infants and children;

(B) counseling and other mental health services, in the case of children; and

(C) comprehensive social services.

(4) Providing therapeutic, comprehensive child care for children during the periods in which the woman is engaged in therapy or in other necessary health and rehabilitative activities.

(5) Training in parenting.

(6) Counseling on the human immunodeficiency virus and on acquired immune deficiency syndrome.

(7) Counseling on domestic violence and sexual abuse.

(8) Counseling on obtaining employment, including the importance of graduating from a secondary school.

(9) Reasonable efforts to preserve and support the family unit of the woman, including promoting the appropriate involvement of parents and others, and counseling the children of the woman.

(10) Planning for and counseling to assist reentry into society, both before and after discharge,

including referrals to any public or nonprofit private entities in the community involved that provide services appropriate for the woman and the children of the woman.

(11) Case management services, including—

(A) assessing the extent to which authorized services are appropriate for the woman and any child of such woman;

(B) in the case of the services that are appropriate, ensuring that the services are provided in a coordinated manner;

(C) assistance in establishing eligibility for assistance under Federal, State, and local programs providing health care services, mental health services, housing services, employment services, educational services, or social services; and

(D) family reunification with children in kinship or foster care arrangements, where safe and appropriate.

(e) Minimum qualifications for receipt of award

(1) Certification by relevant State agency

With respect to the principal agency of the State involved that administers programs relating to substance use disorders, the Director may make an award under subsection (a) to an applicant only if the agency has certified to the Director that—

(A) the applicant has the capacity to carry out a program described in subsection (a);

(B) the plans of the applicant for such a program are consistent with the policies of such agency regarding the treatment of substance use disorders; and

(C) the applicant, or any entity through which the applicant will provide authorized services, meets all applicable State licensure or certification requirements regarding the provision of the services involved.

(2) Status as medicaid provider

(A) In general

Subject to subparagraphs (B) and (C), the Director may make an award under subsection (a) only if, in the case of any authorized service that is available pursuant to the State plan approved under title XIX of the Social Security Act [42 U.S.C. 1396 et seq.] for the State involved—

(i) the applicant for the award will provide the service directly, and the applicant has entered into a participation agreement under the State plan and is qualified to receive payments under such plan; or

(ii) the applicant will enter into an agreement with a public or nonprofit private entity under which the entity will provide the service, and the entity has entered into such a participation agreement plan and is qualified to receive such payments.

(B) Waiver of participation agreements

(i) In general

In the case of an entity making an agreement pursuant to subparagraph (A)(ii) regarding the provision of services, the requirement established in such subparagraph regarding a participation agreement shall be waived by the Director if the entity does not, in providing health care services, impose a charge or accept reimbursement available from any third-party payor, including reimbursement under any insurance policy or under any Federal or State health benefits plan.

(ii) Donations

A determination by the Director of whether an entity referred to in clause (i) meets the criteria for a waiver under such clause shall be made without regard to whether the entity accepts voluntary donations regarding the provision of services to the public.

(C) Nonapplication of certain requirements

With respect to any authorized service that is available pursuant to the State plan described in subparagraph (A), the requirements established in such subparagraph shall not apply to the provision of any such service by an institution for mental diseases to an individual who has attained 21 years of age and who has not attained 65 years of age. For purposes of the preceding sentence, the term "institution for mental diseases" has the meaning given such term in section 1905(i) of the Social Security Act [42 U.S.C. 1396d(i)].

(f) Requirement of matching funds

(1) In general

With respect to the costs of the program to be carried out by an applicant pursuant to subsection (a), a funding agreement for an award under such subsection is that the applicant will make available (directly or through donations from public or private entities) non-Federal contributions toward such costs in an amount that—

(A) for the first fiscal year for which the applicant receives payments under an award under such subsection, is not less than $1 for each $9 of Federal funds provided in the award;

(B) for any second such fiscal year, is not less than $1 for each $9 of Federal funds provided in the award; and

(C) for any subsequent such fiscal year, is not less than $1 for each $3 of Federal funds provided in the award.

(2) Determination of amount contributed

Non-Federal contributions required in paragraph (1) may be in cash or in kind, fairly evaluated, including plant, equipment, or services. Amounts provided by the Federal Government, or services assisted or subsidized to any significant extent by the Federal Government, may not be included in determining the amount of such non-Federal contributions.

(g) Outreach

A funding agreement for an award under subsection (a) for an applicant is that the applicant will provide a plan describing outreach services in the community involved to identify women who have a substance use disorder and to encourage the women to undergo treatment for such disorder. Such plan may include a description of how such applicant will target outreach to women disproportionately impacted by maternal substance use disorder.

(h) Accessibility of program; cultural context of services

A funding agreement for an award under subsection (a) for an applicant is that—

(1) the program operated pursuant to such subsection will be operated at a location that is accessible to low-income pregnant and postpartum women; and

(2) authorized services will be provided in the language and the cultural context that is most appropriate.

(i) Continuing education

A funding agreement for an award under subsection (a) is that the applicant involved will provide for continuing education in treatment services for the individuals who will provide treatment in the program to be operated by the applicant pursuant to such subsection.

(j) Imposition of charges

A funding agreement for an award under subsection (a) for an applicant is that, if a charge is imposed for the provision of authorized services to or on behalf of an eligible woman, such charge—

(1) will be made according to a schedule of charges that is made available to the public;

(2) will be adjusted to reflect the income of the woman involved; and

(3) will not be imposed on any such woman with an income of less than 185 percent of the official poverty line, as established by the Director of the Office of Management and Budget and revised by the Secretary in accordance with section 9902(2) of this title.

(k) Reports to Director

A funding agreement for an award under subsection (a) is that the applicant involved will submit

to the Director a report—

(1) describing the utilization and costs of services provided under the award;

(2) specifying the number of women served, the number of infants served, and the type and costs of services provided; and

(3) providing such other information as the Director determines to be appropriate.

(l) Requirement of application

The Director may make an award under subsection (a) only if an application for the award is submitted to the Director containing such agreements, and the application is in such form, is made in such manner, and contains such other agreements and such assurances and information as the Director determines to be necessary to carry out this section.

(m) Allocation of awards

In making awards under subsection (a), the Director shall give priority to an applicant that agrees to use the award for a program serving an area that is a rural area, an area designated under section 254e of this title by the Secretary as a health professional shortage area, or an area determined by the Director to have a shortage of family-based substance use disorder treatment options.

(n) Duration of award

The period during which payments are made to an entity from an award under subsection (a) may not exceed 5 years. The provision of such payments shall be subject to annual approval by the Director of the payments and subject to the availability of appropriations for the fiscal year involved to make the payments. This subsection may not be construed to establish a limitation on the number of awards under such subsection that may be made to an entity.

(o) Evaluations; dissemination of findings

The Director shall, directly or through contract, provide for the conduct of evaluations of programs carried out pursuant to subsection (a). The Director shall disseminate to the States the findings made as a result of the evaluations.

(p) Reports to Congress

Not later than October 1, 1994, the Director shall submit to the Committee on Energy and Commerce of the House of Representatives, and to the Committee on Labor and Human Resources of the Senate, a report describing programs carried out pursuant to this section (other than subsection (r)). Every 2 years thereafter, the Director shall prepare a report describing such programs carried out during the preceding 2 years, and shall submit the report to the Assistant Secretary for inclusion in the biennial report under section 290aa(m) of this title. Each report under this subsection shall include a summary of any evaluations conducted under subsection (m) during the period with respect to which the report is prepared.

(q) Definitions

For purposes of this section:

(1) The term "authorized services" means treatment services and supplemental services.

(2) The term "eligible woman" means a woman who has been admitted to a program operated pursuant to subsection (a).

(3) The term "funding agreement", with respect to an award under subsection (a), means that the Director may make the award only if the applicant makes the agreement involved.

(4) The term "treatment services" means treatment for a substance use disorder, including the counseling and services described in subsection (c)(2).

(5) The term "supplemental services" means the services described in subsection (d).

(r) Pilot program for State substance abuse agencies

(1) In general

From amounts made available under subsection (s), the Director of the Center for Substance Abuse Treatment shall carry out a pilot program under which competitive grants are made by the Director to State substance abuse agencies—

(A) to enhance flexibility in the use of funds designed to support family-based services for pregnant and postpartum women with a primary diagnosis of a substance use disorder, including opioid use disorders;

(B) to help State substance abuse agencies address identified gaps in services furnished to such women along the continuum of care, including services provided to women in nonresidential-based settings; and

(C) to promote a coordinated, effective, and efficient State system managed by State substance abuse agencies by encouraging new approaches and models of service delivery.

(2) Requirements

In carrying out the pilot program under this subsection, the Director shall—

(A) require State substance abuse agencies to submit to the Director applications, in such form and manner and containing such information as specified by the Director, to be eligible to receive a grant under the program;

(B) identify, based on such submitted applications, State substance abuse agencies that are eligible for such grants;

(C) require services proposed to be furnished through such a grant to support family-based treatment and other services for pregnant and postpartum women with a primary diagnosis of a substance use disorder, including opioid use disorders;

(D) not require that services furnished through such a grant be provided solely to women that reside in facilities;

(E) not require that grant recipients under the program make available through use of the grant all the services described in subsection (d); and

(F) consider not applying the requirements described in paragraphs (1) and (2) of subsection (f) to an applicant, depending on the circumstances of the applicant.

(3) Required services

(A) In general

The Director shall specify a minimum set of services required to be made available to eligible women through a grant awarded under the pilot program under this subsection. Such minimum set of services—

(i) shall include the services requirements described in subsection (c) and be based on the recommendations submitted under subparagraph (B); and

(ii) may be selected from among the services described in subsection (d) and include other services as appropriate.

(B) Stakeholder input

The Director shall convene and solicit recommendations from stakeholders, including State substance abuse agencies, health care providers, persons in recovery from substance abuse, and other appropriate individuals, for the minimum set of services described in subparagraph (A).

(4) Evaluation and report to Congress

(A) In general

The Director of the Center for Behavioral Health Statistics and Quality shall evaluate the pilot program at the conclusion of the first grant cycle funded by the pilot program.

(B) Report

Not later than September 30, 2026, the Director of the Center for Behavioral Health Statistics and Quality, in coordination with the Director of the Center for Substance Abuse Treatment shall submit to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives a report on the evaluation under subparagraph (A). The report shall include, at a minimum—

(i) outcomes information from the pilot program, including any resulting reductions in the use of alcohol and other drugs;

(ii) engagement in treatment services;
(iii) retention in the appropriate level and duration of services;
(iv) increased access to the use of medications approved by the Food and Drug Administration for the treatment of substance use disorders in combination with counseling; and
(v) other appropriate measures.

(C) Recommendation

The report under subparagraph (B) shall include a recommendation by the Director of the Center for Substance Abuse Treatment as to whether the pilot program under this subsection should be extended.

(5) State substance abuse agencies defined

For purposes of this subsection, the term "State substance abuse agency" means, with respect to a State, the agency in such State that manages the Substance Abuse Prevention and Treatment Block Grant under part B of subchapter XVII.

(s) Authorization of appropriations

For the purpose of carrying out this section, there are authorized to be appropriated $38,931,000 for each of fiscal years 2026 through 2030. Of the amounts made available for a year pursuant to the previous sentence to carry out this section, not more than 25 percent of such amounts shall be made available for such year to carry out subsection (r), other than paragraph (5) of such subsection. Notwithstanding the preceding sentence, no funds shall be made available to carry out subsection (r) for a fiscal year unless the amount made available to carry out this section for such fiscal year is more than the amount made available to carry out this section for fiscal year 2016.

(July 1, 1944, ch. 373, title V, §508, as added Pub. L. 102–321, title I, §108(a), July 10, 1992, 106 Stat. 336; amended Pub. L. 106–310, div. B, title XXXIII, §3301(a), Oct. 17, 2000, 114 Stat. 1207; Pub. L. 114–198, title V, §501, July 22, 2016, 130 Stat. 724; Pub. L. 114–255, div. B, title VI, §§6001(c)(2), 6006(b), Dec. 13, 2016, 130 Stat. 1203, 1212; Pub. L. 115–271, title VII, §7062(b), Oct. 24, 2018, 132 Stat. 4020; Pub. L. 117–328, div. FF, title I, §1114, Dec. 29, 2022, 136 Stat. 5647; Pub. L. 119–44, title II, §201, Dec. 1, 2025, 139 Stat. 680.)

EDITORIAL NOTES

REFERENCES IN TEXT

The Social Security Act, referred to in subsec. (e)(2)(A), is act Aug. 14, 1935, ch. 531, 49 Stat. 620. Title XIX of the Act is classified generally to subchapter XIX (§1396 et seq.) of chapter 7 of this title. For complete classification of this Act to the Code, see section 1305 of this title and Tables.

PRIOR PROVISIONS

A prior section 290bb–1, act July 1, 1944, ch. 373, title V, §511, formerly Pub. L. 91–616, title V, §503, formerly §504, as added Pub. L. 94–371, §7, July 26, 1976, 90 Stat. 1039; amended Pub. L. 95–622, title I, §110(d), Nov. 9, 1978, 92 Stat. 3420; Pub. L. 96–180, §16, Jan. 2, 1980, 93 Stat. 1305; renumbered §503 of Pub. L. 91–616 and amended Pub. L. 97–35, title IX, §965(b), (c), Aug. 13, 1981, 95 Stat. 594; renumbered §511 of act July 1, 1944, and amended Apr. 26, 1983, Pub. L. 98–24, §2(b)(9), 97 Stat. 179; Oct. 27, 1986, Pub. L. 99–570, title IV, §4008, 100 Stat. 3207–115, which related to National Alcohol Research Centers and a mandatory grant for research of the effects of alcohol on the elderly, was renumbered section 464J of title IV of act July 1, 1944, by Pub. L. 102–321 and transferred to section 285n–2 of this title.

A prior section 508 of act July 1, 1944, which was classified to section 290aa–6 of this title, was renumbered section 515 of act July 1, 1944, by Pub. L. 102–321 and transferred to section 290bb–21 of this title.

AMENDMENTS

2025—Subsec. (d)(11)(C). Pub. L. 119–44, §201(1), substituted "providing health care services" for "providing health services".

Subsec. (g). Pub. L. 119–44, §201(2), inserted "a plan describing" after "will provide" and "Such plan may

include a description of how such applicant will target outreach to women disproportionately impacted by maternal substance use disorder." at end.

Subsec. (s). Pub. L. 119–44, §201(3), substituted "$38,931,000 for each of fiscal years 2026 through 2030" for "$29,931,000 for each of fiscal years 2019 through 2023".

2022—Subsec. (r)(4). Pub. L. 117–328, §1114(1), (2), redesignated par. (5) as (4) and struck out former par. (4). Prior to amendment, text of par. (4) read as follows: "The pilot program under this subsection shall not exceed 5 years."

Subsec. (r)(4)(B). Pub. L. 117–328, §1114(3), in introductory provisions, substituted "Not later than September 30, 2026, the Director" for "The Director" and "the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives" for "the relevant committees of jurisdiction of the House of Representatives and the Senate".

Subsec. (r)(5), (6). Pub. L. 117–328, §1114(2), redesignated pars. (5) and (6) as (4) and (5), respectively.

2018—Subsec. (s). Pub. L. 115–271 substituted "$29,931,000 for each of fiscal years 2019 through 2023" for "$16,900,000 for each of fiscal years 2017 through 2021".

2016—Subsec. (a). Pub. L. 114–198, §501(a)(1)(A), in introductory provisions, inserted "(referred to in this section as the 'Director')" after "Substance Abuse Treatment" and substituted "grants, including the grants under subsection (r), cooperative agreements" for "grants, cooperative agreement," and "for substance use disorders" for "for substance abuse".

Subsec. (a)(1). Pub. L. 114–198, §501(a)(1)(B), inserted "or receive outpatient treatment services from" after "reside in".

Subsec. (b)(2). Pub. L. 114–198, §501(a)(2), inserted "and her children" before period at end.

Subsec. (c)(1). Pub. L. 114–198, §501(a)(3)(A), substituted "of services for the woman and her children" for "to the woman of the services".

Subsec. (c)(2)(A). Pub. L. 114–198, §501(a)(3)(B)(i), substituted "substance use disorders" for "substance abuse".

Subsec. (c)(2)(B). Pub. L. 114–198, §501(a)(3)(B)(ii), substituted "such a disorder" for "such abuse".

Subsec. (d)(3)(A). Pub. L. 114–198, §501(a)(4)(A), substituted "a maternal substance use disorder" for "maternal substance abuse".

Subsec. (d)(4). Pub. L. 114–198, §501(a)(4)(B), amended par. (4) generally. Prior to amendment, par. (4) read as follows: "Providing supervision of children during periods in which the woman is engaged in therapy or in other necessary health or rehabilitative activities."

Subsec. (d)(9). Pub. L. 114–198, §501(a)(4)(C), (D), substituted "unit" for "units" and "woman" for "women" in two places.

Subsec. (d)(10). Pub. L. 114–198, §501(a)(4)(C), substituted "woman" for "women" in two places.

Subsec. (d)(11)(A). Pub. L. 114–198, §501(a)(4)(C), (E)(i), substituted "the woman" for "the women" and "any child of such woman" for "their children".

Subsec. (d)(11)(D). Pub. L. 114–198, §501(a)(4)(E)(ii)–(iv), added subpar. (D).

Subsec. (e)(1). Pub. L. 114–198, §501(a)(5)(A), substituted "substance use disorders" for "substance abuse" in introductory provisions and in subpar. (B).

Subsec. (e)(2). Pub. L. 114–198, §501(a)(5)(B), inserted headings for subpars. (A) to (C) and for cls. (i) and (ii) of subpar. (B).

Subsec. (g). Pub. L. 114–198, §501(a)(6), substituted "who have a substance use disorder" for "who are engaging in substance abuse" and "such disorder" for "such abuse".

Subsec. (j). Pub. L. 114–198, §501(a)(7)(A), substituted "to or on" for "to on" in introductory provisions.

Subsec. (j)(3). Pub. L. 114–198, §501(a)(7)(B), substituted "Office of" for "Office for".

Subsec. (m). Pub. L. 114–198, §501(a)(8), amended subsec. (m) generally. Prior to amendment, text read as follows: "In making awards under subsection (a) of this section, the Director shall ensure that the awards are equitably allocated among the principal geographic regions of the United States, subject to the availability of qualified applicants for the awards."

Subsec. (p). Pub. L. 114–255, §6006(b), substituted "section 290aa(m)" for "section 290aa(k)".

Pub. L. 114–255, §6001(c)(2), substituted "Assistant Secretary" for "Administrator".

Pub. L. 114–198, §501(b)(1), inserted "(other than subsection (r))" after "pursuant to this section".

Subsec. (q)(3). Pub. L. 114–198, §501(a)(9)(A), substituted "funding agreement" for "funding agreement under subsection (a)".

Subsec. (q)(4). Pub. L. 114–198, §501(a)(9)(B), substituted "a substance use disorder" for "substance abuse".

Subsec. (r). Pub. L. 114–198, §501(c)(1)(B), added subsec. (r). Former subsec. (r) redesignated (s).

Pub. L. 114–198, §501(b)(2), substituted "$16,900,000 for each of fiscal years 2017 through 2021" for

"such sums as may be necessary to fiscal years 2001 through 2003".

Subsec. (s). Pub. L. 114–198, §501(c)(1)(A), (2), redesignated subsec. (r) as (s) and inserted at end "Of the amounts made available for a year pursuant to the previous sentence to carry out this section, not more than 25 percent of such amounts shall be made available for such year to carry out subsection (r), other than paragraph (5) of such subsection. Notwithstanding the preceding sentence, no funds shall be made available to carry out subsection (r) for a fiscal year unless the amount made available to carry out this section for such fiscal year is more than the amount made available to carry out this section for fiscal year 2016."

2000—Subsec. (r). Pub. L. 106–310 reenacted heading without change and amended text generally, substituting provisions authorizing appropriations for fiscal years 2001 to 2003 for provisions authorizing appropriations for fiscal years 1993 and 1994 and authorizing appropriations from the special forfeiture fund of the Director of the Office of National Drug Control Policy.

STATUTORY NOTES AND RELATED SUBSIDIARIES

CHANGE OF NAME

Committee on Labor and Human Resources of Senate changed to Committee on Health, Education, Labor, and Pensions of Senate by Senate Resolution No. 20, One Hundred Sixth Congress, Jan. 19, 1999.

Committee on Energy and Commerce of House of Representatives treated as referring to Committee on Commerce of House of Representatives by section 1(a) of Pub. L. 104–14, set out as a note preceding section 21 of Title 2, The Congress. Committee on Commerce of House of Representatives changed to Committee on Energy and Commerce of House of Representatives, and jurisdiction over matters relating to securities and exchanges and insurance generally transferred to Committee on Financial Services of House of Representatives by House Resolution No. 5, One Hundred Seventh Congress, Jan. 3, 2001.

EFFECTIVE DATE

Section effective Oct. 1, 1992, with provision for programs providing financial assistance, see section 801(c), (d) of Pub. L. 102–321, set out as an Effective Date of 1992 Amendment note under section 236 of this title.

TRANSITIONAL AND SAVINGS PROVISIONS

Pub. L. 102–321, title I, §108(b), July 10, 1992, 106 Stat. 341, provided that:

"(1) SAVINGS PROVISION FOR COMPLETION OF CURRENT PROJECTS.—

"(A) Subject to paragraph (2), in the case of any project for which a grant under former section 509F [former 42 U.S.C. 290aa–13] was provided for fiscal year 1992, the Secretary of Health and Human Services may continue in effect the grant for fiscal year 1993 and subsequent fiscal years, subject to the duration of any such grant not exceeding the period determined by the Secretary in first approving the grant. Subject to approval by the Administrator, such grants may be administered by the Center for Substance Abuse Prevention.

"(B) Subparagraph (A) shall apply with respect to a project notwithstanding that the project is not eligible to receive a grant under current section 508 or 509 [42 U.S.C. 290bb–1, 290bb–2].

"(2) LIMITATION ON FUNDING FOR CERTAIN PROJECTS.—With respect to the amounts appropriated for any fiscal year under current section 508, any such amounts appropriated in excess of the amount appropriated for fiscal year 1992 under former section 509F shall be available only for grants under current section 508.

"(3) DEFINITIONS.—For purposes of this subsection:

"(A) The term 'former section 509F' means section 509F of the Public Health Service Act [former 42 U.S.C. 290aa–13], as in effect for fiscal year 1992.

"(B) The term 'current section 508' means section 508 of the Public Health Service Act [42 U.S.C. 290bb–1], as in effect for fiscal year 1993 and subsequent fiscal years.

"(C) The term 'current section 509' means section 509 of the Public Health Service Act [42 U.S.C. 290bb–2], as in effect for fiscal year 1993 and subsequent fiscal years."

REPORT ON IMPLEMENTATION OF STRATEGY RELATING TO PRENATAL OPIOID USE

Pub. L. 115–271, title VII, §7062(a), Oct. 24, 2018, 132 Stat. 4019, provided that:

"(1) IN GENERAL.—Not later than 60 days after the date of enactment of this Act [Oct. 24, 2018], the Secretary of Health and Human Services (referred to in this section as the 'Secretary') shall submit to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives, and make available to the public on the Internet website of the

Department of Health and Human Services, a report regarding the implementation of the recommendations in the strategy relating to prenatal opioid use, including neonatal abstinence syndrome, developed pursuant to section 2 of the Protecting Our Infants Act of 2015 (Public Law 114–91) [129 Stat. 723]. Such report shall include—

"(A) an update on the implementation of the recommendations in the strategy, including information regarding the agencies involved in the implementation; and

"(B) information on additional funding or authority the Secretary requires, if any, to implement the strategy, which may include authorities needed to coordinate implementation of such strategy across the Department of Health and Human Services.

"(2) PERIODIC UPDATES.—The Secretary shall periodically update the report under paragraph (1)."

§290bb–1a. Transferred

EDITORIAL NOTES

CODIFICATION

Section, act July 1, 1944, ch. 373, title V, §512, as added Oct. 19, 1984, Pub. L. 98–509, title II, §206(a), 98 Stat. 2361, and amended, which related to alcohol abuse and alcoholism demonstration projects, was renumbered section 506 of act July 1, 1944, by Pub. L. 102–321, title I, §106(a), July 10, 1992, 106 Stat. 334, and transferred to section 290aa–5 of this title.

§290bb–2. Priority substance use disorder treatment needs of regional and national significance

(a) Projects

The Secretary shall address priority substance use disorder treatment needs of regional and national significance (as determined under subsection (b)) through the provision of or through assistance for—

(1) knowledge development and application projects for treatment and rehabilitation and the conduct or support of evaluations of such projects;

(2) training and technical assistance; and

(3) targeted capacity response programs that permit States, local governments, communities, and Indian Tribes and Tribal organizations (as such terms are defined in section 5304 of title 25) to focus on emerging trends in substance use disorders and co-occurrence of substance use disorders with mental illness or other conditions.

The Secretary may carry out the activities described in this section directly or through grants, contracts, or cooperative agreements with States, political subdivisions of States, Indian tribes or tribal organizations (as such terms are defined in section 5304 of title 25), health facilities, or programs operated by or in accordance with a contract or grant with the Indian Health Service, or other public or nonprofit private entities.

(b) Priority substance use disorder treatment needs

(1) In general

Priority substance use disorder treatment needs of regional and national significance shall be determined by the Secretary after consultation with States and other interested groups. The Secretary shall meet with the States and interested groups on an annual basis to discuss program priorities.

(2) Special consideration

In developing program priorities under paragraph (1), the Secretary shall give special consideration to promoting the integration of substance use disorder treatment services into

primary health care systems.

(c) Requirements

(1) In general

Recipients of grants, contracts, or cooperative agreements under this section shall comply with information and application requirements determined appropriate by the Secretary.

(2) Duration of award

With respect to a grant, contract, or cooperative agreement awarded under this section, the period during which payments under such award are made to the recipient may not exceed 5 years.

(3) Matching funds

The Secretary may, for projects carried out under subsection (a), require that entities that apply for grants, contracts, or cooperative agreements under that project provide non-Federal matching funds, as determined appropriate by the Secretary, to ensure the institutional commitment of the entity to the projects funded under the grant, contract, or cooperative agreement. Such non-Federal matching funds may be provided directly or through donations from public or private entities and may be in cash or in kind, fairly evaluated, including plant, equipment, or services.

(4) Maintenance of effort

With respect to activities for which a grant, contract, or cooperative agreement is awarded under this section, the Secretary may require that recipients for specific projects under subsection (a) agree to maintain expenditures of non-Federal amounts for such activities at a level that is not less than the level of such expenditures maintained by the entity for the fiscal year preceding the fiscal year for which the entity receives such a grant, contract, or cooperative agreement.

(d) Evaluation

The Secretary shall evaluate each project carried out under subsection (a)(1) and shall disseminate the findings with respect to each such evaluation to appropriate public and private entities.

(e) Information and education

The Secretary shall establish comprehensive information and education programs to disseminate and apply the findings of the knowledge development and application, training and technical assistance programs, and targeted capacity response programs under this section to the general public, to health professionals and other interested groups. The Secretary shall make every effort to provide linkages between the findings of supported projects and State agencies responsible for carrying out substance use disorder prevention and treatment programs.

(f) Authorization of appropriation

There are authorized to be appropriated to carry out this section, $521,517,000 for each of fiscal years 2023 through 2027.

(July 1, 1944, ch. 373, title V, §509, as added Pub. L. 102–321, title I, §108(a), July 10, 1992, 106 Stat. 341; amended Pub. L. 106–310, div. B, title XXXIII, §3301(b), Oct. 17, 2000, 114 Stat. 1207; Pub. L. 114–255, div. B, title VII, §7004, Dec. 13, 2016, 130 Stat. 1223; Pub. L. 117–328, div. FF, title I, §1212, Dec. 29, 2022, 136 Stat. 5661.)

EDITORIAL NOTES

PRIOR PROVISIONS

A prior section 290bb–2, act July 1, 1944, ch. 373, title V, §513, formerly §512, formerly Pub. L. 91–616, title V, §504, formerly §503, as added Pub. L. 94–371, §7, July 26, 1976, 90 Stat. 1039; amended Pub. L. 96–180, §15, Jan. 2, 1980, 93 Stat. 1305; renumbered §504 of Pub. L. 91–616 and amended Pub. L. 97–35, title IX, §965(a), (c), Aug. 13, 1981, 95 Stat. 594; Pub. L. 97–414, §9(e), Jan. 4, 1983, 96 Stat. 2064; renumbered §512 of act July 1, 1944, and amended Apr. 26, 1983, Pub. L. 98–24, §2(b)(9), 97 Stat. 179; renumbered §513 and amended Oct. 19, 1984, Pub. L. 98–509, title II, §§206(a), 207(a), 98 Stat. 2361, 2362; Oct. 27, 1986, Pub. L. 99–570, title IV, §4010(a), 100 Stat. 3207–115; July 22, 1987, Pub. L. 100–77, title VI,

§613(c), 101 Stat. 524; Nov. 4, 1988, Pub. L. 100–607, title VIII, §822, 102 Stat. 3171; Nov. 7, 1988, Pub. L. 100–628, title VI, §622, 102 Stat. 3244; Nov. 18, 1988, Pub. L. 100–690, title II, §2056(a), 102 Stat. 4211; Aug. 16, 1989, Pub. L. 101–93, §5(t)(1), 103 Stat. 615; Nov. 29, 1990, Pub. L. 101–645, title V, §522, 104 Stat. 4734, authorized appropriations to carry out alcohol abuse and alcoholism research, prior to repeal by Pub. L. 102–321, §122(d)[(e)].

A prior section 509 of act July 1, 1944, which was classified to section 290aa–7 of this title, was renumbered section 516 of act July 1, 1944, by Pub. L. 102–321 and transferred to section 290bb–22 of this title.

AMENDMENTS

2022—Pub. L. 117–328, §1212(1), substituted "use disorder" for "abuse" in section catchline.

Subsec. (a)(3). Pub. L. 117–328, §1212(2), substituted "Tribes and Tribal organizations (as such terms are defined" for "tribes and tribal organizations (as the terms 'Indian tribes' and 'tribal organizations' are defined" and "in substance use disorders" for "in substance abuse".

Subsec. (b). Pub. L. 117–328, §1212(3), substituted "use disorder" for "abuse" in heading.

Subsec. (f). Pub. L. 117–328, §1212(4), substituted "$521,517,000 for each of fiscal years 2023 through 2027" for "$333,806,000 for each of fiscal years 2018 through 2022".

2016—Subsec. (a). Pub. L. 114–255, §7004(1)(A), (C), in introductory provisions, substituted "use disorder" for "abuse" and, in concluding provisions, inserted ", contracts," before "or cooperative agreements" and substituted "Indian tribes or tribal organizations (as such terms are defined in section 5304 of title 25), health facilities, or programs operated by or in accordance with a contract or grant with the Indian Health Service, or" for "Indian tribes and tribal organizations,".

Subsec. (a)(3). Pub. L. 114–255, §7004(1)(B), inserted before period at end "that permit States, local governments, communities, and Indian tribes and tribal organizations (as the terms 'Indian tribes' and 'tribal organizations' are defined in section 5304 of title 25) to focus on emerging trends in substance abuse and co-occurrence of substance use disorders with mental illness or other conditions".

Subsec. (b). Pub. L. 114–255, §7004(2), substituted "use disorder" for "abuse" in pars. (1) and (2).

Subsec. (e). Pub. L. 114–255, §7004(3), substituted "use disorder" for "abuse".

Subsec. (f). Pub. L. 114–255, §7004(4), substituted "$333,806,000 for each of fiscal years 2018 through 2022." for "$300,000,000 for fiscal year 2001 and such sums as may be necessary for each of the fiscal years 2002 and 2003."

2000—Pub. L. 106–310 amended section catchline and text generally, substituting provisions relating to priority substance abuse treatment needs of regional and national significance for provisions relating to outpatient treatment programs for pregnant and postpartum women.

STATUTORY NOTES AND RELATED SUBSIDIARIES

EFFECTIVE DATE

Section effective Oct. 1, 1992, with provision for programs providing financial assistance, see section 801(c), (d) of Pub. L. 102–321, set out as an Effective Date of 1992 Amendment note under section 236 of this title.

§290bb–2a. Medical treatment of narcotics addiction; report to Congress

The Secretary of Health and Human Services, after consultation with the Attorney General and with national organizations representative of persons with knowledge and experience in the treatment of narcotic addicts, shall determine the appropriate methods of professional practice in the medical treatment of the narcotic addiction of various classes of narcotic addicts, and shall report thereon from time to time to the Congress.

(Pub. L. 91–513, title I, §4, Oct. 27, 1970, 84 Stat. 1241; Pub. L. 96–88, title V, §509(b), Oct. 17, 1979, 93 Stat. 695.)

EDITORIAL NOTES

CODIFICATION

Section was not enacted as part of the Public Health Service Act which comprises this chapter.
Section was formerly classified to section 257a of this title.

STATUTORY NOTES AND RELATED SUBSIDIARIES

CHANGE OF NAME

"Secretary of Health and Human Services" substituted in text for "Secretary of Health, Education, and Welfare" pursuant to section 509(b) of Pub. L. 96–88, which is classified to section 3508(b) of Title 20, Education.

§§290bb–3 to 290bb–5. Repealed. Pub. L. 106–310, div. B, title XXXIII, §3301(c)(1)–(3), Oct. 17, 2000, 114 Stat. 1209

Section 290bb–3, act July 1, 1944, ch. 373, title V, §510, as added Pub. L. 102–321, title I, §109, July 10, 1992, 106 Stat. 342, related to demonstration projects of national significance.

A prior section 510 of act July 1, 1944, was classified to section 290bb of this title, prior to repeal by Pub. L. 102–321, §122(b)(1). Prior to repeal, section 510(b) of act July 1, 1944, was renumbered section 464H(b) by Pub. L. 102–321 and transferred to section 285n(b) of this title.

Another prior section 510 of act July 1, 1944, which was classified to section 228 of this title, was successively renumbered by subsequent acts and transferred, see section 238g of this title.

Section 290bb–4, act July 1, 1944, ch. 373, title V, §511, as added Pub. L. 102–321, title I, §110, July 10, 1992, 106 Stat. 343, related to grants for substance abuse treatment in State and local criminal justice systems.

A prior section 511 of act July 1, 1944, which was classified to section 290bb–1 of this title, was renumbered section 464J of act July 1, 1944, by Pub. L. 102–321 and transferred to section 285n–2 of this title.

Another prior section 511 of act July 1, 1944, which was classified to section 229 of this title, was successively renumbered by subsequent acts and transferred, see section 238h of this title.

Section 290bb–5, act July 1, 1944, ch. 373, title V, §512, as added Pub. L. 102–321, title I, §111, July 10, 1992, 106 Stat. 344, related to training in provision of treatment services.

A prior section 512 of act July 1, 1944, which was classified to section 290bb–1a of this title, was renumbered section 506 of act July 1, 1944, by Pub. L. 102–321 and transferred to section 290aa–5 of this title.

Another prior section 512 of act July 1, 1944, was renumbered section 513 by Pub. L. 98–509 and classified to section 290bb–2 of this title, prior to repeal by Pub. L. 102–321, §122(d)[(e)].

Another prior section 512 of act July 1, 1944, which was classified to section 229a of this title, was successively renumbered by subsequent acts and transferred, see section 238i of this title.

§290bb–6. Action by Center for Substance Abuse Treatment and States concerning military facilities

(a) Center for Substance Abuse Treatment

The Director of the Center for Substance Abuse Treatment shall—

(1) coordinate with the agencies represented on the Commission on Alternative Utilization of Military Facilities the utilization of military facilities or parts thereof, as identified by such Commission, established under the National Defense Authorization Act of 1989, that could be utilized or renovated to house nonviolent persons for drug treatment purposes;

(2) notify State agencies responsible for the oversight of drug abuse treatment entities and programs of the availability of space at the installations identified in paragraph (1); and

(3) assist State agencies responsible for the oversight of drug abuse treatment entities and programs in developing methods for adapting the installations described in paragraph (1) into residential treatment centers.

(b) States

With regard to military facilities or parts thereof, as identified by the Commission on Alternative

Utilization of Military Facilities established under section 3042 of the Comprehensive Alcohol Abuse, Drug Abuse, and Mental Health Amendments Act of 1988,[1] that could be utilized or renovated to house nonviolent persons for drug treatment purposes, State agencies responsible for the oversight of drug abuse treatment entities and programs shall—

(1) establish eligibility criteria for the treatment of individuals at such facilities;

(2) select treatment providers to provide drug abuse treatment at such facilities;

(3) provide assistance to treatment providers selected under paragraph (2) to assist such providers in securing financing to fund the cost of the programs at such facilities; and

(4) establish, regulate, and coordinate with the military official in charge of the facility, work programs for individuals receiving treatment at such facilities.

(c) Reservation of space

Prior to notifying States of the availability of space at military facilities under subsection (a)(2), the Director may reserve space at such facilities to conduct research or demonstration projects.

(July 1, 1944, ch. 373, title V, §513, formerly §561, as added Pub. L. 100–690, title II, §2081(a), Nov. 18, 1988, 102 Stat. 4215; renumbered §513 and amended Pub. L. 102–321, title I, §112(a), (b)(1), July 10, 1992, 106 Stat. 344, 345.)

EDITORIAL NOTES

REFERENCES IN TEXT

The National Defense Authorization Act of 1989, referred to in subsec. (a)(1), probably means the National Defense Authorization Act, Fiscal Year 1989, Pub. L. 100–456, Sept. 29, 1988, 102 Stat. 1918. For complete classification of this Act to the Code, see Tables.

Section 3042 of the Comprehensive Alcohol Abuse, Drug Abuse, and Mental Health Amendments Act of 1988, referred to in subsec. (b), probably should be a reference to section 2819 of the National Defense Authorization Act, Fiscal Year 1989, Pub. L. 100–456, div. B, title XXVIII, Sept. 29, 1988, 102 Stat. 2119, which established the Commission on Alternative Utilization of Military Facilities and which was set out as a note under section 2391 of Title 10, Armed Forces, prior to repeal by Pub. L. 105–261, div. A, title X, §1031(b), Oct. 17, 1998, 112 Stat. 2123. The Comprehensive Alcohol Abuse, Drug Abuse, and Mental Health Amendments Act of 1988 is subtitle A of title II of Pub. L. 100–690, Nov. 18, 1988, 102 Stat. 4193, and does not contain a section 3042.

CODIFICATION

Section was formerly classified to section 290ff of this title prior to renumbering by Pub. L. 102–321.

PRIOR PROVISIONS

A prior section 513 of act July 1, 1944, was classified to section 290bb–2 of this title prior to repeal by Pub. L. 102–321, title I, §122(d)[(e)], July 10, 1992, 106 Stat. 360.

Another prior section 513 of act July 1, 1944, which was classified to section 229b of this title, was successively renumbered by subsequent acts and transferred, see section 238j of this title.

AMENDMENTS

1992—Subsec. (a). Pub. L. 102–321, §112(b)(1), substituted provisions relating to Center for Substance Abuse Treatment for provisions relating to National Institute on Drug Abuse in heading and text.

STATUTORY NOTES AND RELATED SUBSIDIARIES

EFFECTIVE DATE OF 1992 AMENDMENT

Amendment by Pub. L. 102–321 effective Oct. 1, 1992, with provision for programs providing financial assistance, see section 801(c), (d) of Pub. L. 102–321, set out as a note under section 236 of this title.

[1] *See References in Text note below.*

§290bb–7. Substance use disorder treatment and early intervention services for children, adolescents, and young adults

(a) In general

The Secretary shall award grants, contracts, or cooperative agreements to public and private nonprofit entities, including Indian Tribes or Tribal organizations (as such terms are defined in section 5304 of title 25), or health facilities or programs operated by or in accordance with a contract or grant with the Indian Health Service, for the purpose of—

(1) providing early identification and services to meet the needs of children, adolescents, and young adults who are at risk of substance use disorders;

(2) providing substance use disorder treatment services for children, adolescents, and young adults, including children, adolescents, and young adults with co-occurring mental illness and substance use disorders; and

(3) providing assistance to pregnant women, and parenting women, with substance use disorders, in obtaining treatment services, linking mothers to community resources to support independent family lives, and staying in recovery so that children are in safe, stable home environments and receive appropriate health care services.

(b) Priority

In awarding grants, contracts, or cooperative agreements under subsection (a), the Secretary shall give priority to applicants who propose to—

(1) apply evidence-based and cost-effective methods;

(2) coordinate the provision of services with other social service agencies in the community, including educational, juvenile justice, child welfare, substance abuse, and mental health agencies;

(3) provide a continuum of integrated treatment services, including case management, for children, adolescents, and young adults with substance use disorders, including children, adolescents, and young adults with co-occurring mental illness and substance use disorders, and their families;

(4) provide treatment that is gender-specific and culturally appropriate;

(5) involve and work with families of children, adolescents, and young adults receiving services; and

(6) provide aftercare services for children, adolescents, and young adults and their families after completion of treatment.

(c) Duration of grants

The Secretary shall award grants, contracts, or cooperative agreements under subsection (a) for periods not to exceed 5 fiscal years.

(d) Application

An entity desiring a grant, contract, or cooperative agreement under subsection (a) shall submit an application to the Secretary at such time, in such manner, and accompanied by such information as the Secretary may reasonably require.

(e) Evaluation

An entity that receives a grant, contract, or cooperative agreement under subsection (a) shall submit, in the application for such grant, contract, or cooperative agreement, a plan for the evaluation of any project undertaken with funds provided under this section. Such entity shall provide the Secretary with periodic evaluations of the progress of such project and such evaluation at the completion of such project as the Secretary determines to be appropriate.

(f) Authorization of appropriations

There are authorized to be appropriated to carry out this section, $29,605,000 for each of fiscal years 2023 through 2027.

(July 1, 1944, ch. 373, title V, §514, as added Pub. L. 106–310, div. B, title XXXI, §3104(a), Oct. 17, 2000, 114 Stat. 1171; amended Pub. L. 114–255, div. B, title X, §10003, Dec. 13, 2016, 130 Stat.

1264; Pub. L. 115–271, title VII, §7102(a), Oct. 24, 2018, 132 Stat. 4038; Pub. L. 117–328, div. FF, title I, §1412, Dec. 29, 2022, 136 Stat. 5701.)

EDITORIAL NOTES

CODIFICATION

Another section 514 of act July 1, 1944, was classified to section 290bb–9 of this title prior to repeal by Pub. L. 114–255, div. B, title IX, §9017, Dec. 13, 2016, 130 Stat. 1248.

AMENDMENTS

2022—Subsec. (a). Pub. L. 117–328, §1412(1), substituted "Indian Tribes or Tribal organizations" for "Indian tribes or tribal organizations" in introductory provisions.

Subsec. (f). Pub. L. 117–328, §1412(2), substituted "2023 through 2027" for "2018 through 2022".

2018—Pub. L. 115–271, §7102(a)(3), substituted "children, adolescents, and young adults" for "children and adolescents" wherever appearing.

Pub. L. 115–271, §7102(a)(1), substituted "children, adolescents, and young adults" for "children and adolescents" in section catchline.

Subsec. (a)(2). Pub. L. 115–271, §7102(a)(2), substituted "children, adolescents, and young adults, including" for "children, including".

2016—Pub. L. 114–255, §10003(1), substituted "use disorder treatment and early intervention" for "abuse treatment" in section catchline.

Subsec. (a). Pub. L. 114–255, §10003(2), added subsec. (a) and struck out former subsec. (a). Prior to amendment, text read as follows: "The Secretary shall award grants, contracts, or cooperative agreements to public and private nonprofit entities, including Native Alaskan entities and Indian tribes and tribal organizations, for the purpose of providing substance abuse treatment services for children and adolescents."

Subsec. (b)(1). Pub. L. 114–255, §10003(3)(A), added par. (1) and struck out former par. (1) which read as follows: "apply evidenced-based and cost effective methods for the treatment of substance abuse among children and adolescents;".

Subsec. (b)(2). Pub. L. 114–255, §10003(3)(B), struck out "treatment" after "provision of" and inserted "substance abuse," after "child welfare,".

Subsec. (b)(3). Pub. L. 114–255, §10003(3)(C), substituted "substance use disorders, including children and adolescents with co-occurring mental illness and substance use disorders," for "substance abuse disorders".

Subsec. (b)(5). Pub. L. 114–255, §10003(3)(D), substituted "services; and" for "treatment;".

Subsec. (b)(6). Pub. L. 114–255, §10003(3)(E), substituted "treatment." for "substance abuse treatment; and".

Subsec. (b)(7). Pub. L. 114–255, §10003(3)(F), struck out par. (7) which read as follows: "address the relationship between substance abuse and violence."

Subsec. (f). Pub. L. 114–255, §10003(4), substituted "$29,605,000 for each of fiscal years 2018 through 2022." for "$40,000,000 for fiscal year 2001, and such sums as may be necessary for fiscal years 2002 and 2003."

§290bb–7a. Youth prevention and recovery

(a) Omitted

(b) Resource center

The Secretary of Health and Human Services (referred to in this section as the "Secretary", except as otherwise provided), in consultation with the Secretary of Education and other heads of agencies, including the Assistant Secretary for Mental Health and Substance Use and the Administrator of the Health Resources and Services Administration, as appropriate, shall establish a resource center to provide technical support to recipients of grants under subsection (c).

(c) Youth prevention and recovery initiative

(1) In general

The Secretary, in consultation with the Secretary of Education, shall administer a program to provide support for communities to support the prevention of, treatment of, and recovery from,

substance use disorders for children, adolescents, and young adults.

(2) Definitions

In this subsection:

(A) Eligible entity

The term "eligible entity" means—

(i) a local educational agency, or a consortium of local educational agencies, that is seeking to establish or expand substance use prevention or recovery support services at one or more secondary schools;

(ii) a State educational agency;

(iii) an institution of higher education (or consortia of such institutions), which may include a recovery program at an institution of higher education;

(iv) a local board or one-stop operator;

(v) a nonprofit organization with appropriate expertise in providing services or programs for children, adolescents, or young adults, excluding a school;

(vi) a State, political subdivision of a State, Indian Tribe, or Tribal organization; or

(vii) a high school or dormitory serving high school students that receives funding from the Bureau of Indian Education.

(B) Foster care

The term "foster care" has the meaning given such term in section 1355.20(a) of title 45, Code of Federal Regulations (or any successor regulations).

(C) High school

The term "high school" has the meaning given such term in section 7801 of title 20.

(D) Homeless youth

The term "homeless youth" has the meaning given the term "homeless children or youths" in section 11434a of this title.

(E) Indian Tribe; Tribal organization

The terms "Indian Tribe" and "Tribal organization" have the meanings given such terms in section 5304 of title 25.

(F) Institution of higher education

The term "institution of higher education" has the meaning given such term in section 1001 of title 20 and includes a "postsecondary vocational institution" as defined in section 1002(c) of such title.

(G) Local educational agency

The term "local educational agency" has the meaning given such term in section 7801 of title 20.

(H) Local board; one-stop operator

The terms "local board" and "one-stop operator" have the meanings given such terms in section 3102 of title 29.

(I) Out-of-school youth

The term "out-of-school youth" has the meaning given such term in section 3164(a)(1)(B) of title 29.

(J) Recovery program

The term "recovery program" means a program—

(i) to help children, adolescents, or young adults who are recovering from substance use disorders to initiate, stabilize, and maintain healthy and productive lives in the community; and

(ii) that includes peer-to-peer support delivered by individuals with lived experience in

recovery, and communal activities to build recovery skills and supportive social networks.

(K) Secondary school

The term "secondary school" has the meaning given such term in section 7801 of title 20.

(L) State educational agency

The term "State educational agency" has the meaning given such term in section 7801 of title 20.

(3) Best practices

The Secretary, in consultation with the Secretary of Education, shall—

(A) identify or facilitate the development of evidence-based best practices for prevention of substance misuse by children, adolescents, and young adults, including for specific populations at increased risk for substance misuse such as youth in foster care, homeless youth, out-of-school youth, and youth who are at risk of or have experienced trafficking that address—

(i) primary prevention, which may include strategies to increase education and awareness of the potency and dangers of synthetic opioids (including drugs contaminated with fentanyl) and, as appropriate, other emerging drug use or misuse issues;

(ii) appropriate recovery support services;

(iii) appropriate use of medication-assisted treatment for such individuals, if applicable, and ways of overcoming barriers to the use of medication-assisted treatment in such population; and

(iv) efficient and effective communication, which may include the use of social media, to maximize outreach efforts;

(B) disseminate such best practices to State educational agencies, local educational agencies, schools and dormitories funded by the Bureau of Indian Education, institutions of higher education, recovery programs at institutions of higher education, local boards, one-stop operators, family and youth homeless providers, and nonprofit organizations, as appropriate;

(C) conduct a rigorous evaluation of each grant funded under this subsection, particularly its impact on the indicators described in paragraph (7)(B); and

(D) provide technical assistance for grantees under this subsection.

(4) Grants authorized

The Secretary, in consultation with the Secretary of Education, shall award 3-year grants, on a competitive basis, to eligible entities to enable such entities, in coordination with Indian Tribes, if applicable, and State agencies responsible for carrying out substance use disorder prevention and treatment programs, to carry out evidence-based programs for—

(A) prevention of substance misuse by children, adolescents, and young adults, which may include primary prevention and strategies to increase education and awareness of the potency and dangers of synthetic opioids (including drugs contaminated with fentanyl) and, as appropriate, emerging drug use or misuse issues;

(B) recovery support services for children, adolescents, and young adults, which may include counseling, job training, linkages to community-based services, family support groups, peer-to-peer support, and recovery coaching; or

(C) treatment or referrals for treatment of substance use disorders, which may include the use of medication-assisted treatment, as appropriate.

(5) Special consideration

In awarding grants under this subsection, the Secretary shall give special consideration to the unique needs of Tribal, urban, suburban, and rural populations.

(6) Application

To be eligible for a grant under this subsection, an entity shall submit to the Secretary an application at such time, in such manner, and containing such information as the Secretary may require. Such application shall include—

(A) a description of—

(i) the impact of substance use disorders in the population that will be served by the grant program;

(ii) how the eligible entity has solicited input from relevant stakeholders, which may include faculty, teachers, staff, families, students, and experts in substance use disorder prevention, treatment, and recovery in developing such application;

(iii) the goals of the proposed project, including the intended outcomes;

(iv) how the eligible entity plans to use grant funds for evidence-based activities, in accordance with this subsection to prevent, provide recovery support for, or treat substance use disorders amongst such individuals, or a combination of such activities;

(v) how the eligible entity will collaborate with relevant partners, which may include State educational agencies, local educational agencies, institutions of higher education, juvenile justice agencies, prevention and recovery support providers, local service providers, including substance use disorder treatment programs, providers of mental health services, youth serving organizations, family and youth homeless providers, child welfare agencies, and primary care providers, in carrying out the grant program; and

(vi) a plan to sustain the activities carried out under the grant program, after the grant program has ended; and

(B) an assurance that the eligible entity will participate in the evaluation described in paragraph (3)(C).

(7) Reports to the Secretary

Each eligible entity awarded a grant under this subsection shall submit to the Secretary a report at such time and in such manner as the Secretary may require. Such report shall include—

(A) a description of how the eligible entity used grant funds, in accordance with this subsection, including the number of children, adolescents, and young adults reached through programming; and

(B) a description, including relevant data, of how the grant program has made an impact on the intended outcomes described in paragraph (6)(A)(iii), including—

(i) indicators of student success, which, if the eligible entity is an educational institution, shall include student well-being and academic achievement;

(ii) substance use disorders amongst children, adolescents, and young adults, including the number of overdoses and deaths amongst children, adolescents, and young adults served by the grant during the grant period; and

(iii) other indicators, as the Secretary determines appropriate.

(8) Report to Congress

The Secretary shall, not later than October 1, 2028, submit a report to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce and the Committee on Education and the Workforce of the House of Representatives a report summarizing the effectiveness of the grant program under this subsection, based on the information submitted in reports required under paragraph (7).

(9) Authorization of appropriations

To carry out this subsection, there are authorized to be appropriated—

(A) $10,000,000 for fiscal year 2026;

(B) $12,000,000 for fiscal year 2027;

(C) $13,000,000 for fiscal year 2028;

(D) $14,000,000 for fiscal year 2029; and

(E) $15,000,000 for fiscal year 2030.

(Pub. L. 115–271, title VII, §7102, Oct. 24, 2018, 132 Stat. 4038; Pub. L. 119–44, title I, §110(a), title III, §304, Dec. 1, 2025, 139 Stat. 677, 685.)

EDITORIAL NOTES

CODIFICATION

Section is comprised of section 7102 of Pub. L. 115–271. Subsec. (a) of section 7102 of Pub. L. 115–271 amended section 290bb–7 of this title.

Section was enacted as part of the Substance Use–Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act, also known as the SUPPORT for Patients and Communities Act, and not as part of the Public Health Service Act which comprises this chapter.

AMENDMENTS

2025—Subsec. (c)(2)(A)(i). Pub. L. 119–44, §304(1)(A)(i), inserted ", or a consortium of local educational agencies," after "a local educational agency" and substituted "secondary schools" for "high schools".

Subsec. (c)(2)(A)(vi). Pub. L. 119–44, §304(1)(A)(ii), substituted "Tribe, or Tribal" for "tribe, or tribal".

Subsec. (c)(2)(E). Pub. L. 119–44, §304(1)(B), amended subpar. (E) generally. Prior to amendment, text read as follows: "The terms 'Indian tribe' and 'tribal organization' have the meanings given such terms in section 5304 of title 25."

Subsec. (c)(2)(K), (L). Pub. L. 119–44, §304(1)(C), (D), added subpar. (K) and redesignated former subpar. (K) as (L).

Subsec. (c)(3)(A). Pub. L. 119–44, §304(2), in introductory provisions, struck out "and abuse" before "by children," and inserted "at increased risk for substance misuse" after "specific populations".

Subsec. (c)(3)(A)(i). Pub. L. 119–44, §110(a)(1), inserted ", which may include strategies to increase education and awareness of the potency and dangers of synthetic opioids (including drugs contaminated with fentanyl) and, as appropriate, other emerging drug use or misuse issues" before semicolon at end.

Subsec. (c)(4). Pub. L. 119–44, §304(3)(A), substituted "Indian Tribes" for "Indian tribes" in introductory provisions.

Subsec. (c)(4)(A). Pub. L. 119–44, §304(3)(B), struck out "and abuse" before "by children,".

Pub. L. 119–44, §110(a)(2), inserted "and strategies to increase education and awareness of the potency and dangers of synthetic opioids (including drugs contaminated with fentanyl) and, as appropriate, emerging drug use or misuse issues" before semicolon at end.

Subsec. (c)(4)(B). Pub. L. 119–44, §304(3)(C), substituted "peer-to-peer support" for "peer mentoring".

Subsec. (c)(5). Pub. L. 119–44, §304(4), substituted "Tribal" for "tribal".

Subsec. (c)(6)(A)(vi). Pub. L. 119–44, §304(5), added cl. (vi).

Subsec. (c)(8). Pub. L. 119–44, §304(6), substituted "2028" for "2022".

Subsec. (c)(9). Pub. L. 119–44, §304(7), amended par. (9) generally. Prior to amendment, text read as follows: "There is authorized to be appropriated $10,000,000 to carry out this subsection for each of fiscal years 2019 through 2023."

§§290bb–8, 290bb–9. Repealed. Pub. L. 114–255, div. B, title IX, §9017, Dec. 13, 2016, 130 Stat. 1248

Section 290bb–8, act July 1, 1944, ch. 373, title V, §514A, as added Pub. L. 106–310, div. B, title XXXI, §3104(a), Oct. 17, 2000, 114 Stat. 1172, related to early intervention services for children and adolescents.

Section 290bb–9, act July 1, 1944, ch. 373, title V, §514, as added Pub. L. 106–310, div. B, title XXXVI, §3632, Oct. 17, 2000, 114 Stat. 1236, related to methamphetamine and amphetamine treatment initiative. Another section 514 of act July 1, 1944, is classified to section 290bb–7 of this title.

§290bb–10. Evidence-based prescription opioid and heroin treatment and interventions demonstration

(a) Grants to expand access

(1) Authority to award grants

The Secretary shall award grants, contracts, or cooperative agreements to State substance use disorder agencies, units of local government, nonprofit organizations, and Indian Tribes and Tribal organizations (as defined in section 5304 of title 25) that have a high rate, or have had a rapid increase, in the use of heroin or other opioids, in order to permit such entities to expand activities,

including an expansion in the availability of evidence-based medication-assisted treatment and other clinically appropriate services, with respect to the treatment of substance use disorders in the specific geographical areas of such entities where there is a high rate or rapid increase in the use of heroin or other opioids, such as in rural areas.

(2) Nature of activities

Funds awarded under paragraph (1) shall be used for activities that are based on reliable scientific evidence of efficacy in the treatment of problems related to heroin or other opioids.

(b) Application

To be eligible for a grant, contract, or cooperative agreement under subsection (a), an entity shall submit an application to the Secretary at such time, in such manner, and accompanied by such information as the Secretary may reasonably require.

(c) Evaluation

An entity that receives a grant, contract, or cooperative agreement under subsection (a) shall submit, in the application for such grant, contract, or agreement a plan for the evaluation of any project undertaken with funds provided under this section. Such entity shall provide the Secretary with periodic evaluations of the progress of such project and an evaluation at the completion of such project as the Secretary determines to be appropriate.

(d) Geographic distribution

In awarding grants, contracts, and cooperative agreements under this section, the Secretary shall ensure that not less than 15 percent of funds are awarded to eligible entities that are not located in metropolitan statistical areas (as defined by the Office of Management and Budget). The Secretary shall take into account the unique needs of rural communities, including communities with an incidence of individuals with opioid use disorder that is above the national average and communities with a shortage of prevention and treatment services.

(e) Additional activities

In administering grants, contracts, and cooperative agreements under subsection (a), the Secretary shall—

(1) evaluate the activities supported under such subsection;

(2) disseminate information, as appropriate, derived from evaluations as the Secretary considers appropriate;

(3) provide States, Indian Tribes and Tribal organizations, and providers with technical assistance in connection with the provision of treatment of problems related to heroin and other opioids; and

(4) fund only those applications that specifically support recovery services as a critical component of the program involved.

(f) Authorization of appropriations

To carry out this section, there are authorized to be appropriated $25,000,000 for each of fiscal years 2023 through 2027.

(July 1, 1944, ch. 373, title V, §514B, as added Pub. L. 114–198, title III, §301, July 22, 2016, 130 Stat. 717; amended Pub. L. 117–328, div. FF, title I, §1213, Dec. 29, 2022, 136 Stat. 5661.)

EDITORIAL NOTES

AMENDMENTS

2022—Subsec. (a)(1). Pub. L. 117–328, §1213(1), substituted "substance use disorder" for "substance abuse", "Tribes and Tribal organizations" for "tribes and tribal organizations", and "substance use disorders" for "addiction".

Subsec. (e)(3). Pub. L. 117–328, §1213(2), substituted "Tribes and Tribal organizations" for "tribes and tribal organizations".

Subsec. (f). Pub. L. 117–328, §1213(3), substituted "2023 through 2027" for "2017 through 2021".

§290bb–11. Building capacity for family-focused residential treatment

(a) Definitions

In this section:

(1) Eligible entity

The term "eligible entity" means a State, county, local, or tribal health or child welfare agency, a private nonprofit organization, a research organization, a treatment service provider, an institution of higher education (as defined under section 1001 of title 20), or another entity specified by the Secretary.

(2) Family-focused residential treatment program

The term "family-focused residential treatment program" means a trauma-informed residential program primarily for substance use disorder treatment for pregnant and postpartum women and parents and guardians that allows children to reside with such women or their parents or guardians during treatment to the extent appropriate and applicable.

(3) Secretary

The term "Secretary" means the Secretary of Health and Human Services.

(b) Support for the development of evidence-based family-focused residential treatment programs

(1) Authority to award grants

The Secretary shall award grants to eligible entities for purposes of developing, enhancing, or evaluating family-focused residential treatment programs to increase the availability of such programs that meet the requirements for promising, supported, or well-supported practices specified in section 671(e)(4)(C) of this title) [1] (as added by the Family First Prevention Services Act enacted under title VII of division E of Public Law 115–123).

(2) Evaluation requirement

The Secretary shall require any evaluation of a family-focused residential treatment program by an eligible entity that uses funds awarded under this section for all or part of the costs of the evaluation be designed to assist in the determination of whether the program may qualify as a promising, supported, or well-supported practice in accordance with the requirements of such section 671(e)(4)(C).

(c) Authorization of appropriations

There is authorized to be appropriated to the Secretary to carry out this section, $20,000,000 for fiscal year 2019, which shall remain available through fiscal year 2023.

(Pub. L. 115–271, title VIII, §8083, Oct. 24, 2018, 132 Stat. 4102.)

EDITORIAL NOTES

REFERENCES IN TEXT

Family First Prevention Services Act, referred to in subsec. (b)(1), is title VII of Pub. L. 115–123, div. E, Feb. 9, 2018, 132 Stat. 232. For complete classification of this Act to the Code, see Tables.

CODIFICATION

Section was enacted as part of the Substance Use–Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act, also known as the SUPPORT for Patients and Communities Act, and not as part of the Public Health Service Act which comprises this chapter.

STATUTORY NOTES AND RELATED SUBSIDIARIES

SUPPORTING FAMILY-FOCUSED RESIDENTIAL TREATMENT

Pub. L. 115–271, title VIII, §8081, Oct. 24, 2018, 132 Stat. 4097, provided that:

"(a) DEFINITIONS.—In this section:

"(1) FAMILY-FOCUSED RESIDENTIAL TREATMENT PROGRAM.—The term 'family-focused residential treatment program' means a trauma-informed residential program primarily for substance use disorder treatment for pregnant and postpartum women and parents and guardians that allows children to reside with such women or their parents or guardians during treatment to the extent appropriate and applicable.

"(2) MEDICAID PROGRAM.—The term 'Medicaid program' means the program established under title XIX of the Social Security Act (42 U.S.C. 1396 et seq.).

"(3) SECRETARY.—The term 'Secretary' means the Secretary of Health and Human Services.

"(4) TITLE IV–E PROGRAM.—The term 'title IV–E program' means the program for foster care, prevention, and permanency established under part E of title IV of the Social Security Act (42 U.S.C. 670 et seq.).

"(b) GUIDANCE ON FAMILY-FOCUSED RESIDENTIAL TREATMENT PROGRAMS.—

"(1) IN GENERAL.—Not later than 180 days after the date of enactment of this Act [Oct. 24, 2018], the Secretary, in consultation with divisions of the Department of Health and Human Services administering substance use disorder or child welfare programs, shall develop and issue guidance to States identifying opportunities to support family-focused residential treatment programs for the provision of substance use disorder treatment. Before issuing such guidance, the Secretary shall solicit input from representatives of States, health care providers with expertise in addiction medicine, obstetrics and gynecology, neonatology, child trauma, and child development, health plans, recipients of family-focused treatment services, and other relevant stakeholders.

"(2) ADDITIONAL REQUIREMENTS.—The guidance required under paragraph (1) shall include descriptions of the following:

"(A) Existing opportunities and flexibilities under the Medicaid program, including under waivers authorized under section 1115 or 1915 of the Social Security Act (42 U.S.C. 1315, 1396n), for States to receive Federal Medicaid funding for the provision of substance use disorder treatment for pregnant and postpartum women and parents and guardians and, to the extent applicable, their children, in family-focused residential treatment programs.

"(B) How States can employ and coordinate funding provided under the Medicaid program, the title IV-E program, and other programs administered by the Secretary to support the provision of treatment and services provided by a family-focused residential treatment facility such as substance use disorder treatment and services, including medication-assisted treatment, family, group, and individual counseling, case management, parenting education and skills development, the provision, assessment, or coordination of care and services for children, including necessary assessments and appropriate interventions, non-emergency transportation for necessary care provided at or away from a program site, transitional services and supports for families leaving treatment, and other services.

"(C) How States can employ and coordinate funding provided under the Medicaid program and the title IV–E program (including as amended by the Family First Prevention Services Act enacted under title VII of division E of Public Law 115–123 [132 Stat. 232], and particularly with respect to the authority under subsections (a)(2)(C) and (j) of section 472 and section 474(a)(1) of the Social Security Act (42 U.S.C. 672, 674(a)(1)) (as amended by section 50712 of Public Law 115–123) to provide foster care maintenance payments for a child placed with a parent who is receiving treatment in a licensed residential family-based treatment facility for a substance use disorder) to support placing children with their parents in family-focused residential treatment programs."

[1] *So in original.*

SUBPART 2—CENTER FOR SUBSTANCE ABUSE PREVENTION

§290bb–21. Center for Substance Abuse Prevention

(a) Establishment; Director

There is established in the Administration a Center for Substance Abuse Prevention (hereafter referred to in this part as the "Prevention Center"). The Prevention Center shall be headed by a Director appointed by the Secretary from individuals with extensive experience or academic qualifications in the prevention of drug or alcohol abuse.

(b) Duties of Director

The Director of the Prevention Center shall—

(1) sponsor regional workshops on the prevention of drug and alcohol abuse through the reduction of risk and the promotion of resiliency;

(2) coordinate the findings of research sponsored by agencies of the Service on the prevention of drug and alcohol abuse;

(3) collaborate with the Director of the National Institute on Drug Abuse, the Director of the National Institute on Alcohol Abuse and Alcoholism, and States to promote the study of substance abuse prevention and the dissemination and implementation of research findings that will improve the delivery and effectiveness of substance abuse prevention activities;

(4) develop effective drug and alcohol abuse prevention literature (including educational information on the effects of drugs abused by individuals, including drugs that are emerging as abused drugs);

(5) in cooperation with the Secretary of Education, assure the widespread dissemination of prevention materials among States, political subdivisions, and school systems;

(6) support clinical training programs for health professionals who provide substance use and misuse prevention and treatment services and other health professionals involved in illicit drug use education and prevention;

(7) in cooperation with the Director of the Centers for Disease Control and Prevention, develop and disseminate educational materials to increase awareness for individuals at greatest risk for substance use disorders to prevent the transmission of communicable diseases, such as HIV, hepatitis, tuberculosis, and other communicable diseases;

(8) conduct training, technical assistance, data collection, and evaluation activities of programs supported under the Drug Free Schools and Communities Act of 1986;

(9) support the development of model, innovative, community-based programs that reduce the risk of alcohol and drug abuse among young people and promote resiliency;

(10) collaborate with the Attorney General of the Department of Justice to develop programs to prevent drug abuse among high risk youth;

(11) prepare for distribution documentary films and public service announcements for television and radio to educate the public, especially adolescent audiences, concerning the dangers to health resulting from the consumption of alcohol and drugs and, to the extent feasible, use appropriate private organizations and business concerns in the preparation of such announcements;

(12) develop and support innovative demonstration programs designed to identify and deter the improper use or abuse of anabolic steroids by students, especially students in secondary schools;

(13) ensure the consistent documentation of the application of criteria when awarding grants and the ongoing oversight of grantees after such grants are awarded;

(14) assist and support States in preventing illicit drug use, including emerging illicit drug use issues; and

(15) in consultation with relevant stakeholders and in collaboration with the Director of the Centers for Disease Control and Prevention, develop educational materials for clinicians to use with pregnant women for shared decision making regarding pain management and the prevention of substance use disorders during pregnancy.

(c) Grants, contracts and cooperative agreements

The Director may make grants and enter into contracts and cooperative agreements in carrying out subsection (b).

(d) National data base

The Director of the Prevention Center shall establish a national data base providing information on

programs for the prevention of substance abuse. The data base shall contain information appropriate for use by public entities and information appropriate for use by nonprofit private entities.

(July 1, 1944, ch. 373, title V, §515, formerly §508, as added Pub. L. 99–570, title IV, §4005(a), Oct. 27, 1986, 100 Stat. 3207–111; amended Pub. L. 100–690, title II, §2051(a)–(c), Nov. 18, 1988, 102 Stat. 4206; Pub. L. 101–93, §3(a), Aug. 16, 1989, 103 Stat. 609; Pub. L. 101–647, title XIX, §1906, Nov. 29, 1990, 104 Stat. 4854; renumbered §515 and amended Pub. L. 102–321, title I, §113(b)–(e), July 10, 1992, 106 Stat. 345; Pub. L. 102–531, title III, §312(d)(10), Oct. 27, 1992, 106 Stat. 3505; Pub. L. 106–310, div. B, title XXXI, §3112(b), Oct. 17, 2000, 114 Stat. 1188; Pub. L. 114–255, div. B, title VI, §6007(b), Dec. 13, 2016, 130 Stat. 1212; Pub. L. 115–271, title VII, §7063(a), Oct. 24, 2018, 132 Stat. 4020.)

EDITORIAL NOTES

REFERENCES IN TEXT

The Drug-Free Schools and Communities Act of 1986, referred to in subsec. (b)(8), means title V of Pub. L. 89–10 as added by Pub. L. 100–297, title I, §1001, Apr. 28, 1988, 102 Stat. 252, which was classified generally to subchapter V (§3171 et seq.) of chapter 47 of Title 20, Education, prior to the general amendment of Pub. L. 89–10 by Pub. L. 103–382, title I, §101, Oct. 20, 1994, 108 Stat. 3519.

CODIFICATION

Section was formerly classified to section 290aa–6 of this title prior to renumbering by Pub. L. 102–321.

PRIOR PROVISIONS

A prior section 515 of act July 1, 1944, was classified to section 290cc of this title, prior to repeal by Pub. L. 102–321, title I, §123(c), July 10, 1992, 106 Stat. 363.

Another prior section 515 of act July 1, 1944, which was classified to section 229d of this title, was successively renumbered by subsequent acts and transferred, see section 238l of this title.

AMENDMENTS

2018—Subsec. (b)(15). Pub. L. 115–271 added par. (15).

2016—Pub. L. 114–255, §6007(b)(1), substituted "Center" for "Office" in section catchline.

Subsec. (a). Pub. L. 114–255, §6007(b)(2), substituted "a Center" for "an Office" and "The Prevention Center" for "The Office".

Subsec. (b)(1). Pub. L. 114–255, §6007(b)(3)(A), inserted "through the reduction of risk and the promotion of resiliency" before semicolon.

Subsec. (b)(3). Pub. L. 114–255, §6007(b)(3)(C), added par. (3). Former par. (3) redesignated (4).

Subsec. (b)(4). Pub. L. 114–255, §6007(b)(3)(B), (D), redesignated par. (3) as (4) and substituted "educational information on the effects of drugs abused by individuals, including drugs that are emerging as abused drugs" for "literature on the adverse effects of cocaine free base (known as 'crack')". Former par. (4) redesignated (5).

Subsec. (b)(5). Pub. L. 114–255, §6007(b)(3)(B), redesignated par. (4) as (5). Former par. (5) redesignated (6).

Subsec. (b)(6). Pub. L. 114–255, §6007(b)(3)(B), (E), redesignated par. (5) as (6) and substituted "health professionals who provide substance use and misuse prevention and treatment services" for "substance abuse counselors" and "illicit drug use education and prevention" for "drug abuse education, prevention,". Former par. (6) redesignated (7).

Subsec. (b)(7). Pub. L. 114–255, §6007(b)(3)(B), (F), redesignated par. (6) as (7) and amended par. (7) generally. Prior to amendment, par. (7) read as follows: "in cooperation with the Director of the Centers for Disease Control and Prevention, develop educational materials to reduce the risks of acquired immune deficiency syndrome among intravenous drug abusers;". Former par. (7) redesignated (8).

Subsec. (b)(8). Pub. L. 114–255, §6007(b)(3)(B), redesignated par. (7) as (8). Former par. (8) redesignated (9).

Subsec. (b)(9). Pub. L. 114–255, §6007(b)(3)(B), (G), redesignated par. (8) as (9) and substituted "that reduce the risk of" for "to discourage" and inserted "and promote resiliency" before semicolon. Former par. (9) redesignated (10).

Subsec. (b)(10) to (12). Pub. L. 114–255, §6007(b)(3)(B), redesignated pars. (9) to (11) as (10) to (12), respectively.

Subsec. (b)(13), (14). Pub. L. 114–255, §6007(b)(3)(H)–(J), added pars. (13) and (14).

2000—Subsec. (b)(9). Pub. L. 106–310, §3112(b)(2), added par. (9). Former par. (9) redesignated (10).

Subsec. (b)(10). Pub. L. 106–310, §3112(b)(1), (3), redesignated par. (9) as (10) and substituted "educate the public, especially adolescent audiences, concerning" for "educate the public concerning". Former par. (10) redesignated (11).

Subsec. (b)(11). Pub. L. 106–310, §3112(b)(1), redesignated par. (10) as (11).

1992—Subsec. (a). Pub. L. 102–321, §113(e)(1), substituted "(hereafter referred to in this part as the 'Prevention Center')" for "(hereafter in this part referred to as the 'Office')".

Subsec. (b). Pub. L. 102–321, §113(e)(2), substituted "Prevention Center" for "Office" in introductory provisions.

Subsec. (b)(5). Pub. L. 102–321, §113(c)(1), struck out "and intervention" after "prevention,".

Subsec. (b)(6). Pub. L. 102–531, which directed the amendment of "section 508(b)(6) (42 U.S.C. 290aa–6(b)(6))" of act July 1, 1944, by substituting "Centers for Disease Control and Prevention" for "Centers for Disease Control", was executed to subsec. (b)(6) of this section to reflect the probable intent of Congress and the intervening renumbering of section 508 of act July 1, 1944, as section 515 of that act by Pub. L. 102–321, §113(b)(2).

Subsec. (b)(9). Pub. L. 102–321, §113(c)(4), inserted "and" after semicolon at end.

Subsec. (b)(10) to (12). Pub. L. 102–321, §113(c)(2)–(4), redesignated par. (12) as (10) and struck out former pars. (10) and (11) which read as follows:

"(10)(A) provide assistance to communities to develop comprehensive long-term strategies for the prevention of substance abuse; and

"(B) evaluate the success of different community approaches toward the prevention of substance abuse;

"(11) through schools of health professions, schools of allied health professions, schools of nursing, and schools of social work, carry out programs—

"(A) to train individuals in the diagnosis and treatment of alcohol and drug abuse; and

"(B) to develop appropriate curricula and materials for the training described in subparagraph (A); and".

Subsec. (d). Pub. L. 102–321, §113(d), amended subsec. (d) generally. Prior to amendment, subsec. (d) read as follows:

"(1) For the purpose of carrying out this section and sections 290aa–7, 290aa–8, and 290aa–13 of this title, there are authorized to be appropriated $95,000,000 for fiscal year 1989 and such sums as may be necessary for each of the fiscal years 1990 and 1991.

"(2) Of the amounts appropriated pursuant to paragraph (1) for a fiscal year, the Secretary shall make available not less than $5,000,000 to carry out paragraphs (5) and (11) of subsection (b) of this section."

1990—Subsec. (b)(12). Pub. L. 101–647 added par. (12).

1989—Subsec. (b)(11)(B). Pub. L. 101–93, §3(a)(2), substituted "subparagraph (A)" for "subparagraph (a)".

Subsec. (d)(1). Pub. L. 101–93, §3(a)(1), inserted a comma after "290aa–13 of this title".

1988—Subsec. (b)(5). Pub. L. 100–690, §2051(b)(1), amended par. (5) generally. Prior to amendment, par. (5) read as follows: "support programs of clinical training of substance abuse counselors and other health professionals;".

Subsec. (b)(10). Pub. L. 100–690, §2051(b)(2) added par. (10).

Subsec. (b)(11). Pub. L. 100–690, §2051(c), added par. (11).

Subsec. (d). Pub. L. 100–690, §2051(a), amended subsec. (d) generally. Prior to amendment, subsec. (d) read as follows: "Of the amounts available under the second sentence of section 300y(a) of this title to carry out this section and section 290aa–8 of this title, $20,000,000 shall be available to carry out section 290aa–8 of this title."

STATUTORY NOTES AND RELATED SUBSIDIARIES

EFFECTIVE DATE OF 1992 AMENDMENT

Amendment by Pub. L. 102–321 effective Oct. 1, 1992, with provision for programs providing financial assistance, see section 801(c), (d) of Pub. L. 102–321, set out as a note under section 236 of this title.

§290bb–22. Priority substance use disorder prevention needs of regional and national significance

(a) Projects

The Secretary shall address priority substance use disorder prevention needs of regional and national significance (as determined under subsection (b)) through the provision of or through assistance for—

(1) knowledge development and application projects for prevention and the conduct or support of evaluations of such projects;

(2) training and technical assistance; and

(3) targeted capacity response programs, including such programs that focus on emerging drug use issues.

The Secretary may carry out the activities described in this section directly or through grants, contracts, or cooperative agreements with States, political subdivisions of States, Indian Tribes or Tribal organizations (as such terms are defined in section 5304 of title 25), health facilities, or programs operated by or in accordance with a contract or grant with the Indian Health Service, or other public or nonprofit private entities.

(b) Priority substance use disorder prevention needs

(1) In general

Priority substance use disorder prevention needs of regional and national significance shall be determined by the Secretary in consultation with the States and other interested groups. The Secretary shall meet with the States and interested groups on an annual basis to discuss program priorities.

(2) Special consideration

In developing program priorities under paragraph (1), the Secretary shall give special consideration to—

(A) applying the most promising strategies and research-based primary prevention approaches;

(B) promoting the integration of substance use disorder prevention information and activities into primary health care systems; and

(C) substance use disorder prevention among high-risk groups.

(c) Requirements

(1) In general

Recipients of grants, contracts, and cooperative agreements under this section shall comply with information and application requirements determined appropriate by the Secretary.

(2) Duration of award

With respect to a grant, contract, or cooperative agreement awarded under this section, the period during which payments under such award are made to the recipient may not exceed 5 years.

(3) Matching funds

The Secretary may, for projects carried out under subsection (a), require that entities that apply for grants, contracts, or cooperative agreements under that project provide non-Federal matching funds, as determined appropriate by the Secretary, to ensure the institutional commitment of the entity to the projects funded under the grant, contract, or cooperative agreement. Such non-Federal matching funds may be provided directly or through donations from public or private entities and may be in cash or in kind, fairly evaluated, including plant, equipment, or services.

(4) Maintenance of effort

With respect to activities for which a grant, contract, or cooperative agreement is awarded under this section, the Secretary may require that recipients for specific projects under subsection (a) agree to maintain expenditures of non-Federal amounts for such activities at a level that is not less than the level of such expenditures maintained by the entity for the fiscal year preceding the fiscal year for which the entity receives such a grant, contract, or cooperative agreement.

(d) Evaluation

The Secretary shall evaluate each project carried out under subsection (a)(1) and shall disseminate the findings with respect to each such evaluation to appropriate public and private entities.

(e) Information and education

The Secretary shall establish comprehensive information and education programs to disseminate the findings of the knowledge development and application, training and technical assistance programs, and targeted capacity response programs under this section to the general public and to health professionals. The Secretary shall make every effort to provide linkages between the findings of supported projects and State agencies responsible for carrying out substance use disorder prevention and treatment programs.

(f) Authorization of appropriation

There are authorized to be appropriated to carry out this section, $218,219,000 for each of fiscal years 2023 through 2027.

(July 1, 1944, ch. 373, title V, §516, formerly §509, as added Pub. L. 99–570, title IV, §4005(a), Oct. 27, 1986, 100 Stat. 3207–112; renumbered §516 and amended Pub. L. 102–321, title I, §113(f), July 10, 1992, 106 Stat. 345; Pub. L. 106–310, div. B, title XXXIII, §3302(a), Oct. 17, 2000, 114 Stat. 1209; Pub. L. 114–255, div. B, title VII, §7005, Dec. 13, 2016, 130 Stat. 1224; Pub. L. 117–328, div. FF, title I, §1214, Dec. 29, 2022, 136 Stat. 5661.)

EDITORIAL NOTES

CODIFICATION

Section was formerly classified to section 290aa–7 of this title prior to renumbering by Pub. L. 102–321.

PRIOR PROVISIONS

A prior section 516 of act July 1, 1944, was classified to section 290cc–1 of this title, prior to repeal by Pub. L. 102–321, title I, §123(c), July 10, 1992, 106 Stat. 363.

AMENDMENTS

2022—Subsec. (a). Pub. L. 117–328, §1214(1)(B), substituted "Tribes or Tribal organizations" for "tribes or tribal organizations" in concluding provisions.

Subsec. (a)(3). Pub. L. 117–328, §1214(1)(A), substituted "use" for "abuse".

Subsec. (b). Pub. L. 117–328, §1214(2), substituted "use disorder" for "abuse" in heading.

Subsec. (f). Pub. L. 117–328, §1214(3), substituted "$218,219,000 for each of fiscal years 2023 through 2027" for "$211,148,000 for each of fiscal years 2018 through 2022".

2016—Pub. L. 114–255, §7005(1), substituted "use disorder" for "abuse" in section catchline.

Subsec. (a). Pub. L. 114–255, §7005(2)(A), (C), in introductory provisions, substituted "use disorder" for "abuse" and, in concluding provisions, inserted ", contracts," before "or cooperative agreements" and substituted "Indian tribes or tribal organizations (as such terms are defined in section 5304 of title 25), health facilities, or programs operated by or in accordance with a contract or grant with the Indian Health Service," for "Indian tribes and tribal organizations,".

Subsec. (a)(3). Pub. L. 114–255, §7005(2)(B), inserted ", including such programs that focus on emerging drug abuse issues" before period.

Subsec. (b). Pub. L. 114–255, §7005(3), substituted "use disorder" for "abuse" in pars. (1) and (2)(B) and added par. (2)(C).

Subsec. (e). Pub. L. 114–255, §7005(4), substituted "use disorder" for "abuse".

Subsec. (f). Pub. L. 114–255, §7005(5), substituted "$211,148,000 for each of fiscal years 2018 through 2022." for "$300,000,000 for fiscal year 2001, and such sums as may be necessary for each of the fiscal years 2002 and 2003."

2000—Pub. L. 106–310 amended section catchline and text generally, substituting provisions relating to priority substance abuse prevention needs of regional and national significance for provisions relating to community programs.

1992—Pub. L. 102–321, §113(f)(4), amended section generally, substituting provisions relating to community programs for provisions relating to alcohol and drug abuse information clearinghouse.

STATUTORY NOTES AND RELATED SUBSIDIARIES

EFFECTIVE DATE OF 1992 AMENDMENT

Amendment by Pub. L. 102–321 effective Oct. 1, 1992, with provision for programs providing financial assistance, see section 801(c), (d) of Pub. L. 102–321, set out as a note under section 236 of this title.

§290bb–23. Repealed. Pub. L. 114–255, div. B, title IX, §9017, Dec. 13, 2016, 130 Stat. 1248

Section, act July 1, 1944, ch. 373, title V, §517, formerly §509A, as added Pub. L. 99–570, title IV, §4005(a), Oct. 27, 1986, 100 Stat. 3207–113; amended Pub. L. 100–690, title II, §2051(d), Nov. 18, 1988, 102 Stat. 4206; renumbered §517 and amended Pub. L. 102–321, title I, §114, July 10, 1992, 106 Stat. 346; Pub. L. 106–310, div. B, title XXXI, §3103, Oct. 17, 2000, 114 Stat. 1171, related to prevention, treatment, and rehabilitation model projects for high risk youth.

A prior section 517 of act July 1, 1944, was classified to section 290cc–2 of this title, prior to repeal by Pub. L. 102–321, title I, §123(c), July 10, 1992, 106 Stat. 363.

§290bb–24. Repealed. Pub. L. 106–310, div. B, title XXXIII, §3302(b), Oct. 17, 2000, 114 Stat. 1210

Section, act July 1, 1944, ch. 373, title V, §518, as added Pub. L. 102–321, title I, §171, July 10, 1992, 106 Stat. 377, related to employee assistance programs.

A prior section 518 of act July 1, 1944, was classified to section 290cc–11 of this title, prior to repeal by Pub. L. 102–321, §120(b)(3).

§290bb–25. Grants for services for children of substance abusers

(a) Establishment

(1) In general

The Secretary, acting through the Assistant Secretary for Mental Health and Substance Use, shall make grants to public and nonprofit private entities for the purpose of carrying out programs—

(A) to provide the services described in subsection (b) to children of substance abusers;

(B) to provide the applicable services described in subsection (c) to families in which a member is a substance abuser;

(C) to identify such children and such families through youth service agencies, family social services, child care providers, Head Start, schools and after-school programs, early childhood development programs, community-based family resource and support centers, the criminal justice system, health, substance abuse and mental health providers through screenings conducted during regular childhood examinations and other examinations, self and family member referrals, substance abuse treatment services, and other providers of services to children and families; and

(D) to provide education and training to health, substance abuse and mental health professionals, and other providers of services to children and families through youth service agencies, family social services, child care, Head Start, schools and after-school programs, early childhood development programs, community-based family resource and support centers, the criminal justice system, and other providers of services to children and families.

(2) Administrative consultations

The Assistant Secretary of the Administration for Children, Youth, and Families and the Assistant Secretary of the Health Resources and Services Administration shall be consulted

regarding the promulgation of program guidelines and funding priorities under this section.

(3) Requirement of status as medicaid provider

(A) Subject to subparagraph (B), the Secretary may make a grant under paragraph (1) only if, in the case of any service under such paragraph that is covered in the State plan approved under title XIX of the Social Security Act [42 U.S.C. 1396 et seq.] for the State involved—

(i)(I) the entity involved will provide the service directly, and the entity has entered into a participation agreement under the State plan and is qualified to receive payments under such plan; or

(II) the entity will enter into an agreement with an organization under which the organization will provide the service, and the organization has entered into such a participation agreement and is qualified to receive such payments; and

(ii) the entity will identify children who may be eligible for medical assistance under a State program under title XIX or XXI of the Social Security Act [42 U.S.C. 1396 et seq., 1397aa et seq.].

(B)(i) In the case of an organization making an agreement under subparagraph (A)(ii) [1] regarding the provision of services under paragraph (1), the requirement established in such subparagraph regarding a participation agreement shall be waived by the Secretary if the organization does not, in providing health or mental health services, impose a charge or accept reimbursement available from any third-party payor, including reimbursement under any insurance policy or under any Federal or State health benefits program.

(ii) A determination by the Secretary of whether an organization referred to in clause (i) meets the criteria for a waiver under such clause shall be made without regard to whether the organization accepts voluntary donations regarding the provision of services to the public.

(b) Services for children of substance abusers

The Secretary may make a grant under subsection (a) only if the applicant involved agrees to make available (directly or through agreements with other entities) to children of substance abusers each of the following services:

(1) Periodic evaluation of children for developmental, psychological, alcohol and drug, and medical problems.

(2) Primary pediatric care.

(3) Other necessary health and mental health services.

(4) Therapeutic intervention services for children, including provision of therapeutic child care.

(5) Developmentally and age-appropriate drug and alcohol early intervention, treatment and prevention services.

(6) Counseling related to the witnessing of chronic violence.

(7) Referrals for, and assistance in establishing eligibility for, services provided under—

(A) education and special education programs;

(B) Head Start programs established under the Head Start Act [42 U.S.C. 9831 et seq.];

(C) other early childhood programs;

(D) employment and training programs;

(E) public assistance programs provided by Federal, State, or local governments; and

(F) programs offered by vocational rehabilitation agencies, recreation departments, and housing agencies.

(8) Additional developmental services that are consistent with the provision of early intervention services, as such term is defined in part C of the Individuals with Disabilities Education Act [20 U.S.C. 1431 et seq.].

Services shall be provided under paragraphs (2) through (8) by a public health nurse, social worker, or similar professional, or by a trained worker from the community who is supervised by a professional, or by an entity, where the professional or entity provides assurances that the

professional or entity is licensed or certified by the State if required and is complying with applicable licensure or certification requirements.

(c) Services for affected families

The Secretary may make a grant under subsection (a) only if, in the case of families in which a member is a substance abuser, the applicant involved agrees to make available (directly or through agreements with other entities) each of the following services, as applicable to the family member involved:

(1) Services as follows, to be provided by a public health nurse, social worker, or similar professional, or by a trained worker from the community who is supervised by a professional, or by an entity, where the professional or entity provides assurances that the professional or entity is licensed or certified by the State if required and is complying with applicable licensure or certification requirements:

(A) Counseling to substance abusers on the benefits and availability of substance abuse treatment services and services for children of substance abusers.

(B) Assistance to substance abusers in obtaining and using substance abuse treatment services and in obtaining the services described in subsection (b) for their children.

(C) Visiting and providing support to substance abusers, especially pregnant women, who are receiving substance abuse treatment services or whose children are receiving services under subsection (b).

(D) Aggressive outreach to family members with substance abuse problems.

(E) Inclusion of consumer in the development, implementation, and monitoring of Family Services Plan.

(2) In the case of substance abusers:

(A) Alcohol and drug treatment services, including screening and assessment, diagnosis, detoxification, individual, group and family counseling, relapse prevention, pharmacotherapy treatment, after-care services, and case management.

(B) Primary health care and mental health services, including prenatal and post partum care for pregnant women.

(C) Consultation and referral regarding subsequent pregnancies and life options and counseling on the human immunodeficiency virus and acquired immune deficiency syndrome.

(D) Where appropriate, counseling regarding family violence.

(E) Career planning and education services.

(F) Referrals for, and assistance in establishing eligibility for, services described in subsection (b)(7).

(3) In the case of substance abusers, spouses of substance abusers, extended family members of substance abusers, caretakers of children of substance abusers, and other people significantly involved in the lives of substance abusers or the children of substance abusers:

(A) An assessment of the strengths and service needs of the family and the assignment of a case manager who will coordinate services for the family.

(B) Therapeutic intervention services, such as parental counseling, joint counseling sessions for families and children, and family therapy.

(C) Child care or other care for the child to enable the parent to attend treatment or other activities and respite care services.

(D) Parenting education services and parent support groups which include child abuse and neglect prevention techniques.

(E) Support services, including, where appropriate, transportation services.

(F) Where appropriate, referral of other family members to related services such as job training.

(G) Aftercare services, including continued support through parent groups and home visits.

(d) Training for providers of services to children and families

The Secretary may make a grant under subsection (a) for the training of health, substance abuse and mental health professionals and other providers of services to children and families through youth service agencies, family social services, child care providers, Head Start, schools and after-school programs, early childhood development programs, community-based family resource centers, the criminal justice system, and other providers of services to children and families. Such training shall be to assist professionals in recognizing the drug and alcohol problems of their clients and to enhance their skills in identifying and understanding the nature of substance abuse, and obtaining substance abuse early intervention, prevention and treatment resources.

(e) Eligible entities

The Secretary shall distribute the grants through the following types of entities:

(1) Alcohol and drug early intervention, prevention or treatment programs, especially those providing treatment to pregnant women and mothers and their children.

(2) Public or nonprofit private entities that provide health or social services to disadvantaged populations, and that have—

(A) expertise in applying the services to the particular problems of substance abusers and the children of substance abusers; or

(B) an affiliation or contractual relationship with one or more substance abuse treatment programs or pediatric health or mental health providers and family mental health providers.

(3) Consortia of public or nonprofit private entities that include at least one substance abuse treatment program.

(4) Indian tribes.

(f) Federal share

The Federal share of a program carried out under subsection (a) shall be 90 percent. The Secretary shall accept the value of in-kind contributions, including facilities and personnel, made by the grant recipient as a part or all of the non-Federal share of grants.

(g) Restrictions on use of grant

The Secretary may make a grant under subsection (a) only if the applicant involved agrees that the grant will not be expended—

(1) to provide inpatient hospital services;

(2) to make cash payments to intended recipients of services;

(3) to purchase or improve land, purchase, construct, or permanently improve (other than minor remodeling) any building or other facility, or purchase major medical equipment;

(4) to satisfy any requirement for the expenditure of non-Federal funds as a condition for the receipt of Federal funds; or

(5) to provide financial assistance to any entity other than a public or nonprofit private entity.

(h) Submission to Secretary of certain information

The Secretary may make a grant under subsection (a) only if the applicant involved submits to the Secretary—

(1) a description of the population that is to receive services under this section and a description of such services that are to be provided and measurable goals and objectives;

(2) a description of the mechanism that will be used to involve the local public agencies responsible for health, including maternal and child health [2] mental health, child welfare, education, juvenile justice, developmental disabilities, and substance abuse in planning and providing services under this section, as well as evidence that the proposal has been coordinated with the State agencies responsible for administering those programs, the State agency responsible for administering alcohol and drug programs, the State lead agency, and the State Interagency Coordinating Council under part H [1] of the Individuals with Disabilities Education Act; and; [3]

(3) such other information as the Secretary determines to be appropriate.

(i) Reports to Secretary

The Secretary may make a grant under subsection (a) only if the applicant involved agrees that for each fiscal year for which the applicant receives such a grant the applicant, in accordance with uniform standards developed by the Secretary, will submit to the Secretary a report containing—

(1) a description of specific services and activities provided under the grant;

(2) information regarding progress toward meeting the program's stated goals and objectives;

(3) information concerning the extent of use of services provided under the grant, including the number of referrals to related services and information on other programs or services accessed by children, parents, and other caretakers;

(4) information concerning the extent to which parents were able to access and receive treatment for alcohol and drug abuse and sustain participation in treatment over time until the provider and the individual receiving treatment agree to end such treatment, and the extent to which parents re-enter treatment after the successful or unsuccessful termination of treatment;

(5) information concerning the costs of the services provided and the source of financing for health care services;

(6) information concerning—

(A) the number and characteristics of families, parents, and children served, including a description of the type and severity of childhood disabilities, and an analysis of the number of children served by age;

(B) the number of children served who remained with their parents during the period in which entities provided services under this section; and

(C) the number of case workers or other professionals trained to identify and address substance abuse issues.

(7) information on hospitalization or emergency room use by the family members participating in the program; and

(8) such other information as the Secretary determines to be appropriate.

(j) Requirement of application

The Secretary may make any grant under subsection (a) only if—

(1) an application for the grant is submitted to the Secretary;

(2) the application contains the agreements required in this section and the information required in subsection (h); and

(3) the application is in such form, is made in such manner, and contains such agreements, assurances, and information as the Secretary determines to be necessary to carry out this section.

(k) Evaluations

The Secretary shall periodically conduct evaluations to determine the effectiveness of programs supported under subsection (a)—

(1) in reducing the incidence of alcohol and drug abuse among substance abusers participating in the programs;

(2) in preventing adverse health conditions in children of substance abusers;

(3) in promoting better utilization of health and developmental services and improving the health, developmental, and psychological status of children receiving services under the program; and

(4) in improving parental and family functioning, including increased participation in work or employment-related activities and decreased participation in welfare programs.

(l) Report to Congress

Not later than 2 years after the date on which amounts are first appropriated under subjection [4] (o), the Secretary shall prepare and submit to the Committee on Energy and Commerce of the House of Representatives, and to the Committee on Labor and Human Resources of the Senate, a report that contains a description of programs carried out under this section. At a minimum, the report shall contain—

(1) information concerning the number and type of programs receiving grants;

(2) information concerning the type and use of services offered; and
(3) information concerning—
(A) the number and characteristics of families, parents, and children served; and
(B) the number of children served who remained with their parents during or after the period in which entities provided services under this section.[5]

analyzed by the type of entity described in subsection (e) that provided services; [6]

(m) Data collection

The Secretary shall periodically collect and report on information concerning the numbers of children in substance abusing families, including information on the age, gender and ethnicity of the children, the composition and income of the family, and the source of health care finances. The periodic report shall include a quantitative estimate of the prevalence of alcohol and drug problems in families involved in the child welfare system, the barriers to treatment and prevention services facing these families, and policy recommendations for removing the identified barriers, including training for child welfare workers.

(n) Definitions

For purposes of this section:
(1) The term "caretaker", with respect to a child of a substance abuser, means any individual acting in a parental role regarding the child (including any birth parent, foster parent, adoptive parent, relative of such a child, or other individual acting in such a role).
(2) The term "children of substance abusers" means—
(A) children who have lived or are living in a household with a substance abuser who is acting in a parental role regarding the children; and
(B) children who have been prenatally exposed to alcohol or other drugs.

(3) The term "Indian tribe" means any tribe, band, nation, or other organized group or community of Indians, including any Alaska Native village (as defined in, or established pursuant to, the Alaska Native Claims Settlement Act [43 U.S.C. 1601 et seq.]), that is recognized as eligible for the special programs and services provided by the United States to Indians because of their status as Indians.
(4) The term "public or nonprofit private entities that provide health or social services to disadvantaged populations" includes community-based organizations, local public health departments, community action agencies, hospitals, community health centers, child welfare agencies, developmental disabilities service providers, and family resource and support programs.
(5) The term "substance abuse" means the abuse of alcohol or other drugs.

(o) Authorization of appropriations

For the purpose of carrying out this section, there are authorized to be appropriated $50,000,000 for fiscal year 2001, and such sums as may be necessary for each of fiscal years 2002 and 2003.

(July 1, 1944, ch. 373, title V, §519, formerly title III, §399D, as added Pub. L. 102–321, title IV, §401(a), July 10, 1992, 106 Stat. 419; renumbered §399A, renumbered title V, §519, and amended Pub. L. 106–310, div. A, title V, §502(1), div. B, title XXXI, §3106(a)–(m), Oct. 17, 2000, 114 Stat. 1115, 1175–1179; Pub. L. 108–446, title III, §305(i)(1), (3), Dec. 3, 2004, 118 Stat. 2806; Pub. L. 114–255, div. B, title VI, §6001(c), Dec. 13, 2016, 130 Stat. 1203.)

EDITORIAL NOTES

REFERENCES IN TEXT

The Social Security Act, referred to in subsec. (a)(3)(A), is act Aug. 14, 1935, ch. 531, 49 Stat. 620. Titles XIX and XXI of the Act are classified generally to subchapters XIX (§1396 et seq.) and XXI (§1397aa et seq.), respectively, of chapter 7 of this title. For complete classification of this Act to the Code, see section 1305 of this title and Tables.

Subparagraph (A)(ii), referred to in subsec. (a)(3)(B)(i), meaning subsec. (a)(3)(A)(ii) of this section was redesignated as subsec. (a)(3)(A)(i)(II) and a new subsec. (a)(3)(A)(ii) was added by Pub. L. 106–310, div. B, title XXXI, §3106(a)(3)(B)(i), (C), Oct. 17, 2000, 114 Stat. 1176.

The Head Start Act, referred to in subsec. (b)(7)(B), is subchapter B (§§635–657) of chapter 8 of subtitle A of title VI of Pub. L. 97–35, Aug. 13, 1981, 95 Stat. 499, which is classified generally to subchapter II (§9831 et seq.) of chapter 105 of this title. For complete classification of this Act to the Code, see Short Title note set out under section 9801 of this title and Tables.

The Individuals with Disabilities Education Act, referred to in subsecs. (b)(8) and (h)(2), is title VI of Pub. L. 91–230, Apr. 13, 1970, 84 Stat. 175. Part C of the Act is classified generally to subchapter III (§1431 et seq.) of chapter 33 of Title 20, Education. Part H of the Act was classified generally to subchapter VIII (§1471 et seq.) of chapter 33 of Title 20, prior to repeal by Pub. L. 105–17, title II, §203(b), June 4, 1997, 111 Stat. 157, effective July 1, 1998. For complete classification of this Act to the Code, see section 1400 of Title 20 and Tables.

The Alaska Native Claims Settlement Act, referred to in subsec. (n)(3), is Pub. L. 92–203, Dec. 18, 1971, 85 Stat. 688, which is classified generally to chapter 33 (§1601 et seq.) of Title 43, Public Lands. For complete classification of this Act to the Code, see Short Title note set out under section 1601 of Title 43 and Tables.

CODIFICATION

Section was formerly classified to section 280d of this title.

AMENDMENTS

2016—Subsec. (a)(1). Pub. L. 114–255, §6001(c)(1), substituted "Assistant Secretary for Mental Health and Substance Use" for "Administrator of the Substance Abuse and Mental Health Services Administration" in introductory provisions.

Subsec. (a)(2). Pub. L. 114–255, §6001(c)(2), substituted "Assistant Secretary" for "Administrator" in two places.

2004—Subsecs. (b)(8), (f). Pub. L. 108–446, §305(i)(1), (3), which directed amendment of subsecs. (b)(8) and (f) of section 399A of the Public Health Service Act by substituting "part C" for "part H", was executed to subsec. (b)(8) of this section, which is section 519 of the Public Health Service Act, to reflect the probable intent of Congress and the renumbering of this section and repeal of former subsec. (f). See 2000 Amendments notes below.

2000—Pub. L. 106–310, §3106(a)–(m), which directed numerous amendments to section 399D of the Public Health Service Act and the subsequent renumbering of that section as section 519 of title V of the Act, was executed by amending this section and renumbering this section as section 519 of title V, to reflect the probable intent of Congress, notwithstanding the intervening renumbering of this section as section 399A of the Act by section 502(1) of Pub. L. 106–310. See source credit above and notes below.

Subsec. (a)(1). Pub. L. 106–310, §3106(a)(1)(A), substituted "Administrator of the Substance Abuse and Mental Health Services Administration" for "Administrator of the Health Resources and Services Administration" in introductory provisions.

Subsec. (a)(1)(B). Pub. L. 106–310, §3106(a)(2)(A), struck out "and" at end.

Subsec. (a)(1)(C). Pub. L. 106–310, §3106(a)(2)(B), substituted "through youth service agencies, family social services, child care providers, Head Start, schools and after-school programs, early childhood development programs, community-based family resource and support centers, the criminal justice system, health, substance abuse and mental health providers through screenings conducted during regular childhood examinations and other examinations, self and family member referrals, substance abuse treatment services, and other providers of services to children and families; and" for period at end.

Subsec. (a)(1)(D). Pub. L. 106–310, §3106(a)(2)(C), added subpar. (D).

Subsec. (a)(2). Pub. L. 106–310, §3106(a)(1)(B), substituted "Administrator of the Health Resources and Services Administration" for "Administrator of the Substance Abuse and Mental Health Services Administration".

Subsec. (a)(3)(A). Pub. L. 106–310, §3106(a)(3), redesignated cls. (i) and (ii) as subcls. (I) and (II), respectively, of cl. (i) and added cl. (ii).

Subsec. (b). Pub. L. 106–310, §3106(b)(3), inserted concluding provisions.

Subsec. (b)(1). Pub. L. 106–310, §3106(b)(1), inserted "alcohol and drug," after "psychological,".

Subsec. (b)(5). Pub. L. 106–310, §3106(b)(2), added par. (5) and struck out former par. (5) relating to preventive counseling services.

Subsec. (c)(1). Pub. L. 106–310, §3106(c)(1)(A), inserted ", or by an entity, where the professional or entity

provides assurances that the professional or entity is licensed or certified by the State if required and is complying with applicable licensure or certification requirements" before colon in introductory provisions.

Subsec. (c)(1)(D), (E). Pub. L. 106–310, §3106(c)(1)(B), added subpars. (D) and (E).

Subsec. (c)(2)(A). Pub. L. 106–310, §3106(c)(2)(A), added subpar. (A) and struck out former subpar. (A) relating to encouragement to participate in and referrals to appropriate substance abuse treatment.

Subsec. (c)(2)(C). Pub. L. 106–310, §3106(c)(2)(B), which directed substitution of "and counseling on the human immunodeficiency virus and acquired immune deficiency syndrome" for ", including educational and career planning", was executed by making the substitution for ", including education and career planning" to reflect the probable intent of Congress.

Subsec. (c)(2)(D). Pub. L. 106–310, §3106(c)(2)(C), struck out "conflict and" before "violence".

Subsec. (c)(2)(E). Pub. L. 106–310, §3106(c)(2)(D), substituted "Career planning and education services" for "Remedial education services".

Subsec. (c)(3)(D). Pub. L. 106–310, §3106(c)(3), inserted "which include child abuse and neglect prevention techniques" before period at end.

Subsec. (d). Pub. L. 106–310, §3106(l)(3), (4), added subsec. (d) and redesignated former subsec. (d) as (e).

Pub. L. 106–310, §3106(d)(1), substituted "Eligible entities" for "Considerations in making grants" in heading and "The Secretary shall distribute the grants through the following types of entities:" for "In making grants under subsection (a) of this section, the Secretary shall ensure that the grants are reasonably distributed among the following types of entities:" in introductory provisions.

Subsec. (d)(1). Pub. L. 106–310, §3106(d)(2), substituted "drug early intervention, prevention or treatment programs" for "drug treatment programs".

Subsec. (d)(2)(A). Pub. L. 106–310, §3106(d)(3)(A), substituted "; or" for "; and".

Subsec. (d)(2)(B). Pub. L. 106–310, §3106(d)(3)(B), inserted "or pediatric health or mental health providers and family mental health providers" before period at end.

Subsec. (e). Pub. L. 106–310, §3106(l)(3), redesignated subsec. (d) as (e). Former subsec. (e) redesignated (f).

Subsec. (f). Pub. L. 106–310, §3106(l)(1), (3), redesignated subsec. (e) as (f) and struck out former subsec. (f) relating to coordination with other providers.

Subsec. (h)(2). Pub. L. 106–310, §3106(e)(1), inserted "including maternal and child health" before "mental health", struck out "treatment programs" after "substance abuse", and substituted ", the State agency responsible for administering alcohol and drug programs, the State lead agency, and the State Interagency Coordinating Council under part H of the Individuals with Disabilities Education Act; and" for "and the State agency responsible for administering public maternal and child health services".

Subsec. (h)(3), (4). Pub. L. 106–310, §3106(e)(2), redesignated par. (4) as (3) and struck out former par. (3) relating to requirement to submit to Secretary information demonstrating that the applicant has established a collaborative relationship with child welfare agencies and child protective services.

Subsec. (i)(6)(B). Pub. L. 106–310, §3106(f)(1), inserted "and" at end.

Subsec. (i)(6)(C). Pub. L. 106–310, §3106(f)(2), added subpar. (C) and struck out former subpar. (C) relating to the number of children served who were placed in out-of-home care during the period in which entities provided services under section.

Subsec. (i)(6)(D), (E). Pub. L. 106–310, §3106(f)(2), struck out subpars. (D) and (E) relating to the number of children described in subparagraph (C) who were reunited with their families and the number of children described in subparagraph (C) for whom a permanent plan has not been made or for whom the permanent plan is other than family reunification, respectively.

Subsec. (k). Pub. L. 106–310, §3106(l)(2), (3), redesignated subsec. (l) as (k) and struck out former subsec. (k) relating to peer review.

Subsec. (k)(2). Pub. L. 106–310, §3106(l)(5), which directed amendment of subsec. (k)(2) of this section by substituting "(i)" for "(h)", could not be executed because "(h)" does not appear in subsec. (k)(2).

Subsec. (l). Pub. L. 106–310, §3106(l)(3), redesignated subsec. (m) as (l). Former subsec. (l) redesignated (k).

Subsec. (l)(3). Pub. L. 106–310, §3106(l)(6), which directed substitution of "(e)" for "(d)" in subsec. (m)(3)(E), was executed by making the substitution in concluding provisions of subsec. (l)(3) to reflect the probable intent of Congress and the amendment by Pub. L. 106–310, §3106(l)(3). See above.

Pub. L. 106–310, §3106(g)(1), inserted "and" at end.

Subsec. (l)(4). Pub. L. 106–310, §3106(g)(2), substituted ", including increased participation in work or employment-related activities and decreased participation in welfare programs." for semicolon at end.

Subsec. (l)(5), (6). Pub. L. 106–310, §3106(g)(3), struck out pars. (5) and (6) relating to reducing the incidence of out-of-home placement for children whose parents receive services under the program and

facilitating the reunification of families after children have been placed in out-of-home care, respectively.

Subsec. (m). Pub. L. 106–310, §3106(l)(3), redesignated subsec. (n) as (m). Former subsec. (m) redesignated (l).

Subsec. (m)(2). Pub. L. 106–310, §3106(h)(1), inserted "and" at end.

Subsec. (m)(3)(A). Pub. L. 106–310, §3106(h)(2)(A), inserted "and" at end.

Subsec. (m)(3)(B). Pub. L. 106–310, §3106(h)(2)(B), substituted period for semicolon at end.

Subsec. (m)(3)(C) to (E). Pub. L. 106–310, §3106(h)(2)(C), struck out subpars. (C) to (E) relating to the number of children served who were placed in out-of-home care during the period in which entities provided services under this section, the number of children described in subparagraph (C) who were reunited with their families, and the number of children described in subparagraph (C) who were permanently placed in out-of-home care, respectively.

Subsec. (m)(4). Pub. L. 106–310, §3106(h)(3), struck out par. (4) relating to an analysis of the access provided to, and use of, related services and alcohol and drug treatment through programs carried out under this section.

Subsec. (m)(5). Pub. L. 106–310, §3106(l)(6), which directed amendment of subsec. (m)(5) by substituting "(e)" for "(d)", could not be executed because subsec. (m) did not contain a par. (5) or a reference to "(d)" subsequent to the amendments by Pub. L. 106–310, §3106(h)(3), (l)(3). See notes above and below.

Pub. L. 106–310, §3106(h)(3), struck out par. (5) relating to a comparison of the costs of providing services through each of the types of entities described in subsection (d) of this section.

Subsec. (n). Pub. L. 106–310, §3106(l)(3), redesignated subsec. (o) as (n). Former subsec. (n) redesignated (m).

Pub. L. 106–310, §3106(i), inserted at end "The periodic report shall include a quantitative estimate of the prevalence of alcohol and drug problems in families involved in the child welfare system, the barriers to treatment and prevention services facing these families, and policy recommendations for removing the identified barriers, including training for child welfare workers."

Subsec. (o). Pub. L. 106–310, §3106(l)(3), redesignated subsec. (p) as (o). Former subsec. (o) redesignated (n).

Subsec. (o)(2)(B). Pub. L. 106–310, §3106(j), struck out "dangerous" before "drugs".

Subsec. (p). Pub. L. 106–310, §3106(l)(3), redesignated subsec. (p) as (o).

Pub. L. 106–310, §3106(k), amended heading and text of subsec. (p) generally, substituting provisions relating to authorization of appropriations for provisions relating to funding for carrying out section.

STATUTORY NOTES AND RELATED SUBSIDIARIES

CHANGE OF NAME

Committee on Labor and Human Resources of Senate changed to Committee on Health, Education, Labor, and Pensions of Senate by Senate Resolution No. 20, One Hundred Sixth Congress, Jan. 19, 1999.

Committee on Energy and Commerce of House of Representatives treated as referring to Committee on Commerce of House of Representatives by section 1(a) of Pub. L. 104–14, set out as a note preceding section 21 of Title 2, The Congress. Committee on Commerce of House of Representatives changed to Committee on Energy and Commerce of House of Representatives, and jurisdiction over matters relating to securities and exchanges and insurance generally transferred to Committee on Financial Services of House of Representatives by House Resolution No. 5, One Hundred Seventh Congress, Jan. 3, 2001.

EFFECTIVE DATE

Section effective July 10, 1992, with programs making awards providing financial assistance in fiscal year 1993 and subsequent years effective for awards made on or after Oct. 1, 1992, see section 801(b), (d)(1) of Pub. L. 102–321, set out as an Effective Date of 1992 Amendment note under section 236 of this title.

CONSTRUCTION

Pub. L. 102–321, title IV, §401(b), July 10, 1992, 106 Stat. 426, provided that: "With respect to the program established in section 399D [now 519] of the Public Health Service Act [42 U.S.C. 290bb–25] (as added by subsection (a) of this section), nothing in such section 399D may be construed as establishing for any other Federal program any requirement, authority, or prohibition, including with respect to recipients of funds under such other Federal programs."

REFERENCE TO COMMUNITY, MIGRANT, PUBLIC HOUSING, OR HOMELESS HEALTH CENTER CONSIDERED REFERENCE TO HEALTH CENTER

Reference to community health center, migrant health center, public housing health center, or homeless health center considered reference to health center, see section 4(c) of Pub. L. 104–299, set out as a note under section 254b of this title.

[1] *See References in Text note below.*

[2] *So in original. Probably should be followed by a comma.*

[3] *So in original. The semicolon probably should not appear after "and".*

[4] *So in original. Probably should be "subsection".*

[5] *So in original. The period probably should be a semicolon.*

[6] *So in original. The semicolon probably should be a period.*

§290bb–25a. Repealed. Pub. L. 114–255, div. B, title IX, §9017, Dec. 13, 2016, 130 Stat. 1248

Section, act July 1, 1944, ch. 373, title V, §519A, as added Pub. L. 106–310, div. B, title XXXI, §3108, Oct. 17, 2000, 114 Stat. 1180, related to grants for strengthening families.

§290bb–25b. Programs to reduce underage drinking

(a) Definitions

For purposes of this section:

(1) The term "alcohol beverage industry" means the brewers, vintners, distillers, importers, distributors, and retail or online outlets that sell or serve beer, wine, and distilled spirits.

(2) The term "school-based prevention" means programs, which are institutionalized, and run by staff members or school-designated persons or organizations in any grade of school, kindergarten through 12th grade.

(3) The term "youth" means persons under the age of 21.

(b) Sense of Congress

It is the sense of the Congress that:

(1) A multi-faceted effort is needed to more successfully address the problem of underage drinking in the United States. A coordinated approach to prevention, intervention, treatment, enforcement, and research is key to making progress. This chapter recognizes the need for a focused national effort, and addresses particulars of the Federal portion of that effort, as well as Federal support for State activities.

(2) The Secretary of Health and Human Services shall continue to conduct research and collect data on the short and long-range impact of alcohol use and abuse upon adolescent brain development and other organ systems.

(3) States and communities, including colleges and universities, are encouraged to adopt comprehensive prevention approaches, including—

(A) evidence-based screening, programs and curricula;

(B) brief intervention strategies;

(C) consistent policy enforcement; and

(D) environmental changes that limit underage access to alcohol.

(4) Public health groups, consumer groups, and the alcohol beverage industry should continue and expand evidence-based efforts to prevent and reduce underage drinking.

(5) The entertainment industries have a powerful impact on youth, and they should use rating systems and marketing codes to reduce the likelihood that underage audiences will be exposed to movies, recordings, or television programs with unsuitable alcohol content.

(6) The National Collegiate Athletic Association, its member colleges and universities, and athletic conferences should affirm a commitment to a policy of discouraging alcohol use among underage students and other young fans.

(7) Alcohol is a unique product and should be regulated differently than other products by the States and Federal Government. States have primary authority to regulate alcohol distribution and sale, and the Federal Government should support and supplement these State efforts. States also have a responsibility to fight youth access to alcohol and reduce underage drinking. Continued State regulation and licensing of the manufacture, importation, sale, distribution, transportation and storage of alcoholic beverages are clearly in the public interest and are critical to promoting responsible consumption, preventing illegal access to alcohol by persons under 21 years of age from commercial and non-commercial sources, maintaining industry integrity and an orderly marketplace, and furthering effective State tax collection.

(c) Interagency coordinating committee; annual report on State underage drinking prevention and enforcement activities

(1) Interagency coordinating committee on the prevention of underage drinking

(A) In general

The Secretary, in collaboration with the Federal officials specified in subparagraph (B), shall continue to support and enhance the efforts of the interagency coordinating committee, that began operating in 2004, focusing on underage drinking (referred to in this subsection as the "Committee").

(B) Other agencies

The officials referred to in subparagraph (A) are the Secretary of Education, the Attorney General, the Secretary of Transportation, the Secretary of the Treasury, the Secretary of Defense, the Surgeon General, the Director of the Centers for Disease Control and Prevention, the Director of the National Institute on Alcohol Abuse and Alcoholism, the Assistant Secretary for Mental Health and Substance Use, the Director of the National Institute on Drug Abuse, the Assistant Secretary for Children and Families, the Director of the Office of National Drug Control Policy, the Administrator of the National Highway Traffic Safety Administration, the Administrator of the Office of Juvenile Justice and Delinquency Prevention, the Chairman of the Federal Trade Commission, and such other Federal officials as the Secretary of Health and Human Services determines to be appropriate.

(C) Chair

The Secretary of Health and Human Services shall serve as the chair of the Committee.

(D) Duties

The Committee shall guide policy and program development across the Federal Government with respect to underage drinking, provided, however, that nothing in this section shall be construed as transferring regulatory or program authority from an agency to the Committee.

(E) Consultations

The Committee shall actively seek the input of and shall consult with all appropriate and interested parties, including States, public health research and interest groups, foundations, and alcohol beverage industry trade associations and companies.

(F) Annual report

(i) In general

The Secretary, on behalf of the Committee, shall annually submit to the Congress a report that summarizes—

(I) all programs and policies of Federal agencies designed to prevent and reduce underage drinking, including such programs and policies that support State efforts to prevent or reduce underage drinking;

(II) the extent of progress in preventing and reducing underage drinking at State and national levels;

(III) data that the Secretary shall collect with respect to the information specified in clause (ii); and

(IV) such other information regarding underage drinking as the Secretary determines to be appropriate.

(ii) Certain information

The report under clause (i) shall include information on the following:

(I) Patterns and consequences of underage drinking as reported in research and surveys such as, but not limited to, Monitoring the Future, Youth Risk Behavior Surveillance System, the National Survey on Drug Use and Health, and the Fatality Analysis Reporting System.

(II) Measures of the availability of alcohol from commercial and non-commercial sources to underage populations.

(III) Measures of the exposure of underage populations to messages regarding alcohol in advertising, social media, and the entertainment media.

(IV) Surveillance data, including, to the extent such information is available, information on the onset and prevalence of underage drinking, consumption patterns and beverage preferences, trends related to drinking among different age groups, including between youth and adults, the means of underage access, including trends over time, for these surveillance data, and other data, as appropriate. The Secretary shall develop a plan to improve the collection, measurement, and consistency of reporting Federal underage alcohol data.

(V) Any additional findings resulting from research conducted or supported under subsection (g).

(VI) Evidence-based best practices to prevent and reduce underage drinking and provide treatment services to those youth who need such services.

(2) Annual report on State underage drinking prevention and enforcement activities

(A) In general

The Secretary shall, with input and collaboration from other appropriate Federal agencies, States, Indian Tribes, territories, and public health, consumer, and alcohol beverage industry groups, annually issue a report on each State's performance in enacting, enforcing, and creating laws, regulations, programs, and other actions to prevent or reduce underage drinking based on the best practices identified pursuant to paragraph (1)(F)(ii)(VI). For purposes of this paragraph, each such report, with respect to a year, shall be referred to as the "State Report". Each State Report may be used as a resource to inform the identification and implementation of activities to prevent underage drinking, as determined to be appropriate by such State or other applicable entity.

(B) Contents

(i) Performance measures

The Secretary shall develop, in consultation with the Committee, a set of measures to be used in preparing the State Report on best practices, including as they relate to State laws, regulations, other actions, and enforcement practices.

(ii) State Report content

The State Report shall include updates on State laws, regulations, and other actions, including those described in previous reports to Congress, including with respect to the following:

(I) Whether or not the State has comprehensive anti-underage drinking laws such as for the illegal sale, purchase, attempt to purchase, consumption, or possession of alcohol; illegal use of fraudulent ID; illegal furnishing or obtaining of alcohol for an individual under 21 years; the degree of strictness of the penalties for such offenses; and the prevalence of the enforcement of each of these infractions.

(II) Whether or not the State has comprehensive liability statutes pertaining to underage access to alcohol such as dram shop, social host, and house party laws, and the prevalence of enforcement of each of these laws.

(III) Whether or not the State encourages and conducts comprehensive enforcement efforts to prevent underage access to alcohol at retail outlets, such as random compliance checks and shoulder tap programs, and the number of compliance checks within alcohol retail outlets measured against the number of total alcohol retail outlets in each State, and the result of such checks.

(IV) Whether or not the State encourages training on the proper selling and serving of alcohol for all sellers and servers of alcohol as a condition of employment.

(V) Whether or not the State has policies and regulations with regard to direct sales to consumers and home delivery of alcoholic beverages.

(VI) Whether or not the State has programs or laws to deter adults from purchasing alcohol for minors; and the number of adults targeted by these programs.

(VII) Whether or not the State has enacted graduated drivers licenses and the extent of those provisions.

(VIII) Whether or not the State has adopted any other policies consistent with evidence-based practices related to the prevention of underage alcohol use, which may include any such practices described in relevant reports issued by the Surgeon General and practices related to youth exposure to alcohol-related products and information.

(IX) A description of the degree to which the practices of local jurisdictions within the State vary from one another.

(3) Authorization of appropriations

There is authorized to be appropriated to carry out this subsection $1,000,000 for each of fiscal years 2023 through 2027.

(d) National media campaign to prevent underage drinking

(1) In general

The Secretary, in consultation with the National Highway Traffic Safety Administration, shall develop or continue an intensive, multifaceted national media campaign aimed at adults to reduce underage drinking.

(2) Purpose

The purpose of the national media campaign described in this section shall be to achieve the following objectives:

(A) Promote community awareness of, and a commitment to, reducing underage drinking.

(B) Encourage activities, including activities carried out by adults, that inhibit the illegal use of alcohol by youth.

(C) Discourage activities, including activities carried out by adults, that promote the illegal use of alcohol by youth.

(3) Components

When implementing the national media campaign described in this section, the Secretary shall—

(A) educate the public about the public health and safety benefits of evidence-based strategies to reduce underage drinking, including existing laws related to the minimum legal drinking age, and engage the public and parents in the implementation of such strategies;

(B) educate the public about the negative consequences of underage drinking;

(C) identify specific actions by adults to discourage or inhibit underage drinking;

(D) discourage adult conduct that tends to facilitate underage drinking;

(E) establish collaborative relationships with local and national organizations and institutions to further the goals of the campaign and assure that the messages of the campaign are disseminated from a variety of sources;

(F) conduct the campaign through multi-media sources; and

(G) take into consideration demographics and other relevant factors to most effectively reach target audiences.

(4) Consultation requirement

In developing and implementing the national media campaign described in this section, the Secretary shall review recommendations for reducing underage drinking, including those published by the National Academies of Sciences, Engineering, and Medicine and the Surgeon General. The Secretary shall also consult with interested parties including the alcohol beverage industry, medical, public health, and consumer and parent groups, law enforcement, institutions of higher education, community-based organizations and coalitions, and other relevant stakeholders.

(5) Annual report

The Secretary shall produce an annual report on the progress of the development or implementation of the media campaign described in this subsection, including expenses and projected costs, and, as such information is available, report on the effectiveness of such campaign in affecting adult attitudes toward underage drinking and adult willingness to take actions to decrease underage drinking.

(6) Research on youth-oriented campaign

The Secretary may, based on the availability of funds, conduct or support research on the potential success of a youth-oriented national media campaign to reduce underage drinking. The Secretary shall report to Congress any such results and any related recommendations.

(7) Administration

The Secretary may enter into an agreement with another Federal agency to delegate the authority for execution and administration of the adult-oriented national media campaign.

(8) Authorization of appropriations

There is authorized to be appropriated to carry out this section $2,500,000 for each of fiscal years 2023 through 2027.

(e) Community-based coalition enhancement grants to prevent underage drinking

(1) Authorization of program

The Assistant Secretary for Mental Health and Substance Use, in consultation with the Director of the Office of National Drug Control Policy, shall award enhancement grants to eligible entities to design, implement, evaluate, and disseminate comprehensive strategies to maximize the effectiveness of community-wide approaches to preventing and reducing underage drinking. This subsection is subject to the availability of appropriations.

(2) Purposes

The purposes of this subsection are to—

(A) prevent and reduce alcohol use among youth in communities throughout the United States;

(B) strengthen collaboration among communities, the Federal Government, Tribal Governments, and State and local governments;

(C) enhance intergovernmental cooperation and coordination on the issue of alcohol use among youth;

(D) serve as a catalyst for increased citizen participation and greater collaboration among all sectors and organizations of a community that first demonstrates a long-term commitment to reducing alcohol use among youth;

(E) implement evidence-based strategies to prevent and reduce underage drinking in communities; and

(F) enhance, not supplant, effective local community initiatives for preventing and reducing alcohol use among youth.

(3) Application

An eligible entity desiring an enhancement grant under this subsection shall submit an application to the Assistant Secretary at such time, and in such manner, and accompanied by such information and assurances, as the Assistant Secretary may require. Each application shall include—

(A) a complete description of the entity's current underage alcohol use prevention initiatives and how the grant will appropriately enhance the focus on underage drinking issues; or

(B) a complete description of the entity's current initiatives, and how it will use the grant to enhance those initiatives by adding a focus on underage drinking prevention.

(4) Uses of funds

Each eligible entity that receives a grant under this subsection shall use the grant funds to carry out the activities described in such entity's application submitted pursuant to paragraph (3) and obtain specialized training and technical assistance by the entity funded under section 4 of Public Law 107–82, as amended (21 U.S.C. 1521 note). Grants under this subsection shall not exceed $60,000 per year and may not exceed four years.

(5) Supplement not supplant

Grant funds provided under this subsection shall be used to supplement, not supplant, Federal and non-Federal funds available for carrying out the activities described in this subsection.

(6) Evaluation

Grants under this subsection shall be subject to the same evaluation requirements and procedures as the evaluation requirements and procedures imposed on recipients of drug-free community grants.

(7) Definitions

For purposes of this subsection, the term "eligible entity" means an organization that is currently receiving or has received grant funds under the Drug-Free Communities Act of 1997.

(8) Administrative expenses

Not more than 6 percent of a grant under this subsection may be expended for administrative expenses.

(9) Authorization of appropriations

There is authorized to be appropriated to carry out this subsection $11,500,000 for each of fiscal years 2023 through 2027.

(f) Grants to organizations representing pediatric providers and other related health professionals to reduce underage drinking through screening and brief interventions

(1) In general

The Secretary, acting through the Assistant Secretary for Mental Health and Substance Use, shall make awards to one or more entities representing pediatric providers and other related health professionals with demonstrated ability to increase among the members of such entities effective practices to reduce the prevalence of alcohol use among individuals under the age of 21, including college students.

(2) Purposes

Grants under this subsection shall be made to improve—

(A) screening adolescents for alcohol use;

(B) offering brief interventions to adolescents to discourage such use;

(C) educating parents about the dangers of and methods of discouraging such use;
(D) diagnosing and treating alcohol use disorders; and
(E) referring patients, when necessary, to other appropriate care.

(3) Use of funds

An entity receiving a grant under this section may use the grant funding to promote the practices specified in paragraph (2) among its members by—

(A) providing training to health care providers;
(B) disseminating best practices, including culturally and linguistically appropriate best practices, and developing and distributing materials; and
(C) supporting other activities as determined appropriate by the Assistant Secretary.

(4) Application

To be eligible to receive a grant under this subsection, an entity shall submit an application to the Assistant Secretary at such time, and in such manner, and accompanied by such information and assurances as the Secretary may require. Each application shall include—

(A) a description of the entity;
(B) a description of the activities to be completed that will promote the practices specified in paragraph (2);
(C) a description of the entity's qualifications for performing such activities; and
(D) a timeline for the completion of such activities.

(5) Definitions

For the purpose of this subsection:

(A) Brief intervention

The term "brief intervention" means, after screening a patient, providing the patient with brief advice and other brief motivational enhancement techniques designed to increase the insight of the patient regarding the patient's alcohol use, and any realized or potential consequences of such use to effect the desired related behavioral change.

(B) Screening

The term "screening" means using validated patient interview techniques to identify and assess the existence and extent of alcohol use in a patient.

(6) Authorization of appropriations

There is authorized to be appropriated to carry out this subsection $3,000,000 for each of fiscal years 2023 through 2027.

(g) Data collection and research

(1) Additional research on underage drinking

(A) In general

The Secretary shall, subject to the availability of appropriations, support the collection of data, and conduct or support research that is not duplicative of research currently being conducted or supported by the Department of Health and Human Services, on underage drinking, with respect to the following:

(i) The evaluation, which may include through the development of relevant capabilities of expertise within a State, of the effectiveness of comprehensive community-based programs or strategies and statewide systems to prevent and reduce underage drinking, across the underage years from early childhood to age 21, such as programs funded and implemented by governmental entities, public health interest groups and foundations, and alcohol beverage companies and trade associations.

(ii) Obtaining and reporting more precise information than is currently collected on the scope of the underage drinking problem and patterns of underage alcohol consumption, including improved knowledge about the problem and progress in preventing, reducing, and

treating underage drinking, as well as information on the rate of exposure of youth to advertising and other media messages encouraging and discouraging alcohol consumption.

(iii) The development and identification of evidence-based or evidence-informed strategies to reduce underage drinking, which may include through translational research.

(iv) Improving and conducting public health data collection on alcohol use and alcohol-related conditions in States, which may include by increasing the use of surveys, such as the Behavioral Risk Factor Surveillance System, to monitor binge and excessive drinking and related harms among individuals who are at least 18 years of age, but not more than 20 years of age, including harm caused to self or others as a result of alcohol use that is not duplicative of research currently being conducted or supported by the Department of Health and Human Services.

(B) Authorization of appropriations

There is authorized to be appropriated to carry out this paragraph $5,000,000 for each of fiscal years 2023 through 2027.

(2) National Academies of Sciences, Engineering, and Medicine study

(A) In general

Not later than 12 months after December 29, 2022, the Secretary shall—

(i) contract with the National Academies of Sciences, Engineering, and Medicine to study developments in research on underage drinking and the implications of these developments; and

(ii) report to the Congress on the results of such review.

(B) Authorization of appropriations

There is authorized to be appropriated to carry out this paragraph $500,000 for fiscal year 2023.

(July 1, 1944, ch. 373, title V, §519B, as added Pub. L. 106–310, div. B, title XXXI, §3109, Oct. 17, 2000, 114 Stat. 1182; amended Pub. L. 109–422, §2, Dec. 20, 2006, 120 Stat. 2890; Pub. L. 114–255, div. B, title VI, §6001(c), title IX, §9016, Dec. 13, 2016, 130 Stat. 1203, 1246; Pub. L. 117–328, div. FF, title I, §1215, Dec. 29, 2022, 136 Stat. 5662.)

EDITORIAL NOTES

REFERENCES IN TEXT

The Drug-Free Communities Act of 1997, referred to in subsec. (e)(7), is Pub. L. 105–20, June 27, 1997, 111 Stat. 224, which is classified principally to subchapter II (§1521 et seq.) of chapter 20 of Title 21, Food and Drugs. For complete classification of this Act to the Code, see Short Title of 1997 Amendment note set out under section 1501 of Title 21 and Tables.

AMENDMENTS

2022—Subsec. (a). Pub. L. 117–328, §1215(1), amended subsec. (a) generally. Prior to amendment, subsec. (a) defined "alcohol beverage industry", "school-based prevention", "youth", and "IOM report".

Subsecs. (c) to (g). Pub. L. 117–328, §1215(2), added subsecs. (c) to (g) and struck out former subsecs. (c) to (g) which related to interagency coordinating committee and annual report on State underage drinking prevention and enforcement activities, national media campaign to prevent underage drinking, interventions to prevent and reduce underage drinking, additional research on underage drinking, and reducing underage drinking through screening and brief intervention, respectively.

2016—Subsec. (c)(1)(B). Pub. L. 114–255, §6001(c)(1), substituted "Assistant Secretary for Mental Health and Substance Use" for "Administrator of the Substance Abuse and Mental Health Services Administration".

Subsec. (c)(3). Pub. L. 114–255, §9016(1), substituted "each of the fiscal years 2018 through 2022." for "fiscal year 2007, and $1,000,000 for each of the fiscal years 2008 through 2010."

Subsec. (d)(4). Pub. L. 114–255, §9016(2), substituted "each of the fiscal years 2018 through 2022." for "fiscal year 2007 and $1,000,000 for each of the fiscal years 2008 through 2010."

Subsec. (e)(1)(A). Pub. L. 114–255, §6001(c), substituted "Assistant Secretary for Mental Health and

Substance Use" for "Administrator of the Substance Abuse and Mental Health Services Administration" and "Assistant Secretary" for "Administrator".

Subsec. (e)(1)(C). Pub. L. 114–255, §6001(c)(2), substituted "Assistant Secretary" for "Administrator" in two places.

Subsec. (e)(1)(I). Pub. L. 114–255, §9016(3), substituted "each of the fiscal years 2018 through 2022." for "fiscal year 2007, and $5,000,000 for each of the fiscal years 2008 through 2010."

Subsec. (f)(2). Pub. L. 114–255, §9016(4), substituted "$3,000,000 for each of the fiscal years 2018 through 2022" for "$6,000,000 for fiscal year 2007, and $6,000,000 for each of the fiscal years 2008 through 2010."

Subsec. (g). Pub. L. 114–255, §9016(5), added subsec. (g).

2006—Pub. L. 109–422 added subsecs. (a) to (f) and struck out former subsecs. (a) to (f), which related, respectively, to the Secretary's authority to make grants, cooperative agreements, or contracts for programs to prevent underage drinking; eligibility requirements; evaluation; geographical distribution; duration of award; and authorization of appropriations.

§290bb–25c. Repealed. Pub. L. 114–255, div. B, title IX, §9017, Dec. 13, 2016, 130 Stat. 1248

Section, act July 1, 1944, ch. 373, title V, §519C, as added Pub. L. 106–310, div. B, title XXXI, §3110, Oct. 17, 2000, 114 Stat. 1183; amended Pub. L. 110–154, §1(b)(9), Dec. 21, 2007, 121 Stat. 1827, related to services for individuals with fetal alcohol syndrome.

§290bb–25d. Centers of excellence on services for individuals with fetal alcohol syndrome and alcohol-related birth defects and treatment for individuals with such conditions and their families

(a) In general

The Secretary shall make awards of grants, cooperative agreements, or contracts to public or nonprofit private entities for the purposes of establishing not more than four centers of excellence to study techniques for the prevention of fetal alcohol syndrome and alcohol-related birth defects and adaptations of innovative clinical interventions and service delivery improvements for the provision of comprehensive services to individuals with fetal alcohol syndrome or alcohol-related birth defects and their families and for providing training on such conditions.

(b) Use of funds

An award under subsection (a) may be used to—

(1) study adaptations of innovative clinical interventions and service delivery improvements strategies for children and adults with fetal alcohol syndrome or alcohol-related birth defects and their families;

(2) identify communities which have an exemplary comprehensive system of care for such individuals so that they can provide technical assistance to other communities attempting to set up such a system of care;

(3) provide technical assistance to communities who do not have a comprehensive system of care for such individuals and their families;

(4) train community leaders, mental health and substance abuse professionals, families, law enforcement personnel, judges, health professionals, persons working in financial assistance programs, social service personnel, child welfare professionals, and other service providers on the implications of fetal alcohol syndrome and alcohol-related birth defects, the early identification of and referral for such conditions;

(5) develop innovative techniques for preventing alcohol use by women in child bearing years;

(6) perform other functions, to the extent authorized by the Secretary after consideration of recommendations made by the National Task Force on Fetal Alcohol Syndrome.

(c) Report

(1) In general

A recipient of an award under subsection (a) shall at the end of the period of funding report to the Secretary on any innovative techniques that have been discovered for preventing alcohol use among women of child bearing years.

(2) Dissemination of findings

The Secretary shall upon receiving a report under paragraph (1) disseminate the findings to appropriate public and private entities.

(d) Duration of awards

With respect to an award under subsection (a), the period during which payments under such award are made to the recipient may not exceed 5 years.

(e) Evaluation

The Secretary shall evaluate each project carried out under subsection (a) and shall disseminate the findings with respect to each such evaluation to appropriate public and private entities.

(f) Authorization of appropriations

For the purpose of carrying out this section, there are authorized to be appropriated $5,000,000 for fiscal year 2001, and such sums as may be necessary for each of the fiscal years 2002 and 2003.

(July 1, 1944, ch. 373, title V, §519D, as added Pub. L. 106–310, div. B, title XXXI, §3110, Oct. 17, 2000, 114 Stat. 1185.)

§290bb–25e. Repealed. Pub. L. 114–255, div. B, title IX, §9017, Dec. 13, 2016, 130 Stat. 1248

Section, act July 1, 1944, ch. 373, title V, §519E, as added Pub. L. 106–310, div. B, title XXXI, §3104(c), Oct. 17, 2000, 114 Stat. 1173, related to prevention of methamphetamine and inhalant abuse and addiction.

§290bb–25f. Prevention and education programs

(a) In general

The Secretary of Health and Human Services (referred to in this Act as the "Secretary") shall award grants to public and nonprofit private entities to enable such entities to carry out science-based education programs in elementary and secondary schools to highlight the harmful effects of anabolic steroids.

(b) Eligibility

(1) Application

To be eligible for grants under subsection (a), an entity shall prepare and submit to the Secretary an application at such time, in such manner, and containing such information as the Secretary may require.

(2) Preference

In awarding grants under subsection (a), the Secretary shall give preference to applicants that intend to use grant funds to carry out programs based on—

(A) the Athletes Training and Learning to Avoid Steroids program;

(B) The Athletes Targeting Healthy Exercise and Nutrition Alternatives program; and

(C) other programs determined to be effective by the National Institute on Drug Abuse.

(c) Use of funds

Amounts received under a grant under subsection (a) shall be used for education programs that will directly communicate with teachers, principals, coaches, as well as elementary and secondary school children concerning the harmful effects of anabolic steroids.

(d) Authorization of appropriations

There is authorized to be appropriated to carry out this section, $15,000,000 for each of fiscal years 2005 through 2010.

(Pub. L. 108–358, §4, Oct. 22, 2004, 118 Stat. 1664.)

EDITORIAL NOTES

REFERENCES IN TEXT

This Act, referred to in subsec. (a), means Pub. L. 108–358, October 22, 2004, 92 Stat. 1661, known as the Anabolic Steroid Control Act of 2004. For complete classification of this Act to the Code, see Short Title of 2004 Amendment note set out under section 801 of Title 21, Food and Drugs, and Tables.

CODIFICATION

Section was enacted as part of the Anabolic Steroid Control Act of 2004, and not as part of the Public Health Service Act which comprises this chapter.

§290bb–25g. Awareness campaigns

(a) In general

The Secretary of Health and Human Services, acting through the Director of the Centers for Disease Control and Prevention and in coordination with the heads of other departments and agencies, shall advance education and awareness regarding the risks related to misuse and abuse of opioids, as appropriate, which may include developing or improving existing programs, conducting activities, and awarding grants that advance the education and awareness of—

(1) the public, including patients and consumers—

(A) generally; and

(B) regarding such risks related to unused opioids and the dispensing options under section 829(f) of title 21, as applicable; and

(2) providers, which may include—

(A) providing for continuing education on appropriate prescribing practices;

(B) education related to applicable State or local prescriber limit laws, information on the use of non-addictive alternatives for pain management, and the use of overdose reversal drugs, as appropriate;

(C) disseminating and improving the use of evidence-based opioid prescribing guidelines across relevant health care settings, as appropriate, and updating guidelines as necessary;

(D) implementing strategies, such as best practices, to encourage and facilitate the use of prescriber guidelines, in accordance with State and local law;

(E) disseminating information to providers about prescribing options for controlled substances, including such options under section 829(f) of title 21, as applicable; and

(F) disseminating information, as appropriate, on the National Pain Strategy developed by or in consultation with the Assistant Secretary for Health; and

(3) other appropriate entities.

(b) Topics

The education and awareness campaigns under subsection (a) shall address—

(1) the dangers of opioid misuse and abuse;

(2) the prevention of opioid misuse and abuse, including through non-addictive treatment options, safe disposal options for prescription medications, and other applicable safety precautions; and

(3) the detection of early warning signs of addiction.

(c) Other requirements

The education and awareness campaigns under subsection (a) shall, as appropriate—

(1) take into account any association between prescription opioid abuse and heroin use;

(2) emphasize—

(A) the similarities between heroin and prescription opioids; and

(B) the effects of heroin and prescription opioids on the human body; and

(3) bring greater public awareness to the dangerous effects of fentanyl when mixed with heroin or abused in a similar manner.

(Pub. L. 114–198, title I, §102, July 22, 2016, 130 Stat. 698; Pub. L. 115–271, title VII, §7161(b), Oct. 24, 2018, 132 Stat. 4061.)

EDITORIAL NOTES

CODIFICATION

Section was enacted as part of the Comprehensive Addiction and Recovery Act of 2016, and not as part of the Public Health Service Act which comprises this chapter.

AMENDMENTS

2018—Subsec. (a). Pub. L. 115–271, §7161(b)(1), amended subsec. (a) generally. Prior to amendment, text read as follows: "The Secretary of Health and Human Services, in coordination with the heads of other departments and agencies, shall, as appropriate, through existing programs and activities, advance the education and awareness of the public (including providers, patients, and consumers) and other appropriate entities regarding the risk of abuse of prescription opioids if such drugs are not taken as prescribed."

Subsec. (b)(1). Pub. L. 115–271, §7161(b)(2)(A), substituted "opioid misuse and abuse" for "opioid abuse".

Subsec. (b)(2). Pub. L. 115–271, §7161(b)(2), substituted "opioid misuse and abuse" for "opioid abuse" and "non-addictive treatment options, safe disposal options for prescription medications, and other applicable" for "safe disposal of prescription medications and other".

STATUTORY NOTES AND RELATED SUBSIDIARIES

SYNTHETIC OPIOID AND EMERGING DRUG MISUSE DANGER AWARENESS

Pub. L. 117–328, div. FF, title I, §1272, Dec. 29, 2022, 136 Stat. 5686, provided that:

"(a) IN GENERAL.—Not later than one year after the date of enactment of this Act [Dec. 29, 2022], the Secretary shall provide for the planning and implementation of a public education campaign to raise public awareness of synthetic opioids (including fentanyl and its analogues) and emerging drug use and misuse issues, as appropriate. Such campaign related to synthetic opioids shall include the dissemination of information that—

"(1) promotes awareness about the potency and dangers of fentanyl and its analogues and other synthetic opioids;

"(2) explains services provided by the Substance Abuse and Mental Health Services Administration and the Centers for Disease Control and Prevention (and any entity providing such services under a contract entered into with such agencies) with respect to the use and misuse of opioids (including synthetic opioids) and other emerging drug threats, such as stimulants, as appropriate; and

"(3) relates generally to opioid use and pain management, including information on alternative, nonopioid pain management treatments.

The Secretary shall update such campaign to address emerging drug misuse issues, as appropriate.

"(b) USE OF MEDIA.—The campaign under subsection (a) may be implemented through the use of television, radio, internet, in-person public communications, and other commercial marketing venues and may be targeted to specific demographic groups.

"(c) CONSIDERATION OF REPORT FINDINGS.—In planning and implementing the public education campaign under subsection (a) related to synthetic opioids, the Secretary shall take into consideration the findings of the report required under section 7001 of the SUPPORT for Patients and Communities Act (Public Law 115–271) [132 Stat. 4007].

"(d) CONSULTATION.—In coordinating the campaign under subsection (a), the Secretary shall consult with the Assistant Secretary for Mental Health and Substance Use to provide ongoing advice on the

effectiveness of information disseminated through the campaign.

"(e) REQUIREMENT OF CAMPAIGN.—The campaign implemented under subsection (a) shall not be duplicative of any other Federal efforts relating to eliminating substance use and misuse.

"(f) EVALUATION.—

"(1) IN GENERAL.—The Secretary shall ensure that the campaign implemented under subsection (a) is subject to an independent evaluation, beginning 2 years after the date of enactment of this Act, and 2 years thereafter.

"(2) MEASURES AND BENCHMARKS.—For purposes of an evaluation conducted pursuant to paragraph (1), the Secretary shall—

"(A) establish baseline measures and benchmarks to quantitatively evaluate the impact of the campaign under this section; and

"(B) conduct qualitative assessments regarding the effectiveness of strategies employed under this section.

"(g) REPORT.—The Secretary shall, beginning 2 years after the date of enactment of this Act, and 2 years thereafter, submit to Congress a report on the effectiveness of the campaign implemented under subsection (a) towards meeting the measures and benchmarks established under subsection (f)(2).

"(h) DISSEMINATION OF INFORMATION THROUGH PROVIDERS.—The Secretary shall develop and implement a plan for the dissemination of information related to synthetic opioids, to health care providers who participate in Federal programs, including programs administered by the Department of Health and Human Services, the Indian Health Service, the Department of Veterans Affairs, the Department of Defense, and the Health Resources and Services Administration, the Medicare program under title XVIII of the Social Security Act (42 U.S.C. 1395 et seq.), and the Medicaid program under title XIX of such Act (42 U.S.C. 1396 et seq.).

"(i) TRAINING GUIDE AND OUTREACH ON SYNTHETIC OPIOID EXPOSURE PREVENTION.—

"(1) TRAINING GUIDE.—Not later than 18 months after the date of enactment of this Act, the Secretary shall design, publish, and make publicly available on the internet website of the Department of Health and Human Services, a training guide and webinar for first responders and other individuals who also may be at high risk of exposure to synthetic opioids that details measures to prevent that exposure.

"(2) OUTREACH.—Not later than 18 months after the date of enactment of this Act, the Secretary shall also conduct outreach about the availability of the training guide and webinar published under paragraph (1) to—

"(A) fire department staff;

"(B) law enforcement officers;

"(C) ambulance transport and other first responders;

"(D) hospital emergency department personnel; and

"(E) other high-risk occupations, as identified by the Secretary."

INFORMATION MATERIALS AND RESOURCES TO PREVENT ADDICTION RELATED TO YOUTH SPORTS INJURIES

Pub. L. 114–198, title I, §104, July 22, 2016, 130 Stat. 700, provided that:

"(a) REPORT.—The Secretary of Health and Human Services (referred to in this section as the 'Secretary') shall, not later than 24 months after the date of the enactment of this section [July 22, 2016], make publicly available on the appropriate website of the Department of Health and Human Services a report determining the extent to which informational materials and resources described in subsection (c) are available to teenagers and adolescents who play youth sports, families of such teenagers and adolescents, nurses, youth sports groups, and relevant health care provider groups.

"(b) DEVELOPMENT OF INFORMATIONAL MATERIALS AND RESOURCES.—The Secretary may, for purposes of preventing substance use disorder in teenagers and adolescents who are injured playing youth sports and are subsequently prescribed an opioid, not later than 12 months after the report is made publicly available under subsection (a), and taking into consideration the findings of such report and in coordination with relevant health care provider groups, facilitate the development of informational materials and resources described in subsection (c) for teenagers and adolescents who play youth sports, families of such teenagers and adolescents, nurses, youth sports groups, and relevant health care provider groups.

"(c) MATERIALS AND RESOURCES DESCRIBED.—For purposes of this section, the informational materials and resources described in this subsection are informational materials and resources with respect to youth sports injuries for which opioids are potentially prescribed, including materials and resources focused on the risks associated with opioid use and misuse, treatment options for such injuries that do not involve the use of opioids, and how to seek treatment for addiction.

"(d) NO ADDITIONAL FUNDS.—No additional funds are authorized to be appropriated for the purpose of carrying out this section. This section shall be carried out using amounts otherwise available for such purpose."

SUBPART 3—CENTER FOR MENTAL HEALTH SERVICES

§290bb–31. Center for Mental Health Services

(a) Establishment

There is established in the Administration a Center for Mental Health Services (hereafter in this section referred to as the "Center"). The Center shall be headed by a Director (hereafter in this section referred to as the "Director") appointed by the Secretary from among individuals with extensive experience or academic qualifications in the provision of mental health services or in the evaluation of mental health service systems.

(b) Duties

The Director of the Center shall—

(1) design national goals and establish national priorities for—

(A) the prevention of mental illness; and

(B) the promotion of mental health;

(2) encourage and assist local entities and State agencies to achieve the goals and priorities described in paragraph (1);

(3) collaborate with the Director of the National Institute of Mental Health and the Chief Medical Officer, appointed under section 290aa(g) of this title, to ensure that, as appropriate, programs related to the prevention and treatment of mental illness and the promotion of mental health and recovery support are carried out in a manner that reflects the best available science and evidence-based practices, including culturally and linguistically appropriate services, as appropriate;

(4) collaborate with the Department of Education and the Department of Justice to develop programs to assist local communities in addressing violence among children and adolescents;

(5) develop and coordinate Federal prevention policies and programs and to assure increased focus on the prevention of mental illness and the promotion of mental health, including through programs that reduce risk and promote resiliency;

(6) in collaboration with the Director of the National Institute of Mental Health, develop improved methods of treating individuals with mental health problems and improved methods of assisting the families of such individuals;

(7) administer the mental health services block grant program authorized in section 300x of this title;

(8) promote policies and programs at Federal, State, and local levels and in the private sector that foster independence, increase meaningful participation of individuals with mental illness in programs and activities of the Administration, and protect the legal rights of persons with mental illness, including carrying out the provisions of the Protection and Advocacy of Mentally Ill Individuals Act [1] [42 U.S.C. 10801 et seq.];

(9) carry out the programs under part C; and

(10) carry out responsibilities for the Human Resource Development programs;

(11) conduct services-related assessments, including evaluations of the organization and financing of care, self-help and consumer-run programs, mental health economics, mental health service systems, rural mental health and tele-mental health, and improve the capacity of State to conduct evaluations of publicly funded mental health programs;

(12) disseminate mental health information, including evidence-based practices, to States,

political subdivisions, educational agencies and institutions, treatment and prevention service providers, and the general public, including information concerning the practical application of research supported by the National Institute of Mental Health that is applicable to improving the delivery of services;

(13) provide technical assistance to public and private entities that are providers of mental health services;

(14) monitor and enforce obligations incurred by community mental health centers pursuant to the Community Mental Health Centers Act (as in effect prior to the repeal of such Act on August 13, 1981, by section 902(e)(2)(B) of Public Law 97–35 (95 Stat. 560));

(15) conduct surveys with respect to mental health, such as the National Reporting Program;

(16) assist States in improving their mental health data collection; and

(17) ensure the consistent documentation of the application of criteria when awarding grants and the ongoing oversight of grantees after such grants are awarded.

(c) Grants and contracts

In carrying out the duties established in subsection (b), the Director may make grants to and enter into contracts and cooperative agreements with public and nonprofit private entities.

(July 1, 1944, ch. 373, title V, §520, as added Pub. L. 102–321, title I, §115(a), July 10, 1992, 106 Stat. 346; amended Pub. L. 106–310, div. B, title XXXI, §3112(c), Oct. 17, 2000, 114 Stat. 1188; Pub. L. 114–255, div. B, title VI, §6007(a), Dec. 13, 2016, 130 Stat. 1212.)

EDITORIAL NOTES

REFERENCES IN TEXT

The Protection and Advocacy of Mentally Ill Individuals Act, referred to in subsec. (b)(8), probably means the Protection and Advocacy for Mentally Ill Individuals Act of 1986, which was Pub. L. 99–319, May 23, 1986, 100 Stat. 478. Pub. L. 99–319 was renamed the Protection and Advocacy for Individuals with Mental Illness Act by Pub. L. 106–310, div. B, title XXXII, §3206(a), Oct. 17, 2000, 114 Stat. 1193, and is classified generally to chapter 114 (§10801 et seq.) of this title. For complete classification of this Act to the Code, see Short Title note set out under section 10801 of this title and Tables.

The Community Mental Health Centers Act, referred to in subsec. (b)(14), is title II of Pub. L. 88–164, as added by Pub. L. 94–63, title III, §303, July 29, 1975, 89 Stat. 309, and amended, which was classified principally to subchapter III (§2689 et seq.) of chapter 33 of this title prior to its repeal by Pub. L. 97–35, title IX, §902(e)(2)(B), Aug. 13, 1981, 95 Stat. 560.

PRIOR PROVISIONS

A prior section 520 of act July 1, 1944, which was classified to section 290cc–13 of this title, was renumbered section 520A of act July 1, 1944, by Pub. L. 102–321 and transferred to section 290bb–32 of this title.

Another prior section 520 of act July 1, 1944, was renumbered section 519 by Pub. L. 101–93 and classified to section 290cc–12 of this title, prior to repeal by Pub. L. 102–321, §117.

AMENDMENTS

2016—Subsec. (b)(3). Pub. L. 114–255, §6007(a)(2), added par. (3). Former par. (3) redesignated (4).

Subsec. (b)(4). Pub. L. 114–255, §6007(a)(1), redesignated par. (3) as (4). Former par. (4) redesignated (5).

Subsec. (b)(5). Pub. L. 114–255, §6007(a)(1), (3), redesignated par. (4) as (5) and inserted ", including through programs that reduce risk and promote resiliency" before semicolon. Former par. (5) redesignated (6).

Subsec. (b)(6). Pub. L. 114–255, §6007(a)(1), (4), redesignated par. (5) as (6) and inserted "in collaboration with the Director of the National Institute of Mental Health," before "develop". Former par. (6) redesignated (7).

Subsec. (b)(7). Pub. L. 114–255, §6007(a)(1), redesignated par. (6) as (7). Former par. (7) redesignated (8).

Subsec. (b)(8). Pub. L. 114–255, §6007(a)(1), (5), redesignated par. (7) as (8) and inserted ", increase meaningful participation of individuals with mental illness in programs and activities of the Administration," before "and protect the legal". Former par. (8) redesignated (9).

Subsec. (b)(9). Pub. L. 114–255, §6007(a)(1), redesignated par. (8) as (9). Former par. (9) redesignated (10).

Subsec. (b)(10). Pub. L. 114–255, §6007(a)(6), which directed substitution of "health paraprofessional personnel and health professionals" for "professional and paraprofessional personnel pursuant to section 242a of this title", could not be executed because those words did not appear subsequent to amendment by Pub. L. 106–310, §3112(c)(4). See 2006 Amendment note below.

Pub. L. 114–255, §6007(a)(1), redesignated par. (9) as (10). Former par. (10) redesignated (11).

Subsec. (b)(11). Pub. L. 114–255, §6007(a)(1), (7), redesignated par. (10) as (11) and inserted "and tele-mental health" after "rural mental health". Former par. (11) redesignated (12).

Subsec. (b)(12). Pub. L. 114–255, §6007(a)(1), (8), redesignated par. (11) as (12) and substituted "disseminate mental health information, including evidence-based practices," for "establish a clearinghouse for mental health information to assure the widespread dissemination of such information". Former par. (12) redesignated (13).

Subsec. (b)(13) to (16). Pub. L. 114–255, §6007(a)(1), redesignated pars. (12) to (15) as (13) to (16), respectively.

Subsec. (b)(17). Pub. L. 114–255, §6007(a)(9)–(11), added par. (17).

2000—Subsec. (b)(3) to (7). Pub. L. 106–310, §3112(c)(1), (2), added par. (3) and redesignated former pars. (3) to (6) as (4) to (7), respectively. Former par. (7) redesignated (8).

Subsec. (b)(8). Pub. L. 106–310, §3112(c)(1), (3), redesignated par. (7) as (8) and substituted "programs under part C" for "programs authorized under sections 290bb–32 and 290cc–21 of this title, including the Community Support Program and the Child and Adolescent Service System Programs". Former par. (8) redesignated (9).

Subsec. (b)(9). Pub. L. 106–310, §3112(c)(4), which directed the amendment of par. (9) by substituting "programs" for "program and programs of clinical training for professional and paraprofessional personnel pursuant to section 242a of this title" was executed by making the substitution for the phrase which began with the words "program, and programs", to reflect the probable intent of Congress.

Pub. L. 106–310, §3112(c)(1), redesignated par. (8) as (9). Former par. (9) redesignated (10).

Subsec. (b)(10) to (15). Pub. L. 106–310, §3112(c)(1), redesignated pars. (9) to (14) as (10) to (15), respectively.

STATUTORY NOTES AND RELATED SUBSIDIARIES

EFFECTIVE DATE

Section effective Oct. 1, 1992, with provision for programs providing financial assistance, see section 801(c), (d) of Pub. L. 102–321, set out as an Effective Date of 1992 Amendment note under section 236 of this title.

TASK FORCE ON MATERNAL MENTAL HEALTH

Pub. L. 117–328, div. FF, title I, §1113, Dec. 29, 2022, 136 Stat. 5644, provided that:

"(a) ESTABLISHMENT.—Not later than 180 days after the date of enactment of this Act [Dec. 29, 2022], the Secretary of Health and Human Services, for purposes of identifying, evaluating, and making recommendations to coordinate and improve Federal activities related to addressing maternal mental health conditions, shall—

"(1) establish a task force to be known as the Task Force on Maternal Mental Health (in this section referred to as the 'Task Force'); or

"(2) incorporate the duties, public meetings, and reports specified in subsections (c) through (f) into existing relevant Federal committees or working groups, such as the Maternal Health Interagency Policy Committee and the Maternal Health Working Group, as appropriate.

"(b) MEMBERSHIP.—

"(1) COMPOSITION.—The Task Force shall be composed of—

"(A) the Federal members under paragraph (2); and

"(B) the non-Federal members under paragraph (3).

"(2) FEDERAL MEMBERS.—The Federal members of the Task Force shall consist of the following heads of Federal departments and agencies (or their designees):

"(A) The Assistant Secretary for Health of the Department of Health and Human Services and the Assistant Secretary for Mental Health and Substance Use, who shall serve as co-chairs.

"(B) The Assistant Secretary for Planning and Evaluation of the Department of Health and Human Services.

"(C) The Assistant Secretary of the Administration for Children and Families.

"(D) The Director of the Centers for Disease Control and Prevention.

"(E) The Administrator of the Centers for Medicare & Medicaid Services.

"(F) The Administrator of the Health Resources and Services Administration.

"(G) The Director of the Indian Health Service.

"(H) Such other Federal departments and agencies as the Secretary determines appropriate that serve individuals with maternal mental health conditions.

"(3) NON-FEDERAL MEMBERS.—The non-Federal members of the Task Force shall—

"(A) compose not more than one-half, and not less than one-third, of the total membership of the Task Force;

"(B) be appointed by the Secretary; and

"(C) include—

"(i) representatives of professional medical societies, professional nursing societies, and relevant health paraprofessional societies with expertise in maternal or mental health;

"(ii) representatives of nonprofit organizations with expertise in maternal or mental health;

"(iii) relevant industry representatives; and

"(iv) other representatives, as appropriate.

"(4) DEADLINE FOR DESIGNATING DESIGNEES.—If the Assistant Secretary for Health, the Assistant Secretary for Mental Health and Substance Use, or the head of a Federal department or agency serving as a member of the Task Force under paragraph (2), chooses to be represented on the Task Force by a designee, the Assistant Secretary for Health, the Assistant Secretary for Mental Health and Substance Use, or department or agency head shall designate such designee not later than 90 days after the date of the enactment of this section [Dec. 29, 2022].

"(c) DUTIES.—The Task Force shall—

"(1) prepare and regularly update a report that analyzes and evaluates the state of maternal mental health programs at the Federal level, and identifies best practices with respect to maternal mental health (which may include co-occurring substance use disorders), including—

"(A) a set of evidence-based, evidence-informed, and promising practices with respect to—

"(i) prevention strategies for maternal mental health conditions, including strategies and recommendations to reduce racial, ethnic, geographic, and other health disparities;

"(ii) the identification, screening, diagnosis, intervention, and treatment of maternal mental health conditions and affected families;

"(iii) the timely referral to supports, and implementation of practices, that prevent and mitigate the effects of a maternal mental health condition, including strategies and recommendations to eliminate racial and ethnic disparities that exist in maternal mental health; and

"(iv) community-based or multigenerational practices that provide support related to maternal mental health conditions, including support for affected families; and

"(B) Federal and State programs and activities that support prevention, screening, diagnosis, intervention, and treatment of maternal mental health conditions;

"(2) develop and regularly update a national strategy for maternal mental health, taking into consideration the findings of the report under paragraph (1), on how the Task Force and Federal departments and agencies represented on the Task Force may prioritize options for, and may improve coordination with respect to, addressing maternal mental health conditions, including by—

"(A) increasing prevention, screening, diagnosis, intervention, treatment, and access to maternal mental health care, including clinical and nonclinical care such as peer-support and community health workers, through the public and private sectors;

"(B) providing support relating to the prevention, screening, diagnosis, intervention, and treatment of maternal mental health conditions, including families, as appropriate;

"(C) reducing racial, ethnic, geographic, and other health disparities related to prevention, diagnosis, intervention, treatment, and access to maternal mental health care;

"(D) identifying opportunities to modify, strengthen, and better coordinate existing Federal infant and maternal health programs in order to improve screening, diagnosis, research, prevention, identification, intervention, and treatment with respect to maternal mental health; and

"(E) improving planning, coordination, and collaboration across Federal departments, agencies, offices, and programs;

"(3) solicit public comments, as appropriate, from stakeholders for the report under paragraph (1) and the national strategy under paragraph (2) in order to inform the activities and reports of the Task Force; and

"(4) consider the latest research related to maternal mental health in developing the strategy, including, as applicable and appropriate, data and information disaggregated by relevant factors, such as race, ethnicity, geographical location, age, socioeconomic level, and others, as appropriate.

"(d) MEETINGS.—The Task Force shall—

"(1) meet not less than two times each year; and

"(2) convene public meetings, as appropriate, to fulfill its duties under this section.

"(e) REPORTS TO PUBLIC AND FEDERAL LEADERS.—The Task Force shall make publicly available and submit to the heads of relevant Federal departments and agencies, the Committee on Energy and Commerce of the House of Representatives, the Committee on Health, Education, Labor, and Pensions of the Senate, and other relevant congressional committees, the following:

"(1) Not later than 1 year after the first meeting of the Task Force, an initial report under subsection (c)(1).

"(2) Not later than 2 years after the first meeting of the Task Force, an initial national strategy under subsection (c)(2).

"(3) Each year thereafter—

"(A) an updated report under subsection (c)(1);

"(B) an updated national strategy under subsection (c)(2); or

"(C) if no update is made under subsection (c)(1) or (c)(2), a report summarizing the activities of the Task Force.

"(f) REPORTS TO GOVERNORS.—Upon finalizing the initial national strategy under subsection (c)(2), and upon making relevant updates to such strategy, the Task Force shall submit a report to the Governors of all States describing any opportunities for local- and State-level partnerships identified under subsection (c)(2).

"(g) SUNSET.—The Task Force shall terminate on September 30, 2027.

"(h) NONDUPLICATION OF FEDERAL EFFORTS.—The Secretary may relieve the Task Force, in carrying out subsections (c) through (f), from responsibility for carrying out such activities as may be specified by the Secretary as duplicative of other activities carried out by the Department of Health and Human Services."

MENTAL HEALTH SERVICES FOR INDIVIDUALS IN CORRECTIONAL FACILITIES

Pub. L. 102–321, title VII, §703, July 10, 1992, 106 Stat. 437, directed Secretary of Health and Human Services, acting through Director of Center for Mental Health Services, not later than July 10, 1992, to prepare and submit to Congress a report concerning most effective methods for providing mental health services to individuals who come into contact with the criminal justice system, including those individuals incarcerated in correctional facilities (including local jails and detention facilities), and the obstacles to providing such services, with such study to be carried out in consultation with the National Institute of Mental Health, the Department of Justice, and other appropriate public and private entities.

EXECUTIVE DOCUMENTS

EXECUTIVE ORDER NO. 13263

Ex. Ord. No. 13263, Apr. 29, 2002, 67 F.R. 22337, which established President's New Freedom Commission on Mental Health, was revoked by Ex. Ord. No. 13316, §3(g), Sept. 17, 2003, 68 F.R. 55256, eff. Sept. 30, 2003.

[1] *See References in Text note below.*

§290bb–32. Priority mental health needs of regional and national significance

(a) Projects

The Secretary shall address priority mental health needs of regional and national significance (as determined under subsection (b)) through the provision of or through assistance for—

(1) knowledge development and application projects for prevention, treatment, and rehabilitation, and the conduct or support of evaluations of such projects;

(2) training and technical assistance programs;

(3) targeted capacity response programs; and

(4) systems change grants including statewide family network grants and client-oriented and consumer run self-help activities, which may include technical assistance centers.

The Secretary may carry out the activities described in this subsection directly or through grants, contracts, or cooperative agreements with States, political subdivisions of States, Indian Tribes or Tribal organizations (as such terms are defined in section 5304 of title 25), health facilities, or programs operated by or in accordance with a contract or grant with the Indian Health Service, or,[1] other public or private nonprofit entities.

(b) Priority mental health needs

(1) Determination of needs

Priority mental health needs of regional and national significance shall be determined by the Secretary in consultation with States and other interested groups. The Secretary shall meet with the States and interested groups on an annual basis to discuss program priorities.

(2) Special consideration

In developing program priorities described in paragraph (1), the Secretary shall give special consideration to promoting the integration of mental health services into primary health care systems.

(c) Requirements

(1) In general

Recipients of grants, contracts, and cooperative agreements under this section shall comply with information and application requirements determined appropriate by the Secretary.

(2) Duration of award

With respect to a grant, contract, or cooperative agreement awarded under this section, the period during which payments under such award are made to the recipient may not exceed 5 years.

(3) Matching funds

The Secretary may, for projects carried out under subsection (a), require that entities that apply for grants, contracts, or cooperative agreements under this section provide non-Federal matching funds, as determined appropriate by the Secretary, to ensure the institutional commitment of the entity to the projects funded under the grant, contract, or cooperative agreement. Such non-Federal matching funds may be provided directly or through donations from public or private entities and may be in cash or in kind, fairly evaluated, including plant, equipment, or services.

(4) Maintenance of effort

With respect to activities for which a grant, contract or cooperative agreement is awarded under this section, the Secretary may require that recipients for specific projects under subsection (a) agree to maintain expenditures of non-Federal amounts for such activities at a level that is not less than the level of such expenditures maintained by the entity for the fiscal year preceding the fiscal year for which the entity receives such a grant, contract, or cooperative agreement.

(d) Evaluation

The Secretary shall evaluate each project carried out under subsection (a)(1) and shall disseminate the findings with respect to each such evaluation to appropriate public and private entities.

(e) Information and education

(1) In general

The Secretary shall establish information and education programs to disseminate and apply the findings of the knowledge development and application, training, and technical assistance programs, and targeted capacity response programs, under this section to the general public, to health care professionals, and to interested groups. The Secretary shall make every effort to provide linkages between the findings of supported projects and State agencies responsible for carrying out mental health services.

(2) Rural and underserved areas

In disseminating information on evidence-based practices in the provision of children's mental health services under this subsection, the Secretary shall ensure that such information is distributed to rural and medically underserved areas.

(3) Geriatric mental disorders

The Secretary shall, as appropriate, provide technical assistance to grantees regarding evidence-based practices for the prevention and treatment of geriatric mental disorders and co-occurring mental health and substance use disorders among geriatric populations, as well as disseminate information about such evidence-based practices to States and nongrantees throughout the United States.

(f) Authorization of appropriations

There are authorized to be appropriated to carry out this section $599,036,000 for each of fiscal years 2023 through 2027.

(July 1, 1944, ch. 373, title V, §520A, as added Pub. L. 100–690, title II, §2057(3), Nov. 18, 1988, 102 Stat. 4212; renumbered §520 and amended Pub. L. 101–93, §3(e), (g), Aug. 16, 1989, 103 Stat. 610, 611; Pub. L. 101–639, §2, Nov. 28, 1990, 104 Stat. 4600; renumbered §520A and amended Pub. L. 102–321, title I, §116, July 10, 1992, 106 Stat. 348; Pub. L. 106–310, div. B, title XXXII, §3201(a), Oct. 17, 2000, 114 Stat. 1189; Pub. L. 114–255, div. B, title VII, §7003, title IX, §9012, Dec. 13, 2016, 130 Stat. 1223, 1245; Pub. L. 117–328, div. FF, title I, §1121(d), Dec. 29, 2022, 136 Stat. 5650.)

EDITORIAL NOTES

CODIFICATION

Section was formerly classified to section 290cc–13 of this title prior to renumbering by Pub. L. 102–321.

AMENDMENTS

2022—Subsec. (a). Pub. L. 117–328, §1121(d)(1), substituted "Indian Tribes or Tribal organizations" for "Indian tribes or tribal organizations" in concluding provisions.

Subsec. (f). Pub. L. 117–328, §1121(d)(2), substituted "$599,036,000 for each of fiscal years 2023 through 2027" for "$394,550,000 for each of fiscal years 2018 through 2022".

2016—Subsec. (a). Pub. L. 114–255, §7003(1)(B), in concluding provisions, inserted ", contracts," before "or cooperative agreements" and substituted "Indian tribes or tribal organizations (as such terms are defined in section 5304 of title 25), health facilities, or programs operated by or in accordance with a contract or grant with the Indian Health Service, or" for "Indian tribes and tribal organizations".

Subsec. (a)(4). Pub. L. 114–255, §7003(1)(A), inserted ", which may include technical assistance centers" before period at end.

Subsec. (e)(3). Pub. L. 114–255, §9012, added par. (3).

Subsec. (f). Pub. L. 114–255, §7003(2), amended subsec. (f) generally, substituting appropriations for fiscal years 2018 through 2022 for appropriations for fiscal year 2001, and such sums as may be necessary for each of the fiscal years 2002 and 2003 and data infrastructure provisions.

2000—Pub. L. 106–310 amended section catchline and text generally, substituting provisions relating to priority mental health needs of regional and national significance for provisions relating to establishment of grant programs for demonstration projects.

1992—Subsec. (a)(1). Pub. L. 102–321, §116(b)(1), substituted "Center for Mental Health Services" for "National Institute of Mental Health".

Subsec. (c). Pub. L. 102–321, §116(b)(2), substituted "five" for "three".

Subsec. (e)(1). Pub. L. 102–321, §116(b)(3), amended par. (1) generally. Prior to amendment, par. (1) read as follows: "For the purposes of carrying out this section, there are authorized to be appropriated $40,000,000 for fiscal year 1991, and such sums as may be necessary for each of the fiscal years 1992 and 1993."

1990—Subsec. (a). Pub. L. 101–639, §2(a), amended subsec. (a) generally. Prior to amendment, subsec. (a) read as follows: "The Secretary, acting through the Director, may make grants to States, political subdivisions of States, and nonprofit private agencies—

"(1) for mental health services demonstration projects for the planning, coordination, and improvement of community services (including outreach and self-help services) for seriously mentally ill individuals,

seriously emotionally disturbed children and youth, elderly individuals, and homeless seriously mentally ill individuals, and for the conduct of research concerning such services;

"(2) for demonstration projects for the prevention of youth suicide;

"(3) for demonstration projects for the improvement of the recognition, assessment, treatment, and clinical management of depressive disorders; and

"(4) for demonstration projects for treatment and prevention relating to sex offenses."

Subsec. (e)(1). Pub. L. 101–639, §2(b), amended par. (1) generally. Prior to amendment, par. (1) read as follows: "For the purposes of carrying out this section, there are authorized to be appropriated $60,000,000 for each of the fiscal years 1989 and 1990."

1989—Pub. L. 101–93 substituted "programs" for "program" in section catchline and in subsec. (a) substituted "seriously mentally ill" for "chronically mentally ill" wherever appearing, redesignated par. (5) as (4), and inserted "for" before "demonstration" in pars. (2), (3), and (4).

STATUTORY NOTES AND RELATED SUBSIDIARIES

APPLICABILITY OF AMENDMENT

Amendment by Pub. L. 117–100 applicable only with respect to applications for assistance under this section that are submitted after Mar. 15, 2022, see section 3 of Pub. L. 117–100, set out as an Effective Date note under section 290bb–33 of this title.

EFFECTIVE DATE OF 1992 AMENDMENT

Amendment by Pub. L. 102–321 effective Oct. 1, 1992, with provision for programs providing financial assistance, see section 801(c), (d) of Pub. L. 102–321, set out as a note under section 236 of this title.

COMMUNITY MENTAL HEALTH SERVICES DEMONSTRATION PROJECTS FOR HOMELESS INDIVIDUALS WHO ARE CHRONICALLY MENTALLY ILL

Pub. L. 100–77, title VI, §612, July 22, 1987, 101 Stat. 523, as amended by Pub. L. 100–607, title VIII, §821, Nov. 4, 1988, 102 Stat. 3171; Pub. L. 100–628, title VI, §621, Nov. 7, 1988, 102 Stat. 3244; Pub. L. 101–93, §5(t)(1), (2), Aug. 16, 1989, 103 Stat. 615; Pub. L. 101–645, title V, §521, Nov. 29, 1990, 104 Stat. 4734, which authorized to be appropriated for payments under this section such sums as may be necessary for each of the fiscal years 1991 through 1993, in addition to any other amounts authorized to be appropriated for such payments for each of such fiscal years with such additional amounts to be available only for the provision of community-based mental health services to homeless individuals who are chronically mentally ill, and amounts paid to grantees under subsection (a) of this section that remain unobligated at the end of the fiscal year in which the amounts were received to remain available to grantees during the succeeding fiscal year for the purposes for which the payments were made, was repealed by Pub. L. 106–310, div. B, title XXXII, §3201(b)(3), Oct. 17, 2000, 114 Stat. 1190.

[1] *So in original. The comma probably should not appear.*

§290bb–33. Student suicide awareness and prevention training

(a) In general

In awarding funds under section 290bb–32 of this title, the Secretary shall give priority to applications under such section from a State educational agency, local educational agency, or Tribal educational agency, submitted directly or through a State or Indian Tribe, for funding for activities in secondary schools, where such agency has implemented, or includes in such application a plan to implement, a student suicide awareness and prevention training policy, which may include applicable youth suicide early intervention and prevention strategies implemented through section 290bb–36 of this title—

(1) establishing and implementing a school-based student suicide awareness and prevention training policy in accordance with subsection (c);

(2) consulting with stakeholders (including principals, teachers, parents, local Tribal officials, and other relevant experts) and, as appropriate, utilizing information, models, and other resources made available by the Suicide Prevention Technical Assistance Center authorized under section

290bb–34 of this title in the development of the policy under paragraph (1); and

(3) collecting and reporting information in accordance with subsection (d).

(b) Consideration

In giving priority to applicants as described in subsection (a), the Secretary shall, as appropriate, take into consideration the incidence and prevalence of suicide in the applicable jurisdiction and the costs of establishing and implementing, as applicable, a school-based student suicide awareness and prevention training policy.

(c) School-based student suicide awareness and prevention training policy

A school-based student suicide awareness and prevention training policy implemented pursuant to subsection (a)(1) shall—

(1) be evidence-based;

(2) be culturally- and linguistically-appropriate;

(3) provide evidence-based training to students in grades 6 through 12, in coordination with school-based mental health resources, as applicable, regarding—

(A) suicide prevention education and awareness, including associated risk factors;

(B) methods that students can use to seek help; and

(C) student resources for suicide awareness and prevention; and

(4) provide for periodic retraining of such students.

(d) Collection of information and reporting

Each State educational agency, local educational agency, and Tribal educational agency that receives priority to implement a new training policy pursuant to subsection (a)(1) shall report to the Secretary the following aggregated information, in a manner that protects personal privacy, consistent with applicable Federal and State privacy laws:

(1) The number of trainings conducted, including the number of student trainings conducted, and the training delivery method used.

(2) The number of students trained, disaggregated by age and grade level.

(3) The number of help-seeking reports made by students after implementation of such policy.

(e) Evidence-based program availability

The Secretary shall coordinate with the Secretary of Education and the Secretary of the Interior to—

(1) make publicly available the policies established by State educational agencies, local educational agencies, and Tribal educational agencies pursuant to this section and the training that is available to students and teams pursuant to such policies, in accordance with section 290dd–2a of this title; and

(2) provide technical assistance and disseminate best practices on student suicide awareness and prevention training policies, including through the Suicide Prevention Technical Assistance Center authorized under section 290bb–34 of this title, as applicable, to State educational agencies, local educational agencies, and Tribal agencies.

(f) Implementation

Not later than September 30, 2024, the Secretary shall report to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives the number of recipients of funds under section 290bb–32 of this title who have implemented training policies described in subsection (a)(1) and a summary of the information received under subsection (d).

(g) Definitions

In this section:

(1) The term "evidence-based" has the meaning given such term in section 7801 of title 20.

(2) The term "local educational agency" has the meaning given to such term in section 7801 of title 20.

(3) The term "State educational agency" has the meaning given to such term in section 7801 of title 20.

(4) The term "Tribal educational agency" has the meaning given to the term "tribal educational agency" in section 7452 of title 20.

(July 1, 1944, ch. 373, title V, §520B, as added Pub. L. 117–100, §2(a), Mar. 15, 2022, 136 Stat. 44.)

EDITORIAL NOTES

PRIOR PROVISIONS

A prior section 290bb–33, act July 1, 1944, ch. 373, title V, §520B, as added Pub. L. 111–148, title X, §10410(b), Mar. 23, 2010, 124 Stat. 984, related to national centers of excellence for depression, prior to repeal by Pub. L. 114–255, div. B, title IX, §9017, Dec. 13, 2016, 130 Stat. 1248.

Another prior section 290bb–33, act July 1, 1944, ch. 373, title V, §520B, formerly title XXIV, §2441, as added Pub. L. 100–607, title II, §211, Nov. 4, 1988, 102 Stat. 3092; renumbered title V, §520B, and amended Pub. L. 102–321, title I, §118(a), (b)(2), July 10, 1992, 106 Stat. 348, 349, related to demonstration projects for individuals with positive test results, prior to repeal by Pub. L. 106–310, div. B, title XXXII, §3201(b)(2), Oct. 17, 2000, 114 Stat. 1190.

STATUTORY NOTES AND RELATED SUBSIDIARIES

EFFECTIVE DATE

Pub. L. 117–100, §3, Mar. 15, 2022, 136 Stat. 46, provided that: "The amendment made by this Act [enacting this section] shall apply only with respect to applications for assistance under section 520A of the Public Health Service Act (42 U.S.C. 290bb–32) that are submitted after the date of enactment of this Act [Mar. 15, 2022]."

§290bb–34. Suicide prevention technical assistance center

(a) Program authorized

(1) In general

The Secretary, acting through the Assistant Secretary, shall establish a research, training, and technical assistance resource center to provide appropriate information, training, and technical assistance to States, political subdivisions of States, federally recognized Indian Tribes, Tribal organizations, institutions of higher education, public organizations, or private nonprofit organizations regarding the prevention of suicide among all ages, particularly among groups that are at a high risk for suicide.

(2) Collaboration

In carrying out this subsection, as applicable with respect to assistance to entities serving members of the Armed Forces and veterans, the Secretary shall, as appropriate, collaborate with the Secretary of Defense and the Secretary of Veterans Affairs.

(b) Responsibilities of the Center

The center established under subsection (a) shall conduct activities for the purpose of—

(1) developing and continuing statewide or Tribal suicide early intervention and prevention strategies for all ages, particularly among groups that are at a high risk for suicide;

(2) ensuring the surveillance of suicide early intervention and prevention strategies for all ages, particularly among groups that are at a high risk for suicide;

(3) studying the costs and effectiveness of statewide and Tribal suicide early intervention and prevention strategies in order to provide information concerning relevant issues of importance to State, Tribal, and national policymakers;

(4) further identifying and understanding causes and associated risk factors for suicide;

(5) analyzing the efficacy of new and existing suicide early intervention and prevention

techniques and technology;

(6) ensuring the surveillance of suicidal behaviors and nonfatal suicidal attempts;

(7) studying the effectiveness of State-sponsored statewide and Tribal suicide early intervention and prevention strategies on the overall wellness and health promotion strategies related to suicide attempts;

(8) promoting the sharing of data regarding suicide with Federal agencies involved with suicide early intervention and prevention, and State-sponsored statewide or Tribal suicide early intervention and prevention strategies for the purpose of identifying previously unknown mental health causes and associated risk factors for suicide;

(9) evaluating and disseminating outcomes and best practices of mental health and substance use disorder services at institutions of higher education; and

(10) conducting other activities determined appropriate by the Secretary.

(c) Authorization of appropriations

For the purpose of carrying out this section, there are authorized to be appropriated $9,000,000 for each of fiscal years 2023 through 2027.

(d) Annual report

Not later than 2 years after December 29, 2022, the Secretary shall submit to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives a report on the activities carried out by the center established under subsection (a) during the year involved, including the potential effects of such activities, and the States, organizations, and institutions that have worked with the center.

(July 1, 1944, ch. 373, title V, §520C, as added Pub. L. 106–310, div. B, title XXXI, §3104(b), Oct. 17, 2000, 114 Stat. 1173; amended Pub. L. 108–355, §3(a), Oct. 21, 2004, 118 Stat. 1405; Pub. L. 114–255, div. B, title VI, §6001(c)(1), title IX, §9008(a), Dec. 13, 2016, 130 Stat. 1203, 1241; Pub. L. 117–328, div. FF, title I, §1421, Dec. 29, 2022, 136 Stat. 5702.)

EDITORIAL NOTES

AMENDMENTS

2022—Pub. L. 117–328, §1421(a)(2), substituted "Tribal" for "tribal" wherever appearing.

Subsec. (a). Pub. L. 117–328, §1421(b), designated existing provisions as par. (1), inserted par. heading, and added par. (2).

Pub. L. 117–328, §1421(a)(1), substituted "Tribes" for "tribes".

Subsec. (c). Pub. L. 117–328, §1421(c), substituted "$9,000,000 for each of fiscal years 2023 through 2027" for "$5,988,000 for each of fiscal years 2018 through 2022".

Subsec. (d). Pub. L. 117–328, §1421(d), substituted "Not later than 2 years after December 29, 2022, the Secretary shall submit to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives" for "Not later than 2 years after December 13, 2016, the Secretary shall submit to Congress".

2016—Pub. L. 114–255, §9008(a)(1), substituted "Suicide prevention technical assistance center" for "Youth interagency research, training, and technical assistance centers" in section catchline.

Subsec. (a). Pub. L. 114–255, §9008(a)(2), substituted "acting through the Assistant Secretary, shall establish a research, training, and technical assistance resource center to provide appropriate information, training, and technical assistance to States, political subdivisions of States, federally recognized Indian tribes, tribal organizations, institutions of higher education, public organizations, or private nonprofit organizations regarding the prevention of suicide among all ages, particularly among groups that are at a high risk for suicide." for "acting through the Assistant Secretary for Mental Health and Substance Use, and in consultation with the Administrator of the Office of Juvenile Justice and Delinquency Prevention, the Director of the Bureau of Justice Assistance and the Director of the National Institutes of Health—

"(1) shall award grants or contracts to public or nonprofit private entities to establish not more than four research, training, and technical assistance centers to carry out the activities described in subsection (c); and

"(2) shall award a competitive grant to 1 additional research, training, and technical assistance center to carry out the activities described in subsection (d)."

Pub. L. 114–255, §6001(c)(1), substituted "Assistant Secretary for Mental Health and Substance Use" for "Administrator of the Substance Abuse and Mental Health Services Administration" in introductory provisions.

Subsec. (b). Pub. L. 114–255, §9008(a)(5)(C), substituted "suicide" for "youth suicide" wherever appearing.

Pub. L. 114–255, §9008(a)(5)(B), in introductory provisions, substituted "The center established under subsection (a) shall conduct activities for the purpose of" for "The additional research, training, and technical assistance center established under subsection (a)(2) shall provide appropriate information, training, and technical assistance to States, political subdivisions of a State, Federally recognized Indian tribes, tribal organizations, institutions of higher education, public organizations, or private nonprofit organizations for".

Pub. L. 114–255, §9008(a)(5)(A), substituted "Responsibilities of the Center" for "Additional center" in heading.

Pub. L. 114–255, §9008(a)(3), (4), redesignated subsec. (d) as (b) and struck out former subsec. (b). Text of subsec. (b) read as follows: "A public or private nonprofit entity desiring a grant or contract under subsection (a) shall prepare and submit an application to the Secretary at such time, in such manner, and containing such information as the Secretary may require."

Subsec. (b)(1). Pub. L. 114–255, §9008(a)(5)(D), substituted "developing and continuing" for "the development or continuation of" and inserted "for all ages, particularly among groups that are at a high risk for suicide" before semicolon at end.

Subsec. (b)(2). Pub. L. 114–255, §9008(a)(5)(E), inserted "for all ages, particularly among groups that are at a high risk for suicide" before semicolon at end.

Subsec. (b)(3). Pub. L. 114–255, §9008(a)(5)(F), inserted "and tribal" after "statewide".

Subsec. (b)(5). Pub. L. 114–255, §9008(a)(5)(G), inserted "and prevention" after "intervention".

Subsec. (b)(8). Pub. L. 114–255, §9008(a)(5)(H), struck out "in youth" before semicolon at end.

Subsec. (b)(9). Pub. L. 114–255, §9008(a)(5)(I), substituted "health and substance use disorder" for "and behavioral health".

Subsec. (b)(10). Pub. L. 114–255, §9008(a)(5)(J), inserted "conducting" before "other".

Subsecs. (c) to (e). Pub. L. 114–255, §9008(a)(6), added subsecs. (c) and (d) and struck out subsec. (e) which authorized appropriations for prior fiscal years.

2004—Subsec. (a). Pub. L. 108–355, §3(a)(1), substituted dash for comma after "National Institutes of Health", designated remainder of existing provisions as par. (1), substituted "; and" for period, and added par. (2).

Subsec. (c). Pub. L. 108–355, §3(a)(2), substituted "(a)(1)" for "(a)" in introductory provisions.

Subsec. (d). Pub. L. 108–355, §3(a)(5), added subsec. (d). Former subsec. (d) redesignated (e).

Pub. L. 108–355, §3(a)(3), designated existing provisions as par. (1), substituted "awarding grants or contracts under subsection (a)(1)" for "carrying out this section", and added par. (2).

Subsec. (e). Pub. L. 108–355, §3(a)(4), redesignated subsec. (d) as (e).

§290bb–35. Repealed. Pub. L. 114–255, div. B, title IX, §9017, Dec. 13, 2016, 130 Stat. 1248

Section, act July 1, 1944, ch. 373, title V, §520D, as added Pub. L. 106–310, div. B, title XXXI, §3107, Oct. 17, 2000, 114 Stat. 1179, related to services for youth offenders.

§290bb–36. Youth suicide early intervention and prevention strategies

(a) In general

The Secretary, acting through the Assistant Secretary for Mental Health and Substance Use, shall award grants or cooperative agreements to eligible entities to—

(1) develop and implement State-sponsored statewide or Tribal youth suicide early intervention and prevention strategies in schools, educational institutions, juvenile justice systems, substance use disorder programs, mental health programs, foster care systems, pediatric health programs, and other child and youth support organizations;

(2) support public organizations and private nonprofit organizations actively involved in State-sponsored statewide or Tribal youth suicide early intervention and prevention strategies and in the development and continuation of State-sponsored statewide youth suicide early intervention

and prevention strategies;

(3) provide grants to institutions of higher education to coordinate the implementation of State-sponsored statewide or Tribal youth suicide early intervention and prevention strategies;

(4) collect and analyze data on State-sponsored statewide or Tribal youth suicide early intervention and prevention services that can be used to monitor the effectiveness of such services and for research, technical assistance, and policy development; and

(5) assist eligible entities, through State-sponsored statewide or Tribal youth suicide early intervention and prevention strategies, in achieving targets for youth suicide reductions under title V of the Social Security Act [42 U.S.C. 701 et seq.].

(b) Eligible entity

(1) Definition

In this section, the term "eligible entity" means—

(A) a State;

(B) a public organization or private nonprofit organization designated by a State or Indian Tribe (as defined in section 4 of the Indian Self-Determination and Education Assistance Act [25 U.S.C. 5304]) to develop or direct the State-sponsored statewide or Tribal youth suicide early intervention and prevention strategy; or

(C) a Federally recognized Indian Tribe or Tribal organization (as defined in the Indian Self-Determination and Education Assistance Act [25 U.S.C. 5301 et seq.]) or an urban Indian organization (as defined in the Indian Health Care Improvement Act [25 U.S.C. 1601 et seq.]) that is actively involved in the development and continuation of a Tribal youth suicide early intervention and prevention strategy.

(2) Limitation

In carrying out this section, the Secretary shall ensure that a State does not receive more than 1 grant or cooperative agreement under this section at any 1 time. For purposes of the preceding sentence, a State shall be considered to have received a grant or cooperative agreement if the eligible entity involved is the State or an entity designated by the State under paragraph (1)(B). Nothing in this paragraph shall be construed to apply to entities described in paragraph (1)(C).

(3) Consideration

In awarding grants under this section, the Secretary shall take into consideration the extent of the need of the applicant, including the incidence and prevalence of suicide in the State and among the populations of focus, including rates of suicide determined by the Centers for Disease Control and Prevention for the State or population of focus.

(4) Consultation

An entity described in paragraph (1)(A) or (1)(B) that applies for a grant or cooperative agreement under this section shall agree to consult or confer with entities described in paragraph (1)(C) and Native Hawaiian Health Care Systems, as applicable, in the applicable State with respect to the development and implementation of a statewide early intervention strategy.

(c) Preference

In providing assistance under a grant or cooperative agreement under this section, an eligible entity shall give preference to public organizations, private nonprofit organizations, political subdivisions, institutions of higher education, and Tribal organizations actively involved with the State-sponsored statewide or Tribal youth suicide early intervention and prevention strategy that—

(1) provide early intervention and assessment services, including screening programs, to youth who are at risk for mental or emotional disorders that may lead to a suicide attempt, and that are integrated with school systems, educational institutions, juvenile justice systems, substance use disorder programs, mental health programs, foster care systems, pediatric health programs, and other child and youth support organizations;

(2) demonstrate collaboration among early intervention and prevention services or certify that entities will engage in future collaboration;

(3) employ or include in their applications a commitment to evaluate youth suicide early intervention and prevention practices and strategies adapted to the local community;

(4) provide timely referrals for appropriate community-based mental health care and treatment of youth who are at risk for suicide in child-serving settings and agencies;

(5) provide immediate support and information resources to families of youth who are at risk for suicide;

(6) offer access to services and care to youth with diverse linguistic and cultural backgrounds;

(7) offer appropriate postsuicide intervention services, care, and information to families, friends, schools, educational institutions, juvenile justice systems, substance use disorder programs, mental health programs, foster care systems, pediatric health programs, and other child and youth support organizations of youth who recently completed suicide;

(8) offer continuous and up-to-date information and awareness campaigns that target parents, family members, child care professionals, community care providers, and the general public and highlight the risk factors associated with youth suicide and the life-saving help and care available from early intervention and prevention services;

(9) ensure that information and awareness campaigns on youth suicide risk factors, and early intervention and prevention services, use effective communication mechanisms that are targeted to and reach youth, families, schools, educational institutions, pediatric health programs, and youth organizations;

(10) provide a timely response system to ensure that child-serving professionals and providers are properly trained in youth suicide early intervention and prevention strategies and that child-serving professionals and providers involved in early intervention and prevention services are properly trained in effectively identifying youth who are at risk for suicide;

(11) provide continuous training activities for child care professionals and community care providers on the latest youth suicide early intervention and prevention services practices and strategies;

(12) conduct annual self-evaluations of outcomes and activities, including consulting with interested families and advocacy organizations;

(13) provide services in areas or regions with rates of youth suicide that exceed the national average as determined by the Centers for Disease Control and Prevention;

(14) obtain informed written consent from a parent or legal guardian of an at-risk child before involving the child in a youth suicide early intervention and prevention program; and

(15) provide to parents, legal guardians, and family members of youth, supplies to securely store means commonly used in suicide, if applicable, within the household.

(d) Requirement for suicide prevention activities

Not less than 85 percent of grant funds received under this section shall be used to provide suicide prevention activities.

(e) Coordination and collaboration

(1) In general

In carrying out this section, the Secretary shall collaborate with relevant Federal agencies and suicide working groups responsible for early intervention and prevention services relating to youth suicide.

(2) Consultation

In carrying out this section, the Secretary shall consult with—

(A) State and local agencies, including agencies responsible for early intervention and prevention services under title XIX of the Social Security Act [42 U.S.C. 1396 et seq.], the State Children's Health Insurance Program under title XXI of the Social Security Act [42 U.S.C. 1397aa et seq.], and programs funded by grants under title V of the Social Security Act [42 U.S.C. 701 et seq.];

(B) local and national organizations that serve youth at risk for suicide and their families;

(C) relevant national medical and other health and education specialty organizations;

(D) youth who are at risk for suicide, who have survived suicide attempts, or who are currently receiving care from early intervention services;

(E) families and friends of youth who are at risk for suicide, who have survived suicide attempts, who are currently receiving care from early intervention and prevention services, or who have completed suicide;

(F) qualified professionals who possess the specialized knowledge, skills, experience, and relevant attributes needed to serve youth at risk for suicide and their families; and

(G) third-party payers, managed care organizations, and related commercial industries.

(3) Policy development

In carrying out this section, the Secretary shall—

(A) coordinate and collaborate on policy development at the Federal level with the relevant Department of Health and Human Services agencies and suicide working groups and the Department of Education, as appropriate; and

(B) consult on policy development at the Federal level with the private sector, including consumer, medical, suicide prevention advocacy groups, and other health and education professional-based organizations, with respect to State-sponsored statewide or Tribal youth suicide early intervention and prevention strategies.

(f) Rule of construction; religious and moral accommodation

Nothing in this section shall be construed to require suicide assessment, early intervention, or treatment services for youth whose parents or legal guardians object based on the parents' or legal guardians' religious beliefs or moral objections.

(g) Evaluations and report

(1) Evaluations by eligible entities

Not later than 24 months after receiving a grant or cooperative agreement under this section, an eligible entity shall submit to the Secretary the results of an evaluation to be conducted by the entity concerning the effectiveness of the activities carried out under the grant or agreement.

(2) Report

Not later than December 31, 2025, the Secretary shall submit to the appropriate committees of Congress a report concerning the results of—

(A) the evaluations conducted under paragraph (1); and

(B) an evaluation conducted by the Secretary to analyze the effectiveness and efficacy of the activities conducted with grants, collaborations, and consultations under this section.

(h) Rule of construction; student medication

Nothing in this section or section 290bb–36a of this title shall be construed to allow school personnel to require that a student obtain any medication as a condition of attending school or receiving services.

(i) Prohibition

Funds appropriated to carry out this section, section 290bb–34 of this title, section 290bb–36a of this title, or section 290bb–36b of this title shall not be used to pay for or refer for abortion.

(j) Parental consent

States and entities receiving funding under this section and section 290bb–36a of this title shall obtain prior written, informed consent from the child's parent or legal guardian for assessment services, school-sponsored programs, and treatment involving medication related to youth suicide conducted in elementary and secondary schools. The requirement of the preceding sentence does not apply in the following cases:

(1) In an emergency, where it is necessary to protect the immediate health and safety of the student or other students.

(2) Other instances, as defined by the State, where parental consent cannot reasonably be obtained.

(k) Relation to education provisions

Nothing in this section or section 290bb–36a of this title shall be construed to supersede section 1232g of title 20, including the requirement of prior parental consent for the disclosure of any education records. Nothing in this section or section 290bb–36a of this title shall be construed to modify or affect parental notification requirements for programs authorized under the Elementary and Secondary Education Act of 1965 [20 U.S.C. 6301 et seq.] (as amended by the No Child Left Behind Act of 2001; Public Law 107–110).

(l) Definitions

In this section:

(1) Early intervention

The term "early intervention" means a strategy or approach that is intended to prevent an outcome or to alter the course of an existing condition.

(2) Educational institution; institution of higher education; school

The term—

(A) "educational institution" means a school or institution of higher education;

(B) "institution of higher education" has the meaning given such term in section 1001 of title 20; and

(C) "school" means an elementary school or secondary school (as such terms are defined in section 8101 of the Elementary and Secondary Education Act of 1965 [20 U.S.C. 7801]).

(3) Prevention

The term "prevention" means a strategy or approach that reduces the likelihood or risk of onset, or delays the onset, of adverse health problems that have been known to lead to suicide.

(4) Youth

The term "youth" means individuals who are up to 24 years of age.

(m) Authorization of appropriations

For the purpose of carrying out this section, there are authorized to be appropriated $40,000,000 for each of fiscal years 2023 through 2027.

(July 1, 1944, ch. 373, title V, §520E, as added Pub. L. 108–355, §3(c), Oct. 21, 2004, 118 Stat. 1409; amended Pub. L. 114–95, title IX, §9215(kkk)(3), Dec. 10, 2015, 129 Stat. 2187; Pub. L. 114–255, div. B, title VI, §6001(c)(1), title IX, §9008(b), Dec. 13, 2016, 130 Stat. 1203, 1242; Pub. L. 116–260, div. BB, title III, §315, Dec. 27, 2020, 134 Stat. 2932; Pub. L. 117–328, div. FF, title I, §1422, Dec. 29, 2022, 136 Stat. 5702.)

EDITORIAL NOTES

REFERENCES IN TEXT

The Social Security Act, referred to in subsecs. (a)(5) and (e)(2)(A), is act Aug. 14, 1935, ch. 531, 49 Stat. 620. Titles V, XIX, and XXI of the Act are classified generally to subchapters V (§701 et seq.), XIX (§1396 et seq.), and XXI (§1397aa et seq.), respectively, of chapter 7 of this title. For complete classification of this Act to the Code, see section 1305 of this title and Tables.

The Indian Self-Determination and Education Assistance Act, referred to in subsec. (b)(1)(C), is Pub. L. 93–638, Jan. 4, 1975, 88 Stat. 2203, which is classified principally to chapter 46 (§5301 et seq.) of Title 25, Indians. For complete classification of this Act to the Code, see Short Title note set out under section 5301 of Title 25 and Tables.

The Indian Health Care Improvement Act, referred to in subsec. (b)(1)(C), is Pub. L. 94–437, Sept. 30, 1976, 90 Stat. 1400, which is classified principally to chapter 18 (§1601 et seq.) of Title 25, Indians. For complete classification of this Act to the Code, see Short Title note set out under section 1601 of Title 25 and Tables.

The Elementary and Secondary Education Act of 1965, referred to in subsec. (k), is Pub. L. 89–10, Apr. 11, 1965, 79 Stat. 27, which is classified generally to chapter 70 (§6301 et seq.) of Title 20, Education. For

complete classification of this Act to the Code, see Short Title note set out under section 6301 of Title 20 and Tables.

The No Child Left Behind Act of 2001, referred to in subsec. (k), is Pub. L. 107–110, Jan. 8, 2002, 115 Stat. 1425. For complete classification of this Act to the Code, see Short Title of 2002 Amendment note set out under section 6301 of Title 20, Education, and Tables.

PRIOR PROVISIONS

A prior section 290bb–36, act July 1, 1944, ch. 373, title V, §520E, as added Pub. L. 106–310, div. B, title XXXI, §3111, Oct. 17, 2000, 114 Stat. 1186, and amended, which related to suicide prevention for children and adolescents, was renumbered section 520E–1 of act July 1, 1944, by Pub. L. 108–355, §3(b)(2), Oct. 21, 2004, 118 Stat. 1409, and transferred to section 290bb–36a of this title.

AMENDMENTS

2022—Pub. L. 117–328, §1422(2), substituted "Tribal" for "tribal" wherever appearing.

Subsec. (a)(1). Pub. L. 117–328, §1422(3), inserted "pediatric health programs," after "foster care systems,".

Subsec. (b)(1)(B). Pub. L. 117–328, §1422(4), amended subpar. (B) generally. Prior to amendment, subpar. (B) read as follows: "a public organization or private nonprofit organization designated by a State to develop or direct the State-sponsored statewide youth suicide early intervention and prevention strategy; or".

Subsec. (b)(1)(C). Pub. L. 117–328, §1422(1), substituted "Tribe" for "tribe".

Subsec. (c)(1). Pub. L. 117–328, §1422(5)(A), inserted "pediatric health programs," after "foster care systems,".

Subsec. (c)(7). Pub. L. 117–328, §1422(5)(B), inserted "pediatric health programs," after "foster care systems,".

Subsec. (c)(9). Pub. L. 117–328, §1422(5)(C), inserted "pediatric health programs," after "educational institutions,".

Subsec. (c)(15). Pub. L. 117–328, §1422(5)(D)–(F), added par. (15).

Subsec. (d). Pub. L. 117–328, §1422(6), substituted "suicide prevention activities" for "direct services" in heading and "suicide prevention activities" for "direct services, of which not less than 5 percent shall be used for activities authorized under subsection (a)(3)" in text.

Subsec. (e)(3)(A). Pub. L. 117–328, §1422(7), inserted "and the Department of Education, as appropriate" after "agencies and suicide working groups".

Subsec. (g)(1). Pub. L. 117–328, §1422(8)(A), substituted "24" for "18".

Subsec. (g)(2). Pub. L. 117–328, §1422(8)(B), substituted "December 31, 2025" for "2 years after December 13, 2016".

Subsec. (l)(4). Pub. L. 117–328, §1422(9), substituted "up to 24 years of age" for "between 10 and 24 years of age".

Subsec. (m). Pub. L. 117–328, §1422(10), substituted "$40,000,000 for each of fiscal years 2023 through 2027" for "$30,000,000 for each of fiscal years 2018 through 2022".

2020—Subsec. (b)(4). Pub. L. 116–260 added par. (4).

2016—Subsec. (a). Pub. L. 114–255, §6001(c)(1), substituted "Assistant Secretary for Mental Health and Substance Use" for "Administrator of the Substance Abuse and Mental Health Services Administration" in introductory provisions.

Subsec. (a)(1). Pub. L. 114–255, §9008(b)(1), substituted "substance use disorder" for "substance abuse".

Subsec. (b)(2). Pub. L. 114–255, §9008(b)(2)(A), substituted "ensure that a State does not receive more than 1 grant or cooperative agreement under this section at any 1 time" for "ensure that each State is awarded only 1 grant or cooperative agreement under this section" and "received" for "been awarded".

Subsec. (b)(3). Pub. L. 114–255, §9008(b)(2)(B), added par. (3).

Subsec. (c)(1), (7). Pub. L. 114–255, §9008(b)(1), substituted "substance use disorder" for "substance abuse".

Subsec. (g)(2). Pub. L. 114–255, §9008(b)(3), substituted "2 years after December 13, 2016," for "2 years after October 21, 2004,".

Subsec. (m). Pub. L. 114–255, §9008(b)(4), added subsec. (m) and struck out former subsec. (m) which authorized appropriations for fiscal years 2005 to 2007 and provided that the Secretary should give preference to certain States if less than $3,500,000 was appropriated for any fiscal year.

2015—Subsec. (l)(2)(C). Pub. L. 114–95 substituted "elementary school or secondary school (as such terms are defined in section 8101 of the Elementary and Secondary Education Act of 1965)" for "elementary or secondary school (as such terms are defined in section 9101 of the Elementary and Secondary Education Act

of 1965)".

STATUTORY NOTES AND RELATED SUBSIDIARIES

EFFECTIVE DATE OF 2015 AMENDMENT

Amendment by Pub. L. 114–95 effective Dec. 10, 2015, except with respect to certain noncompetitive programs and competitive programs, see section 5 of Pub. L. 114–95, set out as a note under section 6301 of Title 20, Education.

CONGRESSIONAL FINDINGS

Pub. L. 108–355, §2, Oct. 21, 2004, 118 Stat. 1404, provided that: "Congress makes the following findings:

"(1) More children and young adults die from suicide each year than from cancer, heart disease, AIDS, birth defects, stroke, and chronic lung disease combined.

"(2) Over 4,000 children and young adults tragically take their lives every year, making suicide the third overall cause of death between the ages of 10 and 24. According to the Centers for Disease Control and Prevention, suicide is the third overall cause of death among college-age students.

"(3) According to the National Center for Injury Prevention and Control of the Centers for Disease Control and Prevention, children and young adults accounted for 15 percent of all suicides completed in 2000.

"(4) From 1952 to 1995, the rate of suicide in children and young adults tripled.

"(5) From 1980 to 1997, the rate of suicide among young adults ages 15 to 19 increased 11 percent.

"(6) From 1980 to 1997, the rate of suicide among children ages 10 to 14 increased 109 percent.

"(7) According to the National Center of Health Statistics, suicide rates among Native Americans range from 1.5 to 3 times the national average for other groups, with young people ages 15 to 34 making up 64 percent of all suicides.

"(8) Congress has recognized that youth suicide is a public health tragedy linked to underlying mental health problems and that youth suicide early intervention and prevention activities are national priorities.

"(9) Youth suicide early intervention and prevention have been listed as urgent public health priorities by the President's New Freedom Commission in [probably should be "on"] Mental Health (2002), the Institute of Medicine's Reducing Suicide: A National Imperative (2002), the National Strategy for Suicide Prevention: Goals and Objectives for Action (2001), and the Surgeon General's Call to Action To Prevent Suicide (1999).

"(10) Many States have already developed comprehensive statewide youth suicide early intervention and prevention strategies that seek to provide effective early intervention and prevention services.

"(11) In a recent report, a startling 85 percent of college counseling centers revealed an increase in the number of students they see with psychological problems. Furthermore, the American College Health Association found that 61 percent of college students reported feeling hopeless, 45 percent said they felt so depressed they could barely function, and 9 percent felt suicidal.

"(12) There is clear evidence of an increased incidence of depression among college students. According to a survey described in the Chronicle of Higher Education (February 1, 2002), depression among freshmen has nearly doubled (from 8.2 percent to 16.3 percent). Without treatment, researchers recently noted that 'depressed adolescents are at risk for school failure, social isolation, promiscuity, self-medication with drugs and alcohol, and suicide—now the third leading cause of death among 10–24 year olds.'.

"(13) Researchers who conducted the study 'Changes in Counseling Center Client Problems Across 13 Years' (1989–2001) at Kansas State University stated that 'students are experiencing more stress, more anxiety, more depression than they were a decade ago.' (The Chronicle of Higher Education, February 14, 2003).

"(14) According to the 2001 National Household Survey on Drug Abuse, 20 percent of full-time undergraduate college students use illicit drugs.

"(15) The 2001 National Household Survey on Drug Abuse also reported that 18.4 percent of adults aged 18 to 24 are dependent on or abusing illicit drugs or alcohol. In addition, the study found that 'serious mental illness is highly correlated with substance dependence or abuse. Among adults with serious mental illness in 2001, 20.3 percent were dependent on or abused alcohol or illicit drugs, while the rate among adults without serious mental illness was only 6.3 percent.'.

"(16) A 2003 Gallagher's Survey of Counseling Center Directors found that 81 percent were concerned about the increasing number of students with more serious psychological problems, 67 percent reported a need for more psychiatric services, and 63 percent reported problems with growing demand for services

without an appropriate increase in resources.

"(17) The International Association of Counseling Services accreditation standards recommend 1 counselor per 1,000 to 1,500 students. According to the 2003 Gallagher's Survey of Counseling Center Directors, the ratio of counselors to students is as high as 1 counselor per 2,400 students at institutions of higher education with more than 15,000 students."

§290bb–36a. Suicide prevention for youth

(a) In general

The Secretary shall award grants or cooperative agreements to public organizations, private nonprofit organizations, political subdivisions, consortia of political subdivisions, consortia of States, or Federally recognized Indian tribes or tribal organizations to design early intervention and prevention strategies that will complement the State-sponsored statewide or tribal youth suicide early intervention and prevention strategies developed pursuant to section 290bb–36 of this title.

(b) Collaboration

In carrying out subsection (a), the Secretary shall ensure that activities under this section are coordinated with the relevant Department of Health and Human Services agencies and suicide working groups.

(c) Requirements

A public organization, private nonprofit organization, political subdivision, consortium of political subdivisions, consortium of States, or federally recognized Indian tribe or tribal organization desiring a grant, contract, or cooperative agreement under this section shall demonstrate that the suicide prevention program such entity proposes will—

(1)(A) comply with the State-sponsored statewide early intervention and prevention strategy as developed under section 290bb–36 of this title; and

(B) in the case of a consortium of States, receive the support of all States involved;

(2) provide for the timely assessment, treatment, or referral for mental health or substance abuse services of youth at risk for suicide;

(3) be based on suicide prevention practices and strategies that are adapted to the local community;

(4) integrate its suicide prevention program into the existing health care system in the community including general, mental, and behavioral health services, and substance abuse services;

(5) be integrated into other systems in the community that address the needs of youth including the school systems, educational institutions, juvenile justice system, substance abuse programs, mental health programs, foster care systems, and community child and youth support organizations;

(6) use primary prevention methods to educate and raise awareness in the local community by disseminating evidence-based information about suicide prevention;

(7) include suicide prevention, mental health, and related information and services for the families and friends of those who completed suicide, as needed;

(8) offer access to services and care to youth with diverse linguistic and cultural backgrounds;

(9) conduct annual self-evaluations of outcomes and activities, including consulting with interested families and advocacy organizations; [1]

(10) ensure that staff used in the program are trained in suicide prevention and that professionals involved in the system of care have received training in identifying persons at risk of suicide.

(d) Use of funds

Amounts provided under a grant or cooperative agreement under this section shall be used to supplement, and not supplant, Federal and non-Federal funds available for carrying out the activities described in this section. Applicants shall provide financial information to demonstrate compliance

with this section.

(e) Condition

An applicant for a grant or cooperative agreement under subsection (a) shall demonstrate to the Secretary that the application complies with the State-sponsored statewide early intervention and prevention strategy as developed under section 290bb–36 of this title and the applicant has the support of the local community and relevant public health officials.

(f) Special populations

In awarding grants and cooperative agreements under subsection (a), the Secretary shall ensure that such awards are made in a manner that will focus on the needs of communities or groups that experience high or rapidly rising rates of suicide.

(g) Application

A public organization, private nonprofit organization, political subdivision, consortium of political subdivisions, consortium of States, or Federally recognized Indian tribe or tribal organization receiving a grant or cooperative agreement under subsection (a) shall prepare and submit an application to the Secretary at such time, in such manner, and containing such information as the Secretary may reasonably require. Such application shall include a plan for the rigorous evaluation of activities funded under the grant or cooperative agreement, including a process and outcome evaluation.

(h) Distribution of awards

In awarding grants and cooperative agreements under subsection (a), the Secretary shall ensure that such awards are distributed among the geographical regions of the United States and between urban and rural settings.

(i) Evaluation

A public organization, private nonprofit organization, political subdivision, consortium of political subdivisions, consortium of States, or Federally recognized Indian tribe or tribal organization receiving a grant or cooperative agreement under subsection (a) shall prepare and submit to the Secretary at the end of the program period, an evaluation of all activities funded under this section.

(j) Dissemination and education

The Secretary shall ensure that findings derived from activities carried out under this section are disseminated to State, county and local governmental agencies and public and private nonprofit organizations active in promoting suicide prevention and family support activities.

(k) Duration of projects

With respect to a grant, contract, or cooperative agreement awarded under this section, the period during which payments under such award may be made to the recipient may not exceed 3 years.

(l) Study

Within 1 year after October 17, 2000, the Secretary shall, directly or by grant or contract, initiate a study to assemble and analyze data to identify—

(1) unique profiles of children under 13 who attempt or complete suicide;

(2) unique profiles of youths between ages 13 and 24 who attempt or complete suicide; and

(3) a profile of services available to these groups and the use of these services by children and youths from paragraphs (1) and (2).

(m) Definitions

In this section, the terms "early intervention", "educational institution", "institution of higher education", "prevention", "school", and "youth" have the meanings given to those terms in section 290bb–36 of this title.

(n) Authorization of appropriation

For purposes of carrying out this section, there is authorized to be appropriated $75,000,000 for

fiscal year 2001 and such sums as may be necessary for each of the fiscal years 2002 through 2003.

(July 1, 1944, ch. 373, title V, §520E–1, formerly §520E, as added Pub. L. 106–310, div. B, title XXXI, §3111, Oct. 17, 2000, 114 Stat. 1186; renumbered §520E–1 and amended Pub. L. 108–355, §3(b), Oct. 21, 2004, 118 Stat. 1407.)

EDITORIAL NOTES

CODIFICATION

Section was formerly classified to section 290bb–36 of this title prior to renumbering by Pub. L. 108–355.

AMENDMENTS

2004—Pub. L. 108–355, §3(b)(1)(A), substituted "youth" for "children and adolescents" in section catchline.

Subsec. (a). Pub. L. 108–355, §3(b)(1)(B), added subsec. (a) and struck out heading and text of former subsec. (a). Text read as follows: "The Secretary shall award grants, contracts, or cooperative agreements to States, political subdivisions of States, Indian tribes, tribal organizations, public organizations, or private nonprofit organizations to establish programs to reduce suicide deaths in the United States among children and adolescents."

Subsec. (b). Pub. L. 108–355, §3(b)(1)(C), substituted "with the relevant Department of Health and Human Services agencies and suicide working groups." for "among the Substance Abuse and Mental Health Services Administration, the relevant institutes at the National Institutes of Health, the Centers for Disease Control and Prevention, the Health Resources and Services Administration, and the Administration on Children and Families."

Subsec. (c). Pub. L. 108–355, §3(b)(1)(D)(i), substituted "A public organization, private nonprofit organization, political subdivision, consortium of political subdivisions, consortium of States, or federally recognized Indian tribe or tribal organization desiring" for "A State, political subdivision of a State, Indian tribe, tribal organization, public organization, or private nonprofit organization desiring" in introductory provisions.

Subsec. (c)(1). Pub. L. 108–355, §3(b)(1)(D)(iii), added par. (1). Former par. (1) redesignated (2).

Subsec. (c)(2). Pub. L. 108–355, §3(b)(1)(D)(ii), (iv), redesignated par. (1) as (2) and substituted "youth" for "children and adolescents". Former par. (2) redesignated (3).

Subsec. (c)(3). Pub. L. 108–355, §3(b)(1)(D)(ii), (v), redesignated par. (2) as (3) and struck out "best evidence-based," after "based on". Former par. (3) redesignated (4).

Subsec. (c)(4). Pub. L. 108–355, §3(b)(1)(D)(ii), (vi), redesignated par. (3) as (4) and substituted "general, mental, and behavioral health services, and substance abuse services;" for "primary health care, mental health services, and substance abuse services;". Former par. (4) redesignated (5).

Subsec. (c)(5). Pub. L. 108–355, §3(b)(1)(D)(ii), (vii), redesignated par. (4) as (5) and substituted "youth including the school systems, educational institutions, juvenile justice system, substance abuse programs, mental health programs, foster care systems, and community child and youth support organizations;" for "children and adolescents including the educational system, juvenile justice system, welfare and child protection systems, and community youth support organizations;". Former par. (5) redesignated (6).

Subsec. (c)(6), (7). Pub. L. 108–355, §3(b)(1)(D)(ii), redesignated pars. (5) and (6) as (6) and (7), respectively. Former par. (7) redesignated (8).

Subsec. (c)(8). Pub. L. 108–355, §3(b)(1)(D)(viii), added par. (8) and struck out former par. (8) which read as follows: "provide linguistically appropriate and culturally competent services, as needed;".

Pub. L. 108–355, §3(b)(1)(D)(ii), redesignated par. (7) as (8). Former par. (8) redesignated (9).

Subsec. (c)(9). Pub. L. 108–355, §3(b)(1)(D)(ix), added par. (9) and struck out former par. (9) which read as follows: "provide a plan for the evaluation of outcomes and activities at the local level, according to standards established by the Secretary, and agree to participate in a national evaluation; and".

Pub. L. 108–355, §3(b)(1)(D)(ii), redesignated par. (8) as (9). Former par. (9) redesignated (10).

Subsec. (c)(10). Pub. L. 108–355, §3(b)(1)(D)(ii), redesignated par. (9) as (10).

Subsec. (d). Pub. L. 108–355, §3(b)(1)(E), added subsec. (d) and struck out heading and text of former subsec. (d). Text read as follows: "Amounts provided under grants, contracts, or cooperative agreements under subsection (a) of this section shall be used to supplement and not supplant other Federal, State, and local public funds that are expended to provide services for eligible individuals."

Subsec. (e). Pub. L. 108–355, §3(b)(1)(F), struck out ", contract," after "grant" and inserted "application complies with the State-sponsored statewide early intervention and prevention strategy as developed under

section 290bb–36 of this title and the" after "Secretary that the".

Subsec. (f). Pub. L. 108–355, §3(b)(1)(G), struck out ", contracts," after "grants".

Subsec. (g). Pub. L. 108–355, §3(b)(1)(H), substituted "A public organization, private nonprofit organization, political subdivision, consortium of political subdivisions, consortium of States, or Federally recognized Indian tribe or tribal organization receiving" for "A State, political subdivision of a State, Indian tribe, tribal organization, public organization, or private nonprofit organization receiving" and struck out ", contract," after "grant" in two places.

Subsec. (h). Pub. L. 108–355, §3(b)(1)(I), struck out ", contracts," after "grants".

Subsec. (i). Pub. L. 108–355, §3(b)(1)(J), substituted "A public organization, private nonprofit organization, political subdivision, consortium of political subdivisions, consortium of States, or Federally recognized Indian tribe or tribal organization receiving" for "A State, political subdivision of a State, Indian tribe, tribal organization, public organization, or private nonprofit organization receiving" and struck out ", contract," after "grant".

Subsec. (k). Pub. L. 108–355, §3(b)(1)(K), substituted "3 years" for "5 years".

Subsec. (l)(2). Pub. L. 108–355, §3(b)(1)(L)(i), substituted "24" for "21".

Subsec. (l)(3). Pub. L. 108–355, §3(b)(1)(L)(ii), struck out "which might have been" after "profile of services".

Subsec. (m). Pub. L. 108–355, §3(b)(1)(O), added subsec. (m). Former subsec. (m) redesignated (n).

Pub. L. 108–355, §3(b)(1)(M), struck out par. (1) designation and heading and struck out heading and text of par. (2). Text read as follows: "In carrying out this section, the Secretary shall use 1 percent of the amount appropriated under paragraph (1) for each fiscal year for managing programs under this section."

Subsec. (n). Pub. L. 108–355, §3(b)(1)(N), redesignated subsec. (m) as (n).

STATUTORY NOTES AND RELATED SUBSIDIARIES

TEEN SUICIDE PREVENTION STUDY

Pub. L. 106–386, div. B, title VI, §1602, Oct. 28, 2000, 114 Stat. 1538, provided that:

"(a) SHORT TITLE.—This section may be cited as the 'Teen Suicide Prevention Act of 2000'.

"(b) FINDINGS.—Congress finds that—

"(1) measures that increase public awareness of suicide as a preventable public health problem, and target parents and youth so that suicide risks and warning signs can be recognized, will help to eliminate the ignorance and stigma of suicide as barriers to youth and families seeking preventive care;

"(2) suicide prevention efforts in the year 2000 should—

"(A) target at-risk youth, particularly youth with mental health problems, substance abuse problems, or contact with the juvenile justice system;

"(B) involve—

"(i) the identification of the characteristics of the at-risk youth and other youth who are contemplating suicide, and barriers to treatment of the youth; and

"(ii) the development of model treatment programs for the youth;

"(C) include a pilot study of the outcomes of treatment for juvenile delinquents with mental health or substance abuse problems;

"(D) include a public education approach to combat the negative effects of the stigma of, and discrimination against individuals with, mental health and substance abuse problems; and

"(E) include a nationwide effort to develop, implement, and evaluate a mental health awareness program for schools, communities, and families;

"(3) although numerous symptoms, diagnoses, traits, characteristics, and psychosocial stressors of suicide have been investigated, no single factor or set of factors has ever come close to predicting suicide with accuracy;

"(4) research of United States youth, such as a 1994 study by Lewinsohn, Rohde, and Seeley, has shown predictors of suicide, such as a history of suicide attempts, current suicidal ideation and depression, a recent attempt or completed suicide by a friend, and low self-esteem; and

"(5) epidemiological data illustrate—

"(A) the trend of suicide at younger ages as well as increases in suicidal ideation among youth in the United States; and

"(B) distinct differences in approaches to suicide by gender, with—

"(i) 3 to 5 times as many females as males attempting suicide; and

"(ii) 3 to 5 times as many males as females completing suicide.

"(c) PURPOSE.—The purpose of this section is to provide for a study of predictors of suicide among at-risk

and other youth, and barriers that prevent the youth from receiving treatment, to facilitate the development of model treatment programs and public education and awareness efforts.

"(d) STUDY.—Not later than 1 year after the date of the enactment of this Act [Oct. 28, 2000], the Secretary of Health and Human Services shall carry out, directly or by grant or contract, a study that is designed to identify—

"(1) the characteristics of at-risk and other youth age 13 through 21 who are contemplating suicide;

"(2) the characteristics of at-risk and other youth who are younger than age 13 and are contemplating suicide; and

"(3) the barriers that prevent youth described in paragraphs (1) and (2) from receiving treatment.

"(e) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated to carry out this section such sums as may be necessary."

[For definition of "youth" as used in section 1602 of Pub. L. 106–386, set out above, see section 1002 of Pub. L. 106–386, set out as a note under section 10447 of Title 34, Crime Control and Law Enforcement.]

[1] *So in original. Probably should be followed by "and".*

§290bb–36b. Mental health and substance use disorder services for students in higher education

(a) In general

The Secretary, acting through the Director of the Center for Mental Health Services and in consultation with the Secretary of Education, may award grants on a competitive basis to institutions of higher education to enhance services for students with mental health or substance use disorders that can lead to school failure, such as depression, substance use disorders, and suicide attempts, prevent mental and substance use disorders, reduce stigma, and improve the identification and treatment for students at risk, so that students will successfully complete their studies.

(b) Use of funds

The Secretary may not make a grant to an institution of higher education under this section unless the institution agrees to use the grant only for one or more of the following:

(1) Educating students, families, faculty, and staff to increase awareness of mental health and substance use disorders and promote resiliency.

(2) The operation of hotlines.

(3) Preparing informational material.

(4) Providing outreach services to notify students about available mental health and substance use disorder resources and services.

(5) Administering voluntary mental health and substance use disorder screenings and assessments.

(6) Supporting the training of students, faculty, and staff to recognize and respond effectively and appropriately to students experiencing mental health and substance use disorders.

(7) Creating a network infrastructure to link institutions of higher education with health care providers who treat mental health and substance use disorders.

(8) Providing mental health and substance use.[1] disorders prevention and treatment services to students, which may include recovery support services and programming and early intervention, treatment, and management, including through the use of telehealth services.

(9) Conducting research through a counseling or health center at the institution of higher education involved to improve the behavioral health of students through clinical services, outreach, prevention, promotion of mental health, or academic success, in a manner that is in compliance with all applicable personal privacy laws.

(10) Supporting student groups on campus, including athletic teams, that engage in activities to educate students, including activities to reduce stigma surrounding mental and behavioral health disorders, and promote mental health.

(11) Employing appropriately trained staff.

(12) Developing and supporting evidence-based and emerging best practices, including a focus on culturally and linguistically appropriate best practices, and trauma-informed practices.

(c) Eligible grant recipients

Any institution of higher education receiving a grant under this section may carry out activities under the grant through—

(1) college counseling centers;

(2) college and university psychological service centers;

(3) mental health centers;

(4) psychology training clinics; or

(5) institution of higher education supported, evidence-based, mental health and substance use disorder programs.

(d) Application

To be eligible to receive a grant under this section, an institution of higher education shall prepare and submit an application to the Secretary at such time and in such manner as the Secretary may require. At a minimum, the application shall include the following:

(1) A description of the population to be targeted by the program carried out under the grant, including veterans whenever possible and appropriate, and of identified mental health and substance use disorder needs of students at the institution of higher education.

(2) A description of Federal, State, local, private, and institutional resources currently available to address the needs described in paragraph (1) at the institution of higher education, which may include, as appropriate and in accordance with subsection (b)(7), a plan to seek input from relevant stakeholders in the community, including appropriate public and private entities, in order to carry out the program under the grant.

(3) A description of the outreach strategies of the institution of higher education for promoting mental health and access to services, including a proposed plan for reaching those students most in need of mental health services.

(4) A plan to evaluate program outcomes, including a description of the proposed use of funds, the program objectives, and how the objectives will be met.

(5) An assurance that the institution will submit a report to the Secretary each fiscal year on the activities carried out with the grant and the results achieved through those activities.

(6) An outline of the objectives of the program carried out under the grant.

(7) For an institution of higher education proposing to use the grant for an activity described in paragraph (8) or (9) of subsection (b), a description of the policies and procedures of the institution of higher education that are related to applicable laws regarding access to, and sharing of, treatment records of students at any campus-based mental health center or partner organization, including the policies and State laws governing when such records can be accessed and shared for non-treatment purposes and a description of the process used by the institution of higher education to notify students of these policies and procedures, including the extent to which written consent is required.

(8) An assurance that grant funds will be used to supplement and not supplant any other Federal, State, or local funds available to carry out activities of the type carried out under the grant.

(e) Requirement of matching funds

(1) In general

The Secretary may make a grant under this section to an institution of higher education only if the institution agrees to make available (directly or through donations from public or private entities) non-Federal contributions in an amount that is not less than $1 for each $1 of Federal funds provided in the grant, toward the costs of activities carried out with the grant (as described in subsection (b)) and other activities by the institution to reduce student mental health and substance use disorders.

(2) Determination of amount contributed

Non-Federal contributions required under paragraph (1) may be in cash or in kind. Amounts provided by the Federal Government, or services assisted or subsidized to any significant extent by the Federal Government, may not be included in determining the amount of such non-Federal contributions.

(3) Waiver

The Secretary may waive the requirement established in paragraph (1) with respect to an institution of higher education if the Secretary determines that extraordinary need at the institution justifies the waiver.

(f) Reports

For each fiscal year that grants are awarded under this section, the Secretary shall conduct a study on the results of the grants and submit to the Committee on Energy and Commerce of the House of Representatives and the Committee on Health, Education, Labor, and Pensions of the Senate a report on such results that includes the following:

(1) An evaluation of the grant program outcomes, including a summary of activities carried out with the grant and the results achieved through those activities.

(2) Recommendations on how to improve access to mental health and substance use disorder services at institutions of higher education, including through prevention, early detection, early intervention, and efforts to reduce the incidence of suicide and substance use disorders.

(3) An assessment of the mental health and substance use disorder needs of the populations served by recipients of grants under this section.

(g) Definition

In this section, the term "institution of higher education" has the meaning given such term in section 1001 of title 20.

(h) Technical assistance

The Secretary may provide technical assistance to grantees in carrying out this section.

(i) Authorization of appropriations

For the purpose of carrying out this section, there are authorized to be appropriated $7,000,000 for each of fiscal years 2023 through 2027.

(July 1, 1944, ch. 373, title V, §520E–2, as added Pub. L. 108–355, §3(d), Oct. 21, 2004, 118 Stat. 1413; amended Pub. L. 114–255, div. B, title IX, §9031, Dec. 13, 2016, 130 Stat. 1257; Pub. L. 117–328, div. FF, title I, §1423, Dec. 29, 2022, 136 Stat. 5703.)

EDITORIAL NOTES

AMENDMENTS

2022—Pub. L. 117–328, §1423(1), substituted "for students in higher education" for "on campus" in section catchline.

Subsec. (b)(1). Pub. L. 117–328, §1423(2)(A), substituted "mental health and substance use disorders and promote resiliency" for "mental and substance use disorders".

Subsec. (b)(4). Pub. L. 117–328, §1423(2)(B), substituted "mental health and substance use disorder resources and services." for "mental and substance use disorder services."

Subsec. (b)(5). Pub. L. 117–328, §1423(2)(C), substituted "mental health and substance use" for "mental and substance use".

Subsec. (b)(6). Pub. L. 117–328, §1423(2)(D), substituted "staff to recognize and respond effectively and appropriately to students experiencing mental health and substance use disorders." for "staff to respond effectively to students with mental and substance use disorders."

Subsec. (b)(7). Pub. L. 117–328, §1423(2)(E), substituted "mental health and substance use" for "mental and substance use".

Subsec. (b)(8). Pub. L. 117–328, §1423(2)(F), substituted "mental health and substance use." for "mental and substance use".

Subsec. (b)(9). Pub. L. 117–328, §1423(2)(G), substituted "to improve the behavioral health of students

through clinical services, outreach, prevention, promotion of mental health, or" for "regarding improving the behavioral health of students through clinical services, outreach, prevention, or".

Subsec. (b)(10). Pub. L. 117–328, §1423(2)(H), substituted "mental and behavioral health disorders," for "mental and behavioral disorders,".

Subsec. (b)(12). Pub. L. 117–328, §1423(2)(I), substituted "best practices, and trauma-informed practices." for "best practices."

Subsec. (d)(1). Pub. L. 117–328, §1423(3)(A), substituted "mental health and substance use" for "mental and substance use".

Subsec. (d)(3). Pub. L. 117–328, §1423(3)(B), substituted "promoting mental health and access to services," for "promoting access to services,".

Subsec. (f). Pub. L. 117–328, §1423(4)(A), substituted "the Committee on Energy and Commerce of the House of Representatives and the Committee on Health, Education, Labor, and Pensions of the Senate" for "the Congress" in introductory provisions.

Subsec. (f)(2). Pub. L. 117–328, §1423(4)(B), substituted "including through prevention, early detection, early intervention, and efforts" for "including efforts".

Subsec. (f)(3). Pub. L. 117–328, §1423(4)(C), added par. (3).

Subsec. (i). Pub. L. 117–328, §1423(5), substituted "2023 through 2027" for "2018 through 2022".

2016—Pub. L. 114–255, §9031(1), substituted "health and substance use disorder" for "and behavioral health" in section catchline.

Subsec. (a). Pub. L. 114–255, §9031(2), substituted "Services and" for "Services,", "health or substance use disorders" for "and behavioral health problems", and "substance use disorders, and" for "substance abuse, and", and inserted "prevent mental and substance use disorders, reduce stigma, and improve the identification and treatment for students at risk," after "suicide attempts,".

Subsec. (b). Pub. L. 114–255, §9031(3), substituted "for one or more of the following:" for "for—" in introductory provisions, added pars. (1) to (12), and struck out former pars. (1) to (6) which read as follows:

"(1) educational seminars;

"(2) the operation of hot lines;

"(3) preparation of informational material;

"(4) preparation of educational materials for families of students to increase awareness of potential mental and behavioral health issues of students enrolled at the institution of higher education;

"(5) training programs for students and campus personnel to respond effectively to students with mental and behavioral health problems that can lead to school failure, such as depression, substance abuse, and suicide attempts; or

"(6) the creation of a networking infrastructure to link colleges and universities that do not have mental health services with health care providers who can treat mental and behavioral health problems."

Subsec. (c)(5). Pub. L. 114–255, §9031(4), substituted "substance use disorder" for "substance abuse".

Subsec. (d). Pub. L. 114–255, §9031(5)(A), in introductory provisions, substituted "To be eligible to receive a grant under this section, an institution of higher education" for "An institution of higher education desiring a grant under this section".

Subsec. (d)(1). Pub. L. 114–255, §9031(5)(B), added par. (1) and struck out former par. (1) which read as follows: "A description of identified mental and behavioral health needs of students at the institution of higher education."

Subsec. (d)(2). Pub. L. 114–255, §9031(5)(C), inserted ", which may include, as appropriate and in accordance with subsection (b)(7), a plan to seek input from relevant stakeholders in the community, including appropriate public and private entities, in order to carry out the program under the grant" before period at end.

Subsec. (d)(6) to (8). Pub. L. 114–255, §9031(5)(D), added pars. (6) to (8).

Subsec. (e)(1). Pub. L. 114–255, §9031(6), substituted "health and substance use disorders" for "and behavioral health problems".

Subsec. (f)(2). Pub. L. 114–255, §9031(7), substituted "health and substance use disorder" for "and behavioral health" and "suicide and substance use disorders" for "suicide and substance abuse".

Subsec. (h). Pub. L. 114–255, §9031(9), added subsec. (h). Former subsec. (h) redesignated (i).

Subsec. (i). Pub. L. 114–255, §9031(8), (10), redesignated subsec. (h) as (i) and substituted "$7,000,000 for each of fiscal years 2018 through 2022." for "$5,000,000 for fiscal year 2005, $5,000,000 for fiscal year 2006, and $5,000,000 for fiscal year 2007."

STATUTORY NOTES AND RELATED SUBSIDIARIES

INTERAGENCY WORKING GROUP ON COLLEGE MENTAL HEALTH

Pub. L. 114–255, div. B, title IX, §9032, Dec. 13, 2016, 130 Stat. 1259, provided that:

"(a) PURPOSE.—It is the purpose of this section to provide for the establishment of a College Campus Task Force to discuss mental and behavioral health concerns on campuses of institutions of higher education.

"(b) ESTABLISHMENT.—The Secretary of Health and Human Services (referred to in this section as the 'Secretary') shall establish a College Campus Task Force (referred to in this section as the 'Task Force') to discuss mental and behavioral health concerns on campuses of institutions of higher education.

"(c) MEMBERSHIP.—The Task Force shall be composed of a representative from each Federal agency (as appointed by the head of the agency) that has jurisdiction over, or is affected by, mental health and education policies and projects, including—

"(1) the Department of Education;

"(2) the Department of Health and Human Services;

"(3) the Department of Veterans Affairs; and

"(4) such other Federal agencies as the Assistant Secretary for Mental Health and Substance Use, in consultation with the Secretary, determines to be appropriate.

"(d) DUTIES.—The Task Force shall—

"(1) serve as a centralized mechanism to coordinate a national effort to—

"(A) discuss and evaluate evidence and knowledge on mental and behavioral health services available to, and the prevalence of mental illness among, the age population of students attending institutions of higher education in the United States;

"(B) determine the range of effective, feasible, and comprehensive actions to improve mental and behavioral health on campuses of institutions of higher education;

"(C) examine and better address the needs of the age population of students attending institutions of higher education dealing with mental illness;

"(D) survey Federal agencies to determine which policies are effective in encouraging, and how best to facilitate outreach without duplicating, efforts relating to mental and behavioral health promotion;

"(E) establish specific goals within and across Federal agencies for mental health promotion, including determinations of accountability for reaching those goals;

"(F) develop a strategy for allocating responsibilities and ensuring participation in mental and behavioral health promotion, particularly in the case of competing agency priorities;

"(G) coordinate plans to communicate research results relating to mental and behavioral health amongst the age population of students attending institutions of higher education to enable reporting and outreach activities to produce more useful and timely information;

"(H) provide a description of evidence-based practices, model programs, effective guidelines, and other strategies for promoting mental and behavioral health on campuses of institutions of higher education;

"(I) make recommendations to improve Federal efforts relating to mental and behavioral health promotion on campuses of institutions of higher education and to ensure Federal efforts are consistent with available standards, evidence, and other programs in existence as of the date of enactment of this Act [Dec. 13, 2016];

"(J) monitor Federal progress in meeting specific mental and behavioral health promotion goals as they relate to settings of institutions of higher education; and

"(K) examine and disseminate best practices related to intracampus sharing of treatment records;

"(2) consult with national organizations with expertise in mental and behavioral health, especially those organizations working with the age population of students attending institutions of higher education; and

"(3) consult with and seek input from mental health professionals working on campuses of institutions of higher education as appropriate.

"(e) MEETINGS.—

"(1) IN GENERAL.—The Task Force shall meet not fewer than three times each year.

"(2) ANNUAL CONFERENCE.—The Secretary shall sponsor an annual conference on mental and behavioral health in settings of institutions of higher education to enhance coordination, build partnerships, and share best practices in mental and behavioral health promotion, data collection, analysis, and services.

"(f) DEFINITION.—In this section, the term 'institution of higher education' has the meaning given such term in section 101 of the Higher Education Act of 1965 (20 U.S.C. 1001).

"(g) AUTHORIZATION OF APPROPRIATIONS.—To carry out this section, there are authorized to be appropriated $1,000,000 for the period of fiscal years 2018 through 2022."

[1] *So in original.*

§290bb–36c. National Suicide Prevention Lifeline program

(a) In general

The Secretary, acting through the Assistant Secretary, shall maintain the National Suicide Prevention Lifeline program (referred to in this section as the "program"), authorized under section 290bb–32 of this title and in effect prior to December 13, 2016.

(b) Activities

In maintaining the program, the activities of the Secretary shall include—

(1) supporting and coordinating a network of crisis centers across the United States for providing suicide prevention and mental health crisis intervention services, including appropriate follow-up services, to individuals seeking help at any time, day or night;

(2) maintaining a suicide prevention hotline to link callers to local emergency, mental health, and social services resources;

(3) consulting with the Secretary of Veterans Affairs to ensure that veterans calling the suicide prevention hotline have access to a specialized veterans' suicide prevention hotline;

(4) improving awareness of the program for suicide prevention and mental health crisis intervention services, including by conducting an awareness initiative and ongoing outreach to the public;

(5) improving the collection and analysis of demographic information, in a manner that protects personal privacy, consistent with applicable Federal and State privacy laws, in order to understand disparities in access to the program among individuals who are seeking help; and

(6) taking such steps as may be necessary to ensure the suicide prevention hotline is protected from cybersecurity incidents and eliminates known cybersecurity vulnerabilities.

(c) Plan

(1) In general

For purposes of supporting the crisis centers under subsection (b)(1) and maintaining the suicide prevention hotline under subsection (b)(2), the Secretary shall develop and implement a plan to ensure the provision of high-quality services.

(2) Contents

The plan required by paragraph (1) shall include the following:

(A) Program evaluation, including performance measures to assess progress toward the goals and objectives of the program and to improve the responsiveness and performance of the hotline, including at all backup call centers.

(B) Requirements that crisis centers and backup centers must meet—

(i) to participate in the network under subsection (b)(1); and

(ii) to ensure that each telephone call and applicable other communication received by the hotline, including at backup call centers, is answered in a timely manner, consistent with evidence-based guidance or other guidance or best practices, as appropriate.

(C) Specific recommendations and strategies for implementing evidence-based practices, including with respect to followup and communicating the availability of resources in the community for individuals in need.

(D) Criteria for carrying out periodic testing of the hotline during each fiscal year, including at crisis centers and backup centers, to identify and address any problems in a timely manner.

(3) Consultation

In developing requirements under paragraph (2)(B), the Secretary shall consult with State departments of health, local governments, Indian Tribes, and Tribal organizations.

(4) Initial plan; updates

The Secretary shall—

(A) not later than 1 year after December 29, 2022, complete development of the initial plan under paragraph (1) and make such plan publicly available; and

(B) periodically thereafter, update such plan and make the updated plan publicly available.

(d) Improving epidemiological data

The Secretary shall, as appropriate, formalize and strengthen agreements between the Suicide Prevention Lifeline program and the Centers for Disease Control and Prevention with respect to the secure sharing of de-identified epidemiological data. Such agreements shall include appropriate privacy and security protections that meet the requirements of applicable Federal law, at a minimum.

(e) Data to assist State and local suicide prevention activities

The Secretary shall ensure that the aggregated information collected and any applicable analyses conducted under subsection (b)(5), including from local call centers, as applicable, are made available in a usable format to State and local agencies in order to inform suicide prevention activities.

(f) Cybersecurity reporting

(1) Notification

(A) In general

The program's network administrator receiving Federal funding pursuant to subsection (a) shall report to the Assistant Secretary, in a manner that protects personal privacy, consistent with applicable Federal and State privacy laws—

(i) any identified cybersecurity vulnerabilities to the program within a reasonable amount of time after identification of such a vulnerability; and

(ii) any identified cybersecurity incidents to the program within a reasonable amount of time after identification of such incident.

(B) Local and regional crisis centers

Local and regional crisis centers participating in the program shall report to the program's network administrator identified under subparagraph (A), in a manner that protects personal privacy, consistent with applicable Federal and State privacy laws—

(i) any identified cybersecurity vulnerabilities to the program within a reasonable amount of time after identification of such vulnerability; and

(ii) any identified cybersecurity incidents to the program within a reasonable amount of time after identification of such incident.

(2) Notification

If the program's network administrator receiving funding pursuant to subsection (a) discovers, or is informed by a local or regional crisis center pursuant to paragraph (1)(B) of, a cybersecurity vulnerability or incident, within a reasonable amount of time after such discovery or receipt of information, such entity shall report the vulnerability or incident to the Assistant Secretary.

(3) Clarification

(A) Oversight

(i) Local and regional crisis centers

Except as provided in clause (ii), local and regional crisis centers participating in the program shall oversee all technology each center employs in the provision of services as a participant in the program.

(ii) Network administrator

The program's network administrator receiving Federal funding pursuant to subsection (a) shall oversee the technology each crisis center employs in the provision of services as a

participant in the program if such oversight responsibilities are established in the applicable network participation agreement.

(B) Supplement, not supplant

The cybersecurity incident reporting requirements under this subsection shall supplement, and not supplant, cybersecurity incident reporting requirements under other provisions of applicable Federal law that are in effect on December 1, 2025.

(g) Authorization of appropriations

To carry out this section, there are authorized to be appropriated $101,621,000 for each of fiscal years 2023 through 2027.

(July 1, 1944, ch. 373, title V, §520E–3, as added Pub. L. 114–255, div. B, title IX, §9005, Dec. 13, 2016, 130 Stat. 1239; amended Pub. L. 117–328, div. FF, title I, §1103(a), Dec. 29, 2022, 136 Stat. 5637; Pub. L. 119–44, title I, §108(a), (b), Dec. 1, 2025, 139 Stat. 675, 676.)

EDITORIAL NOTES

AMENDMENTS

2025—Subsec. (b)(6). Pub. L. 119–44, §108(a), added par. (6).

Subsecs. (f), (g). Pub. L. 119–44, §108(b), added subsec. (f) and redesignated former subsec. (f) as (g).

2022—Subsec. (b)(1). Pub. L. 117–328, §1103(a)(1)(A), inserted "supporting and" before "coordinating" and substituted "mental health crisis intervention services, including appropriate follow-up services," for "crisis intervention services".

Subsec. (b)(4), (5). Pub. L. 117–328, §1103(a)(1)(B)–(D), added pars. (4) and (5).

Subsec. (c). Pub. L. 117–328, §1103(a)(2)(B), added subsec. (c). Former subsec. (c) redesignated (f).

Subsecs. (d), (e). Pub. L. 117–328, §1103(a)(3), added subsecs. (d) and (e).

Subsec. (f). Pub. L. 117–328, §1103(a)(4), amended subsec. (f) generally. Prior to amendment, text read as follows: "To carry out this section, there are authorized to be appropriated $7,198,000 for each of fiscal years 2018 through 2022."

Pub. L. 117–328, §1103(a)(2)(A), redesignated subsec. (c) as (f).

STATUTORY NOTES AND RELATED SUBSIDIARIES

PILOT PROGRAM ON INNOVATIVE TECHNOLOGIES

Pub. L. 117–328, div. FF, title I, §1103(b), (e), Dec. 29, 2022, 136 Stat. 5639, 5640, provided that:

"(b) Pilot Program on Innovative Technologies.—

"(1) IN GENERAL.—The Secretary of Health and Human Services, acting through the Assistant Secretary for Mental Health and Substance Use, shall, as appropriate, carry out a pilot program to research, analyze, and employ various technologies and platforms of communication (including social media platforms, texting platforms, and email platforms) for suicide prevention in addition to the telephone and online chat service provided by the Suicide Prevention Lifeline.

"(2) REPORT.—Not later than 24 months after the date on which the pilot program under paragraph (1) commences, the Secretary of Health and Human Services, acting through the Assistant Secretary for Mental Health and Substance Use, shall submit to the Congress a report on the pilot program. With respect to each platform of communication employed pursuant to the pilot program, the report shall include—

"(A) a full description of the program;

"(B) the number of individuals served by the program;

"(C) the average wait time for each individual to receive a response;

"(D) the cost of the program, including the cost per individual served; and

"(E) any other information the Secretary determines appropriate.

"(e) DEFINITION.—In this section, the term 'Suicide Prevention Lifeline' means the suicide prevention hotline maintained pursuant to section 520E–3 of the Public Health Service Act (42 U.S.C. 290bb–36c)."

§290bb–36d. Treatment Referral Routing Service

(a) In general

The Secretary, acting through the Assistant Secretary, shall maintain the National Treatment Referral Routing Service (referred to in this section as the "Routing Service") to assist individuals and families in locating mental and substance use disorders treatment providers.

(b) Activities of the Secretary

To maintain the Routing Service, the activities of the Assistant Secretary shall include administering—

(1) a nationwide, telephone number providing year-round access to information that is updated on a regular basis regarding local behavioral health providers and community-based organizations in a manner that is confidential, without requiring individuals to identify themselves, is in languages that include at least English and Spanish, and is at no cost to the individual using the Routing Service; and

(2) an Internet website to provide a searchable, online treatment services locator of behavioral health treatment providers and community-based organizations, which shall include information on the name, location, contact information, and basic services provided by such providers and organizations.

(c) Removing practitioner contact information

In the event that the Internet website described in subsection (b)(2) contains information on any practitioner who prescribes narcotic drugs in schedule III, IV, or V of section 812 of title 21 for the purpose of maintenance or detoxification treatment, the Assistant Secretary—

(1) shall provide an opportunity to such practitioner to have the contact information of the practitioner removed from the website at the request of the practitioner; and

(2) may evaluate other methods to periodically update the information displayed on such website.

(d) Rule of construction

Nothing in this section shall be construed to prevent the Assistant Secretary from using any unobligated amounts otherwise made available to the Administration to maintain the Routing Service.

(July 1, 1944, ch. 373, title V, §520E–4, as added Pub. L. 114–255, div. B, title IX, §9006, Dec. 13, 2016, 130 Stat. 1239; amended Pub. L. 117–215, title I, §103(b)(3)(A), Dec. 2, 2022, 136 Stat. 2263; Pub. L. 117–328, div. FF, title I, §1262(b)(3), Dec. 29, 2022, 136 Stat. 5682; Pub. L. 119–26, §4(2)(B)(iv), July 16, 2025, 139 Stat. 417.)

EDITORIAL NOTES

AMENDMENTS

2025—Subsec. (c). Pub. L. 119–26, §4(2)(B)(iv), amended Pub. L. 117–328, §1262(b)(3). See 2022 Amendment note below.

2022—Subsec. (c). Pub. L. 117–328, §1262(b)(3), as amended by Pub. L. 119–26, §4(2)(B)(iv), substituted "information on any practitioner who prescribes narcotic drugs in schedule III, IV, or V of section 812 of title 21 for the purpose of maintenance or detoxification treatment" for "information on any qualified practitioner that is certified to prescribe medication for opioid dependency under section 823(h)(2)(B) of title 21" in introductory provisions.

Pub. L. 117–215 substituted "823(h)(2)(B)" for "823(g)(2)(B)" in introductory provisions.

STATUTORY NOTES AND RELATED SUBSIDIARIES

EFFECTIVE DATE OF 2025 AMENDMENT

Pub. L. 119–26, §4, July 16, 2025, 139 Stat. 416, provided that the amendment made by section 4(2)(B)(iv) is effective as if included in the enactment of Pub. L. 117–328.

§290bb–37. Mental health crisis response partnership pilot program

(a) In general

The Secretary shall establish a pilot program under which the Secretary will award competitive grants to States, localities, territories, Indian Tribes, and Tribal organizations to establish new, or enhance existing, mobile crisis response teams that divert the response for mental health and substance use disorder crises from law enforcement to mobile crisis teams, as described in subsection (b).

(b) Mobile crisis teams described

A mobile crisis team, for purposes of this section, is a team of individuals—

(1) that is available to respond to individuals in mental health and substance use disorder crises and provide immediate stabilization, referrals to community-based mental health and substance use disorder services and supports, and triage to a higher level of care if medically necessary;

(2) which may include licensed counselors, clinical social workers, physicians, paramedics, crisis workers, peer support specialists, or other qualified individuals; and

(3) which may provide support to divert mental health and substance use disorder crisis calls from the 9–1–1 system to the 9–8–8 system.

(c) Priority

In awarding grants under this section, the Secretary shall prioritize applications which account for the specific needs of the communities to be served, including children and families, veterans, rural and underserved populations, and other groups at increased risk of death from suicide or overdose.

(d) Report

(1) Initial report

Not later than September 30, 2024, the Secretary shall submit to Congress a report on steps taken by States, localities, territories, Indian Tribes, and Tribal organizations prior to December 29, 2022, to strengthen the partnerships among mental health providers, substance use disorder treatment providers, primary care physicians, mental health and substance use disorder crisis teams, paramedics, law enforcement officers, and other first responders.

(2) Progress reports

Not later than one year after the date on which the first grant is awarded to carry out this section, and for each year thereafter, the Secretary shall submit to Congress a report on the grants made during the year covered by the report, which shall include—

(A) impact data on the teams and people served by such programs, including demographic information of individuals served, volume, and types of service utilization;

(B) outcomes of the number of linkages made to community-based resources or short-term crisis receiving and stabilization facilities, as applicable, and diversion from law enforcement or hospital emergency department settings;

(C) data consistent with the State block grant requirements for continuous evaluation and quality improvement, and other relevant data as determined by the Secretary;

(D) identification and, where appropriate, recommendations of best practices from States and localities providing mobile crisis response and stabilization services for youth and adults; and

(E) identification of any opportunities for improvements to the program established under this section.

(e) Authorization of appropriations

There are authorized to be appropriated to carry out this section, $10,000,000 for each of fiscal years 2023 through 2027.

(July 1, 1944, ch. 373, title V, §520F, as added Pub. L. 106–310, div. B, title XXXII, §3209, Oct. 17, 2000, 114 Stat. 1200; amended Pub. L. 114–255, div. B, title IX, §9007, Dec. 13, 2016, 130 Stat. 1240; Pub. L. 117–328, div. FF, title I, §1122(a), Dec. 29, 2022, 136 Stat. 5650.)

EDITORIAL NOTES

AMENDMENTS

2022—Pub. L. 117–328 amended section generally. Prior to amendment, section provided for competitive grants to enhance community-based crisis response systems or to develop, maintain, or enhance a database of beds at mental health and substance use disorder treatment facilities.

2016—Pub. L. 114–255 amended section generally. Prior to amendment, section provided for grants to support the designation of hospitals and health centers as Emergency Mental Health Centers.

§290bb–38. Grants for jail diversion programs

(a) Program authorized

The Secretary shall make grants to States, political subdivisions of States, and Indian Tribes and Tribal organizations (as the terms "Indian tribes" and "tribal organizations" are defined in section 4 of the Indian Self-Determination and Education Assistance Act [25 U.S.C. 5304]), acting directly or through agreements with other public or nonprofit entities, or a health facility or program operated by or in accordance with a contract or grant with the Indian Health Service, to develop and implement programs to divert individuals with a mental illness from the criminal justice system to community-based services.

(b) Administration

(1) Consultation

The Secretary shall consult with the Attorney General and any other appropriate officials in carrying out this section.

(2) Regulatory authority

The Secretary shall issue regulations and guidelines necessary to carry out this section, including methodologies and outcome measures for evaluating programs carried out by States, political subdivisions of States, Indian Tribes, and Tribal organizations receiving grants under subsection (a).

(c) Applications

(1) In general

To receive a grant under subsection (a), the chief executive of a State, chief executive of a subdivision of a State, an Indian Tribe or Tribal organization, a health facility or program described in subsection (a), or a public or nonprofit entity referred to in subsection (a) shall prepare and submit an application to the Secretary at such time, in such manner, and containing such information as the Secretary shall reasonably require.

(2) Content

Such application shall—

(A) contain an assurance that—

(i) community-based mental health services will be available for the individuals who are diverted from the criminal justice system, and that such services are based on evidence-based practices, reflect current research findings, include case management, assertive community treatment, medication management and access, integrated mental health and co-occurring substance use disorder treatment, peer recovery support services, and psychiatric rehabilitation, and will be coordinated with social services, including life skills training, housing placement, vocational training, education job placement, and health care;

(ii) there has been relevant interagency collaboration between the appropriate criminal justice, mental health, and substance use disorder systems; and

(iii) the Federal support provided will be used to supplement, and not supplant, State, local, Indian Tribe, or Tribal organization sources of funding that would otherwise be available;

(B) demonstrate that the diversion program will be integrated with an existing system of care for those with mental illness;

(C) explain the applicant's inability to fund the program adequately without Federal assistance;

(D) specify plans for obtaining necessary support and continuing the proposed program following the conclusion of Federal support; and

(E) describe methodology and outcome measures that will be used in evaluating the program.

(d) Special consideration regarding veterans

In awarding grants under subsection (a), the Secretary shall, as appropriate, give special consideration to entities proposing to use grant funding to support jail diversion services for veterans.

(e) Use of funds

A State, political subdivision of a State, Indian Tribe, or Tribal organization that receives a grant under subsection (a) may use funds received under such grant to—

(1) integrate the diversion program into the existing system of care;

(2) create or expand community-based mental health and co-occurring mental illness and substance use disorder services to accommodate the diversion program;

(3) train professionals and paraprofessionals involved in the system of care, and law enforcement officers, attorneys, and judges;

(4) provide community outreach and crisis intervention; and

(5) develop programs to divert individuals prior to booking, arrest, or release.

(f) Federal share

(1) In general

The Secretary shall pay to a State, political subdivision of a State, Indian Tribe, or Tribal organization receiving a grant under subsection (a) the Federal share of the cost of activities described in the application.

(2) Federal share

The Federal share of a grant made under this section shall not exceed 75 percent of the total cost of the program carried out by the State, political subdivision of a State, Indian Tribe, or Tribal organization. Such share shall be used for new expenses of the program carried out by such State, political subdivision of a State, Indian Tribe, or Tribal organization.

(3) Non-Federal share

The non-Federal share of payments made under this section may be made in cash or in kind fairly evaluated, including planned equipment or services. The Secretary may waive the requirement of matching contributions.

(g) Geographic distribution

The Secretary shall ensure that such grants awarded under subsection (a) are equitably distributed among the geographical regions of the United States and between urban and rural populations.

(h) Training and technical assistance

Training and technical assistance may be provided by the Secretary to assist a State, political subdivision of a State, Indian Tribe, or Tribal organization receiving a grant under subsection (a) in establishing and operating a diversion program.

(i) Evaluations

The programs described in subsection (a) shall be evaluated not less than one time in every 12-month period using the methodology and outcome measures identified in the grant application.

(j) Authorization of appropriations

There are authorized to be appropriated to carry out this section $14,000,000 for each of fiscal years 2023 through 2027.

(July 1, 1944, ch. 373, title V, §520G, as added Pub. L. 106–310, div. B, title XXXII, §3210, Oct. 17, 2000, 114 Stat. 1201; amended Pub. L. 114–255, div. B, title IX, §9002, Dec. 13, 2016, 130 Stat. 1234; Pub. L. 117–328, div. FF, title I, §1216, Dec. 29, 2022, 136 Stat. 5669.)

EDITORIAL NOTES

AMENDMENTS

2022—Subsec. (a). Pub. L. 117–328, §1216(1), struck out "up to 125" before "grants" and substituted "Tribes and Tribal organizations" for "tribes and tribal organizations".

Subsec. (b)(2). Pub. L. 117–328, §1216(2), substituted "Tribes, and Tribal organizations" for "tribes, and tribal organizations".

Subsec. (c)(1). Pub. L. 117–328, §1216(3)(A), substituted "an Indian Tribe or Tribal organization, a health facility or program described in subsection (a), or a public or nonprofit entity referred to in subsection (a)" for "Indian tribe or tribal organization".

Subsec. (c)(2)(A)(i). Pub. L. 117–328, §1216(3)(B)(i), inserted "peer recovery support services," after "disorder treatment,".

Subsec. (c)(2)(A)(iii). Pub. L. 117–328, §1216(3)(B)(ii), substituted "Tribe, or Tribal organization" for "tribe, or tribal organization".

Subsec. (e). Pub. L. 117–328, §1216(4)(A), substituted "Tribe, or Tribal organization" for "tribe, or tribal organization" in introductory provisions.

Subsec. (e)(3). Pub. L. 117–328, §1216(4)(B), inserted "and paraprofessionals" after "professionals".

Subsec. (e)(5). Pub. L. 117–328, §1216(4)(C), substituted ", arrest, or release" for "or arrest".

Subsec. (f). Pub. L. 117–328, §1216(5), substituted "Tribe, or Tribal organization" for "tribe, or tribal organization" wherever appearing.

Subsec. (h). Pub. L. 117–328, §1216(6), substituted "Tribe, or Tribal organization" for "tribe, or tribal organization".

Subsec. (j). Pub. L. 117–328, §1216(7), substituted "$14,000,000 for each of fiscal years 2023 through 2027" for "$4,269,000 for each of fiscal years 2018 through 2022".

2016—Subsec. (a). Pub. L. 114–255, §9002(2), substituted "and Indian tribes and tribal organizations (as the terms 'Indian tribes' and 'tribal organizations' are defined in section 4 of the Indian Self-Determination and Education Assistance Act)" for "Indian tribes, and tribal organizations" and inserted "or a health facility or program operated by or in accordance with a contract or grant with the Indian Health Service," after "entities,".

Subsec. (c)(2)(A)(i). Pub. L. 114–255, §9002(1), (3), substituted "evidence-based" for "the best known" and "substance use disorder" for "substance abuse".

Subsec. (c)(2)(A)(ii). Pub. L. 114–255, §9002(1), substituted "substance use disorder" for "substance abuse".

Subsec. (d). Pub. L. 114–255, §9002(5), added subsec. (d). Former subsec. (d) redesignated (e).

Subsec. (e). Pub. L. 114–255, §9002(4), redesignated subsec. (d) as (e). Former subsec. (e) redesignated (f).

Subsec. (e)(2). Pub. L. 114–255, §9002(1), substituted "substance use disorder" for "substance abuse".

Subsec. (e)(5). Pub. L. 114–255, §9002(6), added par. (5).

Subsecs. (f) to (i). Pub. L. 114–255, §9002(4), redesignated subsecs. (e) to (h) as (f) to (i), respectively. Former subsec. (i) redesignated (j).

Subsec. (j). Pub. L. 114–255, §9002(4), (7), redesignated subsec. (i) as (j) and substituted "$4,269,000 for each of fiscal years 2018 through 2022" for "$10,000,000 for fiscal year 2001, and such sums as may be necessary for fiscal years 2002 through 2003".

§290bb–39. Peer-supported mental health services

(a) Grants authorized

The Secretary, acting through the Assistant Secretary for Mental Health and Substance Use, shall award grants to eligible entities to enable such entities to develop, expand, and enhance access to mental health peer-delivered services.

(b) Use of funds

Grants awarded under subsection (a) shall be used to develop, expand, and enhance national,

statewide, or community-focused programs, including virtual peer-support services and technology-related capabilities, including by—

(1) carrying out workforce development, recruitment, and retention activities, to train, recruit, and retain peer-support providers;

(2) building connections between mental health treatment programs, including between community organizations and peer-support networks, including virtual peer-support networks, and with other mental health support services;

(3) reducing stigma associated with mental health disorders;

(4) expanding and improving virtual peer mental health support services, including through the adoption of technologies and capabilities to expand access to virtual peer mental health support services, such as by acquiring equipment and software necessary to efficiently run virtual peer-support services; and

(5) conducting research on issues relating to mental illness and the impact peer-support has on resiliency, including identifying—

(A) the signs of mental illness;

(B) the resources available to individuals with mental illness and to their families; and

(C) the resources available to help support individuals living with mental illness.

(c) Special consideration

In carrying out this section, the Secretary shall give special consideration to the unique needs of rural areas.

(d) Definition

In this section, the term "eligible entity" means—

(1) a consumer-run nonprofit organization that—

(A) is principally governed by people living with a mental health condition; and

(B) mobilizes resources within and outside of the mental health community, which may include through peer-support networks, to increase the prevalence and quality of long-term wellness of individuals living with a mental health condition, including those with a co-occurring substance use disorder; or

(2) an Indian Tribe, Tribal organization, Urban Indian organization, or consortium of Tribes or Tribal organizations.

(e) Authorization of appropriations

There is authorized to be appropriated to carry out this section $13,000,000 for each of fiscal years 2023 through 2027.

(July 1, 1944, ch. 373, title V, §520H, as added Pub. L. 117–328, div. FF, title I, §1151, Dec. 29, 2022, 136 Stat. 5658.)

EDITORIAL NOTES

PRIOR PROVISIONS

A prior section 290bb–39, act July 1, 1944, ch. 373, title V, §520H, as added Pub. L. 106–310, div. B, title XXXII, §3211, Oct. 17, 2000, 114 Stat. 1203, related to improving outcomes for children and adolescents through services integration between child welfare and mental health services, prior to repeal by Pub. L. 114–255, div. B, title IX, §9017, Dec. 13, 2016, 130 Stat. 1248.

§290bb–39a. Best practices for behavioral and mental health intervention teams

(a) In general

The Secretary, acting through the Assistant Secretary for Mental Health and Substance Use, and in consultation with the Secretary of Education, shall submit to the Health Education, Labor, and

Pensions Committee of the Senate and the Energy and Commerce Committee of the House of Representatives a report that identifies best practices related to using behavioral and mental health intervention teams, which may be used to assist elementary schools, secondary schools, and institutions of higher education interested in voluntarily establishing and using such teams to support students exhibiting behaviors interfering with learning at school or who are at risk of harm to self or others.

(b) Elements

The report under subsection (a) shall assess evidence supporting such best practices and, as appropriate, include consideration of the following:

(1) How behavioral and mental health intervention teams might operate effectively from an evidence-based, objective perspective while protecting the constitutional and civil rights and privacy of individuals.

(2) The use of behavioral and mental health intervention teams—

(A) to identify and support students exhibiting behaviors interfering with learning or posing a risk of harm to self or others; and

(B) to implement evidence-based interventions to meet the behavioral and mental health needs of such students.

(3) How behavioral and mental health intervention teams can—

(A) access evidence-based professional development to support students described in paragraph (2)(A); and

(B) ensure that such teams—

(i) are composed of trained, diverse stakeholders with expertise in child and youth development, behavioral and mental health, and disability; and

(ii) use cross validation by a wide-range of individual perspectives on the team.

(4) How behavioral and mental health intervention teams can help mitigate inappropriate referral to mental health services or law enforcement by implementing evidence-based interventions that meet student needs.

(c) Consultation

In carrying out subsection (a), the Secretary shall consult with—

(1) the Secretary of Education;

(2) the Director of the National Threat Assessment Center of the United States Secret Service;

(3) the Attorney General;

(4) teachers (which shall include special education teachers), principals and other school leaders, school board members, behavioral and mental health professionals (including school-based mental health professionals), and parents of students;

(5) local law enforcement agencies and campus law enforcement administrators;

(6) privacy, disability, and civil rights experts; and

(7) other education and mental health professionals as the Secretary deems appropriate.

(d) Publication

The Secretary shall publish the report under subsection (a) in an accessible format on the internet website of the Department of Health and Human Services.

(e) Definitions

In this section:

(1) The term "behavioral and mental health intervention team" means a multidisciplinary team of trained individuals who—

(A) are trained to identify and assess the behavioral health needs of children and youth and who are responsible for identifying, supporting, and connecting students exhibiting behaviors interfering with learning at school, or who are at risk of harm to self or others, with appropriate behavioral health services; and

(B) develop and facilitate implementation of evidence-based interventions to—

(i) mitigate the threat of harm to self or others posed by a student described in subparagraph (A);

(ii) meet the mental and behavioral health needs of such students; and

(iii) support positive, safe, and supportive learning environments.

(2) The terms "elementary school", "parent", and "secondary school" have the meanings given to such terms in section 7801 of title 20.

(3) The term "institution of higher education" has the meaning given to such term in section 1002 of title 20.

(July 1, 1944, ch. 373, title V, §520H–1, as added Pub. L. 117–328, div. FF, title I, §1404, Dec. 29, 2022, 136 Stat. 5700.)

§290bb–40. Grants for the integrated treatment of serious mental illness and co-occurring substance abuse

(a) In general

The Secretary shall award grants, contracts, or cooperative agreements to States, political subdivisions of States, Indian tribes, tribal organizations, and private nonprofit organizations for the development or expansion of programs to provide integrated treatment services for individuals with a serious mental illness and a co-occurring substance abuse disorder.

(b) Priority

In awarding grants, contracts, and cooperative agreements under subsection (a), the Secretary shall give priority to applicants that emphasize the provision of services for individuals with a serious mental illness and a co-occurring substance abuse disorder who—

(1) have a history of interactions with law enforcement or the criminal justice system;

(2) have recently been released from incarceration;

(3) have a history of unsuccessful treatment in either an inpatient or outpatient setting;

(4) have never followed through with outpatient services despite repeated referrals; or

(5) are homeless.

(c) Use of funds

A State, political subdivision of a State, Indian tribe, tribal organization, or private nonprofit organization that receives a grant, contract, or cooperative agreement under subsection (a) shall use funds received under such grant—

(1) to provide fully integrated services rather than serial or parallel services;

(2) to employ staff that are cross-trained in the diagnosis and treatment of both serious mental illness and substance abuse;

(3) to provide integrated mental health and substance abuse services at the same location;

(4) to provide services that are linguistically appropriate and culturally competent;

(5) to provide at least 10 programs for integrated treatment of both mental illness and substance abuse at sites that previously provided only mental health services or only substance abuse services; and

(6) to provide services in coordination with other existing public and private community programs.

(d) Condition

The Secretary shall ensure that a State, political subdivision of a State, Indian tribe, tribal organization, or private nonprofit organization that receives a grant, contract, or cooperative agreement under subsection (a) maintains the level of effort necessary to sustain existing mental health and substance abuse programs for other populations served by mental health systems in the community.

(e) Distribution of awards

The Secretary shall ensure that grants, contracts, or cooperative agreements awarded under subsection (a) are equitably distributed among the geographical regions of the United States and between urban and rural populations.

(f) Duration

The Secretary shall award grants, contract, or cooperative agreements under this subsection for a period of not more than 5 years.

(g) Application

A State, political subdivision of a State, Indian tribe, tribal organization, or private nonprofit organization that desires a grant, contract, or cooperative agreement under this subsection shall prepare and submit an application to the Secretary at such time, in such manner, and containing such information as the Secretary may require. Such application shall include a plan for the rigorous evaluation of activities funded with an award under such subsection, including a process and outcomes evaluation.

(h) Evaluation

A State, political subdivision of a State, Indian tribe, tribal organization, or private nonprofit organization that receives a grant, contract, or cooperative agreement under this subsection shall prepare and submit a plan for the rigorous evaluation of the program funded under such grant, contract, or agreement, including both process and outcomes evaluation, and the submission of an evaluation at the end of the project period.

(i) Authorization of appropriation

There is authorized to be appropriated to carry out this subsection $40,000,000 for fiscal year 2001, and such sums as may be necessary for fiscal years 2002 through 2003.

(July 1, 1944, ch. 373, title V, §520I, as added Pub. L. 106–310, div. B, title XXXII, §3212, Oct. 17, 2000, 114 Stat. 1205.)

§290bb–41. Mental health awareness training grants

(a) In general

The Secretary shall award grants in accordance with the provisions of this section.

(b) Mental health awareness training grants

(1) In general

The Secretary shall award grants to States, political subdivisions of States, Indian Tribes, Tribal organizations, and nonprofit private entities to train teachers and other relevant school personnel to recognize symptoms of childhood and adolescent mental disorders, to refer family members to the appropriate mental health services if necessary, to train emergency services personnel [1] veterans, law enforcement, and other categories of individuals, as determined by the Secretary, to identify and appropriately respond to persons with a mental illness, and to provide education to such teachers and personnel regarding resources that are available in the community for individuals with a mental illness.

(2) Emergency services personnel

In this subsection, the term "emergency services personnel" includes paramedics, firefighters, and emergency medical technicians.

(3) Distribution of awards

The Secretary shall ensure that such grants awarded under this subsection are equitably distributed among the geographical regions of the United States and between urban and rural populations.

(4) Application

A State, political subdivision of a State, Indian Tribe, Tribal organization, or nonprofit private entity that desires a grant under this subsection shall submit an application to the Secretary at such time, in such manner, and containing such information as the Secretary may require, including a plan for the rigorous evaluation of activities that are carried out with funds received under a grant under this subsection.

(5) Use of funds

A State, political subdivision of a State, Indian Tribe, Tribal organization, or nonprofit private entity receiving a grant under this subsection shall use funds from such grant for evidence-based programs that provide training and education in accordance with paragraph (1) on matters including—

(A) recognizing the signs and symptoms of mental illness;

(B)(i) resources available in the community for individuals with a mental illness and other relevant resources; or

(ii) safely de-escalating crisis situations involving individuals with a mental illness; and

(C) suicide intervention and prevention.

(6) Evaluation

A State, political subdivision of a State, Indian Tribe, Tribal organization, or nonprofit private entity that receives a grant under this subsection shall prepare and submit an evaluation to the Secretary at such time, in such manner, and containing such information as the Secretary may reasonably require, including an evaluation of activities carried out with funds received under the grant under this subsection and a process and outcome evaluation.

(7) Technical assistance

The Secretary may provide technical assistance to grantees in carrying out this section, which may include assistance with—

(A) program evaluation and related activities, including related data collection and reporting;

(B) implementing and disseminating evidence-based practices and programs; and

(C) facilitating collaboration among grantees.

(8) Authorization of appropriations

There is authorized to be appropriated to carry out this subsection $24,963,000 for each of fiscal years 2023 through 2027.

(July 1, 1944, ch. 373, title V, §520J, as added Pub. L. 106–310, div. B, title XXXII, §3213, Oct. 17, 2000, 114 Stat. 1206; amended Pub. L. 114–255, div. B, title IX, §9010, Dec. 13, 2016, 130 Stat. 1244; Pub. L. 117–328, div. FF, title I, §1122(b), Dec. 29, 2022, 136 Stat. 5651.)

EDITORIAL NOTES

AMENDMENTS

2022—Subsec. (b)(1). Pub. L. 117–328, §1122(b)(1)(A), substituted "Indian Tribes, Tribal organizations" for "Indian tribes, tribal organizations".

Subsec. (b)(2). Pub. L. 117–328, §1122(b)(2)(A), substituted "Emergency services personnel" for "Emergency Services Personnel" in heading.

Subsec. (b)(3). Pub. L. 117–328, §1122(b)(2)(B), substituted "Distribution of awards" for "Distribution of Awards" in heading.

Subsec. (b)(4). Pub. L. 117–328, §1122(b)(1)(B), substituted "Indian Tribe, Tribal organization" for "Indian tribe, tribal organization".

Subsec. (b)(5). Pub. L. 117–328, §1122(b)(1)(C)(i), substituted "Indian Tribe, Tribal organization" for "Indian tribe, tribal organization" in introductory provisions.

Subsec. (b)(5)(C). Pub. L. 117–328, §1122(b)(1)(C)(ii)–(iv), added subpar. (C).

Subsec. (b)(6). Pub. L. 117–328, §1122(b)(1)(D), substituted "Indian Tribe, Tribal organization" for "Indian tribe, tribal organization".

Subsec. (b)(7). Pub. L. 117–328, §1122(b)(1)(F), added par. (7). Former par. (7) redesignated (8).

Subsec. (b)(8). Pub. L. 117–328, §1122(b)(1)(E), (G), redesignated par. (7) as (8) and substituted "$24,963,000 for each of fiscal years 2023 through 2027" for "$14,693,000 for each of fiscal years 2018 through 2022".

2016—Pub. L. 114–255, §9010(1), inserted "Mental health awareness" before "training" in section catchline.

Subsec. (b). Pub. L. 114–255, §9010(2)(A), substituted "health" for "illness" in heading.

Subsec. (b)(1). Pub. L. 114–255, §9010(2)(B), inserted "veterans, law enforcement, and other categories of individuals, as determined by the Secretary," after "emergency services personnel".

Subsec. (b)(5). Pub. L. 114–255, §9010(2)(C), substituted "for evidence-based programs that provide training and education in accordance with paragraph (1) on matters including" for "to" in introductory provisions, added subpars. (A) and (B), and struck out former subpars. (A) to (C) which read as follows:

"(A) train teachers and other relevant school personnel to recognize symptoms of childhood and adolescent mental disorders and appropriately respond;

"(B) train emergency services personnel to identify and appropriately respond to persons with a mental illness; and

"(C) provide education to such teachers and personnel regarding resources that are available in the community for individuals with a mental illness."

Subsec. (b)(7). Pub. L. 114–255, §9010(2)(D), substituted "$14,693,000 for each of fiscal years 2018 through 2022." for ", $25,000,000 for fiscal year 2001 and such sums as may be necessary for each of fiscal years 2002 through 2003."

[1] *So in original. A comma probably should appear.*

§290bb–42. Improving uptake and patient access to integrated care services

(a) Definitions

In this section:

(1) Eligible entity

The term "eligible entity" means a State, or an appropriate State agency, in collaboration with—

(A) 1 or more qualified community programs as described in section 300x–2(b)(1) of this title; or

(B) 1 or more health centers (as defined in section 254b(a) of this title), rural health clinics (as defined in section 1395x(aa) of this title), or Federally qualified health centers (as defined in such section), or primary care practices serving adult or pediatric patients or both.

(2) Integrated care; bidirectional integrated care

(A) The term "integrated care" means collaborative models, including the psychiatric collaborative care model and other evidence-based or evidence-informed models, or practices for coordinating and jointly delivering behavioral and physical health services, which may include practices that share the same space in the same facility.

(B) The term "bidirectional integrated care" means the integration of behavioral health care and specialty physical health care, and the integration of primary and physical health care within specialty behavioral health settings, including within primary health care settings.

(3) Psychiatric collaborative care model

The term "psychiatric collaborative care model" means the evidence-based, integrated behavioral health service delivery method that includes—

(A) care directed by the primary care team;

(B) structured care management;

(C) regular assessments of clinical status using developmentally appropriate, validated tools; and

(D) modification of treatment as appropriate.

(4) Special population

The term "special population" means—

(A) adults with a serious mental illness or adults who have co-occurring mental illness and physical health conditions or chronic disease;

(B) children and adolescents with a serious emotional disturbance who have a co-occurring physical health condition or chronic disease;

(C) individuals with a substance use disorder; or

(D) individuals with a mental illness who have a co-occurring substance use disorder.

(b) Grants and cooperative agreements

(1) In general

The Secretary may award grants and cooperative agreements to eligible entities to support the improvement of integrated care for physical and behavioral health care in accordance with paragraph (2).

(2) Use of funds

A grant or cooperative agreement awarded under this section shall be used—

(A) to promote full integration and collaboration in clinical practices between physical and behavioral health care, including for special populations;

(B) to support the improvement of integrated care models for physical and behavioral health care to improve overall wellness and physical health status, including for special populations;

(C) to promote the implementation and improvement of bidirectional integrated care services provided at entities described in subsection (a)(1), including evidence-based or evidence-informed screening, assessment, diagnosis, prevention, treatment, and recovery services for mental and substance use disorders, and co-occurring physical health conditions and chronic diseases; and

(D) in the case of an eligible entity that is collaborating with a primary care practice, to support the implementation of evidence-based or evidence-informed integrated care models, including the psychiatric collaborative care model, including—

(i) by hiring staff;

(ii) by identifying and formalizing contractual relationships with other health care providers or other relevant entities offering care management and behavioral health consultation to facilitate the adoption of integrated care, including, as applicable, providers who will function as psychiatric consultants and behavioral health care managers in providing behavioral health integration services through the collaborative care model;

(iii) by purchasing or upgrading software and other resources, as applicable, needed to appropriately provide behavioral health integration, including resources needed to establish a patient registry and implement measurement-based care; and

(iv) for such other purposes as the Secretary determines to be applicable and appropriate.

(c) Applications

(1) In general

An eligible entity that is seeking a grant or cooperative agreement under this section shall submit an application to the Secretary at such time, in such manner, and accompanied by such information as the Secretary may require, including the contents described in paragraph (2).

(2) Contents for awards

Any such application of an eligible entity seeking a grant or cooperative agreement under this section shall include, as applicable—

(A) a description of a plan to achieve fully collaborative agreements to provide bidirectional integrated care to special populations;

(B) a summary of the policies, if any, that are barriers to the provision of integrated care, and the specific steps, if applicable, that will be taken to address such barriers;

(C) a description of partnerships or other arrangements with local health care providers to

provide services to special populations and, as applicable, in areas with demonstrated need, such as Tribal, rural, or other medically underserved communities, such as those with a workforce shortage of mental health and substance use disorder, pediatric mental health, or other related professionals;

(D) an agreement and plan to report to the Secretary performance measures necessary to evaluate patient outcomes and facilitate evaluations across participating projects; and

(E) a description of the plan or progress in implementing the psychiatric collaborative care model, as applicable and appropriate;

(F) a description of the plan or progress of evidence-based or evidence-informed integrated care models other than the psychiatric collaborative care model implemented by primary care practices, as applicable and appropriate; and

(G) a plan for sustainability beyond the grant or cooperative agreement period under subsection (e).

(d) Grant and cooperative agreement amounts

(1) Target amount

The target amount that an eligible entity may receive for a year through a grant or cooperative agreement under this section shall be no more than $2,000,000.

(2) Adjustment permitted

The Secretary, taking into consideration the quality of an eligible entity's application and the number of eligible entities that received grants under this section prior to December 29, 2022, may adjust the target amount that an eligible entity may receive for a year through a grant or cooperative agreement under this section.

(3) Limitation

An eligible entity that is receiving funding under subsection (b)—

(A) may not allocate more than 10 percent of the funds awarded to such eligible entity under this section to administrative functions; and

(B) shall allocate the remainder of such funding to health facilities that provide integrated care.

(e) Duration

A grant or cooperative agreement under this section shall be for a period not to exceed 5 years.

(f) Report on program outcomes

An eligible entity receiving a grant or cooperative agreement under this section shall submit an annual report to the Secretary. Such annual report shall include—

(1) the progress made to reduce barriers to integrated care as described in the entity's application under subsection (c);

(2) a description of outcomes with respect to each special population listed in subsection (a)(4), including outcomes related to education, employment, and housing, or, as applicable and appropriate, outcomes for such populations receiving behavioral health care through the psychiatric collaborative care model in primary care practices; and

(3) progress in meeting performance metrics and other relevant benchmarks; and

(4) such other information that the Secretary may require.

(g) Technical assistance for primary-behavioral health care integration

(1) Certain recipients

The Secretary may provide appropriate information, training, and technical assistance to eligible entities that receive a grant or cooperative agreement under subsection (b)(2), in order to help such entities meet the requirements of this section, including assistance with—

(A) development and selection of integrated care models;

(B) dissemination of evidence-based interventions in integrated care;

(C) establishment of organizational practices to support operational and administrative

success; and

(D) as appropriate, appropriate information, training, and technical assistance in implementing the psychiatric collaborative care model when an eligible entity is collaborating with 1 or more primary care practices for the purposes of implementing the psychiatric collaborative care model.

(2) Additional dissemination of technical information

In addition to providing the assistance described in paragraph (1) to recipients of a grant or cooperative agreement under this section, the Secretary may also provide such assistance to other States and political subdivisions of States, Indian Tribes and Tribal organizations, as those terms are defined in section 5304 of title 25, outpatient mental health and addiction treatment centers, community mental health centers that meet the criteria under section 300x–2(c) of this title, certified community behavioral health clinics described in section 223 of the Protecting Access to Medicare Act of 2014, primary care organizations such as Federally qualified health centers or rural health clinics as defined in section 1395x(aa) of this title, primary health care practices, the community-based organizations, and other entities engaging in integrated care activities, as the Secretary determines appropriate.

(h) Report to Congress

Not later than 18 months after December 29, 2022, and annually thereafter, the Secretary shall submit a report to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives summarizing the information submitted in reports to the Secretary under subsection (f), including progress made in meeting performance metrics and the uptake of integrated care models, any adjustments made to target amounts pursuant to subsection (d)(2), and any other relevant information.

(i) Funding

(1) Authorization of appropriations

To carry out this section, there is authorized to be appropriated $60,000,000 for each of fiscal years 2023 through 2027.

(2) Increasing uptake of the psychiatric collaborative care model by primary care practices

Not less than 10 percent of funds appropriated to carry out this section shall be for the purposes of implementing the psychiatric collaborative care model implemented by primary care practices under subsection (b).

(3) Funding contingency

Paragraph (2) shall not apply to a fiscal year unless the amount made available to carry out this section for such fiscal year exceeds the amount appropriated to carry out this section (as in effect before December 29, 2022) for fiscal year 2022.

(July 1, 1944, ch.373, title V, §520K, as added Pub. L. 111–148, title V, §5604, Mar. 23, 2010, 124 Stat. 679; amended Pub. L. 114–255, div. B, title IX, §9003, Dec. 13, 2016, 130 Stat. 1235; Pub. L. 117–328, div. FF, title I, §1301, Dec. 29, 2022, 136 Stat. 5692.)

EDITORIAL NOTES

REFERENCES IN TEXT

Section 223 of the Protecting Access to Medicare Act of 2014, referred to in subsec. (g)(2), is section 223 of Pub. L. 113–93, which is set out as a note under section 1396a of this title.

AMENDMENTS

2022—Pub. L. 117–328 amended section generally. Prior to amendment, section authorized Secretary to award grants and cooperative agreements to eligible entities to support improvement of integrated care for primary care and behavioral health care.

2016—Pub. L. 114–255 amended section generally. Prior to amendment, section related to awards for

co-locating primary and specialty care in community-based mental health settings.

§290bb–43. Adult suicide prevention

(a) Grants

(1) In general

The Assistant Secretary shall award grants to eligible entities described in paragraph (2) to implement suicide prevention and intervention programs, for adult individuals, that are designed to raise awareness of suicide prevention, establish referral processes, and improve care and outcomes for such individuals who are at risk of suicide.

(2) Eligible entities

To be eligible to receive a grant under this section, an entity shall be a community-based primary care or behavioral health care setting, an emergency department, a State mental health agency (or State health agency with mental or behavioral health functions), public health agency, a territory of the United States, or an Indian Tribe or Tribal organization (as the terms "Indian Tribe" and "Tribal organization" are defined in section 5304 of title 25).

(3) Use of funds

The grants awarded under paragraph (1) shall be used to implement programs, in accordance with such paragraph, that include one or more of the following components:

(A) Screening for suicide risk, suicide intervention services, and services for referral for treatment for individuals at risk for suicide.

(B) Implementing evidence-based practices to provide treatment for individuals at risk for suicide, including appropriate followup services.

(C) Raising awareness of suicide prevention resources and promoting help seeking among those at risk for suicide.

(b) Evaluations and technical assistance

The Assistant Secretary shall—

(1) evaluate the activities supported by grants awarded under subsection (a), and disseminate, as appropriate, the findings from the evaluation;

(2) provide appropriate information, training, and technical assistance, as appropriate, to eligible entities that receive a grant under this section, in order to help such entities to meet the requirements of this section, including assistance with selection and implementation of evidence-based interventions and frameworks to prevent suicide; and

(3) identify best practices, as applicable, to improve the identification, assessment, treatment, and timely transition, as appropriate, to additional or follow-up care for individuals in emergency departments who are at risk for suicide and enhance the coordination of care for such individuals during and after discharge, in support of activities under subsection (a).

(c) Duration

A grant under this section shall be for a period of not more than 5 years.

(d) Authorization of appropriations

There are authorized to be appropriated to carry out this section $30,000,000 for each of fiscal years 2023 through 2027.

(July 1, 1944, ch. 373, title V, §520L, as added Pub. L. 114–255, div. B, title IX, §9009, Dec. 13, 2016, 130 Stat. 1243; amended Pub. L. 117–328, div. FF, title I, §1122(c), Dec. 29, 2022, 136 Stat. 5652.)

EDITORIAL NOTES

AMENDMENTS

2022—Subsec. (a)(1). Pub. L. 117–328, §1122(c)(1)(A), substituted "adult individuals" for "individuals who are 25 years of age or older" and inserted "prevention" after "raise awareness of suicide".

Subsec. (a)(2). Pub. L. 117–328, §1122(c)(1)(B), in two places, substituted "Indian Tribe" for "Indian tribe" and "Tribal organization" for "tribal organization".

Subsec. (a)(3)(C). Pub. L. 117–328, §1122(c)(1)(C), amended subpar. (C) generally. Prior to amendment, subpar. (C) read as follows: "Raising awareness and reducing stigma of suicide."

Subsec. (b)(3). Pub. L. 117–328, §1122(c)(2), added par. (3).

Subsec. (d). Pub. L. 117–328, §1122(c)(3), substituted "$30,000,000 for each of fiscal years 2023 through 2027" for "$30,000,000 for the period of fiscal years 2018 through 2022".

§290bb–44. Assertive community treatment grant program

(a) In general

The Assistant Secretary shall award grants to eligible entities—

(1) to establish assertive community treatment programs for adults with a serious mental illness; or

(2) to maintain or expand such programs.

(b) Eligible entities

To be eligible to receive a grant under this section, an entity shall be a State, political subdivision of a State, Indian Tribe or Tribal organization (as such terms are defined in section 5304 of title 25), mental health system, health care facility, or any other entity the Assistant Secretary deems appropriate.

(c) Special consideration

In selecting among applicants for a grant under this section, the Assistant Secretary may give special consideration to the potential of the applicant's program to reduce hospitalization, homelessness, and involvement with the criminal justice system while improving the health and social outcomes of the patient.

(d) Additional activities

The Assistant Secretary shall—

(1) not later than the end of fiscal year 2026, submit a report to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives on the grant program under this section, including an evaluation of—

(A) any cost savings and public health outcomes such as mortality, suicide, substance use disorders, hospitalization, and use of services;

(B) rates of involvement with the criminal justice system of patients;

(C) rates of homelessness among patients; and

(D) patient and family satisfaction with program participation; and

(2) provide appropriate information, training, and technical assistance to grant recipients under this section to help such recipients to establish, maintain, or expand their assertive community treatment programs.

(e) Authorization of appropriations

(1) In general

To carry out this section, there is authorized to be appropriated $9,000,000 for each of fiscal years 2023 through 2027.

(2) Use of certain funds

Of the funds appropriated to carry out this section in any fiscal year, not more than 5 percent shall be available to the Assistant Secretary for carrying out subsection (d).

(July 1, 1944, ch. 373, title V, §520M, as added Pub. L. 114–255, div. B, title IX, §9015, Dec. 13,

2016, 130 Stat. 1245; amended Pub. L. 117–328, div. FF, title I, §1123(a), Dec. 29, 2022, 136 Stat. 5653.)

EDITORIAL NOTES

AMENDMENTS

2022—Subsec. (b). Pub. L. 117–328, §1123(a)(1), substituted "Indian Tribe or Tribal organization" for "Indian tribe or tribal organization".

Subsec. (d)(1). Pub. L. 117–328, §1123(a)(2), in introductory provisions, substituted "not later than the end of fiscal year 2026" for "not later than the end of fiscal year 2021" and "Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives" for "appropriate congressional committees".

Subsec. (e)(1). Pub. L. 117–328, §1123(a)(3), substituted "$9,000,000 for each of fiscal years 2023 through 2027" for "$5,000,000 for the period of fiscal years 2018 through 2022".

§290bb–45. Center of Excellence for Eating Disorders for education and training on eating disorders

(a) In general

The Secretary, acting through the Assistant Secretary, shall maintain, by competitive grant or contract, a Center of Excellence for Eating Disorders (referred to in this section as the "Center") to improve the identification of, interventions for, and treatment of eating disorders in a manner that is developmentally, culturally, and linguistically appropriate.

(b) Subgrants and subcontracts

The Center shall coordinate and implement the activities under subsection (c), in whole or in part, which may include by awarding competitive subgrants or subcontracts—

(1) across geographical regions; and

(2) in a manner that is not duplicative.

(c) Activities

The Center—

(1) shall—

(A) provide training and technical assistance, including for—

(i) primary care and mental health providers to carry out screening, brief intervention, and referral to treatment for individuals experiencing, or at risk for, eating disorders; and

(ii) other paraprofessionals and relevant individuals providing nonclinical community services to identify and support individuals with, or at disproportionate risk for, eating disorders;

(B) facilitate the development of, and provide training materials to, health care providers (including primary care and mental health professionals) regarding the effective treatment and ongoing support of individuals with eating disorders, including children and marginalized populations at disproportionate risk for eating disorders;

(C) collaborate and coordinate, as appropriate, with other centers of excellence, technical assistance centers, and psychiatric consultation lines of the Substance Abuse and Mental Health Services Administration and the Health Resources and Services Administration regarding eating disorders;

(D) coordinate with the Director of the Centers for Disease Control and Prevention and the Administrator of the Health Resources and Services Administration, and other Federal agencies, as appropriate, to disseminate training to primary care and mental health care providers; and

(E) support other activities, as determined appropriate by the Secretary; and

(2) may—

(A) support the integration of protocols pertaining to screening, brief intervention, and referral to treatment for individuals experiencing, or at risk for, eating disorders, with health information technology systems;

(B) develop and provide training materials to health care providers, including primary care and mental health providers, to provide screening, brief intervention, and referral to treatment for members of the military and veterans experiencing, or at risk for, eating disorders; and

(C) consult, as appropriate, with the Secretary of Defense and the Secretary of Veterans Affairs on prevention, identification, intervention for, and treatment of eating disorders.

(d) Authorization of appropriations

To carry out this section, there is authorized to be appropriated $1,000,000 for each of fiscal years 2023 through 2027.

(July 1, 1944, ch. 373, title V, §520N, as added Pub. L. 117–328, div. FF, title I, §1131, Dec. 29, 2022, 136 Stat. 5655.)

§§290cc to 290cc–12. Repealed. Pub. L. 102–321, title I, §§117, 120(b)(3), 123(c), July 10, 1992, 106 Stat. 348, 358, 363

Section 290cc, act July 1, 1944, ch. 373, title V, §515, formerly Pub. L. 92–255, title V, §503, as added Pub. L. 94–237, §13(a), Mar. 19, 1976, 90 Stat. 248; amended Pub. L. 95–461, §2(c), Oct. 14, 1978, 92 Stat. 1268; Pub. L. 96–181, §12, Jan. 2, 1980, 93 Stat. 1315; Pub. L. 97–35, title IX, §972(a), (b), Aug. 13, 1981, 95 Stat. 597; renumbered §515 of act July 1, 1944, and amended Apr. 26, 1983, Pub. L. 98–24, §2(b)(11), 97 Stat. 180; Oct. 19, 1984, Pub. L. 98–509, title II, §§205(a)(2), 206(c)(2), 207(b), 98 Stat. 2361–2363; Oct. 27, 1986, Pub. L. 99–570, title IV, §4009, 100 Stat. 3207–115; Nov. 18, 1988, Pub. L. 100–690, title II, §2058(a)(3), 102 Stat. 4214, related to encouraging drug abuse research.

Section 290cc–1, act July 1, 1944, ch. 373, title V, §516, as added Oct. 19, 1984, Pub. L. 98–509, title II, §206(b), 98 Stat. 2362; amended Nov. 18, 1988, Pub. L. 100–690, title II, §2058(a)(4), 102 Stat. 4214, related to drug abuse demonstration projects.

Section 290cc–2, act July 1, 1944, ch. 373, title V, §517, as added Oct. 19, 1984, Pub. L. 98–509, title II, §207(b), 98 Stat. 2363; amended Oct. 27, 1986, Pub. L. 99–570, title IV, §4010(b), 100 Stat. 3207–115; Nov. 18, 1988, Pub. L. 100–690, title II, §2056(b), 102 Stat. 4211; Aug. 15, 1990, Pub. L. 101–374, §3(a), 104 Stat. 457, authorized appropriations for drug abuse research.

Section 290cc–11, act July 1, 1944, ch. 373, title V, §518, formerly §519, as added Nov. 18, 1988, Pub. L. 100–690, title II, §2057(3), 102 Stat. 4212; renumbered §518, Aug. 16, 1989, Pub. L. 101–93, §3(e)(1)(A), 103 Stat. 610, related to establishment of a mental health research program.

Section 290cc–12, act July 1, 1944, ch. 373, title V, §519, formerly §520, as added Nov. 18, 1988, Pub. L. 100–690, title II, §2057(3), 102 Stat. 4212; renumbered §519, Aug. 16, 1989, Pub. L. 101–93, §3(e)(1)(A), 103 Stat. 610, related to National Mental Health Education Program.

STATUTORY NOTES AND RELATED SUBSIDIARIES

EFFECTIVE DATE OF REPEAL

Repeal effective Oct. 1, 1992, with provision for programs providing financial assistance, see section 801(c), (d) of Pub. L. 102–321, set out as an Effective Date of 1992 Amendment note under section 236 of this title.

§290cc–13. Transferred

EDITORIAL NOTES

CODIFICATION

Section, act July 1, 1944, ch. 373, title V, §520, formerly §520A, as added Nov. 18, 1988, Pub. L. 100–690,

title II, §2057(3), 102 Stat. 4212, and amended, which related to establishment of grant programs for demonstration projects for drug abuse research, was renumbered section 520A of act July 1, 1944 by Pub. L. 102–321, title I, §116(a), July 10, 1992, 106 Stat. 348, and transferred to section 290bb–32 of this title.

PART C—PROJECTS FOR ASSISTANCE IN TRANSITION FROM HOMELESSNESS

§290cc–21. Formula grants to States

For the purpose of carrying out section 290cc–22 of this title, the Secretary, acting through the Director of the Center for Mental Health Services, shall for each of the fiscal years 2023 through 2027 make an allotment for each State in an amount determined in accordance with section 290cc–24 of this title. The Secretary shall make payments, as grants, each such fiscal year to each State from the allotment for the State if the Secretary approves for the fiscal year involved an application submitted by the State pursuant to section 290cc–29 of this title.

(July 1, 1944, ch. 373, title V, §521, as added Pub. L. 100–77, title VI, §611(3), July 22, 1987, 101 Stat. 516; amended Pub. L. 100–607, title VIII, §813(1), Nov. 4, 1988, 102 Stat. 3170; Pub. L. 100–628, title VI, §613(1), Nov. 7, 1988, 102 Stat. 3243; Pub. L. 101–93, §5(t)(1), Aug. 16, 1989, 103 Stat. 615; Pub. L. 101–645, title V, §511, Nov. 29, 1990, 104 Stat. 4726; Pub. L. 102–321, title I, §§162(1), 163(a)(1), July 10, 1992, 106 Stat. 375; Pub. L. 102–352, §2(b)(2), Aug. 26, 1992, 106 Stat. 939; Pub. L. 114–255, div. B, title IX, §9004(a), Dec. 13, 2016, 130 Stat. 1238; Pub. L. 117–328, div. FF, title I, §1217, Dec. 29, 2022, 136 Stat. 5670.)

EDITORIAL NOTES

PRIOR PROVISIONS

A prior section 521 of act July 1, 1944, was renumbered section 542 by section 611(2) of Pub. L. 100–77 and is classified to section 290dd–1 of this title.

AMENDMENTS

2022—Pub. L. 117–328 substituted "2023 through 2027" for "2018 through 2022".

2016—Pub. L. 114–255 substituted "2018 through 2022" for "1991 through 1994".

1992—Pub. L. 102–352 repealed Pub. L. 102–321, §163(a)(1), which directed the substitution of "Administrator of the Substance Abuse and Mental Health Services Administration" for "Director of the National Institute of Mental Health".

Pub. L. 102–321, §162(1), substituted "Center for Mental Health Services" for "National Institute of Mental Health".

1990—Pub. L. 101–645 amended section generally, substituting provisions relating to formula grants to States for provisions relating to establishment of block grant program for services to homeless individuals who are chronically mentally ill.

1989—Subsec. (a). Pub. L. 101–93 directed that subsec. (a) of this section as similarly amended by title VIII of Pub. L. 100–607 and title VI of Pub. L. 100–628 be amended to read as if the amendments made by title VI of Pub. L. 100–628 had not been enacted. See 1988 Amendment note below.

1988—Subsec. (a). Pub. L. 100–607 and Pub. L. 100–628 made identical amendments, amending first sentence generally. Prior to amendment, first sentence read as follows: "The Secretary shall for fiscal years 1987 and 1988 allot to each State an amount determined in accordance with sections 290cc–28 and 290cc–29 of this title."

STATUTORY NOTES AND RELATED SUBSIDIARIES

EFFECTIVE DATE OF 1992 AMENDMENT

Amendment by Pub. L. 102–321 effective Oct. 1, 1992, with provision for programs providing financial

assistance, see section 801(c), (d) of Pub. L. 102–321, set out as a note under section 236 of this title.

EFFECTIVE DATE OF 1988 AMENDMENTS

Amendment by Pub. L. 100–628 effective Nov. 7, 1988, see section 631 of Pub. L. 100–628, set out as a note under section 254e of this title.

Amendment by Pub. L. 100–607 effective Nov. 4, 1988, see section 831 of Pub. L. 100–607, set out as a note under section 254e of this title.

§290cc–22. Purpose of grants

(a) In general

The Secretary may not make payments under section 290cc–21 of this title unless the State involved agrees that the payments will be expended solely for making grants to political subdivisions of the State, and to nonprofit private entities (including community-based veterans organizations and other community organizations), for the purpose of providing the services specified in subsection (b) to individuals who—

(1)(A) are suffering from serious mental illness; or

(B) are suffering from serious mental illness and from a substance use disorder; and

(2) are homeless or at imminent risk of becoming homeless.

(b) Specification of services

The services referred to in subsection (a) are—

(1) outreach services;

(2) screening and diagnostic treatment services;

(3) habilitation and rehabilitation services;

(4) community mental health services;

(5) alcohol or drug treatment services;

(6) staff training, including the training of individuals who work in shelters, mental health clinics, substance use disorder programs, and other sites where homeless individuals require services;

(7) case management services, including—

(A) preparing a plan for the provision of community mental health services to the eligible homeless individual involved, and reviewing such plan not less than once every 3 months;

(B) providing assistance in obtaining and coordinating social and maintenance services for the eligible homeless individuals, including services relating to daily living activities, personal financial planning, transportation services, and habilitation and rehabilitation services, prevocational and vocational services, and housing services;

(C) providing assistance to the eligible homeless individual in obtaining income support services, including housing assistance, supplemental nutrition assistance program benefits, and supplemental security income benefits;

(D) referring the eligible homeless individual for such other services as may be appropriate; and

(E) providing representative payee services in accordance with section 1631(a)(2) of the Social Security Act [42 U.S.C. 1383(a)(2)] if the eligible homeless individual is receiving aid under title XVI of such act [42 U.S.C. 1381 et seq.] and if the applicant is designated by the Secretary to provide such services;

(8) supportive and supervisory services in residential settings;

(9) referrals for primary health services, job training, educational services, and relevant housing services;

(10) subject to subsection (h)(1)—

(A) minor renovation, expansion, and repair of housing;

(B) planning of housing;

(C) technical assistance in applying for housing assistance;

(D) improving the coordination of housing services;

(E) security deposits;

(F) the costs associated with matching eligible homeless individuals with appropriate housing situations; and

(G) 1-time rental payments to prevent eviction; and

(11) other appropriate services, as determined by the Secretary.

(c) Coordination

The Secretary may not make payments under section 290cc–21 of this title unless the State involved agrees to make grants pursuant to subsection (a) only to entities that have the capacity to provide, directly or through arrangements, the services specified in subsection (b), including coordinating the provision of services in order to meet the needs of eligible homeless individuals who are both mentally ill and suffering from a substance use disorder.

(d) Special consideration regarding veterans

The Secretary may not make payments under section 290cc–21 of this title unless the State involved agrees that, in making grants to entities pursuant to subsection (a), the State will give special consideration to entities with a demonstrated effectiveness in serving homeless veterans.

(e) Special rules

The Secretary may not make payments under section 290cc–21 of this title unless the State involved agrees that grants pursuant to subsection (a) will not be made to any entity that—

(1) has a policy of excluding individuals from mental health services due to the existence or suspicion of a substance use disorder; or

(2) has a policy of excluding individuals from substance use disorder services due to the existence or suspicion of mental illness.

(f) Administrative expenses

The Secretary may not make payments under section 290cc–21 of this title unless the State involved agrees that not more than 4 percent of the payments will be expended for administrative expenses regarding the payments.

(g) Restrictions on use of funds

The Secretary may not make payments under section 290cc–21 of this title unless the State involved agrees that—

(1) not more than 20 percent of the payments will be expended for housing services under subsection (b)(10); and

(2) the payments will not be expended—

(A) to support emergency shelters or construction of housing facilities;

(B) for inpatient psychiatric treatment costs or inpatient substance use disorder treatment costs; or

(C) to make cash payments to intended recipients of mental health or substance use disorder services.

(h) Waiver for territories

With respect to the United States Virgin Islands, Guam, American Samoa, Palau, the Marshall Islands, and the Commonwealth of the Northern Mariana Islands, the Secretary may waive the provisions of this part that the Secretary determines to be appropriate.

(July 1, 1944, ch. 373, title V, §522, as added Pub. L. 100–77, title VI, §611(3), July 22, 1987, 101 Stat. 516; amended Pub. L. 101–645, title V, §511, Nov. 29, 1990, 104 Stat. 4726; Pub. L. 106–310, div. B, title XXXII, §3203(a), Oct. 17, 2000, 114 Stat. 1191; Pub. L. 110–234, title IV,

§4002(b)(1)(E), (2)(U), May 22, 2008, 122 Stat. 1096, 1097; Pub. L. 110–246, §4(a), title IV, §4002(b)(1)(E), (2)(U), June 18, 2008, 122 Stat. 1664, 1857, 1858; Pub. L. 114–255, div. B, title IX, §9004(b), Dec. 13, 2016, 130 Stat. 1238.)

EDITORIAL NOTES

REFERENCES IN TEXT

The Social Security Act, referred to in subsec. (b)(7)(E), is act Aug. 14, 1935, ch. 531, 49 Stat. 620. Title XVI of the Act is classified generally to subchapter XVI (§1381 et seq.) of chapter 7 of this title. For complete classification of this Act to the Code, see section 1305 of this title and Tables.

CODIFICATION

Pub. L. 110–234 and Pub. L. 110–246 made identical amendments to this section. The amendments by Pub. L. 110–234 were repealed by section 4(a) of Pub. L. 110–246.

PRIOR PROVISIONS

A prior section 522 of act July 1, 1944, was renumbered section 543 by section 611(2) of Pub. L. 100–77 and is classified to section 290dd–2 of this title.

AMENDMENTS

2016—Subsec. (a)(1)(B). Pub. L. 114–255, §9004(b)(1), substituted "a substance use disorder" for "substance abuse".

Subsec. (b)(6). Pub. L. 114–255, §9004(b)(2), substituted "substance use disorder" for "substance abuse".

Subsec. (c). Pub. L. 114–255, §9004(b)(3), substituted "a substance use disorder" for "substance abuse".

Subsec. (e)(1). Pub. L. 114–255, §9004(b)(4)(A), substituted "a substance use disorder" for "substance abuse".

Subsec. (e)(2). Pub. L. 114–255, §9004(b)(4)(B), substituted "substance use disorder" for "substance abuse".

Subsec. (g). Pub. L. 114–255, §9004(b)(5), redesignated subsec. (h) as (g) and struck out former subsec. (g). Prior to amendment, text of subsec. (g) read as follows: "The Secretary may not make payments under section 290cc–21 of this title unless the State involved agrees that the State will maintain State expenditures for services specified in subsection (b) at a level that is not less than the average level of such expenditures maintained by the State for the 2-year period preceding the fiscal year for which the State is applying to receive such payments."

Subsec. (g)(2)(B), (C). Pub. L. 114–255, §9004(b)(6), substituted "substance use disorder" for "substance abuse".

Subsecs. (h), (i). Pub. L. 114–255, §9004(b)(5), redesignated subsec. (i) as (h). Former subsec. (h) redesignated (g).

2008—Subsec. (b)(7)(C). Pub. L. 110–246, §4002(b)(1)(E), (2)(U), substituted "supplemental nutrition assistance program benefits" for "food stamps".

2000—Subsec. (i). Pub. L. 106–310 added subsec. (i).

1990—Pub. L. 101–645 amended section generally, substituting provisions relating to purpose of grants for provisions relating to requirement of submission of application containing certain agreements.

STATUTORY NOTES AND RELATED SUBSIDIARIES

EFFECTIVE DATE OF 2008 AMENDMENT

Amendment of this section and repeal of Pub. L. 110–234 by Pub. L. 110–246 effective May 22, 2008, the date of enactment of Pub. L. 110–234, except as otherwise provided, see section 4 of Pub. L. 110–246, set out as an Effective Date note under section 8701 of Title 7, Agriculture.

Amendment by section 4002(b)(1)(E), (2)(U) of Pub. L. 110–246 effective Oct. 1, 2008, see section 4407 of Pub. L. 110–246, set out as a note under section 1161 of Title 2, The Congress.

§290cc–23. Requirement of matching funds

(a) In general

The Secretary may not make payments under section 290cc–21 of this title unless, with respect to the costs of providing services pursuant to section 290cc–22 of this title, the State involved agrees to make available, directly or through donations from public or private entities, non-Federal contributions toward such costs in an amount that is not less than $1 for each $3 of Federal funds provided in such payments.

(b) Determination of amount

Non-Federal contributions required in subsection (a) may be in cash or in kind, fairly evaluated, including plant, equipment, or services. Amounts provided by the Federal Government, or services assisted or subsidized to any significant extent by the Federal Government, shall not be included in determining the amount of such non-Federal contributions.

(c) Limitation regarding grants by States

The Secretary may not make payments under section 290cc–21 of this title unless the State involved agrees that the State will not require the entities to which grants are provided pursuant to section 290cc–22(a) of this title to provide non-Federal contributions in excess of the non-Federal contributions described in subsection (a).

(July 1, 1944, ch. 373, title V, §523, as added Pub. L. 100–77, title VI, §611(3), July 22, 1987, 101 Stat. 517; amended Pub. L. 101–645, title V, §511, Nov. 29, 1990, 104 Stat. 4728.)

EDITORIAL NOTES

PRIOR PROVISIONS

A prior section 523 of act July 1, 1944, was renumbered section 544 by section 611(2) of Pub. L. 100–77 and is classified to section 290dd–3 of this title.

AMENDMENTS

1990—Pub. L. 101–645 amended section generally, substituting present provisions for provisions which related to: in subsec. (a), general requirements; and in subsec. (b), determination of amount of non-Federal contribution.

§290cc–24. Determination of amount of allotment

(a) Minimum allotment

The allotment for a State under section 290cc–21 of this title for a fiscal year shall be the greater of—

(1) $300,000 for each of the several States, the District of Columbia, and the Commonwealth of Puerto Rico, and $50,000 for each of Guam, the Virgin Islands, American Samoa, and the Commonwealth of the Northern Mariana Islands; and

(2) an amount determined in accordance with subsection (b).

(b) Determination under formula

The amount referred to in subsection (a)(2) is the product of—

(1) an amount equal to the amount appropriated under section 290cc–35(a) of this title for the fiscal year; and

(2) a percentage equal to the quotient of—

(A) an amount equal to the population living in urbanized areas of the State involved, as indicated by the most recent data collected by the Bureau of the Census; and

(B) an amount equal to the population living in urbanized areas of the United States, as indicated by the sum of the respective amounts determined for the States under subparagraph (A).

(July 1, 1944, ch. 373, title V, §524, as added Pub. L. 100–77, title VI, §611(3), July 22, 1987, 101 Stat. 517; amended Pub. L. 101–645, title V, §511, Nov. 29, 1990, 104 Stat. 4728.)

EDITORIAL NOTES

PRIOR PROVISIONS

A prior section 524 of act July 1, 1944, was renumbered section 545 by section 611(2) of Pub. L. 100–77 and is classified to section 290ee of this title.

AMENDMENTS

1990—Pub. L. 101–645 amended section generally, substituting provisions relating to determination of amount of allotment for provisions relating to requiring provision of certain mental health services.

§290cc–25. Conversion to categorical program in event of failure of State regarding expenditure of grants

(a) In general

Subject to subsection (c), the Secretary shall, from the amounts specified in subsection (b), make grants to public and nonprofit private entities for the purpose of providing to eligible homeless individuals the services specified in section 290cc–22(b) of this title.

(b) Specification of funds

The amounts referred to in subsection (a) are any amounts made available in appropriations Acts for allotments under section 290cc–21 of this title that are not paid to a State as a result of—

(A) the failure of the State to submit an application under section 290cc–29 of this title;

(B) the failure of the State, in the determination of the Secretary, to prepare the application in accordance with such section or to submit the application within a reasonable period of time; or

(C) the State informing the Secretary that the State does not intend to expend the full amount of the allotment made to the State.

(c) Requirement of provision of services in State involved

With respect to grants under subsection (a), amounts made available under subsection (b) as a result of the State involved shall be available only for grants to provide services in such State.

(July 1, 1944, ch. 373, title V, §525, as added Pub. L. 100–77, title VI, §611(3), July 22, 1987, 101 Stat. 518; amended Pub. L. 101–645, title V, §511, Nov. 29, 1990, 104 Stat. 4729.)

EDITORIAL NOTES

PRIOR PROVISIONS

A prior section 525 of act July 1, 1944, was renumbered section 546 by section 611(2) of Pub. L. 100–77 and is classified to section 290ee–1 of this title.

AMENDMENTS

1990—Pub. L. 101–645 amended section generally, substituting provisions relating to conversion to categorical program in event of failure of State regarding expenditure of grants for provisions relating to restrictions on use of payments.

§290cc–26. Provision of certain information from State

The Secretary may not make payments under section 290cc–21 of this title to a State unless, as part of the application required in section 290cc–29 of this title, the State submits to the Secretary a statement—

(1) identifying existing programs providing services and housing to eligible homeless individuals and identify gaps in the delivery systems of such programs;

(2) containing a plan for providing services and housing to eligible homeless individuals, which plan—

(A) describes the coordinated and comprehensive means of providing services and housing to homeless individuals; and

(B) includes documentation that suitable housing for eligible homeless individuals will accompany the provision of services to such individuals;

(3) describes the source of the non-Federal contributions described in section 290cc–23 of this title;

(4) contains assurances that the non-Federal contributions described in section 290cc–23 of this title will be available at the beginning of the grant period;

(5) describe any voucher system that may be used to carry out this part; and

(6) contain such other information or assurances as the Secretary may reasonably require.

(July 1, 1944, ch. 373, title V, §526, as added Pub. L. 100–77, title VI, §611(3), July 22, 1987, 101 Stat. 519; amended Pub. L. 101–645, title V, §511, Nov. 29, 1990, 104 Stat. 4729.)

EDITORIAL NOTES

PRIOR PROVISIONS

A prior section 526 of act July 1, 1944, was renumbered section 547 by section 611(2) of Pub. L. 100–77 and is classified to section 290ee–2 of this title.

AMENDMENTS

1990—Pub. L. 101–645 amended section generally, substituting provisions relating to providing certain information from State for provisions relating to requirement of submission of description of intended use of block grant.

§290cc–27. Description of intended expenditures of grant

(a) In general

The Secretary may not make payments under section 290cc–21 of this title unless—

(1) as part of the application required in section 290cc–29 of this title, the State involved submits to the Secretary a description of the intended use for the fiscal year of the amounts for which the State is applying pursuant to such section;

(2) such description identifies the geographic areas within the State in which the greatest numbers of homeless individuals with a need for mental health, substance use disorder, and housing services are located;

(3) such description provides information relating to the programs and activities to be supported and services to be provided, including information relating to coordinating such programs and activities with any similar programs and activities of public and private entities; and

(4) the State agrees that such description will be revised throughout the year as may be necessary to reflect substantial changes in the programs and activities assisted by the State pursuant to section 290cc–22 of this title.

(b) Opportunity for public comment

The Secretary may not make payments under section 290cc–21 of this title unless the State involved agrees that, in developing and carrying out the description required in subsection (a), the State will provide public notice with respect to the description (including any revisions) and such opportunities as may be necessary to provide interested persons, such as family members, consumers, and mental health, substance use disorder, and housing agencies, an opportunity to present comments and recommendations with respect to the description.

(c) Relationship to State comprehensive mental health services plan

(1) In general

The Secretary may not make payments under section 290cc–21 of this title unless the services

to be provided pursuant to the description required in subsection (a) are consistent with the State comprehensive mental health services plan required in subpart 2 [1] of part B of subchapter XVII.

(2) Special rule

The Secretary may not make payments under section 290cc–21 of this title unless the services to be provided pursuant to the description required in subsection (a) have been considered in the preparation of, have been included in, and are consistent with, the State comprehensive mental health services plan referred to in paragraph (1).

(July 1, 1944, ch. 373, title V, §527, as added Pub. L. 100–77, title VI, §611(3), July 22, 1987, 101 Stat. 520; amended Pub. L. 101–645, title V, §511, Nov. 29, 1990, 104 Stat. 4730; Pub. L. 114–255, div. B, title IX, §9004(c), Dec. 13, 2016, 130 Stat. 1238.)

EDITORIAL NOTES

REFERENCES IN TEXT

Subpart 2 of part B of subchapter XVII, referred to in subsec. (c)(1), which related to State comprehensive mental health services plans and which was classified to section 300x–10 et seq. of this title, was repealed by Pub. L. 102–321, title II, §201(2), July 10, 1992, 106 Stat. 378, and a new subpart 2 of part B of subchapter XVII of this chapter, relating to block grants for prevention and treatment of substance abuse, was added by section 202 of Pub. L. 102–321 and classified to section 300x–21 et seq. of this title.

PRIOR PROVISIONS

A prior section 527 of act July 1, 1944, was renumbered section 548 by section 611(2) of Pub. L. 100–77 and is classified to section 290ee–3 of this title.

AMENDMENTS

2016—Subsecs. (a)(2), (b). Pub. L. 114–255 substituted "substance use disorder" for "substance abuse".

1990—Pub. L. 101–645 amended section generally, substituting provisions relating to description of intended expenditures of grant for provisions relating to requirement of reports by States.

[1] *See References in Text note below.*

§290cc–28. Requirement of reports by States

(a) In general

The Secretary may not make payments under section 290cc–21 of this title unless the State involved agrees that, by not later than January 31 of each fiscal year, the State will prepare and submit to the Secretary a report in such form and containing such information as the Secretary determines (after consultation with the Assistant Secretary for Mental Health and Substance Use) to be necessary for—

(1) securing a record and a description of the purposes for which amounts received under section 290cc–21 of this title were expended during the preceding fiscal year and of the recipients of such amounts; and

(2) determining whether such amounts were expended in accordance with the provisions of this part.

(b) Availability to public of reports

The Secretary may not make payments under section 290cc–21 of this title unless the State involved agrees to make copies of the reports described in subsection (a) available for public inspection.

(c) Evaluations

The Assistant Secretary for Mental Health and Substance Use shall evaluate at least once every 3 years the expenditures of grants under this part by eligible entities in order to ensure that

expenditures are consistent with the provisions of this part, and shall include in such evaluation recommendations regarding changes needed in program design or operations.

(July 1, 1944, ch. 373, title V, §528, as added Pub. L. 100–77, title VI, §611(3), July 22, 1987, 101 Stat. 520; amended Pub. L. 100–607, title VIII, §812(b), Nov. 4, 1988, 102 Stat. 3170; Pub. L. 100–628, title VI, §612(b), Nov. 7, 1988, 102 Stat. 3243; Pub. L. 100–690, title II, §2614(a), Nov. 18, 1988, 102 Stat. 4239; Pub. L. 101–93, §5(t)(1), Aug. 16, 1989, 103 Stat. 615; Pub. L. 101–645, title V, §511, Nov. 29, 1990, 104 Stat. 4730; Pub. L. 102–321, title I, §163(a)(1), formerly §163(a)(2), July 10, 1992, 106 Stat. 375, renumbered §163(a)(1), Pub. L. 102–352, §2(b)(2), Aug. 26, 1992, 106 Stat. 939; Pub. L. 104–316, title I, §122(c), Oct. 19, 1996, 110 Stat. 3836; Pub. L. 114–255, div. B, title VI, §6001(c)(1), Dec. 13, 2016, 130 Stat. 1203.)

EDITORIAL NOTES

AMENDMENTS

2016—Subsecs. (a), (c). Pub. L. 114–255 substituted "Assistant Secretary for Mental Health and Substance Use" for "Administrator of the Substance Abuse and Mental Health Services Administration".

1996—Subsec. (a). Pub. L. 104–316, §122(c)(1), struck out "the Comptroller General of the United States, and" after "(after consultation with".

Subsec. (c). Pub. L. 104–316, §122(c)(2), struck out "Comptroller General of the United States in cooperation with the" before "Administrator" and struck out comma after "Administration".

1992—Subsec. (a). Pub. L. 102–321, §163(a)(1)(A), as renumbered by Pub. L. 102–352, substituted "and the Administrator of the Substance Abuse and Mental Health Services Administration" for "the National Institute of Mental Health, the National Institute on Alcohol Abuse and Alcoholism, and the National Institute on Drug Abuse".

Subsec. (c). Pub. L. 102–321, §163(a)(1)(B), as renumbered by Pub. L. 102–352, substituted "Administrator of the Substance Abuse and Mental Health Services Administration" for "National Institute of Mental Health".

1990—Pub. L. 101–645 amended section generally, substituting provisions relating to requirement of reports by States for provisions relating to determination of amount of allotments.

1989—Subsec. (a)(1). Pub. L. 101–93 directed that subsec. (a)(1) of this section as similarly amended by title VIII of Pub. L. 100–607 and title VI of Pub. L. 100–628 be amended to read as if the amendments made by title VI of Pub. L. 100–628 had not been enacted. See 1988 Amendment note below.

1988—Subsec. (a)(1). Pub. L. 100–690 substituted "the Commonwealth of the Northern Mariana Islands" for "the Northern Mariana Islands".

Pub. L. 100–607 and Pub. L. 100–628 made identical amendments, amending par. (1) generally. Prior to amendment, par. (1) read as follows: "$275,000; and".

STATUTORY NOTES AND RELATED SUBSIDIARIES

EFFECTIVE DATE OF 1992 AMENDMENT

Amendment by Pub. L. 102–321 effective Oct. 1, 1992, with provision for programs providing financial assistance, see section 801(c), (d) of Pub. L. 102–321, set out as a note under section 236 of this title.

EFFECTIVE DATE OF 1988 AMENDMENTS

Amendment by Pub. L. 100–690 effective immediately after enactment of Pub. L. 100–607, which was approved Nov. 4, 1988, see section 2600 of Pub. L. 100–690, set out as a note under section 242m of this title.

Amendment by Pub. L. 100–628 effective Nov. 7, 1988, see section 631 of Pub. L. 100–628, set out as a note under section 254e of this title.

Amendment by Pub. L. 100–607 effective Nov. 4, 1988, see section 831 of Pub. L. 100–607, set out as a note under section 254e of this title.

§290cc–29. Requirement of application

The Secretary may not make payments under section 290cc–21 of this title unless the State involved—

(1) submits to the Secretary an application for the payments containing agreements and

information in accordance with this part;

(2) the agreements are made through certification from the chief executive officer of the State; and

(3) the application otherwise is in such form, is made in such manner, and contains such agreements, assurances, and information as the Secretary determines to be necessary to carry out this part.

(July 1, 1944, ch. 373, title V, §529, as added Pub. L. 100–77, title VI, §611(3), July 22, 1987, 101 Stat. 520; amended Pub. L. 100–607, title VIII, §811(b), Nov. 4, 1988, 102 Stat. 3170; Pub. L. 100–628, title VI, §611(b), Nov. 7, 1988, 102 Stat. 3243; Pub. L. 101–93, §5(t)(1), Aug. 16, 1989, 103 Stat. 615; Pub. L. 101–645, title V, §511, Nov. 29, 1990, 104 Stat. 4731.)

EDITORIAL NOTES

AMENDMENTS

1990—Pub. L. 101–645 amended section generally, substituting provisions relating to requirement of application for provisions relating to conversion to State categorical program in event of failure of State with respect to expending allotment.

1989—Pub. L. 101–93 directed that this section as similarly amended by title VIII of Pub. L. 100–607 and title VI of Pub. L. 100–628 be amended to read as if the amendments made by title VI of Pub. L. 100–628 had not been enacted. See 1988 Amendment note below.

1988—Pub. L. 100–607 and Pub. L. 100–628 made identical amendments, amending section generally by substituting present provisions for provisions which had related to: in subsec. (a), additional allotments for certain States; in subsec. (b), description of funds; and in subsec. (c), determination of amount of allotment.

STATUTORY NOTES AND RELATED SUBSIDIARIES

EFFECTIVE DATE OF 1988 AMENDMENTS

Amendment by Pub. L. 100–628 effective Nov. 7, 1988, see section 631 of Pub. L. 100–628, set out as a note under section 254e of this title.

Amendment by Pub. L. 100–607 effective Nov. 4, 1988, see section 831 of Pub. L. 100–607, set out as a note under section 254e of this title.

§290cc–30. Technical assistance

The Secretary, acting through the Assistant Secretary, shall provide technical assistance to eligible entities in developing planning and operating programs in accordance with the provisions of this part.

(July 1, 1944, ch. 373, title V, §530, as added Pub. L. 100–77, title VI, §611(3), July 22, 1987, 101 Stat. 521; amended Pub. L. 101–645, title V, §511, Nov. 29, 1990, 104 Stat. 4731; Pub. L. 102–321, title I, §§162(2), 163(a)(3), July 10, 1992, 106 Stat. 375; Pub. L. 102–352, §2(b)(2), Aug. 26, 1992, 106 Stat. 939; Pub. L. 114–255, div. B, title IX, §9004(d), Dec. 13, 2016, 130 Stat. 1238.)

EDITORIAL NOTES

AMENDMENTS

2016—Pub. L. 114–255 substituted "acting through the Assistant Secretary" for "through the National Institute of Mental Health, the National Institute of Alcohol Abuse and Alcoholism, and the National Institute on Drug Abuse".

1992—Pub. L. 102–352 repealed Pub. L. 102–321, §163(a)(3), which directed the substitution of "the Administrator of the Substance Abuse and Mental Health Services Administration" for "the National Institute of Mental Health, the National Institute on Alcohol Abuse and Alcoholism, and the National Institute on Drug Abuse".

Pub. L. 102–321, §162(2), which directed the substitution of "through the agencies of the Administration"

for "through the National" and all that followed through "Abuse", was not executed because the word "Abuse" appeared in two places and because of the amendment by Pub. L. 114–255, which presumed that the substitution did not take place. See 2016 Amendment note above.

1990—Pub. L. 101–645 amended section generally, substituting provision relating to technical assistance for provision relating to disbursement and availability of funds.

STATUTORY NOTES AND RELATED SUBSIDIARIES

EFFECTIVE DATE OF 1992 AMENDMENT

Amendment by Pub. L. 102–321 effective Oct. 1, 1992, with provision for programs providing financial assistance, see section 801(c), (d) of Pub. L. 102–321, set out as a note under section 236 of this title.

§290cc–31. Failure to comply with agreements

(a) Repayment of payments

(1) The Secretary may, subject to subsection (c), require a State to repay any payments received by the State under section 290cc–21 of this title that the Secretary determines were not expended by the State in accordance with the agreements required to be contained in the application submitted by the State pursuant to section 290cc–29 of this title.

(2) If a State fails to make a repayment required in paragraph (1), the Secretary may offset the amount of the repayment against the amount of any payment due to be paid to the State under section 290cc–21 of this title.

(b) Withholding of payments

(1) The Secretary may, subject to subsection (c), withhold payments due under section 290cc–21 of this title if the Secretary determines that the State involved is not expending amounts received under such section in accordance with the agreements required to be contained in the application submitted by the State pursuant to section 290cc–29 of this title.

(2) The Secretary shall cease withholding payments from a State under paragraph (1) if the Secretary determines that there are reasonable assurances that the State will expend amounts received under section 290cc–21 of this title in accordance with the agreements referred to in such paragraph.

(3) The Secretary may not withhold funds under paragraph (1) from a State for a minor failure to comply with the agreements referred to in such paragraph.

(c) Opportunity for hearing

Before requiring repayment of payments under subsection (a)(1), or withholding payments under subsection (b)(1), the Secretary shall provide to the State an opportunity for a hearing.

(d) Rule of construction

Notwithstanding any other provision of this part, a State receiving payments under section 290cc–21 of this title may not, with respect to any agreements required to be contained in the application submitted under section 290cc–29 of this title, be considered to be in violation of any such agreements by reason of the fact that the State, in the regular course of providing services under section 290cc–22(b) of this title to eligible homeless individuals, incidentally provides services to homeless individuals who are not eligible homeless individuals.

(July 1, 1944, ch. 373, title V, §531, as added Pub. L. 100–77, title VI, §611(3), July 22, 1987, 101 Stat. 521; amended Pub. L. 101–645, title V, §511, Nov. 29, 1990, 104 Stat. 4731.)

EDITORIAL NOTES

AMENDMENTS

1990—Pub. L. 101–645 amended section generally, substituting provisions relating to failure to comply with agreements for provision relating to technical assistance.

§290cc–32. Prohibition against certain false statements

(a) In general

(1) A person may not knowingly make or cause to be made any false statement or representation of a material fact in connection with the furnishing of items or services for which amounts may be paid by a State from payments received by the State under section 290cc–21 of this title.

(2) A person with knowledge of the occurrence of any event affecting the right of the person to receive any amounts from payments made to the State under section 290cc–21 of this title may not conceal or fail to disclose any such event with the intent of securing such an amount that the person is not authorized to receive or securing such an amount in an amount greater than the amount the person is authorized to receive.

(b) Criminal penalty for violation of prohibition

Any person who violates a prohibition established in subsection (a) may for each violation be fined in accordance with title 18 or imprisoned for not more than 5 years, or both.

(July 1, 1944, ch. 373, title V, §532, as added Pub. L. 100–77, title VI, §611(3), July 22, 1987, 101 Stat. 521; amended Pub. L. 101–645, title V, §511, Nov. 29, 1990, 104 Stat. 4732.)

EDITORIAL NOTES

AMENDMENTS

1990—Pub. L. 101–645 amended section generally, substituting provisions relating to prohibition against certain false statements for provisions relating to failure to comply with agreements.

§290cc–33. Nondiscrimination

(a) In general

(1) Rule of construction regarding certain civil rights laws

For the purpose of applying the prohibitions against discrimination on the basis of age under the Age Discrimination Act of 1975 [42 U.S.C. 6101 et seq.], on the basis of handicap under section 504 of the Rehabilitation Act of 1973 [29 U.S.C. 794], on the basis of sex under title IX of the Education Amendments of 1972 [20 U.S.C. 1681 et seq.], or on the basis of race, color, or national origin under title VI of the Civil Rights Act of 1964 [42 U.S.C. 2000d et seq.], programs and activities funded in whole or in part with funds made available under section 290cc–21 of this title shall be considered to be programs and activities receiving Federal financial assistance.

(2) Prohibition

No person shall on the ground of sex or religion be excluded from participation in, be denied the benefits of, or be subjected to discrimination under, any program or activity funded in whole or in part with funds made available under section 290cc–21 of this title.

(b) Enforcement

(1) Referrals to Attorney General after notice

Whenever the Secretary finds that a State, or an entity that has received a payment pursuant to section 290cc–21 of this title, has failed to comply with a provision of law referred to in subsection (a)(1), with subsection (a)(2), or with an applicable regulation (including one prescribed to carry out subsection (a)(2)), the Secretary shall notify the chief executive officer of the State and shall request the chief executive officer to secure compliance. If within a reasonable period of time, not to exceed 60 days, the chief executive officer fails or refuses to secure compliance, the Secretary may—

(A) refer the matter to the Attorney General with a recommendation that an appropriate civil

action be instituted;

(B) exercise the powers and functions provided by the Age Discrimination Act of 1975 [42 U.S.C. 6101 et seq.], section 504 of the Rehabilitation Act of 1973 [29 U.S.C. 794], title IX of the Education Amendments of 1972 [20 U.S.C. 1681 et seq.], or title VI of the Civil Rights Act of 1964 [42 U.S.C. 2000d et seq.], as may be applicable; or

(C) take such other actions as may be authorized by law.

(2) Authority of Attorney General

When a matter is referred to the Attorney General pursuant to paragraph (1)(A), or whenever the Attorney General has reason to believe that a State or an entity is engaged in a pattern or practice in violation of a provision of law referred to in subsection (a)(1) or in violation of subsection (a)(2), the Attorney General may bring a civil action in any appropriate district court of the United States for such relief as may be appropriate, including injunctive relief.

(July 1, 1944, ch. 373, title V, §533, as added Pub. L. 100–77, title VI, §611(3), July 22, 1987, 101 Stat. 522; amended Pub. L. 101–645, title V, §511, Nov. 29, 1990, 104 Stat. 4732.)

EDITORIAL NOTES

REFERENCES IN TEXT

The Age Discrimination Act of 1975, referred to in subsecs. (a)(1) and (b)(1)(B), is title III of Pub. L. 94–135, Nov. 28, 1975, 89 Stat. 728, which is classified generally to chapter 76 (§6101 et seq.) of this title. For complete classification of this Act to the Code, see Short Title note set out under section 6101 of this title and Tables.

The Education Amendments of 1972, referred to in subsecs. (a)(1) and (b)(1)(B), is Pub. L. 92–318, June 23, 1972, 86 Stat. 235. Title IX of the Act, known as the Patsy Takemoto Mink Equal Opportunity in Education Act, is classified principally to chapter 38 (§1681 et seq.) of Title 20, Education. For complete classification of title IX to the Code, see Short Title note set out under section 1681 of Title 20 and Tables.

The Civil Rights Act of 1964, referred to in subsecs. (a)(1) and (b)(1)(B), is Pub. L. 88–352, July 2, 1964, 78 Stat. 241. Title VI of the Civil Rights Act of 1964 is classified generally to subchapter V (§2000d et seq.) of chapter 21 of this title. For complete classification of this Act to the Code, see Short Title note set out under section 2000a of this title and Tables.

AMENDMENTS

1990—Pub. L. 101–645 amended section generally, substituting provisions relating to nondiscrimination for provision relating to establishment of prohibition against making certain false statements.

§290cc–34. Definitions

For purposes of this part:

(1) Eligible homeless individual

The term "eligible homeless individual" means an individual described in section 290cc–22(a) of this title.

(2) Homeless individual

The term "homeless individual" has the meaning given such term in section 254b(h)(5) of this title.

(3) State

The term "State" means each of the several States, the District of Columbia, the Commonwealth of Puerto Rico, the Virgin Islands, Guam, American Samoa, and the Commonwealth of the Northern Mariana Islands.

(4) Substance use disorder services

The term "substance use disorder services" has the meaning given the term "substance abuse services" in section 254b(h)(5)(C) [1] of this title.

(July 1, 1944, ch. 373, title V, §534, as added Pub. L. 100–77, title VI, §611(3), July 22, 1987, 101 Stat. 522; amended Pub. L. 101–645, title V, §511, Nov. 29, 1990, 104 Stat. 4733; Pub. L. 107–251, title VI, §601(b), Oct. 26, 2002, 116 Stat. 1665; Pub. L. 114–255, div. B, title IX, §9004(e), Dec. 13, 2016, 130 Stat. 1238.)

EDITORIAL NOTES

REFERENCES IN TEXT

Section 254b(h)(5)(C) of this title, referred to in par. (4), was redesignated section 254b(h)(5)(B) of this title and the definition of "substance abuse services" was amended to define "substance use disorder services" by Pub. L. 115–123, div. E, title IX, §50901(b)(8)(B)(ii), (iii), Feb. 9, 2018, 132 Stat. 285.

AMENDMENTS

2016—Par. (4). Pub. L. 114–255 amended par. (4) generally. Prior to amendment, text read as follows: "The term 'substance abuse' means the abuse of alcohol or other drugs."

2002—Par. (2). Pub. L. 107–251 substituted "254b(h)(5) " for "256(r)".

1990—Pub. L. 101–645 amended section generally, substituting provisions relating to definitions for provisions relating to nondiscrimination.

[1] *See References in Text note below.*

§290cc–35. Funding

(a) Authorization of appropriations

For the purpose of carrying out this part, there is authorized to be appropriated $64,635,000 for each of fiscal years 2023 through 2027.

(b) Effect of insufficient appropriations for minimum allotments

(1) In general

If the amounts made available under subsection (a) for a fiscal year are insufficient for providing each State with an allotment under section 290cc–21 of this title of not less than the applicable amount under section 290cc–24(a)(1) of this title, the Secretary shall, from such amounts as are made available under such subsection, make grants to the States for providing to eligible homeless individuals the services specified in section 290cc–22(b) of this title.

(2) Rule of construction

Paragraph (1) may not be construed to require the Secretary to make a grant under such paragraph to each State.

(July 1, 1944, ch. 373, title V, §535, as added Pub. L. 100–77, title VI, §611(3), July 22, 1987, 101 Stat. 523; amended Pub. L. 100–607, title VIII, §811(a), Nov. 4, 1988, 102 Stat. 3169; Pub. L. 100–628, title VI, §611(a), Nov. 7, 1988, 102 Stat. 3242; Pub. L. 101–93, §5(t)(1), Aug. 16, 1989, 103 Stat. 615; Pub. L. 101–645, title V, §511, Nov. 29, 1990, 104 Stat. 4733; Pub. L. 106–310, div. B, title XXXII, §3203(b), Oct. 17, 2000, 114 Stat. 1191; Pub. L. 114–255, div. B, title IX, §9004(f), Dec. 13, 2016, 130 Stat. 1238; Pub. L. 117–328, div. FF, title I, §1218, Dec. 29, 2022, 136 Stat. 5670.)

EDITORIAL NOTES

PRIOR PROVISIONS

A prior section 290cc–36, act July 1, 1944, ch. 373, title V, §536, as added July 22, 1987, Pub. L. 100–77, title VI, §611(3), 101 Stat. 523, and amended Nov. 4, 1988, Pub. L. 100–607, title VIII, §§802(b)(3), 812(a),

102 Stat. 3169, 3170; Nov. 7, 1988, Pub. L. 100–628, title VI, §§602(b)(3), 612(a), 102 Stat. 3242, 3243; Nov. 18, 1988, Pub. L. 100–690, title II, §2614(b), 102 Stat. 4239; Aug. 16, 1989, Pub. L. 101–93, §5(t)(1), 103 Stat. 615, defined terms used in this part, prior to the general revision of this part by Pub. L. 101–645.

AMENDMENTS

2022—Subsec. (a). Pub. L. 117–328 substituted "2023 through 2027" for "2018 through 2022".

2016—Subsec. (a). Pub. L. 114–255 substituted "$64,635,000 for each of fiscal years 2018 through 2022" for "$75,000,000 for each of the fiscal years 2001 through 2003".

2000—Subsec. (a). Pub. L. 106–310 substituted "fiscal years 2001 through 2003" for "fiscal years 1991 through 1994".

1990—Pub. L. 101–645 amended section generally, substituting present provisions for similar provisions authorizing appropriations and providing for minimum allotments.

1989—Pub. L. 101–93 directed that this section as similarly amended by title VIII of Pub. L. 100–607 and title VI of Pub. L. 100–628 be amended to read as if the amendments made by title VI of Pub. L. 100–628 had not been enacted. See 1988 Amendment note below.

1988—Pub. L. 100–607 and Pub. L. 100–628 made identical amendments, amending section generally. Prior to amendment, section read as follows: "There are authorized to be appropriated to carry out this part $35,000,000 for fiscal year 1987 and such sums as may be necessary for fiscal year 1988."

STATUTORY NOTES AND RELATED SUBSIDIARIES

EFFECTIVE DATE OF 1988 AMENDMENTS

Amendment by Pub. L. 100–628 effective Nov. 7, 1988, see section 631 of Pub. L. 100–628, set out as a note under section 254e of this title.

Amendment by Pub. L. 100–607 effective Nov. 4, 1988, see section 831 of Pub. L. 100–607, set out as a note under section 254e of this title.

PART D—MISCELLANEOUS PROVISIONS RELATING TO SUBSTANCE ABUSE AND MENTAL HEALTH

§290dd. Substance abuse among government and other employees

(a) Programs and services

(1) Development

The Secretary, acting through the Assistant Secretary for Mental Health and Substance Use, shall be responsible for fostering substance abuse prevention and treatment programs and services in State and local governments and in private industry.

(2) Model programs

(A) In general

Consistent with the responsibilities described in paragraph (1), the Secretary, acting through the Assistant Secretary for Mental Health and Substance Use, shall develop a variety of model programs suitable for replication on a cost-effective basis in different types of business concerns and State and local governmental entities.

(B) Dissemination of information

The Secretary, acting through the Assistant Secretary for Mental Health and Substance Use, shall disseminate information and materials relative to such model programs to the State agencies responsible for the administration of substance abuse prevention, treatment, and rehabilitation activities and shall, to the extent feasible provide technical assistance to such agencies as requested.

(b) Deprivation of employment

(1) Prohibition

No person may be denied or deprived of Federal civilian employment or a Federal professional or other license or right solely on the grounds of prior substance abuse.

(2) Application

This subsection shall not apply to employment in—

(A) the Central Intelligence Agency;

(B) the Federal Bureau of Investigation;

(C) the National Security Agency;

(D) any other department or agency of the Federal Government designated for purposes of national security by the President; or

(E) in any position in any department or agency of the Federal Government, not referred to in subparagraphs (A) through (D), which position is determined pursuant to regulations prescribed by the head of such agency or department to be a sensitive position.

(3) Rehabilitation Act

The inapplicability of the prohibition described in paragraph (1) to the employment described in paragraph (2) shall not be construed to reflect on the applicability of the Rehabilitation Act of 1973 [29 U.S.C. 701 et seq.] or other anti-discrimination laws to such employment.

(c) Construction

This section shall not be construed to prohibit the dismissal from employment of a Federal civilian employee who cannot properly function in his employment.

(July 1, 1944, ch. 373, title V, §541, formerly Pub. L. 91–616, title III, §301, Dec. 31, 1970, 84 Stat. 1849, as amended Pub. L. 92–554, Oct. 25, 1972, 86 Stat. 1167; Pub. L. 93–282, title I, §105(a), May 14, 1974, 88 Stat. 127; Pub. L. 94–371, §3(a), July 26, 1976, 90 Stat. 1035; Pub. L. 96–180, §7, Jan. 2, 1980, 93 Stat. 1303; Pub. L. 97–35, title IX, §962(a), Aug. 13, 1981, 95 Stat. 592; renumbered §520 of act July 1, 1944, and amended Pub. L. 98–24, §2(b)(13), Apr. 26, 1983, 97 Stat. 181; Pub. L. 98–509, title III, §301(c)(2), Oct. 19, 1984, 98 Stat. 2364; renumbered §541, Pub. L. 100–77, title VI, §611(2), July 22, 1987, 101 Stat. 516; Pub. L. 100–607, title VIII, §813(2), Nov. 4, 1988, 102 Stat. 3170; Pub. L. 100–628, title VI, §613(2), Nov. 7, 1988, 102 Stat. 3243; Pub. L. 101–93, §5(t)(1), Aug. 16, 1989, 103 Stat. 615; Pub. L. 102–321, title I, §131, July 10, 1992, 106 Stat. 366; Pub. L. 114–255, div. B, title VI, §6001(c)(1), Dec. 13, 2016, 130 Stat. 1203.)

EDITORIAL NOTES

REFERENCES IN TEXT

The Rehabilitation Act of 1973, referred to in subsec. (b)(3), is Pub. L. 93–112, Sept. 26, 1973, 87 Stat. 355, which is classified principally to chapter 16 (§701 et seq.) of Title 29, Labor. For complete classification of this Act to the Code, see Short Title note set out under section 701 of Title 29 and Tables.

CODIFICATION

Section was formerly classified to section 4571 of this title prior to renumbering by Pub. L. 98–24.

AMENDMENTS

2016—Subsec. (a). Pub. L. 114–255 substituted "Assistant Secretary for Mental Health and Substance Use" for "Administrator of the Substance Abuse and Mental Health Services Administration" wherever appearing.

1992—Pub. L. 102–321 amended section generally, substituting provisions relating to substance abuse among government and other employees for provisions relating to technical assistance to States relative to alcohol abuse and alcoholism programs.

1989—Subsec. (a)(4). Pub. L. 101–93 directed that subsec. (a)(4) of this section as similarly amended by title VIII of Pub. L. 100–607 and title VI of Pub. L. 100–628 be amended to read as if the amendments made by title VI of Pub. L. 100–628 had not been enacted. See 1988 Amendment note below.

1988—Subsec. (a)(4). Pub. L. 100–607 and Pub. L. 100–628 made identical technical amendments to

reference to section 290dd–2 of this title to reflect renumbering of corresponding section of original act.

1984—Pub. L. 98–509 amended directory language of Pub. L. 98–24, §2(b)(13). See 1983 Amendment note below.

1983—Pub. L. 98–24, §2(b)(13), as amended by Pub. L. 98–509, renumbered section 4571 of this title as this section.

Subsec. (a). Pub. L. 98–24, §2(b)(13)(A)(i), substituted "the National Institute on Alcohol Abuse and Alcoholism" for "the Institute".

Subsec. (a)(4). Pub. L. 98–24, §2(b)(13)(A)(ii), substituted "section 290dd–2 of this title" for "section 4581 of this title".

Subsec. (b). Pub. L. 98–24, §2(b)(13)(A)(iii), substituted "this subchapter" for references to "this chapter", meaning chapter 60 (§4541 et seq.) of this title, and the Drug Abuse Prevention, Treatment, and Rehabilitation Act [21 U.S.C. 1101 et seq.].

1981—Pub. L. 97–35 restructured provisions and substituted provisions relating to technical assistance for enumerated activities, and improvement of coordination with Drug Abuse Prevention, Treatment, and Rehabilitation Act, for provisions authorizing appropriations through fiscal year ending Sept. 30, 1981, for covered activities.

1980—Pub. L. 96–180 authorized appropriation of $60,000,000 and $65,000,000 for fiscal years ending Sept. 30, 1980, and 1981.

1976—Pub. L. 94–371 struck out "and" after "1975" and inserted provisions authorizing $70,000,000 to be appropriated for fiscal year ending Sept. 30, 1977, $77,000,000 to be appropriated for fiscal year ending Sept. 30, 1978, and $85,000,000 to be appropriated for fiscal year ending Sept. 30, 1979.

1974—Pub. L. 93–282 authorized appropriation of $80,000,000 for fiscal years ending June 30, 1975 and June 30, 1976.

1972—Pub. L. 92–554 substituted "for each of the next two fiscal years" for "for the fiscal year ending June 30, 1973".

STATUTORY NOTES AND RELATED SUBSIDIARIES

EFFECTIVE DATE OF 1992 AMENDMENT

Amendment by Pub. L. 102–321 effective Oct. 1, 1992, with provision for programs providing financial assistance, see section 801(c), (d) of Pub. L. 102–321, set out as a note under section 236 of this title.

EFFECTIVE DATE OF 1988 AMENDMENTS

Amendment by Pub. L. 100–628 effective Nov. 7, 1988, see section 631 of Pub. L. 100–628, set out as a note under section 254e of this title.

Amendment by Pub. L. 100–607 effective Nov. 4, 1988, see section 831 of Pub. L. 100–607, set out as a note under section 254e of this title.

§290dd–1. Admission of substance abusers to private and public hospitals and outpatient facilities

(a) Nondiscrimination

Substance abusers who are suffering from medical conditions shall not be discriminated against in admission or treatment, solely because of their substance abuse, by any private or public general hospital, or outpatient facility (as defined in section 300s–3(4) of this title) which receives support in any form from any program supported in whole or in part by funds appropriated to any Federal department or agency.

(b) Regulations

(1) In general

The Secretary shall issue regulations for the enforcement of the policy of subsection (a) with respect to the admission and treatment of substance abusers in hospitals and outpatient facilities which receive support of any kind from any program administered by the Secretary. Such regulations shall include procedures for determining (after opportunity for a hearing if requested) if a violation of subsection (a) has occurred, notification of failure to comply with such subsection,

and opportunity for a violator to comply with such subsection. If the Secretary determines that a hospital or outpatient facility subject to such regulations has violated subsection (a) and such violation continues after an opportunity has been afforded for compliance, the Secretary may suspend or revoke, after opportunity for a hearing, all or part of any support of any kind received by such hospital from any program administered by the Secretary. The Secretary may consult with the officials responsible for the administration of any other Federal program from which such hospital or outpatient facility receives support of any kind, with respect to the suspension or revocation of such other Federal support for such hospital or outpatient facility.

(2) Department of Veterans Affairs

The Secretary of Veterans Affairs, acting through the Under Secretary for Health, shall, to the maximum feasible extent consistent with their responsibilities under title 38, prescribe regulations making applicable the regulations prescribed by the Secretary under paragraph (1) to the provision of hospital care, nursing home care, domiciliary care, and medical services under such title 38 to veterans suffering from substance abuse. In prescribing and implementing regulations pursuant to this paragraph, the Secretary shall, from time to time, consult with the Secretary of Health and Human Services in order to achieve the maximum possible coordination of the regulations, and the implementation thereof, which they each prescribe.

(July 1, 1944, ch. 373, title V, §542, formerly Pub. L. 91–616, title II, §201, Dec. 31, 1970, 84 Stat. 1849, as amended Pub. L. 96–180, §6(a), (b)(1), (2)(B), Jan. 2, 1980, 93 Stat. 1302, 1303; Pub. L. 97–35, title IX, §§961, 966(d), (e), Aug. 13, 1981, 95 Stat. 592, 595; renumbered §521 of act July 1, 1944, and amended Pub. L. 98–24, §2(b)(13), Apr. 26, 1983, 97 Stat. 181; Pub. L. 98–509, title III, §301(c)(2), Oct. 19, 1984, 98 Stat. 2364; Pub. L. 99–570, title VI, §6002(b)(1), Oct. 27, 1986, 100 Stat. 3207–158; renumbered §542, Pub. L. 100–77, title VI, §611(2), July 22, 1987, 101 Stat. 516; Pub. L. 102–321, title I, §131, July 10, 1992, 106 Stat. 368; Pub. L. 103–446, title XII, §1203(a)(2), Nov. 2, 1994, 108 Stat. 4689.)

EDITORIAL NOTES

CODIFICATION

Section was formerly classified to section 4561 of this title prior to renumbering by Pub. L. 98–24.

AMENDMENTS

1994—Subsec. (b)(2). Pub. L. 103–446 substituted "Under Secretary for Health" for "Chief Medical Director".

1992—Pub. L. 102–321 amended section generally, substituting provisions relating to admission of substance abusers to private and public hospitals and outpatient facilities for provisions relating to programs for government and other employees.

1986—Subsec. (a). Pub. L. 99–570, §6002(b)(1), redesignated subsec. (b) as (a), struck out "similar" after "fostering and encouraging" in par. (1), and struck out former subsec. (a) which read as follows: "The Office of Personnel Management shall be responsible for developing and maintaining, in cooperation with the Secretary and with other Federal agencies and departments, and in accordance with the provisions of subpart F of part III of title 5, appropriate prevention, treatment, and rehabilitation programs and services for alcohol abuse and alcoholism among Federal civilian employees, consistent with the purposes of this chapter. Such agencies and departments are encouraged to extend, to the extent feasible, these programs and services to the families of alcoholic employees and to employees who have family members who are alcoholics. Such policies and services shall make optimal use of existing governmental facilities, services, and skills."

Subsecs. (b) to (d). Pub. L. 99–570, §6002(b)(1)(C), redesignated subsecs. (c) and (d) as (b) and (c), respectively. Former subsec. (b) redesignated (a).

1984—Pub. L. 98–509 amended directory language of Pub. L. 98–24, §2(b)(13). See 1983 Amendment note below.

1983—Pub. L. 98–24, §2(b)(13), as amended by Pub. L. 98–509, renumbered section 4561 of this title as this section.

Subsec. (b)(4). Pub. L. 98–24, §2(b)(13)(B)(i), substituted "section 290ee–1 of this title" for "section 1180(b) of title 21".

Subsec. (d). Pub. L. 98–24, §2(b)(13)(B)(ii), substituted "this section" for "this subchapter", meaning subchapter II (§4561 et seq.) of chapter 60 of this title.

1981—Subsec. (b). Pub. L. 97–35, §§961, 966(d), made changes in nomenclature, and substituted provisions relating to responsible State administrative agencies, for provisions relating to single State agencies designated pursuant to section 4573 of this title.

1980—Pub. L. 96–180, §6(b)(2)(A), amended section catchline.

Subsec. (a). Pub. L. 96–180, §6(a), substituted "Office of Personnel Management" for "Civil Service Commission" and inserted provisions that require compliance with provisions of subpart F of part III of title 5 and encourage agencies and departments to extend the programs and services to the families of alcoholic employees and to employees who have family members who are alcoholics.

Subsec. (b). Pub. L. 96–180, §6(b)(1), designated existing provisions as par. (1), made the Secretary responsible for encouragement of programs and services, required the programs and services to be designed for application to families of employees and to employees who have family members who are alcoholics, and added pars. (2) to (4).

STATUTORY NOTES AND RELATED SUBSIDIARIES

EFFECTIVE DATE OF 1992 AMENDMENT

Amendment by Pub. L. 102–321 effective Oct. 1, 1992, with provision for programs providing financial assistance, see section 801(c), (d) of Pub. L. 102–321, set out as a note under section 236 of this title.

§290dd–2. Confidentiality of records

(a) Requirement

Records of the identity, diagnosis, prognosis, or treatment of any patient which are maintained in connection with the performance of any program or activity relating to substance use disorder education, prevention, training, treatment, rehabilitation, or research, which is conducted, regulated, or directly or indirectly assisted by any department or agency of the United States shall, except as provided in subsection (e), be confidential and be disclosed only for the purposes and under the circumstances expressly authorized under subsection (b).

(b) Permitted disclosure

(1) Consent

The following shall apply with respect to the contents of any record referred to in subsection (a):

(A) Such contents may be used or disclosed in accordance with the prior written consent of the patient with respect to whom such record is maintained.

(B) Once prior written consent of the patient has been obtained, such contents may be used or disclosed by a covered entity, business associate, or a program subject to this section for purposes of treatment, payment, and health care operations as permitted by the HIPAA regulations. Any information so disclosed may then be redisclosed in accordance with the HIPAA regulations. Section 17935(c) of this title shall apply to all disclosures pursuant to subsection (b)(1) of this section.

(C) It shall be permissible for a patient's prior written consent to be given once for all such future uses or disclosures for purposes of treatment, payment, and health care operations, until such time as the patient revokes such consent in writing.

(D) Section 17935(a) of this title shall apply to all disclosures pursuant to subsection (b)(1) of this section.

(2) Method for disclosure

Whether or not the patient, with respect to whom any given record referred to in subsection (a) is maintained, gives written consent, the content of such record may be disclosed as follows:

(A) To medical personnel to the extent necessary to meet a bona fide medical emergency.

(B) To qualified personnel for the purpose of conducting scientific research, management

audits, financial audits, or program evaluation, but such personnel may not identify, directly or indirectly, any individual patient in any report of such research, audit, or evaluation, or otherwise disclose patient identities in any manner.

(C) If authorized by an appropriate order of a court of competent jurisdiction granted after application showing good cause therefor, including the need to avert a substantial risk of death or serious bodily harm. In assessing good cause the court shall weigh the public interest and the need for disclosure against the injury to the patient, to the physician-patient relationship, and to the treatment services. Upon the granting of such order, the court, in determining the extent to which any disclosure of all or any part of any record is necessary, shall impose appropriate safeguards against unauthorized disclosure.

(D) To a public health authority, so long as such content meets the standards established in section 164.514(b) of title 45, Code of Federal Regulations (or successor regulations) for creating de-identified information.

(c) Use of records in criminal, civil, or administrative contexts

Except as otherwise authorized by a court order under subsection (b)(2)(C) or by the consent of the patient, a record referred to in subsection (a), or testimony relaying the information contained therein, may not be disclosed or used in any civil, criminal, administrative, or legislative proceedings conducted by any Federal, State, or local authority, against a patient, including with respect to the following activities:

(1) Such record or testimony shall not be entered into evidence in any criminal prosecution or civil action before a Federal or State court.

(2) Such record or testimony shall not form part of the record for decision or otherwise be taken into account in any proceeding before a Federal, State, or local agency.

(3) Such record or testimony shall not be used by any Federal, State, or local agency for a law enforcement purpose or to conduct any law enforcement investigation.

(4) Such record or testimony shall not be used in any application for a warrant.

(d) Application

The prohibitions of this section continue to apply to records concerning any individual who has been a patient, irrespective of whether or when such individual ceases to be a patient.

(e) Nonapplicability

The prohibitions of this section do not apply to any interchange of records—

(1) within the Uniformed Services or within those components of the Department of Veterans Affairs furnishing health care to veterans; or

(2) between such components and the Uniformed Services.

The prohibitions of this section do not apply to the reporting under State law of incidents of suspected child abuse and neglect to the appropriate State or local authorities.

(f) Penalties

The provisions of sections 1176 and 1177 of the Social Security Act [42 U.S.C. 1320d–5, 1320d–6] shall apply to a violation of this section to the extent and in the same manner as such provisions apply to a violation of part C of title XI of such Act [42 U.S.C. 1320d et seq.]. In applying the previous sentence—

(1) the reference to "this subsection" in subsection (a)(2) of such section 1176 shall be treated as a reference to "this subsection (including as applied pursuant to section 290dd–2(f) of this title)"; and

(2) in subsection (b) of such section 1176—

(A) each reference to "a penalty imposed under subsection (a)" shall be treated as a reference to "a penalty imposed under subsection (a) (including as applied pursuant to section 290dd–2(f) of this title)"; and

(B) each reference to "no damages obtained under subsection (d)" shall be treated as a reference to "no damages obtained under subsection (d) (including as applied pursuant to

section 290dd–2(f) of this title)".

(g) Regulations

Except as provided in subsection (h), the Secretary shall prescribe regulations to carry out the purposes of this section. Such regulations may contain such definitions, and may provide for such safeguards and procedures, including procedures and criteria for the issuance and scope of orders under subsection (b)(2)(C), as in the judgment of the Secretary are necessary or proper to effectuate the purposes of this section, to prevent circumvention or evasion thereof, or to facilitate compliance therewith.

(h) Application to Department of Veterans Affairs

The Secretary of Veterans Affairs, acting through the Under Secretary for Health, shall, to the maximum feasible extent consistent with their responsibilities under title 38, prescribe regulations making applicable the regulations prescribed by the Secretary of Health and Human Services under subsection (g) to records maintained in connection with the provision of hospital care, nursing home care, domiciliary care, and medical services under such title 38 to veterans suffering from substance use disorder. In prescribing and implementing regulations pursuant to this subsection, the Secretary of Veterans Affairs shall, from time to time, consult with the Secretary of Health and Human Services in order to achieve the maximum possible coordination of the regulations, and the implementation thereof, which they each prescribe.

(i) Antidiscrimination

(1) In general

No entity shall discriminate against an individual on the basis of information received by such entity pursuant to an inadvertent or intentional disclosure of records, or information contained in records, described in subsection (a) in—

(A) admission, access to, or treatment for health care;

(B) hiring, firing, or terms of employment, or receipt of worker's compensation;

(C) the sale, rental, or continued rental of housing;

(D) access to Federal, State, or local courts; or

(E) access to, approval of, or maintenance of social services and benefits provided or funded by Federal, State, or local governments.

(2) Recipients of Federal funds

No recipient of Federal funds shall discriminate against an individual on the basis of information received by such recipient pursuant to an intentional or inadvertent disclosure of such records or information contained in records described in subsection (a) in affording access to the services provided with such funds.

(j) Notification in case of breach

The provisions of section 17932 of this title shall apply to a program or activity described in subsection (a), in case of a breach of records described in subsection (a), to the same extent and in the same manner as such provisions apply to a covered entity in the case of a breach of unsecured protected health information.

(k) Definitions

For purposes of this section:

(1) Breach

The term "breach" has the meaning given such term for purposes of the HIPAA regulations.

(2) Business associate

The term "business associate" has the meaning given such term for purposes of the HIPAA regulations.

(3) Covered entity

The term "covered entity" has the meaning given such term for purposes of the HIPAA

regulations.

(4) Health care operations

The term "health care operations" has the meaning given such term for purposes of the HIPAA regulations.

(5) HIPAA regulations

The term "HIPAA regulations" has the meaning given such term for purposes of parts 160 and 164 of title 45, Code of Federal Regulations.

(6) Payment

The term "payment" has the meaning given such term for purposes of the HIPAA regulations.

(7) Public health authority

The term "public health authority" has the meaning given such term for purposes of the HIPAA regulations.

(8) Treatment

The term "treatment" has the meaning given such term for purposes of the HIPAA regulations.

(9) Unsecured protected health information

The term "unprotected [1] health information" has the meaning given such term for purposes of the HIPAA regulations.

(July 1, 1944, ch. 373, title V, §543, formerly Pub. L. 91–616, title III, §321, Dec. 31, 1970, 84 Stat. 1852, as amended Pub. L. 93–282, title I, §121(a), May 14, 1974, 88 Stat. 130; Pub. L. 94–371, §11(a), (b), July 26, 1976, 90 Stat. 1041; Pub. L. 94–581, title I, §111(c)(1), Oct. 21, 1976, 90 Stat. 2852; renumbered §522 of act July 1, 1944, and amended Pub. L. 98–24, §2(b)(13), Apr. 26, 1983, 97 Stat. 181; renumbered §543, Pub. L. 100–77, title VI, §611(2), July 22, 1987, 101 Stat. 516; Pub. L. 102–321, title I, §131, July 10, 1992, 106 Stat. 368; Pub. L. 102–405, title III, §302(e)(1), Oct. 9, 1992, 106 Stat. 1985; Pub. L. 105–392, title IV, §402(c), Nov. 13, 1998, 112 Stat. 3588; Pub. L. 116–136, div. A, title III, §3221(a)–(h), Mar. 27, 2020, 134 Stat. 375–378.)

EDITORIAL NOTES

REFERENCES IN TEXT

The Social Security Act, referred to in subsec. (f), is act Aug. 14, 1935, ch. 531, 49 Stat. 620. Part C of title XI of the Act is classified generally to part C (§1320d et seq.) of subchapter XI of chapter 7 of this title. For complete classification of this Act to the Code, see section 1305 of this title and Tables.

CODIFICATION

Section was formerly classified to section 4581 of this title prior to renumbering by Pub. L. 98–24.

AMENDMENTS

2020—Subsec. (a). Pub. L. 116–136, §3221(a), substituted "substance use disorder" for "substance abuse".

Subsec. (b)(1). Pub. L. 116–136, §3221(b), amended par. (1) generally. Prior to amendment, text read as follows: "The content of any record referred to in subsection (a) may be disclosed in accordance with the prior written consent of the patient with respect to whom such record is maintained, but only to such extent, under such circumstances, and for such purposes as may be allowed under regulations prescribed pursuant to subsection (g)."

Subsec. (b)(2)(D). Pub. L. 116–136, §3221(c), added subpar. (D).

Subsec. (c). Pub. L. 116–136, §3221(e), amended subsec. (c) generally. Prior to amendment, text read as follows: "Except as authorized by a court order granted under subsection (b)(2)(C), no record referred to in subsection (a) may be used to initiate or substantiate any criminal charges against a patient or to conduct any investigation of a patient."

Subsec. (f). Pub. L. 116–136, §3221(f), amended subsec. (f) generally. Prior to amendment, text read as follows: "Any person who violates any provision of this section or any regulation issued pursuant to this section shall be fined in accordance with title 18."

Subsec. (h). Pub. L. 116–136, §3221(a), substituted "substance use disorder" for "substance abuse".

Subsec. (i). Pub. L. 116–136, §3221(g), added subsec. (i).

Subsec. (j). Pub. L. 116–136, §3221(h), added subsec. (j).

Subsec. (k). Pub. L. 116–136, §3221(d), added subsec. (k).

1998—Subsec. (e)(1), (2). Pub. L. 105–392 substituted "Uniformed Services" for "Armed Forces".

1992—Pub. L. 102–405 substituted "Under Secretary for Health" for "Chief Medical Director" in subsec. (h).

Pub. L. 102–321 amended section generally, substituting provisions relating to confidentiality of records for provisions relating to admission of alcohol abusers and alcoholics to general hospitals and outpatient facilities.

1983—Pub. L. 98–24, §2(b)(13), renumbered section 4581 of this title as this section.

Subsec. (a). Pub. L. 98–24, §2(b)(13)(C), made a technical amendment to reference to section 300s–3 of this title.

1976—Subsec. (a). Pub. L. 94–371, §11(a), inserted ", or outpatient facility (as defined in section 300s–3(6) of this title)" after "hospital".

Subsec. (b)(1). Pub. L. 94–371, §11(b), inserted "and outpatient facilities" after "hospitals", and "or outpatient facility" after "hospital" wherever appearing, and substituted "shall issue regulations not later than December 31, 1976" for "is authorized to make regulations".

Subsec. (b)(2). Pub. L. 94–581 provided that subsec. (b)(2), which directed the Administrator of Veteran's Affairs, through the Chief Medical Director, to prescribe regulations making applicable the regulations prescribed by the Secretary under subsec. (b)(1) to the provision of hospital care, nursing home care, domiciliary care, and medical services under title 38 to veterans suffering from alcohol abuse or alcoholism and to consult with the Secretary in order to achieve the maximum possible coordination of the regulations, and the implementation thereof, which they each prescribed, was superseded by section 4131 [now 7331] et seq. of Title 38, Veterans' Benefits.

1974—Subsec. (a). Pub. L. 93–282, in revising text, prohibited discrimination because of alcohol abuse, substituted provisions respecting eligibility for admission and treatment based on suffering from medical conditions for former provision based on medical need and ineligibility, because of discrimination, for support in any form from any program supported in whole or in part by funds appropriated to any Federal department or agency for former requirement for treatment by a general hospital which received Federal funds, and deleted prohibition against receiving Federal financial assistance for violation of section and for termination of Federal assistance on failure to comply, now incorporated in regulation authorization of subsec. (b) of this section.

Subsec. (b). Pub. L. 93–282 substituted provisions respecting issuance of regulations by the Secretary concerning enforcement procedures and suspension or revocation of Federal support and by the Administrator concerning applicable regulations for veterans, and for coordination of the respective regulations for former provisions respecting judicial review.

STATUTORY NOTES AND RELATED SUBSIDIARIES

EFFECTIVE DATE OF 1992 AMENDMENT

Amendment by Pub. L. 102–321 effective Oct. 1, 1992, with provision for programs providing financial assistance, see section 801(c), (d) of Pub. L. 102–321, set out as a note under section 236 of this title.

EFFECTIVE DATE OF 1976 AMENDMENT

Amendment by Pub. L. 94–581 effective Oct. 21, 1976, see section 211 of Pub. L. 94–581, set out as a note under section 111 of Title 38, Veterans' Benefits.

REGULATIONS

Pub. L. 116–136, div. A, title III, §3221(i), Mar. 27, 2020, 134 Stat. 378, provided that:

"(1) IN GENERAL.—The Secretary of Health and Human Services, in consultation with appropriate Federal agencies, shall make such revisions to regulations as may be necessary for implementing and enforcing the amendments made by this section [amending this section], such that such amendments shall apply with respect to uses and disclosures of information occurring on or after the date that is 12 months after the date of enactment of this Act [Mar. 27, 2020].

"(2) EASILY UNDERSTANDABLE NOTICE OF PRIVACY PRACTICES.—Not later than 1 year after the date of enactment of this Act, the Secretary of Health and Human Services, in consultation with appropriate legal, clinical, privacy, and civil rights experts, shall update section 164.520 of title 45, Code of Federal Regulations, so that covered entities and entities creating or maintaining the records described in

subsection (a) provide notice, written in plain language, of privacy practices regarding patient records referred to in section 543(a) of the Public Health Service Act (42 U.S.C. 290dd–2(a)), including—

"(A) a statement of the patient's rights, including self-pay patients, with respect to protected health information and a brief description of how the individual may exercise these rights (as required by subsection (b)(1)(iv) of such section 164.520); and

"(B) a description of each purpose for which the covered entity is permitted or required to use or disclose protected health information without the patient's written authorization (as required by subsection (b)(2) of such section 164.520)."

CONSTRUCTION OF 2020 AMENDMENT

Pub. L. 116–136, div. A, title III, §3221(j), Mar. 27, 2020, 134 Stat. 379, provided that: "Nothing in this Act [div. A of Pub. L. 116–136, see Tables for Classification] or the amendments made by this Act shall be construed to limit—

"(1) a patient's right, as described in section 164.522 of title 45, Code of Federal Regulations, or any successor regulation, to request a restriction on the use or disclosure of a record referred to in section 543(a) of the Public Health Service Act (42 U.S.C. 290dd–2(a)) for purposes of treatment, payment, or health care operations; or

"(2) a covered entity's choice, as described in section 164.506 of title 45, Code of Federal Regulations, or any successor regulation, to obtain the consent of the individual to use or disclose a record referred to in such section 543(a) to carry out treatment, payment, or health care operation."

JESSIE'S LAW

Pub. L. 115–271, title VII, §§7051–7053, Oct. 24, 2018, 132 Stat. 4017, 4018, as amended by Pub. L. 119–44, title II, §205, Dec. 1, 2025, 139 Stat. 680, provided that:

"SEC. 7051. INCLUSION OF OPIOID ADDICTION HISTORY IN PATIENT RECORDS.

"(a) BEST PRACTICES.—

"(1) IN GENERAL.—Not later than 1 year after the date of enactment of this Act [Oct. 24, 2018], the Secretary of Health and Human Services (in this section referred to as the 'Secretary'), in consultation with appropriate stakeholders, including a patient with a history of opioid use disorder, an expert in electronic health records, an expert in the confidentiality of patient health information and records, and a health care provider, shall identify or facilitate the development of best practices regarding—

"(A) the circumstances under which information that a patient has provided to a health care provider regarding such patient's history of opioid use disorder should, only at the patient's request, be prominently displayed in the medical records (including electronic health records) of such patient;

"(B) what constitutes the patient's request for the purpose described in subparagraph (A); and

"(C) the process and methods by which the information should be so displayed.

"(2) DISSEMINATION.—The Secretary shall disseminate the best practices developed under paragraph (1) to health care providers and State agencies.

"(b) REQUIREMENTS.—In identifying or facilitating the development of best practices under subsection (a), as applicable, the Secretary, in consultation with appropriate stakeholders, shall consider the following:

"(1) The potential for addiction relapse or overdose, including overdose death, when opioid medications are prescribed to a patient recovering from opioid use disorder.

"(2) The benefits of displaying information about a patient's opioid use disorder history in a manner similar to other potentially lethal medical concerns, including drug allergies and contraindications.

"(3) The importance of prominently displaying information about a patient's opioid use disorder when a physician or medical professional is prescribing medication, including methods for avoiding alert fatigue in providers.

"(4) The importance of a variety of appropriate medical professionals, including physicians, nurses, and pharmacists, having access to information described in this section when prescribing or dispensing opioid medication, consistent with Federal and State laws and regulations.

"(5) The importance of protecting patient privacy, including the requirements related to consent for disclosure of substance use disorder information under all applicable laws and regulations.

"(6) All applicable Federal and State laws and regulations.

"SEC. 7052. COMMUNICATION WITH FAMILIES DURING EMERGENCIES.

"(a) PROMOTING AWARENESS OF AUTHORIZED DISCLOSURES DURING EMERGENCIES .—The Secretary of Health and Human Services shall annually notify health care providers regarding permitted disclosures under Federal health care privacy law during emergencies, including overdoses, of

certain health information to families, caregivers, and health care providers.

"(b) USE OF MATERIAL.—For the purposes of carrying out subsection (a), the Secretary of Health and Human Services may use material produced under section 7053 of this Act or section 11004 of the 21st Century Cures Act (42 U.S.C. 1320d–2 note).

"SEC. 7053. DEVELOPMENT AND DISSEMINATION OF MODEL TRAINING PROGRAMS FOR SUBSTANCE USE DISORDER PATIENT RECORDS.

"(a) INITIAL PROGRAMS AND MATERIALS.—Not later than 1 year after the date of the enactment of this Act [Oct. 24, 2018], the Secretary of Health and Human Services (in this section referred to as the 'Secretary'), in consultation with appropriate experts, shall identify the following model programs and materials (or if no such programs or materials exist, recognize private or public entities to develop and disseminate such programs and materials):

"(1) Model programs and materials for training health care providers (including physicians, emergency medical personnel, psychiatrists, psychologists, counselors, therapists, nurse practitioners, physician assistants, behavioral health facilities and clinics, care managers, and hospitals, including individuals such as general counsels or regulatory compliance staff who are responsible for establishing provider privacy policies) concerning the permitted uses and disclosures, consistent with the standards and regulations governing the privacy and security of substance use disorder patient records promulgated by the Secretary under section 543 of the Public Health Service Act (42 U.S.C. 290dd–2) for the confidentiality of patient records.

"(2) Model programs and materials for training patients and their families regarding their rights to protect and obtain information under the standards and regulations described in paragraph (1).

"(b) REQUIREMENTS.—The model programs and materials described in paragraphs (1) and (2) of subsection (a) shall address circumstances under which disclosure of substance use disorder patient records is needed to—

"(1) facilitate communication between substance use disorder treatment providers and other health care providers to promote and provide the best possible integrated care;

"(2) avoid inappropriate prescribing that can lead to dangerous drug interactions, overdose, or relapse; and

"(3) notify and involve families and caregivers when individuals experience an overdose.

"(c) PERIODIC UPDATES.—The Secretary shall—

"(1) periodically review and update the model program and materials identified or developed under subsection (a); and

"(2) disseminate such updated programs and materials to the individuals described in subsection (a)(1).

"(d) INPUT OF CERTAIN ENTITIES.—In identifying, reviewing, or updating the model programs and materials under this section, the Secretary shall solicit the input of relevant stakeholders."

REPORT OF ADMINISTRATOR OF VETERANS' AFFAIRS TO CONGRESSIONAL COMMITTEES; PUBLICATION IN FEDERAL REGISTER

Pub. L. 93–282, title I, §121(b), May 14, 1974, 88 Stat. 131, which directed Administrator of Veterans' Affairs to submit to appropriate committees of House of Representatives and Senate a full report (1) on regulations (including guidelines, policies, and procedures thereunder) he had prescribed pursuant to section 321(b)(2) of Comprehensive Alcohol Abuse and Alcoholism Prevention, Treatment, and Rehabilitation Act of 1970 [former 42 U.S.C. 290dd–2(b)(2)], (2) explaining bases for any inconsistency between such regulations and regulations of Secretary under section 321(b)(1) of such Act [42 U.S.C. 290dd–2(b)(1)], (3) on extent, substance, and results of his consultations with Secretary respecting prescribing and implementation of Administrator's regulations, and (4) containing such recommendations for legislation and administrative actions as he determined were necessary and desirable, with Administrator to submit report not later than sixty days after effective date of regulations prescribed by Secretary under such section 321(b)(1) [42 U.S.C. 290dd–2(b)(1)], and to publish such report in Federal Register, was characterized by section 111(c)(5) of Pub. L. 94–581 as having been superseded by section 4134 [now 7334] of Title 38, Veterans' Benefits.

[1] *So in original.*

§290dd–2a. Promoting access to information on evidence-based programs and practices

(a) In general

The Assistant Secretary shall, as appropriate, improve access to reliable and valid information on evidence-based programs and practices, including information on the strength of evidence associated with such programs and practices, related to mental and substance use disorders for States, local communities, nonprofit entities, and other stakeholders, by posting on the Internet website of the Administration information on evidence-based programs and practices that have been reviewed by the Assistant Secretary in accordance with the requirements of this section.

(b) Applications

(1) Application period

In carrying out subsection (a), the Assistant Secretary may establish a period for the submission of applications for evidence-based programs and practices to be posted publicly in accordance with subsection (a).

(2) Notice

In establishing the application period under paragraph (1), the Assistant Secretary shall provide for the public notice of such application period in the Federal Register. Such notice may solicit applications for evidence-based programs and practices to address gaps in information identified by the Assistant Secretary, the National Mental Health and Substance Use Policy Laboratory established under section 290aa–0 of this title, or the Assistant Secretary for Planning and Evaluation, including pursuant to the evaluation and recommendations under section 6021 of the Helping Families in Mental Health Crisis Reform Act of 2016 or priorities identified in the strategic plan under section 290aa(l) of this title.

(c) Requirements

The Assistant Secretary may establish minimum requirements for the applications submitted under subsection (b), including applications related to the submission of research and evaluation.

(d) Review and rating

(1) In general

The Assistant Secretary shall review applications prior to public posting in accordance with subsection (a), and may prioritize the review of applications for evidence-based programs and practices that are related to topics included in the notice provided under subsection (b)(2).

(2) System

In carrying out paragraph (1), the Assistant Secretary may utilize a rating and review system, which may include information on the strength of evidence associated with the evidence-based programs and practices and a rating of the methodological rigor of the research supporting the applications.

(3) Public access to metrics and rating

The Assistant Secretary shall make the metrics used to evaluate applications under this section, and any resulting ratings of such applications, publicly available.

(July 1, 1944, ch. 373, title V, §543A, as added Pub. L. 114–255, div. B, title VII, §7002, Dec. 13, 2016, 130 Stat. 1222.)

EDITORIAL NOTES

REFERENCES IN TEXT

Section 6021 of the Helping Families in Mental Health Crisis Reform Act of 2016, referred to in subsec. (b)(2), is section 6021 of Pub. L. 114–255, which is set out as a note under section 290aa of this title.

§290dd–3. Grants for reducing overdose deaths

(a) Establishment

(1) In general

The Secretary shall award grants to eligible entities to expand access to drugs or devices approved, cleared, or otherwise legally marketed under the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 301 et seq.] for emergency treatment of known or suspected opioid overdose.

(2) Eligible entity

For purposes of this section, the term "eligible entity" means a State, Territory, locality, or Indian Tribe or Tribal organization (as those terms are defined in section 5304 of title 25).

(3) Subgrants

For the purposes for which a grant is awarded under this section, the eligible entity receiving the grant may award subgrants to a Federally qualified health center (as defined in section 1395x(aa) of this title), an opioid treatment program (as defined in section 8.2 of title 42, Code of Federal Regulations (or any successor regulations)), any practitioner dispensing narcotic drugs for the purpose of maintenance or detoxification treatment, or any nonprofit organization that the Secretary deems appropriate, which may include Urban Indian organizations (as defined in section 1603 of title 25).

(4) Prescribing

For purposes of this section, the term "prescribing" means, with respect to a drug or device approved, cleared, or otherwise legally marketed under the Federal Food, Drug, and Cosmetic Act for emergency treatment of known or suspected opioid overdose, the practice of prescribing such drug or device—

(A) in conjunction with an opioid prescription for patients at an elevated risk of overdose, including patients prescribed both an opioid and a benzodiazepine;

(B) in conjunction with an opioid agonist approved under section 505 of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 355] for the treatment of opioid use disorder;

(C) to the caregiver or a close relative of patients at an elevated risk of overdose from opioids; or

(D) in other circumstances in which a provider identifies a patient is at an elevated risk for an intentional or unintentional overdose from heroin or prescription opioid therapies.

(b) Application

To be eligible to receive a grant under this section, an eligible entity shall submit to the Secretary, in such form and manner as specified by the Secretary, an application that describes—

(1) the extent to which the area to which the entity will furnish services through use of the grant is experiencing significant morbidity and mortality caused by opioid abuse;

(2) the criteria that will be used to identify eligible patients to participate in such program; and

(3) a plan for sustaining the program after Federal support for the program has ended.

(c) Use of funds

An eligible entity receiving a grant under this section may use amounts under the grant for any of the following activities, but may use not more than 20 percent of the grant funds for activities described in paragraphs (3) and (4):

(1) To establish a program for prescribing a drug or device approved, cleared, or otherwise legally marketed under the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 301 et seq.] for emergency treatment of known or suspected opioid overdose.

(2) To train and provide resources for health care providers and pharmacists on the prescribing of drugs or devices approved, cleared, or otherwise legally marketed under the Federal Food, Drug, and Cosmetic Act for emergency treatment of known or suspected opioid overdose.

(3) To purchase drugs or devices approved, cleared, or otherwise legally marketed under the Federal Food, Drug, and Cosmetic Act for emergency treatment of known or suspected opioid overdose, for distribution under the program described in paragraph (1).

(4) To offset the co-payments and other cost sharing associated with drugs or devices approved,

cleared, or otherwise legally marketed under the Federal Food, Drug, and Cosmetic Act for emergency treatment of known or suspected opioid overdose.

(5) To establish protocols to connect patients who have experienced an overdose with appropriate treatment, including overdose reversal medications, medication assisted treatment, and appropriate counseling and behavioral therapies.

(d) Improving access to overdose treatment

(1) Information on best practices

(A) Health and Human Services

The Secretary of Health and Human Services may provide information to States, localities, Indian Tribes, Tribal organizations, and Urban Indian organizations on best practices for prescribing or co-prescribing a drug or device approved, cleared, or otherwise legally marketed under the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 301 et seq.] for emergency treatment of known or suspected opioid overdose, including for patients receiving chronic opioid therapy and patients being treated for opioid use disorders.

(B) Defense

The Secretary of Health and Human Services may, as appropriate, consult with the Secretary of Defense regarding the provision of information to prescribers within Department of Defense medical facilities on best practices for prescribing or co-prescribing a drug or device approved, cleared, or otherwise legally marketed under the Federal Food, Drug, and Cosmetic Act for emergency treatment of known or suspected opioid overdose, including for patients receiving chronic opioid therapy and patients being treated for opioid use disorders.

(C) Veterans Affairs

The Secretary of Health and Human Services may, as appropriate, consult with the Secretary of Veterans Affairs regarding the provision of information to prescribers within Department of Veterans Affairs medical facilities on best practices for prescribing or co-prescribing a drug or device approved, cleared, or otherwise legally marketed under the Federal Food, Drug, and Cosmetic Act for emergency treatment of known or suspected opioid overdose, including for patients receiving chronic opioid therapy and patients being treated for opioid use disorders.

(2) Rule of construction

Nothing in this subsection shall be construed as establishing or contributing to a medical standard of care.

(e) Evaluations by recipients

As a condition of receipt of a grant under this section, an eligible entity shall, for each year for which the grant is received, submit to the Secretary an evaluation of activities funded by the grant which contains such information as the Secretary may reasonably require.

(f) Reports by the Secretary

Not later than 5 years after the date on which the first grant under this section is awarded, the Secretary shall submit to the appropriate committees of the House of Representatives and of the Senate a report aggregating the information received from the grant recipients for such year under subsection (e) and evaluating the outcomes achieved by the programs funded by grants awarded under this section.

(g) Authorization of appropriations

There is authorized to be appropriated to carry out this section, $5,000,000 for the period of fiscal years 2023 through 2027.

(July 1, 1944, ch. 373, title V, §544, as added Pub. L. 114–198, title I, §107(a), July 22, 2016, 130 Stat. 703; amended Pub. L. 117–215, title I, §103(b)(3)(B), Dec. 2, 2022, 136 Stat. 2263; Pub. L. 117–328, div. FF, title I, §§1219(a)(1)–(7)(A), 1262(b)(4), Dec. 29, 2022, 136 Stat. 5670–5672, 5682.)

EDITORIAL NOTES

REFERENCES IN TEXT

The Federal Food, Drug, and Cosmetic Act, referred to in subsecs. (a)(1), (c)(1) to (4), and (d)(1), is act June 25, 1938, ch. 675, 52 Stat. 1040, which is classified generally to chapter 9 (§301 et seq.) of Title 21, Food and Drugs. For complete classification of this Act to the Code, see section 301 of Title 21 and Tables.

PRIOR PROVISIONS

A prior section 290dd–3, act July 1, 1944, ch. 373, title V, §544, formerly Pub. L. 91–616, title III, §333, Dec. 31, 1970, 84 Stat. 1853, as amended Pub. L. 93–282, title I, §122(a), May 14, 1974, 88 Stat. 131; Pub. L. 94–581, title I, §111(c)(4), Oct. 21, 1976, 90 Stat. 2852; renumbered §523 of act July 1, 1944, Apr. 26, 1983, Pub. L. 98–24, §2(b)(13), 97 Stat. 181; Aug. 27, 1986, Pub. L. 99–401, title I, §106(a), 100 Stat. 907; renumbered §544, July 22, 1987, Pub. L. 100–77, title VI, §611(2), 101 Stat. 516; June 13, 1991, Pub. L. 102–54, §13(q)(1)(A)(ii), 105 Stat. 278, which related to confidentiality of patient records for alcohol abuse and alcoholism programs, was omitted in the general revision of this part by Pub. L. 102–321. See section 290dd–2 of this title.

AMENDMENTS

2022—Pub. L. 117–328, §1219(a)(7)(A), substituted "approved, cleared, or otherwise legally marketed" for "approved or cleared" wherever appearing.

Subsec. (a)(2). Pub. L. 117–328, §1219(a)(1), (2), added par. (2) and struck out former par. (2). Prior to amendment, text read as follows: "A grant awarded under this section may not be for more than $200,000 per grant year."

Subsec. (a)(3). Pub. L. 117–328, §1262(b)(4), substituted "any practitioner dispensing narcotic drugs for the purpose of maintenance or detoxification treatment" for "any practitioner dispensing narcotic drugs pursuant to section 823(g) of title 21".

Pub. L. 117–328, §1219(a)(2), added par. (3) and struck out former par. (3). Prior to amendment, text read as follows: "For purposes of this section, the term 'eligible entity' means a Federally qualified health center (as defined in section 1395x(aa) of this title), an opioid treatment program under part 8 of title 42, Code of Federal Regulations, any practitioner dispensing narcotic drugs pursuant to section 823(h) of title 21, or any other entity that the Secretary deems appropriate."

Pub. L. 117–215 substituted "823(h)" for "823(g)".

Subsec. (a)(4)(A). Pub. L. 117–328, §1219(a)(3)(A), inserted ", including patients prescribed both an opioid and a benzodiazepine" after "overdose".

Subsec. (a)(4)(D). Pub. L. 117–328, §1219(a)(3)(B), substituted "overdose" for "drug overdose".

Subsec. (c)(5). Pub. L. 117–328, §1219(a)(4), amended par. (5) generally. Prior to amendment, par. (5) read as follows: "To establish protocols to connect patients who have experienced a drug overdose with appropriate treatment, including medication-assisted treatment and appropriate counseling and behavioral therapies."

Subsecs. (d), (e). Pub. L. 117–328, §1219(a)(5)(A), (C), added subsec. (d) and redesignated former subsec. (d) as (e). Former subsec. (e) redesignated (f).

Subsec. (f). Pub. L. 117–328, §1219(a)(5)(A), (B), redesignated subsec. (e) as (f) and substituted "subsection (e)" for "subsection (d)". Former subsec. (f) redesignated (g).

Subsec. (g). Pub. L. 117–328, §1219(a)(5)(A), (6), redesignated subsec. (f) as (g) and substituted "fiscal years 2023 through 2027" for "fiscal years 2017 through 2021".

STATUTORY NOTES AND RELATED SUBSIDIARIES

FUNDING FOR COMMUNITY-BASED FUNDING FOR LOCAL SUBSTANCE USE DISORDER SERVICES

Pub. L. 117–2, title II, §2706, Mar. 11, 2021, 135 Stat. 47, provided that:

"(a) IN GENERAL.—In addition to amounts otherwise available, there is appropriated to the Secretary [of Health and Human Services] for fiscal year 2021, out of any money in the Treasury not otherwise appropriated, $30,000,000, to remain available until expended, to carry out the purpose described in subsection (b).

"(b) USE OF FUNDS.—

"(1) IN GENERAL.—The Secretary, acting through the Assistant Secretary for Mental Health and

Substance Use and in consultation with the Director of the Centers for Disease Control and Prevention, shall award grants to support States; local, Tribal, and territorial governments; Tribal organizations; nonprofit community-based organizations; and primary and behavioral health organizations to support community-based overdose prevention programs, syringe services programs, and other harm reduction services.

"(2) USE OF GRANT FUNDS.—Grant funds awarded under this section to eligible entities shall be used for preventing and controlling the spread of infectious diseases and the consequences of such diseases for individuals with substance use disorder, distributing opioid overdose reversal medication to individuals at risk of overdose, connecting individuals at risk for, or with, a substance use disorder to overdose education, counseling, and health education, and encouraging such individuals to take steps to reduce the negative personal and public health impacts of substance use or misuse."

IMPROVING ACCESS TO OVERDOSE TREATMENT

Pub. L. 114–198, title I, §107(b), July 22, 2016, 130 Stat. 705, authorized Secretary of Health and Human Services to provide information to prescribers within certain Federal health facilities on best practices for prescribing or co-prescribing drugs or devices for emergency treatment of opioid overdose, prior to repeal by Pub. L. 117–328, div. FF, title I, §1219(a)(7)(B), Dec. 29, 2022, 136 Stat. 5672. See subsec. (d) of this section.

§290dd–4. Program to support coordination and continuation of care for drug overdose patients

(a) In general

The Secretary of Health and Human Services (referred to in this section as the "Secretary") shall identify or facilitate the development of best practices for—

(1) emergency treatment of known or suspected drug overdose;

(2) the use of recovery coaches, as appropriate, to encourage individuals who experience a non-fatal overdose to seek treatment for substance use disorder and to support coordination and continuation of care;

(3) coordination and continuation of care and treatment, including, as appropriate, through referrals, of individuals after a drug overdose; and

(4) the provision or prescribing of overdose reversal medication, as appropriate.

(b) Grant establishment and participation

(1) In general

The Secretary shall award grants on a competitive basis to eligible entities to support implementation of voluntary programs for care and treatment of individuals after a drug overdose, as appropriate, which may include implementation of the best practices described in subsection (a).

(2) Eligible entity

In this section, the term "eligible entity" means—

(A) a State substance abuse agency;

(B) an Indian Tribe or tribal organization; or

(C) an entity that offers treatment or other services for individuals in response to, or following, drug overdoses or a drug overdose, such as an emergency department, in consultation with a State substance abuse agency.

(3) Application

An eligible entity desiring a grant under this section shall submit an application to the Secretary, at such time and in such manner as the Secretary may require, that includes—

(A) evidence that such eligible entity carries out, or is capable of contracting and coordinating with other community entities to carry out, the activities described in paragraph (4);

(B) evidence that such eligible entity will work with a recovery community organization to

recruit, train, hire, mentor, and supervise recovery coaches and fulfill the requirements described in paragraph (4)(A); and

(C) such additional information as the Secretary may require.

(4) Use of grant funds

An eligible entity awarded a grant under this section shall use such grant funds to—

(A) hire or utilize recovery coaches to help support recovery, including by—

(i) connecting patients to a continuum of care services, such as—

(I) treatment and recovery support programs;

(II) programs that provide non-clinical recovery support services;

(III) peer support networks;

(IV) recovery community organizations;

(V) health care providers, including physicians and other providers of behavioral health and primary care;

(VI) education and training providers;

(VII) employers;

(VIII) housing services; and

(IX) child welfare agencies;

(ii) providing education on overdose prevention and overdose reversal to patients and families, as appropriate;

(iii) providing follow-up services for patients after an overdose to ensure continued recovery and connection to support services;

(iv) collecting and evaluating outcome data for patients receiving recovery coaching services; and

(v) providing other services the Secretary determines necessary to help ensure continued connection with recovery support services, including culturally appropriate services, as applicable;

(B) establish policies and procedures, pursuant to Federal and State law, that address the provision of overdose reversal medication, the administration of all drugs or devices approved or cleared under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.) and all biological products licensed under section 262 of this title to treat substance use disorder, and subsequent continuation of, or referral to, evidence-based treatment for patients with a substance use disorder who have experienced a non-fatal drug overdose, in order to support long-term treatment, prevent relapse, and reduce recidivism and future overdose; and

(C) establish integrated models of care for individuals who have experienced a non-fatal drug overdose which may include patient assessment, follow up, and transportation to and from treatment facilities.

(5) Additional permissible uses

In addition to the uses described in paragraph (4), a grant awarded under this section may be used, directly or through contractual arrangements, to provide—

(A) all drugs or devices approved or cleared under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.) and all biological products licensed under section 262 of this title to treat substance use disorders or reverse overdose, pursuant to Federal and State law;

(B) withdrawal and detoxification services that include patient evaluation, stabilization, and preparation for treatment of substance use disorder, including treatment described in subparagraph (A), as appropriate; or

(C) mental health services provided by a certified professional who is licensed and qualified by education, training, or experience to assess the psychosocial background of patients, to contribute to the appropriate treatment plan for patients with substance use disorder, and to monitor patient progress.

(6) Preference

In awarding grants under this section, the Secretary shall give preference to eligible entities that meet any or all of the following criteria:

(A) The eligible entity is a critical access hospital (as defined in section 1395x(mm)(1) of this title), a low volume hospital (as defined in section 1395ww(d)(12)(C)(i) of such title), a sole community hospital (as defined in section 1395ww(d)(5)(D)(iii) of such title), or a hospital that receives disproportionate share hospital payments under section 1395ww(d)(5)(F) of this title.

(B) The eligible entity is located in a State with an age-adjusted rate of drug overdose deaths that is above the national overdose mortality rate, as determined by the Director of the Centers for Disease Control and Prevention, or under the jurisdiction of an Indian Tribe with an age-adjusted rate of drug overdose deaths that is above the national overdose mortality rate, as determined through appropriate mechanisms as determined by the Secretary in consultation with Indian Tribes.

(C) The eligible entity demonstrates that recovery coaches will be placed in both health care settings and community settings.

(7) Period of grant

A grant awarded to an eligible entity under this section shall be for a period of not more than 5 years.

(c) Definitions

In this section:

(1) Indian Tribe; tribal organization

The terms "Indian Tribe" and "tribal organization" have the meanings given the terms "Indian tribe" and "tribal organization" in section 5304 of title 25.

(2) Recovery coach

the [1] term "recovery coach" means an individual—

(A) with knowledge of, or experience with, recovery from a substance use disorder; and

(B) who has completed training from, and is determined to be in good standing by, a recovery services organization capable of conducting such training and making such determination.

(3) Recovery community organization

The term "recovery community organization" has the meaning given such term in section 290ee–2(a) of this title.

(d) Reporting Requirements

(1) Reports by grantees

Each eligible entity awarded a grant under this section shall submit to the Secretary an annual report for each year for which the entity has received such grant that includes information on—

(A) the number of individuals treated by the entity for non-fatal overdoses, including the number of non-fatal overdoses where overdose reversal medication was administered;

(B) the number of individuals administered medication-assisted treatment by the entity;

(C) the number of individuals referred by the entity to other treatment facilities after a non-fatal overdose, the types of such other facilities, and the number of such individuals admitted to such other facilities pursuant to such referrals; and

(D) the frequency and number of patients with reoccurrences, including readmissions for non-fatal overdoses and evidence of relapse related to substance use disorder.

(2) Report by Secretary

Not later than 5 years after October 24, 2018, the Secretary shall submit to Congress a report that includes an evaluation of the effectiveness of the grant program carried out under this section with respect to long term health outcomes of the population of individuals who have experienced a

drug overdose, the percentage of patients treated or referred to treatment by grantees, and the frequency and number of patients who experienced relapse, were readmitted for treatment, or experienced another overdose.

(e) Privacy

The requirements of this section, including with respect to data reporting and program oversight, shall be subject to all applicable Federal and State privacy laws.

(f) Authorization of appropriations

There is authorized to be appropriated to carry out this section $10,000,000 for each of fiscal years 2019 through 2023.

(Pub. L. 115–271, title VII, §7081, Oct. 24, 2018, 132 Stat. 4032.)

EDITORIAL NOTES

REFERENCES IN TEXT

The Federal Food, Drug, and Cosmetic Act, referred to in subsec. (b)(4)(B), (5)(A), is act June 25, 1938, ch. 675, 52 Stat. 1040, which is classified generally to chapter 9 (§301 et seq.) of Title 21, Food and Drugs. For complete classification of this Act to the Code, see section 301 of Title 21 and Tables.

CODIFICATION

Section was enacted as part of the Substance Use–Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act, also known as the SUPPORT for Patients and Communities Act, and not as part of the Public Health Service Act which comprises this chapter.

[1] *So in original. Probably should be capitalized.*

§290ee. Opioid overdose reversal medication access, education, and co-prescribing grant programs

(a) Grants

The Secretary shall make grants to States, localities, Indian Tribes, and Tribal organizations (as those terms are defined in section 5304 of title 25) to—

(1) implement strategies that increase access to drugs or devices approved, cleared, or otherwise legally marketed under the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 301 et seq.] for emergency treatment of known or suspected opioid overdose, as appropriate, pursuant to a standing order;

(2) encourage pharmacies to dispense opioid overdose reversal medication pursuant to a standing order;

(3) encourage health care providers to co-prescribe, as appropriate, drugs or devices approved, cleared, or otherwise legally marketed under the Federal Food, Drug, and Cosmetic Act for emergency treatment of known or suspected opioid overdose;

(4) develop or provide training materials that persons authorized to prescribe or dispense a drug or device approved, cleared, or otherwise legally marketed under the Federal Food, Drug, and Cosmetic Act for emergency treatment of known or suspected opioid overdose may use to educate the public concerning—

(A) when and how to safely administer such drug or device; and

(B) steps to be taken after administering such drug or device; and

(5) educate the public concerning the availability of drugs or devices approved, cleared, or otherwise legally marketed under the Federal Food, Drug, and Cosmetic Act for emergency treatment of known or suspected opioid overdose without a person-specific prescription.

(b) Certain requirement

A grant may be made under this section only if the State involved has authorized standing orders to be issued for drugs or devices approved, cleared, or otherwise legally marketed under the Federal Food, Drug, and Cosmetic Act for emergency treatment of known or suspected opioid overdose.

(c) Preference in making grants

In making grants under this section, the Secretary may give preference to States that have a significantly higher rate of opioid overdoses than the national average, and that—

(1) have not implemented standing orders regarding drugs or devices approved, cleared, or otherwise legally marketed under the Federal Food, Drug, and Cosmetic Act for emergency treatment of known or suspected opioid overdose;

(2) authorize standing orders to be issued that permit community-based organizations, substance abuse programs, or other nonprofit entities to acquire, dispense, or administer drugs or devices approved, cleared, or otherwise legally marketed under the Federal Food, Drug, and Cosmetic Act for emergency treatment of known or suspected opioid overdose; or

(3) authorize standing orders to be issued that permit police, fire, or emergency medical services agencies to acquire and administer drugs or devices approved, cleared, or otherwise legally marketed under the Federal Food, Drug, and Cosmetic Act for emergency treatment of known or suspected opioid overdose.

(d) Grant terms

(1) Number

A State may not receive more than one grant under this section at a time.

(2) Period

A grant under this section shall be for a period of 5 years.

(3) Limitations

A State may—

(A) use not more than 10 percent of a grant under this section for educating the public pursuant to subsection (a)(5); and

(B) use not less than 20 percent of a grant under this section to offset cost-sharing for distribution and dispensing of drugs or devices approved, cleared, or otherwise legally marketed under the Federal Food, Drug, and Cosmetic Act for emergency treatment of known or suspected opioid overdose.

(e) Applications

To be eligible to receive a grant under this section, a State shall submit an application to the Secretary in such form and manner and containing such information as the Secretary may reasonably require, including detailed proposed expenditures of grant funds.

(f) Reporting

A State that receives a grant under this section shall, at least annually for the duration of the grant, submit a report to the Secretary evaluating the progress of the activities supported through the grant. Such reports shall include information on the number of pharmacies in the State that dispense a drug or device approved, cleared, or otherwise legally marketed under the Federal Food, Drug, and Cosmetic Act for emergency treatment of known or suspected opioid overdose under a standing order, and other information as the Secretary determines appropriate to evaluate the use of grant funds.

(g) Definitions

In this section the term "standing order" means a document prepared by a person authorized to prescribe medication that permits another person to acquire, dispense, or administer medication without a person-specific prescription.

(h) Authorization of appropriations

(1) In general

To carry out this section, there are authorized to be appropriated $5,000,000 for the period of fiscal years 2023 through 2027.

(2) Administrative costs

Not more than 3 percent of the amounts made available to carry out this section may be used by the Secretary for administrative expenses of carrying out this section.

(July 1, 1944, ch. 373, title V, §545, as added Pub. L. 114–198, title I, §110(a), July 22, 2016, 130 Stat. 709; amended Pub. L. 117–328, div. FF, title I, §1220, Dec. 29, 2022, 136 Stat. 5672.)

EDITORIAL NOTES

REFERENCES IN TEXT

The Federal Food, Drug, and Cosmetic Act, referred to in text, is act June 25, 1938, ch. 675, 52 Stat. 1040, which is classified generally to chapter 9 (§301 et seq.) of Title 21, Food and Drugs. For complete classification of this Act to the Code, see section 301 of Title 21 and Tables.

PRIOR PROVISIONS

A prior section 290ee, act July 1, 1944, ch. 373, title V, §545, formerly Pub. L. 92–255, title V, §502, as added Pub. L. 94–237, §12(b)(1), Mar. 19, 1976, 90 Stat. 247, and amended Pub. L. 95–461, §5, Oct. 14, 1978, 92 Stat. 1269; Pub. L. 96–181, §11, Jan. 2, 1980, 93 Stat. 1315; renumbered §524 of act July 1, 1944, and amended Apr. 26, 1983, Pub. L. 98–24, §2(b)(15), 97 Stat. 181; renumbered §545, July 22, 1987, Pub. L. 100–77, title VI, §611(2), 101 Stat. 516; Nov. 4, 1988, Pub. L. 100–607, title VIII, §813(3), 102 Stat. 3170; Nov. 7, 1988, Pub. L. 100–628, title VI, §613(3), 102 Stat. 3243; Aug. 16, 1989, Pub. L. 101–93, §5(t)(1), 103 Stat. 615, which related to technical assistance to State and local agencies by the National Institute on Drug Abuse, was omitted in the general revision of this part by Pub. L. 102–321.

AMENDMENTS

2022—Pub. L. 117–328, §1220(e), substituted "approved, cleared, or otherwise legally marketed" for "approved or cleared" wherever appearing.

Pub. L. 117–328, §1220(a)(1), substituted "access, education, and co-prescribing grant programs" for "access and education grant programs" in section catchline.

Subsec. (a). Pub. L. 117–328, §1220(a)(2), (3), substituted "Grants" for "Grants to States" in heading and "shall make grants to States, localities, Indian Tribes, and Tribal organizations (as those terms are defined in section 5304 of title 25)" for "shall make grants to States" in introductory provisions.

Subsec. (a)(1). Pub. L. 117–328, §1220(a)(4), substituted "implement strategies that increase access to drugs or devices" for "implement strategies for pharmacists to dispense a drug or device".

Subsec. (a)(3) to (5). Pub. L. 117–328, §1220(a)(5), (6), added par. (3) and redesignated former pars. (3) and (4) as (4) and (5), respectively.

Subsec. (d)(2). Pub. L. 117–328, §1220(b), substituted "5 years" for "3 years".

Subsec. (d)(3). Pub. L. 117–328, §1220(c), amended par. (3) generally. Prior to amendment, text read as follows: "A State may use not more than 20 percent of a grant under this section for educating the public pursuant to subsection (a)(4)."

Subsec. (h)(1). Pub. L. 117–328, §1220(d), substituted "fiscal years 2023 through 2027" for "fiscal years 2017 through 2019".

STATUTORY NOTES AND RELATED SUBSIDIARIES

REFERENCES TO OPIOID OVERDOSE REVERSAL AGENTS IN HHS GRANT PROGRAMS

Pub. L. 119–44, title II, §210, Dec. 1, 2025, 139 Stat. 682, provided that:

"(a) IN GENERAL.—The Secretary of Health and Human Services shall ensure that, as appropriate, whenever the Department of Health and Human Services issues a regulation or guidance for any grant program addressing opioid misuse and use disorders, any reference to an opioid overdose reversal drug (such as a reference to naloxone) is inclusive of any opioid overdose reversal drug that has been approved under section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355) for emergency treatment of a known or suspected opioid overdose.

"(b) EXISTING REFERENCES.—

"(1) UPDATE.—Not later than one year after the date of enactment of this Act [Dec. 1, 2025], the Secretary of Health and Human Services shall update all references described in paragraph (2) to be inclusive of any opioid overdose reversal drug that has been approved or otherwise authorized for use by the Food and Drug Administration.

"(2) REFERENCES.—A reference described in this paragraph is any reference to an opioid overdose reversal drug (such as naloxone) in any regulation or guidance of the Department of Health and Human Services that—

"(A) was issued before the date of enactment of this Act; and

"(B) is included in—

"(i) the grant program for State and Tribal response to opioid use disorders under section 1003 of the 21st Century Cures Act [former] (42 U.S.C. 290ee–3 note) [now 42 U.S.C. 290ee–3a] (commonly referred to as 'State Opioid Response Grants' and 'Tribal Opioid Response Grants'); or

"(ii) the grant program for priority substance use disorder prevention needs of regional and national significance under section 516 of the Public Health Service Act (42 U.S.C. 290bb–22)."

§290ee–1. First responder training

(a) Program authorized

The Secretary shall make grants to States, local governmental entities, and Indian Tribes and Tribal organizations (as defined in section 5304 of title 25) to allow first responders and members of other key community sectors to administer a drug or device approved, cleared, or otherwise legally marketed under the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 301 et seq.] for emergency treatment of known or suspected overdose.

(b) Application

(1) In general

An entity seeking a grant under this section shall submit an application to the Secretary—

(A) that meets the criteria under paragraph (2); and

(B) at such time, in such manner, and accompanied by such information as the Secretary may require.

(2) Criteria

An entity, in submitting an application under paragraph (1), shall—

(A) describe the evidence-based methodology and outcome measurements that will be used to evaluate the program funded with a grant under this section, and specifically explain how such measurements will provide valid measures of the impact of the program;

(B) describe how the program could be broadly replicated if demonstrated to be effective;

(C) identify the governmental and community agencies with which the entity will coordinate to implement the program; and

(D) describe how the entity will ensure that law enforcement agencies will coordinate with their corresponding State substance abuse and mental health agencies to identify protocols and resources that are available to overdose victims and families, including information on treatment and recovery resources.

(c) Use of funds

An entity shall use a grant received under this section to—

(1) make a drug or device approved, cleared, or otherwise legally marketed under the Federal Food, Drug, and Cosmetic Act for emergency treatment of known or suspected overdose available to be carried and administered by first responders and members of other key community sectors;

(2) train and provide resources for first responders and members of other key community sectors on carrying and administering a drug or device approved, cleared, or otherwise legally marketed under the Federal Food, Drug, and Cosmetic Act for emergency treatment of known or suspected overdose;

(3) establish processes, protocols, and mechanisms for referral to appropriate treatment, which may include an outreach coordinator or team to connect individuals receiving overdose reversal drugs to followup services; and

(4) train and provide resources for first responders and members of other key community sectors on safety around fentanyl, carfentanil, and other dangerous licit and illicit drugs to protect themselves from exposure to such drugs and respond appropriately when exposure occurs.

(d) Technical assistance grants

The Secretary shall make a grant for the purpose of providing technical assistance and training on the use of a drug or device approved, cleared, or otherwise legally marketed under the Federal Food, Drug, and Cosmetic Act for emergency treatment of known or suspected overdose, mechanisms for referral to appropriate treatment, and safety around fentanyl, carfentanil, and other dangerous licit and illicit drugs.

(e) Geographic distribution

In making grants under this section, the Secretary shall ensure that not less than 20 percent of grant funds are awarded to eligible entities that are not located in metropolitan statistical areas (as defined by the Office of Management and Budget). The Secretary shall take into account the unique needs of rural communities, including communities with an incidence of individuals with opioid use disorder that is above the national average and communities with a shortage of prevention and treatment services.

(f) Evaluation

The Secretary shall conduct an evaluation of grants made under this section to determine—

(1) the number of first responders and members of other key community sectors equipped with a drug or device approved, cleared, or otherwise legally marketed under the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 301 et seq.] for emergency treatment of known or suspected overdose;

(2) the number of opioid, heroin, and other drug overdoses reversed by first responders and members of other key community sectors receiving training and supplies of a drug or device approved, cleared, or otherwise legally marketed under the Federal Food, Drug, and Cosmetic Act for emergency treatment of known or suspected overdose, through a grant received under this section;

(3) the number of responses to requests for services by the entity or subgrantee, to overdose;

(4) the extent to which overdose victims and families receive information about treatment services and available data describing treatment admissions; and

(5) the number of first responders and members of other key community sectors trained on safety around fentanyl, carfentanil, and other dangerous licit and illicit drugs.

(g) Other key community sectors

In this section, the term "other key community sectors" includes substance use disorder treatment providers, emergency medical services agencies, agencies and organizations working with prison and jail populations and offender reentry programs, health care providers, harm reduction groups, pharmacies, community health centers, tribal health facilities, and mental health providers.

(h) Authorization of appropriations

To carry out this section, there are authorized to be appropriated $57,000,000 for each of fiscal years 2026 through 2030.

(July 1, 1944, ch. 373, title V, §546, as added Pub. L. 114–198, title II, §202, July 22, 2016, 130 Stat. 715; amended Pub. L. 115–271, title VII, §7002, Oct. 24, 2018, 132 Stat. 4007; Pub. L. 119–44, title I, §106, Dec. 1, 2025, 139 Stat. 674.)

EDITORIAL NOTES

REFERENCES IN TEXT

The Federal Food, Drug, and Cosmetic Act, referred to in subsecs. (a), (c)(1), (2), (d), and (f)(1), (2), is act June 25, 1938, ch. 675, 52 Stat. 1040, which is classified generally to chapter 9 (§301 et seq.) of Title 21, Food and Drugs. For complete classification of this Act to the Code, see section 301 of Title 21 and Tables.

PRIOR PROVISIONS

A prior section 290ee–1, act July 1, 1944, ch. 373, title V, §546, formerly Pub. L. 92–255, title IV, §413, Mar. 21, 1972, 86 Stat. 84, as amended Pub. L. 96–181, §8(a), (b)(1), Jan. 2, 1980, 93 Stat. 1313, 1314; Pub. L. 97–35, title IX, §973(e), Aug. 13, 1981, 95 Stat. 598; renumbered §525 of act July 1, 1944, and amended Apr. 26, 1983, Pub. L. 98–24, §2(b)(16)(A), 97 Stat. 182; Oct. 27, 1986, Pub. L. 99–570, title VI, §6002(b)(2), 100 Stat. 3207–159; renumbered §546, July 22, 1987, Pub. L. 100–77, title VI, §611(2), 101 Stat. 516; Nov. 4, 1988, Pub. L. 100–607, title VIII, §813(4), 102 Stat. 3171; Nov. 7, 1988, Pub. L. 100–628, title VI, §613(4), 102 Stat. 3243; Aug. 16, 1989, Pub. L. 101–93, §5(t)(1), 103 Stat. 615, which related to drug abuse among government and other employees, was omitted in the general revision of this part by Pub. L. 102–321.

AMENDMENTS

2025—Subsec. (a). Pub. L. 119–44, §106(1), (2), substituted "Tribes and Tribal" for "tribes and tribal" and "approved, cleared, or otherwise legally marketed" for "approved or cleared" and struck out "opioid" before "overdose".

Subsecs. (c), (d). Pub. L. 119–44, §106(2), wherever appearing, substituted "approved, cleared, or otherwise legally marketed" for "approved or cleared" and struck out "opioid" before "overdose".

Subsec. (f)(1). Pub. L. 119–44, §106(3)(A), (B), substituted "approved, cleared, or otherwise legally marketed" for "approved or cleared" and struck out "opioid" before "overdose".

Subsec. (f)(2). Pub. L. 119–44, §106(3)(A), (C), substituted "opioid, heroin, and other drug" for "opioid and heroin", "approved, cleared, or otherwise legally marketed" for "approved or cleared", and "overdose" for "opioid overdose".

Subsec. (f)(3). Pub. L. 119–44, §106(3)(D), struck out "opioid and heroin" before "overdose".

Subsec. (h). Pub. L. 119–44, §106(4), substituted "$57,000,000 for each of fiscal years 2026 through 2030" for "$36,000,000 for each of fiscal years 2019 through 2023".

2018—Subsec. (c)(4). Pub. L. 115–271, §7002(1), added par. (4).

Subsec. (d). Pub. L. 115–271, §7002(2), substituted "mechanisms for referral to appropriate treatment, and safety around fentanyl, carfentanil, and other dangerous licit and illicit drugs" for "and mechanisms for referral to appropriate treatment for an entity receiving a grant under this section".

Subsec. (f)(5). Pub. L. 115–271, §7002(3), added par. (5).

Subsec. (g). Pub. L. 115–271, §7002(5), added subsec. (g). Former subsec. (g) redesignated (h).

Subsec. (h). Pub. L. 115–271, §7002(4), (6), redesignated subsec. (g) as (h) and substituted "$36,000,000 for each of fiscal years 2019 through 2023" for "$12,000,000 for each of fiscal years 2017 through 2021".

§290ee–2. Building communities of recovery

(a) Definition

In this section, the term "recovery community organization" means an independent nonprofit organization that—

(1) mobilizes resources within and outside of the recovery community, which may include through a peer support network, to increase the prevalence and quality of long-term recovery from substance use disorders; and

(2) is wholly or principally governed by people in recovery for substance use disorders who reflect the community served.

(b) Grants authorized

The Secretary shall award grants to recovery community organizations to enable such organizations to develop, expand, and enhance recovery services.

(c) Federal share

The Federal share of the costs of a program funded by a grant under this section may not exceed 85 percent.

(d) Use of funds

Grants awarded under subsection (b)—

(1) shall be used to develop, expand, and enhance community and statewide recovery support services; and

(2) may be used to—

(A) build connections between recovery networks, including between recovery community organizations and peer support networks, and with other recovery support services, including—

(i) behavioral health providers;

(ii) primary care providers and physicians;

(iii) educational and vocational schools;

(iv) employers;

(v) housing services;

(vi) child welfare agencies; and

(vii) other recovery support services that facilitate recovery from substance use disorders, including non-clinical community services;

(B) reduce stigma associated with substance use disorders; and

(C) conduct outreach on issues relating to substance use disorders and recovery, including—

(i) identifying the signs of substance use disorder;

(ii) the resources available to individuals with substance use disorder and to families of an individual with a substance use disorder, including programs that mentor and provide support services to children;

(iii) the resources available to help support individuals in recovery; and

(iv) related medical outcomes of substance use disorders, the potential of acquiring an infection commonly associated with illicit drug use, and neonatal abstinence syndrome among infants exposed to opioids during pregnancy.

(e) Special consideration

In carrying out this section, the Secretary shall give special consideration to the unique needs of rural areas, including areas with an age-adjusted rate of drug overdose deaths that is above the national average and areas with a shortage of prevention and treatment services.

(f) Authorization of appropriations

There is authorized to be appropriated to carry out this section $17,000,000 for each of fiscal years 2026 through 2030.

(July 1, 1944, ch. 373, title V, §547, as added Pub. L. 114–198, title III, §302, July 22, 2016, 130 Stat. 719; amended Pub. L. 115–271, title VII, §7151, Oct. 24, 2018, 132 Stat. 4057; Pub. L. 119–44, title III, §301, Dec. 1, 2025, 139 Stat. 684.)

EDITORIAL NOTES

PRIOR PROVISIONS

A prior section 290ee–2, act July 1, 1944, ch. 373, title V, §547, formerly Pub. L. 92–255, title IV, §407, Mar. 21, 1972, 86 Stat. 78, as amended Pub. L. 94–237, §6(a), Mar. 19, 1976, 90 Stat. 244; Pub. L. 94–581, title I, §111(c)(2), Oct. 21, 1976, 90 Stat. 2852; renumbered §526 of act July 1, 1944, Apr. 26, 1983. Pub. L. 98–24, §2(b)(16)(B), 97 Stat. 182; renumbered §547, July 22, 1987, Pub. L. 100–77, title VI, §611(2), 101 Stat. 516, which related to admission of drug abusers to private and public hospitals, was omitted in the general revision of this part by Pub. L. 102–321.

AMENDMENTS

2025—Subsec. (f). Pub. L. 119–44 substituted "$17,000,000 for each of fiscal years 2026 through 2030" for "$5,000,000 for each of fiscal years 2019 through 2023".

2018—Pub. L. 115–271 amended section generally. Prior to amendment, section authorized the Secretary to award grants to recovery community organizations to enable such organizations to develop, expand, and enhance recovery services, set the Federal share of program costs at no more than 50 percent, and appropriated $1,000,000 for each of fiscal years 2017 through 2021.

§290ee–2a. Peer support technical assistance center

(a) Establishment

The Secretary, acting through the Assistant Secretary, shall establish or operate a National Peer-Run Training and Technical Assistance Center for Addiction Recovery Support (referred to in this section as the "Center").

(b) Functions

The Center established under subsection (a) shall provide technical assistance and support to recovery community organizations and peer support networks, including such assistance and support related to—

(1) training on identifying—

(A) signs of substance use disorder;

(B) resources to assist individuals with a substance use disorder, or resources for families of an individual with a substance use disorder; and

(C) best practices for the delivery of recovery support services;

(2) the provision of translation services, interpretation, or other such services for clients with limited English speaking proficiency;

(3) data collection to support research, including for translational research;

(4) capacity building, such as—

(A) professional development of peer support specialists; and

(B) making recovery support services available in nonclinical settings; and

(5) evaluation and improvement, as necessary, of the effectiveness of such services provided by recovery community organizations.

(c) Best practices

The Center established under subsection (a) shall periodically issue best practices for use by recovery community organizations and peer support networks.

(d) Regional Centers

(1) In general

The Secretary may establish one regional technical assistance center (referred to in this subsection as the "Regional Center"), with existing resources, to assist the Center in carrying out activities described in subsection (b) within the geographic region of such Regional Center in a manner that is tailored to the needs of such region.

(2) Evaluation

Not later than 4 years after December 1, 2025, the Secretary shall evaluate the activities of the Regional Center and submit to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives a report on the findings of such evaluation, including—

(A) a description of the distinct roles and responsibilities of the Regional Center and the Center;

(B) available information relating to the outcomes of the Regional Center under this subsection, such as any impact on the operations and efficiency of the Center relating to requests for technical assistance and support within the region of such Regional Center;

(C) a description of any gaps or areas of duplication relating to the activities of the Regional Center and the Center within such region; and

(D) recommendations relating to the modification, expansion, or termination of the Regional Center under this subsection.

(3) Termination

This subsection shall terminate on September 30, 2030.

(e) Recovery community organization

In this section, the term "recovery community organization" has the meaning given such term in section 290ee–2 of this title.

(f) Authorization of appropriations

There is authorized to be appropriated to carry out this section $2,000,000 for each of fiscal years 2026 through 2030.

(July 1, 1944, ch. 373, title V, §547A, as added Pub. L. 115–271, title VII, §7152, Oct. 24, 2018, 132 Stat. 4058; amended Pub. L. 119–44, title III, §302, Dec. 1, 2025, 139 Stat. 684.)

EDITORIAL NOTES

AMENDMENTS

2025—Subsec. (b)(4). Pub. L. 119–44, §302(1), substituted "building, such as—" for "building; and" and added subpars. (A) and (B).

Subsec. (d). Pub. L. 119–44, §302(3), added subsec. (d). Former subsec. (d) redesignated (e).

Subsec. (e). Pub. L. 119–44, §302(2), redesignated subsec. (d) as (e). Former subsec. (e) redesignated (f).

Subsec. (f). Pub. L. 119–44, §302(2), (4), redesignated subsec. (e) as (f) and substituted "$2,000,000 for each of fiscal years 2026 through 2030" for "$1,000,000 for each of fiscal years 2019 through 2023".

§290ee–3. State demonstration grants for comprehensive opioid abuse response

(a) Definitions

In this section:

(1) Dispenser

The term "dispenser" has the meaning given the term in section 802 of title 21.

(2) Prescriber

The term "prescriber" means a dispenser who prescribes a controlled substance, or the agent of such a dispenser.

(3) Prescriber of a schedule II, III, or IV controlled substance

The term "prescriber of a schedule II, III, or IV controlled substance" does not include a prescriber of a schedule II, III, or IV controlled substance that dispenses the substance—

(A) for use on the premises on which the substance is dispensed;

(B) in a hospital emergency room, when the substance is in short supply;

(C) for a certified opioid treatment program; or

(D) in other situations as the Secretary may reasonably determine.

(4) Schedule II, III, or IV controlled substance

The term "schedule II, III, or IV controlled substance" means a controlled substance that is listed on schedule II, schedule III, or schedule IV of section 812(c) of title 21.

(b) Grants for comprehensive opioid abuse response

(1) In general

The Secretary shall award grants to States, and combinations of States, to implement an integrated opioid abuse response initiative.

(2) Purposes

A State receiving a grant under this section shall establish a comprehensive response plan to opioid abuse, which may include—

(A) education efforts around opioid use, treatment, and addiction recovery, including

education of residents, medical students, and physicians and other prescribers of schedule II, III, or IV controlled substances on relevant prescribing guidelines, the prescription drug monitoring program of the State described in subparagraph (B), and overdose prevention methods;

(B) establishing, maintaining, or improving a comprehensive prescription drug monitoring program to track dispensing of schedule II, III, or IV controlled substances, which may—

(i) provide for data sharing with other States; and

(ii) allow all individuals authorized by the State to write prescriptions for schedule II, III, or IV controlled substances to access the prescription drug monitoring program of the State;

(C) developing, implementing, or expanding prescription drug and opioid addiction treatment programs by—

(i) expanding the availability of treatment for prescription drug and opioid addiction, including medication-assisted treatment and behavioral health therapy, as appropriate;

(ii) developing, implementing, or expanding screening for individuals in treatment for prescription drug and opioid addiction for hepatitis C and HIV, and treating or referring those individuals if clinically appropriate; or

(iii) developing, implementing, or expanding recovery support services and programs at high schools or institutions of higher education;

(D) developing, implementing, and expanding efforts to prevent overdose death from opioid abuse or addiction to prescription medications and opioids; and

(E) advancing the education and awareness of the public, providers, patients, consumers, and other appropriate entities regarding the dangers of opioid abuse, safe disposal of prescription medications, and detection of early warning signs of opioid use disorders.

(3) Application

A State seeking a grant under this section shall submit to the Secretary an application in such form, and containing such information, as the Secretary may reasonably require.

(4) Use of funds

A State that receives a grant under this section shall use the grant for the cost, including the cost for technical assistance, training, and administration expenses, of carrying out an integrated opioid abuse response initiative as outlined by the State's comprehensive response plan to opioid abuse established under paragraph (2).

(5) Priority considerations

In awarding grants under this section, the Secretary shall, as appropriate, give priority to a State that—

(A)(i) provides civil liability protection for first responders, health professionals, and family members who have received appropriate training in administering a drug or device approved or cleared under the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 301 et seq.] for emergency treatment of known or suspected opioid overdose; and

(ii) submits to the Secretary a certification by the attorney general of the State that the attorney general has—

(I) reviewed any applicable civil liability protection law to determine the applicability of the law with respect to first responders, health care professionals, family members, and other individuals who—

(aa) have received appropriate training in administering a drug or device approved or cleared under the Federal Food, Drug, and Cosmetic Act for emergency treatment of known or suspected opioid overdose; and

(bb) may administer a drug or device approved or cleared under the Federal Food, Drug, and Cosmetic Act for emergency treatment of known or suspected opioid overdose; and

(II) concluded that the law described in subclause (I) provides adequate civil liability

protection applicable to such persons;

(B) has a process for enrollment in services and benefits necessary by criminal justice agencies to initiate or continue treatment in the community, under which an individual who is incarcerated may, while incarcerated, enroll in services and benefits that are necessary for the individual to continue treatment upon release from incarceration;

(C) ensures the capability of data sharing with other States, where applicable, such as by making data available to a prescription monitoring hub;

(D) ensures that data recorded in the prescription drug monitoring program database of the State are regularly updated, to the extent possible;

(E) ensures that the prescription drug monitoring program of the State notifies prescribers and dispensers of schedule II, III, or IV controlled substances when overuse or misuse of such controlled substances by patients is suspected; and

(F) has in effect one or more statutes or implements policies that maximize use of prescription drug monitoring programs by individuals authorized by the State to prescribe schedule II, III, or IV controlled substances.

(6) Evaluation

In conducting an evaluation of the program under this section pursuant to section 701 of the Comprehensive Addiction and Recovery Act of 2016, with respect to a State, the Secretary shall report on State legislation or policies related to maximizing the use of prescription drug monitoring programs and the incidence of opioid use disorders and overdose deaths in such State.

(7) States with local prescription drug monitoring programs

(A) In general

In the case of a State that does not have a prescription drug monitoring program, a county or other unit of local government within the State that has a prescription drug monitoring program shall be treated as a State for purposes of this section, including for purposes of eligibility for grants under paragraph (1).

(B) Plan for interoperability

In submitting an application to the Secretary under paragraph (3), a county or other unit of local government shall submit a plan outlining the methods such county or unit of local government shall use to ensure the capability of data sharing with other counties and units of local government within the state [1] and with other States, as applicable.

(c) Authorization of funding

For the purpose of carrying out this section, there are authorized to be appropriated $5,000,000 for each of fiscal years 2017 through 2021.

(July 1, 1944, ch. 373, title V, §548, as added Pub. L. 114–198, title VI, §601, July 22, 2016, 130 Stat. 732.)

EDITORIAL NOTES

REFERENCES IN TEXT

The Federal Food, Drug, and Cosmetic Act, referred to in subsec. (b)(5)(A)(i), (ii)(I), is act June 25, 1938, ch. 675, 52 Stat. 1040, which is classified generally to chapter 9 (§301 et seq.) of Title 21, Food and Drugs. For complete classification of this Act to the Code, see section 301 of Title 21 and Tables.

Section 701 of the Comprehensive Addiction and Recovery Act of 2016, referred to in subsec. (b)(6), is section 701 of Pub. L. 114–198, which enacted sections 290aa–15 and 290aa–16 of this title, sections 10706 and 10707 of Title 34, Crime Control and Law Enforcement, and provisions set out as a note under section 290aa–15 of this title.

PRIOR PROVISIONS

A prior section 290ee–3, act July 1, 1944, ch. 373, title V, §548, formerly Pub. L. 92–255, title IV, §408,

Mar. 21, 1972, 86 Stat. 79, as amended Pub. L. 93–282, title III, §303(a), (b), May 14, 1974, 88 Stat. 137, 138; Pub. L. 94–237, §4(c)(5)(A), Mar. 19, 1976, 90 Stat. 244; Pub. L. 94–581, title I, §111(c)(3), Oct. 21, 1976, 90 Stat. 2852; Pub. L. 97–35, title IX, §973(d), Aug. 13, 1981, 95 Stat. 598; renumbered §527 of act July 1, 1944, and amended Apr. 26, 1983, Pub. L. 98–24, §2(b)(16)(B), 97 Stat. 182; Aug. 27, 1986, Pub. L. 99–401, title I, §106(b), 100 Stat. 907; renumbered §548, July 22, 1987, Pub. L. 100–77, title VI, §611(2), 101 Stat. 516; June 13, 1991, Pub. L. 102–54, §13(q)(1)(A)(iii), (B)(ii), 105 Stat. 278, which related to confidentiality of patient records for drug abuse programs, was omitted in the general revision of this part by Pub. L. 102–321. See section 290dd–2 of this title.

STATUTORY NOTES AND RELATED SUBSIDIARIES

GRANT PROGRAM FOR THE STATE AND TRIBAL RESPONSE TO THE OPIOID ABUSE CRISIS

Pub. L. 114–255, div. A, title I, §1003, Dec. 13, 2016, 130 Stat. 1044, as amended by Pub. L. 115–271, title VII, §7181(a), Oct. 24, 2018, 132 Stat. 4068, which related to grant program to address opioid abuse crisis within States and Indian Tribes, was amended generally by Pub. L. 117–328, div. FF, title I, §1273, Dec. 29, 2022, 136 Stat. 5688, and transferred to section 290ee–3a of this title.

[1] *So in original. Probably should be capitalized.*

§290ee–3a. Grant program for State and Tribal response to opioid use disorders

(a) In general

The Secretary of Health and Human Services (referred to in this section as the "Secretary") shall carry out the grant program described in subsection (b) for purposes of addressing opioid misuse and use disorders and, as applicable and appropriate, stimulant misuse and use disorders, within States, Indian Tribes, and populations served by Tribal organizations and Urban Indian organizations.

(b) Grants program

(1) In general

Subject to the availability of appropriations, the Secretary shall award grants to the single State agency responsible for administering the substance use prevention, treatment, and recovery services block grant under subpart II of part B of title XIX of the Public Health Service Act (42 U.S.C. 300x–21 et seq.), Indian Tribes, and Tribal organizations for the purpose of addressing opioid misuse and use disorders, and as applicable and appropriate, stimulant misuse and use disorders, within such States, such Indian Tribes, and populations served by such Tribal organizations, in accordance with paragraph (2). Indian Tribes or Tribal organizations may also apply for an award as part of a consortia or may include in an application a partnership with an Urban Indian organization.

(2) Minimum allocations

Notwithstanding subsection (i)(3), in determining grant amounts for each recipient of a grant under paragraph (1), the Secretary shall ensure that each State and the District of Columbia receive not less than $4,000,000 and ensure that each Territory receives not less than $250,000.

(3) Formula methodology

(A) In general

At least 30 days before publishing a funding opportunity announcement with respect to grants under this section, the Secretary shall—

(i) develop a formula methodology to be followed in allocating grant funds awarded under this section among grantees, which, where applicable and appropriate based on populations being served by the relevant entity—

(I) with respect to allocations for States, gives preference to States whose populations

have a prevalence of opioid misuse and use disorders or drug overdose deaths that is substantially higher relative to the populations of other States;

(II) with respect to allocations for Tribes and Tribal organizations, gives preferences to Tribes and Tribal organizations (including those applying in partnership with an Urban Indian organization) serving populations with demonstrated need with respect to opioid misuse and use disorders or drug overdose deaths;

(III) includes performance assessments for continuation awards; and

(IV) ensures that the formula avoids a funding cliff between States with similar overdose mortality rates to prevent funding reductions when compared to prior year allocations, as determined by the Secretary; and

(ii) not later than 30 days after developing the formula methodology under clause (i), submit the formula methodology to—

(I) the Committee on Health, Education, Labor, and Pensions and the Committee on Appropriations of the Senate; and

(II) the Committee on Energy and Commerce and the Committee on Appropriations of the House of Representatives.

(B) Report

Not later than two years after December 29, 2022, the Comptroller General of the United States shall submit to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives a report that—

(i) assesses how grant funding is allocated to States under this section and how such allocations have changed over time;

(ii) assesses how any changes in funding under this section have affected the efforts of States to address opioid misuse and use disorders and, as applicable and appropriate, stimulant misuse and use disorders; and

(iii) assesses the use of funding provided through the grant program under this section and other similar grant programs administered by the Substance Abuse and Mental Health Services Administration.

(4) Use of funds

Grants awarded under this subsection shall be used for carrying out activities that supplement activities pertaining to opioid misuse and use disorders and, as applicable and appropriate, stimulant misuse and use disorders (including co-occurring substance misuse and use disorders), undertaken by the entities described in paragraph (1), which may include public health-related activities such as the following:

(A) Implementing substance use disorder and overdose prevention activities, including primary prevention activities, and evaluating such activities to identify effective strategies to prevent substance use disorders and overdoses, which may include drugs or devices approved, cleared, or otherwise legally marketed under the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 301 et seq.].

(B) Establishing or improving prescription drug monitoring programs.

(C) Training for health care practitioners, such as best practices for prescribing opioids, pain management, recognizing potential cases of substance use disorders, referral of patients to treatment programs, preventing diversion of controlled substances, and overdose prevention.

(D) Supporting access to and the provision of substance use disorder-related health care services, including—

(i) services provided by federally certified opioid treatment programs;

(ii) services provided in outpatient and residential substance use disorder treatment programs or facilities, including those that utilize medication-assisted treatment, as appropriate; or

(iii) services provided by other appropriate health care providers to treat substance use disorders, including crisis services and services provided in integrated health care settings by

appropriate health care providers that treat substance use disorders.

(E) Recovery support services, including—
(i) community-based services that include education, outreach, and peer supports such as peer support specialists and recovery coaches to help support recovery;
(ii) mutual aid recovery programs that support medication-assisted treatment;
(iii) services to address housing needs; or
(iv) services related to supporting families that include an individual with a substance use disorder.

(F) Other public health-related activities, as such entity determines appropriate, related to addressing opioid misuse and use disorders and, as applicable and appropriate, stimulant misuse and use disorders, within such entity, including directing resources in accordance with local needs related to substance use disorders.

(c) Accountability and oversight

A State receiving a grant under subsection (b) shall submit to the Secretary a description of—
(1) the purposes for which the grant funds received by the State under such subsection for the preceding fiscal year were expended and a description of the activities of the State under the grant;
(2) the ultimate recipients of amounts provided to the State;
(3) the number of individuals served through the grant; and
(4) such other information as determined appropriate by the Secretary.

(d) Limitations

Any funds made available pursuant to subsection (i) shall not be used for any purpose other than the grant program under subsection (b).

(e) Indian Tribes and Tribal organizations

The Secretary, in consultation with Indian Tribes and Tribal organizations, shall identify and establish appropriate mechanisms for Indian Tribes and Tribal organizations to demonstrate or report the information as required under subsections (b), (c), and (d).

(f) Report to Congress

Not later than September 30, 2024, and biennially thereafter, the Secretary shall submit to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives, and the Committees on Appropriations of the House of Representatives and the Senate, a report that includes a summary of the information provided to the Secretary in reports made pursuant to subsections (c) and (d), including—
(1) the purposes for which grant funds are awarded under this section;
(2) the activities of the grant recipients; and
(3) each entity that receives a grant under this section, including the funding level provided to such recipient.

(g) Technical assistance

The Secretary, including through the Tribal Training and Technical Assistance Center of the Substance Abuse and Mental Health Services Administration, as applicable, shall provide entities described in subsection (b)(1) with technical assistance concerning grant application and submission procedures under this section, award management activities, and enhancing outreach and direct support to rural and underserved communities and providers in addressing substance use disorders.

(h) Definitions

In this section:

(1) Indian Tribe

The term "Indian Tribe" has the meaning given the term "Indian tribe" in section 5304 of title 25.

(2) Tribal organization

The term "Tribal organization" has the meaning given the term "tribal organization" in section 5304 of title 25.

(3) State

The term "State" has the meaning given such term in section 300x–64(b) of this title.

(4) Urban Indian organization

The term "Urban Indian organization" has the meaning given such term in section 1603 of title 25.

(i) Authorization of appropriations

(1) In general

For purposes of carrying out the grant program under subsection (b), there is authorized to be appropriated $1,750,000,000 for each of fiscal years 2023 through 2027.

(2) Federal administrative expenses

Of the amounts made available for each fiscal year to award grants under subsection (b), the Secretary shall not use more than 2 percent for Federal administrative expenses, training, technical assistance, and evaluation.

(3) Set aside

Of the amounts made available for each fiscal year to award grants under subsection (b) for a fiscal year, the Secretary shall—

(A) award not more than 5 percent to Indian Tribes and Tribal organizations; and

(B) of the amount remaining after application of subparagraph (A), set aside up to 15 percent for awards to States with the highest age-adjusted rate of drug overdose death based on the ordinal ranking of States according to the Director of the Centers for Disease Control and Prevention.

(Pub. L. 114–255, div. A, title I, §1003, Dec. 13, 2016, 130 Stat. 1044; Pub. L. 115–271, title VII, §7181(a), Oct. 24, 2018, 132 Stat. 4068; Pub. L. 117–328, div. FF, title I, §1273, Dec. 29, 2022, 136 Stat. 5688.)

EDITORIAL NOTES

REFERENCES IN TEXT

The Public Health Service Act, referred to in subsec. (b)(1), is act July 1, 1944, ch. 373, 58 Stat. 682. Subpart II of part B of title XIX of the Act is classified generally to subpart II (§300x–21 et seq.) of part B of subchapter XVII of chapter 6A of this title. For complete classification of this Act to the Code, see Short Title note set out under section 201 of this title and Tables.

The Federal Food, Drug, and Cosmetic Act, referred to in subsec. (b)(4)(A), is act June 25, 1938, ch. 675, 52 Stat. 1040, which is classified generally to chapter 9 (§301 et seq.) of Title 21, Food and Drugs. For complete classification of this Act to the Code, see section 301 of Title 21 and Tables.

CODIFICATION

Section was formerly classified as a note under section 290ee–3 of this title prior to editorial reclassification and renumbering as this section.

Section was enacted as part of the 21st Century Cures Act, and not as part of the Public Health Service Act which comprises this chapter.

AMENDMENTS

2022—Pub. L. 117–328 amended section generally. Prior to amendment, section related to grant program for purposes of addressing opioid abuse crisis within States and Indian Tribes.

2018—Subsec. (a). Pub. L. 115–271, §7181(a)(1), substituted "subsection (h) to carry out the grant program described in subsection (b)" for "the authorization of appropriations under subsection (b) to carry out the grant program described in subsection (c)" and inserted "and Indian Tribes" after "States".

Subsec. (b). Pub. L. 115–271, §7181(a)(2), (3), redesignated subsec. (c) as (b) and struck out former subsec. (b) which established the Account for the State Response to the Opioid Abuse Crisis in the Treasury.

Subsec. (b)(1). Pub. L. 115–271, §7181(a)(5)(A), inserted "and tribal" after "State" in heading and, in text, substituted "States and Indian Tribes for the purpose of addressing the opioid abuse crisis within such States and Indian Tribes" for "States for the purpose of addressing the opioid abuse crisis within such States" and inserted "or Indian Tribes" after "preference to States" and "or other Indian Tribes, as applicable" after "to other States".

Subsec. (b)(2). Pub. L. 115–271, §7181(a)(5)(B)(i), struck out "to a State" after "Grants awarded" in introductory provisions.

Subsec. (b)(2)(A). Pub. L. 115–271, §7181(a)(5)(B)(ii), substituted "Establishing or improving" for "Improving State".

Subsec. (b)(2)(C). Pub. L. 115–271, §7181(a)(5)(B)(iii), inserted "preventing diversion of controlled substances," after "treatment programs,".

Subsec. (b)(2)(E). Pub. L. 115–271, §7181(a)(5)(B)(iv), substituted "as the State or Indian Tribe determines appropriate, related to addressing the opioid abuse crisis within the State or Indian Tribe, including directing resources in accordance with local needs related to substance use disorders" for "as the State determines appropriate, related to addressing the opioid abuse crisis within the State".

Subsec. (c). Pub. L. 115–271, §7181(a)(6), substituted "subsection (b)" for "subsection (c)" in introductory provisions.

Pub. L. 115–271, §7181(a)(3), redesignated subsec. (d) as (c). Former subsec. (c) redesignated (b).

Subsec. (d). Pub. L. 115–271, §7181(a)(7)(A), substituted "subsection (h)" for "the authorization of appropriations under subsection (b)" in introductory provisions.

Pub. L. 115–271, §7181(a)(3), redesignated subsec. (e) as (d). Former subsec. (d) redesignated (c).

Subsec. (d)(1). Pub. L. 115–271, §7181(a)(7)(B), substituted "subsection (b)" for "subsection (c)".

Subsecs. (e) to (i). Pub. L. 115–271, §7181(a)(8), added subsec. (e) to (i). Former subsecs. (e) and (f) redesignated (d) and (j), respectively.

Subsec. (j). Pub. L. 115–271, §7181(a)(4), redesignated subsec. (f) as (j).

STATUTORY NOTES AND RELATED SUBSIDIARIES

SUBSTANCE USE DISORDER AND OVERDOSE PREVENTION ACTIVITIES

Pub. L. 119–44, title I, §113, Dec. 1, 2025, 139 Stat. 679, provided that: "The activities carried out pursuant to section 1003(b)(4)(A) of the 21st Century Cures Act (42 U.S.C. 290ee–3a(b)(4)(A)) may include facilitating access to products used to prevent overdose deaths by detecting the presence of one or more substances, such as fentanyl and xylazine test strips, to the extent the purchase and possession of such products is consistent with Federal and State law."

§290ee–4. Mental and behavioral health outreach and education at institutions of higher education

(a) Purpose

It is the purpose of this section to increase access to, and reduce the stigma associated with, mental health services to ensure that students at institutions of higher education have the support necessary to successfully complete their studies.

(b) National public education campaign

The Secretary, acting through the Assistant Secretary and in collaboration with the Director of the Centers for Disease Control and Prevention, shall convene an interagency, public-private sector working group to plan, establish, and begin coordinating and evaluating a targeted public education campaign that is designed to focus on mental and behavioral health on the campuses of institutions of higher education. Such campaign shall be designed to—

(1) improve the general understanding of mental health and mental disorders;

(2) encourage help-seeking behaviors relating to the promotion of mental health, prevention of mental disorders, and treatment of such disorders;

(3) make the connection between mental and behavioral health and academic success; and

(4) assist the general public in identifying the early warning signs and reducing the stigma of mental illness.

(c) Composition

The working group convened under subsection (b) shall include—

(1) mental health consumers, including students and family members;

(2) representatives of institutions of higher education, including minority-serving institutions as described in section 1067q(a) of title 20 and community colleges;

(3) representatives of national mental and behavioral health associations and associations of institutions of higher education;

(4) representatives of health promotion and prevention organizations at institutions of higher education;

(5) representatives of mental health providers, including community mental health centers; and

(6) representatives of private-sector and public-sector groups with experience in the development of effective public health education campaigns.

(d) Plan

The working group under subsection (b) shall develop a plan that—

(1) targets promotional and educational efforts to the age population of students at institutions of higher education and individuals who are employed in settings of institutions of higher education, including through the use of roundtables;

(2) develops and proposes the implementation of research-based public health messages and activities;

(3) provides support for local efforts to reduce stigma by using the National Health Information Center as a primary point of contact for information, publications, and service program referrals; and

(4) develops and proposes the implementation of a social marketing campaign that is targeted at the population of students attending institutions of higher education and individuals who are employed in settings of institutions of higher education.

(e) Definition

In this section, the term "institution of higher education" has the meaning given such term in section 1001 of title 20.

(f) Authorization of appropriations

To carry out this section, there are authorized to be appropriated $1,000,000 for the period of fiscal years 2023 through 2027.

(July 1, 1944, ch. 373, title V, §549, as added Pub. L. 114–255, div. B, title IX, §9033, Dec. 13, 2016, 130 Stat. 1261; amended Pub. L. 117–328, div. FF, title I, §1424, Dec. 29, 2022, 136 Stat. 5704.)

EDITORIAL NOTES

AMENDMENTS

2022—Pub. L. 117–328, §1424(1), substituted "at institutions of higher education" for "on college campuses" in section catchline.

Subsec. (c)(2). Pub. L. 117–328, §1424(2), inserted ", including minority-serving institutions as described in section 1067q(a) of title 20 and community colleges" after "higher education".

Subsec. (f). Pub. L. 117–328, §1424(3), substituted "2023 through 2027" for "2018 through 2022".

§290ee–5. National recovery housing best practices

(a) Best practices for operating recovery housing

(1) In general

The Secretary, in consultation with the individuals and entities specified in paragraph (2), shall continue activities to identify, facilitate the development of, and periodically update consensus-based best practices, which may include model laws for implementing suggested minimum standards for operating, and promoting the availability of, high-quality recovery housing.

(2) Consultation

In carrying out the activities described in paragraph (1), the Secretary shall consult with, as appropriate—

(A) officials representing the agencies described in subsection (e)(2);

(B) directors or commissioners, as applicable, of State health departments, Tribal health departments, State Medicaid programs, and State insurance agencies;

(C) representatives of health insurance issuers;

(D) national accrediting entities and reputable providers of, and analysts of, recovery housing services, including Indian Tribes, Tribal organizations, and Tribally designated housing entities that provide recovery housing services, as applicable;

(E) individuals with a history of substance use disorder; and

(F) other stakeholders identified by the Secretary.

(3) Availability

The best practices referred to in paragraph (1) shall be—

(A) made publicly available; and

(B) published on the public website of the Substance Abuse and Mental Health Services Administration.

(4) Exclusion of guideline on treatment services

In facilitating the development of best practices under paragraph (1), the Secretary may not include any best practices with respect to substance use disorder treatment services.

(b) Identification of fraudulent recovery housing operators

(1) In general

The Secretary, in consultation with the individuals and entities described in paragraph (2), shall identify or facilitate the development of common indicators that could be used to identify potentially fraudulent recovery housing operators.

(2) Consultation

In carrying out the activities described in paragraph (1), the Secretary shall consult with, as appropriate, the individuals and entities specified in subsection (a)(2) and the Attorney General of the United States.

(3) Requirements

(A) Practices for identification and reporting

In carrying out the activities described in paragraph (1), the Secretary shall consider how law enforcement, public and private payers, and the public can best identify and report fraudulent recovery housing operators.

(B) Factors to be considered

In carrying out the activities described in paragraph (1), the Secretary shall identify or develop indicators, which may include indicators related to—

(i) unusual billing practices;

(ii) average lengths of stays;

(iii) excessive levels of drug testing (in terms of cost or frequency); and

(iv) unusually high levels of recidivism.

(c) Dissemination

The Secretary shall, as appropriate, disseminate the best practices identified or developed under

subsection (a) and the common indicators identified or developed under subsection (b) to—

(1) State agencies, which may include the provision of technical assistance to State agencies seeking to adopt or implement such best practices;

(2) Indian Tribes, Tribal organizations, and tribally designated housing entities;

(3) the Attorney General of the United States;

(4) the Secretary of Labor;

(5) the Secretary of Housing and Urban Development;

(6) State and local law enforcement agencies;

(7) health insurance issuers;

(8) recovery housing entities; and

(9) the public.

(d) Requirements

In carrying out the activities described in subsections (a) and (b), the Secretary, in consultation with appropriate individuals and entities described in subsections (a)(2) and (b)(2), shall consider how recovery housing is able to support recovery and prevent relapse, recidivism, or overdose (including overdose death), including by improving access and adherence to treatment, including medication-assisted treatment.

(e) Coordination of Federal activities to promote the availability of housing for individuals experiencing homelessness, individuals with a mental illness, and individuals with a substance use disorder

(1) In general

The Secretary, acting through the Assistant Secretary, and the Secretary of Housing and Urban Development shall convene an interagency working group for the following purposes:

(A) To increase collaboration, cooperation, and consultation among the Department of Health and Human Services, the Department of Housing and Urban Development, and the Federal agencies listed in paragraph (2)(B), with respect to promoting the availability of housing, including high-quality recovery housing, for individuals experiencing homelessness, individuals with mental illnesses, and individuals with substance use disorder.

(B) To align the efforts of such agencies and avoid duplication of such efforts by such agencies.

(C) To develop objectives, priorities, and a long-term plan for supporting State, Tribal, and local efforts with respect to the operation of high-quality recovery housing that is consistent with the best practices developed under this section.

(D) To improve information on the quality of recovery housing.

(2) Composition

The interagency working group under paragraph (1) shall be composed of—

(A) the Secretary, acting through the Assistant Secretary, and the Secretary of Housing and Urban Development, who shall serve as the co-chairs; and

(B) representatives of each of the following Federal agencies:

(i) The Centers for Medicare & Medicaid Services.

(ii) The Substance Abuse and Mental Health Services Administration.

(iii) The Health Resources and Services Administration.

(iv) The Office of the Inspector General of the Department of Health and Human Services.

(v) The Indian Health Service.

(vi) The Department of Agriculture.

(vii) The Department of Justice.

(viii) The Office of National Drug Control Policy.

(ix) The Bureau of Indian Affairs.

(x) The Department of Labor.

(xi) The Department of Veterans Affairs.

(xii) Any other Federal agency as the co-chairs determine appropriate.

(3) Meetings

The working group shall meet on a quarterly basis.

(4) Reports to Congress

Not later than 4 years after December 29, 2022, the working group shall submit to the Committee on Health, Education, Labor, and Pensions, the Committee on Agriculture, Nutrition, and Forestry, and the Committee on Finance of the Senate and the Committee on Energy and Commerce, the Committee on Ways and Means, the Committee on Agriculture, and the Committee on Financial Services of the House of Representatives a report describing the work of the working group and any recommendations of the working group to improve Federal, State, and local coordination with respect to recovery housing and other housing resources and operations for individuals experiencing homelessness, individuals with a mental illness, and individuals with a substance use disorder.

(f) Grants for implementing national recovery housing best practices

(1) In general

The Secretary shall award grants to States (and political subdivisions thereof), Indian Tribes, and territories—

(A) for the provision of technical assistance to implement the guidelines and recommendations developed under subsection (a); and

(B) to promote—

(i) the availability of recovery housing for individuals with a substance use disorder; and

(ii) the maintenance of recovery housing in accordance with best practices developed under this section.

(2) State promotion plans

Not later than 90 days after receipt of a grant under paragraph (1), and every 2 years thereafter, each State (or political subdivisions thereof,) [1] Indian Tribe, or territory receiving a grant under paragraph (1) shall submit to the Secretary, and publish on a publicly accessible internet website of the State (or political subdivisions thereof), Indian Tribe, or territory—

(A) the plan of the State (or political subdivisions thereof), Indian Tribe, or territory, with respect to the promotion of recovery housing for individuals with a substance use disorder located within the jurisdiction of such State (or political subdivisions thereof), Indian Tribe, or territory; and

(B) a description of how such plan is consistent with the best practices developed under this section.

(g) Rule of construction

Nothing in this section shall be construed to provide the Secretary with the authority to require States to adhere to minimum standards in the State oversight of recovery housing.

(h) Definitions

In this section:

(1) The term "recovery housing" means a shared living environment free from alcohol and illicit drug use and centered on peer support and connection to services that promote sustained recovery from substance use disorders.

(2) The terms "Indian Tribe" and "Tribal organization" have the meanings given those terms in section 5304 of title 25.

(3) The term "tribally designated housing entity" has the meaning given that term in section 4103 of title 25.

(i) Authorization of appropriations

To carry out this section, there is authorized to be appropriated $5,000,000 for the period of fiscal years 2023 through 2027.

(July 1, 1944, ch. 373, title V, §550, as added Pub. L. 115–271, title VII, §7031, Oct. 24, 2018, 132

Stat. 4014; amended Pub. L. 117–328, div. FF, title I, §§1232, 1233, 1235, 1236, Dec. 29, 2022, 136 Stat. 5674, 5676, 5677.)

EDITORIAL NOTES

REFERENCES IN TEXT

December 29, 2022, referred to in subsec. (e)(4), was in the original "the date of the enactment of this section", and was translated as reading "the date of the enactment of this subsection", meaning the date of enactment of Pub. L. 117–328, which enacted subsec. (e), to reflect the probable intent of Congress.

PRIOR PROVISIONS

A prior section 550 of act July 1, 1944, was renumbered section 550A of act July 1, 1944, and is classified to section 290ee–5a of this title.

AMENDMENTS

2022—Subsec. (a)(1). Pub. L. 117–328, §1232(1), amended par. (1) generally. Prior to amendment, text read as follows: "The Secretary, in consultation with the individuals and entities specified in paragraph (2), shall identify or facilitate the development of best practices, which may include model laws for implementing suggested minimum standards, for operating recovery housing."

Subsec. (a)(2)(A). Pub. L. 117–328, §1232(2)(A), added subpar. (A) and struck out former subpar. (A) which read as follows: "relevant divisions of the Department of Health and Human Services, including the Substance Abuse and Mental Health Services Administration, the Office of Inspector General, the Indian Health Service, and the Centers for Medicare & Medicaid Services;".

Subsec. (a)(2)(B). Pub. L. 117–328, §1232(2)(A)–(C), redesignated subpar. (C) as (B), substituted "Tribal" for "tribal", and struck out former subpar. (B) which read as follows: "the Secretary of Housing and Urban Development;".

Subsec. (a)(2)(C). Pub. L. 117–328, §1232(2)(B), redesignated subpar. (D) as (C). Former subpar. (C) redesignated (B).

Subsec. (a)(2)(D). Pub. L. 117–328, §1232(2)(B), (D), redesignated subpar. (E) as (D) and substituted "Tribes, Tribal organizations, and Tribally" for "tribes, tribal organizations, and tribally". Former subpar. (D) redesignated (C).

Subsec. (a)(2)(E) to (G). Pub. L. 117–328, §1232(2)(B), redesignated subpars. (F) and (G) as (E) and (F), respectively. Former subpar. (E) redesignated (D).

Subsec. (a)(3), (4). Pub. L. 117–328, §1232(3), added pars. (3) and (4).

Subsec. (c)(2). Pub. L. 117–328, §1233(2), substituted "Indian Tribes, Tribal" for "Indian tribes, tribal".

Subsec. (e). Pub. L. 117–328, §1233(4), added subsec. (e). Former subsec. (e) redesignated (g).

Subsec. (f). Pub. L. 117–328, §1235, added subsec. (f). Former subsec. (f) redesignated (h).

Subsec. (g). Pub. L. 117–328, §1233(1), redesignated subsec. (e) as (g). Former subsec. (g) redesignated (i).

Subsec. (h). Pub. L. 117–328, §1233(1), redesignated subsec. (f) as (h).

Subsec. (h)(2). Pub. L. 117–328, §1233(3), substituted "Indian Tribe" for "Indian tribe" and "Tribal organization" for "tribal organization".

Subsec. (i). Pub. L. 117–328, §1236, substituted "$5,000,000 for the period of fiscal years 2023 through 2027" for "$3,000,000 for the period of fiscal years 2019 through 2021".

Pub. L. 117–328, §1233(1), redesignated subsec. (g) as (i).

[1] *So in original. The comma probably should follow the closing parenthesis.*

§290ee–5a. Sobriety treatment and recovery teams

(a) In general

The Secretary may make grants to States, units of local government, or tribal governments to establish or expand Sobriety Treatment And Recovery Team (referred to in this section as "START") or other similar programs to determine the effectiveness of pairing social workers or mentors with families that are struggling with a substance use disorder and child abuse or neglect in order to help provide peer support, intensive treatment, and child welfare services to such families.

(b) Allowable uses

A grant awarded under this section may be used for one or more of the following activities:

(1) Training eligible staff, including social workers, social services coordinators, child welfare specialists, substance use disorder treatment professionals, and mentors.

(2) Expanding access to substance use disorder treatment services and drug testing.

(3) Enhancing data sharing with law enforcement agencies, child welfare agencies, substance use disorder treatment providers, judges, and court personnel.

(4) Program evaluation and technical assistance.

(c) Program requirements

A State, unit of local government, or tribal government receiving a grant under this section shall—

(1) serve only families for which—

(A) there is an open record with the child welfare agency; and

(B) substance use disorder was a reason for the record or finding described in paragraph (1); [1] and

(2) coordinate any grants awarded under this section with any grant awarded under section 629g(f) of this title focused on improving outcomes for children affected by substance abuse.

(d) Technical assistance

The Secretary may reserve not more than 5 percent of funds provided under this section to provide technical assistance on the establishment or expansion of programs funded under this section from the National Center on Substance Abuse and Child Welfare.

(July 1, 1944, ch. 373, title V, §550A, formerly §550, as added Pub. L. 115–271, title VIII, §8214, Oct. 24, 2018, 132 Stat. 4116; renumbered §550A, Pub. L. 117–328, div. FF, title I, §1237, Dec. 29, 2022, 136 Stat. 5677.)

EDITORIAL NOTES

CODIFICATION

Section was formerly classified to section 290ee–10 of this title prior to renumbering by Pub. L. 117–328.

[1] *So in original. Probably should be "subparagraph (A)".*

§290ee–6. Regional Centers of Excellence in Substance Use Disorder Education

(a) In general

The Secretary, in consultation with appropriate agencies, shall award cooperative agreements to eligible entities for the designation of such entities as Regional Centers of Excellence in Substance Use Disorder Education for purposes of improving health professional training resources with respect to substance use disorder prevention, treatment, and recovery.

(b) Eligibility

To be eligible to receive a cooperative agreement under subsection (a), an entity shall—

(1) be an accredited entity that offers education to students in various health professions, which may include—

(A) a teaching hospital;

(B) a medical school;

(C) a certified behavioral health clinic; or

(D) any other health professions school, school of public health, or Cooperative Extension Program at institutions of higher education, as defined in section 1001 of title 20, engaged in the prevention, treatment, or recovery of substance use disorders;

(2) demonstrate community engagement and partnerships with community stakeholders, including entities that train health professionals, mental health counselors, social workers, peer recovery specialists, substance use treatment programs, community health centers, physician offices, certified behavioral health clinics, research institutions, and law enforcement; and

(3) submit to the Secretary an application containing such information, at such time, and in such manner, as the Secretary may require.

(c) Activities

An entity receiving an award under this section shall develop, evaluate, and distribute evidence-based resources regarding the prevention and treatment of, and recovery from, substance use disorders. Such resources may include information on—

(1) the neurology and pathology of substance use disorders;

(2) advancements in the treatment of substance use disorders;

(3) techniques and best practices to support recovery from substance use disorders;

(4) strategies for the prevention and treatment of, and recovery from substance use disorders across patient populations; and

(5) other topic areas that are relevant to the objectives described in subsection (a).

(d) Geographic distribution

In awarding cooperative agreements under subsection (a), the Secretary shall take into account regional differences among eligible entities and shall make an effort to ensure geographic distribution.

(e) Evaluation

The Secretary shall evaluate each project carried out by an entity receiving an award under this section and shall disseminate the findings with respect to each such evaluation to appropriate public and private entities.

(f) Funding

There is authorized to be appropriated to carry out this section, $4,000,000 for each of fiscal years 2019 through 2023.

(July 1, 1944, ch. 373, title V, §551, as added Pub. L. 115–271, title VII, §7101, Oct. 24, 2018, 132 Stat. 4037.)

§290ee–7. Comprehensive opioid recovery centers

(a) In general

The Secretary shall award grants on a competitive basis to eligible entities to establish or operate a comprehensive opioid recovery center (referred to in this section as a "Center"). A Center may be a single entity or an integrated delivery network.

(b) Grant period

(1) In general

A grant awarded under subsection (a) shall be for a period of not less than 3 years and not more than 5 years.

(2) Renewal

A grant awarded under subsection (a) may be renewed, on a competitive basis, for additional periods of time, as determined by the Secretary. In determining whether to renew a grant under this paragraph, the Secretary shall consider the data submitted under subsection (h).

(c) Minimum number of Centers

The Secretary shall allocate the amounts made available under subsection (j) such that not fewer

than 10 grants may be awarded. Not more than one grant shall be made to entities in a single State for any one period.

(d) Application

(1) Eligible entity

An entity is eligible for a grant under this section if the entity offers treatment and other services for individuals with a substance use disorder.

(2) Submission of application

In order to be eligible for a grant under subsection (a), an entity shall submit an application to the Secretary at such time, in such manner, and containing such information and assurances, including relevant documentation, as the Secretary may require. Such application shall include—

(A) evidence that such entity carries out, or has the demonstrated capability to carry out, through referral or contractual arrangements, the activities described in subsection (g); and

(B) such other information as the Secretary may require.

(e) Priority

In awarding grants under subsection (a), the Secretary shall give priority to eligible entities—

(1) located in a State with an age-adjusted rate of drug overdose deaths that is above the national overdose mortality rate, as determined by the Director of the Centers for Disease Control and Prevention; or

(2) serving an Indian Tribe (as defined in section 5304 of title 25) with an age-adjusted rate of drug overdose deaths that is above the national overdose mortality rate, as determined through appropriate mechanisms determined by the Secretary in consultation with Indian Tribes.

(f) Preference

In awarding grants under subsection (a), the Secretary may give preference to eligible entities utilizing technology-enabled collaborative learning and capacity building models, including such models as defined in section 2 of the Expanding Capacity for Health Outcomes Act (Public Law 114–270; 130 Stat. 1395), to conduct the activities described in this section.

(g) Center activities

Each Center shall, at a minimum, carry out the following activities directly, through referral, or through contractual arrangements, which may include carrying out such activities through technology-enabled collaborative learning and capacity building models described in subsection (f):

(1) Treatment and recovery services

Each Center shall—

(A) Ensure that intake, evaluations, and periodic patient assessments meet the individualized clinical needs of patients, including by reviewing patient placement in treatment settings to support meaningful recovery.

(B) Provide the full continuum of treatment services, including—

(i) all drugs and devices approved or cleared under the Federal Food, Drug, and Cosmetic Act and all biological products licensed under section 262 of this title to treat substance use disorders or reverse overdoses, pursuant to Federal and State law;

(ii) medically supervised withdrawal management, that includes patient evaluation, stabilization, and readiness for and entry into treatment;

(iii) counseling provided by a program counselor or other certified professional who is licensed and qualified by education, training, or experience to assess the psychological and sociological background of patients, to contribute to the appropriate treatment plan for the patient, and to monitor patient progress;

(iv) treatment, as appropriate, for patients with co-occurring substance use and mental disorders;

(v) testing, as appropriate, for infections commonly associated with illicit drug use;

(vi) residential rehabilitation, and outpatient and intensive outpatient programs;

(vii) recovery housing;

(viii) community-based and peer recovery support services;

(ix) job training, job placement assistance, and continuing education assistance to support reintegration into the workforce; and

(x) other best practices to provide the full continuum of treatment and services, as determined by the Secretary.

(C) Ensure that all programs covered by the Center include medication-assisted treatment, as appropriate, and do not exclude individuals receiving medication-assisted treatment from any service.

(D) Periodically conduct patient assessments to support sustained and clinically significant recovery, as defined by the Assistant Secretary for Mental Health and Substance Use.

(E) Provide onsite access to medication, as appropriate, and toxicology services; for purposes of carrying out this section.

(F) Operate a secure, confidential, and interoperable electronic health information system.

(G) Offer family support services such as child care, family counseling, and parenting interventions to help stabilize families impacted by substance use disorder, as appropriate.

(2) Outreach

Each Center shall carry out outreach activities regarding the services offered through the Centers, which may include—

(A) training and supervising outreach staff, as appropriate, to work with State and local health departments, health care providers, the Indian Health Service, State and local educational agencies, schools funded by the Indian Bureau of Education, institutions of higher education, State and local workforce development boards, State and local community action agencies, public safety officials, first responders, Indian Tribes, child welfare agencies, as appropriate, and other community partners and the public, including patients, to identify and respond to community needs;

(B) ensuring that the entities described in subparagraph (A) are aware of the services of the Center; and

(C) disseminating and making publicly available, including through the internet, evidence-based resources that educate professionals and the public on opioid use disorder and other substance use disorders, including co-occurring substance use and mental disorders.

(h) Data reporting and program oversight

(1) In general

With respect to a grant awarded under subsection (a), not later than 90 days after the end of the first year of the grant period, and annually thereafter for the duration of the grant period (including the duration of any renewal period for such grant), the entity shall submit data, as appropriate, to the Secretary regarding—

(A) the programs and activities funded by the grant;

(B) health outcomes of the population of individuals with a substance use disorder who received services from the Center, evaluated by an independent program evaluator through the use of outcomes measures, as determined by the Secretary;

(C) the retention rate of program participants; and

(D) any other information that the Secretary may require for the purpose of—ensuring [1] that the Center is complying with all the requirements of the grant, including providing the full continuum of services described in subsection (g)(1)(B).

(2) Additional reporting for certain eligible entities

An entity carrying out activities described in subsection (g) through referral or contractual arrangements shall include in the submissions required under paragraph (1) information related to

the status of such referrals or contractual arrangements, including an assessment of whether such referrals or contractual arrangements are supporting the ability of such entity to carry out such activities.

(i) Privacy

The provisions of this section, including with respect to data reporting and program oversight, shall be subject to all applicable Federal and State privacy laws.

(j) Authorization of appropriations

There is authorized to be appropriated $10,000,000 for each of fiscal years 2026 through 2030 for purposes of carrying out this section.

(July 1, 1944, ch. 373, title V, §552, as added Pub. L. 115–271, title VII, §7121(a), Oct. 24, 2018, 132 Stat. 4043; amended Pub. L. 119–44, title III, §303, Dec. 1, 2025, 139 Stat. 685.)

EDITORIAL NOTES

REFERENCES IN TEXT

Section 2 of the Expanding Capacity for Health Outcomes Act, referred to in subsec. (f), is section 2 of Pub. L. 114–270, Dec. 14, 2016, 130 Stat. 1395, which is not classified to the Code.

The Federal Food, Drug, and Cosmetic Act, referred to in subsec. (g)(1)(B)(i), is act June 25, 1938, ch. 675, 52 Stat. 1040, which is classified generally to chapter 9 (§301 et seq.) of Title 21, Food and Drugs. For complete classification of this Act to the Code, see section 301 of Title 21 and Tables.

AMENDMENTS

2025—Subsec. (d)(2). Pub. L. 119–44, §303(1)(A), substituted ", in such manner, and containing such information and assurances, including relevant documentation," for "and in such manner" in introductory provisions.

Subsec. (d)(2)(A). Pub. L. 119–44, §303(1)(B), substituted "has the demonstrated capability to carry out, through referral or contractual arrangements" for "is capable of coordinating with other entities to carry out".

Subsec. (h). Pub. L. 119–44, §303(2), designated existing provisions as par. (1), inserted heading, redesignated former pars. (1) to (4) as subpars. (A) to (D), respectively, of par. (1) and realigned margins, and added par. (2).

Subsec. (j). Pub. L. 119–44, §303(3), substituted "2026 through 2030" for "2019 through 2023".

[1] *So in original.*

§290ee–8. Career Act; treatment, recovery, and workforce support grants

(a) In general

The Secretary of Health and Human Services (referred to in this section as the "Secretary"), in consultation with the Secretary of Labor, shall continue or establish a program to support individuals in substance use disorder treatment and recovery to live independently and participate in the workforce.

(b) Grants authorized

In carrying out the activities under this section, the Secretary shall, on a competitive basis, award grants each for a period of not more than 5 years to entities to enable such entities to carry out evidence-based programs to help individuals in substance use disorder treatment and recovery to live independently and participate in the workforce. Such entities shall coordinate, as applicable, with Indian tribes or tribal organizations (as applicable), State boards and local boards (as defined in section 3102 of title 29, lead State agencies with responsibility for a workforce investment activity (as defined in such section 3102), and State agencies responsible for carrying out substance use disorder prevention and treatment programs.

(c) Priority

(1) In general

In awarding grants under this section, the Secretary shall give priority based on the State in which the entity is located. Priority shall be given among States according to a formula based on the average rates for calendar years 2018 through 2022 described in paragraph (2) and weighted as described in paragraph (3).

(2) Rates

The rates described in this paragraph are the following:

(A) The highest age-adjusted average rates of drug overdose deaths for calendar years 2018 through 2022 based on data from the Centers for Disease Control and Prevention, including, if necessary, provisional data for calendar year 2022.

(B) The highest average rates of unemployment for calendar years 2018 through 2022 based on data provided by the Bureau of Labor Statistics.

(C) The lowest average labor force participation rates for calendar years 2018 through 2022 based on data provided by the Bureau of Labor Statistics.

(3) Weighting

The rates described in paragraph (2) shall be weighted as follows:

(A) The rate described in paragraph (2)(A) shall be weighted 70 percent.

(B) The rate described in paragraph (2)(B) shall be weighted 15 percent.

(C) The rate described in paragraph (2)(C) shall be weighted 15 percent.

(d) Preference

In awarding grants under this section, the Secretary shall give preference to entities located in areas within States with the greatest need, with such need based on the highest mortality rate related to substance use disorder.

(e) Definitions

In this section:

(1) Eligible entity

The term "eligible entity" means an entity that offers treatment or recovery services for individuals with substance use disorders, and partners with one or more local or State stakeholders, which may include local employers, community organizations, the local workforce development board, local and State governments, and Indian Tribes or tribal organizations, to support recovery, independent living, and participation in the workforce.

(2) Indian Tribes; tribal organization

The terms "Indian Tribe" and "tribal organization" have the meanings given the terms "Indian tribe" and "tribal organization" in section 5304 of title 25.

(3) State

The term "State" includes only the several States and the District of Columbia.

(f) Applications

An eligible entity shall submit an application at such time and in such manner as the Secretary may require. In submitting an application, the entity shall demonstrate the ability to partner with local stakeholders, which may include local employers, community stakeholders, the local workforce development board, local and State governments, and Indian Tribes or tribal organizations, as applicable, to—

(1) identify gaps in the workforce due to the prevalence of substance use disorders;

(2) in coordination with statewide employment and training activities, including coordination and alignment of activities carried out by entities provided grant funds under section 3225a of title 29, help individuals in recovery from a substance use disorder transition into the workforce, including by providing career services, training services as described in paragraph (2) of section 3174(c) of title 29, and related services described in section 3174(a)(3) of such title; and

(3) assist employers with informing their employees of the resources, such as resources related to substance use disorders that are available to their employees.

(g) Use of funds

(1) In general

An entity receiving a grant under this section shall use the funds to conduct one or more of the following activities:

(A) Hire case managers, care coordinators, providers of peer recovery support services, as described in section 290ee–2(a) of this title, or other professionals, as appropriate, to provide services that support treatment, recovery, and rehabilitation, and prevent relapse, recidivism, and overdose, including by encouraging—

(i) the development and strengthening of daily living skills; and

(ii) the use of counseling, care coordination, and other services, as appropriate, to support recovery from substance use disorders.

(B) Implement or utilize innovative technologies, which may include the use of telemedicine.

(C) In coordination with the lead State agency with responsibility for a workforce investment activity or local board described in subsection (b), provide—

(i) short-term prevocational training services; and

(ii) training services that are directly linked to the employment opportunities in the local area or the planning region.

(2) Transportation services

An entity receiving a grant under this section may use not more than 5 percent of the funds for providing transportation for individuals to participate in an activity supported by a grant under this section, which transportation shall be to or from a place of work or a place where the individual is receiving vocational education or job training services or receiving services directly linked to treatment of or recovery from a substance use disorder.

(3) Limitation

The Secretary may not require an entity to, or give priority to an entity that plans to, use the funds of a grant under this section for activities that are not specified in this subsection.

(h) Support for State strategy

An eligible entity shall include in its application under subsection (f) information describing how the services and activities proposed in such application are aligned with the State, outlying area, or Tribal strategy, as applicable, for addressing issues described in such application and how such entity will coordinate with existing systems to deliver services as described in such application.

(i) Data reporting and program oversight

Each eligible entity awarded a grant under this section shall submit to the Secretary a report at such time and in such manner as the Secretary may require. Such report shall include a description of—

(1) the programs and activities funded by the grant;

(2) outcomes of the population of individuals with a substance use disorder the grantee served through activities described in subsection (g), which shall include employment and earnings outcomes described in subclauses (I) and (III) of section 3141(b)(2)(A)(i) of title 29 with respect to the participation of such individuals with a substance use disorder in programs and activities funded by the grant under this section; and

(3) any other information that the Secretary may require for the purpose of ensuring that the grantee is complying with all of the requirements of the grant.

(j) Reports to Congress

(1) Preliminary report

Not later than 2 years after the end of the first year of the grant period under this section for

grants awarded prior to December 1, 2025, the Secretary shall submit to Congress a preliminary report that analyzes reports submitted under subsection (i).

(2) Final report

Not later than September 30, 2030, the Secretary shall submit to Congress a final report that includes—

(A) a description of how the grant funding was used, including the number of individuals who received services under subsection (g)(1)(C) and an evaluation of the effectiveness of the activities conducted by the grantee with respect to outcomes of the population of individuals with substance use disorder who receive services from the grantee; and

(B) recommendations related to best practices for health care professionals to support individuals in substance use disorder treatment or recovery to live independently and participate in the workforce.

(k) Authorization of appropriations

There is authorized to be appropriated $12,000,000 for each of fiscal years 2026 through 2030 for purposes of carrying out this section.

(Pub. L. 115–271, title VII, §7183, Oct. 24, 2018, 132 Stat. 4070; Pub. L. 119–44, title III, §305(a), Dec. 1, 2025, 139 Stat. 686.)

EDITORIAL NOTES

CODIFICATION

Section was enacted as part of the Substance Use–Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act, also known as the SUPPORT for Patients and Communities Act, and not as part of the Public Health Service Act which comprises this chapter.

AMENDMENTS

2025—Pub. L. 119–44, §305(a)(1), inserted "; treatment, recovery, and workforce support grants" after "Career Act" in section catchline.

Subsec. (b). Pub. L. 119–44, §305(a)(2), inserted "each" before "for a period".

Subsec. (c)(1). Pub. L. 119–44, §305(a)(3)(A), substituted "the average rates for calendar years 2018 through 2022 described in paragraph (2)" for "the rates described in paragraph (2)".

Subsec. (c)(2). Pub. L. 119–44, §305(a)(3)(B), amended par. (2) generally. Prior to amendment, text read as follows: "The rates described in this paragraph are the following:

"(A) The amount by which the rate of drug overdose deaths in the State, adjusted for age, is above the national overdose mortality rate, as determined by the Director of the Centers for Disease Control and Prevention.

"(B) The amount by which the rate of unemployment for the State, based on data provided by the Bureau of Labor Statistics for the preceding 5 calendar years for which there is available data, is above the national average.

"(C) The amount by which rate of labor force participation in the State, based on data provided by the Bureau of Labor Statistics for the preceding 5 calendar years for which there is available data, is below the national average."

Subsec. (g). Pub. L. 119–44, §305(a)(4), designated existing provisions as par. (1), inserted heading, redesignated former pars. (1) to (3) as subpars. (A) to (C), respectively, of par. (1), redesignated subpars. (A) and (B) of former pars. (1) and (3) as cls. (i) and (ii), respectively, of subpars. (A) and (C), realigned margins, and added pars. (2) and (3).

Subsec. (i)(2). Pub. L. 119–44, §305(a)(5), inserted ", which shall include employment and earnings outcomes described in subclauses (I) and (III) of section 3141(b)(2)(A)(i) of title 29 with respect to the participation of such individuals with a substance use disorder in programs and activities funded by the grant under this section" after "subsection (g)".

Subsec. (j)(1). Pub. L. 119–44, §305(a)(6)(A), inserted "for grants awarded prior to December 1, 2025" after "grant period under this section".

Subsec. (j)(2). Pub. L. 119–44, §305(a)(6)(B)(i), substituted "September 30, 2030" for "2 years after submitting the preliminary report required under paragraph (1)" in introductory provisions.

Subsec. (j)(2)(A). Pub. L. 119–44, §305(a)(6)(B)(ii), substituted "(g)(1)(C)" for "(g)(3)".

Subsec. (k). Pub. L. 119–44, §305(a)(7), substituted "$12,000,000 for each of fiscal years 2026 through 2030" for "$5,000,000 for each of fiscal years 2019 through 2023".

§290ee–9. Services for families and patients in crisis

(a) In general

The Secretary of Health and Human Services may make grants to entities that focus on addiction and substance use disorders and specialize in family and patient services, advocacy for patients and families, and educational information.

(b) Allowable uses

A grant awarded under this section may be used for nonprofit national, State, or local organizations that engage in the following activities:

(1) Expansion of resource center services with professional, clinical staff that provide, for families and individuals impacted by a substance use disorder, support, access to treatment resources, brief assessments, medication and overdose prevention education, compassionate listening services, recovery support or peer specialists, bereavement and grief support, and case management.

(2) Continued development of health information technology systems that leverage new and upcoming technology and techniques for prevention, intervention, and filling resource gaps in communities that are underserved.

(3) Enhancement and operation of treatment and recovery resources, easy-to-read scientific and evidence-based education on addiction and substance use disorders, and other informational tools for families and individuals impacted by a substance use disorder and community stakeholders, such as law enforcement agencies.

(4) Provision of training and technical assistance to State and local governments, law enforcement agencies, health care systems, research institutions, and other stakeholders.

(5) Expanding upon and implementing educational information using evidence-based information on substance use disorders.

(6) Expansion of training of community stakeholders, law enforcement officers, and families across a broad-range of addiction, health, and related topics on substance use disorders, local issues and community-specific issues related to the drug epidemic.

(7) Program evaluation.

(Pub. L. 114–198, title VII, §709, as added Pub. L. 115–271, title VIII, §8212, Oct. 24, 2018, 132 Stat. 4115.)

EDITORIAL NOTES

CODIFICATION

Section was enacted as part of the Substance Use–Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act, also known as the SUPPORT for Patients and Communities Act, and the Substance Abuse Prevention Act of 2018, and not as part of the Public Health Service Act which comprises this chapter.

§290ee–10. Rural emergency medical service training and equipment assistance program

(a) Grants

The Secretary, acting through the Assistant Secretary, shall award grants to eligible entities to enable such entities to provide for improved emergency medical services in rural areas or to residents of rural areas.

(b) Eligibility; application

To be eligible to receive grant under this section, an entity shall—

(1) be—

(A) an emergency medical services agency operated by a local or tribal government (including fire-based and non-fire based); or

(B) an emergency medical services agency that is described in section 501(c) of title 26 and exempt from tax under section 501(a) of title 26; and

(2) submit an application to the Secretary at such time, in such manner, and containing such information as the Secretary may require.

(c) Use of funds

An entity—

(1) shall use amounts received through a grant under subsection (a) to—

(A) train emergency medical services personnel as appropriate to obtain and maintain licenses and certifications relevant to service in an emergency medical services agency described in subsection (b)(1);

(B) conduct courses that qualify graduates to serve in an emergency medical services agency described in subsection (b)(1) in accordance with State and local requirements;

(C) fund specific training to meet Federal or State licensing or certification requirements;

(D) acquire emergency medical services equipment; and

(E) ensure emergency medical services personnel are trained on mental health and substance use disorders and care for individuals with such disorders in emergency situations; and

(2) may use amounts received through a grant under subsection (a) to—

(A) recruit and retain emergency medical services personnel, which may include volunteer personnel;

(B) develop new ways to educate emergency health care providers through the use of technology-enhanced educational methods;

(C) acquire personal protective equipment for emergency medical services personnel as required by the Occupational Safety and Health Administration; or

(D) acquire drugs or devices approved, cleared, or otherwise legally marketed under the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 301 et seq.] for emergency treatment of known or suspected overdose.

(d) Grant amounts

Each grant awarded under this section shall be in an amount not to exceed $200,000.

(e) Definitions

In this section:

(1) The term "emergency medical services"—

(A) means resources used by a public or private nonprofit licensed entity to deliver medical care outside of a medical facility under emergency conditions that occur as a result of the condition of the patient; and

(B) includes services delivered (either on a compensated or volunteer basis) by an emergency medical services provider or other provider that is licensed or certified by the State involved as an emergency medical technician, a paramedic, or an equivalent professional (as determined by the State).

(2) The term "rural area" means—

(A) a nonmetropolitan statistical area;

(B) an area designated as a rural area by any law or regulation of a State; or

(C) a rural census tract of a metropolitan statistical area (as determined under the most recent rural urban commuting area code as set forth by the Office of Management and Budget).

(f) Authorization of appropriations

(1) In general

There are authorized to be appropriated to carry out this section such sums as may be necessary for each of fiscal years 2024 through 2028.

(2) Administrative costs

The Secretary may use not more than 10 percent of the amount appropriated under paragraph (1) for a fiscal year for the administrative expenses of carrying out this section.

(July 1, 1944, ch. 373, title V, §553, formerly title III, §330J, as added Pub. L. 107–251, title II, §221, Oct. 26, 2002, 116 Stat. 1638; amended Pub. L. 115–334, title XII, §12608, Dec. 20, 2018, 132 Stat. 5008; renumbered title V, §553 and amended Pub. L. 118–84, §2, Sept. 26, 2024, 138 Stat. 1544.)

EDITORIAL NOTES

REFERENCES IN TEXT

The Federal Food, Drug, and Cosmetic Act, referred to in subsec. (c)(2)(D), is act June 25, 1938, ch. 675, 52 Stat. 1040, which is classified generally to chapter 9 (§301 et seq.) of Title 21, Food and Drugs. For complete classification of this Act to the Code, see section 301 of Title 21 and Tables.

CODIFICATION

Section was formerly classified to section 254c–15 of this title prior to renumbering by Pub. L. 118–84.

PRIOR PROVISIONS

A prior section 290ee–10, act July 1, 1944, ch. 373, title V, §550, as added Pub. L. 115–271, title VIII, §8214, Oct. 24, 2018, 132 Stat. 4116, which related to sobriety treatment and recovery teams, was renumbered section 550A of act July 1, 1944, by Pub. L. 117–328, div. FF, title I, §1237, Dec. 29, 2022, 136 Stat. 5677, and transferred to section 290ee–5a of this title.

AMENDMENTS

2024—Subsec. (a). Pub. L. 118–84, §2(1), substituted "the Assistant Secretary," for "the Administrator of the Health Resources and Services Administration (referred to in this section as the 'Secretary')".

Subsec. (c)(1)(E). Pub. L. 118–84, §2(2)(A), added subpar. (E).

Subsec. (c)(2)(D). Pub. L. 118–84, §2(2)(B), added subpar. (D).

Subsec. (f). Pub. L. 118–84, §2(3), (4), redesignated subsec. (g) as (f) and struck out former subsec. (f). Prior to amendment, text of subsec. (f) read as follows: "The Secretary may not award a grant under this section to an entity unless the entity agrees that the entity will make available (directly or through contributions from other public or private entities) non-Federal contributions toward the activities to be carried out under the grant in an amount equal to 10 percent of the amount received under the grant."

Subsec. (f)(1). Pub. L. 118–84, §2(5), substituted "2024 through 2028" for "2019 through 2023".

Subsec. (g). Pub. L. 118–84, §2(4), redesignated subsec. (g) as (f).

2018—Subsec. (a). Pub. L. 115–334, §12608(1), substituted "in rural areas or to residents of rural areas" for "in rural areas".

Subsecs. (b) to (f). Pub. L. 115–334, §12608(2), added subsecs. (b) to (f) and struck out former subsecs. (b) to (f) which related to eligibility for grants, use of funds, preference for certain grant applications, matching requirement, and definition of "emergency medical services", respectively.

Subsec. (g)(1). Pub. L. 115–334, §12608(3), substituted "2019 through 2023" for "2002 through 2006".

PART E—CHILDREN WITH SERIOUS EMOTIONAL DISTURBANCES

§290ff. Comprehensive community mental health services for children with serious emotional disturbances

(a) Grants to certain public entities

(1) In general

The Secretary, acting through the Director of the Center for Mental Health Services, shall make grants to public entities for the purpose of providing comprehensive community mental health services to children with a serious emotional disturbance, which may include efforts to identify and serve children at risk.

(2) "Public entity" defined

For purposes of this part, the term "public entity" means any State, any political subdivision of a State, and any Indian tribe or tribal organization (as defined in section 5304(b) and section 5304(c) [1] of title 25).

(b) Considerations in making grants

(1) Requirement of status as grantee under part B of subchapter XVII

The Secretary may make a grant under subsection (a) to a public entity only if—

(A) in the case of a public entity that is a State, the State is a grantee under section 300x of this title;

(B) in the case of a public entity that is a political subdivision of a State, the State in which the political subdivision is located is such a grantee; and

(C) in the case of a public entity that is an Indian tribe or tribal organization, the State in which the tribe or tribal organization is located is such a grantee.

(2) Requirement of status as medicaid provider

(A) Subject to subparagraph (B), the Secretary may make a grant under subsection (a) only if, in the case of any service under such subsection that is covered in the State plan approved under title XIX of the Social Security Act [42 U.S.C. 1396 et seq.] for the State involved—

(i) the public entity involved will provide the service directly, and the entity has entered into a participation agreement under the State plan and is qualified to receive payments under such plan; or

(ii) the public entity will enter into an agreement with an organization under which the organization will provide the service, and the organization has entered into such a participation agreement and is qualified to receive such payments.

(B)(i) In the case of an organization making an agreement under subparagraph (A)(ii) regarding the provision of services under subsection (a), the requirement established in such subparagraph regarding a participation agreement shall be waived by the Secretary if the organization does not, in providing health or mental health services, impose a charge or accept reimbursement available from any third-party payor, including reimbursement under any insurance policy or under any Federal or State health benefits program.

(ii) A determination by the Secretary of whether an organization referred to in clause (i) meets the criteria for a waiver under such clause shall be made without regard to whether the organization accepts voluntary donations regarding the provision of services to the public.

(3) Certain considerations

In making grants under subsection (a), the Secretary shall—

(A) equitably allocate such assistance among the principal geographic regions of the United States;

(B) consider the extent to which the public entity involved has a need for the grant; and

(C) in the case of any public entity that is a political subdivision of a State or that is an Indian tribe or tribal organization—

(i) shall consider any comments regarding the application of the entity for such a grant that are received by the Secretary from the State in which the entity is located; and

(ii) shall give special consideration to the entity if the State agrees to provide a portion of the non-Federal contributions required in subsection (c) regarding such a grant.

(c) Matching funds

(1) In general

A funding agreement for a grant under subsection (a) is that the public entity involved will, with respect to the costs to be incurred by the entity in carrying out the purpose described in such subsection, make available (directly or through donations from public or private entities) non-Federal contributions toward such costs in an amount that—

(A) for the first fiscal year for which the entity receives payments from a grant under such subsection, is not less than $1 for each $3 of Federal funds provided in the grant;

(B) for any second or third such fiscal year, is not less than $1 for each $3 of Federal funds provided in the grant;

(C) for any fourth such fiscal year, is not less than $1 for each $1 of Federal funds provided in the grant; and

(D) for any fifth and sixth such fiscal year,[2] is not less than $2 for each $1 of Federal funds provided in the grant.

(2) Determination of amount contributed

(A) Non-Federal contributions required in paragraph (1) may be in cash or in kind, fairly evaluated, including plant, equipment, or services. Amounts provided by the Federal Government, or services assisted or subsidized to any significant extent by the Federal Government, may not be included in determining the amount of such non-Federal contributions.

(B) In making a determination of the amount of non-Federal contributions for purposes of subparagraph (A), the Secretary may include only non-Federal contributions in excess of the average amount of non-Federal contributions made by the public entity involved toward the purpose described in subsection (a) for the 2-year period preceding the first fiscal year for which the entity receives a grant under such section.

(July 1, 1944, ch. 373, title V, §561, as added Pub. L. 102–321, title I, §119, July 10, 1992, 106 Stat. 349; amended Pub. L. 103–43, title XX, §2017(1), June 10, 1993, 107 Stat. 218; Pub. L. 106–310, div. B, title XXXI, §3105(a), Oct. 17, 2000, 114 Stat. 1175; Pub. L. 114–255, div. B, title X, §10001(a), Dec. 13, 2016, 130 Stat. 1262.)

EDITORIAL NOTES

REFERENCES IN TEXT

Subsections (b) and (c) of section 5304 of title 25, referred to in subsec. (a)(2), do not contain definitions of the terms "Indian tribe" and "tribal organization". However, such terms are defined elsewhere in that section.

The Social Security Act, referred to in subsec. (b)(2)(A), is act Aug. 14, 1935, ch. 531, 49 Stat. 620. Title XIX of the Act is classified generally to subchapter XIX (§1396 et seq.) of chapter 7 of this title. For complete classification of this Act to the Code, see section 1305 of this title and Tables.

PRIOR PROVISIONS

A prior section 290ff, act July 1, 1944, ch. 373, title V, §561, as added Nov. 18, 1988, Pub. L. 100–690, title II, §2081(a), 102 Stat. 4216, which related to action by National Institute on Drug Abuse and States concerning military facilities, was renumbered section 513 of act July 1, 1944, by Pub. L. 102–321 and transferred to section 290bb–6 of this title.

AMENDMENTS

2016—Subsec. (a)(1). Pub. L. 114–255 inserted ", which may include efforts to identify and serve children at risk" before period at end.

2000—Subsec. (c)(1)(D). Pub. L. 106–310 substituted "fifth and sixth such fiscal year" for "fifth such fiscal year".

1993—Subsec. (a)(2). Pub. L. 103–43, §2017(1)(A), substituted "this part" for "this subpart".

Subsec. (b)(1)(B), (C). Pub. L. 103–43, §2017(1)(B), substituted "is such a grantee" for "is receiving such payments".

STATUTORY NOTES AND RELATED SUBSIDIARIES

EFFECTIVE DATE

Section effective Oct. 1, 1992, with provision for programs providing financial assistance, see section 801(c), (d) of Pub. L. 102–321, set out as an Effective Date of 1992 Amendment note under section 236 of this title.

CURRENT GRANTEES

Pub. L. 106–310, div. B, title XXXI, §3105(e), Oct. 17, 2000, 114 Stat. 1175, provided that:

"(1) IN GENERAL.—Entities with active grants under section 561 of the Public Health Service Act (42 U.S.C. 290ff) on the date of the enactment of this Act [Oct. 17, 2000] shall be eligible to receive a sixth year of funding under the grant in an amount not to exceed the amount that such grantee received in the fifth year of funding under such grant. Such sixth year may be funded without requiring peer and Advisory Council review as required under section 504 of such Act (42 U.S.C. 290aa–3).

"(2) LIMITATION.—Paragraph (1) shall apply with respect to a grantee only if the grantee agrees to comply with the provisions of section 561 as amended by subsection (a)."

[1] See References in Text note below.

[2] So in original. Probably should be "years,".

§290ff–1. Requirements with respect to carrying out purpose of grants

(a) Systems of comprehensive care

(1) In general

A funding agreement for a grant under section 290ff(a) of this title is that, with respect to children with a serious emotional disturbance, the public entity involved will carry out the purpose described in such section only through establishing and operating 1 or more systems of care for making each of the mental health services specified in subsection (c) available to each child provided access to the system. In providing for such a system, the public entity may make grants to, and enter into contracts with, public and nonprofit private entities.

(2) Structure of system

A funding agreement for a grant under section 290ff(a) of this title is that a system of care under paragraph (1) will—

(A) be established in a community selected by the public entity involved;

(B) consist of such public agencies and nonprofit private entities in the community as are necessary to ensure that each of the services specified in subsection (c) is available to each child provided access to the system;

(C) be established pursuant to agreements that the public entity enters into with the agencies and entities described in subparagraph (B);

(D) coordinate the provision of the services of the system; and

(E) establish an office whose functions are to serve as the location through which children are provided access to the system, to coordinate the provision of services of the system, and to provide information to the public regarding the system.

(3) Collaboration of local public entities

A funding agreement for a grant under section 290ff(a) of this title is that, for purposes of the establishment and operation of a system of care under paragraph (1), the public entity involved will seek collaboration among all public agencies that provide human services in the community in which the system is established, including but not limited to those providing mental health services, educational services, child welfare services, or juvenile justice services.

(b) Limitation on age of children provided access to system

A funding agreement for a grant under section 290ff(a) of this title is that a system of care under subsection (a) will provide an individual with access to the system through the age of 21 years.

(c) Required mental health services of system

A funding agreement for a grant under section 290ff(a) of this title is that mental health services provided by a system of care under subsection (a) will include, with respect to a serious emotional disturbance in a child—

(1) diagnostic and evaluation services;

(2) outpatient services provided in a clinic, office, school or other appropriate location, including individual, group and family counseling services, professional consultation, and review and management of medications;

(3) emergency services, available 24-hours a day, 7 days a week;

(4) intensive home-based services for children and their families when the child is at imminent risk of out-of-home placement;

(5) intensive day-treatment services;

(6) respite care;

(7) therapeutic foster care services, and services in therapeutic foster family homes or individual therapeutic residential homes, and groups homes caring for not more than 10 children; and

(8) assisting the child in making the transition from the services received as a child to the services to be received as an adult.

(d) Required arrangements regarding other appropriate services

(1) In general

A funding agreement for a grant under section 290ff(a) of this title is that—

(A) a system of care under subsection (a) will enter into a memorandum of understanding with each of the providers specified in paragraph (2) in order to facilitate the availability of the services of the provider involved to each child provided access to the system; and

(B) the grant under such section 290ff(a) of this title, and the non-Federal contributions made with respect to the grant, will not be expended to pay the costs of providing such non-mental health services to any individual.

(2) Specification of non-mental health services

The providers referred to in paragraph (1) are providers of medical services other than mental health services, providers of educational services, providers of vocational counseling and vocational rehabilitation services, and providers of protection and advocacy services with respect to mental health.

(3) Facilitation of services of certain programs

A funding agreement for a grant under section 290ff(a) of this title is that a system of care under subsection (a) will, for purposes of paragraph (1), enter into a memorandum of understanding regarding facilitation of—

(A) services available pursuant to title XIX of the Social Security Act [42 U.S.C. 1396 et seq.], including services regarding early periodic screening, diagnosis, and treatment;

(B) services available under parts B and C of the Individuals with Disabilities Education Act [20 U.S.C. 1411 et seq., 1431 et seq.]; and

(C) services available under other appropriate programs, as identified by the Secretary.

(e) General provisions regarding services of system

(1) Case management services

A funding agreement for a grant under section 290ff(a) of this title is that a system of care under subsection (a) will provide for the case management of each child provided access to the system in order to ensure that—

(A) the services provided through the system to the child are coordinated and that the need of each such child for the services is periodically reassessed;

(B) information is provided to the family of the child on the extent of progress being made toward the objectives established for the child under the plan of services implemented for the child pursuant to section 290ff–2 of this title; and

(C) the system provides assistance with respect to—

(i) establishing the eligibility of the child, and the family of the child, for financial assistance and services under Federal, State, or local programs providing for health services, mental health services, educational services, social services, or other services; and

(ii) seeking to ensure that the child receives appropriate services available under such programs.

(2) Other provisions

A funding agreement for a grant under section 290ff(a) of this title is that a system of care under subsection (a), in providing the services of the system, will—

(A) provide the services of the system in the cultural context that is most appropriate for the child and family involved;

(B) ensure that individuals providing such services to the child can effectively communicate with the child and family in the most direct manner;

(C) provide the services without discriminating against the child or the family of the child on the basis of race, religion, national origin, sex, disability, or age;

(D) seek to ensure that each child provided access to the system of care remains in the least restrictive, most normative environment that is clinically appropriate; and

(E) provide outreach services to inform individuals, as appropriate, of the services available from the system, including identifying children with a serious emotional disturbance who are in the early stages of such disturbance.

(3) Rule of construction

An agreement made under paragraph (2) may not be construed—

(A) with respect to subparagraph (C) of such paragraph—

(i) to prohibit a system of care under subsection (a) from requiring that, in housing provided by the grantee for purposes of residential treatment services authorized under subsection (c), males and females be segregated to the extent appropriate in the treatment of the children involved; or

(ii) to prohibit the system of care from complying with the agreement made under subsection (b); or

(B) with respect to subparagraph (D) of such paragraph, to authorize the system of care to expend the grant under section 290ff(a) of this title (or the non-Federal contributions made with respect to the grant) to provide legal services or any service with respect to which expenditures regarding the grant are prohibited under subsection (d)(1)(B).

(f) Restrictions on use of grant

A funding agreement for a grant under section 290ff(a) of this title is that the grant, and the non-Federal contributions made with respect to the grant, will not be expended—

(1) to purchase or improve real property (including the construction or renovation of facilities);

(2) to provide for room and board in residential programs serving 10 or fewer children;

(3) to provide for room and board or other services or expenditures associated with care of children in residential treatment centers serving more than 10 children or in inpatient hospital settings, except intensive home-based services and other services provided on an ambulatory or outpatient basis; or

(4) to provide for the training of any individual, except training authorized in section 290ff–3(a)(2) of this title and training provided through any appropriate course in continuing education whose duration does not exceed 2 days.

(g) Waivers

The Secretary may waive one or more of the requirements of subsection (c) for a public entity that

is an Indian Tribe or tribal organization, or American Samoa, Guam, the Marshall Islands, the Federated States of Micronesia, the Commonwealth of the Northern Mariana Islands, the Republic of Palau, or the United States Virgin Islands if the Secretary determines, after peer review, that the system of care is family-centered and uses the least restrictive environment that is clinically appropriate.

(July 1, 1944, ch. 373, title V, §562, as added Pub. L. 102–321, title I, §119, July 10, 1992, 106 Stat. 351; amended Pub. L. 106–310, div. B, title XXXI, §3105(b), Oct. 17, 2000, 114 Stat. 1175; Pub. L. 108–446, title III, §305(i)(4), Dec. 3, 2004, 118 Stat. 2806; Pub. L. 114–255, div. B, title X, §10001(b), Dec. 13, 2016, 130 Stat. 1262.)

EDITORIAL NOTES

REFERENCES IN TEXT

The Social Security Act, referred to in subsec. (d)(3)(A), is act Aug. 14, 1935, ch. 531, 49 Stat. 620. Title XIX of the Act is classified generally to subchapter XIX (§1396 et seq.) of chapter 7 of this title. For complete classification of this Act to the Code, see section 1305 of this title and Tables.

The Individuals with Disabilities Education Act, referred to in subsec. (d)(3)(B), is title VI of Pub. L. 91–230, Apr. 13, 1970, 84 Stat. 175. Parts B and C of the Act are classified generally to subchapters II (§1411 et seq.) and III (§1431 et seq.), respectively, of chapter 33 of Title 20, Education. For complete classification of this Act to the Code, see section 1400 of Title 20 and Tables.

AMENDMENTS

2016—Subsec. (b). Pub. L. 114–255 substituted "will provide an individual with access to the system through the age of 21 years" for "will not provide an individual with access to the system if the individual is more than 21 years of age".

2004—Subsec. (d)(3)(B). Pub. L. 108–446 substituted "and C" for "and H".

2000—Subsec. (g). Pub. L. 106–310 added subsec. (g).

STATUTORY NOTES AND RELATED SUBSIDIARIES

EFFECTIVE DATE

Section effective Oct. 1, 1992, with provision for programs providing financial assistance, see section 801(c), (d) of Pub. L. 102–321, set out as an Effective Date of 1992 Amendment note under section 236 of this title.

§290ff–2. Individualized plan for services

(a) In general

A funding agreement for a grant under section 290ff(a) of this title is that a system of care under section 290ff–1(a) of this title will develop and carry out an individualized plan of services for each child provided access to the system, and that the plan will be developed and carried out with the participation of the family of the child and, unless clinically inappropriate, with the participation of the child.

(b) Multidisciplinary team

A funding agreement for a grant under section 290ff(a) of this title is that the plan required in subsection (a) will be developed, and reviewed and as appropriate revised not less than once each year, by a multidisciplinary team of appropriately qualified individuals who provide services through the system, including as appropriate mental health services, other health services, educational services, social services, and vocational counseling and rehabilitation; [1]

(c) Coordination with services under Individuals with Disabilities Education Act

A funding agreement for a grant under section 290ff(a) of this title is that, with respect to a plan under subsection (a) for a child, the multidisciplinary team required in subsection (b) will—

(1) in developing, carrying out, reviewing, and revising the plan consider any individualized education program in effect for the child pursuant to part B of the Individuals with Disabilities Education Act [42 U.S.C. 1411 et seq.];

(2) ensure that the plan is consistent with such individualized education program and provides for coordinating services under the plan with services under such program; and

(3) ensure that the memorandum of understanding entered into under section 290ff–1(d)(3)(B) of this title regarding such Act [20 U.S.C. 1400 et seq.] includes provisions regarding compliance with this subsection.

(d) Contents of plan

A funding agreement for a grant under section 290ff(a) of this title is that the plan required in subsection (a) for a child will—

(1) identify and state the needs of the child for the services available pursuant to section 290ff–1 of this title through the system;

(2) provide for each of such services that is appropriate to the circumstances of the child, including, except in the case of children who are less than 14 years of age, the provision of appropriate vocational counseling and rehabilitation, and transition services (as defined in section 602 [20 U.S.C. 1401] of the Individuals with Disabilities Education Act);

(3) establish objectives to be achieved regarding the needs of the child and the methodology for achieving the objectives; and

(4) designate an individual to be responsible for providing the case management required in section 290ff–1(e)(1) of this title or certify that case management services will be provided to the child as part of the individualized education program of the child under the Individuals with Disabilities Education Act [20 U.S.C. 1400 et seq.].

(July 1, 1944, ch. 373, title V, §563, as added Pub. L. 102–321, title I, §119, July 10, 1992, 106 Stat. 354; amended Pub. L. 108–446, title III, §305(i)(5), Dec. 3, 2004, 118 Stat. 2806.)

EDITORIAL NOTES

REFERENCES IN TEXT

The Individuals with Disabilities Education Act, referred to in subsecs. (c)(1), (3) and (d)(4), is title VI of Pub. L. 91–230, Apr. 13, 1970, 84 Stat. 175, which is classified generally to chapter 33 (§1400 et seq.) of Title 20, Education. Part B of the Act is classified generally to subchapter II (§1411 et seq.) of chapter 33 of Title 20. For complete classification of this Act to the Code, see section 1400 of Title 20 and Tables.

AMENDMENTS

2004—Subsec. (d)(2). Pub. L. 108–446 substituted "section 602" for "section 602(a)(19)".

STATUTORY NOTES AND RELATED SUBSIDIARIES

EFFECTIVE DATE

Section effective Oct. 1, 1992, with provision for programs providing financial assistance, see section 801(c), (d) of Pub. L. 102–321, set out as an Effective Date of 1992 Amendment note under section 236 of this title.

[1] So in original. The semicolon probably should be a period.

§290ff–3. Additional provisions

(a) Optional services

In addition to services described in subsection (c) of section 290ff–1 of this title, a system of care under subsection (a) of such section may, in expending a grant under section 290ff(a) of this title, provide for—

(1) preliminary assessments to determine whether a child should be provided access to the system;

(2) training in—

(A) the administration of the system;

(B) the provision of intensive home-based services under paragraph (4) of section 290ff–1(c) of this title, intensive day treatment under paragraph (5) of such section, and foster care or group homes under paragraph (7) of such section; and

(C) the development of individualized plans for purposes of section 290ff–2 of this title;

(3) recreational activities for children provided access to the system; and

(4) such other services as may be appropriate in providing for the comprehensive needs with respect to mental health of children with a serious emotional disturbance.

(b) Comprehensive plan

The Secretary may make a grant under section 290ff(a) of this title only if, with respect to the jurisdiction of the public entity involved, the entity has submitted to the Secretary, and has had approved by the Secretary, a plan for the development of a jurisdiction-wide system of care for community-based services for children with a serious emotional disturbance that specifies the progress the public entity has made in developing the jurisdiction-wide system, the extent of cooperation across agencies serving children in the establishment of the system, the Federal and non-Federal resources currently committed to the establishment of the system, and the current gaps in community services and the manner in which the grant under section 290ff(a) of this title will be expended to address such gaps and establish local systems of care.

(c) Limitation on imposition of fees for services

A funding agreement for a grant under section 290ff(a) of this title is that, if a charge is imposed for the provision of services under the grant, such charge—

(1) will be made according to a schedule of charges that is made available to the public;

(2) will be adjusted to reflect the income of the family of the child involved; and

(3) will not be imposed on any child whose family has income and resources of equal to or less than 100 percent of the official poverty line, as established by the Director of the Office of Management and Budget and revised by the Secretary in accordance with section 9902(2) of this title.

(d) Relationship to items and services under other programs

A funding agreement for a grant under section 290ff(a) of this title is that the grant, and the non-Federal contributions made with respect to the grant, will not be expended to make payment for any item or service to the extent that payment has been made, or can reasonably be expected to be made, with respect to such item or service—

(1) under any State compensation program, under an insurance policy, or under any Federal or State health benefits program; or

(2) by an entity that provides health services on a prepaid basis.

(e) Limitation on administrative expenses

A funding agreement for a grant under section 290ff(a) of this title is that not more than 2 percent of the grant will be expended for administrative expenses incurred with respect to the grant by the public entity involved.

(f) Reports to Secretary

A funding agreement for a grant under section 290ff(a) of this title is that the public entity involved will annually submit to the Secretary (and provide a copy to the State involved) a report on the activities of the entity under the grant that includes a description of the number of children provided access to systems of care operated pursuant to the grant, the demographic characteristics of the children, the types and costs of services provided pursuant to the grant, the availability and use of third-party reimbursements, estimates of the unmet need for such services in the jurisdiction of the

entity, and the manner in which the grant has been expended toward the establishment of a jurisdiction-wide system of care for children with a serious emotional disturbance, and such other information as the Secretary may require with respect to the grant.

(g) Description of intended uses of grant

The Secretary may make a grant under section 290ff(a) of this title only if—

(1) the public entity involved submits to the Secretary a description of the purposes for which the entity intends to expend the grant;

(2) the description identifies the populations, areas, and localities in the jurisdiction of the entity with a need for services under this section; and

(3) the description provides information relating to the services and activities to be provided, including a description of the manner in which the services and activities will be coordinated with any similar services or activities of public or nonprofit entities.

(h) Requirement of application

The Secretary may make a grant under section 290ff(a) of this title only if an application for the grant is submitted to the Secretary, the application contains the description of intended uses required in subsection (g), and the application is in such form, is made in such manner, and contains such agreements, assurances, and information as the Secretary determines to be necessary to carry out this section.

(July 1, 1944, ch. 373, title V, §564, as added Pub. L. 102–321, title I, §119, July 10, 1992, 106 Stat. 355; amended Pub. L. 114–255, div. B, title X, §10001(c), Dec. 13, 2016, 130 Stat. 1262.)

EDITORIAL NOTES

AMENDMENTS

2016—Subsec. (f). Pub. L. 114–255 inserted "(and provide a copy to the State involved)" after "to the Secretary".

STATUTORY NOTES AND RELATED SUBSIDIARIES

EFFECTIVE DATE

Section effective Oct. 1, 1992, with provision for programs providing financial assistance, see section 801(c), (d) of Pub. L. 102–321, set out as an Effective Date of 1992 Amendment note under section 236 of this title.

§290ff–4. General provisions

(a) Duration of support

The period during which payments are made to a public entity from a grant under section 290ff(a) of this title may not exceed 6 fiscal years.

(b) Technical assistance

(1) In general

The Secretary shall, upon the request of a public entity, regardless of whether such public entity is receiving a grant under section 290ff(a) of this title—

(A) provide technical assistance to the entity regarding the process of submitting to the Secretary applications for grants under section 290ff(a) of this title; and

(B) provide to the entity training and technical assistance with respect to the planning, development, and operation of systems of care described in section 290ff–1 of this title.

(2) Authority for grants and contracts

The Secretary may provide technical assistance under subsection (a) directly or through grants

to, or contracts with, public and nonprofit private entities.

(c) Evaluations and reports by Secretary

(1) In general

The Secretary shall, directly or through contracts with public or private entities, provide for annual evaluations of programs carried out pursuant to section 290ff(a) of this title. The evaluations shall assess the effectiveness of the systems of care operated pursuant to such section, including longitudinal studies of outcomes of services provided by such systems, other studies regarding such outcomes, the effect of activities under this part on the utilization of hospital and other institutional settings, the barriers to and achievements resulting from interagency collaboration in providing community-based services to children with a serious emotional disturbance, and assessments by parents of the effectiveness of the systems of care.

(2) Report to Congress

The Secretary shall, not later than 1 year after the date on which amounts are first appropriated under subsection (c), and annually thereafter, submit to the Congress a report summarizing evaluations carried out pursuant to paragraph (1) during the preceding fiscal year and making such recommendations for administrative and legislative initiatives with respect to this section as the Secretary determines to be appropriate.

(d) Definitions

For purposes of this part:

(1) The term "child" means an individual through the age of 21 years.

(2) The term "family", with respect to a child provided access to a system of care under section 290ff–1(a) of this title, means—

(A) the legal guardian of the child; and

(B) as appropriate regarding mental health services for the child, the parents of the child (biological or adoptive, as the case may be), kinship caregivers of the child, and any foster parents of the child.

(3) The term "funding agreement", with respect to a grant under section 290ff(a) of this title to a public entity, means that the Secretary may make such a grant only if the public entity makes the agreement involved.

(4) The term "serious emotional disturbance" includes, with respect to a child, any child who has a serious emotional disorder, a serious behavioral disorder, or a serious mental disorder.

(e) Rule of construction

Nothing in this part shall be construed as limiting the rights of a child with a serious emotional disturbance under the Individuals with Disabilities Education Act [20 U.S.C. 1400 et seq.].

(f) Funding

(1) Authorization of appropriations

For the purpose of carrying out this part, there are authorized to be appropriated $125,000,000 for each of fiscal years 2023 through 2027.

(2) Limitation regarding technical assistance

Not more than 10 percent of the amounts appropriated under paragraph (1) for a fiscal year may be expended for carrying out subsection (b).

(July 1, 1944, ch. 373, title V, §565, as added Pub. L. 102–321, title I, §119, July 10, 1992, 106 Stat. 356; amended Pub. L. 103–43, title XX, §2017(2), June 10, 1993, 107 Stat. 218; Pub. L. 106–310, div. B, title XXXI, §3105(c), (d), Oct. 17, 2000, 114 Stat. 1175; Pub. L. 114–255, div. B, title X, §10001(d), Dec. 13, 2016, 130 Stat. 1262; Pub. L. 117–328, div. FF, title I, §1411, Dec. 29, 2022, 136 Stat. 5701.)

EDITORIAL NOTES

REFERENCES IN TEXT

The Individuals with Disabilities Education Act, referred to in subsec. (e), is title VI of Pub. L. 91–230, Apr. 13, 1970, 84 Stat. 175, which is classified generally to chapter 33 (§1400 et seq.) of Title 20, Education. For complete classification of this Act to the Code, see section 1400 of Title 20 and Tables.

AMENDMENTS

2022—Subsec. (d)(2)(B). Pub. L. 117–328, §1411(a), substituted "may be), kinship caregivers of the child," for "may be)".

Subsec. (f)(1). Pub. L. 117–328, §1411(b), substituted "$125,000,000 for each of fiscal years 2023 through 2027" for "$119,026,000 for each of fiscal years 2018 through 2022" and realigned margin.

2016—Subsec. (b)(1). Pub. L. 114–255, §10001(d)(1)(A), substituted ", regardless of whether such public entity is receiving a grant under section 290ff(a) of this title" for "receiving a grant under section 290ff(a) of this title" in introductory provisions.

Subsec. (b)(1)(B). Pub. L. 114–255, §10001(d)(1)(B), substituted "described in" for "pursuant to".

Subsec. (d)(1). Pub. L. 114–255, §10001(d)(2), substituted "through the age of 21 years" for "not more than 21 years of age".

Subsec. (f)(1). Pub. L. 114–255, §10001(d)(3), substituted "$119,026,000 for each of fiscal years 2018 through 2022" for "$100,000,000 for fiscal year 2001, and such sums as may be necessary for each of the fiscal years 2002 and 2003".

2000—Subsec. (a). Pub. L. 106–310, §3105(c), substituted "6 fiscal years" for "5 fiscal years".

Subsec. (f)(1). Pub. L. 106–310, §3105(d), substituted "2001, and such sums as may be necessary for each of the fiscal years 2002 and 2003" for "1993, and such sums as may be necessary for fiscal year 1994".

1993—Subsec. (c)(1), (d), (f)(1). Pub. L. 103–43, §2017(2)(A), (B), (C)(i), substituted "this part" for "this subpart".

Subsec. (f)(2). Pub. L. 103–43, §2017(2)(C)(ii), amended heading and text of par. (2) generally. Prior to amendment, text read as follows: "Of the amounts appropriated under paragraph (1) for a fiscal year, the Secretary shall make available not less than $3,000,000 for the purpose of carrying out subsection (b) of this section."

STATUTORY NOTES AND RELATED SUBSIDIARIES

EFFECTIVE DATE

Section effective Oct. 1, 1992, with provision for programs providing financial assistance, see section 801(c), (d) of Pub. L. 102–321, set out as an Effective Date of 1992 Amendment note under section 236 of this title.

PART F—MODEL COMPREHENSIVE PROGRAM FOR TREATMENT OF SUBSTANCE ABUSE

§290gg. Repealed. Pub. L. 106–310, div. B, title XXXIII, §3301(c)(4), Oct. 17, 2000, 114 Stat. 1209

Section, act July 1, 1944, ch. 373, title V, §571, as added Pub. L. 102–321, title III, §301, July 10, 1992, 106 Stat. 417, related to demonstration program in national capital area.

PART G—PROJECTS FOR CHILDREN AND VIOLENCE

EDITORIAL NOTES

CODIFICATION

This part is comprised of part G of title V of act July 1, 1944. Another part G of title V of act July 1, 1944, was renumbered part J and is classified to part J (§290kk et seq.) of this subchapter.

§290hh. Children and violence

(a) In general

The Secretary, in consultation with the Secretary of Education and the Attorney General, shall carry out directly or through grants, contracts or cooperative agreements with public entities a program to assist local communities in developing ways to assist children in dealing with violence.

(b) Activities

Under the program under subsection (a), the Secretary may—

(1) provide financial support to enable local communities to implement programs to foster the health and development of children;

(2) provide technical assistance to local communities with respect to the development of programs described in paragraph (1);

(3) provide assistance to local communities in the development of policies to address violence when and if it occurs;

(4) assist in the creation of community partnerships among law enforcement, education systems and mental health and substance abuse service systems; and

(5) establish mechanisms for children and adolescents to report incidents of violence or plans by other children or adolescents to commit violence.

(c) Requirements

An application for a grant, contract or cooperative agreement under subsection (a) shall demonstrate that—

(1) the applicant will use amounts received to create a partnership described in subsection (b)(4) to address issues of violence in schools;

(2) the activities carried out by the applicant will provide a comprehensive method for addressing violence, that will include—

(A) security;

(B) educational reform;

(C) the review and updating of school policies;

(D) alcohol and drug abuse prevention and early intervention services;

(E) mental health prevention and treatment services; and

(F) early childhood development and psychosocial services; and

(3) the applicant will use amounts received only for the services described in subparagraphs (D), (E), and (F) of paragraph (2).

(d) Geographical distribution

The Secretary shall ensure that grants, contracts or cooperative agreements under subsection (a) will be distributed equitably among the regions of the country and among urban and rural areas.

(e) Duration of awards

With respect to a grant, contract or cooperative agreement under subsection (a), the period during which payments under such an award will be made to the recipient may not exceed 5 years.

(f) Evaluation

The Secretary shall conduct an evaluation of each project carried out under this section and shall disseminate the results of such evaluations to appropriate public and private entities.

(g) Information and education

The Secretary shall establish comprehensive information and education programs to disseminate

the findings of the knowledge development and application under this section to the general public and to health care professionals.

(h) Authorization of appropriations

There is authorized to be appropriated to carry out this section, $100,000,000 for fiscal year 2001, and such sums as may be necessary for each of fiscal years 2002 and 2003.

(July 1, 1944, ch. 373, title V, §581, as added Pub. L. 106–310, div. B, title XXXI, §3101, Oct. 17, 2000, 114 Stat. 1168.)

EDITORIAL NOTES

CODIFICATION

Another section 581 of act July 1, 1944, was renumbered section 596 and is classified to section 290kk of this title.

§290hh–1. Grants to address the problems of persons who experience traumatic events

(a) In general

The Secretary shall award grants, contracts or cooperative agreements to public and nonprofit private entities, as well as to Indian Tribes and Tribal organizations, for the purpose of developing and maintaining programs that provide for—

(1) the continued operation of the National Child Traumatic Stress Initiative (referred to in this section as the "NCTSI"), which includes a cooperative agreement with a coordinating center, that focuses on the mental, behavioral, and biological aspects of psychological trauma response, prevention of the long-term consequences of child trauma, and early intervention services and treatment to address the long-term consequences of child trauma; and

(2) the development and dissemination of knowledge with regard to evidence-based practices for identifying and treating mental, behavioral, and biological disorders of children and youth resulting from witnessing or experiencing a traumatic event.

(b) Priorities

In awarding grants, contracts or cooperative agreements under subsection (a)(2) (related to the development and dissemination of knowledge on evidence-based practices for treating mental, behavioral, and biological disorders associated with psychological trauma), the Secretary shall give priority to universities, hospitals, mental health agencies, and other programs that have established clinical expertise and research experience in the field of trauma-related mental disorders.

(c) Child outcome data

The NCTSI coordinating center described in subsection (a)(1) shall collect, analyze, report, and make publicly available, as appropriate, NCTSI-wide child treatment process and outcome data regarding the early identification and delivery of evidence-based treatment and services for children and families served by the NCTSI grantees.

(d) Training

(1) Coordinating center

The NCTSI coordinating center shall facilitate the coordination of training initiatives in evidence-based and trauma-informed treatments, interventions, and practices offered to NCTSI grantees, providers, and partners.

(2) NCTSI grantees

In carrying out subsection (a)(2), NCTSI grantees shall develop trainings and other resources, as applicable and appropriate, to support implementation of the evidence-based practices developed

and disseminated under such subsection.

(e) Dissemination and collaboration

(1) Coordinating center

The NCTSI coordinating center shall, as appropriate, collaborate with—

(A) the Secretary, in the dissemination and implementation of evidence-based and trauma-informed interventions, treatments, products, and other resources to appropriate stakeholders; and

(B) appropriate agencies that conduct or fund research within the Department of Health and Human Services, for purposes of sharing NCTSI expertise, evaluation data, and other activities, as appropriate.

(2) NCTSI grantees

NCTSI grantees shall, as appropriate, collaborate with other such grantees, the NCTSI coordinating center, and the Secretary in carrying out subsections (a)(2) and (d)(2).

(f) Review

The Secretary shall, consistent with the peer-review process, ensure that NCTSI applications are reviewed by appropriate experts in the field as part of a consensus-review process. The Secretary shall include review criteria related to expertise and experience in child trauma and evidence-based practices.

(g) Geographical distribution

The Secretary shall ensure that grants, contracts or cooperative agreements under subsection (a) are distributed equitably among the regions of the United States and among urban and rural areas.

(h) Application and evaluation

To be eligible to receive a grant, contract, or cooperative agreement under subsection (a), a public or nonprofit private entity or an Indian Tribe or Tribal organization shall submit to the Secretary an application at such time, in such manner, and containing such information and assurances as the Secretary may require, including—

(1) a plan for the evaluation of the activities funded under the grant, contract, or agreement, including both process and outcomes evaluation, and the submission of an evaluation at the end of the project period; and

(2) a description of how such entity, Indian Tribe, or Tribal organization will support efforts led by the Secretary or the NCTSI coordinating center, as applicable, to evaluate activities carried out under this section.

(i) Duration of awards

With respect to a grant, contract or cooperative agreement under subsection (a), the period during which payments under such an award will be made to the recipient shall not be less than 4 years, but shall not exceed 5 years. Such grants, contracts or agreements may be renewed.

(j) Authorization of appropriations

There is authorized to be appropriated to carry out this section—

(1) $98,887,000 for fiscal year 2026;
(2) $98,887,000 for fiscal year 2027;
(3) $98,887,000 for fiscal year 2028;
(4) $100,000,000 for fiscal year 2029; and
(5) $100,000,000 for fiscal year 2030.

(k) Short title

This section may be cited as the "Donald J. Cohen National Child Traumatic Stress Initiative".

(July 1, 1944, ch. 373, title V, §582, as added Pub. L. 106–310, div. B, title XXXI, §3101, Oct. 17, 2000, 114 Stat. 1169; amended Pub. L. 107–116, title II, §218, Jan. 10, 2002, 115 Stat. 2201; Pub. L. 107–188, title I, §155, June 12, 2002, 116 Stat. 633; Pub. L. 114–255, div. B, title X, §10004, Dec.

13, 2016, 130 Stat. 1265; Pub. L. 115–271, title VII, §7133, Oct. 24, 2018, 132 Stat. 4051; Pub. L. 119–44, title I, §107(b), Dec. 1, 2025, 139 Stat. 674.)

EDITORIAL NOTES

CODIFICATION

Another section 582 of act July 1, 1944, was renumbered section 596A and is classified to section 290kk–1 of this title.

AMENDMENTS

2025—Pub. L. 119–44, §107(b)(1), substituted "traumatic events" for "violence related stress" in section catchline.

Subsec. (a). Pub. L. 119–44, §107(b)(2)(A), substituted "Tribes and Tribal" for "tribes and tribal" in introductory provisions.

Subsec. (a)(2). Pub. L. 119–44, §107(b)(2)(B), inserted "and dissemination" after "the development".

Subsec. (b). Pub. L. 119–44, §107(b)(3), inserted "and dissemination" after "the development".

Subsec. (d). Pub. L. 119–44, §107(b)(4), designated existing provisions as par. (1), inserted heading, and added par. (2).

Subsec. (e). Pub. L. 119–44, §107(b)(5), designated introductory provisions as par. (1) and inserted heading; redesignated former pars. (1) and (2) as subpars. (A) and (B), respectively, and realigned margins; inserted "and implementation" after "the dissemination" in subpar. (A); and added par. (2).

Subsec. (h). Pub. L. 119–44, §107(b)(6), amended subsec. (h) generally. Prior to amendment, text read as follows: "The Secretary, as part of the application process, shall require that each applicant for a grant, contract or cooperative agreement under subsection (a) submit a plan for the rigorous evaluation of the activities funded under the grant, contract or agreement, including both process and outcomes evaluation, and the submission of an evaluation at the end of the project period."

Subsec. (j). Pub. L. 119–44, §107(b)(7), amended subsec. (j) generally. Prior to amendment, text read as follows: "There is authorized to be appropriated to carry out this section, $63,887,000 for each of fiscal years 2019 through 2023."

2018—Subsec. (j). Pub. L. 115–271 substituted "$63,887,000 for each of fiscal years 2019 through 2023" for "$46,887,000 for each of fiscal years 2018 through 2022".

2016—Subsec. (a). Pub. L. 114–255, §10004(1), substituted "developing and maintaining programs that provide for—" and pars. (1) and (2) for "developing programs focusing on the behavioral and biological aspects of psychological trauma response and for developing knowledge with regard to evidence-based practices for treating psychiatric disorders of children and youth resulting from witnessing or experiencing a traumatic event."

Subsec. (b). Pub. L. 114–255, §10004(2), substituted "subsection (a)(2) (related" for "subsection (a) related", "treating mental, behavioral, and biological disorders associated with psychological trauma)" for "treating disorders associated with psychological trauma", and "universities, hospitals, mental health agencies, and other programs that have established clinical expertise and research" for "mental health agencies and programs that have established clinical and basic research".

Subsecs. (c) to (f). Pub. L. 114–255, §10004(4), added subsecs. (c) to (f). Former subsecs. (c) to (f) redesignated (g) to (j), respectively.

Subsec. (g). Pub. L. 114–255, §10004(3), (5), redesignated subsec. (c) as (g) and substituted "are distributed equitably among the regions of the United States" for "with respect to centers of excellence are distributed equitably among the regions of the country". Former subsec. (g) redesignated (k).

Subsec. (h). Pub. L. 114–255, §10004(3), redesignated subsec. (d) as (h).

Subsec. (i). Pub. L. 114–255, §10004(3), (6), redesignated subsec. (e) as (i) and substituted "recipient shall not be less than 4 years, but shall not exceed 5 years" for "recipient may not exceed 5 years".

Subsec. (j). Pub. L. 114–255, §10004(3), (7), redesignated subsec. (f) as (j) and substituted "$46,887,000 for each of fiscal years 2018 through 2022" for "$50,000,000 for fiscal year 2001, and such sums as may be necessary for each of fiscal years 2003 through 2006".

Subsec. (k). Pub. L. 114–255, §10004(3), redesignated subsec. (g) as (k).

2002—Subsec. (f). Pub. L. 107–188 substituted "2003 through 2006" for "2002 and 2003".

Subsec. (g). Pub. L. 107–116 added subsec. (g).

PART H—REQUIREMENT RELATING TO THE RIGHTS OF RESIDENTS OF CERTAIN FACILITIES

§290ii. Requirement relating to the rights of residents of certain facilities

(a) In general

A public or private general hospital, nursing facility, intermediate care facility, or other health care facility, that receives support in any form from any program supported in whole or in part with funds appropriated to any Federal department or agency shall protect and promote the rights of each resident of the facility, including the right to be free from physical or mental abuse, corporal punishment, and any restraints or involuntary seclusions imposed for purposes of discipline or convenience.

(b) Requirements

Restraints and seclusion may only be imposed on a resident of a facility described in subsection (a) if—

(1) the restraints or seclusion are imposed to ensure the physical safety of the resident, a staff member, or others; and

(2) the restraints or seclusion are imposed only upon the written order of a physician, or other licensed practitioner permitted by the State and the facility to order such restraint or seclusion, that specifies the duration and circumstances under which the restraints are to be used (except in emergency circumstances specified by the Secretary until such an order could reasonably be obtained).

(c) Current law

This part shall not be construed to affect or impede any Federal or State law or regulations that provide greater protections than this part regarding seclusion and restraint.

(d) Definitions

In this section:

(1) Restraints

The term "restraints" means—

(A) any physical restraint that is a mechanical or personal restriction that immobilizes or reduces the ability of an individual to move his or her arms, legs, or head freely, not including devices, such as orthopedically prescribed devices, surgical dressings or bandages, protective helmets, or any other methods that involves the physical holding of a resident for the purpose of conducting routine physical examinations or tests or to protect the resident from falling out of bed or to permit the resident to participate in activities without the risk of physical harm to the resident (such term does not include a physical escort); and

(B) a drug or medication that is used as a restraint to control behavior or restrict the resident's freedom of movement that is not a standard treatment for the resident's medical or psychiatric condition.

(2) Seclusion

The term "seclusion" means a behavior control technique involving locked isolation. Such term does not include a time out.

(3) Physical escort

The term "physical escort" means the temporary touching or holding of the hand, wrist, arm, shoulder or back for the purpose of inducing a resident who is acting out to walk to a safe location.

(4) Time out

The term "time out" means a behavior management technique that is part of an approved treatment program and may involve the separation of the resident from the group, in a non-locked

setting, for the purpose of calming. Time out is not seclusion.

(July 1, 1944, ch. 373, title V, §591, as added Pub. L. 106–310, div. B, title XXXII, §3207, Oct. 17, 2000, 114 Stat. 1195.)

§290ii–1. Reporting requirement

(a) In general

Each facility to which the Protection and Advocacy for Mentally Ill Individuals Act of 1986 [1] [42 U.S.C. 10801 et seq.] applies shall notify the appropriate agency, as determined by the Secretary, of each death that occurs at each such facility while a patient is restrained or in seclusion, of each death occurring within 24 hours after the patient has been removed from restraints and seclusion, or where it is reasonable to assume that a patient's death is a result of such seclusion or restraint. A notification under this section shall include the name of the resident and shall be provided not later than 7 days after the date of the death of the individual involved.

(b) Facility

In this section, the term "facility" has the meaning given the term "facilities" in section 102(3) of the Protection and Advocacy for Mentally Ill Individuals Act of 1986 [1] (42 U.S.C. 10802(3)).

(July 1, 1944, ch. 373, title V, §592, as added Pub. L. 106–310, div. B, title XXXII, §3207, Oct. 17, 2000, 114 Stat. 1196.)

EDITORIAL NOTES

REFERENCES IN TEXT

The Protection and Advocacy for Mentally Ill Individuals Act of 1986, referred to in text, was Pub. L. 99–319, May 23, 1986, 100 Stat. 478. Pub. L. 99–319 was renamed the Protection and Advocacy for Individuals with Mental Illness Act by Pub. L. 106–310, div. B, title XXXII, §3206(a), Oct. 17, 2000, 114 Stat. 1193, and is classified generally to chapter 114 (§10801 et seq.) of this title. For complete classification of this Act to the Code, see Short Title note set out under section 10801 of this title and Tables.

[1] *See References in Text note below.*

§290ii–2. Regulations and enforcement

(a) Training

Not later than 1 year after October 17, 2000, the Secretary, after consultation with appropriate State and local protection and advocacy organizations, physicians, facilities, and other health care professionals and patients, shall promulgate regulations that require facilities to which the Protection and Advocacy for Mentally Ill Individuals Act of 1986 [1] (42 U.S.C. 10801 et seq.) applies, to meet the requirements of subsection (b).

(b) Requirements

The regulations promulgated under subsection (a) shall require that—

(1) facilities described in subsection (a) ensure that there is an adequate number of qualified professional and supportive staff to evaluate patients, formulate written individualized, comprehensive treatment plans, and to provide active treatment measures;

(2) appropriate training be provided for the staff of such facilities in the use of restraints and any alternatives to the use of restraints; and

(3) such facilities provide complete and accurate notification of deaths, as required under section 290ii–1(a) of this title.

(c) Enforcement

A facility to which this part applies that fails to comply with any requirement of this part, including a failure to provide appropriate training, shall not be eligible for participation in any program supported in whole or in part by funds appropriated to any Federal department or agency.

(July 1, 1944, ch. 373, title V, §593, as added Pub. L. 106–310, div. B, title XXXII, §3207, Oct. 17, 2000, 114 Stat. 1196.)

EDITORIAL NOTES

REFERENCES IN TEXT

The Protection and Advocacy for Mentally Ill Individuals Act of 1986, referred to in subsec. (a), was Pub. L. 99–319, May 23, 1986, 100 Stat. 478. Pub. L. 99–319 was renamed the Protection and Advocacy for Individuals with Mental Illness Act by Pub. L. 106–310, div. B, title XXXII, §3206(a), Oct. 17, 2000, 114 Stat. 1193, and is classified generally to chapter 114 (§10801 et seq.) of this title. For complete classification of this Act to the Code, see Short Title note set out under section 10801 of this title and Tables.

[1] *See References in Text note below.*

PART I—REQUIREMENT RELATING TO THE RIGHTS OF RESIDENTS OF CERTAIN NON-MEDICAL, COMMUNITY-BASED FACILITIES FOR CHILDREN AND YOUTH

§290jj. Requirement relating to the rights of residents of certain non-medical, community-based facilities for children and youth

(a) Protection of rights

(1) In general

A public or private non-medical, community-based facility for children and youth (as defined in regulations to be promulgated by the Secretary) that receives support in any form from any program supported in whole or in part with funds appropriated under this chapter shall protect and promote the rights of each resident of the facility, including the right to be free from physical or mental abuse, corporal punishment, and any restraints or involuntary seclusions imposed for purposes of discipline or convenience.

(2) Nonapplicability

Notwithstanding this part, a facility that provides inpatient psychiatric treatment services for individuals under the age of 21, as authorized and defined in subsections (a)(16) and (h) of section 1905 of the Social Security Act [42 U.S.C. 1396d], shall comply with the requirements of part H.

(3) Applicability of Medicaid provisions

A non-medical, community-based facility for children and youth funded under the Medicaid program under title XIX of the Social Security Act [42 U.S.C. 1396 et seq.] shall continue to meet all existing requirements for participation in such program that are not affected by this part.

(b) Requirements

(1) In general

Physical restraints and seclusion may only be imposed on a resident of a facility described in subsection (a) if—

(A) the restraints or seclusion are imposed only in emergency circumstances and only to ensure the immediate physical safety of the resident, a staff member, or others and less

restrictive interventions have been determined to be ineffective; and

(B) the restraints or seclusion are imposed only by an individual trained and certified, by a State-recognized body (as defined in regulation promulgated by the Secretary) and pursuant to a process determined appropriate by the State and approved by the Secretary, in the prevention and use of physical restraint and seclusion, including the needs and behaviors of the population served, relationship building, alternatives to restraint and seclusion, de-escalation methods, avoiding power struggles, thresholds for restraints and seclusion, the physiological and psychological impact of restraint and seclusion, monitoring physical signs of distress and obtaining medical assistance, legal issues, position asphyxia, escape and evasion techniques, time limits, the process for obtaining approval for continued restraints, procedures to address problematic restraints, documentation, processing with children, and follow-up with staff, and investigation of injuries and complaints.

(2) Interim procedures relating to training and certification

(A) In general

Until such time as the State develops a process to assure the proper training and certification of facility personnel in the skills and competencies referred [1] in paragraph (1)(B), the facility involved shall develop and implement an interim procedure that meets the requirements of subparagraph (B).

(B) Requirements

A procedure developed under subparagraph (A) shall—

(i) ensure that a supervisory or senior staff person with training in restraint and seclusion who is competent to conduct a face-to-face assessment (as defined in regulations promulgated by the Secretary), will assess the mental and physical well-being of the child or youth being restrained or secluded and assure that the restraint or seclusion is being done in a safe manner;

(ii) ensure that the assessment required under clause (i) take place as soon as practicable, but in no case later than 1 hour after the initiation of the restraint or seclusion; and

(iii) ensure that the supervisory or senior staff person continues to monitor the situation for the duration of the restraint and seclusion.

(3) Limitations

(A) In general

The use of a drug or medication that is used as a restraint to control behavior or restrict the resident's freedom of movement that is not a standard treatment for the resident's medical or psychiatric condition in nonmedical community-based facilities for children and youth described in subsection (a)(1) is prohibited.

(B) Prohibition

The use of mechanical restraints in non-medical, community-based facilities for children and youth described in subsection (a)(1) is prohibited.

(C) Limitation

A non-medical, community-based facility for children and youth described in subsection (a)(1) may only use seclusion when a staff member is continuously face-to-face monitoring the resident and when strong licensing or accreditation and internal controls are in place.

(c) Rule of construction

(1) In general

Nothing in this section shall be construed as prohibiting the use of restraints for medical immobilization, adaptive support, or medical protection.

(2) Current law

This part shall not be construed to affect or impede any Federal or State law or regulations that

provide greater protections than this part regarding seclusion and restraint.

(d) Definitions

In this section:

(1) Mechanical restraint

The term "mechanical restraint" means the use of devices as a means of restricting a resident's freedom of movement.

(2) Physical escort

The term "physical escort" means the temporary touching or holding of the hand, wrist, arm, shoulder or back for the purpose of inducing a resident who is acting out to walk to a safe location.

(3) Physical restraint

The term "physical restraint" means a personal restriction that immobilizes or reduces the ability of an individual to move his or her arms, legs, or head freely. Such term does not include a physical escort.

(4) Seclusion

The term "seclusion" means a behavior control technique involving locked isolation. Such term does not include a time out.

(5) Time out

The term "time out" means a behavior management technique that is part of an approved treatment program and may involve the separation of the resident from the group, in a non-locked setting, for the purpose of calming. Time out is not seclusion.

(July 1, 1944, ch. 373, title V, §595, as added Pub. L. 106–310, div. B, title XXXII, §3208, Oct. 17, 2000, 114 Stat. 1197.)

EDITORIAL NOTES

REFERENCES IN TEXT

The Social Security Act, referred to in subsec. (a)(3), is act Aug. 14, 1935, ch. 531, 49 Stat. 620. Title XIX of the Act is classified generally to subchapter XIX (§1396 et seq.) of chapter 7 of this title. For complete classification of this Act to the Code, see section 1305 of this title and Tables.

[1] So in original. Probably should be followed by "to".

§290jj–1. Reporting requirement

Each facility to which this part applies shall notify the appropriate State licensing or regulatory agency, as determined by the Secretary—

(1) of each death that occurs at each such facility. A notification under this section shall include the name of the resident and shall be provided not later than 24 hours after the time of the individuals [1] death; and

(2) of the use of seclusion or restraints in accordance with regulations promulgated by the Secretary, in consultation with the States.

(July 1, 1944, ch. 373, title V, §595A, as added Pub. L. 106–310, div. B, title XXXII, §3208, Oct. 17, 2000, 114 Stat. 1199.)

[1] So in original. Probably should be "individual's".

§290jj–2. Regulations and enforcement

(a) Training

Not later than 6 months after October 17, 2000, the Secretary, after consultation with appropriate State, local, public and private protection and advocacy organizations, health care professionals, social workers, facilities, and patients, shall promulgate regulations that—

(1) require States that license non-medical, community-based residential facilities for children and youth to develop licensing rules and monitoring requirements concerning behavior management practice that will ensure compliance with Federal regulations and to meet the requirements of subsection (b);

(2) require States to develop and implement such licensing rules and monitoring requirements within 1 year after the promulgation of the regulations referred to in the matter preceding paragraph (1); and

(3) support the development of national guidelines and standards on the quality, quantity, orientation and training, required under this part, as well as the certification or licensure of those staff responsible for the implementation of behavioral intervention concepts and techniques.

(b) Requirements

The regulations promulgated under subsection (a) shall require—

(1) that facilities described in subsection (a) ensure that there is an adequate number of qualified professional and supportive staff to evaluate residents, formulate written individualized, comprehensive treatment plans, and to provide active treatment measures;

(2) the provision of appropriate training and certification of the staff of such facilities in the prevention and use of physical restraint and seclusion, including the needs and behaviors of the population served, relationship building, alternatives to restraint, de-escalation methods, avoiding power struggles, thresholds for restraints, the physiological impact of restraint and seclusion, monitoring physical signs of distress and obtaining medical assistance, legal issues, position asphyxia, escape and evasion techniques, time limits for the use of restraint and seclusion, the process for obtaining approval for continued restraints and seclusion, procedures to address problematic restraints, documentation, processing with children, and follow-up with staff, and investigation of injuries and complaints; and

(3) that such facilities provide complete and accurate notification of deaths, as required under section 290jj–1(1) of this title.

(c) Enforcement

A State to which this part applies that fails to comply with any requirement of this part, including a failure to provide appropriate training and certification, shall not be eligible for participation in any program supported in whole or in part by funds appropriated under this chapter.

(July 1, 1944, ch. 373, title V, §595B, as added Pub. L. 106–310, div. B, title XXXII, §3208, Oct. 17, 2000, 114 Stat. 1199.)

PART J—SERVICES PROVIDED THROUGH RELIGIOUS ORGANIZATIONS

EDITORIAL NOTES

CODIFICATION

Pub. L. 119–44, title I, §107(a)(2), Dec. 1, 2025, 139 Stat. 674, redesignated this part, which was formerly part G of title V of act July 1, 1944, as part J. Another part G of title V of act July 1, 1944, is classified to part G (§290hh et seq.) of this subchapter.

§290kk. Applicability to designated programs

(a) Designated programs

Subject to subsection (b), this part applies to discretionary and formula grant programs administered by the Substance Abuse and Mental Health Services Administration that make awards of financial assistance to public or private entities for the purpose of carrying out activities to prevent or treat substance abuse (in this part referred to as a "designated program"). Designated programs include the program under subpart II of part B of subchapter XVII (relating to formula grants to the States).

(b) Limitation

This part does not apply to any award of financial assistance under a designated program for a purpose other than the purpose specified in subsection (a).

(c) Definitions

For purposes of this part (and subject to subsection (b)):

(1) The term "designated program" has the meaning given such term in subsection (a).

(2) The term "financial assistance" means a grant, cooperative agreement, or contract.

(3) The term "program beneficiary" means an individual who receives program services.

(4) The term "program participant" means a public or private entity that has received financial assistance under a designated program.

(5) The term "program services" means treatment for substance abuse, or preventive services regarding such abuse, provided pursuant to an award of financial assistance under a designated program.

(6) The term "religious organization" means a nonprofit religious organization.

(July 1, 1944, ch. 373, title V, §596, formerly §581, as added Pub. L. 106–554, §1(a)(7) [title I, §144], Dec. 21, 2000, 114 Stat. 2763, 2763A–619; renumbered §596, Pub. L. 119–44, title I, §107(a)(2), Dec. 1, 2025, 139 Stat. 674.)

§290kk–1. Religious organizations as program participants

(a) In general

Notwithstanding any other provision of law, a religious organization, on the same basis as any other nonprofit private provider—

(1) may receive financial assistance under a designated program; and

(2) may be a provider of services under a designated program.

(b) Religious organizations

The purpose of this section is to allow religious organizations to be program participants on the same basis as any other nonprofit private provider without impairing the religious character of such organizations, and without diminishing the religious freedom of program beneficiaries.

(c) Nondiscrimination against religious organizations

(1) Eligibility as program participants

Religious organizations are eligible to be program participants on the same basis as any other nonprofit private organization as long as the programs are implemented consistent with the Establishment Clause and Free Exercise Clause of the First Amendment to the United States Constitution. Nothing in this chapter shall be construed to restrict the ability of the Federal Government, or a State or local government receiving funds under such programs, to apply to religious organizations the same eligibility conditions in designated programs as are applied to any other nonprofit private organization.

(2) Nondiscrimination

Neither the Federal Government nor a State or local government receiving funds under

designated programs shall discriminate against an organization that is or applies to be a program participant on the basis that the organization has a religious character.

(d) Religious character and freedom

(1) Religious organizations

Except as provided in this section, any religious organization that is a program participant shall retain its independence from Federal, State, and local government, including such organization's control over the definition, development, practice, and expression of its religious beliefs.

(2) Additional safeguards

Neither the Federal Government nor a State shall require a religious organization to—

(A) alter its form of internal governance; or

(B) remove religious art, icons, scripture, or other symbols,

in order to be a program participant.

(e) Employment practices

Nothing in this section shall be construed to modify or affect the provisions of any other Federal or State law or regulation that relates to discrimination in employment. A religious organization's exemption provided under section 2000e–1 of this title regarding employment practices shall not be affected by its participation in, or receipt of funds from, a designated program.

(f) Rights of program beneficiaries

(1) In general

If an individual who is a program beneficiary or a prospective program beneficiary objects to the religious character of a program participant, within a reasonable period of time after the date of such objection such program participant shall refer such individual to, and the appropriate Federal, State, or local government that administers a designated program or is a program participant shall provide to such individual (if otherwise eligible for such services), program services that—

(A) are from an alternative provider that is accessible to, and has the capacity to provide such services to, such individual; and

(B) have a value that is not less than the value of the services that the individual would have received from the program participant to which the individual had such objection.

Upon referring a program beneficiary to an alternative provider, the program participant shall notify the appropriate Federal, State, or local government agency that administers the program of such referral.

(2) Notices

Program participants, public agencies that refer individuals to designated programs, and the appropriate Federal, State, or local governments that administer designated programs or are program participants shall ensure that notice is provided to program beneficiaries or prospective program beneficiaries of their rights under this section.

(3) Additional requirements

A program participant making a referral pursuant to paragraph (1) shall—

(A) prior to making such referral, consider any list that the State or local government makes available of entities in the geographic area that provide program services; and

(B) ensure that the individual makes contact with the alternative provider to which the individual is referred.

(4) Nondiscrimination

A religious organization that is a program participant shall not in providing program services or engaging in outreach activities under designated programs discriminate against a program beneficiary or prospective program beneficiary on the basis of religion or religious belief.

(g) Fiscal accountability

(1) In general

Except as provided in paragraph (2), any religious organization that is a program participant shall be subject to the same regulations as other recipients of awards of Federal financial assistance to account, in accordance with generally accepted auditing principles, for the use of the funds provided under such awards.

(2) Limited audit

With respect to the award involved, a religious organization that is a program participant shall segregate Federal amounts provided under award into a separate account from non-Federal funds. Only the award funds shall be subject to audit by the government.

(h) Compliance

With respect to compliance with this section by an agency, a religious organization may obtain judicial review of agency action in accordance with chapter 7 of title 5.

(July 1, 1944, ch. 373, title V, §596A, formerly §582, as added Pub. L. 106–554, §1(a)(7) [title I, §144], Dec. 21, 2000, 114 Stat. 2763, 2763A–620; renumbered §596A, Pub. L. 119–44, title I, §107(a)(2), Dec. 1, 2025, 139 Stat. 674.)

§290kk–2. Limitations on use of funds for certain purposes

No funds provided under a designated program shall be expended for sectarian worship, instruction, or proselytization.

(July 1, 1944, ch. 373, title V, §596B, formerly §583, as added Pub. L. 106–554, §1(a)(7) [title I, §144], Dec. 21, 2000, 114 Stat. 2763, 2763A–622; renumbered §596B, Pub. L. 119–44, title I, §107(a)(2), Dec. 1, 2025, 139 Stat. 674.)

§290kk–3. Educational requirements for personnel in drug treatment programs

(a) Findings

The Congress finds that—

(1) establishing unduly rigid or uniform educational qualification for counselors and other personnel in drug treatment programs may undermine the effectiveness of such programs; and

(2) such educational requirements for counselors and other personnel may hinder or prevent the provision of needed drug treatment services.

(b) Nondiscrimination

In determining whether personnel of a program participant that has a record of successful drug treatment for the preceding three years have satisfied State or local requirements for education and training, a State or local government shall not discriminate against education and training provided to such personnel by a religious organization, so long as such education and training includes basic content substantially equivalent to the content provided by nonreligious organizations that the State or local government would credit for purposes of determining whether the relevant requirements have been satisfied.

(July 1, 1944, ch. 373, title V, §596C, formerly §584, as added Pub. L. 106–554, §1(a)(7) [title I, §144], Dec. 21, 2000, 114 Stat. 2763, 2763A–622; renumbered §596C, Pub. L. 119–44, title I, §107(a)(2), Dec. 1, 2025, 139 Stat. 674.)

PART K—MINORITY FELLOWSHIP PROGRAM

§290*ll*. Fellowships

(a) In general

The Secretary shall maintain a program, to be known as the Minority Fellowship Program, under which the Secretary shall award fellowships, which may include stipends, for the purposes of—

(1) increasing the knowledge of mental and substance use disorders practitioners on issues related to diagnosis, prevention, treatment, and recovery support for individuals who are from racial and ethnic minority populations and who have a mental or substance use disorder;

(2) improving the quality of mental and substance use disorder prevention and treatment services delivered to racial and ethnic minority populations; and

(3) increasing the number of culturally competent mental and substance use disorders professionals who teach, administer services, conduct research, and provide direct mental or substance use disorder services to racial and ethnic minority populations.

(b) Training covered

The fellowships awarded under subsection (a) shall be for postbaccalaureate training (including for master's and doctoral degrees) for mental and substance use disorder treatment professionals, including in the fields of psychiatry, addiction medicine, nursing, social work, psychology, marriage and family therapy, mental health counseling, and substance use disorder and addiction counseling.

(c) Authorization of appropriations

To carry out this section, there are authorized to be appropriated $25,000,000 for each of fiscal years 2023 through 2027.

(July 1, 1944, ch. 373, title V, §597, as added Pub. L. 114–255, div. B, title IX, §9024, Dec. 13, 2016, 130 Stat. 1253; amended Pub. L. 117–328, div. FF, title I, §1312, Dec. 29, 2022, 136 Stat. 5697; Pub. L. 119–44, title II, §202, Dec. 1, 2025, 139 Stat. 680.)

EDITORIAL NOTES

AMENDMENTS

2025—Subsec. (a)(1). Pub. L. 119–44, §202(1), inserted "diagnosis," after "related to".

Subsec. (b). Pub. L. 119–44, §202(2), inserted "addiction medicine," after "psychiatry,".

2022—Subsec. (c). Pub. L. 117–328 substituted "$25,000,000 for each of fiscal years 2023 through 2027" for "$12,669,000 for each of fiscal years 2018 through 2022".

SUBCHAPTER IV—CONSTRUCTION AND MODERNIZATION OF HOSPITALS AND OTHER MEDICAL FACILITIES

§291. Congressional declaration of purpose

The purpose of this subchapter is—

(a) to assist the several States in the carrying out of their programs for the construction and modernization of such public or other nonprofit community hospitals and other medical facilities as may be necessary, in conjunction with existing facilities, to furnish adequate hospital, clinic, or similar services to all their people;

(b) to stimulate the development of new or improved types of physical facilities for medical, diagnostic, preventive, treatment, or rehabilitative services; and

(c) to promote research, experiments, and demonstrations relating to the effective development and utilization of hospital, clinic, or similar services, facilities, and resources, and to promote the coordination of such research, experiments, and demonstrations and the useful application of their

results.

(July 1, 1944, ch. 373, title VI, §600, as added Pub. L. 88–443, §3(a), Aug. 18, 1964, 78 Stat. 447.)

EDITORIAL NOTES

PRIOR PROVISIONS

A prior section 291, act July 1, 1944, ch. 373, title VI, §601, as added Aug. 13, 1946, ch. 958, §2, 60 Stat. 1041; amended Oct. 25, 1949, ch. 722, §6, 63 Stat. 900; July 12, 1954, ch. 471, §4(a), 68 Stat. 464, related to subject matter similar to this section, prior to the general amendment of this subchapter by Pub. L. 88–443.

Provisions similar to those comprising this section were contained in former section 291o, act July 1, 1944, ch. 373, title VI, §641, as added July 12, 1954, ch. 471, §2, 68 Stat. 461, prior to the general amendment of this subchapter by Pub. L. 88–443.

STATUTORY NOTES AND RELATED SUBSIDIARIES

EFFECTIVE DATE

Pub. L. 88–443, §3(b), Aug. 18, 1964, 78 Stat. 461, as amended by Pub. L. 91–296, title I, §120, June 30, 1970, 84 Stat. 343, provided that: "The amendment made by subsection (a) [enacting this section and sections 291a to 291j, 291k to 291m, 291n, and 291o of this title] shall become effective upon the date of enactment of this Act [Aug. 18, 1964], except that—

"(1) all applications approved by the Surgeon General under title VI of the Public Health Service Act [42 U.S.C. 291 et seq.] prior to such date, and allotments of sums appropriated prior to such date, shall be governed by the provisions of such title VI in effect prior to such date;

"(2) allotment percentages promulgated by the Surgeon General under such title VI during 1962 shall continue to be effective for purposes of such title as amended by this Act for the fiscal year ending June 30, 1965;

"(3) the terms of members of the Federal Hospital Council who are serving on such Council prior to such date shall expire on the date they would have expired had this Act not been enacted;

"(4) the provisions of the fourth sentence of section 636(a) of the Public Health Service Act [former 42 U.S.C. 291n(a)], as in effect prior to the enactment of this Act, shall apply in lieu of the fourth sentence of section 624(a) of the Public Health Service Act [former 42 U.S.C. 291n(a)], as amended by this Act, in the case of any project for construction of a facility or for acquisition of equipment with respect to which a grant for any part thereof or for planning such construction or equipment was made prior to the enactment of this Act;

"(5) no application with respect to a project for modernization of any facility in any State may be approved by the Surgeon General, for purposes of receiving funds from an allotment under section 602(a)(2) of the Public Health Service Act, as amended by this Act [42 U.S.C. 291b(a)(2)], before July 1, 1965, or before such State has had a State plan approved by the Surgeon General as meeting the requirements of section 604(a)(4)(E) [42 U.S.C. 291d(a)(4)(E)] as well as the other requirements of section 604 of such Act as so amended [42 U.S.C. 291d];

"(6) the provisions of clause (b) of section 609 of the Public Health Service Act [42 U.S.C. 291i], as amended by this Act, shall apply with respect to any project whether it was approved, and whether the event specified in such clause occurred, before, on, or after the date of enactment of this Act [June 30, 1970], except that it shall not apply in the case of any project with respect to which recovery under title VI of such Act [42 U.S.C. 291 et seq.] has been made prior to the enactment of this paragraph."

PART A—GRANTS AND LOANS FOR CONSTRUCTION AND MODERNIZATION OF HOSPITALS AND OTHER MEDICAL FACILITIES

§291a. Authorization of appropriations

In order to assist the States in carrying out the purposes of section 291 of this title, there are

authorized to be appropriated—

(a) for the fiscal year ending June 30, 1974—

(1) $20,800,000 for grants for the construction of public or other nonprofit facilities for long-term care;

(2) $70,000,000 for grants for the construction of public or other nonprofit outpatient facilities;

(3) $15,000,000 for grants for the construction of public or other nonprofit rehabilitation facilities;

(b) for grants for the construction of public or other nonprofit hospitals and public health centers, $150,000,000 for the fiscal year ending June 30, 1965, $160,000,000 for the fiscal year ending June 30, 1966, $170,000,000 for the fiscal year ending June 30, 1967, $180,000,000 each for the next two fiscal years, $195,000,000 for the fiscal year ending June 30, 1970, $147,500,000 for the fiscal year ending June 30, 1971, $152,500,000 for the fiscal year ending June 30, 1972, $157,500,000 for the fiscal year ending June 30, 1973, and $41,400,000 for the fiscal year ending June 30, 1974; and

(c) for grants for modernization of the facilities referred to in paragraphs (a) and (b), $65,000,000 for the fiscal year ending June 30, 1971, $80,000,000 for the fiscal year ending June 30, 1972, $90,000,000 for the fiscal year ending June 30, 1973, and $50,000,000 for the fiscal year ending June 30, 1974.

(July 1, 1944, ch. 373, title VI, §601, as added Pub. L. 88–443, §3(a), Aug. 18, 1964, 78 Stat. 448; amended Pub. L. 90–574, title IV, §402(a), Oct. 15, 1968, 82 Stat. 1011; Pub. L. 91–296, title I, §§101(a), 102(a), 116(a), June 30, 1970, 84 Stat. 337, 341; Pub. L. 93–45, title I, §108(a), June 18, 1973, 87 Stat. 92.)

EDITORIAL NOTES

PRIOR PROVISIONS

A prior section 291a, act July 1, 1944, ch. 373, title VI, §611, as added Aug. 13, 1946, ch. 958, §2, 60 Stat. 1041, authorized appropriations for surveys and planning, prior to the general amendment of this subchapter by Pub. L. 88–443.

A prior section 291d, act July 1, 1944, ch. 373, title VI, §621, as added Aug. 13, 1946, ch. 958, §2, 60 Stat. 1041; amended Oct. 25, 1949, ch. 722, §2(a), 63 Stat. 897; July 27, 1953, ch. 243, 67 Stat. 196; Aug. 2, 1956, ch. 871, title IV, §401, 70 Stat. 929; Aug. 14, 1958, Pub. L. 85–664, §1(a), 72 Stat. 616, related to subject matter similar to this section, prior to the general amendment of this subchapter by Pub. L. 88–443.

A prior section 291p, act July 1, 1944, ch. 373, title VI, §646, as added July 12, 1954, ch. 471, §2, 68 Stat. 461, related to subject matter similar to this section, prior to the general amendment of this subchapter by Pub. L. 88–443.

A prior section 291s, act July 1, 1944, ch. 373, title VI, §651, as added July 12, 1954, ch. 471, §3, 68 Stat. 462; amended Aug. 2, 1956, ch. 871, title IV, §402, 70 Stat. 929; Aug. 14, 1958, Pub. L. 85–664, §1(b), 72 Stat. 616; Oct. 5, 1961, Pub. L. 87–395, §3(a), 75 Stat. 825, related to subject matter similar to this section, prior to the general amendment of this subchapter by Pub. L. 88–443.

AMENDMENTS

1973—Subsec. (a). Pub. L. 93–45, §108(a)(1), substituted introductory text reading "fiscal year ending June 30, 1974" for "fiscal year ending June 30, 1965, and each of the next eight fiscal years" and in cl. (1) "$20,800,000" for "$85,000,000".

Subsec. (b). Pub. L. 93–45, §108(a)(2), authorized appropriations of $41,400,000 for fiscal year ending June 30, 1974.

Subsec. (c). Pub. L. 93–45, §108(a)(3), authorized appropriations of $50,000,000 for fiscal year ending June 30, 1974.

1970—Par. (a). Pub. L. 91–296, §§101(a)(1), (2), 116(a), substituted "outpatient facilities" for "diagnostic or treatment centers" in enumeration of facilities eligible for construction grants, extended through fiscal year ending June 30, 1973, authority to appropriate funds for construction grants, increased from $70,000,000 to $85,000,000 annual authority to make grants for public or other nonprofit facilities for long-term care, from

$20,000,000 to $70,000,000 authority for public or other nonprofit outpatient facilities, and from $10,000,000 to $15,000,000 authority for public or other nonprofit rehabilitation facilities.

Par. (b). Pub. L. 91–296, §§101(a)(3), 102(a)(1), struck out provisions authorizing grants for modernization of facilities and inserted provisions authorizing appropriation of $147,500,000 for fiscal year ending June 30, 1971, $152,500,000 for fiscal year ending June 30, 1972, and $157,500,000 for fiscal year ending June 30, 1973, for grants for construction of public or other nonprofit hospitals and public health centers.

Par. (c). Pub. L. 91–296, §102(a)(2), added par. (c).

1968—Par. (a). Pub. L. 90–574, §402(a)(1), substituted "next five" for "next four".

Par. (b). Pub. L. 90–574, §402(a)(2), authorized appropriation of $195,000,000 for fiscal year ending June 30, 1970.

STATUTORY NOTES AND RELATED SUBSIDIARIES

EFFECTIVE DATE OF 1970 AMENDMENT

Pub. L. 91–296, title I, §101(b), June 30, 1970, 84 Stat. 337, provided that: "The amendments made by subsection (a) [amending this section] shall take effect with respect to appropriations made under such section 601 [42 U.S.C. 291a] for fiscal years beginning after June 30, 1970."

Pub. L. 91–296, title I, §102(a), June 30, 1970, 84 Stat. 337, provided that the amendment made by that section is effective with respect to appropriations made under this section for fiscal years beginning after June 30, 1970.

§291b. State allotments

(a) Computation for individual States; formulas for both new construction and modernization

(1) Each State shall be entitled for each fiscal year to an allotment bearing the same ratio to the sums appropriated for such year pursuant to subparagraphs (1), (2), and (3), respectively, of section 291a(a) of this title, and to an allotment bearing the same ratio to the sums appropriated for such year pursuant to section 291a(b) of this title, as the product of—

(A) the population of such State, and

(B) the square of its allotment percentage,

bears to the sum of the corresponding products for all of the States.

(2) For each fiscal year, the Secretary shall, in accordance with regulations, make allotments among the States, from the sums appropriated for such year under section 291a(c) of this title, on the basis of the population, the financial need, and the extent of the need for modernization of the facilities referred to in paragraphs (a) and (b) of section 291a of this title, of the respective States.

(b) Minimum allotments

(1) The allotment to any State under subsection (a) for any fiscal year which is less than—

(A) $50,000 for the Virgin Islands, American Samoa, the Trust Territory of the Pacific Islands, or Guam and $100,000 for any other State, in the case of an allotment for grants for the construction of public or other nonprofit rehabilitation facilities,

(B) $100,000 for the Virgin Islands, American Samoa, the Trust Territory of the Pacific Islands, or Guam and $200,000 for any other State in the case of an allotment for grants for the construction of public or other nonprofit outpatient facilities,

(C) $200,000 for the Virgin Islands, American Samoa, the Trust Territory of the Pacific Islands, or Guam and $300,000 for any other State in the case of an allotment for grants for the construction of public or other nonprofit facilities for long-term care or for the construction of public or other nonprofit hospitals and public health centers, or for the modernization of facilities referred to in paragraph (a) or (b) of section 291a of this title, or

(D) $200,000 for the Virgin Islands, American Samoa, the Trust Territory of the Pacific Islands, or Guam and $300,000 for any other State in the case of an allotment for grants for the modernization of facilities referred to in paragraphs (a) and (b) of section 291a of this title,

shall be increased to that amount, the total of the increases thereby required being derived by proportionately reducing the allotment from appropriations under such subparagraph or paragraph to each of the remaining States under subsection (a) of this section, but with such adjustments as may be necessary to prevent the allotment of any of such remaining States from appropriations under such subparagraph or paragraph from being thereby reduced to less than that amount.

(2) An allotment of the Virgin Islands, American Samoa, the Trust Territory of the Pacific Islands, or Guam for any fiscal year may be increased as provided in paragraph (1) only to the extent it satisfies the Surgeon General, at such time prior to the beginning of such year as the Surgeon General may designate, that such increase will be used for payments under and in accordance with the provisions of this part.

(c) Allotment percentages; definitions; determination

For the purposes of this part—

(1) The "allotment percentage" for any State shall be 100 per centum less that percentage which bears the same ratio to 50 per centum as the per capita income of such State bears to the per capita income of the United States, except that (A) the allotment percentage shall in no case be more than 75 per centum or less than 331/3 per centum, and (B) the allotment percentage for the Commonwealth of Puerto Rico, Guam, American Samoa, the Trust Territory of the Pacific Islands, and the Virgin Islands shall be 75 per centum.

(2) The allotment percentages shall be determined by the Surgeon General between July 1 and September 30 of each even-numbered year, on the basis of the average of the per capita incomes of each of the States and of the United States for the three most recent consecutive years for which satisfactory data are available from the Department of Commerce, and the States shall be notified promptly thereof. Such determination shall be conclusive for each of the two fiscal years in the period beginning July 1 next succeeding such determination.

(3) The population of the several States shall be determined on the basis of the latest figures certified by the Department of Commerce.

(4) The term "United States" means (but only for purposes of paragraphs (1) and (2)) the fifty States and the District of Columbia.

(d) Availability of allotments in subsequent years

(1) Any sum allotted to a State, other than the Virgin Islands, American Samoa, the Trust Territory of the Pacific Islands, and Guam for a fiscal year under this section and remaining unobligated at the end of such year shall remain available to such State, for the purpose for which made, for the next two fiscal years (and for such years only), in addition to the sums allotted to such State for such purposes for such next two fiscal years.

(2) Any sum allotted to the Virgin Islands, American Samoa, the Trust Territory of the Pacific Islands, or Guam for a fiscal year under this section and remaining unobligated at the end of such year shall remain available to it, for the purpose for which made, for the next two fiscal years (and for such years only), in addition to the sums allotted to it for such purpose for each of such next two fiscal years.

(e) Transfer of allotments

(1) Upon the request of any State that a specified portion of any allotment of such State under subsection (a) for any fiscal year be added to any other allotment or allotments of such State under such subsection for such year, the Secretary shall promptly (but after application of subsection (b)) adjust the allotments of such State in accordance with such request and shall notify the State agency; except that the aggregate of the portions so transferred from an allotment for a fiscal year pursuant to this paragraph may not exceed the amount specified with respect to such allotment in clause (A), (B), (C), or (D), as the case may be, of subsection (b)(1) which is applicable to such State.

(2) In addition to the transfer of portions of allotments under paragraph (1), upon the request of any State that a specified portion of any allotment of such State under subsection (a), other than an allotment for grants for the construction of public or other nonprofit rehabilitation facilities, be added to another allotment of such State under such subsection, other than an allotment for grants for the

construction of public or other nonprofit hospitals and public health centers, and upon simultaneous certification to the Secretary by the State agency in such State to the effect that—

(A) it has afforded a reasonable opportunity to make applications for the portion so specified and there have been no approvable applications for such portion, or

(B) in the case of a request to transfer a portion of an allotment for grants for the construction of public or other nonprofit hospitals and public health centers, use of such portion as requested by such State agency will better carry out the purposes of this subchapter,

the Secretary shall promptly (but after application of subsection (b)) adjust the allotments of such State in accordance with such request and shall notify the State agency.

(3) In addition to the transfer of portions of allotments under paragraph (1) or (2), upon the request of any State that a specified portion of an allotment of such State under paragraph (2) of subsection (a) be added to an allotment of such State under paragraph (1) of such subsection for grants for the construction of public or other nonprofit hospitals and public health centers, and upon simultaneous certification by the State agency in such State to the effect that the need for new public or other nonprofit hospitals and public health centers is substantially greater than the need for modernization of facilities referred to in paragraph (a) or (b) of section 291a of this title, the Secretary shall promptly (but after application of subsection (b) of this section) adjust the allotments of such State in accordance with such request and shall notify the State agency.

(4) After adjustment of allotments of any State, as provided in paragraph (1), (2), or (3) of this subsection, the allotments as so adjusted shall be deemed to be the State's allotments under this section.

(f) Request by State to transfer portion of allotment

In accordance with regulations, any State may file with the Surgeon General a request that a specified portion of an allotment to it under this part for grants for construction of any type of facility, or for modernization of facilities, be added to the corresponding allotment of another State for the purpose of meeting a portion of the Federal share of the cost of a project for the construction of a facility of that type in such other State, or for modernization of a facility in such other State, as the case may be. If it is found by the Surgeon General (or, in the case of a rehabilitation facility, by the Surgeon General and the Secretary) that construction or modernization of the facility with respect to which the request is made would meet needs of the State making the request and that use of the specified portion of such State's allotment, as requested by it, would assist in carrying out the purposes of this subchapter, such portion of such State's allotment shall be added to the corresponding allotment of the other State, to be used for the purpose referred to above.

(July 1, 1944, ch. 373, title VI, §602, as added Pub. L. 88–443, §3(a), Aug. 18, 1964, 78 Stat. 448; amended Pub. L. 90–574, title IV, §402(b), Oct. 15, 1968, 82 Stat. 1011; Pub. L. 91–296, title I, §§103(a), (b), 104, 116(a), 119(a)–(c), 122, June 30, 1970, 84 Stat. 338, 341, 343, 344.)

EDITORIAL NOTES

PRIOR PROVISIONS

A prior section 291b, act July 1, 1944, ch. 373, title VI, §612, as added Aug. 13, 1946, ch. 958, §2, 60 Stat. 1041, related to a State application for funds, its requirements and its approval, prior to the general amendment of this subchapter by Pub. L. 88–443.

A prior section 291c, act July 1, 1944, ch. 373, title VI, §624, as added Aug. 13, 1946, ch. 958, §2, 60 Stat. 1941, related to subject matter similar to this section, prior to the general amendment of this subchapter by Pub. L. 88–443.

A prior section 291g, act July 1, 1944, ch. 373, title VI, §624, as added Aug. 13, 1946, ch. 958, §2, 60 Stat. 1041; amended June 29, 1948, ch. 728, §1, 62 Stat. 1103; Oct. 25, 1949, ch. 722, §§3(b), 7, 63 Stat. 899, 901; Aug. 1, 1956, ch. 852, §19(c), 70 Stat. 911; Sept. 25, 1962, Pub. L. 87–688, §4(a)(3), 76 Stat. 587, related to subject matter similar to this section, prior to the general amendment of this subchapter by Pub. L. 88–443.

A prior section 291i(a) to (d), act July 1, 1944, ch. 373, title VI, §631, as added Aug. 13, 1946, ch. 958, §2, 60 Stat. 1041; amended June 19, 1948, ch. 544, 62 Stat. 531; Aug. 1, 1956, ch. 852, §19(a), (b), 70 Stat. 911;

June 25, 1959, Pub. L. 86–70, §31(c), 73 Stat. 149; July 12, 1960, Pub. L. 86–624, §29(d), 74 Stat. 419; Sept. 25, 1962, Pub. L. 87–688, §4(a)(2), 76 Stat. 587, related to subject matter similar to this section, prior to the general amendment of this subchapter by Pub. L. 88–443.

A prior section 291n–1, act July 1, 1944, ch. 373, title VI, §637, formerly §654(c), as added July 12, 1954, ch. 471, §3, 68 Stat. 463, renumbered and amended Aug. 14, 1959, Pub. L. 86–158, title II, §201, 73 Stat. 349, related to subject matter similar to this section, prior to the general amendment of this subchapter by Pub. L. 88–443.

A prior section 291r, act July 1, 1944, ch. 373, title VI, §648, as added July 12, 1954, ch. 471, §2, 68 Stat. 462, related to subject matter similar to this section, prior to the general amendment of this subchapter by Pub. L. 88–443.

A prior section 291t, act July 1, 1944, ch. 373, title VI, §652, as added July 12, 1954, ch. 471, §3, 68 Stat. 462; amended Aug. 1, 1956, ch. 852, §19(c), 70 Stat. 911; Oct. 5, 1961, Pub. L. 87–395, §3(b), 75 Stat. 825; Sept. 25, 1962, Pub. L. 87–688, §4(a)(3), 76 Stat. 587, related to subject matter similar to this section, prior to the general amendment of this subchapter by Pub. L. 88–443.

A prior section 291v(b), act July 1, 1944, ch. 373, title VI, §654, as added July 12, 1954, ch. 471, §3, 68 Stat. 463, related to subject matter similar to this section, prior to the general amendment of this subchapter by Pub. L. 88–443.

AMENDMENTS

1970—Subsec. (a)(1). Pub. L. 91–296, §103(a), substituted "sums appropriated for such year" for "new hospital portion of the sums appropriated for such year" and struck out provision setting out a formula for determining new hospital portion of sums appropriated pursuant to section 291a(b) of this title.

Subsec. (a)(2). Pub. L. 91–296, §103(a), substituted "Secretary" for "Surgeon General", and substituted reference to sums appropriated for such year under section 291a(c) of this title for reference to remainder of sums appropriated pursuant to section 291a(b) of this title (which portion was to be available for grants for modernization of facilities referred to in paragraphs (a) and (b) of section 291a of this title).

Subsec. (b)(1)(A). Pub. L. 91–296, §§103(b)(1), 119(a)(1), substituted "$50,000" and "$100,000" for "$25,000" and "$50,000", respectively, and inserted reference to Trust Territory of the Pacific Islands.

Subsec. (b)(1)(B). Pub. L. 91–296, §§103(b)(2), 116(a), 119(a)(1), substituted "$100,000" and "$200,000" for "$50,000" and "$100,000", respectively, substituted "outpatient facilities" for "diagnostic or treatment centers", and inserted reference to Trust Territory of the Pacific Islands.

Subsec. (b)(1)(C). Pub. L. 91–296, §§103(b)(3), 119(a)(1), substituted "$200,000" and "$300,000" for "$100,000" and "$200,000", respectively, and inserted reference to Trust Territory of the Pacific Islands.

Subsec. (b)(1)(D). Pub. L. 91–296, §103(b)(4), added subpar. (D).

Subsecs. (b)(2), (c)(1). Pub. L. 91–296, §119(a)(2), (b), inserted reference to Trust Territory of the Pacific Islands.

Subsec. (d)(1). Pub. L. 91–296, §§119(c), 122, inserted reference to Trust Territory of the Pacific Islands and substituted two years for one year as the time span following a year in which allotted sums remaining unobligated at the end thereof during which such unobligated funds remain available.

Subsec. (d)(2). Pub. L. 91–296, §119(c), inserted references to Trust Territory of the Pacific Islands.

Subsec. (e). Pub. L. 91–296, §104, authorized any State to make transfers of any amount up to the minimum amount allotted to any state for a particular category and authorized all amounts above such minimums to be transferred from one category of assistance to another without restriction on the amounts with the exception that no funds could be transferred from rehabilitation facilities category or to new hospital construction category and that all transfers be justified on the basis that either there are no approvable applications in the category from which funds are transferred or, in case of transfers from new hospital construction category, the purposes of the program would be better served by the transfer, and authorized transfers to new hospital construction from modernization category if need is greater.

1968—Subsec. (a)(1). Pub. L. 90–574, §402(b)(1), inserted provision for two-thirds of the sums appropriated in the case of the fifth fiscal year thereafter.

Subsec. (e)(2)(E). Pub. L. 90–574, §402(b)(2), added subpar. (E).

STATUTORY NOTES AND RELATED SUBSIDIARIES

CHANGE OF NAME

"Secretary of Health and Human Services" substituted for "Secretary of Health, Education, and Welfare" in subsecs. (a)(2), (e), and (f) pursuant to section 509(b) of Pub. L. 96–88, which is classified to section 3508(b) of Title 20, Education.

EFFECTIVE DATE OF 1970 AMENDMENT

Pub. L. 91–296, title I, §103(a), June 30, 1970, 84 Stat. 338, provided that the amendment made by that section is effective with respect to appropriations made pursuant to section 291a of this title for fiscal years beginning after June 30, 1970.

Pub. L. 91–296, title I, §103(b), June 30, 1970, 84 Stat. 338, provided that the amendment made by that section is effective with respect to allotments from appropriations made pursuant to section 291a of this title for fiscal years beginning after June 30, 1970.

Pub. L. 91–296, title I, §104, June 30, 1970, 84 Stat. 338, provided that the amendment made by that section is effective with respect to allotments made pursuant to section 291a of this title for fiscal years beginning after June 30, 1970.

Pub. L. 91–296, title I, §119(e), June 30, 1970, 84 Stat. 343, provided that: "The amendments made by this section [amending this section and section 291o of this title] shall apply with respect to allotments (and grants therefrom) under part A of title VI of the Public Health Service Act [42 U.S.C. 291a et seq.] for fiscal years ending after June 30, 1970, and with respect to loan guarantees and loans under part B of such title [42 U.S.C. 291j–1 et seq.] made after June 30, 1970."

Pub. L. 91–296, title I, §122, June 30, 1970, 84 Stat. 344, provided that the amendment made by that section is effective with respect to allotments made from appropriations under section 291a of this title for fiscal years beginning after June 30, 1970.

AVAILABILITY OF FUNDS FOR OBLIGATION FROM ALLOTMENT FOR ADMINISTRATION OF PLAN

Pub. L. 93–641, §5(b), Jan. 4, 1975, 88 Stat. 2274, provided that any State having in the fiscal year ending June 30, 1975 or the next fiscal year funds available for obligation from its allotments under section 291a et seq. of this title, may in such fiscal year use for the proper and efficient administration during such year of its State plan an amount of such funds not exceeding 4 percentum of such funds or $100,000, whichever is less.

ALLOTMENT STUDY; REPORT TO CONGRESS

Pub. L. 91–296, title I, §103(c), June 30, 1970, 84 Stat. 338, directed Secretary to study effects of the formula specified in subsec. (a)(1) of this section for allotment among the States for construction of health facilities, with results of such study together with recommendations for change to be reported to Congress on May 15, 1972.

APPROVAL OF APPLICATION FOR MODERNIZATION PRIOR TO JULY 1, 1965, OR BEFORE APPROVAL OF A STATE PLAN

Pub. L. 88–443, §3(b)(5), Aug. 18, 1964, 78 Stat. 462, providing that no application for modernization of any facility may be approved for purposes of receiving funds before the approval of a State plan, as well as other requirements, is set out as an Effective Date note under section 291 of this title.

EXECUTIVE DOCUMENTS

TRANSFER OF FUNCTIONS

Office of Surgeon General abolished by section 3 of Reorg. Plan No. 3 of 1966, eff. June 25, 1966, 31 F.R. 8855, 80 Stat. 1610, and functions thereof transferred to Secretary of Health, Education, and Welfare by section 1 of Reorg. Plan No. 3 of 1966, set out as a note under section 202 of this title. Office of Surgeon General reestablished within the Office of the Assistant Secretary for Health, see Notice of Department of Health and Human Services, Office of the Assistant Secretary for Health, Mar. 30, 1987, 52 F.R. 11754.

TERMINATION OF TRUST TERRITORY OF THE PACIFIC ISLANDS

For termination of Trust Territory of the Pacific Islands, see note set out preceding section 1681 of Title 48, Territories and Insular Possessions.

§291c. General regulations

The Surgeon General, with the approval of the Federal Hospital Council and the Secretary of Health and Human Services shall by general regulations prescribe—

(a) Priority of projects; determination

the general manner in which the State agency shall determine the priority of projects based on the relative need of different areas lacking adequate facilities of various types for which assistance is available under this part, giving special consideration—

(1) in the case of projects for the construction of hospitals, to facilities serving areas with relatively small financial resources and, at the option of the State, rural communities;

(2) in the case of projects for the construction of rehabilitation facilities, to facilities operated in connection with a university teaching hospital which will provide an integrated program of medical, psychological, social, and vocational evaluation and services under competent supervision;

(3) in the case of projects for modernization of facilities, to facilities serving densely populated areas;

(4) in the case of projects for construction or modernization of outpatient facilities, to any outpatient facility that will be located in, and provide services for residents of, an area determined by the Secretary to be a rural or urban poverty area;

(5) to projects for facilities which, alone or in conjunction with other facilities, will provide comprehensive health care, including outpatient and preventive care as well as hospitalization;

(6) to facilities which will provide training in health or allied health professions; and

(7) to facilities which will provide to a significant extent, for the treatment of alcoholism;

(b) Standards of construction and equipment

general standards of construction and equipment for facilities of different classes and in different types of location, for which assistance is available under this part;

(c) Criteria for determining needs for beds, hospitals and other facilities; plans for distribution of beds and facilities

criteria for determining needs for general hospital and long-term care beds, and needs for hospitals and other facilities for which aid under this part is available, and for developing plans for the distribution of such beds and facilities;

(d) Criteria for determining need for modernization

criteria for determining the extent to which existing facilities, for which aid under this part is available, are in need of modernization; and

(e) State plan requirements; assurances necessary for approval of application

that the State plan shall provide for adequate hospitals, and other facilities for which aid under this part is available, for all persons residing in the State, and adequate hospitals (and such other facilities) to furnish needed services for persons unable to pay therefor. Such regulations may also require that before approval of an application for a project is recommended by a State agency to the Surgeon General for approval under this part, assurance shall be received by the State from the applicant that (1) the facility or portion thereof to be constructed or modernized will be made available to all persons residing in the territorial area of the applicant; and (2) there will be made available in the facility or portion thereof to be constructed or modernized a reasonable volume of services to persons unable to pay therefor, but an exception shall be made if such a requirement is not feasible from a financial viewpoint.

(July 1, 1944, ch. 373, title VI, §603, as added Pub. L. 88–443, §3(a), Aug. 18, 1964, 78 Stat. 451; amended Pub. L. 88–581, §3(b), Sept. 4, 1964, 78 Stat. 919; Pub. L. 91–296, title I, §110, June 30, 1970, 84 Stat. 339; Pub. L. 96–88, title V, §509(b), Oct. 17, 1979, 93 Stat. 695.)

EDITORIAL NOTES

PRIOR PROVISIONS

A prior section 291c, act July 1, 1944, ch. 373, title VI, §613, as added Aug. 13, 1946, ch. 958, §2, 60 Stat. 1041, related to allotments to States, the determination of their amount, and the disposition of unexpended funds, prior to the general amendment of this subchapter by Pub. L. 88–443. See section 291(a), (b) and (d) of this title.

Provisions similar to those comprising this section were contained in a prior section 291e, act July 1, 1944, ch. 373, title VI, §622, as added Aug. 13, 1946, ch. 958, §2, 60 Stat. 1041; amended 1953 Reorg. Plan No. 1, §§5, 8, eff. Apr. 11, 1953, 18 F.R. 2053, 67 Stat. 631, prior to the general amendment of this subchapter by Pub. L. 88–443.

AMENDMENTS

1970—Subsec. (a). Pub. L. 91–296 struck out from cl. (1) provisions requiring that States give special consideration for projects for hospitals serving rural areas but inserted provisions making such preference optional with each State and added cls. (4) to (7).

1964—Subsec. (a)(4). Pub. L. 88–581 struck out cl. (4) relating to hospital facilities which "will include new or expanded facilities for nurse training".

STATUTORY NOTES AND RELATED SUBSIDIARIES

CHANGE OF NAME

"Secretary of Health and Human Services" substituted in text for "Secretary of Health, Education, and Welfare" pursuant to section 509(b) of Pub. L. 96–88, which is classified to section 3508(b) of Title 20, Education.

EFFECTIVE DATE OF 1970 AMENDMENT

Pub. L. 91–296, title I, §110, June 30, 1970, 84 Stat. 339, provided that the amendment made by that section is effective with respect to applications approved under this subchapter after June 30, 1970.

EFFECTIVE DATE OF 1964 AMENDMENT

Pub. L. 88–581, §3(b), Sept. 4, 1964, 78 Stat. 919, provided that the amendments made by such section 3(b) [amending this section and sections 291o and 293c of this title] are effective with respect to applications for grants from appropriations for fiscal years beginning after June 30, 1965.

EXECUTIVE DOCUMENTS

TRANSFER OF FUNCTIONS

Office of Surgeon General abolished by section 3 of Reorg. Plan No. 3 of 1966, eff. June 25, 1966, 31 F.R. 8855, 80 Stat. 1610, and functions thereof transferred to Secretary of Health, Education, and Welfare by section 1 of Reorg. Plan No. 3 of 1966, set out as a note under section 202 of this title. Office of Surgeon General reestablished within the Office of the Assistant Secretary for Health, see Notice of Department of Health and Human Services, Office of the Assistant Secretary for Health, Mar. 30, 1987, 52 F.R. 11754.

§291d. State plans

(a) Submission; requirements

Any State desiring to participate in this part may submit a State plan. Such plan must—

(1) designate a single State agency as the sole agency for the administration of the plan, or designate such agency as the sole agency for supervising the administration of the plan;

(2) contain satisfactory evidence that the State agency designated in accordance with paragraph (1) of this subsection will have authority to carry out such plan in conformity with this part;

(3) provide for the designation of a State advisory council which shall include (A) representatives of nongovernmental organizations or groups, and of public agencies, concerned with the operation, construction, or utilization of hospital or other facilities for diagnosis, prevention, or treatment of illness or disease, or for provision of rehabilitation services, and representatives particularly concerned with education or training of health professions personnel, and (B) an equal number of representatives of consumers familiar with the need for the services provided by such facilities, to consult with the State agency in carrying out the plan, and provide, if such council does not include any representatives of nongovernmental organizations or groups, or State agencies, concerned with rehabilitation, for consultation with organizations, groups, and State agencies so concerned;

(4) set forth, in accordance with criteria established in regulations prescribed under section 291c of this title and on the basis of a statewide inventory of existing facilities, a survey of need, and (except to the extent provided by or pursuant to such regulations) community, area, or regional plans—

(A) the number of general hospital beds and long-term care beds, and the number and types of hospital facilities and facilities for long-term care, needed to provide adequate facilities for inpatient care of people residing in the State, and a plan for the distribution of such beds and facilities in service areas throughout the State;

(B) the public health centers needed to provide adequate public health services for people residing in the State, and a plan for the distribution of such centers throughout the State;

(C) the outpatient facilities needed to provide adequate diagnostic or treatment services to ambulatory patients residing in the State, and a plan for distribution of such facilities throughout the State;

(D) the rehabilitation facilities needed to assure adequate rehabilitation services for disabled persons residing in the State, and a plan for distribution of such facilities throughout the State; and

(E) effective January 1, 1966, the extent to which existing facilities referred to in section 291a(a) or (b) of this title in the State are in need of modernization;

(5) set forth a construction and modernization program conforming to the provisions set forth pursuant to paragraph (4) of this subsection and regulations prescribed under section 291c of this title and providing for construction or modernization of the hospital or long-term care facilities, public health centers, outpatient facilities, and rehabilitation facilities which are needed, as determined under the provisions so set forth pursuant to paragraph (4) of this subsection;

(6) set forth, with respect to each of such types of medical facilities, the relative need, determined in accordance with regulations prescribed under section 291c of this title, for projects for facilities of that type, and provide for the construction or modernization, insofar as financial resources available therefor and for maintenance and operation make possible, in the order of such relative need;

(7) provide minimum standards (to be fixed in the discretion of the State) for the maintenance and operation of facilities providing inpatient care which receive aid under this part and, effective July 1, 1966, provide for enforcement of such standards with respect to projects approved by the Surgeon General under this part after June 30, 1964;

(8) provide such methods of administration of the State plan, including methods relating to the establishment and maintenance of personnel standards on a merit basis (except that the Surgeon General shall exercise no authority with respect to the selection, tenure of office, or compensation of any individual employed in accordance with such methods), as are found by the Surgeon General to be necessary for the proper and efficient operation of the plan;

(9) provide for affording to every applicant for a construction or modernization project an opportunity for a hearing before the State agency;

(10) provide that the State agency will make such reports, in such form and containing such information, as the Surgeon General may from time to time reasonably require, and will keep such records and afford such access thereto as the Surgeon General may find necessary to assure the correctness and verification of such reports;

(11) provide that the Comptroller General of the United States or his duly authorized representatives shall have access for the purpose of audit and examination to the records specified in paragraph (10) of this subsection;

(12) provide that the State agency will from time to time, but not less often than annually, review its State plan and submit to the Surgeon General any modifications thereof which it considers necessary; and

(13) Effective [1] July 1, 1971, provide that before any project for construction or modernization of any general hospital is approved by the State agency there will be reasonable assurance of adequate provision for extended care services (as determined in accordance with regulations) to

patients of such hospital when such services are medically appropriate for them, with such services being provided in facilities which (A) are structurally part of, physically connected with, or in immediate proximity to, such hospital, and (B) either (i) are under the supervision of the professional staff of such hospital or (ii) have organized medical staffs and have in effect transfer agreements with such hospital; except that the Secretary may, at the request of the State agency, waive compliance with clause (A) or (B), or both such clauses, as the case may be, in the case of any project if the State agency has determined that compliance with such clause or clauses in such case would be inadvisable.

(b) Approval by Surgeon General; hearing after disapproval

The Surgeon General shall approve any State plan and any modification thereof which complies with the provisions of subsection (a). If any such plan or modification thereof shall have been disapproved by the Surgeon General for failure to comply with subsection (a), the Federal Hospital Council shall, upon request of the State agency, afford it an opportunity for hearing. If such Council determines that the plan or modification complies with the provisions of such subsection, the Surgeon General shall thereupon approve such plan or modification.

(July 1, 1944, ch. 373, title VI, §604, as added Pub. L. 88–443, §3(a), Aug. 18, 1964, 78 Stat. 452; amended Pub. L. 91–296, title I, §§115, 116(b), (c), 123, June 30, 1970, 84 Stat. 341, 342, 344.)

EDITORIAL NOTES

PRIOR PROVISIONS

A prior section 291d, act July 1, 1944, ch. 373, title VI, §621, as added Aug. 13, 1946, ch. 958, §2, 60 Stat. 1041; amended Oct. 25, 1949, ch. 722, §2(a), 63 Stat. 898; July 27, 1953, ch. 243, 67 Stat. 196; Aug. 2, 1956, ch. 871, title IV, §401, 70 Stat. 929; Aug. 14, 1958, Pub. L. 85–664, §1(a), 72 Stat. 616, authorized appropriations for construction of hospitals and related facilities, prior to the general amendment of this subchapter by Pub. L. 88–443. See section 291a of this title.

Provisions similar to those comprising this section were contained in a prior section 291f(a), (b), act July 1, 1944, ch. 373, title VI, §623, as added Aug. 13, 1946, ch. 958, §2, 60 Stat. 1041, prior to the general amendment of this subchapter by Pub. L. 88–443.

AMENDMENTS

1970—Subsec. (a)(3). Pub. L. 91–296, §115, inserted requirement that State advisory councils include representatives particularly concerned with education or training of health professions personnel.

Subsec. (a)(4)(C). Pub. L. 91–296, §116(b), substituted "outpatient facilities" for "diagnostic or treatment centers" and "such facilities" for "such centers".

Subsec. (a)(5). Pub. L. 91–296, §116(c), substituted "outpatient facilities" for "diagnostic or treatment centers".

Subsec. (a)(13). Pub. L. 91–296, §123, added par. (13).

STATUTORY NOTES AND RELATED SUBSIDIARIES

CHANGE OF NAME

"Secretary of Health and Human Services" substituted for "Secretary of Health, Education, and Welfare" in subsec. (a)(13) pursuant to section 509(b) of Pub. L. 96–88, which is classified to section 3508(b) of Title 20, Education.

EFFECTIVE DATE OF 1970 AMENDMENT

Pub. L. 91–296, title I, §115, June 30, 1970, 84 Stat. 341, provided that the amendment made by that section is effective July 1, 1970.

TRANSFER OF FUNCTIONS

Functions, powers, and duties of Secretary of Health and Human Services under subsec. (a)(8) of this section, insofar as relates to the prescription of personnel standards on a merit basis, transferred to Office of Personnel Management, see section 4728(a)(3)(C) of this title.

FUNDS FOR MODERNIZATION PROJECTS; CONDITIONS TO BE MET BEFORE APPROVAL

Pub. L. 88–443, §3(b)(5), Aug. 18, 1964, 78 Stat. 462, provided that no application with respect to a modernization project may be approved for purposes of receiving funds from an allotment under section 291(a)(2) of this title before July 1, 1965, or before a State plan has been approved, as well as certain other requirements. See Effective Date note under section 291 of this title.

EXECUTIVE DOCUMENTS

TRANSFER OF FUNCTIONS

Office of Surgeon General abolished by section 3 of Reorg. Plan No. 3 of 1966, eff. June 25, 1966, 31 F.R. 8855, 80 Stat. 1610, and functions thereof transferred to Secretary of Health, Education, and Welfare by section 1 of Reorg. Plan No. 3 of 1966, set out as a note under section 202 of this title. Office of Surgeon General reestablished within the Office of the Assistant Secretary for Health, see Notice of Department of Health and Human Services, Office of the Assistant Secretary for Health, Mar. 30, 1987, 52 F.R. 11754.

[1] *So in original. Probably should not be capitalized.*

§291e. Projects for construction or modernization

(a) Application; contents

For each project pursuant to a State plan approved under this part, there shall be submitted to the Surgeon General, through the State agency, an application by the State or a political subdivision thereof or by a public or other nonprofit agency. If two or more such agencies join in the project, the application may be filed by one or more of such agencies. Such application shall set forth—

(1) a description of the site for such project;

(2) plans and specifications therefor, in accordance with regulations prescribed under section 291c of this title;

(3) reasonable assurance that title to such site is or will be vested in one or more of the agencies filing the application or in a public or other nonprofit agency which is to operate the facility on completion of the project;

(4) reasonable assurance that adequate financial support will be available for the completion of the project and for its maintenance and operation when completed;

(5) reasonable assurance that all laborers and mechanics employed by contractors or subcontractors in the performance of construction or modernization on the project will be paid wages at rates not less than those prevailing on similar work in the locality as determined by the Secretary of Labor in accordance with sections 3141–3144, 3146, and 3147 of title 40; and the Secretary of Labor shall have with respect to the labor standards specified in this paragraph the authority and functions set forth in Reorganization Plan Numbered 14 of 1950 (15 F.R. 3176) and section 3145 of title 40; and

(6) a certification by the State agency of the Federal share for the project.

(b) Approval by Surgeon General; requisites; additional approval by Secretary of Health and Human Services

The Surgeon General shall approve such application if sufficient funds to pay the Federal share of the cost of such project are available from the appropriate allotment to the State, and if the Surgeon General finds (1) that the application contains such reasonable assurance as to title, financial support, and payment of prevailing rates of wages; (2) that the plans and specifications are in accord with the regulations prescribed pursuant to section 291c of this title; (3) that the application is in conformity with the State plan approved under section 291d of this title and contains an assurance that in the operation of the project there will be compliance with the applicable requirements of the regulations prescribed under section 291c(e) of this title, and with State standards for operation and maintenance; and (4) that the application has been approved and recommended by the State agency, opportunity has been provided, prior to such approval and recommendation, for consideration of the

project by the public or nonprofit private agency or organization which has developed the comprehensive regional, metropolitan area, or other local area plan or plans referred to in section 246(b) of this title covering the area in which such project is to be located or, if there is no such agency or organization, by the State agency administering or supervising the administration of the State plan approved under section 246(a) of this title, and the application is for a project which is entitled to priority over other projects within the State in accordance with the regulations prescribed pursuant to section 291c(a) of this title. Notwithstanding the preceding sentence, the Surgeon General may approve such an application for a project for construction or modernization of a rehabilitation facility only if it is also approved by the Secretary of Health and Human Services.

(c) Opportunity for hearing required prior to disapproval

No application shall be disapproved until the Surgeon General has afforded the State agency an opportunity for a hearing.

(d) Amendments subject to same approval as original applications

Amendment of any approved application shall be subject to approval in the same manner as an original application.

(e) Outpatient facilities; requirements of applicants

Notwithstanding any other provision of this subchapter, no application for an outpatient facility shall be approved under this section unless the applicant is (1) a State, political subdivision, or public agency, or (2) a corporation or association which owns and operates a nonprofit hospital (as defined in section 291o of this title) or which provides reasonable assurance that the services of a general hospital will be available to patients of such facility who are in need of hospital care.

(July 1, 1944, ch. 373, title VI, §605, as added Pub. L. 88–443, §3(a), Aug. 18, 1964, 78 Stat. 453; amended Pub. L. 91–296, title I, §§111(a), 116(e), June 30, 1970, 84 Stat. 340, 342; Pub. L. 96–88, title V, §509(b), Oct. 17, 1979, 93 Stat. 695.)

EDITORIAL NOTES

REFERENCES IN TEXT

Reorganization Plan Numbered 14 of 1950, referred to in subsec. (a)(5), is set out in the Appendix to Title 5, Government Organization and Employees.

CODIFICATION

In subsec. (a) (5), "sections 3141–3144, 3146, and 3147 of title 40" substituted for "the Davis-Bacon Act, as amended (40 U.S.C. 276a—276a–5)" and "section 3145 of title 40" substituted for "section 2 of the Act of June 13, 1934, as amended (40 U.S.C. 276c)" on authority of Pub. L. 107–217, §5(c), Aug. 21, 2002, 116 Stat. 1303, the first section of which enacted Title 40, Public Buildings, Property, and Works.

PRIOR PROVISIONS

A prior section 291e, act July 1944, ch. 373, title VI, §622, as added Aug. 13, 1946, ch. 958, §2, 60 Stat. 1041; amended 1953 Reorg. Plan No. 1, §§5, 8, eff. Apr. 11, 1953, 18 F.R. 2053, 67 Stat. 631, authorized Surgeon General to prescribe general regulations, prior to the general amendment of this subchapter by Pub. L. 88–443. See section 291c of this title.

A prior section 291h(a), (c), act July 1, 1944, ch. 373, title VI, §625, as added Aug. 13, 1946, ch. 958, §2, 60 Stat. 1041; amended Oct. 25, 1949, ch. 722, §8, 63 Stat. 901, related to subject matter similar to this section, prior to the general amendment of this subchapter by Pub. L. 88–443.

A prior section 291v(d), act July 1, 1944, ch. 373, title VI, §654, as added July 12, 1954, ch. 471, §3, 68 Stat. 463, related to subject matter similar to this section, prior to the general amendment of this subchapter by Pub. L. 88–443.

AMENDMENTS

1970—Subsec. (b)(4). Pub. L. 91–296, §111(a), inserted provisions requiring that the appropriate area wide health planning agency be given an opportunity to consider the project for which an application is made before approval is given.

Subsec. (e). Pub. L. 91–296, §116(e), substituted "an outpatient facility" for "a diagnostic or treatment

center" and inserted provisions extending coverage to include corporations and associations which, although not owning or operating hospitals offer services of a general hospital to patients in need of hospital care.

STATUTORY NOTES AND RELATED SUBSIDIARIES

CHANGE OF NAME

"Secretary of Health and Human Services" substituted for "Secretary of Health, Education, and Welfare" in subsec. (b) pursuant to section 509(b) of Pub. L. 96–88, which is classified to section 3508(b) of Title 20, Education.

EFFECTIVE DATE OF 1970 AMENDMENT

Pub. L. 91–296, title I, §111(a), June 30, 1970, 84 Stat. 340, provided that the amendment made by that section is effective with respect to applications approved under this subchapter after June 30, 1970.

Pub. L. 91–296, title I, §116(e), June 30, 1970, 84 Stat. 342, applicable with respect to applications approved under this subchapter after June 30, 1970, see section 116(g) of Pub. L. 91–296, set out as a note under section 291o of this title.

APPLICATIONS APPROVED PRIOR TO AUG. 18, 1964

Pub. L. 88–443, §3(b)(1), Aug. 18, 1964, 78 Stat. 462, providing that applications approved, and allotments appropriated prior to Aug. 18, 1964, shall be governed by this subchapter as in effect prior to such date, is set out as an Effective Date note under section 291 of this title.

FUNDS FOR MODERNIZATION PROJECTS; CONDITIONS TO BE MET BEFORE APPROVAL

Pub. L. 88–443, §3(b)(5), Aug. 18, 1964, 78 Stat. 462, provided that no application with respect to a modernization project may be approved for purposes of receiving funds from an allotment under section 291(a)(2) of this title before July 1, 1965, or before a State plan has been approved, as well as certain other requirements. See Effective Date note set out under section 291 of this title.

EXECUTIVE DOCUMENTS

TRANSFER OF FUNCTIONS

Office of Surgeon General abolished by section 3 of Reorg. Plan No. 3 of 1966, eff. June 25, 1966, 31 F.R. 8855, 80 Stat. 1610, and functions thereof transferred to Secretary of Health, Education, and Welfare by section 1 of Reorg. Plan No. 3 of 1966, set out as a note under section 202 of this title. Office of Surgeon General reestablished within the Office of the Assistant Secretary for Health, see Notice of Department of Health and Human Services, Office of the Assistant Secretary for Health, Mar. 30, 1987, 52 F.R. 11754.

§291f. Payments for construction or modernization

(a) Certification of work by Surgeon General; conditions affecting payments

Upon certification to the Surgeon General by the State agency, based upon inspection by it, that work has been performed upon a project, or purchases have been made, in accordance with the approved plans and specifications, and that payment of an installment is due to the applicant, such installment shall be paid to the State, from the applicable allotment of such State, except that (1) if the State is not authorized by law to make payments to the applicant, or if the State so requests, the payment shall be made directly to the applicant, (2) if the Surgeon General, after investigation or otherwise, has reason to believe that any act (or failure to act) has occurred requiring action pursuant to section 291g of this title, payment may, after he has given the State agency notice of opportunity for hearing pursuant to such section, be withheld, in whole or in part, pending corrective action or action based on such hearing, and (3) the total of payments under this subsection with respect to such project may not exceed an amount equal to the Federal share of the cost of construction of such project.

(b) Additional payments in cases of amended applications

In case an amendment to an approved application is approved as provided in section 291e of this

title or the estimated cost of a project is revised upward, any additional payment with respect thereto may be made from the applicable allotment of the State for the fiscal year in which such amendment or revision is approved.

(c) Administration expenses; use of portion of allotments to defray; manner of payment

(1) At the request of any State, a portion of any allotment or allotments of such State under this part shall be available to pay one-half (or such smaller share as the State may request) of the expenditures found necessary by the Surgeon General for the proper and efficient administration during such year of the State plan approved under this part; except that not more than 4 per centum of the total of the allotments of such State for a year, or $100,000, whichever is less, shall be available for such purpose for such year. Payments of amounts due under this paragraph may be made in advance or by way of reimbursement, and in such installments, as the Surgeon General may determine.

(2) Any amount paid under paragraph (1) of this subsection to any State for any fiscal year shall be paid on condition that there shall be expended from State sources for such year for administration of the State plan approved under this part not less than the total amount expended for such purposes from such sources during the fiscal year ending June 30, 1970.

(July 1, 1944, ch. 373, title VI, §606, as added Pub. L. 88–443, §3(a), Aug. 18, 1964, 78 Stat. 454; amended Pub. L. 91–296, title I, §112, June 30, 1970, 84 Stat. 340.)

EDITORIAL NOTES

PRIOR PROVISIONS

A prior section 291f, act July 1, 1944, ch. 373, title VI, §623, as added Aug. 13, 1946, ch. 958, §2, 60 Stat. 1041; amended June 19, 1948, ch. 554, 62 Stat. 536; Oct. 25, 1949, ch. 722, §3(a), 63 Stat. 899, related to State plans, their submission, and their requirements, prior to the general amendment of this subchapter by Pub. L. 88–443. See section 291d of this title.

Provisions similar to those comprising subsec. (a) of this section were contained in former section 291h(b), acts July 1, 1944, ch. 373, title VI, §625, as added Aug. 13, 1946, ch. 958, §2, 60 Stat. 1041; amended Oct. 25, 1949, ch. 722, §3(b), 63 Stat. 899, prior to the general amendment of this subchapter by Pub. L. 88–443.

AMENDMENTS

1970—Subsec. (c)(1). Pub. L. 91–296, §112(1), substituted "4 per centum" for "2 per centum" and "$100,000 for $50,000".

Subsec. (c)(2). Pub. L. 91–296, §112(2), substituted "June 30, 1970" for "June 30, 1964".

STATUTORY NOTES AND RELATED SUBSIDIARIES

CHANGE OF NAME

"Secretary of Health and Human Services" substituted for "Secretary of Health, Education, and Welfare" pursuant to section 509(b) of Pub. L. 96–88, which is classified to section 3508(b) of Title 20, Education.

EFFECTIVE DATE OF 1970 AMENDMENT

Pub. L. 91–296, title I, §112, June 30, 1970, 84 Stat. 340, provided that the amendment made by that section is effective with respect to expenditures under a State plan approved under this subchapter which are made for administration of such plan during any fiscal year beginning after June 30, 1970.

EXECUTIVE DOCUMENTS

TRANSFER OF FUNCTIONS

Office of Surgeon General abolished by section 3 of Reorg. Plan No. 3 of 1966, eff. June 25, 1966, 31 F.R. 8855, 80 Stat. 1610, and functions thereof transferred to Secretary of Health, Education, and Welfare by section 1 of Reorg. Plan No. 3 of 1966, set out as a note under section 202 of this title. Office of Surgeon General reestablished within the Office of the Assistant Secretary for Health, see Notice of Department of Health and Human Services, Office of the Assistant Secretary for Health, Mar. 30, 1987, 52 F.R. 11754.

§291g. Withholding of payments; noncompliance with requirements

Whenever the Surgeon General, after reasonable notice and opportunity for hearing to the State agency designated as provided in section 291d(a)(1) of this title, finds—

(a) that the State agency is not complying substantially with the provisions required by section 291d of this title to be included in its State plan; or

(b) that any assurance required to be given in an application filed under section 291e of this title is not being or cannot be carried out; or

(c) that there is a substantial failure to carry out plans and specifications approved by the Surgeon General under section 291e of this title; or

(d) that adequate State funds are not being provided annually for the direct administration of the State plan,

the Surgeon General may forthwith notify the State agency that—

(e) no further payments will be made to the State under this part, or

(f) no further payments will be made from the allotments of such State from appropriations under any one or more subparagraphs or paragraphs of section 291a of this title, or for any project or projects, designated by the Surgeon General as being affected by the action or inaction referred to in paragraph (a), (b), (c), or (d) of this section,

as the Surgeon General may determine to be appropriate under the circumstances; and, except with regard to any project for which the application has already been approved and which is not directly affected, further payments may be withheld, in whole or in part, until there is no longer any failure to comply (or carry out the assurance or plans and specifications or provide adequate State funds, as the case may be) or, if such compliance (or other action) is impossible, until the State repays or arranges for the repayment of Federal moneys to which the recipient was not entitled.

(July 1, 1944, ch. 373, title VI, §607, as added Pub. L. 88–443, §3(a), Aug. 18, 1964, 78 Stat. 455.)

EDITORIAL NOTES

PRIOR PROVISIONS

A prior section 291g, act July 1, 1944, ch. 373, title VI, §624, as added Aug. 13, 1946, ch. 958, §2, 60 Stat. 1041; amended June 29, 1948, ch. 728, §1, 62 Stat. 1103; Oct. 25, 1949, ch. 722, §§3(b), 7, 63 Stat. 899, 901; Aug. 1, 1956, ch. 852, §19(c), 70 Stat. 911; Sept. 25, 1962, Pub. L. 87–688, §4(a)(3), 76 Stat. 587, authorized allotments to States for construction, specified their amount, and provided for availability for unexpended funds, prior to the general amendment of this subchapter by Pub. L. 88–443. See section 291b of this title.

Provisions similar to those comprising this section were contained in former section 291j(a), acts July 1, 1944, ch. 373, title VI, §632, as added Aug. 13, 1946, ch. 958, §2, 60 Stat. 1041; amended Oct. 25, 1949, ch. 722, §4, 63 Stat. 900; July 12, 1954, ch. 471, §4(g), 68 Stat. 466, prior to the general amendment of this subchapter by Pub. L. 88–443.

STATUTORY NOTES AND RELATED SUBSIDIARIES

CHANGE OF NAME

"Secretary of Health and Human Services" substituted for "Secretary of Health, Education, and Welfare" pursuant to section 509(b) of Pub. L. 96–88, which is classified to section 3508(b) of Title 20, Education.

EXECUTIVE DOCUMENTS

TRANSFER OF FUNCTIONS

Office of Surgeon General abolished by section 3 of Reorg. Plan No. 3 of 1966, eff. June 25, 1966, 31 F.R. 8855, 80 Stat. 1610, and functions thereof transferred to Secretary of Health, Education, and Welfare by section 1 of Reorg. Plan No. 3 of 1966, set out as a note under section 202 of this title. Office of Surgeon

General reestablished within the Office of the Assistant Secretary for Health, see Notice of Department of Health and Human Services, Office of the Assistant Secretary for Health, Mar. 30, 1987, 52 F.R. 11754.

§291h. Judicial review

(a) Refusal to approve application; procedure; jurisdiction of court of appeals

If the Surgeon General refuses to approve any application for a project submitted under section 291e of this title or section 291j of this title, the State agency through which such application was submitted, or if any State is dissatisfied with his action under section 291g of this title such State may appeal to the United States court of appeals for the circuit in which such State is located, by filing a petition with such court within sixty days after such action. A copy of the petition shall be forthwith transmitted by the clerk of the court to the Surgeon General, or any officer designated by him for that purpose. The Surgeon General shall thereupon file in the court the record of the proceedings on which he based his action, as provided in section 2112 of title 28. Upon the filing of such petition, the court shall have jurisdiction to affirm the action of the Surgeon General or to set it aside, in whole or in part, temporarily or permanently, but until the filing of the record, the Surgeon General may modify or set aside his order.

(b) Conclusiveness of Surgeon General's findings; remand; new or modified findings

The findings of the Surgeon General as to the facts, if supported by substantial evidence, shall be conclusive, but the court, for good cause shown, may remand the case to the Surgeon General to take further evidence, and the Surgeon General may thereupon make new or modified findings of fact and may modify his previous action, and shall file in the court the record of the further proceedings. Such new or modified findings of fact shall likewise be conclusive if supported by substantial evidence.

(c) Review by Supreme Court; stay of Surgeon General's action

The judgment of the court affirming or setting aside, in whole or in part, any action of the Surgeon General shall be final, subject to review by the Supreme Court of the United States upon certiorari or certification as provided in section 1254 of title 28. The commencement of proceedings under this section shall not, unless so specifically ordered by the court, operate as a stay of the Surgeon General's action.

(July 1, 1944, ch. 373, title VI, §608, as added Pub. L. 88–443, §3(a), Aug. 18, 1964, 78 Stat. 456.)

EDITORIAL NOTES

PRIOR PROVISIONS

A prior section 291h, act July 1, 1944, ch. 373, title VI, §625, as added Aug. 13, 1946, ch. 958, §2, 60 Stat. 1041; amended Oct. 25, 1949, ch. 722, §§3(b–d), 8, 63 Stat. 899, 901; July 12, 1954, ch. 471, §4(b), 68 Stat. 464, related to projects for construction, the application required and its contents and approval by the Surgeon General, and provided for a hearing prior to disapproval of the application, prior to the general amendment of this subchapter by Pub. L. 88–443. See section 291e of this title.

Provisions similar to those comprising this section were contained in former section 291j(b), act July 1, 1944, ch. 373, title VI, §632, as added Aug. 13, 1946, ch. 958, §2, 60 Stat. 1041; amended June 28, 1948, ch. 646, §32(a), 62 Stat. 991; May 24, 1949, ch. 139, §127, 63 Stat. 107; July 12, 1954, ch. 471, §4(g), 68 Stat. 466; Aug. 28, 1958, Pub. L. 85–791, §27, 72 Stat. 950, prior to the general amendment of this subchapter by Pub. L. 88–443.

STATUTORY NOTES AND RELATED SUBSIDIARIES

CHANGE OF NAME

"Secretary of Health and Human Services" substituted for "Secretary of Health, Education, and Welfare" pursuant to section 509(b) of Pub. L. 96–88, which is classified to section 3508(b) of Title 20, Education.

EXECUTIVE DOCUMENTS

TRANSFER OF FUNCTIONS

Office of Surgeon General abolished by section 3 of Reorg. Plan No. 3 of 1966, eff. June 25, 1966, 31 F.R. 8855, 80 Stat. 1610, and functions thereof transferred to Secretary of Health, Education, and Welfare by section 1 of Reorg. Plan No. 3 of 1966, set out as a note under section 202 of this title. Office of Surgeon General reestablished within the Office of the Assistant Secretary for Health, see Notice of Department of Health and Human Services, Office of the Assistant Secretary for Health, Mar. 30, 1987, 52 F.R. 11754.

§291i. Recovery of expenditures under certain conditions

(a) Persons liable

If any facility with respect to which funds have been paid under section 291f of this title shall, at any time within 20 years after the completion of construction or modernization—

(1) be sold or transferred to any entity (A) which is not qualified to file an application under section 291e of this title, or (B) which is not approved as a transferee by the State agency designated pursuant to section 291d of this title, or its successor, or

(2) cease to be a public health center or a public or other nonprofit hospital, outpatient facility, facility for long-term care, or rehabilitation facility,

the United States shall be entitled to recover, whether from the transferor or the transferee (or, in the case of a facility which has ceased to be public or nonprofit, from the owners thereof) an amount determined under subsection (c).

(b) Notice to Secretary

The transferor of a facility which is sold or transferred as described in subsection (a)(1), or the owner of a facility the use of which is changed as described in subsection (a)(2), shall provide the Secretary written notice of such sale, transfer, or change not later than the expiration of 10 days from the date on which such sale, transfer, or change occurs.

(c) Amount of recovery; interest; interest period

(1) Except as provided in paragraph (2), the amount the United States shall be entitled to recover under subsection (a) is an amount bearing the same ratio to the then value (as determined by the agreement of the parties or in an action brought in the district court of the United States for the district for which the facility involved is situated) of so much of the facility as constituted an approved project or projects as the amount of the Federal participation bore to the cost of the construction or modernization of such project or projects.

(2)(A) After the expiration of—

(i) 180 days after the date of the sale, transfer, or change of use for which a notice is required by subsection (b), in the case of a facility which is sold or transferred or the use of which changes after July 18, 1984, or

(ii) thirty days after July 18, 1984, or if later 180 days after the date of the sale, transfer, or change of use for which a notice is required by subsection (b), in the case of a facility which was sold or transferred or the use of which changed before July 18, 1984.[1]

the amount which the United States is entitled to recover under paragraph (1) with respect to a facility shall be the amount prescribed by paragraph (1) plus interest, during the period described in subparagraph (B), at a rate (determined by the Secretary) based on the average of the bond equivalent of the weekly ninety-day Treasury bill auction rate.

(B) The period referred to in subparagraph (A) is the period beginning—

(i) in the case of a facility which was sold or transferred or the use of which changed before July 18, 1984, thirty days after such date or if later 180 days after the date of the sale, transfer, or change of use for which a notice is required by subsection (b),

(ii) in the case of a facility with respect to which notice is provided in accordance with

subsection (b), upon the expiration of 180 days after the receipt of such notice, or

(iii) in the case of a facility with respect to which such notice is not provided as prescribed by subsection (b), on the date of the sale, transfer, or change of use for which such notice was to be provided,

and ending on the date the amount the United States is entitled to under paragraph (1) is collected.

(d) Waiver

(1) The Secretary may waive the recovery rights of the United States under subsection (a)(1) with respect to a facility in any State if the Secretary determines, in accordance with regulations, that the entity to which the facility was sold or transferred—

(A) has established an irrevocable trust—

(i) in an amount equal to the greater of twice the cost of the remaining obligation of the facility under clause (2) of section 291c(e) of this title or the amount, determined under subsection (c), that the United States is entitled to recover, and

(ii) which will only be used by the entity to provide the care required by clause (2) of section 291c(e) of this title; and

(B) will meet the obligation of the facility under clause (1) of section 291c(e) of this title.

(2) The Secretary may waive the recovery rights of the United States under subsection (a)(2) with respect to a facility in any State if the Secretary determines, in accordance with regulations, that there is good cause for waiving such rights with respect to such facility.

(e) Lien

The right of recovery of the United States under subsection (a) shall not constitute a lien on any facility with respect to which funds have been paid under section 291f of this title.

(July 1, 1944, ch. 373, title VI, §609, as added Pub. L. 88–443, §3(a), Aug. 18, 1964, 78 Stat. 456; amended Pub. L. 91–296, title I §116(d), June 30, 1970, 84 Stat. 342; Pub. L. 98–369, div. B, title III, §2381(a), July 18, 1984, 98 Stat. 1112.)

EDITORIAL NOTES

PRIOR PROVISIONS

A prior section 291i, act July 1, 1944, ch. 373, title VI, §631, as added Aug. 13, 1946, ch. 958, §2, 60 Stat. 1041; amended June 19, 1948, ch. 544, 62 Stat. 531; Oct. 25, 1949, ch. 722, §9, 63 Stat. 901; July 12, 1954, ch. 471, §4(c)–(f), 68 Stat. 465, 466; Aug. 1, 1956, ch. 852, §19(a), (b), 70 Stat. 911; June 25, 1959, Pub. L. 86–70, §31(c), 73 Stat. 149; July 12, 1960, Pub. L. 86–624, §29(d), 74 Stat. 419; Oct. 5, 1961, Pub. L. 87–395, §5, 75 Stat. 826; Sept. 25, 1962, Pub. L. 87–688, §4(a)(2), 76 Stat. 587, related to allotment percentages, and contained various definitions, prior to the general amendment of this subchapter by Pub. L. 88–443. See section 291b of this title.

Provisions similar to those comprising this section were contained in section 291h(e) of this title, act July 1, 1944, ch. 373, title VI, §625, as added Aug. 13, 1946, ch. 958, §2, 60 Stat. 1041; amended Oct. 25, 1949, ch. 722, §3(c), 63 Stat. 899, 901; July 12, 1954, ch. 471, §4(b), 68 Stat. 464, prior to the general amendment of this subchapter by Pub. L. 88–443.

AMENDMENTS

1984—Pub. L. 98–369 amended section generally. Prior to amendment, section read as follows: "If any facility with respect to which funds have been paid under section 291f of this title shall, at any time within twenty years after the completion of construction—

"(a) be sold or transferred to any person, agency, or organization (1) which is not qualified to file an application under section 291e of this title, or (2) which is not approved as a transferee by the State agency designated pursuant to section 291d of this title, or its successor, or

"(b) cease to be a public health center or a public or other nonprofit hospital, outpatient facility, facility for long-term care, or rehabilitation facility, unless the Surgeon General determines, in accordance with regulations, that there is good cause for releasing the applicant or other owner from this obligation,

the United States shall be entitled to recover from either the transferor or the transferee (or, in the case of a facility which has ceased to be public or nonprofit, from the owners thereof) an amount bearing the same ratio to the then value (as determined by the agreement of the parties or by action brought in the district court of the United States for the district in which the facility is situated) of so much of the facility as constituted an approved project or projects, as the amount of the Federal participation bore to the cost of the construction or modernization under such project or projects. Such right of recovery shall not constitute a lien upon said facility prior to judgment."

1970—Cl. (b). Pub. L. 91–296 substituted "outpatient facility" for "diagnostic or treatment center".

STATUTORY NOTES AND RELATED SUBSIDIARIES

CHANGE OF NAME

"Secretary of Health and Human Services" substituted for "Secretary of Health, Education, and Welfare" in subsecs. (b), (c), and (d) pursuant to section 509(b) of Pub. L. 96–88, which is classified to section 3508(b) of Title 20, Education.

REGULATIONS AND PERSONNEL

Pub. L. 98–369, div. B, title III, §2381(c), July 18, 1984, 98 Stat. 1116, provided that: "Not later than the expiration of the one-hundred-and-eighty-day period beginning on the date of the enactment of this section [July 18, 1984], the Secretary shall have in effect regulations and personnel to place in effect the amendments made by this section [amending sections 291i and 300s–1a of this title]."

EXECUTIVE DOCUMENTS

TRANSFER OF FUNCTIONS

Office of Surgeon General abolished by section 3 of Reorg. Plan No. 3 of 1966, eff. June 25, 1966, 31 F.R. 8855, 80 Stat. 1610, and functions thereof transferred to Secretary of Health, Education, and Welfare by section 1 of Reorg. Plan No. 3 of 1966, set out as a note under section 202 of this title. Office of Surgeon General reestablished within the Office of the Assistant Secretary for Health, see Notice of Department of Health and Human Services, Office of the Assistant Secretary for Health, Mar. 30, 1987, 52 F.R. 11754.

[1] *So in original. The period probably should be a comma.*

§291j. Loans

(a) Authorization; conditions

In order further to assist the States in carrying out the purposes of this subchapter, the Surgeon General is authorized to make a loan of funds to the applicant for any project for construction or modernization which meets all of the conditions specified for a grant under this part.

(b) Approval; payments to applicants

Except as provided in this section, an application for a loan with respect to any project under this part shall be submitted, and shall be approved by the Surgeon General, in accordance with the same procedures and subject to the same limitations and conditions as would be applicable to the making of a grant under this part for such project. Any such application may be approved in any fiscal year only if sufficient funds are available from the allotment for the type of project involved. All loans under this section shall be paid directly to the applicant.

(c) Terms

(1) The amount of a loan under this part shall not exceed an amount equal to the Federal share of the estimated cost of construction or modernization under the project. Where a loan and a grant are made under this part with respect to the same project, the aggregate amount of such loan and such grant shall not exceed an amount equal to the Federal share of the estimated cost of construction or modernization under the project. Each loan shall bear interest at the rate arrived at by adding

one-quarter of 1 per centum per annum to the rate which the Secretary of the Treasury determines to be equal to the current average yield on all outstanding marketable obligations of the United States as of the last day of the month preceding the date the application for the loan is approved and by adjusting the result so obtained to the nearest one-eighth of 1 per centum. Each loan made under this part shall mature not more than forty years after the date on which such loan is made, except that nothing in this part shall prohibit the payment of all or part of the loan at any time prior to the maturity date. In addition to the terms and conditions provided for, each loan under this part shall be made subject to such terms, conditions, and covenants relating to repayment of principal, payment of interest, and other matters as may be agreed upon by the applicant and the Surgeon General.

(2) The Surgeon General may enter into agreements modifying any of the terms and conditions of a loan made under this part whenever he determines such action is necessary to protect the financial interest of the United States.

(3) If, at any time before a loan for a project has been repaid in full, any of the events specified in clause (a) or clause (b) of section 291i [1] of this title occurs with respect to such project, the unpaid balance of the loan shall become immediately due and payable by the applicant, and any transferee of the facility shall be liable to the United States for such repayment.

(d) Funds; miscellaneous receipts

Any loan under this part shall be made out of the allotment from which a grant for the project concerned would be made. Payments of interest and repayments of principal on loans under this part shall be deposited in the Treasury as miscellaneous receipts.

(July 1, 1944, ch. 373, title VI, §610, as added Pub. L. 88–443, §3(a), Aug. 18, 1964, 78 Stat. 457.)

EDITORIAL NOTES

REFERENCES IN TEXT

Section 291i of this title, referred to in subsec. (c)(3), was amended generally by Pub. L. 98–369, div. B, title III, §2381(a), July 18, 1984, 98 Stat. 1112, and, as so amended, the provisions contained in former cls. (a) and (b) of section 291i are covered by section 291i(a)(1) and (2).

PRIOR PROVISIONS

A prior section 291j, act July 1, 1944, ch. 373, title VI, §632, as added Aug. 13, 1946, ch. 958, §2, 60 Stat. 1041; amended June 25, 1948, ch. 646, §32(a), 62 Stat. 991; May 24, 1949, ch. 139, §127, 63 Stat. 107; Oct. 25, 1949, ch. 722, §4, 63 Stat. 900; July 12, 1954, ch. 471, §4(g), 68 Stat. 466; Aug. 28, 1958, Pub. L. 85–791, §27, 72 Stat. 950, related to withholding of certification for noncompliance with requirements, appeal, conclusiveness of findings, the jurisdiction of the courts of appeals and to review by the Supreme Court, prior to the general amendment of this subchapter by Pub. L. 88–443. See sections 291g and 291h of this title.

Provisions similar to those comprising this section were contained in sections 291w to 291z of this title, prior to the general amendment of this subchapter by Pub. L. 88–443.

STATUTORY NOTES AND RELATED SUBSIDIARIES

CHANGE OF NAME

"Secretary of Health and Human Services" substituted for "Secretary of Health, Education, and Welfare" pursuant to section 509(b) of Pub. L. 96–88, which is classified to section 3508(b) of Title 20, Education.

EXECUTIVE DOCUMENTS

TRANSFER OF FUNCTIONS

Office of Surgeon General abolished by section 3 of Reorg. Plan No. 3 of 1966, eff. June 25, 1966, 31 F.R. 8855, 80 Stat. 1610, and functions thereof transferred to Secretary of Health, Education, and Welfare by section 1 of Reorg. Plan No. 3 of 1966, set out as a note under section 202 of this title. Office of Surgeon General reestablished within the Office of the Assistant Secretary for Health, see Notice of Department of Health and Human Services, Office of the Assistant Secretary for Health, Mar. 30, 1987, 52 F.R. 11754.

[1] *See References in Text note below.*

PART B—LOAN GUARANTEES AND LOANS FOR MODERNIZATION AND CONSTRUCTION OF HOSPITALS AND OTHER MEDICAL FACILITIES

§291j–1. Loan guarantees and loans

(a) Authority of Secretary

(1) In order to assist nonprofit private agencies to carry out needed projects for the modernization or construction of nonprofit private hospitals, facilities for long-term care, outpatient facilities, and rehabilitation facilities, the Secretary, during the period July 1, 1970, through June 30, 1974, may, in accordance with the provisions of this part, guarantee to non-Federal lenders making loans to such agencies for such projects, payment of principal of and interest on loans, made by such lenders, which are approved under this part.

(2) In order to assist public agencies to carry out needed projects for the modernization or construction of public health centers, and public hospitals, facilities for long-term care, outpatient facilities, and rehabilitation facilities, the Secretary, during the period July 1, 1970, through June 30, 1974, may, in accordance with the provisions of this part, make loans to such agencies which shall be sold and guaranteed in accordance with section 291j–7 of this title.

(b) Cost limitations

(1) No loan guarantee under this part with respect to any modernization or construction project may apply to so much of the principal amount thereof as, when added to the amount of any grant or loan under part A with respect to such project, exceeds 90 per centum of the cost of such project.

(2) No loan to a public agency under this part shall be made in an amount which, when added to the amount of any grant or loan under part A with respect to such project, exceeds 90 per centum of the cost of such project.

(c) Administrative assistance

The Secretary, with the consent of the Secretary of Housing and Urban Development, shall obtain from the Department of Housing and Urban Development such assistance with respect to the administration of this part as will promote efficiency and economy thereof.

(July 1, 1944, ch. 373, title VI, §621, as added Pub. L. 91–296, title II, §201, June 30, 1970, 84 Stat. 344; amended Pub. L. 93–45, title I, §108(b)(1), June 18, 1973, 87 Stat. 93.)

EDITORIAL NOTES

AMENDMENTS

1973—Subsec. (a). Pub. L. 93–45 extended termination date of guarantee and loan making period in pars. (1) and (2) from June 30, 1973, to June 30, 1974.

§291j–2. Allocation among States

(a) Allotment regulations

For each fiscal year, the total amount of principal of loans to nonprofit private agencies which may be guaranteed or loans to public agencies which may be directly made under this part shall be

allotted by the Secretary among the States, in accordance with regulations, on the basis of each State's relative population, financial need, need for construction of the facilities referred to in section 291j–1(a) of this title, and need for modernization of such facilities.

(b) Reallotment

Any amount allotted under subsection (a) to a State for a fiscal year ending before July 1, 1973, and remaining unobligated at the end of such year shall remain available to such State, for the purpose for which made, for the next two fiscal years (and for such years only), and any such amount shall be in addition to the amounts allotted to such State for such purpose for each of such next two fiscal years; except that, with the consent of any such State, any such amount remaining unobligated at the end of the first of such next fiscal year may be reallotted (on such basis as the Secretary deems equitable and consistent with the purposes of this subchapter) to other States which have need therefor. Any amounts so reallotted to a State shall be available for the purposes for which made until the close of the second such next two fiscal years and shall be in addition to the amount allotted and available to such State for the same period.

(c) Time of availability of amounts for subsequent allotment

Any amount allotted or reallotted to a State under this section for a fiscal year shall not, until the expiration of the period during which it is available for obligation, be considered as available for allotment for a subsequent fiscal year.

(d) Modernization or construction commenced on or after January 1, 1968

The allotments of any State under subsection (a) for the fiscal year ending June 30, 1971, and the succeeding fiscal year shall also be available to guarantee loans with respect to any project, for modernization or construction of a nonprofit private hospital or other health facility referred to in section 291j–1(a)(1) of this title, if the modernization or construction of such facility was not commenced earlier than January 1, 1968, and if the State certifies and the Secretary finds that without such guaranteed loan such facility could not be completed and begin to operate or could not continue to operate, but with such guaranteed loan would be able to do so: *Provided*, That this subsection shall not apply to more than two projects in any one State.

(July 1, 1944, ch. 373, title VI, §622, as added Pub. L. 91–296, title II, §201, June 30, 1970, 84 Stat. 345.)

§291j–3. Applications and conditions

(a) Contents of applications

For each project for which a guarantee of a loan to a nonprofit private agency or a direct loan to a public agency is sought under this part, there shall be submitted to the Secretary, through the State agency designated in accordance with section 291d of this title, an application by such private nonprofit agency or by such public agency. If two or more private nonprofit agencies, or two or more public agencies, join in the project, the application may be filed by one or more such agencies. Such application shall (1) set forth all of the descriptions, plans, specifications, assurances, and information which are required by the third sentence of section 291e(a) of this title (other than clause (6) thereof) with respect to applications submitted under that section, (2) contain such other information as the Secretary may require to carry out the purposes of this part, and (3) include a certification by the State agency of the total cost of the project and the amount of the loan for which a guarantee is sought under this part, or the amount of the direct loan sought under this part, as the case may be.

(b) Conditions for approval

The Secretary may approve such application only if—

(1) there remains sufficient balance in the allotment determined for such State pursuant to section 291j–2 of this title to cover the amount of the loan for which a guarantee is sought, or the amount of the direct loan sought (as the case may be), in such application,

(2) he makes each of the findings which are required by clauses (1) through (4) of section 291e(b) of this title for the approval of applications for projects thereunder (except that, in the case of the finding required under such clause (4) of entitlement of a project to a priority established under section 291c(a) of this title; such finding shall be made without regard to the provisions of clauses (1) and (3) of such section),

(3) he finds that there is compliance with section 291e(e) of this title,

(4) he obtains assurances that the applicant will keep such records, and afford such access thereto, and make such reports, in such form and containing such information, as the Secretary may reasonably require, and

(5) he also determines, in the case of a loan for which a guarantee is sought, that the terms, conditions, maturity, security (if any), and schedule and amounts of repayments with respect to the loan are sufficient to protect the financial interests of the United States and are otherwise reasonable and in accord with regulations, including a determination that the rate of interest does not exceed such per centum per annum on the principal obligation outstanding as the Secretary determines to be reasonable, taking into account the range of interest rates prevailing in the private market for similar loans and the risks assumed by the United States.

(c) Hearing

No application under this section shall be disapproved until the Secretary has afforded the State agency an opportunity for a hearing.

(d) Amendment of approved applications

Amendment of an approved application shall be subject to approval in the same manner as an original application.

(e) Recovery rights; terms and conditions

(1) In the case of any loan to a nonprofit private agency, the United States shall be entitled to recover from the applicant the amount of any payments made pursuant to any guarantee of such loan under this part, unless the Secretary for good cause waives its right of recovery, and, upon making any such payment, the United States shall be subrogated to all of the rights of the recipient of the payments with respect to which the guarantee was made.

(2) Guarantees of loans to nonprofit private agencies under this part shall be subject to such further terms and conditions as the Secretary determines to be necessary to assure that the purposes of this part will be achieved, and, to the extent permitted by subsection (f), any of such terms and conditions may be modified by the Secretary to the extent he determines it to be consistent with the financial interest of the United States.

(f) Incontestable guarantee

Any guarantee of a loan to a nonprofit private agency made by the Secretary pursuant to this part shall be incontestable in the hands of an applicant on whose behalf such guarantee is made, and as to any person who makes or contracts to make a loan to such applicant in reliance thereon, except for fraud or misrepresentation on the part of such applicant or such other person.

(July 1, 1944, ch. 373, title VI, §623, as added Pub. L. 91–296, title II, §201, June 30, 1970, 84 Stat. 346.)

§291j–4. Payment of interest on guaranteed loans

(a) Subject to the provisions of subsection (b), in the case of a guarantee of any loan to a nonprofit private agency under this part with respect to a hospital or other medical facility, the Secretary shall pay, to the holder of such loan and for and on behalf of such hospital or other medical facility amounts sufficient to reduce by 3 per centum per annum the net effective interest rate otherwise payable on such loan. Each holder of a loan, to a nonprofit private agency, which is guaranteed under this part shall have a contractual right to receive from the United States interest payments required by the preceding sentence.

(b) Contracts to make the payments provided for in this section shall not carry an aggregate amount greater than such amount as may be provided in appropriations Acts.

(July 1, 1944, ch. 373, title VI, §624, as added Pub. L. 91–296, title II, §201, June 30, 1970, 84 Stat. 347.)

§291j–5. Limitation on amounts of loans guaranteed or directly made

The cumulative total of the principal of the loans outstanding at any time with respect to which guarantees have been issued, or which have been directly made, under this part may not exceed the lesser of—

(1) such limitations as may be specified in appropriations Acts, or

(2) in the case of loans covered by allotments for the fiscal year ending June 30, 1971, $500,000,000; for the fiscal year ending June 30, 1972, $1,000,000,000; and for each of the fiscal years ending June 30, 1973, and June 30, 1974, $1,500,000,000.

(July 1, 1944, ch. 373, title VI, §625, as added Pub. L. 91–296, title II, §201, June 30, 1970, 84 Stat. 347; amended Pub. L. 93–45, title I, §108(b)(2), June 18, 1973, 87 Stat. 93.)

EDITORIAL NOTES

AMENDMENTS

1973—Pub. L. 93–45 provided for a limitation of $1,500,000,000 on amount of loans outstanding in the case of loans covered by allotments for fiscal year ending June 30, 1974.

§291j–6. Loan guarantee and loan fund

(a)(1) There is hereby established in the Treasury a loan guarantee and loan fund (hereinafter in this section referred to as the "fund") which shall be available to the Secretary without fiscal year limitation, in such amounts as may be specified from time to time in appropriations Acts, (i) to enable him to discharge his responsibilities under guarantees issued by him under this part, (ii) for payment of interest on the loans to nonprofit agencies which are guaranteed, (iii) for direct loans to public agencies which are sold and guaranteed, (iv) for payment of interest with respect to such loans, and (v) for repurchase by him of direct loans to public agencies which have been sold and guaranteed. There are authorized to be appropriated to the fund from time to time such amounts as may be necessary to provide capital required for the fund. To the extent authorized from time to time in appropriation Acts, there shall be deposited in the fund amounts received by the Secretary as interest payments or repayments of principal on loans and any other moneys, property, or assets derived by him from his operations under this part, including any moneys derived from the sale of assets.

(2) Of the moneys in the fund, there shall be available to the Secretary for the purpose of making of direct loans to public agencies only such sums as shall have been appropriated for such purpose pursuant to section 291j–7 of this title or sums received by the Secretary from the sale of such loans (in accordance with such section) and authorized in appropriations Acts to be used for such purpose.

(b) If at any time the moneys in the fund are insufficient to enable the Secretary to discharge his responsibilities under this part—

(i) to make payments of interest on loans to nonprofit private agencies which he has guaranteed under this part;

(ii) to otherwise comply with guarantees under this part of loans to nonprofit private agencies;

(iii) to make payments of interest subsidies with respect to loans to public agencies which he has made, sold, and guaranteed under this part;

(iv) in the event of default by public agencies to make payments of principal and interest on loans which the Secretary has made, sold, and guaranteed, under this part, to make such payments to the purchaser of such loan;

(v) to repurchase loans to public agencies which have been sold and guaranteed under this part,

he is authorized to issue to the Secretary of the Treasury notes or other obligations in such forms and denominations, bearing such maturities, and subject to such terms and conditions, as may be prescribed by the Secretary with the approval of the Secretary of the Treasury, but only in such amounts as may be specified from time to time in appropriations Acts. Such notes or other obligations shall bear interest at a rate determined by the Secretary of the Treasury, taking into consideration the current average market yield on outstanding marketable obligations of the United States of comparable maturities during the month preceding the issuance of the notes or other obligations. The Secretary of the Treasury is authorized and directed to purchase any notes and other obligations issued hereunder and for that purpose he is authorized to use as a public debt transaction the proceeds from the sale of any securities issued under chapter 31 of title 31, and the purposes for which securities may be issued under that chapter, are extended to include any purchase of such notes and obligations. The Secretary of the Treasury may at any time sell any of the notes or other obligations acquired by him under this subsection. All redemptions, purchases, and sales by the Secretary of the Treasury of such notes or other obligations shall be treated as public debt transactions of the United States. Sums borrowed under this subsection shall be deposited in the fund and redemption of such notes and obligations shall be made by the Secretary from such fund.

(July 1, 1944, ch. 373, title VI, §626, as added Pub. L. 91–296, title II, §201, June 30, 1970, 84 Stat. 347.)

EDITORIAL NOTES

CODIFICATION

In subsec. (b), "chapter 31 of title 31" and "that chapter" substituted for "the Second Liberty Bond Act, as amended" and "that Act, as amended", respectively, on authority of Pub. L. 97–258, §4(b), Sept. 13, 1982, 96 Stat. 1067, the first section of which enacted Title 31, Money and Finance.

§291j–7. Loans to public facilities

(a) Interest rates; security; equitable geographical distribution

(1) Any loan made by the Secretary to a public agency under this part for the modernization or construction of a public hospital or other health facility shall require such public agency to pay interest thereon at a rate comparable to the current rate of interest prevailing with respect to loans, to nonprofit private agencies, which are guaranteed under this part, for the modernization or construction of similar facilities in the same or similar areas, minus 3 per centum per annum.

(2)(A) No loan to a public agency shall be made under this part unless—

(i) the Secretary is reasonably satisfied that such agency will be able to make payments of principal and interest thereon when due, and

(ii) such agency provides the Secretary with reasonable assurances that there will be available to such agency such additional funds as may be necessary to complete the project with respect to which such loan is requested.

(B) Any loan to a public agency shall have such security, have such maturity date, be repayable in such installments, and be subject to such other terms and conditions (including provision for recovery in case of default) as the Secretary determines to be necessary to carry out the purposes of this part while adequately protecting the financial interests of the United States.

(3) In making loans to public agencies under this part, the Secretary shall give due regard to achieving an equitable geographical distribution of such loans.

(b) Sale

(1) The Secretary shall from time to time, but with due regard to the financial interests of the United States, sell loans referred to in subsection (a)(1) either on the private market or to the Federal

National Mortgage Association in accordance with section 1717 of title 12.

(2) Any loan so sold shall be sold for an amount which is equal (or approximately equal) to the amount of the unpaid principal of such loan as of the time of sale.

(c) Agreements

(1) The Secretary is authorized to enter into an agreement with the purchaser of any loan sold under this part under which the Secretary agrees—

(A) to guarantee to such purchaser (and any successor in interest to such purchaser) payment of the principal and interest payable under such loan, and

(B) to pay as an interest subsidy to such purchaser (and any successor in interest of such purchaser) amounts which when added to the amount of interest payable on such loan, are equivalent to a reasonable rate of interest on such loan as determined by the Secretary, after taking into account the range of prevailing interest rates in the private market on similar loans and the risks assumed by the United States.

(2) Any such agreement—

(A) may provide that the Secretary shall act as agent of any such purchaser, for the purpose of collecting from the public agency to which such loan was made and paying over to such purchaser, any payments of principal and interest payable by such agency under such loan;

(B) may provide for the repurchase by the Secretary of any such loan on such terms and conditions as may be specified in the agreement;

(C) shall provide that, in the event of any default by the public agency to which such loan was made in payment of principal and interest due on such loan, the Secretary shall, upon notification to the purchaser (or to the successor in interest of such purchaser), have the option to close out such loan (and any obligations of the Secretary with respect thereto) by paying to the purchaser (or his successor in interest) the total amount of outstanding principal and interest due thereon at the time of such notification; and

(D) shall provide that, in the event such loan is closed out as provided in subparagraph (C), or in the event of any other loss incurred by the Secretary by reason of the failure of such public agency to make payments of principal and interest on such loan, the Secretary shall be subrogated to all rights of such purchaser for recovery of such loss from such public agency.

(d) Right of recovery; waiver

The Secretary may, for good cause, waive any right of recovery which he has against a public agency by reason of the failure of such agency to make payments of principal and interest on a loan made to such agency under this part.

(e) Interest and interest subsidies as gross income under Internal Revenue Code

After any loan to a public agency under this part has been sold and guaranteed, interest paid on such loan and any interest subsidy paid by the Secretary with respect to such loan which is received by the purchaser thereof (or his successor in interest) shall be included in gross income for the purposes of chapter 1 of title 26.

(f) Sales proceeds; deposit and use

Amounts received by the Secretary as proceeds from the sale of loans under this section shall be deposited in the loan fund established by section 291j–6 of this title, and shall be available to the Secretary for the making of further loans under this part in accordance with the provisions of subsection (a)(2) of such section.

(g) Authorization of appropriations

There is authorized to be appropriated to the Secretary, for deposit in the loan fund established by section 291j–6 of this title, $30,000,000 to provide initial capital for the making of direct loans by the Secretary to public agencies for the modernization or construction of facilities referred to in subsection (a)(1).

(July 1, 1944, ch. 373, title VI, §627, as added Pub. L. 91–296, title II, §201, June 30, 1970, 84 Stat.

349; amended Pub. L. 99–514, §2, Oct. 22, 1986, 100 Stat. 2095.)

EDITORIAL NOTES

AMENDMENTS

1986—Subsec. (e). Pub. L. 99–514 substituted "Internal Revenue Code of 1986" for "Internal Revenue Code of 1954", which for purposes of codification was translated as "title 26" thus requiring no change in text.

STATUTORY NOTES AND RELATED SUBSIDIARIES

COMMITMENTS FOR DIRECT LOANS TO PUBLIC AGENCIES

Pub. L. 91–667, title II, §200, Jan. 11, 1971, 84 Stat. 2007, provided: "That the Secretary is authorized to issue commitments for direct loans to public agencies in accordance with section 627 of the Public Health Service Act [42 U.S.C. 291j–7] which shall constitute contractual obligations of the United States, the total of such outstanding commitments not to exceed $30,000,000 at any given time; to sell obligations received pursuant to such commitments as provided in section 627, and the proceeds of any such sale shall be used to make a direct loan pursuant to the outstanding commitment under which the obligations were received."

PART C—CONSTRUCTION OR MODERNIZATION OF EMERGENCY ROOMS

§291j–8. Authorization of appropriations

In order to assist in the provision of adequate emergency room service in various communities of the Nation for treatment of accident victims and handling of other medical emergencies through special project grants for the construction or modernization of emergency rooms of general hospitals, there are authorized to be appropriated $20,000,000 each for the fiscal year ending June 30, 1971, and the next two fiscal years.

(July 1, 1944, ch. 373, title VI, §631, as added Pub. L. 91–296, title III, §301, June 30, 1970, 84 Stat. 351.)

§291j–9. Eligibility for grants

Funds appropriated pursuant to section 291j–8 of this title shall be available for grants by the Secretary for not to exceed 50 per centum of the cost of construction or modernization of emergency rooms of public or nonprofit general hospitals, including provision or replacement of medical transportation facilities. Such grants shall be made by the Secretary only after consultation with the State agency designated in accordance with section 291d(a)(1) of this title. In order to be eligible for a grant under this part, the project, and the applicant therefor, must meet such criteria as may be prescribed by regulations. Such regulations shall be so designed as to provide aid only with respect to projects for which adequate assistance is not readily available from other Federal, State, local, or other sources, and to assist in providing modern, efficient, and effective emergency room service needed to care for victims of highway, industrial, agricultural, or other accidents and to handle other medical emergencies, and to assist in providing such service in geographical areas which have special need therefor.

(July 1, 1944, ch. 373, title VI, §632, as added Pub. L. 91–296, title III, §301, June 30, 1970, 84 Stat. 351.)

§291j–10. Payments

Grants under this part shall be paid in advance or by way of reimbursement, in such installments and on such conditions, as in the judgment of the Secretary will best carry out the purposes of this part.

(July 1, 1944, ch. 373, title VI, §633, as added Pub. L. 91–296, title III, §301, June 30, 1970, 84 Stat. 351.)

PART D—GENERAL PROVISIONS

§291k. Federal Hospital Council

(a) Membership; qualifications

In administering this subchapter, the Surgeon General shall consult with a Federal Hospital Council consisting of the Surgeon General, who shall serve as Chairman ex officio, and twelve members appointed by the Secretary of Health and Human Services. Six of the twelve appointed members shall be persons who are outstanding in fields pertaining to medical facility and health activities, and three of these six shall be authorities in matters relating to the operation of hospitals or other medical facilities, one of them shall be an authority in matters relating to individuals with intellectual disabilities, and one of them shall be an authority in matters relating to mental health, and the other six members shall be appointed to represent the consumers of the services provided by such facilities and shall be persons familiar with the need for such services in urban or rural areas.

(b) Term of membership

Each appointed member shall hold office for a term of four years, except that any member appointed to fill a vacancy occurring prior to the expiration of the term for which his predecessor was appointed shall be appointed for the remainder of such term. An appointed member shall not be eligible to serve continuously for more than two terms (whether beginning before or after August 18, 1964) but shall be eligible for reappointment if he has not served immediately preceding his reappointment.

(c) Meetings; annual or by call of Surgeon General

The Council shall meet as frequently as the Surgeon General deems necessary, but not less than once each year. Upon request by three or more members, it shall be the duty of the Surgeon General to call a meeting of the Council.

(d) Advisory or technical committees

The Council is authorized to appoint such special advisory or technical committees as may be useful in carrying out its functions.

(July 1, 1944, ch. 373, title VI, §641, formerly §621, as added Pub. L. 88–443, §3(a), Aug. 18, 1964, 78 Stat. 458, renumbered §641, Pub. L. 91–296, title II, §201, June 30, 1970, 84 Stat. 344; amended Pub. L. 91–515, title VI, §601(b)(2), Oct. 30, 1970, 84 Stat. 1311; Pub. L. 96–88, title V, §509(b), Oct. 17, 1979, 93 Stat. 695; Pub. L. 111–256, §2(f)(4), Oct. 5, 2010, 124 Stat. 2644.)

EDITORIAL NOTES

PRIOR PROVISIONS

Provisions similar to those comprising this section were contained in subsec. (b) of a prior section 291k, act July 1, 1944, ch. 373, title VI, §633, as added Aug. 13, 1946, ch. 958, §2, 60 Stat. 1041; amended June 24, 1948, ch. 621, §6(b), 62 Stat. 602; 1953 Reorg. Plan No. 1, §§5, 8, eff. Apr. 11, 1953, 18 F.R. 2053, 67 Stat. 631, prior to the general amendment of this subchapter by Pub. L. 88–443.

AMENDMENTS

2010—Subsec. (a). Pub. L. 111–256 substituted "matters relating to individuals with intellectual disabilities" for "matters relating to the mentally retarded".

1970—Subsec. (e). Pub. L. 91–515 struck out subsec. (e) which related to payment of compensation and travel expenses of appointed Council members and members of advisory or technical committees while serving on Council business.

STATUTORY NOTES AND RELATED SUBSIDIARIES

CHANGE OF NAME

"Secretary of Health and Human Services" substituted for "Secretary of Health, Education, and Welfare" in subsec. (a) pursuant to section 509(b) of Pub. L. 96–88, which is classified to section 3508(b) of Title 20, Education.

TERMS OF FEDERAL HOSPITAL COUNCIL MEMBERS

Pub. L. 88–443, §3(b)(3), Aug. 18, 1964, 78 Stat. 462, providing that the terms of members serving on the Council prior to Aug. 18, 1964, shall expire on the date they would have expired had Pub. L. 88–443 not been enacted, is set out as an Effective Date note under section 291 of this title.

TERMINATION OF ADVISORY COMMITTEES

Pub. L. 93–641, §6, Jan. 4, 1975, 88 Stat. 2275, set out as a note under section 217a of this title, provided that an advisory committee established pursuant to the Public Health Service Act shall terminate at such time as may be specifically prescribed by an Act of Congress enacted after Jan. 4, 1975.

DEFINITIONS

For meaning of references to an intellectual disability and to individuals with intellectual disabilities in provisions amended by section 2 of Pub. L. 111–256, see section 2(k) of Pub. L. 111–256, set out as a note under section 1400 of Title 20, Education.

EXECUTIVE DOCUMENTS

TRANSFER OF FUNCTIONS

Office of Surgeon General abolished by section 3 of Reorg. Plan No. 3 of 1966, eff. June 25, 1966, 31 F.R. 8855, 80 Stat. 1610, and functions thereof transferred to Secretary of Health, Education, and Welfare by section 1 of Reorg. Plan No. 3 of 1966, set out as a note under section 202 of this title. Office of Surgeon General reestablished within the Office of the Assistant Secretary for Health, see Notice of Department of Health and Human Services, Office of the Assistant Secretary for Health, Mar. 30, 1987, 52 F.R. 11754.

§291*l*. Conference of State agencies

Whenever in his opinion the purposes of this subchapter would be promoted by a conference, the Surgeon General may invite representatives of as many State agencies, designated in accordance with section 291d of this title, to confer as he deems necessary or proper. A conference of the representatives of all such State agencies shall be called annually by the Surgeon General. Upon the application of five or more of such State agencies, it shall be the duty of the Surgeon General to call a conference of representatives of all State agencies joining in the request.

(July 1, 1944, ch. 373, title VI, §642, formerly §622, as added Pub. L. 88–443, §3(a), Aug. 18, 1964, 78 Stat. 458, and renumbered §642, Pub. L. 91–296, title II, §201, June 30, 1970, 84 Stat. 344.)

EDITORIAL NOTES

PRIOR PROVISIONS

A prior section 291l, act July 1, 1944, ch. 373, title VI, §634, as added Aug. 13, 1946, ch. 958, §2, 60 Stat. 1041, contained provisions similar to this section, prior to the general amendment of this subchapter by Pub. L. 88–443.

STATUTORY NOTES AND RELATED SUBSIDIARIES

CHANGE OF NAME

"Secretary of Health and Human Services" substituted for "Secretary of Health, Education, and Welfare" pursuant to section 509(b) of Pub. L. 96–88, which is classified to section 3508(b) of Title 20, Education.

EXECUTIVE DOCUMENTS

TRANSFER OF FUNCTIONS

Office of Surgeon General abolished by section 3 of Reorg. Plan No. 3 of 1966, eff. June 25, 1966, 31 F.R. 8855, 80 Stat. 1610, and functions thereof transferred to Secretary of Health, Education, and Welfare by section 1 of Reorg. Plan No. 3 of 1966, set out as a note under section 202 of this title. Office of Surgeon General reestablished within the Office of the Assistant Secretary for Health, see Notice of Department of Health and Human Services, Office of the Assistant Secretary for Health, Mar. 30, 1987, 52 F.R. 11754.

§291m. State control of operations

Except as otherwise specifically provided, nothing in this subchapter shall be construed as conferring on any Federal officer or employee the right to exercise any supervision or control over the administration, personnel, maintenance, or operation of any facility with respect to which any funds have been or may be expended under this subchapter.

(July 1, 1944, ch. 373, title VI, §643, formerly §623, as added Pub. L. 88–443, §3(a), Aug. 18, 1964, 78 Stat. 458, and renumbered §643, Pub. L. 91–296, title II, §201, June 30, 1970, 84 Stat. 344.)

EDITORIAL NOTES

PRIOR PROVISIONS

A prior section 291m, act July 1, 1944, ch. 373, title VI, §635, as added Aug. 13, 1946, ch. 958, §2, 60 Stat. 1041; amended July 12, 1954, ch. 471, §4(h), 68 Stat. 467, contained provisions similar to this section, prior to the general amendment of this subchapter by Pub. L. 88–443.

§291m–1. Loans for certain hospital experimentation projects

(a) Other public or private sources unavailable for alleviation of hardship due to increased construction costs

In order to alleviate hardship on any recipient of a grant under section 291n [1] of this title (as in effect immediately before August 18, 1964) for a project for the construction of an experimental or demonstration facility having as its specific purpose the application of novel means for the reduction of hospital costs with respect to which there has been a substantial increase in the cost of such construction (over the estimated cost of such project on the basis of which such grant was made) through no fault of such recipient, the Secretary is authorized to make a loan to such recipient not exceeding 662/3 per centum of such increased costs, as determined by the Secretary, if the Secretary determines that such recipient is unable to obtain such an amount for such purpose from other public or private sources.

(b) Application; form; information

Any such loan shall be made only on the basis of an application submitted to the Secretary in such form and containing such information and assurances as he may prescribe.

(c) Interest; repayment period

Each such loan shall bear interest at the rate of 2½ per centum per annum on the unpaid balance

thereof and shall be repayable over a period determined by the Secretary to be appropriate, but not exceeding fifty years.

(d) Authorization of appropriation

There are hereby authorized to be appropriated $3,500,000 to carry out the provisions of this section.

(July 1, 1944, ch. 373, title VI, §643A, formerly §623A, as added Pub. L. 90–174, §11, Dec. 5, 1967, 81 Stat. 541, and renumbered §643A, Pub. L. 91–296, title II, §201, June 30, 1970, 84 Stat. 344.)

EDITORIAL NOTES

REFERENCES IN TEXT

Section 291n of this title, referred to in subsec. (a), was repealed by Pub. L. 90–174, §3(b)(1), Dec. 5, 1967, 81 Stat. 535.

[1] *See References in Text note below.*

§291n. Repealed. Pub. L. 90–174, §3(b)(1), Dec. 5, 1967, 81 Stat. 535

Section, act July 1, 1944, ch. 373, title VI, §644, formerly §624, as added Aug. 18, 1964, Pub. L. 88–443, §3(a), 78 Stat. 459, and renumbered §644, June 30, 1970, Pub. L. 91–296, title II, §201, 84 Stat. 344, provided for research, experiments and demonstrations in utilization of medical facilities, authorization, grants-in-aid, amounts, payment, conditions, authorization of appropriations, and right of recovery of United States Government. See section 242b of this title.

Provisions similar to those comprising this section were contained in a prior section 291n, act July 1, 1944, ch. 373, title VI, §636, as added Oct. 25, 1949, ch. 722, §5, 63 Stat. 900; amended Oct. 6, 1961, Pub. L. 87–395, §4, 75 Stat. 825, prior to the general amendment of this subchapter by Pub. L. 88–443.

STATUTORY NOTES AND RELATED SUBSIDIARIES

EFFECTIVE DATE OF REPEAL

Repeal effective with respect to appropriations for fiscal year ending after June 30, 1967, see section 3(b) of Pub. L. 90–174, set out as an Effective Date of 1967 Amendment note under section 246 of this title.

§291n–1. Omitted

EDITORIAL NOTES

CODIFICATION

Section, act July 1, 1944, ch. 373, title VI, §637, formerly §654(c), as added July 12, 1954, ch. 471, §3, 68 Stat. 463; renumbered §637 and amended Aug. 14, 1959, Pub. L. 86–158, title II, §201, 73 Stat. 349, related to transfers of allotments between States, prior to the general amendment of this subchapter by Pub. L. 88–443, Aug. 18, 1964, 78 Stat. 447. See section 291b of this title.

§291*o*. Definitions

For the purposes of this subchapter—

(a) The term "State" includes the Commonwealth of Puerto Rico, Guam, American Samoa, the Trust Territory of the Pacific Islands, the Virgin Islands, and the District of Columbia.

(b)(1) The term "Federal share" with respect to any project means the proportion of the cost of such project to be paid by the Federal Government under this subchapter.

(2) With respect to any project in any State for which a grant is made from an allotment from an appropriation under section 291a of this title, the Federal share shall be the amount determined by the State agency designated in accordance with section 291d of this title, but not more than 662/3 per centum or the State's allotment percentage, whichever is the lower, except that, if the State's allotment percentage is lower than 50 per centum, such allotment percentage shall be deemed to be 50 per centum for purposes of this paragraph.

(3) Prior to the approval of the first project in a State during any fiscal year the State agency designated in accordance with section 291d of this title shall give the Secretary written notification of the maximum Federal share established pursuant to paragraph (2) of this subsection for projects in such State to be approved by the Secretary during such fiscal year and the method for determining the actual Federal share to be paid with respect to such projects; and such maximum Federal share and such method of determination for projects in such State approved during such fiscal year shall not be changed after such approval.

(4) Notwithstanding the provisions of paragraphs (2) and (3) of this subsection, the Federal share shall, at the option of the State agency, be equal to the per centum provided under such paragraphs plus an incentive per centum (which when combined with the per centum provided under such paragraphs shall not exceed 90 per centum) specified by the State agency in the case of (A) projects that will provide services primarily for persons in an area determined by the Secretary to be a rural or urban poverty area, and (B) projects that offer potential for reducing health care costs through shared services among health care facilities, through interfacility cooperation, or through the construction or modernization of free-standing outpatient facilities.

(c) The term "hospital" includes general, tuberculosis, and other types of hospitals, and related facilities, such as laboratories, outpatient departments, nurses' home facilities, extended care facilities, facilities related to programs for home health services, self-care units, and central service facilities, operated in connection with hospitals, and also includes education or training facilities for health professions personnel operated as an integral part of a hospital, but does not include any hospital furnishing primarily domiciliary care.

(d) The term "public health center" means a publicly owned facility for the provision of public health services, including related publicly owned facilities such as laboratories, clinics, and administrative offices operated in connection with such a facility.

(e) The term "nonprofit" as applied to any facility means a facility which is owned and operated by one or more nonprofit corporations or associations no part of the net earnings of which inures, or may lawfully inure, to the benefit of any private shareholder or individual.

(f) The term "outpatient facility" means a facility (located in or apart from a hospital) for the diagnosis or diagnosis and treatment of ambulatory patients (including ambulatory inpatients)—

(1) which is operated in connection with a hospital, or

(2) in which patient care is under the professional supervision of persons licensed to practice medicine or surgery in the State, or, in the case of dental diagnosis or treatment, under the professional supervision of persons licensed to practice dentistry in the State; or

(3) which offers to patients not requiring hospitalization the services of licensed physicians in various medical specialties, and which provides to its patients a reasonably full-range of diagnostic and treatment services.

(g) The term "rehabilitation facility" means a facility which is operated for the primary purpose of assisting in the rehabilitation of disabled persons through an integrated program of—

(1) medical evaluation and services, and

(2) psychological, social, or vocational evaluation and services,

under competent professional supervision, and in the case of which—

(3) the major portion of the required evaluation and services is furnished within the facility; and

(4) either (A) the facility is operated in connection with a hospital, or (B) all medical and related health services are prescribed by, or are under the general direction of, persons licensed to practice medicine or surgery in the State.

(h) The term "facility for long-term care" means a facility (including an extended care facility) providing in-patient care for convalescent or chronic disease patients who require skilled nursing care and related medical services—

(1) which is a hospital (other than a hospital primarily for the care and treatment of mentally ill or tuberculosis patients) or is operated in connection with a hospital, or

(2) in which such nursing care and medical services are prescribed by, or are performed under the general direction of, persons licensed to practice medicine or surgery in the State.

(i) The term "construction" includes construction of new buildings, expansion, remodeling, and alteration of existing buildings, and initial equipment of any such buildings (including medical transportation facilities) and, in any case in which it will help to provide a service not previously provided in the community, equipment of any buildings; including architects' fees, but excluding the cost of off-site improvements and, except with respect to public health centers, the cost of the acquisition of land.

(j) The term "cost" as applied to construction or modernization means the amount found by the Surgeon General to be necessary for construction and modernization respectively, under a project, except that such term, as applied to a project for modernization of a facility for which a grant or loan is to be made from an allotment under section 291b(a)(2) of this title, does not include any amount found by the Surgeon General to be attributable to expansion of the bed capacity of such facility.

(k) The term "modernization" includes alteration, major repair (to the extent permitted by regulations), remodeling, replacement, and renovation of existing buildings (including initial equipment thereof), and replacement of obsolete, built-in (as determined in accordance with regulations) equipment of existing buildings.

(l) The term "title", when used with reference to a site for a project, means a fee simple, or such other estate or interest (including a leasehold on which the rental does not exceed 4 per centum of the value of the land) as the Surgeon General finds sufficient to assure for a period of not less than fifty years' undisturbed use and possession for the purposes of construction and operation of the project.

(July 1, 1944, ch. 373, title VI, §645, formerly §625, as added Pub. L. 88–443, §3(a), Aug. 18, 1964, 78 Stat. 460; amended Pub. L. 88–581, §3(b), Sept. 4, 1964, 78 Stat. 919; renumbered §645 and amended Pub. L. 91–296, title I, §§113, 114(a), 116(f), 117, 118, 119(d), title II, §201, June 30, 1970, 84 Stat. 340, 341, 342, 343, 344.)

EDITORIAL NOTES

PRIOR PROVISIONS

A prior section 291o, act July 1, 1944, ch. 373, title VI, §641, as added July 12, 1954, ch. 471, §2, 68 Stat. 461, related to a declaration of purpose with respect to diagnostic or treatment centers, chronic disease hospitals, rehabilitation facilities, and nursing homes, prior to the general amendment of this subchapter by Pub. L. 88–443. See section 291 of this title.

Provisions similar to those comprising this section were contained in section 291i(d) to (o), act July 1, 1944, ch. 373, title VI, §631, as added Aug. 13, 1946, ch. 958, §2, 60 Stat. 1041; amended June 19, 1948, ch. 544, §1(b), 62 Stat. 531; Oct. 25, 1949, ch. 722, §9, 63 Stat. 901; July 12, 1954, ch. 471, §4(c) to (f), 68 Stat. 465, 466; Aug. 1, 1956, ch. 852, §19(b), 70 Stat. 911; June 25, 1959, Pub. L. 86–70, §31(c), 73 Stat. 149; July 12, 1960, Pub. L. 86–624, §29(d), 74 Stat. 419; Oct. 5, 1961, Pub. L. 87–395, §5, 75 Stat. 826; Sept. 25, 1962, Pub. L. 87–688, §4(a)(2), 76 Stat. 587, prior to the general amendment of this subchapter by Pub. L. 88–443.

AMENDMENTS

1970—Subsec. (a). Pub. L. 91–296, §119(d), inserted reference to Trust Territory of the Pacific Islands.

Subsec. (b). Pub. L. 91–296, §113, provided that Federal share of any project be in such amount, not in excess of two-thirds, as the State agency determined and authorized a higher Federal share of up to 90 per centum, in case of rural or urban poverty projects, and facilities which might reduce health costs through shared services, interfacility cooperation, and free-standing ambulatory care centers.

Subsec. (c). Pub. L. 91–296, §114(a), inserted references to extended care facilities, facilities related to programs for home health services, and self-care units operated in connection with hospitals and education or

training facilities for health professions personnel operated as an integral part of a hospital.

Subsec. (f). Pub. L. 91–296, §116(f), substituted "outpatient facility" for "diagnostic or treatment center", inserted "(located in or apart from a hospital)" after "means at facility", inserted "(including ambulatory inpatients)" after "ambulatory patients", and added par. (3).

Subsec. (h). Pub. L. 91–296, §117, inserted "(including an extended care facility)" after "means a facility".

Subsec. (i). Pub. L. 91–296, §118, inserted reference to equipment of any buildings in cases in which such equipment will help to provide a service not previously provided in the community.

1964—Subsec. (c). Pub. L. 88–581 substituted "nurses' home facilities" for "nurses' home and training facilities".

STATUTORY NOTES AND RELATED SUBSIDIARIES

CHANGE OF NAME

"Secretary of Health and Human Services" substituted for "Secretary of Health, Education, and Welfare" in subsec. (b) pursuant to section 509(b) of Pub. L. 96–88, which is classified to section 3508(b) of Title 20, Education.

EFFECTIVE DATE OF 1970 AMENDMENT

Pub. L. 91–296, title I, §113, June 30, 1970, 84 Stat. 340, provided that the amendment made by that section is effective with respect to projects approved under this subchapter after June 30, 1970.

Pub. L. 91–296, title I, §114(a), June 30, 1970, 84 Stat. 341, provided that the amendment made by that section is effective with respect to applications approved under this subchapter after June 30, 1970.

Pub. L. 91–296, title I, §116(g), June 30, 1970, 84 Stat. 342, provided that: "The amendments made by subsection (e) [amending this section] and paragraphs (2) and (3) of subsection (f) of this section [amending section 291e of this title] shall apply with respect to applications approved under title VI of such Act [42 U.S.C. 291 et seq.] after June 30, 1970."

Pub. L. 91–296, title I, §117, June 30, 1970, 84 Stat. 342, provided that the amendment made by that section is effective with respect to applications approved under this subchapter after June 30, 1970.

Pub. L. 91–296, title I, §118, June 30, 1970, 84 Stat. 342, provided that the amendment made by that section is effective with respect to projects approved under this subchapter after June 30, 1970.

Amendment by section 119(d) of Pub. L. 91–296 applicable with respect to allotments and grants therefrom under part A of this subchapter for fiscal years ending after June 30, 1970, and with respect to loan guarantees and loans under part B of this subchapter made after June 30, 1970, see section 119(e) of Pub. L. 91–296, set out as a note under section 291b of this title.

EFFECTIVE DATE OF 1964 AMENDMENT

Amendment by Pub. L. 88–581 effective with respect to applications for grants from appropriations for fiscal years beginning after June 30, 1965, see section 3(b) of Pub. L. 88–581, set out as a note under section 291c of this title.

EXECUTIVE DOCUMENTS

TRANSFER OF FUNCTIONS

Office of Surgeon General abolished by section 3 of Reorg. Plan No. 3 of 1966, eff. June 25, 1966, 31 F.R. 8855, 80 Stat. 1610, and functions thereof transferred to Secretary of Health, Education, and Welfare by section 1 of Reorg. Plan No. 3 of 1966, set out as a note under section 202 of this title. Office of Surgeon General reestablished within the Office of the Assistant Secretary for Health, see Notice of Department of Health and Human Services, Office of the Assistant Secretary for Health, Mar. 30, 1987, 52 F.R. 11754.

TERMINATION OF TRUST TERRITORY OF THE PACIFIC ISLANDS

For termination of Trust Territory of the Pacific Islands, see note set out preceding section 1681 of Title 48, Territories and Insular Possessions.

§291*o*–1. Financial statements

In the case of any facility for which a grant, loan, or loan guarantee has been made under this subchapter, the applicant for such grant, loan, or loan guarantee (or, if appropriate, such other person

as the Secretary may prescribe) shall file at least annually with the State agency for the State in which the facility is located a statement which shall be in such form, and contain such information, as the Secretary may require to accurately show—

(1) the financial operations of the facility, and

(2) the costs to the facility of providing health services in the facility and the charges made by the facility for providing such services,

during the period with respect to which the statement is filed.

(July 1, 1944, ch. 373, title VI, §646, as added Pub. L. 91–296, title I, §121, June 30, 1970, 84 Stat. 343.)

EDITORIAL NOTES

PRIOR PROVISIONS

Sections 291p to 291z were omitted in the general amendment of this subchapter by Pub. L. 88–443, Aug. 18, 1964, 78 Stat. 447.

Section 291p, act July 1, 1944, ch. 373, title VI, §646, as added July 12, 1954, ch. 471, §2, 68 Stat. 461, related to appropriations to States for carrying out purposes of section 291o(a) of this title.

Section 291q, act July 1, 1944, ch. 373, title VI, §647, as added July 12, 1954, ch. 471, §2, 68 Stat. 461, related to State application for funds for carrying out purposes of section 291o(a) of this title.

Section 291r, act July 1, 1944, ch. 373, title VI, §648, as added July 12, 1954, ch. 471, §2, 68 Stat. 462, related to allotments to States of appropriations made pursuant to section 291p of this title.

Section 291s, act July 1, 1944, ch. 373, title VI, §651, as added July 12, 1954, ch. 471, §3, 68 Stat. 462; amended Aug. 2, 1956, ch. 871, title IV, §402, 70 Stat. 929; Aug. 14, 1958, Pub. L. 85–664, §1(b), 72 Stat. 616; Oct. 5, 1961, Pub. L. 87–395, §3(a), 75 Stat. 825, related to appropriations for assistance to States in carrying out purposes of section 291o(b) of this title.

Section 291t, act July 1, 1944, ch. 373, title VI, 652, as added July 12, 1954, ch. 471, §3, 68 Stat. 462; amended Aug. 1, 1956, ch. 852, §19(c), 70 Stat. 911; Oct. 5, 1961, Pub. L. 87–395, §3(b), 75 Stat. 825; Sept. 25, 1962, Pub. L. 87–688, §4(a)(3), 76 Stat. 587, related to allotments to States of sums appropriated under section 291s of this title.

Section 291u, act July 1, 1944, ch. 373, title VI, §653, as added July 12, 1954, ch. 471, §3, 68 Stat. 463, related to revision of regulations and State plans to cover benefits of sections 291s to 291v of this title.

Section 291v, act July 1, 1944, ch. 373, title VI, §654, as added July 12, 1954, ch. 471, §3, 68 Stat. 463; amended Aug. 14, 1959, Pub. L. 86–158, title II, §201, 73 Stat. 349, related to applications and payments for projects under sections 291s to 291v of this title.

Section 291w, act July 1, 1944, ch. 373, title VI, §661, as added Aug. 1, 1958, Pub. L. 85–589, 72 Stat. 489; amended Oct. 5, 1961, Pub. L. 87–395, §6, 75 Stat. 826, related to an authorization of Surgeon General to make loans for construction.

Section 291x, act July 1, 1944, ch. 373, title VI, §662, as added Aug. 1, 1958, Pub. L. 85–589, 72 Stat. 489, related to approval of construction loans by Surgeon General.

Section 291y, act July 1, 1944, ch. 373, title VI, §663, as added Aug. 1, 1958, Pub. L. 85–589, 72 Stat. 489, related to terms of the loans with respect to sections 291w to 291z of this title.

Section 291z, act July 1, 1944, ch. 373, title VI, §664, as added Aug. 1, 1958, Pub. L. 85–589, 72 Stat. 490, related to allotment of funds for loans under this subchapter.

SUBCHAPTER V—HEALTH PROFESSIONS EDUCATION

STATUTORY NOTES AND RELATED SUBSIDIARIES

HEALTH WORKFORCE COORDINATION

Pub. L. 116–136, div. A, title III, §3402, Mar. 27, 2020, 134 Stat. 387, provided that:

"(a) STRATEGIC PLAN.—

"(1) IN GENERAL.—Not later than 1 year after the date of enactment of this Act [Mar. 27, 2020], the

Secretary of Health and Human Services (referred to in this Act [probably means S. 2997 of the 116th Congress, a related bill which was not enacted into law] as the 'Secretary'), in consultation with the Advisory Committee on Training in Primary Care Medicine and Dentistry and the Advisory Council on Graduate Medical Education, shall develop a comprehensive and coordinated plan with respect to the health care workforce development programs of the Department of Health and Human Services, including education and training programs.

"(2) REQUIREMENTS.—The plan under paragraph (1) shall—

"(A) include performance measures to determine the extent to which the programs described in paragraph (1) are strengthening the Nation's health care system;

"(B) identify any gaps that exist between the outcomes of programs described in paragraph (1) and projected health care workforce needs identified in workforce projection reports conducted by the Health Resources and Services Administration;

"(C) identify actions to address the gaps described in subparagraph (B); and

"(D) identify barriers, if any, to implementing the actions identified under subparagraph (C).

"(b) COORDINATION WITH OTHER AGENCIES.—The Secretary shall coordinate with the heads of other Federal agencies and departments that fund or administer health care workforce development programs, including education and training programs, to—

"(1) evaluate the performance of such programs, including the extent to which such programs are efficient and effective and are meeting the nation's [sic] health workforce needs; and

"(2) identify opportunities to improve the quality and consistency of the information collected to evaluate within and across such programs, and to implement such improvements.

"(c) REPORT.—Not later than 2 years after the date of enactment of this Act [Mar. 27, 2020], the Secretary shall submit to the Committee on Health, Education, Labor, and Pensions of the Senate, and the Committee on Energy and Commerce of the House of Representatives, a report describing the plan developed under subsection (a) and actions taken to implement such plan."

PART A—STUDENT LOANS

SUBPART I—INSURED HEALTH EDUCATION ASSISTANCE LOANS TO GRADUATE STUDENTS

§292. Statement of purpose

The purpose of this subpart is to enable the Secretary to provide a Federal program of student loan insurance for students in (and certain former students of) eligible institutions (as defined in section 292o of this title).

(July 1, 1944, ch. 373, title VII, §701, as added Pub. L. 102–408, title I, §102, Oct. 13, 1992, 106 Stat. 1994.)

EDITORIAL NOTES

PRIOR PROVISIONS

A prior section 292, act July 1, 1944, ch. 373, title VII, §700, as added Oct. 12, 1976, Pub. L. 94–484, title II, §201(b), 90 Stat. 2246, set forth limitations on use of appropriations, prior to repeal by Pub. L. 97–35, title XXVII, §2715, Aug. 13, 1981, 95 Stat. 913.

Another prior section 292, act July 1, 1944, ch. 373, title VII, §701, as added July 30, 1956, ch. 779, §2, 70 Stat. 717; amended Sept. 24, 1963, Pub. L. 88–129, §2(a), 77 Stat. 164, stated Congressional findings and declaration of policy respecting grants for construction of health research facilities, prior to repeal by Pub. L. 94–484, title II, §201(a), Oct. 12, 1976, 90 Stat. 2246.

A prior section 701 of act July 1, 1944, was classified to section 292a of this title prior to the general revision of this subchapter by Pub. L. 102–408.

STATUTORY NOTES AND RELATED SUBSIDIARIES

EFFECTIVE DATE

Pub. L. 102–408, title I, §103, Oct. 13, 1992, 106 Stat. 2069, provided that: "The amendment made by section 102 [enacting this subchapter] takes effect on the date of the enactment of this Act [Oct. 13, 1992], except that section 708 of the Public Health Service Act [42 U.S.C. 292g], as added by section 102 of this Act, takes effect January 1, 1993. Until such date, section 732(c) of the Public Health Service Act [former 42 U.S.C. 294e(c)], as in effect on the day before the date of the enactment of this Act, continues in effect in lieu of such section 708."

TRANSFER OF HEALTH EDUCATION ASSISTANCE LOAN PROGRAM

Pub. L. 113–76, div. H, title V, §525, Jan. 17, 2014, 128 Stat. 413, provided that:

"(a) IN GENERAL.—The Health Education Assistance Loan ('HEAL') program under title VII, part A, subpart I of the PHS [Public Health Service] Act [42 U.S.C. 292 et seq.], and the authority to administer such program, including servicing, collecting, and enforcing any loans that were made under such program that remain outstanding, shall be permanently transferred from the Secretary of Health and Human Services to the Secretary of Education no later than the end of the first fiscal quarter that begins after the date of enactment of this Act [Jan. 17, 2014].

"(b) TRANSFER OF FUNCTIONS, ASSETS, AND LIABILITIES.—The functions, assets, and liabilities of the Secretary of Health and Human Services relating to such program shall be transferred to the Secretary of Education.

"(c) INTERDEPARTMENTAL COORDINATION OF TRANSFER.—The Secretary of Health and Human Services and the Secretary of Education shall carry out the transfer of the HEAL program described in subsection (a), including the transfer of the functions, assets, and liabilities specified in subsection (b), in the manner that they determine is most appropriate.

"(d) USE OF AUTHORITIES UNDER HEA OF 1965.—In servicing, collecting, and enforcing the loans described in subsection (a), the Secretary of Education shall have available any and all authorities available to such Secretary in servicing, collecting, or enforcing a loan made, insured, or guaranteed under part B of title IV of the HEA [Higher Education Act] of 1965 [20 U.S.C. 1071 et seq.].

"(e) CONFORMING AMENDMENTS.—[Amended section 292o of this title.]"

STUDY ON EFFECTIVENESS OF HEALTH PROFESSIONS PROGRAMS

Pub. L. 102–408, title III, §309, Oct. 13, 1992, 106 Stat. 2089, directed the Comptroller General to conduct a study of the programs carried out under this subchapter and subchapter VI of this chapter for the purpose of determining the effectiveness of such programs in increasing the number of primary care providers (physicians, physician assistants, nurse midwives, nurse practitioners and general dentists), nurses and allied health personnel, improving the geographic distribution of health professionals in medically underserved and rural areas, and recruiting and retaining as students in health professions schools individuals who are members of a minority group, and report to the Congress not later than Jan. 1, 1994, on findings and recommendations made as a result of the study relevant to the reauthorization of such programs.

§292a. Scope and duration of loan insurance program

(a) In general

The total principal amount of new loans made and installments paid pursuant to lines of credit (as defined in section 292o of this title) to borrowers covered by Federal loan insurance under this subpart shall not exceed $350,000,000 for fiscal year 1993, $375,000,000 for fiscal year 1994, and $425,000,000 for fiscal year 1995. If the total amount of new loans made and installments paid pursuant to lines of credit in any fiscal year is less than the ceiling established for such year, the difference between the loans made and installments paid and the ceiling shall be carried over to the next fiscal year and added to the ceiling applicable to that fiscal year, and if in any fiscal year no ceiling has been established, any difference carried over shall constitute the ceiling for making new loans (including loans to new borrowers) and paying installments for such fiscal year. Thereafter, Federal loan insurance pursuant to this subpart may be granted only for loans made (or for loan installments paid pursuant to lines of credit) to enable students, who have obtained prior loans

insured under this subpart, to continue or complete their educational program or to obtain a loan under section 292d(a)(1)(B) of this title to pay interest on such prior loans; but no insurance may be granted for any loan made or installment paid after September 30, 1998. The total principal amount of Federal loan insurance available under this subsection shall be granted by the Secretary without regard to any apportionment for the purpose of chapter 15 of title 31 and without regard to any similar limitation.

(b) Certain limitations and priorities

(1) Limitations regarding lenders, States, or areas

The Secretary may, if necessary to assure an equitable distribution of the benefits of this subpart, assign, within the maximum amounts specified in subsection (a), Federal loan insurance quotas applicable to eligible lenders, or to States or areas, and may from time to time reassign unused portions of these quotas.

(2) Priority for certain lenders

In providing certificates of insurance under section 292e of this title through comprehensive contracts, the Secretary shall give priority to eligible lenders that agree—

(A) to make loans to students at interest rates below the rates prevailing, during the period involved, for loans covered by Federal loan insurance pursuant to this subpart; or

(B) to make such loans under terms that are otherwise favorable to the student relative to the terms under which eligible lenders are generally making such loans during such period.

(c) Authority of Student Loan Marketing Association

(1) In general

Subject to paragraph (2), the Student Loan Marketing Association, established under part B of title IV of the Higher Education Act of 1965 [20 U.S.C. 1071 et seq.], is authorized to make advances on the security of, purchase, service, sell, consolidate, or otherwise deal in loans which are insured by the Secretary under this subpart, except that if any loan made under this subpart is included in a consolidated loan pursuant to the authority of the Association under part B of title IV of the Higher Education Act of 1965, the interest rate on such consolidated loan shall be set at the weighted average interest rate of all such loans offered for consolidation and the resultant per centum shall be rounded downward to the nearest one-eighth of 1 per centum, except that the interest rate shall be no less than the applicable interest rate of the guaranteed student loan program established under part B of title IV of the Higher Education Act of 1965. In the case of such a consolidated loan, the borrower shall be responsible for any interest which accrues prior to the beginning of the repayment period of the loan, or which accrues during a period in which principal need not be paid (whether or not such principal is in fact paid) by reason of any provision of the Higher Education Act of 1965 [20 U.S.C. 1001 et seq.].

(2) Applicability of certain Federal regulations

With respect to Federal regulations for lenders, this subpart may not be construed to preclude the applicability of such regulations to the Student Loan Marketing Association or to any other entity in the business of purchasing student loans, including such regulations with respect to applications, contracts, and due diligence.

(July 1, 1944, ch. 373, title VII, §702, as added Pub. L. 102–408, title I, §102, Oct. 13, 1992, 106 Stat. 1994.)

EDITORIAL NOTES

REFERENCES IN TEXT

The Higher Education Act of 1965, referred to in subsec. (c)(1), is Pub. L. 89–329, Nov. 8, 1965, 79 Stat. 1219, which is classified generally to chapter 28 (§1001 et seq.) of Title 20, Education. Part B of title IV of

the Act is classified generally to part B (§1071 et seq.) of subchapter IV of chapter 28 of Title 20. For complete classification of this Act to the Code, see Short Title note set out under section 1001 of Title 20 and Tables.

PRIOR PROVISIONS

A prior section 292a, act July 1, 1944, ch. 373, title VII, §701, formerly §724, as added Sept. 24, 1963, Pub. L. 88–129, §2(b), 77 Stat. 169; amended Oct. 22, 1965, Pub. L. 89–290, §2(b), 79 Stat. 1056; Nov. 2, 1966, Pub. L. 89–709, §2(c), 80 Stat. 1103; Aug. 16, 1968, Pub. L. 90–490, title I, §105(c), 82 Stat. 774; Nov. 18, 1971, Pub. L. 92–157, title I, §102(c)(1)–(4), (f)(2)(B), 85 Stat. 431, 432, 435; renumbered §701 and amended Oct. 12, 1976, Pub. L. 94–484, title II, §201(c), (e), 90 Stat. 2247; Aug. 13, 1981, Pub. L. 97–35, title XXVII, §2716, 95 Stat. 913; Oct. 22, 1985, Pub. L. 99–129, title II, §§201(a), (b), 202, 203, 204(a), (b), 99 Stat. 525–527; Nov. 4, 1988, Pub. L. 100–607, title VI, §§620(a), 623, 628(1), 629(b)(1), (2), 102 Stat. 3141, 3142, 3145, 3146; Aug. 16, 1989, Pub. L. 101–93, §5(l), 103 Stat. 613, defined terms for purposes of this subchapter, prior to the general revision of this subchapter by Pub. L. 102–408. See sections 292o and 295p of this title.

Another prior section 292a, act July 1, 1944, ch. 373, title VII, §702, as added July 30, 1956, ch. 779, §2, 70 Stat. 717; amended Sept. 24, 1963, Pub. L. 88–129, §2(a), 77 Stat. 164, defined "Council", "construction", "cost of construction", "nonprofit institution", and "sciences related to health" as applicable to grants for construction of health research facilities, prior to repeal by Pub. L. 94–484, title II, §201(a), Oct. 12, 1976, 90 Stat. 2246.

A prior section 702 of act July 1, 1944, was classified to section 292b of this title prior to the general revision of this subchapter by Pub. L. 102–408.

§292b. Limitations on individual insured loans and on loan insurance

(a) In general

The total of the loans made to a student in any academic year or its equivalent (as determined by the Secretary) which may be covered by Federal loan insurance under this subpart may not exceed $20,000 in the case of a student enrolled in a school of medicine, osteopathic medicine, dentistry, veterinary medicine, optometry, or podiatric medicine, and $12,500 in the case of a student enrolled in a school of pharmacy, public health, allied health, or chiropractic, or a graduate program in health administration or behavioral and mental health practice, including clinical psychology. The aggregate insured unpaid principal amount for all such insured loans made to any borrower shall not at any time exceed $80,000 in the case of a borrower who is or was a student enrolled in a school of medicine, osteopathic medicine, dentistry, veterinary medicine, optometry, or podiatric medicine, and $50,000 in the case of a borrower who is or was a student enrolled in a school of pharmacy, public health, allied health, or chiropractic, or a graduate program in health administration or clinical psychology. The annual insurable limit per student shall not be exceeded by a line of credit under which actual payments by the lender to the borrower will not be made in any year in excess of the annual limit.

(b) Extent of insurance liability

The insurance liability on any loan insured by the Secretary under this subpart shall be 100 percent of the unpaid balance of the principal amount of the loan plus interest. The full faith and credit of the United States is pledged to the payment of all amounts which may be required to be paid under the provisions of section 292f or 292m of this title.

(July 1, 1944, ch. 373, title VII, §703, as added Pub. L. 102–408, title I, §102, Oct. 13, 1992, 106 Stat. 1995; amended Pub. L. 105–392, title I, §141(c)(1), Nov. 13, 1998, 112 Stat. 3579.)

EDITORIAL NOTES

PRIOR PROVISIONS

A prior section 292b, act July 1, 1944, ch. 373, title VII, §702, formerly §725, as added Sept. 24, 1963, Pub. L. 88–129, §2(b), 77 Stat. 169; amended Sept. 4, 1964, Pub. L. 88–581, §3(c), 78 Stat. 919; Nov. 2, 1966, Pub. L. 89–709, §2(d), 80 Stat. 1103; Nov. 3, 1966, Pub. L. 89–751, §3(a), 80 Stat. 1230; Dec. 5, 1967, Pub.

L. 90–174, §12(c), 81 Stat. 541; Oct. 30, 1970, Pub. L. 91–515, title VI, §601(b)(2), 84 Stat. 1311; Nov. 18, 1971, Pub. L. 92–157, title I, §108(a), 85 Stat. 460; renumbered §702 and amended Oct. 12, 1976, Pub. L. 94–484, title II, §§201(c), 202(a)(1), (2), (b), 90 Stat. 2247, 2248; Oct. 22, 1985, Pub. L. 99–129, title II, §205(a), 99 Stat. 527; Nov. 4, 1988, Pub. L. 100–607, title VI, §§620(b), 628(2), 102 Stat. 3141, 3145, related to National Advisory Council on Education for Health Professions, prior to the general revision of this subchapter by Pub. L. 102–408.

Another prior section 292b, act July 1, 1944, ch. 373, title VII, §703, as added July 30, 1956, ch. 779, §2, 70 Stat. 717; amended Sept. 24, 1963, Pub. L. 88–129, §2(a), 77 Stat. 164; Aug. 16, 1968, Pub. L. 90–490, title IV, §403, 82 Stat. 789; Oct. 30, 1970, Pub. L. 91–515, title VI, §601(a)(1), (b)(2), 84 Stat. 1310, 1311; Nov. 18, 1971, Pub. L. 92–157, title I, §102(k)(2)(A), 85 Stat. 437, related to National Advisory Council on Health Research Facilities, providing for its establishment, composition, selection of members; its functions; and use of its services in administration of grants for construction of health research facilities, prior to repeal by Pub. L. 94–484, title II, §201(a), Oct. 12, 1976, 90 Stat. 2246.

A prior section 703 of act July 1, 1994, was classified to section 292c of this title prior to repeal by Pub. L. 99–129.

AMENDMENTS

1998—Subsec. (a). Pub. L. 105–392 substituted "or behavioral and mental health practice, including clinical psychology" for "or clinical psychology" in first sentence.

§292c. Sources of funds

Loans made by eligible lenders in accordance with this subpart shall be insurable by the Secretary whether made from funds fully owned by the lender or from funds held by the lender in a trust or similar capacity and available for such loans.

(July 1, 1944, ch. 373, title VII, §704, as added Pub. L. 102–408, title I, §102, Oct. 13, 1992, 106 Stat. 1996.)

EDITORIAL NOTES

PRIOR PROVISIONS

A prior section 292c, act July 1, 1944, ch. 373, title VII, §703, formerly §799, as added Nov. 2, 1970, Pub. L. 91–519, title II, §206, 84 Stat. 1354; amended Nov. 18, 1971, Pub. L. 92–157, title I, §109, 85 Stat. 461; renumbered §703 and amended Oct. 12, 1976, Pub. L. 94–484, title II, §§201(c), 203, 90 Stat. 2247, 2248; Aug. 13, 1981, Pub. L. 97–35, title XXVII, §2717, 95 Stat. 914, related to advance funding for grants and contracts, prior to repeal by Pub. L. 99–129, title II, §220(a), Oct. 22, 1985, 99 Stat. 543.

Another prior section 292c, act July 1, 1944, ch. 373, title VII, §704, as added July 30, 1956, 779, §2, 70 Stat. 718; amended Aug. 27, 1958, Pub. L. 85–777, §1(a), 72 Stat. 933; Oct. 5, 1961, Pub. L. 87–395, §8(a), (d), 75 Stat. 827; Oct. 17, 1962, Pub. L. 87–838, §4(a), 76 Stat. 1074; Aug. 9, 1965, Pub. L. 89–115, §2(a), 79 Stat. 448; Aug. 16, 1968, Pub. L. 90–490, title IV, §401(a), 82 Stat. 789, related to authorization of appropriations and availability of funds for grants for construction of health research facilities, prior to repeal by Pub. L. 94–484, title II, §201(a), Oct. 12, 1976, 90 Stat. 2246.

A prior section 704 of act July 1, 1944, was classified to section 292d of this title prior to the general revision of this subchapter by Pub. L. 102–408.

§292d. Eligibility of borrowers and terms of insured loans

(a) In general

A loan by an eligible lender shall be insurable by the Secretary under the provisions of this subpart only if—

(1) made to—

(A) a student who—

(i)(I) has been accepted for enrollment at an eligible institution, or (II) in the case of a student attending an eligible institution, is in good standing at that institution, as determined

by the institution;

(ii) is or will be a full-time student at the eligible institution;

(iii) has agreed that all funds received under such loan shall be used solely for tuition, other reasonable educational expenses, including fees, books, and laboratory expenses, and reasonable living expenses, incurred by such students; and

(iv) in the case of a pharmacy student, has satisfactorily completed three years of training; or

(B) an individual who—

(i) has previously had a loan insured under this subpart when the individual was a full-time student at an eligible institution;

(ii) is in a period during which, pursuant to paragraph (2), the principal amount of such previous loan need not be paid; and

(iii) has agreed that all funds received under the proposed loan shall be used solely for repayment of interest due on previous loans made under this subpart;

(2) evidenced by a note or other written agreement which—

(A) is made without security and without endorsement, except that if the borrower is a minor and such note or other written agreement executed by him would not, under the applicable law, create a binding obligation, an endorsement may be required;

(B) provides for repayment of the principal amount of the loan in installments over a period of not less than 10 years (unless sooner repaid) nor more than 25 years beginning not earlier than 9 months nor later than 12 months after the date of—

(i) the date on which—

(I) the borrower ceases to be a participant in an accredited internship or residency program of not more than four years in duration;

(II) the borrower completes the fourth year of an accredited internship or residency program of more than four years in duration; or

(III) the borrower, if not a participant in a program described in subclause (I) or (II), ceases to carry, at an eligible institution, the normal full-time academic workload as determined by the institution; or

(ii) the date on which a borrower who is a graduate of an eligible institution ceases to be a participant in a fellowship training program not in excess of two years or a participant in a full-time educational activity not in excess of two years, which—

(I) is directly related to the health profession for which the borrower prepared at an eligible institution, as determined by the Secretary; and

(II) may be engaged in by the borrower during such a two-year period which begins within twelve months after the completion of the borrower's participation in a program described in subclause (I) or (II) of clause (i) or prior to the completion of the borrower's participation in such program,

except as provided in subparagraph (C), except that the period of the loan may not exceed 33 years from the date of execution of the note or written agreement evidencing it, and except that the note or other written instrument may contain such provisions relating to repayment in the event of default in the payment of interest or in the payment of the costs of insurance premiums, or other default by the borrower, as may be authorized by regulations of the Secretary in effect at the time the loan is made;

(C) provides that periodic installments of principal and interest need not be paid, but interest shall accrue, during any period (i) during which the borrower is pursuing a full-time course of study at an eligible institution (or at an institution defined by section 1002(a) of title 20); (ii) not in excess of four years during which the borrower is a participant in an accredited internship or residency program (including any period in such a program described in subclause (I) or

subclause (II) of subparagraph (B)(i)); (iii) not in excess of three years, during which the borrower is a member of the Armed Forces of the United States; (iv) not in excess of three years during which the borrower is in service as a volunteer under the Peace Corps Act [22 U.S.C. 2501 et seq.]; (v) not in excess of three years during which the borrower is a member of the National Health Service Corps; (vi) not in excess of three years during which the borrower is in service as a full-time volunteer under title I of the Domestic Volunteer Service Act of 1973 [42 U.S.C. 4951 et seq.]; (vii) not in excess of 3 years, for a borrower who has completed an accredited internship or residency training program in osteopathic general practice, family medicine, general internal medicine, preventive medicine, or general pediatrics and who is practicing primary care; (viii) not in excess of 1 year, for borrowers who are graduates of schools of chiropractic; (ix) any period not in excess of two years which is described in subparagraph (B)(ii); (x) not in excess of three years, during which the borrower is providing health care services to Indians through an Indian health program (as defined in section 1616a(a)(2)(A) of title 25; [1] and (xi) in addition to all other deferments for which the borrower is eligible under clauses (i) through (x), any period during which the borrower is a member of the Armed Forces on active duty during the Persian Gulf conflict, and any period described in clauses (i) through (xi) shall not be included in determining the 25-year period described in subparagraph (B);

(D) provides for interest on the unpaid principal balance of the loan at a yearly rate, not exceeding the applicable maximum rate prescribed and defined by the Secretary (within the limits set forth in subsection (b)) on a national, regional, or other appropriate basis, which interest shall be compounded not more frequently than annually and payable in installments over the period of the loan except as provided in subparagraph (C), except that the note or other written agreement may provide that payment of any interest may be deferred until not later than the date upon which repayment of the first installment of principal falls due or the date repayment of principal is required to resume (whichever is applicable) and may further provide that, on such date, the amount of the interest which has so accrued may be added to the principal for the purposes of calculating a repayment schedule;

(E) offers, in accordance with criteria prescribed by regulation by the Secretary, a schedule for repayment of principal and interest under which payment of a portion of the principal and interest otherwise payable at the beginning of the repayment period (as defined in such regulations) is deferred until a later time in the period;

(F) entitles the borrower to accelerate without penalty repayment of the whole or any part of the loan;

(G) provides that the check for the proceeds of the loan shall be made payable jointly to the borrower and the eligible institution in which the borrower is enrolled; and

(H) contains such other terms and conditions consistent with the provisions of this subpart and with the regulations issued by the Secretary pursuant to this subpart, as may be agreed upon by the parties to such loan, including, if agreed upon, a provision requiring the borrower to pay to the lender, in addition to principal and interest, amounts equal to the insurance premiums payable by the lender to the Secretary with respect to such loan; and

(3) subject to the consent of the student and subject to applicable law, the eligible lender has obtained from the student appropriate demographic information regarding the student, including racial or ethnic background.

(b) Limitation on rate of interest

The rate of interest prescribed and defined by the Secretary for the purpose of subsection (a)(2)(D) may not exceed the average of the bond equivalent rates of the 91-day Treasury bills auctioned for the previous quarter plus 3 percentage points, rounded to the next higher one-eighth of 1 percent.

(c) Minimum annual payment by borrower

The total of the payments by a borrower during any year or any repayment period with respect to the aggregate amount of all loans to that borrower which are insured under this subpart shall not be

less than the annual interest on the outstanding principal, except as provided in subsection (a)(2)(C), unless the borrower, in the written agreement described in subsection (a)(2), agrees to make payments during any year or any repayment period in a lesser amount.

(d) Applicability of certain laws on rate or amount of interest

No provision of any law of the United States (other than subsections (a)(2)(D) and (b)) or of any State that limits the rate or amount of interest payable on loans shall apply to a loan insured under this subpart.

(e) Determination regarding forbearance

Any period of time granted to a borrower under this subpart in the form of forbearance on the loan shall not be included in the 25-year total loan repayment period under subsection (a)(2)(C).

(f) Loan repayment schedule

Lenders and holders under this subpart shall offer borrowers graduated loan repayment schedules that, during the first 5 years of loan repayment, are based on the borrower's debt-to-income ratio.

(g) Rule of construction regarding determination of need of students

With respect to any determination of the financial need of a student for a loan covered by Federal loan insurance under this subpart, this subpart may not be construed to limit the authority of any school to make such allowances for students with special circumstances as the school determines appropriate.

(h) Definitions

For purposes of this section:

(1) The term "active duty" has the meaning given such term in section 101(18) of title 37, except that such term does not include active duty for training.

(2) The term "Persian Gulf conflict" means the period beginning on August 2, 1990, and ending on the date thereafter prescribed by Presidential proclamation or by law.

(July 1, 1944, ch. 373, title VII, §705, as added Pub. L. 102–408, title I, §102, Oct. 13, 1992, 106 Stat. 1996; amended Pub. L. 103–43, title XX, §2014(a)(1), June 10, 1993, 107 Stat. 215; Pub. L. 105–244, title I, §102(a)(13)(A), Oct. 7, 1998, 112 Stat. 1620; Pub. L. 105–392, title I, §141(a)(1), (2), Nov. 13, 1998, 112 Stat. 3578; Pub. L. 117–103, div. R, §104(1), Mar. 15, 2022, 136 Stat. 821.)

EDITORIAL NOTES

REFERENCES IN TEXT

The Peace Corps Act, referred to in subsec. (a)(2)(C), is Pub. L. 87–293, Sept. 22, 1961, 75 Stat. 612, which is classified principally to chapter 34 (§2501 et seq.) of Title 22, Foreign Relations and Intercourse. For complete classification of this Act to the Code, see Short Title note set out under section 2501 of Title 22 and Tables.

The Domestic Volunteer Service Act of 1973, referred to in subsec. (a)(2)(C), is Pub. L. 93–113, Oct. 1, 1973, 87 Stat. 394. Title I of the Act is classified generally to subchapter I (§4951 et seq.) of chapter 66 of this title. For complete classification of this Act to the Code, see Short Title note set out under section 4950 of this title and Tables.

PRIOR PROVISIONS

A prior section 292d, act July 1, 1944, ch. 373, title VII, §704, formerly §799A, as added Nov. 2, 1970, Pub. L. 91–519, title II, §207, 84 Stat. 1355; amended Nov. 18, 1971, Pub. L. 92–157, title I, §110(2), 85 Stat. 461; July 12, 1974, Pub. L. 93–348, title I, §105, 88 Stat. 347; renumbered §704, Oct. 12, 1976, Pub. L. 94–484, title II, §201(c), 90 Stat. 2247; Nov. 4, 1988, Pub. L. 100–607, title VI, §§620(c), 628(3), 629(b)(2), 102 Stat. 3141, 3145, 3146, prohibited discrimination on the basis of sex, prior to the general revision of this subchapter by Pub. L. 102–408. See section 295m of this title.

Another prior section 292d, act July 1, 1944, ch. 373, title VII, §705, as added July 30, 1956, ch. 779, §2, 70 Stat. 718; amended Aug. 27, 1958, Pub. L. 85–777, §1(b), 72 Stat. 933; Oct. 5, 1961, Pub. L. 87–395, §8(b), (d), 75 Stat. 827; Oct. 17, 1962, Pub. L. 87–838, §4(b), 76 Stat. 1074; Sept. 24, 1963, Pub. L. 88–129, §§2(a), 3(a), 77 Stat. 164, 173; Aug. 9, 1965, Pub. L. 89–115, §2(b), 79 Stat. 448; Aug. 16, 1968, Pub. L.

90–490, title IV, §401(b), 82 Stat. 789; Nov. 18, 1971, Pub. L. 92–157, title I, §102(k)(1), (2)(A), 85 Stat. 437, related to applications for grants for construction of health research facilities, providing for time of filing, eligibility, recommendation and approval and requirement of findings, conditional approval, and matters considered, prior to repeal by Pub. L. 94–484, title II, §201(a), Oct. 12, 1976, 90 Stat. 2246.

A prior section 705 of act July 1, 1944, was classified to section 292e of this title prior to the general revision of this subchapter by Pub. L. 102–408.

AMENDMENTS

2022—Subsec. (a)(1)(A)(iv), (v). Pub. L. 117–103, §104(1)(A), redesignated cl. (v) as (iv) and struck out former cl. (iv) which read as follows: "if required under section 3802 of title 50 to present himself for and submit to registration under such section, has presented himself and submitted to registration under such section; and".

Subsec. (a)(1)(B)(iv). Pub. L. 117–103, §104(1)(B), struck out cl. (iv) which read as follows: "if required under section 3802 of title 50 to present himself for and submit to registration under such section, has presented himself and submitted to registration under such section;".

1998—Subsec. (a)(2)(C). Pub. L. 105–392 added cl. (x), redesignated former cl. (x) as (xi) and substituted "(x)" for "(ix)", and substituted "(xi)" for "(x)" in concluding provisions.

Pub. L. 105–244 substituted "section 1002(a)" for "section 1088(a)" in cl. (i).

1993—Subsec. (a)(2)(H), (I). Pub. L. 103–43 redesignated subpar. (I) as (H) and struck out former subpar. (H) which read as follows: "notwithstanding the provisions of the Fair Debt Collection Practices Act, authorizes an institution or postgraduate training program attended by the borrower to assist in the collection of any loan that becomes delinquent, including providing information concerning the borrower to the Secretary and to past and present lenders and holders of the borrower's loans; and".

STATUTORY NOTES AND RELATED SUBSIDIARIES

EFFECTIVE DATE OF 1998 AMENDMENTS

Pub. L. 105–392, title I, §141(a)(3), Nov. 13, 1998, 112 Stat. 3578, provided that: "The amendments made by this subsection [amending this section] shall apply with respect to services provided on or after the first day of the third month that begins after the date of the enactment of this Act [Nov. 13, 1998]."

Amendment by Pub. L. 105–244 effective Oct. 1, 1998, except as otherwise provided in Pub. L. 105–244, see section 3 of Pub. L. 105–244, set out as a note under section 1001 of Title 20, Education.

[1] *So in original. Probably should be preceded by a closing parenthesis.*

§292e. Certificate of loan insurance; effective date of insurance

(a) In general

(1) Authority for issuance of certificate

If, upon application by an eligible lender, made upon such form, containing such information, and supported by such evidence as the Secretary may require, and otherwise in conformity with this section, the Secretary finds that the applicant has made a loan to an eligible borrower which is insurable under the provisions of this subpart, he may issue to the applicant a certificate of insurance covering the loan and setting forth the amount and terms of the insurance.

(2) Effective date of insurance

Insurance evidenced by a certificate of insurance pursuant to subsection (a)(1) shall become effective upon the date of issuance of the certificate, except that the Secretary is authorized, in accordance with regulations, to issue commitments with respect to proposed loans, or with respect to lines (or proposed lines) of credit, submitted by eligible lenders, and in that event, upon compliance with subsection (a)(1) by the lender, the certificate of insurance may be issued effective as of the date when any loan, or any payment by the lender pursuant to a line of credit, to

be covered by such insurance is made to a student described in section 292d(a)(1) of this title. Such insurance shall cease to be effective upon 60 days' default by the lender in the payment of any installment of the premiums payable pursuant to section 292g of this title.

(3) Certain agreements for lenders

An application submitted pursuant to subsection (a)(1) shall contain—

(A) an agreement by the applicant to pay, in accordance with regulations, the premiums fixed by the Secretary pursuant to section 292g of this title; and

(B) an agreement by the applicant that if the loan is covered by insurance the applicant will submit such supplementary reports and statements during the effective period of the loan agreement, upon such forms, at such times, and containing such information as the Secretary may prescribe by or pursuant to regulation.

(b) Authority regarding comprehensive insurance coverage

(1) In general

In lieu of requiring a separate insurance application and issuing a separate certificate of insurance for each loan made by an eligible lender as provided in subsection (a), the Secretary may, in accordance with regulations consistent with section 292a of this title, issue to any eligible lender applying therefor a certificate of comprehensive insurance coverage which shall, without further action by the Secretary, insure all insurable loans made by that lender, on or after the date of the certificate and before a specified cutoff date, within the limits of an aggregate maximum amount stated in the certificate. Such regulations may provide for conditioning such insurance, with respect to any loan, upon compliance by the lender with such requirements (to be stated or incorporated by reference in the certificate) as in the Secretary's judgment will best achieve the purpose of this subsection while protecting the financial interest of the United States and promoting the objectives of this subpart, including (but not limited to) provisions as to the reporting of such loans and information relevant thereto to the Secretary and as to the payment of initial and other premiums and the effect of default therein, and including provision for confirmation by the Secretary from time to time (through endorsement of the certificate) of the coverage of specific new loans by such certificate, which confirmation shall be incontestable by the Secretary in the absence of fraud or misrepresentation of fact or patent error.

(2) Lines of credit beyond cutoff date

If the holder of a certificate of comprehensive insurance coverage issued under this subsection grants to a borrower a line of credit extending beyond the cutoff date specified in that certificate, loans or payments thereon made by the holder after that date pursuant to the line of credit shall not be deemed to be included in the coverage of that certificate except as may be specifically provided therein; but, subject to the limitations of section 292a of this title, the Secretary may, in accordance with regulations, make commitments to insure such future loans or payments, and such commitments may be honored either as provided in subsection (a) or by inclusion of such insurance in comprehensive coverage under this subsection for the period or periods in which such future loans or payments are made.

(c) Assignment of insurance rights

The rights of an eligible lender arising under insurance evidenced by a certificate of insurance issued to it under this section may be assigned by such lender, subject to regulation by the Secretary, only to—

(1) another eligible lender (including a public entity in the business of purchasing student loans); or

(2) the Student Loan Marketing Association.

(d) Effect of refinancing or consolidation of obligations

The consolidation of the obligations of two or more federally insured loans obtained by a borrower in any fiscal year into a single obligation evidenced by a single instrument of indebtedness or the refinancing of a single loan shall not affect the insurance by the United States. If the loans thus

consolidated are covered by separate certificates of insurance issued under subsection (a), the Secretary may upon surrender of the original certificates issue a new certificate of insurance in accordance with that subsection upon the consolidated obligation. If the loans thus consolidated are covered by a single comprehensive certificate issued under subsection (b), the Secretary may amend that certificate accordingly.

(e) Rule of construction regarding consolidation of debts and refinancing

Nothing in this section shall be construed to preclude the lender and the borrower, by mutual agreement, from consolidating all of the borrower's loans insured under this subpart into a single instrument (or, if the borrower obtained only 1 loan insured under this subpart, refinancing the loan 1 time) under the terms applicable to an insured loan made at the same time as the consolidation. The lender or loan holder should provide full information to the borrower concerning the advantages and disadvantages of loan consolidation or refinancing. Nothing in this section shall be construed to preclude the consolidation of the borrower's loans insured under this subpart under section 1078–3 of title 20. Any loans insured pursuant to this subpart that are consolidated under section 1078–3 of title 20 shall not be eligible for special allowance payments under section 1087–1 of title 20.

(July 1, 1944, ch. 373, title VII, §706, as added Pub. L. 102–408, title I, §102, Oct. 13, 1992, 106 Stat. 2000; amended Pub. L. 105–392, title I, §145, Nov. 13, 1998, 112 Stat. 3581.)

EDITORIAL NOTES

PRIOR PROVISIONS

A prior section 292e, act July 1, 1944, ch. 373, title VII, §705, as added Oct. 12, 1976, Pub. L. 94–484, title II, §204, 90 Stat. 2248; amended Nov. 9, 1978, Pub. L. 95–623, §11(f), 92 Stat. 3456; Aug. 13, 1981, Pub. L. 97–35, title XXVII, §2718, 95 Stat. 914, related to establishment and maintenance of records and annual financial reports and audits, prior to the general revision of this subchapter by Pub. L. 102–408.

Another prior section 292e, act July 1, 1944, ch. 373, title VII, §706, as added July 30, 1956, 779, §2, 70 Stat. 719; amended Oct. 5, 1961, Pub. L. 87–395, §8(c), (d), 75 Stat. 827; Sept. 24, 1963, Pub. L. 88–129, §2(a), 77 Stat. 164; Aug. 16, 1968, Pub. L. 90–490, title IV, §402, 82 Stat. 789; Nov. 18, 1971, Pub. L. 92–157, title I, §102(k)(2)(A), (B), 85 Stat. 437, limited amount of grant available for construction of health research facilities, including provisions relating to its maximum, reservation of amount, manner of payment, and exclusion of amounts granted by certain other funds, prior to repeal by Pub. L. 94–484, title II, §201(a), Oct. 12, 1976, 90 Stat. 2246.

A prior section 706 of act July 1, 1944, was classified to section 292f of this title prior to the general revision of this subchapter by Pub. L. 102–408.

Another prior section 706 of act July 1, 1944, was classified to section 230 of this title prior to repeal by act Apr. 27, 1956, ch. 211, §5(e), 70 Stat. 117.

AMENDMENTS

1998—Subsec. (d). Pub. L. 105–392, §145(1), in heading, substituted "refinancing or consolidation" for "consolidation" and, in first sentence, substituted "indebtedness or the refinancing of a single loan" for "indebtedness".

Subsec. (e). Pub. L. 105–392, §145(2), in heading, substituted "debts and refinancing" for "debts", in first sentence, substituted "all of the borrower's loans insured under this subpart into a single instrument (or, if the borrower obtained only 1 loan insured under this subpart, refinancing the loan 1 time)" for "all of the borrower's debts into a single instrument", and in second sentence, substituted "consolidation or refinancing" for "consolidation".

§292f. Default of borrower

(a) Conditions for payment to beneficiary

(1) In general

Upon default by the borrower on any loan covered by Federal loan insurance pursuant to this subpart, and after a substantial collection effort (including, subject to subsection (h),

commencement and prosecution of an action) as determined under regulations of the Secretary, the insurance beneficiary shall promptly notify the Secretary and the Secretary shall, if requested (at that time or after further collection efforts) by the beneficiary, or may on his own motion, if the insurance is still in effect, pay to the beneficiary the amount of the loss sustained by the insured upon that loan as soon as that amount has been determined, except that, if the insurance beneficiary including any servicer of the loan is not designated for "exceptional performance", as set forth in paragraph (2), the Secretary shall pay to the beneficiary a sum equal to 98 percent of the amount of the loss sustained by the insured upon that loan.

(2) Exceptional performance

(A) Authority

Where the Secretary determines that an eligible lender, holder, or servicer has a compliance performance rating that equals or exceeds 97 percent, the Secretary shall designate that eligible lender, holder, or servicer, as the case may be, for exceptional performance.

(B) Compliance performance rating

For purposes of subparagraph (A), a compliance performance rating is determined with respect to compliance with due diligence in the disbursement, servicing, and collection of loans under this subpart for each year for which the determination is made. Such rating shall be equal to the percentage of all due diligence requirements applicable to each loan, on average, as established by the Secretary, with respect to loans serviced during the period by the eligible lender, holder, or servicer.

(C) Annual audits for lenders, holders, and servicers

Each eligible lender, holder, or servicer desiring a designation under subparagraph (A) shall have an annual financial and compliance audit conducted with respect to the loan portfolio of such eligible lender, holder, or servicer, by a qualified independent organization from a list of qualified organizations identified by the Secretary and in accordance with standards established by the Secretary. The standards shall measure the lender's, holder's, or servicer's compliance with due diligence standards and shall include a defined statistical sampling technique designed to measure the performance rating of the eligible lender, holder, or servicer for the purpose of this section. Each eligible lender, holder, or servicer shall submit the audit required by this section to the Secretary.

(D) Secretary's determinations

The Secretary shall make the determination under subparagraph (A) based upon the audits submitted under this paragraph and any information in the possession of the Secretary or submitted by any other agency or office of the Federal Government.

(E) Quarterly compliance audit

To maintain its status as an exceptional performer, the lender, holder, or servicer shall undergo a quarterly compliance audit at the end of each quarter (other than the quarter in which status as an exceptional performer is established through a financial and compliance audit, as described in subparagraph (C)), and submit the results of such audit to the Secretary. The compliance audit shall review compliance with due diligence requirements for the period beginning on the day after the ending date of the previous audit, in accordance with standards determined by the Secretary.

(F) Revocation authority

The Secretary shall revoke the designation of a lender, holder, or servicer under subparagraph (A) if any quarterly audit required under subparagraph (E) is not received by the Secretary by the date established by the Secretary or if the audit indicates the lender, holder, or servicer has failed to meet the standards for designation as an exceptional performer under subparagraph

(A). A lender, holder, or servicer receiving a compliance audit not meeting the standard for designation as an exceptional performer may reapply for designation under subparagraph (A) at any time.

(G) Documentation

Nothing in this section shall restrict or limit the authority of the Secretary to require the submission of claims documentation evidencing servicing performed on loans, except that the Secretary may not require exceptional performers to submit greater documentation than that required for lenders, holders, and servicers not designated under subparagraph (A).

(H) Cost of audits

Each eligible lender, holder, or servicer shall pay for all the costs associated with the audits required under this section.

(I) Additional revocation authority

Notwithstanding any other provision of this section, a designation under subparagraph (A) may be revoked at any time by the Secretary if the Secretary determines that the eligible lender, holder, or servicer has failed to maintain an overall level of compliance consistent with the audit submitted by the eligible lender, holder, or servicer under this paragraph or if the Secretary asserts that the lender, holder, or servicer may have engaged in fraud in securing designation under subparagraph (A) or is failing to service loans in accordance with program requirements.

(J) Noncompliance

A lender, holder, or servicer designated under subparagraph (A) that fails to service loans or otherwise comply with applicable program regulations shall be considered in violation of the Federal False Claims Act.

(b) Subrogation

Upon payment by the Secretary of the amount of the loss pursuant to subsection (a), the United States shall be subrogated for all of the rights of the holder of the obligation upon the insured loan and shall be entitled to an assignment of the note or other evidence of the insured loan by the insurance beneficiary. If the net recovery made by the Secretary on a loan after deduction of the cost of that recovery (including reasonable administrative costs) exceeds the amount of the loss, the excess shall be paid over to the insured. The Secretary may sell without recourse to eligible lenders (or other entities that the Secretary determines are capable of dealing in such loans) notes or other evidence of loans received through assignment under the first sentence.

(c) Forbearance

Nothing in this section or in this subpart shall be construed to preclude any forbearance for the benefit of the borrower which may be agreed upon by the parties to the insured loan and approved by the Secretary or to preclude forbearance by the Secretary in the enforcement of the insured obligation after payment on that insurance.

(d) Reasonable care and diligence regarding loans

Nothing in this section or in this subpart shall be construed to excuse the eligible lender or holder of a federally insured loan from exercising reasonable care and diligence in the making of loans under the provisions of this subpart and from exercising a substantial effort in the collection of loans under the provisions of this subpart. If the Secretary, after reasonable notice and opportunity for hearing to an eligible lender, finds that the lender has failed to exercise such care and diligence, to exercise such substantial efforts, to make the reports and statements required under section 292e(a)(3) of this title, or to pay the required Federal loan insurance premiums, he shall disqualify that lender from obtaining further Federal insurance on loans granted pursuant to this subpart until he is satisfied that its failure has ceased and finds that there is reasonable assurance that the lender will in the future exercise necessary care and diligence, exercise substantial effort, or comply with such requirements, as the case may be.

(e) Definitions

For purposes of this section:

(1) The term "insurance beneficiary" means the insured or its authorized assignee in accordance with section 292e(c) of this title.

(2) The term "amount of the loss" means, with respect to a loan, unpaid balance of the principal amount and interest on such loan, less the amount of any judgment collected pursuant to default proceedings commenced by the eligible lender or holder involved.

(3) The term "default" includes only such defaults as have existed for 120 days.

(4) The term "servicer" means any agency acting on behalf of the insurance beneficiary.

(f) Reductions in Federal reimbursements or payments for defaulting borrowers

The Secretary shall, after notice and opportunity for a hearing, cause to be reduced Federal reimbursements or payments for health services under any Federal law to borrowers who are practicing their professions and have defaulted on their loans insured under this subpart in amounts up to the remaining balance of such loans. Procedures for reduction of payments under the medicare program are provided under section 1395ccc of this title. Notwithstanding such section 1395ccc of this title, any funds recovered under this subsection shall be deposited in the insurance fund established under section 292i of this title.

(g) Conditions for discharge of debt in bankruptcy

Notwithstanding any other provision of Federal or State law, a debt that is a loan insured under the authority of this subpart may be released by a discharge in bankruptcy under any chapter of title 11, only if such discharge is granted—

(1) after the expiration of the seven-year period beginning on the first date when repayment of such loan is required, exclusive of any period after such date in which the obligation to pay installments on the loan is suspended;

(2) upon a finding by the Bankruptcy Court that the nondischarge of such debt would be unconscionable; and

(3) upon the condition that the Secretary shall not have waived the Secretary's rights to apply subsection (f) to the borrower and the discharged debt.

(h) Requirement regarding actions for default

(1) In general

With respect to the default by a borrower on any loan covered by Federal loan insurance under this subpart, the Secretary shall, under subsection (a), require an eligible lender or holder to commence and prosecute an action for such default unless—

(A) in the determination of the Secretary—

(i) the eligible lender or holder has made reasonable efforts to serve process on the borrower involved and has been unsuccessful with respect to such efforts, or

(ii) prosecution of such an action would be fruitless because of the financial or other circumstances of the borrower;

(B) for such loans made before November 4, 1988, the loan involved was made in an amount of less than $5,000; or

(C) for such loans made after November 4, 1988, the loan involved was made in an amount of less than $2,500.

(2) Relationship to claim for payment

With respect to an eligible lender or holder that has commenced an action pursuant to subsection (a), the Secretary shall make the payment required in such subsection, or deny the claim for such payment, not later than 60 days after the date on which the Secretary determines that the lender or holder has made reasonable efforts to secure a judgment and collect on the judgment entered into pursuant to this subsection.

(3) State court judgments

With respect to any State court judgment that is obtained by a lender or holder against a

borrower for default on a loan insured under this subpart and that is subrogated to the United States under subsection (b), any United States attorney may register such judgment with the Federal courts for enforcement.

(i) Inapplicability of Federal and State statute of limitations on actions for loan collection

Notwithstanding any other provision of Federal or State law, there shall be no limitation on the period within which suit may be filed, a judgment may be enforced, or an offset, garnishment, or other action may be initiated or taken by the Secretary, the Attorney General, or other administrative head of another Federal agency, as the case may be, for the repayment of the amount due from a borrower on a loan made under this subpart that has been assigned to the Secretary under subsection (b).

(j) School collection assistance

An institution or postgraduate training program attended by a borrower may assist in the collection of any loan of that borrower made under this subpart which becomes delinquent, including providing information concerning the borrower to the Secretary and to past and present lenders and holders of the borrower's loans, contacting the borrower in order to encourage repayment, and withholding services in accordance with regulations issued by the Secretary under section 292n(a)(7) of this title. The institution or postgraduate training program shall not be subject to section 1692g of title 15 for purposes of carrying out activities authorized by this section.

(July 1, 1944, ch. 373, title VII, §707, as added Pub. L. 102–408, title I, §102, Oct. 13, 1992, 106 Stat. 2002; amended Pub. L. 103–43, title XX, §2014(a)(2), June 10, 1993, 107 Stat. 215; Pub. L. 105–392, title I, §§142(a), (b), 144(a), Nov. 13, 1998, 112 Stat. 3579, 3581.)

EDITORIAL NOTES

REFERENCES IN TEXT

The Federal False Claims Act, referred to in subsec. (a)(2)(J), probably means the False Claims Act which was the popular name for sections 231, 232, 233, and 235 of former Title 31, Money and Finance. Sections 231, 232, 233, and 235 were repealed by Pub. L. 97–258, §5(b), Sept. 13, 1982, 96 Stat. 1084, and reenacted by the first section thereof as sections 3729 to 3731 of Title 31, Money and Finance.

PRIOR PROVISIONS

A prior section 292f, act July 1, 1944, ch. 373, title VII, §706, as added Oct. 12, 1976, Pub. L. 94–484, title II, §204, 90 Stat. 2249, authorized contracts under this subchapter without regard to certain provisions, prior to the general revision of this subchapter by Pub. L. 102–408.

Another prior section 292f, act July 1, 1944, ch. 373, title VII, §707, as added July 30, 1956, ch. 779, §2, 70 Stat. 720; amended Oct. 5, 1961, Pub. L. 87–395, §8(d), 75 Stat. 827; Sept. 24, 1963, Pub. L. 88–129, §2(a), 77 Stat. 164; Nov. 18, 1971, Pub. L. 92–157, title I, §102(k)(2)(A), 85 Stat. 437, provided for recapture of payments relating to grants for construction of health research facilities, prior to repeal by Pub. L. 94–484, title II, §201(a), Oct. 12, 1976, 90 Stat. 2246.

A prior section 707 of act July 1, 1944, was classified to section 292g of this title prior to the general revision of this subchapter by Pub. L. 102–408.

AMENDMENTS

1998—Subsec. (a). Pub. L. 105–392, §142(a), designated existing provisions as par. (1), inserted heading, substituted "determined, except that, if the insurance beneficiary including any servicer of the loan is not designated for 'exceptional performance', as set forth in paragraph (2), the Secretary shall pay to the beneficiary a sum equal to 98 percent of the amount of the loss sustained by the insured upon that loan." for "determined.", struck out at end "Not later than one year after October 13, 1992, the Secretary shall establish performance standards for lenders and holders of loans under this subpart, including fees to be imposed for failing to meet such standards.", and added par. (2).

Subsec. (e)(4). Pub. L. 105–392, §142(b), added par. (4).

Subsec. (g). Pub. L. 105–392, §144(a), substituted "Notwithstanding any other provision of Federal or State law, a debt that is a loan insured" for "A debt which is a loan insured" in introductory provisions.

1993—Subsec. (g)(1). Pub. L. 103–43, §2014(a)(2)(A), amended par. (1) generally. Prior to amendment,

par. (1) read as follows: "after the expiration of the five-year period beginning on the first date, as specified in subparagraphs (B) and (C) of section 292d(a)(2) of this title, when repayment of such loan is required;".

Subsec. (j). Pub. L. 103–43, §2014(a)(2)(B), added subsec. (j).

STATUTORY NOTES AND RELATED SUBSIDIARIES

EFFECTIVE DATE OF 1998 AMENDMENT

Pub. L. 105–392, title I, §142(c), Nov. 13, 1998, 112 Stat. 3581, provided that: "The amendments made by subsections (a) and (b) [amending this section] shall apply with respect to loans submitted to the Secretary for payment on or after the first day of the sixth month that begins after the date of enactment of this Act [Nov. 13, 1998]."

Pub. L. 105–392, title I, §144(b), Nov. 13, 1998, 112 Stat. 3581, provided that: "The amendment made by subsection (a) [amending this section] shall apply to any loan insured under the authority of subpart I of part A of title VII of the Public Health Service Act (42 U.S.C. 292 et seq.) that is listed or scheduled by the debtor in a case under title XI, United States Code [Title 11, Bankruptcy], filed—

"(1) on or after the date of enactment of this Act [Nov. 13, 1998]; or

"(2) prior to such date of enactment in which a discharge has not been granted."

§292g. Risk-based premiums

(a) Authority

With respect to a loan made under this subpart on or after January 1, 1993, the Secretary, in accordance with subsection (b), shall assess a risk-based premium on an eligible borrower and, if required under this section, an eligible institution that is based on the default rate of the eligible institution involved (as defined in section 292o of this title).

(b) Assessment of premium

Except as provided in subsection (d)(2), the risk-based premium to be assessed under subsection (a) shall be as follows:

(1) Low-risk rate

With respect to an eligible borrower seeking to obtain a loan for attendance at an eligible institution that has a default rate of not to exceed five percent, such borrower shall be assessed a risk-based premium in an amount equal to 6 percent of the principal amount of the loan.

(2) Medium-risk rate

(A) In general

With respect to an eligible borrower seeking to obtain a loan for attendance at an eligible institution that has a default rate of in excess of five percent but not to exceed 10 percent—

(i) such borrower shall be assessed a risk-based premium in an amount equal to 8 percent of the principal amount of the loan; and

(ii) such institution shall be assessed a risk-based premium in an amount equal to 5 percent of the principal amount of the loan.

(B) Default management plan

An institution of the type described in subparagraph (A) shall prepare and submit to the Secretary for approval, an annual default management plan, that shall specify the detailed short-term and long-term procedures that such institution will have in place to minimize defaults on loans to borrowers under this subpart. Under such plan the institution shall, among other measures, provide an exit interview to all borrowers that includes information concerning repayment schedules, loan deferments, forbearance, and the consequences of default.

(3) High-risk rate

(A) In general

With respect to an eligible borrower seeking to obtain a loan for attendance at an eligible institution that has a default rate of in excess of 10 percent but not to exceed 20 percent—

(i) such borrower shall be assessed a risk-based premium in an amount equal to 8 percent of the principal amount of the loan; and

(ii) such institution shall be assessed a risk-based premium in an amount equal to 10 percent of the principal amount of the loan.

(B) Default management plan

An institution of the type described in subparagraph (A) shall prepare and submit to the Secretary for approval a plan that meets the requirements of paragraph (2)(B).

(4) Ineligibility

An individual shall not be eligible to obtain a loan under this subpart for attendance at an institution that has a default rate in excess of 20 percent.

(c) Reduction of risk-based premium

Lenders shall reduce by 50 percent the risk-based premium to eligible borrowers if a credit worthy parent or other responsible party co-signs the loan note.

(d) Administrative waivers

(1) Hearing

The Secretary shall afford an institution not less than one hearing, and may consider mitigating circumstances, prior to making such institution ineligible for participation in the program under this subpart.

(2) Exceptions

In carrying out this section with respect to an institution, the Secretary may grant an institution a waiver of requirements of paragraphs (2) through (4) of subsection (b) if the Secretary determines that the default rate for such institution is not an accurate indicator because the volume of the loans under this subpart made by such institution has been insufficient.

(3) Transition for certain institutions

During the 3-year period beginning on October 13, 1992—

(A) subsection (b)(4) shall not apply with respect to any eligible institution that is a Historically Black College or University; and

(B) any such institution that has a default rate in excess of 20 percent, and any eligible borrower seeking a loan for attendance at the institution, shall be subject to subsection (b)(3) to the same extent and in the same manner as eligible institutions and borrowers described in such subsection.

(e) Payoff to reduce risk category

An institution may pay off the outstanding principal and interest owed by the borrowers of such institution who have defaulted on loans made under this subpart in order to reduce the risk category of the institution.

(July 1, 1944, ch. 373, title VII, §708, as added Pub. L. 102–408, title I, §102, Oct. 13, 1992, 106 Stat. 2004.)

EDITORIAL NOTES

PRIOR PROVISIONS

A prior section 292g, act July 1, 1944, ch. 373, title VII, §707, as added Oct. 12, 1976, Pub. L. 94–484, title II, §205, 90 Stat. 2249; amended Aug. 1, 1977, Pub. L. 95–83, title III, §307(r), 91 Stat. 395, related to delegation of authority by the Secretary, prior to the general revision of this subchapter by Pub. L. 102–408.

Another prior section 292g, act July 1, 1944, ch. 373, title VII, §708, as added July 30, 1956, ch. 779, §2, 70 Stat. 720; amended Oct. 5, 1961, Pub. L. 87–395, §8(d), 75 Stat. 827; Sept. 24, 1963, Pub. L. 88–129, §2(a), 77 Stat. 164, prohibited Federal interference with administration of institutions where grants were made

for construction of health research facilities, prior to repeal by Pub. L. 94–484, title II, §201(a), Oct. 12, 1976, 90 Stat. 2246.

A prior section 708 of act July 1, 1944, was classified to section 292h of this title prior to the general revision of this subchapter by Pub. L. 102–408.

STATUTORY NOTES AND RELATED SUBSIDIARIES

EFFECTIVE DATE

Section effective Jan. 1, 1993, and until such date, former section 294e(c) of this title, as in effect on the day before Oct. 13, 1992, to continue in effect in lieu of this section, see section 103 of Pub. L. 102–408, set out as a note under section 292 of this title.

§292h. Office for Health Education Assistance Loan Default Reduction

(a) Establishment

The Secretary shall establish, within the Division of Student Assistance of the Bureau of Health Professions, an office to be known as the Office for Health Education Assistance Loan Default Reduction (in this section referred to as the "Office").

(b) Purpose and functions

It shall be the purpose of the Office to achieve a reduction in the number and amounts of defaults on loans guaranteed under this subpart. In carrying out such purpose the Office shall—

(1) conduct analytical and evaluative studies concerning loans and loan defaults;

(2) carry out activities designed to reduce loan defaults;

(3) respond to special circumstances that may exist in the financial lending environment that may lead to loan defaults;

(4) coordinate with other Federal entities that are involved with student loan programs, including—

(A) with respect to the Department of Education, in the development of a single student loan application form, a single student loan deferment form, a single disability form, and a central student loan database; and

(B) with respect to the Department of Justice, in the recovery of payments from health professionals who have defaulted on loans guaranteed under this subpart; and

(5) provide technical assistance to borrowers, lenders, holders, and institutions concerning deferments and collection activities.

(c) Additional duties

In conjunction with the report submitted under subsection (b), the Office shall—

(1) compile, and publish in the Federal Register, a list of the borrowers who are in default under this subpart; and

(2) send the report and notices of default with respect to these borrowers to relevant Federal agencies and to schools, school associations, professional and specialty associations, State licensing boards, hospitals with which such borrowers may be associated, and any other relevant organizations.

(d) Allocation of funds for Office

In the case of amounts reserved under section 292i(a)(2)(B) of this title for obligation under this subsection, the Secretary may obligate the amounts for the purpose of administering the Office, including 7 full-time equivalent employment positions for such Office. With respect to such purpose, amounts made available under the preceding sentence are in addition to amounts made available to the Health Resources and Services Administration for program management for the fiscal year

involved. With respect to such employment positions, the positions are in addition to the number of full-time equivalent employment positions that otherwise is authorized for the Department of Health and Human Services for the fiscal year involved.

(July 1, 1944, ch. 373, title VII, §709, as added Pub. L. 102–408, title I, §102, Oct. 13, 1992, 106 Stat. 2006; amended Pub. L. 105–392, title I, §141(b), Nov. 13, 1998, 112 Stat. 3579.)

EDITORIAL NOTES

PRIOR PROVISIONS

A prior section 292h, act July 1, 1944, ch. 373, title VII, §708, as added Oct. 12, 1976, Pub. L. 94–484, title II, §206, 90 Stat. 2250; amended Aug. 1, 1977, Pub. L. 95–83, title III, §307(a), 91 Stat. 389; Nov. 9, 1978, Pub. L. 95–623, §12(a), 92 Stat. 3457; Dec. 11, 1980, Pub. L. 96–511, §4(c), 94 Stat. 2826; Aug. 13, 1981, Pub. L. 97–35, title XXVII, §2719, 95 Stat. 914; Oct. 22, 1985, Pub. L. 99–129, title II, §220(b), 99 Stat. 543; Nov. 4, 1988, Pub. L. 100–607, title VI, §§616(c)(1), 626, 102 Stat. 3139, 3144; Nov. 18, 1988, Pub. L. 100–690, title II, §2615(a), 102 Stat. 4239; Aug. 16, 1989, Pub. L. 101–93, §5(m), 103 Stat. 613, related to health professions data, prior to the general revision of this subchapter by Pub. L. 102–408. See section 295k of this title.

Another prior section 292h, act July 1, 1944, ch. 373, title VII, §709, as added July 30, 1956, ch. 779, §2, 70 Stat. 720; amended Sept. 24, 1963, Pub. L. 88–129, §2(a), 77 Stat. 164; Nov. 18, 1971, Pub. L. 92–157, title I, §102(k)(2)(C), 85 Stat. 437, provided for issuance of general, administrative, and other regulations for implementation of grants for construction of health research facilities, prior to repeal by Pub. L. 94–484, title II, §201(a), Oct. 12, 1976, 90 Stat. 2246.

A prior section 709 of act July 1, 1944, was classified to section 292i of this title prior to repeal by Pub. L. 97–35, title XXVII, §2720(a), Aug. 13, 1981, 95 Stat. 915.

AMENDMENTS

1998—Subsec. (b). Pub. L. 105–392 inserted "and" at end of par. (4)(B), substituted a period for "; and" at end of par. (5), and struck out par. (6) which read as follows: "prepare and submit a report not later than March 31, 1993, and annually, thereafter, to the Committee on Labor and Human Resources of the Senate and the Committee on Energy and Commerce of the House of Representatives concerning—

"(A) the default rates for each—

"(i) institution described in section 292o(1) of this title that is participating in the loan programs under this subpart;

"(ii) lender participating in the loan program under this subpart; and

"(iii) loan holder under this subpart;

"(B) the total amounts recovered pursuant to section 292f(b) of this title during the preceding fiscal year; and

"(C) a plan for improving the extent of such recoveries during the current fiscal year."

§292i. Insurance account

(a) In general

(1) Establishment

There is hereby established a student loan insurance account (in this section referred to as the "Account") which shall be available without fiscal year limitation to the Secretary for making payments in connection with the collection and default of loans insured under this subpart by the Secretary.

(2) Funding

(A) Except as provided in subparagraph (B), all amounts received by the Secretary as premium charges for insurance and as receipts, earnings, or proceeds derived from any claim or other assets acquired by the Secretary in connection with his operations under this subpart, and any other moneys, property, or assets derived by the Secretary from the operations of the Secretary in connection with this section, shall be deposited in the Account.

(B) With respect to amounts described in subparagraph (A) that are received by the Secretary for fiscal year 1993 and subsequent fiscal years, the Secretary may, before depositing such amounts in the Account, reserve from the amounts each such fiscal year not more than $1,000,000 for obligation under section 292h(d) of this title.

(3) Expenditures

All payments in connection with the default of loans insured by the Secretary under this subpart shall be paid from the Account.

(b) Contingent authority for issuance of notes or other obligations

If at any time the moneys in the Account are insufficient to make payments in connection with the collection or default of any loan insured by the Secretary under this subpart, the Secretary of the Treasury may lend the Account such amounts as may be necessary to make the payments involved, subject to the Federal Credit Reform Act of 1990 [2 U.S.C. 661 et seq.].

(July 1, 1944, ch. 373, title VII, §710, as added Pub. L. 102–408, title I, §102, Oct. 13, 1992, 106 Stat. 2007; amended Pub. L. 105–392, title I, §143, Nov. 13, 1998, 112 Stat. 3581.)

EDITORIAL NOTES

REFERENCES IN TEXT

The Federal Credit Reform Act of 1990, referred to in subsec. (b), is title V of Pub. L. 93–344, as added by Pub. L. 101–508, title XIII, §13201(a), Nov. 5, 1990, 104 Stat. 1388–609, which is classified generally to subchapter III (§661 et seq.) of chapter 17A of Title 2, The Congress. For complete classification of this Act to the Code, see Short Title of 1990 Amendment note set out under section 621 of Title 2 and Tables.

PRIOR PROVISIONS

A prior section 292i, act July 1, 1944, ch. 373, title VII, §709, as added Oct. 12, 1976, Pub. L. 94–484, title II, §207, 90 Stat. 2252; amended Nov. 9, 1978, Pub. L. 95–623, §12(b), 92 Stat. 3457, related to shared schedule residency training positions, prior to repeal by Pub. L. 97–35, title XXVII, §2720(a), Aug. 13, 1981, 95 Stat. 915.

Another prior section 292i, act July 1, 1944, ch. 373, title VII, §710, as added July 30, 1956, ch. 779, §2, 70 Stat. 720; amended Sept. 24, 1963, Pub. L. 88–129, §2(a), 77 Stat. 164; Nov. 18, 1971, Pub. L. 92–157, title I, §102(k)(2)(A), 85 Stat. 437, related to preparation and submission of annual reports to the Congress through the President, including its contents, as to grants for construction of health research facilities, prior to repeal by Pub. L. 94–484, title II, §201(a), Oct. 12, 1976, 90 Stat. 2246.

A prior section 710 of act July 1, 1944, was classified to section 292k of this title prior to the general revision of this subchapter by Pub. L. 102–408.

Another prior section 710 of act July 1, 1944, was renumbered section 709 by Pub. L. 97–35 and was classified to section 292j of this title prior to the general revision of this subchapter by Pub. L. 102–408.

AMENDMENTS

1998—Subsec. (a)(2)(B). Pub. L. 105–392 substituted "fiscal year 1993 and subsequent fiscal years" for "any of the fiscal years 1993 through 1996".

§292j. Powers and responsibilities of Secretary

(a) In general

In the performance of, and with respect to, the functions, powers, and duties vested in the Secretary by this subpart, the Secretary is authorized as follows:

(1) To prescribe such regulations as may be necessary to carry out the purposes of this subpart.

(2) To sue and be sued in any district court of the United States. Such district courts shall have jurisdiction of civil actions arising under this subpart without regard to the amount in controversy, and any action instituted under this subsection by or against the Secretary shall survive notwithstanding any change in the person occupying the office of Secretary or any vacancy in that office. No attachment, injunction, garnishment, or other similar process, mesne or final, shall be

issued against the Secretary or property under the control of the Secretary. Nothing herein shall be constructed to except litigation arising out of activities under this subpart from the application of sections 517 and 547 of title 28.

(3) To include in any contract for Federal loan insurance such terms, conditions, and covenants relating to repayment of principal and payments of interest, relating to his obligations and rights and to those of eligible lenders, and borrowers in case of default, and relating to such other matters as the Secretary determines to be necessary to assure that the purposes of this subpart will be achieved. Any term, condition, and covenant made pursuant to this paragraph or any other provisions of this subpart may be modified by the Secretary if the Secretary determines that modification is necessary to protect the financial interest of the United States.

(4) Subject to the specific limitations in the subpart, to consent to the modification of any note or other instrument evidencing a loan which has been insured by him under this subpart (including modifications with respect to the rate of interest, time of payment of any installment of principal and interest or any portion thereof, or any other provision).

(5) To enforce, pay, compromise, waive, or release any right, title, claim, lien, or demand, however acquired, including any equity or any right or [1] redemption.

(b) Annual budget; accounts

The Secretary shall, with respect to the financial operations arising by reason of this subpart—

(1) prepare annually and submit a budget program as provided for wholly owned Government corporations by chapter 91 of title 31; and

(2) maintain with respect to insurance under this subpart an integral set of accounts.

(July 1, 1944, ch. 373, title VII, §711, as added Pub. L. 102–408, title I, §102, Oct. 13, 1992, 106 Stat. 2007.)

EDITORIAL NOTES

CODIFICATION

In subsec. (b)(1), "chapter 91 of title 31" was substituted for "the Government Corporation Control Act" on authority of Pub. L. 97–258, §4(b), Sept. 13, 1982, 96 Stat. 1067, the first section of which enacted Title 31, Money and Finance.

PRIOR PROVISIONS

A prior section 292j, act July 1, 1944, ch. 373, title VII, §709, formerly §710, as added Oct. 12, 1976, Pub. L. 94–484, title II, §208, 90 Stat. 2252; renumbered §709 and amended Aug. 13, 1981, Pub. L. 97–35, title XXVII, §§2720(b), 2721, 95 Stat. 915; Oct. 22, 1985, Pub. L. 99–129, title II, §206, 99 Stat. 527, related to payment under grants, prior to the general revision of this subchapter by Pub. L. 102–408.

Another prior section 292j, act July 1, 1944, ch. 373, title VII, §711, as added Sept. 24, 1963, Pub. L. 88–129, §3(b), 77 Stat. 173; amended Nov. 18, 1971, Pub. L. 92–157, title I, §102(k)(2)(A), 85 Stat. 437, provided for technical assistance in connection with grants for construction of health research facilities, prior to repeal by Pub. L. 94–484, title II, §201(a), Oct. 12, 1976, 90 Stat. 2246.

[1] So in original. Probably should be "of".

§292k. Participation by Federal credit unions in Federal, State, and private student loan insurance programs

Notwithstanding any other provision of law, Federal credit unions shall, pursuant to regulations of the Administrator of the National Credit Union Administration, have power to make insured loans to eligible students in accordance with the provisions of this subpart relating to Federal insured loans.

(July 1, 1944, ch. 373, title VII, §712, as added Pub. L. 102–408, title I, §102, Oct. 13, 1992, 106 Stat. 2008.)

EDITORIAL NOTES

PRIOR PROVISIONS

A prior section 292k, act July 1, 1944, ch. 373, title VII, §710, formerly §711, as added Oct. 12, 1976, Pub. L. 94–484, title II, §209, 90 Stat. 2253; renumbered §710 and amended Aug. 13, 1981, Pub. L. 97–35, title XXVII, §§2720(b), 2722, 95 Stat. 915, related to differential tuition and fees, prior to the general revision of this subchapter by Pub. L. 102–408.

STATUTORY NOTES AND RELATED SUBSIDIARIES

TRANSFER OF FUNCTIONS

Functions vested in Administrator of National Credit Union Administration transferred and vested in National Credit Union Administration Board pursuant to section 1752a of Title 12, Banks and Banking.

§292*l*. Determination of eligible students

For purposes of determining eligible students under this part, in the case of a public school in a State that offers an accelerated, integrated program of study combining undergraduate premedical education and medical education leading to advanced entry, by contractual agreement, into an accredited four-year school of medicine which provides the remaining training leading to a degree of doctor of medicine, whenever in this part a provision refers to a student at a school of medicine, such reference shall include only a student enrolled in any of the last four years of such accelerated, integrated program of study.

(July 1, 1944, ch. 373, title VII, §713, as added Pub. L. 102–408, title I, §102, Oct. 13, 1992, 106 Stat. 2008.)

§292m. Repayment by Secretary of loans of deceased or disabled borrowers

If a borrower who has received a loan dies or becomes permanently and totally disabled (as determined in accordance with regulations of the Secretary), the Secretary shall discharge the borrower's liability on the loan by repaying the amount owed on the loan from the account established under section 292i of this title.

(July 1, 1944, ch. 373, title VII, §714, as added Pub. L. 102–408, title I, §102, Oct. 13, 1992, 106 Stat. 2008.)

§292n. Additional requirements for institutions and lenders

(a) In general

Notwithstanding any other provision of this subpart, the Secretary is authorized to prescribe such regulations as may be necessary to provide for—

(1) a fiscal audit of an eligible institution with regard to any funds obtained from a borrower who has received a loan insured under this subpart;

(2) the establishment of reasonable standards of financial responsibility and appropriate institutional capability for the administration by an eligible institution of a program of student financial aid with respect to funds obtained from a student who has received a loan insured under this subpart;

(3) the limitation, suspension, or termination of the eligibility under this subpart of any otherwise eligible institution, whenever the Secretary has determined, after notice and affording an opportunity for hearing, that such institution has violated or failed to carry out any regulation prescribed under this subpart;

(4) the collection of information from the borrower, lender, or eligible institution to assure

compliance with the provisions of section 292d of this title;

(5) the assessing of tuition or fees to borrowers in amounts that are the same or less than the amount of tuition and fees assessed to nonborrowers;

(6) the submission, by the institution or the lender to the Office of Health Education Assistance Loan Default Reduction, of information concerning each loan made under this subpart, including the date when each such loan was originated, the date when each such loan is sold, the identity of the loan holder and information concerning a change in the borrower's status;

(7) the withholding of services, including academic transcripts, financial aid transcripts, and alumni services, by an institution from a borrower upon the default of such borrower of a loan under this subpart, except in case of a borrower who has filed for bankruptcy; and

(8) the offering, by the lender to the borrower, of a variety of repayment options, including fixed-rate, graduated repayment with negative amortization permitted, and income dependent payments for a limited period followed by level monthly payments.

(b) Recording by institution of information on students

The Secretary shall require an eligible institution to record, and make available to the lender and to the Secretary upon request, the name, address, postgraduate destination, and other reasonable identifying information for each student of such institution who has a loan insured under this subpart.

(c) Workshop for student borrowers

Each participating eligible institution must have, at the beginning of each academic year, a workshop concerning the provisions of this subpart that all student borrowers shall be required to attend.

(July 1, 1944, ch. 373, title VII, §715, as added Pub. L. 102–408, title I, §102, Oct. 13, 1992, 106 Stat. 2009.)

§292*o*. Definitions

For purposes of this subpart:

(1) The term "eligible institution" means, with respect to a fiscal year, a school of medicine, osteopathic medicine, dentistry, veterinary medicine, optometry, podiatric medicine, pharmacy, public health, allied health, or chiropractic, or a graduate program in health administration or behavioral and mental health practice, including clinical psychology.

(2) The term "eligible lender" means an eligible institution that became a lender under this subpart prior to September 15, 1992, an agency or instrumentality of a State, a financial or credit institution (including an insurance company) which is subject to examination and supervision by an agency of the United States or of any State, a pension fund approved by the Secretary for this purpose, or a nonprofit private entity designated by the State, regulated by the State, and approved by the Secretary.

(3) The term "line of credit" means an arrangement or agreement between the lender and the borrower whereby a loan is paid out by the lender to the borrower in annual installments, or whereby the lender agrees to make, in addition to the initial loan, additional loans in subsequent years.

(4) The term "school of allied health" means a program in a school of allied health (as defined in section 295p of this title) which leads to a masters' degree or a doctoral degree.

(5)(A) The term "default rate", in the case of an eligible entity, means the percentage constituted by the ratio of—

(i) the principal amount of loans insured under this subpart—

(I) that are made with respect to the entity and that enter repayment status after April 7, 1987; and

(II) for which amounts have been paid under section 292f(a) of this title to insurance beneficiaries, exclusive of any loan for which amounts have been so paid as a result of the death or total and permanent disability of the borrower; exclusive of any loan for which the

borrower begins payments to the Secretary on the loan pursuant to section 292f(b) of this title and maintains payments for 12 consecutive months in accordance with the agreement involved (with the loan subsequently being included or excluded, as the case may be, as amounts paid under section 292f(a) of this title according to whether further defaults occur and whether with respect to the default involved compliance with such requirement regarding 12 consecutive months occurs); and exclusive of any loan on which payments may not be recovered by reason of the obligation under the loan being discharged in bankruptcy under title 11; to

(ii) the total principal amount of loans insured under this subpart that are made with respect to the entity and that enter repayment status after April 7, 1987.

(B) For purposes of subparagraph (A), a loan insured under this subpart shall be considered to have entered repayment status if the applicable period described in subparagraph (B) of section 292d(a)(2) of this title regarding the loan has expired (without regard to whether any period described in subparagraph (C) of such section is applicable regarding the loan).

(C) For purposes of subparagraph (A), the term "eligible entity" means an eligible institution, an eligible lender, or a holder, as the case may be.

(D) For purposes of subparagraph (A), a loan is made with respect to an eligible entity if—

(i) in the case of an eligible institution, the loan was made to students of the institution;

(ii) in the case of an eligible lender, the loan was made by the lender; and

(iii) in the case of a holder, the loan was purchased by the holder.

(6) The term "Secretary" means the Secretary of Education.

(July 1, 1944, ch. 373, title VII, §719, as added Pub. L. 102–408, title I, §102, Oct. 13, 1992, 106 Stat. 2009; amended Pub. L. 105–392, title I, §141(c)(2), Nov. 13, 1998, 112 Stat. 3579; Pub. L. 113–76, div. H, title V, §525(e), Jan. 17, 2014, 128 Stat. 413.)

EDITORIAL NOTES

AMENDMENTS

2014—Par. (6). Pub. L. 113–76 added par. (6).

1998—Par. (1). Pub. L. 105–392 substituted "or behavioral and mental health practice, including clinical psychology" for "or clinical psychology".

STATUTORY NOTES AND RELATED SUBSIDIARIES

EFFECTIVE DATE OF 2014 AMENDMENT

Pub. L. 113–76, div. H, title V, §525(e), Jan. 17, 2014, 128 Stat. 413, provided in part that the amendment made by section 525(e) is effective as of the date on which the transfer of the HEAL program under subsec. (a) of section 525 of Pub. L. 113–76, set out as a note under section 292 of this title, takes effect [no later than the end of the first fiscal quarter that begins after Jan. 17, 2014].

§292p. Authorization of appropriations

(a) In general

For fiscal year 1993 and subsequent fiscal years, there are authorized to be appropriated such sums as may be necessary for the adequacy of the student loan insurance account under this subpart and for the purpose of administering this subpart.

(b) Availability of sums

Sums appropriated under subsection (a) shall remain available until expended.

(July 1, 1944, ch. 373, title VII, §720, as added Pub. L. 102–408, title I, §102, Oct. 13, 1992, 106 Stat. 2011.)

EDITORIAL NOTES

PRIOR PROVISIONS

A prior section 720 of act July 1, 1944, was classified to section 293 of this title prior to the general revision of this subchapter by Pub. L. 102–408.

SUBPART II—FEDERALLY-SUPPORTED STUDENT LOAN FUNDS

§292q. Agreements for operation of school loan funds

(a) Fund agreements

The Secretary is authorized to enter into an agreement for the establishment and operation of a student loan fund in accordance with this subpart with any public or other nonprofit school of medicine, osteopathic medicine, dentistry, pharmacy, podiatric medicine, optometry, or veterinary medicine.

(b) Requirements

Each agreement entered into under this section shall—

(1) provide for establishment of a student loan fund by the school;

(2) provide for deposit in the fund of—

(A) the Federal capital contributions to the fund;

(B) an amount equal to not less than one-ninth of such Federal capital contributions, contributed by such institution;

(C) collections of principal and interest on loans made from the fund;

(D) collections pursuant to section 292r(j) of this title; and

(E) any other earnings of the fund;

(3) provide that the fund shall be used only for loans to students of the school in accordance with the agreement and for costs of collection of such loans and interest thereon;

(4) provide that loans may be made from such funds only to students pursuing a full-time course of study at the school leading to a degree of doctor of medicine, doctor of dentistry or an equivalent degree, doctor of osteopathy, bachelor of science in pharmacy or an equivalent degree, doctor of pharmacy or an equivalent degree, doctor of podiatric medicine or an equivalent degree, doctor of optometry or an equivalent degree, or doctor of veterinary medicine or an equivalent degree;

(5) provide that the school shall advise, in writing, each applicant for a loan from the student loan fund of the provisions of section 292r of this title under which outstanding loans from the student loan fund may be paid (in whole or in part) by the Secretary; and

(6) contain such other provisions as are necessary to protect the financial interests of the United States.

(c) Failure of school to collect loans

(1) In general

Any standard established by the Secretary by regulation for the collection by schools of medicine, osteopathic medicine, dentistry, pharmacy, podiatric medicine, optometry, or veterinary medicine of loans made pursuant to loan agreements under this subpart shall provide that the failure of any such school to collect such loans shall be measured in accordance with this subsection. This subsection may not be construed to require such schools to reimburse the student

loan fund under this subpart for loans that became uncollectible prior to August 1985 or to penalize such schools with respect to such loans.

(2) Extent of failure

The measurement of a school's failure to collect loans made under this subpart shall be the ratio (stated as a percentage) that the defaulted principal amount outstanding of such school bears to the matured loans of such school.

(3) Definitions

For purposes of this subsection:

(A) The term "default" means the failure of a borrower of a loan made under this subpart to—

(i) make an installment payment when due; or

(ii) comply with any other term of the promissory note for such loan,

except that a loan made under this subpart shall not be considered to be in default if the loan is discharged in bankruptcy or if the school reasonably concludes from written contracts with the borrower that the borrower intends to repay the loan.

(B) The term "defaulted principal amount outstanding" means the total amount borrowed from the loan fund of a school that has reached the repayment stage (minus any principal amount repaid or canceled) on loans—

(i) repayable monthly and in default for at least 120 days; and

(ii) repayable less frequently than monthly and in default for at least 180 days;

(C) The term "grace period" means the period of one year beginning on the date on which the borrower ceases to pursue a full-time course of study at a school of medicine, osteopathic medicine, dentistry, pharmacy, podiatric medicine, optometry, or veterinary medicine; and

(D) The term "matured loans" means the total principal amount of all loans made by a school under this subpart minus the total principal amount of loans made by such school to students who are—

(i) enrolled in a full-time course of study at such school; or

(ii) in their grace period.

(July 1, 1944, ch. 373, title VII, §721, as added Pub. L. 102–408, title I, §102, Oct. 13, 1992, 106 Stat. 2011.)

EDITORIAL NOTES

PRIOR PROVISIONS

A prior section 721 of act July 1, 1944, was classified to section 293a of this title prior to the general revision of this subchapter by Pub. L. 102–408.

§292r. Loan provisions

(a) Amount of loan

(1) In general

Loans from a student loan fund (established under an agreement with a school under section 292q of this title) may not, subject to paragraph (2), exceed for any student for a school year (or its equivalent) the cost of attendance (including tuition, other reasonable educational expenses, and reasonable living costs) for that year at the educational institution attended by the student (as determined by such educational institution).

(2) Third and fourth years of medical school

For purposes of paragraph (1), the amount of the loan may, in the case of the third or fourth year of a student at a school of medicine or osteopathic medicine, be increased to the extent necessary

to pay the balances of loans that, from sources other than the student loan fund under section 292q of this title, were made to the individual for attendance at the school. The authority to make such an increase is subject to the school and the student agreeing that such amount (as increased) will be expended to pay such balances.

(b) Terms and conditions

Subject to section 292s of this title, any such loans shall be made on such terms and conditions as the school may determine, but may be made only to a student who is in need of the amount thereof to pursue a full-time course of study at the school leading to a degree of doctor of medicine, doctor of dentistry or an equivalent degree, doctor of osteopathy, bachelor of science in pharmacy or an equivalent degree, doctor of pharmacy or an equivalent degree, doctor of podiatric medicine or an equivalent degree, doctor of optometry or an equivalent degree, or doctor of veterinary medicine or an equivalent degree.

(c) Repayment; exclusions from repayment period

Such loans shall be repayable in equal or graduated periodic installments (with the right of the borrower to accelerate repayment) over the period of not less than 10 years nor more than 25 years, at the discretion of the institution, which begins one year after the student ceases to pursue a full-time course of study at a school of medicine, osteopathic medicine, dentistry, pharmacy, podiatry, optometry, or veterinary medicine, excluding from such period—

(1) all periods—

(A) not in excess of three years of active duty performed by the borrower as a member of a uniformed service;

(B) not in excess of three years during which the borrower serves as a volunteer under the Peace Corps Act [22 U.S.C. 2501 et seq.];

(C) during which the borrower participates in advanced professional training, including internships and residencies; and

(D) during which the borrower is pursuing a full-time course of study at such a school; and

(2) a period—

(A) not in excess of two years during which a borrower who is a full-time student in such a school leaves the school, with the intent to return to such school as a full-time student, in order to engage in a full-time educational activity which is directly related to the health profession for which the borrower is preparing, as determined by the Secretary; or

(B) not in excess of two years during which a borrower who is a graduate of such a school is a participant in a fellowship training program or a full-time educational activity which—

(i) is directly related to the health profession for which such borrower prepared at such school, as determined by the Secretary; and

(ii) may be engaged in by the borrower during such a two-year period which begins within twelve months after the completion of the borrower's participation in advanced professional training described in paragraph (1)(C) or prior to the completion of such borrower's participation in such training.

(d) Cancellation of liability

The liability to repay the unpaid balance of such a loan and accrued interest thereon shall be canceled upon the death of the borrower, or if the Secretary determines that he has become permanently, and totally disabled.

(e) Rate of interest

Such loans shall bear interest, on the unpaid balance of the loan, computed only for periods for which the loan is repayable, at the rate of 5 percent per year.

(f) Security or endorsement

Loans shall be made under this subpart without security or endorsement, except that if the borrower is a minor and the note or other evidence of obligation executed by him would not, under

the applicable law, create a binding obligation, either security or endorsement may be required.

(g) Transferring and assigning loans

No note or other evidence of a loan made under this subpart may be transferred or assigned by the school making the loan except that, if the borrowers transfer to another school participating in the program under this subpart, such note or other evidence of a loan may be transferred to such other school.

(h) Charge with respect to insurance for certain cancellations

Subject to regulations of the Secretary, a school may assess a charge with respect to loans made this subpart [1] to cover the costs of insuring against cancellation of liability under subsection (d).

(i) Charge with respect to late payments

Subject to regulations of the Secretary, and in accordance with this section, a school shall assess a charge with respect to a loan made under this subpart for failure of the borrower to pay all or any part of an installment when it is due and, in the case of a borrower who is entitled to deferment of the loan under subsection (c), for any failure to file timely and satisfactory evidence of such entitlement. No such charge may be made if the payment of such installment or the filing of such evidence is made within 60 days after the date on which such installment or filing is due. The amount of any such charge may not exceed an amount equal to 6 percent of the amount of such installment. The school may elect to add the amount of any such charge to the principal amount of the loan as of the first day after the day on which such installment or evidence was due, or to make the amount of the charge payable to the school not later than the due date of the next installment after receipt by the borrower of notice of the assessment of the charge.

(j) Authority of schools regarding rate of payment

A school may provide, in accordance with regulations of the Secretary, that during the repayment period of a loan from a loan fund established pursuant to an agreement under this subpart payments of principal and interest by the borrower with respect to all the outstanding loans made to him from loan funds so established shall be at a rate equal to not less than $40 per month.

(k) Authority regarding repayments by Secretary

Upon application by a person who received, and is under an obligation to repay, any loan made to such person as a health professions student to enable him to study medicine, osteopathy, dentistry, veterinary medicine, optometry, pharmacy, or podiatry, the Secretary may undertake to repay (without liability to the applicant) all or any part of such loan, and any interest or portion thereof outstanding thereon, upon his determination, pursuant to regulations establishing criteria therefor, that the applicant—

(1) failed to complete such studies leading to his first professional degree;

(2) is in exceptionally needy circumstances;

(3) is from a low-income or disadvantaged family as those terms may be defined by such regulations; and

(4) has not resumed, or cannot reasonably be expected to resume, the study of medicine, osteopathy, dentistry, veterinary medicine, optometry, pharmacy, or podiatric medicine, within two years following the date upon which he terminated such studies.

(l) Collection efforts by Secretary

The Secretary is authorized to attempt to collect any loan which was made under this subpart, which is in default, and which was referred to the Secretary by a school with which the Secretary has an agreement under this subpart, on behalf of that school under such terms and conditions as the Secretary may prescribe (including reimbursement from the school's student loan fund for expenses the Secretary may reasonably incur in attempting collection), but only if the school has complied with such requirements as the Secretary may specify by regulation with respect to the collection of loans under this subpart. A loan so referred shall be treated as a debt subject to section 5514 of title

5. Amounts collected shall be deposited in the school's student loan fund. Whenever the Secretary desires the institution of a civil action regarding any such loan, the Secretary shall refer the matter to the Attorney General for appropriate action.

(m) Elimination of statute of limitation for loan collections

(1) Purpose

It is the purpose of this subsection to ensure that obligations to repay loans under this section are enforced without regard to any Federal or State statutory, regulatory, or administrative limitation on the period within which debts may be enforced.

(2) Prohibition

Notwithstanding any other provision of Federal or State law, no limitation shall terminate the period within which suit may be filed, a judgment may be enforced, or an offset, garnishment, or other action may be initiated or taken by a school that has an agreement with the Secretary pursuant to section 292q of this title that is seeking the repayment of the amount due from a borrower on a loan made under this subpart after the default of the borrower on such loan.

(July 1, 1944, ch. 373, title VII, §722, as added Pub. L. 102–408, title I, §102, Oct. 13, 1992, 106 Stat. 2012; amended Pub. L. 103–43, title XX, §2014(b), June 10, 1993, 107 Stat. 215; Pub. L. 105–392, title I, §134(a), (b)(1), Nov. 13, 1998, 112 Stat. 3577, 3578; Pub. L. 117–103, div. R, §104(2), Mar. 15, 2022, 136 Stat. 821.)

EDITORIAL NOTES

REFERENCES IN TEXT

The Peace Corps Act, referred to in subsec. (c)(1)(B), is Pub. L. 87–293, Sept. 22, 1961, 75 Stat. 612, which is classified principally to chapter 34 (§2501 et seq.) of Title 22, Foreign Relations and Intercourse. For complete classification of this Act to the Code, see Short Title note set out under section 2501 of Title 22 and Tables.

PRIOR PROVISIONS

A prior section 722 of act July 1, 1944, was classified to section 293b of this title prior to the general revision of this subchapter by Pub. L. 102–408.

AMENDMENTS

2022—Subsec. (b). Pub. L. 117–103 substituted "to a student who is in need" for "to a student—

"(1) who is in need"

and struck out par. (2) which read as follows: "who, if required under section 3802 of title 50 to present himself for and submit to registration under such section, has presented himself and submitted to registration under such section."

1998—Subsec. (a)(1). Pub. L. 105–392, §134(a)(1), substituted "the cost of attendance (including tuition, other reasonable educational expenses, and reasonable living costs) for that year at the educational institution attended by the student (as determined by such educational institution)." for "the sum of—

"(A) the cost of tuition for such year at such school, and

"(B) $2,500."

Subsec. (a)(2). Pub. L. 105–392, §134(a)(2), substituted "the amount of the loan may, in the case of the third or fourth year of a student at a school of medicine or osteopathic medicine, be increased to the extent necessary" for "the amount $2,500 may, in the case of the third or fourth year of a student at school of medicine or osteopathic medicine, be increased to the extent necessary (including such $2,500)".

Subsec. (c). Pub. L. 105–392, §134(a)(3), in heading, substituted "repayment" for "ten-year" and, in introductory provisions, substituted "period of not less than 10 years nor more than 25 years, at the discretion of the institution, which begins" for "ten-year period which begins" and "such period" for "such ten-year period".

Subsec. (j). Pub. L. 105–392, §134(a)(4), substituted "$40" for "$15".

Subsec. (m). Pub. L. 105–392, §134(b)(1), added subsec. (m).

1993—Subsec. (a). Pub. L. 103–43, §2014(b)(1), amended heading and text of subsec. (a) generally. Prior to amendment, text read as follows: "Loans from a student loan fund (established under an agreement with a

school under section 292q of this title) may not exceed for any student for each school year (or its equivalent) the sum of—

"(1) the cost of tuition for such year at such school, and

"(2) $2,500."

Subsec. (b)(2), (3). Pub. L. 103–43, §2014(b)(2), redesignated par. (3) as (2) and struck out former par. (2), which read as follows: "who, if pursuing a full-time course of study at the school leading to a degree of doctor of medicine or doctor of osteopathy, is of exceptional financial need (as defined by regulations of the Secretary); and".

STATUTORY NOTES AND RELATED SUBSIDIARIES

EFFECTIVE DATE OF 1998 AMENDMENT

Pub. L. 105–392, title I, §134(b)(2), Nov. 13, 1998, 112 Stat. 3578, provided that: "The amendment made by paragraph (1) [amending this section] shall be effective with respect to actions pending on or after the date of enactment of this Act [Nov. 13, 1998]."

[1] *So in original. Probably should be "under this subpart".*

§292s. Medical schools and primary health care

(a) Requirements for students

(1) In general

Subject to the provisions of this subsection, in the case of student loan funds established under section 292q of this title by schools of medicine or osteopathic medicine, each agreement entered into under such section with such a school shall provide (in addition to the provisions required in subsection (b) of such section) that the school will make a loan from such fund to a student only if the student agrees—

(A) to enter and complete a residency training program in primary health care not later than 4 years after the date on which the student graduates from such school; and

(B) to practice in such care for 10 years (including residency training in primary health care) or through the date on which the loan is repaid in full, whichever occurs first.

(2) Inapplicability to certain students

(A) The requirement established in paragraph (1) regarding the student loan fund of a school does not apply to a student if—

(i) the first loan to the student from such fund is made before July 1, 1993; or

(ii) the loan is made from—

(I) a Federal capital contribution under section 292q of this title that is made from amounts appropriated under section 292t(f) [1] of this title (in this section referred to as an "exempt Federal capital contribution"); or

(II) a school contribution made under section 292q of this title pursuant to such a Federal capital contribution (in this section referred to as an "exempt school contribution").

(B) A Federal capital contribution under section 292q of this title may not be construed as being an exempt Federal capital contribution if the contribution was made from amounts appropriated before October 1, 1990. A school contribution under section 292q of this title may not be construed as being an exempt school contribution if the contribution was made pursuant to a Federal capital contribution under such section that was made from amounts appropriated before such date.

(3) Noncompliance by student

Each agreement entered into with a student pursuant to paragraph (1) shall provide that, if the student fails to comply with such agreement, the loan involved will begin to accrue interest at a

rate of 2 percent per year greater than the rate at which the student would pay if compliant in such year.

(4) Waivers

(A) With respect to the obligation of an individual under an agreement made under paragraph (1) as a student, the Secretary shall provide for the partial or total waiver or suspension of the obligation whenever compliance by the individual is impossible, or would involve extreme hardship to the individual, and if enforcement of the obligation with respect to the individual would be unconscionable.

(B) For purposes of subparagraph (A), the obligation of an individual shall be waived if—

(i) the status of the individual as a student of the school involved is terminated before graduation from the school, whether voluntarily or involuntarily; and

(ii) the individual does not, after such termination, resume attendance at the school or begin attendance at any other school of medicine or osteopathic medicine.

(C) If an individual resumes or begins attendance for purposes of subparagraph (B), the obligation of the individual under the agreement under paragraph (1) shall be considered to have been suspended for the period in which the individual was not in attendance.

(D) This paragraph may not be construed as authorizing the waiver or suspension of the obligation of a student to repay, in accordance with section 292r of this title, loans from student loan funds under section 292q of this title.

(b) Requirements for schools

(1) In general

Subject to the provisions of this subsection, in the case of student loan funds established under section 292q of this title by schools of medicine or osteopathic medicine, each agreement entered into under such section with such a school shall provide (in addition to the provisions required in subsection (b) of such section) that, for the 1-year period ending on June 30, 1997; [2] and for the 1-year period ending on June 30 of each subsequent fiscal year, the school will meet not less than 1 of the conditions described in paragraph (2) with respect to graduates of the school whose date of graduation from the school occurred approximately 4 years before the end of the 1-year period involved.

(2) Description of conditions

With respect to graduates described in paragraph (1) (in this paragraph referred to as "designated graduates"), the conditions referred to in such paragraph for a school for a 1-year period are as follows:

(A) Not less than 50 percent of designated graduates of the school meet the criterion of either being in a residency training program in primary health care, or being engaged in a practice in such care (having completed such a program).

(B) Not less than 25 percent of the designated graduates of the school meet such criterion, and such percentage is not less than 5 percentage points above the percentage of such graduates meeting such criterion for the preceding 1-year period.

(C) In the case of schools of medicine or osteopathic medicine with student loans funds under section 292q of this title, the school involved is at or above the 75th percentile of such schools whose designated graduates meet such criterion.

(3) Determinations by Secretary

Not later than 90 days after the close of each 1-year period described in paragraph (1), the Secretary shall make a determination of whether the school involved has for such period complied with such paragraph and shall in writing inform the school of the determination. Such determination shall be made only after consideration of the report submitted to the Secretary by the school under paragraph (6).

(4) Noncompliance by school

(A)(i) Subject to subparagraph (C), each agreement under section 292q of this title with a school of medicine or osteopathic medicine shall provide that, if the school fails to comply with paragraph (1) for a 1-year period under such paragraph, the school—

(I) will pay to the Secretary the amount applicable under subparagraph (B) for the period; and

(II) will pay such amount not later than 90 days after the school is informed under paragraph (3) of the determination of the Secretary regarding such period.

(ii) Any amount that a school is required to pay under clause (i) may be paid from the student loan fund of the school under section 292q of this title.

(B) For purposes of subparagraph (A), the amount applicable for a school, subject to subparagraph (C), is—

(i) for the 1-year period ending June 30, 1997, an amount equal to 10 percent of the income received during such period by the student loan fund of the school under section 292q of this title;

(ii) for the 1-year period ending June 30, 1998, an amount equal to 20 percent of the income received during such period by the student loan fund; and

(iii) for any subsequent 1-year period under paragraph (1), an amount equal to 30 percent of the income received during such period by the student loan fund.

(C) In determining the amount of income that a student loan fund has received for purposes of subparagraph (B), the Secretary shall exclude any income derived from exempt contributions. Payments made to the Secretary under subparagraph (A) may not be made with such contributions or with income derived from such contributions.

(5) Expenditure of payments

(A) Amounts paid to the Secretary under paragraph (4) shall be expended to make Federal capital contributions to student loan funds under section 292q of this title of schools that are in compliance with paragraph (1).

(B) A Federal capital contribution under section 292q of this title may not be construed as being an exempt Federal capital contribution if the contribution is made from payments under subparagraph (A). A school contribution under such section may not be construed as being an exempt school contribution if the contribution is made pursuant to a Federal capital contribution from such payments.

(6) Reports by schools

Each agreement under section 292q of this title with a school of medicine or osteopathic medicine shall provide that the school will submit to the Secretary a report for each 1-year period under paragraph (1) that provides such information as the Secretary determines to be necessary for carrying out this subsection. Each such report shall include statistics concerning the current training or practice status of all graduates of such school whose date of graduation from the school occurred approximately 4 years before the end of the 1-year period involved.

(c) Definitions

For purposes of this section:

(1) The term "exempt contributions" means exempt Federal capital contributions and exempt school contributions.

(2) The term "exempt Federal capital contribution" means a Federal capital contribution described in subclause (I) of subsection (a)(2)(A)(ii).

(3) The term "exempt school contribution" means a school contribution described in subclause (II) of subsection (a)(2)(A)(ii).

(4) The term "income", with respect to a student fund under section 292q of this title, means payments of principal and interest on any loan made from the fund, and any other earnings of the fund.

(5) The term "primary health care" means family medicine, general internal medicine, general

pediatrics, preventive medicine, or osteopathic general practice.

(d) Sense of Congress

It is the sense of Congress that funds repaid under the loan program under this section should not be transferred to the Treasury of the United States or otherwise used for any other purpose other than to carry out this section.

(July 1, 1944, ch. 373, title VII, §723, as added Pub. L. 102–408, title I, §102, Oct. 13, 1992, 106 Stat. 2015; amended Pub. L. 103–43, title XX, §2014(c), June 10, 1993, 107 Stat. 216; Pub. L. 105–392, title I, §131, Nov. 13, 1998, 112 Stat. 3574; Pub. L. 111–148, title V, §5201(a), Mar. 23, 2010, 124 Stat. 606.)

EDITORIAL NOTES

REFERENCES IN TEXT

Section 292t(f) of this title, referred to in subsec. (a)(2)(A)(ii)(I), contained provisions in par. (1) relating to appropriation of funds for Federal capital contributions to student loan funds, prior to repeal by Pub. L. 105–392, title I, §132(b), Nov. 13, 1998, 112 Stat. 3575, eff. Oct. 1, 2002.

PRIOR PROVISIONS

A prior section 723 of act July 1, 1944, was classified to section 293c of this title prior to the general revision of this subchapter by Pub. L. 102–408.

AMENDMENTS

2010—Subsec. (a)(1)(B). Pub. L. 111–148, §5201(a)(1)(A), added subpar. (B) and struck out former subpar. (B) which read as follows: "to practice in such care through the date on which the loan is repaid in full."

Subsec. (a)(3). Pub. L. 111–148, §5201(a)(1)(B), added par. (3) and struck out former par. (3). Prior to amendment, text read as follows: "Each agreement entered into with a student pursuant to paragraph (1) shall provide that, if the student fails to comply with such agreement, the loan involved will begin to accrue interest at a rate of 18 percent per year beginning on the date of such noncompliance."

Subsec. (d). Pub. L. 111–148, §5201(a)(2), added subsec. (d).

1998—Subsec. (a)(3). Pub. L. 105–392, §131(b), reenacted heading without change and amended text of par. (3) generally. Prior to amendment, text read as follows: "Each agreement entered into with a student pursuant to paragraph (1) shall provide that, if the student fails to comply with the agreement—

"(A) the balance due on the loan involved will be immediately recomputed from the date of issuance at an interest rate of 12 percent per year, compounded annually; and

"(B) the recomputed balance will be paid not later than the expiration of the 3-year period beginning on the date on which the student fails to comply with the agreement."

Subsec. (b)(1). Pub. L. 105–392, §131(a), substituted "4 years before" for "3 years before".

Subsecs. (c), (d). Pub. L. 105–392, §131(c), redesignated subsec. (d) as (c) and struck out heading and text of subsec. (c). Text read as follows: "The Secretary shall each fiscal year submit to the Committee on Energy and Commerce of the House of Representatives, and the Committee on Labor and Human Resources of the Senate, a report regarding the administration of this section, including the extent of compliance with the requirements of this section, during the preceding fiscal year."

1993—Subsec. (a)(4). Pub. L. 103–43, §2014(c)(1), added par. (4).

Subsec. (b)(1). Pub. L. 103–43, §2014(c)(2)(A), substituted "1997;" for "1994," and "3 years before" for "4 years before".

Subsec. (b)(2)(B). Pub. L. 103–43, §2014(c)(2)(B), substituted "25 percent" for "15 percent".

Subsec. (b)(4)(B). Pub. L. 103–43, §2014(c)(2)(C), substituted "1997" for "1994" in cl. (i) and "1998" for "1995" in cl. (ii).

STATUTORY NOTES AND RELATED SUBSIDIARIES

STUDENT LOAN GUIDELINES

Pub. L. 111–148, title V, §5201(b), Mar. 23, 2010, 124 Stat. 607, provided that: "The Secretary of Health and Human Services shall not require parental financial information for an independent student to determine financial need under section 723 of the Public Health Service Act (42 U.S.C. 292s) and the determination of

need for such information shall be at the discretion of applicable school loan officer. The Secretary shall amend guidelines issued by the Health Resources and Services Administration in accordance with the preceding sentence."

[1] *See References in Text note below.*

[2] *So in original. The semicolon probably should be a comma.*

§292t. Individuals from disadvantaged backgrounds

(a) Fund agreements regarding certain amounts

With respect to amounts appropriated under subsection (f), each agreement entered into under section 292q of this title with a school shall provide (in addition to the provisions required in subsection (b) of such section) that—

(1) any Federal capital contribution made to the student loan fund of the school from such amounts, together with the school contribution appropriate under subsection (b)(2)(B) of such section to the amount of the Federal capital contribution, will be utilized only for the purpose of—

(A) making loans to individuals from disadvantaged backgrounds; and

(B) the costs of the collection of the loans and interest on the loans; and

(2) collections of principal and interest on loans made pursuant to paragraph (1), and any other earnings of the student loan fund attributable to amounts that are in the fund pursuant to such paragraph, will be utilized only for the purpose described in such paragraph.

(b) Minimum qualifications for schools

The Secretary may not make a Federal capital contribution for purposes of subsection (a) for a fiscal year unless the health professions school involved—

(1) is carrying out a program for recruiting and retaining students from disadvantaged backgrounds, including racial and ethnic minorities; and

(2) is carrying out a program for recruiting and retaining minority faculty.

(c) Certain agreements regarding education of students; date certain for compliance

The Secretary may not make a Federal capital contribution for purposes of subsection (a) for a fiscal year unless the health professions school involved agrees—

(1) to ensure that adequate instruction regarding minority health issues is provided for in the curricula of the school;

(2) with respect to health clinics providing services to a significant number of individuals who are from disadvantaged backgrounds, including members of minority groups, to enter into arrangements with 1 or more such clinics for the purpose of providing students of the school with experience in providing clinical services to such individuals;

(3) with respect to public or nonprofit private secondary educational institutions and undergraduate institutions of higher education, to enter into arrangements with 1 or more such institutions for the purpose of carrying out programs regarding the educational preparation of disadvantaged students, including minority students, to enter the health professions and regarding the recruitment of such individuals into the health professions;

(4) to establish a mentor program for assisting disadvantaged students, including minority students, regarding the completion of the educational requirements for degrees from the school;

(5) to be carrying out each of the activities specified in any of paragraphs (1) through (4) by not later than 1 year after the date on which the first Federal capital contribution is made to the school for purposes of subsection (a); and

(6) to continue carrying out such activities, and the activities specified in paragraphs (1) and (2) of subsection (b), throughout the period during which the student loan fund established pursuant to section 292q(b) of this title is in operation.

(d) Availability of other amounts

With respect to Federal capital contributions to student loan funds under agreements under section 292q(b) of this title, any such contributions made before October 1, 1990, together with the school contributions appropriate under paragraph (2)(B) of such section to the amount of the Federal capital contributions, may be utilized for the purpose of making loans to individuals from disadvantaged backgrounds, subject to section 292s(a)(2)(B) of this title.

(e) "Disadvantaged" defined

For purposes of this section, the term "disadvantaged", with respect to an individual, shall be defined by the Secretary.

(f) Authorization of appropriations

(1) Repealed. Pub. L. 105–392, title I, §132(b), Nov. 13, 1998, 112 Stat. 3575

(2) Special consideration for certain schools

In making Federal capital contributions to student loan funds for purposes of subsection (a), the Secretary shall give special consideration to health professions schools that have enrollments of underrepresented minorities above the national average for health professions schools.

(July 1, 1944, ch. 373, title VII, §724, as added Pub. L. 102–408, title I, §102, Oct. 13, 1992, 106 Stat. 2018; amended Pub. L. 105–392, title I, §132, Nov. 13, 1998, 112 Stat. 3575.)

EDITORIAL NOTES

PRIOR PROVISIONS

A prior section 724 of act July 1, 1944, was classified to section 293d of this title prior to the general revision of this subchapter by Pub. L. 102–408.

AMENDMENTS

1998—Subsec. (f)(1). Pub. L. 105–392, §132(b), struck out heading and text of par. (1). Text read as follows: "With respect to making Federal capital contributions to student loan funds for purposes of subsection (a) of this section, there is authorized to be appropriated for such contributions $8,000,000 for each of the fiscal years 1998 through 2002."

Pub. L. 105–392, §132(a), substituted "$8,000,000 for each of the fiscal years 1998 through 2002" for "$15,000,000 for fiscal year 1993".

STATUTORY NOTES AND RELATED SUBSIDIARIES

EFFECTIVE DATE OF 1998 AMENDMENT

Pub. L. 105–392, title I, §132(b), Nov. 13, 1998, 112 Stat. 3575, provided that the repeal of subsec. (f)(1) of this section is effective Oct. 1, 2002.

§292u. Administrative provisions

The Secretary may agree to modifications of agreements or loans made under this subpart, and may compromise, waive, or release any right, title, claim, or demand of the United States arising or acquired under this subpart.

(July 1, 1944, ch. 373, title VII, §725, as added Pub. L. 102–408, title I, §102, Oct. 13, 1992, 106 Stat. 2019.)

EDITORIAL NOTES

PRIOR PROVISIONS

A prior section 725 of act July 1, 1944, was classified to section 293e of this title prior to the general revision of this subchapter by Pub. L. 102–408.

STATUTORY NOTES AND RELATED SUBSIDIARIES

HEALTH PROFESSIONS EDUCATION FUND; AVAILABILITY OF FUND; DEPOSIT IN FUND OF: INTEREST PAYMENTS OR REPAYMENTS OF PRINCIPAL ON LOANS; TRANSFER OF EXCESS MONEYS TO GENERAL FUND OF THE TREASURY; AUTHORIZATION OF APPROPRIATIONS FOR PAYMENTS UNDER AGREEMENTS

Pub. L. 94–484, title IV, §406(b), (c), Oct. 12, 1976, 90 Stat. 2268, provided that:

"(b) The health professions education fund created within the Treasury by section 744(d)(1) of the Public Health Service Act (as in effect before the date of enactment of this Act) [former 42 U.S.C. 294d(d)(1)] shall remain available to the Secretary of Health, Education, and Welfare [now Health and Human Services] for the purpose of meeting his responsibilities respecting participations in obligations acquired under such section. The Secretary shall continue to deposit in such fund all amounts received by him as interest payments or repayments of principal on loans under such section 744 [former 42 U.S.C. 294d]. If at any time the Secretary determines the moneys in the fund exceed the present and any reasonable prospective future requirements of such fund, such excess may be transferred to the general fund of the Treasury.

"(c) There are authorized to be appropriated without fiscal year limitation such sums as may be necessary to enable the Secretary to make payments under agreements entered into under section 744(b) [former 42 U.S.C. 294d(b)] of the Public Health Service Act before September 30, 1977."

§292v. Provision by schools of information to students

(a) In general

With respect to loans made by a school under this subpart after June 30, 1986, each school, in order to carry out the provisions of sections 292q and 292r of this title, shall, at any time such school makes such a loan to a student under this subpart, provide thorough and adequate loan information on loans made under this subpart to the student. The loan information required to be provided to the student by this subsection shall include—

(1) the yearly and cumulative maximum amounts that may be borrowed by the student;

(2) the terms under which repayment of the loan will begin;

(3) the maximum number of years in which the loan must be repaid;

(4) the interest rate that will be paid by the borrower and the minimum amount of the required monthly payment;

(5) the amount of any other fees charged to the borrower by the lender;

(6) any options the borrower may have for deferral, cancellation, prepayment, consolidation, or other refinancing of the loan;

(7) a definition of default on the loan and a specification of the consequences which will result to the borrower if the borrower defaults, including a description of any arrangements which may be made with credit bureau organizations;

(8) to the extent practicable, the effect of accepting the loan on the eligibility of the borrower for other forms of student assistance; and

(9) a description of the actions that may be taken by the Federal Government to collect the loan, including a description of the type of information concerning the borrower that the Federal Government may disclose to (A) officers, employees, or agents of the Department of Health and Human Services, (B) officers, employees, or agents of schools with which the Secretary has an agreement under this subpart, or (C) any other person involved in the collection of a loan under this subpart.

(b) Statement regarding loan

Each school shall, immediately prior to the graduation from such school of a student who receives a loan under this subpart after June 30, 1986, provide such student with a statement specifying—

(1) each amount borrowed by the student under this subpart;

(2) the total amount borrowed by the student under this subpart; and

(3) a schedule for the repayment of the amounts borrowed under this subpart, including the

number, amount, and frequency of payments to be made.

(July 1, 1944, ch. 373, title VII, §726, as added Pub. L. 102–408, title I, §102, Oct. 13, 1992, 106 Stat. 2020.)

EDITORIAL NOTES

PRIOR PROVISIONS

A prior section 726 of act July 1, 1944, was classified to section 293f of this title prior to the general revision of this subchapter by Pub. L. 102–408.

Another prior section 726 of act July 1, 1944, was classified to section 293f of this title prior to repeal by Pub. L. 94–484.

§292w. Procedures for appeal of termination of agreements

In any case in which the Secretary intends to terminate an agreement with a school under this subpart, the Secretary shall provide the school with a written notice specifying such intention and stating that the school may request a formal hearing with respect to such termination. If the school requests such a hearing within 30 days after the receipt of such notice, the Secretary shall provide such school with a hearing conducted by an administrative law judge.

(July 1, 1944, ch. 373, title VII, §727, as added Pub. L. 102–408, title I, §102, Oct. 13, 1992, 106 Stat. 2020.)

EDITORIAL NOTES

PRIOR PROVISIONS

A prior section 727 of act July 1, 1944, was classified to section 294 of this title prior to the general revision of this subchapter by Pub. L. 102–408.

Another prior section 727 of act July 1, 1944, was classified to section 293g of this title prior to renumbering by Pub. L. 94–484.

§292x. Distribution of assets from loan funds

(a) Distribution after termination of fund

If a school terminates a loan fund established under an agreement pursuant to section 292q(b) of this title, or if the Secretary for good cause terminates the agreement with the school, there shall be a capital distribution as follows:

(1) The Secretary shall first be paid an amount which bears the same ratio to such balance in such fund on the date of termination of the fund as the total amount of the Federal capital contributions to such fund by the Secretary pursuant to section 292q(b)(2)(A) of this title bears to the total amount in such fund derived from such Federal capital contributions and from funds deposited therein pursuant to section 292q(b)(2)(B) of this title.

(2) The remainder of such balance shall be paid to the school.

(b) Payment of proportionate share to Secretary

If a capital distribution is made under subsection (a), the school involved shall, after the capital distribution, pay to the Secretary, not less often than quarterly, the same proportionate share of amounts received by the school in payment of principal or interest on loans made from the loan fund established pursuant to section 292q(b) of this title as was determined by the Secretary under subsection (a).

(July 1, 1944, ch. 373, title VII, §728, as added Pub. L. 102–408, title I, §102, Oct. 13, 1992, 106 Stat. 2021.)

EDITORIAL NOTES

PRIOR PROVISIONS

A prior section 728 of act July 1, 1944, was classified to section 294a of this title prior to the general revision of this subchapter by Pub. L. 102–408.

Another prior section 728 of act July 1, 1944, was classified to section 293h of this title prior to renumbering by Pub. L. 94–484.

§292y. General provisions

(a) Date certain for applications

The Secretary shall from time to time set dates by which schools must file applications for Federal capital contributions.

(b) Contingent reduction in allotments

If the total of the amounts requested for any fiscal year in such applications exceeds the amounts appropriated under this section for that fiscal year, the allotment to the loan fund of each such school shall be reduced to whichever of the following is the smaller: (A) the amount requested in its application; or (B) an amount which bears the same ratio to the amounts appropriated as the number of students estimated by the Secretary to be enrolled in such school during such fiscal year bears to the estimated total number of students in all such schools during such year. Amounts remaining after allotment under the preceding sentence shall be reallotted in accordance with clause (B) of such sentence among schools whose applications requested more than the amounts so allotted to their loan funds, but with such adjustments as may be necessary to prevent the total allotted to any such school's loan fund from exceeding the total so requested by it.

(c) Allotment of excess funds

Funds available in any fiscal year for payment to schools under this subpart which are in excess of the amount appropriated pursuant to this section for that year shall be allotted among schools in such manner as the Secretary determines will best carry out the purposes of this subpart.

(d) Payment of installments to schools

Allotments to a loan fund of a school shall be paid to it from time to time in such installments as the Secretary determines will not result in unnecessary accumulations in the loan fund at such school.

(e) Disposition of funds returned to Secretary

(1) Expenditure for Federal capital contributions

Subject to section 292s(b)(5) of this title, any amounts from student loan funds under section 292q of this title that are returned to the Secretary by health professions schools shall be expended to make Federal capital contributions to such funds.

(2) Date certain for contributions

Amounts described in paragraph (1) that are returned to the Secretary shall be obligated before the end of the succeeding fiscal year.

(3) Preference in making contributions

In making Federal capital contributions to student loans funds under section 292q of this title for a fiscal year from amounts described in paragraph (1), the Secretary shall give preference to health professions schools of the same disciplines as the health professions schools returning such amounts for the period during which the amounts expended for such contributions were received by the Secretary. Any such amounts that, prior to being so returned, were available only for the purpose of loans under this subpart to individuals from disadvantaged backgrounds shall be available only for such purpose.

(f) Funding for certain medical schools

(1) Authorization of appropriations

For the purpose of making Federal capital contributions to student loan funds established under section 292q of this title by schools of medicine or osteopathic medicine, there is authorized to be appropriated $10,000,000 for each of the fiscal years 1994 through 1996.

(2) Minimum requirements

(A) Subject to subparagraph (B), the Secretary may make a Federal capital contribution pursuant to paragraph (1) only if the school of medicine or osteopathic medicine involved meets the conditions described in subparagraph (A) of section 292s(b)(2) of this title or the conditions described in subparagraph (C) of such section.

(B) For purposes of subparagraph (A), the conditions referred to in such subparagraph shall be applied with respect to graduates of the school involved whose date of graduation occurred approximately 3 years before June 30 of the fiscal year preceding the fiscal year for which the Federal capital contribution involved is made.

(July 1, 1944, ch. 373, title VII, §735, as added Pub. L. 102–408, title I, §102, Oct. 13, 1992, 106 Stat. 2021; amended Pub. L. 102–531, title III, §313(a)(1), Oct. 27, 1992, 106 Stat. 3507; Pub. L. 103–43, title XX, §2014(d), June 10, 1993, 107 Stat. 217; Pub. L. 105–392, title I, §134(c), Nov. 13, 1998, 112 Stat. 3578.)

EDITORIAL NOTES

PRIOR PROVISIONS

A prior section 735 of act July 1, 1944, was classified to section 294h of this title prior to the general revision of this subchapter by Pub. L. 102–408.

AMENDMENTS

1998—Subsec. (e)(2). Pub. L. 105–392 reenacted heading without change and amended text of par. (2) generally. Prior to amendment, text read as follows: "Amounts described in paragraph (1) that are returned to the Secretary before the fourth quarter of a fiscal year shall be obligated before the end of such fiscal year, and may not be obligated before the fourth quarter. For purposes of the preceding sentence, amounts returned to the Secretary during the last quarter of a fiscal year are deemed to have been returned during the first three quarters of the succeeding fiscal year."

1993—Subsec. (f). Pub. L. 103–43 added subsec. (f).

1992—Subsec. (b). Pub. L. 102–531 inserted designations for cls. (A) and (B) in first sentence.

STATUTORY NOTES AND RELATED SUBSIDIARIES

EFFECTIVE DATE OF 1992 AMENDMENT

Pub. L. 102–531, title III, §313(c), Oct. 27, 1992, 106 Stat. 3507, provided that: "The amendments described in this section [amending this section and sections 293j, 293l, 294n, 295j, 295l, 295n, 295o, 296k, and 298b–7 of this title, repealing section 297j of this title, redesignating subpart IV of part B of subchapter VI of this chapter as subpart III, and amending provisions set out as a note under section 295k of this title] are made, and take effect, immediately after the enactment of the bill, H.R. 3508, of the One Hundred Second Congress [Pub. L. 102–408, approved Oct. 13, 1992]."

PART B—HEALTH PROFESSIONS TRAINING FOR DIVERSITY

§293. Centers of excellence

(a) In general

The Secretary shall make grants to, and enter into contracts with, designated health professions schools described in subsection (c), and other public and nonprofit health or educational entities, for the purpose of assisting the schools in supporting programs of excellence in health professions education for under-represented minority individuals.

(b) Required use of funds

The Secretary may not make a grant under subsection (a) unless the designated health professions school involved agrees, subject to subsection (c)(1)(C), to expend the grant—

(1) to develop a large competitive applicant pool through linkages with institutions of higher education, local school districts, and other community-based entities and establish an education pipeline for health professions careers;

(2) to establish, strengthen, or expand programs to enhance the academic performance of under-represented minority students attending the school;

(3) to improve the capacity of such school to train, recruit, and retain under-represented minority faculty including the payment of such stipends and fellowships as the Secretary may determine appropriate;

(4) to carry out activities to improve the information resources, clinical education, curricula and cultural competence of the graduates of the school, as it relates to minority health issues;

(5) to facilitate faculty and student research on health issues particularly affecting under-represented minority groups, including research on issues relating to the delivery of health care;

(6) to carry out a program to train students of the school in providing health services to a significant number of under-represented minority individuals through training provided to such students at community-based health facilities that—

(A) provide such health services; and

(B) are located at a site remote from the main site of the teaching facilities of the school; and

(7) to provide stipends as the Secretary determines appropriate, in amounts as the Secretary determines appropriate.

(c) Centers of excellence

(1) Designated schools

(A) In general

The designated health professions schools referred to in subsection (a) are such schools that meet each of the conditions specified in subparagraphs (B) and (C), and that—

(i) meet each of the conditions specified in paragraph (2)(A);

(ii) meet each of the conditions specified in paragraph (3);

(iii) meet each of the conditions specified in paragraph (4); or

(iv) meet each of the conditions specified in paragraph (5).

(B) General conditions

The conditions specified in this subparagraph are that a designated health professions school—

(i) has a significant number of under-represented minority individuals enrolled in the school, including individuals accepted for enrollment in the school;

(ii) has been effective in assisting under-represented minority students of the school to complete the program of education and receive the degree involved;

(iii) has been effective in recruiting under-represented minority individuals to enroll in and graduate from the school, including providing scholarships and other financial assistance to such individuals and encouraging under-represented minority students from all levels of the educational pipeline to pursue health professions careers; and

(iv) has made significant recruitment efforts to increase the number of under-represented minority individuals serving in faculty or administrative positions at the school.

(C) Consortium

The condition specified in this subparagraph is that, in accordance with subsection (e)(1), the designated health profession school involved has with other health profession schools (designated or otherwise) formed a consortium to carry out the purposes described in subsection (b) at the schools of the consortium.

(D) Application of criteria to other programs

In the case of any criteria established by the Secretary for purposes of determining whether schools meet the conditions described in subparagraph (B), this section may not, with respect to racial and ethnic minorities, be construed to authorize, require, or prohibit the use of such criteria in any program other than the program established in this section.

(2) Centers of excellence at certain historically black colleges and universities

(A) Conditions

The conditions specified in this subparagraph are that a designated health professions school—

(i) is a school described in section 295p(1) of this title; and

(ii) received a contract under section 295g–8b of this title for fiscal year 1987, as such section was in effect for such fiscal year.

(B) Use of grant

In addition to the purposes described in subsection (b), a grant under subsection (a) to a designated health professions school meeting the conditions described in subparagraph (A) may be expended—

(i) to develop a plan to achieve institutional improvements, including financial independence, to enable the school to support programs of excellence in health professions education for under-represented minority individuals; and

(ii) to provide improved access to the library and informational resources of the school.

(C) Exception

The requirements of paragraph (1)(C) shall not apply to a historically black college or university that receives funding under paragraphs [1] (2) or (5).

(3) Hispanic centers of excellence

The conditions specified in this paragraph are that—

(A) with respect to Hispanic individuals, each of clauses (i) through (iv) of paragraph (1)(B) applies to the designated health professions school involved;

(B) the school agrees, as a condition of receiving a grant under subsection (a), that the school will, in carrying out the duties described in subsection (b), give priority to carrying out the duties with respect to Hispanic individuals; and

(C) the school agrees, as a condition of receiving a grant under subsection (a), that—

(i) the school will establish an arrangement with 1 or more public or nonprofit community based Hispanic serving organizations, or public or nonprofit private institutions of higher education, including schools of nursing, whose enrollment of students has traditionally included a significant number of Hispanic individuals, the purposes of which will be to carry out a program—

(I) to identify Hispanic students who are interested in a career in the health profession involved; and

(II) to facilitate the educational preparation of such students to enter the health professions school; and

(ii) the school will make efforts to recruit Hispanic students, including students who have participated in the undergraduate or other matriculation program carried out under arrangements established by the school pursuant to clause (i)(II) and will assist Hispanic

students regarding the completion of the educational requirements for a degree from the school.

(4) Native American centers of excellence

Subject to subsection (e), the conditions specified in this paragraph are that—

(A) with respect to Native Americans, each of clauses (i) through (iv) of paragraph (1)(B) applies to the designated health professions school involved;

(B) the school agrees, as a condition of receiving a grant under subsection (a), that the school will, in carrying out the duties described in subsection (b), give priority to carrying out the duties with respect to Native Americans; and

(C) the school agrees, as a condition of receiving a grant under subsection (a), that—

(i) the school will establish an arrangement with 1 or more public or nonprofit private institutions of higher education, including schools of nursing, whose enrollment of students has traditionally included a significant number of Native Americans, the purpose of which arrangement will be to carry out a program—

(I) to identify Native American students, from the institutions of higher education referred to in clause (i), who are interested in health professions careers; and

(II) to facilitate the educational preparation of such students to enter the designated health professions school; and

(ii) the designated health professions school will make efforts to recruit Native American students, including students who have participated in the undergraduate program carried out under arrangements established by the school pursuant to clause (i) and will assist Native American students regarding the completion of the educational requirements for a degree from the designated health professions school.

(5) Other centers of excellence

The conditions specified in this paragraph are—

(A) with respect to other centers of excellence, the conditions described in clauses (i) through (iv) of paragraph (1)(B); and

(B) that the health professions school involved has an enrollment of under-represented minorities above the national average for such enrollments of health professions schools.

(d) Designation as center of excellence

(1) In general

Any designated health professions school receiving a grant under subsection (a) and meeting the conditions described in paragraph (2) or (5) of subsection (c) shall, for purposes of this section, be designated by the Secretary as a Center of Excellence in Under-Represented Minority Health Professions Education.

(2) Hispanic centers of excellence

Any designated health professions school receiving a grant under subsection (a) and meeting the conditions described in subsection (c)(3) shall, for purposes of this section, be designated by the Secretary as a Hispanic Center of Excellence in Health Professions Education.

(3) Native American centers of excellence

Any designated health professions school receiving a grant under subsection (a) and meeting the conditions described in subsection (c)(4) shall, for purposes of this section, be designated by the Secretary as a Native American Center of Excellence in Health Professions Education. Any consortium receiving such a grant pursuant to subsection (e) shall, for purposes of this section, be so designated.

(e) Authority regarding Native American centers of excellence

With respect to meeting the conditions specified in subsection (c)(4), the Secretary may make a grant under subsection (a) to a designated health professions school that does not meet such

conditions if—

(1) the school has formed a consortium in accordance with subsection (d)(1); and

(2) the schools of the consortium collectively meet such conditions, without regard to whether the schools individually meet such conditions.

(f) Duration of grant

The period during which payments are made under a grant under subsection (a) may not exceed 5 years. Such payments shall be subject to annual approval by the Secretary and to the availability of appropriations for the fiscal year involved to make the payments.

(g) Definitions

In this section:

(1) Designated health professions school

(A) In general

The term "health professions school" means, except as provided in subparagraph (B), a school of medicine, a school of osteopathic medicine, a school of dentistry, a school of pharmacy, or a graduate program in behavioral or mental health.

(B) Exception

The definition established in subparagraph (A) shall not apply to the use of the term "designated health professions school" for purposes of subsection (c)(2).

(2) Program of excellence

The term "program of excellence" means any program carried out by a designated health professions school with a grant made under subsection (a), if the program is for purposes for which the school involved is authorized in subsection (b) or (c) to expend the grant.

(3) Native Americans

The term "Native Americans" means American Indians, Alaskan Natives, Aleuts, and Native Hawaiians.

(h) Formula for allocations

(1) Allocations

Based on the amount appropriated under subsection (i) for a fiscal year, the following subparagraphs shall apply as appropriate:

(A) In general

If the amounts appropriated under subsection (i) for a fiscal year are $24,000,000 or less—

(i) the Secretary shall make available $12,000,000 for grants under subsection (a) to health professions schools that meet the conditions described in subsection (c)(2)(A); and

(ii) and [2] available after grants are made with funds under clause (i), the Secretary shall make available—

(I) 60 percent of such amount for grants under subsection (a) to health professions schools that meet the conditions described in paragraph (3) or (4) of subsection (c) (including meeting the conditions under subsection (e)); and

(II) 40 percent of such amount for grants under subsection (a) to health professions schools that meet the conditions described in subsection (c)(5).

(B) Funding in excess of $24,000,000

If amounts appropriated under subsection (i) for a fiscal year exceed $24,000,000 but are less than $30,000,000—

(i) 80 percent of such excess amounts shall be made available for grants under subsection (a) to health professions schools that meet the requirements described in paragraph (3) or (4) of subsection (c) (including meeting conditions pursuant to subsection (e)); and

(ii) 20 percent of such excess amount shall be made available for grants under subsection

(a) to health professions schools that meet the conditions described in subsection (c)(5).

(C) Funding in excess of $30,000,000

If amounts appropriated under subsection (i) for a fiscal year exceed $30,000,000 but are less than $40,000,000, the Secretary shall make available—

(i) not less than $12,000,000 for grants under subsection (a) to health professions schools that meet the conditions described in subsection (c)(2)(A);

(ii) not less than $12,000,000 for grants under subsection (a) to health professions schools that meet the conditions described in paragraph (3) or (4) of subsection (c) (including meeting conditions pursuant to subsection (e));

(iii) not less than $6,000,000 for grants under subsection (a) to health professions schools that meet the conditions described in subsection (c)(5); and

(iv) after grants are made with funds under clauses (i) through (iii), any remaining excess amount for grants under subsection (a) to health professions schools that meet the conditions described in paragraph (2)(A), (3), (4), or (5) of subsection (c).

(D) Funding in excess of $40,000,000

If amounts appropriated under subsection (i) for a fiscal year are $40,000,000 or more, the Secretary shall make available—

(i) not less than $16,000,000 for grants under subsection (a) to health professions schools that meet the conditions described in subsection (c)(2)(A);

(ii) not less than $16,000,000 for grants under subsection (a) to health professions schools that meet the conditions described in paragraph (3) or (4) of subsection (c) (including meeting conditions pursuant to subsection (e));

(iii) not less than $8,000,000 for grants under subsection (a) to health professions schools that meet the conditions described in subsection (c)(5); and

(iv) after grants are made with funds under clauses (i) through (iii), any remaining funds for grants under subsection (a) to health professions schools that meet the conditions described in paragraph (2)(A), (3), (4), or (5) of subsection (c).

(2) No limitation

Nothing in this subsection shall be construed as limiting the centers of excellence referred to in this section to the designated amount, or to preclude such entities from competing for grants under this section.

(3) Maintenance of effort

(A) In general

With respect to activities for which a grant made under this part are authorized to be expended, the Secretary may not make such a grant to a center of excellence for any fiscal year unless the center agrees to maintain expenditures of non-Federal amounts for such activities at a level that is not less than the level of such expenditures maintained by the center for the fiscal year preceding the fiscal year for which the school receives such a grant.

(B) Use of Federal funds

With respect to any Federal amounts received by a center of excellence and available for carrying out activities for which a grant under this part is authorized to be expended, the center shall, before expending the grant, expend the Federal amounts obtained from sources other than the grant, unless given prior approval from the Secretary.

(i) Authorization of appropriations

To carry out this section, there is authorized to be appropriated $23,711,000 for each of fiscal years 2021 through 2025.

(July 1, 1944, ch. 373, title VII, §736, as added Pub. L. 105–392, title I, §101(a), Nov. 13, 1998, 112 Stat. 3525; amended Pub. L. 111–148, title V, §5401, Mar. 23, 2010, 124 Stat. 642; Pub. L. 116–136, div. A, title III, §3401(1), Mar. 27, 2020, 134 Stat. 385.)

EDITORIAL NOTES

REFERENCES IN TEXT

Section 295g–8b of this title, referred to in subsec. (c)(2)(A)(ii), was omitted in the general amendment of this subchapter by Pub. L. 102–408, title I, §102, Oct. 13, 1992, 106 Stat. 1994.

PRIOR PROVISIONS

A prior section 293, act July 1, 1944, ch. 373, title VII, §736, as added Pub. L. 102–408, title I, §102, Oct. 13, 1992, 106 Stat. 2022, authorized grants to schools of medicine, osteopathic medicine, and dentistry for need-based scholarships, prior to the general amendment of this part by Pub. L. 105–392.

Another prior section 293, act July 1, 1944, ch. 373, title VII, §720, as added Sept. 24, 1963, Pub. L. 88–129, §2(b), 77 Stat. 164; amended Sept. 4, 1964, Pub. L. 88–581, §3(a), 78 Stat. 919; Oct. 22, 1965, Pub. L. 89–290, §3(a), 79 Stat. 1056; Nov. 2, 1966, Pub. L. 89–709, §2(a), 80 Stat. 1103; Aug. 16, 1968, Pub. L. 90–490, title I, §101(a), (b)(1), 82 Stat. 773; Nov. 18, 1971, Pub. L. 92–157, title I, §102(a), 85 Stat. 431; Oct. 12, 1976, Pub. L. 94–484, title I, §101(c), title III, §302, 90 Stat. 2244, 2253; Aug. 13, 1981, Pub. L. 97–35, title XXVII, §2723(a), (b), 95 Stat. 915, authorized grants for construction of teaching facilities for medical, dental, and other health personnel, prior to the general revision of this subchapter by Pub. L. 102–408.

A prior section 736 of act July 1, 1944, was classified to section 294i of this title prior to the general revision of this subchapter by Pub. L. 102–408.

AMENDMENTS

2020—Subsec. (i). Pub. L. 116–136 added subsec. (i) and struck out former subsec. (i). Text read as follows: "There are authorized to be appropriated to carry out this section—

"(1) $50,000,000 for each of the fiscal years 2010 through 2015; and

"(2) and such sums as are necessary for each subsequent fiscal year."

2010—Subsecs. (h), (i). Pub. L. 111–148 added subsecs. (h) and (i) and struck out former subsec. (h) which related to authorization of appropriations for fiscal years 1998 through 2002 and allocations of amounts.

STATUTORY NOTES AND RELATED SUBSIDIARIES

SAVINGS PROVISION

Pub. L. 105–392, title I, §110, Nov. 13, 1998, 112 Stat. 3562, provided that: "In the case of any authority for making awards of grants or contracts that is terminated by the amendments made by this subtitle [subtitle A (§§101–110) of title I of Pub. L. 105–392, see Tables for classification], the Secretary of Health and Human Services may, notwithstanding the termination of the authority, continue in effect any grant or contract made under the authority that is in effect on the day before the date of the enactment of this Act [Nov. 13, 1998], subject to the duration of any such grant or contract not exceeding the period determined by the Secretary in first approving such financial assistance, or in approving the most recent request made (before the date of such enactment) for continuation of such assistance, as the case may be."

[1] So in original. Probably should be "paragraph".

[2] So in original. The word "and" probably should not appear.

§293a. Scholarships for disadvantaged students

(a) In general

The Secretary may make a grant to an eligible entity (as defined in subsection (d)(1)) under this section for the awarding of scholarships by schools to any full-time student who is an eligible individual as defined in subsection (d). Such scholarships may be expended only for tuition expenses, other reasonable educational expenses, and reasonable living expenses incurred in the attendance of such school.

(b) Preference in providing scholarships

The Secretary may not make a grant to an entity under subsection (a) unless the health professions and nursing schools involved agree that, in providing scholarships pursuant to the grant, the schools will give preference to students for whom the costs of attending the schools would constitute a severe financial hardship and, notwithstanding other provisions of this section, to former recipients of scholarships under sections 293 and 293d(d)(2)(B) of this title (as such sections existed on the day before November 13, 1998).

(c) Amount of award

In awarding grants to eligible entities that are health professions and nursing schools, the Secretary shall give priority to eligible entities based on the proportion of graduating students going into primary care, the proportion of underrepresented minority students, and the proportion of graduates working in medically underserved communities.

(d) Definitions

In this section:

(1) Eligible entities

The term "eligible entities" means an entity that—

(A) is a school of medicine, osteopathic medicine, dentistry, nursing (as defined in section 296 of this title), pharmacy, podiatric medicine, optometry, veterinary medicine, public health, chiropractic, or allied health, a school offering a graduate program in behavioral and mental health practice, or an entity providing programs for the training of physician assistants; and

(B) is carrying out a program for recruiting and retaining students from disadvantaged backgrounds, including students who are members of racial and ethnic minority groups.

(2) Eligible individual

The term "eligible individual" means an individual who—

(A) is from a disadvantaged background;

(B) has a financial need for a scholarship; and

(C) is enrolled (or accepted for enrollment) at an eligible health professions or nursing school as a full-time student in a program leading to a degree in a health profession or nursing.

(July 1, 1944, ch. 373, title VII, §737, as added Pub. L. 105–392, title I, §101(a), Nov. 13, 1998, 112 Stat. 3531.)

EDITORIAL NOTES

PRIOR PROVISIONS

A prior section 293a, act July 1, 1944, ch. 373, title VII, §737, as added Pub. L. 102–408, title I, §102, Oct. 13, 1992, 106 Stat. 2023, authorized grants to health professions schools for provision of scholarships and undergraduate assistance, prior to the general amendment of this part by Pub. L. 105–392.

Another prior section 293a, act July 1, 1944, ch. 373, title VII, §721, as added Sept. 24, 1963, Pub. L. 88–129, §2(b), 77 Stat. 165; amended Sept. 4, 1964, Pub. L. 88–581, §3(b), 78 Stat. 919; Oct. 22, 1965, Pub. L. 89–290, §§3(b), (c), 5(a), 79 Stat. 1056–1058; Nov. 2, 1966, Pub. L. 89–709, §2(b), 80 Stat. 1103; Aug. 16, 1968, Pub. L. 90–490, title I, §§103(a)(3), 105(a), (b), 82 Stat. 774; Nov. 18, 1971, Pub. L. 92–157, title I, §§102(e), (f)(1), (2)(A), (g), (h), (j)(2), (3), (7)(A), 108(b)(1), 85 Stat. 434–437, 461; Oct. 12, 1976, Pub. L. 94–484, title III, §§301, 303, 308(a), 90 Stat. 2253, 2254, 2256; Aug. 1, 1977, Pub. L. 95–83, title III, §307(b), 91 Stat. 389; Oct. 17, 1979, Pub. L. 96–88, title III, §301(a)(1), title V, §507, 93 Stat. 677, 692; Aug. 13, 1981, Pub. L. 97–35, title XXVII, §§2723(c), (d), 2724(a), 95 Stat. 916; Nov. 4, 1988, Pub. L. 100–607, title VI, §§628(4), 629(b)(2), 102 Stat. 3145, 3146; Aug. 16, 1989, Pub. L. 101–93, §5(o)(1), 103 Stat. 614, related to applications and eligibility for grants for construction of teaching facilities for medical, dental, and other health personnel, prior to the general revision of this subchapter by Pub. L. 102–408.

A prior section 737 of act July 1, 1944, was classified to section 294j of this title prior to the general revision of this subchapter by Pub. L. 102–408.

§293b. Loan repayments and fellowships regarding faculty positions

(a) Loan repayments

(1) Establishment of program

The Secretary shall establish a program of entering into contracts with individuals described in paragraph (2) under which the individuals agree to serve as members of the faculties of schools described in paragraph (3) in consideration of the Federal Government agreeing to pay, for each year of such service, not more than $30,000 of the principal and interest of the educational loans of such individuals.

(2) Eligible individuals

The individuals referred to in paragraph (1) are individuals from disadvantaged backgrounds who—

(A) have a degree in medicine, osteopathic medicine, dentistry, nursing, or another health profession;

(B) are enrolled in an approved graduate training program in medicine, osteopathic medicine, dentistry, nursing, or other health profession; or

(C) are enrolled as full-time students—

(i) in an accredited (as determined by the Secretary) school described in paragraph (3); and

(ii) in the final year of a course of a study or program, offered by such institution and approved by the Secretary, leading to a degree from such a school.

(3) Eligible health professions schools

The schools described in this paragraph are schools of medicine, nursing (as schools of nursing are defined in section 296 of this title), osteopathic medicine, dentistry, pharmacy, allied health, podiatric medicine, optometry, veterinary medicine, or public health, schools offering physician assistant education programs, or schools offering graduate programs in behavioral and mental health.

(4) Requirements regarding faculty positions

The Secretary may not enter into a contract under paragraph (1) unless—

(A) the individual involved has entered into a contract with a school described in paragraph (3) to serve as a member of the faculty of the school for not less than 2 years; and

(B) the contract referred to in subparagraph (A) provides that—

(i) the school will, for each year for which the individual will serve as a member of the faculty under the contract with the school, make payments of the principal and interest due on the educational loans of the individual for such year in an amount equal to the amount of such payments made by the Secretary for the year;

(ii) the payments made by the school pursuant to clause (i) on behalf of the individual will be in addition to the pay that the individual would otherwise receive for serving as a member of such faculty; and

(iii) the school, in making a determination of the amount of compensation to be provided by the school to the individual for serving as a member of the faculty, will make the determination without regard to the amount of payments made (or to be made) to the individual by the Federal Government under paragraph (1).

(5) Applicability of certain provisions

The provisions of sections 254m, 254p, and 254q–1 of this title shall apply to the program established in paragraph (1) to the same extent and in the same manner as such provisions apply to the National Health Service Corps Loan Repayment Program established in subpart III of part D of subchapter II, including the applicability of provisions regarding reimbursements for increased tax liability and regarding bankruptcy.

(6) Waiver regarding school contributions

The Secretary may waive the requirement established in paragraph (4)(B) if the Secretary

determines that the requirement will impose an undue financial hardship on the school involved.

(b) Fellowships

(1) In general

The Secretary may make grants to and enter into contracts with eligible entities to assist such entities in increasing the number of underrepresented minority individuals who are members of the faculty of such schools.

(2) Applications

To be eligible to receive a grant or contract under this subsection, an entity shall provide an assurance, in the application submitted by the entity, that—

(A) amounts received under such a grant or contract will be used to award a fellowship to an individual only if the individual meets the requirements of paragraphs (3) and (4); and

(B) each fellowship awarded pursuant to the grant or contract will include—

(i) a stipend in an amount not exceeding 50 percent of the regular salary of a similar faculty member for not to exceed 3 years of training; and

(ii) an allowance for other expenses, such as travel to professional meetings and costs related to specialized training.

(3) Eligibility

To be eligible to receive a grant or contract under paragraph (1), an applicant shall demonstrate to the Secretary that such applicant has or will have the ability to—

(A) identify, recruit and select underrepresented minority individuals who have the potential for teaching, administration, or conducting research at a health professions institution;

(B) provide such individuals with the skills necessary to enable them to secure a tenured faculty position at such institution, which may include training with respect to pedagogical skills, program administration, the design and conduct of research, grants writing, and the preparation of articles suitable for publication in peer reviewed journals;

(C) provide services designed to assist such individuals in their preparation for an academic career, including the provision of counselors; and

(D) provide health services to rural or medically underserved populations.

(4) Requirements

To be eligible to receive a grant or contract under paragraph (1) an applicant shall—

(A) provide an assurance that such applicant will make available (directly through cash donations) $1 for every $1 of Federal funds received under this section for the fellowship;

(B) provide an assurance that institutional support will be provided for the individual for the second and third years at a level that is equal to the total amount of institutional funds provided in the year in which the grant or contract was awarded;

(C) provide an assurance that the individual that will receive the fellowship will be a member of the faculty of the applicant school; and

(D) provide an assurance that the individual that will receive the fellowship will have, at a minimum, appropriate advanced preparation (such as a master's or doctoral degree) and special skills necessary to enable such individual to teach and practice.

(5) Definition

For purposes of this subsection, the term "underrepresented minority individuals" means individuals who are members of racial or ethnic minority groups that are underrepresented in the health professions including nursing.

(July 1, 1944, ch. 373, title VII, §738, as added Pub. L. 105–392, title I, §101(a), Nov. 13, 1998, 112 Stat. 3532; amended Pub. L. 111–148, title V, §5402(a), title X, §10501(d), Mar. 23, 2010, 124 Stat. 644, 995.)

EDITORIAL NOTES

REFERENCES IN TEXT

Subpart III of part D of subchapter II, referred to in subsec. (a)(5), is classified to section 254l et seq. of this title.

PRIOR PROVISIONS

A prior section 293b, act July 1, 1944, ch. 373, title VII, §738, as added Pub. L. 102–408, title I, §102, Oct. 13, 1992, 106 Stat. 2025, related to loan repayments and fellowships regarding faculty positions, prior to the general amendment of this part by Pub. L. 105–392.

Another prior section 293b, act July 1, 1944, ch. 373, title VII, §722, as added Sept. 24, 1963, Pub. L. 88–129, §2(b), 77 Stat. 168; amended Aug. 16, 1968, Pub. L. 90–490, title I, §§102(a), 104(a), 82 Stat. 773, 774; Nov. 18, 1971, Pub. L. 92–157, title I, §102(b), (j)(4), (7), 85 Stat. 431, 436, 437; Oct. 12, 1976, Pub. L. 94–484, title III, §304, 90 Stat. 2255; Aug. 13, 1981, Pub. L. 97–35, title XXVII, §2723(e), 95 Stat. 916, related to amounts of grants and grants for multipurpose facilities, prior to the general revision of this subchapter by Pub. L. 102–408.

A prior section 738 of act July 1, 1944, was classified to section 294k of this title prior to the general revision of this subchapter by Pub. L. 102–408.

AMENDMENTS

2010—Subsec. (a)(1). Pub. L. 111–148, §5402(a), substituted "$30,000" for "$20,000".

Subsec. (a)(3). Pub. L. 111–148, §10501(d), inserted "schools offering physician assistant education programs," after "public health,".

§293c. Educational assistance in the health professions regarding individuals from disadvantaged backgrounds

(a) In general

(1) Authority for grants

For the purpose of assisting individuals from disadvantaged backgrounds, as determined in accordance with criteria prescribed by the Secretary, to undertake education to enter a health profession, the Secretary may make grants to and enter into contracts with schools of medicine, osteopathic medicine, public health, dentistry, veterinary medicine, optometry, pharmacy, allied health, chiropractic, and podiatric medicine, public and nonprofit private schools that offer graduate programs in behavioral and mental health, programs for the training of physician assistants, and other public or private nonprofit health or educational entities to assist in meeting the costs described in paragraph (2).

(2) Authorized expenditures

A grant or contract under paragraph (1) may be used by the entity to meet the cost of—

(A) identifying, recruiting, and selecting individuals from disadvantaged backgrounds, as so determined, for education and training in a health profession;

(B) facilitating the entry of such individuals into such a school;

(C) providing counseling, mentoring, or other services designed to assist such individuals to complete successfully their education at such a school;

(D) providing, for a period prior to the entry of such individuals into the regular course of education of such a school, preliminary education and health research training designed to assist them to complete successfully such regular course of education at such a school, or referring such individuals to institutions providing such preliminary education;

(E) publicizing existing sources of financial aid available to students in the education program of such a school or who are undertaking training necessary to qualify them to enroll in such a program;

(F) paying such scholarships as the Secretary may determine for such individuals for any period of health professions education at a health professions school;

(G) paying such stipends as the Secretary may approve for such individuals for any period of education in student-enhancement programs (other than regular courses), except that such a

stipend may not be provided to an individual for more than 12 months, and such a stipend shall be in an amount determined appropriate by the Secretary (notwithstanding any other provision of law regarding the amount of stipends);

(H) carrying out programs under which such individuals gain experience regarding a career in a field of primary health care through working at facilities of public or private nonprofit community-based providers of primary health services; and

(I) conducting activities to develop a larger and more competitive applicant pool through partnerships with institutions of higher education, school districts, and other community-based entities.

(3) Definition

In this section, the term "regular course of education of such a school" as used in subparagraph (D) includes a graduate program in behavioral or mental health.

(b) Requirements for awards

In making awards to eligible entities under subsection (a)(1), the Secretary shall give preference to approved applications for programs that involve a comprehensive approach by several public or nonprofit private health or educational entities to establish, enhance and expand educational programs that will result in the development of a competitive applicant pool of individuals from disadvantaged backgrounds who desire to pursue health professions careers. In considering awards for such a comprehensive partnership approach, the following shall apply with respect to the entity involved:

(1) The entity shall have a demonstrated commitment to such approach through formal agreements that have common objectives with institutions of higher education, school districts, and other community-based entities.

(2) Such formal agreements shall reflect the coordination of educational activities and support services, increased linkages, and the consolidation of resources within a specific geographic area.

(3) The design of the educational activities involved shall provide for the establishment of a competitive health professions applicant pool of individuals from disadvantaged backgrounds by enhancing the total preparation (academic and social) of such individuals to pursue a health professions career.

(4) The programs or activities under the award shall focus on developing a culturally competent health care workforce that will serve the unserved and underserved populations within the geographic area.

(c) Equitable allocation of financial assistance

The Secretary, to the extent practicable, shall ensure that services and activities under subsection (a) are adequately allocated among the various racial and ethnic populations who are from disadvantaged backgrounds.

(d) Matching requirements

The Secretary may require that an entity that applies for a grant or contract under subsection (a), provide non-Federal matching funds, as appropriate, to ensure the institutional commitment of the entity to the projects funded under the grant or contract. As determined by the Secretary, such non-Federal matching funds may be provided directly or through donations from public or private entities and may be in cash or in-kind, fairly evaluated, including plant, equipment, or services.

(July 1, 1944, ch. 373, title VII, §739, as added Pub. L. 105–392, title I, §101(a), Nov. 13, 1998, 112 Stat. 3534.)

EDITORIAL NOTES

PRIOR PROVISIONS

A prior section 293c, act July 1, 1944, ch. 373, title VII, §739, as added Pub. L. 102–408, title I, §102, Oct. 13, 1992, 106 Stat. 2027, related to centers of excellence in health professions education for minority individuals, prior to the general amendment of this part by Pub. L. 105–392. See section 293 of this title.

Another prior section 293c, act July 1, 1944, ch. 373, title VII, §723, as added Sept. 24, 1963, Pub. L. 88–129, §2(b), 77 Stat. 168; amended Aug. 16, 1968, Pub. L. 90–490, title I, §103(a)(1), (2), 82 Stat. 773; Nov. 18, 1971, Pub. L. 92–157,title I, §102(c)(5), (f)(2)(C), (j)(1), (5), 85 Stat. 432, 435–437; Oct. 12, 1976, Pub. L. 94–484, title III, §305, 90 Stat. 2255; Aug. 13, 1981, Pub. L. 97–35, title XXVII, §2723(f), 95 Stat. 916; Oct. 22, 1985, Pub. L. 99–129, title II, §207(a), 99 Stat. 527, related to recovery by United States of grant moneys where facility was no longer owned by a public or nonprofit agency or where it ceased to be used for teaching or training purposes, prior to the general revision of this subchapter by Pub. L. 102–408.

A prior section 739 of act July 1, 1944, was classified to section 294l of this title prior to the general revision of this subchapter by Pub. L. 102–408.

§293d. Authorization of appropriation

(a) Scholarships

There are authorized to be appropriated to carry out section 293a of this title, $51,470,000 for each of fiscal years 2021 through 2025. Of the amount appropriated in any fiscal year, the Secretary shall ensure that not less than 16 percent shall be distributed to schools of nursing.

(b) Loan repayments and fellowships

For the purpose of carrying out section 293b of this title, there is authorized to be appropriated, $1,190,000 for each of fiscal years 2021 through 2025.

(c) Educational assistance in health professions regarding individuals from disadvantaged backgrounds

For the purpose of grants and contracts under section 293c(a)(1) of this title, there is authorized to be appropriated $15,000,000 for each of fiscal years 2021 through 2025. The Secretary may use not to exceed 20 percent of the amount appropriated for a fiscal year under this subsection to provide scholarships under section 293c(a)(2)(F) of this title.

(d) Report

Not later than September 30, 2025, and every five years thereafter, the Secretary shall prepare and submit to the Committee on Health, Education, Labor, and Pensions of the Senate, and the Committee on Energy and Commerce of the House of Representatives, a report concerning the efforts of the Secretary to address the need for a representative mix of individuals from historically minority health professions schools, or from institutions or other entities that historically or by geographic location have a demonstrated record of training or educating underrepresented minorities, within various health professions disciplines, on peer review councils.

(July 1, 1944, ch. 373, title VII, §740, as added Pub. L. 105–392, title I, §101(a), Nov. 13, 1998, 112 Stat. 3536; amended Pub. L. 111–148, title V, §5402(b)–(d), Mar. 23, 2010, 124 Stat. 644; Pub. L. 116–136, div. A, title III, §3401(2), Mar. 27, 2020, 134 Stat. 385.)

EDITORIAL NOTES

PRIOR PROVISIONS

A prior section 293d, act July 1, 1944, ch. 373, title VII, §740, as added Pub. L. 102–408, title I, §102, Oct. 13, 1992, 106 Stat. 2032, related to educational assistance regarding undergraduates, prior to the general amendment of this part by Pub. L. 105–392.

Another prior section 293d, act July 1, 1944, ch. 373, title VII, §724, formerly §727, as added Sept. 24, 1963, Pub. L. 88–129, §2(b), 77 Stat. 170; amended Nov. 18, 1971, Pub. L. 92–157, title I, §102(j)(7)(B), 85 Stat. 437; renumbered §724 and amended Oct. 12, 1976, Pub. L. 94–484, title III, §308(c), (d), 90 Stat. 2257, related to promulgation of regulations by Secretary, prior to the general revision of this subchapter by Pub. L. 102–408.

Another prior section 293d, act July 1, 1944, ch. 373, title VII, §701, formerly §724, as added Sept. 24, 1963, Pub. L. 88–129, §2(b), 77 Stat. 169; amended Oct. 22, 1965, Pub. L. 89–290, §2(b), 79 Stat. 1056; Nov. 2, 1966, Pub. L. 89–709, §2(c), 80 Stat. 1103; Aug. 16, 1968, Pub. L. 90–490, title I, §105(c), 82 Stat. 774; Nov. 18, 1971, Pub. L. 92–157, title I, §102(c)(1)–(4), (f)(2)(B), 85 Stat. 431, 432, 435, which related to

definitions, was renumbered §701 of act July 1, 1944, by Pub. L. 94–484 and transferred to section 292a of this title.

A prior section 740 of act July 1, 1944, was classified to section 294m of this title prior to the general revision of this subchapter by Pub. L. 102–408.

AMENDMENTS

2020—Subsec. (a). Pub. L. 116–136, §3401(2)(A), substituted "$51,470,000 for each of fiscal years 2021 through 2025" for "$51,000,000 for fiscal year 2010, and such sums as may be necessary for each of the fiscal years 2011 through 2014".

Subsec. (b). Pub. L. 116–136, §3401(2)(B), substituted "$1,190,000 for each of fiscal years 2021 through 2025" for "$5,000,000 for each of the fiscal years 2010 through 2014".

Subsec. (c). Pub. L. 116–136, §3401(2)(C), substituted "$15,000,000 for each of fiscal years 2021 through 2025" for "$60,000,000 for fiscal year 2010 and such sums as may be necessary for each of the fiscal years 2011 through 2014".

Subsec. (d). Pub. L. 116–136, §3401(2)(D), which directed substitution of "Not later than September 30, 2025, and every five years thereafter, the Secretary shall prepare and submit to the Committee on Health, Education, Labor, and Pensions of the Senate, and the Committee on Energy and Commerce of the House of Representatives," for "Not Later than 6 months after November 13, 1998, the Secretary shall prepare and submit to the appropriate committees of Congress", was executed by making the substitution for "Not later than 6 months after November 13, 1998, the Secretary shall prepare and submit to the appropriate committees of Congress", to reflect the probable intent of Congress.

2010—Subsec. (a). Pub. L. 111–148, §5402(b), substituted "$51,000,000 for fiscal year 2010, and such sums as may be necessary for each of the fiscal years 2011 through 2014" for "$37,000,000 for fiscal year 1998, and such sums as may be necessary for each of the fiscal years 1999 through 2002".

Subsec. (b). Pub. L. 111–148, §5402(c), substituted "appropriated, $5,000,000 for each of the fiscal years 2010 through 2014" for "appropriated $1,100,000 for fiscal year 1998, and such sums as may be necessary for each of the fiscal years 1999 through 2002".

Subsec. (c). Pub. L. 111–148, §5402(d), substituted "For the purpose of grants and contracts under section 293c(a)(1) of this title, there is authorized to be appropriated $60,000,000 for fiscal year 2010 and such sums as may be necessary for each of the fiscal years 2011 through 2014" for "For the purpose of grants and contracts under section 293c(a)(1) of this title, there is authorized to be appropriated $29,400,000 for fiscal year 1998, and such sums as may be necessary for each of the fiscal years 1999 through 2002".

§293e. Grants for health professions education

(a) Cultural competency, prevention, and public health and individuals with disability grants

(1) In general

The Secretary, acting through the Administrator of the Health Resources and Services Administration, may make awards of grants, contracts, or cooperative agreements to public and nonprofit private entities (including tribal entities) for the development, evaluation, and dissemination of research, demonstration projects, and model curricula for cultural competency, prevention, public health proficiency, reducing health disparities, and aptitude for working with individuals with disabilities training for use in health professions schools and continuing education programs, and for other purposes determined as appropriate by the Secretary.

(2) Eligible entities

Unless specifically required otherwise in this subchapter, the Secretary shall accept applications for grants or contracts under this section from health professions schools, academic health centers, State or local governments, or other appropriate public or private nonprofit entities (or consortia of entities, including entities promoting multidisciplinary approaches) for funding and participation in health professions training activities. The Secretary may accept applications from for-profit private entities as determined appropriate by the Secretary.

(b) Collaboration

In carrying out subsection (a), the Secretary shall collaborate with health professional societies, licensing and accreditation entities, health professions schools, and experts in minority health and

cultural competency, prevention, and public health and disability groups, community-based organizations, and other organizations as determined appropriate by the Secretary. The Secretary shall coordinate with curricula and research and demonstration projects developed under section 296e–1 of this title.

(c) Dissemination

(1) In general

Model curricula developed under this section shall be disseminated through the Internet Clearinghouse under section 270 [1] and such other means as determined appropriate by the Secretary.

(2) Evaluation

The Secretary shall evaluate the adoption and the implementation of cultural competency, prevention, and public health, and working with individuals with a disability training curricula, and the facilitate [2] inclusion of these competency measures in quality measurement systems as appropriate.

(d) Authorization of appropriations

There is authorized to be appropriated to carry out this section such sums as may be necessary for each of fiscal years 2010 through 2015.

(July 1, 1944, ch. 373, title VII, §741, as added Pub. L. 106–525, title IV, §401(a), Nov. 22, 2000, 114 Stat. 2508; amended Pub. L. 111–148, title V, §5307(a), Mar. 23, 2010, 124 Stat. 628.)

EDITORIAL NOTES

PRIOR PROVISIONS

A prior section 293e, act July 1, 1944, ch. 373, title VII, §725, formerly §728, as added Sept. 24, 1963, Pub. L. 88–129, §2(b), 77 Stat. 170; amended Sept. 4, 1964, Pub. L. 88–581, §3(d), 78 Stat. 919; Nov. 18, 1971, Pub. L. 92–157, title I, §102(i), 85 Stat. 436; renumbered §725, Oct. 12, 1976, Pub. L. 94–484, title III, §308(d), 90 Stat. 2257, related to technical assistance to applicants for grants for construction of teaching facilities for medical, dental, and other health personnel, and to States or interstate planning agencies to plan programs for relieving shortages of training of health personnel, prior to the general amendment of this subchapter by Pub. L. 102–408, title I, §102, Oct. 13, 1992, 106 Stat. 1994.

Another prior section 293e, act July 1, 1944, ch. 373, title VII, §702, formerly §725, as added Sept. 24, 1963, Pub. L. 88–129, §2(b), 77 Stat. 169; amended Sept. 4, 1964, Pub. L. 88–581, §3(c), 78 Stat. 919; Nov. 2, 1966, Pub. L. 89–709, §2(d), 80 Stat. 1103; Nov. 3, 1966, Pub. L. 89–751, §3(a), 80 Stat. 1230; Dec. 5, 1967, Pub. L. 90–174, §12(c), 81 Stat. 541; Oct. 30, 1970, Pub. L. 91–515, title VI, §601(b)(2), 84 Stat. 1311; Nov. 18, 1971, Pub. L. 92–157, title I, §108(a), 85 Stat. 460, was renumbered §702 of act July 1, 1944, by Pub. L. 94–484 and transferred to section 292b of this title, and subsequently omitted in the general amendment of this subchapter by Pub. L. 102–408.

A prior section 293f, act July 1, 1944, ch. 373, title VII, §726, formerly §729, as added Nov. 18, 1971, Pub. L. 92–157, title I, §102(d), 85 Stat. 432; renumbered §726 and amended Oct. 12, 1976, Pub. L. 94–484, title I, §101(d), title III, §§306, 308(d), 90 Stat. 2244, 2256, 2257; Aug. 13, 1981, Pub. L. 97–35, title XXVII, §2725, 95 Stat. 916, related to loan guarantees and interest subsidies, prior to the general amendment of this subchapter by Pub. L. 102–408, title I, §102, Oct. 13, 1992, 106 Stat. 1994.

Another prior section 293f, act July 1, 1944, ch. 373, title VII, §726, as added Sept. 24, 1963, Pub. L. 88–129, §2(b), 77 Stat. 170, provided for noninterference with administration of institutions, prior to repeal by Pub. L. 94–484, title III, §308(b), Oct. 12, 1976, 90 Stat. 2257.

A prior section 293g, act July 1, 1944, ch. 373, title VII, §727, as added Sept. 24, 1963, Pub. L. 88–129, §2(b), 77 Stat. 170; amended Nov. 18, 1971, Pub. L. 92–157, title I, §102(j)(7)(B), 85 Stat. 437, which related to regulations, was renumbered section 724 of act July 1, 1944, by Pub. L. 94–484 and transferred to section 293d of this title, and subsequently omitted in the general amendment of this subchapter by Pub. L. 102–408.

A prior section 293h, act July 1, 1944, ch. 373, title VII, §728, as added Sept. 24, 1963, Pub. L. 88–129, §2(b), 77 Stat. 170; amended Sept. 4, 1964, Pub. L. 88–581, §3(d), 78 Stat. 919; Nov. 18, 1971, Pub. L.

92–157, title I, §102(i), 85 Stat. 436, which related to technical assistance, was renumbered section 726 of act July 1, 1944, by Pub. L. 94–484 and transferred to section 293e of this title, and subsequently omitted in the general amendment of this subchapter by Pub. L. 102–408.

A prior section 293i, act July 1, 1944, ch. 373, title VII, §729, as added Nov. 18, 1971, Pub. L. 92–157, title I, §102(d), 85 Stat. 432, which related to loan guarantees and interest subsidies, was renumbered section 726 of act July 1, 1944, by Pub. L. 94–484 and transferred to section 293f of this title, and subsequently omitted in the general amendment of this subchapter by Pub. L. 102–408.

AMENDMENTS

2010—Subsec. (a). Pub. L. 111–148, §5307(a)(1)(A), substituted "Cultural competency, prevention, and public health and individuals with disability grants" for "Grants for health professions education in health disparities and cultural competency" in heading.

Subsec. (a)(1). Pub. L. 111–148, §5307(a)(1)(B), substituted "for the development, evaluation, and dissemination of research, demonstration projects, and model curricula for cultural competency, prevention, public health proficiency, reducing health disparities, and aptitude for working with individuals with disabilities training for use in health professions schools and continuing education programs, and for other purposes determined as appropriate by the Secretary" for "for the purpose of carrying out research and demonstration projects (including research and demonstration projects for continuing health professions education) for training and education of health professionals for the reduction of disparities in health care outcomes and the provision of culturally competent health care".

Subsecs. (b) to (d). Pub. L. 111–148, §5307(a)(2), added subsecs. (b) to (d) and struck out former subsec. (b). Prior to amendment, text of subsec. (b) read as follows: "There are authorized to be appropriated to carry out subsection (a) of this section, $3,500,000 for fiscal year 2001, $7,000,000 for fiscal year 2002, $7,000,000 for fiscal year 2003, and $3,500,000 for fiscal year 2004."

STATUTORY NOTES AND RELATED SUBSIDIARIES

NATIONAL CONFERENCE ON HEALTH PROFESSIONS EDUCATION AND HEALTH DISPARITIES

Pub. L. 106–525, title IV, §402, Nov. 22, 2000, 114 Stat. 2509, provided that:

"(a) IN GENERAL.—Not later than 1 year after the date of enactment of this Act [Nov. 22, 2000], the Secretary of Health and Human Services (in this section referred to as the 'Secretary'), acting through the Administrator of the Health Resources and Services Administration, shall convene a national conference on health professions education as a method for reducing disparities in health outcomes.

"(b) PARTICIPANTS.—The Secretary shall include in the national conference convened under subsection (a) advocacy groups and educational entities as described in section 741 of the Public Health Service Act [42 U.S.C. 293e] (as added by section 401), tribal health programs, health centers under section 330 of such Act [42 U.S.C. 254b], and other interested parties.

"(c) ISSUES.—The national conference convened under subsection (a) shall include, but is not limited to, issues that address the role and impact of health professions education on the reduction of disparities in health outcomes, including the role of education on cultural competency. The conference shall focus on methods to achieve reductions in disparities in health outcomes through health professions education (including continuing education programs) and strategies for outcomes measurement to assess the effectiveness of education in reducing disparities.

"(d) PUBLICATION OF FINDINGS.—Not later than 6 months after the national conference under subsection (a) has convened, the Secretary shall publish in the Federal Register a summary of the proceedings and findings of the conference.

"(e) AUTHORIZATION OF APPROPRIATIONS.—There is authorized to be appropriated such sums as may be necessary to carry out this section."

[1] So in original. Act July 1, 1944, does not contain a section 270.

[2] So in original.

PART C—TRAINING IN FAMILY MEDICINE, GENERAL INTERNAL

MEDICINE, GENERAL PEDIATRICS, PHYSICIAN ASSISTANTS, GENERAL DENTISTRY, AND PEDIATRIC DENTISTRY

SUBPART 1—MEDICAL TRAINING GENERALLY

§293j. Repealed. Pub. L. 105–392, title I, §102(2), Nov. 13, 1998, 112 Stat. 3537

Section, act July 1, 1944, ch. 373, title VII, §746, as added Pub. L. 102–408, title I, §102, Oct. 13, 1992, 106 Stat. 2034; amended Pub. L. 102–531, title III, §313(a)(2), Oct. 27, 1992, 106 Stat. 3507; Pub. L. 103–43, title XX, §2008(i)(3), June 10, 1993, 107 Stat. 213, related to area health education center programs.

A prior section 746 of act July 1, 1944, was classified to section 294q–2 of this title prior to the general revision of this subchapter by Pub. L. 102–408.

§293k. Primary care training and enhancement

(a) Support and development of primary care training programs

(1) In general

The Secretary may make grants to, or enter into contracts with, an accredited public or nonprofit private hospital, school of medicine or osteopathic medicine, academically affiliated physician assistant training program, or a public or private nonprofit entity which the Secretary has determined is capable of carrying out such grant or contract—

(A) to plan, develop, operate, or participate in an accredited professional training program, including an accredited residency or internship program in the field of family medicine, general internal medicine, or general pediatrics for medical students, interns, residents, or practicing physicians as defined by the Secretary;

(B) to provide need-based financial assistance in the form of traineeships and fellowships to medical students, interns, residents, practicing physicians, or other medical personnel, who are participants in any such program, and who plan to specialize or work in the practice of the fields defined in subparagraph (A);

(C) to plan, develop, and operate a program for the training of physicians who plan to teach in family medicine, general internal medicine, or general pediatrics training programs;

(D) to plan, develop, and operate a program for the training of physicians teaching in community-based settings;

(E) to provide financial assistance in the form of traineeships and fellowships to physicians who are participants in any such programs and who plan to teach or conduct research in a family medicine, general internal medicine, or general pediatrics training program;

(F) to plan, develop, and operate a physician assistant education program, and for the training of individuals who will teach in programs to provide such training;

(G) to plan, develop, and operate a program that identifies or develops innovative models of providing care, and trains primary care physicians on such models and in new competencies, as recommended by the Advisory Committee on Training in Primary Care Medicine and Dentistry and the National Health Care Workforce Commission established in section 294q of this title, which may include—

(i) providing training to primary care physicians relevant to providing care through patient-centered medical homes (as defined by the Secretary for purposes of this section);

(ii) developing tools and curricula relevant to patient-centered medical homes; and

(iii) providing continuing education to primary care physicians relevant to patient-centered medical homes; and

(H) to plan, develop, and operate joint degree programs to provide interdisciplinary and interprofessional graduate training in public health and other health professions to provide training in environmental health, infectious disease control, disease prevention and health promotion, epidemiological studies and injury control.

(2) Duration of awards

The period during which payments are made to an entity from an award of a grant or contract under this subsection shall be 5 years.

(3) Priorities in making awards

In awarding grants or contracts under paragraph (1), the Secretary may give priority to qualified applicants that train residents in rural areas, including for Tribes or Tribal Organizations in such areas.

(b) Capacity building in primary care

(1) In general

The Secretary may make grants to or enter into contracts with accredited schools of medicine or osteopathic medicine to establish, maintain, or improve—

(A) academic units or programs that improve clinical teaching and research in fields defined in subsection (a)(1)(A); or

(B) programs that integrate academic administrative units in fields defined in subsection (a)(1)(A) to enhance interdisciplinary recruitment, training, and faculty development.

(2) Preference in making awards under this subsection

In making awards of grants and contracts under paragraph (1), the Secretary shall give preference to any qualified applicant for such an award that agrees to expend the award for the purpose of—

(A) establishing academic units or programs in fields defined in subsection (a)(1)(A); or

(B) substantially expanding such units or programs.

(3) Priorities in making awards

In awarding grants or contracts under paragraph (1), the Secretary shall give priority to qualified applicants that—

(A) proposes [1] a collaborative project between academic administrative units of primary care;

(B) proposes [1] innovative approaches to clinical teaching using models of primary care, such as the patient centered medical home, team management of chronic disease, and interprofessional integrated models of health care that incorporate transitions in health care settings and integration physical and mental health provision;

(C) have a record of training the greatest percentage of providers, or that have demonstrated significant improvements in the percentage of providers trained, who enter and remain in primary care practice;

(D) have a record of training individuals who are from underrepresented minority groups or from a rural or disadvantaged background;

(E) provide training in the care of vulnerable populations such as children, older adults, homeless individuals, victims of abuse or trauma, individuals with mental health or substance use disorders, individuals with HIV/AIDS, and individuals with disabilities;

(F) establish formal relationships and submit joint applications with federally qualified health centers, rural health clinics, area health education centers, or clinics located in underserved areas or that serve underserved populations;

(G) teach trainees the skills to provide interprofessional, integrated care through collaboration among health professionals;

(H) provide training in enhanced communication with patients, evidence-based practice, chronic disease management, preventive care, health information technology, or other competencies as recommended by the Advisory Committee on Training in Primary Care

Medicine and Dentistry and the National Health Care Workforce Commission established in section 294q of this title; or

(I) provide training in cultural competency and health literacy.

(4) Duration of awards

The period during which payments are made to an entity from an award of a grant or contract under this subsection shall be 5 years.

(c) Authorization of appropriations

(1) In general

For purposes of carrying out this section (other than subsection (b)(1)(B)), there are authorized to be appropriated $48,924,000 for each of fiscal years 2021 through 2025.

(2) Training programs

Fifteen percent of the amount appropriated pursuant to paragraph (1) in each such fiscal year shall be allocated to the physician assistant training programs described in subsection (a)(1)(F), which prepare students for practice in primary care.

(3) Integrating academic administrative units

For purposes of carrying out subsection (b)(1)(B), there are authorized to be appropriated $750,000 for each of fiscal years 2010 through 2014.

(July 1, 1944, ch. 373, title VII, §747, as added Pub. L. 111–148, title V, §5301, Mar. 23, 2010, 124 Stat. 615; amended Pub. L. 116–136, div. A, title III, §3401(3), Mar. 27, 2020, 134 Stat. 386.)

EDITORIAL NOTES

CODIFICATION

Pub. L. 111–148, title V, §5301, Mar. 23, 2010, 124 Stat. 615, which directed the amendment of part C of title VII by striking out section 747 and inserting a new section 747, without specifying the act to be amended, was executed as an amendment to part C of title VII of act July 1, 1944, by adding this section and repealing former section 293k of this title, to reflect the probable intent of Congress.

PRIOR PROVISIONS

A prior section 293k, act July 1, 1944, ch. 373, title VII, §747, as added Pub. L. 102–408, title I, §102, Oct. 13, 1992, 106 Stat. 2042; amended Pub. L. 105–392, title I, §102(3), Nov. 13, 1998, 112 Stat. 3537, related to grants and contracts for training in family medicine, general internal medicine, general pediatrics, general dentistry, and pediatric dentistry, and training for physician assistants, prior to repeal by Pub. L. 111–148, title V, §5301, Mar. 23, 2010, 124 Stat. 615. See Codification note above.

A prior section 747 of act July 1, 1944, was classified to section 294q–3 of this title prior to the general revision of this subchapter by Pub. L. 102–408.

Another prior section 747 of act July 1, 1944, was classified to section 294g of this title prior to repeal by Pub. L. 94–484.

AMENDMENTS

2020—Subsec. (a)(1)(G). Pub. L. 116–136, §3401(3)(A)(i), substituted "to plan, develop, and operate a program that identifies or develops innovative models of providing care, and trains primary care physicians on such models and" for "to plan, develop, and operate a demonstration program that provides training" in introductory provisions.

Subsec. (a)(3). Pub. L. 116–136, §3401(3)(A)(ii), added par. (3).

Subsec. (b)(3)(E). Pub. L. 116–136, §3401(3)(B), substituted "substance use disorders" for "substance-related disorders".

Subsec. (c)(1). Pub. L. 116–136, §3401(3)(C), substituted "$48,924,000 for each of fiscal years 2021 through 2025" for "$125,000,000 for fiscal year 2010, and such sums as may be necessary for each of fiscal years 2011 through 2014".

[1] *So in original. Probably should be "propose".*

§293k–1. Training opportunities for direct care workers

(a) In general

The Secretary shall award grants to eligible entities to enable such entities to provide new training opportunities for direct care workers who are employed in long-term care settings such as nursing homes (as defined in section 1396g(e)(1) of this title), assisted living facilities and skilled nursing facilities, intermediate care facilities for individuals with mental retardation, home and community based settings, and any other setting the Secretary determines to be appropriate.

(b) Eligibility

To be eligible to receive a grant under this section, an entity shall—

(1) be an institution of higher education (as defined in section 1002 of title 20) that—

(A) is accredited by a nationally recognized accrediting agency or association listed under section 1001(c) of title 20; and

(B) has established a public-private educational partnership with a nursing home or skilled nursing facility, agency or entity providing home and community based services to individuals with disabilities, or other long-term care provider; and

(2) submit to the Secretary an application at such time, in such manner, and containing such information as the Secretary may require.

(c) Use of funds

An eligible entity shall use amounts awarded under a grant under this section to provide assistance to eligible individuals to offset the cost of tuition and required fees for enrollment in academic programs provided by such entity.

(d) Eligible individual

(1) Eligibility

To be eligible for assistance under this section, an individual shall be enrolled in courses provided by a grantee under this subsection and maintain satisfactory academic progress in such courses.

(2) Condition of assistance

As a condition of receiving assistance under this section, an individual shall agree that, following completion of the assistance period, the individual will work in the field of geriatrics, disability services, long term services and supports, or chronic care management for a minimum of 2 years under guidelines set by the Secretary.

(e) Authorization of appropriations

There is authorized to be appropriated to carry out this section, $10,000,000 for the period of fiscal years 2011 through 2013.

(July 1, 1944, ch. 373, title VII, §747A, as added Pub. L. 111–148, title V, §5302, Mar. 23, 2010, 124 Stat. 617.)

§293k–2. Training in general, pediatric, and public health dentistry

(a) Support and development of dental training programs

(1) In general

The Secretary may make grants to, or enter into contracts with, a school of dentistry, public or nonprofit private hospital, or a public or private nonprofit entity which the Secretary has determined is capable of carrying out such grant or contract—

(A) to plan, develop, and operate, or participate in, an approved professional training program

in the field of general dentistry, pediatric dentistry, or public health dentistry for dental students, residents, practicing dentists, dental hygienists, or other approved primary care dental trainees, that emphasizes training for general, pediatric, or public health dentistry;

(B) to provide financial assistance to dental students, residents, practicing dentists, and dental hygiene students who are in need thereof, who are participants in any such program, and who plan to work in the practice of general, pediatric, public heath dentistry, or dental hygiene;

(C) to plan, develop, and operate a program for the training of oral health care providers who plan to teach in general, pediatric, public health dentistry, or dental hygiene;

(D) to provide financial assistance in the form of traineeships and fellowships to dentists who plan to teach or are teaching in general, pediatric, or public health dentistry;

(E) to meet the costs of projects to establish, maintain, or improve dental faculty development programs in primary care (which may be departments, divisions or other units);

(F) to meet the costs of projects to establish, maintain, or improve predoctoral and postdoctoral training in primary care programs;

(G) to create a loan repayment program for faculty in dental programs; and

(H) to provide technical assistance to pediatric training programs in developing and implementing instruction regarding the oral health status, dental care needs, and risk-based clinical disease management of all pediatric populations with an emphasis on underserved children.

(2) Faculty loan repayment

(A) In general

A grant or contract under subsection (a)(1)(G) may be awarded to a program of general, pediatric, or public health dentistry described in such subsection to plan, develop, and operate a loan repayment program under which—

(i) individuals agree to serve full-time as faculty members; and

(ii) the program of general, pediatric or public health dentistry agrees to pay the principal and interest on the outstanding student loans of the individuals.

(B) Manner of payments

With respect to the payments described in subparagraph (A)(ii), upon completion by an individual of each of the first, second, third, fourth, and fifth years of service, the program shall pay an amount equal to 10, 15, 20, 25, and 30 percent, respectively, of the individual's student loan balance as calculated based on principal and interest owed at the initiation of the agreement.

(b) Eligible entity

For purposes of this subsection, entities eligible for such grants or contracts in general, pediatric, or public health dentistry shall include entities that have programs in dental or dental hygiene schools, or approved residency or advanced education programs in the practice of general, pediatric, or public health dentistry. Eligible entities may partner with schools of public health to permit the education of dental students, residents, and dental hygiene students for a master's year in public health at a school of public health.

(c) Priorities in making awards

With respect to training provided for under this section, the Secretary shall give priority in awarding grants or contracts to the following:

(1) Qualified applicants that propose collaborative projects between departments of primary care medicine and departments of general, pediatric, or public health dentistry.

(2) Qualified applicants that have a record of training the greatest percentage of providers, or that have demonstrated significant improvements in the percentage of providers, who enter and remain in general, pediatric, or public health dentistry.

(3) Qualified applicants that have a record of training individuals who are from a rural or disadvantaged background, or from underrepresented minorities.

(4) Qualified applicants that establish formal relationships with Federally qualified health centers, rural health centers, or accredited teaching facilities and that conduct training of students, residents, fellows, or faculty at the center or facility.

(5) Qualified applicants that conduct teaching programs targeting vulnerable populations such as older adults, homeless individuals, victims of abuse or trauma, individuals with mental health or substance use disorders, individuals with disabilities, and individuals with HIV/AIDS, and in the risk-based clinical disease management of all populations.

(6) Qualified applicants that include educational activities in cultural competency and health literacy.

(7) Qualified applicants that have a high rate for placing graduates in practice settings that serve underserved areas or health disparity populations, or who achieve a significant increase in the rate of placing graduates in such settings.

(8) Qualified applicants that intend to establish a special populations oral health care education center or training program for the didactic and clinical education of dentists, dental health professionals, and dental hygienists who plan to teach oral health care for people with developmental disabilities, cognitive impairment, complex medical problems, significant physical limitations, and vulnerable elderly.

(d) Application

An eligible entity desiring a grant under this section shall submit to the Secretary an application at such time, in such manner, and containing such information as the Secretary may require.

(e) Duration of award

The period during which payments are made to an entity from an award of a grant or contract under subsection (a) shall be 5 years. The provision of such payments shall be subject to annual approval by the Secretary and subject to the availability of appropriations for the fiscal year involved to make the payments.

(f) Authorizations of appropriations

For the purpose of carrying out subsections (a) and (b), there is authorized to be appropriated $28,531,000 for each of fiscal years 2021 through 2025.

(g) Carryover funds

An entity that receives an award under this section may carry over funds from 1 fiscal year to another without obtaining approval from the Secretary. In no case may any funds be carried over pursuant to the preceding sentence for more than 3 years.

(July 1, 1944, ch. 373, title VII, §748, as added Pub. L. 111–148, title V, §5303(2), Mar. 23, 2010, 124 Stat. 618; amended Pub. L. 116–136, div. A, title III, §3401(4), Mar. 27, 2020, 134 Stat. 386.)

EDITORIAL NOTES

PRIOR PROVISIONS

A prior section 748 of act July 1, 1944, was renumbered section 749 and is classified to section 293l of this title.

Another prior section 748 of act July 1, 1944, was classified to section 293l of this title prior to repeal by Pub. L. 105–392.

Another prior section 748 of act July 1, 1944, was classified to section 294r of this title prior to renumbering by Pub. L. 97–35.

AMENDMENTS

2020—Subsec. (c)(5). Pub. L. 116–136, §3401(4)(A), substituted "substance use disorders" for "substance-related disorders".

Subsec. (f). Pub. L. 116–136, §3401(4)(B), substituted "$28,531,000 for each of fiscal years 2021 through 2025" for "$30,000,000 for fiscal year 2010 and such sums as may be necessary for each of fiscal years 2011 through 2015".

§293*l*. Advisory Committee on Training in Primary Care Medicine and Dentistry

(a) Establishment

The Secretary shall establish an advisory committee to be known as the Advisory Committee on Training in Primary Care Medicine and Dentistry (in this section referred to as the "Advisory Committee").

(b) Composition

(1) In general

The Secretary shall determine the appropriate number of individuals to serve on the Advisory Committee. Such individuals shall not be officers or employees of the Federal Government.

(2) Appointment

Not later than 90 days after November 13, 1998, the Secretary shall appoint the members of the Advisory Committee from among individuals who are health professionals. In making such appointments, the Secretary shall ensure a fair balance between the health professions, that at least 75 percent of the members of the Advisory Committee are health professionals, a broad geographic representation of members and a balance between urban and rural members. Members shall be appointed based on their competence, interest, and knowledge of the mission of the profession involved.

(3) Minority representation

In appointing the members of the Advisory Committee under paragraph (2), the Secretary shall ensure the adequate representation of women and minorities.

(c) Terms

(1) In general

A member of the Advisory Committee shall be appointed for a term of 3 years, except that of the members first appointed—

(A) 1/3 of such members shall serve for a term of 1 year;
(B) 1/3 of such members shall serve for a term of 2 years; and
(C) 1/3 of such members shall serve for a term of 3 years.

(2) Vacancies

(A) In general

A vacancy on the Advisory Committee shall be filled in the manner in which the original appointment was made and shall be subject to any conditions which applied with respect to the original appointment.

(B) Filling unexpired term

An individual chosen to fill a vacancy shall be appointed for the unexpired term of the member replaced.

(d) Duties

The Advisory Committee shall—

(1) provide advice and recommendations to the Secretary concerning policy and program development and other matters of significance concerning the activities under section 293k of this title;

(2) not later than 3 years after November 13, 1998, and annually thereafter, prepare and submit to the Secretary, and the Committee on Health, Education, Labor, and Pensions of the Senate, and the Committee on Energy and Commerce of the House of Representatives, a report describing the activities of the Committee, including findings and recommendations made by the Committee concerning the activities under section 293k of this title;

(3) develop, publish, and implement performance measures for programs under this part;

(4) develop and publish guidelines for longitudinal evaluations (as described in section 294n(d)(2) of this title) for programs under this part; and

(5) recommend appropriation levels for programs under this part.

(e) Meetings and documents

(1) Meetings

The Advisory Committee shall meet not less than 2 times each year. Such meetings shall be held jointly with other related entities established under this subchapter where appropriate.

(2) Documents

Not later than 14 days prior to the convening of a meeting under paragraph (1), the Advisory Committee shall prepare and make available an agenda of the matters to be considered by the Advisory Committee at such meeting. At any such meeting, the Advisory Council [1] shall distribute materials with respect to the issues to be addressed at the meeting. Not later than 30 days after the adjourning of such a meeting, the Advisory Committee shall prepare and make available a summary of the meeting and any actions taken by the Committee based upon the meeting.

(f) Compensation and expenses

(1) Compensation

Each member of the Advisory Committee shall be compensated at a rate equal to the daily equivalent of the annual rate of basic pay prescribed for level IV of the Executive Schedule under section 5315 of title 5 for each day (including travel time) during which such member is engaged in the performance of the duties of the Committee.

(2) Expenses

The members of the Advisory Committee shall be allowed travel expenses, including per diem in lieu of subsistence, at rates authorized for employees of agencies under subchapter I of chapter 57 of title 5 while away from their homes or regular places of business in the performance of services for the Committee.

(g) Chapter 10 of title 5

Chapter 10 of title 5 shall apply to the Advisory Committee under this section only to the extent that the provisions of chapter 10 of title 5 do not conflict with the requirements of this section.

(July 1, 1944, ch. 373, title VII, §749, formerly §748, as added Pub. L. 105–392, title I, §102(4), Nov. 13, 1998, 112 Stat. 3539; renumbered §749 and amended Pub. L. 111–148, title V, §§5103(d)(1), 5303(1), Mar. 23, 2010, 124 Stat. 605, 618; Pub. L. 116–136, div. A, title III, §3401(5), Mar. 27, 2020, 134 Stat. 386; Pub. L. 117–286, §4(a)(237), Dec. 27, 2022, 136 Stat. 4331.)

EDITORIAL NOTES

CODIFICATION

November 13, 1998, referred to in subsec. (b)(2), was in the original "the date of enactment of this Act", which was translated as meaning the date of enactment of Pub. L. 105–392, which enacted this section, to reflect the probable intent of Congress.

PRIOR PROVISIONS

A prior section 293l, act July 1, 1944, ch. 373, title VII, §748, as added Pub. L. 102–408, title I, §102, Oct. 13, 1992, 106 Stat. 2043; amended Pub. L. 102–531, title III, §313(a)(3), Oct. 27, 1992, 106 Stat. 3507, authorized grants and contracts for development of general internal medicine and general pediatrics training programs, prior to repeal by Pub. L. 105–392, title I, §102(4), Nov. 13, 1998, 112 Stat. 3539.

A prior section 749 of act July 1, 1944, was classified to section 293m of this title prior to repeal by Pub. L. 105–392.

Another prior section 749 of act July 1, 1944, was classified to section 294s of this title prior to renumbering by Pub. L. 97–35.

AMENDMENTS

2022—Subsec. (g). Pub. L. 117–286 substituted "Chapter 10 of title 5" for "FACA" in heading and "Chapter 10 of title 5 shall apply to the Advisory Committee under this section only to the extent that the provisions of chapter 10 of title 5" for "The Federal Advisory Committee Act shall apply to the Advisory Committee under this section only to the extent that the provisions of such Act" in text.

2020—Subsec. (d)(2). Pub. L. 116–136 substituted "Committee on Health, Education, Labor, and Pensions of the Senate, and the Committee on Energy and Commerce of the House of Representatives" for "Committee on Labor and Human Resources of the Senate, and the Committee on Commerce of the House of Representatives".

2010—Subsec. (d)(3) to (5). Pub. L. 111–148, §5103(d)(1), added pars. (3) to (5).

STATUTORY NOTES AND RELATED SUBSIDIARIES

TERMINATION OF ADVISORY COMMITTEES

Pub. L. 93–641, §6, Jan. 4, 1975, 88 Stat. 2275, set out as a note under section 217a of this title, provided that an advisory committee established pursuant to the Public Health Service Act shall terminate at such time as may be specifically prescribed by an Act of Congress enacted after Jan. 4, 1975.

[1] *So in original. Probably should be "Committee".*

§293*l*–1. Teaching health centers development grants

(a) Program authorized

The Secretary may award grants under this section to teaching health centers for the purpose of establishing new accredited or expanded primary care residency programs.

(b) Amount and duration

Grants awarded under this section shall be for a term of not more than 3 years and the maximum award may not be more than $500,000.

(c) Use of funds

Amounts provided under a grant under this section shall be used to cover the costs of—

(1) establishing or expanding a primary care residency training program described in subsection (a), including costs associated with—

(A) curriculum development;

(B) recruitment, training and retention of residents and faculty: [1]

(C) accreditation by the Accreditation Council for Graduate Medical Education (ACGME), the American Dental Association (ADA), or the American Osteopathic Association (AOA); and

(D) faculty salaries during the development phase; and

(2) technical assistance provided by an eligible entity.

(d) Application

A teaching health center seeking a grant under this section shall submit an application to the Secretary at such time, in such manner, and containing such information as the Secretary may require.

(e) Preference for certain applications

In selecting recipients for grants under this section, the Secretary shall give preference to any such application that documents an existing affiliation agreement with an area health education center program as defined in sections 294a and 295p of this title.

(f) Definitions

In this section:

(1) Eligible entity

The term "eligible entity" means an organization capable of providing technical assistance including an area health education center program as defined in sections 294a and 295p of this title.

(2) Primary care residency program

The term "primary care residency program" means an approved graduate medical residency training program (as defined in section 256h of this title) in family medicine, internal medicine, pediatrics, internal medicine-pediatrics, obstetrics and gynecology, psychiatry, general dentistry, pediatric dentistry, and geriatrics.

(3) Teaching health center

(A) In general

The term "teaching health center" means an entity that—

(i) is a community based, ambulatory patient care center; and

(ii) operates a primary care residency program.

(B) Inclusion of certain entities

Such term includes the following:

(i) A Federally qualified health center (as defined in section 1396d(l)(2)(B) of this title).

(ii) A community mental health center (as defined in section 1395x(ff)(3)(B) of this title).

(iii) A rural health clinic, as defined in section 1395x(aa) of this title.

(iv) A health center operated by the Indian Health Service, an Indian tribe or tribal organization, or an urban Indian organization (as defined in section 1603 of title 25).

(v) An entity receiving funds under subchapter VIII.

(g) Authorization of appropriations

There is authorized to be appropriated, $25,000,000 for fiscal year 2010, $50,000,000 for fiscal year 2011, $50,000,000 for fiscal year 2012, and such sums as may be necessary for each fiscal year thereafter to carry out this section. Not to exceed $5,000,000 annually may be used for technical assistance program grants.

(July 1, 1944, ch. 373, title VII, §749A, as added Pub. L. 111–148, title V, §5508(a), Mar. 23, 2010, 124 Stat. 668.)

[1] *So in original. The colon probably should be a semicolon.*

SUBPART 2—TRAINING IN UNDERSERVED COMMUNITIES

§293m. Rural physician training grants

(a) In general

The Secretary, acting through the Administrator of the Health Resources and Services Administration, shall establish a grant program for the purposes of assisting eligible entities in recruiting students most likely to practice medicine in underserved rural communities, providing rural-focused training and experience, and increasing the number of recent allopathic and osteopathic medical school graduates who practice in underserved rural communities.

(b) Eligible entities

In order to be eligible to receive a grant under this section, an entity shall—

(1) be a school of allopathic or osteopathic medicine accredited by a nationally recognized accrediting agency or association approved by the Secretary for this purpose, or any combination

or consortium of such schools; and

(2) submit an application to the Secretary that includes a certification that such entity will use amounts provided to the institution as described in subsection (d)(1).

(c) Priority

In awarding grant funds under this section, the Secretary shall give priority to eligible entities that—

(1) demonstrate a record of successfully training students, as determined by the Secretary, who practice medicine in underserved rural communities;

(2) demonstrate that an existing academic program of the eligible entity produces a high percentage, as determined by the Secretary, of graduates from such program who practice medicine in underserved rural communities;

(3) demonstrate rural community institutional partnerships, through such mechanisms as matching or contributory funding, documented in-kind services for implementation, or existence of training partners with interprofessional expertise in community health center training locations or other similar facilities; or

(4) submit, as part of the application of the entity under subsection (b), a plan for the long-term tracking of where the graduates of such entity practice medicine.

(d) Use of funds

(1) Establishment

An eligible entity receiving a grant under this section shall use the funds made available under such grant to establish, improve, or expand a rural-focused training program (referred to in this section as the "Program") meeting the requirements described in this subsection and to carry out such program.

(2) Structure of Program

An eligible entity shall—

(A) enroll no fewer than 10 students per class year into the Program; and

(B) develop criteria for admission to the Program that gives priority to students—

(i) who have originated from or lived for a period of 2 or more years in an underserved rural community; and

(ii) who express a commitment to practice medicine in an underserved rural community.

(3) Curricula

The Program shall require students to enroll in didactic coursework and clinical experience particularly applicable to medical practice in underserved rural communities, including—

(A) clinical rotations in underserved rural communities, and in applicable specialties, or other coursework or clinical experience deemed appropriate by the Secretary; and

(B) in addition to core school curricula, additional coursework or training experiences focused on medical issues prevalent in underserved rural communities.

(4) Residency placement assistance

Where available, the Program shall assist all students of the Program in obtaining clinical training experiences in locations with postgraduate programs offering residency training opportunities in underserved rural communities, or in local residency training programs that support and train physicians to practice in underserved rural communities.

(5) Program student cohort support

The Program shall provide and require all students of the Program to participate in group activities designed to further develop, maintain, and reinforce the original commitment of such students to practice in an underserved rural community.

(e) Annual reporting

An eligible entity receiving a grant under this section shall submit an annual report to the Secretary on the success of the Program, based on criteria the Secretary determines appropriate,

including the residency program selection of graduating students who participated in the Program.

(f) Regulations

Not later than 60 days after March 23, 2010, the Secretary shall by regulation define "underserved rural community" for purposes of this section.

(g) Supplement not supplant

Any eligible entity receiving funds under this section shall use such funds to supplement, not supplant, any other Federal, State, and local funds that would otherwise be expended by such entity to carry out the activities described in this section.

(h) Maintenance of effort

With respect to activities for which funds awarded under this section are to be expended, the entity shall agree to maintain expenditures of non-Federal amounts for such activities at a level that is not less than the level of such expenditures maintained by the entity for the fiscal year preceding the fiscal year for which the entity receives a grant under this section.

(i) Authorization of appropriations

There are authorized to be appropriated $4,000,000 for each of the fiscal years 2010 through 2013.

(July 1, 1944, ch. 373, title VII, §749B, as added Pub. L. 111–148, title X, §10501(l)(2), Mar. 23, 2010, 124 Stat. 1000.)

EDITORIAL NOTES

PRIOR PROVISIONS

A prior section 293m, act July 1, 1944, ch. 373, title VII, §749, as added Pub. L. 102–408, title I, §102, Oct. 13, 1992, 106 Stat. 2043, authorized grants and contracts for development of programs in general practice of dentistry, prior to repeal by Pub. L. 105–392, title I, §102(4), Nov. 13, 1998, 112 Stat. 3539.

§§293n to 293p. Repealed. Pub. L. 105–392, title I, §102(4), Nov. 13, 1998, 112 Stat. 3539

Section 293n, act July 1, 1944, ch. 373, title VII, §750, as added Pub. L. 102–408, title I, §102, Oct. 13, 1992, 106 Stat. 2044, authorized grants and contracts for development of training programs for physician assistants.

Section 293o, act July 1, 1944, ch. 373, title VII, §751, as added Pub. L. 102–408, title I, §102, Oct. 13, 1992, 106 Stat. 2044, authorized grants and contracts for implementation of training projects for podiatric physicians.

Section 293p, act July 1, 1944, ch. 373, title VII, §752, as added Pub. L. 102–408, title I, §102, Oct. 13, 1992, 106 Stat. 2045, set forth general provisions relating to traineeships and fellowships.

PART D—INTERDISCIPLINARY, COMMUNITY-BASED LINKAGES

§294. General provisions

(a) Collaboration

To be eligible to receive assistance under this part, an academic institution shall use such assistance in collaboration with 2 or more disciplines.

(b) Activities

An entity shall use assistance under this part to carry out innovative demonstration projects for strategic workforce supplementation activities as needed to meet national goals for interdisciplinary,

community-based linkages. Such assistance may be used consistent with this part—

(1) to develop and support training programs;
(2) for faculty development;
(3) for model demonstration programs;
(4) for the provision of stipends for fellowship trainees;
(5) to provide technical assistance; and
(6) for other activities that will produce outcomes consistent with the purposes of this part.

(July 1, 1944, ch. 373, title VII, §750, as added Pub. L. 105–392, title I, §103, Nov. 13, 1998, 112 Stat. 3541.)

EDITORIAL NOTES

PRIOR PROVISIONS

A prior section 294, act July 1, 1944, ch. 373, title VII, §761, as added Pub. L. 102–408, title I, §102, Oct. 13, 1992, 106 Stat. 2045; amended Pub. L. 103–43, title XX, §2014(e), June 10, 1993, 107 Stat. 217, authorized grants for traineeships in health professions fields experiencing severe shortages of health professionals, prior to the general amendment of this part by Pub. L. 105–392.

Another prior section 294, act July 1, 1944, ch. 373, title VII, §727, as added Oct. 12, 1976, Pub. L. 94–484, title IV, §401(b)(3), 90 Stat. 2257; amended Dec. 19, 1977, Pub. L. 95–215, §4(e)(1), 91 Stat. 1506, stated purpose of and authorized appropriations for Federal program of student loan insurance, prior to the general amendment of this subchapter by Pub. L. 102–408. See sections 292 and 292p of this title.

Another prior section 294, act July 1, 1944, ch. 373, title VII, §740, as added Sept. 24, 1963, Pub. L. 88–129, §2(b), 77 Stat. 170; amended Oct. 13, 1964, Pub. L. 88–654, §1(a), (b), 78 Stat. 1086; Oct. 22, 1965, Pub. L. 89–290, §§2(b), 4(a), (f)(1), (2), 79 Stat. 1056 to 1058; Nov. 2, 1966, Pub. L. 89–709, §3(a), (b), 80 Stat. 1103; Nov. 3, 1966, Pub. L. 89–751, §5(c)(1), 80 Stat. 1232; Aug. 16, 1968, Pub. L. 90–490, title I §121(a)(1), (2), (5)(B), 82 Stat. 777, 778; Nov. 18, 1971, Pub. L. 92–157, title I, §105(e)(1), (4), (f)(2), 85 Stat. 451; Aug. 23, 1974, Pub. L. 93–385, §2(b), 88 Stat. 741; Apr. 22, 1976, Pub. L. 94–278, title XI, 1105(b), 90 Stat. 416; Oct. 12, 1976, Pub. L. 94–484, title IV, §402, 90 Stat. 2266, which related to loan agreements for the establishment of student loan funds, was transferred to section 294m of this title.

A prior section 750 of act July 1, 1944, was classified to section 293n of this title prior to repeal by Pub. L. 105–392.

§294a. Area health education centers

(a) Establishment of awards

The Secretary shall make the following 2 types of awards in accordance with this section:

(1) Infrastructure development award

The Secretary shall make awards to eligible entities to enable such entities to initiate health care workforce educational programs or to continue to carry out comparable programs that are operating at the time the award is made by planning, developing, operating, and evaluating an area health education center program.

(2) Point of service maintenance and enhancement award

The Secretary shall make awards to eligible entities to maintain and improve the effectiveness and capabilities of an existing area health education center program, and make other modifications to the program that are appropriate due to changes in demographics, needs of the populations served, or other similar issues affecting the area health education center program. For the purposes of this section, the term "Program" refers to the area health education center program.

(b) Eligible entities; application

(1) Eligible entities

(A) Infrastructure development

For purposes of subsection (a)(1), the term "eligible entity" means a school of medicine or

osteopathic medicine, an incorporated consortium of such schools, or the parent institutions of such a school. With respect to a State in which no area health education center program is in operation, the Secretary may award a grant or contract under subsection (a)(1) to a school of nursing.

(B) Point of service maintenance and enhancement

For purposes of subsection (a)(2), the term "eligible entity" means an entity that has received funds under this section, is operating an area health education center program, including an area health education center or centers, and has a center or centers that are no longer eligible to receive financial assistance under subsection (a)(1).

(2) Application

An eligible entity desiring to receive an award under this section shall submit to the Secretary an application at such time, in such manner, and containing such information as the Secretary may require.

(c) Use of funds

(1) Required activities

An eligible entity shall use amounts awarded under a grant under subsection (a)(1) or (a)(2) to carry out the following activities:

(A) Develop and implement strategies, in coordination with the applicable one-stop delivery system under section 3151(e) of title 29, to recruit individuals from underrepresented minority populations or from disadvantaged or rural backgrounds into health professions, and support such individuals in attaining such careers.

(B) Develop and implement strategies to foster and provide community-based training and education to individuals seeking careers in health professions within underserved areas for the purpose of developing and maintaining a diverse health care workforce that is prepared to deliver high-quality care, with an emphasis on primary care, in underserved areas or for health disparity populations, in collaboration with other Federal and State health care workforce development programs, the State workforce agency, and local workforce investment boards, and in health care safety net sites.

(C) Prepare individuals to more effectively provide health services to underserved areas and health disparity populations through field placements or preceptorships in conjunction with community-based organizations, accredited primary care residency training programs, Federally qualified health centers, rural health clinics, public health departments, or other appropriate facilities.

(D) Conduct and participate in interdisciplinary training that involves physicians, physician assistants, nurse practitioners, nurse midwives, dentists, psychologists, pharmacists, optometrists, community health workers, public and allied health professionals, or other health professionals, as practicable.

(E) Deliver or facilitate continuing education and information dissemination programs for health care professionals, with an emphasis on individuals providing care in underserved areas and for health disparity populations.

(F) Propose and implement effective program and outcomes measurement and evaluation strategies.

(G) Establish a youth public health program to expose and recruit high school students into health careers, with a focus on careers in public health.

(2) Innovative opportunities

An eligible entity may use amounts awarded under a grant under subsection (a)(1) or subsection (a)(2) to carry out any of the following activities:

(A) Develop and implement innovative curricula in collaboration with community-based accredited primary care residency training programs, Federally qualified health centers, rural health clinics, behavioral and mental health facilities, public health departments, or other

appropriate facilities, with the goal of increasing the number of primary care physicians and other primary care providers prepared to serve in underserved areas and health disparity populations.

(B) Coordinate community-based participatory research with academic health centers, and facilitate rapid flow and dissemination of evidence-based health care information, research results, and best practices to improve quality, efficiency, and effectiveness of health care and health care systems within community settings.

(C) Develop and implement other strategies to address identified workforce needs and increase and enhance the health care workforce in the area served by the area health education center program.

(d) Requirements

(1) Area health education center program

In carrying out this section, the Secretary shall ensure the following:

(A) An entity that receives an award under this section shall conduct at least 10 percent of clinical education required for medical students in community settings that are removed from the primary teaching facility of the contracting institution for grantees that operate a school of medicine or osteopathic medicine. In States in which an entity that receives an award under this section is a nursing school or its parent institution, the Secretary shall alternatively ensure that—

(i) the nursing school conducts at least 10 percent of clinical education required for nursing students in community settings that are remote from the primary teaching facility of the school; and

(ii) the entity receiving the award maintains a written agreement with a school of medicine or osteopathic medicine to place students from that school in training sites in the area health education center program area.

(B) An entity receiving funds under subsection (a)(2) does not distribute such funding to a center that is eligible to receive funding under subsection (a)(1).

(2) Area health education center

The Secretary shall ensure that each area health education center program includes at least 1 area health education center, and that each such center—

(A) is a public or private organization whose structure, governance, and operation is independent from the awardee and the parent institution of the awardee;

(B) is not a school of medicine or osteopathic medicine, the parent institution of such a school, or a branch campus or other subunit of a school of medicine or osteopathic medicine or its parent institution, or a consortium of such entities;

(C) designates an underserved area or population to be served by the center which is in a location removed from the main location of the teaching facilities of the schools participating in the program with such center and does not duplicate, in whole or in part, the geographic area or population served by any other center;

(D) fosters networking and collaboration among communities and between academic health centers and community-based centers;

(E) serves communities with a demonstrated need of health professionals in partnership with academic medical centers;

(F) addresses the health care workforce needs of the communities served in coordination with the public workforce investment system; and

(G) has a community-based governing or advisory board that reflects the diversity of the communities involved.

(e) Matching funds

With respect to the costs of operating a program through a grant under this section, to be eligible for financial assistance under this section, an entity shall make available (directly or through

contributions from State, county or municipal governments, or the private sector) recurring non-Federal contributions in cash or in kind, toward such costs in an amount that is equal to not less than 50 percent of such costs. At least 25 percent of the total required non-Federal contributions shall be in cash. An entity may apply to the Secretary for a waiver of not more than 75 percent of the matching fund amount required by the entity for each of the first 3 years the entity is funded through a grant under subsection (a)(1).

(f) Limitation

Not less than 75 percent of the total amount provided to an area health education center program under subsection (a)(1) or (a)(2) shall be allocated to the area health education centers participating in the program under this section. To provide needed flexibility to newly funded area health education center programs, the Secretary may waive the requirement in the sentence for the first 2 years of a new area health education center program funded under subsection (a)(1).

(g) Award

An award to an entity under this section shall be not less than $250,000 annually per area health education center included in the program involved. If amounts appropriated to carry out this section are not sufficient to comply with the preceding sentence, the Secretary may reduce the per center amount provided for in such sentence as necessary, provided the distribution established in subsection (j)(2) is maintained.

(h) Project terms

(1) In general

Except as provided in paragraph (2), the period during which payments may be made under an award under subsection (a)(1) may not exceed—

(A) in the case of a program, 12 years; or

(B) in the case of a center within a program, 6 years.

(2) Exception

The periods described in paragraph (1) shall not apply to programs receiving point of service maintenance and enhancement awards under subsection (a)(2) to maintain existing centers and activities.

(i) Inapplicability of provision

Notwithstanding any other provision of this subchapter, section 295j(a) of this title shall not apply to an area health education center funded under this section.

(j) Authorization of appropriations

(1) In general

There is authorized to be appropriated to carry out this section $41,250,000 for each of fiscal years 2021 through 2025.

(2) Requirements

Of the amounts appropriated for a fiscal year under paragraph (1)—

(A) not more than 35 percent shall be used for awards under subsection (a)(1);

(B) not less than 60 percent shall be used for awards under subsection (a)(2);

(C) not more than 1 percent shall be used for grants and contracts to implement outcomes evaluation for the area health education centers; and

(D) not more than 4 percent shall be used for grants and contracts to provide technical assistance to entities receiving awards under this section.

(3) Carryover funds

An entity that receives an award under this section may carry over funds from 1 fiscal year to another without obtaining approval from the Secretary. In no case may any funds be carried over pursuant to the preceding sentence for more than 3 years.

(k) Sense of Congress

It is the sense of the Congress that every State have an area health education center program in effect under this section.

(July 1, 1944, ch. 373, title VII, §751, as added Pub. L. 105–392, title I, §103, Nov. 13, 1998, 112 Stat. 3541; amended Pub. L. 111–148, title V, §5403(a), Mar. 23, 2010, 124 Stat. 644; Pub. L. 113–128, title V, §512(z)(2), July 22, 2014, 128 Stat. 1716; Pub. L. 116–136, div. A, title III, §3401(6), Mar. 27, 2020, 134 Stat. 386.)

EDITORIAL NOTES

PRIOR PROVISIONS

A prior section 294a, act July 1, 1944, ch. 373, title VII, §762, as added Pub. L. 102–408, title I, §102, Oct. 13, 1992, 106 Stat. 2046, authorized grants and contracts for public health special projects, prior to the general amendment of this part by Pub. L. 105–392.

Another prior section 294a, act July 1, 1944, ch. 373, title VII, §728, as added Oct. 12, 1976, Pub. L. 94–484, title IV, §401(b)(3), 90 Stat. 2257; amended Dec. 19, 1977, Pub. L. 95–215, §4(e)(2)–(4), 91 Stat. 1506; Dec. 17, 1980, Pub. L. 96–538, title IV, §401, 94 Stat. 3192; Aug. 13, 1981, Pub. L. 97–35, title XXVII, §2726, 95 Stat. 916; Oct. 22, 1985, Pub. L. 99–129, title I, §101, title II, §208(h), 99 Stat. 523, 532; Nov. 4, 1988, Pub. L. 100–607, title VI, §§602(a)–(d), 636, title VII, §707, 102 Stat. 3122, 3149, 3159; Nov. 18, 1988, Pub. L. 100–690, title II, §2615(b), 102 Stat. 4239; Aug. 16, 1989, Pub. L. 101–93, §5(g)(1), 103 Stat. 612, related to Federal student loan insurance program, prior to the general amendment of this subchapter by Pub. L. 102–408. See section 292a of this title.

Another prior section 294a, act July 1, 1944, ch. 373, title VII, §741, as added Sept. 24, 1963, Pub. L. 88–129, §2(b), 77 Stat. 171; amended Oct. 13, 1964, Pub. L. 88–654, §1(c), (d), 78 Stat. 1086; Oct. 22, 1965, Pub. L. 89–290, §4(b), (f)(3), (4), (g)(1), 79 Stat. 1057, 1058; Nov. 2, 1966, Pub. L. 89–709, §3(c), (d), 80 Stat. 1103; Nov. 3, 1966, Pub. L. 89–751, §4, 80 Stat. 1230; Aug. 16, 1968, Pub. L. 90–490, title I, §121(a)(3), (4), (5)(A), 82 Stat. 777; Nov. 18, 1971, Pub. L. 92–157, title I, §105(b)–(d), (e)(4), (f)(2), 85 Stat. 449–451; Oct. 27, 1972, Pub. L. 92–585, §4, 86 Stat. 1293; Oct. 12, 1976, Pub. L. 94–484, title IV, §§403(a), (b), (d), 407(d)(1), 90 Stat. 2266, 2279, which related to loan provisions, was transferred to section 294n of this title.

A prior section 751 of act July 1, 1944, was classified to section 293o of this title prior to repeal by Pub. L. 105–392.

Another prior section 751 of act July 1, 1944, was classified to section 294r of this title prior to the general amendment of this subchapter by Pub. L. 102–408.

Another prior section 751 of act July 1, 1944, was classified to section 294t of this title prior to renumbering by Pub. L. 97–35.

AMENDMENTS

2020—Subsec. (j)(1). Pub. L. 116–136 substituted "$41,250,000 for each of fiscal years 2021 through 2025" for "$125,000,000 for each of the fiscal years 2010 through 2014".

2014—Subsec. (c)(1)(A). Pub. L. 113–128 substituted "the applicable one-stop delivery system under section 3151(e) of title 29," for "the applicable one-stop delivery system under section 2864(c) of title 29,".

2010—Pub. L. 111–148 amended section generally. Prior to amendment, section consisted of subsecs. (a) to (c) which related to authority for provision of financial assistance, requirements for centers, and allocations and costs.

STATUTORY NOTES AND RELATED SUBSIDIARIES

EFFECTIVE DATE OF 2014 AMENDMENT

Amendment by Pub. L. 113–128 effective on the first day of the first full program year after July 22, 2014 (July 1, 2015), see section 506 of Pub. L. 113–128, set out as an Effective Date note under section 3101 of Title 29, Labor.

WAIVER OF REQUIREMENTS

Pub. L. 119–75, div. B, title II, Feb. 3, 2026, 140 Stat. 258, provided in part: "That for any program operating under section 751 of the PHS [Public Health Service] Act [42 U.S.C. 294a] on or before January 1,

2009, the Secretary of Health and Human Services (referred to in this title as the 'Secretary') may hereafter waive any of the requirements contained in sections 751(d)(2)(A) and 751(d)(2)(B) of such Act for the full project period of a grant under such section".

Similar provisions were contained in the following prior appropriation acts:
Pub. L. 118–47, div. D, title II, Mar. 23, 2024, 138 Stat. 649.
Pub. L. 117–328, div. H, title II, Dec. 29, 2022, 136 Stat. 4854.
Pub. L. 117–103, div. H, title II, Mar. 15, 2022, 136 Stat. 442.
Pub. L. 116–260, div. H, title II, Dec. 27, 2020, 134 Stat. 1567.
Pub. L. 116–94, div. A, title II, Dec. 20, 2019, 133 Stat. 2556.
Pub. L. 115–245, div. B, title II, Sept. 28, 2018, 132 Stat. 3068.
Pub. L. 115–141, div. H, title II, Mar. 23, 2018, 132 Stat. 715.
Pub. L. 115–31, div. H, title II, May 5, 2017, 131 Stat. 519.
Pub. L. 114–113, div. H, title II, Dec. 18, 2015, 129 Stat. 2600.
Pub. L. 113–235, div. G, title II, Dec. 16, 2014, 128 Stat. 2467.
Pub. L. 113–76, div. H, title II, Jan. 17, 2014, 128 Stat. 363.

§294b. Continuing educational support for health professionals serving in rural and underserved communities

(a) In general

The Secretary, as appropriate, shall make grants to, and enter into contracts with, eligible entities to support access to accredited continuing medical education for primary care physicians and health care providers at community health centers or rural health clinics to improve and increase access to care for patients in rural and medically underserved areas. Such grants or contracts may be used to improve health care, increase retention, increase representation of minority health care providers, enhance the practice environment, increase primary care physician and health care provider knowledge, and provide information dissemination and educational support to reduce professional isolation through the timely dissemination of research findings using relevant resources.

(b) Eligible entities

For purposes of this section, the term "eligible entity" means an entity described in section 295o–1(b) of this title, such as a community health center or rural health clinic.

(c) Application

An eligible entity desiring to receive an award under this section shall submit to the Secretary an application at such time, in such manner, and containing such information as the Secretary may require, including—

(1) a description of how participation in activities funded under this section will help improve access to, and quality of, health care services and training needs of primary care physicians and health care providers; and

(2) a plan for providing peer-to-peer training, as appropriate.

(d) Use of funds

(1) In general

An eligible entity shall use amounts awarded under a grant or contract under this section to provide innovative supportive activities to enhance education for primary care physicians and health care providers described in subsection (a) through distance learning, continuing educational activities, collaborative conferences, and electronic and telelearning activities, with priority for primary care providers who are seeking additional education in specialty fields such as infectious disease, endocrinology, pediatrics, mental health and substance use disorders, pain management, geriatrics, and other areas, as appropriate, in order to—

(A) improve retention of primary care physicians and health care providers and increase access to specialty health care services for patients; and

(B) support access to the integration of specialty care through existing service delivery

locations and care across settings.

(2) Clarification

Entities may use amounts awarded under a grant or contract under this section for continuing educational activities that include a clinical training component, including in-person patient care, in the respective community health center or rural health clinic, with the primary care physician or health care provider at such site and the clinical specialist from whom such additional training is being provided.

(e) Administrative expenses

An entity that revives a grant or contract under this section shall use not more than 5 percent of the amounts received under the grant or contract under this section for administrative expenses.

(f) Non-duplication of effort

The Secretary shall ensure that activities under this section do not unnecessarily duplicate efforts of other programs overseen by the Health Resources and Services Administration, including activities described in section 254c–20 of this title.

(g) Authorization

There is authorized to be appropriated to carry out this section $5,000,000 for each of fiscal years 2023 through 2025.

(July 1, 1944, ch. 373, title VII, §752, as added Pub. L. 111–148, title V, §5403(b), Mar. 23, 2010, 124 Stat. 648; amended Pub. L. 117–328, div. FF, title II, §2227, Dec. 29, 2022, 136 Stat. 5751.)

EDITORIAL NOTES

PRIOR PROVISIONS

A prior section 294b, act July 1, 1944, ch. 373, title VII, §752, as added Pub. L. 105–392, title I, §103, Nov. 13, 1998, 112 Stat. 3544, related to health education and training centers, prior to repeal by Pub. L. 111–148, title V, §5403(b), Mar. 23, 2010, 124 Stat. 648.

Another prior section 294b, act July 1, 1944, ch. 373, title VII, §763, as added Pub. L. 102–408, title I, §102, Oct. 13, 1992, 106 Stat. 2047, authorized grants and contracts for development of preventive medicine and dental public health programs, prior to the general amendment of this part by Pub. L. 105–392.

Another prior section 294b, act July 1, 1944, ch. 373, title VII, §729, as added Oct. 12, 1976, Pub. L. 94–484, title IV, §401(b)(3), 90 Stat. 2258; amended Dec. 19, 1977, Pub. L. 95–215, §4(e)(5), 91 Stat. 1506; Sept. 29, 1979, Pub. L. 96–76, title II, §201, 93 Stat. 582; Aug. 13, 1981, Pub. L. 97–35, title XXVII, §2727, 95 Stat. 917; Oct. 22, 1985, Pub. L. 99–129, title II, §208(g)(1), 99 Stat. 531; Nov. 4, 1988, Pub. L. 100–607, title VI, §§628(5), 629(b)(2), 102 Stat. 3145, 3146, related to limitations on individually insured loans and loan insurance, prior to the general revision of this subchapter by Pub. L. 102–408. See section 292b of this title.

Another prior section 294b, act July 1, 1944, ch. 373, title VII, §742, as added Sept. 24, 1963, Pub. L. 88–129, §2(b), 77 Stat. 172; amended Oct. 22, 1965, Pub. L. 89–290, §4(c), 79 Stat. 1057; Nov. 2, 1966, Pub. L. 89–709, §3(e), 80 Stat. 1103; Nov. 3, 1966, Pub. L. 89–751, §5(b), 80 Stat. 1232; Aug. 16, 1968, Pub. L. 90–490, title I, §121(b), 82 Stat. 778; July 9, 1971, Pub. L. 92–52, §1(a), 85 Stat. 144; Nov. 18, 1971, Pub. L. 92–157, title I, §105(a), (f)(2), 85 Stat. 449, 451; Aug. 23, 1974, Pub. L. 93–385, §2(a), 88 Stat. 741; Apr. 22, 1976, Pub. L. 94–278, title XI, §1105(a), 90 Stat. 416; Oct. 12, 1976, Pub. L. 94–484, title I, §101(e), title IV, §§404, 406(d), 90 Stat. 2244, 2267, 2268, which related to authorization of appropriations, was transferred to section 294o of this title.

A prior section 752 of act July 1, 1944, was classified to section 293p of this title prior to repeal by Pub. L. 105–392.

Another prior section 752 of act July 1, 1944, was classified to section 294u of this title prior to renumbering by Pub. L. 97–35.

AMENDMENTS

2022—Pub. L. 117–328, §2227(1), inserted "rural and" after "serving in" in section catchline.

Subsec. (a). Pub. L. 117–328, §2227(2), substituted ", as appropriate, shall make grants to, and enter into contracts with, eligible entities to support access to accredited continuing medical education for primary care

physicians and health care providers at community health centers or rural health clinics to improve and increase access to care for patients in rural and medically underserved areas. Such grants or contracts may be used" for "shall make grants to, and enter into contracts with, eligible entities" and "health care providers" for "faculty members" and inserted "increase primary care physician and health care provider knowledge," after "practice environment,".

Subsec. (b). Pub. L. 117–328, §2227(3), inserted ", such as a community health center or rural health clinic" before period at end.

Subsec. (c). Pub. L. 117–328, §2227(4), which directed substitution of "may require, including—" and pars. (1) and (2) for "by require.", was executed by making the substitution for "may require.", to reflect the probable intent of Congress.

Subsec. (d). Pub. L. 117–328, §2227(5), amended subsec. (d) generally. Prior to amendment, text read as follows: "An eligible entity shall use amounts awarded under a grant or contract under this section to provide innovative supportive activities to enhance education through distance learning, continuing educational activities, collaborative conferences, and electronic and telelearning activities, with priority for primary care."

Subsecs. (e), (f). Pub. L. 117–328, §2227(7), added subsecs. (e) and (f). Former subsec. (e) redesignated (g).

Subsec. (g). Pub. L. 117–328, §2227(6), (8), redesignated subsec. (e) as (g) and substituted "fiscal years 2023 through 2025" for "the fiscal years 2010 through 2014, and such sums as may be necessary for each subsequent fiscal year".

§294c. Education and training relating to geriatrics

(a) Geriatrics Workforce Enhancement Program

(1) In general

The Secretary shall award grants, contracts, or cooperative agreements under this subsection to entities described in paragraph (1), (3), or (4) of section 295p of this title, section 296(2) of this title, or section 298(d) of this title, or other health professions schools or programs approved by the Secretary, for the establishment or operation of Geriatrics Workforce Enhancement Programs that meet the requirements of paragraph (2).

(2) Requirements

(A) In general

A Geriatrics Workforce Enhancement Program receiving an award under this section shall support the training of health professionals in geriatrics, including traineeships or fellowships. Such programs shall emphasize, as appropriate, patient and family engagement, integration of geriatrics with primary care and other appropriate specialties, and collaboration with community partners to address gaps in health care for older adults.

(B) Activities

Activities conducted by a program under this section may include the following:

(i) Clinical training on providing integrated geriatrics and primary care delivery services.

(ii) Interprofessional training to practitioners from multiple disciplines and specialties, including training on the provision of care to older adults.

(iii) Establishing or maintaining training-related community-based programs for older adults and caregivers to improve health outcomes for older adults.

(iv) Providing education on Alzheimer's disease and related dementias to families and caregivers of older adults, direct care workers, and health professions students, faculty, and providers.

(3) Duration

Each grant, contract, or cooperative agreement or contract awarded under paragraph (1) shall be for a period not to exceed 5 years.

(4) Applications

To be eligible to receive a grant, contract, or cooperative agreement under paragraph (1), an

entity described in such paragraph shall submit to the Secretary an application at such time, in such manner, and containing such information as the Secretary may require.

(5) Program requirements

(A) In general

In awarding grants, contracts, and cooperative agreements under paragraph (1), the Secretary—

(i) shall give priority to programs that demonstrate coordination with another Federal or State program or another public or private entity;

(ii) shall give priority to applicants with programs or activities that are expected to substantially benefit rural or medically underserved populations of older adults, or serve older adults in Indian Tribes or Tribal organizations; and

(iii) may give priority to any program that—

(I) integrates geriatrics into primary care practice;

(II) provides training to integrate geriatric care into other specialties across care settings, including practicing clinical specialists, health care administrators, faculty without backgrounds in geriatrics, and students from all health professions;

(III) emphasizes integration of geriatric care into existing service delivery locations and care across settings, including primary care clinics, medical homes, Federally qualified health centers, ambulatory care clinics, critical access hospitals, emergency care, assisted living and nursing facilities, and home- and community-based services, which may include adult daycare;

(IV) supports the training and retraining of faculty, primary care providers, other direct care providers, and other appropriate professionals on geriatrics;

(V) emphasizes education and engagement of family caregivers on disease management and strategies to meet the needs of caregivers of older adults; or

(VI) proposes to conduct outreach to communities that have a shortage of geriatric workforce professionals.

(B) Special consideration

In awarding grants, contracts, and cooperative agreements under this section, the Secretary shall give special consideration to entities that provide services in areas with a shortage of geriatric workforce professionals.

(6) Priority

The Secretary may provide awardees with additional support for activities in areas of demonstrated need, which may include education and training for home health workers, family caregivers, and direct care workers on care for older adults.

(7) Reporting

(A) Reports from entities

Each entity awarded a grant, contract, or cooperative agreement under this section shall submit an annual report to the Secretary on the activities conducted under such grant, contract, or cooperative agreement, which may include information on the number of trainees, the number of professions and disciplines, the number of partnerships with health care delivery sites, the number of faculty and practicing professionals who participated in such programs, and other information, as the Secretary may require.

(B) Report to Congress

Not later than 4 years after March 27, 2020, and every 5 years thereafter, the Secretary shall submit to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives a report that provides a summary of the activities and outcomes associated with grants, contracts, and cooperative agreements made under this section. Such reports shall include—

(i) information on the number of trainees, faculty, and professionals who participated in programs under this section;

(ii) information on the impact of the program conducted under this section on the health status of older adults, including in areas with a shortage of health professionals; and

(iii) information on outreach and education provided under this section to families and caregivers of older adults.

(C) Public availability

The Secretary shall make reports submitted under paragraph (B) publically available on the internet website of the Department of Health and Human Services.

(b) Geriatric academic career awards

(1) Establishment of program

The Secretary shall, as appropriate, establish or maintain a program to provide geriatric academic career awards to eligible entities applying on behalf of eligible individuals to promote the career development of such individuals as academic geriatricians or other academic geriatrics health professionals.

(2) Eligibility

(A) Eligible entity

For purposes of this subsection, the term "eligible entity" means—

(i) an entity described in paragraph (1), (3), or (4) of section 295p of this title or section 296(2) of this title; or

(ii) another accredited health professions school or graduate program approved by the Secretary.

(B) Eligible individual

For purposes of this subsection, the term "eligible individual" means an individual who—

(i)(I) is board certified or board eligible in internal medicine, family practice, psychiatry, or licensed dentistry, or has completed required training in a discipline and is employed in an accredited health professions school or graduate program that is approved by the Secretary; or

(II) has completed an approved fellowship program in geriatrics, or has completed specialty training in geriatrics as required by the discipline and any additional geriatrics training as required by the Secretary; and

(ii) has a junior, nontenured, faculty appointment at an accredited health professions school or graduate program in geriatrics or a geriatrics health profession.

(C) Clarification

If an eligible individual is promoted during the period of an award under this subsection and thereby no longer meets the criteria of subparagraph (B)(ii), the individual shall continue to be treated as an eligible individual through the term of the award.

(3) Application requirements

In order to receive an award under paragraph (1), an eligible entity, on behalf of an eligible individual, shall—

(A) submit to the Secretary an application, at such time, in such manner, and containing such information as the Secretary may require;

(B) provide, in such form and manner as the Secretary may require, assurances that the eligible individual will meet the service requirement described in paragraph (6); and

(C) provide, in such form and manner as the Secretary may require, assurances that the individual has a full-time faculty appointment in a health professions institution and documented commitment from such eligible entity that the individual will spend 75 percent of the individual's time that is supported by the award on teaching and developing skills in interdisciplinary education in geriatrics.

(4) Equitable distribution

In making awards under this subsection, the Secretary shall seek to ensure geographical distribution among award recipients, including among rural or medically underserved areas of the United States.

(5) Amount and duration

(A) Amount

The amount of an award under this subsection shall be at least $75,000 for fiscal year 2021, adjusted for subsequent years in accordance with the consumer price index. The Secretary shall determine the amount of an award under this subsection for individuals who are not physicians.

(B) Duration

The Secretary shall make awards under paragraph (1) for a period not to exceed 5 years.

(6) Service requirement

An individual who receives an award under this subsection shall provide training in clinical geriatrics, including the training of interprofessional teams of health care professionals. The provision of such training shall constitute at least 75 percent of the obligations of such individual under the award.

(c) Nonapplicability of provision

Notwithstanding any other provision of this subchapter, section 295j(a) of this title shall not apply to awards made under this section.

(d) Authorization of appropriations

There is authorized to be appropriated $40,737,000 for each of fiscal years 2021 through 2025 for purposes of carrying out this section.

(July 1, 1944, ch. 373, title VII, §753, as added Pub. L. 105–392, title I, §103, Nov. 13, 1998, 112 Stat. 3544; amended Pub. L. 107–205, title II, §202(b), Aug. 1, 2002, 116 Stat. 817; Pub. L. 111–148, title V, §5305(a), (b), Mar. 23, 2010, 124 Stat. 622, 624; Pub. L. 111–256, §2(f)(5), Oct. 5, 2010, 124 Stat. 2644; Pub. L. 116–136, div. A, title III, §3403, Mar. 27, 2020, 134 Stat. 388; Pub. L. 116–260, div. BB, title III, §331(a), Dec. 27, 2020, 134 Stat. 2938.)

EDITORIAL NOTES

PRIOR PROVISIONS

A prior section 294c, act July 1, 1944, ch. 373, title VII, §765, as added Pub. L. 102–408, title I, §102, Oct. 13, 1992, 106 Stat. 2047, authorized appropriations for purpose of carrying out subpart I of this part, prior to the general amendment of this part by Pub. L. 105–392.

Another prior section 294c, act July 1, 1944, ch. 373, title VII, §730, as added Oct. 12, 1976, Pub. L. 94–484, title IV, §401(b)(3), 90 Stat. 2258, related to sources of funds for eligible student loans, prior to the general amendment of this subchapter by Pub. L. 102–408. See section 292c of this title.

Another prior section 294c, act July 1, 1944, ch. 373, title VII, §743, as added Sept. 24, 1963, Pub. L. 88–129, §2(b), 77 Stat. 172; amended Oct. 22, 1965, Pub. L. 89–290, §4(d), 79 Stat. 1057; Nov. 3, 1966, Pub. L. 89–751, §5(c)(2), (3), 80 Stat. 1233; Aug. 16, 1968, Pub. L. 90–490, title I, §121(c), 82 Stat. 778; July 9, 1971, Pub. L. 92–52, §1(b), 85 Stat. 144; Nov. 18, 1971, Pub. L. 92–157, title I, §105(e)(2), (f)(2), 85 Stat. 451; Oct. 12, 1976, Pub. L. 94–484, title IV, §§405, 406(e), 90 Stat. 2267, 2268, which related to the distribution of assets from loan funds, was transferred to section 294p of this title.

AMENDMENTS

2020—Pub. L. 116–136 amended section generally. Prior to amendment, section consisted of subsecs. (a) to (e) which related to geriatric education centers, geriatric training regarding physicians and dentists, geriatric faculty fellowships, geriatric workforce development, and geriatric career incentive awards, respectively.

Subsec. (a)(7)(B). Pub. L. 116–260, in introductory provisions, substituted "Coronavirus Aid, Relief, and Economic Security Act" for "Title VII Health Care Workforce Reauthorization Act of 2019" in the original, and accordingly, "the date of enactment of the Coronavirus Aid, Relief, and Economic Security Act" was

translated to "March 27, 2020". The Coronavirus Aid, Relief, and Economic Security Act, Pub. L. 116–136, was approved Mar. 27, 2020.

2010—Subsec. (b)(2)(E). Pub. L. 111–256 substituted "elderly individuals with intellectual disabilities" for "elderly mentally retarded individuals".

Subsec. (c)(2) to (4). Pub. L. 111–148, §5305(b)(2), added pars. (2) to (4) and struck out former pars. (2) and (3) which described eligible individuals and limitations for Geriatric Academic Career Awards. Former par. (4) redesignated (5).

Subsec. (c)(5). Pub. L. 111–148, §5305(b)(1), redesignated par. (4) as (5). Former par. (5) redesignated (6).

Subsec. (c)(5)(A). Pub. L. 111–148, §5305(b)(3)(A), inserted "for individuals who are physicians" before "shall equal" and inserted at end "The Secretary shall determine the amount of an Award under this section for individuals who are not physicians."

Subsec. (c)(5)(C). Pub. L. 111–148, §5305(b)(3)(B), added subpar. (C).

Subsec. (c)(6). Pub. L. 111–148, §5305(b)(1), redesignated par. (5) as (6).

Subsecs. (d), (e). Pub. L. 111–148, §5305(a), added subsecs. (d) and (e).

2002—Subsec. (a)(1). Pub. L. 107–205 substituted ", and section 296(2) of this title," for ", and section 298b(2) of this title,".

STATUTORY NOTES AND RELATED SUBSIDIARIES

EFFECTIVE DATE OF 2020 AMENDMENT

Pub. L. 116–260, div. BB, title III, §331(d), Dec. 27, 2020, 134 Stat. 2938, provided that: "The amendments made by subsections (a), (b), and (c) [amending this section and sections 297n–1 and 297t of this title] shall take effect as if included in the enactment of the Coronavirus Aid, Relief, and Economic Security Act (Public Law 116–136)."

DEFINITIONS

For meaning of references to an intellectual disability and to individuals with intellectual disabilities in provisions amended by section 2 of Pub. L. 111–256, see section 2(k) of Pub. L. 111–256, set out as a note under section 1400 of Title 20, Education.

§294d. Quentin N. Burdick program for rural interdisciplinary training

(a) Grants

The Secretary may make grants or contracts under this section to help entities fund authorized activities under an application approved under subsection (c).

(b) Use of amounts

(1) In general

Amounts provided under subsection (a) shall be used by the recipients to fund interdisciplinary training projects designed to—

(A) use innovative or evidence-based methods to train health care practitioners to provide services in rural areas;

(B) demonstrate and evaluate innovative interdisciplinary methods and models designed to provide access to cost-effective comprehensive health care;

(C) deliver health care services to individuals residing in rural areas;

(D) enhance the amount of relevant research conducted concerning health care issues in rural areas; and

(E) increase the recruitment and retention of health care practitioners from rural areas and make rural practice a more attractive career choice for health care practitioners.

(2) Methods

A recipient of funds under subsection (a) may use various methods in carrying out the projects described in paragraph (1), including—

(A) the distribution of stipends to students of eligible applicants;

(B) the establishment of a post-doctoral fellowship program;

(C) the training of faculty in the economic and logistical problems confronting rural health care delivery systems; or

(D) the purchase or rental of transportation and telecommunication equipment where the need for such equipment due to unique characteristics of the rural area is demonstrated by the recipient.

(3) Administration

(A) In general

An applicant shall not use more than 10 percent of the funds made available to such applicant under subsection (a) for administrative expenses.

(B) Training

Not more than 10 percent of the individuals receiving training with funds made available to an applicant under subsection (a) shall be trained as doctors of medicine or doctors of osteopathy.

(C) Limitation

An institution that receives a grant under this section shall use amounts received under such grant to supplement, not supplant, amounts made available by such institution for activities of the type described in subsection (b)(1) in the fiscal year preceding the year for which the grant is received.

(c) Applications

Applications submitted for assistance under this section shall—

(1) be jointly submitted by at least two eligible applicants with the express purpose of assisting individuals in academic institutions in establishing long-term collaborative relationships with health care providers in rural areas; and

(2) designate a rural health care agency or agencies for clinical treatment or training, including hospitals, community health centers, migrant health centers, rural health clinics, community behavioral and mental health centers, long-term care facilities, Native Hawaiian health centers, or facilities operated by the Indian Health Service or an Indian tribe or tribal organization or Indian organization under a contract with the Indian Health Service under the Indian Self-Determination Act [25 U.S.C. 5321 et seq.].

(d) Definitions

For the purposes of this section, the term "rural" means geographic areas that are located outside of standard metropolitan statistical areas.

(July 1, 1944, ch. 373, title VII, §754, as added Pub. L. 105–392, title I, §103, Nov. 13, 1998, 112 Stat. 3547; amended Pub. L. 116–136, div. A, title III, §3401(7), Mar. 27, 2020, 134 Stat. 386.)

EDITORIAL NOTES

REFERENCES IN TEXT

The Indian Self-Determination Act, referred to in subsec. (c)(2), is title I of Pub. L. 93–638, Jan. 4, 1975, 88 Stat. 2206, which is classified principally to subchapter I (§5321 et seq.) of chapter 46 of Title 25, Indians. For complete classification of this Act to the Code, see Short Title note set out under section 5301 of Title 25 and Tables.

PRIOR PROVISIONS

A prior section 294d, act July 1, 1944, ch. 373, title VII, §766, as added Pub. L. 102–408, title I, §102, Oct. 13, 1992, 106 Stat. 2047, authorized grants and contracts for development of advanced training of allied health professionals, prior to the general amendment of this part by Pub. L. 105–392.

Another prior section 294d, act July 1, 1944, ch. 373, title VII, §731, as added Oct. 12, 1976, Pub. L. 94–484, title IV, §401(b)(3), 90 Stat. 2258; amended Aug. 1, 1977, Pub. L. 95–83, title III, §307(c)(1), (2), 91 Stat. 389, 390; Dec. 19, 1977, Pub. L. 95–215, §4(a)–(d), (e)(6), 91 Stat. 1505, 1506; Dec. 17, 1980, Pub. L. 96–538, title IV, §402, 94 Stat. 3192; Aug. 13, 1981, Pub. L. 97–35, title XXVII, §2728, 95 Stat. 918; Oct. 22,

1985, Pub. L. 99–129, title II, §§208(a), (b)(1), (2), (c)(1), (d), (i), 211(a)(2), 99 Stat. 529–532, 539; Nov. 4, 1988, Pub. L. 100–607, title VI, §602(e), (f), 102 Stat. 3123; Apr. 6, 1991, Pub. L. 102–25, title III, §374, 105 Stat. 95; July 23, 1992, Pub. L. 102–325, title IV, §427(b)(2), 106 Stat. 549, related to eligibility of borrowers and terms of insurance, prior to the general amendment of this subchapter by Pub. L. 102–408. See section 292d of this title.

Another prior section 294d, act July 1, 1944, ch. 373, title VII, §744, as added Sept. 24, 1963, Pub. L. 88–129, §2(b), 77 Stat. 173; amended Oct. 22, 1965, Pub. L. 89–290, §4(e), 79 Stat. 1057; Nov. 3, 1966, Pub. L. 89–751, §5(a), 80 Stat. 1230; Aug. 16, 1968, Pub. L. 90–490, title I, §121(d), 82 Stat. 778; July 9, 1971, Pub. L. 92–52, §1(c), 85 Stat. 144; Nov. 18, 1971, Pub. L. 92–157, title I, §105(e)(3), (f)(2), 85 Stat. 451, provided for loans to schools to capitalize health professions student loan funds, prior to repeal by Pub. L. 94–484, title IV, §406(a)(1), Oct. 12, 1976, 90 Stat. 2268.

AMENDMENTS

2020—Subsec. (b)(1)(A). Pub. L. 116–136 substituted "innovative or evidence-based" for "new and innovative".

§294e. Allied health and other disciplines

(a) In general

The Secretary may make grants or contracts under this section to help entities fund activities of the type described in subsection (b).

(b) Activities

Activities of the type described in this subsection include the following:

(1) Assisting entities in meeting the costs associated with expanding or establishing programs that will increase the number of individuals trained in allied health professions. Programs and activities funded under this paragraph may include—

(A) those that expand enrollments in allied health professions with the greatest shortages or whose services are most needed by geriatric populations or for maternal and child health;

(B) those that provide rapid transition training programs in allied health fields to individuals who have baccalaureate degrees in health-related sciences;

(C) those that establish community-based allied health training programs that link academic centers to rural clinical settings;

(D) those that provide career advancement training for practicing allied health professionals;

(E) those that expand or establish clinical training sites for allied health professionals in medically underserved or rural communities in order to increase the number of individuals trained;

(F) those that develop curriculum that will emphasize knowledge and practice in the areas of prevention and health promotion, geriatrics, long-term care, home health and hospice care, and ethics;

(G) those that expand or establish interdisciplinary training programs that promote the effectiveness of allied health practitioners in geriatric assessment and the rehabilitation of the elderly;

(H) those that expand or establish demonstration centers to emphasize innovative models to link allied health clinical practice, education, and research;

(I) those that provide financial assistance (in the form of traineeships) to students who are participants in any such program; and

(i) who plan to pursue a career in an allied health field that has a demonstrated personnel shortage; and

(ii) who agree upon completion of the training program to practice in a medically underserved community;

that shall be utilized to assist in the payment of all or part of the costs associated with tuition, fees and such other stipends as the Secretary may consider necessary; and

(J) those to meet the costs of projects to plan, develop, and operate or maintain graduate programs in behavioral and mental health practice.

(2) Planning and implementing projects in preventive and primary care training for podiatric physicians in approved or provisionally approved residency programs that shall provide financial assistance in the form of traineeships to residents who participate in such projects and who plan to specialize in primary care.

(3) Carrying out demonstration projects in which chiropractors and physicians collaborate to identify and provide effective treatment for spinal and lower-back conditions.

(4) Increasing educational opportunities in physical therapy, occupational therapy, respiratory therapy, audiology, and speech-language pathology professions, which may include offering scholarships or stipends and carrying out other activities to improve retention, for individuals from disadvantaged backgrounds or individuals who are underrepresented in such professions.

(July 1, 1944, ch. 373, title VII, §755, as added Pub. L. 105–392, title I, §103, Nov. 13, 1998, 112 Stat. 3548; amended Pub. L. 116–136, div. A, title III, §3401(8), Mar. 27, 2020, 134 Stat. 386; Pub. L. 117–328, div. FF, title II, §2224, Dec. 29, 2022, 136 Stat. 5749.)

EDITORIAL NOTES

PRIOR PROVISIONS

A prior section 294e, act July 1, 1944, ch. 373, title VII, §767, as added Pub. L. 102–408, title I, §102, Oct. 13, 1992, 106 Stat. 2048, authorized grants and contracts for establishment of programs to increase number of allied health professionals, prior to the general amendment of this part by Pub. L. 105–392.

Another prior section 294e, act July 1, 1944, ch. 373, title VII, §732, as added Oct. 12, 1976, Pub. L. 94–484, title IV, §401(b)(3), 90 Stat. 2260; amended Aug. 1, 1977, Pub. L. 95–83, title III, §307(c)(3), (4), 91 Stat. 390; Dec. 19, 1977, Pub. L. 95–215, §4(e)(8), (9), 91 Stat. 1506; Aug. 13, 1981, Pub. L. 97–35, title XXVII, §2729, 95 Stat. 918; Oct. 22, 1985, Pub. L. 99–129, title II, §208(e), 99 Stat. 531; Nov. 4, 1988, Pub. L. 100–607, title VI, §602(g), 102 Stat. 3123, related to certificates of loan insurance, prior to the general amendment of this subchapter by Pub. L. 102–408. See section 292e of this title.

Another prior section 294e, act July 1, 1944, ch. 373, title VII, §744, formerly §745, as added Sept. 24, 1963, Pub. L. 88–129, §2(b), 77 Stat. 173; amended Nov. 18, 1971, Pub. L. 92–157, title I, §105(f)(2), 85 Stat. 451; renumbered §744, Oct. 12, 1976, Pub. L. 94–484, title IV, §406(a)(2), 90 Stat. 2268, which related to administrative provisions, was transferred to section 294q of this title.

AMENDMENTS

2022—Subsec. (b)(4). Pub. L. 117–328 added par. (4).

2020—Subsec. (b)(1)(A). Pub. L. 116–136 substituted "geriatric populations or for maternal and child health" for "the elderly".

§294e–1. Mental and behavioral health education and training grants

(a) Grants authorized

The Secretary may award grants to eligible institutions to support the recruitment of students for, and education and clinical experience of the students in—

(1) accredited institutions of higher education or accredited professional training programs that are establishing or expanding internships or other field placement programs in mental health in psychiatry, psychology, school psychology, behavioral pediatrics, psychiatric nursing (which may include master's and doctoral level programs), social work, school social work, substance use disorder prevention and treatment, marriage and family therapy, occupational therapy (which may include master's and doctoral level programs), school counseling, or professional counseling, including such programs with a focus on child and adolescent mental health, trauma, and transitional-age youth;

(2) accredited doctoral, internship, and post-doctoral residency programs of health service

psychology (including clinical psychology, counseling, and school psychology) for the development and implementation of interdisciplinary training of psychology graduate students for providing behavioral health services, including trauma-informed care and substance use disorder prevention and treatment services, as well as the development of faculty in health service psychology;

(3) accredited master's and doctoral degree programs of social work for the development and implementation of interdisciplinary training of social work graduate students for providing behavioral health services, including trauma-informed care and substance use disorder prevention and treatment services, and the development of faculty in social work; and

(4) State-licensed mental health nonprofit and for-profit organizations to enable such organizations to pay for programs for preservice or in-service training in a behavioral health-related paraprofessional field with preference for preservice or in-service training of paraprofessional child and adolescent mental health workers, including training to increase skills and capacity to meet the needs of children and adolescents who have experienced trauma.

(b) Eligibility requirements

To be eligible for a grant under this section, an institution shall demonstrate—

(1) an ability to recruit and place the students described in subsection (a) in areas with a high need and high demand population;

(2) participation in the institutions' programs of individuals and groups from different racial, ethnic, cultural, geographic, religious, linguistic, and class backgrounds, and different genders and sexual orientations;

(3) knowledge and understanding of the concerns of the individuals and groups described in paragraph (2), especially individuals with mental disorder symptoms or diagnoses, particularly children and adolescents, and transitional-age youth;

(4) any internship or other field placement program assisted under the grant will prioritize cultural and linguistic competency; and

(5) the institution will provide to the Secretary such data, assurances, and information as the Secretary may require.

(c) Institutional requirement

For grants awarded under paragraphs (2) and (3) of subsection (a), at least 4 of the grant recipients shall be historically black colleges or universities or other minority-serving institutions.

(d) Priority

In selecting grant recipients under this section, the Secretary shall give priority to—

(1) programs that have demonstrated the ability to train psychology, psychiatry, and social work professionals to work in integrated care settings for purposes of recipients under paragraphs (1), (2), and (3) of subsection (a); and

(2) programs for paraprofessionals that emphasize the role of the family and the lived experience of the consumer and family-paraprofessional partnerships for purposes of recipients under subsection (a)(4).

(e) Report to Congress

Not later than 4 years after December 13, 2016, the Secretary shall include in the biennial report submitted to Congress under section 290aa(m) of this title an assessment on the effectiveness of the grants under this section in—

(1) providing graduate students support for experiential training (internship or field placement);

(2) recruiting students interested in behavioral health practice;

(3) recruiting students in accordance with subsection (b)(1);

(4) developing and implementing interprofessional training and integration within primary care;

(5) developing and implementing accredited field placements and internships; and

(6) collecting data on the number of students trained in behavioral health care and the number of available accredited internships and field placements.

(f) Authorization of appropriations

For each of fiscal years 2026 through 2030, there are authorized to be appropriated to carry out this section $50,000,000, to be allocated as follows:

(1) For grants described in subsection (a)(1), $15,000,000.
(2) For grants described in subsection (a)(2), $15,000,000.
(3) For grants described in subsection (a)(3), $10,000,000.
(4) For grants described in subsection (a)(4), $10,000,000.

(July 1, 1944, ch. 373, title VII, §756, as added Pub. L. 111–148, title V, §5306(a)(3), Mar. 23, 2010, 124 Stat. 626; amended Pub. L. 114–255, div. B, title IX, §9021, Dec. 13, 2016, 130 Stat. 1248; Pub. L. 115–271, title VII, §7073(b), Oct. 24, 2018, 132 Stat. 4032; Pub. L. 117–328, div. FF, title I, §1311(a), Dec. 29, 2022, 136 Stat. 5696; Pub. L. 119–44, title II, §203, Dec. 1, 2025, 139 Stat. 680.)

EDITORIAL NOTES

CODIFICATION

Pub. L. 111–148, title V, §5306(a)(3), Mar. 23, 2010, 124 Stat. 626, which directed the amendment of part D of title VII by inserting section 756 after section 755, without specifying the act to be amended, was executed by inserting section 756 after section 755 of act July 1, 1944, to reflect the probable intent of Congress.

PRIOR PROVISIONS

A prior section 756 of act July 1, 1944, was renumbered section 757 and is classified to section 294f of this title.

Another prior section 756 of act July 1, 1944, was renumbered section 338G, transferred to section 254q of this title, and subsequently repealed by Pub. L. 100–177.

Another prior section 756 of act July 1, 1944, was classified to section 294f of this title prior to repeal by Pub. L. 94–484.

AMENDMENTS

2025—Subsec. (f). Pub. L. 119–44 substituted "fiscal years 2026 through 2030" for "fiscal years 2023 through 2027".

2022—Subsec. (a)(1). Pub. L. 117–328, §1311(a)(1)(A), inserted "(which may include master's and doctoral level programs)" after "occupational therapy".

Subsec. (a)(4). Pub. L. 117–328, §1311(a)(1)(B), inserted ", including training to increase skills and capacity to meet the needs of children and adolescents who have experienced trauma" after "workers".

Subsec. (f). Pub. L. 117–328, §1311(a)(2), substituted "For each of fiscal years 2023 through 2027" for "For each of fiscal years 2019 through 2023" in introductory provisions.

2018—Subsec. (a)(1). Pub. L. 115–271, §7073(b)(1)(A), inserted ", trauma," after "focus on child and adolescent mental health".

Subsec. (a)(2), (3). Pub. L. 115–271, §7073(b)(1)(B), inserted "trauma-informed care and" before "substance use disorder prevention and treatment services".

Subsec. (f). Pub. L. 115–271, §7073(b)(2), substituted "2019 through 2023" for "2018 through 2022" in introductory provisions.

2016—Subsec. (a). Pub. L. 114–255, §9021(1), struck out "of higher education" after "eligible institutions" in introductory provisions, added pars. (1) to (4), and struck out former pars. (1) to (4) which read as follows:

"(1) baccalaureate, master's, and doctoral degree programs of social work, as well as the development of faculty in social work;

"(2) accredited master's, doctoral, internship, and post-doctoral residency programs of psychology for the development and implementation of interdisciplinary training of psychology graduate students for providing behavioral and mental health services, including substance abuse prevention and treatment services;

"(3) accredited institutions of higher education or accredited professional training programs that are establishing or expanding internships or other field placement programs in child and adolescent mental health in psychiatry, psychology, school psychology, behavioral pediatrics, psychiatric nursing, social work, school social work, substance abuse prevention and treatment, marriage and family therapy, school counseling, or professional counseling; and

"(4) State-licensed mental health nonprofit and for-profit organizations to enable such organizations to pay

for programs for preservice or in-service training of paraprofessional child and adolescent mental health workers."

Subsec. (b)(1), (2). Pub. L. 114–255, §9021(2)(B), (C), added par. (1) and redesignated former par. (1) as (2). Former par. (2) redesignated (3).

Subsec. (b)(3). Pub. L. 114–255, §9021(2)(B), (D), redesignated par. (2) as (3) and substituted "paragraph (2), especially individuals with mental disorder symptoms or diagnoses, particularly children and adolescents, and transitional-age youth" for "subsection (a)". Former par. (3) redesignated (4).

Subsec. (b)(4). Pub. L. 114–255, §9021(2)(B), (E), redesignated par. (3) as (4) and inserted "and" at end. Former par. (4) redesignated (5).

Subsec. (b)(5). Pub. L. 114–255, §9021(2)(A), (B), (F), redesignated par. (4) as (5), substituted period for "; and" at end, and struck out former par. (5) which read as follows: "with respect to any violation of the agreement between the Secretary and the institution, the institution will pay such liquidated damages as prescribed by the Secretary by regulation."

Subsec. (c). Pub. L. 114–255, §9021(3), substituted "awarded under paragraphs (2) and (3) of subsection (a)" for "authorized under subsection (a)(1)".

Subsec. (d). Pub. L. 114–255, §9021(4), amended subsec. (d) generally. Prior to amendment, subsec. (d) related to priority in selecting grant recipients in social work, graduate psychology, and training programs in child and adolescent mental health.

Subsecs. (e), (f). Pub. L. 114–255, §9021(5), added subsecs. (e) and (f) and struck out former subsec. (e) which authorized appropriations for fiscal years 2010 through 2013.

§294f. Advisory Committee on Interdisciplinary, Community-Based Linkages

(a) Establishment

The Secretary shall establish an advisory committee to be known as the Advisory Committee on Interdisciplinary, Community-Based Linkages (in this section referred to as the "Advisory Committee").

(b) Composition

(1) In general

The Secretary shall determine the appropriate number of individuals to serve on the Advisory Committee. Such individuals shall not be officers or employees of the Federal Government.

(2) Appointment

Not later than 90 days after November 13, 1998, the Secretary shall appoint the members of the Advisory Committee from among individuals who are health professionals from schools of the types described in sections 294a(b)(1)(A), 294c(b), and 294e(b) of this title. In making such appointments, the Secretary shall ensure a fair balance between the health professions, that at least 75 percent of the members of the Advisory Committee are health professionals, a broad geographic representation of members and a balance between urban and rural members. Members shall be appointed based on their competence, interest, and knowledge of the mission of the profession involved.

(3) Minority representation

In appointing the members of the Advisory Committee under paragraph (2), the Secretary shall ensure the adequate representation of women and minorities.

(c) Terms

(1) In general

A member of the Advisory Committee shall be appointed for a term of 3 years, except that of the members first appointed—

(A) 1/3 of the members shall serve for a term of 1 year;

(B) 1/3 of the members shall serve for a term of 2 years; and

(C) 1/3 of the members shall serve for a term of 3 years.

(2) Vacancies

(A) In general

A vacancy on the Advisory Committee shall be filled in the manner in which the original appointment was made and shall be subject to any conditions which applied with respect to the original appointment.

(B) Filling unexpired term

An individual chosen to fill a vacancy shall be appointed for the unexpired term of the member replaced.

(d) Duties

The Advisory Committee shall—

(1) provide advice and recommendations to the Secretary concerning policy and program development and other matters of significance concerning the activities under this part;

(2) not later than 3 years after November 13, 1998, and annually thereafter, prepare and submit to the Secretary, and the Committee on Labor and Human Resources of the Senate, and the Committee on Commerce of the House of Representatives, a report describing the activities of the Committee, including findings and recommendations made by the Committee concerning the activities under this part;

(3) develop, publish, and implement performance measures for programs under this part;

(4) develop and publish guidelines for longitudinal evaluations (as described in section 294n(d)(2) of this title) for programs under this part; and

(5) recommend appropriation levels for programs under this part.

(e) Meetings and documents

(1) Meetings

The Advisory Committee shall meet not less than 3 times each year. Such meetings shall be held jointly with other related entities established under this subchapter where appropriate.

(2) Documents

Not later than 14 days prior to the convening of a meeting under paragraph (1), the Advisory Committee shall prepare and make available an agenda of the matters to be considered by the Advisory Committee at such meeting. At any such meeting, the Advisory Council [1] shall distribute materials with respect to the issues to be addressed at the meeting. Not later than 30 days after the adjourning of such a meeting, the Advisory Committee shall prepare and make available a summary of the meeting and any actions taken by the Committee based upon the meeting.

(f) Compensation and expenses

(1) Compensation

Each member of the Advisory Committee shall be compensated at a rate equal to the daily equivalent of the annual rate of basic pay prescribed for level IV of the Executive Schedule under section 5315 of title 5 for each day (including travel time) during which such member is engaged in the performance of the duties of the Committee.

(2) Expenses

The members of the Advisory Committee shall be allowed travel expenses, including per diem in lieu of subsistence, at rates authorized for employees of agencies under subchapter I of chapter 57 of title 5 while away from their homes or regular places of business in the performance of services for the Committee.

(g) Chapter 10 of title 5

Chapter 10 of title 5 shall apply to the Advisory Committee under this section only to the extent that the provisions of chapter 10 of title 5 do not conflict with the requirements of this section.

(July 1, 1944, ch. 373, title VII, §757, formerly §756, as added Pub. L. 105–392, title I, §103, Nov. 13, 1998, 112 Stat. 3549; renumbered §757 and amended Pub. L. 111–148, title V, §§5103(d)(2), 5306(a)(2), (b), Mar. 23, 2010, 124 Stat. 606, 626, 628; Pub. L. 117–286, §4(a)(238), Dec. 27, 2022, 136 Stat. 4331.)

EDITORIAL NOTES

CODIFICATION

Pub. L. 111–148, title V, §5306(a)(2), Mar. 23, 2010, 124 Stat. 626, which directed the amendment of part D of title VII by redesignating section 756 as section 757, without specifying the act to be amended, was executed by redesignating section 756 of act July 1, 1944, as section 757 of the Act, to reflect the probable intent of Congress.

November 13, 1998, referred to in subsec. (b)(2), was in the original "the date of enactment of this Act", which was translated as meaning the date of enactment of Pub. L. 105–392, which amended this part generally, to reflect the probable intent of Congress.

PRIOR PROVISIONS

A prior section 294f, act July 1, 1944, ch. 373, title VII, §733, as added Oct. 12, 1976, Pub. L. 94–484, title IV, §401(b)(3), 90 Stat. 2262; amended Dec. 19, 1977, Pub. L. 95–215, §4(e)(10), 91 Stat. 1506; Nov. 6, 1978, Pub. L. 95–598, title III, §327, 92 Stat. 2679; Aug. 13, 1981, Pub. L. 97–35, title XXVII, §2730, 95 Stat. 919; July 1, 1988, Pub. L. 100–360, title IV, §411(f)(10)(C)(ii), 102 Stat. 781; Nov. 4, 1988, Pub. L. 100–607, title VI, §602(h)–(k), 102 Stat. 3123; Aug. 16, 1989, Pub. L. 101–93, §7, 103 Stat. 615, related to procedures upon default by borrower under student loan insurance program, prior to the general amendment of this subchapter by Pub. L. 102–408. See section 292f of this title.

Another prior section 294f, act July 1, 1944, ch. 373, title VII, §746, as added Aug. 16, 1968, Pub. L. 90–490, title I, §121(e), 82 Stat. 778; amended Nov. 18, 1971, Pub. L. 92–157, title I, §§105(f)(2), 106(b)(5), 85 Stat. 451, 453, provided for transfer of funds to scholarships in relation to loans to students studying in United States, prior to repeal by Pub. L. 94–484, title IV, §406(a)(1), Oct. 12, 1976, 90 Stat. 2268.

A prior section 757 of act July 1, 1944, was classified to section 294g of this title, prior to repeal by Pub. L. 111–148, title V, §5306(a)(1), Mar. 23, 2010, 124 Stat. 626.

AMENDMENTS

2022—Subsec. (g). Pub. L. 117–286 substituted "Chapter 10 of title 5" for "FACA" in heading and "Chapter 10 of title 5 shall apply to the Advisory Committee under this section only to the extent that the provisions of chapter 10 of title 5" for "The Federal Advisory Committee Act shall apply to the Advisory Committee under this section only to the extent that the provisions of such Act" in text.

2010—Subsec. (b)(2). Pub. L. 111–148, §5306(b), substituted "294a(b)(1)(A), 294c(b), and 294e(b)" for "294a(a)(1)(A), 294a(a)(1)(B), 294c(b), 294d(3)(A), and 294e(b)".

Subsec. (d)(3) to (5). Pub. L. 111–148, §5103(d)(2), added pars. (3) to (5).

STATUTORY NOTES AND RELATED SUBSIDIARIES

CHANGE OF NAME

Committee on Commerce of House of Representatives changed to Committee on Energy and Commerce of House of Representatives, and jurisdiction over matters relating to securities and exchanges and insurance generally transferred to Committee on Financial Services of House of Representatives by House Resolution No. 5, One Hundred Seventh Congress, Jan. 3, 2001.

Committee on Labor and Human Resources of Senate changed to Committee on Health, Education, Labor, and Pensions of Senate by Senate Resolution No. 20, One Hundred Sixth Congress, Jan. 19, 1999.

TERMINATION OF ADVISORY COMMITTEES

Pub. L. 93–641, §6, Jan. 4, 1975, 88 Stat. 2275, set out as a note under section 217a of this title, provided that an advisory committee established pursuant to the Public Health Service Act shall terminate at such time as may be specifically prescribed by an Act of Congress enacted after Jan. 4, 1975.

[1] *So in original. Probably should be "Committee".*

§294g. Repealed. Pub. L. 111–148, title V, §5306(a)(1), Mar. 23, 2010, 124 Stat. 626

Section, act July 1, 1944, ch. 373, title VII, §757, as added Pub. L. 105–392, title I, §103, Nov. 13, 1998, 112 Stat. 3551, authorized appropriations to carry out this part.

EDITORIAL NOTES

CODIFICATION

Pub. L. 111–148, title V, §5306(a)(1), Mar. 23, 2010, 124 Stat. 626, which directed the amendment of part D of title VII by striking section 757, without specifying the act to be amended, was executed by repealing this section, which was section 757 of act July 1, 1944, to reflect the probable intent of Congress.

PRIOR PROVISIONS

A prior section 294g, act July 1, 1944, ch. 373, title VII, §734, as added Oct. 12, 1976, Pub. L. 94–484, title IV, §401(b)(3), 90 Stat. 2263; amended Oct. 22, 1985, Pub. L. 99–129, title II, §208(f), 99 Stat. 531, related to establishment of a student loan insurance fund, prior to the general amendment of this subchapter by Pub. L. 102–408. See section 292i of this title.

Another prior section 294g, act July 1, 1944, ch. 373, title VII, §747, as added Nov. 18, 1971, Pub. L. 92–157, title I, §105(f)(4), 85 Stat. 451; amended Oct. 12, 1976, Pub. L. 94–484, title I, §101(f), 90 Stat. 2244, provided for student loans to citizens of United States who were full-time students in schools of medicine located outside United States, prior to repeal by Pub. L. 94–484, title IV, §401(a), Oct. 12, 1976, 90 Stat. 2257, effective Oct. 1, 1976.

§294h. Repealed. Pub. L. 113–4, title V, §501(b)(2), Mar. 7, 2013, 127 Stat. 101

Section, act July 1, 1944, ch. 373, title VII, §758, as added Pub. L. 109–162, title V, §503, Jan. 5, 2006, 119 Stat. 3024; amended Pub. L. 109–271, §4(c), Aug. 12, 2006, 120 Stat. 758, provided for grants for interdisciplinary training and education on domestic violence and other types of violence and abuse.

A prior section 294h, act July 1, 1944, ch. 373, title VII, §735, as added Oct. 12, 1976, Pub. L. 94–484, title IV, §401(b)(3), 90 Stat. 2263; amended Aug. 1, 1977, Pub. L. 95–83, title III, §307(c)(5), 91 Stat. 390; Aug. 13, 1981, Pub. L. 97–35, title XXVII, §2709(e)(4)(B), 95 Stat. 911; Nov. 16, 1990, Pub. L. 101–597, title IV, §401(b)[(a)], 104 Stat. 3035, related to functions, powers, and duties of the Secretary under the Federal student loan insurance program, prior to the general amendment of this subchapter by Pub. L. 102–408. See section 292j of this title.

§294i. Program for education and training in pain care

(a) In general

The Secretary may make awards of grants, cooperative agreements, and contracts to health professions schools, hospices, tribal health programs (as defined in section 1603 of title 25), and other public and nonprofit private entities for the development and implementation of programs to provide education and training to health care professionals in pain care.

(b) Certain topics

An entity receiving an award under this section shall develop a comprehensive education and training plan that includes information and education on—

(1) recognized means for assessing, diagnosing, preventing, treating, and managing pain and related signs and symptoms, including non-addictive medical products and non-pharmacologic treatments and the medically appropriate use of controlled substances;

(2) applicable Federal, State, and local laws, regulations, rules, and policies on controlled substances, including opioids;

(3) interdisciplinary approaches to the delivery of pain care, including delivery through specialized centers providing comprehensive pain care treatment expertise, integrated,

evidence-based pain management, and, as appropriate, non-pharmacotherapy;

(4) cultural, linguistic, literacy, geographic, and other barriers to care in underserved populations;

(5) recent findings, developments, and advancements in pain care research and the provision of pain care, which may include non-addictive medical products and non-pharmacologic treatments intended to treat pain; and

(6) the dangers of opioid abuse and misuse, detection of early warning signs of opioid use disorders (which may include best practices related to screening for opioid use disorders, training on screening, brief intervention, and referral to treatment), and safe disposal options for prescription medications (including such options provided by law enforcement or other innovative deactivation mechanisms).

(c) Evaluation of programs

The Secretary shall (directly or through grants or contracts) provide for the evaluation of programs implemented under subsection (a) in order to determine the effect of such programs on knowledge and practice of pain care.

(d) Pain care defined

For purposes of this section the term "pain care" means the assessment, diagnosis, prevention, treatment, or management of acute or chronic pain regardless of causation or body location.

(e) Authorization of appropriations

There is authorized to be appropriated to carry out this section, such sums as may be necessary for each of the fiscal years 2019 through 2023. Amounts appropriated under this subsection shall remain available until expended.

(July 1, 1944, ch. 373, title VII, §759, as added Pub. L. 111–148, title IV, §4305(c), Mar. 23, 2010, 124 Stat. 586; amended Pub. L. 115–271, title VII, §7073(a), Oct. 24, 2018, 132 Stat. 4031.)

EDITORIAL NOTES

PRIOR PROVISIONS

A prior section 294i, act July 1, 1944, ch. 373, title VII, §771, as added Pub. L. 102–408, title I, §102, Oct. 13, 1992, 106 Stat. 2049, authorized grants to educational entities offering programs in health administration, hospital administration, or health policy analysis and planning, prior to the general amendment of this part by Pub. L. 105–392.

Another prior section 294i, act July 1, 1944, ch. 373, title VII, §736, as added Oct. 12, 1976, Pub. L. 94–484, title IV, §401(b)(3), 90 Stat. 2265; amended Aug. 1, 1977, Pub. L. 95–83, title III, §307(d), 91 Stat. 390, related to participation by Federal credit unions in Federal, State, and private student loan insurance programs, prior to the general amendment of this subchapter by Pub. L. 102–408. See section 292k of this title.

A prior section 759 of act July 1, 1944, was classified to section 294aa of this title prior to the general amendment of this subchapter by Pub. L. 102–408.

AMENDMENTS

2018—Subsec. (a). Pub. L. 115–271, §7073(a)(1), substituted "hospices, tribal health programs (as defined in section 1603 of title 25), and other public and nonprofit private entities" for "hospices, and other public and private entities".

Subsec. (b). Pub. L. 115–271, §7073(a)(2)(A), substituted "entity receiving an award under this section shall develop a comprehensive education and training plan that includes" for "award may be made under subsection (a) only if the applicant for the award agrees that the program carried out with the award will include" in introductory provisions.

Subsec. (b)(1). Pub. L. 115–271, §7073(a)(2)(B), inserted "preventing," after "diagnosing," and "non-addictive medical products and non-pharmacologic treatments and" after "including".

Subsec. (b)(2). Pub. L. 115–271, §7073(a)(2)(C), inserted "Federal, State, and local" after "applicable" and substituted "opioids" for "the degree to which misconceptions and concerns regarding such laws, regulations, rules, and policies, or the enforcement thereof, may create barriers to patient access to appropriate and

effective pain care".

Subsec. (b)(3). Pub. L. 115–271, §7073(a)(2)(D), inserted ", integrated, evidence-based pain management, and, as appropriate, non-pharmacotherapy" before semicolon.

Subsec. (b)(5), (6). Pub. L. 115–271, §7073(a)(2)(E), (F), added pars. (5) and (6) and struck out former par. (5) which read as follows: "recent findings, developments, and improvements in the provision of pain care."

Subsec. (d). Pub. L. 115–271, §7073(a)(3), inserted "prevention," after "diagnosis,".

Subsec. (e). Pub. L. 115–271, §7073(a)(4), substituted "2019 through 2023" for "2010 through 2012".

STATUTORY NOTES AND RELATED SUBSIDIARIES

EMERGENCY DEPARTMENT ALTERNATIVES TO OPIOIDS DEMONSTRATION PROGRAM

Pub. L. 115–271, title VII, §7091, Oct. 24, 2018, 132 Stat. 4035, which related to emergency department alternatives to opioids demonstration program, was editorially reclassified as section 294i–1 of this title.

§294i–1. Emergency department alternatives to opioids program

(a) Grant program

(1) In general

The Secretary of Health and Human Services (in this section referred to as the "Secretary") shall carry out a program for purposes of awarding grants to hospitals and emergency departments, including freestanding emergency departments, to develop, implement, enhance, or study alternatives to opioids for pain management in such settings.

(2) Eligibility

To be eligible to receive a grant under paragraph (1), a hospital or emergency department shall submit an application to the Secretary at such time, in such manner, and containing such information as the Secretary may require.

(3) Geographic distribution

In awarding grants under this section, the Secretary shall seek to ensure geographical distribution among grant recipients.

(4) Use of funds

Grants under paragraph (1) shall be used to—

(A) target treatment approaches for painful conditions frequently treated in such settings;

(B) train providers and other hospital personnel on protocols or best practices related to the use and prescription of opioids and alternatives to opioids for pain management in the emergency department; and

(C) develop or continue strategies to provide alternatives to opioids, as appropriate.

(b) Additional program

The Secretary may carry out a demonstration program [1] similar to the program under subsection (a) for other acute care settings.

(c) Consultation

The Secretary shall implement a process for recipients of grants under subsection (a) or (b) to share evidence-based and best practices and promote consultation with persons having robust knowledge, including emergency departments and physicians that have successfully implemented programs that use alternatives to opioids for pain management, as appropriate, such as approaches studied through the National Center for Complimentary and Integrative Health or other institutes and centers at the National Institutes of Health, as appropriate. The Secretary shall offer to each recipient of a grant under subsection (a) or (b) technical assistance as necessary.

(d) Technical assistance

The Secretary shall identify or facilitate the development of best practices on alternatives to

opioids for pain management and provide technical assistance to hospitals and other acute care settings on alternatives to opioids for pain management. The technical assistance provided shall be for the purpose of—

(1) utilizing information from recipients of a grant under subsection (a) or (b) that have successfully implemented alternatives to opioids programs;

(2) identifying or facilitating the development of best practices on the use of alternatives to opioids, which may include pain-management strategies that involve non-addictive medical products, non-pharmacologic treatments, and technologies or techniques to identify patients at risk for opioid use disorder;

(3) identifying or facilitating the development of best practices on the use of alternatives to opioids that target common painful conditions and include certain patient populations, such as geriatric patients, pregnant women, and children; and

(4) disseminating information on the use of alternatives to opioids to providers in acute care settings, which may include emergency departments, outpatient clinics, critical access hospitals, Federally qualified health centers, Indian Health Service health facilities, and Tribal hospitals.

(e) Report to the Secretary

Each recipient of a grant under this section shall submit to the Secretary (during the period of such grant) annual reports on the progress of the program funded through the grant. These reports shall include, in accordance with all applicable State and Federal privacy laws—

(1) a description of and specific information about the opioid alternative pain management programs, including the demographic characteristics of patients who were treated with an alternative pain management protocol, implemented in hospitals, emergency departments, and other acute care settings;

(2) data on the opioid alternative pain management strategies used, including the number of opioid prescriptions written—

(A) during a baseline period before the program began; or

(B) at various stages of the program; and

(3) data on patients who were eventually prescribed opioids after alternative pain management protocols and treatments were utilized; and

(4) any other information the Secretary determines appropriate.

(f) Reports to Congress

Not later than the end of each of fiscal years 2024 and 2027, the Secretary shall submit to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives a report on the results of the program and include in the report—

(1) the number of applications received and the number funded;

(2) a summary of the reports described in subsection (e), including data that allows for comparison of programs; and

(3) recommendations for broader implementation of pain management strategies that encourage the use of alternatives to opioids in hospitals, emergency departments, or other acute care settings.

(g) Authorization of appropriations

To carry out this section, there is authorized to be appropriated $10,000,000 for each of fiscal years 2023 through 2027.

(Pub. L. 115–271, title VII, §7091, Oct. 24, 2018, 132 Stat. 4035; Pub. L. 117–328, div. FF, title I, §1221, Dec. 29, 2022, 136 Stat. 5673.)

EDITORIAL NOTES

CODIFICATION

Section was formerly classified as a note under section 294i of this title prior to editorial reclassification

and renumbering as this section.

Section was enacted as part of the Substance Use–Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act or the SUPPORT for Patients and Communities Act, and not as part of the Public Health Service Act which comprises this chapter.

AMENDMENTS

2022—Pub. L. 117–328, §1221(1), struck out "demonstration" before "program" in section catchline.

Subsec. (a). Pub. L. 117–328, §1221(2)(A), amended heading generally. Prior to amendment, heading read as follows: "Demonstration program grants".

Subsec. (a)(1). Pub. L. 117–328, §1221(2)(B), struck out "demonstration" before "program".

Subsec. (b). Pub. L. 117–328, §1221(3), struck out "demonstration" before "program" in heading.

Subsec. (d)(4). Pub. L. 117–328, §1221(4), substituted "Tribal" for "tribal".

Subsec. (f). Pub. L. 117–328, §1221(5), substituted "Reports" for "Report" in heading and "Not later than the end of each of fiscal years 2024 and 2027, the Secretary shall submit to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives a report on the results of the program" for "Not later than 1 year after completion of the demonstration program under this section, the Secretary shall submit a report to the Congress on the results of the demonstration program" in introductory provisions.

Subsec. (g). Pub. L. 117–328, §1221(6), substituted "2023 through 2027" for "2019 through 2021".

[1] *So in original. Probably should be "a program".*

§294j. Demonstration program to integrate quality improvement and patient safety training into clinical education of health professionals

(a) In general

The Secretary may award grants to eligible entities or consortia under this section to carry out demonstration projects to develop and implement academic curricula that integrates [1] quality improvement and patient safety in the clinical education of health professionals. Such awards shall be made on a competitive basis and pursuant to peer review.

(b) Eligibility

To be eligible to receive a grant under subsection (a), an entity or consortium shall—

(1) submit to the Secretary an application at such time, in such manner, and containing such information as the Secretary may require;

(2) be or include—

(A) a health professions school;

(B) a school of public health;

(C) a school of social work;

(D) a school of nursing;

(E) a school of pharmacy;

(F) an institution with a graduate medical education program; or

(G) a school of health care administration;

(3) collaborate in the development of curricula described in subsection (a) with an organization that accredits such school or institution;

(4) provide for the collection of data regarding the effectiveness of the demonstration project; and

(5) provide matching funds in accordance with subsection (c).

(c) Matching funds

(1) In general

The Secretary may award a grant to an entity or consortium under this section only if the entity or consortium agrees to make available non-Federal contributions toward the costs of the program

to be funded under the grant in an amount that is not less than $1 for each $5 of Federal funds provided under the grant.

(2) Determination of amount contributed

Non-Federal contributions under paragraph (1) may be in cash or in-kind, fairly evaluated, including equipment or services. Amounts provided by the Federal Government, or services assisted or subsidized to any significant extent by the Federal Government, may not be included in determining the amount of such contributions.

(d) Evaluation

The Secretary shall take such action as may be necessary to evaluate the projects funded under this section and publish, make publicly available, and disseminate the results of such evaluations on as wide a basis as is practicable.

(e) Reports

Not later than 2 years after March 23, 2010, and annually thereafter, the Secretary shall submit to the Committee on Health, Education, Labor, and Pensions and the Committee on Finance of the Senate and the Committee on Energy and Commerce and the Committee on Ways and Means of the House of Representatives a report that—

(1) describes the specific projects supported under this section; and

(2) contains recommendations for Congress based on the evaluation conducted under subsection (d).

(Pub. L. 111–148, title III, §3508, Mar. 23, 2010, 124 Stat. 530.)

EDITORIAL NOTES

CODIFICATION

Section was enacted as part of the Patient Protection and Affordable Care Act, and not as part of the Public Health Service Act which comprises this chapter.

PRIOR PROVISIONS

A prior section 294j, act July 1, 1944, ch. 373, title VII, §737, as added Oct. 12, 1976, Pub. L. 94–484, title IV, §401(b)(3), 90 Stat. 2265; amended Aug. 1, 1977, Pub. L. 95–83, title III, §307(c)(6), 91 Stat. 390; Dec. 19, 1977, Pub. L. 95–215, §4(f), 91 Stat. 1506; Aug. 13, 1981, Pub. L. 97–35, title XXVII, §2731, 95 Stat. 919; Jan. 4, 1983, Pub. L. 97–414, §8(i), 96 Stat. 2061; Oct. 22, 1985, Pub. L. 99–129, title II, §§201(c), 204(c), 208(g)(2), 99 Stat. 525, 527, 531; Nov. 4, 1988, Pub. L. 100–607, title VI, §§602(l), 628(6), 629(b)(2), 102 Stat. 3124, 3145, 3146, defined "eligible institution", "eligible lender", "line of credit", and "school of allied health", prior to the general amendment of this subchapter by Pub. L. 102–408, title I, §102, Oct. 13, 1992, 106 Stat. 1994. See section 292o of this title.

Section 294j–1, act July 1, 1944, ch. 373, title VII, §737A, as added Aug. 13, 1981, Pub. L. 97–35, title XXVII, §2732, 95 Stat. 919, which related to determination of eligible students, was omitted in the general amendment of this subchapter by Pub. L. 102–408, title I, §102, Oct. 13, 1992, 106 Stat. 1994.

[1] *So in original. Probably should be "integrate".*

§294k. Training demonstration program

(a) In general

The Secretary shall establish a training demonstration program to award grants to eligible entities to support—

(1) training for medical residents and fellows to practice psychiatry and addiction medicine in underserved, community-based settings that integrate primary care with mental health and substance use disorder prevention and treatment services;

(2) training (including for individuals completing clinical training requirements for licensure)

for nurse practitioners, physician assistants, health service psychologists, counselors, nurses, and social workers to provide mental health and substance use disorder services in underserved community-based settings that integrate primary care and mental health and substance use disorder services, including such settings that serve pediatric populations; and

(3) establishing, maintaining, or improving academic units or programs that—

(A) provide training for students or faculty, including through clinical experiences and research, to improve the ability to be able to recognize, diagnose, and treat mental health and substance use disorders, with a special focus on addiction or pediatric populations; or

(B) develop evidence-based practices or recommendations for the design of the units or programs described in subparagraph (A), including curriculum content standards.

(b) Activities

(1) Training for residents and fellows

A recipient of a grant under subsection (a)(1)—

(A) shall use the grant funds—

(i)(I) to plan, develop, and operate a training program for medical psychiatry residents and fellows in addiction medicine practicing in eligible entities described in subsection (c)(1); or

(II) to train new psychiatric residents and fellows in addiction medicine to provide and expand access to integrated mental health and substance use disorder services; and

(ii) to provide at least 1 training track that is—

(I) a virtual training track that includes an in-person rotation at a teaching health center or in a community-based setting, followed by a virtual rotation in which the resident or fellow continues to support the care of patients at the teaching health center or in the community-based setting through the use of health information technology and, as appropriate, telehealth services;

(II) an in-person training track that includes a rotation, during which the resident or fellow practices at a teaching health center or in a community-based setting; or

(III) an in-person training track that includes a rotation during which the resident practices in a community-based setting that specializes in the treatment of infants, children, adolescents, or pregnant or postpartum women; and

(B) may use the grant funds to provide additional support for the administration of the program or to meet the costs of projects to establish, maintain, or improve faculty development, or departments, divisions, or other units necessary to implement such training.

(2) Training for other providers

A recipient of a grant under subsection (a)(2)—

(A) shall use the grant funds to plan, develop, or operate a training program to provide mental health and substance use disorder services in underserved, community-based settings (including such settings that serve pediatric populations), as appropriate, that integrate primary care and mental health and substance use disorder prevention and treatment services; and

(B) may use the grant funds to provide additional support for the administration of the program or to meet the costs of projects to establish, maintain, or improve faculty development, or departments, divisions, or other units necessary to implement such program.

(3) Academic units or programs

A recipient of a grant under subsection (a)(3) shall enter into a partnership with organizations such as an education accrediting organization (such as the Liaison Committee on Medical Education, the Accreditation Council for Graduate Medical Education, the Commission on Osteopathic College Accreditation, the Accreditation Commission for Education in Nursing, the Commission on Collegiate Nursing Education, the Accreditation Council for Pharmacy Education, the Council on Social Work Education, American Psychological Association Commission on Accreditation, or the Accreditation Review Commission on Education for the Physician Assistant) to carry out activities under subsection (a)(3).

(c) Eligible entities

(1) Training for residents and fellows

To be eligible to receive a grant under subsection (a)(1), an entity shall—

(A) be a consortium consisting of—

(i) at least one teaching health center; and

(ii) the sponsoring institution (or parent institution of the sponsoring institution) of—

(I) a psychiatry residency program that is accredited by the Accreditation Council of Graduate Medical Education (or the parent institution of such a program); or

(II) a fellowship in addiction medicine, as determined appropriate by the Secretary; or

(B) be an entity described in subparagraph (A)(ii) that provides opportunities for residents or fellows to train in community-based settings that integrate primary care with mental health and substance use disorder prevention and treatment services.

(2) Training for other providers

To be eligible to receive a grant under subsection (a)(2), an entity shall be—

(A) a teaching health center (as defined in section 293l–1(f) of this title);

(B) a Federally qualified health center (as defined in section 1396d(l)(2)(B) of this title);

(C) a community mental health center (as defined in section 1395x(ff)(3)(B) of this title);

(D) a rural health clinic (as defined in section 1395x(aa) of this title);

(E) a health center operated by the Indian Health Service, an Indian tribe, a tribal organization, or an urban Indian organization (as defined in section 1603 of title 25); or

(F) an entity with a demonstrated record of success in providing training for nurse practitioners, physician assistants, health service psychologists counselors, nurses,,[1] and social workers, including such entities that serve pediatric populations.

(3) Academic units or programs

To be eligible to receive a grant under subsection (a)(3), an entity shall be a school of medicine or osteopathic medicine, a nursing school, a physician assistant training program, a school of pharmacy, a school of social work, an accredited public or nonprofit private hospital, an accredited medical residency program, or a public or private nonprofit entity which the Secretary has determined is capable of carrying out such grant.

(d) Priority

(1) In general

In awarding grants under subsection (a)(1) or (a)(2), the Secretary shall give priority to eligible entities that—

(A) demonstrate sufficient size, scope, and capacity to undertake the requisite training of an appropriate number of psychiatric residents, fellows, health service psychologists, nurses nurse [1] practitioners, physician assistants counselors,,[1] or social workers in addiction medicine per year to meet the needs of the area served;

(B) demonstrate experience in training providers to practice team-based care that integrates mental health and substance use disorder prevention and treatment services with primary care in community-based settings, which may include such settings that serve pediatric populations;

(C) demonstrate experience in using health information technology and, as appropriate, telehealth to support—

(i) the delivery of mental health and substance use disorder services at the eligible entities described in subsections (c)(1) and (c)(2); and

(ii) community health centers in integrating primary care and mental health and substance use disorder treatment; or

(D) have the capacity to expand access to mental health and substance use disorder services in areas with demonstrated need, as determined by the Secretary, such as tribal, rural, or other

underserved communities.

(2) Academic units or programs

In awarding grants under subsection (a)(3), the Secretary shall give priority to eligible entities that—

(A) have a record of training the greatest percentage of mental health and substance use disorder providers who enter and remain in these fields or who enter and remain in settings with integrated primary care and mental and substance use disorder prevention and treatment services;

(B) have a record of training individuals who are from underrepresented minority groups, including native populations, or from a rural or disadvantaged background;

(C) provide training in the care (which may include trauma-informed care, as appropriate) of vulnerable populations such as infants, children, adolescents, pregnant and postpartum women, older adults, homeless individuals, victims of abuse or trauma, individuals with disabilities, and other groups as defined by the Secretary;

(D) teach trainees the skills to provide interprofessional, integrated care through collaboration among health professionals; or

(E) provide training in cultural competency and health literacy.

(e) Duration

Grants awarded under this section shall be for a minimum of 5 years.

(f) Study and report

(1) Study

(A) In general

The Secretary, acting through the Administrator of the Health Resources and Services Administration, shall conduct a study on the results of the demonstration program under this section.

(B) Data submission

Not later than 90 days after the completion of the first year of the training program and each subsequent year that the program is in effect, each recipient of a grant under subsection (a) shall submit to the Secretary such data as the Secretary may require for analysis for the report described in paragraph (2).

(2) Report to Congress

Not later than 1 year after receipt of the data described in paragraph (1)(B), the Secretary shall submit to Congress a report that includes—

(A) an analysis of the effect of the demonstration program under this section on the quality, quantity, and distribution of mental health and substance use disorder services;

(B) an analysis of the effect of the demonstration program on the prevalence of untreated mental health and substance use disorders in the surrounding communities of health centers participating in the demonstration; and

(C) recommendations on whether the demonstration program should be expanded.

(g) Authorization of appropriations

There are authorized to be appropriated to carry out this section, and [1] $31,700,000 for each of fiscal years 2023 through 2027.

(July 1, 1944, ch. 373, title VII, §760, as added Pub. L. 114–255, div. B, title IX, §9022, Dec. 13, 2016, 130 Stat. 1250; amended Pub. L. 117–328, div. FF, title I, §1311(b), Dec. 29, 2022, 136 Stat. 5696.)

EDITORIAL NOTES

PRIOR PROVISIONS

A prior section 294k, act July 1, 1944, ch. 373, title VII, §738, as added Oct. 12, 1976, Pub. L. 94–484, title IV, §401(b)(3), 90 Stat. 2265; amended Dec. 19, 1977, Pub. L. 95–215, §4(e)(12), 91 Stat. 1506, related to repayment of loans of deceased or disabled borrowers from student loan insurance fund, prior to the general amendment of this subchapter by Pub. L. 102–408, title I, §102, Oct. 13, 1992, 106 Stat. 1994. See section 292m of this title.

Sections 294l to 294m were omitted in the general amendment of this subchapter by Pub. L. 102–408.

Section 294l, act July 1, 1944, ch. 373, title VII, §739, as added Oct. 12, 1976, Pub. L. 94–484, title IV, §401(b)(3), 90 Stat. 2266; amended Dec. 19, 1977, Pub. L. 95–215, §4(e)(13), 91 Stat. 1506; Aug. 13, 1981, Pub. L. 97–35, title XXVII, §2733, 95 Stat. 920, related to eligibility of institutions and recordation and availability of information. See section 292n of this title.

Section 294l–1, act July 1, 1944, ch. 373, title VII, §739A, as added Nov. 4, 1988, Pub. L. 100–607, title VI, §602(m), 102 Stat. 3124, related to reissuance and refinancing of certain loans.

Section 294m, act July 1, 1944, ch. 373, title VII, §740, as added Sept. 24, 1963, Pub. L. 88–129, §2(b), 77 Stat. 170; amended Oct. 13, 1964, Pub. L. 88–654, §1(a), (b), 78 Stat. 1086; Oct. 22, 1965, Pub. L. 89–290, §§2(b), 4 (a), (f)(1), (2), 79 Stat. 1056–1058; Nov. 2, 1966, Pub. L. 89–709, §3(a), (b), 80 Stat. 1103; Nov. 3, 1966, Pub. L. 89–751, §5(c)(1), 80 Stat. 1232; Aug. 16, 1968, Pub. L. 90–490, title I, §121(a)(1), (2), (5)(B), 82 Stat. 777, 778; Nov. 18, 1971, Pub. L. 92–157, title I, §105(e)(1), (4), (f)(2), 85 Stat. 451; Aug. 23, 1974, Pub. L. 93–385, §2(b), 88 Stat. 741; Apr. 22, 1976, Pub. L. 94–278, title XI, §1105(b), 90 Stat. 416; Oct. 12, 1976, Pub. L. 94–484, title IV, §402, 90 Stat. 2266; Oct. 22, 1985, Pub. L. 99–129, title II, §209(a)(1), (j)(1), 99 Stat. 532, 536; Nov. 4, 1988, Pub. L. 100–607, title VI, §§603(a), 628(7), 629(b)(2), 102 Stat. 3125, 3145, 3146; Nov. 6, 1990, Pub. L. 101–527, §5(a), (b), 104 Stat. 2322, 2323, related to loan agreements for establishment of student loan funds. See section 292q of this title.

AMENDMENTS

2022—Pub. L. 117–328, §1311(b)(1), substituted "mental health and substance use disorder" for "mental and substance use disorders" wherever appearing.

Subsec. (a)(2). Pub. L. 117–328, §1311(b)(2), inserted "(including for individuals completing clinical training requirements for licensure)" after "training" and "counselors, nurses," after "psychologists," and substituted "services, including such settings that serve pediatric populations;" for "services;".

Subsec. (a)(3)(A). Pub. L. 117–328, §1311(b)(3), substituted "disorders" for "disorder" and inserted "or pediatric populations" after "addiction".

Subsec. (b)(2)(A). Pub. L. 117–328, §1311(b)(4), inserted "(including such settings that serve pediatric populations)" after "settings".

Subsec. (c)(2)(F). Pub. L. 117–328, §1311(b)(5), inserted "counselors, nurses," after "psychologists" and substituted "workers, including such entities that serve pediatric populations." for "workers."

Subsec. (d)(1)(A). Pub. L. 117–328, §1311(b)(6), inserted "health service psychologists, nurses" after "fellows," and "counselors," after "physician assistants".

Subsec. (d)(1)(B). Pub. L. 117–328, §1311(b)(7), inserted "health" after "mental" and ", which may include such settings that serve pediatric populations" after "settings".

Subsec. (d)(2)(C). Pub. L. 117–328, §1311(b)(8), inserted "(which may include trauma-informed care, as appropriate)" after "care".

Subsec. (f)(2)(B). Pub. L. 117–328, §1311(b)(10), substituted "disorders" for "disorder".

Subsec. (g). Pub. L. 117–328, §1311(b)(9), substituted ", and $31,700,000 for each of fiscal years 2023 through 2027" for "$10,000,000 for each of fiscal years 2018 through 2022".

[1] *So in original.*

PART E—HEALTH PROFESSIONS AND PUBLIC HEALTH WORKFORCE

SUBPART 1—HEALTH PROFESSIONS WORKFORCE INFORMATION AND ANALYSIS

STATUTORY NOTES AND RELATED SUBSIDIARIES

FUNDING FOR MENTAL HEALTH AND SUBSTANCE USE DISORDER TRAINING FOR HEALTH CARE PROFESSIONALS, PARAPROFESSIONALS, AND PUBLIC SAFETY OFFICERS

Pub. L. 117–2, title II, §2703, Mar. 11, 2021, 135 Stat. 46, provided that:

"(a) IN GENERAL.—In addition to amounts otherwise available, there is appropriated to the Secretary [of Health and Human Services] for fiscal year 2021, out of any money in the Treasury not otherwise appropriated, $80,000,000, to remain available until expended, for the purpose described in subsection (b).

"(b) USE OF FUNDING.—The Secretary, acting through the Administrator of the Health Resources and Services Administration, shall, taking into consideration the needs of rural and medically underserved communities, use amounts appropriated by subsection (a) to award grants or contracts to health professions schools, academic health centers, State or local governments, Indian Tribes and Tribal organizations, or other appropriate public or private nonprofit entities (or consortia of entities, including entities promoting multidisciplinary approaches), to plan, develop, operate, or participate in health professions and nursing training activities for health care students, residents, professionals, paraprofessionals, trainees, and public safety officers, and employers of such individuals, in evidence-informed strategies for reducing and addressing suicide, burnout, mental health conditions, and substance use disorders among health care professionals."

FUNDING FOR EDUCATION AND AWARENESS CAMPAIGN ENCOURAGING HEALTHY WORK CONDITIONS AND USE OF MENTAL HEALTH AND SUBSTANCE USE DISORDER SERVICES BY HEALTH CARE PROFESSIONALS

Pub. L. 117–2, title II, §2704, Mar. 11, 2021, 135 Stat. 46, provided that:

"(a) IN GENERAL.—In addition to amounts otherwise available, there is appropriated to the Secretary [of Health and Human Services] for fiscal year 2021, out of any money in the Treasury not otherwise appropriated, $20,000,000, to remain available until expended, for the purpose described in subsection (b).

"(b) Use of Funds.—The Secretary, acting through the Director of the Centers for Disease Control and Prevention and in consultation with the medical professional community, shall use amounts appropriated by subsection (a) to carry out a national evidence-based education and awareness campaign directed at health care professionals and first responders (such as emergency medical service providers), and employers of such professionals and first responders. Such awareness campaign shall—

"(1) encourage primary prevention of mental health conditions and substance use disorders and secondary and tertiary prevention by encouraging health care professionals to seek support and treatment for their own mental health and substance use concerns; and

"(2) help such professionals to identify risk factors in themselves and others and respond to such risks."

FUNDING FOR GRANTS FOR HEALTH CARE PROVIDERS TO PROMOTE MENTAL HEALTH AMONG THEIR HEALTH PROFESSIONAL WORKFORCE

Pub. L. 117–2, title II, §2705, Mar. 11, 2021, 135 Stat. 46, provided that:

"(a) IN GENERAL.—In addition to amounts otherwise available, there is appropriated to the Secretary [of Health and Human Services] for fiscal year 2021, out of any money in the Treasury not otherwise appropriated, $40,000,000, to remain available until expended, for the purpose described in subsection (b).

"(b) USE OF FUNDS.—The Secretary, acting through the Administrator of the Health Resources and Services Administration, shall, taking into consideration the needs of rural and medically underserved communities, use amounts appropriated by subsection (a) to award grants or contracts to entities providing health care, including health care providers associations and Federally qualified health centers, to establish, enhance, or expand evidence-informed programs or protocols to promote mental health among their providers, other personnel, and members."

§294n. Health professions workforce information and analysis

(a) Purpose

It is the purpose of this section to—

(1) provide for the development of information describing the health professions workforce and

the analysis of workforce related issues; and

(2) provide necessary information for decision-making regarding future directions in health professions and nursing programs in response to societal and professional needs.

(b) National Center for Health Care Workforce Analysis

(1) Establishment

The Secretary shall establish the National Center for Health Workforce Analysis (referred to in this section as the "National Center").

(2) Purposes

The National Center, in coordination to the extent practicable with the National Health Care Workforce Commission (established in section 294q of this title), and relevant regional and State centers and agencies, shall—

(A) provide for the development of information describing and analyzing the health care workforce and workforce related issues;

(B) carry out the activities under section 295k(a) of this title;

(C) annually evaluate programs under this subchapter;

(D) develop and publish performance measures and benchmarks for programs under this subchapter; and

(E) establish, maintain, and publicize a national Internet registry of each grant awarded under this subchapter and a database to collect data from longitudinal evaluations (as described in subsection (d)(2)) on performance measures (as developed under sections 293l(d)(3), 294f(d)(3), and 294o(a)(3) of this title).

(3) Collaboration and data sharing

(A) In general

The National Center shall collaborate with Federal agencies and relevant professional and educational organizations or societies for the purpose of linking data regarding grants awarded under this subchapter.

(B) Contracts for health workforce analysis

For the purpose of carrying out the activities described in subparagraph (A), the National Center may enter into contracts with relevant professional and educational organizations or societies.

(c) State and regional Centers for Health Workforce Analysis

(1) In general

The Secretary shall award grants to, or enter into contracts with, eligible entities for purposes of—

(A) collecting, analyzing, and reporting data regarding programs under this subchapter to the National Center and to the public; and

(B) providing technical assistance to local and regional entities on the collection, analysis, and reporting of data.

(2) Eligible entities

To be eligible for a grant or contract under this subsection, an entity shall—

(A) be a State, a State workforce investment board, a public health or health professions school, an academic health center, or an appropriate public or private nonprofit entity; and

(B) submit to the Secretary an application at such time, in such manner, and containing such information as the Secretary may require.

(d) Increase in grants for longitudinal evaluations

(1) In general

The Secretary shall increase the amount awarded to an eligible entity under this subchapter for a

longitudinal evaluation of individuals who have received education, training, or financial assistance from programs under this subchapter.

(2) Capability

A longitudinal evaluation shall be capable of—

(A) studying practice patterns; and

(B) collecting and reporting data on performance measures developed under sections 293l(d)(3), 294f(d)(3), and 294o(a)(3) of this title.

(3) Guidelines

A longitudinal evaluation shall comply with guidelines issued under sections 293l(d)(4), 294f(d)(4), and 294o(a)(4) of this title.

(4) Eligible entities

To be eligible to obtain an increase under this section, an entity shall be a recipient of a grant or contract under this subchapter.

(e) Authorization of appropriations

(1) In general

(A) National Center

To carry out subsection (b), there are authorized to be appropriated $5,663,000 for each of fiscal years 2021 through 2025.

(B) State and regional Centers

To carry out subsection (c), there are authorized to be appropriated $4,500,000 for each of fiscal years 2010 through 2014.

(C) Grants for longitudinal evaluations

To carry out subsection (d), there are authorized to be appropriated such sums as may be necessary for fiscal years 2010 through 2014.

(2) Reservation

Of the amounts appropriated under paragraph (1) for a fiscal year, the Secretary shall reserve not less than $600,000 for conducting health professions research and for carrying out data collection and analysis in accordance with section 295k of this title.

(3) Availability of additional funds

Amounts otherwise appropriated for programs or activities under this subchapter may be used for activities under subsection (b) with respect to the programs or activities from which such amounts were made available.

(July 1, 1944, ch. 373, title VII, §761, as added Pub. L. 105–392, title I, §104(a), Nov. 13, 1998, 112 Stat. 3552; amended Pub. L. 111–148, title V, §5103(a), Mar. 23, 2010, 124 Stat. 603; Pub. L. 116–136, div. A, title III, §3401(9), Mar. 27, 2020, 134 Stat. 386.)

EDITORIAL NOTES

PRIOR PROVISIONS

A prior section 294n, act July 1, 1944, ch. 373, title VII, §776, as added Pub. L. 102–408, title I, §102, Oct. 13, 1992, 106 Stat. 2050, and amended, which related to grants and contracts to provide health care for individuals with acquired immune deficiency syndrome, was renumbered section 2692 of title XXVI of act July 1, 1944, by Pub. L. 104–146, §3(h)(3), May 20, 1996, 110 Stat. 1364, and transferred to section 300ff–111 of this title.

Another prior section 294n, act July 1, 1944, ch. 373, title VII, §741, as added Sept. 24, 1963, Pub. L. 88–129, §2(b), 77 Stat. 171; amended Oct. 13, 1964, Pub. L. 88–654, §1(c), (d), 78 Stat. 1086; Oct. 22, 1965, Pub. L. 89–290, §4(b), (f)(3), (4), (g)(1), 79 Stat. 1057, 1058; Nov. 2, 1966, Pub. L. 89–709, §3(c), (d), 80 Stat. 1103; Nov. 3, 1966, Pub. L. 89–751, §4, 80 Stat. 1230; Aug. 16, 1968, Pub. L. 90–490, title I,

§121(a)(3), (4), (5)(A), 82 Stat. 777; Nov. 18, 1971, Pub. L. 92–157, title I, §105(b)–(d), (e)(4), (f)(2), 85 Stat. 449–451; Oct. 27, 1972, Pub. L. 92–585, §4, 86 Stat. 1293; Oct. 12, 1976, Pub. L. 94–484, title IV, §§403(a), (b), (d), 407(d)(1), 90 Stat. 2266, 2267, 2279; Aug. 1, 1977, Pub. L. 95–83, title III, §307(e)(1), (2), 91 Stat. 390; Aug. 13, 1981, Pub. L. 97–35, title XXVII, §2735, 95 Stat. 920; Oct. 22, 1985, Pub. L. 99–129, title II, §209(a)(2), (3), (b), (c)(1), (d)–(f), 99 Stat. 532, 534; Nov. 4, 1988, Pub. L. 100–607, title VI, §§603(b), (c), 628(8), 629(b)(2), 102 Stat. 3125, 3145, 3146; Nov. 16, 1990, Pub. L. 101–597, title IV, §401(b)[(a)], 104 Stat. 3035, outlined provisions for loans from a student loan fund, prior to the general amendment of this subchapter by Pub. L. 102–408. See section 292r of this title.

A prior section 761 of act July 1, 1944, was classified to section 294 of this title prior to the general amendment of part D of this subchapter by Pub. L. 105–392.

Another prior section 761 of act July 1, 1944, was classified to section 294cc of this title prior to the general amendment of this subchapter by Pub. L. 102–408.

Another prior section 761 of act July 1, 1944, was classified to section 295 of this title prior to repeal by Pub. L. 99–129.

Another prior section 761 of act July 1, 1944, was classified to section 295 of this title prior to the general amendment of part D of this subchapter by Pub. L. 91–696.

AMENDMENTS

2020—Subsec. (e)(1)(A). Pub. L. 116–136, §3401(9)(A), substituted "$5,663,000 for each of fiscal years 2021 through 2025" for "$7,500,000 for each of fiscal years 2010 through 2014".

Subsec. (e)(2). Pub. L. 116–136, §3401(9)(B), substituted "paragraph (1)" for "subsection (a)".

2010—Subsecs. (b) to (e). Pub. L. 111–148, §5103(a)(1), (2), added subsecs. (b) to (d), redesignated former subsec. (c) as (e), and struck out former subsec. (b) which related to award of grants or contracts.

Subsec. (e)(1). Pub. L. 111–148, §5103(a)(3)(A), added par. (1) and struck out former par. (1). Prior to amendment, text read as follows: "There are authorized to be appropriated to carry out this section, $750,000 for fiscal year 1998, and such sums as may be necessary for each of the fiscal years 1999 through 2002."

Subsec. (e)(2). Pub. L. 111–148, §5103(a)(4), which directed amendment of "paragraph (2)", without specifying the subsec. to be amended, by substituting "paragraph (1)" for "subsection (a)", could not be executed.

STATUTORY NOTES AND RELATED SUBSIDIARIES

TRANSFER OF FUNCTIONS

Pub. L. 111–148, title V, §5103(b), Mar. 23, 2010, 124 Stat. 605, provided that: "Not later than 180 days after the date of enactment of this Act [Mar. 23, 2010], the responsibilities and resources of the National Center for Health Workforce Analysis, as in effect on the date before the date of enactment of this Act, shall be transferred to the National Center for Health Care Workforce Analysis established under section 761 of the Public Health Service Act [42 U.S.C. 294n], as amended by subsection (a)."

§294*o*. Advisory Council on Graduate Medical Education

(a) Establishment; duties

There is established the Council on Graduate Medical Education (in this section referred to as the "Council"). The Council shall—

(1) make recommendations to the Secretary of Health and Human Services (in this section referred to as the "Secretary"), and to the Committee on Health, Education, Labor, and Pensions of the Senate, and the Committee on Energy and Commerce of the House of Representatives, with respect to—

(A) the supply and distribution of physicians in the United States;

(B) current and future shortages or excesses of physicians in medical and surgical specialties and subspecialties;

(C) issues relating to foreign medical school graduates;

(D) appropriate Federal policies with respect to the matters specified in subparagraphs (A), (B), and (C), including policies concerning changes in the financing of undergraduate and graduate medical education programs and changes in the types of medical education training in

graduate medical education programs;

(E) appropriate efforts to be carried out by hospitals, schools of medicine, schools of osteopathic medicine, and accrediting bodies with respect to the matters specified in subparagraphs (A), (B), and (C), including efforts for changes in undergraduate and graduate medical education programs; and

(F) deficiencies in, and needs for improvements in, existing data bases concerning the supply and distribution of, and postgraduate training programs for, physicians in the United States and steps that should be taken to eliminate those deficiencies;

(2) encourage entities providing graduate medical education to conduct activities to voluntarily achieve the recommendations of the Council under paragraph (1)(E);

(3) develop, publish, and implement performance measures for programs under this subchapter, except for programs under part C or D;

(4) develop and publish guidelines for longitudinal evaluations (as described in section 294n(d)(2) of this title) for programs under this subchapter, except for programs under part C or D; and

(5) recommend appropriation levels for programs under this subchapter, except for programs under part C or D.

(b) Composition

The Council shall be composed of—

(1) the Assistant Secretary for Health or the designee of the Assistant Secretary;

(2) the Administrator of the Centers for Medicare & Medicaid Services;

(3) the Chief Medical Director of the Department of Veterans Affairs;

(4) the Administrator of the Health Resources and Services Administration;

(5) 6 members appointed by the Secretary to include representatives of practicing primary care physicians, national and specialty physician organizations, foreign medical graduates, and medical student and house staff associations;

(6) 4 members appointed by the Secretary to include representatives of schools of medicine and osteopathic medicine and public and private teaching hospitals; and

(7) 4 members appointed by the Secretary to include representatives of health insurers, business, and labor.

(c) Terms of appointed members

(1) In general; staggered rotation

Members of the Council appointed under paragraphs (4), (5), and (6) of subsection (b) shall be appointed for a term of 4 years, except that the term of office of the members first appointed shall expire, as designated by the Secretary at the time of appointment, 4 at the end of 1 year, 4 at the end of 2 years, 3 at the end of 3 years, and 3 at the end of 4 years.

(2) Date certain for appointment

The Secretary shall appoint the first members to the Council under paragraphs (4), (5), and (6) of subsection (b) within 60 days after October 13, 1992.

(d) Chair

The Council shall elect one of its members as Chairman of the Council.

(e) Quorum

Nine members of the Council shall constitute a quorum, but a lesser number may hold hearings.

(f) Vacancies

Any vacancy in the Council shall not affect its power to function.

(g) Compensation

Each member of the Council who is not otherwise employed by the United States Government shall receive compensation at a rate equal to the daily rate prescribed for GS–18 under the General

Schedule under section 5332 of title 5 for each day, including traveltime,[1] such member is engaged in the actual performance of duties as a member of the Council. A member of the Council who is an officer or employee of the United States Government shall serve without additional compensation. All members of the Council shall be reimbursed for travel, subsistence, and other necessary expenses incurred by them in the performance of their duties.

(h) Certain authorities and duties

(1) Authorities

In order to carry out the provisions of this section, the Council is authorized to—

(A) collect such information, hold such hearings, and sit and act at such times and places, either as a whole or by subcommittee, and request the attendance and testimony of such witnesses and the production of such books, records, correspondence, memoranda, papers, and documents as the Council or such subcommittee may consider available; and

(B) request the cooperation and assistance of Federal departments, agencies, and instrumentalities, and such departments, agencies, and instrumentalities are authorized to provide such cooperation and assistance.

(2) Coordination of activities

The Council shall coordinate its activities with the activities of the Secretary under section 295k of this title. The Secretary shall, in cooperation with the Council and pursuant to the recommendations of the Council, take such steps as are practicable to eliminate deficiencies in the data base established under section 295k of this title and shall make available in its reports such comprehensive data sets as are developed pursuant to this section.

(i) Reports

Not later than September 30, 2023, and not less than every 5 years thereafter, the Council shall submit to the Secretary, and to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives, a report on the recommendations described in subsection (a).

(j) Funding

Amounts otherwise appropriated under this subchapter may be utilized by the Secretary to support the activities of the Council.

(July 1, 1944, ch. 373, title VII, §762, formerly Pub. L. 102–408, title III, §301, Oct. 13, 1992, 106 Stat. 2080, as amended Pub. L. 102–531, title III, §313(b), Oct. 27, 1992, 106 Stat. 3507; renumbered §762 of act July 1, 1944, and amended Pub. L. 105–392, title I, §104(b), Nov. 13, 1998, 112 Stat. 3552; Pub. L. 107–251, title V, §502, Oct. 26, 2002, 116 Stat. 1664; Pub. L. 111–148, title V, §5103(d)(3), Mar. 23, 2010, 124 Stat. 606; Pub. L. 116–136, div. A, title III, §3401(10), Mar. 27, 2020, 134 Stat. 386.)

EDITORIAL NOTES

CODIFICATION

Section was formerly set out as a note under section 295k of this title prior to renumbering by Pub. L. 105–392.

PRIOR PROVISIONS

A prior section 294o, act July 1, 1944, ch. 373, title VII, §777, as added Pub. L. 102–408, title I, §102, Oct. 13, 1992, 106 Stat. 2052, authorized grants and contracts for improvement of training in geriatrics, prior to the general amendment of this part by Pub. L. 105–392.

Another prior section 294o, act July 1, 1944, ch. 373, title VII, §742, as added Sept. 24, 1963, Pub. L. 88–129, §2(b), 77 Stat. 172; amended Oct. 22, 1965, Pub. L. 89–290, §4(c), 79 Stat. 1057; Nov. 2, 1966, Pub. L. 89–709, §3(e), 80 Stat. 1103; Nov. 3, 1966, Pub. L. 89–751, §5(b), 80 Stat. 1232; Aug. 16, 1968, Pub. L. 90–490, title I, §121(b), 82 Stat. 778; July 9, 1971, Pub. L. 92–52, §1(a), 85 Stat. 144; Nov. 18, 1971, Pub. L. 92–157, title I, §105(a), (f)(2), 85 Stat. 449, 451; Aug. 23, 1974, Pub. L. 93–385, §2(a), 88 Stat. 741; Apr. 22,

1976, Pub. L. 94–278, title XI, §1105(a), 90 Stat. 416; Oct. 12, 1976, Pub. L. 94–484, title I, §101(e), title IV, §§404, 406(d), 90 Stat. 2244, 2267, 2268; Aug. 13, 1981, Pub. L. 97–35, title XXVII, §2734, 95 Stat. 920; Oct. 22, 1985, Pub. L. 99–129, title II, §209(g), 99 Stat. 534; Nov. 6, 1990, Pub. L. 101–527, §5(c), 104 Stat. 2323, provided for authorization of appropriations for purpose of making Federal contributions into student loan funds, prior to the general amendment of this subchapter by Pub. L. 102–408. See section 292y of this title.

A prior section 762 of act July 1, 1944, was classified to section 295a of this title prior to repeal by Pub. L. 99–129.

Another prior section 762 of act July 1, 1944, was classified to section 295a of this title prior to the general amendment of part D of this subchapter by Pub. L. 91–696.

AMENDMENTS

2020—Subsec. (a)(1). Pub. L. 116–136, §3401(10)(A), substituted "Committee on Health, Education, Labor, and Pensions" for "Committee on Labor and Human Resources" in introductory provisions.

Subsec. (b)(2). Pub. L. 116–136, §3401(10)(B)(i), substituted "Centers for Medicare & Medicaid Services" for "Health Care Financing Administration".

Subsec. (b)(4) to (7). Pub. L. 116–136, §3401(10)(B)(ii), (iii), added par. (4) and redesignated former pars. (4) to (6) as (5) to (7), respectively.

Subsecs. (i) to (l). Pub. L. 116–136, §3401(10)(C), (D), added subsec. (i), redesignated subsec. (l) as (j), and struck out former subsecs. (i) to (k) which related to requirement regarding reports, final report, and termination of the Council, respectively.

2010—Subsec. (a)(3) to (5). Pub. L. 111–148 added pars. (3) to (5).

2002—Subsec. (k). Pub. L. 107–251 substituted "2003" for "2002".

1998—Subsec. (j). Pub. L. 105–392, §104(b)(1), substituted "2002" for "1995".

Subsec. (k). Pub. L. 105–392, §104(b)(2), substituted "2002" for "1995".

Subsec. (l). Pub. L. 105–392, §104(b)(3), added subsec. (l).

1992—Subsec. (a)(2). Pub. L. 102–531 substituted "voluntarily" for "voluntary".

STATUTORY NOTES AND RELATED SUBSIDIARIES

CHANGE OF NAME

Committee on Energy and Commerce of House of Representatives treated as referring to Committee on Commerce of House of Representatives by section 1(a) of Pub. L. 104–14, set out as a note preceding section 21 of Title 2, The Congress. Committee on Commerce of House of Representatives changed to Committee on Energy and Commerce of House of Representatives, and jurisdiction over matters relating to securities and exchanges and insurance generally transferred to Committee on Financial Services of House of Representatives by House Resolution No. 5, One Hundred Seventh Congress, Jan. 3, 2001.

Reference to Chief Medical Director of Department of Veterans Affairs deemed to refer to Under Secretary for Health of Department of Veterans Affairs pursuant to section 302(e) of Pub. L. 102–405, set out as a note under section 305 of Title 38, Veterans' Benefits.

EFFECTIVE DATE OF 1992 AMENDMENT

Amendment by Pub. L. 102–531 effective immediately after enactment of Pub. L. 102–408, see section 313(c) of Pub. L. 102–531, set out as a note under section 292y of this title.

REFERENCES IN OTHER LAWS TO GS–16, 17, OR 18 PAY RATES

References in laws to the rates of pay for GS–16, 17, or 18, or to maximum rates of pay under the General Schedule, to be considered references to rates payable under specified sections of Title 5, Government Organization and Employees, see section 529 [title I, §101(c)(1)] of Pub. L. 101–509, set out in a note under section 5376 of Title 5.

FUNDING FOR COUNCIL ON GRADUATE MEDICAL EDUCATION

Pub. L. 112–74, div. F, title II, §215, Dec. 23, 2011, 125 Stat. 1085, provided that: "Notwithstanding any other provisions of law, discretionary funds made available in this Act [div. F of Pub. L. 112–74, see Tables for classification] may be used to continue operating the Council on Graduate Medical Education established by section 301 of Public Law 102–408 [now section 762 of act July 1, 1944, which is classified to this section]."

Similar provisions were contained in the following prior appropriation acts:

Pub. L. 111–117, div. D, title II, §216, Dec. 16, 2009, 123 Stat. 3259.
Pub. L. 111–8, div. F, title II, §216, Mar. 11, 2009, 123 Stat. 782.
Pub. L. 110–161, div. G, title II, §217, Dec. 26, 2007, 121 Stat. 2187.
Pub. L. 109–149, title II, §219, Dec. 30, 2005, 119 Stat. 2861.
Pub. L. 108–447, div. F, title II, §218, Dec. 8, 2004, 118 Stat. 3141.
Pub. L. 108–199, div. E, title II, §219, Jan. 23, 2004, 118 Stat. 255.

[1] *So in original. Probably should be "travel time,".*

§294p. Training for health care providers

(a) Grant program

The Secretary shall establish a program to award grants to accredited schools of allopathic medicine, osteopathic medicine, and nursing, and other health professional training programs for the training of health care professionals to improve the provision of prenatal care, labor care, birthing, and postpartum care for racial and ethnic minority populations, including with respect to perceptions and biases that may affect the approach to, and provision of, care.

(b) Eligibility

To be eligible for a grant under subsection (a), an entity described in such subsection shall submit to the Secretary an application at such time, in such manner, and containing such information as the Secretary may require.

(c) Reporting requirements

(1) Periodic grantee reports

Each entity awarded a grant under this section shall periodically submit to the Secretary a report on the status of activities conducted using the grant, including a description of the impact of such training on patient outcomes, as applicable.

(2) Report to Congress

Not later than September 30, 2026, the Secretary shall submit a report to Congress on the activities conducted using grants under subsection (a) and any best practices identified and disseminated under subsection (d).

(d) Best practices

The Secretary may identify and disseminate best practices for the training described in subsection (a).

(e) Authorization of appropriations

To carry out this section, there are authorized to be appropriated $5,000,000 for each of fiscal years 2023 through 2027.

(July 1, 1944, ch. 373, title VII, §763, as added Pub. L. 117–103, div. P, title I, §132, Mar. 15, 2022, 136 Stat. 795.)

EDITORIAL NOTES

PRIOR PROVISIONS

A prior section 294p, act July 1, 1944, ch. 373, title VII, §763, as added Pub. L. 106–310, div. A, title III, §301(b), Oct. 17, 2000, 114 Stat. 1111, related to pediatric rheumatologists, prior to repeal by Pub. L. 117–103, div. P, title I, §132, Mar. 15, 2022, 136 Stat. 795.

Another prior section 294p, act July 1, 1944, ch. 373, title VII, §778, as added Pub. L. 102–408, title I, §102, Oct. 13, 1992, 106 Stat. 2054, authorized grants and contracts to assist provision of health care in rural areas, prior to the general amendment of this part by Pub. L. 105–392.

Another prior section 294p, act July 1, 1944, ch. 373, title VII, §743, as added Sept. 24, 1963, Pub. L.

88–129, §2(b), 77 Stat. 172; amended Oct. 22, 1965, Pub. L. 89–290, §4(d), 79 Stat. 1057; Nov. 3, 1966, Pub. L. 89–751, §5(c)(2), (3), 80 Stat. 1233; Aug. 16, 1968, Pub. L. 90–490, title I, §121(c), 82 Stat. 778; July 9, 1971, Pub. L. 92–52, §1(b), 85 Stat. 144; Nov. 18, 1971, Pub. L. 92–157, title I, §105(e)(2), (f)(2), 85 Stat. 451; Oct. 12, 1976, Pub. L. 94–484, title IV, §§405, 406(e), 90 Stat. 2267, 2268; Aug. 13, 1981, Pub. L. 97–35, title XXVII, §2736, 95 Stat. 920; Oct. 22, 1985, Pub. L. 99–129, title II, §209(i), 99 Stat. 536; Nov. 4, 1988, Pub. L. 100–607, title VI, §603(d), 102 Stat. 3125, related to distribution of assets from loan funds, prior to the general amendment of this subchapter by Pub. L. 102–408. See section 292x of this title.

A prior section 763 of act July 1, 1944, was classified to section 294b of this title prior to the general amendment of part D of this subchapter by Pub. L. 105–392.

Another prior section 763 of act July 1, 1944, was classified to section 295b of this title prior to repeal by Pub. L. 99–129.

Another prior section 763 of act July 1, 1944, was classified to section 295b of this title prior to the general amendment of former part D of this subchapter by Pub. L. 91–696.

§294q. National Health Care Workforce Commission

(a) Purpose

It is the purpose of this section to establish a National Health Care Workforce Commission that—

(1) serves as a national resource for Congress, the President, States, and localities;

(2) communicates and coordinates with the Departments of Health and Human Services, Labor, Veterans Affairs, Homeland Security, and Education on related activities administered by one or more of such Departments;

(3) develops and commissions evaluations of education and training activities to determine whether the demand for health care workers is being met;

(4) identifies barriers to improved coordination at the Federal, State, and local levels and recommend ways to address such barriers; and

(5) encourages innovations to address population needs, constant changes in technology, and other environmental factors.

(b) Establishment

There is hereby established the National Health Care Workforce Commission (in this section referred to as the "Commission").

(c) Membership

(1) Number and appointment

The Commission shall be composed of 15 members to be appointed by the Comptroller General, without regard to section 1004 of title 5.

(2) Qualifications

(A) In general

The membership of the Commission shall include individuals—

(i) with national recognition for their expertise in health care labor market analysis, including health care workforce analysis; health care finance and economics; health care facility management; health care plans and integrated delivery systems; health care workforce education and training; health care philanthropy; providers of health care services; and other related fields; and

(ii) who will provide a combination of professional perspectives, broad geographic representation, and a balance between urban, suburban, rural, and frontier representatives.

(B) Inclusion

(i) In general

The membership of the Commission shall include no less than one representative of—

(I) the health care workforce and health professionals;

(II) employers, including representatives of small business and self-employed

individuals;

(III) third-party payers;

(IV) individuals skilled in the conduct and interpretation of health care services and health economics research;

(V) representatives of consumers;

(VI) labor unions;

(VII) State or local workforce investment boards; and

(VIII) educational institutions (which may include elementary and secondary institutions, institutions of higher education, including 2 and 4 year institutions, or registered apprenticeship programs).

(ii) Additional members

The remaining membership may include additional representatives from clause (i) and other individuals as determined appropriate by the Comptroller General of the United States.

(C) Majority non-providers

Individuals who are directly involved in health professions education or practice shall not constitute a majority of the membership of the Commission.

(D) Ethical disclosure

The Comptroller General shall establish a system for public disclosure by members of the Commission of financial and other potential conflicts of interest relating to such members. Members of the Commission shall be treated as employees of Congress for purposes of applying subchapter I of chapter 131 of title 5. Members of the Commission shall not be treated as special government employees under title 18.

(3) Terms

(A) In general

The terms of members of the Commission shall be for 3 years except that the Comptroller General shall designate staggered terms for the members first appointed.

(B) Vacancies

Any member appointed to fill a vacancy occurring before the expiration of the term for which the member's predecessor was appointed shall be appointed only for the remainder of that term. A member may serve after the expiration of that member's term until a successor has taken office. A vacancy in the Commission shall be filled in the manner in which the original appointment was made.

(C) Initial appointments

The Comptroller General shall make initial appointments of members to the Commission not later than September 30, 2010.

(4) Compensation

While serving on the business of the Commission (including travel time), a member of the Commission shall be entitled to compensation at the per diem equivalent of the rate provided for level IV of the Executive Schedule under section 5315 of tile [1] 5, and while so serving away from home and the member's regular place of business, a member may be allowed travel expenses, as authorized by the Chairman of the Commission. Physicians serving as personnel of the Commission may be provided a physician comparability allowance by the Commission in the same manner as Government physicians may be provided such an allowance by an agency under section 5948 of title 5, and for such purpose subsection (i) of such section shall apply to the Commission in the same manner as it applies to the Tennessee Valley Authority. For purposes of pay (other than pay of members of the Commission) and employment benefits, rights, and

privileges, all personnel of the Commission shall be treated as if they were employees of the United States Senate. Personnel of the Commission shall not be treated as employees of the Government Accountability Office for any purpose.

(5) Chairman, Vice Chairman

The Comptroller General shall designate a member of the Commission, at the time of appointment of the member, as Chairman and a member as Vice Chairman for that term of appointment, except that in the case of vacancy of the chairmanship or vice chairmanship, the Comptroller General may designate another member for the remainder of that member's term.

(6) Meetings

The Commission shall meet at the call of the chairman, but no less frequently than on a quarterly basis.

(d) Duties

(1) Recognition, dissemination, and communication

The Commission shall—

(A) recognize efforts of Federal, State, and local partnerships to develop and offer health care career pathways of proven effectiveness;

(B) disseminate information on promising retention practices for health care professionals; and

(C) communicate information on important policies and practices that affect the recruitment, education and training, and retention of the health care workforce.

(2) Review of health care workforce and annual reports

In order to develop a fiscally sustainable integrated workforce that supports a high-quality, readily accessible health care delivery system that meets the needs of patients and populations, the Commission, in consultation with relevant Federal, State, and local agencies, shall—

(A) review current and projected health care workforce supply and demand, including the topics described in paragraph (3);

(B) make recommendations to Congress and the Administration concerning national health care workforce priorities, goals, and policies;

(C) by not later than October 1 of each year (beginning with 2011), submit a report to Congress and the Administration containing the results of such reviews and recommendations concerning related policies; and

(D) by not later than April 1 of each year (beginning with 2011), submit a report to Congress and the Administration containing a review of, and recommendations on, at a minimum one high priority area as described in paragraph (4).

(3) Specific topics to be reviewed

The topics described in this paragraph include—

(A) current health care workforce supply and distribution, including demographics, skill sets, and demands, with projected demands during the subsequent 10 and 25 year periods;

(B) health care workforce education and training capacity, including the number of students who have completed education and training, including registered apprenticeships; the number of qualified faculty; the education and training infrastructure; and the education and training demands, with projected demands during the subsequent 10 and 25 year periods;

(C) the education loan and grant programs in titles VII and VIII of the Public Health Service Act (42 U.S.C. 292 et seq. and 296 et seq.), with recommendations on whether such programs should become part of the Higher Education Act of 1965 (20 U.S.C. 1001 et seq [2]);

(D) the implications of new and existing Federal policies which affect the health care workforce, including Medicare and Medicaid graduate medical education policies, titles VII and VIII of the Public Health Service Act (42 U.S.C. 292 et seq. and 296 et seq.), the National Health Service Corps (with recommendations for aligning such programs with national health workforce priorities and goals), and other health care workforce programs, including those

supported through the Workforce Innovation and Opportunity Act, the Carl D. Perkins Career and Technical Education Act of 2006 (20 U.S.C. 2301 et seq.), the Higher Education Act of 1965 (20 U.S.C. 1001 et seq.), and any other Federal health care workforce programs;

(E) the health care workforce needs of special populations, such as minorities, rural populations, medically underserved populations, gender specific needs, individuals with disabilities, and geriatric and pediatric populations with recommendations for new and existing Federal policies to meet the needs of these special populations; and

(F) recommendations creating or revising national loan repayment programs and scholarship programs to require low-income, minority medical students to serve in their home communities, if designated as medical underserved community.[3]

(4) High priority areas

(A) In general

The initial high priority topics described in this paragraph include each of the following:

(i) Integrated health care workforce planning that identifies health care professional skills needed and maximizes the skill sets of health care professionals across disciplines.

(ii) An analysis of the nature, scopes of practice, and demands for health care workers in the enhanced information technology and management workplace.

(iii) An analysis of how to align Medicare and Medicaid graduate medical education policies with national workforce goals.

(iv) An analysis of, and recommendations for, eliminating the barriers to entering and staying in primary care, including provider compensation.

(v) The education and training capacity, projected demands, and integration with the health care delivery system of each of the following:

(I) Nursing workforce capacity at all levels.

(II) Oral health care workforce capacity at all levels.

(III) Mental and behavioral health care workforce capacity at all levels.

(IV) Allied health and public health care workforce capacity at all levels.

(V) Emergency medical service workforce capacity, including the retention and recruitment of the volunteer workforce, at all levels.

(VI) The geographic distribution of health care providers as compared to the identified health care workforce needs of States and regions.

(B) Future determinations

The Commission may require that additional topics be included under subparagraph (A). The appropriate committees of Congress may recommend to the Commission the inclusion of other topics for health care workforce development areas that require special attention.

(5) Grant program

The Commission shall—

(A) review implementation progress reports on, and report to Congress about, the State Health Care Workforce Development Grant program established in section 294r of this title;

(B) in collaboration with the Department of Labor and in coordination with the Department of Education and other relevant Federal agencies, make recommendations to the fiscal and administrative agent under section 294r(b) of this title for grant recipients under section 294r of this title;

(C) assess the implementation of the grants under such section; and

(D) collect performance and report information, including identified models and best practices, on grants from the fiscal and administrative agent under such section and distribute this information to Congress, relevant Federal agencies, and to the public.

(6) Study

The Commission shall study effective mechanisms for financing education and training for careers in health care, including public health and allied health.

(7) Recommendations

The Commission shall submit recommendations to Congress, the Department of Labor, and the Department of Health and Human Services about improving safety, health, and worker protections in the workplace for the health care workforce.

(8) Assessment

The Commission shall assess and receive reports from the National Center for Health Care Workforce Analysis established under section 761(b) of the Public Service Health Act [42 U.S.C. 294n(b)] (as amended by section 5103).[4]

(e) Consultation with Federal, State, and local agencies, Congress, and other organizations

(1) In general

The Commission shall consult with Federal agencies (including the Departments of Health and Human Services, Labor, Education, Commerce, Agriculture, Defense, and Veterans Affairs and the Environmental Protection Agency), Congress, the Medicare Payment Advisory Commission, the Medicaid and CHIP Payment and Access Commission, and, to the extent practicable, with State and local agencies, Indian tribes, voluntary health care organizations, professional societies, and other relevant public-private health care partnerships.

(2) Obtaining official data

The Commission, consistent with established privacy rules, may secure directly from any department or agency of the Executive Branch information necessary to enable the Commission to carry out this section.

(3) Detail of Federal Government employees

An employee of the Federal Government may be detailed to the Commission without reimbursement. The detail of such an employee shall be without interruption or loss of civil service status.

(f) Director and staff; experts and consultants

Subject to such review as the Comptroller General of the United States determines to be necessary to ensure the efficient administration of the Commission, the Commission may—

(1) employ and fix the compensation of an executive director that shall not exceed the rate of basic pay payable for level V of the Executive Schedule and such other personnel as may be necessary to carry out its duties (without regard to the provisions of title 5 governing appointments in the competitive service);

(2) seek such assistance and support as may be required in the performance of its duties from appropriate Federal departments and agencies;

(3) enter into contracts or make other arrangements, as may be necessary for the conduct of the work of the Commission (without regard to section 6101 of title 41);

(4) make advance, progress, and other payments which relate to the work of the Commission;

(5) provide transportation and subsistence for persons serving without compensation; and

(6) prescribe such rules and regulations as the Commission determines to be necessary with respect to the internal organization and operation of the Commission.

(g) Powers

(1) Data collection

In order to carry out its functions under this section, the Commission shall—

(A) utilize existing information, both published and unpublished, where possible, collected and assessed either by its own staff or under other arrangements made in accordance with this section, including coordination with the Bureau of Labor Statistics;

(B) carry out, or award grants or contracts for the carrying out of, original research and development, where existing information is inadequate, and

(C) adopt procedures allowing interested parties to submit information for the Commission's

use in making reports and recommendations.

(2) Access of the Government Accountability Office to information

The Comptroller General of the United States shall have unrestricted access to all deliberations, records, and data of the Commission, immediately upon request.

(3) Periodic audit

The Commission shall be subject to periodic audit by an independent public accountant under contract to the Commission.

(h) Authorization of appropriations

(1) Request for appropriations

The Commission shall submit requests for appropriations in the same manner as the Comptroller General of the United States submits requests for appropriations. Amounts so appropriated for the Commission shall be separate from amounts appropriated for the Comptroller General.

(2) Authorization

There are authorized to be appropriated such sums as may be necessary to carry out this section.

(3) Gifts and services

The Commission may not accept gifts, bequeaths, or donations of property, but may accept and use donations of services for purposes of carrying out this section.

(i) Definitions

In this section:

(1) Health care workforce

The term "health care workforce" includes all health care providers with direct patient care and support responsibilities, such as physicians, nurses, nurse practitioners, primary care providers, preventive medicine physicians, optometrists, ophthalmologists, physician assistants, pharmacists, dentists, dental hygienists, and other oral healthcare professionals, allied health professionals, doctors of chiropractic, community health workers, health care paraprofessionals, direct care workers, psychologists and other behavioral and mental health professionals (including substance abuse prevention and treatment providers), social workers, physical and occupational therapists, certified nurse midwives, podiatrists, the EMS workforce (including professional and volunteer ambulance personnel and firefighters who perform emergency medical services), licensed complementary and alternative medicine providers, integrative health practitioners, public health professionals, and any other health professional that the Comptroller General of the United States determines appropriate.

(2) Health professionals

The term "health professionals" includes—

(A) dentists, dental hygienists, primary care providers, specialty physicians, nurses, nurse practitioners, physician assistants, psychologists and other behavioral and mental health professionals (including substance abuse prevention and treatment providers), social workers, physical and occupational therapists, optometrists, ophthalmologists,[5] public health professionals, clinical pharmacists, allied health professionals, doctors of chiropractic, community health workers, school nurses, certified nurse midwives, podiatrists, licensed complementary and alternative medicine providers, the EMS workforce (including professional and volunteer ambulance personnel and firefighters who perform emergency medical services), and integrative health practitioners;

(B) national representatives of health professionals;

(C) representatives of schools of medicine, osteopathy, nursing, dentistry, optometry, pharmacy, chiropractic, allied health, educational programs for public health professionals, behavioral and mental health professionals (as so defined), social workers, pharmacists,

physical and occupational therapists, optometrists, ophthalmologists,[5] oral health care industry dentistry and dental hygiene, and physician assistants;

(D) representatives of public and private teaching hospitals, and ambulatory health facilities, including Federal medical facilities; and

(E) any other health professional the Comptroller General of the United States determines appropriate.

(Pub. L. 111–148, title V, §5101, title X, §10501(a), Mar. 23, 2010, 124 Stat. 592, 993; Pub. L. 113–128, title V, §512(y), July 22, 2014, 128 Stat. 1716; Pub. L. 117–286, §4(a)(239), (c)(40), Dec. 27, 2022, 136 Stat. 4332, 4359.)

EDITORIAL NOTES

REFERENCES IN TEXT

The Public Health Service Act, referred to in subsec. (d)(3)(C), (D), is act July 1, 1944, ch. 373, 58 Stat. 682. Titles VII and VIII of the Act are classified generally to this subchapter and subchapter VI (§296 et seq.) of this chapter, respectively. For complete classification of this Act to the Code, see Short Title note set out under section 201 of this title and Tables.

The Higher Education Act of 1965, referred to in subsec. (d)(3)(C), (D), is Pub. L. 89–329, Nov. 8, 1965, 79 Stat. 1219, which is classified generally to chapter 28 (§1001 et seq.) of Title 20, Education. For complete classification of this Act to the Code, see Short Title note set out under section 1001 of Title 20 and Tables.

The Workforce Innovation and Opportunity Act, referred to in subsec. (d)(3)(D), is Pub. L. 113–128, July 22, 2014, 128 Stat. 1425, which enacted chapter 32 (§3101 et seq.) of Title 29, Labor, repealed chapter 30 (§2801 et seq.) of Title 29 and chapter 73 (§9201 et seq.) of Title 20, Education, and made amendments to numerous other sections and notes in the Code. For complete classification of this Act to the Code, see Short Title note set out under section 3101 of Title 29 and Tables.

The Carl D. Perkins Career and Technical Education Act of 2006, referred to in subsec. (d)(3)(D), is Pub. L. 88–210, Dec. 18, 1963, 77 Stat. 403, as amended generally by Pub. L. 109–270, §1(b), Aug. 12, 2006, 120 Stat. 683, which is classified generally to chapter 44 (§2301 et seq.) of Title 20, Education. For complete classification of this Act to the Code, see Short Title note set out under section 2301 of Title 20 and Tables.

Section 5103, referred to in subsec. (d)(8), means section 5103 of Pub. L. 111–148.

Level V of the Executive Schedule, referred to in subsec. (f)(1), is set out in section 5316 of Title 5, Government Organization and Employees.

CODIFICATION

In subsec. (f)(3), "section 6101 of title 41" substituted for "section 3709 of the Revised Statutes (41 U.S.C. 5)" on authority of Pub. L. 111–350, §6(c), Jan. 4, 2011, 124 Stat. 3854, which Act enacted Title 41, Public Contracts.

Section was enacted as part of the Patient Protection and Affordable Care Act, and not as part of the Public Health Service Act which comprises this chapter.

PRIOR PROVISIONS

Prior sections 294q to 294q–3 were omitted in the general amendment of this subchapter by Pub. L. 102–408.

Section 294q, act July 1, 1944, ch. 373, title VII, §744, formerly §745, as added Sept. 24, 1963, Pub. L. 88–129, §2(b), 77 Stat. 173; amended Nov. 18, 1971, Pub. L. 92–157, title I, §105(f)(2), 85 Stat. 451; renumbered §744, Oct. 12, 1976, Pub. L. 94–484, title IV, §406(a)(2), 90 Stat. 2268, related to administrative provisions. See section 292u of this title.

Section 294q–1, act July 1, 1944, ch. 373, title VII, §745, as added Oct. 22, 1985, Pub. L. 99–129, title II, §209(h)(2), 99 Stat. 535, related to student loan information to be furnished to students. See section 292v of this title.

Section 294q–2, act July 1, 1944, ch. 373, title VII, §746, as added Oct. 22, 1985, Pub. L. 99–129, title II, §209(h)(2), 99 Stat. 536, related to procedures for appeal of terminations of agreements with schools. See section 292w of this title.

Section 294q–3, act July 1, 1944, ch. 373, title VII, §747, formerly §745, as added and renumbered §747, Oct. 22, 1985, Pub. L. 99–129, title II, §209(a)(4), (h)(1), 99 Stat. 532, 535, defined "school of pharmacy".

AMENDMENTS

2022—Subsec. (c)(1). Pub. L. 117–286, §4(a)(239), substituted "section 1004 of title 5." for "section 5 of the Federal Advisory Committee Act (5 U.S.C. App.)."

Subsec. (c)(2)(D). Pub. L. 117–286, §4(c)(40), substituted "subchapter I of chapter 131 of title 5." for "title I of the Ethics in Government Act of 1978."

2014—Subsec. (d)(3)(D). Pub. L. 113–128 substituted "other health care workforce programs, including those supported through the Workforce Innovation and Opportunity Act," for "other health care workforce programs, including those supported through the Workforce Investment Act of 1998 (29 U.S.C. 2801 et seq.),".

2010—Subsec. (c)(2)(B)(i)(II). Pub. L. 111–148, §10501(a)(1), inserted ", including representatives of small business and self-employed individuals" after "employers".

Subsec. (d)(4)(A)(iv), (v). Pub. L. 111–148, §10501(a)(2), added cl. (iv) and redesignated former cl. (iv) as (v).

Subsec. (i)(2)(A), (C). Pub. L. 111–148, §10501(a)(3), which directed insertion of "optometrists, ophthalmologists," after "occupational therapists," in subpar. (B) of subsec. (i)(2), was executed by making the insertion in subpars. (A) and (C). The words "occupational therapists," do not appear in subpar. (B).

STATUTORY NOTES AND RELATED SUBSIDIARIES

EFFECTIVE DATE OF 2014 AMENDMENT

Amendment by Pub. L. 113–128 effective on the first day of the first full program year after July 22, 2014 (July 1, 2015), see section 506 of Pub. L. 113–128, set out as an Effective Date note under section 3101 of Title 29, Labor.

PURPOSE

Pub. L. 111–148, title V, §5001, Mar. 23, 2010, 124 Stat. 588, provided that: "The purpose of this title [see Tables for classification] is to improve access to and the delivery of health care services for all individuals, particularly low income, underserved, uninsured, minority, health disparity, and rural populations by—

"(1) gathering and assessing comprehensive data in order for the health care workforce to meet the health care needs of individuals, including research on the supply, demand, distribution, diversity, and skills needs of the health care workforce;

"(2) increasing the supply of a qualified health care workforce to improve access to and the delivery of health care services for all individuals;

"(3) enhancing health care workforce education and training to improve access to and the delivery of health care services for all individuals; and

"(4) providing support to the existing health care workforce to improve access to and the delivery of health care services for all individuals."

DEFINITIONS

Pub. L. 111–148, title V, §5002(a), Mar. 23, 2010, 124 Stat. 588, provided that: "In this title [see Tables for classification]:

"(1) ALLIED HEALTH PROFESSIONAL.—The term 'allied health professional' means an allied health professional as defined in section 799B(5) of the Public Heath Service Act (42 U.S.C. 295p(5)) who—

"(A) has graduated and received an allied health professions degree or certificate from an institution of higher education; and

"(B) is employed with a Federal, State, local or tribal public health agency, or in a setting where patients might require health care services, including acute care facilities, ambulatory care facilities, personal residences, and other settings located in health professional shortage areas, medically underserved areas, or medically underserved populations, as recognized by the Secretary of Health and Human Services.

"(2) HEALTH CARE CAREER PATHWAY.—The term 'healthcare career pathway' means a rigorous, engaging, and high quality set of courses and services that—

"(A) includes an articulated sequence of academic and career courses, including 21st century skills;

"(B) is aligned with the needs of healthcare industries in a region or State;

"(C) prepares students for entry into the full range of postsecondary education options, including registered apprenticeships, and careers;

"(D) provides academic and career counseling in student-to-counselor ratios that allow students to

make informed decisions about academic and career options;

"(E) meets State academic standards, State requirements for secondary school graduation and is aligned with requirements for entry into postsecondary education, and applicable industry standards; and

"(F) leads to 2 or more credentials, including—

"(i) a secondary school diploma; and

"(ii) a postsecondary degree, an apprenticeship or other occupational certification, a certificate, or a license.

"(3) INSTITUTION OF HIGHER EDUCATION.—The term 'institution of higher education' has the meaning given the term in sections 101 and 102 of the Higher Education Act of 1965 (20 U.S.C. 1001 and 1002).

"(4) LOW INCOME INDIVIDUAL, STATE WORKFORCE INVESTMENT BOARD, AND LOCAL WORKFORCE INVESTMENT BOARD.—

"(A) LOW-INCOME INDIVIDUAL.—The term 'low-income individual' has the meaning given that term in [former] section 101 of the Workforce investment [sic] Act of 1998 ([former] 29 U.S.C. 2801).

"(B) STATE WORKFORCE INVESTMENT BOARD; LOCAL WORKFORCE INVESTMENT BOARD.—The terms 'State workforce investment board' and 'local workforce investment board', [sic] refer to a State workforce investment board established under [former] section 111 of the Workforce Investment Act of 1998 ([former] 29 U.S.C. 2821) and a local workforce investment board established under [former] section 117 of such Act ([former] 29 U.S.C. 2832), respectively.

"(5) POSTSECONDARY EDUCATION.—The term 'postsecondary education' means—

"(A) a 4-year program of instruction, or not less than a 1-year program of instruction that is acceptable for credit toward an associate or a baccalaureate degree, offered by an institution of higher education; or

"(B) a certificate or registered apprenticeship program at the postsecondary level offered by an institution of higher education or a non-profit educational institution.

"(6) REGISTERED APPRENTICESHIP PROGRAM.—The term 'registered apprenticeship program' means an industry skills training program at the postsecondary level that combines technical and theoretical training through structure on the job learning with related instruction (in a classroom or through distance learning) while an individual is employed, working under the direction of qualified personnel or a mentor, and earning incremental wage increases aligned to enhance job proficiency, resulting in the acquisition of a nationally recognized and portable certificate, under a plan approved by the Office of Apprenticeship or a State agency recognized by the Department of Labor."

[1] So in original. Probably should be "title".

[2] So in original. Probably should be followed by a period.

[3] So in original.

[4] See References in Text note below.

[5] See 2010 Amendment note below.

§294r. State health care workforce development grants

(a) Establishment

There is established a competitive health care workforce development grant program (referred to in this section as the "program") for the purpose of enabling State partnerships to complete comprehensive planning and to carry out activities leading to coherent and comprehensive health care workforce development strategies at the State and local levels.

(b) Fiscal and administrative agent

The Health Resources and Services Administration of the Department of Health and Human Services (referred to in this section as the "Administration") shall be the fiscal and administrative

agent for the grants awarded under this section. The Administration is authorized to carry out the program, in consultation with the National Health Care Workforce Commission (referred to in this section as the "Commission"), which shall review reports on the development, implementation, and evaluation activities of the grant program, including—

(1) administering the grants;

(2) providing technical assistance to grantees; and

(3) reporting performance information to the Commission.

(c) Planning grants

(1) Amount and duration

A planning grant shall be awarded under this subsection for a period of not more than one year and the maximum award may not be more than $150,000.

(2) Eligibility

To be eligible to receive a planning grant, an entity shall be an eligible partnership. An eligible partnership shall be a State workforce investment board, if it includes or modifies the members to include at least one representative from each of the following: health care employer, labor organization, a public 2-year institution of higher education, a public 4-year institution of higher education, the recognized State federation of labor, the State public secondary education agency, the State P–16 or P–20 Council if such a council exists, and a philanthropic organization that is actively engaged in providing learning, mentoring, and work opportunities to recruit, educate, and train individuals for, and retain individuals in, careers in health care and related industries.

(3) Fiscal and administrative agent

The Governor of the State receiving a planning grant has the authority to appoint a fiscal and an administrative agency for the partnership.

(4) Application

Each State partnership desiring a planning grant shall submit an application to the Administrator of the Administration at such time and in such manner, and accompanied by such information as the Administrator may reasonable [1] require. Each application submitted for a planning grant shall describe the members of the State partnership, the activities for which assistance is sought, the proposed performance benchmarks to be used to measure progress under the planning grant, a budget for use of the funds to complete the required activities described in paragraph (5), and such additional assurance and information as the Administrator determines to be essential to ensure compliance with the grant program requirements.

(5) Required activities

A State partnership receiving a planning grant shall carry out the following:

(A) Analyze State labor market information in order to create health care career pathways for students and adults, including dislocated workers.

(B) Identify current and projected high demand State or regional health care sectors for purposes of planning career pathways.

(C) Identify existing Federal, State, and private resources to recruit, educate or train, and retain a skilled health care workforce and strengthen partnerships.

(D) Describe the academic and health care industry skill standards for high school graduation, for entry into postsecondary education, and for various credentials and licensure.

(E) Describe State secondary and postsecondary education and training policies, models, or practices for the health care sector, including career information and guidance counseling.

(F) Identify Federal or State policies or rules to developing [2] a coherent and comprehensive health care workforce development strategy and barriers and a plan to resolve these barriers.

(G) Participate in the Administration's evaluation and reporting activities.

(6) Performance and evaluation

Before the State partnership receives a planning grant, such partnership and the Administrator

of the Administration shall jointly determine the performance benchmarks that will be established for the purposes of the planning grant.

(7) Match

Each State partnership receiving a planning grant shall provide an amount, in cash or in kind, that is not less that 15 percent of the amount of the grant, to carry out the activities supported by the grant. The matching requirement may be provided from funds available under other Federal, State, local or private sources to carry out the activities.

(8) Report

(A) Report to administration

Not later than 1 year after a State partnership receives a planning grant, the partnership shall submit a report to the Administration on the State's performance of the activities under the grant, including the use of funds, including matching funds, to carry out required activities, and a description of the progress of the State workforce investment board in meeting the performance benchmarks.

(B) Report to Congress

The Administration shall submit a report to Congress analyzing the planning activities, performance, and fund utilization of each State grant recipient, including an identification of promising practices and a profile of the activities of each State grant recipient.

(d) Implementation grants

(1) In general

The Administration shall—

(A) competitively award implementation grants to State partnerships to enable such partnerships to implement activities that will result in a coherent and comprehensive plan for health workforce development that will address current and projected workforce demands within the State; and

(B) inform the Commission and Congress about the awards made.

(2) Duration

An implementation grant shall be awarded for a period of no more than 2 years, except in those cases where the Administration determines that the grantee is high performing and the activities supported by the grant warrant up to 1 additional year of funding.

(3) Eligibility

To be eligible for an implementation grant, a State partnership shall have—

(A) received a planning grant under subsection (c) and completed all requirements of such grant; or

(B) completed a satisfactory application, including a plan to coordinate with required partners and complete the required activities during the 2 year period of the implementation grant.

(4) Fiscal and administrative agent

A State partnership receiving an implementation grant shall appoint a fiscal and an administration agent for the implementation of such grant.

(5) Application

Each eligible State partnership desiring an implementation grant shall submit an application to the Administration at such time, in such manner, and accompanied by such information as the Administration may reasonably require. Each application submitted shall include—

(A) a description of the members of the State partnership;

(B) a description of how the State partnership completed the required activities under the planning grant, if applicable;

(C) a description of the activities for which implementation grant funds are sought, including grants to regions by the State partnership to advance coherent and comprehensive regional

health care workforce planning activities;

(D) a description of how the State partnership will coordinate with required partners and complete the required partnership activities during the duration of an implementation grant;

(E) a budget proposal of the cost of the activities supported by the implementation grant and a timeline for the provision of matching funds required;

(F) proposed performance benchmarks to be used to assess and evaluate the progress of the partnership activities;

(G) a description of how the State partnership will collect data to report progress in grant activities; and

(H) such additional assurances as the Administration determines to be essential to ensure compliance with grant requirements.

(6) Required activities

(A) In general

A State partnership that receives an implementation grant may reserve not less than 60 percent of the grant funds to make grants to be competitively awarded by the State partnership, consistent with State procurement rules, to encourage regional partnerships to address health care workforce development needs and to promote innovative health care workforce career pathway activities, including career counseling, learning, and employment.

(B) Eligible partnership duties

An eligible State partnership receiving an implementation grant shall—

(i) identify and convene regional leadership to discuss opportunities to engage in statewide health care workforce development planning, including the potential use of competitive grants to improve the development, distribution, and diversity of the regional health care workforce; the alignment of curricula for health care careers; and the access to quality career information and guidance and education and training opportunities;

(ii) in consultation with key stakeholders and regional leaders, take appropriate steps to reduce Federal, State, or local barriers to a comprehensive and coherent strategy, including changes in State or local policies to foster coherent and comprehensive health care workforce development activities, including health care career pathways at the regional and State levels, career planning information, retraining for dislocated workers, and as appropriate, requests for Federal program or administrative waivers;

(iii) develop, disseminate, and review with key stakeholders a preliminary statewide strategy that addresses short- and long-term health care workforce development supply versus demand;

(iv) convene State partnership members on a regular basis, and at least on a semiannual basis;

(v) assist leaders at the regional level to form partnerships, including technical assistance and capacity building activities;

(vi) collect and assess data on and report on the performance benchmarks selected by the State partnership and the Administration for implementation activities carried out by regional and State partnerships; and

(vii) participate in the Administration's evaluation and reporting activities.

(7) Performance and evaluation

Before the State partnership receives an implementation grant, it and the Administrator shall jointly determine the performance benchmarks that shall be established for the purposes of the implementation grant.

(8) Match

Each State partnership receiving an implementation grant shall provide an amount, in cash or in kind that is not less than 25 percent of the amount of the grant, to carry out the activities supported by the grant. The matching funds may be provided from funds available from other Federal, State,

local, or private sources to carry out such activities.

(9) Reports

(A) Report to administration

For each year of the implementation grant, the State partnership receiving the implementation grant shall submit a report to the Administration on the performance of the State of the grant activities, including a description of the use of the funds, including matched funds, to complete activities, and a description of the performance of the State partnership in meeting the performance benchmarks.

(B) Report to Congress

The Administration shall submit a report to Congress analyzing implementation activities, performance, and fund utilization of the State grantees, including an identification of promising practices and a profile of the activities of each State grantee.

(e) Authorization for appropriations

(1) Planning grants

There are authorized to be appropriated to award planning grants under subsection (c) $8,000,000 for fiscal year 2010, and such sums as may be necessary for each subsequent fiscal year.

(2) Implementation grants

There are authorized to be appropriated to award implementation grants under subsection (d), $150,000,000 for fiscal year 2010, and such sums as may be necessary for each subsequent fiscal year.

(Pub. L. 111–148, title V, §5102, Mar. 23, 2010, 124 Stat. 599.)

EDITORIAL NOTES

CODIFICATION

Section was enacted as part of the Patient Protection and Affordable Care Act, and not as part of the Public Health Service Act which comprises this chapter.

PRIOR PROVISIONS

A prior section 294r, act July 1, 1944, ch. 373, title VII, §751, as added Nov. 4, 1988, Pub. L. 100–607, title VI, §604, 102 Stat. 3126, which related to establishment of a loan repayment program for allied health personnel, was omitted in the general amendment of this subchapter by Pub. L. 102–408.

Another prior section 294r, act July 1, 1944, ch. 373, title VII, §748, as added Oct. 12, 1976, Pub. L. 94–484, title IV, §408(a), 90 Stat. 2279; amended Aug. 1, 1977, Pub. L. 95–83, title III, §307(f), 91 Stat. 391; Dec. 19, 1977, Pub. L. 95–215, §3, 91 Stat. 1504; Sept. 29, 1979, Pub. L. 96–76, title II, §206(a), 93 Stat. 583, which related to traineeships for students in schools of public health, was renumbered section 792 of act July 1, 1944, by Pub. L. 97–35 and transferred to section 295h–1b of this title, and was subsequently omitted in the general amendment of this subchapter by Pub. L. 102–408.

STATUTORY NOTES AND RELATED SUBSIDIARIES

DEFINITIONS

For definitions of terms used in this section, see section 5002(a) of Pub. L. 111–148, set out as a note under section 294q of this title.

[1] *So in original. Probably should be "reasonably".*

[2] *So in original. Probably should be "develop".*

§294s. Rural maternal and obstetric care training demonstration

(a) In general

The Secretary shall award grants to accredited schools of allopathic medicine, osteopathic medicine, and nursing, and other appropriate health professional training programs, to establish a training demonstration program to support—

(1) training for physicians, medical residents, fellows, nurse practitioners, physician assistants, nurses, certified nurse midwives, relevant home visiting workforce professionals and paraprofessionals, or other professionals who meet relevant State training and licensing requirements, as applicable, to reduce preventable maternal mortality and severe maternal morbidity by improving prenatal care, labor care, birthing, and postpartum care in rural community-based settings; and

(2) developing recommendations for such training programs.

(b) Application

To be eligible to receive a grant under subsection (a), an entity shall submit to the Secretary an application at such time, in such manner, and containing such information as the Secretary may require.

(c) Activities

(1) Training for health care professionals

A recipient of a grant under subsection (a)—

(A) shall use the grant funds to plan, develop, and operate a training program to provide prenatal care, labor care, birthing, and postpartum care in rural areas; and

(B) may use the grant funds to provide additional support for the administration of the program or to meet the costs of projects to establish, maintain, or improve faculty development, or departments, divisions, or other units necessary to implement such training.

(2) Training program requirements

The recipient of a grant under subsection (a) shall ensure that training programs carried out under the grant are evidence-based and address improving prenatal care, labor care, birthing, and postpartum care in rural areas, and such programs may include training on topics such as—

(A) maternal mental health, including perinatal depression and anxiety;

(B) substance use disorders;

(C) social determinants of health that affect individuals living in rural areas; and

(D) improving the provision of prenatal care, labor care, birthing, and postpartum care for racial and ethnic minority populations, including with respect to perceptions and biases that may affect the approach to, and provision of, care.

(d) Evaluation and report

(1) Evaluation

(A) In general

The Secretary shall evaluate the outcomes of the demonstration program under this section.

(B) Data submission

Recipients of a grant under subsection (a) shall submit to the Secretary performance metrics and other related data in order to evaluate the program for the report described in paragraph (2).

(2) Report to Congress

Not later than January 1, 2026, the Secretary shall submit to Congress a report that includes—

(A) an analysis of the effects of the demonstration program under this section on the quality, quantity, and distribution of maternal health care services, including prenatal care, labor care, birthing, and postpartum care services, and the demographics of the recipients of those services;

(B) an analysis of maternal and infant health outcomes (including quality of care, morbidity,

and mortality) before and after implementation of the program in the communities served by entities participating in the demonstration; and

(C) recommendations on whether the demonstration program should be continued.

(e) Authorization of appropriations

There are authorized to be appropriated to carry out this section $5,000,000 for each of fiscal years 2023 through 2027.

(July 1, 1944, ch. 373, title VII, §764, as added Pub. L. 117–103, div. P, title I, §144, Mar. 15, 2022, 136 Stat. 800.)

EDITORIAL NOTES

CODIFICATION

Another section 764 of act July 1, 1944, was renumbered section 764A and is classified to section 294t of this title.

PRIOR PROVISIONS

A prior section 294s, act July 1, 1944, ch. 373, title VII, §749, as added Oct. 12, 1976, Pub. L. 94–484, title IV, §408(a), 90 Stat. 2280; amended Aug. 1, 1977, Pub. L. 95–83, title III, §307(f), 91 Stat. 391, Pub. L. 96–88, title III, §301(a)(1), title V, §507, 93 Stat. 677, 692, which related to traineeships for students in other graduate programs, was renumbered section 791A of act July 1, 1944, by Pub. L. 97–35 and transferred to section 295h–1a of this title, and was subsequently omitted in the general amendment of this subchapter by Pub. L. 102–408.

§294t. Programs to promote mental health among the health professional workforce

(a) Programs to promote mental health among health care professionals

(1) In general

The Secretary shall award grants or contracts to health care entities, including entities that provide health care services, such as hospitals, community health centers, and rural health clinics, or to medical professional associations, to establish or enhance evidence-based or evidence-informed programs dedicated to improving mental health and resiliency for health care professionals.

(2) Use of funds

An eligible entity receiving a grant or contract under this subsection shall use funds received through the grant or contract to implement a new program or enhance an existing program to promote mental health among health care professionals, which may include—

(A) improving awareness among health care professionals about risk factors for, and signs of, suicide and mental health or substance use disorders, in accordance with evidence-based or evidence-informed practices;

(B) establishing new, or enhancing existing, evidence-based or evidence-informed programs for preventing suicide and improving mental health and resiliency among health care professionals;

(C) establishing new, or enhancing existing, peer-support programs among health care professionals; or

(D) providing mental health care, follow-up services and care, or referral for such services and care, as appropriate.

(3) Priority

In awarding grants and contracts under this subsection, the Secretary shall give priority to eligible entities that—

(A) are in health professional shortage areas or rural areas; or
(B) have a focus on the reduction of administrative burden on health care workers.

(b) Training grants

The Secretary may establish a program to award grants to health professions schools, academic health centers, State or local governments, Indian Tribes or Tribal organizations, or other appropriate public or private nonprofit entities (or consortia of entities, including entities promoting multidisciplinary approaches) to support the training of health care students, residents, or health care professionals in evidence-based or evidence-informed strategies to address mental and substance use disorders and improve mental health and resiliency among health care professionals.

(c) Grant terms

A grant or contract awarded under subsection (a) or (b) shall be for a period of not less than 3 years.

(d) Application submission

An entity seeking a grant or contract under subsection (a) or (b) shall submit an application to the Secretary at such time, in such manner, and accompanied by such information as the Secretary may require.

(e) Reporting

An entity awarded a grant or contract under subsection (a) or (b) shall periodically submit to the Secretary a report evaluating the activities supported by the grant or contract.

(f) Authorization of appropriations

To carry out this section and section 5 of the Dr. Lorna Breen Health Care Provider Protection Act, there are authorized to be appropriated $35,000,000 for each of fiscal years 2026 through 2030.

(July 1, 1944, ch. 373, title VII, §764A, formerly §764, as added Pub. L. 117–105, §4, Mar. 18, 2022, 136 Stat. 1119; renumbered §764A and amended Pub. L. 119–75, div. J, title V, §6508(b), (c), Feb. 3, 2026, 140 Stat. 695.)

EDITORIAL NOTES

REFERENCES IN TEXT

Section 5 of the Dr. Lorna Breen Health Care Provider Protection Act, referred to in subsec. (f), is section 5 of Pub. L. 117–105, Mar. 18, 2022, 136 Stat. 1120, which is not classified to the Code.

PRIOR PROVISIONS

A prior section 294t, act July 1, 1944, ch. 373, title VII, §751, as added Oct. 12, 1976, Pub. L. 94–484, title IV, §408(b)(1), 90 Stat. 2281; amended Dec. 19, 1977, Pub. L. 95–215, §5, 91 Stat. 1506; Nov. 9, 1978, Pub. L. 95–623, §12(c), 92 Stat. 3457; Nov. 10, 1978, Pub. L. 95–626, title I, §113(b), 92 Stat. 3563; July 10, 1979, Pub. L. 96–32, §7(i), 93 Stat. 84, which related to National Health Service Corps Scholarships Program, was renumbered section 338A of act July 1, 1944, by Pub. L. 97–35 and transferred to section 254l of this title.

A prior section 294u, act July 1, 1944, ch. 373, title VII, §752, as added Oct. 12, 1976, Pub. L. 94–484, title IV, §408(b)(1), 90 Stat. 2284; amended Nov. 10, 1978, Pub. L. 95–626, title I, §113(b), 92 Stat. 3563; Sept. 29, 1979, Pub. L. 96–76, title II, §202(a), (b), 93 Stat. 582, which related to obligated service under contract, was renumbered section 338B of act July 1, 1944, by Pub. L. 97–35 and transferred to section 254m of this title, and subsequently renumbered section 338C of act July 1, 1944, by Pub. L. 100–177.

A prior section 294v, act July 1, 1944, ch. 373, title VII, §753, as added Oct. 12, 1976, Pub. L. 94–484, title IV, §408(b)(1), 90 Stat. 2285; amended Dec. 17, 1980, Pub. L. 96–538, title IV, §403, 94 Stat. 3192, which related to private practice, was renumbered section 338C of act July 1, 1944, by Pub. L. 97–35 and transferred to section 254n of this title, and subsequently renumbered section 338D of act July 1, 1944, by Pub. L. 100–177.

A prior section 294w, act July 1, 1944, ch. 373, title VII, §754, as added Oct. 12, 1976, Pub. L. 94–484, title IV, §408(b)(1), 90 Stat. 2286; amended Aug. 1, 1977, Pub. L. 95–83, title III, §307(g), 91 Stat. 391, which

related to breach of scholarship contract, was renumbered section 338D of act July 1, 1944, by Pub. L. 97–35 and transferred to section 254o of this title, and subsequently renumbered section 338E of act July 1, 1944, by Pub. L. 100–177.

A prior section 294x, act July 1, 1944, ch. 373, title VII, §755, as added Oct. 12, 1976, Pub. L. 94–484, title IV, §408(b)(1), 90 Stat. 2287, which related to special grants for former Corps member to enter private practice, was renumbered section 338E of act July 1, 1944, by Pub. L. 97–35 and transferred to section 254p of this title, and subsequently renumbered section 338F of act July 1, 1944, by Pub. L. 100–177, and section 338G of act July 1, 1944, by Pub. L. 101–597.

A prior section 294y, act July 1, 1944, ch. 373, title VII, §756, as added Oct. 12, 1976, Pub. L. 94–484, title IV, §408(b)(1), 90 Stat. 2288, which related to authorization of appropriations, was renumbered section 338F of act July 1, 1944, by Pub. L. 97–35 and transferred to section 254q of this title, and subsequently renumbered section 338G of act July 1, 1944, prior to repeal by Pub. L. 100–177, title II, §§201(2), 203, Dec. 1, 1987, 101 Stat. 992, 999.

A prior section 294y–1, act July 1, 1944, ch. 373, title VII, §757, as added Aug. 1, 1977, Pub. L. 95–83, title III, §307(n)(1), 91 Stat. 392; amended Dec. 17, 1980, Pub. L. 96–537, §3(d), 94 Stat. 3174, which related to Indian Health Scholarships, was renumbered section 338G of act July 1, 1944, by Pub. L. 97–35 and transferred to section 254r of this title, and subsequently renumbered section 338I of act July 1, 1944, by Pub. L. 100–177, prior to repeal by Pub. L. 100–713, title I, §104(b)(1), Nov. 23, 1988, 102 Stat. 4787.

Prior sections 294z to 294cc were omitted in the general amendment of this subchapter by Pub. L. 102–408.

Section 294z, act July 1, 1944, ch. 373, title VII, §758, as added Oct. 12, 1976, Pub. L. 94–484, title IV, §408(c), 90 Stat. 2289; amended Aug. 1, 1977, Pub. L. 95–83, title III, §307(h), 91 Stat. 391; Aug. 13, 1981, Pub. L. 97–35, title XXVII, §2737, 95 Stat. 920; Oct. 22, 1985, Pub. L. 99–129, title I, §102, title II, §210(a), 99 Stat. 523, 537; Nov. 4, 1988, Pub. L. 100–607, title VI, §§605, 628(9), 629(b)(2), 102 Stat. 3126, 3146, related to scholarships for students of exceptional financial need.

Section 294aa, act July 1, 1944, ch. 373, title VII, §759, as added Oct. 12, 1976, Pub. L. 94–484, title IV, §408(c), 90 Stat. 2289; amended Nov. 16, 1990, Pub. L. 101–597, title IV, §401(b)[(a)], 104 Stat. 3035, established a Lister Hill scholarship program of grants for family practice of medicine.

Section 294bb, act July 1, 1944, ch. 373, title VII, §760, as added Nov. 6, 1990, Pub. L. 101–527, §6, 104 Stat. 2323, related to grants and other assistance for students from disadvantaged backgrounds. See section 293a of this title.

Section 294cc, act July 1, 1944, ch. 373, title VII, §761, as added Nov. 6, 1990, Pub. L. 101–527, §6, 104 Stat. 2325, related to a loan repayment program regarding service on faculties of certain health professions schools. See section 293b of this title.

AMENDMENTS

2026—Subsec. (a)(3). Pub. L. 119–75, §6508(c)(2), substituted "to eligible entities that—" for "to eligible entities in", inserted "(A) are in" before "health professional shortage", and added subpar. (B).

Subsec. (c). Pub. L. 119–75, §6508(c)(3), inserted "not less than" after "period of".

Subsec. (f). Pub. L. 119–75, §6508(c)(4), substituted "2026 through 2030" for "2022 through 2024".

STATUTORY NOTES AND RELATED SUBSIDIARIES

DISSEMINATION OF BEST PRACTICES

Pub. L. 117–105, §2, Mar. 18, 2022, 136 Stat. 1118, as amended by Pub. L. 119–75, div. J, title V, §6508(a), Feb. 3, 2026, 140 Stat. 695, provided that: "Not later than 5 years after the date of the enactment of this Act [Mar. 18, 2022], the Secretary of Health and Human Services (referred to in this Act [see Short Title of 2022 Amendment note set out under section 201 of this title] as the 'Secretary') shall identify and disseminate evidence-based or evidence-informed best practices for preventing suicide and improving mental health and resiliency among health care professionals, and for training health care professionals in appropriate strategies to promote their mental health. Such best practices shall include recommendations related to preventing suicide and improving mental health and resiliency among health care professionals."

EDUCATION AND AWARENESS INITIATIVE ENCOURAGING USE OF MENTAL HEALTH AND SUBSTANCE USE DISORDER SERVICES BY HEALTH CARE PROFESSIONALS

Pub. L. 117–105, §3, Mar. 18, 2022, 136 Stat. 1118, which required establishment of a national evidence-based or evidence-informed education and awareness initiative for health care professionals to seek support and care for their mental health or substance use concerns, was transferred to section 294u of this title.

§294u. Education and awareness initiative encouraging use of mental health and substance use disorder services by health care professionals

(a) In general

The Secretary, in consultation with relevant stakeholders, including medical professional associations, shall establish a national evidence-based or evidence-informed education and awareness initiative—

(1) to encourage health care professionals to seek support and care for their mental health or substance use concerns, to help such professionals identify risk factors associated with suicide and mental health conditions, and to help such professionals learn how best to respond to such risks, with the goal of preventing suicide, mental health conditions, and substance use disorders; and

(2) to address stigma associated with seeking mental health and substance use disorder services.

(b) Reporting

Not later than 2 years after March 18, 2022, and annually thereafter, the Secretary shall provide to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives an update on the activities and outcomes of the initiative under subsection (a), including a description of quantitative and qualitative metrics used to evaluate such activities and outcomes.

(c) Authorization of appropriations

To carry out this section, there are authorized to be appropriated $10,000,000 for each of fiscal years 2026 through 2030.

(Pub. L. 117–105, §3, Mar. 18, 2022, 136 Stat. 1118; Pub. L. 119–75, div. J, title V, §6508(b), Feb. 3, 2026, 140 Stat. 695.)

EDITORIAL NOTES

CODIFICATION

Section was enacted as part of the Dr. Lorna Breen Health Care Provider Protection Act, and not as part of the Public Health Service Act which comprises this chapter.

Section was formerly set out as a note under section 294t of this title.

AMENDMENTS

2026—Subsec. (b). Pub. L. 119–75, §6508(b)(1), inserted "and annually thereafter," for "March 18, 2022".

Subsec. (c). Pub. L. 119–75, §6508(b)(2), substituted "2026 through 2030" for "2022 through 2024".

SUBPART 2—PUBLIC HEALTH WORKFORCE

§295. General provisions

(a) In general

The Secretary may award grants or contracts to eligible entities to increase the number of individuals in the public health workforce, to enhance the quality of such workforce, and to enhance the ability of the workforce to meet national, State, and local health care needs.

(b) Eligibility

To be eligible to receive a grant or contract under subsection (a) an entity shall—

(1) be—

(A) a health professions school, including an accredited school or program of public health, health administration, preventive medicine, or dental public health or a school providing health

management programs;

(B) an academic health center;

(C) a State or local government; or

(D) any other appropriate public or private nonprofit entity; and

(2) prepare and submit to the Secretary an application at such time, in such manner, and containing such information as the Secretary may require.

(c) Preference

In awarding grants or contracts under this section the Secretary may grant a preference to entities—

(1) serving individuals who are from disadvantaged backgrounds (including underrepresented racial and ethnic minorities); and

(2) graduating large proportions of individuals who serve in underserved communities.

(d) Activities

Amounts provided under a grant or contract awarded under this section may be used for—

(1) the costs of planning, developing, or operating demonstration training programs;

(2) faculty development;

(3) trainee support;

(4) technical assistance;

(5) to meet the costs of projects—

(A) to plan and develop new residency training programs and to maintain or improve existing residency training programs in preventive medicine and dental public health, that have available full-time faculty members with training and experience in the fields of preventive medicine and dental public health; and

(B) to provide financial assistance to residency trainees enrolled in such programs;

(6) the retraining of existing public health workers as well as for increasing the supply of new practitioners to address priority public health, preventive medicine, public health dentistry, and health administration needs;

(7) preparing public health professionals for employment at the State and community levels;

(8) public health workforce loan repayment programs; or

(9) other activities that may produce outcomes that are consistent with the purposes of this section.

(e) Traineeships

(1) In general

With respect to amounts used under this section for the training of health professionals, such training programs shall be designed to—

(A) make public health education more accessible to the public and private health workforce;

(B) increase the relevance of public health academic preparation to public health practice in the future;

(C) provide education or training for students from traditional on-campus programs in practice-based sites; or

(D) develop educational methods and distance-based approaches or technology that address adult learning requirements and increase knowledge and skills related to community-based cultural diversity in public health education.

(2) Severe shortage disciplines

Amounts provided under grants or contracts under this section may be used for the operation of programs designed to award traineeships to students in accredited schools of public health who enter educational programs in fields where there is a severe shortage of public health professionals, including epidemiology, biostatistics, environmental health, toxicology, public

health nursing, nutrition, preventive medicine, maternal and child health, and behavioral and mental health professions.

(July 1, 1944, ch. 373, title VII, §765, as added Pub. L. 105–392, title I, §105, Nov. 13, 1998, 112 Stat. 3553; amended Pub. L. 111–148, title V, §5206(a), Mar. 23, 2010, 124 Stat. 611.)

EDITORIAL NOTES

PRIOR PROVISIONS

A prior section 295, act July 1, 1944, ch. 373, title VII, §781, as added Pub. L. 102–408, title I, §102, Oct. 13, 1992, 106 Stat. 2055; amended Pub. L. 105–12, §12(b), Apr. 30, 1997, 111 Stat. 29, authorized grants and contracts for research on certain health professions issues, prior to repeal by Pub. L. 105–392, title I, §106(a)(1), Nov. 13, 1998, 112 Stat. 3557.

Another prior section 295, act July 1, 1944, ch. 373, title VII, §761, as added Dec. 25, 1970, Pub. L. 91–696, §101, 84 Stat. 2080–1; amended Oct. 17, 1979, Pub. L. 96–88, title III, §301(a)(1), title V, §507, 93 Stat. 677, 692, provided Congressional declaration of purpose for former part D of this subchapter, prior to repeal by Pub. L. 99–129, title II, §220(c), Oct. 22, 1985, 99 Stat. 544.

Another prior section 295, act July 1, 1944, ch. 373, title VII, §761, as added Oct. 31, 1963, Pub. L. 88–164, title I, §101, 77 Stat. 282, related to authorization of appropriations respecting grants for construction of mental retardation facilities, prior to the general amendment of former part D of this subchapter by section 101 of Pub. L. 91–696.

A prior section 765 of act July 1, 1944, was classified to section 294c of this title prior to the general amendment of part D of this subchapter by Pub. L. 105–392.

Another prior section 765 of act July 1, 1944, was classified to section 295d of this title prior to repeal by Pub. L. 99–129.

Another prior section 765 of act July 1, 1944, was classified to section 295d of this title prior to the general amendment of part D of this subchapter by Pub. L. 91–696.

AMENDMENTS

2010—Subsec. (d)(8), (9). Pub. L. 111–148 added par. (8) and redesignated former par. (8) as (9).

STATUTORY NOTES AND RELATED SUBSIDIARIES

FUNDING FOR PUBLIC HEALTH WORKFORCE

Pub. L. 117–2, title II, §2501, Mar. 11, 2021, 135 Stat. 42, provided that:

"(a) IN GENERAL.—In addition to amounts otherwise available, there is appropriated to the Secretary of Health and Human Services (in this subtitle [subtitle F (§§2501, 2502) of title II of Pub. L. 117–2, enacting this note] referred to as the 'Secretary') for fiscal year 2021, out of any money in the Treasury not otherwise appropriated, $7,660,000,000, to remain available until expended, to carry out activities related to establishing, expanding, and sustaining a public health workforce, including by making awards to State, local, and territorial public health departments.

"(b) USE OF FUNDS FOR PUBLIC HEALTH DEPARTMENTS.—Amounts made available to an awardee pursuant to subsection (a) shall be used for the following:

"(1) Costs, including wages and benefits, related to the recruiting, hiring, and training of individuals—

"(A) to serve as case investigators, contact tracers, social support specialists, community health workers, public health nurses, disease intervention specialists, epidemiologists, program managers, laboratory personnel, informaticians, communication and policy experts, and any other positions as may be required to prevent, prepare for, and respond to COVID–19; and

"(B) who are employed by—

"(i) the State, territorial, or local public health department involved; or

"(ii) a nonprofit private or public organization with demonstrated expertise in implementing public health programs and established relationships with such State, territorial, or local public health departments, particularly in medically underserved areas.

"(2) Personal protective equipment, data management and other technology, or other necessary supplies.

"(3) Administrative costs and activities necessary for awardees to implement activities funded under this section.

"(4) Subawards from recipients of awards under subsection (a) to local health departments for the

purposes of the activities funded under this section."

§295a. Public health training centers

(a) In general

The Secretary may make grants or contracts for the operation of public health training centers.

(b) Eligible entities

(1) In general

A public health training center shall be an accredited school of public health, or another public or nonprofit private institution accredited for the provision of graduate or specialized training in public health, that plans, develops, operates, and evaluates projects to improve preventive medicine, health promotion and disease prevention, or access to and quality of health care services in rural or medically underserved communities.

(2) Preference

In awarding grants or contracts under this section the Secretary shall give preference to accredited schools of public health.

(c) Certain requirements

With respect to a public health training center, an award may not be made under subsection (a) unless the program agrees that it—

(1) will establish or strengthen field placements for students in public or nonprofit private health agencies or organizations;

(2) will involve faculty members and students in collaborative projects to enhance public health services to medically underserved communities;

(3) will specifically designate a geographic area or medically underserved population to be served by the center that shall be in a location removed from the main location of the teaching facility of the school that is participating in the program with such center; and

(4) will assess the health personnel needs of the area to be served by the center and assist in the planning and development of training programs to meet such needs.

(July 1, 1944, ch. 373, title VII, §766, as added Pub. L. 105–392, title I, §105, Nov. 13, 1998, 112 Stat. 3554; amended Pub. L. 116–136, div. A, title III, §3401(11), Mar. 27, 2020, 134 Stat. 387.)

EDITORIAL NOTES

PRIOR PROVISIONS

A prior section 295a, act July 1, 1944, ch. 373, title VII, §782, as added Pub. L. 102–408, title I, §102, Oct. 13, 1992, 106 Stat. 2057, authorized grants and contracts for chiropractic demonstration projects, prior to repeal by Pub. L. 105–392, title I, §106(a)(1), Nov. 13, 1998, 112 Stat. 3557.

Another prior section 295a, act July 1, 1944, ch. 373, title VII, §762, as added Dec. 25, 1970, Pub. L. 91–696, §101, 84 Stat. 2080–2, authorized appropriations for former part D of this subchapter, prior to repeal by Pub. L. 99–129, title II, §220(c), Oct. 22, 1985, 99 Stat. 544.

Another prior section 295a, act July 1, 1944, ch. 373, title VII, §762, as added Oct. 31, 1963, Pub. L. 88–164, title I, §101, 77 Stat. 282, related to applications for grants for construction of mental retardation facilities, including their approval by Surgeon General and consideration of certain matters, prior to the general amendment of former part D of this subchapter by section 101 of Pub. L. 91–696.

A prior section 766 of act July 1, 1944, was classified to section 294d of this title prior to the general amendment of part D of this subchapter by Pub. L. 105–392.

Another prior section 766 of act July 1, 1944, was classified to section 295d–1 of this title prior to repeal by Pub. L. 99–129.

Another prior section 766 of act July 1, 1944, was classified to section 295d–1 of this title prior to the general amendment of part D of this subchapter by Pub. L. 91–696.

AMENDMENTS

2020—Subsec. (b)(1). Pub. L. 116–136 substituted "that plans, develops, operates, and evaluates projects to improve preventive medicine, health promotion and disease prevention, or access to and quality of health care services in rural or medically underserved communities." for "that plans, develops, operates, and evaluates projects that are in furtherance of the goals established by the Secretary for the year 2000 in the areas of preventive medicine, health promotion and disease prevention, or improving access to and quality of health services in medically underserved communities."

§295b. Public health traineeships

(a) In general

The Secretary may make grants to accredited schools of public health, and to other public or nonprofit private institutions accredited for the provision of graduate or specialized training in public health, for the purpose of assisting such schools and institutions in providing traineeships to individuals described in subsection (b)(3).

(b) Certain requirements

(1) Amount

The amount of any grant under this section shall be determined by the Secretary.

(2) Use of grant

Traineeships awarded under grants made under subsection (a) shall provide for tuition and fees and such stipends and allowances (including travel and subsistence expenses and dependency allowances) for the trainees as the Secretary may deem necessary.

(3) Eligible individuals

The individuals referred to in subsection (a) are individuals who are pursuing a course of study in a health professions field in which there is a severe shortage of health professionals (which fields include the fields of epidemiology, environmental health, biostatistics, toxicology, nutrition, and maternal and child health).

(July 1, 1944, ch. 373, title VII, §767, as added Pub. L. 105–392, title I, §105, Nov. 13, 1998, 112 Stat. 3555.)

EDITORIAL NOTES

PRIOR PROVISIONS

A prior section 295b, act July 1, 1944, ch. 373, title VII, §763, as added Dec. 25, 1970, Pub. L. 91–696, §101, 84 Stat. 2080–2, authorized Secretary to make grants and to set limitations and conditions on grants, required applications for grants, limited use of grant funds, set forth method of payment of grants, and provided for protection of financial interests of the United States, prior to repeal by Pub. L. 99–129, title II, §220(c), Oct. 22, 1985, 99 Stat. 544.

Another prior section 295b, act July 1, 1944, ch. 373, title VII, §763, as added Oct. 31, 1963, Pub. L. 88–164, title I, §101, 77 Stat. 283, related to amount of grants for construction of mental retardation facilities, including maximum payments, advances or reimbursement, installments, conditions, and nonduplication of grants, prior to the general amendment of former part D of this subchapter by section 101 of Pub. L. 91–696.

A prior section 767 of act July 1, 1944, was classified to section 295e–1 of this title prior to repeal by Pub. L. 99–129.

Another prior section 767 of act July 1, 1944, was classified to section 295d–2 of this title prior to repeal by Pub. L. 99–129.

§295c. Preventive medicine and public health training grant program

(a) Grants

The Secretary, acting through the Administrator of the Health Resources and Services

Administration and in consultation with the Director of the Centers for Disease Control and Prevention, shall award grants to, or enter into contracts with, eligible entities to provide training to graduate medical residents in preventive medicine specialties.

(b) Eligibility

To be eligible for a grant or contract under subsection (a), an entity shall be—

(1) an accredited school of public health or school of medicine or osteopathic medicine;

(2) an accredited public or private nonprofit hospital;

(3) a State, local, or tribal health department; or

(4) a consortium of 2 or more entities described in paragraphs (1) through (3).

(c) Use of funds

Amounts received under a grant or contract under this section shall be used to—

(1) plan, develop (including the development of curricula), operate, or participate in an accredited residency or internship program in preventive medicine or public health;

(2) defray the costs of practicum experiences, as required in such a program; and

(3) establish, maintain, or improve—

(A) academic administrative units (including departments, divisions, or other appropriate units) in preventive medicine and public health; or

(B) programs that improve clinical teaching in preventive medicine and public health.

(d) Report

The Secretary shall submit to the Congress an annual report on the program carried out under this section.

(July 1, 1944, ch. 373, title VII, §768, as added Pub. L. 105–392, title I, §105, Nov. 13, 1998, 112 Stat. 3555; amended Pub. L. 111–148, title X, §10501(m)(1), Mar. 23, 2010, 124 Stat. 1001.)

EDITORIAL NOTES

PRIOR PROVISIONS

A prior section 295c, act July 1, 1944, ch. 373, title VII, §764, as added Dec. 25, 1970, Pub. L. 91–696, §101, 84 Stat. 2080–2; amended Oct. 17, 1979, Pub. L. 96–88, title III, §301(a)(1), title V, §507, 93 Stat. 677, 692, established requirements of eligibility for grants, prior to repeal by Pub. L. 99–129, title II, §220(c), Oct. 22, 1985, 99 Stat. 544.

Another prior section 295c, act July 1, 1944, ch. 373, title VII, §764, as added Oct. 31, 1963, Pub. L. 88–164, title I, §101, 77 Stat. 283, related to recovery of expenditures under certain conditions respecting grants for construction of mental retardation facilities, prior to the general amendment of former part D of this subchapter by section 101 of Pub. L. 91–696.

AMENDMENTS

2010—Pub. L. 111–148 amended section generally. Prior to amendment, section related to grants and contracts for residency training programs in preventive medicine and dental public health and provision of financial assistance to residency trainees.

§295d. Health administration traineeships and special projects

(a) In general

The Secretary may make grants to State or local governments (that have in effect preventive medical and dental public health residency programs) or public or nonprofit private educational entities (including graduate schools of social work and business schools that have health management programs) that offer a program described in subsection (b)—

(1) to provide traineeships for students enrolled in such a program; and

(2) to assist accredited programs health administration in the development or improvement of programs to prepare students for employment with public or nonprofit private entities.

(b) Relevant programs

The program referred to in subsection (a) is an accredited program in health administration, hospital administration, or health policy analysis and planning, which program is accredited by a body or bodies approved for such purpose by the Secretary of Education and which meets such other quality standards as the Secretary of Health and Human Services by regulation may prescribe.

(c) Preference in making grants

In making grants under subsection (a), the Secretary shall give preference to qualified applicants that meet the following conditions:

(1) Not less than 25 percent of the graduates of the applicant are engaged in full-time practice settings in medically underserved communities.

(2) The applicant recruits and admits students from medically underserved communities.

(3) For the purpose of training students, the applicant has established relationships with public and nonprofit providers of health care in the community involved.

(4) In training students, the applicant emphasizes employment with public or nonprofit private entities.

(d) Certain provisions regarding traineeships

(1) Use of grant

Traineeships awarded under grants made under subsection (a) shall provide for tuition and fees and such stipends and allowances (including travel and subsistence expenses and dependency allowances) for the trainees as the Secretary may deem necessary.

(2) Preference for certain students

Each entity applying for a grant under subsection (a) for traineeships shall assure to the satisfaction of the Secretary that the entity will give priority to awarding the traineeships to students who demonstrate a commitment to employment with public or nonprofit private entities in the fields with respect to which the traineeships are awarded.

(July 1, 1944, ch. 373, title VII, §769, as added Pub. L. 105–392, title I, §105, Nov. 13, 1998, 112 Stat. 3556.)

EDITORIAL NOTES

PRIOR PROVISIONS

A prior section 295d, act July 1, 1944, ch. 373, title VII, §765, as added Dec. 25, 1970, Pub. L. 91–696, §101, 84 Stat. 2080–3; amended Oct. 17, 1979, Pub. L. 96–88, title III, §301(a)(1), title V, §507, 93 Stat. 677, 692, related to requisites for approval of grants, establishment of separate medical school departments of family medicine, establishment of special hospital programs of family medicine, and supplementation of non-Federal funds, prior to repeal by Pub. L. 99–129, title II, §220(c), Oct. 22, 1985, 99 Stat. 544.

Another prior section 295d, act July 1, 1944, ch. 373, title VII, §765, as added Oct. 31, 1963, Pub. L. 88–164, title I, §101, 77 Stat. 284, related to noninterference with administration of institutions respecting grants for construction of mental retardation facilities, prior to the general amendment of former part D of this subchapter by section 101 of Pub. L. 91–696.

Prior sections 295d–1 and 295d–2 were repealed by Pub. L. 99–129, title II, §220(c), Oct. 22, 1985, 99 Stat. 544.

Section 295d–1, act July 1, 1944, ch. 373, title VII, §766, as added Dec. 25, 1970, Pub. L. 91–696, §101, 84 Stat. 2080–4, related to establishment and funding of planning and developmental grants.

Another prior section 295d–1, act July 1, 1944, ch. 373, title VII, §766, as added Oct. 31, 1963, Pub. L. 88–164, title I, §101, 77 Stat. 284, related to definitions in connection with grants for construction of mental retardation research facilities, prior to the general amendment of former part D of this subchapter by section 101 of Pub. L. 91–696.

Section 295d–2, act July 1, 1944, ch. 373, title VII, §767, as added Dec. 25, 1970, Pub. L. 91–696, §101, 84 Stat. 2080–4, established Advisory Council on Family Medicine and provided for its composition, term and compensation of its members, and its duties and functions.

§295e. Authorization of appropriations

(a) In general

For the purpose of carrying out this subpart, there is authorized to be appropriated $17,000,000 for each of fiscal years 2021 through 2025.

(b) Limitation regarding certain program

In obligating amounts appropriated under subsection (a), the Secretary may not obligate more than 30 percent for carrying out section 295b of this title.

(July 1, 1944, ch. 373, title VII, §770, as added Pub. L. 105–392, title I, §105, Nov. 13, 1998, 112 Stat. 3556; amended Pub. L. 111–148, title X, §10501(m)(2), Mar. 23, 2010, 124 Stat. 1002; Pub. L. 116–136, div. A, title III, §3401(12), Mar. 27, 2020, 134 Stat. 387.)

EDITORIAL NOTES

PRIOR PROVISIONS

A prior section 295e, act July 1, 1944, ch. 373, title VII, §768, as added Dec. 25, 1970, Pub. L. 91–696, §101, 84 Stat. 2080–5, set forth definitions for former part D of this subchapter, prior to repeal by Pub. L. 99–129, title II, §220(c), Oct. 22, 1985, 99 Stat. 544.

Another prior section 295e consisted of section 766 of act July 1, 1944. The classification of section 766 of act July 1, 1944, was changed to section 295d–1 of this title for purposes of codification.

Prior sections 295e–1 to 295e–5 were repealed by Pub. L. 99–129, title II, §220(c), Oct. 22, 1985, 99 Stat. 544.

Section 295e–1, act July 1, 1944, ch. 373, title VII, §767, as added Nov. 18, 1971, Pub. L. 92–157, title I, §107(b), 85 Stat. 457; amended Oct. 12, 1976, Pub. L. 94–484, title I, §101(g), 90 Stat. 2244, authorized appropriations for grants to public or nonprofit private hospitals for training, traineeships, and fellowships in family medicine.

Section 295e–2, act July 1, 1944, ch. 373, title VII, §768, as added Nov. 18, 1971, Pub. L. 92–157, title I, §107(b), 85 Stat. 458; amended Oct. 12, 1976, Pub. L. 94–484, title I, §101(h), 90 Stat. 2244, established grants for postgraduate training programs for physicians and dentists and authorized appropriations for those grants.

Section 295e–3, act July 1, 1944, ch. 373, title VII, §769, as added Nov. 18, 1971, Pub. L. 92–157, title I, §107(b), 85 Stat. 459; amended Oct. 12, 1976, Pub. L. 94–484, title I, §101(i), 90 Stat. 2245, authorized the Secretary to make grants for training, traineeships, and fellowships for health professions teaching personnel and authorized appropriations for those grants.

Section 295e–4, act July 1, 1944, ch. 373, title VII, §769A, as added Nov. 18, 1971, Pub. L. 92–157, title I, §107(b), 85 Stat. 459; amended Oct. 12, 1976, Pub. L. 94–484, title I, §101(j), 90 Stat. 2245, authorized appropriations for grants for computer technology health care demonstration programs.

Section 295e–5, act July 1, 1944, ch. 373, title VII, §769B, as added Nov. 18, 1971, Pub. L. 92–157, title I, §107(b), 85 Stat. 460, required applications for grants and approval of grants by Secretary and set forth payment limitations.

AMENDMENTS

2020—Subsec. (a). Pub. L. 116–136 substituted "$17,000,000 for each of fiscal years 2021 through 2025" for "$43,000,000 for fiscal year 2011, and such sums as may be necessary for each of the fiscal years 2012 through 2015".

2010—Subsec. (a). Pub. L. 111–148 amended subsec. (a) generally. Prior to amendment, text read as follows: "For the purpose of carrying out this subpart, there is authorized to be appropriated $9,100,000 for fiscal year 1998, and such sums as may be necessary for each of the fiscal years 1999 through 2002."

SUBPART 3—RECRUITMENT AND RETENTION PROGRAMS

§295f. Investment in tomorrow's pediatric health care workforce

(a) Establishment

The Secretary shall establish and carry out a pediatric specialty loan repayment program under which the eligible individual agrees to be employed full-time for a specified period (which shall not be less than 2 years) in providing pediatric medical subspecialty, pediatric surgical specialty, or child and adolescent mental and behavioral health care, including substance abuse prevention and treatment services.

(b) Program administration

Through the program established under this section, the Secretary shall enter into contracts with qualified health professionals under which—

(1) such qualified health professionals will agree to provide pediatric medical subspecialty, pediatric surgical specialty, or child and adolescent mental and behavioral health care in an area with a shortage of the specified pediatric subspecialty that has a sufficient pediatric population to support such pediatric subspecialty, as determined by the Secretary; and

(2) the Secretary agrees to make payments on the principal and interest of undergraduate, graduate, or graduate medical education loans of professionals described in paragraph (1) of not more than $35,000 a year for each year of agreed upon service under such paragraph for a period of not more than 3 years during the qualified health professional's—

(A) participation in an accredited pediatric medical subspecialty, pediatric surgical specialty, or child and adolescent mental health subspecialty residency or fellowship; or

(B) employment as a pediatric medical subspecialist, pediatric surgical specialist, or child and adolescent mental health professional serving an area or population described in such paragraph.

(c) In general

(1) Eligible individuals

(A) Pediatric medical specialists and pediatric surgical specialists

For purposes of contracts with respect to pediatric medical specialists and pediatric surgical specialists, the term "qualified health professional" means a licensed physician who—

(i) is entering or receiving training in an accredited pediatric medical subspecialty or pediatric surgical specialty residency or fellowship; or

(ii) has completed (but not prior to the end of the calendar year in which this section is enacted) the training described in subparagraph (B).

(B) Child and adolescent mental and behavioral health

For purposes of contracts with respect to child and adolescent mental and behavioral health care, the term "qualified health professional" means a health care professional who—

(i) has received specialized training or clinical experience in child and adolescent mental health in psychiatry, psychology, school psychology, behavioral pediatrics, psychiatric nursing, social work, school social work, substance abuse disorder prevention and treatment, marriage and family therapy, school counseling, or professional counseling;

(ii) has a license or certification in a State to practice allopathic medicine, osteopathic medicine, psychology, school psychology, psychiatric nursing, social work, school social work, marriage and family therapy, school counseling, or professional counseling; or

(iii) is a mental health service professional who completed (but not before the end of the calendar year in which this section is enacted) specialized training or clinical experience in child and adolescent mental health described in clause (i).

(2) Additional eligibility requirements

The Secretary may not enter into a contract under this subsection with an eligible individual unless—

(A) the individual agrees to work in, or for a provider serving, a health professional shortage

area or medically underserved area, or to serve a medically underserved population;

(B) the individual is a United States citizen or a permanent legal United States resident; and

(C) if the individual is enrolled in a graduate program, the program is accredited, and the individual has an acceptable level of academic standing (as determined by the Secretary).

(d) Priority

In entering into contracts under this subsection, the Secretary shall give priority to applicants who—

(1) are or will be working in a school or other pre-kindergarten, elementary, or secondary education setting;

(2) have familiarity with evidence-based methods and cultural and linguistic competence health care services; and

(3) demonstrate financial need.

(e) Authorization of appropriations

There is authorized to be appropriated such sums as may be necessary for each of fiscal years 2021 through 2025.

(July 1, 1944, ch. 373, title VII, §775, as added Pub. L. 111–148, title V, §5203, Mar. 23, 2010, 124 Stat. 607; amended Pub. L. 116–136, div. A, title III, §3401(13), Mar. 27, 2020, 134 Stat. 387.)

EDITORIAL NOTES

REFERENCES IN TEXT

The calendar year in which this section is enacted, referred to in subsec. (c)(1)(A)(ii), (B)(iii), probably means the calendar year in which Pub. L. 111–148 was enacted. Such Act was approved Mar. 23, 2010.

PRIOR PROVISIONS

A prior section 295f, act July 1, 1944, ch. 373, title VII, §770, as added Oct. 22, 1965, Pub. L. 89–290, §2(a), 79 Stat. 1052; amended Aug. 16, 1968, Pub. L. 90–490, title I, §111(a), 82 Stat. 774; Nov. 18, 1971, Pub. L. 92–157, title I, §104(a), 85 Stat. 437; Oct. 12, 1976, Pub. L. 94–484, title I, §101(k), title V, §501(a)–(c), 90 Stat. 2245, 2290, 2291; Aug. 13, 1981, Pub. L. 97–35, title XXVII, §2746(a)(1), 95 Stat. 927; Oct. 22, 1985, Pub. L. 99–129, title II, §211(a)(1), 99 Stat. 537; Nov. 4, 1988, Pub. L. 100–607, title VI, §606(a), 102 Stat. 3127, related to capitation grants for schools of public health, prior to repeal by act July 1, 1944, ch. 373, title VII, §773, as added Nov. 4, 1988, Pub. L. 100–607, title VI, §606(b), 102 Stat. 3127, effective Oct. 1, 1990.

A prior section 775 of act July 1, 1944, was renumbered section 772 by Pub. L. 94–484, and was classified to section 295f–2 of this title prior to repeal by act July 1, 1944, ch. 373, title VII, §773, as added Nov. 4, 1988, Pub. L. 100–607, title VI, §606(b), 102 Stat. 3127.

AMENDMENTS

2020—Subsec. (e). Pub. L. 116–136 substituted "such sums as may be necessary for each of fiscal years 2021 through 2025." for "$30,000,000 for each of fiscal years 2010 through 2014 to carry out subsection (c)(1)(A) and $20,000,000 for each of fiscal years 2010 through 2013 to carry out subsection (c)(1)(B)."

§295f–1. Public Health Workforce Loan Repayment Program

(a) Establishment

The Secretary shall establish the Public Health Workforce Loan Repayment Program (referred to in this section as the "Program") to assure an adequate supply of, and encourage recruitment and retention of, public health professionals to eliminate critical public health workforce shortages in State, local, and Tribal public health agencies.

(b) Eligibility

To be eligible to participate in the Program, an individual shall—

(1)(A)(i) be accepted for enrollment, or be enrolled, as a student in an accredited institution of

higher education or school of public health in the final semester (or equivalent) of a program leading to a certificate or degree, including a master's or doctoral degree, in public health, epidemiology, laboratory sciences, data systems, data science, data analytics, informatics, statistics, or another subject matter related to public health; and

(ii) be employed by, or have accepted employment with, a State, local, or Tribal public health agency, or a related training fellowship at such State, local, or Tribal public health agency, as recognized by the Secretary, to commence upon graduation; or

(B)(i) have graduated, during the preceding 10-year period, from an accredited institution of higher education or school of public health and received a certificate or degree, including a master's or doctoral degree, in public health, epidemiology, laboratory sciences, data systems, data science, data analytics, informatics, statistics, or another subject matter related to public health; and

(ii) be employed by, or have accepted employment with, a State, local, or Tribal public health agency or a related training fellowship at such State, local, or Tribal public health agency, as recognized by the Secretary;

(2) be a United States citizen; and

(3)(A) submit an application to the Secretary to participate in the Program;

(B) execute a written contract as required in subsection (c); and

(4) not have received, for the same service, a reduction of loan obligations under section 1087e(m), 1078–10, 1078–11, 1078–12, or 1087j of title 20.

(c) Contract

The written contract (referred to in this section as the "written contract") between the Secretary and an individual shall contain—

(1) an agreement on the part of the Secretary that the Secretary will repay on behalf of the individual loans incurred by the individual in the pursuit of the relevant degree or certificate in accordance with the terms of the contract;

(2) an agreement on the part of the individual that the individual will serve in the full-time employment of a State, local, or Tribal public health agency or a related fellowship program in a position related to the course of study or program for which the contract was awarded for a period of time (referred to in this section as the "period of obligated service") of at least 3 consecutive years;

(3) an agreement, as appropriate, on the part of the individual to relocate to a priority service area (as determined by the Secretary) in exchange for an additional loan repayment incentive amount to be determined by the Secretary;

(4) a provision that any financial obligation of the United States arising out of a contract entered into under this section and any obligation of the individual that is conditioned thereon, is contingent on funds being appropriated for loan repayments under this section;

(5) a statement of the damages to which the United States is entitled,[1] under this section for the individual's breach of the contract; and

(6) such other statements of the rights and liabilities of the Secretary and of the individual, not inconsistent with this section.

(d) Payments

(1) In general

A loan repayment provided for an individual under a written contract under the Program shall consist of payment, in accordance with paragraph (2), for the individual toward the outstanding principal and interest on education loans incurred by the individual in the pursuit of the relevant degree or certificate described in subsection (b)(1) in accordance with the terms of the contract.

(2) Payments for years served

(A) In general

For each year of obligated service that an individual contracts to serve under subsection (c) the Secretary may pay up to $50,000 on behalf of the individual for loans described in paragraph (1). With respect to participants under the Program whose total eligible loans are less than $150,000, the Secretary shall pay an amount that does not exceed 1/3 of the eligible loan balance for each year of obligated service of the individual.

(B) Considerations

The Secretary may take action in making awards under this section to ensure that—

(i) an appropriate proportion of contracts are awarded to individuals who are eligible to participate in the program pursuant to subsection (b)(1)(A); and

(ii) contracts awarded under this section are equitably distributed among—

(I) the geographical regions of the United States;

(II) local, State, and Tribal public health departments; and

(III) such public health departments under subclause (II) serving rural and urban areas.

(3) Tax liability

For the purpose of providing reimbursements for tax liability resulting from payments under paragraph (2) on behalf of an individual, the Secretary shall, in addition to such payments, make payments to the individual in an amount not to exceed 39 percent of the total amount of loan repayments made for the taxable year involved.

(e) Postponing obligated service

With respect to an individual with a contract to serve under subsection (c), the date of the initiation of the period of obligated service may be postponed as approved by the Secretary.

(f) Breach of contract

An individual who fails to comply with the contract entered into under subsection (c) shall be subject to the same financial penalties as provided for under section 254o of this title for breaches of loan repayment contracts under section 254l–1 of this title. In the event that a participant fails to either begin or complete the obligated service requirement of the loan repayment contract under this section, the Secretary may waive or suspend either the unfulfilled service or the assessed damages as provided for under section 254o(d) of this title, as appropriate.

(g) Eligible loans

The loans eligible for repayment under this section are each of the following:

(1) Any loan for education or training for employment by a health department.

(2) Any loan under part E of subchapter VI (relating to nursing student loans).

(3) Any Federal Direct Stafford Loan, Federal Direct PLUS Loan, Federal Direct Unsubsidized Stafford Loan, or Federal Direct Consolidation Loan (as such terms are used in section 455 of the Higher Education Act of 1965 [20 U.S.C. 1087e]).

(4) Any Federal Perkins Loan under part E of title I [2] of the Higher Education Act of 1965.

(5) Any other Federal loan, as the Secretary determines appropriate.

(h) Pilot program

(1) In general

The Secretary shall, as appropriate, establish a pilot program, to be known as the Bio-Preparedness Workforce Pilot Program, to provide for loan repayment for health professionals with expertise in infectious diseases and emergency preparedness and response activities to ensure an adequate supply of such professionals. Such program shall be administered consistent with the requirements of this section, except that, to be eligible to participate in the pilot program, an individual shall—

(A)(i) be accepted for enrollment, or be enrolled, as a student in an accredited institution of higher education in the final semester (or equivalent) of a program leading to a health professions degree or certificate program relevant to such program; or

(ii) have graduated, during the preceding 10-year period, from an accredited institution of

higher education with a health professions degree or certificate program relevant to such program; and

(B) be employed by, or have accepted employment with—

(i) a Federal health care facility;

(ii) a nonprofit health care facility that is located in a health professional shortage area (as defined in section 254e of this title), a frontier health professional shortage area (as defined in section 295p of this title), or a medically underserved community (as defined in section 295p of this title);

(iii) an entity receiving assistance under subchapter XXIV for the provision of clinical services;

(iv) a health program, or a facility, operated by an Indian Tribe or Tribal organization (as those terms are defined in section 5304 of title 25) or by an urban Indian organization (as defined in section 1603 of title 25); or

(v) another relevant entity determined appropriate by the Secretary, as a health professional with expertise in infectious diseases or emergency preparedness and response.

(2) Non-duplication of effort

The Secretary shall ensure that the pilot program established under paragraph (1) does not unnecessarily duplicate the National Health Service Corps Loan Repayment Program, or any other loan repayment program operated by the Department of Health and Human Services.

(3) Evaluation and report to Congress

(A) In general

The Secretary shall evaluate the pilot program at the conclusion of the first cycle of recipients funded by the pilot program.

(B) Report

(i) In general

The Secretary shall submit to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives a report on the evaluation under subparagraph (A). The report shall include, at a minimum, outcomes information from the pilot program, including any impact on recruitment and retention of health professionals with expertise in infectious diseases and emergency preparedness and response activities.

(ii) Recommendation

The report under this subparagraph shall include a recommendation by the Secretary as to whether the pilot program under this subsection should be extended.

(i) Authorization of appropriations

There is authorized to be appropriated to carry out this section $100,000,000 for each of fiscal years 2023 through 2025.

(July 1, 1944, ch. 373, title VII, §776, as added Pub. L. 111–148, title V, §5204, Mar. 23, 2010, 124 Stat. 609; amended Pub. L. 117–328, div. FF, title II, §2221(a), Dec. 29, 2022, 136 Stat. 5741.)

EDITORIAL NOTES

REFERENCES IN TEXT

The Higher Education Act of 1965, referred to in subsec. (g)(4), is Pub. L. 89–329, Nov. 8, 1965, 79 Stat. 1219. Part E of title IV of the Act, which relates to Federal Perkins Loans, is classified to part E (§1087aa et seq.) of subchapter IV of chapter 28 of Title 20, Education. For complete classification of this Act to the Code, see section 1 of Pub. L. 89–329, set out as a Short Title note under section 1001 of Title 20 and Tables.

PRIOR PROVISIONS

A prior section 295f–1, act July 1, 1944, ch. 373, title VII, §771, as added Oct. 12, 1976, Pub. L. 94–484,

title V, §502, 90 Stat. 2293; amended Aug. 1, 1977, Pub. L. 95–83, title III, §307(i), 91 Stat. 391; Dec. 19, 1977, Pub. L. 95–215, §§1(a), 2, 91 Stat. 1503, 1504; Nov. 9, 1978, Pub. L. 95–623, §§11(g), 12(d), 92 Stat. 3456, 3457; Sept. 29, 1979, Pub. L. 96–76, title II, §207, 93 Stat. 583; Aug. 13, 1981, Pub. L. 97–35, title XXVII, §2746(a)(2), 95 Stat. 927; Oct. 22, 1985, Pub. L. 99–129, title II, §211(b), 99 Stat. 539, related to eligibility for capitation grants, prior to repeal by act July 1, 1944, ch. 373, title VII, §773, as added Nov. 4, 1988, Pub. L. 100–607, title VI, §606(b), 102 Stat. 3127, effective Oct. 1, 1990.

Another prior section 295f–1, act July 1, 1944, ch. 373, title VII, §771, as added Oct. 22, 1965, Pub. L. 89–290, §2(a), 79 Stat. 1052; amended Aug. 16, 1968, Pub. L. 90–490, title I, §111(a), 82 Stat. 775; Nov. 2, 1970, Pub. L. 91–519, title I, §101(a), 84 Stat. 1343; Nov. 18, 1971, Pub. L. 92–157, title I, §104(a), 85 Stat. 443; Oct. 12, 1976, Pub. L. 94–484, title I, §101(l), 90 Stat. 2245, authorized start-up assistance, prior to repeal by Pub. L. 94–484, title V, §502, Oct. 12, 1976, 90 Stat. 2293, effective with respect to fiscal years beginning after Sept. 30, 1977.

A prior section 776 of act July 1, 1944, was renumbered section 2692 and is classified to section 300ff–111 of this title.

Another prior section 776 of act July 1, 1944, was renumbered section 789, and was classified to section 295g–9 of this title prior to repeal by Pub. L. 99–129, title II, §220(g), Oct. 22, 1985, 99 Stat. 544.

AMENDMENTS

2022—Subsec. (a). Pub. L. 117–328, §2221(a)(10), substituted "Tribal" for "tribal".

Pub. L. 117–328, §2221(a)(1), substituted "supply of, and encourage recruitment and retention of," for "supply of" and struck out "Federal," before "State,".

Subsec. (b)(1)(A). Pub. L. 117–328, §2221(a)(2)(A), amended subpar. (A) generally. Prior to amendment, subpar. (A) read as follows: "be accepted for enrollment, or be enrolled, as a student in an accredited academic educational institution in a State or territory in the final year of a course of study or program leading to a public health or health professions degree or certificate; and have accepted employment with a Federal, State, local, or tribal public health agency, or a related training fellowship, as recognized by the Secretary, to commence upon graduation;".

Subsec. (b)(1)(B)(i). Pub. L. 117–328, §2221(a)(2)(B)(i), substituted "accredited institution of higher education or school of public health" for "accredited educational institution in a State or territory" and "a certificate or degree, including a master's or doctoral degree, in public health, epidemiology, laboratory sciences, data systems, data science, data analytics, informatics, statistics, or another subject matter related to public health" for "a public health or health professions degree or certificate".

Subsec. (b)(1)(B)(ii). Pub. L. 117–328, §2221(a)(10), substituted "Tribal public health agency or" for "tribal public health agency or".

Pub. L. 117–328, §2221(a)(2)(B)(ii), struck out "Federal," before "State," and substituted "fellowship at such State, local, or Tribal public health agency," for "fellowship,".

Subsec. (c)(2). Pub. L. 117–328, §2221(a)(10), substituted "Tribal" for "tribal".

Pub. L. 117–328, §2221(a)(3), struck out "Federal," before "State," and substituted "of at least 3 consecutive years;" for "equal to the greater of—

"(A) 3 years; or

"(B) such longer period of time as determined appropriate by the Secretary and the individual;".

Subsec. (d)(1). Pub. L. 117–328, §2221(a)(4)(A), amended par. (1) generally. Prior to amendment, text read as follows: "A loan repayment provided for an individual under a written contract under the Program shall consist of payment, in accordance with paragraph (2), on behalf of the individual of the principal, interest, and related expenses on government and commercial loans received by the individual regarding the undergraduate or graduate education of the individual (or both), which loans were made for tuition expenses incurred by the individual."

Subsec. (d)(2). Pub. L. 117–328, §2221(a)(4)(B), designated existing provisions as subpar. (A) and inserted heading, substituted "$50,000" for "$35,000" and "$150,000" for "$105,000", and added subpar. (B).

Subsec. (e). Pub. L. 117–328, §2221(a)(5), substituted "with a contract to serve under subsection (c)" for "receiving a degree or certificate from a health professions or other related school".

Subsec. (f). Pub. L. 117–328, §2221(a)(6), inserted at end "In the event that a participant fails to either begin or complete the obligated service requirement of the loan repayment contract under this section, the Secretary may waive or suspend either the unfulfilled service or the assessed damages as provided for under section 254o(d) of this title, as appropriate."

Subsecs. (g), (h). Pub. L. 117–328, §2221(a)(8), added subsecs. (g) and (h). Former subsec. (g) redesignated (i).

Subsec. (i). Pub. L. 117–328, §2221(a)(7), (9), redesignated subsec. (g) as (i) and substituted "$100,000,000

for each of fiscal years 2023 through 2025" for "$195,000,000 for fiscal year 2010, and such sums as may be necessary for each of fiscal years 2011 through 2015".

[1] So in original. The comma probably should not appear.

[2] So in original. Probably should be "part E of title IV".

§295f–2. Training for mid-career public and allied health professionals

(a) In general

The Secretary may make grants to, or enter into contracts with, any eligible entity to award scholarships to eligible individuals to enroll in degree or professional training programs for the purpose of enabling mid-career professionals in the public health and allied health workforce to receive additional training in the field of public health and allied health.

(b) Eligibility

(1) Eligible entity

The term "eligible entity" indicates an accredited educational institution that offers a course of study, certificate program, or professional training program in public or allied health or a related discipline, as determined by the Secretary [1]

(2) Eligible individuals

The term "eligible individuals" includes those individuals employed in public and allied health positions at the Federal, State, tribal, or local level who are interested in retaining or upgrading their education.

(c) Authorization of appropriations

There is authorized to be appropriated to carry out this section, $60,000,000 for fiscal year 2010 and such sums as may be necessary for each of fiscal years 2011 through 2015. Fifty percent of appropriated funds shall be allotted to public health mid-career professionals and 50 percent shall be allotted to allied health mid-career professionals.

(July 1, 1944, ch. 373, title VII, §777, as added Pub. L. 111–148, title V, §5206(b), Mar. 23, 2010, 124 Stat. 612.)

EDITORIAL NOTES

PRIOR PROVISIONS

A prior section 295f–2, act July 1, 1944, ch. 373, title VII, §772, formerly §775, as added Nov. 18, 1971, Pub. L. 92–157, title I, §104(a), 85 Stat. 448; renumbered §772 and amended Oct. 12, 1976, Pub. L. 94–484, title V, §503(a), 90 Stat. 2300; Dec. 19, 1977, Pub. L. 95–215, §§1(b), 8(c), 91 Stat. 1504, 1507; Nov. 9, 1978, Pub. L. 95–623, §12(j), 92 Stat. 3457; Oct. 22, 1985, Pub. L. 99–129, title II, §211(c), 99 Stat. 539, related to applications for capitation grants, prior to repeal by act July 1, 1944, ch. 373, title VII, §773, as added Nov. 4, 1988, Pub. L. 100–607, title VI, §606(b), 102 Stat. 3127, effective Oct. 1, 1990.

Another prior section 295f–2, act July 1, 1944, ch. 373, title VII, §772, as added Oct. 22, 1965, Pub. L. 89–290, §2(a), 79 Stat. 1053; amended Aug. 16, 1968, Pub. L. 90–490, title I, §111(a), (e), 82 Stat. 776, 777; Nov. 2, 1970, Pub. L. 91–519, title I, §102(a), 84 Stat. 1343; Nov. 18, 1971, Pub. L. 92–157, title I, §104(a), 85 Stat. 444; Nov. 16, 1973, Pub. L. 93–154, §3(b), 87 Stat. 604; July 12, 1974, Pub. L. 93–348, title II, §215, 88 Stat. 354; Oct. 12, 1976, Pub. L. 94–484, title I, §101(m), 90 Stat. 2245, provided special project grants and contracts, prior to repeal by Pub. L. 94–484, title V, §502, Oct. 12, 1976, 90 Stat. 2293, effective with respect to fiscal years beginning after Sept. 30, 1977.

A prior section 777 of act July 1, 1944, was classified to section 294o of this title prior to the general amendment of this part by Pub. L. 105–392.

[1] *So in original. Probably should be followed by a period.*

§295f–3. Fellowship training in applied public health epidemiology, public health laboratory science, public health informatics, and expansion of the Epidemic Intelligence Service

(a) In general

The Secretary may carry out activities to address documented workforce shortages in State and local health departments in the critical areas of applied public health epidemiology and public health laboratory science and informatics and may expand the Epidemic Intelligence Service.

(b) Specific uses

In carrying out subsection (a), the Secretary shall provide for the expansion of existing fellowship programs operated through the Centers for Disease Control and Prevention in a manner that is designed to alleviate shortages of the type described in subsection (a).

(c) Other programs

The Secretary may provide for the expansion of other applied epidemiology training programs that meet objectives similar to the objectives of the programs described in subsection (b).

(d) Work obligation

Participation in fellowship training programs under this section shall be deemed to be service for purposes of satisfying work obligations stipulated in contracts under section 254q–1(j) of this title.

(e) General support

Amounts may be used from grants awarded under this section to expand the Public Health Informatics Fellowship Program at the Centers for Disease Control and Prevention to better support all public health systems at all levels of government.

(f) Authorization of appropriations

There are authorized to be appropriated to carry out this section $39,500,000 for each of fiscal years 2010 through 2013, of which—

(1) $5,000,000 shall be made available in each such fiscal year for epidemiology fellowship training program activities under subsections (b) and (c);

(2) $5,000,000 shall be made available in each such fiscal year for laboratory fellowship training programs under subsection (b);

(3) $5,000,000 shall be made available in each such fiscal year for the Public Health Informatics Fellowship Program under subsection (e); and

(4) $24,500,000 shall be made available for expanding the Epidemic Intelligence Service under subsection (a).

(July 1, 1944, ch. 373, title VII, §778, as added Pub. L. 111–148, title V, §5314, Mar. 23, 2010, 124 Stat. 636.)

EDITORIAL NOTES

PRIOR PROVISIONS

A prior section 295f–3, act July 1, 1944, ch. 373, title VII, §773, as added Nov. 4, 1988, Pub. L. 100–607, title VI, §606(b), 102 Stat. 3127, provided for repeal of former part D of this subchapter, effective Oct. 1, 1990, prior to repeal by act July 1, 1944, ch. 373, title VII, §773, as added Nov. 4, 1988, Pub. L. 100–607, title VI, §606(b), 102 Stat. 3127, effective Oct. 1, 1990.

Another prior section 295f–3, act July 1, 1944, ch. 373, title VII, §773, as added Oct. 22, 1965, Pub. L. 89–290, §2(a), 79 Stat. 1053; amended Aug. 16, 1968, Pub. L. 90–490, title I, §111(b), 82 Stat. 776; Nov. 18, 1971, Pub. L. 92–157, title I, §104(a), 85 Stat. 446; July 12, 1974, Pub. L. 93–348, title I, §106, 88 Stat. 347; Oct. 12, 1976, Pub. L. 94–484, title I, §101(n), 90 Stat. 2245, authorized grants to assist health professions

schools which were in financial distress, prior to repeal by Pub. L. 94–484, title V, §502, Oct. 12, 1976, 90 Stat. 2293, effective with respect to fiscal years beginning after Sept. 30, 1977.

A prior section 778 of act July 1, 1944, was classified to section 294p of this title prior to the general amendment of this part by Pub. L. 105–392.

A prior section 295f–4, act July 1, 1944, ch. 373, title VII, §774, as added Oct. 22, 1965, Pub. L. 89–290, §2(a), 79 Stat. 1054; amended Aug. 16, 1968, Pub. L. 90–490, title I, §111(c)(1), (2), 82 Stat. 777; Oct. 30, 1970, Pub. L. 91–515, title VI, §601(b)(2), 84 Stat. 1311; Nov. 18, 1971, Pub. L. 92–157, title I, §104(a), 85 Stat. 446; Nov. 16, 1973, Pub. L. 93–154, §3(c), 87 Stat. 605; Oct. 12, 1976, Pub. L. 94–484, title I, §101(o), 90 Stat. 2245, authorized health manpower education initiative awards prior to repeal by Pub. L. 94–484, title V, §502, Oct. 12, 1976, 90 Stat. 2293, effective with respect to fiscal years beginning after Sept. 30, 1977.

A prior section 295f–5, act July 1, 1944, ch. 373, title VII, §775, as added Nov. 18, 1971, Pub. L. 92–157, title I, §104(a), 85 Stat. 448, which related to applications for capitation, start-up, special project, and financial distress grants, was renumbered section 772 of act July 1, 1944, by Pub. L. 94–484 and transferred to section 295f–2 of this title.

A prior section 295f–6, act July 1, 1944, ch. 373, title VII, §776, as added Nov. 16, 1973, Pub. L. 93–154, §3(a), 87 Stat. 604, which related to training in emergency medical services, was renumbered section 789 of act July 1, 1944, by Pub. L. 94–484 and transferred to section 295g–9 of this title.

Prior sections 295g to 295g–2 were omitted in the general amendment of this subchapter by Pub. L. 102–408.

Section 295g, act July 1, 1944, ch. 373, title VII, §780, as added Oct. 12, 1976, Pub. L. 94–484, title VIII, §801(a), 90 Stat. 2311; amended Aug. 13, 1981, Pub. L. 97–35, title XXVII, §2738, 95 Stat. 921; Oct. 22, 1985, Pub. L. 99–129, title I, §103, title II, §212, 99 Stat. 523, 540; Nov. 4, 1988, Pub. L. 100–607, title VI, §§607, 629(b)(1), 102 Stat. 3127, 3146; Aug. 16, 1989, Pub. L. 101–93, §5(o)(3), 103 Stat. 614, related to project grants for establishment of departments of family medicine.

Another prior section 295g, act July 1, 1944, ch. 373, title VII, §780, as added Oct. 22, 1965, Pub. L. 89–290, §2(a), 79 Stat. 1055; amended Aug. 16, 1968, Pub. L. 90–490, title I, §§111(c)(4), 122(a) to (c), 82 Stat. 777, 779; July 9, 1971, Pub. L. 92–52, §2, 85 Stat. 144; Nov. 18, 1971, Pub. L. 92–157, title I, §§106(a), (b)(3), (4), 108(b)(2), title III, §301(g), 85 Stat. 452, 453, 461, 464; Oct. 12, 1976, Pub. L. 94–484, title I, §101(p), 90 Stat. 2245, related to scholarship grants for study in United States, prior to repeal by Pub. L. 94–484, title IV, §409(a), Oct. 12, 1976, 90 Stat. 2290, effective Oct. 1, 1976.

Section 295g–1, act July 1, 1944, ch. 373, title VII, §781, as added Oct. 12, 1976, Pub. L. 94–484, title VIII, §801(a), 90 Stat. 2312; amended Aug. 1, 1977, Pub. L. 95–83, title III, §307(j), 91 Stat. 392; Sept. 29, 1979, Pub. L. 96–76, title II, §203, 93 Stat. 582; Aug. 13, 1981, Pub. L. 97–35, title XXVII, §2739, 95 Stat. 921; Jan. 4, 1983, Pub. L. 97–414, §8(j), 96 Stat. 2061; Aug. 15, 1985, Pub. L. 99–91, §7, 99 Stat. 392; Oct. 22, 1985, Pub. L. 99–129, title I, §104, title II, §213, 99 Stat. 523, 540; Nov. 4, 1988, Pub. L. 100–607, title VI, §§608, 629(b)(3), 102 Stat. 3127, 3146; Aug. 16, 1989, Pub. L. 101–93, §5(o)(3), (5), (6), 103 Stat. 614; Nov. 16, 1990, Pub. L. 101–597, title IV, §401(b)[(a)], 104 Stat. 3035, related to area health education centers.

Another prior section 295g–1, act July 1, 1944, ch. 373, title VII, §781, as added Aug. 16, 1968, Pub. L. 90–490, title I, §122(d), 82 Stat. 779; amended Nov. 18, 1971, Pub. L. 92–157, title I, §§105(f)(3), 106(b)(4), 85 Stat. 451, 453, provided for transfer of monies to student loan fund, prior to repeal by Pub. L. 94–484, title IV, §409(a), Oct. 12, 1976, 90 Stat. 2290, effective Oct. 1, 1976.

Section 295g–2, act July 1, 1944, ch. 373, title VII, §782, formerly §788A, as added Aug. 18, 1987, Pub. L. 100–97, §3, 101 Stat. 713; renumbered §782 and amended Nov. 4, 1988, Pub. L. 100–607, title VI, §614, 102 Stat. 3136; amended Aug. 16, 1989, Pub. L. 101–93, §5(i), 103 Stat. 613; Nov. 6, 1990, Pub. L. 101–527, §4(a), 104 Stat. 2318, provided for programs of excellence in health professions education for minorities. See section 293 of this title.

Another prior section 295g–2, act July 1, 1944, ch. 373, title VII, §782, as added Oct. 12, 1976, Pub. L. 94–484, title VIII, §801(a), 90 Stat. 2314; amended Nov. 9, 1978, Pub. L. 95–623, §12(e), 92 Stat. 3457, authorized Secretary to make grants to schools of medicine and osteopathy for programs to train United States citizens formerly enrolled in medical schools in foreign countries, authorized appropriations for those grants, and set forth reporting requirements, prior to repeal by Pub. L. 99–129, title II, §220(d), Oct. 22, 1985, 99 Stat. 544.

A prior section 295g–3, act July 1, 1944, ch. 373, title VII, §783, as added Oct. 12, 1976, Pub. L. 94–484, title VIII, §801(a), 90 Stat. 2314; amended Aug. 13, 1981, Pub. L. 97–35, title XXVII, §2740, 95 Stat. 922; Oct. 22, 1985, Pub. L. 99–129, title I, §105, 99 Stat. 524, related to programs for physician assistants, prior to repeal by Pub. L. 100–607, title VI, §615(b), Nov. 4, 1988, 102 Stat. 3138.

Prior sections 295g–4 to 295g–8 were omitted in the general amendment of this subchapter by Pub. L. 102–408.

Section 295g–4, act July 1, 1944, ch. 373, title VII, §784, as added Oct. 12, 1976, Pub. L. 94–484, title VIII, §801(a), 90 Stat. 2315; amended Aug. 13, 1981, Pub. L. 97–35, title XXVII, §2741, 95 Stat. 922; Jan. 4, 1983, Pub. L. 97–414, §9(f), 96 Stat. 2064; Oct. 22, 1985, Pub. L. 99–129, title I, §106, title II, §214, 99 Stat. 524, 540; Nov. 4, 1988, Pub. L. 100–607, title VI, §609, 102 Stat. 3130; Nov. 18, 1988, Pub. L. 100–690, title II, §2615(c), 102 Stat. 4239; Aug. 16, 1989, Pub. L. 101–93, §5(o)(3), 103 Stat. 614, related to grants and contracts for training, traineeships, and fellowships in general internal medicine and general pediatrics.

Section 295g–5, act July 1, 1944, ch. 373, title VII, §785, as added Nov. 4, 1988, Pub. L. 100–607, title VI, §610(a)(2), 102 Stat. 3130, related to residency programs in the general practice of dentistry.

Another prior section 295g–5, act July 1, 1944, ch. 373, title VII, §785, as added Oct. 12, 1976, Pub. L. 94–484, title VIII, §801(a), 90 Stat. 2315, established grants to public or private nonprofit colleges or universities for occupational health training and education centers and authorized appropriations for those grants, prior to repeal by Pub. L. 99–129, title II, §220(e), Oct. 22, 1985, 99 Stat. 544.

Section 295g–6, act July 1, 1944, ch. 373, title VII, §786, as added Oct. 12, 1976, Pub. L. 94–484, title VIII, §801(a), 90 Stat. 2316; amended Aug. 13, 1981, Pub. L. 97–35, title XXVII, §2742, 95 Stat. 923; Oct. 22, 1985, Pub. L. 99–129, title I, §107, title II, §215, 99 Stat. 524, 540; Nov. 4, 1988, Pub. L. 100–607, title VI, §610(a)(1), (b), 102 Stat. 3130, 3131; Aug. 16, 1989, Pub. L. 101–93, §5(o)(3), (6), 103 Stat. 614, related to grants and contracts for specified family medicine programs.

Section 295g–7, act July 1, 1944, ch. 373, title VII, §787, as added Oct. 12, 1976, Pub. L. 94–484, title VIII, §801(a), 90 Stat. 2317; amended Aug. 13, 1981, Pub. L. 97–35, title XXVII, §2743, 95 Stat. 923; Oct. 22, 1985, Pub. L. 99–129, title I, §108, title II, §216, 99 Stat. 524, 541; Nov. 4, 1988, Pub. L. 100–607, title VI, §§611(a)–(e), 628(10), 629(b)(2), 102 Stat. 3131, 3132, 3146; Nov. 18, 1988, Pub. L. 100–690, title II, §2615(d), (e), 102 Stat. 4239; Aug. 16, 1989, Pub. L. 101–93, §5(h), (o)(2), 103 Stat. 612, 614, related to educational assistance to individuals from disadvantaged backgrounds. See section 293c of this title.

Section 295g–7a, act July 1, 1944, ch. 373, title VII, §787A, as added and amended Nov. 4, 1988, Pub. L. 100–607, title VI, §§612, 629(b)(2), 102 Stat. 3132, 3146, related to a retention program for health professions schools with individuals from disadvantaged backgrounds. See section 293 et seq. of this title.

Section 295g–8, act July 1, 1944, ch. 373, title VII, §788, as added Oct. 12, 1976, Pub. L. 94–484, title VIII, §801(a), 90 Stat. 2318; amended Nov. 9, 1978, Pub. L. 95–623, §12(f), 92 Stat. 3457; Sept. 29, 1979, Pub. L. 96–76, title II, §205, 93 Stat. 583; Aug. 13, 1981, Pub. L. 97–35, title XXVII, §2744(a)(1), (b)–(f), 95 Stat. 923, 924; Oct. 22, 1985, Pub. L. 99–129, title I, §109, title II, §217, 99 Stat. 524, 541; Nov. 14, 1986, Pub. L. 99–660, title VI, §601, 100 Stat. 3797; Dec. 1, 1987, Pub. L. 100–177, title IV, §401, 101 Stat. 1007; Nov. 4, 1988, Pub. L. 100–607, title VI, §§613(a), 628(11), 629(b)(2), 102 Stat. 3133, 3146; Aug. 16, 1989, Pub. L. 101–93, §5(o)(2), (3), 103 Stat. 614; July 23, 1992, Pub. L. 102–325, title XV, §1559, 106 Stat. 841, related to grants and contracts for special projects.

Another prior section 295g–8, act July 1, 1944, ch. 373, title VII, §788A, as added Aug. 18, 1987, Pub. L. 100–97, §3, 101 Stat. 713, which related to grants for minority education, was renumbered section 782 of act July 1, 1944, by Pub. L. 100–607 and transferred to section 295g–2 of this title.

A prior section 295g–8a, act July 1, 1944, ch. 373, title VII, §788A, as added Aug. 13, 1981, Pub. L. 97–35, title XXVII, §2745, 95 Stat. 925, authorized Secretary to make grants or enter into contracts with schools in serious financial distress to assist their operations, under certain terms and conditions, prior to repeal by Pub. L. 99–129, title II, §220(f)(1), Oct. 22, 1985, 99 Stat. 544.

Prior sections 295g–8b to 295g–10 were omitted in the general amendment of this subchapter by Pub. L. 102–408.

Section 295g–8b, act July 1, 1944, ch. 373, title VII, §788A, formerly §788B, as added Aug. 13, 1981, Pub. L. 97–35, title XXVII, §2745, 95 Stat. 926; amended Oct. 22, 1985, Pub. L. 99–129, title I, §110, title II, §§218, 220(f)(2)–(4), 99 Stat. 524, 543, 544; Nov. 4, 1988, Pub. L. 100–607, title VI, §§622, 629(b)(2), 102 Stat. 3141, 3146; Nov. 18, 1988, Pub. L. 100–690, title II, §2615(g), 102 Stat. 4239; renumbered §788A and amended Aug. 16, 1989, Pub. L. 101–93, §5(k), (o)(4), 103 Stat. 613, 614, related to training with respect to acquired immune deficiency syndrome. See section 300ff–111 of this title.

Section 295g–9, act July 1, 1944, ch. 373, title VII, §789, as added and amended Nov. 4, 1988, Pub. L. 100–607, title VI, §§615(a), 629(b)(1), 102 Stat. 3136, 3146; Aug. 16, 1989, Pub. L. 101–93, §5(o)(3), 103 Stat. 614, related to geriatric education centers and geriatric training.

Another prior section 295g–9, act July 1, 1944, ch. 373, title VII, §789, formerly §776, as added Nov. 16, 1973, Pub. L. 93–154, §3(a), 87 Stat. 604; renumbered §789, Oct. 12, 1976, Pub. L. 94–484, title VIII, §801(b), 90 Stat. 2322; amended Oct. 21, 1976, Pub. L. 94–573, §12, 90 Stat. 2717; July 10, 1979, Pub. L. 96–32, §7(h), 93 Stat. 84; Aug. 1, 1977, Pub. L. 95–83, title III, §307(k), 91 Stat. 392; Dec. 12, 1979, Pub. L. 96–142, title I, §102, 93 Stat. 1067, authorized Secretary to make grants and enter into contracts for training in emergency medical services, set forth eligibility requirements and amounts, directed Secretary to use a

uniform funding cycle, and authorized appropriations for those grants and contracts, prior to repeal by Pub. L. 99–129, title II, §220(g), Oct. 22, 1985, 99 Stat. 544.

Section 295g–10, act July 1, 1944, ch. 373, title VII, §790, as added Oct. 12, 1976, Pub. L. 94–484, title VIII, §801(c), 90 Stat. 2322; amended Nov. 4, 1988, Pub. L. 100–607, title VI, §616(a), (b), 102 Stat. 3138, provided general provisions.

A prior section 295g–10a, Pub. L. 100–607, title VI, §633, Nov. 4, 1988, 102 Stat. 3147, required with respect to the application and award process for certain health personnel training programs the semiannual issuance of solicitations for grant applications and the preliminary review of applications for technical sufficiency, prior to repeal by Pub. L. 102–408, title III, §311, Oct. 13, 1992, 106 Stat. 2091.

A prior section 295g–11, act July 1, 1944, ch. 373, title VII, §790A, as added Nov. 4, 1988, Pub. L. 100–607, title VI, §617, 102 Stat. 3140, related to public health special projects, prior to the general amendment of this subchapter by Pub. L. 102–408.

Another prior section 295g–11, act July 1, 1944, ch. 373, title VII, §785, as added Nov. 18, 1971, Pub. L. 92–157, title I, §106(b)(6), 85 Stat. 453; amended Oct. 12, 1976, Pub. L. 94–484, title I, §101(q), 90 Stat. 2245, provided scholarship grants for study abroad, prior to repeal by Pub. L. 94–484, title IV, §409(a), Oct. 12, 1976, 90 Stat. 2290, effective Oct. 1, 1976.

Prior sections 295g–21 to 295g–23 were repealed by Pub. L. 94–484, title IV, §409(a), Oct. 12, 1976, 90 Stat. 2290, effective Oct. 1, 1976.

Section 295g–21, act July 1, 1944, ch. 373, title VII, §784, as added Nov. 18, 1971, Pub. L. 92–157, title I, §106(c), 85 Stat. 455, provided scholarship grants in relation to physician shortage area scholarship program.

Section 295g–22, act July 1, 1944, ch. 373, title VII, §785, as added Nov. 18, 1971, Pub. L. 92–157, title I, §106(c), 85 Stat. 457, related to administration of and contractual arrangements for implementation of the physician shortage area scholarship program.

Section 295g–23, act July 1, 1944, ch. 373, title VII, §786, as added Nov. 18, 1971 Pub. L. 92–157, title I, §106(c), 85 Stat. 457; amended Apr. 22, 1976, Pub. L. 94–278, title XI, §1104, 90 Stat. 416; Oct. 12, 1976, Pub. L. 94–484, title I, §101(r), 90 Stat. 2246, authorized appropriations for physician shortage area scholarships in amount of $2,500,000; $3,000,000; $3,500,000; $3,500,000; and $2,000,000 for fiscal years ending June 30, 1972, through 1976, and for fiscal years ending Sept. 30, 1977, and thereafter such sums necessary to continue making grants to students who prior to July 1, 1976, received grants and were eligible for grants during the succeeding fiscal year.

PART F—SUBSTANCE USE DISORDER TREATMENT WORKFORCE

EDITORIAL NOTES

CODIFICATION

A prior part F, consisting of sections 295j to 295p, was redesignated part G of this subchapter.

§295h. Loan repayment program for substance use disorder treatment workforce

(a) In general

The Secretary, acting through the Administrator of the Health Resources and Services Administration, shall carry out a program under which—

(1) the Secretary enters into agreements with individuals to make payments in accordance with subsection (b) on the principal of and interest on any eligible loan; and

(2) the individuals each agree to the requirements of service in substance use disorder treatment employment, as described in subsection (d).

(b) Payments

For each year of obligated service by an individual pursuant to an agreement under subsection (a), the Secretary shall make a payment to such individual as follows:

(1) Service in a shortage area

The Secretary shall pay—

(A) for each year of obligated service by an individual pursuant to an agreement under subsection (a), 1/6 of the principal of and interest on each eligible loan of the individual which is outstanding on the date the individual began service pursuant to the agreement; and

(B) for completion of the sixth and final year of such service, the remainder of such principal and interest.

(2) Maximum amount

The total amount of payments under this section to any individual shall not exceed $250,000.

(c) Eligible loans

The loans eligible for repayment under this section are each of the following:

(1) Any loan for education or training for a substance use disorder treatment employment.

(2) Any loan under part E of subchapter VI (relating to nursing student loans).

(3) Any Federal Direct Stafford Loan, Federal Direct PLUS Loan, Federal Direct Unsubsidized Stafford Loan, or Federal Direct Consolidation Loan (as such terms are used in section 455 of the Higher Education Act of 1965 [20 U.S.C. 1087e]).

(4) Any Federal Perkins Loan under part E of title I [1] of the Higher Education Act of 1965.

(5) Any other Federal loan as determined appropriate by the Secretary.

(d) Requirements of service

Any individual receiving payments under this program as required by an agreement under subsection (a) shall agree to an annual commitment to full-time employment, with no more than 1 year passing between any 2 years of covered employment, in substance use disorder treatment employment in the United States in—

(1) a Mental Health Professional Shortage Area, as designated under section 254e of this title; or

(2) a county (or a municipality, if not contained within any county) where the mean drug overdose death rate per 100,000 people over the past 3 years for which official data is available from the State, is higher than the most recent available national average overdose death rate per 100,000 people, as reported by the Centers for Disease Control and Prevention.

(e) Ineligibility for double benefits

No borrower may, for the same service, receive a reduction of loan obligations or a loan repayment under both—

(1) this section; and

(2) any Federally supported loan forgiveness program, including under section 254l–1, 254q–1, or 297n of this title, or section 428J, 428L, 455(m), or 460 of the Higher Education Act of 1965 [20 U.S.C. 1078–10, 1078–12, 1087e(m), 1087j].

(f) Breach

(1) Liquidated damages formula

The Secretary may establish a liquidated damages formula to be used in the event of a breach of an agreement entered into under subsection (a).

(2) Limitation

The failure by an individual to complete the full period of service obligated pursuant to such an agreement, taken alone, shall not constitute a breach of the agreement, so long as the individual completed in good faith the years of service for which payments were made to the individual under this section.

(g) Additional criteria

The Secretary—

(1) may establish such criteria and rules to carry out this section as the Secretary determines are needed and in addition to the criteria and rules specified in this section; and

(2) shall give notice to the committees specified in subsection (h) of any criteria and rules so established.

(h) Report to Congress

Not later than 5 years after October 24, 2018, and every other year thereafter, the Secretary shall prepare and submit to the Committee on Energy and Commerce of the House of Representatives and the Committee on Health, Education, Labor, and Pensions of the Senate a report on—

(1) the number and location of borrowers who have qualified for loan repayments under this section; and

(2) the impact of this section on the availability of substance use disorder treatment employees nationally and in shortage areas and counties described in subsection (d).

(i) Definition

In this section:

(1) The terms "Indian tribe" and "tribal organization" have the meanings given those terms in section 5304 of title 25.

(2) The term "municipality" means a city, town, or other public body created by or pursuant to State law, or an Indian tribe.

(3) The term "substance use disorder treatment employment" means full-time employment (including a fellowship)—

(A) where the primary intent and function of the position is the direct treatment or recovery support of patients with or in recovery from a substance use disorder, including master's level social workers, psychologists, counselors, marriage and family therapists, psychiatric mental health practitioners, occupational therapists, psychology doctoral interns, and behavioral health paraprofessionals and physicians, physician assistants, and nurses, who are licensed or certified in accordance with applicable State and Federal laws; and

(B) which is located at a substance use disorder treatment program, private physician practice, hospital or health system-affiliated inpatient treatment center or outpatient clinic (including an academic medical center-affiliated treatment program), correctional facility or program, youth detention center or program, inpatient psychiatric facility, crisis stabilization unit, community health center, community mental health or other specialty community behavioral health center, recovery center, school, community-based organization, telehealth platform, migrant health center, health program or facility operated by an Indian tribe or tribal organization, Federal medical facility, or any other facility as determined appropriate for purposes of this section by the Secretary.

(j) Authorization of appropriations

There are authorized to be appropriated to carry out this section $40,000,000 for each of fiscal years 2026 through 2030.

(July 1, 1944, ch. 373, title VII, §781, as added Pub. L. 115–271, title VII, §7071(2), Oct. 24, 2018, 132 Stat. 4028; amended Pub. L. 119–44, title II, §204, Dec. 1, 2025, 139 Stat. 680.)

EDITORIAL NOTES

REFERENCES IN TEXT

The Higher Education Act of 1965, referred to in subsec. (c)(4), is Pub. L. 89–329, Nov. 8, 1965, 79 Stat. 1219. Part E of title IV of the Act, which relates to Federal Perkins Loans, is classified to part E (§1087aa et seq.) of subchapter IV of chapter 28 of Title 20, Education. For complete classification of this Act to the Code, see section 1 of Pub. L. 89–329, set out as a Short Title note under section 1001 of Title 20 and Tables.

PRIOR PROVISIONS

A prior section 295h, act July 1, 1944, ch. 373, title VII, §791, as added Oct. 12, 1976, Pub. L. 94–484, title VII, §701(a), 90 Stat. 2303; amended Oct. 17, 1979, Pub. L. 96–88, title III, §301(a)(1), title V, §507, 93 Stat. 677, 692; Aug. 13, 1981, Pub. L. 97–35, title XXVII, §2746(b)(1), 95 Stat. 927; Jan. 4, 1983, Pub. L. 97–414, §8(k)(2), 96 Stat. 2061; Oct. 22, 1985, Pub. L. 99–129, title I, §111, title II, §219, 99 Stat. 524, 543; Nov. 4,

1988, Pub. L. 100–607, title VI, §618, 102 Stat. 3140; Nov. 18, 1988, Pub. L. 100–690, title II, §2615(f), 102 Stat. 4239; Aug. 16, 1989, Pub. L. 101–93, §5(j), 103 Stat. 613, related to grants for graduate programs in health administration, prior to the general amendment of this subchapter by Pub. L. 102–408.

Another prior section 295h, act July 1, 1944, ch. 373, title VII, §791, as added Nov. 3, 1966, Pub. L. 89–751, §2, 80 Stat. 1222; amended Aug. 16, 1968, Pub. L. 90–490, title III, §301(a)(1), 82 Stat. 788; Nov. 2, 1970, Pub. L. 91–519, title II, §201, 84 Stat. 1344, provided for grants for construction of teaching facilities of allied health professions personnel, prior to the general amendment of this part by Pub. L. 94–484.

A prior section 295h–1, act July 1, 1944, ch. 373, title VII, §792, as added Oct. 12, 1976, Pub. L. 94–484, title VII, §701(a), 90 Stat. 2304; amended Nov. 10, 1978, Pub. L. 95–626, title I, §121, 92 Stat. 3570; Sept. 29, 1979, Pub. L. 96–76, title II, §206(b), 93 Stat. 583, related to special projects for accredited schools of public health and graduate programs in health administration, prior to repeal by Pub. L. 97–35, title XXVII, §2746(c), Aug. 13, 1981, 95 Stat. 927.

Another prior section 295h–1, act July 1, 1944, ch. 373, title VII, §792, as added Nov. 3, 1966, Pub. L. 89–751, §2, 80 Stat. 1226; amended Aug. 16, 1968, Pub. L. 90–490, title III, §301(a)(2), 82 Stat. 788; Nov. 2, 1970, Pub. L. 91–519, title II, §202(a), (b), 84 Stat. 1344, 1345; June 18, 1973, Pub. L. 93–45, title I, §109(a), (b), 87 Stat. 93; Oct. 12, 1976, Pub. L. 94–484, title I, §101(s)(1), (2), 90 Stat. 2246, provided for grants to improve quality of training centers for allied health professions, prior to the general amendment of this part by Pub. L. 94–484.

Prior sections 295h–1a to 295h–2 were omitted in the general amendment of this subchapter by Pub. L. 102–408.

Section 295h–1a, act July 1, 1944, ch. 373, title VII, §791A, formerly §749, as added Oct. 12, 1976, Pub. L. 94–484, title IV, §408(a), 90 Stat. 2280; amended Aug. 1, 1977, Pub. L. 95–83, title III, §307(f), 91 Stat. 391; Oct. 17, 1979, Pub. L. 96–88, title III, §301(a)(1), title V, §507, 93 Stat. 677, 692; renumbered §791A and amended Aug. 13, 1981, Pub. L. 97–35, title XXVII, §2746(b)(2), 95 Stat. 927; Jan. 4, 1983, Pub. L. 97–414, §8(k)(1), 96 Stat. 2061; Oct. 22, 1985, Pub. L. 99–129, title I, §112, 99 Stat. 525; Nov. 4, 1988, Pub. L. 100–607, title VI, §619, 102 Stat. 3140, related to traineeships for students in other graduate programs.

Section 295h–1b, act July 1, 1944, ch. 373, title VII, §792; formerly §748, as added Oct. 12, 1976, Pub. L. 94–484, title IV, §408(a), 90 Stat. 2279; amended Aug. 1, 1977, Pub. L. 95–83, title III, §307(f), 91 Stat. 391; Dec. 19, 1977, Pub. L. 95–215, §3, 91 Stat. 1504; Sept. 29, 1979, Pub. L. 96–76, title II, §206(a), 93 Stat. 583; renumbered §792 and amended Aug. 13, 1981, Pub. L. 97–35, title XXVII, §2746(d), 95 Stat. 927; Oct. 22, 1985, Pub. L. 99–129, title I, §113, 99 Stat. 525; Nov. 4, 1988, Pub. L. 100–607, title VI, §621, 102 Stat. 3141, related to traineeships for students in schools of public health.

Section 295h–1c, act July 1, 1944, ch. 373, title VII, §793, as added Aug. 13, 1981, Pub. L. 97–35, title XXVII, §2746(f), 95 Stat. 928; amended Oct. 22, 1985, Pub. L. 99–129, title I, §114, 99 Stat. 525; Nov. 4, 1988, Pub. L. 100–607, title VI, §629(b)(2), 102 Stat. 3146, related to training in preventive medicine.

Section 295h–2, act July 1, 1944, ch. 373, title VII, §794, formerly §793, as added Oct. 12, 1976, Pub. L. 94–484, title VII, §701(a), 90 Stat. 2305; amended S. Res. No. 4, Feb. 4, 1977; Nov. 9, 1978, Pub. L. 95–623, §12(g), 92 Stat. 3457; S. Res. No. 30, Mar. 7, 1979; H. Res. No. 549, Mar. 25, 1980; renumbered §794, Aug. 13, 1981, Pub. L. 97–35, title XXVII, §2746(f), 95 Stat. 928, related to statistics and annual report to Congress.

Another prior section 295h–2, act July 1, 1944, ch. 373, title VII, §793, as added Nov. 3, 1966, Pub. L. 89–751, §2, 80 Stat. 1228; amended Aug. 16, 1968, Pub. L. 90–490, title III, §301(a)(3), 82 Stat. 788; Nov. 2, 1970, Pub. L. 91–519, title II, §203, 84 Stat. 1436; June 18, 1973, Pub. L. 93–45, title I, §109(c), 87 Stat. 93; Oct. 12, 1976, Pub. L. 94–484, title I, §101(s)(3), 90 Stat. 2246, provided traineeships for advanced training of allied health professions personnel, including authorization of appropriations, prior to the general amendment of this part by Pub. L. 94–484.

A prior section 295h–3, act July 1, 1944, ch. 373, title VII, §794, as added Nov. 3, 1966, Pub. L. 89–751, §2, 80 Stat. 1228; amended Aug. 16, 1968, Pub. L. 90–490, title III, §301(a)(4), (b), 82 Stat. 788, authorized appropriations for grants to public or nonprofit private agencies, institutions, and organizations for projects to develop, demonstrate, or evaluate curriculums and methods for the training of health technologists, prior to repeal by Pub. L. 91–519, title II, §202(d), Nov. 2, 1970, 84 Stat. 1345, effective with respect to the fiscal year beginning July 1, 1970.

Prior sections 295h–3a to 295h–3d were omitted in the general amendment of this part by Pub. L. 94–484.

Section 295h–3a, act July 1, 1944, ch. 373, title VII, §794A, as added Nov. 2, 1970, Pub. L. 91–519, title II, §204, 84 Stat. 1346; amended June 18, 1973, Pub. L. 93–45, title I, §109(d), 87 Stat. 93; Oct. 12, 1976, Pub. L. 94–484, title I, §101(s)(4), 90 Stat. 2246, provided for grants and contracts to encourage full utilization of educational talent for allied health professions and authorizing appropriations.

Section 295h–3b, act July 1, 1944, ch. 373, title VII, §794B, as added Nov. 2, 1970, Pub. L. 91–519, title II,

§204, 84 Stat. 1346, provided for scholarship grants for training in allied health professions.

Section 295h–3c, act July 1, 1944, ch. 373, title VII, §794C, as added Nov. 2, 1970, Pub. L. 91–519, title II, §204, 84 Stat. 1347, provided for work-study programs in training in allied health professions.

Section 295h–3d, act July 1, 1944, ch. 373, title VII, §794D, as added Nov. 2, 1970, Pub. L. 91–519, title II, §204, 84 Stat. 1349; amended Nov. 18, 1971, Pub. L. 92–157, title III, §301(e), 85 Stat. 464, provided for loans for students of allied health professions.

Prior sections 295h–4 to 295h–7 were omitted in the general amendment of this subchapter by Pub. L. 102–408.

Section 295h–4, act July 1, 1944, ch. 373, title VII, §795, as added Oct. 12, 1976, Pub. L. 94–484, title VII, §701(a), 90 Stat. 2306; amended Oct. 17, 1979, Pub. L. 96–88, title III, §301(a)(1), title V, §507, 93 Stat. 677, 692, defined "allied health personnel", "training center for allied health professions", and "nonprofit". See section 295p of this title.

Another prior section 295h–4, act July 1, 1944, ch. 373, title VII, §795, as added Nov. 3, 1966, Pub. L. 89–751, §2, 80 Stat. 1228; amended Dec. 5, 1967, Pub. L. 90–174, §12(e), 81 Stat. 542; Nov. 2, 1970, Pub. L. 91–519, title II, §202(c), 84 Stat. 1344; Nov. 18, 1971, Pub. L. 92–157, title III, §301(f), 85 Stat. 464, defined "training center for allied health professions"; "full-time student"; "nonprofit"; "construction" and "cost of construction"; and "affiliated hospital", prior to the general amendment of this part by Pub. L. 94–484.

Section 295h–5, act July 1, 1944, ch. 373, title VII, §796, as added Oct. 12, 1976, Pub. L. 94–484, title VII, §701(a), 90 Stat. 2307; amended Aug. 1, 1977, Pub. L. 95–83, title III, §307(l), (m), 91 Stat. 392; Nov. 4, 1988, Pub. L. 100–607, title VI, §624, 102 Stat. 3143; Nov. 18, 1988, Pub. L. 100–690, title II, §2615(f) [(h)], 102 Stat. 4240, related to project grants and contracts with eligible entities to improve the effectiveness of allied health administration and practitioners. See section 294e of this title.

Another prior section 295h–5, act July 1, 1944, ch. 373, title VII, §796, as added Nov. 3, 1966, Pub. L. 89–751, §2, 80 Stat. 1230, provided for keeping of records and audits in relation to training in allied health professions, prior to the general amendment of this part by Pub. L. 94–484.

Section 295h–6, act July 1, 1944, ch. 373, title VII, §797, as added Oct. 12, 1976, Pub. L. 94–484, title VII, §701(a), 90 Stat. 2308; amended Nov. 4, 1988, Pub. L. 100–607, title VI, §625, 102 Stat. 3144, related to traineeships for advanced training of allied health personnel.

Another prior section 295h–6, act July 1, 1944, ch. 373, title VII, §797, as added Aug. 16, 1968, Pub. L. 90–490, title III, §301(c), 82 Stat. 788, authorized the use of up to one-half of one per centum of appropriated funds for evaluation of programs covered thereby, prior to repeal by Pub. L. 91–296, title IV, §401(b)(1)(E), June 30, 1970, 84 Stat. 352, effective with respect to appropriations for fiscal years beginning after June 30, 1970.

Section 295h–7, act July 1, 1944, ch. 373, title VII, §798, as added Oct. 12, 1976, Pub. L. 94–484, title VII, §701(a), 90 Stat. 2309, related to educational assistance to disadvantaged individuals in allied health training.

Another prior section 295h–7, act July 1, 1944, ch. 373, title VII, §798, as added Aug. 16, 1968, Pub. L. 90–490, title III, §301(d), 82 Stat. 788; amended Nov. 2, 1970, Pub. L. 91–519, title II, §205, 84 Stat. 1354, directed Secretary to conduct a study of the allied health programs, prior to the general amendment of this part by Pub. L. 94–484.

A prior section 295h–8, act July 1, 1944, ch. 373, title VII, §799, as added Nov. 2, 1970, Pub. L. 91–519, title II, §206, 84 Stat. 1354; amended Nov. 18, 1971, Pub. L. 92–157, title I, §109, 85 Stat. 461, which related to advance funding, was renumbered section 703 of act July 1, 1944, by Pub. L. 94–484 and transferred to section 292c of this title.

A prior section 295h–9, act July 1, 1944, ch. 373, title VII, §799A, as added Nov. 2, 1970, Pub. L. 91–519, title II, §207, 84 Stat. 1355, §704; amended Nov. 18, 1971, Pub. L. 92–157, title I, §110(2), 85 Stat. 461; July 12, 1974, Pub. L. 93–348, title I, §105, 88 Stat. 347, which related to sexual discrimination, was renumbered section 704 of act July 1, 1944, by Pub. L. 94–484 and transferred to section 292d of this title.

A prior section 295i, act July 1, 1944, ch. 373, title VII, §799, as added Apr. 7, 1986, Pub. L. 99–272, title XVII, §17001, 100 Stat. 357; amended Oct. 25, 1988, Pub. L. 100–527, §10(4), 102 Stat. 2641; Nov. 4, 1988, Pub. L. 100–607, title VI, §§627, 629(b)(1), 102 Stat. 3145, 3146; Aug. 16, 1989, Pub. L. 101–93, §5(o)(3), 103 Stat. 614; Oct. 9, 1992, Pub. L. 102–405, title III, §302(e)(1), 106 Stat. 1985, established a Council on Graduate Medical Education, prior to the general amendment of this subchapter by Pub. L. 102–408. See section 294o of this title.

AMENDMENTS

2025—Subsec. (j). Pub. L. 119–44 substituted "$40,000,000 for each of fiscal years 2026 through 2030" for "$25,000,000 for each of fiscal years 2019 through 2023".

[1] *So in original. Probably should be "part E of title IV of the Higher Education Act of 1965".*

PART G—GENERAL PROVISIONS

EDITORIAL NOTES

CODIFICATION

Pub. L. 115–271, title VII, §7071(1), Oct. 24, 2018, 132 Stat. 4028, redesignated part F as G.
Pub. L. 105–392, title I, §106(a)(2)(A), Nov. 13, 1998, 112 Stat. 3557, redesignated part G as F.

§295j. Preferences and required information in certain programs

(a) Preferences in making awards

(1) In general

Subject to paragraph (2), in making awards of grants or contracts under any of sections 293k and 294 of this title, the Secretary shall give preference to any qualified applicant that—

(A) has a high rate for placing graduates in practice settings having the principal focus of serving residents of medically underserved communities;

(B) during the 2-year period preceding the fiscal year for which such an award is sought, has achieved a significant increase in the rate of placing graduates in such settings; or

(C) utilizes a longitudinal evaluation (as described in section 294n(d)(2) of this title) and reports data from such system to the national workforce database (as established under section 294n(b)(2)(E) of this title).

(2) Limitation regarding peer review

For purposes of paragraph (1), the Secretary may not give an applicant preference if the proposal of the applicant is ranked at or below the 20th percentile of proposals that have been recommended for approval by peer review groups.

(b) "Graduate" defined

For purposes of this section, the term "graduate" means, unless otherwise specified, an individual who has successfully completed all training and residency requirements necessary for full certification in the health profession selected by the individual.

(c) Exceptions for new programs

(1) In general

To permit new programs to compete equitably for funding under this section, those new programs that meet at least 4 of the criteria described in paragraph (3) shall qualify for a funding preference under this section.

(2) Definition

As used in this subsection, the term "new program" means any program that has graduated less than three classes. Upon graduating at least three classes, a program shall have the capability to provide the information necessary to qualify the program for the general funding preferences described in subsection (a).

(3) Criteria

The criteria referred to in paragraph (1) are the following:

(A) The mission statement of the program identifies a specific purpose of the program as being the preparation of health professionals to serve underserved populations.

(B) The curriculum of the program includes content which will help to prepare practitioners

to serve underserved populations.

(C) Substantial clinical training experience is required under the program in medically underserved communities.

(D) A minimum of 20 percent of the clinical faculty of the program spend at least 50 percent of their time providing or supervising care in medically underserved communities.

(E) The entire program or a substantial portion of the program is physically located in a medically underserved community.

(F) Student assistance, which is linked to service in medically underserved communities following graduation, is available to the students in the program.

(G) The program provides a placement mechanism for deploying graduates to medically underserved communities.

(July 1, 1944, ch. 373, title VII, §791, as added Pub. L. 102–408, title I, §102, Oct. 13, 1992, 106 Stat. 2058; amended Pub. L. 102–531, title III, §313(a)(5), Oct. 27, 1992, 106 Stat. 3507; Pub. L. 105–392, title I, §§106(a)(2)(B), 107, Nov. 13, 1998, 112 Stat. 3557, 3560; Pub. L. 111–148, title V, §5103(c), Mar. 23, 2010, 124 Stat. 605.)

EDITORIAL NOTES

PRIOR PROVISIONS

A prior section 295j, act July 1, 1944, ch. 373, title VII, §799A, as added Nov. 4, 1988, Pub. L. 100–607, title VI, §637(a), 102 Stat. 3149; amended Nov. 18, 1988, Pub. L. 100–690, title II, §2615(g)[(i)], 102 Stat. 4240; Aug. 16, 1989, Pub. L. 101–93, §5(n), 103 Stat. 613, related to grants and contracts to provide health care in rural areas, prior to the general amendment of this subchapter by Pub. L. 102–408.

Another prior section 295j, act July 1, 1944, ch. 373, title VII, §799A, as added Nov. 23, 1988, Pub. L. 100–713, title VII, §714, 102 Stat. 4834, relating to grants and contracts to provide health care in rural areas, prior to repeal by Pub. L. 100–607, title VI, §637(b), Nov. 4, 1988, 102 Stat. 3151. Subsequently, section 637(b) of Pub. L. 100–607 was repealed by Pub. L. 101–93, §5(n)(1), Aug. 16, 1989, 103 Stat. 613, and section 5(n)(2) of Pub. L. 101–93 amended this subchapter to read as if the amendment made by section 714 of Pub. L. 100–713 had not been enacted.

A prior section 791 of act July 1, 1944, was classified to section 295h of this title prior to the general amendment of this subchapter by Pub. L. 102–408.

AMENDMENTS

2010—Subsec. (a)(1)(C). Pub. L. 111–148 added subpar. (C).

1998—Subsec. (a)(1). Pub. L. 105–392, §107(b)(1), substituted "sections 293k and 294 of this title" for "sections 293k through 293o of this title, under section 294b of this title, or under section 294d or 294e of this title" in introductory provisions.

Subsec. (a)(2). Pub. L. 105–392, §107(b)(2), struck out "under section 295o(a) of this title" before period at end.

Subsec. (b). Pub. L. 105–392, §106(a)(2)(B), redesignated subsec. (c) as (b) and struck out former subsec. (b) which required submission of certain information by applicant.

Subsec. (c). Pub. L. 105–392, §§106(a)(2)(B)(ii), 107(a), added subsec. (c) and redesignated former subsec. (c) as (b).

1992—Subsec. (b). Pub. L. 102–531, in introductory provisions, inserted references to sections 294d and 294e of this title and substituted reference to section 295o(f)(2) of this title for reference to section 293p(a) of this title.

STATUTORY NOTES AND RELATED SUBSIDIARIES

EFFECTIVE DATE OF 1992 AMENDMENT

Amendment by Pub. L. 102–531 effective immediately after enactment of Pub. L. 102–408, see section 313(c) of Pub. L. 102–531, set out as a note under section 292y of this title.

REQUIRED ASSURANCES REGARDING BLOODBORNE DISEASES

Pub. L. 102–408, title III, §308, Oct. 13, 1992, 106 Stat. 2089, provided that: "With respect to awards of grants or contracts under title VII or VIII of the Public Health Service Act [42 U.S.C. 292 et seq., 296 et seq.],

the Secretary of Health and Human Services may make such an award for the provision of traineeships only if the applicant for the award provides assurances satisfactory to the Secretary that all trainees will, as appropriate, receive instruction in the utilization of universal precautions and infection control procedures for the prevention of the transmission of bloodborne diseases."

§295k. Health professions data

(a) In general

The Secretary shall establish a program, including a uniform health professions data reporting system, to collect, compile, and analyze data on health professions personnel which program shall initially include data respecting all physicians and dentists in the States. The Secretary is authorized to expand the program to include, whenever he determines it necessary, the collection, compilation, and analysis of data respecting pharmacists, optometrists, podiatrists, veterinarians, public health personnel, audiologists, speech pathologists, health care administration personnel, nurses, allied health personnel, medical technologists, chiropractors, clinical psychologists, professional counselors, and any other health personnel in States designated by the Secretary to be included in the program. Such data shall include data respecting the training, licensure status (including permanent, temporary, partial, limited, or institutional), place or places of practice, professional specialty, practice characteristics, place and date of birth, sex, and socioeconomic background of health professions personnel and such other demographic information regarding health professions personnel as the Secretary may require.

(b) Certain authorities and requirements

(1) Sources of information

In carrying out subsection (a), the Secretary shall collect available information from appropriate local, State, and Federal agencies and other appropriate sources.

(2) Contracts for studies of health professions

The Secretary shall conduct or enter into contracts for the conduct of analytic and descriptive studies of the health professions, including evaluations and projections of the supply of, and requirements for, the health professions by specialty and geographic location. Such studies shall include studies determining by specialty and geographic location the number of health professionals (including allied health professionals and health care administration personnel) who are members of minority groups, including Hispanics, and studies providing by specialty and geographic location evaluations and projections of the supply of, and requirements for, health professionals (including allied health professionals and health care administration personnel) to serve minority groups, including Hispanics.

(3) Grants and contracts regarding States

The Secretary is authorized to make grants and to enter into contracts with States (or an appropriate nonprofit private entity in any State) for the purpose of participating in the program established under subsection (a). The Secretary shall determine the amount and scope of any such grant or contract. To be eligible for a grant or contract under this paragraph a State or entity shall submit an application in such form and manner and containing such information as the Secretary shall require. Such application shall include reasonable assurance, satisfactory to the Secretary, that—

(A) such State (or nonprofit entity within a State) will establish a program of mandatory annual registration of the health professions personnel described in subsection (a) who reside or practice in such State and of health institutions licensed by such State, which registration shall include such information as the Secretary shall determine to be appropriate;

(B) such State or entity shall collect such information and report it to the Secretary in such form and manner as the Secretary shall prescribe; and

(C) such State or entity shall comply with the requirements of subsection (e).

(d) [1] Reports to Congress

The Secretary shall submit to the Congress on October 1, 1993, and biennially thereafter, the following reports:

(1) A comprehensive report regarding the status of health personnel according to profession, including a report regarding the analytic and descriptive studies conducted under this section.

(2) A comprehensive report regarding applicants to, and students enrolled in, programs and institutions for the training of health personnel, including descriptions and analyses of student indebtedness, student need for financial assistance, financial resources to meet the needs of students, student career choices such as practice specialty and geographic location and the relationship, if any, between student indebtedness and career choices.

(e) Requirements regarding personal data

(1) In general

The Secretary and each program entity shall in securing and maintaining any record of individually identifiable personal data (hereinafter in this subsection referred to as "personal data") for purposes of this section—

(A) inform any individual who is asked to supply personal data whether he is legally required, or may refuse, to supply such data and inform him of any specific consequences, known to the Secretary or program entity, as the case may be, of providing or not providing such data;

(B) upon request, inform any individual if he is the subject of personal data secured or maintained by the Secretary or program entity, as the case may be, and make the data available to him in a form comprehensible to him;

(C) assure that no use is made of personal data which use is not within the purposes of this section unless an informed consent has been obtained from the individual who is the subject of such data; and

(D) upon request, inform any individual of the use being made of personal data respecting such individual and of the identity of the individuals and entities which will use the data and their relationship to the programs under this section.

(2) Consent as precondition to disclosure

Any entity which maintains a record of personal data and which receives a request from the Secretary or a program entity for such data for purposes of this section shall not transfer any such data to the Secretary or to a program entity unless the individual whose personal data is to be so transferred gives an informed consent for such transfer.

(3) Disclosure by Secretary

(A) Notwithstanding any other provision of law, personal data collected by the Secretary or any program entity under this section may not be made available or disclosed by the Secretary or any program entity to any person other than the individual who is the subject of such data unless (i) such person requires such data for purposes of this section, or (ii) in response to a demand for such data made by means of compulsory legal process. Any individual who is the subject of personal data made available or disclosed under clause (ii) shall be notified of the demand for such data.

(B) Subject to all applicable laws regarding confidentiality, only the data collected by the Secretary under this section which is not personal data shall be made available to bona fide researchers and policy analysts (including the Congress) for the purposes of assisting in the conduct of studies respecting health professions personnel.

(4) "Program entity" defined

For purposes of this subsection, the term "program entity" means any public or private entity which collects, compiles, or analyzes health professions data under a grant, contract, or other arrangement with the Secretary under this section.

(g) [2] Technical assistance

The Secretary shall provide technical assistance to the States and political subdivisions thereof in the development of systems (including model laws) concerning confidentiality and comparability of data collected pursuant to this section.

(h) Grants and contracts regarding nonprofit entities

(1) In general

In carrying out subsection (a), the Secretary may make grants, or enter into contracts and cooperative agreements with, and provide technical assistance to, any nonprofit entity in order to establish a uniform allied health professions data reporting system to collect, compile, and analyze data on the allied health professions personnel.

(2) Reports

With respect to reports required in subsection (d), each such report made on or after October 1, 1991, shall include a description and analysis of data collected pursuant to paragraph (1).

(July 1, 1944, ch. 373, title VII, §792, as added Pub. L. 102–408, title I, §102, Oct. 13, 1992, 106 Stat. 2058; amended Pub. L. 105–392, title I, §106(b), Nov. 13, 1998, 112 Stat. 3559.)

EDITORIAL NOTES

PRIOR PROVISIONS

A prior section 792 of act July 1, 1944, was classified to section 295h–1b of this title prior to the general amendment of this subchapter by Pub. L. 102–408.

Another prior section 792 of act July 1, 1944, was classified to section 295h–1 of this title prior to repeal by Pub. L. 97–35.

AMENDMENTS

1998—Subsec. (a). Pub. L. 105–392 inserted "professional counselors," after "clinical psychologists,".

STATUTORY NOTES AND RELATED SUBSIDIARIES

STUDY REGARDING SHORTAGES OF LICENSED PHARMACISTS

Pub. L. 106–129, §5, Dec. 6, 1999, 113 Stat. 1675, provided that:

"(a) IN GENERAL.—The Secretary of Health and Human Services (in this section referred to as the 'Secretary'), acting through the appropriate agencies of the Public Health Service, shall conduct a study to determine whether and to what extent there is a shortage of licensed pharmacists. In carrying out the study, the Secretary shall seek the comments of appropriate public and private entities regarding any such shortage.

"(b) REPORT TO CONGRESS.—Not later than 1 year after the date of the enactment of this Act [Dec. 6, 1999], the Secretary shall complete the study under subsection (a) and submit to the Congress a report that describes the findings made through the study and that contains a summary of the comments received by the Secretary pursuant to such subsection."

ADVISORY COUNCIL ON GRADUATE MEDICAL EDUCATION

Pub. L. 102–408, title III, §301, Oct. 13, 1992, 106 Stat. 2080, as amended by Pub. L. 102–531, title III, §313(b), Oct. 27, 1992, 106 Stat. 3507; Pub. L. 105–392, title I, §104(b)(1)–(3), Nov. 13, 1998, 112 Stat. 3552, which was formerly set out as a note under this section, was renumbered section 762 of the Public Health Service Act by Pub. L. 105–392, title I, §104(b)(4)–(6), Nov. 13, 1998, 112 Stat. 3553, and is classified to section 294o of this title.

COMMISSION ON ALLIED HEALTH

Pub. L. 102–408, title III, §302, Oct. 13, 1992, 106 Stat. 2082, provided for establishment of a National Commission on Allied Health, charged with (1) making recommendations to the Secretary of Health and Human Services and Congress with respect to nationwide supply and distribution of allied health personnel, current and future shortages of personnel, priority research needs within allied health professions, Federal policies relating to personnel and research as well as undergraduate and graduate financing, concerted efforts on part of allied health facilities and educational institutions to address such matters, and needs with respect to nationwide data bases concerning supply and distribution of allied health personnel, and (2) encouraging

entities providing allied health education to voluntarily achieve recommendations of Commission, and further provided for composition of Commission, date certain for appointments to Commission, resources for Commission activities, an interim progress report due not later than Oct. 1, 1993, a final report due not later than Apr. 1, 1994, and termination of Commission 60 days after submission of final report.

STUDY REGARDING SHORTAGE OF CLINICAL LABORATORY TECHNOLOGISTS FOR MEDICALLY UNDERSERVED AND RURAL COMMUNITIES

Pub. L. 102–408, title III, §303, Oct. 13, 1992, 106 Stat. 2083, directed Secretary of Health and Human Services, with respect to the shortage of clinical laboratory technologists, to conduct a study for the purpose of determining whether there are special or unique factors affecting the supply of clinical laboratory technologists in medically underserved and rural communities, and assessing alternative routes for certification of the competence of individuals to serve as such technologists, with consideration of the role of entities providing such certifications, and, not later than Oct. 1, 1993, complete the study and submit to Committee on Energy and Commerce of House of Representatives, and to Committee on Labor and Human Resources of Senate, a report describing the findings made as result of the study.

NATIONAL ADVISORY COUNCIL ON MEDICAL LICENSURE

Pub. L. 102–408, title III, §307, Oct. 13, 1992, 106 Stat. 2086, directed Secretary of Health and Human Services to establish National Advisory Council on Medical Licensure to advise Secretary on American Medical Association's system of verifying and maintaining information regarding qualifications of individuals to practice medicine, as well as advice regarding establishment and operation of any similar system, provided for activities of Council, including review of private credentials verification system and recommendations on how it could be improved, as well as review of State procedures for licensing individuals licensed in other States and procedures for licensing international medical graduates, provided for composition of Council and appointment of members, required submission of an interim report to Congress not later than Sept. 30, 1993, and a final report with recommendations not later than Sept. 30, 1995, provided for termination of Council not later than Sept. 30, 1995, or upon submission of final report, whichever is earlier, and further directed Secretary, in cooperation with Council to submit to Congress, not later than Sept. 30, 1994, study of not less than 10 States for purposes of determining average time required for States to process licensure applications of domestic and international medical graduates as well as percentages of domestic and international licensure applications approved.

[1] So in original. No subsec. (c) has been enacted.

[2] So in original. No subsec. (f) has been enacted.

§295*l*. Repealed. Pub. L. 105–392, title I, §106(a)(2)(C), Nov. 13, 1998, 112 Stat. 3557

Section, act July 1, 1944, ch. 373, title VII, §793, as added Pub. L. 102–408, title I, §102, Oct. 13, 1992, 106 Stat. 2061; amended Pub. L. 102–531, title III, §313(a)(6), Oct. 27, 1992, 106 Stat. 3507, required development, publication, dissemination, and biennial report to Congress on statistics respecting public and community health personnel.

A prior section 793 of act July 1, 1944, was classified to section 295h–1c of this title prior to the general amendment of this subchapter by Pub. L. 102–408.

Another prior section 793 of act July 1, 1944, was renumbered section 794 by Pub. L. 97–35 and classified to section 295h–2 of this title.

§295m. Prohibition against discrimination on basis of sex

The Secretary may not make a grant, loan guarantee, or interest subsidy payment under this subchapter to, or for the benefit of, any school of medicine, osteopathic medicine, dentistry, veterinary medicine, optometry, pharmacy, podiatric medicine, or public health or any training center for allied health personnel, or graduate program in clinical psychology, unless the application for the grant, loan guarantee, or interest subsidy payment contains assurances satisfactory to the Secretary

that the school or training center will not discriminate on the basis of sex in the admission of individuals to its training programs. The Secretary may not enter into a contract under this subchapter with any such school or training center unless the school, training center, or graduate program furnishes assurances satisfactory to the Secretary that it will not discriminate on the basis of sex in the admission of individuals to its training programs. In the case of a school of medicine which—

(1) on October 13, 1992, is in the process of changing its status as an institution which admits only female students to that of an institution which admits students without regard to their sex, and

(2) is carrying out such change in accordance with a plan approved by the Secretary,

the provisions of the preceding sentences of this section shall apply only with respect to a grant, contract, loan guarantee, or interest subsidy to, or for the benefit of such a school for a fiscal year beginning after June 30, 1979.

(July 1, 1944, ch. 373, title VII, §794, as added Pub. L. 102–408, title I, §102, Oct. 13, 1992, 106 Stat. 2063.)

EDITORIAL NOTES

PRIOR PROVISIONS

A prior section 794 of act July 1, 1944, was classified to section 295h–2 of this title prior to the general amendment of this subchapter by Pub. L. 102–408.

Another prior section 794 of act July 1, 1944, was classified to section 294h–3 of this title prior to repeal by Pub. L. 91–519.

§295n. Repealed. Pub. L. 105–392, title I, §101(b)(1), Nov. 13, 1998, 112 Stat. 3537

Section, act July 1, 1944, ch. 373, title VII, §795, as added Pub. L. 102–408, title I, §102, Oct. 13, 1992, 106 Stat. 2063; amended Pub. L. 102–531, title III, §313(a)(7), Oct. 27, 1992, 106 Stat. 3507, related to obligated service regarding certain programs.

A prior section 795 of act July 1, 1944, was classified to section 295h–4 of this title prior to the general amendment of this subchapter by Pub. L. 102–408.

Another prior section 795 of act July 1, 1944, was classified to section 295h–4 of this title prior to the general amendment of part G of this subchapter by Pub. L. 94–484.

STATUTORY NOTES AND RELATED SUBSIDIARIES

SAVINGS PROVISION

Pub. L. 105–392, title I, §101(b)(2), Nov. 13, 1998, 112 Stat. 3537, provided that: "The amendments made by this section [enacting sections 293 to 293d of this title, amending section 287a–2 of this title, and repealing this section and former sections 293 to 293d of this title] shall not be construed to terminate agreements that, on the day before the date of enactment of this Act [Nov. 13, 1998], are in effect pursuant to section 795 of the Public Health Service Act (42 U.S.C. 795 [295n]) as such section existed on such date. Such agreements shall continue in effect in accordance with the terms of the agreements. With respect to compliance with such agreements, any period of practice as a provider of primary health services shall be counted towards the satisfaction of the requirement of practice pursuant to such section 795."

§295n–1. Application

(a) In general

To be eligible to receive a grant or contract under this subchapter, an eligible entity shall prepare and submit to the Secretary an application that meets the requirements of this section, at such time, in such manner, and containing such information as the Secretary may require.

(b) Plan

An application submitted under this section shall contain the plan of the applicant for carrying out a project with amounts received under this subchapter. Such plan shall be consistent with relevant Federal, State, or regional health professions program plans.

(c) Performance outcome standards

An application submitted under this section shall contain a specification by the applicant entity of performance outcome standards that the project to be funded under the grant or contract will be measured against. Such standards shall address relevant health workforce needs that the project will meet. The recipient of a grant or contract under this section shall meet the standards set forth in the grant or contract application.

(d) Linkages

An application submitted under this section shall contain a description of the linkages with relevant educational and health care entities, including training programs for other health professionals as appropriate, that the project to be funded under the grant or contract will establish. To the extent practicable, grantees under this section shall establish linkages with health care providers who provide care for underserved communities and populations.

(July 1, 1944, ch. 373, title VII, §796, as added Pub. L. 105–392, title I, §106(a)(2)(F), Nov. 13, 1998, 112 Stat. 3557.)

§295n–2. Use of funds

(a) In general

Amounts provided under a grant or contract awarded under this subchapter may be used for training program development and support, faculty development, model demonstrations, trainee support including tuition, books, program fees and reasonable living expenses during the period of training, technical assistance, workforce analysis, dissemination of information, and exploring new policy directions, as appropriate to meet recognized health workforce objectives, in accordance with this subchapter.

(b) Maintenance of effort

With respect to activities for which a grant awarded under this subchapter is to be expended, the entity shall agree to maintain expenditures of non-Federal amounts for such activities at a level that is not less than the level of such expenditures maintained by the entity for the fiscal year preceding the fiscal year for which the entity receives such a grant.

(July 1, 1944, ch. 373, title VII, §797, as added Pub. L. 105–392, title I, §106(a)(2)(F), Nov. 13, 1998, 112 Stat. 3557.)

§295*o*. Matching requirement

The Secretary may require that an entity that applies for a grant or contract under this subchapter provide non-Federal matching funds, as appropriate, to ensure the institutional commitment of the entity to the projects funded under the grant. As determined by the Secretary, such non-Federal matching funds may be provided directly or through donations from public or private entities and may be in cash or in-kind, fairly evaluated, including plant, equipment, or services.

(July 1, 1944, ch. 373, title VII, §798, as added Pub. L. 105–392, title I, §106(a)(2)(F), Nov. 13, 1998, 112 Stat. 3558.)

EDITORIAL NOTES

PRIOR PROVISIONS

A prior section 295o, act July 1, 1944, ch. 373, title VII, §798, as added Pub. L. 102–408, title I, §102, Oct. 13, 1992, 106 Stat. 2064; amended Pub. L. 102–531, title III, §313(a)(8), Oct. 27, 1992, 106 Stat. 3507, set forth certain general provisions relating to this subchapter, prior to repeal by Pub. L. 105–392, title I, §106(a)(2)(D), Nov. 13, 1998, 112 Stat. 3557.

A prior section 798 of act July 1, 1944, was classified to section 295h–7 of this title prior to the general amendment of this subchapter by Pub. L. 102–408.

Another prior section 798 of act July 1, 1944, was classified to section 295h–7 of this title prior to the general amendment of part G of this subchapter by Pub. L. 94–484.

§295*o*–1. Generally applicable provisions

(a) Awarding of grants and contracts

The Secretary shall ensure that grants and contracts under this subchapter are awarded on a competitive basis, as appropriate, to carry out innovative demonstration projects or provide for strategic workforce supplementation activities as needed to meet health workforce goals and in accordance with this subchapter. Contracts may be entered into under this subchapter with public or private entities as may be necessary.

(b) Eligible entities

Unless specifically required otherwise in this subchapter, the Secretary shall accept applications for grants or contracts under this subchapter from health professions schools, academic health centers, State or local governments, or other appropriate public or private nonprofit entities for funding and participation in health professions and nursing training activities. The Secretary may accept applications from for-profit private entities if determined appropriate by the Secretary.

(c) Information requirements

(1) In general

Recipients of grants and contracts under this subchapter shall meet information requirements as specified by the Secretary.

(2) Data collection

The Secretary shall establish procedures to ensure that, with respect to any data collection required under this subchapter, such data is collected in a manner that takes into account age, sex, race, and ethnicity.

(3) Use of funds

The Secretary shall establish procedures to permit the use of amounts appropriated under this subchapter to be used for data collection purposes.

(4) Evaluations

The Secretary shall establish procedures to ensure the annual evaluation of programs and projects operated by recipients of grants or contracts under this subchapter. Such procedures shall ensure that continued funding for such programs and projects will be conditioned upon a demonstration that satisfactory progress has been made by the program or project in meeting the objectives of the program or project.

(d) Training programs

Training programs conducted with amounts received under this subchapter shall meet applicable accreditation and quality standards.

(e) Duration of assistance

(1) In general

Subject to paragraph (2), in the case of an award to an entity of a grant, cooperative agreement, or contract under this subchapter, the period during which payments are made to the entity under the award may not exceed 5 years. The provision of payments under the award shall be subject to

annual approval by the Secretary of the payments and subject to the availability of appropriations for the fiscal year involved to make the payments. This paragraph may not be construed as limiting the number of awards under the program involved that may be made to the entity.

(2) Limitation

In the case of an award to an entity of a grant, cooperative agreement, or contract under this subchapter, paragraph (1) shall apply only to the extent not inconsistent with any other provision of this subchapter that relates to the period during which payments may be made under the award.

(f) Peer review regarding certain programs

(1) In general

Each application for a grant under this subchapter, except any scholarship or loan program, including those under sections [1] 292, 292q, or 292s of this title, shall be submitted to a peer review group for an evaluation of the merits of the proposals made in the application. The Secretary may not approve such an application unless a peer review group has recommended the application for approval.

(2) Composition

Each peer review group under this subsection shall be composed principally of individuals who are not officers or employees of the Federal Government. In providing for the establishment of peer review groups and procedures, the Secretary shall ensure sex, racial, ethnic, and geographic balance among the membership of such groups.

(3) Administration

This subsection shall be carried out by the Secretary acting through the Administrator of the Health Resources and Services Administration.

(g) Preference or priority considerations

In considering a preference or priority for funding which is based on outcome measures for an eligible entity under this subchapter, the Secretary may also consider the future ability of the eligible entity to meet the outcome preference or priority through improvements in the eligible entity's program design.

(h) Analytic activities

The Secretary shall ensure that—

(1) cross-cutting workforce analytical activities are carried out as part of the workforce information and analysis activities under section 294n of this title; and

(2) discipline-specific workforce information and analytical activities are carried out as part of—

(A) the community-based linkage program under part D; and

(B) the health workforce development program under subpart 2 of part E.

(i) Osteopathic Schools

For purposes of this subchapter, any reference to—

(1) medical schools shall include osteopathic medical schools; and

(2) medical students shall include osteopathic medical students.

(July 1, 1944, ch. 373, title VII, §799, as added Pub. L. 105–392, title I, §106(a)(2)(F), Nov. 13, 1998, 112 Stat. 3558.)

EDITORIAL NOTES

PRIOR PROVISIONS

A prior section 799 of act July 1, 1944, was renumbered section 799B by Pub. L. 105–392 and classified to section 295p of this title.

Another prior section 799 of act July 1, 1944, was classified to section 295i of this title prior to the general

amendment of this subchapter by Pub. L. 102–408.

[1] *So in original. Probably should be "section".*

§295*o*–2. Technical assistance

Funds appropriated under this subchapter may be used by the Secretary to provide technical assistance in relation to any of the authorities under this subchapter.

(July 1, 1944, ch. 373, title VII, §799A, as added Pub. L. 105–392, title I, §106(a)(2)(F), Nov. 13, 1998, 112 Stat. 3559.)

§295p. Definitions

For purposes of this subchapter:

(1)(A) The terms "school of medicine", "school of dentistry", "school of osteopathic medicine", "school of pharmacy", "school of optometry", "school of podiatric medicine", "school of veterinary medicine", "school of public health", and "school of chiropractic" mean an accredited public or nonprofit private school in a State that provides training leading, respectively, to a degree of doctor of medicine, a degree of doctor of dentistry or an equivalent degree, a degree of doctor of osteopathy, a degree of bachelor of science in pharmacy or an equivalent degree or a degree of doctor of pharmacy or an equivalent degree, a degree of doctor of optometry or an equivalent degree, a degree of doctor of podiatric medicine or an equivalent degree, a degree of doctor of veterinary medicine or an equivalent degree, a graduate degree in public health or an equivalent degree, and a degree of doctor of chiropractic or an equivalent degree, and including advanced training related to such training provided by any such school.

(B) The terms "graduate program in health administration" and "graduate program in clinical psychology" mean an accredited graduate program in a public or nonprofit private institution in a State that provides training leading, respectively, to a graduate degree in health administration or an equivalent degree and a doctoral degree in clinical psychology or an equivalent degree.

(C) The terms "graduate program in clinical social work" and "graduate program in marriage and family therapy" and "graduate program in professional counseling" mean an accredited graduate program in a public or nonprofit private institution in a State that provides training, respectively, in a concentration in health or mental health care leading to a graduate degree in social work and a concentration leading to a graduate degree in marriage and family therapy and a concentration leading to a graduate degree in counseling.

(D) The term "graduate program in behavioral health and mental health practice" means a graduate program in clinical psychology, behavioral health and mental health practice, clinical social work, professional counseling, or marriage and family therapy.

(E) The term "accredited", when applied to a school of medicine, osteopathic medicine, dentistry, veterinary medicine, optometry, podiatry, pharmacy, public health, or chiropractic, or a graduate program in health administration, clinical psychology, clinical social work, professional counseling, or marriage and family therapy, means a school or program that is accredited by a recognized body or bodies approved for such purpose by the Secretary of Education, except that a new school or program that, by reason of an insufficient period of operation, is not, at the time of application for a grant or contract under this subchapter, eligible for accreditation by such a recognized body or bodies, shall be deemed accredited for purposes of this subchapter, if the Secretary of Education finds, after consultation with the appropriate accreditation body or bodies, that there is reasonable assurance that the school or program will meet the accreditation standards of such body or bodies prior to the beginning of the academic year following the normal graduation date of the first entering class in such school or program.

(2) The term "teaching facilities" means areas dedicated for use by students, faculty, or administrative or maintenance personnel for clinical purposes, research activities, libraries,

classrooms, offices, auditoriums, dining areas, student activities, or other related purposes necessary for, and appropriate to, the conduct of comprehensive programs of education. Such term includes interim facilities but does not include off-site improvements or living quarters.

(3) PHYSICIAN ASSISTANT EDUCATION PROGRAM.—The term "physician assistant education program" means an educational program in a public or private institution in a State that—

(A) has as its objective the education of individuals who, upon completion of their studies in the program, be [1] qualified to provide primary care medical services with the supervision of a physician; and

(B) is accredited by the Accreditation Review Commission on Education for the Physician Assistant.

(4) The term "school of allied health" means a public or nonprofit private college, junior college, or university or hospital-based educational entity that—

(A) provides, or can provide, programs of education to enable individuals to become allied health professionals or to provide additional training for allied health professionals;

(B) provides training for not less than a total of twenty persons in the allied health curricula (except that this subparagraph shall not apply to any hospital-based educational entity);

(C) includes or is affiliated with a teaching hospital; and

(D) is accredited by a recognized body or bodies approved for such purposes by the Secretary of Education, or which provides to the Secretary satisfactory assurance by such accrediting body or bodies that reasonable progress is being made toward accreditation.

(5) The term "allied health professionals" means a health professional (other than a registered nurse or physician assistant)—

(A) who has received a certificate, an associate's degree, a bachelor's degree, a master's degree, a doctoral degree, or postbaccalaureate training, in a science relating to health care;

(B) who shares in the responsibility for the delivery of health care services or related services, including—

(i) services relating to the identification, evaluation, and prevention of disease and disorders;

(ii) dietary and nutrition services;

(iii) health promotion services;

(iv) rehabilitation services; or

(v) health systems management services; and

(C) who has not received a degree of doctor of medicine, a degree of doctor of osteopathy, a degree of doctor of dentistry or an equivalent degree, a degree of doctor of veterinary medicine or an equivalent degree, a degree of doctor of optometry or an equivalent degree, a degree of doctor of podiatric medicine or an equivalent degree, a degree of bachelor of science in pharmacy or an equivalent degree, a degree of doctor of pharmacy or an equivalent degree, a graduate degree in public health or an equivalent degree, a degree of doctor of chiropractic or an equivalent degree, a graduate degree in health administration or an equivalent degree, a doctoral degree in clinical psychology or an equivalent degree, or a degree in social work or an equivalent degree or a degree in counseling or an equivalent degree.

(6) The term "medically underserved community" means an urban or rural area or population that—

(A) is eligible for designation under section 254e of this title as a health professional shortage area;

(B) is eligible to be served by a migrant health center under section 254b [2] of this title, a community health center under section 254c [2] of this title, a grantee under section 254b(h) of

this title (relating to homeless individuals), or a grantee under section 256a [2] of this title (relating to residents of public housing);

(C) has a shortage of personal health services, as determined under criteria issued by the Secretary under section 1395x(aa)(2) of this title (relating to rural health clinics); or

(D) is designated by a State Governor (in consultation with the medical community) as a shortage area or medically underserved community.

(7) The term "Department" means the Department of Health and Human Services.

(8) The term "nonprofit" refers to the status of an entity owned and operated by one or more corporations or associations no part of the net earnings of which inures, or may lawfully inure, to the benefit of any private shareholder or individual.

(9) The term "State" includes, in addition to the several States, only the District of Columbia, the Commonwealth of Puerto Rico, the Commonwealth of the Northern Mariana Islands, the Virgin Islands, Guam, American Samoa, and the Trust Territory of the Pacific Islands.

(10)(A) Subject to subparagraph (B), the term "underrepresented minorities" means, with respect to a health profession, racial and ethnic populations that are underrepresented in the health profession relative to the number of individuals who are members of the population involved.

(B) For purposes of subparagraph (A), Asian individuals shall be considered by the various subpopulations of such individuals.

(11) The term "psychologist" means an individual who—

(A) holds a doctoral degree in psychology; and

(B) is licensed or certified on the basis of the doctoral degree in psychology, by the State in which the individual practices, at the independent practice level of psychology to furnish diagnostic, assessment, preventive, and therapeutic services directly to individuals.

(12) AREA HEALTH EDUCATION CENTER.—The term "area health education center" means a public or nonprofit private organization that has a cooperative agreement or contract in effect with an entity that has received an award under subsection (a)(1) or (a)(2) of section 294a of this title, satisfies the requirements in section 294a(d)(1) of this title, and has as one of its principal functions the operation of an area health education center. Appropriate organizations may include hospitals, health organizations with accredited primary care training programs, accredited physician assistant educational programs associated with a college or university, and universities or colleges not operating a school of medicine or osteopathic medicine.

(13) AREA HEALTH EDUCATION CENTER PROGRAM.—The term "area health education center program" means [3] cooperative program consisting of an entity that has received an award under subsection (a)(1) or (a)(2) of section 294a of this title for the purpose of planning, developing, operating, and evaluating an area health education center program and one or more area health education centers, which carries out the required activities described in section 294a(c) of this title, satisfies the program requirements in such section,[4] has as one of its principal functions identifying and implementing strategies and activities that address health care workforce needs in its service area, in coordination with the local workforce investment boards.

(14) CLINICAL SOCIAL WORKER.—The term "clinical social worker" has the meaning given the term in section 1395x(hh)(1) of this title.

(15) CULTURAL COMPETENCY.—The term "cultural competency" shall be defined by the Secretary in a manner consistent with section 300u–6(d)(3) of this title.

(16) DIRECT CARE WORKER.—The term "direct care worker" has the meaning given that term in the 2010 Standard Occupational Classifications of the Department of Labor for Home Health Aides [31–1011], Psychiatric Aides [31–1013], Nursing Assistants [31–1014], and Personal Care Aides [39–9021].

(17) FEDERALLY QUALIFIED HEALTH CENTER.—The term "Federally qualified health center" has the meaning given that term in section 1395x(aa) of this title.

(18) FRONTIER HEALTH PROFESSIONAL SHORTAGE AREA.—The term "frontier health professional shortage area" means an area—

(A) with a population density less than 6 persons per square mile within the service area; and
(B) with respect to which the distance or time for the population to access care is excessive.

(19) GRADUATE PSYCHOLOGY.—The term "graduate psychology" means an accredited program in professional psychology.

(20) HEALTH DISPARITY POPULATION.—The term "health disparity population" has the meaning given such term in section 299a–1(d)(1) of this title.

(21) HEALTH LITERACY.—The term "health literacy" means the degree to which an individual has the capacity to obtain, communicate, process, and understand health information and services in order to make appropriate health decisions.

(22) MENTAL HEALTH SERVICE PROFESSIONAL.—The term "mental health service professional" means an individual with a graduate or postgraduate degree from an accredited institution of higher education in psychiatry, psychology, school psychology, behavioral pediatrics, psychiatric nursing, social work, school social work, substance abuse disorder prevention and treatment, marriage and family counseling, school counseling, or professional counseling.

(23) ONE-STOP DELIVERY SYSTEM CENTER.—The term "one-stop delivery system" means a one-stop delivery system described in section 3151(e) of title 29.

(24) PARAPROFESSIONAL CHILD AND ADOLESCENT MENTAL HEALTH WORKER .—The term "paraprofessional child and adolescent mental health worker" means an individual who is not a mental or behavioral health service professional, but who works at the first stage of contact with children and families who are seeking mental or behavioral health services, including substance abuse prevention and treatment services.

(25) RACIAL AND ETHNIC MINORITY GROUP; RACIAL AND ETHNIC MINORITY POPULATION.—The terms "racial and ethnic minority group" and "racial and ethnic minority population" have the meaning given the term "racial and ethnic minority group" in section 300u–6 of this title.

(26) RURAL HEALTH CLINIC.—The term "rural health clinic" has the meaning given that term in section 1395x(aa) of this title.

(July 1, 1944, ch. 373, title VII, §799B, formerly §799, as added Pub. L. 102–408, title I, §102, Oct. 13, 1992, 106 Stat. 2066; renumbered §799B and amended Pub. L. 105–392, title I, §§106(a)(2)(E), 108, Nov. 13, 1998, 112 Stat. 3557, 3560; Pub. L. 107–251, title VI, §601(a), Oct. 26, 2002, 116 Stat. 1664; Pub. L. 111–148, title V, §5002(b), Mar. 23, 2010, 124 Stat. 590; Pub. L. 113–128, title V, §512(z)(3), July 22, 2014, 128 Stat. 1716.)

EDITORIAL NOTES

REFERENCES IN TEXT

The reference to section 254b of this title the first place appearing and the reference to section 254c of this title, referred to in par. (6)(B), were in the original references to sections 329 and 330, meaning sections 329 and 330 of act July 1, 1944, which were omitted in the general amendment of subpart I (§254b et seq.) of part D of subchapter II of this chapter by Pub. L. 104–299, §2, Oct. 11, 1996, 110 Stat. 3626. Sections 2 and 3(a) of Pub. L. 104–299 enacted new sections 330 and 330A of act July 1, 1944, which are classified, respectively, to sections 254b and 254c of this title.

Section 256a of this title, referred to in par. (6)(B), was repealed by Pub. L. 104–299, §4(a)(3), Oct. 11, 1996, 110 Stat. 3645.

AMENDMENTS

2014—Par. (23). Pub. L. 113–128 substituted "one-stop delivery system described in section 3151(e) of title 29" for "one-stop delivery system described in section 2864(c) of title 29".

2010—Par. (3). Pub. L. 111–148, §5002(b)(1), added par. (3) and struck out former par. (3) which defined "program for the training of physician assistants" by describing its objective, duration, minimum enrollment, and specific areas of instruction.

Pars. (12) to (26). Pub. L. 111–148, §5002(b)(2), added pars. (12) to (26).

2002—Par. (6)(B). Pub. L. 107–251 substituted "254b(h)" for "256".

1998—Par. (1)(C). Pub. L. 105–392, §108(b)(1)(A), inserted "and 'graduate program in professional counseling' " before "mean an" and "and a concentration leading to a graduate degree in counseling" before period at end.

Par. (1)(D). Pub. L. 105–392, §108(a), (b)(1)(B), inserted "behavioral health and" before "mental", "behavioral health and mental health practice," before "clinical", and "professional counseling," after "social work,".

Par. (1)(E). Pub. L. 105–392, §108(b)(1)(C), inserted "professional counseling," after "social work,".

Par. (3). Pub. L. 105–392, §108(d), amended par. (3) generally. Prior to amendment, par. (3) read as follows: "The term 'program for the training of physician assistants' means an educational program that—

"(A) has as its objective the education of individuals who will, upon completion of their studies in the program, be qualified to provide primary health care under the supervision of a physician; and

"(B) meets regulations prescribed by the Secretary in accordance with section 293n(b) of this title."

Par. (5)(C). Pub. L. 105–392, §108(b)(2), inserted "or a degree in counseling or an equivalent degree" before period at end.

Par. (6)(D). Pub. L. 105–392, §108(c), added subpar. (D).

Par. (11). Pub. L. 105–392, §108(e), added par. (11).

STATUTORY NOTES AND RELATED SUBSIDIARIES

EFFECTIVE DATE OF 2014 AMENDMENT

Amendment by Pub. L. 113–128 effective on the first day of the first full program year after July 22, 2014 (July 1, 2015), see section 506 of Pub. L. 113–128, set out as an Effective Date note under section 3101 of Title 29, Labor.

REFERENCE TO COMMUNITY, MIGRANT, PUBLIC HOUSING, OR HOMELESS HEALTH CENTER CONSIDERED REFERENCE TO HEALTH CENTER

Reference to community health center, migrant health center, public housing health center, or homeless health center considered reference to health center, see section 4(c) of Pub. L. 104–299, set out as a note under section 254b of this title.

EXECUTIVE DOCUMENTS

TERMINATION OF TRUST TERRITORY OF THE PACIFIC ISLANDS

For termination of Trust Territory of the Pacific Islands, see note set out preceding section 1681 of Title 48, Territories and Insular Possessions.

[1] So in original. Probably should be "will be".

[2] See References in Text notes below.

[3] So in original. The word "a" probably should appear.

[4] So in original. The word "and" probably should appear.

SUBCHAPTER VI—NURSING WORKFORCE DEVELOPMENT

EDITORIAL NOTES

CODIFICATION

Pub. L. 105–392, title I, §123(1), Nov. 13, 1998, 112 Stat. 3562, added subchapter VI heading and struck out former subchapter VI heading "NURSE EDUCATION".

Pub. L. 99–92, §9(b)(3), Aug. 16, 1985, 99 Stat. 400, substituted "NURSE EDUCATION" for "NURSE

TRAINING" in subchapter VI heading.

PART A—GENERAL PROVISIONS

EDITORIAL NOTES

CODIFICATION

Pub. L. 105–392, title I, §123(4), Nov. 13, 1998, 112 Stat. 3563, added part A heading and struck out former part A heading "Special Projects".

Pub. L. 99–92, §9(b)(1), (2), Aug. 16, 1985, 99 Stat. 400, substituted "Special Projects" for "Assistance for Expansion and Improvement of Nurse Training" as part A heading, and struck out headings for subparts I, II, III, and IV of part A which read as follows: "Subpart I—Construction Assistance", "Subpart II—Capitation Grants", "Subpart III—Financial Distress Grants", and "Subpart IV—Special Projects".

§296. Definitions

As used in this subchapter:

(1) Eligible entities

The term "eligible entities" means schools of nursing, nursing centers, academic health centers, State or local governments, and other public or private nonprofit entities determined appropriate by the Secretary that submit to the Secretary an application in accordance with section 296a of this title.

(2) School of nursing

The term "school of nursing" means an accredited (as defined in paragraph 6) collegiate, associate degree, or diploma school of nursing in a State where graduates are—

(A) authorized to sit for the National Council Licensure EXamination-Registered Nurse (NCLEX–RN); or

(B) licensed registered nurses who will receive a graduate or equivalent degree or training to become an advanced education nurse as defined by section 296j(b) of this title.

(3) Collegiate school of nursing

The term "collegiate school of nursing" means a department, division, or other administrative unit in a college or university which provides primarily or exclusively a program of education in professional nursing and related subjects leading to the degree of bachelor of arts, bachelor of science, bachelor of nursing, or to an equivalent degree, or to a graduate degree in nursing, or to an equivalent degree, and including advanced training related to such program of education provided by such school, but only if such program, or such unit, college or university is accredited.

(4) Associate degree school of nursing

The term "associate degree school of nursing" means a department, division, or other administrative unit in a junior college, community college, college, or university which provides primarily or exclusively a two-year program of education in professional nursing and allied subjects leading to an associate degree in nursing or to an equivalent degree, but only if such program, or such unit, college, or university is accredited.

(5) Diploma school of nursing

The term "diploma school of nursing" means a school affiliated with a hospital or university, or an independent school, which provides primarily or exclusively a program of education in professional nursing and allied subjects leading to a diploma or to equivalent indicia that such program has been satisfactorily completed, but only if such program, or such affiliated school or such hospital or university or such independent school is accredited.

(6) Accredited

(A) In general

Except as provided in subparagraph (B), the term "accredited" when applied to any program of nurse education means a program accredited by a recognized body or bodies, or by a State agency, approved for such purpose by the Secretary of Education and when applied to a hospital, school, college, or university (or a unit thereof) means a hospital, school, college, or university (or a unit thereof) which is accredited by a recognized body or bodies, or by a State agency, approved for such purpose by the Secretary of Education. For the purpose of this paragraph, the Secretary of Education shall publish a list of recognized accrediting bodies, and of State agencies, which the Secretary of Education determines to be reliable authority as to the quality of education offered.

(B) New programs

A new program of nursing that, by reason of an insufficient period of operation, is not, at the time of the submission of an application for a grant or contract under this subchapter, eligible for accreditation by such a recognized body or bodies or State agency, shall be deemed accredited for purposes of this subchapter if the Secretary of Education finds, after consultation with the appropriate accreditation body or bodies, that there is reasonable assurance that the program will meet the accreditation standards of such body or bodies prior to the beginning of the academic year following the normal graduation date of students of the first entering class in such a program.

(7) Nonprofit

The term "nonprofit" as applied to any school, agency, organization, or institution means one which is a corporation or association, or is owned and operated by one or more corporations or associations, no part of the net earnings of which inures, or may lawfully inure, to the benefit of any private shareholder or individual.

(8) State

The term "State" means a State, the Commonwealth of Puerto Rico, the District of Columbia, the Commonwealth of the Northern Mariana Islands, Guam, American Samoa, the Virgin Islands, or the Trust Territory of the Pacific Islands.

(9) Ambulatory surgical center

The term "ambulatory surgical center" has the meaning applicable to such term under title XVIII of the Social Security Act [42 U.S.C. 1395 et seq.].

(10) Federally qualified health center

The term "Federally qualified health center" has the meaning given such term under section 1861(aa)(4) of the Social Security Act [42 U.S.C. 1395x(aa)(4)].

(11) Health care facility

The term "health care facility" means an Indian Health Service health center, a Native Hawaiian health center, a hospital, a Federally qualified health center, a rural health clinic, a nursing home, a home health agency, a hospice program, a public health clinic, a State or local department of public health, a skilled nursing facility, an ambulatory surgical center, or any other facility designated by the Secretary.

(12) Home health agency

The term "home health agency" has the meaning given such term in section 1861(o) of the Social Security Act [42 U.S.C. 1395x(o)].

(13) Hospice program

The term "hospice program" has the meaning given such term in section 1861(dd)(2) of the Social Security Act [42 U.S.C. 1395x(dd)(2)].

(14) Rural health clinic

The term "rural health clinic" has the meaning given such term in section 1861(aa)(2) of the Social Security Act [42 U.S.C. 1395x(aa)(2)].

(15) Skilled nursing facility

The term "skilled nursing facility" has the meaning given such term in section 1819(a) of the Social Security Act [42 U.S.C. 1395i–3(a)].

(16) Accelerated nursing degree program

The term "accelerated nursing degree program" means a program of education in professional nursing offered by an accredited school of nursing in which an individual holding a bachelors degree in another discipline receives a BSN or MSN degree in an accelerated time frame as determined by the accredited school of nursing.

(17) Bridge or degree completion program

The term "bridge or degree completion program" means a program of education in professional nursing offered by an accredited school of nursing, as defined in paragraph (2), that leads to a baccalaureate degree in nursing. Such programs may include, Registered Nurse (RN) to Bachelor's of Science of Nursing (BSN) programs, RN to MSN (Master of Science of Nursing) programs, or BSN to Doctoral programs.

(18) Nurse managed health clinic

The term "nurse managed health clinic" means a nurse-practice arrangement, managed by advanced practice nurses, that provides primary care or wellness services to underserved or vulnerable populations and that is associated with a school, college, university or department of nursing, federally qualified health center, or independent nonprofit health or social services agency.

(July 1, 1944, ch. 373, title VIII, §801, as added Pub. L. 105–392, title I, §123(4), Nov. 13, 1998, 112 Stat. 3562; amended Pub. L. 107–205, title I, §101, Aug. 1, 2002, 116 Stat. 811; Pub. L. 111–148, title V, §5002(c), Mar. 23, 2010, 124 Stat. 591; Pub. L. 116–136, div. A, title III, §3404(a)(1), Mar. 27, 2020, 134 Stat. 391.)

EDITORIAL NOTES

REFERENCES IN TEXT

The Social Security Act, referred to in par. (9), is act Aug. 14, 1935, ch. 531, 49 Stat. 620. Title XVIII of the Act is classified generally to subchapter XVIII (§1395 et seq.) of chapter 7 of this title. For complete classification of this Act to the Code, see section 1305 of this title and Tables.

PRIOR PROVISIONS

A prior section 296, act July 1, 1944, ch. 373, title VIII, §801 as added Sept. 4, 1964, Pub. L. 88–581, §2, 78 Stat. 908; amended Nov. 3, 1966, Pub. L. 89–751, §8(a), 80 Stat. 1236; Aug. 16, 1968, Pub. L. 90–490, title II, §201(a), 82 Stat. 780; Nov. 18, 1971, Pub. L. 92–158, §2(a), 85 Stat. 465; July 29, 1975, Pub. L. 94–63, title IX, §§902(a), 910(a)(1), 89 Stat. 354, 355; Sept. 29, 1979, Pub. L. 96–76, title I, §102, 93 Stat. 579, authorized appropriations for construction grants, prior to repeal by Pub. L. 99–92, §§9(a)(1), 10(a), Aug. 16, 1985, 99 Stat. 400, 402, effective Oct. 1, 1985.

AMENDMENTS

2020—Par. (18). Pub. L. 116–136 added par. (18).

2010—Par. (2). Pub. L. 111–148, §5002(c)(1), substituted "means an accredited (as defined in paragraph 6) collegiate, associate degree, or diploma school of nursing in a State where graduates are—" for "means a collegiate, associate degree, or diploma school of nursing in a State." and added subpars. (A) and (B).

Pars. (16), (17). Pub. L. 111–148, §5002(c)(2), added pars. (16) and (17).

2002—Pars. (9) to (15). Pub. L. 107–205 added pars. (9) to (15).

STATUTORY NOTES AND RELATED SUBSIDIARIES

SAVINGS PROVISION

Pub. L. 105–392, title I, §124, Nov. 13, 1998, 112 Stat. 3574, provided that: "In the case of any authority for making awards of grants or contracts that is terminated by the amendment made by section 123 [enacting sections 296, 296a to 296f, 296j, 296m, 296p, 297q, and 297t of this title, transferring section 298b–2 of this title to section 296g of this title, and repealing sections 296k to 296m, 296r, 297, 297–1, 297c, 298, 298a, 298b, 298b–1, 298b–3 to 298b–5, and 298b–7 of this title], the Secretary of Health and Human Services may, notwithstanding the termination of the authority, continue in effect any grant or contract made under the authority that is in effect on the day before the date of the enactment of this Act [Nov. 13, 1998], subject to the duration of any such grant or contract not exceeding the period determined by the Secretary in first approving such financial assistance, or in approving the most recent request made (before the date of such enactment) for continuation of such assistance, as the case may be."

REPORTS BY GOVERNMENT ACCOUNTABILITY OFFICE

Pub. L. 107–205, title II, §204, Aug. 1, 2002, 116 Stat. 818, provided that:

"(a) NATIONAL VARIATIONS.—Not later than 4 years after the date of the enactment of this Act [Aug. 1, 2002], the Comptroller General of the United States shall conduct a survey to determine national variations in the nursing shortage at hospitals, nursing homes, and other health care providers, and submit a report, including recommendations, to the Congress on Federal remedies to ease nursing shortages. The Comptroller General shall submit to the Congress this report describing the findings relating to ownership status and associated remedies.

"(b) HIRING DIFFERENCES AMONG CERTAIN PRIVATE ENTITIES.—The Comptroller General of the United States shall conduct a study to determine differences in the hiring of nurses by nonprofit private entities as compared to the hiring of nurses by private entities that are not nonprofit. In carrying out the study, the Comptroller General shall determine the effect of the inclusion of private entities that are not nonprofit in the program under section 846 of the Public Health Service Act [42 U.S.C. 297n]. Not later than 4 years after the date of the enactment of this Act [Aug. 1, 2002], the Comptroller General shall submit to the Congress a report describing the findings of the study.

"(c) NURSING SCHOLARSHIPS.—The Comptroller General of the United States shall conduct an evaluation of whether the program carried out under section 846(d) of the Public Health Service Act [42 U.S.C. 297n(d)] has demonstrably increased the number of applicants to schools of nursing and, not later than 4 years after the date of the enactment of this Act [Aug. 1, 2002], submit a report to the Congress on the results of such evaluation."

PURPOSE

Pub. L. 105–392, title I, §122, Nov. 13, 1998, 112 Stat. 3562, provided that: "It is the purpose of this subtitle [subtitle B (§§121–124) of title I of Pub. L. 105–392, see Short Title of 1998 Amendment note set out under section 201 of this title] to restructure the nurse education authorities of title VIII of the Public Health Service Act [42 U.S.C. 296 et seq.] to permit a comprehensive, flexible, and effective approach to Federal support for nursing workforce development."

INFORMATION RESPECTING SUPPLY AND DISTRIBUTION OF AND REQUIREMENTS FOR NURSES; DETERMINATION PROCEDURES; SURVEYS AND COLLECTION OF DATES; ANNUAL REPORT TO CONGRESS ON DETERMINATIONS, ETC.; REVIEW BY OFFICE OF MANAGEMENT AND BUDGET OF REPORT PRIOR TO SUBMISSION

Pub. L. 94–63, title IX, §951, July 29, 1975, 89 Stat. 367, as amended by Pub. L. 95–623, §12(h), Nov. 9, 1978, 92 Stat. 3457, provided that:

"(a)(1) Using procedures developed in accordance with paragraph (3), the Secretary of Health, Education, and Welfare [now Health and Human Services] (hereinafter in this section referred to as the 'Secretary') shall determine on a continuing basis—

"(A) the supply (both current and projected and within the United States and within each State) of registered nurses, licensed practical and vocational nurses, nurse's aides, registered nurses with advanced training or graduate degrees, and nurse practitioners;

"(B) the distribution within the United States and within each State, of such nurses so as to determine (i) those areas of the United States which are oversupplied or undersupplied, or which have an adequate supply of such nurses in relation to the population of the area, and (ii) the demand for the services which such nurses provide; and

"(C) the current and future requirements for such nurses, nationally and within each State.

"(2) The Secretary shall survey and gather data, on a continuing basis, on—

"(A) the number and distribution of nurses, by type of employment and location of practice;

"(B) the number of nurses who are practicing full time and those who are employed part time, within the United States and within each State;

"(C) the average rates of compensation for nurses, by type of practice and location of practice;

"(D) the activity status of the total number of registered nurses within the United States and within each State;

"(E) the number of nurses with advanced training or graduate degrees in nursing, by specialty, including nurse practitioners, nurse clinicians, nurse researchers, nurse educators, and nurse supervisors and administrators; and

"(F) the number of registered nurses entering the United States annually from other nations, by country of nurse training and by immigrant status.

"(3) Within six months of the date of the enactment of this Act [July 29, 1975], the Secretary shall develop procedures for determining (on both a current and projected basis) the supply and distribution of and requirements for nurses within the United States and within each State.

"(b) Not later than October 1, 1979, and October 1 of each odd-numbered year thereafter, the Secretary shall report to the Congress—

"(1) his determinations under subsection (a)(1) and the data gathered under subsection (a)(2);

"(2) an analysis of such determination and data; and

"(3) recommendations for such legislation as the Secretary determines, based on such determinations and data, will achieve (A) an equitable distribution of nurses within the United States and within each State, and (B) adequate supplies of nurses within the United States and within each State.

"(c) The Office of Management and Budget may review the Secretary's report under subsection (b) before its submission to the Congress, but the Office may not revise the report or delay its submission, and it may submit to the Congress its comments (and those of other departments or agencies of the Government) respecting such report."

EXECUTIVE DOCUMENTS

TERMINATION OF TRUST TERRITORY OF THE PACIFIC ISLANDS

For termination of Trust Territory of the Pacific Islands, see note set out preceding section 1681 of Title 48, Territories and Insular Possessions.

§296a. Application

(a) In general

To be eligible to receive a grant or contract under this subchapter, an eligible entity shall prepare and submit to the Secretary an application that meets the requirements of this section, at such time, in such manner, and containing such information as the Secretary may require.

(b) Plan

An application submitted under this section shall contain the plan of the applicant for carrying out a project with amounts received under this subchapter. Such plan shall be consistent with relevant Federal, State, or regional program plans.

(c) Performance outcome standards

An application submitted under this section shall contain a specification by the applicant entity of performance outcome standards that the project to be funded under the grant or contract will be measured against. Such standards shall address relevant national nursing needs that the project will meet, and how such project aligns with the goals in section 296e(a) of this title. The recipient of a grant or contract under this section shall meet the standards set forth in the grant or contract application.

(d) Linkages

An application submitted under this section shall contain a description of the linkages with relevant educational and health care entities, including training programs for other health professionals as appropriate, that the project to be funded under the grant or contract will establish.

(July 1, 1944, ch. 373, title VIII, §802, as added Pub. L. 105–392, title I, §123(4), Nov. 13, 1998, 112 Stat. 3564; amended Pub. L. 116–136, div. A, title III, §3404(a)(2), Mar. 27, 2020, 134 Stat. 392.)

EDITORIAL NOTES

PRIOR PROVISIONS

A prior section 296a, act July 1, 1944, ch. 373, title VIII, §802, as added Sept. 4, 1964, Pub. L. 88–581, §2, 78 Stat. 909; amended Aug. 16, 1968, Pub. L. 90–490, title II, §201(b), 82 Stat. 780; Nov. 18, 1971, Pub. L. 92–158, §§2(d)(3), (e), (f), 13, 85 Stat. 468, 480; July 29, 1975, Pub. L. 94–63, title IX, §§910(a)(2), 941(a), 89 Stat. 355, 363, related to time of submission, determinations, etc., respecting applications for construction grants, prior to repeal by Pub. L. 99–92, §§9(a)(1), 10(a), Aug. 16, 1985, 99 Stat. 400, 402, effective Oct. 1, 1985.

AMENDMENTS

2020—Subsec. (c). Pub. L. 116–136 inserted ", and how such project aligns with the goals in section 296e(a) of this title" after "project will meet".

§296b. Use of funds

(a) In general

Amounts provided under a grant or contract awarded under this subchapter may be used for training program development and support, faculty development, model demonstrations, trainee support including tuition, books, program fees and reasonable living expenses during the period of training, technical assistance, workforce analysis, and dissemination of information, as appropriate to meet recognized nursing objectives, in accordance with this subchapter.

(b) Maintenance of effort

With respect to activities for which a grant awarded under this subchapter is to be expended, the entity shall agree to maintain expenditures of non-Federal amounts for such activities at a level that is not less than the level of such expenditures maintained by the entity for the fiscal year preceding the fiscal year for which the entity receives such a grant. Such Federal funds are intended to supplement, not supplant, existing non-Federal expenditures for such activities.

(July 1, 1944, ch. 373, title VIII, §803, as added Pub. L. 105–392, title I, §123(4), Nov. 13, 1998, 112 Stat. 3564; amended Pub. L. 116–136, div. A, title III, §3404(a)(3), Mar. 27, 2020, 134 Stat. 392.)

EDITORIAL NOTES

PRIOR PROVISIONS

A prior section 296b, act July 1, 1944, ch. 373, title VIII, §803, as added Sept. 4, 1964, Pub. L. 88–581, §2, 78 Stat. 911; amended Aug. 16, 1968, Pub. L. 90–490, title II, §202, 82 Stat. 780; Nov. 18, 1971, Pub. L. 92–158, §§2(b), 13, 85 Stat. 465, 480; July 29, 1975, Pub. L. 94–63, title IX, §941(b), 89 Stat. 364, set forth provisions relating to amount of construction grant, prior to repeal by Pub. L. 99–92, §§9(a)(1), 10(a), Aug. 16, 1985, 99 Stat. 400, 402, effective Oct. 1, 1985.

AMENDMENTS

2020—Subsec. (b). Pub. L. 116–136 inserted at end "Such Federal funds are intended to supplement, not supplant, existing non-Federal expenditures for such activities."

§296c. Matching requirement

The Secretary may require that an entity that applies for a grant or contract under this subchapter

provide non-Federal matching funds, as appropriate, to ensure the institutional commitment of the entity to the projects funded under the grant. Such non-Federal matching funds may be provided directly or through donations from public or private entities and may be in cash or in-kind, fairly evaluated, including plant, equipment, or services.

(July 1, 1944, ch. 373, title VIII, §804, as added Pub. L. 105–392, title I, §123(4), Nov. 13, 1998, 112 Stat. 3565.)

EDITORIAL NOTES

PRIOR PROVISIONS

A prior section 296c, act July 1, 1944, ch. 373, title VIII, §804, as added Sept. 4, 1964, Pub. L. 88–581, §2, 78 Stat. 911; amended Nov. 18, 1971, Pub. L. 92–158, §§2(d)(3), 13, 85 Stat. 468, 480; July 29, 1975, Pub. L. 94–63, title IX, §941(c), 89 Stat. 364, which related to recovery of payments of funds by United States for construction of facilities, was renumbered section 858 of act July 1, 1944, by Pub. L. 99–92 and transferred to section 298b–5 of this title.

§296d. Preference

In awarding grants or contracts under this subchapter, the Secretary shall give preference to applicants with projects that will substantially benefit rural or underserved populations, or help meet public health nursing needs in State or local health departments.

(July 1, 1944, ch. 373, title VIII, §805, as added Pub. L. 105–392, title I, §123(4), Nov. 13, 1998, 112 Stat. 3565.)

EDITORIAL NOTES

PRIOR PROVISIONS

A prior section 296d, act July 1, 1944, ch. 373, title VIII, §805, formerly §809, as added Nov. 18, 1971, Pub. L. 92–158, §2(c), 85 Stat. 465; renumbered §805 and amended July 29, 1975, Pub. L. 94–63, title IX, §§902(d), 910(b)(1)(A), (B)(i), (2), (c), 911(b), 941(d), 89 Stat. 355, 356, 364; Sept. 29, 1979, Pub. L. 96–76, title I, §103, 93 Stat. 579, related to applications, amounts, etc., for loan guarantees and interest subsidies for construction of training facilities by nonprofit nursing schools, prior to repeal by Pub. L. 99–92, §§9(a)(1), 10(a), Aug. 16, 1985, 99 Stat. 400, 402, effective Oct. 1, 1985.

Another prior section 296d, act July 1, 1944, ch. 373, title VIII, §805, as added Sept. 4, 1964, Pub. L. 88–581, §2, 78 Stat. 912; amended Aug. 16, 1968, Pub. L. 90–490, title II, §§211, 215, 82 Stat. 780, 783; Nov. 18, 1971, Pub. L. 92–158, §3(b), 85 Stat. 469, relating to special project grants and contracts for nurse training programs, was repealed by Pub. L. 94–63, title IX, §922, July 29, 1975, 89 Stat. 359, eff. July 1, 1975.

§296e. Generally applicable provisions

(a) Awarding of grants and contracts

The Secretary shall ensure that grants and contracts under this subchapter are awarded on a competitive basis, as appropriate, to carry out innovative demonstration projects or provide for strategic workforce supplementation activities as needed to address national nursing needs, including—

(1) addressing challenges, including through supporting training and education of nursing students, related to the distribution of the nursing workforce and existing or projected nursing workforce shortages in geographic areas that have been identified as having, or that are projected to have, a nursing shortage;

(2) increasing access to and the quality of health care services, including by supporting the training of professional registered nurses, advanced practice registered nurses, and advanced

education nurses within community based settings and in a variety of health delivery system settings; or

(3) addressing the strategic goals and priorities identified by the Secretary and that are in accordance with this subchapter.

Contracts may be entered into under this subchapter with public or private entities as determined necessary by the Secretary.

(b) Information requirements

(1) In general

Recipients of grants and contracts under this subchapter shall meet information requirements as specified by the Secretary.

(2) Evaluations

The Secretary shall establish procedures to ensure the annual evaluation of programs and projects operated by recipients of grants under this subchapter. Such procedures shall ensure that continued funding for such programs and projects will be conditioned upon the reporting of data and information demonstrating that satisfactory progress has been made by the program or project in meeting the performance outcome standards (as described in section 296a of this title) of such program or project.

(c) Training programs

Training programs conducted with amounts received under this subchapter shall meet applicable accreditation and quality standards.

(d) Duration of assistance

(1) In general

Subject to paragraph (2), in the case of an award to an entity of a grant, cooperative agreement, or contract under this subchapter, the period during which payments are made to the entity under the award may not exceed 5 years. The provision of payments under the award shall be subject to annual approval by the Secretary of the payments and subject to the availability of appropriations for the fiscal year involved to make the payments. This paragraph may not be construed as limiting the number of awards under the program involved that may be made to the entity.

(2) Limitation

In the case of an award to an entity of a grant, cooperative agreement, or contract under this subchapter, paragraph (1) shall apply only to the extent not inconsistent with any other provision of this subchapter that relates to the period during which payments may be made under the award.

(e) Peer review regarding certain programs

(1) In general

Each application for a grant under this subchapter, except advanced nurse traineeship grants under section 296j(a)(2) of this title, shall be submitted to a peer review group for an evaluation of the merits of the proposals made in the application. The Secretary may not approve such an application unless a peer review group has recommended the application for approval.

(2) Composition

Each peer review group under this subsection shall be composed principally of individuals who are not officers or employees of the Federal Government, and have relevant expertise and experience. In providing for the establishment of peer review groups and procedures, the Secretary shall, except as otherwise provided, ensure sex, racial, ethnic, and geographic representation among the membership of such groups.

(3) Administration

This subsection shall be carried out by the Secretary acting through the Administrator of the

Health Resources and Services Administration.

(f) Analytic activities

The Secretary shall ensure that—

(1) cross-cutting workforce analytical activities are carried out as part of the workforce information and analysis activities under this subchapter; and

(2) discipline-specific workforce information is developed and analytical activities are carried out as part of—

(A) the advanced education nursing activities under part B;

(B) the workforce diversity activities under part C; and

(C) basic nursing education and practice activities under part D.

(g) State and regional priorities

Activities under grants or contracts under this subchapter shall, to the extent practicable, be consistent with related Federal, State, or regional nursing professions program plans and priorities.

(h) Filing of applications

(1) In general

Applications for grants or contracts under this subchapter may be submitted by health professions schools, schools of nursing, academic health centers, State or local governments, or other appropriate public or private nonprofit entities as determined appropriate by the Secretary in accordance with this subchapter.

(2) For-profit entities

Notwithstanding paragraph (1), a for-profit entity may be eligible for a grant or contract under this subchapter as determined appropriate by the Secretary.

(i) Biennial report on nursing workforce program improvements

Not later than September 30, 2020, and biennially thereafter, the Secretary shall submit to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives, a report that contains an assessment of the programs and activities of the Department of Health and Human Services related to enhancing the nursing workforce, including the extent to which programs and activities under this subchapter meet the identified goals and performance measures developed for the respective programs and activities, and the extent to which the Department coordinates with other Federal departments regarding programs designed to improve the nursing workforce.

(July 1, 1944, ch. 373, title VIII, §806, as added Pub. L. 105–392, title I, §123(4), Nov. 13, 1998, 112 Stat. 3565; amended Pub. L. 116–136, div. A, title III, §3404(a)(4), Mar. 27, 2020, 134 Stat. 392.)

EDITORIAL NOTES

PRIOR PROVISIONS

A prior section 296e, act July 1, 1944, ch. 373, title VIII, §810, formerly §806, as added Sept. 4, 1964, Pub. L. 88–581, §2, 78 Stat. 912; amended Dec. 5, 1967, Pub. L. 90–174, §12(a), 81 Stat. 541; Aug. 16, 1968, Pub. L. 90–490, title II, §211, 82 Stat. 781; Nov. 18, 1971, Pub. L. 92–158, §4(a), 85 Stat. 470; renumbered §810 and amended July 29, 1975, Pub. L. 94–63, title IX, §§902(b), 915(a)–(c), 916(a), (b), 941(e), 89 Stat. 354, 356, 358, 365; Aug. 1, 1977, Pub. L. 95–83, title III, §307(o)(1)–(4), 91 Stat. 393; Sept. 29, 1979, Pub. L. 96–76, title I, §104, 93 Stat. 579, set forth provisions relating to computation, requirements, etc., respecting grants for institutional support, prior to repeal by Pub. L. 99–92, §§9(a)(1), 10(a), Aug. 16, 1985, 99 Stat. 400, 402, effective Oct. 1, 1985.

AMENDMENTS

2020—Subsec. (a). Pub. L. 116–136, §3404(a)(4)(A), substituted "as needed to address national nursing needs, including—", pars. (1) to (3), and concluding provisions for "as needed to meet national nursing service goals and in accordance with this subchapter. Contracts may be entered into under this subchapter with public

or private entities as determined necessary by the Secretary."

Subsec. (b)(2). Pub. L. 116–136, §3404(a)(4)(B), substituted "the reporting of data and information demonstrating that satisfactory progress has been made by the program or project in meeting the performance outcome standards (as described in section 296a of this title) of such program or project." for "a demonstration that satisfactory progress has been made by the program or project in meeting the objectives of the program or project."

Subsec. (e)(2). Pub. L. 116–136, §3404(a)(4)(C), inserted ", and have relevant expertise and experience" before period at end of first sentence.

Subsec. (i). Pub. L. 116–136, §3404(a)(4)(D), added subsec. (i).

§296e–1. Grants for health professions education

(a) Cultural competency, prevention, and public health and individuals with disability grants

The Secretary, acting through the Administrator of the Health Resources and Services Administration, may make awards of grants, contracts, or cooperative agreements to eligible entities for the development, evaluation, and dissemination of research, demonstration projects, and model curricula for cultural competency, prevention, public health proficiency, reducing health disparities, and aptitude for working with individuals with disabilities training for use in health professions schools and continuing education programs, and for other purposes determined as appropriate by the Secretary. Grants under this section shall be the same as provided in section 293e of this title.

(b) Collaboration

In carrying out subsection (a), the Secretary shall collaborate with the entities described in section 293e(b) of this title. The Secretary shall coordinate with curricula and research and demonstration projects developed under such section 293e.

(c) Dissemination

Model curricula developed under this section shall be disseminated and evaluated in the same manner as model curricula developed under section 293e of this title, as described in subsection (c) of such section.

(d) Authorization of appropriations

There are to be appropriated to carry out this section such sums as may be necessary for each of the fiscal years 2010 through 2015.

(July 1, 1944, ch. 373, title VIII, §807, as added Pub. L. 106–525, title IV, §401(b)(2), Nov. 22, 2000, 114 Stat. 2508; amended Pub. L. 111–148, title V, §5307(b), Mar. 23, 2010, 124 Stat. 628.)

EDITORIAL NOTES

PRIOR PROVISIONS

A prior section 807 of act July 1, 1944, was renumbered section 808 by Pub. L. 106–525 and is classified to section 296f of this title.

Another prior section 807 of act July 1, 1944, was renumbered section 811 and classified to section 296f of this title prior to repeal by Pub. L. 99–92, §9(a)(1), Aug. 16, 1985, 99 Stat. 400.

AMENDMENTS

2010—Subsec. (a). Pub. L. 111–148, §5307(b)(1), in heading, substituted "Cultural competency, prevention, and public health and individuals with disability grants" for "Grants for health professions education in health disparities and cultural competency" and, in text, substituted "for the development, evaluation, and dissemination of research, demonstration projects, and model curricula for cultural competency, prevention, public health proficiency, reducing health disparities, and aptitude for working with individuals with disabilities training for use in health professions schools and continuing education programs, and for other purposes determined as appropriate by the Secretary" for "for the purpose of carrying out

research and demonstration projects (including research and demonstration projects for continuing health professions education) for training and education for the reduction of disparities in health care outcomes and the provision of culturally competent health care".

Subsecs. (b) to (d). Pub. L. 111–148, §5307(b)(2)–(4), added subsecs. (b) and (c), redesignated former subsec. (b) as (d), and, in subsec. (d), substituted "this section" for "subsection (a) of this section" and "2010 through 2015" for "2001 through 2004".

§296f. Technical assistance

Funds appropriated under this subchapter may be used by the Secretary to provide technical assistance in relation to any of the authorities under this subchapter.

(July 1, 1944, ch. 373, title VIII, §808, formerly §807, as added Pub. L. 105–392, title I, §123(4), Nov. 13, 1998, 112 Stat. 3566; renumbered §808, Pub. L. 106–525, title IV, §401(b)(1), Nov. 22, 2000, 114 Stat. 2508.)

EDITORIAL NOTES

PRIOR PROVISIONS

A prior section 296f, act July 1, 1944, ch. 373, title VIII, §811, formerly §807, as added Aug. 16, 1968, Pub. L. 90–490, title II, §212, 82 Stat. 782; amended Nov. 18, 1971, Pub. L. 92–158, §4(c), 85 Stat. 475; renumbered §811 and amended July 29, 1975, Pub. L. 94–63, title IX, §941(f), 89 Stat. 365, related to filing dates, etc., for applications for grants, prior to repeal by Pub. L. 99–92, §§9(a)(1), 10(a), Aug. 16, 1985, 99 Stat. 400, 402, effective Oct. 1, 1985.

A prior section 808 of act July 1, 1944, was classified to section 296g of this title prior to repeal by Pub. L. 94–63, title IX, §922, July 29, 1975, 89 Stat. 359.

§296g. Prohibition against discrimination by schools on basis of sex

The Secretary may not make a grant, loan guarantee, or interest subsidy payment under this subchapter to, or for the benefit of, any school of nursing unless the application for the grant, loan guarantee, or interest subsidy payment contains assurances satisfactory to the Secretary that the school will not discriminate on the basis of sex in the admission of individuals to its training programs. The Secretary may not enter into a contract under this subchapter with any school unless the school furnishes assurances satisfactory to the Secretary that it will not discriminate on the basis of sex in the admission of individuals to its training programs.

(July 1, 1944, ch. 373, title VIII, §809, formerly §845, as added Pub. L. 92–158, §11, Nov. 18, 1971, 85 Stat. 479; renumbered §855, Pub. L. 94–63, title IX, §941(k)(1), July 29, 1975, 89 Stat. 366; renumbered §810, Pub. L. 105–392, title I, §123(6), Nov. 13, 1998, 112 Stat. 3574; renumbered §809, Pub. L. 111–148, title V, §5310(b)(1), Mar. 23, 2010, 124 Stat. 631.)

EDITORIAL NOTES

CODIFICATION

Section was formerly classified to section 298b–2 of this title prior to renumbering by Pub. L. 105–392.

PRIOR PROVISIONS

A prior section 296g, act July 1, 1944, ch. 373, title VIII, §808, as added Aug. 16, 1968, Pub. L. 90–490, title II §212, 82 Stat. 783; amended Nov. 18, 1971, Pub. L. 92–158, §3(a), 85 Stat. 469; July 29, 1975, Pub. L. 94–63, title IX, §902(c), 89 Stat. 354, authorized appropriations for special project grants and contracts and financial distress grants from the fiscal year ending June 30, 1972 through the fiscal year ending June 30, 1975, prior to repeal by Pub. L. 94–63, title IX, §§905, 922, July 29, 1975, 89 Stat. 355, 359, effective July 1, 1975.

A prior section 296h, act July 1, 1944, ch. 373, title VIII, §809, as added Nov. 18, 1971, Pub. L. 92–158, §2(c), 85 Stat. 465, which related to loan guarantees and interest subsidies for construction of training

facilities by nonprofit nursing schools, was renumbered section 805 of act July 1, 1944, by Pub. L. 94–63 and transferred to section 296d of this title.

A prior section 296i, act July 1, 1944, ch. 373, title VIII, §810, as added Nov. 18, 1971, Pub. L. 92–158, §4(b), 85 Stat. 474; amended July 29, 1975, Pub. L. 94–63, title IX, §902(e), 89 Stat. 355, authorized grants for start-up programs for new nurse training programs, and set out prerequisites, etc., prior to repeal by Pub. L. 94–63, title IX, §§905, 931(b), July 29, 1975, 89 Stat. 355, 362, effective July 1, 1975.

PART B—NURSE PRACTITIONERS, NURSE MIDWIVES, NURSE ANESTHETISTS, AND OTHER ADVANCED EDUCATION NURSES

EDITORIAL NOTES

PRIOR PROVISIONS

A prior part B related to assistance to nursing students and consisted of sections 297 to 297n, prior to the general amendment of this subchapter by Pub. L. 105–392.

§296j. Advanced education nursing grants

(a) In general

The Secretary may award grants to and enter into contracts with eligible entities to meet the costs of—

(1) projects that support the enhancement of advanced nursing education and practice; and

(2) traineeships for individuals in advanced nursing education programs.

(b) Definition of advanced education nurses

For purposes of this section, the term "advanced education nurses" means individuals trained in advanced degree programs including individuals in combined R.N./graduate degree programs, post-nursing master's certificate programs, or, in the case of nurse midwives, in certificate programs in existence on the date that is one day prior to November 13, 1998, to serve as nurse practitioners, clinical nurse specialists, nurse midwives, nurse anesthetists, nurse educators, nurse administrators, clinical nurse leaders, or public health nurses, or in other nurse specialties determined by the Secretary to require advanced education.

(c) Authorized nurse practitioner

Nurse practitioner programs eligible for support under this section are educational programs for registered nurses (irrespective of the type of school of nursing in which the nurses received their training) that—

(1) meet guidelines prescribed by the Secretary; and

(2) have as their objective the education of nurses who will upon completion of their studies in such programs, be qualified to effectively provide primary health care, including primary health care in homes and in ambulatory care facilities, long-term care facilities, acute care, and other health care settings.

(d) Authorized nurse-midwifery programs

Midwifery programs that are eligible for support under this section are educational programs that—

(1) have as their objective the education of midwives; and

(2) are accredited by the American College of Nurse-Midwives Accreditation Commission for Midwifery Education.

(e) Authorized nurse anesthesia programs

Nurse anesthesia programs eligible for support under this section are education programs that—

(1) provide registered nurses with full-time anesthetist education; and

(2) are accredited by the Council on Accreditation of Nurse Anesthesia Educational Programs.

(f) Authorized clinical nurse specialist programs

Clinical nurse specialist programs eligible for support under this section are education programs that—

(1) provide registered nurses with full-time clinical nurse specialist education; and

(2) have as their objective the education of clinical nurse specialists who will, upon completion of such a program, be qualified to effectively provide care through the wellness and illness continuum to inpatients and outpatients experiencing acute and chronic illness.

(g) Other authorized educational programs

The Secretary shall prescribe guidelines as appropriate for other advanced nurse education programs eligible for support under this section.

(h) Traineeships

(1) In general

The Secretary may not award a grant to an applicant under subsection (a) unless the applicant involved agrees that traineeships provided with the grant will only pay all or part of the costs of—

(A) the tuition, books, and fees of the program of advanced nurse education with respect to which the traineeship is provided; and

(B) the reasonable living expenses of the individual during the period for which the traineeship is provided.

(2) Special consideration

In making awards of grants and contracts under subsection (a)(2), the Secretary shall give special consideration to an eligible entity that agrees to expend the award to train advanced education nurses who will practice in health professional shortage areas designated under section 254e of this title.

(July 1, 1944, ch. 373, title VIII, §811, as added Pub. L. 105–392, title I, §123(4), Nov. 13, 1998, 112 Stat. 3566; amended Pub. L. 111–148, title V, §5308, Mar. 23, 2010, 124 Stat. 629; Pub. L. 116–136, div. A, title III, §3404(a)(5), Mar. 27, 2020, 134 Stat. 393.)

EDITORIAL NOTES

PRIOR PROVISIONS

A prior section 296j, act July 1, 1944, ch. 373, title VIII, §815, as added July 29, 1975, Pub. L. 94–63, title IX, §921, 89 Stat. 358; amended Aug. 13, 1981, Pub. L. 97–35, title XXVII, §2752, 95 Stat. 929, set forth provisions relating to authorization, terms and conditions, etc., respecting grants for operational costs or meeting accreditation requirements, prior to repeal by Pub. L. 99–92, §§9(a)(1), 10(a), Aug. 16, 1985, 99 Stat. 400, 402, effective Oct. 1, 1985.

AMENDMENTS

2020—Subsec. (b). Pub. L. 116–136, §3404(a)(5)(A), substituted "R.N./graduate" for "R.N./Master's" and inserted "clinical nurse leaders," after "nurse administrators,".

Subsecs. (f) to (h). Pub. L. 116–136, §3404(a)(5)(B), (C), added subsec. (f) and redesignated former subsecs. (f) and (g) as (g) and (h), respectively.

2010—Subsec. (c). Pub. L. 111–148, §5308(1), struck out "and nurse midwifery programs" after "practitioner" in heading and "and nurse midwifery" after "practitioner" in introductory provisions.

Subsecs. (d), (e). Pub. L. 111–148, §5308(3), (4), added subsec. (d) and redesignated former subsec. (d) as (e). Former subsec. (e) redesignated (f).

Subsec. (f). Pub. L. 111–148, §5308(3), redesignated subsec. (e) as (f). Former subsec. (f) redesignated (g).

Subsec. (f)(2), (3). Pub. L. 111–148, §5308(2), redesignated par. (3) as (2) and struck out former par. (2). Prior to amendment, text of par. (2) read as follows: "The Secretary may not obligate more than 10 percent of the traineeships under subsection (a) of this section for individuals in doctorate degree programs."

Subsec. (g). Pub. L. 111–148, §5308(3), redesignated subsec. (f) as (g).

§296j–1. Demonstration grants for family nurse practitioner training programs

(a) Establishment of program

The Secretary of Health and Human Services (referred to in this section as the "Secretary") shall establish a training demonstration program for family nurse practitioners (referred to in this section as the "program") to employ and provide 1-year training for nurse practitioners who have graduated from a nurse practitioner program for careers as primary care providers in Federally qualified health centers (referred to in this section as "FQHCs") and nurse-managed health clinics (referred to in this section as "NMHCs").

(b) Purpose

The purpose of the program is to enable each grant recipient to—

(1) provide new nurse practitioners with clinical training to enable them to serve as primary care providers in FQHCs and NMHCs;

(2) train new nurse practitioners to work under a model of primary care that is consistent with the principles set forth by the Institute of Medicine and the needs of vulnerable populations; and

(3) create a model of FQHC and NMHC training for nurse practitioners that may be replicated nationwide.

(c) Grants

The Secretary shall award 3-year grants to eligible entities that meet the requirements established by the Secretary, for the purpose of operating the nurse practitioner primary care programs described in subsection (a) in such entities.

(d) Eligible entities

To be eligible to receive a grant under this section, an entity shall—

(1)(A) be a FQHC as defined in section 1395x(aa) of this title; or

(B) be a nurse-managed health clinic, as defined in section 330A–1 of the Public Health Service Act [42 U.S.C. 254c–1a] (as added by section 5208 of this Act); [1] and

(2) submit to the Secretary an application at such time, in such manner, and containing such information as the Secretary may require.

(e) Priority in awarding grants

In awarding grants under this section, the Secretary shall give priority to eligible entities that—

(1) demonstrate sufficient infrastructure in size, scope, and capacity to undertake the requisite training of a minimum of 3 nurse practitioners per year, and to provide to each awardee 12 full months of full-time, paid employment and benefits consistent with the benefits offered to other full-time employees of such entity;

(2) will assign not less than 1 staff nurse practitioner or physician to each of 4 precepted clinics;

(3) will provide to each awardee specialty rotations, including specialty training in prenatal care and women's health, adult and child psychiatry, orthopedics, geriatrics, and at least 3 other high-volume, high-burden specialty areas;

(4) provide sessions on high-volume, high-risk health problems and have a record of training health care professionals in the care of children, older adults, and underserved populations; and

(5) collaborate with other safety net providers, schools, colleges, and universities that provide health professions training.

(f) Eligibility of nurse practitioners

(1) In general

To be eligible for acceptance to a program funded through a grant awarded under this section, an individual shall—

(A) be licensed or eligible for licensure in the State in which the program is located as an advanced practice registered nurse or advanced practice nurse and be eligible or board-certified

as a family nurse practitioner; and

(B) demonstrate commitment to a career as a primary care provider in a FQHC or in a NMHC.

(2) Preference

In selecting awardees under the program, each grant recipient shall give preference to bilingual candidates that meet the requirements described in paragraph (1).

(3) Deferral of certain service

The starting date of required service of individuals in the National Health Service Corps Service program under title II of the Public Health Service Act (42 U.S.C. 202 et seq.) who receive training under this section shall be deferred until the date that is 22 days after the date of completion of the program.

(g) Grant amount

Each grant awarded under this section shall be in an amount not to exceed $600,000 per year. A grant recipient may carry over funds from 1 fiscal year to another without obtaining approval from the Secretary.

(h) Technical assistance grants

The Secretary may award technical assistance grants to 1 or more FQHCs or NMHCs that have demonstrated expertise in establishing a nurse practitioner residency training program. Such technical assistance grants shall be for the purpose of providing technical assistance to other recipients of grants under subsection (c).

(i) Authorization of appropriations

To carry out this section, there is authorized to be appropriated such sums as may be necessary for each of fiscal years 2011 through 2014.

(Pub. L. 111–148, title V, §5316, as added Pub. L. 111–148, title X, §10501(e), Mar. 23, 2010, 124 Stat. 995.)

EDITORIAL NOTES

REFERENCES IN TEXT

This Act, referred to in subsec. (d)(1)(B), is Pub. L. 111–148, Mar. 23, 2010, 124 Stat. 119, known as the Patient Protection and Affordable Care Act. For complete classification of this Act to the Code, see Short Title note set out under section 18001 of this title and Tables.

The Public Health Service Act, referred to in subsec. (f)(3), is act July 1, 1944, ch. 373, 58 Stat. 682. Title II of the Act is classified generally to subchapter I (§201 et seq.) of this chapter. For complete classification of this Act to the Code, see Short Title note set out under section 201 of this title and Tables.

CODIFICATION

Section was enacted as part of the Patient Protection and Affordable Care Act, and not as part of the Public Health Service Act which comprises this chapter.

PRIOR PROVISIONS

Prior sections 296k and 296l were repealed by Pub. L. 105–392, title I, §123(1), Nov. 13, 1998, 112 Stat. 3562.

Section 296k, act July 1, 1944, ch. 373, title VIII, §820, as added Pub. L. 94–63, title IX, §931(a), July 29, 1975, 89 Stat. 359; amended Pub. L. 96–76, title I, §105, Sept. 29, 1979, 93 Stat. 579; Pub. L. 97–35, title XXVII, §2753(a)(1), (b), Aug. 13, 1981, 95 Stat. 929; Pub. L. 99–92, §3, Aug. 16, 1985, 99 Stat. 393; Pub. L. 99–129, title II, §227(a), Oct. 22, 1985, 99 Stat. 547; Pub. L. 100–607, title VII, §§701(a)(2), (b)–(i), 721(b)(1), Nov. 4, 1988, 102 Stat. 3153–3156, 3165; Pub. L. 102–408, title II, §202(a), Oct. 13, 1992, 106 Stat. 2069; Pub. L. 102–531, title III, §313(a)(9), Oct. 27, 1992, 106 Stat. 3507, authorized grants and contracts for special projects.

Section 296l, act July 1, 1944, ch. 373, title VIII, §821, as added Pub. L. 94–63, title IX, §931(a), July 29, 1975, 89 Stat. 361; amended Pub. L. 96–76, title I, §106, Sept. 29, 1979, 93 Stat. 579; Pub. L. 97–35, title

XXVII, §2754, Aug. 13, 1981, 95 Stat. 930; Pub. L. 99–92, §4, Aug. 16, 1985, 99 Stat. 394; Pub. L. 99–129, title II, §227(b), Oct. 22, 1985, 99 Stat. 548; Pub. L. 100–607, title VII, §702, Nov. 4, 1988, 102 Stat. 3157; Pub. L. 102–408, title II, §203, Oct. 13, 1992, 106 Stat. 2072, authorized grants and contracts for advanced nurse education.

[1] *See References in Text note below.*

PART C—INCREASING NURSING WORKFORCE DIVERSITY

EDITORIAL NOTES

PRIOR PROVISIONS

A prior part C set forth general provisions and consisted of sections 298 to 298b–7, prior to the general amendment of this subchapter by Pub. L. 105–392.

§296m. Workforce diversity grants

(a) In general

(1) [1] Authority

The Secretary may award grants to and enter into contracts with eligible entities to meet the costs of special projects to increase nursing education opportunities for individuals who are from disadvantaged backgrounds (including racial and ethnic minorities underrepresented among registered nurses) by providing student scholarships or stipends, stipends for diploma or associate degree nurses to enter a bridge or degree completion program, student scholarships or stipends for accelerated nursing degree programs, pre-entry preparation, advanced education preparation, and retention activities.

(b) Guidance

In carrying out subsection (a), the Secretary shall take into consideration the recommendations of the National Advisory Council on Nurse Education and Practice and consult with nursing associations including the National Coalition of Ethnic Minority Nurse Associations, American [2] Nurses Association, the National League for Nursing, the American Association of Colleges of Nursing, the National Black Nurses Association, the National Association of Hispanic Nurses, the Association of Asian American and Pacific Islander Nurses, the Native American Indian and Alaskan Nurses Association, and the National Council of State Boards of Nursing, and other organizations determined appropriate by the Secretary.

(c) Required information and conditions for award recipients

(1) In general

Recipients of awards under this section may be required, where requested, to report to the Secretary concerning the annual admission, retention, and graduation rates for individuals from disadvantaged backgrounds and ethnic and racial minorities in the school or schools involved in the projects.

(2) Falling rates

If any of the rates reported under paragraph (1) fall below the average of the two previous years, the grant or contract recipient shall provide the Secretary with plans for immediately improving such rates.

(3) Ineligibility

A recipient described in paragraph (2) shall be ineligible for continued funding under this

section if the plan of the recipient fails to improve the rates within the 1-year period beginning on the date such plan is implemented.

(July 1, 1944, ch. 373, title VIII, §821, as added Pub. L. 105–392, title I, §123(4), Nov. 13, 1998, 112 Stat. 3568; amended Pub. L. 111–148, title V, §5404, Mar. 23, 2010, 124 Stat. 649.)

EDITORIAL NOTES

PRIOR PROVISIONS

A prior section 296m, act July 1, 1944, ch. 373, title VIII, §822, as added Pub. L. 94–63, title IX, §931(a), July 29, 1975, 89 Stat. 361; amended Pub. L. 95–83, title III, §307(o)(5)(A), Aug. 1, 1977, 91 Stat. 393; Pub. L. 96–76, title I, §107, Sept. 29, 1979, 93 Stat. 579; Pub. L. 97–35, title XXVII, §2755, Aug. 13, 1981, 95 Stat. 930; Pub. L. 99–92, §5, Aug. 16, 1985, 99 Stat. 394; Pub. L. 99–129, title II, §227(c), Oct. 22, 1985, 99 Stat. 548; Pub. L. 100–607, title VII, §703, Nov. 4, 1988, 102 Stat. 3157; Pub. L. 101–93, §5(q), Aug. 16, 1989, 103 Stat. 614; Pub. L. 101–597, title IV, §401(b)[(a)], Nov. 16, 1990, 104 Stat. 3035; Pub. L. 102–408, title II, §204, Oct. 13, 1992, 106 Stat. 2072, authorized grants and contracts for nurse practitioner and nurse midwife programs, prior to repeal by Pub. L. 105–392, title I, §123(1), Nov. 13, 1998, 112 Stat. 3562.

A prior section 821 of act July 1, 1944, was classified to section 296l of this title prior to repeal by Pub. L. 105–392.

AMENDMENTS

2010—Subsec. (a). Pub. L. 111–148, §5404(1), designated existing provisions as par. (1), inserted heading, and substituted "stipends for diploma or associate degree nurses to enter a bridge or degree completion program, student scholarships or stipends for accelerated nursing degree programs, pre-entry preparation, advanced education preparation, and retention activities" for "pre-entry preparation, and retention activities".

Subsec. (b). Pub. L. 111–148, §5404(2), substituted "National Advisory Council on Nurse Education and Practice and consult with nursing associations including the National Coalition of Ethnic Minority Nurse Associations," for "First, Second and Third Invitational Congresses for Minority Nurse Leaders on 'Caring for the Emerging Majority,' in 1992, 1993 and 1997, and consult with nursing associations including the" and inserted ", and other organizations determined appropriate by the Secretary" before period at end.

[1] So in original. No par. (2) has been enacted.

[2] So in original. Probably should be preceded by "the".

PART D—STRENGTHENING CAPACITY FOR BASIC NURSE EDUCATION AND PRACTICE

EDITORIAL NOTES

PRIOR PROVISIONS

A prior part D related to scholarship grants to schools of nursing and consisted of sections 298c to 298c–8, prior to the general amendment of this subchapter by Pub. L. 105–392.

§296p. Nurse education, practice, quality, and retention grants

(a) Education priority areas

The Secretary may award grants to or enter into contracts with eligible entities for—

(1) expanding the enrollment in baccalaureate nursing programs; or

(2) providing education in new technologies, including distance learning methodologies.

(b) Practice priority areas

The Secretary may award grants to or enter into contracts with eligible entities for—

(1) establishing or expanding nursing practice arrangements in noninstitutional settings to demonstrate methods to improve access to primary health care in medically underserved communities;

(2) providing care for underserved populations and high risk groups, such as the elderly, individuals with HIV/AIDS, individuals with mental health or substance use disorders, individuals who are homeless, and survivors of domestic violence;

(3) providing coordinated care, and other skills needed to practice in existing and emerging organized health care systems; or

(4) developing cultural competencies among nurses.

(c) Retention priority areas

The Secretary may award grants to and enter into contracts with eligible entities to enhance the nursing workforce by initiating and maintaining nurse retention programs pursuant to paragraph (1) or (2).

(1) Grants for career ladder programs

The Secretary may award grants to and enter into contracts with eligible entities for programs—

(A) to promote career advancement for—

(i) nursing in a variety of training settings, cross training or specialty training among diverse population groups, and the advancement of individuals including to become professional registered nurses, advanced practice registered nurses, and nurses with graduate nursing education; and

(ii) individuals including licensed practical nurses, licensed vocational nurses, certified nurse assistants, home health aides, diploma degree or associate degree nurses, and other health professionals, such as health aides or community health practitioners certified under the Community Health Aide Program of the Indian Health Service, to become registered nurses with baccalaureate degrees or nurses with graduate nursing education;

(B) to assist individuals in obtaining education and training required to enter the nursing profession and advance within such profession, such as by providing career counseling and mentoring; and

(C) developing and implementing internships, accredited fellowships, and accredited residency programs in collaboration with one or more accredited schools of nursing, to encourage the mentoring and development of specialties.

(2) Enhancing patient care delivery systems

(A) Grants

The Secretary may award grants to eligible entities to improve the retention of nurses and enhance patient care that is directly related to nursing activities by enhancing collaboration and communication among nurses and other health care professionals, and by promoting nurse involvement in the organizational and clinical decisionmaking processes of a health care facility.

(B) Preference

In making awards of grants under this paragraph, the Secretary shall give a preference to applicants that have not previously received an award under this paragraph.

(C) Continuation of an award

The Secretary shall make continuation of any award under this paragraph beyond the second year of such award contingent on the recipient of such award having demonstrated to the Secretary measurable and substantive improvement in nurse retention or patient care.

(d) Other priority areas

The Secretary may award grants to or enter into contracts with eligible entities to address other areas that are of high priority to nurse education, practice, and retention, as determined by the

Secretary.

(e) Report

As part of the report on nursing workforce programs described in section 296e(i) of this title, the Secretary shall include a report on the grants awarded and the contracts entered into under this section. Each such report shall identify the overall number of such grants and contracts and provide an explanation of why each such grant or contract will meet the priority need of the nursing workforce.

(f) Eligible entity

For purposes of this section, the term "eligible entity" includes an accredited school of nursing, as defined in section 296(2) of this title, a health care facility, including federally qualified health centers or nurse-managed health clinics, or a partnership of such a school and facility a health care facility, or a partnership of such a school and facility.[1]

(July 1, 1944, ch. 373, title VIII, §831, as added Pub. L. 105–392, title I, §123(4), Nov. 13, 1998, 112 Stat. 3568; amended Pub. L. 107–205, title II, §201, Aug. 1, 2002, 116 Stat. 815; Pub. L. 111–148, title V, §5309(a), Mar. 23, 2010, 124 Stat. 629; Pub. L. 116–136, div. A, title III, §3404(a)(6), Mar. 27, 2020, 134 Stat. 393.)

EDITORIAL NOTES

PRIOR PROVISIONS

A prior section 831 of act July 1, 1944, was classified to section 297–1 of this title prior to repeal by Pub. L. 105–392.

AMENDMENTS

2020—Pub. L. 116–136, §3404(a)(6)(A), substituted "quality, and retention grants" for "and quality grants" in section catchline.

Subsec. (b)(2). Pub. L. 116–136, §3404(a)(6)(B), substituted "high risk groups, such as the elderly, individuals with HIV/AIDS, individuals with mental health or substance use disorders, individuals who are homeless, and survivors" for "other high-risk groups such as the elderly, individuals with HIV/AIDS, substance abusers, the homeless, and victims".

Subsec. (c)(1)(A). Pub. L. 116–136, §3404(a)(6)(C)(i)(I), substituted "advancement for—" for "advancement for nursing personnel" and inserted "(i) nursing" before "in a variety".

Subsec. (c)(1)(A)(i). Pub. L. 116–136, §3404(a)(6)(C)(i)(II), substituted "professional registered nurses, advanced practice registered nurses, and nurses with graduate nursing education" for "professional nurses, advanced education nurses, licensed practical nurses, certified nurse assistants, and home health aides".

Subsec. (c)(1)(A)(ii). Pub. L. 116–136, §3404(a)(6)(C)(i)(III), added cl. (ii).

Subsec. (c)(1)(C). Pub. L. 116–136, §3404(a)(6)(C)(ii), (iii), added subpar. (C).

Subsec. (e). Pub. L. 116–136, §3404(a)(6)(F), substituted "As part of the report on nursing workforce programs described in section 296e(i) of this title, the Secretary shall include" for "The Secretary shall submit to the Congress before the end of each fiscal year".

Pub. L. 116–136, §3404(a)(6)(D), (E), redesignated subsec. (f) as (e) and struck out former subsec. (e). Prior to amendment, text of subsec. (e) read as follows: "For purposes of any amount of funds appropriated to carry out this section for fiscal year 2003, 2004, or 2005 that is in excess of the amount of funds appropriated to carry out this section for fiscal year 2002, the Secretary shall give preference to awarding grants or entering into contracts under subsections (a)(2) and (c)."

Subsec. (f). Pub. L. 116–136, §3404(a)(6)(G), substituted "an accredited school of nursing, as defined in section 296(2) of this title, a health care facility, including federally qualified health centers or nurse-managed health clinics, or a partnership of such a school and facility" for "a school of nursing, as defined in section 296(2) of this title,,".

Pub. L. 116–136, §3404(a)(6)(E), redesignated subsec. (g) as (f). Former subsec. (f) redesignated (e).

Subsec. (g). Pub. L. 116–136, §3404(a)(6)(E), redesignated subsec. (g) as (f).

Subsec. (h). Pub. L. 116–136, §3404(a)(6)(D), struck out subsec. (h). Text read as follows: "There are authorized to be appropriated to carry out this section such sums as may be necessary for each of fiscal years 2010 through 2014."

2010—Pub. L. 111–148, §5309(a)(1), substituted "quality" for "retention" in section catchline.

Subsec. (a). Pub. L. 111–148, §5309(a)(2), in par. (1), inserted "or" at end, redesignated par. (3) as (2), and struck out former par. (2) which read as follows: "developing and implementing internship and residency programs to encourage mentoring and the development of specialties; or".

Subsec. (b)(3). Pub. L. 111–148, §5309(a)(3), substituted "coordinated care" for "managed care, quality improvement".

Subsec. (g). Pub. L. 111–148, §5309(a)(4), inserted ", as defined in section 296(2) of this title," after "school of nursing".

Subsec. (h). Pub. L. 111–148, §5309(a)(5), substituted "2010 through 2014" for "2003 through 2007".

2002—Pub. L. 107–205 amended section catchline and text generally. Prior to amendment, text read as follows:

"(a) IN GENERAL.—The Secretary may award grants to and enter into contracts with eligible entities for projects to strengthen capacity for basic nurse education and practice.

"(b) PRIORITY AREAS.—In awarding grants or contracts under this section the Secretary shall give priority to entities that will use amounts provided under such a grant or contract to enhance the educational mix and utilization of the basic nursing workforce by strengthening programs that provide basic nurse education, such as through—

"(1) establishing or expanding nursing practice arrangements in noninstitutional settings to demonstrate methods to improve access to primary health care in medically underserved communities;

"(2) providing care for underserved populations and other high-risk groups such as the elderly, individuals with HIV-AIDS, substance abusers, the homeless, and victims of domestic violence;

"(3) providing managed care, quality improvement, and other skills needed to practice in existing and emerging organized health care systems;

"(4) developing cultural competencies among nurses;

"(5) expanding the enrollment in baccalaureate nursing programs;

"(6) promoting career mobility for nursing personnel in a variety of training settings and cross training or specialty training among diverse population groups;

"(7) providing education in informatics, including distance learning methodologies; or

"(8) other priority areas as determined by the Secretary."

[1] *So in original.*

§296p–1. Repealed. Pub. L. 116–136, div. A, title III, §3404(a)(7), Mar. 27, 2020, 134 Stat. 394

Section, act July 1, 1944, ch. 373, title VIII, §831A, as added Pub. L. 111–148, title V, §5309(b), Mar. 23, 2010, 124 Stat. 630, authorized the Secretary to award nurse retention grants to eligible entities.

Prior sections 296r, 297, and 297–1 were repealed by Pub. L. 105–392, title I, §123(1), Nov. 13, 1998, 112 Stat. 3562.

Section 296r, act July 1, 1944, ch. 373, title VIII, §827, as added Pub. L. 100–607, title VII, §701(a)(3), Nov. 4, 1988, 102 Stat. 3153; amended Pub. L. 102–408, title II, §205, Oct. 13, 1992, 106 Stat. 2073, authorized grants and contracts for special projects to increase nursing education opportunities for individuals from disadvantaged backgrounds.

Section 297, act July 1, 1944, ch. 373, title VIII, §830, formerly §821, as added Pub. L. 88–581, §2, Sept. 4, 1964, 78 Stat. 913; amended Pub. L. 90–490, title II, §221, Aug. 16, 1968, 82 Stat. 783; Pub. L. 92–52, §5, July 9, 1971, 85 Stat. 145; Pub. L. 92–158, §§5, 13, Nov. 18, 1971, 85 Stat. 475, 480; renumbered §830 and amended Pub. L. 94–63, title IX, §§935, 941(g)(2), July 29, 1975, 89 Stat. 362, 365; Pub. L. 94–484, title IX, §901, Oct. 12, 1976, 90 Stat. 2323; Pub. L. 95–83, title III, §307(o)(5)(B), Aug. 1, 1977, 91 Stat. 394; Pub. L. 96–76, title I, §108, Sept. 29, 1979, 93 Stat. 579; Pub. L. 97–35, title XXVII, §2756, Aug. 13, 1981, 95 Stat. 931; Pub. L. 99–92, §6, Aug. 16, 1985, 99 Stat. 395; Pub. L. 100–607, title VII, §711, Nov. 4, 1988, 102 Stat. 3159; Pub. L. 102–408, title II, §206, Oct. 13, 1992, 106 Stat. 2073; Pub. L. 103–43, title XX, §2014(f), June 10, 1993, 107 Stat. 217, authorized grants for traineeships for advanced education of professional nurses.

Section 297–1, act July 1, 1944, ch. 373, title VIII, §831, as added Pub. L. 96–76, title I, §111, Sept. 29, 1979, 93 Stat. 580; amended Pub. L. 97–414, §8(l), Jan. 4, 1983, 96 Stat. 2061; Pub. L. 99–92, §7, Aug. 16, 1985, 99 Stat. 396; Pub. L. 100–607, title VII, §712, Nov. 4, 1988, 102 Stat. 3160; Pub. L. 102–408, title II, §207, Oct. 13, 1992, 106 Stat. 2074, authorized grants for training of nurse anesthetists.

PART E—STUDENT LOANS

EDITORIAL NOTES

CODIFICATION

Pub. L. 105–392, title I, §123(2), Nov. 13, 1998, 112 Stat. 3562, redesignated subpart II of part B as part E.
Pub. L. 94–63, title IX, §941(g)(3), July 29, 1975, 89 Stat. 365, inserted subpart II heading.

§297a. Student loan fund

(a) Agreements to establish and operate fund authorized

The Secretary is authorized to enter into an agreement for the establishment and operation of a student loan fund in accordance with this part with any public or nonprofit private school of nursing which is located in a State.

(b) Provisions of agreements

Each agreement entered into under this section shall—

(1) provide for establishment of a student loan fund by the school;

(2) provide for deposit in the fund, except as provided in section 298d of this title, of (A) the Federal capital contributions paid from allotments under section 297d of this title to the school by the Secretary, (B) an additional amount from other sources equal to not less than one-ninth of such Federal capital contributions, (C) collections of principal and interest on loans made from the fund, (D) collections pursuant to section 297b(f) of this title, and (E) any other earnings of the fund;

(3) provide that the fund, except as provided in section 298d of this title, shall be used only for loans to students of the school in accordance with the agreement and for costs of collection of such loans and interest thereon;

(4) provide that loans may be made from such fund only to students pursuing a full-time or half-time course of study at the school leading to a baccalaureate or associate degree in nursing or an equivalent degree or a diploma in nursing, or to a graduate degree in nursing; and

(5) contain such other provisions as are necessary to protect the financial interests of the United States.

(c) Regulatory standards applicable to collection of loans

(1) Any standard established by the Secretary by regulation for the collection by schools of nursing of loans made pursuant to loan agreements under this part shall provide that the failure of any such school to collect such loans shall be measured in accordance with this subsection. With respect to the student loan fund established pursuant to such agreements, this subsection may not be construed to require such schools to reimburse such loan fund for loans that became uncollectable prior to 1983.

(2) The measurement of a school's failure to collect loans made under this part shall be the ratio (stated as a percentage) that the defaulted principal amount outstanding of such school bears to the matured loans of such school.

(3) For purposes of this subsection—

(A) the term "default" means the failure of a borrower of a loan made under this part to—

(i) make an installment payment when due; or

(ii) comply with any other term of the promissory note for such loan,

except that a loan made under this part shall not be considered to be in default if the loan is discharged in bankruptcy or if the school reasonably concludes from written contacts with the borrower that the borrower intends to repay the loan;

(B) the term "defaulted principal amount outstanding" means the total amount borrowed from the loan fund of a school that has reached the repayment stage (minus any principal amount repaid or cancelled) on loans—

(i) repayable monthly and in default for at least 120 days; and

(ii) repayable less frequently than monthly and in default for at least 180 days;

(C) the term "grace period" means the period of nine months beginning on the date on which the borrower ceases to pursue a full-time or half-time course of study at a school of nursing; and

(D) the term "matured loans" means the total principal amount of all loans made by a school of nursing under this part minus the total principal amount of loans made by such school to students who are—

(i) enrolled in a full-time or half-time course of study at such school; or

(ii) in their grace period.

(July 1, 1944, ch. 373, title VIII, §835, formerly §822, as added Pub. L. 88–581, §2, Sept. 4, 1964, 78 Stat. 913; amended Pub. L. 90–490, title II, §222(a), (c)(2), Aug. 16, 1968, 82 Stat. 783, 784; Pub. L. 92–158, §6(d)(3), (e), Nov. 18, 1971, 85 Stat. 478; Pub. L. 93–385, §3(b), Aug. 23, 1974, 88 Stat. 741; renumbered §835 and amended Pub. L. 94–63, title IX, §§936(a), 941(h)(1)–(3), (i)(1), (2), July 29, 1975, 89 Stat. 362, 365, 366; Pub. L. 96–76, title I, §109(a), Sept. 29, 1979, 93 Stat. 579; Pub. L. 97–35, title XXVII, §2757(a), Aug. 13, 1981, 95 Stat. 931; Pub. L. 99–92, §8(a), Aug. 16, 1985, 99 Stat. 397; Pub. L. 99–129, title II, §209(j)(2), Oct. 22, 1985, 99 Stat. 536; Pub. L. 100–607, title VII, §713(a), Nov. 4, 1988, 102 Stat. 3160; Pub. L. 111–148, title V, §5310(b)(2), (6), Mar. 23, 2010, 124 Stat. 631.)

EDITORIAL NOTES

AMENDMENTS

2010—Subsec. (a). Pub. L. 111–148, §5310(b)(2), substituted "this part" for "this subpart".

Subsec. (b). Pub. L. 111–148, §5310(b)(6), substituted "298d" for "297h" in pars. (2) and (3).

Subsec. (c). Pub. L. 111–148, §5310(b)(2), substituted "this part" for "this subpart" wherever appearing.

1988—Subsec. (c)(1). Pub. L. 100–607 inserted provisions relating to reimbursement of student loan fund for certain uncollectable loans.

1985—Subsec. (c). Pub. L. 99–92 added subsec. (c).

Subsec. (c)(3)(C). Pub. L. 99–129, §209(j)(2)(A), substituted provisions defining "grace period" as the period of nine months beginning on the date on which the borrower ceases to pursue a full-time or half-time course of study at a school of nursing for former provisions defining "grace period" as the period of one year beginning on (i) the date on which the borrower ceased to pursue a full-time or half-time course of study at a school of nursing; or (ii) the date on which ended any period described in clause (A) or (B) of section 297b(b)(2) of this title which was applicable to such borrower, whichever was later.

Subsec. (c)(3)(D)(ii). Pub. L. 99–129, §209(j)(2)(B), struck out "first" before "grace period."

1981—Subsec. (b)(4). Pub. L. 97–35 struck out provisions respecting prohibition on loans to students attending school before Oct. 1, 1980.

1979—Subsec. (b)(4). Pub. L. 96–76 substituted "1980" for "1978".

1975—Subsec. (a). Pub. L. 94–63, §941(h)(1), (2), substituted "subpart" for "part" and struck out "of Health, Education, and Welfare" after "Secretary".

Subsec. (b). Pub. L. 94–63, §§936(a), 941(h)(3), (i)(2), in cl. (2) substituted "from allotments under section 297d of this title" for "under this part", in cl. (4) substituted "October 1, 1978" for "July 1, 1975", and in cls. (2) and (3) substituted references to sections 836 and 841 of the Act for references to sections 823 and 829, which had previously been translated as sections 297b and 297h of this title, respectively, requiring no further translations in the text as a result of the renumbering of the Public Health Service Act.

1974—Subsec. (b)(4). Pub. L. 93–385 substituted "1975" for "1974".

1971—Subsec. (b)(4). Pub. L. 92–158 substituted "full-time or half-time course of study" for "full-time course of study" and "1974" for "1971".

1968—Subsec. (b)(2). Pub. L. 90–490, §222(a)(1), (c)(2), inserted ", except as provided in section 297h of this title," after "fund" where first appearing and added cl. (D) and redesignated former cl. (D) as (E), respectively.

Subsec. (b)(3). Pub. L. 90–490, §222(a)(1), inserted ", except as provided in section 297h of this title" after "fund" where first appearing and authorized the cancellation of an additional 50 per centum of a nursery student loan.

Subsec. (b)(4). Pub. L. 90–490, §222(a)(2), substituted "1971" for "1969".

STATUTORY NOTES AND RELATED SUBSIDIARIES

EFFECTIVE DATE OF 1985 AMENDMENTS

Amendment by Pub. L. 99–129 effective June 30, 1984, see section 228(b)(5) of Pub. L. 99–129, set out as a note under section 254l of this title.

Pub. L. 99–92, §10, Aug. 16, 1985, 99 Stat. 402, provided that:

"(a) Except as provided in subsection (b), this Act [enacting section 297i of this title, transferring section 296c to section 298b–5 of this title, amending this section, sections 296k, 296l, 296m, 297, 297–1, 297b, 297d, 297e, 298, 298b, and 298b–5 of this title, sections 1332, 1333, 1336, and 1341 of Title 15, Commerce and Trade, and section 6103 of Title 26, Internal Revenue Code, repealing sections 296 to 296b, 296d to 296f, 296j, 297h, and 297j of this title, and enacting provisions set out as notes under sections 201 and 298b–5 of this title and section 1333 of Title 15] and the amendments and repeals made by this Act shall take effect on October 1, 1985.

"(b)(1) The provisions of section 9(c) of this Act [transferring section 296c of this title to section 298b–5 of this title, amending section 298b–5 of this title, and enacting provisions set out as notes under section 298b–5 of this title] and the amendment made by paragraph (1) of such section shall take effect on the date of enactment of this Act [Aug. 16, 1985].

"(2) The amendment made by section 8(a) of this Act [amending section 297a of this title] shall take effect June 30, 1984."

EFFECTIVE DATE OF 1975 AMENDMENT

Pub. L. 94–63, title IX, §905, July 29, 1975, 89 Stat. 355, provided that: "Except as may otherwise be specifically provided, the amendments made by this part [part B (§§905–937) of title IX of Pub. L. 94–63, enacting sections 296j to 296m of this title, amending sections 296, 296a, 296d, 296e, 297 to 297c, 297e, and 297j of this title, repealing sections 296d, 296g, 296i, 297f, and 298c–7 of this title, and enacting provisions set out as notes under sections 296, 296a, 296d, 296e, 296m, 297, 297b, and 297f of this title] shall take effect July 1, 1975. The amendments made by this part to provisions of title VIII of the Public Health Service Act [42 U.S.C. 296 et seq.] (hereinafter in this part referred to as the 'Act') are made to such provisions as amended by part A of this title [amending sections 296, 296d, 296e, 296g, 296i, 297j, and 298c–7 of this title]."

Pub. L. 94–63, title IX, §942, July 29, 1975, 89 Stat. 367, provided that: "The amendments made by section 941 [enacting section 298b–3 of this title, amending sections 296a to 296d, 296f, 297a to 297e, 297g to 297k, 298, and 298b of this title, and repealing section 298c–8 of this title] shall take effect July 1, 1975. Except as otherwise specifically provided, the amendments made by section 941 to provisions of title VIII of the Act [42 U.S.C. 296 et seq.] are made to such provisions as in effect July 1, 1975, and as amended by part B of this title [see note set out above]."

EFFECTIVE DATE OF 1968 AMENDMENT

Amendment by section 222(c)(2) of Pub. L. 90–490 applicable with respect to loans made after June 30, 1969, see section 222(i) of Pub. L. 90–490, set out as a note under section 297b of this title.

§297b. Loan provisions

(a) Maximum amount per individual per year; preference to first year students

The total of the loans for any academic year (or its equivalent, as determined under regulations of the Secretary) made by schools of nursing from loan funds established pursuant to agreements under this part may not exceed $3,300 in the case of any student, except that for the final two academic years of the program involved, such total may not exceed $5,200. The aggregate of the loans for all years from such funds may not exceed $17,000 in the case of any student during fiscal years 2010 and 2011. After fiscal year 2011, such amounts shall be adjusted to provide for a cost-of-attendance increase for the yearly loan rate and the aggregate of the loans. In the granting of such loans, a school

shall give preference to licensed practical nurses, to persons with exceptional financial need, and to persons who enter as first-year students after enactment of this subchapter.

(b) Terms and conditions

Loans from any such student loan fund by any school shall be made on such terms and conditions as the school may determine; subject, however, to such conditions, limitations, and requirements as the Secretary may prescribe (by regulation or in the agreement with the school) with a view to preventing impairment of the capital of such fund to the maximum extent practicable in the light of the objective of enabling the student to complete his course of study; and except that—

(1) such a loan may be made only to a student who (A) is in need of the amount of the loan to pursue a full-time or half-time course of study at the school leading to a baccalaureate or associate degree in nursing or an equivalent degree, or a diploma in nursing, or a graduate degree in nursing, (B) is capable, in the opinion of the school, of maintaining good standing in such course of study, and (C) with respect to any student enrolling in the school after June 30, 2000, is of financial need (as defined in regulations issued by the Secretary);; [1]

(2) such a loan shall be repayable in equal or graduated periodic installments (with the right of the borrower to accelerate repayment) over the ten-year period which begins nine months after the student ceases to pursue a full-time or half-time course of study at a school of nursing, excluding from such 10-year period all (A) periods (up to three years) of (i) active duty performed by the borrower as a member of a uniformed service, or (ii) service as a volunteer under the Peace Corps Act [22 U.S.C. 2501 et seq.], (B) periods (up to ten years) during which the borrower is pursuing a full-time or half-time course of study at a collegiate school of nursing leading to baccalaureate degree in nursing or an equivalent degree, or to graduate degree in nursing, or is otherwise pursuing advanced professional training in nursing (or training to be a nurse anesthetist), and (C) such additional periods under the terms of paragraph (8) of this subsection;

(3) in the case of a student who received such a loan before September 29, 1995, an amount up to 85 per centum of any such loan made before such date (plus interest thereon) shall be canceled for full-time employment as a professional nurse (including teaching in any of the fields of nurse training and service as an administrator, supervisor, or consultant in any of the fields of nursing) in any public or nonprofit private agency, institution, or organization (including neighborhood health centers), at the rate of 15 per centum of the amount of such loan (plus interest) unpaid on the first day of such service for each of the first, second, and third complete year of such service, and 20 per centum of such amount (plus interest) for each complete fourth and fifth year of such service;

(4) the liability to repay the unpaid balance of such loan and accrued interest thereon shall be canceled upon the death of the borrower, or if the Secretary determines that he has become permanently and totally disabled;

(5) such a loan shall bear interest on the unpaid balance of the loan, computed only for periods during which the loan is repayable, at the rate of 5 percent per annum;

(6) such a loan shall be made without security or endorsement, except that if the borrower is a minor and the note or other evidence of obligation executed by him would not, under the applicable law, create a binding obligation, either security or endorsement may be required;

(7) no note or other evidence of any such loan may be transferred or assigned by the school making the loan except that, if the borrower transfers to another school participating in the program under this part such note or other evidence of a loan may be transferred to such other school; and

(8) pursuant to uniform criteria established by the Secretary, the repayment period established under paragraph (2) for any student borrower who during the repayment period failed to make consecutive payments and who, during the last 12 months of the repayment period, has made at least 12 consecutive payments may be extended for a period not to exceed 10 years.

(c) Cancellation

Where all or any part of a loan, or interest, is canceled under this section, the Secretary shall pay to the school an amount equal to the school's proportionate share of the canceled portion, as determined by the Secretary.

(d) Installments

Any loan for any year by a school from a student loan fund established pursuant to an agreement under this part shall be made in such installments as may be provided in regulations of the Secretary or such agreement and, upon notice to the Secretary by the school that any recipient of a loan is failing to maintain satisfactory standing, any or all further installments of his loan shall be withheld, as may be appropriate.

(e) Availability to eligible students in need

An agreement under this part with any school shall include provisions designed to make loans from the student loan fund established thereunder reasonably available (to the extent of the available funds in such fund) to all eligible students in the school in need thereof.

(f) Penalty for late payment

Subject to regulations of the Secretary and in accordance with this section, a school shall assess a charge with respect to a loan from the loan fund established pursuant to an agreement under this part for failure of the borrower to pay all or any part of an installment when it is due and, in the case of a borrower who is entitled to deferment of the loan under subsection (b)(2) or cancellation of part or all of the loan under subsection (b)(3), for any failure to file timely and satisfactory evidence of such entitlement. No such charge may be made if the payment of such installment or the filing of such evidence is made within 60 days after the date on which such installment or filing is due. The amount of any such charge may not exceed an amount equal to 6 percent of the amount of such installment. The school may elect to add the amount of any such charge to the principal amount of the loan as of the first day after the day on which such installment or evidence was due, or to make the amount of the charge payable to the school not later than the due date of the next installment after receipt by the borrower of notice of the assessment of the charge.

(g) Minimum monthly repayment

A school may provide in accordance with regulations of the Secretary, that during the repayment period of a loan from a loan fund established pursuant to an agreement under this part payments of principal and interest by the borrower with respect to all the outstanding loans made to him from loan funds so established shall be at a rate equal to not less than $40 per month.

(h) Loan cancellation

Notwithstanding the amendment made by section 6(b) of the Nurse Training Act of 1971 to this section—

(A) any person who obtained one or more loans from a loan fund established under this part, who before November 18, 1971, became eligible for cancellation of all or part of such loans (including accrued interest) under this section (as in effect on the day before such date), and who on such date was not engaged in a service for which loan cancellation was authorized under this section (as so in effect), may at any time elect to receive such cancellation in accordance with this subsection (as so in effect); and

(B) in the case of any person who obtained one or more loans from a loan fund established under this part and who on such date was engaged in a service for which cancellation of all or part of such loans (including accrued interest) was authorized under this section (as so in effect), this section (as so in effect) shall continue to apply to such person for purposes of providing such loan cancellation until he terminates such service.

(i) Loan repayment

Upon application by a person who received, and is under an obligation to repay, any loan made to such person as a nursing student, the Secretary may undertake to repay (without liability to the applicant) all or any part of such loan, and any interest or portion thereof outstanding thereon, upon his determination, pursuant to regulations establishing criteria therefor, that the applicant—

(1) failed to complete the nursing studies with respect to which such loan was made;

(2) is in exceptionally needy circumstances; and

(3) has not resumed, or cannot reasonably be expected to resume, such nursing studies within

two years following the date upon which the applicant terminated the studies with respect to which such loan was made.

(j) Collection by Secretary of loan in default; preconditions and procedures applicable

The Secretary is authorized to attempt to collect any loan which was made under this part, which is in default, and which was referred to the Secretary by a school of nursing with which the Secretary has an agreement under this part, on behalf of that school under such terms and conditions as the Secretary may prescribe (including reimbursement from the school's student loan fund for expenses the Secretary may reasonably incur in attempting collection), but only if the school has complied with such requirements as the Secretary may specify by regulation with respect to the collection of loans under this part. A loan so referred shall be treated as a debt subject to section 5514 of title 5. Amounts collected shall be deposited in the school's student loan fund. Whenever the Secretary desires the institution of a civil action regarding any such loan, the Secretary shall refer the matter to the Attorney General for appropriate action.

(k) Elimination of statute of limitation for loan collections

(1) Purpose

It is the purpose of this subsection to ensure that obligations to repay loans under this section are enforced without regard to any Federal or State statutory, regulatory, or administrative limitation on the period within which debts may be enforced.

(2) Prohibition

Notwithstanding any other provision of Federal or State law, no limitation shall terminate the period within which suit may be filed, a judgment may be enforced, or an offset, garnishment, or other action may be initiated or taken by a school of nursing that has an agreement with the Secretary pursuant to section 297a of this title that is seeking the repayment of the amount due from a borrower on a loan made under this part after the default of the borrower on such loan.

(July 1, 1944, ch. 373, title VIII, §836, formerly §823, as added Pub. L. 88–581, §2, Sept. 4, 1964, 78 Stat. 914; amended Pub. L. 89–290, §4(g)(2), Oct. 22, 1965, 79 Stat. 1058; Pub. L. 90–490, title II, §222(b), (c)(1), Aug. 16, 1968, 82 Stat. 783, 784; Pub. L. 92–158, §6(a), (b)(1), (e), Nov. 18, 1971, 85 Stat. 475, 476, 478; renumbered §836 and amended Pub. L. 94–63, title IX, §§936(b), 941(h)(1), (2), (5), (i)(1), July 29, 1975, 89 Stat. 363, 365; Pub. L. 96–76, title I, §112, Sept. 29, 1979, 93 Stat. 580; Pub. L. 97–35, title XXVII, §2757(b), Aug. 13, 1981, 95 Stat. 931; Pub. L. 99–92, §8(b)–(d), Aug. 16, 1985, 99 Stat. 398; Pub. L. 100–607, title VII, §§713(b)–(g), 714(a)–(c), Nov. 4, 1988, 102 Stat. 3160, 3161; Pub. L. 101–93, §5(r), Aug. 16, 1989, 103 Stat. 614; Pub. L. 102–408, title II, §211(a)(1), Oct. 13, 1992, 106 Stat. 2078; Pub. L. 105–392, title I, §133(a)–(c)(1), Nov. 13, 1998, 112 Stat. 3575; Pub. L. 111–148, title V, §§5202, 5310(b)(2)–(4), Mar. 23, 2010, 124 Stat. 607, 631.)

EDITORIAL NOTES

REFERENCES IN TEXT

The Peace Corps Act, referred to in subsec. (b)(2), is Pub. L. 87–293, Sept. 22, 1961, 75 Stat. 612, which is classified principally to chapter 34 (§2501 et seq.) of Title 22, Foreign Relations and Intercourse. For complete classification of this Act to the Code, see Short Title note set out under section 2501 of Title 22 and Tables.

Section 6(b) of the Nurse Training Act of 1971, referred to in subsec. (h), is section 6(b) of Pub. L. 92–158, Nov. 18, 1971, 85 Stat. 477. Section 6(b)(1) amended subsec. (b)(3) of this section, added former subsec. (h) of this section, and enacted the provisions editorially classified to subsec. (i) [now (h)] of this section. Section 6(b)(2) enacted section 297i of this title which was transferred and redesignated as subsec. (j) [now (i)] of this section pursuant to section 941(h)(5) of Pub. L. 94–63.

CODIFICATION

Provisions of subsec. (h) of this section were, in the original, enacted by section 6(b)(1) of Pub. L. 92–158, without directory language with respect to classification in the Code and were editorially set out as subsec. (i)

[now (h)] as the probable intent of Congress.

AMENDMENTS

2010—Subsec. (a). Pub. L. 111–148, §5310(b)(2), substituted "this part" for "this subpart".

Pub. L. 111–148, §5202(a), substituted "$3,300" for "$2,500", "$5,200" for "$4,000", and "$17,000 in the case of any student during fiscal years 2010 and 2011. After fiscal year 2011, such amounts shall be adjusted to provide for a cost-of-attendance increase for the yearly loan rate and the aggregate of the loans." for "$13,000 in the case of any student."

Subsec. (b)(1)(C). Pub. L. 111–148, §5202(b)(1), substituted "2000" for "1986".

Subsec. (b)(3). Pub. L. 111–148, §5202(b)(2), substituted "September 29, 1995" for "September 29, 1979".

Subsecs. (b)(7), (d) to (g). Pub. L. 111–148, §5310(b)(2), substituted "this part" for "this subpart".

Subsec. (h). Pub. L. 111–148, §5310(b)(3), struck out concluding provisions which read as follows: "Nothing in this subsection shall be construed to prevent any person from entering into an agreement for loan cancellation under subsection (h) of this section (as amended by section 6(b)(2) of the Nurse Training Act of 1971)."

Pub. L. 111–148, §5310(b)(2), substituted "this part" for "this subpart" in two places.

Subsec. (j). Pub. L. 111–148, §5310(b)(2), substituted "this part" for "this subpart" wherever appearing.

Subsecs. (k), (l). Pub. L. 111–148, §5310(b)(4), redesignated subsec. (l) as (k).

Subsec. (l)(2). Pub. L. 111–148, §5310(b)(2), substituted "this part" for "this subpart".

1998—Subsec. (b)(1). Pub. L. 105–392, §133(a)(1), substituted semicolon for period at end.

Subsec. (b)(2)(C). Pub. L. 105–392, §133(a)(2), added subpar. (C).

Subsec. (b)(8). Pub. L. 105–392, §133(a)(3), (4), added par. (8).

Subsec. (g). Pub. L. 105–392, §133(b), substituted "$40" for "$15".

Subsec. (l). Pub. L. 105–392, §133(c)(1), added subsec. (l).

1992—Subsecs. (h) to (k). Pub. L. 102–408 redesignated subsecs. (i) to (k) as (h) to (j), respectively, and struck out former subsec. (h) which provided for a loan repayment program. See section 297n of this title.

1989—Subsec. (h)(6)(C). Pub. L. 101–93 substituted "means a skilled nursing facility, as such term is defined in section 1395x(j) of this title, and an intermediate care facility, as such term is defined in section 1396d(c) of this title" for "means an intermediate care facility and a skilled nursing facility, as such terms are defined in subsections (c) and (i), respectively, of section 1396d of this title".

1988—Subsec. (a). Pub. L. 100–607, §713(b), (c), inserted in first sentence ", except that for the final two academic years of the program involved, such total may not exceed $4,000", substituted "$13,000" for "$10,000" in second sentence, and inserted ", to persons with exceptional financial need," after "nurses" in third sentence.

Subsec. (b)(1)(C). Pub. L. 100–607, §713(d), amended subpar. (C) generally. Prior to amendment, subpar. (C) read as follows: "if a student who will enroll in the school after June 30, 1986, is of exceptional financial need (as defined by regulations of the Secretary)".

Subsec. (b)(2)(B). Pub. L. 100–607, §713(e), substituted "ten" for "five" and inserted "or half-time" after "a full-time".

Subsec. (b)(5). Pub. L. 100–607, §713(f), substituted "5 percent" for "6 per centum".

Subsec. (h)(1)(C). Pub. L. 100–607, §714(a), amended subpar. (C) generally. Prior to amendment, subpar. (C) read as follows: "who enters into an agreement with the Secretary to serve as a nurse for a period of at least two years in an area in a State determined by the Secretary, after consultation with the appropriate State health authority (as determined by the Secretary by regulations), to have a shortage of and need for nurses;".

Subsecs. (h)(5), (6). Pub. L. 100–607, §714(b), (c), added pars. (5) and (6).

Subsec. (j)(2) to (4). Pub. L. 100–607, §713(g), redesignated par. (4) as (3) and struck out former par. (3) which related to low-income or disadvantaged family.

1985—Subsec. (b)(1). Pub. L. 99–92, §8(b), which directed that cl. (C) be inserted before period, was executed by inserting cl. (C) before the semicolon as the probable intent of Congress.

Subsec. (f). Pub. L. 99–92, §8(c), substituted "the Secretary and in accordance with this section, a school shall" for "the Secretary, a school may", and substituted provisions relating to charges not allowed in certain cases and allowed where payment is late for provisions relating to maximum amount of late charges.

Subsec. (k). Pub. L. 99–92, §8(d), added subsec. (k).

1981—Subsec. (b)(5). Pub. L. 97–35 substituted "6" for "3".

1979—Subsec. (b)(3). Pub. L. 96–76 inserted provisions requiring conditions to be applicable to loans arising prior to Sept. 29, 1979.

1975—Subsec. (a). Pub. L. 94–63, §941(h)(1), substituted "subpart" for "part".

Subsec. (b). Pub. L. 94–63, §941(h)(2), struck out "of Health, Education, and Welfare" after "Secretary".

Subsec. (b)(2)(B). Pub. L. 94–63, §936(b), inserted "(or training to be a nurse anesthetist)" after "professional training in nursing".

Subsec. (b)(7). Pub. L. 94–63, §941(h)(1), substituted "subpart" for "part".

Subsec. (c). Pub. L. 94–63, §941(h)(2), struck out "of Health, Education, and Welfare" after "Secretary".

Subsecs. (d) to (i). Pub. L. 94–63, §941(h)(1), substituted "subpart" for "part" whenever appearing.

Subsec. (j). Pub. L. 94–63, §941(h)(5), added subsec. (j), formerly classified as section 297i of this title pursuant to enactment as section 830 of act July 1, 1944, ch. 373. Section 941(h)(5)(A) of Pub. L. 94–63 transferred such former section to this section and section 941(h)(5)(B) redesignated provision as subsec. (j).

1971—Subsec. (a). Pub. L. 92–158, §6(a), substituted "$2,500" for "$1,500" and "$10,000" for "$60,000".

Subsec. (b)(1). Pub. L. 92–158, §6(e), substituted "full-time or half-time course of study" for "full-time course of study".

Subsec. (b)(2). Pub. L. 92–158, §6(e), in text preceding cl. (A), substituted "full-time or half-time course of study" for "full-time course of study".

Subsec. (b)(3). Pub. L. 92–158, §6(b)(1)(A), substituted provisions cancelling up to 85 per centum of loan, for provisions cancelling up to 50 per centum of loan, where borrower holds full-time employment as a professional nurse, added to areas of possible employment under this par. by inserting reference to any public or nonprofit organization including neighborhood health centers, substituted, with regard to the rate of cancellation of loan, the rate of 15 per centum of the amount unpaid on the first day of service, continuing at such rate with each of the first, second and third complete years of such service and 20 per centum of such amount with each complete fourth and fifth year of service for the rate of 10 per centum of the amount unpaid on the first day of service and to continue with each complete year of service, and struck out reference to 15 per centum rate of cancellation per complete year of service plus, for the purpose of such higher rate, the cancellation of an additional 50 per centum of such loan where such service is in a public or nonprofit hospital in any area which is determined, in accordance with the regulations of the Secretary, to be in an area having a substantial shortage of such nurses at such hospitals.

Subsec. (h). Pub. L. 92–158, §6(b)(1)(B), added subsec. (h).

1968—Subsec. (a). Pub. L. 90–490, §222(b)(1), increased limitation on amount of annual loans per student from $1,000 to $1,500, required preferences in granting of loans to licensed practical nurses, and limited aggregate of loans for all years to any one student to $6,000.

Subsec. (b)(2). Pub. L. 90–490, §222(b)(2), provided for commencement of repayment nine months, rather than one year, after student ceases to pursue full-time course of study, excluded from ten-year repayment period periods (up to three years) of active duty as member of a uniformed service or Peace Corps volunteer service and periods (up to five years) as undergraduate or graduate degree student in nursing, including advanced professional training in nursing, and struck out prohibition against accrual of interest on loans.

Subsec. (b)(3). Pub. L. 90–490, §222(b)(3), authorized cancellation of an additional 50 per centum of a nursing student loan (plus interest) at rate of 15 per centum for each complete year of service in a public or other nonprofit hospital in an area with a substantial shortage of nurses.

Subsec. (b)(5). Pub. L. 90–490, §222(b)(4), struck out provisions for an interest rate which is the greater of 3 per centum or the going Federal rate at time loan is made, defining going Federal rate, and making rate determined for first loan applicable to any subsequent loan.

Subsecs. (f), (g). Pub. L. 90–490, §222(c)(1), added subsecs. (f) and (g).

1965—Subsec. (b)(5). Pub. L. 89–290 applied rate of interest for first loan obtained by a student from a loan fund established under this part to any subsequent loan to such student from such fund during his course of study.

STATUTORY NOTES AND RELATED SUBSIDIARIES

EFFECTIVE DATE OF 1998 AMENDMENT

Pub. L. 105–392, title I, §133(c)(2), Nov. 13, 1998, 112 Stat. 3576, provided that: "The amendment made by paragraph (1) [amending this section] shall be effective with respect to actions pending on or after the date of enactment of this Act [Nov. 13, 1998]."

EFFECTIVE DATE OF 1985 AMENDMENT

Amendment by Pub. L. 99–92 effective Oct. 1, 1985, see section 10(a) of Pub. L. 99–92, set out as a note under section 297a of this title.

EFFECTIVE DATE OF 1975 AMENDMENT

Pub. L. 94–63, title IX, §936(b), July 29, 1975, 89 Stat. 363, provided that the amendment made by that

section is effective with respect to periods of training to be a nurse anesthetist undertaken on or after July 29, 1975.

Amendment by section 941(h)(1), (2), (5), (i)(1) of Pub. L. 94–63 effective July 1, 1975, see section 942 of Pub. L. 94–63, set out as a note under section 297a of this title.

EFFECTIVE DATE OF 1971 AMENDMENT

Pub. L. 92–158, §6(a)(1), Nov. 18, 1971, 85 Stat. 475, provided that the amendment made by that section is effective with respect to academic years (or their equivalent as determined under regulations of the Secretary of Health, Education, and Welfare under this section) beginning after June 30, 1971.

EFFECTIVE DATE OF 1968 AMENDMENT

Pub. L. 90–490, title II, §222(i), Aug. 16, 1968, 82 Stat. 785, provided that: "The amendments made by subsection (b)(1) and (2) [amending this section] shall apply with respect to all loans made after June 30, 1969, and with respect to loans made from a student loan fund established under an agreement pursuant to section 822 [now 835] [42 U.S.C. 297a], before July 1, 1969, to the extent agreed to by the school which made the loans and the Secretary (but then only for years beginning after June 30, 1968). The amendments made by subsection (b)(4) [amending this section] and subsection (c) [amending this section and section 297a of this title] shall apply with respect to loans made after June 30, 1969. The amendment made by subsection (h) [enacting section 297h of this title] shall apply with respect to appropriations for fiscal years beginning after June 30, 1969. The amendment made by subsection (b)(3) [amending this section] shall apply with respect to service, specified in section 823(b)(3) [now 836(b)(3)] of such Act [42 U.S.C. 297b(b)(3)] performed during academic years beginning after the enactment of this Act, whether the loan was made before or after such enactment [Aug. 16, 1968]."

CONSTRUCTION OF 1992 AMENDMENT

Pub. L. 102–408, title II, §211(b), Oct. 13, 1992, 106 Stat. 2079, provided that: "With respect to section 836(h) of the Public Health Service Act [former 42 U.S.C. 297b(h)], as in effect prior to the date of the enactment of this Act [Oct. 13, 1992], any agreement entered into under such section that is in effect on the day before such date remains in effect in accordance with the terms of the agreement, notwithstanding the amendment made by subsection (a) of this section [enacting section 297n of this title, amending this section, and repealing section 297c–1 of this title]."

[1] *So in original.*

§297c. Repealed. Pub. L. 105–392, title I, §123(3), Nov. 13, 1998, 112 Stat. 3562

Section, act July 1, 1944, ch. 373, title VIII, §837, formerly §824, as added Pub. L. 88–581, §2, Sept. 4, 1964, 78 Stat. 915; amended Pub. L. 89–751, §6(b), Nov. 3, 1966, 80 Stat. 1235; Pub. L. 90–490, title II, §222(d), Aug. 16, 1968, 82 Stat. 784; Pub. L. 92–52, §3(a), July 9, 1971, 85 Stat. 144; Pub. L. 92–158, §6(c), Nov. 18, 1971, 85 Stat. 477; Pub. L. 93–385, §3(a), Aug. 23, 1974, 88 Stat. 741; renumbered §837 and amended Pub. L. 94–63, title IX, §§936(c), 941(i)(1), (3), July 29, 1975, 89 Stat. 363, 365, 366; Pub. L. 96–76, title I, §109(b), Sept. 29, 1979, 93 Stat. 580; Pub. L. 97–35, title XXVII, §2757(c), Aug. 13, 1981, 95 Stat. 931, authorized appropriations for student loan funds for certain fiscal years.

§297c–1. Repealed. Pub. L. 102–408, title II, §211(a)(2), Oct. 13, 1992, 106 Stat. 2078

Section, act July 1, 1944, ch. 373, title VIII, §837A, as added Nov. 4, 1988, Pub. L. 100–607, title VII, §714(d), 102 Stat. 3162, authorized appropriations for educational loan repayments for service in certain health facilities.

§297d. Allotments and payments of Federal capital contributions

(a) Application for allotment; reduction or adjustment of amount requested in application; reallotment; continued availability of funds

(1) The Secretary shall from time to time set dates by which schools of nursing must file applications for Federal capital contributions.

(2)(A) If the total of the amounts requested for any fiscal year in such applications exceeds the total amount appropriated under section 297c [1] of this title for that fiscal year, the allotment from such total amount to the loan fund of each school of nursing shall be reduced to whichever of the following is the smaller:

(i) The amount requested in its application.

(ii) An amount which bears the same ratio to the total amount appropriated as the number of students estimated by the Secretary to be enrolled on a full-time basis in such school during such fiscal year bears to the estimated total number of students enrolled in all such schools on a full-time basis during such year.

(B) Amounts remaining after allotment under subparagraph (A) shall be reallotted in accordance with clause (ii) of such subparagraph among schools whose applications requested more than the amounts so allotted to their loan funds, but with such adjustments as may be necessary to prevent the total allotted to any such school's loan fund under this paragraph and paragraph (3) from exceeding the total so requested by it.

(3) Funds which, pursuant to section 297e(c) of this title or pursuant to a loan agreement under section 297a of this title are returned to the Secretary in any fiscal year, shall be available for allotment until expended. Funds described in the preceding sentence shall be allotted among schools of nursing in such manner as the Secretary determines will best carry out this part.

(b) Installment payment of allotments

Allotments to a loan fund of a school shall be paid to it from time to time in such installments as the Secretary determines will not result in unnecessary accumulations in the loan fund at such school.

(c) Manner of payment

The Federal capital contributions to a loan fund of a school under this part shall be paid to it from time to time in such installments as the Secretary determines will not result in unnecessary accumulations in the loan fund at such school.

(July 1, 1944, ch. 373, title VIII, §838, formerly §825, as added Pub. L. 88–581, §2, Sept. 4, 1964, 78 Stat. 915; amended Pub. L. 89–751, §6(c), Nov. 3, 1966, 80 Stat. 1235; Pub. L. 90–490, title II, §222(e), Aug. 16, 1968, 82 Stat. 785; renumbered §838 and amended Pub. L. 94–63, title IX, §941(h)(1), (2), (4)(A), (i)(1), (4), July 29, 1975, 89 Stat. 365, 366; Pub. L. 99–92, §8(e), Aug. 16, 1985, 99 Stat. 398; Pub. L. 100–607, title VII, §713(h)(1), Nov. 4, 1988, 102 Stat. 3161; Pub. L. 102–408, title II, §208(a), Oct. 13, 1992, 106 Stat. 2075; Pub. L. 111–148, title V, §5310(b)(2), Mar. 23, 2010, 124 Stat. 631.)

EDITORIAL NOTES

REFERENCES IN TEXT

Section 297c of this title, referred to in subsec. (a)(2)(A), was repealed by Pub. L. 105–392, title I, §123(3), Nov. 13, 1998, 112 Stat. 3562.

AMENDMENTS

2010—Subsecs. (a)(3), (c). Pub. L. 111–148 substituted "this part" for "this subpart".

1992—Subsec. (a)(3). Pub. L. 102–408 struck out "(A)" after "(3)", substituted "available for allotment until expended." for "available for allotment in such fiscal year and in the fiscal year succeeding the fiscal year." and "this subpart." for "this subpart, except that in making such allotments, the Secretary shall give priority to schools of nursing which established student loan funds under this subpart after September 30, 1975.", and struck out subpar. (B) which read as follows: "With respect to funds available pursuant to subparagraph (A), any such funds returned to the Secretary and not allotted by the Secretary, during the period of availability specified in such subparagraph, shall be available to carry out section 297j of this title and, for such purpose, shall remain available until expended."

1988—Subsec. (a)(3). Pub. L. 100–607 designated existing provisions as subpar. (A) and added subpar. (B).

1985—Subsec. (a). Pub. L. 99–92 amended subsec. (a) generally, substituting provisions relating to application for allotment, reduction or adjustment of amount requested in application, reallotment, and availability of funds for allotment during fiscal years for provisions relating to determination of amount of allotment.

Subsec. (b). Pub. L. 99–92 amended subsec. (b) generally, substituting provisions relating to payment to a loan fund of a school of allotments for provisions relating to application for allotment, adjustment or reduction of amount requested in application, and reallotment.

1975—Subsec. (a). Pub. L. 94–63, §941(h)(1), (4)(A)(i), (i)(4), substituted "subpart" for "part" wherever appearing, struck out "(whether as Federal capital contributions or as loans to schools under section 297f of this title)" before "which are in excess", and substituted references to section 847 of the Act for references to section 824, which had previously been translated as section 297c of this title, requiring no further translations in text as a result of renumbering of the Public Health Service Act.

Subsec. (b)(1). Pub. L. 94–63, §941(h)(4)(A)(ii), struck out ", and for loans pursuant to section 297f of this title," after "contributions".

Subsec. (b)(2). Pub. L. 94–63, §941(h)(2), struck out "of Health, Education, and Welfare" after "Secretary".

Subsec. (c). Pub. L. 94–63, §941(h)(1), substituted "subpart" for "part".

1968—Subsec. (a). Pub. L. 90–490 substituted a new formula for distribution of Federal funds among schools of nursing by providing for allotment of funds among the schools entirely on the basis of their relative enrollments for former provisions which allocated funds among the States, 50 per centum on the basis of relative number of high school graduates, and 50 per centum on the basis of relative number of students enrolled in schools of nursing, and provided for determination of number of persons enrolled in such schools for most recent year for which satisfactory data are available to the Secretary.

1966—Subsec. (a). Pub. L. 89–751, §6(c)(1), authorized allotment of appropriations for payment as Federal capital contributions or as loans to schools under section 297f of this title, and directed that funds available in any fiscal year for payment to schools under this part (whether as Federal capital contributions or as loans to schools under section 297f of this title) which are in excess of the amount appropriated pursuant to section 297c of this title for that year shall be allotted among States and among schools within States in such manner as the Secretary determinates will best carry out the purposes of this part.

Subsec. (b)(1). Pub. L. 89–751, §6(c)(2), substituted "schools of nursing in a State must file applications for Federal capital contributions, and for loans pursuant to section 297f of this title, from the allotment of such State under the first two sentences of subsection (a) of this section" for "schools of nursing with which he has in effect agreements under this part must file applications for Federal capital contributions to their loan funds pursuant to section 297a(b)(2)(A) of this title".

STATUTORY NOTES AND RELATED SUBSIDIARIES

EFFECTIVE DATE OF 1988 AMENDMENT

Pub. L. 100–607, title VII, §713(h)(2), Nov. 4, 1988, 102 Stat. 3161, provided that: "Except as provided in Public Law 100–436 [Sept. 20, 1988, 102 Stat. 1680, see Tables for classification], the amendment made by paragraph (1) [amending this section] shall take effect as if such amendment had been effective on September 30, 1988, and as if section 843 of the Public Health Service Act [42 U.S.C. 297j], as added by section 715 of this title, had been effective on such date."

EFFECTIVE DATE OF 1985 AMENDMENT

Amendment by Pub. L. 99–92 effective Oct. 1, 1985, see section 10(a) of Pub. L. 99–92, set out as a note under section 297a of this title.

EFFECTIVE DATE OF 1975 AMENDMENT

Amendment by Pub. L. 94–63 effective July 1, 1975, see section 942 of Pub. L. 94–63, set out as a note under section 297a of this title.

EFFECTIVE DATE OF 1966 AMENDMENT

Pub. L. 89–751, §6(e)(1), Nov. 3, 1966, 80 Stat. 1236, provided that: "The amendments made by this section [amending this section and sections 297c, 297e, and 297f of this title] shall be effective in the case of

payments to student loan funds made after the enactment of this Act [Nov. 3, 1966], except in the case of payments pursuant to commitments (made prior to enactment of this Act) to make loans under section 827 of the Public Health Service Act [42 U.S.C. 297f] as in effect prior to the enactment of this Act."

APPLICABILITY OF REORG. PLAN NO. 3 OF 1966

Pub. L. 89–751, §9, Nov. 3, 1966, 80 Stat. 1240, provided that: "The amendments made by this Act [enacting former sections 295h to 295h–5 and 298c to 298c–8 of this title and amending this section, former sections 292b, 294d, 294n to 294p, 296, and 297c, section 297e, former section 297f, and section 298 of this title, and section 1717 of Title 12, Banks and Banking] shall be subject to the provisions of Reorganization Plan Numbered 3 of 1966 [42 U.S.C. 202 note]."

[1] *See References in Text note below.*

§297e. Distribution of assets from loan funds

(a) Capital distribution of balance of loan fund

If a school terminates a loan fund established under an agreement pursuant to section 297a(b) of this title, or if the Secretary for good cause terminates the agreement with the school, there shall be a capital distribution as follows:

(1) The Secretary shall first be paid an amount which bears the same ratio to such balance in such fund on the date of termination of the fund as the total amount of the Federal capital contributions to such fund by the Secretary pursuant to section 297a(b)(2)(A) of this title bears to the total amount in such fund derived from such Federal capital contributions and from funds deposited therein pursuant to section 297a(b)(2)(B) of this title.

(2) The remainder of such balance shall be paid to the school.

(b) Payment of principal or interest on loans

If a capital distribution is made under subsection (a), the school involved shall, after such capital distribution, pay to the Secretary, not less often than quarterly, the same proportionate share of amounts received by the school in payment of principal or interest on loans made from the loan fund established under section 297a(b) of this title as determined by the Secretary under subsection (a).

(c) Payment of balance of loan fund

(1) Within 90 days after the termination of any agreement with a school under section 297a of this title or the termination in any other manner of a school's participation in the loan program under this part,[1] such school shall pay to the Secretary from the balance of the loan fund of such school established under section 297a of this title, an amount which bears the same ratio to the balance in such fund on the date of such termination as the total amount of the Federal capital contributions to such fund by the Secretary pursuant to section 297a(b)(2)(A) of this title bears to the total amount in such fund on such date derived from such Federal capital contributions and from funds deposited in the fund pursuant to section 297a(b)(2)(B) of this title. The remainder of such balance shall be paid to the school.

(2) A school to which paragraph (1) applies shall pay to the Secretary after the date on which payment is made under such paragraph and not less than quarterly, the same proportionate share of amounts received by the school after the date of termination referred to in paragraph (1) in payment of principal or interest on loans made from the loan fund as was determined for the Secretary under such paragraph.

(July 1, 1944, ch. 373, title VIII, §839, formerly §826, as added Pub. L. 88–581, §2, Sept. 4, 1964, 78 Stat. 916; amended Pub. L. 89–751, §6(d), Nov. 3, 1966, 80 Stat. 1235; Pub. L. 90–490, title II, §222(f), Aug. 16, 1968, 82 Stat. 785; Pub. L. 92–52, §3(b), July 9, 1971, 85 Stat. 145; Pub. L. 92–158, §6(d)(1), Nov. 18, 1971, 85 Stat. 478; renumbered §839 and amended Pub. L. 94–63, title IX, §§936(d), 941(h)(1), (2), (4)(B), (i)(1), (5), July 29, 1975, 89 Stat. 363, 365, 366; Pub. L. 96–32, §7(j), July 10, 1979, 93 Stat. 84; Pub. L. 96–76, title I, §109(c), Sept. 29, 1979, 93 Stat. 580; Pub. L.

97–35, title XXVII, §2757(d), Aug. 13, 1981, 95 Stat. 931; Pub. L. 99–92, §8(f), Aug. 16, 1985, 99 Stat. 399; Pub. L. 100–607, title VII, §713(i), Nov. 4, 1988, 102 Stat. 3161; Pub. L. 102–408, title II, §208(b), Oct. 13, 1992, 106 Stat. 2075; Pub. L. 105–392, title I, §133(e), Nov. 13, 1998, 112 Stat. 3577; Pub. L. 111–148, title V, §5310(b)(5), Mar. 23, 2010, 124 Stat. 631.)

EDITORIAL NOTES

REFERENCES IN TEXT

This part, referred to in subsec. (c)(1), was in the original "this subpart" and was translated to reflect the probable intent of Congress and the redesignation of subpart II of part B of this subchapter as part E of this subchapter by Pub. L. 105–392, title I, §123(2), Nov. 13, 1998, 112 Stat. 3562.

AMENDMENTS

2010—Pub. L. 111–148 made technical amendment to section and subsec. (a) designations resulting in no change in text.

1998—Subsec. (a). Pub. L. 105–392, §133(e)(1)(A), added introductory provisions and struck out former introductory provisions which read as follows: "After September 30, 1996, and not later than December 31, 1999, there shall be a capital distribution of the balance of the loan fund established under an agreement pursuant to section 297a of this title by each school as follows:".

Subsec. (a)(1). Pub. L. 105–392, §133(e)(1)(B), substituted "on the date of termination of the fund" for "at the close of September 30, 1999,".

Subsec. (b). Pub. L. 105–392, §133(e)(2), amended subsec. (b) generally. Prior to amendment, subsec. (b) read as follows: "After December 31, 1999, each school with which the Secretary has made an agreement under this subpart shall pay to the Secretary, not less often than quarterly, the same proportionate share of amounts received by the school after September 30, 1999, in payment of principal or interest on loans made from the loan fund established pursuant to such agreement as was determined for the Secretary under subsection (a) of this section."

1992—Subsec. (a). Pub. L. 102–408, §208(b)(2), substituted "1999" for "1994" in introductory provisions and in par. (1).

Pub. L. 102–408, §208(b)(1), substituted "1996" for "1991" in introductory provisions.

Subsec. (b). Pub. L. 102–408, §208(b)(2), substituted "1999" for "1994" in two places.

1988—Subsec. (a). Pub. L. 100–607, §713(i)(1)(A), which directed substitution of "1994" for "1991" in text preceding par. (1), was executed by making the substitution for "1991" the second time appearing to reflect the probable intent of Congress.

Subsec. (a)(1). Pub. L. 100–607, §713(i)(1)(B), substituted "1994" for "1991".

Subsec. (b). Pub. L. 100–607, §713(i)(2), substituted "1994" for "1991" in two places.

1985—Subsecs. (a), (b). Pub. L. 99–92, §8(f)(1), substituted "1991" for "1987" wherever appearing.

Subsec. (c). Pub. L. 99–92, §8(f)(2), added subsec. (c).

1981—Pub. L. 97–35 substituted "1987" for "1983" wherever appearing.

1979—Subsec. (a). Pub. L. 96–76, §109(c)(1), substituted "September 30, 1983, and not later than December 31, 1983" for "September 30, 1980, and not later than December 31, 1981". Prior to amendment, subsec. (a) referred to "December 31, 1980" rather than to "December 31, 1981" as cited in directory language of Pub. L. 96–76. See below for explanation of amendment by Pub. L. 96–32.

Pub. L. 96–32 substituted "December 31, 1980" for "September 30, 1977".

Subsec. (a)(1). Pub. L. 96–76, §109(c)(2), substituted "1983" for "1980".

Subsec. (b). Pub. L. 96–76, §109(c)(3), substituted "1983" for "1980" wherever appearing.

1975—Subsec. (a). Pub. L. 94–63, §§936(d), 941(h)(2), (i)(5), substituted "September 30, 1980" for "June 30, 1977" wherever appearing, struck out "of Health, Education, and Welfare" after "Secretary", and substituted references to section 835 of the Act for references to section 822, which had previously been translated as section 297a of this title, requiring no further translations in text as a result of renumbering of the Public Health Service Act.

Subsec. (b). Pub. L. 94–63, §§936(d), 941(h)(1), (4)(B), substituted "subpart" for "part", "September 30, 1980" for "June 30, 1977", and "December 31, 1980" for "September 30, 1977" and struck out provisions relating to payments from revolving fund established by section 297f(d) of this title.

1971—Pub. L. 92–158 substituted "1977" for "1975" wherever appearing.

Pub. L. 92–52 substituted "1975" for "1974" wherever appearing.

1968—Pub. L. 90–490 substituted "1974" for "1972" wherever appearing.

1966—Subsec. (a). Pub. L. 89–751, §6(d)(1), (2), substituted "an agreement pursuant to section 297a(b) of this title" for "this part" in opening provisions, and in par. (1) substituted "such balance" for "the balance".

Subsec. (b). Pub. L. 89–751, §6(d)(3), inserted "(other than so much of such fund as relates to payments from the revolving fund established by section 297f(d) of this title)".

STATUTORY NOTES AND RELATED SUBSIDIARIES

EFFECTIVE DATE OF 1985 AMENDMENT

Amendment by Pub. L. 99–92 effective Oct. 1, 1985, see section 10(a) of Pub. L. 99–92, set out as a note under section 297a of this title.

EFFECTIVE DATE OF 1975 AMENDMENT

Amendment by section 936(d) of Pub. L. 94–63 effective July 1, 1975, see section 905 of Pub. L. 94–63, set out as a note under section 297a of this title.

Amendment by section 941(h)(1), (2), (4)(B), (i)(1), (5) of Pub. L. 94–63 effective July 1, 1975, see section 942 of Pub. L. 94–63, set out as a note under section 297a of this title.

EFFECTIVE DATE OF 1966 AMENDMENT

Amendment by Pub. L. 89–751 effective in the case of payments to student loan funds made after Nov. 3, 1966, except in the case of payments pursuant to commitments (made prior to Nov. 3, 1966) to make loans under section 297f of this title as in effect prior to Nov. 3, 1966, see section 6(e)(1) of Pub. L. 89–751, set out as a note under section 297d of this title.

[1] *See References in Text note below.*

§297f. Repealed. Pub. L. 94–63, title IX, §936(e)(1), July 29, 1975, 89 Stat. 363

Section, act July 1, 1944, ch. 373, title VIII, §827, as added Sept. 4, 1964, Pub. L. 88–581, §2, 78 Stat. 917; amended Nov. 3, 1966, Pub. L. 89–751, §6(a), 80 Stat. 1233; Aug. 16, 1968, Pub. L. 90–490, title II, §222(g), 82 Stat. 785; July 9, 1971, Pub. L. 92–52, §3(c), 85 Stat. 145; Nov. 18, 1971, Pub. L. 92–158, §6(d)(2), 85 Stat. 478, set out provisions relating to terms, conditions, limitations, manner of payment, etc., of loans to schools of nursing to capitalize student loan funds.

STATUTORY NOTES AND RELATED SUBSIDIARIES

EFFECTIVE DATE OF REPEAL

Repeal effective July 1, 1975, see section 905 of Pub. L. 94–63, set out as an Effective Date of 1975 Amendment note under section 297a of this title.

AVAILABILITY OF NURSE TRAINING REVOLVING FUND FOR PAYMENT OF OBLIGATIONS DEPOSITS INTO FUND; TRANSFER OF EXCESS AMOUNTS TO GENERAL FUND OF TREASURY AUTHORIZATION OF APPROPRIATIONS

Pub. L. 94–63, title IX, §936(e)(2), (3), July 29, 1975, 89 Stat. 363, provided that:

"(2) The nurse training fund created within the Treasury by section 827(d)(1) of the Act [42 U.S.C. 297f(d)(1)] shall remain available to the Secretary of Health, Education, and Welfare [now Health and Human Services] for the purpose of meeting his responsibilities respecting participations in obligations acquired under section 827 of the Act [42 U.S.C. 297f]. The Secretary shall continue to deposit in such fund all amounts received by him as interest payments or repayments of principal on loans under such section 27[827]. If at any time the Secretary determines the moneys in the funds exceed the present and any reasonable prospective further requirements of such fund, such excess may be transferred to the general fund of the Treasury.

"(3) There are authorized to be appropriated without fiscal year limitation such sums as may be necessary to enable the Secretary to make payments under agreements entered into under section 827(b) of the Act [42 U.S.C. 297f(b)] before the date of the enactment of this Act [July 29, 1975]."

CONVERSION OF FEDERAL CAPITAL CONTRIBUTION TO A LOAN UNDER SECTION 297F OF THIS TITLE

Pub. L. 89–751, §6(e)(2), Nov. 3, 1966, 80 Stat. 1236, authorized the Secretary of Health, Education, and Welfare to convert a Federal capital contribution to a student loan fund of a particular institution, made under this subchapter, from funds appropriated pursuant thereto for the fiscal year ending June 30, 1967, to a loan under section 297f of this title.

§297g. Modification of agreements; compromise, waiver or release

The Secretary may agree to modifications of agreements made under this part, and may compromise, waive, or release any right, title, claim, or demand of the United States arising or acquired under this part.

(July 1, 1944, ch. 373, title VIII, §840, formerly §828, as added Pub. L. 88–581, §2, Sept. 4, 1964, 78 Stat. 917; renumbered §840 and amended Pub. L. 94–63, title IX, §941(h)(1), (4)(C), (i)(1), July 29, 1975, 89 Stat. 365; Pub. L. 111–148, title V, §5310(b)(2), Mar. 23, 2010, 124 Stat. 631.)

EDITORIAL NOTES

AMENDMENTS

2010—Pub. L. 111–148 substituted "this part" for "this subpart" in two places.

1975—Pub. L. 94–63, §941(h)(1), (4)(C), substituted "subpart" for "part" in two places and struck out "or loans" after "agreements".

STATUTORY NOTES AND RELATED SUBSIDIARIES

EFFECTIVE DATE OF 1975 AMENDMENT

Amendment by Pub. L. 94–63 effective July 1, 1975, see section 942 of Pub. L. 94–63, set out as a note under section 297a of this title.

§297h. Repealed. Pub. L. 99–92, §9(a)(1), Aug. 16, 1985, 99 Stat. 400

Section, act July 1, 1944, ch. 373, title VIII, §841, formerly §829, as added Aug. 16, 1968, Pub. L. 90–490, title II, §222(h), 82 Stat. 785; renumbered §841 and amended July 29, 1975, Pub. L. 94–63, title IX, §941(i)(1), (6), 89 Stat. 365, 366, related to transfers to the scholarship program.

STATUTORY NOTES AND RELATED SUBSIDIARIES

EFFECTIVE DATE OF REPEAL

Repeal effective Oct. 1, 1985, see section 10(a) of Pub. L. 99–92, set out as an Effective Date of 1985 Amendment note under section 297a of this title.

§297i. Procedures for appeal of terminations

In any case in which the Secretary intends to terminate an agreement with a school of nursing under this part, the Secretary shall provide the school with a written notice specifying such intention and stating that the school may request a formal hearing with respect to such termination. If the school requests such a hearing within 30 days after the receipt of such notice, the Secretary shall provide such school with a hearing conducted by an administrative law judge.

(July 1, 1944, ch. 373, title VIII, §842, as added Pub. L. 99–92, §8(g), Aug. 16, 1985, 99 Stat. 399; amended Pub. L. 111–148, title V, §5310(b)(2), Mar. 23, 2010, 124 Stat. 631.)

EDITORIAL NOTES

PRIOR PROVISIONS

A prior section 297i, act July 1, 1944, ch. 373, title VIII, §830, as added Nov. 18, 1971, Pub. L. 92–158, §6(b)(2), 85 Stat. 477, relating to loan forgiveness, was transferred to and redesignated as subsec. (j) of section 823 of act July 1, 1944, which is classified to section 297b of this title, by Pub. L. 94–63, title IX, §941(h)(5), July 29, 1975, 89 Stat. 365.

A prior section 842 of act July 1, 1944, was renumbered section 852, and was classified to section 298a of this title prior to repeal by Pub. L. 105–392.

A prior section 297j, act July 1, 1944, ch. 373, title VIII, §843, as added Nov. 4, 1988, Pub. L. 100–607, title VII, §715, 102 Stat. 3162; amended Nov. 18, 1988, Pub. L. 100–690, title II, §2616(a), 102 Stat. 4240; Aug. 16, 1989, Pub. L. 101–93, §5(s), 103 Stat. 614, provided grant authority for scholarships for undergraduate education of professional nurses, prior to repeal by Pub. L. 102–531, title III, §313(a)(11), (c), Oct. 27, 1992, 106 Stat. 3507, effective immediately after enactment of Pub. L. 102–408, approved Oct. 13, 1992.

A prior section 843 of act July 1, 1944, was renumbered section 853, and was classified to section 298b of this title prior to repeal by Pub. L. 105–392.

Another prior section 297j, act July 1, 1944, ch. 373, title VIII, §845, formerly §860, as added Aug. 16, 1968, Pub. L. 90–490, title II, §223(a), 82 Stat. 785; amended July 9, 1971, Pub. L. 92–52, §4, 85 Stat. 145; Nov. 18, 1971, Pub. L. 92–158, §7, 85 Stat. 478; renumbered §845 and amended July 29, 1975, Pub. L. 94–63, title IX, §§902(f), 937, 941(j)(1), (2), 89 Stat. 355, 363, 366; Sept. 29, 1979, Pub. L. 96–76, title I, §110(a), (b), 93 Stat. 580; Aug. 13, 1981, Pub. L. 97–35, title XXVII, §2758(a), (b), 95 Stat. 932, set forth provisions relating to scholarship grants to schools of nursing, prior to repeal by Pub. L. 99–92, §9(a)(2), Aug. 16, 1985, 99 Stat. 400, eff. Oct. 1, 1985.

A prior section 845 of act July 1, 1944, was renumbered section 855, and was classified to section 298b–2 of this title prior to repeal by Pub. L. 105–392.

A prior section 297k, act July 1, 1944, ch. 373, title VIII, §846, formerly §861, as added Aug. 16, 1968, Pub. L. 90–490, title II, §223(a), 82 Stat. 786; renumbered §846 and amended July 29, 1975, Pub. L. 94–63, title IX, §§941(j)(1), (3), 89 Stat. 366, related to transfers of funds to student loan program, prior to repeal by Pub. L. 97–35, title XXVII, §2758(c), Aug. 13, 1981, 95 Stat. 932.

AMENDMENTS

2010—Pub. L. 111–148 substituted "this part" for "this subpart".

STATUTORY NOTES AND RELATED SUBSIDIARIES

EFFECTIVE DATE

Section effective Oct. 1, 1985, see section 10(a) of Pub. L. 99–92, set out as an Effective Date of 1985 Amendment note under section 297a of this title.

§297n. Loan repayment and scholarship programs

(a) In general

In the case of any individual—

(1) who has received a baccalaureate or associate degree in nursing (or an equivalent degree), a diploma in nursing, or a graduate degree in nursing;

(2) who obtained (A) one or more loans from a loan fund established under subpart II,[1] or (B) any other educational loan for nurse training costs; and

(3) who enters into an agreement with the Secretary to serve as nurse for a period of not less than two years at a health care facility with a critical shortage of nurses, or in a [2] accredited school of nursing, as defined by section 296(2) of this title, as nurse faculty;

the Secretary shall make payments in accordance with subsection (b), for and on behalf of that individual, on the principal of and interest on any loan of that individual described in paragraph (2) of this subsection which is outstanding on the date the individual begins the service specified in the agreement described in paragraph (3) of this subsection.

(b) Manner of payments

The payments described in subsection (a) shall be made by the Secretary as follows:

(1) Upon completion by the individual for whom the payments are to be made of the first year of the service specified in the agreement entered into with the Secretary under subsection (a), the Secretary shall pay 30 percent of the principal of, and the interest on each loan of such individual described in subsection (a)(2) which is outstanding on the date the individual began such practice.

(2) Upon completion by that individual of the second year of such service, the Secretary shall pay another 30 percent of the principal of, and the interest on each such loan.

(3) Upon completion by that individual of a third year of such service, the Secretary shall pay another 25 percent of the principal of, and the interest on each such loan.

(c) Payment by due date

Notwithstanding the requirement of completion of practice specified in subsection (b), the Secretary shall, on or before the due date thereof, pay any loan or loan installment which may fall due within the period of service for which the borrower may receive payments under this subsection, upon the declaration of such borrower, at such times and in such manner as the Secretary may prescribe (and supported by such other evidence as the Secretary may reasonably require), that the borrower is then serving as described by subsection (a)(3), and that the borrower will continue to so serve for the period required (in the absence of this subsection) to entitle the borrower to have made the payments provided by this subsection for such period; except that not more than 85 percent of the principal of any such loan shall be paid pursuant to this subsection.

(d) Scholarship program

(1) In general

The Secretary shall (for fiscal years 2003 and 2004) and may (for fiscal years thereafter) carry out a program of entering into contracts with eligible individuals under which such individuals agree to serve as nurses for a period of not less than 2 years at a health care facility with a critical shortage of nurses, in consideration of the Federal Government agreeing to provide to the individuals scholarships for attendance at schools of nursing.

(2) Eligible individuals

In this subsection, the term "eligible individual" means an individual who is enrolled or accepted for enrollment as a full-time or part-time student in a school of nursing.

(3) Service requirement

(A) In general

The Secretary may not enter into a contract with an eligible individual under this subsection unless the individual agrees to serve as a nurse at a health care facility with a critical shortage of nurses for a period of full-time service of not less than 2 years, or for a period of part-time service in accordance with subparagraph (B).

(B) Part-time service

An individual may complete the period of service described in subparagraph (A) on a part-time basis if the individual has a written agreement that—

(i) is entered into by the facility and the individual and is approved by the Secretary; and

(ii) provides that the period of obligated service will be extended so that the aggregate amount of service performed will equal the amount of service that would be performed through a period of full-time service of not less than 2 years.

(4) Applicability of certain provisions

The provisions of subpart III of part D of subchapter II shall, except as inconsistent with this section, apply to the program established in paragraph (1) in the same manner and to the same extent as such provisions apply to the National Health Service Corps Scholarship Program established in such subpart.

(e) Preferences regarding participants

In entering into agreements under subsection (a) or (d), the Secretary shall give preference to qualified applicants with the greatest financial need.

(f) Condition of agreement

The Secretary may make payments under subsection (a) on behalf of an individual only if the agreement under such subsection provides that section 298b–7(c) [1] of this title is applicable to the individual.

(g) Breach of agreement

(1) In general

In the case of any program under this section under which an individual makes an agreement to provide health services for a period of time in accordance with such program in consideration of receiving an award of Federal funds regarding education as a nurse (including an award for the repayment of loans), the following applies if the agreement provides that this subsection is applicable:

(A) In the case of a program under this section that makes an award of Federal funds for attending an accredited program of nursing (in this section referred to as a "nursing program"), the individual is liable to the Federal Government for the amount of such award (including amounts provided for expenses related to such attendance), and for interest on such amount at the maximum legal prevailing rate, if the individual—

(i) fails to maintain an acceptable level of academic standing in the nursing program (as indicated by the program in accordance with requirements established by the Secretary);

(ii) is dismissed from the nursing program for disciplinary reasons; or

(iii) voluntarily terminates the nursing program.

(B) The individual is liable to the Federal Government for the amount of such award (including amounts provided for expenses related to such attendance), and for interest on such amount at the maximum legal prevailing rate, if the individual fails to provide health services in accordance with the program under this section for the period of time applicable under the program.

(2) Waiver or suspension of liability

In the case of an individual or health facility making an agreement for purposes of paragraph (1), the Secretary shall provide for the waiver or suspension of liability under such subsection if compliance by the individual or the health facility, as the case may be, with the agreements involved is impossible, or would involve extreme hardship to the individual or facility, and if enforcement of the agreements with respect to the individual or facility would be unconscionable.

(3) Date certain for recovery

Subject to paragraph (2), any amount that the Federal Government is entitled to recover under paragraph (1) shall be paid to the United States not later than the expiration of the 3-year period beginning on the date the United States becomes so entitled.

(4) Availability

Amounts recovered under paragraph (1) with respect to a program under this section shall be available for the purposes of such program, and shall remain available for such purposes until expended.

(h) Reports

Not later than 18 months after August 1, 2002, and annually thereafter, the Secretary shall prepare and submit to the Congress a report describing the programs carried out under this section, including statements regarding—

(1) the number of enrollees, scholarships, loan repayments, and grant recipients;

(2) the number of graduates;

(3) the amount of scholarship payments and loan repayments made;

(4) which educational institution the recipients attended;

(5) the number and placement location of the scholarship and loan repayment recipients at health care facilities with a critical shortage of nurses;

(6) the default rate and actions required;

(7) the amount of outstanding default funds of both the scholarship and loan repayment programs;

(8) to the extent that it can be determined, the reason for the default;

(9) the demographics of the individuals participating in the scholarship and loan repayment programs;

(10) justification for the allocation of funds between the scholarship and loan repayment programs; and

(11) an evaluation of the overall costs and benefits of the programs.

(i) Allocations

Of the amounts appropriated under section 298d(b) of this title,,[3] the Secretary may, as determined appropriate by the Secretary, allocate amounts between the program under subsection (a) and the program under subsection (d).

(July 1, 1944, ch. 373, title VIII, §846, as added Pub. L. 102–408, title II, §211(a)(3), Oct. 13, 1992, 106 Stat. 2078; amended Pub. L. 105–392, title I, §133(d), Nov. 13, 1998, 112 Stat. 3576; Pub. L. 107–205, title I, §103, Aug. 1, 2002, 116 Stat. 813; Pub. L. 111–148, title V, §5310(a), Mar. 23, 2010, 124 Stat. 631; Pub. L. 116–136, div. A, title III, §3404(a)(8), Mar. 27, 2020, 134 Stat. 394.)

EDITORIAL NOTES

REFERENCES IN TEXT

Subpart II, referred to in subsec. (a)(2), probably should be "this part" to reflect the redesignation of subpart II of former part B of this subchapter as part E of this subchapter by Pub. L. 105–392, title I, §123(2), Nov. 13, 1998, 112 Stat. 3562.

Section 298b–7(c) of this title, referred to in subsec. (f), was repealed by Pub. L. 105–392, title I, §123(1), Nov. 13, 1998, 112 Stat. 3562.

PRIOR PROVISIONS

A prior section 297n, act July 1, 1944, ch. 373, title VIII, §847, as added Nov. 4, 1988, Pub. L. 100–607, title VII, §716, 102 Stat. 3163; amended Nov. 18, 1988, Pub. L. 100–690, title II, §2616(b), 102 Stat. 4240, established a demonstration program for student loans with respect to service in certain health care facilities in underserved areas, prior to repeal by Pub. L. 102–408, title II, §210, Oct. 13, 1992, 106 Stat. 2078.

A prior section 846 of act July 1, 1944, was classified to section 297k of this title and was repealed by Pub. L. 97–35.

AMENDMENTS

2020—Subsec. (a). Pub. L. 116–136, §3404(a)(8)(A), struck out at end of concluding provisions "After fiscal year 2007, the Secretary may not, pursuant to any agreement entered into under this subsection, assign a nurse to any private entity unless that entity is nonprofit."

Subsec. (b)(1). Pub. L. 116–136, §3404(a)(8)(B), substituted "the individual began such practice" for "he began such practice".

Subsec. (i). Pub. L. 116–136, §3404(a)(8)(C), substituted "Allocations" for "Funding" in heading, struck out par. (1) and par. (2) designation and heading, and substituted "Of the amounts appropriated under section 298d(b) of this title," for "Of the amounts appropriated under paragraph (1)". Prior to amendment, text of par. (1) read as follows: "For the purpose of payments under agreements entered into under subsection (a) or (d), there are authorized to be appropriated such sums as may be necessary for each of fiscal years 2003 through 2007."

2010—Subsec. (a)(3). Pub. L. 111–148 inserted ", or in a accredited school of nursing, as defined by section 296(2) of this title, as nurse faculty" before semicolon at end.

2002—Pub. L. 107–205, §103(b)(1), substituted "Loan repayment and scholarship programs" for "Loan repayment program" in section catchline.

Subsec. (a). Pub. L. 107–205, §103(a)(2), inserted at end of concluding provisions "After fiscal year 2007,

the Secretary may not, pursuant to any agreement entered into under this subsection, assign a nurse to any private entity unless that entity is nonprofit."

Subsec. (a)(3). Pub. L. 107–205, §103(a)(1), substituted "at a health care facility with a critical shortage of nurses" for "in an Indian Health Service health center, in a Native Hawaiian health center, in a public hospital, in a migrant health center, in a community health center, in a rural health clinic, or in a public or nonprofit private health facility determined by the Secretary to have a critical shortage of nurses".

Subsec. (d). Pub. L. 107–205, §103(b)(4), added subsec. (d). Former subsec. (d) redesignated (f).

Subsec. (e). Pub. L. 107–205, §103(c), substituted "under subsection (a) or (d), the Secretary shall give preference to qualified applicants with the greatest financial need." for "under subsection (a), the Secretary shall give preference—

"(1) to qualified applicants with the greatest financial need; and

"(2) to qualified applicants that, with respect to health facilities described in such subsection, agree to serve in such health facilities located in geographic areas with a shortage of and need for nurses, as determined by the Secretary."

Subsec. (f). Pub. L. 107–205, §103(b)(2), (3), redesignated subsec. (d) as (f) and transferred it to appear after subsec. (e). Former subsec. (f) redesignated (h).

Subsec. (g). Pub. L. 107–205, §103(b)(2), (3), redesignated subsec. (h) as (g) and transferred it to appear after subsec. (f). Former subsec. (g) redesignated (i).

Subsec. (h). Pub. L. 107–205, §103(b)(2), (d), redesignated subsec. (f) as (h) and amended it generally. Prior to amendment, text of subsec. read as follows: "For purposes of this section:

"(1) The term 'community health center' has the meaning given such term in section 254c(a) of this title.

"(2) The term 'migrant health center' has the meaning given such term in section 254b(a)(1) of this title.

"(3) The term 'rural health clinic' has the meaning given such term in section 1395x(aa)(2) of this title."

Former subsec. (h) redesignated (g).

Subsec. (i). Pub. L. 107–205, §103(b)(2), (e), redesignated subsec. (g) as (i) and amended it generally. Prior to amendment, text of subsec. read as follows: "For the purpose of payments under agreements entered into under subsection (a) of this section, there are authorized to be appropriated $5,000,000 for fiscal year 1993, and $6,000,000 for fiscal year 1994."

1998—Subsec. (h). Pub. L. 105–392 added subsec. (h).

STATUTORY NOTES AND RELATED SUBSIDIARIES

REFERENCE TO COMMUNITY, MIGRANT, PUBLIC HOUSING, OR HOMELESS HEALTH CENTER CONSIDERED REFERENCE TO HEALTH CENTER

Reference to community health center, migrant health center, public housing health center, or homeless health center considered reference to health center, see section 4(c) of Pub. L. 104–299, set out as a note under section 254b of this title.

[1] See References in Text note below.

[2] So in original. Probably should be "an".

[3] So in original.

§297n–1. Nurse faculty loan program

(a) School of nursing student loan fund

The Secretary, acting through the Administrator of the Health Resources and Services Administration, may enter into an agreement with any accredited school of nursing for the establishment and operation of a student loan fund in accordance with this section, to increase the number of qualified nursing faculty.

(b) Agreements

Each agreement entered into under subsection (a) shall—

(1) provide for the establishment of a student loan fund by the school involved;

(2) provide for deposit in the fund of—

(A) the Federal capital contributions to the fund;

(B) an amount equal to not less than one-ninth of such Federal capital contributions, contributed by such school;

(C) collections of principal and interest on loans made from the fund; and

(D) any other earnings of the fund;

(3) provide that the fund will be used only for loans to students of the school in accordance with subsection (c) and for costs of collection of such loans and interest thereon;

(4) provide that loans may be made from such fund only to students pursuing a full-time course of study or, at the discretion of the Secretary, a part-time course of study in an advanced degree program described in section 296j(b) of this title; and

(5) contain such other provisions as are necessary to protect the financial interests of the United States.

(c) Loan provisions

Loans from any student loan fund established by a school pursuant to an agreement under subsection (a) shall be made to an individual on such terms and conditions as the school may determine, except that—

(1) such terms and conditions are subject to any conditions, limitations, and requirements prescribed by the Secretary;

(2) in the case of any individual, the total of the loans for any academic year made by schools of nursing from loan funds established pursuant to agreements under subsection (a) may not exceed $35,500,[1] during fiscal years 2010 and 2011 fiscal years [2] (after fiscal year 2011, such amounts shall be adjusted to provide for a cost-of-attendance increase for the yearly loan rate and the aggregate loan; [3]

(3) an amount up to 85 percent of any such loan (plus interest thereon) shall be canceled by the school as follows:

(A) upon completion by the individual of each of the first, second, and third year of full-time employment, required by the loan agreement entered into under this subsection, as a faculty member in an accredited a [4] school of nursing, the school shall cancel 20 percent of the principle [5] of, and the interest on, the amount of such loan unpaid on the first day of such employment; and

(B) upon completion by the individual of the fourth year of full-time employment, required by the loan agreement entered into under this subsection, as a faculty member in a school of nursing, the school shall cancel 25 percent of the principle [5] of, and the interest on, the amount of such loan unpaid on the first day of such employment;

(4) such a loan may be used to pay the cost of tuition, fees, books, laboratory expenses, and other reasonable education expenses;

(5) such a loan shall be repayable in equal or graduated periodic installments (with the right of the borrower to accelerate repayment) over the 10-year period that begins 9 months after the individual ceases to pursue a course of study at a school of nursing; and

(6) such a loan shall—

(A) beginning on the date that is 3 months after the individual ceases to pursue a course of study at a school of nursing, bear interest on the unpaid balance of the loan at the rate of 3 percent per annum; or

(B) subject to subsection (e), if the school of nursing determines that the individual will not complete such course of study or serve as a faculty member as required under the loan

agreement under this subsection, bear interest on the unpaid balance of the loan at the prevailing market rate.

(d) Payment of proportionate share

Where all or any part of a loan, or interest, is canceled under this section, the Secretary shall pay to the school an amount equal to the school's proportionate share of the canceled portion, as determined by the Secretary.

(e) Review by Secretary

At the request of the individual involved, the Secretary may review any determination by an accredited school of nursing under subsection (c)(6)(B).

(July 1, 1944, ch. 373, title VIII, §846A, as added Pub. L. 107–205, title II, §203, Aug. 1, 2002, 116 Stat. 817; amended Pub. L. 111–148, title V, §5311(a), Mar. 23, 2010, 124 Stat. 631; Pub. L. 116–136, div. A, title III, §3404(a)(9), Mar. 27, 2020, 134 Stat. 394; Pub. L. 116–260, div. BB, title III, §331(c), Dec. 27, 2020, 134 Stat. 2938.)

EDITORIAL NOTES

AMENDMENTS

2020—Subsec. (f). Pub. L. 116–136, §3404(a)(9), as amended by Pub. L. 116–260, §331(c), struck out subsec. (f). Text read as follows: "There are authorized to be appropriated to carry out this section such sums as may be necessary for each of fiscal years 2010 through 2014."

2010—Subsec. (a). Pub. L. 111–148, §5311(a)(1), substituted "School of nursing student loan fund" for "Establishment" in heading and inserted "accredited" before "school" in text.

Subsec. (c)(2). Pub. L. 111–148, §5311(a)(2)(A), substituted "$35,500, during fiscal years 2010 and 2011 fiscal years (after fiscal year 2011, such amounts shall be adjusted to provide for a cost-of-attendance increase for the yearly loan rate and the aggregate loan;" for "$30,000, plus any amount determined by the Secretary on an annual basis to reflect inflation;".

Subsec. (c)(3)(A). Pub. L. 111–148, §5311(a)(2)(B), inserted "an accredited" before "a school of nursing".

Subsec. (e). Pub. L. 111–148, §5311(a)(3), substituted "an accredited school" for "a school".

Subsec. (f). Pub. L. 111–148, §5311(a)(4), substituted "2010 through 2014" for "2003 through 2007".

STATUTORY NOTES AND RELATED SUBSIDIARIES

EFFECTIVE DATE OF 2020 AMENDMENT

Amendment by Pub. L. 116–260 effective as if included in the enactment of Pub. L. 116–136, see section 331(d) of div. BB of Pub. L. 116–260, set out as a note under section 294c of this title.

[1] So in original. The comma probably should not appear.

[2] So in original.

[3] So in original. A closing parenthesis probably should appear before the semicolon.

[4] So in original. The word "a" probably should not appear.

[5] So in original. Probably should be "principal".

§297*o*. Eligible individual student loan repayment

(a) In general

The Secretary, acting through the Administrator of the Health Resources and Services Administration, may enter into an agreement with eligible individuals for the repayment of education

loans, in accordance with this section, to increase the number of qualified nursing faculty.

(b) Agreements

Each agreement entered into under this subsection shall require that the eligible individual shall serve as a full-time member of the faculty of an accredited school of nursing, for a total period, in the aggregate, of at least 4 years during the 6-year period beginning on the later of—

(1) the date on which the individual receives a master's or doctorate nursing degree from an accredited school of nursing; or

(2) the date on which the individual enters into an agreement under this subsection.

(c) Agreement provisions

Agreements entered into pursuant to subsection (b) shall be entered into on such terms and conditions as the Secretary may determine, except that—

(1) not more than 10 months after the date on which the 6-year period described under subsection (b) begins, but in no case before the individual starts as a full-time member of the faculty of an accredited school of nursing [1] the Secretary shall begin making payments, for and on behalf of that individual, on the outstanding principal of, and interest on, any loan of that individual obtained to pay for such degree;

(2) for an individual who has completed a master's in nursing or equivalent degree in nursing—

(A) payments may not exceed $10,000 per calendar year; and

(B) total payments may not exceed $40,000 during the 2010 and 2011 fiscal years (after fiscal year 2011, such amounts shall be adjusted to provide for a cost-of-attendance increase for the yearly loan rate and the aggregate loan); and

(3) for an individual who has completed a doctorate or equivalent degree in nursing—

(A) payments may not exceed $20,000 per calendar year; and

(B) total payments may not exceed $80,000 during the 2010 and 2011 fiscal years (adjusted for subsequent fiscal years as provided for in the same manner as in paragraph (2)(B)).

(d) Breach of agreement

(1) In general

In the case of any agreement made under subsection (b), the individual is liable to the Federal Government for the total amount paid by the Secretary under such agreement, and for interest on such amount at the maximum legal prevailing rate, if the individual fails to meet the agreement terms required under such subsection.

(2) Waiver or suspension of liability

In the case of an individual making an agreement for purposes of paragraph (1), the Secretary shall provide for the waiver or suspension of liability under such paragraph if compliance by the individual with the agreement involved is impossible or would involve extreme hardship to the individual or if enforcement of the agreement with respect to the individual would be unconscionable.

(3) Date certain for recovery

Subject to paragraph (2), any amount that the Federal Government is entitled to recover under paragraph (1) shall be paid to the United States not later than the expiration of the 3-year period beginning on the date the United States becomes so entitled.

(4) Availability

Amounts recovered under paragraph (1) shall be available to the Secretary for making loan repayments under this section and shall remain available for such purpose until expended.

(e) Eligible individual defined

For purposes of this section, the term "eligible individual" means an individual who—

(1) is a United States citizen, national, or lawful permanent resident;

(2) holds an unencumbered license as a registered nurse; and

(3) has either already completed a master's or doctorate nursing program at an accredited school of nursing or is currently enrolled on a full-time or part-time basis in such a program.

(f) Priority

For the purposes of this section and section 297n–1 of this title, funding priority will be awarded to School of Nursing Student Loans [2] that support doctoral nursing students or Individual Student Loan Repayment [3] that support doctoral nursing students.

(July 1, 1944, ch. 373, title VIII, §847, as added Pub. L. 111–148, title V, §5311(b), Mar. 23, 2010, 124 Stat. 632; amended Pub. L. 116–136, div. A, title III, §3404(a)(10), Mar. 27, 2020, 134 Stat. 394.)

EDITORIAL NOTES

PRIOR PROVISIONS

A prior section 847 of act July 1, 1944, was classified to section 297n of this title prior to repeal by Pub. L. 102–408.

A prior section 297q, act July 1, 1944, ch. 373, title VIII, §841, as added Pub. L. 105–392, title I, §123(5), Nov. 13, 1998, 112 Stat. 3569, was renumbered section 871 of act July 1, 1944, and amended by Pub. L. 111–148, title V, §§5310(b)(7), 5312, Mar. 23, 2010, 124 Stat. 631, 633, and transferred to section 298d of this title.

AMENDMENTS

2020—Subsec. (g). Pub. L. 116–136 struck out subsec. (g). Text read as follows: "There are authorized to be appropriated to carry out this section such sums as may be necessary for each of fiscal years 2010 through 2014."

[1] So in original. Probably should be followed by a comma.

[2] So in original. Probably should not be capitalized.

[3] So in original. Probably should be "individual student loan repayments".

PART F—NATIONAL ADVISORY COUNCIL ON NURSE EDUCATION AND PRACTICE

EDITORIAL NOTES

CODIFICATION

Pub. L. 111–148, title V, §5310(b)(8)(B), Mar. 23, 2010, 124 Stat. 631, redesignated part G "National Advisory Council on Nurse Education and Practice" as F.

PRIOR PROVISIONS

A prior part F, consisting of section 297q, was redesignated part I (§298d) of this subchapter.

§297t. National Advisory Council on Nurse Education and Practice

(a) Establishment

The Secretary shall establish an advisory council to be known as the National Advisory Council on Nurse Education and Practice (in this section referred to as the "Advisory Council").

(b) Composition

(1) In general

The Advisory Council shall be composed of—

(A) not less than 21, nor more than 23 individuals, who are not officers or employees of the Federal Government, appointed by the Secretary without regard to the Federal civil service laws, of which—

(i) 2 shall be selected from full-time students enrolled in schools of nursing;

(ii) 2 shall be selected from the general public;

(iii) 2 shall be selected from practicing professional nurses; and

(iv) 9 shall be selected from among the leading authorities in the various fields of nursing, higher, secondary education, and associate degree schools of nursing, and from representatives of advanced education nursing groups (such as nurse practitioners, nurse midwives, nurse anesthetists, and clinical nurse specialists), hospitals, and other institutions and organizations which provide nursing services; and

(B) the Secretary (or the delegate of the Secretary (who shall be an ex officio member and shall serve as the Chairperson)).

(2) Appointment

Not later than 90 days after November 13, 1998, the Secretary shall appoint the members of the Advisory Council and each such member shall serve a 4 year term. In making such appointments, the Secretary shall ensure a fair balance between the nursing professions, a broad geographic representation of members and a balance between urban and rural members. Members shall be appointed based on their competence, interest, and knowledge of the mission of the profession involved. A majority of the members shall be nurses.

(3) Minority representation

In appointing the members of the Advisory Council under paragraph (1), the Secretary shall ensure the adequate representation of minorities.

(c) Vacancies

(1) In general

A vacancy on the Advisory Council shall be filled in the manner in which the original appointment was made and shall be subject to any conditions which applied with respect to the original appointment.

(2) Filling unexpired term

An individual chosen to fill a vacancy shall be appointed for the unexpired term of the member replaced.

(d) Duties

The Advisory Council shall—

(1) provide advice and recommendations to the Secretary and Congress concerning policy matters arising in the administration of this subchapter, including the range of issues relating to the nurse workforce, education, and practice improvement;

(2) provide advice to the Secretary and Congress in the preparation of general regulations and with respect to policy matters arising in the administration of this subchapter, including the range of issues relating to nurse supply, education and practice improvement; and

(3) not later than 2 years after March 27, 2020, and annually thereafter, prepare and submit to the Secretary, the Committee on Health, Education, Labor, and Pensions of the Senate, and the Committee on Energy and Commerce of the House of Representatives, a report describing the activities of the Council, including findings and recommendations made by the Council concerning the activities under this subchapter.

(e) Meetings and documents

(1) Meetings

The Advisory Council shall meet not less than 2 times each year. Such meetings shall be held jointly with other related entities established under this subchapter where appropriate.

(2) Documents

Not later than 14 days prior to the convening of a meeting under paragraph (1), the Advisory Council shall prepare and make available an agenda of the matters to be considered by the Advisory Council at such meeting. At any such meeting, the Advisory Council shall distribute materials with respect to the issues to be addressed at the meeting. Not later than 30 days after the adjourning of such a meeting, the Advisory Council shall prepare and make available a summary of the meeting and any actions taken by the Council based upon the meeting.

(f) Compensation and expenses

(1) Compensation

Each member of the Advisory Council shall be compensated at a rate equal to the daily equivalent of the annual rate of basic pay prescribed for level IV of the Executive Schedule under section 5315 of title 5 for each day (including travel time) during which such member is engaged in the performance of the duties of the Council. All members of the Council who are officers or employees of the United States shall serve without compensation in addition to that received for their services as officers or employees of the United States.

(2) Expenses

The members of the Advisory Council shall be allowed travel expenses, including per diem in lieu of subsistence, at rates authorized for employees of agencies under subchapter I of chapter 57 of title 5 while away from their homes or regular places of business in the performance of services for the Council.

(g) Funding

Amounts appropriated for carrying out parts B, C, and D may be utilized by the Secretary to support the nurse education and practice activities of the Council.

(h) Chapter 10 of title 5

Chapter 10 of title 5 shall apply to the Advisory Committee under this section only to the extent that the provisions of chapter 10 of title 5 do not conflict with the requirements of this section.

(July 1, 1944, ch. 373, title VIII, §851, formerly §845, as added Pub. L. 105–392, title I, §123(5), Nov. 13, 1998, 112 Stat. 3572; renumbered §851, Pub. L. 111–148, title V, §5310(b)(8)(A), Mar. 23, 2010, 124 Stat. 631; amended Pub. L. 116–136, div. A, title III, §3404(a)(11), Mar. 27, 2020, 134 Stat. 394; Pub. L. 116–260, div. BB, title III, §331(b), Dec. 27, 2020, 134 Stat. 2938; Pub. L. 117–286, §4(a)(240), Dec. 27, 2022, 136 Stat. 4332.)

EDITORIAL NOTES

CODIFICATION

November 13, 1998, referred to in subsec. (b)(2), was in the original "the date of enactment of this Act", which was translated as meaning the date of enactment of Pub. L. 105–392, which enacted this part, to reflect the probable intent of Congress.

PRIOR PROVISIONS

A prior section 851 of act July 1, 1944, was renumbered section 861 and classified to section 297w of this title, prior to repeal by Pub. L. 116–136.

Another prior section 851 of act July 1, 1944, was classified to section 298 of this title, prior to repeal by Pub. L. 105–392.

AMENDMENTS

2022—Subsec. (h). Pub. L. 117–286 substituted "Chapter 10 of title 5" for "FACA" in heading and "Chapter 10 of title 5 shall apply to the Advisory Committee under this section only to the extent that the

provisions of chapter 10 of title 5" for "The Federal Advisory Committee Act shall apply to the Advisory Committee under this section only to the extent that the provisions of such Act" in text.

2020—Subsec. (b)(1)(A)(iv). Pub. L. 116–136, §3404(a)(11)(A), substituted "nurse anesthetists, and clinical nurse specialists" for "and nurse anesthetists".

Subsec. (d)(3). Pub. L. 116–260 substituted "Coronavirus Aid, Relief, and Economic Security Act" for "Title VIII Nursing Reauthorization Act" in the original, and accordingly, "the date of enactment of the Coronavirus Aid, Relief, and Economic Security Act" was translated to "March 27, 2020". The Coronavirus Aid, Relief, and Economic Security Act, Pub. L. 116–136, was approved Mar. 27, 2020.

Pub. L. 116–136, §3404(a)(11)(B), substituted "2 years after the date of enactment of the Title VIII Nursing Reauthorization Act" for "3 years after November 13, 1998" and "Health, Education, Labor, and Pensions" for "Labor and Human Resources" and inserted "Energy and" before "Commerce".

Subsec. (g). Pub. L. 116–136, §3404(a)(11)(C), substituted "for carrying out parts B, C, and D" for "under this subchapter".

STATUTORY NOTES AND RELATED SUBSIDIARIES

EFFECTIVE DATE OF 2020 AMENDMENT

Amendment by Pub. L. 116–260 effective as if included in the enactment of Pub. L. 116–136, see section 331(d) of div. BB of Pub. L. 116–260, set out as a note under section 294c of this title.

TERMINATION OF ADVISORY COMMITTEES

Pub. L. 93–641, §6, Jan. 4, 1975, 88 Stat. 2275, set out as a note under section 217a of this title, provided that an advisory committee established pursuant to the Public Health Service Act shall terminate at such time as may be specifically prescribed by an Act of Congress enacted after Jan. 4, 1975.

PART G—PUBLIC SERVICE ANNOUNCEMENTS

EDITORIAL NOTES

CODIFICATION

Pub. L. 111–148, title V, §5310(b)(9)(B), Mar. 23, 2010, 124 Stat. 631, redesignated part H "Public Service Announcements" as G.

PRIOR PROVISIONS

A prior part G, consisting of section 297t, was redesignated part F of this subchapter.

§§297w, 297x. Repealed. Pub. L. 116–136, div. A, title III, §3404(a)(12), Mar. 27, 2020, 134 Stat. 394

Section 297w, act July 1, 1944, ch. 373, title VIII, §861, formerly §851, as added Pub. L. 107–205, title I, §102, Aug. 1, 2002, 116 Stat. 812; renumbered §861, Pub. L. 111–148, title V, §5310(b)(9)(A), Mar. 23, 2010, 124 Stat. 631, related to public service announcements by the Secretary to promote the nursing profession.

A prior section 861 of act July 1, 1944, was classified to section 298c of this title, prior to the reorganization and amendment of this subchapter by Pub. L. 90–490.

Another prior section 861 of act July 1, 1944, was classified to section 298c–1 of this title, prior to renumbering as section 846 by Pub. L. 94–63, transfer to section 297k of this title, and subsequent repeal.

Section 297x, act July 1, 1944, ch. 373, title VIII, §862, formerly §852, as added Pub. L. 107–205, title I, §102, Aug. 1, 2002, 116 Stat. 812; renumbered §862, Pub. L. 111–148, title V, §5310(b)(9)(A), Mar. 23, 2010, 124 Stat. 631, related to State and local public service announcements to promote the nursing profession.

A prior section 862 of act July 1, 1944, was classified to section 298c–1 of this title, prior to the reorganization and amendment of this subchapter by Pub. L. 90–490.

PART H—COMPREHENSIVE GERIATRIC EDUCATION

EDITORIAL NOTES

CODIFICATION

Pub. L. 111–148, title V, §5310(b)(10)(B), Mar. 23, 2010, 124 Stat. 631, redesignated part I "Comprehensive Geriatric Education" as H.

PRIOR PROVISIONS

A prior part H, consisting of sections 297w and 297x, was redesignated part G of this subchapter.

§298. Comprehensive geriatric education

(a) Program authorized

The Secretary shall award grants to eligible entities to develop and implement, in coordination with programs under section 294c of this title, programs and initiatives to train and educate individuals in providing geriatric care for the elderly.

(b) Use of funds

An eligible entity that receives a grant under subsection (a) shall use funds under such grant to—

(1) provide training to individuals who will provide geriatric care for the elderly;

(2) develop and disseminate curricula relating to the treatment of the health problems of elderly individuals;

(3) train faculty members in geriatrics;

(4) provide continuing education to individuals who provide geriatric care; or

(5) establish traineeships for individuals who are preparing for advanced education nursing degrees in geriatric nursing, long-term care, gero-psychiatric nursing or other nursing areas that specialize in the care of the elderly population.

(c) Application

An eligible entity desiring a grant under subsection (a) shall submit an application to the Secretary at such time, in such manner, and containing such information as the Secretary may reasonably require.

(d) Eligible entity

For purposes of this section, the term "eligible entity" includes a school of nursing, a health care facility, a program leading to certification as a certified nurse assistant, a partnership of such a school and facility, or a partnership of such a program and facility.

(e) Authorization of appropriations

There are authorized to be appropriated to carry out this section such sums as may be necessary for each of fiscal years 2010 through 2014.

(July 1, 1944, ch. 373, title VIII, §865, formerly §855, as added Pub. L. 107–205, title II, §202(a), Aug. 1, 2002, 116 Stat. 816; renumbered §865 and amended Pub. L. 111–148, title V, §§5305(c), 5310(b)(10)(A), Mar. 23, 2010, 124 Stat. 625, 631.)

EDITORIAL NOTES

PRIOR PROVISIONS

A prior section 298, act July 1, 1944, ch. 373, title VIII, §851, formerly §841, as added Pub. L. 88–581, §2, Sept. 4, 1964, 78 Stat. 917; amended Pub. L. 89–751, §3(b), Nov. 3, 1966, 80 Stat. 1230; Pub. L. 91–515, title VI, §601(b)(2), Oct. 30, 1970, 84 Stat. 1311; Pub. L. 92–158, §§9, 13, Nov. 18, 1971, 85 Stat. 479, 480;

renumbered §851 and amended Pub. L. 94–63, title IX, §941(k)(1), (2), July 29, 1975, 89 Stat. 366; Pub. L. 97–35, title XXVII, §2759(a), Aug. 13, 1981, 95 Stat. 932; Pub. L. 99–92, §9(d), Aug. 16, 1985, 99 Stat. 402; Pub. L. 100–607, title VII, §721(a), Nov. 4, 1988, 102 Stat. 3165; Pub. L. 102–408, title II, §212, Oct. 13, 1992, 106 Stat. 2079, related to Advisory Council on Nurse Education and Practice, prior to repeal by Pub. L. 105–392, title I, §123(1), Nov. 13, 1998, 112 Stat. 3562. See section 297t of this title.

A prior section 865 of act July 1, 1944, was classified to section 298c–4 of this title, prior to the reorganization and amendment of this subchapter by Pub. L. 90–490.

Prior sections 298a to 298b–1 were repealed by Pub. L. 105–392, title I, §123(1), Nov. 13, 1998, 112 Stat. 3562.

Section 298a, act July 1, 1944, ch. 373, title VIII, §852, formerly §842, as added Pub. L. 88–581, §2, Sept. 4, 1964, 78 Stat. 918; renumbered §852 and amended Pub. L. 94–63, title IX, §941(k)(1), July 29, 1975, 89 Stat. 366, directed Federal noninterference with administration of institutions.

Section 298b, act July 1, 1944, ch. 373, title VIII, §853, formerly §843, as added Pub. L. 88–581, §2, Sept. 4, 1964, 78 Stat. 918; amended Pub. L. 89–290, §5(b), Oct. 22, 1965, 79 Stat. 1058; Pub. L. 90–490, title II, §§203, 204, 213, 231, Aug. 16, 1968, 82 Stat. 780, 783, 787; Pub. L. 92–158, §2(d)(1), (2), Nov. 18, 1971, 85 Stat. 467, 468; renumbered §853 and amended Pub. L. 94–63, title IX, §941(k)(1), (3), July 29, 1975, 89 Stat. 366, 367; Pub. L. 96–32, §7(k), July 10, 1979, 93 Stat. 84; Pub. L. 97–35, title XXVII, §2759(b), Aug. 13, 1981, 95 Stat. 932; Pub. L. 99–92, §9(e), (f), Aug. 16, 1985, 99 Stat. 402; Pub. L. 102–408, title II, §202(b), Oct. 13, 1992, 106 Stat. 2071, defined terms.

Section 298b–1, act July 1, 1944, ch. 373, title VIII, §854, formerly §844, as added Pub. L. 92–158, §10, Nov. 18, 1971, 85 Stat. 479; renumbered §854, Pub. L. 94–63, title IX, §941(k)(1), July 29, 1975, 89 Stat. 366, authorized advance funding for grants, contracts, or other payments.

A prior section 298b–2, act July 1, 1944, ch. 373, title VIII, §855, formerly §845, as added Pub. L. 92–158, §11, Nov. 18, 1971, 85 Stat. 479; renumbered §855, Pub. L. 94–63, title IX, §941(k)(1), July 29, 1975, 89 Stat. 366, which prohibited discrimination by schools on basis of sex, was renumbered section 810 of act July 1, 1944, by Pub. L. 105–392 and transferred to section 296g of this title.

Prior sections 298b–3 to 298b–5 were repealed by Pub. L. 105–392, title I, §123(1), Nov. 13, 1998, 112 Stat. 3562.

Section 298b–3, act July 1, 1944, ch. 373, title VIII, §856, as added Pub. L. 94–63, title IX, §941(k)(4), July 29, 1975, 89 Stat. 367; amended Pub. L. 97–35, title XXVII, §2759(c), Aug. 13, 1981, 95 Stat. 932; Pub. L. 100–607, title VII, §721(b)(2), Nov. 4, 1988, 102 Stat. 3165, related to delegation of authority to administer programs.

Section 298b–4, act July 1, 1944, ch. 373, title VIII, §857, as added Pub. L. 97–414, §8(m), Jan. 4, 1983, 96 Stat. 2061, authorized use of funds to provide technical assistance.

Section 298b–5, act July 1, 1944, ch. 373, title VIII, §858, formerly §804, as added Pub. L. 88–581, §2, Sept. 4, 1964, 78 Stat. 911; amended Pub. L. 92–158, §§2(d)(3), 13, Nov. 18, 1971, 85 Stat. 468, 480; Pub. L. 94–63, title IX, §941(c), July 29, 1975, 89 Stat. 364; renumbered §858 and amended Pub. L. 99–92, §9(c)(1), Aug. 16, 1985, 99 Stat. 400; Pub. L. 99–129, title II, §207(e)(1)–(3), Oct. 22, 1985, 99 Stat. 529, described conditions for United States recovery for construction assistance.

A prior section 298b–6, act July 1, 1944, ch. 373, title VIII, §859, as added Nov. 4, 1988, Pub. L. 100–607, title VII, §722, 102 Stat. 3165; amended Oct. 13, 1992, Pub. L. 102–408, title II, §213, 106 Stat. 2080, directed Secretary to provide for evaluations of projects carried out pursuant to this subchapter and submit reports to Congress summarizing evaluations, and made one percent of amount appropriated each fiscal year available to carry out section, prior to repeal by Pub. L. 104–66, title I, §1061(c), Dec. 21, 1995, 109 Stat. 719.

A prior section 298b–7, act July 1, 1944, ch. 373, title VIII, §860, as added Pub. L. 102–408, title II, §209, Oct. 13, 1992, 106 Stat. 2075; amended Pub. L. 102–531, title III, §313(a)(10), Oct. 27, 1992, 106 Stat. 3507; Pub. L. 103–43, title XX, §2014(g), June 10, 1993, 107 Stat. 217, set forth certain generally applicable provisions, prior to repeal by Pub. L. 105–392, title I, §123(1), Nov. 13, 1998, 112 Stat. 3562.

A prior section 298c, act July 1, 1944, ch. 373, title VIII, §860, as added Aug. 16, 1968, Pub. L. 90–490, title II, §223(a), 82 Stat. 785; amended July 9, 1971, Pub. L. 92–52, §4, 85 Stat. 145; Nov. 18, 1971, Pub. L. 92–158, §7, 85 Stat. 478, which related to scholarship grants, was renumbered section 845 of act July 1, 1944, by Pub. L. 94–63 and transferred to section 297j of this title and subsequently repealed.

Another prior section 298c, act July 1, 1944, ch. 373, title VIII, §861, as added Nov. 3, 1966, Pub. L. 89–751, §8(b), 80 Stat. 1236, stated the purposes of opportunity grants for nursing education and authorized appropriations of $3,000,000, $5,000,000, and $7,000,000 for fiscal years ending June 30, 1967, 1968, and 1969, respectively, to be available for payments to institutions until close of fiscal year succeeding fiscal year for which appropriated, prior to the reorganization and amendment of this subchapter by Pub. L. 90–490.

A prior section 298c–1, act July 1, 1944, ch. 373, title VIII, §861, as added Aug. 16, 1968, Pub. L. 90–490,

title II, §223(a), 82 Stat. 786, related to transfers to student loan program, was renumbered section 846 of act July 1, 1944, by Pub. L. 94–63 and transferred to section 297k of this title and subsequently repealed.

Another prior section 298c–1, act July 1, 1944, ch. 373, title VIII, §862, as added Nov. 3, 1966, Pub. L. 89–751, §8(b), 80 Stat. 1237, prescribed amount of nursing educational opportunity grant and provided for its annual determination, prior to the reorganization and amendment of this subchapter by Pub. L. 90–490.

Sections 298c–2 to 298c–6 were omitted in the reorganization and amendment of this subchapter by Pub. L. 90–490, title II, §223, Aug. 16, 1968, 82 Stat. 785.

Section 298c–2, act July 1, 1944, ch. 373, title VIII, §863, as added Nov. 3, 1966, Pub. L. 89–751, §8(b), 80 Stat. 1237, related to duration of a nursing educational opportunity grant.

Section 298c–3, act July 1, 1944, ch. 373, title VIII, §864, as added Nov. 3, 1966, Pub. L. 89–751, §8(b), 80 Stat. 1238, related to selection of recipients of nursing educational opportunity grants.

Section 298c–4, act July 1, 1944, ch. 373, title VIII, §865, as added Nov. 3, 1966, Pub. L. 89–751, §8(b), 80 Stat. 1238, related to allotment of nursing educational opportunity grant funds among States.

Section 298c–5, act July 1, 1944, ch. 373, title VIII, §866, as added Nov. 3, 1966, Pub. L. 89–751, §8(b), 80 Stat. 1238, related to allocation of allotted funds to schools of nursing.

Section 298c–6, act July 1, 1944, ch. 373, title VIII, §867, as added Nov. 3, 1966, Pub. L. 89–751, §8(b), 80 Stat. 1239, related to agreements with schools of nursing.

A prior section 298c–7, act July 1, 1944, ch. 373, title VIII, §868, as added Nov. 3, 1966, Pub. L. 89–751, §8(b), 80 Stat. 1239; amended Nov. 18, 1971, Pub. L. 92–158, §8, 85 Stat. 478; July 29, 1975, Pub. L. 94–63, title IX, §902(g), 89 Stat. 355, authorized grants and contracts to encourage full utilization of educational talent for nursing profession and authorized appropriations from fiscal year ending June 30, 1972 through fiscal year ending June 30, 1975 for implementation, prior to repeal by Pub. L. 94–63, title IX, §§905, 931(b), July 29, 1975, 89 Stat. 355, 362, effective July 1, 1975.

A prior section 298c–8, act July 1, 1944, ch. 373, title VIII, §869, as added Nov. 3, 1966, Pub. L. 89–751, §8(b), 80 Stat. 1240, defined "academic year", prior to repeal by Pub. L. 94–63, title IX, §§941(j)(4), 942, July 29, 1975, 89 Stat. 366, 367, effective July 1, 1975.

AMENDMENTS

2010—Subsec. (b)(5). Pub. L. 111–148, §5305(c)(1), added par. (5).

Subsec. (e). Pub. L. 111–148, §5305(c)(2), substituted "2010 through 2014" for "2003 through 2007".

PART I—FUNDING

EDITORIAL NOTES

CODIFICATION

Pub. L. 111–148, title V, §5310(b)(7), Mar. 23, 2010, 124 Stat. 631, redesignated part F "Funding" as I.

PRIOR PROVISIONS

A prior part I, consisting of section 298, was redesignated part H of this subchapter.

§298d. Authorization of appropriations

(a) In general

For the purpose of carrying out parts B, C, and D (subject to section 297t(g) of this title), there are authorized to be appropriated $137,837,000 for each of fiscal years 2021 through 2025.

(b) Part E

For the purpose of carrying out part E, there are authorized to be appropriated $117,135,000 for each of the fiscal years 2021 through 2025.

(July 1, 1944, ch. 373, title VIII, §871, formerly §841, as added Pub. L. 105–392, title I, §123(5), Nov. 13, 1998, 112 Stat. 3569; renumbered §871 and amended Pub. L. 111–148, title V, §§5310(b)(7), 5312, Mar. 23, 2010, 124 Stat. 631, 633; Pub. L. 116–136, div. A, title III,

§3404(a)(13), Mar. 27, 2020, 134 Stat. 394.)

EDITORIAL NOTES

CODIFICATION

Section was classified to section 297q of this title prior to renumbering by Pub. L. 111–148.

AMENDMENTS

2020—Pub. L. 116–136 designated existing provisions as subsec. (a) and inserted heading, substituted "$137,837,000 for each of fiscal years 2021 through 2025" for "$338,000,000 for fiscal year 2010, and such sums as may be necessary for each of the fiscal years 2011 through 2016", and added subsec. (b).

2010—Pub. L. 111–148, §5312, amended section generally. Prior to amendment, section related to authorization of appropriations for fiscal years 1998 through 2002, allocations of amounts, and use of methodology.

SUBCHAPTER VII—AGENCY FOR HEALTHCARE RESEARCH AND QUALITY

EDITORIAL NOTES

PRIOR PROVISIONS

A prior subchapter VII, related to the Agency for Health Care Policy and Research and consisted of sections 299 to 299c–6, prior to the general amendment of this subchapter by Pub. L. 106–129, §2(a), Dec. 6, 1999, 113 Stat. 1653.

Another prior subchapter VII, related to education, research, training, and demonstrations in heart disease, cancer, stroke, and related diseases and consisted of sections 299 to 299j, prior to repeal by Pub. L. 99–117, §12(d), Oct. 7, 1985, 99 Stat. 495.

PART A—ESTABLISHMENT AND GENERAL DUTIES

§299. Mission and duties

(a) In general

There is established within the Public Health Service an agency to be known as the Agency for Healthcare Research and Quality, which shall be headed by a director appointed by the Secretary. The Secretary shall carry out this subchapter acting through the Director.

(b) Mission

The purpose of the Agency is to enhance the quality, appropriateness, and effectiveness of health services, and access to such services, through the establishment of a broad base of scientific research and through the promotion of improvements in clinical and health system practices, including the prevention of diseases and other health conditions. The Agency shall promote health care quality improvement by conducting and supporting—

(1) research that develops and presents scientific evidence regarding all aspects of health care, including—

(A) the development and assessment of methods for enhancing patient participation in their own care and for facilitating shared patient-physician decision-making;

(B) the outcomes, effectiveness, and cost-effectiveness of health care practices, including preventive measures and long-term care;

(C) existing and innovative technologies;

(D) the costs and utilization of, and access to health care;

(E) the ways in which health care services are organized, delivered, and financed and the interaction and impact of these factors on the quality of patient care;

(F) methods for measuring quality and strategies for improving quality; and

(G) ways in which patients, consumers, purchasers, and practitioners acquire new information about best practices and health benefits, the determinants and impact of their use of this information;

(2) the synthesis and dissemination of available scientific evidence for use by patients, consumers, practitioners, providers, purchasers, policy makers, and educators; and

(3) initiatives to advance private and public efforts to improve health care quality.

(c) Requirements with respect to rural and inner-city areas and priority populations

(1) Research, evaluations and demonstration projects

In carrying out this subchapter, the Director shall conduct and support research and evaluations, and support demonstration projects, with respect to—

(A) the delivery of health care in inner-city areas, and in rural areas (including frontier areas); and

(B) health care for priority populations, which shall include—

(i) low-income groups;

(ii) minority groups;

(iii) women;

(iv) children;

(v) the elderly; and

(vi) individuals with special health care needs, including individuals with disabilities and individuals who need chronic care or end-of-life health care.

(2) Process to ensure appropriate research

The Director shall establish a process to ensure that the requirements of paragraph (1) are reflected in the overall portfolio of research conducted and supported by the Agency.

(3) Office of Priority Populations

The Director shall establish an Office of Priority Populations to assist in carrying out the requirements of paragraph (1).

(July 1, 1944, ch. 373, title IX, §901, as added Pub. L. 106–129, §2(a), Dec. 6, 1999, 113 Stat. 1653.)

EDITORIAL NOTES

PRIOR PROVISIONS

A prior section 299, act July 1, 1944, ch. 373, title IX, §901, as added Pub. L. 101–239, title VI, §6103(a), Dec. 19, 1989, 103 Stat. 2189; amended Pub. L. 102–410, §2(a), Oct. 13, 1992, 106 Stat. 2094, established the Agency for Health Care Policy and Research, prior to the general amendment of this subchapter by Pub. L. 106–129.

Another prior section 299, act July 1, 1944, ch. 373, title IX, §900, as added Oct. 6, 1965, Pub. L. 89–239, §2, 79 Stat. 926; amended Oct. 30, 1970, Pub. L. 91–515, title I, §102, 84 Stat. 1297, set forth Congressional declaration of purpose of this subchapter to encourage and assist regional cooperative arrangements among medical schools, research institutions, and hospitals for research, training and medical data exchange, and to improve quality and capacity of health manpower and facilities available throughout the nation, prior to repeal by Pub. L. 99–117, §12(d), Oct. 7, 1985, 99 Stat. 495.

A prior section 901 of act July 1, 1944, was classified to section 299a of this title prior to repeal by Pub. L. 99–117.

STATUTORY NOTES AND RELATED SUBSIDIARIES

TRANSITIONAL AND SAVINGS PROVISIONS

Pub. L. 101–239, title VI, §6103(f), Dec. 19, 1989, 103 Stat. 2208, provided that personnel of the Department of Health and Human Services employed, and Department assets used in connection with Department functions, on Dec. 19, 1989, be transferred to the Administrator for Health Care Policy and Research for appropriate allocation, and provided that orders, rules, regulations, grants, contracts, certificates, licenses, privileges, and other determinations, actions, or official documents would continue in effect according to their terms unless changed pursuant to law.

CONSTRUCTION

Pub. L. 106–129, §2(b), Dec. 6, 1999, 113 Stat. 1670, provided that:

"(1) IN GENERAL.—Section 901(a) of the Public Health Service Act [42 U.S.C. 299(a)] (as added by subsection (a) of this section) applies as a redesignation of the agency that carried out title IX of such Act [42 U.S.C. 299 et seq.] on the day before the date of the enactment of this Act [Dec. 6, 1999], and not as the termination of such agency and the establishment of a different agency. The amendment made by subsection (a) of this section [enacting this subchapter] does not affect appointments of the personnel of such agency who were employed at the agency on the day before such date, including the appointments of members of advisory councils or study sections of the agency who were serving on the day before such date of enactment.

"(2) REFERENCES.—Any reference in law to the Agency for Health Care Policy and Research is deemed to be a reference to the Agency for Healthcare Research and Quality, and any reference in law to the Administrator for Health Care Policy and Research is deemed to be a reference to the Director of the Agency for Healthcare Research and Quality."

IOM REPORTS ON BEST PRACTICES FOR DEVELOPING CLINICAL PROTOCOLS

Pub. L. 110–275, title III, §304(b), July 15, 2008, 122 Stat. 2595, as amended by Pub. L. 111–148, title X, §10303(c), Mar. 23, 2010, 124 Stat. 938, provided that:

"(1) STUDY.—Not later than 60 days after the date of the enactment of this Act [July 15, 2008], the Secretary of Health and Human Services shall enter into a contract with the Institute of Medicine of the National Academies (in this section [this note] referred to as the 'Institute') under which the Institute shall conduct a study on the best methods used in developing clinical practice guidelines in order to ensure that organizations developing such guidelines have information on approaches that are objective, scientifically valid, and consistent.

"(2) REPORT.—Not later than 18 months after the effective date of the contract under paragraph (1), the Institute, as part of such contract, shall submit to the Secretary of Health and Human Services and the appropriate committees of jurisdiction of Congress a report containing the results of the study conducted under paragraph (1), together with recommendations for such legislation and administrative action as the Institute determines appropriate.

"(3) PARTICIPATION.—The contract under paragraph (1) shall require that stakeholders with expertise in making clinical recommendations participate on the panel responsible for conducting the study under paragraph (1) and preparing the report under paragraph (2).

"(4) IDENTIFICATION.—

"(A) IN GENERAL.—Following receipt of the report submitted under paragraph (2), and not less than every 3 years thereafter, the Secretary shall contract with the Institute to employ the results of the study performed under paragraph (1) and the best methods identified by the Institute for the purpose of identifying existing and new clinical practice guidelines that were developed using such best methods, including guidelines listed in the National Guideline Clearinghouse.

"(B) CONSULTATION.—In carrying out the identification process under subparagraph (A), the Secretary shall allow for consultation with professional societies, voluntary health care organizations, and expert panels."

IOM STUDY ON DRUG SAFETY AND QUALITY

Pub. L. 108–173, title I, §107(c), Dec. 8, 2003, 117 Stat. 2170, provided that:

"(1) IN GENERAL.—The Secretary [of Health and Human Services] shall enter into a contract with the Institutes of Medicine of the National Academies of Science (such Institutes referred to in this subsection as the 'IOM') to carry out a comprehensive study (in this subsection referred to as the 'study') of drug safety and quality issues in order to provide a blueprint for system-wide change.

"(2) OBJECTIVES.—

"(A) The study shall develop a full understanding of drug safety and quality issues through an evidence-based review of literature, case studies, and analysis. This review will consider the nature and causes of medication errors, their impact on patients, the differences in causation, impact, and prevention

across multiple dimensions of health care delivery-including patient populations, care settings, clinicians, and institutional cultures.

"(B) The study shall attempt to develop credible estimates of the incidence, severity, costs of medication errors that can be useful in prioritizing resources for national quality improvement efforts and influencing national health care policy.

"(C) The study shall evaluate alternative approaches to reducing medication errors in terms of their efficacy, cost-effectiveness, appropriateness in different settings and circumstances, feasibility, institutional barriers to implementation, associated risks, and the quality of evidence supporting the approach.

"(D) The study shall provide guidance to consumers, providers, payers, and other key stakeholders on high-priority strategies to achieve both short-term and long-term drug safety goals, to elucidate the goals and expected results of such initiatives and support the business case for them, and to identify critical success factors and key levers for achieving success.

"(E) The study shall assess the opportunities and key impediments to broad nationwide implementation of medication error reductions, and to provide guidance to policy-makers and government agencies (including the Food and Drug Administration, the Centers for Medicare & Medicaid Services, and the National Institutes of Health) in promoting a national agenda for medication error reduction.

"(F) The study shall develop an applied research agenda to evaluate the health and cost impacts of alternative interventions, and to assess collaborative public and private strategies for implementing the research agenda through AHRQ and other government agencies.

"(3) CONDUCT OF STUDY.—

"(A) EXPERT COMMITTEE.—In conducting the study, the IOM shall convene a committee of leading experts and key stakeholders in pharmaceutical management and drug safety, including clinicians, health services researchers, pharmacists, system administrators, payer representatives, and others.

"(B) COMPLETION.—The study shall be completed within an 18-month period.

"(4) REPORT.—A report on the study shall be submitted to Congress upon the completion of the study.

"(5) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated to carry out this section such sums as may be necessary."

HEALTH CARE THAT WORKS FOR ALL AMERICANS: CITIZENS HEALTH CARE WORKING GROUP

Pub. L. 108–173, title X, §1014, Dec. 8, 2003, 117 Stat. 2441, directed the Secretary of Health and Human Services to establish the Citizens' Health Care Working Group, composed of the Secretary and 14 other members, which was to hold hearings to examine various public and private health care coverage issues, make final recommendations to the President and Congress, and terminate 2 years after the members were chosen (Feb. 28, 2005) and appropriations were first made available.

EXECUTIVE DOCUMENTS

EXECUTIVE ORDER NO. 13017

Ex. Ord. No. 13017, Sept. 5, 1996, 61 F.R. 47659, as amended by Ex. Ord. No. 13040, Mar. 25, 1997, 62 F.R. 14773; Ex. Ord. No. 13056, July 21, 1997, 62 F.R. 39415, which established the Advisory Commission on Consumer Protection and Quality in the Health Care Industry, was revoked by Ex. Ord. No. 13138, §3(a), Sept. 30, 1999, 64 F.R. 53880, formerly set out as a note under section 1013 of Title 5, Government Organization and Employees.

§299a. General authorities

(a) In general

In carrying out section 299(b) of this title, the Director shall conduct and support research, evaluations, and training, support demonstration projects, research networks, and multidisciplinary centers, provide technical assistance, and disseminate information on health care and on systems for the delivery of such care, including activities with respect to—

(1) the quality, effectiveness, efficiency, appropriateness and value of health care services;

(2) quality measurement and improvement;

(3) the outcomes, cost, cost-effectiveness, and use of health care services and access to such services;

(4) clinical practice, including primary care and practice-oriented research;
(5) health care technologies, facilities, and equipment;
(6) health care costs, productivity, organization, and market forces;
(7) health promotion and disease prevention, including clinical preventive services;
(8) health statistics, surveys, database development, and epidemiology; and
(9) medical liability.

(b) Health services training grants

(1) In general

The Director may provide training grants in the field of health services research related to activities authorized under subsection (a), to include pre- and post-doctoral fellowships and training programs, young investigator awards, and other programs and activities as appropriate. In carrying out this subsection, the Director shall make use of funds made available under section 288(d)(3) [1] of this title as well as other appropriated funds.

(2) Requirements

In developing priorities for the allocation of training funds under this subsection, the Director shall take into consideration shortages in the number of trained researchers who are addressing health care issues for the priority populations identified in section 299(c)(1)(B) of this title and in addition, shall take into consideration indications of long-term commitment, amongst applicants for training funds, to addressing health care needs of the priority populations.

(c) Multidisciplinary centers

The Director may provide financial assistance to assist in meeting the costs of planning and establishing new centers, and operating existing and new centers, for multidisciplinary health services research, demonstration projects, evaluations, training, and policy analysis with respect to the matters referred to in subsection (a).

(d) Relation to certain authorities regarding social security

Activities authorized in this section shall be appropriately coordinated with experiments, demonstration projects, and other related activities authorized by the Social Security Act [42 U.S.C. 301 et seq.] and the Social Security Amendments of 1967. Activities under subsection (a)(2) of this section that affect the programs under titles XVIII, XIX and XXI of the Social Security Act [42 U.S.C. 1395 et seq., 1396 et seq., 1397aa et seq.] shall be carried out consistent with section 1142 of such Act [42 U.S.C. 1320b–12].

(e) Disclaimer

The Agency shall not mandate national standards of clinical practice or quality health care standards. Recommendations resulting from projects funded and published by the Agency shall include a corresponding disclaimer.

(f) Rule of construction

Nothing in this section shall be construed to imply that the Agency's role is to mandate a national standard or specific approach to quality measurement and reporting. In research and quality improvement activities, the Agency shall consider a wide range of choices, providers, health care delivery systems, and individual preferences.

(July 1, 1944, ch. 373, title IX, §902, as added Pub. L. 106–129, §2(a), Dec. 6, 1999, 113 Stat. 1654; amended Pub. L. 106–525, title II, §201(a)(1), Nov. 22, 2000, 114 Stat. 2505.)

EDITORIAL NOTES

REFERENCES IN TEXT

Section 288(d)(3) of this title, referred to in subsec. (b)(1), was repealed by Pub. L. 109–482, title I, §103(b)(47), Jan. 15, 2007, 120 Stat. 3688.

The Social Security Act, referred to in subsec. (d), is act Aug. 14, 1935, ch. 531, 49 Stat. 620, which is

classified generally to chapter 7 (§301 et seq.) of this title. Titles XVIII, XIX, and XXI of the Act are classified generally to subchapters XVIII (§1395 et seq.), XIX (§1396 et seq.), and XXI (§1397aa et seq.), respectively, of chapter 7 of this title. For complete classification of this Act to the Code, see section 1305 of this title and Tables.

The Social Security Amendments of 1967, referred to in subsec. (d), is Pub. L. 90–248, Jan. 2, 1968, 81 Stat. 821. For complete classification of this Act to the Code, see Short Title of 1968 Amendment note set out under section 1305 of this title and Tables.

PRIOR PROVISIONS

A prior section 299a, act July 1, 1944, ch. 373, title IX, §902, as added Pub. L. 101–239, title VI, §6103(a), Dec. 19, 1989, 103 Stat. 2189; amended Pub. L. 101–639, §3(d), Nov. 28, 1990, 104 Stat. 4603; Pub. L. 102–410, §2(b), Oct. 13, 1992, 106 Stat. 2094, required Administrator to conduct and support research, demonstration projects, evaluations, training, guideline development, and dissemination of information on health care services and on systems for delivery of such services, prior to the general amendment of this subchapter by Pub. L. 106–129.

Another prior section 299a, act July 1, 1944, ch. 373, title IX, §901, as added Oct. 6, 1965, Pub. L. 89–239, §2, 79 Stat. 926; amended Oct. 15, 1968, Pub. L. 90–574, title I, §§101, 102, 107, 82 Stat. 1005, 1006; June 30, 1970, Pub. L. 91–296, title IV, §401(b)(1)(F), 84 Stat. 352; Oct. 30, 1970, Pub. L. 91–515, title I, §103, 84 Stat. 1298; June 18, 1973, Pub. L. 93–45, title I, §110, 87 Stat. 93, authorized appropriations for grants and contracts to carry out purposes of this subchapter and set forth extent of and limitations on grants, prior to repeal by Pub. L. 99–117, §12(d), Oct. 7, 1985, 99 Stat. 495.

A prior section 902 of act July 1, 1944, was classified to section 299b of this title prior to repeal by Pub. L. 99–117.

AMENDMENTS

2000—Subsec. (g). Pub. L. 106–525 struck out heading and text of subsec. (g). Text read as follows: "Beginning with fiscal year 2003, the Director shall annually submit to the Congress a report regarding prevailing disparities in health care delivery as it relates to racial factors and socioeconomic factors in priority populations."

STATUTORY NOTES AND RELATED SUBSIDIARIES

REDUCING ADMINISTRATIVE HEALTH CARE COSTS

Pub. L. 103–43, title XIX, §1909, June 10, 1993, 107 Stat. 205, as amended by Pub. L. 106–129, §2(b)(2), Dec. 6, 1999, 113 Stat. 1670; Pub. L. 108–173, title IX, §900(e)(6)(F), Dec. 8, 2003, 117 Stat. 2374, provided that: "The Secretary of Health and Human Services, acting through the Agency for Healthcare Research and Quality and, to the extent possible, in consultation with the Centers for Medicare & Medicaid Services, may fund research to develop a text-based standardized billing process, through the utilization of text-based information retrieval and natural language processing techniques applied to automatic coding and analysis of textual patient discharge summaries and other text-based electronic medical records, within a parallel general purpose (shared memory) high performance computing environment. The Secretary shall determine whether such a standardized approach to medical billing, through the utilization of the text-based hospital discharge summary as well as electronic patient records can reduce the administrative billing costs of health care delivery."

EXECUTIVE DOCUMENTS

DEMONSTRATION GRANTS FOR THE DEVELOPMENT, IMPLEMENTATION, AND EVALUATION OF ALTERNATIVES TO THE CURRENT MEDICAL LIABILITY SYSTEM

Memorandum of President of the United States, Sept. 17, 2009, 74 F.R. 48133, provided:

Memorandum for the Secretary of Health And Human Services

As part of my Administration's ongoing effort to reform our health care system, we have reached out to members of both political parties and listened to the concerns many have raised about the need to improve patient safety and to reform our medical liability system. Between 44,000 and 98,000 patients die each year from medical errors. Many physicians continue to struggle to pay their medical malpractice premiums, which vary tremendously by specialty and by State. The cost of insurance continues to be one of the highest practice expenses for some specialties. And although malpractice premiums do not account for a large percentage of

total medical costs, many physicians report that fear of lawsuits leads them to practice defensive medicine, which may contribute to higher costs.

We should explore medical liability reform as one way to improve the quality of care and patient-safety practices and to reduce defensive medicine. But whatever steps we pursue, medical liability reform must be just one part of broader health insurance reform—reform that offers more security and stability to Americans who have insurance, offers insurance to Americans who lack coverage, and slows the growth of health care costs for families, businesses, and government.

In recent years, there have been calls from organizations like The Joint Commission and the Institute of Medicine to begin funding demonstration projects that can test a variety of medical liability models and determine which reforms work. These groups and others have identified several important goals and core commitments of malpractice reform that should serve as a starting point for such projects. We must put patient safety first and work to reduce preventable injuries. We must foster better communication between doctors and their patients. We must ensure that patients are compensated in a fair and timely manner for medical injuries, while also reducing the incidence of frivolous lawsuits. And we must work to reduce liability premiums.

In 1999, the Congress authorized the Agency for Healthcare Research and Quality, which is located within the Department of Health and Human Services, to support demonstration projects and to evaluate the effectiveness of projects regarding all aspects of health care, including medical liability. I hereby request that you announce, within 30 days of this memorandum, that the Department will make available demonstration grants to States, localities, and health systems for the development, implementation, and evaluation of alternatives to our current medical liability system, consistent with the goals and core commitments outlined above.

This memorandum is not intended to, and does not, create any right or benefit, substantive or procedural, enforceable at law or in equity by any party against the United States, its departments, agencies, or entities, its officers, employees, or agents, or any other person.

You are authorized and directed to publish this memorandum in the Federal Register.

BARACK OBAMA.

[1] *See References in Text note below.*

§299a–1. Research on health disparities

(a) In general

The Director shall—

(1) conduct and support research to identify populations for which there is a significant disparity in the quality, outcomes, cost, or use of health care services or access to and satisfaction with such services, as compared to the general population;

(2) conduct and support research on the causes of and barriers to reducing the health disparities identified in paragraph (1), taking into account such factors as socioeconomic status, attitudes toward health, the language spoken, the extent of formal education, the area or community in which the population resides, and other factors the Director determines to be appropriate;

(3) conduct and support research and support demonstration projects to identify, test, and evaluate strategies for reducing or eliminating health disparities, including development or identification of effective service delivery models, and disseminate effective strategies and models;

(4) develop measures and tools for the assessment and improvement of the outcomes, quality, and appropriateness of health care services provided to health disparity populations;

(5) in carrying out section 299a(c) of this title, provide support to increase the number of researchers who are members of health disparity populations, and the health services research capacity of institutions that train such researchers; and

(6) beginning with fiscal year 2003, annually submit to the Congress a report regarding prevailing disparities in health care delivery as it relates to racial factors and socioeconomic factors in priority populations.

(b) Research and demonstration projects

(1) In general

In carrying out subsection (a), the Director shall conduct and support research and support demonstrations to—

(A) identify the clinical, cultural, socioeconomic, geographic, and organizational factors that contribute to health disparities, including minority health disparity populations, which research shall include behavioral research, such as examination of patterns of clinical decisionmaking, and research on access, outreach, and the availability of related support services (such as cultural and linguistic services);

(B) identify and evaluate clinical and organizational strategies to improve the quality, outcomes, and access to care for health disparity populations, including minority health disparity populations;

(C) test such strategies and widely disseminate those strategies for which there is scientific evidence of effectiveness; and

(D) determine the most effective approaches for disseminating research findings to health disparity populations, including minority populations.

(2) Use of certain strategies

In carrying out this section, the Director shall implement research strategies and mechanisms that will enhance the involvement of individuals who are members of minority health disparity populations or other health disparity populations, health services researchers who are such individuals, institutions that train such individuals as researchers, members of minority health disparity populations or other health disparity populations for whom the Agency is attempting to improve the quality and outcomes of care, and representatives of appropriate tribal or other community-based organizations with respect to health disparity populations. Such research strategies and mechanisms may include the use of—

(A) centers of excellence that can demonstrate, either individually or through consortia, a combination of multi-disciplinary expertise in outcomes or quality improvement research, linkages to relevant sites of care, and a demonstrated capacity to involve members and communities of health disparity populations, including minority health disparity populations, in the planning, conduct, dissemination, and translation of research;

(B) provider-based research networks, including health plans, facilities, or delivery system sites of care (especially primary care), that make extensive use of health care providers who are members of health disparity populations or who serve patients in such populations and have the capacity to evaluate and promote quality improvement;

(C) service delivery models (such as health centers under section 254b of this title and the Indian Health Service) to reduce health disparities; and

(D) innovative mechanisms or strategies that will facilitate the translation of past research investments into clinical practices that can reasonably be expected to benefit these populations.

(c) Quality measurement development

(1) In general

To ensure that health disparity populations, including minority health disparity populations, benefit from the progress made in the ability of individuals to measure the quality of health care delivery, the Director shall support the development of quality of health care measures that assess the experience of such populations with health care systems, such as measures that assess the access of such populations to health care, the cultural competence of the care provided, the quality of the care provided, the outcomes of care, or other aspects of health care practice that the Director determines to be important.

(2) Examination of certain practices

The Director shall examine the practices of providers that have a record of reducing health disparities or have experience in providing culturally competent health services to minority health

disparity populations or other health disparity populations. In examining such practices of providers funded under the authorities of this chapter, the Director shall consult with the heads of the relevant agencies of the Public Health Service.

(3) Report

Not later than 36 months after November 22, 2000, the Secretary, acting through the Director, shall prepare and submit to the appropriate committees of Congress a report describing the state-of-the-art of quality measurement for minority and other health disparity populations that will identify critical unmet needs, the current activities of the Department to address those needs, and a description of related activities in the private sector.

(d) Definition

For purposes of this section:

(1) The term "health disparity population" has the meaning given such term in section 285t of this title, except that in addition to the meaning so given, the Director may determine that such term includes populations for which there is a significant disparity in the quality, outcomes, cost, or use of health care services or access to or satisfaction with such services as compared to the general population.

(2) The term "minority", with respect to populations, refers to racial and ethnic minority groups as defined in section 300u–6 of this title.

(July 1, 1944, ch. 373, title IX, §903, as added Pub. L. 106–525, title II, §201(a)(2), Nov. 22, 2000, 114 Stat. 2505; amended Pub. L. 111–148, title X, §10334(c)(3)(B), Mar. 23, 2010, 124 Stat. 974.)

EDITORIAL NOTES

PRIOR PROVISIONS

A prior section 299a–1, act July 1, 1944, ch. 373, title IX, §903, as added Pub. L. 101–239, title VI, §6103(a), Dec. 19, 1989, 103 Stat. 2190; amended Pub. L. 102–410, §3, Oct. 13, 1992, 106 Stat. 2094; Pub. L. 103–43, title XIV, §1422(a), June 10, 1993, 107 Stat. 172, related to public dissemination of information about studies and projects prior to the general amendment of this subchapter by Pub. L. 106–129. See section 299c–3 of this title.

A prior section 903 of act July 1, 1944, was classified to section 299c of this title prior to repeal by Pub. L. 99–117.

Prior sections 299a–2 and 299a–3 were omitted in the general amendment of this subchapter by Pub. L. 106–129.

Section 299a–2, act July 1, 1944, ch. 373, title IX, §904, as added Pub. L. 101–239, title VI, §6103(a), Dec. 19, 1989, 103 Stat. 2191; amended Pub. L. 102–410, §4(a), Oct. 13, 1992, 106 Stat. 2095; Pub. L. 103–43, title XX, §2013(1), June 10, 1993, 107 Stat. 214, related to health care technology assessment. See section 299b–5 of this title.

Section 299a–3, act July 1, 1944, ch. 373, title IX, §905, as added Pub. L. 105–115, title IV, §409, Nov. 21, 1997, 111 Stat. 2371, established demonstration program regarding centers for education and research on therapeutics. See section 299b–1(b) of this title.

AMENDMENTS

2010—Subsec. (d)(1). Pub. L. 111–148 substituted "285t" for "287c–31".

PART B—HEALTH CARE IMPROVEMENT RESEARCH

§299b. Health care outcome improvement research

(a) Evidence rating systems

In collaboration with experts from the public and private sector, the Agency shall identify and

disseminate methods or systems to assess health care research results, particularly methods or systems to rate the strength of the scientific evidence underlying health care practice, recommendations in the research literature, and technology assessments. The Agency shall make methods or systems for evidence rating widely available. Agency publications containing health care recommendations shall indicate the level of substantiating evidence using such methods or systems.

(b) Health care improvement research centers and provider-based research networks

(1) In general

In order to address the full continuum of care and outcomes research, to link research to practice improvement, and to speed the dissemination of research findings to community practice settings, the Agency shall employ research strategies and mechanisms that will link research directly with clinical practice in geographically diverse locations throughout the United States, including—

(A) health care improvement research centers that combine demonstrated multidisciplinary expertise in outcomes or quality improvement research with linkages to relevant sites of care;

(B) provider-based research networks, including plan, facility, or delivery system sites of care (especially primary care), that can evaluate outcomes and evaluate and promote quality improvement; and

(C) other innovative mechanisms or strategies to link research with clinical practice.

(2) Requirements

The Director is authorized to establish the requirements for entities applying for grants under this subsection.

(July 1, 1944, ch. 373, title IX, §911, as added Pub. L. 106–129, §2(a), Dec. 6, 1999, 113 Stat. 1656.)

EDITORIAL NOTES

PRIOR PROVISIONS

A prior section 299b, act July 1, 1944, ch. 373, title IX, §911, as added Pub. L. 101–239, title VI, §6103(a), Dec. 19, 1989, 103 Stat. 2192; amended Pub. L. 102–410, §5(b), Oct. 13, 1992, 106 Stat. 2097, related to establishment of Office of the Forum for Quality and Effectiveness in Health Care, prior to the general amendment of this subchapter by Pub. L. 106–129.

Another prior section 299b, act July 1, 1944, ch. 373, title IX, §902, as added Oct. 6, 1965, Pub. L. 89–239, §2, 79 Stat. 927; amended Oct. 15, 1968, Pub. L. 90–574, title I, §103, 82 Stat. 1005; Oct. 30, 1970, Pub. L. 91–515, title I, §§104, 111(b), 84 Stat. 1299, 1301, defined terms for purposes of this subchapter, prior to repeal by Pub. L. 99–117, §12(d), Oct. 7, 1985, 99 Stat. 495.

§299b–1. Private-public partnerships to improve organization and delivery

(a) Support for efforts to develop information on quality

(1) Scientific and technical support

In its role as the principal agency for health care research and quality, the Agency may provide scientific and technical support for private and public efforts to improve health care quality, including the activities of accrediting organizations.

(2) Role of the Agency

With respect to paragraph (1), the role of the Agency shall include—

(A) the identification and assessment of methods for the evaluation of the health of—

(i) enrollees in health plans by type of plan, provider, and provider arrangements; and

(ii) other populations, including those receiving long-term care services;

(B) the ongoing development, testing, and dissemination of quality measures, including measures of health and functional outcomes;

(C) the compilation and dissemination of health care quality measures developed in the

private and public sector;

(D) assistance in the development of improved health care information systems;

(E) the development of survey tools for the purpose of measuring participant and beneficiary assessments of their health care; and

(F) identifying and disseminating information on mechanisms for the integration of information on quality into purchaser and consumer decision-making processes.

(b) Centers for education and research on therapeutics

(1) In general

The Secretary, acting through the Director and in consultation with the Commissioner of Food and Drugs, shall establish a program for the purpose of making one or more grants for the establishment and operation of one or more centers to carry out the activities specified in paragraph (2).

(2) Required activities

The activities referred to in this paragraph are the following:

(A) The conduct of state-of-the-art research for the following purposes:

(i) To increase awareness of—

(I) new uses of drugs, biological products, and devices;

(II) ways to improve the effective use of drugs, biological products, and devices; and

(III) risks of new uses and risks of combinations of drugs and biological products.

(ii) To provide objective clinical information to the following individuals and entities:

(I) Health care practitioners and other providers of health care goods or services.

(II) Pharmacists, pharmacy benefit managers and purchasers.

(III) Health maintenance organizations and other managed health care organizations.

(IV) Health care insurers and governmental agencies.

(V) Patients and consumers.

(iii) To improve the quality of health care while reducing the cost of health care through—

(I) an increase in the appropriate use of drugs, biological products, or devices; and

(II) the prevention of adverse effects of drugs, biological products, and devices and the consequences of such effects, such as unnecessary hospitalizations.

(B) The conduct of research on the comparative effectiveness, cost-effectiveness, and safety of drugs, biological products, and devices.

(C) Such other activities as the Secretary determines to be appropriate, except that a grant may not be expended to assist the Secretary in the review of new drugs, biological products, and devices.

(c) Reducing errors in medicine

The Director shall, in accordance with part C, conduct and support research and build private-public partnerships to—

(1) identify the causes of preventable health care errors and patient injury in health care delivery;

(2) develop, demonstrate, and evaluate strategies for reducing errors and improving patient safety; and

(3) disseminate such effective strategies throughout the health care industry.

(July 1, 1944, ch. 373, title IX, §912, as added Pub. L. 106–129, §2(a), Dec. 6, 1999, 113 Stat. 1656; amended Pub. L. 109–41, §2(a)(1), July 29, 2005, 119 Stat. 424.)

EDITORIAL NOTES

PRIOR PROVISIONS

A prior section 299b–1, act July 1, 1944, ch. 373, title IX, §912, as added Pub. L. 101–239, title VI, §6103(a), Dec. 19, 1989, 103 Stat. 2192; amended Pub. L. 102–410, §§5(a)(1), (c)(1), 6(b), Oct. 13, 1992, 106 Stat. 2096, 2097, 2100, related to the duties of the Office of the Forum for Quality and Effectiveness in Health Care, prior to the general amendment of this subchapter by Pub. L. 106–129.

AMENDMENTS

2005—Subsec. (c). Pub. L. 109–41 inserted ", in accordance with part C," after "The Director shall" in introductory provisions.

§299b–2. Information on quality and cost of care

(a) In general

The Director shall—

(1) conduct a survey to collect data on a nationally representative sample of the population on the cost, use and, for fiscal year 2001 and subsequent fiscal years, quality of health care, including the types of health care services Americans use, their access to health care services, frequency of use, how much is paid for the services used, the source of those payments, the types and costs of private health insurance, access, satisfaction, and quality of care for the general population including rural residents and also for populations identified in section 299(c) of this title; and

(2) develop databases and tools that provide information to States on the quality, access, and use of health care services provided to their residents.

(b) Quality and outcomes information

(1) In general

Beginning in fiscal year 2001, the Director shall ensure that the survey conducted under subsection (a)(1) will—

(A) identify determinants of health outcomes and functional status, including the health care needs of populations identified in section 299(c) of this title, provide data to study the relationships between health care quality, outcomes, access, use, and cost, measure changes over time, and monitor the overall national impact of Federal and State policy changes on health care;

(B) provide information on the quality of care and patient outcomes for frequently occurring clinical conditions for a nationally representative sample of the population including rural residents; and

(C) provide reliable national estimates for children and persons with special health care needs through the use of supplements or periodic expansions of the survey.

In expanding the Medical Expenditure Panel Survey, as in existence on December 6, 1999, in fiscal year 2001 to collect information on the quality of care, the Director shall take into account any outcomes measurements generally collected by private sector accreditation organizations.

(2) Annual report

Beginning in fiscal year 2003, the Secretary, acting through the Director, shall submit to Congress an annual report on national trends in the quality of health care provided to the American people.

(July 1, 1944, ch. 373, title IX, §913, as added Pub. L. 106–129, §2(a), Dec. 6, 1999, 113 Stat. 1658.)

EDITORIAL NOTES

CODIFICATION

December 6, 1999, referred to in subsec. (b)(1), was in the original "the date of the enactment of this title", which was translated as meaning the date of enactment of Pub. L. 106–129, which amended this subchapter generally, to reflect the probable intent of Congress.

PRIOR PROVISIONS

A prior section 299b–2, act July 1, 1944, ch. 373, title IX, §913, as added Pub. L. 101–239, title VI, §6103(a), Dec. 19, 1989, 103 Stat. 2193; amended Pub. L. 102–410, §5(c)(2), (f)(1)(A), Oct. 13, 1992, 106 Stat. 2097, 2098, related to development of guidelines and standards, prior to the general amendment of this subchapter by Pub. L. 106–129.

§299b–3. Information systems for health care improvement

(a) In general

In order to foster a range of innovative approaches to the management and communication of health information, the Agency shall conduct and support research, evaluations, and initiatives to advance—

(1) the use of information systems for the study of health care quality and outcomes, including the generation of both individual provider and plan-level comparative performance data;

(2) training for health care practitioners and researchers in the use of information systems;

(3) the creation of effective linkages between various sources of health information, including the development of information networks;

(4) the delivery and coordination of evidence-based health care services, including the use of real-time health care decision-support programs;

(5) the utility and comparability of health information data and medical vocabularies by addressing issues related to the content, structure, definitions and coding of such information and data in consultation with appropriate Federal, State and private entities;

(6) the use of computer-based health records in all settings for the development of personal health records for individual health assessment and maintenance, and for monitoring public health and outcomes of care within populations; and

(7) the protection of individually identifiable information in health services research and health care quality improvement.

(b) Demonstration

The Agency shall support demonstrations into the use of new information tools aimed at improving shared decision-making between patients and their care-givers.

(c) Facilitating public access to information

The Director shall work with appropriate public and private sector entities to facilitate public access to information regarding the quality of and consumer satisfaction with health care.

(July 1, 1944, ch. 373, title IX, §914, as added Pub. L. 106–129, §2(a), Dec. 6, 1999, 113 Stat. 1658.)

EDITORIAL NOTES

PRIOR PROVISIONS

A prior section 299b–3, act July 1, 1944, ch. 373, title IX, §914, as added Pub. L. 101–239, title VI, §6103(a), Dec. 19, 1989, 103 Stat. 2193; amended Pub. L. 102–410, §§5(c)(3), 6(a), 7, Oct. 13, 1992, 106 Stat. 2097, 2099, 2100; Pub. L. 103–43, title XX, §2013(2), June 10, 1993, 107 Stat. 215, related to creation of an agenda and additional requirements, prior to the general amendment of this subchapter by Pub. L. 106–129.

§299b–4. Research supporting primary care and access in underserved areas

(a) Preventive Services Task Force

(1) Establishment and purpose

The Director shall convene an independent Preventive Services Task Force (referred to in this subsection as the "Task Force") to be composed of individuals with appropriate expertise. Such

Task Force shall review the scientific evidence related to the effectiveness, appropriateness, and cost-effectiveness of clinical preventive services for the purpose of developing recommendations for the health care community, and updating previous clinical preventive recommendations, to be published in the Guide to Clinical Preventive Services (referred to in this section as the "Guide"), for individuals and organizations delivering clinical services, including primary care professionals, health care systems, professional societies, employers, community organizations, non-profit organizations, Congress and other policy-makers, governmental public health agencies, health care quality organizations, and organizations developing national health objectives. Such recommendations shall consider clinical preventive best practice recommendations from the Agency for Healthcare Research and Quality, the National Institutes of Health, the Centers for Disease Control and Prevention, the Institute of Medicine, specialty medical associations, patient groups, and scientific societies.

(2) Duties

The duties of the Task Force shall include—

(A) the development of additional topic areas for new recommendations and interventions related to those topic areas, including those related to specific sub-populations and age groups;

(B) at least once during every 5-year period, review [1] interventions and update [2] recommendations related to existing topic areas, including new or improved techniques to assess the health effects of interventions;

(C) improved integration with Federal Government health objectives and related target setting for health improvement;

(D) the enhanced dissemination of recommendations;

(E) the provision of technical assistance to those health care professionals, agencies and organizations that request help in implementing the Guide [3] recommendations; and

(F) the submission of yearly reports to Congress and related agencies identifying gaps in research, such as preventive services that receive an insufficient evidence statement, and recommending priority areas that deserve further examination, including areas related to populations and age groups not adequately addressed by current recommendations.

(3) Role of Agency

The Agency shall provide ongoing administrative, research, and technical support for the operations of the Task Force, including coordinating and supporting the dissemination of the recommendations of the Task Force, ensuring adequate staff resources, and assistance to those organizations requesting it for implementation of the Guide's recommendations.

(4) Coordination with Community Preventive Services Task Force

The Task Force shall take appropriate steps to coordinate its work with the Community Preventive Services Task Force and the Advisory Committee on Immunization Practices, including the examination of how each task force's recommendations interact at the nexus of clinic and community.

(5) Operation

Operation.[4] In carrying out the duties under paragraph (2), the Task Force is not subject to the provisions of chapter 10 of title 5.

(6) Independence

All members of the Task Force convened under this subsection, and any recommendations made by such members, shall be independent and, to the extent practicable, not subject to political pressure.

(7) Authorization of appropriations

There are authorized to be appropriated such sums as may be necessary for each fiscal year to carry out the activities of the Task Force.

(b) Primary care research

(1) In general

There is established within the Agency a Center for Primary Care Research (referred to in this subsection as the "Center") that shall serve as the principal source of funding for primary care practice research in the Department of Health and Human Services. For purposes of this paragraph, primary care research focuses on the first contact when illness or health concerns arise, the diagnosis, treatment or referral to specialty care, preventive care, and the relationship between the clinician and the patient in the context of the family and community.

(2) Research

In carrying out this section, the Center shall conduct and support research concerning—

(A) the nature and characteristics of primary care practice;
(B) the management of commonly occurring clinical problems;
(C) the management of undifferentiated clinical problems; and
(D) the continuity and coordination of health services.

(July 1, 1944, ch. 373, title IX, §915, as added Pub. L. 106–129, §2(a), Dec. 6, 1999, 113 Stat. 1659; amended Pub. L. 111–148, title IV, §4003(a), Mar. 23, 2010, 124 Stat. 541; Pub. L. 117–286, §4(a)(241), Dec. 27, 2022, 136 Stat. 4332.)

EDITORIAL NOTES

AMENDMENTS

2022—Subsec. (a)(5). Pub. L. 117–286 substituted "chapter 10 of title 5." for "Appendix 2 of title 5."

2010—Subsec. (a). Pub. L. 111–148 added subsec. (a) and struck out former subsec. (a) which related to establishment and purpose of Preventive Services Task Force, provision of support by Agency, and nonapplicability of provisions of Appendix 2 of title 5.

[1] *So in original. Probably should be "review of".*

[2] *So in original. Probably should be "updating of".*

[3] *So in original. Probably should be "Guide's".*

[4] *So in original.*

§299b–4a. Studies on preventive interventions in primary care for older Americans

(a) Studies

The Secretary of Health and Human Services, acting through the United States Preventive Services Task Force, shall conduct a series of studies designed to identify preventive interventions that can be delivered in the primary care setting and that are most valuable to older Americans.

(b) Mission statement

The mission statement of the United States Preventive Services Task Force is amended to include the evaluation of services that are of particular relevance to older Americans.

(c) Report

Not later than 1 year after December 21, 2000, and annually thereafter, the Secretary of Health and Human Services shall submit to Congress a report on the conclusions of the studies conducted under subsection (a), together with recommendations for such legislation and administrative actions as the Secretary considers appropriate.

(Pub. L. 106–554, §1(a)(6) [title I, §126], Dec. 21, 2000, 114 Stat. 2763, 2763A–479.)

EDITORIAL NOTES

CODIFICATION

Section was enacted as part of the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000, and also as part of the Consolidated Appropriations Act, 2001, and not as part of the Public Health Service Act which comprises this chapter.

§299b–5. Health care practice and technology innovation

(a) In general

The Director shall promote innovation in evidence-based health care practices and technologies by—

(1) conducting and supporting research on the development, diffusion, and use of health care technology;

(2) developing, evaluating, and disseminating methodologies for assessments of health care practices and technologies;

(3) conducting intramural and supporting extramural assessments of existing and new health care practices and technologies;

(4) promoting education and training and providing technical assistance in the use of health care practice and technology assessment methodologies and results; and

(5) working with the National Library of Medicine and the public and private sector to develop an electronic clearinghouse of currently available assessments and those in progress.

(b) Specification of process

(1) In general

Not later than December 31, 2000, the Director shall develop and publish a description of the methods used by the Agency and its contractors for health care practice and technology assessment.

(2) Consultations

In carrying out this subsection, the Director shall cooperate and consult with the Assistant Secretary for Health, the Administrator of the Centers for Medicare & Medicaid Services, the Director of the National Institutes of Health, the Commissioner of Food and Drugs, and the heads of any other interested Federal department or agency, and shall seek input, where appropriate, from professional societies and other private and public entities.

(3) Methodology

The Director shall, in developing the methods used under paragraph (1), consider—

(A) safety, efficacy, and effectiveness;

(B) legal, social, and ethical implications;

(C) costs, benefits, and cost-effectiveness;

(D) comparisons to alternate health care practices and technologies; and

(E) requirements of Food and Drug Administration approval to avoid duplication.

(c) Specific assessments

(1) In general

The Director shall conduct or support specific assessments of health care technologies and practices.

(2) Requests for assessments

The Director is authorized to conduct or support assessments, on a reimbursable basis, for the Centers for Medicare & Medicaid Services, the Department of Defense, the Department of Veterans Affairs, the Office of Personnel Management, and other public or private entities.

(3) Grants and contracts

In addition to conducting assessments, the Director may make grants to, or enter into cooperative agreements or contracts with, entities described in paragraph (4) for the purpose of conducting assessments of experimental, emerging, existing, or potentially outmoded health care technologies, and for related activities.

(4) Eligible entities

An entity described in this paragraph is an entity that is determined to be appropriate by the Director, including academic medical centers, research institutions and organizations, professional organizations, third party payers, governmental agencies, minority institutions of higher education (such as Historically Black Colleges and Universities, and Hispanic institutions), and consortia of appropriate research entities established for the purpose of conducting technology assessments.

(d) Medical examination of certain victims

(1) In general

The Director shall develop and disseminate a report on evidence-based clinical practices for—

(A) the examination and treatment by health professionals of individuals who are victims of sexual assault (including child molestation) or attempted sexual assault; and

(B) the training of health professionals, in consultation with the Health Resources and Services Administration, on performing medical evidentiary examinations of individuals who are victims of child abuse or neglect, sexual assault, elder abuse, or domestic violence.

(2) Certain considerations

In identifying the issues to be addressed by the report, the Director shall, to the extent practicable, take into consideration the expertise and experience of Federal and State law enforcement officials regarding the victims referred to in paragraph (1), and of other appropriate public and private entities (including medical societies, victim services organizations, sexual assault prevention organizations, and social services organizations).

(July 1, 1944, ch. 373, title IX, §916, as added Pub. L. 106–129, §2(a), Dec. 6, 1999, 113 Stat. 1660; amended Pub. L. 108–173, title IX, §900(e)(2)(C), Dec. 8, 2003, 117 Stat. 2372.)

EDITORIAL NOTES

AMENDMENTS

2003—Subsecs. (b)(2), (c)(2). Pub. L. 108–173 substituted "Centers for Medicare & Medicaid Services" for "Health Care Financing Administration".

§299b–6. Coordination of Federal Government quality improvement efforts

(a) Requirement

(1) In general

To avoid duplication and ensure that Federal resources are used efficiently and effectively, the Secretary, acting through the Director, shall coordinate all research, evaluations, and demonstrations related to health services research, quality measurement and quality improvement activities undertaken and supported by the Federal Government.

(2) Specific activities

The Director, in collaboration with the appropriate Federal officials representing all concerned executive agencies and departments, shall develop and manage a process to—

(A) improve interagency coordination, priority setting, and the use and sharing of research findings and data pertaining to Federal quality improvement programs, technology assessment, and health services research;

(B) strengthen the research information infrastructure, including databases, pertaining to Federal health services research and health care quality improvement initiatives;

(C) set specific goals for participating agencies and departments to further health services research and health care quality improvement; and

(D) strengthen the management of Federal health care quality improvement programs.

(b) Study by the Institute of Medicine

(1) In general

To provide Congress, the Department of Health and Human Services, and other relevant departments with an independent, external review of their quality oversight, quality improvement and quality research programs, the Secretary shall enter into a contract with the Institute of Medicine—

(A) to describe and evaluate current quality improvement, quality research and quality monitoring processes through—

(i) an overview of pertinent health services research activities and quality improvement efforts conducted by all Federal programs, with particular attention paid to those under titles XVIII, XIX, and XXI of the Social Security Act [42 U.S.C. 1395 et seq., 1396 et seq., 1397aa et seq.]; and

(ii) a summary of the partnerships that the Department of Health and Human Services has pursued with private accreditation, quality measurement and improvement organizations; and

(B) to identify options and make recommendations to improve the efficiency and effectiveness of quality improvement programs through—

(i) the improved coordination of activities across the medicare, medicaid and child health insurance programs under titles XVIII, XIX and XXI of the Social Security Act and health services research programs;

(ii) the strengthening of patient choice and participation by incorporating state-of-the-art quality monitoring tools and making information on quality available; and

(iii) the enhancement of the most effective programs, consolidation as appropriate, and elimination of duplicative activities within various Federal agencies.

(2) Requirements

(A) In general

The Secretary shall enter into a contract with the Institute of Medicine for the preparation—

(i) not later than 12 months after December 6, 1999, of a report providing an overview of the quality improvement programs of the Department of Health and Human Services for the medicare, medicaid, and CHIP programs under titles XVIII, XIX, and XXI of the Social Security Act; and

(ii) not later than 24 months after December 6, 1999, of a final report containing recommendations.

(B) Reports

The Secretary shall submit the reports described in subparagraph (A) to the Committee on Finance and the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Ways and Means and the Committee on Commerce of the House of Representatives.

(July 1, 1944, ch. 373, title IX, §917, as added Pub. L. 106–129, §2(a), Dec. 6, 1999, 113 Stat. 1661.)

EDITORIAL NOTES

REFERENCES IN TEXT

The Social Security Act, referred to in subsec. (b), is act Aug. 14, 1935, ch. 531, 49 Stat. 620. Titles XVIII, XIX, and XXI of the Act are classified generally to subchapters XVIII (§1395 et seq.), XIX (§1396 et seq.),

and XXI (§1397aa et seq.), respectively, of chapter 7 of this title. For complete classification of this Act to the Code, see section 1305 of this title and Tables.

CODIFICATION

December 6, 1999, referred to in subsec. (b)(2)(A), was in the original "the date of the enactment of this title", which was translated as meaning the date of enactment of Pub. L. 106–129, which amended this subchapter generally, to reflect the probable intent of Congress.

STATUTORY NOTES AND RELATED SUBSIDIARIES

CHANGE OF NAME

Committee on Commerce of House of Representatives changed to Committee on Energy and Commerce of House of Representatives, and jurisdiction over matters relating to securities and exchanges and insurance generally transferred to Committee on Financial Services of House of Representatives by House Resolution No. 5, One Hundred Seventh Congress, Jan. 3, 2001.

§299b–7. Research on outcomes of health care items and services

(a) Research, demonstrations, and evaluations

(1) Improvement of effectiveness and efficiency

(A) In general

To improve the quality, effectiveness, and efficiency of health care delivered pursuant to the programs established under titles XVIII, XIX, and XXI of the Social Security Act [42 U.S.C. 1395 et seq., 1396 et seq., 1397aa et seq.], the Secretary [1] acting through the Director of the Agency for Healthcare Research and Quality (in this section referred to as the "Director"), shall conduct and support research to meet the priorities and requests for scientific evidence and information identified by such programs with respect to—

(i) the outcomes, comparative clinical effectiveness, and appropriateness of health care items and services (including prescription drugs); and

(ii) strategies for improving the efficiency and effectiveness of such programs, including the ways in which such items and services are organized, managed, and delivered under such programs.

(B) Specification

To respond to priorities and information requests in subparagraph (A), the Secretary may conduct or support, by grant, contract, or interagency agreement, research, demonstrations, evaluations, technology assessments, or other activities, including the provision of technical assistance, scientific expertise, or methodological assistance.

(2) Priorities

(A) In general

The Secretary shall establish a process to develop priorities that will guide the research, demonstrations, and evaluation activities undertaken pursuant to this section.

(B) Initial list

Not later than 6 months after December 8, 2003, the Secretary shall establish an initial list of priorities for research related to health care items and services (including prescription drugs).

(C) Process

In carrying out subparagraph (A), the Secretary—

(i) shall ensure that there is broad and ongoing consultation with relevant stakeholders in identifying the highest priorities for research, demonstrations, and evaluations to support and improve the programs established under titles XVIII, XIX, and XXI of the Social Security

Act [42 U.S.C. 1395 et seq., 1396 et seq., 1397aa et seq.];

(ii) may include health care items and services which impose a high cost on such programs, as well as those which may be underutilized or overutilized and which may significantly improve the prevention, treatment, or cure of diseases and conditions (including chronic conditions) which impose high direct or indirect costs on patients or society; and

(iii) shall ensure that the research and activities undertaken pursuant to this section are responsive to the specified priorities and are conducted in a timely manner.

(3) Evaluation and synthesis of scientific evidence

(A) In general

The Secretary shall—

(i) evaluate and synthesize available scientific evidence related to health care items and services (including prescription drugs) identified as priorities in accordance with paragraph (2) with respect to the comparative clinical effectiveness, outcomes, appropriateness, and provision of such items and services (including prescription drugs);

(ii) identify issues for which existing scientific evidence is insufficient with respect to such health care items and services (including prescription drugs);

(iii) disseminate to prescription drug plans and MA–PD plans under part D of title XVIII of the Social Security Act [42 U.S.C. 1395w–101 et seq.], other health plans, and the public the findings made under clauses (i) and (ii); and

(iv) work in voluntary collaboration with public and private sector entities to facilitate the development of new scientific knowledge regarding health care items and services (including prescription drugs).

(B) Initial research

The Secretary shall complete the evaluation and synthesis of the initial research required by the priority list developed under paragraph (2)(B) not later than 18 months after the development of such list.

(C) Dissemination

(i) In general

To enhance patient safety and the quality of health care, the Secretary shall make available and disseminate in appropriate formats to prescription drugs plans under part D, and MA–PD plans under part C, of title XVIII of the Social Security Act [42 U.S.C. 1395w–101 et seq., 1395w–21 et seq.], other health plans, and the public the evaluations and syntheses prepared pursuant to subparagraph (A) and the findings of research conducted pursuant to paragraph (1). In carrying out this clause the Secretary, in order to facilitate the availability of such evaluations and syntheses or findings at every decision point in the health care system, shall—

(I) present such evaluations and syntheses or findings in a form that is easily understood by the individuals receiving health care items and services (including prescription drugs) under such plans and periodically assess that the requirements of this subclause have been met; and

(II) provide such evaluations and syntheses or findings and other relevant information through easily accessible and searchable electronic mechanisms, and in hard copy formats as appropriate.

(ii) Rule of construction

Nothing in this section shall be construed as—

(I) affecting the authority of the Secretary or the Commissioner of Food and Drugs under the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 301 et seq.] or the Public Health Service Act [42 U.S.C. 201 et seq.]; or

(II) conferring any authority referred to in subclause (I) to the Director.

(D) Accountability

In carrying out this paragraph, the Secretary shall implement activities in a manner that—

(i) makes publicly available all scientific evidence relied upon and the methodologies employed, provided such evidence and method are not protected from public disclosure by section 1905 of title 18 or other applicable law so that the results of the research, analyses, or syntheses can be evaluated or replicated; and

(ii) ensures that any information needs and unresolved issues identified in subparagraph (A)(ii) are taken into account in priority-setting for future research conducted by the Secretary.

(4) Confidentiality

(A) In general

In making use of administrative, clinical, and program data and information developed or collected with respect to the programs established under titles XVIII, XIX, and XXI of the Social Security Act [42 U.S.C. 1395 et seq., 1396 et seq., 1397aa et seq.], for purposes of carrying out the requirements of this section or the activities authorized under title IX of the Public Health Service Act (42 U.S.C. 299 et seq.), such data and information shall be protected in accordance with the confidentiality requirements of title IX of the Public Health Service Act.

(B) Rule of construction

Nothing in this section shall be construed to require or permit the disclosure of data provided to the Secretary that is otherwise protected from disclosure under the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 301 et seq.], section 1905 of title 18, or other applicable law.

(5) Evaluations

The Secretary shall conduct and support evaluations of the activities carried out under this section to determine the extent to which such activities have had an effect on outcomes and utilization of health care items and services.

(6) Improving information available to health care providers, patients, and policymakers

Not later than 18 months after December 8, 2003, the Secretary shall identify options that could be undertaken in voluntary collaboration with private and public entities (as appropriate) for the—

(A) provision of more timely information through the programs established under titles XVIII, XIX, and XXI of the Social Security Act [42 U.S.C. 1395 et seq., 1396 et seq., 1397aa et seq.], regarding the outcomes and quality of patient care, including clinical and patient-reported outcomes, especially with respect to interventions and conditions for which clinical trials would not be feasible or raise ethical concerns that are difficult to address;

(B) acceleration of the adoption of innovation and quality improvement under such programs; and

(C) development of management tools for the programs established under titles XIX and XXI of the Social Security Act [42 U.S.C. 1396 et seq., 1397aa et seq.], and with respect to the programs established under such titles, assess the feasibility of using administrative or claims data, to—

(i) improve oversight by State officials;

(ii) support Federal and State initiatives to improve the quality, safety, and efficiency of services provided under such programs; and

(iii) provide a basis for estimating the fiscal and coverage impact of Federal or State program and policy changes.

(b) Recommendations

(1) Disclaimer

In carrying out this section, the Director shall—

(A) not mandate national standards of clinical practice or quality health care standards; and

(B) include in any recommendations resulting from projects funded and published by the Director, a corresponding reference to the prohibition described in subparagraph (A).

(2) Requirement for implementation

Research, evaluation, and communication activities performed pursuant to this section shall reflect the principle that clinicians and patients should have the best available evidence upon which to make choices in health care items and services, in providers, and in health care delivery systems, recognizing that patient subpopulations and patient and physician preferences may vary.

(3) Rule of construction

Nothing in this section shall be construed to provide the Director with authority to mandate a national standard or require a specific approach to quality measurement and reporting.

(c) Research with respect to dissemination

The Secretary, acting through the Director, may conduct or support research with respect to improving methods of disseminating information in accordance with subsection (a)(3)(C).

(d) Limitation on CMS

The Administrator of the Centers for Medicare & Medicaid Services may not use data obtained in accordance with this section to withhold coverage of a prescription drug.

(e) Authorization of appropriations

There is authorized to be appropriated to carry out this section, $50,000,000 for fiscal year 2004, and such sums as may be necessary for each fiscal year thereafter.

(Pub. L. 108–173, title X, §1013, Dec. 8, 2003, 117 Stat. 2438.)

EDITORIAL NOTES

REFERENCES IN TEXT

The Social Security Act, referred to in subsec. (a)(1)(A), (2)(C)(i), (3)(A)(iii), (C)(i), (4)(A), (6)(A), (C), is act Aug. 14, 1935, ch. 531, 49 Stat. 620. Titles XVIII, XIX, and XXI of the Act are classified generally to subchapters XVIII (§1395 et seq.), XIX (§1396 et seq.), and XXI (§1397aa et seq.), respectively, of chapter 7 of this title. Parts C and D of title XVIII of the Act are classified generally to parts C (§1395w–21 et seq.) and D (§1395w–101 et seq.), respectively, of subchapter XVIII of chapter 7 of this title. For complete classification of this Act to the Code, see section 1305 of this title and Tables.

The Federal Food, Drug, and Cosmetic Act, referred to in subsec. (a)(3)(C)(ii)(I), (4)(B), is act June 25, 1938, ch. 675, 52 Stat. 1040, which is classified generally to chapter 9 (§301 et seq.) of Title 21, Food and Drugs. For complete classification of this Act to the Code, see section 301 of Title 21 and Tables.

The Public Health Service Act, referred to in subsec. (a)(3)(C)(ii)(I), (4)(A), is act July 1, 1944, ch. 373, 58 Stat. 682, which is classified generally to this chapter. Title IX of the Act is classified generally to this subchapter. For complete classification of this Act to the Code, see Short Title note set out under section 201 of this title and Tables.

CODIFICATION

Section was enacted as part of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, and not as part of the Public Health Service Act which comprises this chapter.

STATUTORY NOTES AND RELATED SUBSIDIARIES

DEFINITION OF "SECRETARY"

"Secretary" means the Secretary of Health and Human Services, see section 1(c)(2) of Pub. L. 108–173, set out as a note under section 1301 of this title.

[1] *So in original. Probably should be followed by a comma.*

§299b–8. Omitted

EDITORIAL NOTES

CODIFICATION

Section, Pub. L. 111–5, div. A, title VIII, §804, Feb. 17, 2009, 123 Stat. 187, established the Federal Coordinating Council for Comparative Effectiveness Research.

STATUTORY NOTES AND RELATED SUBSIDIARIES

TERMINATION OF FEDERAL COORDINATING COUNCIL FOR COMPARATIVE EFFECTIVENESS RESEARCH

Pub. L. 111–148, title VI, §6302, Mar. 23, 2010, 124 Stat. 747, provided that the Federal Coordinating Council for Comparative Effectiveness Research established under this section terminated on Mar. 23, 2010.

PART C—PATIENT SAFETY IMPROVEMENT

§299b–21. Definitions

In this part:

(1) HIPAA confidentiality regulations

The term "HIPAA confidentiality regulations" means regulations promulgated under section 264(c) of the Health Insurance Portability and Accountability Act of 1996 (Public Law 104–191; 110 Stat. 2033).

(2) Identifiable patient safety work product

The term "identifiable patient safety work product" means patient safety work product that—

(A) is presented in a form and manner that allows the identification of any provider that is a subject of the work product, or any providers that participate in activities that are a subject of the work product;

(B) constitutes individually identifiable health information as that term is defined in the HIPAA confidentiality regulations; or

(C) is presented in a form and manner that allows the identification of an individual who reported information in the manner specified in section 299b–22(e) of this title.

(3) Nonidentifiable patient safety work product

The term "nonidentifiable patient safety work product" means patient safety work product that is not identifiable patient safety work product (as defined in paragraph (2)).

(4) Patient safety organization

The term "patient safety organization" means a private or public entity or component thereof that is listed by the Secretary pursuant to section 299b–24(d) of this title.

(5) Patient safety activities

The term "patient safety activities" means the following activities:

(A) Efforts to improve patient safety and the quality of health care delivery.

(B) The collection and analysis of patient safety work product.

(C) The development and dissemination of information with respect to improving patient safety, such as recommendations, protocols, or information regarding best practices.

(D) The utilization of patient safety work product for the purposes of encouraging a culture of safety and of providing feedback and assistance to effectively minimize patient risk.

(E) The maintenance of procedures to preserve confidentiality with respect to patient safety work product.

(F) The provision of appropriate security measures with respect to patient safety work

product.

(G) The utilization of qualified staff.

(H) Activities related to the operation of a patient safety evaluation system and to the provision of feedback to participants in a patient safety evaluation system.

(6) Patient safety evaluation system

The term "patient safety evaluation system" means the collection, management, or analysis of information for reporting to or by a patient safety organization.

(7) Patient safety work product

(A) In general

Except as provided in subparagraph (B), the term "patient safety work product" means any data, reports, records, memoranda, analyses (such as root cause analyses), or written or oral statements—

(i) which—

(I) are assembled or developed by a provider for reporting to a patient safety organization and are reported to a patient safety organization; or

(II) are developed by a patient safety organization for the conduct of patient safety activities;

and which could result in improved patient safety, health care quality, or health care outcomes; or

(ii) which identify or constitute the deliberations or analysis of, or identify the fact of reporting pursuant to, a patient safety evaluation system.

(B) Clarification

(i) Information described in subparagraph (A) does not include a patient's medical record, billing and discharge information, or any other original patient or provider record.

(ii) Information described in subparagraph (A) does not include information that is collected, maintained, or developed separately, or exists separately, from a patient safety evaluation system. Such separate information or a copy thereof reported to a patient safety organization shall not by reason of its reporting be considered patient safety work product.

(iii) Nothing in this part shall be construed to limit—

(I) the discovery of or admissibility of information described in this subparagraph in a criminal, civil, or administrative proceeding;

(II) the reporting of information described in this subparagraph to a Federal, State, or local governmental agency for public health surveillance, investigation, or other public health purposes or health oversight purposes; or

(III) a provider's recordkeeping obligation with respect to information described in this subparagraph under Federal, State, or local law.

(8) Provider

The term "provider" means—

(A) an individual or entity licensed or otherwise authorized under State law to provide health care services, including—

(i) a hospital, nursing facility, comprehensive outpatient rehabilitation facility, home health agency, hospice program, renal dialysis facility, ambulatory surgical center, pharmacy, physician or health care practitioner's office, long term care facility, behavior health residential treatment facility, clinical laboratory, or health center; or

(ii) a physician, physician assistant, nurse practitioner, clinical nurse specialist, certified registered nurse anesthetist, certified nurse midwife, psychologist, certified social worker, registered dietitian or nutrition professional, physical or occupational therapist, pharmacist, or other individual health care practitioner; or

(B) any other individual or entity specified in regulations promulgated by the Secretary.

(July 1, 1944, ch. 373, title IX, §921, as added Pub. L. 109–41, §2(a)(5), July 29, 2005, 119 Stat. 424.)

EDITORIAL NOTES

REFERENCES IN TEXT

Section 264(c) of the Health Insurance Portability and Accountability Act of 1996, referred to in par. (1), is section 264(c) of Pub. L. 104–191, which is set out as a note under section 1320d–2 of this title.

PRIOR PROVISIONS

A prior section 921 of act July 1, 1944, was renumbered section 941 and is classified to section 299c of this title.

Another prior section 921 of act July 1, 1944, was classified to section 299c of this title prior to the general amendment of this subchapter by Pub. L. 106–129.

§299b–22. Privilege and confidentiality protections

(a) Privilege

Notwithstanding any other provision of Federal, State, or local law, and subject to subsection (c), patient safety work product shall be privileged and shall not be—

(1) subject to a Federal, State, or local civil, criminal, or administrative subpoena or order, including in a Federal, State, or local civil or administrative disciplinary proceeding against a provider;

(2) subject to discovery in connection with a Federal, State, or local civil, criminal, or administrative proceeding, including in a Federal, State, or local civil or administrative disciplinary proceeding against a provider;

(3) subject to disclosure pursuant to section 552 of title 5 (commonly known as the Freedom of Information Act) or any other similar Federal, State, or local law;

(4) admitted as evidence in any Federal, State, or local governmental civil proceeding, criminal proceeding, administrative rulemaking proceeding, or administrative adjudicatory proceeding, including any such proceeding against a provider; or

(5) admitted in a professional disciplinary proceeding of a professional disciplinary body established or specifically authorized under State law.

(b) Confidentiality of patient safety work product

Notwithstanding any other provision of Federal, State, or local law, and subject to subsection (c), patient safety work product shall be confidential and shall not be disclosed.

(c) Exceptions

Except as provided in subsection (g)(3)—

(1) Exceptions from privilege and confidentiality

Subsections (a) and (b) shall not apply to (and shall not be construed to prohibit) one or more of the following disclosures:

(A) Disclosure of relevant patient safety work product for use in a criminal proceeding, but only after a court makes an in camera determination that such patient safety work product contains evidence of a criminal act and that such patient safety work product is material to the proceeding and not reasonably available from any other source.

(B) Disclosure of patient safety work product to the extent required to carry out subsection (f)(4)(A).

(C) Disclosure of identifiable patient safety work product if authorized by each provider identified in such work product.

(2) Exceptions from confidentiality

Subsection (b) shall not apply to (and shall not be construed to prohibit) one or more of the following disclosures:

(A) Disclosure of patient safety work product to carry out patient safety activities.

(B) Disclosure of nonidentifiable patient safety work product.

(C) Disclosure of patient safety work product to grantees, contractors, or other entities carrying out research, evaluation, or demonstration projects authorized, funded, certified, or otherwise sanctioned by rule or other means by the Secretary, for the purpose of conducting research to the extent that disclosure of protected health information would be allowed for such purpose under the HIPAA confidentiality regulations.

(D) Disclosure by a provider to the Food and Drug Administration with respect to a product or activity regulated by the Food and Drug Administration.

(E) Voluntary disclosure of patient safety work product by a provider to an accrediting body that accredits that provider.

(F) Disclosures that the Secretary may determine, by rule or other means, are necessary for business operations and are consistent with the goals of this part.

(G) Disclosure of patient safety work product to law enforcement authorities relating to the commission of a crime (or to an event reasonably believed to be a crime) if the person making the disclosure believes, reasonably under the circumstances, that the patient safety work product that is disclosed is necessary for criminal law enforcement purposes.

(H) With respect to a person other than a patient safety organization, the disclosure of patient safety work product that does not include materials that—

(i) assess the quality of care of an identifiable provider; or

(ii) describe or pertain to one or more actions or failures to act by an identifiable provider.

(3) Exception from privilege

Subsection (a) shall not apply to (and shall not be construed to prohibit) voluntary disclosure of nonidentifiable patient safety work product.

(d) Continued protection of information after disclosure

(1) In general

Patient safety work product that is disclosed under subsection (c) shall continue to be privileged and confidential as provided for in subsections (a) and (b), and such disclosure shall not be treated as a waiver of privilege or confidentiality, and the privileged and confidential nature of such work product shall also apply to such work product in the possession or control of a person to whom such work product was disclosed.

(2) Exception

Notwithstanding paragraph (1), and subject to paragraph (3)—

(A) if patient safety work product is disclosed in a criminal proceeding, the confidentiality protections provided for in subsection (b) shall no longer apply to the work product so disclosed; and

(B) if patient safety work product is disclosed as provided for in subsection (c)(2)(B) (relating to disclosure of nonidentifiable patient safety work product), the privilege and confidentiality protections provided for in subsections (a) and (b) shall no longer apply to such work product.

(3) Construction

Paragraph (2) shall not be construed as terminating or limiting the privilege or confidentiality protections provided for in subsection (a) or (b) with respect to patient safety work product other than the specific patient safety work product disclosed as provided for in subsection (c).

(4) Limitations on actions

(A) Patient safety organizations

(i) In general

A patient safety organization shall not be compelled to disclose information collected or developed under this part whether or not such information is patient safety work product unless such information is identified, is not patient safety work product, and is not reasonably available from another source.

(ii) Nonapplication

The limitation contained in clause (i) shall not apply in an action against a patient safety organization or with respect to disclosures pursuant to subsection (c)(1).

(B) Providers

An accrediting body shall not take an accrediting action against a provider based on the good faith participation of the provider in the collection, development, reporting, or maintenance of patient safety work product in accordance with this part. An accrediting body may not require a provider to reveal its communications with any patient safety organization established in accordance with this part.

(e) Reporter protection

(1) In general

A provider may not take an adverse employment action, as described in paragraph (2), against an individual based upon the fact that the individual in good faith reported information—

(A) to the provider with the intention of having the information reported to a patient safety organization; or

(B) directly to a patient safety organization.

(2) Adverse employment action

For purposes of this subsection, an "adverse employment action" includes—

(A) loss of employment, the failure to promote an individual, or the failure to provide any other employment-related benefit for which the individual would otherwise be eligible; or

(B) an adverse evaluation or decision made in relation to accreditation, certification, credentialing, or licensing of the individual.

(f) Enforcement

(1) Civil monetary penalty

Subject to paragraphs (2) and (3), a person who discloses identifiable patient safety work product in knowing or reckless violation of subsection (b) shall be subject to a civil monetary penalty of not more than $10,000 for each act constituting such violation.

(2) Procedure

The provisions of section 1320a–7a of this title, other than subsections (a) and (b) and the first sentence of subsection (c)(1), shall apply to civil money penalties under this subsection in the same manner as such provisions apply to a penalty or proceeding under section 1320a–7a of this title.

(3) Relation to HIPAA

Penalties shall not be imposed both under this subsection and under the regulations issued pursuant to section 264(c)(1) of the Health Insurance Portability and Accountability Act of 1996 (42 U.S.C. 1320d–2 note) for a single act or omission.

(4) Equitable relief

(A) In general

Without limiting remedies available to other parties, a civil action may be brought by any aggrieved individual to enjoin any act or practice that violates subsection (e) and to obtain other appropriate equitable relief (including reinstatement, back pay, and restoration of benefits) to redress such violation.

(B) Against State employees

An entity that is a State or an agency of a State government may not assert the privilege described in subsection (a) unless before the time of the assertion, the entity or, in the case of and with respect to an agency, the State has consented to be subject to an action described in subparagraph (A), and that consent has remained in effect.

(g) Rule of construction

Nothing in this section shall be construed—

(1) to limit the application of other Federal, State, or local laws that provide greater privilege or confidentiality protections than the privilege and confidentiality protections provided for in this section;

(2) to limit, alter, or affect the requirements of Federal, State, or local law pertaining to information that is not privileged or confidential under this section;

(3) except as provided in subsection (i), to alter or affect the implementation of any provision of the HIPAA confidentiality regulations or section 1320d–5 of this title (or regulations promulgated under such section);

(4) to limit the authority of any provider, patient safety organization, or other entity to enter into a contract requiring greater confidentiality or delegating authority to make a disclosure or use in accordance with this section;

(5) as preempting or otherwise affecting any State law requiring a provider to report information that is not patient safety work product; or

(6) to limit, alter, or affect any requirement for reporting to the Food and Drug Administration information regarding the safety of a product or activity regulated by the Food and Drug Administration.

(h) Clarification

Nothing in this part prohibits any person from conducting additional analysis for any purpose regardless of whether such additional analysis involves issues identical to or similar to those for which information was reported to or assessed by a patient safety organization or a patient safety evaluation system.

(i) Clarification of application of HIPAA confidentiality regulations to patient safety organizations

For purposes of applying the HIPAA confidentiality regulations—

(1) patient safety organizations shall be treated as business associates; and

(2) patient safety activities of such organizations in relation to a provider are deemed to be health care operations (as defined in such regulations) of the provider.

(j) Reports on strategies to improve patient safety

(1) Draft report

Not later than the date that is 18 months after any network of patient safety databases is operational, the Secretary, in consultation with the Director, shall prepare a draft report on effective strategies for reducing medical errors and increasing patient safety. The draft report shall include any measure determined appropriate by the Secretary to encourage the appropriate use of such strategies, including use in any federally funded programs. The Secretary shall make the draft report available for public comment and submit the draft report to the Institute of Medicine for review.

(2) Final report

Not later than 1 year after the date described in paragraph (1), the Secretary shall submit a final report to the Congress.

(July 1, 1944, ch. 373, title IX, §922, as added Pub. L. 109–41, §2(a)(5), July 29, 2005, 119 Stat. 427.)

EDITORIAL NOTES

REFERENCES IN TEXT

Section 264(c)(1) of the Health Insurance Portability and Accountability Act of 1996, referred to in subsec. (f)(3), is section 264(c)(1) of Pub. L. 104–191, which is set out as a note under section 1320d–2 of this title.

PRIOR PROVISIONS

A prior section 922 of act July 1, 1944, was renumbered section 942 and is classified to section 299c–1 of this title.

Another prior section 922 of act July 1, 1944, was classified to section 299c–1 of this title prior to the general amendment of this subchapter by Pub. L. 106–129.

§299b–23. Network of patient safety databases

(a) In general

The Secretary shall facilitate the creation of, and maintain, a network of patient safety databases that provides an interactive evidence-based management resource for providers, patient safety organizations, and other entities. The network of databases shall have the capacity to accept, aggregate across the network, and analyze nonidentifiable patient safety work product voluntarily reported by patient safety organizations, providers, or other entities. The Secretary shall assess the feasibility of providing for a single point of access to the network for qualified researchers for information aggregated across the network and, if feasible, provide for implementation.

(b) Data standards

The Secretary may determine common formats for the reporting to and among the network of patient safety databases maintained under subsection (a) of nonidentifiable patient safety work product, including necessary work product elements, common and consistent definitions, and a standardized computer interface for the processing of such work product. To the extent practicable, such standards shall be consistent with the administrative simplification provisions of part C of title XI of the Social Security Act [42 U.S.C. 1320d et seq.].

(c) Use of information

Information reported to and among the network of patient safety databases under subsection (a) shall be used to analyze national and regional statistics, including trends and patterns of health care errors. The information resulting from such analyses shall be made available to the public and included in the annual quality reports prepared under section 299b–2(b)(2) of this title.

(July 1, 1944, ch. 373, title IX, §923, as added Pub. L. 109–41, §2(a)(5), July 29, 2005, 119 Stat. 431.)

EDITORIAL NOTES

REFERENCES IN TEXT

The Social Security Act, referred to in subsec. (b), is act Aug. 14, 1935, ch. 531, 49 Stat. 620. Part C of title XI of the Act is classified generally to part C (§1320d et seq.) of subchapter XI of chapter 7 of this title. For complete classification of this Act to the Code, see section 1305 of this title and Tables.

PRIOR PROVISIONS

A prior section 923 of act July 1, 1944, was renumbered section 943 and is classified to section 299c–2 of this title.

Another prior section 923 of act July 1, 1944, was classified to section 299c–2 of this title prior to the general amendment of this subchapter by Pub. L. 106–129.

§299b–24. Patient safety organization certification and listing

(a) Certification

(1) Initial certification

An entity that seeks to be a patient safety organization shall submit an initial certification to the Secretary that the entity—

(A) has policies and procedures in place to perform each of the patient safety activities described in section 299b–21(5) of this title; and

(B) upon being listed under subsection (d), will comply with the criteria described in subsection (b).

(2) Subsequent certifications

An entity that is a patient safety organization shall submit every 3 years after the date of its initial listing under subsection (d) a subsequent certification to the Secretary that the entity—

(A) is performing each of the patient safety activities described in section 299b–21(5) of this title; and

(B) is complying with the criteria described in subsection (b).

(b) Criteria

(1) In general

The following are criteria for the initial and subsequent certification of an entity as a patient safety organization:

(A) The mission and primary activity of the entity are to conduct activities that are to improve patient safety and the quality of health care delivery.

(B) The entity has appropriately qualified staff (whether directly or through contract), including licensed or certified medical professionals.

(C) The entity, within each 24-month period that begins after the date of the initial listing under subsection (d), has bona fide contracts, each of a reasonable period of time, with more than 1 provider for the purpose of receiving and reviewing patient safety work product.

(D) The entity is not, and is not a component of, a health insurance issuer (as defined in section 300gg–91(b)(2) of this title).

(E) The entity shall fully disclose—

(i) any financial, reporting, or contractual relationship between the entity and any provider that contracts with the entity; and

(ii) if applicable, the fact that the entity is not managed, controlled, and operated independently from any provider that contracts with the entity.

(F) To the extent practical and appropriate, the entity collects patient safety work product from providers in a standardized manner that permits valid comparisons of similar cases among similar providers.

(G) The utilization of patient safety work product for the purpose of providing direct feedback and assistance to providers to effectively minimize patient risk.

(2) Additional criteria for component organizations

If an entity that seeks to be a patient safety organization is a component of another organization, the following are additional criteria for the initial and subsequent certification of the entity as a patient safety organization:

(A) The entity maintains patient safety work product separately from the rest of the organization, and establishes appropriate security measures to maintain the confidentiality of the patient safety work product.

(B) The entity does not make an unauthorized disclosure under this part of patient safety work product to the rest of the organization in breach of confidentiality.

(C) The mission of the entity does not create a conflict of interest with the rest of the organization.

(c) Review of certification

(1) In general

(A) Initial certification

Upon the submission by an entity of an initial certification under subsection (a)(1), the Secretary shall determine if the certification meets the requirements of subparagraphs (A) and (B) of such subsection.

(B) Subsequent certification

Upon the submission by an entity of a subsequent certification under subsection (a)(2), the Secretary shall review the certification with respect to requirements of subparagraphs (A) and (B) of such subsection.

(2) Notice of acceptance or non-acceptance

If the Secretary determines that—

(A) an entity's initial certification meets requirements referred to in paragraph (1)(A), the Secretary shall notify the entity of the acceptance of such certification; or

(B) an entity's initial certification does not meet such requirements, the Secretary shall notify the entity that such certification is not accepted and the reasons therefor.

(3) Disclosures regarding relationship to providers

The Secretary shall consider any disclosures under subsection (b)(1)(E) by an entity and shall make public findings on whether the entity can fairly and accurately perform the patient safety activities of a patient safety organization. The Secretary shall take those findings into consideration in determining whether to accept the entity's initial certification and any subsequent certification submitted under subsection (a) and, based on those findings, may deny, condition, or revoke acceptance of the entity's certification.

(d) Listing

The Secretary shall compile and maintain a listing of entities with respect to which there is an acceptance of a certification pursuant to subsection (c)(2)(A) that has not been revoked under subsection (e) or voluntarily relinquished.

(e) Revocation of acceptance of certification

(1) In general

If, after notice of deficiency, an opportunity for a hearing, and a reasonable opportunity for correction, the Secretary determines that a patient safety organization does not meet the certification requirements under subsection (a)(2), including subparagraphs (A) and (B) of such subsection, the Secretary shall revoke the Secretary's acceptance of the certification of such organization.

(2) Supplying confirmation of notification to providers

Within 15 days of a revocation under paragraph (1), a patient safety organization shall submit to the Secretary a confirmation that the organization has taken all reasonable actions to notify each provider whose patient safety work product is collected or analyzed by the organization of such revocation.

(3) Publication of decision

If the Secretary revokes the certification of an organization under paragraph (1), the Secretary shall—

(A) remove the organization from the listing maintained under subsection (d); and

(B) publish notice of the revocation in the Federal Register.

(f) Status of data after removal from listing

(1) New data

With respect to the privilege and confidentiality protections described in section 299b–22 of this title, data submitted to an entity within 30 days after the entity is removed from the listing under subsection (e)(3)(A) shall have the same status as data submitted while the entity was still listed.

(2) Protection to continue to apply

If the privilege and confidentiality protections described in section 299b–22 of this title applied to patient safety work product while an entity was listed, or to data described in paragraph (1), such protections shall continue to apply to such work product or data after the entity is removed from the listing under subsection (e)(3)(A).

(g) Disposition of work product and data

If the Secretary removes a patient safety organization from the listing as provided for in subsection (e)(3)(A), with respect to the patient safety work product or data described in subsection (f)(1) that the patient safety organization received from another entity, such former patient safety organization shall—

(1) with the approval of the other entity and a patient safety organization, transfer such work product or data to such patient safety organization;

(2) return such work product or data to the entity that submitted the work product or data; or

(3) if returning such work product or data to such entity is not practicable, destroy such work product or data.

(July 1, 1944, ch. 373, title IX, §924, as added Pub. L. 109–41, §2(a)(5), July 29, 2005, 119 Stat. 431.)

EDITORIAL NOTES

PRIOR PROVISIONS

A prior section 924 of act July 1, 1944, was renumbered section 944 and is classified to section 299c–3 of this title.

Another prior section 924 of act July 1, 1944, was classified to section 299c–3 of this title prior to the general amendment of this subchapter by Pub. L. 106–129.

§299b–24a. Activities regarding women's health

(a) Establishment

There is established within the Office of the Director, an Office of Women's Health and Gender-Based Research (referred to in this section as the "Office"). The Office shall be headed by a director who shall be appointed by the Director of Healthcare and Research Quality.

(b) Purpose

The official designated under subsection (a) shall—

(1) report to the Director on the current Agency level of activity regarding women's health, across, where appropriate, age, biological, and sociocultural contexts, in all aspects of Agency work, including the development of evidence reports and clinical practice protocols and the conduct of research into patient outcomes, delivery of health care services, quality of care, and access to health care;

(2) establish short-range and long-range goals and objectives within the Agency for research important to women's health and, as relevant and appropriate, coordinate with other appropriate offices on activities within the Agency that relate to health services and medical effectiveness research, for issues of particular concern to women;

(3) identify projects in women's health that should be conducted or supported by the Agency;

(4) consult with health professionals, nongovernmental organizations, consumer organizations, women's health professionals, and other individuals and groups, as appropriate, on Agency policy with regard to women; and

(5) serve as a member of the Department of Health and Human Services Coordinating Committee on Women's Health (established under section 237a(b)(4) of this title).

(c) Authorization of appropriations

For the purpose of carrying out this section, there are authorized to be appropriated such sums as may be necessary for each of the fiscal years 2010 through 2014.

(July 1, 1944, ch. 373, title IX, §925, as added Pub. L. 111–148, title III, §3509(e)(2), Mar. 23, 2010, 124 Stat. 534.)

EDITORIAL NOTES

PRIOR PROVISIONS

A prior section 925 of act July 1, 1944, was renumbered section 926 and is classified to section 299b–25 of this title.

Another prior section 925 of act July 1, 1944, was renumbered section 945 and is classified to section 299c–4 of this title.

Another prior section 925 of act July 1, 1944, was classified to section 299c–4 of this title prior to the general amendment of this subchapter by Pub. L. 106–129.

§299b–25. Technical assistance

The Secretary, acting through the Director, may provide technical assistance to patient safety organizations, including convening annual meetings for patient safety organizations to discuss methodology, communication, data collection, or privacy concerns.

(July 1, 1944, ch. 373, title IX, §926, formerly §925, as added Pub. L. 109–41, §2(a)(5), July 29, 2005, 119 Stat. 434; renumbered §926, Pub. L. 111–148, title III, §3509(e)(1), Mar. 23, 2010, 124 Stat. 534.)

EDITORIAL NOTES

PRIOR PROVISIONS

A prior section 926 of act July 1, 1944, was renumbered section 927 and is classified to section 299b–26 of this title.

Another prior section 926 of act July 1, 1944, was renumbered section 946 and is classified to section 299c–5 of this title.

Another prior section 926 of act July 1, 1944, was classified to section 299c–5 of this title prior to the general amendment of this subchapter by Pub. L. 106–129.

§299b–26. Severability

If any provision of this part is held to be unconstitutional, the remainder of this part shall not be affected.

(July 1, 1944, ch. 373, title IX, §927, formerly §926, as added Pub. L. 109–41, §2(a)(5), July 29, 2005, 119 Stat. 434; renumbered §927, Pub. L. 111–148, title III, §3509(e)(1), Mar. 23, 2010, 124 Stat. 534.)

EDITORIAL NOTES

PRIOR PROVISIONS

A prior section 927 of act July 1, 1944, was renumbered section 947, and is classified to section 299c–6 of this title.

Another prior section 927 of act July 1, 1944, was classified to section 299c–6 of this title prior to the general amendment of this subchapter by Pub. L. 106–129.

PART D—HEALTH CARE QUALITY IMPROVEMENT

EDITORIAL NOTES

PRIOR PROVISIONS

A prior part D, consisting of sections 299c to 299c–7, was redesignated part E of this subchapter.

SUBPART 1—QUALITY MEASURE DEVELOPMENT

§299b–31. Quality measure development

(a) Quality measure

In this subpart, the term "quality measure" means a standard for measuring the performance and improvement of population health or of health plans, providers of services, and other clinicians in the delivery of health care services.

(b) Identification of quality measures

(1) Identification

The Secretary, in consultation with the Director of the Agency for Healthcare Research and Quality and the Administrator of the Centers for Medicare & Medicaid Services, shall identify, not less often than triennially, gaps where no quality measures exist and existing quality measures that need improvement, updating, or expansion, consistent with the national strategy under section 280j of this title, to the extent available, for use in Federal health programs. In identifying such gaps and existing quality measures that need improvement, the Secretary shall take into consideration—

(A) the gaps identified by the entity with a contract under section 1890(a) of the Social Security Act [42 U.S.C. 1395aaa(a)] and other stakeholders;

(B) quality measures identified by the pediatric quality measures program under section 1139A of the Social Security Act [42 U.S.C. 1320b–9a]; and

(C) quality measures identified through the Medicaid Quality Measurement Program under section 1139B of the Social Security Act [42 U.S.C. 1320b–9b].

(2) Publication

The Secretary shall make available to the public on an Internet website a report on any gaps identified under paragraph (1) and the process used to make such identification.

(c) Grants or contracts for quality measure development

(1) In general

The Secretary shall award grants, contracts, or intergovernmental agreements to eligible entities for purposes of developing, improving, updating, or expanding quality measures identified under subsection (b).

(2) Prioritization in the development of quality measures

In awarding grants, contracts, or agreements under this subsection, the Secretary shall give priority to the development of quality measures that allow the assessment of—

(A) health outcomes and functional status of patients;

(B) the management and coordination of health care across episodes of care and care transitions for patients across the continuum of providers, health care settings, and health plans;

(C) the experience, quality, and use of information provided to and used by patients, caregivers, and authorized representatives to inform decisionmaking about treatment options, including the use of shared decisionmaking tools and preference sensitive care (as defined in

section 299b–36 of this title);

(D) the meaningful use of health information technology;

(E) the safety, effectiveness, patient-centeredness, appropriateness, and timeliness of care;

(F) the efficiency of care;

(G) the equity of health services and health disparities across health disparity populations (as defined in section 285t [1] of this title) and geographic areas;

(H) patient experience and satisfaction;

(I) the use of innovative strategies and methodologies identified under section 299b–33 of this title; and

(J) other areas determined appropriate by the Secretary.

(3) Eligible entities

To be eligible for a grant or contract under this subsection, an entity shall—

(A) have demonstrated expertise and capacity in the development and evaluation of quality measures;

(B) have adopted procedures to include in the quality measure development process—

(i) the views of those providers or payers whose performance will be assessed by the measure; and

(ii) the views of other parties who also will use the quality measures (such as patients, consumers, and health care purchasers);

(C) collaborate with the entity with a contract under section 1890(a) of the Social Security Act [42 U.S.C. 1395aaa(a)] and other stakeholders, as practicable, and the Secretary so that quality measures developed by the eligible entity will meet the requirements to be considered for endorsement by the entity with a contract under such section 1890(a);

(D) have transparent policies regarding governance and conflicts of interest; and

(E) submit an application to the Secretary at such time and in such manner, as the Secretary may require.

(4) Use of funds

An entity that receives a grant, contract, or agreement under this subsection shall use such award to develop quality measures that meet the following requirements:

(A) Such measures support measures required to be reported under the Social Security Act [42 U.S.C. 301 et seq.], where applicable, and in support of gaps and existing quality measures that need improvement, as described in subsection (b)(1)(A).

(B) Such measures support measures developed under section 1139A of the Social Security Act [42 U.S.C. 1320b–9a] and the Medicaid Quality Measurement Program under section 1139B of such Act [42 U.S.C. 1320b–9b], where applicable.

(C) To the extent practicable, data on such quality measures is able to be collected using health information technologies.

(D) Each quality measure is free of charge to users of such measure.

(E) Each quality measure is publicly available on an Internet website.

(d) Other activities by the Secretary

The Secretary may use amounts available under this section to update and test, where applicable, quality measures endorsed by the entity with a contract under section 1890(a) of the Social Security Act [42 U.S.C. 1395aaa(a)] or adopted by the Secretary.

(e) Coordination of grants

The Secretary shall ensure that grants or contracts awarded under this section are coordinated with grants and contracts awarded under sections 1139A(5) [2] and 1139B(4)(A) [2] of the Social Security Act.

(f) Development of outcome measures

(1) In general

The Secretary shall develop, and periodically update (not less than every 3 years), provider-level outcome measures for hospitals and physicians, as well as other providers as determined appropriate by the Secretary.

(2) Categories of measures

The measures developed under this subsection shall include, to the extent determined appropriate by the Secretary—

(A) outcome measurement for acute and chronic diseases, including, to the extent feasible, the 5 most prevalent and resource-intensive acute and chronic medical conditions; and

(B) outcome measurement for primary and preventative care, including, to the extent feasible, measurements that cover provision of such care for distinct patient populations (such as healthy children, chronically ill adults, or infirm elderly individuals).

(3) Goals

In developing such measures, the Secretary shall seek to—

(A) address issues regarding risk adjustment, accountability, and sample size;

(B) include the full scope of services that comprise a cycle of care; and

(C) include multiple dimensions.

(4) Timeframe

(A) Acute and chronic diseases

Not later than 24 months after March 23, 2010,[1] the Secretary shall develop not less than 10 measures described in paragraph (2)(A).

(B) Primary and preventive care

Not later than 36 months after March 23, 2010,[1] the Secretary shall develop not less than 10 measures described in paragraph (2)(B).

(July 1, 1944, ch. 373, title IX, §931, as added and amended Pub. L. 111–148, title III, §3013(a)(4), title X, §10303(a), Mar. 23, 2010, 124 Stat. 381, 937.)

EDITORIAL NOTES

REFERENCES IN TEXT

Section 285t of this title, referred to in subsec. (c)(2)(G), was in the original "section 485E", meaning section 485E of act July 1, 1944, which was renumbered section 464z–3 by Pub. L. 111–148, title X, §10334(c)(1)(D)(i), Mar. 23, 2010, 124 Stat. 973, and is classified to section 285t of this title. The act of July 1, 1944, no longer contains a section 485E.

The Social Security Act, referred to in subsec. (c)(4)(A), is act Aug. 14, 1935, ch. 531, 49 Stat. 620, which is classified generally to chapter 7 (§301 et seq.) of this title. For complete classification of this Act to the Code, see section 1305 of this title and Tables.

March 23, 2010, referred to in subsec. (f)(4)(A), (B), was in the original "the date of enactment of this Act" which was translated as meaning the date of the enactment of Pub. L. 111–148 which added and amended this section, to reflect the probable intent of Congress.

PRIOR PROVISIONS

A prior section 931 of act July 1, 1944, was renumbered 941 and is classified to section 299c of this title.

AMENDMENTS

2010—Subsec. (f). Pub. L. 111–148, §10303(a), added subsec. (f).

[1] *See References in Text note below.*

[2] *So in original. The subsection designation is missing.*

SUBPART 2—HEALTH CARE QUALITY IMPROVEMENT PROGRAMS

§299b–33. Health care delivery system research

(a) Purpose

The purposes of this section are to—

(1) enable the Director to identify, develop, evaluate, disseminate, and provide training in innovative methodologies and strategies for quality improvement practices in the delivery of health care services that represent best practices (referred to as "best practices") in health care quality, safety, and value; and

(2) ensure that the Director is accountable for implementing a model to pursue such research in a collaborative manner with other related Federal agencies.

(b) General functions of the Center

The Center for Quality Improvement and Patient Safety of the Agency for Healthcare Research and Quality (referred to in this section as the "Center"), or any other relevant agency or department designated by the Director, shall—

(1) carry out its functions using research from a variety of disciplines, which may include epidemiology, health services, sociology, psychology, human factors engineering, biostatistics, health economics, clinical research, and health informatics;

(2) conduct or support activities consistent with the purposes described in subsection (a), and for—

(A) best practices for quality improvement practices in the delivery of health care services; and

(B) that include changes in processes of care and the redesign of systems used by providers that will reliably result in intended health outcomes, improve patient safety, and reduce medical errors (such as skill development for health care providers in team-based health care delivery and rapid cycle process improvement) and facilitate adoption of improved workflow;

(3) identify health care providers, including health care systems, single institutions, and individual providers, that—

(A) deliver consistently high-quality, efficient health care services (as determined by the Secretary); and

(B) employ best practices that are adaptable and scalable to diverse health care settings or effective in improving care across diverse settings;

(4) assess research, evidence, and knowledge about what strategies and methodologies are most effective in improving health care delivery;

(5) find ways to translate such information rapidly and effectively into practice, and document the sustainability of those improvements;

(6) create strategies for quality improvement through the development of tools, methodologies, and interventions that can successfully reduce variations in the delivery of health care;

(7) identify, measure, and improve organizational, human, or other causative factors, including those related to the culture and system design of a health care organization, that contribute to the success and sustainability of specific quality improvement and patient safety strategies;

(8) provide for the development of best practices in the delivery of health care services that—

(A) have a high likelihood of success, based on structured review of empirical evidence;

(B) are specified with sufficient detail of the individual processes, steps, training, skills, and knowledge required for implementation and incorporation into workflow of health care practitioners in a variety of settings;

(C) are designed to be readily adapted by health care providers in a variety of settings; and

(D) where applicable, assist health care providers in working with other health care providers

across the continuum of care and in engaging patients and their families in improving the care and patient health outcomes;

(9) provide for the funding of the activities of organizations with recognized expertise and excellence in improving the delivery of health care services, including children's health care, by involving multiple disciplines, managers of health care entities, broad development and training, patients, caregivers and families, and frontline health care workers, including activities for the examination of strategies to share best quality improvement practices and to promote excellence in the delivery of health care services; and

(10) build capacity at the State and community level to lead quality and safety efforts through education, training, and mentoring programs to carry out the activities under paragraphs (1) through (9).

(c) Research functions of Center

(1) In general

The Center shall support, such as through a contract or other mechanism, research on health care delivery system improvement and the development of tools to facilitate adoption of best practices that improve the quality, safety, and efficiency of health care delivery services. Such support may include establishing a Quality Improvement Network Research Program for the purpose of testing, scaling, and disseminating of interventions to improve quality and efficiency in health care. Recipients of funding under the Program may include national, State, multi-State, or multi-site quality improvement networks.

(2) Research requirements

The research conducted pursuant to paragraph (1) shall—

(A) address the priorities identified by the Secretary in the national strategic plan established under section 280j of this title;

(B) identify areas in which evidence is insufficient to identify strategies and methodologies, taking into consideration areas of insufficient evidence identified by the entity with a contract under section 1395aaa(a) of this title in the report required under section 280j–2 of this title;

(C) address concerns identified by health care institutions and providers and communicated through the Center pursuant to subsection (d);

(D) reduce preventable morbidity, mortality, and associated costs of morbidity and mortality by building capacity for patient safety research;

(E) support the discovery of processes for the reliable, safe, efficient, and responsive delivery of health care, taking into account discoveries from clinical research and comparative effectiveness research;

(F) allow communication of research findings and translate evidence into practice recommendations that are adaptable to a variety of settings, and which, as soon as practicable after the establishment of the Center, shall include—

(i) the implementation of a national application of Intensive Care Unit improvement projects relating to the adult (including geriatric), pediatric, and neonatal patient populations;

(ii) practical methods for addressing health care associated infections, including Methicillin-Resistant Staphylococcus Aureus and Vancomycin-Resistant Entercoccus infections and other emerging infections; and

(iii) practical methods for reducing preventable hospital admissions and readmissions;

(G) expand demonstration projects for improving the quality of children's health care and the use of health information technology, such as through Pediatric Quality Improvement Collaboratives and Learning Networks, consistent with provisions of section 1320b–9a of this title for assessing and improving quality, where applicable;

(H) identify and mitigate hazards by—

(i) analyzing events reported to patient safety reporting systems and patient safety organizations; and

(ii) using the results of such analyses to develop scientific methods of response to such events;

(I) include the conduct of systematic reviews of existing practices that improve the quality, safety, and efficiency of health care delivery, as well as new research on improving such practices; and

(J) include the examination of how to measure and evaluate the progress of quality and patient safety activities.

(d) Dissemination of research findings

(1) Public availability

The Director shall make the research findings of the Center available to the public through multiple media and appropriate formats to reflect the varying needs of health care providers and consumers and diverse levels of health literacy.

(2) Linkage to health information technology

The Secretary shall ensure that research findings and results generated by the Center are shared with the Office of the National Coordinator of Health Information Technology and used to inform the activities of the health information technology extension program under section 300jj–32 of this title, as well as any relevant standards, certification criteria, or implementation specifications.

(e) Prioritization

The Director shall identify and regularly update a list of processes or systems on which to focus research and dissemination activities of the Center, taking into account—

(1) the cost to Federal health programs;

(2) consumer assessment of health care experience;

(3) provider assessment of such processes or systems and opportunities to minimize distress and injury to the health care workforce;

(4) the potential impact of such processes or systems on health status and function of patients, including vulnerable populations including children;

(5) the areas of insufficient evidence identified under subsection (c)(2)(B); and

(6) the evolution of meaningful use of health information technology, as defined in section 300jj of this title.

(f) Coordination

The Center shall coordinate its activities with activities conducted by the Center for Medicare and Medicaid Innovation established under section 1315a of this title.

(g) Funding

There is authorized to be appropriated to carry out this section $20,000,000 for fiscal years 2010 through 2014.

(July 1, 1944, ch. 373, title IX, §933, as added Pub. L. 111–148, title III, §3501, Mar. 23, 2010, 124 Stat. 508.)

EDITORIAL NOTES

PRIOR PROVISIONS

A prior section 933 of act July 1, 1944, was renumbered section 943 and is classified to section 299c–2 of this title.

§299b–34. Quality improvement technical assistance and implementation

(a) In general

The Director, through the Center for Quality Improvement and Patient Safety of the Agency for

Healthcare Research and Quality (referred to in this section as the "Center"), shall award—

(1) technical assistance grants or contracts to eligible entities to provide technical support to institutions that deliver health care and health care providers (including rural and urban providers of services and suppliers with limited infrastructure and financial resources to implement and support quality improvement activities, providers of services and suppliers with poor performance scores, and providers of services and suppliers for which there are disparities in care among subgroups of patients) so that such institutions and providers understand, adapt, and implement the models and practices identified in the research conducted by the Center, including the Quality Improvement Networks Research Program; and

(2) implementation grants or contracts to eligible entities to implement the models and practices described under paragraph (1).

(b) Eligible entities

(1) Technical assistance award

To be eligible to receive a technical assistance grant or contract under subsection (a)(1), an entity—

(A) may be a health care provider, health care provider association, professional society, health care worker organization, Indian health organization, quality improvement organization, patient safety organization, local quality improvement collaborative, the Joint Commission, academic health center, university, physician-based research network, primary care extension program established under section 280g–12 of this title, a Federal Indian Health Service program or a health program operated by an Indian tribe (as defined in section 1603 of title 25), or any other entity identified by the Secretary; and

(B) shall have demonstrated expertise in providing information and technical support and assistance to health care providers regarding quality improvement.

(2) Implementation award

To be eligible to receive an implementation grant or contract under subsection (a)(2), an entity—

(A) may be a hospital or other health care provider or consortium or [1] providers, as determined by the Secretary; and

(B) shall have demonstrated expertise in providing information and technical support and assistance to health care providers regarding quality improvement.

(c) Application

(1) Technical assistance award

To receive a technical assistance grant or contract under subsection (a)(1), an eligible entity shall submit an application to the Secretary at such time, in such manner, and containing—

(A) a plan for a sustainable business model that may include a system of—

(i) charging fees to institutions and providers that receive technical support from the entity; and

(ii) reducing or eliminating such fees for such institutions and providers that serve low-income populations; and

(B) such other information as the Director may require.

(2) Implementation award

To receive a grant or contract under subsection (a)(2), an eligible entity shall submit an application to the Secretary at such time, in such manner, and containing—

(A) a plan for implementation of a model or practice identified in the research conducted by the Center including—

(i) financial cost, staffing requirements, and timeline [2] for implementation; and

(ii) pre- and projected post-implementation quality measure performance data in targeted improvement areas identified by the Secretary; and

(B) such other information as the Director may require.

(d) Matching funds

The Director may not award a grant or contract under this section to an entity unless the entity agrees that it will make available (directly or through contributions from other public or private entities) non-Federal contributions toward the activities to be carried out under the grant or contract in an amount equal to $1 for each $5 of Federal funds provided under the grant or contract. Such non-Federal matching funds may be provided directly or through donations from public or private entities and may be in cash or in-kind, fairly evaluated, including plant, equipment, or services.

(e) Evaluation

(1) In general

The Director shall evaluate the performance of each entity that receives a grant or contract under this section. The evaluation of an entity shall include a study of—

(A) the success of such entity in achieving the implementation, by the health care institutions and providers assisted by such entity, of the models and practices identified in the research conducted by the Center under section 299b–33 of this title;

(B) the perception of the health care institutions and providers assisted by such entity regarding the value of the entity; and

(C) where practicable, better patient health outcomes and lower cost resulting from the assistance provided by such entity.

(2) Effect of evaluation

Based on the outcome of the evaluation of the entity under paragraph (1), the Director shall determine whether to renew a grant or contract with such entity under this section.

(f) Coordination

The entities that receive a grant or contract under this section shall coordinate with health information technology regional extension centers under section 300jj–32(c) of this title and the primary care extension program established under section 280g–12 of this title regarding the dissemination of quality improvement, system delivery reform, and best practices information.

(July 1, 1944, ch. 373, title IX, §934, as added and amended Pub. L. 111–148, title III, §3501, title X, §10501(f)(3), Mar. 23, 2010, 124 Stat. 511, 996.)

EDITORIAL NOTES

PRIOR PROVISIONS

A prior section 934 of act July 1, 1944, was renumbered section 944 and is classified to section 299c–3 of this title.

AMENDMENTS

2010—Subsecs. (b)(1)(A), (f). Pub. L. 111–148, §10501(f)(3), made technical amendment to reference in original act which appears in text as reference to section 280g–12 of this title.

[1] So in original. Probably should be "of".

[2] So in original. Probably should be "a timeline".

§299b–35. Grants or contracts to implement medication management services in treatment of chronic diseases

(a) In general

The Secretary, acting through the Patient Safety Research Center established in section 299b–33 of this title (referred to in this section as the "Center"), shall establish a program to provide grants or contracts to eligible entities to implement medication management (referred to in this section as "MTM") services provided by licensed pharmacists, as a collaborative, multidisciplinary, inter-professional approach to the treatment of chronic diseases for targeted individuals, to improve the quality of care and reduce overall cost in the treatment of such diseases. The Secretary shall commence the program under this section not later than May 1, 2010.

(b) Eligible entities

To be eligible to receive a grant or contract under subsection (a), an entity shall—

(1) provide a setting appropriate for MTM services, as recommended by the experts described in subsection (e);

(2) submit to the Secretary a plan for achieving long-term financial sustainability;

(3) where applicable, submit a plan for coordinating MTM services through local community health teams established in section 256a–1 of this title or in collaboration with primary care extension programs established in section 280g–12 of this title;

(4) submit a plan for meeting the requirements under subsection (c); and

(5) submit to the Secretary such other information as the Secretary may require.

(c) MTM services to targeted individuals

The MTM services provided with the assistance of a grant or contract awarded under subsection (a) shall, as allowed by State law including applicable collaborative pharmacy practice agreements, include—

(1) performing or obtaining necessary assessments of the health and functional status of each patient receiving such MTM services;

(2) formulating a medication treatment plan according to therapeutic goals agreed upon by the prescriber and the patient or caregiver or authorized representative of the patient;

(3) selecting, initiating, modifying, recommending changes to, or administering medication therapy;

(4) monitoring, which may include access to, ordering, or performing laboratory assessments, and evaluating the response of the patient to therapy, including safety and effectiveness;

(5) performing an initial comprehensive medication review to identify, resolve, and prevent medication-related problems, including adverse drug events, quarterly targeted medication reviews for ongoing monitoring, and additional followup interventions on a schedule developed collaboratively with the prescriber;

(6) documenting the care delivered and communicating essential information about such care, including a summary of the medication review, and the recommendations of the pharmacist to other appropriate health care providers of the patient in a timely fashion;

(7) providing education and training designed to enhance the understanding and appropriate use of the medications by the patient, caregiver, and other authorized representative;

(8) providing information, support services, and resources and strategies designed to enhance patient adherence with therapeutic regimens;

(9) coordinating and integrating MTM services within the broader health care management services provided to the patient; and

(10) such other patient care services allowed under pharmacist scopes of practice in use in other Federal programs that have implemented MTM services.

(d) Targeted individuals

MTM services provided by licensed pharmacists under a grant or contract awarded under subsection (a) shall be offered to targeted individuals who—

(1) take 4 or more prescribed medications (including over-the-counter medications and dietary supplements);

(2) take any "high risk" medications;

(3) have 2 or more chronic diseases, as identified by the Secretary; or

(4) have undergone a transition of care, or other factors, as determined by the Secretary, that are likely to create a high risk of medication-related problems.

(e) Consultation with experts

In designing and implementing MTM services provided under grants or contracts awarded under subsection (a), the Secretary shall consult with Federal, State, private, public-private, and academic entities, pharmacy and pharmacist organizations, health care organizations, consumer advocates, chronic disease groups, and other stakeholders involved with the research, dissemination, and implementation of pharmacist-delivered MTM services, as the Secretary determines appropriate. The Secretary, in collaboration with this group, shall determine whether it is possible to incorporate rapid cycle process improvement concepts in use in other Federal programs that have implemented MTM services.

(f) Reporting to the Secretary

An entity that receives a grant or contract under subsection (a) shall submit to the Secretary a report that describes and evaluates, as requested by the Secretary, the activities carried out under subsection (c), including quality measures endorsed by the entity with a contract under section 1395aaa of this title, as determined by the Secretary.

(g) Evaluation and report

The Secretary shall submit to the relevant committees of Congress a report which shall—

(1) assess the clinical effectiveness of pharmacist-provided services under the MTM services program, as compared to usual care, including an evaluation of whether enrollees maintained better health with fewer hospitalizations and emergency room visits than similar patients not enrolled in the program;

(2) assess changes in overall health care resource use by targeted individuals;

(3) assess patient and prescriber satisfaction with MTM services;

(4) assess the impact of patient-cost sharing requirements on medication adherence and recommendations for modifications;

(5) identify and evaluate other factors that may impact clinical and economic outcomes, including demographic characteristics, clinical characteristics, and health services use of the patient, as well as characteristics of the regimen, pharmacy benefit, and MTM services provided; and

(6) evaluate the extent to which participating pharmacists who maintain a dispensing role have a conflict of interest in the provision of MTM services, and if such conflict is found, provide recommendations on how such a conflict might be appropriately addressed.

(h) Grants or contracts to fund development of performance measures

The Secretary may, through the quality measure development program under section 299b–31 of this title, award grants or contracts to eligible entities for the purpose of funding the development of performance measures that assess the use and effectiveness of medication therapy management services.

(July 1, 1944, ch. 373, title IX, §935, as added and amended Pub. L. 111–148, title III, §3503, title X, §10501(f)(4), Mar. 23, 2010, 124 Stat. 516, 996.)

EDITORIAL NOTES

PRIOR PROVISIONS

A prior section 935 of act July 1, 1944, was renumbered section 945 and is classified to section 299c–4 of this title.

AMENDMENTS

2010—Subsec. (b)(3). Pub. L. 111–148, §10501(f)(4), made technical amendment to reference in original act which appears in text as reference to section 280g–12 of this title.

§299b–36. Program to facilitate shared decisionmaking

(a) Purpose

The purpose of this section is to facilitate collaborative processes between patients, caregivers or authorized representatives, and clinicians that engages [1] the patient, caregiver or authorized representative in decisionmaking, provides [2] patients, caregivers or authorized representatives with information about trade-offs among treatment options, and facilitates [3] the incorporation of patient preferences and values into the medical plan.

(b) Definitions

In this section:

(1) Patient decision aid

The term "patient decision aid" means an educational tool that helps patients, caregivers or authorized representatives understand and communicate their beliefs and preferences related to their treatment options, and to decide with their health care provider what treatments are best for them based on their treatment options, scientific evidence, circumstances, beliefs, and preferences.

(2) Preference sensitive care

The term "preference sensitive care" means medical care for which the clinical evidence does not clearly support one treatment option such that the appropriate course of treatment depends on the values of the patient or the preferences of the patient, caregivers or authorized representatives regarding the benefits, harms and scientific evidence for each treatment option, the [4] use of such care should depend on the informed patient choice among clinically appropriate treatment options.

(c) Establishment of independent standards for patient decision aids for preference sensitive care

(1) Contract with entity to establish standards and certify patient decision aids

(A) In general

For purposes of supporting consensus-based standards for patient decision aids for preference sensitive care and a certification process for patient decision aids for use in the Federal health programs and by other interested parties, the Secretary shall have in effect a contract with the entity with a contract under section 1395aaa of this title. Such contract shall provide that the entity perform the duties described in paragraph (2).

(B) Timing for first contract

As soon as practicable after March 23, 2010, the Secretary shall enter into the first contract under subparagraph (A).

(C) Period of contract

A contract under subparagraph (A) shall be for a period of 18 months (except such contract may be renewed after a subsequent bidding process).

(2) Duties

The following duties are described in this paragraph:

(A) Develop and identify standards for patient decision aids

The entity shall synthesize evidence and convene a broad range of experts and key stakeholders to develop and identify consensus-based standards to evaluate patient decision aids for preference sensitive care.

(B) Endorse patient decision aids

The entity shall review patient decision aids and develop a certification process whether [5] patient decision aids meet the standards developed and identified under subparagraph (A). The entity shall give priority to the review and certification of patient decision aids for preference

sensitive care.

(d) Program to develop, update and produce patient decision aids to assist health care providers and patients

(1) In general

The Secretary, acting through the Director, and in coordination with heads of other relevant agencies, such as the Director of the Centers for Disease Control and Prevention and the Director of the National Institutes of Health, shall establish a program to award grants or contracts—

(A) to develop, update, and produce patient decision aids for preference sensitive care to assist health care providers in educating patients, caregivers, and authorized representatives concerning the relative safety, relative effectiveness (including possible health outcomes and impact on functional status), and relative cost of treatment or, where appropriate, palliative care options;

(B) to test such materials to ensure such materials are balanced and evidence based in aiding health care providers and patients, caregivers, and authorized representatives to make informed decisions about patient care and can be easily incorporated into a broad array of practice settings; and

(C) to educate providers on the use of such materials, including through academic curricula.

(2) Requirements for patient decision aids

Patient decision aids developed and produced pursuant to a grant or contract under paragraph (1)—

(A) shall be designed to engage patients, caregivers, and authorized representatives in informed decisionmaking with health care providers;

(B) shall present up-to-date clinical evidence about the risks and benefits of treatment options in a form and manner that is age-appropriate and can be adapted for patients, caregivers, and authorized representatives from a variety of cultural and educational backgrounds to reflect the varying needs of consumers and diverse levels of health literacy;

(C) shall, where appropriate, explain why there is a lack of evidence to support one treatment option over another; and

(D) shall address health care decisions across the age span, including those affecting vulnerable populations including children.

(3) Distribution

The Director shall ensure that patient decision aids produced with grants or contracts under this section are available to the public.

(4) Nonduplication of efforts

The Director shall ensure that the activities under this section of the Agency and other agencies, including the Centers for Disease Control and Prevention and the National Institutes of Health, are free of unnecessary duplication of effort.

(e) Grants to support shared decisionmaking implementation

(1) In general

The Secretary shall establish a program to provide for the phased-in development, implementation, and evaluation of shared decisionmaking using patient decision aids to meet the objective of improving the understanding of patients of their medical treatment options.

(2) Shared decisionmaking resource centers

(A) In general

The Secretary shall provide grants for the establishment and support of Shared Decisionmaking Resource Centers (referred to in this subsection as "Centers") to provide

technical assistance to providers and to develop and disseminate best practices and other information to support and accelerate adoption, implementation, and effective use of patient decision aids and shared decisionmaking by providers.

(B) Objectives

The objective of a Center is to enhance and promote the adoption of patient decision aids and shared decisionmaking through—

(i) providing assistance to eligible providers with the implementation and effective use of, and training on, patient decision aids; and

(ii) the dissemination of best practices and research on the implementation and effective use of patient decision aids.

(3) Shared decisionmaking participation grants

(A) In general

The Secretary shall provide grants to health care providers for the development and implementation of shared decisionmaking techniques and to assess the use of such techniques.

(B) Preference

In order to facilitate the use of best practices, the Secretary shall provide a preference in making grants under this subsection to health care providers who participate in training by Shared Decisionmaking Resource Centers or comparable training.

(C) Limitation

Funds under this paragraph shall not be used to purchase or implement use of patient decision aids other than those certified under the process identified in subsection (c).

(4) Guidance

The Secretary may issue guidance to eligible grantees under this subsection on the use of patient decision aids.

(f) Funding

For purposes of carrying out this section there are authorized to be appropriated such sums as may be necessary for fiscal year 2010 and each subsequent fiscal year.

(July 1, 1944, ch. 373, title IX, §936, as added Pub. L. 111–148, title III, §3506, Mar. 23, 2010, 124 Stat. 527.)

EDITORIAL NOTES

PRIOR PROVISIONS

A prior section 936 of act July 1, 1944, was renumbered section 946 and is classified to section 299c–5 of this title.

[1] *So in original. Probably should be "engage".*

[2] *So in original. Probably should be "provide".*

[3] *So in original. Probably should be "facilitate".*

[4] *So in original. Probably should be "option. The".*

[5] *So in original.*

§299b–37. Dissemination and building capacity for research

(a) In general

(1) Dissemination

The Office of Communication and Knowledge Transfer (referred to in this section as the "Office") at the Agency for Healthcare Research and Quality (or any other relevant office designated by Agency for Healthcare Research and Quality), in consultation with the National Institutes of Health, shall broadly disseminate the research findings that are published by the Patient Centered Outcomes Research Institute established under section 1320e(b) of this title (referred to in this section as the "Institute") and other government-funded research relevant to comparative clinical effectiveness research. The Office shall create informational tools that organize and disseminate research findings for physicians, health care providers, patients, payers, and policy makers. The Office shall also develop a publicly available resource database that collects and contains government-funded evidence and research from public, private, not-for profit, and academic sources.

(2) Requirements

The Office shall provide for the dissemination of the Institute's research findings and government-funded research relevant to comparative clinical effectiveness research to physicians, health care providers, patients, vendors of health information technology focused on clinical decision support, appropriate professional associations, and Federal and private health plans. Materials, forums, and media used to disseminate the findings, informational tools, and resource databases shall—

(A) include a description of considerations for specific subpopulations, the research methodology, and the limitations of the research, and the names of the entities, agencies, instrumentalities, and individuals who conducted any research which was published by the Institute; and

(B) not be construed as mandates, guidelines, or recommendations for payment, coverage, or treatment.

(b) Incorporation of research findings

The Office, in consultation with relevant medical and clinical associations, shall assist users of health information technology focused on clinical decision support to promote the timely incorporation of research findings disseminated under subsection (a) into clinical practices and to promote the ease of use of such incorporation.

(c) Feedback

The Office shall establish a process to receive feedback from physicians, health care providers, patients, and vendors of health information technology focused on clinical decision support, appropriate professional associations, and Federal and private health plans about the value of the information disseminated and the assistance provided under this section.

(d) Rule of construction

Nothing in this section shall preclude the Institute from making its research findings publicly available as required under section 1320e(d)(8) of this title.

(e) Training of researchers

The Agency for Health Care Research and Quality, in consultation with the National Institutes of Health, shall build capacity for comparative clinical effectiveness research by establishing a grant program that provides for the training of researchers in the methods used to conduct such research, including systematic reviews of existing research and primary research such as clinical trials. At a minimum, such training shall be in methods that meet the methodological standards adopted under section 1320e(d)(9) of this title.

(f) Building data for research

The Secretary shall provide for the coordination of relevant Federal health programs to build data capacity for comparative clinical effectiveness research, including the development and use of

clinical registries and health outcomes research data networks, in order to develop and maintain a comprehensive, interoperable data network to collect, link, and analyze data on outcomes and effectiveness from multiple sources, including electronic health records.

(g) Authority to contract with the Institute

Agencies and instrumentalities of the Federal Government may enter into agreements with the Institute, and accept and retain funds, for the conduct and support of research described in this part, provided that the research to be conducted or supported under such agreements is authorized under the governing statutes of such agencies and instrumentalities.

(July 1, 1944, ch. 373, title IX, §937, as added Pub. L. 111–148, title VI, §6301(b), Mar. 23, 2010, 124 Stat. 738.)

EDITORIAL NOTES

PRIOR PROVISIONS

A prior section 937 of act July 1, 1944, was renumbered section 947 and is classified to section 299c–6 of this title.

PART E—GENERAL PROVISIONS

EDITORIAL NOTES

CODIFICATION

Pub. L. 111–148, title III, §3013(a)(1), Mar. 23, 2010, 124 Stat. 381, redesignated part D "General Provisions" as E.

Pub. L. 109–41, §2(a)(2), July 29, 2005, 119 Stat. 424, redesignated part C "General Provisions" as D.

§299c. Advisory Council for Healthcare Research and Quality

(a) Establishment

There is established an advisory council to be known as the National Advisory Council for Healthcare Research and Quality.

(b) Duties

(1) In general

The Advisory Council shall advise the Secretary and the Director with respect to activities proposed or undertaken to carry out the mission of the Agency under section 299(b) of this title.

(2) Certain recommendations

Activities of the Advisory Council under paragraph (1) shall include making recommendations to the Director regarding—

(A) priorities regarding health care research, especially studies related to quality, outcomes, cost and the utilization of, and access to, health care services;

(B) the field of health care research and related disciplines, especially issues related to training needs, and dissemination of information pertaining to health care quality; and

(C) the appropriate role of the Agency in each of these areas in light of private sector activity and identification of opportunities for public-private sector partnerships.

(c) Membership

(1) In general

The Advisory Council shall, in accordance with this subsection, be composed of appointed

members and ex officio members. All members of the Advisory Council shall be voting members other than the individuals designated under paragraph (3)(B) as ex officio members.

(2) Appointed members

The Secretary shall appoint to the Advisory Council 21 appropriately qualified individuals. At least 17 members of the Advisory Council shall be representatives of the public who are not officers or employees of the United States and at least 1 member who shall be a specialist in the rural aspects of 1 or more of the professions or fields described in subparagraphs (A) through (G). The Secretary shall ensure that the appointed members of the Council, as a group, are representative of professions and entities concerned with, or affected by, activities under this subchapter and under section 1320b–12 of this title. Of such members—

(A) three shall be individuals distinguished in the conduct of research, demonstration projects, and evaluations with respect to health care;

(B) three shall be individuals distinguished in the fields of health care quality research or health care improvement;

(C) three shall be individuals distinguished in the practice of medicine of which at least one shall be a primary care practitioner;

(D) three shall be individuals distinguished in the other health professions;

(E) three shall be individuals either representing the private health care sector, including health plans, providers, and purchasers or individuals distinguished as administrators of health care delivery systems;

(F) three shall be individuals distinguished in the fields of health care economics, information systems, law, ethics, business, or public policy; and

(G) three shall be individuals representing the interests of patients and consumers of health care.

(3) Ex officio members

The Secretary shall designate as ex officio members of the Advisory Council—

(A) the Assistant Secretary for Health, the Director of the National Institutes of Health, the Director of the Centers for Disease Control and Prevention, the Administrator of the Centers for Medicare & Medicaid Services, the Commissioner of the Food and Drug Administration, the Director of the Office of Personnel Management, the Assistant Secretary of Defense (Health Affairs), and the Under Secretary for Health of the Department of Veterans Affairs; and

(B) such other Federal officials as the Secretary may consider appropriate.

(d) Terms

(1) In general

Members of the Advisory Council appointed under subsection (c)(2) shall serve for a term of 3 years.

(2) Staggered terms

To ensure the staggered rotation of one-third of the members of the Advisory Council each year, the Secretary is authorized to appoint the initial members of the Advisory Council for terms of 1, 2, or 3 years.

(3) Service beyond term

A member of the Council appointed under subsection (c)(2) may continue to serve after the expiration of the term of the members until a successor is appointed.

(e) Vacancies

If a member of the Advisory Council appointed under subsection (c)(2) does not serve the full term applicable under subsection (d), the individual appointed to fill the resulting vacancy shall be appointed for the remainder of the term of the predecessor of the individual.

(f) Chair

The Director shall, from among the members of the Advisory Council appointed under subsection

(c)(2), designate an individual to serve as the chair of the Advisory Council.

(g) Meetings

The Advisory Council shall meet not less than once during each discrete 4-month period and shall otherwise meet at the call of the Director or the chair.

(h) Compensation and reimbursement of expenses

(1) Appointed members

Members of the Advisory Council appointed under subsection (c)(2) shall receive compensation for each day (including travel time) engaged in carrying out the duties of the Advisory Council unless declined by the member. Such compensation may not be in an amount in excess of the daily equivalent of the annual rate of basic pay prescribed for level IV of the Executive Schedule under section 5315 of title 5 for each day during which such member is engaged in the performance of the duties of the Advisory Council.

(2) Ex officio members

Officials designated under subsection (c)(3) as ex officio members of the Advisory Council may not receive compensation for service on the Advisory Council in addition to the compensation otherwise received for duties carried out as officers of the United States.

(i) Staff

The Director shall provide to the Advisory Council such staff, information, and other assistance as may be necessary to carry out the duties of the Council.

(j) Duration

Notwithstanding section 1013(a) of title 5, the Advisory Council shall continue in existence until otherwise provided by law.

(July 1, 1944, ch. 373, title IX, §941, formerly §921, as added Pub. L. 106–129, §2(a), Dec. 6, 1999, 113 Stat. 1663; amended Pub. L. 108–173, title IX, §900(e)(2)(D), Dec. 8, 2003, 117 Stat. 2372; renumbered §931, Pub. L. 109–41, §2(a)(3), July 29, 2005, 119 Stat. 424; renumbered §941, Pub. L. 111–148, title III, §3013(a)(2), Mar. 23, 2010, 124 Stat. 381; Pub. L. 117–286, §4(a)(242), Dec. 27, 2022, 136 Stat. 4332.)

EDITORIAL NOTES

PRIOR PROVISIONS

A prior section 299c, act July 1, 1944, ch. 373, title IX, §921, as added Pub. L. 101–239, title VI, §6103(c), Dec. 19, 1989, 103 Stat. 2199; amended Pub. L. 102–410, §8, Oct. 13, 1992, 106 Stat. 2100, established the Advisory Council for Health Care Policy, Research, and Evaluation, prior to the general amendment of this subchapter by Pub. L. 106–129.

Another prior section 299c, act July 1, 1944, ch. 373, title IX, §903, as added Oct. 6, 1965, Pub. L. 89–239, §2, 79 Stat. 927; amended Oct. 15, 1968, Pub. L. 90–574, title I, §104, 82 Stat. 1005; Oct. 30, 1970, Pub. L. 91–515, title I, §§105, 111(b), 84 Stat. 1299, 1301, authorized Secretary to make planning grants and set forth requirements for grant applications, prior to repeal by Pub. L. 99–117, §12(d), Oct. 7, 1985, 99 Stat. 495.

AMENDMENTS

2022—Subsec. (j). Pub. L. 117–286, which directed amendment of "Section 942(j) of the Public Health Service Act" by substituting "section 1013(a) of title 5," for "section 14(a) of the Federal Advisory Committee Act,", was executed to this section, which is section 941 of the Public Health Service Act, to reflect the probable intent of Congress.

2003—Subsec. (c)(3)(A). Pub. L. 108–173 substituted "Centers for Medicare & Medicaid Services" for "Health Care Financing Administration".

§299c–1. Peer review with respect to grants and contracts

(a) Requirement of review

(1) In general

Appropriate technical and scientific peer review shall be conducted with respect to each application for a grant, cooperative agreement, or contract under this subchapter.

(2) Reports to Director

Each peer review group to which an application is submitted pursuant to paragraph (1) shall report its finding and recommendations respecting the application to the Director in such form and in such manner as the Director shall require.

(b) Approval as precondition of awards

The Director may not approve an application described in subsection (a)(1) unless the application is recommended for approval by a peer review group established under subsection (c).

(c) Establishment of peer review groups

(1) In general

The Director shall establish such technical and scientific peer review groups as may be necessary to carry out this section. Such groups shall be established without regard to the provisions of title 5 that govern appointments in the competitive service, and without regard to the provisions of chapter 51, and subchapter III of chapter 53, of such title that relate to classification and pay rates under the General Schedule.

(2) Membership

The members of any peer review group established under this section shall be appointed from among individuals who by virtue of their training or experience are eminently qualified to carry out the duties of such peer review group. Officers and employees of the United States may not constitute more than 25 percent of the membership of any such group. Such officers and employees may not receive compensation for service on such groups in addition to the compensation otherwise received for these duties carried out as such officers and employees.

(3) Duration

Notwithstanding section 1013(a) of title 5, peer review groups established under this section may continue in existence until otherwise provided by law.

(4) Qualifications

Members of any peer review group shall, at a minimum, meet the following requirements:

(A) Such members shall agree in writing to treat information received, pursuant to their work for the group, as confidential information, except that this subparagraph shall not apply to public records and public information.

(B) Such members shall agree in writing to recuse themselves from participation in the peer review of specific applications which present a potential personal conflict of interest or appearance of such conflict, including employment in a directly affected organization, stock ownership, or any financial or other arrangement that might introduce bias in the process of peer review.

(d) Authority for procedural adjustments in certain cases

In the case of applications for financial assistance whose direct costs will not exceed $100,000, the Director may make appropriate adjustments in the procedures otherwise established by the Director for the conduct of peer review under this section. Such adjustments may be made for the purpose of encouraging the entry of individuals into the field of research, for the purpose of encouraging clinical practice-oriented or provider-based research, and for such other purposes as the Director may determine to be appropriate.

(e) Regulations

The Director shall issue regulations for the conduct of peer review under this section.

(July 1, 1944, ch. 373, title IX, §942, formerly §922, as added Pub. L. 106–129, §2(a), Dec. 6, 1999, 113 Stat. 1665; renumbered §932, Pub. L. 109–41, §2(a)(3), July 29, 2005, 119 Stat. 424; renumbered §942, Pub. L. 111–148, title III, §3013(a)(2), Mar. 23, 2010, 124 Stat. 381; amended Pub. L. 117–286, §4(a)(243), Dec. 27, 2022, 136 Stat. 4332.)

EDITORIAL NOTES

REFERENCES IN TEXT

The provisions of title 5 that govern appointments in the competitive service, referred to in subsec. (c)(1), are classified generally to section 3301 et seq. of Title 5, Government Organization and Employees.

PRIOR PROVISIONS

A prior section 299c–1, act July 1, 1944, ch. 373, title IX, §922, as added Pub. L. 101–239, title VI, §6103(c), Dec. 19, 1989, 103 Stat. 2201; amended Pub. L. 101–508, title IV, §4118(f)(2)(F), Nov. 5, 1990, 104 Stat. 1388–70; Pub. L. 102–410, §5(d), Oct. 13, 1992, 106 Stat. 2098, related to peer review with respect to grants and contracts, prior to the general amendment of this subchapter by Pub. L. 106–129.

AMENDMENTS

2022—Subsec. (c)(3). Pub. L. 117–286, which directed amendment of "Section 941(c)(3) of the Public Health Service Act" by substituting "section 1013(a) of title 5," for "section 14(a) of the Federal Advisory Committee Act,", was executed to this section, which is section 942 of the Public Health Service Act, to reflect the probable intent of Congress.

§299c–2. Certain provisions with respect to development, collection, and dissemination of data

(a) Standards with respect to utility of data

(1) In general

To ensure the utility, accuracy, and sufficiency of data collected by or for the Agency for the purpose described in section 299(b) of this title, the Director shall establish standard methods for developing and collecting such data, taking into consideration—

(A) other Federal health data collection standards; and

(B) the differences between types of health care plans, delivery systems, health care providers, and provider arrangements.

(2) Relationship with other Department programs

In any case where standards under paragraph (1) may affect the administration of other programs carried out by the Department of Health and Human Services, including the programs under title XVIII, XIX or XXI of the Social Security Act [42 U.S.C. 1395 et seq., 1396 et seq., 1397aa et seq.], or may affect health information that is subject to a standard developed under part C of title XI of the Social Security Act [42 U.S.C. 1320d et seq.], they shall be in the form of recommendations to the Secretary for such program.

(b) Statistics and analyses

The Director shall—

(1) take appropriate action to ensure that statistics and analyses developed under this subchapter are of high quality, timely, and duly comprehensive, and that the statistics are specific, standardized, and adequately analyzed and indexed; and

(2) publish, make available, and disseminate such statistics and analyses on as wide a basis as is practicable.

(c) Authority regarding certain requests

Upon request of a public or private entity, the Director may conduct or support research or analyses otherwise authorized by this subchapter pursuant to arrangements under which such entity

will pay the cost of the services provided. Amounts received by the Director under such arrangements shall be available to the Director for obligation until expended.

(July 1, 1944, ch. 373, title IX, §943, formerly §923, as added Pub. L. 106–129, §2(a), Dec. 6, 1999, 113 Stat. 1666; renumbered §933, Pub. L. 109–41, §2(a)(3), July 29, 2005, 119 Stat. 424; renumbered §943, Pub. L. 111–148, title III, §3013(a)(2), Mar. 23, 2010, 124 Stat. 381.)

EDITORIAL NOTES

REFERENCES IN TEXT

The Social Security Act, referred to in subsec. (a)(2), is act Aug. 14, 1935, ch. 531, 49 Stat. 620. Part C of title XI of the Act is classified generally to part C (§1320d et seq.) of title XI of chapter 7 of this title. Titles XVIII, XIX, and XXI of the Act are classified generally to subchapters XVIII (§1395 et seq.), XIX (§1396 et seq.), and XXI (§1397aa et seq.), respectively, of chapter 7 of this title. For complete classification of this Act to the Code, see section 1305 of this title and Tables.

PRIOR PROVISIONS

A prior section 299c–2, act July 1, 1944, ch. 373, title IX, §923, as added Pub. L. 101–239, title VI, §6103(c), Dec. 19, 1989, 103 Stat. 2202; amended Pub. L. 102–410, §5(e), Oct. 12, 1992, 106 Stat. 2098, related to development, collection, and dissemination of data, prior to the general amendment of this subchapter by Pub. L. 106–129.

§299c–3. Dissemination of information

(a) In general

The Director shall—

(1) without regard to section 501 of title 44, promptly publish, make available, and otherwise disseminate, in a form understandable and on as broad a basis as practicable so as to maximize its use, the results of research, demonstration projects, and evaluations conducted or supported under this subchapter;

(2) ensure that information disseminated by the Agency is science-based and objective and undertakes consultation as necessary to assess the appropriateness and usefulness of the presentation of information that is targeted to specific audiences;

(3) promptly make available to the public data developed in such research, demonstration projects, and evaluations;

(4) provide, in collaboration with the National Library of Medicine where appropriate, indexing, abstracting, translating, publishing, and other services leading to a more effective and timely dissemination of information on research, demonstration projects, and evaluations with respect to health care to public and private entities and individuals engaged in the improvement of health care delivery and the general public, and undertake programs to develop new or improved methods for making such information available; and

(5) as appropriate, provide technical assistance to State and local government and health agencies and conduct liaison activities to such agencies to foster dissemination.

(b) Prohibition against restrictions

Except as provided in subsection (c), the Director may not restrict the publication or dissemination of data from, or the results of, projects conducted or supported under this subchapter.

(c) Limitation on use of certain information

No information, if an establishment or person supplying the information or described in it is identifiable, obtained in the course of activities undertaken or supported under this subchapter may be used for any purpose other than the purpose for which it was supplied unless such establishment or person has consented (as determined under regulations of the Director) to its use for such other

purpose. Such information may not be published or released in other form if the person who supplied the information or who is described in it is identifiable unless such person has consented (as determined under regulations of the Director) to its publication or release in other form.

(d) Penalty

Any person who violates subsection (c) shall be subject to a civil monetary penalty of not more than $10,000 for each such violation involved. Such penalty shall be imposed and collected in the same manner as civil money penalties under subsection (a) of section 1320a–7a of this title are imposed and collected.

(July 1, 1944, ch. 373, title IX, §944, formerly §924, as added Pub. L. 106–129, §2(a), Dec. 6, 1999, 113 Stat. 1667; renumbered §934, Pub. L. 109–41, §2(a)(3), July 29, 2005, 119 Stat. 424; renumbered §944, Pub. L. 111–148, title III, §3013(a)(2), Mar. 23, 2010, 124 Stat. 381.)

EDITORIAL NOTES

PRIOR PROVISIONS

A prior section 299c–3, act July 1, 1944, ch. 373, title IX, §924, as added Pub. L. 101–239, title VI, §6103(c), Dec. 19, 1989, 103 Stat. 2202; amended Pub. L. 102–410, §9, Oct. 13, 1992, 106 Stat. 2100, related to additional provisions with respect to grants and contracts, prior to the general amendment of this subchapter by Pub. L. 106–129. See section 299c–4 of this title.

§299c–4. Additional provisions with respect to grants and contracts

(a) Financial conflicts of interest

With respect to projects for which awards of grants, cooperative agreements, or contracts are authorized to be made under this subchapter, the Director shall by regulation define—

(1) the specific circumstances that constitute financial interests in such projects that will, or may be reasonably expected to, create a bias in favor of obtaining results in the projects that are consistent with such interests; and

(2) the actions that will be taken by the Director in response to any such interests identified by the Director.

(b) Requirement of application

The Director may not, with respect to any program under this subchapter authorizing the provision of grants, cooperative agreements, or contracts, provide any such financial assistance unless an application for the assistance is submitted to the Secretary and the application is in such form, is made in such manner, and contains such agreements, assurances, and information as the Director determines to be necessary to carry out the program involved.

(c) Provision of supplies and services in lieu of funds

(1) In general

Upon the request of an entity receiving a grant, cooperative agreement, or contract under this subchapter, the Secretary may, subject to paragraph (2), provide supplies, equipment, and services for the purpose of aiding the entity in carrying out the project involved and, for such purpose, may detail to the entity any officer or employee of the Department of Health and Human Services.

(2) Corresponding reduction in funds

With respect to a request described in paragraph (1), the Secretary shall reduce the amount of the financial assistance involved by an amount equal to the costs of detailing personnel and the fair market value of any supplies, equipment, or services provided by the Director. The Secretary shall, for the payment of expenses incurred in complying with such request, expend the amounts withheld.

(d) Applicability of certain provisions with respect to contracts

Contracts may be entered into under this part without regard to section 3324(a) and (b) of title 31 and section 6101 of title 41.

(July 1, 1944, ch. 373, title IX, §945, formerly §925, as added Pub. L. 106–129, §2(a), Dec. 6, 1999, 113 Stat. 1668; renumbered §935, Pub. L. 109–41, §2(a)(3), July 29, 2005, 119 Stat. 424; renumbered §945, Pub. L. 111–148, title III, §3013(a)(2), Mar. 23, 2010, 124 Stat. 381.)

EDITORIAL NOTES

CODIFICATION

In subsec. (d), "section 3324(a) and (b) of title 31 and section 6101 of title 41" substituted for "sections 3648 and 3709 of the Revised Statutes (31 U.S.C. 529 and 41 U.S.C. 5)" on authority of Pub. L. 97–258, §4(b), Sept. 13, 1982, 96 Stat. 1067, which Act enacted Title 31, Money and Finance, and Pub. L. 111–350, §6(c), Jan. 4, 2011, 124 Stat. 3854, which Act enacted Title 41, Public Contracts.

PRIOR PROVISIONS

A prior section 299c–4, act July 1, 1944, ch. 373, title IX, §925, as added Pub. L. 101–239, title VI, §6103(c), Dec. 19, 1989, 103 Stat. 2203; amended Pub. L. 104–201, div. A, title XVII, §1723(a)(3)(B), Sept. 23, 1996, 110 Stat. 2759, related to certain administrative authorities, prior to the general amendment of this subchapter by Pub. L. 106–129. See section 299c–5 of this title.

§299c–5. Certain administrative authorities

(a) Deputy director and other officers and employees

(1) Deputy director

The Director may appoint a deputy director for the Agency.

(2) Other officers and employees

The Director may appoint and fix the compensation of such officers and employees as may be necessary to carry out this subchapter. Except as otherwise provided by law, such officers and employees shall be appointed in accordance with the civil service laws and their compensation fixed in accordance with title 5.

(b) Facilities

The Secretary, in carrying out this subchapter—

(1) may acquire, without regard to section 8141 of title 40, by lease or otherwise through the Administrator of General Services, buildings or portions of buildings in the District of Columbia or communities located adjacent to the District of Columbia for use for a period not to exceed 10 years; and

(2) may acquire, construct, improve, repair, operate, and maintain laboratory, research, and other necessary facilities and equipment, and such other real or personal property (including patents) as the Secretary deems necessary.

(c) Provision of financial assistance

The Director, in carrying out this subchapter, may make grants to public and nonprofit entities and individuals, and may enter into cooperative agreements or contracts with public and private entities and individuals.

(d) Utilization of certain personnel and resources

(1) Department of Health and Human Services

The Director, in carrying out this subchapter, may utilize personnel and equipment, facilities, and other physical resources of the Department of Health and Human Services, permit appropriate (as determined by the Secretary) entities and individuals to utilize the physical resources of such Department, and provide technical assistance and advice.

(2) Other agencies

The Director, in carrying out this subchapter, may use, with their consent, the services, equipment, personnel, information, and facilities of other Federal, State, or local public agencies, or of any foreign government, with or without reimbursement of such agencies.

(e) Consultants

The Secretary, in carrying out this subchapter, may secure, from time to time and for such periods as the Director deems advisable but in accordance with section 3109 of title 5, the assistance and advice of consultants from the United States or abroad.

(f) Experts

(1) In general

The Secretary may, in carrying out this subchapter, obtain the services of not more than 50 experts or consultants who have appropriate scientific or professional qualifications. Such experts or consultants shall be obtained in accordance with section 3109 of title 5, except that the limitation in such section on the duration of service shall not apply.

(2) Travel expenses

(A) In general

Experts and consultants whose services are obtained under paragraph (1) shall be paid or reimbursed for their expenses associated with traveling to and from their assignment location in accordance with sections 5724, 5724a(a), 5724a(c), and 5726(c) of title 5.

(B) Limitation

Expenses specified in subparagraph (A) may not be allowed in connection with the assignment of an expert or consultant whose services are obtained under paragraph (1) unless and until the expert agrees in writing to complete the entire period of assignment, or 1 year, whichever is shorter, unless separated or reassigned for reasons that are beyond the control of the expert or consultant and that are acceptable to the Secretary. If the expert or consultant violates the agreement, the money spent by the United States for the expenses specified in subparagraph (A) is recoverable from the expert or consultant as a statutory obligation owed to the United States. The Secretary may waive in whole or in part a right of recovery under this subparagraph.

(g) Voluntary and uncompensated services

The Director, in carrying out this subchapter, may accept voluntary and uncompensated services.

(July 1, 1944, ch. 373, title IX, §946, formerly §926, as added Pub. L. 106–129, §2(a), Dec. 6, 1999, 113 Stat. 1668; renumbered §936, Pub. L. 109–41, §2(a)(3), July 29, 2005, 119 Stat. 424; renumbered §946, Pub. L. 111–148, title III, §3013(a)(2), Mar. 23, 2010, 124 Stat. 381.)

EDITORIAL NOTES

CODIFICATION

In subsec. (b)(1), "section 8141 of title 40" substituted for "the Act of March 3, 1877 (40 U.S.C. 34)" on authority of Pub. L. 107–217, §5(c), Aug. 21, 2002, 116 Stat. 1303, the first section of which enacted Title 40, Public Buildings, Property, and Works.

PRIOR PROVISIONS

A prior section 299c–5, act July 1, 1944, ch. 373, title IX, §926, as added Pub. L. 101–239, title VI, §6103(c), Dec. 19, 1989, 103 Stat. 2204; amended Pub. L. 101–381, title I, §102(7), Aug. 18, 1990, 104 Stat. 586; Pub. L. 102–410, §10, Oct. 13, 1992, 106 Stat. 2101; Pub. L. 103–43, title XX, §2010(b)(8), June 10, 1993, 107 Stat. 214, authorized appropriations to carry out this subchapter, prior to the general amendment of this subchapter by Pub. L. 106–129. See section 299c–6 of this title.

§299c–6. Funding

(a) Intent

To ensure that the United States investment in biomedical research is rapidly translated into improvements in the quality of patient care, there must be a corresponding investment in research on the most effective clinical and organizational strategies for use of these findings in daily practice. The authorization levels in subsections (b) and (c) provide for a proportionate increase in health care research as the United States investment in biomedical research increases.

(b) Authorization of appropriations

For the purpose of carrying out this subchapter, there are authorized to be appropriated $250,000,000 for fiscal year 2000, and such sums as may be necessary for each of the fiscal years 2001 through 2005.

(c) Evaluations

In addition to amounts available pursuant to subsection (b) for carrying out this subchapter, there shall be made available for such purpose, from the amounts made available pursuant to section 238j of this title (relating to evaluations), an amount equal to 40 percent of the maximum amount authorized in such section 238j of this title to be made available for a fiscal year.

(d) Health disparities research

For the purpose of carrying out the activities under section 299a–1 of this title, there are authorized to be appropriated $50,000,000 for fiscal year 2001, and such sums as may be necessary for each of the fiscal years 2002 through 2005.

(e) Patient safety and quality improvement

For the purpose of carrying out part C, there are authorized to be appropriated such sums as may be necessary for each of the fiscal years 2006 through 2010.

(July 1, 1944, ch. 373, title IX, §947, formerly §927, as added Pub. L. 106–129, §2(a), Dec. 6, 1999, 113 Stat. 1670; amended Pub. L. 106–525, title II, §201(b), Nov. 22, 2000, 114 Stat. 2507; renumbered §937 and amended Pub. L. 109–41, §2(a)(3), (b), July 29, 2005, 119 Stat. 424, 434; renumbered §947, Pub. L. 111–148, title III, §3013(a)(2), Mar. 23, 2010, 124 Stat. 381.)

EDITORIAL NOTES

PRIOR PROVISIONS

A prior section 299c–6, act July 1, 1944, ch. 373, title IX, §927, as added Pub. L. 101–239, title VI, §6103(c), Dec. 19, 1989, 103 Stat. 2204, set out definitions, prior to the general amendment of this subchapter by Pub. L. 106–129. See section 299c–7 of this title.

AMENDMENTS

2005—Subsec. (e). Pub. L. 109–41, §2(b), added subsec. (e).
2000—Subsec. (d). Pub. L. 106–525 added subsec. (d).

§299c–7. Definitions

In this subchapter:

(1) Advisory Council

The term "Advisory Council" means the National Advisory Council on Healthcare Research and Quality established under section 299c of this title.

(2) Agency

The term "Agency" means the Agency for Healthcare Research and Quality.

(3) Director

The term "Director" means the Director of the Agency for Healthcare Research and Quality.

(July 1, 1944, ch. 373, title IX, §948, formerly §928, as added Pub. L. 106–129, §2(a), Dec. 6, 1999, 113 Stat. 1670; renumbered §938 and amended Pub. L. 109–41, §2(a)(3), (4), July 29, 2005, 119 Stat. 424; renumbered §948 and amended Pub. L. 111–148, title III, §3013(a)(2), (3), Mar. 23, 2010, 124 Stat. 381.)

EDITORIAL NOTES

PRIOR PROVISIONS

Prior sections 299d to 299j were repealed by Pub. L. 99–117, §12(d), Oct. 7, 1985, 99 Stat. 495.

Section 299d, act July 1, 1944, ch. 373, title IX, §904, as added Oct. 6, 1965, Pub. L. 89–239, §2, 79 Stat. 928; amended Oct. 15, 1968, Pub. L. 90–574, title I, §104, 82 Stat. 1005; Oct. 30, 1970, Pub. L. 91–515, title I, §§106, 111(b), 84 Stat. 1299, 1301, authorized Secretary to make grants for establishment and operation of regional medical programs and set forth requirements for grant applications.

Section 299e, act July 1, 1944, ch. 373, title IX, §905, as added Oct. 6, 1965, Pub. L. 89–239, §2, 79 Stat. 929; amended Oct. 15, 1968, Pub. L. 90–574, title I, §105, 82 Stat. 1005; Oct. 30, 1970, Pub. L. 91–515, title I, §§107(a), 111(b), title VI, §601(b)(2), (4), 84 Stat. 1299, 1301, 1311; Oct. 17, 1979, Pub. L. 96–88, title V, §509(b), 93 Stat. 695, provided for establishment of a National Advisory Council on Regional Medical Programs and its functions.

Section 299f, act July 1, 1944, ch. 373, title IX, §906, as added Oct. 6, 1965, Pub. L. 89–239, §2, 79 Stat. 930; amended Oct. 30, 1970, Pub. L. 91–515, title I, §111(b), 84 Stat. 1301, authorized Secretary to establish rules and regulations covering terms of approval of grant applications and coordination of programs.

Section 299g, act July 1, 1944, ch. 373, title IX, §907, as added Oct. 6, 1965, Pub. L. 89–239, §2, 79 Stat. 930; amended Oct. 30, 1970, Pub. L. 91–515, title I, §§108, 111(b), 84 Stat. 1300, 1301, directed Secretary to compile a list of facilities equipped and staffed to provide most advanced methods for diagnosing and treating certain diseases and illnesses.

Section 299h, act July 1, 1944, ch. 373, title IX, §908, as added Oct. 6, 1965, Pub. L. 89–239, §2, 79 Stat. 930, called for a report to the President and the Congress on or before June 30, 1967, by Surgeon General concerning activities under this subchapter with required statements, appraisals, and recommendations.

Section 299i, act July 1, 1944, ch. 373, title IX, §909, as added Oct. 6, 1965, Pub. L. 89–239, §2, 79 Stat. 930; amended Oct. 30, 1970, Pub. L. 91–515, title I, §§109, 111(b), 84 Stat. 1300, 1301; Oct. 17, 1979, Pub. L. 96–88, title V, §509(b), 93 Stat. 695, provided for recordkeeping by grant recipients and for accessibility of records for audit and examination.

Section 299j, act July 1, 1944, ch. 373, title IX, §910, as added Oct. 15, 1968, Pub. L. 90–574, title I, §106, 82 Stat. 1005; amended Oct. 30, 1970, Pub. L. 91–515, title I, §110, 84 Stat. 1300, related to grants and contracts for multiprogram services, costs of special projects, and support of research, studies, investigations, training, and demonstrations.

AMENDMENTS

2010—Par. (1). Pub. L. 111–148, §3013(a)(3), made technical amendment to reference in original act which appears in text as reference to section 299c of this title, requiring no change in text.

2005—Par. (1). Pub. L. 109–41, §2(a)(4), made technical amendment to reference in original act which appears in text as reference to section 299c of this title, requiring no change in text.

SUBCHAPTER VIII—POPULATION RESEARCH AND VOLUNTARY FAMILY PLANNING PROGRAMS

§300. Project grants and contracts for family planning services

(a) Authority of Secretary

The Secretary is authorized to make grants to and enter into contracts with public or nonprofit private entities to assist in the establishment and operation of voluntary family planning projects which shall offer a broad range of acceptable and effective family planning methods and services

(including natural family planning methods, infertility services, and services for adolescents). To the extent practical, entities which receive grants or contracts under this subsection shall encourage familiy [1] participation in projects assisted under this subsection.

(b) Factors determining awards; establishment and preservation of rights of local and regional entities

In making grants and contracts under this section the Secretary shall take into account the number of patients to be served, the extent to which family planning services are needed locally, the relative need of the applicant, and its capacity to make rapid and effective use of such assistance. Local and regional entities shall be assured the right to apply for direct grants and contracts under this section, and the Secretary shall by regulation fully provide for and protect such right.

(c) Reduction of grant amount

The Secretary, at the request of a recipient of a grant under subsection (a), may reduce the amount of such grant by the fair market value of any supplies or equipment furnished the grant recipient by the Secretary. The amount by which any such grant is so reduced shall be available for payment by the Secretary of the costs incurred in furnishing the supplies or equipment on which the reduction of such grant is based. Such amount shall be deemed as part of the grant and shall be deemed to have been paid to the grant recipient.

(d) Authorization of appropriations

For the purpose of making grants and contracts under this section, there are authorized to be appropriated $30,000,000 for the fiscal year ending June 30, 1971; $60,000,000 for the fiscal year ending June 30, 1972; $111,500,000 for the fiscal year ending June 30, 1973, $111,500,000 each for the fiscal years ending June 30, 1974, and June 30, 1975; $115,000,000 for fiscal year 1976; $115,000,000 for the fiscal year ending September 30, 1977; $136,400,000 for the fiscal year ending September 30, 1978; $200,000,000 for the fiscal year ending September 30, 1979; $230,000,000 for the fiscal year ending September 30, 1980; $264,500,000 for the fiscal year ending September 30, 1981; $126,510,000 for the fiscal year ending September 30, 1982; $139,200,000 for the fiscal year ending September 30, 1983; $150,830,000 for the fiscal year ending September 30, 1984; and $158,400,000 for the fiscal year ending September 30, 1985.

(July 1, 1944, ch. 373, title X, §1001, as added Pub. L. 91–572, §6(c), Dec. 24, 1970, 84 Stat. 1506; amended Pub. L. 92–449, title III, §301, Sept. 30, 1972, 86 Stat. 754; Pub. L. 93–45, title I, §111(a), June 18, 1973, 87 Stat. 93; Pub. L. 94–63, title II, §§202(a), 204(a), (b), title VII, §701(d), July 29, 1975, 89 Stat. 306–308, 352; Pub. L. 95–83, title III, §305(a), Aug. 1, 1977, 91 Stat. 388; Pub. L. 95–613, §1(a)(1), (b)(1), Nov. 8, 1978, 92 Stat. 3093; Pub. L 97–35, title IX, §931(a)(1), (b)(1), Aug. 13, 1981, 95 Stat. 570; Pub. L. 97–414, §§8(n), 9(a), Jan. 4, 1983, 96 Stat. 2061, 2064; Pub. L. 98–512, §3(a), Oct. 19, 1984, 98 Stat. 2409; Pub. L. 98–555, §9, Oct. 30, 1984, 98 Stat. 2857.)

EDITORIAL NOTES

AMENDMENTS

1984—Subsec. (c). Pub. L. 98–555 added subsec. (c). Former subsec. (c) redesignated (d).

Pub. L. 98–512 inserted provisions authorizing appropriations for the fiscal year ending Sept. 30, 1985.

Subsec. (d). Pub. L. 98–555 redesignated former subsec. (c) as (d).

1983—Subsec. (c). Pub. L. 97–414, §8(n), substituted a semicolon for a comma after "1981".

Pub. L. 97–414, §9(a), amended directory language of Pub. L. 97–35, §931(a)(1), to correct a typographical error and did not involve any change in text. See 1981 Amendment note below.

1981—Subsec. (a). Pub. L. 97–35, §931(b)(1), inserted provisions relating to family participation in projects.

Subsec. (c). Pub. L. 97–35, §931(a)(1), as amended by Pub. L. 97–414, §9(a), inserted provisions authorizing appropriations for fiscal years ending Sept. 30, 1982, 1983, and 1984.

1978—Subsec. (a). Pub. L. 95–613, §1(a)(1), inserted provisions relating to infertility services and services for adolescents.

Subsec. (c). Pub. L. 95–613, §1(b)(1), inserted provisions authorizing appropriations for fiscal years ending

Sept. 30, 1979, 1980, and 1981.

1977—Subsec. (c). Pub. L. 95–83 substituted provision authorizing appropriations for fiscal years ending Sept. 30, 1977 and 1978, for prior such authorization for fiscal year 1977.

1975—Subsec. (a). Pub. L. 94–63, §204(a), inserted provision relating to scope of family planning projects to be offered.

Subsec. (b). Pub. L. 94–63, §204(b), inserted provision relating to direct grants and contracts for local and regional entities.

Subsec. (c). Pub. L. 94–63, §§202(a), 701(d), inserted provisions authorizing appropriations for fiscal years ending June 30, 1975, 1976, and 1977.

1973—Subsec. (c). Pub. L. 93–45 inserted provisions authorizing appropriations for fiscal year ending June 30, 1974.

1972—Subsec. (c). Pub. L. 92–449 increased appropriations authorization for fiscal year ending June 30, 1973, to $111,500,000 from $90,000,000.

STATUTORY NOTES AND RELATED SUBSIDIARIES

EFFECTIVE DATE OF 1975 AMENDMENT

Amendment by sections 202(a) and 204(a), (b) of Pub. L. 94–63 effective July 1, 1975, see section 608 of Pub. L. 94–63, set out as a note under section 247b of this title.

STUDY AS TO DISCRIMINATION BY SCHOOLS OF MEDICINE, NURSING, OR OSTEOPATHY AGAINST APPLICANTS BECAUSE OF RELUCTANCE OR WILLINGNESS TO PARTICIPATE IN ABORTIONS OR STERILIZATIONS; REPORT NOT LATER THAN FEBRUARY 1, 1978

Pub. L. 95–215, §7, Dec. 19, 1977, 91 Stat. 1507, required Secretary of Health, Education, and Welfare to conduct a study and report to specific committees of Congress not later than Feb. 1, 1978, as to whether schools of medicine, nursing, or osteopathy discriminate against applicants because of applicant's reluctance or unwillingness to participate in performance of abortions or sterilizations contrary to religious beliefs or moral convictions.

CONGRESSIONAL DECLARATION OF PURPOSE

Pub. L. 91–572, §2, Dec. 24, 1970, 84 Stat. 1504, provided that: "It is the purpose of this Act [see Short Title of 1970 Amendment note set out under section 201 of this title]—

"(1) to assist in making comprehensive voluntary family planning services readily available to all persons desiring such services;

"(2) to coordinate domestic population and family planning research with the present and future needs of family planning programs;

"(3) to improve administrative and operational supervision of domestic family planning services and of population research programs related to such services;

"(4) to enable public and nonprofit private entities to plan and develop comprehensive programs of family planning services;

"(5) to develop and make readily available information (including educational materials) on family planning and population growth to all persons desiring such information;

"(6) to evaluate and improve the effectiveness of family planning service programs and of population research;

"(7) to assist in providing trained manpower needed to effectively carry out programs of population research and family planning services; and

"(8) to establish an Office of Population Affairs in the Department of Health, Education, and Welfare as a primary focus within the Federal Government on matters pertaining to population research and family planning, through which the Secretary of Health, Education, and Welfare [now Health and Human Services] (hereafter in this Act referred to as the 'Secretary') shall carry out the purposes of this Act."

EXECUTIVE DOCUMENTS

EXECUTIVE ORDER NO. 14076

Ex. Ord. No. 14076, July 8, 2022, 87 F.R. 42053, which related to protecting access to reproductive healthcare services following the overturn of Roe v. Wade, was revoked by Ex. Ord. No. 14182, §2(a), Jan.

24, 2025, 90 F.R. 8751.

EXECUTIVE ORDER NO. 14079

Ex. Ord. No. 14079, Aug. 3, 2022, 87 F.R. 49505, which related to further action to protect access to reproductive healthcare services and addressing women's health and public health, was revoked by Ex. Ord. No. 14182, §2(b), Jan. 24, 2025, 90 F.R. 8751.

EX. ORD. NO. 14101. STRENGTHENING ACCESS TO AFFORDABLE, HIGH-QUALITY CONTRACEPTION AND FAMILY PLANNING SERVICES

Ex. Ord. No. 14101, June 23, 2023, 88 F.R. 41815, provided:

By the authority vested in me as President by the Constitution and the laws of the United States of America, it is hereby ordered as follows:

SECTION 1. *Policy*. Women should have access to the healthcare they need, including contraception and family planning services. Access to contraception is essential to ensuring that all people have control over personal decisions about their own health, lives, and families. High-quality contraception improves health outcomes, advances economic stability, and promotes women's overall well-being. Contraception access is linked to improved maternal and child health, expanded educational and professional opportunities, and higher lifetime earnings.

Through new requirements for private health coverage and expanded access to Medicaid, the [Patient Protection and] Affordable Care Act [Pub. L. 111–148, see Tables for classification] extended access to affordable contraception to millions of women, helping them save billions of dollars on birth control. Yet access to high-quality contraception continues to vary based on income, location, health insurance coverage, and the availability of healthcare providers. Millions of people continue to face barriers to obtaining the contraception they need even as access has become more critical in the wake of the Supreme Court's decision in *Dobbs v. Jackson Women's Health Organization*, 142 S. Ct. 2228 (2022), to overturn *Roe v. Wade*, 410 U.S. 113 (1973).

Given that the Supreme Court overruled *Roe*, which rested on the fundamental right to privacy in matters of health, bodily autonomy, and family, it has never been more important to protect and expand access to family planning services. *Dobbs* has already had, and will continue to have, devastating implications for women's health. In States with laws that restrict access to abortion, health clinics that provide contraception and other essential health services have shuttered, eliminating critical points of care. Some State officials have adopted policies interfering with access to emergency contraception, including for vulnerable populations. Such policies further threaten women's ability to make decisions about their own bodies, families, and futures. These threats persist despite decades of Supreme Court precedent, beginning with *Griswold v. Connecticut*, 381 U.S. 479 (1965), and *Eisenstadt v. Baird*, 405 U.S. 438 (1972), affirming the right to contraception. Moreover, an overwhelming majority of Americans support access to contraception.

In the wake of the Supreme Court's decision in *Dobbs*, I issued Executive Order 14076 of July 8, 2022 (Protecting Access to Reproductive Healthcare Services) [set out above], and Executive Order 14079 of August 3, 2022 (Securing Access to Reproductive and Other Healthcare Services) [set out above], to direct my Administration to take action to protect access to reproductive healthcare services, including contraception and abortion. In Executive Order 14076, I directed the Secretary of Health and Human Services and the Director of the Gender Policy Council to establish an Interagency Task Force on Reproductive Healthcare Access to coordinate these efforts across my Administration. Consistent with these Executive Orders and other applicable authorities, executive departments and agencies have taken numerous steps to protect and strengthen access to contraception, including:

(a) issuing guidance and convening sponsors of employee benefit plans and health insurers to clarify contraception coverage requirements under the Affordable Care Act;

(b) expanding walk-in contraceptive care services for active duty service members and other Military Health System beneficiaries;

(c) issuing a Notice of Proposed Rulemaking to improve access to affordable contraception for certain dependents of veterans;

(d) providing additional funding to bolster training, develop and expand telehealth infrastructure and capacity, and provide technical assistance for clinics funded under Title X of the Public Health Service Act (42 U.S.C. 300 et seq.) (Title X);

(e) strengthening the inclusion of family planning providers in insurance networks for qualified health plans under the Affordable Care Act;

(f) issuing a Notice of Proposed Rulemaking to provide a new pathway for women to access contraceptives when their private health coverage is exempt from covering this benefit;

(g) issuing a Notice of Proposed Rulemaking to strengthen privacy protections under the Health Insurance

Portability and Accountability Act of 1996, Public Law 104–191, 110 Stat. 1936 [see Tables for classification], as amended by Public Law 111–5, 123 Stat. 115 (2009), by proposing to prohibit doctors, other healthcare providers, and health plans from using or disclosing individuals' protected health information related to lawful reproductive healthcare, such as contraception use, under certain circumstances;

(h) issuing a Notice of Proposed Rulemaking to ensure healthcare providers that receive Federal financial assistance do not deny healthcare, including contraception, on the basis of any ground protected by Federal law; and

(i) reminding Health Resources and Services Administration (HRSA)-funded health centers of their obligations to provide family planning services to patients consistent with Federal requirements.

Through this order, I direct my Administration to build on this progress and further strengthen and bolster access to affordable, high-quality contraception. It remains the policy of my Administration to support access to reproductive healthcare services and to protect and defend reproductive rights in the face of ongoing efforts to strip Americans of their fundamental freedoms.

SEC. 2. *Improving Access and Affordability Under the Affordable Care Act*. (a) The Secretaries of the Treasury, Labor, and Health and Human Services (Secretaries) shall consider issuing guidance, consistent with applicable law, to further improve Americans' ability to access contraception, without out-of-pocket expenses, under the Affordable Care Act. In doing so, the Secretaries shall consider actions that would, to the greatest extent permitted by law:

(i) ensure coverage of comprehensive contraceptive care, including all contraceptives approved, granted, or cleared by the Food and Drug Administration, without cost sharing for enrollees, participants, and beneficiaries; and

(ii) streamline the process for patients and healthcare providers to request coverage, without cost sharing, of medically necessary contraception.

(b) The Secretaries shall consider additional actions, as appropriate and consistent with applicable law, to promote increased access to affordable over-the-counter contraception, including emergency contraception.

SEC. 3. *Supporting Access Through Medicaid and Medicare*. The Secretary of Health and Human Services, through the Administrator of the Centers for Medicare and Medicaid Services, shall consider taking steps, as appropriate and consistent with applicable law, to:

(a) expand access to affordable family planning services and supplies across the Medicaid program, including by identifying and disseminating best practices for providing high-quality family planning services and supplies, including through Medicaid-managed care; and

(b) improve coverage and payment for contraceptives for Medicare beneficiaries through Medicare Advantage and Medicare Part D plans.

SEC. 4. *Additional Actions to Support Contraception Access*. (a) To promote access to affordable, high-quality contraception, the Secretary of Defense, the Secretary of Veterans Affairs, and the Director of the Office of Personnel Management shall consider additional actions, as appropriate and consistent with applicable law, to:

(i) ensure, where appropriate, robust coverage of contraception under Federal programs;

(ii) offer technical assistance to help promote access to contraception, where relevant; and

(iii) educate Federal program participants and beneficiaries on how to access affordable, high-quality contraception, including through public awareness initiatives that provide timely and accurate information about such access.

(b) To promote access to affordable, high-quality contraception across Federal healthcare programs and relevant human services programs, including through Title X clinics, HRSA-funded health centers, and the Indian Health Service, the Secretary of Health and Human Services shall consider taking actions, as appropriate and consistent with applicable law, to:

(i) encourage all federally funded health centers, including HRSA-funded health centers, to expand the availability and quality of voluntary family planning services offered to beneficiaries;

(ii) support healthcare providers that participate in the Title X program through new technical assistance and training;

(iii) support access to culturally and linguistically appropriate care, including by developing and disseminating materials on family planning services available at federally funded health centers;

(iv) provide guidance on contraception-related obligations, such as confidentiality protections, and technical assistance resources to funding recipients, where relevant; and

(v) support research and data analysis to document gaps and disparities in access to contraception, as well as the benefits of comprehensive coverage for contraception and family planning services through public and private healthcare programs.

(c) The Secretary of Labor shall identify best practices for making affordable, high-quality contraception

available to health plan enrollees, participants, and beneficiaries to share with employers and organizations that sponsor private health coverage.

(d) The Secretary of Education shall convene institutions of higher education to share best practices for making affordable, high-quality contraception available, as well as ways to raise awareness of options for accessing contraception.

SEC. 5. *General Provisions*. (a) Nothing in this order shall be construed to impair or otherwise affect:

(i) the authority granted by law to an executive department or agency, or the head thereof; or

(ii) the functions of the Director of the Office of Management and Budget relating to budgetary, administrative, or legislative proposals.

(b) This order shall be implemented consistent with applicable law and subject to the availability of appropriations.

(c) This order is not intended to, and does not, create any right or benefit, substantive or procedural, enforceable at law or in equity by any party against the United States, its departments, agencies, or entities, its officers, employees, or agents, or any other person.

J.R. BIDEN, JR.

THE MEXICO CITY POLICY

Memorandum of President of the United States, Jan. 24, 2025, 90 F.R. 8753, provided:

Memorandum for the Secretary of State[,] the Secretary of Defense[,] the Secretary of Health and Human Services[, and] the Administrator of the United States Agency for International Development

I hereby revoke the Presidential Memorandum of January 28, 2021, for the Secretary of State, the Secretary of Defense, the Secretary of Health and Human Services, and the Administrator of the United States Agency for International Development (Protecting Women's Health at Home and Abroad) [86 F.R. 33077], and reinstate the Presidential Memorandum of January 23, 2017, for the Secretary of State, the Secretary of Health and Human Services, and the Administrator of the United States Agency for International Development (The Mexico City Policy) [82 F.R. 8495].

I direct the Secretary of State, in coordination with the Secretary of Health and Human Services, to the extent allowable by law, to implement a plan to extend the requirements of the reinstated Memorandum to global health assistance furnished by all departments or agencies.

I further direct the Secretary of State to take all necessary actions, to the extent permitted by law, to ensure that U.S. taxpayer dollars do not fund organizations or programs that support or participate in the management of a program of coercive abortion or involuntary sterilization.

This memorandum is not intended to, and does not, create any right or benefit, substantive or procedural, enforceable at law or in equity by any party against the United States, its departments, agencies, or entities, its officers, employees, or agents, or any other person.

The Secretary of State is authorized and directed to publish this memorandum in the Federal Register.

DONALD J. TRUMP.

Prior memoranda relating to Federal funding for family planning under this subchapter were contained in the following:

Memorandum of President of the United States, Jan. 28, 2021, 86 F.R. 33077, revoked by Memorandum of President of the United States, Jan. 24, 2025, 90 F.R. 8753.

Memorandum of President of the United States, Jan. 23, 2017, 82 F.R. 8495, revoked by Memorandum of President of the United States, §2(b), Jan. 28, 2021, 86 F.R. 33078, reinstated by Memorandum of President of the United States, Jan. 24, 2025, 90 F.R. 8753.

Memorandum of President of the United States, Jan. 23, 2009, 74 F.R. 4903, revoked by Memorandum of President of the United States, Jan. 23, 2017, 82 F.R. 8495.

Memorandum of President of the United States, Jan. 29, 2003, 68 F.R. 52323, revoked by Memorandum of President of the United States, Jan. 23, 2009, 74 F.R. 4903.

Memorandum of President of the United States, Jan. 22, 2001, (not published in Federal Register) revoked by Memorandum of President of the United States, Jan. 23, 2009, 74 F.R. 4903.

Memorandum of President of the United States, Jan. 22, 1993, 58 F.R. 7455, revoked by Memorandum of President of the United States, Jan. 22, 2001 (not published in Federal Register).

FURTHER EFFORTS TO PROTECT ACCESS TO REPRODUCTIVE HEALTHCARE SERVICES

Memorandum of President of the United States, Jan. 22, 2023, 88 F.R. 4895, provided:

Memorandum for the Attorney General[,] the Secretary of Health and Human Services[, and] the Secretary

of Homeland Security

By the authority vested in me as President by the Constitution and the laws of the United States of America, it is hereby ordered as follows:

SECTION 1. *Policy*. Since 2000, the medication mifepristone has been approved by the Food and Drug Administration (FDA) for use in the United States as a safe and effective method to end early pregnancy.

The Food and Drug Administration Amendments Act of 2007 (Public Law 110–85) [see Tables for classification] requires the FDA, working with drug manufacturers, to specify conditions for the use of certain drugs after considering six congressionally mandated factors. The Act sets forth a detailed administrative process to develop such conditions for use, known collectively as the Risk Evaluation and Mitigation Strategies (REMS), for individual drugs. Mifepristone has long had a REMS specifying the conditions for its use.

On January 3, 2023, the FDA, after an independent and comprehensive review of the risks and benefits of the drug, modified the REMS for mifepristone. The FDA took evidence-based action that supports access to mifepristone by helping ensure that healthcare providers and patients can continue to use telehealth to prescribe and receive mifepristone by mail after the end of the COVID–19 public health emergency. During the COVID–19 public health emergency, the FDA stopped enforcing a prior requirement that mifepristone be dispensed in person, and the FDA's January 2023 REMS permanently removed the in-person dispensing requirement. Additionally, pharmacies can now choose to become certified to dispense mifepristone to patients. These changes seek to reduce the burden on the healthcare delivery system while ensuring the benefits of the medication outweigh the risks. These changes also help ensure that patients can access mifepristone similarly to how they would access other prescribed medications.

In the wake of the new REMS for mifepristone, there have been reports of efforts to suppress access to medication abortion. Some State officials have announced that they will impose restrictions to limit access to this evidence-based, safe, and effective medication. In a letter to the FDA, for example, 22 State Attorneys General threatened to enforce State laws that purport to interfere with access to mifepristone. In Florida, the Governor recently said that major pharmacy chains in the State will not offer mifepristone. Florida health officials issued guidance discouraging pharmacies from dispensing mifepristone, claiming that State law limits where abortion medication can be provided to hospitals, clinics, or physician offices. These actions have stoked confusion, sowed fear, and may prevent patients from accessing safe and effective FDA-approved medication.

At the same time, those who provide reproductive healthcare continue to face heightened safety concerns. There are reports that some have vowed to make people uncomfortable entering pharmacies that dispense mifepristone.

In Executive Order 14076 of July 8, 2022 (Protecting Access to Reproductive Healthcare Services) [set out above], I directed the Secretary of Health and Human Services (HHS) to identify potential actions to protect and expand access to abortion care, including medication abortion. In that order, I directed the Attorney General and the Secretary of Homeland Security to consider actions, as appropriate and consistent with applicable law, that would protect the safety and security of patients, providers, and third parties, and that would protect the security of pharmacies and other entities providing, dispensing, or delivering reproductive and related healthcare services.

Since the issuance of Executive Order 14076, my Administration has taken steps to clarify the protections available to those who seek reproductive health services. The Department of Justice announced the formation of a Reproductive Rights Task Force, which, among other things, is focused on evaluating and monitoring State and local legislation, regulation, and enforcement actions that threaten to infringe on Federal legal protections relating to the provision or pursuit of reproductive care. HHS has published a report detailing its efforts to protect access to reproductive healthcare, including abortion care; protect patients' privacy and promote access to accurate information about reproductive healthcare services; and ensure that patients receive appropriate medical treatment under the law. Furthermore, HHS has continued taking action to help ensure non-discrimination in healthcare service delivery, including with respect to reproductive healthcare services and pharmacy access.

My Administration remains committed to supporting safe access to mifepristone, consistent with applicable law, and defending women's fundamental freedoms. Defending and protecting reproductive rights is essential to our Nation's health, safety, and progress. It is the policy of my Administration to protect against threats to the liberty and autonomy of those who live in this country.

SEC. 2. *Continuing to Protect Access to FDA-Approved Medication*. In light of recent developments and consistent with Executive Order 14076, within 60 days of the date of this memorandum [Jan. 22, 2023]:

(a) The Secretary of HHS, in consultation with the Attorney General and the Secretary of Homeland Security, shall consider:

(i) issuing guidance for patients seeking legal access to mifepristone, as well as for providers and entities, including pharmacies, that provide reproductive healthcare and seek to legally prescribe and provide mifepristone; and

(ii) any further actions, as appropriate and consistent with applicable law, to educate individuals on their ability to seek legal reproductive care, free from threats or violence.

(b) The Attorney General, the Secretary of Homeland Security, and the Secretary of HHS shall, as appropriate, provide the Interagency Task Force on Reproductive Healthcare Access, established in Executive Order 14076, with information concerning:

(i) potential barriers faced by patients seeking legal access to mifepristone or other reproductive healthcare, as well as by providers and entities, including pharmacies, that provide reproductive healthcare in providing mifepristone or other reproductive healthcare, and any recommendations for addressing these barriers; and

(ii) whether any additional institutional resources may be necessary to address these barriers.

SEC. 3. *General Provisions*. (a) Nothing in this memorandum shall be construed to impair or otherwise affect:

(i) the authority granted by law to an executive department or agency, or the head thereof; or

(ii) the functions of the Director of the Office of Management and Budget relating to budgetary, administrative, or legislative proposals.

(b) This memorandum shall be implemented consistent with applicable law and subject to the availability of appropriations.

(c) This memorandum is not intended to, and does not, create any right or benefit, substantive or procedural, enforceable at law or in equity by any party against the United States, its departments, agencies, or entities, its officers, employees, or agents, or any other person.

(d) The Attorney General is authorized and directed to publish this memorandum in the Federal Register.

J.R. BIDEN, JR.

[1] *So in original. Probably should be "family".*

§300a. Formula grants to States for family planning services

(a) Authority of Secretary; prerequisites

The Secretary is authorized to make grants, from allotments made under subsection (b), to State health authorities to assist in planning, establishing, maintaining, coordinating, and evaluating family planning services. No grant may be made to a State health authority under this section unless such authority has submitted, and had approved by the Secretary, a State plan for a coordinated and comprehensive program of family planning services.

(b) Factors determining amount of State allotments

The sums appropriated to carry out the provisions of this section shall be allotted to the States by the Secretary on the basis of the population and the financial need of the respective States.

(c) "State" defined

For the purposes of this section, the term "State" includes the Commonwealth of Puerto Rico, the Northern Mariana Islands, Guam, American Samoa, the Virgin Islands, the District of Columbia, and the Trust Territory of the Pacific Islands.

(d) Authorization of appropriations

For the purpose of making grants under this section, there are authorized to be appropriated $10,000,000 for the fiscal year ending June 30, 1971; $15,000,000 for the fiscal year ending June 30, 1972; and $20,000,000 for the fiscal year ending June 30, 1973.

(July 1, 1944, ch. 373, title X, §1002, as added Pub. L. 91–572, §6(c), Dec. 24, 1970, 84 Stat. 1506; amended Pub. L. 94–484, title IX, §905(b)(1), Oct. 12, 1976, 90 Stat. 2325.)

EDITORIAL NOTES

AMENDMENTS

1976—Subsec. (c). Pub. L. 94–484 defined "State" to include Northern Mariana Islands.

STATUTORY NOTES AND RELATED SUBSIDIARIES

STUDY OF STATE DELIVERY OF SERVICES; REPORT TO CONGRESS

Pub. L. 97–35, title IX, §931(c), Aug. 13, 1981, 95 Stat. 570, directed Secretary of Health and Human Services to conduct a study of possible ways of State delivery of services for which assistance is authorized by title X of the Public Health Service Act [42 U.S.C. 300 et seq.] and to report to Congress on results of such study 18 months after Aug. 13, 1981.

EXECUTIVE DOCUMENTS

TERMINATION OF TRUST TERRITORY OF THE PACIFIC ISLANDS

For termination of Trust Territory of the Pacific Islands, see note set out preceding section 1681 of Title 48, Territories and Insular Possessions.

§300a–1. Training grants and contracts; authorization of appropriations

(a) The Secretary is authorized to make grants to public or nonprofit private entities and to enter into contracts with public or private entities and individuals to provide the training for personnel to carry out family planning service programs described in section 300 or 300a of this title.

(b) For the purpose of making payments pursuant to grants and contracts under this section, there are authorized to be appropriated $2,000,000 for the fiscal year ending June 30, 1971; $3,000,000 for the fiscal year ending June 30, 1972; $4,000,000 for the fiscal year ending June 30, 1973; $3,000,000 each for the fiscal years ending June 30, 1974 and June 30, 1975; $4,000,000 for fiscal year ending 1976; $5,000,000 for the fiscal year ending September 30, 1977; $3,000,000 for the fiscal year ending September 30, 1978; $3,100,000 for the fiscal year ending September 30, 1979; $3,600,000 for the fiscal year ending September 30, 1980; $4,100,000 for the fiscal year ending September 30, 1981; $2,920,000 for the fiscal year ending September 30, 1982; $3,200,000 for the fiscal year ending September 30, 1983; $3,500,000 for the fiscal year ending September 30, 1984; and $3,500,000 for the fiscal year ending September 30, 1985.

(July 1, 1944, ch. 373, title X, §1003, as added Pub. L. 91–572, §6(c), Dec. 24, 1970, 84 Stat. 1507; amended Pub. L. 93–45, title I, §111(b), June 18, 1973, 87 Stat. 93; Pub. L. 94–63, title II, §202(b), title VII, §701(d), July 29, 1975, 89 Stat. 306, 352; Pub. L. 95–83, title III, §305(b), Aug. 1, 1977, 91 Stat. 389; Pub. L. 95–613, §1(b)(2), Nov. 8, 1978, 92 Stat. 3093; Pub. L. 97–35, title IX, §931(a)(2), Aug. 13, 1981, 95 Stat. 570; Pub. L. 97–414, §§8(n), 9(a), Jan. 4, 1983, 96 Stat. 2061, 2064; Pub. L. 98–512, §3(b), Oct. 19, 1984, 98 Stat. 2410.)

EDITORIAL NOTES

AMENDMENTS

1984—Subsec. (b). Pub. L. 98–512 inserted provisions authorizing appropriations for fiscal year ending Sept. 30, 1985.

1983—Subsec. (b). Pub. L. 97–414, §8(n), substituted a semicolon for a comma after "1981".

Pub. L. 97–414, §9(a), amended directory language of Pub. L. 97–35, §931(a)(2), to correct a typographical error and did not involve any change in text. See 1981 Amendment note below.

1981—Subsec. (b). Pub. L. 97–35, as amended by Pub. L. 97–414, §9(a), inserted provisions authorizing appropriations for fiscal years ending Sept. 30, 1982, 1983, and 1984.

1978—Subsec. (b). Pub. L. 95–613 inserted provisions authorizing appropriations for fiscal years ending Sept. 30, 1979, 1980, and 1981.

1977—Subsec. (b). Pub. L. 95–83 substituted provision authorizing appropriations for fiscal years ending Sept. 30, 1977 and 1978, for prior such authorization for fiscal year 1977.

1975—Subsec. (b). Pub. L. 94–63 inserted provisions authorizing appropriations for fiscal years ending

June 30, 1975, 1976, and 1977.

1973—Subsec. (b). Pub. L. 93–45 inserted provisions authorizing appropriations for fiscal year ending June 30, 1974.

STATUTORY NOTES AND RELATED SUBSIDIARIES

EFFECTIVE DATE OF 1975 AMENDMENT

Amendment by section 202(b) of Pub. L. 94–63 effective July 1, 1975, see section 608 of Pub. L. 94–63, set out as a note under section 247b of this title.

§300a–2. Conduct, etc., of research activities

The Secretary may—

(1) conduct, and

(2) make grants to public or nonprofit private entities and enter into contracts with public or private entities and individuals for projects for,

research in the biomedical, contraceptive development, behavioral, and program implementation fields related to family planning and population.

(July 1, 1944, ch. 373, title X, §1004, as added Pub. L. 91–572, §6(c), Dec. 24, 1970, 84 Stat. 1507; amended Pub. L. 93–45, title I, §111(c), June 18, 1973, 87 Stat. 93; Pub. L. 94–63, title II, §202(c), title VII, §701(d), July 29, 1975, 89 Stat. 306, 352; Pub. L. 95–83, title III, §305(c), Aug. 1, 1977, 91 Stat. 389; Pub. L. 95–613, §1(b)(3), Nov. 8, 1978, 92 Stat. 3093; Pub. L. 96–32, §1(a), July 10, 1979, 93 Stat. 82; Pub. L. 97–35, title IX, §931(b)(2), Aug. 13, 1981, 95 Stat. 570.)

EDITORIAL NOTES

AMENDMENTS

1981—Pub. L. 97–35 redesignated existing subsec. (a) as entire section, and struck out subsec. (b) which related to authorization and availability of appropriations.

1979—Subsec. (b)(1). Pub. L. 95–613, as amended by Pub. L. 96–32, substituted "$120,800,000" for "$3,600,000" as authorized appropriation for fiscal year ending Sept. 30, 1980.

1978—Subsec. (b)(1). Pub. L. 95–613 inserted provisions authorizing appropriations for fiscal years ending Sept. 30, 1979, 1980, and 1981.

1977—Subsec. (b). Pub. L. 95–83 in par. (1) substituted provisions authorizing appropriations for fiscal years ending Sept. 30, 1977 and 1978, for prior such authorization for fiscal year 1977, and in par. (2) prohibited use of funds for administration of this section.

1975—Subsec. (a). Pub. L. 94–63, §202(c), revised structure of provisions, inserted authorization for Secretary to conduct research, and struck out authority for grants and contracts in research training in specified fields.

Subsec. (b). Pub. L. 94–63, §§202(c), 701(d), revised structure of provisions and substituted provisions relating to authorization of appropriations for fiscal years 1976 and 1977 and availability of appropriated funds, for provisions authorizing appropriations for fiscal years ending June 30, 1971, through fiscal year ending June 30, 1975.

1973—Subsec. (b). Pub. L. 93–45 inserted provisions authorizing appropriations for fiscal year ending June 30, 1974.

STATUTORY NOTES AND RELATED SUBSIDIARIES

EFFECTIVE DATE OF 1979 AMENDMENT

Pub. L. 96–32, §1(b), July 10, 1979, 93 Stat. 82, provided that: "The amendment made by subsection (a) [amending this section] shall be effective as of November 8, 1978."

EFFECTIVE DATE OF 1975 AMENDMENT

Amendment by section 202(c) of Pub. L. 94–63 effective July 1, 1975, see section 608 of Pub. L. 94–63, set out as a note under section 247b of this title.

§300a–3. Informational and educational materials development grants and contracts; authorization of appropriations

(a) The Secretary is authorized to make grants to public or nonprofit private entities and to enter into contracts with public or private entities and individuals to assist in developing and making available family planning and population growth information (including educational materials) to all persons desiring such information (or materials).

(b) For the purpose of making payments pursuant to grants and contracts under this section, there are authorized to be appropriated $750,000 for the fiscal year ending June 30, 1971; $1,000,000 for the fiscal year ending June 30, 1972; $1,250,000 for the fiscal year ending June 30, 1973; $909,000 each for the fiscal years ending June 30, 1974, and June 30, 1975; $2,000,000 for fiscal year 1976; $2,500,000 for the fiscal year ending September 30, 1977; $600,000 for the fiscal year ending September 30, 1978; $700,000 for the fiscal year ending September 30, 1979; $805,000 for the fiscal year ending September 30, 1980; $926,000 for the fiscal year ending September 30, 1981; $570,000 for the fiscal year ending September 30, 1982; $600,000 for the fiscal year ending September 30, 1983; $670,000 for the fiscal year ending September 30, 1984; and $700,000 for the fiscal year ending September 30, 1985.

(July 1, 1944, ch. 373, title X, §1005, as added Pub. L. 91–572, §6(c), Dec. 24, 1970, 84 Stat. 1507; amended Pub. L. 93–45, title I, §111(d), June 18, 1973, 87 Stat. 93; Pub. L. 94–63, title II, §202(d), title VII, §701(d), July 29, 1975, 89 Stat. 307, 352; Pub. L. 95–83, title III, §305(d), Aug. 1, 1977, 91 Stat. 389; Pub. L. 95–613, §1(b)(4), Nov. 8, 1978, 92 Stat. 3093; Pub. L. 97–35, title IX, §931(a)(3), Aug. 13, 1981, 95 Stat. 570; Pub. L. 97–414, §§8(n), 9(a), Jan. 4, 1983, 96 Stat. 2061, 2064; Pub. L. 98–512, §3(c), Oct. 19, 1984, 98 Stat. 2410.)

EDITORIAL NOTES

AMENDMENTS

1984—Subsec. (b). Pub. L. 98–512 inserted provisions authorizing appropriations for fiscal year ending Sept. 30, 1985.

1983—Subsec. (b). Pub. L. 97–414, §8(n), substituted a semicolon for a comma after "1981".

Pub. L. 97–414, §9(a), amended directory language of Pub. L. 97–35, §931(a)(3), to correct typographical error and did not involve any change in text. See 1981 Amendment note below.

1981—Subsec. (b). Pub. L. 97–35, as amended by Pub. L. 97–414, §9(a), inserted provisions authorizing appropriations for fiscal years ending Sept. 30, 1982, 1983, and 1984.

1978—Subsec. (b). Pub. L. 95–613 inserted provisions authorizing appropriations for fiscal years ending Sept. 30, 1979, 1980, and 1981.

1977—Subsec. (b). Pub. L. 95–83 substituted provisions authorizing appropriations for fiscal years ending Sept. 30, 1977 and 1978, for prior such authorization for fiscal year 1977.

1975—Subsec. (b). Pub. L. 94–63 inserted provisions authorizing appropriations for fiscal years ending June 30, 1975, 1976, and 1977.

1973—Subsec. (b). Pub. L. 93–45 inserted provisions authorizing appropriations for fiscal year ending June 30, 1974.

STATUTORY NOTES AND RELATED SUBSIDIARIES

EFFECTIVE DATE OF 1975 AMENDMENT

Amendment by section 202(d) of Pub. L. 94–63 effective July 1, 1975, see section 608 of Pub. L. 94–63, set out as a note under section 247b of this title.

§300a–4. Grants and contracts

(a) Promulgation of regulations governing execution; amount of grants

Grants and contracts made under this subchapter shall be made in accordance with such regulations as the Secretary may promulgate. The amount of any grant under any section of this subchapter shall be determined by the Secretary; except that no grant under any such section for any program or project for a fiscal year beginning after June 30, 1975, may be made for less than 90 per centum of its costs (as determined under regulations of the Secretary) unless the grant is to be made for a program or project for which a grant was made (under the same section) for the fiscal year ending June 30, 1975, for less than 90 per centum of its costs (as so determined), in which case a grant under such section for that program or project for a fiscal year beginning after that date may be made for a percentage which shall not be less than the percentage of its costs for which the fiscal year 1975 grant was made.

(b) Payment of grants

Grants under this subchapter shall be payable in such installments and subject to such conditions as the Secretary may determine to be appropriate to assure that such grants will be effectively utilized for the purposes for which made.

(c) Prerequisites; "low-income family" defined

A grant may be made or contract entered into under section 300 or 300a of this title for a family planning service project or program only upon assurances satisfactory to the Secretary that—

(1) priority will be given in such project or program to the furnishing of such services to persons from low-income families; and

(2) no charge will be made in such project or program for services provided to any person from a low-income family except to the extent that payment will be made by a third party (including a government agency) which is authorized or is under legal obligation to pay such charge.

For purposes of this subsection, the term "low-income family" shall be defined by the Secretary in accordance with such criteria as he may prescribe so as to insure that economic status shall not be a deterrent to participation in the programs assisted under this subchapter.

(d) Suitability of informational or educational materials

(1) A grant may be made or a contract entered into under section 300 or 300a–3 of this title only upon assurances satisfactory to the Secretary that informational or educational materials developed or made available under the grant or contract will be suitable for the purposes of this subchapter and for the population or community to which they are to be made available, taking into account the educational and cultural background of the individuals to whom such materials are addressed and the standards of such population or community with respect to such materials.

(2) In the case of any grant or contract under section 300 of this title, such assurances shall provide for the review and approval of the suitability of such materials, prior to their distribution, by an advisory committee established by the grantee or contractor in accordance with the Secretary's regulations. Such a committee shall include individuals broadly representative of the population or community to which the materials are to be made available.

(July 1, 1944, ch. 373, title X, §1006, as added Pub. L. 91–572, §6(c), Dec. 24, 1970, 84 Stat. 1507; amended Pub. L. 94–63, title II, §204(c), (d), July 29, 1975, 89 Stat. 308; Pub. L. 95–613, §1(a)(2), Nov. 8, 1978, 92 Stat. 3093.)

EDITORIAL NOTES

AMENDMENTS

1978—Pub. L. 95–613 added subsec. (d).

1975—Subsec. (a). Pub. L. 94–63, §204(c), inserted provisions relating to amount of grants authorized pursuant to sections of this subchapter.

Subsec. (c). Pub. L. 94–63, §204(d), inserted provision relating to economic status as part of the criteria to

be included within definition of "low-income family".

STATUTORY NOTES AND RELATED SUBSIDIARIES

EFFECTIVE DATE OF 1975 AMENDMENT

Amendment by Pub. L. 94–63 effective July 1, 1975, see section 608 of Pub. L. 94–63, set out as a note under section 247b of this title.

§300a–5. Voluntary participation by individuals; participation not prerequisite for eligibility or receipt of other services and information

The acceptance by any individual of family planning services or family planning or population growth information (including educational materials) provided through financial assistance under this subchapter (whether by grant or contract) shall be voluntary and shall not be a prerequisite to eligibility for or receipt of any other service or assistance from, or to participation in, any other program of the entity or individual that provided such service or information.

(July 1, 1944, ch. 373, title X, §1007, as added Pub. L. 91–572, §6(c), Dec. 24, 1970, 84 Stat. 1508.)

§300a–6. Prohibition against funding programs using abortion as family planning method

None of the funds appropriated under this subchapter shall be used in programs where abortion is a method of family planning.

(July 1, 1944, ch. 373, title X, §1008, as added Pub. L. 91–572, §6(c), Dec. 24, 1970, 84 Stat. 1508.)

§300a–6a. Repealed. Pub. L. 105–362, title VI, §601(a)(1)(G), Nov. 10, 1998, 112 Stat. 3285

Section, act July 1, 1944, ch. 373, title X, §1009, as added Pub. L. 94–63, title II, §203(a), July 29, 1975, 89 Stat. 307; amended Pub. L. 96–88, title V, §509(b), Oct. 17, 1979, 93 Stat. 695; Pub. L. 104–66, title I, §1062(c), Dec. 21, 1995, 109 Stat. 720, related to plans and reports concerning family planning services.

§300a–7. Sterilization or abortion

(a) Omitted

(b) Prohibition of public officials and public authorities from imposition of certain requirements contrary to religious beliefs or moral convictions

The receipt of any grant, contract, loan, or loan guarantee under the Public Health Service Act [42 U.S.C. 201 et seq.], the Community Mental Health Centers Act [42 U.S.C. 2689 et seq.], or the Developmental Disabilities Services and Facilities Construction Act [42 U.S.C. 6000 et seq.] by any individual or entity does not authorize any court or any public official or other public authority to require—

(1) such individual to perform or assist in the performance of any sterilization procedure or abortion if his performance or assistance in the performance of such procedure or abortion would be contrary to his religious beliefs or moral convictions; or

(2) such entity to—

(A) make its facilities available for the performance of any sterilization procedure or abortion if the performance of such procedure or abortion in such facilities is prohibited by the entity on the basis of religious beliefs or moral convictions, or

(B) provide any personnel for the performance or assistance in the performance of any sterilization procedure or abortion if the performance or assistance in the performance of such procedures or abortion by such personnel would be contrary to the religious beliefs or moral convictions of such personnel.

(c) Discrimination prohibition

(1) No entity which receives a grant, contract, loan, or loan guarantee under the Public Health Service Act [42 U.S.C. 201 et seq.], the Community Mental Health Centers Act [42 U.S.C. 2689 et seq.], or the Developmental Disabilities Services and Facilities Construction Act [42 U.S.C. 6000 et seq.] after June 18, 1973, may—

(A) discriminate in the employment, promotion, or termination of employment of any physician or other health care personnel, or

(B) discriminate in the extension of staff or other privileges to any physician or other health care personnel,

because he performed or assisted in the performance of a lawful sterilization procedure or abortion, because he refused to perform or assist in the performance of such a procedure or abortion on the grounds that his performance or assistance in the performance of the procedure or abortion would be contrary to his religious beliefs or moral convictions, or because of his religious beliefs or moral convictions respecting sterilization procedures or abortions.

(2) No entity which receives after July 12, 1974, a grant or contract for biomedical or behavioral research under any program administered by the Secretary of Health and Human Services may—

(A) discriminate in the employment, promotion, or termination of employment of any physician or other health care personnel, or

(B) discriminate in the extension of staff or other privileges to any physician or other health care personnel,

because he performed or assisted in the performance of any lawful health service or research activity, because he refused to perform or assist in the performance of any such service or activity on the grounds that his performance or assistance in the performance of such service or activity would be contrary to his religious beliefs or moral convictions, or because of his religious beliefs or moral convictions respecting any such service or activity.

(d) Individual rights respecting certain requirements contrary to religious beliefs or moral convictions

No individual shall be required to perform or assist in the performance of any part of a health service program or research activity funded in whole or in part under a program administered by the Secretary of Health and Human Services if his performance or assistance in the performance of such part of such program or activity would be contrary to his religious beliefs or moral convictions.

(e) Prohibition on entities receiving Federal grant, etc., from discriminating against applicants for training or study because of refusal of applicant to participate on religious or moral grounds

No entity which receives, after September 29, 1979, any grant, contract, loan, loan guarantee, or interest subsidy under the Public Health Service Act [42 U.S.C. 201 et seq.], the Community Mental Health Centers Act [42 U.S.C. 2689 et seq.], or the Developmental Disabilities Assistance and Bill of Rights Act of 2000 [42 U.S.C. 15001 et seq.] may deny admission or otherwise discriminate against any applicant (including applicants for internships and residencies) for training or study because of the applicant's reluctance, or willingness, to counsel, suggest, recommend, assist, or in any way participate in the performance of abortions or sterilizations contrary to or consistent with the applicant's religious beliefs or moral convictions.

(Pub. L. 93–45, title IV, §401, June 18, 1973, 87 Stat. 95; Pub. L. 93–348, title II, §214, July 12, 1974, 88 Stat. 353; Pub. L. 96–76, title II, §208, Sept. 29, 1979, 93 Stat. 583; Pub. L. 96–88, title V, §509(b), Oct. 17, 1979, 93 Stat. 695; Pub. L. 106–402, title IV, §401(b)(5), Oct. 30, 2000, 114 Stat.

1738.)

EDITORIAL NOTES

REFERENCES IN TEXT

The Public Health Service Act, referred to in subsecs. (b), (c)(1), and (e), is act July 1, 1944, ch. 373, 58 Stat. 682, which is classified generally to this chapter (§201 et seq.). For complete classification of this Act to the Code, see Short Title note set out under section 201 of this title and Tables.

The Community Mental Health Centers Act, referred to in subsecs. (b), (c)(1), and (e), is title II of Pub. L. 88–164, as added Pub. L. 94–63, title III, §303, July 29, 1975, 89 Stat. 309, and amended, which was classified principally to subchapter III (§2689 et seq.) of chapter 33 of this title prior to its repeal by Pub. L. 97–35, title IX, §902(e)(2)(B), Aug. 13, 1981, 95 Stat. 560.

The Developmental Disabilities Services and Facilities Construction Act, referred to in subsecs. (b) and (c)(1), is title I of Pub. L. 88–164, Oct. 31, 1963, 77 Stat. 282, as renamed by Pub. L. 91–518, title II, §207(a), Oct. 30, 1970, 84 Stat. 1327. Title I of Pub. L. 88–164, which was subsequently renamed the Developmental Disabilities Assistance and Bill of Rights Act by Pub. L. 95–602, title V, §502, Nov. 6, 1978, 92 Stat. 3003, and amended generally by Pub. L. 98–527, §2, Oct. 19, 1984, 98 Stat. 2662, was classified generally to chapter 75 (§6000 et seq.) of this title, prior to repeal by Pub. L. 106–402, title IV, §401(a), Oct. 30, 2000, 114 Stat. 1737. For complete classification of this Act to the Code, see Tables.

The Developmental Disabilities Assistance and Bill of Rights Act of 2000, referred to in subsec. (e), is Pub. L. 106–402, Oct. 30, 2000, 114 Stat. 1677, which is classified principally to chapter 144 (§15001 et seq.) of this title. For complete classification of this Act to the Code, see Short Title note set out under section 15001 of this title and Tables.

CODIFICATION

Section was enacted as part of Health Programs Extension Act of 1973, and not as part of Public Health Services Act which comprises this chapter.

Subsec. (a) of this section amended section 601 of Pub. L. 91–296, which is set out as an Availability of Appropriations note under section 201 of this title.

AMENDMENTS

2000—Subsec. (e). Pub. L. 106–402 substituted "or the Developmental Disabilities Assistance and Bill of Rights Act of 2000 may deny" for "or the Developmental Disabilities Assistance and Bill of Rights Act may deny".

1979—Subsec. (e). Pub. L. 96–76 added subsec. (e).

1974—Subsec. (c). Pub. L. 93–348, §214, designated existing provisions as par. (1), redesignated pars. (1) and (2) of such provisions as subpars. (A) and (B), and added par. (2).

Subsec. (d). Pub. L. 93–348, §214(b), added subsec. (d).

STATUTORY NOTES AND RELATED SUBSIDIARIES

CHANGE OF NAME

"Secretary of Health and Human Services" substituted for "Secretary of Health, Education, and Welfare" in subsecs. (c)(2) and (d) pursuant to section 509(b) of Pub. L. 96–88, which is classified to section 3508(b) of Title 20, Education.

§300a–8. Penalty for United States, etc., officer or employee coercing or endeavoring to coerce procedure upon beneficiary of Federal program

Any—

(1) officer or employee of the United States,

(2) officer or employee of any State, political subdivision of a State, or any other entity, which administers or supervises the administration of any program receiving Federal financial assistance, or

(3) person who receives, under any program receiving Federal financial assistance,

compensation for services,

who coerces or endeavors to coerce any person to undergo an abortion or sterilization procedure by threatening such person with the loss of, or disqualification for the receipt of, any benefit or service under a program receiving Federal financial assistance shall be fined not more than $1,000 or imprisoned for not more than one year, or both.

(Pub. L. 94–63, title II, §205, July 29, 1975, 89 Stat. 308.)

EDITORIAL NOTES

CODIFICATION

Section was enacted as part of the Family Planning and Population Research Act of 1975, and not as part of the Public Health Service Act which comprises this chapter.

STATUTORY NOTES AND RELATED SUBSIDIARIES

EFFECTIVE DATE

Section effective July 1, 1975, see section 608 of Pub. L. 94–63, set out as an Effective Date of 1975 Amendment note under section 247b of this title.

SUBCHAPTER VIII–A—ADOLESCENT PREGNANCIES

PART A—GRANT PROGRAM

§§300a–21 to 300a–28. Repealed. Pub. L. 97–35, title IX, §955(b), title XXI, §2193(f), Aug. 13, 1981, 95 Stat. 592, 828

Section 300a–21, Pub. L. 95–626, title VI, §601, Nov. 10, 1978, 92 Stat. 3595, set forth Congressional findings and declaration of purpose with respect to grant program.

Section 300a–22, Pub. L. 95–626, title VI, §602, Nov. 10, 1978, 92 Stat. 3595; Pub. L. 96–88, title V, §509(b), Oct. 17, 1979, 93 Stat. 695, defined terms "Secretary", "eligible person", "eligible grant recipient", "core services", "supplemental services", "adolescent parent".

Section 300a–23, Pub. L. 95–626, title VI, §603, Nov. 10, 1978, 92 Stat. 3596, set forth authority to make grants.

Section 300a–24, Pub. L. 95–626, title VI, §604, Nov. 10, 1978, 92 Stat. 3597, set forth authorized uses for grants.

Section 300a–25, Pub. L. 95–626, title VI, §605, Nov. 10, 1978, 92 Stat. 3597, set forth provisions respecting priorities, amounts, and duration of grants.

Section 300a–26, Pub. L. 95–626, title VI, §606, Nov. 10, 1978, 92 Stat. 3598, set forth application, etc., requirements for grant approval.

Section 300a–27, Pub. L. 95–626, title VI, §607, Nov. 10, 1978, 92 Stat. 3601; Pub. L. 97–35, title XXI, §2193(a)(2), Aug. 13, 1981, 95 Stat. 827, authorized appropriations from fiscal year ending Sept. 30, 1979, through fiscal year ending Sept. 30, 1982.

Section 300a–28, Pub. L. 95–626, title VI, §608, Nov. 10, 1978, 92 Stat. 3601, set forth prohibition respecting use of funds to pay for performance of abortion.

See section 300z et seq. of this title.

STATUTORY NOTES AND RELATED SUBSIDIARIES

EFFECTIVE DATE OF REPEAL

Pub. L. 97–35, title IX, §955(b), Aug. 13, 1981, 95 Stat. 592, provided that the repeal of sections 300a–21 to 300a–28 of this title is effective Oct. 1, 1981.

For effective date, savings, and transitional provisions relating to the repeal of sections 321a–21 to 321a–28 of this title by section 2193(f) of Pub. L. 97–35, and relating to the amendment of section 300a–27 of this title by section 2193(a)(2) of Pub. L. 97–35, see section 2194 of Pub. L. 97–35, set out as a note under section 701 of this title.

STUDY OF ADOLESCENT PREGNANCY; REPORT NOT LATER THAN NOVEMBER 10, 1979

Pub. L. 95–626, title VIII, §801, Nov. 10, 1978, 92 Stat. 3602, which provided for a study of the problem of adolescent pregnancies and the effectiveness of existing programs and a report, was repealed by section 955(b) of Pub. L. 97–35.

§300a–29. Omitted

EDITORIAL NOTES

CODIFICATION

Section, Pub. L. 95–626, title III, §301, Nov. 10, 1978, 92 Stat. 3590, provided that grants or contracts made under this subchapter would be considered to have been made under this chapter for the purposes of sections 300l–2(e) and 300m–3(c)(6) of this title.

PART B—IMPROVING COORDINATION OF FEDERAL AND STATE PROGRAMS

§300a–41. Repealed. Pub. L. 97–35, title IX, §955(b), title XXI, §2193(f), Aug. 13, 1981, 95 Stat. 592, 828

Section, Pub. L. 95–626, title VII, §701, Nov. 10, 1978, 92 Stat. 3601; Pub. L. 96–88, title V, §509(b), Oct. 17, 1979, 93 Stat. 695, related to improving coordination of Federal and State policies and programs.

STATUTORY NOTES AND RELATED SUBSIDIARIES

EFFECTIVE DATE OF REPEAL

Pub. L. 97–35, title IX, §955(b), Aug. 13, 1981, 95 Stat. 592, provided that the repeal of this section is effective Oct. 1, 1981.

For effective date, savings, and transitional provisions relating to the repeal of this section by section 2193(f) of Pub. L. 97–35, see section 2194 of Pub. L. 97–35, set out as a note under section 701 of this title.

SUBCHAPTER IX—GENETIC DISEASES, HEMOPHILIA PROGRAMS, AND SUDDEN INFANT DEATH SYNDROME

EDITORIAL NOTES

CODIFICATION

Pub. L. 94–278, title IV, §403(b)(3), Apr. 22, 1976, 90 Stat. 409, substituted "GENETIC DISEASES" for "GENETIC BLOOD DISORDERS" and inserted "HEMOPHILIA PROGRAMS" in subchapter heading.

Pub. L. 93–270, §3(b), Apr. 22, 1974, 88 Stat. 92, inserted "AND SUDDEN INFANT DEATH SYNDROME" at end of subchapter heading.

Pub. L. 92–414, §4(1), Aug. 29, 1972, 86 Stat. 652, substituted "GENETIC BLOOD DISORDERS" for "SICKLE CELL ANEMIA PROGRAM" as subchapter heading and designated such former subchapter heading as part A heading, substituting "Programs" for "Program".

PART A—GENETIC DISEASES

EDITORIAL NOTES

CODIFICATION

Pub. L. 94–278, title IV, §403(a), Apr. 22, 1976, 90 Stat. 407, substituted "Genetic Diseases" for "Sickle Cell Anemia Programs" in part A heading.

Pub. L. 92–414, §4(1), Aug. 29, 1972, 86 Stat. 652, redesignated subchapter IX heading as part A heading and substituted "Sickle Cell Anemia Programs" for "Sickle Cell Anemia Program".

§300b. Repealed. Pub. L. 97–35, title XXI, §2193(b)(1), Aug. 13, 1981, 95 Stat. 827

Section, act July 1, 1944, ch. 373, title XI, §1101, as added Apr. 22, 1976, Pub. L. 94–278, title IV, §403(a), 90 Stat. 407; amended Nov. 10, 1978, Pub. L. 95–626, title II, §205(b), (d)(2), (e), 92 Stat. 3583, 3584; Pub. L. 96–88, title V, §509(b), Oct. 17, 1979, 93 Stat. 695; Aug. 13, 1981, Pub. L. 97–35, title XXI, §2193(a)(1)(B), 95 Stat. 826; Jan. 4, 1983, Pub. L. 97–414, §8(o), 96 Stat. 2061, related to testing, counseling, information and education programs.

A prior section 300b, act July 1, 1944, ch. 373, title XI, §1101, as added May 16, 1972, Pub. L. 92–294, §3(c), 86 Stat. 137; amended Aug. 29, 1972, Pub. L. 92–414, §4(2), 86 Stat. 652, authorized Secretary to make grants and enter contracts with public and nonprofit private entities with respect to establishment of voluntary sickle cell anemia screening and counseling programs and to develop and disseminate informational and educational materials relating to sickle cell anemia, prior to repeal by Pub. L. 94–278, title IV, §403(a), Apr. 22, 1976, 90 Stat. 407.

STATUTORY NOTES AND RELATED SUBSIDIARIES

EFFECTIVE DATE OF 1981 AMENDMENT AND REPEAL, SAVINGS, AND TRANSITIONAL PROVISIONS

For effective date, savings, and transitional provisions relating to the amendment and repeal of this section by Pub. L. 97–35, see section 2194 of Pub. L. 97–35, set out as a note under section 701 of this title.

§300b–1. Research project grants and contracts

In carrying out section 241 of this title, the Secretary may make grants to public and nonprofit private entities, and may enter into contracts with public and private entities and individuals, for projects for (1) basic or applied research leading to the understanding, diagnosis, treatment, and control of genetic diseases, (2) planning, establishing, demonstrating, and developing special programs for the training of genetic counselors, social and behavioral scientists, and other health professionals, (3) the development of programs to educate practicing physicians, other health professionals, and the public regarding the nature of genetic processes, the inheritance patterns of genetic diseases, and the means, methods, and facilities available to diagnose, control, counsel, and treat genetic diseases, and (4) the development of counseling and testing programs and other programs for the diagnosis, control, and treatment of genetic diseases. In making grants and entering into contracts for projects described in clause (1) of the preceding sentence, the Secretary shall give priority to applications for such grants or contracts which are submitted for research on sickle cell anemia and for research on Cooley's anemia.

(July 1, 1944, ch. 373, title XI, §1102, as added Pub. L. 94–278, title IV, §403(a), Apr. 22, 1976, 90 Stat. 408.)

EDITORIAL NOTES

PRIOR PROVISIONS

A prior section 300b–1, act July 1, 1944, ch. 373, title XI, §1102, as added May 16, 1972, Pub. L. 92–294, §3(c), 86 Stat. 138, authorized Secretary to make grants and enter contracts with public and private entities and individuals for projects concerned with research, research training in diagnosis, treatment and control of sickle cell anemia, informational and educational programs with respect to sickle cell anemia and development of counseling and testing programs, prior to repeal by Pub. L. 94–278, title IV, §403(a), Apr. 22, 1976, 90 Stat. 407.

STATUTORY NOTES AND RELATED SUBSIDIARIES

EFFECTIVE DATE

Pub. L. 94–278, title IV, §403(c), Apr. 22, 1976, 90 Stat. 410, provided that: "The amendments made by subsections (a) and (b) [see section 401 of Pub. L. 94–278, set out as a Short Title of 1976 Amendment note under section 201 of this title] shall take effect July 1, 1976."

SHORT TITLE OF 1976 AMENDMENT

For short title of title IV of Pub. L. 94–278, which enacted this part, omitted former part B of this subchapter, redesignated former parts C and D of this subchapter as parts B and C of this subchapter, respectively, as the "National Sickle Cell Anemia, Cooley's Anemia, Tay-Sachs, and Genetic Diseases Act", see section 401 of Pub. L. 94–278, set out as a note under section 201 of this title.

DEMONSTRATION PROGRAM FOR THE DEVELOPMENT AND ESTABLISHMENT OF SYSTEMIC MECHANISMS FOR THE PREVENTION AND TREATMENT OF SICKLE CELL DISEASE

Pub. L. 108–357, title VII, §712(c), Oct. 22, 2004, 118 Stat. 1559, as amended by Pub. L. 115–327, §3(a), Dec. 18, 2018, 132 Stat. 4469, which was formerly set out as a note under this section, was transferred to section 300b–5(b) of this title by Pub. L. 115–327, §3(b), Dec. 18, 2018, 132 Stat. 4470.

CONGRESSIONAL DECLARATION OF PURPOSE

Pub. L. 94–278, title IV, §402, Apr. 22, 1976, 90 Stat. 407, as amended by Pub. L. 95–626, title II, §205(a), Nov. 10, 1978, 92 Stat. 3583; Pub. L. 111–256, §2(i), Oct. 5, 2010, 124 Stat. 2644, provided that: "In order to preserve and protect the health and welfare of all citizens, it is the purpose of this title [see section 401 of Pub. L. 94–278, set out as a Short Title of 1976 Amendment note under section 201 of this title] to establish a national program to provide for basic and applied research, research training, testing, counseling, and information and education programs with respect to genetic diseases, and genetic conditions, such as Sickle Cell anemia, Cooley's Anemia, Tay–Sachs disease, cystic fibrosis, dysautonomia, hemophilia, retinitis pigmentosa, Huntington's chorea, muscular dystrophy, and genetic conditions leading to intellectual disabilities or genetically caused mental disorders."

[For meaning of references to an intellectual disability and to individuals with intellectual disabilities in provisions amended by section 2 of Pub. L. 111–256, see section 2(k) of Pub. L. 111–256, set out as a note under section 1400 of Title 20, Education.]

§300b–2. Voluntary participation by individuals

The participation by any individual in any program or portion thereof under this part shall be wholly voluntary and shall not be a prerequisite to eligibility for or receipt of any other service or assistance from, or to participation in, any other program.

(July 1, 1944, ch. 373, title XI, §1103, as added Pub. L. 94–278, title IV, §403(a), Apr. 22, 1976, 90 Stat. 408.)

EDITORIAL NOTES

PRIOR PROVISIONS

A prior section 300b–2, act July 1, 1944, ch. 373, title XI, §1103, as added May 16, 1972, Pub. L. 92–294, §3(c), 86 Stat. 138; amended Aug. 29, 1972, Pub. L. 92–414, §4(3), 86 Stat. 652, was identical to this section, prior to repeal by Pub. L. 94–278, title IV, §403(a), Apr. 22, 1976, 90 Stat. 407.

§300b–3. Application; special consideration to prior sickle cell anemia grant recipients

(a) Manner of submission; contents

A grant or contract under this part may be made upon application submitted to the Secretary at such time, in such manner, and containing and accompanied by such information, as the Secretary may require, including assurances for an evaluation whether performed by the applicant or by the Secretary. Such grant or contract may be made available on less than a statewide or regional basis. Each applicant shall—

(1) provide that the programs and activities for which assistance under this part is sought will be administered by or under the supervision of the applicant;

(2) provide for strict confidentiality of all test results, medical records, and other information regarding testing, diagnosis, counseling, or treatment of any person treated, except for (A) such information as the patient (or his guardian) gives informed consent to be released, or (B) statistical data compiled without reference to the identity of any such patient;

(3) provide for community representation where appropriate in the development and operation of voluntary genetic testing or counseling programs funded by a grant or contract under this part; and

(4) establish fiscal control and fund accounting procedures as may be necessary to assure proper disbursement of and accounting of Federal funds paid to the applicant under this part.

(b) Considerations for grants and contracts under section 300b–1 of this title

In making grants and entering into contracts for any fiscal year under section 241 of this title for projects described in section 300b–1 of this title the Secretary shall give special consideration to applications from entities that received grants from, or entered into contracts with, the Secretary for the preceding fiscal year for the conduct of comprehensive sickle cell centers or sickle cell screening and education clinics.

(July 1, 1944, ch. 373, title XI, §1104, as added Pub. L. 94–278, title IV, §403(a), Apr. 22, 1976, 90 Stat. 408; amended Pub. L. 95–626, title II, §205(c), Nov. 10, 1978, 92 Stat. 3584; Pub. L. 97–35, title XXI, §2193(b)(2), (3), Aug. 13, 1981, 95 Stat. 827.)

EDITORIAL NOTES

PRIOR PROVISIONS

A prior section 300b–3, act July 1, 1944, ch. 373, title XI, §1104, as added May 16, 1972, Pub. L. 92–294, §3(c), 86 Stat. 138; amended Aug. 29, 1972, Pub. L. 92–414, §4(3), 86 Stat. 652, authorized grants to be made upon application to Secretary and required supervision of programs by applicant, confidentiality of test results, medical records and other information obtained from treated person, community representation in programs, assurances by applicant that priority will be given to persons of child bearing years, and demonstration by applicant of proper fiscal control and accounting procedures, prior to repeal by Pub. L. 94–278, title IV, §403(a), Apr. 22, 1976, 90 Stat. 407.

AMENDMENTS

1981—Subsec. (a)(4), (5). Pub. L. 97–35, §2193(b)(2), redesignated par. (5) as (4). Former par. (4), which related to testing and counseling requirements, was struck out.

Subsec. (b). Pub. L. 97–35, §2193(b)(3), struck out subsec. (b) which related to grants and contracts under section 300b of this title. Former subsec. (c) was redesignated (b) and, as so redesignated, struck out reference

to section 300b of this title.

Subsec. (c). Pub. L. 97–35, §2193(b)(3), redesignated subsec. (c) as (b).

Subsec. (d). Pub. L. 97–35, §2193(b)(3), struck out subsec. (d) which related to procedures applicable to grants, etc., under section 300b of this title.

1978—Subsec. (a). Pub. L. 95–626, §205(c)(1), inserted requirement that application contain assurances for an evaluation whether performed by applicant or by Secretary and that grant or contract be made available on less than a statewide or regional basis.

Subsec. (d). Pub. L. 95–626, §205(c)(2), added subsec. (d).

STATUTORY NOTES AND RELATED SUBSIDIARIES

EFFECTIVE DATE OF 1981 AMENDMENT, SAVINGS, AND TRANSITIONAL PROVISIONS

For effective date, savings, and transitional provisions relating to amendment by Pub. L. 97–35, see section 2194 of Pub. L. 97–35, set out as a note under section 701 of this title.

§300b–4. Public Health Service facilities

The Secretary shall establish a program within the Service to provide voluntary testing, diagnosis, counseling, and treatment of individuals respecting genetic diseases. Services under such program shall be made available through facilities of the Service to persons requesting such services, and the program shall provide appropriate publicity of the availability and voluntary nature of such services.

(July 1, 1944, ch. 373, title XI, §1105, as added Pub. L. 94–278, title IV, §403(a), Apr. 22, 1976, 90 Stat. 409.)

EDITORIAL NOTES

PRIOR PROVISIONS

A prior section 300b–4, act July 1, 1944, ch. 373, title XI, §1105, as added May 16, 1972, Pub. L. 92–294, §3(c), 86 Stat. 139, authorized Secretary to establish a program within the Public Health Service with respect to sickle cell anemia with such program to be made available through facilities of Public Health Service, prior to repeal by Pub. L. 94–278, title IV, §403(a), Apr. 22, 1976, 90 Stat. 407.

§300b–5. Sickle cell disease and other heritable blood disorders research, surveillance, prevention, and treatment

(a) Grants

(1) In general

The Secretary may award grants related to heritable blood disorders, including sickle cell disease, for one or more of the following purposes:

(A) To collect and maintain data on such diseases and conditions, including subtypes as applicable, and their associated health outcomes and complications, including for the purpose of—

(i) improving national incidence and prevalence data;

(ii) identifying health disparities, including the geographic distribution, related to such diseases and conditions;

(iii) assessing the utilization of therapies and strategies to prevent complications; and

(iv) evaluating the effects of genetic, environmental, behavioral, and other risk factors that may affect such individuals.

(B) To conduct public health activities with respect to such conditions, which may include—

(i) developing strategies to improve health outcomes and access to quality health care for the screening for, and treatment and management of, such diseases and conditions, including

through public-private partnerships;

(ii) providing support to community-based organizations and State and local health departments in conducting education and training activities for patients, communities, and health care providers concerning such diseases and conditions;

(iii) supporting State health departments and regional laboratories, including through training, in testing to identify such diseases and conditions, including specific forms of sickle cell disease, in individuals of all ages; and

(iv) the identification and evaluation of best practices for treatment of such diseases and conditions, and prevention and management of their related complications.

(2) Population included

The Secretary shall, to the extent practicable, award grants under this subsection to eligible entities across the United States to improve data on the incidence and prevalence of heritable blood disorders, including sickle cell disease, and the geographic distribution of such diseases and conditions.

(3) Application

To seek a grant under this subsection, an eligible entity shall submit an application to the Secretary at such time, in such manner, and containing such information as the Secretary may require.

(4) Priority

In awarding grants under this subsection, the Secretary may give priority, as appropriate, to eligible entities that have a relationship with a community-based organization that has experience in, or is capable of, providing services to individuals with heritable blood disorders, including sickle cell disease.

(5) Eligible entity

In this subsection, the term "eligible entity" includes the 50 States, the District of Columbia, the Commonwealth of Puerto Rico, the United States Virgin Islands, the Commonwealth of the Northern Mariana Islands, American Samoa, Guam, the Federated States of Micronesia, the Republic of Marshall [1] Islands, the Republic of Palau, Indian tribes, a State or local health department, an institution of higher education, or a nonprofit entity with appropriate experience to conduct the activities under this subsection.

(b) Demonstration program for the development and establishment of systemic mechanisms for the prevention and treatment of sickle cell disease

(1) Authority to conduct demonstration program

(A) In general

The Administrator, through the Bureau of Primary Health Care and the Maternal and Child Health Bureau, shall continue efforts, including by awarding grants, to develop or establish mechanisms to improve the treatment of sickle cell disease, and to improve the prevention and treatment of complications of sickle cell disease, in populations with a high proportion of individuals with sickle cell disease, including through—

(i) the coordination of service delivery for individuals with sickle cell disease;

(ii) genetic counseling and testing;

(iii) bundling of technical services related to the treatment of sickle cell disease and the prevention and treatment of complications of sickle cell disease;

(iv) training of health professionals; and

(v) identifying and establishing other efforts related to the expansion and coordination of education, treatment, and continuity of care programs for individuals with sickle cell disease.

(B) Geographic diversity

The Administrator shall, to the extent practicable, award grants under this section [2] to eligible

entities located in different regions of the United States.

(2) Additional requirements

An eligible entity awarded a grant under this subsection shall use funds made available under the grant to carry out, in addition to the activities described in paragraph (1)(A), the following activities:

(A) To facilitate and coordinate the delivery of education, treatment, and continuity of care for individuals with sickle cell disease under—

(i) the entity's collaborative agreement with a community-based sickle cell disease organization or a nonprofit entity that works with individuals who have sickle cell disease;

(ii) the sickle cell disease newborn screening program for the State in which the entity is located; and

(iii) the maternal and child health program under title V of the Social Security Act (42 U.S.C. 701 et seq.) for the State in which the entity is located.

(B) To train nursing and other health staff who provide care for individuals with sickle cell disease.

(C) To enter into a partnership with adult or pediatric hematologists in the region and other regional experts in sickle cell disease at tertiary and academic health centers and State and county health offices.

(D) To identify and secure resources for ensuring reimbursement under the medicaid program, State children's health insurance program, and other health programs for the treatment of sickle cell disease and the prevention and treatment of complications of sickle cell disease.

(E) To provide or coordinate services for adolescents with sickle cell disease making the transition to adult health care.

(3) National coordinating center

(A) Establishment

The Administrator shall make a grant to, or enter into a contract or cooperative agreement with, an entity to serve as the National Coordinating Center for the demonstration program conducted under this subsection.

(B) Activities described

The National Coordinating Center shall—

(i) collect, coordinate, monitor, and distribute data, best practices, and findings regarding the activities funded under grants made to eligible entities under the demonstration program;

(ii) develop a model protocol for eligible entities with respect to the treatment of sickle cell disease and the prevention and treatment of complications of sickle cell disease;

(iii) develop educational materials regarding the treatment of sickle cell disease and the prevention and treatment of complications of sickle cell disease; and

(iv) prepare and submit to Congress a final report that includes recommendations regarding the effectiveness of the demonstration program conducted under this subsection and such direct outcome measures as—

(I) the number and type of health care resources utilized (such as emergency room visits, hospital visits, length of stay, and physician visits for individuals with sickle cell disease); and

(II) the number of individuals that were tested and subsequently received genetic counseling for the sickle cell trait.

(4) Application

An eligible entity desiring a grant under this subsection shall submit an application to the Administrator at such time, in such manner, and containing such information as the Administrator may require.

(5) Definitions

In this subsection:

(A) Administrator

The term "Administrator" means the Administrator of the Health Resources and Services Administration.

(B) Eligible entity

The term "eligible entity" means a Federally-qualified health center, a nonprofit hospital or clinic, or a university health center that provides primary health care, that—

(i) has a collaborative agreement with a community-based sickle cell disease organization or a nonprofit entity with experience in working with individuals who have sickle cell disease; and

(ii) demonstrates to the Administrator that either the Federally-qualified health center, the nonprofit hospital or clinic, the university health center, the organization or entity described in clause (i), or the experts described in paragraph (2)(C), has at least 5 years of experience in working with individuals who have sickle cell disease.

(C) Federally-qualified health center

The term "Federally-qualified health center" has the meaning given that term in section 1905(l)(2)(B) of the Social Security Act (42 U.S.C. 1396d(l)(2)(B)).

(6) Authorization of appropriations

There is authorized to be appropriated to carry out this subsection, $8,205,000 for each of fiscal years 2026 through 2030.

(July 1, 1944, ch. 373, title XI, §1106, as added and amended Pub. L. 115–327, §§2, 3, Dec. 18, 2018, 132 Stat. 4468, 4469; Pub. L. 119–75, div. J, title V, §6505(a), Feb. 3, 2026, 140 Stat. 693.)

EDITORIAL NOTES

REFERENCES IN TEXT

The Social Security Act, referred to in subsec. (b)(2)(A)(iii), is act Aug. 14, 1935, ch. 531, 49 Stat. 620. Title V of the Act is classified generally to subchapter V (§701 et seq.) of chapter 7 of this title. For complete classification of this Act to the Code, see section 1305 of this title and Tables.

CODIFICATION

Section 712(c) of Pub. L. 108–357, formerly set out as a note under section 300b–1 of this title, which was transferred to this section, redesignated as subsec. (b), and amended by Pub. L. 115–327, §3, was based on Pub. L. 108–357, title VII, §712(c), Oct. 22, 2004, 118 Stat. 1559.

PRIOR PROVISIONS

A prior section 300b–5, act July 1, 1944, ch. 373, title XI, §1106, as added Apr. 22, 1976, Pub. L. 94–278, title IV, §403(a), 90 Stat. 409, related to an annual report to President and Congress on administration of this part, prior to repeal by Pub. L. 97–35, title XXI, §2193(b)(4), Aug. 13, 1981, 95 Stat. 827.

Another prior section 300b–5, act July 1, 1944, ch. 373, title XI, §1106, as added May 16, 1972, Pub. L. 92–294, §3(c), 86 Stat. 139; amended Aug. 29, 1972, Pub. L. 92–414, §4(3), 86 Stat. 652, related to an annual report to President and Congress on administration of this part, prior to repeal by Pub. L. 94–278, title IV, §403(a), Apr. 22, 1976, 90 Stat. 407.

AMENDMENTS

2026—Subsec. (b)(1)(A)(iii), (2)(D). Pub. L. 119–75, §6505(a)(1), (2), substituted "treatment of sickle cell disease and the prevention and treatment of complications of sickle cell disease" for "prevention and treatment of sickle cell disease".

Subsec. (b)(3)(A). Pub. L. 119–75, §6505(a)(3)(A), substituted "make a grant to, or enter into a contract or cooperative agreement with," for "enter into a contract with".

Subsec. (b)(3)(B)(ii), (iii). Pub. L. 119–75, §6505(a)(3)(B), substituted "treatment of sickle cell disease and the prevention and treatment of complications of sickle cell disease" for "prevention and treatment of sickle cell disease".

Subsec. (b)(6). Pub. L. 119–75, §6505(a)(4), substituted "$8,205,000 for each of fiscal years 2026 through 2030" for "$4,455,000 for each of fiscal years 2019 through 2023".

2018—Subsec. (b). Pub. L. 115–327, §3(b), transferred section 712(c) of Pub. L. 108–357 to this section and redesignated it as subsec. (b). See Codification note above.

Pub. L. 115–327, §3(a)(1), substituted "sickle cell disease" for "Sickle Cell Disease" wherever appearing.

Subsec. (b)(1)(A). Pub. L. 115–327, §3(a)(2), substituted "shall continue efforts, including by awarding grants, to develop or establish mechanisms to improve the treatment of sickle cell disease, and to improve the prevention and treatment of complications of sickle cell disease, in populations with a high proportion of individuals with sickle cell disease" for "shall conduct a demonstration program by making grants to up to 40 eligible entities for each fiscal year in which the program is conducted under this section for the purpose of developing and establishing systemic mechanisms to improve the prevention and treatment of Sickle Cell Disease".

Subsec. (b)(1)(B). Pub. L. 115–327, §3(a)(3), substituted "Geographic diversity" for "Grant award requirements" in heading, struck out cl. (i) designation and heading before "The Administrator shall", and struck out cl. (ii) which related to priority in awarding grants.

Subsec. (b)(2)(E). Pub. L. 115–327, §3(a)(4), added subpar. (E).

Subsec. (b)(6). Pub. L. 115–327, §3(a)(5), substituted "$4,455,000 for each of fiscal years 2019 through 2023" for "$10,000,000 for each of fiscal years 2005 through 2009".

[1] So in original. Probably should be preceded by "the".

[2] So in original. Probably should be "this subsection".

§300b–6. Applied technology

The Secretary, acting through an identifiable administrative unit, shall—

(1) conduct epidemiological assessments and surveillance of genetic diseases to define the scope and extent of such diseases and the need for programs for the diagnosis, treatment, and control of such diseases, screening for such diseases, and the counseling of persons with such diseases;

(2) on the basis of the assessments and surveillance described in paragraph (1), develop for use by the States programs which combine in an effective manner diagnosis, treatment, and control of such diseases, screening for such diseases, and counseling of persons with such diseases; and

(3) on the basis of the assessments and surveillance described in paragraph (1), provide technical assistance to States to implement the programs developed under paragraph (2) and train appropriate personnel for such programs.

In carrying out this section, the Secretary may, from funds allotted for use under section 702(a) of this title, make grants to or contracts with public or nonprofit private entities (including grants and contracts for demonstration projects).

(July 1, 1944, ch. 373, title XI, §1107, as added Pub. L. 95–626, title II, §205(d)(1), Nov. 10, 1978, 92 Stat. 3584; amended Pub. L. 97–35, title XXI, §2193(b)(5), Aug. 13, 1981, 95 Stat. 827.)

EDITORIAL NOTES

AMENDMENTS

1981—Pub. L. 97–35 substituted provisions relating to allotments under section 702(a) of this title for provisions relating to appropriations under section 300b(b) of this title.

STATUTORY NOTES AND RELATED SUBSIDIARIES

EFFECTIVE DATE OF 1981 AMENDMENT, SAVINGS, AND TRANSITIONAL PROVISIONS

For effective date, savings, and transitional provisions relating to amendment by Pub. L. 97–35, see section

2194 of Pub. L. 97–35, set out as a note under section 701 of this title.

§300b–7. Tourette Syndrome

(a) In general

The Secretary shall develop and implement outreach programs to educate the public, health care providers, educators and community based organizations about the etiology, symptoms, diagnosis and treatment of Tourette Syndrome, with a particular emphasis on children with Tourette Syndrome. Such programs may be carried out by the Secretary directly and through awards of grants or contracts to public or nonprofit private entities.

(b) Certain activities

Activities under subsection (a) shall include—

(1) the production and translation of educational materials, including public service announcements;

(2) the development of training material for health care providers, educators and community based organizations; and

(3) outreach efforts directed at the misdiagnosis and underdiagnosis of Tourette Syndrome in children and in minority groups.

(c) Authorization of appropriations

For the purpose of carrying out this section, there are authorized to be appropriated such sums as may be necessary for each of the fiscal years 2001 through 2005.

(July 1, 1944, ch. 373, title XI, §1108, as added Pub. L. 106–310, div. A, title XXIII, §2301, Oct. 17, 2000, 114 Stat. 1157.)

§300b–8. Improved newborn and child screening for heritable disorders

(a) Authorization of grant program

From amounts appropriated under section 300b–16 of this title, the Secretary, acting through the Administrator of the Health Resources and Services Administration (referred to in this section as the "Administrator") and taking into consideration the expertise of the Advisory Committee on Heritable Disorders in Newborns and Children (referred to in this section as the "Advisory Committee"), shall award grants to eligible entities to enable such entities—

(1) to enhance, improve or expand the ability of State and local public health agencies to provide screening, counseling, or health care services to newborns and children having or at risk for heritable disorders;

(2) to assist in providing health care professionals and newborn screening laboratory personnel with education in newborn screening, counseling, and training in—

(A) relevant and new technologies in newborn screening and congenital, genetic, and metabolic disorders;

(B) the importance of the timeliness of collection, delivery, receipt, and screening of specimens; and

(C) sharing of medical and diagnostic information with providers and families;

(3) to develop and deliver educational programs (at appropriate literacy levels) about newborn screening counseling, testing, follow-up, treatment, and specialty services to parents, families, and patient advocacy and support groups;

(4) to establish, maintain, and operate a system to assess and coordinate followup and treatment relating to congenital, genetic, and metabolic disorders; and

(5) to improve the timeliness of—

(A) the collection, delivery, receipt, and screening of specimens; and

(B) the diagnosis of heritable disorders in newborns.

(b) Eligible entity

In this section, the term "eligible entity" means—

(1) a State or a political subdivision of a State;

(2) a consortium of 2 or more States or political subdivisions of States;

(3) a territory;

(4) a health facility or program operated by or pursuant to a contract with or grant from the Indian Health Service; or

(5) any other entity with appropriate expertise in newborn screening, as determined by the Secretary.

(c) Approval factors

An application for a grant under this section shall not be approved by the Secretary unless the application contains assurances that the eligible entity has adopted and implemented, is in the process of adopting and implementing, or will use amounts received under such grant to adopt and implement the guidelines and recommendations of the Advisory Committee that are adopted by the Secretary and in effect at the time the grant is awarded or renewed under this section, which shall include the screening of each newborn for the heritable disorders recommended by the Advisory Committee and adopted by the Secretary.

(d) Coordination

The Secretary shall take all necessary steps to coordinate programs funded with grants received under this section and to coordinate with existing newborn screening activities.

(e) Limitation

An eligible entity may not use amounts received under this section to—

(1) provide cash payments to or on behalf of affected individuals;

(2) provide inpatient services;

(3) purchase land or make capital improvements to property; or

(4) provide for proprietary research or training.

(f) Voluntary participation

The participation by any individual in any program or portion thereof established or operated with funds received under this section shall be wholly voluntary and shall not be a prerequisite to eligibility for or receipt of any other service or assistance from, or to participation in, another Federal or State program.

(g) Supplement not supplant

Funds appropriated under this section shall be used to supplement and not supplant other Federal, State, and local public funds provided for activities of the type described in this section.

(h) Publication

(1) In general

An application for a grant under this section shall be made public by the State in such a manner as to facilitate comment from any person, including through hearings and other methods used to facilitate comments from the public.

(2) Comments

Comments received by the State after the publication described in paragraph (1) shall be addressed in the application for a grant under this section.

(i) Technical assistance

The Secretary shall provide to entities receiving grants under subsection (a) such technical assistance as may be necessary to ensure the quality of programs conducted under this section.

(July 1, 1944, ch. 373, title XI, §1109, as added Pub. L. 106–310, div. A, title XXVI, §2601, Oct. 17,

2000, 114 Stat. 1164; amended Pub. L. 110–204, §2, Apr. 24, 2008, 122 Stat. 705; Pub. L. 110–237, §1(a)(1), May 27, 2008, 122 Stat. 1556; Pub. L. 113–240, §2, Dec. 18, 2014, 128 Stat. 2851.)

EDITORIAL NOTES

AMENDMENTS

2014—Subsec. (a). Pub. L. 113–240, §2(1)(A), in introductory provisions, substituted "section 300b–16 of this title" for "subsection (j)" and "and taking into consideration the expertise of the Advisory Committee" for "and in consultation with the Advisory Committee".

Subsec. (a)(2). Pub. L. 113–240, §2(1)(B), amended par. (2) generally. Prior to amendment, par. (2) read as follows: "to assist in providing health care professionals and newborn screening laboratory personnel with education in newborn screening and training in relevant and new technologies in newborn screening and congenital, genetic, and metabolic disorders;".

Subsec. (a)(4). Pub. L. 113–240, §2(1)(D)(i), substituted "followup and treatment" for "treatment".

Subsec. (a)(5). Pub. L. 113–240, §2(1)(C), (D)(ii), (E), added par. (5).

Subsec. (c). Pub. L. 113–240, §2(2), substituted "application for a grant under this section" for "application submitted for a grant under subsection (a)(1)".

Subsec. (h). Pub. L. 113–240, §2(3), substituted "application for a grant under this section" for "application submitted under subsection (c)(2) of this section" in pars. (1) and (2).

Subsec. (j). Pub. L. 113–240, §2(4), struck out subsec. (j) which authorized appropriations for fiscal years 2009 to 2013 to provide grants for carrying out activities under subsec. (a).

2008—Subsecs. (a) to (c). Pub. L. 110–204, §2(1), added subsecs. (a) to (c) and struck out former subsecs. (a) to (c) which provided for grants to promote screening, counseling, or health care services to newborns and children having or at risk for heritable disorders, enumerated permissible uses of grants, and set out grant applicants' eligibility requirements.

Subsecs. (d) to (i). Pub. L. 110–204, §2(2), (3), added subsec. (d) and redesignated former subsecs. (d) to (h) as (e) to (i), respectively. Former subsec. (i) redesignated (j).

Subsec. (j). Pub. L. 110–237 added subsec. (j) and struck out former subsec. (j). Prior to amendment, text read as follows: "There is authorized to be appropriated—

"(1) to provide grants for the purpose of carrying activities under section (a)(1), $15,000,000 for fiscal year 2008; $15,187,500 for fiscal year 2009, $15,375,000 for fiscal year 2010, $15,562,500 for fiscal year 2011, and $15,750,000 for fiscal year 2012; and

"(2) to provide grant for the purpose of carrying out activities under paragraphs (2), (3), and (4) of subsection (a), $15,000,000 for fiscal year 2008, $15,187,500 for fiscal year 2009, $15,375,000 for fiscal year 2010, $15,562,500 for fiscal year 2011, and $15,750,000 for fiscal year 2012."

Pub. L. 110–204, §2(4), added subsec. (j) and struck out former subsec. (j). Prior to amendment, text read as follows: "There are authorized to be appropriated to carry out this section such sums as may be necessary for each of the fiscal years 2001 through 2005."

Pub. L. 110–204, §2(2), redesignated subsec. (i) as (j).

§300b–9. Evaluating the effectiveness of newborn and child screening and followup programs

(a) In general

The Secretary shall award grants to eligible entities to provide for the conduct of demonstration programs to evaluate the effectiveness, including with respect to timeliness, of screening, followup, counseling or health care services in reducing the morbidity and mortality caused by heritable disorders in newborns and children.

(b) Demonstration programs

A demonstration program conducted under a grant under this section shall be designed to evaluate and assess, within the jurisdiction of the entity receiving such grant—

(1) the effectiveness of screening, treatment, counseling, testing, followup, or specialty services for newborns and children at risk for heritable disorders in reducing the morbidity and mortality associated with such disorders, including, as appropriate, through the assessment of health and

development outcomes for such children through adolescence;

(2) the effectiveness of screening, treatment, counseling, testing, followup, or specialty services in accurately and reliably diagnosing heritable disorders in newborns and children in a timely manner;

(3) the availability of screening, counseling, testing or specialty services for newborns and children at risk for heritable disorders;

(4) methods that may be identified to improve quality in the diagnosis, treatment, and disease management of heritable disorders based on gaps in services or care; or

(5) methods or best practices by which the eligible entities described in section 300b–8 of this title can achieve in a timely manner—

(A) collection, delivery, receipt, and screening of newborn screening specimens; and

(B) diagnosis of heritable disorders in newborns.

(c) Eligible entities

To be eligible to receive a grant under subsection (a) an entity shall be a State or political subdivision of a State, or a consortium of two or more States or political subdivisions of States.

(July 1, 1944, ch. 373, title XI, §1110, as added Pub. L. 106–310, div. A, title XXVI, §2601, Oct. 17, 2000, 114 Stat. 1165; amended Pub. L. 110–204, §3, Apr. 24, 2008, 122 Stat. 706; Pub. L. 110–237, §1(a)(2), May 27, 2008, 122 Stat. 1556; Pub. L. 113–240, §3, Dec. 18, 2014, 128 Stat. 2852.)

EDITORIAL NOTES

AMENDMENTS

2014—Pub. L. 113–240, §3(1), inserted "and followup" after "child screening" in section catchline.

Subsec. (a). Pub. L. 113–240, §3(2), substituted ", including with respect to timeliness, of screening, followup," for "of screening,".

Subsec. (b)(1). Pub. L. 113–240, §3(3)(A), substituted "treatment, counseling, testing, followup," for "counseling, testing" and inserted before semicolon at end ", including, as appropriate, through the assessment of health and development outcomes for such children through adolescence".

Subsec. (b)(2). Pub. L. 113–240, §3(3)(B)(i), (ii), substituted "treatment, counseling, testing, followup," for "counseling, testing" and inserted "in a timely manner" after "in newborns and children".

Subsec. (b)(4), (5). Pub. L. 113–240, §3(3)(B)(iii)–(D), added pars. (4) and (5).

Subsec. (d). Pub. L. 113–240, §3(4), struck out subsec. (d). Text read as follows: "There are authorized to be appropriated to carry out this section $5,000,000 for fiscal year 2009, $5,062,500 for fiscal year 2010, $5,125,000 for fiscal year 2011, $5,187,500 for fiscal year 2012, and $5,250,000 for fiscal year 2013."

2008—Subsec. (d). Pub. L. 110–237 substituted "2009, $5,062,500 for fiscal year 2010, $5,125,000 for fiscal year 2011, $5,187,500 for fiscal year 2012, and $5,250,000 for fiscal year 2013." for "2008, $5,062,500 for fiscal year 2009, $5,125,000 for fiscal year 2010, $5,187,500 for fiscal year 2011, and $5,250,000 for fiscal year 2012."

Pub. L. 110–204 added subsec. (d).

§300b–10. Advisory Committee on Heritable Disorders in Newborns and Children

(a) Establishment

The Secretary shall establish an advisory committee to be known as the "Advisory Committee on Heritable Disorders in Newborns and Children" (referred to in this section as the "Advisory Committee").

(b) Duties

The Advisory Committee shall—

(1) provide advice and recommendations to the Secretary concerning grants and projects awarded or funded under section 300b–8 of this title;

(2) provide technical information to the Secretary for the development of policies and priorities

for the administration of grants under section 300b–8 of this title;

(3) make systematic evidence-based and peer-reviewed recommendations that include the heritable disorders that have the potential to significantly impact public health for which all newborns should be screened, including secondary conditions that may be identified as a result of the laboratory methods used for screening;

(4) provide technical assistance, as appropriate, to individuals and organizations regarding the submission of nominations to the uniform screening panel, including prior to the submission of such nominations;

(5) take appropriate steps, at its discretion, to prepare for the review of nominations prior to their submission, including for conditions for which a screening method has been validated but other nomination criteria are not yet met, in order to facilitate timely action by the Advisory Committee once such submission has been received by the Committee;

(6) develop a model decision-matrix for newborn screening expansion, including an evaluation of the potential public health impact, including the cost of such expansion, and periodically update the recommended uniform screening panel, as appropriate, based on such decision-matrix;

(7) consider ways to ensure that all States attain the capacity to screen for the conditions described in paragraph (3), and include in such consideration the results of grant funding under section 300b–8 of this title; and

(8) provide such recommendations, advice or information as may be necessary to enhance, expand or improve the ability of the Secretary to reduce the mortality or morbidity from heritable disorders, which may include recommendations, advice, or information dealing with—

(A) follow-up activities, including those necessary to achieve best practices in rapid diagnosis and appropriate treatment in the short-term, and those that ascertain long-term case management outcomes and appropriate access to related services;

(B) implementation, monitoring, and evaluation of newborn screening activities, including diagnosis, screening, follow-up, and treatment activities;

(C) diagnostic and other technology used in screening;

(D) the availability and reporting of testing for conditions for which there is no existing treatment, including information on cost and incidence;

(E) conditions not included in the recommended uniform screening panel that are treatable with Food and Drug Administration-approved products or other safe and effective treatments, as determined by scientific evidence and peer review;

(F) minimum standards and related policies and procedures used by State newborn screening programs, such as language and terminology used by State newborn screening programs to include standardization of case definitions and names of disorders for which newborn screening tests are performed;

(G) quality assurance, oversight, and evaluation of State newborn screening programs, including ensuring that tests and technologies used by each State meet established standards for detecting and reporting positive screening results;

(H) public and provider awareness and education;

(I) the cost and effectiveness of newborn screening and medical evaluation systems and intervention programs conducted by State-based programs;

(J) identification of the causes of, public health impacts of, and risk factors for heritable disorders;

(K) coordination of surveillance activities, including standardized data collection and reporting, harmonization of laboratory definitions for heritable disorders and testing results, and confirmatory testing and verification of positive results, in order to assess and enhance monitoring of newborn diseases; and

(L) the timeliness of collection, delivery, receipt, and screening of specimens to be tested for heritable disorders in newborns in order to ensure rapid diagnosis and followup.

(c) Membership

(1) In general

The Secretary shall appoint not to exceed 15 members to the Advisory Committee. In appointing such members, the Secretary shall ensure that the total membership of the Advisory Committee is an odd number.

(2) Required members

The Secretary shall appoint to the Advisory Committee under paragraph (1)—

(A) the Administrator of the Health Resources and Services Administration;

(B) the Director of the Centers for Disease Control and Prevention;

(C) the Director of the National Institutes of Health;

(D) the Director of the Agency for Healthcare Research and Quality;

(E) the Commissioner of the Food and Drug Administration;

(F) medical, technical, or scientific professionals with special expertise in heritable disorders, or in providing screening, counseling, testing or specialty services for newborns and children at risk for heritable disorders;

(G) individuals with expertise in ethics and infectious diseases who have worked and published material in the area of newborn screening;

(H) members of the public having special expertise about or concern with heritable disorders; and

(I) representatives from such Federal agencies, public health constituencies, and medical professional societies as determined to be necessary by the Secretary, to fulfill the duties of the Advisory Committee, as established under subsection (b).

(d) Decision on recommendations

(1) In general

Not later than 120 days after the Advisory Committee issues a recommendation pursuant to this section, the Secretary shall adopt or reject such recommendation. If the Secretary is unable to make a determination to adopt or reject such recommendation within such 120-day period, the Secretary shall notify the Advisory Committee and the appropriate committees of Congress of such determination together with an explanation for why the Secretary was unable to comply within such 120-day period, as well as a plan of action for consideration of such pending recommendation.

(2) Determinations to be made public

The Secretary shall publicize any determination on adopting or rejecting a recommendation of the Advisory Committee pursuant to this subsection, including the justification for the determination.

(3) Deadline for review

For each condition nominated to be added to the recommended uniform screening panel in accordance with the requirements of this section, the Advisory Committee shall review and vote on the nominated condition within 9 months of the date on which the Advisory Committee referred the nominated condition to the condition review workgroup.

(e) Annual report

Not later than 3 years after April 24, 2008, and each fiscal year thereafter, the Advisory Committee shall—

(1) publish a report on peer-reviewed newborn screening guidelines, including follow-up and treatment, in the United States;

(2) submit such report to the appropriate committees of Congress, the Secretary, the Interagency Coordinating Committee established under section 300b–13 of this title, and the State departments of health; and

(3) disseminate such report on as wide a basis as practicable, including through posting on the internet clearinghouse established under section 300b–11 of this title.

(f) Meetings

The Advisory Committee shall meet at least 4 times each calendar year, or at the discretion of the Designated Federal Officer in consultation with the Chair.

(g) Continuation of operation of Committee

(1) In general

Notwithstanding section 1013 of title 5, the Advisory Committee shall continue to operate through the end of fiscal year 2019.

(2) Continuation if not reauthorized

If at the end of fiscal year 2019 the duration of the Advisory Committee has not been extended by statute, the Advisory Committee may be deemed, for purposes of chapter 10 of title 5, an advisory committed [1] established by the President or an officer of the Federal Government under section 1008(a) of title 5.

(July 1, 1944, ch. 373, title XI, §1111, as added Pub. L. 106–310, div. A, title XXVI, §2601, Oct. 17, 2000, 114 Stat. 1166; amended Pub. L. 110–204, §4, Apr. 24, 2008, 122 Stat. 706; Pub. L. 110–237, §1(a)(3), (b)(2), May 27, 2008, 122 Stat. 1556, 1557; Pub. L. 113–240, §4, Dec. 18, 2014, 128 Stat. 2853; Pub. L. 117–286, §4(a)(244), Dec. 27, 2022, 136 Stat. 4332.)

EDITORIAL NOTES

AMENDMENTS

2022—Subsec. (g)(1). Pub. L. 117–286, §4(a)(244)(A), substituted "section 1013 of title 5," for "section 14 of the Federal Advisory Committee Act,".

Subsec. (g)(2). Pub. L. 117–286, §4(a)(244)(B), substituted "chapter 10 of title 5, an advisory committed established by the President or an officer of the Federal Government under section 1008(a) of title 5." for "the Federal Advisory Committee Act, an advisory committee established by the President or an officer of the Federal Government under section 9(a) of such Act."

2014—Subsec. (b)(4), (5). Pub. L. 113–240, §4(1)(B), added pars. (4) and (5). Former pars. (4) and (5) redesignated (6) and (7), respectively.

Subsec. (b)(6). Pub. L. 113–240, §4(1)(A), (C), redesignated par. (4) as (6) and inserted ", including the cost" after "public health impact". Former par. (6) redesignated (8).

Subsec. (b)(7). Pub. L. 113–240, §4(1)(A), redesignated par. (5) as (7).

Subsec. (b)(8). Pub. L. 113–240, §4(1)(A), redesignated par. (6) as (8).

Subsec. (b)(8)(A). Pub. L. 113–240, §4(1)(D)(i), substituted "achieve best practices in rapid diagnosis and appropriate treatment" for "achieve rapid diagnosis".

Subsec. (b)(8)(D). Pub. L. 113–240, §4(1)(D)(ii), inserted ", including information on cost and incidence" before semicolon at end.

Subsec. (b)(8)(L). Pub. L. 113–240, §4(1)(D)(iii)–(v), added subpar. (L).

Subsec. (d)(1). Pub. L. 113–240, §4(2)(A), substituted "120 days" for "180 days" and inserted at end "If the Secretary is unable to make a determination to adopt or reject such recommendation within such 120-day period, the Secretary shall notify the Advisory Committee and the appropriate committees of Congress of such determination together with an explanation for why the Secretary was unable to comply within such 120-day period, as well as a plan of action for consideration of such pending recommendation."

Subsec. (d)(2). Pub. L. 113–240, §4(2)(B), (C), redesignated par. (3) as (2) and struck out former par. (2). Prior to amendment, text of par. (2) read as follows: "The Secretary shall adopt or reject any recommendation issued by the Advisory Committee that is pending on April 24, 2008, by not later than 180 days after April 24, 2008."

Subsec. (d)(3). Pub. L. 113–240, §4(2)(D), added par. (3). Former par. (3) redesignated (2).

Subsec. (f). Pub. L. 113–240, §4(4), added subsec. (f). Former subsec. (f) redesignated (g).

Subsec. (g). Pub. L. 113–240, §4(3), (5), redesignated subsec. (f) as (g) and amended it generally. Prior to amendment, text read as follows: "Notwithstanding section 14 of the Federal Advisory Committee Act (5 U.S.C. App.), the Advisory Committee shall continue to operate during the 5-year period beginning on April 24, 2008."

Subsec. (h). Pub. L. 113–240, §4(3), (6), redesignated subsec. (g) as (h) and struck it out. Prior to amendment, text read as follows: "There are authorized to be appropriated to carry out this section, $1,000,000 for fiscal year 2009, $1,012,500 for fiscal year 2010, $1,025,000 for fiscal year 2011, $1,037,500

for fiscal year 2012, and $1,050,000 for fiscal year 2013."

2008—Subsec. (b)(3) to (5). Pub. L. 110–204, §4(1)(B), (C), added pars. (3) to (5). Former par. (3) redesignated (6).

Subsec. (b)(6). Pub. L. 110–204, §4(1)(A), (D), redesignated par. (3) as (6), substituted ", which may include recommendations, advice, or information dealing with—" for period at end, and added subpars. (A) to (K).

Subsec. (c)(2)(E) to (I). Pub. L. 110–204, §4(2), as amended by Pub. L. 110–237, §1(b)(2), added subpars. (E) and (G) and redesignated former subpars. (E), (F), and (G) as (F), (H), and (I), respectively.

Subsec. (d). Pub. L. 110–204, §4(3), added subsec. (d).

Subsec. (d)(2). Pub. L. 110–237, §1(a)(3)(A), made technical amendment to reference in original act which appears in text as the first reference to April 24, 2008.

Subsecs. (e), (f). Pub. L. 110–237, §1(a)(3)(B), (C), made technical amendment to references in original act which appear in text as references to April 24, 2008.

Pub. L. 110–204, §4(3), added subsecs. (e) and (f).

Subsec. (g). Pub. L. 110–237, §1(a)(3)(D), substituted "2009, $1,012,500 for fiscal year 2010, $1,025,000 for fiscal year 2011, $1,037,500 for fiscal year 2012, and $1,050,000 for fiscal year 2013." for "2008, $1,012,500 for fiscal year 2009, $1,025,000 for fiscal year 2010, $1,037,500 for fiscal year 2011, and $1,050,000 for fiscal year 2012."

Pub. L. 110–204, §4(3), added subsec. (g).

STATUTORY NOTES AND RELATED SUBSIDIARIES

TERMINATION OF ADVISORY COMMITTEES

Advisory committees established after Jan. 5, 1973, to terminate not later than the expiration of the 2-year period beginning on the date of their establishment, unless, in the case of a committee established by the President or an officer of the Federal Government, such committee is renewed by appropriate action prior to the expiration of such 2-year period, or in the case of a committee established by the Congress, its duration is otherwise provided by law. See section 1013 of Title 5, Government Organization and Employees.

Pub. L. 93–641, §6, Jan. 4, 1975, 88 Stat. 2275, set out as a note under section 217a of this title, provided that an advisory committee established pursuant to the Public Health Service Act shall terminate at such time as may be specifically prescribed by an Act of Congress enacted after Jan. 4, 1975.

[1] *So in original. Probably should be "committee".*

§300b–11. Clearinghouse of newborn screening information

(a) In general

The Secretary, acting through the Administrator of the Health Resources and Services Administration (referred to in this part as the "Administrator"), in consultation with the Director of the Centers for Disease Control and Prevention and the Director of the National Institutes of Health, shall establish and maintain a central clearinghouse of current educational and family support and services information, materials, resources, research, and data on newborn screening to—

(1) enable parents and family members of newborns, health professionals, industry representatives, and other members of the public to increase their awareness, knowledge, and understanding of newborn screening;

(2) increase awareness, knowledge, and understanding of newborn diseases and screening services for expectant individuals and families;

(3) maintain current information on quality indicators to measure performance of newborn screening, such as false-positive rates and other quality indicators as determined by the Advisory Committee under section 300b–10 of this title;

(4) maintain current information on the number of conditions for which screening is conducted in each State; and

(5) disseminate available evidence-based guidelines related to diagnosis, counseling, and treatment with respect to conditions detected by newborn screening.

(b) Internet availability

The Secretary, acting through the Administrator, shall ensure that the clearinghouse described under subsection (a)—

(1) is available on the Internet;

(2) includes an interactive forum;

(3) is updated on a regular basis, but not less than quarterly; and

(4) provides—

(A) links to Government-sponsored, non-profit, and other Internet websites of laboratories that have demonstrated expertise in newborn screening that supply research-based information on newborn screening tests currently available throughout the United States;

(B) information about newborn conditions and screening services available in each State from laboratories certified under subpart 2 of part F of subchapter II, including information about supplemental screening that is available but not required, in the State where the infant is born;

(C) current research on both treatable and not-yet treatable conditions for which newborn screening tests are available;

(D) the availability of Federal funding for newborn and child screening for heritable disorders including grants authorized under the Newborn Screening Saves Lives Reauthorization Act of 2014; and

(E) other relevant information as determined appropriate by the Secretary.

(c) Nonduplication

In carrying out activities under this section, the Secretary shall ensure that such activities minimize duplication and supplement, not supplant, existing information sharing efforts.

(July 1, 1944, ch. 373, title XI, §1112, as added Pub. L. 110–204, §5, Apr. 24, 2008, 122 Stat. 708; amended Pub. L. 110–237, §1(a)(4), May 27, 2008, 122 Stat. 1557; Pub. L. 113–240, §5, Dec. 18, 2014, 128 Stat. 2854.)

EDITORIAL NOTES

REFERENCES IN TEXT

The Newborn Screening Saves Lives Reauthorization Act of 2014, referred to in subsec. (b)(4)(D), is Pub. L. 113–240, Dec. 18, 2014, 128 Stat. 2851. For complete classification of this Act to the Code, see Short Title of 2014 Amendment note set out under section 201 of this title and Tables.

AMENDMENTS

2014—Subsec. (a)(3). Pub. L. 113–240, §5(1)(B)(i), substituted "information" for "data".

Subsec. (a)(4), (5). Pub. L. 113–240, §5(1)(A), (B)(ii), (C), added pars. (4) and (5).

Subsec. (b)(4)(D). Pub. L. 113–240, §5(2), substituted "Newborn Screening Saves Lives Reauthorization Act of 2014" for "Newborn Screening Saves Lives Act of 2008".

Subsec. (c). Pub. L. 113–240, §5(3), substituted "carrying out activities" for "developing the clearinghouse" and "activities minimize duplication and supplement, not supplant" for "clearinghouse minimizes duplication and supplements, not supplants".

Subsec. (d). Pub. L. 113–240, §5(4), struck out subsec. (d). Text read as follows: "There are authorized to be appropriated to carry out this section, $2,500,000 for fiscal year 2009, $2,531,250 for fiscal year 2010, $2,562,500 for fiscal year 2011, $2,593,750 for fiscal year 2012, and $2,625,000 for fiscal year 2013."

2008—Subsec. (b)(4)(D). Pub. L. 110–237, §1(a)(4)(A), substituted "2008" for "2007".

Subsec. (d). Pub. L. 110–237, §1(a)(4)(B), substituted "2009, $2,531,250 for fiscal year 2010, $2,562,500 for fiscal year 2011, $2,593,750 for fiscal year 2012, and $2,625,000 for fiscal year 2013." for "2008, $2,531,250 for fiscal year 2009, $2,562,500 for fiscal year 2010, $2,593,750 for fiscal year 2011, and $2,625,000 for fiscal year 2012."

§300b–12. Laboratory quality and surveillance

(a) In general

The Secretary, acting through the Director of the Centers for Disease Control and Prevention and taking into consideration the expertise of the Advisory Committee on Heritable Disorders in Newborns and Children established under section 300b–10 of this title, shall provide for—

(1) quality assurance for laboratories involved in screening newborns and children for heritable disorders, including quality assurance for newborn-screening tests, timeliness for processing such tests, performance evaluation services, and technical assistance and technology transfer to newborn screening laboratories to ensure analytic validity and utility of screening tests; and

(2) appropriate quality control and other performance test materials to evaluate the performance of new screening tools.

(b) Surveillance activities

The Secretary, acting through the Director of the Centers for Disease Control and Prevention, and taking into consideration the expertise of the Advisory Committee on Heritable Disorders in Newborns and Children established under section 300b–10 of this title, may provide, as appropriate, for the coordination of surveillance activities, including—

(1) through standardized data collection and reporting, as well as the use of electronic health records; and

(2) by promoting data sharing regarding newborn screening with State-based birth defects and developmental disabilities monitoring programs.

(July 1, 1944, ch. 373, title XI, §1113, as added Pub. L. 110–204, §6, Apr. 24, 2008, 122 Stat. 710; amended Pub. L. 110–237, §1(a)(5), May 27, 2008, 122 Stat. 1557; Pub. L. 113–240, §6, Dec. 18, 2014, 128 Stat. 2854.)

EDITORIAL NOTES

AMENDMENTS

2014—Pub. L. 113–240, §6(1), inserted "and surveillance" after "quality" in section catchline.

Subsec. (a). Pub. L. 113–240, §6(2)(A), substituted "and taking into consideration the expertise of the Advisory Committee" for "and in consultation with the Advisory Committee" in introductory provisions.

Subsec. (a)(1). Pub. L. 113–240, §6(2)(B), inserted "timeliness for processing such tests," after "newborn-screening tests,".

Subsec. (b). Pub. L. 113–240, §6(3), added subsec. (b) and struck out former subsec. (b). Prior to amendment, text read as follows: "For the purpose of carrying out this section, there are authorized to be appropriated $5,000,000 for fiscal year 2009, $5,062,500 for fiscal year 2010, $5,125,000 for fiscal year 2011, $5,187,500 for fiscal year 2012, and $5,250,000 for fiscal year 2013."

2008—Subsec. (b). Pub. L. 110–237 substituted "2009, $5,062,500 for fiscal year 2010, $5,125,000 for fiscal year 2011, $5,187,500 for fiscal year 2012, and $5,250,000 for fiscal year 2013." for "2008, $5,062,500 for fiscal year 2009, $5,125,000 for fiscal year 2010, $5,187,500 for fiscal year 2011, and $5,250,000 for fiscal year 2012."

§300b–13. Interagency Coordinating Committee on Newborn and Child Screening

(a) Purpose

It is the purpose of this section to—

(1) assess existing activities and infrastructure, including activities on birth defects and developmental disabilities authorized under section 247b–4 of this title, in order to make recommendations for programs to collect, analyze, and make available data on the heritable disorders recommended by the Advisory Committee on Heritable Disorders in Newborns and Children under section 300b–10 of this title, including data on the incidence and prevalence of, as well as poor health outcomes resulting from, such disorders; and

(2) make recommendations for the establishment of regional centers for the conduct of applied

epidemiological research on effective interventions to promote the prevention of poor health outcomes resulting from such disorders as well as providing information and education to the public on such effective interventions.

(b) Establishment

The Secretary shall establish an Interagency Coordinating Committee on Newborn and Child Screening (referred to in this section as the "Interagency Coordinating Committee") to carry out the purpose of this section.

(c) Composition

The Interagency Coordinating Committee shall be composed of the Director of the Centers for Disease Control and Prevention, the Administrator of the Health Resources and Services Administration, the Director of the Agency for Healthcare Research and Quality, the Commissioner of Food and Drugs, and the Director of the National Institutes of Health, or their designees.

(d) Activities

The Interagency Coordinating Committee shall—

(1) report to the Secretary and the appropriate committees of Congress on its recommendations related to the purpose described in subsection (a); and

(2) carry out other activities determined appropriate by the Secretary.

(July 1, 1944, ch. 373, title XI, §1114, as added Pub. L. 110–204, §6, Apr. 24, 2008, 122 Stat. 710; amended Pub. L. 110–237, §1(a)(6), May 27, 2008, 122 Stat. 1557; Pub. L. 113–240, §7, Dec. 18, 2014, 128 Stat. 2855.)

EDITORIAL NOTES

AMENDMENTS

2014—Subsec. (c). Pub. L. 113–240, §7(1), substituted "the Administrator of the Health Resources and Services Administration, the Director of the Agency for Healthcare Research and Quality, the Commissioner of Food and Drugs," for "the Administrator, the Director of the Agency for Healthcare Research and Quality,".

Subsec. (e). Pub. L. 113–240, §7(2), struck out subsec. (e). Text read as follows: "For the purpose of carrying out this section, there are authorized to be appropriated $1,000,000 for fiscal year 2009, $1,012,500 for fiscal year 2010, $1,025,000 for fiscal year 2011, $1,037,500 for fiscal year 2012, and $1,050,000 for fiscal year 2013."

2008—Subsec. (e). Pub. L. 110–237 substituted "2009, $1,012,500 for fiscal year 2010, $1,025,000 for fiscal year 2011, $1,037,500 for fiscal year 2012, and $1,050,000 for fiscal year 2013." for "2008, $1,012,500 for fiscal year 2009, $1,025,000 for fiscal year 2010, $1,037,500 for fiscal year 2011, and $1,050,000 for fiscal year 2012."

§300b–14. National contingency plan for newborn screening

(a) In general

Not later than 180 days after April 24, 2008, the Secretary, acting through the Director of the Centers for Disease Control and Prevention and in consultation with the Administrator and State departments of health (or related agencies), shall develop a national contingency plan for newborn screening for use by a State, region, or consortium of States in the event of a public health emergency. The plan shall be updated as needed and at least every five years.

(b) Contents

The contingency plan developed under subsection (a) shall include a plan for—

(1) the collection and transport of specimens;

(2) the shipment of specimens to State newborn screening laboratories;

(3) the processing of specimens;

(4) the reporting of screening results to physicians and families;

(5) the diagnostic confirmation of positive screening results;
(6) ensuring the availability of treatment and management resources;
(7) educating families about newborn screening; and
(8) carrying out other activities determined appropriate by the Secretary.

(July 1, 1944, ch. 373, title XI, §1115, as added Pub. L. 110–204, §7, Apr. 24, 2008, 122 Stat. 711; amended Pub. L. 113–240, §8, Dec. 18, 2014, 128 Stat. 2855.)

EDITORIAL NOTES

AMENDMENTS

2014—Subsec. (a). Pub. L. 113–240 substituted "consortium" for "consortia" and inserted at end "The plan shall be updated as needed and at least every five years."

§300b–15. Hunter Kelly Research Program

(a) Newborn screening activities

(1) In general

The Secretary, in conjunction with the Director of the National Institutes of Health and taking into consideration the recommendations of the Advisory Committee, may continue carrying out, coordinating, and expanding research in newborn screening (to be known as "Hunter Kelly Newborn Screening Research Program") including—

(A) identifying, developing, and testing the most promising new screening technologies, in order to improve already existing screening tests, increase the specificity of newborn screening, and expand the number of conditions for which screening tests are available;

(B) experimental treatments and disease management strategies for additional newborn conditions, and other genetic, metabolic, hormonal, or functional conditions that can be detected through newborn screening for which treatment is not yet available;

(C) providing research findings and data for newborn conditions under review by the Advisory Committee on Heritable Disorders in Newborns and Children to be added to the recommended uniform screening panel;

(D) conducting pilot studies on conditions recommended by the Advisory Committee on Heritable Disorders in Newborns and Children to ensure that screenings are ready for nationwide implementation; and

(E) other activities that would improve newborn screening, as identified by the Director.

(2) Additional newborn condition

For purposes of this subsection, the term "additional newborn condition" means any condition that is not one of the core conditions recommended by the Advisory Committee and adopted by the Secretary.

(b) Funding

In carrying out the research program under this section, the Secretary and the Director shall ensure that entities receiving funding through the program will provide assurances, as practicable, that such entities will work in consultation with the appropriate State departments of health, and, as practicable, focus their research on screening technology not currently performed in the States in which the entities are located, and the conditions on the uniform screening panel (or the standard test existing on the uniform screening panel).

(c) Reports

The Director is encouraged to include information about the activities carried out under this section in the biennial report required under section 283 of this title. If such information is included, the Director shall make such information available to be included on the Internet Clearinghouse established under section 300b–11 of this title.

(d) Nonduplication

In carrying out programs under this section, the Secretary shall minimize duplication and supplement, not supplant, existing efforts of the type carried out under this section.

(e) Peer review

Nothing in this section shall be construed to interfere with the scientific peer-review process at the National Institutes of Health.

(July 1, 1944, ch. 373, title XI, §1116, as added Pub. L. 110–204, §7, Apr. 24, 2008, 122 Stat. 711; amended Pub. L. 110–237, §1(a)(7), May 27, 2008, 122 Stat. 1557; Pub. L. 113–240, §9, Dec. 18, 2014, 128 Stat. 2855.)

EDITORIAL NOTES

AMENDMENTS

2014—Subsec. (a)(1)(C) to (E). Pub. L. 113–240, §9(1), added subpars. (C) and (D) and redesignated former subpar. (C) as (E).

Subsec. (c). Pub. L. 113–240, §9(2), substituted "section 283 of this title" for "section 403 of the National Institutes of Health Reform Act of 2006".

2008—Subsec. (a)(1)(B). Pub. L. 110–237 substituted ", or" for "and or".

§300b–16. Authorization of appropriations for newborn screening programs and activities

There are authorized to be appropriated—

(1) to carry out sections 300b–8, 300b–9, 300b–10, and 300b–11 of this title, $11,900,000 for each of fiscal years 2015 through 2019; and

(2) to carry out section 300b–12 of this title, $8,000,000 for each of fiscal years 2015 through 2019.

(July 1, 1944, ch. 373, title XI, §1117, as added Pub. L. 113–240, §10, Dec. 18, 2014, 128 Stat. 2856.)

§300b–17. Report by Secretary

(1) In general

The Secretary of Health and Human Services shall—

(A) not later than 1 year after December 18, 2014, submit to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives a report on activities related to—

(i) newborn screening; and

(ii) screening children who have or are at risk for heritable disorders; and

(B) not less than every 2 years, submit to such committees an updated version of such report.

(2) Contents

The report submitted under this section shall contain a description of—

(A) the ongoing activities under sections 300b–8, 300b–9, and 300b–11 through 300b–14 of this title; and

(B) the amounts expended on such activities.

(Pub. L. 113–240, §11(b), Dec. 18, 2014, 128 Stat. 2856.)

EDITORIAL NOTES

CODIFICATION

Section was enacted as part of the Newborn Screening Saves Lives Reauthorization Act of 2014, and not as part of the Public Health Service Act which comprises this chapter.

PRIOR PROVISIONS

Prior sections 300c to 300c–4 were repealed by Pub. L. 94–278, title IV, §403(a), Apr. 22, 1976, 90 Stat. 407.

Section 300c, act July 1, 1944, ch. 373, title XI, §1111, as added Aug. 29, 1972, Pub. L. 92–414, §3, 86 Stat. 650, authorized Secretary to make grants and enter contracts with public and private entities for establishment of screening, treatment, and counseling programs with respect to Cooley's Anemia.

Section 300c–1, act July 1, 1944, ch. 373, title XI, §1112, as added Aug. 29, 1972, Pub. L. 92–414, §3, 86 Stat. 651, required that any participation by an individual in any Cooley's Anemia programs should be on a purely voluntary basis.

Section 300c–2, act July 1, 1944, ch. 373, title XI, §1113, as added Aug. 29, 1972, Pub. L. 92–414, §3, 86 Stat. 651, provided for making of grant upon application to Secretary and listed certain requirements to be met by applicant.

Section 300c–3, act July 1, 1944, ch. 373, title XI, §1114, as added Aug. 29, 1972, Pub. L. 92–414, §3, 86 Stat. 652, authorized Secretary to establish a program with Public Health Service to provide for screening, counseling, and treatment with respect to Cooley's Anemia.

Section 300c–4, act July 1, 1944, ch. 373, title XI, §1115, as added Aug. 29, 1972, Pub. L. 92–414, §3, 86 Stat. 652, provided for Secretary's submission of a report to President for transmittal to Congress annually.

PART B—SUDDEN UNEXPECTED INFANT DEATH, SUDDEN INFANT DEATH SYNDROME, AND SUDDEN UNEXPECTED DEATH IN CHILDHOOD

EDITORIAL NOTES

CODIFICATION

Pub. L. 116–273, §2(1), Dec. 31, 2020, 134 Stat. 3352, substituted "Sudden Unexpected Infant Death, Sudden Infant Death Syndrome, and Sudden Unexpected Death in Childhood" for "Sudden Infant Death Syndrome" in part heading.

Pub. L. 94–278, title IV, §403(b)(2), Apr. 22, 1976, 90 Stat. 409, redesignated part C heading as part B heading.

§300c–11. Addressing sudden unexpected infant death and sudden unexpected death in childhood

(a) In general

The Secretary may develop, support, or maintain programs or activities to address sudden unexpected infant death and sudden unexpected death in childhood, including by—

(1) continuing to support the Sudden Unexpected Infant Death and Sudden Death in the Young Case Registry of the Centers for Disease Control and Prevention and other fatality case reporting systems that include data pertaining to sudden unexpected infant death and sudden unexpected death in childhood, as appropriate, including such systems supported by the Health Resources and Services Administration, in order to—

(A) increase the number of States and jurisdictions participating in such registries or systems; and

(B) improve the utility of such registries or systems, which may include—

(i) making summary data available to the public in a timely manner on the internet website of the Department of Health and Human Services, in a manner that, at a minimum, protects

personal privacy to the extent required by applicable Federal and State law; and

(ii) making the data submitted to such registries or systems available to researchers, in a manner that, at a minimum, protects personal privacy to the extent required by applicable Federal and State law; and

(2) awarding grants or cooperative agreements to States, Indian Tribes, and Tribal organizations for purposes of—

(A) supporting fetal and infant mortality and child death review programs for sudden unexpected infant death and sudden unexpected death in childhood, including by establishing such programs at the local level;

(B) improving data collection related to sudden unexpected infant death and sudden unexpected death in childhood, including by—

(i) improving the completion of death scene investigations and comprehensive autopsies that include a review of clinical history and circumstances of death with appropriate ancillary testing; and

(ii) training medical examiners, coroners, death scene investigators, law enforcement personnel, emergency medical technicians, paramedics, emergency department personnel, and others who perform death scene investigations with respect to the deaths of infants and children, as appropriate;

(C) identifying, developing, and implementing best practices to reduce or prevent sudden unexpected infant death and sudden unexpected death in childhood, including practices to reduce sleep-related infant deaths;

(D) increasing the voluntary inclusion, in registries established for the purpose of conducting research on sudden unexpected infant death and sudden unexpected death in childhood, of samples of tissues or genetic materials from autopsies that have been collected pursuant to Federal or State law and for which the parent or guardian has provided informed consent for inclusion in such registries;

(E) disseminating information and materials to health care professionals and the public on risk factors that contribute to sudden unexpected infant death and sudden unexpected death in childhood, which may include information on risk factors that contribute to sleep-related sudden unexpected infant death or sudden unexpected death in childhood; or

(F) providing information, referrals, or peer or follow-up support services to families who have experienced sudden unexpected infant death or sudden unexpected death in childhood.

(b) Application

To be eligible to receive a grant or cooperative agreement under subsection (a)(2), a State, Indian Tribe, or Tribal organization shall submit to the Secretary an application at such time, in such manner, and containing such information as the Secretary may require, including information on how such State will ensure activities conducted under this section are coordinated with other federally-funded programs to reduce infant and child mortality, as appropriate.

(c) Technical assistance

The Secretary shall provide technical assistance to States, Tribes, and Tribal organizations receiving a grant or cooperative agreement under subsection (a)(2) for purposes of carrying out the program in accordance with this section.

(d) Reporting forms

(1) In general

The Secretary shall, as appropriate, encourage the use of sudden unexpected infant death and sudden unexpected death in childhood reporting forms developed in collaboration with the Centers for Disease Control and Prevention to improve the quality of data submitted to the Sudden

Unexpected Infant Death and Sudden Death in the Young Case Registry, and other fatality case reporting systems that include data pertaining to sudden unexpected infant death and sudden unexpected death in childhood.

(2) Update of forms

The Secretary shall assess whether updates are needed to the sudden unexpected infant death investigation reporting form used by the Centers for Disease Control and Prevention in order to improve the use of such form with other fatality case reporting systems supported by the Department of Health and Human Services, and shall make such updates as appropriate.

(e) Definitions

In this section:

(1) Sudden infant death syndrome

The term "sudden infant death syndrome" means a sudden unexpected infant death that remains unexplained after a thorough case investigation.

(2) Sudden unexpected infant death

The term "sudden unexpected infant death" means the sudden death of an infant under 1 year of age that when first discovered did not have an obvious cause. Such term includes such deaths that are explained, as well as deaths that remain unexplained (which are known as sudden infant death syndrome).

(3) Sudden unexpected death in childhood

The term "sudden unexpected death in childhood" means the sudden death of a child who is at least 1 year of age but not more than 17 years of age that, when first discovered, did not have an obvious cause. Such term includes such deaths that are explained, as well as deaths that remain unexplained (which are known as sudden unexplained death in childhood).

(4) Sudden unexplained death in childhood

The term "sudden unexplained death in childhood" means a sudden unexpected death in childhood that remains unexplained after a thorough case investigation.

(f) Authorization of appropriations

For the purpose of carrying out this section, there is authorized to be appropriated $12,000,000 for each of fiscal years 2022 through 2026.

(July 1, 1944, ch. 373, title XI, §1121, as added Pub. L. 116–273, §2(2), Dec. 31, 2020, 134 Stat. 3352.)

EDITORIAL NOTES

PRIOR PROVISIONS

A prior section 300c–11, act July 1, 1944, ch. 373, title XI, §1121, as added Apr. 22, 1974, Pub. L. 93–270, §3(a), 88 Stat. 91; amended Apr. 22, 1976, Pub. L. 94–278, title IV, §403(b)(1), 90 Stat. 409; S. Res. 4, Feb. 4, 1977; Aug. 1, 1977, Pub. L. 95–83, title III, §306(a), 91 Stat. 389; Dec. 19, 1977, Pub. L. 95–215, §8(a), 91 Stat. 1507; Nov. 8, 1978, Pub. L. 95–613, §2, 92 Stat. 3094; Dec. 12, 1979, Pub. L. 96–142, title II, §202, 93 Stat. 1070; H. Res. 549, Mar. 25, 1980; Aug. 13, 1981, Pub. L. 97–35, title XXI, §2193(a)(1)(C), 95 Stat. 827, related to sudden infant death syndrome counseling, information, educational, and statistical programs, prior to repeal by Pub. L. 97–35, title XXI, §2193(b)(1), Aug. 13, 1981, 95 Stat. 827. For effective date, savings, and transitional provisions relating to the amendment and repeal of prior section by Pub. L. 97–35, see section 2194 of Pub. L. 97–35, set out as a note under section 701 of this title.

§300c–12. Sudden infant death syndrome research

From the sums appropriated to the Eunice Kennedy Shriver National Institute of Child Health and Human Development, the Secretary shall assure that there are applied to research of the type

described in subparagraphs (A) and (B) of subsection (b)(1) [1] of this section such amounts each year as will be adequate, given the leads and findings then available from such research, in order to make maximum feasible progress toward identification of infants at risk of sudden infant death syndrome and prevention of sudden infant death syndrome.

(July 1, 1944, ch. 373, title XI, §1122, as added Pub. L. 96–142, title II, §202, Dec. 12, 1979, 93 Stat. 1072; amended Pub. L. 99–158, §3(a)(6), Nov. 20, 1985, 99 Stat. 879; Pub. L. 103–437, §15(a)(1), Nov. 2, 1994, 108 Stat. 4591; Pub. L. 109–482, title I, §104(b)(2)(B), Jan. 15, 2007, 120 Stat. 3693; Pub. L. 110–154, §1(b)(10), Dec. 21, 2007, 121 Stat. 1827.)

EDITORIAL NOTES

REFERENCES IN TEXT

Subsection (b), referred to in text, was repealed by Pub. L. 109–482, title I, §104(b)(2)(B)(ii), Jan. 15, 2007, 120 Stat. 3693. Prior to repeal, subparagraphs (A) and (B) of subsection (b)(1) read as follows:

"(A) the (i) number of applications approved by the Secretary in the fiscal year reported on for grants and contracts under this chapter for research which relates specifically to sudden infant death syndrome, (ii) total amount requested under such applications, (iii) number of such applications for which funds were provided in such fiscal year, and (iv) total amount of such funds; and

"(B) the (i) number of applications approved by the Secretary in such fiscal year for grants and contracts under this chapter for research which relates generally to sudden infant death syndrome, including high-risk pregnancy and high-risk infancy research which directly relates to sudden infant death syndrome, (ii) relationship of the high-risk pregnancy and high-risk infancy research to sudden infant death syndrome, (iii) total amount requested under such applications, (iv) number of such applications for which funds were provided in such fiscal year, and (v) total amount of such funds."

AMENDMENTS

2007—Pub. L. 110–154 substituted "Eunice Kennedy Shriver National Institute of Child Health and Human Development" for "National Institute of Child Health and Human Development".

Pub. L. 109–482 struck out subsec. (a) designation before "From the sums" and subsecs. (b) and (c) which related to annual report on data relating to applications for grants and contracts for research on sudden infant death syndrome and annual estimate of amounts requested for such research.

1994—Subsecs. (b)(1), (c). Pub. L. 103–437 substituted "Energy and Commerce" for "Interstate and Foreign Commerce".

1985—Subsec. (a). Pub. L. 99–158 struck out "under section 289d of this title" before ", the Secretary".

STATUTORY NOTES AND RELATED SUBSIDIARIES

EFFECTIVE DATE OF 2007 AMENDMENT

Amendment by Pub. L. 109–482 applicable only with respect to amounts appropriated for fiscal year 2007 or subsequent fiscal years, see section 109 of Pub. L. 109–482, set out as a note under section 281 of this title.

[1] *See References in Text note below.*

§300c–13. Continuing activities related to stillbirth, sudden unexpected infant death and sudden unexplained death in childhood

(a) In general

The Secretary of Health and Human Services shall continue activities related to still birth, sudden unexpected infant death, and sudden unexplained death in childhood, including, as appropriate—

(1) collecting information, such as socio-demographic, death scene investigation, clinical history, and autopsy information, on stillbirth, sudden unexpected infant death, and sudden unexplained death in childhood through the utilization of existing surveillance systems and collaborating with States to improve the quality, consistency, and collection of such data;

(2) disseminating information to educate the public, health care providers, and other stakeholders on stillbirth, sudden unexpected infant death and sudden unexplained death in childhood; and

(3) collaborating with the Attorney General, State and local departments of health, and other experts, as appropriate, to provide consistent information for medical examiners and coroners, law enforcement personnel, and health care providers related to death scene investigations and autopsies for sudden unexpected infant death and sudden unexplained death in childhood, in order to improve the quality and consistency of the data collected at such death scenes and to promote consistent reporting on the cause of death after autopsy to inform prevention, intervention, and other activities.

(b) Report to Congress

Not later than 2 years after December 18, 2014, the Secretary of Health and Human Services shall submit to Congress a report that includes a description of any activities that are being carried out by agencies within the Department of Health and Human Services, including the Centers for Disease Control and Prevention and the National Institutes of Health, related to stillbirth, sudden unexpected infant death, and sudden unexplained death in childhood, including those activities identified under subsection (a).

(Pub. L. 113–236, §2, Dec. 18, 2014, 128 Stat. 2831.)

EDITORIAL NOTES

CODIFICATION

Section was enacted as part of the Sudden Unexpected Death Data Enhancement and Awareness Act, and not as part of the Public Health Service Act which comprises this chapter.

§300c–14. Report to Congress

(a) In general

Not later than 2 years after December 31, 2020, and biennially thereafter, the Secretary of Health and Human Services shall submit to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives a report that contains, with respect to the reporting period—

(1) information regarding the incidence and number of sudden unexpected infant death and sudden unexpected death in childhood (including the number of such infant and child deaths that remain unexplained after investigation), including, to the extent practicable—

(A) a summary of such information by racial and ethnic group, and by State;

(B) aggregate information obtained from death scene investigations and autopsies; and

(C) recommendations for reducing the incidence of sudden unexpected infant death and sudden unexpected death in childhood;

(2) an assessment of the extent to which various approaches of reducing and preventing sudden unexpected infant death and sudden unexpected death in childhood have been effective; and

(3) a description of the activities carried out under section 300c–11 of this title.

(b) Definitions

In this section, the terms "sudden unexpected infant death" and "sudden unexpected death in childhood" have the meanings given such terms in section 300c–11 of this title.

(Pub. L. 116–273, §3, Dec. 31, 2020, 134 Stat. 3354.)

EDITORIAL NOTES

CODIFICATION

Section was enacted as part of the Scarlett's Sunshine on Sudden Unexpected Death Act, and not as part of the Public Health Service Act which comprises this chapter.

PART C—HEMOPHILIA PROGRAMS

EDITORIAL NOTES

CODIFICATION

Pub. L. 94–278, title IV, §403(b)(2), Apr. 22, 1976, 90 Stat. 409, redesignated part D heading as part C heading.

§300c–21. Repealed. Pub. L. 97–35, title XXI, §2193(b)(1), Aug. 13, 1981, 95 Stat. 827

Section, act July 1, 1944, ch. 373, title XI, §1131, as added July 29, 1975, Pub. L. 94–63, title VI, §606, 89 Stat. 350; amended Aug. 1, 1977, Pub. L. 95–83, title III, §306(b), 91 Stat. 389; Nov. 10, 1978, Pub. L. 95–626, title II, §206(a), 92 Stat. 3584; Aug. 13, 1981, Pub. L. 97–35, title XXI, §2193(a)(1)(D), 95 Stat. 827, related to comprehensive hemophilia diagnostic and treatment centers.

STATUTORY NOTES AND RELATED SUBSIDIARIES

EFFECTIVE DATE OF 1981 AMENDMENT AND REPEAL, SAVINGS, AND TRANSITIONAL PROVISIONS

For effective date, savings, and transitional provisions relating to the amendment and repeal of this section by Pub. L. 97–35, see section 2194 of Pub. L. 97–35, set out as a note under section 701 of this title.

§300c–22. Blood-separation centers

(a) Grants and contracts with public and nonprofit private entities for projects to develop and expand existing facilities; definitions

The Secretary may make grants to and enter into contracts with public and nonprofit private entities for projects to develop and expand, within existing facilities, blood-separation centers to separate and make available for distribution blood components to providers of blood services and manufacturers of blood fractions. For purposes of this section—

(1) the term "blood components" means those constituents of whole blood which are used for therapy and which are obtained by physical separation processes which result in licensed products such as red blood cells, platelets, white blood cells, AHF-rich plasma, fresh-frozen plasma, cryoprecipitate, and single unit plasma for infusion; and

(2) the term "blood fractions" means those constituents of plasma which are used for therapy and which are obtained by licensed fractionation processes presently used in manufacturing which result in licensed products such as normal serum albumin, plasma, protein fraction, prothrombin complex, fibrinogen, AHF concentrate, immune serum globulin, and hyperimmune globulins.

(b) Grants for alleviation of insufficient supplies of blood fractions

In the event the Secretary finds that there is an insufficient supply of blood fractions available to meet the needs for treatment of persons suffering from hemophilia, and that public and other nonprofit private centers already engaged in the production of blood fractions could alleviate such insufficiency with assistance under this subsection, he may make grants not to exceed $500,000 to such centers for the purposes of alleviating the insufficiency.

(c) Approval of application as prerequisite for grant or contract; form, manner of submission,

and contents of application

No grant or contract may be made under subsection (a) or (b) unless an application therefor has been submitted to and approved by the Secretary. Such an application shall be in such form, submitted in such manner, and contain such information as the Secretary shall by regulation prescribe.

(d) Nonapplicability of statutory provisions to contracts

Contracts may be entered into under subsection (a) without regard to section 3324(a) and (b) of title 31 and section 6101 of title 41.

(e) Authorization of appropriations

For the purpose of making payments under grants and contracts under subsections (a) and (b), there are authorized to be appropriated $4,000,000 for fiscal year 1976, $5,000,000 for the fiscal year ending September 30, 1977, $3,450,000 for the fiscal year ending September 30, 1978, $2,500,000 for the fiscal year ending September 30, 1979, $3,000,000 for the fiscal year ending September 30, 1980, and $3,500,000 for the fiscal year ending September 30, 1981.

(July 1, 1944, ch. 373, title XI, §1132, as added Pub. L. 94–63, title VI, §606, July 29, 1975, 89 Stat. 351; amended Pub. L. 95–83, title III, §306(c), Aug. 1, 1977, 91 Stat. 389; Pub. L. 95–626, title II, §206(b), Nov. 10, 1978, 92 Stat. 3584.)

EDITORIAL NOTES

CODIFICATION

In subsec. (d), "section 3324(a) and (b) of title 31 and section 6101 of title 41" substituted for "section 3648 and 3709 of the Revised Statutes (31 U.S.C. 529; 41 U.S.C. 5)" on authority of Pub. L. 97–258, §4(b), Sept. 13, 1982, 96 Stat. 1067, which Act enacted Title 31, Money and Finance, and Pub. L. 111–350, §6(c), Jan. 4, 2011, 124 Stat. 3854, which Act enacted Title 41, Public Contracts.

AMENDMENTS

1978—Subsec. (e). Pub. L. 95–626 inserted provisions authorizing appropriations for fiscal years ending Sept. 30, 1979, 1980, and 1981.

1977—Subsec. (e). Pub. L. 95–83 substituted provisions authorizing appropriations for fiscal years ending Sept. 30, 1977 and 1978, for prior such authorization for fiscal year 1977.

STATUTORY NOTES AND RELATED SUBSIDIARIES

EFFECTIVE DATE

Section effective July 1, 1975, see section 608 of Pub. L. 94–63, set out as an Effective Date of 1975 Amendment note under section 247b of this title.

RICKY RAY HEMOPHILIA RELIEF FUND

Pub. L. 105–369, Nov. 12, 1998, 112 Stat. 3368, as amended by Pub. L. 106–554, §1(a)(6) [title IX, §932], Dec. 21, 2000, 114 Stat. 2763, 2763A–585, provided that:

"SECTION 1. SHORT TITLE; TABLE OF CONTENTS.

"(a) SHORT TITLE.—This Act may be cited as the 'Ricky Ray Hemophilia Relief Fund Act of 1998'.

"(b) TABLE OF CONTENTS.—[Omitted.]

"TITLE I—HEMOPHILIA RELIEF FUND

"SEC. 101. RICKY RAY HEMOPHILIA RELIEF FUND.

"(a) ESTABLISHMENT.—There is established in the Treasury of the United States a trust fund to be known as the 'Ricky Ray Hemophilia Relief Fund', which shall be administered by the Secretary of the Treasury.

"(b) INVESTMENT OF AMOUNTS IN FUND.—Amounts in the Fund shall be invested in accordance with section 9702 of title 31, United States Code, and any interest on and proceeds from any such investment shall be credited to and become part of the Fund.

"(c) AVAILABILITY OF FUND.—Amounts in the Fund shall be available only for disbursement by the Secretary of Health and Human Services under section 103.

"(d) TERMINATION.—The Fund shall terminate upon the expiration of the 5-year period beginning on the date of the enactment of this Act [Nov. 12, 1998]. If all of the amounts in the Fund have not been expended by the end of the 5-year period, investments of amounts in the Fund shall be liquidated, the receipts of such liquidation shall be deposited in the Fund, and all funds remaining in the Fund shall be deposited in the miscellaneous receipts account in the Treasury of the United States.

"(e) AUTHORIZATION OF APPROPRIATIONS.—There is authorized to be appropriated to the Fund to carry out this title $750,000,000. There is appropriated to the Fund $475,000,000 for fiscal year 2001, to remain available until expended.

"SEC. 102. COMPASSIONATE PAYMENT RELATING TO INDIVIDUALS WITH BLOOD-CLOTTING DISORDERS AND HIV.

"(a) IN GENERAL.—If the conditions described in subsection (b) are met and if there are sufficient amounts in the Fund to make each payment, the Secretary shall make a single payment of $100,000 from the Fund to any individual who has an HIV infection and who is described in one of the following paragraphs:

"(1) The individual has any form of blood-clotting disorder, such as hemophilia, and was treated with antihemophilic factor at any time during the period beginning on July 1, 1982, and ending on December 31, 1987.

"(2) The individual—

"(A) is the lawful spouse of an individual described in paragraph (1); or

"(B) is the former lawful spouse of an individual described in paragraph (1) and was the lawful spouse of the individual at any time after a date, within the period described in such subparagraph, on which the individual was treated as described in such paragraph and through medical documentation can assert reasonable certainty of transmission of HIV from individual described in paragraph (1).

"(3) The individual acquired the HIV infection through perinatal transmission from a parent who is an individual described in paragraph (1) or (2).

"(b) CONDITIONS.—The conditions described in this subsection are, with respect to an individual, as follows:

"(1) SUBMISSION OF MEDICAL DOCUMENTATION OF HIV INFECTION.—The individual submits to the Secretary written medical documentation that the individual has an HIV infection.

"(2) PETITION.—A petition for the payment is filed with the Secretary by or on behalf of the individual.

"(3) DETERMINATION.—The Secretary determines, in accordance with section 103(b), that the petition meets the requirements of this title.

"SEC. 103. DETERMINATION AND PAYMENT.

"(a) ESTABLISHMENT OF FILING PROCEDURES.—The Secretary of Health and Human Services shall establish procedures under which individuals may submit petitions for payment under this title. The procedures shall include a requirement that each petition filed under this Act include written medical documentation that the relevant individual described in section 102(a)(1) has (or had) a blood-clotting disorder, such as hemophilia, and was treated as described in such section.

"(b) DETERMINATION.—For each petition filed under this title, the Secretary shall determine whether the petition meets the requirements of this title.

"(c) PAYMENT.—

"(1) IN GENERAL.—To the extent there are sufficient amounts in the Fund to cover each payment, the Secretary shall pay, from the Fund, each petition that the Secretary determines meets the requirements of this title in the order received.

"(2) PAYMENTS IN CASE OF DECEASED INDIVIDUALS.—

"(A) IN GENERAL.—In the case of an individual referred to in section 102(a) who is deceased at the time that payment is made under this section on a petition filed by or on behalf of the individual, the payment shall be made as follows:

"(i) If the individual is survived by a spouse who is living at the time of payment, the payment shall be made to such surviving spouse.

"(ii) If the individual is not survived by a spouse described in clause (i), the payment shall be made in equal shares to all children of the individual who are living at the time of the payment.

"(iii) If the individual is not survived by a person described in clause (i) or (ii), the payment shall be made in equal shares to the parents of the individual who are living at the time of the payment.

"(iv) If the individual is not survived by a person described in clause (i), (ii), or (iii), the

payment shall revert back to the Fund.

"(B) FILING OF PETITION BY SURVIVOR.—If an individual eligible for payment under section 102(a) dies before filing a petition under this title, a survivor of the individual may file a petition for payment under this title on behalf of the individual if the survivor may receive payment under subparagraph (A).

"(C) DEFINITIONS.—For purposes of this paragraph:

"(i) The term 'spouse' means an individual who was lawfully married to the relevant individual at the time of death.

"(ii) The term 'child' includes a recognized natural child, a stepchild who lived with the relevant individual in a regular parent-child relationship, and an adopted child.

"(iii) The term 'parent' includes fathers and mothers through adoption.

"(3) TIMING OF PAYMENT.—The Secretary may not make a payment on a petition under this title before the expiration of the 120-day period beginning on the date of the enactment of this Act [Nov. 12, 1998] or after the expiration of the 5-year period beginning on the date of the enactment of this Act.

"(d) ACTION ON PETITIONS.—The Secretary shall complete the determination required by subsection (b) regarding a petition not later than 120 days after the date the petition is filed under this title.

"(e) HUMANITARIAN NATURE OF PAYMENT.—This Act does not create or admit any claim of or on behalf of the individual against the United States or against any officer, employee, or agent thereof acting within the scope of employment or agency that relate to an HIV infection arising from treatment with antihemophilic factor, at any time during the period beginning on July 1, 1982, and ending on December 31, 1987. A payment under this Act shall, however, when accepted by or on behalf of the individual, be in full satisfaction of all such claims by or on behalf of that individual.

"(f) ADMINISTRATIVE COSTS NOT PAID FROM FUND.—No costs incurred by the Secretary in carrying out this title may be paid from the Fund or set off against, or otherwise deducted from, any payment made under subsection (c)(1).

"(g) TERMINATION OF DUTIES OF SECRETARY.—The duties of the Secretary under this section shall cease when the Fund terminates.

"(h) TREATMENT OF PAYMENTS UNDER OTHER LAWS.—A payment under subsection (c)(1) to an individual—

"(1) shall be treated for purposes of the Internal Revenue Code of 1986 as damages described in section 104(a)(2) of such Code;

"(2) shall not be included as income or resources for purposes of determining the eligibility of the individual to receive benefits described in section 3803(c)(2)(C) of title 31, United States Code, or the amount of such benefits, and such benefits shall not be secondary to, conditioned upon reimbursement from, or subject to any reduction because of receipt of, any such payment; and

"(3) shall not be treated as a third party payment or payment in relation to a legal liability with respect to such benefits and shall not be subject (whether by subrogation or otherwise) to recovery, recoupment, reimbursement, or collection with respect to such benefits (including the Federal or State governments or any entity that provides such benefits under a contract).

"(i) REGULATORY AUTHORITY.—The Secretary may issue regulations necessary to carry out this title.

"(j) TIME OF ISSUANCE OF PROCEDURES.—The Secretary shall, through the promulgation of appropriate regulations, guidelines, or otherwise, first establish the procedures to carry out this title not later than 120 days after the date of the enactment of this Act [Nov. 12, 1998].

"SEC. 104. LIMITATION ON TRANSFER OF RIGHTS AND NUMBER OF PETITIONS.

"(a) RIGHTS NOT ASSIGNABLE OR TRANSFERABLE.—Any right under this title shall not be assignable or transferable.

"(b) ONE PETITION WITH RESPECT TO EACH VICTIM.—With respect to each individual described in paragraph (1), (2), or (3) of section 102(a), the Secretary may not make payment with respect to more than one petition filed in respect to an individual.

"SEC. 105. TIME LIMITATION.

"The Secretary may not make any payment with respect to any petition filed under this title unless the petition is filed within 3 years after the date of the enactment of this Act [Nov. 12, 1998].

"SEC. 106. CERTAIN CLAIMS NOT AFFECTED BY PAYMENT.

"A payment made under section 103(c)(1) shall not be considered as any form of compensation, or reimbursement for a loss, for purposes of imposing liability on the individual receiving the payment, on the basis of such receipt, to repay any insurance carrier for insurance payments or to repay any person on account

of worker's compensation payments. A payment under this title shall not affect any claim against an insurance carrier with respect to insurance or against any person with respect to worker's compensation.

"SEC. 107. LIMITATION ON AGENT AND ATTORNEY FEES.

"Notwithstanding any contract, the representative of an individual may not receive, for services rendered in connection with the petition of an individual under this title, more than 5 percent of a payment made under this title on the petition. Any such representative who violates this section shall be fined not more than $50,000.

"SEC. 108. DEFINITIONS.

"For purposes of this title:

"(1) The term 'AIDS' means acquired immune deficiency syndrome.

"(2) The term 'Fund' means the Ricky Ray Hemophilia Relief Fund.

"(3) The term 'HIV' means human immunodeficiency virus.

"(4) Unless otherwise provided, the term 'Secretary' means Secretary of Health and Human Services.

"TITLE II—TREATMENT OF CERTAIN PAYMENTS IN HEMOPHILIA-CLOTTING-FACTOR SUIT UNDER THE SSI PROGRAM

"SEC. 201. TREATMENT OF CERTAIN PAYMENTS IN HEMOPHILIA-CLOTTING-FACTOR SUIT UNDER THE MEDICAID AND SSI PROGRAMS.

"(a) PRIVATE PAYMENTS.—

"(1) IN GENERAL.—Notwithstanding any other provision of law, the payments described in paragraph (2) shall not be considered income or resources in determining eligibility for, or the amount of—

"(A) medical assistance under title XIX of the Social Security Act [42 U.S.C. 1396 et seq.]; or

"(B) supplemental security income benefits under title XVI of the Social Security Act [42 U.S.C. 1381 et seq.].

"(2) PRIVATE PAYMENTS DESCRIBED.—The payments described in this subsection are—

"(A) payments made from any fund established pursuant to a class settlement in the case of Susan Walker v. Bayer Corporation, et al., 96–C–5024 (N.D. Ill.); and

"(B) payments made pursuant to a release of all claims in a case—

"(i) that is entered into in lieu of the class settlement referred to in subparagraph (A); and

"(ii) that is signed by all affected parties in such case on or before the later of—

"(I) December 31, 1997; or

"(II) the date that is 270 days after the date on which such release is first sent to the persons (or the legal representative of such persons) to whom the payment is to be made.

"(b) GOVERNMENT PAYMENTS.—

"(1) IN GENERAL.—Notwithstanding any other provision of law, the payments described in paragraph (2) shall not be considered income or resources in determining eligibility for, or the amount of supplemental security income benefits under title XVI of the Social Security Act [42 U.S.C. 1381 et seq.].

"(2) GOVERNMENT PAYMENTS DESCRIBED.—The payments described in this subsection are payments made from the Fund established pursuant to section 101 of this Act."

SUBCHAPTER X—TRAUMA CARE

PART A—GENERAL AUTHORITY AND DUTIES OF SECRETARY

§300d. Establishment

(a) In general

The Secretary shall, with respect to trauma care—

(1) conduct and support research, training, evaluations, and demonstration projects;

(2) foster the development of appropriate, modern systems of such care through the sharing of

information among agencies and individuals involved in the study and provision of such care;

(3) collect, compile, analyze, and disseminate information on the achievements of, and problems experienced by, State and local agencies and private entities in providing trauma care and emergency medical services and, in so doing, give special consideration to the unique needs of rural areas and medically underserved areas;

(4) provide to State and local agencies technical assistance to enhance each State's capability to develop, implement, and sustain the trauma care component of each State's plan for the provision of emergency medical services; and

(5) promote the collection and categorization of trauma data in a consistent and standardized manner.

(b) Trauma care readiness and coordination

The Secretary, acting through the Assistant Secretary for Preparedness and Response, shall support the efforts of States and consortia of States to coordinate and improve emergency medical services and trauma care during a public health emergency declared by the Secretary pursuant to section 247d of this title or a major disaster or emergency declared by the President under section 5170 or 5191, respectively, of this title. Such support may include—

(1) developing, issuing, and updating guidance, as appropriate, to support the coordinated medical triage and evacuation to appropriate medical institutions based on patient medical need, taking into account regionalized systems of care;

(2) disseminating, as appropriate, information on evidence-based or evidence-informed trauma care practices, taking into consideration emergency medical services and trauma care systems, including such practices identified through activities conducted under subsection (a) and which may include the identification and dissemination of performance metrics, as applicable and appropriate; and

(3) other activities, as appropriate, to optimize a coordinated and flexible approach to the emergency response and medical surge capacity of hospitals, other health care facilities, critical care, and emergency medical systems.

(c) Grants, cooperative agreements, and contracts

The Secretary may make grants, and enter into cooperative agreements and contracts, for the purpose of carrying out subsection (a).

(July 1, 1944, ch. 373, title XII, §1201, as added Pub. L. 101–590, §3, Nov. 16, 1990, 104 Stat. 2916; amended Pub. L. 103–183, title VI, §601(a), Dec. 14, 1993, 107 Stat. 2238; Pub. L. 104–146, §12(b), May 20, 1996, 110 Stat. 1373; Pub. L. 110–23, §2, May 3, 2007, 121 Stat. 90; Pub. L. 117–328, div. FF, title II, §2113(a), Dec. 29, 2022, 136 Stat. 5722.)

EDITORIAL NOTES

PRIOR PROVISIONS

A prior section 300d, act July 1, 1944, ch. 373, title XII, §1201, as added Nov. 16, 1973, Pub. L. 93–154, §2(a), 87 Stat. 594; amended Oct. 12, 1976, Pub. L. 94–484, title IX, §905(b)(1), 90 Stat. 2325; Oct. 21, 1976, Pub. L. 94–573, §§2, 14(2), 90 Stat. 2709, 2718, defined terms applicable to this subchapter, prior to repeal by Pub. L. 97–35, title IX, §902(d)(1), (h), Aug. 13, 1981, 95 Stat. 560, 561, effective Oct. 1, 1981.

A prior section 1201 of act July 1, 1944, ch. 373, title XII, formerly §1205, as added Nov. 16, 1973, Pub. L. 93–154, §2(a), 87 Stat. 597, was classified to section 300d–4 of this title prior to repeal by Pub. L. 99–117, §12(e), Oct. 7, 1985, 99 Stat. 495.

AMENDMENTS

2022—Subsec. (a)(3). Pub. L. 117–328, §2113(a)(1)(A), inserted "analyze," after "compile," and "and medically underserved areas" after "rural areas".

Subsec. (a)(5), (6). Pub. L. 117–328, §2113(a)(1)(B)–(D), redesignated par. (6) as (5) and struck out former par. (5) which read as follows: "sponsor workshops and conferences; and".

Subsecs. (b), (c). Pub. L. 117–328, §2113(a)(2), (3), added subsec. (b) and redesignated former subsec. (b) as (c).

2007—Pub. L. 110–23 amended section generally. Prior to amendment, section required the Secretary to provide support to trauma care, authorized the Secretary to make grants and enter into agreements for such support, and required the Administrator of the Health Resources and Services Administration to ensure that the Division of Trauma and Emergency Medical Systems administered this subchapter.

1996—Subsec. (a). Pub. L. 104–146, in introductory provisions, substituted "The Secretary shall," for "The Secretary, acting through the Administrator of the Health Resources and Services Administration, shall,".

1993—Subsec. (a). Pub. L. 103–183, §601(a)(1), in introductory provisions inserted ", acting through the Administrator of the Health Resources and Services Administration," after "Secretary".

Subsec. (c). Pub. L. 103–183, §601(a)(2), added subsec. (c).

STATUTORY NOTES AND RELATED SUBSIDIARIES

EFFECTIVE DATE OF 1996 AMENDMENT

Amendment by Pub. L. 104–146 effective Oct. 1, 1996, see section 13 of Pub. L. 104–146, set out as a note under section 300ff–11 of this title.

CONGRESSIONAL STATEMENT OF FINDINGS

Pub. L. 101–590, §2, Nov. 16, 1990, 104 Stat. 2915, provided that: "The Congress finds that—

"(1) the Federal Government and the governments of the States have established a history of cooperation in the development, implementation, and monitoring of integrated, comprehensive systems for the provision of emergency medical services throughout the United States;

"(2) physical trauma is the leading cause of death of Americans between the ages of 1 and 44 and is the third leading cause of death in the general population of the United States;

"(3) physical trauma in the United States results in an aggregate annual cost of $180,000,000,000 in medical expenses, insurance, lost wages, and property damage;

"(4) barriers to the provision of prompt and appropriate emergency medical services exist in many areas of the United States;

"(5) few States and communities have developed and implemented trauma care systems;

"(6) many trauma centers have incurred substantial uncompensated costs in providing trauma care, and such costs have caused many such centers to cease participation in trauma care systems; and

"(7) the number of incidents of physical trauma in the United States is a serious medical and social problem, and the number of deaths resulting from such incidents can be substantially reduced by improving the trauma-care components of the systems for the provision of emergency medical services in the United States."

§300d–1. Repealed. Pub. L. 103–183, title VI, §601(b)(1), Dec. 14, 1993, 107 Stat. 2238; Pub. L. 105–392, title IV, §401(a)(1)(A), Nov. 13, 1998, 112 Stat. 3587

Section, act July 1, 1944, ch. 373, title XII, §1202, as added Nov. 16, 1990, Pub. L. 101–590, §3, 104 Stat. 2916, provided for establishment, membership, duties, etc., of Advisory Council on Trauma Care Systems.

A prior section 300d–1, act July 1, 1944, ch. 373, title XII, §1202, as added Nov. 16, 1973, Pub. L. 93–154, §2(a), 87 Stat. 595; amended Oct. 21, 1976, Pub. L. 94–573, §3, 90 Stat. 2709; Dec. 12, 1979, Pub. L. 96–142, title I, §103, 93 Stat. 1067, set forth provisions relating to grants and contracts for feasibility studies and planning, prior to repeal by Pub. L. 97–35, title IX, §902(d)(1), (h), Aug. 13, 1981, 95 Stat. 560, 561, effective Oct. 1, 1981.

§300d–2. Repealed. Pub. L. 110–23, §3(1), May 3, 2007, 121 Stat. 90

Section, act July 1, 1944, ch. 373, title XII, §1202, formerly §1203, as added Pub. L. 101–590, §3, Nov. 16, 1990, 104 Stat. 2917; renumbered §1202, Pub. L. 103–183, title VI, §601(b)(2), Dec. 14, 1993, 107 Stat. 2238; amended Pub. L. 105–392, title IV, §401(a)(1)(A), Nov. 13, 1998, 112 Stat. 3587, required the Secretary to provide for the establishment and operation of a National Clearinghouse on Trauma Care and Emergency Medical Services.

A prior section 300d–2, act July 1, 1944, ch. 373, title XII, §1203, as added Nov. 16, 1973, Pub. L. 93–154, §2(a), 87 Stat. 596; amended Oct. 21, 1976, Pub. L. 94–573, §4, 90 Stat. 2710; Nov. 10, 1978, Pub. L. 95–626, title II, §210(a), 92 Stat. 3588; July 10, 1979, Pub. L. 96–32, §7(l), 93 Stat. 84, set forth provisions

relating to grants and contracts for establishing and initial operation of emergency medical services systems, prior to repeal by Pub. L. 97–35, title IX, §902(d)(1), (h), Aug. 13, 1981, 95 Stat. 560, 561, effective Oct. 1, 1981.

§300d–3. Grants to improve trauma care in rural areas

(a) In general

The Secretary shall award grants to eligible entities for the purpose of carrying out research and demonstration projects to support the improvement of emergency medical services and trauma care in rural areas through the development of innovative uses of technology, training and education, transportation of seriously injured patients for the purposes of receiving such emergency medical services, access to prehospital care, evaluation of protocols for the purposes of improvement of outcomes and dissemination of any related best practices, activities to facilitate clinical research, as applicable and appropriate, and increasing communication and coordination with applicable State or Tribal trauma systems.

(b) Eligible entities

(1) In general

To be eligible to receive a grant under this section, an entity shall be a public or private entity that provides trauma care in a rural area.

(2) Priority

In awarding grants under this section, the Secretary shall give priority to eligible entities that will provide services under the grant in any rural area identified by a State under section 300d–14(d)(1) of this title.

(c) Requirement of application

The Secretary may not make a grant under subsection (a) unless an application for the grant is submitted to the Secretary and the application is in such form, is made in such manner, and contains such agreements, assurances, and information as the Secretary determines to be necessary to carry out this section.

(d) Reports

An entity that receives a grant under this section shall submit to the Secretary such reports as the Secretary may require to inform administration of the program under this section.

(July 1, 1944, ch. 373, title XII, §1202, formerly §1204, as added Pub. L. 101–590, §3, Nov. 16, 1990, 104 Stat. 2918; renumbered §1203 and amended Pub. L. 103–183, title VI, §601(b)(2), (f)(1), Dec. 14, 1993, 107 Stat. 2238, 2239; Pub. L. 105–392, title IV, §401(a)(1), Nov. 13, 1998, 112 Stat. 3587; renumbered §1202 and amended Pub. L. 110–23, §§3(2), 4, May 3, 2007, 121 Stat. 90, 91; Pub. L. 117–328, div. FF, title II, §2113(b), Dec. 29, 2022, 136 Stat. 5723.)

EDITORIAL NOTES

PRIOR PROVISIONS

A prior section 300d–3, act July 1, 1944, ch. 373, title XII, §1204, as added Nov. 16, 1973, Pub. L. 93–154, §2(a), 87 Stat. 597; amended Oct. 21, 1976, Pub. L. 94–573, §5, 90 Stat. 2711; Nov. 10, 1978, Pub. L. 95–626, title II, §210(b), 92 Stat. 3588; Dec. 12, 1979, Pub. L. 96–142, title I, §104(a), (b), 93 Stat. 1067, 1068, set forth provisions relating to grants and contracts for expansion and improvements, prior to repeal by Pub. L. 97–35, title IX, §902(d)(1), (h), Aug. 13, 1981, 95 Stat. 560, 561, effective Oct. 1, 1981.

A prior section 1202 of act July 1, 1944, was classified to section 300d–2 of this title prior to repeal by Pub. L. 110–23.

Another prior section 1202 of act July 1, 1944, was classified to section 300d–1 of this title prior to repeal by Pub. L. 103–183.

Another prior section 1202 of act July 1, 1944, was classified to section 300d–6 of this title prior to repeal

by Pub. L. 99–117.

AMENDMENTS

2022—Pub. L. 117–328, §2113(b)(1), amended section catchline generally. Prior to amendment, section catchline read as follows: "Establishment of programs for improving trauma care in rural areas".

Subsecs. (a), (b). Pub. L. 117–328, §2113(b)(2), amended subsecs. (a) and (b) generally. Prior to amendment, subsecs. (a) and (b) related to authority to make grants to public and nonprofit private entities to carry out research and demonstration projects with respect to improving the availability and quality of emergency medical services in rural areas and special consideration for certain rural areas, respectively.

Subsec. (d). Pub. L. 117–328, §2113(b)(3), added subsec. (d).

2007—Pub. L. 110–23, §4, amended section generally. Prior to amendment, section provided for establishment of programs for improving trauma care in rural areas.

1998—Pub. L. 105–392, §401(a)(1), made technical corrections to directory language of Pub. L. 103–183, §601(b)(2), which renumbered this section, and to directory language of Pub. L. 103–183, §601(f)(1). See 1993 Amendment note below.

1993—Subsec. (c). Pub. L. 103–183, §601(f)(1), as amended by Pub. L. 105–392, §401(a)(1)(B), inserted "determines to be necessary to carry out this section" before period at end.

STATUTORY NOTES AND RELATED SUBSIDIARIES

EFFECTIVE DATE OF 1998 AMENDMENT

Amendment by Pub. L. 105–392 deemed to have taken effect immediately after enactment of Pub. L. 103–183, see section 401(e) of Pub. L. 105–392, set out as a note under section 242m of this title.

§300d–4. Emergency medical services

(a) Federal Interagency Committee on Emergency Medical Services

(1) Establishment

The Secretary of Transportation, the Secretary of Health and Human Services, and the Secretary of Homeland Security, acting through the Under Secretary for Emergency Preparedness and Response, shall establish a Federal Interagency Committee on Emergency Medical Services.

(2) Membership

The Interagency Committee shall consist of the following officials, or their designees:

(A) The Administrator, National Highway Traffic Safety Administration.

(B) The Director, Preparedness Division, Directorate of Emergency Preparedness and Response of the Department of Homeland Security.

(C) The Administrator, Health Resources and Services Administration, Department of Health and Human Services.

(D) The Director, Centers for Disease Control and Prevention, Department of Health and Human Services.

(E) The Administrator, United States Fire Administration, Directorate of Emergency Preparedness and Response of the Department of Homeland Security.

(F) The Administrator, Centers for Medicare and Medicaid Services, Department of Health and Human Services.

(G) The Under Secretary of Defense for Personnel and Readiness.

(H) The Director, Indian Health Service, Department of Health and Human Services.

(I) The Chief, Wireless Telecommunications Bureau, Federal Communications Commission.

(J) A representative of any other Federal agency appointed by the Secretary of Transportation or the Secretary of Homeland Security through the Under Secretary for Emergency Preparedness and Response, in consultation with the Secretary of Health and Human Services, as having a significant role in relation to the purposes of the Interagency Committee.

(K) A State emergency medical services director appointed by the Secretary.

(3) Purposes

The purposes of the Interagency Committee are as follows:

(A) To ensure coordination among the Federal agencies involved with State, local, tribal, or regional emergency medical services and 9–1–1 systems.

(B) To identify State, local, tribal, or regional emergency medical services and 9–1–1 needs.

(C) To recommend new or expanded programs, including grant programs, for improving State, local, tribal, or regional emergency medical services and implementing improved emergency medical services communications technologies, including wireless 9–1–1.

(D) To identify ways to streamline the process through which Federal agencies support State, local, tribal or regional emergency medical services.

(E) To assist State, local, tribal or regional emergency medical services in setting priorities based on identified needs.

(F) To advise, consult, and make recommendations on matters relating to the implementation of the coordinated State emergency medical services programs.

(4) Administration

The Administrator of the National Highway Traffic Safety Administration, in cooperation with the Administrator of the Health Resources and Services Administration of the Department of Health and Human Services and the Director of the Preparedness Division, Directorate of Emergency Preparedness and Response of the Department of Homeland Security, shall provide administrative support to the Interagency Committee, including scheduling meetings, setting agendas, keeping minutes and records, and producing reports.

(5) Leadership

The members of the Interagency Committee shall select a chairperson of the Committee each year.

(6) Meetings

The Interagency Committee shall meet as frequently as is determined necessary by the chairperson of the Committee.

(7) Annual reports

The Interagency Committee shall prepare an annual report to Congress regarding the Committee's activities, actions, and recommendations.

(b) National Emergency Medical Services Advisory Council

(1) Establishment

The Secretary of Transportation, in coordination with the Secretary of Health and Human Services and the Secretary of Homeland Security, shall establish a National Emergency Medical Services Advisory Council (referred to in this subsection as the "Advisory Council").

(2) Membership

The Advisory Council shall be composed of 25 members, who—

(A) shall be appointed by the Secretary of Transportation; and

(B) shall collectively be representative of all sectors of the emergency medical services community.

(3) Purposes

The purposes of the Advisory Council are to advise and consult with—

(A) the Federal Interagency Committee on Emergency Medical Services on matters relating to emergency medical services issues; and

(B) the Secretary of Transportation on matters relating to emergency medical services issues affecting the Department of Transportation.

(4) Administration

The Administrator of the National Highway Traffic Safety Administration shall provide

administrative support to the Advisory Council, including scheduling meetings, setting agendas, keeping minutes and records, and producing reports.

(5) Leadership

The members of the Advisory Council shall annually select a chairperson of the Advisory Council.

(6) Meetings

The Advisory Council shall meet as frequently as is determined necessary by the chairperson of the Advisory Council.

(7) Annual reports

The Advisory Council shall prepare an annual report to the Secretary of Transportation regarding the Advisory Council's actions and recommendations.

(Pub. L. 109–59, title X, §10202, Aug. 10, 2005, 119 Stat. 1932; Pub. L. 112–141, div. C, title I, §31108, July 6, 2012, 126 Stat. 756.)

EDITORIAL NOTES

CODIFICATION

Section was enacted as part of the Safe, Accountable, Flexible, Efficient Transportation Equity Act: A Legacy for Users or SAFETEA–LU, and not as part of the Public Health Service Act which comprises this chapter.

PRIOR PROVISIONS

A prior section 300d–4, act July 1, 1944, ch. 373, title XII, §1201, formerly §1205, as added Nov. 16, 1973, Pub. L. 93–154, §2(a), 87 Stat. 597; amended Oct. 21, 1976, Pub. L. 94–573, §6, 90 Stat. 2713, renumbered §1201 and amended Aug. 13, 1981, Pub. L. 97–35, title IX, §902(d)(1), (3), 95 Stat. 560, authorized Secretary to make grants and enter into contracts to support research in emergency medical techniques, methods, devices, and delivery, prior to repeal by Pub. L. 99–117, §12(e), Oct. 7, 1985, 99 Stat. 495.

AMENDMENTS

2012—Subsec. (b). Pub. L. 112–141 added subsec. (b).

STATUTORY NOTES AND RELATED SUBSIDIARIES

EFFECTIVE DATE OF 2012 AMENDMENT

Amendment by Pub. L. 112–141 effective Oct. 1, 2012, see section 3(a) of Pub. L. 112–141, set out as an Effective and Termination Dates of 2012 Amendment note under section 101 of Title 23, Highways.

§300d–5. Competitive grants for trauma systems for the improvement of trauma care

(a) In general

The Secretary, acting through the Assistant Secretary for Preparedness and Response, may make grants to States, political subdivisions, or consortia of States or political subdivisions for the purpose of improving access to and enhancing the development of trauma care systems.

(b) Use of funds

The Secretary may make a grant under this section only if the applicant agrees to use the grant—

(1) to integrate and broaden the reach of a trauma care system, such as by developing innovative protocols to increase access to prehospital care;

(2) to strengthen, develop, and improve an existing trauma care system;

(3) to expand communications between the trauma care system and emergency medical services through improved equipment or a telemedicine system;

(4) to improve data collection and retention; or

(5) to increase education, training, and technical assistance opportunities, such as training and continuing education in the management of emergency medical services accessible to emergency medical personnel in rural areas through telehealth, home studies, and other methods.

(c) Preference

In selecting among States, political subdivisions, and consortia of States or political subdivisions for purposes of making grants under this section, the Secretary shall give preference to applicants that—

(1) have developed a process, using national standards, for designating trauma centers;

(2) recognize protocols for the delivery of seriously injured patients to trauma centers;

(3) implement a process for evaluating the performance of the trauma system; and

(4) agree to participate in information systems described in section 300d–3 of this title by collecting, providing, and sharing information.

(d) Priority

In making grants under this section, the Secretary shall give priority to applicants that will use the grants to focus on improving access to trauma care systems.

(e) Special consideration

In awarding grants under this section, the Secretary shall give special consideration to projects that demonstrate strong State or local support, including availability of non-Federal contributions.

(July 1, 1944, ch. 373, title XII, §1203, as added Pub. L. 110–23, §5, May 3, 2007, 121 Stat. 91; amended Pub. L. 111–148, title III, §3504(a)(1), Mar. 23, 2010, 124 Stat. 518.)

EDITORIAL NOTES

PRIOR PROVISIONS

A prior section 300d–5, act July 1, 1944, ch. 373, title XII, §1206, as added Nov. 16, 1973, Pub. L. 93–154, §2(a), 87 Stat. 598; amended Oct. 21, 1976, Pub. L. 94–573, §§7, 14(2), 90 Stat. 2713, 2718; Nov. 10, 1978, Pub. L. 95–626, title II, §210(c), 92 Stat. 3588; Dec. 12, 1979, Pub. L. 96–142, title I, §104(c), 93 Stat. 1068, set forth general provisions respecting grants and contracts, prior to repeal by Pub. L. 97–35, title IX, §902(d)(1), (h), Aug. 13, 1981, 95 Stat. 560, 561, effective Oct. 1, 1981.

A prior section 1203 of act July 1, 1994, was renumbered section 1202 and is classified to section 300d–3 of this title.

Another prior section 1203 of act July 1, 1994, was renumbered section 1202 and was classified to section 300d–2 of this title prior to repeal by Pub. L. 110–23.

AMENDMENTS

2010—Pub. L. 111–148 inserted "for trauma systems" after "grants" in section catchline and substituted "Assistant Secretary for Preparedness and Response" for "Administrator of the Health Resources and Services Administration" in subsec. (a).

§300d–6. Competitive grants for trauma centers

(a) In general

The Secretary, acting through the Assistant Secretary for Preparedness and Response, shall award not fewer than 4 multiyear contracts or competitive grants to eligible entities to support pilot projects to design, implement, and evaluate new or existing innovative models of regionalized, comprehensive, and accountable emergency medical and trauma systems, and improve access to trauma care within such systems.

(b) Eligible entity; region

In this section:

(1) Eligible entity

The term "eligible entity" means—

(A) a State or consortia of States;

(B) an Indian Tribe or Tribal organization (as defined in section 5304 of title 25);

(C) a consortium of level I, II, or III trauma centers designated by applicable State or local agencies within an applicable State or region, and, as applicable, other emergency services providers; or

(D) a consortium or partnership of nonprofit Indian Health Service, Indian Tribal, and urban Indian trauma centers.

(2) Region

The term "region" means an area within a State, an area that lies within multiple States, or a similar area (such as a multicounty area), as determined by the Secretary.

(3) Emergency services

The term "emergency services" includes acute, prehospital, and trauma care.

(c) Pilot projects

The Secretary shall award a contract or grant under subsection (a) to an eligible entity to design, implement, and evaluate a new or existing emergency medical and trauma system. Such eligible entity shall use amounts awarded under this subsection to carry out 2 or more of the following activities:

(1) Strengthening coordination and communication with public health and safety services, emergency medical services, medical facilities, trauma centers, and other entities in a region to develop approaches to improve situational awareness and emergency medical and trauma system access.

(2) Providing a mechanism, such as a regional medical direction or transport communications system, that operates throughout the region to support patient movement to ensure that the patient is taken to the medically appropriate facility (whether an initial facility or a higher-level facility) in a timely fashion.

(3) Improving the tracking of prehospital and hospital resources, including inpatient bed capacity, emergency department capacity, trauma center capacity, on-call specialist coverage, ambulance diversion status, and the coordination of such tracking with regional communications and hospital destination decisions.

(4) Supporting a consistent region-wide prehospital, hospital, and interfacility data management system that—

(A) submits data to the National EMS Information System, the National Trauma Data Bank, and others;

(B) reports data to appropriate Federal and State databanks and registries; and

(C) contains information sufficient to evaluate key elements of prehospital care, hospital destination decisions, including initial hospital and interfacility decisions, and relevant health outcomes of hospital care.

(5) Establishing, implementing, and disseminating, or utilizing existing, as applicable, evidence-based or evidence-informed practices across facilities within such emergency medical and trauma system to improve health outcomes, including such practices related to management of injuries, and the ability of such facilities to surge.

(6) Conducting activities to facilitate clinical research, as applicable and appropriate.

(d) Application

(1) In general

An eligible entity that seeks a contract or grant described in subsection (a) shall submit to the Secretary an application at such time and in such manner as the Secretary may require.

(2) Application information

Each application shall include—

(A) an assurance from the eligible entity that the applicable emergency medical and trauma system system— [1]

(i) has been coordinated with the applicable State Office of Emergency Medical Services (or equivalent State office or Tribal entity);

(ii) includes consistent indirect and direct medical oversight of prehospital, hospital, and interfacility transport throughout the region;

(iii) coordinates prehospital treatment and triage, hospital destination, and interfacility transport throughout the region;

(iv) includes a categorization or designation system for special medical facilities throughout the region that is integrated with transport and destination protocols;

(v) includes a regional medical direction, patient tracking, and resource allocation system that supports day-to-day emergency care and surge capacity and is integrated with other components of the national and State emergency preparedness system; and

(vi) addresses pediatric concerns related to integration, planning, preparedness, and coordination of emergency medical services for infants, children and adolescents;

(B) for eligible entities described in subparagraph (C) or (D) of subsection (b)(1), a description of, and evidence of, coordination with the applicable State Office of Emergency Medical Services (or equivalent State Office) or applicable such office for a Tribe or Tribal organization; and

(C) such other information as the Secretary may require.

(e) Requirement of matching funds

(1) In general

The Secretary may not make a grant under this section unless the State (or consortia of States) involved agrees, with respect to the costs to be incurred by the State (or consortia) in carrying out the purpose for which such grant was made, to make available non-Federal contributions (in cash or in kind under paragraph (2)) toward such costs in an amount equal to not less than $1 for each $3 of Federal funds provided in the grant. Such contributions may be made directly or through donations from public or private entities.

(2) Non-Federal contributions

Non-Federal contributions required in paragraph (1) may be in cash or in kind, fairly evaluated, including equipment or services (and excluding indirect or overhead costs). Amounts provided by the Federal Government, or services assisted or subsidized to any significant extent by the Federal Government, may not be included in determining the amount of such non-Federal contributions.

(3) Effective date

The matching requirement described in paragraph (1) shall take effect on October 1, 2025.

(f) Priority

The Secretary shall give priority for the award of the contracts or grants described in subsection (a) to any eligible entity that serves a medically underserved population (as defined in section 254b(b)(3) of this title).

(g) Report

Not later than 90 days after the completion of a pilot project under subsection (a), the recipient of such contract or grant shall submit to the Secretary a report containing the results of an evaluation of the program, including an identification of—

(1) the impact of the regional, accountable emergency care and trauma system on patient health outcomes for various critical care categories, such as trauma, stroke, cardiac emergencies, neurological emergencies, and pediatric emergencies;

(2) opportunities for improvement, including recommendations for how to improve the effectiveness and efficiency of the program (or lack thereof);

(3) methods of assuring the long-term financial sustainability of the emergency care and trauma system;

(4) the barriers to developing regionalized, accountable emergency care and trauma systems, as well as the methods to overcome such barriers;

(5) recommendations on the utilization of available funding for future regionalization efforts; and

(6) any evidence-based or evidence-informed strategies developed or utilized pursuant to subsection (c)(5).

(h) Dissemination of findings

Not later than 1 year after the completion of the final project under subsection (a), the Secretary shall submit to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives a report describing the information contained in each report submitted pursuant to subsection (g) and any additional actions planned by the Secretary related to regionalized emergency care and trauma systems.

(July 1, 1944, ch. 373, title XII, §1204, as added Pub. L. 111–148, title III, §3504(a)(2), Mar. 23, 2010, 124 Stat. 518; amended Pub. L. 117–328, div. FF, title II, §2113(c), Dec. 29, 2022, 136 Stat. 5724.)

EDITORIAL NOTES

PRIOR PROVISIONS

A prior section 300d–6, act July 1, 1944, ch. 373, title XII, §1202, formerly §1207, as added Nov. 16, 1973, Pub. L. 93–154, §2(a), 87 Stat. 602; amended Oct. 21, 1976, Pub. L. 94–573, §8, 90 Stat. 2714; Nov. 10, 1978, Pub. L. 95–626, title II, §210(d), 92 Stat. 3588; Dec. 12, 1979, Pub. L. 96–142, title I, §105, 93 Stat. 1068; renumbered §1202 and amended Aug. 13, 1981, Pub. L. 97–35, title IX, §902(d)(1), (4), 95 Stat. 560, authorized appropriations for purposes of this subchapter, prior to repeal by Pub. L. 99–117, §12(e), Oct. 7, 1985, 99 Stat. 495.

A prior section 1204 of act July 1, 1944, was classified to section 300d–3 of this title prior to repeal by Pub. L. 97–35.

Prior sections 300d–7 to 300d–9 were repealed by Pub. L. 97–35, title IX, §902(d)(1), (h), Aug. 13, 1981, 95 Stat. 560, 561, effective Oct. 1, 1981.

Section 300d–7, act July 1, 1944, ch. 373, title XII, §1208, as added Nov. 16, 1973, Pub. L. 93–154, §2(a), 87 Stat. 602; amended Oct. 12, 1976, Pub. L. 94–484, title VIII, §801(b), 90 Stat. 2322; Oct. 21, 1976, Pub. L. 94–573, §9, 90 Stat. 2715, set forth provisions relating to administration of emergency medical services administrative unit.

Section 300d–8, act July 1, 1944, ch. 373, title XII, §1209, as added Nov. 16, 1973, Pub. L. 93–154, §2(a), 87 Stat. 602; amended Oct. 21, 1976, Pub. L. 94–573, §10, 90 Stat. 2716; Oct. 17, 1979, Pub. L. 96–88, title V, §509(b), 93 Stat. 695; Dec. 12, 1979, Pub. L. 96–142, title I, §106, 93 Stat. 1069, related to Interagency Committee on Emergency Medical Services.

Section 300d–9, act July 1, 1944, ch. 373, title XII, §1210, as added Nov. 16, 1973, Pub. L. 93–154, §2(a), 87 Stat. 603; amended Oct. 21, 1976, Pub. L. 94–573, §11, 90 Stat. 2717, related to annual report to Congress.

AMENDMENTS

2022—Pub. L. 117–328, §2113(c)(1), amended section catchline generally. Prior to amendment, section catchline read as follows: "Competitive grants for regionalized systems for emergency care response".

Subsec. (a). Pub. L. 117–328, §2113(c)(2), substituted "to design, implement, and evaluate new or existing" for "that design, implement, and evaluate" and "emergency medical" for "emergency care" and inserted ", and improve access to trauma care within such systems" before period at end.

Subsec. (b)(1). Pub. L. 117–328, §2113(c)(3), added subpars. (A) to (D) and struck out former subpars. (A) and (B) which read as follows:

"(A) a State or a partnership of 1 or more States and 1 or more local governments; or

"(B) an Indian tribe (as defined in section 1603 of title 25) or a partnership of 1 or more Indian tribes."

Subsec. (c). Pub. L. 117–328, §2113(c)(4)(A), struck out "that proposes a pilot project" after "an eligible entity" and substituted "a new or existing emergency medical and trauma system. Such eligible entity shall use amounts awarded under this subsection to carry out 2 or more of the following activities:" for "an emergency

medical and trauma system that—" in introductory provisions.

Subsec. (c)(1). Pub. L. 117–328, §2113(c)(4)(B), substituted "Strengthening coordination and communication" for "coordinates" and "approaches to improve situational awareness and emergency medical and trauma system access." for "an approach to emergency medical and trauma system access throughout the region, including 9–1–1 Public Safety Answering Points and emergency medical dispatch;".

Subsec. (c)(2). Pub. L. 117–328, §2113(c)(4)(C), substituted "Providing" for "includes" and "fashion." for "fashion;" and inserted "support patient movement to" after "region to".

Subsec. (c)(3). Pub. L. 117–328, §2113(c)(4)(D), substituted "Improving" for "allows for" and "decisions." for "decisions; and".

Subsec. (c)(4). Pub. L. 117–328, §2113(c)(4)(E), substituted "Supporting a consistent" for "includes a consistent" in introductory provisions.

Subsec. (c)(5), (6). Pub. L. 117–328, §2113(c)(4)(F), added pars. (5) and (6).

Subsec. (d)(2)(A). Pub. L. 117–328, §2113(c)(5)(A)(i), substituted "the applicable emergency medical and trauma system" for "the proposed" in introductory provisions.

Subsec. (d)(2)(A)(i). Pub. L. 117–328, §2113(c)(5)(A)(ii), inserted "or Tribal entity" after "equivalent State office".

Subsec. (d)(2)(B), (C). Pub. L. 117–328, §2113(c)(5)(A)(iii)–(C), added subpar. (B) and redesignated former subpar. (B) as (C).

Subsec. (e)(3). Pub. L. 117–328, §2113(c)(6), added par. (3).

Subsec. (f). Pub. L. 117–328, §2113(c)(7), substituted "medically underserved population" for "population in a medically underserved area".

Subsec. (g). Pub. L. 117–328, §2113(c)(8)(A), struck out "described in" after "grant" in introductory provisions.

Subsec. (g)(2). Pub. L. 117–328, §2113(c)(8)(B), substituted "opportunities for improvement, including recommendations for how to improve" for "the system characteristics that contribute to".

Subsec. (g)(4) to (6). Pub. L. 117–328, §2113(c)(8)(C)–(G), added par. (6), redesignated former pars. (5) and (6) as (4) and (5), respectively, and struck out former par. (4) which read as follows: "the State and local legislation necessary to implement and to maintain the system;".

Subsec. (h). Pub. L. 117–328, §2113(c)(9), amended subsec. (h) generally. Prior to amendment, text read as follows: "The Secretary shall, as appropriate, disseminate to the public and to the appropriate Committees of the Congress, the information contained in a report made under subsection (g)."

[1] *So in original.*

PART B—FORMULA GRANTS WITH RESPECT TO MODIFICATIONS OF STATE PLANS

§300d–11. Establishment of program

(a) Requirement of allotments for States

The Secretary shall for each fiscal year make an allotment for each State in an amount determined in accordance with section 300d–18 of this title. The Secretary shall make payments, as grants, each fiscal year to each State from the allotment for the State if the Secretary approves for the fiscal year involved an application submitted by the State pursuant to section 300d–17 of this title.

(b) Purpose

Except as provided in section 300d–33 [1] of this title, the Secretary may not make payments under this part for a fiscal year unless the State involved agrees that, with respect to the trauma care component of the State plan for the provision of emergency medical services, the payments will be expended only for the purpose of developing, implementing, and monitoring the modifications to such component described in section 300d–13 of this title.

(July 1, 1944, ch. 373, title XII, §1211, as added Pub. L. 101–590, §3, Nov. 16, 1990, 104 Stat. 2919.)

EDITORIAL NOTES

REFERENCES IN TEXT

Section 300d–33 of this title, referred to in subsec. (b), was repealed by Pub. L. 103–183, title VI, §601(e), Dec. 14, 1993, 107 Stat. 2239.

[1] *See References in Text note below.*

§300d–12. Requirement of matching funds for fiscal years subsequent to first fiscal year of payments

(a) Non-Federal contributions

(1) In general

The Secretary may not make payments under section 300d–11(a) of this title unless the State involved agrees, with respect to the costs described in paragraph (2), to make available non-Federal contributions (in cash or in kind under subsection (b)(1)) toward such costs in an amount that—

(A) for the second and third fiscal years of such payments to the State, is not less than $1 for each $1 of Federal funds provided in such payments for such fiscal years; and

(B) for the fourth and subsequent fiscal years of such payments to the State, is not less than $2 for each $1 of Federal funds provided in such payments for such fiscal years.

(2) Program costs

The costs referred to in paragraph (1) are—

(A) the costs to be incurred by the State in carrying out the purpose described in section 300d–11(b) of this title; or

(B) the costs of improving the quality and availability of emergency medical services in rural areas of the State.

(3) Initial year of payments

The Secretary may not require a State to make non-Federal contributions as a condition of receiving payments under section 300d–11(a) of this title for the first fiscal year of such payments to the State.

(b) Determination of amount of non-Federal contribution

With respect to compliance with subsection (a) as a condition of receiving payments under section 300d–11(a) of this title—

(1) a State may make the non-Federal contributions required in such subsection in cash or in kind, fairly evaluated, including plant, equipment, or services; and

(2) the Secretary may not, in making a determination of the amount of non-Federal contributions, include amounts provided by the Federal Government or services assisted or subsidized to any significant extent by the Federal Government.

(July 1, 1944, ch. 373, title XII, §1212, as added Pub. L. 101–590, §3, Nov. 16, 1990, 104 Stat. 2919; amended Pub. L. 103–183, title VI, §601(f)(2), Dec. 14, 1993, 107 Stat. 2239; Pub. L. 110–23, §6, May 3, 2007, 121 Stat. 92.)

EDITORIAL NOTES

AMENDMENTS

2007—Pub. L. 110–23 amended section generally. Prior to amendment, section related to requirement of matching funds for fiscal years subsequent to first fiscal year of payments.

1993—Subsec. (a)(2)(A). Pub. L. 103–183 substituted "section 300d–11(b)" for "section 300d–11(c)".

§300d–13. Requirements with respect to carrying out purpose of allotments

(a) Trauma care modifications to State plan for emergency medical services

With respect to the trauma care component of a State plan for the provision of emergency medical services, the modifications referred to in section 300d–11(b) of this title are such modifications to the State plan as may be necessary for the State involved to ensure that the plan provides for access to the highest possible quality of trauma care, and that the plan—

(1) specifies that the modifications required pursuant to paragraphs (2) through (11) will be implemented by the principal State agency with respect to emergency medical services or by the designee of such agency;

(2) specifies a public or private entity that will designate trauma care regions and trauma centers in the State;

(3) subject to subsection (b), contains national standards and requirements of the American College of Surgeons or another appropriate entity for the designation of level I and level II trauma centers, and in the case of rural areas level III trauma centers (including trauma centers with specified capabilities and expertise in the care of pediatric trauma patients), by such entity, including standards and requirements for—

(A) the number and types of trauma patients for whom such centers must provide care in order to ensure that such centers will have sufficient experience and expertise to be able to provide quality care for victims of injury;

(B) the resources and equipment needed by such centers; and

(C) the availability of rehabilitation services for trauma patients;

(4) contains standards and requirements for the implementation of regional trauma care systems, including standards and guidelines (consistent with the provisions of section 1395dd of this title) for medically directed triage and transportation of trauma patients (including patients injured in rural areas) prior to care in designated trauma centers;

(5) subject to subsection (b), contains national standards and requirements, including those of the American Academy of Pediatrics and the American College of Emergency Physicians, for medically directed triage and transport of severely injured children to designated trauma centers with specified capabilities and expertise in the care of pediatric trauma patients;

(6) utilizes a program with procedures for the evaluation of designated trauma centers (including trauma centers described in paragraph (5)) and trauma care systems;

(7) provides for the establishment and collection of data in accordance with data collection requirements developed in consultation with surgical, medical, and nursing specialty groups, State and local emergency medical services directors, and other trained professionals in trauma care, from each designated trauma center in the State of a central data reporting and analysis system—

(A) to identify the number of severely injured trauma patients and the number of deaths from trauma within trauma care systems in the State;

(B) to identify the cause of the injury and any factors contributing to the injury;

(C) to identify the nature and severity of the injury;

(D) to monitor trauma patient care (including prehospital care) in each designated trauma center within regional trauma care systems in the State (including relevant emergency-department discharges and rehabilitation information) for the purpose of evaluating the diagnosis, treatment, and treatment outcome of such trauma patients;

(E) to identify the total amount of uncompensated trauma care expenditures for each fiscal year by each designated trauma center in the State; and

(F) to identify patients transferred within a regional trauma system, including reasons for such transfer and the outcomes of such patients;

(8) provides for the use of procedures by paramedics and emergency medical technicians to assess the severity of the injuries incurred by trauma patients;

(9) provides for appropriate transportation and transfer policies to ensure the delivery of patients to designated trauma centers and other facilities within and outside of the jurisdiction of such system, including policies to ensure that only individuals appropriately identified as trauma patients are transferred to designated trauma centers, and to provide periodic reviews of the transfers and the auditing of such transfers that are determined to be appropriate;

(10) conducts public education activities concerning injury prevention and obtaining access to trauma care;

(11) coordinates planning for trauma systems with State disaster emergency planning and bioterrorism hospital preparedness planning; and

(12) with respect to the requirements established in this subsection, provides for coordination and cooperation between the State and any other State with which the State shares any standard metropolitan statistical area.

(b) Certain standards with respect to trauma care centers and systems

(1) In general

The Secretary may not make payments under section 300d–11(a) of this title for a fiscal year unless the State involved agrees that, in carrying out paragraphs (3) through (5) of subsection (a), the State will adopt standards for the designation of trauma centers, and for triage, transfer, and transportation policies, and that the State will, in adopting such standards—

(A) take into account national standards that outline resources for optimal care of injured patients;

(B) consult with medical, surgical, and nursing speciality groups, hospital associations, emergency medical services State and local directors, concerned advocates, and other interested parties;

(C) conduct hearings on the proposed standards after providing adequate notice to the public concerning such hearing; and

(D) beginning in fiscal year 2008, take into account the model plan described in subsection (c).

(2) Quality of trauma care

The highest quality of trauma care shall be the primary goal of State standards adopted under this subsection.

(3) Approval by the Secretary

The Secretary may not make payments under section 300d–11(a) of this title to a State if the Secretary determines that—

(A) in the case of payments for fiscal year 2008 and subsequent fiscal years, the State has not taken into account national standards, including those of the American College of Surgeons, the American College of Emergency Physicians, and the American Academy of Pediatrics, in adopting standards under this subsection; or

(B) in the case of payments for fiscal year 2008 and subsequent fiscal years, the State has not, in adopting such standards, taken into account the model plan developed under subsection (c).

(c) Model trauma care plan

(1) In general

Not later than 1 year after May 3, 2007, the Secretary shall update the model plan for the designation of trauma centers and for triage, transfer, and transportation policies that may be adopted for guidance by the State. Such plan shall—

(A) take into account national standards, including those of the American College of Surgeons, American College of Emergency Physicians, and the American Academy of Pediatrics;

(B) take into account existing State plans;

(C) be developed in consultation with medical, surgical, and nursing speciality groups, hospital associations, emergency medical services State directors and associations, and other interested parties; and

(D) include standards for the designation of rural health facilities and hospitals best able to receive, stabilize, and transfer trauma patients to the nearest appropriate designated trauma center, and for triage, transfer, and transportation policies as they relate to rural areas.

(2) Applicability

Standards described in paragraph (1)(D) shall be applicable to all rural areas in the State, including both non-metropolitan areas and frontier areas that have populations of less than 6,000 per square mile.

(d) Rule of construction with respect to number of designated trauma centers

With respect to compliance with subsection (a) as a condition of the receipt of a grant under section 300d–11(a) of this title, such subsection may not be construed to specify the number of trauma care centers designated pursuant to such subsection.

(July 1, 1944, ch. 373, title XII, §1213, as added Pub. L. 101–590, §3, Nov. 16, 1990, 104 Stat. 2920; amended Pub. L. 103–183, title VI, §601(f)(3), Dec. 14, 1993, 107 Stat. 2239; Pub. L. 105–392, title IV, §401(b)(4), Nov. 13, 1998, 112 Stat. 3587; Pub. L. 110–23, §7, May 3, 2007, 121 Stat. 93.)

EDITORIAL NOTES

AMENDMENTS

2007—Pub. L. 110–23 amended section generally. Prior to amendment, section related to requirements with respect to carrying out purpose of allotments.

1998—Subsec. (a)(8). Pub. L. 105–392 substituted "provides for" for "provides for for".

1993—Subsec. (a)(4). Pub. L. 103–183, §601(f)(3)(A), substituted "section 1395dd of this title)" for "section 1395dd of this title".

Subsec. (a)(8), (9). Pub. L. 103–183, §601(f)(3)(B), substituted "provides for" for "to provide" wherever appearing.

Subsec. (a)(10). Pub. L. 103–183, §601(f)(3)(C), substituted "conducts" for "to conduct".

STATUTORY NOTES AND RELATED SUBSIDIARIES

EFFECTIVE DATE OF 1998 AMENDMENT

Amendment by Pub. L. 105–392 deemed to have taken effect immediately after enactment of Pub. L. 103–183, see section 401(e) of Pub. L. 105–392, set out as a note under section 242m of this title.

§300d–14. Requirement of submission to Secretary of trauma plan and certain information

(a) In general

For each fiscal year, the Secretary may not make payments to a State under section 300d–11(a) of this title unless, subject to subsection (b), the State submits to the Secretary the trauma care component of the State plan for the provision of emergency medical services, including any changes to the trauma care component and any plans to address deficiencies in the trauma care component.

(b) Interim plan or description of efforts

For each fiscal year, if a State has not completed the trauma care component of the State plan described in subsection (a), the State may provide, in lieu of such completed component, an interim component or a description of efforts made toward the completion of the component.

(c) Information received by State reporting and analysis system

The Secretary may not make payments to a State under section 300d–11(a) of this title unless the

State agrees that the State will, not less than once each year, provide to the Secretary the information received by the State pursuant to section 300d–13(a)(7) of this title.

(d) Availability of emergency medical services in rural areas

The Secretary may not make payments to a State under section 300d–11(a) of this title unless—

(1) the State identifies any rural area in the State for which—

(A) there is no system of access to emergency medical services through the telephone number 911;

(B) there is no basic life-support system; or

(C) there is no advanced life-support system; and

(2) the State submits to the Secretary a list of rural areas identified pursuant to paragraph (1) or, if there are no such areas, a statement that there are no such areas.

(July 1, 1944, ch. 373, title XII, §1214, as added Pub. L. 101–590, §3, Nov. 16, 1990, 104 Stat. 2922; amended Pub. L. 110–23, §8, May 3, 2007, 121 Stat. 96.)

EDITORIAL NOTES

AMENDMENTS

2007—Pub. L. 110–23 amended section generally. Prior to amendment, section related to requirement of submission to Secretary of trauma plan and certain information for fiscal year 1991 and subsequent fiscal years.

§300d–15. Restrictions on use of payments

(a) In general

The Secretary may not, except as provided in subsection (b), make payments under section 300d–11(a) of this title for a fiscal year unless the State involved agrees that the payments will not be expended—

(1) for any purpose other than developing, implementing, and monitoring the modifications required by section 300d–11(b) of this title to be made to the State plan for the provision of emergency medical services;

(2) to make cash payments to intended recipients of services provided pursuant to this section;

(3) to purchase or improve real property (other than minor remodeling of existing improvements to real property);

(4) to satisfy any requirement for the expenditure of non-Federal funds as a condition for the receipt of Federal funds; or

(5) to provide financial assistance to any entity other than a public or nonprofit private entity.

(b) Waiver

The Secretary may waive a restriction under subsection (a) only if the Secretary determines that the activities outlined by the State plan submitted under section 300d–14(a) of this title by the State involved cannot otherwise be carried out.

(July 1, 1944, ch. 373, title XII, §1215, as added Pub. L. 101–590, §3, Nov. 16, 1990, 104 Stat. 2923; amended Pub. L. 110–23, §9, May 3, 2007, 121 Stat. 97.)

EDITORIAL NOTES

AMENDMENTS

2007—Pub. L. 110–23 amended section generally. Prior to amendment, section related to restrictions on use of payments.

§300d–16. Repealed. Pub. L. 110–23, §10, May 3, 2007, 121 Stat. 97

Section, act July 1, 1944, ch. 373, title XII, §1216, as added Pub. L. 101–590, §3, Nov. 16, 1990, 104 Stat. 2923; amended Pub. L. 103–183, title VI, §601(c), Dec. 14, 1993, 107 Stat. 2238; Pub. L. 104–316, title I, §122(d), Oct. 19, 1996, 110 Stat. 3837, provided for requirement of reports by States.

§300d–17. Requirement of submission of application containing certain agreements and assurances

The Secretary may not make payments under section 300d–11(a) of this title to a State for a fiscal year unless—

(1) the State submits to the Secretary an application for the payments containing agreements in accordance with this part;

(2) the agreements are made through certification from the chief executive officer of the State;

(3) with respect to such agreements, the application provides assurances of compliance satisfactory to the Secretary;

(4) the application contains the plan provisions and the information required to be submitted to the Secretary pursuant to section 300d–14 of this title; and

(5) the application otherwise is in such form, is made in such manner, and contains such agreements, assurances, and information as the Secretary determines to be necessary to carry out this part.

(July 1, 1944, ch. 373, title XII, §1217, as added Pub. L. 101–590, §3, Nov. 16, 1990, 104 Stat. 2924.)

§300d–18. Determination of amount of allotment

(a) Minimum allotment

Subject to the extent of amounts made available in appropriations Acts, the amount of an allotment under section 300d–11(a) of this title for a State for a fiscal year shall be the greater of—

(1) the amount determined under subsection (b)(1); and

(2) $250,000 in the case of each of the several States, the District of Columbia, and the Commonwealth of Puerto Rico, and $50,000 in the case of each of the Virgin Islands, Guam, American Samoa, and the Commonwealth of the Northern Mariana Islands.

(b) Determination under formula

(1) In general

The amount referred to in subsection (a)(1) for a State for a fiscal year is the sum of—

(A) an amount determined under paragraph (2); and

(B) an amount determined under paragraph (3).

(2) Amount relating to population

The amount referred to in subparagraph (A) of paragraph (1) for a State for a fiscal year is the product of—

(A) an amount equal to 80 percent of the amounts appropriated under section 300d–32(a) of this title for the fiscal year and available for allotment under section 300d–11(a) of this title; and

(B) a percentage equal to the quotient of—

(i) an amount equal to the population of the State; divided by

(ii) an amount equal to the population of all States.

(3) Amount relating to square mileage

The amount referred to in subparagraph (B) of paragraph (1) for a State for a fiscal year is the product of—

(A) an amount equal to 20 percent of the amounts appropriated under section 300d–32(a) of

this title for the fiscal year and available for allotment under section 300d–11(a) of this title; and

(B) a percentage equal to the quotient of—

(i) an amount equal to the lesser of 266,807 and the amount of the square mileage of the State; divided by

(ii) an amount equal to the sum of the respective amounts determined for the States under clause (i).

(c) Disposition of certain funds appropriated for allotments

(1) In general

Amounts described in paragraph (2) shall, in accordance with paragraph (3), be allotted by the Secretary to States receiving payments under section 300d–11(a) of this title for the fiscal year (other than any State referred to in paragraph (2)(C)).

(2) Type of amounts

The amounts referred to in paragraph (1) are any amounts made available pursuant to 300d–32(b)(3) of this title that are not paid under section 300d–11(a) of this title to a State as a result of—

(A) the failure of the State to submit an application under section 300d–17 of this title;

(B) the failure, in the determination of the Secretary, of the State to prepare within a reasonable period of time such application in compliance with such section; or

(C) the State informing the Secretary that the State does not intend to expend the full amount of the allotment made for the State.

(3) Amount

The amount of an allotment under paragraph (1) for a State for a fiscal year shall be an amount equal to the product of—

(A) an amount equal to the amount described in paragraph (2) for the fiscal year involved; and

(B) the percentage determined under subsection (b)(2) for the State.

(July 1, 1944, ch. 373, title XII, §1218, as added Pub. L. 101–590, §3, Nov. 16, 1990, 104 Stat. 2924.)

§300d–19. Failure to comply with agreements

(a) Repayment of payments

(1) Requirement

The Secretary may, in accordance with subsection (b), require a State to repay any payments received by the State pursuant to section 300d–11(a) of this title that the Secretary determines were not expended by the State in accordance with the agreements required to be made by the State as a condition of the receipt of payments under such section.

(2) Offset of amounts

If a State fails to make a repayment required in paragraph (1), the Secretary may offset the amount of the repayment against any amount due to be paid to the State under section 300d–11(a) of this title.

(b) Opportunity for hearing

Before requiring repayment of payments under subsection (a)(1), the Secretary shall provide to the State an opportunity for a hearing.

(July 1, 1944, ch. 373, title XII, §1219, as added Pub. L. 101–590, §3, Nov. 16, 1990, 104 Stat. 2925.)

§300d–20. Prohibition against certain false statements

(a) In general

(1) False statements or representations

A person may not knowingly and willfully make or cause to be made any false statement or representation of a material fact in connection with the furnishing of items or services for which payments may be made by a State from amounts paid to the State under section 300d–11(a) of this title.

(2) Concealing or failing to disclose information

A person with knowledge of the occurrence of any event affecting the right of the person to receive any payments from amounts paid to the State under section 300d–11(a) of this title may not conceal or fail to disclose any such event with the intent of fraudulently securing such amount.

(b) Criminal penalty for violation of prohibition

Any person who violates a prohibition established in subsection (a) may for each violation be fined in accordance with title 18, or imprisoned for not more than 5 years, or both.

(July 1, 1944, ch. 373, title XII, §1220, as added Pub. L. 101–590, §3, Nov. 16, 1990, 104 Stat. 2925.)

§300d–21. Technical assistance and provision by Secretary of supplies and services in lieu of grant funds

(a) Technical assistance

The Secretary shall, without charge to a State receiving payments under section 300d–11(a) of this title, provide to the State (or to any public or nonprofit private entity designated by the State) technical assistance with respect to the planning, development, and operation of any program carried out pursuant to section 300d–11(b) of this title. The Secretary may provide such technical assistance directly, through contract, or through grants.

(b) Provision by Secretary of supplies and services in lieu of grant funds

(1) In general

Upon the request of a State receiving payments under section 300d–11(a) of this title, the Secretary may, subject to paragraph (2), provide supplies, equipment, and services for the purpose of aiding the State in carrying out section 300d–11(b) of this title and, for such purpose, may detail to the State any officer or employee of the Department of Health and Human Services.

(2) Reduction in payments

With respect to a request described in paragraph (1), the Secretary shall reduce the amount of payments to the State under section 300d–11(a) of this title by an amount equal to the costs of detailing personnel and the fair market value of any supplies, equipment, or services provided by the Secretary. The Secretary shall, for the payment of expenses incurred in complying with such request, expend the amounts withheld.

(July 1, 1944, ch. 373, title XII, §1221, as added Pub. L. 101–590, §3, Nov. 16, 1990, 104 Stat. 2926.)

EDITORIAL NOTES

PRIOR PROVISIONS

A prior section 300d–21, act July 1, 1944, ch. 373, title XII, §1221, as added Oct. 21, 1976, Pub. L. 94–573, §14(3), 90 Stat. 2718; amended Dec. 12, 1979, Pub. L. 96–142, title I, §107(a)–(c), 93 Stat. 1069, related to programs for burn, trauma, and poison injuries, prior to repeal by Pub. L. 97–35, title IX, §902(d)(1), (h), Aug. 13, 1981, 95 Stat. 560, 561, effective Oct. 1, 1981.

§300d–22. Report by Secretary

Not later than October 1, 2008, the Secretary shall report to the appropriate committees of Congress on the activities of the States carried out pursuant to section 300d–11 of this title. Such report shall include an assessment of the extent to which Federal and State efforts to develop systems of trauma care and to designate trauma centers have reduced the incidence of mortality, and the incidence of permanent disability, resulting from trauma. Such report may include any recommendations of the Secretary for appropriate administrative and legislative initiatives with respect to trauma care.

(July 1, 1944, ch. 373, title XII, §1222, as added Pub. L. 101–590, §3, Nov. 16, 1990, 104 Stat. 2926; amended Pub. L. 103–183, title VI, §601(d), Dec. 14, 1993, 107 Stat. 2238; Pub. L. 110–23, §11, May 3, 2007, 121 Stat. 97.)

EDITORIAL NOTES

AMENDMENTS

2007—Pub. L. 110–23 amended section generally. Prior to amendment, section required Secretary to submit report no later than Oct. 1, 1995.

1993—Pub. L. 103–183 substituted "1995" for "1992" and inserted after first sentence "Such report shall include an assessment of the extent to which Federal and State efforts to develop systems of trauma care and to designate trauma centers have reduced the incidence of mortality, and the incidence of permanent disability, resulting from trauma."

PART C—GENERAL PROVISIONS REGARDING PARTS A AND B

§300d–31. Definitions

For purposes of this part and parts A and B:

(1) Designated trauma center

The term "designated trauma center" means a trauma center designated in accordance with the modifications to the State plan described in section 300d–13 of this title.

(2) State plan regarding emergency medical services

The term "State plan", with respect to the provision of emergency medical services, means a plan for a comprehensive, organized system to provide for the access, response, triage, field stabilization, transport, hospital stabilization, definitive care, and rehabilitation of patients of all ages with respect to emergency medical services.

(3) State

The term "State" means each of the several States, the District of Columbia, the Commonwealth of Puerto Rico, the Virgin Islands, Guam, American Samoa, and the Commonwealth of the Northern Mariana Islands.

(4) Trauma

The term "trauma" means an injury resulting from exposure to—

(A) a mechanical force; or

(B) another extrinsic agent, including an extrinsic agent that is thermal, electrical, chemical, or radioactive.

(5) Trauma care component of State plan

The term "trauma care component", with respect to components of the State plan for the provision of emergency medical services, means a plan for a comprehensive health care system, within rural and urban areas of the State, for the prompt recognition, prehospital care, emergency medical care, acute surgical and medical care, rehabilitation, and outcome evaluation of seriously injured patients.

(July 1, 1944, ch. 373, title XII, §1231, as added Pub. L. 101–590, §3, Nov. 16, 1990, 104 Stat. 2926; amended Pub. L. 102–321, title VI, §602(2), July 10, 1992, 106 Stat. 436; Pub. L. 103–183, title VI, §601(f)(4), Dec. 14, 1993, 107 Stat. 2239; Pub. L. 113–152, §2(a), Aug. 8, 2014, 128 Stat. 1825.)

EDITORIAL NOTES

AMENDMENTS

2014—Par. (4). Pub. L. 113–152 amended par. (4) generally. Prior to amendment, text read as follows: "The term 'trauma' means an injury resulting from exposure to a mechanical force."

1993—Par. (3). Pub. L. 103–183 substituted "Puerto Rico," for "Puerto Rico;".

1992—Pub. L. 102–321 substituted "this part and parts A and B" for "this subchapter" in introductory provisions.

STATUTORY NOTES AND RELATED SUBSIDIARIES

EFFECTIVE DATE OF 1992 AMENDMENT

Amendment by Pub. L. 102–321 effective July 10, 1992, with provision for programs providing financial assistance, see section 801(b), (d) of Pub. L. 102–321, set out as a note under section 236 of this title.

§300d–32. Funding

(a) Authorization of appropriations

For the purpose of carrying out parts A and B, subject to subsections (b) and (c), there are authorized to be appropriated $24,000,000 for each of fiscal years 2023 through 2027.

(b) Reservation of funds

If the amount appropriated under subsection (a) for a fiscal year is equal to or less than $1,000,000, such appropriation is available only for the purpose of carrying out part A. If the amount so appropriated is greater than $1,000,000, 50 percent of such appropriation shall be made available for the purpose of carrying out part A and 50 percent shall be made available for the purpose of carrying out part B.

(c) Allocation of part A funds

Of the amounts appropriated under subsection (a) for a fiscal year to carry out part A—

(1) 10 percent of such amounts for such year shall be allocated for administrative purposes; and

(2) 10 percent of such amounts for such year shall be allocated for the purpose of carrying out section 300d–3 of this title.

(d) Authority

For the purpose of carrying out parts A through C, beginning on March 23, 2010, the Secretary shall transfer authority in administering grants and related authorities under such parts from the Administrator of the Health Resources and Services Administration to the Assistant Secretary for Preparedness and Response.

(July 1, 1944, ch. 373, title XII, §1232, as added Pub. L. 101–590, §3, Nov. 16, 1990, 104 Stat. 2927; amended Pub. L. 102–321, title VI, §602(3), July 10, 1992, 106 Stat. 436; Pub. L. 103–183, title VI, §602, Dec. 14, 1993, 107 Stat. 2239; Pub. L. 105–392, title IV, §§401(a)(2), 413, Nov. 13, 1998, 112

Stat. 3587, 3590; Pub. L. 110–23, §12, May 3, 2007, 121 Stat. 97; Pub. L. 111–148, title III, §3504(a)(3), Mar. 23, 2010, 124 Stat. 520; Pub. L. 117–328, div. FF, title II, §2113(d), Dec. 29, 2022, 136 Stat. 5726.)

EDITORIAL NOTES

AMENDMENTS

2022—Subsec. (a). Pub. L. 117–328 substituted "2023 through 2027" for "2010 through 2014".

2010—Subsec. (a). Pub. L. 111–148, §3504(a)(3)(A), substituted "$24,000,000 for each of fiscal years 2010 through 2014" for "$12,000,000 for fiscal year 2008, $10,000,000 for fiscal year 2009, and $8,000,000 for each of the fiscal years 2010 through 2012".

Subsec. (d). Pub. L. 111–148, §3504(a)(3)(B), added subsec. (d).

2007—Pub. L. 110–23 amended section generally. Prior to amendment, section related to funding for fiscal years 1994 through 2002.

1998—Subsec. (a). Pub. L. 105–392, §413, substituted "through 2002" for "and 1996".

Pub. L. 105–392, §401(a)(2), amended directory language of Pub. L. 103–183. See 1993 Amendment note below.

1993—Subsec. (a). Pub. L. 103–183, as amended by Pub. L. 105–392, §401(a)(2), substituted "For the purpose of carrying out parts A and B of this subchapter, there are authorized to be appropriated $6,000,000 for fiscal year 1994, and such sums as may be necessary for each of the fiscal years 1995 and 1996" for "For the purpose of carrying out parts A and B of this subchapter, there are authorized to be appropriated $60,000,000 for fiscal year 1991 and such sums as may be necessary for each of the fiscal years 1992 and 1993".

1992—Subsec. (a). Pub. L. 102–321 substituted "parts A and B of this subchapter" for "this subchapter".

STATUTORY NOTES AND RELATED SUBSIDIARIES

EFFECTIVE DATE OF 1998 AMENDMENT

Amendment by section 401(a)(2) of Pub. L. 105–392 deemed to have taken effect immediately after enactment of Pub. L. 103–183, see section 401(e) of Pub. L. 105–392, set out as a note under section 242m of this title.

EFFECTIVE DATE OF 1992 AMENDMENT

Amendment by Pub. L. 102–321 effective July 10, 1992, with provision for programs providing financial assistance, see section 801(b), (d) of Pub. L. 102–321, set out as a note under section 236 of this title.

§300d–33. Repealed. Pub. L. 103–183, title VI, §601(e), Dec. 14, 1993, 107 Stat. 2239

Section, act July 1, 1944, ch. 373, title XII, §1233, as added Nov. 16, 1990, Pub. L. 101–590, §3, 104 Stat. 2927, related to waiver of requirement regarding purpose of grants.

PART D—TRAUMA CENTERS OPERATING IN AREAS SEVERELY AFFECTED BY DRUG-RELATED VIOLENCE

§300d–41. Grants for certain trauma centers

(a) In general

The Secretary shall establish 3 programs to award grants to qualified public, nonprofit Indian Health Service, Indian tribal, and urban Indian trauma centers—

(1) to assist in defraying substantial uncompensated care costs;

(2) to further the core missions of such trauma centers, including by addressing costs associated with patient stabilization and transfer, trauma education and outreach, coordination with local and regional trauma systems, essential personnel and other fixed costs, and expenses associated with employee and non-employee physician services; and

(3) to provide emergency relief to ensure the continued and future availability of trauma services.

(b) Minimum qualifications of trauma centers

(1) Participation in trauma care system operating under certain professional guidelines

Except as provided in paragraph (2), the Secretary may not award a grant to a trauma center under subsection (a) unless the trauma center is a participant in a trauma system that substantially complies with section 300d–13 of this title.

(2) Exemption

Paragraph (1) shall not apply to trauma centers that are located in States with no existing trauma care system.

(3) Qualification for substantial uncompensated care costs

The Secretary shall award substantial uncompensated care grants under subsection (a)(1) only to trauma centers meeting at least 1 of the criteria in 1 of the following 3 categories:

(A) Category A

The criteria for category A are as follows:

(i) At least 40 percent of the visits in the emergency department of the hospital in which the trauma center is located were charity or self-pay patients.

(ii) At least 50 percent of the visits in such emergency department were Medicaid (under title XIX of the Social Security Act (42 U.S.C. 1396 et seq.)) and charity and self-pay patients combined.

(B) Category B

The criteria for category B are as follows:

(i) At least 35 percent of the visits in the emergency department were charity or self-pay patients.

(ii) At least 50 percent of the visits in the emergency department were Medicaid and charity and self-pay patients combined.

(C) Category C

The criteria for category C are as follows:

(i) At least 20 percent of the visits in the emergency department were charity or self-pay patients.

(ii) At least 30 percent of the visits in the emergency department were Medicaid and charity and self-pay patients combined.

(4) Trauma centers in 1115 waiver States

Notwithstanding paragraph (3), the Secretary may award a substantial uncompensated care grant to a trauma center under subsection (a)(1) if the trauma center qualifies for funds under a Low Income Pool or Safety Net Care Pool established through a waiver approved under section 1115 of the Social Security Act (42 U.S.C. 1315).

(5) Designation

The Secretary may not award a grant to a trauma center unless such trauma center is verified by the American College of Surgeons or designated by an equivalent State or local agency.

(c) Additional requirements

The Secretary may not award a grant to a trauma center under subsection (a)(1) unless such trauma center—

(1) submits to the Secretary a plan satisfactory to the Secretary that demonstrates a continued

commitment to serving trauma patients regardless of their ability to pay; and

(2) has policies in place to assist patients who cannot pay for part or all of the care they receive, including a sliding fee scale, and to ensure fair billing and collection practices.

(July 1, 1944, ch. 373, title XII, §1241, as added Pub. L. 102–321, title VI, §601, July 10, 1992, 106 Stat. 433; amended Pub. L. 111–148, title III, §3505(a)(1), Mar. 23, 2010, 124 Stat. 522.)

EDITORIAL NOTES

REFERENCES IN TEXT

The Social Security Act, referred to in subsec. (b)(3)(A)(ii), is act Aug. 14, 1935, ch. 531, 49 Stat. 620. Title XIX of the Act is classified generally to subchapter XIX (§1396 et seq.) of chapter 7 of this title. For complete classification of this Act to the Code, see section 1305 of this title and Tables.

AMENDMENTS

2010—Pub. L. 111–148 added subsecs. (a) to (c) and struck out former subsecs. (a) and (b) which related to grants for trauma centers in geographic areas with a significant incidence of violence arising from illicit trafficking in drugs and set forth minimum qualifications of such centers.

STATUTORY NOTES AND RELATED SUBSIDIARIES

EFFECTIVE DATE

Section effective July 10, 1992, with programs making awards providing financial assistance in fiscal year 1993 and subsequent years effective for awards made on or after Oct. 1, 1992, see section 801(b), (d)(1) of Pub. L. 102–321, set out as an Effective Date of 1992 Amendment note under section 236 of this title.

§300d–42. Preferences in making grants

(a) Substantial uncompensated care awards

(1) In general

The Secretary shall establish an award basis for each eligible trauma center for grants under section 300d–41(a)(1) of this title according to the percentage described in paragraph (2), subject to the requirements of section 300d–41(b)(3) of this title.

(2) Percentages

The applicable percentages are as follows:

(A) With respect to a category A trauma center, 100 percent of the uncompensated care costs.

(B) With respect to a category B trauma center, not more than 75 percent of the uncompensated care costs.

(C) With respect to a category C trauma center, not more than 50 percent of the uncompensated care costs.

(b) Core mission awards

(1) [1] In general

In awarding grants under section 300d–41(a)(2) of this title, the Secretary shall—

(A) reserve 25 percent of the amount allocated for core mission awards for Level III and Level IV trauma centers; and

(B) reserve 25 percent of the amount allocated for core mission awards for large urban Level I and II trauma centers—

(i) that have at least 1 graduate medical education fellowship in trauma or trauma related specialties for which demand is exceeding supply;

(ii) for which—

(I) annual uncompensated care costs exceed $10,000,000; or

(II) at least 20 percent of emergency department visits are charity or self-pay or

Medicaid patients; and

(iii) that are not eligible for substantial uncompensated care awards under section 300d–41(a)(1) of this title.

(c) Emergency awards

In awarding grants under section 300d–41(a)(3) of this title, the Secretary shall—

(1) give preference to any application submitted by a trauma center that provides trauma care in a geographic area in which the availability of trauma care has significantly decreased or will significantly decrease if the center is forced to close or downgrade service or growth in demand for trauma services exceeds capacity; and

(2) reallocate any emergency awards funds not obligated due to insufficient, or a lack of qualified, applications to the significant uncompensated care award program.

(July 1, 1944, ch. 373, title XII, §1242, as added Pub. L. 102–321, title VI, §601, July 10, 1992, 106 Stat. 434; amended Pub. L. 111–148, title III, §3505(a)(2), Mar. 23, 2010, 124 Stat. 523.)

EDITORIAL NOTES

AMENDMENTS

2010—Pub. L. 111–148 added subsecs. (a) to (c) and struck out former subsecs. (a) and (b) which related to preferences in making grants and preferences for certain applications.

STATUTORY NOTES AND RELATED SUBSIDIARIES

EFFECTIVE DATE

Section effective July 10, 1992, with programs making awards providing financial assistance in fiscal year 1993 and subsequent years effective for awards made on or after Oct. 1, 1992, see section 801(b), (d)(1) of Pub. L. 102–321, set out as an Effective Date of 1992 Amendment note under section 236 of this title.

[1] So in original. No par. (2) has been enacted.

§300d–43. Certain agreements

(a) Maintenance of financial support

The Secretary may require a trauma center receiving a grant under section 300d–41(a) of this title to maintain access to trauma services at comparable levels to the prior year during the grant period.

(b) Trauma care registry

The Secretary may require the trauma center receiving a grant under section 300d–41(a) of this title to provide data to a national and centralized registry of trauma cases, in accordance with guidelines developed by the American College of Surgeons, and as the Secretary may otherwise require.

(July 1, 1944, ch. 373, title XII, §1243, as added Pub. L. 102–321, title VI, §601, July 10, 1992, 106 Stat. 434; amended Pub. L. 111–148, title III, §3505(a)(3), Mar. 23, 2010, 124 Stat. 524.)

EDITORIAL NOTES

AMENDMENTS

2010—Pub. L. 111–148 added subsecs. (a) and (b) and struck out former subsecs. (a) to (c) which related to commitment regarding continued participation in trauma care system, maintenance of financial support, and trauma care registry.

STATUTORY NOTES AND RELATED SUBSIDIARIES

EFFECTIVE DATE

Section effective July 10, 1992, with programs making awards providing financial assistance in fiscal year 1993 and subsequent years effective for awards made on or after Oct. 1, 1992, see section 801(b), (d)(1) of Pub. L. 102–321, set out as an Effective Date of 1992 Amendment note under section 236 of this title.

§300d–44. General provisions

(a) Application

The Secretary may not award a grant to a trauma center under section 300d–41(a) of this title unless such center submits an application for the grant to the Secretary and the application is in such form, is made in such manner, and contains such agreements, assurances, and information as the Secretary determines to be necessary to carry out this part.

(b) Limitation on duration of support

The period during which a trauma center receives payments under a grant under section 300d–41(a)(3) of this title shall be for 3 fiscal years, except that the Secretary may waive such requirement for a center and authorize such center to receive such payments for 1 additional fiscal year.

(c) Limitation on amount of grant

Notwithstanding section 300d–42(a) of this title, a grant under section 300d–41 of this title may not be made in an amount exceeding $2,000,000 for each fiscal year.

(d) Eligibility

Except as provided in section 300d–42(b)(1)(B)(iii) of this title, acquisition of, or eligibility for, a grant under section 300d–41(a) of this title shall not preclude a trauma center from being eligible for other grants described in such section.

(e) Funding distribution

Of the total amount appropriated for a fiscal year under section 300d–45 of this title, 70 percent shall be used for substantial uncompensated care awards under section 300d–41(a)(1) of this title, 20 percent shall be used for core mission awards under section 300d–41(a)(2) of this title, and 10 percent shall be used for emergency awards under section 300d–41(a)(3) of this title.

(f) Minimum allowance

Notwithstanding subsection (e), if the amount appropriated for a fiscal year under section 300d–45 of this title is less than $25,000,000, all available funding for such fiscal year shall be used for substantial uncompensated care awards under section 300d–41(a)(1) of this title.

(g) Substantial uncompensated care award distribution and proportional share

Notwithstanding section 300d–42(a) of this title, of the amount appropriated for substantial uncompensated care grants for a fiscal year, the Secretary shall—

(1) make available—

(A) 50 percent of such funds for category A trauma center grantees;

(B) 35 percent of such funds for category B trauma center grantees; and

(C) 15 percent of such funds for category C trauma center grantees; and

(2) provide available funds within each category in a manner proportional to the award basis specified in section 300d–42(a)(2) of this title to each eligible trauma center.

(h) Report

Beginning 2 years after March 23, 2010, and every 2 years thereafter, the Secretary shall biennially report to Congress regarding the status of the grants made under section 300d–41 of this title and on the overall financial stability of trauma centers.

(July 1, 1944, ch. 373, title XII, §1244, as added Pub. L. 102–321, title VI, §601, July 10, 1992, 106 Stat. 435; amended Pub. L. 111–148, title III, §3505(a)(4), Mar. 23, 2010, 124 Stat. 524.)

EDITORIAL NOTES

AMENDMENTS

2010—Pub. L. 111–148 added subsecs. (a) to (h) and struck out former subsecs. (a) to (c) which related to application for grant, limitation on duration of support, and limitation on amount of grant.

STATUTORY NOTES AND RELATED SUBSIDIARIES

EFFECTIVE DATE

Section effective July 10, 1992, with programs making awards providing financial assistance in fiscal year 1993 and subsequent years effective for awards made on or after Oct. 1, 1992, see section 801(b), (d)(1) of Pub. L. 102–321, set out as an Effective Date of 1992 Amendment note under section 236 of this title.

§300d–45. Authorization of appropriations

For the purpose of carrying out this part, there are authorized to be appropriated $100,000,000 for fiscal year 2009, and such sums as may be necessary for each of fiscal years 2010 through 2015. Such authorization of appropriations is in addition to any other authorization of appropriations or amounts that are available for such purpose.

(July 1, 1944, ch. 373, title XII, §1245, as added Pub. L. 102–321, title VI, §601, July 10, 1992, 106 Stat. 435; amended Pub. L. 111–148, title III, §3505(a)(5), Mar. 23, 2010, 124 Stat. 525.)

EDITORIAL NOTES

AMENDMENTS

2010—Pub. L. 111–148 amended section generally. Prior to amendment, text read as follows: "For the purpose of carrying out this part, there are authorized to be appropriated $100,000,000 for fiscal year 1993, and such sums as may be necessary for fiscal year 1994. Such authorization of appropriations is in addition to any other authorization of appropriations or amounts that are available for such purpose."

STATUTORY NOTES AND RELATED SUBSIDIARIES

EFFECTIVE DATE

Section effective July 10, 1992, with programs making awards providing financial assistance in fiscal year 1993 and subsequent years effective for awards made on or after Oct. 1, 1992, see section 801(b), (d)(1) of Pub. L. 102–321, set out as an Effective Date of 1992 Amendment note under section 236 of this title.

§300d–46. Definition

In this part, the term "uncompensated care costs" means unreimbursed costs from serving self-pay, charity, or Medicaid patients, without regard to payment under section 1396r–4 of this title, all of which are attributable to emergency care and trauma care, including costs related to subsequent inpatient admissions to the hospital.

(July 1, 1944, ch. 373, title XII, §1246, as added Pub. L. 111–148, title III, §3505(a)(6), Mar. 23, 2010, 124 Stat. 525.)

PART E—MISCELLANEOUS PROGRAMS

§300d–51. Residency training programs in emergency medicine

(a) In general

The Secretary may make grants to public and nonprofit private entities for the purpose of planning and developing approved residency training programs in emergency medicine.

(b) Identification and referral of domestic violence

The Secretary may make a grant under subsection (a) only if the applicant involved agrees that the training programs under subsection (a) will provide education and training in identifying and referring cases of domestic violence.

(c) Authorization of appropriations

For the purpose of carrying out this section, there is authorized to be appropriated $400,000 for each of the fiscal years 2008 though 2012.

(July 1, 1944, ch. 373, title XII, §1251, as added Pub. L. 102–408, title III, §304, Oct. 13, 1992, 106 Stat. 2084; amended Pub. L. 110–23, §13, May 3, 2007, 121 Stat. 98.)

EDITORIAL NOTES

AMENDMENTS

2007—Pub. L. 110–23 amended section generally. Prior to amendment, section related to residency training programs in emergency medicine and authorized appropriations for fiscal years 1993 through 1995.

§300d–52. State grants for projects regarding traumatic brain injury

(a) In general

The Secretary, acting through the Administrator for the Administration for Community Living, may make grants to States and American Indian consortia for the purpose of carrying out projects to improve access to rehabilitation and other services regarding traumatic brain injury.

(b) State advisory board

(1) In general

The Secretary may make a grant under subsection (a) only if the State or American Indian consortium involved agrees to establish an advisory board within the appropriate health department of the State or American Indian consortium or within another department as designated by the chief executive officer of the State or American Indian consortium.

(2) Functions

An advisory board established under paragraph (1) shall advise and make recommendations to the State or American Indian consortium on ways to improve services coordination regarding traumatic brain injury. Such advisory boards shall encourage citizen participation through the establishment of public hearings and other types of community outreach programs. In developing recommendations under this paragraph, such boards shall consult with Federal, State, and local governmental agencies and with citizens groups and other private entities.

(3) Composition

An advisory board established under paragraph (1) shall be composed of—

(A) representatives of—

(i) the corresponding State or American Indian consortium agencies involved;

(ii) public and nonprofit private health related organizations;

(iii) other disability advisory or planning groups within the State or American Indian consortium;

(iv) members of an organization or foundation representing individuals with traumatic brain injury in that State or American Indian consortium; and

(v) injury control programs at the State or local level if such programs exist; and

(B) a substantial number of individuals with traumatic brain injury, or the family members of such individuals.

(c) Matching funds

(1) In general

With respect to the costs to be incurred by a State or American Indian consortium in carrying out the purpose described in subsection (a), the Secretary may make a grant under such subsection only if the State or American Indian consortium agrees to make available non-Federal contributions toward such costs in an amount that is not less than $1 for each $2 of Federal funds provided under the grant.

(2) Determination of amount contributed

Non-Federal contributions under paragraph (1) may be in cash or in kind, fairly evaluated, including plant, equipment, or services. Amounts provided by the Federal Government, or services assisted or subsidized to any significant extent by the Federal Government, may not be included in determining the amount of such contributions.

(d) Application for grant

The Secretary may make a grant under subsection (a) only if an application for the grant is submitted to the Secretary and the application is in such form, is made in such manner, and contains such agreements, assurances, and information as the Secretary determines to be necessary to carry out this section.

(e) Use of State and American Indian consortium grants

(1) Community services and supports

A State or American Indian consortium shall (directly or through awards of contracts to nonprofit private entities) use amounts received under a grant under this section for the following:

(A) To develop, change, or enhance community-based service delivery systems that include timely access to comprehensive appropriate services and supports. Such service and supports—

(i) shall promote full participation by individuals with traumatic brain injury and their families in decision making regarding the services and supports; and

(ii) shall be designed for children, youth, and adults with traumatic brain injury.

(B) To focus on outreach to underserved and inappropriately served individuals, such as individuals in institutional settings, individuals with low socioeconomic resources, individuals in rural communities, and individuals in culturally and linguistically diverse communities.

(C) To award contracts to nonprofit entities for consumer or family service access training, consumer support, peer mentoring, and parent to parent programs.

(D) To develop individual and family service coordination or case management systems.

(E) To support other needs identified by the advisory board under subsection (b) for the State or American Indian consortium involved.

(2) Best practices

(A) In general

State or American Indian consortium services and supports provided under a grant under this section shall reflect the best practices in the field of traumatic brain injury, shall be in compliance with title II of the Americans with Disabilities Act of 1990 [42 U.S.C. 12131 et seq.], and shall be supported by quality assurance measures as well as state-of-the-art health care and integrated community supports, regardless of the severity of injury.

(B) Demonstration by State agency

The State or American Indian consortium agency responsible for administering amounts received under a grant under this section shall demonstrate that it has obtained knowledge and expertise of traumatic brain injury and the unique needs associated with traumatic brain injury.

(3) State capacity building

A State or American Indian consortium may use amounts received under a grant under this section to—

(A) educate consumers and families;

(B) train professionals in public and private sector financing (such as third party payers, State agencies, community-based providers, schools, and educators);

(C) develop or improve case management or service coordination systems;

(D) develop best practices in areas such as family or consumer support, return to work, housing or supportive living personal assistance services, assistive technology and devices, behavioral health services, substance abuse services, and traumatic brain injury treatment and rehabilitation;

(E) tailor existing State or American Indian consortium systems to provide accommodations to the needs of individuals with traumatic brain injury (including systems administered by the State or American Indian consortium departments responsible for health, mental health, labor/employment, education, intellectual disabilities or developmental disorders, transportation, and correctional systems);

(F) improve data sets coordinated across systems and other needs identified by a State or American Indian consortium plan supported by its advisory council; and

(G) develop capacity within targeted communities.

(f) Coordination of activities

The Secretary shall ensure that activities under this section are coordinated as appropriate with other Federal agencies that carry out activities regarding traumatic brain injury.

(g) Report

Not less than biennially, the Secretary shall submit to the Committee on Energy and Commerce of the House of Representatives, and to the Committee on Health, Education, Labor, and Pensions of the Senate, a report describing the findings and results of the programs established under this section and section 300d–53 of this title, including measures of outcomes and consumer and surrogate satisfaction.

(h) Definitions

For purposes of this section:

(1) The terms "American Indian consortium" and "State" have the meanings given to those terms in section 300d–53 of this title.

(2) The term "traumatic brain injury" means an acquired injury to the brain. Such term does not include brain dysfunction caused by congenital or degenerative disorders, nor birth trauma, but may include brain injuries caused by anoxia due to trauma. The Secretary may revise the definition of such term as the Secretary determines necessary, after consultation with States and other appropriate public or nonprofit private entities.

(i) Authorization of appropriations

For the purpose of carrying out this section, there are authorized to be appropriated $7,321,000 for each of fiscal years 2020 through 2024.

(July 1, 1944, ch. 373, title XII, §1252, as added Pub. L. 104–166, §3, July 29, 1996, 110 Stat. 1446; amended Pub. L. 106–310, div. A, title XIII, §1304, Oct. 17, 2000, 114 Stat. 1139; Pub. L. 110–23, §14, May 3, 2007, 121 Stat. 99; Pub. L. 110–206, §6(a), Apr. 28, 2008, 122 Stat. 716; Pub. L. 111–256, §2(f)(6), Oct. 5, 2010, 124 Stat. 2644; Pub. L. 113–196, §3, Nov. 26, 2014, 128 Stat. 2052; Pub. L. 115–377, §3, Dec. 21, 2018, 132 Stat. 5114.)

EDITORIAL NOTES

REFERENCES IN TEXT

The Americans with Disabilities Act of 1990, referred to in subsec. (e)(2)(A), is Pub. L. 101–336, July 26, 1990, 104 Stat. 327. Title II of the Act is classified generally to subchapter II (§12131 et seq.) of chapter 126 of this title. For complete classification of this Act to the Code, see Short Title note set out under section 12101 of this title and Tables.

AMENDMENTS

2018—Subsec. (a). Pub. L. 115–377, §3(1), inserted ", acting through the Administrator for the Administration for Community Living," after "The Secretary".

Subsecs. (e) to (j). Pub. L. 115–377, §3(2)–(4), redesignated subsecs. (f) to (j) as (e) to (i), respectively, in subsec. (i), substituted "$7,321,000 for each of fiscal years 2020 through 2024" for "$5,500,000 for each of the fiscal years 2015 through 2019", and struck out subsec. (e) which provided for continuation of previously awarded demonstration projects.

2014—Subsec. (a). Pub. L. 113–196, §3(1), struck out ", acting through the Administrator of the Health Resources and Services Administration," after "The Secretary".

Subsec. (f)(1)(A)(i), (3)(E). Pub. L. 113–196, §3(2), substituted "traumatic brain injury" for "brain injury".

Subsec. (h). Pub. L. 113–196, §3(3), substituted "under this section and section 300d–53 of this title, including" for "under this section, and section 300d–53 of this title including".

Subsec. (j). Pub. L. 113–196, §3(4), substituted "$5,500,000 for each of the fiscal years 2015 through 2019" for "such sums as may be necessary for each of the fiscal years 2001 through 2005, and such sums as may be necessary for each of the fiscal years 2009 through 2012".

2010—Subsec. (f)(3)(E). Pub. L. 111–256 substituted "intellectual disabilities or developmental disorders," for "mental retardation/developmental disorders,".

2008—Subsec. (a). Pub. L. 110–206, §6(a)(1), substituted "may make grants to States and American Indian consortia" for "may make grants to States" and "rehabilitation and other services" for "health and other services".

Subsec. (b)(1). Pub. L. 110–206, §6(a)(2)(A), substituted "State or American Indian consortium" for "State" wherever appearing.

Subsec. (b)(2). Pub. L. 110–206, §6(a)(2)(B), substituted "recommendations to the State or American Indian consortium" for "recommendations to the State".

Subsec. (b)(3)(A)(i), (iii), (iv). Pub. L. 110–206, §6(a)(2)(A), substituted "State or American Indian consortium" for "State".

Subsec. (c)(1). Pub. L. 110–206, §6(a)(3), substituted "State or American Indian consortium" for "State" in two places.

Subsec. (e). Pub. L. 110–206, §6(a)(4), added text of subsec. (e) and struck out former text of subsec. (e) which read as follows: "A State that received a grant under this section prior to October 17, 2000, may compete for new project grants under this section after October 17, 2000."

Subsec. (f). Pub. L. 110–206, §6(a)(5)(A), (B), inserted "and American Indian consortium" after "State" in heading and substituted in text "State or American Indian consortium" for "State" wherever appearing, except in par. (3)(B).

Subsec. (f)(1)(A)(ii). Pub. L. 110–206, §6(a)(5)(C), substituted "children, youth, and adults" for "children and other individuals".

Subsec. (h). Pub. L. 110–206, §6(a)(6), substituted "Not less than biennially, the Secretary" for "Not later than 2 years after July 29, 1996, the Secretary" and "Energy and Commerce of the House of Representatives, and to the Committee on Health, Education, Labor, and Pensions" for "Commerce of the House of Representatives, and to the Committee on Labor and Human Resources" and inserted "and section 300d–53 of this title" after "programs established under this section,".

Subsec. (i). Pub. L. 110–206, §6(a)(7), amended subsec. (i) generally. Prior to amendment, text read as follows: "For purposes of this section, the term 'traumatic brain injury' means an acquired injury to the brain. Such term does not include brain dysfunction caused by congenital or degenerative disorders, nor birth trauma, but may include brain injuries caused by anoxia due to trauma. The Secretary may revise the definition of such term as the Secretary determines necessary, after consultation with States and other appropriate public or nonprofit private entities."

Subsec. (j). Pub. L. 110–206, §6(a)(8), inserted ", and such sums as may be necessary for each of the fiscal years 2009 through 2012" before period at end.

2007—Pub. L. 110–23, which directed amendment of section by striking "demonstration" in section

catchline, could not be executed because the word "demonstration" did not appear after amendment by Pub. L. 106–310, §1304(1). See 2000 Amendment note below.

2000—Pub. L. 106–310, §1304(1), struck out "demonstration" before "projects" in section catchline.

Subsec. (a). Pub. L. 106–310, §1304(2), struck out "demonstration" before "projects".

Subsec. (b)(3)(A)(iv). Pub. L. 106–310, §1304(3)(A), substituted "representing individuals with traumatic brain injury" for "representing traumatic brain injury survivors".

Subsec. (b)(3)(B). Pub. L. 106–310, §1304(3)(B), substituted "with traumatic brain injury" for "who are survivors of traumatic brain injury".

Subsec. (c)(1). Pub. L. 106–310, §1304(4)(A), struck out ", in cash," before "non-Federal contributions".

Subsec. (c)(2). Pub. L. 106–310, §1304(4)(B), reenacted heading without change and amended text generally. Prior to amendment, text read as follows: "In determining the amount of non-Federal contributions in cash that a State has provided pursuant to paragraph (1), the Secretary may not include any amounts provided to the State by the Federal Government."

Subsecs. (e), (f). Pub. L. 106–310, §1304(6), added subsecs. (e) and (f). Former subsecs. (e) and (f) redesignated (g) and (h), respectively.

Subsec. (g). Pub. L. 106–310, §1304(5), (7), redesignated subsec. (e) as (g) and substituted "Federal agencies" for "agencies of the Public Health Service". Former subsec. (g) redesignated (i).

Subsec. (h). Pub. L. 106–310, §1304(5), redesignated subsec. (f) as (h). Former subsec. (h) redesignated (j).

Subsec. (i). Pub. L. 106–310, §1304(5), (8), redesignated subsec. (g) as (i), substituted "anoxia due to trauma" for "anoxia due to near drowning" in second sentence, and inserted before period at end ", after consultation with States and other appropriate public or nonprofit private entities".

Subsec. (j). Pub. L. 106–310, §1304(9), reenacted heading without change and amended text generally. Prior to amendment, text read as follows: "For the purpose of carrying out this section, there is authorized to be appropriated $5,000,000 for each of the fiscal years 1997 through 1999."

Pub. L. 106–310, §1304(5), redesignated subsec. (h) as (j).

STATUTORY NOTES AND RELATED SUBSIDIARIES

DEFINITIONS

For meaning of references to an intellectual disability and to individuals with intellectual disabilities in provisions amended by section 2 of Pub. L. 111–256, see section 2(k) of Pub. L. 111–256, set out as a note under section 1400 of Title 20, Education.

§300d–53. State grants for protection and advocacy services

(a) In general

The Secretary, acting through the Administrator for the Administration for Community Living, shall make grants to protection and advocacy systems for the purpose of enabling such systems to provide services to individuals with traumatic brain injury.

(b) Services provided

Services provided under this section may include the provision of—

(1) information, referrals, and advice;

(2) individual and family advocacy;

(3) legal representation; and

(4) specific assistance in self-advocacy.

(c) Application

To be eligible to receive a grant under this section, a protection and advocacy system shall submit an application to the Secretary at such time, in such form and manner, and accompanied by such information and assurances as the Secretary may require.

(d) Appropriations less than $2,700,000

(1) In general

With respect to any fiscal year in which the amount appropriated under subsection (l) to carry

out this section is less than $2,700,000, the Secretary shall make grants from such amount to individual protection and advocacy systems within States to enable such systems to plan for, develop outreach strategies for, and carry out services authorized under this section for individuals with traumatic brain injury.

(2) Amount

The amount of each grant provided under paragraph (1) shall be determined as set forth in paragraphs (2) and (3) of subsection (e).

(e) Appropriations of $2,700,000 or more

(1) Population basis

Except as provided in paragraph (2), with respect to each fiscal year in which the amount appropriated under subsection (l) to carry out this section is $2,700,000 or more, the Secretary shall make a grant to a protection and advocacy system within each State.

(2) Amount

The amount of a grant provided to a system under paragraph (1) shall be equal to an amount bearing the same ratio to the total amount appropriated for the fiscal year involved under subsection (l) as the population of the State in which the grantee is located bears to the population of all States.

(3) Minimums

Subject to the availability of appropriations, the amount of a grant [1] a protection and advocacy system under paragraph (1) for a fiscal year shall—

(A) in the case of a protection and advocacy system located in American Samoa, Guam, the United States Virgin Islands, or the Commonwealth of the Northern Mariana Islands, and the protection and advocacy system serving the American Indian consortium, not be less than $20,000; and

(B) in the case of a protection and advocacy system in a State not described in subparagraph (A), not be less than $50,000.

(4) Inflation adjustment

For each fiscal year in which the total amount appropriated under subsection (l) to carry out this section is $5,000,000 or more, and such appropriated amount exceeds the total amount appropriated to carry out this section in the preceding fiscal year, the Secretary shall increase each of the minimum grants amount described in subparagraphs (A) and (B) of paragraph (3) by a percentage equal to the percentage increase in the total amount appropriated under subsection (l) to carry out this section between the preceding fiscal year and the fiscal year involved.

(f) Carryover

Any amount paid to a protection and advocacy system that serves a State or the American Indian consortium for a fiscal year under this section that remains unobligated at the end of such fiscal year shall remain available to such system for obligation during the next fiscal year for the purposes for which such amount was originally provided.

(g) Direct payment

Notwithstanding any other provision of law, each fiscal year not later than October 1, the Secretary shall pay directly to any protection and advocacy system that complies with the provisions of this section, the total amount of the grant for such system, unless the system provides otherwise for such payment.

(h) Reporting

(1) Reports by systems

Each protection and advocacy system that receives a payment under this section shall submit an annual report to the Secretary concerning the services provided to individuals with traumatic brain

injury by such system.

(2) Report by Secretary

Not later than 1 year after November 26, 2014, the Secretary shall prepare and submit to the appropriate committees of Congress a report describing the services and activities carried out under this section during the period for which the report is being prepared.

(i) Data collection

The Secretary shall facilitate agreements to coordinate the collection of data by agencies within the Department of Health and Human Services regarding protection and advocacy services.

(j) Training and technical assistance

(1) Grants

For any fiscal year for which the amount appropriated to carry out this section is $6,000,000 or greater, the Secretary shall use 2 percent of such amount to make a grant to an eligible national association for providing for training and technical assistance to protection and advocacy systems.

(2) Definition

In this subsection, the term "eligible national association" means a national association with demonstrated experience in providing training and technical assistance to protection and advocacy systems.

(k) System authority

In providing services under this section, a protection and advocacy system shall have the same authorities, including access to records, as such system would have for purposes of providing services under subtitle C of title I of the Developmental Disabilities Assistance and Bill of Rights Act of 2000 (42 U.S.C. 15041 et seq.).

(l) Authorization of appropriations

There are authorized to be appropriated to carry out this section $4,000,000 for each of fiscal years 2020 through 2024.

(m) Definitions

In this section:

(1) American Indian consortium

The term "American Indian consortium" means a consortium established under subtitle C of title I of the Developmental Disabilities Assistance and Bill of Rights Act of 2000 (42 U.S.C. 15041 et seq.).

(2) Protection and advocacy system

The term "protection and advocacy system" means a protection and advocacy system established under subtitle C of title I of the Developmental Disabilities Assistance and Bill of Rights Act of 2000 (42 U.S.C. 15041 et seq.).

(3) State

The term "State", unless otherwise specified, means the several States of the United States, the District of Columbia, the Commonwealth of Puerto Rico, the United States Virgin Islands, Guam, American Samoa, and the Commonwealth of the Northern Mariana Islands.

(July 1, 1944, ch. 373, title XII, §1253, as added Pub. L. 106–310, div. A, title XIII, §1305, Oct. 17, 2000, 114 Stat. 1141; amended Pub. L. 110–206, §6(b), Apr. 28, 2008, 122 Stat. 717; Pub. L. 113–196, §4, Nov. 26, 2014, 128 Stat. 2053; Pub. L. 115–377, §4, Dec. 21, 2018, 132 Stat. 5114.)

EDITORIAL NOTES

REFERENCES IN TEXT

The Developmental Disabilities Assistance and Bill of Rights Act of 2000, referred to in subsecs. (k) and

(m)(1), (2), is Pub. L. 106–402, Oct. 30, 2000, 114 Stat. 1677. Subtitle C of title I of the Act is classified generally to part C (§15041 et seq.) of subchapter I of chapter 144 of this title. For complete classification of this Act to the Code, see Short Title note set out under section 15001 of this title and Tables.

AMENDMENTS

2018—Subsec. (a). Pub. L. 115–377, §4(1), inserted ", acting through the Administrator for the Administration for Community Living," after "The Secretary".

Subsec. (l). Pub. L. 115–377, §4(2), substituted "$4,000,000 for each of fiscal years 2020 through 2024" for "$3,100,000 for each of the fiscal years 2015 through 2019".

2014—Subsec. (a). Pub. L. 113–196, §4(1), struck out ", acting through the Administrator of the Health Resources and Services Administration (referred to in this section as the 'Administrator')," after "The Secretary".

Subsecs. (c), (d)(1), (e)(1), (4), (g). Pub. L. 113–196, §4(2), substituted "Secretary" for "Administrator" wherever appearing.

Subsec. (h). Pub. L. 113–196, §4(2), (3), substituted "Reporting" for "Annual report" in heading; designated existing provisions as par. (1), inserted heading, and substituted "Secretary" for "Administrator"; and added par. (2).

Subsec. (i). Pub. L. 113–196, §4(4), substituted "The Secretary shall facilitate agreements to coordinate the collection of data by agencies within the Department of Health and Human Services regarding" for "The Administrator of the Health Resources and Services Administration and the Commissioner of the Administration on Developmental Disabilities shall enter into an agreement to coordinate the collection of data by the Administrator and the Commissioner regarding".

Subsec. (j)(1). Pub. L. 113–196, §4(2), substituted "Secretary" for "Administrator".

Subsec. (k). Pub. L. 113–196, §4(5), substituted "subtitle C of title I of the Developmental Disabilities Assistance and Bill of Rights Act of 2000 (42 U.S.C. 15041 et seq.)" for "subtitle C of the Developmental Disabilities Assistance and Bill of Rights Act of 2000".

Subsec. (l). Pub. L. 113–196, §4(6), substituted "$3,100,000 for each of the fiscal years 2015 through 2019" for "$5,000,000 for fiscal year 2001, and such sums as may be necessary for each the fiscal years 2009 through 2012".

Subsec. (m)(1). Pub. L. 113–196, §4(7)(A), substituted "subtitle C of title I of the Developmental Disabilities Assistance and Bill of Rights Act of 2000 (42 U.S.C. 15041 et seq.)" for "part C of the Developmental Disabilities Assistance Bill of Rights Act (42 U.S.C. 6042 et seq.)".

Subsec. (m)(2). Pub. L. 113–196, §4(7)(B), substituted "subtitle C of title I of the Developmental Disabilities Assistance and Bill of Rights Act of 2000 (42 U.S.C. 15041 et seq.)" for "part C of the Developmental Disabilities Assistance and Bill of Rights Act (42 U.S.C. 6042 et seq.)".

2008—Subsecs. (d), (e). Pub. L. 110–206, §6(b)(1), substituted "subsection (l)" for "subsection (i)" wherever appearing.

Subsec. (g). Pub. L. 110–206, §6(b)(2), inserted "each fiscal year not later than October 1," before "the Administrator shall pay".

Subsecs. (i) to (k). Pub. L. 110–206, §6(b)(4), added subsecs. (i) to (k). Former subsecs. (i) and (j) redesignated (l) and (m), respectively.

Subsec. (l). Pub. L. 110–206, §6(b)(3), (5), redesignated subsec. (i) as (l) and substituted "2009 through 2012" for "2002 through 2005".

Subsec. (m). Pub. L. 110–206, §6(b)(3), redesignated subsec. (j) as (m).

[1] *So in original. Probably should be followed by "to".*

§300d–54. Stop, Observe, Ask, and Respond to Health and Wellness Training Program

(a) In general

The Secretary shall establish a program to be known as the Stop, Observe, Ask, and Respond to Health and Wellness Training Program or the SOAR to Health and Wellness Training Program (in this section referred to as the "Program") to provide training to health care and social service providers on human trafficking in accordance with this section.

(b) Activities

(1) In general

The Program shall include the Stop, Observe, Ask, and Respond to Health and Wellness Training Program's activities existing on the day before December 31, 2018, and the authorized initiatives described in paragraph (2).

(2) Authorized initiatives

The authorized initiatives of the Program shall include—

(A) engaging stakeholders, including victims of human trafficking and Federal, State, local, and tribal partners, to develop a flexible training module—

(i) for supporting activities under subsection (c); and

(ii) that adapts to changing needs, settings, health care providers, and social service providers;

(B) providing technical assistance to grantees related to implementing activities described in subsection (c) and reporting on any best practices identified by the grantees;

(C) developing a reliable methodology for collecting data, and reporting such data, on the number of human trafficking victims identified and served by grantees in a manner that, at a minimum, prevents disclosure of individually identifiable information consistent with all applicable privacy laws and regulations; and

(D) integrating, as appropriate, the training described in paragraphs (1) through (4) of subsection (c) with training programs, in effect on December 31, 2018, for health care and social service providers for victims of intimate partner violence, sexual assault, stalking, child abuse, child neglect, child maltreatment, and child sexual exploitation.

(c) Grants

The Secretary may award grants to appropriate entities to train health care and social service providers to—

(1) identify potential human trafficking victims;

(2) implement best practices for working with law enforcement to report and facilitate communication with human trafficking victims, in accordance with all applicable Federal, State, local, and tribal laws, including legal confidentiality requirements for patients and health care and social service providers;

(3) implement best practices for referring such victims to appropriate health care, social, or victims service agencies or organizations; and

(4) provide such victims with coordinated, age-appropriate, culturally relevant, trauma-informed, patient-centered, and evidence-based care.

(d) Consideration in awarding grants

The Secretary, in making awards under this section, shall give consideration to—

(1) geography;

(2) the demographics of the population to be served;

(3) the predominant types of human trafficking cases involved; and

(4) health care and social service provider profiles.

(e) Data collection and reporting

(1) In general

The Secretary shall collect data and report on the following:

(A) The total number of entities that received a grant under this section.

(B) The total number and geographic distribution of health care and social service providers trained through the Program.

(2) Initial report

In addition to the data required to be collected under paragraph (1), for purposes of the initial

report to be submitted under paragraph (3), the Secretary shall collect data on the total number of facilities and health care professional organizations that were operating under, and the total number of health care and social service providers trained through, the Stop, Observe, Ask, and Respond to Health and Wellness Training Program existing prior to the establishment of the Program under this section.

(3) Annual report

Not later than 1 year after December 31, 2018, and annually thereafter, the Secretary shall submit an annual report to Congress on the data collected under this subsection in a manner that, at a minimum, prevents the disclosure of individually identifiable information consistent with all applicable privacy laws and regulations.

(f) Sharing best practices

The Secretary shall make available, on the Internet website of the Department of Health and Human Services, a description of the best practices and procedures used by entities that receive a grant for carrying out activities under this section.

(g) Definition

In this section, the term "human trafficking" has the meaning given the term "severe forms of trafficking in persons" as defined in section 7102 of title 22.

(h) Authorization of appropriations

There is authorized to be appropriated to carry out this section, $4,000,000 for each of fiscal years 2020 through 2024.

(July 1, 1944, ch. 373, title XII, §1254, as added Pub. L. 115–398, §2, Dec. 31, 2018, 132 Stat. 5328.)

EDITORIAL NOTES

REFERENCES IN TEXT

This section, referred to in subsec. (h), was in the original "this Act", and was translated, to reflect the probable intent of Congress, as meaning Pub. L. 115–398, Dec. 31, 2018, 132 Stat. 5328, which enacted this section and provisions set out as a note under section 201 of this title.

PART F—INTERAGENCY PROGRAM FOR TRAUMA RESEARCH

§300d–61. Establishment of Program

(a) In general

The Secretary, acting through the Director of the National Institutes of Health (in this section referred to as the "Director"), shall establish a comprehensive program of conducting basic and clinical research on trauma (in this section referred to as the "Program"). The Program shall include research regarding the diagnosis, treatment, rehabilitation, and general management of trauma.

(b) Plan for Program

(1) In general

The Director, in consultation with the Trauma Research Interagency Coordinating Committee established under subsection (g), shall establish and implement a plan for carrying out the activities of the Program, including the activities described in subsection (d). All such activities shall be carried out in accordance with the plan. The plan shall be periodically reviewed, and revised as appropriate.

(2) Submission to Congress

Not later than December 1, 1993, the Director shall submit the plan required in paragraph (1) to the Committee on Energy and Commerce of the House of Representatives, and to the Committee on Health, Education, Labor, and Pensions of the Senate, together with an estimate of the funds needed for each of the fiscal years 1994 through 1996 to implement the plan.

(c) Participating agencies; coordination and collaboration

The Director—

(1) shall provide for the conduct of activities under the Program by the Directors of the agencies of the National Institutes of Health involved in research with respect to trauma;

(2) shall ensure that the activities of the Program are coordinated among such agencies; and

(3) shall, as appropriate, provide for collaboration among such agencies in carrying out such activities.

(d) Certain activities of Program

The Program shall include—

(1) studies with respect to all phases of trauma care, including prehospital, resuscitation, surgical intervention, critical care, infection control, wound healing, nutritional care and support, and medical rehabilitation care;

(2) basic and clinical research regarding the response of the body to trauma and the acute treatment and medical rehabilitation of individuals who are the victims of trauma;

(3) basic and clinical research regarding trauma care for pediatric and geriatric patients; and

(4) the authority to make awards of grants or contracts to public or nonprofit private entities for the conduct of basic and applied research regarding traumatic brain injury, which research may include—

(A) the development of new methods and modalities for the more effective diagnosis, measurement of degree of brain injury, post-injury monitoring and prognostic assessment of head injury for acute, subacute and later phases of care;

(B) the development, modification and evaluation of therapies that retard, prevent or reverse brain damage after acute head injury, that arrest further deterioration following injury and that provide the restitution of function for individuals with long-term injuries;

(C) the development of research on a continuum of care from acute care through rehabilitation, designed, to the extent practicable, to integrate rehabilitation and long-term outcome evaluation with acute care research;

(D) the development of programs that increase the participation of academic centers of excellence in brain injury treatment and rehabilitation research and training; and

(E) carrying out subparagraphs (A) through (D) with respect to cognitive disorders and neurobehavioral consequences arising from traumatic brain injury, including the development, modification, and evaluation of therapies and programs of rehabilitation toward reaching or restoring normal capabilities in areas such as reading, comprehension, speech, reasoning, and deduction.

(e) Mechanisms of support

In carrying out the Program, the Director, acting through the Directors of the agencies referred to in subsection (c)(1), may make grants to public and nonprofit entities, including designated trauma centers.

(f) Resources

The Director shall assure the availability of appropriate resources to carry out the Program, including the plan established under subsection (b) (including the activities described in subsection (d)).

(g) Coordinating Committee

(1) In general

There shall be established a Trauma Research Interagency Coordinating Committee (in this

section referred to as the "Coordinating Committee").

(2) Duties

The Coordinating Committee shall make recommendations regarding—

(A) the activities of the Program to be carried out by each of the agencies represented on the Committee and the amount of funds needed by each of the agencies for such activities; and

(B) effective collaboration among the agencies in carrying out the activities.

(3) Composition

The Coordinating Committee shall be composed of the Directors of each of the agencies that, under subsection (c), have responsibilities under the Program, and any other individuals who are practitioners in the trauma field as designated by the Director of the National Institutes of Health.

(h) Definitions

For purposes of this section:

(1) The term "designated trauma center" has the meaning given such term in section 300d–31(1) of this title.

(2) The term "Director" means the Director of the National Institutes of Health.

(3) The term "trauma" means an injury resulting from exposure to—

(A) a mechanical force; or

(B) another extrinsic agent, including an extrinsic agent that is thermal, electrical, chemical, or radioactive.

(4) The term "traumatic brain injury" means an acquired injury to the brain. Such term does not include brain dysfunction caused by congenital or degenerative disorders, nor birth trauma, but may include brain injuries caused by anoxia due to trauma. The Secretary may revise the definition of such term as the Secretary determines necessary, after consultation with States and other appropriate public or nonprofit private entities.

(i) Authorization of appropriations

For the purpose of carrying out this section, there are authorized to be appropriated such sums as may be necessary for each of the fiscal years 2001 through 2005, and such sums as may be necessary for each of the fiscal years 2009 through 2012.

(July 1, 1944, ch. 373, title XII, §1261, as added Pub. L. 103–43, title III, §303(a), June 10, 1993, 107 Stat. 151; amended Pub. L. 104–166, §2, July 29, 1996, 110 Stat. 1445; Pub. L. 106–310, div. A, title XIII, §1303, Oct. 17, 2000, 114 Stat. 1138; Pub. L. 110–206, §5, Apr. 28, 2008, 122 Stat. 716; Pub. L. 113–152, §2(b), Aug. 8, 2014, 128 Stat. 1825.)

EDITORIAL NOTES

AMENDMENTS

2014—Subsec. (h)(3). Pub. L. 113–152 amended par. (3) generally. Prior to amendment, text read as follows: "The term 'trauma' means any serious injury that could result in loss of life or in significant disability and that would meet pre-hospital triage criteria for transport to a designated trauma center."

2008—Subsec. (b)(2). Pub. L. 110–206, §5(1), substituted "Health, Education, Labor, and Pensions" for "Labor and Human Resources".

Subsec. (d)(4)(D). Pub. L. 110–206, §5(2), substituted "brain injury" for "head brain injury".

Subsec. (i). Pub. L. 110–206, §5(3), inserted ", and such sums as may be necessary for each of the fiscal years 2009 through 2012" before period at end.

2000—Subsec. (d)(4)(A). Pub. L. 106–310, §1303(a)(1), substituted "degree of brain injury" for "degree of injury".

Subsec. (d)(4)(B). Pub. L. 106–310, §1303(a)(2), which directed amendment of subpar. (B) by substituting "acute brain injury" for "acute injury", could not be executed because the phrase "acute injury" does not appear in text.

Subsec. (d)(4)(C). Pub. L. 106–310, §1303(c)(1), struck out "and" after semicolon at end.

Subsec. (d)(4)(D). Pub. L. 106–310, §1303(a)(3), (c)(2), substituted "brain injury treatment" for "injury

treatment" and "; and" for period at end.

Subsec. (d)(4)(E). Pub. L. 106–310, §1303(c)(3), added subpar. (E).

Subsec. (h)(4). Pub. L. 106–310, §1303(b), substituted "anoxia due to trauma" for "anoxia due to near drowning" in second sentence and inserted before period at end ", after consultation with States and other appropriate public or nonprofit private entities".

Subsec. (i). Pub. L. 106–310, §1303(d), added subsec. (i).

1996—Subsec. (d)(4). Pub. L. 104–166, §2(1), added par. (4).

Subsec. (h)(4). Pub. L. 104–166, §2(2), added par. (4).

STATUTORY NOTES AND RELATED SUBSIDIARIES

CHANGE OF NAME

Committee on Energy and Commerce of House of Representatives treated as referring to Committee on Commerce of House of Representatives by section 1(a) of Pub. L. 104–14, set out as a note preceding section 21 of Title 2, The Congress. Committee on Commerce of House of Representatives changed to Committee on Energy and Commerce of House of Representatives, and jurisdiction over matters relating to securities and exchanges and insurance generally transferred to Committee on Financial Services of House of Representatives by House Resolution No. 5, One Hundred Seventh Congress, Jan. 3, 2001.

TRAUMATIC BRAIN INJURY STUDY; CONSENSUS CONFERENCE

Pub. L. 104–166, §4, July 29, 1996, 110 Stat. 1448, as amended by Pub. L. 106–310, div. A, title XIII, §1302, Oct. 17, 2000, 114 Stat. 1138, required the Secretary of Health and Human Services to conduct a study of traumatic brain injuries, to submit a report to Congress within 18 months of July 29, 1996 on the findings of such study and a report within 3 years of that date on certain therapeutic interventions and guidelines developed in the study, and to conduct a national consensus conference on managing traumatic brain injury and related rehabilitation concerns.

PART G—POISON CONTROL

§300d–71. Maintenance of the national toll-free number and other communication capabilities

(a) In general

The Secretary—

(1) shall provide coordination and assistance to poison control centers for the establishment and maintenance of a nationwide toll-free phone number, to be used to access such centers; and

(2) may provide coordination and assistance to poison control centers and consult with professional organizations for the establishment, implementation, and maintenance of other communication technologies to be used to access such centers.

(b) Routing contacts with poison control centers

Not later than 18 months after December 20, 2019, the Secretary shall coordinate with the Chairman of the Federal Communications Commission, to the extent technically and economically feasible, to ensure that communications with the national toll-free number are routed to the appropriate poison control center based on the physical location of the contact rather than the area code of the contact device.

(c) Authorization of appropriations

There is authorized to be appropriated to carry out this section, $700,000 for each of fiscal years 2025 through 2029 for the establishment, implementation, and maintenance activities carried out under subsections (a) and (b).

(July 1, 1944, ch. 373, title XII, §1271, as added Pub. L. 108–194, §3, Dec. 19, 2003, 117 Stat. 2889;

amended Pub. L. 110–377, §3, Oct. 8, 2008, 122 Stat. 4064; Pub. L. 113–77, §2, Jan. 24, 2014, 128 Stat. 644; Pub. L. 116–94, div. N, title I, §403(a), Dec. 20, 2019, 133 Stat. 3114; Pub. L. 118–86, §2(a), Sept. 26, 2024, 138 Stat. 1549.)

EDITORIAL NOTES

AMENDMENTS

2024—Subsec. (c). Pub. L. 118–86 substituted "fiscal years 2025 through 2029" for "fiscal years 2020 through 2024".

2019—Pub. L. 116–94, §403(a)(1), inserted "and other communication capabilities" after "toll-free number" in section catchline.

Subsec. (a). Pub. L. 116–94, §403(a)(2), added subsec. (a) and struck out former subsec. (a). Prior to amendment, text read as follows: "The Secretary shall provide coordination and assistance to poison control centers for the establishment of a nationwide toll-free phone number, and the maintenance of such number, to be used to access such centers."

Subsec. (b). Pub. L. 116–94, §403(a)(4), added subsec. (b). Former subsec. (b) redesignated (c).

Subsec. (c). Pub. L. 116–94, §403(a)(3), (5), redesignated subsec. (b) as (c) and substituted "2020 through 2024" for "2015 through 2019" and "establishment, implementation, and maintenance activities carried out under subsections (a) and (b)" for "maintenance of the nationwide toll free phone number under subsection (a)".

2014—Subsec. (b). Pub. L. 113–77 added subsec. (b) and struck out former subsec. (b). Prior to amendment, text read as follows: "There is authorized to be appropriated $2,000,000 for fiscal year 2009 to carry out this section, and $700,000 for each of fiscal years 2010 through 2014 for the maintenance of the nationwide toll free phone number under subsection (a)."

2008—Pub. L. 110–377 amended section generally. Prior to amendment, section required the Secretary to coordinate and assist in establishment of nationwide poison control center toll-free phone number, allowed for establishment and continued operation of privately funded nationwide toll-free numbers, and authorized appropriations for fiscal years 2000 through 2009.

STATUTORY NOTES AND RELATED SUBSIDIARIES

FINDINGS

Pub. L. 110–377, §2, Oct. 8, 2008, 122 Stat. 4063, provided that: "Congress makes the following findings:

"(1) Poison control centers are the primary defense of the United States against injury and deaths from poisoning. Twenty-four hours a day, the general public as well as health care practitioners contact their local poison control centers for help in diagnosing and treating victims of poisoning. In 2007, more than 4,000,000 calls were managed by poison control centers providing ready and direct access for all people of the United States, including many underserved populations in the United States, with vital emergency public health information and response.

"(2) Poisoning is the second most common form of unintentional death in the United States. In any given year, there will be between 3,000,000 and 5,000,000 poison exposures. Sixty percent of these exposures will involve children under the age of 6 who are exposed to toxins in their home. Poisoning accounts for 285,000 hospitalizations, 1,200,000 days of acute hospital care, and more than 26,000 fatalities in 2005.

"(3) In 2008, the Harvard Injury Control Research Center reported that poisonings from accidents and unknown circumstances more than tripled in rate since 1990. In 2005, the last year for which data are available, 26,858 people died from accidental or unknown poisonings. This represents an increase of 20,000 since 1990 and an increase of 2,400 between 2004 and 2005. Fatalities from poisoning are increasing in the United States in near epidemic proportions. The funding of programs to reverse this trend is needed now more than ever.

"(4) In 2004, The Institute of Medicine of the National Academy of Sciences recommended that 'Congress should amend the current Poison Control Center Enhancement and Awareness Act Amendments of 2003 [Pub. L. 108–194, see Short Title of 2003 Amendments note set out under section 201 of this title] to provide sufficient funding to support the proposed Poison Prevention and Control System with its national network of poison centers. Support for the core activities at the current level of service is estimated to require more than $100 million annually.'.

"(5) Sustaining the funding structure and increasing accessibility to poison control centers will

promote the utilization of poison control centers and reduce the inappropriate use of emergency medical services and other more costly health care services. The 2004 Institute of Medicine Report to Congress determined that for every $1 invested in the Nation's poison control centers $7 of health care costs are saved. In 2005, direct Federal health care program savings totaled in excess of $525,000,000 as the result of poison control center public health services.

"(6) More than 30 percent of the cost savings and financial benefits of the Nation's network of poison control centers are realized annually by Federal health care programs (estimated to be more than $1,000,000,000), yet Federal funding support (as demonstrated by the annual authorization of $30,100,000 in Public Law 108–194) comprises less than 11 percent of the annual network expenditures of poison centers.

"(7) Real-time data collected from the Nation's certified poison control centers can be an important source of information for the detection, monitoring, and response for contamination of the air, water, pharmaceutical, or food supply.

"(8) In the event of a terrorist event, poison control centers will be relied upon as a critical source for accurate medical information and public health emergency response concerning the treatment of patients who have had an exposure to a chemical, radiological, or biological agent."

Pub. L. 108–194, §2, Dec. 19, 2003, 117 Stat. 2888, provided that: "The Congress finds the following:

"(1) Poison control centers are our Nation's primary defense against injury and deaths from poisoning. Twenty-four hours a day, the general public as well as health care practitioners contact their local poison centers for help in diagnosing and treating victims of poisoning and other toxic exposures.

"(2) Poisoning is the third most common form of unintentional death in the United States. In any given year, there will be between 2,000,000 and 4,000,000 poison exposures. More than 50 percent of these exposures will involve children under the age of 6 who are exposed to toxic substances in their home. Poisoning accounts for 285,000 hospitalizations, 1,200,000 days of acute hospital care, and 13,000 fatalities annually.

"(3) Stabilizing the funding structure and increasing accessibility to poison control centers will promote the utilization of poison control centers, and reduce the inappropriate use of emergency medical services and other more costly health care services.

"(4) The tragic events of September 11, 2001, and the anthrax cases of October 2001, have dramatically changed our Nation. During this time period, poison centers in many areas of the country were answering thousands of additional calls from concerned residents. Many poison centers were relied upon as a source for accurate medical information about the disease and the complications resulting from prophylactic antibiotic therapy.

"(5) The 2001 Presidential Task Force on Citizen Preparedness in the War on Terrorism recommended that the Poison Control Centers be used as a source of public information and public education regarding potential biological, chemical, and nuclear domestic terrorism.

"(6) The increased demand placed upon poison centers to provide emergency information in the event of a terrorist event involving a biological, chemical, or nuclear toxin will dramatically increase call volume."

§300d–72. Promoting poison control center utilization

(a) In general

The Secretary shall carry out, and expand upon, a national media campaign to educate and support outreach to the public and health care providers about poisoning and toxic exposure prevention and the availability of poison control center resources in local communities and to conduct advertising campaigns concerning the nationwide toll-free number and other available communication technologies established, implemented, or maintained under section 300d–71(a) of this title.

(b) Contract with entity

The Secretary may carry out subsection (a) by entering into contracts with one or more public or private entities, including nationally recognized organizations in the field of poison control and national media firms, for the development and implementation of a nationwide poisoning and toxic exposure prevention and poison control center awareness campaign, which may include—

(1) the development and distribution of poisoning and toxic exposure prevention awareness materials, applicable public health emergency preparedness and response information, and poison

control center awareness materials;

(2) television, radio, Internet, and newspaper public service announcements; and

(3) other activities to provide for public and professional awareness and education.

(c) Authorization of appropriations

There is authorized to be appropriated to carry out this section, $800,000 for each of fiscal years 2025 through 2029.

(July 1, 1944, ch. 373, title XII, §1272, as added Pub. L. 108–194, §3, Dec. 19, 2003, 117 Stat. 2889; amended Pub. L. 110–377, §4(a), Oct. 8, 2008, 122 Stat. 4064; Pub. L. 113–77, §3, Jan. 24, 2014, 128 Stat. 644; Pub. L. 116–94, div. N, title I, §403(b), Dec. 20, 2019, 133 Stat. 3114; Pub. L. 118–86, §2(b), Sept. 26, 2024, 138 Stat. 1549.)

EDITORIAL NOTES

AMENDMENTS

2024—Subsec. (c). Pub. L. 118–86 substituted "fiscal years 2025 through 2029" for "fiscal years 2020 through 2024".

2019—Pub. L. 116–94, §403(b)(1), substituted "Promoting" for "Nationwide media campaign to promote" in section catchline.

Subsec. (a). Pub. L. 116–94, §403(b)(2), inserted "and support outreach to" after "educate", and substituted "poisoning and toxic exposure prevention" for "poison prevention" and "and other available communication technologies established, implemented, or maintained under" for "established under".

Subsec. (b). Pub. L. 116–94, §403(b)(3)(A), substituted "nationwide poisoning and toxic exposure prevention" for "nationwide poison prevention" in introductory provisions.

Subsec. (b)(1). Pub. L. 116–94, §403(b)(3)(B), substituted "poisoning and toxic exposure prevention awareness materials, applicable public health emergency preparedness and response information, and poison control center" for "poison prevention and poison control center".

Subsecs. (c), (d). Pub. L. 116–94, §403(b)(4)–(6), redesignated subsec. (d) as (c), substituted "2020 through 2024" for "2015 through 2019", and struck out former subsec. (c). Prior to amendment, text of subsec. (c) read as follows: "The Secretary shall—

"(1) establish baseline measures and benchmarks to quantitatively evaluate the impact of the nationwide media campaign carried out under this section; and

"(2) on an annual basis, prepare and submit to the appropriate committees of Congress an evaluation of the nationwide media campaign."

2014—Subsec. (c)(2). Pub. L. 113–77, §3(1), struck out comma after "Congress".

Subsec. (d). Pub. L. 113–77, §3(2), added subsec. (d) and struck out former subsec. (d). Prior to amendment, text read as follows: "There is authorized to be appropriated to carry out this section, such sums as may be necessary for fiscal year 2009, and $800,000 for each of fiscal years 2010 through 2014."

2008—Pub. L. 110–377 amended section generally. Prior to amendment, section required the Secretary to establish a national media campaign to educate the public and health care providers about poison control and prevention and authorized appropriations for fiscal years 2000 through 2009.

STATUTORY NOTES AND RELATED SUBSIDIARIES

EFFECTIVE DATE OF 2008 AMENDMENT

Pub. L. 110–377, §4(b), Oct. 8, 2008, 122 Stat. 4065, provided that: "The amendment made by this section [amending this section] shall be effective on the date of the enactment of this Act [Oct. 8, 2008] and shall apply to contracts entered into on or after January 1, 2009."

§300d–73. Maintenance of the poison control center grant program

(a) Authorization of program

The Secretary shall award grants to poison control centers accredited under subsection (c) (or granted a waiver under subsection (d)) and professional organizations in the field of poison control

for the purposes of preventing, and providing treatment recommendations for, poisonings and toxic exposures and complying with the operational requirements needed to sustain the accreditation of the center under subsection (c).

(b) Additional uses of funds

In addition to the purposes described in subsection (a), a poison center or professional organization awarded a grant, contract, or cooperative agreement under such subsection may also use amounts received under such grant, contract, or cooperative agreement—

(1) to research, establish, implement, and evaluate best practices in the United States for poisoning and toxic exposure prevention, poison control center outreach, and emergency preparedness and response programs;

(2) to research, develop, implement, revise, and communicate standard patient management guidelines for commonly encountered toxic exposures;

(3) to improve national toxic exposure surveillance by enhancing cooperative activities between poison control centers in the United States, the Centers for Disease Control and Prevention, and other government agencies as determined to be appropriate and nonduplicative by the Secretary;

(4) to research, improve, and enhance the communications and response capability and capacity of the nation's network of poison control centers to facilitate increased access to the centers through the integration and modernization of the current poison control centers communications and data system, including enhancing the network's telephony, Internet, data and social networking technologies;

(5) to develop, support, and enhance technology and capabilities of professional organizations in the field of poison control to collect national poisoning, toxic occurrence, and related public health data;

(6) to develop initiatives to foster the enhanced public health utilization of national poison data collected by organizations described in paragraph (5);

(7) to support and expand the toxicologic expertise within poison control centers; and

(8) to improve the capacity of poison control centers to answer high volumes of contacts and Internet communications, and to sustain and enhance the poison control center's network capability to respond during times of national crisis or other public health emergencies.

(c) Accreditation

Except as provided in subsection (d), the Secretary may award a grant to a poison control center under subsection (a) only if—

(1) the center has been accredited by a professional organization in the field of poison control, and the Secretary has approved the organization as having in effect standards for accreditation that reasonably provide for the protection of the public health with respect to poisoning; or

(2) the center has been accredited by a State government, and the Secretary has approved the State government as having in effect standards for accreditation that reasonably provide for the protection of the public health with respect to poisoning.

(d) Waiver of accreditation requirements

(1) In general

The Secretary may grant a waiver of the accreditation requirements of subsection (c) with respect to a nonaccredited poison control center that applies for a grant under this section if such center can reasonably demonstrate that the center will obtain such an accreditation within a reasonable period of time as determined appropriate by the Secretary.

(2) Renewal

The Secretary may renew a waiver under paragraph (1).

(3) Limitation

(A) In general

The sum of the number of years for a waiver under paragraph (1) and a renewal under

paragraph (2) may not exceed 5 years.

(B) Public health emergency

Notwithstanding any previous waivers, in the case of a poison control center whose accreditation is affected by a public health emergency declared pursuant to section 247d of this title, the Secretary may, as the circumstances of the emergency reasonably require, provide a waiver under paragraph (1) or a renewal under paragraph (2), not to exceed 2 years. The Secretary may require quarterly reports and other information related to such a waiver or renewal under this paragraph.

(e) Supplement not supplant

Amounts made available to a poison control center under this section shall be used to supplement and not supplant other Federal, State or local funds provided for such center.

(f) Maintenance of effort

With respect to activities for which a grant is awarded under this section, the Secretary may require that poison control centers agree to maintain the expenditures of the center for such activities at a level that is not less than the level of expenditures maintained by the center for the fiscal year preceding the fiscal year for which the grant is received.

(g) Authorization of appropriations

There is authorized to be appropriated to carry out this section, $28,600,000 for each of fiscal years 2025 through 2029. The Secretary may utilize an amount not to exceed 6 percent of the amount appropriated under this preceding sentence in each fiscal year for coordination, dissemination, technical assistance, program evaluation, data activities, and other program administration functions, which are determined by the Secretary to be appropriate for carrying out the program under this section.

(h) Biennial report to Congress

Not later than 2 years after December 20, 2019, and every 2 years thereafter, the Secretary shall submit to the Committee on Health, Education, Labor, and Pensions of the Senate and Committee on Energy and Commerce of the House of Representatives a report concerning the operations of, and trends identified by, the Poison Control Network. Such report shall include—

(1) descriptions of the activities carried out pursuant to sections 300d–71, 300d–72, and 300d–73 of this title, and the alignment of such activities with the purposes provided under subsection (a);

(2) a description of trends in volume of contacts to poison control centers;

(3) a description of trends in poisonings and toxic exposures reported to poison control centers, as applicable and appropriate;

(4) an assessment of the impact of the public awareness campaign, including any geographic variations;

(5) a description of barriers, if any, preventing poison control centers from achieving the purposes and programs under this section and sections 300d–71 and 300d–72 of this title;

(6) a description of the standards for accreditation described in subsection (c), including any variations in those standards, and any efforts to create and maintain consistent standards across organizations that accredit poison control centers; and

(7) the number of and reason for any waivers provided under subsection (d).

(July 1, 1944, ch. 373, title XII, §1273, as added Pub. L. 108–194, §3, Dec. 19, 2003, 117 Stat. 2889; amended Pub. L. 110–377, §5(a), Oct. 8, 2008, 122 Stat. 4065; Pub. L. 113–77, §4(a), Jan. 24, 2014, 128 Stat. 644; Pub. L. 116–94, div. N, title I, §403(c), Dec. 20, 2019, 133 Stat. 3115; Pub. L. 118–86, §2(c), Sept. 26, 2024, 138 Stat. 1549.)

EDITORIAL NOTES

AMENDMENTS

2024—Subsec. (g). Pub. L. 118–86 substituted "fiscal years 2025 through 2029" for "fiscal years 2020 through 2024".

2019—Subsec. (a). Pub. L. 116–94, §403(c)(1), inserted "and toxic exposures" after "poisonings".

Subsec. (b)(1). Pub. L. 116–94, §403(c)(2)(A), substituted "for poisoning and toxic exposure" for "for poison" and "preparedness and response" for "and preparedness".

Subsec. (b)(3). Pub. L. 116–94, §403(c)(2)(B), substituted "United States," for "United States and" and inserted ", and other government agencies as determined to be appropriate and nonduplicative by the Secretary" before semicolon at end.

Subsec. (b)(8). Pub. L. 116–94, §403(c)(2)(C), substituted "contacts" for "calls".

Subsec. (d)(3). Pub. L. 116–94, §403(c)(3), added par. (3) and struck out former par. (3). Prior to amendment, text read as follows: "In no case may the sum of the number of years for a waiver under paragraph (1) and a renewal under paragraph (2) exceed—

"(A) 5 years; or

"(B) in the case of a nonaccredited poison control center operating pursuant to a waiver under this subsection as of October 1, 2014, 6 years."

Subsec. (f). Pub. L. 116–94, §403(c)(4), added subsec. (f) and struck out former subsec. (f). Prior to amendment, text read as follows: "A poison control center, in utilizing the proceeds of a grant under this section, shall maintain the expenditures of the center for its activities at a level that is not less than the level of expenditures maintained by the center for the fiscal year preceding the fiscal year for which the grant is received."

Subsec. (g). Pub. L. 116–94, §403(c)(5), substituted "2020 through 2024" for "2015 through 2019".

Subsec. (h). Pub. L. 116–94, §403(c)(6), added subsec. (h).

2014—Subsec. (a). Pub. L. 113–77, §4(a)(1), substituted "accredited" for "certified" and "accreditation" for "certification".

Subsec. (b)(1). Pub. L. 113–77, §4(a)(2)(A), substituted "research, establish, implement," for "establish".

Subsec. (b)(4). Pub. L. 113–77, §4(a)(2)(C), added par. (4). Former par. (4) redesignated (5).

Subsec. (b)(5). Pub. L. 113–77, §4(a)(2)(B), redesignated par. (4) as (5). Former par. (5) redesignated (6).

Subsec. (b)(6). Pub. L. 113–77, §4(a)(2)(B), (D), redesignated par. (5) as (6) and substituted "paragraph (5)" for "paragraph (4)". Former par. (6) redesignated (7).

Subsec. (b)(7). Pub. L. 113–77, §4(a)(2)(B), redesignated par. (6) as (7). Former par. (7) redesignated (8).

Subsec. (b)(8). Pub. L. 113–77, §4(a)(2)(B), (E), redesignated par. (7) as (8) and substituted "and Internet communications, and to sustain and enhance the poison control center's network capability to respond" for "and respond".

Subsec. (c). Pub. L. 113–77, §4(a)(3), substituted "Accreditation" for "Certification" in heading and "accredited" for "certified" and "accreditation" for "certification" in pars. (1) and (2).

Subsec. (d). Pub. L. 113–77, §4(a)(4)(A), substituted "accreditation" for "certification" in heading.

Subsec. (d)(1). Pub. L. 113–77, §4(a)(4)(B), substituted "the accreditation" for "the certification", "a nonaccredited" for "a noncertified", and "an accreditation" for "a certification".

Subsec. (d)(3). Pub. L. 113–77, §4(a)(4)(C), substituted "exceed—" for "exceed 5 years. The preceding sentence shall take effect as of October 8, 2008." and added subpars. (A) and (B).

Subsec. (f). Pub. L. 113–77, §4(a)(5), substituted "for its activities" for "for activities of the center".

Subsec. (g). Pub. L. 113–77, §4(a)(6), added subsec. (g) and struck out former subsec. (g) which authorized appropriations for fiscal years 2009 through 2014 and limited the amount allowed to be spent on certain administrative functions.

2008—Pub. L. 110–377 amended section generally. Prior to amendment, section related to awarding of grants to certified regional poison control centers and additional uses of appropriated funds by Secretary and authorized appropriations for fiscal years 2000 through 2009.

STATUTORY NOTES AND RELATED SUBSIDIARIES

EFFECTIVE DATE OF 2014 AMENDMENT

Pub. L. 113–77, §4(b), Jan. 24, 2014, 128 Stat. 646, provided that: "The amendments made by subsection (a) [amending this section] shall take effect on the date of the enactment of this Act [Jan. 24, 2014] and shall apply to grants made on or after October 1, 2014."

EFFECTIVE DATE OF 2008 AMENDMENT

Pub. L. 110–377, §5(b), Oct. 8, 2008, 122 Stat. 4067, provided that: "The amendment made by this section [amending this section] shall be effective as of the date of the enactment of this Act [Oct. 8, 2008] and shall

apply to grants made on or after January 1, 2009."

§300d–74. Rule of construction

Nothing in this part may be construed to ease any restriction in Federal law applicable to the amount or percentage of funds appropriated to carry out this part that may be used to prepare or submit a report.

(July 1, 1944, ch. 373, title XII, §1274, as added Pub. L. 108–194, §3, Dec. 19, 2003, 117 Stat. 2891.)

PART H—TRAUMA SERVICE AVAILABILITY

§300d–81. Grants to States

(a) Establishment

To promote universal access to trauma care services provided by trauma centers and trauma-related physician specialties, the Secretary shall provide funding to States to enable such States to award grants to eligible entities for the purposes described in this section.

(b) Awarding of grants by States

Each State may award grants to eligible entities within the State for the purposes described in subparagraph (d).

(c) Eligibility

(1) In general

To be eligible to receive a grant under subsection (b) an entity shall—

(A) be—

(i) a public or nonprofit trauma center or consortium thereof that meets that [1] requirements of paragraphs (1), (2), and (5) of section 300d–41(b) of this title;

(ii) a safety net public or nonprofit trauma center that meets the requirements of paragraphs (1) through (5) of section 300d–41(b) of this title; or

(iii) a hospital in an underserved area (as defined by the State) that seeks to establish new trauma services; and

(B) submit to the State an application at such time, in such manner, and containing such information as the State may require.

(2) Limitation

A State shall use at least 40 percent of the amount available to the State under this part for a fiscal year to award grants to safety net trauma centers described in paragraph (1)(A)(ii).

(d) Use of funds

The recipient of a grant under subsection (b) shall carry out 1 or more of the following activities consistent with subsection (b):

(1) Providing trauma centers with funding to support physician compensation in trauma-related physician specialties where shortages exist in the region involved, with priority provided to safety net trauma centers described in subsection (c)(1)(A)(ii).

(2) Providing for individual safety net trauma center fiscal stability and costs related to having service that is available 24 hours a day, 7 days a week, with priority provided to safety net trauma centers described in subsection (c)(1)(A)(ii) located in urban, border, and rural areas.

(3) Reducing trauma center overcrowding at specific trauma centers related to throughput of

trauma patients.

(4) Establishing new trauma services in underserved areas as defined by the State.

(5) Enhancing collaboration between trauma centers and other hospitals and emergency medical services personnel related to trauma service availability.

(6) Making capital improvements to enhance access and expedite trauma care, including providing helipads and associated safety infrastructure.

(7) Enhancing trauma surge capacity at specific trauma centers.

(8) Ensuring expedient receipt of trauma patients transported by ground or air to the appropriate trauma center.

(9) Enhancing interstate trauma center collaboration.

(e) Limitation

(1) In general

A State may use not more than 20 percent of the amount available to the State under this part for a fiscal year for administrative costs associated with awarding grants and related costs.

(2) Maintenance of effort

The Secretary may not provide funding to a State under this part unless the State agrees that such funds will be used to supplement and not supplant State funding otherwise available for the activities and costs described in this part.

(f) Distribution of funds

The following shall apply with respect to grants provided in this part:

(1) Less than $10,000,000

If the amount of appropriations for this part in a fiscal year is less than $10,000,000, the Secretary shall divide such funding evenly among only those States that have 1 or more trauma centers eligible for funding under section 300d–41(b)(3)(A) of this title.

(2) Less than $20,000,000

If the amount of appropriations in a fiscal year is less than $20,000,000, the Secretary shall divide such funding evenly among only those States that have 1 or more trauma centers eligible for funding under subparagraphs (A) and (B) of section 300d–41(b)(3) of this title.

(3) Less than $30,000,000

If the amount of appropriations for this part in a fiscal year is less than $30,000,000, the Secretary shall divide such funding evenly among only those States that have 1 or more trauma centers eligible for funding under section 300d–41(b)(3) of this title.

(4) $30,000,000 or more

If the amount of appropriations for this part in a fiscal year is $30,000,000 or more, the Secretary shall divide such funding evenly among all States.

(July 1, 1944, ch. 373, title XII, §1281, as added Pub. L. 111–148, title III, §3505(b), Mar. 23, 2010, 124 Stat. 525.)

[1] So in original. Probably should be "the".

§300d–82. Authorization of appropriations

For the purpose of carrying out this part, there is authorized to be appropriated $100,000,000 for each of fiscal years 2010 through 2015.

(July 1, 1944, ch. 373, title XII, §1282, as added Pub. L. 111–148, title III, §3505(b), Mar. 23, 2010, 124 Stat. 527.)

PART I—MILITARY AND CIVILIAN PARTNERSHIP FOR TRAUMA READINESS GRANT PROGRAM

§300d–91. Military and civilian partnership for trauma readiness grant program

(a) Military trauma team placement program

(1) In general

The Secretary, acting through the Assistant Secretary for Preparedness and Response and in consultation with the Secretary of Defense, shall award grants to not more than 20 eligible high-acuity trauma centers to enable military trauma teams to provide, on a full-time basis, trauma care and related acute care at such trauma centers.

(2) Limitations

In the case of a grant awarded under paragraph (1) to an eligible high-acuity trauma center, such grant—

(A) shall be for a period of at least 3 years and not more than 5 years (and may be renewed at the end of such period); and

(B) shall be in an amount that does not exceed $1,000,000 per year.

(3) Availability of funds

Notwithstanding section 1552 of title 31 or any other provision of law, funds available to the Secretary for obligation for a grant under this subsection shall remain available for expenditure for 100 days after the last day of the performance period of such grant.

(b) Military trauma care provider placement program

(1) In general

The Secretary, acting through the Assistant Secretary for Preparedness and Response and in consultation with the Secretary of Defense, shall award grants to eligible trauma centers to enable military trauma care providers to provide trauma care and related acute care at such trauma centers.

(2) Limitations

In the case of a grant awarded under paragraph (1) to an eligible trauma center, such grant—

(A) shall be for a period of at least 1 year and not more than 3 years (and may be renewed at the end of such period); and

(B) shall be in an amount that does not exceed, in a year—

(i) $100,000 for each military trauma care provider that is a physician at such eligible trauma center; and

(ii) $50,000 for each other military trauma care provider at such eligible trauma center.

(c) Grant requirements

(1) Deployment and public health emergencies

As a condition of receipt of a grant under this section, a grant recipient shall agree to allow military trauma care providers providing care pursuant to such grant to—

(A) be deployed by the Secretary of Defense for military operations, for training, or for response to a mass casualty incident; and

(B) be deployed by the Secretary of Defense, in consultation with the Secretary of Health and Human Services, for response to a public health emergency pursuant to section 247d of this title.

(2) Use of funds

Grants awarded under this section to an eligible trauma center may be used to train and

incorporate military trauma care providers into such trauma center, including incorporation into operational exercises and training drills related to public health emergencies, expenditures for malpractice insurance, office space, information technology, specialty education and supervision, trauma programs, research, and applicable license fees for such military trauma care providers.

(d) Rule of construction

Nothing in this section shall be construed to affect any other provision of law that preempts State licensing requirements for health care professionals, including with respect to military trauma care providers.

(e) Reporting requirements

(1) Report to the Secretary and the Secretary of Defense

Each eligible trauma center or eligible high-acuity trauma center awarded a grant under subsection (a) or (b) for a year shall submit to the Secretary and the Secretary of Defense a report for such year that includes information on—

(A) the number and types of trauma cases managed by military trauma teams or military trauma care providers pursuant to such grant during such year;

(B) the ability to maintain the integration of the military trauma providers or teams of providers as part of the trauma center, including the financial effect of such grant on the trauma center;

(C) the educational effect on resident trainees in centers where military trauma teams are assigned;

(D) any research conducted during such year supported by such grant; and

(E) any other information required by the Secretaries for the purpose of evaluating the effect of such grant.

(2) Report to Congress

Not less than once every 2 years, the Secretary, in consultation with the Secretary of Defense, shall submit a report to the congressional committees of jurisdiction that includes information on the effect of placing military trauma care providers in trauma centers awarded grants under this section on—

(A) maintaining military trauma care providers' readiness and ability to respond to and treat battlefield injuries;

(B) providing health care to civilian trauma patients in urban and rural settings;

(C) the capability of trauma centers and military trauma care providers to increase medical surge capacity, including as a result of a large-scale event;

(D) the ability of grant recipients to maintain the integration of the military trauma providers or teams of providers as part of the trauma center;

(E) efforts to incorporate military trauma care providers into operational exercises and training and drills for public health emergencies; and

(F) the capability of military trauma care providers to participate as part of a medical response during or in advance of a public health emergency, as determined by the Secretary, or a mass casualty incident.

(f) Definitions

For purposes of this part:

(1) Eligible high-acuity trauma center

The term "eligible high-acuity trauma center" means a Level I trauma center that satisfies each of the following:

(A) Such trauma center has an agreement with the Secretary of Defense to enable military trauma teams to provide trauma care and related acute care at such trauma center.

(B) At least 20 percent of patients treated at such trauma center in the most recent 3-month period for which data are available are treated for a major trauma at such trauma center.

(C) Such trauma center utilizes a risk-adjusted benchmarking system and metrics to measure

performance, quality, and patient outcomes.

(D) Such trauma center is an academic training center—

(i) affiliated with a medical school;

(ii) that maintains residency programs and fellowships in critical trauma specialties and subspecialties, and provides education and supervision of military trauma team members according to those specialties and subspecialties; and

(iii) that undertakes research in the prevention and treatment of traumatic injury.

(E) Such trauma center serves as a medical and public health preparedness and response leader for its community, such as by participating in a partnership for State and regional hospital preparedness established under section 247d–3b or 247d–3c of this title.

(2) Eligible trauma center

The term "eligible trauma center" means a Level I, II, or III trauma center that satisfies each of the following:

(A) Such trauma center has an agreement with the Secretary of Defense to enable military trauma care providers to provide trauma care and related acute care at such trauma center.

(B) Such trauma center utilizes a risk-adjusted benchmarking system and metrics to measure performance, quality, and patient outcomes.

(C) Such trauma center demonstrates a need for integrated military trauma care providers to maintain or improve the trauma clinical capability of such trauma center.

(3) Major trauma

The term "major trauma" means an injury that is greater than or equal to 15 on the injury severity score.

(4) Military trauma team

The term "military trauma team" means a complete military trauma team consisting of military trauma care providers.

(5) Military trauma care provider

The term "military trauma care provider" means a member of the Armed Forces who furnishes emergency, critical care, and other trauma acute care services (including a physician, surgeon, physician assistant, nurse, nurse practitioner, respiratory therapist, flight paramedic, combat medic, or enlisted medical technician) or other military trauma care provider as the Secretary determines appropriate.

(g) Authorization of appropriations

To carry out this section, there is authorized to be appropriated $11,500,000 for each of fiscal years 2019 through 2023.

(July 1, 1944, ch. 373, title XII, §1291, as added Pub. L. 116–22, title II, §204, June 24, 2019, 133 Stat. 915.)

SUBCHAPTER XI—HEALTH MAINTENANCE ORGANIZATIONS

§300e. Requirements of health maintenance organizations

(a) "Health maintenance organization" defined

For purposes of this subchapter, the term "health maintenance organization" means a public or private entity which is organized under the laws of any State and which (1) provides basic and supplemental health services to its members in the manner prescribed by subsection (b), and (2) is organized and operated in the manner prescribed by subsection (c).

(b) Manner of supplying basic and supplemental health services to members

A health maintenance organization shall provide, without limitations as to time or cost other than those prescribed by or under this subchapter, basic and supplemental health services to its members in the following manner:

(1) Each member is to be provided basic health services for a basic health services payment which (A) is to be paid on a periodic basis without regard to the dates health services (within the basic health services) are provided; (B) is fixed without regard to the frequency, extent, or kind of health service (within the basic health services) actually furnished; (C) except in the case of basic health services provided a member who is a full-time student (as defined by the Secretary) at an accredited institution of higher education, is fixed under a community rating system; and (D) may be supplemented by additional nominal payments which may be required for the provision of specific services (within the basic health services), except that such payments may not be required where or in such a manner that they serve (as determined under regulations of the Secretary) as a barrier to the delivery of health services. Such additional nominal payments shall be fixed in accordance with the regulations of the Secretary. If a health maintenance organization offers to its members the opportunity to obtain basic health services through a physician not described in subsection (b)(3)(A), the organization may require, in addition to payments described in clause (D) of this paragraph, a reasonable deductible to be paid by a member when obtaining a basic health service from such a physician. A health maintenance organization may include a health service, defined as a supplemental health service by section 300e–1(2) of this title, in the basic health services provided its members for a basic health services payment described in the first sentence. In the case of an entity which before it became a qualified health maintenance organization (within the meaning of section 300e–9(d) [1] of this title) provided comprehensive health services on a prepaid basis, the requirement of clause (C) shall not apply to such entity until the expiration of the forty-eight month period beginning with the month following the month in which the entity became such a qualified health organization. The requirements of this paragraph respecting the basic health services payment shall not apply to the provision of basic health services to a member for an illness or injury for which the member is entitled to benefits under a workmen's compensation law or an insurance policy but only to the extent such benefits apply to such services. For the provision of such services for an illness or injury for which a member is entitled to benefits under such a law, the health maintenance organization may, if authorized by such law, charge or authorize the provider of such services to charge, in accordance with the charges allowed under such law, the insurance carrier, employer, or other entity which under such law is to pay for the provision of such services or, to the extent that such member has been paid under such law for such services, such member. For the provision of such services for an illness or injury for which a member is entitled to benefits under an insurance policy, a health maintenance organization may charge or authorize the provider of such services to charge the insurance carrier under such policy or, to the extent that such member has been paid under such policy for such services, such member.

(2) For such payment or payments (hereinafter in this subchapter referred to as "supplemental health services payments") as the health maintenance organization may require in addition to the basic health services payment, the organization may provide to each of its members any of the health services which are included in supplemental health services (as defined in section 300e–1(2) of this title). Supplemental health services payments which are fixed on a prepayment basis shall be fixed under a community rating system unless the supplemental health services payment is for a supplemental health service provided a member who is a full-time student (as defined by the Secretary) at an accredited institution of higher education, except that, in the case of an entity which before it became a qualified health maintenance organization (within the meaning of section 300e–9(d) [1] of this title) provided comprehensive health services on a prepaid basis, the requirement of this sentence shall not apply to such entity during the forty-eight month period beginning with the month following the month in which the entity became such a qualified health maintenance organization.

(3)(A) Except as provided in subparagraph (B), at least 90 percent of the services of a physician

which are provided as basic health services shall be provided through—

(i) members of the staff of the health maintenance organization,

(ii) a medical group (or groups),

(iii) an individual practice association (or associations),

(iv) physicians or other health professionals who have contracted with the health maintenance organization for the provision of such services, or

(v) any combination of such staff, medical group (or groups), individual practice association (or associations) or physicians or other health professionals under contract with the organization.

(B) Subparagraph (A) does not apply to the provision of the services of a physician—

(i) which the health maintenance organization determines, in conformity with regulations of the Secretary, are unusual or infrequently used, or

(ii) which are provided a member of the organization in a manner other than that prescribed by subparagraph (A) because of an emergency which made it medically necessary that the service be provided to the member before it could be provided in a manner prescribed by subparagraph (A).

(C) Contracts between a health maintenance organization and health professionals for the provision of basic and supplemental health services shall include such provisions as the Secretary may require, but only to the extent that such requirements are designed to insure the delivery of quality health care services and sound fiscal management.

(D) For purposes of this paragraph the term "health professional" means physicians, dentists, nurses, podiatrists, optometrists, and such other individuals engaged in the delivery of health services as the Secretary may by regulation designate.

(4) Basic health services (and only such supplemental health services as members have contracted for) shall within the area served by the health maintenance organization be available and accessible to each of its members with reasonable promptness and in a manner which assures continuity, and when medically necessary be available and accessible twenty-four hours a day and seven days a week, except that a health maintenance organization which has a service area located wholly in a nonmetropolitan area may make a basic health service available outside its service area if that basic health service is not a primary care or emergency health care service and if there is an insufficient number of providers of that basic health service within the service area who will provide such service to members of the health maintenance organization. A member of a health maintenance organization shall be reimbursed by the organization for his expenses in securing basic and supplemental health services other than through the organization if the services were medically necessary and immediately required because of an unforeseen illness, injury, or condition.

(5) To the extent that a natural disaster, war, riot, civil insurrection, or any other similar event not within the control of a health maintenance organization (as determined under regulations of the Secretary) results in the facilities, personnel, or financial resources of a health maintenance organization not being available to provide or arrange for the provision of a basic or supplemental health service in accordance with the requirements of paragraphs (1) through (4) of this subsection, such requirements only require the organization to make a good-faith effort to provide or arrange for the provision of such service within such limitation on its facilities, personnel, or resources.

(6) A health maintenance organization that otherwise meets the requirements of this subchapter may offer a high-deductible health plan (as defined in section 220(c)(2) of title 26).

(c) Organizational requirements

Each health maintenance organization shall—

(1)(A) have—

(i) a fiscally sound operation, and

(ii) adequate provision against the risk of insolvency,

which is satisfactory to the Secretary, and (B) have administrative and managerial arrangements satisfactory to the Secretary;

(2) assume full financial risk on a prospective basis for the provision of basic health services, except that a health maintenance organization may (A) obtain insurance or make other arrangements for the cost of providing to any member basic health services the aggregate value of which exceeds $5,000 in any year, (B) obtain insurance or make other arrangements for the cost of basic health services provided to its members other than through the organization because medical necessity required their provision before they could be secured through the organization, (C) obtain insurance or make other arrangements for not more than 90 per centum of the amount by which its costs for any of its fiscal years exceed 115 per centum of its income for such fiscal year, and (D) make arrangements with physicians or other health professionals, health care institutions, or any combination of such individuals or institutions to assume all or part of the financial risk on a prospective basis for the provision of basic health services by the physicians or other health professionals or through the institutions;

(3)(A) enroll persons who are broadly representative of the various age, social, and income groups within the area it serves, except that in the case of a health maintenance organization which has a medically underserved population located (in whole or in part) in the area it serves, not more than 75 per centum of the members of that organization may be enrolled from the medically underserved population unless the area in which such population resides is also a rural area (as designated by the Secretary), and (B) carry out enrollment of members who are entitled to medical assistance under a State plan approved under title XIX of the Social Security Act [42 U.S.C. 1396 et seq.] in accordance with procedures approved under regulations promulgated by the Secretary;

(4) not expel or refuse to re-enroll any member because of his health status or his requirements for health services;

(5) be organized in such a manner that provides meaningful procedures for hearing and resolving grievances between the health maintenance organization (including the medical group or groups and other health delivery entities providing health services for the organization) and the members of the organization;

(6) have organizational arrangements, established in accordance with regulations of the Secretary, for an ongoing quality assurance program for its health services which program (A) stresses health outcomes, and (B) provides review by physicians and other health professionals of the process followed in the provision of health services;

(7) adopt at least one of the following arrangements to protect its members from incurring liability for payment of any fees which are the legal obligation of such organization—

(A) a contractual arrangement with any hospital that is regularly used by the members of such organization prohibiting such hospital from holding any such member liable for payment of any fees which are the legal obligation of such organization;

(B) insolvency insurance, acceptable to the Secretary;

(C) adequate financial reserve, acceptable to the Secretary; and

(D) other arrangements, acceptable to the Secretary, to protect members,

except that the requirements of this paragraph shall not apply to a health maintenance organization if applicable State law provides the members of such organization with protection from liability for payment of any fees which are the legal obligation of such organization; and

(8) provide, in accordance with regulations of the Secretary (including safeguards concerning the confidentiality of the doctor-patient relationship), and effective procedure for developing, compiling, evaluating, and reporting to the Secretary, statistics and other information (which the Secretary shall publish and disseminate on an annual basis and which the health maintenance organization shall disclose, in a manner acceptable to the Secretary, to its members and the general public) relating to (A) the cost of its operations, (B) the patterns of utilization of its services, (C)

the availability, accessibility, and acceptability of its services, (D) to the extent practical, developments in the health status of its members, and (E) such other matters as the Secretary may require.

The Secretary shall issue regulations stating the circumstances under which the Secretary, in administering paragraph (1)(A), will consider the resources of an organization which owns or controls a health maintenance organization. Such regulations shall require as a condition to consideration of resources that an organization which owns or controls a health maintenance organization shall provide satisfactory assurances that it will assume the financial obligations of the health maintenance organization.

(d) Application of rules by certain health maintenance organizations

An organization that offers health benefits coverage shall not be considered as failing to meet the requirements of this section notwithstanding that it provides, with respect to coverage offered in connection with a group health plan in the small or large group market (as defined in section 300gg–91(e) of this title), an affiliation period consistent with the provisions of section 2701(g).[1]

(July 1, 1944, ch. 373, title XIII, §1301, as added Pub. L. 93–222, §2, Dec. 29, 1973, 87 Stat. 914; amended Pub. L. 94–460, title I, §§101, 102(a), 103, 105(a), Oct. 8, 1976, 90 Stat. 1945–1947; Pub. L. 95–559, §§9(b), 10, 11(a)–(d), Nov. 1, 1978, 92 Stat. 2137–2139; Pub. L. 96–32, §2(b), July 10, 1979, 93 Stat. 82; Pub. L. 97–35, title IX, §942(a)(1), (2), (b)–(e), Aug. 13, 1981, 95 Stat. 573, 574; Pub. L. 100–517, §§2–4(a), 5(a)(1), (2), (b), Oct. 24, 1988, 102 Stat. 2578, 2579; Pub. L. 104–191, title I, §§102(b), 193, Aug. 21, 1996, 110 Stat. 1976, 1988.)

EDITORIAL NOTES

REFERENCES IN TEXT

Section 300e–9(d) of this title, referred to in subsec. (b)(1), (2), was redesignated section 300e–9(c) of this title by Pub. L. 100–517, §7(b), Oct. 24, 1988, 102 Stat. 2580.

The Social Security Act, referred to in subsec. (c)(3)(B), is act Aug. 14, 1935, ch. 531, 49 Stat. 620. Title XIX of the Social Security Act is classified generally to subchapter XIX (§1396 et seq.) of chapter 7 of this title. For complete classification of this Act to the Code, see section 1305 of this title and Tables.

Section 2701, referred to in subsec. (d), is a reference to section 2701 of act July 1, 1944. Section 2701, which was classified to section 300gg of this title, was renumbered section 2704, effective for plan years beginning on or after Jan. 1, 2014, with certain exceptions, and amended, by Pub. L. 111–148, title I, §§1201(2), 1563(c)(1), formerly §1562(c)(1), title X, §10107(b)(1), Mar. 23, 2010, 124 Stat. 154, 264, 911, and was transferred to section 300gg–3 of this title. A new section 2701 of act July 1, 1944, related to fair health insurance premiums, was added, effective for plan years beginning on or after Jan. 1, 2014, and amended, by Pub. L. 111–148, title I, §1201(4), title X, §10103(a), Mar. 23, 2010, 124 Stat. 155, 892, and is classified to section 300gg of this title.

CODIFICATION

Amendment to subsec. (b)(3)(D) by section 942(b)(2) of Pub. L. 97–35 was executed before redesignation by section 942(a)(1)(B) of Pub. L. 97–35, to reflect the probable intent of Congress.

AMENDMENTS

1996—Subsec. (b)(6). Pub. L. 104–191, §193, added par. (6).

Subsec. (d). Pub. L. 104–191, §102(b), added subsec. (d).

1988—Subsec. (a). Pub. L. 100–517, §2, substituted "public or private entity which is organized under the laws of any State and" for "legal entity".

Subsec. (b)(1). Pub. L. 100–517, §3, inserted after second sentence "If a health maintenance organization offers to its members the opportunity to obtain basic health services through a physician not described in subsection (b)(3)(A), the organization may require, in addition to payments described in clause (D) of this paragraph, a reasonable deductible to be paid by a member when obtaining a basic health service from such a physician."

Subsec. (b)(3)(A). Pub. L. 100–517, §4(a), substituted "at least 90 percent of the services of a physician" for "the services of a physician".

Subsec. (c). Pub. L. 100–517, §5(a)(2), inserted at end "The Secretary shall issue regulations stating the circumstances under which the Secretary, in administering paragraph (1)(A), will consider the resources of an organization which owns or controls a health maintenance organization. Such regulations shall require as a condition to consideration of resources that an organization which owns or controls a health maintenance organization shall provide satisfactory assurances that it will assume the financial obligations of the health maintenance organization."

Subsec. (c)(1)(A). Pub. L. 100–517, §5(a)(1), amended subpar. (A) generally. Prior to amendment, subpar. (A) read as follows: "have a fiscally sound operation and adequate provision against the risk of insolvency which is satisfactory to the Secretary, and".

Subsec. (c)(5) to (9). Pub. L. 100–517, §5(b), redesignated pars. (6) to (9) as (5) to (8), respectively, and struck out former par. (5) which read as follows: "(A) in the case of a private health maintenance organization, be organized in such a manner that assures that (i) at least one-third of the membership of the policymaking body of the health maintenance organization will be members of the organization, and (ii) there will be equitable representation on such body of members from medically underserved populations served by the organization, and (B) in the case of a public health maintenance organization, have an advisory board to the policymaking body of the public entity operating the organization which board meets the requirements of clause (A) of this paragraph and to which may be delegated policymaking authority for the organization;".

1981—Subsec. (b)(3)(A)(iv). Pub. L. 97–35, §942(a)(2), substituted "physicians" for "subject to subparagraph (C), physicians".

Subsec. (b)(3)(B). Pub. L. 97–35, §942(b)(1), substituted "(B)" for "(B)(i)", "(i)" for "(I)", and "(ii)" for "(II)" and struck out former cl. (ii) which related to the forty-eight-month period beginning after the month of qualification of a health maintenance organization.

Subsec. (b)(3)(C). Pub. L. 97–35, §942(a)(1), redesignated subpar. (D) as (C) and struck out former subpar. (C) which related to the expiration of the first four fiscal years as a qualified organization.

Subsec. (b)(3)(D). Pub. L. 97–35, §942(b)(2), amended subpar. (D) generally. Prior to amendment, subpar. (D) read as follows: "Contracts between a health maintenance organization and health professionals for the provision of basic and supplemental health services shall include such provisions as the Secretary may require (including provisions requiring appropriate continuing education)." See Codification note above.

Pub. L. 97–35, §942(a)(1)(B), redesignated subpar. (E) as (D). Former subpar. (D) redesignated (C).

Subsec. (b)(4). Pub. L. 97–35, §942(c), substituted "with reasonable promptness" for "promptly as appropriate" and inserted ", except that a health maintenance organization which has a service area located wholly in a nonmetropolitan area may make a basic health service available outside its service area if that basic health service is not a primary care or emergency health care service and if there is an insufficient number of providers of that basic health service within the service area who will provide such service to members of the health maintenance organization" after "week".

Subsec. (c). Pub. L. 97–35, §942(d)(1), (e), in par. (2) substituted provisions specifying requirements with respect to insurance, etc., for provisions generalizing such insurance, etc., requirements, and added cl. (D), struck out par. (4) which related to open enrollment period, redesignated pars. (5) to (8) as (4) to (7), respectively, added par. (8), struck out pars. (9) and (10) which related to medical social and health education services, and continuing education, respectively, and redesignated par. (11) as (9).

Subsec. (d). Pub. L. 97–35, §942(d)(2), struck out subsec. (d) which related to requirements, etc., respecting open enrollment period.

1979—Subsec. (b)(3). Pub. L. 96–32 amended directory language of section 11(a) of Pub. L. 95–559 by substituting reference to section "1301" for "1310" of the Public Health Service Act, as section to be amended, and required no change in text because amendment made by Pub. L. 95–559 had been executed to this section as the probable intent of Congress.

1978—Subsec. (b)(1). Pub. L. 95–559, §§10(a), 11(b), inserted "except in the case of basic health services provided a member who is a full-time student (as defined by the Secretary) at an accredited institution of higher education," after "the requirement of clause (C)" and inserted provisions permitting the health maintenance organization to seek reimbursement for the cost of services provided to a member who is entitled to benefits under a workmen's compensation law or insurance policy.

Subsec. (b)(2). Pub. L. 95–559, §10(a), inserted "unless the supplemental health services payment is for a supplemental health service provided a member who is a full-time student (as defined by the Secretary) at an accredited institution of higher education," after "community rating system".

Subsec. (b)(3). Pub. L. 95–559, §11(a), as amended by Pub. L. 96–32, inserted provisions limiting the health maintenance organization from entering into contracts for health services with physicians other than members of the staff of the health maintenance organization, medical groups, or individual practice associations.

Subsec. (b)(4). Pub. L. 95–559, §11(c), substituted "basic and supplemental" for "basic or supplemental" and "if the services were medically necessary and immediately required because of an unforeseen illness, injury, or condition" for "if it was medically necessary that the services be provided before it could secure them through the organization".

Subsec. (b)(5). Pub. L. 95–559, §11(d), added par. (5).

Subsec. (c)(1). Pub. L. 95–559, §10(b), designated existing provisions as subpar. (A) and added subpar. (B).

Subsec. (c)(3). Pub. L. 95–559, §9(b), designated existing provisions as subpar. (A) and added subpar. (B).

Subsec. (c)(6). Pub. L. 95–559, §10(c), designated existing provisions as subpar. (A), inserted "in the case of a private health maintenance organization," before "be organized in such", and substituted "(i)" for "(A)" and "(ii)" for "(B)", and added subpar. (B).

1976—Subsec. (b)(1). Pub. L. 94–460, §§101(a), 105(a)(1), provided that a health maintenance organization may include a health service, defined as a supplemental health service by section 300e–1(2) of this title, in the basic health services provided its members for a basic health service payment described in the first sentence, and also provided that, in the case of an entity which before it became a qualified health maintenance organization (within the meaning of section 300e–9(d) of this title) provided comprehensive health services on a prepaid basis, the requirement of clause (C) would not apply to such entity until the expiration of the forty-eight month period beginning with the month following the month in which the entity became such a qualified health organization.

Subsec. (b)(2). Pub. L. 94–460, §§101(b), 105(a)(2), substituted "the organization may provide to each of its members any of the health services which are included in supplemental health services (as defined in section 300e–1(2) of this title)" for "the organization shall provide to each of its members each health service (A) which is included in supplemental health services (as defined in section 300e–1(2) of this title), (B) for which the required health manpower are available in the area served by the organization, and (C) for the provision of which the member has contracted with the organization" and inserted "except that, in the case of an entity which before it became a qualified health maintenance organization (within the meaning of section 300e–9(d) of this title) provided comprehensive health services on a prepaid basis, the requirement of this sentence shall not apply to such entity during the forty-eight month period beginning with the month following the month in which the entity became such a qualified health maintenance organization" after "Supplemental health services payments which are fixed on a prepayment basis shall be fixed under a community rating system".

Subsec. (b)(3). Pub. L. 94–460, §102(a), inserted references to health professionals who have contracted with the health maintenance organization for the provision of such services and to the combination of staff, medical groups, individual practice associations, or health professionals under contract with the health maintenance organization, and inserted provisions allowing a health maintenance organization, during the thirty-six month period beginning with the month following the month in which the organization becomes a qualified health maintenance organization (within the meaning of section 300e–9(d) of this title), to provide basic and supplemental health services through an entity which but for the requirement of section 300e–1(4)(C)(i) of this title would be a medical group for purposes of this subchapter, directing that after the expiration of such period, the organization may provide basic or supplemental health services through such an entity only if authorized by the Secretary in accordance with regulations which take into consideration the unusual circumstances of such entity, directing that a health maintenance organization may not, in any of its fiscal years, enter into contracts with health professionals or entities other than medical groups or individual practice associations if the amounts paid under such contracts for basic and supplemental health services exceed fifteen percent of the total amount to be paid in such fiscal year by the health maintenance organization to physicians for the provision of basic and supplemental health services, or, if the health maintenance organization principally serves a rural area, thirty percent of such amount, except that the sentence would not apply to the entering into of contracts for the purchase of basic and supplemental health services through an entity which but for the requirements of section 300e–1(4)(C)(i) of this title would be a medical group for purposes of this subchapter, and directing that contracts between a health maintenance organization and health professionals for the provision of basic and supplemental health services include such provisions as the Secretary may require (including provisions requiring appropriate continuing education).

Subsec. (b)(4). Pub. L. 94–460, §101(c), substituted "and only such supplemental health services as members have contracted for" for "and supplemental health services in the case of the members who have contracted therefor".

Subsec. (c)(4). Pub. L. 94–460, §103(a), substituted provisions making a simple reference to an open enrollment period in accordance with the provisions of subsec. (d) of this section for provisions spelling out in detail the requirements for a health maintenance organization with regard to an open enrollment period.

Subsec. (d). Pub. L. 94–460, §103(b), added subsec. (d).

STATUTORY NOTES AND RELATED SUBSIDIARIES

EFFECTIVE DATE OF 1976 AMENDMENT

Pub. L. 94–460, title I, §118, Oct. 8, 1976, 90 Stat. 1955, provided that:

"(a) Except as provided in subsection (b), the amendments made by this title [enacting section 300e–15 of this title and amending this section, sections 300e–1 to 300e–11, 300e–13, and 300n–1 of this title, and section 8902 of Title 5, Government Organization and Employees] shall take effect on the date of the enactment of this Act [Oct. 8, 1976].

"(b)(1) The amendments made by sections 101 [amending this section], 102 [amending this section and section 300e–1 of this title], 103 [amending this section], 104 [amending section 300e–1 of this title], and 106 [amending section 300e–1 of this title] shall (A) apply with respect to grants, contracts, loans, and loan guarantees made under sections 1303, 1304, and 1305 of the Public Health Service Act [42 U.S.C. 300e–2, 300e–3, 300e–4] for fiscal years beginning after September 30, 1976, (B) apply with respect to health benefit plans offered under section 1310 of such Act [42 U.S.C. 300e–9] after such date, and (C) for purposes of section 1312 [42 U.S.C. 300e–11] take effect October 1, 1976.

"(2) Subsection (d) of section 1301 of the Public Health Service Act [42 U.S.C. 300e(d)] (added by section 103(b) of this Act) shall take effect with respect to fiscal years of health maintenance organizations beginning on or after the date of the enactment of this Act [Oct. 8, 1976].

"(3) The amendments made by section 107 [amending sections 300e–2, 300e–3, and 300e–4 of this title] shall apply with respect to grants, contracts, loans, and loan guarantees made under sections 1303, 1304, and 1305 of the Public Health Service Act [42 U.S.C. 300e–2, 300e–3, 300e–4] for fiscal years beginning after September 30, 1976.

"(4) The amendments made by sections 109(a)(1) [amending section 300e–4 of this title] and 109(c) [amending section 300e–7 of this title] shall apply with respect to loan guarantees made under section 1305 of the Public Health Service Act [42 U.S.C. 300e–4] after September 30, 1976.

"(5) The amendment made by section 109(e) [amending section 300e–3 of this title] shall apply with respect to projects assisted under section 1304 of the Public Health Service Act [42 U.S.C. 300e–3] after September 30, 1976.

"(6) The amendments made by paragraphs (1) and (2) of section 110(a) [amending section 300e–9 of this title] shall apply with respect to calendar quarters which begin after the date of the enactment of this Act [Oct. 8, 1976].

"(7) The amendments made by paragraphs (3) and (4) of section 110 [amending section 300e–9 of this title] shall apply with respect to failures of employers to comply with section 1310(a) of the Public Health Service Act [42 U.S.C. 300e–9(a)] after the date of the enactment of this Act [Oct. 8, 1976].

"(8) The amendment made by section 111 [amending section 300e–11 of this title] shall apply with respect to determinations of the Secretary of Health, Education, and Welfare described in section 1312(a) of the Public Health Service Act [42 U.S.C. 300e–11(a)] and made after the date of the enactment of this Act [Oct. 8, 1976]."

SHORT TITLE OF 1978 AMENDMENT

For short title of Pub. L. 95–559 as the "Health Maintenance Organization Amendments of 1978", see section 1 of Pub. L. 95–559, set out as a note under section 201 of this title.

SHORT TITLE OF 1976 AMENDMENT

For short title of Pub. L. 94–460 which substantially amended this subchapter, as the "Health Maintenance Organization Amendments of 1976", see section 1(a) of Pub. L. 94–460, set out as a note under section 201 of this title.

SHORT TITLE

For short title of Pub. L. 93–222, which enacted this subchapter, as the "Health Maintenance Organization Act of 1973", see section 1 of Pub. L. 93–222, set out as a Short Title of 1973 Amendments note under section 201 of this title.

QUALIFICATION OF HEALTH MAINTENANCE ORGANIZATION CONTINGENT UPON CONTROLLING ORGANIZATION'S ASSUMPTION OF FINANCIAL OBLIGATIONS AND MEETING OTHER REQUIREMENTS

Pub. L. 100–517, §5(a)(3), Oct. 24, 1988, 102 Stat. 2579, provided that: "During the period prior to the

effective date of regulations issued under section 1301(c) of the Public Health Service Act [42 U.S.C. 300e(c)] (as amended by paragraph (2)), the Secretary of Health and Human Services shall consider the application for qualification under section 1301(c)(1)(A) of such Act of a health maintenance organization—

"(A) which is owned or controlled by another organization, and

"(B) which requests that the resources of the other organization be considered in determining its qualification under such section,

if the Secretary receives satisfactory assurances from the other organization that it will assume the financial obligations of the health maintenance organization and if the Secretary determines that the other organization meets such other requirements as the Secretary determines are necessary."

STUDY ON HEALTH MAINTENANCE ORGANIZATION PROGRAM

Pub. L. 99–660, title VIII, §813, Nov. 14, 1986, 100 Stat. 3801, which provided for a study to assess the operation and impact of the provisions of this subchapter and a report to Congress on the findings and conclusions of such study within 18 months after Nov. 14, 1986, was repealed by Pub. L. 102–531, title III, §311(a), Oct. 27, 1992, 106 Stat. 3503, effective as if such repeal was enacted on Nov. 14, 1986.

HEALTH CARE QUALITY ASSURANCE PROGRAMS STUDY

Pub. L. 93–222, §4, Dec. 29, 1973, 87 Stat. 934, required Secretary of Health, Education, and Welfare to contract for conduct of a study of health care quality assurance programs and submit a final report to specific committees of Congress by Jan. 31, 1976.

[1] See References in Text note below.

§300e–1. Definitions

For purposes of this subchapter:

(1) The term "basic health services" means—

(A) physician services (including consultant and referral services by a physician);

(B) inpatient and outpatient hospital services;

(C) medically necessary emergency health services;

(D) short-term (not to exceed twenty visits), outpatient evaluative and crisis intervention mental health services;

(E) medical treatment and referral services (including referral services to appropriate ancillary services) for the abuse of or addiction to alcohol and drugs;

(F) diagnostic laboratory and diagnostic and therapeutic radiologic services;

(G) home health services; and

(H) preventive health services (including (i) immunizations, (ii) well-child care from birth, (iii) periodic health evaluations for adults, (iv) voluntary family planning services, (v) infertility services, and (vi) children's eye and ear examinations conducted to determine the need for vision and hearing correction).

Such term does not include a health service which the Secretary, upon application of a health maintenance organization, determines is unusual and infrequently provided and not necessary for the protection of individual health. The Secretary shall publish in the Federal Register each determination made by him under the preceding sentence. If a service of a physician described in the preceding sentence may also be provided under applicable State law by a dentist, optometrist, podiatrist, psychologist, or other health care personnel, a health maintenance organization may provide such service through a dentist, optometrist, podiatrist, psychologist, or other health care personnel (as the case may be) licensed to provide such service. Such term includes a health service directly associated with an organ transplant only if such organ transplant was required to be included in basic health services on April 15, 1985. For purposes of this paragraph, the term "home health services" means health services provided at a member's home by health care personnel, as prescribed or directed by the responsible physician or other authority designated by the health maintenance organization.

(2) The term "supplemental health services" means any health service which is not included as a basic health service under paragraph (1) of this section. If a health service provided by a physician may also be provided under applicable State law by a dentist, optometrist, podiatrist, psychologist, or other health care personnel, a health maintenance organization may provide such service through an optometrist, dentist, podiatrist, psychologist, or other health care personnel (as the case may be) licensed to provide such service.

(3) The term "member" when used in connection with a health maintenance organization means an individual who has entered into a contractual arrangement, or on whose behalf a contractual arrangement has been entered into, with the organization under which the organization assumes the responsibility for the provision to such individual of basic health services and of such supplemental health services as may be contracted for.

(4) The term "medical group" means a partnership, association, or other group—

(A) which is composed of health professionals licensed to practice medicine or osteopathy and of such other licensed health professionals (including dentists, optometrists, podiatrists, and psychologists) as are necessary for the provision of health services for which the group is responsible;

(B) a majority of the members of which are licensed to practice medicine or osteopathy; and

(C) the members of which (i) as their principal professional activity engage in the coordinated practice of their profession and as a group responsibility have substantial responsibility for the delivery of health services to members of a health maintenance organization, except that this clause does not apply before the end of the forty-eight month period beginning after the month in which the health maintenance oranization [1] becomes a qualified health maintenance organization as defined in section 300e–9(d) [2] of this title, or as authorized by the Secretary in accordance with regulations that take into consideration the unusual circumstances of the group; (ii) pool their income from practice as members of the group and distribute it among themselves according to a prearranged salary or drawing account or other similar plan unrelated to the provision of specific health services; (iii) share medical and other records and substantial portions of major equipment and of professional, technical, and administrative staff; (iv) arrange for and encourage continuing education in the field of clinical medicine and related areas for the members of the group; and (v) establish an arrangement whereby a member's enrollment status is not known to the health professional who provides health services to the member.

(5) The term "individual practice association" means a partnership, corporation, association, or other legal entity which has entered into a services arrangement (or arrangements) with persons who are licensed to practice medicine, osteopathy, dentistry, podiatry, optometry, psychology, or other health profession in a State and a majority of whom are licensed to practice medicine or osteopathy. Such an arrangement shall provide—

(A) that such persons shall provide their professional services in accordance with a compensation arrangement established by the entity; and

(B) to the extent feasible, for the sharing by such persons of medical and other records, equipment, and professional, technical, and administrative staff.

(6) The term "health systems agency" means an entity which is designated in accordance with section 300l–4 of this title.

(7) The term "medically underserved population" means the population of an urban or rural area designated by the Secretary as an area with a shortage of personal health services or a population group designated by the Secretary as having a shortage of such services. Such a designation may be made by the Secretary only after consideration of the comments (if any) of (A) each State health planning and development agency which covers (in whole or in part) such urban or rural area or the area in which such population group resides, and (B) each health systems agency designated for a health service area which covers (in whole or in part) such urban or rural area or the area in which such population group resides.

(8)(A) The term "community rating system" means the systems, described in subparagraphs (B)

and (C), of fixing rates of payments for health services. A health maintenance organization may fix its rates of payments under the system described in subparagraph (B) or (C) or under both such systems, but a health maintenance organization may use only one such system for fixing its rates of payments for any one group.

(B) A system of fixing rates of payment for health services may provide that the rates shall be fixed on a per-person or per-family basis and may authorize the rates to vary with the number of persons in a family, but, except as authorized in subparagraph (D), such rates must be equivalent for all individuals and for all families of similar composition.

(C) A system of fixing rates of payment for health services may provide that the rates shall be fixed for individuals and families by groups. Except as authorized in subparagraph (D), such rates must be equivalent for all individuals in the same group and for all families of similar composition in the same group. If a health maintenance organization is to fix rates of payment for individuals and families by groups, it shall—

(i)(I) classify all of the members of the organization into classes based on factors which the health maintenance organization determines predict the differences in the use of health services by the individuals or families in each class and which have not been disapproved by the Secretary,

(II) determine its revenue requirements for providing services to the members of each class established under subclause (I), and

(III) fix the rates of payments for the individuals and families of a group on the basis of a composite of the organization's revenue requirements determined under subclause (II) for providing services to them as members of the classes established under subclause (I), or

(ii) fix the rates of payments for the individuals and families of a group on the basis of the organization's revenue requirements for providing services to the group, except that the rates of payments for the individuals and families of a group of less than 100 persons may not be fixed at rates greater than 110 percent of the rate that would be fixed for such individuals and families under subparagraph (B) or clause (i) of this subparagraph.

The Secretary shall review the factors used by each health maintenance organization to establish classes under clause (i). If the Secretary determines that any such factor may not reasonably be used to predict the use of the health services by individuals and families, the Secretary shall disapprove such factor for such purpose. If a health maintenance organization is to fix rates of payment for a group under clause (ii), it shall, upon request of the entity with which it contracts to provide services to such group, disclose to that entity the method and data used in calculating the rates of payment.

(D) The following differentials in rates of payments may be established under the systems described in subparagraphs (B) and (C):

(i) Nominal differentials in such rates may be established to reflect differences in marketing costs and the different administrative costs of collecting payments from the following categories of members:

(I) Individual members (including their families).

(II) Small groups of members (as determined under regulations of the Secretary).

(III) Large groups of members (as determined under regulations of the Secretary).

(ii) Nominal differentials in such rates may be established to reflect the compositing of the rates of payment in a systematic manner to accommodate group purchasing practices of the various employers.

(iii) Differentials in such rates may be established for members enrolled in a health maintenance organization pursuant to a contract with a governmental authority under section 1079 or 1086 of title 10 or under any other governmental program (other than the health benefits program authorized by chapter 89 of title 5) or any health benefits program for employees of States, political subdivision of States, and other public entities.

(9) The term "non-metropolitan area" means an area no part of which is within an area designated as a standard metropolitan statistical area by the Office of Management and Budget and which does

not contain a city whose population exceeds fifty thousand individuals.

(July 1, 1944, ch. 373, title XIII, §1302, as added Pub. L. 93–222, §2, Dec. 29, 1973, 87 Stat. 917; amended Pub. L. 94–460, title I, §§102(b), 104, 105(b), (c), 106, 117(b)(1), (2), Oct. 8, 1976, 90 Stat. 1946–1948, 1955; Pub. L. 95–559, §11(e), Nov. 1, 1978, 92 Stat. 2139; Pub. L. 97–35, title IX, §942(f)–(j), Aug. 13, 1981, 95 Stat. 574, 575; Pub. L. 97–414, §9(c), Jan. 4, 1983, 96 Stat. 2064; Pub. L. 99–660, title VIII, §§812(a), 814, Nov. 14, 1986, 100 Stat. 3801, 3802; Pub. L. 100–517, §6(b), Oct. 24, 1988, 102 Stat. 2579.)

EDITORIAL NOTES

REFERENCES IN TEXT

Section 300e–9(d) of this title, referred to in par. (4)(C), was redesignated section 300e–9(c) of this title by Pub. L. 100–517, §7(b), Oct. 24, 1988, 102 Stat. 2580.

AMENDMENTS

1988—Par. (8)(C). Pub. L. 100–517, §6(b)(1), amended third sentence generally. Prior to amendment, third sentence read as follows: "If a health maintenance organization is to fix rates of payment for individuals and families by groups, it shall—

"(i) classify all of the members of the organization into classes based on factors which the health maintenance organization determines predict the differences in the use of health services by the individuals or families in each class and which have not been disapproved by the Secretary,

"(ii) determine its revenue requirements for providing services to the members of each class established under clause (i), and

"(iii) fix the rates of payment for the individuals and families of a group on the basis of a composite of the organization's revenue requirements determined under clause (ii) for providing services to them as members of the classes established under clause (i)."

Pub. L. 100–517, §6(b)(2), inserted at end "If a health maintenance organization is to fix rates of payment for a group under clause (ii), it shall, upon request of the entity with which it contracts to provide services to such group, disclose to that entity the method and data used in calculating the rates of payment."

1986—Par. (1). Pub. L. 99–660, §814(a), inserted "psychologist," in two places in fourth sentence.

Pub. L. 99–660, §812(a), (b)(1), temporarily inserted "Such term includes a health service directly associated with an organ transplant only if such organ transplant was required to be included in basic health services on April 15, 1985." in closing provisions. See Effective and Termination Dates of 1986 Amendment note below.

Par. (2). Pub. L. 99–660, §814(a), inserted "psychologist," in two places.

Par. (4)(A). Pub. L. 99–660, §814(b), substituted "podiatrists, and psychologists" for "and podiatrists".

Par. (5). Pub. L. 99–660, §814(c), inserted "psychology,".

1983—Par. (5)(B). Pub. L. 97–414 amended directory language of Pub. L. 97–35, §942(i), to correct a typographical error, and did not involve any change in text. See 1981 Amendment note below.

1981—Par. (1). Pub. L. 97–35, §942(f), struck out provisions authorizing health maintenance organizations to maintain, etc., drug use profiles of members.

Par. (2). Pub. L. 97–35, §942(g), substituted provisions to include services not included under par. (1), for provisions enumerating specific services, substituted "health service provided by a physician" for "service of a physician described in the preceding sentence", and struck out provisions authorizing health maintenance organizations to maintain, etc., drug use profiles of members.

Par. (4)(C)(i). Pub. L. 97–35, §942(h), inserted provisions relating to applicability to qualified organizations.

Par. (5)(B). Pub. L. 97–35, §942(i), as amended by Pub. L. 97–414, §9(c), struck out "(i)" after "feasible", and struck out cl. (ii) which related to continuing education.

Par. (8). Pub. L. 97–35, §942(j), reorganized and restructured provisions and, among many changes, provided for determinations based upon subpars. (B) and (C), and set out determinations respecting differentials contained in former subpars. (B) and (C) as subpar. (D).

1978—Par. (1). Pub. L. 95–559 inserted provisions to exclude a health service which the Secretary, upon application of a health maintenance organization, determines is unusual and infrequently provided and not necessary for protection of individual health and that the Secretary publish in Federal Register each determination made by him under preceding sentence.

1976—Par. (1). Pub. L. 94–460, §104(a), substituted reference to immunization, well-child care from birth,

periodic health evaluations for adults, and children's ear examinations conducted to determine need for hearing correction for reference to preventive dental care for children in (H) and, in the provisions following subpar. (H), inserted reference to "other health care personnel".

Par. (2). Pub. L. 94–460, §104(b), substituted "basic health service" for "basic health service under paragraph (1)(A) or (1)(H)" in subpars. (B) and (C), added subpar. (G), and inserted reference to "other health care personnel" in provisions following subpar. (G).

Par. (4)(C). Pub. L. 94–460, §§102(b)(1), 106, substituted "as their principal professional activity engage in the coordinated practice of their profession and as a group responsibility have substantial responsibility for the delivery of health services to members of a health maintenance organization" for "as their principal professional activity and as a group responsibility engage in the coordinated practice of their profession for a health maintenance organization" in cl. (i), substituted "similar plan unrelated to the provision of specific health services" for "plan" in cl. (ii), struck out former cl. (iv) which covered the utilization of additional professional personnel, allied health professions personnel, and other health personnel as are available and appropriate for the effective and efficient delivery of the services of the members of the group, redesignated former cl. (v) as (iv), and added cl. (v).

Par. (5)(B). Pub. L. 94–460, §102(b)(2), struck out former cl. (i) which covered the utilization of additional professional personnel, allied health professions personnel, and other personnel as are available and appropriate for the effective and efficient delivery of the services of the persons who are parties to the arrangement, and redesignated former cls. (ii) and (iii) as (i) and (ii), respectively.

Par. (6). Pub. L. 94–460, §117(b)(1), substituted provisions defining "health systems agency" for provisions defining "section 314(a) State health planning agency" and "section 314(b) areawide health planning agency".

Par. (7). Pub. L. 94–460, §117(b)(2), substituted "State health planning and development agency which" for "section 314(a) State health planning agency whose section 314(a) plan" and "health systems agency designated for a health service area which" for "section 314(b) areawide health planning agency whose section 314(b) plan".

Par. (8). Pub. L. 94–460, §105(b), (c), substituted "to reflect differences in marketing costs and the different administrative costs" for "to reflect the different administrative costs" in subpar. (A) preceding cl. (i), added subpar. (B), and redesignated former subpar. (B) as (C).

STATUTORY NOTES AND RELATED SUBSIDIARIES

EFFECTIVE AND TERMINATION DATES OF 1986 AMENDMENT

Pub. L. 99–660, title VIII, §812(b)(1), Nov. 14, 1986, 100 Stat. 3801, which provided that amendment by subsection (a), amending this section, was to take effect on Oct. 1, 1985, and was to cease to be in effect on Apr. 1, 1988, was repealed by Pub. L. 100–517, §6(a), Oct. 24, 1988, 102 Stat. 2579.

Pub. L. 99–660, title VIII, §815, Nov. 14, 1986, 100 Stat. 3802, provided that:

"(a) Except as provided in subsection (b) and section 812(b) [enacting provisions set out as notes above and below], this title and the amendments made by this title [amending this section and sections 300e–4, 300e–5 to 300e–10, 300e–16, and 300e–17 of this title, repealing sections 300e–2, 300e–3, and 300e–4a of this title, and enacting provisions set out as notes under this section and sections 201, 300e, 300e–4, and 300e–5 of this title] shall take effect on October 1, 1985.

"(b) Section 813 [enacting provisions set out as a note under section 300e of this title] shall take effect on the date of enactment of this Act [Nov. 14, 1986]."

EFFECTIVE DATE OF 1976 AMENDMENT

Amendment by Pub. L. 94–460 effective Oct. 8, 1976, except that amendment of pars. (1) and (2) of this section by section 104 of Pub. L. 94–460 and the amendment of pars. (4)(C) and (5)(B) of this section by sections 102 and 106 of Pub. L. 94–460 applicable with respect to grants, contracts, loans, and loan guarantees made under sections 300e–2, 300e–3, and 300e–4 of this title for fiscal years beginning after Sept. 30, 1976, applicable with respect to health benefit plans offered under section 300e–9 of this title after Sept. 30, 1976, and effective for purposes of section 300e–11 of this title on Oct. 1, 1976, see section 118 of Pub. L. 94–460, set out as a note under section 300e of this title.

CONSTRUCTION

Pub. L. 99–660, title VIII, §816, Nov. 14, 1986, 100 Stat. 3802, provided that: "The provisions of this title and of the amendments made by this title [amending this section and sections 300e–4, 300e–5 to 300e–10,

300e–16, and 300e–17 of this title, repealing sections 300e–2, 300e–3, and 300e–4a of this title, and enacting provisions set out as notes under this section and sections 201, 300e, 300e–4, and 300e–5 of this title] do not authorize the appropriation of any funds for fiscal year 1986."

BASIC HEALTH SERVICE STATUS OF CERTAIN ORGAN TRANSPLANT SERVICES AFTER APRIL 1, 1988

Pub. L. 99–660, title VIII, §812(b)(2), Nov. 14, 1986, 100 Stat. 3801, which provided that after Apr. 1, 1988, for purposes of this subchapter, no health service directly associated with an organ transplant was to be considered to be a basic health service if such service would otherwise have been added as a basic health service between Apr. 15, 1985, and Apr. 1, 1988, was repealed by Pub. L. 100–517, §6(a), Oct. 24, 1988, 102 Stat. 2579.

REPORTS RESPECTING MEDICALLY UNDERSERVED AREAS AND POPULATION GROUPS AND NON-METROPOLITAN AREAS

Pub. L. 93–222, §5, Dec. 29, 1973, 87 Stat. 935, directed Secretary of Health, Education, and Welfare to report to Congress the criteria used in the designation of medically underserved areas and population groups for purposes of par. (7) of this section by Dec. 29, 1973, and report to Congress the areas and population groups designated under par. (7) of this section, the comments of State and areawide health planning agencies, and areas which meet the definitional standards of par. (9) of this section for non-metropolitan areas by Dec. 29, 1974, and that the Office of Management and Budget may review such reports before their submission to Congress.

[1] So in original. Probably should be "organization".

[2] See References in Text note below.

§§300e–2, 300e–3. Repealed. Pub. L. 99–660, title VIII, §803(a), Nov. 14, 1986, 100 Stat. 3799

Section 300e–2, act July 1, 1944, ch. 373, title XIII, §1303, as added Dec. 29, 1973, Pub. L. 93–222, §2, 87 Stat. 920; amended Oct. 8, 1976, Pub. L. 94–460, title I, §§107(a), 109(d)(1), 117(b)(3), 90 Stat. 1948, 1950, 1955; Aug. 13, 1981, Pub. L. 97–35, title IX, §947(a), 95 Stat. 577, provided for grants and contracts for feasibility surveys.

Section 300e–3, act July 1, 1944, ch. 373, title XIII, §1304, as added Dec. 29, 1973, Pub. L. 93–222, §2, 87 Stat. 921; amended Apr. 21, 1976, Pub. L. 94–273, §40, 90 Stat. 381; Oct. 8, 1976, Pub. L. 94–460, title I, §§107(b), 108(a), (b), (d)(1), 109(d)(2), (3), (e), 113(a), 117(b)(4), 90 Stat. 1948–1950, 1953, 1955; Nov. 1, 1978, Pub. L. 95–559, §§2(a), 3(a)–(c), 6, 92 Stat. 2131, 2134; July 10, 1979, Pub. L. 96–32, §2(a), 93 Stat. 82; Aug. 13, 1981, Pub. L. 97–35, title IX, §§941(c), 947(b), 95 Stat. 573, 577, provided for grants, contracts, and loan guarantees for planning and for initial development costs.

STATUTORY NOTES AND RELATED SUBSIDIARIES

EFFECTIVE DATE OF REPEAL

Repeal not applicable to any grant made or contract entered into under this subchapter before Oct. 1, 1985, see section 803(c) of Pub. L. 99–660, set out as an Effective Date of 1986 Amendment note under section 300e–5 of this title.

Repeal effective Oct. 1, 1985, see section 815(a) of Pub. L. 99–660, set out as an Effective and Termination Dates of 1986 Amendment note under section 300e–1 of this title.

§300e–4. Loans and loan guarantees for initial operation costs

(a) Authority

The Secretary may—

(1) make loans to public or private health maintenance organizations to assist them in meeting

the amount by which their costs of operation during a period not to exceed the first sixty months of their operation exceed their revenues in that period;

(2) make loans to public or private health maintenance organizations to assist them in meeting the amount by which their costs of operation, which the Secretary determines are attributable to significant expansion in their membership or area served and which are incurred during a period not to exceed the first sixty months of their operation after such expansion, exceed their revenues in that period which the Secretary determines are attributable to such expansion; and

(3) guarantee to non-Federal lenders payment of the principal of and the interest on loans made to private health maintenance organizations for the amounts referred to in paragraphs (1) and (2).

No loan or loan guarantee may be made under this subsection for the costs of operation of a health maintenance organization unless the Secretary determines that the organization has made all reasonable attempts to meet such costs, and unless the Secretary has made a grant or loan to, entered into a contract with, or guaranteed a loan for, the organization in fiscal year 1981, 1982, 1983, 1984, or 1985 under this section or section 300e–3(b) [1] of this title (as in effect before October 1, 1985).

(b) Limitations

(1) Except as provided in paragraph (2), the aggregate amount of principal of loans made or guaranteed, or both, under subsection (a) for a health maintenance organization may not exceed $7,000,000. In any twelve-month period the amount disbursed to a health maintenance organization under this section (either directly by the Secretary, by an escrow agent under the terms of an escrow agreement, or by a lender under a guaranteed loan) may not exceed $3,000,000.

(2) The cumulative total of the principal of the loans outstanding at any time which have been directly made, or with respect to which guarantees have been issued, under subsection (a) may not exceed such limitations as may be specified in appropriation Acts.

(c) Source of loan funds

Loans under this section shall be made from the fund established under section 300e–7(e) of this title.

(d) Time limit on loans and loan guarantees

No loan may be made or guaranteed under this section after September 30, 1986.

(e) Repealed. Pub. L. 97–35, title IX, §947(c), Aug. 13, 1981, 95 Stat. 577

(f) Medically underserved populations

In considering applications for loan guarantees under this section, the Secretary shall give special consideration to applications for health maintenance organizations which will serve medically underserved populations.

(July 1, 1944, ch. 373, title XIII, §1305, as added Pub. L. 93–222, §2, Dec. 29, 1973, 87 Stat. 924; amended Pub. L. 93–641, §8, Jan. 4, 1975, 88 Stat. 2276; Pub. L. 94–273, §2(21), Apr. 21, 1976, 90 Stat. 376; Pub. L. 94–460, title I, §§107(c), 108(c), (d)(2), 109(a)(1), (2), 113(b), Oct. 8, 1976, 90 Stat. 1949, 1953; Pub. L. 95–559, §§2(b), 4(a), (b), Nov. 1, 1978, 92 Stat. 2131, 2132; Pub. L. 96–32, §2(d), July 10, 1979, 93 Stat. 82; Pub. L. 97–35, title IX, §§943(a)–(c), 947(c), Aug. 13, 1981, 95 Stat. 576, 577; Pub. L. 99–660, title VIII, §804(a), Nov. 14, 1986, 100 Stat. 3800.)

EDITORIAL NOTES

REFERENCES IN TEXT

Section 300e–3(b) of this title, referred to in subsec. (a), was repealed by Pub. L. 99–660, title VIII, §803(a), Nov. 14, 1986, 100 Stat. 3799.

AMENDMENTS

1986—Subsec. (a). Pub. L. 99–660 inserted ", and unless the Secretary has made a grant or loan to, entered into a contract with, or guaranteed a loan for, the organization in fiscal year 1981, 1982, 1983, 1984, or 1985 under this section or section 300e–3(b) of this title (as in effect before October 1, 1985)" at end of last

sentence.

1981—Subsec. (a). Pub. L. 97–35, §943(a), in pars. (1) and (2) struck out "nonprofit" before "private", and in par. (3) substituted provisions respecting guarantees for private health maintenance organizations, for guarantees for nonprofit private health maintenance organizations.

Subsec. (b)(1). Pub. L. 97–35, §943(b), generally revised limitations and, among many changes, increased amounts subject to coverage, and struck out requirements respecting Congressional oversight for increases in amounts.

Subsec. (d). Pub. L. 97–35, §943(c), substituted "1986" for "1981".

Subsec. (e). Pub. L. 97–35, §947(c), struck out subsec. (e) which related to projects in nonmetropolitan areas.

1979—Subsec. (b)(1). Pub. L. 96–32 substituted "$4,500,000" for "$4,000,000" in two places.

1978—Subsec. (a). Pub. L. 95–559, §4(b)(1), substituted "costs of operation" for "operating costs" wherever appearing.

Subsec. (b)(1). Pub. L. 95–559, §4(a), (b)(2), inserted "(or $4,000,000 if the Secretary makes a written determination that such loans or loan guarantees are necessary to preserve the fiscally sound operation of the health maintenance organization and to protect against the risk of insolvency of the health maintenance organization and, within 30 days of the making of such loans or loan guarantees, furnishes the Committee on Human Resources of the Senate and the Committee on Interstate and Foreign Commerce of the House of Representatives with written notification of the making of the loans or loan guarantees and a copy of the written determination made with respect to the loans or loan guarantees and the reasons for the determination) through September 30, 1979, and $4,000,000 thereafter" after "$2,500,000" and "(or $2,000,000 if the Secretary makes a written determination that such disbursements are necessary to preserve the fiscally sound operation of the health maintenance organization and protect against the risk of insolvency of the health maintenance organization and, within 30 days of such disbursement, furnishes the Committee on Human Resources of the Senate and the Committee on Interstate and Foreign Commerce of the House of Representatives with written notification of the making of the disbursement and a copy of the written determination made with respect to it and the reasons for the determination) through September 30, 1979, and $2,000,000 thereafter" after "$1,000,000" and substituted "any twelve-month period" for "any fiscal year".

Subsec. (d). Pub. L. 95–559, §2(b), substituted "September 30, 1981" for "September 30, 1980".

1976—Subsec. (a)(1), (2). Pub. L. 94–460, §§107(c), 109(a)(1), substituted "during a period not to exceed the first sixty months" for "in the period of the first thirty-six months".

Subsec. (a)(3). Pub. L. 94–460, §108(c), substituted reference to loans made to nonprofit private health maintenance organizations for the amounts referred to in paragraph (1) or (2), or to other private health maintenance organizations for such amounts but only if the health maintenance organization will serve a medically underserved population for reference to loans made to any private health maintenance organization (other than a private nonprofit health maintenance organization) for the amounts referred to in paragraph (1) or (2), but only if such health maintenance organization will serve a medically underserved population.

Subsec. (b)(1). Pub. L. 94–460, §109(a)(2), substituted "In any fiscal year the amount disbursed to a health maintenance organization under this section (either directly by the Secretary or by an escrow agent under the terms of an escrow agreement or by a lender under a loan guaranteed under this section) may not exceed $1,000,000" for "In any fiscal year, the amount disbursed under a loan or loans made or guaranteed under this section for a health maintenance organization may not exceed $1,000,000,000".

Subsec. (d). Pub. L. 94–460, §113(b), substituted "No loan may be made or guaranteed under this section after September 30, 1980" for "A loan or loan guarantee may be made under this section through the fiscal year ending June 30, 1978".

Pub. L. 94–273 substituted "September" for "June".

Subsec. (f). Pub. L. 94–460, §108(d)(2), added subsec. (f).

1975—Subsec. (b)(1). Pub. L. 93–641 substituted provisions that amount disbursed under a loan or loans made or guaranteed under this section for a health maintenance organization may not exceed $1,000,000,000 for provisions that principal amount of any loan made or guaranteed under subsec. (a) of this section for a health maintenance organization may not exceed $1,000,000.

STATUTORY NOTES AND RELATED SUBSIDIARIES

EFFECTIVE DATE OF 1986 AMENDMENT

Pub. L. 99–660, title VIII, §804(b), Nov. 14, 1986, 100 Stat. 3800, provided that: "The amendment made by subsection (a) [amending this section] does not apply to any loan or loan guarantee for the initial costs of

operation of a health maintenance organization made under title XIII of the Public Health Service Act [42 U.S.C. 300e et seq.] before October 1, 1985."

Amendment by Pub. L. 99–660 effective Oct. 1, 1985, see section 815(a) of Pub. L. 99–660, set out as an Effective and Termination Dates of 1986 Amendment note under section 300e–1 of this title.

EFFECTIVE DATE OF 1978 AMENDMENT

Pub. L. 95–559, §4(d), Nov. 1, 1978, 92 Stat. 2133, provided that: "The amendments made by this section [amending this section and section 300e–7 of this title] shall only be effective for fiscal years beginning on or after October 1, 1978."

EFFECTIVE DATE OF 1976 AMENDMENT

Amendment by Pub. L. 94–460 effective Oct. 8, 1976, except that the amendment of subsec. (a)(1), (2) of this section by section 107(c) of Pub. L. 94–460 applicable with respect to grants, contracts, loans, and loan guarantees made under this section and sections 300e–2 and 300e–3 of this title for fiscal years beginning after Sept. 30, 1976, and except that the amendment of subsec. (a)(1), (2) of this section by section 109(a)(1) of Pub. L. 94–460 applicable with respect to loan guarantees made under this section after Sept. 30, 1976, see section 118 of Pub. L. 94–460, set out as a note under section 300e of this title.

[1] *See References in Text note below.*

§300e–4a. Repealed. Pub. L. 99–660, title VIII, §805(a), Nov. 14, 1986, 100 Stat. 3800

Section, act July 1, 1944, ch. 373, title XIII, §1305A, as added Nov. 1, 1978, Pub. L. 95–559, §5(a), 92 Stat. 2133; amended July 10, 1979, Pub. L. 96–32, §2(e), 93 Stat. 82; Aug. 13, 1981, Pub. L. 97–35, title IX, §944, 95 Stat. 576, related to loans and loan guarantees for acquisition and construction of ambulatory health care facilities.

STATUTORY NOTES AND RELATED SUBSIDIARIES

EFFECTIVE DATE OF REPEAL

Repeal not applicable to any loan or loan guarantee made under this section before Oct. 1, 1985, see section 805(c) of Pub. L. 99–660, set out as an Effective Date of 1986 Amendment note under section 300e–5 of this title.

Repeal effective Oct. 1, 1985, see section 815(a) of Pub. L. 99–660, set out as an Effective and Termination Dates of 1986 Amendment note under section 300e–1 of this title.

§300e–5. Application requirements

(a) Submission to and approval by Secretary required for making loans and loan guarantees

No loan or loan guarantee may be made under this subchapter unless an application therefor has been submitted to, and approved by, the Secretary.

(b) Application contents

The Secretary may not approve an application for a loan or loan guarantee under this subchapter unless—

(1) such application meets the requirements of section 300e–7 of this title;

(2) in the case of an application for assistance under section 300e–4 of this title, he determines that the applicant making the application would not be able to complete the project or undertaking for which the application is submitted without the assistance applied for;

(3) the application contains satisfactory specification of the existing or anticipated (A) population group or groups to be served by the proposed or existing health maintenance organization described in the application, (B) membership of such organization, (C) methods, terms, and periods of the enrollment of members of such organization, (D) estimated costs per

member of the health and educational services to be provided by such organization and the nature of such costs, (E) sources of professional services for such organization, and organizational arrangements of such organization for providing health and educational services, (F) organizational arrangements of such organization for an ongoing quality assurance program in conformity with the requirements of section 300e(c) of this title, (G) sources of prepayment and other forms of payment for the services to be provided by such organization, (H) facilities, and additional capital investments and sources of financing therefor, available to such organization to provide the level and scope of services proposed, (I) administrative, managerial, and financial arrangements and capabilities of such organization, (J) role for members in the planning and policymaking for such organization, (K) grievance procedures for members of such organization, and (L) evaluations of the support for and acceptance of such organization by the population to be served, the sources of operating support, and the professional groups to be involved or affected thereby;

(4) contains or is supported by assurances satisfactory to the Secretary that the applicant making the application will, in accordance with such criteria as the Secretary shall by regulation prescribe, enroll, and maintain an enrollment of the maximum number of members that its available and potential resources (as determined under regulations of the Secretary) will enable it to effectively serve;

(5) in the case of an application made for a project which previously received a grant, contract, loan, or loan guarantee under this subchapter, such application contains or is supported by assurances satisfactory to the Secretary that the applicant making the application has the financial capability to adequately carry out the purposes of such project and has developed and operated such project in accordance with the requirements of this subchapter and with the plans contained in previous applications for such assistance;

(6) the application contains such assurances as the Secretary may require respecting the intent and the ability of the applicant to meet the requirements of paragraphs (1) and (2) of section 300e(b) of this title respecting the fixing of basic health services payments and supplemental health services payments under a community rating system; and

(7) the application is submitted in such form and manner, and contains such additional information, as the Secretary shall prescribe in regulations.

An organization making multiple applications for more than one loan or loan guarantee under this subchapter, simultaneously or over the course of time, shall not be required to submit duplicate or redundant information but shall be required to update the specifications (required by paragraph (3)) respecting the existing or proposed health maintenance organization in such manner and with such frequency as the Secretary may by regulation prescribe. In determining, for purposes of paragraph (2), whether an applicant would be able to complete a project or undertaking without the assistance applied for, the Secretary shall not consider any asset of the applicant the obligation of which for such undertaking or project would jeopardize the fiscal soundness of the applicant.

(c) Regulations

The Secretary shall by regulation establish standards and procedures for health systems agencies to follow in reviewing and commenting on applications for loans and loan guarantees under this subchapter.

(July 1, 1944, ch. 373, title XIII, §1306, as added Pub. L. 93–222, §2, Dec. 29, 1973, 87 Stat. 925; amended Pub. L. 94–460, title I, §§105(a)(3), 117(b)(5), (6), Oct. 8, 1976, 90 Stat. 1948, 1955; Pub. L. 95–559, §12(b), (c), Nov. 1, 1978, 92 Stat. 2140; Pub. L. 99–660, title VIII, §§803(b)(1), 805(b), 806, Nov. 14, 1986, 100 Stat. 3799, 3800.)

EDITORIAL NOTES

AMENDMENTS

1986—Subsec. (a). Pub. L. 99–660, §803(b)(1)(A), substituted "loan" for "grant, contract, loan,".

Subsec. (b). Pub. L. 99–660, §803(b)(1)(A), substituted "loan" for "grant, contract, loan," in introductory text and in second sentence.

Subsec. (b)(1). Pub. L. 99–660, §803(b)(1)(B), struck out "in the case of an application for assistance under section 300e–2 or 300e–3 of this title, such application meets the application requirements of such section and in the case of an application for a loan or loan guarantee," before "such application".

Subsec. (b)(2). Pub. L. 99–660, §805(b), struck out reference to section 300e–4a.

Pub. L. 99–660, §803(b)(1)(C), struck out reference to section 300e–3.

Subsec. (b)(5) to (8). Pub. L. 99–660, §806, redesignated pars. (6), (7), and (8) as (5), (6), and (7), respectively, and struck out former par. (5) which read as follows: "each health systems agency designated for a health service area which covers (in whole or in part) the area to be served by the health maintenance organization for which such application is submitted;".

Subsec. (c). Pub. L. 99–660, §803(b)(1)(D), substituted "loans" for "grants, contracts, loans,".

1978—Subsec. (b). Pub. L. 95–559 in par. (2) inserted "in the case of an application for assistance under section 300e–3, 300e–4, or 300e–4a of this title," before "he determines" and in provisions following par. (8) inserted provision that in determining, for purposes of par. (2), whether an applicant would be able to complete a project or undertaking without the assistance applied for, the Secretary not consider any asset of the applicant the obligation of which for such undertaking or project would jeopardize the fiscal soundness of the applicant.

1976—Subsec. (b)(5). Pub. L. 94–460, §117(b)(5), substituted "each health systems agency designated for a health service area which covers (in whole or in part) the area to be served by the health maintenance organization for which such application is submitted;" for "the section 314(b) areawide health planning agency whose section 314(b) plan covers (in whole or in part) the area to be served by the health maintenance organization for which such application is submitted, or if there is no such agency, the section 314(a) State health planning agency whose section 314(a) plan covers (in whole or in part) such area, has, in accordance with regulations of the Secretary under subsection (c) of this section, been provided an opportunity to review the application and to submit to the Secretary for his consideration its recommendations respecting approval of the application or if under applicable State law such an application may not be submitted without the approval of the section 314(b) areawide health planning agency or the section 314(a) State health planning agency, the required approval has been obtained;".

Subsec. (b)(7), (8). Pub. L. 94–460, §105(a)(3), added par. (7) and redesignated former par. (7) as (8).

Subsec. (c). Pub. L. 94–460, §117(b)(6), substituted "health systems agencies" for "section 314(b) areawide health planning agencies and section 314(a) State health planning agencies".

STATUTORY NOTES AND RELATED SUBSIDIARIES

EFFECTIVE DATE OF 1986 AMENDMENT

Pub. L. 99–660, title VIII, §803(c), Nov. 14, 1986, 100 Stat. 3800, provided that: "The amendments made by this section [amending this section and sections 300e–6, 300e–8, and 300e–16 of this title and repealing sections 300e–2 and 300e–3 of this title] do not apply to any grant made or contract entered into under title XIII of the Public Health Service Act [42 U.S.C. 300e et seq.] before October 1, 1985."

Pub. L. 99–660, title VIII, §805(c), Nov. 14, 1986, 100 Stat. 3800, provided that: "The amendments made by this section [amending this section and repealing section 300e–4a of this title] do not apply to any loan or loan guarantee made under section 1305A of the Public Health Service Act [former 42 U.S.C. 300e–4a] before October 1, 1985."

Amendment by Pub. L. 99–660 effective Oct. 1, 1985, see section 815(a) of Pub. L. 99–660, set out as an Effective and Termination Dates of 1986 Amendment note under section 300e–1 of this title.

EFFECTIVE DATE OF 1976 AMENDMENT

Amendment by Pub. L. 94–460 effective Oct. 8, 1976, see section 118 of Pub. L. 94–460, set out as a note under section 300e of this title.

§300e–6. Administration of assistance programs

(a) Recordkeeping; audit and examination

(1) Each recipient of a loan or loan guarantee under this subchapter shall keep such records as the Secretary shall prescribe, including records which fully disclose the amount and disposition by such

recipient of the proceeds of the loan (directly made or guaranteed), the total cost of the undertaking in connection with which the loan was given or used, the amount of that portion of the cost of the undertaking supplied by other sources, and such other records as will facilitate an effective audit.

(2) The Secretary, or any of his duly authorized representatives, shall have access for the purpose of audit and examination to any books, documents, papers, and records of the recipients of a loan or loan guarantee under this subchapter which relate to such assistance.

(b) Report upon expiration of period

Upon expiration of the period for which a loan or loan guarantee was provided an entity under this subchapter, such entity shall make a full and complete report to the Secretary in such manner as he may by regulation prescribe. Each such report shall contain, among such other matters as the Secretary may by regulation require, descriptions of plans, developments, and operations relating to the matters referred to in section 300e–5(b)(3) of this title.

(c) Repealed. Pub. L. 99–660, title VIII, §803(a), Nov. 14, 1986, 100 Stat. 3799

(d) Other entities considered health maintenance organizations

An entity which provides health services to a defined population on a prepaid basis and which has members who are entitled to insurance benefits under title XVIII of the Social Security Act [42 U.S.C. 1395 et seq.] or to medical assistance under a State plan approved under title XIX of such Act [42 U.S.C. 1396 et seq.] may be considered as a health maintenance organization for purposes of receiving assistance under this subchapter if—

(1) with respect to its members who are entitled to such insurance benefits or to such medical assistance it (A) provides health services in accordance with section 300e(b) of this title, except that (i) it does not furnish to those members the health services (within the basic health services) for which it may not be compensated under such title XVIII [42 U.S.C. 1395 et seq.] or such State plan, and (ii) it does not fix the basic or supplemental health services payment for such members under a community rating system, and (B) is organized and operated in the manner prescribed by section 300e(c) of this title, except that it does not assume full financial risk on a prospective basis for the provision to such members of basic or supplemental health services with respect to which it is not required under such title XVIII or such State plan to assume such financial risk; and

(2) with respect to its other members it provides health services in accordance with section 300e(b) of this title and is organized and operated in the manner prescribed by section 300e(c) of this title.

An entity which provides health services to a defined population on a prepaid basis and which has members who are enrolled under the health benefits program authorized by chapter 89 of title 5, may be considered as a health maintenance organization for purposes of receiving assistance under this subchapter if with respect to its other members it provides health services in accordance with section 300e(b) of this title and is organized and operated in the manner prescribed by section 300e(c) of this title.

(July 1, 1944, ch. 373, title XIII, §1307, as added Pub. L. 93–222, §2, Dec. 29, 1973, 87 Stat. 926; amended Pub. L. 94–460, title I, §§109(b)(1), 112, Oct. 8, 1976, 90 Stat. 1950, 1953; Pub. L. 97–35, title IX, §943(d), Aug. 13, 1981, 95 Stat. 576; Pub. L. 99–660, title VIII, §803(a), (b)(2), Nov. 14, 1986, 100 Stat. 3799, 3800.)

EDITORIAL NOTES

REFERENCES IN TEXT

The Social Security Act, referred to in subsec. (d), is act Aug. 14, 1935, ch. 531, 49 Stat. 620. Titles XVIII and XIX of the Social Security Act are classified generally to subchapters XVIII (§1395 et seq.) and XIX (§1396 et seq.), respectively, of chapter 7 of this title. For complete classification of this Act to the Code, see section 1305 of this title and Tables.

AMENDMENTS

1986—Subsec. (a)(1). Pub. L. 99–660, §803(b)(2), substituted "loan or loan guarantee" for "grant, contract, loan, or loan guarantee", "proceeds of the loan" for "proceeds of the grant, contract, or loan", and "with which the loan was given" for "with which such assistance was given".

Subsecs. (a)(2), (b). Pub. L. 99–660, §803(b)(2)(A), substituted "loan or loan guarantee" for "grant, contract, loan, or loan guarantee".

Subsec. (c). Pub. L. 99–660, §803(a), struck out subsec. (c) which read as follows: "If in any fiscal year the funds appropriated under section 300e–8 of this title are insufficient to fund all applications approved under this subchapter for that fiscal year, the Secretary shall, after applying the applicable priorities under sections 300e–2 and 300e–3 of this title, give priority to the funding of applications for projects which the Secretary determines are the most likely to be economically viable."

1981—Subsec. (e). Pub. L. 97–35 struck out subsec. (e) which related to limitation on cumulative total of loan guarantees in any fiscal year.

1976—Subsec. (d). Pub. L. 94–460, §112, inserted sentence at end setting conditions upon which an entity providing health services to a defined population on a prepaid basis may be considered as a health maintenance organization for purposes of receiving assistance under this subchapter.

Subsec. (e). Pub. L. 94–460, §109(b)(1), inserted "for a private health maintenance organization (other than a private nonprofit health maintenance organization)" after "may be made", and "for private health maintenance organizations (other than private nonprofit health maintenance organizations)" after "guaranteed".

STATUTORY NOTES AND RELATED SUBSIDIARIES

EFFECTIVE DATE OF 1986 AMENDMENT

Amendment by Pub. L. 99–660 not applicable to any grant made or contract entered into under this subchapter before Oct. 1, 1985, see section 803(c) of Pub. L. 99–660, set out as a note under section 300e–5 of this title.

Amendment by Pub. L. 99–660 effective Oct. 1, 1985, see section 815(a) of Pub. L. 99–660, set out as an Effective and Termination Dates of 1986 Amendment note under section 300e–1 of this title.

EFFECTIVE DATE OF 1976 AMENDMENT

Amendment by Pub. L. 94–460 effective Oct. 8, 1976, see section 118 of Pub. L. 94–460, set out as a note under section 300e of this title.

§300e–7. General provisions relating to loan guarantees and loans

(a) Conditions

(1) The Secretary may not approve an application for a loan guarantee under this subchapter unless he determines that (A) the terms, conditions, security (if any), and schedule and amount of repayments with respect to the loan are sufficient to protect the financial interests of the United States and are otherwise reasonable, including a determination that the rate of interest does not exceed such per centum per annum on the principal obligation outstanding as the Secretary determines to be reasonable, taking into account the range of interest rates prevailing in the private market for loans with similar maturities, terms, conditions, and security and the risks assumed by the United States, and (B) the loan would not be available on reasonable terms and conditions without the guarantee under this subchapter.

(2)(A) The United States shall be entitled to recover from the applicant for a loan guarantee under this subchapter the amount of any payment made pursuant to such guarantee, unless the Secretary for good cause waives such right of recovery; and, upon making any such payment, the United States shall be subrogated to all of the rights of the recipient of the payments with respect to which the guarantee was made.

(B) To the extent permitted by subparagraph (C), any terms and conditions applicable to a loan guarantee under this subchapter (including terms and conditions imposed under subparagraph (D)) may be modified by the Secretary to the extent he determines it to be consistent with the financial interest of the United States.

(C) Any loan guarantee made by the Secretary under this subchapter shall be incontestable (i) in

the hands of an applicant on whose behalf such guarantee is made unless the applicant engaged in fraud or misrepresentation in securing such guarantee, and (ii) as to any person (or his successor in interest) who makes or contracts to make a loan to such applicant in reliance thereon unless such person (or his successor in interest) engaged in fraud or misrepresentation in making or contracting to make such loan.

(D) Guarantees of loans under this subchapter shall be subject to such further terms and conditions as the Secretary determines to be necessary to assure that the purposes of this subchapter will be achieved.

(b) Application requirements

(1) The Secretary may not approve an application for a loan under this subchapter unless—

(A) the Secretary is reasonably satisfied that the applicant therefor will be able to make payments of principal and interest thereon when due, and

(B) the applicant provides the Secretary with reasonable assurances that there will be available to it such additional funds as may be necessary to complete the project or undertaking with respect to which such loan is requested.

(2) Any loan made under this subchapter shall (A) have such security, (B) have such maturity date, (C) be repayable in such installments, (D) on the date the loan is made, bear interest at a rate comparable to the rate of interest prevailing on such date with respect to marketable obligations of the United States of comparable maturities, adjusted to provide for appropriate administrative charges, and (E) be subject to such other terms and conditions (including provisions for recovery in case of default) as the Secretary determines to be necessary to carry out the purposes of this subchapter while adequately protecting the financial interests of the United States. On the date disbursements are made under a loan after the initial disbursement under the loan, the Secretary may change the rate of interest on the amount of the loan disbursed on that date to a rate which is comparable to the rate of interest prevailing on the date the subsequent disbursement is made with respect to marketable obligations of the United States of comparable maturities, adjusted to provide for appropriate administrative charges.

(3) The Secretary may, for good cause but with due regard to the financial interests of the United States, waive any right of recovery which he has by reason of the failure of a borrower to make payments of principal of and interest on a loan made under this subchapter, except that if such loan is sold and guaranteed, any such waiver shall have no effect upon the Secretary's guarantee of timely payment of principal and interest.

(c) Sale of loans

(1) The Secretary may from time to time, but with due regard to the financial interests of the United States, sell loans made by him under this subchapter.

(2) The Secretary may agree, prior to his sale of any such loan, to guarantee to the purchaser (and any successor in interest of the purchaser) compliance by the borrower with the terms and conditions of such loan. Any such agreement shall contain such terms and conditions as the Secretary considers necessary to protect the financial interests of the United States or as otherwise appropriate. Any such agreement may (A) provide that the Secretary shall act as agent of any such purchaser for the purpose of collecting from the borrower to which such loan was made and paying over to such purchaser, any payments of principal and interest payable by such organization under such loan; and (B) provide for the repurchase by the Secretary of any such loan on such terms and conditions as may be specified in the agreement. The full faith and credit of the United States is pledged to the payment of all amounts which may be required to be paid under any guarantee under this paragraph.

(3) After any loan under this subchapter to a public health maintenance organization has been sold and guaranteed under this subsection, interest paid on such loan which is received by the purchaser thereof (or his successor in interest) shall be included in the gross income of the purchaser of the loan (or his successor in interest) for the purpose of chapter 1 of title 26.

(4) Amounts received by the Secretary as proceeds from the sale of loans under this subsection shall be deposited in the loan fund established under subsection (e).

(5) Any reference in this subchapter (other than in this subsection and in subsection (d)) to a loan guarantee under this subchapter does not include a loan guarantee made under this subsection.

(d) Loan guarantee fund

(1) There is established in the Treasury a loan guarantee fund (hereinafter in this subsection referred to as the "fund") which shall be available to the Secretary without fiscal year limitation, in such amounts as may be specified from time to time in appropriation Acts, to enable him to discharge his responsibilities under loan guarantees issued by him under this subchapter and to take the action authorized by subsection (f). There are authorized to be appropriated from time to time such amounts as may be necessary to provide the sums required for the fund. To the extent authorized in appropriation Acts, there shall also be deposited in the fund amounts received by the Secretary in connection with loan guarantees under this subchapter and other property or assets derived by him from his operations respecting such loan guarantees, including any money derived from the sale of assets.

(2) If at any time the sums in the funds are insufficient to enable the Secretary to discharge his responsibilities under guarantees issued by him before October 1, 1986, under this subchapter and to take the action authorized by subsection (f), he is authorized to issue to the Secretary of the Treasury notes or other obligations in such forms and denominations, bearing such maturities, and subject to such terms and conditions, as may be prescribed by the Secretary with the approval of the Secretary of the Treasury. Such notes or other obligations shall bear interest at a rate determined by the Secretary of the Treasury, taking into consideration the current average market yield on outstanding marketable obligations of the United States of comparable maturities during the month preceding the issuance of the notes or other obligations. The Secretary of the Treasury shall purchase any notes and other obligations issued under this paragraph and for that purpose he may use as a public debt transaction the proceeds from the sale of any securities issued under chapter 31 of title 31, and the purposes for which the securities may be issued under that chapter are extended to include any purchase of such notes and obligations. The Secretary of the Treasury may at any time sell any of the notes or other obligations acquired by him under this paragraph. All redemptions, purchases, and sales by the Secretary of the Treasury of such notes or other obligations shall be treated as public debt transactions of the United States. Sums borrowed under this paragraph shall be deposited in the fund and redemption of such notes and obligations shall be made by the Secretary from the fund.

(e) Loan fund

There is established in the Treasury a loan fund (hereinafter in this subsection referred to as the "fund") which shall be available to the Secretary without fiscal year limitation, in such amounts as may be specified from time to time in appropriation Acts, to enable him to make loans under this subchapter and to take the action authorized by subsection (f). There shall also be deposited in the fund amounts received by the Secretary as interest payments and repayment of principal on loans made under this subchapter and other property or assets derived by him from his operations respecting such loans, from the sale of loans under subsection (c) of this section, or from the sale of assets.

(f) Actions to protect interest of United States in event of default

The Secretary may take such action as he deems appropriate to protect the interest of the United States in the event of a default on a loan made or guaranteed under this subchapter, including taking possession of, holding, and using real property pledged as security for such a loan or loan guarantee.

(July 1, 1944, ch. 373, title XIII, §1308, as added Pub. L. 93–222, §2, Dec. 29, 1973, 87 Stat. 927; amended Pub. L. 94–460, title I, §109(b)(2), (c), Oct. 8, 1976, 90 Stat. 1950; Pub. L. 95–559, §4(c), Nov. 1, 1978, 92 Stat. 2132; Pub. L. 97–35, title IX, §945, Aug. 13, 1981, 95 Stat. 577; Pub. L. 99–514, §2, Oct. 22, 1986, 100 Stat. 2095; Pub. L. 99–660, title VIII, §807, Nov. 14, 1986, 100 Stat. 3800.)

EDITORIAL NOTES

CODIFICATION

In subsec. (d)(2), "chapter 31 of title 31" and "that chapter" substituted for "the Second Liberty Bond Act" and "that Act", respectively, on authority of Pub. L. 97–258, §4(b), Sept. 13, 1982, 96 Stat. 1067, the first section of which enacted Title 31, Money and Finance.

AMENDMENTS

1986—Subsec. (c)(3). Pub. L. 99–514 substituted "Internal Revenue Code of 1986" for "Internal Revenue Code of 1954", which for purposes of codification was translated as "title 26" thus requiring no change in text.

Subsec. (d)(2). Pub. L. 99–660 inserted "before October 1, 1986," after "guarantees issued by him".

1981—Subsec. (b)(2). Pub. L. 97–35 inserted provisions relating to changes in the rate of interest by the Secretary, and in cl. (D) made changes in nomenclature.

1978—Subsec. (d). Pub. L. 95–559, §4(c)(2)(A), in pars. (1) and (2) inserted "and to take the action authorized by subsection (f)" after "by him under this subchapter".

Subsec. (e). Pub. L. 95–559, §4(c)(2)(B), inserted "and to take the action authorized by subsection (f)" after "loans under this subchapter".

Subsec. (f). Pub. L. 95–559, §4(c)(1), added subsec. (f).

1976—Subsec. (a)(1)(A). Pub. L. 94–460, §109(c)(1), substituted "for loans with similar maturities, terms, conditions, and security" for "for similar loans".

Subsec. (b)(2)(D). Pub. L. 94–460, §109(c)(2), substituted "marketable obligations of the United States of comparable maturities, adjusted to provide for appropriate administrative charges" for "loans guaranteed under this subchapter".

Subsec. (c)(5). Pub. L. 94–460, §109(b)(2), added par. (5).

STATUTORY NOTES AND RELATED SUBSIDIARIES

EFFECTIVE DATE OF 1986 AMENDMENT

Amendment by Pub. L. 99–660 effective Oct. 1, 1985, see section 815(a) of Pub. L. 99–660, set out as an Effective and Termination Dates of 1986 Amendment note under section 300e–1 of this title.

EFFECTIVE DATE OF 1978 AMENDMENT

Amendment by Pub. L. 95–559 effective only for fiscal years beginning on or after October 1, 1978, see section 4(d) of Pub. L. 95–559, set out as a note under section 300e–4 of this title.

EFFECTIVE DATE OF 1976 AMENDMENT

Amendment by Pub. L. 94–460 effective Oct. 8, 1976, except that the amendment by section 109(c) of Pub. L. 94–460 applicable with respect to loan guarantees made under section 300e–4 of this title after Sept. 30, 1976, see section 118 of Pub. L. 94–460, set out as a note under section 300e of this title.

§300e–8. Authorization of appropriations

(a) For grants under section 300e–16 of this title there is authorized to be appropriated $1,000,000 for each of the fiscal years 1982, 1983, and 1984.

(b) To meet the obligations of the loan fund established under section 300e–7(e) of this title resulting from defaults on loans made from the fund and to meet the other obligations of the fund, there is authorized to be appropriated to the loan fund for fiscal years 1987, 1988, and 1989, such sums as may be necessary.

(July 1, 1944, ch. 373, title XIII, §1309, as added Pub. L. 93–222, §2, Dec. 29, 1973, 87 Stat. 930; amended Pub. L. 94–460, title I, §113(c), Oct. 8, 1976, 90 Stat. 1954; Pub. L. 95–83, title I, §105(b), Aug. 1, 1977, 91 Stat. 384; Pub. L. 95–559, §§2(c), 7(b), Nov. 1, 1978, 92 Stat. 2131, 2135; Pub. L. 97–35, title IX, §941(a), (b), Aug. 13, 1981, 95 Stat. 572; Pub. L. 99–660, title VIII, §§803(b)(3), 811, Nov. 14, 1986, 100 Stat. 3800, 3801.)

EDITORIAL NOTES

AMENDMENTS

1986—Subsec. (a). Pub. L. 99–660, §803(b)(3), struck out par. (2) designation and struck out par. (1) which read as follows: "For grants and contracts under sections 300e–2 and 300e–3 of this title there is authorized to be appropriated $20,000,000 for the fiscal years 1982, 1983, and 1984. No funds appropriated under this paragraph may be expended or obligated for a grant or contract unless the entity received a grant or contract under section 242a or 242b of this title during or before the fiscal year 1981."

Subsec. (b). Pub. L. 99–660, §811, amended subsec. (b) generally. Prior to amendment, subsec. (b) read as follows: "To maintain in the loan fund established under section 300e–7(e) of this title for the purpose of making new loans a balance of at least $5,000,000 at the end of each fiscal year and to meet the obligations of the loan fund resulting from defaults on loans made from the fund and to meet the other obligations of the fund, there is authorized to be appropriated to the loan fund for fiscal years 1982, 1983, and 1984, such sums as may be necessary to assure such balance and meet such obligations."

1981—Subsec. (a). Pub. L. 97–35, §941(a), substituted provisions authorizing appropriations for fiscal years 1982, 1983, and 1984, and provisions respecting prior receipt of funds, for provisions authorizing appropriations for fiscal years ending June 30, 1974, 1975, and 1976, and Sept. 30, 1977, 1978, 1979, 1980, and 1981.

Subsec. (b). Pub. L. 97–35, §941(b), substituted provisions relating to maintenance of the loan fund for fiscal years 1982, 1983, and 1984, for provisions relating to maintenance of the loan fund for fiscal years ending June 30, 1974, and 1975.

1978—Subsec. (a). Pub. L. 95–559 substituted "300e–3(b) and 300e–16 of this title" for "and 300e–3(b) of this title" and ", $31,000,000 for the fiscal year ending September 30, 1979, $65,000,000 for the fiscal year ending September 30, 1980, and $68,000,000 for the fiscal year ending September 30, 1981" for "; and for the purpose of making payments under grants and contracts under section 300e–3(b) of this title for the fiscal year ending September 30, 1979, there is authorized to be appropriated $50,000,000".

1977—Subsec. (a). Pub. L. 95–83 substituted, where appearing the second time, "September 30, 1979" for "September 30, 1977".

1976—Subsec. (a). Pub. L. 94–460 substituted "$40,000,000 for the fiscal year ending June 30, 1976, $45,000,000 for the fiscal year ending September 30, 1977, and $45,000,000 for the fiscal year ending September 30, 1978;" for "and $85,000,000 for the fiscal year ending June 30, 1976;" and "for the fiscal year ending September 30, 1977, there is authorized to be appropriated $50,000,000" for "for the fiscal year ending June 30, 1977, there is authorized to be appropriated $85,000,000".

STATUTORY NOTES AND RELATED SUBSIDIARIES

EFFECTIVE DATE OF 1986 AMENDMENT

Amendment by section 803(b)(3) of Pub. L. 99–660 not applicable to any grant made or contract entered into under this subchapter before Oct. 1, 1985, see section 803(c) of Pub. L. 99–660, set out as a note under section 300e–5 of this title.

Amendment by Pub. L. 99–660 effective Oct. 1, 1985, see section 815(a) of Pub. L. 99–660, set out as an Effective and Termination Dates of 1986 Amendment note under section 300e–1 of this title.

EFFECTIVE DATE OF 1978 AMENDMENT

Amendment by section 7(b) of Pub. L. 95–559 effective only for fiscal years beginning on or after Oct. 1, 1978, see section 7(c) of Pub. L. 95–559, set out as an Effective Date note under section 300e–16 of this title.

EFFECTIVE DATE OF 1976 AMENDMENT

Amendment by Pub. L. 94–460 effective Oct. 8, 1976, see section 118 of Pub. L. 94–460, set out as a note under section 300e of this title.

§300e–9. Employees' health benefits plans

(a) Regulations; membership option

In accordance with regulations which the Secretary shall prescribe—

(1) each employer—

(A) which is required during any calendar quarter to pay its employees the minimum wage prescribed by section 206 of title 29 (or would be required to pay its employees such wage but for section 213(a) of title 29), and

(B) which during such calendar quarter employed an average number of employees of not less than 25, and

(2) any State and each political subdivision thereof which during any calendar quarter employed an average number of employees of not less than 25, as a condition of payment to the State of funds under section 247b, 247c, or 300a of this title,

which offers to its employees in the calendar year beginning after such calendar quarter the option of membership in a qualified health maintenance organization which is engaged in the provision of basic health services in a health maintenance organization service area in which at least 25 of such employees reside shall meet the requirements of subsection (b) with respect to any qualified health maintenance organization offered by the employer or State or political subdivision.

(b) Nondiscriminatory contributions for services; payroll deductions; effect on costs

(1) If a health benefits plan offered by an employer or a State or political subdivision includes contributions for services offered under the plan, the employer or State or political subdivision shall make a contribution under the plan for services offered by a qualified health maintenance organization in an amount which does not financially discriminate against an employee who enrolls in such organization. For purposes of the preceding sentence, an employer's or a State's or political subdivision's contribution does not financially discriminate if the employer's or State's or political subdivision's method of determining the contributions on behalf of all employees is reasonable and is designed to assure employees a fair choice among health benefits plans.

(2) Each employer or State or political subdivision which provides payroll deductions as a means of paying employees' contributions for health benefits or which provides a health benefits plan to which an employee contribution is not required shall, with the consent of an employee who exercises option of membership in a qualified health maintenance organization, arrange for the employee's contribution for membership in the organization to be paid through payroll deductions.

(3) No employer or State or political subdivision shall be required to pay more for health benefits as a result of the application of this subsection than would otherwise be required by any prevailing collective bargaining agreement or other legally enforceable contract for the provision of health benefits between the employer or State or political subdivision and its employees.

(c) "Qualified health maintenance organization" defined

For purposes of this section, the term "qualified health maintenance organization" means (1) a health maintenance organization which has provided assurances satisfactory to the Secretary that it provides basic and supplemental health services to its members in the manner prescribed by section 300e(b) of this title and that it is organized and operated in the manner prescribed by section 300e(c) of this title, and (2) an entity which proposes to become a health maintenance organization and which the Secretary determines will when it becomes operational provide basic and supplemental health services to its members in the manner prescribed by section 300e(b) of this title and will be organized and operated in the manner prescribed by section 300e(c) of this title.

(d) Civil penalty; notice and presentation of views; review

(1) Any employer who knowingly does not comply with one or more of the requirements of paragraph (1) or (2) of subsection (b) shall be subject to a civil penalty of not more than $10,000. If such noncompliance continues, a civil penalty may be assessed and collected under this subsection for each thirty-day period such noncompliance continues. Such penalty may be assessed by the Secretary and collected in a civil action brought by the United States in a United States district court.

(2) In any proceeding by the Secretary to assess a civil penalty under this subsection, no penalty shall be assessed until the employer charged shall have been given notice and an opportunity to present its views on such charge. In determining the amount of the penalty, or the amount agreed upon in compromise, the Secretary shall consider the gravity of the noncompliance and the demonstrated good faith of the employer charged in attempting to achieve rapid compliance after notification by the Secretary of a noncompliance.

(3) In any civil action brought to review the assessment of a civil penalty assessed under this subsection, the court shall, at the request of any party to such action, hold a trial de novo on the assessment of such civil penalty and in any civil action to collect such a civil penalty, the court shall, at the request of any party to such action, hold a trial de novo on the assessment of such civil penalty unless in a prior civil action to review the assessment of such penalty the court held a trial de novo on such assessment.

(e) "Employer" defined

For purposes of this section, the term "employer" does not include (1) the Government of the United States, the government of the District of Columbia or any territory or possession of the United States, a State or any political subdivision thereof, or any agency or instrumentality (including the United States Postal Service and Postal Regulatory Commission) of any of the foregoing, except that such term includes nonappropriated fund instrumentalities of the Government of the United States; or (2) a church, convention or association of churches, or any organization operated, supervised or controlled by a church, convention or association of churches which organization (A) is an organization described in section 501(c)(3) of title 26, and (B) does not discriminate (i) in the employment, compensation, promotion, or termination of employment of any personnel, or (ii) in the extension of staff or other privileges to any physician or other health personnel, because such persons seek to obtain or obtained health care, or participate in providing health care, through a health maintenance organization.

(f) Termination of payment for failure to comply

If the Secretary, after reasonable notice and opportunity for a hearing to a State, finds that it or any of its political subdivisions has failed to comply with paragraph (1) or (2) of subsection (b), the Secretary shall terminate payments to such State under sections 247b, 247c, and 300a of this title and notify the Governor of such State that further payments under such sections will not be made to the State until the Secretary is satisfied that there will no longer be any such failure to comply.

(July 1, 1944, ch. 373, title XIII, §1310, as added Pub. L. 93–222, §2, Dec. 29, 1973, 87 Stat. 930; amended Pub. L. 94–460, title I, §110(a), Oct. 8, 1976, 90 Stat. 1950; Pub. L. 95–559, §§8, 12(a)(1), Nov. 1, 1978, 92 Stat. 2135, 2140; Pub. L. 96–32, §2(f), July 10, 1979, 93 Stat. 82; Pub. L. 97–35, title IX, §§942(a)(3), (4), 946, Aug. 13, 1981, 95 Stat. 573, 577; Pub. L. 99–514, §2, Oct. 22, 1986, 100 Stat. 2095; Pub. L. 99–660, title VIII, §808, Nov. 14, 1986, 100 Stat. 3801; Pub. L. 100–517, §§4(b), 7(a)(1), (2), (b), Oct. 24, 1988, 102 Stat. 2578, 2580; Pub. L. 109–435, title VI, §604(f), Dec. 20, 2006, 120 Stat. 3242.)

EDITORIAL NOTES

AMENDMENTS

2006—Subsec. (e). Pub. L. 109–435 substituted "Postal Regulatory Commission" for "Postal Rate Commission".

1988—Pub. L. 100–517, §7(b), amended section generally, substituting subsecs. (a) to (f) for former subsecs. (a) to (g).

Subsec. (b). Pub. L. 100–517, §§4(b), 7(a)(1)(A), in introductory provisions, substituted "or a State or political subdivision" for "subject to subsection (a) of this section", in par. (1), inserted "and provides at least 90 percent of such services through physicians described in section 300e(b)(3)(A) of this title", in par. (2), inserted "and provides no more than 10 percent of such services through physicians who are not described in section 300e(b)(3)(A) of this title", and in concluding provisions, substituted "employer or State or political subdivision pursuant" for "employer pursuant".

Subsec. (c). Pub. L. 100–517, §7(a)(1)(B), (2), substituted "No employer or State or political subdivision" for "No employer", "between the employer or State or political subdivision" for "between the employer", and "Each employer or State or political subdivision" for "Each employer", and inserted at end "If a health benefits plan offered by an employer or a State or political subdivision under subsection (a) of this section includes contributions for services offered under the plan, the employer or State or political subdivision shall make a contribution under the plan for services offered by a qualified health maintenance organization in an amount which does not financially discriminate against an employee who enrolls in such organization. For purposes of

the preceding sentence, an employer's or a State's or political subdivision's contribution does not financially discriminate if the employer's or State's or political subdivision's method of determining the contributions on behalf of all employees is reasonable and is designed to assure employees a fair choice among health benefits plans."

1986—Subsec. (d). Pub. L. 99–660 struck out last sentence which read as follows: "Every two years (or such longer period as the Secretary may by regulation prescribe) after the date a health maintenance organization becomes a qualified health maintenance organization under this subsection, the health maintenance organization must demonstrate to the Secretary that it is qualified within the meaning of this subsection."

Subsec. (f). Pub. L. 99–514 substituted "Internal Revenue Code of 1986" for "Internal Revenue Code of 1954", which for purposes of codification was translated as "title 26" thus requiring no change in text.

1981—Subsec. (b)(1). Pub. L. 97–35, §942(a)(3)(A), substituted provisions respecting provision of more than one-half of the basic services provided by physicians, for provisions respecting provision of basic services.

Subsec. (b)(2). Pub. L. 97–35, §942(a)(3)(B), (4), inserted reference to provision by physicians, added cl. (B), and redesignated former cl. (B) as (C).

Subsec. (d). Pub. L. 97–35, §946(a), inserted provisions relating to demonstration of continued qualification of organization.

Subsec. (f)(1). Pub. L. 97–35, §946(b), inserted reference to United States nonappropriated fund instrumentalities.

1979—Subsec. (e)(1). Pub. L. 96–32 substituted "subsection (a), (b), or (c)" for "subsection (a)".

1978—Subsec. (b). Pub. L. 95–559, §8(b), substituted in par. (1) "through physicians or other health professionals who are members of the staff of the organization or a medical group (or groups)" for "(A) without the use of an individual practice association and (B) without the use of contracts (except for contracts for unusual or infrequently used services) with health professionals" and in par. (2) "(B) a combination of such association (or associations), medical group (or groups), staff, and individual physicians and other health professionals under contract with the organization" for "(B) health professionals who have contracted with the health maintenance organization for the provision of such services, or (C) a combination of such association (or associations) or health professionals under contract with the organization".

Subsec. (c). Pub. L. 95–559, §8(a), inserted provision that each employer which provides payroll deductions as a means of paying employees' contributions for health benefits or which provides a health benefits plan to which an employee contribution is not required and which is required by subsection (a) of this section to offer his employees the option of membership in a qualified health maintenance organization shall, with the consent of an employee who exercises such option, arrange for the employee's contribution for such membership to be paid through payroll deductions.

Subsec. (h). Pub. L. 95–559, §12(a)(1), struck out subsec. (h) which provided that the duties and functions of the Secretary, insofar as they involve determinations as to whether an organization is a qualified health maintenance organization within the meaning of subsection (d) of this section, be administered through the Assistant Secretary for Health and in the Office of the Assistant Secretary for Health, and the administration of such duties and functions be integrated with the administration of section 300e–11(a) of this title.

1976—Subsec. (a). Pub. L. 94–460, §110(a)(1), substituted reference to each employer which is now or hereafter required for reference to each employer which is required, reference to basic health services in health maintenance organization service areas in which at least 25 of such employees reside for reference to basic and supplemental health services in the areas in which such employees reside, and inserted provisions requiring certain States and political subdivisions thereof to include in any health benefits plan the option of membership in qualified health maintenance organizations as a condition of payment to the State of funds under section 246(d), 247b, 247c, 300a, 300m–4, or 300p–3 of this title, and that the offer of membership in such an organization be first made to the employees' representative, if any, and then be made to each employee if the offer is accepted by the representative.

Subsec. (b)(1). Pub. L. 94–460, §110(a)(2), substituted "(A) without the use of an individual practice association and (B) without the use of contracts (except for contracts for unusual or infrequently used services) with health professionals" for "through professionals who are members of the staff of the organization or a medical group (or groups)".

Subsec. (b)(2). Pub. L. 94–460, §110(a)(2), substituted "basic health services through (A) an individual practice association (or associations), (B) health professionals who have contracted with the health maintenance organization for the provision of such services, or (C) a combination of such association (or associations) or health professionals under contract with the organization" for "such services through an individual practice association (or associations)".

Subsec. (c). Pub. L. 94–460, §110(a)(3), struck out provision that failure of any employer to comply with the requirements of subsection (a) of this section be considered a willful violation of section 215 of title 29.

Subsecs. (e) to (h). Pub. L. 94–460, §110(a)(4), added subsecs. (e) to (h).

STATUTORY NOTES AND RELATED SUBSIDIARIES

EFFECTIVE DATE OF 1988 AMENDMENT

Pub. L. 100–517, §7(b), Oct. 24, 1988, 102 Stat. 2580, provided that the amendment made by section 7(b) is effective 7 years after Oct. 24, 1988.

EFFECTIVE DATE OF 1986 AMENDMENT

Amendment by Pub. L. 99–660 effective Oct. 1, 1985, see section 815(a) of Pub. L. 99–660, set out as an Effective and Termination Dates of 1986 Amendment note under section 300e–1 of this title.

EFFECTIVE DATE OF 1981 AMENDMENT

Pub. L. 97–35, title IX, §942(a)(5), Aug. 13, 1981, 95 Stat. 573, provided that: "The amendment made by paragraph (3)(A) [amending this section] shall apply with respect to the offering of a health maintenance organization in accordance with section 1310(b)(1) of the Public Health Service Act [42 U.S.C. 300e–9(b)(1)] after four years after the date the organization becomes a qualified health maintenance organization for purposes of section 1310 of such Act [42 U.S.C. 300e–9] if the health maintenance organization provides assurances satisfactory to the Secretary that upon the expiration of such four years it will provide more than one half of its basic health services which are provided by physicians through physicians or other health professionals who are members of the staff of the organization or a medical group (or groups)."

EFFECTIVE DATE OF 1976 AMENDMENT

Amendment by section 110(a)(1), (2) of Pub. L. 94–460 applicable with respect to calendar quarters which began after Oct. 8, 1976, and amendment by section 110(a)(3), (4) of Pub. L. 94–460 applicable with respect to failures of employers to comply with section 300e–9 of this title after Oct. 8, 1976, see section 118 of Pub. L. 94–460, set out as a note under section 300e of this title.

COLLECTIVE BARGAINING AGREEMENTS IN EFFECT ON OCTOBER 24, 1988, UNAFFECTED

Pub. L. 100–517, §7(a)(3), Oct. 24, 1988, 102 Stat. 2580, provided that: "Nothing in section 1310 of the Public Health Service Act (42 U.S.C. 300e–9), as amended by this Act, shall be construed to supersede any provision of a collective bargaining agreement in effect on the date of enactment of this Act [Oct. 24, 1988]."

§300e–10. Restrictive State laws and practices

(a) Entities operating as health maintenance organizations

In the case of any entity—

(1) which cannot do business as a health maintenance organization in a State in which it proposes to furnish basic and supplemental health services because that State by law, regulation, or otherwise—

(A) requires as a condition to doing business in that State that a medical society approve the furnishing of services by the entity,

(B) requires that physicians constitute all or a percentage of its governing body,

(C) requires that all physicians or a percentage of physicians in the locale participate or be permitted to participate in the provision of services for the entity,

(D) requires that the entity meet requirements for insurers of health care services doing business in that State respecting initial capitalization and establishment of financial reserves against insolvency, or

(E) imposes requirements which would prohibit the entity from complying with the requirements of this subchapter, and

(2) for which a grant, contract, loan, or loan guarantee was made under this subchapter or which

is a qualified health maintenance organization for purposes of section 300e–9 of this title (relating to employees' health benefits plans),

such requirements shall not apply to that entity so as to prevent it from operating as a health maintenance organization in accordance with section 300e of this title.

(b) Advertising

No State may establish or enforce any law which prevents a health maintenance organization for which a grant, contract, loan, or loan guarantee was made under this subchapter or which is a qualified health maintenance organization for purposes of section 300e–9 of this title (relating to employees' health benefits plans), from soliciting members through advertising its services, charges, or other nonprofessional aspects of its operation. This subsection does not authorize any advertising which identifies, refers to, or makes any qualitative judgement concerning, any health professional who provides services for a health maintenance organization.

(c) Digest of State laws, regulations, and practices; legal consultative assistance

The Secretary shall, within 6 months after October 8, 1976, develop a digest of State laws, regulations, and practices pertaining to development, establishment, and operation of health maintenance organizations which shall be updated at least annually and relevant sections of which shall be provided to the Governor of each State annually. Such digest shall indicate which State laws, regulations, and practices appear to be inconsistent with the operation of this section. The Secretary shall also insure that appropriate legal consultative assistance is available to the States for the purpose of complying with the provisions of this section.

(July 1, 1944, ch. 373, title XIII, §1311, as added Pub. L. 93–222, §2, Dec. 29, 1973, 87 Stat. 931; amended Pub. L. 94–460, title I, §114, Oct. 8, 1976, 90 Stat. 1954; Pub. L. 99–660, title VIII, §809, Nov. 14, 1986, 100 Stat. 3801; Pub. L. 100–517, §8, Oct. 24, 1988, 102 Stat. 2583.)

EDITORIAL NOTES

PRIOR PROVISIONS

A prior section 1311 of act July 1, 1944, was classified to section 211a of this title prior to repeal by Pub. L. 93–222, §7(b).

AMENDMENTS

1988—Subsec. (a)(1)(E). Pub. L. 100–517 added subpar. (E).
1986—Subsec. (c). Pub. L. 99–660 substituted "annually" for "quarterly" after "at least".
1976—Subsec. (c). Pub. L. 94–460 added subsec. (c).

STATUTORY NOTES AND RELATED SUBSIDIARIES

EFFECTIVE DATE OF 1986 AMENDMENT

Amendment by Pub. L. 99–660 effective Oct. 1, 1985, see section 815(a) of Pub. L. 99–660, set out as an Effective and Termination Dates of 1986 Amendment note under section 300e–1 of this title.

EFFECTIVE DATE OF 1976 AMENDMENT

Amendment by Pub. L. 94–460 effective Oct. 8, 1976, see section 118 of Pub. L. 94–460, set out as a note under section 300e of this title.

§300e–11. Continued regulation of health maintenance organizations

(a) Determination of deficiency

If the Secretary determines that an entity which received a grant, contract, loan, or loan guarantee under this subchapter as a health maintenance organization or which was included in a health benefits plan offered to employees pursuant to section 300e–9 of this title—

(1) fails to provide basic and supplemental services to its members,
(2) fails to provide such services in the manner prescribed by section 300e(b) of this title, or
(3) is not organized or operated in the manner prescribed by section 300e(c) of this title,

the Secretary may take the action authorized by subsection (b).

(b) Action by Secretary upon determination

(1) If the Secretary makes, with respect to any entity which provided assurances to the Secretary under section 300e–9(d)(1) [1] of this title, a determination described in subsection (a), the Secretary shall notify the entity in writing of the determination. Such notice shall specify the manner in which the entity has not complied with such assurances and direct that the entity initiate (within 30 days of the date the notice is issued by the Secretary or within such longer period as the Secretary determines is reasonable) such action as may be necessary to bring (within such period as the Secretary shall prescribe) the entity into compliance with the assurances. If the entity fails to initiate corrective action within the period prescribed by the notice or fails to comply with the assurances within such period as the Secretary prescribes, then after the Secretary provides the entity a reasonable opportunity for reconsideration of his determination, including, at the entity's election, a fair hearing (A) the entity shall not be a qualified health maintenance organization for purposes of section 300e–9 of this title until such date as the Secretary determines that it is in compliance with the assurances, and (B) each employer which has offered membership in the entity in compliance with section 300e–9 of this title, each lawfully recognized collective bargaining representative or other employee representative which represents the employees of each such employer, and the members of such entity shall be notified by the entity that the entity is not a qualified health maintenance organization for purposes of such section. The notice required by clause (B) of the preceding sentence shall contain, in readily understandable language, the reasons for the determination that the entity is not a qualified health maintenance organization. The Secretary shall publish in the Federal Register each determination referred to in this paragraph.

(2) If the Secretary makes, with respect to an entity which has received a grant, contract, loan, or loan guarantee under this subchapter, a determination described in subsection (a), the Secretary may, in addition to any other remedies available to him, bring a civil action in the United States district court for the district in which such entity is located to enforce its compliance with the assurances it furnished respecting the provision of basic and supplemental health services or its organization or operation, as the case may be, which assurances were made in connection with its application under this subchapter for the grant, contract, loan, or loan guarantee.

(July 1, 1944, ch. 373, title XIII, §1312, as added Pub. L. 93–222, §2, Dec. 29, 1973, 87 Stat. 931; amended Pub. L. 94–460, title I, §111, Oct. 8, 1976, 90 Stat. 1952; Pub. L. 95–559, §12(a)(2), Nov. 1, 1978, 92 Stat. 2140; Pub. L. 97–35, title IX, §949(a), Aug. 13, 1981, 95 Stat. 578.)

EDITORIAL NOTES

REFERENCES IN TEXT

Section 300e–9(d)(1) of this title, referred to in subsec. (b)(1), was redesignated section 300e–9(c)(1) of this title by Pub. L. 100–517, §7(b), Oct. 24, 1988, 102 Stat. 2580.

PRIOR PROVISIONS

A prior section 1312 of act July 1, 1944, was classified to section 212a of this title prior to repeal by Pub. L. 93–222, §7(b).

AMENDMENTS

1981—Subsec. (b)(1). Pub. L. 97–35 inserted provisions relating to opportunity for reconsideration of determination of Secretary.

1978—Subsec. (c). Pub. L. 95–559 struck out subsec. (c) which provided that the Secretary, acting through the Assistant Secretary for Health, administer subsections (a) and (b) of this section in the Office of the Assistant Secretary for Health.

1976—Subsec. (a). Pub. L. 94–460, §111(a), substituted "the Secretary may take the action authorized by subsection (b)" for "the Secretary may, in addition to any other remedies available to him, bring a civil action in the United States district court for the district in which such entity is located to enforce its compliance with any assurances it furnished him respecting the provision of basic and supplemental health services or its organization or operation, as the case may be, which assurances were made under section 300e–9 of this title or when application was made under this subchapter for a grant, contract, loan, or loan guarantee".

Subsecs. (b), (c). Pub. L. 94–460, §111(b), (c), added subsec. (b), redesignated former subsec. (b) as (c), and substituted "acting through the Assistant Secretary for Health, shall administer subsections (a) and (b)" for "through the Assistant Secretary for Health, shall administer subsection (a)".

STATUTORY NOTES AND RELATED SUBSIDIARIES

EFFECTIVE DATE OF 1976 AMENDMENT

Amendment by Pub. L. 94–460 applicable with respect to determinations of the Secretary of Health, Education, and Welfare described in subsec. (a) of this section and made after Oct. 8, 1976, see section 118 of Pub. L. 94–460, set out as a note under section 300e of this title.

[1] *See References in Text note below.*

§300e–12. Limitation on source of funding for health maintenance organizations

No funds appropriated under any provision of this chapter (except as provided in sections 254b [1] and 254b of this title) other than this subchapter may be used—

(1) for grants or contracts for surveys or other activities to determine the feasibility of developing or expanding health maintenance organizations or other entities which provide, directly or indirectly, health services to a defined population on a prepaid basis;

(2) for grants or contracts, or for payments under loan guarantees, for planning projects for the establishment or expansion of such organizations or entities;

(3) for grants or contracts, or for payments under loan guarantees, for projects for the initial development or expansion of such organizations or entities; or

(4) for loans, or for payments under loan guarantees, to assist in meeting the costs of the initial operation after establishment or expansion of such organizations or entities or in meeting the costs of such organizations in acquiring or constructing ambulatory health care facilities.

(July 1, 1944, ch. 373, title XIII, §1313, as added Pub. L. 93–222, §2, Dec. 29, 1973, 87 Stat. 932; amended Pub. L. 95–559, §5(b), Nov. 1, 1978, 92 Stat. 2133; Pub. L. 95–626, title I, §107, Nov. 10, 1978, 92 Stat. 3562; Pub. L. 107–251, title VI, §601(a), Oct. 26, 2002, 116 Stat. 1664; Pub. L. 108–163, §2(m)(2), Dec. 6, 2003, 117 Stat. 2023.)

EDITORIAL NOTES

REFERENCES IN TEXT

The reference to section 254b of this title the first place appearing in text was in the original a reference to section 329, meaning section 329 of act July 1, 1944, which was omitted in the general amendment of subpart I (§254b et seq.) of part D of this subchapter by Pub. L. 104–299, §2, Oct. 11, 1996, 110 Stat. 3626.

AMENDMENTS

2003—Pub. L. 108–163 substituted "254b and 254b" for "254b, 254c, and 254b(h)" in introductory provisions.

2002—Pub. L. 107–251 substituted "254b(h)" for "256" in introductory provisions.

1978—Pub. L. 95–626 inserted "(except as provided in sections 254b, 254c, and 256 of this title)" after "under any provision of this chapter" in provisions preceding par. (1).

Par. (4). Pub. L. 95–559 inserted "or in meeting the costs of such organizations in acquiring or constructing ambulatory health care facilities" after "or entities".

STATUTORY NOTES AND RELATED SUBSIDIARIES

EFFECTIVE DATE OF 2003 AMENDMENT

Amendment by Pub. L. 108–163 deemed to have taken effect immediately after the enactment of Pub. L. 107–251, see section 3 of Pub. L. 108–163, set out as a note under section 233 of this title.

[1] *See References in Text note below.*

§300e–13. Repealed. Pub. L. 97–35, title IX, §949(b), Aug. 13, 1981, 95 Stat. 578

Section, acts July 1, 1944, ch. 373, title XIII, §1314, as added Dec. 29, 1973, Pub. L. 93–222, §2, 87 Stat. 932; amended Oct. 8, 1976, Pub. L. 94–460, title I, §115, 90 Stat. 1954; Nov. 1, 1978, Pub. L. 95–559, §13, 92 Stat. 2140, required the Comptroller General to: (a) evaluate the operations, particularly, specified aspects of the operations, of at least ten or one-half, whichever is greater, of the health maintenance organizations for which assistance was provided under sections 300e–2, 300e–3, and 300e–4 of this title, and which, by Dec. 31, 1976, were designated by the Secretary under section 300e–9(d) of this title as qualified health maintenance organizations, to Congress by June 30, 1978; (b) conduct a study of the economic effects on employers resulting from their compliance with the requirements of section 300e–9 of this title and report to Congress not later than 36 months after Dec. 29, 1973; (c) evaluate the operations of health maintenance organizations in comparison with others in distinct categories, in comparison with alternative forms of health care delivery, and their impact on the health of the public and report to Congress not later than 36 months after Dec. 29, 1973; and (d) evaluate the adequacy and effectiveness of the policies and procedures of the Secretary for the management of the grant and loan programs established by this subchapter and the adequacy of the amounts of assistance available under these programs and report to Congress not later than May 1, 1979.

§300e–14. Annual report

(a) The Secretary shall periodically review the programs of assistance authorized by this subchapter and make an annual report to the Congress of a summary of the activities under each program. The Secretary shall include in such summary—

(1) a summary of each grant, contract, loan, or loan guarantee made under this subchapter in the period covered by the report and a list of the health maintenance organizations which during such period became qualified health maintenance organizations for purposes of section 300e–9 of this title;

(2) the statistics and other information reported in such period to the Secretary in accordance with section 300e(c)(11) [1] of this title;

(3) findings with respect to the ability of the health maintenance organizations assisted under this subchapter—

(A) to operate on a fiscally sound basis without continued Federal financial assistance,

(B) to meet the requirements of section 300e(c) of this title respecting their organization and operation,

(C) to provide basic and supplemental health services in the manner prescribed by section 300e(b) of this title,

(D) to include indigent and high-risk individuals in their membership, and

(E) to provide services to medically underserved populations; and

(4) findings with respect to—

(A) the operation of distinct categories of health maintenance organizations in comparison with each other,

(B) health maintenance organizations as a group in comparison with alternative forms of health care delivery, and

(C) the impact that health maintenance organizations, individually, by category, and as a group, have on the health of the public.

(b) The Office of Management and Budget may review the Secretary's report under subsection (a) before its submission to the Congress, but the Office may not revise the report or delay its submission, and it may submit to the Congress its comments (and those of other departments or agencies of the Government) respecting such report.

(July 1, 1944, ch. 373, title XIII, §1315, as added Pub. L. 93–222, §2, Dec. 29, 1973, 87 Stat. 933.)

EDITORIAL NOTES

REFERENCES IN TEXT

Section 300e(c)(11) of this title, referred to in subsec. (a)(2), was redesignated section 300e(c)(9) of this title by Pub. L. 97–35, title IX, §942(d)(1), Aug. 13, 1981, 95 Stat. 574, and redesignated section 300e(c)(8) of this title by Pub. L. 100–517, §5(b), Oct. 24, 1988, 102 Stat. 2579.

[1] *See References in Text note below.*

§300e–14a. Health services for Indians and domestic agricultural migratory and seasonal workers

The Secretary of Health and Human Services, in connection with existing authority (except section 254b [1] of this title) for the provisions of health services to domestic agricultural migratory workers, to persons who perform seasonal agricultural services similar to the services performed by such workers, and to the families of such workers and persons, is authorized to arrange for the provision of health services to such workers and persons and their families through health maintenance organizations. In carrying out this section the Secretary may only use sums appropriated after December 29, 1973.

(Pub. L. 93–222, §6(b), Dec. 29, 1973, 87 Stat. 936; Pub. L. 95–626, title I, §102(b)(2), Nov. 10, 1978, 92 Stat. 3551; Pub. L. 96–88, title V, §509(b), Oct. 17, 1979, 93 Stat. 695.)

EDITORIAL NOTES

REFERENCES IN TEXT

Section 254b of this title, referred to in text, was in the original a reference to section 329 of the Public Health Service Act, act July 1, 1944, which was omitted in the general amendment of subpart I (§254b et seq.) of part D of subchapter II of this chapter by Pub. L. 104–299, §2, Oct. 11, 1996, 110 Stat. 3626. Section 2 of Pub. L. 104–299 enacted a new section 330 of act July 1, 1944, which is classified to section 254b of this title.

CODIFICATION

Section was enacted as part of the Health Maintenance Organization Act of 1973, and not as part of the Public Health Service Act which comprises this chapter.

AMENDMENTS

1978—Pub. L. 95–626 substituted "section 254b" for "section 247d".

STATUTORY NOTES AND RELATED SUBSIDIARIES

CHANGE OF NAME

"Secretary of Health and Human Services" substituted in text for "Secretary of Health, Education, and Welfare" pursuant to section 509(b) of Pub. L. 96–88, which is classified to section 3508(b) of Title 20, Education.

[1] *See References in Text note below.*

§300e–15. Repealed. Pub. L. 97–35, title IX, §949(b), Aug. 13, 1981, 95 Stat. 578

Section, act July 1, 1944, ch. 373, title XIII, §1316, as added Oct. 8, 1976, Pub. L. 94–460, title I, §116, 90 Stat. 1954, related to administration of programs.

§300e–16. Training and technical assistance

(a) National Health Maintenance Organization Intern Program

(1) The Secretary shall establish a National Health Maintenance Organization Intern Program (hereinafter in this subsection referred to as the "Program") for the purpose of providing training to individuals to become administrators and medical directors of health maintenance organizations or to assume other managerial positions with health maintenance organizations. Under the Program the Secretary may directly provide internships for such training and may make grants to or enter into contracts with health maintenance organizations and other entities to provide such internships.

(2) No internship may be provided by the Secretary and no grant may be made or contract entered into by the Secretary for the provision of internships unless an application therefor has been submitted to and approved by the Secretary. Such an application shall be in such form and contain such information, and be submitted to the Secretary in such manner, as the Secretary shall prescribe. Section 300e–5 of this title does not apply to an application submitted under this section.

(3) Internships under the Program shall provide for such stipends and allowances (including travel and subsistence expenses and dependency allowances) for the recipients of the internships as the Secretary deems necessary. An internship provided an individual for training at a health maintenance organization or any other entity shall also provide for payments to be made to the organization or other entity for the cost of support services (including the cost of salaries, supplies, equipment, and related items) provided such individual by such organization or other entity. The amount of any such payments to any organization or other entity shall be determined by the Secretary and shall bear a direct relationship to the reasonable costs of the organization or other entity for establishing and maintaining its training programs.

(4) Payments under grants under the Program may be made in advance or by way of reimbursement, and at such intervals and on such conditions, as the Secretary finds necessary.

(b) Technical assistance

The Secretary shall provide technical assistance (1) to entities intending to become a qualified health maintenance organization within the meaning of section 300e–9(d) [1] of this title, and (2) to health maintenance organizations. The Secretary may provide such technical assistance through grants to public and nonprofit private entities and contracts with public and private entities.

(c) Amounts provided in advance in appropriation acts

The authority of the Secretary to enter into contracts under subsections (a) and (b) shall be effective for any fiscal year only to such extent or in such amounts as are provided in advance by appropriation Acts.

(July 1, 1944, ch. 373, title XIII, §1317, as added Pub. L. 95–559, §7(a), Nov. 1, 1978, 92 Stat. 2134; amended Pub. L. 99–660, title VIII, §803(b)(4), Nov. 14, 1986, 100 Stat. 3800.)

EDITORIAL NOTES

REFERENCES IN TEXT

Section 300e–9(d) of this title, referred to in subsec. (b), was redesignated section 300e–9(c) of this title by Pub. L. 100–517, §7(b), Oct. 24, 1988, 102 Stat. 2580.

AMENDMENTS

1986—Subsec. (b). Pub. L. 99–660 redesignated cls. (2) and (3) as (1) and (2), respectively, and struck out

former cl. (1) which read as follows: "to entities in connection with projects for which assistance is being provided under section 300e–2 or 300e–3 of this title,".

STATUTORY NOTES AND RELATED SUBSIDIARIES

EFFECTIVE DATE OF 1986 AMENDMENT

Amendment by Pub. L. 99–660 not applicable to any grant made or contract entered into under this subchapter before Oct. 1, 1985, see section 803(c) of Pub. L. 99–660, set out as a note under section 300e–5 of this title.

Amendment by Pub. L. 99–660 effective Oct. 1, 1985, see section 815(a) of Pub. L. 99–660, set out as an Effective and Termination Dates of 1986 Amendment note under section 300e–1 of this title.

EFFECTIVE DATE

Pub. L. 95–559, §7(c), Nov. 1, 1978, 92 Stat. 2135, provided that: "The amendments made by this section [enacting this section and amending section 300e–8 of this title] shall only be effective for fiscal years beginning on or after October 1, 1978."

[1] *See References in Text note below.*

§300e–17. Financial disclosure

(a) Financial information reported to Secretary

Each health maintenance organization shall, in accordance with regulations of the Secretary, report to the Secretary financial information which shall include the following:

(1) Such information as the Secretary may require demonstrating that the health maintenance organization has a fiscally sound operation.

(2) A copy of the report, if any, filed with the Centers for Medicare & Medicaid Services containing the information required to be reported under section 1320a–3 of this title by disclosing entities and the information required to be supplied under section 1396a(a)(38) of this title.

(3) A description of transactions, as specified by the Secretary, between the health maintenance organization and a party in interest. Such transactions shall include—

(A) any sale or exchange, or leasing of any property between the health maintenance organization and a party in interest;

(B) any furnishing for consideration of goods, services (including management services), or facilities between the health maintenance organization and a party in interest, but not including salaries paid to employees for services provided in the normal course of their employment and health services provided to members by hospitals and other providers and by staff, medical group (or groups), individual practice association (or associations), or any combination thereof; and

(C) any lending of money or other extension of credit between a health maintenance organization and a party in interest.

The Secretary may require that information reported respecting a health maintenance organization which controls, is controlled by, or is under common control with, another entity be in the form of a consolidated financial statement for the organization and such entity.

(b) "Party in interest" defined

For the purposes of this section the term "party in interest" means:

(1) any director, officer, partner, or employee responsible for management or administration of a health maintenance organization, any person who is directly or indirectly the beneficial owner of more than 5 per centum of the equity of the organization, any person who is the beneficial owner of a mortgage, deed of trust, note, or other interest secured by, and valuing more than 5 per centum of the health maintenance organization, and, in the case of a health maintenance

organization organized as a nonprofit corporation, an incorporator or member of such corporation under applicable State corporation law;

(2) any entity in which a person described in paragraph (1)—

(A) is an officer or director;

(B) is a partner (if such entity is organized as a partnership);

(C) has directly or indirectly a beneficial interest of more than 5 per centum of the equity; or

(D) has a mortgage, deed of trust, note, on other interest valuing more than 5 per centum of the assets of such entity;

(3) any person directly or indirectly controlling, controlled by, or under common control with a health maintenance organization; and

(4) any spouse, child, or parent of an individual described in paragraph (1).

(c) Information availability

Each health maintenance organization shall make the information reported pursuant to subsection (a) available to its enrollees upon reasonable request.

(d) Evaluation of transactions

The Secretary shall, as he deems necessary, conduct an evaluation of transactions reported to the Secretary under subsection (a)(3) for the purpose of determining their adverse impact, if any, on the fiscal soundness and reasonableness of charges to the health maintenance organization with respect to which they transpired. The Secretary shall evaluate the reported transactions of not less than five, or if there are more than twenty health maintenance organizations reporting such transactions, not less than one-fourth of the health maintenance organizations reporting any such transactions under subsection (a)(3).

(e) Repealed. Pub. L. 99–660, title VIII, §810, Nov. 14, 1986, 100 Stat. 3801

(f) Rates

Nothing in this section shall be construed to confer upon the Secretary any authority to approve or disapprove the rates charged by any health maintenance organization.

(g) Annual financial statement

Any health maintenance organization failing to file with the Secretary the annual financial statement required in subsection (a) shall be ineligible for any Federal assistance under this subchapter until such time as such statement is received by the Secretary and shall not be a qualified health maintenance organization for purposes of section 300e–9 of this title.

(h) Penalties

Whoever knowingly and willfully makes or causes to be made any false statement or representation of a material fact in any statement filed pursuant to this section shall be guilty of a felony and upon conviction thereof shall be fined not more than $25,000 or imprisoned for not more than five years, or both.

(July 1, 1944, ch. 373, title XIII, §1318, as added Pub. L. 95–559, §9(a), Nov. 1, 1978, 92 Stat. 2135; amended Pub. L. 97–35, title IX, §948, Aug. 13, 1981, 95 Stat. 577; Pub. L. 99–660, title VIII, §810, Nov. 14, 1986, 100 Stat. 3801; Pub. L. 108–173, title IX, §900(e)(2)(E), Dec. 8, 2003, 117 Stat. 2372.)

EDITORIAL NOTES

AMENDMENTS

2003—Subsec. (a)(2). Pub. L. 108–173 substituted "Centers for Medicare & Medicaid Services" for "Health Care Financing Administration".

1986—Subsec. (e). Pub. L. 99–660 struck out subsec. (e) which read as follows: "The Secretary shall file an annual report with the Congress on the operation of this section. Such report shall include—

"(1) an enumeration of standards and norms utilized to make the evaluations required under subsection

(d) of this section;

"(2) an assessment of the degree of conformity or nonconformity of each health maintenance organization evaluated by the Secretary under subsection (d) of this section with such standards and norms;

"(3) what action, if any, the Secretary considers necessary under section 300e–11 of this title with respect to health maintenance organizations evaluated under subsection (d) of this section."

1981—Subsec. (a). Pub. L. 97–35, §948(a), (b), in par. (2) inserted reference to copy of the report, if any, filed with the Health Care Financing Administration, and in par. (3)(B) reorganized excluding provisions and, among revisions, inserted salaries paid to employees for services.

Subsec. (b)(1). Pub. L. 97–35, §948(c), inserted "responsible for management or administration" after "employee".

Subsec. (b)(4). Pub. L. 97–35, §948(d), substituted "spouse, child, or parent" for "member of the immediate family".

STATUTORY NOTES AND RELATED SUBSIDIARIES

EFFECTIVE DATE OF 1986 AMENDMENT

Amendment by Pub. L. 99–660 effective Oct. 1, 1985, see section 815(a) of Pub. L. 99–660, set out as an Effective and Termination Dates of 1986 Amendment note under section 300e–1 of this title.

SUBCHAPTER XII—SAFETY OF PUBLIC WATER SYSTEMS

PART A—DEFINITIONS

§300f. Definitions

For purposes of this subchapter:

(1) The term "primary drinking water regulation" means a regulation which—

(A) applies to public water systems;

(B) specifies contaminants which, in the judgment of the Administrator, may have any adverse effect on the health of persons;

(C) specifies for each such contaminant either—

(i) a maximum contaminant level, if, in the judgment of the Administrator, it is economically and technologically feasible to ascertain the level of such contaminant in water in public water systems, or

(ii) if, in the judgment of the Administrator, it is not economically or technologically feasible to so ascertain the level of such contaminant, each treatment technique known to the Administrator which leads to a reduction in the level of such contaminant sufficient to satisfy the requirements of section 300g–1 of this title; and

(D) contains criteria and procedures to assure a supply of drinking water which dependably complies with such maximum contaminant levels; including accepted methods for quality control and testing procedures to insure compliance with such levels and to insure proper operation and maintenance of the system, and requirements as to (i) the minimum quality of water which may be taken into the system and (ii) siting for new facilities for public water systems.

At any time after promulgation of a regulation referred to in this paragraph, the Administrator may add equally effective quality control and testing procedures by guidance published in the Federal Register. Such procedures shall be treated as an alternative for public water systems to the quality control and testing procedures listed in the regulation.

(2) The term "secondary drinking water regulation" means a regulation which applies to public water systems and which specifies the maximum contaminant levels which, in the judgment of the Administrator, are requisite to protect the public welfare. Such regulations may apply to any contaminant in drinking water (A) which may adversely affect the odor or appearance of such water and consequently may cause a substantial number of the persons served by the public water system providing such water to discontinue its use, or (B) which may otherwise adversely affect the public welfare. Such regulations may vary according to geographic and other circumstances.

(3) The term "maximum contaminant level" means the maximum permissible level of a contaminant in water which is delivered to any user of a public water system.

(4) PUBLIC WATER SYSTEM.—

(A) IN GENERAL.—The term "public water system" means a system for the provision to the public of water for human consumption through pipes or other constructed conveyances, if such system has at least fifteen service connections or regularly serves at least twenty-five individuals. Such term includes (i) any collection, treatment, storage, and distribution facilities under control of the operator of such system and used primarily in connection with such system, and (ii) any collection or pretreatment storage facilities not under such control which are used primarily in connection with such system.

(B) CONNECTIONS.—

(i) IN GENERAL.—For purposes of subparagraph (A), a connection to a system that delivers water by a constructed conveyance other than a pipe shall not be considered a connection, if—

(I) the water is used exclusively for purposes other than residential uses (consisting of drinking, bathing, and cooking, or other similar uses);

(II) the Administrator or the State (in the case of a State exercising primary enforcement responsibility for public water systems) determines that alternative water to achieve the equivalent level of public health protection provided by the applicable national primary drinking water regulation is provided for residential or similar uses for drinking and cooking; or

(III) the Administrator or the State (in the case of a State exercising primary enforcement responsibility for public water systems) determines that the water provided for residential or similar uses for drinking, cooking, and bathing is centrally treated or treated at the point of entry by the provider, a pass-through entity, or the user to achieve the equivalent level of protection provided by the applicable national primary drinking water regulations.

(ii) IRRIGATION DISTRICTS.—An irrigation district in existence prior to May 18, 1994, that provides primarily agricultural service through a piped water system with only incidental residential or similar use shall not be considered to be a public water system if the system or the residential or similar users of the system comply with subclause (II) or (III) of clause (i).

(C) TRANSITION PERIOD.—A water supplier that would be a public water system only as a result of modifications made to this paragraph by the Safe Drinking Water Act Amendments of 1996 shall not be considered a public water system for purposes of the Act until the date that is two years after August 6, 1996. If a water supplier does not serve 15 service connections (as defined in subparagraphs (A) and (B)) or 25 people at any time after the conclusion of the 2-year period, the water supplier shall not be considered a public water system.

(5) The term "supplier of water" means any person who owns or operates a public water system.

(6) The term "contaminant" means any physical, chemical, biological, or radiological substance or matter in water.

(7) The term "Administrator" means the Administrator of the Environmental Protection Agency.

(8) The term "Agency" means the Environmental Protection Agency.

(9) The term "Council" means the National Drinking Water Advisory Council established under

section 300j–5 of this title.

(10) The term "municipality" means a city, town, or other public body created by or pursuant to State law, or an Indian Tribe.

(11) The term "Federal agency" means any department, agency, or instrumentality of the United States.

(12) The term "person" means an individual, corporation, company, association, partnership, State, municipality, or Federal agency (and includes officers, employees, and agents of any corporation, company, association, State, municipality, or Federal agency).

(13)(A) Except as provided in subparagraph (B), the term "State" includes, in addition to the several States, only the District of Columbia, Guam, the Commonwealth of Puerto Rico, the Northern Mariana Islands, the Virgin Islands, American Samoa, and the Trust Territory of the Pacific Islands.

(B) For purposes of section 300j–12 of this title, the term "State" means each of the 50 States, the District of Columbia, and the Commonwealth of Puerto Rico.

(14) The term "Indian Tribe" means any Indian tribe having a Federally recognized governing body carrying out substantial governmental duties and powers over any area. For purposes of sections 300j–12, 300j–19a, and 300j–19b of this title, the term includes any Native village (as defined in section 1602(c) of title 43).

(15) COMMUNITY WATER SYSTEM.—The term "community water system" means a public water system that—

(A) serves at least 15 service connections used by year-round residents of the area served by the system; or

(B) regularly serves at least 25 year-round residents.

(16) NONCOMMUNITY WATER SYSTEM.—The term "noncommunity water system" means a public water system that is not a community water system.

(July 1, 1944, ch. 373, title XIV, §1401, as added Pub. L. 93–523, §2(a), Dec. 16, 1974, 88 Stat. 1660; amended Pub. L. 94–317, title III, §301(b)(2), June 23, 1976, 90 Stat. 707; Pub. L. 94–484, title IX, §905(b)(1), Oct. 12, 1976, 90 Stat. 2325; Pub. L. 95–190, §8(b), Nov. 16, 1977, 91 Stat. 1397; Pub. L. 99–339, title III, §302(b), June 19, 1986, 100 Stat. 666; Pub. L. 104–182, title I, §101(a), (b)(1), Aug. 6, 1996, 110 Stat. 1615, 1616; Pub. L. 114–322, title II, §2111, Dec. 16, 2016, 130 Stat. 1729.)

EDITORIAL NOTES

REFERENCES IN TEXT

The Safe Drinking Water Act Amendments of 1996, referred to in par. (4)(C), is Pub. L. 104–182, Aug. 6, 1996, 110 Stat. 1613. For complete classification of this Act to the Code, see Short Title of 1996 Amendment note set out under section 201 of this title and Tables.

AMENDMENTS

2016—Par. (14). Pub. L. 114–322 substituted "sections 300j–12, 300j–19a, and 300j–19b of this title" for "section 300j–12 of this title".

1996—Par. (1). Pub. L. 104–182, §101(a)(1)(B), inserted at end "At any time after promulgation of a regulation referred to in this paragraph, the Administrator may add equally effective quality control and testing procedures by guidance published in the Federal Register. Such procedures shall be treated as an alternative for public water systems to the quality control and testing procedures listed in the regulation."

Par. (1)(D). Pub. L. 104–182, §101(a)(1)(A), inserted "accepted methods for" before "quality control".

Par. (4). Pub. L. 104–182, §101(b)(1), designated existing provisions as subpar. (A), inserted par. and subpar. headings, redesignated former subpars. (A) and (B) as cls. (i) and (ii), respectively, substituted "water for human consumption through pipes or other constructed conveyances" for "piped water for human consumption" in first sentence, and added subpars. (B) and (C).

Par. (13). Pub. L. 104–182, §101(a)(2), designated existing provisions as subpar. (A), substituted "Except as provided in subparagraph (B), the term" for "The term", and added subpar. (B).

Par. (14). Pub. L. 104–182, §101(a)(3), inserted at end "For purposes of section 300j–12 of this title, the

term includes any Native village (as defined in section 1602(c) of title 43)."

Pars. (15), (16). Pub. L. 104–182, §101(a)(4), added pars. (15) and (16).

1986—Par. (10). Pub. L. 99–339, §302(b)(2), substituted "Indian Tribe" for "Indian tribal organization authorized by law".

Par. (14). Pub. L. 99–339, §302(b)(1), added par. (14).

1977—Par. (12). Pub. L. 95–190 expanded definition of "person" to include Federal agency, and officers, employees, and agents of any corporation, company, etc.

1976—Par. (13). Pub. L. 94–484 defined "State" to include Northern Mariana Islands.

Pub. L. 94–317 added par. (13).

STATUTORY NOTES AND RELATED SUBSIDIARIES

EFFECTIVE DATE OF 1996 AMENDMENT

Pub. L. 104–182, §2(b), Aug. 6, 1996, 110 Stat. 1614, provided that: "Except as otherwise specified in this Act [enacting sections 300g–7 to 300g–9, 300h–8, 300j–3c, and 300j–12 to 300j–18 of this title and section 1263a of Title 33, Navigation and Navigable Waters, amending this section, sections 300g–1 to 300g–6, 300h, 300h–5 to 300h–7, 300i, 300i–1, 300j to 300j–2, 300j–4 to 300j–8, 300j–11, and 300j–21 to 300j–25 of this title, sections 4701 and 4721 of Title 16, Conservation, and section 349 of Title 21, Food and Drugs, repealing section 13551 of this title, enacting provisions set out as notes under this section, sections 201, 300g–1, 300j–1, and 300j–12 of this title, section 1281 of Title 33, and section 45 of former Title 40, Public Buildings, Property, and Works, and amending provisions set out as a note under section 201 of this title] or in the amendments made by this Act, this Act and the amendments made by this Act shall take effect on the date of enactment of this Act [Aug. 6, 1996]."

SHORT TITLE

This subchapter is known as the "Safe Drinking Water Act", see note set out under section 201 of this title.

TERMINATION OF ADVISORY COMMITTEES

Pub. L. 93–641, §6, Jan. 4, 1975, 88 Stat. 2275, set out as a note under section 217a of this title, provided that an advisory committee established pursuant to the Public Health Service Act shall terminate at such time as may be specifically prescribed by an Act of Congress enacted after Jan. 4, 1975.

EFFECT OF PUBLIC LAW 104–182 ON FEDERAL WATER POLLUTION CONTROL ACT

Pub. L. 104–182, §2(c), Aug. 6, 1996, 110 Stat. 1614, provided that: "Except for the provisions of section 302 [42 U.S.C. 300j–12 note] (relating to transfers of funds), nothing in this Act [see Effective Date of 1996 Amendment note above] or in any amendments made by this Act to title XIV of the Public Health Service Act [42 U.S.C. 300f et seq.] (commonly known as the 'Safe Drinking Water Act') or any other law shall be construed by the Administrator of the Environmental Protection Agency or the courts as affecting, modifying, expanding, changing, or altering—

"(1) the provisions of the Federal Water Pollution Control Act [33 U.S.C. 1251 et seq.];

"(2) the duties and responsibilities of the Administrator under that Act; or

"(3) the regulation or control of point or nonpoint sources of pollution discharged into waters covered by that Act.

The Administrator shall identify in the agency's annual budget all funding and full-time equivalents administering such title XIV separately from funding and staffing for the Federal Water Pollution Control Act."

CONGRESSIONAL FINDINGS

Pub. L. 104–182, §3, Aug. 6, 1996, 110 Stat. 1614, provided that: "The Congress finds that—

"(1) safe drinking water is essential to the protection of public health;

"(2) because the requirements of the Safe Drinking Water Act (42 U.S.C. 300f et seq.) now exceed the financial and technical capacity of some public water systems, especially many small public water systems, the Federal Government needs to provide assistance to communities to help the communities meet Federal drinking water requirements;

"(3) the Federal Government commits to maintaining and improving its partnership with the States in the administration and implementation of the Safe Drinking Water Act;

"(4) States play a central role in the implementation of safe drinking water programs, and States need increased financial resources and appropriate flexibility to ensure the prompt and effective development and

implementation of drinking water programs;

"(5) the existing process for the assessment and selection of additional drinking water contaminants needs to be revised and improved to ensure that there is a sound scientific basis for setting priorities in establishing drinking water regulations;

"(6) procedures for assessing the health effects of contaminants establishing drinking water standards should be revised to provide greater opportunity for public education and participation;

"(7) in considering the appropriate level of regulation for contaminants in drinking water, risk assessment, based on sound and objective science, and benefit-cost analysis are important analytical tools for improving the efficiency and effectiveness of drinking water regulations to protect human health;

"(8) more effective protection of public health requires—

"(A) a Federal commitment to set priorities that will allow scarce Federal, State, and local resources to be targeted toward the drinking water problems of greatest public health concern;

"(B) maximizing the value of the different and complementary strengths and responsibilities of the Federal and State governments in those States that have primary enforcement responsibility for the Safe Drinking Water Act; and

"(C) prevention of drinking water contamination through well-trained system operators, water systems with adequate managerial, technical, and financial capacity, and enhanced protection of source waters of public water systems;

"(9) compliance with the requirements of the Safe Drinking Water Act continues to be a concern at public water systems experiencing technical and financial limitations, and Federal, State, and local governments need more resources and more effective authority to attain the objectives of the Safe Drinking Water Act; and

"(10) consumers served by public water systems should be provided with information on the source of the water they are drinking and its quality and safety, as well as prompt notification of any violation of drinking water regulations."

GAO STUDY

Pub. L. 104–182, title I, §101(b)(2), Aug. 6, 1996, 110 Stat. 1617, required the Comptroller General to study the reliance for residential water on various nonpublic water systems and to submit a report on the results of the study to Congress within 3 years after Aug. 6, 1996.

SAFE DRINKING WATER AMENDMENTS OF 1977 RESTRICTIONS ON APPROPRIATIONS FOR RESEARCH

Pub. L. 95–190, §2(e), Nov. 16, 1977, 91 Stat. 1393, provided that: "Nothing in this Act [see Short Title of 1977 Amendment note set out under section 201 of this title] shall be construed to authorize the appropriation of any amount for research under title XIV of the Public Health Service Act [42 U.S.C. 300f et seq.] (relating to safe drinking water)."

SAFE DRINKING WATER AMENDMENTS OF 1977 AS NOT AFFECTING AUTHORITY OF ADMINISTRATOR WITH RESPECT TO CONTAMINANTS

Pub. L. 95–190, §3(e)(2), Nov. 16, 1977, 91 Stat. 1394, provided that: "Nothing in this Act [see Short Title of 1977 Amendment note set out under section 201 of this title] shall be construed to alter or affect the Administrator's authority or duty under title 14 of the Public Health Service Act [42 U.S.C. 300f et seq.] to promulgate regulations or take other action with respect to any contaminant."

RURAL WATER SURVEY; REPORT TO PRESIDENT AND CONGRESS; AUTHORIZATION OF APPROPRIATIONS

Pub. L. 93–523, §3, Dec. 16, 1974, 88 Stat. 1693, as amended by Pub. L. 95–190, §§2(d), 3(d), Nov. 16, 1977, 91 Stat. 1393, 1394, directed Administrator of Environmental Protection Agency, after consultation with Secretary of Agriculture and the several States, to enter into arrangements with public or private entities to conduct a survey of quantity, quality, and availability of rural drinking water supplies, which survey was to include, but not be limited to, consideration of number of residents in each rural area who presently are being inadequately served by a public or private drinking water supply system, or by an individual home drinking water supply system, or who presently have limited or otherwise inadequate access to drinking water, or who, due to absence or inadequacy of a drinking water supply system, are exposed to an increased health hazard, and who have experienced incidents of chronic or acute illness, which may be attributed to inadequacy of a drinking water supply system. Survey to be completed within eighteen months of Dec. 16, 1974, and a final report thereon submitted, not later than six months after completion of survey, to President and to Congress.

EXECUTIVE DOCUMENTS

TERMINATION OF TRUST TERRITORY OF THE PACIFIC ISLANDS

For termination of Trust Territory of the Pacific Islands, see note set out preceding section 1681 of Title 48, Territories and Insular Possessions.

FEDERAL COMPLIANCE WITH POLLUTION CONTROL STANDARDS

For provisions relating to the responsibility of the head of each Executive agency for compliance with applicable pollution control standards, see Ex. Ord. No. 12088, Oct. 13, 1978, 43 F.R. 47707, set out as a note under section 4321 of this title.

PART B—PUBLIC WATER SYSTEMS

§300g. Coverage

Subject to sections 300g–4 and 300g–5 of this title, national primary drinking water regulations under this part shall apply to each public water system in each State; except that such regulations shall not apply to a public water system—

(1) which consists only of distribution and storage facilities (and does not have any collection and treatment facilities);

(2) which obtains all of its water from, but is not owned or operated by, a public water system to which such regulations apply;

(3) which does not sell water to any person; and

(4) which is not a carrier which conveys passengers in interstate commerce.

(July 1, 1944, ch. 373, title XIV, §1411, as added Pub. L. 93–523, §2(a), Dec. 16, 1974, 88 Stat. 1662.)

§300g–1. National drinking water regulations

(a) National primary drinking water regulations; maximum contaminant level goals; simultaneous publication of regulations and goals

(1) Effective on June 19, 1986, each national interim or revised primary drinking water regulation promulgated under this section before June 19, 1986, shall be deemed to be a national primary drinking water regulation under subsection (b). No such regulation shall be required to comply with the standards set forth in subsection (b)(4) unless such regulation is amended to establish a different maximum contaminant level after June 19, 1986.

(2) After June 19, 1986, each recommended maximum contaminant level published before June 19, 1986, shall be treated as a maximum contaminant level goal.

(3) Whenever a national primary drinking water regulation is proposed under subsection (b) for any contaminant, the maximum contaminant level goal for such contaminant shall be proposed simultaneously. Whenever a national primary drinking water regulation is promulgated under subsection (b) for any contaminant, the maximum contaminant level goal for such contaminant shall be published simultaneously.

(4) Paragraph (3) shall not apply to any recommended maximum contaminant level published before June 19, 1986.

(b) Standards

(1) IDENTIFICATION OF CONTAMINANTS FOR LISTING.—

(A) GENERAL AUTHORITY.—The Administrator shall, in accordance with the procedures established by this subsection, publish a maximum contaminant level goal and promulgate a national primary drinking water regulation for a contaminant (other than a contaminant referred to

in paragraph (2) for which a national primary drinking water regulation has been promulgated as of August 6, 1996) if the Administrator determines that—

(i) the contaminant may have an adverse effect on the health of persons;

(ii) the contaminant is known to occur or there is a substantial likelihood that the contaminant will occur in public water systems with a frequency and at levels of public health concern; and

(iii) in the sole judgment of the Administrator, regulation of such contaminant presents a meaningful opportunity for health risk reduction for persons served by public water systems.

(B) REGULATION OF UNREGULATED CONTAMINANTS.—

(i) LISTING OF CONTAMINANTS FOR CONSIDERATION.—(I) Not later than 18 months after August 6, 1996, and every 5 years thereafter, the Administrator, after consultation with the scientific community, including the Science Advisory Board, after notice and opportunity for public comment, and after considering the occurrence data base established under section 300j–4(g) of this title, shall publish a list of contaminants which, at the time of publication, are not subject to any proposed or promulgated national primary drinking water regulation, which are known or anticipated to occur in public water systems, and which may require regulation under this subchapter.

(II) The unregulated contaminants considered under subclause (I) shall include, but not be limited to, substances referred to in section 9601(14) of this title, and substances registered as pesticides under the Federal Insecticide, Fungicide, and Rodenticide Act [7 U.S.C. 136 et seq.].

(III) The Administrator's decision whether or not to select an unregulated contaminant for a list under this clause shall not be subject to judicial review.

(ii) DETERMINATION TO REGULATE.—(I) Not later than 5 years after August 6, 1996, and every 5 years thereafter, the Administrator shall, after notice of the preliminary determination and opportunity for public comment, for not fewer than 5 contaminants included on the list published under clause (i), make determinations of whether or not to regulate such contaminants.

(II) A determination to regulate a contaminant shall be based on findings that the criteria of clauses (i), (ii), and (iii) of subparagraph (A) are satisfied. Such findings shall be based on the best available public health information, including the occurrence data base established under section 300j–4(g) of this title.

(III) The Administrator may make a determination to regulate a contaminant that does not appear on a list under clause (i) if the determination to regulate is made pursuant to subclause (II).

(IV) A determination under this clause not to regulate a contaminant shall be considered final agency action and subject to judicial review.

(iii) REVIEW.—Each document setting forth the determination for a contaminant under clause (ii) shall be available for public comment at such time as the determination is published.

(C) PRIORITIES.—In selecting unregulated contaminants for consideration under subparagraph (B), the Administrator shall select contaminants that present the greatest public health concern. The Administrator, in making such selection, shall take into consideration, among other factors of public health concern, the effect of such contaminants upon subgroups that comprise a meaningful portion of the general population (such as infants, children, pregnant women, the elderly, individuals with a history of serious illness, or other subpopulations) that are identifiable as being at greater risk of adverse health effects due to exposure to contaminants in drinking water than the general population.

(D) URGENT THREATS TO PUBLIC HEALTH.—The Administrator may promulgate an interim national primary drinking water regulation for a contaminant without making a determination for the contaminant under paragraph (4)(C), or completing the analysis under paragraph (3)(C), to address an urgent threat to public health as determined by the Administrator after consultation with and written response to any comments provided by the Secretary of Health and Human Services, acting through the director of the Centers for Disease Control and

Prevention or the director of the National Institutes of Health. A determination for any contaminant in accordance with paragraph (4)(C) subject to an interim regulation under this subparagraph shall be issued, and a completed analysis meeting the requirements of paragraph (3)(C) shall be published, not later than 3 years after the date on which the regulation is promulgated and the regulation shall be repromulgated, or revised if appropriate, not later than 5 years after that date.

(E) REGULATION.—For each contaminant that the Administrator determines to regulate under subparagraph (B), the Administrator shall publish maximum contaminant level goals and promulgate, by rule, national primary drinking water regulations under this subsection. The Administrator shall propose the maximum contaminant level goal and national primary drinking water regulation for a contaminant not later than 24 months after the determination to regulate under subparagraph (B), and may publish such proposed regulation concurrent with the determination to regulate. The Administrator shall publish a maximum contaminant level goal and promulgate a national primary drinking water regulation within 18 months after the proposal thereof. The Administrator, by notice in the Federal Register, may extend the deadline for such promulgation for up to 9 months.

(F) HEALTH ADVISORIES AND OTHER ACTIONS.—The Administrator may publish health advisories (which are not regulations) or take other appropriate actions for contaminants not subject to any national primary drinking water regulation.

(2) SCHEDULES AND DEADLINES.—

(A) IN GENERAL.—In the case of the contaminants listed in the Advance Notice of Proposed Rulemaking published in volume 47, Federal Register, page 9352, and in volume 48, Federal Register, page 45502, the Administrator shall publish maximum contaminant level goals and promulgate national primary drinking water regulations—

(i) not later than 1 year after June 19, 1986, for not fewer than 9 of the listed contaminants;

(ii) not later than 2 years after June 19, 1986, for not fewer than 40 of the listed contaminants; and

(iii) not later than 3 years after June 19, 1986, for the remainder of the listed contaminants.

(B) SUBSTITUTION OF CONTAMINANTS.—If the Administrator identifies a drinking water contaminant the regulation of which, in the judgment of the Administrator, is more likely to be protective of public health (taking into account the schedule for regulation under subparagraph (A)) than a contaminant referred to in subparagraph (A), the Administrator may publish a maximum contaminant level goal and promulgate a national primary drinking water regulation for the identified contaminant in lieu of regulating the contaminant referred to in subparagraph (A). Substitutions may be made for not more than 7 contaminants referred to in subparagraph (A). Regulation of a contaminant identified under this subparagraph shall be in accordance with the schedule applicable to the contaminant for which the substitution is made.

(C) DISINFECTANTS AND DISINFECTION BYPRODUCTS.—The Administrator shall promulgate an Interim Enhanced Surface Water Treatment Rule, a Final Enhanced Surface Water Treatment Rule, a Stage I Disinfectants and Disinfection Byproducts Rule, and a Stage II Disinfectants and Disinfection Byproducts Rule in accordance with the schedule published in volume 59, Federal Register, page 6361 (February 10, 1994), in table III.13 of the proposed Information Collection Rule. If a delay occurs with respect to the promulgation of any rule in the schedule referred to in this subparagraph, all subsequent rules shall be completed as expeditiously as practicable but no later than a revised date that reflects the interval or intervals for the rules in the schedule.

(3) RISK ASSESSMENT, MANAGEMENT, AND COMMUNICATION.—

(A) USE OF SCIENCE IN DECISIONMAKING.—In carrying out this section, and, to the degree that an Agency action is based on science, the Administrator shall use—

(i) the best available, peer-reviewed science and supporting studies conducted in accordance

with sound and objective scientific practices; and

(ii) data collected by accepted methods or best available methods (if the reliability of the method and the nature of the decision justifies use of the data).

(B) PUBLIC INFORMATION.—In carrying out this section, the Administrator shall ensure that the presentation of information on public health effects is comprehensive, informative, and understandable. The Administrator shall, in a document made available to the public in support of a regulation promulgated under this section, specify, to the extent practicable—

(i) each population addressed by any estimate of public health effects;

(ii) the expected risk or central estimate of risk for the specific populations;

(iii) each appropriate upper-bound or lower-bound estimate of risk;

(iv) each significant uncertainty identified in the process of the assessment of public health effects and studies that would assist in resolving the uncertainty; and

(v) peer-reviewed studies known to the Administrator that support, are directly relevant to, or fail to support any estimate of public health effects and the methodology used to reconcile inconsistencies in the scientific data.

(C) HEALTH RISK REDUCTION AND COST ANALYSIS.—

(i) MAXIMUM CONTAMINANT LEVELS.—When proposing any national primary drinking water regulation that includes a maximum contaminant level, the Administrator shall, with respect to a maximum contaminant level that is being considered in accordance with paragraph (4) and each alternative maximum contaminant level that is being considered pursuant to paragraph (5) or (6)(A), publish, seek public comment on, and use for the purposes of paragraphs (4), (5), and (6) an analysis of each of the following:

(I) Quantifiable and nonquantifiable health risk reduction benefits for which there is a factual basis in the rulemaking record to conclude that such benefits are likely to occur as the result of treatment to comply with each level.

(II) Quantifiable and nonquantifiable health risk reduction benefits for which there is a factual basis in the rulemaking record to conclude that such benefits are likely to occur from reductions in co-occurring contaminants that may be attributed solely to compliance with the maximum contaminant level, excluding benefits resulting from compliance with other proposed or promulgated regulations.

(III) Quantifiable and nonquantifiable costs for which there is a factual basis in the rulemaking record to conclude that such costs are likely to occur solely as a result of compliance with the maximum contaminant level, including monitoring, treatment, and other costs and excluding costs resulting from compliance with other proposed or promulgated regulations.

(IV) The incremental costs and benefits associated with each alternative maximum contaminant level considered.

(V) The effects of the contaminant on the general population and on groups within the general population such as infants, children, pregnant women, the elderly, individuals with a history of serious illness, or other subpopulations that are identified as likely to be at greater risk of adverse health effects due to exposure to contaminants in drinking water than the general population.

(VI) Any increased health risk that may occur as the result of compliance, including risks associated with co-occurring contaminants.

(VII) Other relevant factors, including the quality and extent of the information, the uncertainties in the analysis supporting subclauses (I) through (VI), and factors with respect to the degree and nature of the risk.

(ii) TREATMENT TECHNIQUES.—When proposing a national primary drinking water regulation that includes a treatment technique in accordance with paragraph (7)(A), the Administrator shall publish and seek public comment on an analysis of the health risk reduction

benefits and costs likely to be experienced as the result of compliance with the treatment technique and alternative treatment techniques that are being considered, taking into account, as appropriate, the factors described in clause (i).

(iii) APPROACHES TO MEASURE AND VALUE BENEFITS.—The Administrator may identify valid approaches for the measurement and valuation of benefits under this subparagraph, including approaches to identify consumer willingness to pay for reductions in health risks from drinking water contaminants.

(iv) AUTHORIZATION.—There are authorized to be appropriated to the Administrator, acting through the Office of Ground Water and Drinking Water, to conduct studies, assessments, and analyses in support of regulations or the development of methods, $35,000,000 for each of fiscal years 1996 through 2003.

(4) GOALS AND STANDARDS.—

(A) MAXIMUM CONTAMINANT LEVEL GOALS.—Each maximum contaminant level goal established under this subsection shall be set at the level at which no known or anticipated adverse effects on the health of persons occur and which allows an adequate margin of safety.

(B) MAXIMUM CONTAMINANT LEVELS.—Except as provided in paragraphs (5) and (6), each national primary drinking water regulation for a contaminant for which a maximum contaminant level goal is established under this subsection shall specify a maximum contaminant level for such contaminant which is as close to the maximum contaminant level goal as is feasible.

(C) DETERMINATION.—At the time the Administrator proposes a national primary drinking water regulation under this paragraph, the Administrator shall publish a determination as to whether the benefits of the maximum contaminant level justify, or do not justify, the costs based on the analysis conducted under paragraph (3)(C).

(D) DEFINITION OF FEASIBLE.—For the purposes of this subsection, the term "feasible" means feasible with the use of the best technology, treatment techniques and other means which the Administrator finds, after examination for efficacy under field conditions and not solely under laboratory conditions, are available (taking cost into consideration). For the purpose of this paragraph, granular activated carbon is feasible for the control of synthetic organic chemicals, and any technology, treatment technique, or other means found to be the best available for the control of synthetic organic chemicals must be at least as effective in controlling synthetic organic chemicals as granular activated carbon.

(E) FEASIBLE TECHNOLOGIES.—

(i) IN GENERAL.—Each national primary drinking water regulation which establishes a maximum contaminant level shall list the technology, treatment techniques, and other means which the Administrator finds to be feasible for purposes of meeting such maximum contaminant level, but a regulation under this subsection shall not require that any specified technology, treatment technique, or other means be used for purposes of meeting such maximum contaminant level.

(ii) LIST OF TECHNOLOGIES FOR SMALL SYSTEMS.—The Administrator shall include in the list any technology, treatment technique, or other means that is affordable, as determined by the Administrator in consultation with the States, for small public water systems serving—

(I) a population of 10,000 or fewer but more than 3,300;

(II) a population of 3,300 or fewer but more than 500; and

(III) a population of 500 or fewer but more than 25;

and that achieves compliance with the maximum contaminant level or treatment technique, including packaged or modular systems and point-of-entry or point-of-use treatment units. Point-of-entry and point-of-use treatment units shall be owned, controlled and maintained by the public water system or by a person under contract with the public water system to ensure proper operation and maintenance and compliance with the maximum contaminant level or treatment technique and equipped with mechanical warnings to ensure that customers are automatically notified of operational problems. The Administrator shall not include in the list

any point-of-use treatment technology, treatment technique, or other means to achieve compliance with a maximum contaminant level or treatment technique requirement for a microbial contaminant (or an indicator of a microbial contaminant). If the American National Standards Institute has issued product standards applicable to a specific type of point-of-entry or point-of-use treatment unit, individual units of that type shall not be accepted for compliance with a maximum contaminant level or treatment technique requirement unless they are independently certified in accordance with such standards. In listing any technology, treatment technique, or other means pursuant to this clause, the Administrator shall consider the quality of the source water to be treated.

(iii) LIST OF TECHNOLOGIES THAT ACHIEVE COMPLIANCE.—Except as provided in clause (v), not later than 2 years after August 6, 1996, and after consultation with the States, the Administrator shall issue a list of technologies that achieve compliance with the maximum contaminant level or treatment technique for each category of public water systems described in subclauses (I), (II), and (III) of clause (ii) for each national primary drinking water regulation promulgated prior to June 19, 1986.

(iv) ADDITIONAL TECHNOLOGIES.—The Administrator may, at any time after a national primary drinking water regulation has been promulgated, supplement the list of technologies describing additional or new or innovative treatment technologies that meet the requirements of this paragraph for categories of small public water systems described in subclauses (I), (II), and (III) of clause (ii) that are subject to the regulation.

(v) TECHNOLOGIES THAT MEET SURFACE WATER TREATMENT RULE.—Within one year after August 6, 1996, the Administrator shall list technologies that meet the Surface Water Treatment Rule for each category of public water systems described in subclauses (I), (II), and (III) of clause (ii).

(5) ADDITIONAL HEALTH RISK CONSIDERATIONS.—

(A) IN GENERAL.—Notwithstanding paragraph (4), the Administrator may establish a maximum contaminant level for a contaminant at a level other than the feasible level, if the technology, treatment techniques, and other means used to determine the feasible level would result in an increase in the health risk from drinking water by—

(i) increasing the concentration of other contaminants in drinking water; or

(ii) interfering with the efficacy of drinking water treatment techniques or processes that are used to comply with other national primary drinking water regulations.

(B) ESTABLISHMENT OF LEVEL.—If the Administrator establishes a maximum contaminant level or levels or requires the use of treatment techniques for any contaminant or contaminants pursuant to the authority of this paragraph—

(i) the level or levels or treatment techniques shall minimize the overall risk of adverse health effects by balancing the risk from the contaminant and the risk from other contaminants the concentrations of which may be affected by the use of a treatment technique or process that would be employed to attain the maximum contaminant level or levels; and

(ii) the combination of technology, treatment techniques, or other means required to meet the level or levels shall not be more stringent than is feasible (as defined in paragraph (4)(D)).

(6) ADDITIONAL HEALTH RISK REDUCTION AND COST CONSIDERATIONS.—

(A) IN GENERAL.—Notwithstanding paragraph (4), if the Administrator determines based on an analysis conducted under paragraph (3)(C) that the benefits of a maximum contaminant level promulgated in accordance with paragraph (4) would not justify the costs of complying with the level, the Administrator may, after notice and opportunity for public comment, promulgate a maximum contaminant level for the contaminant that maximizes health risk reduction benefits at a cost that is justified by the benefits.

(B) EXCEPTION.—The Administrator shall not use the authority of this paragraph to promulgate a maximum contaminant level for a contaminant, if the benefits of compliance with a

national primary drinking water regulation for the contaminant that would be promulgated in accordance with paragraph (4) experienced by—

(i) persons served by large public water systems; and

(ii) persons served by such other systems as are unlikely, based on information provided by the States, to receive a variance under section 300g–4(e) of this title (relating to small system variances);

would justify the costs to the systems of complying with the regulation. This subparagraph shall not apply if the contaminant is found almost exclusively in small systems eligible under section 300g–4(e) of this title for a small system variance.

(C) DISINFECTANTS AND DISINFECTION BYPRODUCTS.—The Administrator may not use the authority of this paragraph to establish a maximum contaminant level in a Stage I or Stage II national primary drinking water regulation (as described in paragraph (2)(C)) for contaminants that are disinfectants or disinfection byproducts, or to establish a maximum contaminant level or treatment technique requirement for the control of cryptosporidium. The authority of this paragraph may be used to establish regulations for the use of disinfection by systems relying on ground water sources as required by paragraph (8).

(D) JUDICIAL REVIEW.—A determination by the Administrator that the benefits of a maximum contaminant level or treatment requirement justify or do not justify the costs of complying with the level shall be reviewed by the court pursuant to section 300j–7 of this title only as part of a review of a final national primary drinking water regulation that has been promulgated based on the determination and shall not be set aside by the court under that section unless the court finds that the determination is arbitrary and capricious.

(7)(A) The Administrator is authorized to promulgate a national primary drinking water regulation that requires the use of a treatment technique in lieu of establishing a maximum contaminant level, if the Administrator makes a finding that it is not economically or technologically feasible to ascertain the level of the contaminant. In such case, the Administrator shall identify those treatment techniques which, in the Administrator's judgment, would prevent known or anticipated adverse effects on the health of persons to the extent feasible. Such regulations shall specify each treatment technique known to the Administrator which meets the requirements of this paragraph, but the Administrator may grant a variance from any specified treatment technique in accordance with section 300g–4(a)(3) of this title.

(B) Any schedule referred to in this subsection for the promulgation of a national primary drinking water regulation for any contaminant shall apply in the same manner if the regulation requires a treatment technique in lieu of establishing a maximum contaminant level.

(C)(i) Not later than 18 months after June 19, 1986, the Administrator shall propose and promulgate national primary drinking water regulations specifying criteria under which filtration (including coagulation and sedimentation, as appropriate) is required as a treatment technique for public water systems supplied by surface water sources. In promulgating such rules, the Administrator shall consider the quality of source waters, protection afforded by watershed management, treatment practices (such as disinfection and length of water storage) and other factors relevant to protection of health.

(ii) In lieu of the provisions of section 300g–4 of this title the Administrator shall specify procedures by which the State determines which public water systems within its jurisdiction shall adopt filtration under the criteria of clause (i). The State may require the public water system to provide studies or other information to assist in this determination. The procedures shall provide notice and opportunity for public hearing on this determination. If the State determines that filtration is required, the State shall prescribe a schedule for compliance by the public water system with the filtration requirement. A schedule shall require compliance within 18 months of a determination made under clause (iii).

(iii) Within 18 months from the time that the Administrator establishes the criteria and procedures under this subparagraph, a State with primary enforcement responsibility shall adopt any necessary

regulations to implement this subparagraph. Within 12 months of adoption of such regulations the State shall make determinations regarding filtration for all the public water systems within its jurisdiction supplied by surface waters.

(iv) If a State does not have primary enforcement responsibility for public water systems, the Administrator shall have the same authority to make the determination in clause (ii) in such State as the State would have under that clause. Any filtration requirement or schedule under this subparagraph shall be treated as if it were a requirement of a national primary drinking water regulation.

(v) As an additional alternative to the regulations promulgated pursuant to clauses (i) and (iii), including the criteria for avoiding filtration contained in 40 CFR 141.71, a State exercising primary enforcement responsibility for public water systems may, on a case-by-case basis, and after notice and opportunity for public comment, establish treatment requirements as an alternative to filtration in the case of systems having uninhabited, undeveloped watersheds in consolidated ownership, and having control over access to, and activities in, those watersheds, if the State determines (and the Administrator concurs) that the quality of the source water and the alternative treatment requirements established by the State ensure greater removal or inactivation efficiencies of pathogenic organisms for which national primary drinking water regulations have been promulgated or that are of public health concern than would be achieved by the combination of filtration and chlorine disinfection (in compliance with this section).

(8) DISINFECTION.—At any time after the end of the 3-year period that begins on August 6, 1996, but not later than the date on which the Administrator promulgates a Stage II rulemaking for disinfectants and disinfection byproducts (as described in paragraph (2)(C)), the Administrator shall also promulgate national primary drinking water regulations requiring disinfection as a treatment technique for all public water systems, including surface water systems and, as necessary, ground water systems. After consultation with the States, the Administrator shall (as part of the regulations) promulgate criteria that the Administrator, or a State that has primary enforcement responsibility under section 300g–2 of this title, shall apply to determine whether disinfection shall be required as a treatment technique for any public water system served by ground water. The Administrator shall simultaneously promulgate a rule specifying criteria that will be used by the Administrator (or delegated State authorities) to grant variances from this requirement according to the provisions of sections 300g–4(a)(1)(B) and 300g–4(a)(3) of this title. In implementing section 300j–1(e) of this title the Administrator or the delegated State authority shall, where appropriate, give special consideration to providing technical assistance to small public water systems in complying with the regulations promulgated under this paragraph.

(9) REVIEW AND REVISION.—The Administrator shall, not less often than every 6 years, review and revise, as appropriate, each national primary drinking water regulation promulgated under this subchapter. Any revision of a national primary drinking water regulation shall be promulgated in accordance with this section, except that each revision shall maintain, or provide for greater, protection of the health of persons.

(10) EFFECTIVE DATE.—A national primary drinking water regulation promulgated under this section (and any amendment thereto) shall take effect on the date that is 3 years after the date on which the regulation is promulgated unless the Administrator determines that an earlier date is practicable, except that the Administrator, or a State (in the case of an individual system), may allow up to 2 additional years to comply with a maximum contaminant level or treatment technique if the Administrator or State (in the case of an individual system) determines that additional time is necessary for capital improvements.

(11) No national primary drinking water regulation may require the addition of any substance for preventive health care purposes unrelated to contamination of drinking water.

(12) CERTAIN CONTAMINANTS.—

(A) ARSENIC.—

(i) SCHEDULE AND STANDARD.—Notwithstanding the deadlines set forth in paragraph (1), the Administrator shall promulgate a national primary drinking water regulation for arsenic pursuant to this subsection, in accordance with the schedule established by this paragraph.

(ii) STUDY PLAN.—Not later than 180 days after August 6, 1996, the Administrator shall develop a comprehensive plan for study in support of drinking water rulemaking to reduce the uncertainty in assessing health risks associated with exposure to low levels of arsenic. In conducting such study, the Administrator shall consult with the National Academy of Sciences, other Federal agencies, and interested public and private entities.

(iii) COOPERATIVE AGREEMENTS.—In carrying out the study plan, the Administrator may enter into cooperative agreements with other Federal agencies, State and local governments, and other interested public and private entities.

(iv) PROPOSED REGULATIONS.—The Administrator shall propose a national primary drinking water regulation for arsenic not later than January 1, 2000.

(v) FINAL REGULATIONS.—Not later than January 1, 2001, after notice and opportunity for public comment, the Administrator shall promulgate a national primary drinking water regulation for arsenic.

(vi) AUTHORIZATION.—There are authorized to be appropriated $2,500,000 for each of fiscal years 1997 through 2000 for the studies required by this paragraph.

(B) SULFATE.—

(i) ADDITIONAL STUDY.—Prior to promulgating a national primary drinking water regulation for sulfate, the Administrator and the Director of the Centers for Disease Control and Prevention shall jointly conduct an additional study to establish a reliable dose-response relationship for the adverse human health effects that may result from exposure to sulfate in drinking water, including the health effects that may be experienced by groups within the general population (including infants and travelers) that are potentially at greater risk of adverse health effects as the result of such exposure. The study shall be conducted in consultation with interested States, shall be based on the best available, peer-reviewed science and supporting studies conducted in accordance with sound and objective scientific practices, and shall be completed not later than 30 months after August 6, 1996.

(ii) DETERMINATION.—The Administrator shall include sulfate among the 5 or more contaminants for which a determination is made pursuant to paragraph (3)(B) not later than 5 years after August 6, 1996.

(iii) PROPOSED AND FINAL RULE.—Notwithstanding the deadlines set forth in paragraph (2), the Administrator may, pursuant to the authorities of this subsection and after notice and opportunity for public comment, promulgate a final national primary drinking water regulation for sulfate. Any such regulation shall include requirements for public notification and options for the provision of alternative water supplies to populations at risk as a means of complying with the regulation in lieu of a best available treatment technology or other means.

(13) RADON IN DRINKING WATER.—

(A) NATIONAL PRIMARY DRINKING WATER REGULATION.—Notwithstanding paragraph (2), the Administrator shall withdraw any national primary drinking water regulation for radon proposed prior to August 6, 1996, and shall propose and promulgate a regulation for radon under this section, as amended by the Safe Drinking Water Act Amendments of 1996.

(B) RISK ASSESSMENT AND STUDIES.—

(i) ASSESSMENT BY NAS.—Prior to proposing a national primary drinking water regulation for radon, the Administrator shall arrange for the National Academy of Sciences to prepare a risk assessment for radon in drinking water using the best available science in accordance with the requirements of paragraph (3). The risk assessment shall consider each of the risks associated with exposure to radon from drinking water and consider studies on the health effects of radon at levels and under conditions likely to be experienced through residential exposure. The risk assessment shall be peer-reviewed.

(ii) STUDY OF OTHER MEASURES.—The Administrator shall arrange for the National Academy of Sciences to prepare an assessment of the health risk reduction benefits associated with various mitigation measures to reduce radon levels in indoor air. The assessment may be

conducted as part of the risk assessment authorized by clause (i) and shall be used by the Administrator to prepare the guidance and approve State programs under subparagraph (G).

(iii) OTHER ORGANIZATION.—If the National Academy of Sciences declines to prepare the risk assessment or studies required by this subparagraph, the Administrator shall enter into a contract or cooperative agreement with another independent, scientific organization to prepare such assessments or studies.

(C) HEALTH RISK REDUCTION AND COST ANALYSIS.—Not later than 30 months after August 6, 1996, the Administrator shall publish, and seek public comment on, a health risk reduction and cost analysis meeting the requirements of paragraph (3)(C) for potential maximum contaminant levels that are being considered for radon in drinking water. The Administrator shall include a response to all significant public comments received on the analysis with the preamble for the proposed rule published under subparagraph (D).

(D) PROPOSED REGULATION.—Not later than 36 months after August 6, 1996, the Administrator shall propose a maximum contaminant level goal and a national primary drinking water regulation for radon pursuant to this section.

(E) FINAL REGULATION.—Not later than 12 months after the date of the proposal under subparagraph (D), the Administrator shall publish a maximum contaminant level goal and promulgate a national primary drinking water regulation for radon pursuant to this section based on the risk assessment prepared pursuant to subparagraph (B) and the health risk reduction and cost analysis published pursuant to subparagraph (C). In considering the risk assessment and the health risk reduction and cost analysis in connection with the promulgation of such a standard, the Administrator shall take into account the costs and benefits of control programs for radon from other sources.

(F) ALTERNATIVE MAXIMUM CONTAMINANT LEVEL.—If the maximum contaminant level for radon in drinking water promulgated pursuant to subparagraph (E) is more stringent than necessary to reduce the contribution to radon in indoor air from drinking water to a concentration that is equivalent to the national average concentration of radon in outdoor air, the Administrator shall, simultaneously with the promulgation of such level, promulgate an alternative maximum contaminant level for radon that would result in a contribution of radon from drinking water to radon levels in indoor air equivalent to the national average concentration of radon in outdoor air. If the Administrator promulgates an alternative maximum contaminant level under this subparagraph, the Administrator shall, after notice and opportunity for public comment and in consultation with the States, publish guidelines for State programs, including criteria for multimedia measures to mitigate radon levels in indoor air, to be used by the States in preparing programs under subparagraph (G). The guidelines shall take into account data from existing radon mitigation programs and the assessment of mitigation measures prepared under subparagraph (B).

(G) MULTIMEDIA RADON MITIGATION PROGRAMS.—

(i) IN GENERAL.—A State may develop and submit a multimedia program to mitigate radon levels in indoor air for approval by the Administrator under this subparagraph. If, after notice and the opportunity for public comment, such program is approved by the Administrator, public water systems in the State may comply with the alternative maximum contaminant level promulgated under subparagraph (F) in lieu of the maximum contaminant level in the national primary drinking water regulation promulgated under subparagraph (E).

(ii) ELEMENTS OF PROGRAMS.—State programs may rely on a variety of mitigation measures including public education, testing, training, technical assistance, remediation grant and loan or incentive programs, or other regulatory or nonregulatory measures. The effectiveness of elements in State programs shall be evaluated by the Administrator based on the assessment prepared by the National Academy of Sciences under subparagraph (B) and the guidelines published by the Administrator under subparagraph (F).

(iii) APPROVAL.—The Administrator shall approve a State program submitted under this paragraph if the health risk reduction benefits expected to be achieved by the program are equal to or greater than the health risk reduction benefits that would be achieved if each public water

system in the State complied with the maximum contaminant level promulgated under subparagraph (E). The Administrator shall approve or disapprove a program submitted under this paragraph within 180 days of receipt. A program that is not disapproved during such period shall be deemed approved. A program that is disapproved may be modified to address the objections of the Administrator and be resubmitted for approval.

(iv) REVIEW.—The Administrator shall periodically, but not less often than every 5 years, review each multimedia mitigation program approved under this subparagraph to determine whether it continues to meet the requirements of clause (iii) and shall, after written notice to the State and an opportunity for the State to correct any deficiency in the program, withdraw approval of programs that no longer comply with such requirements.

(v) EXTENSION.—If, within 90 days after the promulgation of an alternative maximum contaminant level under subparagraph (F), the Governor of a State submits a letter to the Administrator committing to develop a multimedia mitigation program under this subparagraph, the effective date of the national primary drinking water regulation for radon in the State that would be applicable under paragraph (10) shall be extended for a period of 18 months.

(vi) LOCAL PROGRAMS.—In the event that a State chooses not to submit a multimedia mitigation program for approval under this subparagraph or has submitted a program that has been disapproved, any public water system in the State may submit a program for approval by the Administrator according to the same criteria, conditions, and approval process that would apply to a State program. The Administrator shall approve a multimedia mitigation program if the health risk reduction benefits expected to be achieved by the program are equal to or greater than the health risk reduction benefits that would result from compliance by the public water system with the maximum contaminant level for radon promulgated under subparagraph (E).

(14) RECYCLING OF FILTER BACKWASH.—The Administrator shall promulgate a regulation to govern the recycling of filter backwash water within the treatment process of a public water system. The Administrator shall promulgate such regulation not later than 4 years after August 6, 1996, unless such recycling has been addressed by the Administrator's Enhanced Surface Water Treatment Rule prior to such date.

(15) VARIANCE TECHNOLOGIES.—

(A) IN GENERAL.—At the same time as the Administrator promulgates a national primary drinking water regulation for a contaminant pursuant to this section, the Administrator shall issue guidance or regulations describing the best treatment technologies, treatment techniques, or other means (referred to in this paragraph as "variance technology") for the contaminant that the Administrator finds, after examination for efficacy under field conditions and not solely under laboratory conditions, are available and affordable, as determined by the Administrator in consultation with the States, for public water systems of varying size, considering the quality of the source water to be treated. The Administrator shall identify such variance technologies for public water systems serving—

(i) a population of 10,000 or fewer but more than 3,300;

(ii) a population of 3,300 or fewer but more than 500; and

(iii) a population of 500 or fewer but more than 25,

if, considering the quality of the source water to be treated, no treatment technology is listed for public water systems of that size under paragraph (4)(E). Variance technologies identified by the Administrator pursuant to this paragraph may not achieve compliance with the maximum contaminant level or treatment technique requirement of such regulation, but shall achieve the maximum reduction or inactivation efficiency that is affordable considering the size of the system and the quality of the source water. The guidance or regulations shall not require the use of a technology from a specific manufacturer or brand.

(B) LIMITATION.—The Administrator shall not identify any variance technology under this paragraph, unless the Administrator has determined, considering the quality of the source water to be treated and the expected useful life of the technology, that the variance technology is protective

of public health.

(C) ADDITIONAL INFORMATION.—The Administrator shall include in the guidance or regulations identifying variance technologies under this paragraph any assumptions supporting the public health determination referred to in subparagraph (B), where such assumptions concern the public water system to which the technology may be applied, or its source waters. The Administrator shall provide any assumptions used in determining affordability, taking into consideration the number of persons served by such systems. The Administrator shall provide as much reliable information as practicable on performance, effectiveness, limitations, costs, and other relevant factors including the applicability of variance technology to waters from surface and underground sources.

(D) REGULATIONS AND GUIDANCE.—Not later than 2 years after August 6, 1996, and after consultation with the States, the Administrator shall issue guidance or regulations under subparagraph (A) for each national primary drinking water regulation promulgated prior to August 6, 1996, for which a variance may be granted under section 300g–4(e) of this title. The Administrator may, at any time after a national primary drinking water regulation has been promulgated, issue guidance or regulations describing additional variance technologies. The Administrator shall, not less often than every 7 years, or upon receipt of a petition supported by substantial information, review variance technologies identified under this paragraph. The Administrator shall issue revised guidance or regulations if new or innovative variance technologies become available that meet the requirements of this paragraph and achieve an equal or greater reduction or inactivation efficiency than the variance technologies previously identified under this subparagraph. No public water system shall be required to replace a variance technology during the useful life of the technology for the sole reason that a more efficient variance technology has been listed under this subparagraph.

(c) Secondary regulations; publication of proposed regulations; promulgation; amendments

The Administrator shall publish proposed national secondary drinking water regulations within 270 days after December 16, 1974. Within 90 days after publication of any such regulation, he shall promulgate such regulation with such modifications as he deems appropriate. Regulations under this subsection may be amended from time to time.

(d) Regulations; public hearings; administrative consultations

Regulations under this section shall be prescribed in accordance with section 553 of title 5 (relating to rulemaking), except that the Administrator shall provide opportunity for public hearing prior to promulgation of such regulations. In proposing and promulgating regulations under this section, the Administrator shall consult with the Secretary and the National Drinking Water Advisory Council.

(e) Science Advisory Board comments

The Administrator shall request comments from the Science Advisory Board (established under the Environmental Research, Development, and Demonstration Act of 1978) prior to proposal of a maximum contaminant level goal and national primary drinking water regulation. The Board shall respond, as it deems appropriate, within the time period applicable for promulgation of the national primary drinking water standard concerned. This subsection shall, under no circumstances, be used to delay final promulgation of any national primary drinking water standard.

(July 1, 1944, ch. 373, title XIV, §1412, as added Pub. L. 93–523, §2(a), Dec. 16, 1974, 88 Stat. 1662; amended Pub. L. 95–190, §§3(c), 12(a), Nov. 16, 1977, 91 Stat. 1394, 1398; Pub. L. 99–339, title I, §101(a)–(c)(1), (d), (e), June 19, 1986, 100 Stat. 642–646; Pub. L. 104–182, title I, §§102(a), (c)(2), 103, 104(a), (c), 105–111(a), title V, §501(a)(1), (2), Aug. 6, 1996, 110 Stat. 1617, 1621–1623, 1625–1631, 1691.)

EDITORIAL NOTES

REFERENCES IN TEXT

The Federal Insecticide, Fungicide, and Rodenticide Act, referred to in subsec. (b)(1)(B)(i)(II), is act June 25, 1947, ch. 125, as amended generally by Pub. L. 92–516, Oct. 21, 1972, 86 Stat. 973, which is classified generally to subchapter II (§136 et seq.) of chapter 6 of Title 7, Agriculture. For complete classification of this Act to the Code, see Short Title note set out under section 136 of Title 7 and Tables.

The Safe Drinking Water Act Amendments of 1996, referred to in subsec. (b)(13)(A), is Pub. L. 104–182, Aug. 6, 1996, 110 Stat. 1613. For complete classification of this Act to the Code, see Short Title of 1996 Amendment note set out under section 201 of this title and Tables.

The Environmental Research, Development, and Demonstration Act of 1978, referred to in subsec. (e), probably means the Environmental Research, Development, and Demonstration Authorization Act of 1978 which is Pub. L. 95–155, Nov. 8, 1977, 91 Stat. 1257. Provisions of the Act establishing the Science Advisory Board are classified to section 4365 of this title. For complete classification of this Act to the Code, see Tables.

AMENDMENTS

1996—Subsec. (a)(3). Pub. L. 104–182, §102(c)(2), struck out "paragraph (1), (2), or (3) of" before "subsection (b)" in two places.

Subsec. (b). Pub. L. 104–182, §102(a), inserted heading.

Subsec. (b)(1), (2). Pub. L. 104–182, §102(a), added pars. (1) and (2) and struck out former pars. (1) and (2) which related to publication of maximum contaminant level goals and promulgation of national primary drinking water regulations for certain listed contaminants or substituted contaminants.

Subsec. (b)(3). Pub. L. 104–182, §103, added par. (3).

Pub. L. 104–182, §102(a), struck out par. (3) which related to publication of maximum contaminant level goals and promulgation of national primary drinking water regulations for contaminants, other than those referred to in pars. (1) or (2), which may have an adverse effect on human health and are known to occur in public water systems.

Subsec. (b)(4). Pub. L. 104–182, §104(a)(1), designated first sentence as subpar. (A), inserted par. and subpar. (A) headings, designated second sentence as subpar. (B), inserted subpar. (B) heading, substituted "Except as provided in paragraphs (5) and (6), each national" for "Each national" and "specify a maximum contaminant level" for "specify a maximum level", and added subpar. (C).

Subsec. (b)(4)(D). Pub. L. 104–182, §104(a)(2), (3), redesignated par. (5) as subpar. (D) of par. (4), inserted subpar. heading, and substituted "this paragraph" for "paragraph (4)".

Subsec. (b)(4)(E). Pub. L. 104–182, §§104(a)(4), (5), 105, redesignated par. (6) as subpar. (E)(i) of par. (4), inserted subpar. and cl. headings, substituted "this subsection" for "this paragraph", and added cls. (ii) to (v).

Subsec. (b)(5), (6). Pub. L. 104–182, §104(a)(6), added pars. (5) and (6). Former pars. (5) and (6) redesignated subpars. (D) and (E)(i), respectively, of par. (4).

Subsec. (b)(7)(C)(v). Pub. L. 104–182, §106, added cl. (v).

Subsec. (b)(8). Pub. L. 104–182, §501(a)(2), substituted "section 300j–1(e)" for "section 300j–1(g)".

Pub. L. 104–182, §107, inserted heading, realigned margins, and substituted "At any time after the end of the 3-year period that begins on August 6, 1996, but not later than the date on which the Administrator promulgates a Stage II rulemaking for disinfectants and disinfection byproducts (as described in paragraph (2)(C)), the Administrator shall also promulgate national primary drinking water regulations requiring disinfection as a treatment technique for all public water systems, including surface water systems and, as necessary, ground water systems. After consultation with the States, the Administrator shall (as part of the regulations) promulgate criteria that the Administrator, or a State that has primary enforcement responsibility under section 300g–2 of this title, shall apply to determine whether disinfection shall be required as a treatment technique for any public water system served by ground water." for "Not later than 36 months after June 19, 1986, the Administrator shall propose and promulgate national primary drinking water regulations requiring disinfection as a treatment technique for all public water systems."

Subsec. (b)(9). Pub. L. 104–182, §104(c), amended par. (9) generally. Prior to amendment, par. (9) read as follows: "National primary drinking water regulations shall be amended whenever changes in technology, treatment techniques, and other means permit greater protection of the health of persons, but in any event such regulations shall be reviewed at least once every 3 years. Such review shall include an analysis of innovations or changes in technology, treatment techniques or other activities that have occurred over the previous 3-year period and that may provide for greater protection of the health of persons. The findings of such review shall be published in the Federal Register. If, after opportunity for public comment, the Administrator concludes that the technology, treatment techniques, or other means resulting from such innovations or changes are not feasible within the meaning of paragraph (5), an explanation of such conclusion shall be published in the Federal Register."

Subsec. (b)(10). Pub. L. 104–182, §108, amended par. (10) generally. Prior to amendment, par. (10) read as follows: "National primary drinking water regulations promulgated under this subsection (and amendments thereto) shall take effect eighteen months after the date of their promulgation. Regulations under subsection (a) of this section shall be superseded by regulations under this subsection to the extent provided by the regulations under this subsection."

Subsec. (b)(11). Pub. L. 104–182, §501(a)(1), realigned margins.

Subsec. (b)(12). Pub. L. 104–182, §109(a), added par. (12).

Subsec. (b)(13). Pub. L. 104–182, §109(b), added par. (13).

Subsec. (b)(14). Pub. L. 104–182, §110, added par. (14).

Subsec. (b)(15). Pub. L. 104–182, §111(a), added par. (15).

1986—Subsec. (a). Pub. L. 99–339, §101(a), amended subsec. (a) generally. Prior to amendment, subsec. (a) read as follows:

"(1) The Administrator shall publish proposed national interim primary drinking water regulations within 90 days after December 16, 1974. Within 180 days after December 16, 1974, he shall promulgate such regulations with such modifications as he deems appropriate. Regulations under this paragraph may be amended from time to time.

"(2) National interim primary drinking water regulations promulgated under paragraph (1) shall protect health to the extent feasible, using technology, treatment techniques, and other means, which the Administrator determines are generally available (taking costs into consideration) on December 16, 1974.

"(3) The interim primary regulations first promulgated under paragraph (1) shall take effect eighteen months after the date of their promulgation."

Subsec. (b)(1). Pub. L. 99–339, §101(b), substituted provisions establishing standard setting schedules and deadlines for provisions relating to establishment of maximum contaminant levels and a list of contaminants with adverse effect but of undetermined levels.

Subsec. (b)(2). Pub. L. 99–339, §101(b), substituted provisions authorizing the Administrator to substitute contaminants for those referred to in par. (1) and to supply a list of the contaminants proposed for substitution, with the decision of the Administrator to regulate such contaminant not subject to judicial review, for provisions which authorized the Administrator to publish in the Federal Register proposed revised national interim primary drinking water regulations and 180 days after the date of such proposed regulations to promulgate such revised regulations with modification as deemed appropriate.

Subsec. (b)(3). Pub. L. 99–339, §101(b), substituted provisions directing the Administrator to publish maximum contaminant level goals and promulgate national primary drinking water regulations for contaminants, other than specified in par. (1) or (2), which may have an adverse effect on health and are known or anticipated to occur in public water systems, to establish an advisory working group to aid in establishing a list of such contaminants, and to publish, within a specified time, both proposed and final goals and regulations for provisions which required that revised national primary drinking water regulations specify a maximum contaminant level or require the use of treatment techniques for each contaminant, which level or technique was to be as close to the recommended level or technique as feasible, and defined the term "feasible".

Subsec. (b)(4) to (11). Pub. L. 99–339, §101(b), (c)(1), (d), added pars. (4) to (8), redesignated former pars. (4) to (6) as pars. (9) to (11), respectively, in par. (9) substituted "National" for "Revised National" and inserted provision that review include analysis, and publication in Federal Register, of innovations in technology, treatment techniques or other activities occurring during previous three years and their feasibility, and in par. (10) substituted "National" for "Revised National".

Subsec. (e). Pub. L. 99–339, §101(e), amended subsec. (e) generally, substituting provisions which relate to the request by the Administrator of comments by the Science Advisory Board prior to proposal of a maximum contaminant level goal and national primary drinking water regulation for provisions which related to study by the National Academy of Sciences to determine the maximum contaminant levels, report to Congress, and funding therefor.

1977—Subsec. (e)(2). Pub. L. 95–190 inserted provisions relating to revisions of the required report and cl. (G).

STATUTORY NOTES AND RELATED SUBSIDIARIES

NATIONAL PRIMARY DRINKING WATER REGULATION FOR ARSENIC

Pub. L. 106–377, §1(a)(1) [title III], Oct. 27, 2000, 114 Stat. 1441, 1441A–41, provided in part: "That notwithstanding section 1412(b)(12)(A)(v) of the Safe Drinking Water Act, as amended [42 U.S.C. 300g–1(b)(12)(A)(v)], the Administrator shall promulgate a national primary drinking water regulation for

arsenic not later than June 22, 2001."

APPLICABILITY OF PRIOR REQUIREMENTS

Pub. L. 104–182, title I, §102(b), Aug. 6, 1996, 110 Stat. 1620, provided that: "The requirements of subparagraphs (C) and (D) of section 1412(b)(3) of the Safe Drinking Water Act [42 U.S.C. 300g–1(b)(3)(C), (D)] as in effect before the date of enactment of this Act [Aug. 6, 1996], and any obligation to promulgate regulations pursuant to such subparagraphs not promulgated as of the date of enactment of this Act, are superseded by the amendments made by subsection (a) [amending this section]."

DISINFECTANTS AND DISINFECTION BYPRODUCTS

Pub. L. 104–182, title I, §104(b), Aug. 6, 1996, 110 Stat. 1625, provided that: "The Administrator of the Environmental Protection Agency may use the authority of section 1412(b)(5) of the Safe Drinking Water Act [42 U.S.C. 300g–1(b)(5)] (as amended by this Act) to promulgate the Stage I and Stage II Disinfectants and Disinfection Byproducts Rules as proposed in volume 59, Federal Register, page 38668 (July 29, 1994). The considerations used in the development of the July 29, 1994, proposed national primary drinking water regulation on disinfectants and disinfection byproducts shall be treated as consistent with such section 1412(b)(5) for purposes of such Stage I and Stage II rules."

§300g–2. State primary enforcement responsibility

(a) In general

For purposes of this subchapter, a State has primary enforcement responsibility for public water systems during any period for which the Administrator determines (pursuant to regulations prescribed under subsection (b)) that such State—

(1) has adopted drinking water regulations that are no less stringent than the national primary drinking water regulations promulgated by the Administrator under subsections (a) and (b) of section 300g–1 of this title not later than 2 years after the date on which the regulations are promulgated by the Administrator, except that the Administrator may provide for an extension of not more than 2 years if, after submission and review of appropriate, adequate documentation from the State, the Administrator determines that the extension is necessary and justified;

(2) has adopted and is implementing adequate procedures for the enforcement of such State regulations, including conducting such monitoring and making such inspections as the Administrator may require by regulation;

(3) will keep such records and make such reports with respect to its activities under paragraphs (1) and (2) as the Administrator may require by regulation;

(4) if it permits variances or exemptions, or both, from the requirements of its drinking water regulations which meet the requirements of paragraph (1), permits such variances and exemptions under conditions and in a manner which is not less stringent than the conditions under, and the manner in which variances and exemptions may be granted under sections 300g–4 and 300g–5 of this title;

(5) has adopted and can implement an adequate plan for the provision of safe drinking water under emergency circumstances including earthquakes, floods, hurricanes, and other natural disasters, as appropriate;

(6) has adopted and is implementing procedures for requiring public water systems to assess options for consolidation or transfer of ownership or other actions in accordance with the regulations issued by the Administrator under section 300g–3(h)(6) of this title; and

(7) has adopted authority for administrative penalties (unless the constitution of the State prohibits the adoption of the authority) in a maximum amount—

(A) in the case of a system serving a population of more than 10,000, that is not less than $1,000 per day per violation; and

(B) in the case of any other system, that is adequate to ensure compliance (as determined by the State);

except that a State may establish a maximum limitation on the total amount of administrative

penalties that may be imposed on a public water system per violation.

(b) Regulations

(1) The Administrator shall, by regulation (proposed within 180 days of December 16, 1974), prescribe the manner in which a State may apply to the Administrator for a determination that the requirements of subsection (a) are satisfied with respect to the State, the manner in which the determination is made, the period for which the determination will be effective, and the manner in which the Administrator may determine that such requirements are no longer met. Such regulations shall require that before a determination of the Administrator that such requirements are met or are no longer met with respect to a State may become effective, the Administrator shall notify such State of the determination and the reasons therefor and shall provide an opportunity for public hearing on the determination. Such regulations shall be promulgated (with such modifications as the Administrator deems appropriate) within 90 days of the publication of the proposed regulations in the Federal Register. The Administrator shall promptly notify in writing the chief executive officer of each State of the promulgation of regulations under this paragraph. Such notice shall contain a copy of the regulations and shall specify a State's authority under this subchapter when it is determined to have primary enforcement responsibility for public water systems.

(2) When an application is submitted in accordance with the Administrator's regulations under paragraph (1), the Administrator shall within 90 days of the date on which such application is submitted (A) make the determination applied for, or (B) deny the application and notify the applicant in writing of the reasons for his denial.

(c) Interim primary enforcement authority

A State that has primary enforcement authority under this section with respect to each existing national primary drinking water regulation shall be considered to have primary enforcement authority with respect to each new or revised national primary drinking water regulation during the period beginning on the effective date of a regulation adopted and submitted by the State with respect to the new or revised national primary drinking water regulation in accordance with subsection (b)(1) and ending at such time as the Administrator makes a determination under subsection (b)(2)(B) with respect to the regulation.

(July 1, 1944, ch. 373, title XIV, §1413, as added Pub. L. 93–523, §2(a), Dec. 16, 1974, 88 Stat. 1665; amended Pub. L. 99–339, title I, §101(c)(2), June 19, 1986, 100 Stat. 646; Pub. L. 104–182, title I, §§112, 113(b), Aug. 6, 1996, 110 Stat. 1633, 1635; Pub. L. 115–270, title II, §2010(b), Oct. 23, 2018, 132 Stat. 3848.)

EDITORIAL NOTES

AMENDMENTS

2018—Subsec. (a)(6), (7). Pub. L. 115–270, §2010(b)(1), added par. (6) and redesignated former par. (6) as (7).

Subsec. (b)(1). Pub. L. 115–270, §2010(b)(2), struck out "of paragraphs (1), (2), (3), and (4)" after "the requirements".

1996—Subsec. (a)(1). Pub. L. 104–182, §112(a)(1), amended par. (1) generally. Prior to amendment, par. (1) read as follows: "has adopted drinking water regulations which are no less stringent than the national primary drinking water regulations in effect under sections 300g–1(a) and 300g–1(b) of this title;".

Subsec. (a)(5). Pub. L. 104–182, §112(b), inserted "including earthquakes, floods, hurricanes, and other natural disasters, as appropriate" after "emergency circumstances".

Subsec. (a)(6). Pub. L. 104–182, §113(b), added par. (6).

Subsec. (c). Pub. L. 104–182, §112(a)(2), added subsec. (c).

1986—Subsec. (a)(1). Pub. L. 99–339 substituted "are no less stringent than the national primary drinking water regulations in effect under sections 300g–1(a) and 300g–1(b) of this title" for subpars. (A) and (B) which related to stringency of State drinking water regulations between period of promulgation and effective date of national interim drinking water regulations and during the period after such effective date.

§300g–3. Enforcement of drinking water regulations

(a) Notice to State and public water system; issuance of administrative order; civil action

(1)(A) Whenever the Administrator finds during a period during which a State has primary enforcement responsibility for public water systems (within the meaning of section 300g–2(a) of this title) that any public water system—

(i) for which a variance under section 300g–4 or an exemption under section 300g–5 of this title is not in effect, does not comply with any applicable requirement, or

(ii) for which a variance under section 300g–4 or an exemption under section 300g–5 of this title is in effect, does not comply with any schedule or other requirement imposed pursuant thereto,

he shall so notify the State and such public water system and provide such advice and technical assistance to such State and public water system as may be appropriate to bring the system into compliance with the requirement by the earliest feasible time.

(B) If, beyond the thirtieth day after the Administrator's notification under subparagraph (A), the State has not commenced appropriate enforcement action, the Administrator shall issue an order under subsection (g) requiring the public water system to comply with such applicable requirement or the Administrator shall commence a civil action under subsection (b).

(2) ENFORCEMENT IN NONPRIMACY STATES.—

(A) IN GENERAL.—If, on the basis of information available to the Administrator, the Administrator finds, with respect to a period in which a State does not have primary enforcement responsibility for public water systems, that a public water system in the State—

(i) for which a variance under section 300g–4 of this title or an exemption under section 300g–5 of this title is not in effect, does not comply with any applicable requirement; or

(ii) for which a variance under section 300g–4 of this title or an exemption under section 300g–5 of this title is in effect, does not comply with any schedule or other requirement imposed pursuant to the variance or exemption;

the Administrator shall issue an order under subsection (g) requiring the public water system to comply with the requirement, or commence a civil action under subsection (b).

(B) NOTICE.—If the Administrator takes any action pursuant to this paragraph, the Administrator shall notify an appropriate local elected official, if any, with jurisdiction over the public water system of the action prior to the time that the action is taken.

(b) Judicial determinations in appropriate Federal district courts; civil penalties, separate violations

The Administrator may bring a civil action in the appropriate United States district court to require compliance with any applicable requirement, with an order issued under subsection (g), or with any schedule or other requirement imposed pursuant to a variance or exemption granted under section 300g–4 or 300g–5 of this title if—

(1) authorized under paragraph (1) or (2) of subsection (a), or

(2) if requested by (A) the chief executive officer of the State in which is located the public water system which is not in compliance with such regulation or requirement, or (B) the agency of such State which has jurisdiction over compliance by public water systems in the State with national primary drinking water regulations or State drinking water regulations.

The court may enter, in an action brought under this subsection, such judgement as protection of public health may require, taking into consideration the time necessary to comply and the availability of alternative water supplies; and, if the court determines that there has been a violation of the regulation or schedule or other requirement with respect to which the action was brought, the court may, taking into account the seriousness of the violation, the population at risk, and other appropriate factors, impose on the violator a civil penalty of not to exceed $25,000 for each day in which such violation occurs.

(c) Notice to States, the Administrator, and persons served

(1) In general

Each owner or operator of a public water system shall give notice of each of the following to the persons served by the system:

(A) Notice of any failure on the part of the public water system to—

(i) comply with an applicable maximum contaminant level or treatment technique requirement of, or a testing procedure prescribed by, a national primary drinking water regulation; or

(ii) perform monitoring required by section 300j–4(a) of this title.

(B) If the public water system is subject to a variance granted under subsection (a)(1)(A), (a)(2), or (e) of section 300g–4 of this title for an inability to meet a maximum contaminant level requirement or is subject to an exemption granted under section 300g–5 of this title, notice of—

(i) the existence of the variance or exemption; and

(ii) any failure to comply with the requirements of any schedule prescribed pursuant to the variance or exemption.

(C) Notice of the concentration level of any unregulated contaminant for which the Administrator has required public notice pursuant to paragraph (2)(F).

(D) Notice that the public water system exceeded the lead action level under section 141.80(c) of title 40, Code of Federal Regulations (or a prescribed level of lead that the Administrator establishes for public education or notification in a successor regulation promulgated pursuant to section 300g–1 of this title).

(2) Form, manner, and frequency of notice

(A) In general

The Administrator shall, by regulation, and after consultation with the States, prescribe the manner, frequency, form, and content for giving notice under this subsection. The regulations shall—

(i) provide for different frequencies of notice based on the differences between violations that are intermittent or infrequent and violations that are continuous or frequent; and

(ii) take into account the seriousness of any potential adverse health effects that may be involved.

(B) State requirements

(i) In general

A State may, by rule, establish alternative notification requirements—

(I) with respect to the form and content of notice given under and in a manner in accordance with subparagraph (C); and

(II) with respect to the form and content of notice given under subparagraph (E).

(ii) Contents

The alternative requirements shall provide the same type and amount of information as required pursuant to this subsection and regulations issued under subparagraph (A).

(iii) Relationship to section 300g–2

Nothing in this subparagraph shall be construed or applied to modify the requirements of section 300g–2 of this title.

(C) Notice of violations or exceedances with potential to have serious adverse effects on human health

Regulations issued under subparagraph (A) shall specify notification procedures for each violation, and each exceedance described in paragraph (1)(D), by a public water system that has

the potential to have serious adverse effects on human health as a result of short-term exposure. Each notice of violation or exceedance provided under this subparagraph shall—

(i) be distributed as soon as practicable, but not later than 24 hours, after the public water system learns of the violation or exceedance;

(ii) provide a clear and readily understandable explanation of—

(I) the violation or exceedance;

(II) the potential adverse effects on human health;

(III) the steps that the public water system is taking to correct the violation or exceedance; and

(IV) the necessity of seeking alternative water supplies until the violation or exceedance is corrected;

(iii) be provided to the Administrator and the head of the State agency that has primary enforcement responsibility under section 300g–2 of this title, as applicable, as soon as practicable, but not later than 24 hours after the public water system learns of the violation or exceedance; and

(iv) as required by the State agency in general regulations of the State agency, or on a case-by-case basis after the consultation referred to in clause (iii), considering the health risks involved—

(I) be provided to appropriate media, including broadcast media;

(II) be prominently published in a newspaper of general circulation serving the area not later than 1 day after distribution of a notice pursuant to clause (i) or the date of publication of the next issue of the newspaper; or

(III) be provided by posting or door-to-door notification.

(D) Notice by the Administrator

If the State with primary enforcement responsibility or the owner or operator of a public water system has not issued a notice under subparagraph (C) for an exceedance of the lead action level under section 141.80(c) of title 40, Code of Federal Regulations (or a prescribed level of lead that the Administrator establishes for public education or notification in a successor regulation promulgated pursuant to section 300g–1 of this title) that has the potential to have serious adverse effects on human health as a result of short-term exposure, not later than 24 hours after the Administrator is notified of the exceedance, the Administrator shall issue the required notice under that subparagraph.

(E) Written notice

(i) In general

Regulations issued under subparagraph (A) shall specify notification procedures for violations other than the violations covered by subparagraph (C). The procedures shall specify that a public water system shall provide written notice to each person served by the system by notice (I) in the first bill (if any) prepared after the date of occurrence of the violation, (II) in an annual report issued not later than 1 year after the date of occurrence of the violation, or (III) by mail or direct delivery as soon as practicable, but not later than 1 year after the date of occurrence of the violation.

(ii) Form and manner of notice

The Administrator shall prescribe the form and manner of the notice to provide a clear and readily understandable explanation of the violation, any potential adverse health effects, and the steps that the system is taking to seek alternative water supplies, if any, until the violation is corrected.

(F) Unregulated contaminants

The Administrator may require the owner or operator of a public water system to give notice to the persons served by the system of the concentration levels of an unregulated contaminant

required to be monitored under section 300j–4(a) of this title.

(3) Reports

(A) Annual report by State

(i) In general

Not later than January 1, 1998, and annually thereafter, each State that has primary enforcement responsibility under section 300g–2 of this title shall prepare, make readily available to the public, and submit to the Administrator an annual report on violations of national primary drinking water regulations by public water systems in the State, including violations with respect to (I) maximum contaminant levels, (II) treatment requirements, (III) variances and exemptions, and (IV) monitoring requirements determined to be significant by the Administrator after consultation with the States.

(ii) Distribution

The State shall publish and distribute summaries of the report and indicate where the full report is available for review.

(B) Annual report by Administrator

Not later than July 1, 1998, and annually thereafter, the Administrator shall prepare and make available to the public an annual report summarizing and evaluating reports submitted by States pursuant to subparagraph (A), notices submitted by public water systems serving Indian Tribes provided to the Administrator pursuant to subparagraph (C) or (E) of paragraph (2), and notices issued by the Administrator with respect to public water systems serving Indian Tribes under subparagraph (D) of that paragraph and making recommendations concerning the resources needed to improve compliance with this subchapter. The report shall include information about public water system compliance on Indian reservations and about enforcement activities undertaken and financial assistance provided by the Administrator on Indian reservations, and shall make specific recommendations concerning the resources needed to improve compliance with this subchapter on Indian reservations.

(4) Consumer confidence reports by community water systems

(A) Reports to consumers

The Administrator, in consultation with public water systems, environmental groups, public interest groups, risk communication experts, and the States, and other interested parties, shall issue regulations within 24 months after August 6, 1996, to require each community water system to mail, or provide by electronic means, to each customer of the system at least once annually a report on the level of contaminants in the drinking water purveyed by that system (referred to in this paragraph as a "consumer confidence report"). Such regulations shall provide a brief and plainly worded definition of the terms "maximum contaminant level goal", "maximum contaminant level", "variances", and "exemptions" and brief statements in plain language regarding the health concerns that resulted in regulation of each regulated contaminant. The regulations shall also include a brief and plainly worded explanation regarding contaminants that may reasonably be expected to be present in drinking water, including bottled water. The regulations shall also provide for an Environmental Protection Agency toll-free hotline that consumers can call for more information and explanation.

(B) Contents of report

The consumer confidence reports under this paragraph shall include, but not be limited to, each of the following:

(i) Information on the source of the water purveyed.

(ii) A brief and plainly worded definition of the terms "action level", "maximum contaminant level goal", "maximum contaminant level", "variances", and "exemptions" as provided in the regulations of the Administrator.

(iii) If any regulated contaminant is detected in the water purveyed by the public water

system, a statement describing, as applicable—

(I) the maximum contaminant level goal;

(II) the maximum contaminant level;

(III) the level of the contaminant in the water system;

(IV) the action level for the contaminant; and

(V) for any contaminant for which there has been a violation of the maximum contaminant level during the year concerned, a brief statement in plain language regarding the health concerns that resulted in regulation of the contaminant, as provided by the Administrator in regulations under subparagraph (A).

(iv) Information on compliance with national primary drinking water regulations, as required by the Administrator, including corrosion control efforts, and notice if the system is operating under a variance or exemption and the basis on which the variance or exemption was granted.

(v) Information on the levels of unregulated contaminants for which monitoring is required under section 300j–4(a)(2) of this title (including levels of cryptosporidium and radon where States determine they may be found).

(vi) A statement that the presence of contaminants in drinking water does not necessarily indicate that the drinking water poses a health risk and that more information about contaminants and potential health effects can be obtained by calling the Environmental Protection Agency hotline.

(vii) Identification of, if any—

(I) exceedances described in paragraph (1)(D) for which corrective action has been required by the Administrator or the State (in the case of a State exercising primary enforcement responsibility for public water systems) during the monitoring period covered by the consumer confidence report; and

(II) violations that occurred during the monitoring period covered by the consumer confidence report.

A public water system may include such additional information as it deems appropriate for public education. The Administrator may, for not more than 3 regulated contaminants other than those referred to in clause (iii)(V), require a consumer confidence report under this paragraph to include the brief statement in plain language regarding the health concerns that resulted in regulation of the contaminant or contaminants concerned, as provided by the Administrator in regulations under subparagraph (A).

(C) Coverage

The Governor of a State may determine not to apply the mailing requirement of subparagraph (A) to a community water system serving fewer than 10,000 persons. Any such system shall—

(i) inform, in the newspaper notice required by clause (iii) or by other means, its customers that the system will not be mailing the report as required by subparagraph (A);

(ii) make the consumer confidence report available upon request to the public; and

(iii) publish the report referred to in subparagraph (A) annually in one or more local newspapers serving the area in which customers of the system are located.

(D) Alternative to publication

For any community water system which, pursuant to subparagraph (C), is not required to meet the mailing requirement of subparagraph (A) and which serves 500 persons or fewer, the community water system may elect not to comply with clause (i) or (iii) of subparagraph (C). If the community water system so elects, the system shall, at a minimum—

(i) prepare an annual consumer confidence report pursuant to subparagraph (B); and

(ii) provide notice at least once per year to each of its customers by mail, by door-to-door delivery, by posting or by other means authorized by the regulations of the Administrator that the consumer confidence report is available upon request.

(E) Alternative form and content

A State exercising primary enforcement responsibility may establish, by rule, after notice and public comment, alternative requirements with respect to the form and content of consumer confidence reports under this paragraph.

(F) Revisions

(i) Understandability and frequency

Not later than 24 months after October 23, 2018, the Administrator, in consultation with the parties identified in subparagraph (A), shall issue revisions to the regulations issued under subparagraph (A)—

(I) to increase—

(aa) the readability, clarity, and understandability of the information presented in consumer confidence reports; and

(bb) the accuracy of information presented, and risk communication, in consumer confidence reports; and

(II) with respect to community water systems that serve 10,000 or more persons, to require each such community water system to provide, by mail, electronic means, or other methods described in clause (ii), a consumer confidence report to each customer of the system at least biannually.

(ii) Electronic delivery

Any revision of regulations pursuant to clause (i) shall allow delivery of consumer confidence reports by methods consistent with methods described in the memorandum "Safe Drinking Water Act–Consumer Confidence Report Rule Delivery Options" issued by the Environmental Protection Agency on January 3, 2013.

(5) Exceedance of lead level at households

(A) Strategic plan

Not later than 180 days after December 16, 2016, the Administrator shall, in collaboration with owners and operators of public water systems and States, establish a strategic plan for how the Administrator, a State with primary enforcement responsibility, and owners and operators of public water systems shall provide targeted outreach, education, technical assistance, and risk communication to populations affected by the concentration of lead in a public water system, including dissemination of information described in subparagraph (C).

(B) EPA initiation of notice

(i) Forwarding of data by employee of the Agency

If the Agency develops, or receives from a source other than a State or a public water system, data that meets the requirements of section 300g–1(b)(3)(A)(ii) of this title that indicates that the drinking water of a household served by a public water system contains a level of lead that exceeds the lead action level under section 141.80(c) of title 40, Code of Federal Regulations (or a prescribed level of lead that the Administrator establishes for public education or notification in a successor regulation promulgated pursuant to section 300g–1 of this title) (referred to in this paragraph as an "affected household"), the Administrator shall require an appropriate employee of the Agency to forward the data, and information on the sampling techniques used to obtain the data, to the owner or operator of the public water system and the State in which the affected household is located within a time period determined by the Administrator.

(ii) Dissemination of information by owner or operator

The owner or operator of a public water system shall disseminate to affected households the information described in subparagraph (C) within a time period established by the Administrator, if the owner or operator—

(I) receives data and information under clause (i); and

(II) has not, since the date of the test that developed the data, notified the affected households—

(aa) with respect to the concentration of lead in the drinking water of the affected households; and

(bb) that the concentration of lead in the drinking water of the affected households exceeds the lead action level under section 141.80(c) of title 40, Code of Federal Regulations (or a prescribed level of lead that the Administrator establishes for public education or notification in a successor regulation promulgated pursuant to section 300g–1 of this title).

(iii) Consultation

(I) Deadline

If the owner or operator of the public water system does not disseminate to the affected households the information described in subparagraph (C) as required under clause (ii) within the time period established by the Administrator, not later than 24 hours after the Administrator becomes aware of the failure by the owner or operator of the public water system to disseminate the information, the Administrator shall consult, within a period not to exceed 24 hours, with the applicable Governor to develop a plan, in accordance with the strategic plan, to disseminate the information to the affected households not later than 24 hours after the end of the consultation period.

(II) Delegation

The Administrator may only delegate the duty to consult under subclause (I) to an employee of the Agency who, as of the date of the delegation, works in the Office of Water at the headquarters of the Agency.

(iv) Dissemination by Administrator

The Administrator shall, as soon as practicable, disseminate to affected households the information described in subparagraph (C) if—

(I) the owner or operator of the public water system does not disseminate the information to the affected households within the time period determined by the Administrator, as required by clause (ii); and

(II)(aa) the Administrator and the applicable Governor do not agree on a plan described in clause (iii)(I) during the consultation period under that clause; or

(bb) the applicable Governor does not disseminate the information within 24 hours after the end of the consultation period.

(C) Information required

The information described in this subparagraph includes—

(i) a clear explanation of the potential adverse effects on human health of drinking water that contains a concentration of lead that exceeds the lead action level under section 141.80(c) of title 40, Code of Federal Regulations (or a prescribed level of lead that the Administrator establishes for public education or notification in a successor regulation promulgated pursuant to section 300g–1 of this title);

(ii) the steps that the owner or operator of the public water system is taking to mitigate the concentration of lead; and

(iii) the necessity of seeking alternative water supplies until the date on which the concentration of lead is mitigated.

(6) Privacy

Any notice to the public or an affected household under this subsection shall protect the privacy of individual customer information.

(d) Notice of noncompliance with secondary drinking water regulations

Whenever, on the basis of information available to him, the Administrator finds that within a reasonable time after national secondary drinking water regulations have been promulgated, one or more public water systems in a State do not comply with such secondary regulations, and that such noncompliance appears to result from a failure of such State to take reasonable action to assure that public water systems throughout such State meet such secondary regulations, he shall so notify the State.

(e) State authority to adopt or enforce laws or regulations respecting drinking water regulations or public water systems unaffected

Nothing in this subchapter shall diminish any authority of a State or political subdivision to adopt or enforce any law or regulation respecting drinking water regulations or public water systems, but no such law or regulation shall relieve any person of any requirement otherwise applicable under this subchapter.

(f) Notice and public hearing; availability of recommendations transmitted to State and public water system

If the Administrator makes a finding of noncompliance (described in subparagraph (A) or (B) of subsection (a)(1)) with respect to a public water system in a State which has primary enforcement responsibility, the Administrator may, for the purpose of assisting that State in carrying out such responsibility and upon the petition of such State or public water system or persons served by such system, hold, after appropriate notice, public hearings for the purpose of gathering information from technical or other experts, Federal, State, or other public officials, representatives of such public water system, persons served by such system, and other interested persons on—

(1) the ways in which such system can within the earliest feasible time be brought into compliance with the regulation or requirement with respect to which such finding was made, and

(2) the means for the maximum feasible protection of the public health during any period in which such system is not in compliance with a national primary drinking water regulation or requirement applicable to a variance or exemption.

On the basis of such hearings the Administrator shall issue recommendations which shall be sent to such State and public water system and shall be made available to the public and communications media.

(g) Administrative order requiring compliance; notice and hearing; civil penalty; civil actions

(1) In any case in which the Administrator is authorized to bring a civil action under this section or under section 300j–4 of this title with respect to any applicable requirement, the Administrator also may issue an order to require compliance with such applicable requirement.

(2) An order issued under this subsection shall not take effect, in the case of a State having primary enforcement responsibility for public water systems in that State, until after the Administrator has provided the State with an opportunity to confer with the Administrator regarding the order. A copy of any order issued under this subsection shall be sent to the appropriate State agency of the State involved if the State has primary enforcement responsibility for public water systems in that State. Any order issued under this subsection shall state with reasonable specificity the nature of the violation. In any case in which an order under this subsection is issued to a corporation, a copy of such order shall be issued to appropriate corporate officers.

(3)(A) Any person who violates, or fails or refuses to comply with, an order under this subsection shall be liable to the United States for a civil penalty of not more than $25,000 per day of violation.

(B) In a case in which a civil penalty sought by the Administrator under this paragraph does not exceed $5,000, the penalty shall be assessed by the Administrator after notice and opportunity for a public hearing (unless the person against whom the penalty is assessed requests a hearing on the record in accordance with section 554 of title 5). In a case in which a civil penalty sought by the Administrator under this paragraph exceeds $5,000, but does not exceed $25,000, the penalty shall be assessed by the Administrator after notice and opportunity for a hearing on the record in accordance with section 554 of title 5.

(C) Whenever any civil penalty sought by the Administrator under this subsection for a violation of an applicable requirement exceeds $25,000, the penalty shall be assessed by a civil action brought by the Administrator in the appropriate United States district court (as determined under the provisions of title 28).

(D) If any person fails to pay an assessment of a civil penalty after it has become a final and unappealable order, or after the appropriate court of appeals has entered final judgment in favor of the Administrator, the Attorney General shall recover the amount for which such person is liable in any appropriate district court of the United States. In any such action, the validity and appropriateness of the final order imposing the civil penalty shall not be subject to review.

(h) Consolidation incentive

(1) In general

An owner or operator of a public water system may submit to the State in which the system is located (if the State has primary enforcement responsibility under section 300g–2 of this title) or to the Administrator (if the State does not have primary enforcement responsibility) a plan (including specific measures and schedules) for—

(A) the physical consolidation of the system with 1 or more other systems;

(B) the consolidation of significant management and administrative functions of the system with 1 or more other systems;

(C) the transfer of ownership of the system that may reasonably be expected to improve drinking water quality; or

(D) entering into a contractual agreement for significant management or administrative functions of the system to correct violations identified in the plan.

(2) Consequences of approval

If the State or the Administrator approves a plan pursuant to paragraph (1), no enforcement action shall be taken pursuant to this part with respect to a specific violation identified in the approved plan prior to the date that is the earlier of the date on which consolidation is completed according to the plan or the date that is 2 years after the plan is approved.

(3) Authority for mandatory assessment

(A) Authority

A State with primary enforcement responsibility or the Administrator (if the State does not have primary enforcement responsibility) may require the owner or operator of a public water system to assess options for consolidation, or transfer of ownership of the system, as described in paragraph (1), or other actions expected to achieve compliance with national primary drinking water regulations described in clause (i)(I), if—

(i) the public water system—

(I) has repeatedly violated one or more national primary drinking water regulations and such repeated violations are likely to adversely affect human health; and

(II)(aa) is unable or unwilling to take feasible and affordable actions, as determined by the State with primary enforcement responsibility or the Administrator (if the State does not have primary enforcement responsibility), that will result in the public water system complying with the national primary drinking water regulations described in subclause (I), including accessing technical assistance and financial assistance through the State loan fund pursuant to section 300j–12 of this title; or

(bb) has already undertaken actions described in item (aa) without achieving compliance;

(ii) such consolidation, transfer, or other action is feasible; and

(iii) such consolidation, transfer, or other action could result in greater compliance with national primary drinking water regulations.

(B) Tailoring of assessments

Requirements for any assessment to be conducted pursuant to subparagraph (A) shall be tailored with respect to the size, type, and characteristics, of the public water system to be assessed.

(C) Approved entities

An assessment conducted pursuant to subparagraph (A) may be conducted by an entity approved by the State requiring such assessment (or the Administrator, if the State does not have primary enforcement responsibility), which may include such State (or the Administrator, as applicable), the public water system, or a third party.

(D) Burden of assessments

It is the sense of Congress that any assessment required pursuant to subparagraph (A) should not be overly burdensome on the public water system that is assessed.

(4) Financial assistance

Notwithstanding section 300j–12(a)(3) of this title, a public water system undertaking consolidation or transfer of ownership or other actions pursuant to an assessment completed under paragraph (3) may receive a loan described in section 300j–12(a)(2)(A) of this title to carry out such consolidation, transfer, or other action.

(5) Protection of nonresponsible system

(A) Identification of liabilities

(i) In general

An owner or operator of a public water system that submits a plan pursuant to paragraph (1) based on an assessment conducted with respect to such public water system under paragraph (3) shall identify as part of such plan—

(I) any potential and existing liability for penalties and damages arising from each specific violation identified in the plan of which the owner or operator is aware; and

(II) any funds or other assets that are available to satisfy such liability, as of the date of submission of such plan, to the public water system that committed such violation.

(ii) Inclusion

In carrying out clause (i), the owner or operator shall take reasonable steps to ensure that all potential and existing liabilities for penalties and damages arising from each specific violation identified in the plan are identified.

(B) Reservation of funds

A public water system that, consistent with the findings of an assessment conducted pursuant to paragraph (3), has completed the actions under a plan submitted and approved pursuant to this subsection shall not be liable under this subchapter for a violation of this subchapter identified in the plan, except to the extent to which funds or other assets are identified pursuant to subparagraph (A)(i)(II) as available to satisfy such liability.

(6) Regulations

Not later than 2 years after October 23, 2018, the Administrator shall promulgate regulations to implement paragraphs (3), (4), and (5).

(i) "Applicable requirement" defined

In this section, the term "applicable requirement" means—

(1) a requirement of section 300g–1, 300g–3, 300g–4, 300g–5, 300g–6, 300i–2, 300j, or 300j–4 of this title;

(2) a regulation promulgated pursuant to a section referred to in paragraph (1);

(3) a schedule or requirement imposed pursuant to a section referred to in paragraph (1); and

(4) a requirement of, or permit issued under, an applicable State program for which the Administrator has made a determination that the requirements of section 300g–2 of this title have been satisfied, or an applicable State program approved pursuant to this part.

(j) Improved accuracy and availability of compliance monitoring data

(1) Strategic plan

Not later than 1 year after October 23, 2018, the Administrator, in coordination with States (including States without primary enforcement responsibility under section 300g–2 of this title), public water systems, and other interested stakeholders, shall develop and provide to Congress a strategic plan for improving the accuracy and availability of monitoring data collected to demonstrate compliance with national primary drinking water regulations and submitted—

(A) by public water systems to States; or

(B) by States to the Administrator.

(2) Evaluation

In developing the strategic plan under paragraph (1), the Administrator shall evaluate any challenges faced—

(A) in ensuring the accuracy and integrity of submitted data described in paragraph (1);

(B) by States and public water systems in implementing an electronic system for submitting such data, including the technical and economic feasibility of implementing such a system; and

(C) by users of such electronic systems in being able to access such data.

(3) Findings and recommendations

The Administrator shall include in the strategic plan provided to Congress under paragraph (1)—

(A) a summary of the findings of the evaluation under paragraph (2); and

(B) recommendations on practicable, cost-effective methods and means that can be employed to improve the accuracy and availability of submitted data described in paragraph (1).

(4) Consultation

In developing the strategic plan under paragraph (1), the Administrator may, as appropriate, consult with States or other Federal agencies that have experience using practicable methods and means to improve the accuracy and availability of submitted data described in such paragraph.

(July 1, 1944, ch. 373, title XIV, §1414, as added Pub. L. 93–523, §2(a), Dec. 16, 1974, 88 Stat. 1666; amended Pub. L. 95–190, §12(b), Nov. 16, 1977, 91 Stat. 1398; Pub. L. 99–339, title I, §§102, 103, June 19, 1986, 100 Stat. 647, 648; Pub. L. 104–182, title I, §§113(a), 114(a), Aug. 6, 1996, 110 Stat. 1634, 1636; Pub. L. 107–188, title IV, §403(1), June 12, 2002, 116 Stat. 687; Pub. L. 114–322, title II, §2106(a), Dec. 16, 2016, 130 Stat. 1722; Pub. L. 115–270, title II, §§2008–2010(a), 2011, Oct. 23, 2018, 132 Stat. 3846, 3847, 3849.)

EDITORIAL NOTES

AMENDMENTS

2018—Subsec. (c)(4)(A). Pub. L. 115–270, §2008(1), (2), substituted "Reports" for "Annual reports" in heading and inserted ", or provide by electronic means," after "to mail" in text.

Subsec. (c)(4)(B)(iv). Pub. L. 115–270, §2008(3)(A), substituted "the Administrator, including corrosion control efforts, and" for "the Administrator, and".

Subsec. (c)(4)(B)(vii). Pub. L. 115–270, §2008(3)(B), which directed amendment of subpar. (B) by adding cl. (vii) at the end, was executed by adding cl. (vii) after cl. (vi) and before concluding provisions, to reflect the probable intent of Congress.

Subsec. (c)(4)(F). Pub. L. 115–270, §2008(4), added subpar. (F).

Subsec. (h)(1)(D). Pub. L. 115–270, §2009(a), added subpar. (D).

Subsec. (h)(3) to (6). Pub. L. 115–270, §2010(a), added pars. (3) to (6).

Subsec. (i)(1). Pub. L. 115–270, §2009(b), inserted a comma after "300g–6".

Subsec. (j). Pub. L. 115–270, §2011, added subsec. (j).

2016—Subsec. (c). Pub. L. 114–322, §2106(a)(1), substituted "Notice to States, the Administrator, and" for "Notice to" in heading.

Subsec. (c)(1)(C). Pub. L. 114–322, §2106(a)(2)(A), substituted "paragraph (2)(F)" for "paragraph (2)(E)".

Subsec. (c)(1)(D). Pub. L. 114–322, §2106(a)(2)(B), added subpar. (D).

Subsec. (c)(2)(B)(i)(II). Pub. L. 114–322, §2106(a)(3)(A), substituted "subparagraph (E)" for "subparagraph (D)".

Subsec. (c)(2)(C). Pub. L. 114–322, §2106(a)(3)(B)(i), (ii), substituted, in heading, "Notice of violations or exceedances" for "Violations" and, in introductory provisions, "each violation, and each exceedance described in paragraph (1)(D)," for "each violation" and "notice of violation or exceedance" for "notice of violation".

Subsec. (c)(2)(C)(i). Pub. L. 114–322, §2106(a)(3)(B)(iii), added cl. (i) and struck out former cl. (i) which read as follows: "be distributed as soon as practicable after the occurrence of the violation, but not later than 24 hours after the occurrence of the violation;".

Subsec. (c)(2)(C)(ii). Pub. L. 114–322, §2106(a)(3)(B)(iv), inserted "or exceedance" after "violation" wherever appearing.

Subsec. (c)(2)(C)(iii). Pub. L. 114–322, §2106(a)(3)(B)(v), added cl. (iii) and struck out former cl. (iii) which read as follows: "be provided to the Administrator or the head of the State agency that has primary enforcement responsibility under section 300g–2 of this title as soon as practicable, but not later than 24 hours after the occurrence of the violation; and".

Subsec. (c)(2)(C)(iv)(I). Pub. L. 114–322, §2106(a)(3)(B)(vi)(I), substituted "media, including broadcast media" for "broadcast media".

Subsec. (c)(2)(C)(iv)(III). Pub. L. 114–322, §2106(a)(3)(B)(vi)(II), struck out "in lieu of notification by means of broadcast media or newspaper" after "notification".

Subsec. (c)(2)(D) to (F). Pub. L. 114–322, §2106(a)(3)(C), (D), added subpar. (D) and redesignated former subpars. (D) and (E) as (E) and (F), respectively.

Subsec. (c)(3)(B). Pub. L. 114–322, §2106(a)(4), substituted "subparagraph (A)," for "subparagraph (A) and" and "subparagraph (C) or (E) of paragraph (2), and notices issued by the Administrator with respect to public water systems serving Indian Tribes under subparagraph (D) of that paragraph" for "subparagraph (C) or (D) of paragraph (2)".

Subsec. (c)(4)(B). Pub. L. 114–322, §2106(a)(5)(C), substituted "clause (iii)(V)" for "subclause (IV) of clause (iii)" in concluding provisions.

Subsec. (c)(4)(B)(ii). Pub. L. 114–322, §2106(a)(5)(A), substituted "the terms 'action level'," for "the terms".

Subsec. (c)(4)(B)(iii). Pub. L. 114–322, §2106(a)(5)(B), added cl. (iii) and struck out former cl. (iii) which read as follows: "If any regulated contaminant is detected in the water purveyed by the public water system, a statement setting forth (I) the maximum contaminant level goal, (II) the maximum contaminant level, (III) the level of such contaminant in such water system, and (IV) for any regulated contaminant for which there has been a violation of the maximum contaminant level during the year concerned, the brief statement in plain language regarding the health concerns that resulted in regulation of such contaminant, as provided by the Administrator in regulations under subparagraph (A)."

Subsec. (c)(5), (6). Pub. L. 114–322, §2106(a)(6), added pars. (5) and (6).

2002—Subsec. (i)(1). Pub. L. 107–188 inserted "300i–2" after "300g–6".

1996—Subsec. (a)(1)(A). Pub. L. 104–182, §113(a)(1)(A)(i)(II), substituted "with the requirement" for "with such regulation or requirement" in concluding provisions.

Subsec. (a)(1)(A)(i). Pub. L. 104–182, §113(a)(1)(A)(i)(I), substituted "any applicable requirement" for "any national primary drinking water regulation in effect under section 300g–1 of this title".

Subsec. (a)(1)(B). Pub. L. 104–182, §113(a)(1)(A)(ii), substituted "such applicable requirement" for "such regulation or requirement".

Subsec. (a)(2). Pub. L. 104–182, §113(a)(1)(B), added par. (2) and struck out former par. (2) which read as follows: "Whenever, on the basis of information available to him, the Administrator finds during a period during which a State does not have primary enforcement responsibility for public water systems that a public water system in such State—

"(A) for which a variance under section 300g–4(a)(2) or an exemption under section 300g–5(f) of this title is not in effect, does not comply with any national primary drinking water regulation in effect under section 300g–1 of this title, or

"(B) for which a variance under section 300g–4(a)(2) or an exemption under section 300g–5(f) of this title is in effect, does not comply with any schedule or other requirement imposed pursuant thereto,

the Administrator shall issue an order under subsection (g) of this section requiring the public water system to comply with such regulation or requirement or the Administrator shall commence a civil action under subsection (b) of this section."

Subsec. (b). Pub. L. 104–182, §113(a)(2), substituted "any applicable requirement" for "a national primary drinking water regulation" in introductory provisions.

Subsec. (c). Pub. L. 104–182, §114(a), amended subsec. (c) generally. Prior to amendment, subsec. (c) related to notice of owner or operator of public water system to persons served, regulations for form, manner, and frequency of notice, amendment of regulations to provide different types and frequencies of notice, and penalties.

Subsec. (g)(1). Pub. L. 104–182, §113(a)(3)(A), substituted "applicable requirement" for "regulation, schedule, or other requirement" in two places.

Subsec. (g)(2). Pub. L. 104–182, §113(a)(3)(B), substituted "effect, in the case" for "effect until after notice and opportunity for public hearing and, in the case" and "regarding the order" for "regarding the proposed order" and struck out "proposed to be" after "A copy of any order".

Subsec. (g)(3)(B). Pub. L. 104–182, §113(a)(3)(C)(i), added subpar. (B) and struck out former subpar. (B) which read as follows: "Whenever any civil penalty sought by the Administrator under this paragraph does not exceed a total of $5,000, the penalty shall be assessed by the Administrator after notice and opportunity for a hearing on the record in accordance with section 554 of title 5."

Subsec. (g)(3)(C). Pub. L. 104–182, §113(a)(3)(C)(ii), substituted "subsection for a violation of an applicable requirement exceeds $25,000" for "paragraph exceeds $5,000".

Subsecs. (h), (i). Pub. L. 104–182, §113(a)(4), added subsecs. (h) and (i).

1986—Pub. L. 99–339, §102(d)(2), substituted "Enforcement" for "Failure of State to assure enforcement" in section catchline.

Subsec. (a)(1)(A). Pub. L. 99–339, §102(a), inserted "and such public water system" after "notify the State" in provisions following cl. (ii).

Subsec. (a)(1)(B). Pub. L. 99–339, §102(b)(1), amended subpar. (B) generally, substituting provisions which relate to issuance of an order to public water system to comply with regulations, or commencement of civil action if the State has not commenced appropriate enforcement action for provisions which related to public notice of noncompliance and commencement of civil action by Administrator if State failed to take steps to obtain compliance by public water system.

Subsec. (a)(2). Pub. L. 99–339, §102(b)(2), substituted "the Administrator shall issue an order under subsection (g) of this section requiring the public water system to comply with such regulation or requirement or the Administrator shall commence a civil action under subsection (b) of this section" for "he may commence a civil action under subsection (b) of this section".

Subsec. (b). Pub. L. 99–339, §102(c), inserted ", with an order issued under subsection (g)," before "or with any schedule" and substituted "there has been a violation" for "there has been a willful violation" and "$25,000" for "$5,000".

Subsec. (c). Pub. L. 99–339, §103, substituted provisions relating to amendment of regulations within fifteen months after June 19, 1986, to provide different types and frequencies of notice based on the differences between violations which are intermittent or continuous, manner and content of notices, notice required to public served by owner or operator of public water system, and civil penalty of $25,000, for provisions relating to form, manner, and frequency of notice based on three month billing period for water bills, notice required to public served by owner or operator of public water system, and civil penalty of $5,000.

Subsec. (g). Pub. L. 99–339, §102(d), added subsec. (g).

1977—Subsec. (c). Pub. L. 95–190 inserted provisions relating to frequency of required notice, and notice respecting contaminant levels, and substituted "issued under this subsection" for "thereunder".

§300g–4. Variances

(a) Characteristics of raw water sources; specific treatment technique; notice to Administrator, reasons for variance; compliance, enforcement; approval or revision of schedules and revocation of variances; review of variances and schedules; publication in Federal Register, notice and results of review; notice to State; considerations respecting abuse of discretion in granting variances or failing to prescribe schedules; State corrective action; authority of Administrator in a State without primary enforcement responsibility; alternative treatment techniques

Notwithstanding any other provision of this part, variances from national primary drinking water regulations may be granted as follows:

(1)(A) A State which has primary enforcement responsibility for public water systems may grant one or more variances from an applicable national primary drinking water regulation to one

or more public water systems within its jurisdiction which, because of characteristics of the raw water sources which are reasonably available to the systems, cannot meet the requirements respecting the maximum contaminant levels of such drinking water regulation. A variance may be issued to a system on condition that the system install the best technology, treatment techniques, or other means, which the Administrator finds are available (taking costs into consideration), and based upon an evaluation satisfactory to the State that indicates that alternative sources of water are not reasonably available to the system. The Administrator shall propose and promulgate his finding of the best available technology, treatment techniques or other means available for each contaminant for purposes of this subsection at the time he proposes and promulgates a maximum contaminant level for each such contaminant. The Administrator's finding of best available technology, treatment techniques or other means for purposes of this subsection may vary depending on the number of persons served by the system or for other physical conditions related to engineering feasibility and costs of compliance with maximum contaminant levels as considered appropriate by the Administrator. Before a State may grant a variance under this subparagraph, the State must find that the variance will not result in an unreasonable risk to health. If a State grants a public water system a variance under this subparagraph, the State shall prescribe at the the [1] time the variance is granted, a schedule for—

(i) compliance (including increments of progress) by the public water system with each contaminant level requirement with respect to which the variance was granted, and

(ii) implementation by the public water system of such additional control measures as the State may require for each contaminant, subject to such contaminant level requirement, during the period ending on the date compliance with such requirement is required.

Before a schedule prescribed by a State pursuant to this subparagraph may take effect, the State shall provide notice and opportunity for a public hearing on the schedule. A notice given pursuant to the preceding sentence may cover the prescribing of more than one such schedule and a hearing held pursuant to such notice shall include each of the schedules covered by the notice. A schedule prescribed pursuant to this subparagraph for a public water system granted a variance shall require compliance by the system with each contaminant level requirement with respect to which the variance was granted as expeditiously as practicable (as the State may reasonably determine).

(B) A State which has primary enforcement responsibility for public water systems may grant to one or more public water systems within its jurisdiction one or more variances from any provision of a national primary drinking water regulation which requires the use of a specified treatment technique with respect to a contaminant if the public water system applying for the variance demonstrates to the satisfaction of the State that such treatment technique is not necessary to protect the health of persons because of the nature of the raw water source of such system. A variance granted under this subparagraph shall be conditioned on such monitoring and other requirements as the Administrator may prescribe.

(C) Before a variance proposed to be granted by a State under subparagraph (A) or (B) may take effect, such State shall provide notice and opportunity for public hearing on the proposed variance. A notice given pursuant to the preceding sentence may cover the granting of more than one variance and a hearing held pursuant to such notice shall include each of the variances covered by the notice. The State shall promptly notify the Administrator of all variances granted by it. Such notification shall contain the reason for the variance (and in the case of a variance under subparagraph (A), the basis for the finding required by that subparagraph before the granting of the variance) and documentation of the need for the variance.

(D) Each public water system's variance granted by a State under subparagraph (A) shall be conditioned by the State upon compliance by the public water system with the schedule prescribed by the State pursuant to that subparagraph. The requirements of each schedule prescribed by a State pursuant to that subparagraph shall be enforceable by the State under its laws. Any requirement of a schedule on which a variance granted under that subparagraph is conditioned may be enforced under section 300g–3 of this title as if such requirement was part of a national primary drinking water regulation.

(E) Each schedule prescribed by a State pursuant to subparagraph (A) shall be deemed approved by the Administrator unless the variance for which it was prescribed is revoked by the Administrator under subparagraph (G) or the schedule is revised by the Administrator under such subparagraph.

(F) Not later than 18 months after the effective date of the interim national primary drinking water regulations the Administrator shall complete a comprehensive review of the variances granted under subparagraph (A) (and schedules prescribed pursuant thereto) and under subparagraph (B) by the States during the one-year period beginning on such effective date. The Administrator shall conduct such subsequent reviews of variances and schedules as he deems necessary to carry out the purposes of this subchapter, but each subsequent review shall be completed within each 3-year period following the completion of the first review under this subparagraph. Before conducting any review under this subparagraph, the Administrator shall publish notice of the proposed review in the Federal Register. Such notice shall (i) provide information respecting the location of data and other information respecting the variances to be reviewed (including data and other information concerning new scientific matters bearing on such variances), and (ii) advise of the opportunity to submit comments on the variances reviewed and on the need for continuing them. Upon completion of any such review, the Administrator shall publish in the Federal Register the results of his review together with findings responsive to comments submitted in connection with such review.

(G)(i) If the Administrator finds that a State has, in a substantial number of instances, abused its discretion in granting variances under subparagraph (A) or (B) or that in a substantial number of cases the State has failed to prescribe schedules in accordance with subparagraph (A), the Administrator shall notify the State of his findings. In determining if a State has abused its discretion in granting variances in a substantial number of instances, the Administrator shall consider the number of persons who are affected by the variances and if the requirements applicable to the granting of the variances were complied with. A notice under this clause shall—

(I) identify each public water system with respect to which the finding was made,

(II) specify the reasons for the finding, and

(III) as appropriate, propose revocations of specific variances or propose revised schedules or other requirements for specific public water systems granted variances, or both.

(ii) The Administrator shall provide reasonable notice and public hearing on the provisions of each notice given pursuant to clause (i) of this subparagraph. After a hearing on a notice pursuant to such clause, the Administrator shall (I) rescind the finding for which the notice was given and promptly notify the State of such rescission, or (II) promulgate (with such modifications as he deems appropriate) such variance revocations and revised schedules or other requirements proposed in such notice as he deems appropriate. Not later than 180 days after the date a notice is given pursuant to clause (i) of this subparagraph, the Administrator shall complete the hearing on the notice and take the action required by the preceding sentence.

(iii) If a State is notified under clause (i) of this subparagraph of a finding of the Administrator made with respect to a variance granted a public water system within that State or to a schedule or other requirement for a variance and if, before a revocation of such variance or a revision of such schedule or other requirement promulgated by the Administrator takes effect, the State takes corrective action with respect to such variance or schedule or other requirement which the Administrator determines makes his finding inapplicable to such variance or schedule or other requirement, the Administrator shall rescind the application of his finding to that variance or schedule or other requirement. No variance revocation or revised schedule or other requirement may take effect before the expiration of 90 days following the date of the notice in which the revocation or revised schedule or other requirement was proposed.

(2) If a State does not have primary enforcement responsibility for public water systems, the Administrator shall have the same authority to grant variances in such State as the State would have under paragraph (1) if it had primary enforcement responsibility.

(3) The Administrator may grant a variance from any treatment technique requirement of a

national primary drinking water regulation upon a showing by any person that an alternative treatment technique not included in such requirement is at least as efficient in lowering the level of the contaminant with respect to which such requirement was prescribed. A variance under this paragraph shall be conditioned on the use of the alternative treatment technique which is the basis of the variance.

(b) Enforcement of schedule or other requirement

Any schedule or other requirement on which a variance granted under paragraph (1)(B) or (2) of subsection (a) is conditioned may be enforced under section 300g–3 of this title as if such schedule or other requirement was part of a national primary drinking water regulation.

(c) Applications for variances; regulations: reasonable time for acting

If an application for a variance under subsection (a) is made, the State receiving the application or the Administrator, as the case may be, shall act upon such application within a reasonable period (as determined under regulations prescribed by the Administrator) after the date of its submission.

(d) "Treatment technique requirement" defined

For purposes of this section, the term "treatment technique requirement" means a requirement in a national primary drinking water regulation which specifies for a contaminant (in accordance with section 300f(1)(C)(ii) of this title) each treatment technique known to the Administrator which leads to a reduction in the level of such contaminant sufficient to satisfy the requirements of section 300g–1(b) of this title.

(e) Small system variances

(1) In general

A State exercising primary enforcement responsibility for public water systems under section 300g–2 of this title (or the Administrator in nonprimacy States) may grant a variance under this subsection for compliance with a requirement specifying a maximum contaminant level or treatment technique contained in a national primary drinking water regulation to—

(A) public water systems serving 3,300 or fewer persons; and

(B) with the approval of the Administrator pursuant to paragraph (9), public water systems serving more than 3,300 persons but fewer than 10,000 persons,

if the variance meets each requirement of this subsection.

(2) Availability of variances

A public water system may receive a variance pursuant to paragraph (1), if—

(A) the Administrator has identified a variance technology under section 300g–1(b)(15) of this title that is applicable to the size and source water quality conditions of the public water system;

(B) the public water system installs, operates, and maintains, in accordance with guidance or regulations issued by the Administrator, such treatment technology, treatment technique, or other means; and

(C) the State in which the system is located determines that the conditions of paragraph (3) are met.

(3) Conditions for granting variances

A variance under this subsection shall be available only to a system—

(A) that cannot afford to comply, in accordance with affordability criteria established by the Administrator (or the State in the case of a State that has primary enforcement responsibility under section 300g–2 of this title), with a national primary drinking water regulation, including compliance through—

(i) treatment;

(ii) alternative source of water supply; or

(iii) restructuring or consolidation (unless the Administrator (or the State in the case of a

State that has primary enforcement responsibility under section 300g–2 of this title) makes a written determination that restructuring or consolidation is not practicable); and

(B) for which the Administrator (or the State in the case of a State that has primary enforcement responsibility under section 300g–2 of this title) determines that the terms of the variance ensure adequate protection of human health, considering the quality of the source water for the system and the removal efficiencies and expected useful life of the treatment technology required by the variance.

(4) Compliance schedules

A variance granted under this subsection shall require compliance with the conditions of the variance not later than 3 years after the date on which the variance is granted, except that the Administrator (or the State in the case of a State that has primary enforcement responsibility under section 300g–2 of this title) may allow up to 2 additional years to comply with a variance technology, secure an alternative source of water, restructure or consolidate if the Administrator (or the State) determines that additional time is necessary for capital improvements, or to allow for financial assistance provided pursuant to section 300j–12 of this title or any other Federal or State program.

(5) Duration of variances

The Administrator (or the State in the case of a State that has primary enforcement responsibility under section 300g–2 of this title) shall review each variance granted under this subsection not less often than every 5 years after the compliance date established in the variance to determine whether the system remains eligible for the variance and is conforming to each condition of the variance.

(6) Ineligibility for variances

A variance shall not be available under this subsection for—

(A) any maximum contaminant level or treatment technique for a contaminant with respect to which a national primary drinking water regulation was promulgated prior to January 1, 1986; or

(B) a national primary drinking water regulation for a microbial contaminant (including a bacterium, virus, or other organism) or an indicator or treatment technique for a microbial contaminant.

(7) Regulations and guidance

(A) In general

Not later than 2 years after August 6, 1996, and in consultation with the States, the Administrator shall promulgate regulations for variances to be granted under this subsection. The regulations shall, at a minimum, specify—

(i) procedures to be used by the Administrator or a State to grant or deny variances, including requirements for notifying the Administrator and consumers of the public water system that a variance is proposed to be granted (including information regarding the contaminant and variance) and requirements for a public hearing on the variance before the variance is granted;

(ii) requirements for the installation and proper operation of variance technology that is identified (pursuant to section 300g–1(b)(15) of this title) for small systems and the financial and technical capability to operate the treatment system, including operator training and certification;

(iii) eligibility criteria for a variance for each national primary drinking water regulation, including requirements for the quality of the source water (pursuant to section 300g–1(b)(15)(A) of this title); and

(iv) information requirements for variance applications.

(B) Affordability criteria

Not later than 18 months after August 6, 1996, the Administrator, in consultation with the States and the Rural Utilities Service of the Department of Agriculture, shall publish information to assist the States in developing affordability criteria. The affordability criteria shall be reviewed by the States not less often than every 5 years to determine if changes are needed to the criteria.

(8) Review by the Administrator

(A) In general

The Administrator shall periodically review the program of each State that has primary enforcement responsibility for public water systems under section 300g–2 of this title with respect to variances to determine whether the variances granted by the State comply with the requirements of this subsection. With respect to affordability, the determination of the Administrator shall be limited to whether the variances granted by the State comply with the affordability criteria developed by the State.

(B) Notice and publication

If the Administrator determines that variances granted by a State are not in compliance with affordability criteria developed by the State and the requirements of this subsection, the Administrator shall notify the State in writing of the deficiencies and make public the determination.

(9) Approval of variances

A State proposing to grant a variance under this subsection to a public water system serving more than 3,300 and fewer than 10,000 persons shall submit the variance to the Administrator for review and approval prior to the issuance of the variance. The Administrator shall approve the variance if it meets each of the requirements of this subsection. The Administrator shall approve or disapprove the variance within 90 days. If the Administrator disapproves a variance under this paragraph, the Administrator shall notify the State in writing of the reasons for disapproval and the variance may be resubmitted with modifications to address the objections stated by the Administrator.

(10) Objections to variances

(A) By the Administrator

The Administrator may review and object to any variance proposed to be granted by a State, if the objection is communicated to the State not later than 90 days after the State proposes to grant the variance. If the Administrator objects to the granting of a variance, the Administrator shall notify the State in writing of each basis for the objection and propose a modification to the variance to resolve the concerns of the Administrator. The State shall make the recommended modification or respond in writing to each objection. If the State issues the variance without resolving the concerns of the Administrator, the Administrator may overturn the State decision to grant the variance if the Administrator determines that the State decision does not comply with this subsection.

(B) Petition by consumers

Not later than 30 days after a State exercising primary enforcement responsibility for public water systems under section 300g–2 of this title proposes to grant a variance for a public water system, any person served by the system may petition the Administrator to object to the granting of a variance. The Administrator shall respond to the petition and determine whether to object to the variance under subparagraph (A) not later than 60 days after the receipt of the petition.

(C) Timing

No variance shall be granted by a State until the later of the following:

(i) 90 days after the State proposes to grant a variance.

(ii) If the Administrator objects to the variance, the date on which the State makes the

recommended modifications or responds in writing to each objection.

(July 1, 1944, ch. 373, title XIV, §1415, as added Pub. L. 93–523, §2(a), Dec. 16, 1974, 88 Stat. 1669; amended Pub. L. 99–339, title I, §104, June 19, 1986, 100 Stat. 649; Pub. L. 104–182, title I, §§102(c)(1), 115, 116, title V, §501(a)(3), Aug. 6, 1996, 110 Stat. 1621, 1641, 1691.)

EDITORIAL NOTES

AMENDMENTS

1996—Subsec. (a)(1)(A). Pub. L. 104–182, §501(a)(3), inserted "the" before "time the variance is granted," in introductory provisions.

Pub. L. 104–182, §115, in second sentence, substituted "be issued to a system on condition that the system install" for "only be issued to a system after the system's application of" and inserted ", and based upon an evaluation satisfactory to the State that indicates that alternative sources of water are not reasonably available to the system" after "(taking costs into consideration)".

Subsec. (d). Pub. L. 104–182, §102(c)(1), substituted "section 300g–1(b)" for "section 300g–1(b)(3)".

Subsec. (e). Pub. L. 104–182, §116, added subsec. (e).

1986—Subsec. (a)(1)(A). Pub. L. 99–339, §104(1)–(3), substituted "such drinking water regulation. A variance may only be issued to a system after the system's application" for "such drinking water regulation despite application", struck out "generally" after "finds are", inserted provisions relating to proposal and promulgation by Administrator of a finding on best available technology, treatment techniques or other means available for each contaminant at time of proposal and promulgation of maximum contaminant levels, and substituted "at the time" for "within one year of the date".

Subsec. (a)(1)(A)(ii). Pub. L. 99–339, §104(4), substituted "water system of such additional control" for "water system of such control".

[1] *So in original.*

§300g–5. Exemptions

(a) Requisite findings

A State which has primary enforcement responsibility may exempt any public water system within the State's jurisdiction from any requirement respecting a maximum contaminant level or any treatment technique requirement, or from both, of an applicable national primary drinking water regulation upon a finding that—

(1) due to compelling factors (which may include economic factors, including qualification of the public water system as a system serving a disadvantaged community pursuant to section 300j–12(d) of this title), the public water system is unable to comply with such contaminant level or treatment technique requirement, or to implement measures to develop an alternative source of water supply,

(2) the public water system was in operation on the effective date of such contaminant level or treatment technique requirement, or, for a system that was not in operation by that date, only if no reasonable alternative source of drinking water is available to such new system,

(3) the granting of the exemption will not result in an unreasonable risk to health; [1] and

(4) management or restructuring changes (or both) cannot reasonably be made that will result in compliance with this subchapter or, if compliance cannot be achieved, improve the quality of the drinking water.

(b) Compliance schedule and implementation of control measures; notice and hearing; dates for compliance with schedule; compliance, enforcement; approval or revision of schedules and revocation of exemptions

(1) If a State grants a public water system an exemption under subsection (a), the State shall prescribe, at the time the exemption is granted, a schedule for—

(A) compliance (including increments of progress or measures to develop an alternative source

of water supply) by the public water system with each contaminant level requirement or treatment technique requirement with respect to which the exemption was granted, and

(B) implementation by the public water system of such control measures as the State may require for each contaminant, subject to such contaminant level requirement or treatment technique requirement, during the period ending on the date compliance with such requirement is required.

Before a schedule prescribed by a State pursuant to this subsection may take effect, the State shall provide notice and opportunity for a public hearing on the schedule. A notice given pursuant to the preceding sentence may cover the prescribing of more than one such schedule and a hearing held pursuant to such notice shall include each of the schedules covered by the notice.

(2)(A) A schedule prescribed pursuant to this subsection for a public water system granted an exemption under subsection (a) shall require compliance by the system with each contaminant level and treatment technique requirement with respect to which the exemption was granted as expeditiously as practicable (as the State may reasonably determine) but not later than 3 years after the otherwise applicable compliance date established in section 300g–1(b)(10) of this title.

(B) No exemption shall be granted unless the public water system establishes that—

(i) the system cannot meet the standard without capital improvements which cannot be completed prior to the date established pursuant to section 300g–1(b)(10) of this title;

(ii) in the case of a system which needs financial assistance for the necessary improvements, the system has entered into an agreement to obtain such financial assistance or assistance pursuant to section 300j–12 of this title, or any other Federal or State program is reasonably likely to be available within the period of the exemption; or

(iii) the system has entered into an enforceable agreement to become a part of a regional public water system; and

the system is taking all practicable steps to meet the standard.

(C) In the case of a system which does not serve more than a population of 3,300 and which needs financial assistance for the necessary improvements, an exemption granted under clause (i) or (ii) of subparagraph (B) may be renewed for one or more additional 2-year periods, but not to exceed a total of 6 years, if the system establishes that it is taking all practicable steps to meet the requirements of subparagraph (B).

(D) LIMITATION.—A public water system may not receive an exemption under this section if the system was granted a variance under section 300g–4(e) of this title.

(3) Each public water system's exemption granted by a State under subsection (a) shall be conditioned by the State upon compliance by the public water system with the schedule prescribed by the State pursuant to this subsection. The requirements of each schedule prescribed by a State pursuant to this subsection shall be enforceable by the State under its laws. Any requirement of a schedule on which an exemption granted under this section is conditioned may be enforced under section 300g–3 of this title as if such requirement was part of a national primary drinking water regulation.

(4) Each schedule prescribed by a State pursuant to this subsection shall be deemed approved by the Administrator unless the exemption for which it was prescribed is revoked by the Administrator under subsection (d)(2) or the schedule is revised by the Administrator under such subsection.

(c) Notice to Administrator; reasons for exemption

Each State which grants an exemption under subsection (a) shall promptly notify the Administrator of the granting of such exemption. Such notification shall contain the reasons for the exemption (including the basis for the finding required by subsection (a)(3) before the exemption may be granted) and document the need for the exemption.

(d) Review of exemptions and schedules; publication in Federal Register, notice and results of review; notice to State; considerations respecting abuse of discretion in granting exemptions or failing to prescribe schedules; State corrective action

(1) Not later than 18 months after the effective date of the interim national primary drinking water regulations the Administrator shall complete a comprehensive review of the exemptions granted (and schedules prescribed pursuant thereto) by the States during the one-year period beginning on such effective date. The Administrator shall conduct such subsequent reviews of exemptions and schedules as he deems necessary to carry out the purposes of this subchapter, but each subsequent review shall be completed within each 3-year period following the completion of the first review under this subparagraph. Before conducting any review under this subparagraph, the Administrator shall publish notice of the proposed review in the Federal Register. Such notice shall (A) provide information respecting the location of data and other information respecting the exemptions to be reviewed (including data and other information concerning new scientific matters bearing on such exemptions), and (B) advise of the opportunity to submit comments on the exemptions reviewed and on the need for continuing them. Upon completion of any such review, the Administrator shall publish in the Federal Register the results of his review, together with findings responsive to comments submitted in connection with such review.

(2)(A) If the Administrator finds that a State has, in a substantial number of instances, abused its discretion in granting exemptions under subsection (a) or failed to prescribe schedules in accordance with subsection (b), the Administrator shall notify the State of his findings. In determining if a State has abused its discretion in granting exemptions in a substantial number of instances, the Administrator shall consider the number of persons who are affected by the exemptions and if the requirements applicable to the granting of the exemptions were complied with. A notice under this subparagraph shall—

(i) identify each exempt public water system with respect to which the finding was made,

(ii) specify the reasons for the finding, and

(iii) as appropriate, propose revocations of specific exemptions or propose revised schedules for specific exempt public water systems, or both.

(B) The Administrator shall provide reasonable notice and public hearing on the provisions of each notice given pursuant to subparagraph (A). After a hearing on notice pursuant to subparagraph (A), the Administrator shall (i) rescind the finding for which the notice was given and promptly notify the State of such rescission, or (ii) promulgate (with such modifications as he deems appropriate) such exemption revocations and revised schedules proposed in such notice as he deems appropriate. Not later than 180 days after the date a notice is given pursuant to subparagraph (A), the Administrator shall complete the hearing on the notice and take the action required by the preceding sentence.

(C) If a State is notified under subparagraph (A) of a finding of the Administrator made with respect to an exemption granted a public water system within that State or to a schedule prescribed pursuant to such an exemption and if before a revocation of such exemption or a revision of such schedule promulgated by the Administrator takes effect the State takes corrective action with respect to such exemption or schedule which the Administrator determines makes his finding inapplicable to such exemption or schedule, the Administrator shall rescind the application of his finding to that exemption or schedule. No exemption revocation or revised schedule may take effect before the expiration of 90 days following the date of the notice in which the revocation or revised schedule was proposed.

(e) "Treatment technique requirement" defined

For purposes of this section, the term "treatment technique requirement" means a requirement in a national primary drinking water regulation which specifies for a contaminant (in accordance with section 300f(1)(C)(ii) of this title) each treatment technique known to the Administrator which leads to a reduction in the level of such contaminant sufficient to satisfy the requirements of section 300g–1(b) of this title.

(f) Authority of Administrator in a State without primary enforcement responsibility

If a State does not have primary enforcement responsibility for public water systems, the Administrator shall have the same authority to exempt public water systems in such State from

maximum contaminant level requirements and treatment technique requirements under the same conditions and in the same manner as the State would be authorized to grant exemptions under this section if it had primary enforcement responsibility.

(g) Applications for exemptions; regulations; reasonable time for acting

If an application for an exemption under this section is made, the State receiving the application or the Administrator, as the case may be, shall act upon such application within a reasonable period (as determined under regulations prescribed by the Administrator) after the date of its submission.

(July 1, 1944, ch. 373, title XIV, §1416, as added Pub. L. 93–523, §2(a), Dec. 16, 1974, 88 Stat. 1672; amended Pub. L. 95–190, §10(a), Nov. 16, 1977, 91 Stat. 1398; Pub. L. 96–502, §§1, 4(b), Dec. 5, 1980, 94 Stat. 2737, 2738; Pub. L. 99–339, title I, §§101(c)(4), 105, June 19, 1986, 100 Stat. 646, 649; Pub. L. 104–182, title I, §117(a), Aug. 6, 1996, 110 Stat. 1644.)

EDITORIAL NOTES

AMENDMENTS

1996—Subsec. (a)(1). Pub. L. 104–182, §117(a)(1), inserted ", including qualification of the public water system as a system serving a disadvantaged community pursuant to section 300j–12(d) of this title" after "(which may include economic factors" and "or to implement measures to develop an alternative source of water supply," after "treatment technique requirement,".

Subsec. (a)(4). Pub. L. 104–182, §117(a)(2), added par. (4).

Subsec. (b)(1)(A). Pub. L. 104–182, §117(a)(3), substituted "(including increments of progress or measures to develop an alternative source of water supply)" for "(including increments of progress)" and "requirement or treatment" for "requirement and treatment".

Subsec. (b)(2)(A). Pub. L. 104–182, §117(a)(4)(A), substituted "not later than 3 years after the otherwise applicable compliance date established in section 300g–1(b)(10) of this title." for "(except as provided in subparagraph (B))—

"(i) in the case of an exemption granted with respect to a contaminant level or treatment technique requirement prescribed by the national primary drinking water regulations promulgated under section 300g–1(a) of this title, not later than 12 months after June 19, 1986; and

"(ii) in the case of an exemption granted with respect to a contaminant level or treatment technique requirement prescribed by national primary drinking water regulations, other than a regulation referred to in section 300g–1(a) of this title, 12 months after the date of the issuance of the exemption."

Subsec. (b)(2)(B). Pub. L. 104–182, §117(a)(4)(A), substituted "No exemption shall be granted unless" for "The final date for compliance provided in any schedule in the case of any exemption may be extended by the State (in the case of a State which has primary enforcement responsibility) or by the Administrator (in any other case) for a period not to exceed 3 years after the date of the issuance of the exemption if" in introductory provisions.

Subsec. (b)(2)(B)(i). Pub. L. 104–182, §117(a)(4)(B), substituted "prior to the date established pursuant to section 300g–1(b)(10) of this title" for "within the period of such exemption".

Subsec. (b)(2)(B)(ii). Pub. L. 104–182, §117(a)(4)(C), inserted "or assistance pursuant to section 300j–12 of this title, or any other Federal or State program is reasonably likely to be available within the period of the exemption" after "such financial assistance".

Subsec. (b)(2)(C). Pub. L. 104–182, §117(a)(4)(D), substituted "a population of 3,300" for "500 service connections" and inserted ", but not to exceed a total of 6 years," after "for one or more additional 2-year periods".

Subsec. (b)(2)(D). Pub. L. 104–182, §117(a)(4)(E), added subpar. (D).

1986—Subsec. (b)(1). Pub. L. 99–339, §105(a)(1), substituted "at the time" for "within one year of the date".

Subsec. (b)(2)(A)(i). Pub. L. 99–339, §105(a)(2), struck out "interim" before "national primary" and substituted "not later than 12 months after June 19, 1986" for "not later than January 1, 1984".

Subsec. (b)(2)(A)(ii). Pub. L. 99–339, §105(a)(3), struck out "revised" before "national primary" and substituted "other than a regulation referred to in section 300g–1(a) of this title, 12 months after the date of the issuance of the exemption" for "not later than seven years after the date such requirement takes effect".

Subsec. (b)(2)(B). Pub. L. 99–339, §105(a)(4), amended subpar. (B) generally. Prior to amendment, subpar. (B) read as follows: "Notwithstanding clauses (i) and (ii) of subparagraph (A) of this paragraph, the final date for compliance prescribed in a schedule prescribed pursuant to this subsection for an exemption granted for a

public water system which (as determined by the State granting the exemption) has entered into an enforceable agreement to become a part of a regional public water system shall—

"(i) in the case of a schedule prescribed for an exemption granted with respect to a contaminant level or treatment technique requirement prescribed by interim national primary drinking water regulations, be not later than January 1, 1986; and

"(ii) in the case of a schedule prescribed for an exemption granted with respect to a contaminant level or treatment technique requirement prescribed by revised national primary drinking water regulations, be not later than nine years after such requirement takes effect."

Subsec. (b)(2)(C). Pub. L. 99–339, §105(a)(4), added subpar. (C).

Subsec. (e). Pub. L. 99–339, §101(c)(4), substituted "300g–1(b)" for "300g–1(b)(3)".

1980—Subsec. (a)(2). Pub. L. 96–502, §4(b), substituted "treatment technique requirement, or, for a system that was not in operation by that date, only if no reasonable alternative source of drinking water is available to such new system, and" for "treatment technique requirement, and".

Subsec. (b)(2)(A)(i). Pub. L. 96–502, §1, substituted "January 1, 1984" for "January 1, 1981".

Subsec. (b)(2)(B)(i). Pub. L. 96–502, §1, substituted "January 1, 1986" for "January 1, 1983".

1977—Subsec. (b)(1). Pub. L. 95–190 substituted "contaminant" for "containment" wherever appearing.

[1] *So in original. The semicolon probably should be a comma.*

§300g–6. Prohibition on use of lead pipes, solder, and flux

(a) In general

(1) Prohibitions

(A) In general

No person may use any pipe, any pipe or plumbing fitting or fixture, any solder, or any flux, after June 19, 1986, in the installation or repair of—

(i) any public water system; or

(ii) any plumbing in a residential or nonresidential facility providing water for human consumption,

that is not lead free (within the meaning of subsection (d)).

(B) Leaded joints

Subparagraph (A) shall not apply to leaded joints necessary for the repair of cast iron pipes.

(2) Public notice requirements

(A) In general

Each owner or operator of a public water system shall identify and provide notice to persons that may be affected by lead contamination of their drinking water where such contamination results from either or both of the following:

(i) The lead content in the construction materials of the public water distribution system.

(ii) Corrosivity of the water supply sufficient to cause leaching of lead.

The notice shall be provided in such manner and form as may be reasonably required by the Administrator. Notice under this paragraph shall be provided notwithstanding the absence of a violation of any national drinking water standard.

(B) Contents of notice

Notice under this paragraph shall provide a clear and readily understandable explanation of—

(i) the potential sources of lead in the drinking water,

(ii) potential adverse health effects,

(iii) reasonably available methods of mitigating known or potential lead content in drinking water,

(iv) any steps the system is taking to mitigate lead content in drinking water, and
(v) the necessity for seeking alternative water supplies, if any.

(3) Unlawful acts

Effective 2 years after August 6, 1996, it shall be unlawful—

(A) for any person to introduce into commerce any pipe, or any pipe or plumbing fitting or fixture, that is not lead free, except for a pipe that is used in manufacturing or industrial processing;

(B) for any person engaged in the business of selling plumbing supplies, except manufacturers, to sell solder or flux that is not lead free; or

(C) for any person to introduce into commerce any solder or flux that is not lead free unless the solder or flux bears a prominent label stating that it is illegal to use the solder or flux in the installation or repair of any plumbing providing water for human consumption.

(4) Exemptions

The prohibitions in paragraphs (1) and (3) shall not apply to—

(A) pipes, pipe fittings, plumbing fittings, or fixtures, including backflow preventers, that are used exclusively for nonpotable services such as manufacturing, industrial processing, irrigation, outdoor watering, or any other uses where the water is not anticipated to be used for human consumption; or

(B) toilets, bidets, urinals, fill valves, flushometer valves, tub fillers, shower valves, fire hydrants, service saddles, or water distribution main gate valves that are 2 inches in diameter or larger.

(b) State enforcement

(1) Enforcement of prohibition

The requirements of subsection (a)(1) shall be enforced in all States effective 24 months after June 19, 1986. States shall enforce such requirements through State or local plumbing codes, or such other means of enforcement as the State may determine to be appropriate.

(2) Enforcement of public notice requirements

The requirements of subsection (a)(2) shall apply in all States effective 24 months after June 19, 1986.

(c) Penalties

If the Administrator determines that a State is not enforcing the requirements of subsection (a) as required pursuant to subsection (b), the Administrator may withhold up to 5 percent of Federal funds available to that State for State program grants under section 300j–2(a) of this title.

(d) Definition of lead free

(1) In general

For the purposes of this section, the term "lead free" means—

(A) not containing more than 0.2 percent lead when used with respect to solder and flux; and

(B) not more than a weighted average of 0.25 percent lead when used with respect to the wetted surfaces of pipes, pipe fittings, plumbing fittings, and fixtures.

(2) Calculation

The weighted average lead content of a pipe, pipe fitting, plumbing fitting, or fixture shall be calculated by using the following formula: For each wetted component, the percentage of lead in the component shall be multiplied by the ratio of the wetted surface area of that component to the total wetted surface area of the entire product to arrive at the weighted percentage of lead of the component. The weighted percentage of lead of each wetted component shall be added together, and the sum of these weighted percentages shall constitute the weighted average lead content of

the product. The lead content of the material used to produce wetted components shall be used to determine compliance with paragraph (1)(B). For lead content of materials that are provided as a range, the maximum content of the range shall be used.

(e) Plumbing fittings and fixtures

(1) In general

The Administrator shall provide accurate and timely technical information and assistance to qualified third-party certifiers in the development of voluntary standards and testing protocols for the leaching of lead from new plumbing fittings and fixtures that are intended by the manufacturer to dispense water for human ingestion.

(2) Standards

(A) In general

If a voluntary standard for the leaching of lead is not established by the date that is 1 year after August 6, 1996, the Administrator shall, not later than 2 years after August 6, 1996, promulgate regulations setting a health-effects-based performance standard establishing maximum leaching levels from new plumbing fittings and fixtures that are intended by the manufacturer to dispense water for human ingestion. The standard shall become effective on the date that is 5 years after the date of promulgation of the standard.

(B) Alternative requirement

If regulations are required to be promulgated under subparagraph (A) and have not been promulgated by the date that is 5 years after August 6, 1996, no person may import, manufacture, process, or distribute in commerce a new plumbing fitting or fixture, intended by the manufacturer to dispense water for human ingestion, that contains more than 4 percent lead by dry weight.

(f) Public education

(1) In general

The Administrator shall make information available to the public regarding lead in drinking water, including information regarding—

(A) risks associated with lead in drinking water;

(B) the conditions that contribute to drinking water containing lead in a residence;

(C) steps that States, public water systems, and consumers can take to reduce the risks of lead in drinking water; and

(D) the availability of additional resources that consumers can use to minimize lead exposure, including information on sampling for lead in drinking water.

(2) Vulnerable populations

In making information available to the public under this subsection, the Administrator shall, subject to the availability of appropriations, carry out targeted outreach strategies that focus on educating groups within the general population that may be at greater risk than the general population of adverse health effects from exposure to lead in drinking water.

(July 1, 1944, ch. 373, title XIV, §1417, as added Pub. L. 99–339, title I, §109(a), June 19, 1986, 100 Stat. 651; amended Pub. L. 104–182, title I, §118, title V, §501(f)(1), Aug. 6, 1996, 110 Stat. 1645, 1691; Pub. L. 111–380, §2(a), Jan. 4, 2011, 124 Stat. 4131; Pub. L. 113–64, §2, Dec. 20, 2013, 127 Stat. 668; Pub. L. 114–322, title II, §2106(b), Dec. 16, 2016, 130 Stat. 1726.)

EDITORIAL NOTES

AMENDMENTS

2016—Subsec. (f). Pub. L. 114–322 added subsec. (f).

2013—Subsec. (a)(4)(B). Pub. L. 113–64 inserted "fire hydrants," after "shower valves,".

2011—Subsec. (a)(4). Pub. L. 111–380, §2(a)(1), added par. (4).

Subsec. (d). Pub. L. 111–380, §2(a)(2), amended subsec. (d) generally. Prior to amendment, subsec. (d) defined "lead free" when used with respect to solders and flux, pipes and pipe fittings, and plumbing fittings and fixtures.

1996—Pub. L. 104–182, §501(f)(1), made technical amendment to section catchline and subsec. (a) designation.

Subsec. (a)(1). Pub. L. 104–182, §118(1), substituted "Prohibitions" for "Prohibition" in heading and amended text generally. Prior to amendment, text read as follows: "Any pipe, solder, or flux, which is used after June 19, 1986, in the installation or repair of—

"(A) any public water system, or

"(B) any plumbing in a residential or nonresidential facility providing water for human consumption which is connected to a public water system,

shall be lead free (within the meaning of subsection (d) of this section). This paragraph shall not apply to leaded joints necessary for the repair of cast iron pipes."

Subsec. (a)(2)(A). Pub. L. 104–182, §118(2), inserted "owner or operator of a" after "Each" in introductory provisions.

Subsec. (a)(3). Pub. L. 104–182, §118(3), added par. (3).

Subsec. (d)(3). Pub. L. 104–182, §118(4), added par. (3).

Subsec. (e). Pub. L. 104–182, §118(5), added subsec. (e).

STATUTORY NOTES AND RELATED SUBSIDIARIES

EFFECTIVE DATE OF 2011 AMENDMENT

Pub. L. 111–380, §2(b), Jan. 4, 2011, 124 Stat. 4132, provided that: "The provisions of subsections (a)(4) and (d) of section 1417 of the Safe Drinking Water Act [42 U.S.C. 300g–6(a)(4), (d)], as added by this section, apply beginning on the day that is 36 months after the date of the enactment of this Act [Jan. 4, 2011]."

EVALUATION OF SOURCES OF LEAD IN WATER DISTRIBUTION SYSTEMS AND ALTERNATE ROUTING SYSTEMS

Pub. L. 113–64, §3, Dec. 20, 2013, 127 Stat. 668, provided that: "The Administrator of the Environmental Protection Agency shall—

"(1) consult with and seek the advice of the National Drinking Water Advisory Council on potential changes to the regulations pertaining to lead under the Safe Drinking Water Act (42 U.S.C. 300f et seq.); and

"(2) request the Council to consider sources of lead throughout drinking water distribution systems, including through components used to reroute drinking water during distribution system repairs."

NOTIFICATION TO STATES

Pub. L. 99–339, title I, §109(b), June 19, 1986, 100 Stat. 652, provided that: "The Administrator of the Environmental Protection Agency shall notify all States with respect to the requirements of section 1417 of the Public Health Service Act [42 U.S.C. 300g–6] within 90 days after the enactment of this Act [June 19, 1986]."

BAN ON LEAD WATER PIPES, SOLDER, AND FLUX IN VA AND HUD INSURED OR ASSISTED PROPERTY

Pub. L. 99–339, title I, §109(c), June 19, 1986, 100 Stat. 652, as amended by Pub. L. 102–54, §13(q)(2), June 13, 1991, 105 Stat. 279, provided that:

"(1) PROHIBITION.—The Secretary of Housing and Urban Development and the Secretary of Veterans Affairs may not insure or guarantee a mortgage or furnish assistance with respect to newly constructed residential property which contains a potable water system unless such system uses only lead free pipe, solder, and flux.

"(2) DEFINITION OF LEAD FREE.—For purposes of paragraph (1) the term 'lead free'—

"(A) when used with respect to solders and flux refers to solders and flux containing not more than 0.2 percent lead, and

"(B) when used with respect to pipes and pipe fittings refers to pipes and pipe fittings containing not more than 8.0 percent lead.

"(3) EFFECTIVE DATE.—Paragraph (1) shall become effective 24 months after the enactment of this Act [June 19, 1986]."

§300g–7. Monitoring of contaminants

(a) Interim monitoring relief authority

(1) In general

A State exercising primary enforcement responsibility for public water systems may modify the monitoring requirements for any regulated or unregulated contaminants for which monitoring is required other than microbial contaminants (or indicators thereof), disinfectants and disinfection byproducts or corrosion byproducts for an interim period to provide that any public water system serving 10,000 persons or fewer shall not be required to conduct additional quarterly monitoring during an interim relief period for such contaminants if—

(A) monitoring, conducted at the beginning of the period for the contaminant concerned and certified to the State by the public water system, fails to detect the presence of the contaminant in the ground or surface water supplying the public water system; and

(B) the State, considering the hydrogeology of the area and other relevant factors, determines in writing that the contaminant is unlikely to be detected by further monitoring during such period.

(2) Termination; timing of monitoring

The interim relief period referred to in paragraph (1) shall terminate when permanent monitoring relief is adopted and approved for such State, or at the end of 36 months after August 6, 1996, whichever comes first. In order to serve as a basis for interim relief, the monitoring conducted at the beginning of the period must occur at the time determined by the State to be the time of the public water system's greatest vulnerability to the contaminant concerned in the relevant ground or surface water, taking into account in the case of pesticides the time of application of the pesticide for the source water area and the travel time for the pesticide to reach such waters and taking into account, in the case of other contaminants, seasonality of precipitation and contaminant travel time.

(b) Permanent monitoring relief authority

(1) In general

Each State exercising primary enforcement responsibility for public water systems under this subchapter and having an approved source water assessment program may adopt, in accordance with guidance published by the Administrator, tailored alternative monitoring requirements for public water systems in such State (as an alternative to the monitoring requirements for chemical contaminants set forth in the applicable national primary drinking water regulations) where the State concludes that (based on data available at the time of adoption concerning susceptibility, use, occurrence, or wellhead protection, or from the State's drinking water source water assessment program) such alternative monitoring would provide assurance that it complies with the Administrator's guidelines. The State program must be adequate to assure compliance with, and enforcement of, applicable national primary drinking water regulations. Alternative monitoring shall not apply to regulated microbiological contaminants (or indicators thereof), disinfectants and disinfection byproducts, or corrosion byproducts. The preceding sentence is not intended to limit other authority of the Administrator under other provisions of this subchapter to grant monitoring flexibility.

(2) Guidelines

(A) In general

The Administrator shall issue, after notice and comment and at the same time as guidelines are issued for source water assessment under section 300j–13 of this title, guidelines for States to follow in proposing alternative monitoring requirements under paragraph (1) for chemical contaminants. The Administrator shall publish such guidelines in the Federal Register. The guidelines shall assure that the public health will be protected from drinking water

contamination. The guidelines shall require that a State alternative monitoring program apply on a contaminant-by-contaminant basis and that, to be eligible for such alternative monitoring program, a public water system must show the State that the contaminant is not present in the drinking water supply or, if present, it is reliably and consistently below the maximum contaminant level.

(B) Definition

For purposes of subparagraph (A), the phrase "reliably and consistently below the maximum contaminant level" means that, although contaminants have been detected in a water supply, the State has sufficient knowledge of the contamination source and extent of contamination to predict that the maximum contaminant level will not be exceeded. In determining that a contaminant is reliably and consistently below the maximum contaminant level, States shall consider the quality and completeness of data, the length of time covered and the volatility or stability of monitoring results during that time, and the proximity of such results to the maximum contaminant level. Wide variations in the analytical results, or analytical results close to the maximum contaminant level, shall not be considered to be reliably and consistently below the maximum contaminant level.

(3) Effect of detection of contaminants

The guidelines issued by the Administrator under paragraph (2) shall require that if, after the monitoring program is in effect and operating, a contaminant covered by the alternative monitoring program is detected at levels at or above the maximum contaminant level or is no longer reliably or consistently below the maximum contaminant level, the public water system must either—

(A) demonstrate that the contamination source has been removed or that other action has been taken to eliminate the contamination problem; or

(B) test for the detected contaminant pursuant to the applicable national primary drinking water regulation.

(4) States not exercising primary enforcement responsibility

The Governor of any State not exercising primary enforcement responsibility under section 300g–2 of this title on August 6, 1996, may submit to the Administrator a request that the Administrator modify the monitoring requirements established by the Administrator and applicable to public water systems in that State. After consultation with the Governor, the Administrator shall modify the requirements for public water systems in that State if the request of the Governor is in accordance with each of the requirements of this subsection that apply to alternative monitoring requirements established by States that have primary enforcement responsibility. A decision by the Administrator to approve a request under this clause shall be for a period of 3 years and may subsequently be extended for periods of 5 years.

(c) Treatment as NPDWR

All monitoring relief granted by a State to a public water system for a regulated contaminant under subsection (a) or (b) shall be treated as part of the national primary drinking water regulation for that contaminant.

(d) Other monitoring relief

Nothing in this section shall be construed to affect the authority of the States under applicable national primary drinking water regulations to alter monitoring requirements through waivers or other existing authorities. The Administrator shall periodically review and, as appropriate, revise such authorities.

(July 1, 1944, ch. 373, title XIV, §1418, as added Pub. L. 104–182, title I, §125(b), Aug. 6, 1996, 110 Stat. 1654.)

§300g–8. Operator certification

(a) Guidelines

Not later than 30 months after August 6, 1996, and in cooperation with the States, the Administrator shall publish guidelines in the Federal Register, after notice and opportunity for comment from interested persons, including States and public water systems, specifying minimum standards for certification (and recertification) of the operators of community and nontransient noncommunity public water systems. Such guidelines shall take into account existing State programs, the complexity of the system, and other factors aimed at providing an effective program at reasonable cost to States and public water systems, taking into account the size of the system.

(b) State programs

Beginning 2 years after the date on which the Administrator publishes guidelines under subsection (a), the Administrator shall withhold 20 percent of the funds a State is otherwise entitled to receive under section 300j–12 of this title unless the State has adopted and is implementing a program for the certification of operators of community and nontransient noncommunity public water systems that meets the requirements of the guidelines published pursuant to subsection (a) or that has been submitted in compliance with subsection (c) and that has not been disapproved.

(c) Existing programs

For any State exercising primary enforcement responsibility for public water systems or any other State which has an operator certification program, the guidelines under subsection (a) shall allow the State to enforce such program in lieu of the guidelines under subsection (a) if the State submits the program to the Administrator within 18 months after the publication of the guidelines unless the Administrator determines (within 9 months after the State submits the program to the Administrator) that such program is not substantially equivalent to such guidelines. In making this determination, an existing State program shall be presumed to be substantially equivalent to the guidelines, notwithstanding program differences, based on the size of systems or the quality of source water, providing the State program meets the overall public health objectives of the guidelines. If disapproved, the program may be resubmitted within 6 months after receipt of notice of disapproval.

(d) Expense reimbursement

(1) In general

The Administrator shall provide reimbursement for the costs of training, including an appropriate per diem for unsalaried operators, and certification for persons operating systems serving 3,300 persons or fewer that are required to undergo training pursuant to this section.

(2) State grants

The reimbursement shall be provided through grants to States with each State receiving an amount sufficient to cover the reasonable costs for training all such operators in the State, as determined by the Administrator, to the extent required by this section. Grants received by a State pursuant to this paragraph shall first be used to provide reimbursement for training and certification costs of persons operating systems serving 3,300 persons or fewer. If a State has reimbursed all such costs, the State may, after notice to the Administrator, use any remaining funds from the grant for any of the other purposes authorized for grants under section 300j–12 of this title.

(3) Authorization

There are authorized to be appropriated to the Administrator to provide grants for reimbursement under this section $30,000,000 for each of fiscal years 1997 through 2003.

(4) Reservation

If the appropriation made pursuant to paragraph (3) for any fiscal year is not sufficient to satisfy the requirements of paragraph (1), the Administrator shall, prior to any other allocation or reservation, reserve such sums as necessary from the funds appropriated pursuant to section 300j–12(m) of this title to provide reimbursement for the training and certification costs mandated by this subsection.

(July 1, 1944, ch. 373, title XIV, §1419, as added Pub. L. 104–182, title I, §123, Aug. 6, 1996, 110 Stat. 1652.)

§300g–9. Capacity development

(a) State authority for new systems

A State shall receive only 80 percent of the allotment that the State is otherwise entitled to receive under section 300j–12 of this title (relating to State loan funds) unless the State has obtained the legal authority or other means to ensure that all new community water systems and new nontransient, noncommunity water systems commencing operation after October 1, 1999, demonstrate technical, managerial, and financial capacity with respect to each national primary drinking water regulation in effect, or likely to be in effect, on the date of commencement of operations.

(b) Systems in significant noncompliance

(1) List

Beginning not later than 1 year after August 6, 1996, each State shall prepare, periodically update, and submit to the Administrator a list of community water systems and nontransient, noncommunity water systems that have a history of significant noncompliance with this subchapter (as defined in guidelines issued prior to August 6, 1996, or any revisions of the guidelines that have been made in consultation with the States) and, to the extent practicable, the reasons for noncompliance.

(2) Report

Not later than 5 years after August 6, 1996, and as part of the capacity development strategy of the State, each State shall report to the Administrator on the success of enforcement mechanisms and initial capacity development efforts in assisting the public water systems listed under paragraph (1) to improve technical, managerial, and financial capacity.

(3) Withholding

The list and report under this subsection shall be considered part of the capacity development strategy of the State required under subsection (c) of this section for purposes of the withholding requirements of section 300j–12(a)(1)(G)(i) of this title (relating to State loan funds).

(c) Capacity development strategy

(1) In general

Beginning 4 years after August 6, 1996, a State shall receive only—

(A) 90 percent in fiscal year 2001;

(B) 85 percent in fiscal year 2002; and

(C) 80 percent in each subsequent fiscal year,

of the allotment that the State is otherwise entitled to receive under section 300j–12 of this title (relating to State loan funds), unless the State is developing and implementing a strategy to assist public water systems in acquiring and maintaining technical, managerial, and financial capacity.

(2) Content

In preparing the capacity development strategy, the State shall consider, solicit public comment on, and include as appropriate—

(A) the methods or criteria that the State will use to identify and prioritize the public water systems most in need of improving technical, managerial, and financial capacity;

(B) a description of the institutional, regulatory, financial, tax, or legal factors at the Federal, State, or local level that encourage or impair capacity development;

(C) a description of how the State will use the authorities and resources of this subchapter or other means to—

(i) assist public water systems in complying with national primary drinking water

regulations;

(ii) encourage the development of partnerships between public water systems to enhance the technical, managerial, and financial capacity of the systems; and

(iii) assist public water systems in the training and certification of operators;

(D) a description of how the State will establish a baseline and measure improvements in capacity with respect to national primary drinking water regulations and State drinking water law;

(E) an identification of the persons that have an interest in and are involved in the development and implementation of the capacity development strategy (including all appropriate agencies of Federal, State, and local governments, private and nonprofit public water systems, and public water system customers); and

(F) a description of how the State will, as appropriate—

(i) encourage development by public water systems of asset management plans that include best practices for asset management; and

(ii) assist, including through the provision of technical assistance, public water systems in training operators or other relevant and appropriate persons in implementing such asset management plans.

(3) Report

Not later than 2 years after the date on which a State first adopts a capacity development strategy under this subsection, and every 3 years thereafter, the head of the State agency that has primary responsibility to carry out this subchapter in the State shall submit to the Governor a report that shall also be available to the public on the efficacy of the strategy and progress made toward improving the technical, managerial, and financial capacity of public water systems in the State, including efforts of the State to encourage development by public water systems of asset management plans and to assist public water systems in training relevant and appropriate persons in implementing such asset management plans.

(4) Review

The decisions of the State under this section regarding any particular public water system are not subject to review by the Administrator and may not serve as the basis for withholding funds under section 300j–12 of this title.

(d) Federal assistance

(1) In general

The Administrator shall support the States in developing capacity development strategies.

(2) Informational assistance

(A) In general

Not later than 180 days after August 6, 1996, the Administrator shall—

(i) conduct a review of State capacity development efforts in existence on August 6, 1996, and publish information to assist States and public water systems in capacity development efforts; and

(ii) initiate a partnership with States, public water systems, and the public to develop information for States on recommended operator certification requirements.

(B) Publication of information

The Administrator shall publish the information developed through the partnership under subparagraph (A)(ii) not later than 18 months after August 6, 1996.

(3) Promulgation of drinking water regulations

In promulgating a national primary drinking water regulation, the Administrator shall include an analysis of the likely effect of compliance with the regulation on the technical, financial, and managerial capacity of public water systems.

(4) Guidance for new systems

Not later than 2 years after August 6, 1996, the Administrator shall publish guidance developed in consultation with the States describing legal authorities and other means to ensure that all new community water systems and new nontransient, noncommunity water systems demonstrate technical, managerial, and financial capacity with respect to national primary drinking water regulations.

(5) Information on asset management practices

Not later than 5 years after October 23, 2018, and not less often than every 5 years thereafter, the Administrator shall review and, if appropriate, update educational materials, including handbooks, training materials, and technical information, made available by the Administrator to owners, managers, and operators of public water systems, local officials, technical assistance providers (including nonprofit water associations), and State personnel concerning best practices for asset management strategies that may be used by public water systems.

(e) Variances and exemptions

Based on information obtained under subsection (c)(3), the Administrator shall, as appropriate, modify regulations concerning variances and exemptions for small public water systems to ensure flexibility in the use of the variances and exemptions. Nothing in this subsection shall be interpreted, construed, or applied to affect or alter the requirements of section 300g–4 or 300g–5 of this title.

(f) Small public water systems technology assistance centers

(1) Grant program

The Administrator is authorized to make grants to institutions of higher learning to establish and operate small public water system technology assistance centers in the United States.

(2) Responsibilities of the centers

The responsibilities of the small public water system technology assistance centers established under this subsection shall include the conduct of training and technical assistance relating to the information, performance, and technical needs of small public water systems or public water systems that serve Indian Tribes.

(3) Applications

Any institution of higher learning interested in receiving a grant under this subsection shall submit to the Administrator an application in such form and containing such information as the Administrator may require by regulation.

(4) Selection criteria

The Administrator shall select recipients of grants under this subsection on the basis of the following criteria:

(A) The small public water system technology assistance center shall be located in a State that is representative of the needs of the region in which the State is located for addressing the drinking water needs of small and rural communities or Indian Tribes.

(B) The grant recipient shall be located in a region that has experienced problems, or may reasonably be foreseen to experience problems, with small and rural public water systems.

(C) The grant recipient shall have access to expertise in small public water system technology management.

(D) The grant recipient shall have the capability to disseminate the results of small public water system technology and training programs.

(E) The projects that the grant recipient proposes to carry out under the grant are necessary and appropriate.

(F) The grant recipient has regional support beyond the host institution.

(5) Consortia of States

At least 2 of the grants under this subsection shall be made to consortia of States with low

population densities.

(6) Authorization of appropriations

There are authorized to be appropriated to make grants under this subsection $2,000,000 for each of the fiscal years 1997 through 1999, and $5,000,000 for each of the fiscal years 2000 through 2003.

(g) Environmental finance centers

(1) In general

The Administrator shall provide initial funding for one or more university-based environmental finance centers for activities that provide technical assistance to State and local officials in developing the capacity of public water systems. Any such funds shall be used only for activities that are directly related to this subchapter.

(2) National capacity development clearinghouse

The Administrator shall establish a national public water system capacity development clearinghouse to receive and disseminate information with respect to developing, improving, and maintaining financial and managerial capacity at public water systems. The Administrator shall ensure that the clearinghouse does not duplicate other federally supported clearinghouse activities.

(3) Capacity development techniques

The Administrator may request an environmental finance center funded under paragraph (1) to develop and test managerial, financial, and institutional techniques for capacity development. The techniques may include capacity assessment methodologies, manual and computer based public water system rate models and capital planning models, public water system consolidation procedures, and regionalization models.

(4) Authorization of appropriations

There are authorized to be appropriated to carry out this subsection $1,500,000 for each of the fiscal years 1997 through 2003.

(5) Limitation

No portion of any funds made available under this subsection may be used for lobbying expenses.

(July 1, 1944, ch. 373, title XIV, §1420, as added Pub. L. 104–182, title I, §119, Aug. 6, 1996, 110 Stat. 1647; amended Pub. L. 115–270, title II, §2012, Oct. 23, 2018, 132 Stat. 3849.)

EDITORIAL NOTES

AMENDMENTS

2018—Subsec. (c)(2)(F). Pub. L. 115–270, §2012(1), added subpar. (F).

Subsec. (c)(3). Pub. L. 115–270, §2012(2), inserted ", including efforts of the State to encourage development by public water systems of asset management plans and to assist public water systems in training relevant and appropriate persons in implementing such asset management plans" before period at end.

Subsec. (d)(5). Pub. L. 115–270, §2012(3), added par. (5).

§300g–10. Cybersecurity support for public water systems

(a) Definitions

In this section:

(1) Appropriate Congressional committees

The term "appropriate Congressional committees" means—

(A) the Committee on Environment and Public Works of the Senate;

(B) the Committee on Homeland Security and Governmental Affairs of the Senate;

(C) the Committee on Energy and Commerce of the House of Representatives; and
(D) the Committee on Homeland Security of the House of Representatives.

(2) Director

The term "Director" means the Director of the Cybersecurity and Infrastructure Security Agency.

(3) Incident

The term "incident" has the meaning given the term in section 3552 of title 44.

(4) Prioritization Framework

The term "Prioritization Framework" means the prioritization framework developed by the Administrator under subsection (b)(1)(A).

(5) Support Plan

The term "Support Plan" means the Technical Cybersecurity Support Plan developed by the Administrator under subsection (b)(2)(A).

(b) Identification of and support for public water systems

(1) Prioritization Framework

(A) In general

Not later than 180 days after November 15, 2021, the Administrator, in coordination with the Director, shall develop a prioritization framework to identify public water systems (including sources of water for those public water systems) that, if degraded or rendered inoperable due to an incident, would lead to significant impacts on the health and safety of the public.

(B) Considerations

In developing the Prioritization Framework, to the extent practicable, the Administrator shall incorporate consideration of—

(i) whether cybersecurity vulnerabilities for a public water system have been identified under section 300i–2 of this title;

(ii) the capacity of a public water system to remediate a cybersecurity vulnerability without additional Federal support;

(iii) whether a public water system serves a defense installation or critical national security asset; and

(iv) whether a public water system, if degraded or rendered inoperable due to an incident, would cause a cascading failure of other critical infrastructure.

(2) Technical Cybersecurity Support Plan

(A) In general

Not later than 270 days after November 15, 2021, the Administrator, in coordination with the Director and using existing authorities of the Administrator and the Director for providing voluntary support to public water systems and the Prioritization Framework, shall develop a Technical Cybersecurity Support Plan for public water systems.

(B) Requirements

The Support Plan—

(i) shall establish a methodology for identifying specific public water systems for which cybersecurity support should be prioritized;

(ii) shall establish timelines for making voluntary technical support for cybersecurity available to specific public water systems;

(iii) may include public water systems identified by the Administrator, in coordination with the Director, as needing technical support for cybersecurity;

(iv) shall include specific capabilities of the Administrator and the Director that may be utilized to provide support to public water systems under the Support Plan, including—

(I) site vulnerability and risk assessments;
(II) penetration tests; and
(III) any additional support determined to be appropriate by the Administrator; and

(v) shall only include plans for providing voluntary support to public water systems.

(3) Consultation required

In developing the Prioritization Framework pursuant to paragraph (1) and the Support Plan pursuant to paragraph (2), the Administrator shall consult with such Federal or non-Federal entities as determined to be appropriate by the Administrator.

(4) Reports required

(A) Prioritization Framework

Not later than 190 days after November 15, 2021, the Administrator shall submit to the appropriate Congressional committees a report describing the Prioritization Framework.

(B) Technical Cybersecurity Support Plan

Not later than 280 days after November 15, 2021, the Administrator shall submit to the appropriate Congressional committees—

(i) the Support Plan; and

(ii) a list describing any public water systems identified by the Administrator, in coordination with the Director, as needing technical support for cybersecurity during the development of the Support Plan.

(c) Rules of construction

Nothing in this section—

(1) alters the existing authorities of the Administrator; or

(2) compels a public water system to accept technical support offered by the Administrator.

(July 1, 1944, ch. 373, title XIV, §1420A, as added Pub. L. 117–58, div. E, title I, §50113, Nov. 15, 2021, 135 Stat. 1155.)

PART C—PROTECTION OF UNDERGROUND SOURCES OF DRINKING WATER

§300h. Regulations for State programs

(a) Publication of proposed regulations; promulgation; amendments; public hearings; administrative consultations

(1) The Administrator shall publish proposed regulations for State underground injection control programs within 180 days after December 16, 1974. Within 180 days after publication of such proposed regulations, he shall promulgate such regulations with such modifications as he deems appropriate. Any regulation under this subsection may be amended from time to time.

(2) Any regulation under this section shall be proposed and promulgated in accordance with section 553 of title 5 (relating to rulemaking), except that the Administrator shall provide opportunity for public hearing prior to promulgation of such regulations. In proposing and promulgating regulations under this section the Administrator shall consult with the Secretary, the National Drinking Water Advisory Council, and other appropriate Federal entities and with interested State entities.

(b) Minimum requirements; restrictions

(1) Regulations under subsection (a) for State underground injection programs shall contain

minimum requirements for effective programs to prevent underground injection which endangers drinking water sources within the meaning of subsection (d)(2). Such regulations shall require that a State program, in order to be approved under section 300h–1 of this title—

(A) shall prohibit, effective on the date on which the applicable underground injection control program takes effect, any underground injection in such State which is not authorized by a permit issued by the State (except that the regulations may permit a State to authorize underground injection by rule);

(B) shall require (i) in the case of a program which provides for authorization of underground injection by permit, that the applicant for the permit to inject must satisfy the State that the underground injection will not endanger drinking water sources, and (ii) in the case of a program which provides for such an authorization by rule, that no rule may be promulgated which authorizes any underground injection which endangers drinking water sources;

(C) shall include inspection, monitoring, recordkeeping, and reporting requirements; and

(D) shall apply (i) as prescribed by section 300j–6(b) [1] of this title, to underground injections by Federal agencies, and (ii) to underground injections by any other person whether or not occurring on property owned or leased by the United States.

(2) Regulations of the Administrator under this section for State underground injection control programs may not prescribe requirements which interfere with or impede—

(A) the underground injection of brine or other fluids which are brought to the surface in connection with oil or natural gas production or natural gas storage operations, or

(B) any underground injection for the secondary or tertiary recovery of oil or natural gas,

unless such requirements are essential to assure that underground sources of drinking water will not be endangered by such injection.

(3)(A) The regulations of the Administrator under this section shall permit or provide for consideration of varying geologic, hydrological, or historical conditions in different States and in different areas within a State.

(B)(i) In prescribing regulations under this section the Administrator shall, to the extent feasible, avoid promulgation of requirements which would unnecessarily disrupt State underground injection control programs which are in effect and being enforced in a substantial number of States.

(ii) For the purpose of this subparagraph, a regulation prescribed by the Administrator under this section shall be deemed to disrupt a State underground injection control program only if it would be infeasible to comply with both such regulation and the State underground injection control program.

(iii) For the purpose of this subparagraph, a regulation prescribed by the Administrator under this section shall be deemed unnecessary only if, without such regulation, underground sources of drinking water will not be endangered by an underground injection.

(C) Nothing in this section shall be construed to alter or affect the duty to assure that underground sources of drinking water will not be endangered by any underground injection.

(c) Temporary permits; notice and hearing

(1) The Administrator may, upon application of the Governor of a State which authorizes underground injection by means of permits, authorize such State to issue (without regard to subsection (b)(1)(B)(i)) temporary permits for underground injection which may be effective until the, expiration of four years after December 16, 1974, if—

(A) the Administrator finds that the State has demonstrated that it is unable and could not reasonably have been able to process all permit applications within the time available;

(B) the Administrator determines the adverse effect on the environment of such temporary permits is not unwarranted;

(C) such temporary permits will be issued only with respect to injection wells in operation on the date on which such State's permit program approved under this part first takes effect and for which there was inadequate time to process its permit application; and

(D) the Administrator determines the temporary permits require the use of adequate safeguards

established by rules adopted by him.

(2) The Administrator may, upon application of the Governor of a State which authorizes underground injection by means of permits, authorize such State to issue (without regard to subsection (b)(1)(B)(i)), but after reasonable notice and hearing, one or more temporary permits each of which is applicable to a particular injection well and to the underground injection of a particular fluid and which may be effective until the expiration of four years after December 16, 1974, if the State finds, on the record of such hearing—

(A) that technology (or other means) to permit safe injection of the fluid in accordance with the applicable underground injection control program is not generally available (taking costs into consideration);

(B) that injection of the fluid would be less harmful to health than the use of other available means of disposing of waste or producing the desired product; and

(C) that available technology or other means have been employed (and will be employed) to reduce the volume and toxicity of the fluid and to minimize the potentially adverse effect of the injection on the public health.

(d) "Underground injection" defined; underground injection endangerment of drinking water sources

For purposes of this part:

(1) UNDERGROUND INJECTION.—The term "underground injection"—

(A) means the subsurface emplacement of fluids by well injection; and

(B) excludes—

(i) the underground injection of natural gas for purposes of storage; and

(ii) the underground injection of fluids or propping agents (other than diesel fuels) pursuant to hydraulic fracturing operations related to oil, gas, or geothermal production activities.

(2) Underground injection endangers drinking water sources if such injection may result in the presence in underground water which supplies or can reasonably be expected to supply any public water system of any contaminant, and if the presence of such contaminant may result in such system's not complying with any national primary drinking water regulation or may otherwise adversely affect the health of persons.

(July 1, 1944, ch. 373, title XIV, §1421, as added Pub. L. 93–523, §2(a), Dec. 16, 1974, 88 Stat. 1674; amended Pub. L. 95–190, §6(b), Nov. 16, 1977, 91 Stat. 1396; Pub. L. 96–502, §§3, 4(c), Dec. 5, 1980, 94 Stat. 2738; Pub. L. 99–339, title II, §201(a), June 19, 1986, 100 Stat. 653; Pub. L. 104–182, title V, §501(b)(1), Aug. 6, 1996, 110 Stat. 1691; Pub. L. 109–58, title III, §322, Aug. 8, 2005, 119 Stat. 694.)

EDITORIAL NOTES

REFERENCES IN TEXT

Section 300j–6(b) of this title, referred to in subsec. (b)(1)(D), was repealed, and a new section 300j–6(b) relating to administrative penalty orders was added, by Pub. L. 104–182, title I, §129(a), Aug. 6, 1996, 110 Stat. 1660.

AMENDMENTS

2005—Subsec. (d)(1). Pub. L. 109–58 inserted heading and amended text of par. (1) generally. Prior to amendment, par. (1) read as follows: "The term 'underground injection' means the subsurface emplacement of fluids by well injection. Such term does not include the underground injection of natural gas for purposes of storage."

1996—Subsec. (b)(3)(B)(i). Pub. L. 104–182 substituted "number of States" for "number or States".

1986—Subsec. (b)(2)(A). Pub. L. 99–339 inserted "or natural gas storage operations" after "production".

1980—Subsec. (b)(1)(A). Pub. L. 96–502, §4(c), substituted "effective on the date on which the applicable underground injection control program takes effect" for "effective three years after December 16, 1974".

Subsec. (d)(1). Pub. L. 96–502, §3, inserted provision that such term does not include the underground injection of natural gas for purposes of storage.

1977—Subsec. (b)(3). Pub. L. 95–190 added par. (3).

[1] *See References in Text note below.*

§300h–1. State primary enforcement responsibility

(a) List of States in need of a control program; amendment of list

Within 180 days after December 16, 1974, the Administrator shall list in the Federal Register each State for which in his judgment a State underground injection control program may be necessary to assure that underground injection will not endanger drinking water sources. Such list may be amended from time to time.

(b) State applications; notice to Administrator of compliance with revised or added requirements; approval or disapproval by Administrator; duration of State primary enforcement responsibility; public hearing

(1)(A) Each State listed under subsection (a) shall within 270 days after the date of promulgation of any regulation under section 300h of this title (or, if later, within 270 days after such State is first listed under subsection (a)) submit to the Administrator an application which contains a showing satisfactory to the Administrator that the State—

(i) has adopted after reasonable notice and public hearings, and will implement, an underground injection control program which meets the requirements of regulations in effect under section 300h of this title; and

(ii) will keep such records and make such reports with respect to its activities under its underground injection control program as the Administrator may require by regulation.

The Administrator may, for good cause, extend the date for submission of an application by any State under this subparagraph for a period not to exceed an additional 270 days.

(B) Within 270 days of any amendment of a regulation under section 300h of this title revising or adding any requirement respecting State underground injection control programs, each State listed under subsection (a) shall submit (in such form and manner as the Administrator may require) a notice to the Administrator containing a showing satisfactory to him that the State underground injection control program meets the revised or added requirement.

(2) Within ninety days after the State's application under paragraph (1)(A) or notice under paragraph (1)(B) and after reasonable opportunity for presentation of views, the Administrator shall by rule either approve, disapprove, or approve in part and disapprove in part, the State's underground injection control program.

(3) If the Administrator approves the State's program under paragraph (2), the State shall have primary enforcement responsibility for underground water sources until such time as the Administrator determines, by rule, that such State no longer meets the requirements of clause (i) or (ii) of paragraph (1)(A) of this subsection.

(4) Before promulgating any rule under paragraph (2) or (3) of this subsection, the Administrator shall provide opportunity for public hearing respecting such rule.

(c) Program by Administrator for State without primary enforcement responsibility; restrictions

If the Administrator disapproves a State's program (or part thereof) under subsection (b)(2), if the Administrator determines under subsection (b)(3) that a State no longer meets the requirements of clause (i) or (ii) of subsection (b)(1)(A), or if a State fails to submit an application or notice before the date of expiration of the period specified in subsection (b)(1), the Administrator shall by regulation within 90 days after the date of such disapproval, determination, or expiration (as the case may be) prescribe (and may from time to time by regulation revise) a program applicable to such

State meeting the requirements of section 300h(b) of this title. Such program may not include requirements which interfere with or impede—

(1) the underground injection of brine or other fluids which are brought to the surface in connection with oil or natural gas production or natural gas storage operations, or

(2) any underground injection for the secondary or tertiary recovery of oil or natural gas,

unless such requirements are essential to assure that underground sources of drinking water will not be endangered by such injection. Such program shall apply in such State to the extent that a program adopted by such State which the Administrator determines meets such requirements is not in effect. Before promulgating any regulation under this section, the Administrator shall provide opportunity for public hearing respecting such regulation.

(d) "Applicable underground injection control program" defined

For purposes of this subchapter, the term "applicable underground injection control program" with respect to a State means the program (or most recent amendment thereof) (1) which has been adopted by the State and which has been approved under subsection (b), or (2) which has been prescribed by the Administrator under subsection (c).

(e) Primary enforcement responsibility by Indian Tribe

An Indian Tribe may assume primary enforcement responsibility for underground injection control under this section consistent with such regulations as the Administrator has prescribed pursuant to this part and section 300j–11 of this title. The area over which such Indian Tribe exercises governmental jurisdiction need not have been listed under subsection (a) of this section, and such Tribe need not submit an application to assume primary enforcement responsibility within the 270-day deadline noted in subsection (b)(1)(A) of this section. Until an Indian Tribe assumes primary enforcement responsibility, the currently applicable underground injection control program shall continue to apply. If an applicable underground injection control program does not exist for an Indian Tribe, the Administrator shall prescribe such a program pursuant to subsection (c) of this section, and consistent with section 300h(b) of this title, within 270 days after June 19, 1986, unless an Indian Tribe first obtains approval to assume primary enforcement responsibility for underground injection control.

(July 1, 1944, ch. 373, title XIV, §1422, as added Pub. L. 93–523, §2(a), Dec. 16, 1974, 88 Stat. 1676; amended Pub. L. 95–190, §6(a), Nov. 16, 1977, 91 Stat. 1396; Pub. L. 99–339, title II, §201(a), title III, §302(c), June 19, 1986, 100 Stat. 653, 666.)

EDITORIAL NOTES

AMENDMENTS

1986—Subsec. (c)(1). Pub. L. 99–339, §201(a), inserted "or natural gas storage operations, or" after "production".

Subsec. (e). Pub. L. 99–339, §302(c), added subsec. (e).

1977—Subsec. (b)(1)(A). Pub. L. 95–190 inserted provisions relating to extension of date for submission of applications by any State.

§300h–2. Enforcement of program

(a) Notice to State and violator; issuance of administrative order; civil action

(1) Whenever the Administrator finds during a period during which a State has primary enforcement responsibility for underground water sources (within the meaning of section 300h–1(b)(3) of this title or section 300h–4(c) of this title) that any person who is subject to a requirement of an applicable underground injection control program in such State is violating such requirement, he shall so notify the State and the person violating such requirement. If beyond the thirtieth day after the Administrator's notification the State has not commenced appropriate

enforcement action, the Administrator shall issue an order under subsection (c) requiring the person to comply with such requirement or the Administrator shall commence a civil action under subsection (b).

(2) Whenever the Administrator finds during a period during which a State does not have primary enforcement responsibility for underground water sources that any person subject to any requirement of any applicable underground injection control program in such State is violating such requirement, the Administrator shall issue an order under subsection (c) requiring the person to comply with such requirement or the Administrator shall commence a civil action under subsection (b).

(b) Civil and criminal actions

Civil actions referred to in paragraphs (1) and (2) of subsection (a) shall be brought in the appropriate United States district court. Such court shall have jurisdiction to require compliance with any requirement of an applicable underground injection program or with an order issued under subsection (c). The court may enter such judgment as protection of public health may require. Any person who violates any requirement of an applicable underground injection control program or an order requiring compliance under subsection (c)—

(1) shall be subject to a civil penalty of not more than $25,000 for each day of such violation, and

(2) if such violation is willful, such person may, in addition to or in lieu of the civil penalty authorized by paragraph (1), be imprisoned for not more than 3 years, or fined in accordance with title 18, or both.

(c) Administrative orders

(1) In any case in which the Administrator is authorized to bring a civil action under this section with respect to any regulation or other requirement of this part other than those relating to—

(A) the underground injection of brine or other fluids which are brought to the surface in connection with oil or natural gas production, or

(B) any underground injection for the secondary or tertiary recovery of oil or natural gas,

the Administrator may also issue an order under this subsection either assessing a civil penalty of not more than $10,000 for each day of violation for any past or current violation, up to a maximum administrative penalty of $125,000, or requiring compliance with such regulation or other requirement, or both.

(2) In any case in which the Administrator is authorized to bring a civil action under this section with respect to any regulation, or other requirement of this part relating to—

(A) the underground injection of brine or other fluids which are brought to the surface in connection with oil or natural gas production, or

(B) any underground injection for the secondary or tertiary recovery of oil or natural gas,

the Administrator may also issue an order under this subsection either assessing a civil penalty of not more than $5,000 for each day of violation for any past or current violation, up to a maximum administrative penalty of $125,000, or requiring compliance with such regulation or other requirement, or both.

(3)(A) An order under this subsection shall be issued by the Administrator after opportunity (provided in accordance with this subparagraph) for a hearing. Before issuing the order, the Administrator shall give to the person to whom it is directed written notice of the Administrator's proposal to issue such order and the opportunity to request, within 30 days of the date the notice is received by such person, a hearing on the order. Such hearing shall not be subject to section 554 or 556 of title 5, but shall provide a reasonable opportunity to be heard and to present evidence.

(B) The Administrator shall provide public notice of, and reasonable opportunity to comment on, any proposed order.

(C) Any citizen who comments on any proposed order under subparagraph (B) shall be given notice of any hearing under this subsection and of any order. In any hearing held under subparagraph (A), such citizen shall have a reasonable opportunity to be heard and to present evidence.

(D) Any order issued under this subsection shall become effective 30 days following its issuance unless an appeal is taken pursuant to paragraph (6).

(4)(A) Any order issued under this subsection shall state with reasonable specificity the nature of the violation and may specify a reasonable time for compliance.

(B) In assessing any civil penalty under this subsection, the Administrator shall take into account appropriate factors, including (i) the seriousness of the violation; (ii) the economic benefit (if any) resulting from the violation; (iii) any history of such violations; (iv) any good-faith efforts to comply with the applicable requirements; (v) the economic impact of the penalty on the violator; and (vi) such other matters as justice may require.

(5) Any violation with respect to which the Administrator has commenced and is diligently prosecuting an action, or has issued an order under this subsection assessing a penalty, shall not be subject to an action under subsection (b) of this section or section 300h–3(c) or 300j–8 of this title, except that the foregoing limitation on civil actions under section 300j–8 of this title shall not apply with respect to any violation for which—

(A) a civil action under section 300j–8(a)(1) of this title has been filed prior to commencement of an action under this subsection, or

(B) a notice of violation under section 300j–8(b)(1) of this title has been given before commencement of an action under this subsection and an action under section 300j–8(a)(1) of this title is filed before 120 days after such notice is given.

(6) Any person against whom an order is issued or who commented on a proposed order pursuant to paragraph (3) may file an appeal of such order with the United States District Court for the District of Columbia or the district in which the violation is alleged to have occurred. Such an appeal may only be filed within the 30-day period beginning on the date the order is issued. Appellant shall simultaneously send a copy of the appeal by certified mail to the Administrator and to the Attorney General. The Administrator shall promptly file in such court a certified copy of the record on which such order was imposed. The district court shall not set aside or remand such order unless there is not substantial evidence on the record, taken as a whole, to support the finding of a violation or, unless the Administrator's assessment of penalty or requirement for compliance constitutes an abuse of discretion. The district court shall not impose additional civil penalties for the same violation unless the Administrator's assessment of a penalty constitutes an abuse of discretion. Notwithstanding section 300j–7(a)(2) of this title, any order issued under paragraph (3) shall be subject to judicial review exclusively under this paragraph.

(7) If any person fails to pay an assessment of a civil penalty—

(A) after the order becomes effective under paragraph (3), or

(B) after a court, in an action brought under paragraph (6), has entered a final judgment in favor of the Administrator,

the Administrator may request the Attorney General to bring a civil action in an appropriate district court to recover the amount assessed (plus costs, attorneys' fees, and interest at currently prevailing rates from the date the order is effective or the date of such final judgment, as the case may be). In such an action, the validity, amount, and appropriateness of such penalty shall not be subject to review.

(8) The Administrator may, in connection with administrative proceedings under this subsection, issue subpoenas compelling the attendance and testimony of witnesses and subpoenas duces tecum, and may request the Attorney General to bring an action to enforce any subpoena under this section. The district courts shall have jurisdiction to enforce such subpoenas and impose sanction.

(d) State authority to adopt or enforce laws or regulations respecting underground injection unaffected

Nothing in this subchapter shall diminish any authority of a State or political subdivision to adopt or enforce any law or regulation respecting underground injection but no such law or regulation shall relieve any person of any requirement otherwise applicable under this subchapter.

(July 1, 1944, ch. 373, title XIV, §1423, as added Pub. L. 93–523, §2(a), Dec. 16, 1974, 88 Stat. 1677; amended Pub. L. 96–502, §2(b), Dec. 5, 1980, 94 Stat. 2738; Pub. L. 99–339, title II, §202, June 19, 1986, 100 Stat. 654.)

EDITORIAL NOTES

AMENDMENTS

1986—Pub. L. 99–339, §202(d), substituted "Enforcement" for "Failure of State to assure enforcement" in section catchline.

Subsec. (a)(1). Pub. L. 99–339, §202(a)(1), substituted provisions which related to issuance of an order of compliance or commencement of a civil action by the Administrator if the State has not commenced enforcement against the violator for provisions directing the Administrator to give public notice and request that the State report within 15 days thereafter as to steps taken to enforce compliance and authorizing the Administrator to commence a civil action upon failure by the State to comply timely.

Subsec. (a)(2). Pub. L. 99–339, §202(a)(2), substituted provision that the Administrator issue an order under subsec. (c) of this section or commence a civil action under subsec. (b) of this section for provision that he commence a civil action under subsec. (b)(1) of this section.

Subsec. (b). Pub. L. 99–339, §202(b), amended subsec. (b) generally, substituting provisions relating to jurisdiction of the appropriate Federal district court, entry of judgment, civil penalty of $25,000 per day, criminal liability and fine for willful violation for provisions which related to judicial determinations in appropriate Federal district courts, civil penalties of $5,000 per day, and fines of $10,000 per day for willful violations.

Subsecs. (c), (d). Pub. L. 99–339, §202(c), added subsec. (c) and redesignated former subsec. (c) as (d).

1980—Subsec. (a)(1). Pub. L. 96–502 inserted reference to section 300h–4(c) of this title.

§300h–3. Interim regulation of underground injections

(a) Necessity for well operation permit; designation of one aquifer areas

(1) Any person may petition the Administrator to have an area of a State (or States) designated as an area in which no new underground injection well may be operated during the period beginning on the date of the designation and ending on the date on which the applicable underground injection control program covering such area takes effect unless a permit for the operation of such well has been issued by the Administrator under subsection (b). The Administrator may so designate an area within a State if he finds that the area has one aquifer which is the sole or principal drinking water source for the area and which, if contaminated, would create a significant hazard to public health.

(2) Upon receipt of a petition under paragraph (1) of this subsection, the Administrator shall publish it in the Federal Register and shall provide an opportunity to interested persons to submit written data, views, or arguments thereon. Not later than the 30th day following the date of the publication of a petition under this paragraph in the Federal Register, the Administrator shall either make the designation for which the petition is submitted or deny the petition.

(b) Well operation permits; publication in Federal Register; notice and hearing; issuance or denial; conditions for issuance

(1) During the period beginning on the date an area is designated under subsection (a) and ending on the date the applicable underground injection control program covering such area takes effect, no new underground injection well may be operated in such area unless the Administrator has issued a permit for such operation.

(2) Any person may petition the Administrator for the issuance of a permit for the operation of such a well in such an area. A petition submitted under this paragraph shall be submitted in such manner and contain such information as the Administrator may require by regulation. Upon receipt of such a petition, the Administrator shall publish it in the Federal Register. The Administrator shall give notice of any proceeding on a petition and shall provide opportunity for agency hearing. The Administrator shall act upon such petition on the record of any hearing held pursuant to the preceding sentence respecting such petition. Within 120 days of the publication in the Federal

Register of a petition submitted under this paragraph, the Administrator shall either issue the permit for which the petition was submitted or shall deny its issuance.

(3) The Administrator may issue a permit for the operation of a new underground injection well in an area designated under subsection (a) only, if he finds that the operation of such well will not cause contamination of the aquifer of such area so as to create a significant hazard to public health. The Administrator may condition the issuance of such a permit upon the use of such control measures in connection with the operation of such well, for which the permit is to be issued, as he deems necessary to assure that the operation of the well will not contaminate the aquifer of the designated area in which the well is located so as to create a significant hazard to public health.

(c) Civil penalties; separate violations; penalties for willful violations; temporary restraining order or injunction

Any person who operates a new underground injection well in violation of subsection (b), (1) shall be subject to a civil penalty of not more than $5,000 for each day in which such violation occurs, or (2) if such violation is willful, such person may, in lieu of the civil penalty authorized by clause (1), be fined not more than $10,000 for each day in which such violation occurs. If the Administrator has reason to believe that any person is violating or will violate subsection (b), he may petition the United States district court to issue a temporary restraining order or injunction (including a mandatory injunction) to enforce such subsection.

(d) "New underground injection well" defined

For purposes of this section, the term "new underground injection well" means an underground injection well whose operation was not approved by appropriate State and Federal agencies before December 16, 1974.

(e) Areas with one aquifer; publication in Federal Register; commitments for Federal financial assistance

If the Administrator determines, on his own initiative or upon petition, that an area has an aquifer which is the sole or principal drinking water source for the area and which, if contaminated, would create a significant hazard to public health, he shall publish notice of that determination in the Federal Register. After the publication of any such notice, no commitment for Federal financial assistance (through a grant, contract, loan guarantee, or otherwise) may be entered into for any project which the Administrator determines may contaminate such aquifer through a recharge zone so as to create a significant hazard to public health, but a commitment for Federal financial assistance may, if authorized under another provision of law, be entered into to plan or design the project to assure that it will not so contaminate the aquifer.

(July 1, 1944, ch. 373, title XIV, §1424, as added Pub. L. 93–523, §2(a), Dec. 16, 1974, 88 Stat. 1678.)

§300h–4. Optional demonstration by States relating to oil or natural gas

(a) Approval of State underground injection control program; alternative showing of effectiveness of program by State

For purposes of the Administrator's approval or disapproval under section 300h–1 of this title of that portion of any State underground injection control program which relates to—

(1) the underground injection of brine or other fluids which are brought to the surface in connection with oil or natural gas production or natural gas storage operations, or

(2) any underground injection for the secondary or tertiary recovery of oil or natural gas,

in lieu of the showing required under subparagraph (A) of section 300h–1(b)(1) of this title the State may demonstrate that such portion of the State program meets the requirements of

subparagraphs (A) through (D) of section 300h(b)(1) of this title and represents an effective program (including adequate recordkeeping and reporting) to prevent underground injection which endangers drinking water sources.

(b) Revision or amendment of requirements of regulation; showing of effectiveness of program by State

If the Administrator revises or amends any requirement of a regulation under section 300h of this title relating to any aspect of the underground injection referred to in subsection (a), in the case of that portion of a State underground injection control program for which the demonstration referred to in subsection (a) has been made, in lieu of the showing required under section 300h–1(b)(1)(B) of this title the State may demonstrate that, with respect to that aspect of such underground injection, the State program meets the requirements of subparagraphs (A) through (D) of section 300h(b)(1) of this title and represents an effective program (including adequate recordkeeping and reporting) to prevent underground injection which endangers drinking water sources.

(c) Primary enforcement responsibility of State; voiding by Administrator under duly promulgated rule

(1) Section 300h–1(b)(3) of this title shall not apply to that portion of any State underground injection control program approved by the Administrator pursuant to a demonstration under subsection (a) of this section (and under subsection (b) of this section where applicable).

(2) If pursuant to such a demonstration, the Administrator approves such portion of the State program, the State shall have primary enforcement responsibility with respect to that portion until such time as the Administrator determines, by rule, that such demonstration is no longer valid. Following such a determination, the Administrator may exercise the authority of subsection (c) of section 300h–1 of this title in the same manner as provided in such subsection with respect to a determination described in such subsection.

(3) Before promulgating any rule under paragraph (2), the Administrator shall provide opportunity for public hearing respecting such rule.

(July 1, 1944, ch. 373, title XIV, §1425, as added Pub. L. 96–502, §2(a), Dec. 5, 1980, 94 Stat. 2737; amended Pub. L. 99–339, title II, §201(a), June 19, 1986, 100 Stat. 653.)

EDITORIAL NOTES

AMENDMENTS

1986—Subsec. (a)(1). Pub. L. 99–339 inserted "or natural gas storage operations, or" after "production".

§300h–5. Regulation of State programs

Not later than 18 months after June 19, 1986, the Administrator shall modify regulations issued under this chapter for Class I injection wells to identify monitoring methods, in addition to those in effect on November 1, 1985, including groundwater monitoring. In accordance with such regulations, the Administrator, or delegated State authority, shall determine the applicability of such monitoring methods, wherever appropriate, at locations and in such a manner as to provide the earliest possible detection of fluid migration into, or in the direction of, underground sources of drinking water from such wells, based on its assessment of the potential for fluid migration from the injection zone that may be harmful to human health or the environment. For purposes of this subsection, a class I injection well is defined in accordance with 40 CFR 146.05 as in effect on November 1, 1985.

(July 1, 1944, ch. 373, title XIV, §1426, as added Pub. L. 99–339, title II, §201(b), June 19, 1986, 100 Stat. 653; amended Pub. L. 104–66, title II, §2021(f), Dec. 21, 1995, 109 Stat. 727; Pub. L. 104–182, title V, §501(f)(2), Aug. 6, 1996, 110 Stat. 1691.)

EDITORIAL NOTES

AMENDMENTS

1996—Pub. L. 104–182 directed technical amendment of section catchline and subsec. (a) designation. The provision directing amendment of subsec. (a) designation could not be executed because section does not contain a subsec. (a).

1995—Pub. L. 104–66 struck out subsec. (a) designation and heading before "Not later than" and struck out heading and text of subsec. (b). Text read as follows: "The Administrator shall submit a report to Congress, no later than September 1987, summarizing the results of State surveys required by the Administrator under this section. The report shall include each of the following items of information:

"(1) The numbers and categories of class V wells which discharge nonhazardous waste into or above an underground source of drinking water.

"(2) The primary contamination problems associated with different categories of these disposal wells.

"(3) Recommendations for minimum design, construction, installation, and siting requirements that should be applied to protect underground sources of drinking water from such contamination wherever necessary."

§300h–6. Sole source aquifer demonstration program

(a) Purpose

The purpose of this section is to establish procedures for development, implementation, and assessment of demonstration programs designed to protect critical aquifer protection areas located within areas designated as sole or principal source aquifers under section 300h–3(e) of this title.

(b) "Critical aquifer protection area" defined

For purposes of this section, the term "critical aquifer protection area" means either of the following:

(1) All or part of an area located within an area for which an application or designation as a sole or principal source aquifer pursuant to section 300h–3(e) of this title, has been submitted and approved by the Administrator and which satisfies the criteria established by the Administrator under subsection (d).

(2) All or part of an area which is within an aquifer designated as a sole source aquifer as of June 19, 1986, and for which an areawide ground water quality protection plan has been approved under section 208 of the Clean Water Act [33 U.S.C. 1288] prior to June 19, 1986.

(c) Application

Any State, municipal or local government or political subdivision thereof or any planning entity (including any interstate regional planning entity) that identifies a critical aquifer protection area over which it has authority or jurisdiction may apply to the Administrator for the selection of such area for a demonstration program under this section. Any applicant shall consult with other government or planning entities with authority or jurisdiction in such area prior to application. Applicants, other than the Governor, shall submit the application for a demonstration program jointly with the Governor.

(d) Criteria

Not later than 1 year after June 19, 1986, the Administrator shall, by rule, establish criteria for identifying critical aquifer protection areas under this section. In establishing such criteria, the Administrator shall consider each of the following:

(1) The vulnerability of the aquifer to contamination due to hydrogeologic characteristics.

(2) The number of persons or the proportion of population using the ground water as a drinking water source.

(3) The economic, social and environmental benefits that would result to the area from maintenance of ground water of high quality.

(4) The economic, social and environmental costs that would result from degradation of the quality of the ground water.

(e) Contents of application

An application submitted to the Administrator by any applicant for a demonstration program under this section shall meet each of the following requirements:

(1) The application shall propose boundaries for the critical aquifer protection area within its jurisdiction.

(2) The application shall designate or, if necessary, establish a planning entity (which shall be a public agency and which shall include representation of elected local and State governmental officials) to develop a comprehensive management plan (hereinafter in this section referred to as the "plan") for the critical protection area. Where a local government planning agency exists with adequate authority to carry out this section with respect to any proposed critical protection area, such agency shall be designated as the planning entity.

(3) The application shall establish procedures for public participation in the development of the plan, for review, approval, and adoption of the plan, and for assistance to municipalities and other public agencies with authority under State law to implement the plan.

(4) The application shall include a hydrogeologic assessment of surface and ground water resources within the critical protection area.

(5) The application shall include a comprehensive management plan for the proposed protection area.

(6) The application shall include the measures and schedule proposed for implementation of such plan.

(f) Comprehensive plan

(1) The objective of a comprehensive management plan submitted by an applicant under this section shall be to maintain the quality of the ground water in the critical protection area in a manner reasonably expected to protect human health, the environment and ground water resources. In order to achieve such objective, the plan may be designed to maintain, to the maximum extent possible, the natural vegetative and hydrogeological conditions. Each of the following elements shall be included in such a protection plan:

(A) A map showing the detailed boundary of the critical protection area.

(B) An identification of existing and potential point and nonpoint sources of ground water degradation.

(C) An assessment of the relationship between activities on the land surface and ground water quality.

(D) Specific actions and management practices to be implemented in the critical protection area to prevent adverse impacts on ground water quality.

(E) Identification of authority adequate to implement the plan, estimates of program costs, and sources of State matching funds.

(2) Such plan may also include the following:

(A) A determination of the quality of the existing ground water recharged through the special protection area and the natural recharge capabilities of the special protection area watershed.

(B) Requirements designed to maintain existing underground drinking water quality or improve underground drinking water quality if prevailing conditions fail to meet drinking water standards, pursuant to this chapter and State law.

(C) Limits on Federal, State, and local government, financially assisted activities and projects which may contribute to degradation of such ground water or any loss of natural surface and subsurface infiltration of purification capability of the special protection watershed.

(D) A comprehensive statement of land use management including emergency contingency planning as it pertains to the maintenance of the quality of underground sources of drinking water or to the improvement of such sources if necessary to meet drinking water standards pursuant to this chapter and State law.

(E) Actions in the special protection area which would avoid adverse impacts on water quality, recharge capabilities, or both.

(F) Consideration of specific techniques, which may include clustering, transfer of development rights, and other innovative measures sufficient to achieve the objectives of this section.

(G) Consideration of the establishment of a State institution to facilitate and assist funding a development transfer credit system.

(H) A program for State and local implementation of the plan described in this subsection in a manner that will insure the continued, uniform, consistent protection of the critical protection area in accord with the purposes of this section.

(I) Pollution abatement measures, if appropriate.

(g) Plans under section 208 of Clean Water Act

A plan approved before June 19, 1986, under section 208 of the Clean Water Act [33 U.S.C. 1288] to protect a sole source aquifer designated under section 300h–3(e) of this title shall be considered a comprehensive management plan for the purposes of this section.

(h) Consultation and hearings

During the development of a comprehensive management plan under this section, the planning entity shall consult with, and consider the comments of, appropriate officials of any municipality and State or Federal agency which has jurisdiction over lands and waters within the special protection area, other concerned organizations and technical and citizen advisory committees. The planning entity shall conduct public hearings at places within the special protection area for the purpose of providing the opportunity to comment on any aspect of the plan.

(i) Approval or disapproval

Within 120 days after receipt of an application under this section, the Administrator shall approve or disapprove the application. The approval or disapproval shall be based on a determination that the critical protection area satisfies the criteria established under subsection (d) and that a demonstration program for the area would provide protection for ground water quality consistent with the objectives stated in subsection (f). The Administrator shall provide to the Governor a written explanation of the reasons for the disapproval of any such application. Any petitioner may modify and resubmit any application which is not approved. Upon approval of an application, the Administrator may enter into a cooperative agreement with the applicant to establish a demonstration program under this section.

(j) Grants and reimbursement

Upon entering a cooperative agreement under subsection (i), the Administrator may provide to the applicant, on a matching basis, a grant of 50 per centum of the costs of implementing the plan established under this section. The Administrator may also reimburse the applicant of an approved plan up to 50 per centum of the costs of developing such plan, except for plans approved under section 208 of the Clean Water Act [33 U.S.C. 1288]. The total amount of grants under this section for any one aquifer, designated under section 300h–3(e) of this title, shall not exceed $4,000,000 in any one fiscal year.

(k) Activities funded under other law

No funds authorized under this section may be used to fund activities funded under other sections of this chapter or the Clean Water Act [33 U.S.C. 1251 et seq.], the Solid Waste Disposal Act [42 U.S.C. 6901 et seq.], the Comprehensive Environmental Response, Compensation, and Liability Act of 1980 [42 U.S.C. 9601 et seq.] or other environmental laws.

(l) Savings provision

Nothing under this section shall be construed to amend, supersede or abrogate rights to quantities of water which have been established by interstate water compacts, Supreme Court decrees, or State water laws; or any requirement imposed or right provided under any Federal or State environmental or public health statute.

(m) Authorization of appropriations

There are authorized to be appropriated to carry out this section not more than the following

amounts:

Fiscal year:	*Amount*
1987	$10,000,000
1988	15,000,000
1989	17,500,000
1990	17,500,000
1991	17,500,000
1992–2003	15,000,000.

Matching grants under this section may also be used to implement or update any water quality management plan for a sole or principal source aquifer approved (before June 19, 1986) by the Administrator under section 208 of the Federal Water Pollution Control Act [33 U.S.C. 1288].

(July 1, 1944, ch. 373, title XIV, §1427, as added and amended Pub. L. 99–339, title II, §203, title III, §301(f), June 19, 1986, 100 Stat. 657, 664; Pub. L. 104–66, title II, §2021(g), Dec. 21, 1995, 109 Stat. 727; Pub. L. 104–182, title I, §120(a), title V, §501(b)(2), (f)(3), Aug. 6, 1996, 110 Stat. 1650, 1691.)

EDITORIAL NOTES

REFERENCES IN TEXT

The Clean Water Act, referred to in subsec. (k), is act June 30, 1948, ch. 758, as amended generally by Pub. L. 92–500, §2, Oct. 18, 1972, 86 Stat. 816, also known as the Federal Water Pollution Control Act, which is classified generally to chapter 26 (§1251 et seq.) of Title 33, Navigation and Navigable Waters. For complete classification of this Act to the Code, see Short Title note set out under section 1251 of Title 33 and Tables.

The Solid Waste Disposal Act, referred to in subsec. (k), is title II of Pub. L. 89–272, Oct. 20, 1965, 79 Stat. 997, as amended generally by Pub. L. 94–580, §2, Oct. 21, 1976, 90 Stat. 2795, which is classified generally to chapter 82 (§6901 et seq.) of this title. For complete classification of this Act to the Code, see Short Title note set out under section 6901 of this title and Tables.

The Comprehensive Environmental Response, Compensation, and Liability Act of 1980, referred to in subsec. (k), is Pub. L. 96–510, Dec. 11, 1980, 94 Stat. 2767, which is classified principally to chapter 103 (§9601 et seq.) of this title. For complete classification of this Act to the Code, see Short Title note set out under section 9601 of this title and Tables.

AMENDMENTS

1996—Pub. L. 104–182, §501(f)(3), made technical amendment to section catchline and subsec. (a) designation.

Subsec. (b)(1). Pub. L. 104–182, §120(a)(1), struck out "not later than 24 months after June 19, 1986," after "by the Administrator".

Subsec. (k). Pub. L. 104–182, §501(b)(2), substituted "this section" for "this subsection".

Subsec. (m). Pub. L. 104–182, §120(a)(2), inserted table item relating to fiscal years 1992 through 2003.

1995—Subsecs. (l) to (n). Pub. L. 104–66 redesignated subsecs. (m) and (n) as (l) and (m), respectively, and struck out heading and text of former subsec. (l). Text read as follows: "Not later than December 31, 1989, each State shall submit to the Administrator a report assessing the impact of the program on ground water quality and identifying those measures found to be effective in protecting ground water resources. No later than September 30, 1990, the Administrator shall submit to Congress a report summarizing the State reports, and assessing the accomplishments of the sole source aquifer demonstration program including an identification of protection methods found to be most effective and recommendations for their application to protect ground water resources from contamination whenever necessary."

1986—Subsec. (n). Pub. L. 99–339 added subsec. (n).

§300h–7. State programs to establish wellhead protection areas

(a) State programs

The Governor or Governor's designee of each State shall, within 3 years of June 19, 1986, adopt and submit to the Administrator a State program to protect wellhead areas within their jurisdiction from contaminants which may have any adverse effect on the health of persons. Each State program under this section shall, at a minimum—

(1) specify the duties of State agencies, local governmental entities, and public water supply systems with respect to the development and implementation of programs required by this section;

(2) for each wellhead, determine the wellhead protection area as defined in subsection (e) based on all reasonably available hydrogeologic information on ground water flow, recharge and discharge and other information the State deems necessary to adequately determine the wellhead protection area;

(3) identify within each wellhead protection area all potential anthropogenic sources of contaminants which may have any adverse effect on the health of persons;

(4) describe a program that contains, as appropriate, technical assistance, financial assistance, implementation of control measures, education, training, and demonstration projects to protect the water supply within wellhead protection areas from such contaminants;

(5) include contingency plans for the location and provision of alternate drinking water supplies for each public water system in the event of well or wellfield contamination by such contaminants; and

(6) include a requirement that consideration be given to all potential sources of such contaminants within the expected wellhead area of a new water well which serves a public water supply system.

(b) Public participation

To the maximum extent possible, each State shall establish procedures, including but not limited to the establishment of technical and citizens' advisory committees, to encourage the public to participate in developing the protection program for wellhead areas and source water assessment programs under section 300j–13 of this title. Such procedures shall include notice and opportunity for public hearing on the State program before it is submitted to the Administrator.

(c) Disapproval

(1) In general

If, in the judgment of the Administrator, a State program or portion thereof under subsection (a) is not adequate to protect public water systems as required by subsection (a) or a State program under section 300j–13 of this title or section 300g–7(b) of this title does not meet the applicable requirements of section 300j–13 of this title or section 300g–7(b) of this title, the Administrator shall disapprove such program or portion thereof. A State program developed pursuant to subsection (a) shall be deemed to be adequate unless the Administrator determines, within 9 months of the receipt of a State program, that such program (or portion thereof) is inadequate for the purpose of protecting public water systems as required by this section from contaminants that may have any adverse effect on the health of persons. A State program developed pursuant to section 300j–13 of this title or section 300g–7(b) of this title shall be deemed to meet the applicable requirements of section 300j–13 of this title or section 300g–7(b) of this title unless the Administrator determines within 9 months of the receipt of the program that such program (or portion thereof) does not meet such requirements. If the Administrator determines that a proposed State program (or any portion thereof) is disapproved, the Administrator shall submit a written statement of the reasons for such determination to the Governor of the State.

(2) Modification and resubmission

Within 6 months after receipt of the Administrator's written notice under paragraph (1) that any proposed State program (or portion thereof) is disapproved, the Governor or Governor's designee, shall modify the program based upon the recommendations of the Administrator and resubmit the

modified program to the Administrator.

(d) Federal assistance

After the date 3 years after June 19, 1986, no State shall receive funds authorized to be appropriated under this section except for the purpose of implementing the program and requirements of paragraphs (4) and (6) of subsection (a).

(e) "Wellhead protection area" defined

As used in this section, the term "wellhead protection area" means the surface and subsurface area surrounding a water well or wellfield, supplying a public water system, through which contaminants are reasonably likely to move toward and reach such water well or wellfield. The extent of a wellhead protection area, within a State, necessary to provide protection from contaminants which may have any adverse effect on the health of persons is to be determined by the State in the program submitted under subsection (a). Not later than one year after June 19, 1986, the Administrator shall issue technical guidance which States may use in making such determinations. Such guidance may reflect such factors as the radius of influence around a well or wellfield, the depth of drawdown of the water table by such well or wellfield at any given point, the time or rate of travel of various contaminants in various hydrologic conditions, distance from the well or wellfield, or other factors affecting the likelihood of contaminants reaching the well or wellfield, taking into account available engineering pump tests or comparable data, field reconnaissance, topographic information, and the geology of the formation in which the well or wellfield is located.

(f) Prohibitions

(1) Activities under other laws

No funds authorized to be appropriated under this section may be used to support activities authorized by the Federal Water Pollution Control Act [33 U.S.C. 1251 et seq.], the Solid Waste Disposal Act [42 U.S.C. 6901 et seq.], the Comprehensive Environmental Response, Compensation, and Liability Act of 1980 [42 U.S.C. 9601 et seq.], or other sections of this chapter.

(2) Individual sources

No funds authorized to be appropriated under this section may be used to bring individual sources of contamination into compliance.

(g) Implementation

Each State shall make every reasonable effort to implement the State wellhead area protection program under this section within 2 years of submitting the program to the Administrator. Each State shall submit to the Administrator a biennial status report describing the State's progress in implementing the program. Such report shall include amendments to the State program for water wells sited during the biennial period.

(h) Federal agencies

Each department, agency, and instrumentality of the executive, legislative, and judicial branches of the Federal Government having jurisdiction over any potential source of contaminants identified by a State program pursuant to the provisions of subsection (a)(3) shall be subject to and comply with all requirements of the State program developed according to subsection (a)(4) applicable to such potential source of contaminants, both substantive and procedural, in the same manner, and to the same extent, as any other person is subject to such requirements, including payment of reasonable charges and fees. The President may exempt any potential source under the jurisdiction of any department, agency, or instrumentality in the executive branch if the President determines it to be in the paramount interest of the United States to do so. No such exemption shall be granted due to the lack of an appropriation unless the President shall have specifically requested such appropriation as part of the budgetary process and the Congress shall have failed to make available such requested appropriations.

(i) Additional requirement

(1) In general

In addition to the provisions of subsection (a) of this section, States in which there are more than 2,500 active wells at which annular injection is used as of January 1, 1986, shall include in their State program a certification that a State program exists and is being adequately enforced that provides protection from contaminants which may have any adverse effect on the health of persons and which are associated with the annular injection or surface disposal of brines associated with oil and gas production.

(2) "Annular injection" defined

For purposes of this subsection, the term "annular injection" means the reinjection of brines associated with the production of oil or gas between the production and surface casings of a conventional oil or gas producing well.

(3) Review

The Administrator shall conduct a review of each program certified under this subsection.

(4) Disapproval

If a State fails to include the certification required by this subsection or if in the judgment of the Administrator the State program certified under this subsection is not being adequately enforced, the Administrator shall disapprove the State program submitted under subsection (a) of this section.

(j) Coordination with other laws

Nothing in this section shall authorize or require any department, agency, or other instrumentality of the Federal Government or State or local government to apportion, allocate or otherwise regulate the withdrawal or beneficial use of ground or surface waters, so as to abrogate or modify any existing rights to water established pursuant to State or Federal law, including interstate compacts.

(k) Authorization of appropriations

Unless the State program is disapproved under this section, the Administrator shall make grants to the State for not less than 50 or more than 90 percent of the costs incurred by a State (as determined by the Administrator) in developing and implementing each State program under this section. For purposes of making such grants there is authorized to be appropriated not more than the following amounts:

Fiscal year:	*Amount*
1987	$20,000,000
1988	20,000,000
1989	35,000,000
1990	35,000,000
1991	35,000,000
1992–2003	30,000,000.

(July 1, 1944, ch. 373, title XIV, §1428, as added and amended Pub. L. 99–339, title II, §205, title III, §301(e), June 19, 1986, 100 Stat. 660, 664; Pub. L. 104–182, title I, §§120(b), 132(b), title V, §501(f)(4), Aug. 6, 1996, 110 Stat. 1650, 1674, 1692.)

EDITORIAL NOTES

REFERENCES IN TEXT

The Federal Water Pollution Control Act, referred to in subsec. (f)(1), is act June 30, 1948, ch. 758, as amended generally by Pub. L. 92–500, §2, Oct. 18, 1972, 86 Stat. 816, which is classified generally to chapter

26 (§1251 et seq.) of Title 33, Navigation and Navigable Waters. For complete classification of this Act to the Code, see Short Title note set out under section 1251 of Title 33 and Tables.

The Solid Waste Disposal Act, referred to in subsec. (f)(1), is title II of Pub. L. 89–272, Oct. 20, 1965, 79 Stat. 997, as amended generally by Pub. L. 94–580, §2, Oct. 21, 1976, 90 Stat. 2795, which is classified generally to chapter 82 (§6901 et seq.) of this title. For complete classification of this Act to the Code, see Short Title note set out under section 6901 of this title and Tables.

The Comprehensive Environmental Response, Compensation, and Liability Act of 1980, referred to in subsec. (f)(1), is Pub. L. 96–510, Dec. 11, 1980, 94 Stat. 2767, which is classified principally to chapter 103 (§9601 et seq.) of this title. For complete classification of this Act to the Code, see Short Title note set out under section 9601 of this title and Tables.

AMENDMENTS

1996—Pub. L. 104–182, §501(f)(4), made technical amendment to section catchline and subsec. (a) designation.

Subsec. (b). Pub. L. 104–182, §132(b)(4), inserted before period at end of first sentence "and source water assessment programs under section 300j–13 of this title".

Subsec. (c)(1). Pub. L. 104–182, §132(b)(3), which directed substitution of "is disapproved" for "is inadequate" in third sentence, was executed by making the substitution in fourth sentence to reflect the probable intent of Congress and the amendment by Pub. L. 104–182, §132(b)(2). See below.

Pub. L. 104–182, §132(b)(2), inserted after second sentence "A State program developed pursuant to section 300j–13 of this title or section 300g–7(b) of this title shall be deemed to meet the applicable requirements of section 300j–13 of this title or section 300g–7(b) of this title unless the Administrator determines within 9 months of the receipt of the program that such program (or portion thereof) does not meet such requirements."

Pub. L. 104–182, §132(b)(1), amended first sentence generally. Prior to amendment, first sentence read as follows: "If, in the judgment of the Administrator, a State program (or portion thereof, including the definition of a wellhead protection area), is not adequate to protect public water systems as required by this section, the Administrator shall disapprove such program (or portion thereof)."

Subsec. (c)(2). Pub. L. 104–182, §132(b)(3), substituted "is disapproved" for "is inadequate".

Subsec. (k). Pub. L. 104–182, §120(b), inserted table item relating to fiscal years 1992 through 2003.

1986—Subsec. (k). Pub. L. 99–339, §301(e), added subsec. (k).

§300h–8. State ground water protection grants

(a) In general

The Administrator may make a grant to a State for the development and implementation of a State program to ensure the coordinated and comprehensive protection of ground water resources within the State.

(b) Guidance

Not later than 1 year after August 6, 1996, and annually thereafter, the Administrator shall publish guidance that establishes procedures for application for State ground water protection program assistance and that identifies key elements of State ground water protection programs.

(c) Conditions of grants

(1) In general

The Administrator shall award grants to States that submit an application that is approved by the Administrator. The Administrator shall determine the amount of a grant awarded pursuant to this paragraph on the basis of an assessment of the extent of ground water resources in the State and the likelihood that awarding the grant will result in sustained and reliable protection of ground water quality.

(2) Innovative program grants

The Administrator may also award a grant pursuant to this subsection for innovative programs proposed by a State for the prevention of ground water contamination.

(3) Allocation of funds

The Administrator shall, at a minimum, ensure that, for each fiscal year, not less than 1 percent of funds made available to the Administrator by appropriations to carry out this section are allocated to each State that submits an application that is approved by the Administrator pursuant to this section.

(4) Limitation on grants

No grant awarded by the Administrator may be used for a project to remediate ground water contamination.

(d) Amount of grants

The amount of a grant awarded pursuant to paragraph (1) shall not exceed 50 percent of the eligible costs of carrying out the ground water protection program that is the subject of the grant (as determined by the Administrator) for the 1-year period beginning on the date that the grant is awarded. The State shall pay a State share to cover the costs of the ground water protection program from State funds in an amount that is not less than 50 percent of the cost of conducting the program.

(e) Evaluations and reports

Not later than 3 years after August 6, 1996, and every 3 years thereafter, the Administrator shall evaluate the State ground water protection programs that are the subject of grants awarded pursuant to this section and report to the Congress on the status of ground water quality in the United States and the effectiveness of State programs for ground water protection.

(f) Authorization of appropriations

There are authorized to be appropriated to carry out this section $15,000,000 for each of fiscal years 1997 through 2003.

(July 1, 1944, ch. 373, title XIV, §1429, as added Pub. L. 104–182, title I, §131, Aug. 6, 1996, 110 Stat. 1672.)

§300h–9. Secure geologic storage permitting

(a) Definitions

In this section:

(1) Administrator

The term "Administrator" means the Administrator of the Environmental Protection Agency.

(2) Class VI well

The term "Class VI well" means a well described in section 144.6(f) of title 40, Code of Federal Regulations (or successor regulations).

(b) Authorization of appropriations for geologic sequestration permitting

There is authorized to be appropriated to the Administrator for the permitting of Class VI wells by the Administrator for the injection of carbon dioxide for the purpose of geologic sequestration in accordance with the requirements of the Safe Drinking Water Act (42 U.S.C. 300f et seq.) and the final rule of the Administrator entitled "Federal Requirements Under the Underground Injection Control (UIC) Program for Carbon Dioxide (CO2) Geologic Sequestration (GS) Wells" (75 Fed. Reg. 77230 (December 10, 2010)), $5,000,000 for each of fiscal years 2022 through 2026.

(c) State permitting program grants

(1) Establishment

The Administrator shall award grants to States that, pursuant to section 1422 of the Safe Drinking Water Act (42 U.S.C. 300h–1), receive the approval of the Administrator for a State underground injection control program for permitting Class VI wells for the injection of carbon dioxide.

(2) Use of funds

A State that receives a grant under paragraph (1) shall use the amounts received under the grant to defray the expenses of the State related to the establishment and operation of a State underground injection control program described in paragraph (1).

(3) Authorization of appropriations

There is authorized to be appropriated to the Administrator to carry out this subsection $50,000,000 for the period of fiscal years 2022 through 2026.

(Pub. L. 117–58, div. D, title III, §40306, Nov. 15, 2021, 135 Stat. 1002.)

EDITORIAL NOTES

REFERENCES IN TEXT

The Safe Drinking Water Act, referred to in subsec. (b), is title XIV of act July 1, 1944, as added Dec. 16, 1974, Pub. L. 93–523, §2(a), 88 Stat. 1660, which is classified generally to subchapter XII (§300f et seq.) of chapter 6A of this title. For complete classification of this Act to the Code, see Short Title note set out under section 201 of this title and Tables.

CODIFICATION

Section was enacted as part of the Infrastructure Investment and Jobs Act, and not as part of the Public Health Service Act which comprises this chapter.

STATUTORY NOTES AND RELATED SUBSIDIARIES

WAGE RATE REQUIREMENTS

For provisions relating to rates of wages to be paid to laborers and mechanics on projects for construction, alteration, or repair work funded under div. D or an amendment by div. D of Pub. L. 117–58, including authority of Secretary of Labor, see section 18851 of this title.

PART D—EMERGENCY POWERS

§300i. Emergency powers

(a) Actions authorized against imminent and substantial endangerment to health

Notwithstanding any other provision of this subchapter the Administrator, upon receipt of information that a contaminant which is present in or is likely to enter a public water system or an underground source of drinking water, or that there is a threatened or potential terrorist attack (or other intentional act designed to disrupt the provision of safe drinking water or to impact adversely the safety of drinking water supplied to communities and individuals), which may present an imminent and substantial endangerment to the health of persons, and that appropriate State and local authorities have not acted to protect the health of such persons, may take such actions as he may deem necessary in order to protect the health of such persons. To the extent he determines it to be practicable in light of such imminent endangerment, he shall consult with the State and local authorities in order to confirm the correctness of the information on which action proposed to be taken under this subsection is based and to ascertain the action which such authorities are or will be taking. The action which the Administrator may take may include (but shall not be limited to) (1) issuing such orders as may be necessary to protect the health of persons who are or may be users of such system (including travelers), including orders requiring the provision of alternative water supplies by persons who caused or contributed to the endangerment, and (2) commencing a civil action for appropriate relief, including a restraining order or permanent or temporary injunction.

(b) Penalties for violations; separate offenses

Any person who violates or fails or refuses to comply with any order issued by the Administrator under subsection (a)(1) may, in an action brought in the appropriate United States district court to enforce such order, be subject to a civil penalty of not to exceed $15,000 for each day in which such violation occurs or failure to comply continues.

(July 1, 1944, ch. 373, title XIV, §1431, as added Pub. L. 93–523, §2(a), Dec. 16, 1974, 88 Stat. 1680; amended Pub. L. 99–339, title II, §204, June 19, 1986, 100 Stat. 660; Pub. L. 104–182, title I, §113(d), Aug. 6, 1996, 110 Stat. 1636; Pub. L. 107–188, title IV, §403(2), June 12, 2002, 116 Stat. 687.)

EDITORIAL NOTES

AMENDMENTS

2002—Subsec. (a). Pub. L. 107–188, in first sentence, inserted ", or that there is a threatened or potential terrorist attack (or other intentional act designed to disrupt the provision of safe drinking water or to impact adversely the safety of drinking water supplied to communities and individuals), which" after "drinking water".

1996—Subsec. (b). Pub. L. 104–182 substituted "$15,000" for "$5,000".

1986—Subsec. (a). Pub. L. 99–339, §204(1), (2), inserted "or an underground source of drinking water" after "to enter a public water system" and "including orders requiring the provision of alternative water supplies by persons who caused or contributed to the endangerment," after "including travelers),".

Subsec. (b). Pub. L. 99–339, §204(3), struck out "willfully" after "person who" and substituted "subject to a civil penalty of not to exceed" for "fined not more than".

§300i–1. Tampering with public water systems

(a) Tampering

Any person who tampers with a public water system shall be imprisoned for not more than 20 years, or fined in accordance with title 18, or both.

(b) Attempt or threat

Any person who attempts to tamper, or makes a threat to tamper, with a public drinking water system be imprisoned for not more than 10 years, or fined in accordance with title 18, or both.

(c) Civil penalty

The Administrator may bring a civil action in the appropriate United States district court (as determined under the provisions of title 28) against any person who tampers, attempts to tamper, or makes a threat to tamper with a public water system. The court may impose on such person a civil penalty of not more than $1,000,000 for such tampering or not more than $100,000 for such attempt or threat.

(d) "Tamper" defined

For purposes of this section, the term "tamper" means—

(1) to introduce a contaminant into a public water system with the intention of harming persons; or

(2) to otherwise interfere with the operation of a public water system with the intention of harming persons.

(July 1, 1944, ch. 373, title XIV, §1432, as added Pub. L. 99–339, title I, §108, June 19, 1986, 100 Stat. 651; amended Pub. L. 104–182, title V, §501(f)(5), Aug. 6, 1996, 110 Stat. 1692; Pub. L. 107–188, title IV, §403(3), June 12, 2002, 116 Stat. 687.)

EDITORIAL NOTES

AMENDMENTS

2002—Subsec. (a). Pub. L. 107–188, §403(3)(A), substituted "20 years" for "5 years".

Subsec. (b). Pub. L. 107–188, §403(3)(B), substituted "10 years" for "3 years".

Subsec. (c). Pub. L. 107–188, §403(3)(C), (D), substituted "$1,000,000" for "$50,000" and "$100,000" for "$20,000".

1996—Pub. L. 104–182 made technical amendment to section catchline and subsec. (a) designation.

§300i–2. Community water system risk and resilience

(a) Risk and resilience assessments

(1) In general

Each community water system serving a population of greater than 3,300 persons shall conduct an assessment of the risks to, and resilience of, its system. Such an assessment—

(A) shall include an assessment of—

(i) the risk to the system from malevolent acts and natural hazards;

(ii) the resilience of the pipes and constructed conveyances, physical barriers, source water, water collection and intake, pretreatment, treatment, storage and distribution facilities, electronic, computer, or other automated systems (including the security of such systems) which are utilized by the system;

(iii) the monitoring practices of the system;

(iv) the financial infrastructure of the system;

(v) the use, storage, or handling of various chemicals by the system; and

(vi) the operation and maintenance of the system; and

(B) may include an evaluation of capital and operational needs for risk and resilience management for the system.

(2) Baseline information

The Administrator, not later than August 1, 2019, after consultation with appropriate departments and agencies of the Federal Government and with State and local governments, shall provide baseline information on malevolent acts of relevance to community water systems, which shall include consideration of acts that may—

(A) substantially disrupt the ability of the system to provide a safe and reliable supply of drinking water; or

(B) otherwise present significant public health or economic concerns to the community served by the system.

(3) Certification

(A) Certification

Each community water system described in paragraph (1) shall submit to the Administrator a certification that the system has conducted an assessment complying with paragraph (1). Such certification shall be made prior to—

(i) March 31, 2020, in the case of systems serving a population of 100,000 or more;

(ii) December 31, 2020, in the case of systems serving a population of 50,000 or more but less than 100,000; and

(iii) June 30, 2021, in the case of systems serving a population greater than 3,300 but less than 50,000.

(B) Review and revision

Each community water system described in paragraph (1) shall review the assessment of such system conducted under such paragraph at least once every 5 years after the applicable deadline for submission of its certification under subparagraph (A) to determine whether such assessment should be revised. Upon completion of such a review, the community water system shall submit

to the Administrator a certification that the system has reviewed its assessment and, if applicable, revised such assessment.

(4) Contents of certifications

A certification required under paragraph (3) shall contain only—

(A) information that identifies the community water system submitting the certification;

(B) the date of the certification; and

(C) a statement that the community water system has conducted, reviewed, or revised the assessment, as applicable.

(5) Provision to other entities

No community water system shall be required under State or local law to provide an assessment described in this section (or revision thereof) to any State, regional, or local governmental entity solely by reason of the requirement set forth in paragraph (3) that the system submit a certification to the Administrator.

(b) Emergency response plan

Each community water system serving a population greater than 3,300 shall prepare or revise, where necessary, an emergency response plan that incorporates findings of the assessment conducted under subsection (a) for such system (and any revisions thereto). Each community water system shall certify to the Administrator, as soon as reasonably possible after October 23, 2018, but not later than 6 months after completion of the assessment under subsection (a), that the system has completed such plan. The emergency response plan shall include—

(1) strategies and resources to improve the resilience of the system, including the physical security and cybersecurity of the system;

(2) plans and procedures that can be implemented, and identification of equipment that can be utilized, in the event of a malevolent act or natural hazard that threatens the ability of the community water system to deliver safe drinking water;

(3) actions, procedures, and equipment which can obviate or significantly lessen the impact of a malevolent act or natural hazard on the public health and the safety and supply of drinking water provided to communities and individuals, including the development of alternative source water options, relocation of water intakes, and construction of flood protection barriers; and

(4) strategies that can be used to aid in the detection of malevolent acts or natural hazards that threaten the security or resilience of the system.

(c) Coordination

Community water systems shall, to the extent possible, coordinate with existing local emergency planning committees established pursuant to the Emergency Planning and Community Right-To-Know Act of 1986 (42 U.S.C. 11001 et seq.) when preparing or revising an assessment or emergency response plan under this section.

(d) Record maintenance

Each community water system shall maintain a copy of the assessment conducted under subsection (a) and the emergency response plan prepared under subsection (b) (including any revised assessment or plan) for 5 years after the date on which a certification of such assessment or plan is submitted to the Administrator under this section.

(e) Guidance to small public water systems

The Administrator shall provide guidance and technical assistance to community water systems serving a population of less than 3,300 persons on how to conduct resilience assessments, prepare emergency response plans, and address threats from malevolent acts and natural hazards that threaten to disrupt the provision of safe drinking water or significantly affect the public health or significantly affect the safety or supply of drinking water provided to communities and individuals.

(f) Alternative preparedness and operational resilience programs

(1) Satisfaction of requirement

A community water system that is required to comply with the requirements of subsections (a) and (b) may satisfy such requirements by—

(A) using and complying with technical standards that the Administrator has recognized under paragraph (2); and

(B) submitting to the Administrator a certification that the community water system is complying with subparagraph (A).

(2) Authority to recognize

Consistent with section 12(d) of the National Technology Transfer and Advancement Act of 1995, the Administrator shall recognize technical standards that are developed or adopted by third-party organizations or voluntary consensus standards bodies that carry out the objectives or activities required by this section as a means of satisfying the requirements under subsection (a) or (b).

(g) Technical assistance and grants

(1) In general

The Administrator shall establish and implement a program, to be known as the Drinking Water Infrastructure Risk and Resilience Program, under which the Administrator may award grants in each of fiscal years 2020 and 2021 to owners or operators of community water systems for the purpose of increasing the resilience of such community water systems.

(2) Use of funds

As a condition on receipt of a grant under this section, an owner or operator of a community water system shall agree to use the grant funds exclusively to assist in the planning, design, construction, or implementation of a program or project consistent with an emergency response plan prepared pursuant to subsection (b), which may include—

(A) the purchase and installation of equipment for detection of drinking water contaminants or malevolent acts;

(B) the purchase and installation of fencing, gating, lighting, or security cameras;

(C) the tamper-proofing of manhole covers, fire hydrants, and valve boxes;

(D) the purchase and installation of improved treatment technologies and equipment to improve the resilience of the system;

(E) improvements to electronic, computer, financial, or other automated systems and remote systems;

(F) participation in training programs, and the purchase of training manuals and guidance materials, relating to security and resilience;

(G) improvements in the use, storage, or handling of chemicals by the community water system;

(H) security screening of employees or contractor support services;

(I) equipment necessary to support emergency power or water supply, including standby and mobile sources; and

(J) the development of alternative source water options, relocation of water intakes, and construction of flood protection barriers.

(3) Exclusions

A grant under this subsection may not be used for personnel costs, or for monitoring, operation, or maintenance of facilities, equipment, or systems.

(4) Technical assistance

For each fiscal year, the Administrator may use not more than $5,000,000 from the funds made available to carry out this subsection to provide technical assistance to community water systems to assist in responding to and alleviating a vulnerability that would substantially disrupt the ability of the system to provide a safe and reliable supply of drinking water (including sources of water for such systems) which the Administrator determines to present an immediate and urgent need.

(5) Grants for small systems

For each fiscal year, the Administrator may use not more than $10,000,000 from the funds made available to carry out this subsection to make grants to community water systems serving a population of less than 3,300 persons, or nonprofit organizations receiving assistance under section 300j–1(e) of this title, for activities and projects undertaken in accordance with the guidance provided to such systems under subsection (e) of this section.

(6) Authorization of appropriations

To carry out this subsection, there are authorized to be appropriated $25,000,000 for each of fiscal years 2020 and 2021.

(h) Definitions

In this section—

(1) the term "resilience" means the ability of a community water system or an asset of a community water system to adapt to or withstand the effects of a malevolent act or natural hazard without interruption to the asset's or system's function, or if the function is interrupted, to rapidly return to a normal operating condition; and

(2) the term "natural hazard" means a natural event that threatens the functioning of a community water system, including an earthquake, tornado, flood, hurricane, wildfire, and hydrologic changes.

(July 1, 1944, ch. 373, title XIV, §1433, as added Pub. L. 107–188, title IV, §401, June 12, 2002, 116 Stat. 682; amended Pub. L. 115–270, title II, §2013(a), Oct. 23, 2018, 132 Stat. 3850.)

EDITORIAL NOTES

REFERENCES IN TEXT

The Emergency Planning and Community Right-To-Know Act of 1986, referred to in subsec. (c), is Pub. L. 99–499, title III, Oct. 17, 1986, 100 Stat. 1728, which is classified generally to chapter 116 (§11001 et seq.) of this title. For complete classification of this Act to the Code, see Short Title note set out under section 11001 of this title and Tables.

Section 12(d) of the National Technology Transfer and Advancement Act of 1995, referred to in subsec. (f)(2), is section 12(d) of Pub. L. 104–113, which is set out as a note under section 272 of Title 15, Commerce and Trade.

AMENDMENTS

2018—Pub. L. 115–270 amended section generally. Prior to amendment, section related to terrorist and other intentional acts.

STATUTORY NOTES AND RELATED SUBSIDIARIES

SENSITIVE INFORMATION

Pub. L. 115–270, title II, §2013(b), Oct. 23, 2018, 132 Stat. 3854, provided that:

"(1) PROTECTION FROM DISCLOSURE.—Information submitted to the Administrator of the Environmental Protection Agency pursuant to section 1433 of the Safe Drinking Water Act [42 U.S.C. 300i–2], as in effect on the day before the date of enactment of America's Water Infrastructure Act of 2018 [Oct. 23, 2018], shall be protected from disclosure in accordance with the provisions of such section as in effect on such day.

"(2) DISPOSAL.—The Administrator, in partnership with community water systems (as defined in section 1401 of the Safe Drinking Water Act [42 U.S.C. 300f]), shall develop a strategy to, in a timeframe determined appropriate by the Administrator, securely and permanently dispose of, or return to the applicable community water system, any information described in paragraph (1)."

§300i–3. Contaminant prevention, detection and response

(a) In general

The Administrator, in consultation with the Centers for Disease Control and, after consultation with appropriate departments and agencies of the Federal Government and with State and local governments, shall review (or enter into contracts or cooperative agreements to provide for a review of) current and future methods to prevent, detect and respond to the intentional introduction of chemical, biological or radiological contaminants into community water systems and source water for community water systems, including each of the following:

(1) Methods, means and equipment, including real time monitoring systems, designed to monitor and detect various levels of chemical, biological, and radiological contaminants or indicators of contaminants and reduce the likelihood that such contaminants can be successfully introduced into public water systems and source water intended to be used for drinking water.

(2) Methods and means to provide sufficient notice to operators of public water systems, and individuals served by such systems, of the introduction of chemical, biological or radiological contaminants and the possible effect of such introduction on public health and the safety and supply of drinking water.

(3) Methods and means for developing educational and awareness programs for community water systems.

(4) Procedures and equipment necessary to prevent the flow of contaminated drinking water to individuals served by public water systems.

(5) Methods, means, and equipment which could negate or mitigate deleterious effects on public health and the safety and supply caused by the introduction of contaminants into water intended to be used for drinking water, including an examination of the effectiveness of various drinking water technologies in removing, inactivating, or neutralizing biological, chemical, and radiological contaminants.

(6) Biomedical research into the short-term and long-term impact on public health of various chemical, biological and radiological contaminants that may be introduced into public water systems through terrorist or other intentional acts.

(b) Funding

For the authorization of appropriations to carry out this section, see section 300i–4(e) of this title.

(July 1, 1944, ch. 373, title XIV, §1434, as added Pub. L. 107–188, title IV, §402, June 12, 2002, 116 Stat. 685.)

STATUTORY NOTES AND RELATED SUBSIDIARIES

CHANGE OF NAME

Centers for Disease Control changed to Centers for Disease Control and Prevention by Pub. L. 102–531, title III, §312, Oct. 27, 1992, 106 Stat. 3504.

§300i–4. Supply disruption prevention, detection and response

(a) Disruption of supply or safety

The Administrator, in coordination with the appropriate departments and agencies of the Federal Government, shall review (or enter into contracts or cooperative agreements to provide for a review of) methods and means by which terrorists or other individuals or groups could disrupt the supply of safe drinking water or take other actions against water collection, pretreatment, treatment, storage and distribution facilities which could render such water significantly less safe for human consumption, including each of the following:

(1) Methods and means by which pipes and other constructed conveyances utilized in public water systems could be destroyed or otherwise prevented from providing adequate supplies of drinking water meeting applicable public health standards.

(2) Methods and means by which collection, pretreatment, treatment, storage and distribution

facilities utilized or used in connection with public water systems and collection and pretreatment storage facilities used in connection with public water systems could be destroyed or otherwise prevented from providing adequate supplies of drinking water meeting applicable public health standards.

(3) Methods and means by which pipes, constructed conveyances, collection, pretreatment, treatment, storage and distribution systems that are utilized in connection with public water systems could be altered or affected so as to be subject to cross-contamination of drinking water supplies.

(4) Methods and means by which pipes, constructed conveyances, collection, pretreatment, treatment, storage and distribution systems that are utilized in connection with public water systems could be reasonably protected from terrorist attacks or other acts intended to disrupt the supply or affect the safety of drinking water.

(5) Methods and means by which information systems, including process controls and supervisory control and data acquisition and cyber systems at community water systems could be disrupted by terrorists or other groups.

(b) Alternative sources

The review under this section shall also include a review of the methods and means by which alternative supplies of drinking water could be provided in the event of the destruction, impairment or contamination of public water systems.

(c) Requirements and considerations

In carrying out this section and section 300i–3 of this title—

(1) the Administrator shall ensure that reviews carried out under this section reflect the needs of community water systems of various sizes and various geographic areas of the United States; and

(2) the Administrator may consider the vulnerability of, or potential for forced interruption of service for, a region or service area, including community water systems that provide service to the National Capital area.

(d) Information sharing

As soon as practicable after reviews carried out under this section or section 300i–3 of this title have been evaluated, the Administrator shall disseminate, as appropriate as determined by the Administrator, to community water systems information on the results of the project through the Information Sharing and Analysis Center, or other appropriate means.

(e) Funding

There are authorized to be appropriated to carry out this section and section 300i–3 of this title not more than $15,000,000 for the fiscal year 2002 and such sums as may be necessary for the fiscal years 2003 through 2005.

(July 1, 1944, ch. 373, title XIV, §1435, as added Pub. L. 107–188, title IV, §402, June 12, 2002, 116 Stat. 686.)

PART E—GENERAL PROVISIONS

§300j. Assurances of availability of adequate supplies of chemicals necessary for treatment of water

(a) Certification of need application

If any person who uses chlorine, activated carbon, lime, ammonia, soda ash, potassium permanganate, caustic soda, or other chemical or substance for the purpose of treating water in any public water system or in any public treatment works determines that the amount of such chemical or

substance necessary to effectively treat such water is not reasonably available to him or will not be so available to him when required for the effective treatment of such water, such person may apply to the Administrator for a certification (hereinafter in this section referred to as a "certification of need") that the amount of such chemical or substance which such person requires to effectively treat such water is not reasonably available to him or will not be so available when required for the effective treatment of such water.

(b) Application requirements; publication in Federal Register; waiver; certification, issuance or denial

(1) An application for a certification of need shall be in such form and submitted in such manner as the Administrator may require and shall (A) specify the persons the applicant determines are able to provide the chemical or substance with respect to which the application is submitted, (B) specify the persons from whom the applicant has sought such chemical or substance, and (C) contain such other information as the Administrator may require.

(2) Upon receipt of an application under this section, the Administrator shall (A) publish in the Federal Register a notice of the receipt of the application and a brief summary of it, (B) notify in writing each person whom the President or his delegate (after consultation with the Administrator) determines could be made subject to an order required to be issued upon the issuance of the certification of need applied for in such application, and (C) provide an opportunity for the submission of written comments on such application. The requirements of the preceding sentence of this paragraph shall not apply when the Administrator for good cause finds (and incorporates the finding with a brief statement of reasons therefor in the order issued) that waiver of such requirements is necessary in order to protect the public health.

(3) Within 30 days after—

(A) the date a notice is published under paragraph (2) in the Federal Register with respect to an application submitted under this section for the issuance of a certification of need, or

(B) the date on which such application is received if as authorized by the second sentence of such paragraph no notice is published with respect to such application,

the Administrator shall take action either to issue or deny the issuance of a certification of need.

(c) Certification of need; issuance; executive orders; implementation of orders; equitable apportionment of orders; factors considered

(1) If the Administrator finds that the amount of a chemical or substance necessary for an applicant under an application submitted under this section to effectively treat water in a public water system or in a public treatment works is not reasonably available to the applicant or will not be so available to him when required for the effective treatment of such water, the Administrator shall issue a certification of need. Not later than seven days following the issuance of such certification, the President or his delegate shall issue an order requiring the provision to such person of such amounts of such chemical or substance as the Administrator deems necessary in the certification of need issued for such person. Such order shall apply to such manufactures, producers, processors, distributors, and repackagers of such chemical or substance as the President or his delegate deems necessary and appropriate, except that such order may not apply to any manufacturer, producer, or processor of such chemical or substance who manufactures, produces, or processes (as the case may be) such chemical or substance solely for its own use. Persons subject to an order issued under this section shall be given a reasonable opportunity to consult with the President or his delegate with respect to the implementation of the order.

(2) Orders which are to be issued under paragraph (1) to manufacturers, producers, and processors of a chemical or substance shall be equitably apportioned, as far as practicable, among all manufacturers, producers, and processors of such chemical or substance; and orders which are to be issued under paragraph (1) to distributors and repackagers of a chemical or substance shall be equitably apportioned, as far as practicable, among all distributors and repackagers of such chemical

or substance. In apportioning orders issued under paragraph (1) to manufacturers, producers, processors, distributors, and repackagers of chlorine, the President or his delegate shall, in carrying out the requirements of the preceding sentence, consider—

(A) the geographical relationships and established commercial relationships between such manufacturers, producers, processors, distributors, and repackagers and the persons for whom the orders are issued;

(B) in the case of orders to be issued to producers of chlorine, the (i) amount of chlorine historically supplied by each such producer to treat water in public water systems and public treatment works, and (ii) share of each such producer of the total annual production of chlorine in the United States; and

(C) such other factors as the President or his delegate may determine are relevant to the apportionment of orders in accordance with the requirements of the preceding sentence.

(3) Subject to subsection (f), any person for whom a certification of need has been issued under this subsection may upon the expiration of the order issued under paragraph (1) upon such certification apply under this section for additional certifications.

(d) Breach of contracts; defense

There shall be available as a defense to any action brought for breach of contract in a Federal or State court arising out of delay or failure to provide, sell, or offer for sale or exchange a chemical or substance subject to an order issued pursuant to subsection (c)(1), that such delay or failure was caused solely by compliance with such order.

(e) Penalties for noncompliance with orders; temporary restraining orders and preliminary or permanent injunctions

(1) Whoever knowingly fails to comply with any order issued pursuant to subsection (c)(1) shall be fined not more than $5,000 for each such failure to comply.

(2) Whoever fails to comply with any order issued pursuant to subsection (c)(1) shall be subject to a civil penalty of not more than $2,500 for each such failure to comply.

(3) Whenever the Administrator or the President or his delegate has reason to believe that any person is violating or will violate any order issued pursuant to subsection (c)(1), he may petition a United States district court to issue a temporary restraining order or preliminary or permanent injunction (including a mandatory injunction) to enforce the provision of such order.

(f) Termination date

No certification of need or order issued under this section may remain in effect for more than one year.

(July 1, 1944, ch. 373, title XIV, §1441, as added Pub. L. 93–523, §2(a), Dec. 16, 1974, 88 Stat. 1680; amended Pub. L. 95–190, §7, Nov. 16, 1977, 91 Stat. 1396; Pub. L. 96–63, §3, Sept. 6, 1979, 93 Stat. 411; Pub. L. 99–339, title III, §301(d), June 19, 1986, 100 Stat. 664; Pub. L. 104–182, title V, §501(c), Aug. 6, 1996, 110 Stat. 1691.)

EDITORIAL NOTES

AMENDMENTS

1996—Subsec. (f). Pub. L. 104–182 inserted a period after "year".

1986—Subsec. (f). Pub. L. 99–339 substituted "in effect for more than one year" for "in effect— (1) for more than one year, or (2) September 30, 1982, whichever occurs first."

1979—Subsec. (f)(2). Pub. L. 96–63 substituted "September 30, 1982" for "September 30, 1979".

1977—Subsec. (f). Pub. L. 95–190 substituted "September 30, 1979" for "June 30, 1977".

EXECUTIVE DOCUMENTS

EX. ORD. NO. 11879. DELEGATION OF FUNCTIONS TO SECRETARY OF COMMERCE

RELATING TO ORDERS FOR PROVISION OF CHEMICALS OR SUBSTANCES NECESSARY FOR TREATMENT OF WATER

Ex. Ord. No. 11879, Sept. 17, 1975, 40 F.R. 43197, provided:

By virtue of the authority vested in me by Section 1441 of the Public Health Service Act, as amended by the Safe Drinking Water Act [now Safe Drinking Water Act of 1974] (88 Stat. 1680, 42 U.S.C. 300j), and as President of the United States, the Secretary of Commerce is hereby delegated, with power to redelegate to agencies, officers and employees of the Government, the functions of the President contained in said section 1441 [42 U.S.C. 300j]. Those functions shall be administered under regulations or agreements which are identical or compatible with other regulations and agreements, including those provided pursuant to Executive Order No. 10480, as amended [former 50 U.S.C. App. 2153 note], for the allocation of similar chemicals or substances.

GERALD R. FORD.

§300j–1. Research, technical assistance, information, training of personnel

(a) Specific powers and duties of Administrator

(1) The Administrator may conduct research, studies, and demonstrations relating to the causes, diagnosis, treatment, control, and prevention of physical and mental diseases and other impairments of man resulting directly or indirectly from contaminants in water, or to the provision of a dependably safe supply of drinking water, including—

(A) improved methods (i) to identify and measure the existence of contaminants in drinking water (including methods which may be used by State and local health and water officials), and (ii) to identify the source of such contaminants;

(B) improved methods to identify and measure the health effects of contaminants in drinking water;

(C) new methods of treating raw water to prepare it for drinking, so as to improve the efficiency of water treatment and to remove contaminants from water;

(D) improved methods for providing a dependably safe supply of drinking water, including improvements in water purification and distribution, and methods of assessing the health related hazards of drinking water;

(E) improved methods of protecting underground water sources of public water systems from contamination; and

(F) innovative water technologies (including technologies to improve water treatment to ensure compliance with this subchapter and technologies to identify and mitigate sources of drinking water contamination, including lead contamination).

(2) INFORMATION AND RESEARCH FACILITIES.—In carrying out this subchapter, the Administrator is authorized to—

(A) collect and make available information pertaining to research, investigations, and demonstrations with respect to providing a dependably safe supply of drinking water, together with appropriate recommendations in connection with the information; and

(B) make available research facilities of the Agency to appropriate public authorities, institutions, and individuals engaged in studies and research relating to this subchapter.

(3) The Administrator shall carry out a study of polychlorinated biphenyl contamination of actual or potential sources of drinking water, contamination of such sources by other substances known or suspected to be harmful to public health, the effects of such contamination, and means of removing, treating, or otherwise controlling such contamination. To assist in carrying out this paragraph, the Administrator is authorized to make grants to public agencies and private nonprofit institutions.

(4) The Administrator shall conduct a survey and study of—

(A) disposal of waste (including residential waste) which may endanger underground water which supplies, or can reasonably be expected to supply, any public water systems, and

(B) means of control of such waste disposal.

Not later than one year after December 16, 1974, he shall transmit to the Congress the results of such survey and study, together with such recommendations as he deems appropriate.

(5) The Administrator shall carry out a study of methods of underground injection which do not result in the degradation of underground drinking water sources.

(6) The Administrator shall carry out a study of methods of preventing, detecting, and dealing with surface spills of contaminants which may degrade underground water sources for public water systems.

(7) The Administrator shall carry out a study of virus contamination of drinking water sources and means of control of such contamination.

(8) The Administrator shall carry out a study of the nature and extent of the impact on underground water which supplies or can reasonably be expected to supply public water systems of (A) abandoned injection or extraction wells; (B) intensive application of pesticides and fertilizers in underground water recharge areas; and (C) ponds, pools, lagoons, pits, or other surface disposal of contaminants in underground water recharge areas.

(9) The Administrator shall conduct a comprehensive study of public water supplies and drinking water sources to determine the nature, extent, sources of and means of control of contamination by chemicals or other substances suspected of being carcinogenic. Not later than six months after December 16, 1974, he shall transmit to the Congress the initial results of such study, together with such recommendations for further review and corrective action as he deems appropriate.

(10) The Administrator shall carry out a study of the reaction of chlorine and humic acids and the effects of the contaminants which result from such reaction on public health and on the safety of drinking water, including any carcinogenic effect.

(11) COMPLIANCE EVALUATION.—

(A) IN GENERAL.—Not later than 1 year after November 15, 2021, the Administrator shall—

(i) evaluate, based on the compliance data found in the Safe Drinking Water Information System of the Administrator, the compliance of community water systems and wastewater systems with environmental, health, and safety requirements under this subchapter, including water quality sampling, testing, and reporting requirements; and

(ii) submit to Congress a report describing trends seen as a result of the evaluation under clause (i), including trends that demonstrate how the characteristics of community water systems and wastewater systems correlate to trends in compliance or noncompliance with the requirements described in that clause.

(B) REQUIREMENT.—To the extent practicable, in carrying out subparagraph (A), the Administrator shall determine whether, in aggregate, community water systems and wastewater systems maintain asset management plans.

(b) Emergency situations

The Administrator is authorized to provide technical assistance and to make grants to States, or publicly owned water systems to assist in responding to and alleviating any emergency situation (including an emergency situation resulting from a cybersecurity event) affecting public water systems (including sources of water for such systems) which the Administrator determines to present substantial danger to the public health, including a threat to public health resulting from contaminants, such as, but not limited to, heightened exposure to lead in drinking water. Grants provided under this subsection shall be used only to support those actions which (i) are necessary for preventing, limiting or mitigating danger to the public health in such emergency situation and (ii) would not, in the judgment of the Administrator, be taken without such emergency assistance. The Administrator may carry out the program authorized under this subsection as part of, and in accordance with the terms and conditions of, any other program of assistance for environmental emergencies which the Administrator is authorized to carry out under any other provision of law. No limitation on appropriations for any such other program shall apply to amounts appropriated under this subsection.

(c) Establishment of training programs and grants for training; training fees

The Administrator shall—

(1) provide training for, and make grants for training (including postgraduate training) of (A) personnel of State agencies which have primary enforcement responsibility and of agencies or units of local government to which enforcement responsibilities have been delegated by the State, and (B) personnel who manage or operate public water systems, and

(2) make grants for postgraduate training of individuals (including grants to educational institutions for traineeships) for purposes of qualifying such individuals to work as personnel referred to in paragraph (1).

(3) make grants to, and enter into contracts with, any public agency, educational institution, and any other organization, in accordance with procedures prescribed by the Administrator, under which he may pay all or part of the costs (as may be determined by the Administrator) of any project or activity which is designed—

(A) to develop, expand, or carry out a program (which may combine training education and employment) for training persons for occupations involving the public health aspects of providing safe drinking water;

(B) to train inspectors and supervisory personnel to train or supervise persons in occupations involving the public health aspects of providing safe drinking water; or

(C) to develop and expand the capability of programs of States and municipalities to carry out the purposes of this subchapter (other than by carrying out State programs of public water system supervision or underground water source protection (as defined in section 300j–2(c) of this title)).

Reasonable fees may be charged for training provided under paragraph (1)(B) to persons other than personnel of State or local agencies but such training shall be provided to personnel of State or local agencies without charge.

(d) Authorization of appropriations

There is authorized to be appropriated to carry out subsection (b) $35,000,000 for each of fiscal years 2022 through 2026.

(e) Technical assistance to small public water systems

(1) The Administrator may provide technical assistance to small public water systems to enable such systems to achieve and maintain compliance with applicable national primary drinking water regulations.

(2) Such assistance may include circuit-rider and multi-State regional technical assistance programs, training, and preliminary engineering evaluations.

(3) The Administrator shall ensure that technical assistance pursuant to this subsection is available in each State.

(4) Each nonprofit organization receiving assistance under this subsection shall consult with the State in which the assistance is to be expended or otherwise made available before using assistance to undertake activities to carry out this subsection.

(5) AUTHORIZATION OF APPROPRIATIONS.—There is authorized to be appropriated to the Administrator to carry out this subsection $15,000,000 for each of fiscal years 2022 through 2026.

(6) No portion of any State loan fund established under section 300j–12 of this title (relating to State loan funds) and no portion of any funds made available under this subsection may be used for lobbying expenses.

(7) Of the total amount appropriated under this subsection, 3 percent shall be used for technical assistance to public water systems owned or operated by Indian Tribes, including grants to provide training and operator certification services under section 300j–12(i)(5) of this title.

(8) NONPROFIT ORGANIZATIONS.—

(A) IN GENERAL.—The Administrator may use amounts made available to carry out this section to provide grants or cooperative agreements to nonprofit organizations that provide to small public water systems onsite technical assistance, circuit-rider technical assistance programs,

multistate, regional technical assistance programs, onsite and regional training, assistance with implementing source water protection plans, and assistance with implementing monitoring plans, rules, regulations, and water security enhancements.

(B) PREFERENCE.—To ensure that technical assistance funding is used in a manner that is most beneficial to the small and rural communities of a State, the Administrator shall give preference under this paragraph to nonprofit organizations that, as determined by the Administrator, are the most qualified and experienced in providing training and technical assistance to small public water systems and that the small community water systems in that State find to be the most beneficial and effective.

(C) LIMITATION.—No grant or cooperative agreement provided or otherwise made available under this section may be used for litigation pursuant to section 300j–8 of this title.

(f) State-based nonprofit organizations

(1) In general

The Administrator may provide technical assistance consistent with the authority provided under subsection (e) to State-based nonprofit organizations that are governed by community water systems.

(2) Communication

Each State-based nonprofit organization that receives funding under paragraph (1) shall, before using that funding to undertake activities to carry out this subsection, consult with the State in which the assistance is to be expended or otherwise made available.

(g) Technical assistance for innovative water technologies

(1) The Administrator may provide technical assistance to public water systems to facilitate use of innovative water technologies.

(2) There are authorized to be appropriated to the Administrator for use in providing technical assistance under paragraph (1) $10,000,000 for each of fiscal years 2017 through 2021.

(July 1, 1944, ch. 373, title XIV, §1442, as added Pub. L. 93–523, §2(a), Dec. 16, 1974, 88 Stat. 1682; amended Pub. L. 95–190, §§2(a), 3(a), (b), (e)(1), 4, 9, 10(b), 13, Nov. 16, 1977, 91 Stat. 1393–1395, 1397–1399; Pub. L. 96–63, §1, Sept. 6, 1979, 93 Stat. 411; Pub. L. 96–502, §5, Dec. 5, 1980, 94 Stat. 2738; Pub. L. 99–339, title I, §107, title III, §§301(a), (g), 304(a), June 19, 1986, 100 Stat. 651, 663, 665, 667; Pub. L. 104–66, title II, §2021(h), Dec. 21, 1995, 109 Stat. 727; Pub. L. 104–182, title I, §§121, 122, Aug. 6, 1996, 110 Stat. 1651; Pub. L. 107–188, title IV, §403(4), June 12, 2002, 116 Stat. 687; Pub. L. 114–98, §4, Dec. 11, 2015, 129 Stat. 2200; Pub. L. 114–322, title II, §§2109(a), (b), 2112(a), Dec. 16, 2016, 130 Stat. 1729; Pub. L. 117–58, div. E, title I, §50101, Nov. 15, 2021, 135 Stat. 1135.)

EDITORIAL NOTES

AMENDMENTS

2021—Subsec. (a)(11). Pub. L. 117–58, §50101(1), added par. (11).

Subsec. (b). Pub. L. 117–58, §50101(2), inserted "(including an emergency situation resulting from a cybersecurity event)" after "any emergency situation" and ", including a threat to public health resulting from contaminants, such as, but not limited to, heightened exposure to lead in drinking water" after "substantial danger to the public health".

Subsec. (d). Pub. L. 117–58, §50101(3), added subsec. (d) and struck out former subsec. (d). Prior to amendment, text read as follows: "There are authorized to be appropriated to carry out subsection (b) not more than $35,000,000 for the fiscal year 2002 and such sums as may be necessary for each fiscal year thereafter."

Subsec. (e)(5). Pub. L. 117–58, §50101(4), added par. (5) and struck out former par. (5) which read as follows: "There are authorized to be appropriated to the Administrator to be used for such technical assistance $15,000,000 for each of the fiscal years 2015 through 2020."

Subsecs. (f), (g). Pub. L. 117–58, §50101(5), (6), added subsec. (f) and redesignated former subsec. (f) as (g).

2016—Subsec. (a)(1)(F). Pub. L. 114–322, §2109(a), added subpar. (F).

Subsec. (e). Pub. L. 114–322, §2109(b)(1), inserted "to small public water systems" after "assistance" in heading.

Subsec. (e)(7). Pub. L. 114–322, §2112(a), substituted "Tribes, including grants to provide training and operator certification services under section 300j–12(i)(5) of this title" for "Tribes".

Subsec. (f). Pub. L. 114–322, §2109(b)(2), added subsec. (f).

2015—Subsec. (e). Pub. L. 114–98, §4(1), designated first to seventh sentences of existing provisions as pars. (1) to (7), respectively.

Subsec. (e)(5). Pub. L. 114–98, §4(2), substituted "2015 through 2020" for "1997 through 2003".

Subsec. (e)(8). Pub. L. 114–98, §4(3), added par. (8).

2002—Subsec. (b). Pub. L. 107–188, §403(4)(A), which directed substitution of "this subsection" for "this subparagraph", was executed by making the substitution in three places to reflect the probable intent of Congress.

Subsec. (d). Pub. L. 107–188, §403(4)(B), amended subsec. (d) generally, substituting provisions relating to authorization of appropriations to carry out subsec. (b) in fiscal year 2002 and subsequent fiscal years for provisions relating to authorization of appropriations to carry out this section in fiscal year 1991 and earlier.

1996—Subsec. (a)(2). Pub. L. 104–182, §121(4)(A), added heading and text of par. (2) and struck out former par. (2) which read as follows: "(2)(A) The Administrator shall, to the maximum extent feasible, provide technical assistance to the States and municipalities in the establishment and administration of public water system supervision programs (as defined in section 300j–2(c)(1) of this title)."

Subsec. (a)(2)(B). Pub. L. 104–182, §121(3), redesignated subpar. (B) as subsec. (b) and transferred that subsec. to appear after subsec. (a).

Subsec. (a)(3), (11). Pub. L. 104–182, §121(4)(B), (C), redesignated par. (11) as (3), transferred that par. to appear before par. (4), and struck out former par. (3) which provided that the Administrator was to conduct studies, and make periodic reports to Congress, on the costs of carrying out regulations prescribed under section 300g–1 of this title.

Subsec. (b). Pub. L. 104–182, §121(2), (3), redesignated subsec. (a)(2)(B) as subsec. (b), transferred that subsec. to appear after subsec. (a), and struck out former subsec. (b) which read as follows: "In carrying out this subchapter, the Administrator is authorized to—

"(1) collect and make available information pertaining to research, investigations, and demonstrations with respect to providing a dependably safe supply of drinking water together with appropriate recommendations in connection therewith;

"(2) make available research facilities of the Agency to appropriate public authorities, institutions, and individuals engaged in studies and research relating to the purposes of this subchapter;".

Subsecs. (b)(3), (c)(3). Pub. L. 104–182, §121(1), which directed redesignation of subsec. (b)(3) as par. (3) of subsec. (d) and transfer of that par. to follow par. (2) of subsec. (d), was executed by redesignating subsec. (b)(3) as par. (3) of subsec. (c) and transferring that par. to follow par. (2) of subsec. (c) to reflect the probable intent of Congress and the redesignation of subsec. (d) as (c) by Pub. L. 104–66. See 1995 Amendment note below. Moreover, subsec. (d) does not have any pars.

Subsec. (e). Pub. L. 104–182, §122, amended subsec. (e) generally. Prior to amendment, subsec. (e) read as follows: "The Administrator is authorized to provide technical assistance to small public water systems to enable such systems to achieve and maintain compliance with national drinking water regulations. Such assistance may include 'circuit-rider' programs, training, and preliminary engineering studies. There are authorized to be appropriated to carry out this subsection $10,000,000 for each of the fiscal years 1987 through 1991. Not less than the greater of—

"(1) 3 percent of the amounts appropriated under this subsection, or

"(2) $280,000

shall be utilized for technical assistance to public water systems owned or operated by Indian tribes."

1995—Subsecs. (c) to (g). Pub. L. 104–66 redesignated subsecs. (d), (f), and (g) as (c), (d), and (e), respectively, and struck out former subsec. (c) which read as follows: "Not later than eighteen months after November 16, 1977, the Administrator shall submit a report to Congress on the present and projected future availability of an adequate and dependable supply of safe drinking water to meet present and projected future need. Such report shall include an analysis of the future demand for drinking water and other competing uses of water, the availability and use of methods to conserve water or reduce demand, the adequacy of present measures to assure adequate and dependable supplies of safe drinking water, and the problems (financial, legal, or other) which need to be resolved in order to assure the availability of such supplies for the future. Existing information and data complied by the National Water Commission and others shall be utilized to the extent possible."

1986—Subsec. (e). Pub. L. 99–339, §304(a), struck out subsec. (e) which authorized the Administrator to

make grants to public water systems which are required, under State or local law, to meet standards relating to drinking turbidity which are more stringent than the standards in effect under this subchapter.

Subsec. (f). Pub. L. 99–339, §301(a), authorized appropriations to carry out subsec. (a)(2)(B) of this section for fiscal years 1987 to 1991 and to carry out provisions of this section other than subsecs. (a)(2)(B) and (g) and provisions relating to research for fiscal years 1987 to 1991.

Subsec. (g). Pub. L. 99–339, §301(g), authorized appropriations to carry out this subsection of $10,000,000 for each of fiscal years 1987 through 1991 and specified amount to be utilized for public water systems owned or operated by Indian tribes.

Pub. L. 99–339, §107 added subsec. (g).

1980—Subsecs. (e), (f). Pub. L. 96–502 added subsec. (e) and redesignated former subsec. (e) as (f).

1979—Subsec. (e). Pub. L. 96–63 authorized appropriations of $21,405,000 for fiscal year ending Sept. 30, 1980, $30,000,000 for fiscal year ending Sept. 30, 1981, and $35,000,000 for fiscal year ending Sept. 30, 1982 for purposes other than those of subsec. (a)(2)(B) of this section and for purposes of subsec. (a)(2)(B) of this section, $8,000,000 for fiscal years 1980 through 1982.

1977—Subsec. (a)(2). Pub. L. 95–190, §§9, 13, designated existing provisions as subpar. (A), added subpar. (B) and, in subpar. (B) as added, substituted provisions authorizing Administrator to make grants and provide technical assistance for any emergency situation affecting public water systems and criteria for such grants and assistance for provisions authorizing Administrator to make grants and provide technical assistance for any emergency situation respecting drinking water and criteria for determination of such situations.

Subsec. (a)(3). Pub. L. 95–190, §3(a), designated existing provisions as subpar. (A) and added subpar. (B).

Subsec. (a)(10), (11). Pub. L. 95–190, §3(e)(1), added pars. (10) and (11).

Subsec. (b)(3)(C). Pub. L. 95–190, §10(b), substituted "300j–2(c)" for "300j–2(d)".

Subsecs. (c), (d). Pub. L. 95–190, §§3(b), 4, added subsecs. (c) and (d). Former subsec. (c) redesignated (e).

Subsec. (e). Pub. L. 95–190, §§2(a), 3(b), redesignated former subsec. (c) as (e) and inserted provisions authorizing appropriations for fiscal years 1978 and 1979, and provisions relating to appropriations for subsec. (a)(2)(B) of this section and for research.

STATUTORY NOTES AND RELATED SUBSIDIARIES

REPORT ON INNOVATIVE WATER TECHNOLOGIES

Pub. L. 114–322, title II, §2109(c), Dec. 16, 2016, 130 Stat. 1729, provided that: "Not later than 1 year after the date of enactment of the Water and Waste Act of 2016 [Dec. 16, 2016], and not less frequently than every 5 years thereafter, the Administrator [of the Environmental Protection Agency] shall report to Congress on—

"(1) the amount of funding used to provide technical assistance under section 1442(f) [now 1442(g)] of the Safe Drinking Water Act [42 U.S.C. 300j–1(g)] to deploy innovative water technologies;

"(2) the barriers impacting greater use of innovative water technologies; and

"(3) the cost-saving potential to cities and future infrastructure investments from innovative water technologies."

FINDINGS

Pub. L. 114–98, §2, Dec. 11, 2015, 129 Stat. 2199, provided that: "Congress finds that—

"(1) the Safe Drinking Water Act Amendments of 1996 (Public Law 104–182) [see Short Title of 1996 Amendments note set out under section 201 of this title] authorized technical assistance for small and rural communities to assist those communities in complying with regulations promulgated pursuant to the Safe Drinking Water Act (42 U.S.C. 300f et seq.);

"(2) technical assistance and compliance training—

"(A) ensures that Federal regulations do not overwhelm the resources of small and rural communities; and

"(B) provides small and rural communities lacking technical resources with the necessary skills to improve and protect water resources;

"(3) across the United States, more than 90 percent of the community water systems serve a population of less than 10,000 individuals;

"(4) small and rural communities have the greatest difficulty providing safe, affordable public drinking water and wastewater services due to limited economies of scale and lack of technical expertise; and

"(5) in addition to being the main source of compliance assistance, small and rural water technical assistance has been the main source of emergency response assistance in small and rural communities."

SCIENTIFIC RESEARCH REVIEW

Pub. L. 104–182, title II, §202, Aug. 6, 1996, 110 Stat. 1682, provided that:

"(a) IN GENERAL.—The Administrator shall—

"(1) develop a strategic plan for drinking water research activities throughout the Environmental Protection Agency (in this section referred to as the 'Agency');

"(2) integrate that strategic plan into ongoing Agency planning activities; and

"(3) review all Agency drinking water research to ensure the research—

"(A) is of high quality; and

"(B) does not duplicate any other research being conducted by the Agency.

"(b) PLAN.—The Administrator shall transmit the plan to the Committees on Commerce [now Energy and Commerce] and Science [now Science, Space, and Technology] of the House of Representatives and the Committee on Environment and Public Works of the Senate and the plan shall be made available to the public."

NATIONAL CENTER FOR GROUND WATER RESEARCH

Pub. L. 104–182, title II, §203, Aug. 6, 1996, 110 Stat. 1683, provided that: "The Administrator of the Environmental Protection Agency, acting through the Robert S. Kerr Environmental Research Laboratory, is authorized to reestablish a partnership between the Laboratory and the National Center for Ground Water Research, a university consortium, to conduct research, training, and technology transfer for ground water quality protection and restoration. No funds are authorized by this section."

COMPARATIVE HEALTH EFFECTS ASSESSMENT

Pub. L. 99–339, title III, §304(b), June 19, 1986, 100 Stat. 667, required the Administrator of the Environmental Protection Agency to conduct an assessment comparing the public health effects associated with water treatment chemicals and their byproducts to the public health effects associated with contaminants found in public water supplies and to submit a report to Congress on the assessment no later than 18 months after June 19, 1986.

§300j–1a. Innovative water technology grant program

(a) Definitions

In this section:

(1) Administrator

The term "Administrator" means the Administrator of the Environmental Protection Agency.

(2) Eligible entity

The term "eligible entity" means—

(A) a public water system (as defined under section 300f(4) of this title);

(B) an institution of higher education;

(C) a research institution or foundation;

(D) a regional water organization; or

(E) a nonprofit organization described in section 300j–1(e)(8) of this title.

(b) Grant program authorized

The Administrator shall carry out a grant program for the purpose of accelerating the development and deployment of innovative water technologies that address pressing drinking water supply, quality, treatment, or security challenges of public water systems, areas served by private wells, or source waters.

(c) Grants

In carrying out the program under subsection (b), the Administrator shall make grants to eligible entities—

(1) to develop, test, and deploy innovative water technologies; or

(2) to provide technical assistance to deploy demonstrated innovative water technologies.

(d) Selection criteria

In making grants under this section, the Administrator shall—

(1) award grants through a competitive process to eligible entities the Administrator determines are best able to carry out the purpose of the program; and

(2) give priority to projects that have the potential—

(A) to reduce ratepayer or community costs or costs of future capital investments;

(B) to significantly improve human health or the environment; or

(C) to provide additional drinking water supplies with minimal environmental impact.

(e) Cost-sharing

The Federal share of the cost of activities carried out using a grant under this section shall be not more than 65 percent.

(f) Limitation

The maximum amount of a grant under this section shall be $5,000,000.

(g) Report

Each year, the Administrator shall submit to Congress and make publicly available on the website of the Administrator a report that describes any advancements during the previous year in development of innovative water technologies made as a result of funding provided under this section.

(h) Partnerships

Grants awarded under this program may include projects that are carried out by an eligible entity in cooperation with a private entity, including a farmer, farmer cooperative, or manufacturer of water technologies.

(i) Authorization of appropriations

There is authorized to be appropriated to carry out this section $10,000,000 for each of fiscal years 2019 and 2020.

(Pub. L. 115–270, title II, §2007, Oct. 23, 2018, 132 Stat. 3845.)

EDITORIAL NOTES

CODIFICATION

Section was enacted as part of the America's Water Infrastructure Act of 2018, and not as part of the Public Health Service Act which comprises this chapter.

§300j–2. Grants for State programs

(a) Public water systems supervision programs; applications for grants; allotment of sums; waiver of grant restrictions; notice of approval or disapproval of application; authorization of appropriations

(1) From allotments made pursuant to paragraph (4), the Administrator may make grants to States to carry out public water system supervision programs.

(2) No grant may be made under paragraph (1) unless an application therefor has been submitted to the Administrator in such form and manner as he may require. The Administrator may not approve an application of a State for its first grant under paragraph (1) unless he determines that the State—

(A) has established or will establish within one year from the date of such grant a public water system supervision program, and

(B) will, within that one year, assume primary enforcement responsibility for public water systems within the State.

No grant may be made to a State under paragraph (1) for any period beginning more than one year after the date of the State's first grant unless the State has assumed and maintains primary enforcement responsibility for public water systems within the State. The prohibitions contained in

the preceding two sentences shall not apply to such grants when made to Indian Tribes.

(3) A grant under paragraph (1) shall be made to cover not more than 75 per centum of the grant recipient's costs (as determined under regulations of the Administrator) in carrying out, during the one-year period beginning on the date the grant is made, a public water system supervision program.

(4) In each fiscal year the Administrator shall, in accordance, with regulations, allot the sums appropriated for such year under paragraph (5) among the States on the basis of population, geographical area, number of public water systems, and other relevant factors. No State shall receive less than 1 per centum of the annual appropriation for grants under paragraph (1): *Provided*, That the Administrator may, by regulation, reduce such percentage in accordance with the criteria specified in this paragraph: *And provided further*, That such percentage shall not apply to grants allotted to Guam, American Samoa, or the Virgin Islands.

(5) The prohibition contained in the last sentence of paragraph (2) may be waived by the Administrator with respect to a grant to a State through fiscal year 1979 but such prohibition may only be waived if, in the judgment of the Administrator—

(A) the State is making a diligent effort to assume and maintain primary enforcement responsibility for public water systems within the State;

(B) the State has made significant progress toward assuming and maintaining such primary enforcement responsibility; and

(C) there is reason to believe the State will assume such primary enforcement responsibility by October 1, 1979.

The amount of any grant awarded for the fiscal years 1978 and 1979 pursuant to a waiver under this paragraph may not exceed 75 per centum of the allotment which the State would have received for such fiscal year if it had assumed and maintained such primary enforcement responsibility. The remaining 25 per centum of the amount allotted to such State for such fiscal year shall be retained by the Administrator, and the Administrator may award such amount to such State at such time as the State assumes such responsibility before the beginning of fiscal year 1980. At the beginning of each fiscal years 1979 and 1980 the amounts retained by the Administrator for any preceding fiscal year and not awarded by the beginning of fiscal year 1979 or 1980 to the States to which such amounts were originally allotted may be removed from the original allotment and reallotted for fiscal year 1979 or 1980 (as the case may be) to States which have assumed primary enforcement responsibility by the beginning of such fiscal year.

(6) The Administrator shall notify the State of the approval or disapproval of any application for a grant under this section—

(A) within ninety days after receipt of such application, or

(B) not later than the first day of the fiscal year for which the grant application is made,

whichever is later.

(7) AUTHORIZATION.—For the purpose of making grants under paragraph (1), there are authorized to be appropriated $125,000,000 for each of fiscal years 2020 and 2021.

(8) RESERVATION OF FUNDS BY THE ADMINISTRATOR.—If the Administrator assumes the primary enforcement responsibility of a State public water system supervision program, the Administrator may reserve from funds made available pursuant to this subsection an amount equal to the amount that would otherwise have been provided to the State pursuant to this subsection. The Administrator shall use the funds reserved pursuant to this paragraph to ensure the full and effective administration of a public water system supervision program in the State.

(9) STATE LOAN FUNDS.—

(A) RESERVATION OF FUNDS.—For any fiscal year for which the amount made available to the Administrator by appropriations to carry out this subsection is less than the amount that the Administrator determines is necessary to supplement funds made available pursuant to paragraph (8) to ensure the full and effective administration of a public water system supervision program in a State, the Administrator may reserve from the funds made available to the State under section 300j–12 of this title (relating to State loan funds) an amount that is equal to the amount of the

shortfall. This paragraph shall not apply to any State not exercising primary enforcement responsibility for public water systems as of August 6, 1996.

(B) DUTY OF ADMINISTRATOR.—If the Administrator reserves funds from the allocation of a State under subparagraph (A), the Administrator shall carry out in the State each of the activities that would be required of the State if the State had primary enforcement authority under section 300g–2 of this title.

(b) Underground water source protection programs; applications for grants; allotment of sums; authorization of appropriations

(1) From allotments made pursuant to paragraph (4), the Administrator may make grants to States to carry out underground water source protection programs.

(2) No grant may be made under paragraph (1) unless an application therefor has been submitted to the Administrator in such form and manner as he may require. No grant may be made to any State under paragraph (1) unless the State has assumed primary enforcement responsibility within two years after the date the Administrator promulgates regulations for State underground injection control programs under section 300h of this title. The prohibition contained in the preceding sentence shall not apply to such grants when made to Indian Tribes.

(3) A grant under paragraph (1) shall be made to cover not more than 75 per centum of the grant recipient's cost (as determined under regulations of the Administrator) in carrying out, during the one-year period beginning on the date the grant is made, and underground water source protection program.

(4) In each fiscal year the Administrator shall, in accordance with regulations, allot the sums appropriated for such year under paragraph (5) among the States on the basis of population, geographical area, and other relevant factors.

(5) For purposes of making grants under paragraph (1) there are authorized to be appropriated $5,000,000 for the fiscal year ending June 30, 1976, $7,500,000 for the fiscal year ending June 30, 1977, $10,000,000 for each of the fiscal years 1978 and 1979, $7,795,000 for the fiscal year ending September 30, 1980, $18,000,000 for the fiscal year ending September 30, 1981, and $21,000,000 for the fiscal year ending September 30, 1982. For the purpose of making grants under paragraph (1) there are authorized to be appropriated not more than the following amounts:

Fiscal year:	*Amount*
1987	$19,700,000
1988	19,700,000
1989	20,850,000
1990	20,850,000
1991	20,850,000
1992–2003	15,000,000.

(c) Definitions

For purposes of this section:

(1) The term "public water system supervision program" means a program for the adoption and enforcement of drinking water regulations (with such variances and exemptions from such regulations under conditions and in a manner which is not less stringent than the conditions under, and the manner in, which variances and exemptions may be granted under sections 300g–4 and 300g–5 of this title) which are no less stringent than the national primary drinking water regulations under section 300g–1 of this title, and for keeping records and making reports required by section 300g–2(a)(3) of this title.

(2) The term "underground water source protection program" means a program for the adoption and enforcement of a program which meets the requirements of regulations under section 300h of

this title, and for keeping records and making reports required by section 300h–1(b)(1)(A)(ii) of this title. Such term includes, where applicable, a program which meets the requirements of section 300h–4 of this title.

(d) New York City watershed protection program

(1) In general

The Administrator is authorized to provide financial assistance to the State of New York for demonstration projects implemented as part of the watershed program for the protection and enhancement of the quality of source waters of the New York City water supply system, including projects that demonstrate, assess, or provide for comprehensive monitoring and surveillance and projects necessary to comply with the criteria for avoiding filtration contained in 40 CFR 141.71. Demonstration projects which shall be eligible for financial assistance shall be certified to the Administrator by the State of New York as satisfying the purposes of this subsection. In certifying projects to the Administrator, the State of New York shall give priority to monitoring projects that have undergone peer review.

(2) Report

Not later than 5 years after the date on which the Administrator first provides assistance pursuant to this paragraph, the Governor of the State of New York shall submit a report to the Administrator on the results of projects assisted.

(3) Matching requirements

Federal assistance provided under this subsection shall not exceed 50 percent of the total cost of the protection program being carried out for any particular watershed or ground water recharge area.

(4) Authorization

There are authorized to be appropriated to the Administrator to carry out this subsection for each of fiscal years 2003 through 2010, $15,000,000 for the purpose of providing assistance to the State of New York to carry out paragraph (1).

(July 1, 1944, ch. 373, title XIV, §1443, as added Pub. L. 93–523, §2(a), Dec. 16, 1974, 88 Stat. 1684; amended Pub. L. 95–190, §§2(b), (c), 5(a), Nov. 16, 1977, 91 Stat. 1393, 1395; Pub. L. 96–63, §2, Sept. 6, 1979, 93 Stat. 411; Pub. L. 96–502, §§2(c), 4(d), Dec. 5, 1980, 94 Stat. 2738; Pub. L. 99–339, title III, §§301(b), (c), 302(d), June 19, 1986, 100 Stat. 664, 666; Pub. L. 104–182, title I, §§120(c), 124, 128, Aug. 6, 1996, 110 Stat. 1651, 1653, 1659; Pub. L. 108–328, §1, Oct. 16, 2004, 118 Stat. 1273; Pub. L. 115–270, title II, §2014, Oct. 23, 2018, 132 Stat. 3854.)

EDITORIAL NOTES

AMENDMENTS

2018—Subsec. (a)(7). Pub. L. 115–270 substituted "$125,000,000 for each of fiscal years 2020 and 2021" for "$100,000,000 for each of fiscal years 1997 through 2003".

2004—Subsec. (d)(4). Pub. L. 108–328 substituted "2003 through 2010" for "1997 through 2003".

1996—Subsec. (a)(7). Pub. L. 104–182, §124(1), inserted heading and amended text generally. Prior to amendment, text read as follows: "For purposes of making grants under paragraph (1) there are authorized to be appropriated $15,000,000 for the fiscal year ending June 30, 1976, $25,000,000 for the fiscal year ending June 30, 1977, $35,000,000 for fiscal year 1978, $45,000,000 for fiscal year 1979, $29,450,000 for the fiscal year ending September 30, 1980, $32,000,000 for the fiscal year ending September 30, 1981, and $34,000,000 for the fiscal year ending September 30, 1982. For the purposes of making grants under paragraph (1) there are authorized to be appropriated not more than the following amounts:

"Fiscal year:	*Amount*
1987	$37,200,000

1988	37,200,000
1989	40,150,000
1990	40,150,000
1991	40,150,000".

Subsec. (a)(8), (9). Pub. L. 104–182, §124(2), added pars. (8) and (9).

Subsec. (b)(5). Pub. L. 104–182, §120(c), inserted table item relating to fiscal years 1992 through 2003.

Subsec. (d). Pub. L. 104–182, §128, added subsec. (d).

1986—Subsec. (a)(2). Pub. L. 99–339, §302(d)(1), inserted provision that prohibitions contained in preceding two sentences not apply to such grants when made to Indian Tribes.

Subsec. (a)(7). Pub. L. 99–339, §301(b), authorized appropriations for grants under par. (1) of not more than $37,200,000 for fiscal years 1987 and 1988 and of not more than $40,150,000 for fiscal years 1989 to 1991.

Subsec. (b)(2). Pub. L. 99–339, §302(d)(2), inserted provision that prohibition contained in preceding sentence not apply to such grants when made to Indian Tribes.

Subsec. (b)(5). Pub. L. 99–339, §301(c), authorized appropriations for grants under par. (1) of not more than $19,700,000 for fiscal years 1987 and 1988 and of not more than $20,850,000 for fiscal years 1989 to 1991.

1980—Subsec. (b)(2). Pub. L. 96–502, §4(d), substituted provisions that no grant may be made to any State under par. (1) unless the State has assumed primary enforcement responsibility within two years after the date the Administrator promulgates regulations for State underground injection control programs under section 300h of this title for provisions that the Administrator may not approve an application of a State for its first grant under par. (1) unless he determines that the State has established or will establish within two years from the date of such grant an underground water source protection, and will, within such two years, assume primary enforcement responsibility for underground water sources within the State and that no grant may be made to a State under par. (1) for any period beginning more than two years after the date of the State's first grant unless the State has assumed and maintains primary enforcement responsibility for underground water sources within the State.

Subsec. (c)(2). Pub. L. 96–502, §2(c), inserted provision that such term includes, where applicable, a program which meets requirements of section 300h–4 of this title.

1979—Subsec. (a)(7). Pub. L. 96–63, §2(a), authorized appropriation of $29,450,000, $32,000,000, and $34,000,000 for fiscal years ending Sept. 30, 1980, through 1982, respectively.

Subsec. (b)(5). Pub. L. 96–63, §2(b), authorized appropriation of $7,795,000, $18,000,000, and $21,000,000 for fiscal years ending Sept. 30, 1980, through 1982, respectively.

1977—Subsec. (a)(5), (6). Pub. L. 95–190, §5(a), added pars. (5) and (6). Former par. (5) redesignated (7).

Subsec. (a)(7). Pub. L. 95–190, §§2(b), 5(a), redesignated former par. (5) as (7) and authorized appropriations for fiscal years 1978 and 1979.

Subsec. (b)(5). Pub. L. 95–190, §2(c), inserted provisions authorizing appropriations for fiscal years 1978 and 1979.

§300j–3. Special project grants and guaranteed loans

(a) Special study and demonstration project grants

The Administrator may make grants to any person for the purposes of—

(1) assisting in the development and demonstration (including construction) of any project which will demonstrate a new or improved method, approach, or technology, for providing a dependably safe supply of drinking water to the public; and

(2) assisting in the development and demonstration (including construction) of any project which will investigate and demonstrate health implications involved in the reclamation, recycling, and reuse of waste waters for drinking and the processes and methods for the preparation of safe and acceptable drinking water.

(b) Limitations

Grants made by the Administrator under this section shall be subject to the following limitations:

(1) Grants under this section shall not exceed 662/3 per centum of the total cost of construction of any facility and 75 per centum of any other costs, as determined by the Administrator.

(2) Grants under this section shall not be made for any project involving the construction or modification of any facilities for any public water system in a State unless such project has been approved by the State agency charged with the responsibility for safety of drinking water (or if there is no such agency in a State, by the State health authority).

(3) Grants under this section shall not be made for any project unless the Administrator determines, after consulting the National Drinking Water Advisory Council, that such project will serve a useful purpose relating to the development and demonstration of new or improved techniques, methods, or technologies for the provision of safe water to the public for drinking.

(4) Priority for grants under this section shall be given where there are known or potential public health hazards which require advanced technology for the removal of particles which are too small to be removed by ordinary treatment technology.

(c) Authorization of appropriations

For the purposes of making grants under subsections (a) and (b) of this section there are authorized to be appropriated $7,500,000 for the fiscal year ending June 30, 1975; and $7,500,000 for the fiscal year ending June 30, 1976; and $10,000,000 for the fiscal year ending June 30, 1977.

(d) Loan guarantees to public water systems; conditions; indebtedness limitation; regulations

The Administrator during the fiscal years ending June 30, 1975, and June 30, 1976, shall carry out a program of guaranteeing loans made by private lenders to small public water systems for the purpose of enabling such systems to meet national primary drinking water regulations prescribed under section 300g–1 of this title. No such guarantee may be made with respect to a system unless (1) such system cannot reasonably obtain financial assistance necessary to comply with such regulations from any other source, and (2) the Administrator determines that any facilities constructed with a loan guaranteed under this subsection is not likely to be made obsolete by subsequent changes in primary regulations. The aggregate amount of indebtedness guaranteed with respect to any system may not exceed $50,000. The aggregate amount of indebtedness guaranteed under this subsection may not exceed $50,000,000. The Administrator shall prescribe regulations to carry out this subsection.

(July 1, 1944, ch. 373, title XIV, §1444, as added Pub. L. 93–523, §2(a), Dec. 16, 1974, 88 Stat. 1685; amended Pub. L. 99–339, title I, §101(c)(3), June 19, 1986, 100 Stat. 646.)

EDITORIAL NOTES

AMENDMENTS

1986—Subsec. (d). Pub. L. 99–339 struck out "(including interim regulations)" before "prescribed" in first sentence.

§300j–3a. Grants to public sector agencies

(a) Assistance for development and demonstration projects

The Administrator of the Environmental Protection Agency shall offer grants to public sector agencies for the purposes of—

(1) assisting in the development and demonstration (including construction) of any project which will demonstrate a new or improved method, approach, or technology for providing a dependably safe supply of drinking water to the public; and

(2) assisting in the development and demonstration (including construction) of any project which will investigate and demonstrate health and conservation implications involved in the reclamation, recycling, and reuse of wastewaters for drinking and agricultural use or the processes and methods for the preparation of safe and acceptable drinking water.

(b) Limitations

Grants made by the Administrator under this section shall be subject to the following limitations:

(1) Grants under this section shall not exceed 662/3 per centum of the total cost of construction of any facility and 75 per centum of any other costs, as determined by the Administrator.

(2) Grants under this section shall not be made for any project involving the construction or modification of any facilities for any public water system in a State unless such project has been approved by the State agency charged with the responsibility for safety of drinking water (or if there is no such agency in a State, by the State health authority).

(3) Grants under this section shall not be made for any project unless the Administrator determines, after consultation, that such project will serve a useful purpose relating to the development and demonstration of new or improved techniques, methods, or technologies for the provision of safe water to the public for drinking.

(c) Authorization of appropriations

There are authorized to be appropriated for the purposes of this section $25,000,000 for fiscal year 1978.

(Pub. L. 95–155, §5, Nov. 8, 1977, 91 Stat. 1258; Pub. L. 95–477, §7(a)(1), Oct. 18, 1978, 92 Stat. 1511.)

EDITORIAL NOTES

CODIFICATION

Section was enacted as part of the Environmental Research, Development, and Demonstration Authorization Act of 1978, and not as part of the Public Health Service Act which comprises this chapter.

AMENDMENTS

1978—Subsec. (a)(2). Pub. L. 95–477 inserted "agricultural use or" after "drinking and".

STATUTORY NOTES AND RELATED SUBSIDIARIES

EFFECTIVE DATE OF 1978 AMENDMENT

Pub. L. 95–477, §7(a)(2), Oct. 18, 1978, 92 Stat. 1511, provided that: "This subsection [amending this section] shall become effective October 1, 1978."

§300j–3b. Contaminant standards or treatment technique guidelines

(1) Not later than nine months after October 18, 1978, the Administrator shall promulgate guidelines establishing supplemental standards or treatment technique requirements for microbiological, viral, radiological, organic, and inorganic contaminants, which guidelines shall be conditions, as provided in paragraph (2), of any grant for a demonstration project for water reclamation, recycling, and reuse funded under section 300j–3a of this title or under section 300j–3(a)(2) of this title, where such project involves direct human consumption of treated wastewater. Such guidelines shall provide for sufficient control of each such contaminant, such that in the Administrator's judgement, no adverse effects on the health of persons may reasonably be anticipated to occur, allowing an adequate margin of safety.

(2) A grant referred to in paragraph (1) for a project which involves direct human consumption of treated wastewater may be awarded on or after the date of promulgation of guidelines under this section only if the applicant demonstrates to the satisfaction of the Administrator that the project—

(A) will comply with all national primary drinking water regulations under section 300g–1 of this title;

(B) will comply with all guidelines under this section; and

(C) will in other respects provide safe drinking water.

Any such grant awarded before the date of promulgation of such guidelines shall be conditioned on the applicant's agreement to comply to the maximum feasible extent with such guidelines as expeditiously as practicable following the date of promulgation thereof.

(3) Guidelines under this section may, in the discretion of the Administrator—

(A) be nationally and uniformly applicable to all projects funded under section 300j–3a of this title or section 300j–1(a)(2) [1] of this title;

(B) vary for different classes or categories of such projects (as determined by the Administrator);

(C) be established and applicable on a project-by-project basis; or

(D) any combination of the above.

(4) Nothing in this section shall be construed to prohibit or delay the award of any grant referred to in paragraph (1) prior to the date of promulgation of such guidelines.

(Pub. L. 95–477, §7(b), Oct. 18, 1978, 92 Stat. 1511.)

EDITORIAL NOTES

REFERENCES IN TEXT

Section 300j–1(a)(2) of this title, referred to in par. (3)(A), was amended by Pub. L. 104–182, title I, §121(3), (4)(A), Aug. 6, 1996, 110 Stat. 1651, to redesignate par. (2)(B) as subsec. (b) of section 300j–1, strike par. (2)(A), and add a new par. (2) relating to information and research facilities.

CODIFICATION

Section was enacted as part of the Environmental Research, Development, and Demonstration Authorization Act of 1979, and not as part of the Public Health Service Act which comprises this chapter.

[1] *See References in Text note below.*

§300j–3c. National assistance program for water infrastructure and watersheds

(a) Technical and financial assistance

The Administrator of the Environmental Protection Agency may provide technical and financial assistance in the form of grants to States (1) for the construction, rehabilitation, and improvement of water supply systems, and (2) consistent with nonpoint source management programs established under section 1329 of title 33, for source water quality protection programs to address pollutants in navigable waters for the purpose of making such waters usable by water supply systems.

(b) Limitation

Not more than 30 percent of the amounts appropriated to carry out this section in a fiscal year may be used for source water quality protection programs described in subsection (a)(2).

(c) Condition

As a condition to receiving assistance under this section, a State shall ensure that such assistance is carried out in the most cost-effective manner, as determined by the State.

(d) Authorization of appropriations

(1) Unconditional authorization

There are authorized to be appropriated to carry out this section $25,000,000 for each of fiscal years 1997 through 2003. Such sums shall remain available until expended.

(2) Conditional authorization

In addition to amounts authorized under paragraph (1), there are authorized to be appropriated to carry out this section $25,000,000 for each of fiscal years 1997 through 2003, provided that

such authorization shall be in effect for a fiscal year only if at least 75 percent of the total amount of funds authorized to be appropriated for such fiscal year by section 300j–12(m) of this title are appropriated.

(e) Acquisition of lands

Assistance provided with funds made available under this section may be used for the acquisition of lands and other interests in lands; however, nothing in this section authorizes the acquisition of lands or other interests in lands from other than willing sellers.

(f) Federal share

The Federal share of the cost of activities for which grants are made under this section shall be 50 percent.

(g) Definitions

In this section, the following definitions apply:

(1) State

The term "State" means a State, the District of Columbia, the Commonwealth of Puerto Rico, the Virgin Islands, Guam, American Samoa, and the Commonwealth of the Northern Mariana Islands.

(2) Water supply system

The term "water supply system" means a system for the provision to the public of piped water for human consumption if such system has at least 15 service connections or regularly serves at least 25 individuals and a draw and fill system for the provision to the public of water for human consumption. Such term does not include a system owned by a Federal agency. Such term includes (A) any collection, treatment, storage, and distribution facilities under control of the operator of such system and used primarily in connection with such system, and (B) any collection or pretreatment facilities not under such control that are used primarily in connection with such system.

(Pub. L. 104–182, title IV, §401, Aug. 6, 1996, 110 Stat. 1690.)

EDITORIAL NOTES

CODIFICATION

Section was enacted as part of the Safe Drinking Water Act Amendments of 1996, and not as part of the Public Health Service Act which comprises this chapter.

STATUTORY NOTES AND RELATED SUBSIDIARIES

INDIAN RESERVATION DRINKING WATER PROGRAM

Pub. L. 115–270, title II, §2001, Oct. 23, 2018, 132 Stat. 3840, as amended by Pub. L. 117–58, div. E, title I, §50111, Nov. 15, 2021, 135 Stat. 1152, provided that:

"(a) IN GENERAL.—The Administrator of the Environmental Protection Agency (referred to in this section as the 'Administrator') shall carry out a program to implement eligible projects described in subsection (b).

"(b) ELIGIBLE PROJECTS.—A project eligible to participate in the program under subsection (a) is a project—

"(1) that is on a reservation (as defined in section 3 of the Indian Financing Act of 1974 (25 U.S.C. 1452)) that serves a federally recognized Indian Tribe; and

"(2) that will—

"(A) improve water quality, water pressure, or water services through means such as connecting to, expanding, repairing, improving, or obtaining water from a public water system (as defined in section 1401 of the Safe Drinking Water Act (42 U.S.C. 300f)); or

"(B) improve water quality or sanitation or wastewater services at a treatment works (as defined in section 212 of the Federal Water Pollution Control Act (33 U.S.C. 1292)).

"(c) REQUIRED PROJECTS.—

"(1) IN GENERAL.—If sufficient projects exist, of the funds made available to carry out this section, the Administrator shall use 50 percent to carry out—

"(A) 10 eligible projects described in subsection (b) that are within the Upper Missouri River Basin;

"(B) 10 eligible projects described in subsection (b) that are within the Upper Rio Grande Basin;

"(C) 10 eligible projects described in subsection (b) that are within the Columbia River Basin;

"(D) 10 eligible projects described in subsection (b) that are within the Lower Colorado River Basin; and

"(E) 10 eligible projects described in subsection (b) that are within the Arkansas-White-Red River Basin.

"(2) REQUIREMENT.—In carrying out paragraph (1)(A), the Administrator shall select not fewer than 2 eligible projects for a reservation that serves more than 1 federally recognized Indian Tribe.

"(d) PRIORITY.—In selecting projects to carry out under this section, the Administrator shall give priority to projects that—

"(1) respond to emergency situations occurring due to or resulting in a lack of access to clean drinking water that threatens the health of Tribal populations;

"(2) would serve a Tribal population that would qualify as a disadvantaged community based on the affordability criteria established by the applicable State under section 1452(d)(3) of the Safe Drinking Water Act (42 U.S.C. 300j–12(d)(3)); or

"(3) would address the underlying factors contributing to—

"(A) an enforcement action commenced pursuant to the Safe Drinking Water Act (42 U.S.C. 300f et seq.) against the applicable public water system (as defined in section 1401 of that Act (42 U.S.C. 300f)) as of the date of enactment of this subparagraph [Nov. 15, 2021]; or

"(B) an enforcement action commenced pursuant to the Federal Water Pollution Control Act (33 U.S.C. 1251 et seq.) against the applicable treatment works (as defined in section 212 of that Act (33 U.S.C. 1292)) as of the date of enactment of this subparagraph.

"(e) FEDERAL SHARE.—The Federal share of the cost of a project carried out under this section shall be 100 percent.

"(f) REPORT.—Not later than 2 years after the date of enactment of this subsection [Nov. 15, 2021], the Administrator shall submit to Congress a report that describes the implementation of the program established under subsection (a), which shall include a description of the use and deployment of amounts made available under that program.

"(g) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated to carry out the program under subsection (a)—

"(1) $20,000,000 for each of fiscal years 2019 through 2021; and

"(2) $50,000,000 for each of fiscal years 2022 through 2026."

§300j–3d. Water supply cost savings

(a) Drinking water technology clearinghouse

The Administrator, in consultation with the Secretary of Agriculture, shall—

(1) develop a technology clearinghouse for information on the cost-effectiveness of innovative and alternative drinking water delivery systems, including wells and well systems; and

(2) disseminate such information to the public and to communities and not-for-profit organizations seeking Federal funding for drinking water delivery systems serving 500 or fewer persons.

(b) Water system assessment

In any application for a grant or loan for the purpose of construction, replacement, or rehabilitation of a drinking water delivery system serving 500 or fewer persons, the funding for which would come from the Federal Government (either directly or through a State), a unit of local government or not-for-profit organization shall self-certify that the unit of local government or organization has considered, as an alternative drinking water supply, drinking water delivery systems sourced by publicly owned—

(1) individual wells;

(2) shared wells; and
(3) community wells.

(c) Report to Congress

Not later than 3 years after December 16, 2016, the Comptroller General of the United States shall submit to Congress a report that describes—

(1) the use of innovative and alternative drinking water delivery systems described in this section;

(2) the range of cost savings for communities using innovative and alternative drinking water delivery systems described in this section; and

(3) the use of drinking water technical assistance programs operated by the Administrator and the Secretary of Agriculture.

(Pub. L. 114–322, title II, §2108, Dec. 16, 2016, 130 Stat. 1728.)

EDITORIAL NOTES

CODIFICATION

Section was enacted as part of the Water and Waste Act of 2016, and also as part of the Water Infrastructure Improvements for the Nation Act, also known as the WIIN Act, and not as part of the Public Health Service Act which comprises this chapter.

STATUTORY NOTES AND RELATED SUBSIDIARIES

DEFINITION OF "ADMINISTRATOR"

Pub. L. 114–322, title II, §2002, Dec. 16, 2016, 130 Stat. 1716, provided that: "In this title [see section 2001 of Pub. L. 114–322, set out as a Short Title of 2016 Amendment note under section 201 of this title], the term 'Administrator' means the Administrator of the Environmental Protection Agency."

§300j–4. Records and inspections

(a) Provision of information to Administrator; monitoring program for unregulated contaminants

(1)(A) Every person who is subject to any requirement of this subchapter or who is a grantee, shall establish and maintain such records, make such reports, conduct such monitoring, and provide such information as the Administrator may reasonably require by regulation to assist the Administrator in establishing regulations under this subchapter, in determining whether such person has acted or is acting in compliance with this subchapter, in administering any program of financial assistance under this subchapter, in evaluating the health risks of unregulated contaminants, or in advising the public of such risks. In requiring a public water system to monitor under this subsection, the Administrator may take into consideration the system size and the contaminants likely to be found in the system's drinking water.

(B) Every person who is subject to a national primary drinking water regulation under section 300g–1 of this title shall provide such information as the Administrator may reasonably require, after consultation with the State in which such person is located if such State has primary enforcement responsibility for public water systems, on a case-by-case basis, to determine whether such person has acted or is acting in compliance with this subchapter.

(C) Every person who is subject to a national primary drinking water regulation under section 300g–1 of this title shall provide such information as the Administrator may reasonably require to assist the Administrator in establishing regulations under section 300g–1 of this title, after consultation with States and suppliers of water. The Administrator may not require under this subparagraph the installation of treatment equipment or process changes, the testing of treatment

technology, or the analysis or processing of monitoring samples, except where the Administrator provides the funding for such activities. Before exercising this authority, the Administrator shall first seek to obtain the information by voluntary submission.

(D) The Administrator shall not later than 2 years after August 6, 1996, after consultation with public health experts, representatives of the general public, and officials of State and local governments, review the monitoring requirements for not fewer than 12 contaminants identified by the Administrator, and promulgate any necessary modifications.

(2) MONITORING PROGRAM FOR UNREGULATED CONTAMINANTS.—

(A) ESTABLISHMENT.—The Administrator shall promulgate regulations establishing the criteria for a monitoring program for unregulated contaminants. The regulations shall require monitoring of drinking water supplied by public water systems and shall vary the frequency and schedule for monitoring requirements for systems based on the number of persons served by the system, the source of supply, and the contaminants likely to be found, ensuring that only a representative sample of systems serving 10,000 persons or fewer are required to monitor.

(B) MONITORING PROGRAM FOR CERTAIN UNREGULATED CONTAMINANTS.—

(i) INITIAL LIST.—Not later than 3 years after August 6, 1996, and every 5 years thereafter, the Administrator shall issue a list pursuant to subparagraph (A) of not more than 30 unregulated contaminants to be monitored by public water systems and to be included in the national drinking water occurrence data base maintained pursuant to subsection (g).

(ii) GOVERNORS' PETITION.—The Administrator shall include among the list of contaminants for which monitoring is required under this paragraph each contaminant recommended in a petition signed by the Governor of each of 7 or more States, unless the Administrator determines that the action would prevent the listing of other contaminants of a higher public health concern.

(C) MONITORING PLAN FOR SMALL AND MEDIUM SYSTEMS.—

(i) IN GENERAL.—Based on the regulations promulgated by the Administrator, each State may develop a representative monitoring plan to assess the occurrence of unregulated contaminants in public water systems that serve a population of 10,000 or fewer in that State. The plan shall require monitoring for systems representative of different sizes, types, and geographic locations in the State.

(ii) GRANTS FOR SMALL SYSTEM COSTS.—From funds reserved under section 300j–12(o) of this title or appropriated under subparagraph (H), the Administrator shall pay the reasonable cost of such testing and laboratory analysis as are necessary to carry out monitoring under the plan.

(D) MONITORING RESULTS.—Each public water system that conducts monitoring of unregulated contaminants pursuant to this paragraph shall provide the results of the monitoring to the primary enforcement authority for the system.

(E) NOTIFICATION.—Notification of the availability of the results of monitoring programs required under paragraph (2)(A) shall be given to the persons served by the system.

(F) WAIVER OF MONITORING REQUIREMENT.—The Administrator shall waive the requirement for monitoring for a contaminant under this paragraph in a State, if the State demonstrates that the criteria for listing the contaminant do not apply in that State.

(G) ANALYTICAL METHODS.—The State may use screening methods approved by the Administrator under subsection (i) in lieu of monitoring for particular contaminants under this paragraph.

(H) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated to carry out this paragraph $10,000,000 for each of the fiscal years 2019 through 2021.

(b) Entry of establishments, facilities, or other property; inspections; conduct of certain tests; audit and examination of records; entry restrictions; prohibition against informing of a proposed entry

(1) Except as provided in paragraph (2), the Administrator, or representatives of the Administrator

duly designated by him, upon presenting appropriate credentials and a written notice to any supplier of water or other person subject to (A) a national primary drinking water regulation prescribed under section 300g–1 of this title, (B) an applicable underground injection control program, or (C) any requirement to monitor an unregulated contaminant pursuant to subsection (a), or person in charge of any of the property of such supplier or other person referred to in clause (A), (B), or (C), is authorized to enter any establishment, facility, or other property of such supplier or other person in order to determine whether such supplier or other person has acted or is acting in compliance with this subchapter, including for this purpose, inspection, at reasonable times, of records, files, papers, processes, controls, and facilities, or in order to test any feature of a public water system, including its raw water source. The Administrator or the Comptroller General (or any representative designated by either) shall have access for the purpose of audit and examination to any records, reports, or information of a grantee which are required to be maintained under subsection (a) or which are pertinent to any financial assistance under this subchapter.

(2) No entry may be made under the first sentence of paragraph (1) in an establishment, facility, or other property of a supplier of water or other person subject to a national primary drinking water regulation if the establishment, facility, or other property is located in a State which has primary enforcement responsibility for public water systems unless, before written notice of such entry is made, the Administrator (or his representative) notifies the State agency charged with responsibility for safe drinking water of the reasons for such entry. The Administrator shall, upon a showing by the State agency that such an entry will be detrimental to the administration of the State's program of primary enforcement responsibility, take such showing into consideration in determining whether to make such entry. No State agency which receives notice under this paragraph of an entry proposed to be made under paragraph (1) may use the information contained in the notice to inform the person whose property is proposed to be entered of the proposed entry; and if a State agency so uses such information, notice to the agency under this paragraph is not required until such time as the Administrator determines the agency has provided him satisfactory assurances that it will no longer so use information contained in a notice under this paragraph.

(c) Penalty

Whoever fails or refuses to comply with any requirement of subsection (a) or to allow the Administrator, the Comptroller General, or representatives of either, to enter and conduct any audit or inspection authorized by subsection (b) shall be subject to a civil penalty of not to exceed $25,000.

(d) Confidential information; trade secrets and secret processes; information disclosure; "information required under this section" defined

(1) Subject to paragraph (2), upon a showing satisfactory to the Administrator by any person that any information required under this section from such person, if made public, would divulge trade secrets or secret processes of such person, the Administrator shall consider such information confidential in accordance with the purposes of section 1905 of title 18. If the applicant fails to make a showing satisfactory to the Administrator, the Administrator shall give such applicant thirty days' notice before releasing the information to which the application relates (unless the public health or safety requires an earlier release of such information).

(2) Any information required under this section (A) may be disclosed to other officers, employees, or authorized representatives of the United States concerned with carrying out this subchapter or to committees of the Congress, or when relevant in any proceeding under this subchapter, and (B) shall be disclosed to the extent it deals with the level of contaminants in drinking water. For purposes of this subsection the term "information required under this section" means any papers, books, documents, or information, or any particular part thereof, reported to or otherwise obtained by the Administrator under this section.

(e) "Grantee" and "person" defined

For purposes of this section, (1) the term "grantee" means any person who applies for or receives financial assistance, by grant, contract, or loan guarantee under this subchapter, and (2) the term "person" includes a Federal agency.

(f) Information regarding drinking water coolers

The Administrator may utilize the authorities of this section for purposes of part F. Any person who manufactures, imports, sells, or distributes drinking water coolers in interstate commerce shall be treated as a supplier of water for purposes of applying the provisions of this section in the case of persons subject to part F.

(g) Occurrence data base

(1) In general

Not later than 3 years after August 6, 1996, the Administrator shall assemble and maintain a national drinking water contaminant occurrence data base, using information on the occurrence of both regulated and unregulated contaminants in public water systems obtained under subsection (a)(1)(A) or subsection (a)(2) and reliable information from other public and private sources.

(2) Public input

In establishing the occurrence data base, the Administrator shall solicit recommendations from the Science Advisory Board, the States, and other interested parties concerning the development and maintenance of a national drinking water contaminant occurrence data base, including such issues as the structure and design of the data base, data input parameters and requirements, and the use and interpretation of data.

(3) Use

The data shall be used by the Administrator in making determinations under section 300g–1(b)(1) of this title with respect to the occurrence of a contaminant in drinking water at a level of public health concern.

(4) Public recommendations

The Administrator shall periodically solicit recommendations from the appropriate officials of the National Academy of Sciences and the States, and any person may submit recommendations to the Administrator, with respect to contaminants that should be included in the national drinking water contaminant occurrence data base, including recommendations with respect to additional unregulated contaminants that should be listed under subsection (a)(2). Any recommendation submitted under this clause shall be accompanied by reasonable documentation that—

(A) the contaminant occurs or is likely to occur in drinking water; and

(B) the contaminant poses a risk to public health.

(5) Public availability

The information from the data base shall be available to the public in readily accessible form.

(6) Regulated contaminants

With respect to each contaminant for which a national primary drinking water regulation has been established, the data base shall include information on the detection of the contaminant at a quantifiable level in public water systems (including detection of the contaminant at levels not constituting a violation of the maximum contaminant level for the contaminant).

(7) Unregulated contaminants

With respect to contaminants for which a national primary drinking water regulation has not been established, the data base shall include—

(A) monitoring information collected by public water systems that serve a population of more than 10,000, as required by the Administrator under subsection (a);

(B) monitoring information collected from a representative sampling of public water systems that serve a population of 10,000 or fewer;

(C) if applicable, monitoring information collected by public water systems pursuant to subsection (j) that is not duplicative of monitoring information included in the data base under subparagraph (B) or (D); and

(D) other reliable and appropriate monitoring information on the occurrence of the

contaminants in public water systems that is available to the Administrator.

(h) Availability of information on small system technologies

For purposes of sections 300g–1(b)(4)(E) and 300g–4(e) of this title (relating to small system variance program), the Administrator may request information on the characteristics of commercially available treatment systems and technologies, including the effectiveness and performance of the systems and technologies under various operating conditions. The Administrator may specify the form, content, and submission date of information to be submitted by manufacturers, States, and other interested persons for the purpose of considering the systems and technologies in the development of regulations or guidance under sections 300g–1(b)(4)(E) and 300g–4(e) of this title.

(i) Screening methods

The Administrator shall review new analytical methods to screen for regulated contaminants and may approve such methods as are more accurate or cost-effective than established reference methods for use in compliance monitoring.

(j) Monitoring by certain systems

(1) In general

Notwithstanding subsection (a)(2)(A), the Administrator shall, subject to the availability of appropriations for such purpose—

(A) require public water systems serving between 3,300 and 10,000 persons to monitor for unregulated contaminants in accordance with this section; and

(B) ensure that only a representative sample of public water systems serving fewer than 3,300 persons are required to monitor.

(2) Effective date

Paragraph (1) shall take effect 3 years after October 23, 2018.

(3) Limitation

Paragraph (1) shall take effect unless the Administrator determines that there is not sufficient laboratory capacity to accommodate the analysis necessary to carry out monitoring required under such paragraph.

(4) Limitation on enforcement

The Administrator may not enforce a requirement to monitor pursuant to paragraph (1) with respect to any public water system serving fewer than 3,300 persons, including by subjecting such a public water system to any civil penalty.

(5) Authorization of appropriations

There are authorized to be appropriated $15,000,000 in each fiscal year for which monitoring is required to be carried out under this subsection for the Administrator to pay the reasonable cost of such testing and laboratory analysis as are necessary to carry out monitoring required under this subsection.

(July 1, 1944, ch. 373, title XIV, §1445, as added Pub. L. 93–523, §2(a), Dec. 16, 1974, 88 Stat. 1686; amended Pub. L. 95–190, §12(c), (d), Nov. 16, 1977, 91 Stat. 1398; Pub. L. 99–339, title I, §106, title III, §301(h), June 19, 1986, 100 Stat. 650, 665; Pub. L. 100–572, §5, Oct. 31, 1988, 102 Stat. 2889; Pub. L. 104–182, title I, §§111(b), 125(a), (c), (d), 126, Aug. 6, 1996, 110 Stat. 1633, 1653, 1656–1658; Pub. L. 115–270, title II, §2021, Oct. 23, 2018, 132 Stat. 3861.)

EDITORIAL NOTES

AMENDMENTS

2018—Subsec. (a)(2)(H). Pub. L. 115–270, §2021(b), substituted "2019 through 2021" for "1997 through 2003".

Subsec. (g)(7)(C), (D). Pub. L. 115–270, §2021(c), added subpar. (C) and redesignated former subpar. (C) as (D).

Subsec. (j). Pub. L. 115–270, §2021(a), added subsec. (j).

1996—Subsec. (a)(1). Pub. L. 104–182, §125(a), amended par. (1) generally. Prior to amendment, par. (1) read as follows: "Every person who is a supplier of water, who is or may be otherwise subject to a primary drinking water regulation prescribed under section 300g–1 of this title or to an applicable underground injection control program (as defined in section 300h–1(c) of this title), who is or may be subject to the permit requirement of section 300h–3 of this title, or to an order issued under section 300j of this title, or who is a grantee, shall establish and maintain such records, make such reports, conduct such monitoring, and provide such information as the Administrator may reasonably require by regulation to assist him in establishing regulations under this subchapter, in determining whether such person has acted or is acting in compliance with this subchapter in administering any program of financial assistance under this subchapter, in evaluating the health risks of unregulated contaminants, or in advising the public of such risks. In requiring a public water system to monitor under this subsection, the Administrator may take into consideration the system size and the contaminants likely to be found in the system's drinking water."

Subsec. (a)(2) to (8). Pub. L. 104–182, §125(c), added heading and text of par. (2) and struck out former pars. (2) to (8) which directed Administrator, not later than 18 months after June 19, 1986, to promulgate regulations requiring every public water system to conduct a monitoring program for unregulated contaminants, specified contents of regulations, provided for reporting and notification of availability of results of monitoring, waiver of monitoring requirements, and compliance by small systems, and authorized appropriations for fiscal year ending Sept. 30, 1987.

Subsec. (g). Pub. L. 104–182, §126, added subsec. (g).

Subsec. (h). Pub. L. 104–182, §111(b), added subsec. (h).

Subsec. (i). Pub. L. 104–182, §125(d), added subsec. (i).

1988—Subsec. (f). Pub. L. 100–572 added subsec. (f).

1986—Subsec. (a)(1). Pub. L. 99–339, §106(a), (b), designated existing provisions as par. (1) and inserted provisions permitting Administrator to consider size of system and contaminants likely to be found.

Subsec. (a)(2) to (7). Pub. L. 99–339, §106(b), added pars. (2) to (7).

Subsec. (a)(8). Pub. L. 99–339, §301(h), added par. (8).

Subsec. (c). Pub. L. 99–339, §106(c), substituted "shall be subject to a civil penalty of not to exceed $25,000" for "may be fined not more than $5,000".

1977—Subsec. (a). Pub. L. 95–190, §12(c), inserted provisions relating to evaluating and advising of health risks of unregulated contaminants.

Subsec. (b)(1). Pub. L. 95–190, §12(d), designated existing provisions as cls. (A) and (B) and added cl. (C) and reference to such cls. (A) to (C).

§300j–5. National Drinking Water Advisory Council

(a) Establishment; membership; representation of interests; term of office, vacancies; reappointment

There is established a National Drinking Water Advisory Council which shall consist of fifteen members appointed by the Administrator after consultation with the Secretary. Five members shall be appointed from the general public; five members shall be appointed from appropriate State and local agencies concerned with water hygiene and public water supply; and five members shall be appointed from representatives of private organizations or groups demonstrating an active interest in the field of water hygiene and public water supply, of which two such members shall be associated with small, rural public water systems. Each member of the Council shall hold office for a term of three years, except that—

(1) any member appointed to fill a vacancy occurring prior to the expiration of the term for which his predecessor was appointed shall be appointed for the remainder of such term; and

(2) the terms of the members first taking office shall expire as follows: Five shall expire three years after December 16, 1974, five shall expire two years after such date, and five shall expire one year after such date, as designated by the Administrator at the time of appointment.

The members of the Council shall be eligible for reappointment.

(b) Functions

The Council shall advise, consult with, and make recommendations to, the Administrator on matters relating to activities, functions, and policies of the Agency under this subchapter.

(c) Compensation and allowances; travel expenses

Members of the Council appointed under this section shall, while attending meetings or conferences of the Council or otherwise engaged in business of the Council, receive compensation and allowances at a rate to be fixed by the Administrator, but not exceeding the daily equivalent of the annual rate of basic pay in effect for grade GS–18 of the General Schedule for each day (including traveltime) during which they are engaged in the actual performance of duties vested in the Council. While away from their homes or regular places of business in the performance of services for the Council, members of the Council shall be allowed travel expenses, including per diem in lieu of subsistence, in the same manner as persons employed intermittently in the Government service are allowed expenses under section 5703(b) [1] of title 5.

(d) Advisory committee termination provision inapplicable

Section 1013(a) of title 5 (relating to termination),[2] shall not apply to the Council.

(July 1, 1944, ch. 373, title XIV, §1446, as added Pub. L. 93–523, §2(a), Dec. 16, 1974, 88 Stat. 1688; amended Pub. L. 104–182, title I, §127, Aug. 6, 1996, 110 Stat. 1659; Pub. L. 117–286, §4(a)(245), Dec. 27, 2022, 136 Stat. 4332.)

EDITORIAL NOTES

REFERENCES IN TEXT

Section 5703 of title 5, referred to in subsec. (c), was amended generally by Pub. L. 94–22, §4, May 19, 1975, 89 Stat. 85, and, as so amended, does not contain a subsec. (b).

AMENDMENTS

2022—Subsec. (d). Pub. L. 117–286 substituted "Section 1013(a) of title 5 (relating to termination)," for "Section 14(a) of the Federal Advisory Committee Act (relating to termination)".

1996—Subsec. (a). Pub. L. 104–182 inserted ", of which two such members shall be associated with small, rural public water systems" before period at end of second sentence.

STATUTORY NOTES AND RELATED SUBSIDIARIES

TERMINATION OF ADVISORY COMMITTEES

Pub. L. 93–641, §6, Jan. 4, 1975, 88 Stat. 2275, set out as a note under section 217a of this title, provided that an advisory committee established pursuant to the Public Health Service Act shall terminate at such time as may be specifically prescribed by an Act of Congress enacted after Jan. 4, 1975.

REFERENCES IN OTHER LAWS TO GS–16, 17, OR 18 PAY RATES

References in laws to the rates of pay for GS–16, 17, or 18, or to maximum rates of pay under the General Schedule, to be considered references to rates payable under specified sections of Title 5, Government Organization and Employees, see section 529 [title I, §101(c)(1)] of Pub. L. 101–509, set out in a note under section 5376 of Title 5.

[1] See References in Text note below.

[2] So in original. The comma probably should not appear.

§300j–6. Federal agencies

(a) In general

Each department, agency, and instrumentality of the executive, legislative, and judicial branches

of the Federal Government—

(1) owning or operating any facility in a wellhead protection area;

(2) engaged in any activity at such facility resulting, or which may result, in the contamination of water supplies in any such area;

(3) owning or operating any public water system; or

(4) engaged in any activity resulting, or which may result in, underground injection which endangers drinking water (within the meaning of section 300h(d)(2) of this title),

shall be subject to, and comply with, all Federal, State, interstate, and local requirements, both substantive and procedural (including any requirement for permits or reporting or any provisions for injunctive relief and such sanctions as may be imposed by a court to enforce such relief), respecting the protection of such wellhead areas, respecting such public water systems, and respecting any underground injection in the same manner and to the same extent as any person is subject to such requirements, including the payment of reasonable service charges. The Federal, State, interstate, and local substantive and procedural requirements referred to in this subsection include, but are not limited to, all administrative orders and all civil and administrative penalties and fines, regardless of whether such penalties or fines are punitive or coercive in nature or are imposed for isolated, intermittent, or continuing violations. The United States hereby expressly waives any immunity otherwise applicable to the United States with respect to any such substantive or procedural requirement (including, but not limited to, any injunctive relief, administrative order or civil or administrative penalty or fine referred to in the preceding sentence, or reasonable service charge). The reasonable service charges referred to in this subsection include, but are not limited to, fees or charges assessed in connection with the processing and issuance of permits, renewal of permits, amendments to permits, review of plans, studies, and other documents, and inspection and monitoring of facilities, as well as any other nondiscriminatory charges that are assessed in connection with a Federal, State, interstate, or local regulatory program respecting the protection of wellhead areas or public water systems or respecting any underground injection. Neither the United States, nor any agent, employee, or officer thereof, shall be immune or exempt from any process or sanction of any State or Federal Court [1] with respect to the enforcement of any such injunctive relief. No agent, employee, or officer of the United States shall be personally liable for any civil penalty under any Federal, State, interstate, or local law concerning the protection of wellhead areas or public water systems or concerning underground injection with respect to any act or omission within the scope of the official duties of the agent, employee, or officer. An agent, employee, or officer of the United States shall be subject to any criminal sanction (including, but not limited to, any fine or imprisonment) under any Federal or State requirement adopted pursuant to this subchapter, but no department, agency, or instrumentality of the executive, legislative, or judicial branch of the Federal Government shall be subject to any such sanction. The President may exempt any facility of any department, agency, or instrumentality in the executive branch from compliance with such a requirement if he determines it to be in the paramount interest of the United States to do so. No such exemption shall be granted due to lack of appropriation unless the President shall have specifically requested such appropriation as a part of the budgetary process and the Congress shall have failed to make available such requested appropriation. Any exemption shall be for a period not in excess of 1 year, but additional exemptions may be granted for periods not to exceed 1 year upon the President's making a new determination. The President shall report each January to the Congress all exemptions from the requirements of this section granted during the preceding calendar year, together with his reason for granting each such exemption.

(b) Administrative penalty orders

(1) In general

If the Administrator finds that a Federal agency has violated an applicable requirement under this subchapter, the Administrator may issue a penalty order assessing a penalty against the Federal agency.

(2) Penalties

The Administrator may, after notice to the agency, assess a civil penalty against the agency in an amount not to exceed $25,000 per day per violation.

(3) Procedure

Before an administrative penalty order issued under this subsection becomes final, the Administrator shall provide the agency an opportunity to confer with the Administrator and shall provide the agency notice and an opportunity for a hearing on the record in accordance with chapters 5 and 7 of title 5.

(4) Public review

(A) In general

Any interested person may obtain review of an administrative penalty order issued under this subsection. The review may be obtained in the United States District Court for the District of Columbia or in the United States District Court for the district in which the violation is alleged to have occurred by the filing of a complaint with the court within the 30-day period beginning on the date the penalty order becomes final. The person filing the complaint shall simultaneously send a copy of the complaint by certified mail to the Administrator and the Attorney General.

(B) Record

The Administrator shall promptly file in the court a certified copy of the record on which the order was issued.

(C) Standard of review

The court shall not set aside or remand the order unless the court finds that there is not substantial evidence in the record, taken as a whole, to support the finding of a violation or that the assessment of the penalty by the Administrator constitutes an abuse of discretion.

(D) Prohibition on additional penalties

The court may not impose an additional civil penalty for a violation that is subject to the order unless the court finds that the assessment constitutes an abuse of discretion by the Administrator.

(c) Limitation on State use of funds collected from Federal Government

Unless a State law in effect on August 6, 1996, or a State constitution requires the funds to be used in a different manner, all funds collected by a State from the Federal Government from penalties and fines imposed for violation of any substantive or procedural requirement referred to in subsection (a) shall be used by the State only for projects designed to improve or protect the environment or to defray the costs of environmental protection or enforcement.

(d) Indian rights and sovereignty as unaffected; "Federal agency" defined

(1) Nothing in the Safe Drinking Water Amendments of 1977 shall be construed to alter or affect the status of American Indian lands or water rights nor to waive any sovereignty over Indian lands guaranteed by treaty or statute.

(2) For the purposes of this chapter, the term "Federal agency" shall not be construed to refer to or include any American Indian tribe, nor to the Secretary of the Interior in his capacity as trustee of Indian lands.

(e) Washington Aqueduct

The Secretary of the Army shall not pass the cost of any penalty assessed under this subchapter on to any customer, user, or other purchaser of drinking water from the Washington Aqueduct system, including finished water from the Dalecarlia or McMillan treatment plant.

(July 1, 1944, ch. 373, title XIV, §1447, as added Pub. L. 93–523, §2(a), Dec. 16, 1974, 88 Stat. 1688; amended Pub. L. 95–190, §8(a), (d), Nov. 16, 1977, 91 Stat. 1396, 1397; Pub. L. 104–182, title I, §129(a), (c), Aug. 6, 1996, 110 Stat. 1660, 1662.)

EDITORIAL NOTES

REFERENCES IN TEXT

The Safe Drinking Water Amendments of 1977, referred to in subsec. (d)(1), is Pub. L. 95–190, Nov. 16, 1977, 91 Stat. 1393. For complete classification of this Act to the Code, see Short Title of 1977 Amendment note set out under section 201 of this title and Tables.

AMENDMENTS

1996—Subsecs. (a) to (d). Pub. L. 104–182, §129(a), added subsecs. (a) to (c), redesignated former subsec. (c) as (d), and struck out former subsecs. (a) and (b) which related to compliance by Federal agencies with Federal, State, and local requirements respecting provision of safe drinking water and respecting underground injection programs, liability for civil penalties, and waiver of compliance requirements when necessary in interest of national security.

Subsec. (e). Pub. L. 104–182, §129(c), added subsec. (e).

1977—Subsec. (a). Pub. L. 95–190, §8(a), substituted provisions relating to compliance by Federal agencies having jurisdiction over federally owned or maintained public water systems, or engaged in underground injection activities with Federal, State, and local requirements, etc., for provisions relating to compliance by Federal agencies having jurisdiction over federally owned or maintained public water systems with national primary drinking water regulations.

Subsec. (c). Pub. L. 95–190, §8(d), added subsec. (c).

[1] So in original. Probably should not be capitalized.

§300j–7. Judicial review

(a) Courts of appeals; petition for review: actions respecting regulations; filing period; grounds arising after expiration of filing period; exclusiveness of remedy

A petition for review of—

(1) actions pertaining to the establishment of national primary drinking water regulations (including maximum contaminant level goals) may be filed only in the United States Court of Appeals for the District of Columbia circuit; and

(2) any other final action of the Administrator under this chapter may be filed in the circuit in which the petitioner resides or transacts business which is directly affected by the action.

Any such petition shall be filed within the 45-day period beginning on the date of the promulgation of the regulation or any other final Agency action with respect to which review is sought or on the date of the determination with respect to which review is sought, and may be filed after the expiration of such 45-day period if the petition is based solely on grounds arising after the expiration of such period. Action of the Administrator with respect to which review could have been obtained under this subsection shall not be subject to judicial review in any civil or criminal proceeding for enforcement or in any civil action to enjoin enforcement. In any petition concerning the assessment of a civil penalty pursuant to section 300g–3(g)(3)(B) of this title, the petitioner shall simultaneously send a copy of the complaint by certified mail to the Administrator and the Attorney General. The court shall set aside and remand the penalty order if the court finds that there is not substantial evidence in the record to support the finding of a violation or that the assessment of the penalty by the Administrator constitutes an abuse of discretion.

(b) District courts; petition for review: actions respecting variances or exemptions; filing period; grounds arising after expiration of filing period; exclusiveness of remedy

The United States district courts shall have jurisdiction of actions brought to review (1) the granting of, or the refusing to grant, a variance or exemption under section 300g–4 or 300g–5 of this title or (2) the requirements of any schedule prescribed for a variance or exemption under such section or the failure to prescribe such a schedule. Such an action may only be brought upon a petition for review filed with the court within the 45-day period beginning on the date the action

sought to be reviewed is taken or, in the case of a petition to review the refusal to grant a variance or exemption or the failure to prescribe a schedule, within the 45-day period beginning on the date action is required to be taken on the variance, exemption, or schedule, as the case may be. A petition for such review may be filed after the expiration of such period if the petition is based solely on grounds arising after the expiration of such period. Action with respect to which review could have been obtained under this subsection shall not be subject to judicial review in any civil or criminal proceeding for enforcement or in any civil action to enjoin enforcement.

(c) Judicial order for additional evidence before Administrator; modified or new findings; recommendation for modification or setting aside of original determination

In any judicial proceeding in which review is sought of a determination under this subchapter required to be made on the record after notice and opportunity for hearing, if any party applies to the court for leave to adduce additional evidence and shows to the satisfaction of the court that such additional evidence is material and that there were reasonable grounds for the failure to adduce such evidence in the proceeding before the Administrator, the court may order such additional evidence (and evidence in rebuttal thereof) to be taken before the Administrator, in such manner and upon such term and conditions as the court may deem proper. The Administrator may modify his findings as to the facts, or make new findings, by reason of the additional evidence so taken, and he shall file such modified or new findings, and his recommendation, if any, for the modification or setting aside of his original determination, with the return of such additional evidence.

(July 1, 1944, ch. 373, title XIV, §1448, as added Pub. L. 93–523, §2(a), Dec. 16, 1974, 88 Stat. 1689; amended Pub. L. 99–339, title III, §303, June 19, 1986, 100 Stat. 667; Pub. L. 104–182, title I, §113(c), Aug. 6, 1996, 110 Stat. 1636.)

EDITORIAL NOTES

AMENDMENTS

1996—Subsec. (a). Pub. L. 104–182, §113(c)(2), (3), in concluding provisions, substituted "or any other final Agency action" for "or issuance of the order" and inserted at end "In any petition concerning the assessment of a civil penalty pursuant to section 300g–3(g)(3)(B) of this title, the petitioner shall simultaneously send a copy of the complaint by certified mail to the Administrator and the Attorney General. The court shall set aside and remand the penalty order if the court finds that there is not substantial evidence in the record to support the finding of a violation or that the assessment of the penalty by the Administrator constitutes an abuse of discretion."

Subsec. (a)(2). Pub. L. 104–182, §113(c)(1), substituted "any other final action" for "any other action".

1986—Subsec. (a)(1). Pub. L. 99–339, §303(1), amended par. (1) generally. Prior to amendment, par. (1) read as follows: "action of the Administrator in promulgating any national primary drinking water regulation under section 300g–1 of this title, any regulation under section 300g–2(b)(1) of this title, any regulation under section 300g–3(c) of this title, any regulation for State underground injection control programs under section 300h of this title, or any general regulation for the administration of this subchapter may be filed only in the United States Court of Appeals for the District of Columbia Circuit; and".

Subsec. (a)(2). Pub. L. 99–339, §303(2), amended par. (2) generally. Prior to amendment, par. (2) read as follows: "action of the Administrator in promulgating any other regulation under this subchapter, issuing any order under this subchapter, or making any determination under this subchapter may be filed only in the United States court of appeals for the appropriate circuit."

§300j–8. Citizen's civil action

(a) Persons subject to civil action; jurisdiction of enforcement proceedings

Except as provided in subsection (b) of this section, any person may commence a civil action on his own behalf—

(1) against any person (including (A) the United States, and (B) any other governmental instrumentality or agency to the extent permitted by the eleventh amendment to the Constitution) who is alleged to be in violation of any requirement prescribed by or under this subchapter;

(2) against the Administrator where there is alleged a failure of the Administrator to perform any act or duty under this subchapter which is not discretionary with the Administrator; or

(3) for the collection of a penalty by the United States Government (and associated costs and interest) against any Federal agency that fails, by the date that is 18 months after the effective date of a final order to pay a penalty assessed by the Administrator under section 300h–8(b) [1] of this title, to pay the penalty.

No action may be brought under paragraph (1) against a public water system for a violation of a requirement prescribed by or under this subchapter which occurred within the 27-month period beginning on the first day of the month in which this subchapter is enacted. The United States district courts shall have jurisdiction, without regard to the amount in controversy or the citizenship of the parties, to enforce in an action brought under this subsection any requirement prescribed by or under this subchapter or to order the Administrator to perform an act or duty described in paragraph (2), as the case may be.

(b) Conditions for commencement of civil action; notice

No civil action may be commenced—

(1) under subsection (a)(1) of this section respecting violation of a requirement prescribed by or under this subchapter—

(A) prior to sixty days after the plaintiff has given notice of such violation (i) to the Administrator, (ii) to any alleged violator of such requirement and (iii) to the State in which the violation occurs, or

(B) if the Administrator, the Attorney General, or the State has commenced and is diligently prosecuting a civil action in a court of the United States to require compliance with such requirement, but in any such action in a court of the United States any person may intervene as a matter of right; or

(2) under subsection (a)(2) of this section prior to sixty days after the plaintiff has given notice of such action to the Administrator; or

(3) under subsection (a)(3) prior to 60 days after the plaintiff has given notice of such action to the Attorney General and to the Federal agency.

Notice required by this subsection shall be given in such manner as the Administrator shall prescribe by regulation. No person may commence a civil action under subsection (a) to require a State to prescribe a schedule under section 300g–4 or 300g–5 of this title for a variance or exemption, unless such person shows to the satisfaction of the court that the State has in a substantial number of cases failed to prescribe such schedules.

(c) Intervention of right

In any action under this section, the Administrator or the Attorney General, if not a party, may intervene as a matter of right.

(d) Costs; attorney fees; expert witness fees; filing of bond

The court, in issuing any final order in any action brought under subsection (a) of this section, may award costs of litigation (including reasonable attorney and expert witness fees) to any party whenever the court determines such an award is appropriate. The court may, if a temporary restraining order or preliminary injunction is sought, require the filing of a bond or equivalent security in accordance with the Federal Rules of Civil Procedure.

(e) Availability of other relief

Nothing in this section shall restrict any right which any person (or class of persons) may have under any statute or common law to seek enforcement of any requirement prescribed by or under this subchapter or to seek any other relief. Nothing in this section or in any other law of the United States shall be construed to prohibit, exclude, or restrict any State or local government from—

(1) bringing any action or obtaining any remedy or sanction in any State or local court, or

(2) bringing any administrative action or obtaining any administrative remedy or sanction,

against any agency of the United States under State or local law to enforce any requirement respecting the provision of safe drinking water or respecting any underground injection control program. Nothing in this section shall be construed to authorize judicial review of regulations or orders of the Administrator under this subchapter, except as provided in section 300j–7 of this title. For provisions providing for application of certain requirements to such agencies in the same manner as to nongovernmental entities, see section 300j–6 of this title.

(July 1, 1944, ch. 373, title XIV, §1449, as added Pub. L. 93–523, §2(a), Dec. 16, 1974, 88 Stat. 1690; amended Pub. L. 95–190, §8(c), Nov. 16, 1977, 91 Stat. 1397; Pub. L. 104–182, title I, §129(b), Aug. 6, 1996, 110 Stat. 1662.)

EDITORIAL NOTES

REFERENCES IN TEXT

The Federal Rules of Civil Procedure, referred to in subsec. (d), are set out in the Appendix to Title 28, Judiciary and Judicial Procedure.

AMENDMENTS

1996—Subsec. (a)(3). Pub. L. 104–182, §129(b)(1), added par. (3).
Subsec. (b)(3). Pub. L. 104–182, §129(b)(2), added par. (3).
1977—Subsec. (e). Pub. L. 95–190 inserted provisions relating to suits by State or local governments for enforcement of safe drinking water, etc., requirements.

[1] So in original. Probably should be section "300j–6(b)".

§300j–9. General provisions

(a) Regulations; delegation of functions

(1) The Administrator is authorized to prescribe such regulations as are necessary or appropriate to carry out his functions under this subchapter.

(2) The Administrator may delegate any of his functions under this subchapter (other than prescribing regulations) to any officer or employee of the Agency.

(b) Utilization of officers and employees of Federal agencies

The Administrator, with the consent of the head of any other agency of the United States, may utilize such officers and employees of such agency as he deems necessary to assist him in carrying out the purposes of this subchapter.

(c) Assignment of Agency personnel to State or interstate agencies

Upon the request of a State or interstate agency, the Administrator may assign personnel of the Agency to such State or interstate agency for the purposes of carrying out the provisions of this subchapter.

(d) Payments of grants; adjustments; advances; reimbursement; installments; conditions; eligibility for grants; "nonprofit agency or institution" defined

(1) The Administrator may make payments of grants under this subchapter (after necessary adjustment on account of previously made underpayments or overpayments) in advance or by way of reimbursement, and in such installments and on such conditions as he may determine.

(2) Financial assistance may be made available in the form of grants only to individuals and nonprofit agencies or institutions. For purposes of this paragraph, the term "nonprofit agency or institution" means an agency or institution no part of the net earnings of which inure, or may lawfully inure, to the benefit of any private shareholder or individual.

(e) Labor standards

The Administrator shall take such action as may be necessary to assure compliance with provisions of sections 3141–3144, 3146, and 3147 of title 40. The Secretary of Labor shall have, with respect to the labor standards specified in this subsection, the authority and functions set forth in Reorganization Plan Numbered 14 of 1950 (15 F.R. 3176; 64 Stat. 1267) and section 3145 of title 40.

(f) Appearance and representation of Administrator through Attorney General or attorney appointees

The Administrator shall request the Attorney General to appear and represent him in any civil action instituted under this subchapter to which the Administrator is a party. Unless, within a reasonable time, the Attorney General notifies the Administrator that he will appear in such action, attorneys appointed by the Administrator shall appear and represent him.

(g) Authority of Administrator under other provisions unaffected

The provisions of this subchapter shall not be construed as affecting any authority of the Administrator under part G of subchapter II of this chapter.

(h) Reports to Congressional committees; review by Office of Management and Budget: submittal of comments to Congressional committees

Not later than April 1 of each year, the Administrator shall submit to the Committee on Commerce, Science, and Transportation of the Senate and the Committee on Energy and Commerce of the House of Representatives a report respecting the activities of the Agency under this subchapter and containing such recommendations for legislation as he considers necessary. The report of the Administrator under this subsection which is due not later than April 1, 1975, and each subsequent report of the Administrator under this subsection shall include a statement on the actual and anticipated cost to public water systems in each State of compliance with the requirements of this subchapter. The Office of Management and Budget may review any report required by this subsection before its submission to such committees of Congress, but the Office may not revise any such report, require any revision in any such report, or delay its submission beyond the day prescribed for its submission, and may submit to such committees of Congress its comments respecting any such report.

(i) Discrimination prohibition; filing of complaint; investigation; orders of Secretary; notice and hearing; settlements; attorneys' fees; judicial review; filing of petition; procedural requirements; stay of orders; exclusiveness of remedy; civil actions for enforcement of orders; appropriate relief; mandamus proceedings; prohibition inapplicable to undirected but deliberate violations

(1) No employer may discharge any employee or otherwise discriminate against any employee with respect to his compensation, terms, conditions, or privileges of employment because the employee (or any person acting pursuant to a request of the employee) has—

(A) commenced, caused to be commenced, or is about to commence or cause to be commenced a proceeding under this subchapter or a proceeding for the administration or enforcement of drinking water regulations or underground injection control programs of a State,

(B) testified or is about to testify in any such proceeding, or

(C) assisted or participated or is about to assist or participate in any manner in such a proceeding or in any other action to carry out the purposes of this subchapter.

(2)(A) Any employee who believes that he has been discharged or otherwise discriminated against by any person in violation of paragraph (1) may, within 30 days after such violation occurs, file (or have any person file on his behalf) a complaint with the Secretary of Labor (hereinafter in this subsection referred to as the "Secretary") alleging such discharge or discrimination. Upon receipt of such a complaint, the Secretary shall notify the person named in the complaint of the filing of the complaint.

(B)(i) Upon receipt of a complaint filed under subparagraph (A), the Secretary shall conduct an investigation of the violation alleged in the complaint. Within 30 days of the receipt of such

complaint, the Secretary shall complete such investigation and shall notify in writing the complainant (and any person acting in his behalf) and the person alleged to have committed such violation of the results of the investigation conducted pursuant to this subparagraph. Within 90 days of the receipt of such complaint the Secretary shall, unless the proceeding on the complaint is terminated by the Secretary on the basis of a settlement entered into by the Secretary and the person alleged to have committed such violation, issue an order either providing the relief prescribed by clause (ii) or denying the complaint. An order of the Secretary shall be made on the record after notice and opportunity for agency hearing. The Secretary may not enter into a settlement terminating a proceeding on a complaint without the participation and consent of the complainant.

(ii) If in response to a complaint filed under subparagraph (A) the Secretary determines that a violation of paragraph (1) has occurred, the Secretary shall order (I) the person who committed such violation to take affirmative action to abate the violation, (II) such person to reinstate the complainant to his former position together with the compensation (including back pay), terms, conditions, and privileges of his employment, (III) compensatory damages, and (IV) where appropriate, exemplary damages. If such an order is issued, the Secretary, at the request of the complainant, shall assess against the person against whom the order is issued a sum equal to the aggregate amount of all costs and expenses (including attorneys' fees) reasonably incurred, as determined by the Secretary, by the complainant for, or in connection with, the bringing of the complaint upon which the order was issued.

(3)(A) Any person adversely affected or aggrieved by an order issued under paragraph (2) may obtain review of the order in the United States Court of Appeals for the circuit in which the violation, with respect to which the order was issued, allegedly occurred. The petition for review must be filed within sixty days from the issuance of the Secretary's order. Review shall conform to chapter 7 of title 5. The commencement of proceedings under this subparagraph shall not, unless ordered by the court, operate as a stay of the Secretary's order.

(B) An order of the Secretary with respect to which review could have been obtained under subparagraph (A) shall not be subject to judicial review in any criminal or other civil proceeding.

(4) Whenever a person has failed to comply with an order issued under paragraph (2)(B), the Secretary shall file a civil action in the United States District Court for the district in which the violation was found to occur to enforce such order. In actions brought under this paragraph, the district courts shall have jurisdiction to grant all appropriate relief including, but not limited to, injunctive relief, compensatory, and exemplary damages.

(5) Any nondiscretionary duty imposed by this section is enforceable in mandamus proceeding brought under section 1361 of title 28.

(6) Paragraph (1) shall not apply with respect to any employee who, acting without direction from his employer (or the employer's agent), deliberately causes a violation of any requirement of this subchapter.

(July 1, 1944, ch. 373, title XIV, §1450, as added Pub. L. 93–523, §2(a), Dec. 16, 1974, 88 Stat. 1691; amended Pub. L. 98–620, title IV, §402(38), Nov. 8, 1984, 98 Stat. 3360; Pub. L. 103–437, §15(a)(2), Nov. 2, 1994, 108 Stat. 4591.)

EDITORIAL NOTES

REFERENCES IN TEXT

Reorganization Plan Numbered 14 of 1950 (15 F.R. 3176; 64 Stat. 1267), referred to in subsec. (e), is set out in the Appendix to Title 5, Government Organization and Employees.

Part G of subchapter II of this chapter, referred to in subsec. (g), is classified to section 264 et seq. of this title.

CODIFICATION

In subsec. (e), "sections 3141–3144, 3146, and 3147 of title 40" substituted for "the Act of March 3, 1931 (known as the Davis-Bacon Act; 40 U.S.C. 276a—276a(5))" and "section 3145 of title 40" substituted for "section 2 of the Act of June 13, 1934 (40 U.S.C. 276c)" on authority of Pub. L. 107–217, §5(c), Aug. 21, 2002, 116 Stat. 1303, the first section of which enacted Title 40, Public Buildings, Property, and Works.

AMENDMENTS

1994—Subsec. (h). Pub. L. 103–437 substituted "Committee on Commerce, Science, and Transportation of the Senate and the Committee on Energy and Commerce of the House" for "Committee on Commerce of the Senate and the Committee on Interstate and Foreign Commerce of the House".

1984—Subsec. (i)(4). Pub. L. 98–620 struck out provision which required civil actions filed under par. (4) to be heard and decided expeditiously.

STATUTORY NOTES AND RELATED SUBSIDIARIES

CHANGE OF NAME

Committee on Energy and Commerce of House of Representatives treated as referring to Committee on Commerce of House of Representatives by section 1(a) of Pub. L. 104–14, set out as a note preceding section 21 of Title 2, The Congress. Committee on Commerce of House of Representatives changed to Committee on Energy and Commerce of House of Representatives, and jurisdiction over matters relating to securities and exchanges and insurance generally transferred to Committee on Financial Services of House of Representatives by House Resolution No. 5, One Hundred Seventh Congress, Jan. 3, 2001.

EFFECTIVE DATE OF 1984 AMENDMENT

Amendment by Pub. L. 98–620 not applicable to cases pending on Nov. 8, 1984, see section 403 of Pub. L. 98–620, set out as an Effective Date note under section 1657 of Title 28, Judiciary and Judicial Procedure.

APPLICABILITY OF LABOR STANDARDS TO DRINKING WATER TREATMENT CONSTRUCTION PROJECTS

Pub. L. 112–74, div. E, title II, Dec. 23, 2011, 125 Stat. 1020, provided in part: "For fiscal year 2012 and each fiscal year thereafter, the requirements of section 1450(e) of the Safe Drinking Water Act (42 U.S.C. 300j–9(e)) shall apply to any construction project carried out in whole or in part with assistance made available by a drinking water treatment revolving loan fund as authorized by section 1452 of that Act (42 U.S.C. 300j–12)."

§300j–10. Appointment of scientific, etc., personnel by Administrator of Environmental Protection Agency for implementation of responsibilities; compensation

To the extent that the Administrator of the Environmental Protection Agency deems such action necessary to the discharge of his functions under title XIV of the Public Health Service Act [42 U.S.C. 300f et seq.] (relating to safe drinking water) and under other provisions of law, he may appoint personnel to fill not more than thirty scientific, engineering, professional, legal, and administrative positions within the Environmental Protection Agency without regard to the civil service laws and may fix the compensation of such personnel not in excess of the maximum rate payable for GS–18 of the General Schedule under section 5332 of title 5.

(Pub. L. 95–190, §11(b), Nov. 16, 1977, 91 Stat. 1398.)

EDITORIAL NOTES

REFERENCES IN TEXT

The Public Health Service Act, referred to in text, is act July 1, 1944, ch. 373, 58 Stat. 682. Title XIV of the Public Health Service Act is classified generally to this subchapter (§300f et seq.). For complete classification of this Act to the Code, see Short Title note set out under section 201 of this title and Tables.

CODIFICATION

Section was enacted as part of the Safe Drinking Water Amendments of 1977, and not as part of the Public Health Service Act which comprises this chapter.

STATUTORY NOTES AND RELATED SUBSIDIARIES

REFERENCES IN OTHER LAWS TO GS–16, 17, OR 18 PAY RATES

References in laws to the rates of pay for GS–16, 17, or 18, or to maximum rates of pay under the General Schedule, to be considered references to rates payable under specified sections of Title 5, Government Organization and Employees, see section 529 [title I, §101(c)(1)] of Pub. L. 101–509, set out in a note under section 5376 of Title 5.

§300j–11. Indian Tribes

(a) In general

Subject to the provisions of subsection (b), the Administrator—

(1) is authorized to treat Indian Tribes as States under this subchapter,

(2) may delegate to such Tribes primary enforcement responsibility for public water systems and for underground injection control, and

(3) may provide such Tribes grant and contract assistance to carry out functions provided by this subchapter.

(b) EPA regulations

(1) Specific provisions

The Administrator shall, within 18 months after June 19, 1986, promulgate final regulations specifying those provisions of this subchapter for which it is appropriate to treat Indian Tribes as States. Such treatment shall be authorized only if:

(A) the Indian Tribe is recognized by the Secretary of the Interior and has a governing body carrying out substantial governmental duties and powers;

(B) the functions to be exercised by the Indian Tribe are within the area of the Tribal Government's jurisdiction; and

(C) the Indian Tribe is reasonably expected to be capable, in the Administrator's judgment, of carrying out the functions to be exercised in a manner consistent with the terms and purposes of this subchapter and of all applicable regulations.

(2) Provisions where treatment as State inappropriate

For any provision of this subchapter where treatment of Indian Tribes as identical to States is inappropriate, administratively infeasible or otherwise inconsistent with the purposes of this subchapter, the Administrator may include in the regulations promulgated under this section, other means for administering such provision in a manner that will achieve the purpose of the provision. Nothing in this section shall be construed to allow Indian Tribes to assume or maintain primary enforcement responsibility for public water systems or for underground injection control in a manner less protective of the health of persons than such responsibility may be assumed or maintained by a State. An Indian tribe [1] shall not be required to exercise criminal enforcement jurisdiction for purposes of complying with the preceding sentence.

(July 1, 1944, ch. 373, title XIV, §1451, as added Pub. L. 99–339, title III, §302(a), June 19, 1986, 100 Stat. 665; amended Pub. L. 104–182, title V, §501(f)(6), Aug. 6, 1996, 110 Stat. 1692.)

EDITORIAL NOTES

AMENDMENTS

1996—Pub. L. 104–182 made technical amendment to section catchline and subsec. (a) designation.

[1] *So in original. Probably should be capitalized.*

§300j–12. State revolving loan funds

(a) General authority

(1) Grants to States to establish State loan funds

(A) In general

The Administrator shall offer to enter into agreements with eligible States to make capitalization grants, including letters of credit, to the States under this subsection to further the health protection objectives of this subchapter, promote the efficient use of fund resources, and for other purposes as are specified in this subchapter.

(B) Establishment of fund

To be eligible to receive a capitalization grant under this section, a State shall establish a drinking water treatment revolving loan fund (referred to in this section as a "State loan fund") and comply with the other requirements of this section. Each grant to a State under this section shall be deposited in the State loan fund established by the State, except as otherwise provided in this section and in other provisions of this subchapter. No funds authorized by other provisions of this subchapter to be used for other purposes specified in this subchapter shall be deposited in any State loan fund.

(C) Extended period

The grant to a State shall be available to the State for obligation during the fiscal year for which the funds are authorized and during the following fiscal year, except that grants made available from funds provided prior to fiscal year 1997 shall be available for obligation during each of the fiscal years 1997 and 1998.

(D) Allotment formula

Except as otherwise provided in this section, funds made available to carry out this section shall be allotted to States that have entered into an agreement pursuant to this section (other than the District of Columbia) in accordance with—

(i) for each of fiscal years 1995 through 1997, a formula that is the same as the formula used to distribute public water system supervision grant funds under section 300j–2 of this title in fiscal year 1995, except that the minimum proportionate share established in the formula shall be 1 percent of available funds and the formula shall be adjusted to include a minimum proportionate share for the State of Wyoming and the District of Columbia; and

(ii) for fiscal year 1998 and each subsequent fiscal year, a formula that allocates to each State the proportional share of the State needs identified in the most recent survey conducted pursuant to subsection (h), except that the minimum proportionate share provided to each State shall be the same as the minimum proportionate share provided under clause (i).

(E) Reallotment

The grants not obligated by the last day of the period for which the grants are available shall be reallotted according to the appropriate criteria set forth in subparagraph (D), except that the Administrator may reserve and allocate 10 percent of the remaining amount for financial assistance to Indian Tribes in addition to the amount allotted under subsection (i) and none of the funds reallotted by the Administrator shall be reallotted to any State that has not obligated all sums allotted to the State pursuant to this section during the period in which the sums were available for obligation.

(F) Nonprimacy States

The State allotment for a State not exercising primary enforcement responsibility for public water systems shall not be deposited in any such fund but shall be allotted by the Administrator under this subparagraph. Pursuant to section 300j–2(a)(9)(A) of this title such sums allotted under this subparagraph shall be reserved as needed by the Administrator to exercise primary enforcement responsibility under this subchapter in such State and the remainder shall be reallotted to States exercising primary enforcement responsibility for public water systems for deposit in such funds. Whenever the Administrator makes a final determination pursuant to

section 300g–2(b) of this title that the requirements of section 300g–2(a) of this title are no longer being met by a State, additional grants for such State under this subchapter shall be immediately terminated by the Administrator. This subparagraph shall not apply to any State not exercising primary enforcement responsibility for public water systems as of August 6, 1996.

(G) Other programs

(i) New system capacity

Beginning in fiscal year 1999, the Administrator shall withhold 20 percent of each capitalization grant made pursuant to this section to a State unless the State has met the requirements of section 300g–9(a) of this title (relating to capacity development) and shall withhold 10 percent for fiscal year 2001, 15 percent for fiscal year 2002, and 20 percent for fiscal year 2003 if the State has not complied with the provisions of section 300g–9(c) of this title (relating to capacity development strategies). Not more than a total of 20 percent of the capitalization grants made to a State in any fiscal year may be withheld under the preceding provisions of this clause. All funds withheld by the Administrator pursuant to this clause shall be reallotted by the Administrator on the basis of the same ratio as is applicable to funds allotted under subparagraph (D). None of the funds reallotted by the Administrator pursuant to this paragraph shall be allotted to a State unless the State has met the requirements of section 300g–9 of this title (relating to capacity development).

(ii) Operator certification

The Administrator shall withhold 20 percent of each capitalization grant made pursuant to this section unless the State has met the requirements of 300g–8 [1] of this title (relating to operator certification). All funds withheld by the Administrator pursuant to this clause shall be reallotted by the Administrator on the basis of the same ratio as applicable to funds allotted under subparagraph (D). None of the funds reallotted by the Administrator pursuant to this paragraph shall be allotted to a State unless the State has met the requirements of section 300g–8 of this title (relating to operator certification).

(2) Use of funds

(A) In general

Except as otherwise authorized by this subchapter, amounts deposited in a State loan fund, including loan repayments and interest earned on such amounts, shall be used only for providing loans or loan guarantees, or as a source of reserve and security for leveraged loans, the proceeds of which are deposited in a State loan fund established under paragraph (1), or other financial assistance authorized under this section to community water systems and nonprofit noncommunity water systems, other than systems owned by Federal agencies.

(B) Limitation

Financial assistance under this section may be used by a public water system only for expenditures (including expenditures for planning, design, siting, and associated preconstruction activities, or for replacing or rehabilitating aging treatment, storage, or distribution facilities of public water systems, but not including monitoring, operation, and maintenance expenditures) of a type or category which the Administrator has determined, through guidance, will facilitate compliance with national primary drinking water regulations applicable to the system under section 300g–1 of this title or otherwise significantly further the health protection objectives of this subchapter.

(C) Sale of bonds

Funds may also be used by a public water system as a source of revenue (restricted solely to interest earnings of the applicable State loan fund) or security for payment of the principal and

interest on revenue or general obligation bonds issued by the State to provide matching funds under subsection (e), if the proceeds of the sale of the bonds will be deposited in the State loan fund.

(D) Water treatment loans

The funds under this section may also be used to provide loans to a system referred to in section 300f(4)(B) of this title for the purpose of providing the treatment described in section 300f(4)(B)(i)(III) of this title.

(E) Acquisition of real property

The funds under this section shall not be used for the acquisition of real property or interests therein, unless the acquisition is integral to a project authorized by this paragraph and the purchase is from a willing seller.

(F) Loan assistance

Of the amount credited to any State loan fund established under this section in any fiscal year, 15 percent shall be available solely for providing loan assistance to public water systems which regularly serve fewer than 10,000 persons to the extent such funds can be obligated for eligible projects of public water systems.

(G) Emerging contaminants

(i) In general

Notwithstanding any other provision of law and subject to clause (ii), amounts deposited under subsection (t) in a State loan fund established under this section may only be used to provide grants for the purpose of addressing emerging contaminants, with a focus on perfluoroalkyl and polyfluoroalkyl substances.

(ii) Requirements

(I) Small and disadvantaged communities

Not less than 25 percent of the amounts described in clause (i) shall be used to provide grants to—

(aa) disadvantaged communities (as defined in subsection (d)(3)); or

(bb) public water systems serving fewer than 25,000 persons.

(II) Priorities

In selecting the recipient of a grant using amounts described in clause (i), a State shall use the priorities described in subsection (b)(3)(A).

(iii) No increased bonding authority

The amounts deposited in the State loan fund of a State under subsection (t) may not be used as a source of payment of, or security for (directly or indirectly), in whole or in part, any obligation the interest on which is exempt from the tax imposed under chapter 1 of the Internal Revenue Code of 1986.

(3) Limitation

(A) In general

Except as provided in subparagraph (B), no assistance under this section shall be provided to a public water system that—

(i) does not have the technical, managerial, and financial capability to ensure compliance with the requirements of this subchapter; or

(ii) is in significant noncompliance with any requirement of a national primary drinking water regulation or variance.

(B) Restructuring

A public water system described in subparagraph (A) may receive assistance under this section if—

(i) the use of the assistance will ensure compliance; and

(ii) if subparagraph (A)(i) applies to the system, the owner or operator of the system agrees to undertake feasible and appropriate changes in operations (including ownership, management, accounting, rates, maintenance, consolidation, alternative water supply, or other procedures) if the State determines that the measures are necessary to ensure that the system has the technical, managerial, and financial capability to comply with the requirements of this subchapter over the long term.

(C) Review

Prior to providing assistance under this section to a public water system that is in significant noncompliance with any requirement of a national primary drinking water regulation or variance, the State shall conduct a review to determine whether subparagraph (A)(i) applies to the system.

(4) American iron and steel products

(A) In general

Funds made available from a State loan fund established pursuant to this section may not be used for a project for the construction, alteration, or repair of a public water system unless all of the iron and steel products used in the project are produced in the United States.

(B) Definition of iron and steel products

In this paragraph, the term "iron and steel products" means the following products made primarily of iron or steel:

(i) Lined or unlined pipes and fittings.

(ii) Manhole covers and other municipal castings.

(iii) Hydrants.

(iv) Tanks.

(v) Flanges.

(vi) Pipe clamps and restraints.

(vii) Valves.

(viii) Structural steel.

(ix) Reinforced precast concrete.

(x) Construction materials.

(C) Application

Subparagraph (A) shall be waived in any case or category of cases in which the Administrator finds that—

(i) applying subparagraph (A) would be inconsistent with the public interest;

(ii) iron and steel products are not produced in the United States in sufficient and reasonably available quantities and of a satisfactory quality; or

(iii) inclusion of iron and steel products produced in the United States will increase the cost of the overall project by more than 25 percent.

(D) Waiver

If the Administrator receives a request for a waiver under this paragraph, the Administrator shall make available to the public, on an informal basis, a copy of the request and information available to the Administrator concerning the request, and shall allow for informal public input on the request for at least 15 days prior to making a finding based on the request. The Administrator shall make the request and accompanying information available by electronic means, including on the official public Internet site of the Agency.

(E) International agreements

This paragraph shall be applied in a manner consistent with United States obligations under international agreements.

(F) Management and oversight

The Administrator may retain up to 0.25 percent of the funds appropriated for this section for management and oversight of the requirements of this paragraph.

(G) Effective date

This paragraph does not apply with respect to a project if a State agency approves the engineering plans and specifications for the project, in that agency's capacity to approve such plans and specifications prior to a project requesting bids, prior to December 16, 2016.

(5) Prevailing wages

The requirements of section 300j–9(e) of this title shall apply to any construction project carried out in whole or in part with assistance made available by a State loan fund.

(b) Intended use plans

(1) In general

After providing for public review and comment, each State that has entered into a capitalization agreement pursuant to this section shall annually prepare a plan that identifies the intended uses of the amounts available to the State loan fund of the State.

(2) Contents

An intended use plan shall include—

(A) a list of the projects to be assisted in the first fiscal year that begins after the date of the plan, including a description of the project, the expected terms of financial assistance, and the size of the community served;

(B) the criteria and methods established for the distribution of funds; and

(C) a description of the financial status of the State loan fund and the short-term and long-term goals of the State loan fund.

(3) Use of funds

(A) In general

An intended use plan shall provide, to the maximum extent practicable, that priority for the use of funds be given to projects that—

(i) address the most serious risk to human health;

(ii) are necessary to ensure compliance with the requirements of this subchapter (including requirements for filtration); and

(iii) assist systems most in need on a per household basis according to State affordability criteria.

(B) List of projects

Each State shall, after notice and opportunity for public comment, publish and periodically update a list of projects in the State that are eligible for assistance under this section, including the priority assigned to each project and, to the extent known, the expected funding schedule for each project.

(c) Fund management

Each State loan fund under this section shall be established, maintained, and credited with repayments and interest. The fund corpus shall be available in perpetuity for providing financial assistance under this section. To the extent amounts in the fund are not required for current obligation or expenditure, such amounts shall be invested in interest bearing obligations.

(d) Assistance for disadvantaged communities

(1) Loan subsidy

(A) In general

Notwithstanding any other provision of this section, in any case in which the State makes a loan pursuant to subsection (a)(2) to a disadvantaged community or to a community that the State expects to become a disadvantaged community as the result of a proposed project, the

State may provide additional subsidization (including forgiveness of principal, grants, negative interest loans, other loan forgiveness, and through buying, refinancing, or restructuring debt).

(B) Exclusion

A loan from a State loan fund with an interest rate equal to or greater than 0 percent shall not be considered additional subsidization for purposes of this subsection.

(2) Total amount of subsidies

For each fiscal year, of the amount of the capitalization grant received by the State for the year, the total amount of loan subsidies made by a State pursuant to paragraph (1)—

(A) may not exceed 35 percent; and

(B) to the extent that there are sufficient applications for loans to communities described in paragraph (1), may not be less than 12 percent.

(3) "Disadvantaged community" defined

In this subsection, the term "disadvantaged community" means the service area of a public water system that meets affordability criteria established after public review and comment by the State in which the public water system is located. The Administrator may publish information to assist States in establishing affordability criteria.

(e) State contribution

Each agreement under subsection (a) shall require that the State deposit in the State loan fund from State moneys an amount equal to at least 20 percent of the total amount of the grant to be made to the State on or before the date on which the grant payment is made to the State, except that a State shall not be required to deposit such amount into the fund prior to the date on which each grant payment is made for fiscal years 1994, 1995, 1996, and 1997 if the State deposits the State contribution amount into the State loan fund prior to September 30, 1999.

(f) Types of assistance

Except as otherwise limited by State law, the amounts deposited into a State loan fund under this section may be used only—

(1) to make loans, on the condition that—

(A) the interest rate for each loan is less than or equal to the market interest rate, including an interest free loan;

(B) principal and interest payments on each loan will commence not later than 18 months after completion of the project for which the loan was made;

(C) each loan will be fully amortized not later than 30 years after the completion of the project, except that in the case of a disadvantaged community (as defined in subsection (d)(3)) a State may provide an extended term for a loan, if the extended term—

(i) terminates not later than the date that is 40 years after the date of project completion; and

(ii) does not exceed the expected design life of the project;

(D) the recipient of each loan will establish a dedicated source of revenue (or, in the case of a privately owned system, demonstrate that there is adequate security) for the repayment of the loan; and

(E) the State loan fund will be credited with all payments of principal and interest on each loan;

(2) to buy or refinance the debt obligation of a municipality or an intermunicipal or interstate agency within the State at an interest rate that is less than or equal to the market interest rate in any case in which a debt obligation is incurred after July 1, 1993;

(3) to guarantee, or purchase insurance for, a local obligation (all of the proceeds of which finance a project eligible for assistance under this section) if the guarantee or purchase would improve credit market access or reduce the interest rate applicable to the obligation;

(4) as a source of revenue or security for the payment of principal and interest on revenue or general obligation bonds issued by the State if the proceeds of the sale of the bonds will be deposited into the State loan fund; and

(5) to earn interest on the amounts deposited into the State loan fund.

(g) Administration of State loan funds

(1) Combined financial administration

Notwithstanding subsection (c), a State may (as a convenience and to avoid unnecessary administrative costs) combine, in accordance with State law, the financial administration of a State loan fund established under this section with the financial administration of any other revolving fund established by the State if otherwise not prohibited by the law under which the State loan fund was established and if the Administrator determines that—

(A) the grants under this section, together with loan repayments and interest, will be separately accounted for and used solely for the purposes specified in subsection (a); and

(B) the authority to establish assistance priorities and carry out oversight and related activities (other than financial administration) with respect to assistance remains with the State agency having primary responsibility for administration of the State program under section 300g–2 of this title, after consultation with other appropriate State agencies (as determined by the State): *Provided*, That in nonprimacy States eligible to receive assistance under this section, the Governor shall determine which State agency will have authority to establish priorities for financial assistance from the State loan fund.

(2) Cost of administering fund

(A) Authorization

(i) In general

For each fiscal year, a State may use the amount described in clause (ii)—

(I) to cover the reasonable costs of administration of the programs under this section, including the recovery of reasonable costs expended to establish a State loan fund that are incurred after August 6, 1996; and

(II) to provide technical assistance to public water systems within the State.

(ii) Description of amount

The amount referred to in clause (i) is an amount equal to the sum of—

(I) the amount of any fees collected by the State for use in accordance with clause (i)(I), regardless of the source; and

(II) the greatest of—

(aa) $400,000;

(bb) 1/5 percent of the current valuation of the fund; and

(cc) an amount equal to 4 percent of all grant awards to the fund under this section for the fiscal year.

(B) Additional use of funds

For fiscal year 1995 and each fiscal year thereafter, each State may use up to an additional 10 percent of the funds allotted to the State under this section—

(i) for public water system supervision programs under section 300j–2(a) of this title;

(ii) to administer or provide technical assistance through source water protection programs;

(iii) to develop and implement a capacity development strategy under section 300g–9(c) of this title; and

(iv) for an operator certification program for purposes of meeting the requirements of section 300g–8 of this title.

(C) Technical assistance

An additional 2 percent of the funds annually allotted to each State under this section may be used by the State to provide technical assistance to public water systems serving 10,000 or

fewer persons in the State.

(D) Enforcement actions

Funds used under subparagraph (B)(ii) shall not be used for enforcement actions.

(3) Guidance and regulations

The Administrator shall publish guidance and promulgate regulations as may be necessary to carry out the provisions of this section, including—

(A) provisions to ensure that each State commits and expends funds allotted to the State under this section as efficiently as possible in accordance with this subchapter and applicable State laws;

(B) guidance to prevent waste, fraud, and abuse; and

(C) guidance to avoid the use of funds made available under this section to finance the expansion of any public water system in anticipation of future population growth.

The guidance and regulations shall also ensure that the States, and public water systems receiving assistance under this section, use accounting, audit, and fiscal procedures that conform to generally accepted accounting standards.

(4) State report

Each State administering a loan fund and assistance program under this subsection shall publish and submit to the Administrator a report every 2 years on its activities under this section, including the findings of the most recent audit of the fund and the entire State allotment. The Administrator shall periodically audit all State loan funds established by, and all other amounts allotted to, the States pursuant to this section in accordance with procedures established by the Comptroller General.

(h) Needs survey

(1) The Administrator shall conduct an assessment of water system capital improvement needs of all eligible public water systems in the United States and submit a report to the Congress containing the results of the assessment within 180 days after August 6, 1996, and every 4 years thereafter.

(2) Any assessment conducted under paragraph (1) after October 23, 2018, shall include an assessment of costs to replace all lead service lines (as defined in section 300j–19b(a)(4) of this title) of all eligible public water systems in the United States, and such assessment shall describe separately the costs associated with replacing the portions of such lead service lines that are owned by an eligible public water system and the costs associated with replacing any remaining portions of such lead service lines, to the extent practicable.

(i) Indian Tribes

(1) In general

1½ percent of the amounts appropriated annually to carry out this section may be used by the Administrator to make grants to Indian Tribes, Alaska Native villages, and, for the purpose of carrying out paragraph (5), intertribal consortia or tribal organizations, that have not otherwise received either grants from the Administrator under this section or assistance from State loan funds established under this section. Except as otherwise provided, the grants may only be used for expenditures by tribes and villages for public water system expenditures referred to in subsection (a)(2).

(2) Use of funds

Funds reserved pursuant to paragraph (1) shall be used to address the most significant threats to public health associated with public water systems that serve Indian Tribes, as determined by the Administrator in consultation with the Director of the Indian Health Service and Indian Tribes.

(3) Alaska Native villages

In the case of a grant for a project under this subsection in an Alaska Native village, the Administrator is also authorized to make grants to the State of Alaska for the benefit of Native

villages. An amount not to exceed 4 percent of the grant amount may be used by the State of Alaska for project management.

(4) Needs assessment

The Administrator, in consultation with the Director of the Indian Health Service and Indian Tribes, shall, in accordance with a schedule that is consistent with the needs surveys conducted pursuant to subsection (h), prepare surveys and assess the needs of drinking water treatment facilities to serve Indian Tribes, including an evaluation of the public water systems that pose the most significant threats to public health.

(5) Training and operator certification

(A) In general

The Administrator may use funds made available under this subsection and section 300j–1(e)(7) of this title to make grants to intertribal consortia or tribal organizations for the purpose of providing operations and maintenance training and operator certification services to Indian Tribes to enable public water systems that serve Indian Tribes to achieve and maintain compliance with applicable national primary drinking water regulations.

(B) Eligible tribal organizations

Intertribal consortia or tribal organizations eligible for a grant under subparagraph (A) are intertribal consortia or tribal organizations that—

(i) as determined by the Administrator, are the most qualified and experienced to provide training and technical assistance to Indian Tribes; and

(ii) the Indian Tribes find to be the most beneficial and effective.

(j) Other areas

Of the funds annually available under this section for grants to States, the Administrator shall make allotments in accordance with section 300j–2(a)(4) of this title for the Virgin Islands, the Commonwealth of the Northern Mariana Islands, American Samoa, and Guam. The grants allotted as provided in this subsection may be provided by the Administrator to the governments of such areas, to public water systems in such areas, or to both, to be used for the public water system expenditures referred to in subsection (a)(2). The grants, and grants for the District of Columbia, shall not be deposited in State loan funds. The total allotment of grants under this section for all areas described in this subsection in any fiscal year shall not exceed 0.33 percent of the aggregate amount made available to carry out this section in that fiscal year.

(k) Other authorized activities

(1) In general

Notwithstanding subsection (a)(2), a State may take each of the following actions:

(A) Provide assistance, only in the form of a loan, to one or more of the following:

(i) Any public water system described in subsection (a)(2) to acquire land or a conservation easement from a willing seller or grantor, if the purpose of the acquisition is to protect the source water of the system from contamination and to ensure compliance with national primary drinking water regulations.

(ii) Any community water system to implement local, voluntary source water protection measures to protect source water in areas delineated pursuant to section 300j–13 of this title, in order to facilitate compliance with national primary drinking water regulations applicable to the system under section 300g–1 of this title or otherwise significantly further the health protection objectives of this subchapter. Funds authorized under this clause may be used to fund only voluntary, incentive-based mechanisms.

(iii) Any community water system to provide funding in accordance with section 300j–14(a)(1)(B)(i) of this title.

(B) Provide assistance, including technical and financial assistance, to any public water

system as part of a capacity development strategy developed and implemented in accordance with section 300g–9(c) of this title.

(C) Make expenditures from the capitalization grant of the State to delineate, assess, and update assessments for source water protection areas in accordance with section 300j–13 of this title, except that funds set aside for such expenditure shall be obligated within 4 fiscal years.

(D) Make expenditures from the fund for the establishment and implementation of wellhead protection programs under section 300h–7 of this title and for the implementation of efforts (other than actions authorized under subparagraph (A)) to protect source water in areas delineated pursuant to section 300j–13 of this title.

(2) Limitation

For each fiscal year, the total amount of assistance provided and expenditures made by a State under this subsection may not exceed 15 percent of the amount of the capitalization grant received by the State for that year and may not exceed 10 percent of that amount for any one of the following activities:

(A) To acquire land or conservation easements pursuant to paragraph (1)(A)(i).

(B) To provide funding to implement voluntary, incentive-based source water quality protection measures pursuant to clauses (ii) and (iii) of paragraph (1)(A).

(C) To provide assistance through a capacity development strategy pursuant to paragraph (1)(B).

(D) To make expenditures to delineate or assess source water protection areas pursuant to paragraph (1)(C).

(E) To make expenditures to establish and implement wellhead protection programs, and to implement efforts to protect source water, pursuant to paragraph (1)(D).

(3) Statutory construction

Nothing in this section creates or conveys any new authority to a State, political subdivision of a State, or community water system for any new regulatory measure, or limits any authority of a State, political subdivision of a State or community water system.

(l) Savings

The failure or inability of any public water system to receive funds under this section or any other loan or grant program, or any delay in obtaining the funds, shall not alter the obligation of the system to comply in a timely manner with all applicable drinking water standards and requirements of this subchapter.

(m) Authorization of appropriations

(1) There are authorized to be appropriated to carry out the purposes of this section, except for subsections (a)(2)(G) and (t)—

(A) $1,174,000,000 for fiscal year 2019;
(B) $1,300,000,000 for fiscal year 2020;
(C) $1,950,000,000 for fiscal year 2021;
(D) $2,400,000,000 for fiscal year 2022;
(E) $2,750,000,000 for fiscal year 2023;
(F) $3,000,000,000 for fiscal year 2024; and
(G) $3,250,000,000 for each of fiscal years 2025 and 2026.

(2) To the extent amounts authorized to be appropriated under this subsection in any fiscal year are not appropriated in that fiscal year, such amounts are authorized to be appropriated in a subsequent fiscal year. Such sums shall remain available until expended.

(n) Health effects studies

From funds appropriated pursuant to this section for each fiscal year, the Administrator shall reserve $10,000,000 for health effects studies on drinking water contaminants authorized by the Safe Drinking Water Act Amendments of 1996. In allocating funds made available under this subsection,

the Administrator shall give priority to studies concerning the health effects of cryptosporidium (as authorized by section 300j–18(c) of this title), disinfection byproducts (as authorized by section 300j–18(c) of this title), and arsenic (as authorized by section 300g–1(b)(12)(A) of this title), and the implementation of a plan for studies of subpopulations at greater risk of adverse effects (as authorized by section 300j–18(a) of this title).

(o) Monitoring for unregulated contaminants

From funds appropriated pursuant to this section for each fiscal year beginning with fiscal year 1998, the Administrator shall reserve $2,000,000 to pay the costs of monitoring for unregulated contaminants under section 300j–4(a)(2)(C) of this title.

(p) Demonstration project for State of Virginia

Notwithstanding the other provisions of this section limiting the use of funds deposited in a State loan fund from any State allotment, the State of Virginia may, as a single demonstration and with the approval of the Virginia General Assembly and the Administrator, conduct a program to demonstrate alternative approaches to intergovernmental coordination to assist in the financing of new drinking water facilities in the following rural communities in southwestern Virginia where none exists on August 6, 1996, and where such communities are experiencing economic hardship: Lee County, Wise County, Scott County, Dickenson County, Russell County, Buchanan County, Tazewell County, and the city of Norton, Virginia. The funds allotted to that State and deposited in the State loan fund may be loaned to a regional endowment fund for the purpose set forth in this subsection under a plan to be approved by the Administrator. The plan may include an advisory group that includes representatives of such counties.

(q) Small system technical assistance

The Administrator may reserve up to 2 percent of the total funds made available to carry out this section for each of fiscal years 2022 through 2026 to carry out the provisions of section 300j–1(e) of this title (relating to technical assistance for small systems), except that the total amount of funds made available for such purpose in any fiscal year through appropriations (as authorized by section 300j–1(e) of this title) and reservations made pursuant to this subsection shall not exceed the amount authorized by section 300j–1(e) of this title.

(r) Evaluation

The Administrator shall conduct an evaluation of the effectiveness of the State loan funds through fiscal year 2001. The evaluation shall be submitted to the Congress at the same time as the President submits to the Congress, pursuant to section 1108 of title 31, an appropriations request for fiscal year 2003 relating to the budget of the Environmental Protection Agency.

(s) Best practices for State loan fund administration

The Administrator shall—

(1) collect information from States on administration of State loan funds established pursuant to subsection (a)(1), including—

(A) efforts to streamline the process for applying for assistance through such State loan funds;

(B) programs in place to assist with the completion of applications for assistance through such State loan funds;

(C) incentives provided to public water systems that partner with small public water systems to assist with the application process for assistance through such State loan funds;

(D) practices to ensure that amounts in such State loan funds are used to provide loans, loan guarantees, or other authorized assistance in a timely fashion;

(E) practices that support effective management of such State loan funds;

(F) practices and tools to enhance financial management of such State loan funds; and

(G) key financial measures for use in evaluating State loan fund operations, including—

(i) measures of lending capacity, such as current assets and current liabilities or undisbursed loan assistance liability; and

(ii) measures of growth or sustainability, such as return on net interest;

(2) not later than 3 years after October 23, 2018, disseminate to the States best practices for administration of such State loan funds, based on the information collected pursuant to this subsection; and

(3) periodically update such best practices, as appropriate.

(t) Emerging contaminants

(1) In general

Amounts made available under this subsection shall be allotted to a State as if allotted under subsection (a)(1)(D) as a capitalization grant, for deposit into the State loan fund of the State, for the purposes described in subsection (a)(2)(G).

(2) Authorization of appropriations

There is authorized to be appropriated to carry out this subsection $100,000,000 for each of fiscal years 2020 through 2024, to remain available until expended.

(July 1, 1944, ch. 373, title XIV, §1452, as added Pub. L. 104–182, title I, §130, Aug. 6, 1996, 110 Stat. 1662; amended Pub. L. 114–322, title II, §§2102, 2103, 2110, 2112(b), 2113, Dec. 16, 2016, 130 Stat. 1717, 1729, 1730; Pub. L. 115–270, title II, §§2002, 2015, 2022, 2023, Oct. 23, 2018, 132 Stat. 3840, 3854, 3862; Pub. L. 116–92, div. F, title LXXIII, §7312, Dec. 20, 2019, 133 Stat. 2277; Pub. L. 117–58, div. E, title I, §50102, Nov. 15, 2021, 135 Stat. 1136.)

EDITORIAL NOTES

REFERENCES IN TEXT

The Internal Revenue Code of 1986, referred to in subsec. (a)(2)(G)(iii), is classified generally to Title 26, Internal Revenue Code.

The Safe Drinking Water Act Amendments of 1996, referred to in subsec. (n), is Pub. L. 104–182, Aug. 6, 1996, 110 Stat. 1613. For complete classification of this Act to the Code, see Short Title of 1996 Amendment note set out under section 201 of this title and Tables.

AMENDMENTS

2021—Subsec. (a)(4)(A). Pub. L. 117–58, §50102(a)(1), substituted "Funds" for "During fiscal years 2019 through 2023, funds".

Subsec. (d)(1). Pub. L. 117–58, §50102(b)(1), designated existing provisions as subpar. (A), inserted subpar. heading, inserted ", grants, negative interest loans, other loan forgiveness, and through buying, refinancing, or restructuring debt" after "forgiveness of principal", and added subpar. (B).

Subsec. (d)(2)(B). Pub. L. 117–58, §50102(b)(2), added subpar. (B) and struck out former subpar. (B) which read as follows: "to the extent that there are sufficient applications for loans to communities described in paragraph (1), may not be less than 6 percent."

Subsec. (m)(1)(D) to (G). Pub. L. 117–58, §50102(a)(2), added subpars. (D) to (G).

Subsec. (q). Pub. L. 117–58, §50102(a)(3), substituted "2022 through 2026" for "2016 through 2021".

2019—Subsec. (a)(2)(G). Pub. L. 116–92, §7312(1), added subpar. (G).

Subsec. (m)(1). Pub. L. 116–92, §7312(2), substituted "this section, except for subsections (a)(2)(G) and (t)" for "this section" in introductory provisions.

Subsec. (t). Pub. L. 116–92, §7312(3), added subsec. (t).

2018—Subsec. (a)(2)(B). Pub. L. 115–270, §2015(a), substituted "(including expenditures for planning, design, siting, and associated preconstruction activities, or for replacing or rehabilitating aging treatment, storage, or distribution facilities of public water systems, but not" for "(including expenditures for planning, design, and associated preconstruction activities, including activities relating to the siting of the facility, but not".

Subsec. (a)(4)(A). Pub. L. 115–270, §2022, substituted "fiscal years 2019 through 2023" for "fiscal year 2017".

Subsec. (a)(5). Pub. L. 115–270, §2015(b), added par. (5).

Subsec. (d)(2). Pub. L. 115–270, §2015(c), amended par. (2) generally. Prior to amendment, text read as follows: "For each fiscal year, the total amount of loan subsidies made by a State pursuant to paragraph (1)

may not exceed 30 percent of the amount of the capitalization grant received by the State for the year."

Subsec. (f)(1)(B). Pub. L. 115–270, §2015(d)(3), substituted "18 months after completion of the project for which the loan was made;" for "1 year after completion of the project for which the loan was made, and each loan will be fully amortized not later than 20 years after the completion of the project, except that in the case of a disadvantaged community (as defined in subsection (d)(3)), a State may provide an extended term for a loan, if the extended term—

"(i) terminates not later than the date that is 30 years after the date of project completion; and

"(ii) does not exceed the expected design life of the project;".

Subsec. (f)(1)(C) to (E). Pub. L. 115–270, §2015(d)(1), (2), added subpar. (C) and redesignated former subpars. (C) and (D) as (D) and (E), respectively.

Subsec. (h). Pub. L. 115–270, §2015(e), designated existing provisions as par. (1) and added par. (2).

Subsec. (k)(1)(C). Pub. L. 115–270, §2015(f), substituted "to delineate, assess, and update assessments for source water protection areas in accordance with section 300j–13 of this title" for "for fiscal years 1996 and 1997 to delineate and assess source water protection areas in accordance with section 300j–13 of this title".

Subsec. (k)(1)(D). Pub. L. 115–270, §2002(1), inserted "and for the implementation of efforts (other than actions authorized under subparagraph (A)) to protect source water in areas delineated pursuant to section 300j–13 of this title" before period at end.

Subsec. (k)(2)(E). Pub. L. 115–270, §2002(2), inserted ", and to implement efforts to protect source water," after "wellhead protection programs".

Subsec. (m). Pub. L. 115–270, §2023, substituted par. (1) for first sentence which read "There are authorized to be appropriated to carry out the purposes of this section $599,000,000 for the fiscal year 1994 and $1,000,000,000 for each of the fiscal years 1995 through 2003.", designated second and third sentences as par. (2), and, in par. (2), struck out "(prior to the fiscal year 2004)" after "subsequent fiscal year".

Subsec. (s). Pub. L. 115–270, §2015(g), added subsec. (s).

2016—Subsec. (a)(2)(A). Pub. L. 114–322, §2102(5), designated first sentence of par. (2) as subpar. (A) and inserted heading.

Subsec. (a)(2)(B). Pub. L. 114–322, §2102(4), (6), designated second sentence of par. (2) as subpar. (B), inserted heading, and substituted "(including expenditures for planning, design, and associated preconstruction activities, including activities relating to the siting of the facility, but not" for "(not".

Subsec. (a)(2)(C). Pub. L. 114–322, §2102(7), added subpar. (C).

Subsec. (a)(2)(D). Pub. L. 114–322, §2102(3), designated third sentence of par. (2) as subpar. (D), inserted heading, and substituted "The funds under this section" for "The funds".

Subsec. (a)(2)(E). Pub. L. 114–322, §2102(2), designated fourth sentence of par. (2) as subpar. (E), inserted heading, and substituted "The funds under this section" for "The funds".

Subsec. (a)(2)(F). Pub. L. 114–322, §2102(1), designated fifth sentence of par. (2) as subpar. (F) and inserted heading.

Subsec. (a)(4). Pub. L. 114–322, §2113, added par. (4).

Subsec. (g)(2). Pub. L. 114–322, §2103(4), struck out third sentence of par. (2) which read as follows: "At least half of the match must be additional to the amount expended by the State for public water supervision in fiscal year 1993."

Subsec. (g)(2)(A). Pub. L. 114–322, §2103(6), added subpar. (A) and struck out first sentence of par. (2) which read as follows: "Each State may annually use up to 4 percent of the funds allotted to the State under this section to cover the reasonable costs of administration of the programs under this section, including the recovery of reasonable costs expended to establish a State loan fund which are incurred after August 6, 1996, and to provide technical assistance to public water systems within the State." Former subpar. (A) redesignated subpar. (B)(i).

Subsec. (g)(2)(B). Pub. L. 114–322, §2103(7)(B), struck out "if the State matches the expenditures with at least an equal amount of State funds." before "At least half" in concluding provisions.

Pub. L. 114–322, §2103(1), (5), redesignated second sentence of par. (2) as subpar. (B), inserted heading, and redesignated former pars. (A) to (D) as cls. (i) to (iv), respectively, of subpar. (B).

Subsec. (g)(2)(B)(iv). Pub. L. 114–322, §2103(7)(A), substituted "300g–8 of this title." for "300g–8 of this title,".

Subsec. (g)(2)(C). Pub. L. 114–322, §2103(3), designated fourth sentence of par. (2) as subpar. (C) and inserted heading. Former subpar. (C) redesignated subpar. (B)(iii).

Subsec. (g)(2)(D). Pub. L. 114–322, §2103(2), added subpar. (D) and struck out fifth sentence of par. (2) which read as follows: "Funds utilized under subparagraph (B) shall not be used for enforcement actions." Former subpar. (D) redesignated subpar. (B)(iv).

Subsec. (i)(1). Pub. L. 114–322, §2112(b)(1), substituted "Tribes, Alaska Native villages, and, for the

purpose of carrying out paragraph (5), intertribal consortia or tribal organizations," for "Tribes and Alaska Native villages" and "Except as otherwise provided, the grants" for "The grants".

Subsec. (i)(5). Pub. L. 114–322, §2112(b)(2), added par. (5).

Subsec. (q). Pub. L. 114–322, §2110, substituted "made available to carry out this section for each of fiscal years 2016 through 2021" for "appropriated pursuant to subsection (m) for each of the fiscal years 1997 through 2003".

STATUTORY NOTES AND RELATED SUBSIDIARIES

ASSISTANCE FOR AREAS AFFECTED BY NATURAL DISASTERS

Pub. L. 115–270, title II, §2020, Oct. 23, 2018, 132 Stat. 3859, provided that:

"(a) DEFINITIONS.—In this section:

"(1) COMMUNITY WATER SYSTEM.—The term 'community water system' has the meaning given such term in section 1401(15) of the Safe Drinking Water Act (42 U.S.C. 300f(15)).

"(2) ELIGIBLE STATE.—The term 'eligible State' means a State, as defined in section 1401(13)(B) of the Safe Drinking Water Act (42 U.S.C. 300f(13)(B)).

"(3) ELIGIBLE SYSTEM.—The term 'eligible system' means a community water system—

"(A) that serves an area for which, after January 1, 2017, the President under the Robert T. Stafford Disaster Relief and Emergency Assistance Act (42 U.S.C. 5121 et seq.)—

"(i) has issued a major disaster declaration; and

"(ii) provided disaster assistance; or

"(B) that is capable of extending its potable drinking water service into an underserved area.

"(4) NATIONAL PRIMARY DRINKING WATER REGULATION.—The term 'national primary drinking water regulation' means a national primary drinking water regulation under section 1412 of the Safe Drinking Water Act (42 U.S.C. 300g–1).

"(5) UNDERSERVED AREA.—The term 'underserved area' means a geographic area in an eligible State that—

"(A) is served by a community water system serving fewer than 50,000 persons where delivery of, or access to, potable water is or was disrupted; and

"(B) received disaster assistance pursuant to a declaration described in paragraph (3)(A).

"(b) STATE REVOLVING LOAN FUND ASSISTANCE.—

"(1) IN GENERAL.—An eligible State may use funds provided pursuant to subsection (e)(1) to provide assistance to an eligible system within the eligible State for the purpose of restoring or increasing compliance with national primary drinking water regulations in an underserved area.

"(2) INCLUSION.—

"(A) ADDITIONAL SUBSIDIZATION.—With respect to assistance provided under paragraph (1), an eligible system shall be eligible to receive loans with additional subsidization (including forgiveness of principal, negative-interest loans, or grants (or any combination thereof)) for the purpose described in paragraph (1).

"(B) NONDESIGNATION.—Assistance provided under paragraph (1) may include additional subsidization, as described in subparagraph (A), even if the service area of the eligible system has not been designated by the applicable eligible State as a disadvantaged community pursuant to section 1452(d)(3) of the Safe Drinking Water Act (42 U.S.C. 300j–12(d)(3)).

"(c) EXCLUSION.—Assistance provided under this section shall not include assistance for a project that is financed (directly or indirectly), in whole or in part, with proceeds of any obligation issued after the date of enactment of this Act [Oct. 23, 2018] the interest of which is exempt from the tax imposed under chapter 1 of the Internal Revenue Code of 1986 [26 U.S.C. 1 et seq.].

"(d) NONDUPLICATION OF WORK.—An activity carried out pursuant to this section shall not duplicate the work or activity of any other Federal or State department or agency.

"(e) ADDITIONAL DRINKING WATER STATE REVOLVING FUND CAPITALIZATION GRANTS.—

"(1) IN GENERAL.—There is authorized to be appropriated to the Administrator of the Environmental Protection Agency $100,000,000 to provide additional capitalization grants pursuant to section 1452 of the Safe Drinking Water Act (42 U.S.C. 300j–12) to eligible States, to be available—

"(A) for a period of 24 months beginning on the date on which the funds are made available for the purpose described in subsection (b)(1); and

"(B) after the end of such 24-month period, until expended for the purpose described in paragraph (3) of this subsection.

"(2) SUPPLEMENTED INTENDED USE PLANS.—

"(A) OBLIGATION OF AMOUNTS.—Not later than 30 days after the date on which an eligible State submits to the Administrator a supplemental intended use plan under section 1452(b) of the Safe Drinking Water Act (42 U.S.C. 300j–12(b)), from funds made available under paragraph (1), the Administrator shall obligate to such eligible State such amounts as are appropriate to address the needs identified in such supplemental intended use plan for the purpose described in subsection (b)(1).

"(B) PLANS.—A supplemental intended use plan described in subparagraph (A) shall include information regarding projects to be funded using the assistance provided under subsection (b)(1), including, with respect to each such project—

"(i) a description of the project;

"(ii) an explanation of the means by which the project will restore or improve compliance with national primary drinking water regulations in an underserved area;

"(iii) the estimated cost of the project; and

"(iv) the projected start date for the project.

"(3) UNOBLIGATED AMOUNTS.—Any amounts made available to the Administrator under paragraph (1) that are unobligated on the date that is 24 months after the date on which the amounts are made available shall be available for the purpose of providing additional grants to States to capitalize State loan funds as provided under section 1452 of the Safe Drinking Water Act (42 U.S.C. 300j–12).

"(4) APPLICABILITY.—

"(A) IN GENERAL.—Except as otherwise provided in this section, all requirements of the Safe Drinking Water Act (42 U.S.C. 300f et seq.) shall apply to funding provided under this section.

"(B) INTENDED USE PLANS.—Section 1452(b)(1) of the Safe Drinking Water Act (42 U.S.C. 300j–12(b)(1)) shall not apply to a supplemental intended use plan under paragraph (2).

"(C) STATE CONTRIBUTION.—For amounts authorized to be appropriated under paragraph (1), the matching requirements in section 1452(e) of the Safe Drinking Water Act (42 U.S.C. 300j–12(e)) shall not apply to any funds provided to the Commonwealth of Puerto Rico under this section."

DRINKING WATER INFRASTRUCTURE

Pub. L. 114–322, title II, §2201, Dec. 16, 2016, 130 Stat. 1731, provided that:

"(a) DEFINITIONS.—In this section:

"(1) ELIGIBLE STATE.—The term 'eligible State' means a State for which the President has declared an emergency under the Robert T. Stafford Disaster Relief and Emergency Assistance Act (42 U.S.C. 5121 et seq.) relating to the public health threats associated with the presence of lead or other contaminants in drinking water provided by a public water system.

"(2) ELIGIBLE SYSTEM.—The term 'eligible system' means a public water system that has been the subject of an emergency declaration referred to in paragraph (1).

"(3) LEAD SERVICE LINE.—The term 'lead service line' means a pipe and its fittings, which are not lead free (as defined under section 1417 of the Safe Drinking Water Act (42 U.S.C. 300g–6)), that connect the drinking water main to the building inlet.

"(4) PUBLIC WATER SYSTEM.—The term 'public water system' has the meaning given such term in section 1401(4) of the Safe Drinking Water Act (42 U.S.C. 300f(4)).

"(b) STATE REVOLVING LOAN FUND ASSISTANCE.—

"(1) IN GENERAL.—An eligible system shall be—

"(A) considered to be a disadvantaged community under section 1452(d) of the Safe Drinking Water Act (42 U.S.C. 300j–12(d)); and

"(B) eligible to receive loans with additional subsidization under section 1452(d)(1) of that Act (42 U.S.C. 300j–12(d)(1)), including forgiveness of principal under that section.

"(2) AUTHORIZATION.—

"(A) IN GENERAL.—Using funds provided pursuant to subsection (d), an eligible State may provide assistance to an eligible system within the eligible State for the purpose of addressing lead or other contaminants in drinking water, including repair and replacement of lead service lines and public water system infrastructure.

"(B) INCLUSION.—Assistance provided under subparagraph (A) may include additional subsidization under section 1452(d)(1) of the Safe Drinking Water Act (42 U.S.C. 300j–12(d)(1)), as described in paragraph (1)(B).

"(C) EXCLUSION.—Assistance provided under subparagraph (A) shall not include assistance for a project that is financed (directly or indirectly), in whole or in part, with proceeds of any obligation issued after the date of enactment of this Act [Dec. 16, 2016]—

"(i) the interest of which is exempt from the tax imposed under chapter 1 of the Internal Revenue Code of 1986 [26 U.S.C. 1 et seq.]; or

"(ii) with respect to which credit is allowable under subpart I [former 26 U.S.C. 54A et seq.] or J [former 26 U.S.C. 54AA] of part IV of subchapter A of chapter 1 of such Code.

"(3) INAPPLICABILITY OF LIMITATION.—Section 1452(d)(2) of the Safe Drinking Water Act (42 U.S.C. 300j–12(d)(2)) shall not apply to—

"(A) any funds provided pursuant to subsection (d) of this section;

"(B) any other assistance provided to an eligible system; or

"(C) any funds required to match the funds provided under subsection (d).

"(c) NONDUPLICATION OF WORK.—An activity carried out pursuant to this section shall not duplicate the work or activity of any other Federal or State department or agency.

"(d) ADDITIONAL DRINKING WATER STATE REVOLVING FUND CAPITALIZATION GRANTS.—

"(1) IN GENERAL.—There is authorized to be appropriated to the Administrator [of the Environmental Protection Agency] a total of $100,000,000 to provide additional capitalization grants to eligible States pursuant to section 1452 of the Safe Drinking Water Act (42 U.S.C. 300j–12), to be available for a period of 18 months beginning on the date on which the funds are made available, for the purposes described in subsection (b)(2), and after the end of the 18-month period, until expended for the purposes described in paragraph (3).

"(2) SUPPLEMENTED INTENDED USE PLANS.—From funds made available under paragraph (1), the Administrator shall obligate to an eligible State such amounts as are necessary to meet the needs identified in a supplemented intended use plan for the purposes described in subsection (b)(2) by not later than 30 days after the date on which the eligible State submits to the Administrator a supplemented intended use plan under section 1452(b) of the Safe Drinking Water Act (42 U.S.C. 300j–12(b)) that includes preapplication information regarding projects to be funded using the additional assistance, including, with respect to each such project—

"(A) a description of the project;

"(B) an explanation of the means by which the project will address a situation causing a declared emergency in the eligible State;

"(C) the estimated cost of the project; and

"(D) the projected start date for construction of the project.

"(3) UNOBLIGATED AMOUNTS.—Any amounts made available to the Administrator under paragraph (1) that are unobligated on the date that is 18 months after the date on which the amounts are made available shall be available to provide additional grants to States to capitalize State loan funds as provided under section 1452 of the Safe Drinking Water Act (42 U.S.C. 300j–12).

"(4) APPLICABILITY.—

"(A) Section 1452(b)(1) of the Safe Drinking Water Act (42 U.S.C. 300j–12(b)(1)) shall not apply to a supplement to an intended use plan under paragraph (2).

"(B) Unless explicitly waived, all requirements under the Safe Drinking Water Act (42 U.S.C. 300f et seq.) shall apply to funding provided under this subsection.

"(e) HEALTH EFFECTS EVALUATION.—

"(1) IN GENERAL.—Pursuant to section 104(i)(1)(E) of the Comprehensive Environmental Response, Compensation, and Liability Act of 1980 (42 U.S.C. 9604(i)(1)(E)), and on receipt of a request of an appropriate State or local health official of an eligible State, the Director of the Agency for Toxic Substances and Disease Registry of the National Center for Environmental Health shall in coordination with other agencies, as appropriate, conduct voluntary surveillance activities to evaluate any adverse health effects on individuals exposed to lead from drinking water in the affected communities.

"(2) CONSULTATIONS.—Pursuant to section 104(i)(4) of the Comprehensive Environmental Response, Compensation, and Liability Act of 1980 (42 U.S.C. 9604(i)(4)), and on receipt of a request of an appropriate State or local health official of an eligible State, the Director of the Agency for Toxic Substances and Disease Registry of the National Center for Environmental Health shall provide consultations regarding health issues described in paragraph (1).

"(f) NO EFFECT ON OTHER PROJECTS.—This section shall not affect the application of any provision of the Water Infrastructure Finance and Innovation Act of 2014 (33 U.S.C. 3901 et seq.) or the Safe Drinking Water Act (42 U.S.C. 300f et seq.) to any project that does not receive assistance pursuant to this subtitle [subtitle B (§§2201–2204) of title II of Pub. L. 114–322, enacting provisions set out as this note and section 300j–27 of this title]."

COMBINING FUND ASSETS FOR ENHANCEMENT OF LENDING CAPACITY

Pub. L. 105–276, title III, Oct. 21, 1998, 112 Stat. 2498, provided in part: "That, consistent with section 1452(g) of the Safe Drinking Water Act (42 U.S.C. 300j–12(g)), section 302 of the Safe Drinking Water Act Amendments of 1996 (Public Law 104–182) [set out as a note below] and the accompanying joint explanatory statement of the committee of conference (H. Rept. No. 104–741 to accompany S. 1316, the Safe Drinking Water Act Amendments of 1996), and notwithstanding any other provision of law, beginning in fiscal year 1999 and thereafter, States may combine the assets of State Revolving Funds (SRFs) established under section 1452 of the Safe Drinking Water Act, as amended, and title VI of the Federal Water Pollution Control Act [33 U.S.C. 1381 et seq.], as amended, as security for bond issues to enhance the lending capacity of one or both SRFs, but not to acquire the state match for either program, provided that revenues from the bonds are allocated to the purposes of the Safe Drinking Water Act [42 U.S.C. 300f et seq.] and the Federal Water Pollution Control Act [33 U.S.C. 1251 et seq.] in the same portion as the funds are used as security for the bonds".

TRANSFER OF FUNDS

Pub. L. 112–74, div. E, title II, Dec. 23, 2011, 125 Stat. 1018, provided in part: "That for fiscal year 2012 and hereafter, the Administrator may transfer funds provided for tribal set-asides through funds appropriated for the Clean Water State Revolving Funds and for the Drinking Water State Revolving Funds between those accounts in such manner as the Administrator deems appropriate, but not to exceed the transfer limits given to States under section 302(a) of Public Law 104–182 [set out below]."

Pub. L. 109–54, title II, Aug. 2, 2005, 119 Stat. 530, provided in part: "That for fiscal year 2006 and thereafter, State authority under section 302(a) of Public Law 104–182 [set out as a note below] shall remain in effect".

Similar provisions were contained in the following prior appropriation acts:

Pub. L. 108–447, div. I, title III, Dec. 8, 2004, 118 Stat. 3330.

Pub. L. 108–199, div. G, title III, Jan. 23, 2004, 118 Stat. 406.

Pub. L. 108–7, div. K, title III, Feb. 20, 2003, 117 Stat. 512.

Pub. L. 107–73, title III, Nov. 26, 2001, 115 Stat. 685.

Pub. L. 104–182, title III, §302, Aug. 6, 1996, 110 Stat. 1683, provided that:

"(a) IN GENERAL.—Notwithstanding any other provision of law, at any time after the date 1 year after a State establishes a State loan fund pursuant to section 1452 of the Safe Drinking Water Act [42 U.S.C. 300j–12] but prior to fiscal year 2002, a Governor of the State may—

"(1) reserve up to 33 percent of a capitalization grant made pursuant to such section 1452 and add the funds reserved to any funds provided to the State pursuant to section 601 of the Federal Water Pollution Control Act (33 U.S.C. 1381); and

"(2) reserve in any year a dollar amount up to the dollar amount that may be reserved under paragraph (1) for that year from capitalization grants made pursuant to section 601 of such Act (33 U.S.C. 1381) and add the reserved funds to any funds provided to the State pursuant to section 1452 of the Safe Drinking Water Act.

"(b) REPORT.—Not later than 4 years after the date of enactment of this Act [Aug. 6, 1996], the Administrator shall submit a report to the Congress regarding the implementation of this section, together with the Administrator's recommendations, if any, for modifications or improvement.

"(c) STATE MATCH.—Funds reserved pursuant to this section shall not be considered to be a State match of a capitalization grant required pursuant to section 1452 of the Safe Drinking Water Act or the Federal Water Pollution Control Act (33 U.S.C. 1251 et seq.)."

[1] *So in original. Probably should be preceded by "section".*

§300j–13. Source water quality assessment

(a) Source water assessment

(1) Guidance

Within 12 months after August 6, 1996, after notice and comment, the Administrator shall publish guidance for States exercising primary enforcement responsibility for public water systems to carry out directly or through delegation (for the protection and benefit of public water systems and for the support of monitoring flexibility) a source water assessment program within

the State's boundaries. Each State adopting modifications to monitoring requirements pursuant to section 300g–7(b) of this title shall, prior to adopting such modifications, have an approved source water assessment program under this section and shall carry out the program either directly or through delegation.

(2) Program requirements

A source water assessment program under this subsection shall—

(A) delineate the boundaries of the assessment areas in such State from which one or more public water systems in the State receive supplies of drinking water, using all reasonably available hydrogeologic information on the sources of the supply of drinking water in the State and the water flow, recharge, and discharge and any other reliable information as the State deems necessary to adequately determine such areas; and

(B) identify for contaminants regulated under this subchapter for which monitoring is required under this subchapter (or any unregulated contaminants selected by the State, in its discretion, which the State, for the purposes of this subsection, has determined may present a threat to public health), to the extent practical, the origins within each delineated area of such contaminants to determine the susceptibility of the public water systems in the delineated area to such contaminants.

(3) Approval, implementation, and monitoring relief

A State source water assessment program under this subsection shall be submitted to the Administrator within 18 months after the Administrator's guidance is issued under this subsection and shall be deemed approved 9 months after the date of such submittal unless the Administrator disapproves the program as provided in section 300h–7(c) of this title. States shall begin implementation of the program immediately after its approval. The Administrator's approval of a State program under this subsection shall include a timetable, established in consultation with the State, allowing not more than 2 years for completion after approval of the program. Public water systems seeking monitoring relief in addition to the interim relief provided under section 300g–7(a) of this title shall be eligible for monitoring relief, consistent with section 300g–7(b) of this title, upon completion of the assessment in the delineated source water assessment area or areas concerned.

(4) Timetable

The timetable referred to in paragraph (3) shall take into consideration the availability to the State of funds under section 300j–12 of this title (relating to State loan funds) for assessments and other relevant factors. The Administrator may extend any timetable included in a State program approved under paragraph (3) to extend the period for completion by an additional 18 months.

(5) Demonstration project

The Administrator shall, as soon as practicable, conduct a demonstration project, in consultation with other Federal agencies, to demonstrate the most effective and protective means of assessing and protecting source waters serving large metropolitan areas and located on Federal lands.

(6) Use of other programs

To avoid duplication and to encourage efficiency, the program under this section may make use of any of the following:

(A) Vulnerability assessments, sanitary surveys, and monitoring programs.

(B) Delineations or assessments of ground water sources under a State wellhead protection program developed pursuant to this section.

(C) Delineations or assessments of surface or ground water sources under a State pesticide management plan developed pursuant to the Pesticide and Ground Water State Management Plan Regulation (subparts I and J of part 152 of title 40, Code of Federal Regulations), promulgated under section 136a(d) of title 7.

(D) Delineations or assessments of surface water sources under a State watershed initiative or to satisfy the watershed criterion for determining if filtration is required under the Surface

Water Treatment Rule (section 141.70 of title 40, Code of Federal Regulations).

(E) Delineations or assessments of surface or ground water sources under programs or plans pursuant to the Federal Water Pollution Control Act [33 U.S.C. 1251 et seq.].

(7) Public availability

The State shall make the results of the source water assessments conducted under this subsection available to the public.

(b) Approval and disapproval

For provisions relating to program approval and disapproval, see section 300h–7(c) of this title.

(July 1, 1944, ch. 373, title XIV, §1453, as added Pub. L. 104–182, title I, §132(a), Aug. 6, 1996, 110 Stat. 1673.)

EDITORIAL NOTES

REFERENCES IN TEXT

The Federal Water Pollution Control Act, referred to in subsec. (a)(6)(E), is act June 30, 1948, ch. 758, as amended generally by Pub. L. 92–500, §2, Oct. 18, 1972, 86 Stat. 816, which is classified generally to chapter 26 (§1251 et seq.) of Title 33, Navigation and Navigable Waters. For complete classification of this Act to the Code, see Short Title note set out under section 1251 of Title 33 and Tables.

§300j–14. Source water petition program

(a) Petition program

(1) In general

(A) Establishment

A State may establish a program under which an owner or operator of a community water system in the State, or a municipal or local government or political subdivision of a State (including a county that is designated by the State to act on behalf of an unincorporated area within that county, with the agreement of that unincorporated area), may submit a source water quality protection partnership petition to the State requesting that the State assist in the local development of a voluntary, incentive-based partnership, among the owner, operator, or government and other persons likely to be affected by the recommendations of the partnership, to—

(i) reduce the presence in drinking water of contaminants that may be addressed by a petition by considering the origins of the contaminants, including to the maximum extent practicable the specific activities that affect the drinking water supply of a community;

(ii) obtain financial or technical assistance necessary to facilitate establishment of a partnership, or to develop and implement recommendations of a partnership for the protection of source water to assist in the provision of drinking water that complies with national primary drinking water regulations with respect to contaminants addressed by a petition; and

(iii) develop recommendations regarding voluntary and incentive-based strategies for the long-term protection of the source water of community water systems.

(B) Funding

Each State may—

(i) use funds set aside pursuant to section 300j–12(k)(1)(A)(iii) of this title by the State to carry out a program described in subparagraph (A), including assistance to voluntary local partnerships for the development and implementation of partnership recommendations for the protection of source water such as source water quality assessment, contingency plans, and demonstration projects for partners within a source water area delineated under section 300j–13(a) of this title; and

(ii) provide assistance in response to a petition submitted under this subsection using funds

referred to in subsection (b)(2)(B).

(2) Objectives

The objectives of a petition submitted under this subsection shall be to—

(A) facilitate the local development of voluntary, incentive-based partnerships among owners and operators of community water systems, governments, and other persons in source water areas; and

(B) obtain assistance from the State in identifying resources which are available to implement the recommendations of the partnerships to address the origins of drinking water contaminants that may be addressed by a petition (including to the maximum extent practicable the specific activities contributing to the presence of the contaminants) that affect the drinking water supply of a community.

(3) Contaminants addressed by a petition

A petition submitted to a State under this subsection may address only those contaminants—

(A) that are pathogenic organisms for which a national primary drinking water regulation has been established or is required under section 300g–1 of this title; or

(B) for which a national primary drinking water regulation has been promulgated or proposed and that are detected by adequate monitoring methods in the source water at the intake structure or in any collection, treatment, storage, or distribution facilities by the community water systems at levels—

(i) above the maximum contaminant level; or

(ii) that are not reliably and consistently below the maximum contaminant level.

(4) Contents

A petition submitted under this subsection shall, at a minimum—

(A) include a delineation of the source water area in the State that is the subject of the petition;

(B) identify, to the maximum extent practicable, the origins of the drinking water contaminants that may be addressed by a petition (including to the maximum extent practicable the specific activities contributing to the presence of the contaminants) in the source water area delineated under section 300j–13 of this title;

(C) identify any deficiencies in information that will impair the development of recommendations by the voluntary local partnership to address drinking water contaminants that may be addressed by a petition;

(D) specify the efforts made to establish the voluntary local partnership and obtain the participation of—

(i) the municipal or local government or other political subdivision of the State (including a county that is designated by the State to act on behalf of an unincorporated area within that county) with jurisdiction over the source water area delineated under section 300j–13 of this title; and

(ii) each person in the source water area delineated under section 300j–13 of this title—

(I) who is likely to be affected by recommendations of the voluntary local partnership; and

(II) whose participation is essential to the success of the partnership;

(E) outline how the voluntary local partnership has or will, during development and implementation of recommendations of the voluntary local partnership, identify, recognize and take into account any voluntary or other activities already being undertaken by persons in the source water area delineated under section 300j–13 of this title under Federal or State law to reduce the likelihood that contaminants will occur in drinking water at levels of public health concern; and

(F) specify the technical, financial, or other assistance that the voluntary local partnership requests of the State to develop the partnership or to implement recommendations of the

partnership.

(5) Savings provision

Unless otherwise provided within the agreement, an agreement between an unincorporated area and a county for the county to submit a petition under paragraph (1)(A) on behalf of the unincorporated area shall not authorize the county to act on behalf of the unincorporated area in any matter not within a program under this section.

(b) Approval or disapproval of petitions

(1) In general

After providing notice and an opportunity for public comment on a petition submitted under subsection (a), the State shall approve or disapprove the petition, in whole or in part, not later than 120 days after the date of submission of the petition.

(2) Approval

The State may approve a petition if the petition meets the requirements established under subsection (a). The notice of approval shall, at a minimum, include for informational purposes—

(A) an identification of technical, financial, or other assistance that the State will provide to assist in addressing the drinking water contaminants that may be addressed by a petition based on—

(i) the relative priority of the public health concern identified in the petition with respect to the other water quality needs identified by the State;

(ii) any necessary coordination that the State will perform of the program established under this section with programs implemented or planned by other States under this section; and

(iii) funds available (including funds available from a State revolving loan fund established under title VI of the Federal Water Pollution Control Act (33 U.S.C. 1381 et seq.)) or section 300j–12 of this title;

(B) a description of technical or financial assistance pursuant to Federal and State programs that is available to assist in implementing recommendations of the partnership in the petition, including—

(i) any program established under the Federal Water Pollution Control Act (33 U.S.C. 1251 et seq.);

(ii) the program established under section 1455b of title 16;

(iii) the agricultural water quality protection program established under chapter 2 of subtitle D of title XII of the Food Security Act of 1985 (16 U.S.C. 3838 et seq.);[1]

(iv) the sole source aquifer protection program established under section 300h–6 of this title;

(v) the community wellhead protection program established under section 300h–7 of this title;

(vi) any pesticide or ground water management plan;

(vii) any voluntary agricultural resource management plan or voluntary whole farm or whole ranch management plan developed and implemented under a process established by the Secretary of Agriculture; and

(viii) any abandoned well closure program; and

(C) a description of activities that will be undertaken to coordinate Federal and State programs to respond to the petition.

(3) Disapproval

If the State disapproves a petition submitted under subsection (a), the State shall notify the entity submitting the petition in writing of the reasons for disapproval. A petition may be resubmitted at any time if—

(A) new information becomes available;

(B) conditions affecting the source water that is the subject of the petition change; or
(C) modifications are made in the type of assistance being requested.

(c) Grants to support State programs

(1) In general

The Administrator may make a grant to each State that establishes a program under this section that is approved under paragraph (2). The amount of each grant shall not exceed 50 percent of the cost of administering the program for the year in which the grant is available.

(2) Approval

In order to receive grant assistance under this subsection, a State shall submit to the Administrator for approval a plan for a source water quality protection partnership program that is consistent with the guidance published under subsection (d). The Administrator shall approve the plan if the plan is consistent with the guidance published under subsection (d).

(d) Guidance

(1) In general

Not later than 1 year after August 6, 1996, the Administrator, in consultation with the States, shall publish guidance to assist—

(A) States in the development of a source water quality protection partnership program; and
(B) municipal or local governments or political subdivisions of a State and community water systems in the development of source water quality protection partnerships and in the assessment of source water quality.

(2) Contents of the guidance

The guidance shall, at a minimum—

(A) recommend procedures for the approval or disapproval by a State of a petition submitted under subsection (a);
(B) recommend procedures for the submission of petitions developed under subsection (a);
(C) recommend criteria for the assessment of source water areas within a State; and
(D) describe technical or financial assistance pursuant to Federal and State programs that is available to address the contamination of sources of drinking water and to develop and respond to petitions submitted under subsection (a).

(e) Authorization of appropriations

There are authorized to be appropriated to carry out this section $5,000,000 for each of the fiscal years 2020 through 2026. Each State with a plan for a program approved under subsection (b) shall receive an equitable portion of the funds available for any fiscal year.

(f) Statutory construction

Nothing in this section—

(1)(A) creates or conveys new authority to a State, political subdivision of a State, or community water system for any new regulatory measure; or
(B) limits any authority of a State, political subdivision, or community water system; or
(2) precludes a community water system, municipal or local government, or political subdivision of a government from locally developing and carrying out a voluntary, incentive-based, source water quality protection partnership to address the origins of drinking water contaminants of public health concern.

(July 1, 1944, ch. 373, title XIV, §1454, as added Pub. L. 104–182, title I, §133(a), Aug. 6, 1996, 110 Stat. 1675; amended Pub. L. 115–270, title II, §2016, Oct. 23, 2018, 132 Stat. 3856; Pub. L. 117–58, div. E, title I, §50103, Nov. 15, 2021, 135 Stat. 1137.)

EDITORIAL NOTES

REFERENCES IN TEXT

The Federal Water Pollution Control Act, referred to in subsec. (b)(2)(A)(iii), (B)(i), is act June 30, 1948, ch. 758, as amended generally by Pub. L. 92–500, §2, Oct. 18, 1972, 86 Stat. 816, which is classified generally to chapter 26 (§1251 et seq.) of Title 33, Navigation and Navigable Waters. Title VI of the Act is classified generally to subchapter VI (§1381 et seq.) of chapter 26 of Title 33. For complete classification of this Act to the Code, see Short Title note set out under section 1251 of Title 33 and Tables.

The Food Security Act of 1985, referred to in subsec. (b)(2)(B)(iii), is Pub. L. 99–198, Dec. 23, 1985, 99 Stat. 1354. Chapter 2 of subtitle D of title XII of the Act means chapter 2 of subtitle D of title XII of Pub. L. 99–198, as added by Pub. L. 101–624, title XIV, §1439, Nov. 28, 1990, 104 Stat. 3590, which was classified generally to part II (§3838 et seq.) of subchapter IV of chapter 58 of Title 16, Conservation, prior to repeal by Pub. L. 104–127, title III, §336(h), Apr. 4, 1996, 110 Stat. 1007. For complete classification of this Act to the Code, see Short Title of 1985 Amendment note set out under section 1281 of Title 7, Agriculture, and Tables.

AMENDMENTS

2021—Subsec. (a)(1)(A). Pub. L. 117–58, §50103(1)(A), substituted "political subdivision of a State (including a county that is designated by the State to act on behalf of an unincorporated area within that county, with the agreement of that unincorporated area)," for "political subdivision of a State," in introductory provisions.

Subsec. (a)(4)(D)(i). Pub. L. 117–58, §50103(1)(B), inserted "(including a county that is designated by the State to act on behalf of an unincorporated area within that county)" after "of the State".

Subsec. (a)(5). Pub. L. 117–58, §50103(1)(C), added par. (5).

Subsec. (e). Pub. L. 117–58, §50103(2), substituted "2026" for "2021".

2018—Subsec. (e). Pub. L. 115–270 substituted "2020 through 2021" for "1997 through 2003".

[1] *See References in Text note below.*

§300j–15. Water conservation plan

(a) Guidelines

Not later than 2 years after August 6, 1996, the Administrator shall publish in the Federal Register guidelines for water conservation plans for public water systems serving fewer than 3,300 persons, public water systems serving between 3,300 and 10,000 persons, and public water systems serving more than 10,000 persons, taking into consideration such factors as water availability and climate.

(b) Loans or grants

Within 1 year after publication of the guidelines under subsection (a), a State exercising primary enforcement responsibility for public water systems may require a public water system, as a condition of receiving a loan or grant from a State loan fund under section 300j–12 of this title, to submit with its application for such loan or grant a water conservation plan consistent with such guidelines.

(July 1, 1944, ch. 373, title XIV, §1455, as added Pub. L. 104–182, title I, §134, Aug. 6, 1996, 110 Stat. 1679.)

§300j–16. Assistance to colonias

(a) Definitions

As used in this section:

(1) Border State

The term "border State" means Arizona, California, New Mexico, and Texas.

(2) Eligible community

The term "eligible community" means a low-income community with economic hardship that—

(A) is commonly referred to as a colonia;

(B) is located along the United States-Mexico border (generally in an unincorporated area);

and

(C) lacks a safe drinking water supply or adequate facilities for the provision of safe drinking water for human consumption.

(b) Grants to alleviate health risks

The Administrator of the Environmental Protection Agency and the heads of other appropriate Federal agencies are authorized to award grants to a border State to provide assistance to eligible communities to facilitate compliance with national primary drinking water regulations or otherwise significantly further the health protection objectives of this subchapter.

(c) Use of funds

Each grant awarded pursuant to subsection (b) shall be used to provide assistance to one or more eligible communities with respect to which the residents are subject to a significant health risk (as determined by the Administrator or the head of the Federal agency making the grant) attributable to the lack of access to an adequate and affordable drinking water supply system.

(d) Cost sharing

The amount of a grant awarded pursuant to this section shall not exceed 50 percent of the costs of carrying out the project that is the subject of the grant.

(e) Authorization of appropriations

There are authorized to be appropriated to carry out this section $25,000,000 for each of the fiscal years 1997 through 1999.

(July 1, 1944, ch. 373, title XIV, §1456, as added Pub. L. 104–182, title I, §135, Aug. 6, 1996, 110 Stat. 1679.)

§300j–17. Estrogenic substances screening program

In addition to the substances referred to in section 346a(p)(3)(B) of title 21 the Administrator may provide for testing under the screening program authorized by section 346a(p) of title 21, in accordance with the provisions of section 346a(p) of title 21, of any other substance that may be found in sources of drinking water if the Administrator determines that a substantial population may be exposed to such substance.

(July 1, 1944, ch. 373, title XIV, §1457, as added Pub. L. 104–182, title I, §136, Aug. 6, 1996, 110 Stat. 1680.)

§300j–18. Drinking water studies

(a) Subpopulations at greater risk

(1) In general

The Administrator shall conduct a continuing program of studies to identify groups within the general population that may be at greater risk than the general population of adverse health effects from exposure to contaminants in drinking water. The study shall examine whether and to what degree infants, children, pregnant women, the elderly, individuals with a history of serious illness, or other subpopulations that can be identified and characterized are likely to experience elevated health risks, including risks of cancer, from contaminants in drinking water.

(2) Report

Not later than 4 years after August 6, 1996, and periodically thereafter as new and significant information becomes available, the Administrator shall report to the Congress on the results of the studies.

(b) Biological mechanisms

The Administrator shall conduct biomedical studies to—

(1) understand the mechanisms by which chemical contaminants are absorbed, distributed, metabolized, and eliminated from the human body, so as to develop more accurate physiologically based models of the phenomena;

(2) understand the effects of contaminants and the mechanisms by which the contaminants cause adverse effects (especially noncancer and infectious effects) and the variations in the effects among humans, especially subpopulations at greater risk of adverse effects, and between test animals and humans; and

(3) develop new approaches to the study of complex mixtures, such as mixtures found in drinking water, especially to determine the prospects for synergistic or antagonistic interactions that may affect the shape of the dose-response relationship of the individual chemicals and microbes, and to examine noncancer endpoints and infectious diseases, and susceptible individuals and subpopulations.

(c) Studies on harmful substances in drinking water

(1) Development of studies

The Administrator shall, not later than 180 days after August 6, 1996, and after consultation with the Secretary of Health and Human Services, the Secretary of Agriculture, and, as appropriate, the heads of other Federal agencies, conduct the studies described in paragraph (2) to support the development and implementation of the most current version of each of the following:

(A) Enhanced Surface Water Treatment Rule (59 Fed. Reg. 38832 (July 29, 1994)).

(B) Disinfectant and Disinfection Byproducts Rule (59 Fed. Reg. 38668 (July 29, 1994)).

(C) Ground Water Disinfection Rule (availability of draft summary announced at (57 Fed. Reg. 33960; July 31, 1992)).

(2) Contents of studies

The studies required by paragraph (1) shall include, at a minimum, each of the following:

(A) Toxicological studies and, if warranted, epidemiological studies to determine what levels of exposure from disinfectants and disinfection byproducts, if any, may be associated with developmental and birth defects and other potential toxic end points.

(B) Toxicological studies and, if warranted, epidemiological studies to quantify the carcinogenic potential from exposure to disinfection byproducts resulting from different disinfectants.

(C) The development of dose-response curves for pathogens, including cryptosporidium and the Norwalk virus.

(3) Authorization of appropriations

There are authorized to be appropriated to carry out this subsection $12,500,000 for each of fiscal years 1997 through 2003.

(d) Waterborne disease occurrence study

(1) System

The Director of the Centers for Disease Control and Prevention, and the Administrator shall jointly—

(A) within 2 years after August 6, 1996, conduct pilot waterborne disease occurrence studies for at least 5 major United States communities or public water systems; and

(B) within 5 years after August 6, 1996, prepare a report on the findings of the pilot studies, and a national estimate of waterborne disease occurrence.

(2) Training and education

The Director and Administrator shall jointly establish a national health care provider training and public education campaign to inform both the professional health care provider community and the general public about waterborne disease and the symptoms that may be caused by infectious agents, including microbial contaminants. In developing such a campaign, they shall

seek comment from interested groups and individuals, including scientists, physicians, State and local governments, environmental groups, public water systems, and vulnerable populations.

(3) Funding

There are authorized to be appropriated for each of the fiscal years 1997 through 2001, $3,000,000 to carry out this subsection. To the extent funds under this subsection are not fully appropriated, the Administrator may use not more than $2,000,000 of the funds from amounts reserved under section 300j–12(n) of this title for health effects studies for purposes of this subsection. The Administrator may transfer a portion of such funds to the Centers for Disease Control and Prevention for such purposes.

(July 1, 1944, ch. 373, title XIV, §1458, as added Pub. L. 104–182, title I, §137, Aug. 6, 1996, 110 Stat. 1680.)

STATUTORY NOTES AND RELATED SUBSIDIARIES

PUBLIC HEALTH ASSESSMENT OF EXPOSURE TO PERCHLORATE

Pub. L. 108–136, div. A, title III, §323, Nov. 24, 2003, 117 Stat. 1440, provided that:

"(a) EPIDEMIOLOGICAL STUDY OF EXPOSURE TO PERCHLORATE.—The Secretary of Defense shall provide for an independent epidemiological study of exposure to perchlorate in drinking water. The entity conducting the study shall—

"(1) assess the incidence of thyroid disease and measurable effects of thyroid function in relation to exposure to perchlorate;

"(2) ensure that the study is of sufficient scope and scale to permit the making of meaningful conclusions of the measurable public health threat associated with exposure to perchlorate, especially the threat to sensitive subpopulations; and

"(3) examine thyroid function, including measurements of urinary iodine and thyroid hormone levels, in a sufficient number of pregnant women, neonates, and infants exposed to perchlorate in drinking water and match measurements of perchlorate levels in the drinking water of each study participant in order to permit the development of meaningful conclusions on the public health threat to individuals exposed to perchlorate.

"(b) REVIEW OF EFFECTS OF PERCHLORATE ON ENDOCRINE SYSTEM.—The Secretary shall provide for an independent review of the effects of perchlorate on the human endocrine system. The entity conducting the review shall assess—

"(1) available data on human exposure to perchlorate, including clinical data and data on exposure of sensitive subpopulations, and the levels at which health effects were observed; and

"(2) available data on other substances that have endocrine effects similar to perchlorate to which the public is frequently exposed.

"(c) PERFORMANCE OF STUDY AND REVIEW.—(1) The Secretary shall provide for the performance of the study under subsection (a) through the Centers for Disease Control and Prevention, the National Institutes of Health, or another Federal entity with experience in environmental toxicology selected by the Secretary.

"(2) The Secretary shall provide for the performance of the review under subsection (b) through the Centers for Disease Control and Prevention, the National Institutes of Health, or another appropriate Federal research entity with experience in human endocrinology selected by the Secretary. The Secretary shall ensure that the panel conducting the review is composed of individuals with expertise in human endocrinology.

"(d) REPORTING REQUIREMENTS.—Not later than June 1, 2005, the Federal entities conducting the study and review under this section shall submit to the Secretary reports containing the results of the study and review."

§300j–18a. Annual study on boil water advisories

(a) In general

Not later than 1 year after November 15, 2021, and annually thereafter, the Administrator shall conduct a study on the prevalence of boil water advisories issued in the United States.

(b) Report

(1) In general

The Administrator shall submit to Congress a report describing the results of the most recent study conducted under subsection (a) as part of the annual budget request transmitted to Congress under section 1105(a) of title 31.

(2) Requirement

In the annual report required under paragraph (1), the Administrator shall include a description of the reasons for which boil water advisories were issued during the year covered by the report.

(Pub. L. 117–58, div. E, title I, §50115, Nov. 15, 2021, 135 Stat. 1157.)

EDITORIAL NOTES

CODIFICATION

Section enacted as part of the Drinking Water and Wastewater Infrastructure Act of 2021 and also as part of the Infrastructure Investment and Jobs Act, and not as part of the Public Health Service Act which comprises this chapter.

STATUTORY NOTES AND RELATED SUBSIDIARIES

DEFINITION OF ADMINISTRATOR

Pub. L. 117–58, div. E, §50002, Nov. 15, 2021, 135 Stat. 1135, provided that: "In this division [see Short Title of 2021 Amendment note set out under section 1251 of Title 33, Navigation and Navigable Waters], the term 'Administrator' means the Administrator of the Environmental Protection Agency."

§300j–19. Algal toxin risk assessment and management

(a) Strategic plan

(1) Development

Not later than 90 days after August 7, 2015, the Administrator shall develop and submit to Congress a strategic plan for assessing and managing risks associated with algal toxins in drinking water provided by public water systems. The strategic plan shall include steps and timelines to—

(A) evaluate the risk to human health from drinking water provided by public water systems contaminated with algal toxins;

(B) establish, publish, and update a comprehensive list of algal toxins which the Administrator determines may have an adverse effect on human health when present in drinking water provided by public water systems, taking into account likely exposure levels;

(C) summarize—

(i) the known adverse human health effects of algal toxins included on the list published under subparagraph (B) when present in drinking water provided by public water systems; and

(ii) factors that cause toxin-producing cyanobacteria and algae to proliferate and express toxins;

(D) with respect to algal toxins included on the list published under subparagraph (B), determine whether to—

(i) publish health advisories pursuant to section 300g–1(b)(1)(F) of this title for such algal toxins in drinking water provided by public water systems;

(ii) establish guidance regarding feasible analytical methods to quantify the presence of algal toxins; and

(iii) establish guidance regarding the frequency of monitoring necessary to determine if such algal toxins are present in drinking water provided by public water systems;

(E) recommend feasible treatment options, including procedures, equipment, and source water protection practices, to mitigate any adverse public health effects of algal toxins included on the list published under subparagraph (B); and

(F) enter into cooperative agreements with, and provide technical assistance to, affected States and public water systems, as identified by the Administrator, for the purpose of managing risks associated with algal toxins included on the list published under subparagraph (B).

(2) Updates

The Administrator shall, as appropriate, update and submit to Congress the strategic plan developed under paragraph (1).

(b) Information coordination

In carrying out this section the Administrator shall—

(1) identify gaps in the Agency's understanding of algal toxins, including—

(A) the human health effects of algal toxins included on the list published under subsection (a)(1)(B); and

(B) methods and means of testing and monitoring for the presence of harmful algal toxins in source water of, or drinking water provided by, public water systems;

(2) as appropriate, consult with—

(A) other Federal agencies that—

(i) examine or analyze cyanobacteria or algal toxins; or

(ii) address public health concerns related to harmful algal blooms;

(B) States;

(C) operators of public water systems;

(D) multinational agencies;

(E) foreign governments;

(F) research and academic institutions; and

(G) companies that provide relevant drinking water treatment options; and

(3) assemble and publish information from each Federal agency that has—

(A) examined or analyzed cyanobacteria or algal toxins; or

(B) addressed public health concerns related to harmful algal blooms.

(c) Use of science

The Administrator shall carry out this section in accordance with the requirements described in section 300g–1(b)(3)(A) of this title, as applicable.

(d) Feasible

For purposes of this section, the term "feasible" has the meaning given such term in section 300g–1(b)(4)(D) of this title.

(July 1, 1944, ch. 373, title XIV, §1459, as added Pub. L. 114–45, §2(a), Aug. 7, 2015, 129 Stat. 473.)

§300j–19a. Assistance for small and disadvantaged communities

(a) Definition of underserved community

In this section:

(1) In general

The term "underserved community" means a political subdivision of a State that, as determined by the Administrator, has an inadequate system for obtaining drinking water.

(2) Inclusions

The term "underserved community" includes a political subdivision of a State that either, as determined by the Administrator—

(A) does not have household drinking water or wastewater services; or

(B) is served by a public water system that violates, or exceeds, as applicable, a requirement of a national primary drinking water regulation issued under section 300g–1 of this title, including—

(i) a maximum contaminant level;

(ii) a treatment technique; and

(iii) an action level.

(b) Establishment

(1) In general

The Administrator shall establish a program under which grants are provided to eligible entities for use in carrying out projects and activities the primary purposes of which are to assist public water systems in meeting the requirements of this subchapter.

(2) Inclusions

Projects and activities under paragraph (1) include—

(A) investments necessary for the public water system to comply with the requirements of this subchapter;

(B) assistance that directly and primarily benefits the disadvantaged community on a per-household basis;

(C) programs to provide household water quality testing, including testing for unregulated contaminants;

(D) the purchase of point-of-entry or point-of-use filters and filtration systems that are certified by a third party using science-based test methods for the removal of contaminants of concern;

(E) investments necessary for providing accurate and current information about—

(i) the need for filtration and filter safety, including proper use and maintenance practices; and

(ii) the options for replacing lead service lines (as defined in section 300j–19b(a) of this title) and removing other sources of lead in water; and

(F) entering into contracts, including contracts with nonprofit organizations that have water system technical expertise, to assist—

(i) an eligible entity; or

(ii) the State of an eligible entity, on behalf of that eligible entity.

(c) Eligible entities

Except for purposes of subsections (j) and (m), an eligible entity under this section—

(1) is—

(A) a public water system;

(B) a water system that is located in an area governed by an Indian Tribe; or

(C) a State, on behalf of an underserved community; and

(2) serves a community—

(A) that, under affordability criteria established by the State under section 300j–12(d)(3) of this title, is determined by the State—

(i) to be a disadvantaged community; or

(ii) to be a community that may become a disadvantaged community as a result of carrying out a project or activity under subsection (b); or

(B) with a population of less than 10,000 individuals that the Administrator determines does not have the capacity to incur debt sufficient to finance a project or activity under subsection

(b).

(d) Priority

In prioritizing projects and activities for implementation under this section, the Administrator shall give priority to projects and activities that benefit underserved communities.

(e) Local participation

In prioritizing projects and activities for implementation under this section, the Administrator shall consult with and consider the priorities of States, Indian Tribes, and local governments in which communities described in subsection (c)(2) are located.

(f) Technical, managerial, and financial capability

The Administrator may provide assistance to increase the technical, managerial, and financial capability of an eligible entity receiving a grant under this section if the Administrator determines that the eligible entity lacks appropriate technical, managerial, or financial capability and is not receiving such assistance under another Federal program.

(g) Cost sharing

Before providing a grant to an eligible entity under this section, the Administrator shall enter into a binding agreement with the eligible entity to require the eligible entity—

(1) except as provided in subsection (l)(5) and subject to subsection (h), to pay not less than 10 percent of the total costs of the project or activity, which may include services, materials, supplies, or other in-kind contributions;

(2) to provide any land, easements, rights-of-way, and relocations necessary to carry out the project or activity; and

(3) to pay 100 percent of any operation and maintenance costs associated with the project or activity.

(h) Waiver

The Administrator may waive, in whole or in part, the requirement under subsection (g)(1) if the Administrator determines that an eligible entity is unable to pay, or would experience significant financial hardship if required to pay, the non-Federal share.

(i) Limitation on use of funds

Not more than 4 percent of funds made available for grants under this section may be used to pay the administrative costs of the Administrator.

(j) State response to contaminants

(1) In general

The Administrator may, subject to the terms and conditions of this section, issue a grant to a requesting State, on behalf of a community described in subsection (c)(2), so the State may assist in, or otherwise carry out, necessary and appropriate activities related to a contaminant—

(A) that is determined by the State to—

(i) be present in, or likely to enter into, a public water system serving, or an underground source of drinking water for, that community; and

(ii) potentially present an imminent and substantial endangerment to the health of persons; and

(B) with respect to which the State determines appropriate authorities have not acted sufficiently to protect the health of such persons.

(2) Recovery of funds

If, subsequent to the Administrator's award of a grant to a State under this subsection, any person or entity (including an eligible entity), is found by the Administrator or a court of competent jurisdiction to have caused or contributed to contamination that was detected as a result of testing conducted, or treated, with funds provided under this subsection, and such

contamination violated a law administered by the Administrator, such person or entity shall, upon issuance of a final judgment or settlement and the exhaustion of all appellate and administrative remedies—

(A) notify the Administrator in writing not later than 30 days after such issuance of a final judgment or settlement and the exhaustion of all appellate and administrative remedies; and

(B) promptly pay the Administrator an amount equal to the amount of such funds.

(k) Authorization of appropriations

There are authorized to be appropriated to carry out subsections (a) through (j)—

(1) $70,000,000 for fiscal year 2022;
(2) $80,000,000 for fiscal year 2023;
(3) $100,000,000 for fiscal year 2024;
(4) $120,000,000 for fiscal year 2025; and
(5) $140,000,000 for fiscal year 2026.

(l) Drinking water infrastructure resilience and sustainability

(1) Resilience and natural hazard

The terms "resilience" and "natural hazard" have the meaning given such terms in section 300i–2(h) of this title.

(2) In general

The Administrator shall establish and carry out a program, to be known as the Drinking Water System Infrastructure Resilience and Sustainability Program, under which the Administrator, subject to the availability of appropriations for such purpose, shall award grants in each of fiscal years 2022 through 2026 to eligible entities for the purpose of increasing resilience to natural hazards.

(3) Use of funds

An eligible entity may only use grant funds received under this subsection to assist in the planning, design, construction, implementation, operation, or maintenance of a program or project that increases resilience to natural hazards through—

(A) the conservation of water or the enhancement of water use efficiency;

(B) the modification or relocation of existing drinking water system infrastructure made, or that is at risk of being, significantly impaired by natural hazards, including risks to drinking water from flooding;

(C) the design or construction of desalination facilities to serve existing communities;

(D) the enhancement of water supply through the use of watershed management and source water protection;

(E) the enhancement of energy efficiency or the use and generation of renewable energy in the conveyance or treatment of drinking water; or

(F) the development and implementation of measures to increase the resilience of the eligible entity to natural hazards.

(4) Application

To seek a grant under this subsection, the eligible entity shall submit to the Administrator an application that—

(A) includes a proposal of the program or project to be planned, designed, constructed, implemented, operated, or maintained by the eligible entity;

(B) identifies the natural hazard risk to be addressed by the proposed program or project;

(C) provides documentation prepared by a Federal, State, regional, or local government agency of the natural hazard risk to the area where the proposed program or project is to be located;

(D) includes a description of any recent natural hazard events that have affected the applicable water system;

(E) includes a description of how the proposed program or project would improve the

performance of the system under the anticipated natural hazards; and

(F) explains how the proposed program or project is expected to enhance the resilience of the system to the anticipated natural hazards.

(5) Federal share for small, rural, and disadvantaged communities

(A) In general

Subject to subparagraph (B), with respect to a program or project that serves an eligible entity and is carried out using a grant under this subsection, the Federal share of the cost of the program or project shall be 90 percent.

(B) Waiver

The Administrator may increase the Federal share under subparagraph (A) to 100 percent if the Administrator determines that an eligible entity is unable to pay, or would experience significant financial hardship if required to pay, the non-Federal share.

(6) Authorization of appropriations

There is authorized to be appropriated to carry out this subsection $25,000,000 for each of fiscal years 2022 through 2026.

(m) Connection to public water systems

(1) Definitions

In this subsection:

(A) Eligible entity

The term "eligible entity" means—

(i) an owner or operator of a public water system that assists or is seeking to assist eligible individuals with connecting the household of the eligible individual to the public water system; or

(ii) a nonprofit entity that assists or is seeking to assist eligible individuals with the costs associated with connecting the household of the eligible individual to a public water system.

(B) Eligible individual

The term "eligible individual" has the meaning given the term in section 1383(j) of title 33.

(C) Program

The term "program" means the competitive grant program established under paragraph (2).

(2) Establishment

Subject to the availability of appropriations, the Administrator shall establish a competitive grant program for the purpose of improving the general welfare under which the Administrator awards grants to eligible entities to provide funds to assist eligible individuals in covering the costs incurred by the eligible individual in connecting the household of the eligible individual to a public water system.

(3) Application

An eligible entity seeking a grant under the program shall submit to the Administrator an application at such time, in such manner, and containing such information as the Administrator may require.

(4) Voluntary connection

Before providing funds to an eligible individual for the costs described in paragraph (2), an eligible entity shall ensure and certify to the Administrator that—

(A) the eligible individual is voluntarily seeking connection to the public water system;

(B) if the eligible entity is not the owner or operator of the public water system to which the eligible individual seeks to connect, the public water system to which the eligible individual seeks to connect has agreed to the connection; and

(C) the connection of the household of the eligible individual to the public water system meets all applicable local and State regulations, requirements, and codes.

(5) Report

Not later than 3 years after November 15, 2021, the Administrator shall submit to Congress a report that describes the implementation of the program, which shall include a description of the use and deployment of amounts made available under the program.

(6) Authorization of appropriations

There is authorized to be appropriated to carry out the program $20,000,000 for each of fiscal years 2022 through 2026.

(n) State competitive grants for underserved communities

(1) In general

In addition to amounts authorized to be appropriated under subsection (k), there is authorized to be appropriated to carry out subsections (a) through (j) $50,000,000 for each of fiscal years 2022 through 2026 in accordance with paragraph (2).

(2) Competitive grants

(A) In general

Notwithstanding any other provision of this section, the Administrator shall distribute amounts made available under paragraph (1) to States through a competitive grant program.

(B) Applications

To seek a grant under the competitive grant program under subparagraph (A), a State shall submit to the Administrator an application at such time, in such manner, and containing such information as the Administrator may require.

(C) Criteria

In selecting recipients of grants under the competitive grant program under subparagraph (A), the Administrator shall establish criteria that give priority to States with a high proportion of underserved communities that meet the condition described in subsection (a)(2)(A).

(3) Report

Not later than 2 years after November 15, 2021, the Administrator shall submit to Congress a report that describes the implementation of the competitive grant program under paragraph (2)(A), which shall include a description of the use and deployment of amounts made available under the competitive grant program.

(4) Savings provision

Nothing in this paragraph affects the distribution of amounts made available under subsection (k), including any methods used by the Administrator for distribution of amounts made available under that subsection as in effect on the day before November 15, 2021.

(July 1, 1944, ch. 373, title XIV, §1459A, as added Pub. L. 114–322, title II, §2104, Dec. 16, 2016, 130 Stat. 1718; amended Pub. L. 115–270, title II, §2005, Oct. 23, 2018, 132 Stat. 3842; Pub. L. 117–58, div. E, title I, §§50104, 50114, Nov. 15, 2021, 135 Stat. 1137, 1157.)

EDITORIAL NOTES

AMENDMENTS

2021—Subsec. (b)(2)(D) to (F). Pub. L. 117–58, §50104(a)(1), added subpars. (D) to (F).

Subsec. (c). Pub. L. 117–58, §50104(a)(2), substituted "Except for purposes of subsections (j) and (m), an eligible entity" for "An eligible entity" in introductory provisions.

Subsec. (g)(1). Pub. L. 117–58, §50104(a)(3), substituted "except as provided in subsection (l)(5) and subject to subsection (h), to pay not less than 10 percent" for "to pay not less than 45 percent".

Subsec. (j)(1). Pub. L. 117–58, §50114(1), substituted "a community described in subsection (c)(2)" for "an

underserved community" in introductory provisions.

Subsec. (j)(1)(A)(i). Pub. L. 117–58, §50114(2), substituted "that" for "such underserved".

Subsec. (k). Pub. L. 117–58, §50104(a)(4), added subsec. (k) and struck out former subsec. (k). Prior to amendment, text read as follows: "There are authorized to be appropriated to carry out subsections (a) through (j) of this section, $60,000,000 for each of fiscal years 2017 through 2021."

Subsec. (l)(2). Pub. L. 117–58, §50104(a)(5)(A), substituted "The Administrator shall" for "The Administrator may" and "fiscal years 2022 through 2026" for "fiscal years 2019 and 2020".

Subsec. (l)(5). Pub. L. 117–58, §50104(a)(5)(C), (D), added par. (5) and redesignated former par. (5) as (6).

Pub. L. 117–58, §50104(a)(5)(B), substituted "$25,000,000 for each of fiscal years 2022 through 2026" for "$4,000,000 for each of fiscal years 2019 and 2020".

Subsec. (l)(6). Pub. L. 117–58, §50104(a)(5)(C), redesignated par. (5) as (6).

Subsec. (m). Pub. L. 117–58, §50104(b), added subsec. (m).

Subsec. (n). Pub. L. 117–58, §50104(c), added subsec. (n).

2018—Subsec. (j). Pub. L. 115–270, §2005(3), added subsec. (j). Former subsec. (j) redesignated (k).

Subsec. (k). Pub. L. 115–270, §2005(1), (2), redesignated subsec. (j) as (k) and substituted "subsections (a) through (j) of this section" for "this section".

Subsec. (l). Pub. L. 115–270, §2005(4), added subsec. (l).

STATUTORY NOTES AND RELATED SUBSIDIARIES

RURAL AND URBAN LOW-INCOME COMMUNITY WATER ASSISTANCE; NEEDS ASSESSMENT; PILOT PROGRAM

Pub. L. 117–58, div. E, title I, §§50108, 50109, Nov. 15, 2021, 135 Stat. 1146, 1148, provided that:

"SEC. 50108. NEEDS ASSESSMENT FOR NATIONWIDE RURAL AND URBAN LOW-INCOME COMMUNITY WATER ASSISTANCE.

"(a) DEFINITIONS.—In this section and section 50109:

"(1) COMMUNITY WATER SYSTEM.—The term 'community water system' has the meaning given the term in section 1401 of the Safe Drinking Water Act (42 U.S.C. 300f).

"(2) LARGE WATER SERVICE PROVIDER.—The term 'large water service provider' means a community water system, treatment works, or municipal separate storm sewer system that serves more than 100,000 people.

"(3) MEDIUM WATER SERVICE PROVIDER.—The term 'medium water service provider' means a community water system, treatment works, or municipal separate storm sewer system that serves more than 10,000 people and not more than 100,000 people.

"(4) NEED.—The term 'need', with respect to a qualifying household, means the expenditure of a disproportionate amount of household income on access to public drinking water or wastewater services.

"(5) QUALIFYING HOUSEHOLD.—The term 'qualifying household' means a household that—

"(A) includes an individual who is—

"(i) the holder of an account for drinking water or wastewater service that is provided to that household by a large water service provider, a medium water service provider, or a rural water service provider; or

"(ii) separately billed by a landlord that holds an account with a large water service provider, a medium water service provider, or a rural water service provider for the cost of drinking water or wastewater service provided to that household by the respective large water service provider, medium water service provider, or rural water service provider; and

"(B) is determined—

"(i) by a large water service provider, a medium water service provider, or a rural water service provider to be eligible for assistance through a low-income ratepayer assistance program;

"(ii) by the Governor of the State in which the household is located to be low-income, based on the affordability criteria established by the State under section 1452(d)(3) of the Safe Drinking Water Act (42 U.S.C. 300j–12(d)(3));

"(iii) by the Administrator [of the Environmental Protection Agency] to experience drinking water and wastewater service costs that exceed the metrics of affordability established in the most recent guidance of the Administrator entitled 'Financial Capability Assessment Guidance'; or

"(iv) in the case of a household serviced by a rural water service provider, by the State in which the household is located to have an annual income that does not exceed the greater of—

"(I) an amount equal to 150 percent of the poverty level of that State; and

"(II) an amount equal to 60 percent of the State median income for that State.

"(6) RURAL WATER SERVICE PROVIDER.—The term 'rural water service provider' means a community water system, treatment works, or municipal separate storm sewer system that serves not more than 10,000 people.

"(7) TREATMENT WORKS.—The term 'treatment works' has the meaning given the term in section 212 of the Federal Water Pollution Control Act (33 U.S.C. 1292).

"(b) STUDY; REPORT.—

"(1) IN GENERAL.—The Administrator shall conduct, and submit to Congress a report describing the results of, a study that examines the prevalence throughout the United States of municipalities, public entities, or Tribal governments that—

"(A) are serviced by rural water service providers, medium water service providers, or large water service providers that service a disproportionate percentage, as determined by the Administrator, of qualifying households with need; or

"(B) as determined by the Administrator, have taken on an unsustainable level of debt due to customer nonpayment for the services provided by a large water service provider, a medium water service provider, or a rural water service provider.

"(2) AFFORDABILITY INCLUSIONS.—The report under paragraph (1) shall include—

"(A) a definition of the term 'affordable access to water services';

"(B) a description of the criteria used in defining 'affordable access to water services' under subparagraph (A);

"(C) a definition of the term 'lack of affordable access to water services';

"(D) a description of the methodology and criteria used in defining 'lack of affordable access to water services' under subparagraph (C);

"(E) a determination of the prevalence of a lack of affordable access to water services, as defined under subparagraph (C);

"(F) the methodology and criteria used to determine the prevalence of a lack of affordable access to water services under subparagraph (E);

"(G) any additional information with respect to the affordable access to water services, as defined under subparagraph (A), provided by rural water service providers, medium water service providers, and large water service providers;

"(H) with respect to the development of the report, a consultation with all relevant stakeholders, including rural advocacy associations;

"(I) recommendations of the Administrator regarding the best methods to reduce the prevalence of a lack of affordable access to water services, as defined under subparagraph (C); and

"(J) a description of the cost of each method described in subparagraph (I).

"(3) AGREEMENTS.—The Administrator may enter into an agreement with another Federal agency to carry out the study under paragraph (1).

"SEC. 50109. RURAL AND LOW-INCOME WATER ASSISTANCE PILOT PROGRAM.

"(a) DEFINITIONS.—In this section:

"(1) ELIGIBLE ENTITY.—The term 'eligible entity' means—

"(A) a municipality, Tribal government, or other entity that—

"(i) owns or operates a community water system, treatment works, or municipal separate storm sewer system; or

"(ii) as determined by the Administrator [of the Environmental Protection Agency], has taken on an unsustainable level of debt due to customer nonpayment for the services provided by a community water system, treatment works, or municipal separate storm sewer system; and

"(B) a State exercising primary enforcement responsibility over a rural water service provider under the Safe Drinking Water Act (42 U.S.C. 300f et seq.) or the Federal Water Pollution Control Act (33 U.S.C. 1251 et seq.), as applicable.

"(2) PILOT PROGRAM.—The term 'pilot program' means the pilot program established by the Administrator under subsection (b)(1).

"(3) WATER SERVICES NEEDS ASSESSMENT.—The term 'water services needs assessment' means the report required under section 50108(b)(1).

"(b) ESTABLISHMENT.—

"(1) IN GENERAL.—Not later than 2 years after the date of enactment of this Act [Nov. 15, 2021], the Administrator shall establish a pilot program to award grants to eligible entities to develop and implement programs to assist qualifying households with need in maintaining access to drinking water and wastewater treatment.

"(2) REQUIREMENT.—In establishing the pilot program, the Administrator shall ensure that data from the water services needs assessment directly contributes to the structure of the pilot program by informing the types of assistance and criteria used for priority consideration with the demonstrated need from the study conducted under section 50108(b)(1) and the water services needs assessment.

"(3) USE OF FUNDS LIMITATIONS.—A grant under the pilot program—

"(A) shall not be used to replace funds for any existing similar program; but

"(B) may be used to supplement or enhance an existing program, including a program that receives assistance from other Federal grants.

"(4) TERM.—The term of a grant awarded under the pilot program shall be subject to the availability of appropriations.

"(5) TYPES OF ASSISTANCE.—In establishing the pilot program, the Administrator may include provisions for—

"(A) direct financial assistance;

"(B) a lifeline rate;

"(C) bill discounting;

"(D) special hardship provisions;

"(E) a percentage-of-income payment plan; or

"(F) debt relief for the eligible entity or the community water system owned by the eligible entity for debt that is due to customer nonpayment for the services provided by the eligible entity or the community water system that is determined by the Administrator to be in the interest of public health.

"(6) REQUIREMENT.—The Administrator shall award not more than 40 grants under the pilot program, of which—

"(A) not more than 8 shall be to eligible entities that own, operate, or exercise primary enforcement responsibility over a rural water service provider under the Safe Drinking Water Act (42 U.S.C. 300f et seq.) or the Federal Water Pollution Control Act (33 U.S.C. 1251 et seq.), as applicable;

"(B) not more than 8 shall be to eligible entities that own or operate a medium water service provider;

"(C) not more than 8 shall be to eligible entities that own or operate a large water service provider that serves not more than 500,000 people;

"(D) not more than 8 shall be to eligible entities that own or operate a large water service provider that serves more than 500,000 people; and

"(E) not more than 8 shall be to eligible entities that own or operate a community water system, treatment works, or municipal separate storm sewer system that services a disadvantaged community (consistent with the affordability criteria established by the applicable State under section 1452(d)(3) of the Safe Drinking Water Act (42 U.S.C. 300j–12(d)(3)) or section 603(i)(2) of the Federal Water Pollution Control Act (33 U.S.C. 1383(i)(2)), as applicable).

"(7) CRITERIA.—In addition to any priority criteria established by the Administrator in response to the findings in the water services needs assessment, in awarding grants under the pilot program, the Administrator shall give priority consideration to eligible entities that—

"(A) serve a disproportionate percentage, as determined by the Administrator, of qualifying households with need, as identified in the water services needs assessment;

"(B) are subject to State or Federal enforcement actions relating to compliance with the Federal Water Pollution Control Act (33 U.S.C. 1251 et seq.) or the Safe Drinking Water Act (42 U.S.C. 300f et seq.); or

"(C) maintain or participate in an existing community assistance program with objectives similar to the objectives of the pilot program, as determined by the Administrator.

"(8) REPORTING REQUIREMENTS.—

"(A) IN GENERAL.—In addition to any other applicable Federal or agency-specific grant reporting requirements, as a condition of receiving a grant under the pilot program, an eligible entity (or a State, on behalf of an eligible entity) shall submit to the Administrator an annual report that summarizes, in a manner determined by the Administrator, the use of grant funds by the eligible entity, including—

"(i) key features of the assistance provided by the eligible entity;

"(ii) sources of funding used to supplement Federal funds; and

"(iii) eligibility criteria.

"(B) PUBLICATION.—The Administrator shall publish each report submitted under subparagraph (A).

"(c) TECHNICAL ASSISTANCE.—The Administrator shall provide technical assistance to each eligible entity, and each State, on behalf of an eligible entity, that receives a grant under the pilot program to support

implementation of the program.

"(d) REPORT.—Not later than 2 years after the date on which grant funds are first disbursed to an eligible entity (or a State, on behalf of an eligible entity) under the program, and every year thereafter for the duration of the terms of the grants, the Administrator shall submit to Congress a report on the results of the pilot program."

§300j–19b. Reducing lead in drinking water

(a) Definitions

In this section:

(1) Eligible entity

The term "eligible entity" means—

(A) a community water system;

(B) a water system located in an area governed by an Indian Tribe;

(C) a nontransient noncommunity water system;

(D) a qualified nonprofit organization with experience in lead reduction, as determined by the Administrator; and

(E) a municipality or State, interstate, or intermunicipal agency.

(2) Lead reduction project

(A) In general

The term "lead reduction project" means a project or activity the primary purpose of which is to reduce the concentration of lead in water for human consumption by—

(i) replacement of lead service lines;

(ii) testing, planning, or other relevant activities, as determined by the Administrator, to identify and address conditions (including corrosion control) that contribute to increased concentration of lead in water for human consumption; and

(iii) providing assistance to eligible entities to replace lead service lines, with priority for disadvantaged communities based on the affordability criteria established by the applicable State under section 300j–12(d)(3) of this title, low-income homeowners, and landlords or property owners providing housing to low-income renters.

(B) Limitation

The term "lead reduction project" does not include a partial lead service line replacement if, at the conclusion of the service line replacement, drinking water is delivered to a household through a publicly or privately owned portion of a lead service line.

(3) Low-income

The term "low-income", with respect to assistance under this section, has such meaning as may be given the term by the Governor of the State in which the eligible entity is located, based upon the affordability criteria established by the State under section 300j–12(d)(3) of this title.

(4) Lead service line

The term "lead service line" means a pipe and its fittings, which are not lead free (as defined in section 300g–6(d) of this title), that connect the drinking water main to the building inlet.

(5) Nontransient noncommunity water system

The term "nontransient noncommunity water system" means a public water system that is not a community water system and that regularly serves at least 25 of the same persons over 6 months per year.

(b) Grant program

(1) Establishment

The Administrator shall establish a grant program to provide assistance to eligible entities for

lead reduction projects in the United States.

(2) Precondition

As a condition of receipt of assistance under this section, an eligible entity shall take steps to identify—

(A) the source of lead in the public water system that is subject to human consumption; and

(B) the means by which the proposed lead reduction project would meaningfully reduce the concentration of lead in water provided for human consumption by the applicable public water system.

(3) Priority application

In providing grants under this subsection, the Administrator shall give priority to an eligible entity that—

(A) the Administrator determines, based on affordability criteria established by the State under section 300j–12(d)(3) of this title, to be a disadvantaged community; and

(B) proposes to—

(i) carry out a lead reduction project at a public water system or nontransient noncommunity water system that has exceeded the lead action level established by the Administrator under section 300g–1 of this title at any time during the 3-year period preceding the date of submission of the application of the eligible entity; or

(ii) address lead levels in water for human consumption at a school, daycare, or other facility that primarily serves children or other vulnerable human subpopulation described in section 300j–18(a)(1) of this title.

(4) Cost sharing

(A) In general

Subject to subparagraph (B), the non-Federal share of the total cost of a project funded by a grant under this subsection shall be not less than 20 percent.

(B) Waiver

The Administrator may reduce or eliminate the non-Federal share under subparagraph (A) for reasons of affordability, as the Administrator determines to be appropriate.

(5) Low-income assistance

(A) In general

Subject to subparagraph (B), an eligible entity may use a grant provided under this subsection to replace lead service lines, with first priority given to assisting disadvantaged communities based on the affordability criteria established by the applicable State under section 300j–12(d)(3) of this title, low-income homeowners, and landlords or property owners providing housing to low-income renters.

(B) Limitation

The amount of a grant provided to a low-income homeowner under this paragraph shall not exceed the standard cost of replacement of the privately owned portion of the lead service lines.

(6) Special consideration for lead service line replacement

In carrying out lead service line replacement using a grant under this subsection, an eligible entity—

(A) shall notify customers of the replacement of the lead service line;

(B) may, in the case of a homeowner who is not low-income, offer to replace the privately owned portion of the lead service line at the cost of replacement for that homeowner's property;

(C) shall, in the case of a low-income homeowner, and may, for other homeowners, offer to replace the privately owned portion of the lead service line at no cost to the homeowner;

(D) shall notify each customer that a planned replacement of any publicly owned portion of a lead service line that is funded by a grant made under this subsection will not be carried out

unless the customer agrees to the simultaneous replacement of the privately owned portion of the lead service line;

(E) shall demonstrate that the eligible entity has considered feasible alternatives for reducing the concentration of lead in drinking water, such as corrosion control; and

(F) shall notify the State of any planned replacement of lead service lines under this program and coordinate, where practicable, with other relevant infrastructure projects.

(c) Limitation on use of funds

Not more than 4 percent of funds made available for grants under this section may be used to pay the administrative costs of the Administrator.

(d) Lead inventorying utilization grant pilot program

(1) Definitions

In this subsection:

(A) Eligible entity

The term "eligible entity" means a municipality that is served by a community water system or a nontransient noncommunity water system in which not less than 30 percent of the service lines are known, or suspected, to contain lead, based on available data, information, or resources, including existing lead inventorying.

(B) Pilot program

The term "pilot program" means the pilot program established under paragraph (2).

(2) Establishment

The Administrator shall establish a pilot program under which the Administrator shall provide grants to eligible entities to carry out lead reduction projects that are demonstrated to exist or are suspected to exist, based on available data, information, or resources, including existing lead inventorying of those eligible entities.

(3) Selection

(A) Application

To be eligible to receive a grant under the pilot program, an eligible entity shall submit to the Administrator an application at such time, in such manner, and containing such information as the Administrator may require.

(B) Prioritization

In selecting recipients under the pilot program, the Administrator shall give priority to—

(i) an eligible entity that meets the affordability criteria of the applicable State established under section 300j–12(d)(3) of this title; and

(ii) an eligible entity that is located in an area other than a State that has established affordability criteria under section 300j–12(d)(3) of this title.

(4) Report

Not later 2 years after the Administrator first awards a grant under the pilot program, the Administrator shall submit to the Committee on Environment and Public Works of the Senate and the Committee on Energy and Commerce of the House of Representatives a report describing—

(A) the recipients of grants under the pilot program;

(B) the existing lead inventorying that was available to recipients of grants under the pilot program; and

(C) how useful and accurate the lead inventorying described in subparagraph (B) was in locating lead service lines of the eligible entity.

(5) Authorization of appropriations

There is authorized to be appropriated to carry out the pilot program $10,000,000, to remain available until expended.

(e) Authorization of appropriations

There is authorized to be appropriated to carry out this section (except for subsection (d)) $100,000,000 for each of fiscal years 2022 through 2026.

(f) Savings clause

Nothing in this section affects whether a public water system is responsible for the replacement of a lead service line that is—

(1) subject to the control of the public water system; and

(2) located on private property.

(July 1, 1944, ch. 373, title XIV, §1459B, as added Pub. L. 114–322, title II, §2105, Dec. 16, 2016, 130 Stat. 1720; amended Pub. L. 117–58, div. E, title I, §50105, Nov. 15, 2021, 135 Stat. 1140.)

EDITORIAL NOTES

AMENDMENTS

2021—Subsec. (a)(1)(D). Pub. L. 117–58, §50105(1)(A), added subpar. (D) and struck out former subpar. (D) which read as follows: "a qualified nonprofit organization, as determined by the Administrator, servicing a public water system; and".

Subsec. (a)(2)(A)(i). Pub. L. 117–58, §50105(1)(B)(i), struck out "publicly owned" before "lead".

Subsec. (a)(2)(A)(iii). Pub. L. 117–58, §50105(1)(B)(ii), added cl. (iii) and struck out former cl. (iii) which read as follows: "providing assistance to low-income homeowners to replace lead service lines."

Subsec. (a)(3). Pub. L. 117–58, §50105(1)(C), struck out "an individual provided" before "assistance".

Subsec. (b)(5)(A). Pub. L. 117–58, §50105(2)(A)(i), substituted "to replace lead service lines, with first priority given to assisting disadvantaged communities based on the affordability criteria established by the applicable State under section 300j–12(d)(3) of this title, low-income homeowners, and landlords or property owners providing housing to low-income renters." for "to provide assistance to low-income homeowners to replace the lead service lines of such homeowners."

Subsec. (b)(5)(B). Pub. L. 117–58, §50105(2)(A)(ii), substituted "lines" for "line".

Subsec. (b)(6)(A). Pub. L. 117–58, §50105(2)(B)(i), struck out "any publicly owned portion of" before "the lead".

Subsec. (b)(6)(C). Pub. L. 117–58, §50105(2)(B)(ii), substituted "shall, in the case of a low-income homeowner, and may, for other homeowners, offer to replace the privately owned portion of the lead service line at no cost to the homeowner;" for "may, in the case of a low-income homeowner, offer to replace the privately owned portion of the lead service line at a cost that is equal to the difference between—

"(i) the cost of replacement; and

"(ii) the amount of assistance available to the low-income homeowner under paragraph (5);".

Subsec. (b)(6)(E). Pub. L. 117–58, §50105(2)(B)(iv), substituted "feasible alternatives for reducing the concentration of lead in drinking water, such as corrosion control; and" for "other options for reducing the concentration of lead in its drinking water, including an evaluation of options for corrosion control."

Subsec. (b)(6)(F). Pub. L. 117–58, §50105(2)(B)(iii), (v), added subpar. (F).

Subsec. (d). Pub. L. 117–58, §50105(4), (5), added subsec. (d) and redesignated former subsec. (d) as (e).

Pub. L. 117–58, §50105(3), substituted "this section (except for subsection (d)) $100,000,000 for each of fiscal years 2022 through 2026" for "this section $60,000,000 for each of fiscal years 2017 through 2021".

Subsecs. (e), (f). Pub. L. 117–58, §50105(4), redesignated subsecs. (d) and (e) as (e) and (f), respectively.

§300j–19c. Study on intractable water systems

(a) Definition of intractable water system

In this section, the term "intractable water system" means a community water system or a noncommunity water system—

(1) that serves fewer than 1,000 individuals;

(2) the owner or operator of which—

(A) is unable or unwilling to provide safe and adequate service to those individuals;

(B) has abandoned or effectively abandoned the community water system or noncommunity

water system, as applicable;

(C) has defaulted on a financial obligation relating to the community water system or noncommunity water system, as applicable; or

(D) fails to maintain the facilities of the community water system or noncommunity water system, as applicable, in a manner so as to prevent a potential public health hazard; and

(3) that is, as of October 23, 2018—

(A) in significant noncompliance with this chapter or any regulation promulgated pursuant to this chapter; or

(B) listed as having a history of significant noncompliance with this subchapter pursuant to section 300g–9(b)(1) of this title.

(b) Study required

(1) In general

Not later than 2 years after October 23, 2018, the Administrator, in consultation with the Secretary of Agriculture and the Secretary of Health and Human Services, shall complete a study that—

(A) identifies intractable water systems; and

(B) describes barriers to delivery of potable water to individuals served by an intractable water system.

(2) Report to Congress

Not later than 2 years after October 23, 2018, the Administrator shall submit to Congress a report describing findings and recommendations based on the study under this subsection.

(July 1, 1944, ch. 373, title XIV, §1459C, as added Pub. L. 115–270, title II, §2003, Oct. 23, 2018, 132 Stat. 3841.)

§300j–19d. Review of technologies

(a) Review

The Administrator, after consultation with appropriate departments and agencies of the Federal Government and with State and local governments, shall review (or enter into contracts or cooperative agreements to provide for a review of) existing and potential methods, means, equipment, and technologies (including review of cost, availability, and efficacy of such methods, means, equipment, and technologies) that—

(1) ensure the physical integrity of community water systems;

(2) prevent, detect, and respond to any contaminant for which a national primary drinking water regulation has been promulgated in community water systems and source water for community water systems;

(3) allow for use of alternate drinking water supplies from nontraditional sources; and

(4) facilitate source water assessment and protection.

(b) Inclusions

The review under subsection (a) shall include review of methods, means, equipment, and technologies—

(1) that are used for corrosion protection, metering, leak detection, or protection against water loss;

(2) that are intelligent systems, including hardware, software, or other technology, used to assist in protection and detection described in paragraph (1);

(3) that are point-of-use devices or point-of-entry devices;

(4) that are physical or electronic systems that monitor, or assist in monitoring, contaminants in drinking water in real-time; and

(5) that allow for the use of nontraditional sources for drinking water, including physical

separation and chemical and biological transformation technologies.

(c) Availability

The Administrator shall make the results of the review under subsection (a) available to the public.

(d) Authorization of appropriations

There is authorized to be appropriated to the Administrator to carry out this section $10,000,000 for fiscal year 2019, which shall remain available until expended.

(July 1, 1944, ch. 373, title XIV, §1459D, as added Pub. L. 115–270, title II, §2017, Oct. 23, 2018, 132 Stat. 3856.)

§300j–19e. Water infrastructure and workforce investment

(a) Definition of public works department or agency

In this section, the term "public works department or agency" means a political subdivision of a local, county, or regional government that designs, builds, operates, and maintains water infrastructure, sewage and refuse disposal systems, and other public water systems and facilities.

(b) Sense of Congress

It is the sense of Congress that—

(1) water and wastewater utilities provide a unique opportunity for access to stable, high-quality careers;

(2) as water and wastewater utilities make critical investments in infrastructure, water and wastewater utilities can invest in the development of local workers and local small businesses to strengthen communities and ensure a strong pipeline of skilled and diverse workers for today and tomorrow; and

(3) to further the goal of ensuring a strong pipeline of skilled and diverse workers in the water and wastewater utilities sector, Congress urges—

(A) increased collaboration among Federal, State, Tribal, and local governments; and

(B) institutions of higher education, apprentice programs, high schools, and other community-based organizations and public works departments or agencies to align water and wastewater utility workforce recruitment efforts, training programs, retention efforts, and community resources with water and wastewater utilities—

(i) to accelerate career pipelines;

(ii) to ensure the sustainability of the water and wastewater utility workforce; and

(iii) to provide access to workforce opportunities.

(c) Innovative water infrastructure workforce development program

(1) Grants authorized

The Administrator of the Environmental Protection Agency (referred to in this section as the "Administrator"), in consultation with the Secretary of Agriculture, shall establish a competitive grant program to assist the development and utilization of innovative activities relating to workforce development and career opportunities in the water utility sector, which may include—

(A) expanding the use and availability of activities and resources that relate to the recruitment, including the promotion of diversity within that recruitment, of individuals to careers in the water and wastewater utility sector;

(B) expanding the availability of training opportunities for—

(i) individuals entering into the water and wastewater utility sector; and

(ii) individuals seeking to advance careers within the water and wastewater utility sector; and

(C) expanding the use and availability of activities and strategies, including the development of innovative activities and strategies, that relate to the maintenance and retention of a

sustainable workforce in the water and wastewater utility sector.

(2) Selection of grant recipients

In awarding grants under paragraph (1), the Administrator shall, to the extent practicable, select nonprofit professional or service organizations, labor organizations, community colleges, institutions of higher education, or other training and educational institutions, or public works departments and agencies—

(A) that have qualifications and experience—

(i) in the development of educational or recruitment materials and activities, including those materials and activities that specifically promote diversity within recruitment, for the water and wastewater utility workforce;

(ii) in the development of training programs and curricula relevant to workforce needs of water utilities; or

(iii) developing activities and strategies that relate to the maintenance and retention of a sustainable workforce in the water and wastewater utility sector; and

(B) that will address the human resources and workforce needs of water utilities that—

(i) are geographically diverse;

(ii) are of varying sizes; and

(iii) serve urban, suburban, and rural populations.

(3) Use of funds

Grants awarded under paragraph (1) may be used for activities such as—

(A) targeted internship, apprenticeship, pre-apprenticeship, and post-secondary bridge programs for skilled water utility trades that provide—

(i) on-the-job training;

(ii) skills development;

(iii) test preparation for skilled trade apprenticeships;

(iv) advance training in the water utility sector relating to construction, utility operations, treatment and distribution, green infrastructure, customer service, maintenance, and engineering; or

(v) other support services to facilitate post-secondary success;

(B) education programs designed for elementary, secondary, and higher education students that—

(i) inform people about the role of water and wastewater utilities in their communities;

(ii) increase the awareness of career opportunities and exposure of students to water utility careers through various work-based learning opportunities inside and outside the classroom; and

(iii) connect students to career pathways related to water utilities;

(C) regional industry and workforce development collaborations to address water utility employment needs and coordinate candidate development, particularly in areas of high unemployment or for water utilities with a high proportion of retirement eligible employees;

(D) integrated learning laboratories in secondary educational institutions that provide students with—

(i) hands-on, contextualized learning opportunities;

(ii) dual enrollment credit for post-secondary education and training or certification programs; and

(iii) direct connection to industry employers; and

(E) leadership development, occupational training, mentoring, or cross-training programs that are designed to retain incumbent water and wastewater utility workforce workers by ensuring that those workers are prepared for higher level supervisory or management-level positions.

(4) Working group; report

(A) In general

The Administrator shall establish and coordinate a Federal interagency working group to address recruitment, training, and retention challenges in the water and wastewater utility workforce, which shall include representatives from—

(i) the Department of Education;
(ii) the Department of Labor;
(iii) the Department of Agriculture;
(iv) the Department of Veterans Affairs; and
(v) other Federal agencies, as determined to be appropriate by the Administrator.

(B) Report

Not later than 2 years after November 15, 2021, the Administrator, in coordination with the working group established under subparagraph (A), shall submit to Congress a report describing potential solutions to recruitment, training, and retention challenges in the water and wastewater utility workforce.

(C) Consultation

In carrying out the duties of the working group established under subparagraph (A), the working group shall consult with State operator certification programs.

(5) Authorization of appropriations

There is authorized to be appropriated to carry out this subsection $5,000,000 for each of fiscal years 2022 through 2026.

(Pub. L. 115–270, title IV, §4304, Oct. 23, 2018, 132 Stat. 3882; Pub. L. 117–58, div. E, title II, §50211, Nov. 15, 2021, 135 Stat. 1170.)

EDITORIAL NOTES

CODIFICATION

Section enacted as part of the America's Water Infrastructure Act of 2018, and not as part of the Public Health Service Act which comprises this chapter.

AMENDMENTS

2021—Subsec. (a). Pub. L. 117–58, §50211(4), added subsec. (a). Former subsec. (a) redesignated (b).

Subsec. (a)(3)(A). Pub. L. 117–58, §50211(1)(A), inserted "Tribal," after "State,".

Subsec. (a)(3)(B). Pub. L. 117–58, §50211(1)(B), substituted "community-based organizations and public works departments or agencies to align water and wastewater utility workforce recruitment efforts, training programs, retention efforts, and community resources with water and wastewater utilities—" and cls. (i) to (iii) for "community-based organizations to align workforce training programs and community resources with water and wastewater utilities to accelerate career pipelines and provide access to workforce opportunities."

Subsec. (b). Pub. L. 117–58, §50211(3), redesignated subsec. (a) as (b). Former subsec. (b) redesignated (c).

Subsec. (b)(1). Pub. L. 117–58, §50211(2)(A), added subpars. (A) to (C), struck out former subpar. (A) designation before "to assist", substituted "program" for "program—" and ", which may include—" for "; and" in introductory provsions, and struck out former subpar. (B) which read as follows: "to expand public awareness about water utilities and connect individuals to careers in the water utility sector."

Subsec. (b)(2). Pub. L. 117–58, §50211(2)(B)(i), substituted "institutions, or public works departments and agencies—" for "institutions—" in introductory provisions.

Subsec. (b)(2)(A). Pub. L. 117–58, §50211(2)(B)(ii), added cls. (i) and (iii), redesignated former cl. (i) as (ii), and struck out former cls. (ii) and (iii) which read as follows:

"(ii) working in cooperation with water utilities; or

"(iii) developing public education materials appropriate for communicating with groups of different ages and educational backgrounds; and".

Subsec. (b)(3)(D)(ii). Pub. L. 117–58, §50211(2)(C)(i), inserted "or certification" after "training".

Subsec. (b)(3)(E). Pub. L. 117–58, §50211(2)(C)(ii), substituted "are designed to retain incumbent water

and wastewater utility workforce workers by ensuring that those workers" for "ensure that incumbent water and waste water utilities workers".

Subsec. (b)(4), (5). Pub. L. 117–58, §50211(2)(D), added pars. (4) and (5) and struck out former par. (4). Prior to amendment, text of par. (4) read as follows: "There is authorized to be appropriated to carry out this subsection $1,000,000 for each of fiscal years 2019 and 2020."

Subsec. (c). Pub. L. 117–58, §50211(3), redesignated subsec. (b) as (c).

§300j–19f. Operational sustainability of small public water systems

(a) Definitions

In this section:

(1) Eligible entity

The term "eligible entity" means—

(A) a State;

(B) a unit of local government;

(C) a public corporation established by a unit of local government to provide water service;

(D) a nonprofit corporation, public trust, or cooperative association that owns or operates a public water system;

(E) an Indian Tribe that owns or operates a public water system;

(F) a nonprofit organization that provides technical assistance to public water systems; and

(G) a Tribal consortium.

(2) Operational sustainability

The term "operational sustainability" means the ability to improve the operation of a small system through the identification and prevention of potable water loss due to leaks, breaks, and other metering or infrastructure failures.

(3) Program

The term "program" means the grant program established under subsection (b).

(4) Small system

The term "small system", for the purposes of this section, means a public water system that—

(A) serves fewer than 10,000 people; and

(B) is owned or operated by—

(i) a unit of local government;

(ii) a public corporation;

(iii) a nonprofit corporation;

(iv) a public trust;

(v) a cooperative association; or

(vi) an Indian Tribe.

(b) Establishment

Subject to the availability of appropriations, the Administrator shall establish a program to award grants to eligible entities for the purpose of improving the operational sustainability of 1 or more small systems.

(c) Applications

To be eligible to receive a grant under the program, an eligible entity shall submit to the Administrator an application at such time, in such manner, and containing such information as the Administrator may require, including—

(1) a proposal of the project to be carried out using grant funds under the program;

(2) documentation provided by the eligible entity describing the deficiencies or suspected deficiencies in operational sustainability of 1 or more small systems that are to be addressed through the proposed project;

(3) a description of how the proposed project will improve the operational sustainability of 1 or more small systems;

(4) a description of how the improvements described in paragraph (3) will be maintained beyond the life of the proposed project, including a plan to maintain and update any asset data collected as a result of the proposed project; and

(5) any additional information the Administrator may require.

(d) Additional required information

Before the award of funds for a grant under the program to a grant recipient, the grant recipient shall submit to the Administrator—

(1) if the grant recipient is located in a State that has established a State drinking water treatment revolving loan fund under section 300j–12 of this title, a copy of a written agreement between the grant recipient and the State in which the grant recipient agrees to provide a copy of any data collected under the proposed project to the State agency administering the State drinking water treatment revolving loan fund (or a designee); or

(2) if the grant recipient is located in an area other than a State that has established a State drinking water treatment revolving loan fund under section 300j–12 of this title, a copy of a written agreement between the grant recipient and the Administrator in which the eligible entity agrees to provide a copy of any data collected under the proposed project to the Administrator (or a designee).

(e) Use of funds

An eligible entity that receives a grant under the program shall use the grant funds to carry out projects that improve the operational sustainability of 1 or more small systems through—

(1) the development of a detailed asset inventory, which may include drinking water sources, wells, storage, valves, treatment systems, distribution lines, hydrants, pumps, controls, and other essential infrastructure;

(2) the development of an infrastructure asset map, including a map that uses technology such as—

(A) geographic information system software; and

(B) global positioning system software;

(3) the deployment of leak detection technology;

(4) the deployment of metering technology;

(5) training in asset management strategies, techniques, and technologies for appropriate staff employed by—

(A) the eligible entity; or

(B) the small systems for which the grant was received;

(6) the deployment of strategies, techniques, and technologies to enhance the operational sustainability and effective use of water resources through water reuse; and

(7) the development or deployment of other strategies, techniques, or technologies that the Administrator may determine to be appropriate under the program.

(f) Cost share

(1) In general

Subject to paragraph (2), the Federal share of the cost of a project carried out using a grant under the program shall be 90 percent of the total cost of the project.

(2) Waiver

The Administrator may increase the Federal share under paragraph (1) to 100 percent.

(g) Report

Not later than 2 years after November 15, 2021, the Administrator shall submit to Congress a report that describes the implementation of the program, which shall include a description of the use

and deployment of amounts made available under the program.

(h) Authorization of appropriations

There is authorized to be appropriated to carry out this section $50,000,000 for each of fiscal years 2022 through 2026.

(July 1, 1944, ch. 373, title XIV, §1459E, as added Pub. L. 117–58, div. E, title I, §50106, Nov. 15, 2021, 135 Stat. 1142.)

§300j–19g. Midsize and Large Drinking Water System Infrastructure Resilience and Sustainability Program

(a) Definitions

In this section:

(1) Eligible entity

The term "eligible entity" means a public water system that serves a community with a population of 10,000 or more.

(2) Natural hazard; resilience

The terms "resilience" and "natural hazard" have the meanings given those terms in section 300i–2(h) of this title.

(3) Resilience and sustainability program

The term "resilience and sustainability program" means the Midsize and Large Drinking Water System Infrastructure Resilience and Sustainability Program established under subsection (b).

(b) Establishment

The Administrator shall establish and carry out a program, to be known as the "Midsize and Large Drinking Water System Infrastructure Resilience and Sustainability Program", under which the Administrator, subject to the availability of appropriations for the resilience and sustainability program, shall award grants to eligible entities for the purpose of—

(1) increasing resilience to natural hazards and extreme weather events; and

(2) reducing cybersecurity vulnerabilities.

(c) Use of funds

An eligible entity may only use grant funds received under the resilience and sustainability program to assist in the planning, design, construction, implementation, operation, or maintenance of a program or project that increases resilience to natural hazards and extreme weather events, or reduces cybersecurity vulnerabilities, through—

(1) the conservation of water or the enhancement of water-use efficiency;

(2) the modification or relocation of existing drinking water system infrastructure made, or that is at risk of being, significantly impaired by natural hazards or extreme weather events, including risks to drinking water from flooding;

(3) the design or construction of new or modified desalination facilities to serve existing communities;

(4) the enhancement of water supply through the use of watershed management and source water protection;

(5) the enhancement of energy efficiency or the use and generation of renewable energy in the conveyance or treatment of drinking water;

(6) the development and implementation of measures—

(A) to increase the resilience of the eligible entity to natural hazards and extreme weather events; or

(B) to reduce cybersecurity vulnerabilities;

(7) the conservation of water or the enhancement of a water supply through the implementation of water reuse measures; or

(8) the formation of regional water partnerships to collaboratively address documented water shortages.

(d) Application

To seek a grant under the resilience and sustainability program, an eligible entity shall submit to the Administrator an application at such time, in such manner, and containing such information as the Administrator may require, including—

(1) a proposal of the program or project to be planned, designed, constructed, implemented, operated, or maintained by the eligible entity;

(2) an identification of the natural hazard risks, extreme weather events, or potential cybersecurity vulnerabilities, as applicable, to be addressed by the proposed program or project;

(3) documentation prepared by a Federal, State, regional, or local government agency of the natural hazard risk, potential cybersecurity vulnerability, or risk for extreme weather events to the area where the proposed program or project is to be located;

(4) a description of any recent natural hazards, cybersecurity events, or extreme weather events that have affected the community water system of the eligible entity;

(5) a description of how the proposed program or project would improve the performance of the community water system of the eligible entity under the anticipated natural hazards, cybersecurity vulnerabilities, or extreme weather events; and

(6) an explanation of how the proposed program or project is expected—

(A) to enhance the resilience of the community water system of the eligible entity to the anticipated natural hazards or extreme weather events; or

(B) to reduce cybersecurity vulnerabilities.

(e) Report

Not later than 2 years after November 15, 2021, the Administrator shall submit to Congress a report that describes the implementation of the resilience and sustainability program, which shall include a description of the use and deployment of amounts made available to carry out the resilience and sustainability program.

(f) Authorization of appropriations

(1) In general

There is authorized to be appropriated to carry out the resilience and sustainability program $50,000,000 for each of fiscal years 2022 through 2026.

(2) Use of funds

Of the amounts made available under paragraph (1) for grants to eligible entities under the resilience and sustainability program—

(A) 50 percent shall be used to provide grants to eligible entities that serve a population of—

(i) equal to or greater than 10,000; and

(ii) fewer than 100,000; and

(B) 50 percent shall be used to provide grants to eligible entities that serve a population equal to or greater than 100,000.

(3) Administrative costs

Of the amounts made available under paragraph (1), not more than 2 percent may be used by the Administrator for the administrative costs of carrying out the resilience and sustainability program.

(July 1, 1944, ch. 373, title XIV, §1459F, as added Pub. L. 117–58, div. E, title I, §50107, Nov. 15, 2021, 135 Stat. 1144.)

§300j–19h. Advanced drinking water technologies

(a) Study

(1) In general

Subject to the availability of appropriations, not later than 1 year after November 15, 2021, the Administrator shall carry out a study that examines the state of existing and potential future technology, including technology that could address cybersecurity vulnerabilities, that enhances or could enhance the treatment, monitoring, affordability, efficiency, and safety of drinking water provided by a public water system.

(2) Report

The Administrator shall submit to the Committee on Environment and Public Works of the Senate and the Committee on Energy and Commerce of the House of Representatives a report that describes the results of the study under paragraph (1).

(b) Advanced drinking water technology grant program

(1) Definitions

In this subsection:

(A) Eligible entity

The term "eligible entity" means the owner or operator of a public water system that—

(i) serves—

(I) a population of not more than 100,000 people; or

(II) a community described in section 300j–19a(c)(2) of this title;

(ii) has plans to identify or has identified opportunities in the operations of the public water system to employ new, existing, or emerging, yet proven, technologies, including technology that could address cybersecurity vulnerabilities, as determined by the Administrator, that enhance treatment, monitoring, affordability, efficiency, or safety of the drinking water provided by the public water system, including technologies not identified in the study conducted under subsection (a)(1); and

(iii) has expressed an interest in the opportunities in the operation of the public water system to employ new, existing, or emerging, yet proven, technologies, including technology that could address cybersecurity vulnerabilities, as determined by the Administrator, that enhance treatment, monitoring, affordability, efficiency, or safety of the drinking water provided by the public water system, including technologies not identified in the study conducted under subsection (a)(1).

(B) Program

The term "program" means the competitive grant program established under paragraph (2).

(2) Establishment

The Administrator shall establish a competitive grant program under which the Administrator shall award grants to eligible entities for the purpose of identifying, deploying, or identifying and deploying technologies described in paragraph (1)(A)(ii).

(3) Requirements

(A) Applications

To be eligible to receive a grant under the program, an eligible entity shall submit to the Administrator an application at such time, in such manner, and containing such information as the Administrator may require.

(B) Federal share

(i) In general

Subject to clause (ii), the Federal share of the cost of a project carried out using a grant

under the program shall not exceed 90 percent of the total cost of the project.

(ii) Waiver

The Administrator may increase the Federal share under clause (i) to 100 percent if the Administrator determines that an eligible entity is unable to pay, or would experience significant financial hardship if required to pay, the non-Federal share.

(4) Report

Not later than 2 years after the date on which the Administrator first awards a grant under the program, and annually thereafter, the Administrator shall submit to Congress a report describing—

(A) each recipient of a grant under the program during the previous 1-year period; and

(B) a summary of the activities carried out using grants awarded under the program.

(5) Funding

(A) Authorization of appropriations

There is authorized to be appropriated to carry out the program $10,000,000 for each of fiscal years 2022 through 2026, to remain available until expended.

(B) Administrative costs

Not more than 2 percent of the amount made available for a fiscal year under subparagraph (A) to carry out the program may be used by the Administrator for the administrative costs of carrying out the program.

(July 1, 1944, ch. 373, title XIV, §1459G, as added Pub. L. 117–58, div. E, title I, §50112, Nov. 15, 2021, 135 Stat. 1154.)

PART F—ADDITIONAL REQUIREMENTS TO REGULATE SAFETY OF DRINKING WATER

§300j–21. Definitions

As used in this part—

(1) Drinking water cooler

The term "drinking water cooler" means any mechanical device affixed to drinking water supply plumbing which actively cools water for human consumption.

(2) Lead free

The term "lead free" means, with respect to a drinking water cooler, that each part or component of the cooler which may come in contact with drinking water contains not more than 8 percent lead, except that no drinking water cooler which contains any solder, flux, or storage tank interior surface which may come in contact with drinking water shall be considered lead free if the solder, flux, or storage tank interior surface contains more than 0.2 percent lead. The Administrator may establish more stringent requirements for treating any part or component of a drinking water cooler as lead free for purposes of this part whenever he determines that any such part may constitute an important source of lead in drinking water.

(3) Local educational agency

The term "local educational agency" means—

(A) any local educational agency as defined in section 7801 of title 20,

(B) the owner of any private, nonprofit elementary or secondary school building, and

(C) the governing authority of any school operating under the defense dependent's education system provided for under the Defense Dependent's Education Act of 1978 (20 U.S.C. 921 and following).

(4) Repair

The term "repair" means, with respect to a drinking water cooler, to take such corrective action as is necessary to ensure that water cooler is lead free.

(5) Replacement

The term "replacement", when used with respect to a drinking water cooler or drinking water fountain, means the permanent removal of the water cooler or drinking water fountain and the installation of a lead free water cooler or drinking water fountain.

(6) School

The term "school" means any elementary school or secondary school as defined in section 7801 of title 20 and any kindergarten or day care facility.

(7) Lead-lined tank

The term "lead-lined tank" means a water reservoir container in a drinking water cooler which container is constructed of lead or which has an interior surface which is not lead free.

(July 1, 1944, ch. 373, title XIV, §1461, as added Pub. L. 100–572, §2(a), Oct. 31, 1988, 102 Stat. 2884; amended Pub. L. 103–382, title III, §391(p), Oct. 20, 1994, 108 Stat. 4024; Pub. L. 104–182, title V, §501(f)(7), Aug. 6, 1996, 110 Stat. 1692; Pub. L. 107–110, title X, §1076(x), Jan. 8, 2002, 115 Stat. 2093; Pub. L. 114–95, title IX, §9215(ooo), Dec. 10, 2015, 129 Stat. 2188; Pub. L. 115–270, title II, §2006(b)(2), Oct. 23, 2018, 132 Stat. 3844.)

EDITORIAL NOTES

REFERENCES IN TEXT

The Defense Dependent's Education Act of 1978, referred to in par. (3)(C), probably means the Defense Dependents' Education Act of 1978, title XIV of Pub. L. 95–561, Nov. 1, 1978, 92 Stat. 2365, which is classified principally to chapter 25A (§921 et seq.) of Title 20, Education. For complete classification of this Act to the Code, see Short Title note set out under section 921 of Title 20 and Tables.

AMENDMENTS

2018—Par. (5). Pub. L. 115–270 inserted "or drinking water fountain" after "water cooler" wherever appearing.

2015—Pars. (3)(A), (6). Pub. L. 114–95 made technical amendment to references in original act which appear in text as references to section 7801 of title 20.

2002—Pars. (3)(A), (6). Pub. L. 107–110 substituted "section 7801 of title 20" for "section 8801 of title 20".

1996—Pub. L. 104–182 made technical amendment to section catchline and first word of text.

1994—Par. (3)(A). Pub. L. 103–382, §391(p)(1), substituted "section 8801 of title 20" for "section 198 of the Elementary and Secondary Education Act of 1965 (20 U.S.C. 3381)".

Par. (6). Pub. L. 103–382, §391(p)(2), substituted "section 8801 of title 20" for "section 198 of the Elementary and Secondary Education Act of 1965 (20 U.S.C. 2854)".

STATUTORY NOTES AND RELATED SUBSIDIARIES

EFFECTIVE DATE OF 2015 AMENDMENT

Amendment by Pub. L. 114–95 effective Dec. 10, 2015, except with respect to certain noncompetitive programs and competitive programs, see section 5 of Pub. L. 114–95, set out as a note under section 6301 of Title 20, Education.

EFFECTIVE DATE OF 2002 AMENDMENT

Amendment by Pub. L. 107–110 effective Jan. 8, 2002, except with respect to certain noncompetitive programs and competitive programs, see section 5 of Pub. L. 107–110, set out as an Effective Date note under section 6301 of Title 20, Education.

§300j–22. Recall of drinking water coolers with lead-lined tanks

For purposes of the Consumer Product Safety Act [15 U.S.C. 2051 et seq.], all drinking water coolers identified by the Administrator on the list under section 300j–23 of this title as having a lead-lined tank shall be considered to be imminently hazardous consumer products within the meaning of section 12 of such Act (15 U.S.C. 2061). After notice and opportunity for comment, including a public hearing, the Consumer Product Safety Commission shall issue an order requiring the manufacturers and importers of such coolers to repair, replace, or recall and provide a refund for such coolers within 1 year after October 31, 1988. For purposes of enforcement, such order shall be treated as an order under section 15(d) of that Act (15 U.S.C. 2064(d)).

(July 1, 1944, ch. 373, title XIV, §1462, as added Pub. L. 100–572, §2(a), Oct. 31, 1988, 102 Stat. 2885; amended Pub. L. 104–182, title V, §501(f)(8), Aug. 6, 1996, 110 Stat. 1692.)

EDITORIAL NOTES

REFERENCES IN TEXT

The Consumer Product Safety Act, referred to in text, is Pub. L. 92–573, Oct. 27, 1972, 86 Stat. 1207, which is classified generally to chapter 47 (§2051 et seq.) of Title 15, Commerce and Trade. For complete classification of this Act to the Code, see Short Title note set out under section 2051 of Title 15 and Tables.

AMENDMENTS

1996—Pub. L. 104–182 made technical amendment to section catchline and first word of text.

§300j–23. Drinking water coolers containing lead

(a) Publication of lists

The Administrator shall, after notice and opportunity for public comment, identify each brand and model of drinking water cooler which is not lead free, including each brand and model of drinking water cooler which has a lead-lined tank. For purposes of identifying the brand and model of drinking water coolers under this subsection, the Administrator shall use the best information available to the Environmental Protection Agency. Within 100 days after October 31, 1988, the Administrator shall publish a list of each brand and model of drinking water cooler identified under this subsection. Such list shall separately identify each brand and model of cooler which has a lead-lined tank. The Administrator shall continue to gather information regarding lead in drinking water coolers and shall revise and republish the list from time to time as may be appropriate as new information or analysis becomes available regarding lead contamination in drinking water coolers.

(b) Prohibition

No person may sell in interstate commerce, or manufacture for sale in interstate commerce, any drinking water cooler listed under subsection (a) or any other drinking water cooler which is not lead free, including a lead-lined drinking water cooler.

(c) Criminal penalty

Any person who knowingly violates the prohibition contained in subsection (b) shall be imprisoned for not more than 5 years, or fined in accordance with title 18, or both.

(d) Civil penalty

The Administrator may bring a civil action in the appropriate United States District Court (as determined under the provisions of title 28) to impose a civil penalty on any person who violates subsection (b). In any such action the court may impose on such person a civil penalty of not more than $5,000 ($50,000 in the case of a second or subsequent violation).

(July 1, 1944, ch. 373, title XIV, §1463, as added Pub. L. 100–572, §2(a), Oct. 31, 1988, 102 Stat. 2885; amended Pub. L. 104–182, title V, §501(f)(9), Aug. 6, 1996, 110 Stat. 1692.)

EDITORIAL NOTES

AMENDMENTS

1996—Pub. L. 104–182 made technical amendment to section catchline and subsec. (a) designation.

§300j–24. Lead contamination in school drinking water

(a) Distribution of drinking water cooler list

Within 100 days after October 31, 1988, the Administrator shall distribute to the States a list of each brand and model of drinking water cooler identified and listed by the Administrator under section 300j–23(a) of this title.

(b) Guidance document and testing protocol

The Administrator shall publish a guidance document and a testing protocol to assist public water systems and schools in determining the source and degree of lead contamination in school drinking water supplies and in remedying such contamination. The guidance document shall include guidelines for sample preservation. The guidance document shall also include guidance to assist States, schools, public water systems, and the general public in ascertaining the levels of lead contamination in drinking water coolers and in taking appropriate action to reduce or eliminate such contamination. The guidance document shall contain a testing protocol for the identification of drinking water coolers which contribute to lead contamination in drinking water. Such document and protocol may be revised, republished and redistributed as the Administrator deems necessary. The Administrator shall distribute the guidance document and testing protocol to the States within 100 days after October 31, 1988.

(c) Dissemination to schools, etc.

Each State shall provide for the dissemination to local educational agencies, private nonprofit elementary or secondary schools and to day care centers of the guidance document and testing protocol published under subsection (b), together with the list of drinking water coolers published under section 300j–23(a) of this title.

(d) Voluntary school and child care program lead testing and reduction grant program

(1) Definitions

In this subsection:

(A) Child care program

The term "child care program" has the meaning given the term "early childhood education program" in section 1003(8) of title 20.

(B) Local educational agency

The term "local educational agency" means—

(i) a local educational agency (as defined in section 7801 of title 20);

(ii) a tribal education agency (as defined in section 5502 of title 20); and

(iii) a person that owns or operates a child care program facility.

(2) Establishment

(A) In general

Not later than 180 days after December 16, 2016, the Administrator shall establish a voluntary school and child care program lead testing, compliance monitoring, and lead reduction grant program to make grants available to—

(i) States to assist local educational agencies, public water systems that serve schools and child care programs under the jurisdiction of those local educational agencies, and qualified

nonprofit organizations in voluntary testing or compliance monitoring for and remediation of lead contamination in drinking water at schools and child care programs under the jurisdiction of those local educational agencies; and

(ii) tribal consortia to assist tribal education agencies (as defined in section 5502 of title 20), public water systems that serve schools and child care programs under the jurisdiction of those tribal education agencies, and qualified nonprofit organizations in voluntary testing or compliance monitoring for and remediation of lead contamination in drinking water at schools and child care programs under the jurisdiction of those tribal education agencies.

(B) Direct grants to local educational agencies

The Administrator may make a grant for the voluntary testing or compliance monitoring for or remediation of lead contamination described in subparagraph (A) directly available to—

(i) any local educational agency described in clause (i) or (iii) of paragraph (1)(B) located in a State that does not participate in the voluntary grant program established under subparagraph (A);

(ii) any local educational agency described in clause (ii) of paragraph (1)(B);

(iii) any public water system that is located in a State that does not participate in the voluntary grant program established under subparagraph (A) that—

(I) assists schools or child care programs in lead testing;

(II) assists schools or child care programs with compliance monitoring;

(III) assists schools with carrying out projects to remediate lead contamination in drinking water; or

(IV) provides technical assistance to schools or child care programs in carrying out lead testing; or

(iv) a qualified nonprofit organization, as determined by the Administrator.

(C) Technical assistance

In carrying out the grant program under subparagraph (A), beginning not later than 1 year after October 23, 2018, the Administrator shall provide technical assistance to recipients of grants under this subsection—

(i) to assist in identifying the source of lead contamination in drinking water at schools and child care programs under the jurisdiction of the grant recipient;

(ii) to assist in identifying and applying for other Federal and State grant programs that may assist the grant recipient in eliminating lead contamination described in clause (i);

(iii) to provide information on other financing options in eliminating lead contamination described in clause (i); and

(iv) to connect grant recipients with nonprofit and other organizations that may be able to assist with the elimination of lead contamination described in clause (i).

(3) Application

To be eligible to receive a grant under this subsection, a State, local educational agency, public water system, tribal consortium, or qualified nonprofit organization shall submit to the Administrator an application at such time, in such manner, and containing such information as the Administrator may require.

(4) Priority

In making grants under this subsection, the Administrator shall give priority to States, local educational agencies, public water systems, tribal consortia, and qualified nonprofit organizations that will assist in voluntary testing for or the remediation of lead contamination in drinking water at schools and child care programs that are in low-income areas.

(5) Limitation on use of funds

Not more than 4 percent of grant funds accepted by a State, local educational agency, public water system, tribal consortium, or qualified nonprofit organization for a fiscal year under this

subsection shall be used to pay the administrative costs of carrying out this subsection.

(6) Guidance; public availability

As a condition of receiving a grant under this subsection, the recipient State, local educational agency, public water system, tribal consortium, or qualified nonprofit organization shall ensure that each local educational agency, public water system, tribal consortium, or qualified nonprofit organization to which grant funds are distributed shall—

(A) expend grant funds in accordance with—

(i) the guidance of the Environmental Protection Agency entitled "3Ts for Reducing Lead in Drinking Water in Schools: Revised Technical Guidance" and dated October 2006 (or any successor guidance); or

(ii) applicable State or tribal regulations or guidance regarding voluntary testing or compliance monitoring for and remediation of lead contamination in drinking water in schools and child care programs that are not less stringent than the guidance referred to in clause (i); and

(B)(i) make available, if applicable, in the administrative offices and, to the extent practicable, on the Internet website of the applicable local educational agency for inspection by the public (including teachers, other school personnel, and parents) a copy of the results of any voluntary testing for lead contamination in school and child care program drinking water carried out using grant funds under this subsection; and

(ii) notify parent, teacher, and employee organizations of the availability of the results described in clause (i).

(7) Maintenance of effort

If resources are available to a State, local educational agency, public water system, tribal consortium, or qualified nonprofit organization from any other Federal agency, a State, or a private foundation for testing or compliance monitoring for or remediation of lead contamination in drinking water, the State, local educational agency, public water system, tribal consortium, or qualified nonprofit organization shall demonstrate that the funds provided under this subsection will not displace those resources.

(8) Authorization of appropriations

There are authorized to be appropriated to carry out this subsection—

(A) $30,000,000 for fiscal year 2022;

(B) $35,000,000 for fiscal year 2023;

(C) $40,000,000 for fiscal year 2024;

(D) $45,000,000 for fiscal year 2025; and

(E) $50,000,000 for fiscal year 2026.

(July 1, 1944, ch. 373, title XIV, §1464, as added Pub. L. 100–572, §2(a), Oct. 31, 1988, 102 Stat. 2886; amended Pub. L. 104–182, title V, §501(f)(10), Aug. 6, 1996, 110 Stat. 1692; Pub. L. 114–322, title II, §2107(a), Dec. 16, 2016, 130 Stat. 1727; Pub. L. 115–270, title II, §2006(a), Oct. 23, 2018, 132 Stat. 3843; Pub. L. 117–58, div. E, title I, §50110, Nov. 15, 2021, 135 Stat. 1150.)

EDITORIAL NOTES

AMENDMENTS

2021—Subsec. (b). Pub. L. 117–58, §50110(1), inserted "public water systems and" after "protocol to assist" and "public water systems," after "schools,".

Subsec. (d). Pub. L. 117–58, §50110(2)(A), inserted "and reduction" after "lead testing" in heading.

Subsec. (d)(2)(A). Pub. L. 117–58, §50110(2)(B)(i), substituted "the Administrator shall establish a voluntary school and child care program lead testing, compliance monitoring, and lead reduction grant program to make grants available to—" and cls. (i) and (ii) for "the Administrator shall establish a voluntary

school and child care program lead testing grant program to make grants available to States to assist local educational agencies in voluntary testing for lead contamination in drinking water at schools and child care programs under the jurisdiction of the local educational agencies."

Subsec. (d)(2)(B). Pub. L. 117–58, §50110(2)(B)(ii)(I), inserted "or compliance monitoring for or remediation of lead contamination" after "voluntary testing" in introductory provisions.

Subsec. (d)(2)(B)(iii), (iv). Pub. L. 117–58, §50110(2)(B)(ii)(II)–(IV), added cls. (iii) and (iv).

Subsec. (d)(3). Pub. L. 117–58, §50110(2)(C), substituted "State, local educational agency, public water system, tribal consortium, or qualified nonprofit organization" for "State or local educational agency".

Subsec. (d)(4). Pub. L. 117–58, §50110(2)(D), substituted "States, local educational agencies, public water systems, tribal consortia, and qualified nonprofit organizations" for "States and local educational agencies" and inserted "or the remediation of" after "testing for".

Subsec. (d)(5). Pub. L. 117–58, §50110(2)(C), substituted "State, local educational agency, public water system, tribal consortium, or qualified nonprofit organization" for "State or local educational agency".

Subsec. (d)(6). Pub. L. 117–58, §50110(2)(E)(i)(II), inserted ", public water system, tribal consortium, or qualified nonprofit organization" after "each local educational agency" in introductory provisions.

Pub. L. 117–58, §50110(2)(E)(i)(I), which directed substitution of "State, local educational agency, public water system, tribal consortium, or qualified nonprofit agency" for "State or local educational agency" in introductory provisions, could not be executed because of the intervening amendment by Pub. L. 117–58, §50110(2)(C). See Amendment note below.

Pub. L. 117–58, §50110(2)(C), substituted "State, local educational agency, public water system, tribal consortium, or qualified nonprofit organization" for "State or local educational agency" in introductory provisions.

Subsec. (d)(6)(A)(ii). Pub. L. 117–58, §50110(2)(E)(ii), inserted "or tribal" after "applicable State" and substituted "voluntary testing or compliance monitoring for and remediation of lead contamination" for "reducing lead".

Subsec. (d)(6)(B)(i). Pub. L. 117–58, §50110(2)(E)(iii), inserted "applicable" before "local educational agency".

Subsec. (d)(7). Pub. L. 117–58, §50110(2)(C), (F), substituted "State, local educational agency, public water system, tribal consortium, or qualified nonprofit organization" for "State or local educational agency" in two places and "testing or compliance monitoring for or remediation of" for "testing for".

Subsec. (d)(8). Pub. L. 117–58, §50110(2)(G), added par. (8) and struck out former par. (8). Prior to amendment, text read as follows: "There are authorized to be appropriated to carry out this subsection $20,000,000 for each of fiscal years 2017 through 2019, and $25,000,000 for each of fiscal years 2020 and 2021."

2018—Subsec. (d)(2)(C). Pub. L. 115–270, §2006(a)(1), added subpar. (C).

Subsec. (d)(4) to (7). Pub. L. 115–270, §2006(a)(2), (3), added par. (4) and redesignated former pars. (4) to (6) as (5) to (7), respectively. Former par. (7) redesignated (8).

Subsec. (d)(8). Pub. L. 115–270, §2006(a)(2), (4), redesignated par. (7) as (8) and substituted "are authorized" for "is authorized" and "2019, and $25,000,000 for each of fiscal years 2020 and 2021" for "2021".

2016—Subsec. (d). Pub. L. 114–322 added subsec. (d) and struck out former subsec. (d) which related to a remedial action program to assist local educational agencies in testing for, and remedying, lead contamination in drinking water at schools.

1996—Pub. L. 104–182 made technical amendment to section catchline and subsec. (a) designation.

§300j–25. Drinking water fountain replacement for schools

(a) Establishment

Not later than 1 year after October 23, 2018, the Administrator shall establish a grant program to provide assistance to local educational agencies for the replacement of drinking water fountains manufactured prior to 1988.

(b) Use of funds

Funds awarded under the grant program—

(1) shall be used to pay the costs of replacement of drinking water fountains in schools; and

(2) may be used to pay the costs of monitoring and reporting of lead levels in the drinking water

of schools of a local educational agency receiving such funds, as determined appropriate by the Administrator.

(c) Priority

In awarding funds under the grant program, the Administrator shall give priority to local educational agencies based on economic need.

(d) Authorization of appropriations

There are authorized to be appropriated to carry out this section $5,000,000 for each of fiscal years 2019 through 2021.

(July 1, 1944, ch. 373, title XIV, §1465, as added Pub. L. 115–270, title II, §2006(b)(1), Oct. 23, 2018, 132 Stat. 3844.)

EDITORIAL NOTES

PRIOR PROVISIONS

A prior section 300j–25, act July 1, 1944, ch. 373, title XIV, §1465, as added Pub. L. 100–572, §2(a), Oct. 31, 1988, 102 Stat. 2887; amended Pub. L. 104–182, title V, §501(d), (f)(11), Aug. 6, 1996, 110 Stat. 1691, 1692, related to Federal assistance for State programs regarding lead contamination in school drinking water, prior to repeal by Pub. L. 114–322, title II, §2107(b), Dec. 16, 2016, 130 Stat. 1728.

§300j–26. Certification of testing laboratories

The Administrator of the Environmental Protection Agency shall assure that programs for the certification of testing laboratories which test drinking water supplies for lead contamination certify only those laboratories which provide reliable accurate testing. The Administrator (or the State in the case of a State to which certification authority is delegated under this subsection) shall publish and make available to the public upon request the list of laboratories certified under this subsection.[1]

(Pub. L. 100–572, §4, Oct. 31, 1988, 102 Stat. 2889.)

EDITORIAL NOTES

CODIFICATION

Section was enacted as part of the Lead Contamination Control Act of 1988, and not as part of the Public Health Service Act which comprises this chapter.

[1] *So in original. Probably should be "section."*

§300j–27. Registry for lead exposure and Advisory Committee

(a) Definitions

In this section:

(1) City

The term "City" means a city exposed to lead contamination in the local drinking water system.

(2) Committee

The term "Committee" means the Advisory Committee established under subsection (c).

(3) Secretary

The term "Secretary" means the Secretary of Health and Human Services.

(b) Lead exposure registry

The Secretary shall establish within the Agency for Toxic Substances and Disease Registry or the Centers for Disease Control and Prevention at the discretion of the Secretary, or establish through a grant award or contract, a lead exposure registry to collect data on the lead exposure of residents of a City on a voluntary basis.

(c) Advisory Committee

(1) Membership

(A) In general

The Secretary shall establish, within the Agency for Toxic Substances and Disease Registry an Advisory Committee in coordination with the Director of the Centers for Disease Control and Prevention and other relevant agencies as determined by the Secretary consisting of Federal members and non-Federal members, and which shall include—

(i) an epidemiologist;
(ii) a toxicologist;
(iii) a mental health professional;
(iv) a pediatrician;
(v) an early childhood education expert;
(vi) a special education expert;
(vii) a dietician; and
(viii) an environmental health expert.

(B) Requirements

Membership in the Committee shall not exceed 15 members and not less than ½ of the members shall be Federal members.

(2) Chair

The Secretary shall designate a chair from among the Federal members appointed to the Committee.

(3) Terms

Members of the Committee shall serve for a term of not more than 3 years and the Secretary may reappoint members for consecutive terms.

(4) Application of FACA

The Committee shall be subject to the Federal Advisory Committee Act (5 U.S.C. App.).[1]

(5) Responsibilities

The Committee shall, at a minimum—

(A) review the Federal programs and services available to individuals and communities exposed to lead;

(B) review current research on lead poisoning to identify additional research needs;

(C) review and identify best practices, or the need for best practices, regarding lead screening and the prevention of lead poisoning;

(D) identify effective services, including services relating to healthcare, education, and nutrition for individuals and communities affected by lead exposure and lead poisoning, including in consultation with, as appropriate, the lead exposure registry as established in subsection (b); and

(E) undertake any other review or activities that the Secretary determines to be appropriate.

(6) Report

Annually for 5 years and thereafter as determined necessary by the Secretary or as required by Congress, the Committee shall submit to the Secretary, the Committees on Finance, Health, Education, Labor, and Pensions, and Agriculture, Nutrition, and Forestry of the Senate and the Committees on Education and the Workforce, Energy and Commerce, and Agriculture of the House of Representatives a report that includes—

(A) an evaluation of the effectiveness of the Federal programs and services available to individuals and communities exposed to lead;

(B) an evaluation of additional lead poisoning research needs;

(C) an assessment of any effective screening methods or best practices used or developed to prevent or screen for lead poisoning;

(D) input and recommendations for improved access to effective services relating to health care, education, or nutrition for individuals and communities impacted by lead exposure; and

(E) any other recommendations for communities affected by lead exposure, as appropriate.

(d) Authorization of appropriations

There are authorized to be appropriated for the period of fiscal years 2017 through 2021—

(1) $17,500,000 to carry out subsection (b); and

(2) $2,500,000 to carry out subsection (c).

(Pub. L. 114–322, title II, §2203, Dec. 16, 2016, 130 Stat. 1734.)

EDITORIAL NOTES

REFERENCES IN TEXT

The Federal Advisory Committee Act, referred to in subsec. (c)(4), is Pub. L. 92–463, Oct. 6, 1972, 86 Stat. 770, which was set out in the Appendix to Title 5, Government Organization and Employees, and was substantially repealed and restated in chapter 10 (§1001 et seq.) of Title 5 by Pub. L. 117–286, §§3(a), 7, Dec. 27, 2022, 136 Stat. 4197, 4361. For disposition of sections of the Act into chapter 10 of Title 5, see Disposition Table preceding section 101 of Title 5.

CODIFICATION

Section was enacted as part of the Water and Waste Act of 2016, and also as part of the Water Infrastructure Improvements for the Nation Act, also known as the WIIN Act, and not as part of the Public Health Service Act which comprises this chapter.

[1] *See References in Text note below.*

SUBCHAPTER XIII—PREVENTIVE HEALTH MEASURES WITH RESPECT TO BREAST AND CERVICAL CANCERS

§300k. Establishment of program of grants to States

(a) In general

The Secretary, acting through the Director of the Centers for Disease Control and Prevention, may make grants to States on the basis of an established competitive review process for the purpose of carrying out programs—

(1) to screen women for breast and cervical cancer as a preventive health measure;

(2) to provide appropriate referrals for medical treatment of women screened pursuant to paragraph (1) and to ensure, to the extent practicable, the provision of appropriate follow-up services and support services such as case management;

(3) to develop and disseminate public information and education programs for the detection and control of breast and cervical cancer;

(4) to improve the education, training, and skills of health professionals (including allied health professionals) in the detection and control of breast and cervical cancer;

(5) to establish mechanisms through which the States can monitor the quality of screening procedures for breast and cervical cancer, including the interpretation of such procedures; and

(6) to evaluate activities conducted under paragraphs (1) through (5) through appropriate

surveillance or program-monitoring activities.

(b) Grant and contract authority of States

(1) In general

A State receiving a grant under subsection (a) may, subject to paragraphs (2) and (3), expend the grant to carry out the purpose described in such subsection through grants to public and nonprofit private entities and through contracts with public and private entities.

(2) Certain applications

If a nonprofit private entity and a private entity that is not a nonprofit entity both submit applications to a State to receive an award of a grant or contract pursuant to paragraph (1), the State may give priority to the application submitted by the nonprofit private entity in any case in which the State determines that the quality of such application is equivalent to the quality of the application submitted by the other private entity.

(3) Payments for screenings

The amount paid by a State to an entity under this subsection for a screening procedure under subsection (a)(1) may not exceed the amount that would be paid under part B of title XVIII of the Social Security Act [42 U.S.C. 1395j et seq.] if payment were made under such part for furnishing the procedure to a woman enrolled under such part.

(c) Special consideration for certain States

In making grants under subsection (a) to States whose initial grants under such subsection are made for fiscal year 1995 or any subsequent fiscal year, the Secretary shall give special consideration to any State whose proposal for carrying out programs under such subsection—

(1) has been approved through a process of peer review; and

(2) is made with respect to geographic areas in which there is—

(A) a substantial rate of mortality from breast or cervical cancer; or

(B) a substantial incidence of either of such cancers.

(d) Coordinating committee regarding year 2020 health objectives

The Secretary, acting through the Director of the Centers for Disease Control and Prevention, shall establish a committee to coordinate the activities of the agencies of the Public Health Service (and other appropriate Federal agencies) that are carried out toward achieving the objectives established by the Secretary for reductions in the rate of mortality from breast and cervical cancer in the United States by the year 2020. Such committee shall be comprised of Federal officers or employees designated by the heads of the agencies involved to serve on the committee as representatives of the agencies, and such representatives from other public or private entities as the Secretary determines to be appropriate.

(July 1, 1944, ch. 373, title XV, §1501, as added Pub. L. 101–354, §2, Aug. 10, 1990, 104 Stat. 409; amended Pub. L. 103–43, title XX, §2008(c)(1), June 10, 1993, 107 Stat. 211; Pub. L. 103–183, title I, §101(a), (b), (f), (g)(1), Dec. 14, 1993, 107 Stat. 2227–2229; Pub. L. 105–340, title II, §203(a), (b), Oct. 31, 1998, 112 Stat. 3194; Pub. L. 105–392, title IV, §401(b)(5), Nov. 13, 1998, 112 Stat. 3587; Pub. L. 110–18, §2(1), Apr. 20, 2007, 121 Stat. 80.)

EDITORIAL NOTES

REFERENCES IN TEXT

The Social Security Act, referred to in subsec. (b)(3), is act Aug. 14, 1935, ch. 531, 49 Stat. 620. Part B of title XVIII of the Act is classified generally to part B (§1395j et seq.) of subchapter XVIII of chapter 7 of this title. For complete classification of this Act to the Code, see section 1305 of this title and Tables.

PRIOR PROVISIONS

A prior section 300k, Pub. L. 93–641, §2, Jan. 4, 1975, 88 Stat. 2226, set forth Congressional findings relating to national health planning and development, prior to omission in connection with repeal of former

section 300k–1 et seq. of this title.

A prior section 1501 of act July 1, 1944, ch. 373, title XV, as added Jan. 4, 1975, Pub. L. 93–641, §3, 88 Stat. 2227; amended Oct. 4, 1979, Pub. L. 96–79, title I, §101(a)(1)(A), (2), (3), 93 Stat. 593; Dec. 17, 1980, Pub. L. 96–538, title III, §301, 94 Stat. 3190, which related to guidelines for national health policy, was classified to section 300k–1 of this title, prior to repeal by Pub. L. 99–660, title VII, §701(a), Nov. 14, 1986, 100 Stat. 3799, effective Jan. 1, 1987.

Prior sections 300k–2 and 300k–3 were repealed by Pub. L. 99–660, title VII, §701(a), Nov. 14, 1986, 100 Stat. 3799, effective Jan. 1, 1987.

Section 300k–2, act July 1, 1944, ch. 373, title XV, §1502, as added Jan. 4, 1975, Pub. L. 93–641, §3, 88 Stat. 2227; amended Nov. 9, 1978, Pub. L. 95–619, title III, §303(a), 92 Stat. 3248; Oct. 4, 1979, Pub. L. 96–79, title I, §§102(a), 103(a), (b), 93 Stat. 594, 595, related to national health priorities and strengthening competition in supply of services.

Section 300k–3, act July 1, 1944, ch. 373, title XV, §1503, as added Jan. 4, 1975, Pub. L. 93–641, §3, 88 Stat. 2228; amended Aug. 1, 1977, Pub. L. 95–83, title I, §106(a), 91 Stat. 384; July 10, 1979, Pub. L. 96–32, §7(g), 93 Stat. 84; Oct. 4, 1979, Pub. L. 96–79, title I, §102(b), 93 Stat. 594; Oct. 17, 1979, Pub. L. 96–88, title V, §509(b), 93 Stat. 695, related to National Council on Health Planning and Development.

AMENDMENTS

2007—Subsec. (d). Pub. L. 110–18 substituted "2020" for "2000" in heading and "by the year 2020" for "by the year 2000" in text.

1998—Subsec. (a)(2). Pub. L. 105–340, §203(a), inserted "and support services such as case management" before semicolon at end.

Subsec. (b)(1). Pub. L. 105–340, §203(b)(1), substituted "through grants to public and nonprofit private entities and through contracts with public and private entities." for "through grants to, and contracts with, public or nonprofit private entities."

Subsec. (b)(2). Pub. L. 105–340, §203(b)(2), added par. (2) and struck out heading and text of former par. (2). Text read as follows: "In addition to the authority established in paragraph (1) for a State with respect to grants and contracts, the State may provide for screenings under subsection (a)(1) of this section through entering into contracts with private entities that are not nonprofit entities."

Subsecs. (c), (d). Pub. L. 105–392 redesignated subsec. (c), relating to coordinating committee regarding year 2000 health objectives, as (d).

1993—Subsec. (a). Pub. L. 103–183, §101(g)(1), substituted "Control and Prevention" for "Control" in introductory provisions.

Subsec. (b). Pub. L. 103–183, §101(a), substituted "paragraphs (2) and (3)" for "paragraph (2)" in par. (1), added pars. (2) and (3), and struck out heading and text of former par. (2). Text read as follows: "In addition to the authority established in paragraph (1) for a State with respect to grants and contracts, the State may provide for screenings under subsection (a)(1) of this section through entering into contracts with private entities. The amount paid by a State to a private entity under the preceding sentence for a screening procedure may not exceed the amount that would be paid under part B of title XVIII of the Social Security Act if payment were made under such part for furnishing the procedure to a woman enrolled under such part."

Pub. L. 103–43, §2008(c)(1), designated existing provisions as par. (1), inserted par. heading, substituted "may, subject to paragraph (2), expend" for "may expend", and added par. (2).

Subsec. (c). Pub. L. 103–183, §101(f), added subsec. (c) relating to coordinating committee regarding year 2000 health objectives.

Pub. L. 103–183, §101(b), added subsec. (c) relating to special consideration for certain States.

STATUTORY NOTES AND RELATED SUBSIDIARIES

EFFECTIVE DATE OF 1998 AMENDMENT

Amendment by Pub. L. 105–392 deemed to have taken effect immediately after enactment of Pub. L. 103–183, see section 401(e) of Pub. L. 105–392, set out as a note under section 242m of this title.

§300*l*. Requirement of matching funds

(a) In general

The Secretary may not make a grant under section 300k of this title unless the State involved

agrees, with respect to the costs to be incurred by the State in carrying out the purpose described in such section, to make available non-Federal contributions (in cash or in kind under subsection (b)) toward such costs in an amount equal to not less than $1 for each $3 of Federal funds provided in the grant. Such contributions may be made directly or through donations from public or private entities.

(b) Determination of amount of non-Federal contribution

(1) In general

Non-Federal contributions required in subsection (a) may be in cash or in kind, fairly evaluated, including equipment or services (and excluding indirect or overhead costs). Amounts provided by the Federal Government, or services assisted or subsidized to any significant extent by the Federal Government, may not be included in determining the amount of such non-Federal contributions.

(2) Maintenance of effort

In making a determination of the amount of non-Federal contributions for purposes of subsection (a), the Secretary may include only non-Federal contributions in excess of the average amount of non-Federal contributions made by the State involved toward the purpose described in section 300k of this title for the 2-year period preceding the first fiscal year for which the State is applying to receive a grant under such section.

(3) Inclusion of relevant non-Federal contributions for medicaid

In making a determination of the amount of non-Federal contributions for purposes of subsection (a), the Secretary shall, subject to paragraphs (1) and (2) of this subsection, include any non-Federal amounts expended pursuant to title XIX of the Social Security Act [42 U.S.C. 1396 et seq.] by the State involved toward the purpose described in paragraphs (1) and (2) of section 300k(a) of this title.

(July 1, 1944, ch. 373, title XV, §1502, as added Pub. L. 101–354, §2, Aug. 10, 1990, 104 Stat. 410.)

EDITORIAL NOTES

REFERENCES IN TEXT

The Social Security Act, referred to in subsec. (b)(3), is act Aug. 14, 1935, ch. 531, 49 Stat. 620. Title XIX of the Social Security Act is classified generally to subchapter XIX (§1396 et seq.) of chapter 7 of this title. For complete classification of this Act to the Code, see section 1305 of this title and Tables.

PRIOR PROVISIONS

A prior section 300l, act July 1, 1944, ch. 373, title XV, §1511, as added Jan. 4, 1975, Pub. L. 93–641, §3, 88 Stat. 2229; amended Apr. 22, 1976, Pub. L. 94–278, title XI, §1106(a), 90 Stat. 416; Aug. 1, 1977, Pub. L. 95–83, title I, §106(b), 91 Stat. 384; Oct. 4, 1979, Pub. L. 96–79, title I, §104(a)(1), (b), 93 Stat. 595, 596, related to establishment of health service areas, prior to repeal by Pub. L. 99–660, title VII, §701(a), Nov. 14, 1986, 100 Stat. 3799, effective Jan. 1, 1987.

A prior section 1502 of act July 1, 1944, ch. 373, title XV, was classified to section 300k–2 of this title prior to repeal by Pub. L. 99–660.

§300*l*–1. Requirement regarding medicaid

The Secretary may not make a grant under section 300k of this title for a program in a State unless the State plan under title XIX of the Social Security Act [42 U.S.C. 1396 et seq.] for the State includes the screening procedures specified in subparagraphs (A) and (B) of section 300m(a)(2) of this title as medical assistance provided under the plan.

(July 1, 1944, ch. 373, title XV, §1502A, as added Pub. L. 102–531, title III, §307, Oct. 27, 1992, 106 Stat. 3495.)

EDITORIAL NOTES

REFERENCES IN TEXT

The Social Security Act, referred to in text, is act Aug. 14, 1935, ch. 531, 49 Stat. 620. Title XIX of the Act is classified generally to subchapter XIX (§1396 et seq.) of chapter 7 of this title. For complete classification of this Act to the Code, see section 1305 of this title and Tables.

PRIOR PROVISIONS

Prior sections 300l–1 to 300l–5 were repealed by Pub. L. 99–660, title VII, §701(a), Nov. 14, 1986, 100 Stat. 3799, effective Jan. 1, 1987.

Section 300l–1, act July 1, 1944, ch. 373, title XV, §1512, as added Jan. 4, 1975, Pub. L. 93–641, §3, 88 Stat. 2232; amended Mar. 19, 1976, Pub. L. 94–237, §14(b), 90 Stat. 249; Oct. 12, 1976, Pub. L. 94–484, title IX, §902(a), 90 Stat. 2324; Aug. 1, 1977, Pub. L. 95–83, title I, §106(c), (d), 91 Stat. 384; Oct. 4, 1979, Pub. L. 96–79, title I, §§108(a)–(d)(1), (e), 109, 110(a)–(d)(1), (e)(1), (2)(A), (3), 111(a), (b), 112, 113(a), 114, 93 Stat. 601–607; Aug. 13, 1981, Pub. L. 97–35, title IX, §935(d), 95 Stat. 571; Oct. 22, 1986, Pub. L. 99–514, §2, 100 Stat. 2095, related to composition and operation of health systems agencies.

Section 300l–2, act July 1, 1944, ch. 373, title XV, §1513, as added Jan. 4, 1975, Pub. L. 93–641, §3, 88 Stat. 2235; amended Mar. 19, 1976, Pub. L. 94–237, §14(a), 90 Stat. 249; Aug. 1, 1977, Pub. L. 95–83, title I, §106(e)–(i), 91 Stat. 384, 385; July 10, 1979, Pub. L. 96–32, §7(m), 93 Stat. 84; Oct. 4, 1979, Pub. L. 96–79, title I, §§101(b)(1), 103(c), 107(a), 110(e)(4), (f), 115(b)(1), (2), (c)(2), (d)(1), (2), (e), (f), (h), (i)(1), 118(a)(1), (b)(1), (c), 119(b), 120(a), 121, 122(a), 123(c)(1)(B), 93 Stat. 593, 595, 600, 604, 607–610, 620–625; Oct. 17, 1979, Pub. L. 96–88, title V, §509(b), 93 Stat. 695; Jan. 2, 1980, Pub. L. 96–181, §15(b), 93 Stat. 1316; Oct. 7, 1980, Pub. L. 96–398, title VIII, §804(d), 94 Stat. 1608; Aug. 13, 1981, Pub. L. 97–35, title IX, §902(g)(4), 95 Stat. 561, related to functions of health systems agencies.

Section 300l–3, act July 1, 1944, ch. 373, title XV, §1514, as added Jan. 4, 1975, Pub. L. 93–641, §3, 88 Stat. 2239; amended Aug. 1, 1977, Pub. L. 95–83, title I, §106(j), 91 Stat. 385; Oct. 4, 1979, Pub. L. 96–79, title I, §105(f), 93 Stat. 598, provided for assistance to entities desiring to be designated as health systems agencies.

Section 300l–4, act July 1, 1944, ch. 373, title XV, §1515, as added Jan. 4, 1975, Pub. L. 93–641, §3, 88 Stat. 2239; amended Aug. 1, 1977, Pub. L. 95–83, title I, §106(k), 91 Stat. 385; Dec. 19, 1977, Pub. L. 95–215, §6(a)(1), 91 Stat. 1507; Oct. 4, 1979, Pub. L. 96–79, title I, §105(a)–(d)(1)(A), (2), (e), (g), (h), 93 Stat. 596–598; Oct. 17, 1979, Pub. L. 96–88, title V, §509(b), 93 Stat. 695, provided for designation of health systems agencies.

Section 300l–5, act July 1, 1944, ch. 373, title XV, §1516, as added Jan. 4, 1975, Pub. L. 93–641, §3, 88 Stat. 2241; amended Aug. 1, 1977, Pub. L. 95–83, title I, §102(a), 91 Stat. 383; Dec. 19, 1977, Pub. L. 95–215, §6(a)(2), 91 Stat. 1507; Oct. 4, 1979, Pub. L. 96–79, title I, §§106, 107(b), 127(a), 93 Stat. 598, 600, 629; Dec. 17, 1980, Pub. L. 96–538, title III, §302, 94 Stat. 3190; Aug. 13, 1981, Pub. L. 97–35, title IX, §§933(a)(1), 934(a), 95 Stat. 570, 571, provided for planning grants to health systems agencies.

§300m. Requirements with respect to type and quality of services

(a) Requirement of provision of all services by date certain

The Secretary may not make a grant under section 300k of this title unless the State involved agrees—

(1) to ensure that, initially and throughout the period during which amounts are received pursuant to the grant, not less than 60 percent of the grant is expended to provide each of the services or activities described in paragraphs (1) and (2) of section 300k(a) of this title, including making available screening procedures for both breast and cervical cancers;

(2) subject to subsection (b), to ensure that—

(A) in the case of breast cancer, both a physical examination of the breasts and the screening procedure known as a mammography are conducted; and

(B) in the case of cervical cancer, both a pelvic examination and the screening procedure known as a pap smear are conducted;

(3) to ensure that, by the end of any second fiscal year of payments pursuant to the grant, each of the services or activities described in section 300k(a) of this title is provided; and

(4) to ensure that not more than 40 percent of the grant is expended to provide the services or

activities described in paragraphs (3) through (6) of such section.

(b) Use of improved screening procedures

The Secretary may not make a grant under section 300k of this title unless the State involved agrees that, if any screening procedure superior to a procedure described in subsection (a)(2) becomes commonly available and is recommended for use, any entity providing screening procedures pursuant to the grant will utilize the superior procedure rather than the procedure described in such subsection.

(c) Quality assurance regarding screening procedures

The Secretary may not make a grant under section 300k of this title unless the State involved agrees that the State will, in accordance with applicable law, assure the quality of screening procedures conducted pursuant to such section.

(d) Waiver of services requirement on division of funds

(1) In general

The Secretary shall establish a demonstration project under which the Secretary may waive the requirements of paragraphs (1) and (4) of subsection (a) for not more than 5 States, if—

(A) the State involved will use the waiver to leverage non-Federal funds to supplement each of the services or activities described in paragraphs (1) and (2) of section 300k(a) of this title;

(B) the application of such requirement would result in a barrier to the enrollment of qualifying women;

(C) the State involved—

(i) demonstrates, to the satisfaction of the Secretary, the manner in which the State will use such waiver to expand the level of screening and follow-up services provided immediately prior to the date on which the waiver is granted; and

(ii) provides assurances, satisfactory to the Secretary, that the State will, on an annual basis, demonstrate, through such documentation as the Secretary may require, that the State has used such waiver as described in clause (i);

(D) the State involved submits to the Secretary—

(i) assurances, satisfactory to the Secretary, that the State will maintain the average annual level of State fiscal year expenditures for the services and activities described in paragraphs (1) and (2) of section 300k(a) of this title for the period for which the waiver is granted, and for the period for which any extension of such wavier [1] is granted, at a level that is not less than—

(I) the level of the State fiscal year expenditures for such services and activities for the fiscal year preceding the first fiscal year for which the waiver is granted; or

(II) at the option of the State and upon approval by the Secretary, the average level of the State expenditures for such services and activities for the 3-fiscal year period preceding the first fiscal year for which the waiver is granted; and

(ii) a plan, satisfactory to the Secretary, for maintaining the level of activities carried out under the waiver after the expiration of the waiver and any extension of such waiver;

(E) the Secretary finds that granting such a waiver to a State will increase the number of women in the State that receive each of the services or activities described in paragraphs (1) and (2) of section 300k(a) of this title, including making available screening procedures for both breast and cervical cancers; and

(F) the Secretary finds that granting such a waiver to a State will not adversely affect the quality of each of the services or activities described in paragraphs (1) and (2) of section 300k(a) of this title.

(2) Duration of waiver

(A) In general

In granting waivers under paragraph (1), the Secretary—

(i) shall grant such waivers for a period that is not less than 1 year but not more than 2 years; and

(ii) upon request of a State, may extend a waiver for an additional period that is not less than 1 year but not more than 2 years in accordance with subparagraph (B).

(B) Additional period

The Secretary, upon the request of a State that has received a waiver under paragraph (1), shall, at the end of the waiver period described in subparagraph (A)(i), review performance under the waiver and may extend the waiver for an additional period if the Secretary determines that—

(i) without an extension of the waiver, there will be a barrier to the enrollment of qualifying women;

(ii) the State requesting such extended waiver will use the waiver to leverage non-Federal funds to supplement the services or activities described in paragraphs (1) and (2) of section 300k(a) of this title;

(iii) the waiver has increased, and will continue to increase, the number of women in the State that receive the services or activities described in paragraphs (1) and (2) of section 300k(a) of this title;

(iv) the waiver has not, and will not, result in lower quality in the State of the services or activities described in paragraphs (1) and (2) of section 300k(a) of this title; and

(v) the State has maintained the average annual level of State fiscal expenditures for the services and activities described in paragraphs (1) and (2) of section 300k(a) of this title for the period for which the waiver was granted at a level that is not less than—

(I) the level of the State fiscal year expenditures for such services and activities for the fiscal year preceding the first fiscal year for which the waiver is granted; or

(II) at the option of the State and upon approval by the Secretary, the average level of the State expenditures for such services and activities for the 3-fiscal year period preceding the first fiscal year for which the waiver is granted.

(3) Reporting requirements

The Secretary shall include as part of the evaluations and reports required under section 300n–4 of this title, the following:

(A) A description of the total amount of dollars leveraged annually from Non-Federal [2] entities in States receiving a waiver under paragraph (1) and how these amounts were used.

(B) With respect to States receiving a waiver under paragraph (1), a description of the percentage of the grant that is expended on providing each of the services or activities described in—

(i) paragraphs (1) and (2) of section 300k(a) of this title; and

(ii) paragraphs (3) through (6) of section 300k(a) of this title.

(C) A description of the number of States receiving waivers under paragraph (1) annually.

(D) With respect to States receiving a waiver under paragraph (1), a description of—

(i) the number of women receiving services under paragraphs (1), (2), and (3) of section 300k(a) of this title in programs before and after the granting of such waiver; and

(ii) the average annual level of State fiscal expenditures for the services and activities described in paragraphs (1) and (2) of section 300k(a) of this title for the year preceding the first year for which the waiver was granted.

(4) Limitation

Amounts to which a waiver applies under this subsection shall not be used to increase the number of salaried employees.

(5) Definitions

In this subsection:

(A) Indian tribe

The term "Indian tribe" has the meaning given the term in section 1603 of title 25.

(B) Tribal organization

The term "tribal organization" has the meaning given the term in section 1603 of title 25.

(C) State

The term "State" means each of the several States of the United States, the District of Columbia, the Commonwealth of Puerto Rico, American Samoa, the Commonwealth of the Northern Mariana Islands, the Republic of the Marshall Islands, the Federated States of Micronesia, the Republic of Palau, an Indian tribe, and a tribal organization.

(6) Sunset

The Secretary may not grant a waiver or extension under this subsection after September 30, 2012.

(July 1, 1944, ch. 373, title XV, §1503, as added Pub. L. 101–354, §2, Aug. 10, 1990, 104 Stat. 410; amended Pub. L. 103–183, title I, §101(c)(1), Dec. 14, 1993, 107 Stat. 2227; Pub. L. 110–18, §2(2), Apr. 20, 2007, 121 Stat. 80.)

EDITORIAL NOTES

PRIOR PROVISIONS

Prior sections 300m to 300m–6 were repealed by Pub. L. 99–660, title VII, §701(a), Nov. 14, 1986, 100 Stat. 3799, effective Jan. 1, 1987.

Section 300m, act July 1, 1944, ch. 373, title XV, §1521, as added Jan. 4, 1975, Pub. L. 93–641, §3, 88 Stat. 2242; amended Aug. 1, 1977, Pub. L. 95–83, title I, §106(l), (m), 91 Stat. 385; Dec. 19, 1977, Pub. L. 95–215, §6(b), 91 Stat. 1507; July 16, 1979, Pub. L. 96–33, 93 Stat. 86; Oct. 4, 1979, Pub. L. 96–79, title I, §123(a), (b)(1)(A), (2), (d), (f), (g)(2), 93 Stat. 624–627; Oct. 17, 1979, Pub. L. 96–88, title V, §509(b), 93 Stat. 695; Jan. 2, 1980, Pub. L. 96–181, §15(b), 93 Stat. 1316; Dec. 17, 1980, Pub. L. 96–538, title III, §303(b), 94 Stat. 3190; Aug. 13, 1981, Pub. L. 97–35, title IX, §§902(g)(5), 936(b), 95 Stat. 561, 572; Jan. 4, 1983, Pub. L. 97–414, §9(b), 96 Stat. 2064, provided for designation of State health planning and development agencies.

A prior section 1503 of act July 1, 1944, ch. 373, title XV, as added Jan. 4, 1975, Pub. L. 93–641, §3, 88 Stat. 2228; amended Aug. 1, 1977, Pub. L. 95–83, title I, §106(a), 91 Stat. 384; July 10, 1979, Pub. L. 96–32, §7(g), 93 Stat. 84; Oct. 4, 1979, Pub. L. 96–79, title I, §102(b), 93 Stat. 594; Oct. 17, 1979, Pub. L. 96–88, title V, §509(b), 93 Stat. 695, which related to National Council on Health Planning and Development, was classified to section 300k–3 of this title.

Section 300m–1, act July 1, 1944, ch. 373, title XV, §1522, as added Jan. 4, 1975, Pub. L. 93–641, §3, 88 Stat. 2244; amended 1978 Reorg. Plan No. 2, §102, eff. Jan. 1, 1979, 43 F.R. 36037, 92 Stat. 3783; Oct. 4, 1979, Pub. L. 96–79, title I, §§101(b)(2), 111(c), 115(b)(3), 117(b)(4), 120(b), 122(b), 123(c)(1)(A), (e)(1), 93 Stat. 594, 605, 607, 620, 622, 624, 625, 626; Oct. 17, 1979, Pub. L. 96–88, title V, §509(b), 93 Stat. 695, related to State administrative programs.

Section 300m–2, act July 1, 1944, ch. 373, title XV, §1523, as added Jan. 4, 1975, Pub. L. 93–641, §3, 88 Stat. 2246; amended Aug. 1, 1977, Pub. L. 95–83, title I, §106(n), 91 Stat. 385; Oct. 4, 1979, Pub. L. 96–79, title I, §§115(c)(1)(A)–(C), (i)(2), 117(b)(1), (2), 118(a)(2), (b)(2), 123(c)(2), (3), (e)(2), (g)(1), 93 Stat. 607, 608, 610, 618, 619, 621, 625–627; Oct. 7, 1980, Pub. L. 96–398, title III, §303, 94 Stat. 1588, related to State health planning and development functions.

Section 300m–3, act July 1, 1944, ch. 373, title XV, §1524, as added Jan. 4, 1975, Pub. L. 93–641, §3, 88 Stat. 2247; amended Oct. 4, 1979, Pub. L. 96–79, title I, §§110(d)(2), 113(b), 115(a), (c)(1)(D), (d)(3), (g), (i)(2)–(4), 119(a), 124, 93 Stat. 604, 606–610, 621, 627; Jan. 2, 1980, Pub. L. 96–181, §15(b), 93 Stat. 1316; Dec. 17, 1980, Pub. L. 96–538, title III, §§304, 305, 94 Stat. 3191; Aug. 13, 1981, Pub. L. 97–35, title IX, §902(g)(6), 95 Stat. 561, related to composition and functions of Statewide Health Coordinating Councils.

Section 300m–4, act July 1, 1944, ch. 373, title XV, §1525, as added Jan. 4, 1975, Pub. L. 93–641, §3, 88 Stat. 2249; amended Aug. 1, 1977, Pub. L. 95–83, title I, §102(b), 91 Stat. 383; Oct. 4, 1979, Pub. L. 96–79, title I, §§107(c), 127(b), 93 Stat. 600, 629; Aug. 13, 1981, Pub. L. 97–35, title IX, §933(a)(2), 95 Stat. 570, provided for grants for State health planning and development.

Section 300m–5, act July 1, 1944, ch. 373, title XV, §1526, as added Jan. 4, 1975, Pub. L. 93–641, §3, 88 Stat. 2249; amended Aug. 1, 1977, Pub. L. 95–83, title I, §§102(c), 106(o), 91 Stat. 383, 385; Oct. 4, 1979, Pub. L. 96–79, title I, §§107(d), 120(c), 127(c), 93 Stat. 600, 622, 629, provided for grants for rate regulation.

Section 300m–6, act July 1, 1944, ch. 373, title XV, §1527, as added Oct. 4, 1979, Pub. L. 96–79, title I, §117(a), 93 Stat. 614; amended Dec. 17, 1980, Pub. L. 96–538, title III, §§306, 307, 94 Stat. 3191; Aug. 13, 1981, Pub. L. 97–35, title IX, §949(c), 95 Stat. 578, related to certificate of need program.

AMENDMENTS

2007—Subsec. (d). Pub. L. 110–18 added subsec. (d).

1993—Subsecs. (c) to (e). Pub. L. 103–183 added subsec. (c) and struck out former subsecs. (c) which related to quality assurance regarding screening for breast cancer, (d) which related to quality assurance regarding screening for cervical cancer, and (e) which related to issuance by Secretary of guidelines with respect to quality of mammography and cytological services.

STATUTORY NOTES AND RELATED SUBSIDIARIES

TRANSITION RULE REGARDING MAMMOGRAPHIES

Pub. L. 103–183, title I, §101(c)(2), Dec. 14, 1993, 107 Stat. 2228, provided that: "With respect to the screening procedure for breast cancer known as a mammography, the requirements in effect on the day before the date of the enactment of this Act [Dec. 14, 1993] under section 1503(c) of the Public Health Service Act [42 U.S.C. 300m(c)] remain in effect (for an individual or facility conducting such procedures pursuant to a grant to a State under section 1501 of such Act [42 U.S.C. 300k]) until there is in effect for the facility a certificate (or provisional certificate) issued under section 354 of such Act [42 U.S.C. 263b]."

[1] So in original. Probably should be "waiver".

[2] So in original. Probably should be "non-Federal".

§300n. Additional required agreements

(a) Priority for low-income women

The Secretary may not make a grant under section 300k of this title unless the State involved agrees that low-income women will be given priority in the provision of services and activities pursuant to paragraphs (1) and (2) of section 300k(a) of this title.

(b) Limitation on imposition of fees for services

The Secretary may not make a grant under section 300k of this title unless the State involved agrees that, if a charge is imposed for the provision of services or activities under the grant, such charge—

(1) will be made according to a schedule of charges that is made available to the public;

(2) will be adjusted to reflect the income of the woman involved; and

(3) will not be imposed on any woman with an income of less than 100 percent of the official poverty line, as established by the Director of the Office of Management and Budget and revised by the Secretary in accordance with section 9902(2) of this title.

(c) Statewide provision of services

(1) In general

The Secretary may not make a grant under section 300k of this title unless the State involved agrees that services and activities under the grant will be made available throughout the State, including availability to members of any Indian tribe or tribal organization (as such terms are defined in section 5304 of title 25).

(2) Waiver

The Secretary may waive the requirement established in paragraph (1) for a State if the

Secretary determines that compliance by the State with the requirement would result in an inefficient allocation of resources with respect to carrying out the purpose described in section 300k(a) of this title.

(3) Grants to tribes and tribal organizations

(A) The Secretary, acting through the Director of the Centers for Disease Control and Prevention, may make grants to tribes and tribal organizations (as such terms are used in paragraph (1)) for the purpose of carrying out programs described in section 300k(a) of this title. This subchapter applies to such a grant (in relation to the jurisdiction of the tribe or organization) to the same extent and in the same manner as such subchapter applies to a grant to a State under section 300k of this title (in relation to the jurisdiction of the State).

(B) If a tribe or tribal organization is receiving a grant under subparagraph (A) and the State in which the tribe or organization is located is receiving a grant under section 300k of this title, the requirement established in paragraph (1) for the State regarding the tribe or organization is deemed to have been waived under paragraph (2).

(d) Relationship to items and services under other programs

The Secretary may not make a grant under section 300k of this title unless the State involved agrees that the grant will not be expended to make payment for any item or service to the extent that payment has been made, or can reasonably be expected to be made, with respect to such item or service—

(1) under any State compensation program, under an insurance policy, or under any Federal or State health benefits program; or

(2) by an entity that provides health services on a prepaid basis.

(e) Coordination with other breast and cervical cancer programs

The Secretary may not make a grant under section 300k of this title unless the State involved agrees that the services and activities funded through the grant shall be coordinated with other Federal, State, and local breast and cervical cancer programs.

(f) Limitation on administrative expenses

The Secretary may not make a grant under section 300k of this title unless the State involved agrees that not more than 10 percent of the grant will be expended for administrative expenses with respect to the grant.

(g) Restrictions on use of grant

The Secretary may not make a grant under section 300k of this title unless the State involved agrees that the grant will not be expended to provide inpatient hospital services for any individual.

(h) Records and audits

The Secretary may not make a grant under section 300k of this title unless the State involved agrees that—

(1) the State will establish such fiscal control and fund accounting procedures as may be necessary to ensure the proper disbursal of, and accounting for, amounts received by the State under such section; and

(2) upon request, the State will provide records maintained pursuant to paragraph (1) to the Secretary or the Comptroller of the United States for purposes of auditing the expenditures by the State of the grant.

(i) Reports to Secretary

The Secretary may not make a grant under section 300k of this title unless the State involved agrees to submit to the Secretary such reports as the Secretary may require with respect to the grant.

(July 1, 1944, ch. 373, title XV, §1504, as added Pub. L. 101–354, §2, Aug. 10, 1990, 104 Stat. 412; amended Pub. L. 103–183, title I, §101(d), Dec. 14, 1993, 107 Stat. 2228.)

EDITORIAL NOTES

PRIOR PROVISIONS

A prior section 300n, act July 1, 1944, ch. 373, title XV, §1531, as added Jan. 4, 1975, Pub. L. 93–641, §3, 88 Stat. 2250; amended Mar. 19, 1976, Pub. L. 94–237, §14(c), 90 Stat. 249; Oct. 12, 1976, Pub. L. 94–484, title IX, §902(b), 90 Stat. 2324; Oct. 4, 1979, Pub. L. 96–79, title I, §§104(c)(2), 108(d)(2), 117(b)(3), 126(a)(1), (b), 93 Stat. 596, 602, 619, 628; Dec. 17, 1980, Pub. L. 96–538, title III, §§308, 309, 94 Stat. 3192; Aug. 13, 1981, Pub. L. 97–35, title IX, §936(a), 95 Stat. 572, defined terms applicable to this subchapter, prior to repeal by Pub. L. 99–660, title VII, §701(a), Nov. 14, 1986, 100 Stat. 3799, effective Jan. 1, 1987.

AMENDMENTS

1993—Subsec. (c)(3). Pub. L. 103–183 added par. (3).

§300n–1. Description of intended uses of grant

The Secretary may not make a grant under section 300k of this title unless—

(1) the State involved submits to the Secretary a description of the purposes for which the State intends to expend the grant;

(2) the description identifies the populations, areas, and localities in the State with a need for the services or activities described in section 300k(a) of this title;

(3) the description provides information relating to the services and activities to be provided, including a description of the manner in which the services and activities will be coordinated with any similar services or activities of public and private entities; and

(4) the description provides assurances that the grant funds will be used in the most cost-effective manner.

(July 1, 1944, ch. 373, title XV, §1505, as added Pub. L. 101–354, §2, Aug. 10, 1990, 104 Stat. 414; amended Pub. L. 103–43, title XX, §2008(c)(2), June 10, 1993, 107 Stat. 211; Pub. L. 103–183, title I, §101(g)(2), Dec. 14, 1993, 107 Stat. 2229; Pub. L. 105–392, title IV, §401(b)(6), Nov. 13, 1998, 112 Stat. 3587.)

EDITORIAL NOTES

PRIOR PROVISIONS

A prior section 300n–1, act July 1, 1944, ch. 373, title XV, §1532, as added Jan. 4, 1975, Pub. L. 93–641, §3, 88 Stat. 2251; amended Oct. 8, 1976, Pub. L. 94–460, title I, §117(a), 90 Stat. 1954; Nov. 9, 1978, Pub. L. 95–619, title III, §303(b), (c), 92 Stat. 3248; Oct. 4, 1979, Pub. L. 96–79, title I, §§103(d), 116, 117(b)(5), 93 Stat. 595, 610, 620; Dec. 17, 1980, Pub. L. 96–538, title III, §310, 94 Stat. 3192, provided for procedures and criteria for review of proposed health system changes, prior to repeal by Pub. L. 99–660, title VII, §701(a), Nov. 14, 1986, 100 Stat. 3799, effective Jan. 1, 1987.

AMENDMENTS

1998—Par. (3). Pub. L. 105–392 struck out "nonprofit" before "private entities".

1993—Par. (3). Pub. L. 103–183, §101(g)(2)(A), substituted "public and nonprofit private entities; and" for "public or nonprivate entities (and additionally, in the case of services and activities under section 300k(a)(1) of this title, with any similar services or activities of private entities); and".

Pub. L. 103–43 inserted before semicolon "(and additionally, in the case of services and activities under section 300k(a)(1) of this title, with any similar services or activities of private entities)".

Par. (4). Pub. L. 103–183, §101(g)(2)(B), inserted "will" after "grant funds".

STATUTORY NOTES AND RELATED SUBSIDIARIES

EFFECTIVE DATE OF 1998 AMENDMENT

Amendment by Pub. L. 105–392 deemed to have taken effect immediately after enactment of Pub. L. 103–183, see section 401(e) of Pub. L. 105–392, set out as a note under section 242m of this title.

§300n–2. Requirement of submission of application

The Secretary may not make a grant under section 300k of this title unless an application for the grant is submitted to the Secretary, the application contains the description of intended uses required in section 300n–1 of this title, and the application is in such form, is made in such manner, and contains such agreements, assurances, and information as the Secretary determines to be necessary to carry out this subchapter.

(July 1, 1944, ch. 373, title XV, §1506, as added Pub. L. 101–354, §2, Aug. 10, 1990, 104 Stat. 414.)

EDITORIAL NOTES

PRIOR PROVISIONS

A prior section 300n–2, act July 1, 1944, ch. 373, title XV, §1533, as added Jan. 4, 1975, Pub. L. 93–641, §3, 88 Stat. 2253, provided for technical assistance to health systems agencies and State agencies, prior to repeal by Pub. L. 99–660, title VII, §701(a), Nov. 14, 1986, 100 Stat. 3799, effective Jan. 1, 1987.

§300n–3. Technical assistance and provision of supplies and services in lieu of grant funds

(a) Technical assistance

The Secretary may provide training and technical assistance with respect to the planning, development, and operation of any program or service carried out pursuant to section 300k of this title. The Secretary may provide such technical assistance directly or through grants to, or contracts with, public and private entities.

(b) Provision of supplies and services in lieu of grant funds

(1) In general

Upon the request of a State receiving a grant under section 300k of this title, the Secretary may, subject to paragraph (2), provide supplies, equipment, and services for the purpose of aiding the State in carrying out such section and, for such purpose, may detail to the State any officer or employee of the Department of Health and Human Services.

(2) Corresponding reduction in payments

With respect to a request described in paragraph (1), the Secretary shall reduce the amount of payments under the grant under section 300k of this title to the State involved by an amount equal to the costs of detailing personnel (including pay, allowances, and travel expenses) and the fair market value of any supplies, equipment, or services provided by the Secretary. The Secretary shall, for the payment of expenses incurred in complying with such request, expend the amounts withheld.

(July 1, 1944, ch. 373, title XV, §1507, as added Pub. L. 101–354, §2, Aug. 10, 1990, 104 Stat. 414.)

EDITORIAL NOTES

PRIOR PROVISIONS

A prior section 300n–3, act July 1, 1944, ch. 373, title XV, §1534, as added Jan. 4, 1975, Pub. L. 93–641, §3, 88 Stat. 2255; amended Aug. 1, 1977, Pub. L. 95–83, title I, §102(d), 91 Stat. 383; Oct. 4, 1979, Pub. L. 96–79, title I, §§125, 127(d), 93 Stat. 628, 629; Aug. 13, 1981, Pub. L. 97–35, title IX, §933(a)(3), 95 Stat. 570, provided for developing new centers for health planning, prior to repeal by Pub. L. 99–660, title VII, §701(a), Nov. 14, 1986, 100 Stat. 3799, effective Jan. 1, 1987.

§300n–4. Evaluations and reports

(a) Evaluations

The Secretary shall, directly or through contracts with public or private entities, provide for annual evaluations of programs carried out pursuant to section 300k of this title. Such evaluations shall include evaluations of—

(1) the extent to which States carrying out such programs are in compliance with section 300k(a)(2) of this title and with section 300n(c) of this title; and

(2) the extent to which each State receiving a grant under this subchapter is in compliance with section 300l of this title, including identification of—

(A) the amount of the non-Federal contributions by the State for the preceding fiscal year, disaggregated according to the source of the contributions; and

(B) the proportion of such amount of non-Federal contributions relative to the amount of Federal funds provided through the grant to the State for the preceding fiscal year.

(b) Report to Congress

The Secretary shall, not later than 1 year after April 20, 2007,[1] and annually thereafter, submit to the Committee on Energy and Commerce of the House of Representatives, and to the Committee on Labor and Human Resources of the Senate, a report summarizing evaluations carried out pursuant to subsection (a) during the preceding fiscal year and making such recommendations for administrative and legislative initiatives with respect to this subchapter as the Secretary determines to be appropriate, including recommendations regarding compliance by the States with section 300k(a)(2) of this title and with section 300n(c) of this title.

(July 1, 1944, ch. 373, title XV, §1508, as added Pub. L. 101–354, §2, Aug. 10, 1990, 104 Stat. 415; amended Pub. L. 103–183, title I, §101(e), Dec. 14, 1993, 107 Stat. 2228; Pub. L. 110–18, §2(3), Apr. 20, 2007, 121 Stat. 83.)

EDITORIAL NOTES

REFERENCES IN TEXT

April 20, 2007, referred to in subsec. (b), was in the original "the date of the enactment of the National Breast and Cervical Cancer Early Detection Program Reauthorization of 2007", and was translated as reading "the date of the enactment of the National Breast and Cervical Cancer Early Detection Program Reauthorization Act of 2007", to reflect the probable intent of Congress.

PRIOR PROVISIONS

A prior section 300n–4, act July 1, 1944, ch. 373, title XV, §1535, as added Jan. 4, 1975, Pub. L. 93–641, §3, 88 Stat. 2256, provided for review by Secretary of operations of designated health systems agencies and State agencies, prior to repeal by Pub. L. 99–660, title VII, §701(a), Nov. 14, 1986, 100 Stat. 3799, effective Jan. 1, 1987.

AMENDMENTS

2007—Subsec. (a). Pub. L. 110–18, §2(3)(A), substituted "evaluations of—" and pars. (1) and (2) for "evaluations of the extent to which States carrying out such programs are in compliance with section 300k(a)(2) of this title and with section 300n(c) of this title."

Subsec. (b). Pub. L. 110–18, §2(3)(B), substituted "not later than 1 year after April 20, 2007, and annually thereafter" for "not later than 1 year after the date on which amounts are first appropriated pursuant to section 300n–5(a) of this title, and annually thereafter".

1993—Subsec. (a). Pub. L. 103–183, §101(e)(1), inserted at end "Such evaluations shall include evaluations of the extent to which States carrying out such programs are in compliance with section 300k(a)(2) of this title and with section 300n(c) of this title."

Subsec. (b). Pub. L. 103–183, §101(e)(2), inserted before period at end ", including recommendations regarding compliance by the States with section 300k(a)(2) of this title and with section 300n(c) of this title".

STATUTORY NOTES AND RELATED SUBSIDIARIES

CHANGE OF NAME

Committee on Labor and Human Resources of Senate changed to Committee on Health, Education, Labor, and Pensions of Senate by Senate Resolution No. 20, One Hundred Sixth Congress, Jan. 19, 1999.

Committee on Energy and Commerce of House of Representatives treated as referring to Committee on Commerce of House of Representatives by section 1(a) of Pub. L. 104–14, set out as a note preceding section 21 of Title 2, The Congress. Committee on Commerce of House of Representatives changed to Committee on Energy and Commerce of House of Representatives, and jurisdiction over matters relating to securities and exchanges and insurance generally transferred to Committee on Financial Services of House of Representatives by House Resolution No. 5, One Hundred Seventh Congress, Jan. 3, 2001.

[1] *See References in Text note below.*

§300n–4a. Supplemental grants for additional preventive health services

(a) Demonstration projects

In the case of States receiving grants under section 300k of this title, the Secretary, acting through the Director of the Centers for Disease Control and Prevention, may make grants to not more than 3 such States to carry out demonstration projects for the purpose of—

(1) providing preventive health services in addition to the services authorized in such section, including screenings regarding blood pressure and cholesterol, and including health education;

(2) providing appropriate referrals for medical treatment of women receiving services pursuant to paragraph (1) and ensuring, to the extent practicable, the provision of appropriate follow-up services; and

(3) evaluating activities conducted under paragraphs (1) and (2) through appropriate surveillance or program-monitoring activities.

(b) Status as participant in program regarding breast and cervical cancer

The Secretary may not make a grant under subsection (a) unless the State involved agrees that services under the grant will be provided only through entities that are screening women for breast or cervical cancer pursuant to a grant under section 300k of this title.

(c) Applicability of provisions of general program

This subchapter applies to a grant under subsection (a) to the same extent and in the same manner as such subchapter applies to a grant under section 300k of this title.

(d) Funding

(1) In general

Subject to paragraph (2), for the purpose of carrying out this section, there are authorized to be appropriated $3,000,000 for fiscal year 1994, and such sums as may be necessary for each of the fiscal years 1995 through 2003.

(2) Limitation regarding funding with respect to breast and cervical cancer

The authorization of appropriations established in paragraph (1) is not effective for a fiscal year unless the amount appropriated under section 300n–5(a) of this title for the fiscal year is equal to or greater than $100,000,000.

(July 1, 1944, ch. 373, title XV, §1509, as added Pub. L. 103–183, title I, §102(a)(2), Dec. 14, 1993, 107 Stat. 2229; amended Pub. L. 105–340, title II, §203(c)(1), Oct. 31, 1998, 112 Stat. 3194.)

EDITORIAL NOTES

PRIOR PROVISIONS

A prior section 1509 of act July 1, 1944, was renumbered section 1510 and is classified to section 300n–5 of this title.

AMENDMENTS

1998—Subsec. (d)(1). Pub. L. 105–340 substituted "2003" for "1998".

§300n–5. Funding for general program

(a) Authorization of appropriations

For the purpose of carrying out this subchapter, there are authorized to be appropriated $50,000,000 for fiscal year 1991, such sums as may be necessary for each of the fiscal years 1992 and 1993, $150,000,000 for fiscal year 1994, such sums as may be necessary for each of the fiscal years 1995 through 2003, $225,000,000 for fiscal year 2008, $245,000,000 for fiscal year 2009, $250,000,000 for fiscal year 2010, $255,000,000 for fiscal year 2011, and $275,000,000 for fiscal year 2012.

(b) Set-aside for technical assistance and provision of supplies and services

Of the amounts appropriated under subsection (a) for a fiscal year, the Secretary shall reserve not more than 20 percent for carrying out section 300n–3 of this title.

(July 1, 1944, ch. 373, title XV, §1510, formerly §1509, as added Pub. L. 101–354, §2, Aug. 10, 1990, 104 Stat. 415; renumbered §1510 and amended Pub. L. 103–183, title I, §§102(a)(1), (b), 103, Dec. 14, 1993, 107 Stat. 2229, 2230; Pub. L. 105–340, title II, §203(c)(2), Oct. 31, 1998, 112 Stat. 3194; Pub. L. 110–18, §2(4), Apr. 20, 2007, 121 Stat. 83.)

EDITORIAL NOTES

PRIOR PROVISIONS

Prior sections 300n–5 and 300n–6 were repealed by Pub. L. 99–660, title VII, §701(a), Nov. 14, 1986, 100 Stat. 3799, effective Jan. 1, 1987.

Section 300n–5, act July 1, 1944, ch. 373, title XV, §1536, as added Jan. 4, 1975, Pub. L. 93–641, §3, 88 Stat. 2257; amended Aug. 1, 1977, Pub. L. 95–83, title I, §106(p), (q), 91 Stat. 385; Oct. 4, 1979, Pub. L. 96–79, title I, §104(c)(1), 93 Stat. 596; Aug. 13, 1981, Pub. L. 97–35, title IX, §935(a), 95 Stat. 571; Jan. 4, 1983, Pub. L. 97–414, §8(p), 96 Stat. 2062, made special provisions for certain States and territories.

Section 300n–6, act July 1, 1944, ch. 373, title XV, §1537, as added Aug. 13, 1981, Pub. L. 97–35, title IX, §933(b), 95 Stat. 570, authorized appropriations for grants and contracts under former sections 300l–5(a), 300m–4(a), and 300n–3(a) of this title.

AMENDMENTS

2007—Subsec. (a). Pub. L. 110–18 struck out "and" after "$150,000,000 for fiscal year 1994," and inserted before period at end ", $225,000,000 for fiscal year 2008, $245,000,000 for fiscal year 2009, $250,000,000 for fiscal year 2010, $255,000,000 for fiscal year 2011, and $275,000,000 for fiscal year 2012".

1998—Subsec. (a). Pub. L. 105–340 substituted "2003" for "1998".

1993—Pub. L. 103–183, §102(b), inserted "for general program" after "Funding" in section catchline.

Subsec. (a). Pub. L. 103–183, §103, struck out "and" after "1991," and inserted before period at end ", $150,000,000 for fiscal year 1994, and such sums as may be necessary for each of the fiscal years 1995 through 1998".

SUBCHAPTER XIV—HEALTH RESOURCES DEVELOPMENT

§§300*o* to 300*o*–3. Repealed. Pub. L. 96–79, title II, §202(a), Oct. 4, 1979, 93 Stat. 632

Sections 300o to 300o–3, act July 1, 1944, ch. 373, title XVI, §§1601–1604, as added Jan. 4, 1975, Pub. L. 93–641, §4, 88 Stat. 2258–2260; amended Aug. 1, 1977, Pub. L. 95–83, title I, §106(r)–(v), 91 Stat. 385, were repealed by Pub. L. 96–79, title II, §202(a), Oct. 4, 1979, 93 Stat. 632.

Section 300o related to statement of purpose.

Section 300o–1 provided for promulgation of regulations and required provisions.

Section 300o–2 related to State medical facilities plans, submission and approval of plans as prerequisite for approval of project assistance applications, required provisions, and procedure upon disapproval of plans.

Section 300o–3 provided for medical facility project applications, covering in submission of applications, required provisions, waivers, and projects subject to requirements, criteria for approval, procedure for disapproval, amendment of approved applications, and review by health systems agencies.

STATUTORY NOTES AND RELATED SUBSIDIARIES

EFFECTIVE DATE OF REPEAL

Repeal effective Oct. 1, 1979, see section 204 of Pub. L. 96–79, set out as an Effective Date of 1979 Amendment note under section 300q of this title.

§§300p to 300p–3. Repealed. Pub. L. 96–79, title II, §201(a), Oct. 4, 1979, 93 Stat. 630

Sections 300p to 300p–3, act July 1, 1944, ch. 373, title XVI, §§1610–1613, as added Jan. 4, 1975, Pub. L. 93–641, §4, 88 Stat. 2262–2264; amended Apr. 22, 1976, Pub. L. 94–278, title XI, §1106(b), 90 Stat. 416; Aug. 1, 1977, Pub. L. 95–83, title I, §§103(a), 106(w), 91 Stat. 383, 385, were repealed by Pub. L. 96–79, title II, §201(a), Oct. 4, 1979, 93 Stat. 632.

Section 300p related to allotments to States for health resources development.

Section 300p–1 related to payments to States for approved medical facility projects.

Section 300p–2 related to compliance provisions and withholding of payments for noncompliance.

Section 300p–3 authorized appropriations for allotments to States.

STATUTORY NOTES AND RELATED SUBSIDIARIES

EFFECTIVE DATE OF REPEAL

Repeal effective Oct. 1, 1979, see section 204 of Pub. L. 96–79, set out as an Effective Date of 1979 Amendment note under section 300q of this title.

PART A—LOANS AND LOAN GUARANTEES

EDITORIAL NOTES

CODIFICATION

Pub. L. 96–79, title II, §202(a), Oct. 4, 1979, 93 Stat. 632, repealed part A relating to purpose, State plan, and project approval, and comprising former sections 300o to 300o–3 of this title, and redesignated former part C as part A relating to loans and loan guarantees.

§300q. Loan and loan guarantee authority

(a) Covered projects: duration; payment of principal and interest on loans for covered projects: duration; payments for reduction of interest rate

(1) The Secretary, during the period ending September 30, 1982, may, in accordance with this part, make loans from the fund established under section 300q–2(d) of this title to any public or nonprofit private entity for projects for—

(A) the discontinuance of unneeded hospital services or facilities,[1]

(B) the conversion of unneeded hospital services and facilities to needed health services and medical facilities, including outpatient medical facilities and facilities for long-term care;

(C) the renovation and modernization of medical facilities, particularly projects for the prevention or elimination of safety hazards, projects to avoid noncompliance with licensure or accreditation standards, or projects to replace obsolete facilities;

(D) the construction of new outpatient medical facilities; and

(E) the construction of new inpatient medical facilities in areas which have experienced (as determined by the Secretary) recent rapid population growth.

(2)(A) The Secretary, during the period ending September 30, 1982, may, in accordance with this part, guarantee to—

(i) non-Federal lenders for their loans to public and nonprofit private entities for medical facilities projects described in paragraph (1), and

(ii) the Federal Financing Bank for its loans to public and nonprofit private entities for such projects,

payment of principal and interest on such loans.

(B) In the case of a guarantee of any loan to a public or nonprofit private entity under subparagraph (A)(i) which is located in an urban or rural poverty area, the Secretary may pay, to the holder of such loan and for and on behalf of the project for which the loan was made, amounts sufficient to reduce by not more than one half the net effective interest rate otherwise payable on such loan if the Secretary finds that without such assistance the project could not be undertaken.

(b) Amount of loans for medical facilities projects and such projects in urban or rural poverty areas

The principal amount of a loan directly made or guaranteed under subsection (a) for a medical facilities project, when added to any other assistance provided such project under part B, may not exceed 90 per centum of the cost of such project unless the project is located in an area determined by the Secretary to be an urban or rural poverty area, in which case the principal amount, when added to other assistance under part B, may cover up to 100 per centum of such costs.

(c) Limitation on cumulative total of principal of outstanding loans

The cumulative total of the principal of the loans outstanding at any time with respect to which guarantees have been issued, or which have been directly made, may not exceed such limitations as may be specified in appropriation Acts.

(d) Administrative assistance of Department of Housing and Urban Development

The Secretary, with the consent of the Secretary of Housing and Urban Development, shall obtain from the Department of Housing and Urban Development such assistance with respect to the administration of this part as will promote efficiency and economy thereof.

(July 1, 1944, ch. 373, title XVI, §1601, formerly §1620, as added Pub. L. 93–641, §4, Jan. 4, 1975, 88 Stat. 2264; amended Pub. L. 94–273, §2(21), Apr. 21, 1976, 90 Stat. 376; Pub. L. 95–83, title I, §106(x)(1), Aug. 1, 1977, 91 Stat. 385; renumbered §1601 and amended Pub. L. 96–79, title II, §§201(b)(1), 203(a)(1), (2), Oct. 4, 1979, 93 Stat. 630, 635.)

EDITORIAL NOTES

PRIOR PROVISIONS

A prior section 1601 of act July 1, 1944, ch. 373, title XVI, as added Jan. 4, 1975, Pub. L. 93–641, §4, 88 Stat. 2258, was classified to section 300o of this title, prior to repeal by Pub. L. 96–79, §202(a).

AMENDMENTS

1979—Subsec. (a). Pub. L. 96–79, §§201(b)(1), 203(a)(2), added par. (1); substituted reference to section 1602(d) for 1622(d), set out in text as "section 300q–2(d) of this title"; incorporated in par. (2) former subsec. (b) provisions made applicable for period ending Sept. 30, 1982, previously covering period beginning July 1, 1974, and ending Sept. 30, 1978, extended provisions to public entities, struck out existing condition that applications for assistance under subchapter be approved under former section 300o–3 of this title, substituted

in subpar. (2)(B) provision for payment of amounts sufficient to reduce by not more than one half net effective interest otherwise payable on the loan for prior provision for amounts sufficient to reduce by 3 per centum per annum net effective interest rate on the loan, and struck out provision granting contractual right of holder of a guaranteed loan to receive from the United States such interest payments.

Subsec. (b). Pub. L. 96–79, §201(b)(1), added subsec. (b) and incorporated existing provisions of subsec. (b) relating to loan guarantee authority for payment of principal and interest on loans for approved projects, their duration, and payments for reduction of interest rate in subsec. (a)(2) of this section.

1977—Subsecs. (a), (b)(1). Pub. L. 95–83 substituted "September 30, 1978" for "September 30, 1977".

1976—Subsecs. (a), (b)(1). Pub. L. 94–273 substituted "September" for "June".

STATUTORY NOTES AND RELATED SUBSIDIARIES

EFFECTIVE DATE OF 1979 AMENDMENT

Pub. L. 96–79, title II, §204, Oct. 4, 1979, 93 Stat. 636, provided that: "The amendments made by this title [enacting sections 300s, 300s–1, and 300s–6, amending this section and sections 201, 300q–2, 300r, 300s–1a, 300s–3, and 300s–5, and repealing sections 300o to 300o–3, 300p to 300p–3, 300q–1, and 300s of this title] shall take effect October 1, 1979, except that the amendments made by section 201(b) [amending this section and section 300q–2 of this title] respecting the payment of an interest subsidy for a loan or loan guarantee made under part A of title XVI of the Public Health Service Act [42 U.S.C. 300q et seq.] shall apply only with respect to loans and loan guarantees made after October 1, 1979, and with respect to loans and loan guarantees made under such part before such date the Secretary shall continue to pay the interest subsidy authorized for such loans and loan guarantees before such date."

[1] So in original. The comma probably should be a semicolon.

§300q–1. Repealed. Pub. L. 96–79, title II, §203(a)(1), Oct. 4, 1979, 93 Stat. 635

Section, act July 1, 1944, ch. 373, title XVI, §1621, as added Jan. 4, 1975, Pub. L. 93–641, §4, 88 Stat. 2265, related to allocation among States of total amount of principal, criteria, availability of unobligated amounts, and reallotments.

STATUTORY NOTES AND RELATED SUBSIDIARIES

EFFECTIVE DATE OF REPEAL

Repeal effective Oct. 1, 1979, see section 204 of Pub. L. 96–79, set out as an Effective Date of 1979 Amendment note under section 300q of this title.

§300q–2. General provisions

(a) Loan guarantees; criteria for approval; recovery of payments by United States; modification, etc., of terms and conditions; incontestability

(1) The Secretary may not approve a loan guarantee for a project under this part unless he determines that (A) the terms, conditions, security (if any), and schedule and amount of repayments with respect to the loan are sufficient to protect the financial interests of the United States and are otherwise reasonable, including a determination that the rate of interest does not exceed such per centum per annum on the principal obligation outstanding as the Secretary determines to be reasonable, taking into account the range of interest rates prevailing in the private market for similar loans and the risks assumed by the United States, and (B) the loan would not be available on reasonable terms and conditions without the guarantee under this part.

(2)(A) The United States shall be entitled to recover from the applicant for a loan guarantee under this part the amount of any payment made pursuant to such guarantee, unless the Secretary for good

cause waives such right of recovery; and, upon making any such payment, the United States shall be subrogated to all of the rights of the recipient of the payments with respect to which the guarantee was made.

(B) To the extent permitted by subparagraph (C), any terms and conditions applicable to a loan guarantee under this part (including terms and conditions imposed under subparagraph (D)) may be modified by the Secretary to the extent he determines it to be consistent with the financial interest of the United States.

(C) Any loan guarantee made by the Secretary under this part shall be incontestable (i) in the hands of an applicant on whose behalf such guarantee is made unless the applicant engaged in fraud or misrepresentation in securing such guarantee, and (ii) as to any person (or his successor in interest) who makes or contracts to make a loan to such applicant in reliance thereon unless such person (or his successor in interest) engaged in fraud or misrepresentation in making or contracting to make such loan.

(D) Guarantees of loans under this part shall be subject to such further terms and conditions as the Secretary determines to be necessary to assure that the purposes of this subchapter will be achieved.

(b) Loans; criteria for approval; terms and conditions; waiver of recovery of payments by United States

(1) The Secretary may not approve a loan under this part unless—

(A) the Secretary is reasonably satisfied that the applicant under the project for which the loan would be made will be able to make payments of principal and interest thereon when due, and

(B) the applicant provides the Secretary with reasonable assurances that there will be available to it such additional funds as may be necessary to complete the project or undertaking with respect to which such loan is requested.

(2) Any loan made under this part shall (A) have such security, (B) have such maturity date, (C) be repayable in such installments, (D) bear interest at a rate comparable to the current rate of interest prevailing, on the date the loan is made, with respect to loans guaranteed under this part, minus any interest subsidy made in accordance with section 300q(a)(2)(B) of this title with respect to a loan made for a project located in an urban or rural poverty area, and (E) be subject to such other terms and conditions (including provisions for recovery in case of default), as the Secretary determines to be necessary to carry out the purposes of this subchapter while adequately protecting the financial interests of the United States.

(3) The Secretary may, for good cause but with due regard to the financial interests of the United States, waive any right of recovery which he has by reasons of the failure of a borrower to make payments of principal of and interest on a loan made under this part, except that if such loan is sold and guaranteed, any such waiver shall have no effect upon the Secretary's guarantee of timely payment of principal and interest.

(c) Sale of loans; authority; amount; agreements with purchasers; deposit of proceeds

(1) The Secretary shall from time to time, but with due regard to the financial interests of the United States, sell loans made under this part either on the private market or to the Federal National Mortgage Association in accordance with section 1717 of title 12 or to the Federal Financing Bank.

(2) Any loan so sold shall be sold for an amount which is equal (or approximately equal) to the amount of the unpaid principal of such loans as of time of sale.

(3)(A) The Secretary is authorized to enter into an agreement with the purchaser of any loan sold under this part under which the Secretary agrees—

(i) to guarantee to such purchaser (and any successor in interest to such purchaser) payments of the principal and interest payable under such loan, and

(ii) to pay as an interest subsidy to such purchaser (and any successor in interest of such purchaser) amounts which, when added to the amount of interest payable on such loan, are equivalent to a reasonable rate of interest on such loan as determined by the Secretary after taking into account the range of prevailing interest rates in the private market on similar loans and the risks assumed by the United States.

(B) Any agreement under subparagraph (A)—

(i) may provide that the Secretary shall act as agent of any such purchaser, for the purpose of collecting from the entity to which such loan was made and paying over to such purchaser any payments of principal and interest payable by such entity under such loan;

(ii) may provide for the repurchase by the Secretary of any such loan on such terms and conditions as may be specified in the agreement;

(iii) shall provide that, in the event of any default by the entity to which such loan was made in payment of principal or interest due on such loan, the Secretary shall, upon notification to the purchaser (or to the successor in interest of such purchaser), have the option to close out such loan (and any obligations of the Secretary with respect thereto) by paying to the purchaser (or his successor in interest) the total amount of outstanding principal and interest due thereon at the time of such notification; and

(iv) shall provide that, in the event such loan is closed out as provided in clause (iii), or in the event of any other loss incurred by the Secretary by reason of the failure of such entity to make payments of principal or interest on such loan, the Secretary shall be subrogated to all rights of such purchaser for recovery of such loss from such entity.

(4) Amounts received by the Secretary as proceeds from the sale of loans under this subsection shall be deposited in the fund established under subsection (d).

(5) If any loan to a public entity under this part is sold and guaranteed by the Secretary under this subsection, interest paid on such loan after its sale and any interest subsidy paid, under paragraph (3)(A)(ii), by the Secretary with respect to such loan which is received by the purchaser of the loan (or the purchaser's successor in interest) shall be included in the gross income of the purchaser or successor for the purpose of chapter 1 of title 26.

(d) Loan and loan guarantee fund; establishment; amounts authorized to be appropriated; issuance, purchase, and sale of notes, obligations, etc.; interest rates; public debt transactions

(1) There is established in the Treasury a loan and loan guarantee fund (hereinafter in this subsection referred to as the "fund") which shall be available to the Secretary without fiscal year limitation, in such amounts as may be specified from time to time in appropriations Acts—

(A) to enable him to make loans under this part,

(B) to enable him to discharge his responsibilities under loan guarantees issued by him under this part,

(C) for payment of interest under section 300q(a)(2)(B) of this title on loans guaranteed under this part,

(D) for repurchase of loans under subsection (c)(3)(B),

(E) for payment of interest on loans which are sold and guaranteed, and

(F) to enable the Secretary to take the action authorized by subsection (f).

There are authorized to be appropriated from time to time such amounts as may be necessary to provide the sums required for the fund. There shall also be deposited in the fund amounts received by the Secretary in connection with loans and loan guarantees under this part and other property or assets derived by him from his operations respecting such loans and loan guarantees, including any money derived from the sale of assets.

(2) If at any time the sums in the funds are insufficient to enable the Secretary—

(A) to make payments of interest under section 300q(a)(2)(B) of this title,

(B) to otherwise comply with guarantees under this part of loans to nonprofit private entities,

(C) in the case of a loan which was made, sold, and guaranteed under this part, to make to the purchaser of such loan payments of principal and interest on such loan after default by the entity to which the loan was made, or

(D) to repurchase loans under subsection (c)(3)(B),

(E) to make payments of interest on loans which are sold and guaranteed, and

(F) to enable the Secretary to take the action authorized by subsection (f),

he is authorized to issue to the Secretary of the Treasury notes or other obligations in such forms and denominations, bearing such maturities, and subject to such terms and conditions, as may be prescribed by the Secretary with the approval of the Secretary of the Treasury. Such notes or other obligations shall bear interest at a rate determined by the Secretary of the Treasury, taking into consideration the current average market yield on outstanding marketable obligations of the United States of comparable maturities during the month preceding the issuance of the notes or other obligations. The Secretary of the Treasury shall purchase any notes and other obligations issued under this paragraph and for that purpose he may use as a public debt transaction the proceeds from the sale of any securities issued under chapter 31 of title 31, and the purposes for which the securities may be issued under that chapter are extended to include any purchase of such notes and obligations. The Secretary of the Treasury may at any time sell any of the notes or other obligations acquired by him under this paragraph. All redemptions, purchases, and sales by the Secretary of the Treasury of such notes or other obligations shall be treated as public debt transactions of the United States. Sums borrowed under this paragraph shall be deposited in the fund and redemption of such notes and obligations shall be made by the Secretary from the fund.

(e) Transfers to and additional capitalization of loan and loan guarantee fund

(1) The assets, commitments, obligations, and outstanding balances of the loan guarantee and loan fund established in the Treasury by section 291j–6 of this title shall be transferred to the fund established by subsection (d) of this section.

(2) To provide additional capitalization for the fund established under subsection (d) there are authorized to be appropriated to the fund, such sums as may be necessary for the fiscal years ending June 30, 1975, June 30, 1976, September 30, 1977, September 30, 1978, September 30, 1979, September 30, 1980, September 30, 1981, and September 30, 1982.

(f) Default prevention measures; terms and conditions; implementation of reforms; foreclosures; protection of Federal interest on default

(1) The Secretary may take such action as may be necessary to prevent a default on a loan made or guaranteed under this part or under subchapter IV, including the waiver of regulatory conditions, deferral of loan payments, renegotiation of loans, and the expenditure of funds for technical and consultative assistance, for the temporary payment of the interest and principal on such a loan, and for other purposes. Any such expenditure made under the preceding sentence on behalf of a medical facility shall be made under such terms and conditions as the Secretary shall prescribe, including the implementation of such organizational, operational, and financial reforms as the Secretary determines are appropriate and the disclosure of such financial or other information as the Secretary may require to determine the extent of the implementation of such reforms.

(2) The Secretary may take such action, consistent with State law respecting foreclosure procedures, as he deems appropriate to protect the interest of the United States in the event of a default on a loan made or guaranteed under this part or under subchapter IV, including selling real property pledged as security for such a loan or loan guarantee and for a reasonable period of time taking possession of, holding, and using real property pledged as security for such a loan or loan guarantee.

(July 1, 1944, ch. 373, title XVI, §1602, formerly §1622, as added Pub. L. 93–641, §4, Jan. 4, 1975, 88 Stat. 2265; amended Pub. L. 95–83, title I, §106(x)(2), (y), Aug. 1, 1977, 91 Stat. 385; renumbered §1602 and amended Pub. L. 96–79, title II, §§201(b)(2), (3), 203(a)(1), (3), (g), Oct. 4, 1979, 93 Stat. 631, 635; Pub. L. 97–414, §8(q), Jan. 4, 1983, 96 Stat. 2062; Pub. L. 99–514, §2, Oct. 22, 1986, 100 Stat. 2095.)

EDITORIAL NOTES

CODIFICATION

In subsec. (d), "chapter 31 of title 31" and "that chapter" substituted for "the Second Liberty Bond Act" and

"that Act", respectively, on authority of Pub. L. 97–258, §4(b), Sept. 13, 1982, 96 Stat. 1067, the first section of which enacted Title 31, Money and Finance.

PRIOR PROVISIONS

A prior section 1602 of act July 1, 1944, ch. 373, title XVI, as added Jan. 4, 1975, Pub. L. 93–641, §4, 88 Stat. 2258; amended Aug. 1, 1977, Pub. L. 95–83, title I, §106(r), (s), 91 Stat. 385, was classified to section 300o–1 of this title, prior to repeal by Pub. L. 96–79, title II, §202(a), Oct. 4, 1979, 93 Stat. 632.

AMENDMENTS

1986—Subsec. (c)(5). Pub. L. 99–514 substituted "Internal Revenue Code of 1986" for "Internal Revenue Code of 1954", which for purposes of codification was translated as "title 26" thus requiring no change in text.

1983—Subsec. (f)(2). Pub. L. 97–414 inserted "selling real property pledged as security for such a loan or loan guarantee and" after "including".

1979—Subsec. (b)(2)(D). Pub. L. 96–79, §201(b)(2), substituted "minus any interest subsidy made in accordance with section 300q(a)(2)(B) of this title (with respect to a loan made for a project located in an urban or rural poverty area" for "minus 3 per centum per annum".

Subsec. (d)(1). Pub. L. 96–79, §203(a)(3), (g)(2), substituted in subpar. (C) reference to section "300q(a)(2)(B)" for "300q(b)(2)" of this title, and added subpar. (F).

Subsec. (d)(2). Pub. L. 96–79, §203(a)(3), (g)(3), substituted in subpar. (A) reference to section "300q(a)(2)(B)" for "300q(b)(2)" of this title, and added subpar. (F).

Subsec. (e)(2). Pub. L. 96–79, §201(b)(3), authorized appropriations for fiscal years ending Sept. 30, 1979 through 1982.

Subsec. (f). Pub. L. 96–79, §203(g)(1), added subsec. (f).

1977—Subsec. (c)(5). Pub. L. 95–83, §106(y), added subsec. (c)(5).

Subsec. (e)(2). Pub. L. 95–83, §106(x)(2), substituted provisions authorizing appropriations for fiscal years ending Sept. 30, 1977 and 1978, for prior such authorization for fiscal year ending June 30, 1977.

STATUTORY NOTES AND RELATED SUBSIDIARIES

EFFECTIVE DATE OF 1979 AMENDMENT

Amendment by Pub. L. 96–79 effective Oct. 1, 1979, except that amendment of subsec. (b)(2)(D) respecting interest subsidy payments for loans or loan guarantees applicable only with respect to loans and loan guarantees made after Oct. 1, 1979, and that subsidies for such commitments made before Oct. 1, 1979, payable as authorized before Oct. 1, 1979, see section 204 of Pub. L. 96–79, set out as a note under section 300q of this title.

PART B—PROJECT GRANTS

EDITORIAL NOTES

CODIFICATION

Pub. L. 96–79, title II, §§201(a), 202(a), Oct. 4, 1979, 93 Stat. 630, 632, repealed part B relating to allotments, and comprising former sections 300p to 300p–3 of this title, and redesignated former part D as part B relating to project grants.

§300r. Grants for construction or modernization projects

(a) Authority; objectives; eligible grantees; maximum amounts; authorization of appropriations; availability of unobligated funds

(1)(A) The Secretary may make grants for construction or modernization projects designed to—

(i) eliminate or prevent in medical facilities imminent safety hazards as defined by Federal, State, or local fire, building, or life safety codes or regulations, or

(ii) avoid noncompliance by medical facilities with State or voluntary licensure or accreditation

standards.

(B) A grant under subparagraph (A) may only be made to—

(i) a State or political subdivision of a State, including any city, town, county, borough, hospital district authority, or public or quasi-public corporation, for any medical facility owned or operated by the State or political subdivision; and

(ii) a nonprofit private entity for any medical facility owned or operated by the entity but only if the Secretary determines—

(I) the level of community service provided by the facility and the proportion of its patients who are unable to pay for services rendered in the facility is similar to such level and proportion in a medical facility of a State or political subdivision, and

(II) that without a grant under subparagraph (A) there would be a disruption of the provision of health care to low-income individuals.

(2) The amount of any grant under paragraph (1) may not exceed 75 per centum of the cost of the project for which the grant is made unless the project is located in an area determined by the Secretary to be an urban or rural poverty area, in which case the grant may cover up to 100 per centum of such costs.

(3) There are authorized to be appropriated for grants under paragraph (1) $40,000,000 for the fiscal year ending September 30, 1980, $50,000,000 for the fiscal year ending September 30, 1981, and $50,000,000 for the fiscal year ending September 30, 1982. Funds available for obligation under this subsection (as in effect before October 4, 1979) in the fiscal year ending September 30, 1979, shall remain available for obligation under this subsection in the succeeding fiscal year.

(b) Projects for medically underserved populations; eligible grantees; maximum amounts; authorization of appropriations

(1) The Secretary may make grants to public and nonprofit private entities for projects for (A) construction or modernization of outpatient medical facilities which are located apart from hospitals and which will provide services for medically underserved populations, and (B) conversion of existing facilities into outpatient medical facilities or facilities for long-term care to provide services for such populations.

(2) The amount of any grant under paragraph (1) may not exceed 80 per centum of the cost of the project for which the grant is made unless the project is located in an area determined by the Secretary to be an urban or rural poverty area, in which case the grant may cover up to 100 per centum of such costs.

(3) There are authorized to be appropriated for grants under paragraph (1) $15,000,000 for the fiscal year ending September 30, 1981, and $15,000,000 for the fiscal year ending September 30, 1982.

(July 1, 1944, ch. 373, title XVI, §1610, formerly §1625, as added Pub. L. 93–641, §4, Jan. 4, 1975, 88 Stat. 2268; amended Pub. L. 95–83, title I, §103(b), Aug. 1, 1977, 91 Stat. 383; renumbered §1610 and amended Pub. L. 96–79, title II, §§201(c), 203(b), Oct. 4, 1979, 93 Stat. 631, 635.)

EDITORIAL NOTES

PRIOR PROVISIONS

A prior section 1610 of act July 1, 1944, ch. 373, title XVI, as added Jan. 4, 1975, Pub. L. 93–641, §4, 88 Stat. 2262; amended Aug. 1, 1977, Pub. L. 95–83, title I, §106(w), 91 Stat. 385, was classified to section 300p of this title, prior to repeal by Pub. L. 96–79, title II, §201(a), Oct. 4, 1979, 93 Stat. 630.

AMENDMENTS

1979—Subsec. (a). Pub. L. 96–79, §201(c), incorporated existing provisions in par. (1); inserted in subpar. (A) in cls. (i) and (ii) the phrases "in medical facilities" and "by medical facilities"; substituted in subpar.

(B)(i) "for any medical facility owned or operated by the State or political subdivision" for "for a project described in the preceding sentence for any medical facility owned or operated by it"; added cl. (a)(1)(B)(ii); redesignated former subsec. (c) as par. (2); and added par. (3).

Subsec. (b). Pub. L. 96–79, §201(c), inserted provisions respecting projects for medically underserved populations and struck out provisions respecting criteria for approval of applications under former section 300o–3 of this title.

Subsec. (c). Pub. L. 96–79, §201(c), redesignated subsec. (c) as par. (2) of subsec. (a).

Subsec. (d). Pub. L. 96–79, §201(c), struck out subsec. (d) which related to provisions making available 22 per centum of sums appropriated under former section 300p–3 of this title for subsec. (a) grants, including an additional appropriations authorization of $67,500,000 for such grants for fiscal year ending Sept. 30, 1978.

1977—Subsec. (d). Pub. L. 95–83 authorized additional grant appropriations of $67,500,000 for fiscal year ending Sept. 30, 1978.

STATUTORY NOTES AND RELATED SUBSIDIARIES

EFFECTIVE DATE OF 1979 AMENDMENT

Amendment by Pub. L. 96–79 effective Oct. 1, 1979, see section 204 of Pub. L. 96–79, set out as a note under section 300q of this title.

PART C—GENERAL PROVISIONS

EDITORIAL NOTES

CODIFICATION

Pub. L. 96–79, title II, §202(a), Oct. 4, 1979, 93 Stat. 632, redesignated former part E as part C relating to general provisions and former part C as part A.

§300s. General regulations

The Secretary shall by regulation—

(1) prescribe the manner in which he shall determine the priority among projects for which assistance is available under part A or B, based on the relative need of different areas for such projects and giving special consideration—

(A) to projects for medical facilities serving areas with relatively small financial resources and for medical facilities serving rural communities,

(B) in the case of projects for modernization of medical facilities, to projects for facilities serving densely populated areas,

(C) in the case of projects for construction of outpatient medical facilities, to projects that will be located in, and provide services for residents of, areas determined by the Secretary to be rural or urban poverty areas,

(D) to projects designed to (i) eliminate or prevent imminent safety hazards as defined by Federal, State, or local fire, building, or life safety codes or regulations, or (ii) avoid noncompliance with State or voluntary licensure or accreditation standards, and

(E) to projects for medical facilities which, alone or in conjunction with other facilities, will provide comprehensive health care, including outpatient and preventive care as well as hospitalization;

(2) prescribe for medical facilities projects assisted under part A or B general standards of construction, modernization, and equipment, which standards may vary on the basis of the class of facilities and their location; and

(3) prescribe the general manner in which each entity which receives financial assistance under part A or B or has received financial assistance under part A or B or subchapter IV shall be

required to comply with the assurances required to be made at the time such assistance was received and the means by which such entity shall be required to demonstrate compliance with such assurances.

An entity subject to the requirements prescribed pursuant to paragraph (3) respecting compliance with assurances made in connection with receipt of financial assistance shall submit periodically to the Secretary data and information which reasonably supports the entity's compliance with such assurances. The Secretary may not waive the requirement of the preceding sentence.

(July 1, 1944, ch. 373, title XVI, §1620, as added Pub. L. 96–79, title II, §202(b), Oct. 4, 1979, 93 Stat. 632.)

EDITORIAL NOTES

PRIOR PROVISIONS

A prior section 300s, act July 1, 1944, ch. 373, title XVI, §1630, as added Jan. 4, 1975, Pub. L. 93–641, §4, 88 Stat. 2269, provided for judicial review by the United States Court of Appeals, prior to repeal by Pub. L. 96–79, §202(b), eff. Oct. 1, 1979.

A prior section 1620 of act July 1, 1944, was renumbered section 1601 by Pub. L. 96–79, title II, §203(a)(1), Oct. 4, 1979, 93 Stat. 635, and is classified to section 300q of this title.

STATUTORY NOTES AND RELATED SUBSIDIARIES

EFFECTIVE DATE

Section effective Oct. 1, 1979, see section 204 of Pub. L. 96–79, set out as an Effective Date of 1979 Amendment note under section 300q of this title.

§300s–1. Medical facility project applications

(a) Submissions

No loan, loan guarantee, or grant may be made under part A or B for a medical facilities project unless an application for such project has been submitted to and approved by the Secretary. If two or more entities join in a project, an application for such project may be filed by any of such entities or by all of them.

(b) Form; required provisions; waiver; projects subject to requirements

(1) An application for a medical facilities project shall be submitted in such form and manner as the Secretary shall by regulation prescribe and shall, except as provided in paragraph (2), set forth—

(A) in the case of a modernization project for a medical facility for continuation of existing health services, a finding by the State Agency of a continued need for such services, and, in the case of any other project for a medical facility, a finding by the State Agency of the need for the new health services to be provided through the medical facility upon completion of the project;

(B) in the case of an application for a grant, assurances satisfactory to the Secretary that (i) the applicant making the application would not be able to complete the project for which the application is submitted without the grant applied for, and (ii) in the case of a project to construct a new medical facility, it would be inappropriate to convert an existing medical facility to provide the services to be provided through the new medical facility;

(C) in the case of a project for the discontinuance of a service or facility or the conversion of a service or a facility, an evaluation of the impact of such discontinuance or conversion on the provision of health care in the health service area in which such service was provided or facility located;

(D) a description of the site of such project;

(E) plans and specifications therefor which meet the requirements of the regulations prescribed under section 300s(2) of this title;

(F) reasonable assurance that title to such site is or will be vested in one or more of the entities filing the application or in a public or other nonprofit entity which is to operate the facility on completion of the project;

(G) reasonable assurance that adequate financial support will be available for the completion of the project and for its maintenance and operation when completed, and, for the purpose of determining if the requirements of this subparagraph are met, Federal assistance provided directly to a medical facility which is located in an area determined by the Secretary to be an urban or rural poverty area or through benefits provided individuals served at such facility shall be considered as financial support;

(H) the type of assistance being sought under part A or B for the project;

(I) reasonable assurance that all laborers and mechanics employed by contractors or subcontractors in the performance of work on a project will be paid wages at rates not less than those prevailing on similar construction in the locality as determined by the Secretary of Labor in accordance with sections 3141–3144, 3146, and 3147 of title 40, and the Secretary of Labor shall have with respect to such labor standards the authority and functions set forth in Reorganization Plan Numbered 14 of 1950 (15 FR 3176; 5 U.S.C. Appendix) and section 3145 of title 40;

(J) in the case of a project for the construction or modernization of an outpatient facility, reasonable assurance that the services of a general hospital will be available to patients at such facility who are in need of hospital care; and

(K) reasonable assurance that at all times after such application is approved (i) the facility or portion thereof to be constructed, modernized, or converted will be made available to all persons residing or employed in the area served by the facility, and (ii) there will be made available in the facility or portion thereof to be constructed, modernized, or converted a reasonable volume of services to persons unable to pay therefor and the Secretary, in determining the reasonableness of the volume of services provided, shall take into consideration the extent to which compliance is feasible from a financial viewpoint.

(2)(A) The Secretary may waive—

(i) the requirements of subparagraph (D) of paragraph (1) for compliance with modernization and equipment standards prescribed pursuant to section 300s(2) of this title, and

(ii) the requirement of subparagraph (E) of paragraph (1) respecting title to a project site,

in the case of an application for a project described in subparagraph (B) of this paragraph.

(B) A project referred to in subparagraph (A) is a project—

(i) for the modernization of an outpatient medical facility which will provide general purpose health services, which is not part of a hospital, and which will serve a medically underserved population as defined in section 300s–3 of this title or as designated by a health systems agency, and

(ii) for which the applicant seeks a loan under part A the principal amount of which does not exceed $20,000.

(July 1, 1944, ch. 373, title XVI, §1621, as added Pub. L. 96–79, title II, §202(b), Oct. 4, 1979, 93 Stat. 633.)

EDITORIAL NOTES

CODIFICATION

In subsec. (b)(1)(I), "sections 3141–3144, 3146, and 3147 of title 40" substituted for "the Act of March 3, 1931 (40 U.S.C. 276a—276a–5, known as the Davis-Bacon Act)" and "section 3145 of title 40" substituted for "section 2 of the Act of June 13, 1934 (40 U.S.C. 276c)" on authority of Pub. L. 107–217, §5(c), Aug. 21, 2002, 116 Stat. 1303, the first section of which enacted Title 40, Public Buildings, Property, and Works.

PRIOR PROVISIONS

A prior section 300s–1 was redesignated 300s–1a and amended as part of the general revision of this subchapter by Pub. L. 96–79.

A prior section 1621 of act July 1, 1944, as added Jan. 4, 1975, Pub. L. 93–641, §4, 88 Stat. 2265, which related to the allocation among States of the total amount of principal of loans and loan guarantees, was classified to section 300q–1 of this title, prior to repeal as part of the general revision of this subchapter by Pub. L. 96–79.

STATUTORY NOTES AND RELATED SUBSIDIARIES

EFFECTIVE DATE

Section effective Oct. 1, 1979, see section 204 of Pub. L. 96–79, set out as an Effective Date of 1979 Amendment note under section 300q of this title.

§300s–1a. Recovery of expenditures under certain conditions

(a) Persons liable

If any facility with respect to which funds have been paid under this subchapter shall, at any time within 20 years after the completion of construction or modernization—

(1) be sold or transferred to any entity (A) which is not qualified to file an application under section 300s–1 or 300t–12 of this title or (B) which is not approved as a transferee by the State Agency of the State in which such facility is located, or its successor, or

(2) cease to be a public health center or a public or other nonprofit hospital, outpatient facility, facility for long-term care, or rehabilitation facility,

the United States shall be entitled to recover, whether from the transferor or the transferee (or, in the case of a facility which has ceased to be public or nonprofit, from the owners thereof) an amount determined under subsection (c).

(b) Notice to Secretary

The transferor of a facility which is sold or transferred as described in subsection (a)(1), or the owner of a facility the use of which is changed as described in subsection (a)(2), shall provide the Secretary written notice of such sale, transfer, or change not later than the expiration of 10 days from the date on which such sale, transfer, or change occurs.

(c) Amount of recovery; interest; interest period

(1) Except as provided in paragraph (2), the amount the United States shall be entitled to recover under subsection (a) is an amount bearing the same ratio to the then value (as determined by the agreement of the parties or in an action brought in the district court of the United States for the district for which the facility involved is situated) of so much of the facility as constituted an approved project or projects as the amount of the Federal participation bore to the cost of the construction or modernization of such project or projects.

(2)(A) After the expiration of—

(i) 180 days after the date of the sale, transfer, or change of use for which a notice is required by subsection (b) in the case of a facility which is sold or transferred or the use of which changes after July 18, 1984, or

(ii) thirty days after July 18, 1984, or if later 180 days after the date of the sale, transfer, or change of use for which a notice is required by subsection (b), in the case of a facility which was sold or transferred or the use of which changed before July 18, 1984,

the amount which the United States is entitled to recover under paragraph (1) with respect to a facility shall be the amount prescribed by paragraph (1) plus interest, during the period described in subparagraph (B), at a rate (determined by the Secretary) based on the average of the bond equivalent of the weekly 90-day Treasury bill auction rate.

(B) The period referred to in subparagraph (A) is the period beginning—

(i) in the case of a facility which was sold or transferred or the use of which changed before July

18, 1984, thirty days after such date or if later 180 days after the date of the sale, transfer, or change of use for which a notice is required by subsection (b).[1]

(ii) in the case of a facility with respect to which notice is provided in accordance with subsection (b), upon the expiration of 180 days after the receipt of such notice, or

(iii) in the case of a facility with respect to which such notice is not provided as prescribed by subsection (b), on the date of the sale, transfer, or changes of use for which such notice was to be provided,

and ending on the date the amount the United States is entitled to under paragraph (1) is collected.

(d) Waiver

(1) The Secretary may waive the recovery rights of the United States under subsection (a)(1) with respect to a facility in any State if the Secretary determines, in accordance with regulations, that the entity to which the facility was sold or transferred—

(A) has established an irrevocable trust—

(i) in an amount equal to the greater of twice the cost of the remaining obligation of the facility under clause (ii) of section 300s–1(b)(1)(K) of this title or the amount, determined under subsection (c), that the United States is entitled to recover, and

(ii) which will only be used by the entity to provide the care required by clause (ii) of section 300s–1(b)(1)(K) of this title; and

(B) will meet the obligation of the facility under clause (i) of section 300s–1(b)(1)(K) of this title.

(2) The Secretary may waive the recovery rights of the United States under subsection (a)(2) with respect to a facility in any State if the Secretary determines, in accordance with regulations, that there is good cause for waiving such rights with respect to such facility.

(e) Lien

The right of recovery of the United States under subsection (a) shall not constitute a lien on any facility with respect to which funds have been paid under this subchapter.

(July 1, 1944, ch. 373, title XVI, §1622, formerly §1631, as added Pub. L. 93–641, §4, Jan. 4, 1975, 88 Stat. 2269; amended Pub. L. 94–278, title XI, §1106(c), Apr. 22, 1976, 90 Stat. 416; renumbered §1622 and amended Pub. L. 96–79, title II, §§202(b), 203(c), Oct. 4, 1979, 93 Stat. 632, 635; Pub. L. 98–369, div. B. title III, §2381(b), July 18, 1984, 98 Stat. 1114.)

EDITORIAL NOTES

CODIFICATION

Section was formerly classified to section 300s–1 of this title prior to the general revision of this subchapter by Pub. L. 96–79.

PRIOR PROVISIONS

A prior section 1622 of act July 1, 1944, as added Jan. 4, 1975, Pub. L. 93–641, §4, 88 Stat. 2265, was renumbered section 1602 as part of the general revision of this subchapter by Pub. L. 96–79 and is classified to section 300q–2 of this title.

AMENDMENTS

1984—Pub. L. 98–369 amended section generally. Prior to the amendment, section read as follows:

"(a) If any facility constructed, modernized, or converted with funds provided under this subchapter is, at any time within twenty years after the completion of such construction, modernization, or conversion with such funds—

"(1) sold or transferred to any person or entity (A) which is not qualified to file an application under section 300s–1 or 300t–12 of this title or (B) which is not approved as a transferee by the State Agency of the State in which such facility is located, or its successor; or

"(2) not used as a medical facility, and the Secretary has not determined that there is good cause for termination of such use,

the United States shall be entitled to recover from either the transferor or the transferee in the case of a sale or transfer or from the owner in the case of termination of use an amount bearing the same ratio to the then value (as determined by the agreement of the parties or by action brought in the district court of the United States for the district in which the facility is situated) of so much of such facility as constituted an approved project or projects, as the amount of the Federal participation bore to the cost of the construction, modernization, or conversion of such project or projects. Such right of recovery shall not constitute a lien upon such facility prior to judgment.

"(b) The Secretary may waive the recovery rights of the United States under subsection (a) of this section with respect to a facility in any State—

"(1) if (as determined under regulations prescribed by the Secretary) the amount which could be recovered under subsection (a) of this section with respect to such facility is applied to the development, expansion, or support of another medical facility located in such State which has been approved by the Statewide Health Coordinating Council for such State as consistent with the State health plan established pursuant to section 300m–3(c) of this title; or

"(2) if the Secretary determines, in accordance with regulations, that there is good cause for waiving such requirement with respect to such facility.

If the amount which the United States is entitled to recover under subsection (a) of this section exceeds 90 per centum of the total cost of the construction or modernization project for a facility, a waiver under this subsection shall only apply with respect to an amount which is not more than 90 per centum of such total cost."

1979—Subsec. (a)(1)(A). Pub. L. 96–79, §203(c), substituted "section 300s–1 or 300t–12 of this title" for "section 300o–3 of this title".

STATUTORY NOTES AND RELATED SUBSIDIARIES

EFFECTIVE DATE OF 1979 AMENDMENT

Amendment by Pub. L. 96–79 effective Oct. 1, 1979, see section 204 of Pub. L. 96–79, set out as a note under section 300q of this title.

REGULATIONS AND PERSONNEL

Requirements for regulations and personnel to implement this section, see section 2381(c) of Pub. L. 98–369, set out as a note under section 291i of this title.

[1] *So in original. The period probably should be a comma.*

§300s–2. State supervision or control of operations of facilities receiving funds

Except as otherwise specifically provided, nothing in this subchapter shall be construed as conferring on any Federal officer or employee, the right to exercise any supervision or control over the administration, personnel, maintenance, or operation of any facility with respect to which any funds have been or may be expended under this subchapter.

(July 1, 1944, ch. 373, title XVI, §1623, formerly §1632, as added Pub. L. 93–641, §4, Jan. 4, 1975, 88 Stat. 2270; renumbered §1623, Pub. L. 96–79, title II, §202(b), Oct. 4, 1979, 93 Stat. 632.)

§300s–3. Definitions

Except as provided in section 300t–12(e) of this title, for purposes of this subchapter—

(1) The term "hospital" includes general, tuberculosis, and other types of hospitals, and related facilities, such as laboratories, outpatient departments, nurses' home facilities, extended care facilities, facilities related to programs for home health services, self-care units, and central service

facilities, operated in connection with hospitals, and also includes education or training facilities for health professonal [1] personnel operated as an integral part of a hospital, but does not include any hospital furnishing primarily domiciliary care.

(2) The term "public health center" means a publicly owned facility for the provision of public health services, including related publicly owned facilities such as laboratories, clinics, and administrative offices operated in connection with such a facility.

(3) The term "nonprofit" as applied to any facility means a facility which is owned and operated by one or more nonprofit corporations or associations no part of the net earnings of which inures, or may lawfully inure, to the benefit of any private shareholder or individual.

(4) The term "outpatient medical facility" means a medical facility (located in or apart from a hospital) for the diagnosis or diagnosis and treatment of ambulatory patients (including ambulatory inpatients)—

(A) which is operated in connection with a hospital,

(B) in which patient care is under the professional supervision of persons licensed to practice medicine or surgery in the State, or in the case of dental diagnosis or treatment, under the professional supervision of persons licensed to practice dentistry in the State; or

(C) which offers to patients not requiring hospitalization the services of licensed physicians in various medical specialties, and which provides to its patients a reasonably full-range of diagnostic and treatment services.

(5) The term "rehabilitation facility" means a facility which is operated for the primary purpose of assisting in the rehabilitation of disabled persons through an integrated program of—

(A) medical evaluation and services, and

(B) psychological, social, or vocational evaluation and services,

under competent professional supervision, and in the case of which the major portion of the required evaluation and services is furnished within the facility; and either the facility is operated in connection with a hospital, or all medical and related health services are prescribed by, or are under the general direction of, persons licensed to practice medicine or surgery in the State.

(6) The term "facility for long-term care" means a facility (including a skilled nursing or intermediate care facility) providing in-patient care for convalescent or chronic disease patients who required skilled nursing or intermediate care and related medical services—

(A) which is a hospital (other than a hospital primarily for the care and treatment of mentally ill or tuberculous patients) or is operated in connection with a hospital, or

(B) in which such care and medical services are prescribed by, or are performed under the general direction of, persons licensed to practice medicine or surgery in the State.

(7) The term "construction" means construction of new buildings and initial equipment of such buildings and, in any case in which it will help to provide a service not previously provided in the community, equipment of any buildings; including architects' fees, but excluding the cost of off-site improvements and, except with respect to public health centers, the cost of the acquisition of land.

(8) The term "cost" as applied to construction, modernization, or conversion means the amount found by the Secretary to be necessary for construction, modernization, or conversion, respectively, under a project, except that, in the case of a modernization project or a project assisted under part B, such term does not include any amount found by the Secretary to be attributable to expansion of the bed capacity of any facility.

(9) The term "modernization" includes the alteration, expansion, major repair (to the extent permitted by regulations), remodeling, replacement, and renovation of existing buildings (including initial equipment thereof), and the replacement of obsolete equipment of existing buildings.

(10) The term "title," [2] when used with reference to a site for a project, means a fee simple, or such other estate or interest (including a leasehold on which the rental does not exceed 4 per centum of the value of the land) as the Secretary finds sufficient to assure for a period of not less than twenty-five years' undisturbed use and possession for the purposes of construction, modernization, or

conversion and operation of the project for a period of not less than (A) twenty years in the case of a project assisted under an allotment or grant under this subchapter, or (B) the term of repayment of a loan made or guaranteed under this subchapter in the case of a project assisted by a loan or loan guarantee.

(11) The term "medical facility" means a hospital, public health center, outpatient medical facility, rehabilitation facility, facility for long-term care, or other facility (as may be designated by the Secretary) for the provision of health care to ambulatory patients.

(12) The term "State Agency" means the State health planning and development agency of a State designated under subchapter XIII.[3]

(13) The term "urban or rural poverty area" means an urban or rural geographical area (as defined by the Secretary) in which a percentage (as defined by the Secretary in accordance with the next sentence) of the residents of the area have incomes below the poverty level (as defined by the Secretary of Commerce). The percentage referred to in the preceding sentence shall be defined so that the percentage of the population of the United States residing in urban and rural poverty areas is—

(A) not more than the percentage of the total population of the United States with incomes below the poverty level (as so defined) plus five per centum, and

(B) not less than such percentage minus five per centum.

(14) The term "medically underserved population" means the population of an urban or rural area designated by the Secretary as an area with a shortage of health facilities or a population group designated by the Secretary as having a shortage of such facilities.

(July 1, 1944, ch. 373, title XVI, §1624, formerly §1633, as added Pub. L. 93–641, §4, Jan. 4, 1975, 88 Stat. 2270; amended Pub. L. 94–484, title IX, §905(b)(1), Oct. 12, 1976, 90 Stat. 2325; Pub. L. 95–83, title I, §106(z), Aug. 1, 1977, 91 Stat. 386; renumbered §1624 and amended Pub. L. 96–79, title II, §§202(b), 203(e)(1), title III, §301(b), Oct. 4, 1979, 93 Stat. 632, 635, 640.)

EDITORIAL NOTES

REFERENCES IN TEXT

Subchapter XIII, referred to in par. (12), was repealed effective Jan. 1, 1987, by Pub. L. 99–660, title VII, §701(a), Nov. 14, 1986, 100 Stat. 3799.

CODIFICATION

"Part B" substituted for "Part D" in par. (8) pursuant to the redesignation of former part D of this subchapter as B by Pub. L. 96–79, title II, §202(a), Oct. 4, 1979, 93 Stat. 632.

AMENDMENTS

1979—Pub. L. 96–79, §301(b), inserted "Except as provided in section 300t–12(e) of this title".

Pars. (1) to (16). Pub. L. 96–79, §203(e)(1), struck out pars. (1) and (2) which defined "State" and "Federal share" and redesignated pars. (3) through (16) as pars. (1) through (14), respectively.

1977—Par. (14). Pub. L. 95–83 substituted "subchapter XIII" for "subchapter XII".

1976—Par. (1). Pub. L. 94–484 defined "State" to include Northern Mariana Islands.

STATUTORY NOTES AND RELATED SUBSIDIARIES

EFFECTIVE DATE OF 1979 AMENDMENT

Amendment by Pub. L. 96–79 effective Oct. 1, 1979, see section 204 of Pub. L. 96–79, set out as a note under section 300q of this title.

[1] So in original. Probably should be "professional".

[2] So in original. The comma probably should follow the ending quotations.

[3] *See References in Text note below.*

§300s–4. Reporting and audit requirements for recipients

(a) Filing of financial statement with appropriate State Agency; form and contents

In the case of any facility for which an allotment payment, grant, loan, or loan guarantee has been made under this subchapter, the applicant for such payment, grant, loan, or loan guarantee (or, if appropriate, such other person as the Secretary may prescribe) shall file at least annually with the State Agency for the State in which the facility is located a statement which shall be in such form, and contain such information, as the Secretary may require to accurately show—

(1) the financial operations of the facility, and

(2) the costs of the facility of providing health services in the facility and the charges made by the facility for providing such services,

during the period with respect to which the statement is filed.

(b) Maintenance of records; access to books, etc., for audit and examination

(1) Each entity receiving Federal assistance under this subchapter shall keep such records as the Secretary shall prescribe, including records which fully disclose the amount and disposition by such entity of the proceeds of such assistance, the total cost of the project in connection with which such assistance is given or used, the amount of that portion of the cost of the project supplied by other sources, and such other records as will facilitate an effective audit.

(2) The Secretary and the Comptroller General of the United States, or any of their duly authorized representatives, shall have access for the purpose of audit and examination to any books, documents, papers, and records of such entities which in the opinion of the Secretary or the Comptroller General may be related or pertinent to the assistance referred to in paragraph (1).

(c) Filing of financial statement with Secretary; form and contents

Each such entity shall file at least annually with the Secretary a statement which shall be in such form, and contain such information, as the Secretary may require to accurately show—

(1) the financial operations of the facility constructed or modernized with such assistance, and

(2) the costs to such facility of providing health services in such facility, and the charges made for such services, during the period with respect to which the statement is filed.

(July 1, 1944, ch. 373, title XVI, §1625, formerly §1634, as added Pub. L. 93–641, §4, Jan. 4, 1975, 88 Stat. 2273; renumbered §1625, Pub. L. 96–79, title II, §202(b), Oct. 4, 1979, 93 Stat. 632.)

EDITORIAL NOTES

PRIOR PROVISIONS

A prior section 1625 of act July 1, 1944, was renumbered section 1610 by Pub. L. 96–79, title II, §203(b), Oct. 4, 1979, 93 Stat. 635, and is classified to section 300r of this title.

§300s–5. Availability of technical and other nonfinancial assistance to eligible applicants

The Secretary shall provide (either through the Department of Health and Human Services or by contract) all necessary technical and other nonfinancial assistance to any public or other entity which is eligible to apply for assistance under this subchapter to assist such entity in developing applications to be submitted to the Secretary under section 300s–1 or 300t–12 of this title. The Secretary shall make every effort to inform eligible applicants of the availability of assistance under this subchapter.

(July 1, 1944, ch. 373, title XVI, §1626, formerly §1635, as added Pub. L. 93–641, §4, Jan. 4, 1975, 88 Stat. 2273; renumbered §1626 and amended Pub. L. 96–79, title II, §§202(b), 203(f), Oct. 4, 1979, 93 Stat. 632, 635; Pub. L. 96–88, title V, §509(b), Oct. 17, 1979, 93 Stat. 695.)

EDITORIAL NOTES

AMENDMENTS

1979—Pub. L. 96–79, §203(f), substituted "other entity" for "other nonprofit entity" and "section 300s–1 or 300t–12 of this title" for "section 300o–3 of this title."

STATUTORY NOTES AND RELATED SUBSIDIARIES

CHANGE OF NAME

"Department of Health and Human Services" substituted in text for "Department of Health, Education, and Welfare" pursuant to section 509(b) of Pub. L. 96–88, which is classified to section 3508(b) of Title 20, Education.

EFFECTIVE DATE OF 1979 AMENDMENT

Amendment by Pub. L. 96–79 effective Oct. 1, 1979, see section 204 of Pub. L. 96–79, set out as a note under section 300q of this title.

§300s–6. Enforcement of assurances

The Secretary shall investigate and ascertain, on a periodic basis, with respect to each entity which is receiving financial assistance under this subchapter or which has received financial assistance under subchapter IV or this subchapter, the extent of compliance by such entity with the assurances required to be made at the time such assistance was received. If the Secretary finds that such an entity has failed to comply with any such assurance, the Secretary shall report such noncompliance to the health systems agency for the health service area in which such entity is located and the State health planning and development agency of the State in which the entity is located and shall take any action authorized by law (including an action for specific performance brought by the Attorney General upon request of the Secretary) which will effect compliance by the entity with such assurances. An action to effectuate compliance with any such assurance may be brought by a person other than the Secretary only if a complaint has been filed by such person with the Secretary and the Secretary has dismissed such complaint or the Attorney General has not brought a civil action for compliance with such assurance within six months after the date on which the complaint was filed with the Secretary.

(July 1, 1944, ch. 373, title XVI, §1627, as added Pub. L. 96–79, title II, §202(c), Oct. 4, 1979, 93 Stat. 634.)

STATUTORY NOTES AND RELATED SUBSIDIARIES

EFFECTIVE DATE

Section effective Oct. 1, 1979, see section 204 of Pub. L. 96–79, set out as an Effective Date of 1979 Amendment note under section 300q of this title.

PART D—AREA HEALTH SERVICES DEVELOPMENT FUNDS

EDITORIAL NOTES

CODIFICATION

Pub. L. 96–79, title II, §202(a), Oct. 4, 1979, 93 Stat. 632, redesignated former part F as part D relating to area health services development funds and former part D as part B.

§300t. Development grants for health systems agencies

(a) Eligible recipients; purpose of grants

The Secretary shall make in each fiscal year a grant to each health system agency—

(1) with which there is in effect a designation agreement under section 300*l*–4(c) [1] of this title,

(2) which has in effect an HSP and AIP reviewed by the Statewide Health Coordinating Council, and

(3) which, as determined under the review made under section 300n–4(c) [1] of this title, is organized and operated in the manner prescribed by section 300*l*–1(b) [1] of this title and is performing its functions under section 300*l*–2 [1] of this title in a manner satisfactory to the Secretary,

to enable the agency to establish and maintain an Area Health Service Development Fund from which it may make grants and enter into contracts in accordance with section 300*l*–2(c)(3) [1] of this title.

(b) Determination of amounts; maximum amounts

(1) Except as provided in paragraph (2), the amount of any grant under subsection (a) shall be determined by the Secretary after taking into consideration the population of the health service area for which the health systems agency is designated, the average family income of the area, and the supply of health services in the area.

(2) The amount of any grant under subsection (a) to a health systems agency for any fiscal year may not exceed the product of $1 and the population of the health service area for which such agency is designated.

(c) Applications; submission and approval as prerequisite; form and contents

No grant may be made under subsection (a) unless an application therefor has been submitted to, and approved by, the Secretary. Such an application shall be submitted in such form and manner and contain such information as the Secretary may require.

(d) Authorization of appropriations

For the purpose of making payments pursuant to grants under subsection (a), there are authorized to be appropriated $25,000,000 for the fiscal year ending June 30, 1975, $75,000,000 for the fiscal year ending June 30, 1976, $120,000,000 each for the fiscal years ending September 30, 1977, and September 30, 1978, $20,000,000 for the fiscal year ending September 30, 1981, and $30,000,000 for the fiscal year ending September 30, 1982.

(July 1, 1944, ch. 373, title XVI, §1640, as added Pub. L. 93–641, §4, Jan. 4, 1975, 88 Stat. 2273; amended Pub. L. 95–83, title I, §103(c), Aug. 1, 1977, 91 Stat. 383; Pub. L. 96–79, title I, §127(e), Oct. 4, 1979, 93 Stat. 629.)

EDITORIAL NOTES

REFERENCES IN TEXT

Sections 300l–2, 300l–4, and 300n–4 of this title, referred to in subsec. (a), were repealed effective Jan. 1, 1987, by Pub. L. 99–660, title VII, §701(a), Nov. 14, 1986, 100 Stat. 3799.

Section 300l–1 of this title, referred to in subsec. (a)(3), was in the original a reference to section 1512 of act July 1, 1944, which was repealed effective Jan. 1, 1987, by Pub. L. 99–660, title VII, §701(a), Nov. 14, 1986, 100 Stat. 3799. Pub. L. 102–531, title III, §307, Oct. 27, 1992, 106 Stat. 3495, enacted section 1502A of act July 1, 1944, which is classified to section 300l–1 of this title.

AMENDMENTS

1979—Subsec. (d). Pub. L. 96–79 authorized appropriations of $20,000,000 for fiscal year ending Sept. 30, 1981, and $30,000,000 for fiscal year ending Sept. 30, 1982.

1977—Subsec. (d). Pub. L. 95–83 substituted "each for the fiscal years ending September 30, 1977, and September 30, 1978" for "for the fiscal year ending June 30, 1977".

[1] *See References in Text note below.*

PART E—PROGRAM TO ASSIST AND ENCOURAGE VOLUNTARY DISCONTINUANCE OF UNNEEDED HOSPITAL SERVICES AND CONVERSION OF UNNEEDED HOSPITAL SERVICES TO OTHER HEALTH SERVICES NEEDED BY COMMUNITY

EDITORIAL NOTES

CODIFICATION

Pub. L. 96–79, title II, §202(a), title III, §301(a), Oct. 4, 1979, 93 Stat. 632, 636, added part E relating to program to assist and encourage voluntary discontinuance of unneeded hospital services and conversion of unneeded hospital services to other health services needed by the community and redesignated former part E as part C.

§300t–11. Grants and assistance for establishment of program

The Secretary shall, by April 1, 1980, establish a program under which—

(1) grants and technical assistance may be provided to hospitals in operation on October 4, 1979, (A) for the discontinuance of unneeded hospital services, and (B) for the conversion of unneeded hospital services to other health services needed by the community; and

(2) grants may be provided to State Agencies designated under section 300m(b)(3) [1] of this title for reducing excesses in resources and facilities of hospitals.

(July 1, 1944, ch. 373, title XVI, §1641, as added Pub. L. 96–79, title III, §301(a), Oct. 4, 1979, 93 Stat. 636.)

EDITORIAL NOTES

REFERENCES IN TEXT

Section 300m of this title, referred to in par. (2), was in the original a reference to section 1521 of act July 1, 1944, which was repealed effective Jan. 1, 1987, by Pub. L. 99–660, title VII, §701(a), Nov. 14, 1986, 100 Stat. 3799. Pub. L. 101–354, §2, Aug. 10, 1990, 104 Stat. 410, enacted section 1503 of act July 1, 1944, which is classified to section 300m of this title.

STATUTORY NOTES AND RELATED SUBSIDIARIES

UNNEEDED HOSPITAL SERVICES; STUDY AND REPORT OF EFFECT OF ELIMINATION

Section 302 of Pub. L. 96–79, as amended by Pub. L. 96–88, title V, §509(b), Oct. 17, 1979, 93 Stat. 695, which provided that the Secretary of Health and Human Services conduct a study of the effect on the elimination of unneeded hospital services made during the two fiscal year period ending Sept. 30, 1981, by the program authorized by this part, and not later than Jan. 1, 1982, report the results of the study to Congress, was repealed by Pub. L. 97–414, §9(h), Jan. 4, 1983, 96 Stat. 2064.

[1] *See References in Text note below.*

§300t–12. Grants for discontinuance and conversion

(a) Terms and conditions; determination of amount; authorized uses

(1) A grant to a hospital under the program shall be subject to such terms and conditions as the Secretary may by regulation prescribe to assure that the grant is used for the purpose for which it was made.

(2) The amount of any such grant shall be determined by the Secretary. The recipient of such a grant may use the grant—

(A) in the case of a grantee which discontinues the provision of all hospital services or all inpatient hospital services or an identifiable part of a hospital facility which provides inpatient hospital services, for the liquidation of the outstanding debt on the facilities of the grantee used for the provision of the services or for the liquidation of the outstanding debt of the grantee on such identifiable part;

(B) in the case of a grantee which in discontinuing the provision of an inpatient hospital service converts or proposes to convert an identifiable part of a hospital facility used in the provision of the discontinued service to the delivery of other health services, for the planning, development (including construction and acquisition of equipment), and delivery of the health service;

(C) to provide reasonable termination pay for personnel of the grantee who will lose employment because of the discontinuance of hospital services made by the grantee, retraining of such personnel, assisting such personnel in securing employment, and other costs of implementing arrangements described in subsection (c); and

(D) for such other costs which the Secretary determines may need to be incurred by the grantee in discontinuing hospital services.

(b) Application; submission and approval; form; required provisions; review by health systems agency; basis of State Agency's recommendations; urban or rural poverty population considerations; approval by Secretary; restrictions and special considerations

(1) No grant may be made to a hospital unless an application therefor is submitted to and approved by the Secretary. Such an application shall be in such form and submitted in such manner as the Secretary may prescribe and shall include—

(A) a description of each service to be discontinued and, if a part of a hospital is to be discontinued or converted to another use in connection with such discontinuance, a description of such part;

(B) an evaluation of the impact of such discontinuance and conversion on the provision of health care in the health service area in which such service is provided;

(C) an estimate of the change in the applicant's costs which will result from such discontinuance and conversion; and

(D) reasonable assurance that all laborers and mechanics employed by contractors or subcontractors in the performance of work on a project will be paid wages at rates not less than those prevailing on similar construction in the locality as determined by the Secretary of Labor in accordance with sections 3141–3144, 3146, and 3147 of title 40, and the Secretary of Labor shall have with respect to such labor standards the authority and functions set forth in Reorganization Plan Numbered 14 of 1950 (15 FR 3176; 5 U.S.C. Appendix) and section 3145 of title 40;

(E) such other information as the Secretary may require.

(2)(A) The health systems agency for the health service area in which is located a hospital applying for a grant under the program shall (i) in making the review of the applicant's application under section 300l–2(e) [1] of this title, determine the need for each service or part proposed to be discontinued by the applicant, (ii) in the case of an application for the conversion of a facility, determine the need for each service which will be provided as a result of the conversion, and (iii) make a recommendation to the State Agency for the State in which the applicant is located respecting approval by the Secretary of the applicant's application.

(B) A State Agency which has received a recommendation from a health systems agency under subparagraph (A) respecting an application shall, after consideration of such recommendation, make a recommendation to the Secretary respecting the approval by the Secretary of the application. A State Agency's recommendation under this subparagraph respecting the approval of an application (i) shall be based upon (I) the need for each service or part proposed to be discontinued by the applicant, (II) in the case of an application for the conversion of a facility, the need for each service which will be provided as a result of the conversion, and (III) such other criteria as the Secretary may prescribe, and (ii) shall be accompanied by the health systems agency's recommendation made with respect to the approval of the application.

(C) In determining, under subparagraphs (A) and (B), the need for the service (or services) or part proposed to be discontinued or converted by an applicant for a grant, a health systems agency and State Agency shall give special consideration to the unmet needs and existing access patterns of urban or rural poverty populations.

(3)(A) The Secretary may not approve an application of a hospital for a grant—

(i) if a State Agency recommended that the application not be approved, or

(ii) if the Secretary is unable to determine that the cost of providing inpatient health services in the health service area in which the applicant is located will be less than if the inpatient health services proposed to be discontinued were not discontinued.

(B) In considering applications of hospitals for grants the Secretary shall consider the recommendations of health systems agencies and State Agencies and shall give special consideration to applications (i) which will assist health systems agencies and State Agencies to meet the goals in their health systems plans and State health plans, or (ii) which will result in the greatest reduction in hospital costs within a health service area.

(c) Certification of protective arrangements for employment benefits and interests; guidelines; satisfactory arrangement determinations

(1) Except as provided in paragraph (3), the Secretary may not approve an application submitted under subsection (b) unless the Secretary of Labor has certified that fair and equitable arrangements have been made to protect the interests of employees affected by the discontinuance of services against a worsening of their positions with respect to their employment, including arrangements to preserve the rights of employees under collective-bargaining agreements, continuation of collective-bargaining rights consistent with the provisions of the National Labor Relations Act [29 U.S.C. 151 et seq.], reassignment of affected employees to other jobs, retraining programs, protecting pension, health benefits, and other fringe benefits of affected employees, and arranging adequate severance pay, if necessary.

(2) The Secretary of Labor shall by regulation prescribe guidelines for arrangements for the protection of the interests of employees affected by the discontinuance of hospital services. The Secretary of Labor shall consult with the Secretary of Health and Human Services in the promulgation of such guidelines. Such guidelines shall first be promulgated not later than the promulgation of regulations by the Secretary for the administration of the grants authorized by section 300t–11 of this title.

(3) The Secretary of Labor shall review each application submitted under subsection (b) to determine if the arrangements described in paragraph (1) have been made and if they are satisfactory and shall notify the Secretary respecting his determination. Such review shall be completed within—

(A) ninety days from the date of the receipt of the application from the Secretary of Health and Human Services, or

(B) one hundred and twenty days from such date if the Secretary of Labor has by regulation prescribed the circumstances under which the review will require at least one hundred and twenty days.

If within the applicable period, the Secretary of Labor does not notify the Secretary of Health and Human Services respecting his determination, the Secretary of Health and Human Services shall review the application to determine if the applicant has made the arrangements described in

paragraph (1) and if such arrangements are satisfactory. The Secretary may not approve the application unless he determines that such arrangements have been made and that they are satisfactory.

(d) Records and audits requirements

The records and audits requirements of section 292e [1] of this title shall apply with respect to grants made under subsection (a).

(e) "Hospital" defined

For purposes of this part, the term "hospital" means, with respect to any fiscal year, an institution (including a distinct part of an institution participating in the programs established under title XVIII of the Social Security Act [42 U.S.C. 1395 et seq.])—

(1) which satisfies paragraphs (1) and (7) of section 1861(e) of such Act [42 U.S.C. 1395x(e)],

(2) imposes charges or accepts payments for services provided to patients, and

(3) the average duration of a patient's stay in which was thirty days or less in the preceding fiscal year,

but such term does not include a Federal hospital or a psychiatric hospital (as described in section 1861(f)(1) of the Social Security Act [42 U.S.C. 1395x(f)(1)]).

(July 1, 1944, ch. 373, title XVI, §1642, as added Pub. L. 96–79, title III, §301(a), Oct. 4, 1979, 93 Stat. 637; amended Pub. L. 96–88, title V, §509(b), Oct. 17, 1979, 93 Stat. 695.)

EDITORIAL NOTES

REFERENCES IN TEXT

Section 300l–2 of this title, referred to in subsec. (b)(2)(A), was repealed effective Jan. 1, 1987, by Pub. L. 99–660, title VII, §701(a), Nov. 14, 1986, 100 Stat. 3799.

The National Labor Relations Act, referred to in subsec. (c)(1), is act July 5, 1935, ch. 372, 49 Stat. 452, which is classified generally to subchapter II (§151 et seq.) of chapter 7 of Title 29, Labor. For complete classification of this Act to the Code, see section 167 of Title 29 and Tables.

Section 292e of this title, referred to in subsec. (d), was in the original a reference to section 705 of act July 1, 1944. Section 705 of that Act was omitted in the general revision of subchapter V of this chapter by Pub. L. 102–408, title I, §102, Oct. 13, 1992, 106 Stat. 1994. Pub. L. 102–408 enacted a new section 705 of act July 1, 1944, relating to eligibility of borrowers and terms of insured loans, and a new section 706, relating to certificates of loan insurance, which are classified to sections 292d and 292e, respectively, of this title.

The Social Security Act, referred to in subsec. (e), is act Aug. 14, 1935, ch. 531, 49 Stat. 620. Title XVIII of the Social Security Act is classified generally to subchapter XVIII (§1395 et seq.) of chapter 7 of this title. For complete classification of this Act to the Code, see section 1305 of this title and Tables.

CODIFICATION

In subsec. (b)(1)(D), "sections 3141–3144, 3146, and 3147 of title 40" substituted for "the Act of March 3, 1931 (40 U.S.C. 276a—276a–5, known as the Davis-Bacon Act)" and "section 3145 of title 40" substituted for "section 2 of the Act of June 13, 1934 (40 U.S.C. 276c)" on authority of Pub. L. 107–217, §5(c), Aug. 21, 2002, 116 Stat. 1303, the first section of which enacted Title 40, Public Buildings, Property, and Works.

STATUTORY NOTES AND RELATED SUBSIDIARIES

CHANGE OF NAME

"Secretary of Health and Human Services" substituted for "Secretary of Health, Education, and Welfare" in subsecs. (a), (b), and (c) pursuant to section 509(b) of Pub. L. 96–88, which is classified to section 3508(b) of Title 20, Education.

[1] *See References in Text note below.*

§300t–13. Grants to States for reduction of excess hospital capacity

(a) "Excess hospital capacity" defined; particular activities

For the purpose of demonstrating the effectiveness of various means for reducing excesses in resources and facilities of hospitals (referred to in this section as "excess hospital capacity"), the Secretary may make grants to State Agencies designated under section 300m(b)(3) [1] of this title to assist such Agencies in—

(1) identifying (by geographic region or by health service) excess hospital capacity,

(2) developing programs to inform the public of the costs associated with excess hospital capacity,

(3) developing programs to reduce excess hospital capacity in a manner which will produce the greatest savings in the cost of health care delivery,

(4) developing means to overcome barriers to the reduction of excess hospital capacity,

(5) in planning, evaluating, and carrying out programs to decertify health care facilities providing health services that are not appropriate, and

(6) any other activity related to the reduction of excess hospital capacity.

(b) Terms and conditions

Grants under subsection (a) shall be made on such terms and conditions as the Secretary may prescribe.

(July 1, 1944, ch. 373, title XVI, §1643, as added Pub. L. 96–79, title III, §301(a), Oct. 4, 1979, 93 Stat. 639.)

EDITORIAL NOTES

REFERENCES IN TEXT

Section 300m of this title, referred to in subsec. (a), was in the original a reference to section 1521 of act July 1, 1944, which was repealed effective Jan. 1, 1987, by Pub. L. 99–660, title VII, §701(a), Nov. 14, 1986, 100 Stat. 3799. Pub. L. 101–354, §2, Aug. 10, 1990, 104 Stat. 410, enacted section 1503 of act July 1, 1944, which is classified to section 300m of this title.

[1] *See References in Text note below.*

§300t–14. Authorization of appropriations

To make payments under grants under sections 300t–12 and 300t–13 of this title there are authorized to be appropriated $30,000,000 for the fiscal year ending September 30, 1980, $50,000,000 for the fiscal year ending September 30, 1981, and $75,000,000 for the fiscal year ending September 30, 1982, except that in any fiscal year not more than 10 percent of the amount appropriated under this section may be obligated for grants under section 300t–13 of this title.

(July 1, 1944, ch. 373, title XVI, §1644, as added Pub. L. 96–79, title III, §301(a), Oct. 4, 1979, 93 Stat. 640.)

SUBCHAPTER XV—HEALTH INFORMATION AND HEALTH PROMOTION

§300u. General authority of Secretary

(a) Development, support, and implementation of programs, activities, etc.

The Secretary shall—

(1) formulate national goals, and a strategy to achieve such goals, with respect to health information and health promotion, preventive health services, and education in the appropriate use of health care;

(2) analyze the necessary and available resources for implementing the goals and strategy formulated pursuant to paragraph (1), and recommend appropriate educational and quality assurance policies for the needed manpower resources identified by such analysis;

(3) undertake and support necessary activities and programs to—

(A) incorporate appropriate health education components into our society, especially into all aspects of education and health care,

(B) increase the application and use of health knowledge, skills, and practices by the general population in its patterns of daily living, and

(C) establish systematic processes for the exploration, development, demonstration, and evaluation of innovative health promotion concepts;

(4) undertake and support research and demonstrations respecting health information and health promotion, preventive health services, and education in the appropriate use of health care;

(5) undertake and support appropriate training in, and undertake and support appropriate training in the operation of programs concerned with, health information and health promotion, preventive health services, and education in the appropriate use of health care;

(6) undertake and support, through improved planning and implementation of tested models and evaluation of results, effective and efficient programs respecting health information and health promotion, preventive health services, and education in the appropriate use of health care;

(7)(A) develop model programs through which employers in the public sector, and employers that are small businesses (as defined in section 632 of title 15), can provide for their employees a program to promote healthy behaviors and to discourage participation in unhealthy behaviors;

(B) provide technical assistance to public and private employers in implementing such programs (including private employers that are not small businesses and that will implement programs other than the programs developed by the Secretary pursuant to subparagraph (A)); and

(C) in providing such technical assistance, give preference to small businesses;

(8) foster the exchange of information respecting, and foster cooperation in the conduct of, research, demonstration, and training programs respecting health information and health promotion, preventive health services, and education in the appropriate use of health care;

(9) provide technical assistance in the programs referred to in paragraph (8);

(10) use such other authorities for programs respecting health information and health promotion, preventive health services, and education in the appropriate use of health care as are available and coordinate such use with programs conducted under this subchapter; and

(11) establish in the Office of the Assistant Secretary for Health an Office of Disease Prevention and Health Promotion, which shall—

(A) coordinate all activities within the Department which relate to disease prevention, health promotion, preventive health services, and health information and education with respect to the appropriate use of health care;

(B) coordinate such activities with similar activities in the private sector;

(C) establish a national information clearinghouse to facilitate the exchange of information concerning matters relating to health information and health promotion, preventive health services (which may include information concerning models and standards for insurance coverage of such services), and education in the appropriate use of health care, to facilitate access to such information, and to assist in the analysis of issues and problems relating to such matters; and

(D) support projects, conduct research, and disseminate information relating to preventive medicine, health promotion, and physical fitness and sports medicine.

The Secretary shall appoint a Director for the Office of Disease Prevention and Health Promotion

established pursuant to paragraph (11) of this subsection. The Secretary shall administer this subchapter in cooperation with health care providers, educators, voluntary organizations, businesses, and State and local health agencies in order to encourage the dissemination of health information and health promotion activities.

(b) Authorization of appropriations

For the purpose of carrying out this section and sections 300u–1 through 300u–4 of this title, there are authorized to be appropriated $10,000,000 for fiscal year 1992, and such sums as may be necessary for each of the fiscal years 1993 through 2002.

(c) Application; submission and approval as prerequisite; form and content

No grant may be made or contract entered into under this subchapter unless an application therefor has been submitted to and approved by the Secretary. Such an application shall be submitted in such form and manner and contain such information as the Secretary may prescribe. Contracts may be entered into under this subchapter without regard to section 3324(a) and (b) of title 31 and section 6101 of title 41.

(July 1, 1944, ch. 373, title XVII, §1701, as added Pub. L. 94–317, title I, §102, June 23, 1976, 90 Stat. 695; amended Pub. L. 96–32, §7(n), July 10, 1979, 93 Stat. 85; Pub. L. 96–76, title II, §209, Sept. 29, 1979, 93 Stat. 584; Pub. L. 98–551, §2(a), Oct. 30, 1984, 98 Stat. 2815; Pub. L. 100–607, title III, §312(a)(1), (b)(1), (c), Nov. 4, 1988, 102 Stat. 3113, 3114; Pub. L. 102–168, title I, §101, Nov. 26, 1991, 105 Stat. 1102; Pub. L. 102–531, title III, §311(b)(1), Oct. 27, 1992, 106 Stat. 3503; Pub. L. 105–392, title IV, §414, Nov. 13, 1998, 112 Stat. 3590.)

EDITORIAL NOTES

CODIFICATION

In subsec. (c), "section 3324(a) and (b) of title 31 and section 6101 of title 41" substituted for "sections 3648 and 3709 of the Revised Statutes (31 U.S.C. 529; 41 U.S.C. 5)" on authority of Pub. L. 97–258, §4(b), Sept. 13, 1982, 96 Stat. 1067, which Act enacted Title 31, Money and Finance, and Pub. L. 111–350, §6(c), Jan. 4, 2011, 124 Stat. 3854, which Act enacted Title 41, Public Contracts.

AMENDMENTS

1998—Subsec. (b). Pub. L. 105–392 substituted "2002" for "1996".

1992—Subsec. (a)(11)(C). Pub. L. 102–531 substituted "preventive health services (which may include information concerning models and standards for insurance coverage of such services)," for "preventive health services,".

1991—Subsec. (b). Pub. L. 102–168 amended subsec. (b) generally. Prior to amendment, subsec. (b) read as follows: "To carry out sections 300u through 300u–4 of this title, there are authorized to be appropriated $9,000,000 for the fiscal year ending September 30, 1985, $9,500,000 for the fiscal year ending September 30, 1986, $10,000,000 for the fiscal year ending September 30, 1987, and $10,000,000 for each of the fiscal years 1989 through 1991."

1988—Subsec. (a). Pub. L. 100–607, §312(c)(2), in concluding provisions, struck out "The Secretary shall administer this subchapter in a manner consistent with the national health priorities set forth in section 300k–2 of this title." before "The Secretary shall appoint", and substituted "paragraph (11)" for "paragraph (10)".

Subsec. (a)(7), (8). Pub. L. 100–607, §312(b)(1), added par. (7) and redesignated former par. (7) as (8). Former par. (8) redesignated (9).

Subsec. (a)(9). Pub. L. 100–607, §312(c)(1), substituted "paragraph (8)" for "paragraph (7)".

Pub. L. 100–607, §312(b)(1)(A), redesignated par. (8) as (9). Former par. (9) redesignated (10).

Subsec. (a)(10), (11). Pub. L. 100–607, §312(b)(1)(A), redesignated pars. (9) and (10) as (10) and (11), respectively.

Subsec. (b). Pub. L. 100–607, §312(a)(1), substituted "sections 300u through 300u–4 of this title" for "this subchapter", struck out "and" after "September 30, 1986,", and inserted ", and $10,000,000 for each of the fiscal years 1989 through 1991".

1984—Subsec. (a). Pub. L. 98–551, §2(a)(1), added par. (10), and in provisions following par. (10) struck out "and with health planning and resource development activities undertaken under subchapters XIII and XIV of this chapter" after "section 300k–2 of this title" and inserted provisions for appointment of a Director for

Office of Disease Prevention and Health Promotion and cooperation in administration of this subchapter.

Subsec. (b). Pub. L. 98–551, §2(a)(2), substituted "To carry out this subchapter, there are authorized to be appropriated $9,000,000 for the fiscal year ending September 30, 1985, $9,500,000 for the fiscal year ending September 30, 1986, and $10,000,000 for the fiscal year ending September 30, 1987" for "For payments under grants and contracts under this subchapter (other than grants and contracts under sections 300u–6, 300u–7, and 300u–8 of this title) there are authorized to be appropriated $7,000,000 for the fiscal year ending September 30, 1977, $10,000,000 for the fiscal year ending September 30, 1978, $14,000,000 for the fiscal year ending September 30, 1979, $14,000,000 for the fiscal year ending September 30, 1980, $15,000,000 for the fiscal year ending September 30, 1981, and $16,000,000 for the fiscal year ending September 30, 1982."

1979—Subsec. (b). Pub. L. 96–76 inserted provisions authorizing appropriations for fiscal years ending Sept. 30, 1980, Sept. 30, 1981, and Sept. 30, 1982.

Pub. L. 96–32 inserted "(other than grants and contracts under sections 300u–6, 300u–7, and 300u–8 of this title)" after "grants and contracts under this subchapter".

STATUTORY NOTES AND RELATED SUBSIDIARIES

SHORT TITLE

For short title of title I of Pub. L. 94–317, which enacted this subchapter as the "National Consumer Health Information and Health Promotion Act of 1976", see section 101 of Pub. L. 94–317, set out as a Short Title of 1976 Amendments note under section 201 of this title.

MODEL PROGRAMS FOR EMPLOYEE HEALTH PROMOTION AND DISEASE PREVENTION; DEVELOPMENT COMPLETION

Section 312(b)(2) of Pub. L. 100–607 required Secretary of Health and Human Services, not later than 18 months after Nov. 4, 1988, to complete development of model programs required in section 1701(a)(7)(A) of the Public Health Service Act (subsec. (a)(7)(A) of this section).

EXECUTIVE DOCUMENTS

EXECUTIVE ORDER NO. 12345

Ex. Ord. No. 12345, Feb. 2, 1982, 47 F.R. 5189, as amended by Ex. Ord. No. 12539, Dec. 3, 1985, 50 F.R. 49829; Ex. Ord. No. 12694, Oct. 11, 1989, 54 F.R. 42285; Ex. Ord. No. 12709, Apr. 4, 1990, 55 F.R. 13097; Ex. Ord. No. 13138, §8, Sept. 30, 1999, 64 F.R. 53881, which provided for the Secretary of Health and Human Services to develop and coordinate a national program for physical fitness and sports, continued the President's Council on Physical Fitness and Sports, and provided for termination of the Council on Dec. 31, 1982, was revoked by Ex. Ord. No. 13265, §5(h), formerly §5(c), June 6, 2002, 67 F.R. 39842, as renumbered and amended by Ex. Ord. No. 14327, §2(c), 90 F.R. 37995.

EX. ORD. NO. 13265. PRESIDENT'S COUNCIL ON SPORTS, FITNESS, AND NUTRITION, AND THE REESTABLISHMENT OF THE PRESIDENTIAL FITNESS TEST

Ex. Ord. No. 13265, June 6, 2002, 67 F.R. 39841, as amended by Ex. Ord. No. 13545, June 22, 2010, 75 F.R. 37283; Ex. Ord. No. 13824, Feb. 26, 2018, 83 F.R. 8923; Ex. Ord. No. 14048, §7, Sept. 30, 2021, 86 F.R. 55467; Ex. Ord. No. 14327, July 31, 2025, 90 F.R. 37933, provided:

By the authority vested in me as President by the Constitution and the laws of the United States of America, and to establish the President's Council on Sports, Fitness, and Nutrition, and to reestablish the Presidential Fitness Test, it is hereby ordered:

SECTION 1. *Purpose*. As the United States prepares to celebrate its semiquincentennial anniversary in 2026, we must address the threat to the vitality and longevity of our country that is posed by America's declining health and physical fitness. For far too long, the physical and mental health of the American people has been neglected. Rates of obesity, chronic disease, inactivity, and poor nutrition are at crisis levels, particularly among our children. These trends weaken our economy, military readiness, academic performance, and national morale. President Eisenhower recognized this issue when he created the President's Council on Youth Fitness in response to reports on the poor state of youth fitness in America. As President-elect, John F. Kennedy famously published an essay titled "The Soft American," which outlined the imperative for improved health in order to maintain a strong and vital America. During my first term, I renamed the council the "President's Council on Sports, Fitness, and Nutrition" and directed the development of a National Youth Sports Strategy, among other activities.

My Administration has taken decisive action to reverse this health crisis. In the first month of my second term, I created the President's Make America Healthy Again Commission to restore the urgency of improving the health of Americans. Now, we build further. To advance this commitment, I hereby reestablish the Presidential Fitness Test, which shall be administered by the Secretary of Health and Human Services with the support of the Secretary of Education.

With this order, I revitalize the President's Council on Sports, Fitness, and Nutrition as a cornerstone of our national health renewal. In 2026, we will celebrate the 250th anniversary of our great Nation, honor the 70th anniversary of the original President's Council on Youth Fitness, and showcase America's continued global dominance in sports. Over the next 3 years, America will host the Ryder Cup, the President's Cup, the FIFA World Cup, and the Olympic Games—the world's premiere sporting competitions. These events will provide inspiration for all generations of Americans.

SEC. 2. *Policy*. It is the policy of my Administration to:

(a) prioritize and expand children's participation in youth sports and active play;

(b) promote the physical, mental, and civic benefits of daily movement, exercise, and good nutrition; and

(c) engage every sector—public and private, civilian and military—in creating a national culture of strength, vitality, and excellence.

SEC. 3. *President's Council on Sports, Fitness, and Nutrition*. (a) There is hereby established the President's Council on Sports, Fitness, and Nutrition (Council).

(b) The Council shall consist of up to 30 members appointed by the President. Members shall serve for a term of 2 years, shall be eligible for reappointment, and may continue to serve after the expiration of their terms until the appointment of a successor. The President may designate one or more of the members as Chair or Vice Chair.

(c) The President shall designate an Executive Director of the Council who shall manage day-to-day operations; serve as a liaison to the President on matters and activities pertaining to the Council; and oversee engagement with executive departments and agencies, athletic institutions, and community partners.

SEC. 4. *Functions of the Council*. (a) The Council shall advise the President concerning progress made in carrying out the provisions of this order and shall recommend to the President actions to accelerate such progress.

(b) In advising the President pursuant to subsection (a) of this section, the Council shall recommend:

(i) strategies for reestablishing the Presidential Fitness Test, with any appropriate improvements, as the main assessment tool for a Presidential Fitness Award;

(ii) strategies for the development and promotion of Presidential challenges and school-based programs that reward excellence in physical education;

(iii) actions to expand opportunities at the global, national, State, and local levels for participation in sports and engagement in physical fitness;

(iv) bold and innovative fitness goals for American youth with the aim of fostering a new generation of healthy, active citizens;

(v) campaigns and events that elevate American sports, military readiness, and health traditions;

(vi) opportunities at the global, national, State, and local levels that expand participation in sports and emphasize the importance of an active lifestyle and good nutrition, which should include partnerships with professional athletes, sports organizations, player's associations, influential figures, nonprofit organizations, and community groups to inspire all Americans, among other initiatives; and

(vii) strategies to address the growing national security threat posed by the increasing rates of childhood obesity, chronic diseases, and sedentary lifestyles, which threaten the future readiness of the United States workforce and military.

SEC. 5. *Administration*. (a) Each executive department and agency shall, to the extent permitted by law and subject to the availability of funds, furnish such information and assistance to the Council as it may request.

(b) Members of the Council shall serve without compensation but may receive travel reimbursement, including per diem in lieu of subsistence, as allowed under applicable law (5 U.S.C. 5701–5707), consistent with the availability of funds.

(c) The Department of Health and Human Services shall provide such funding and administrative and technical support as the Council may require, to the extent permitted by law and as authorized by existing appropriations.

(d) The Council may, with the approval of the President, establish subcommittees as appropriate to aid in its work.

(e) The seal prescribed by Executive Order 10830 of July 24, 1959 (Establishing a Seal for the President's Council on Physical Fitness and Sports), as amended, shall be modified to reflect the name of the Council as established by this order.

(f) Insofar as the Federal Advisory Committee Act, as amended (5 U.S.C. 1001 et seq.) (the "Act"), may apply to the administration of any portion of this order, any functions of the President under the Act, except that of reporting to the Congress, shall be performed by the Secretary of Health and Human Services in accordance with the guidelines and procedures issued by the Administrator of General Services.

(g) In accordance with the Act, the Council shall terminate 2 years from the date of this order [July 31, 2025], unless extended by the President.

(h) Executive Order 12345 of February 2, 1982 (Physical Fitness and Sports) [formerly set out above], as amended, is revoked.

SEC. 6. *General Provisions*. (a) Nothing in this order shall be construed to impair or otherwise affect:

(i) the authority granted by law to an executive department or agency, or the head thereof; or

(ii) the functions of the Director of the Office of Management and Budget relating to budgetary, administrative, or legislative proposals.

(b) This order shall be implemented consistent with applicable law and subject to the availability of appropriations.

(c) This order is not intended to, and does not, create any right or benefit, substantive or procedural, enforceable at law or in equity by any party against the United States, its departments, agencies, or entities, its officers, employees, or agents, or any other person.

[Ex. Ord. No. 14327, §2(c), (d), which directed amendment of Ex. Ord. No. 13265, set out above, by adding sections 1 to 6 and striking former sections 1 to 5, was executed by striking former sections 1 to 6 to reflect the probable intent of the President.]

[Ex. Ord. No. 13824, §2(c), (d), which directed amendment of Ex. Ord. No. 13265, set out above, by revising sections "1 through 5" and renumbering section 5 as 6 (with additional amendments), was executed by substituting sections 1 to 5 for former sections 1 to 4 and renumbering former section 5 as 6.]

[Ex. Ord. No. 13824, §1, revoked Ex. Ord. No. 13545, which had amended Ex. Ord. No. 13265, set out above.]

EXTENSION OF TERM OF PRESIDENT'S COUNCIL ON SPORTS, FITNESS, AND NUTRITION

Term of President's Council on Sports, Fitness, and Nutrition extended until Sept. 30, 2027, by Ex. Ord. No. 14354, Sept. 29, 2025, 90 F.R. 48145, set out as a note under section 1013 of Title 5, Government Organization and Employees.

Previous extensions of term of President's Council on Sports, Fitness, and Nutrition (formerly President's Council on Fitness, Sports, and Nutrition and President's Council on Physical Fitness and Sports) were contained in the following prior Executive Orders:

Ex. Ord. No. 14109, Sept. 29, 2023, 88 F.R. 68447, extended term until Sept. 30, 2025.
Ex. Ord. No. 14048, Sept. 30, 2021, 86 F.R. 55465, extended term until Sept. 30, 2023.
Ex. Ord. No. 13889, Sept. 27, 2019, 84 F.R. 52743, extended term until Sept. 30, 2021.
Ex. Ord. No. 13811, Sept. 29, 2017, 82 F.R. 46363, extended term until Sept. 30, 2019.
Ex. Ord. No. 13708, Sept. 30, 2015, 80 F.R. 60271, extended term until Sept. 30, 2017.
Ex. Ord. No. 13652, Sept. 30, 2013, 78 F.R. 61817, extended term until Sept. 30, 2015.
Ex. Ord. No. 13585, Sept. 30, 2011, 76 F.R. 62281, extended term until Sept. 30, 2013.
Ex. Ord. No. 13511, Sept. 29, 2009, 74 F.R. 50909, extended term until Sept. 30, 2011.
Ex. Ord. No. 13446, Sept. 28, 2007, 72 F.R. 56175, extended term until Sept. 30, 2009.
Ex. Ord. No. 13385, Sept. 29, 2005, 70 F.R. 57989, extended term until Sept. 30, 2007.
Ex. Ord. No. 13316, Sept. 17, 2003, 68 F.R. 55255, extended term until Sept. 30, 2005.
Ex. Ord. No. 13225, Sept. 28, 2001, 66 F.R. 50291, extended term until Sept. 30, 2003.
Ex. Ord. No. 13138, Sept. 30, 1999, 64 F.R. 53879, extended term until Sept. 30, 2001.
Ex. Ord. No. 13062, Sept. 29, 1997, 62 F.R. 51755, extended term until Sept. 30, 1999.
Ex. Ord. No. 12974, Sept. 29, 1995, 60 F.R. 51875, extended term until Sept. 30, 1997.
Ex. Ord. No. 12869, Sept. 30, 1993, 58 F.R. 51751, extended term until Sept. 30, 1995.
Ex. Ord. No. 12774, Sept. 27, 1991, 56 F.R. 49835, extended term until Sept. 30, 1993.
Ex. Ord. No. 12692, Sept. 29, 1989, 54 F.R. 40627, extended term until Sept. 30, 1991.
Ex. Ord. No. 12610, Sept. 30, 1987, 52 F.R. 36901, extended term until Sept. 30, 1989.
Ex. Ord. No. 12534, Sept. 30, 1985, 50 F.R. 40319, extended term until Sept. 30, 1987.
Ex. Ord. No. 12489, Sept. 28, 1984, 49 F.R. 38927, extended term until Sept. 30, 1985.
Ex. Ord. No. 12399, Dec. 31, 1982, 48 F.R. 379, extended term until Sept. 30, 1984.

EX. ORD. NO. 13266. ACTIVITIES TO PROMOTE PERSONAL FITNESS

Ex. Ord. No. 13266, June 20, 2002, 67 F.R. 42467, provided:

By the authority vested in me as President by the Constitution and the laws of the United States of America,

and in order to improve the efficiency and coordination of Federal policies related to personal fitness of the general public, it is hereby ordered as follows:

SECTION 1. *Policy*. This order is issued consistent with the following findings and principles:

(a) Growing scientific evidence indicates that an increasing number of Americans are suffering from negligible physical activity, poor dietary habits, insufficient utilization of preventive health screenings, and engaging in risky behaviors such as abuse of alcohol, tobacco, and drugs.

(b) Existing information on the importance of appropriate physical activity, diet, preventive health screenings, and avoiding harmful substances is often not received by the public, or, if received, is not acted on sufficiently.

(c) Individuals of all ages, locations, and levels of personal fitness can benefit from some level of appropriate physical activity, dietary guidance, preventive health screening, and making healthy choices.

(d) While personal fitness is an individual responsibility, the Federal Government may, within the authority and funds otherwise available, expand the opportunities for individuals to empower themselves to improve their general health. Such opportunities may include improving the flow of information about personal fitness, assisting in the utilization of that information, increasing the accessibility of resources for physical activity, and reducing barriers to achieving good personal fitness.

SEC. 2. *Agency Responsibilities in Promoting Personal Fitness.*

(a) The Secretaries of Agriculture, Education, Health and Human Services (HHS), Housing and Urban Development, Interior, Labor, Transportation, and Veterans Affairs, and the Director of the Office of National Drug Policy shall review and evaluate the policies, programs, and regulations of their respective departments and offices that in any way relate to the personal fitness of the general public. Based on that review, the Secretaries and the Director shall determine whether existing policies, programs, and regulations of their respective departments and offices should be modified or whether new policies or programs could be implemented. These new policies and programs shall be consistent with otherwise available authority and appropriated funds, and shall improve the Federal Government's assistance of individuals, private organizations, and State and local governments to (i) increase physical activity; (ii) promote responsible dietary habits; (iii) increase utilization of preventive health screenings; and (iv) encourage healthy choices concerning alcohol, tobacco, drugs, and safety among the general public.

(b) Each department and office included in section 2(a) shall report to the President, through the Secretary of Health and Human Services, its proposed actions within 90 days of the date of this order.

(c) There shall be a Personal Fitness Interagency Working Group (Working Group), composed of the Secretaries or Director of the departments and office included in section 2(a) (or their designees) and chaired by the Secretary of HHS or his designee. In order to improve efficiency through information sharing and to eliminate waste and overlap, the Working Group shall work to ensure the cooperation of Federal agencies in coordinating Federal personal fitness activities. The Working Group shall meet subject to the call of the Chair, but not less than twice a year. The Department of Health and Human Services shall provide such administrative support to the Working Group as the Secretary of HHS deems necessary. Each member of the Working Group shall be a full-time or permanent part-time officer or employee of the Federal Government.

SEC. 3. *General Provisions*. This order is intended only to improve the internal management of the executive branch and it is not intended to, and does not, create any right, benefit, trust, or responsibility, substantive or procedural, enforceable at law or equity by a party against the United States, its departments, agencies or entities, its officers or employees, or any person.

GEORGE W. BUSH.

EX. ORD. NO. 13335. INCENTIVES FOR THE USE OF HEALTH INFORMATION TECHNOLOGY AND ESTABLISHING THE POSITION OF THE NATIONAL HEALTH INFORMATION TECHNOLOGY COORDINATOR

Ex. Ord. No. 13335, Apr. 27, 2004, 69 F.R. 24059, provided:

By the authority vested in me as President by the Constitution and the laws of the United States of America, and to provide leadership for the development and nationwide implementation of an interoperable health information technology infrastructure to improve the quality and efficiency of health care, it is hereby ordered as follows:

SECTION 1. *Establishment*. (a) The Secretary of Health and Human Services (Secretary) shall establish within the Office of the Secretary the position of National Health Information Technology Coordinator.

(b) The National Health Information Technology Coordinator (National Coordinator), appointed by the Secretary in consultation with the President or his designee, will report directly to the Secretary.

(c) The Secretary shall provide the National Coordinator with appropriate staff, administrative support, and other resources to meet its responsibilities under this order.

(d) The Secretary shall ensure that the National Coordinator begins operations within 90 days of the date of this order.

SEC. 2. *Policy*. In fulfilling its responsibilities, the work of the National Coordinator shall be consistent with a vision of developing a nationwide interoperable health information technology infrastructure that:

(a) Ensures that appropriate information to guide medical decisions is available at the time and place of care;

(b) Improves health care quality, reduces medical errors, and advances the delivery of appropriate, evidence-based medical care;

(c) Reduces health care costs resulting from inefficiency, medical errors, inappropriate care, and incomplete information;

(d) Promotes a more effective marketplace, greater competition, and increased choice through the wider availability of accurate information on health care costs, quality, and outcomes;

(e) Improves the coordination of care and information among hospitals, laboratories, physician offices, and other ambulatory care providers through an effective infrastructure for the secure and authorized exchange of health care information; and

(f) Ensures that patients' individually identifiable health information is secure and protected.

SEC. 3. *Responsibilities of the National Health Information Technology Coordinator*. (a) The National Coordinator shall, to the extent permitted by law, develop, maintain, and direct the implementation of a strategic plan to guide the nationwide implementation of interoperable health information technology in both the public and private health care sectors that will reduce medical errors, improve quality, and produce greater value for health care expenditures. The National Coordinator shall report to the Secretary regarding progress on the development and implementation of the strategic plan within 90 days after the National Coordinator begins operations and periodically thereafter. The plan shall:

(i) Advance the development, adoption, and implementation of health care information technology standards nationally through collaboration among public and private interests, and consistent with current efforts to set health information technology standards for use by the Federal Government;

(ii) Ensure that key technical, scientific, economic, and other issues affecting the public and private adoption of health information technology are addressed;

(iii) Evaluate evidence on the benefits and costs of interoperable health information technology and assess to whom these benefits and costs accrue;

(iv) Address privacy and security issues related to interoperable health information technology and recommend methods to ensure appropriate authorization, authentication, and encryption of data for transmission over the Internet;

(v) Not assume or rely upon additional Federal resources or spending to accomplish adoption of interoperable health information technology; and

(vi) Include measurable outcome goals.

(b) The National Coordinator shall:

(i) Serve as the Secretary's principal advisor on the development, application, and use of health information technology, and direct the Department of Health and Human Service's health information technology programs;

(ii) Ensure that health information technology policy and programs of the Department of Health and Human Services (HHS) are coordinated with those of relevant executive branch agencies (including Federal commissions) with a goal of avoiding duplication of efforts and of helping to ensure that each agency undertakes activities primarily within the areas of its greatest expertise and technical capability;

(iii) To the extent permitted by law, coordinate outreach and consultation by the relevant executive branch agencies (including Federal commissions) with public and private parties of interest, including consumers, providers, payers, and administrators; and

(iv) At the request of the Office of Management and Budget, provide comments and advice regarding specific Federal health information technology programs.

SEC. 4. *Reports*. To facilitate the development of interoperable health information technologies, the Secretary of Health and Human Services shall report to the President within 90 days of this order on options to provide incentives in HHS programs that will promote the adoption of interoperable health information technology. In addition, the following reports shall be submitted to the President through the Secretary:

(a) The Director of the Office of Personnel Management shall report within 90 days of this order on options to provide incentives in the Federal Employee Health Benefit Program that will promote the adoption of interoperable health information technology; and

(b) Within 90 days, the Secretary of Veterans Affairs and the Secretary of Defense shall jointly report on the approaches the Departments could take to work more actively with the private sector to make their health

information systems available as an affordable option for providers in rural and medically underserved communities.

SEC. 5. *Administration and Judicial Review*. (a) The actions directed by this order shall be carried out subject to the availability of appropriations and to the extent permitted by law.

(b) This order is not intended to, and does not, create any right or benefit, substantive or procedural, enforceable at law or in equity against the United States, its agencies, its entities or instrumentalities, its officers or employees, or any other person.

GEORGE W. BUSH.

EX. ORD. NO. 13410. PROMOTING QUALITY AND EFFICIENT HEALTH CARE IN FEDERAL GOVERNMENT ADMINISTERED OR SPONSORED HEALTH CARE PROGRAMS

Ex. Ord. No. 13410, Aug. 22, 2006, 71 F.R. 51089, provided:

By the authority vested in me as President by the Constitution and the laws of the United States, and in order to promote federally led efforts to implement more transparent and high-quality health care, it is hereby ordered as follows:

SECTION 1. *Purpose*. It is the purpose of this order to ensure that health care programs administered or sponsored by the Federal Government promote quality and efficient delivery of health care through the use of health information technology, transparency regarding health care quality and price, and better incentives for program beneficiaries, enrollees, and providers. It is the further purpose of this order to make relevant information available to these beneficiaries, enrollees, and providers in a readily useable manner and in collaboration with similar initiatives in the private sector and non-Federal public sector. Consistent with the purpose of improving the quality and efficiency of health care, the actions and steps taken by Federal Government agencies should not incur additional costs for the Federal Government.

SEC. 2. *Definitions*. For purposes of this order:

(a) "Agency" means an agency of the Federal Government that administers or sponsors a Federal health care program.

(b) "Federal health care program" means the Federal Employees Health Benefit Program, the Medicare program, programs operated directly by the Indian Health Service, the TRICARE program for the Department of Defense and other uniformed services, and the health care program operated by the Department of Veterans Affairs. For purposes of this order, "Federal health care program" does not include State operated or funded federally subsidized programs such as Medicaid, the State Children's Health Insurance Program, or services provided to Department of Veterans' Affairs beneficiaries under 38 U.S.C. 1703.

(c) "Interoperability" means the ability to communicate and exchange data accurately, effectively, securely, and consistently with different information technology systems, software applications, and networks in various settings, and exchange data such that clinical or operational purpose and meaning of the data are preserved and unaltered.

(d) "Recognized interoperability standards" means interoperability standards recognized by the Secretary of Health and Human Services (the "Secretary"), in accordance with guidance developed by the Secretary, as existing on the date of the implementation, acquisition, or upgrade of health information technology systems under subsections (1) or (2) of section 3(a) of this order.

SEC. 3. *Directives for Agencies*. Agencies shall perform the following functions:

(a) Health Information Technology.

(1) For Federal Agencies. As each agency implements, acquires, or upgrades health information technology systems used for the direct exchange of health information between agencies and with non-Federal entities, it shall utilize, where available, health information technology systems and products that meet recognized interoperability standards.

(2) For Contracting Purposes. Each agency shall require in contracts or agreements with health care providers, health plans, or health insurance issuers that as each provider, plan, or issuer implements, acquires, or upgrades health information technology systems, it shall utilize, where available, health information technology systems and products that meet recognized interoperability standards.

(b) Transparency of Quality Measurements.

(1) In General. Each agency shall implement programs measuring the quality of services supplied by health care providers to the beneficiaries or enrollees of a Federal health care program. Such programs shall be based upon standards established by multi-stakeholder entities identified by the Secretary or by another agency subject to this order. Each agency shall develop its quality measurements in collaboration with similar initiatives in the private and non-Federal public sectors.

(2) Facilitation. An agency satisfies the requirements of this subsection if it participates in the aggregation of claims and other appropriate data for the purposes of quality measurement. Such aggregation shall be based

upon standards established by multi-stakeholder entities identified by the Secretary or by another agency subject to this order.

(c) Transparency of Pricing Information. Each agency shall make available (or provide for the availability) to the beneficiaries or enrollees of a Federal health care program (and, at the option of the agency, to the public) the prices that it, its health insurance issuers, or its health insurance plans pay for procedures to providers in the health care program with which the agency, issuer, or plan contracts. Each agency shall also, in collaboration with multi-stakeholder groups such as those described in subsection (b)(1), participate in the development of information regarding the overall costs of services for common episodes of care and the treatment of common chronic diseases.

(d) Promoting Quality and Efficiency of Care. Each agency shall develop and identify, for beneficiaries, enrollees, and providers, approaches that encourage and facilitate the provision and receipt of high-quality and efficient health care. Such approaches may include pay-for-performance models of reimbursement consistent with current law. An agency will satisfy the requirements of this subsection if it makes available to beneficiaries or enrollees consumer-directed health care insurance products.

SEC. 4. *Implementation Date*. Agencies shall comply with the requirements of this order by January 1, 2007.

SEC. 5. *Administration and Judicial Review*.

(a) This order does not assume or rely upon additional Federal resources or spending to promote quality and efficient health care. Further, the actions directed by this order shall be carried out subject to the availability of appropriations and to the maximum extent permitted by law.

(b) This order shall be implemented in new contracts or new contract cycles as they may be renewed from time to time. Renegotiation outside of the normal contract cycle processes should be avoided.

(c) This order is not intended to, and does not, create any right or benefit, substantive or procedural, enforceable at law or in equity against the United States, its departments, agencies, or entities, its officers, employees, or agents, or any other person.

GEORGE W. BUSH.

§300u–1. Grants and contracts for research programs; authority of Secretary; review of applications; additional functions; periodic public survey

(a) The Secretary is authorized to conduct and support by grant or contract (and encourage others to support) research in health information and health promotion, preventive health services, and education in the appropriate use of health care. Applications for grants and contracts under this section shall be subject to appropriate peer review. The Secretary shall also—

(1) provide consultation and technical assistance to persons who need help in preparing research proposals or in actually conducting research;

(2) determine the best methods of disseminating information concerning personal health behavior, preventive health services and the appropriate use of health care and of affecting behavior so that such information is applied to maintain and improve health, and prevent disease, reduce its risk, or modify its course or severity;

(3) determine and study environmental, occupational, social, and behavioral factors which affect and determine health and ascertain those programs and areas for which educational and preventive measures could be implemented to improve health as it is affected by such factors;

(4) develop (A) methods by which the cost and effectiveness of activities respecting health information and health promotion, preventive health services, and education in the appropriate use of health care, can be measured, including methods for evaluating the effectiveness of various settings for such activities and the various types of persons engaged in such activities, (B) methods for reimbursement or payment for such activities, and (C) models and standards for the conduct of such activities, including models and standards for the education, by providers of institutional health services, of individuals receiving such services respecting the nature of the institutional health services provided the individuals and the symptoms, signs, or diagnoses which led to provision of such services;

(5) develop a method for assessing the cost and effectiveness of specific medical services and procedures under various conditions of use, including the assessment of the sensitivity and

specificity of screening and diagnostic procedures; and

(6) enumerate and assess, using methods developed under paragraph (5), preventive health measures and services with respect to their cost and effectiveness under various conditions of use (which measures and services may include blood pressure screening, cholesterol screening and control, smoking cessation programs, substance abuse programs, cancer screening, dietary and nutritional counseling, diabetes screening and education, intraocular pressure screening, and stress management).

(b) The Secretary shall make a periodic survey of the needs, interest, attitudes, knowledge, and behavior of the American public regarding health and health care. The Secretary shall take into consideration the findings of such surveys and the findings of similar surveys conducted by national and community health education organizations, and other organizations and agencies for formulating policy respecting health information and health promotion, preventive health services, and education in the appropriate use of health care.

(July 1, 1944, ch. 373, title XVII, §1702, as added Pub. L. 94–317, title I, §102, June 23, 1976, 90 Stat. 696; amended Pub. L. 102–531, title III, §311(b)(2), Oct. 27, 1992, 106 Stat. 3504.)

EDITORIAL NOTES

AMENDMENTS

1992—Subsec. (a)(6). Pub. L. 102–531 inserted before period "(which measures and services may include blood pressure screening, cholesterol screening and control, smoking cessation programs, substance abuse programs, cancer screening, dietary and nutritional counseling, diabetes screening and education, intraocular pressure screening, and stress management)".

§300u–2. Grants and contracts for community health programs

(a) Authority of Secretary; particular activities

The Secretary is authorized to conduct and support by grant or contract (and encourage others to support) new and innovative programs in health information and health promotion, preventive health services, and education in the appropriate use of health care, and may specifically—

(1) support demonstration and training programs in such matters which programs (A) are in hospitals, ambulatory care settings, home care settings, schools, day care programs for children, and other appropriate settings representative of broad cross sections of the population, and include public education activities of voluntary health agencies, professional medical societies, and other private nonprofit health organizations, (B) focus on objectives that are measurable, and (C) emphasize the prevention or moderation of illness or accidents that appear controllable through individual knowledge and behavior;

(2) provide consultation and technical assistance to organizations that request help in planning, operating, or evaluating programs in such matters;

(3) develop health information and health promotion materials and teaching programs including (A) model curriculums for the training of educational and health professionals and paraprofessionals in health education by medical, dental, and nursing schools, schools of public health, and other institutions engaged in training of educational or health professionals, (B) model curriculums to be used in elementary and secondary schools and institutions of higher learning, (C) materials and programs for the continuing education of health professionals and paraprofessionals in the health education of their patients, (D) materials for public service use by the printed and broadcast media, and (E) materials and programs to assist providers of health care in providing health education to their patients; and

(4) support demonstration and evaluation programs for individual and group self-help programs designed to assist the participant in using his individual capacities to deal with health problems, including programs concerned with obesity, hypertension, and diabetes.

(b) Grants to States and other public and nonprofit private entities; costs of demonstrating and evaluating programs; development of models

The Secretary is authorized to make grants to States and other public and nonprofit private entities to assist them in meeting the costs of demonstrating and evaluating programs which provide information respecting the costs and quality of health care or information respecting health insurance policies and prepaid health plans, or information respecting both. After the development of models pursuant to section 300u–3(4) and 300u–3(5) of this title for such information, no grant may be made under this subsection for a program unless the information to be provided under the program is provided in accordance with one of such models applicable to the information.

(c) Private nonprofit entities; limitation on amount of grant or contract

The Secretary is authorized to support by grant or contract (and to encourage others to support) private nonprofit entities working in health information and health promotion, preventive health services, and education in the appropriate use of health care. The amount of any grant or contract for a fiscal year beginning after September 30, 1978, for an entity may not exceed 25 per centum of the expenses of the entity for such fiscal year for health information and health promotion, preventive health services, and education in the appropriate use of health care.

(July 1, 1944, ch. 373, title XVII, §1703, as added Pub. L. 94–317, title I, §102, June 23, 1976, 90 Stat. 697.)

§300u–3. Grants and contracts for information programs; authority of Secretary; particular activities

The Secretary is authorized to conduct and support by grant or contract (and encourage others to support) such activities as may be required to make information respecting health information and health promotion, preventive health services, and education in the appropriate use of health care available to the consumers of medical care, providers of such care, schools, and others who are or should be informed respecting such matters. Such activities may include at least the following:

(1) The publication of information, pamphlets, and other reports which are specially suited to interest and instruct the health consumer, which information, pamphlets, and other reports shall be updated annually, shall pertain to the individual's ability to improve and safeguard his own health; shall include material, accompanied by suitable illustrations, on child care, family life and human development, disease prevention (particularly prevention of pulmonary disease, cardiovascular disease, and cancer), physical fitness, dental health, environmental health, nutrition, safety and accident prevention, drug abuse and alcoholism, mental health, management of chronic diseases (including diabetes and arthritis), and venereal diseases; and shall be designed to reach populations of different languages and of different social and economic backgrounds.

(2) Securing the cooperation of the communications media, providers of health care, schools, and others in activities designed to promote and encourage the use of health maintaining information and behavior.

(3) The study of health information and promotion in advertising and the making to concerned Federal agencies and others such recommendations respecting such advertising as are appropriate.

(4) The development of models and standards for the publication by States, insurance carriers, prepaid health plans, and others (except individual health practitioners) of information for use by the public respecting the cost and quality of health care, including information to enable the public to make comparisons of the cost and quality of health care.

(5) The development of models and standards for the publication by States, insurance carriers, prepaid health plans, and others of information for use by the public respecting health insurance policies and prepaid health plans, including information on the benefits provided by the various types of such policies and plans, the premium charges for such policies and plans, exclusions from

coverage or eligibility for coverage, cost sharing requirements, and the ratio of the amounts paid as benefits to the amounts received as premiums and information to enable the public to make relevant comparisons of the costs and benefits of such policies and plans.

(July 1, 1944, ch. 373, title XVII, §1704, as added Pub. L. 94–317, title I, §102, June 23, 1976, 90 Stat. 698; amended Pub. L. 98–551, §2(b), Oct. 30, 1984, 98 Stat. 2816.)

EDITORIAL NOTES

AMENDMENTS

1984—Par. (6). Pub. L. 98–551 struck out par. (6) which provided grant authority to the Secretary to assess, with respect to the effectiveness, safety, cost, and required training for and conditions of use, of new aspects of health care, and new activities, programs, and services designed to improve human health and publish in readily understandable language for public and professional use such assessments and, in the case of controversial aspects of health care, activities, programs, or services, publish differing views or opinions respecting the effectiveness, safety, cost, and required training for and conditions of use, of such aspects of health care, activities, programs, or services.

§300u–4. Status reports to President and Congress; study of health education and preventive health services with respect to insurance coverage

(a) The Secretary shall, not later than two years after June 23, 1976, and biannually thereafter, submit to the President for transmittal to Congress a report on the status of health information and health promotion, preventive health services, and education in the appropriate use of health care. Each such report shall include—

(1) a statement of the activities carried out under this subchapter since the last report and the extent to which each such activity achieves the purposes of this subchapter;

(2) an assessment of the manpower resources needed to carry out programs relating to health information and health promotion, preventive health services, and education in the appropriate use of health care, and a statement describing the activities currently being carried out under this subchapter designed to prepare teachers and other manpower for such programs;

(3) the goals and strategy formulated pursuant to section 300u(a)(1) of this title, the models and standards developed under this subchapter, and the results of the study required by subsection (b) of this section; and

(4) such recommendations as the Secretary considers appropriate for legislation respecting health information and health promotion, preventive health services, and education in the appropriate use of health care, including recommendations for revisions to and extension of this subchapter.

(b) The Secretary shall conduct a study of health education services and preventive health services to determine the coverage of such services under public and private health insurance programs, including the extent and nature of such coverage and the cost sharing requirements required by such programs for coverage of such services.

(July 1, 1944, ch. 373, title XVII, §1705, as added Pub. L. 94–317, title I, §102, June 23, 1976, 90 Stat. 699; amended Pub. L. 104–66, title I, §1062(d), Dec. 21, 1995, 109 Stat. 720.)

EDITORIAL NOTES

AMENDMENTS

1995—Subsec. (a). Pub. L. 104–66 substituted "biannually" for "annually" in introductory provisions.

STATUTORY NOTES AND RELATED SUBSIDIARIES

TERMINATION OF REPORTING REQUIREMENTS

For termination, effective May 15, 2000, of provisions of law requiring submittal to Congress of any annual, semiannual, or other regular periodic report listed in House Document No. 103–7 (in which item 4 on page 96 identifies a reporting provision which, as subsequently amended, is contained in subsec. (a) of this section), see section 3003 of Pub. L. 104–66, as amended, set out as a note under section 1113 of Title 31, Money and Finance.

§300u–5. Centers for research and demonstration of health promotion and disease prevention

(a) Establishment; grants; contracts; research and demonstration projects

The Secretary shall make grants or enter into contracts with academic health centers for the establishment, maintenance, and operation of centers for research and demonstration with respect to health promotion and disease prevention. Centers established, maintained, or operated under this section shall undertake research and demonstration projects in health promotion, disease prevention, and improved methods of appraising health hazards and risk factors, and shall serve as demonstration sites for the use of new and innovative research in public health techniques to prevent chronic diseases.

(b) Location; types of research and projects

Each center established, maintained, or operated under this section shall—

(1) be located in an academic health center with—

(A) a multidisciplinary faculty with expertise in public health and which has working relationships with relevant groups in such fields as medicine, psychology, nursing, social work, education and business;

(B) graduate training programs relevant to disease prevention;

(C) a core faculty in epidemiology, biostatistics, social sciences, behavioral and environmental health sciences, and health administration;

(D) a demonstrated curriculum in disease prevention;

(E) a capability for residency training in public health or preventive medicine; and

(F) such other qualifications as the Secretary may prescribe;

(2) conduct—

(A) health promotion and disease prevention research, including retrospective studies and longitudinal prospective studies in population groups and communities;

(B) demonstration projects for the delivery of services relating to health promotion and disease prevention to defined population groups using, as appropriate, community outreach and organization techniques and other methods of educating and motivating communities; and

(C) evaluation studies on the efficacy of demonstration projects conducted under subparagraph (B) of this paragraph.

The design of any evaluation study conducted under subparagraph (C) shall be established prior to the commencement of the demonstration project under subparagraph (B) for which the evaluation will be conducted.

(c) Equitable geographic distribution of centers; procedures

(1) In making grants and entering into contracts under this section, the Secretary shall provide for an equitable geographical distribution of centers established, maintained, and operated under this section and for the distribution of such centers among areas containing a wide range of population groups which exhibit incidences of diseases which are most amenable to preventive intervention.

(2) The Secretary, through the Director of the Centers for Disease Control and Prevention and in consultation with the Director of the National Institutes of Health, shall establish procedures for the appropriate peer review of applications for grants and contracts under this section by peer review

groups composed principally of non-Federal experts.

(d) "Academic health center" defined

For purposes of this section, the term "academic health center" means a school of medicine, a school of osteopathy, or a school of public health, as such terms are defined in section 292a(4) [1] of this title.

(e) Authorization of appropriations

For the purpose of carrying out this section, there are authorized to be appropriated $10,000,000 for fiscal year 1992, and such sums as may be necessary for each of the fiscal years 1993 through 2003.

(July 1, 1944, ch. 373, title XVII, §1706, as added Pub. L. 98–551, §2(d), Oct. 30, 1984, 98 Stat. 2816; amended Pub. L. 100–607, title III, §312(a)(2), Nov. 4, 1988, 102 Stat. 3113; Pub. L. 102–168, title I, §102, Nov. 26, 1991, 105 Stat. 1102; Pub. L. 102–531, title III, §312(d)(12), Oct. 27, 1992, 106 Stat. 3505; Pub. L. 103–183, title VII, §705(d), Dec. 14, 1993, 107 Stat. 2241; Pub. L. 105–340, title II, §204, Oct. 31, 1998, 112 Stat. 3195.)

EDITORIAL NOTES

REFERENCES IN TEXT

Section 292a of this title, referred to in subsec. (d), was in the original a reference to section 701 of act July 1, 1944. Section 701 of that Act was omitted in the general revision of subchapter V of this chapter by Pub. L. 102–408, title I, §102, Oct. 13, 1992, 106 Stat. 1994. Pub. L. 102–408 enacted a new section 701 of act July 1, 1944, relating to statement of purpose, and a new section 702, relating to scope and duration of loan insurance program, which are classified to sections 292 and 292a, respectively, of this title. For provisions relating to definitions, see section 295p of this title.

PRIOR PROVISIONS

A prior section 300u–5, act July 1, 1944, ch. 373, title XVII, §1706, as added June 23, 1976, Pub. L. 94–317, title I, §102, 90 Stat. 700; amended Nov. 10, 1978, Pub. L. 95–626, title V, §501, 92 Stat. 3592; Jan. 4, 1983, Pub. L. 97–414, §8(r), 96 Stat. 2062, related to establishment of the Office of Health Promotion, prior to repeal by Pub. L. 98–551, §2(c), Oct. 30, 1984, 98 Stat. 2816.

AMENDMENTS

1998—Subsec. (e). Pub. L. 105–340 substituted "2003" for "1998".

1993—Subsec. (e). Pub. L. 103–183 substituted "through 1998" for "through 1996".

1992—Subsec. (c)(2). Pub. L. 102–531, which directed amendment of subsec. (c)(2)(B) by substituting "Centers for Disease Control and Prevention" for "Centers for Disease Control", was executed by making the substitution in subsec. (c)(2) to reflect the probable intent of Congress and the redesignation of subsec. (c)(2)(B) as subsec. (c)(2) by Pub. L. 102–168. See 1991 Amendment note below.

1991—Subsec. (c). Pub. L. 102–168, §102(b), redesignated subpars. (A) and (B) of par. (2) as pars. (1) and (2), respectively, and struck out former par. (1), which read as follows: "During fiscal year 1985, the Secretary shall make grants or enter into contracts for the establishment of three centers under this section. During fiscal year 1986, the Secretary shall make grants and enter into contracts for the establishment of five centers under this section and the maintenance and operation of the three centers established under this section in fiscal year 1985. During fiscal year 1987, the Secretary shall make grants and enter into contracts for the establishment of five centers under this section and the operation and maintenance of the eight centers established under this section in fiscal years 1985 and 1986."

Subsec. (e). Pub. L. 102–168, §102(a), amended subsec. (e) generally. Prior to amendment, subsec. (e) read as follows: "To carry out this section, there are authorized to be appropriated $3,000,000 for the fiscal year ending September 30, 1985, $8,000,000 for the fiscal year ending September 30, 1986, $13,000,000 for the fiscal year ending September 30, 1987, $6,000,000 for fiscal year 1989, $8,000,000 for fiscal year 1990, and $10,000,000 for fiscal year 1991."

1988—Subsec. (e). Pub. L. 100–607 struck out "and" after "1986," and inserted ", $6,000,000 for fiscal year 1989, $8,000,000 for fiscal year 1990, and $10,000,000 for fiscal year 1991" before period at end.

[1] *See References in Text note below.*

§300u–6. Office of Minority Health

(a) In general

There is established an Office of Minority Health. The Office of Minority Health as existing on March 23, 2010, shall be transferred to the Office of the Secretary in such manner that there is established in the Office of the Secretary, the Office of Minority Health, which shall be headed by the Deputy Assistant Secretary for Minority Health who shall report directly to the Secretary, and shall retain and strengthen authorities (as in existence on March 23, 2010) for the purpose of improving minority health and the quality of health care minorities receive, and eliminating racial and ethnic disparities. In carrying out this subsection, the Secretary, acting through the Deputy Assistant Secretary, shall award grants, contracts, enter into memoranda of understanding, cooperative, interagency, intra-agency and other agreements with public and nonprofit private entities, agencies, as well as Departmental and Cabinet agencies and organizations, and with organizations that are indigenous human resource providers in communities of color to assure improved health status of racial and ethnic minorities, and shall develop measures to evaluate the effectiveness of activities aimed at reducing health disparities and supporting the local community. Such measures shall evaluate community outreach activities, language services, workforce cultural competence, and other areas as determined by the Secretary.

(b) Duties

With respect to improving the health of racial and ethnic minority groups, the Secretary, acting through the Deputy Assistant Secretary for Minority Health (in this section referred to as the "Deputy Assistant Secretary"), shall carry out the following:

(1) Establish short-range and long-range goals and objectives and coordinate all other activities within the Public Health Service that relate to disease prevention, health promotion, service delivery, and research concerning such individuals. The heads of each of the agencies of the Service shall consult with the Deputy Assistant Secretary to ensure the coordination of such activities.

(2) Enter into interagency agreements with other agencies of the Public Health Service.

(3) Support research, demonstrations and evaluations to test new and innovative models.

(4) Increase knowledge and understanding of health risk factors.

(5) Develop mechanisms that support better information dissemination, education, prevention, and service delivery to individuals from disadvantaged backgrounds, including individuals who are members of racial or ethnic minority groups.

(6) Ensure that the National Center for Health Statistics collects data on the health status of each minority group.

(7) With respect to individuals who lack proficiency in speaking the English language, enter into contracts with public and nonprofit private providers of primary health services for the purpose of increasing the access of the individuals to such services by developing and carrying out programs to provide bilingual or interpretive services.

(8) Support a national minority health resource center to carry out the following:

(A) Facilitate the exchange of information regarding matters relating to health information and health promotion, preventive health services, and education in the appropriate use of health care.

(B) Facilitate access to such information.

(C) Assist in the analysis of issues and problems relating to such matters.

(D) Provide technical assistance with respect to the exchange of such information (including facilitating the development of materials for such technical assistance).

(9) Carry out programs to improve access to health care services for individuals with limited

proficiency in speaking the English language. Activities under the preceding sentence shall include developing and evaluating model projects.

(10) Advise in matters related to the development, implementation, and evaluation of health professions education in decreasing disparities in health care outcomes, including cultural competency as a method of eliminating health disparities.

(c) Advisory Committee

(1) In general

The Secretary shall establish an advisory committee to be known as the Advisory Committee on Minority Health (in this subsection referred to as the "Committee").

(2) Duties

The Committee shall provide advice to the Deputy Assistant Secretary carrying out this section, including advice on the development of goals and specific program activities under paragraphs (1) through (10) of subsection (b) for each racial and ethnic minority group.

(3) Chair

The chairperson of the Committee shall be selected by the Secretary from among the members of the voting members of the Committee. The term of office of the chairperson shall be 2 years.

(4) Composition

(A) The Committee shall be composed of 12 voting members appointed in accordance with subparagraph (B), and nonvoting, ex officio members designated in subparagraph (C).

(B) The voting members of the Committee shall be appointed by the Secretary from among individuals who are not officers or employees of the Federal Government and who have expertise regarding issues of minority health. The racial and ethnic minority groups shall be equally represented among such members.

(C) The nonvoting, ex officio members of the Committee shall be such officials of the Department of Health and Human Services as the Secretary determines to be appropriate.

(5) Terms

Each member of the Committee shall serve for a term of 4 years, except that the Secretary shall initially appoint a portion of the members to terms of 1 year, 2 years, and 3 years.

(6) Vacancies

If a vacancy occurs on the Committee, a new member shall be appointed by the Secretary within 90 days from the date that the vacancy occurs, and serve for the remainder of the term for which the predecessor of such member was appointed. The vacancy shall not affect the power of the remaining members to execute the duties of the Committee.

(7) Compensation

Members of the Committee who are officers or employees of the United States shall serve without compensation. Members of the Committee who are not officers or employees of the United States shall receive compensation, for each day (including travel time) they are engaged in the performance of the functions of the Committee. Such compensation may not be in an amount in excess of the daily equivalent of the annual maximum rate of basic pay payable under the General Schedule (under title 5) for positions above GS–15.

(d) Certain requirements regarding duties

(1) Recommendations regarding language

(A) Proficiency in speaking English

The Deputy Assistant Secretary shall consult with the Director of the Office of International and Refugee Health, the Director of the Office of Civil Rights, and the Directors of other appropriate departmental entities regarding recommendations for carrying out activities under subsection (b)(9).

(B) Health professions education regarding health disparities

The Deputy Assistant Secretary shall carry out the duties under subsection (b)(10) in collaboration with appropriate personnel of the Department of Health and Human Services, other Federal agencies, and other offices, centers, and institutions, as appropriate, that have responsibilities under the Minority Health and Health Disparities Research and Education Act of 2000.

(2) Equitable allocation regarding activities

In carrying out subsection (b), the Secretary shall ensure that services provided under such subsection are equitably allocated among all groups served under this section by the Secretary.

(3) Cultural competency of services

The Secretary shall ensure that information and services provided pursuant to subsection (b) are provided in the language, educational, and cultural context that is most appropriate for the individuals for whom the information and services are intended.

(e) Grants and contracts regarding duties

(1) In general

In carrying out subsection (b), the Secretary acting through the Deputy Assistant Secretary may make awards of grants, cooperative agreements, and contracts to public and nonprofit private entities.

(2) Process for making awards

The Deputy Assistant Secretary shall ensure that awards under paragraph (1) are made, to the extent practical, only on a competitive basis, and that a grant is awarded for a proposal only if the proposal has been recommended for such an award through a process of peer review.

(3) Evaluation and dissemination

The Deputy Assistant Secretary, directly or through contracts with public and private entities, shall provide for evaluations of projects carried out with awards made under paragraph (1) during the preceding 2 fiscal years. The report shall be included in the report required under subsection (f) for the fiscal year involved.

(f) Reports

(1) In general

Not later than February 1 of fiscal year 1999 and of each second year thereafter, the Secretary shall submit to the Committee on Energy and Commerce of the House of Representatives, and to the Committee on Labor and Human Resources of the Senate, a report describing the activities carried out under this section during the preceding 2 fiscal years and evaluating the extent to which such activities have been effective in improving the health of racial and ethnic minority groups. Each such report shall include the biennial reports submitted under subsections (e)(3) and (f)(2) [1] for such years by the heads of the Public Health Service agencies.

(2) Agency reports

Not later than February 1, 1999, and biennially thereafter, the heads of the Public Health Service agencies shall submit to the Deputy Assistant Secretary a report summarizing the minority health activities of each of the respective agencies.

(g) Definitions

For purposes of this section:

(1) The term "racial and ethnic minority group" means American Indians (including Alaska Natives, Eskimos, and Aleuts); Asian Americans; Native Hawaiians and other Pacific Islanders; Blacks; and Hispanics.

(2) The term "Hispanic" means individuals whose origin is Mexican, Puerto Rican, Cuban, Central or South American, or any other Spanish-speaking country.

(h) Authorization of appropriations

For the purpose of carrying out this section, there are authorized to be appropriated such sums as may be necessary for each of fiscal years 2011 through 2016.

(July 1, 1944, ch. 373, title XVII, §1707, as added Pub. L. 101–527, §2, Nov. 6, 1990, 104 Stat. 2312; amended Pub. L. 101–557, title IV, §401(a)(1), Nov. 15, 1990, 104 Stat. 2770; Pub. L. 105–392, title II, §201(a), (c), Nov. 13, 1998, 112 Stat. 3582, 3585; Pub. L. 106–525, title IV, §403, title VI, §601, Nov. 22, 2000, 114 Stat. 2509, 2511; Pub. L. 111–148, title X, §10334(a)(1), Mar. 23, 2010, 124 Stat. 971.)

EDITORIAL NOTES

REFERENCES IN TEXT

The General Schedule, referred to in subsec. (c)(7), is set out under section 5332 of Title 5, Government Organization and Employees.

The Minority Health and Health Disparities Research and Education Act of 2000, referred to in subsec. (d)(1)(B), is Pub. L. 106–525, Nov. 22, 2000, 114 Stat. 2495. For complete classification of this Act to the Code, see Short Title of 2000 Amendments note set out under section 201 of this title and Tables.

Subsections (e)(3) and (f)(2), referred to in subsec. (f)(1), were in the original "sections 201(e)(3) and 201(f)(2)", and were translated to reflect the probable intent of Congress, because section 201 of act July 1, 1944, which is classified to section 202 of this title, does not contain subsections, and subsections (e)(3) and (f)(2) of this section require biennial reporting.

PRIOR PROVISIONS

A prior section 300u–6, act July 1, 1944, ch. 373, title XVII, §1707, as added Nov. 10, 1978, Pub. L. 95–626, title V, §502, 92 Stat. 3593; amended July 10, 1979, Pub. L. 96–32, §6(k), 93 Stat. 84, related to project grants to State Councils on Physical Fitness for physical fitness improvement, prior to repeal by Pub. L. 98–551, §2(c), Oct. 30, 1984, 98 Stat. 2816.

AMENDMENTS

2010—Subsec. (a). Pub. L. 111–148, §10334(a)(1)(A), amended text of subsec. (a) generally. Prior to amendment, text read as follows: "There is established an Office of Minority Health within the Office of Public Health and Science. There shall be in the Department of Health and Human Services a Deputy Assistant Secretary for Minority Health, who shall be the head of the Office of Minority Health. The Secretary, acting through such Deputy Assistant Secretary, shall carry out this section."

Subsec. (h). Pub. L. 111–148, §10334(a)(1)(B), added subsec. (h) and struck out former subsec. (h). Prior to amendment, text of subsec. (h), which consisted only of a par. (1), read as follows:

"(1) AUTHORIZATION OF APPROPRIATIONS.—For the purpose of carrying out this section, there are authorized to be appropriated $30,000,000 for fiscal year 1998, and such sums as may be necessary for each of the fiscal years 1999 through 2002."

2000—Subsec. (b)(10). Pub. L. 106–525, §403(1), added par. (10).

Subsec. (c)(2). Pub. L. 106–525, §403(2), substituted "paragraphs (1) through (10)" for "paragraphs (1) through (9)".

Subsec. (d)(1). Pub. L. 106–525, §403(3), amended heading and text of par. (1) generally. Prior to amendment, text read as follows: "The Deputy Assistant Secretary for Minority Health shall consult with the Director of the Office of International and Refugee Health, the Director of the Office of Civil Rights, and the Directors of other appropriate departmental entities regarding recommendations for carrying out activities under subsection (b)(9) of this section."

Subsec. (g)(1). Pub. L. 106–525, §601, substituted "Asian Americans;" for "Asian Americans and" and inserted "Native Hawaiians and other" before "Pacific Islanders;".

1998—Pub. L. 105–392, §201(c)(1), struck out "Establishment of" before "Office" in section catchline.

Subsec. (a). Pub. L. 105–392, §201(c)(2), substituted "Public Health and Science" for "the Assistant Secretary for Health".

Subsecs. (b) to (h). Pub. L. 105–392, §201(a), added subsecs. (b) to (h) and struck out former subsecs. (b) to (f), which related, respectively, to duties of Secretary, certain requirements regarding duties, grants and contracts regarding duties, reports, and funding.

1990—Subsec. (b)(8). Pub. L. 101–557 added par. (8).

STATUTORY NOTES AND RELATED SUBSIDIARIES

CHANGE OF NAME

Committee on Labor and Human Resources of Senate changed to Committee on Health, Education, Labor, and Pensions of Senate by Senate Resolution No. 20, One Hundred Sixth Congress, Jan. 19, 1999.

Committee on Energy and Commerce of House of Representatives treated as referring to Committee on Commerce of House of Representatives by section 1(a) of Pub. L. 104–14, set out as a note preceding section 21 of Title 2, The Congress. Committee on Commerce of House of Representatives changed to Committee on Energy and Commerce of House of Representatives, and jurisdiction over matters relating to securities and exchanges and insurance generally transferred to Committee on Financial Services of House of Representatives by House Resolution No. 5, One Hundred Seventh Congress, Jan. 3, 2001.

EFFECTIVE DATE OF 1990 AMENDMENT

Pub. L. 101–557, title IV, §401(a)(2), Nov. 15, 1990, 104 Stat. 2771, provided that: "The amendments made by paragraph (1) [amending this section] shall take effect on the date of the enactment of the Disadvantaged Minority Health Improvement Act of 1990 [Nov. 6, 1990]."

TRANSFER OF FUNCTIONS

Pub. L. 111–148, title X, §10334(a)(2), Mar. 23, 2010, 124 Stat. 971, provided that: "There are transferred to the Office of Minority Health in the office of the Secretary of Health and Human Services, all duties, responsibilities, authorities, accountabilities, functions, staff, funds, award mechanisms, and other entities under the authority of the Office of Minority Health of the Public Health Service as in effect on the date before the date of enactment of this Act [Mar. 23, 2010], which shall continue in effect according to the terms in effect on the date before such date of enactment, until modified, terminated, superseded, set aside, or revoked in accordance with law by the President, the Secretary, a court of competent jurisdiction, or by operation of law."

TERMINATION OF ADVISORY COMMITTEES

Advisory committees established after Jan. 5, 1973, to terminate not later than the expiration of the 2-year period beginning on the date of their establishment, unless, in the case of a committee established by the President or an officer of the Federal Government, such committee is renewed by appropriate action prior to the expiration of such 2-year period, or in the case of a committee established by the Congress, its duration is otherwise provided by law. See section 1013 of Title 5, Government Organization and Employees.

Pub. L. 93–641, §6, Jan. 4, 1975, 88 Stat. 2275, set out as a note under section 217a of this title, provided that an advisory committee established pursuant to the Public Health Service Act shall terminate at such time as may be specifically prescribed by an Act of Congress enacted after Jan. 4, 1975.

REPORTS

Pub. L. 111–148, title X, §10334(a)(3), Mar. 23, 2010, 124 Stat. 972, provided that: "Not later than 1 year after the date of enactment of this section [Mar. 23, 2010], and biennially thereafter, the Secretary of Health and Human Services shall prepare and submit to the appropriate committees of Congress a report describing the activities carried out under section 1707 of the Public Health Service Act [42 U.S.C. 300u–6] (as amended by this subsection) during the period for which the report is being prepared. Not later than 1 year after the date of enactment of this section, and biennially thereafter, the heads of each of the agencies of the Department of Health and Human Services shall submit to the Deputy Assistant Secretary for Minority Health a report summarizing the minority health activities of each of the respective agencies."

CONGRESSIONAL FINDINGS

Pub. L. 101–527, §1(b), Nov. 6, 1990, 104 Stat. 2311, provided that: "The Congress finds that—

"(1) racial and ethnic minorities are disproportionately represented among individuals from disadvantaged backgrounds;

"(2) the health status of individuals from disadvantaged backgrounds, including racial and ethnic minorities, in the United States is significantly lower than the health status of the general population of the United States;

"(3) minorities suffer disproportionately high rates of cancer, stroke, heart diseases, diabetes, substance abuse, acquired immune deficiency syndrome, and other diseases and disorders;

"(4) the incidence of infant mortality among minorities is almost double that for the general population;

"(5) Blacks, Hispanics, and Native Americans constitute approximately 12 percent, 7.9 percent, and

0.01 percent, respectively, of the population of the United States;

"(6) Blacks, Hispanics, and Native Americans in the United States constitute approximately 3 percent, 4 percent, and less than 0.01 percent, respectively, of physicians, 2.7 percent, 1.7 percent, and less than 0.01 percent, respectively, of dentists, and 4.5 percent, 1.6 percent, and less than 0.01 percent, respectively, of nurses;

"(7) the number of individuals who are from disadvantaged backgrounds in health professions should be increased for the purpose of improving the access of other such individuals to health services;

"(8) minority health professionals have historically tended to practice in low-income areas and to serve minorities;

"(9) minority health professionals have historically tended to engage in the general practice of medicine and specialties providing primary care;

"(10) reports published in leading medical journals indicate that access to health care among minorities can be substantially improved by increasing the number of minority health professionals;

"(11) increasing the number of minorities serving on the faculties of health professions schools can be an important factor in attracting minorities to pursue a career in the health professions;

"(12) diversity in the faculty and student body of health professions schools enhances the quality of education for all students attending the schools;

"(13) the Report of the Secretary's Task Force on Black and Minority Health (prepared for the Secretary of Health and Human Services and issued in 1985) described the health status problems of minorities, and made recommendations concerning measures that should be implemented by the Secretary with respect to improving the health status of minorities through programs for providing health information and education; and

"(14) the Office of Minority Health, created in 1985 by the Secretary of Health and Human Services, should be authorized pursuant to statute and should receive increased funding to support efforts to improve the health of individuals from disadvantaged backgrounds, including minorities, including the implementation of the recommendations made by the Secretary's Task Force on Black and Minority Health."

[1] *See References in Text note below.*

§300u–6a. Individual offices of minority health within the Department

(a) In general

The head of each agency specified in subsection (b)(1) [1] shall establish within the agency an office to be known as the Office of Minority Health. The head of each such Office shall be appointed by the head of the agency within which the Office is established, and shall report directly to the head of the agency. The head of such agency shall carry out this section (as this section relates to the agency) acting through such Director.

(b) Specified agencies

The agencies referred to in subsection (a) are the Centers for Disease Control and Prevention, the Health Resources and Services Administration, the Substance Abuse and Mental Health Services Administration, the Agency for Healthcare Research and Quality, the Food and Drug Administration, and the Centers for Medicare & Medicaid Services.

(c) Director; appointment

Each Office of Minority Health established in an agency listed in subsection (a) [2] shall be headed by a director, with documented experience and expertise in minority health services research and health disparities elimination.

(d) References

Except as otherwise specified, any reference in Federal law to an Office of Minority Health (in the Department of Health and Human Services) is deemed to be a reference to the Office of Minority Health in the Office of the Secretary.

(e) Funding

(1) Allocations

Of the amounts appropriated for a specified agency for a fiscal year, the Secretary must designate an appropriate amount of funds for the purpose of carrying out activities under this section through the minority health office of the agency. In reserving an amount under the preceding sentence for a minority health office for a fiscal year, the Secretary shall reduce, by substantially the same percentage, the amount that otherwise would be available for each of the programs of the designated agency involved.

(2) Availability of funds for staffing

The purposes for which amounts made available under paragraph [3] may be expended by a minority health office include the costs of employing staff for such office.

(July 1, 1944, ch. 373, title XVII, §1707A, as added Pub. L. 111–148, title X, §10334(b)(1), Mar. 23, 2010, 124 Stat. 972.)

STATUTORY NOTES AND RELATED SUBSIDIARIES

CONSTRUCTION

Pub. L. 111–148, title X, §10334(b)(2), Mar. 23, 2010, 124 Stat. 973, provided that: "Nothing in this subsection [enacting this section and provisions set out as a note under this section] and the amendments made by this subsection may be construed as establishing regulatory authority or modifying any existing regulatory authority."

APPLICATION OF ALLOCATION REQUIREMENTS

Pub. L. 112–10, div. B, title VIII, §1827, Apr. 15, 2011, 125 Stat. 162, provided that: "Hereafter, no funds appropriated by this division or by any previous or subsequent Act shall be subject to the allocation requirements of section 1707A(e) [42 U.S.C. 300u–6a(e)] of the PHS Act [Public Health Service Act]."

LIMITATION ON TERMINATION

Pub. L. 111–148, title X, §10334(b)(3), Mar. 23, 2010, 124 Stat. 973, provided that: "Notwithstanding any other provision of law, a Federal office of minority health or Federal appointive position with primary responsibility over minority health issues that is in existence in an office of [or] agency of the Department of Health and Human Services on the date of enactment of this section [Mar. 23, 2010] shall not be terminated, reorganized, or have any of its power or duties transferred unless such termination, reorganization, or transfer is approved by an Act of Congress."

[1] So in original. Subsec. (b) does not contain a par. (1).

[2] So in original. Probably should be "subsection (b)".

[3] So in original. Probably should be "paragraph (1)".

§300u–7. Office of Adolescent Health

(a) In general

There is established an Office of Adolescent Health within the Office of the Assistant Secretary for Health, which office [1] shall be headed by a director [1] appointed by the Secretary. The Secretary shall carry out this section acting through the Director of such Office.

(b) Duties

With respect to adolescent health, the Secretary shall—

(1) coordinate all activities within the Department of Health and Human Services that relate to disease prevention, health promotion, preventive health services, and health information and education with respect to the appropriate use of health care, including coordinating—

(A) the design of programs, support for programs, and the evaluation of programs;
(B) the monitoring of trends;
(C) projects of research (including multidisciplinary projects) on adolescent health; and
(D) the training of health providers who work with adolescents, particularly nurse practitioners, physician assistants, and social workers;

(2) coordinate the activities described in paragraph (1) with similar activities in the private sector; and
(3) support projects, conduct research, and disseminate information relating to preventive medicine, health promotion, and physical fitness and sports medicine.

(c) Certain demonstration projects

(1) In general

In carrying out subsection (b)(3), the Secretary may make grants to carry out demonstration projects for the purpose of improving adolescent health, including—
(A) projects to train health care providers in providing services to adolescents; and
(B) projects to reduce the incidence of violence among adolescents, particularly violence related to teen dating, which shall include projects to develop and implement educational program to increase abuse awareness and prevention.

(2) Authorization of appropriations

For the purpose of carrying out paragraph (1), there are authorized to be appropriated $8,000,000 for each of fiscal years 2023 through 2027.

(d) Information clearinghouse

In carrying out subsection (b), the Secretary shall establish and maintain a National Information Clearinghouse on Adolescent Health to collect and disseminate to health professionals and the general public information on adolescent health.

(e) National plan

In carrying out subsection (b), the Secretary shall develop a national plan for improving adolescent health. The plan shall be consistent with the applicable objectives established by the Secretary for the health status of the people of the United States for the year 2000, and shall be periodically reviewed, and as appropriate, revised. The plan, and any revisions in the plan, shall be submitted to the Committee on Energy and Commerce of the House of Representatives and the Committee on Labor and Human Resources of the Senate.

(f) Adolescent health

For purposes of this section, the term "adolescent health", with respect to adolescents of all ethnic and racial groups, means all diseases, disorders, and conditions (including with respect to mental health)—
(1) unique to adolescents, or more serious or more prevalent in adolescents;
(2) for which the factors of medical risk or types of medical intervention are different for adolescents, or for which it is unknown whether such factors or types are different for adolescents; or
(3) with respect to which there has been insufficient clinical research involving adolescents as subjects or insufficient clinical data on adolescents.

(g) Interagency Work Group

(1) Establishment

The Secretary shall establish the Federal Interagency Work Group on Teen Dating Violence (referred to in this section as the "Work Group").

(2) In general

(A) Composition

Not later than 120 days after March 15, 2022, the Secretary shall appoint representatives to the Work Group from the Administration for Children and Families, the Centers for Disease Control and Prevention, the Health Resources and Services Administration, the Department of Education, the Department of Justice, and other Federal agencies as determined appropriate by the Secretary.

(B) Consultation

The Work Group shall consult with—

(i) experts at the State, Tribal, and local levels with relevant backgrounds in reducing and preventing the incidence of teen dating violence;

(ii) victims of teen dating violence; and

(iii) family members of teens who were killed by a dating partner.

(3) Duties

The Work Group shall—

(A) examine all Federal efforts directed towards reducing and preventing teen dating violence;

(B) identify strategies, resources, and supports to improve State, Tribal, and local responses to the incidence of teen dating violence;

(C) make recommendations to Congress for improving Federal programs and efforts and coordination across such programs and efforts to reduce and prevent teen dating violence; and

(D) make recommendations for educating middle and high school students on teen dating violence.

(4) Annual report to Secretary

The Work Group shall annually prepare and submit to the Secretary, the Committee on Health, Education, Labor, and Pensions of the Senate, and the Committee on Education and Labor of the House of Representatives, a report on the activities carried out by the Work Group under subsection (c), including recommendations to reduce and prevent teen dating violence.

(July 1, 1944, ch. 373, title XVII, §1708, as added Pub. L. 102–531, title III, §302, Oct. 27, 1992, 106 Stat. 3483; amended Pub. L. 117–103, div. W, title XIII, §1315(b), Mar. 15, 2022, 136 Stat. 938.)

EDITORIAL NOTES

PRIOR PROVISIONS

A prior section 300u–7, act July 1, 1944, ch. 373, title XVII, §1708, as added Nov. 10, 1978, Pub. L. 95–626, title V, §502, 92 Stat. 3594; amended July 10, 1979, Pub. L. 96–32, §6(l), 93 Stat. 84, related to project grants for physical fitness improvement and research projects, prior to repeal by Pub. L. 98–551, §2(c), Oct. 30, 1984, 98 Stat. 2816.

AMENDMENTS

2022—Subsec. (c). Pub. L. 117–103, §1315(b)(1), added subsec. (c) and struck out former subsec. (c) which related to grants to carry out certain demonstration projects and authorizations of appropriations for fiscal years 1993 through 1997.

Subsec. (g). Pub. L. 117–103, §1315(b)(2), added subsec. (g).

STATUTORY NOTES AND RELATED SUBSIDIARIES

CHANGE OF NAME

Committee on Education and Labor of House of Representatives changed to Committee on Education and the Workforce of House of Representatives by House Resolution No. 5, One Hundred Eighteenth Congress, Jan. 9, 2023.

Committee on Labor and Human Resources of Senate changed to Committee on Health, Education, Labor, and Pensions of Senate by Senate Resolution No. 20, One Hundred Sixth Congress, Jan. 19, 1999.

Committee on Energy and Commerce of House of Representatives treated as referring to Committee on Commerce of House of Representatives by section 1(a) of Pub. L. 104–14, set out as a note preceding section 21 of Title 2, The Congress. Committee on Commerce of House of Representatives changed to Committee on Energy and Commerce of House of Representatives, and jurisdiction over matters relating to securities and exchanges and insurance generally transferred to Committee on Financial Services of House of Representatives by House Resolution No. 5, One Hundred Seventh Congress, Jan. 3, 2001.

EFFECTIVE DATE OF 2022 AMENDMENT

Amendment by Pub. L. 117–103 not effective until Oct. 1 of the first fiscal year beginning after Mar. 15, 2022, see section 4(a) of div. W of Pub. L. 117–103, set out as an Effective Date note under section 6851 of Title 15, Commerce and Trade.

[1] *So in original. Probably should be capitalized.*

§300u–8. Biennial report regarding nutrition and health

(a) Biennial report

The Secretary shall require the Surgeon General of the Public Health Service to prepare biennial reports on the relationship between nutrition and health. Such reports may, with respect to such relationship, include any recommendations of the Secretary and the Surgeon General.

(b) Submission to Congress

The Secretary shall ensure that, not later than February 1 of 1995 and of every second year thereafter, a report under subsection (a) is submitted to the Committee on Energy and Commerce of the House of Representatives and the Committee on Labor and Human Resources of the Senate.

(July 1, 1944, ch. 373, title XVII, §1709, as added Pub. L. 103–183, title VII, §704, Dec. 14, 1993, 107 Stat. 2240.)

EDITORIAL NOTES

PRIOR PROVISIONS

A prior section 300u–8, act July 1, 1944, ch. 373, title XVII, §1709, as added Nov. 10, 1978, Pub. L. 95–626, title V, §502, 92 Stat. 3594, related to establishment of national program on sports medicine research, prior to repeal by Pub. L. 98–551, §2(c), Oct. 30, 1984, 98 Stat. 2816.

STATUTORY NOTES AND RELATED SUBSIDIARIES

CHANGE OF NAME

Committee on Labor and Human Resources of Senate changed to Committee on Health, Education, Labor, and Pensions of Senate by Senate Resolution No. 20, One Hundred Sixth Congress, Jan. 19, 1999.

Committee on Energy and Commerce of House of Representatives treated as referring to Committee on Commerce of House of Representatives by section 1(a) of Pub. L. 104–14, set out as a note preceding section 21 of Title 2, The Congress. Committee on Commerce of House of Representatives changed to Committee on Energy and Commerce of House of Representatives, and jurisdiction over matters relating to securities and exchanges and insurance generally transferred to Committee on Financial Services of House of Representatives by House Resolution No. 5, One Hundred Seventh Congress, Jan. 3, 2001.

§300u–9. Education regarding DES

(a) In general

The Secretary, acting through the heads of the appropriate agencies of the Public Health Service, shall carry out a national program for the education of health professionals and the public with respect to the drug diethylstilbestrol (commonly known as DES). To the extent appropriate, such

national program shall use methodologies developed through the education demonstration program carried out under section 283a–3 [1] of this title. In developing and carrying out the national program, the Secretary shall consult closely with representatives of nonprofit private entities that represent individuals who have been exposed to DES and that have expertise in community-based information campaigns for the public and for health care providers. The implementation of the national program shall begin during fiscal year 1999.

(b) Authorization of appropriations

For the purpose of carrying out this section, there are authorized to be appropriated such sums as may be necessary for each of the fiscal years 1999 through 2003. The authorization of appropriations established in the preceding sentence is in addition to any other authorization of appropriation that is available for such purpose.

(July 1, 1944, ch. 373, title XVII, §1710, as added Pub. L. 105–340, title I, §101(b), Oct. 31, 1998, 112 Stat. 3191; amended Pub. L. 109–482, title I, §104(a)(2), Jan. 15, 2007, 120 Stat. 3689.)

EDITORIAL NOTES

REFERENCES IN TEXT

Section 283a–3 of this title, referred to in subsec. (a), was in the original "section 403C", and was translated as meaning section 403D of act July 1, 1944, ch. 373, as renumbered section 403C by section 104(a)(1) of Pub. L. 109–482 and then section 403D by section 1104(4) of Pub. L. 110–85. Another section 403C of act July 1, 1944, ch. 373, as added by section 104(a)(3) of Pub. L. 109–482, is classified to section 283a–2 of this title.

PRIOR PROVISIONS

A prior section 300u–9, act July 1, 1944, ch. 373, title XVII, §1710, as added Nov. 10, 1978, Pub. L. 95–626, title V, §502, 92 Stat. 3594; amended Oct. 17, 1979, Pub. L. 96–88, title III, §301(b)(2), title V, §507, 93 Stat. 678, 692, related to Conference on Education in Lifetime Sports, prior to repeal by Pub. L. 98–551, §2(c), Oct. 30, 1984, 98 Stat. 2816.

AMENDMENTS

2007—Subsec. (a). Pub. L. 109–482 substituted "section 283a–3" for "section 283a".

STATUTORY NOTES AND RELATED SUBSIDIARIES

EFFECTIVE DATE OF 2007 AMENDMENT

Amendment by Pub. L. 109–482 applicable only with respect to amounts appropriated for fiscal year 2007 or subsequent fiscal years, see section 109 of Pub. L. 109–482, set out as a note under section 281 of this title.

[1] *See References in Text note below.*

§300u–10. National Prevention, Health Promotion and Public Health Council

(a) Establishment

The President shall establish, within the Department of Health and Human Services, a council to be known as the "National Prevention, Health Promotion and Public Health Council" (referred to in this section as the "Council").

(b) Chairperson

The President shall appoint the Surgeon General to serve as the chairperson of the Council.

(c) Composition

The Council shall be composed of—

(1) the Secretary of Health and Human Services;

(2) the Secretary of Agriculture;
(3) the Secretary of Education;
(4) the Chairman of the Federal Trade Commission;
(5) the Secretary of Transportation;
(6) the Secretary of Labor;
(7) the Secretary of Homeland Security;
(8) the Administrator of the Environmental Protection Agency;
(9) the Director of the Office of National Drug Control Policy;
(10) the Director of the Domestic Policy Council;
(11) the Assistant Secretary for Indian Affairs;
(12) the Chairman of the Corporation for National and Community Service; and
(13) the head of any other Federal agency that the chairperson determines is appropriate.

(d) Purposes and duties

The Council shall—

(1) provide coordination and leadership at the Federal level, and among all Federal departments and agencies, with respect to prevention, wellness and health promotion practices, the public health system, and integrative health care in the United States;

(2) after obtaining input from relevant stakeholders, develop a national prevention, health promotion, public health, and integrative health care strategy that incorporates the most effective and achievable means of improving the health status of Americans and reducing the incidence of preventable illness and disability in the United States;

(3) provide recommendations to the President and Congress concerning the most pressing health issues confronting the United States and changes in Federal policy to achieve national wellness, health promotion, and public health goals, including the reduction of tobacco use, sedentary behavior, and poor nutrition;

(4) consider and propose evidence-based models, policies, and innovative approaches for the promotion of transformative models of prevention, integrative health, and public health on individual and community levels across the United States;

(5) establish processes for continual public input, including input from State, regional, and local leadership communities and other relevant stakeholders, including Indian tribes and tribal organizations;

(6) submit the reports required under subsection (g); [1] and
(7) carry out other activities determined appropriate by the President.

(e) Meetings

The Council shall meet at the call of the Chairperson.

(f) Advisory Group

(1) In general

The President shall establish an Advisory Group to the Council to be known as the "Advisory Group on Prevention, Health Promotion, and Integrative and Public Health" (hereafter referred to in this section as the "Advisory Group"). The Advisory Group shall be within the Department of Health and Human Services and report to the Surgeon General.

(2) Composition

(A) In general

The Advisory Group shall be composed of not more than 25 non-Federal members to be appointed by the President.

(B) Representation

In appointing members under subparagraph (A), the President shall ensure that the Advisory Group includes a diverse group of licensed health professionals, including integrative health practitioners who have expertise in—

(i) worksite health promotion;
(ii) community services, including community health centers;
(iii) preventive medicine;
(iv) health coaching;
(v) public health education;
(vi) geriatrics; and
(vii) rehabilitation medicine.

(3) Purposes and duties

The Advisory Group shall develop policy and program recommendations and advise the Council on lifestyle-based chronic disease prevention and management, integrative health care practices, and health promotion.

(g) National prevention and health promotion strategy

Not later than 1 year after March 23, 2010, the Chairperson, in consultation with the Council, shall develop and make public a national prevention, health promotion and public health strategy, and shall review and revise such strategy periodically. Such strategy shall—

(1) set specific goals and objectives for improving the health of the United States through federally-supported prevention, health promotion, and public health programs, consistent with ongoing goal setting efforts conducted by specific agencies;

(2) establish specific and measurable actions and timelines to carry out the strategy, and determine accountability for meeting those timelines, within and across Federal departments and agencies; and

(3) make recommendations to improve Federal efforts relating to prevention, health promotion, public health, and integrative health care practices to ensure Federal efforts are consistent with available standards and evidence.

(h) Report

Not later than July 1, 2010, and annually thereafter through January 1, 2015, the Council shall submit to the President and the relevant committees of Congress, a report that—

(1) describes the activities and efforts on prevention, health promotion, and public health and activities to develop a national strategy conducted by the Council during the period for which the report is prepared;

(2) describes the national progress in meeting specific prevention, health promotion, and public health goals defined in the strategy and further describes corrective actions recommended by the Council and taken by relevant agencies and organizations to meet these goals;

(3) contains a list of national priorities on health promotion and disease prevention to address lifestyle behavior modification (smoking cessation, proper nutrition, appropriate exercise, mental health, behavioral health, substance use disorder, and domestic violence screenings) and the prevention measures for the 5 leading disease killers in the United States;

(4) contains specific science-based initiatives to achieve the measurable goals of Healthy People 2020 regarding nutrition, exercise, and smoking cessation, and targeting the 5 leading disease killers in the United States;

(5) contains specific plans for consolidating Federal health programs and Centers that exist to promote healthy behavior and reduce disease risk (including eliminating programs and offices determined to be ineffective in meeting the priority goals of Healthy People 2020);

(6) contains specific plans to ensure that all Federal health care programs are fully coordinated with science-based prevention recommendations by the Director of the Centers for Disease Control and Prevention; and

(7) contains specific plans to ensure that all non-Department of Health and Human Services prevention programs are based on the science-based guidelines developed by the Centers for Disease Control and Prevention under paragraph (4).

(i) Periodic reviews

The Secretary shall conduct periodic reviews, not less than every 5 years, and evaluations of every

Federal disease prevention and health promotion initiative, program, and agency. Such reviews shall be evaluated based on effectiveness in meeting metrics-based goals with an analysis posted on such agencies' public Internet websites.

(Pub. L. 111–148, title IV, §4001, title X, §10401(a), Mar. 23, 2010, 124 Stat. 538, 974; Pub. L. 113–188, title IX, §902(a), Nov. 26, 2014, 128 Stat. 2020.)

EDITORIAL NOTES

CODIFICATION

Section was enacted as part of the Patient Protection and Affordable Care Act, and not as part of the Public Health Service Act which comprises this chapter.

AMENDMENTS

2014—Subsec. (i). Pub. L. 113–188 substituted "The Secretary shall conduct periodic reviews" for "The Secretary and the Comptroller General of the United States shall jointly conduct periodic reviews".

2010—Subsec. (h)(4), (5). Pub. L. 111–148, §10401(a), substituted "2020" for "2010".

EXECUTIVE DOCUMENTS

EX. ORD. NO. 13544. ESTABLISHING THE NATIONAL PREVENTION, HEALTH PROMOTION, AND PUBLIC HEALTH COUNCIL

Ex. Ord. No. 13544, June 10, 2010, 75 F.R. 33983, provided:

By the authority vested in me as President by the Constitution and the laws of the United States of America, including section 4001 of the Patient Protection and Affordable Care Act (Public Law 111–148), it is hereby ordered as follows:

SECTION 1. *Establishment.* There is established within the Department of Health and Human Services, the National Prevention, Health Promotion, and Public Health Council (Council).

SEC. 2. *Membership.*

(a) The Surgeon General shall serve as the Chair of the Council, which shall be composed of:

(1) the Secretary of Agriculture;

(2) the Secretary of Labor;

(3) the Secretary of Health and Human Services;

(4) the Secretary of Transportation;

(5) the Secretary of Education;

(6) the Secretary of Homeland Security;

(7) the Administrator of the Environmental Protection Agency;

(8) the Chair of the Federal Trade Commission;

(9) the Director of National Drug Control Policy;

(10) the Assistant to the President and Director of the Domestic Policy Council;

(11) the Assistant Secretary of the Interior for Indian Affairs;

(12) the Chairman of the Corporation for National and Community Service; and

(13) the head of any other executive department or agency that the Chair may, from time to time, determine is appropriate.

(b) The Council shall meet at the call of the Chair.

SEC. 3. *Purposes and Duties*. The Council shall:

(a) provide coordination and leadership at the Federal level, and among all executive departments and agencies, with respect to prevention, wellness, and health promotion practices, the public health system, and integrative health care in the United States;

(b) develop, after obtaining input from relevant stakeholders, a national prevention, health promotion, public health, and integrative health-care strategy that incorporates the most effective and achievable means of improving the health status of Americans and reducing the incidence of preventable illness and disability in the United States, as further described in section 5 of this order;

(c) provide recommendations to the President and the Congress concerning the most pressing health issues confronting the United States and changes in Federal policy to achieve national wellness, health promotion, and public health goals, including the reduction of tobacco use, sedentary behavior, and poor nutrition;

(d) consider and propose evidence-based models, policies, and innovative approaches for the promotion of

transformative models of prevention, integrative health, and public health on individual and community levels across the United States;

(e) establish processes for continual public input, including input from State, regional, and local leadership communities and other relevant stakeholders, including Indian tribes and tribal organizations;

(f) submit the reports required by section 6 of this order; and

(g) carry out such other activities as are determined appropriate by the President.

SEC. 4. *Advisory Group.*

(a) There is established within the Department of Health and Human Services an Advisory Group on Prevention, Health Promotion, and Integrative and Public Health (Advisory Group), which shall report to the Chair of the Council.

(b) The Advisory Group shall be composed of not more than 25 members or representatives from outside the Federal Government appointed by the President and shall include a diverse group of licensed health professionals, including integrative health practitioners who are representative of or have expertise in:

(1) worksite health promotion;

(2) community services, including community health centers;

(3) preventive medicine;

(4) health coaching;

(5) public health education;

(6) geriatrics; and

(7) rehabilitation medicine.

(c) The Advisory Group shall develop policy and program recommendations and advise the Council on lifestyle-based chronic disease prevention and management, integrative health care practices, and health promotion.

SEC. 5. *National Prevention and Health Promotion Strategy*. Not later than March 23, 2011, the Chair, in consultation with the Council, shall develop and make public a national prevention, health promotion, and public health strategy (national strategy), and shall review and revise it periodically. The national strategy shall:

(a) set specific goals and objectives for improving the health of the United States through federally supported prevention, health promotion, and public health programs, consistent with ongoing goal setting efforts conducted by specific agencies;

(b) establish specific and measurable actions and timelines to carry out the strategy, and determine accountability for meeting those timelines, within and across Federal departments and agencies; and

(c) make recommendations to improve Federal efforts relating to prevention, health promotion, public health, and integrative health-care practices to ensure that Federal efforts are consistent with available standards and evidence.

SEC. 6. *Reports*. Not later than July 1, 2010, and annually thereafter until January 1, 2015, the Council shall submit to the President and the relevant committees of the Congress, a report that:

(a) describes the activities and efforts on prevention, health promotion, and public health and activities to develop the national strategy conducted by the Council during the period for which the report is prepared;

(b) describes the national progress in meeting specific prevention, health promotion, and public health goals defined in the national strategy and further describes corrective actions recommended by the Council and actions taken by relevant agencies and organizations to meet these goals;

(c) contains a list of national priorities on health promotion and disease prevention to address lifestyle behavior modification (including smoking cessation, proper nutrition, appropriate exercise, mental health, behavioral health, substance-use disorder, and domestic violence screenings) and the prevention measures for the five leading disease killers in the United States;

(d) contains specific science-based initiatives to achieve the measurable goals of the Healthy People 2020 program of the Department of Health and Human Services regarding nutrition, exercise, and smoking cessation, and targeting the five leading disease killers in the United States;

(e) contains specific plans for consolidating Federal health programs and centers that exist to promote healthy behavior and reduce disease risk (including eliminating programs and offices determined to be ineffective in meeting the priority goals of the Healthy People 2020 program of the Department of Health and Human Services);

(f) contains specific plans to ensure that all Federal health-care programs are fully coordinated with science-based prevention recommendations by the Director of the Centers for Disease Control and Prevention; and

(g) contains specific plans to ensure that all prevention programs outside the Department of Health and Human Services are based on the science-based guidelines developed by the Centers for Disease Control and

Prevention under subsection (d) of this section.

SEC. 7. *Administration.*

(a) The Department of Health and Human Services shall provide funding and administrative support for the Council and the Advisory Group to the extent permitted by law and within existing appropriations.

(b) All executive departments and agencies shall provide information and assistance to the Council as the Chair may request for purposes of carrying out the Council's functions, to the extent permitted by law.

(c) Members of the Advisory Group shall serve without compensation, but shall be allowed travel expenses, including per diem in lieu of subsistence, as authorized by law for persons serving intermittently in Government service (5 U.S.C. 5701–5707), consistent with the availability of funds.

SEC. 8. *General Provisions.*

(a) Insofar as the Federal Advisory Committee Act, as amended ([former] 5 U.S.C App.) [see 5 U.S.C. 1001 et seq.] may apply to the Advisory Group, any functions of the President under that Act, except that of reporting to the Congress, shall be performed by the Secretary of Health and Human Services in accordance with the guidelines that have been issued by the Administrator of General Services.

(b) Nothing in this order shall be construed to impair or otherwise affect:

(1) authority granted by law to an executive department, agency, or the head thereof; or

(2) functions of the Director of the Office of Management and Budget relating to budgetary, administrative, or legislative proposals.

(c) This order is not intended to, and does not, create any right or benefit, substantive or procedural, enforceable at law or in equity by any party against the United States, its departments, agencies, or entities, its officers, employees, or agents, or any other person.

BARACK OBAMA.

EXTENSION OF TERM OF ADVISORY GROUP ON PREVENTION, HEALTH PROMOTION, AND INTEGRATIVE AND PUBLIC HEALTH

Term of Advisory Group on Prevention, Health Promotion, and Integrative and Public Health extended until Sept. 30, 2012, by Ex. Ord. No. 13591, Nov. 23, 2011, 76 F.R. 74623, formerly set out as a note under section 1013 of Title 5, Government Organization and Employees.

For extensions of Advisory Group after its reestablishment, see table following Ex. Ord. No. 13631, set out below.

EX. ORD. NO. 13631. REESTABLISHMENT OF ADVISORY GROUP

Ex. Ord. No. 13631, Dec. 7, 2012, 77 F.R. 74101, provided:

By the authority vested in me as President by the Constitution and the laws of the United States of America, including section 4001 of the Patient Protection and Affordable Care Act (Public Law 111–148), 42 U.S.C. 300u–10, it is hereby ordered as follows:

SECTION 1. *Reestablishing the Advisory Group on Prevention, Health Promotion, and Integrative and Public Health*. The Advisory Group on Prevention, Health Promotion, and Integrative and Public Health (Advisory Group), as set forth under the provisions of Executive Order 13544 of June 10, 2010, and continued by section 2 of Executive Order 13591 of November 23, 2011, is hereby reestablished and shall terminate on September 30, 2013, unless extended by the President. The same members who were serving on the Advisory Group on September 30, 2012, are hereby reappointed to the Advisory Group as reestablished by this order, as if the Advisory Group had continued without termination through the date of this Executive Order.

SEC. 2. *General Provisions*. (a) Nothing in this order shall be construed to impair or otherwise affect:

(1) the authority granted by law to an executive department, agency, or the head thereof; or

(2) the functions of the Director of the Office of Management and Budget relating to budgetary, administrative, or legislative proposals.

(b) This order is not intended to, and does not, create any right or benefit, substantive or procedural, enforceable at law or in equity by any party against the United States, its departments, agencies, or entities, its officers, employees, or agents, or any other person.

BARACK OBAMA.

EXTENSION OF TERM OF ADVISORY GROUP ON PREVENTION, HEALTH PROMOTION, AND INTEGRATIVE AND PUBLIC HEALTH

Term of Advisory Group on Prevention, Health Promotion, and Integrative and Public Health extended until Sept. 30, 2017, by Ex. Ord. No. 13708, Sept. 30, 2015, 80 F.R. 60271, formerly set out as a note under section 1013 of Title 5, Government Organization and Employees.

Previous extension of term of Advisory Group on Prevention, Health Promotion, and Integrative and Public

Health was contained in the following prior Executive Order:
Ex. Ord. No. 13652, Sept. 30, 2013, 78 F.R. 61817, extended term until Sept. 30, 2015.

[1] *So in original. Probably should be "(h);".*

§300u–11. Prevention and Public Health Fund

(a) Purpose

It is the purpose of this section to establish a Prevention and Public Health Fund (referred to in this section as the "Fund"), to be administered through the Department of Health and Human Services, Office of the Secretary, to provide for expanded and sustained national investment in prevention and public health programs to improve health and help restrain the rate of growth in private and public sector health care costs.

(b) Funding

There are hereby authorized to be appropriated, and appropriated, to the Fund, out of any monies in the Treasury not otherwise appropriated—

(1) for fiscal year 2010, $500,000,000;
(2) for each of fiscal years 2012 through 2017, $1,000,000,000;
(3) for fiscal year 2018, $900,000,000;
(4) for fiscal year 2019, $900,000,000;
(5) for each of fiscal years 2020 and 2021, $950,000,000;
(6) for each of fiscal years 2022 and 2023, $1,000,000,000;
(7) for each of fiscal years 2024 and 2025, $1,300,000,000;
(8) for each of fiscal years 2026 and 2027, $1,525,000,000;
(9) for each of fiscal years 2028 and 2029, $1,725,000,000; and
(10) for fiscal year 2030 and each fiscal year thereafter, $2,000,000,000.

(c) Use of Fund

The Secretary shall transfer amounts in the Fund to accounts within the Department of Health and Human Services to increase funding, over the fiscal year 2008 level, for programs authorized by the Public Health Service Act [42 U.S.C. 201 et seq.], for prevention, wellness, and public health activities including prevention research, health screenings, and initiatives, such as the Community Transformation grant program, the Education and Outreach Campaign Regarding Preventive Benefits, and immunization programs.

(d) Transfer authority

The Committee on Appropriations of the Senate and the Committee on Appropriations of the House of Representatives may provide for the transfer of funds in the Fund to eligible activities under this section, subject to subsection (c).

(Pub. L. 111–148, title IV, §4002, title X, §10401(b), Mar. 23, 2010, 124 Stat. 541, 974; Pub. L. 112–96, title III, §3205, Feb. 22, 2012, 126 Stat. 194; Pub. L. 114–255, div. A, title V, §5009, Dec. 13, 2016, 130 Stat. 1197; Pub. L. 115–96, div. C, title I, §3103, Dec. 22, 2017, 131 Stat. 2049; Pub. L. 115–123, div. E, title XII, §53119, Feb. 9, 2018, 132 Stat. 308; Pub. L. 117–328, div. FF, title VII, §7701(c), Dec. 29, 2022, 136 Stat. 5966.)

EDITORIAL NOTES

REFERENCES IN TEXT

The Public Health Service Act, referred to in subsec. (c), is act July 1, 1944, ch. 373, 58 Stat. 682, which is classified generally to this chapter. For complete classification of this Act to the Code, see Short Title note set out under section 201 of this title and Tables.

CODIFICATION

Section was enacted as part of the Patient Protection and Affordable Care Act, and not as part of the Public Health Service Act which comprises this chapter.

AMENDMENTS

2022—Subsec. (b)(8). Pub. L. 117–328, §7701(c)(1), substituted "$1,525,000,000;" for "$1,800,000,000; and".

Subsec. (b)(9). Pub. L. 117–328, §7701(c)(2), added par. (9) and struck out former par. (9) which read as follows: "for fiscal year 2028 and each fiscal year thereafter, $2,000,000,000."

Subsec. (b)(10). Pub. L. 117–328, §7701(c)(3), added par. (10).

2018—Subsec. (b)(4) to (9). Pub. L. 115–123 added pars. (4) to (9) and struck out former pars. (4) to (9) which read as follows:

"(4) for fiscal year 2019, $800,000,000;

"(5) for each of fiscal years 2020 and 2021, $800,000,000; and

"(6) for fiscal year 2022, $1,250,000,000;

"(7) for fiscal year 2023, $1,000,000,000;

"(8) for fiscal year 2024, $1,700,000,000; and

"(9) for fiscal year 2025 and each fiscal year thereafter, $2,000,000,000."

2017—Subsec. (b)(3). Pub. L. 115–96, §3103(1), substituted "fiscal year 2018" for "each of fiscal years 2018 and 2019".

Subsec. (b)(4). Pub. L. 115–96, §3103(3), added par. (4). Former par. (4) redesignated (5).

Subsec. (b)(5). Pub. L. 115–96, §3103(2), (4), redesignated par. (4) as (5) and substituted "$800,000,000" for "$1,000,000,000". Former par. (5) redesignated (6).

Subsec. (b)(6). Pub. L. 115–96, §3103(2), (5), redesignated par. (5) as (6) and substituted "$1,250,000,000" for "$1,500,000,000". Former par. (6) redesignated (7).

Subsec. (b)(7) to (9). Pub. L. 115–96, §3103(2), redesignated pars. (6) to (8) as (7) to (9), respectively.

2016—Subsec. (b)(3). Pub. L. 114–255, §5009(1), substituted "$900,000,000" for "$1,250,000,000".

Subsec. (b)(4). Pub. L. 114–255, §5009(2), substituted "$1,000,000,000" for "$1,500,000,000".

Subsec. (b)(5) to (8). Pub. L. 114–255, §5009(3), added pars. (5) to (8) and struck out former par. (5) which read as follows: "for fiscal year 2022, and each fiscal year thereafter, $2,000,000,000."

2012—Subsec. (b)(2) to (6). Pub. L. 112–96 added pars. (2) to (5) and struck out former pars. (2) to (6) which appropriated amounts for fiscal years 2011 through 2015 and each fiscal year thereafter.

2010—Subsec. (c). Pub. L. 111–148, §10401(b), substituted "research, health screenings, and initiatives" for "research and health screenings" and "Regarding Preventive" for "for Preventive".

STATUTORY NOTES AND RELATED SUBSIDIARIES

WEBSITE

Pub. L. 115–31, div. H, title II, §219, May 5, 2017, 131 Stat. 541, provided that:

"(a) The Secretary shall establish a publicly accessible Web site to provide information regarding the uses of funds made available under section 4002 of the Patient Protection and Affordable Care Act of 2010 ('ACA') [42 U.S.C. 300u–11].

"(b) With respect to funds provided under section 4002 of the ACA, the Secretary shall include on the Web site established under subsection (a) at a minimum the following information:

"(1) In the case of each transfer of funds under section 4002(c), a statement indicating the program or activity receiving funds, the operating division or office that will administer the funds, and the planned uses of the funds, to be posted not later than the day after the transfer is made.

"(2) Identification (along with a link to the full text) of each funding opportunity announcement, request for proposals, or other announcement or solicitation of proposals for grants, cooperative agreements, or contracts intended to be awarded using such funds, to be posted not later than the day after the announcement or solicitation is issued.

"(3) Identification of each grant, cooperative agreement, or contract with a value of $25,000 or more awarded using such funds, including the purpose of the award and the identity of the recipient, to be posted not later than 5 days after the award is made.

"(4) A report detailing the uses of all funds transferred under section 4002(c) during the fiscal year, to be posted not later than 90 days after the end of the fiscal year.

"(c) With respect to awards made in fiscal years 2013 through 2017, the Secretary shall also include on the Web site established under subsection (a), semi-annual reports from each entity awarded a grant, cooperative agreement, or contract from such funds with a value of $25,000 or more, summarizing the activities

undertaken and identifying any sub-grants or sub-contracts awarded (including the purpose of the award and the identity of the recipient), to be posted not later than 30 days after the end of each 6-month period.

"(d) In carrying out this section, the Secretary shall—

"(1) present the information required in subsection (b)(1) on a single webpage or on a single database;

"(2) ensure that all information required in this section is directly accessible from the single webpage or database; and

"(3) ensure that all information required in this section is able to be organized by program or State."

Similar provisions were contained in the following prior appropriation acts:

Pub. L. 114–113, div. H, title II, §220, Dec. 18, 2015, 129 Stat. 2622.

Pub. L. 113–235, div. G, title II, §218, Dec. 16, 2014, 128 Stat. 2488.

Pub. L. 113–76, div. H, title II, §218, Jan. 17, 2014, 128 Stat. 385.

Pub. L. 112–74, div. F, title II, §220(a), Dec. 23, 2011, 125 Stat. 1085.

§300u–12. Education and outreach campaign regarding preventive benefits

(a) In general

The Secretary of Health and Human Services (referred to in this section as the "Secretary") shall provide for the planning and implementation of a national public–private partnership for a prevention and health promotion outreach and education campaign to raise public awareness of health improvement across the life span. Such campaign shall include the dissemination of information that—

(1) describes the importance of utilizing preventive services to promote wellness, reduce health disparities, and mitigate chronic disease;

(2) promotes the use of preventive services recommended by the United States Preventive Services Task Force and the Community Preventive Services Task Force;

(3) encourages healthy behaviors linked to the prevention of chronic diseases;

(4) explains the preventive services covered under health plans offered through an Exchange;

(5) describes additional preventive care supported by the Centers for Disease Control and Prevention, the Health Resources and Services Administration, the Substance Abuse and Mental Health Services Administration, the Advisory Committee on Immunization Practices, and other appropriate agencies; and

(6) includes general health promotion information.

(b) Consultation

In coordinating the campaign under subsection (a), the Secretary shall consult with the Institute of Medicine to provide ongoing advice on evidence-based scientific information for policy, program development, and evaluation.

(c) Media campaign

(1) In general

Not later than 1 year after March 23, 2010, the Secretary, acting through the Director of the Centers for Disease Control and Prevention, shall establish and implement a national science-based media campaign on health promotion and disease prevention.

(2) Requirement of campaign

The campaign implemented under paragraph (1)—

(A) shall be designed to address proper nutrition, regular exercise, smoking cessation, obesity reduction, the 5 leading disease killers in the United States, and secondary prevention through disease screening promotion;

(B) shall be carried out through competitively bid contracts awarded to entities providing for the professional production and design of such campaign;

(C) may include the use of television, radio, Internet, and other commercial marketing venues and may be targeted to specific age groups based on peer-reviewed social research;

(D) shall not be duplicative of any other Federal efforts relating to health promotion and

disease prevention; and

(E) may include the use of humor and nationally recognized positive role models.

(3) Evaluation

The Secretary shall ensure that the campaign implemented under paragraph (1) is subject to an independent evaluation every 2 years and shall report every 2 years to Congress on the effectiveness of such campaigns towards meeting science-based metrics.

(d) Website

The Secretary, in consultation with private-sector experts, shall maintain or enter into a contract to maintain an Internet website to provide science-based information on guidelines for nutrition, regular exercise, obesity reduction, smoking cessation, and specific chronic disease prevention. Such website shall be designed to provide information to health care providers and consumers.

(e) Dissemination of information through providers

The Secretary, acting through the Centers for Disease Control and Prevention, shall develop and implement a plan for the dissemination of health promotion and disease prevention information consistent with national priorities, to health care providers who participate in Federal programs, including programs administered by the Indian Health Service, the Department of Veterans Affairs, the Department of Defense, and the Health Resources and Services Administration, and Medicare and Medicaid.

(f) Personalized prevention plans

(1) Contract

The Secretary, acting through the Director of the Centers for Disease Control and Prevention, shall enter into a contract with a qualified entity for the development and operation of a Federal Internet website personalized prevention plan tool.

(2) Use

The website developed under paragraph (1) shall be designed to be used as a source of the most up-to-date scientific evidence relating to disease prevention for use by individuals. Such website shall contain a component that enables an individual to determine their disease risk (based on personal health and family history, BMI, and other relevant information) relating to the 5 leading diseases in the United States, and obtain personalized suggestions for preventing such diseases.

(g) Internet portal

The Secretary shall establish an Internet portal for accessing risk-assessment tools developed and maintained by private and academic entities.

(h) Priority funding

Funding for the activities authorized under this section shall take priority over funding provided through the Centers for Disease Control and Prevention for grants to States and other entities for similar purposes and goals as provided for in this section. Not to exceed $500,000,000 shall be expended on the campaigns and activities required under this section.

(i) Public awareness of preventive and obesity-related services

(1) Information to States

The Secretary of Health and Human Services shall provide guidance and relevant information to States and health care providers regarding preventive and obesity-related services that are available to Medicaid enrollees, including obesity screening and counseling for children and adults.

(2) Information to enrollees

Each State shall design a public awareness campaign to educate Medicaid enrollees regarding availability and coverage of such services, with the goal of reducing incidences of obesity.

(3) Report

Not later than January 1, 2011, and every 3 years thereafter through January 1, 2017, the Secretary of Health and Human Services shall report to Congress on the status and effectiveness of efforts under paragraphs (1) and (2), including summaries of the States' efforts to increase awareness of coverage of obesity-related services.

(j) Authorization of appropriations

There are authorized to be appropriated such sums as may be necessary to carry out this section.

(Pub. L. 111–148, title IV, §4004, title X, §10401(c), Mar. 23, 2010, 124 Stat. 544, 975.)

EDITORIAL NOTES

CODIFICATION

Section was enacted as part of the Patient Protection and Affordable Care Act, and not as part of the Public Health Service Act which comprises this chapter.

AMENDMENTS

2010—Subsec. (a)(4). Pub. L. 111–148, §10401(c), substituted "an Exchange" for "a Gateway".

§300u–13. Community transformation grants

(a) In general

The Secretary of Health and Human Services (referred to in this section as the "Secretary"), acting through the Director of the Centers for Disease Control and Prevention (referred to in this section as the "Director"), shall award competitive grants to State and local governmental agencies and community-based organizations for the implementation, evaluation, and dissemination of evidence-based community preventive health activities in order to reduce chronic disease rates, prevent the development of secondary conditions, address health disparities, and develop a stronger evidence-base of effective prevention programming, with not less than 20 percent of such grants being awarded to rural and frontier areas.

(b) Eligibility

To be eligible to receive a grant under subsection (a), an entity shall—

(1) be—

(A) a State governmental agency;

(B) a local governmental agency;

(C) a national network of community-based organizations;

(D) a State or local non-profit organization; or

(E) an Indian tribe; and

(2) submit to the Director an application at such time, in such a manner, and containing such information as the Director may require, including a description of the program to be carried out under the grant; and

(3) demonstrate a history or capacity, if funded, to develop relationships necessary to engage key stakeholders from multiple sectors within and beyond health care and across a community, such as healthy futures corps and health care providers.

(c) Use of funds

(1) In general

An eligible entity shall use amounts received under a grant under this section to carry out programs described in this subsection.

(2) Community transformation plan

(A) In general

An eligible entity that receives a grant under this section shall submit to the Director (for approval) a detailed plan that includes the policy, environmental, programmatic, and [1] as appropriate [1] infrastructure changes needed to promote healthy living and reduce disparities.

(B) Activities

Activities within the plan may focus on (but not be limited to)—

(i) creating healthier school environments, including increasing healthy food options, physical activity opportunities, promotion of healthy lifestyle, emotional wellness, and prevention curricula, and activities to prevent chronic diseases;

(ii) creating the infrastructure to support active living and access to nutritious foods in a safe environment;

(iii) developing and promoting programs targeting a variety of age levels to increase access to nutrition, physical activity and smoking cessation, improve social and emotional wellness, enhance safety in a community, or address any other chronic disease priority area identified by the grantee;

(iv) assessing and implementing worksite wellness programming and incentives;

(v) working to highlight healthy options at restaurants and other food venues;

(vi) prioritizing strategies to reduce racial and ethnic disparities, including social, economic, and geographic determinants of health; and

(vii) addressing special populations needs, including all age groups and individuals with disabilities, and individuals in urban, rural, and frontier areas.

(3) Community-based prevention health activities

(A) In general

An eligible entity shall use amounts received under a grant under this section to implement a variety of programs, policies, and infrastructure improvements to promote healthier lifestyles.

(B) Activities

An eligible entity shall implement activities detailed in the community transformation plan under paragraph (2).

(C) In-kind support

An eligible entity may provide in-kind resources such as staff, equipment, or office space in carrying out activities under this section.

(4) Evaluation

(A) In general

An eligible entity shall use amounts provided under a grant under this section to conduct activities to measure changes in the prevalence of chronic disease risk factors among community members participating in preventive health activities [2]

(B) Types of measures

In carrying out subparagraph (A), the eligible entity shall, with respect to residents in the community, measure—

(i) changes in weight;

(ii) changes in proper nutrition;

(iii) changes in physical activity;

(iv) changes in tobacco use prevalence;

(v) changes in emotional well-being and overall mental health;

(vi) other factors using community-specific data from the Behavioral Risk Factor Surveillance Survey; and

(vii) other factors as determined by the Secretary.

(C) Reporting

An eligible entity shall annually submit to the Director a report containing an evaluation of

activities carried out under the grant.

(5) Dissemination

A grantee under this section shall—

(A) meet at least annually in regional or national meetings to discuss challenges, best practices, and lessons learned with respect to activities carried out under the grant; and

(B) develop models for the replication of successful programs and activities and the mentoring of other eligible entities.

(d) Training

(1) In general

The Director shall develop a program to provide training for eligible entities on effective strategies for the prevention and control of chronic disease and the link between physical, emotional, and social well-being.

(2) Community transformation plan

The Director shall provide appropriate feedback and technical assistance to grantees to establish community transformation plans [2]

(3) Evaluation

The Director shall provide a literature review and framework for the evaluation of programs conducted as part of the grant program under this section, in addition to working with academic institutions or other entities with expertise in outcome evaluation.

(e) Prohibition

A grantee shall not use funds provided under a grant under this section to create video games or to carry out any other activities that may lead to higher rates of obesity or inactivity.

(f) Authorization of appropriations

There are authorized to be appropriated to carry out this section, such sums as may be necessary for each of fiscal year [3] 2010 through 2014.

(Pub. L. 111–148, title IV, §4201, title X, §10403, Mar. 23, 2010, 124 Stat. 564, 975.)

EDITORIAL NOTES

CODIFICATION

Section was enacted as part of the Patient Protection and Affordable Care Act, and not as part of the Public Health Service Act which comprises this chapter.

AMENDMENTS

2010—Subsec. (a). Pub. L. 111–148, §10403(1), inserted ", with not less than 20 percent of such grants being awarded to rural and frontier areas" before period at end.

Subsec. (c)(2)(B)(vii). Pub. L. 111–148, §10403(2), substituted "urban, rural, and frontier areas" for "both urban and rural areas".

Subsec. (f). Pub. L. 111–148, §10403(3), substituted "each of fiscal year" for "each fiscal years".

[1] So in original. Probably should be followed by a comma.

[2] So in original. Probably should be followed by a period.

[3] So in original. Probably should be "years".

§300u–14. Healthy aging, living well; evaluation of community-based prevention

and wellness programs for Medicare beneficiaries

(a) Healthy aging, living well

(1) In general

The Secretary of Health and Human Services (referred to in this section as the "Secretary"), acting through the Director of the Centers for Disease Control and Prevention, shall award grants to State or local health departments and Indian tribes to carry out 5-year pilot programs to provide public health community interventions, screenings, and where necessary, clinical referrals for individuals who are between 55 and 64 years of age.

(2) Eligibility

To be eligible to receive a grant under paragraph (1), an entity shall—

(A) be—

(i) a State health department;

(ii) a local health department; or

(iii) an Indian tribe;

(B) submit to the Secretary an application at such time, in such manner, and containing such information as the Secretary may require including a description of the program to be carried out under the grant;

(C) design a strategy for improving the health of the 55-to-64 year-old population through community-based public health interventions; and

(D) demonstrate the capacity, if funded, to develop the relationships necessary with relevant health agencies, health care providers, community-based organizations, and insurers to carry out the activities described in paragraph (3), such relationships to include the identification of a community-based clinical partner, such as a community health center or rural health clinic.

(3) Use of funds

(A) In general

A State or local health department shall use amounts received under a grant under this subsection to carry out a program to provide the services described in this paragraph to individuals who are between 55 and 64 years of age.

(B) Public health interventions

(i) In general

In developing and implementing such activities, a grantee shall collaborate with the Centers for Disease Control and Prevention and the Administration on Aging, and relevant local agencies and organizations.

(ii) Types of intervention activities

Intervention activities conducted under this subparagraph may include efforts to improve nutrition, increase physical activity, reduce tobacco use and substance abuse, improve mental health, and promote healthy lifestyles among the target population.

(C) Community preventive screenings

(i) In general

In addition to community-wide public health interventions, a State or local health department shall use amounts received under a grant under this subsection to conduct ongoing health screening to identify risk factors for cardiovascular disease, cancer, stroke, and diabetes among individuals in both urban and rural areas who are between 55 and 64 years of age.

(ii) Types of screening activities

Screening activities conducted under this subparagraph may include—

(I) mental health/behavioral health and substance use disorders;
(II) physical activity, smoking, and nutrition; and
(III) any other measures deemed appropriate by the Secretary.

(iii) Monitoring

Grantees under this section shall maintain records of screening results under this subparagraph to establish the baseline data for monitoring the targeted population [1]

(D) Clinical referral/treatment for chronic diseases

(i) In general

A State or local health department shall use amounts received under a grant under this subsection to ensure that individuals between 55 and 64 years of age who are found to have chronic disease risk factors through the screening activities described in subparagraph (C)(ii), receive clinical referral/treatment for follow-up services to reduce such risk.

(ii) Mechanism

(I) Identification and determination of status

With respect to each individual with risk factors for or having heart disease, stroke, diabetes, or any other condition for which such individual was screened under subparagraph (C), a grantee under this section shall determine whether or not such individual is covered under any public or private health insurance program.

(II) Insured individuals

An individual determined to be covered under a health insurance program under subclause (I) shall be referred by the grantee to the existing providers under such program or, if such individual does not have a current provider, to a provider who is in-network with respect to the program involved.

(III) Uninsured individuals

With respect to an individual determined to be uninsured under subclause (I), the grantee's community-based clinical partner described in paragraph (4)(D) [2] shall assist the individual in determining eligibility for available public coverage options and identify other appropriate community health care resources and assistance programs.

(iii) Public health intervention program

A State or local health department shall use amounts received under a grant under this subsection to enter into contracts with community health centers or rural health clinics and mental health and substance use disorder service providers to assist in the referral/treatment of at risk patients to community resources for clinical follow-up and help determine eligibility for other public programs.

(E) Grantee evaluation

An eligible entity shall use amounts provided under a grant under this subsection to conduct activities to measure changes in the prevalence of chronic disease risk factors among participants.

(4) Pilot program evaluation

The Secretary shall conduct an annual evaluation of the effectiveness of the pilot program under this subsection. In determining such effectiveness, the Secretary shall consider changes in the prevalence of uncontrolled chronic disease risk factors among new Medicare enrollees (or individuals nearing enrollment, including those who are 63 and 64 years of age) who reside in States or localities receiving grants under this section as compared with national and historical data for those States and localities for the same population.

(5) Authorization of appropriations

There are authorized to be appropriated to carry out this subsection, such sums as may be

necessary for each of fiscal years 2010 through 2014.

(b) Evaluation and plan for community-based prevention and wellness programs for Medicare beneficiaries

(1) In general

The Secretary shall conduct an evaluation of community-based prevention and wellness programs and develop a plan for promoting healthy lifestyles and chronic disease self-management for Medicare beneficiaries.

(2) Medicare evaluation of prevention and wellness programs

(A) In general

The Secretary shall evaluate community prevention and wellness programs including those that are sponsored by the Administration on Aging, are evidence-based, and have demonstrated potential to help Medicare beneficiaries (particularly beneficiaries that have attained 65 years of age) reduce their risk of disease, disability, and injury by making healthy lifestyle choices, including exercise, diet, and self-management of chronic diseases.

(B) Evaluation

The evaluation under subparagraph (A) shall consist of the following:

(i) Evidence review

The Secretary shall review available evidence, literature, best practices, and resources that are relevant to programs that promote healthy lifestyles and reduce risk factors for the Medicare population. The Secretary may determine the scope of the evidence review and such issues to be considered, which shall include, at a minimum—

(I) physical activity, nutrition, and obesity;
(II) falls;
(III) chronic disease self-management; and
(IV) mental health.

(ii) Independent evaluation of evidence-based community prevention and wellness programs

The Administrator of the Centers for Medicare & Medicaid Services, in consultation with the Assistant Secretary for Aging, shall, to the extent feasible and practicable, conduct an evaluation of existing community prevention and wellness programs that are sponsored by the Administration on Aging to assess the extent to which Medicare beneficiaries who participate in such programs—

(I) reduce their health risks, improve their health outcomes, and adopt and maintain healthy behaviors;
(II) improve their ability to manage their chronic conditions; and
(III) reduce their utilization of health services and associated costs under the Medicare program for conditions that are amenable to improvement under such programs.

(3) Report

Not later than September 30, 2013, the Secretary shall submit to Congress a report that includes—

(A) recommendations for such legislation and administrative action as the Secretary determines appropriate to promote healthy lifestyles and chronic disease self-management for Medicare beneficiaries;
(B) any relevant findings relating to the evidence review under paragraph (2)(B)(i); and
(C) the results of the evaluation under paragraph (2)(B)(ii).

(4) Funding

For purposes of carrying out this subsection, the Secretary shall provide for the transfer, from the Federal Hospital Insurance Trust Fund under section 1817 of the Social Security Act (42

U.S.C. 1395i) and the Federal Supplemental [3] Medical Insurance Trust Fund under section 1841 of such Act (42 U.S.C. 1395t), in such proportion as the Secretary determines appropriate, of $50,000,000 to the Centers for Medicare & Medicaid Services Program Management Account. Amounts transferred under the preceding sentence shall remain available until expended.

(5) Administration

Chapter 35 of title 44 shall not apply to the [4] this subsection.

(6) Medicare beneficiary

In this subsection, the term "Medicare beneficiary" means an individual who is entitled to benefits under part A of title XVIII of the Social Security Act [42 U.S.C. 1395c et seq.] and enrolled under part B of such title [42 U.S.C. 1395j et seq.].

(Pub. L. 111–148, title IV, §4202, Mar. 23, 2010, 124 Stat. 566.)

EDITORIAL NOTES

REFERENCES IN TEXT

The Social Security Act, referred to in subsec. (b)(6), is act Aug. 14, 1935, ch. 531, 49 Stat. 620. Parts A and B of title XVIII of the Act are classified generally to parts A (§1395c et seq.) and B (§1395j et seq.), respectively, of subchapter XVIII of chapter 7 of this title. For complete classification of this Act to the Code, see section 1305 of this title and Tables.

CODIFICATION

Section was enacted as part of the Patient Protection and Affordable Care Act, and not as part of the Public Health Service Act which comprises this chapter.

[1] So in original. Probably should be followed by a period.

[2] So in original. Paragraph (4) does not contain subpars.

[3] So in original. Probably should be "Supplementary".

[4] So in original. The word "the" probably should not appear.

§300u–15. Research on optimizing the delivery of public health services

(a) In general

The Secretary of Health and Human Services (referred to in this section as the "Secretary"), acting through the Director of the Centers for Disease Control and Prevention, shall provide funding for research in the area of public health services and systems.

(b) Requirements of research

Research supported under this section shall include—

(1) examining evidence-based practices relating to prevention, with a particular focus on high priority areas as identified by the Secretary in the National Prevention Strategy or Healthy People 2020, and including comparing community-based public health interventions in terms of effectiveness and cost;

(2) analyzing the translation of interventions from academic settings to real world settings; and

(3) identifying effective strategies for organizing, financing, or delivering public health services in real world community settings, including comparing State and local health department structures and systems in terms of effectiveness and cost.

(c) Existing partnerships

Research supported under this section shall be coordinated with the Community Preventive Services Task Force and carried out by building on existing partnerships within the Federal Government while also considering initiatives at the State and local levels and in the private sector.

(d) Annual report

The Secretary shall, on an annual basis, submit to Congress a report concerning the activities and findings with respect to research supported under this section.

(Pub. L. 111–148, title IV, §4301, Mar. 23, 2010, 124 Stat. 578.)

EDITORIAL NOTES

CODIFICATION

Section was enacted as part of the Patient Protection and Affordable Care Act, and not as part of the Public Health Service Act which comprises this chapter.

§300u–16. Establishment of substance use disorder information dashboard

(a) In general

Not later than 6 months after October 24, 2018, the Secretary of Health and Human Services shall, in consultation with the Director of National Drug Control Policy, establish and periodically update, on the Internet website of the Department of Health and Human Services, a public information dashboard that—

(1) provides links to information on programs within the Department of Health and Human Services related to the reduction of opioid and other substance use disorders;

(2) provides access, to the extent practicable and appropriate, to publicly available data, which may include data from agencies within the Department of Health and Human Services and—

(A) other Federal agencies;

(B) State, local, and Tribal governments;

(C) nonprofit organizations;

(D) law enforcement;

(E) medical experts;

(F) public health educators; and

(G) research institutions regarding prevention, treatment, recovery, and other services for opioid and other substance use disorders;

(3) provides data on substance use disorder prevention and treatment strategies in different regions of and populations in the United States;

(4) identifies information on alternatives to controlled substances for pain management, such as approaches studied by the National Institutes of Health Pain Consortium, the National Center for Complimentary and Integrative Health, and other institutes and centers at the National Institutes of Health, as appropriate; and

(5) identifies guidelines and best practices for health care providers regarding treatment of substance use disorders.

(b) Controlled substance defined

In this section, the term "controlled substance" has the meaning given that term in section 802 of title 21.

(July 1, 1944, ch. 373, title XVII, §1711, as added Pub. L. 115–271, title VII, §7021, Oct. 24, 2018, 132 Stat. 4009.)

STATUTORY NOTES AND RELATED SUBSIDIARIES

NATIONAL MILESTONES TO MEASURE SUCCESS IN CURTAILING THE OPIOID CRISIS

Pub. L. 115–271, title VII, §7023, Oct. 24, 2018, 132 Stat. 4012, provided that:

"(a) IN GENERAL.—Not later than 180 days after the date of enactment of this Act [Oct. 24, 2018], the Secretary of Health and Human Services (referred to in this section as the 'Secretary'), in coordination with the Administrator of the Drug Enforcement Administration and the Director of the Office of National Drug Control Policy, shall develop or identify existing national indicators (referred to in this section as the 'national milestones') to measure success in curtailing the opioid crisis, with the goal of significantly reversing the incidence and prevalence of opioid misuse and abuse, and opioid-related morbidity and mortality in the United States within 5 years of such date of enactment.

"(b) NATIONAL MILESTONES TO END THE OPIOID CRISIS.—The national milestones under subsection (a) shall include the following:

"(1) Not fewer than 10 indicators or metrics to accurately and expediently measure progress in meeting the goal described in subsection (a), which shall, as appropriate, include, indicators or metrics related to—

"(A) the number of fatal and non-fatal opioid overdoses;

"(B) the number of emergency room visits related to opioid misuse and abuse;

"(C) the number of individuals in sustained recovery from opioid use disorder;

"(D) the number of infections associated with illicit drug use, such as HIV, viral hepatitis, and infective endocarditis, and available capacity for treating such infections;

"(E) the number of providers prescribing medication-assisted treatment for opioid use disorders, including in primary care settings, community health centers, jails, and prisons;

"(F) the number of individuals receiving treatment for opioid use disorder; and

"(G) additional indicators or metrics, as appropriate, such as metrics pertaining to specific populations, including women and children, American Indians and Alaskan Natives, individuals living in rural and non-urban areas, and justice-involved populations, that would further clarify the progress made in addressing the opioid crisis.

"(2) A reasonable goal, such as a percentage decrease or other specified metric, that signifies progress in meeting the goal described in subsection (a), and annual targets to help achieve that goal.

"(c) CONSIDERATION OF OTHER SUBSTANCE USE DISORDERS.—In developing the national milestones under subsection (b), the Secretary shall, as appropriate, consider other substance use disorders in addition to opioid use disorder.

"(d) EXTENSION OF PERIOD.—If the Secretary determines that the goal described in subsection (a) will not be achieved with respect to any indicator or metric established under subsection (b)(2) within 5 years of the date of enactment of this Act, the Secretary may extend the timeline for meeting such goal with respect to that indicator or metric. The Secretary shall include with any such extension a rationale for why additional time is needed and information on whether significant changes are needed in order to achieve such goal with respect to the indicator or metric.

"(e) ANNUAL STATUS UPDATE.—Not later than one year after the date of enactment of this Act, the Secretary shall make available on the Internet website of the Department of Health and Human Services, and submit to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives, an update on the progress, including expected progress in the subsequent year, in achieving the goals detailed in the national milestones. Each such update shall include the progress made in the first year or since the previous report, as applicable, in meeting each indicator or metric in the national milestones."

SUBCHAPTER XVI—PRESIDENT'S COMMISSION FOR THE STUDY OF ETHICAL PROBLEMS IN MEDICINE AND BIOMEDICAL AND BEHAVIOR RESEARCH

§§300v to 300v–3. Omitted

EDITORIAL NOTES

CODIFICATION

Sections 300v to 300v–3, which provided for the establishment, duties, administration, funding, and

termination of the President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research, were omitted pursuant to section 300v–3, which provided for the Commission's termination on Dec. 31, 1982. See 48 F.R. 34408.

Section 300v, act July 1, 1944, ch. 373, title XVIII, §1801, as added Pub. L. 95–622, title III, §301, Nov. 9, 1978, 92 Stat. 3437; amended Pub. L. 96–88, title V, §509(b), Oct. 17, 1979, 93 Stat. 695; Pub. L. 100–527, §10(1), Oct. 25, 1988, 102 Stat. 2640, established the President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research and directed the President to appoint eleven members.

Section 300v–1, act July 1, 1944, ch. 373, title XVIII, §1802, as added Pub. L. 95–622, title III, §301, Nov. 9, 1978, 92 Stat. 3439; amended Pub. L. 96–32, §4, July 10, 1979, 93 Stat. 82, related to duties of the Commission.

Section 300v–2, act July 1, 1944, ch. 373, title XVIII, §1803, as added Pub. L. 95–622, title III, §301, Nov. 9, 1978, 92 Stat. 3440, related to administrative provisions.

Section 300v–3, act July 1, 1944, ch. 373, title XVIII, §1804, as added Pub. L. 95–622, title III, §301, Nov. 9, 1978, 92 Stat. 3441, related to authorization of appropriations and termination of the Commission.

SUBCHAPTER XVII—BLOCK GRANTS

PART A—PREVENTIVE HEALTH AND HEALTH SERVICES BLOCK GRANTS

§300w. Authorization of appropriations

(a) For the purpose of allotments under section 300w–1 of this title, there are authorized to be appropriated $205,000,000 for fiscal year 1993, and such sums as may be necessary for each of the fiscal years 1994 through 1998.

(b) Of the amount appropriated for any fiscal year under subsection (a), at least $7,000,000 shall be made available for allotments under section 300w–1(b) of this title.

(July 1, 1944, ch. 373, title XIX, §1901, as added Pub. L. 97–35, title IX, §901, Aug. 13, 1981, 95 Stat. 535; amended Pub. L. 98–555, §4, Oct. 30, 1984, 98 Stat. 2855; Pub. L. 100–607, title III, §301(a), Nov. 4, 1988, 102 Stat. 3111; Pub. L. 102–531, title I, §101, Oct. 27, 1992, 106 Stat. 3469; Pub. L. 103–183, title VII, §705(e), Dec. 14, 1993, 107 Stat. 2241.)

EDITORIAL NOTES

AMENDMENTS

1993—Subsec. (a). Pub. L. 103–183 substituted "through 1998" for "through 1997".

1992—Subsec. (a). Pub. L. 102–531, §101(a), amended subsec. (a) generally. Prior to amendment, subsec. (a) read as follows: "For the purpose of allotments under section 300w–1 of this title, there is authorized to be appropriated $95,000,000 for fiscal year 1982, $96,500,000 for fiscal year 1983, $98,500,000 for fiscal year 1984, $98,500,000 for the fiscal year ending September 30, 1985, $98,500,000 for the fiscal year ending September 30, 1986, $98,500,000 for the fiscal year ending September 30, 1987, $110,000,000 for fiscal year 1989, and such sums as may be necessary for each of the fiscal years 1990 and 1991."

Subsec. (b). Pub. L. 102–531, §101(b), substituted "$7,000,000" for "$3,500,000".

1988—Subsec. (a). Pub. L. 100–607 struck out "and" after "1986," and inserted ", $110,000,000 for fiscal year 1989, and such sums as may be necessary for each of the fiscal years 1990 and 1991" before period at end.

1984—Subsec. (a). Pub. L. 98–555, §4(a), inserted provisions authorizing appropriations for fiscal years ending Sept. 30, 1985, 1986, and 1987.

Subsec. (b). Pub. L. 98–555, §4(b), substituted "$3,500,000" for "$3,000,000".

STATUTORY NOTES AND RELATED SUBSIDIARIES

EFFECTIVE DATE

Pub. L. 97–35, title IX, §901, Aug. 13, 1981, 95 Stat. 535, provided in part that this subchapter is effective Oct. 1, 1981.

§300w–1. Allotments

(a) Availability based upon prior year distributions

(1) From the amounts appropriated under section 300w of this title for any fiscal year and available for allotment under this subsection, the Secretary shall allot to each State an amount which bears the same ratio to the available amounts for that fiscal year as the amounts provided by the Secretary under the provisions of law listed in paragraph (2) to the State and entities in the State for fiscal year 1981 bore to the total amount appropriated for such provisions of law for fiscal year 1981.

(2) The provisions of law referred to in paragraph (1) are the following provisions of law as in effect on September 30, 1981:

(A) The authority for grants under section 247b of this title for preventive health service programs for the control of rodents.

(B) The authority for grants under section 247b of this title for establishing and maintaining community and school-based fluoridation programs.

(C) The authority for grants under section 247b of this title for preventive health service programs for hypertension.

(D) Sections 247b–1 [1] and 247b–2 of this title.

(E) Section 246(d) [1] of this title.

(F) Section 255(a) [1] of this title.

(G) Sections 300d–1,[1] 300d–2,[1] and 300d–3 [1] of this title.

(b) Population

From the amount required to be made available under section 300w(b) of this title for allotments under this subsection for any fiscal year, the Secretary shall make allotments to each State on the basis of the population of the State.

(c) Distribution of appropriated funds not allotted

To the extent that all the funds appropriated under section 300w of this title for a fiscal year and available for allotment in such fiscal year are not otherwise allotted to States because—

(1) one or more States have not submitted an application or description of activities in accordance with section 300w–4 of this title for the fiscal year;

(2) one or more States have notified the Secretary that they do not intend to use the full amount of their allotment; or

(3) some State allotments are offset or repaid under section 300w–5(b)(3) of this title;

such excess shall be allotted among each of the remaining States in proportion to the amount otherwise allotted to such States for the fiscal year without regard to this subsection.

(d) Distributions to Indian tribes

(1) If the Secretary—

(A) receives a request from the governing body of an Indian tribe or tribal organization within any State that funds under this part be provided directly by the Secretary to such tribe or organization, and

(B) determines that the members of such tribe or tribal organization would be better served by means of grants made directly by the Secretary under this part,

the Secretary shall reserve from amounts which would otherwise be allotted to such State under subsection (a) for the fiscal year the amount determined under paragraph (2).

(2) The Secretary shall reserve for the purpose of paragraph (1) from amounts that would otherwise be allotted to such State under subsection (a) an amount equal to the amount which bears the same ratio to the State's allotment for the fiscal year involved as the total amount provided or allotted for fiscal year 1981 by the Secretary to such tribe or tribal organization under the provisions of law referred to in subsection (a) bore to the total amount provided or allotted for such fiscal year by the Secretary to the State and entities (including Indian tribes and tribal organizations) in the State under such provisions of law.

(3) The amount reserved by the Secretary on the basis of a determination under this subsection shall be granted to the Indian tribe or tribal organization serving the individuals for whom such a determination has been made.

(4) In order for an Indian tribe or tribal organization to be eligible for a grant for a fiscal year under this subsection, it shall submit to the Secretary a plan for such fiscal year which meets such criteria as the Secretary may prescribe.

(5) The terms "Indian tribe" and "tribal organization" have the same meaning given such terms in section 5304(b) and (c) [1] of title 25.

(e) Report on equitable distribution of available funds

The Secretary shall conduct a study for the purpose of devising a formula for the equitable distribution of funds available for allotment to the States under this section. In conducting the study, the Secretary shall take into account—

(1) the financial resources of the various States,

(2) the populations of the States, and

(3) any other factor which the Secretary may consider appropriate.

Before June 30, 1982, the Secretary shall submit a report to the Congress respecting the development of a formula and make such recommendations as the Secretary may deem appropriate in order to ensure the most equitable distribution of funds under allotments under this section.

(July 1, 1944, ch. 373, title XIX, §1902, as added Pub. L. 97–35, title IX, §901, Aug. 13, 1981, 95 Stat. 535.)

EDITORIAL NOTES

REFERENCES IN TEXT

Section 247b–1 of this title, referred to in subsec. (a)(2)(D), was in the original a reference to section 401 of the Health Services and Centers Amendments of 1978, Pub. L. 95–626, which was repealed effective Oct. 1, 1981, by Pub. L. 97–35, title IX, §902(a), (h), Aug. 13, 1981, 95 Stat. 559, 561. Pub. L. 100–572, §3, Oct. 31, 1988, 102 Stat. 2887, enacted section 317A of act July 1, 1944, which is classified to section 247b–1 of this title.

Section 247b–2 of this title, referred to in subsec. (a)(2)(D), was repealed effective Oct. 1, 1981, by Pub. L. 97–35, title IX, §902(a), (h), Aug. 13, 1981, 95 Stat. 559, 561.

Section 246(d) of this title, referred to in subsec. (a)(2)(E), was repealed effective Oct. 1, 1981, by Pub. L. 97–35, title IX, §902(b), (h), Aug. 13, 1981, 95 Stat. 559, 561.

Section 255 of this title, referred to in subsec. (a)(2)(F), was in the original a reference to section 339 of act July 1, 1944, which was repealed effective Oct. 1, 1981, by Pub. L. 97–35, title IX, §902(b), (h), Aug. 13, 1981, 95 Stat. 559, 561. Pub. L. 97–414, §6(a), Jan. 4, 1983, 96 Stat. 2057, added a new section 339 of act July 1, 1944, which is classified to section 255 of this title.

Sections 300d–1, 300d–2, and 300d–3 of this title, referred to in subsec. (a)(2)(G), were in the original references to sections 1202, 1203, and 1204, respectively, of act July 1, 1944, which were repealed effective Oct. 1, 1981, by Pub. L. 97–35, title IX, §902(d)(1), (h), Aug. 13, 1981, 95 Stat. 560, 561. Pub. L. 101–590, §3, Nov. 16, 1990, 104 Stat. 2916–2918, enacted new sections 1202, 1203, and 1204 of act July 1, 1944, which were classified to sections 300d–1, 300d–2, and 300d–3, respectively, of this title. Pub. L. 103–183, title VI, §601(b), Dec. 14, 1983, 107 Stat. 2238, repealed section 1202 and renumbered sections 1203 and 1204 as 1202 and 1203, respectively. Pub. L. 110–23, §§3, 5, May 3, 2007, 121 Stat. 90, 91, repealed section

1202, renumbered section 1203 as 1202, and enacted new section 1203 of act July 1, 1944, which is classified to section 300d–5 of this title.

Section 5304 of title 25, referred to in subsec. (d)(5), has been amended, and subsecs. (b) and (c) of section 5304 no longer define the terms "Indian tribe" and "tribal organization". However, such terms are defined elsewhere in that section.

STATUTORY NOTES AND RELATED SUBSIDIARIES

EFFECTIVE DATE

Section effective Oct. 1, 1981, see section 901 of Pub. L. 97–35, set out in part as a note under section 300w of this title.

[1] *See References in Text note below.*

§300w–2. Payments under allotments to States

(a)(1) For each fiscal year, the Secretary shall make payments, as provided by section 6503(a) of title 31, to each State from its allotment under section 300w–1 of this title (other than any amount reserved under section 300w–1(d) of this title) from amounts appropriated for that fiscal year.

(2) Any amount paid to a State for a fiscal year and remaining unobligated at the end of such year shall remain available for the next fiscal year to such State for the purposes for which it was made.

(b) The Secretary, at the request of a State, may reduce the amount of payments under subsection (a) by—

(1) the fair market value of any supplies or equipment furnished the State, and

(2) the amount of the pay, allowances, and travel expenses of any officer or employee of the Government when detailed to the State and the amount of any other costs incurred in connection with the detail of such officer or employee,

when the furnishing of supplies or equipment or the detail of an officer or employee is for the convenience of and at the request of the State and for the purpose of conducting activities described in section 300w–3 of this title. The amount by which any payment is so reduced shall be available for payment by the Secretary of the costs incurred in furnishing the supplies or equipment or in detailing the personnel, on which the reduction of the payment is based, and the amount shall be deemed to be part of the payment and shall be deemed to have been paid to the State.

(July 1, 1944, ch. 373, title XIX, §1903, as added Pub. L. 97–35, title IX, §901, Aug. 13, 1981, 95 Stat. 537.)

EDITORIAL NOTES

CODIFICATION

In subsec. (a)(1), "section 6503(a) of title 31" substituted for "section 203 of the Intergovernmental Cooperation Act of 1968 (42 U.S.C. 4213)" on authority of Pub. L. 97–258, §4(b), Sept. 13, 1982, 96 Stat. 1067, the first section of which enacted Title 31, Money and Finance.

STATUTORY NOTES AND RELATED SUBSIDIARIES

EFFECTIVE DATE

Section effective Oct. 1, 1981, see section 901 of Pub. L. 97–35, set out in part as a note under section 300w of this title.

§300w–3. Use of allotments

(a) Preventive health services, comprehensive public health services, emergency medical services, etc.

(1) Except as provided in subsections (b) and (c), payments made to a State under section 300w–2 of this title may be used for the following:

(A) Activities consistent with making progress toward achieving the objectives established by the Secretary for the health status of the population of the United States for the year 2000 (in this part referred to as "year 2000 health objectives").

(B) Preventive health service programs for the control of rodents and for community and school-based fluoridation programs.

(C) Feasibility studies and planning for emergency medical services systems and the establishment, expansion, and improvement of such systems. Amounts for such systems may not be used for the costs of the operation of the systems or the purchase of equipment for the systems, except that such amounts may be used for the payment of not more than 50 percent of the costs of purchasing communications equipment for the systems. Amounts may be expended for feasibility studies or planning for the trauma-care components of such systems only if the studies or planning, respectively, is consistent with the requirements of section 300d–13(a) of this title.

(D) Providing services to victims of sex offenses and for prevention of sex offenses.

(E) The establishment, operation, and coordination of effective and cost-efficient systems to reduce the prevalence of illness due to asthma and asthma-related illnesses, especially among children, by reducing the level of exposure to cockroach allergen or other known asthma triggers through the use of integrated pest management, as applied to cockroaches or other known allergens. Amounts expended for such systems may include the costs of building maintenance and the costs of programs to promote community participation in the carrying out at such sites of integrated pest management, as applied to cockroaches or other known allergens. For purposes of this subparagraph, the term "integrated pest management" means an approach to the management of pests in public facilities that combines biological, cultural, physical, and chemical tools in a way that minimizes economic, health, and environmental risks.

(F) With respect to activities described in any of subparagraphs (A) through (E), related planning, administration, and educational activities.

(G) Monitoring and evaluation of activities carried out under any of subparagraphs (A) through (F).

(2) Except as provided in subsection (b), amounts paid to a State under section 300w–2 of this title from its allotment under section 300w–1(b) of this title may only be used for providing services to rape victims and for rape prevention.

(3) The Secretary may provide technical assistance to States in planning and operating activities to be carried out under this part.

(b) Prohibited uses

A State may not use amounts paid to it under section 300w–2 of this title to—

(1) provide inpatient services,

(2) make cash payments to intended recipients of health services,

(3) purchase or improve land, purchase, construct, or permanently improve (other than minor remodeling) any building or other facility, or purchase major medical equipment,

(4) satisfy any requirement for the expenditure of non-Federal funds as a condition for the receipt of Federal funds, or

(5) provide financial assistance to any entity other than a public or nonprofit private entity.

Except as provided in subsection (a)(1)(E), the Secretary may waive the limitation contained in paragraph (3) upon the request of a State if the Secretary finds that there are extraordinary circumstances to justify the waiver and that granting the waiver will assist in carrying out this part.

(c) Transfer of funds

A State may transfer not more than 7 percent of the amount allotted to the State under section

300w–1(a) of this title for any fiscal year for use by the State under part B of this subchapter and title V of the Social Security Act [42 U.S.C. 701 et seq.] in such fiscal year as follows: At any time in the first three quarters of the fiscal year a State may transfer not more than 3 percent of the allotment of the State for the fiscal year for such use, and in the last quarter of a fiscal year a State may transfer for such use not more than the remainder of the amount of its allotment which may be transferred.

(d) Limitation on administrative costs

Of the amount paid to any State under section 300w–2 of this title, not more than 10 percent paid from each of its allotments under subsections (a) and (b) of section 300w–1 of this title may be used for administering the funds made available under section 300w–2 of this title. The State will pay from non-Federal sources the remaining costs of administering such funds.

(July 1, 1944, ch. 373, title XIX, §1904, as added Pub. L. 97–35, title IX, §901, Aug. 13, 1981, 95 Stat. 537; amended Pub. L. 97–414, §8(s), Jan. 4, 1983, 96 Stat. 2062; Pub. L. 99–646, §87(d)(1)(A), Nov. 10, 1986, 100 Stat. 3623; Pub. L. 99–654, §3(b)(1)(A), Nov. 14, 1986, 100 Stat. 3663; Pub. L. 100–607, title III, §301(b), Nov. 4, 1988, 102 Stat. 3111; Pub. L. 102–531, title I, §102, Oct. 27, 1992, 106 Stat. 3470; Pub. L. 106–310, div. A, title V, §511, Oct. 17, 2000, 114 Stat. 1116.)

EDITORIAL NOTES

REFERENCES IN TEXT

The Social Security Act, referred to in subsec. (c), is act Aug. 14, 1935, ch. 531, 49 Stat. 620. Title V of the Social Security Act is classified generally to subchapter V (§701 et seq.) of chapter 7 of this title. For complete classification of this Act to the Code, see section 1305 of this title and Tables.

AMENDMENTS

2000—Subsec. (a)(1)(E). Pub. L. 106–310, §511(3), added subpar. (E). Former subpar. (E) redesignated (F).

Subsec. (a)(1)(F). Pub. L. 106–310, §511(1), (4), redesignated subpar. (E) as (F) and substituted "subparagraphs (A) through (E)" for "subparagraphs (A) through (D)". Former subpar. (F) redesignated (G).

Subsec. (a)(1)(G). Pub. L. 106–310, §511(1), (2), (5), redesignated subpar. (F) as (G) and substituted "subparagraphs (A) through (F)." for "subparagraphs (A) through (E)".

1992—Subsec. (a)(1). Pub. L. 102–531, §102(a), amended par. (1) generally, substituting present provisions for provisions authorizing, except as provided in subsecs. (b) and (c), use of the amounts paid to a State under section 300w–2 of this title from its allotment under section 300w–1(a) of this title and amounts transferred by the State, for use in preventive health service programs, including hypertension and high cholesterol services, health-risk reduction programs, immunization services, home health agencies, emergency medical services, services to victims of sex offenses, and uterine cancer and breast cancer services.

Subsec. (c). Pub. L. 102–531, §102(b), substituted "part B" for "parts B and C".

1988—Subsec. (a)(1)(B). Pub. L. 100–607, §301(b)(1), inserted "and elevated serum cholesterol" before period at end.

Subsec. (a)(1)(C). Pub. L. 100–607, §301(b)(2), inserted ", including programs designed to reduce the incidence of chronic diseases" before period at end.

Subsec. (a)(1)(D). Pub. L. 100–607, §301(b)(3), inserted ", including immunization services" before period at end.

Subsec. (a)(1)(F). Pub. L. 100–607, §301(b)(4), substituted "systems, except that such amounts may be used for the payment of not more than 50 percent of the costs of purchasing communications equipment for the systems" for "systems (other than systems with respect to which grants were made as prescribed by section 300w–4(c)(2) of this title)".

Subsec. (a)(1)(H). Pub. L. 100–607, §301(b)(5), added subpar. (H).

1986—Subsec. (a)(1)(G). Pub. L. 99–646 and Pub. L. 99–654 amended subpar. (G) identically, substituting "victims of sex offenses and for prevention of sex offenses" for "rape victims and for rape prevention".

1983—Subsec. (a)(1)(F). Pub. L. 97–414 inserted "(other than systems with respect to which grants were made as prescribed by section 300w–4(c)(2) of this title)" after "equipment for the systems".

STATUTORY NOTES AND RELATED SUBSIDIARIES

EFFECTIVE DATE OF 1986 AMENDMENTS

Amendments by Pub. L. 99–646 and Pub. L. 99–654 effective 30 days after Nov. 10, 1986, and 30 days after Nov. 14, 1986, respectively, see section 87(e) of Pub. L. 99–646 and section 4 of Pub. L. 99–654, set out as an Effective Date note under section 2241 of Title 18, Crimes and Criminal Procedure.

EFFECTIVE DATE

Section effective Oct. 1, 1981, see section 901 of Pub. L. 97–35, set out in part as a note under section 300w of this title.

§300w–4. Application for payments; State plan

(a) In general

The Secretary may make payments under section 300w–2 of this title to a State for a fiscal year only if—

(1) the State submits to the Secretary an application for the payments;

(2) the application contains a State plan in accordance with subsection (b);

(3) the application contains the certification described in subsection (c);

(4) the application contains such assurances as the Secretary may require regarding the compliance of the State with the requirements of this part (including assurances regarding compliance with the agreements described in subsection (c)); and

(5) the application is in such form and is submitted by such date as the Secretary may require.

(b) State plan

A State plan required in subsection (a)(2) for a fiscal year is in accordance with this subsection if the plan meets the following conditions:

(1) The plan is developed by the State agency with principal responsibility for public health programs, in consultation with the advisory committee established pursuant to subsection (c)(2).

(2) The plan specifies the activities authorized in section 300w–3 of this title that are to be carried out with payments made to the State under section 300w–2 of this title, including a specification of the year 2000 health objectives for which the State will expend the payments.

(3) The plan specifies the populations in the State for which such activities are to be carried out.

(4) The plan specifies any populations in the State that have a disparate need for such activities.

(5) With respect to each population specified under paragraph (3), the plan contains a strategy for expending such payments to carry out such activities to make progress toward improving the health status of the population, which strategy includes—

(A) a description of the programs and projects to be carried out;

(B) an estimate of the number of individuals to be served by the programs and projects; and

(C) an estimate of the number of public health personnel needed to carry out the strategy.

(6) The plan specifies the amount of such payments to be expended for each of such activities and, with respect to the activity involved—

(A) the amount to be expended for each population specified under paragraph (3); and

(B) the amount to be expended for each population specified under paragraph (4).

(c) State certification

The certification referred to in subsection (a)(3) for a fiscal year is a certification to the Secretary by the chief executive officer of the State involved as follows:

(1)(A) In the development of the State plan required in subsection (a)(2)—

(i) the chief health officer of the State held public hearings on the plan; and

(ii) proposals for the plan were made public in a manner that facilitated comments from public and private entities (including Federal and other public agencies).

(B) The State agrees that, if any revisions are made in such plan during the fiscal year, the State will, with respect to the revisions, hold hearings and make proposals public in accordance with

subparagraph (A), and will submit to the Secretary a description of the revisions.

(2) The State has established an advisory committee in accordance with subsection (d).

(3) The State agrees to expend payments under section 300w–2 of this title only for the activities authorized in section 300w–3 of this title.

(4) The State agrees to expend such payments in accordance with the State plan submitted under subsection (a)(2) (with any revisions submitted to the Secretary under paragraph (1)(B)), including making expenditures to carry out the strategy contained in the plan pursuant to subsection (b)(5).

(5)(A) The State agrees that, in the case of each population for which such strategy is carried out, the State will measure the extent of progress being made toward improving the health status of the population.

(B) The State agrees that—

(i) the State will collect and report data in accordance with section 300w–5(a) of this title; and

(ii) for purposes of subparagraph (A), progress will be measured through use of each of the applicable uniform data items developed by the Secretary under paragraph (2) of such section, or if no such items are applicable, through use of the uniform criteria developed by the Secretary under paragraph (3) of such section.

(6) With respect to the activities authorized in section 300w–3 of this title, the State agrees to maintain State expenditures for such activities at a level that is not less than the average level of such expenditures maintained by the State for the 2-year period preceding the fiscal year for which the State is applying to receive payments under section 300w–2 of this title.

(7) The State agrees to establish reasonable criteria to evaluate the effective performance of entities that receive funds from such payments and procedures for procedural and substantive independent State review of the failure by the State to provide funds for any such entity.

(8) The State agrees to permit and cooperate with Federal investigations undertaken in accordance with section 300w–6 of this title.

(9) The State has in effect a system to protect from inappropriate disclosure patient and sex offense victim records maintained by the State in connection with an activity funded under this part or by any entity which is receiving payments from the allotment of the State under this part.

(10) The State agrees to provide the officer of the State government responsible for the administration of the State highway safety program with an opportunity to—

(A) participate in the development of any plan by the State relating to emergency medical services, as such plan relates to highway safety; and

(B) review and comment on any proposal by any State agency to use any Federal grant or Federal payment received by the State for the provision of emergency medical services as such proposal relates to highway safety.

(d) State Advisory Committee

(1) In general

For purposes of subsection (c)(2), an advisory committee is in accordance with this subsection if such committee is known as the State Preventive Health Advisory Committee (in this subsection referred to as the "Committee") and the Committee meets the conditions described in the subsequent paragraphs of this subsection.

(2) Duties

A condition under paragraph (1) for a State is that the duties of the Committee are—

(A) to hold public hearings on the State plan required in subsection (a)(2); and

(B) to make recommendations pursuant to subsection (b)(1) regarding the development and implementation of such plan, including recommendations on—

(i) the conduct of assessments of the public health;

(ii) which of the activities authorized in section 300w–3 of this title should be carried out in the State;

(iii) the allocation of payments made to the State under section 300w–2 of this title;

(iv) the coordination of activities carried out under such plan with relevant programs of other entities; and

(v) the collection and reporting of data in accordance with section 300w–5(a) of this title.

(3) Composition

(A) A condition under paragraph (1) for a State is that the Committee is composed of such members of the general public, and such officials of the health departments of political subdivisions of the State, as may be necessary to provide adequate representation of the general public and of such health departments.

(B) With respect to compliance with subparagraph (A), the membership of advisory committees established pursuant to subsection (c)(2) may include representatives of community-based organizations (including minority community-based organizations), schools of public health, and entities to which the State involved awards grants or contracts to carry out activities authorized in section 300w–3 of this title.

(4) Chair; meetings

A condition under paragraph (1) for a State is that the State public health officer serves as the chair of the Committee, and that the Committee meets not less than twice each fiscal year.

(July 1, 1944, ch. 373, title XIX, §1905, as added Pub. L. 97–35, title IX, §901, Aug. 13, 1981, 95 Stat. 538; amended Pub. L. 98–555, §5(a), (d), Oct. 30, 1984, 98 Stat. 2855, 2856; Pub. L. 99–646, §87(d)(1)(B), Nov. 10, 1986, 100 Stat. 3624; Pub. L. 99–654, §3(b)(1)(B), Nov. 14, 1986, 100 Stat. 3663; Pub. L. 100–607, title III, §301(c), Nov. 4, 1988, 102 Stat. 3112; Pub. L. 101–590, §4, Nov. 16, 1990, 104 Stat. 2928; Pub. L. 102–531, title I, §103(a), Oct. 27, 1992, 106 Stat. 3470.)

EDITORIAL NOTES

AMENDMENTS

1992—Pub. L. 102–531 amended section generally, substituting present provisions for provisions relating to submission and form of application for assistance under this part as well as required assurances, public hearings on proposed use and distribution of funds, certifications by chief executive officer of State, and a description of intended use of funds as well as public access to and revision of such description.

1990—Subsec. (c). Pub. L. 101–590, which directed amendment of subsec. (c) by adding at the end thereof a new par. (7), was executed by adding par. (7) after par. (6) and before the last sentence to reflect the probable intent of Congress.

1988—Subsec. (d). Pub. L. 100–607 inserted at end "The description shall include a statement of the public health objectives expected to be achieved by the State through the use of the payments the State will receive under section 300w–2 of this title."

1986—Subsec. (c)(6). Pub. L. 99–646 and Pub. L. 99–654 amended par. (6) identically, substituting "sex offense" for "rape".

1984—Subsec. (c)(2). Pub. L. 98–555, §5(a), redesignated par. (3) as (2). Former par. (2), which related to grants for fiscal year 1982, was struck out.

Subsec. (c)(3). Pub. L. 98–555, §5(a), redesignated par. (5) as (3). Former par. (3) redesignated (2).

Subsec. (c)(4). Pub. L. 98–555, §5(a), redesignated par. (6) as (4). Former par. (4), which related to grants for preventive health service programs for hypertension, was struck out.

Subsec. (c)(5) to (8). Pub. L. 98–555, §5(a), redesignated pars. (7) and (8) as (5) and (6), respectively. Former pars. (5) and (6) redesignated (3) and (4), respectively.

Subsec. (e). Pub. L. 98–555, §5(d), struck out subsec. (e) which related to grants by States.

STATUTORY NOTES AND RELATED SUBSIDIARIES

EFFECTIVE DATE OF 1986 AMENDMENTS

Amendments by Pub. L. 99–646 and Pub. L. 99–654 effective 30 days after Nov. 10, 1986, and 30 days after Nov. 14, 1986, respectively, see section 87(e) of Pub. L. 99–646 and section 4 of Pub. L. 99–654, set out as an Effective Date note under section 2241 of Title 18, Crimes and Criminal Procedure.

EFFECTIVE DATE

Section effective Oct. 1, 1981, see section 901 of Pub. L. 97–35, set out in part as a note under section 300w of this title.

DELAYED APPLICABILITY OF REQUIREMENT REGARDING ADVISORY COMMITTEES

Pub. L. 102–531, title I, §103(b), Oct. 27, 1992, 106 Stat. 3473, provided that: "With respect to compliance with the requirement established in subsection (c)(2) of section 1905 of the Public Health Service Act [42 U.S.C. 300w–4(c)(2)] (as amended by subsection (a) of this section), a State is deemed, notwithstanding such section, to be in compliance with such requirement if the State establishes an advisory committee in accordance with subsection (d) of such section not later than 180 days after the date of the enactment of this Act [Oct. 27, 1992]."

§300w–5. Reports, data, and audits

(a) Annual reports; contents; data collection; copies

(1) For purposes of section 300w–4(c)(5)(B)(i) of this title, a State is collecting and reporting data for a fiscal year in accordance with this subsection if the State submits to the Secretary, not later than February 1 of the succeeding fiscal year, a report that—

(A) describes the purposes for which the State expended payments made to the State under section 300w–2 of this title;

(B) pursuant to section 300w–4(c)(5)(A) of this title, describes the extent of progress made by the State for purposes of such section;

(C) meets the conditions described in the subsequent paragraphs of this subsection; and

(D) contains such additional information regarding activities authorized in section 300w–3 of this title, and is submitted in such form, as the Secretary may require.

(2)(A) The Secretary, in consultation with the States, shall develop sets of data for uniformly defining health status for purposes of the year 2000 health objectives (which sets are in this subsection referred to as "uniform data sets"). Each of such sets shall consist of one or more categories of information (in this subsection individually referred to as a "uniform data item"). The Secretary shall develop formats for the uniform collecting and reporting of information on such items.

(B) A condition under paragraph (1)(C) for a fiscal year is that the State involved will, in accordance with the applicable format under subparagraph (A), collect during such year, and include in the report under paragraph (1), the necessary information for one uniform data item from each of the uniform data sets, which items are selected for the State by the Secretary.

(C) In the case of fiscal year 1995 and each subsequent fiscal year, a condition under paragraph (1) for a State is that the State will, in accordance with the applicable format under subparagraph (A), collect during such year, and include in the report under paragraph (1), the necessary information for each of the uniform data sets appropriate to the year 2000 health objectives that the State has, in the State plan submitted under section 300w–4 of this title for the fiscal year, specified as a purpose for which payments under section 300w–2 of this title are to be expended.

(3) The Secretary, in consultation with the States, shall establish criteria for the uniform collection and reporting of data on activities authorized in section 300w–3 of this title with respect to which no uniform data items exist.

(4) A condition under paragraph (1) for a fiscal year is that the State involved will make copies of the report submitted under such paragraph for the fiscal year available for public inspection, and will upon request provide a copy of the report to any individual for a charge not exceeding the cost of providing the copy.

(b) Fiscal control; accounting procedures; annual audits; repayments and offsets; public inspection; Comptroller General evaluations; report to Congress

(1) Each State shall establish fiscal control and fund accounting procedures as may be necessary to assure the proper disbursal of and accounting for Federal funds paid to the State under section 300w–2 of this title and funds transferred under section 300w–3(c) of this title for use under this

part.

(2) Each State shall annually audit its expenditures from payments received under section 300w–2 of this title. Such State audits shall be conducted by an entity independent of any agency administering a program funded under this part and, in so far as practical, in accordance with the Comptroller General's standards for auditing governmental organizations, programs, activities, and functions. Within 30 days following the date each audit is completed, the chief executive officer of the State shall transmit a copy of that audit to the Secretary.

(3) Each State shall, after being provided by the Secretary with adequate notice and opportunity for a hearing within the State, repay to the United States amounts found not to have been expended in accordance with the requirements of this part or the certification provided by the State under section 300w–4 of this title. If such repayment is not made, the Secretary shall, after providing the State with adequate notice and opportunity for a hearing within the State, offset such amounts against the amount of any allotment to which the State is or may become entitled under this part.

(4) The State shall make copies of the reports and audits required by this section available for public inspection within the State.

(5) The Comptroller General of the United States shall, from time to time, evaluate the expenditures by States of grants under this part in order to assure that expenditures are consistent with the provisions of this part and the certification provided by the State under section 300w–4 of this title.

(6) Not later than October 1, 1990, the Secretary shall report to the Congress on the activities of the States that have received funds under this part and may include in the report any recommendations for appropriate changes in legislation.

(c) Inapplicability of title XVII of Omnibus Budget Reconciliation Act of 1981

Title XVII of the Omnibus Budget Reconciliation Act of 1981 shall not apply with respect to audits of funds allotted under this part.

(July 1, 1944, ch. 373, title XIX, §1906, as added Pub. L. 97–35, title IX, §901, Aug. 13, 1981, 95 Stat. 540; amended Pub. L. 98–555, §5(b), (c), Oct. 30, 1984, 98 Stat. 2855, 2856; Pub. L. 100–607, title III, §301(d), Nov. 4, 1988, 102 Stat. 3112; Pub. L. 102–531, title I, §104, Oct. 27, 1992, 106 Stat. 3473.)

EDITORIAL NOTES

REFERENCES IN TEXT

The Omnibus Budget Reconciliation Act of 1981, referred to in subsec. (c), is Pub. L. 97–35, Aug. 13, 1981, 95 Stat. 357. Title XVII of the Omnibus Budget Reconciliation Act of 1981 enacted sections 3595, and 4511 to 4514 of Title 5, Government Organization and Employees, amended sections 3393, 3593, 3596, 4501, 4502, 4505, 4506, 7542, 7543, 8340, and 8345 of Title 5, and sections 2003 and 2401 of Title 39, Postal Service, and enacted provisions set out as notes under sections 3595, 4501, 5303, 5343, 8340, and 8345 of Title 5, section 1243 of former Title 31, Money and Finance, and sections 403, 2003, 2004, and 2401 of Title 39. For complete classification of this Act to the Code, see Tables.

AMENDMENTS

1992—Pub. L. 102–531, §104(b)(1), substituted "Reports, data, and audits" for "Reports and audits" in section catchline.

Subsec. (a). Pub. L. 102–531, §104(a), amended subsec. (a) generally, substituting present provisions for provisions requiring an annual report by each State of its activities under this part, outlining the contents of such report, and for providing copies of the report to interested persons.

Subsec. (d). Pub. L. 102–531, §104(b)(2), struck out subsec. (d) which provided for development of model criteria and forms for collection of data and information on services provided under this part.

1988—Subsec. (a)(3). Pub. L. 100–607, §301(d)(1), added par. (3).

Subsec. (b)(6). Pub. L. 100–607, §301(d)(2), substituted "1990" for "1983".

1984—Subsec. (a)(1)(B). Pub. L. 98–555, §5(b), substituted "preventive health and preventive health services programs in the State assisted by funds from allotments under this part, including a summary of the services which were provided, the providers of such services, and the individuals who received such services"

for "activities of the State under this part".

Subsec. (d). Pub. L. 98–555, §5(c), added subsec. (d).

STATUTORY NOTES AND RELATED SUBSIDIARIES

EFFECTIVE DATE

Section effective Oct. 1, 1981, see section 901 of Pub. L. 97–35, set out in part as a note under section 300w of this title.

§300w–6. Withholding of funds

(a) Prerequisites

(1) The Secretary shall, after adequate notice and an opportunity for a hearing conducted within the affected State, withhold funds from any State which does not use its allotment in accordance with the requirements of this part or the certification provided under section 300w–4 of this title. The Secretary shall withhold such funds until the Secretary finds that the reason for the withholding has been removed and there is reasonable assurance that it will not recur.

(2) The Secretary may not institute proceedings to withhold funds under paragraph (1) unless the Secretary has conducted an investigation concerning whether the State has used its allotment in accordance with the requirements of this part or the certification provided under section 300w–4 of this title. Investigations required by this paragraph shall be conducted within the affected State by qualified investigators.

(3) The Secretary shall respond in an expeditious manner to complaints of a substantial or serious nature that a State has failed to use funds in accordance with the requirements of this part or certifications provided under section 300w–4 of this title.

(4) The Secretary may not withhold funds under paragraph (1) from a State for a minor failure to comply with the requirements of this part or certifications provided under section 300w–4 of this title.

(b) Investigations

(1) The Secretary shall conduct in several States in each fiscal year investigations of the use of funds received by the States under this part in order to evaluate compliance with the requirements of this part and certifications provided under section 300w–4 of this title.

(2) The Comptroller General of the United States may conduct investigations of the use of funds received under this part by a State in order to insure compliance with the requirements of this part and certifications provided under section 300w–4 of this title.

(c) Availability of books, documents, papers, and records

Each State, and each entity which has received funds from an allotment made to a State under this part, shall make appropriate books, documents, papers, and records available to the Secretary or the Comptroller General of the United States, or any of their duly authorized representatives, for examination, copying, or mechanical reproduction on or off the premises of the appropriate entity upon a reasonable request therefor.

(d) Information not readily available

(1) In conducting any investigation in a State, the Secretary or the Comptroller General of the United States may not make a request for any information not readily available to such State or an entity which has received funds from an allotment made to the State under this part or make an unreasonable request for information to be compiled, collected, or transmitted in any form not readily available.

(2) Paragraph (1) does not apply to the collection, compilation, or transmittal of data in the course of a judicial proceeding.

(July 1, 1944, ch. 373, title XIX, §1907, as added Pub. L. 97–35, title IX, §901, Aug. 13, 1981, 95

Stat. 541.)

STATUTORY NOTES AND RELATED SUBSIDIARIES

EFFECTIVE DATE

Section effective Oct. 1, 1981, see section 901 of Pub. L. 97–35, set out in part as a note under section 300w of this title.

§300w–7. Nondiscrimination provisions

(a) Programs and activities receiving Federal financial assistance

(1) For the purpose of applying the prohibitions against discrimination on the basis of age under the Age Discrimination Act of 1975 [42 U.S.C. 6101 et seq.], on the basis of handicap under section 504 of the Rehabilitation Act of 1973 [29 U.S.C. 794], on the basis of sex under title IX of the Education Amendments of 1972 [20 U.S.C. 1681 et seq.], or on the basis of race, color, or national origin under title VI of the Civil Rights Act of 1964 [42 U.S.C. 2000d et seq.], programs and activities funded in whole or in part with funds made available under this part are considered to be programs and activities receiving Federal financial assistance.

(2) No person shall on the ground of sex or religion be excluded from participation in, be denied the benefits of, or be subjected to discrimination under, any program or activity funded in whole or in part with funds made available under this part.

(b) Failure to comply

Whenever the Secretary finds that a State, or an entity that has received a payment from an allotment to a State under section 300w–1 of this title, has failed to comply with a provision of law referred to in subsection (a)(1), with subsection (a)(2), or with an applicable regulation (including one prescribed to carry out subsection (a)(2)), the Secretary shall notify the chief executive officer of the State and shall request him to secure compliance. If within a reasonable period of time, not to exceed sixty days, the chief executive officer fails or refuses to secure compliance, the Secretary may—

(1) refer the matter to the Attorney General with a recommendation that an appropriate civil action be instituted,

(2) exercise the powers and functions provided by title VI of the Civil Rights Act of 1964 [42 U.S.C. 2000d et seq.], the Age Discrimination Act of 1975 [42 U.S.C. 6101 et seq.], or section 504 of the Rehabilitation Act of 1973 [29 U.S.C. 794], as may be applicable, or

(3) take such other action as may be provided by law.

(c) Civil actions by Attorney General

When a matter is referred to the Attorney General pursuant to subsection (b)(1), or whenever he has reason to believe that a State or an entity is engaged in a pattern or practice in violation of a provision of law referred to in subsection (a)(1) or in violation of subsection (a)(2), the Attorney General may bring a civil action in any appropriate district court of the United States for such relief as may be appropriate, including injunctive relief.

(July 1, 1944, ch. 373, title XIX, §1908, as added Pub. L. 97–35, title IX, §901, Aug. 13, 1981, 95 Stat. 542.)

EDITORIAL NOTES

REFERENCES IN TEXT

The Age Discrimination Act of 1975, referred to in subsecs. (a)(1) and (b)(2), is title III of Pub. L. 94–135, Nov. 28, 1975, 89 Stat. 728, which is classified generally to chapter 76 (§6101 et seq.) of this title. For complete classification of this Act to the Code, see Short Title note set out under section 6101 of this title and Tables.

The Education Amendments of 1972, referred to in subsec. (a)(1), is Pub. L. 92–318, June 23, 1972, 86 Stat. 235. Title IX of the Act, known as the Patsy Takemoto Mink Equal Opportunity in Education Act, is classified principally to chapter 38 (§1681 et seq.) of Title 20, Education. For complete classification of title IX to the Code, see Short Title note set out under section 1681 of Title 20 and Tables.

The Civil Rights Act of 1964, referred to in subsecs. (a)(1) and (b)(2), is Pub. L. 88–352, July 2, 1964, 78 Stat. 241. Title VI of the Civil Rights Act of 1964 is classified generally to subchapter V (§2000d et seq.) of chapter 21 of this title. For complete classification of this Act to the Code, see Short Title note set out under section 2000a of this title and Tables.

STATUTORY NOTES AND RELATED SUBSIDIARIES

EFFECTIVE DATE

Section effective Oct. 1, 1981, see section 901 of Pub. L. 97–35, set out in part as a note under section 300w of this title.

§300w–8. Criminal penalty for false statements

Whoever—

(1) knowingly and willfully makes or causes to be made any false statement or representation of a material fact in connection with the furnishing of items or services for which payment may be made by a State from funds allotted to the State under this part, or

(2) having knowledge of the occurrence of any event affecting his initial or continued right to any such payment conceals or fails to disclose such event with an intent fraudulently to secure such payment either in a greater amount than is due or when no such payment is authorized,

shall be fined not more than $25,000 or imprisoned for not more than five years, or both.

(July 1, 1944, ch. 373, title XIX, §1909, as added Pub. L. 97–35, title IX, §901, Aug. 13, 1981, 95 Stat. 542.)

STATUTORY NOTES AND RELATED SUBSIDIARIES

EFFECTIVE DATE

Section effective Oct. 1, 1981, see section 901 of Pub. L. 97–35, set out in part as a note under section 300w of this title.

§300w–9. Emergency medical services for children

(a) Grant authority

For activities in addition to the activities which may be carried out by States under section 300w–3(a)(1)(F) [1] of this title, the Secretary may make grants to States or accredited schools of medicine in States to support a program of demonstration projects for the expansion and improvement of emergency medical services for children who need treatment for trauma or critical care. Any grant made under this subsection shall be for not more than a 4-year period (with an optional 5th year based on performance), subject to annual evaluation by the Secretary. Only 3 grants under this subsection may be made in a State (to a State or to a school of medicine in such State) in any fiscal year.

(b) Renewals

The Secretary may renew a grant made under subsection (a) for one additional one-year period only if the Secretary determines that renewal of such grant will provide significant benefits through the collection, analysis, and dissemination of information or data which will be useful to States in which grants under such subsection have not been made.

(c) Definitions

For purposes of this section—

(1) the term "school of medicine" has the same meaning as in section 292a(4) [1] of this title; and

(2) the term "accredited" has the same meaning as in section 292a(5) [1] of this title.

(d) Authorization of appropriations

To carry out this section, there are authorized to be appropriated $2,000,000 for fiscal year 1985 and for each of the two succeeding fiscal years, $3,000,000 for fiscal year 1989, $4,000,000 for fiscal year 1990, $5,000,000 for each of the fiscal years 1991 and 1992, such sums as may be necessary for each of the fiscal years 1993 through 2005, $25,000,000 for fiscal year 2010, $26,250,000 for fiscal year 2011, $27,562,500 for fiscal year 2012, $28,940,625 for fiscal year 2013, $30,387,656 for fiscal year 2014, $20,213,000 for each of fiscal years 2015 through 2019, $22,334,000 for each of fiscal years 2020 through 2024, and $24,334,000 for each of fiscal years 2025 through 2029.

(July 1, 1944, ch. 373, title XIX, §1910, as added Pub. L. 98–555, §7, Oct. 30, 1984, 98 Stat. 2856; amended Pub. L. 99–272, title XVII, §17004, Apr. 7, 1986, 100 Stat. 360; Pub. L. 100–607, title III, §302, Nov. 4, 1988, 102 Stat. 3112; Pub. L. 101–590, §5, Nov. 16, 1990, 104 Stat. 2928; Pub. L. 102–410, §11, Oct. 13, 1992, 106 Stat. 2101; Pub. L. 105–392, title IV, §415, Nov. 13, 1998, 112 Stat. 3590; Pub. L. 111–148, title V, §5603, Mar. 23, 2010, 124 Stat. 679; Pub. L. 113–180, §2, Sept. 26, 2014, 128 Stat. 1915; Pub. L. 116–49, §2, Aug. 22, 2019, 133 Stat. 1072; Pub. L. 118–178, §2, Dec. 23, 2024, 138 Stat. 2612.)

EDITORIAL NOTES

REFERENCES IN TEXT

Section 300w–3(a)(1) of this title, referred to in subsec. (a), was amended generally by Pub. L. 102–531, title I, §102(a), Oct. 27, 1992, 106 Stat. 3470, and, as so amended, provisions formerly appearing in subpar. (F) are contained in subpar. (C).

Section 292a of this title, referred to in subsec. (c), was in the original a reference to section 701 of act July 1, 1944. Section 701 of that Act was omitted in the general revision of subchapter V of this chapter by Pub. L. 102–408, title I, §102, Oct. 13, 1992, 106 Stat. 1994. Pub. L. 102–408 enacted a new section 701 of act July 1, 1944, relating to statement of purpose, and a new section 702, relating to scope and duration of loan insurance program, which are classified to sections 292 and 292a, respectively, of this title. For provisions relating to definitions, see section 295p of this title.

AMENDMENTS

2024—Subsec. (d). Pub. L. 118–178 substituted "$22,334,000 for each of fiscal years 2020 through 2024, and $24,334,000 for each of fiscal years 2025 through 2029" for "and $22,334,000 for each of fiscal years 2020 through 2024".

2019—Subsec. (d). Pub. L. 116–49 substituted "2014," for "2014, and" and inserted before period at end ", and $22,334,000 for each of fiscal years 2020 through 2024".

2014—Subsec. (d). Pub. L. 113–180 substituted "$30,387,656" for "and $30,387,656" and inserted before period at end ", and $20,213,000 for each of fiscal years 2015 through 2019".

2010—Subsec. (a). Pub. L. 111–148, §5603(1), substituted "4-year period (with an optional 5th year" for "3-year period (with an optional 4th year".

Subsec. (d). Pub. L. 111–148, §5603(2), substituted "such sums" for "and such sums" and inserted ", $25,000,000 for fiscal year 2010, $26,250,000 for fiscal year 2011, $27,562,500 for fiscal year 2012, $28,940,625 for fiscal year 2013, and $30,387,656 for fiscal year 2014" before period at end.

1998—Subsec. (a). Pub. L. 105–392, §415(1), substituted "3-year period (with an optional 4th year based on performance)" for "two-year period" and "3 grants" for "one grant".

Subsec. (d). Pub. L. 105–392, §415(2), substituted "2005" for "1997".

1992—Subsec. (a). Pub. L. 102–410, §11(1), substituted "grants" for "not more than four grants in any fiscal year" after "Secretary may make" in first sentence.

Subsec. (d). Pub. L. 102–410, §11(2), substituted "$5,000,000" for "and $5,000,000" and inserted before period ", and such sums as may be necessary for each of the fiscal years 1993 through 1997".

1990—Subsec. (a). Pub. L. 101–590, §5(1)(A), which directed the substitution of "grants" for "not more that four grants in any fiscal year" could not be executed because the language to be stricken did not appear in text.

Pub. L. 101–590, §5(1)(B), struck out "in such States" after "demonstration projects" in first sentence.

Subsec. (d). Pub. L. 101–590, §5(2), substituted "each of the fiscal years 1991 and 1992" for "fiscal year 1991".

1988—Subsec. (a). Pub. L. 100–607, §302(a), substituted "shall be for not more than a two-year period, subject to annual evaluation by the Secretary" for "shall be for a one-year period".

Subsec. (d). Pub. L. 100–607, §302(b), inserted ", $3,000,000 for fiscal year 1989, $4,000,000 for fiscal year 1990, and $5,000,000 for fiscal year 1991" before period at end.

1986—Subsec. (a). Pub. L. 99–272, §17004(1), which directed substitution of "not more than four grants in any fiscal year to States or accredited schools of medicine in States" for "grant to not more than four States in any fiscal year" was made by substituting former phrase for "grants to not more than four States in any fiscal year", as the probable intent of Congress.

Pub. L. 99–272, §17004(2), inserted at end "Only one grant under this subsection may be made in a State (to a State or to a school of medicine in such State) in any fiscal year."

Subsec. (b). Pub. L. 99–272, §17004(3), substituted "States in which grants under such subsection have not been made" for "other States".

Subsecs. (c), (d). Pub. L. 99–272, §17004(4), (5), added subsec. (c) and redesignated former subsec. (c) as (d).

[1] See References in Text note below.

§300w–10. Repealed. Pub. L. 106–386, div. B, title IV, §1401(b), Oct. 28, 2000, 114 Stat. 1513

Section, act July 1, 1944, ch. 373, title XIX, §1910A, as added Pub. L. 103–322, title IV, §40151, Sept. 13, 1994, 108 Stat. 1920, related to use of allotments for rape prevention education. See section 280b–1b of this title.

A prior section 300w–10, act July 1, 1944, ch. 373, title XIX, §1910A, as added Oct. 30, 1984, Pub. L. 98–555, §8, 98 Stat. 2856, related to State planning grants, prior to repeal by Pub. L. 100–607, title III, §303, Nov. 4, 1988, 102 Stat. 3112.

PART B—BLOCK GRANTS REGARDING MENTAL HEALTH AND SUBSTANCE USE

EDITORIAL NOTES

CODIFICATION

Pub. L. 117–328, div. FF, title I, §1241(a)(1), Dec. 29, 2022, 136 Stat. 5677, substituted "Substance Use" for "Substance Abuse" in part heading.

SUBPART I—BLOCK GRANTS FOR COMMUNITY MENTAL HEALTH SERVICES

§300x. Formula grants to States

(a) In general

For the purpose described in subsection (b), the Secretary, acting through the Director of the

Center for Mental Health Services, shall make an allotment each fiscal year for each State in an amount determined in accordance with section 300x–7 of this title. The Secretary shall make a grant to the State of the allotment made for the State for the fiscal year if the State submits to the Secretary an application in accordance with section 300x–6 of this title.

(b) Purpose of grants

A funding agreement for a grant under subsection (a) is that, subject to section 300x–5 of this title, the State involved will expend the grant only for the purpose of—

(1) providing community mental health services for adults with a serious mental illness and children with a serious emotional disturbance as defined in accordance with section 300x–1(c) of this title;

(2) carrying out the plan submitted under section 300x–1(a) of this title by the State for the fiscal year involved;

(3) evaluating programs and services carried out under the plan; and

(4) planning, administration, and educational activities related to providing services under the plan.

(July 1, 1944, ch. 373, title XIX, §1911, as added Pub. L. 102–321, title II, §201(2), July 10, 1992, 106 Stat. 378; amended Pub. L. 114–255, div. B, title VIII, §8001(a), Dec. 13, 2016, 130 Stat. 1225.)

EDITORIAL NOTES

PRIOR PROVISIONS

A prior section 300x, act July 1, 1944, ch. 373, title XIX, §1911, as added Aug. 13, 1981, Pub. L. 97–35, title IX, §901, 95 Stat. 543; amended Oct. 19, 1984, Pub. L. 98–509, title I, §§101, 106(a), 98 Stat. 2353, 2358; Nov. 18, 1988, Pub. L. 100–690, title II, §2021, 102 Stat. 4194, authorized appropriations in fiscal years 1990 and 1991 for purpose of carrying out this subpart and section 290aa–11 of this title, prior to repeal by Pub. L. 102–321, §201(2).

AMENDMENTS

2016—Subsec. (b). Pub. L. 114–255 added par. (1) and redesignated former pars. (1) to (3) as (2) to (4), respectively.

STATUTORY NOTES AND RELATED SUBSIDIARIES

EFFECTIVE DATE

Part effective July 10, 1992, with programs making awards providing financial assistance in fiscal year 1993 and subsequent years effective for awards made on or after Oct. 1, 1992, and with provision that section 205(a) of Pub. L. 102–321, set out below, regarding allotments made for fiscal year 1992 under this part as in effect on the day before July 10, 1992, applies with respect to the program established in this part, see section 801(b), (d) of Pub. L. 102–321, set out as an Effective Date of 1992 Amendment note under section 236 of this title.

STATE GUIDANCE RELATED TO INDIVIDUALS WITH SERIOUS MENTAL ILLNESS AND CHILDREN WITH SERIOUS EMOTIONAL DISTURBANCE

Pub. L. 119–44, title II, §208, Dec. 1, 2025, 139 Stat. 681, provided that:

"(a) REVIEW OF USE OF CERTAIN FUNDING.—Not later than 1 year after the date of enactment of this Act [Dec. 1, 2025], the Secretary of Health and Human Services (referred to in this section as the 'Secretary'), acting through the Assistant Secretary for Mental Health and Substance Use, shall conduct a review of State use of funds made available under the Community Mental Health Services Block Grant program under subpart I of part B of title XIX of the Public Health Service Act (42 U.S.C. 300x et seq.) (referred to in this section as the 'block grant program') for first episode psychosis activities. Such review shall consider the following:

"(1) How States use funds for evidence-based treatments and services according to the standard of care for individuals with early serious mental illness and children with a serious emotional disturbance.

"(2) The percentages of the State funding under the block grant program expended on early serious mental illness and first episode psychosis, and the number of individuals served under such funds.

"(b) REPORT AND GUIDANCE.—

"(1) REPORT.—Not later than 180 days after the completion of the review under subsection (a), the Secretary shall submit to the Committee on Health, Education, Labor, and Pensions and the Committee on Appropriations of the Senate and the Committee on Energy and Commerce and the Committee on Appropriations of the House of Representatives a report describing—

"(A) the findings of the review under subsection (a); and

"(B) any recommendations for changes to the block grant program that would facilitate improved outcomes for individuals with serious mental illness and children with serious emotional disturbance.

"(2) GUIDANCE.—Not later than 1 year after the date on which the report is submitted under paragraph (1), the Secretary shall update the guidance provided to States under the block grant program on coordinated specialty care and other evidence-based mental health care services for individuals with serious mental illness and children with a serious emotional disturbance, based on the findings and recommendations of such report."

TEMPORARY PROVISIONS REGARDING FUNDING

Section 205 of Pub. L. 102–321, as amended by Pub. L. 102–352, §2(c), Aug. 26, 1992, 106 Stat. 939; Pub. L. 102–408, title III, §312, Oct. 13, 1992, 106 Stat. 2091, provided that, with respect to allotments made for fiscal year 1992 under this part, as in effect on the day before July 10, 1992, any portion of the total of such allotments that has not been paid to the States as of the first day of the fourth quarter of such fiscal year be reallotted with the result that the total allotment made for a State for fiscal year 1992 be the amount indicated for the State in a specified table, authorized Secretary of Health and Human Services to make a grant to a State of the reallotment if the State agrees that the grant be subject to all conditions upon which allotments and payments under this part, as in effect on the day before July 10, 1992, are made for fiscal 1992, with specified exceptions, permitted transfers of allotments made in fiscal years 1993 and 1994 between this part and subpart II, section 300x–21 of this title, under certain circumstances, defined terms as used, and directed funding, subject to a limitation, of a program for pregnant and postpartum women for fiscal year 1993.

REPORT ON ALLOTMENT FORMULA

Section 707 of Pub. L. 102–321 directed Secretary of Health and Human Services to enter into a contract with National Academy of Sciences, or if such Academy declines, with another public or nonprofit private agency, for purpose of conducting a study or studies concerning statutory formulae under which funds made available under this section and section 300x–21 of this title are allocated among States and territories, specified findings to be made by the study or studies, directed Secretary to ensure that not later than 6 months after July 10, 1992, the study was completed and a report submitted to Committee on Energy and Commerce of House of Representatives and Committee on Labor and Human Resources of Senate, and directed entity preparing the report to consult with Comptroller General with Comptroller General to review the study after its submittal and within three months make appropriate recommendations concerning such report to such committees.

§300x–1. State plan for comprehensive community mental health services for certain individuals

(a) In general

The Secretary may make a grant under section 300x of this title only if—

(1) the State involved submits to the Secretary a plan for providing comprehensive community mental health services to adults with a serious mental illness and to children with a serious emotional disturbance;

(2) the plan meets the criteria specified in subsection (b); and

(3) the plan is approved by the Secretary.

(b) Criteria for plan

In accordance with subsection (a), a State shall submit to the Secretary a plan every two years that, at a minimum, includes each of the following:

(1) System of care

A description of the State's system of care that contains the following:

(A) Comprehensive community-based health systems

The plan shall—

(i) identify the single State agency to be responsible for the administration of the program under the grant, including any third party who administers mental health services and is responsible for complying with the requirements of this part with respect to the grant;

(ii) provide for an organized community-based system of care for individuals with mental illness, and describe available services and resources in a comprehensive system of care, including services for individuals with co-occurring disorders;

(iii) include a description of the manner in which the State and local entities will coordinate services to maximize the efficiency, effectiveness, quality, and cost-effectiveness of services and programs to produce the best possible outcomes (including health services, rehabilitation services, employment services, housing services, educational services, substance use disorder services, legal services, law enforcement services, social services, child welfare services, medical and dental care services, and other support services to be provided with Federal, State, and local public and private resources) with other agencies to enable individuals receiving services to function outside of inpatient or residential institutions, to the maximum extent of their capabilities, including services to be provided by local school systems under the Individuals with Disabilities Education Act [20 U.S.C. 1400 et seq.];

(iv) include a description of how the State promotes evidence-based practices, including those evidence-based programs that address the needs of individuals with early serious mental illness regardless of the age of the individual at onset, provide comprehensive individualized treatment, or integrate mental and physical health services;

(v) include a description of case management services;

(vi) include a description of activities that seek to engage adults with a serious mental illness or children with a serious emotional disturbance and their caregivers where appropriate in making health care decisions, including activities that enhance communication among individuals, families, caregivers, and treatment providers; and

(vii) as appropriate to, and reflective of, the uses the State proposes for the block grant funds, include—

(I) a description of the activities intended to reduce hospitalizations and hospital stays using the block grant funds;

(II) a description of the activities intended to reduce incidents of suicide using the block grant funds;

(III) a description of how the State integrates mental health and primary care using the block grant funds, which may include providing, in the case of individuals with co-occurring mental and substance use disorders, both mental and substance use disorders services in primary care settings or arrangements to provide primary and specialty care services in community-based mental and substance use disorders settings; and

(IV) a description of recovery and recovery support services for adults with a serious mental illness and children with a serious emotional disturbance.

(B) Mental health system data and epidemiology

The plan shall contain an estimate of the incidence and prevalence in the State of serious mental illness among adults and serious emotional disturbance among children and present quantitative targets and outcome measures for programs and services provided under this subpart.

(C) Children's services

In the case of children with a serious emotional disturbance (as defined pursuant to subsection (c)), the plan shall provide for a system of integrated social services, educational services, child welfare services, juvenile justice services, law enforcement services, and

substance use disorder services that, together with health and mental health services, will be provided in order for such children to receive care appropriate for their multiple needs (such system to include services provided under the Individuals with Disabilities Education Act).

(D) Targeted services to rural and homeless populations

The plan shall describe the State's outreach to and services for individuals who are homeless and how community-based services will be provided to individuals residing in rural areas.

(E) Management services

The plan shall describe the financial resources available, the existing mental health workforce, and the workforce trained in treating individuals with co-occurring mental and substance use disorders, and shall provide for the training of providers of emergency health services regarding mental health. The plan shall further describe the manner in which the State intends to expend the grant under section 300x of this title for the fiscal year involved, and the manner in which the State intends to comply with each of the funding agreements in this subpart and subpart III.

(2) Goals and objectives

The establishment of goals and objectives for the period of the plan, including targets and milestones that are intended to be met, and the activities that will be undertaken to achieve those targets.

(c) Definitions regarding mental illness and emotional disturbance; methods for estimate of incidence and prevalence

(1) Establishment by Secretary of definitions; dissemination

For purposes of this subpart, the Secretary shall establish definitions for the terms "adults with a serious mental illness" and "children with a serious emotional disturbance". The Secretary shall disseminate the definitions to the States.

(2) Standardized methods

The Secretary shall establish standardized methods for making the estimates required in subsection (b)(11) [1] with respect to a State. A funding agreement for a grant under section 300x of this title for the State is that the State will utilize such methods in making the estimates.

(3) Date certain for compliance by Secretary

Not later than 90 days after July 10, 1992, the Secretary shall establish the definitions described in paragraph (1), shall begin dissemination of the definitions to the States, and shall establish the standardized methods described in paragraph (2).

(d) Requirement of implementation of plan

(1) Complete implementation

Except as provided in paragraph (2), in making a grant under section 300x of this title to a State for a fiscal year, the Secretary shall make a determination of the extent to which the State has implemented the plan required in subsection (a). If the Secretary determines that a State has not completely implemented the plan, the Secretary shall reduce the amount of the allotment under section 300x of this title for the State for the fiscal year involved by an amount equal to 10 percent of the amount determined under section 300x–7 of this title for the State for the fiscal year.

(2) Substantial implementation and good faith effort regarding fiscal year 1993

(A) In making a grant under section 300x of this title to a State for fiscal year 1993, the Secretary shall make a determination of the extent to which the State has implemented the plan required in subsection (a). If the Secretary determines that the State has not substantially implemented the plan, the Secretary shall, subject to subparagraph (B), reduce the amount of the

allotment under section 300x of this title for the State for such fiscal year by an amount equal to 10 percent of the amount determined under section 300x–7 of this title for the State for the fiscal year.

(B) In carrying out subparagraph (A), if the Secretary determines that the State is making a good faith effort to implement the plan required in subsection (a), the Secretary may make a reduction under such subparagraph in an amount that is less than the amount specified in such subparagraph, except that the reduction may not be made in an amount that is less than 5 percent of the amount determined under section 300x–7 of this title for the State for fiscal year 1993.

(July 1, 1944, ch. 373, title XIX, §1912, as added Pub. L. 102–321, title II, §201(2), July 10, 1992, 106 Stat. 379; amended Pub. L. 106–310, div. B, title XXXII, §3204(a), Oct. 17, 2000, 114 Stat. 1192; Pub. L. 114–255, div. B, title VIII, §8001(b), Dec. 13, 2016, 130 Stat. 1225.)

EDITORIAL NOTES

REFERENCES IN TEXT

The Individuals with Disabilities Education Act, referred to in subsec. (b)(1)(A)(iii), (C), is title VI of Pub. L. 91–230, Apr. 13, 1970, 84 Stat. 175, which is classified generally to chapter 33 (§1400 et seq.) of Title 20, Education. For complete classification of this Act to the Code, see section 1400 of Title 20 and Tables.

Subsection (b)(11), referred to in subsec. (c)(2), was repealed by Pub. L. 106–310, div. B, title XXXII, §3204(a), Oct. 17, 2000, 114 Stat. 1192. Provisions relating to estimates formerly contained in subsec. (b)(11) are now contained in subsec. (b)(1)(B) of this section.

PRIOR PROVISIONS

Prior sections 300x–1 to 300x–1b were repealed by Pub. L. 102–321, title II, §201(2), July 10, 1992, 106 Stat. 378.

Section 300x–1, act July 1, 1944, ch. 373, title XIX, §1912, as added Oct. 19, 1984, Pub. L. 98–509, title I, §102(a), 98 Stat. 2353, authorized grants for training of employees adversely affected by changes in delivery of mental health services and for providing assistance in securing employment.

Another prior section 300x–1, act July 1, 1944, ch. 373, title XIX, §1912, as added Aug. 13, 1981, Pub. L. 97–35, title IX, §901, 95 Stat. 543; amended Jan. 4, 1983, Pub. L. 97–414, §8(t), 96 Stat. 2062; Oct. 19, 1984, Pub. L. 98–509, title I, §106(e), 98 Stat. 2358, contained provisions relating to grants and allotment of grants for alcohol, drug abuse, and mental health services, prior to repeal by section 102(a) of Pub. L. 98–509.

Section 300x–1a, act July 1, 1944, ch. 373, title XIX, §1912A, as added and amended Nov. 18, 1988, Pub. L. 100–690, title II, §§2022(a)–(c), 2023, 102 Stat. 4194, 4196, 4197; Aug. 16, 1989, Pub. L. 101–93, §2(a), 103 Stat. 603, related to allotments of grants for alcohol, drug abuse, and mental health services.

Another prior section 300x–1a, act July 1, 1944, ch. 373, title XIX, §1913, as added Oct. 19, 1984, Pub. L. 98–509, title I, §102(a), 98 Stat. 2353, was transferred to section 300x–1b of this title.

Section 300x–1b, act July 1, 1944, ch. 373, title XIX, §1913, as added Oct. 19, 1984, Pub. L. 98–509, title I, §102(a), 98 Stat. 2353; amended Nov. 18, 1988, Pub. L. 100–690, title II, §2022(d), 102 Stat. 4197; Aug. 16, 1989, Pub. L. 101–93, §2(b), 103 Stat. 605, related to allotments to States and Indian tribes or tribal organizations for alcohol, drug abuse, and mental health services.

AMENDMENTS

2016—Subsec. (b). Pub. L. 114–255, §8001(b)(3), (10), substituted, in introductory provisions, "In accordance with subsection (a), a State shall submit to the Secretary a plan every two years that, at a minimum, includes each of the following:" for "With respect to the provision of comprehensive community mental health services to individuals who are either adults with a serious mental illness or children with a serious emotional disturbance, the criteria referred to in subsection (a) regarding a plan are as follows:" and struck out concluding provisions which read as follows: "Except as provided for in paragraph (3), the State plan shall contain the information required under this subsection with respect to both adults with serious mental illness and children with serious emotional disturbance."

Subsec. (b)(1). Pub. L. 114–255, §8001(b)(4), inserted par. (1) designation, heading, and introductory provisions. Former par. (1) redesignated subpar. (A) of par. (1).

Subsec. (b)(1)(A). Pub. L. 114–255, §8001(b)(5), added subpar. (A) and struck out former subpar. (A) which related to comprehensive community-based mental health systems.

Pub. L. 114–255, §8001(b)(2), redesignated par. (1) as subpar. (A) of par. (1) and realigned margins.

Subsec. (b)(1)(B). Pub. L. 114–255, §8001(b)(6), substituted "The plan shall contain" for "The plan

contains" and "present quantitative targets and outcome measures for programs and services provided under this subpart" for "presents quantitative targets to be achieved in the implementation of the system described in paragraph (1)".

Pub. L. 114–255, §8001(b)(2), redesignated par. (2) as subpar. (B) of par. (1) and realigned margins.

Subsec. (b)(1)(C). Pub. L. 114–255, §8001(b)(7), substituted "a serious emotional disturbance (as defined pursuant to subsection (c)), the plan shall provide for a system of integrated social services, educational services, child welfare services, juvenile justice services, law enforcement services, and substance use disorder services" for "serious emotional disturbance, the plan—(i) subject to subparagraph (B), provides for a system of integrated social services, educational services, juvenile services, and substance abuse services" and "Education Act)." for "Education Act);" and struck out cls. (ii) and (iii), which related to use of grants under section 300x of this title and to establishment of a defined geographic area for the provision of the services, respectively.

Pub. L. 114–255, §8001(b)(2), redesignated par. (3) as subpar. (C) of par. (1) and realigned margins.

Pub. L. 114–255, §8001(b)(1), redesignated subpars. (A) to (C) of par. (3) as cls. (i) to (iii) of subpar. (C) of par. (1) and realigned margins.

Subsec. (b)(1)(D). Pub. L. 114–255, §8001(b)(8), substituted "plan shall describe" for "plan describes".

Pub. L. 114–255, §8001(b)(2), redesignated par. (4) as subpar. (D) of par. (1) and realigned margins.

Subsec. (b)(1)(E). Pub. L. 114–255, §8001(b)(9), in heading substituted "services" for "systems", in first sentence substituted, "plan shall describe the financial resources available, the existing mental health workforce, and the workforce trained in treating individuals with co-occurring mental and substance use disorders, and shall provide for" for "plan describes the financial resources, staffing and training for mental health providers that is necessary to implement the plan, and provides for", and in second sentence substituted, "shall further describe" for "further describes" and "involved, and the manner in which the State intends to comply with each of the funding agreements in this subpart and subpart III." for "involved."

Pub. L. 114–255, §8001(b)(2), redesignated par. (5) as subpar. (E) of par. (1) and realigned margins.

Subsec. (b)(2). Pub. L. 114–255, §8001(b)(11), added par. (2). Former par. (2) redesignated subpar. (B) of par. (1).

Subsec. (b)(3) to (5). Pub. L. 114–255, §8001(b)(2), redesignated pars. (3) to (5) as subpars. (C) to (E), respectively, of par. (1).

2000—Subsec. (b). Pub. L. 106–310 added pars. (1) to (5) and concluding provisions and struck out former pars. (1) to (12) relating to criteria for plan.

[1] *See References in Text note below.*

§300x–2. Certain agreements

(a) Allocation for systems of integrated services for children

(1) In general

With respect to children with a serious emotional disturbance, a funding agreement for a grant under section 300x of this title is that—

(A) in the case of a grant for fiscal year 1993, the State involved will expend not less than 10 percent of the grant to increase (relative to fiscal year 1992) funding for the system of integrated services described in section 300x–1(b)(9) [1] of this title;

(B) in the case of a grant for fiscal year 1994, the State will expend not less than 10 percent of the grant to increase (relative to fiscal year 1993) funding for such system; and

(C) in the case of a grant for any subsequent fiscal year, the State will expend for such system not less than an amount equal to the amount expended by the State for fiscal year 1994.

(2) Waiver

(A) Upon the request of a State, the Secretary may provide to the State a waiver of all or part of the requirement established in paragraph (1) if the Secretary determines that the State is providing an adequate level of comprehensive community mental health services for children with a serious emotional distrubance,[2] as indicated by a comparison of the number of such children for which such services are sought with the availability in the State of the services.

(B) The Secretary shall approve or deny a request for a waiver under subparagraph (A) not later than 120 days after the date on which the request is made.

(C) Any waiver provided by the Secretary under subparagraph (A) shall be applicable only to the fiscal year involved.

(b) Providers of services

A funding agreement for a grant under section 300x of this title for a State is that, with respect to the plan submitted under section 300x–1(a) of this title for the fiscal year involved—

(1) services under the plan will be provided only through appropriate, qualified community programs (which may include community mental health centers, child mental-health programs, psychosocial rehabilitation programs, mental health peer-support programs, and mental-health primary consumer-directed programs); and

(2) services under the plan will be provided through community mental health centers only if the centers meet the criteria specified in subsection (c).

(c) Criteria for mental health centers

The criteria referred to in subsection (b)(2) regarding community mental health centers are as follows:

(1) With respect to mental health services, the centers provide services as follows:

(A) Services principally to individuals residing in a defined geographic area (hereafter in this subsection referred to as a "service area").

(B) Outpatient services, including specialized outpatient services for children, the elderly, individuals with a serious mental illness, and residents of the service areas of the centers who have been discharged from inpatient treatment at a mental health facility.

(C) 24-hour-a-day emergency care services.

(D) Day treatment or other partial hospitalization services, or psychosocial rehabilitation services.

(E) Screening for patients being considered for admission to State mental health facilities to determine the appropriateness of such admission.

(2) The mental health services of the centers are provided, within the limits of the capacities of the centers, to any individual residing or employed in the service area of the center regardless of ability to pay for such services.

(3) The mental health services of the centers are available and accessible promptly, as appropriate and in a manner which preserves human dignity and assures continuity and high quality care.

(July 1, 1944, ch. 373, title XIX, §1913, as added Pub. L. 102–321, title II, §201(2), July 10, 1992, 106 Stat. 381.)

EDITORIAL NOTES

REFERENCES IN TEXT

Section 300x–1(b)(9) of this title, referred to in subsec. (a)(1)(A), was repealed by Pub. L. 106–310, div. B, title XXXII, §3204(a), Oct. 17, 2000, 114 Stat. 1192. Provisions relating to a system of integrated social services formerly contained in section 300x–1(b)(9) are now contained in section 300x–1(b)(3) of this title.

PRIOR PROVISIONS

A prior section 300x–2, act July 1, 1944, ch. 373, title XIX, §1914, formerly §1913, as added Aug. 13, 1981, Pub. L. 97–35, title IX, §901, 95 Stat. 545; renumbered §1914 and amended Oct. 19, 1984, Pub. L. 98–509, title I, §106(a), (c)–(e), (g), 98 Stat. 2358, 2359; Nov. 18, 1988, Pub. L. 100–690, title II, §2022(e), 102 Stat. 4197; Aug. 16, 1989, Pub. L. 101–93, §2(c)(1), 103 Stat. 605, related to payment to States of allotments of grants for alcohol, drug abuse, and mental health services, prior to repeal by Pub. L. 102–321, §201(2).

A prior section 1913 of act July 1, 1944, was classified to section 300x–1b of this title and repealed by Pub. L. 102–321.

[1] *See References in Text note below.*

[2] *So in original. Probably should be "disturbance,".*

§300x–3. State mental health planning council

(a) In general

A funding agreement for a grant under section 300x of this title is that the State involved will establish and maintain a State mental health planning council in accordance with the conditions described in this section.

(b) Duties

A condition under subsection (a) for a Council is that the duties of the Council are—

(1) to review plans provided to the Council pursuant to section 300x–4(a) of this title by the State involved and to submit to the State any recommendations of the Council for modifications to the plans;

(2) to serve as an advocate for adults with a serious mental illness, children with a severe emotional disturbance, and other individuals with mental illnesses or emotional problems; and

(3) to monitor, review, and evaluate, not less than once each year, the allocation and adequacy of mental health services within the State.

(c) Membership

(1) In general

A condition under subsection (a) for a Council is that the Council be composed of residents of the State, including representatives of—

(A) the principal State agencies with respect to—

(i) mental health, education, vocational rehabilitation, criminal justice, housing, and social services; and

(ii) the development of the plan submitted pursuant to title XIX of the Social Security Act [42 U.S.C. 1396 et seq.];

(B) public and private entities concerned with the need, planning, operation, funding, and use of mental health services and related support services;

(C) adults with serious mental illnesses who are receiving (or have received) mental health services; and

(D) the families of such adults or families of children with emotional disturbance.

(2) Certain requirements

A condition under subsection (a) for a Council is that—

(A) with respect to the membership of the Council, the ratio of parents of children with a serious emotional disturbance to other members of the Council is sufficient to provide adequate representation of such children in the deliberations of the Council; and

(B) not less than 50 percent of the members of the Council are individuals who are not State employees or providers of mental health services.

(d) "Council" defined

For purposes of this section, the term "Council" means a State mental health planning council.

(July 1, 1944, ch. 373, title XIX, §1914, as added Pub. L. 102–321, title II, §201(2), July 10, 1992, 106 Stat. 382.)

EDITORIAL NOTES

REFERENCES IN TEXT

The Social Security Act, referred to in subsec. (c)(1)(A)(ii), is act Aug. 14, 1935, ch. 531, 49 Stat. 620. Title XIX of the Act is classified generally to subchapter XIX (§1396 et seq.) of chapter 7 of this title. For complete classification of this Act to the Code, see section 1305 of this title and Tables.

PRIOR PROVISIONS

A prior section 300x–3, act July 1, 1944, ch. 373, title XIX, §1915, formerly §1914, as added Aug. 13, 1981, Pub. L. 97–35, title IX, §901, 95 Stat. 545; renumbered §1915 and amended Oct. 19, 1984, Pub. L. 98–509, title I, §§105(b), 106(a), (b), (d), (g), 98 Stat. 2358, 2359; Nov. 18, 1988, Pub. L. 100–690, title II, §§2024–2026, 102 Stat. 4198, 4199; Aug. 16, 1989, Pub. L. 101–93, §2(d), 103 Stat. 606; Nov. 28, 1990, Pub. L. 101–639, §3(a)(2), 104 Stat. 4601, related to the use of grant allotments for alcohol, drug abuse, and mental health services, prior to repeal by Pub. L. 102–321, §201(2).

A prior section 1914 of act July 1, 1944, was classified to section 300x–2 of this title prior to repeal by Pub. L. 102–321.

§300x–4. Additional provisions

(a) Review of State plan by mental health planning council

The Secretary may make a grant under section 300x of this title to a State only if—

(1) the plan submitted under section 300x–1(a) of this title with respect to the grant and the report of the State under section 300x–52(a) of this title concerning the preceding fiscal year has been reviewed by the State mental health planning council under section 300x–3 of this title; and

(2) the State submits to the Secretary any recommendations received by the State from such council for modifications to the plan (without regard to whether the State has made the recommended modifications) and any comments concerning the annual report.

(b) Maintenance of effort regarding State expenditures for mental health

(1) In general

A funding agreement for a grant under section 300x of this title is that the State involved will maintain State expenditures for community mental health services at a level that is not less than the average level of such expenditures maintained by the State for the 2-year period preceding the fiscal year for which the State is applying for the grant.

(2) Exclusion of certain funds

The Secretary may exclude from the aggregate State expenditures under subsection (a), funds appropriated to the principle agency for authorized activities which are of a non-recurring nature and for a specific purpose.

(3) Waiver

(A) In general

The Secretary may, upon the request of a State, waive the requirement established in paragraph (1) in whole or in part if the Secretary determines that extraordinary economic conditions in the State in the fiscal year involved or in the previous fiscal year justify the waiver [1]

(B) Date certain for action upon request

The Secretary shall approve or deny a request for a waiver under this paragraph not later than 120 days after the date on which the request is made.

(C) Applicability of waiver

A waiver provided by the Secretary under this paragraph shall be applicable only to the fiscal year involved.

(4) Noncompliance by State

(A) In general

(i) Determination

In making a grant under section 300x of this title to a State for a fiscal year, the Secretary shall make a determination of whether, for the previous fiscal year, the State maintained material compliance with the agreement made under paragraph (1). If the Secretary determines that a State has failed to maintain such compliance, the Secretary shall reduce the amount of the allotment under section 300x of this title for the State for the fiscal year for which the grant is being made by an amount equal to the amount constituting such failure for the previous fiscal year.

(ii) Alternative

A State that has failed to comply with paragraph (1) and would otherwise be subject to a reduction in the State's allotment under section 300x of this title may, upon request by the State, in lieu of having the amount of the allotment under section 300x of this title for the State reduced for the fiscal year of the grant, agree to comply with a negotiated agreement that is approved by the Secretary and carried out in accordance with guidelines issued by the Secretary. If a State fails to enter into or comply with a negotiated agreement, the Secretary may take action under this paragraph or the terms of the negotiated agreement.

(B) Submission of information to the secretary

The Secretary may make a grant under section 300x of this title for a fiscal year only if the State involved submits to the Secretary information sufficient for the Secretary to make the determination required in subparagraph (A)(i).

(July 1, 1944, ch. 373, title XIX, §1915, as added Pub. L. 102–321, title II, §201(2), July 10, 1992, 106 Stat. 383; amended Pub. L. 106–310, div. B, title XXXII, §3204(b), (c), Oct. 17, 2000, 114 Stat. 1193; Pub. L. 114–255, div. B, title VIII, §8001(d), Dec. 13, 2016, 130 Stat. 1228.)

EDITORIAL NOTES

PRIOR PROVISIONS

Prior sections 300x–4 and 300x–4a were repealed by Pub. L. 102–321, title II, §201(2), July 10, 1992, 106 Stat. 378.

Section 300x–4, act July 1, 1944, ch. 373, title XIX, §1916, formerly §1915, as added Aug. 13, 1981, Pub. L. 97–35, title IX, §901, 95 Stat. 546; amended Jan. 4, 1983, Pub. L. 97–414, §8(u), 96 Stat. 2063; renumbered §1916 and amended Oct. 19, 1984, Pub. L. 98–509, title I, §§103, 106(a)–(c), (f), (g), 98 Stat. 2355, 2358, 2359; Oct. 7, 1985, Pub. L. 99–117, §7(a), 99 Stat. 492; Nov. 14, 1986, Pub. L. 99–660, title V, §503, 100 Stat. 3797; Nov. 18, 1988, Pub. L. 100–690, title II, §§2027–2035, 2037(a)(2), 102 Stat. 4199–4201, 4203; Aug. 16, 1989, Pub. L. 101–93, §2(e)–(l), (p)(1), (q)(1), 103 Stat. 606–609; Aug. 15, 1990, Pub. L. 101–374, §4(b), 104 Stat. 459, required States to make application and describe their activities in relation to allotments for grants for alcohol, drug abuse, and mental health services.

A prior section 1915 of act July 1, 1944, was classified to section 300x–3 of this title prior to repeal by Pub. L. 102–321.

Section 300x–4a, act July 1, 1944, ch. 373, title XIX, §1916A, as added Nov. 18, 1988, Pub. L. 100–690, title II, §2036, 102 Stat. 4202; amended Aug. 16, 1989, Pub. L. 101–93, §2(m), 103 Stat. 608, related to group homes for recovering substance abusers.

AMENDMENTS

2016—Subsec. (b)(3). Pub. L. 114–255, §8001(d)(1), designated existing provisions as subpar. (A) and inserted heading, substituted "paragraph (1) in whole or in part if" for "paragraph (1) if" and "State in the fiscal year involved or in the previous fiscal year justify the waiver" for "State justify the waiver.", and added subpars. (B) and (C).

Subsec. (b)(4)(A). Pub. L. 114–255, §8001(d)(2)(A), designated existing provisions as cl. (i), inserted subpar. (A) and cl. (i) headings, and added cl. (ii).

Subsec. (b)(4)(B). Pub. L. 114–255, §8001(d)(2)(B), inserted heading and substituted "subparagraph (A)(i)" for "subparagraph (A)" in text.

2000—Subsec. (a)(1). Pub. L. 106–310, §3204(b)(1), inserted "and the report of the State under section 300x–52(a) of this title concerning the preceding fiscal year" after "to the grant".

Subsec. (a)(2). Pub. L. 106–310, §3204(b)(2), inserted "and any comments concerning the annual report" before period at end.

Subsec. (b)(2) to (4). Pub. L. 106–310, §3204(c), added par. (2) and redesignated former pars. (2) and (3) as (3) and (4), respectively.

[1] *So in original. Probably should be followed by a period.*

§300x–5. Restrictions on use of payments

(a) In general

A funding agreement for a grant under section 300x of this title is that the State involved will not expend the grant—

(1) to provide inpatient services;

(2) to make cash payments to intended recipients of health services;

(3) to purchase or improve land, purchase, construct, or permanently improve (other than minor remodeling) any building or other facility, or purchase major medical equipment;

(4) to satisfy any requirement for the expenditure of non-Federal funds as a condition for the receipt of Federal funds; or

(5) to provide financial assistance to any entity other than a public or nonprofit private entity.

(b) Limitation on administrative expenses

A funding agreement for a grant under section 300x of this title is that the State involved will not expend more than 5 percent of the grant for administrative expenses with respect to the grant.

(July 1, 1944, ch. 373, title XIX, §1916, as added Pub. L. 102–321, title II, §201(2), July 10, 1992, 106 Stat. 384.)

EDITORIAL NOTES

PRIOR PROVISIONS

A prior section 300x–5, act July 1, 1944, ch. 373, title XIX, §1917, formerly §1916, as added Aug. 13, 1981, Pub. L. 97–35, title IX, §901, 95 Stat. 549; renumbered §1917 and amended Oct. 19, 1984, Pub. L. 98–509, title I, §§104, 106(a), (b), (d), (g), 98 Stat. 2357–2359; Oct. 7, 1985, Pub. L. 99–117, §7(b), 99 Stat. 493; Nov. 18, 1988, Pub. L. 100–690, title II, §§2037(a)(1), (b), 2052(b), 102 Stat. 4203, 4208; Aug. 16, 1989, Pub. L. 101–93, §2(p)(2), 103 Stat. 609, related to reports and audits relative to grants for alcohol, drug abuse, and mental health services, prior to repeal by Pub. L. 102–321, §201(2).

A prior section 1916 of act July 1, 1944, was classified to section 300x–4 of this title prior to repeal by Pub. L. 102–321.

§300x–6. Application for grant

(a) In general

For purposes of section 300x of this title, an application for a grant under such section for a fiscal year in accordance with this section if, subject to subsection (b)—

(1) the plan is received by the Secretary not later than September 1 of the fiscal year prior to the fiscal year for which a State is seeking funds, and the report from the previous fiscal year as required under section 300x–52(a) of this title is received by December 1 of the fiscal year of the grant;

(2) the application contains each funding agreement that is described in this subpart or subpart III for such a grant (other than any such agreement that is not applicable to the State);

(3) the agreements are made through certification from the chief executive officer of the State;

(4) with respect to such agreements, the application provides assurances of compliance satisfactory to the Secretary;

(5) the application contains the plan required in section 300x–1(a) of this title, the information required in section 300x–4(b) of this title, and the report required in section 300x–52(a) of this title;

(6) the application contains recommendations in compliance with section 300x–4(a) of this title, or if no such recommendations are received by the State, the application otherwise demonstrates compliance with such section; and

(7) the application (including the plan under section 300x–1(a) of this title) is otherwise in such form, is made in such manner, and contains such agreements, assurances, and information as the Secretary determines to be necessary to carry out this subpart.

(b) Waivers regarding certain territories

In the case of any territory of the United States except Puerto Rico, the Secretary may waive such provisions of this subpart and subpart III as the Secretary determines to be appropriate, other than the provisions of section 300x–5 of this title.

(July 1, 1944, ch. 373, title XIX, §1917, as added Pub. L. 102–321, title II, §201(2), July 10, 1992, 106 Stat. 384; amended Pub. L. 106–310, div. B, title XXXII, §3204(d), (e), Oct. 17, 2000, 114 Stat. 1193; Pub. L. 114–255, div. B, title VIII, §8001(e), Dec. 13, 2016, 130 Stat. 1229.)

EDITORIAL NOTES

PRIOR PROVISIONS

A prior section 300x–6, act July 1, 1944, ch. 373, title XIX, §1918, formerly §1917, as added Aug. 13, 1981, Pub. L. 97–35, title IX, §901, 95 Stat. 550; renumbered §1918 and amended Oct. 19, 1984, Pub. L. 98–509, title I, §106(d), (g), 98 Stat. 2358, 2359, authorized withholding funds from States which did not use allotments of grants for alcohol, drug abuse, and mental health services in accordance with requirements, prior to repeal by Pub. L. 102–321, §201(2).

A prior section 1917 of act July 1, 1944, was classified to section 300x–5 of this title prior to repeal by Pub. L. 102–321.

AMENDMENTS

2016—Subsec. (a)(1). Pub. L. 114–255, §8001(e)(1), substituted "300x–52(a)" for "300x–51".

Subsec. (a)(5). Pub. L. 114–255, §8001(e)(2), substituted "300x–4(b)" for "300x–4(b)(3)(B)".

2000—Subsec. (a)(1). Pub. L. 106–310, §3204(d), amended par. (1) generally. Prior to amendment, par. (1) read as follows: "the State involved submits the application not later than the date specified by the Secretary as being the date after which applications for such a grant will not be considered (in any case in which the Secretary specifies such a date);".

Subsec. (b). Pub. L. 106–310, §3204(e), substituted "except Puerto Rico" for "whose allotment under section 300x of this title for the fiscal year is the amount specified in section 300x–7(c)(2)(B) of this title".

§300x–7. Determination of amount of allotment

(a) States

(1) Determination under formula

Subject to subsection (b), the Secretary shall determine the amount of the allotment required in section 300x of this title for a State for a fiscal year in accordance with the following formula:

$$A \quad \left(\frac{X}{U} \right)$$

(2) Determination of term "A"

For purposes of paragraph (1), the term "A" means the difference between—

(A) the amount appropriated under section 300x–9(a) of this title for allotments under section 300x of this title for the fiscal year involved; and

(B) an amount equal to 1.5 percent of the amount referred to in subparagraph (A).

(3) Determination of term "U"

For purposes of paragraph (1), the term "U" means the sum of the respective terms "X" determined for the States under paragraph (4).

(4) Determination of term "X"

For purposes of paragraph (1), the term "X" means the product of—

(A) an amount equal to the product of—

(i) the term "P", as determined for the State involved under paragraph (5); and

(ii) the factor determined under paragraph (8) for the State; and

(B) the greater of—

(i) 0.4; and

(ii) an amount equal to an amount determined for the State in accordance with the following formula:

$$1.35 \left(\frac{R\%}{P\%} \right)$$

(5) Determination of term "P"

(A) For purposes of paragraph (4), the term "P" means the sum of—

(i) an amount equal to the product of 0.107 and the number of individuals in the State who are between 18 and 24 years of age (inclusive);

(ii) an amount equal to the product of 0.166 and the number of individuals in the State who are between 25 and 44 years of age (inclusive);

(iii) an amount equal to the product of 0.099 and the number of individuals in the State who are between 45 and 64 years of age (inclusive); and

(iv) an amount equal to the product of 0.082 and the number of individuals in the State who are 65 years of age or older.

(B) With respect to data on population that is necessary for purposes of making a determination under subparagraph (A), the Secretary shall use the most recent data that is available from the Secretary of Commerce pursuant to the decennial census and pursuant to reasonable estimates by such Secretary of changes occurring in the data in the ensuing period.

(6) Determination of term "R%"

(A) For purposes of paragraph (4), the term "R%", except as provided in subparagraph (D), means the percentage constituted by the ratio of the amount determined under subparagraph (B) for the State involved to the amount determined under subparagraph (C).

(B) The amount determined under this subparagraph for the State involved is the quotient of—

(i) the most recent 3-year arithmetic mean of the total taxable resources of the State, as determined by the Secretary of the Treasury; divided by

(ii) the factor determined under paragraph (8) for the State.

(C) The amount determined under this subparagraph is the sum of the respective amounts determined for the States under subparagraph (B) (including the District of Columbia).

(D)(i) In the case of the District of Columbia, for purposes of paragraph (4), the term "R%" means the percentage constituted by the ratio of the amount determined under clause (ii) for such District to the amount determined under clause (iii).

(ii) The amount determined under this clause for the District of Columbia is the quotient of—

(I) the most recent 3-year arithmetic mean of total personal income in such District, as determined by the Secretary of Commerce; divided by

(II) the factor determined under paragraph (8) for the District.

(iii) The amount determined under this clause is the sum of the respective amounts determined for the States (including the District of Columbia) by making, for each State, the same determination as is described in clause (ii) for the District of Columbia.

(7) Determination of term "P%"

For purposes of paragraph (4), the term "P%" means the percentage constituted by the ratio of the term "P" determined under paragraph (5) for the State involved to the sum of the respective terms "P" determined for the States.

(8) Determination of certain factor

(A) The factor determined under this paragraph for the State involved is a factor whose purpose is to adjust the amount determined under clause (i) of paragraph (4)(A), and the amounts determined under each of subparagraphs (B)(i) and (D)(ii)(I) of paragraph (6), to reflect the differences that exist between the State and other States in the costs of providing comprehensive community mental health services to adults with a serious mental illness and to children with a serious emotional disturbance.

(B) Subject to subparagraph (C), the factor determined under this paragraph and in effect for the fiscal year involved shall be determined according to the methodology described in the report entitled "Adjusting the Alcohol, Drug Abuse and Mental Health Services Block Grant Allocations for Poverty Populations and Cost of Service", dated March 30, 1990, and prepared by Health Economics Research, a corporation, pursuant to a contract with the National Institute on Drug Abuse.

(C) The factor determined under this paragraph for the State involved may not for any fiscal year be greater than 1.1 or less than 0.9.

(D)(i) Not later than October 1, 1992, the Secretary, after consultation with the Comptroller General, shall in accordance with this section make a determination for each State of the factor that is to be in effect for the State under this paragraph. The factor so determined shall remain in effect through fiscal year 1994, and shall be recalculated every third fiscal year thereafter.

(ii) After consultation with the Comptroller General, the Secretary shall, through publication in the Federal Register, periodically make such refinements in the methodology referred to in subparagraph (B) as are consistent with the purpose described in subparagraph (A).

(b) Minimum allotments for States

With respect to fiscal year 2000, and subsequent fiscal years, the amount of the allotment of a State under section 300x of this title shall not be less than the amount the State received under such section for fiscal year 1998.

(c) Territories

(1) Determination under formula

Subject to paragraphs (2) and (4), the amount of an allotment under section 300x of this title for a territory of the United States for a fiscal year shall be the product of—

(A) an amount equal to the amounts reserved under paragraph (3) for the fiscal year; and

(B) a percentage equal to the quotient of—

(i) the civilian population of the territory, as indicated by the most recently available data;

divided by

(ii) the aggregate civilian population of the territories of the United States, as indicated by such data.

(2) Minimum allotment for territories

The amount of an allotment under section 300x of this title for a territory of the United States for a fiscal year shall be the greater of—

(A) the amount determined under paragraph (1) for the territory for the fiscal year;

(B) $50,000; and

(C) with respect to fiscal years 1993 and 1994, an amount equal to 20.6 percent of the amount received by the territory from allotments made pursuant to this part for fiscal year 1992.

(3) Reservation of amounts

The Secretary shall each fiscal year reserve for the territories of the United States 1.5 percent of the amounts appropriated under section 300x–9(a) of this title for allotments under section 300x of this title for the fiscal year.

(4) Availability of data on population

With respect to data on the civilian population of the territories of the United States, if the Secretary determines for a fiscal year that recent such data for purposes of paragraph (1)(B) do not exist regarding a territory, the Secretary shall for such purposes estimate the civilian population of the territory by modifying the data on the territory to reflect the average extent of change occurring during the ensuing period in the population of all territories with respect to which recent such data do exist.

(5) Applicability of certain provisions

For purposes of subsection (a), the term "State" does not include the territories of the United States.

(July 1, 1944, ch. 373, title XIX, §1918, as added Pub. L. 102–321, title II, §201(2), July 10, 1992, 106 Stat. 385; amended Pub. L. 102–352, §2(a)(8), (9), Aug. 26, 1992, 106 Stat. 938; Pub. L. 105–277, div. A, §101(f) [title II, §218(a)], Oct. 21, 1998, 112 Stat. 2681–337, 2681–362; Pub. L. 106–113, div. B, §1000(a)(4) [title II, §212(a)], Nov. 29, 1999, 113 Stat. 1535, 1501A–239; Pub. L. 106–310, div. B, title XXXII, §3205, Oct. 17, 2000, 114 Stat. 1193.)

EDITORIAL NOTES

PRIOR PROVISIONS

A prior section 300x–7, act July 1, 1944, ch. 373, title XIX, §1919, formerly §1918, as added Aug. 13, 1981, Pub. L. 97–35, title IX, §901, 95 Stat. 551; renumbered §1919 and amended Oct. 19, 1984, Pub. L. 98–509, title I, §106(a), (g), 98 Stat. 2358, 2359, related to nondiscrimination provisions with respect to alcohol, drug abuse, and mental health programs, prior to repeal by Pub. L. 102–321, §201(2).

A prior section 1918 of act July 1, 1944, was classified to section 300x–6 of this title prior to repeal by Pub. L. 102–321.

AMENDMENTS

2000—Subsec. (b). Pub. L. 106–310 reenacted heading without change and amended text generally. Prior to amendment, text read as follows: "With respect to fiscal year 2000, the amount of the allotment of a State under section 300x of this title shall not be less than the amount the State received under section 300x of this title for fiscal year 1998."

1999—Subsec. (b). Pub. L. 106–113 amended heading and text of subsec. (b) generally. Prior to amendment, text read as follows: "For each of the fiscal years 1993 and 1994, the amount of the allotment required in section 300x of this title for a State for the fiscal year involved shall be the greater of—

"(1) the amount determined under subsection (a) of this section for the State for the fiscal year; and

"(2) an amount equal to 20.6 percent of the amount received by the State from allotments made pursuant to this part for fiscal year 1992 (including reallotments under section 205(a) of the ADAMHA Reorganization Act)."

1998—Subsec. (b). Pub. L. 105–277, temporarily amended subsec. (b) to read as follows: "(b) MINIMUM ALLOTMENTS FOR STATES.—

"(1) IN GENERAL.—With respect to fiscal year 1999, the amount of the allotment of a State under section 300x of this title shall not be less than the amount the State received under section 300x of this title for fiscal year 1998."

See Effective and Termination Dates of 1998 Amendment note below.

1992—Subsec. (a)(5)(A)(iii). Pub. L. 102–352, §2(a)(8), substituted "45" for "25".

Subsec. (c)(2)(C). Pub. L. 102–352, §2(a)(9), added subpar. (C).

STATUTORY NOTES AND RELATED SUBSIDIARIES

EFFECTIVE AND TERMINATION DATES OF 1998 AMENDMENT

Pub. L. 105–277, div. A, §101(f) [title II, §218(c)], Oct. 21, 1998, 112 Stat. 2681–337, 2681–363, provided that:

"(1) IN GENERAL.—The amendments made by subsections (a) and (b) [amending this section and section 300x–33 of this title] shall become effective as if enacted on October 1, 1998 and shall only apply during fiscal year 1999.

"(2) APPLICATION.—Upon the expiration of the fiscal year described in paragraph (1), the provisions of sections 1918(b) and 1933(b) of the Public Health Service Act (42 U.S.C. 300x–7(b) and 300x–33(b)), as in effect on September 30, 1998, shall be applied as if the amendments made by this section had not been enacted."

EFFECTIVE DATE OF 1992 AMENDMENTS

Amendment by Pub. L. 102–352 effective immediately upon effectuation of amendment made by Pub. L. 102–321, see section 3(1) of Pub. L. 102–352, set out as a note under section 285n of this title.

§300x–8. Definitions

For purposes of this subpart:

(1) The terms "adults with a serious mental illness" and "children with a serious emotional disturbance" have the meanings given such terms under section 300x–1(c)(1) of this title.

(2) The term "funding agreement", with respect to a grant under section 300x of this title to a State, means that the Secretary may make such a grant only if the State makes the agreement involved.

(July 1, 1944, ch. 373, title XIX, §1919, as added Pub. L. 102–321, title II, §201(2), July 10, 1992, 106 Stat. 388.)

EDITORIAL NOTES

PRIOR PROVISIONS

A prior section 300x–8, act July 1, 1944, ch. 373, title XIX, §1920, formerly §1919, as added Aug. 13, 1981, Pub. L. 97–35, title IX, §901, 95 Stat. 552; renumbered §1920, Oct. 19, 1984, Pub. L. 98–509, title I, §106(g), 98 Stat. 2359, authorized criminal penalty for false statements in connection with services furnished relative to alcohol, drug abuse, and mental health services block grant, prior to repeal by Pub. L. 102–321, §201(2).

A prior section 1919 of act July 1, 1944, was classified to section 300x–7 of this title prior to repeal by Pub. L. 102–321.

§300x–9. Funding

(a) Authorization of appropriations

For the purpose of carrying out this subpart, and subpart III and section 290aa–4(c) of this title with respect to mental health, there are authorized to be appropriated $857,571,000 for each of fiscal years 2023 through 2027.

(b) Allocations for technical assistance, data collection, and program evaluation

(1) In general

For the purpose of carrying out section 300x–58(a) of this title with respect to mental health and the purposes specified in paragraphs (2) and (3), the Secretary shall obligate 5 percent of the amounts appropriated under subsection (a) for a fiscal year.

(2) Data collection

The purpose specified in this paragraph is carrying out sections 290aa–4(c) and 300y of this title with respect to mental health.

(3) Program evaluation

The purpose specified in this paragraph is the conduct of evaluations of prevention and treatment programs and services with respect to mental health to determine methods for improving the availability and quality of such programs and services.

(c) Early serious mental illness

(1) In general

Except as provided in paragraph (2), a State shall expend not less than 10 percent of the amount the State receives for carrying out this section for each fiscal year to support evidence-based programs that address the needs of individuals with early serious mental illness, including psychotic disorders, regardless of the age of the individual at onset.

(2) State flexibility

In lieu of expending 10 percent of the amount the State receives under this section for a fiscal year as required under paragraph (1), a State may elect to expend not less than 20 percent of such amount by the end of such succeeding fiscal year.

(d) Crisis care

(1) In general

Except as provided in paragraph (3), a State shall expend at least 5 percent of the amount the State receives pursuant to section 300x of this title for each fiscal year to support evidenced-based programs that address the crisis care needs of individuals with serious mental illnesses and children with serious emotional disturbances, which may include individuals (including children and adolescents) experiencing mental health crises demonstrating serious mental illness or serious emotional disturbance, as applicable.

(2) Core elements

At the discretion of the single State agency responsible for the administration of the program of the State under a grant under section 300x of this title, funds expended pursuant to paragraph (1) may be used to fund some or all of the core crisis care service components, as applicable and appropriate, including the following:

(A) Crisis call centers.

(B) 24/7 mobile crisis services.

(C) Crisis stabilization programs offering acute care or subacute care in a hospital or appropriately licensed facility, as determined by such State, with referrals to inpatient or outpatient care.

(3) State flexibility

In lieu of expending 5 percent of the amount the State receives pursuant to section 300x of this title for a fiscal year to support evidence-based programs as required by paragraph (1), a State may elect to expend not less than 10 percent of such amount to support such programs by the end of two consecutive fiscal years.

(4) Rule of construction

Section 300x–1(b)(1)(A)(vi) shall not be construed as limiting the provision of crisis care

services pursuant to paragraph (1).

(July 1, 1944, ch. 373, title XIX, §1920, as added Pub. L. 102–321, title II, §201(2), July 10, 1992, 106 Stat. 388; amended Pub. L. 106–310, div. B, title XXXII, §3204(f), Oct. 17, 2000, 114 Stat. 1193; Pub. L. 114–255, div. B, title VIII, §8001(c), (f), Dec. 13, 2016, 130 Stat. 1228, 1229; Pub. L. 117–328, div. FF, title I, §1141(a), (b), Dec. 29, 2022, 136 Stat. 5657.)

EDITORIAL NOTES

PRIOR PROVISIONS

Prior sections 300x–9 to 300x–13 were repealed by Pub. L. 102–321, title II, §201(2), July 10, 1992, 106 Stat. 378.

Section 300x–9, act July 1, 1944, ch. 373, title XIX, §1921, formerly §1920, as added Aug. 13, 1981, Pub. L. 97–35, title IX, §901, 95 Stat. 552; renumbered §1920A and amended Oct. 19, 1984, Pub. L. 98–509, title I, §§105(a), 106(g), 98 Stat. 2358, 2359; Oct. 7, 1985, Pub. L. 99–117, §7(c), 99 Stat. 493; renumbered §1921 and amended Nov. 18, 1988, Pub. L. 100–690, title II, §2038(2), (6), 102 Stat. 4203, authorized technical assistance with respect to development of services under alcohol, drug abuse, and mental health services block grants.

A prior section 1920 of act July 1, 1944, was classified to section 300x–8 of this title and repealed by Pub. L. 102–321.

Section 300x–9a, act July 1, 1944, ch. 373, title XIX, §1922, as added Nov. 18, 1988, Pub. L. 100–690, title II, §2039(a), 102 Stat. 4204; amended Aug. 16, 1989, Pub. L. 101–93, §2(n)(1), 103 Stat. 608, related to service research on community-based alcohol and drug abuse treatment programs.

Section 300x–9b, act July 1, 1944, ch. 373, title XIX, §1923, as added Nov. 18, 1988, Pub. L. 100–690, title II, §2040, 102 Stat. 4204; amended Aug. 16, 1989, Pub. L. 101–93, §2(q)(2), 103 Stat. 609, related to service research on community-based mental health treatment programs.

Section 300x–10, act July 1, 1944, ch. 373, title XIX, §1924, formerly §1920B, as added Nov. 14, 1986, Pub. L. 99–660, title V, §502(2), 100 Stat. 3795; renumbered §1924 and amended Nov. 18, 1988, Pub. L. 100–690, title II, §2038(3), (4), 102 Stat. 4203; Nov. 28, 1990, Pub. L. 101–639, §3(a)(1), 104 Stat. 4601, related to development grants for State comprehensive mental health services plans.

Section 300x–11, act July 1, 1944, ch. 373, title XIX, §1925, formerly §1920C, as added Nov. 14, 1986, Pub. L. 99–660, title V, §502(2), 100 Stat. 3795; renumbered §1925 and amended Nov. 18, 1988, Pub. L. 100–690, title II, §§2038(3), 2041(a), 102 Stat. 4203, 4205; Aug. 16, 1989, Pub. L. 101–93, §2(o)(1), 103 Stat. 608; Nov. 28, 1990, Pub. L. 101–639, §3(b), 104 Stat. 4601, related to State comprehensive mental health services plans.

Section 300x–12, act July 1, 1944, ch. 373, title XIX, §1926, formerly §1920D, as added Nov. 14, 1986, Pub. L. 99–660, title V, §502(2), 100 Stat. 3796; renumbered §1926 and amended Nov. 18, 1988, Pub. L. 100–690, title II, §2038(3), (5), 102 Stat. 4203; Aug. 16, 1989, Pub. L. 101–93, §2(o)(2), 103 Stat. 609; Nov. 28, 1990, Pub. L. 101–639, §3(c), 104 Stat. 4602, related to enforcement of requirement of developing State comprehensive mental health services plans.

Section 300x–13, act July 1, 1944, ch. 373, title XIX, §1927, formerly §1920E, as added Nov. 14, 1986, Pub. L. 99–660, title V, §502(2), 100 Stat. 3797; renumbered §1927, Nov. 18, 1988, Pub. L. 100–690, title II, §2038(3), 102 Stat. 4203, related to development of model standards for provision of care to chronically mentally ill persons.

AMENDMENTS

2022—Subsec. (a). Pub. L. 117–328, §1141(a), substituted "$857,571,000 for each of fiscal years 2023 through 2027" for "$532,571,000 for each of fiscal years 2018 through 2022".

Subsec. (d). Pub. L. 117–328, §1141(b), added subsec. (d).

2016—Subsec. (a). Pub. L. 114–255, §8001(f)(1), substituted "section 290aa–4(c) of this title" for "section 290aa–4 of this title" and "$532,571,000 for each of fiscal years 2018 through 2022." for "$450,000,000 for fiscal year 2001, and such sums as may be necessary for each of the fiscal years 2002 and 2003."

Subsec. (b)(2). Pub. L. 114–255, §8001(f)(2), substituted "sections 290aa–4(c) and" for "sections 290aa–4 and".

Subsec. (c). Pub. L. 114–255, §8001(c), added subsec. (c).

2000—Subsec. (a). Pub. L. 106–310, §3204(f)(1), substituted "$450,000,000 for fiscal year 2001, and such sums as may be necessary for each of the fiscal years 2002 and 2003" for "$450,000,000 for fiscal year 1993, and such sums as may be necessary for fiscal year 1994".

Subsec. (b)(2). Pub. L. 106–310, §3204(f)(2), substituted "sections 290aa–4 and 300y of this title" for "section 290aa–4 of this title".

STATUTORY NOTES AND RELATED SUBSIDIARIES

REPORT TO CONGRESS

Pub. L. 117–328, div. FF, title I, §1141(c), Dec. 29, 2022, 136 Stat. 5657, provided that: "Not later than September 30, 2025, and biennially thereafter, the Secretary shall provide a report to the Congress on the crisis care strategies and programs pursued by States pursuant to subsection (d) of section 1920 of the Public Health Service Act (42 U.S.C. 300x–9), as added by subsection (b). Such report shall include—

"(1) a description of each State's crisis care activities;

"(2) the population served, including information on demographics, including age;

"(3) the outcomes of such activities, including—

"(A) how such activities reduced hospitalizations and hospital stays;

"(B) how such activities reduced incidents of suicidal ideation and behaviors; and

"(C) how such activities reduced the severity of onset of serious mental illness and serious emotional disturbance, as applicable; and

"(4) any other relevant information the Secretary determines is necessary."

SUBPART II—BLOCK GRANTS FOR SUBSTANCE USE PREVENTION, TREATMENT, AND RECOVERY SERVICES

EDITORIAL NOTES

CODIFICATION

Pub. L. 117–328, div. FF, title I, §1241(a)(2), Dec. 29, 2022, 136 Stat. 5677, amended subpart heading generally. Prior to amendment, subpart heading read as follows: "Block Grants for Prevention and Treatment of Substance Abuse".

§300x–21. Formula grants to States

(a) In general

For the purpose described in subsection (b), the Secretary, acting through the Center for Substance Abuse Treatment, shall make an allotment each fiscal year for each State in an amount determined in accordance with section 300x–33 of this title. The Secretary shall make a grant to the State of the allotment made for the State for the fiscal year if the State submits to the Secretary an application in accordance with section 300x–32 of this title.

(b) Authorized activities

A funding agreement for a grant under subsection (a) is that, subject to section 300x–31 of this title, the State involved will expend the grant only for the purpose of carrying out the plan developed in accordance with section 300x–32(b) of this title and for planning, carrying out, and evaluating activities to prevent, treat, and provide recovery support services for substance use disorders and for related activities authorized in section 300x–24 of this title.

(July 1, 1944, ch. 373, title XIX, §1921, as added Pub. L. 102–321, title II, §202, July 10, 1992, 106 Stat. 388; amended Pub. L. 114–255, div. B, title VIII, §8002(a), Dec. 13, 2016, 130 Stat. 1229; Pub. L. 117–328, div. FF, title I, §1242, Dec. 29, 2022, 136 Stat. 5678.)

EDITORIAL NOTES

PRIOR PROVISIONS

A prior section 1921 of act July 1, 1944, was classified to section 300x–9 of this title prior to repeal by Pub. L. 102–321.

Another prior section 1921 of act July 1, 1944, was classified to section 300y of this title prior to repeal by Pub. L. 100–690.

AMENDMENTS

2022—Subsec. (b). Pub. L. 117–328 substituted "activities to prevent, treat, and provide recovery support services for substance use disorders" for "activities to prevent and treat substance use disorders".

2016—Subsec. (b). Pub. L. 114–255 inserted "carrying out the plan developed in accordance with section 300x–32(b) of this title and for" after "for the purpose of" and substituted "use disorders" for "abuse".

§300x–22. Certain allocations

(a) Allocation regarding primary prevention programs

A funding agreement for a grant under section 300x–21 of this title is that, in expending the grant, the State involved—

(1) will expend not less than 20 percent for programs for individuals who do not require treatment for substance use disorders, which programs—

(A) educate and counsel the individuals on such disorders; and

(B) provide for activities to reduce the risk of such disorders by the individuals;

(2) will, in carrying out paragraph (1)—

(A) give priority to programs for populations that are at risk of developing a pattern of such disorders; and

(B) ensure that programs receiving priority under subparagraph (A) develop community-based strategies for the prevention of such disorders, including strategies to discourage the use of alcoholic beverages and tobacco products by individuals to whom it is unlawful to sell or distribute such beverages or products.

(b) Allocations regarding women

(1) In general

Subject to paragraph (2), a funding agreement for a grant under section 300x–21 of this title for a fiscal year is that—

(A) in the case of a grant for fiscal year 1993, the State involved will expend not less than 5 percent of the grant to increase (relative to fiscal year 1992) the availability of treatment services designed for pregnant women and women with dependent children (either by establishing new programs or expanding the capacity of existing programs);

(B) in the case of a grant for fiscal year 1994, the State will expend not less than 5 percent of the grant to so increase (relative to fiscal year 1993) the availability of such services for such women; and

(C) in the case of a grant for any subsequent fiscal year, the State will expend for such services for such women not less than an amount equal to the amount expended by the State for fiscal year 1994.

(2) Waiver

(A) Upon the request of a State, the Secretary may provide to the State a waiver of all or part of the requirement established in paragraph (1) if the Secretary determines that the State is providing an adequate level of treatments services for women described in such paragraph, as indicated by a comparison of the number of such women seeking the services with the availability in the State of the services.

(B) The Secretary shall approve or deny a request for a waiver under subparagraph (A) not later than 120 days after the date on which the request is made.

(C) Any waiver provided by the Secretary under subparagraph (A) shall be applicable only to the fiscal year involved.

(3) Childcare and prenatal care

A funding agreement for a grant under section 300x–21 of this title for a State is that each entity providing treatment services with amounts reserved under paragraph (1) by the State will, directly or through arrangements with other public or nonprofit private entities, make available prenatal care to women receiving such services and, while the women are receiving the services, childcare.

(July 1, 1944, ch. 373, title XIX, §1922, as added Pub. L. 102–321, title II, §202, July 10, 1992, 106 Stat. 389; amended Pub. L. 106–310, div. B, title XXXIII, §3303(a), (f)(2)(A), Oct. 17, 2000, 114 Stat. 1210, 1211; Pub. L. 117–328, div. FF, title I, §1241(a)(3), Dec. 29, 2022, 136 Stat. 5677.)

AMENDMENT OF SUBSECTION (B)(2), (3)

Pub. L. 106–310, div. B, title XXXIII, §3303(f)(2), Oct. 17, 2000, 114 Stat. 1211, provided that, effective upon publication of regulations developed in accordance with section 300x–32(e)(1) of this title, subsection (c) of this section [now subsection (b)] is amended by striking out paragraph (2) and redesignating paragraph (3) as paragraph (2).

EDITORIAL NOTES

PRIOR PROVISIONS

A prior section 1922 of act July 1, 1944, was classified to section 300x–9a of this title prior to repeal by Pub. L. 102–321.

Another prior section 1922 of act July 1, 1944, was classified to section 300y–1 of this title prior to repeal by Pub. L. 100–690.

AMENDMENTS

2022—Subsec. (a). Pub. L. 117–328, §1241(a)(3)(B), substituted "such disorders" for "such abuse" wherever appearing.

Subsec. (a)(1). Pub. L. 117–328, §1241(a)(3)(A), substituted "substance use disorders" for "substance abuse" in introductory provisions.

2000—Subsec. (a). Pub. L. 106–310, §3303(a), redesignated subsec. (b) as (a) and struck out heading and text of former subsec. (a). Text read as follows: "A funding agreement for a grant under section 300x–21 of this title is that, in expending the grant, the State involved will expend—

"(1) not less than 35 percent for prevention and treatment activities regarding alcohol; and

"(2) not less than 35 percent for prevention and treatment activities regarding other drugs."

Subsec. (b). Pub. L. 106–310, §3303(a)(2), redesignated subsec. (c) as (b). Former subsec. (b) redesignated (a).

Subsec. (c). Pub. L. 106–310, §3303(a)(2), redesignated subsec. (c) as (b).

STATUTORY NOTES AND RELATED SUBSIDIARIES

EFFECTIVE DATE OF 2000 AMENDMENT

Pub. L. 106–310, div. B, title XXXIII, §3303(f)(2), Oct. 17, 2000, 114 Stat. 1211, provided that the amendment made by section 3303(f)(2) is effective upon the publication of the regulations developed in accordance with section 300x–32(e)(1) of this title.

§300x–23. Intravenous substance use

(a) Capacity of treatment programs

(1) Notification of reaching capacity

A funding agreement for a grant under section 300x–21 of this title is that the State involved will, in the case of programs of treatment for intravenous substance use disorders, require that any such program receiving amounts from the grant, upon reaching 90 percent of its capacity to admit individuals to the program, provide to the State a notification of such fact.

(2) Provision of treatment

A funding agreement for a grant under section 300x–21 of this title is that the State involved will, with respect to notifications under paragraph (1), ensure that each individual who requests and is in need of treatment for intravenous substance use disorders is admitted to a program of such treatment not later than—

(A) 14 days after making the request for admission to such a program; or

(B) 120 days after the date of such request, if no such program has the capacity to admit the individual on the date of such request and if interim services are made available to the individual not later than 48 hours after such request.

(b) Outreach to persons who inject drugs

A funding agreement for a grant under section 300x–21 of this title is that the State involved, in providing amounts from the grant to any entity for treatment services for persons who inject drugs, will require the entity to carry out activities to encourage individuals in need of such treatment to undergo treatment.

(July 1, 1944, ch. 373, title XIX, §1923, as added Pub. L. 102–321, title II, §202, July 10, 1992, 106 Stat. 390; amended Pub. L. 114–255, div. B, title VIII, §8002(b), Dec. 13, 2016, 130 Stat. 1229; Pub. L. 117–328, div. FF, title I, §1241(a)(4), Dec. 29, 2022, 136 Stat. 5677.)

EDITORIAL NOTES

PRIOR PROVISIONS

A prior section 1923 of act July 1, 1944, was classified to section 300x–9b of this title prior to repeal by Pub. L. 102–321.

Another prior section 1923 of act July 1, 1944, was classified to section 300y–2 of this title prior to repeal by Pub. L. 100–690.

AMENDMENTS

2022—Pub. L. 117–328, §1241(a)(4)(A), substituted "substance use" for "substance abuse" in section catchline.

Subsec. (a). Pub. L. 117–328, §1241(a)(4)(B), which directed amendment of subsec. (a) by substituting "substance use disorders" for "drug abuse", was executed by making the substitution both places "drug abuse" appeared, to reflect the probable intent of Congress.

2016—Subsec. (b). Pub. L. 114–255 substituted "to persons who inject drugs" for "regarding intravenous substance abuse" in heading and "for persons who inject drugs" for "for intravenous drug abuse" in text.

§300x–24. Requirements regarding tuberculosis and human immunodeficiency virus

(a) Tuberculosis

(1) In general

A funding agreement for a grant under section 300x–21 of this title is that the State involved will require that any entity receiving amounts from the grant for operating a program of treatment for substance use disorders—

(A) will, directly or through arrangements with other public or nonprofit private entities, routinely make available tuberculosis services to each individual receiving treatment for such disorders; and

(B) in the case of an individual in need of such treatment who is denied admission to the program on the basis of the lack of the capacity of the program to admit the individual, will refer the individual to another provider of tuberculosis services.

(2) Tuberculosis services

For purposes of paragraph (1), the term "tuberculosis services", with respect to an individual, means—

(A) counseling the individual with respect to tuberculosis;

(B) testing to determine whether the individual has contracted such disease and testing to determine the form of treatment for the disease that is appropriate for the individual; and

(C) providing such treatment to the individual.

(b) Human immunodeficiency virus

(1) Requirement for certain States

In the case of a State described in paragraph (2), a funding agreement for a grant under section 300x–21 of this title is that—

(A) with respect to individuals undergoing treatment for substance use disorders, the State will, subject to paragraph (3), carry out 1 or more projects to make available to the individuals early intervention services for HIV disease at the sites at which the individuals are undergoing such treatment;

(B) for the purpose of providing such early intervention services through such projects, the State will make available from the grant the percentage that is applicable for the State under paragraph (4); and

(C) the State will, subject to paragraph (5), carry out such projects only in geographic areas of the State that have the greatest need for the projects.

(2) Designated States

For purposes of this subsection, a State described in this paragraph is any State whose rate of cases of acquired immune deficiency syndrome is 10 or more such cases per 100,000 individuals (as indicated by the number of such cases reported to and confirmed by the Director of the Centers for Disease Control and Prevention for the most recent calendar year for which such data are available).

(3) Use of existing programs regarding substance use disorders

With respect to programs that provide treatment services for substance use disorders, a funding agreement for a grant under section 300x–21 of this title for a designated State is that each such program participating in a project under paragraph (1) will be a program that began operation prior to the fiscal year for which the State is applying to receive the grant. A program that so began operation may participate in a project under paragraph (1) without regard to whether the program has been providing early intervention services for HIV disease.

(4) Applicable percentage regarding expenditures for services

(A)(i) For purposes of paragraph (1)(B), the percentage that is applicable under this paragraph for a designated State is, subject to subparagraph (B), the percentage by which the amount of the grant under section 300x–21 of this title for the State for the fiscal year involved is an increase over the amount specified in clause (ii).

(ii) The amount specified in this clause is the amount that was reserved by the designated State involved from the allotment of the State under section 300x–1a [1] of this title for fiscal year 1991 in compliance with section 300x–4(c)(6)(A)(ii) [1] of this title (as such sections were in effect for such fiscal year).

(B) If the percentage determined under subparagraph (A) for a designated State for a fiscal year is less than 2 percent (including a negative percentage, in the case of a State for which there is no increase for purposes of such subparagraph), the percentage applicable under this paragraph for the State is 2 percent. If the percentage so determined is 2 percent or more, the percentage applicable under this paragraph for the State is the percentage determined under subparagraph (A), subject to not exceeding 5 percent.

(5) Requirement regarding rural areas

(A) A funding agreement for a grant under section 300x–21 of this title for a designated State is that, if the State will carry out 2 or more projects under paragraph (1), the State will carry out 1 such project in a rural area of the State, subject to subparagraph (B).

(B) The Secretary shall waive the requirement established in subparagraph (A) if the State involved certifies to the Secretary that—

(i) there is insufficient demand in the State to carry out a project under paragraph (1) in any rural area of the State; or

(ii) there are no rural areas in the State.

(6) Manner of providing services

With respect to the provision of early intervention services for HIV disease to an individual, a funding agreement for a grant under section 300x–21 of this title for a designated State is that—

(A) such services will be undertaken voluntarily by, and with the informed consent of, the individual; and

(B) undergoing such services will not be required as a condition of receiving treatment services for substance use disorders or any other services.

(7) Definitions

For purposes of this subsection:

(A) The term "designated State" means a State described in paragraph (2).

(B) The term "early intervention services", with respect to HIV disease, means—

(i) appropriate pretest counseling;

(ii) testing individuals with respect to such disease, including tests to confirm the presence of the disease, tests to diagnose the extent of the deficiency in the immune system, and tests to provide information on appropriate therapeutic measures for preventing and treating the deterioration of the immune system and for preventing and treating conditions arising from the disease;

(iii) appropriate post-test counseling; and

(iv) providing the therapeutic measures described in clause (ii).

(C) The term "HIV disease" means infection with the etiologic agent for acquired immune deficiency syndrome.

(c) Expenditure of grant for compliance with agreements

(1) In general

A grant under section 300x–21 of this title may be expended for purposes of compliance with the agreements required in this section, subject to paragraph (2).

(2) Limitation

A funding agreement for a grant under section 300x–21 of this title for a State is that the grant will not be expended to make payment for any service provided for purposes of compliance with this section to the extent that payment has been made, or can reasonably be expected to be made, with respect to such service—

(A) under any State compensation program, under any insurance policy, or under any Federal or State health benefits program (including the program established in title XVIII of the Social Security Act [42 U.S.C. 1395 et seq.] and the program established in title XIX of such Act [42 U.S.C. 1396 et seq.]); or

(B) by an entity that provides health services on a prepaid basis.

(d) Applicability of certain provision

Section 300x–31 of this title applies to this section (and to each other provision of this subpart).

(July 1, 1944, ch. 373, title XIX, §1924, as added Pub. L. 102–321, title II, §202, July 10, 1992, 106 Stat. 391; amended Pub. L. 114–255, div. B, title VIII, §8002(c), Dec. 13, 2016, 130 Stat. 1229.)

EDITORIAL NOTES

REFERENCES IN TEXT

Section 300x–1a of this title, referred to in subsec. (b)(4)(A)(ii), was repealed by Pub. L. 102–321, title II,

§201(2), July 10, 1992, 106 Stat. 378.

Section 300x–4 of this title, referred to in subsec. (b)(4)(A)(ii), was in the original a reference to section 1916 of act July 1, 1944, which was repealed by Pub. L. 102–321, title II, §201(2), July 10, 1992, 106 Stat. 378. Section 201(2) of Pub. L. 102–321 enacted new sections 1915 and 1916 of act July 1, 1944, which are classified to sections 300x–4 and 300x–5, respectively, of this title.

The Social Security Act, referred to in subsec. (c)(2)(A), is act Aug. 14, 1935, ch. 531, 49 Stat. 620. Titles XVIII and XIX of the Act are classified generally to subchapters XVIII (§1395 et seq.) and XIX (§1396 et seq.) of chapter 7 of this title. For complete classification of this Act to the Code, see section 1305 of this title and Tables.

PRIOR PROVISIONS

A prior section 1924 of act July 1, 1944, was classified to section 300x–10 of this title prior to repeal by Pub. L. 102–321.

Another prior section 1924 of act July 1, 1944, was classified to section 300y–3 of this title prior to repeal by Pub. L. 99–280.

AMENDMENTS

2016—Subsec. (a)(1). Pub. L. 114–255, §8002(c)(1)(A), substituted "substance use disorders" for "substance abuse" in introductory provisions.

Subsec. (a)(1)(A). Pub. L. 114–255, §8002(c)(1)(B), substituted "such disorders" for "such abuse".

Subsec. (b)(1)(A). Pub. L. 114–255, §8002(c)(2)(A), substituted "substance use disorders" for "substance abuse".

Subsec. (b)(2). Pub. L. 114–255, §8002(c)(2)(B), inserted "and Prevention" after "Disease Control".

Subsec. (b)(3). Pub. L. 114–255, §8002(c)(2)(C), substituted "use disorders" for "abuse" in heading and "substance use disorders" for "substance abuse" in text.

Subsec. (b)(6)(B). Pub. L. 114–255, §8002(c)(2)(D), substituted "substance use disorders" for "substance abuse".

Subsecs. (d), (e). Pub. L. 114–255, §8002(c)(3), (4), redesignated subsec. (e) as (d) and struck out former subsec. (d). Prior to amendment, text of subsec. (d) read as follows: "With respect to services provided for by a State for purposes of compliance with this section, a funding agreement for a grant under section 300x–21 of this title is that the State will maintain expenditures of non-Federal amounts for such services at a level that is not less than average level of such expenditures maintained by the State for 2-year period preceding the first fiscal year for which the State receives such a grant."

STATUTORY NOTES AND RELATED SUBSIDIARIES

CHANGE OF NAME

Centers for Disease Control changed to Centers for Disease Control and Prevention by Pub. L. 102–531, title III, §312, Oct. 27, 1992, 106 Stat. 3504.

[1] *See References in Text note below.*

§300x–25. Group homes for persons in recovery from substance use disorders

(a) State revolving funds for establishment of homes

A State, using funds available under section 300x–21 of this title, may establish and maintain the ongoing operation of a revolving fund in accordance with this section to support group homes for persons in recovery from substance use disorders as follows:

(1) The purpose of the fund is to make loans for the costs of establishing programs for the provision of housing in which individuals recovering from alcohol or other substance use disorders may reside in groups of not less than 6 individuals. The fund is established directly by the State or through the provision of a grant or contract to a nonprofit private entity.

(2) The programs are carried out in accordance with guidelines issued under subsection (b).

(3) Not less than $100,000 is available for the fund.

(4) Loans made from the revolving fund do not exceed $4,000 and each such loan is repaid to

the revolving fund by the residents of the housing involved not later than 2 years after the date on which the loan is made.

(5) Each such loan is repaid by such residents through monthly installments, and a reasonable penalty is assessed for each failure to pay such periodic installments by the date specified in the loan agreement involved.

(6) Such loans are made only to nonprofit private entities agreeing that, in the operation of the program established pursuant to the loan—

(A) the use of alcohol or any illegal drug in the housing provided by the program will be prohibited;

(B) any resident of the housing who violates such prohibition will be expelled from the housing;

(C) the costs of the housing, including fees for rent and utilities, will be paid by the residents of the housing; and

(D) the residents of the housing will, through a majority vote of the residents, otherwise establish policies governing residence in the housing, including the manner in which applications for residence in the housing are approved.

(b) Issuance by Secretary of guidelines

The Secretary shall ensure that there are in effect guidelines under this subpart for the operation of programs described in subsection (a).

(c) Applicability to territories

The requirements established in subsection (a) shall not apply to any territory of the United States other than the Commonwealth of Puerto Rico.

(July 1, 1944, ch. 373, title XIX, §1925, as added Pub. L. 102–321, title II, §202, July 10, 1992, 106 Stat. 393; amended Pub. L. 106–310, div. B, title XXXIII, §3303(b), Oct. 17, 2000, 114 Stat. 1210; Pub. L. 114–255, div. B, title VIII, §8002(d), Dec. 13, 2016, 130 Stat. 1230; Pub. L. 117–328, div. FF, title I, §1241(a)(5), Dec. 29, 2022, 136 Stat. 5677.)

EDITORIAL NOTES

PRIOR PROVISIONS

A prior section 1925 of act July 1, 1944, was classified to section 300x–11 of this title prior to repeal by Pub. L. 102–321.

Another prior section 1925 of act July 1, 1944, was classified to section 300y–4 of this title prior to repeal by Pub. L. 99–280.

AMENDMENTS

2022—Subsec. (a)(1). Pub. L. 117–328 substituted "alcohol or other substance use disorders" for "alcohol or drug abuse".

2016—Pub. L. 114–255, §8002(d)(1), substituted "persons in recovery from substance use disorders" for "recovering substance abusers" in section catchline.

Subsec. (a). Pub. L. 114–255, §8002(d)(2), substituted "persons in recovery from substance use disorders" for "recovering substance abusers" in introductory provisions.

2000—Subsec. (a). Pub. L. 106–310, in introductory provisions, substituted "A State, using funds available under section 300x–21 of this title, may establish and maintain the ongoing operation of a revolving fund in accordance with this section to support group homes for recovering substance abusers as follows:" for "For fiscal year 1993 and subsequent fiscal years, the Secretary may make a grant under section 300x–21 of this title only if the State involved has established, and is providing for the ongoing operation of, a revolving fund as follows:".

§300x–26. Sale of tobacco products to individuals under age of 21

(a) In general

A funding agreement for a grant under section 300x–21 of this title is that the State involved will—

(1) annually conduct random, unannounced inspections to ensure that retailers do not sell tobacco products to individuals under the age of 21; and

(2) annually submit to the Secretary a report describing—

(A) the activities carried out by the State to ensure that retailers do not sell tobacco products to individuals under the age of 21;

(B) the extent of success the State has achieved in ensuring that retailers do not sell tobacco products to individuals under the age of 21; and

(C) the strategies to be utilized by the State to ensure that retailers do not sell tobacco products to individuals under the age of 21 during the fiscal year for which the grant is sought.

(b) Noncompliance of State

(1) In general

Before making a grant under section 300x–21 of this title to a State, the Secretary shall make a determination of whether the State has maintained compliance with subsection (a). If, after notice to the State and an opportunity for a hearing, the Secretary determines that the State is not in compliance with such subsections, the Secretary shall reduce the amount of the allotment under such section for the State for the fiscal year involved by an amount up to 10 percent of the amount determined under section 300x–33 of this title for the State for the applicable fiscal year.

(2) Limitation

(A) In general

A State shall not have funds withheld pursuant to paragraph (1) if such State for which the Secretary has made a determination of noncompliance under such paragraph—

(i) certifies to the Secretary by May 1 of the fiscal year for which the funds are appropriated, consistent with subparagraph (B), that the State will commit additional State funds, in accordance with paragraph (1), to ensure that retailers do not sell tobacco products to individuals under 21 years of age;

(ii) agrees to comply with a negotiated agreement for a corrective action plan that is approved by the Secretary and carried out in accordance with guidelines issued by the Secretary; or

(iii) is a territory that receives less than $1,000,000 for a fiscal year under section 300x–21 of this title.

(B) Certification

(i) In general

The amount of funds to be committed by a State pursuant to subparagraph (A)(i) shall be equal to 1 percent of such State's allocation determined under section 300x–33 of this title for each percentage point by which the State misses the retailer compliance rate goal established by the Secretary.

(ii) State expenditures

For a fiscal year in which a State commits funds as described in clause (i), such State shall maintain State expenditures for tobacco prevention programs and for compliance activities at a level that is not less than the level of such expenditures maintained by the State for the preceding fiscal year, plus the additional funds for tobacco compliance activities required under clause (i). The State shall submit a report to the Secretary on all State obligations of funds for such fiscal year and all State expenditures for the preceding fiscal year for tobacco prevention and compliance activities by program activity by July 31 of such fiscal year.

(iii) Discretion

The Secretary shall exercise discretion in enforcing the timing of the State obligation of the additional funds required by the certification described in subparagraph (A)(i) as late as July

31 of such fiscal year.

(C) Failure to certify

If a State described in subparagraph (A) fails to certify to the Secretary pursuant to subparagraph (A)(i) or enter into, or comply with, a negotiated agreement under subparagraph (A)(ii), the Secretary may take action pursuant to paragraph (1).

(c) Implementation of reporting requirements

(1) Transition period

The Secretary shall—

(A) not withhold amounts under subsection (b) for the 3-year period immediately following December 20, 2019; and

(B) use discretion in exercising its authority under subsection (b) during the 2-year period immediately following the 3-year period described in subparagraph (A), to allow for a transition period for implementation of the reporting requirements under subsection (a)(2).

(2) Regulations or guidance

Not later than 180 days after December 20, 2019, the Secretary shall update regulations under part 96 of title 45, Code of Federal Regulations [1] or guidance on the retailer compliance rate goal under subsection (b), the use of funds provided under section 300x–21 of this title for purposes of meeting the requirements of this section, and reporting requirements under subsection (a)(2).

(3) Coordination

The Secretary shall ensure the Assistant Secretary for Mental Health and Substance Use coordinates, as appropriate, with the Commissioner of Food and Drugs to ensure that the technical assistance provided to States under subsection (e) is consistent with applicable regulations for retailers issued under part 1140 of title 21, Code of Federal Regulations.

(d) Transitional grants

(1) In general

The Secretary shall award grants under this subsection to each State that receives funding under section 300x–21 of this title to ensure compliance of each such State with this section.

(2) Use of funds

A State receiving a grant under this subsection—

(A) shall use amounts received under such grant for activities to plan for or ensure compliance in the State with subsection (a); and

(B) in the case of a State for which the Secretary has made a determination under subsection (b) that the State is prepared to meet, or has met, the requirements of subsection (a), may use such funds for tobacco cessation activities, strategies to prevent the use of tobacco products by individuals under the age of 21, or allowable uses under section 300x–21 of this title.

(3) Supplement not supplant

Grants under this subsection shall be used to supplement and not supplant other Federal, State, and local public funds provided for activities under paragraph (2).

(4) Authorization of appropriations

To carry out this subsection, there are authorized to be appropriated $18,580,790 for each of fiscal years 2020 through 2024.

(5) Sunset

This subsection shall have no force or effect after September 30, 2024.

(e) Technical assistance

The Secretary shall provide technical assistance to States related to the activities required under this section.

(July 1, 1944, ch. 373, title XIX, §1926, as added Pub. L. 102–321, title II, §202, July 10, 1992, 106 Stat. 394; amended Pub. L. 116–94, div. N, title I, §604(a), Dec. 20, 2019, 133 Stat. 3124; Pub. L. 117–328, div. FF, title I, §1241(a)(6), Dec. 29, 2022, 136 Stat. 5677.)

EDITORIAL NOTES

PRIOR PROVISIONS

A prior section 1926 of act July 1, 1944, was classified to section 300x–12 of this title prior to repeal by Pub. L. 102–321.

Another prior section 1926 of act July 1, 1944, was classified to section 300y–5 of this title prior to repeal by Pub. L. 99–280.

AMENDMENTS

2022—Subsec. (b)(2)(B)(i). Pub. L. 117–328 struck out "substance abuse" before "allocation".

2019—Pub. L. 116–94, §604(a)(1), struck out "State law regarding" before "sale" and substituted "21" for "18" in section catchline.

Subsec. (a). Pub. L. 116–94, §604(a)(3), (4), redesignated subsec. (b) as (a) and amended subsec. (a) generally. Prior to amendment, subsec. (a) related to the requirement of State enforcement of law in a manner that can reasonably be expected to reduce the extent to which tobacco products are available to individuals under the age of 18 in order to qualify for funding agreements for grants under section 300x–21 of this title, and activities and reports regarding such enforcement.

Pub. L. 116–94, §604(a)(2), struck out subsec. (a), which required grants under section 300x–21 of this title for fiscal year 1994 and subsequent fiscal years to be based on the existence of State law forbidding sale or distribution of tobacco products to any individual under the age of 18, and providing delayed applicability of requirement for certain States.

Subsec. (b). Pub. L. 116–94, §604(a)(5), designated introductory provisions as par. (1), inserted par. heading, struck out "for the first applicable fiscal year or any subsequent fiscal year" after "a State", substituted "subsection (a)" for "subsections (a) and (b)" and "up to 10 percent of the amount determined under section 300x–33 of this title for the State for the applicable fiscal year." for "equal to—", added par. (2), and struck out former pars. (1) to (4), which related to allotment reductions for first applicable fiscal years and three following fiscal years.

Pub. L. 116–94, §604(a)(3), redesignated subsec. (c) as (b). Former subsec. (b) redesignated (a).

Subsec. (c). Pub. L. 116–94, §604(a)(6), added subsec. (c). Former subsec. (c) redesignated (b).

Subsec. (d). Pub. L. 116–94, §604(a)(2), (6), added subsec. (d) and struck out former subsec. (d) which defined "first applicable fiscal year".

Subsec. (e). Pub. L. 116–94, §604(a)(6), added subsec. (e).

[1] So in original. Probably should be followed by a comma.

§300x–26a. Repealed. Pub. L. 116–94, div. N, title I, §604(c), Dec. 20, 2019, 133 Stat. 3127

Section, Pub. L. 111–117, div. D, title II, §212, Dec. 16, 2009, 123 Stat. 3257, related to withholding of substance abuse funding under section 300x–26 of this title.

§300x–27. Treatment services for pregnant women

(a) In general

A funding agreement for a grant under section 300x–21 of this title is that the State involved—

(1) will ensure that each pregnant woman in the State who seeks or is referred for and would benefit from such services is given preference in admissions to treatment facilities receiving funds pursuant to the grant; and

(2) will, in carrying out paragraph (1), publicize the availability to such women of services from the facilities and the fact that the women receive such preference.

(b) Referrals regarding States

A funding agreement for a grant under section 300x–21 of this title is that, in carrying out subsection (a)(1)—

(1) the State involved will require that, in the event that a treatment facility has insufficient capacity to provide treatment services to any woman described in such subsection who seeks the services from the facility, the facility refer the woman to the State; and

(2) the State, in the case of each woman for whom a referral under paragraph (1) is made to the State—

(A) will refer the woman to a treatment facility that has the capacity to provide treatment services to the woman; or

(B) will, if no treatment facility has the capacity to admit the woman, make interim services available to the woman not later than 48 hours after the women [1] seeks the treatment services.

(July 1, 1944, ch. 373, title XIX, §1927, as added Pub. L. 102–321, title II, §202, July 10, 1992, 106 Stat. 395; amended Pub. L. 102–352, §2(a)(10), Aug. 26, 1992, 106 Stat. 938.)

EDITORIAL NOTES

PRIOR PROVISIONS

A prior section 1927 of act July 1, 1944, was classified to section 300x–12 of this title prior to repeal by Pub. L. 102–321.

Another prior section 1927 of act July 1, 1944, was classified to section 300y–6 of this title prior to repeal by Pub. L. 99–280.

AMENDMENTS

1992—Subsec. (b)(2)(B). Pub. L. 102–352 struck out "available" before "interim services available".

STATUTORY NOTES AND RELATED SUBSIDIARIES

EFFECTIVE DATE OF 1992 AMENDMENT

Amendment by Pub. L. 102–352 effective immediately upon effectuation of amendment made by Pub. L. 102–321, see section 3(1) of Pub. L. 102–352, set out as a note under section 285n of this title.

[1] So in original. Probably should be "woman".

§300x–28. Additional agreements

(a) Improvement of process for appropriate referrals for treatment

With respect to individuals seeking treatment services, a funding agreement for a grant under section 300x–21 of this title is that the State involved will improve the process in the State for referring the individuals to treatment facilities that can provide to the individuals the treatment modality that is most appropriate for the individuals.

(b) Professional development

A funding agreement for a grant under section 300x–21 of this title is that the State involved will ensure that prevention, treatment, and recovery personnel operating in the State's substance use disorder prevention, treatment, and recovery systems have an opportunity to receive training, on an ongoing basis, concerning—

(1) recent trends in substance use disorders in the State;

(2) improved methods and evidence-based practices for providing substance use disorder prevention and treatment services;

(3) performance-based accountability;

(4) data collection and reporting requirements; and

(5) any other matters that would serve to further improve the delivery of substance use disorder prevention and treatment services within the State.

(c) Coordination of various activities and services

A funding agreement for a grant under section 300x–21 of this title is that the State involved will coordinate prevention and treatment activities with the provision of other appropriate services (including health, social, correctional and criminal justice, educational, vocational rehabilitation, and employment services).

(d) Waiver of requirement

(1) In general

Upon the request of a State, the Secretary may provide to a State a waiver of any or all of the requirements established in this section if the Secretary determines that, with respect to services for the prevention and treatment of substance use disorders, the requirement involved is unnecessary for maintaining quality in the provision of such services in the State.

(2) Date certain for acting upon request

The Secretary shall approve or deny a request for a waiver under paragraph (1) not later than 120 days after the date on which the request is made.

(3) Applicability of waiver

Any waiver provided by the Secretary under paragraph (1) shall be applicable only to the fiscal year involved.

(July 1, 1944, ch. 373, title XIX, §1928, as added Pub. L. 102–321, title II, §202, July 10, 1992, 106 Stat. 396; amended Pub. L. 106–310, div. B, title XXXIII, §3303(f)(2)(B), Oct. 17, 2000, 114 Stat. 1211; Pub. L. 114–255, div. B, title VIII, §8002(e), Dec. 13, 2016, 130 Stat. 1230.)

REPEAL OF SUBSECTION (D)

Pub. L. 106–310, div. B, title XXXIII, §3303(f)(2), Oct. 17, 2000, 114 Stat. 1211, provided that, effective upon publication of regulations developed in accordance with section 300x–32(e)(1) of this title, subsection (d) of this section is repealed.

EDITORIAL NOTES

PRIOR PROVISIONS

A prior section 1928 of act July 1, 1944, was classified to section 300y–7 of this title prior to repeal by Pub. L. 99–280.

AMENDMENTS

2016—Subsec. (a). Pub. L. 114–255, §8002(e)(1), struck out "(relative to fiscal year 1992)" after "State involved will improve".

Subsec. (b). Pub. L. 114–255, §8002(e)(2), added subsec. (b) and struck out former subsec. (b). Prior to amendment, text read as follows: "With respect to any facility for treatment services or prevention actitivities that is receiving amounts from a grant under section 300x–21 of this title, a funding agreement for a State for a grant under such section is that continuing education in such services or activities (or both, as the case may be) will be made available to employees of the facility who provide the services or activities."

Subsec. (d)(1). Pub. L. 114–255, §8002(e)(3), substituted "substance use disorders" for "substance abuse".

STATUTORY NOTES AND RELATED SUBSIDIARIES

EFFECTIVE DATE OF 2000 AMENDMENT

Pub. L. 106–310, div. B, title XXXIII, §3303(f)(2), Oct. 17, 2000, 114 Stat. 1211, provided that the amendment made by section 3303(f)(2) is effective upon the publication of the regulations developed in accordance with section 300x–32(e)(1) of this title.

§300x–29. Repealed. Pub. L. 114–255, div. B, title VIII, §8002(f), Dec. 13, 2016, 130 Stat. 1230

Section, act July 1, 1944, ch. 373, title XIX, §1929, as added Pub. L. 102–321, title II, §202, July 10, 1992, 106 Stat. 396, related to submission to Secretary of statewide assessment of needs.

A prior section 1929 of act July 1, 1944, was classified to section 300y–8 of this title prior to repeal by Pub. L. 99–280.

§300x–30. Maintenance of effort regarding State expenditures

(a) In general

With respect to the principal agency of a State for carrying out authorized activities, a funding agreement for a grant under section 300x–21 of this title for the State for a fiscal year is that such agency will for such year maintain aggregate State expenditures for authorized activities at a level that is not less than the average level of such expenditures maintained by the State for the 2-year period preceding the fiscal year for which the State is applying for the grant.

(b) Exclusion of certain funds

The Secretary may exclude from the aggregate State expenditures under subsection (a), funds appropriated to the principle agency for authorized activities which are of a non-recurring nature and for a specific purpose.

(c) Waiver

(1) In general

Upon the request of a State, the Secretary may waive all or part of the requirement established in subsection (a) if the Secretary determines that extraordinary economic conditions exist in the State, or any part of the State, to justify the waiver.

(2) Date certain for acting upon request

The Secretary shall approve or deny a request for a waiver under paragraph (1) not later than 120 days after the date on which the request is made.

(3) Applicability of waiver

Any waiver provided by the Secretary under paragraph (1) shall be applicable only to the fiscal year involved.

(d) Noncompliance by State

(1) In general

In making a grant under section 300x–21 of this title to a State for a fiscal year, the Secretary shall make a determination of whether, for the previous fiscal year, the State maintained material compliance with any agreement made under subsection (a). If the Secretary determines that a State has failed to maintain such compliance, the Secretary shall reduce the amount of the allotment under section 300x–21 of this title for the State for the fiscal year for which the grant is being made by an amount equal to the amount constituting such failure for the previous fiscal year.

(2) Submission of information to Secretary

The Secretary may make a grant under section 300x–21 of this title for a fiscal year only if the State involved submits to the Secretary information sufficient for the Secretary to make the determination required in paragraph (1).

(3) Alternative

A State that has failed to comply with this section and would otherwise be subject to a reduction in the State's allotment under section 300x–21 of this title, may, upon request by the State, in lieu of having the State's allotment under section 300x–21 of this title reduced, agree to comply with a negotiated agreement that is approved by the Secretary and carried out in accordance with

guidelines issued by the Secretary. If a State fails to enter into or comply with a negotiated agreement, the Secretary may take action under this paragraph or the terms of the negotiated agreement.

(July 1, 1944, ch. 373, title XIX, §1930, as added Pub. L. 102–321, title II, §202, July 10, 1992, 106 Stat. 397; amended Pub. L. 106–310, div. B, title XXXIII, §3303(c), Oct. 17, 2000, 114 Stat. 1210; Pub. L. 114–255, div. B, title VIII, §8002(g), Dec. 13, 2016, 130 Stat. 1230.)

EDITORIAL NOTES

PRIOR PROVISIONS

A prior section 1930 of act July 1, 1944, was classified to section 300y–9 of this title prior to repeal by Pub. L. 99–280.

AMENDMENTS

2016—Subsec. (c)(1). Pub. L. 114–255, §8002(g)(1), substituted "exist in the State, or any part of the State, to justify the waiver" for "in the State justify the waiver".

Subsec. (d)(3). Pub. L. 114–255, §8002(g)(2), added par. (3).

2000—Subsecs. (b) to (d). Pub. L. 106–310 added subsec. (b) and redesignated former subsecs. (b) and (c) as (c) and (d), respectively.

§300x–31. Restrictions on expenditure of grant

(a) In general

(1) Certain restrictions

A funding agreement for a grant under section 300x–21 of this title is that the State involved will not expend the grant—

(A) to provide inpatient hospital services, except as provided in subsection (b);

(B) to make cash payments to intended recipients of health services;

(C) to purchase or improve land, purchase, construct, or permanently improve (other than minor remodeling) any building or other facility, or purchase major medical equipment;

(D) to satisfy any requirement for the expenditure of non-Federal funds as a condition for the receipt of Federal funds;

(E) to provide financial assistance to any entity other than a public or nonprofit private entity; or

(F) to carry out any program prohibited by section 300ee–5 of this title.

(2) Limitation on administrative expenses

A funding agreement for a grant under section 300x–21 of this title is that the State involved will not expend more than 5 percent of the grant to pay the costs of administering the grant.

(3) Limitation regarding penal and correctional institutions

A funding agreement for a State for a grant under section 300x–21 of this title is that, in expending the grant for the purpose of providing treatment services in penal or correctional institutions of the State, the State will not expend more than an amount equal to the amount expended for such purpose by the State from the grant made under section 300x–1a [1] of this title to the State for fiscal year 1991 (as section 300x–1a [1] of this title was in effect for such fiscal year).

(b) Exception regarding inpatient hospital services

(1) Medical necessity as precondition

With respect to compliance with the agreement made under subsection (a), a State may expend a grant under section 300x–21 of this title to provide inpatient hospital services as treatment for substance use disorders only if it has been determined, in accordance with guidelines issued by the

Secretary, that such treatment is a medical necessity for the individual involved, and that the individual cannot be effectively treated in a community-based, nonhospital, residential program of treatment.

(2) Rate of payment

In the case of an individual for whom a grant under section 300x–21 of this title is expended to provide inpatient hospital services described in paragraph (1), a funding agreement for the grant for the State involved is that the daily rate of payment provided to the hospital for providing the services to the individual will not exceed the comparable daily rate provided for community-based, nonhospital, residential programs of treatment for substance use disorders.

(c) Waiver regarding construction of facilities

(1) In general

The Secretary may provide to any State a waiver of the restriction established in subsection (a)(1)(C) for the purpose of authorizing the State to expend a grant under section 300x–21 of this title for the construction of a new facility or rehabilitation of an existing facility, but not for land acquisition.

(2) Standard regarding need for waiver

The Secretary may approve a waiver under paragraph (1) only if the State demonstrates to the Secretary that adequate treatment cannot be provided through the use of existing facilities and that alternative facilities in existing suitable buildings are not available.

(3) Amount

In granting a waiver under paragraph (1), the Secretary shall allow the use of a specified amount of funds to construct or rehabilitate a specified number of beds for residential treatment and a specified number of slots for outpatient treatment, based on reasonable estimates by the State of the costs of construction or rehabilitation. In considering waiver applications, the Secretary shall ensure that the State has carefully designed a program that will minimize the costs of additional beds.

(4) Matching funds

The Secretary may grant a waiver under paragraph (1) only if the State agrees, with respect to the costs to be incurred by the State in carrying out the purpose of the waiver, to make available non-Federal contributions in cash toward such costs in an amount equal to not less than $1 for each $1 of Federal funds provided under section 300x–21 of this title.

(5) Date certain for acting upon request

The Secretary shall act upon a request for a waiver under paragraph (1) not later than 120 days after the date on which the request is made.

(July 1, 1944, ch. 373, title XIX, §1931, as added Pub. L. 102–321, title II, §202, July 10, 1992, 106 Stat. 397; amended Pub. L. 114–255, div. B, title VIII, §8002(h), Dec. 13, 2016, 130 Stat. 1230; Pub. L. 117–328, div. FF, title I, §1241(a)(7), Dec. 29, 2022, 136 Stat. 5677.)

EDITORIAL NOTES

REFERENCES IN TEXT

Section 300x–1a of this title, referred to in subsec. (a)(3), was repealed by Pub. L. 102–321, title II, §201(2), July 10, 1992, 106 Stat. 378.

PRIOR PROVISIONS

A prior section 1931 of act July 1, 1944, was classified to section 300y–21 of this title and subsequently omitted from the Code.

Another prior section 1931 of act July 1, 1944, was classified to section 300y–10 of this title prior to repeal by Pub. L. 99–280.

AMENDMENTS

2022—Subsec. (b)(2). Pub. L. 117–328 substituted "substance use disorders" for "substance abuse".
2016—Subsec. (b)(1). Pub. L. 114–255 substituted "substance use disorders" for "substance abuse".

[1] *See References in Text note below.*

§300x–32. Application for grant; approval of State plan

(a) In general

For purposes of section 300x–21 of this title, an application for a grant under such section for a fiscal year is in accordance with this section if, subject to subsection (c)—

(1) the application is received by the Secretary not later than October 1 of the fiscal year for which the State is seeking funds;

(2) the application contains each funding agreement that is described in this subpart or subpart III for such a grant (other than any such agreement that is not applicable to the State);

(3) the agreements are made through certification from the chief executive officer of the State;

(4) with respect to such agreements, the application provides assurances of compliance satisfactory to the Secretary;

(5) the application contains the report required in section 300x–52(a) of this title;

(6)(A) the application contains a plan in accordance with subsection (b) and the plan is approved by the Secretary; and

(B) the State provides assurances satisfactory to the Secretary that the State complied with the provisions of the plan under subparagraph (A) that was approved by the Secretary for the most recent fiscal year for which the State received a grant under section 300x–21 of this title; and

(7) the application (including the plan under paragraph (6)) is otherwise in such form, is made in such manner, and contains such agreements, assurances, and information as the Secretary determines to be necessary to carry out this subpart.

(b) State plan

(1) In general

In order for a State to be in compliance with subsection (a)(6), the State shall submit to the Secretary a plan that, at a minimum, includes the following:

(A) A description of the State's system of care that—

(i) identifies the single State agency responsible for the administration of the program, including any third party who administers substance use disorder services and is responsible for complying with the requirements of the grant;

(ii) provides information on the need for substance use disorder prevention and treatment services in the State, including estimates on the number of individuals who need treatment, who are pregnant women, women with dependent children, individuals with a co-occurring mental health and substance use disorder, persons who inject drugs, and persons who are experiencing homelessness;

(iii) provides aggregate information on the number of individuals in treatment within the State, including the number of such individuals who are pregnant women, women with dependent children, individuals with a co-occurring mental health and substance use disorder, persons who inject drugs, and persons who are experiencing homelessness;

(iv) provides a description of the system that is available to provide services by modality, including the provision of recovery support services;

(v) provides a description of the State's comprehensive statewide prevention efforts, including the number of individuals being served in the system, target populations, and priority needs, and provides a description of the amount of funds from the prevention set-aside expended on primary prevention;

(vi) provides a description of—

(I) the State's comprehensive statewide recovery support services activities, including the number of individuals being served, target populations, workforce capacity (consistent with clause (viii)), and priority needs; and

(II) the amount of funds received under this subpart expended on recovery support services, disaggregated by the amount expended for type of service activity;

(vii) provides a description of the financial resources available;

(viii) describes the existing substance use disorders workforce, including with respect to prevention, treatment, and recovery, and workforce trained in treating co-occurring substance use and mental disorders;

(ix) includes a description of how the State promotes evidence-based practices; and

(x) describes how the State integrates substance use disorder services and primary health care, which in the case of those individuals with co-occurring mental health and substance use disorders may include providing both mental health and substance use disorder services in primary care settings or providing primary and specialty care services in community-based mental health and substance use disorder service settings.

(B) The establishment of goals and objectives for the period of the plan, including targets and milestones that are intended to be met, and the activities that will be undertaken to achieve those targets.

(C) A description of how the State will comply with each funding agreement for a grant under section 300x–21 of this title that is applicable to the State, including a description of the manner in which the State intends to expend grant funds.

(2) Modifications

(A) Authority of Secretary

As a condition; [1] of making a grant under section 300x–21 of this title to a State for a fiscal year, the Secretary may require that the State modify any provision of the plan submitted by the State under subsection (a)(6) (including provisions on priorities in carrying out authorized activities). If the Secretary approves the plan and makes the grant to the State for the fiscal year, the Secretary may not during such year require the State to modify the plan.

(B) State request for modification

If the State determines that a modification to such plan is necessary, the State may request the Secretary to approve the modification. Any such modification shall be in accordance with paragraph (1) and section 300x–51 of this title.

(3) Authority of Center for Substance Abuse Prevention

With respect to plans submitted by the States under subsection (a)(6), including any modification under paragraph (2), the Secretary, acting through the Director of the Center for Substance Abuse Prevention, shall review and approve or disapprove the provisions of the plans that relate to prevention activities.

(c) Waivers regarding certain territories

In the case of any territory of the United States except Puerto Rico, the Secretary may waive such provisions of this subpart and subpart III as the Secretary determines to be appropriate, other than the provisions of section 300x–31 of this title.

(d) Issuance of regulations; precondition to making grants

(1) Regulations

Not later than August 25, 1992, the Secretary, acting as appropriate through the Director of the Center for Treatment Improvement or the Director of the Center for Substance Abuse Prevention,

shall by regulation establish standards specifying the circumstances in which the Secretary will consider an application for a grant under section 300x–21 of this title to be in accordance with this section.

(2) Issuance as precondition to making grants

The Secretary may not make payments under any grant under section 300x–21 of this title for fiscal year 1993 on or after January 1, 1993, unless the Secretary has issued standards under paragraph (1).

(e) Waiver authority for certain requirements

(1) In general

Upon the request of a State, the Secretary may waive the requirements of all or part of the sections described in paragraph (2) using objective criteria established by the Secretary by regulation after consultation with the States and other interested parties including consumers and providers.

(2) Sections

The sections described in paragraph (1) are sections 300x–22(b), 300x–23, 300x–24 and 300x–28 of this title.

(3) Date certain for acting upon request

The Secretary shall approve or deny a request for a waiver under paragraph (1) and inform the State of that decision not later than 120 days after the date on which the request and all the information needed to support the request are submitted.

(4) Annual reporting requirement

The Secretary shall annually report to the general public on the States that receive a waiver under this subsection.

(July 1, 1944, ch. 373, title XIX, §1932, as added Pub. L. 102–321, title II, §202, July 10, 1992, 106 Stat. 399; amended Pub. L. 106–310, div. B, title XXXIII, §3303(d)–(f)(1), Oct. 17, 2000, 114 Stat. 1211; Pub. L. 114–255, div. B, title VIII, §8002(i), Dec. 13, 2016, 130 Stat. 1231; Pub. L. 117–328, div. FF, title I, §1243, Dec. 29, 2022, 136 Stat. 5678.)

EDITORIAL NOTES

PRIOR PROVISIONS

A prior section 1932 of act July 1, 1944, was classified to section 300y–22 of this title and subsequently omitted from the Code.

Another prior section 1932 of act July 1, 1944, was classified to section 300y–11 of this title prior to repeal by Pub. L. 99–280.

AMENDMENTS

2022—Subsec. (b)(1)(A)(vi), (vii). Pub. L. 117–328, §1243(1), (2), added cl. (vi) and redesignated former cl. (vi) as (vii). Former cl. (vii) redesignated (viii).

Subsec. (b)(1)(A)(viii). Pub. L. 117–328, §1243(1), (3), redesignated cl. (vii) as (viii) and substituted "disorders workforce, including with respect to prevention, treatment, and recovery," for "disorders workforce". Former cl. (viii) redesignated (ix).

Subsec. (b)(1)(A)(ix), (x). Pub. L. 117–328, §1243(1), redesignated cls. (viii) and (ix) as (ix) and (x), respectively.

2016—Subsec. (a). Pub. L. 114–255, §8002(i)(1)(A), substituted "subsection (c)" for "subsections (c) and (d)(2)" in introductory provisions.

Subsec. (a)(5). Pub. L. 114–255, §8002(i)(1)(B), struck out "the information required in section 300x–29 of this title, the information required in section 300x–30(c)(2) of this title, and" after "the application contains".

Subsec. (b)(1). Pub. L. 114–255, §8002(i)(2)(A), added par. (1) and struck out former par. (1). Prior to amendment, text read as follows: "A plan submitted by a State under subsection (a)(6) is in accordance with this subsection if the plan contains detailed provisions for complying with each funding agreement for a grant

under section 300x–21 of this title that is applicable to the State, including a description of the manner in which the State intends to expend the grant."

Subsec. (b)(2). Pub. L. 114–255, §8002(i)(2)(B), substituted "Modifications" for "Authority of Secretary regarding modifications" in heading, designated existing provisions as subpar. (A), substituted "As a condition;" for "As a condition" and inserted heading in subpar. (A), and added subpar. (B).

Subsec. (b)(3). Pub. L. 114–255, §8002(i)(2)(C), inserted ", including any modification under paragraph (2)" after "subsection (a)(6)".

Subsec. (e)(2). Pub. L. 114–255, §8002(i)(3), which directed substitution of "section 300x–22(b)" for "section 300x–22(c)", was executed by substituting "sections 300x–22(b)" for "sections 300x–22(c)" to reflect the probable intent of Congress.

2000—Subsec. (a)(1). Pub. L. 106–310, §3303(d), amended par. (1) generally. Prior to amendment, par. (1) read as follows: "the State involved submits the application not later than the date specified by the Secretary;".

Subsec. (c). Pub. L. 106–310, §3303(e), substituted "except Puerto Rico" for "whose allotment under section 300x–21 of this title for the fiscal year is the amount specified in section 300x–33(c)(2)(B) of this title".

Subsec. (e). Pub. L. 106–310, §3303(f)(1), added subsec. (e).

[1] *So in original. The semicolon probably should not appear.*

§300x–33. Determination of amount of allotment

(a) States

(1) In general

Subject to subsection (b), the Secretary shall determine the amount of the allotment required in section 300x–21 of this title for a State for a fiscal year as follows:

(A) The formula established in paragraph (1) of section 300x–7(a) of this title shall apply to this subsection to the same extent and in the same manner as the formula applies for purposes of section 300x–7(a) of this title, except that, in the application of such formula for purposes of this subsection, the modifications described in subparagraph (B) shall apply.

(B) For purposes of subparagraph (A), the modifications described in this subparagraph are as follows:

(i) The amount specified in paragraph (2)(A) of section 300x–7(a) of this title is deemed to be the amount appropriated under section 300x–35(a) of this title for allotments under section 300x–21 of this title for the fiscal year involved.

(ii) The term "P" is deemed to have the meaning given in paragraph (2) of this subsection. Section 300x–7(a)(5)(B) of this title applies to the data used in determining such term for the States.

(iii) The factor determined under paragraph (8) of section 300x–7(a) of this title is deemed to have the purpose of reflecting the differences that exist between the State involved and other States in the costs of providing authorized services.

(2) Determination of term "P"

For purposes of this subsection, the term "P" means the percentage that is the arithmetic mean of the percentage determined under subparagraph (A) and the percentage determined under subparagraph (B), as follows:

(A) The percentage constituted by the ratio of—

(i) an amount equal to the sum of the total number of individuals who reside in the State involved and are between 18 and 24 years of age (inclusive) and the number of individuals in the State who reside in urbanized areas of the State and are between such years of age; to

(ii) an amount equal to the total of the respective sums determined for the States under clause (i).

(B) The percentage constituted by the ratio of—

(i) the total number of individuals in the State who are between 25 and 64 years of age (inclusive); to

(ii) an amount equal to the sum of the respective amounts determined for the States under clause (i).

(b) Minimum allotments for States

(1) In general

With respect to fiscal year 2000, and each subsequent fiscal year, the amount of the allotment of a State under section 300x–21 of this title shall not be less than the amount the State received under such section for the previous fiscal year increased by an amount equal to 30.65 percent of the percentage by which the aggregate amount allotted to all States for such fiscal year exceeds the aggregate amount allotted to all States for the previous fiscal year.

(2) Limitations

(A) In general

Except as provided in subparagraph (B), a State shall not receive an allotment under section 300x–21 of this title for a fiscal year in an amount that is less than an amount equal to 0.375 percent of the amount appropriated under section 300x–35(a) of this title for such fiscal year.

(B) Exception

In applying subparagraph (A), the Secretary shall ensure that no State receives an increase in its allotment under section 300x–21 of this title for a fiscal year (as compared to the amount allotted to the State in the prior fiscal year) that is in excess of an amount equal to 300 percent of the percentage by which the amount appropriated under section 300x–35(a) of this title for such fiscal year exceeds the amount appropriated for the prior fiscal year.

(3) Decrease in or equal appropriations

If the amount appropriated under section 300x–35(a) of this title for a fiscal year is equal to or less than the amount appropriated under such section for the prior fiscal year, the amount of the State allotment under section 300x–21 of this title shall be equal to the amount that the State received under section 300x–21 of this title in the prior fiscal year decreased by the percentage by which the amount appropriated for such fiscal year is less than the amount appropriated or [1] such section for the prior fiscal year.

(c) Territories

(1) Determination under formula

Subject to paragraphs (2) and (4), the amount of an allotment under section 300x–21 of this title for a territory of the United States for a fiscal year shall be the product of—

(A) an amount equal to the amounts reserved under paragraph (3) for the fiscal year; and

(B) a percentage equal to the quotient of—

(i) the civilian population of the territory, as indicated by the most recently available data; divided by

(ii) the aggregate civilian population of the territories of the United States, as indicated by such data.

(2) Minimum allotment for territories

The amount of an allotment under section 300x–21 of this title for a territory of the United States for a fiscal year shall be the greater of—

(A) the amount determined under paragraph (1) for the territory for the fiscal year;

(B) $50,000; and

(C) with respect to fiscal years 1993 and 1994, an amount equal to 79.4 percent of the amount received by the territory from allotments made pursuant to this part for fiscal year 1992.

(3) Reservation of amounts

The Secretary shall each fiscal year reserve for the territories of the United States 1.5 percent of

the amounts appropriated under section 300x–35(a) of this title for allotments under section 300x–21 of this title for the fiscal year.

(4) Availability of data on population

With respect to data on the civilian population of the territories of the United States, if the Secretary determines for a fiscal year that recent such data for purposes of paragraph (1)(B) do not exist regarding a territory, the Secretary shall for such purposes estimate the civilian population of the territory by modifying the data on the territory to reflect the average extent of change occurring during the ensuing period in the population of all territories with respect to which recent such data do exist.

(5) Applicability of certain provisions

For purposes of subsections (a) and (b), the term "State" does not include the territories of the United States.

(d) Indian Tribes and Tribal organizations

(1) In general

If the Secretary—

(A) receives a request from the governing body of an Indian Tribe or Tribal organization within any State that funds under this subpart be provided directly by the Secretary to such Tribe or organization; and

(B) makes a determination that the members of such Tribe or Tribal organization would be better served by means of grants made directly by the Secretary under this subpart;

the Secretary shall reserve from the allotment under section 300x–21 of this title for the State for the fiscal year involved an amount that bears the same ratio to the allotment as the amount provided under this subpart to the Tribe or Tribal organization for fiscal year 1991 for activities relating to the prevention and treatment of the use of substances bore to the amount of the portion of the allotment under this subpart for the State for such fiscal year that was expended for such activities.

(2) Indian Tribe or Tribal organization as grantee

The amount reserved by the Secretary on the basis of a determination under this subsection shall be granted to the Indian Tribe or Tribal organization serving the individuals for whom such a determination has been made.

(3) Application

In order for an Indian Tribe or Tribal organization to be eligible for a grant for a fiscal year under this paragraph,[2] it shall submit to the Secretary a plan for such fiscal year that meets such criteria as the Secretary may prescribe.

(4) Definitions

The terms "Indian Tribe" and "Tribal organization" have the meanings given the terms "Indian tribe" and "tribal organization" in subsections (b) and (c) [3] of section 5304 of title 25.

(July 1, 1944, ch. 373, title XIX, §1933, as added Pub. L. 102–321, title II, §202, July 10, 1992, 106 Stat. 400; amended Pub. L. 102–352, §2(a)(11), Aug. 26, 1992, 106 Stat. 938; Pub. L. 105–277, div. A, §101(f) [title II, §218(b)], Oct. 21, 1998, 112 Stat. 2681–337, 2681–362; Pub. L. 106–113, div. B, §1000(a)(4) [title II, §212(b)], Nov. 29, 1999, 113 Stat. 1535, 1501A–239; Pub. L. 106–310, div. B, title XXXIII, §3304, Oct. 17, 2000, 114 Stat. 1212; Pub. L. 117–328, div. FF, title I, §§1241(a)(8), 1244, Dec. 29, 2022, 136 Stat. 5678, 5679.)

EDITORIAL NOTES

REFERENCES IN TEXT

Section 5304 of title 25, referred to in subsec. (d)(4), was amended, and subsecs. (b) and (c) of section 5304

no longer define the terms "Indian tribe" and "tribal organization". However, such terms are defined elsewhere in that section.

PRIOR PROVISIONS

A prior section 1933 of act July 1, 1944, was classified to section 300y–23 of this title and subsequently omitted from the Code.

AMENDMENTS

2022—Subsec. (d)(1). Pub. L. 117–328, §1244(1)(C), substituted "Tribe or Tribal organization" for "tribe or tribal organization" in concluding provisions.

Pub. L. 117–328, §1241(a)(8), substituted "use of substances" for "abuse of alcohol and other drugs" in concluding provisions.

Subsec. (d)(1)(A). Pub. L. 117–328, §1244(1)(A), substituted "of an Indian Tribe or Tribal organization" for "of an Indian tribe or tribal organization" and "such Tribe" for "such tribe".

Subsec. (d)(1)(B). Pub. L. 117–328, §1244(1)(B), substituted "Tribe or Tribal organization" for "tribe or tribal organization" and "Secretary under this subpart" for "Secretary under this".

Subsec. (d)(2). Pub. L. 117–328, §1244(2), amended par. (2) generally. Prior to amendment, text read as follows: "The amount reserved by the Secretary on the basis of a determination under this paragraph shall be granted to the Indian tribe or tribal organization serving the individuals for whom such a determination has been made."

Subsec. (d)(3). Pub. L. 117–328, §1244(3), substituted "Tribe or Tribal organization" for "tribe or tribal organization".

Subsec. (d)(4). Pub. L. 117–328, §1244(4), substituted "Definitions" for "Definition" in heading and "The terms 'Indian Tribe' and 'Tribal organization' have the meanings given the terms 'Indian tribe' and 'tribal organization' " for "The terms 'Indian tribe' and 'tribal organization' have the same meaning given such terms" in text.

2000—Subsec. (b). Pub. L. 106–310 reenacted heading without change and amended text generally. Prior to amendment, text read as follows: "Each State's allotment for fiscal year 2000 for programs under this subpart shall be equal to such State's allotment for such programs for fiscal year 1999, except that, if the amount appropriated in fiscal year 2000 is less than the amount appropriated in fiscal year 1999, then the amount of a State's allotment under section 300x–21 of this title shall be equal to the amount that the State received under section 300x–21 of this title in fiscal year 1999 decreased by the percentage by which the amount appropriated for fiscal year 2000 is less than the amount appropriated for such section for fiscal year 1999."

1999—Subsec. (b). Pub. L. 106–113 amended heading and text of subsec. (b) generally. Prior to amendment, text read as follows: "For each of the fiscal years 1993 and 1994, the amount of the allotment required in section 300x–21 of this title for a State for the fiscal year involved shall be the greater of—

"(1) the amount determined under subsection (a) of this section for the State for the fiscal year; and

"(2) an amount equal to 79.4 percent of the amount received by the State from allotments made pursuant to this part for fiscal year 1992 (including reallotments under section 205(a) of the ADAMHA Reorganization Act)."

1998—Subsec. (b). Pub. L. 105–277, temporarily amended subsec. (b) to read as follows: "(b) MINIMUM ALLOTMENTS FOR STATES.—

"(1) IN GENERAL.—With respect to fiscal year 1999, the amount of the allotment of a State under section 300x–21 of this title shall not be less than the amount the State received under section 300x–21 of this title for fiscal year 1998 increased by 30.65 percent of the percentage by which the amount allotted to the States for fiscal year 1999 exceeds the amount allotted to the States for fiscal year 1998.

"(2) LIMITATION

"(A) IN GENERAL.—Except as provided in subparagraph (B), a State shall not receive an allotment under section 300x–21 of this title for fiscal year 1999 in an amount that is less than an amount equal to 0.375 percent of the amount appropriated under section 300x–35(a) of this title for such fiscal year.

"(B) EXCEPTION.—In applying subparagraph (A), the Secretary shall ensure that no State receives an increase in its allotment under section 300x–21 of this title for fiscal year 1999 (as compared to the amount allotted to the State in the fiscal year 1998) that is in excess of an amount equal to 300 percent of the percentage by which the amount appropriated under section 300x–35(a) of this title for fiscal year 1999 exceeds the amount appropriated for the prior fiscal year.

"(3) Only for the purposes of calculating minimum allotments under this subsection, any reference to

the amount appropriated under section 300x–35(a) of this title for fiscal year 1998, allotments to States under section 300x–21 of this title and any references to amounts received by States in fiscal year 1998 shall include amounts appropriated or received under the amendments made by section 105 of the Contract with America Advancement Act of 1996 (Public Law 104–121)."

See Effective and Termination Dates of 1998 Amendment note below.

1992—Subsec. (c)(2)(C). Pub. L. 102–352 added subpar. (C).

STATUTORY NOTES AND RELATED SUBSIDIARIES

EFFECTIVE AND TERMINATION DATES OF 1998 AMENDMENT

Amendment by Pub. L. 105–277 effective as if enacted on Oct. 1, 1998, and applicable only during fiscal year 1999, and upon expiration of fiscal year 1999, subsec. (b) of this section, as in effect on Sept. 30, 1998, to be applied as if such amendment had not been enacted, see section 101(f) [title II, §218(c)] of Pub. L. 105–277, set out as a note under section 300x–7 of this title.

EFFECTIVE DATE OF 1992 AMENDMENT

Amendment by Pub. L. 102–352 effective immediately upon effectuation of amendment made by Pub. L. 102–321, see section 3(1) of Pub. L. 102–352, set out as a note under section 285n of this title.

[1] So in original. Probably should be "for".

[2] So in original. Probably should be "subsection,".

[3] See References in Text note below.

§300x–34. Definitions

For purposes of this subpart:

(1) The term "authorized activities", subject to section 300x–31 of this title, means the activities described in section 300x–21(b) of this title.

(2) The term "funding agreement", with respect to a grant under section 300x–21 of this title to a State, means that the Secretary may make such a grant only if the State makes the agreement involved.

(3) The term "prevention activities", subject to section 300x–31 of this title, means activities to prevent substance use disorders.

(4) The term "substance use disorder" means the recurrent use of alcohol or other drugs that causes clinically significant impairment.

(5) The term "treatment activities" means treatment services and, subject to section 300x–31 of this title, authorized activities that are related to treatment services.

(6) The term "treatment facility" means an entity that provides treatment services.

(7) The term "treatment services", subject to section 300x–31 of this title, means treatment for substance use disorders.

(July 1, 1944, ch. 373, title XIX, §1934, as added Pub. L. 102–321, title II, §202, July 10, 1992, 106 Stat. 402; amended Pub. L. 114–255, div. B, title VIII, §8002(j), Dec. 13, 2016, 130 Stat. 1232; Pub. L. 117–328, div. FF, title I, §1241(a)(9), Dec. 29, 2022, 136 Stat. 5678.)

EDITORIAL NOTES

PRIOR PROVISIONS

A prior section 1934 of act July 1, 1944, was classified to section 300y–24 of this title and subsequently omitted from the Code.

AMENDMENTS

2022—Par. (4). Pub. L. 117–328 amended par. (4) generally. Prior to amendment, par. (4) read as follows: "The term 'substance abuse' means the abuse of alcohol or other drugs."

2016—Pars. (3), (7). Pub. L. 114–255 substituted "substance use disorders" for "substance abuse".

§300x–35. Funding

(a) Authorization of appropriations

For the purpose of carrying out this subpart, subpart III and section 290aa–4(d) of this title with respect to substance use disorders, and section 290bb–21(d) of this title, there are authorized to be appropriated $1,908,079,000 for each of fiscal years 2023 through 2027.

(b) Allocations for technical assistance, national data base, data collection, and program evaluations

(1) In general

(A) For the purpose of carrying out section 300x–58(a) of this title with respect to substance use disorders, section 290bb–21(d) of this title, and the purposes specified in subparagraphs (B) and (C), the Secretary shall obligate 5 percent of the amounts appropriated under subsection (a) each fiscal year.

(B) The purpose specified in this subparagraph is carrying out sections 290aa–4(d) and 300y of this title with respect to substance use disorders.

(C) The purpose specified in this subparagraph is the conduct of evaluations of authorized activities to determine methods for improving the availability and quality of such activities.

(2) Activities of Center for Substance Abuse Prevention

Of the amounts reserved under paragraph (1) for a fiscal year, the Secretary, acting through the Director of the Center for Substance Abuse Prevention, shall obligate 20 percent for carrying out paragraph (1)(C), section 300x–58(a) of this title with respect to prevention activities, and section 290bb–21(d) of this title.

(3) Core data set

A State that receives a new grant, contract, or cooperative agreement from amounts available to the Secretary under paragraph (1), for the purposes of improving the data collection, analysis and reporting capabilities of the State, shall be required, as a condition of receipt of funds, to collect, analyze, and report to the Secretary for each fiscal year subsequent to receiving such funds a core data set to be determined by the Secretary in conjunction with the States.

(July 1, 1944, ch. 373, title XIX, §1935, as added Pub. L. 102–321, title II, §202, July 10, 1992, 106 Stat. 403; amended Pub. L. 106–310, div. B, title XXXIII, §3303(g), Oct. 17, 2000, 114 Stat. 1211; Pub. L. 114–255, div. B, title VIII, §8002(k), Dec. 13, 2016, 130 Stat. 1232; Pub. L. 117–328, div. FF, title I, §§1241(a)(10), 1245, Dec. 29, 2022, 136 Stat. 5678, 5679.)

EDITORIAL NOTES

PRIOR PROVISIONS

A prior section 1935 of act July 1, 1944, was classified to section 300y–25 of this title and subsequently omitted from the Code.

AMENDMENTS

2022—Subsec. (a). Pub. L. 117–328, §1245(a), substituted "appropriated $1,908,079,000 for each of fiscal years 2023 through 2027." for "appropriated $1,858,079,000 for each of fiscal years 2018 through 2022.."

Pub. L. 117–328, §1241(a)(10)(A), substituted "substance use disorders" for "substance abuse".

Subsec. (b)(1). Pub. L. 117–328, §1241(a)(10)(B), substituted "substance use disorders" for "substance abuse" in subpars. (A) and (B).

Subsec. (b)(1)(B). Pub. L. 117–328, §1245(b), struck out "the collection of data in this paragraph is" after "this subparagraph is".

2016—Subsec. (a). Pub. L. 114–255, §8002(k)(1), substituted "section 290aa–4(d) of this title" for "section 290aa–4 of this title" and "$1,858,079,000 for each of fiscal years 2018 through 2022." for "$2,000,000,000 for fiscal year 2001, and such sums as may be necessary for each of the fiscal years 2002 and 2003".

Subsec. (b)(1)(B). Pub. L. 114–255, §8002(k)(2), substituted "sections 290aa–4(d) and" for "sections 290aa–4 and".

2000—Subsec. (a). Pub. L. 106–310, §3303(g)(1), substituted "$2,000,000,000 for fiscal year 2001, and such sums as may be necessary for each of the fiscal years 2002 and 2003" for "$1,500,000,000 for fiscal year 1993, and such sums as may be necessary for fiscal year 1994".

Subsec. (b)(1)(B). Pub. L. 106–310, §3303(g)(2), substituted "sections 290aa–4 and 300y of this title" for "section 290aa–4 of this title".

Subsec. (b)(2). Pub. L. 106–310, §3303(g)(3), made technical amendment to reference in original act which appears in text as reference to section 300x–58(a) of this title.

Subsec. (b)(3). Pub. L. 106–310, §3303(g)(4), added par. (3).

SUBPART III—GENERAL PROVISIONS

§300x–51. Opportunity for public comment on State plans

A funding agreement for a grant under section 300x or 300x–21 of this title is that the State involved will make the plan required in section 300x–1 of this title, and the plan required in section 300x–32 of this title, respectively, public within the State in such manner as to facilitate comment from any person (including any Federal or other public agency) during the development of the plan (including any revisions) and after the submission of the plan to the Secretary.

(July 1, 1944, ch. 373, title XIX, §1941, as added Pub. L. 102–321, title II, §203(a), July 10, 1992, 106 Stat. 403.)

§300x–52. Requirement of reports and audits by States

(a) Report

A funding agreement for a grant under section 300x or 300x–21 of this title is that the State involved will submit to the Secretary a report in such form and containing such information as the Secretary determines (after consultation with the States) to be necessary for securing a record and a description of—

(1) the purposes for which the grant received by the State for the preceding fiscal year under the program involved were expended and a description of the activities of the State under the program;

(2) the recipients of amounts provided in the grant; and

(3) the amount provided to each recipient in the previous fiscal year.

(b) Audits

A funding agreement for a grant under section 300x or 300x–21 of this title is that the State will, with respect to the grant, comply with chapter 75 of title 31.

(c) Availability to public

A funding agreement for a grant under section 300x or 300x–21 of this title is that the State involved will—

(1) make copies of the reports and audits described in this section available for public inspection within the State; and

(2) provide copies of the report under subsection (a), upon request, to any interested person (including any public agency).

(July 1, 1944, ch. 373, title XIX, §1942, as added Pub. L. 102–321, title II, §203(a), July 10, 1992,

106 Stat. 403; amended Pub. L. 104–316, title I, §122(e), Oct. 19, 1996, 110 Stat. 3837; Pub. L. 117–328, div. FF, title I, §1246, Dec. 29, 2022, 136 Stat. 5679.)

EDITORIAL NOTES

AMENDMENTS

2022—Subsec. (a)(3). Pub. L. 117–328 added par. (3).

1996—Subsec. (a). Pub. L. 104–316 struck out "and the Comptroller General" after "with the States" in introductory provisions.

§300x–53. Additional requirements

(a) In general

A funding agreement for a grant under section 300x or 300x–21 of this title is that the State involved will—

(1)(A) for the fiscal year for which the grant involved is provided, provide for independent peer review to assess the quality, appropriateness, and efficacy of treatment services provided in the State to individuals under the program involved; and

(B) ensure that, in the conduct of such peer review, not fewer than 5 percent of the entities providing services in the State under such program are reviewed (which 5 percent is representative of the total population of such entities);

(2) permit and cooperate with Federal investigations undertaken in accordance with section 300x–55 of this title; and

(3) provide to the Secretary any data required by the Secretary pursuant to subsections (c) and (d) of section 290aa–4 of this title and will cooperate with the Secretary in the development of uniform criteria for the collection of data pursuant to such section.

(b) Patient records

The Secretary may make a grant under section 300x or 300x–21 of this title only if the State involved has in effect a system to protect from inappropriate disclosure patient records maintained by the State in connection with an activity funded under the program involved or by any entity which is receiving amounts from the grant.

(July 1, 1944, ch. 373, title XIX, §1943, as added Pub. L. 102–321, title II, §203(a), July 10, 1992, 106 Stat. 404; amended Pub. L. 102–352, §2(a)(12), Aug. 26, 1992, 106 Stat. 939; Pub. L. 114–255, div. B, title VIII, §8003(1), Dec. 13, 2016, 130 Stat. 1232.)

EDITORIAL NOTES

AMENDMENTS

2016—Subsec. (a)(3). Pub. L. 114–255 substituted "subsections (c) and (d) of section 290aa–4 of this title" for "section 290aa–4 of this title".

1992—Subsec. (a)(3). Pub. L. 102–352 substituted "section 290aa–4 of this title" for "section 290bb–21 of this title".

STATUTORY NOTES AND RELATED SUBSIDIARIES

EFFECTIVE DATE OF 1992 AMENDMENT

Amendment by Pub. L. 102–352 effective immediately upon effectuation of amendment made by Pub. L. 102–321, see section 3(1) of Pub. L. 102–352, set out as a note under section 285n of this title.

§300x–54. Disposition of certain funds appropriated for allotments

(a) In general

Amounts described in subsection (b) and available for a fiscal year pursuant to section 300x or 300x–21 of this title, as the case may be, shall be allotted by the Secretary and paid to the States receiving a grant under the program involved, other than any State referred to in subsection (b) with respect to such program. Such amounts shall be allotted in a manner equivalent to the manner in which the allotment under the program involved was determined.

(b) Specification of amounts

The amounts referred to in subsection (a) are any amounts that—

(1) are not paid to States under the program involved as a result of—

(A) the failure of any State to submit an application in accordance with the program;

(B) the failure of any State to prepare such application in compliance with the program; or

(C) any State informing the Secretary that the State does not intend to expend the full amount of the allotment made to the State under the program;

(2) are terminated, repaid, or offset under section 300x–55 of this title;

(3) in the case of the program established in section 300x of this title, are available as a result of reductions in allotments under such section pursuant to section 300x–1(d) or 300x–4(b) of this title; or

(4) in the case of the program established in section 300x–21 of this title, are available as a result of reductions in allotments under such section pursuant to section 300x–26 or 300x–30 of this title.

(July 1, 1944, ch. 373, title XIX, §1944, as added Pub. L. 102–321, title II, §203(a), July 10, 1992, 106 Stat. 404.)

§300x–55. Failure to comply with agreements

(a) Suspension or termination of payments

Subject to subsection (e), if the Secretary determines that a State has materially failed to comply with the agreements or other conditions required for the receipt of a grant under the program involved, the Secretary may in whole or in part suspend payments under the grant, terminate the grant for cause, or employ such other remedies (including the remedies provided for in subsections (b) and (c)) as may be legally available and appropriate in the circumstances involved.

(b) Repayment of payments

(1) In general

Subject to subsection (e), the Secretary may require a State to repay with interest any payments received by the State under section 300x or 300x–21 of this title that the Secretary determines were not expended by the State in accordance with the agreements required under the program involved.

(2) Offset against payments

If a State fails to make a repayment required in paragraph (1), the Secretary may offset the amount of the repayment against the amount of any payment due to be paid to the State under the program involved.

(c) Withholding of payments

(1) In general

Subject to subsections (e) and (g)(3), the Secretary may withhold payments due under section 300x or 300x–21 of this title if the Secretary determines that the State involved is not expending amounts received under the program involved in accordance with the agreements required under the program.

(2) Termination of withholding

The Secretary shall cease withholding payments from a State under paragraph (1) if the Secretary determines that there are reasonable assurances that the State will expend amounts received under the program involved in accordance with the agreements required under the program.

(d) Applicability of remedies to certain violations

(1) In general

With respect to agreements or other conditions for receiving a grant under the program involved, in the case of the failure of a State to maintain material compliance with a condition referred to in paragraph (2), the provisions for noncompliance with the condition that are provided in the section establishing the condition shall apply in lieu of subsections (a) through (c) of this section.

(2) Relevant conditions

For purposes of paragraph (1):

(A) In the case of the program established in section 300x of this title, a condition referred to in this paragraph is the condition established in section 300x–1(d) of this title and the condition established in section 300x–4(b) of this title.

(B) In the case of the program established in section 300x–21 of this title, a condition referred to in this paragraph is the condition established in section 300x–26 of this title and the condition established in section 300x–30 of this title.

(e) Opportunity for hearing

Before taking action against a State under any of subsections (a) through (c) (or under a section referred to in subsection (d)(2), as the case may be), the Secretary shall provide to the State involved adequate notice and an opportunity for a hearing.

(f) Requirement of hearing in certain circumstances

(1) In general

If the Secretary receives a complaint that a State has failed to maintain material compliance with the agreements or other conditions required for receiving a grant under the program involved (including any condition referred to for purposes of subsection (d)), and there appears to be reasonable evidence to support the complaint, the Secretary shall promptly conduct a hearing with respect to the complaint.

(2) Finding of material noncompliance

If in a hearing under paragraph (1) the Secretary finds that the State involved has failed to maintain material compliance with the agreement or other condition involved, the Secretary shall take such action under this section as may be appropriate to ensure that material compliance is so maintained, or such action as may be required in a section referred to in subsection (d)(2), as the case may be.

(g) Certain investigations

(1) Requirement regarding Secretary

The Secretary shall in fiscal year 1994 and each subsequent fiscal year conduct in not less than 10 States investigations of the expenditure of grants received by the States under section 300x or 300x–21 of this title in order to evaluate compliance with the agreements required under the program involved.

(2) Provision of records, etc., upon request

Each State receiving a grant under section 300x or 300x–21 of this title, and each entity receiving funds from the grant, shall make appropriate books, documents, papers, and records

available to the Secretary or the Comptroller General, or any of their duly authorized representatives, for examination, copying, or mechanical reproduction on or off the premises of the appropriate entity upon a reasonable request therefor.

(3) Limitations on authority

The Secretary may not institute proceedings under subsection (c) unless the Secretary has conducted an investigation concerning whether the State has expended payments under the program involved in accordance with the agreements required under the program. Any such investigation shall be conducted within the State by qualified investigators.

(July 1, 1944, ch. 373, title XIX, §1945, as added Pub. L. 102–321, title II, §203(a), July 10, 1992, 106 Stat. 405.)

§300x–56. Prohibitions regarding receipt of funds

(a) Establishment

(1) Certain false statements and representations

A person shall not knowingly and willfully make or cause to be made any false statement or representation of a material fact in connection with the furnishing of items or services for which payments may be made by a State from a grant made to the State under section 300x or 300x–21 of this title.

(2) Concealing or failing to disclose certain events

A person with knowledge of the occurrence of any event affecting the initial or continued right of the person to receive any payments from a grant made to a State under section 300x or 300x–21 of this title shall not conceal or fail to disclose any such event with an intent fraudulently to secure such payment either in a greater amount than is due or when no such amount is due.

(b) Criminal penalty for violation of prohibition

Any person who violates any prohibition established in subsection (a) shall for each violation be fined in accordance with title 18 or imprisoned for not more than 5 years, or both.

(July 1, 1944, ch. 373, title XIX, §1946, as added Pub. L. 102–321, title II, §203(a), July 10, 1992, 106 Stat. 406.)

§300x–57. Nondiscrimination

(a) In general

(1) Rule of construction regarding certain civil rights laws

For the purpose of applying the prohibitions against discrimination on the basis of age under the Age Discrimination Act of 1975 [42 U.S.C. 6101 et seq.], on the basis of handicap under section 504 of the Rehabilitation Act of 1973 [29 U.S.C. 794], on the basis of sex under title IX of the Education Amendments of 1972 [20 U.S.C. 1681 et seq.], or on the basis of race, color, or national origin under title VI of the Civil Rights Act of 1964 [42 U.S.C. 2000d et seq.], programs and activities funded in whole or in part with funds made available under section 300x or 300x–21 of this title shall be considered to be programs and activities receiving Federal financial assistance.

(2) Prohibition

No person shall on the ground of sex (including, in the case of a woman, on the ground that the woman is pregnant), or on the ground of religion, be excluded from participation in, be denied the benefits of, or be subjected to discrimination under, any program or activity funded in whole or in part with funds made available under section 300x or 300x–21 of this title.

(b) Enforcement

(1) Referrals to Attorney General after notice

Whenever the Secretary finds that a State, or an entity that has received a payment pursuant to section 300x or 300x–21 of this title, has failed to comply with a provision of law referred to in subsection (a)(1), with subsection (a)(2), or with an applicable regulation (including one prescribed to carry out subsection (a)(2)), the Secretary shall notify the chief executive officer of the State and shall request the chief executive officer to secure compliance. If within a reasonable period of time, not to exceed 60 days, the chief executive officer fails or refuses to secure compliance, the Secretary may—

(A) refer the matter to the Attorney General with a recommendation that an appropriate civil action be instituted;

(B) exercise the powers and functions provided by the Age Discrimination Act of 1975 [42 U.S.C. 6101 et seq.], section 504 of the Rehabilitation Act of 1973 [29 U.S.C. 794], title IX of the Education Amendments of 1972 [20 U.S.C. 1681 et seq.], or title VI of the Civil Rights Act of 1964 [42 U.S.C. 2000d et seq.], as may be applicable; or

(C) take such other actions as may be authorized by law.

(2) Authority of Attorney General

When a matter is referred to the Attorney General pursuant to paragraph (1)(A), or whenever the Attorney General has reason to believe that a State or an entity is engaged in a pattern or practice in violation of a provision of law referred to in subsection (a)(1) or in violation of subsection (a)(2), the Attorney General may bring a civil action in any appropriate district court of the United States for such relief as may be appropriate, including injunctive relief.

(July 1, 1944, ch. 373, title XIX, §1947, as added Pub. L. 102–321, title II, §203(a), July 10, 1992, 106 Stat. 407.)

EDITORIAL NOTES

REFERENCES IN TEXT

The Age Discrimination Act of 1975, referred to in subsecs. (a)(1) and (b)(1)(B), is title III of Pub. L. 94–135, Nov. 28, 1975, 89 Stat. 728, which is classified generally to chapter 76 (§6101 et seq.) of this title. For complete classification of this Act to the Code, see Short Title note set out under section 6101 of this title and Tables.

The Education Amendments of 1972, referred to in subsecs. (a)(1) and (b)(1)(B), is Pub. L. 92–318, June 23, 1972, 86 Stat. 235. Title IX of the Act, known as the Patsy Takemoto Mink Equal Opportunity in Education Act, is classified principally to chapter 38 (§1681 et seq.) of Title 20, Education. For complete classification of title IX to the Code, see Short Title note set out under section 1681 of Title 20 and Tables.

The Civil Rights Act of 1964, referred to in subsecs. (a)(1) and (b)(1)(B), is Pub. L. 88–352, July 2, 1964, 78 Stat. 241. Title VI of the Act is classified generally to subchapter V (§2000d et seq.) of chapter 21 of this title. For complete classification of this Act to the Code, see Short Title note set out under section 2000a of this title and Tables.

§300x–58. Technical assistance and provision of supplies and services in lieu of grant funds

(a) Technical assistance

The Secretary shall, without charge to a State receiving a grant under section 300x or 300x–21 of this title, provide to the State (or to any public or nonprofit private entity within the State) technical assistance with respect to the planning, development, and operation of any program or service carried out pursuant to the program involved. The Secretary may provide such technical assistance directly, through contract, or through grants.

(b) Provision of supplies and services in lieu of grant funds

(1) In general

Upon the request of a State receiving a grant under section 300x or 300x–21 of this title, the Secretary may, subject to paragraph (2), provide supplies, equipment, and services for the purpose of aiding the State in carrying out the program involved and, for such purpose, may detail to the State any officer or employee of the Department of Health and Human Services.

(2) Corresponding reduction in payments

With respect to a request described in paragraph (1), the Secretary shall reduce the amount of payments under the program involved to the State by an amount equal to the costs of detailing personnel and the fair market value of any supplies, equipment, or services provided by the Secretary. The Secretary shall, for the payment of expenses incurred in complying with such request, expend the amounts withheld.

(July 1, 1944, ch. 373, title XIX, §1948, as added Pub. L. 102–321, title II, §203(a), July 10, 1992, 106 Stat. 408.)

§300x–59. Plans for performance partnerships

(a) Development

The Secretary in conjunction with States and other interested groups shall develop separate plans for the programs authorized under subparts I and II for creating more flexibility for States and accountability based on outcome and other performance measures. The plans shall each include—

(1) a description of the flexibility that would be given to the States under the plan;

(2) the common set of performance measures that would be used for accountability, including measures that would be used for the program under subpart II for pregnant addicts, HIV transmission, tuberculosis, and those with a co-occurring substance use disorders and mental disorders, and for programs under subpart I for children with serious emotional disturbance and adults with serious mental illness and for individuals with co-occurring mental health and substance use disorders disorders; [1]

(3) the definitions for the data elements to be used under the plan;

(4) the obstacles to implementation of the plan and the manner in which such obstacles would be resolved;

(5) the resources needed to implement the performance partnerships under the plan; and

(6) an implementation strategy complete with recommendations for any necessary legislation.

(b) Submission

Not later than 2 years after October 17, 2000, the plans developed under subsection (a) shall be submitted to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Commerce of the House of Representatives.

(c) Information

As the elements of the plans described in subsection (a) are developed, States are encouraged to provide information to the Secretary on a voluntary basis.

(d) Participants

The Secretary shall include among those interested groups that participate in the development of the plan consumers of mental health or substance use disorders services, providers, representatives of political divisions of States, and representatives of racial and ethnic groups including Native Americans.

(July 1, 1944, ch. 373, title XIX, §1949, as added Pub. L. 102–321, title II, §203(a), July 10, 1992, 106 Stat. 408; amended Pub. L. 106–310, div. B, title XXXIV, §3403(a), Oct. 17, 2000, 114 Stat. 1219; Pub. L. 117–328, div. FF, title I, §1241(a)(11), Dec. 29, 2022, 136 Stat. 5678.)

EDITORIAL NOTES

CODIFICATION

October 17, 2000, referred to in subsec. (b), was in the original "the date of the enactment of this Act", which was translated as meaning the date of enactment of Pub. L. 106–310, which amended this section generally, to reflect the probable intent of Congress.

AMENDMENTS

2022—Subsecs. (a)(2). Pub. L. 117–328 substituted "substance use disorders" for "substance abuse" in two places.

Subsecs. (d). Pub. L. 117–328 substituted "substance use disorders" for "substance abuse".

2000—Pub. L. 106–310 amended section catchline and text generally. Prior to amendment, text read as follows: "Not later than January 24, 1994, the Secretary shall submit to the Committee on Energy and Commerce of the House of Representatives, and to the Committee on Labor and Human Resources of the Senate, a report on the activities of the States carried out pursuant to the programs established in sections 300x and 300x–21 of this title. Such report may include any recommendations of the Secretary for appropriate changes in legislation."

STATUTORY NOTES AND RELATED SUBSIDIARIES

CHANGE OF NAME

Committee on Commerce of House of Representatives changed to Committee on Energy and Commerce of House of Representatives, and jurisdiction over matters relating to securities and exchanges and insurance generally transferred to Committee on Financial Services of House of Representatives by House Resolution No. 5, One Hundred Seventh Congress, Jan. 3, 2001.

[1] *So in original.*

§300x–60. Rule of construction regarding delegation of authority to States

With respect to States receiving grants under section 300x or 300x–21 of this title, this part may not be construed to authorize the Secretary to delegate to the States the primary responsibility for interpreting the governing provisions of this part.

(July 1, 1944, ch. 373, title XIX, §1950, as added Pub. L. 102–321, title II, §203(a), July 10, 1992, 106 Stat. 408.)

§300x–61. Solicitation of views of certain entities

In carrying out this part, the Secretary, as appropriate, shall solicit the views of the States and other appropriate entities.

(July 1, 1944, ch. 373, title XIX, §1951, as added Pub. L. 102–321, title II, §203(a), July 10, 1992, 106 Stat. 408.)

§300x–62. Availability to States of grant payments

Any amounts paid to a State for a fiscal year under section 300x or 300x–21 of this title shall be available for obligation and expenditure until the end of the fiscal year following the fiscal year for which the amounts were paid.

(July 1, 1944, ch. 373, title XIX, §1952, as added Pub. L. 102–321, title II, §203(a), July 10, 1992, 106 Stat. 409; amended Pub. L. 106–310, div. B, title XXXIV, §3403(b), Oct. 17, 2000, 114 Stat. 1220.)

EDITORIAL NOTES

AMENDMENTS

2000—Pub. L. 106–310 reenacted section catchline without change and amended text generally. Prior to amendment, text read as follows:

"(a) IN GENERAL.—Subject to subsection (b) of this section, any amounts paid to a State under the program involved shall be available for obligation until the end of the fiscal year for which the amounts were paid, and if obligated by the end of such year, shall remain available for expenditure until the end of the succeeding fiscal year.

"(b) EXCEPTION REGARDING NONCOMPLIANCE OF SUBGRANTEES.—If a State has in accordance with subsection (a) of this section obligated amounts paid to the State under the program involved, in any case in which the Secretary determines that the obligation consists of a grant or contract awarded by the State, and that the State has terminated or reduced the amount of such financial assistance on the basis of the failure of the recipient of the assistance to comply with the terms upon which the assistance was conditioned—

"(1) the amounts involved shall be available for reobligation by the State through September 30 of the fiscal year following the fiscal year for which the amounts were paid to the State; and

"(2) any of such amounts that are obligated by the State in accordance with paragraph (1) shall be available for expenditure through such date."

§300x–63. Continuation of certain programs

(a) In general

Of the amount allotted to the State of Hawaii under section 300x of this title, and the amount allotted to such State under section 300x–21 of this title, an amount equal to the proportion of Native Hawaiians residing in the State to the total population of the State shall be available, respectively, for carrying out the program involved for Native Hawaiians.

(b) Expenditure of amounts

The amount made available under subsection (a) may be expended only through contracts entered into by the State of Hawaii with public and private nonprofit organizations to enable such organizations to plan, conduct, and administer comprehensive substance use disorder and treatment programs for the benefit of Native Hawaiians. In entering into contracts under this section, the State of Hawaii shall give preference to Native Hawaiian organizations and Native Hawaiian health centers.

(c) Definitions

For the purposes of this subsection,[1] the terms "Native Hawaiian", "Native Hawaiian organization", and "Native Hawaiian health center" have the meaning given such terms in section 11707 of this title.

(July 1, 1944, ch. 373, title XIX, §1953, as added Pub. L. 102–321, title II, §203(a), July 10, 1992, 106 Stat. 409; amended Pub. L. 114–255, div. B, title VIII, §8003(2), Dec. 13, 2016, 130 Stat. 1233.)

EDITORIAL NOTES

AMENDMENTS

2016—Subsec. (b). Pub. L. 114–255 substituted "substance use disorder" for "substance abuse".

[1] *So in original. Probably should be "section,".*

§300x–64. Definitions

(a) Definitions for this subpart

For purposes of this subpart:

(1) The term "program involved" means the program of grants established in section 300x or 300x–21 of this title, or both, as indicated by whether the State involved is receiving or is applying to receive a grant under section 300x or 300x–21 of this title, or both.

(2)(A) The term "funding agreement", with respect to a grant under section 300x of this title, has the meaning given such term in section 300x–8 of this title.

(B) The term "funding agreement", with respect to a grant under section 300x–21 of this title, has the meaning given such term in section 300x–34 of this title.

(b) Definitions for this part

For purposes of this part:

(1) The term "Comptroller General" means the Comptroller General of the United States.

(2) The term "State", except as provided in sections 300x–7(c)(5) of this title and 300x–33(c)(5) of this title, means each of the several States, the District of Columbia, and each of the territories of the United States.

(3) The term "territories of the United States" means each of the Commonwealth of Puerto Rico, American Samoa, Guam, the Commonwealth of the Northern Mariana Islands, the Virgin Islands, Palau, the Marshall Islands, and Micronesia.

(4) The term "interim services", in the case of an individual in need of treatment for substance use disorders who has been denied admission to a program of such treatment on the basis of the lack of the capacity of the program to admit the individual, means services for reducing the adverse health effects of such disorders, for promoting the health of the individual, and for reducing the risk of transmission of disease, which services are provided until the individual is admitted to such a program.

(July 1, 1944, ch. 373, title XIX, §1954, as added Pub. L. 102–321, title II, §203(a), July 10, 1992, 106 Stat. 409; amended Pub. L. 117–328, div. FF, title I, §1241(a)(12), Dec. 29, 2022, 136 Stat. 5678.)

EDITORIAL NOTES

AMENDMENTS

2022—Subsec. (b)(4). Pub. L. 117–328 substituted "substance use disorders" for "substance abuse" and "such disorders" for "such abuse".

§300x–65. Services provided by nongovernmental organizations

(a) Purposes

The purposes of this section are—

(1) to prohibit discrimination against nongovernmental organizations and certain individuals on the basis of religion in the distribution of government funds to provide substance abuse services under this subchapter and subchapter III–A, and the receipt of services under such subchapters; and

(2) to allow the organizations to accept the funds to provide the services to the individuals without impairing the religious character of the organizations or the religious freedom of the individuals.

(b) Religious organizations included as nongovernmental providers

(1) In general

A State may administer and provide substance abuse services under any program under this subchapter or subchapter III–A through grants, contracts, or cooperative agreements to provide assistance to beneficiaries under such subchapters with nongovernmental organizations.

(2) Requirement

A State that elects to utilize nongovernmental organizations as provided for under paragraph (1)

shall consider, on the same basis as other nongovernmental organizations, religious organizations to provide services under substance abuse programs under this subchapter or subchapter III–A, so long as the programs under such subchapters are implemented in a manner consistent with the Establishment Clause of the first amendment to the Constitution. Neither the Federal Government nor a State or local government receiving funds under such programs shall discriminate against an organization that provides services under, or applies to provide services under, such programs, on the basis that the organization has a religious character.

(c) Religious character and independence

(1) In general

A religious organization that provides services under any substance abuse program under this subchapter or subchapter III–A shall retain its independence from Federal, State, and local governments, including such organization's control over the definition, development, practice, and expression of its religious beliefs.

(2) Additional safeguards

Neither the Federal Government nor a State or local government shall require a religious organization—

(A) to alter its form of internal governance; or

(B) to remove religious art, icons, scripture, or other symbols,

in order to be eligible to provide services under any substance abuse program under this subchapter or subchapter III–A.

(d) Employment practices

(1) Substance abuse

A religious organization that provides services under any substance abuse program under this subchapter or subchapter III–A may require that its employees providing services under such program adhere to rules forbidding the use of drugs or alcohol.

(2) Title VII exemption

The exemption of a religious organization provided under section 702 or 703(e)(2) of the Civil Rights Act of 1964 (42 U.S.C. 2000e–1, 2000e–2(e)(2)) regarding employment practices shall not be affected by the religious organization's provision of services under, or receipt of funds from, any substance abuse program under this subchapter or subchapter III–A.

(e) Rights of beneficiaries of assistance

(1) In general

If an individual described in paragraph (3) has an objection to the religious character of the organization from which the individual receives, or would receive, services funded under any substance abuse program under this subchapter or subchapter III–A, the appropriate Federal, State, or local governmental entity shall provide to such individual (if otherwise eligible for such services) within a reasonable period of time after the date of such objection, services that—

(A) are from an alternative provider that is accessible to the individual; and

(B) have a value that is not less than the value of the services that the individual would have received from such organization.

(2) Notice

The appropriate Federal, State, or local governmental entity shall ensure that notice is provided to individuals described in paragraph (3) of the rights of such individuals under this section.

(3) Individual described

An individual described in this paragraph is an individual who receives or applies for services under any substance abuse program under this subchapter or subchapter III–A.

(f) Nondiscrimination against beneficiaries

A religious organization providing services through a grant, contract, or cooperative agreement under any substance abuse program under this subchapter or subchapter III–A shall not discriminate, in carrying out such program, against an individual described in subsection (e)(3) on the basis of religion, a religious belief, a refusal to hold a religious belief, or a refusal to actively participate in a religious practice.

(g) Fiscal accountability

(1) In general

Except as provided in paragraph (2), any religious organization providing services under any substance abuse program under this subchapter or subchapter III–A shall be subject to the same regulations as other nongovernmental organizations to account in accord with generally accepted accounting principles for the use of such funds provided under such program.

(2) Limited audit

Such organization shall segregate government funds provided under such substance abuse program into a separate account. Only the government funds shall be subject to audit by the government.

(h) Compliance

Any party that seeks to enforce such party's rights under this section may assert a civil action for injunctive relief exclusively in an appropriate Federal or State court against the entity, agency or official that allegedly commits such violation.

(i) Limitations on use of funds for certain purposes

No funds provided through a grant or contract to a religious organization to provide services under any substance abuse program under this subchapter or subchapter III–A shall be expended for sectarian worship, instruction, or proselytization.

(j) Effect on State and local funds

If a State or local government contributes State or local funds to carry out any substance abuse program under this subchapter or subchapter III–A, the State or local government may segregate the State or local funds from the Federal funds provided to carry out the program or may commingle the State or local funds with the Federal funds. If the State or local government commingles the State or local funds, the provisions of this section shall apply to the commingled funds in the same manner, and to the same extent, as the provisions apply to the Federal funds.

(k) Treatment of intermediate contractors

If a nongovernmental organization (referred to in this subsection as an "intermediate organization"), acting under a contract or other agreement with the Federal Government or a State or local government, is given the authority under the contract or agreement to select nongovernmental organizations to provide services under any substance abuse program under this subchapter or subchapter III–A, the intermediate organization shall have the same duties under this section as the government but shall retain all other rights of a nongovernmental organization under this section.

(July 1, 1944, ch. 373, title XIX, §1955, as added Pub. L. 106–310, div. B, title XXXIII, §3305, Oct. 17, 2000, 114 Stat. 1212.)

§300x–66. Services for individuals with co-occurring disorders

States may use funds available for treatment under sections 300x and 300x–21 of this title to treat persons with co-occurring substance use disorders and mental disorders as long as funds available under such sections are used for the purposes for which they were authorized by law and can be tracked for accounting purposes.

(July 1, 1944, ch. 373, title XIX, §1956, as added Pub. L. 106–310, div. B, title XXXIV, §3407, Oct.

17, 2000, 114 Stat. 1222; amended Pub. L. 117–328, div. FF, title I, §1241(a)(13), Dec. 29, 2022, 136 Stat. 5678.)

EDITORIAL NOTES

AMENDMENTS

2022—Pub. L. 117–328 substituted "substance use disorders" for "substance abuse".

§300x–67. Public health emergencies

In the case of a public health emergency (as determined under section 247d of this title), the Secretary, on a State by State basis, may, as the circumstances of the emergency reasonably require and for the period of the emergency, grant an extension, or waive application deadlines or compliance with any other requirement, of a grant authorized under section 290cc–21, 300x, or 300x–21 of this title or an allotment authorized under Public Law 99–319 (42 U.S.C. 10801 et seq.).

(July 1, 1944, ch. 373, title XIX, §1957, as added Pub. L. 114–255, div. B, title VIII, §8003(3), Dec. 13, 2016, 130 Stat. 1233.)

EDITORIAL NOTES

REFERENCES IN TEXT

Public Law 99–319, referred to in text, is Pub. L. 99–319, May 23, 1986, 100 Stat. 478, popularly known as the Protection and Advocacy for Individuals with Mental Illness Act, which is classified generally to chapter 114 (§10801 et seq.) of this title. For complete classification of this Act to the Code, see Short Title note set out under section 10801 of this title and Tables.

§300x–68. Joint applications

The Secretary, acting through the Assistant Secretary for Mental Health and Substance Use, shall permit a joint application to be submitted for grants under subpart I and subpart II upon the request of a State. Such application may be jointly reviewed and approved by the Secretary with respect to such subparts, consistent with the purposes and authorized activities of each such grant program. A State submitting such a joint application shall otherwise meet the requirements with respect to each such subpart.

(July 1, 1944, ch. 373, title XIX, §1958, as added Pub. L. 114–255, div. B, title VIII, §8003(3), Dec. 13, 2016, 130 Stat. 1233.)

PART C—CERTAIN PROGRAMS REGARDING MENTAL HEALTH AND SUBSTANCE USE

EDITORIAL NOTES

CODIFICATION

Pub. L. 117–328, div. FF, title I, §1241(b)(1), Dec. 29, 2022, 136 Stat. 5678, substituted "Substance Use" for "Substance Abuse" in part heading.

Pub. L. 106–310, div. B, title XXXIV, §3404(1), Oct. 17, 2000, 114 Stat. 1220, added part C heading and struck out former part C heading "Certain Programs Regarding Substance Abuse".

SUBPART I—DATA INFRASTRUCTURE DEVELOPMENT

EDITORIAL NOTES

CODIFICATION

Pub. L. 106–310, div. B, title XXXIV, §3404(1), Oct. 17, 2000, 114 Stat. 1220, added subpart I heading and struck out former subpart I heading "Expansion of Capacity for Providing Treatment".

§300y. Data infrastructure development

(a) In general

The Secretary may make grants to, and enter into contracts or cooperative agreements with States for the purpose of developing and operating mental health or substance use data collection, analysis, and reporting systems with regard to performance measures including capacity, process, and outcomes measures.

(b) Projects

The Secretary shall establish criteria to ensure that services will be available under this section to States that have a fundamental basis for the collection, analysis, and reporting of mental health and substance use performance measures and States that do not have such basis. The Secretary will establish criteria for determining whether a State has a fundamental basis for the collection, analysis, and reporting of data.

(c) Condition of receipt of funds

As a condition of the receipt of an award under this section a State shall agree to collect, analyze, and report to the Secretary within 2 years of the date of the award on a core set of performance measures to be determined by the Secretary in conjunction with the States.

(d) Matching requirement

(1) In general

With respect to the costs of the program to be carried out under subsection (a) by a State, the Secretary may make an award under such subsection only if the applicant agrees to make available (directly or through donations from public or private entities) non-Federal contributions toward such costs in an amount that is not less than 50 percent of such costs.

(2) Determination of amount contributed

Non-Federal contributions under paragraph (1) may be in cash or in kind, fairly evaluated, including plant, equipment, or services. Amounts provided by the Federal Government, or services assisted or subsidized to any significant extent by the Federal Government, may not be included in determining the amount of such contributions.

(e) Duration of support

The period during which payments may be made for a project under subsection (a) may be not less than 3 years nor more than 5 years.

(f) Authorization of appropriation

(1) In general

For the purpose of carrying out this section, there are authorized to be appropriated such sums as may be necessary for each of the fiscal years 2001, 2002 and 2003.

(2) Allocation

Of the amounts appropriated under paragraph (1) for a fiscal year, 50 percent shall be expended to support data infrastructure development for mental health and 50 percent shall be expended to support data infrastructure development for substance use.

(July 1, 1944, ch. 373, title XIX, §1971, as added Pub. L. 106–310, div. B, title XXXIV, §3404(2), Oct. 17, 2000, 114 Stat. 1220; amended Pub. L. 117–328, div. FF, title I, §1241(b)(2), Dec. 29, 2022, 136 Stat. 5678.)

EDITORIAL NOTES

PRIOR PROVISIONS

A prior section 300y, act July 1, 1944, ch. 373, title XIX, §1971, as added Pub. L. 102–321, title II, §204, July 10, 1992, 106 Stat. 410; amended Pub. L. 102–352, §2(a)(13), Aug. 26, 1992, 106 Stat. 939, related to categorical grants to States for programs regarding substance abuse, prior to repeal by Pub. L. 106–310, div. B, title XXXIV, §3404(2), Oct. 17, 2000, 114 Stat. 1220.

Another prior section 300y, act July 1, 1944, ch. 373, title XIX, §1921, as added Oct. 27, 1986, Pub. L. 99–570, title IV, §4002, 100 Stat. 3207–103, related to establishment of special alcohol abuse and drug abuse programs, prior to repeal by Pub. L. 100–690, title II, §2038(1), Nov. 18, 1988, 102 Stat. 4203.

Another prior section 300y, act July 1, 1944, ch. 373, title XIX, §1921, as added Aug. 13, 1981, Pub. L. 97–35, title IX, §901, 95 Stat. 552, related to planning grants, prior to repeal by Pub. L. 99–280, §5, Apr. 24, 1986, 100 Stat. 400.

Prior sections 300y–1 and 300y–2 were repealed by Pub. L. 100–690, title II, §2038(1), Nov. 18, 1988, 102 Stat. 4203.

Section 300y–1, act July 1, 1944, ch. 373, title XIX, §1922, as added Oct. 27, 1986, Pub. L. 99–570, title IV, §4002, 100 Stat. 3207–106, related to transfer of funds to Administrator of Veterans' Affairs.

Another prior section 300y–1, act July 1, 1944, ch. 373, title XIX, §1922, as added Aug. 13, 1981, Pub. L. 97–35, title IX, §901, 95 Stat. 552, authorized appropriations, prior to repeal by Pub. L. 99–280, §5, Apr. 24, 1986, 100 Stat. 400.

Section 300y–2, act July 1, 1944, ch. 373, title XIX, §1923, as added Oct. 27, 1986, Pub. L. 99–570, title IV, §4002, 100 Stat. 3207–106, related to evaluation of treatment programs.

Another prior section 300y–2, act July 1, 1944, ch. 373, title XIX, §1923, as added Aug. 13, 1981, Pub. L. 97–35, title IX, §901, 95 Stat. 552, provided for grants under section 254c of this title, prior to repeal by Pub. L. 99–280, §5, Apr. 24, 1986, 100 Stat. 400.

Prior sections 300y–3 to 300y–10 were repealed by Pub. L. 99–280, §5, Apr. 24, 1986, 100 Stat. 400.

Section 300y–3, act July 1, 1944, ch. 373, title XIX, §1924, as added Aug. 13, 1981, Pub. L. 97–35, title IX, §901, 95 Stat. 553, provided that allotments be based upon prior year distributions and provided for direct distributions to Indian tribes.

Section 300y–4, act July 1, 1944, ch. 373, title XIX, §1925, as added Aug. 13, 1981, Pub. L. 97–35, title IX, §901, 95 Stat. 553, related to payments under allotments to States.

Section 300y–5, act July 1, 1944, ch. 373, title XIX, §1926, as added Aug. 13, 1981, Pub. L. 97–35, title IX, §901, 95 Stat. 554, related to State grants to community health centers from allotments.

Section 300y–6, act July 1, 1944, ch. 373, title XIX, §1927, as added Aug. 13, 1981, Pub. L. 97–35, title IX, §901, 95 Stat. 556, related to application requirements and submittal, availability for public comment, and revision of a description of intended use of funds.

Section 300y–7, act July 1, 1944, ch. 373, title XIX, §1928, as added Aug. 13, 1981, Pub. L. 97–35, title IX, §901, 95 Stat. 557, related to reporting and auditing requirements.

Section 300y–8, act July 1, 1944, ch. 373, title XIX, §1929, as added Aug. 13, 1981, Pub. L. 97–35, title IX, §901, 95 Stat. 558, related to withholding of funds from a State not in compliance.

Section 300y–9, act July 1, 1944, ch. 373, title XIX, §1930, as added Aug. 13, 1981, Pub. L. 97–35, title IX, §901, 95 Stat. 558, related to nondiscrimination requirements.

Section 300y–10, act July 1, 1944, ch. 373, title XIX, §1931, as added Aug. 13, 1981, Pub. L. 97–35, title IX, §901, 95 Stat. 559, provided criminal penalty for false statements.

AMENDMENTS

2022—Subsecs. (a), (b), (f)(2). Pub. L. 117–328 substituted "substance use" for "substance abuse".

SUBPART II—INTERIM MAINTENANCE TREATMENT OF NARCOTICS DEPENDENCE

§300y–11. Interim maintenance treatment

(a) Requirement regarding Secretary

Subject to the following subsections of this section, for the purpose of reducing the incidence of the transmission of HIV disease pursuant to the intravenous use of heroin or other morphine-like drugs, the Secretary, in establishing conditions for the use of methadone in public or nonprofit private programs of treatment for dependence on such drugs, shall authorize such programs—

(1) to dispense methadone for treatment purposes to individuals who—

(A) meet the conditions for admission to such programs that dispense methadone as part of comprehensive treatment for such dependence; and

(B) are seeking admission to such programs that so dispense methadone, but as a result of the limited capacity of the programs, will not gain such admission until 14 or more days after seeking admission to the programs; and

(2) in dispensing methadone to such individuals, to provide only minimum ancillary services during the period in which the individuals are waiting for admission to programs of comprehensive treatment.

(b) Inapplicability of requirement in certain circumstances

(1) In general

The requirement established in subsection (a) for the Secretary does not apply if any or all of the following conditions are met:

(A) The preponderance of scientific research indicates that the risk of the transmission of HIV disease pursuant to the intravenous use of drugs is minimal.

(B) The preponderance of scientific research indicates that the medically supervised dispensing of methadone is not an effective method of reducing the extent of dependence on heroin and other morphine-like drugs.

(C) The preponderance of available data indicates that, of treatment programs that dispense methadone as part of comprehensive treatment, a substantial majority admit all individuals seeking services to the programs not later than 14 days after the individuals seek admission to the programs.

(2) Evaluation by Secretary

In evaluating whether any or all of the conditions described in paragraph (1) have been met, the Secretary shall consult with the National Commission on Acquired Immune Deficiency Syndrome.

(c) Conditions for obtaining authorization from Secretary

(1) In general

In carrying out the requirement established in subsection (a), the Secretary shall, after consultation with the National Commission on Acquired Immune Deficiency Syndrome, by regulation issue such conditions for treatment programs to obtain authorization from the Secretary to provide interim maintenance treatment as may be necessary to carry out the purpose described in such subsection. Such conditions shall include conditions for preventing the unauthorized use of methadone.

(2) Counseling on HIV disease

The regulations issued under paragraph (1) shall provide that an authorization described in such paragraph may not be issued to a treatment program unless the program provides to recipients of the treatment counseling on preventing exposure to and the transmission of HIV disease.

(3) Permission of relevant State as condition of authorization

The regulations issued under paragraph (1) shall provide that the Secretary may not provide an authorization described in such paragraph to any treatment program in a State unless the chief public health officer of the State has certified to the Secretary that—

(A) such officer does not object to the provision of such authorizations to treatment programs in the State; and

(B) the provision of interim maintenance services in the State will not reduce the capacity of comprehensive treatment programs in the State to admit individuals to the programs (relative to the date on which such officer so certifies).

(4) Date certain for issuance of regulations; failure of Secretary

The Secretary shall issue the final rule for purposes of the regulations required in paragraph (1), and such rule shall be effective, not later than the expiration of the 180-day period beginning on July 10, 1992. If the Secretary fails to meet the requirement of the preceding sentence, the proposed rule issued on March 2, 1989, with respect to part 291 of title 21, Code of Federal Regulations (docket numbered 88N–0444; 54 Fed. Reg. 8973 et seq.) is deemed to take effect as a final rule upon the expiration of such period, and the provisions of paragraph (3) of this subsection are deemed to be incorporated into such rule.

(d) Definitions

For purposes of this section:

(1) The term "interim maintenance services" means the provision of methadone in a treatment program under the circumstances described in paragraphs (1) and (2) of subsection (a).

(2) The term "HIV disease" means infection with the etiologic agent for acquired immune deficiency syndrome.

(3) The term "treatment program" means a public or nonprofit private program of treatment for dependence on heroin or other morphine-like drugs.

(July 1, 1944, ch. 373, title XIX, §1976, as added Pub. L. 102–321, title II, §204, July 10, 1992, 106 Stat. 412; amended Pub. L. 117–328, div. FF, title I, §1241(b)(3), Dec. 29, 2022, 136 Stat. 5678.)

EDITORIAL NOTES

PRIOR PROVISIONS

A prior section 300y–11, act July 1, 1944, ch. 373, title XIX, §1932, as added Aug. 13, 1981, Pub. L. 97–35, title IX, §901, 95 Stat. 559; amended Jan. 4, 1983, Pub. L. 97–414, §8(v), 96 Stat. 2063, related to applicability of other provisions and promulgation of regulations, prior to repeal by Pub. L. 99–280, §5, Apr. 24, 1986, 100 Stat. 400.

Sections 300y–21 to 300y–27 terminated Jan. 1, 1991, pursuant to section 300y–27 and were omitted from the Code.

Section 300y–21, act July 1, 1944, ch. 373, title XIX, §1931, as added Nov. 4, 1988, Pub. L. 100–607, title IV, §408(a), 102 Stat. 3117, provided definitions for this part.

A prior section 1931 of act July 1, 1944, ch. 373, title XIX, as added Aug. 13, 1981, Pub. L. 97–35, title IX, §901, 95 Stat. 559, provided criminal penalty for false statements and was classified to former section 300y–10 of this title, prior to repeal by Pub. L. 99–280, §5, Apr. 24, 1986, 100 Stat. 400.

Section 300y–22, act July 1, 1944, ch. 373, title XIX, §1932, as added Nov. 4, 1988, Pub. L. 100–607, title IV, §408(a), 102 Stat. 3117, authorized appropriations for this part.

A prior section 1932 of act July 1, 1944, ch. 373, title XIX, as added Aug. 13, 1981, Pub. L. 97–35, title IX, §901, 95 Stat. 559; amended Jan. 4, 1983, Pub. L. 97–414, §8(v), 96 Stat. 2063, related to applicability of other provisions and promulgation of regulations and was classified to former section 300y–11 of this title, prior to repeal by Pub. L. 99–280, §5, Apr. 24, 1986, 100 Stat. 400.

Section 300y–23, act July 1, 1944, ch. 373, title XIX, §1933, as added Nov. 4, 1988, Pub. L. 100–607, title IV, §408(a), 102 Stat. 3117, provided for allotments under this part.

Section 300y–24, act July 1, 1944, ch. 373, title XIX, §1934, as added Nov. 4, 1988, Pub. L. 100–607, title IV, §408(a), 102 Stat. 3118, provided for payments under allotments to States.

Section 300y–25, act July 1, 1944, ch. 373, title XIX, §1935, as added Nov. 4, 1988, Pub. L. 100–607, title IV, §408(a), 102 Stat. 3118, specified use of allotments.

Section 300y–26, act July 1, 1944, ch. 373, title XIX, §1936, as added Nov. 4, 1988, Pub. L. 100–607, title IV, §408(a), 102 Stat. 3119, provided for applications, requirements of the application, and description of activities.

Section 300y–27, act July 1, 1944, ch. 373, title XIX, §1937, as added Nov. 4, 1988, Pub. L. 100–607, title

IV, §408(a), 102 Stat. 3120; amended Aug. 16, 1989, Pub. L. 101–93, §5(f)(1)(B), 103 Stat. 612, provided for termination of this part effective Jan. 1, 1991.

AMENDMENTS

2022—Subsecs. (a), (b)(1)(A). Pub. L. 117–328 substituted "intravenous use" for "intravenous abuse".

STATUTORY NOTES AND RELATED SUBSIDIARIES

EFFECTIVE DATE

Section effective July 10, 1992, with programs making awards providing financial assistance in fiscal year 1993 and subsequent years effective for awards made on or after Oct. 1, 1992, see section 801(b), (d)(1) of Pub. L. 102–321, set out as an Effective Date of 1992 Amendment note under section 236 of this title.

SUBCHAPTER XVIII—ADOLESCENT FAMILY LIFE DEMONSTRATION PROJECTS

§300z. Findings and purposes

(a) The Congress finds that—

(1) in 1978, an estimated one million one hundred thousand teenagers became pregnant, more than five hundred thousand teenagers carried their babies to term, and over one-half of the babies born to such teenagers were born out of wedlock;

(2) adolescents aged seventeen and younger accounted for more than one-half of the out of wedlock births to teenagers;

(3) in a high proportion of cases, the pregnant adolescent is herself the product of an unmarried parenthood during adolescence and is continuing the pattern in her own lifestyle;

(4) it is estimated that approximately 80 per centum of unmarried teenagers who carry their pregnancies to term live with their families before and during their pregnancy and remain with their families after the birth of the child;

(5) pregnancy and childbirth among unmarried adolescents, particularly young adolescents, often results in severe adverse health, social, and economic consequences including: a higher percentage of pregnancy and childbirth complications; a higher incidence of low birth weight babies; a higher infant mortality and morbidity; a greater likelihood that an adolescent marriage will end in divorce; a decreased likelihood of completing schooling; and higher risks of unemployment and welfare dependency; and therefore, education, training, and job research services are important for adolescent parents;

(6)(A) adoption is a positive option for unmarried pregnant adolescents who are unwilling or unable to care for their children since adoption is a means of providing permanent families for such children from available approved couples who are unable or have difficulty in conceiving or carrying children of their own to term; and

(B) at present, only 4 per centum of unmarried pregnant adolescents who carry their babies to term enter into an adoption plan or arrange for their babies to be cared for by relatives or friends;

(7) an unmarried adolescent who becomes pregnant once is likely to experience recurrent pregnancies and childbearing, with increased risks;

(8)(A) the problems of adolescent premarital sexual relations, pregnancy, and parenthood are multiple and complex and are frequently associated with or are a cause of other troublesome situations in the family; and

(B) such problems are best approached through a variety of integrated and essential services provided to adolescents and their families by other family members, religious and charitable organizations, voluntary associations, and other groups in the private sector as well as services provided by publicly sponsored initiatives;

(9) a wide array of educational, health, and supportive services are not available to adolescents with such problems or to their families, or when available frequently are fragmented and thus are of limited effectiveness in discouraging adolescent premarital sexual relations and the consequences of such relations;

(10)(A) prevention of adolescent sexual activity and adolescent pregnancy depends primarily upon developing strong family values and close family ties, and since the family is the basic social unit in which the values and attitudes of adolescents concerning sexuality and pregnancy are formed, programs designed to deal with issues of sexuality and pregnancy will be successful to the extent that such programs encourage and sustain the role of the family in dealing with adolescent sexual activity and adolescent pregnancy;

(B) Federal policy therefore should encourage the development of appropriate health, educational, and social services where such services are now lacking or inadequate, and the better coordination of existing services where they are available; and

(C) services encouraged by the Federal Government should promote the involvement of parents with their adolescent children, and should emphasize the provision of support by other family members, religious and charitable organizations, voluntary associations, and other groups in the private sector in order to help adolescents and their families deal with complex issues of adolescent premarital sexual relations and the consequences of such relations; and

(11)(A) there has been limited research concerning the societal causes and consequences of adolescent pregnancy;

(B) there is limited knowledge concerning which means of intervention are effective in mediating or eliminating adolescent premarital sexual relations and adolescent pregnancy; and

(C) it is necessary to expand and strengthen such knowledge in order to develop an array of approaches to solving the problems of adolescent premarital sexual relations and adolescent pregnancy in both urban and rural settings.

(b) Therefore, the purposes of this subchapter are—

(1) to find effective means, within the context of the family, of reaching adolescents before they become sexually active in order to maximize the guidance and support available to adolescents from parents and other family members, and to promote self discipline and other prudent approaches to the problem of adolescent premarital sexual relations, including adolescent pregnancy;

(2) to promote adoption as an alternative for adolescent parents;

(3) to establish innovative, comprehensive, and integrated approaches to the delivery of care services both for pregnant adolescents, with primary emphasis on unmarried adolescents who are seventeen years of age or under, and for adolescent parents, which shall be based upon an assessment of existing programs and, where appropriate, upon efforts to establish better coordination, integration, and linkages among such existing programs in order to—

(A) enable pregnant adolescents to obtain proper care and assist pregnant adolescents and adolescent parents to become productive independent contributors to family and community life; and

(B) assist families of adolescents to understand and resolve the societal causes which are associated with adolescent pregnancy;

(4) to encourage and support research projects and demonstration projects concerning the societal causes and consequences of adolescent premarital sexual relations, contraceptive use, pregnancy, and child rearing;

(5) to support evaluative research to identify effective services which alleviate, eliminate, or resolve any negative consequences of adolescent premarital sexual relations and adolescent childbearing for the parents, the child, and their families; and

(6) to encourage and provide for the dissemination of results, findings, and information from programs and research projects relating to adolescent premarital sexual relations, pregnancy, and parenthood.

(July 1, 1944, ch. 373, title XX, §2001, as added Pub. L. 97–35, title IX, §955(a), Aug. 13, 1981, 95 Stat. 578; amended Pub. L. 98–512, §2(b), (c), Oct. 19, 1984, 98 Stat. 2409.)

EDITORIAL NOTES

AMENDMENTS

1984—Subsec. (a)(5). Pub. L. 98–512, §2(b), struck out reference relating to developmental disabilities and inserted provision relating to importance of education, training, and job research services for adolescent parents.

Subsec. (b)(3). Pub. L. 98–512, §2(c), inserted "both" before "for pregnant adolescents".

§300z–1. Definitions; regulations applicable

(a) For the purposes of this subchapter, the term—

(1) "Secretary" means the Secretary of Health and Human Services;

(2) "eligible person" means—

(A) with regard to the provision of care services, a pregnant adolescent, an adolescent parent, or the family of a pregnant adolescent or an adolescent parent; or

(B) with regard to the provision of prevention services and referral to such other services which may be appropriate, a nonpregnant adolescent;

(3) "eligible grant recipient" means a public or nonprofit private organization or agency which demonstrates, to the satisfaction of the Secretary—

(A) in the case of an organization which will provide care services, the capability of providing all core services in a single setting or the capability of creating a network through which all core services would be provided; or

(B) in the case of an organization which will provide prevention services, the capability of providing such services;

(4) "necessary services" means services which may be provided by grantees which are—

(A) pregnancy testing and maternity counseling;

(B) adoption counseling and referral services which present adoption as an option for pregnant adolescents, including referral to licensed adoption agencies in the community if the eligible grant recipient is not a licensed adoption agency;

(C) primary and preventive health services including prenatal and postnatal care;

(D) nutrition information and counseling;

(E) referral for screening and treatment of venereal disease;

(F) referral to appropriate pediatric care;

(G) educational services relating to family life and problems associated with adolescent premarital sexual relations, including—

(i) information about adoption;

(ii) education on the responsibilities of sexuality and parenting;

(iii) the development of material to support the role of parents as the provider of sex education; and

(iv) assistance to parents, schools, youth agencies, and health providers to educate adolescents and preadolescents concerning self-discipline and responsibility in human sexuality;

(H) appropriate educational and vocational services;

(I) referral to licensed residential care or maternity home services; and

(J) mental health services and referral to mental health services and to other appropriate physical health services;

(K) child care sufficient to enable the adolescent parent to continue education or to enter into

employment;

(L) consumer education and homemaking;

(M) counseling for the immediate and extended family members of the eligible person;

(N) transportation;

(O) outreach services to families of adolescents to discourage sexual relations among unemancipated minors;

(P) family planning services; and

(Q) such other services consistent with the purposes of this subchapter as the Secretary may approve in accordance with regulations promulgated by the Secretary;

(5) "core services" means those services which shall be provided by a grantee, as determined by the Secretary by regulation;

(6) "supplemental services" means those services which may be provided by a grantee, as determined by the Secretary by regulation;

(7) "care services" means necessary services for the provision of care to pregnant adolescents and adolescent parents and includes all core services with respect to the provision of such care prescribed by the Secretary by regulation;

(8) "prevention services" means necessary services to prevent adolescent sexual relations, including the services described in subparagraphs (A), (D), (E), (G), (H), (M), (N), (O), and (Q) of paragraph (4);

(9) "adolescent" means an individual under the age of nineteen; and

(10) "unemancipated minor" means a minor who is subject to the control, authority, and supervision of his or her parents or guardians, as determined under State law.

(b) Until such time as the Secretary promulgates regulations pursuant to the second sentence of this subsection, the Secretary shall use the regulations promulgated under title VI of the Health Services and Centers Amendments of 1978 [42 U.S.C. 300a–21 et seq.] which were in effect on August 13, 1981, to determine which necessary services are core services for purposes of this subchapter. The Secretary may promulgate regulations to determine which necessary services are core services for purposes of this subchapter based upon an evaluation of and information concerning which necessary services are essential to carry out the purposes of this subchapter and taking into account (1) factors such as whether services are to be provided in urban or rural areas, the ethnic groups to be served, and the nature of the populations to be served, and (2) the results of the evaluations required under section 300z–5(b) of this title. The Secretary may from time to time revise such regulations.

(July 1, 1944, ch. 373, title XX, §2002, as added Pub. L. 97–35, title IX, §955(a), Aug. 13, 1981, 95 Stat. 580; amended Pub. L. 98–512, §2(d), Oct. 19, 1984, 98 Stat. 2409.)

EDITORIAL NOTES

REFERENCES IN TEXT

The Health Services and Centers Amendments of 1978, referred to in subsec. (b), is Pub. L. 95–626, Nov. 10, 1978, 92 Stat. 3551. Title VI of the Health Services and Centers Amendments of 1978 was classified generally to part A (§300a–21 et seq.) of subchapter VIII–A of this chapter prior to its repeal by Pub. L. 97–35, title IX, §955(b), title XXI, §2193(f), Aug. 13, 1981, 95 Stat. 592, 828. For complete classification of this Act to the Code, see Short Title of 1978 Amendments note set out under section 201 of this title and Tables.

AMENDMENTS

1984—Subsec. (a)(4)(H). Pub. L. 98–512 struck out "and referral to such services" after "vocational services".

§300z–2. Demonstration projects; grant authorization, etc.

(a) The Secretary may make grants to further the purposes of this subchapter to eligible grant recipients which have submitted an application which the Secretary finds meets the requirements of section 300z–5 of this title for demonstration projects which the Secretary determines will help communities provide appropriate care and prevention services in easily accessible locations. Demonstration projects shall, as appropriate, provide, supplement, or improve the quality of such services. Demonstration projects shall use such methods as will strengthen the capacity of families to deal with the sexual behavior, pregnancy, or parenthood of adolescents and to make use of support systems such as other family members, friends, religious and charitable organizations, and voluntary associations.

(b) Grants under this subchapter for demonstration projects may be for the provision of—

(1) care services;

(2) prevention services; or

(3) a combination of care services and prevention services.

(July 1, 1944, ch. 373, title XX, §2003, as added Pub. L. 97–35, title IX, §955(a), Aug. 13, 1981, 95 Stat. 582.)

§300z–3. Uses of grants for demonstration projects for services

(a) Covered projects

Except as provided in subsection (b), funds provided for demonstration projects for services under this subchapter may be used by grantees only to—

(1) provide to eligible persons—

(A) care services;

(B) prevention services; or

(C) care and prevention services (in the case of a grantee who is providing a combination of care and prevention services);

(2) coordinate, integrate, and provide linkages among providers of care, prevention, and other services for eligible persons in furtherance of the purposes of this subchapter;

(3) provide supplemental services where such services are not adequate or not available to eligible persons in the community and which are essential to the care of pregnant adolescents and to the prevention of adolescent premarital sexual relations and adolescent pregnancy;

(4) plan for the administration and coordination of pregnancy prevention services and programs of care for pregnant adolescents and adolescent parents which will further the objectives of this subchapter; and

(5) fulfill assurances required for grant approval by section 300z–5 of this title.

(b) Family planning services; availability in community

(1) No funds provided for a demonstration project for services under this subchapter may be used for the provision of family planning services (other than counseling and referral services) to adolescents unless appropriate family planning services are not otherwise available in the community.

(2) Any grantee who receives funds for a demonstration project for services under this subchapter and who, after determining under paragraph (1) that appropriate family planning services are not otherwise available in the community, provides family planning services (other than counseling and referral services) to adolescents may only use funds provided under this subchapter for such family planning services if all funds received by such grantee from all other sources to support such family planning services are insufficient to support such family planning services.

(c) Fees for services: criteria

Grantees who receive funds for a demonstration project for services under this subchapter shall

charge fees for services pursuant to a fee schedule approved by the Secretary as a part of the application described in section 300z–5 of this title which bases fees charged by the grantee on the income of the eligible person or the parents or legal guardians of the eligible person and takes into account the difficulty adolescents face in obtaining resources to pay for services. A grantee who receives funds for a demonstration project for services under this subchapter may not, in any case, discriminate with regard to the provision of services to any individual because of that individual's inability to provide payment for such services, except that in determining the ability of an unemancipated minor to provide payment for services, the income of the family of an unemancipated minor shall be considered in determining the ability of such minor to make such payments unless the parents or guardians of the unemancipated minor refuse to make such payments.

(July 1, 1944, ch. 373, title XX, §2004, as added Pub. L. 97–35, title IX, §955(a), Aug. 13, 1981, 95 Stat. 583.)

§300z–4. Grants for demonstration projects for services

(a) Priorities

In approving applications for grants for demonstration projects for services under this subchapter, the Secretary shall give priority to applicants who—

(1) serve an area where there is a high incidence of adolescent pregnancy;

(2) serve an area with a high proportion of low-income families and where the availability of programs of care for pregnant adolescents and adolescent parents is low;

(3) show evidence—

(A) in the case of an applicant who will provide care services, of having the ability to bring together a wide range of needed core services and, as appropriate, supplemental services in comprehensive single-site projects, or to establish a well-integrated network of such services (appropriate for the target population and geographic area to be served including the special needs of rural areas) for pregnant adolescents or adolescent parents; or

(B) in the case of an applicant who will provide prevention services, of having the ability to provide prevention services for adolescents and their families which are appropriate for the target population and the geographic area to be served, including the special needs of rural areas;

(4) will utilize to the maximum extent feasible existing available programs and facilities such as neighborhood and primary health care centers, maternity homes which provide or can be equipped to provide services to pregnant adolescents, agencies serving families, youth, and children with established programs of service to pregnant adolescents and vulnerable families, licensed adoption agencies, children and youth centers, maternal and infant health centers, regional rural health facilities, school and other educational programs, mental health programs, nutrition programs, recreation programs, and other ongoing pregnancy prevention services and programs of care for pregnant adolescents and adolescent parents;

(5) make use, to the maximum extent feasible, of other Federal, State, and local funds, programs, contributions, and other third-party reimbursements;

(6) can demonstrate a community commitment to the program by making available to the demonstration project non-Federal funds, personnel, and facilities;

(7) have involved the community to be served, including public and private agencies, adolescents, and families, in the planning and implementation of the demonstration project; and

(8) will demonstrate innovative and effective approaches in addressing the problems of adolescent premarital sexual relations, pregnancy, or parenthood, including approaches to provide pregnant adolescents with adequate information about adoption.

(b) Factors to be considered in making grants; special needs of rural areas

(1) The amount of a grant for a demonstration project for services under this subchapter shall be

determined by the Secretary, based on factors such as the incidence of adolescent pregnancy in the geographic area to be served, and the adequacy of pregnancy prevention services and programs of care for pregnant adolescents and adolescent parents in such area.

(2) In making grants for demonstration projects for services under this subchapter, the Secretary shall consider the special needs of rural areas and, to the maximum extent practicable, shall distribute funds taking into consideration the relative number of adolescents in such areas in need of such services.

(c) Duration; Federal share

(1) A grantee may not receive funds for a demonstration project for services under this subchapter for a period in excess of 5 years.

(2)(A) Subject to paragraph (3), a grant for a demonstration project for services under this subchapter may not exceed—

(i) 70 per centum of the costs of the project for the first and second years of the project;

(ii) 60 per centum of such costs for the third year of the project;

(iii) 50 per centum of such costs for the fourth year of the project; and

(iv) 40 per centum of such costs for the fifth year of the project.

(B) Non-Federal contributions required by subparagraph (A) may be in cash or in kind, fairly evaluated, including plant, equipment, or services.

(3) The Secretary may waive the limitation specified in paragraph (2)(A) for any year in accordance with criteria established by regulation.

(July 1, 1944, ch. 373, title XX, §2005, as added Pub. L. 97–35, title IX, §955(a), Aug. 13, 1981, 95 Stat. 584.)

§300z–5. Requirements for applications

(a) Form, content, and assurances

An application for a grant for a demonstration project for services under this subchapter shall be in such form and contain such information as the Secretary may require, and shall include—

(1) an identification of the incidence of adolescent pregnancy and related problems;

(2) a description of the economic conditions and income levels in the geographic area to be served;

(3) a description of existing pregnancy prevention services and programs of care for pregnant adolescents and adolescent parents (including adoption services), and including where, how, by whom, and to which population groups such services are provided, and the extent to which they are coordinated in the geographic area to be served;

(4) a description of the major unmet needs for services for adolescents at risk of initial or recurrent pregnancies and an estimate of the number of adolescents not being served in the area;

(5)(A) in the case of an applicant who will provide care services, a description of how all core services will be provided in the demonstration project using funds under this subchapter or will otherwise be provided by the grantee in the area to be served, the population to which such services will be provided, how such services will be coordinated, integrated, and linked with other related programs and services and the source or sources of funding of such core services in the public and private sectors; or

(B) in the case of an applicant who will provide prevention services, a description of the necessary services to be provided and how the applicant will provide such services;

(6) a description of the manner in which adolescents needing services other than the services provided directly by the applicant will be identified and how access and appropriate referral to such other services (such as medicaid; licensed adoption agencies; maternity home services; public

assistance; employment services; child care services for adolescent parents; and other city, county, and State programs related to adolescent pregnancy) will be provided, including a description of a plan to coordinate such other services with the services supported under this subchapter;

(7) a description of the applicant's capacity to continue services as Federal funds decrease and in the absence of Federal assistance;

(8) a description of the results expected from the provision of services, and the procedures to be used for evaluating those results;

(9) a summary of the views of public agencies, providers of services, and the general public in the geographic area to be served, concerning the proposed use of funds provided for a demonstration project for services under this subchapter and a description of procedures used to obtain those views, and, in the case of applicants who propose to coordinate services administered by a State, the written comments of the appropriate State officials responsible for such services;

(10) assurances that the applicant will have an ongoing quality assurance program;

(11) assurances that, where appropriate, the applicant shall have a system for maintaining the confidentiality of patient records in accordance with regulations promulgated by the Secretary;

(12) assurances that the applicant will demonstrate its financial responsibility by the use of such accounting procedures and other requirements as may be prescribed by the Secretary;

(13) assurances that the applicant (A) has or will have a contractual or other arrangement with the agency of the State (in which the applicant provides services) that administers or supervises the administration of a State plan approved under title XIX of the Social Security Act [42 U.S.C. 1396 et seq.] for the payment of all or a part of the applicant's costs in providing health services to persons who are eligible for medical assistance under such a State plan, or (B) has made or will make every reasonable effort to enter into such an arrangement;

(14) assurances that the applicant has made or will make and will continue to make every reasonable effort to collect appropriate reimbursement for its costs in providing health services to persons who are entitled to benefits under title V of the Social Security Act [42 U.S.C. 701 et seq.], to medical assistance under a State plan approved under title XIX of such Act [42 U.S.C. 1396 et seq.], or to assistance for medical expenses under any other public assistance program or private health insurance program;

(15) assurances that the applicant has or will make and will continue to make every reasonable effort to collect appropriate reimbursement for its costs in providing services to persons entitled to services under parts B and E of title IV [42 U.S.C. 620 et seq., 670 et seq.] and title XX of the Social Security Act [42 U.S.C. 1397 et seq.];

(16)(A) a description of—

(i) the schedule of fees to be used in the provision of services, which shall comply with section 300z–3(c) of this title and which shall be designed to cover all reasonable direct and indirect costs incurred by the applicant in providing services; and

(ii) a corresponding schedule of discounts to be applied to the payment of such fees, which shall comply with section 300z–3(c) of this title and which shall be adjusted on the basis of the ability of the eligible person to pay;

(B) assurances that the applicant has made and will continue to make every reasonable effort—

(i) to secure from eligible persons payment for services in accordance with such schedules;

(ii) to collect reimbursement for health or other services provided to persons who are entitled to have payment made on their behalf for such services under any Federal or other government program or private insurance program; and

(iii) to seek such reimbursement on the basis of the full amount of fees for services without application of any discount; and

(C) assurances that the applicant has submitted or will submit to the Secretary such reports as the Secretary may require to determine compliance with this paragraph;

(17) assurances that the applicant will make maximum use of funds available under subchapter VIII of this chapter;

(18) assurances that the acceptance by any individual of family planning services or family planning information (including educational materials) provided through financial assistance under this subchapter shall be voluntary and shall not be a prerequisite to eligibility for or receipt of any other service furnished by the applicant;

(19) assurances that fees collected by the applicant for services rendered in accordance with this subchapter shall be used by the applicant to further the purposes of this subchapter;

(20) assurances that the applicant, if providing both prevention and care services will not exclude or discriminate against any adolescent who receives prevention services and subsequently requires care services as a pregnant adolescent;

(21) a description of how the applicant will, as appropriate in the provision of services—

(A) involve families of adolescents in a manner which will maximize the role of the family in the solution of problems relating to the parenthood or pregnancy of the adolescent;

(B) involve religious and charitable organizations, voluntary associations, and other groups in the private sector as well as services provided by publicly sponsored initiatives;

(22)(A) assurances that—

(i) except as provided in subparagraph (B) and subject to clause (ii), the applicant will notify the parents or guardians of any unemancipated minor requesting services from the applicant and, except as provided in subparagraph (C), will obtain the permission of such parents or guardians with respect to the provision of such services; and

(ii) in the case of a pregnant unemancipated minor requesting services from the applicant, the applicant will notify the parents or guardians of such minor under clause (i) within a reasonable period of time;

(B) assurances that the applicant will not notify or request the permission of the parents or guardian of any unemancipated minor without the consent of the minor—

(i) who solely is requesting from the applicant pregnancy testing or testing or treatment for venereal disease;

(ii) who is the victim of incest involving a parent; or

(iii) if an adult sibling of the minor or an adult aunt, uncle, or grandparent who is related to the minor by blood certifies to the grantee that notification of the parents or guardians of such minor would result in physical injury to such minor; and

(C) assurances that the applicant will not require, with respect to the provision of services, the permission of the parents or guardians of any pregnant unemancipated minor if such parents or guardians are attempting to compel such minor to have an abortion;

(23) assurances that primary emphasis for services supported under this subchapter shall be given to adolescents seventeen and under who are not able to obtain needed assistance through other means;

(24) assurances that funds received under this subchapter shall supplement and not supplant funds received from any other Federal, State, or local program or any private sources of funds; and

(25) a plan for the conduct of, and assurances that the applicant will conduct, evaluations of the effectiveness of the services supported under this subchapter in accordance with subsection (b).

(b) Evaluations: amount, conduct, and technical assistance

(1) Each grantee which receives funds for a demonstration project for services under this subchapter shall expend at least 1 per centum but not in excess of 5 per centum of the amounts received under this subchapter for the conduct of evaluations of the services supported under this subchapter. The Secretary may, for a particular grantee upon good cause shown, waive the provisions of the preceding sentence with respect to the amounts to be expended on evaluations, but may not waive the requirement that such evaluations be conducted.

(2) Evaluations required by paragraph (1) shall be conducted by an organization or entity which is independent of the grantee providing services supported under this subchapter. To assist in conducting the evaluations required by paragraph (1), each grantee shall develop a working

relationship with a college or university located in the grantee's State which will provide or assist in providing monitoring and evaluation of services supported under this subchapter unless no college or university in the grantee's State is willing or has the capacity to provide or assist in providing such monitoring and assistance.

(3) The Secretary may provide technical assistance with respect to the conduct of evaluations required under this subsection to any grantee which is unable to develop a working relationship with a college or university in the applicant's State for the reasons described in paragraph (2).

(c) Reports

Each grantee which receives funds for a demonstration project for services under this subchapter shall make such reports concerning its use of Federal funds as the Secretary may require. Reports shall include, at such times as are considered appropriate by the Secretary, the results of the evaluations of the services supported under this subchapter.

(d) Notification of parents; "adult" defined

(1) A grantee shall periodically notify the Secretary of the exact number of instances in which a grantee does not notify the parents or guardians of a pregnant unemancipated minor under subsection (a)(22)(B)(iii).

(2) For purposes of subsection (a)(22)(B)(iii), the term "adult" means an adult as defined by State law.

(e) Submission of applications to Governor; comments by Governor

Each applicant shall provide the Governor of the State in which the applicant is located a copy of each application submitted to the Secretary for a grant for a demonstration project for services under this subchapter. The Governor shall submit to the applicant comments on any such application within the period of sixty days beginning on the day when the Governor receives such copy. The applicant shall include the comments of the Governor with such application.

(f) Availability of core services

No application submitted for a grant for a demonstration project for care services under this subchapter may be approved unless the Secretary is satisfied that core services shall be available through the applicant within a reasonable time after such grant is received.

(July 1, 1944, ch. 373, title XX, §2006, as added Pub. L. 97–35, title IX, §955(a), Aug. 13, 1981, 95 Stat. 585.)

EDITORIAL NOTES

REFERENCES IN TEXT

The Social Security Act, referred to in subsec. (a)(13) to (15), is act Aug. 14, 1935, ch. 531, 49 Stat. 620. Parts B and E of title IV of the Social Security Act are classified generally to part B (§620 et seq.) and part E (§670 et seq.) of subchapter IV of chapter 7 of this title. Titles V, XIX, and XX of the Social Security Act are classified generally to subchapters V (§701 et seq.), XIX (§1396 et seq.), and XX (§1397 et seq.), respectively, of chapter 7 of this title. For complete classification of this Act to the Code, see section 1305 of this title and Tables.

§300z–6. Coordination of programs

(a) The Secretary shall coordinate Federal policies and programs providing services relating to the prevention of adolescent sexual relations and initial and recurrent adolescent pregnancies and providing care services for pregnant adolescents. In achieving such coordination, the Secretary shall—

(1) require grantees who receive funds for demonstration projects for services under this subchapter to report periodically to the Secretary concerning Federal, State, and local policies and programs that interfere with the delivery of and coordination of pregnancy prevention services and

other programs of care for pregnant adolescents and adolescent parents;

(2) provide technical assistance to facilitate coordination by State and local recipients of Federal assistance;

(3) review all programs administered by the Department of Health and Human Services which provide prevention services or care services to determine if the policies of such programs are consistent with the policies of this subchapter, consult with other departments and agencies of the Federal Government who administer programs that provide such services, and encourage such other departments and agencies to make recommendations, as appropriate, for legislation to modify such programs in order to facilitate the use of all Government programs which provide such services as a basis for delivery of more comprehensive prevention services and more comprehensive programs of care for pregnant adolescents and adolescent parents;

(4) give priority in the provision of funds, where appropriate, to applicants using single or coordinated grant applications for multiple programs; and

(5) give priority, where appropriate, to the provision of funds under Federal programs administered by the Secretary (other than the program established by this subchapter) to projects providing comprehensive prevention services and comprehensive programs of care for pregnant adolescents and adolescent parents.

(b) Any recipient of a grant for a demonstration project for services under this subchapter shall coordinate its activities with any other recipient of such a grant which is located in the same locality.

(July 1, 1944, ch. 373, title XX, §2007, as added Pub. L. 97–35, title IX, §955(a), Aug. 13, 1981, 95 Stat. 589.)

§300z–7. Research

(a) Grants and contracts; duration; renewal; amount

(1) The Secretary may make grants and enter into contracts with public agencies or private organizations or institutions of higher education to support the research and dissemination activities described in paragraphs (4), (5), and (6) of section 300z(b) of this title.

(2) The Secretary may make grants or enter into contracts under this section for a period of one year. A grant or contract under this section for a project may be renewed for four additional one-year periods, which need not be consecutive.

(3) A grant or contract for any one-year period under this section may not exceed $100,000 for the direct costs of conducting research or disemination [1] activities under this section and may include such additional amounts for the indirect costs of conducting such activities as the Secretary determines appropriate. The Secretary may waive the preceding sentence with respect to a specific project if he determines that—

(A) exceptional circumstances warrant such waiver and that the project will have national impact; or

(B) additional amounts are necessary for the direct costs of conducting limited demonstration projects for the provision of necessary services in order to provide data for research carried out under this subchapter.

(4) The amount of any grant or contract made under this section may remain available for obligation or expenditure after the close of the one-year period for which such grant or contract is made in order to assist the recipient in preparing the report required by subsection (f)(1).

(b) Scope of permissible activities

(1) Funds provided for research under this section may be used for descriptive or explanatory surveys, longitudinal studies, or limited demonstration projects for services that are for the purpose of increasing knowledge and understanding of the matters described in paragraphs (4) and (5) of section 300z(b) of this title.

(2) Funds provided under this section may not be used for the purchase or improvement of land, or the purchase, construction, or permanent improvement (other than minor remodeling) of any building or facility.

(c) Applications

The Secretary may not make any grant or enter into any contract to support research or dissemination activities under this section unless—

(1) the Secretary has received an application for such grant or contract which is in such form and which contains such information as the Secretary may by regulation require;

(2) the applicant has demonstrated that the applicant is capable of conducting one or more of the types of research or dissemination activities described in paragraph (4), (5), or (6) of section 300z(b) of this title; and

(3) in the case of an application for a research project, the panel established by subsection (e)(2) has determined that the project is of scientific merit.

(d) Coordination with National Institutes of Health

The Secretary shall, where appropriate, coordinate research and dissemination activities carried out under this section with research and dissemination activities carried out by the National Institutes of Health.

(e) Review of applications for grants and contracts; establishment of review panel

(1) The Secretary shall establish a system for the review of applications for grants and contracts under this section. Such system shall be substantially similar to the system for scientific peer review of the National Institutes of Health and shall meet the requirements of paragraphs (2) and (3).

(2) In establishing the system required by paragraph (1), the Secretary shall establish a panel to review applications under this section. Not more than 25 per centum of the members of the panel shall be physicians. The panel shall meet as often as may be necessary to facilitate the expeditious review of applications under this section, but not less than once each year. The panel shall review each project for which an application is made under this section, evaluate the scientific merit of the project, determine whether the project is of scientific merit, and make recommendations to the Secretary concerning whether the application for the project should be approved.

(3) The Secretary shall make grants under this section from among the projects which the panel established by paragraph (2) has determined to be of scientific merit and may only approve an application for a project if the panel has made such determination with respect to such a project. The Secretary shall make a determination with respect to an application within one month after receiving the determinations and recommendations of such panel with respect to the application.

(f) Reports

(1)(A) The recipient of a grant or contract for a research project under this section shall prepare and transmit to the Secretary a report describing the results and conclusions of such research. Except as provided in subparagraph (B), such report shall be transmitted to the Secretary not later than eighteen months after the end of the year for which funds are provided under this section. The recipient may utilize reprints of articles published or accepted for publication in professional journals to supplement or replace such report if the research contained in such articles was supported under this section during the year for which the report is required.

(B) In the case of any research project for which assistance is provided under this section for two or more consecutive one-year periods, the recipient of such assistance shall prepare and transmit the report required by subparagraph (A) to the Secretary not later than twelve months after the end of each one-year period for which such funding is provided.

(2) Recipients of grants and contracts for dissemination under this section shall submit to the Secretary such reports as the Secretary determines appropriate.

(July 1, 1944, ch. 373, title XX, §2008, as added Pub. L. 97–35, title IX, §955(a), Aug. 13, 1981, 95 Stat. 589; amended Pub. L. 98–512, §2(e), Oct. 19, 1984, 98 Stat. 2409.)

EDITORIAL NOTES

AMENDMENTS

1984—Subsec. (g). Pub. L. 98–512 struck out subsec. (g) which provided for collection of survey data used primarily for generation of national population estimates.

[1] *So in original. Probably should be "dissemination".*

§300z–8. Evaluation and administration

(a) Of the funds appropriated under this subchapter, the Secretary shall reserve not less than 1 per centum and not more than 3 per centum for the evaluation of activities carried out under this subchapter. The Secretary shall submit to the appropriate committees of the Congress a summary of each evaluation conducted under this section.

(b) The officer or employee of the Department of Health and Human Services designated by the Secretary to carry out the provisions of this subchapter shall report directly to the Assistant Secretary for Health with respect to the activities of such officer or employee in carrying out such provisions.

(July 1, 1944, ch. 373, title XX, §2009, as added Pub. L. 97–35, title IX, §955(a), Aug. 13, 1981, 95 Stat. 591.)

§300z–9. Authorization of appropriations

(a) For the purpose of carrying out this subchapter, there are authorized to be appropriated $30,000,000 for the fiscal year ending September 30, 1982, $30,000,000 for the fiscal year ending September 30, 1983, $30,000,000 for the fiscal year ending September 30, 1984, and $30,000,000 for the fiscal year ending September 30, 1985.

(b) At least two-thirds of the amounts appropriated to carry out this subchapter shall be used to make grants for demonstration projects for services.

(c) Not more than one-third of the amounts specified under subsection (b) for use for grants for demonstration projects for services shall be used for grants for demonstration projects for prevention services.

(July 1, 1944, ch. 373, title XX, §2010, as added Pub. L. 97–35, title IX, §955(a), Aug. 13, 1981, 95 Stat. 591; amended Pub. L. 98–512, §2(a), Oct. 19, 1984, 98 Stat. 2409.)

EDITORIAL NOTES

AMENDMENTS

1984—Subsec. (a). Pub. L. 98–509 inserted provisions authorizing appropriations for fiscal year ending Sept. 30, 1985.

§300z–10. Restrictions

(a) Grants or payments may be made only to programs or projects which do not provide abortions or abortion counseling or referral, or which do not subcontract with or make any payment to any person who provides abortions or abortion counseling or referral, except that any such program or project may provide referral for abortion counseling to a pregnant adolescent if such adolescent and the parents or guardians of such adolescent request such referral; and grants may be made only to projects or programs which do not advocate, promote, or encourage abortion.

(b) The Secretary shall ascertain whether programs or projects comply with subsection (a) and take appropriate action if programs or projects do not comply with such subsection, including withholding of funds.

(July 1, 1944, ch. 373, title XX, §2011, as added Pub. L. 97–35, title IX, §955(a), Aug. 13, 1981, 95 Stat. 592.)

SUBCHAPTER XIX—VACCINES

EDITORIAL NOTES

PRIOR PROVISIONS

A prior subchapter XIX (§300aa et seq.), comprised of title XXI of the Public Health Service Act, act July 1, 1944, ch. 373, §§2101 to 2116, was renumbered title XXIII, §§2301 to 2316, of the Public Health Service Act, and transferred to subchapter XXI (§300cc et seq.) of this chapter, renumbered title XXV, §§2501 to 2514, of the Public Health Service Act, and transferred to subchapter XXV (§300aaa et seq.) of this chapter, renumbered title XXVI, §§2601 to 2614, of the Public Health Service Act, renumbered title XXVII, §§2701 to 2714, of the Public Health Service Act, and renumbered title II, part B, §§231 to 244, of the Public Health Service Act, and transferred to part B (§238 et seq.) of subchapter I of this chapter.

PART 1—NATIONAL VACCINE PROGRAM

§300aa–1. Establishment

The Secretary shall establish in the Department of Health and Human Services a National Vaccine Program to achieve optimal prevention of human infectious diseases through immunization and to achieve optimal prevention against adverse reactions to vaccines. The Program shall be administered by a Director selected by the Secretary.

(July 1, 1944, ch. 373, title XXI, §2101, as added Pub. L. 99–660, title III, §311(a), Nov. 14, 1986, 100 Stat. 3756.)

EDITORIAL NOTES

PRIOR PROVISIONS

A prior section 300aa–1, act July 1, 1944, §2102, was successively renumbered by subsequent acts and transferred, see section 238a of this title.

A prior section 2101 of act July 1, 1944, was successively renumbered by subsequent acts and transferred, see section 238 of this title.

STATUTORY NOTES AND RELATED SUBSIDIARIES

EFFECTIVE DATE

Pub. L. 99–660, title III, §323, Nov. 14, 1986, 100 Stat. 3784, as amended by Pub. L. 100–203, title IV, §4302(a), Dec. 22, 1987, 101 Stat. 1330–221; Pub. L. 102–168, title II, §201(a), Nov. 26, 1991, 105 Stat. 1102, provided that: "Subtitle 1 of title XXI of the Public Health Service Act [42 U.S.C. 300aa–1 et seq.] shall take effect on the date of the enactment of this Act [Nov. 14, 1986] and parts A and B of subtitle 2 of such title [42 U.S.C. 300aa–10 et seq., 300aa–21 et seq.] shall take effect on October 1, 1988 and parts C and D of such title [42 U.S.C. 300aa–25 et seq., 300aa–31 et seq.] and this title [probably means provisions of title III of Pub. L. 99–660 other than those that enacted this subchapter and redesignated former sections 300aa to 300aa–15 of this title as sections 300cc to 300cc–15 of this title; these other provisions amended sections 218, 242c, 262, 286, and 289f of this title and enacted provisions set out as notes under sections 201, 300aa–1, and 300aa–4 of this title] shall take effect on the date of the enactment of the Vaccine Compensation Amendments of 1987 [Dec. 22, 1987]."

SEVERABILITY

Pub. L. 99–660, title III, §322, Nov. 14, 1986, 100 Stat. 3783, as amended by Pub. L. 101–239, title VI, §6602, Dec. 19, 1989, 103 Stat. 2293; Pub. L. 101–502, §5(g)(1), Nov. 3, 1990, 104 Stat. 1288, provided that:

"(a) IN GENERAL.—Except as provided in subsection (b), if any provision [of] part A or B of subtitle 2 of title XXI of the Public Health Service Act [42 U.S.C. 300aa–10 et seq., 300aa–21 et seq.], as added by section 311(a), or the application of such a provision to any person or circumstance is held invalid by reason of a violation of the Constitution, both such parts shall be considered invalid.

"(b) SPECIAL RULE.—If any amendment made by section 6601 of the Omnibus Budget Reconciliation Act of 1989 [Pub. L. 101–239, amending sections 300aa–10 to 300aa–17, 300aa–21, 300aa–23, 300aa–26, and 300aa–27 of this title] to title XXI of the Public Health Service Act [42 U.S.C. 300aa–1 et seq.] or the application of such a provision to any person or circumstance is held invalid by reason of the Constitution, subsection (a) shall not apply and such title XXI of the Public Health Service Act without such amendment shall continue in effect."

[Amendment by section 5(g)(1) of Pub. L. 101–502 to section 322(a) of Pub. L. 99–660, set out above, effective Nov. 14, 1986, see section 5(h) of Pub. L. 101–502, set out as an Effective Date of 1990 Amendment note under section 300aa–11 of this title.]

EVALUATION OF PROGRAM; STUDY AND REPORT TO CONGRESS

Pub. L. 101–239, title VI, §6601(t), Dec. 19, 1989, 103 Stat. 2293, as amended by Pub. L. 102–168, title II, §201(b), Nov. 26, 1991, 105 Stat. 1103, directed the Secretary of Health and Human Services to evaluate the National Vaccine Injury Compensation Program under this subchapter and report results of such study to Committee on Energy and Commerce of House of Representatives and Committee on Labor and Human Resources of Senate not later than Jan. 1, 1993.

RELATED STUDIES

Pub. L. 99–660, title III, §312, Nov. 14, 1986, 100 Stat. 3779, directed Secretary of Health and Human Services, not later than 3 years after the effective date of this title (see Effective Date note above), to conduct, through studies by the Institute of Medicine of the National Academy of Sciences or other appropriate nonprofit private groups or associations, a review of pertussis vaccines and related illnesses and conditions and MMR vaccines, vaccines containing material intended to prevent or confer immunity against measles, mumps, and rubella disease, and related illnesses and conditions, make specific findings and report these findings in the Federal Register not later than 3 years after the effective date of this title, and at the same time these findings are published in the Federal Register, propose regulations as a result of such findings, and not later than 42 months after the effective date of this title, promulgate such proposed regulations with such modifications as may be necessary after opportunity for public hearing.

STUDY OF OTHER VACCINE RISKS

Pub. L. 99–660, title III, §313, Nov. 14, 1986, 100 Stat. 3781, provided that:

"(a) STUDY.—

"(1) Not later than 3 years after the effective date of this title [see Effective Date note above], the Secretary shall, after consultation with the Advisory Commission on Childhood Vaccines established under section 2119 of the Public Health Service Act [42 U.S.C. 300aa–19]—

"(A) arrange for a broad study of the risks (other than the risks considered under section 102 [21 U.S.C. 382]) to children associated with each vaccine set forth in the Vaccine Injury Table under section 2114 of such Act [42 U.S.C. 300aa–14], and

"(B) establish guidelines, after notice and opportunity for public hearing and consideration of all relevant medical and scientific information, respecting the administration of such vaccines which shall include—

"(i) the circumstances under which any such vaccine should not be administered,

"(ii) the circumstances under which administration of any such vaccine should be delayed beyond its usual time of administration, and

"(iii) the groups, categories, or characteristics of potential recipients of such vaccine who may be at significantly higher risk of major adverse reactions to such vaccine than the general population of potential recipients.

"(2)(A) The Secretary shall request the Institute of Medicine of the National Academy of Sciences to conduct the study required by paragraph (1) under an arrangement by which the actual expenses incurred by such Academy in conducting such study will be paid by the Secretary.

"(B) If the Institute of Medicine is unwilling to conduct such study under such an arrangement, the Secretary shall enter into a similar arrangement with other appropriate nonprofit private groups or

associations under which such groups or associations will conduct such study.

"(C) The Institute of Medicine or other group or association conducting the study required by paragraph (1) shall conduct such studies in consultation with the Advisory Commission on Childhood Vaccines established under section 2119 of the Public Health Service Act [42 U.S.C. 300aa–19].

"(b) REVISION OF GUIDELINES.—The Secretary shall periodically, but at least every 3 years after establishing guidelines under subsection (a), review and revise such guidelines after notice and opportunity for public hearing and consideration of all relevant medical and scientific information, unless the Secretary finds that on the basis of all relevant information no revision of such guidelines is warranted and publishes such finding in the Federal Register.

"(c) FACTORS AFFECTING GUIDELINES.—Guidelines under subsection (a) shall take into account—

"(1) the risk to potential recipients of the vaccines with respect to which the guidelines are established,

"(2) the medical and other characteristics of such potential recipients, and

"(3) the risks to the public of not having such vaccines administered.

"(d) DISSEMINATION.—The Secretary shall widely disseminate the guidelines established under subsection (a) to—

"(1) physicians and other health care providers,

"(2) professional health associations,

"(3) State and local governments and agencies, and

"(4) other relevant entities."

REVIEW OF WARNINGS, USE INSTRUCTIONS, AND PRECAUTIONARY INFORMATION

Pub. L. 99–660, title III, §314, Nov. 14, 1986, 100 Stat. 3782, directed Secretary of Health and Human Services, not later than 1 year after the effective date of this title (see Effective Date note above) and after consultation with Advisory Commission on Childhood Vaccines and with other appropriate entities, to review the warnings, use instructions, and precautionary information presently issued by manufacturers of vaccines set forth in the Vaccine Injury Table set out in section 300aa–14 of this title and by rule determine whether such warnings, instructions, and information adequately warn health care providers of the nature and extent of dangers posed by such vaccines, and, if any such warning, instruction, or information is determined to be inadequate for such purpose in any respect, require at the same time that the manufacturers revise and reissue such warning, instruction, or information as expeditiously as practical, but not later than 18 months after the effective date of this title.

STUDY OF IMPACT ON SUPPLY OF VACCINES

Pub. L. 99–660, title III, §316, Nov. 14, 1986, 100 Stat. 3786, provided that: "On June 30, 1987, and on June 30 of each second year thereafter, the Secretary of Health and Human Services shall submit to the Committee on Energy and Commerce of the House of Representatives and the Committee on Labor and Human Resources [now Committee on Health, Education, Labor, and Pensions] of the Senate—

"(1) an assessment of the impact of the amendments made by this title [enacting this subchapter, amending sections 218, 242c, 262, 286, and 289f of this title, redesignating former sections 300aa to 300aa–15 of this title as sections 300cc to 300cc–15 of this title, and enacting provisions set out as notes under this section and sections 201 and 300aa–1 of this title] on the supply of vaccines listed in the Vaccine Injury Table under section 2114 of the Public Health Service Act [42 U.S.C. 300aa–14], and

"(2) an assessment of the ability of the administrators of vaccines (including public clinics and private administrators) to provide such vaccines to children."

WAIVER OF PAPERWORK REDUCTION

Pub. L. 99–660, title III, §321, Nov. 14, 1986, 100 Stat. 3783, provided that: "Chapter 35 of title 44, United States Code, shall not apply to information required for purposes of carrying out this title and implementing the amendments made by this title [enacting this subchapter, amending sections 218, 242c, 262, 286, and 289f of this title, redesignating former sections 300aa to 300aa–15 of this title as sections 300cc to 300cc–15 of this title, and enacting provisions set out as notes under sections 201, 300aa–1, and 300aa–4 of this title]."

§300aa–2. Program responsibilities

(a) The Director of the Program shall have the following responsibilities:

(1) Vaccine research

The Director of the Program shall, through the plan issued under section 300aa–3 of this title,

coordinate and provide direction for research carried out in or through the National Institutes of Health, the Centers for Disease Control and Prevention, the Office of Biologics Research and Review of the Food and Drug Administration, the Department of Defense, and the Agency for International Development on means to induce human immunity against naturally occurring infectious diseases and to prevent adverse reactions to vaccines.

(2) Vaccine development

The Director of the Program shall, through the plan issued under section 300aa–3 of this title, coordinate and provide direction for activities carried out in or through the National Institutes of Health, the Office of Biologics Research and Review of the Food and Drug Administration, the Department of Defense, and the Agency for International Development to develop the techniques needed to produce safe and effective vaccines.

(3) Safety and efficacy testing of vaccines

The Director of the Program shall, through the plan issued under section 300aa–3 of this title, coordinate and provide direction for safety and efficacy testing of vaccines carried out in or through the National Institutes of Health, the Centers for Disease Control and Prevention, the Office of Biologics Research and Review of the Food and Drug Administration, the Department of Defense, and the Agency for International Development.

(4) Licensing of vaccine manufacturers and vaccines

The Director of the Program shall, through the plan issued under section 300aa–3 of this title, coordinate and provide direction for the allocation of resources in the implementation of the licensing program under section 263a of this title.

(5) Production and procurement of vaccines

The Director of the Program shall, through the plan issued under section 300aa–3 of this title, ensure that the governmental and non-governmental production and procurement of safe and effective vaccines by the Public Health Service, the Department of Defense, and the Agency for International Development meet the needs of the United States population and fulfill commitments of the United States to prevent human infectious diseases in other countries.

(6) Distribution and use of vaccines

The Director of the Program shall, through the plan issued under section 300aa–3 of this title, coordinate and provide direction to the Centers for Disease Control and Prevention and assistance to States, localities, and health practitioners in the distribution and use of vaccines, including efforts to encourage public acceptance of immunizations and to make health practitioners and the public aware of potential adverse reactions and contraindications to vaccines.

(7) Evaluating the need for and the effectiveness and adverse effects of vaccines and immunization activities

The Director of the Program shall, through the plan issued under section 300aa–3 of this title, coordinate and provide direction to the National Institutes of Health, the Centers for Disease Control and Prevention, the Office of Biologics Research and Review of the Food and Drug Administration, the National Center for Health Statistics, the National Center for Health Services Research and Health Care Technology Assessment, and the Centers for Medicare & Medicaid Services in monitoring the need for and the effectiveness and adverse effects of vaccines and immunization activities.

(8) Coordinating governmental and non-governmental activities

The Director of the Program shall, through the plan issued under section 300aa–3 of this title, provide for the exchange of information between Federal agencies involved in the implementation of the Program and non-governmental entities engaged in the development and production of vaccines and in vaccine research and encourage the investment of non-governmental resources complementary to the governmental activities under the Program.

(9) Funding of Federal agencies

The Director of the Program shall make available to Federal agencies involved in the implementation of the plan issued under section 300aa–3 of this title funds appropriated under section 300aa–6 of this title to supplement the funds otherwise available to such agencies for activities under the plan.

(b) In carrying out subsection (a) and in preparing the plan under section 300aa–3 of this title, the Director shall consult with all Federal agencies involved in research on and development, testing, licensing, production, procurement, distribution, and use of vaccines.

(July 1, 1944, ch. 373, title XXI, §2102, as added Pub. L. 99–660, title III, §311(a), Nov. 14, 1986, 100 Stat. 3756; amended Pub. L. 102–531, title III, §312(d)(13), Oct. 27, 1992, 106 Stat. 3505; Pub. L. 108–173, title IX, §900(e)(2)(F), Dec. 8, 2003, 117 Stat. 2372.)

EDITORIAL NOTES

PRIOR PROVISIONS

A prior section 300aa–2, act July 1, 1944, §2103, was successively renumbered by subsequent acts and transferred, see section 238b of this title.

A prior section 2102 of act July 1, 1944, was successively renumbered by subsequent acts and transferred, see section 238a of this title.

AMENDMENTS

2003—Subsec. (a)(7). Pub. L. 108–173 substituted "Centers for Medicare & Medicaid Services" for "Health Care Financing Administration".

1992—Subsec. (a)(1), (3), (6), (7). Pub. L. 102–531 substituted "Centers for Disease Control and Prevention" for "Centers for Disease Control".

STATUTORY NOTES AND RELATED SUBSIDIARIES

ENCOURAGING VACCINE INNOVATION; MEETINGS

Pub. L. 114–255, div. A, title III, §3093(a), Dec. 13, 2016, 130 Stat. 1151, provided that: "The Director of the Centers for Disease Control and Prevention shall ensure that appropriate staff within the relevant centers and divisions of the Office of Infectious Diseases, and others, as appropriate, coordinate with respect to the public health needs, epidemiology, and program planning and implementation considerations related to immunization, including with regard to meetings with stakeholders related to such topics."

GRANTS FOR RESEARCH ON VACCINE AGAINST VALLEY FEVER

Pub. L. 109–432, div. B, title IV, §402, Dec. 20, 2006, 120 Stat. 2994, authorized the Secretary of Health and Human Services to make grants for research on the development of a vaccine against coccidioidomycosis (commonly known as Valley Fever) before Oct. 1, 2012.

DEMONSTRATION PROJECTS FOR OUTREACH PROGRAMS

Pub. L. 101–502, §2(b), Nov. 3, 1990, 104 Stat. 1285, provided that:

"(1) IN GENERAL.—The Secretary of Health and Human Services, acting through the Director of the Centers for Disease Control, may make grants to public and nonprofit private entities for the purpose of carrying out demonstration projects—

"(A) to provide, without charge, immunizations against vaccine-preventable diseases to children not more than 2 years of age who reside in communities whose population includes a significant number of low-income individuals; and

"(B) to provide outreach services to identify such children and to inform the parents (or other guardians) of the children of the availability from the entities of the immunizations specified in subparagraph (A).

"(2) AUTHORIZATION OF APPROPRIATIONS.—For the purpose of carrying out paragraph (1), there are authorized to be appropriated such sums as may be necessary for each of the fiscal years 1991 through 1993."

[Centers for Disease Control changed to Centers for Disease Control and Prevention by Pub. L. 102–531, title III, §312, Oct. 27, 1992, 106 Stat. 3504.]

SUPPLY OF VACCINES

Pub. L. 101–502, §3, Nov. 3, 1990, 104 Stat. 1285, provided that:

"(a) IN GENERAL.—The Secretary of Health and Human Services, acting through the Director of the Centers for Disease Control, shall acquire and maintain a supply of vaccines sufficient to provide vaccinations throughout a 6-month period. Any proceeds received by the Secretary from the sale of vaccines from such supply shall be available to the Secretary for the purpose of purchasing vaccines for the supply. Such proceeds shall remain available for such purpose until expended.

"(b) AUTHORIZATION OF APPROPRIATIONS.—For the purpose of carrying out subsection (a), there are authorized to be appropriated $5,000,000 for fiscal year 1991, and such sums as may be necessary for each of the fiscal years 1992 through 1995."

[Centers for Disease Control changed to Centers for Disease Control and Prevention by Pub. L. 102–531, title III, §312, Oct. 27, 1992, 106 Stat. 3504.]

Pub. L. 100–177, title I, §110(b), Dec. 1, 1987, 101 Stat. 991, provided that:

"(1) IN GENERAL.—The Secretary of Health and Human Services, acting through the Director of the Centers for Disease Control, shall acquire and maintain a supply of vaccines sufficient to provide vaccinations throughout a 6-month period.

"(2) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated to carry out paragraph (1) $5,000,000 for fiscal year 1988, and such sums as may be necessary for each of the fiscal years 1989 and 1990."

[Centers for Disease Control changed to Centers for Disease Control and Prevention by Pub. L. 102–531, title III, §312, Oct. 27, 1992, 106 Stat. 3504.]

§300aa–3. Plan

The Director of the Program shall prepare and issue a plan for the implementation of the responsibilities of the Director under section 300aa–2 of this title. The plan shall establish priorities in research and the development, testing, licensing, production, procurement, distribution, and effective use of vaccines, describe an optimal use of resources to carry out such priorities, and describe how each of the various departments and agencies will carry out their vaccine functions in consultation and coordination with the Program and in conformity with such priorities. The first plan under this section shall be prepared not later than January 1, 1987, and shall be revised not later than January 1 of each succeeding year.

(July 1, 1944, ch. 373, title XXI, §2103, as added Pub. L. 99–660, title III, §311(a), Nov. 14, 1986, 100 Stat. 3757.)

EDITORIAL NOTES

PRIOR PROVISIONS

A prior section 300aa–3, act July 1, 1944, §2104, which was renumbered section 2304 by Pub. L. 99–660, was transferred to section 300cc–3 of this title, prior to repeal by Pub. L. 98–621, §10(s), Nov. 8, 1984, 98 Stat. 3381.

A prior section 2103 of act July 1, 1944, was successively renumbered by subsequent acts and transferred, see section 238b of this title.

§300aa–4. Repealed. Pub. L. 105–362, title VI, §601(a)(1)(H), Nov. 10, 1998, 112 Stat. 3285

Section, act July 1, 1944, ch. 373, title XXI, §2104, as added Pub. L. 99–660, title III, §311(a), Nov. 14, 1986, 100 Stat. 3757, related to national vaccine program report.

A prior section 300aa–4, act July 1, 1944, §2105, was repealed by Pub. L. 99–117, §12(f), Oct. 7, 1985, 99 Stat. 495. See section 300cc–4 of this title.

A prior section 2104 of act July 1, 1944, was renumbered section 2304 by Pub. L. 99–660 and classified to section 300cc–3 of this title, and was repealed by Pub. L. 98–621, §10(s), Nov. 8, 1984, 98 Stat. 3381.

§300aa–5. National Vaccine Advisory Committee

(a) There is established the National Vaccine Advisory Committee. The members of the Committee shall be appointed by the Director of the Program, in consultation with the National Academy of Sciences, from among individuals who are engaged in vaccine research or the manufacture of vaccines or who are physicians, members of parent organizations concerned with immunizations, or representatives of State or local health agencies or public health organizations.

(b) The Committee shall—

(1) study and recommend ways to encourage the availability of an adequate supply of safe and effective vaccination products in the States,

(2) recommend research priorities and other measures the Director of the Program should take to enhance the safety and efficacy of vaccines,

(3) advise the Director of the Program in the implementation of sections 300aa–2, 300aa–3, and 300aa–4 [1] of this title, and

(4) identify annually for the Director of the Program the most important areas of government and non-government cooperation that should be considered in implementing sections 300aa–2, 300aa–3, and 300aa–4 [1] of this title.

(July 1, 1944, ch. 373, title XXI, §2105, as added Pub. L. 99–660, title III, §311(a), Nov. 14, 1986, 100 Stat. 3758.)

EDITORIAL NOTES

REFERENCES IN TEXT

Section 300aa–4 of this title, referred to in subsec. (b)(3), (4), was repealed by Pub. L. 105–362, title VI, §601(a)(1)(H), Nov. 10, 1998, 112 Stat. 3285.

PRIOR PROVISIONS

A prior section 300aa–5, act July 1, 1944, §2106, was successively renumbered by subsequent acts and transferred, see section 238c of this title.

A prior section 2105 of act July 1, 1944, was repealed by Pub. L. 99–117, §12(f), Oct. 7, 1985, 99 Stat. 495. See section 300cc–4 of this title.

STATUTORY NOTES AND RELATED SUBSIDIARIES

TERMINATION OF ADVISORY COMMITTEES

Advisory committees established after Jan. 5, 1973, to terminate not later than the expiration of the 2-year period beginning on the date of their establishment, unless, in the case of a committee established by the President or an officer of the Federal Government, such committee is renewed by appropriate action prior to the expiration of such 2-year period, or in the case of a committee established by the Congress, its duration is otherwise provided by law. See section 1013 of Title 5, Government Organization and Employees.

Pub. L. 93–641, §6, Jan. 4, 1975, 88 Stat. 2275, set out as a note under section 217a of this title, provided that an advisory committee established pursuant to the Public Health Service Act shall terminate at such time as may be specifically prescribed by an Act of Congress enacted after Jan. 4, 1975.

[1] *See References in Text note below.*

§300aa–6. Authorization of appropriations

(a) To carry out this part other than section 300aa–2(9) of this title there are authorized to be appropriated such sums as may be necessary for each of the fiscal years 2004 and 2005.

(b) To carry out section 300aa–2(9) of this title there are authorized to be appropriated such sums as may be necessary for each of the fiscal years 2004 and 2005.

(July 1, 1944, ch. 373, title XXI, §2106, as added Pub. L. 99–660, title III, §311(a), Nov. 14, 1986,

100 Stat. 3758; amended Pub. L. 101–502, §4, Nov. 3, 1990, 104 Stat. 1286; Pub. L. 108–276, §2(c), July 21, 2004, 118 Stat. 842.)

EDITORIAL NOTES

PRIOR PROVISIONS

A prior section 300aa–6, act July 1, 1944, §2107, was successively renumbered by subsequent acts and transferred, see section 238d of this title.

A prior section 2106 of act July 1, 1944, was successively renumbered by subsequent acts and transferred, see section 238c of this title.

Prior sections 300aa–7 to 300aa–9, act July 1, 1944, §§2108–2110, respectively, were successively renumbered by subsequent acts and transferred, see sections 238e to 238g, respectively, of this title.

AMENDMENTS

2004—Pub. L. 108–276 substituted provisions authorizing appropriations for fiscal years 2004 and 2005 for provisions authorizing appropriations for fiscal years 1991 through 1995 in subsecs. (a) and (b).

1990—Pub. L. 101–502 substituted provisions authorizing appropriations for fiscal years 1991 through 1995 for provisions authorizing appropriations for fiscal years 1987 through 1991 in subsecs. (a) and (b).

PART 2—NATIONAL VACCINE INJURY COMPENSATION PROGRAM

SUBPART A—PROGRAM REQUIREMENTS

§300aa–10. Establishment of program

(a) Program established

There is established the National Vaccine Injury Compensation Program to be administered by the Secretary under which compensation may be paid for a vaccine-related injury or death.

(b) Attorney's obligation

It shall be the ethical obligation of any attorney who is consulted by an individual with respect to a vaccine-related injury or death to advise such individual that compensation may be available under the program [1] for such injury or death.

(c) Publicity

The Secretary shall undertake reasonable efforts to inform the public of the availability of the Program.

(July 1, 1944, ch. 373, title XXI, §2110, as added Pub. L. 99–660, title III, §311(a), Nov. 14, 1986, 100 Stat. 3758; amended Pub. L. 101–239, title VI, §6601(b), Dec. 19, 1989, 103 Stat. 2285.)

EDITORIAL NOTES

PRIOR PROVISIONS

A prior section 300aa–10, act July 1, 1944, §2111, was successively renumbered by subsequent acts and transferred, see section 238h of this title.

A prior section 2110 of act July 1, 1944, was successively renumbered by subsequent acts and transferred, see section 238g of this title.

AMENDMENTS

1989—Subsec. (c). Pub. L. 101–239 added subsec. (c).

STATUTORY NOTES AND RELATED SUBSIDIARIES

EFFECTIVE DATE OF 1989 AMENDMENT

Section 6601(s) of Pub. L. 101–239, as amended by Pub. L. 102–572, title IX, §902(b)(1), Oct. 29, 1992, 106 Stat. 4516, provided that:

"(1) Except as provided in paragraph (2), the amendments made by this section [amending this section and sections 300aa–11 to 300aa–17, 300aa–21, 300aa–23, 300aa–26, and 300aa–27 of this title] shall apply as follows:

"(A) Petitions filed after the date of enactment of this section [Dec. 19, 1989] shall proceed under the National Vaccine Injury Compensation Program under title XXI of the Public Health Service Act [42 U.S.C. 300aa–1 et seq.] as amended by this section.

"(B) Petitions currently pending in which the evidentiary record is closed shall continue to proceed under the Program in accordance with the law in effect before the date of the enactment of this section, except that if the United States Court of Federal Claims is to review the findings of fact and conclusions of law of a special master on such a petition, the court may receive further evidence in conducting such review.

"(C) Petitions currently pending in which the evidentiary record is not closed shall proceed under the Program in accordance with the law as amended by this section.

All pending cases which will proceed under the Program as amended by this section shall be immediately suspended for 30 days to enable the special masters and parties to prepare for proceeding under the Program as amended by this section. In determining the 240-day period prescribed by section 2112(d) of the Public Health Service Act [42 U.S.C. 300aa–12(d)], as amended by this section, or the 420-day period prescribed by section 2121(b) of such Act [42 U.S.C. 300aa–21(b)], as so amended, any period of suspension under the preceding sentence shall be excluded.

"(2) The amendments to section 2115 of the Public Health Service Act [42 U.S.C. 300aa–15] shall apply to all pending and subsequently filed petitions."

EFFECTIVE DATE

Subpart effective Oct. 1, 1988, see section 323 of Pub. L. 99–660, as amended, set out as a note under section 300aa–1 of this title.

[1] *So in original. Probably should be capitalized.*

§300aa–11. Petitions for compensation

(a) General rule

(1) A proceeding for compensation under the Program for a vaccine-related injury or death shall be initiated by service upon the Secretary and the filing of a petition containing the matter prescribed by subsection (c) with the United States Court of Federal Claims. The clerk of the United States Court of Federal Claims shall immediately forward the filed petition to the chief special master for assignment to a special master under section 300aa–12(d)(1) of this title.

(2)(A) No person may bring a civil action for damages in an amount greater than $1,000 or in an unspecified amount against a vaccine administrator or manufacturer in a State or Federal court for damages arising from a vaccine-related injury or death associated with the administration of a vaccine after October 1, 1988, and no such court may award damages in an amount greater than $1,000 in a civil action for damages for such a vaccine-related injury or death, unless a petition has been filed, in accordance with section 300aa–16 of this title, for compensation under the Program for such injury or death and—

(i)(I) the United States Court of Federal Claims has issued a judgment under section 300aa–12 of this title on such petition, and

(II) such person elects under section 300aa–21(a) of this title to file such an action, or

(ii) such person elects to withdraw such petition under section 300aa–21(b) of this title or such petition is considered withdrawn under such section.

(B) If a civil action which is barred under subparagraph (A) is filed in a State or Federal court, the court shall dismiss the action. If a petition is filed under this section with respect to the injury or death for which such civil action was brought, the date such dismissed action was filed shall, for purposes of the limitations of actions prescribed by section 300aa–16 of this title, be considered the date the petition was filed if the petition was filed within one year of the date of the dismissal of the civil action.

(3) No vaccine administrator or manufacturer may be made a party to a civil action (other than a civil action which may be brought under paragraph (2)) for damages for a vaccine-related injury or death associated with the administration of a vaccine after October 1, 1988.

(4) If in a civil action brought against a vaccine administrator or manufacturer before October 1, 1988, damages were denied for a vaccine-related injury or death or if such civil action was dismissed with prejudice, the person who brought such action may file a petition under subsection (b) for such injury or death.

(5)(A) A plaintiff who on October 1, 1988, has pending a civil action for damages for a vaccine-related injury or death may, at any time within 2 years after October 1, 1988, or before judgment, whichever occurs first, petition to have such action dismissed without prejudice or costs and file a petition under subsection (b) for such injury or death.

(B) If a plaintiff has pending a civil action for damages for a vaccine-related injury or death, such person may not file a petition under subsection (b) for such injury or death.

(6) If a person brings a civil action after November 15, 1988 for damages for a vaccine-related injury or death associated with the administration of a vaccine before November 15, 1988, such person may not file a petition under subsection (b) for such injury or death.

(7) If in a civil action brought against a vaccine administrator or manufacturer for a vaccine-related injury or death damages are awarded under a judgment of a court or a settlement of such action, the person who brought such action may not file a petition under subsection (b) for such injury or death.

(8) If on October 1, 1988, there was pending an appeal or rehearing with respect to a civil action brought against a vaccine administrator or manufacturer and if the outcome of the last appellate review of such action or the last rehearing of such action is the denial of damages for a vaccine-related injury or death, the person who brought such action may file a petition under subsection (b) for such injury or death.

(9) This subsection applies only to a person who has sustained a vaccine-related injury or death and who is qualified to file a petition for compensation under the Program.

(10) The Clerk of the United States Claims Court [1] is authorized to continue to receive, and forward, petitions for compensation for a vaccine-related injury or death associated with the administration of a vaccine on or after October 1, 1992.

(b) Petitioners

(1)(A) Except as provided in subparagraph (B), any person who has sustained a vaccine-related injury, the legal representative of such person if such person is a minor or is disabled, or the legal representative of any person who died as the result of the administration of a vaccine set forth in the Vaccine Injury Table may, if the person meets the requirements of subsection (c)(1), file a petition for compensation under the Program.

(B) No person may file a petition for a vaccine-related injury or death associated with a vaccine administered before October 1, 1988, if compensation has been paid under this part for 3500 petitions for such injuries or deaths.

(2) Only one petition may be filed with respect to each administration of a vaccine. A covered vaccine administered to a pregnant woman shall constitute more than one administration, one to the mother and one to each child (as such term is defined in subsection (f)(2)) who was in utero at the time such woman was administered the vaccine.

(c) Petition content

A petition for compensation under the Program for a vaccine-related injury or death shall

contain—

(1) except as provided in paragraph (3), an affidavit, and supporting documentation, demonstrating that the person who suffered such injury or who died—

(A) received a vaccine set forth in the Vaccine Injury Table or, if such person did not receive such a vaccine, contracted polio, directly or indirectly, from another person who received an oral polio vaccine,

(B)(i) if such person received a vaccine set forth in the Vaccine Injury Table—

(I) received the vaccine in the United States or in its trust territories,

(II) received the vaccine outside the United States or a trust territory and at the time of the vaccination such person was a citizen of the United States serving abroad as a member of the Armed Forces or otherwise as an employee of the United States or a dependent of such a citizen, or

(III) received the vaccine outside the United States or a trust territory and the vaccine was manufactured by a vaccine manufacturer located in the United States and such person returned to the United States not later than 6 months after the date of the vaccination,

(ii) if such person did not receive such a vaccine but contracted polio from another person who received an oral polio vaccine, was a citizen of the United States or a dependent of such a citizen,

(C)(i) sustained, or had significantly aggravated, any illness, disability, injury, or condition set forth in the Vaccine Injury Table in association with the vaccine referred to in subparagraph (A) or died from the administration of such vaccine, and the first symptom or manifestation of the onset or of the significant aggravation of any such illness, disability, injury, or condition or the death occurred within the time period after vaccine administration set forth in the Vaccine Injury Table, or

(ii)(I) sustained, or had significantly aggravated, any illness, disability, injury, or condition not set forth in the Vaccine Injury Table but which was caused by a vaccine referred to in subparagraph (A), or

(II) sustained, or had significantly aggravated, any illness, disability, injury, or condition set forth in the Vaccine Injury Table the first symptom or manifestation of the onset or significant aggravation of which did not occur within the time period set forth in the Table but which was caused by a vaccine referred to in subparagraph (A),

(D)(i) suffered the residual effects or complications of such illness, disability, injury, or condition for more than 6 months after the administration of the vaccine, or (ii) died from the administration of the vaccine, or (iii) suffered such illness, disability, injury, or condition from the vaccine which resulted in inpatient hospitalization and surgical intervention, and

(E) has not previously collected an award or settlement of a civil action for damages for such vaccine-related injury or death,

(2) except as provided in paragraph (3), maternal prenatal and delivery records, newborn hospital records (including all physicians' and nurses' notes and test results), vaccination records associated with the vaccine allegedly causing the injury, pre- and post-injury physician or clinic records (including all relevant growth charts and test results), all post-injury inpatient and outpatient records (including all provider notes, test results, and medication records), if applicable, a death certificate, and if applicable, autopsy results, and

(3) an identification of any records of the type described in paragraph (1) or (2) which are unavailable to the petitioner and the reasons for their unavailability.

(d) Additional information

A petition may also include other available relevant medical records relating to the person who suffered such injury or who died from the administration of the vaccine.

(e) Schedule

The petitioner shall submit in accordance with a schedule set by the special master assigned to the

petition assessments, evaluations, and prognoses and such other records and documents as are reasonably necessary for the determination of the amount of compensation to be paid to, or on behalf of, the person who suffered such injury or who died from the administration of the vaccine.

(f) Maternal immunization

(1) In general

Notwithstanding any other provision of law, for purposes of this subpart, both a woman who received a covered vaccine while pregnant and any child who was in utero at the time such woman received the vaccine shall be considered persons to whom the covered vaccine was administered and persons who received the covered vaccine.

(2) Definition

As used in this subsection, the term "child" shall have the meaning given that term by subsections (a) and (b) of section 8 of title 1 except that, for purposes of this subsection, such section 8 shall be applied as if the term "include" in subsection (a) of such section were replaced with the term "mean".

(July 1, 1944, ch. 373, title XXI, §2111, as added Pub. L. 99–660, title III, §311(a), Nov. 14, 1986, 100 Stat. 3758; amended Pub. L. 100–203, title IV, §§4302(b), 4304(a), (b), 4306, 4307(1), (2), Dec. 22, 1987, 101 Stat. 1330–221, 1330–223, 1330–224; Pub. L. 101–239, title VI, §6601(c)(1)–(7), Dec. 19, 1989, 103 Stat. 2285, 2286; Pub. L. 101–502, §5(a), Nov. 3, 1990, 104 Stat. 1286; Pub. L. 102–168, title II, §201(h)(1), Nov. 26, 1991, 105 Stat. 1104; Pub. L. 102–572, title IX, §902(b)(1), Oct. 29, 1992, 106 Stat. 4516; Pub. L. 103–43, title XX, §2012, June 10, 1993, 107 Stat. 214; Pub. L. 105–277, div. C, title XV, §1502, Oct. 21, 1998, 112 Stat. 2681–741; Pub. L. 106–310, div. A, title XVII, §1701(a), Oct. 17, 2000, 114 Stat. 1151; Pub. L. 114–255, div. A, title III, §3093(c)(2), (3), Dec. 13, 2016, 130 Stat. 1152.)

EDITORIAL NOTES

CODIFICATION

In subsecs. (a)(2)(A), (3), (4), (5)(A), (8), and (b)(1)(B), "October 1, 1988" substituted for "the effective date of this subpart" on authority of section 323 of Pub. L. 99–660, as amended, set out as an Effective Date note under section 300aa–1 of this title.

PRIOR PROVISIONS

A prior section 300aa–11, act July 1, 1944, §2112, was successively renumbered by subsequent acts and transferred, see section 238i of this title.

A prior section 2111 of act July 1, 1944, was successively renumbered by subsequent acts and transferred, see section 238h of this title.

AMENDMENTS

2016—Subsec. (b)(2). Pub. L. 114–255, §3093(c)(3), inserted at end "A covered vaccine administered to a pregnant woman shall constitute more than one administration, one to the mother and one to each child (as such term is defined in subsection (f)(2)) who was in utero at the time such woman was administered the vaccine."

Subsec. (f). Pub. L. 114–255, §3093(c)(2), added subsec. (f).

2000—Subsec. (c)(1)(D)(iii). Pub. L. 106–310 added cl. (iii).

1998—Subsec. (c)(1)(D)(i). Pub. L. 105–277 struck out "and incurred unreimbursable expenses due in whole or in part to such illness, disability, injury, or condition in an amount greater than $1,000" before ", or (ii) died".

1993—Subsec. (a)(10). Pub. L. 103–43 added par. (10).

1992—Subsec. (a)(1), (2)(A)(i)(I). Pub. L. 102–572 substituted "United States Court of Federal Claims" for "United States Claims Court" wherever appearing.

1991—Subsec. (a)(2)(A)(i), (ii). Pub. L. 102–168 realigned margins of cls. (i) and (ii).

1990—Subsec. (a)(2)(A). Pub. L. 101–502, §5(a)(1), substituted "unless a petition has been filed, in accordance with section 300aa–16 of this title, for compensation under the Program for such injury or death and—" and cls. (i) and (ii) for "unless—

"(i) a petition has been filed, in accordance with section 300aa–16 of this title, for compensation under the Program for such injury or death,

"(ii) the United States Claims Court has issued a judgment under section 300aa–12 of this title on such petition, and

"(iii) such person elects under section 300aa–21(a) of this title to file such an action."

Subsec. (a)(5)(A). Pub. L. 101–502, §5(a)(2), struck out "without prejudice" after "without prejudice or costs".

Subsec. (a)(5)(B). Pub. L. 101–502, §5(a)(3), substituted "plaintiff" for "plaintiff who".

Subsec. (d). Pub. L. 101–502, §5(a)(4), struck out "(d) except as provided in paragraph (3)," before "(d) Additional information".

Subsec. (e). Pub. L. 101–502, §5(a)(5), substituted "(e) Schedule" for "(e)(e) Schedule".

1989—Subsec. (a)(1). Pub. L. 101–239, §6601(c)(1), substituted "filing of a petition containing the matter prescribed in subsection (c)" for "filing of a petition" and inserted at end "The clerk of the United States Claims Court shall immediately forward the filed petition to the chief special master for assignment to a special master under section 300aa–12(d)(1) of this title."

Subsec. (a)(2)(A)(i). Pub. L. 101–239, §6601(c)(2), struck out "under subsection (b) of this section" after "section 300aa–16 of this title,".

Subsec. (a)(5)(A). Pub. L. 101–239, §6601(c)(3)(A), substituted "petition to have such action dismissed without prejudice or costs" for "elect to withdraw such action".

Subsec. (a)(5)(B). Pub. L. 101–239, §6601(c)(3)(B), substituted "has pending" for "on October 1, 1988, had pending" and struck out "does not withdraw the action under subparagraph (A)" after "vaccine-related injury or death".

Subsec. (a)(6). Pub. L. 101–239, §6601(c)(4), substituted "November 15, 1988" for "the effective date of this subpart" in two places.

Subsec. (a)(8). Pub. L. 101–239, §6601(c)(5), added par. (8). Former par. (8) redesignated (9).

Subsec. (a)(9). Pub. L. 101–239, §6601(c)(5), (7), redesignated par. (8) as (9) and realigned margin.

Subsec. (c)(1). Pub. L. 101–239, §6601(c)(6)(A), inserted "except as provided in paragraph (3)," after "(1)" in introductory provisions.

Subsec. (c)(2). Pub. L. 101–239, §6601(c)(6)(B), (C), added par. (2) and redesignated former par. (2) as subsec. (d).

Pub. L. 101–239, §6601(c)(6)(A), inserted "except as provided in paragraph (3)," after "(2)".

Subsec. (c)(3). Pub. L. 101–239, §6601(c)(6)(C), (D), added par. (3). Former par. (3) redesignated subsec. (e).

Subsec. (d). Pub. L. 101–239, §6601(c)(6)(B), redesignated former subsec. (c)(2) as subsec. (d), expanded margin to full measure, inserted subsec. designation and heading, substituted "A petition may also include other available" for "all available", struck out "(including autopsy reports, if any)" after "relevant medical records", and substituted "administration of the vaccine." for "administration of the vaccine and an identification of any unavailable records known to the petitioner and the reasons for their unavailability, and".

Subsec. (e). Pub. L. 101–239, §6601(c)(6)(D), redesignated former subsec. (c)(3) as subsec. (e), expanded margin to full measure, inserted subsec. designation and heading, and substituted "The petitioner shall submit in accordance with a schedule set by the special master assigned to the petition" for "appropriate".

1987—Subsec. (a)(1). Pub. L. 100–203, §4307(1), which directed that par. (1) be amended by substituting "with the United States Claims Court" for "with the United States district court for the district in which the petitioner resides or the injury or death occurred", was executed making the substitution for "with the United States district court for the district in which the petitioner resides or in which the injury or death occurred", as the probable intent of Congress.

Subsec. (a)(2)(A). Pub. L. 100–203, §4306, substituted "vaccine administrator or manufacturer" for "vaccine manufacturer".

Pub. L. 100–203, §4302(b)(1), substituted "effective date of this subpart" for "effective date of this part".

Subsec. (a)(2)(A)(ii). Pub. L. 100–203, §4307(2), substituted "the United States Claims Court" for "a district court of the United States".

Subsec. (a)(3). Pub. L. 100–203, §4306, substituted "vaccine administrator or manufacturer" for "vaccine manufacturer".

Pub. L. 100–203, §4302(b)(1), substituted "effective date of this subpart" for "effective date of this part".

Subsec. (a)(4). Pub. L. 100–203, §4306, substituted "vaccine administrator or manufacturer" for "vaccine manufacturer".

Pub. L. 100–203, §4302(b)(1), substituted "effective date of this subpart" for "effective date of this part".

Subsec. (a)(5)(A). Pub. L. 100–203, §4302(b)(2), substituted "after the effective date of this subpart" for

"after the effective date of this subchapter".

Pub. L. 100–203, §4302(b)(1), substituted "who on the effective date of this subpart" for "who on the effective date of this part".

Subsec. (a)(5)(B). Pub. L. 100–203, §4302(b)(1), substituted "effective date of this subpart" for "effective date of this part".

Subsec. (a)(6). Pub. L. 100–203, §4302(b)(1), substituted "effective date of this subpart" for "effective date of this part" in two places.

Subsec. (a)(7). Pub. L. 100–203, §4306, substituted "vaccine administrator or manufacturer" for "vaccine manufacturer".

Subsec. (a)(8). Pub. L. 100–203, §4304(a), added par. (8).

Subsec. (b)(1)(A). Pub. L. 100–203, §4304(b)(1), substituted "may, if the person meets the requirements of subsection (c)(1), file" for "may file".

Subsec. (b)(1)(B). Pub. L. 100–203, §4302(b)(1), substituted "effective date of this subpart" for "effective date of this part".

Subsec. (c)(1)(D). Pub. L. 100–203, §4304(b)(2), substituted "for more than 6 months" for "for more than 1 year", "and incurred" for ", (ii) incurred", and "(ii)" for "(iii)".

STATUTORY NOTES AND RELATED SUBSIDIARIES

CHANGE OF NAME

References to United States Claims Court deemed to refer to United States Court of Federal Claims, see section 902(b) of Pub. L. 102–572, set out as a note under section 171 of Title 28, Judiciary and Judicial Procedure.

EFFECTIVE DATE OF 2000 AMENDMENT

Pub. L. 106–310, div. A, title XVII, §1701(b), Oct. 17, 2000, 114 Stat. 1151, provided that: "The amendment made by subsection (a) [amending this section] takes effect upon the date of the enactment of this Act [Oct. 17, 2000], including with respect to petitions under section 2111 of the Public Health Service Act [42 U.S.C. 300aa–11] that are pending on such date."

EFFECTIVE DATE OF 1992 AMENDMENT

Amendment by Pub. L. 102–572 effective Oct. 29, 1992, see section 911 of Pub. L. 102–572, set out as a note under section 171 of Title 28, Judiciary and Judicial Procedure.

EFFECTIVE DATE OF 1991 AMENDMENT

Pub. L. 102–168, title II, §201(i), Nov. 26, 1991, 105 Stat. 1104, provided that:

"(1) Except as provided in paragraph (2), the amendments made by this section [amending this section and sections 300aa–12, 300aa–15, 300aa–16, 300aa–19, and 300aa–21 of this title and provisions set out as a note under section 300aa–1 of this title] shall take effect on the date of the enactment of this Act [Nov. 26, 1991].

"(2) The amendments made by subsections (d) and (f) [amending sections 300aa–12, 300aa–15, 300aa–16, and 300aa–21 of this title] shall take effect as if the amendments had been in effect on and after October 1, 1988."

EFFECTIVE DATE OF 1990 AMENDMENT

Pub. L. 101–502, §5(h), Nov. 3, 1990, 104 Stat. 1289, provided that: "The amendments made by subsections (f)(1) and (g) [amending section 300aa–21 of this title and provisions set out as a note under section 300aa–1 of this title and enacting provisions set out as a note under section 300aa–12 of this title] shall take effect as of November 14, 1986, and the amendments made by subsections (a) through (e) and subsection (f)(2) [amending this section and sections 300aa–12, 300aa–13, 300aa–15, 300aa–16, and 300aa–21 of this title] shall take effect as of September 30, 1990."

EFFECTIVE DATE OF 1989 AMENDMENT

For applicability of amendments by Pub. L. 101–239 to petitions filed after Dec. 19, 1989, petitions currently pending in which the evidentiary record is closed, and petitions currently pending in which the evidentiary record is not closed, with provision for an immediate suspension for 30 days of all pending cases, see section 6601(s)(1) of Pub. L. 101–239, set out as a note under section 300aa–10 of this title.

[1] *See Change of Name note below.*

§300aa–12. Court jurisdiction

(a) General rule

The United States Court of Federal Claims and the United States Court of Federal Claims special masters shall, in accordance with this section, have jurisdiction over proceedings to determine if a petitioner under section 300aa–11 of this title is entitled to compensation under the Program and the amount of such compensation. The United States Court of Federal Claims may issue and enforce such orders as the court deems necessary to assure the prompt payment of any compensation awarded.

(b) Parties

(1) In all proceedings brought by the filing of a petition under section 300aa–11(b) of this title, the Secretary shall be named as the respondent, shall participate, and shall be represented in accordance with section 518(a) of title 28.

(2) Within 30 days after the Secretary receives service of any petition filed under section 300aa–11 of this title the Secretary shall publish notice of such petition in the Federal Register. The special master designated with respect to such petition under subsection (c) shall afford all interested persons an opportunity to submit relevant, written information—

(A) relating to the existence of the evidence described in section 300aa–13(a)(1)(B) of this title, or

(B) relating to any allegation in a petition with respect to the matters described in section 300aa–11(c)(1)(C)(ii) of this title.

(c) United States Court of Federal Claims special masters

(1) There is established within the United States Court of Federal Claims an office of special masters which shall consist of not more than 8 special masters. The judges of the United States Court of Federal Claims shall appoint the special masters, 1 of whom, by designation of the judges of the United States Court of Federal Claims, shall serve as chief special master. The appointment and reappointment of the special masters shall be by the concurrence of a majority of the judges of the court.

(2) The chief special master and other special masters shall be subject to removal by the judges of the United States Court of Federal Claims for incompetency, misconduct, or neglect of duty or for physical or mental disability or for other good cause shown.

(3) A special master's office shall be terminated if the judges of the United States Court of Federal Claims determine, upon advice of the chief special master, that the services performed by that office are no longer needed.

(4) The appointment of any individual as a special master shall be for a term of 4 years, subject to termination under paragraphs (2) and (3). Individuals serving as special masters on December 19, 1989, shall serve for 4 years from the date of their original appointment, subject to termination under paragraphs (2) and (3). The chief special master in office on December 19, 1989, shall continue to serve as chief special master for the balance of the master's term, subject to termination under paragraphs (2) and (3).

(5) The compensation of the special masters shall be determined by the judges of the United States Court of Federal Claims, upon advice of the chief special master. The salary of the chief special master shall be the annual rate of basic pay for level IV of the Executive Schedule, as prescribed by section 5315, title 5. The salaries of the other special masters shall not exceed the annual rate of basic pay of level V of the Executive Schedule, as prescribed by section 5316, title 5.

(6) The chief special master shall be responsible for the following:

(A) Administering the office of special masters and their staff, providing for the efficient, expeditious, and effective handling of petitions, and performing such other duties related to the Program as may be assigned to the chief special master by a concurrence of a majority of the United States Claims Courts [1] judges.

(B) Appointing and fixing the salary and duties of such administrative staff as are necessary. Such staff shall be subject to removal for good cause by the chief special master.

(C) Managing and executing all aspects of budgetary and administrative affairs affecting the special masters and their staff, subject to the rules and regulations of the Judicial Conference of the United States. The Conference rules and regulations pertaining to United States magistrate judges shall be applied to the special masters.

(D) Coordinating with the United States Court of Federal Claims the use of services, equipment, personnel, information, and facilities of the United States Court of Federal Claims without reimbursement.

(E) Reporting annually to the Congress and the judges of the United States Court of Federal Claims on the number of petitions filed under section 300aa–11 of this title and their disposition, the dates on which the vaccine-related injuries and deaths for which the petitions were filed occurred, the types and amounts of awards, the length of time for the disposition of petitions, the cost of administering the Program, and recommendations for changes in the Program.

(d) Special masters

(1) Following the receipt and filing of a petition under section 300aa–11 of this title, the clerk of the United States Court of Federal Claims shall forward the petition to the chief special master who shall designate a special master to carry out the functions authorized by paragraph (3).

(2) The special masters shall recommend rules to the Court of Federal Claims and, taking into account such recommended rules, the Court of Federal Claims shall promulgate rules pursuant to section 2071 of title 28. Such rules shall—

(A) provide for a less-adversarial, expeditious, and informal proceeding for the resolution of petitions,

(B) include flexible and informal standards of admissibility of evidence,

(C) include the opportunity for summary judgment,

(D) include the opportunity for parties to submit arguments and evidence on the record without requiring routine use of oral presentations, cross examinations, or hearings, and

(E) provide for limitations on discovery and allow the special masters to replace the usual rules of discovery in civil actions in the United States Court of Federal Claims.

(3)(A) A special master to whom a petition has been assigned shall issue a decision on such petition with respect to whether compensation is to be provided under the Program and the amount of such compensation. The decision of the special master shall—

(i) include findings of fact and conclusions of law, and

(ii) be issued as expeditiously as practicable but not later than 240 days, exclusive of suspended time under subparagraph (C), after the date the petition was filed.

The decision of the special master may be reviewed by the United States Court of Federal Claims in accordance with subsection (e).

(B) In conducting a proceeding on a petition a special master—

(i) may require such evidence as may be reasonable and necessary,

(ii) may require the submission of such information as may be reasonable and necessary,

(iii) may require the testimony of any person and the production of any documents as may be reasonable and necessary,

(iv) shall afford all interested persons an opportunity to submit relevant written information—

(I) relating to the existence of the evidence described in section 300aa–13(a)(1)(B) of this title, or

(II) relating to any allegation in a petition with respect to the matters described in section 300aa–11(c)(1)(C)(ii) of this title, and

(v) may conduct such hearings as may be reasonable and necessary.

There may be no discovery in a proceeding on a petition other than the discovery required by the

special master.

(C) In conducting a proceeding on a petition a special master shall suspend the proceedings one time for 30 days on the motion of either party. After a motion for suspension is granted, further motions for suspension by either party may be granted by the special master, if the special master determines the suspension is reasonable and necessary, for an aggregate period not to exceed 150 days.

(D) If, in reviewing proceedings on petitions for vaccine-related injuries or deaths associated with the administration of vaccines before October 1, 1988, the chief special master determines that the number of filings and resultant workload place an undue burden on the parties or the special master involved in such proceedings, the chief special master may, in the interest of justice, suspend proceedings on any petition for up to 30 months (but for not more than 6 months at a time) in addition to the suspension time under subparagraph (C).

(4)(A) Except as provided in subparagraph (B), information submitted to a special master or the court in a proceeding on a petition may not be disclosed to a person who is not a party to the proceeding without the express written consent of the person who submitted the information.

(B) A decision of a special master or the court in a proceeding shall be disclosed, except that if the decision is to include information—

(i) which is trade secret or commercial or financial information which is privileged and confidential, or

(ii) which are medical files and similar files the disclosure of which would constitute a clearly unwarranted invasion of privacy,

and if the person who submitted such information objects to the inclusion of such information in the decision, the decision shall be disclosed without such information.

(e) Action by United States Court of Federal Claims

(1) Upon issuance of the special master's decision, the parties shall have 30 days to file with the clerk of the United States Court of Federal Claims a motion to have the court review the decision. If such a motion is filed, the other party shall file a response with the clerk of the United States Court of Federal Claims no later than 30 days after the filing of such motion.

(2) Upon the filing of a motion under paragraph (1) with respect to a petition, the United States Court of Federal Claims shall have jurisdiction to undertake a review of the record of the proceedings and may thereafter—

(A) uphold the findings of fact and conclusions of law of the special master and sustain the special master's decision,

(B) set aside any findings of fact or conclusion of law of the special master found to be arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law and issue its own findings of fact and conclusions of law, or

(C) remand the petition to the special master for further action in accordance with the court's direction.

The court shall complete its action on a petition within 120 days of the filing of a response under paragraph (1) excluding any days the petition is before a special master as a result of a remand under subparagraph (C). The court may allow not more than 90 days for remands under subparagraph (C).

(3) In the absence of a motion under paragraph (1) respecting the special master's decision or if the United States Court of Federal Claims takes the action described in paragraph (2)(A) with respect to the special master's decision, the clerk of the United States Court of Federal Claims shall immediately enter judgment in accordance with the special master's decision.

(f) Appeals

The findings of fact and conclusions of law of the United States Court of Federal Claims on a petition shall be final determinations of the matters involved, except that the Secretary or any petitioner aggrieved by the findings or conclusions of the court may obtain review of the judgment of the court in the United States court of appeals for the Federal Circuit upon petition filed within 60

days of the date of the judgment with such court of appeals within 60 days of the date of entry of the United States Claims Court's [1] judgment with such court of appeals.

(g) Notice

If—

(1) a special master fails to make a decision on a petition within the 240 days prescribed by subsection (d)(3)(A)(ii) (excluding (A) any period of suspension under subsection (d)(3)(C) or (d)(3)(D), and (B) any days the petition is before a special master as a result of a remand under subsection (e)(2)(C)), or

(2) the United States Court of Federal Claims fails to enter a judgment under this section on a petition within 420 days (excluding (A) any period of suspension under subsection (d)(3)(C) or (d)(3)(D), and (B) any days the petition is before a special master as a result of a remand under subsection (e)(2)(C)) after the date on which the petition was filed,

the special master or court shall notify the petitioner under such petition that the petitioner may withdraw the petition under section 300aa–21(b) of this title or the petitioner may choose under section 300aa–21(b) of this title to have the petition remain before the special master or court, as the case may be.

(July 1, 1944, ch. 373, title XXI, §2112, as added Pub. L. 99–660, title III, §311(a), Nov. 14, 1986, 100 Stat. 3761; amended Pub. L. 100–203, title IV, §§4303(d)(2)(A), 4307(3), 4308(a), (b), Dec. 22, 1987, 101 Stat. 1330–222, 1330–224; Pub. L. 100–360, title IV, §411(o)(2), (3)(A), July 1, 1988, 102 Stat. 808; Pub. L. 101–239, title VI, §6601(d)–(i), Dec. 19, 1989, 103 Stat. 2286–2290; Pub. L. 101–502, §5(b), Nov. 3, 1990, 104 Stat. 1286; Pub. L. 101–650, title III, §321, Dec. 1, 1990, 104 Stat. 5117; Pub. L. 102–168, title II, §201(c), (d)(1), (h)(2), (3), Nov. 26, 1991, 105 Stat. 1103, 1104; Pub. L. 102–572, title IX, §902(b), Oct. 29, 1992, 106 Stat. 4516; Pub. L. 103–66, title XIII, §13632(c), Aug. 10, 1993, 107 Stat. 646.)

EDITORIAL NOTES

CODIFICATION

In subsec. (c)(4), "on December 19, 1989," substituted for "upon the date of the enactment of this subsection" and "on the date of the enactment of this subsection".

In subsec. (d)(3)(D), "October 1, 1988," substituted for "the effective date of this part".

PRIOR PROVISIONS

A prior section 300aa–12, act July 1, 1944, §2113, was successively renumbered by subsequent acts and transferred, see section 238j of this title.

A prior section 2112 of act July 1, 1944, was successively renumbered by subsequent acts and transferred, see section 238i of this title.

AMENDMENTS

1993—Subsec. (d)(3)(D). Pub. L. 103–66 substituted "30 months (but for not more than 6 months at a time)" for "540 days".

1992—Subsecs. (a), (c) to (g). Pub. L. 102–572 substituted "United States Court of Federal Claims" for "United States Claims Court" and "Court of Federal Claims" for "Claims Court", wherever appearing.

1991—Subsec. (d)(3)(D). Pub. L. 102–168, §201(c), (h)(2), realigned margin and substituted "540 days" for "180 days".

Subsec. (g). Pub. L. 102–168, §201(h)(3), made technical amendment to underlying provisions of original Act.

Pub. L. 102–168, §201(d)(1), substituted "or the petitioner may choose under section 300aa–21(b) of this title to have the petition remain before the special master or court, as the case may be" for "and the petition will be considered withdrawn under such section if the petitioner, the special master, or the court do not take certain actions" before period at end.

1990—Subsec. (d)(3)(D). Pub. L. 101–502, §5(b)(1), added subpar. (D).

Subsec. (g). Pub. L. 101–502, §5(b)(2), added subsec. (g).

1989—Subsec. (a). Pub. L. 101–239, §6601(d), substituted "and the United States Claims Court special masters shall, in accordance with this section, have jurisdiction" for "shall have jurisdiction (1)", ". The United States Claims Court may issue" for ", and (2) to issue", and "deems" for "deem".

Subsec. (b)(1). Pub. L. 101–239, §6601(f), substituted "In all proceedings brought by the filing of a petition under section 300aa–11(b) of this title, the Secretary shall be named as the respondent, shall participate, and shall be represented in accordance with section 518(a) of title 28." for "The Secretary shall be named as the respondent in all proceedings brought by the filing of a petition under section 300aa–11(b) of this title. Except as provided in paragraph (2), no other person may intervene in any such proceeding."

Subsec. (c). Pub. L. 101–239, §6601(e)(2), added subsec. (c). Former subsec. (c) redesignated (d).

Subsec. (d). Pub. L. 101–239, §6601(e)(1), redesignated subsec. (c) as (d). Former subsec. (d) redesignated (e).

Subsec. (d)(1). Pub. L. 101–239, §6601(g)(1), amended par. (1) generally. Prior to amendment, par. (1) read as follows: "Following receipt of a petition under subsection (a) of this section, the United States Claims Court shall designate a special master to carry out the functions authorized by paragraph (2)."

Subsec. (d)(2) to (4). Pub. L. 101–239, §6601(g)(2), added pars. (2) to (4) and struck out former par. (2) which prescribed functions of special masters.

Subsec. (e). Pub. L. 101–239, §6601(h), substituted "Action by United States Claims Court" for "Action by court" as heading and amended text generally. Prior to amendment, text read as follows:

"(1) Upon objection by the petitioner or respondent to the proposed findings of fact or conclusions of law prepared by the special master or upon the court's own motion, the court shall undertake a review of the record of the proceedings and may thereafter make a de novo determination of any matter and issue its judgment accordingly, including findings of fact and conclusions of law, or remand for further proceedings.

"(2) If no objection is filed under paragraph (1) or if the court does not choose to review the proceeding, the court shall adopt the proposed findings of fact and conclusions of law of the special master as its own and render judgment thereon.

"(3) The court shall render its judgment on any petition filed under the Program as expeditiously as practicable but not later than 365 days after the date on which the petition was filed."

Pub. L. 101–239, §6601(e)(1), redesignated subsec. (d) as (e). Former subsec. (e) redesignated (f).

Subsec. (f). Pub. L. 101–239, §6601(i), inserted "within 60 days of the date of entry of the United States Claims Court's judgment with such court of appeals" after "with such court of appeals".

Pub. L. 101–239, §6601(e)(1), redesignated subsec. (e) as (f).

1988—Subsec. (c)(2). Pub. L. 100–360, §411(o)(3)(A), added Pub. L. 100–203, §4308(a), see 1987 Amendment note below.

Subsec. (e). Pub. L. 100–360, §411(o)(2), made technical amendment to directory language of Pub. L. 100–203, §4307(3)(C), see 1987 Amendment note below.

Pub. L. 100–360, §411(o)(3)(A), added Pub. L. 100–203, §4308(b), see 1987 Amendment note below.

1987—Subsec. (a). Pub. L. 100–203, §4307(3)(A), substituted "United States Claims Court" for "district courts of the United States" and "the court" for "the courts".

Subsec. (c)(1). Pub. L. 100–203, §4307(3)(B), substituted "the United States Claims Court" for "the district court of the United States in which the petition is filed".

Subsec. (c)(2). Pub. L. 100–203, §4308(a), as added by Pub. L. 100–360, §411(o)(3)(A), inserted ", shall prepare and submit to the court proposed findings of fact and conclusions of law," in introductory provisions and struck out subpar. (E) which read as follows: "prepare and submit to the court proposed findings of fact and conclusions of law."

Subsec. (e). Pub. L. 100–203, §4308(b), as added by Pub. L. 100–360, §411(o)(3)(A), inserted "within 60 days of the date of the judgment" after "petition filed".

Pub. L. 100–203, §4307(3)(C), as amended by Pub. L. 100–360, §411(o)(2), substituted "the United States Claims Court" for "a district court of the United States" and "for the Federal Circuit" for "for the circuit in which the court is located".

Pub. L. 100–203, §4303(d)(2)(A), redesignated subsec. (g) as (e) and struck out former subsec. (e) relating to administration of an award.

Subsec. (f). Pub. L. 100–203, §4303(d)(2)(A), struck out subsec. (f) which related to revision of an award.

Subsec. (g). Pub. L. 100–203, §4303(d)(2)(A), redesignated subsec. (g) as (e).

STATUTORY NOTES AND RELATED SUBSIDIARIES

CHANGE OF NAME

"United States magistrate judges" substituted for "United States magistrates" in subsec. (c)(6)(C) pursuant

to section 321 of Pub. L. 101–650, set out as a note under section 631 of Title 28, Judiciary and Judicial Procedure.

EFFECTIVE DATE OF 1992 AMENDMENT

Amendment by Pub. L. 102–572 effective Oct. 29, 1992, see section 911 of Pub. L. 102–572, set out as a note under section 171 of Title 28, Judiciary and Judicial Procedure.

EFFECTIVE DATE OF 1991 AMENDMENT

Amendment by section 201(d)(1) of Pub. L. 102–168 effective as if in effect on and after Oct. 1, 1988, see section 201(i)(2) of Pub. L. 102–168, set out as a note under section 300aa–11 of this title.

EFFECTIVE DATE OF 1990 AMENDMENT

Amendment by Pub. L. 101–502 effective Sept. 30, 1990, see section 5(h) of Pub. L. 101–502, set out as a note under section 300aa–11 of this title.

EFFECTIVE DATE OF 1989 AMENDMENT

For applicability of amendments by Pub. L. 101–239 to petitions filed after Dec. 19, 1989, petitions currently pending in which the evidentiary record is closed, and petitions currently pending in which the evidentiary record is not closed, with provision for an immediate suspension for 30 days of all pending cases, except that such suspension be excluded in determining the 240-day period prescribed in subsec. (d) of this section, see section 6601(s)(1) of Pub. L. 101–239, set out as a note under section 300aa–10 of this title.

EFFECTIVE DATE OF 1988 AMENDMENT

Except as specifically provided in section 411 of Pub. L. 100–360, amendment by Pub. L. 100–360, as it relates to a provision in the Omnibus Budget Reconciliation Act of 1987, Pub. L. 100–203, effective as if included in the enactment of that provision in Pub. L. 100–203, see section 411(a) of Pub. L. 100–360, set out as a Reference to OBRA; Effective Date note under section 106 of Title 1, General Provisions.

TERMINATION OF REPORTING REQUIREMENTS

For termination, effective May 15, 2000, of provisions in subsec. (c)(6)(E) of this section relating to reporting annually to the Congress, see section 3003 of Pub. L. 104–66, as amended, set out as a note under section 1113 of Title 31, Money and Finance, and page 13 of House Document No. 103–7.

REVIEW BY 3-JUDGE PANEL

Section 322(c) of Pub. L. 99–660, as added by Pub. L. 101–502, §5(g)(2), Nov. 3, 1990, 104 Stat. 1288, and amended by Pub. L. 102–572, title IX, §902(b)(1), Oct. 29, 1992, 106 Stat. 4516, provided that: "If the review authorized by section 2112(f) [42 U.S.C. 300aa–12(f)] is held invalid because the judgment of the United States Court of Federal Claims being reviewed did not arise from a case or controversy under Article III of the Constitution, such judgment shall be reviewed by a 3-judge panel of the United States Court of Federal Claims. Such panel shall not include the judge who participated in such judgment."

[Enactment of section 322(c) of Pub. L. 99–660 by section 5(g)(2) of Pub. L. 101–502, set out above, effective Nov. 14, 1986, see section 5(h) of Pub. L. 101–502, set out as an Effective Date of 1990 Amendment note under section 300aa–11 of this title.]

[1] So in original. Probably should be a reference to the United States Court of Federal Claims.

§300aa–13. Determination of eligibility and compensation

(a) General rule

(1) Compensation shall be awarded under the Program to a petitioner if the special master or court finds on the record as a whole—

(A) that the petitioner has demonstrated by a preponderance of the evidence the matters required in the petition by section 300aa–11(c)(1) of this title, and

(B) that there is not a preponderance of the evidence that the illness, disability, injury, condition, or death described in the petition is due to factors unrelated to the administration of the vaccine described in the petition.

The special master or court may not make such a finding based on the claims of a petitioner alone, unsubstantiated by medical records or by medical opinion.

(2) For purposes of paragraph (1), the term "factors unrelated to the administration of the vaccine"—

(A) does not include any idiopathic, unexplained, unknown, hypothetical, or undocumentable cause, factor, injury, illness, or condition, and

(B) may, as documented by the petitioner's evidence or other material in the record, include infection, toxins, trauma (including birth trauma and related anoxia), or metabolic disturbances which have no known relation to the vaccine involved, but which in the particular case are shown to have been the agent or agents principally responsible for causing the petitioner's illness, disability, injury, condition, or death.

(b) Matters to be considered

(1) In determining whether to award compensation to a petitioner under the Program, the special master or court shall consider, in addition to all other relevant medical and scientific evidence contained in the record—

(A) any diagnosis, conclusion, medical judgment, or autopsy or coroner's report which is contained in the record regarding the nature, causation, and aggravation of the petitioner's illness, disability, injury, condition, or death, and

(B) the results of any diagnostic or evaluative test which are contained in the record and the summaries and conclusions.

Any such diagnosis, conclusion, judgment, test result, report, or summary shall not be binding on the special master or court. In evaluating the weight to be afforded to any such diagnosis, conclusion, judgment, test result, report, or summary, the special master or court shall consider the entire record and the course of the injury, disability, illness, or condition until the date of the judgment of the special master or court.

(2) The special master or court may find the first symptom or manifestation of onset or significant aggravation of an injury, disability, illness, condition, or death described in a petition occurred within the time period described in the Vaccine Injury Table even though the occurrence of such symptom or manifestation was not recorded or was incorrectly recorded as having occurred outside such period. Such a finding may be made only upon demonstration by a preponderance of the evidence that the onset or significant aggravation of the injury, disability, illness, condition, or death described in the petition did in fact occur within the time period described in the Vaccine Injury Table.

(c) "Record" defined

For purposes of this section, the term "record" means the record established by the special masters of the United States Court of Federal Claims in a proceeding on a petition filed under section 300aa–11 of this title.

(July 1, 1944, ch. 373, title XXI, §2113, as added Pub. L. 99–660, title III, §311(a), Nov. 14, 1986, 100 Stat. 3763; amended Pub. L. 100–203, title IV, §4307(4), Dec. 22, 1987, 101 Stat. 1330–224; Pub. L. 101–239, title VI, §6601(j), Dec. 19, 1989, 103 Stat. 2290; Pub. L. 101–502, §5(c), Nov. 3, 1990, 104 Stat. 1287; Pub. L. 102–572, title IX, §902(b)(1), Oct. 29, 1992, 106 Stat. 4516.)

EDITORIAL NOTES

PRIOR PROVISIONS

A prior section 300aa–13, act July 1, 1944, §2114, was successively renumbered by subsequent acts and transferred, see section 238k of this title.

A prior section 2113 of act July 1, 1944, was successively renumbered by subsequent acts and transferred, see section 238j of this title.

AMENDMENTS

1992—Subsec. (c). Pub. L. 102–572 substituted "United States Court of Federal Claims" for "United States Claims Court".

1990—Subsec. (c). Pub. L. 101–502 inserted "the" after "special masters of".

1989—Subsecs. (a)(1), (b). Pub. L. 101–239, §6601(j)(1), substituted "special master or court" for "court" wherever appearing.

Subsec. (c). Pub. L. 101–239, §6601(j)(2), inserted "special masters of" after "established by the".

1987—Subsec. (c). Pub. L. 100–203 substituted "the United States Claims Court" for "a district court of the United States".

STATUTORY NOTES AND RELATED SUBSIDIARIES

EFFECTIVE DATE OF 1992 AMENDMENT

Amendment by Pub. L. 102–572 effective Oct. 29, 1992, see section 911 of Pub. L. 102–572, set out as a note under section 171 of Title 28, Judiciary and Judicial Procedure.

EFFECTIVE DATE OF 1990 AMENDMENT

Amendment by Pub. L. 101–502 effective Sept. 30, 1990, see section 5(h) of Pub. L. 101–502, set out as a note under section 300aa–11 of this title.

EFFECTIVE DATE OF 1989 AMENDMENT

For applicability of amendments by Pub. L. 101–239 to petitions filed after Dec. 19, 1989, petitions currently pending in which the evidentiary record is closed, and petitions currently pending in which the evidentiary record is not closed, with provision for an immediate suspension for 30 days of all pending cases, see section 6601(s)(1) of Pub. L. 101–239, set out as a note under section 300aa–10 of this title.

§300aa–14. Vaccine Injury Table

(a) Initial table

The following is a table of vaccines, the injuries, disabilities, illnesses, conditions, and deaths resulting from the administration of such vaccines, and the time period in which the first symptom or manifestation of onset or of the significant aggravation of such injuries, disabilities, illnesses, conditions, and deaths is to occur after vaccine administration for purposes of receiving compensation under the Program:

VACCINE INJURY TABLE

I.	DTP; P; DTP/Polio Combination; or Any Other Vaccine Containing Whole Cell Pertussis Bacteria, Extracted or Partial Cell Bacteria, or Specific Pertussis Antigen(s).	
	Illness, disability, injury, or condition covered:	Time period for first symptom or manifestation of onset or of significant aggravation after vaccine administration:
	A. Anaphylaxis or anaphylactic shock	24 hours
	B. Encephalopathy (or encephalitis)	3 days
	C. Shock-collapse or hypotonic-hyporesponsive collapse	3 days
	D. Residual seizure disorder in accordance with subsection (b)(2)	3 days
	E. Any acute complication or sequela (including death) of an illness, disability, injury, or condition referred	Not applicable

to above which illness, disability, injury, or condition arose within the time period prescribed	
II. Measles, mumps, rubella, or any vaccine containing any of the foregoing as a component; DT; Td; or Tetanus Toxoid.	
A. Anaphylaxis or anaphylactic shock	24 hours
B. Encephalopathy (or encephalitis)	15 days (for mumps, rubella, measles, or any vaccine containing any of the foregoing as a component). 3 days (for DT, Td, or tetanus toxoid).
C. Residual seizure disorder in accordance with subsection (b)(2)	15 days (for mumps, rubella, measles, or any vaccine containing any of the foregoing as a component). 3 days (for DT, Td, or tetanus toxoid).
D. Any acute complication or sequela (including death) of an illness, disability, injury, or condition referred to above which illness, disability, injury, or condition arose within the time period prescribed	Not applicable
III. Polio Vaccines (other than Inactivated Polio Vaccine).	
A. Paralytic polio	
—in a non-immunodeficient recipient	30 days
—in an immunodeficient recipient	6 months
—in a vaccine-associated community case	Not applicable
B. Any acute complication or sequela (including death) of an illness, disability, injury, or condition referred to above which illness, disability, injury, or condition arose within the time period prescribed	Not applicable
IV. Inactivated Polio Vaccine.	
A. Anaphylaxis or anaphylactic shock	24 hours
B. Any acute complication or sequela (including death) of an illness, disability, injury, or condition referred to above which illness, disability, injury, or condition arose within the time period prescribed	Not applicable

(b) Qualifications and aids to interpretation

The following qualifications and aids to interpretation shall apply to the Vaccine Injury Table in subsection (a):

(1) A shock-collapse or a hypotonic-hyporesponsive collapse may be evidenced by indicia or symptoms such as decrease or loss of muscle tone, paralysis (partial or complete), hemiplegia or hemiparesis, loss of color or turning pale white or blue, unresponsiveness to environmental stimuli, depression of consciousness, loss of consciousness, prolonged sleeping with difficulty arousing, or cardiovascular or respiratory arrest.

(2) A petitioner may be considered to have suffered a residual seizure disorder if the petitioner did not suffer a seizure or convulsion unaccompanied by fever or accompanied by a fever of less than 102 degrees Fahrenheit before the first seizure or convulsion after the administration of the vaccine involved and if—

(A) in the case of a measles, mumps, or rubella vaccine or any combination of such vaccines, the first seizure or convulsion occurred within 15 days after administration of the vaccine and 2 or more seizures or convulsions occurred within 1 year after the administration of the vaccine which were unaccompanied by fever or accompanied by a fever of less than 102 degrees Fahrenheit, and

(B) in the case of any other vaccine, the first seizure or convulsion occurred within 3 days after administration of the vaccine and 2 or more seizures or convulsions occurred within 1 year after the administration of the vaccine which were unaccompanied by fever or accompanied by a fever of less than 102 degrees Fahrenheit.

(3)(A) The term "encephalopathy" means any significant acquired abnormality of, or injury to, or impairment of function of the brain. Among the frequent manifestations of encephalopathy are focal and diffuse neurologic signs, increased intracranial pressure, or changes lasting at least 6 hours in level of consciousness, with or without convulsions. The neurological signs and symptoms of encephalopathy may be temporary with complete recovery, or may result in various degrees of permanent impairment. Signs and symptoms such as high pitched and unusual screaming, persistent unconsolable crying, and bulging fontanel are compatible with an encephalopathy, but in and of themselves are not conclusive evidence of encephalopathy. Encephalopathy usually can be documented by slow wave activity on an electroencephalogram.

(B) If in a proceeding on a petition it is shown by a preponderance of the evidence that an encephalopathy was caused by infection, toxins, trauma, or metabolic disturbances the encephalopathy shall not be considered to be a condition set forth in the table. If at the time a judgment is entered on a petition filed under section 300aa–11 of this title for a vaccine-related injury or death it is not possible to determine the cause, by a preponderance of the evidence, of an encephalopathy, the encephalopathy shall be considered to be a condition set forth in the table. In determining whether or not an encephalopathy is a condition set forth in the table, the court shall consider the entire medical record.

(4) For purposes of paragraphs (2) and (3), the terms "seizure" and "convulsion" include grand mal, petit mal, absence, myoclonic, tonic-clonic, and focal motor seizures and signs. If a provision of the table to which paragraph (1), (2), (3), or (4) applies is revised under subsection (c) or (d), such paragraph shall not apply to such provision after the effective date of the revision unless the revision specifies that such paragraph is to continue to apply.

(c) Administrative revision of table

(1) The Secretary may promulgate regulations to modify in accordance with paragraph (3) the Vaccine Injury Table. In promulgating such regulations, the Secretary shall provide for notice and opportunity for a public hearing and at least 180 days of public comment.

(2) Any person (including the Advisory Commission on Childhood Vaccines) may petition the Secretary to propose regulations to amend the Vaccine Injury Table. Unless clearly frivolous, or initiated by the Commission, any such petition shall be referred to the Commission for its recommendations. Following—

(A) receipt of any recommendation of the Commission, or

(B) 180 days after the date of the referral to the Commission,

whichever occurs first, the Secretary shall conduct a rulemaking proceeding on the matters proposed in the petition or publish in the Federal Register a statement of reasons for not conducting such proceeding.

(3) A modification of the Vaccine Injury Table under paragraph (1) may add to, or delete from, the list of injuries, disabilities, illnesses, conditions, and deaths for which compensation may be provided or may change the time periods for the first symptom or manifestation of the onset or the significant aggravation of any such injury, disability, illness, condition, or death.

(4) Any modification under paragraph (1) of the Vaccine Injury Table shall apply only with respect to petitions for compensation under the Program which are filed after the effective date of such regulation.

(d) Role of Commission

Except with respect to a regulation recommended by the Advisory Commission on Childhood Vaccines, the Secretary may not propose a regulation under subsection (c) or any revision thereof, unless the Secretary has first provided to the Commission a copy of the proposed regulation or

revision, requested recommendations and comments by the Commission, and afforded the Commission at least 90 days to make such recommendations.

(e) Additional vaccines

(1) Vaccines recommended before August 1, 1993

By August 1, 1995, the Secretary shall revise the Vaccine Injury Table included in subsection (a) to include—

(A) vaccines which are recommended to the Secretary by the Centers for Disease Control and Prevention before August 1, 1993, for routine administration to children,

(B) the injuries, disabilities, illnesses, conditions, and deaths associated with such vaccines, and

(C) the time period in which the first symptoms or manifestations of onset or other significant aggravation of such injuries, disabilities, illnesses, conditions, and deaths associated with such vaccines may occur.

(2) Vaccines recommended after August 1, 1993

When after August 1, 1993, the Centers for Disease Control and Prevention recommends a vaccine to the Secretary for routine administration to children, the Secretary shall, within 2 years of such recommendation, amend the Vaccine Injury Table included in subsection (a) to include—

(A) vaccines which were recommended for routine administration to children,

(B) the injuries, disabilities, illnesses, conditions, and deaths associated with such vaccines, and

(C) the time period in which the first symptoms or manifestations of onset or other significant aggravation of such injuries, disabilities, illnesses, conditions, and deaths associated with such vaccines may occur.

(3) Vaccines recommended for use in pregnant women

The Secretary shall revise the Vaccine Injury Table included in subsection (a), through the process described in subsection (c), to include vaccines recommended by the Centers for Disease Control and Prevention for routine administration in pregnant women and the information described in subparagraphs (B) and (C) of paragraph (2) with respect to such vaccines.

(July 1, 1944, ch. 373, title XXI, §2114, as added Pub. L. 99–660, title III, §311(a), Nov. 14, 1986, 100 Stat. 3764; amended Pub. L. 101–239, title VI, §6601(k), Dec. 19, 1989, 103 Stat. 2290; Pub. L. 103–66, title XIII, §13632(a)(2), Aug. 10, 1993, 107 Stat. 645; Pub. L. 114–255, div. A, title III, §3093(c)(1), Dec. 13, 2016, 130 Stat. 1152.)

EDITORIAL NOTES

PRIOR PROVISIONS

A prior section 300aa–14, act July 1, 1944, §2115, was successively renumbered by subsequent acts and transferred, see section 238l of this title.

A prior section 2114 of act July 1, 1944, was successively renumbered by subsequent acts and transferred, see section 238k of this title.

AMENDMENTS

2016—Subsec. (e)(3). Pub. L. 114–255 added par. (3).

1993—Subsec. (e). Pub. L. 103–66 amended heading and text of subsec. (e) generally. Prior to amendment, text read as follows: "The Secretary may recommend to Congress revisions of the table to change the vaccines covered by the table."

1989—Subsec. (a). Pub. L. 101–239, §6601(k)(1), substituted "(b)(2)" for "(c)(2)" in items I.D. and II.C. in table.

Subsec. (b)(3)(B). Pub. L. 101–239, §6601(k)(2), substituted "300aa–11 of this title" for "300aa–11(b) of this title".

STATUTORY NOTES AND RELATED SUBSIDIARIES

EFFECTIVE DATE OF 1989 AMENDMENT

For applicability of amendments by Pub. L. 101–239 to petitions filed after Dec. 19, 1989, petitions currently pending in which the evidentiary record is closed, and petitions currently pending in which the evidentiary record is not closed, with provision for an immediate suspension for 30 days of all pending cases, see section 6601(s)(1) of Pub. L. 101–239, set out as a note under section 300aa–10 of this title.

REVISIONS OF VACCINE INJURY TABLE

The Vaccine Injury Table as modified by regulations promulgated by the Secretary of Health and Human Services is set out at 42 CFR 100.3.

Pub. L. 103–66, title XIII, §13632(a)(3), Aug. 10, 1993, 107 Stat. 646, provided that: "A revision by the Secretary under section 2114(e) of the Public Health Service Act (42 U.S.C. 300aa–14(e)) (as amended by paragraph (2)) shall take effect upon the effective date of a tax enacted to provide funds for compensation paid with respect to the vaccine to be added to the vaccine injury table in section 2114(a) of the Public Health Service Act (42 U.S.C. 300aa–14(a))."

§300aa–15. Compensation

(a) General rule

Compensation awarded under the Program to a petitioner under section 300aa–11 of this title for a vaccine-related injury or death associated with the administration of a vaccine after October 1, 1988, shall include the following:

(1)(A) Actual unreimbursable expenses incurred from the date of the judgment awarding such expenses and reasonable projected unreimbursable expenses which—

(i) result from the vaccine-related injury for which the petitioner seeks compensation,

(ii) have been or will be incurred by or on behalf of the person who suffered such injury, and

(iii)(I) have been or will be for diagnosis and medical or other remedial care determined to be reasonably necessary, or

(II) have been or will be for rehabilitation, developmental evaluation, special education, vocational training and placement, case management services, counseling, emotional or behavioral therapy, residential and custodial care and service expenses, special equipment, related travel expenses, and facilities determined to be reasonably necessary.

(B) Subject to section 300aa–16(a)(2) of this title, actual unreimbursable expenses incurred before the date of the judgment awarding such expenses which—

(i) resulted from the vaccine-related injury for which the petitioner seeks compensation,

(ii) were incurred by or on behalf of the person who suffered such injury, and

(iii) were for diagnosis, medical or other remedial care, rehabilitation, developmental evaluation, special education, vocational training and placement, case management services, counseling, emotional or behavioral therapy, residential and custodial care and service expenses, special equipment, related travel expenses, and facilities determined to be reasonably necessary.

(2) In the event of a vaccine-related death, an award of $250,000 for the estate of the deceased.

(3)(A) In the case of any person who has sustained a vaccine-related injury after attaining the age of 18 and whose earning capacity is or has been impaired by reason of such person's vaccine-related injury for which compensation is to be awarded, compensation for actual and anticipated loss of earnings determined in accordance with generally recognized actuarial principles and projections.

(B) In the case of any person who has sustained a vaccine-related injury before attaining the age of 18 and whose earning capacity is or has been impaired by reason of such person's vaccine-related injury for which compensation is to be awarded and whose vaccine-related injury is of sufficient severity to permit reasonable anticipation that such person is likely to suffer

impaired earning capacity at age 18 and beyond, compensation after attaining the age of 18 for loss of earnings determined on the basis of the average gross weekly earnings of workers in the private, non-farm sector, less appropriate taxes and the average cost of a health insurance policy, as determined by the Secretary.

(4) For actual and projected pain and suffering and emotional distress from the vaccine-related injury, an award not to exceed $250,000.

(b) Vaccines administered before effective date

Compensation awarded under the Program to a petitioner under section 300aa–11 of this title for a vaccine-related injury or death associated with the administration of a vaccine before October 1, 1988, may include the compensation described in paragraphs (1)(A) and (2) of subsection (a) and may also include an amount, not to exceed a combined total of $30,000, for—

(1) lost earnings (as provided in paragraph (3) of subsection (a)),

(2) pain and suffering (as provided in paragraph (4) of subsection (a)), and

(3) reasonable attorneys' fees and costs (as provided in subsection (e).[1]

(c) Residential and custodial care and service

The amount of any compensation for residential and custodial care and service expenses under subsection (a)(1) shall be sufficient to enable the compensated person to remain living at home.

(d) Types of compensation prohibited

Compensation awarded under the Program may not include the following:

(1) Punitive or exemplary damages.

(2) Except with respect to compensation payments under paragraphs (2) and (3) of subsection (a), compensation for other than the health, education, or welfare of the person who suffered the vaccine-related injury with respect to which the compensation is paid.

(e) Attorneys' fees

(1) In awarding compensation on a petition filed under section 300aa–11 of this title the special master or court shall also award as part of such compensation an amount to cover—

(A) reasonable attorneys' fees, and

(B) other costs,

incurred in any proceeding on such petition. If the judgment of the United States Court of Federal Claims on such a petition does not award compensation, the special master or court may award an amount of compensation to cover petitioner's reasonable attorneys' fees and other costs incurred in any proceeding on such petition if the special master or court determines that the petition was brought in good faith and there was a reasonable basis for the claim for which the petition was brought.

(2) If the petitioner, before October 1, 1988, filed a civil action for damages for any vaccine-related injury or death for which compensation may be awarded under the Program, and petitioned under section 300aa–11(a)(5) of this title to have such action dismissed and to file a petition for compensation under the Program, in awarding compensation on such petition the special master or court may include an amount of compensation limited to the costs and expenses incurred by the petitioner and the attorney of the petitioner before October 1, 1988, in preparing, filing, and prosecuting such civil action (including the reasonable value of the attorney's time if the civil action was filed under contingent fee arrangements).

(3) No attorney may charge any fee for services in connection with a petition filed under section 300aa–11 of this title which is in addition to any amount awarded as compensation by the special master or court under paragraph (1).

(f) Payment of compensation

(1) Except as provided in paragraph (2), no compensation may be paid until an election has been made, or has been deemed to have been made, under section 300aa–21(a) of this title to receive compensation.

(2) Compensation described in subsection (a)(1)(A)(iii) shall be paid from the date of the judgment of the United States Court of Federal Claims under section 300aa–12 of this title awarding the compensation. Such compensation may not be paid after an election under section 300aa–21(a) of this title to file a civil action for damages for the vaccine-related injury or death for which such compensation was awarded.

(3) Payments of compensation under the Program and the costs of carrying out the Program shall be exempt from reduction under any order issued under part C of the Balanced Budget and Emergency Deficit Control Act of 1985 [2 U.S.C. 900 et seq.].

(4)(A) Except as provided in subparagraph (B), payment of compensation under the Program shall be determined on the basis of the net present value of the elements of the compensation and shall be paid from the Vaccine Injury Compensation Trust Fund established under section 9510 of title 26 in a lump sum of which all or a portion may be used as ordered by the special master to purchase an annuity or otherwise be used, with the consent of the petitioner, in a manner determined by the special master to be in the best interests of the petitioner.

(B) In the case of a payment of compensation under the Program to a petitioner for a vaccine-related injury or death associated with the administration of a vaccine before October 1, 1988, the compensation shall be determined on the basis of the net present value of the elements of compensation and shall be paid from appropriations made available under subsection (j) in a lump sum of which all or a portion may be used as ordered by the special master to purchase an annuity or otherwise be used, with the consent of the petitioner, in a manner determined by the special master to be in the best interests of the petitioner. Any reasonable attorneys' fees and costs shall be paid in a lump sum. If the appropriations under subsection (j) are insufficient to make a payment of an annual installment, the limitation on civil actions prescribed by section 300aa–21(a) of this title shall not apply to a civil action for damages brought by the petitioner entitled to the payment.

(C) In purchasing an annuity under subparagraph (A) or (B), the Secretary may purchase a guarantee for the annuity, may enter into agreements regarding the purchase price for and rate of return of the annuity, and may take such other actions as may be necessary to safeguard the financial interests of the United States regarding the annuity. Any payment received by the Secretary pursuant to the preceding sentence shall be paid to the Vaccine Injury Compensation Trust Fund established under section 9510 of title 26, or to the appropriations account from which the funds were derived to purchase the annuity, whichever is appropriate.

(g) Program not primarily liable

Payment of compensation under the Program shall not be made for any item or service to the extent that payment has been made, or can reasonably be expected to be made, with respect to such item or service (1) under any State compensation program, under an insurance policy, or under any Federal or State health benefits program (other than under title XIX of the Social Security Act [42 U.S.C. 1396 et seq.]), or (2) by an entity which provides health services on a prepaid basis.

(h) Liability of health insurance carriers, prepaid health plans, and benefit providers

No policy of health insurance may make payment of benefits under the policy secondary to the payment of compensation under the Program and—

(1) no State, and

(2) no entity which provides health services on a prepaid basis or provides health benefits,

may make the provision of health services or health benefits secondary to the payment of compensation under the Program, except that this subsection shall not apply to the provision of services or benefits under title XIX of the Social Security Act [42 U.S.C. 1396 et seq.].

(i) Source of compensation

(1) Payment of compensation under the Program to a petitioner for a vaccine-related injury or death associated with the administration of a vaccine before October 1, 1988, shall be made by the Secretary from appropriations under subsection (j).

(2) Payment of compensation under the Program to a petitioner for a vaccine-related injury or

death associated with the administration of a vaccine on or after October 1, 1988, shall be made from the Vaccine Injury Compensation Trust Fund established under section 9510 of title 26.

(j) Authorization

For the payment of compensation under the Program to a petitioner for a vaccine-related injury or death associated with the administration of a vaccine before October 1, 1988, there are authorized to be appropriated to the Department of Health and Human Services $80,000,000 for fiscal year 1989, $80,000,000 for fiscal year 1990, $80,000,000 for fiscal year 1991, $80,000,000 for fiscal year 1992, $110,000,000 for fiscal year 1993, and $110,000,000 for each succeeding fiscal year in which a payment of compensation is required under subsection (f)(4)(B). Amounts appropriated under this subsection shall remain available until expended.

(July 1, 1944, ch. 373, title XXI, §2115, as added Pub. L. 99–660, title III, §311(a), Nov. 14, 1986, 100 Stat. 3767; amended Pub. L. 100–203, title IV, §§4302(b), 4303(a)–(d)(1), (e), (g), 4307(5), (6), Dec. 22, 1987, 101 Stat. 1330–221 to 1330–223, 1330–225; Pub. L. 100–360, title IV, §411(o)(1), July 1, 1988, 102 Stat. 808; Pub. L. 101–239, title VI, §6601(c)(8), (l), Dec. 19, 1989, 103 Stat. 2286, 2290; Pub. L. 101–502, §5(d), Nov. 3, 1990, 104 Stat. 1287; Pub. L. 102–168, title II, §201(e), (f), Nov. 26, 1991, 105 Stat. 1103; Pub. L. 102–531, title III, §314, Oct. 27, 1992, 106 Stat. 3508; Pub. L. 102–572, title IX, §902(b)(1), Oct. 29, 1992, 106 Stat. 4516; Pub. L. 103–66, title XIII, §13632(b), Aug. 10, 1993, 107 Stat. 646.)

EDITORIAL NOTES

REFERENCES IN TEXT

The Balanced Budget and Emergency Deficit Control Act of 1985, referred to in subsec. (f)(3), is title II of Pub. L. 99–177, Dec. 12, 1985, 99 Stat. 1038. Part C of the Act is classified generally to subchapter I (§900 et seq.) of chapter 20 of Title 2, The Congress. For complete classification of this Act to the Code, see Short Title note set out under section 900 of Title 2 and Tables.

The Social Security Act, referred to in subsecs. (g) and (h), is act Aug. 14, 1935, ch. 531, 49 Stat. 620. Title XIX of the Social Security Act is classified generally to subchapter XIX (§1396 et seq.) of chapter 7 of this title. For complete classification of this Act to the Code, see section 1305 of this title and Tables.

CODIFICATION

In subsecs. (a), (b), (e)(2), (f)(4)(B), (i), and (j), "October 1, 1988" substituted for "the effective date of this subpart" on authority of section 323 of Pub. L. 99–660, as amended, set out as an Effective Date note under section 300aa–1 of this title.

PRIOR PROVISIONS

A prior section 300aa–15, act July 1, 1944, §2116, was successively renumbered by subsequent acts and transferred, see section 238m of this title.

A prior section 2115 of act July 1, 1944, was successively renumbered by subsequent acts and transferred, see section 238l of this title.

AMENDMENTS

1993—Subsec. (j). Pub. L. 103–66 substituted "$110,000,000 for each succeeding fiscal year" for "$80,000,000 for each succeeding fiscal year".

1992—Subsecs. (e)(1), (f)(2). Pub. L. 102–572 substituted "United States Court of Federal Claims" for "United States Claims Court".

Subsec. (j). Pub. L. 102–531 increased authorization for fiscal year 1993 from $80,000,000 to $110,000,000.

1991—Subsec. (f)(4)(A). Pub. L. 102–168, §201(e)(1)(A), (2), struck out "of the proceeds" after "portion" and substituted "Vaccine Injury Compensation Trust Fund established under section 9510 of title 26" for "trust fund".

Subsec. (f)(4)(B). Pub. L. 102–168, §201(e)(1)(B), which directed substitution of "shall be paid from appropriations made available under subsection (j) in a lump sum of which all or a portion" for "paid in 4

equal installments of which all or portion of the proceeds" was executed by making the substitution for "paid in 4 equal annual installments of which all or a portion of the proceeds" to reflect the probable intent of Congress.

Subsec. (f)(4)(C). Pub. L. 102–168, §201(f), added subpar. (C).

1990—Subsec. (e)(2). Pub. L. 101–502, §5(d)(1), inserted "of compensation" before "limited to the costs".

Subsec. (f)(2). Pub. L. 101–502, §5(d)(2)(A), substituted "section 300aa–21(a)" for "section 300aa–21(b)".

Subsec. (f)(4)(B). Pub. L. 101–502, §5(d)(2)(B), substituted "subsection (j)" for "subsection (i)" and "the limitation on civil actions prescribed by section 300aa–21(a) of this title" for "section 300aa–11(a) of this title".

Subsec. (j). Pub. L. 101–502, §5(d)(3), inserted before period at end of first sentence ", and $80,000,000 for each succeeding fiscal year in which a payment of compensation is required under subsection (f)(4)(B)".

1989—Subsec. (b). Pub. L. 101–239, §6601(l)(1), substituted "may include the compensation described in paragraphs (1)(A) and (2) of subsection (a) and may also include an amount, not to exceed a combined total of $30,000, for—" and cls. (1) to (3) for "may not include the compensation described in paragraph (1)(B) of subsection (a) of this section and may include attorneys' fees and other costs included in a judgment under subsection (e) of this section, except that the total amount that may be paid as compensation under paragraphs (3) and (4) of subsection (a) of this section and included as attorneys' fees and other costs under subsection (e) of this section may not exceed $30,000."

Subsec. (e)(1). Pub. L. 101–239, §6601(l)(2)(A), substituted "In awarding compensation on a petition filed under section 300aa–11 of this title the special master or court shall also award as part of such compensation an amount to cover" for "The judgment of the United States Claims Court on a petition filed under section 300aa–11 of this title awarding compensation shall include an amount to cover".

Pub. L. 101–239, §6601(l)(2)(B), (C), substituted "the special master or court may award an amount of compensation to cover" for "the court may include in the judgment an amount to cover" and "the special master or court determines that the petition was brought in good faith and there was a reasonable basis for the claim for which the petition" for "the court determines that the civil action was brought in good faith and there was a reasonable basis for the claim for which the civil action".

Subsec. (e)(2). Pub. L. 101–239, §6601(l)(2)(D), which directed amendment of par. (2) by substituting "the special master or court may also award an amount of compensation" for "the judgment of the court on such petition may include an amount", could not be executed because of the prior amendment by Pub. L. 101–239, §6601(c)(8)(B), see Amendment note below.

Pub. L. 101–239, §6601(c)(8), substituted "and petitioned under section 300aa–11(a)(5) of this title to have such action dismissed" for "and elected under section 300aa–11(a)(4) of this title to withdraw such action" and "in awarding compensation on such petition the special master or court may include" for "the judgment of the court on such petition may include".

Subsec. (e)(3). Pub. L. 101–239, §6601(l)(2)(E), substituted "awarded as compensation by the special master or court under paragraph (1)" for "included under paragraph (1) in a judgment on such petition".

Subsec. (f)(3). Pub. L. 101–239, §6601(l)(3)(A), inserted "under the Program and the costs of carrying out the Program" after "Payments of compensation".

Subsec. (f)(4)(A). Pub. L. 101–239, §6601(l)(3)(B), struck out "made in a lump sum" after "the Program shall be" and inserted "and shall be paid from the trust fund in a lump sum of which all or a portion of the proceeds may be used as ordered by the special master to purchase an annuity or otherwise be used, with the consent of the petitioner, in a manner determined by the special master to be in the best interests of the petitioner" after "elements of the compensation".

Subsec. (f)(4)(B). Pub. L. 101–239, §6601(l)(3)(C), substituted "determined on the basis of the net present value of the elements of compensation and paid in 4 equal annual installments of which all or a portion of the proceeds may be used as ordered by the special master to purchase an annuity or otherwise be used, with the consent of the petitioner, in a manner determined by the special master to be in the best interests of the petitioner. Any reasonable attorneys' fees and costs shall be paid in a lump sum" for "paid in 4 equal annual installments".

Subsec. (g). Pub. L. 101–239, §6601(l)(4)(A), inserted "(other than under title XIX of the Social Security Act)" after "State health benefits program".

Subsec. (h). Pub. L. 101–239, §6601(l)(4)(B), inserted before period at end ", except that this subsection shall not apply to the provision of services or benefits under title XIX of the Social Security Act".

Subsec. (i)(1). Pub. L. 101–239, §6601(l)(5), which directed amendment of par. (1) by substituting "(j)" for "(i)", could not be executed because "(i)" did not appear.

Subsec. (j). Pub. L. 101–239, §6601(l)(6), struck out "and" after "fiscal year 1991," and inserted ", $80,000,000 for fiscal year 1993" after "fiscal year 1992".

1988—Subsec. (i)(1). Pub. L. 100–360, §411(o)(1)(A), substituted "by the Secretary from appropriations under subsection (j)" for "from appropriations under subsection (i)".

Subsec. (j). Pub. L. 100–360, §411(o)(1)(B), inserted "to the Department of Health and Human Services".

1987—Subsec. (a). Pub. L. 100–203, §4302(b)(1), substituted "effective date of this subpart" for "effective date of this part".

Pub. L. 100–203, §4303(d)(1)(A), struck out last two sentences which read as follows: "Payments for projected expenses shall be paid on a periodic basis (but no payment may be made for a period in excess of 1 year). Payments for pain and suffering and emotional distress and incurred expenses may be paid in a lump sum."

Subsec. (a)(1). Pub. L. 100–203, §4303(c), struck out last sentence of subpars. (A) and (B) each of which read as follows: "The amount of unreimbursable expenses which may be recovered under this subparagraph shall be limited to the amount in excess of the amount set forth in section 300aa–11(c)(1)(D)(ii) of this title."

Subsec. (b). Pub. L. 100–203, §4303(e), substituted "may not include the compensation described in paragraph (1)(B) of subsection (a) of this section and may include attorneys' fees and other costs included in a judgment under subsection (e) of this section, except that the total amount that may be paid as compensation under paragraphs (3) and (4) of subsection (a) of this section and included as attorneys' fees and other costs under subsection (e) of this section may not exceed $30,000" for "shall only include the compensation described in paragraphs (1)(A) and (2) of subsection (a) of this section".

Pub. L. 100–203, §4302(b)(1), substituted "effective date of this subpart" for "effective date of this part".

Subsec. (e)(1). Pub. L. 100–203, §4307(5), substituted "of the United States Claims Court" for "of a court" in two places.

Subsec. (e)(2). Pub. L. 100–203, §4302(b), substituted "effective date of this subpart, filed a" for "effective date of this subchapter, filed a" and "effective date of this subpart in preparing" for "effective date of this part in preparing".

Subsec. (f). Pub. L. 100–203, §4303(d)(1)(B), (g), added par. (4) and redesignated a second subsec. (f), relating to the Program not being primarily liable, as subsec. (g).

Subsec. (f)(2). Pub. L. 100–203, §4307(6), substituted "United States Claims Court" for "district court of the United States".

Subsecs. (g), (h). Pub. L. 100–203, §4303(g), redesignated a second subsec. (f), relating to the Program not being liable, as (g) and redesignated former subsec. (g) as (h).

Subsecs. (i), (j). Pub. L. 100–203, §4303(a), (b), added subsecs. (i) and (j).

STATUTORY NOTES AND RELATED SUBSIDIARIES

EFFECTIVE DATE OF 1992 AMENDMENT

Amendment by Pub. L. 102–572 effective Oct. 29, 1992, see section 911 of Pub. L. 102–572, set out as a note under section 171 of Title 28, Judiciary and Judicial Procedure.

EFFECTIVE DATE OF 1991 AMENDMENT

Amendment by section 201(f) of Pub. L. 102–168 effective as if in effect on and after Oct. 1, 1988, see section 201(i)(2) of Pub. L. 102–168, set out as a note under section 300aa–11 of this title.

EFFECTIVE DATE OF 1990 AMENDMENT

Amendment by Pub. L. 101–502 effective Sept. 30, 1990, see section 5(h) of Pub. L. 101–502, set out as a note under section 300aa–11 of this title.

EFFECTIVE DATE OF 1989 AMENDMENT

Amendment by Pub. L. 101–239 applicable to all pending and subsequently filed petitions, see section 6601(s)(2) of Pub. L. 101–239, set out as a note under section 300aa–10 of this title.

EFFECTIVE DATE OF 1988 AMENDMENT

Except as specifically provided in section 411 of Pub. L. 100–360, amendment by Pub. L. 100–360, as it relates to a provision in the Omnibus Budget Reconciliation Act of 1987, Pub. L. 100–203, effective as if included in the enactment of that provision in Pub. L. 100–203, see section 411(a) of Pub. L. 100–360, set out as a Reference to OBRA; Effective Date note under section 106 of Title 1, General Provisions.

[1] *So in original. Probably should be preceded by another closing parenthesis.*

§300aa–16. Limitations of actions

(a) General rule

In the case of—

(1) a vaccine set forth in the Vaccine Injury Table which is administered before October 1, 1988, if a vaccine-related injury or death occurred as a result of the administration of such vaccine, no petition may be filed for compensation under the Program for such injury or death after the expiration of 28 months after October 1, 1988, and no such petition may be filed if the first symptom or manifestation of onset or of the significant aggravation of such injury occurred more than 36 months after the date of administration of the vaccine,

(2) a vaccine set forth in the Vaccine Injury Table which is administered after October 1, 1988, if a vaccine-related injury occurred as a result of the administration of such vaccine, no petition may be filed for compensation under the Program for such injury after the expiration of 36 months after the date of the occurrence of the first symptom or manifestation of onset or of the significant aggravation of such injury, and

(3) a vaccine set forth in the Vaccine Injury Table which is administered after October 1, 1988, if a death occurred as a result of the administration of such vaccine, no petition may be filed for compensation under the Program for such death after the expiration of 24 months from the date of the death and no such petition may be filed more than 48 months after the date of the occurrence of the first symptom or manifestation of onset or of the significant aggravation of the injury from which the death resulted.

(b) Effect of revised table

If at any time the Vaccine Injury Table is revised and the effect of such revision is to permit an individual who was not, before such revision, eligible to seek compensation under the Program, or to significantly increase the likelihood of obtaining compensation, such person may, notwithstanding section 300aa–11(b)(2) of this title, file a petition for such compensation not later than 2 years after the effective date of the revision, except that no compensation may be provided under the Program with respect to a vaccine-related injury or death covered under the revision of the table if—

(1) the vaccine-related death occurred more than 8 years before the date of the revision of the table, or

(2) the vaccine-related injury occurred more than 8 years before the date of the revision of the table.

(c) State limitations of actions

If a petition is filed under section 300aa–11 of this title for a vaccine-related injury or death, limitations of actions under State law shall be stayed with respect to a civil action brought for such injury or death for the period beginning on the date the petition is filed and ending on the date (1) an election is made under section 300aa–21(a) of this title to file the civil action or (2) an election is made under section 300aa–21(b) of this title to withdraw the petition.

(July 1, 1944, ch. 373, title XXI, §2116, as added Pub. L. 99–660, title III, §311(a), Nov. 14, 1986, 100 Stat. 3769; amended Pub. L. 100–203, title IV, §4302(b)(2), Dec. 22, 1987, 101 Stat. 1330–221; Pub. L. 101–239, title VI, §6601(m)(1), Dec. 19, 1989, 103 Stat. 2291; Pub. L. 101–502, §5(e), Nov. 3, 1990, 104 Stat. 1287; Pub. L. 102–168, title II, §201(d)(2), Nov. 26, 1991, 105 Stat. 1103; Pub. L. 103–66, title XIII, §13632(a)(1), Aug. 10, 1993, 107 Stat. 645.)

EDITORIAL NOTES

CODIFICATION

In subsec. (a)(1) to (3), "October 1, 1988" and "October 1, 1988," substituted for "the effective date of this subpart" on authority of section 323 of Pub. L. 99–660, as amended, set out as an Effective Date note under section 300aa–1 of this title.

PRIOR PROVISIONS

A prior section 2116 of act July 1, 1944, was successively renumbered by subsequent acts and transferred, see section 238m of this title.

AMENDMENTS

1993—Subsec. (b). Pub. L. 103–66 substituted "or to significantly increase the likelihood of obtaining compensation, such person may, notwithstanding section 300aa–11(b)(2) of this title, file" for "such person may file".

1991—Subsec. (c). Pub. L. 102–168 substituted "or (2)" for ", (2)" and struck out ", or (3) the petition is considered withdrawn under section 300aa–21(b) of this title."

1990—Subsec. (a)(1). Pub. L. 101–502, §5(e)(1), substituted "28 months" for "24 months" and inserted before comma at end "and no such petition may be filed if the first symptom or manifestation of onset or of the significant aggravation of such injury occurred more than 36 months after the date of administration of the vaccine".

Subsec. (c). Pub. L. 101–502, §5(e)(2), substituted "and ending on the date (1) an election is made under section 300aa–21(a) of this title to file the civil action, (2) an election is made under section 300aa–21(b) of this title to withdraw the petition, or (3) the petition is considered withdrawn under section 300aa–21(b) of this title" for "and ending on the date a final judgment is entered on the petition".

1989—Subsec. (c). Pub. L. 101–239 substituted "300aa–11 of this title" for "300aa–11(b) of this title".

1987—Subsec. (a). Pub. L. 100–203 substituted "effective date of this subpart" for "effective date of this subchapter" in pars. (1) to (3).

STATUTORY NOTES AND RELATED SUBSIDIARIES

EFFECTIVE DATE OF 1991 AMENDMENT

Amendment by Pub. L. 102–168 effective as if in effect on and after Oct. 1, 1988, see section 201(i)(2) of Pub. L. 102–168, set out as a note under section 300aa–11 of this title.

EFFECTIVE DATE OF 1990 AMENDMENT

Amendment by Pub. L. 101–502 effective Sept. 30, 1990, see section 5(h) of Pub. L. 101–502, set out as a note under section 300aa–11 of this title.

EFFECTIVE DATE OF 1989 AMENDMENT

For applicability of amendments by Pub. L. 101–239 to petitions filed after Dec. 19, 1989, petitions currently pending in which the evidentiary record is closed, and petitions currently pending in which the evidentiary record is not closed, with provision for an immediate suspension for 30 days of all pending cases, see section 6601(s)(1) of Pub. L. 101–239, set out as a note under section 300aa–10 of this title.

§300aa–17. Subrogation

(a) General rule

Upon payment of compensation to any petitioner under the Program, the trust fund which has been established to provide such compensation shall be subrogated [1] to all rights of the petitioner with respect to the vaccine-related injury or death for which compensation was paid, except that the trust fund may not recover under such rights an amount greater than the amount of compensation paid to the petitioner.

(b) Disposition of amounts recovered

Amounts recovered under subsection (a) shall be collected on behalf of, and deposited in, the Vaccine Injury Compensation Trust Fund established under section 9510 of title 26.

(July 1, 1944, ch. 373, title XXI, §2117, as added Pub. L. 99–660, title III, §311(a), Nov. 14, 1986, 100 Stat. 3770; amended Pub. L. 100–203, title IV, §4307(7), Dec. 22, 1987, 101 Stat. 1330–225; Pub. L. 101–239, title VI, §6601(m)(2), Dec. 19, 1989, 103 Stat. 2291.)

EDITORIAL NOTES

AMENDMENTS

1989—Subsec. (b). Pub. L. 101–239 substituted "the Vaccine Injury Compensation Trust Fund established under section 9510 of title 26" for "the trust fund which has been established to provide compensation under the Program".

1987—Subsec. (a). Pub. L. 100–203 struck out par. (1) designation before "Upon" and struck out par. (2) which read as follows: "In any case in which it deems such action appropriate, a district court of the United States may, after entry of a final judgment providing for compensation to be paid under section 300aa–15 of this title for a vaccine-related injury or death, refer the record of such proceeding to the Secretary and the Attorney General with such recommendation as the court deems appropriate with respect to the investigation or commencement of a civil action by the Secretary under paragraph (1)."

STATUTORY NOTES AND RELATED SUBSIDIARIES

EFFECTIVE DATE OF 1989 AMENDMENT

For applicability of amendments by Pub. L. 101–239 to petitions filed after Dec. 19, 1989, petitions currently pending in which the evidentiary record is closed, and petitions currently pending in which the evidentiary record is not closed, with provision for an immediate suspension for 30 days of all pending cases, see section 6601(s)(1) of Pub. L. 101–239, set out as a note under section 300aa–10 of this title.

[1] So in original. Probably should be "subrogated".

§300aa–18. Repealed. Pub. L. 100–203, title IV, §4303(d)(2)(B), Dec. 22, 1987, 101 Stat. 1330–222

Section, act July 1, 1944, ch. 373, title XXI, §2118, as added Nov. 14, 1986, Pub. L. 99–660, title III, §311(a), 100 Stat. 3771, provided for annual increases for inflation of compensation under subsections (a)(2) and (a)(4) of section 300aa–15 of this title and civil penalty under section 300aa–27(b) of this title.

§300aa–19. Advisory Commission on Childhood Vaccines

(a) Establishment

There is established the Advisory Commission on Childhood Vaccines. The Commission shall be composed of:

(1) Nine members appointed by the Secretary as follows:

(A) Three members who are health professionals, who are not employees of the United States, and who have expertise in the health care of children, the epidemiology, etiology, and prevention of childhood diseases, and the adverse reactions associated with vaccines, of whom at least two shall be pediatricians.

(B) Three members from the general public, of whom at least two shall be legal representatives of children who have suffered a vaccine-related injury or death.

(C) Three members who are attorneys, of whom at least one shall be an attorney whose specialty includes representation of persons who have suffered a vaccine-related injury or death and of whom one shall be an attorney whose specialty includes representation of vaccine manufacturers.

(2) The Director of the National Institutes of Health, the Assistant Secretary for Health, the Director of the Centers for Disease Control and Prevention, and the Commissioner of Food and Drugs (or the designees of such officials), each of whom shall be a nonvoting ex officio member.

The Secretary shall select members of the Commission within 90 days of October 1, 1988. The members of the Commission shall select a Chair from among the members.

(b) Term of office

Appointed members of the Commission shall be appointed for a term of office of 3 years, except that of the members first appointed, 3 shall be appointed for a term of 1 year, 3 shall be appointed for a term of 2 years, and 3 shall be appointed for a term of 3 years, as determined by the Secretary.

(c) Meetings

The Commission shall first meet within 60 days after all members of the Commission are appointed, and thereafter shall meet not less often than four times per year and at the call of the chair. A quorum for purposes of a meeting is 5. A decision at a meeting is to be made by a ballot of a majority of the voting members of the Commission present at the meeting.

(d) Compensation

Members of the Commission who are officers or employees of the Federal Government shall serve as members of the Commission without compensation in addition to that received in their regular public employment. Members of the Commission who are not officers or employees of the Federal Government shall be compensated at a rate not to exceed the daily equivalent of the rate in effect for grade GS–18 of the General Schedule for each day (including traveltime) they are engaged in the performance of their duties as members of the Commission. All members, while so serving away from their homes or regular places of business, may be allowed travel expenses, including per diem in lieu of subsistence, in the same manner as such expenses are authorized by section 5703 of title 5 for employees serving intermittently.

(e) Staff

The Secretary shall provide the Commission with such professional and clerical staff, such information, and the services of such consultants as may be necessary to assist the Commission in carrying out effectively its functions under this section.

(f) Functions

The Commission shall—

(1) advise the Secretary on the implementation of the Program,

(2) on its own initiative or as the result of the filing of a petition, recommend changes in the Vaccine Injury Table,

(3) advise the Secretary in implementing the Secretary's responsibilities under section 300aa–27 of this title regarding the need for childhood vaccination products that result in fewer or no significant adverse reactions,

(4) survey Federal, State, and local programs and activities relating to the gathering of information on injuries associated with the administration of childhood vaccines, including the adverse reaction reporting requirements of section 300aa–25(b) of this title, and advise the Secretary on means to obtain, compile, publish, and use credible data related to the frequency and severity of adverse reactions associated with childhood vaccines, and

(5) recommend to the Director of the National Vaccine Program research related to vaccine injuries which should be conducted to carry out this part.

(July 1, 1944, ch. 373, title XXI, §2119, as added Pub. L. 99–660, title III, §311(a), Nov. 14, 1986, 100 Stat. 3771; amended Pub. L. 100–203, title IV, §4302(b)(1), Dec. 22, 1987, 101 Stat. 1330–221; Pub. L. 102–168, title II, §201(g), Nov. 26, 1991, 105 Stat. 1104; Pub. L. 102–531, title III, §312(d)(14), Oct. 27, 1992, 106 Stat. 3505.)

EDITORIAL NOTES

CODIFICATION

In subsec. (a), "October 1, 1988" substituted for "the effective date of this subpart" on authority of section 323 of Pub. L. 99–660, as amended, set out as an Effective Date note under section 300aa–1 of this title.

AMENDMENTS

1992—Subsec. (a)(2). Pub. L. 102–531 substituted "Centers for Disease Control and Prevention" for

"Centers for Disease Control".

1991—Subsec. (c). Pub. L. 102–168 inserted "present at the meeting" before period at end.

1987—Subsec. (a). Pub. L. 100–203 substituted "effective date of this subpart" for "effective date of this part" in last sentence.

STATUTORY NOTES AND RELATED SUBSIDIARIES

TERMINATION OF ADVISORY COMMISSIONS

Advisory commissions established after Jan. 5, 1973, to terminate not later than the expiration of the 2-year period beginning on the date of their establishment, unless, in the case of a commission established by the President or an officer of the Federal Government, such commission is renewed by appropriate action prior to the expiration of such 2-year period, or in the case of a commission established by the Congress, its duration is otherwise provided by law. See sections 1001(2) and 1013 of Title 5, Government Organization and Employees.

Pub. L. 93–641, §6, Jan. 4, 1975, 88 Stat. 2275, set out as a note under section 217a of this title, provided that an advisory committee established pursuant to the Public Health Service Act shall terminate at such time as may be specifically prescribed by an Act of Congress enacted after Jan. 4, 1975.

REFERENCES IN OTHER LAWS TO GS–16, 17, OR 18 PAY RATES

References in laws to the rates of pay for GS–16, 17, or 18, or to maximum rates of pay under the General Schedule, to be considered references to rates payable under specified sections of Title 5, Government Organization and Employees, see section 529 [title I, §101(c)(1)] of Pub. L. 101–509, set out in a note under section 5376 of Title 5.

SUBPART B—ADDITIONAL REMEDIES

§300aa–21. Authority to bring actions

(a) Election

After judgment has been entered by the United States Court of Federal Claims or, if an appeal is taken under section 300aa–12(f) of this title, after the appellate court's mandate is issued, the petitioner who filed the petition under section 300aa–11 of this title shall file with the clerk of the United States Court of Federal Claims—

(1) if the judgment awarded compensation, an election in writing to receive the compensation or to file a civil action for damages for such injury or death, or

(2) if the judgment did not award compensation, an election in writing to accept the judgment or to file a civil action for damages for such injury or death.

An election shall be filed under this subsection not later than 90 days after the date of the court's final judgment with respect to which the election is to be made. If a person required to file an election with the court under this subsection does not file the election within the time prescribed for filing the election, such person shall be deemed to have filed an election to accept the judgment of the court. If a person elects to receive compensation under a judgment of the court in an action for a vaccine-related injury or death associated with the administration of a vaccine before October 1, 1988, or is deemed to have accepted the judgment of the court in such an action, such person may not bring or maintain a civil action for damages against a vaccine administrator or manufacturer for the vaccine-related injury or death for which the judgment was entered. For limitations on the bringing of civil actions for vaccine-related injuries or deaths associated with the administration of a vaccine after October 1, 1988, see section 300aa–11(a)(2) of this title.

(b) Continuance or withdrawal of petition

A petitioner under a petition filed under section 300aa–11 of this title may submit to the United

States Court of Federal Claims a notice in writing choosing to continue or to withdraw the petition if—

(1) a special master fails to make a decision on such petition within the 240 days prescribed by section 300aa–12(d)(3)(A)(ii) of this title (excluding (i) any period of suspension under section 300aa–12(d)(3)(C) or 300aa–12(d)(3)(D) of this title, and (ii) any days the petition is before a special master as a result of a remand under section 300aa–12(e)(2)(C) of this title), or

(2) the court fails to enter a judgment under section 300aa–12 of this title on the petition within 420 days (excluding (i) any period of suspension under section 300aa–12(d)(3)(C) or 300aa–12(d)(3)(D) of this title, and (ii) any days the petition is before a special master as a result of a remand under section 300aa–12(e)(2)(C) of this title) after the date on which the petition was filed.

Such a notice shall be filed within 30 days of the provision of the notice required by section 300aa–12(g) of this title.

(c) Limitations of actions

A civil action for damages arising from a vaccine-related injury or death for which a petition was filed under section 300aa–11 of this title shall, except as provided in section 300aa–16(c) of this title, be brought within the period prescribed by limitations of actions under State law applicable to such civil action.

(July 1, 1944, ch. 373, title XXI, §2121, as added Pub. L. 99–660, title III, §311(a), Nov. 14, 1986, 100 Stat. 3772; amended Pub. L. 100–203, title IV, §§4304(c), 4307(8), 4308(c), Dec. 22, 1987, 101 Stat. 1330–224, 1330–225; Pub. L. 100–360, title IV, §411(o)(3)(A), July 1, 1988, 102 Stat. 808; Pub. L. 101–239, title VI, §6601(n), Dec. 19, 1989, 103 Stat. 2291; Pub. L. 101–502, §5(f), Nov. 3, 1990, 104 Stat. 1287; Pub. L. 102–168, title II, §201(d)(3), Nov. 26, 1991, 105 Stat. 1103; Pub. L. 102–572, title IX, §902(b)(1), Oct. 29, 1992, 106 Stat. 4516.)

EDITORIAL NOTES

CODIFICATION

In subsec. (a), "October 1, 1988," and "October 1, 1988" substituted for "the effective date of this part".

AMENDMENTS

1992—Subsecs. (a), (b). Pub. L. 102–572 substituted "United States Court of Federal Claims" for "United States Claims Court" wherever appearing.

1991—Subsec. (b). Pub. L. 102–168 substituted "Continuance or withdrawal of petition" for "Withdrawal of petition" in heading, redesignated introductory provisions of par. (1) as introductory provisions of subsec. (b) and substituted "a notice in writing choosing to continue or to withdraw the petition" for "a notice in writing withdrawing the petition", redesignated subpars. (A) and (B) of former par. (1) as pars. (1) and (2), respectively, and realigned margins, struck out at end of former par. (1) "If such a notice is not filed before the expiration of such 30 days, the petition with respect to which the notice was to be filed shall be considered withdrawn under this paragraph.", and struck out par. (2) which read as follows: "If a special master or the court does not enter a decision or make a judgment on a petition filed under section 300aa–11 of this title within 30 days of the provision of the notice in accordance with section 300aa–12(g) of this title, the special master or court shall no longer have jurisdiction over such petition and such petition shall be considered as withdrawn under paragraph (1)."

1990—Subsec. (a). Pub. L. 101–502, §5(f)(1), in closing provisions, inserted after second sentence "If a person elects to receive compensation under a judgment of the court in an action for a vaccine-related injury or death associated with the administration of a vaccine before October 1, 1988, or is deemed to have accepted the judgment of the court in such an action, such person may not bring or maintain a civil action for damages against a vaccine administrator or manufacturer for the vaccine-related injury or death for which the judgment was entered." and inserted "for vaccine-related injuries or deaths associated with the administration of a vaccine after October 1, 1988" after "actions" in last sentence.

Subsec. (b). Pub. L. 101–502, §5(f)(2), amended subsec. (b) generally. Prior to amendment, subsec. (b) read as follows: "If the United States Claims Court fails to enter a judgment under section 300aa–12 of this title on

a petition filed under section 300aa–11 of this title within 420 days (excluding any period of suspension under section 300aa–12(d) of this title and excluding any days the petition is before a special master as a result of a remand under section 300aa–12(e)(2)(C) of this title) after the date on which the petition was filed, the petitioner may submit to the court a notice in writing withdrawing the petition. An election shall be filed under this subsection not later than 90 days after the date of the entry of the Claims Court's judgment or the appellate court's mandate with respect to which the election is to be made. A person who has submitted a notice under this subsection may, notwithstanding section 300aa–11(a)(2) of this title, thereafter maintain a civil action for damages in a State or Federal court without regard to this subpart and consistent with otherwise applicable law."

1989—Subsec. (a). Pub. L. 101–239, §6601(n)(1)(A), amended introductory provisions generally. Prior to amendment, introductory provisions read as follows: "After the judgment of the United States Claims Court under section 300aa–11 of this title on a petition filed for compensation under the Program for a vaccine-related injury or death has become final, the person who filed the petition shall file with the court—".

Pub. L. 101–239, §6601(n)(1)(B), amended last sentence generally. Prior to amendment, last sentence read as follows: "If a person elects to receive compensation under a judgment of the court or is deemed to have accepted the judgment of the court, such person may not bring or maintain a civil action for damages against a vaccine manufacturer for the vaccine-related injury or death for which the judgment was entered."

Subsec. (b). Pub. L. 101–239, §6601(n)(2), substituted "within 420 days (excluding any period of suspension under section 300aa–12(d) of this title and excluding any days the petition is before a special master as a result of a remand under section 300aa–12(e)(2)(C) of this title)" for "within 365 days" in first sentence and amended second sentence generally. Prior to amendment, second sentence read as follows: "Such a notice shall be filed not later than 90 days after the expiration of such 365-day period."

1988—Subsec. (a). Pub. L. 100–360 added Pub. L. 100–203, §4308(c), see 1987 Amendment note below.

1987—Subsec. (a). Pub. L. 100–203, §4308(c), as added by Pub. L. 100–360, substituted "the court's final judgment" for "the entry of the court's judgment" in concluding provisions.

Pub. L. 100–203, §4307(8), substituted "the United States Claims Court" for "a district court of the United States" and "the court" for "a court" in three places.

Subsecs. (b), (c). Pub. L. 100–203, §4304(c), added subsec. (b) and redesignated former subsec. (b) as (c).

STATUTORY NOTES AND RELATED SUBSIDIARIES

EFFECTIVE DATE OF 1992 AMENDMENT

Amendment by Pub. L. 102–572 effective Oct. 29, 1992, see section 911 of Pub. L. 102–572, set out as a note under section 171 of Title 28, Judiciary and Judicial Procedure.

EFFECTIVE DATE OF 1991 AMENDMENT

Amendment by Pub. L. 102–168 effective as in effect on and after Oct. 1, 1988, see section 201(i)(2) of Pub. L. 102–168, set out as a note under section 300aa–11 of this title.

EFFECTIVE DATE OF 1990 AMENDMENT

Amendment by section 5(f)(1) of Pub. L. 101–502 effective Nov. 14, 1986, and amendment by section 5(f)(2) of Pub. L. 101–502 effective Sept. 30, 1990, see section 5(h) of Pub. L. 101–502, set out as a note under section 300aa–11 of this title.

EFFECTIVE DATE OF 1989 AMENDMENT

For applicability of amendments by Pub. L. 101–239 to petitions filed after Dec. 19, 1989, petitions currently pending in which the evidentiary record is closed, and petitions currently pending in which the evidentiary record is not closed, with provision for an immediate suspension for 30 days of all pending cases, except that such suspension be excluded in determining the 420-day period prescribed in subsec. (b) of this section, see section 6601(s)(1) of Pub. L. 101–239, set out as a note under section 300aa–10 of this title.

EFFECTIVE DATE OF 1988 AMENDMENT

Except as specifically provided in section 411 of Pub. L. 100–360, amendment by Pub. L. 100–360, as it relates to a provision in the Omnibus Budget Reconciliation Act of 1987, Pub. L. 100–203, effective as if included in the enactment of that provision in Pub. L. 100–203, see section 411(a) of Pub. L. 100–360, set out as a Reference to OBRA; Effective Date note under section 106 of Title 1, General Provisions.

EFFECTIVE DATE

Subpart effective Oct. 1, 1988, see section 323 of Pub. L. 99–660, set out as a note under section 300aa–1 of this title.

§300aa–22. Standards of responsibility

(a) General rule

Except as provided in subsections (b), (c), and (e) State law shall apply to a civil action brought for damages for a vaccine-related injury or death.

(b) Unavoidable adverse side effects; warnings

(1) No vaccine manufacturer shall be liable in a civil action for damages arising from a vaccine-related injury or death associated with the administration of a vaccine after October 1, 1988, if the injury or death resulted from side effects that were unavoidable even though the vaccine was properly prepared and was accompanied by proper directions and warnings.

(2) For purposes of paragraph (1), a vaccine shall be presumed to be accompanied by proper directions and warnings if the vaccine manufacturer shows that it complied in all material respects with all requirements under the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 301 et seq.] and section 262 of this title (including regulations issued under such provisions) applicable to the vaccine and related to vaccine-related injury or death for which the civil action was brought unless the plaintiff shows—

(A) that the manufacturer engaged in the conduct set forth in subparagraph (A) or (B) of section 300aa–23(d)(2) of this title, or

(B) by clear and convincing evidence that the manufacturer failed to exercise due care notwithstanding its compliance with such Act and section (and regulations issued under such provisions).

(c) Direct warnings

No vaccine manufacturer shall be liable in a civil action for damages arising from a vaccine-related injury or death associated with the administration of a vaccine after October 1, 1988, solely due to the manufacturer's failure to provide direct warnings to the injured party (or the injured party's legal representative) of the potential dangers resulting from the administration of the vaccine manufactured by the manufacturer.

(d) Construction

The standards of responsibility prescribed by this section are not to be construed as authorizing a person who brought a civil action for damages against a vaccine manufacturer for a vaccine-related injury or death in which damages were denied or which was dismissed with prejudice to bring a new civil action against such manufacturer for such injury or death.

(e) Preemption

No State may establish or enforce a law which prohibits an individual from bringing a civil action against a vaccine manufacturer for damages for a vaccine-related injury or death if such civil action is not barred by this part.

(July 1, 1944, ch. 373, title XXI, §2122, as added Pub. L. 99–660, title III, §311(a), Nov. 14, 1986, 100 Stat. 3773; amended Pub. L. 100–203, title IV, §4302(b)(1), Dec. 22, 1987, 101 Stat. 1330–221.)

EDITORIAL NOTES

REFERENCES IN TEXT

The Federal Food, Drug, and Cosmetic Act, referred to in subsec. (b)(2), is act June 25, 1938, ch. 675, 52 Stat. 1040, which is classified generally to chapter 9 (§301 et seq.) of Title 21, Food and Drugs. For complete classification of this Act to the Code, see Tables.

CODIFICATION

In subsecs. (b)(1), (c), "October 1, 1988" was substituted for "the effective date of this subpart" on authority of section 323 of Pub. L. 99–660, as amended, set out as an Effective Date note under section 300aa–1 of this title.

AMENDMENTS

1987—Subsecs. (b)(1), (c). Pub. L. 100–203 substituted "effective date of this subpart" for "effective date of this part".

§300aa–23. Trial

(a) General rule

A civil action against a vaccine manufacturer for damages for a vaccine-related injury or death associated with the administration of a vaccine after October 1, 1988, which is not barred by section 300aa–11(a)(2) of this title shall be tried in three stages.

(b) Liability

The first stage of such a civil action shall be held to determine if a vaccine manufacturer is liable under section 300aa–22 of this title.

(c) General damages

The second stage of such a civil action shall be held to determine the amount of damages (other than punitive damages) a vaccine manufacturer found to be liable under section 300aa–22 of this title shall be required to pay.

(d) Punitive damages

(1) If sought by the plaintiff, the third stage of such an action shall be held to determine the amount of punitive damages a vaccine manufacturer found to be liable under section 300aa–22 of this title shall be required to pay.

(2) If in such an action the manufacturer shows that it complied, in all material respects, with all requirements under the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 301 et seq.] and this chapter applicable to the vaccine and related to the vaccine injury or death with respect to which the action was brought, the manufacturer shall not be held liable for punitive damages unless the manufacturer engaged in—

(A) fraud or intentional and wrongful withholding of information from the Secretary during any phase of a proceeding for approval of the vaccine under section 262 of this title,

(B) intentional and wrongful withholding of information relating to the safety or efficacy of the vaccine after its approval, or

(C) other criminal or illegal activity relating to the safety and effectiveness of vaccines,

which activity related to the vaccine-related injury or death for which the civil action was brought.

(e) Evidence

In any stage of a civil action, the Vaccine Injury Table, any finding of fact or conclusion of law of the United States Court of Federal Claims or a special master in a proceeding on a petition filed under section 300aa–11 of this title and the final judgment of the United States Court of Federal Claims and subsequent appellate review on such a petition shall not be admissible.

(July 1, 1944, ch. 373, title XXI, §2123, as added Pub. L. 99–660, title III, §311(a), Nov. 14, 1986, 100 Stat. 3774; amended Pub. L. 100–203, title IV, §§4302(b)(1), 4307(9), Dec. 22, 1987, 101 Stat. 1330–221, 1330–225; Pub. L. 101–239, title VI, §6601(o), Dec. 19, 1989, 103 Stat. 2292; Pub. L. 102–572, title IX, §902(b)(1), Oct. 29, 1992, 106 Stat. 4516.)

EDITORIAL NOTES

REFERENCES IN TEXT

The Federal Food, Drug, and Cosmetic Act, referred to in subsec. (d)(2), is act June 25, 1938, ch. 675, 52 Stat. 1040, which is classified generally to chapter 9 (§301 et seq.) of Title 21, Food and Drugs. For complete classification of this Act to the Code, see Tables.

CODIFICATION

In subsec. (a), "October 1, 1988" substituted for "the effective date of this subpart" on authority of section 323 of Pub. L. 99–660, as amended, set out as an Effective Date note under section 300aa–1 of this title.

AMENDMENTS

1992—Subsec. (e). Pub. L. 102–572 substituted "United States Court of Federal Claims" for "United States Claims Court" in two places.

1989—Subsec. (e). Pub. L. 101–239 substituted "finding of fact or conclusion of law" for "finding", "special master" for "master appointed by such court", and directed substitution of "the United States Claims Court and subsequent appellate review" for "a district court of the United States" which was executed by inserting "and subsequent appellate review" after "the United States Claims Court" the second place it appeared to reflect the probable intent of Congress and the amendment by Pub. L. 100–203, §4307(a), see 1987 Amendment note below.

1987—Subsec. (a). Pub. L. 100–203, §4302(b)(1), substituted "effective date of this subpart" for "effective date of this part".

Subsec. (e). Pub. L. 100–203, §4307(9), substituted "the United States Claims Court" for "a district court of the United States" in two places.

STATUTORY NOTES AND RELATED SUBSIDIARIES

EFFECTIVE DATE OF 1992 AMENDMENT

Amendment by Pub. L. 102–572 effective Oct. 29, 1992, see section 911 of Pub. L. 102–572, set out as a note under section 171 of Title 28, Judiciary and Judicial Procedure.

EFFECTIVE DATE OF 1989 AMENDMENT

For applicability of amendments by Pub. L. 101–239 to petitions filed after Dec. 19, 1989, petitions currently pending in which the evidentiary record is closed, and petitions currently pending in which the evidentiary record is not closed, with provision for an immediate suspension for 30 days of all pending cases, see section 6601(s)(1) of Pub. L. 101–239, set out as a note under section 300aa–10 of this title.

SUBPART C—ASSURING A SAFER CHILDHOOD VACCINATION PROGRAM IN UNITED STATES

§300aa–25. Recording and reporting of information

(a) General rule

Each health care provider who administers a vaccine set forth in the Vaccine Injury Table to any person shall record, or ensure that there is recorded, in such person's permanent medical record (or in a permanent office log or file to which a legal representative shall have access upon request) with respect to each such vaccine—

(1) the date of administration of the vaccine,

(2) the vaccine manufacturer and lot number of the vaccine,

(3) the name and address and, if appropriate, the title of the health care provider administering the vaccine, and

(4) any other identifying information on the vaccine required pursuant to regulations promulgated by the Secretary.

(b) Reporting

(1) Each health care provider and vaccine manufacturer shall report to the Secretary—

(A) the occurrence of any event set forth in the Vaccine Injury Table, including the events set forth in section 300aa–14(b) of this title which occur within 7 days of the administration of any vaccine set forth in the Table or within such longer period as is specified in the Table or section,

(B) the occurrence of any contraindicating reaction to a vaccine which is specified in the manufacturer's package insert, and

(C) such other matters as the Secretary may by regulation require.

Reports of the matters referred to in subparagraphs (A) and (B) shall be made beginning 90 days after December 22, 1987. The Secretary shall publish in the Federal Register as soon as practicable after such date a notice of the reporting requirement.

(2) A report under paragraph (1) respecting a vaccine shall include the time periods after the administration of such vaccine within which vaccine-related illnesses, disabilities, injuries, or conditions, the symptoms and manifestations of such illnesses, disabilities, injuries, or conditions, or deaths occur, and the manufacturer and lot number of the vaccine.

(3) The Secretary shall issue the regulations referred to in paragraph (1)(C) within 180 days of December 22, 1987.

(c) Release of information

(1) Information which is in the possession of the Federal Government and State and local governments under this section and which may identify an individual shall not be made available under section 552 of title 5, or otherwise, to any person except—

(A) the person who received the vaccine, or

(B) the legal representative of such person.

(2) For purposes of paragraph (1), the term "information which may identify an individual" shall be limited to the name, street address, and telephone number of the person who received the vaccine and of that person's legal representative and the medical records of such person relating to the administration of the vaccine, and shall not include the locality and State of vaccine administration, the name of the health care provider who administered the vaccine, the date of the vaccination, or information concerning any reported illness, disability, injury, or condition resulting from the administration of the vaccine, any symptom or manifestation of such illness, disability, injury, or condition, or death resulting from the administration of the vaccine.

(3) Except as provided in paragraph (1), all information reported under this section shall be available to the public.

(July 1, 1944, ch. 373, title XXI, §2125, as added Pub. L. 99–660, title III, §311(a), Nov. 14, 1986, 100 Stat. 3774; amended Pub. L. 100–203, title IV, §4302(b)(1), Dec. 22, 1987, 101 Stat. 1330–221.)

EDITORIAL NOTES

CODIFICATION

In subsec. (b)(1), (3), "December 22, 1987" was substituted for "the effective date of this subpart" on authority of section 323 of Pub. L. 99–660, as amended, set out as an Effective Date note under section 300aa–1 of this title.

AMENDMENTS

1987—Subsec. (b)(1), (3). Pub. L. 100–203 substituted "effective date of this subpart" for "effective date of this part".

STATUTORY NOTES AND RELATED SUBSIDIARIES

EFFECTIVE DATE

Subpart effective Dec. 22, 1987, see section 323 of Pub. L. 99–660, set out as a note under section 300aa–1 of this title.

§300aa–26. Vaccine information

(a) General rule

Not later than 1 year after December 22, 1987, the Secretary shall develop and disseminate vaccine information materials for distribution by health care providers to the legal representatives of any child or to any other individual receiving a vaccine set forth in the Vaccine Injury Table. Such materials shall be published in the Federal Register and may be revised.

(b) Development and revision of materials

Such materials shall be developed or revised—

(1) after notice to the public and 60 days of comment thereon, and

(2) in consultation with the Advisory Commission on Childhood Vaccines, appropriate health care providers and parent organizations, the Centers for Disease Control and Prevention, and the Food and Drug Administration.

(c) Information requirements

The information in such materials shall be based on available data and information, shall be presented in understandable terms and shall include—

(1) a concise description of the benefits of the vaccine,

(2) a concise description of the risks associated with the vaccine,

(3) a statement of the availability of the National Vaccine Injury Compensation Program, and

(4) such other relevant information as may be determined by the Secretary.

(d) Health care provider duties

On and after a date determined by the Secretary which is—

(1) after the Secretary develops the information materials required by subsection (a), and

(2) not later than 6 months after the date such materials are published in the Federal Register,

each health care provider who administers a vaccine set forth in the Vaccine Injury Table shall provide to the legal representatives of any child or to any other individual to whom such provider intends to administer such vaccine a copy of the information materials developed pursuant to subsection (a), supplemented with visual presentations or oral explanations, in appropriate cases. Such materials shall be provided prior to the administration of such vaccine.

(July 1, 1944, ch. 373, title XXI, §2126, as added Pub. L. 99–660, title III, §311(a), Nov. 14, 1986, 100 Stat. 3775; amended Pub. L. 100–203, title IV, §4302(b)(1), Dec. 22, 1987, 101 Stat. 1330–221; Pub. L. 101–239, title VI, §6601(p), Dec. 19, 1989, 103 Stat. 2292; Pub. L. 102–531, title III, §312(d)(15), Oct. 27, 1992, 106 Stat. 3505; Pub. L. 103–183, title VII, §708, Dec. 14, 1993, 107 Stat. 2242.)

EDITORIAL NOTES

CODIFICATION

In subsec. (a), "December 22, 1987" substituted for "the effective date of this subpart" on authority of section 323 of Pub. L. 99–660, as amended, set out as an Effective Date note under section 300aa–1 of this title.

AMENDMENTS

1993—Subsec. (a). Pub. L. 103–183, §708(c), inserted "or to any other individual" after "to the legal representatives of any child".

Subsec. (b). Pub. L. 103–183, §708(a), struck out "by rule" after "revised" in introductory provisions and substituted "and 60" for ", opportunity for a public hearing, and 90" in par. (1).

Subsec. (c). Pub. L. 103–183, §708(b), inserted in introductory provisions "shall be based on available data and information," after "such materials", added pars. (1) to (4), and struck out former pars. (1) to (10) which read as follows:

"(1) the frequency, severity, and potential long-term effects of the disease to be prevented by the vaccine,

"(2) the symptoms or reactions to the vaccine which, if they occur, should be brought to the immediate attention of the health care provider,

"(3) precautionary measures legal representatives should take to reduce the risk of any major adverse reactions to the vaccine that may occur,

"(4) early warning signs or symptoms to which legal representatives should be alert as possible precursors to such major adverse reactions,

"(5) a description of the manner in which legal representatives should monitor such major adverse reactions, including a form on which reactions can be recorded to assist legal representatives in reporting information to appropriate authorities,

"(6) a specification of when, how, and to whom legal representatives should report any major adverse reaction,

"(7) the contraindications to (and bases for delay of) the administration of the vaccine,

"(8) an identification of the groups, categories, or characteristics of potential recipients of the vaccine who may be at significantly higher risk of major adverse reaction to the vaccine than the general population,

"(9) a summary of—

"(A) relevant Federal recommendations concerning a complete schedule of childhood immunizations, and

"(B) the availability of the Program, and

"(10) such other relevant information as may be determined by the Secretary."

Subsec. (d). Pub. L. 103–183, §708(c), (d), in concluding provisions, inserted "or to any other individual" after "to the legal representatives of any child", substituted "supplemented with visual presentations or oral explanations, in appropriate cases" for "or other written information which meets the requirements of this section", and struck out "or other information" after "Such materials".

1992—Subsec. (b)(2). Pub. L. 102–531 substituted "Centers for Disease Control and Prevention" for "Centers for Disease Control".

1989—Subsec. (c)(9). Pub. L. 101–239 amended par. (9) generally. Prior to amendment, par. (9) read as follows: "a summary of relevant State and Federal laws concerning the vaccine, including information on—

"(A) the number of vaccinations required for school attendance and the schedule recommended for such vaccinations, and

"(B) the availability of the Program, and".

1987—Subsec. (a). Pub. L. 100–203 substituted "effective date of this subpart" for "effective date of this part".

STATUTORY NOTES AND RELATED SUBSIDIARIES

EFFECTIVE DATE OF 1989 AMENDMENT

For applicability of amendments by Pub. L. 101–239 to petitions filed after Dec. 19, 1989, petitions currently pending in which the evidentiary record is closed, and petitions currently pending in which the evidentiary record is not closed, with provision for an immediate suspension for 30 days of all pending cases, see section 6601(s)(1) of Pub. L. 101–239, set out as a note under section 300aa–10 of this title.

§300aa–27. Mandate for safer childhood vaccines

(a) General rule

In the administration of this part and other pertinent laws under the jurisdiction of the Secretary, the Secretary shall—

(1) promote the development of childhood vaccines that result in fewer and less serious adverse reactions than those vaccines on the market on December 22, 1987, and promote the refinement of such vaccines, and

(2) make or assure improvements in, and otherwise use the authorities of the Secretary with respect to, the licensing, manufacturing, processing, testing, labeling, warning, use instructions, distribution, storage, administration, field surveillance, adverse reaction reporting, and recall of reactogenic lots or batches, of vaccines, and research on vaccines, in order to reduce the risks of adverse reactions to vaccines.

(b) Task force

(1) The Secretary shall establish a task force on safer childhood vaccines which shall consist of the Director of the National Institutes of Health, the Commissioner of the Food and Drug Administration, and the Director of the Centers for Disease Control.

(2) The Director of the National Institutes of Health shall serve as chairman of the task force.

(3) In consultation with the Advisory Commission on Childhood Vaccines, the task force shall prepare recommendations to the Secretary concerning implementation of the requirements of subsection (a).

(c) Report

Within 2 years after December 22, 1987, and periodically thereafter, the Secretary shall prepare and transmit to the Committee on Energy and Commerce of the House of Representatives and the Committee on Labor and Human Resources of the Senate a report describing the actions taken pursuant to subsection (a) during the preceding 2-year period.

(July 1, 1944, ch. 373, title XXI, §2127, as added Pub. L. 99–660, title III, §311(a), Nov. 14, 1986, 100 Stat. 3777; amended Pub. L. 100–203, title IV, §4302(b)(1), Dec. 22, 1987, 101 Stat. 1330–221; Pub. L. 101–239, title VI, §6601(q), Dec. 19, 1989, 103 Stat. 2292.)

EDITORIAL NOTES

CODIFICATION

In subsecs. (a)(1), (c), "December 22, 1987" substituted for "the effective date of this subpart" on authority of section 323 of Pub. L. 99–660, as amended, set out as an Effective Date note under section 300aa–1 of this title.

AMENDMENTS

1989—Subsecs. (b), (c). Pub. L. 101–239 added subsec. (b) and redesignated former subsec. (b) as (c).

1987—Subsecs. (a)(1), (b). Pub. L. 100–203 substituted "effective date of this subpart" for "effective date of this part".

STATUTORY NOTES AND RELATED SUBSIDIARIES

CHANGE OF NAME

Committee on Labor and Human Resources of Senate changed to Committee on Health, Education, Labor, and Pensions of Senate by Senate Resolution No. 20, One Hundred Sixth Congress, Jan. 19, 1999.

Committee on Energy and Commerce of House of Representatives treated as referring to Committee on Commerce of House of Representatives by section 1(a) of Pub. L. 104–14, set out as a note preceding section 21 of Title 2, The Congress. Committee on Commerce of House of Representatives changed to Committee on Energy and Commerce of House of Representatives, and jurisdiction over matters relating to securities and exchanges and insurance generally transferred to Committee on Financial Services of House of Representatives by House Resolution No. 5, One Hundred Seventh Congress, Jan. 3, 2001.

Centers for Disease Control changed to Centers for Disease Control and Prevention by Pub. L. 102–531, title III, §312, Oct. 27, 1992, 106 Stat. 3504.

EFFECTIVE DATE OF 1989 AMENDMENT

For applicability of amendments by Pub. L. 101–239 to petitions filed after Dec. 19, 1989, petitions currently pending in which the evidentiary record is closed, and petitions currently pending in which the evidentiary record is not closed, with provision for an immediate suspension for 30 days of all pending cases, see section 6601(s)(1) of Pub. L. 101–239, set out as a note under section 300aa–10 of this title.

§300aa–28. Manufacturer recordkeeping and reporting

(a) General rule

Each vaccine manufacturer of a vaccine set forth in the Vaccine Injury Table or any other vaccine the administration of which is mandated by the law or regulations of any State, shall, with respect to

each batch, lot, or other quantity manufactured or licensed after December 22, 1987—

(1) prepare and maintain records documenting the history of the manufacturing, processing, testing, repooling, and reworking of each batch, lot, or other quantity of such vaccine, including the identification of any significant problems encountered in the production, testing, or handling of such batch, lot, or other quantity,

(2) if a safety test on such batch, lot, or other quantity indicates a potential imminent or substantial public health hazard is presented, report to the Secretary within 24 hours of such safety test which the manufacturer (or manufacturer's representative) conducted, including the date of the test, the type of vaccine tested, the identity of the batch, lot, or other quantity tested, whether the batch, lot, or other quantity tested is the product of repooling or reworking of previous batches, lots, or other quantities (and, if so, the identity of the previous batches, lots, or other quantities which were repooled or reworked), the complete test results, and the name and address of the person responsible for conducting the test,

(3) include with each such report a certification signed by a responsible corporate official that such report is true and complete, and

(4) prepare, maintain, and upon request submit to the Secretary product distribution records for each such vaccine by batch, lot, or other quantity number.

(b) Sanction

Any vaccine manufacturer who intentionally destroys, alters, falsifies, or conceals any record or report required under paragraph (1) or (2) of subsection (a) shall—

(1) be subject to a civil penalty of up to $100,000 per occurrence, or

(2) be fined $50,000 or imprisoned for not more than 1 year, or both.

Such penalty shall apply to the person who intentionally destroyed, altered, falsified, or concealed such record or report, to the person who directed that such record or report be destroyed, altered, falsified, or concealed, and to the vaccine manufacturer for which such person is an agent, employee, or representative. Each act of destruction, alteration, falsification, or concealment shall be treated as a separate occurrence.

(July 1, 1944, ch. 373, title XXI, §2128, as added Pub. L. 99–660, title III, §311(a), Nov. 14, 1986, 100 Stat. 3777; amended Pub. L. 100–203, title IV, §4302(b)(1), Dec. 22, 1987, 101 Stat. 1330–221.)

EDITORIAL NOTES

CODIFICATION

In subsec. (a), "December 22, 1987" substituted for "the effective date of this subpart" on authority of section 323 of Pub. L. 99–660, as amended, set out as an Effective Date note under section 300aa–1 of this title.

AMENDMENTS

1987—Subsec. (a). Pub. L. 100–203 substituted "effective date of this subpart" for "effective date of this part".

SUBPART D—GENERAL PROVISIONS

§300aa–31. Citizen's actions

(a) General rule

Except as provided in subsection (b), any person may commence in a district court of the United States a civil action on such person's own behalf against the Secretary where there is alleged a failure of the Secretary to perform any act or duty under this part.

(b) Notice

No action may be commenced under subsection (a) before the date which is 60 days after the person bringing the action has given written notice of intent to commence such action to the Secretary.

(c) Costs of litigation

The court, in issuing any final order in any action under this section, may award costs of litigation (including reasonable attorney and expert witness fees) to any plaintiff who substantially prevails on one or more significant issues in the action.

(July 1, 1944, ch. 373, title XXI, §2131, as added Pub. L. 99–660, title III, §311(a), Nov. 14, 1986, 100 Stat. 3778; amended Pub. L. 100–203, title IV, §4305, Dec. 22, 1987, 101 Stat. 1330–224.)

EDITORIAL NOTES

AMENDMENTS

1987—Subsec. (c). Pub. L. 100–203, which directed that subsec. (c) be amended by substituting "to any plaintiff who substantially prevails on one or more significant issues in the action" for "to any party, whenever the court determines that such award is appropriate", was executed by making the substitution for "to any party, whenever the court determines such award is appropriate", to reflect the probable intent of Congress.

STATUTORY NOTES AND RELATED SUBSIDIARIES

EFFECTIVE DATE

Subpart effective Dec. 22, 1987, see section 323 of Pub. L. 99–660, set out as a note under section 300aa–1 of this title.

§300aa–32. Judicial review

A petition for review of a regulation under this part may be filed in a court of appeals of the United States within 60 days from the date of the promulgation of the regulation or after such date if such petition is based solely on grounds arising after such 60th day.

(July 1, 1944, ch. 373, title XXI, §2132, as added Pub. L. 99–660, title III, §311(a), Nov. 14, 1986, 100 Stat. 3778.)

§300aa–33. Definitions

For purposes of this part:

(1) The term "health care provider" means any licensed health care professional, organization, or institution, whether public or private (including Federal, State, and local departments, agencies, and instrumentalities) under whose authority a vaccine set forth in the Vaccine Injury Table is administered.

(2) The term "legal representative" means a parent or an individual who qualifies as a legal guardian under State law.

(3) The term "manufacturer" means any corporation, organization, or institution, whether public or private (including Federal, State, and local departments, agencies, and instrumentalities), which manufactures, imports, processes, or distributes under its label any vaccine set forth in the Vaccine Injury Table, except that, for purposes of section 300aa–28 of this title, such term shall include the manufacturer of any other vaccine covered by that section. The term "manufacture" means to manufacture, import, process, or distribute a vaccine.

(4) The term "significant aggravation" means any change for the worse in a preexisting condition which results in markedly greater disability, pain, or illness accompanied by substantial deterioration of health.

(5) The term "vaccine-related injury or death" means an illness, injury, condition, or death associated with one or more of the vaccines set forth in the Vaccine Injury Table, except that the term does not include an illness, injury, condition, or death associated with an adulterant or contaminant intentionally added to such a vaccine.

(6)(A) The term "Advisory Commission on Childhood Vaccines" means the Commission established under section 300aa–19 of this title.

(B) The term "Vaccine Injury Table" means the table set out in section 300aa–14 of this title.

(July 1, 1944, ch. 373, title XXI, §2133, as added Pub. L. 99–660, title III, §311(a), Nov. 14, 1986, 100 Stat. 3778; amended Pub. L. 107–296, title XVII, §§1714–1716, Nov. 25, 2002, 116 Stat. 2320, 2321; Pub. L. 108–7, div. L, §102(a), Feb. 20, 2003, 117 Stat. 528.)

EDITORIAL NOTES

AMENDMENTS

2003—Pars. (3), (5), (7). Pub. L. 108–7 repealed Pub. L. 107–296, §§1714–1717, and provided that this chapter shall be applied as if the sections repealed had never been enacted. See 2002 Amendment notes below.

2002—Par. (3). Pub. L. 107–296, §1714, which directed amendment of first sentence by substituting "any vaccine set forth in the Vaccine Injury table, including any component or ingredient of any such vaccine" for "under its label any vaccine set forth in the Vaccine Injury Table" and of second sentence by inserting "including any component or ingredient of any such vaccine" before period at end, was repealed by Pub. L. 108–7.

Par. (5). Pub. L. 107–296, §1715, which directed insertion of "For purposes of the preceding sentence, an adulterant or contaminant shall not include any component or ingredient listed in a vaccine's product license application or product label." at end, was repealed by Pub. L. 108–7.

Par. (7). Pub. L. 107–296, §1716, which directed addition of par. (7), was repealed by Pub. L. 108–7, §102(a). Par. (7) read as follows: "The term 'vaccine' means any preparation or suspension, including but not limited to a preparation or suspension containing an attenuated or inactive microorganism or subunit thereof or toxin, developed or administered to produce or enhance the body's immune response to a disease or diseases and includes all components and ingredients listed in the vaccines's product license application and product label."

STATUTORY NOTES AND RELATED SUBSIDIARIES

EFFECTIVE DATE OF 2002 AMENDMENT

Pub. L. 107–296, title XVII, §1717, Nov. 25, 2002, 116 Stat. 2321, which provided that the amendments made by sections 1714, 1715, and 1716 (amending this section) shall apply to all actions or proceedings pending on or after Nov. 25, 2002, unless a court of competent jurisdiction has entered judgment (regardless of whether the time for appeal has expired) in such action or proceeding disposing of the entire action or proceeding, was repealed by Pub. L. 108–7, div. L, §102(a), Feb. 20, 2003, 117 Stat. 528.

CONSTRUCTION OF AMENDMENTS

Pub. L. 108–7, div. L, §102(b), (c), Feb. 20, 2003, 117 Stat. 528, provided that:

"(b) APPLICATION OF THE PUBLIC HEALTH SERVICE ACT.—The Public Health Service Act (42 U.S.C. 201 et seq.) shall be applied and administered as if the sections repealed by subsection (a) [repealing sections 1714 to 1717 of Pub. L. 107–296, which amended this section and enacted provisions set out as a note under this section] had never been enacted.

"(c) RULE OF CONSTRUCTION.—No inference shall be drawn from the enactment of sections 1714 through 1717 of the Homeland Security Act of 2002 (Public Law 107–296), or from this repeal [repealing sections 1714 to 1717 of Pub. L. 107–296], regarding the law prior to enactment of sections 1714 through 1717 of the Homeland Security Act of 2002 (Public Law 107–296) [Nov. 25, 2002]. Further, no inference shall be drawn that subsection (a) or (b) affects any change in that prior law, or that Leroy v. Secretary of Health and Human Services, Office of Special Master, No. 02–392V (October 11, 2002), was incorrectly decided."

§300aa–34. Termination of program

(a) Reviews

The Secretary shall review the number of awards of compensation made under the program to petitioners under section 300aa–11 of this title for vaccine-related injuries and deaths associated with the administration of vaccines on or after December 22, 1987, as follows:

(1) The Secretary shall review the number of such awards made in the 12-month period beginning on December 22, 1987.

(2) At the end of each 3-month period beginning after the expiration of the 12-month period referred to in paragraph (1) the Secretary shall review the number of such awards made in the 3-month period.

(b) Report

(1) If in conducting a review under subsection (a) the Secretary determines that at the end of the period reviewed the total number of awards made by the end of that period and accepted under section 300aa–21(a) of this title exceeds the number of awards listed next to the period reviewed in the table in paragraph (2)—

(A) the Secretary shall notify the Congress of such determination, and

(B) beginning 180 days after the receipt by Congress of a notification under paragraph (1), no petition for a vaccine-related injury or death associated with the administration of a vaccine on or after December 22, 1987, may be filed under section 300aa–11 of this title.

Section 300aa–11(a) of this title and subpart B of this part shall not apply to civil actions for damages for a vaccine-related injury or death for which a petition may not be filed because of subparagraph (B).

(2) The table referred to in paragraph (1) is as follows:

Period reviewed:	**Total number of awards by the end of the period reviewed**
12 months after December 22, 1987	150
13th through the 15th month after December 22, 1987	188
16th through the 18th month after December 22, 1987	225
19th through the 21st month after December 22, 1987	263
22nd through the 24th month after December 22, 1987	300
25th through the 27th month after December 22, 1987	338
28th through the 30th month after December 22, 1987	375
31st through the 33rd month after December 22, 1987	413
34th through the 36th month after December 22, 1987	450
37th through the 39th month after December 22, 1987	488
40th through the 42nd month after December 22, 1987	525
43rd through the 45th month after	563

December 22, 1987 46th through the 48th month after December 22, 1987	600.

(July 1, 1944, ch. 373, title XXI, §2134, as added Pub. L. 100–203, title IV, §4303(f), Dec. 22, 1987, 101 Stat. 1330–222.)

EDITORIAL NOTES

CODIFICATION

In subsecs. (a) and (b), "December 22, 1987" substituted for "the effective date of this subpart" on authority of section 323 of Pub. L. 99–660, as amended, set out as an Effective Date note under section 300aa–1 of this title.

SUBCHAPTER XX—REQUIREMENTS FOR CERTAIN GROUP HEALTH PLANS FOR CERTAIN STATE AND LOCAL EMPLOYEES

§300bb–1. State and local governmental group health plans must provide continuation coverage to certain individuals

(a) In general

In accordance with regulations which the Secretary shall prescribe, each group health plan that is maintained by any State that receives funds under this chapter, by any political subdivision of such a State, or by any agency or instrumentality of such a State or political subdivision, shall provide, in accordance with this subchapter, that each qualified beneficiary who would lose coverage under the plan as a result of a qualifying event is entitled, under the plan, to elect, within the election period, continuation coverage under the plan.

(b) Exception for certain plans

Subsection (a) shall not apply to—

(1) any group health plan for any calendar year if all employers maintaining such plan normally employed fewer than 20 employees on a typical business day during the preceding calendar year, or

(2) any group health plan maintained for employees by the government of the District of Columbia or any territory or possession of the United States or any agency or instrumentality.

(July 1, 1944, ch. 373, title XXII, §2201, as added Pub. L. 99–272, title X, §10003(a), Apr. 7, 1986, 100 Stat. 232; amended Pub. L. 101–239, title VI, §6801(a)(1), Dec. 19, 1989, 103 Stat. 2296.)

EDITORIAL NOTES

AMENDMENTS

1989—Subsec. (b). Pub. L. 101–239 struck out at end "Under regulations, rules similar to the rules of subsections (a) and (b) of section 52 of title 26 (relating to employers under common control) shall apply for purposes of paragraph (1)."

STATUTORY NOTES AND RELATED SUBSIDIARIES

EFFECTIVE DATE OF 1989 AMENDMENT

Pub. L. 101–239, title VI, §6801(a)(2), Dec. 19, 1989, 103 Stat. 2297, provided that: "The amendment

made by paragraph (1) [amending this section] shall apply to years beginning after December 31, 1986."

EFFECTIVE DATE

Pub. L. 99–272, title X, §10003(b), Apr. 7, 1986, 100 Stat. 236, provided that:

"(1) GENERAL RULE.—The amendments made by this section [enacting this subchapter] shall apply to plan years beginning on or after July 1, 1986.

"(2) SPECIAL RULE FOR COLLECTIVE BARGAINING AGREEMENTS.—In the case of a group health plan maintained pursuant to one or more collective bargaining agreements between employee representatives and one or more employers ratified before the date of the enactment of this Act [Apr. 7, 1986], the amendments made by this section shall not apply to plan years beginning before the later of—

"(A) the date on which the last of the collective bargaining agreements relating to the plan terminates (determined without regard to any extension thereof agreed to after the date of the enactment of this Act), or

"(B) January 1, 1987.

For purposes of subparagraph (A), any plan amendment made pursuant to a collective bargaining agreement relating to the plan which amends the plan solely to conform to any requirement added by this section shall not be treated as a termination of such collective bargaining agreement."

§300bb–2. Continuation coverage

For purposes of section 300bb–1 of this title, the term "continuation coverage" means coverage under the plan which meets the following requirements:

(1) Type of benefit coverage

The coverage must consist of coverage which, as of the time the coverage is being provided, is identical to the coverage provided under the plan to similarly situated beneficiaries under the plan with respect to whom a qualifying event has not occurred. If coverage is modified under the plan for any group of similarly situated beneficiaries, such coverage shall also be modified in the same manner for all individuals who are qualified beneficiaries under the plan pursuant to this part [1] in connection with such group.

(2) Period of coverage

The coverage must extend for at least the period beginning on the date of the qualifying event and ending not earlier than the earliest of the following:

(A) Maximum required period

(i) General rule for terminations and reduced hours

In the case of a qualifying event described in section 300bb–3(2) of this title, except as provided in clause (ii), the date which is 18 months after the date of the qualifying event.

(ii) Special rule for multiple qualifying events

If a qualifying event occurs during the 18 months after the date of a qualifying event described in section 300bb–3(2) of this title, the date which is 36 months after the date of the qualifying event described in section 300bb–3(2) of this title.

(iii) General rule for other qualifying events

In the case of a qualifying event not described in section 300bb–3(2) of this title, the date which is 36 months after the date of the qualifying event.

(iv) Special rule for TAA-eligible individuals

In the case of a qualifying event described in section 300bb–3(2) of this title with respect to a covered employee who is (as of the date that the period of coverage would, but for this clause or clause (v), otherwise terminate under clause (i) or (ii)) a TAA-eligible individual (as defined in section 300bb–5(b)(4)(B) of this title), the period of coverage shall not terminate by reason of clause (i) or (ii), as the case may be, before the later of the date specified in such

clause or the date on which such individual ceases to be such a TAA-eligible individual. The preceding sentence shall not require any period of coverage to extend beyond January 1, 2014.

(v) Medicare entitlement followed by qualifying event

In the case of a qualifying event described in section 300bb–3(2) of this title that occurs less than 18 months after the date the covered employee became entitled to benefits under title XVIII of the Social Security Act [42 U.S.C. 1395 et seq.], the period of coverage for qualified beneficiaries other than the covered employee shall not terminate under this subparagraph before the close of the 36-month period beginning on the date the covered employee became so entitled.

(vi) Special rule for disability

In the case of a qualified beneficiary who is determined, under title II or XVI of the Social Security Act [42 U.S.C. 401 et seq., 1381 et seq.], to have been disabled at any time during the first 60 days of continuation coverage under this subchapter, any reference in clause (i) or (ii) to 18 months is deemed a reference to 29 months (with respect to all qualified beneficiaries), but only if the qualified beneficiary has provided notice of such determination under section 300bb–6(3) of this title before the end of such 18 months.

(B) End of plan

The date on which the employer ceases to provide any group health plan to any employee.

(C) Failure to pay premium

The date on which coverage ceases under the plan by reason of a failure to make timely payment of any premium required under the plan with respect to the qualified beneficiary. The payment of any premium (other than any payment referred to in the last sentence of paragraph (3)) shall be considered to be timely if made within 30 days after the date due or within such longer period as applies to or under the plan.

(D) Group health plan coverage or medicare entitlement

The date on which the qualified beneficiary first becomes, after the date of the election—

(i) covered under any other group health plan (as an employee or otherwise) which does not contain any exclusion or limitation with respect to any preexisting condition of such beneficiary (other than such an exclusion or limitation which does not apply to (or is satisfied by) such beneficiary by reason of chapter 100 of title 26, part 7 of subtitle B of title I of the Employee Retirement Income Security Act of 1974 [29 U.S.C. 1181 et seq.], or subchapter XXV of this chapter), or

(ii) entitled to benefits under title XVIII of the Social Security Act [42 U.S.C. 1395 et seq.].

(E) Termination of extended coverage for disability

In the case of a qualified beneficiary who is disabled at any time during the first 60 days of continuation coverage under this subchapter, the month that begins more than 30 days after the date of the final determination under title II or XVI of the Social Security Act [42 U.S.C. 401 et seq., 1381 et seq.] that the qualified beneficiary is no longer disabled.

(3) Premium requirements

The plan may require payment of a premium for any period of continuation coverage, except that such premium—

(A) shall not exceed 102 percent of the applicable premium for such period, and

(B) may, at the election of the payor, be made in monthly installments.

In no event may the plan require the payment of any premium before the day which is 45 days after the day on which the qualified beneficiary made the initial election for continuation coverage.[2] In the case of an individual described in the last sentence of paragraph (2)(A), any

reference in subparagraph (A) of this paragraph to "102 percent" is deemed a reference to "150 percent" for any month after the 18th month of continuation coverage described in clause (i) or (ii) of paragraph (2)(A).

(4) No requirement of insurability

The coverage may not be conditioned upon, or discriminate on the basis of lack of, evidence of insurability.

(5) Conversion option

In the case of a qualified beneficiary whose period of continuation coverage expires under paragraph (2)(A), the plan must, during the 180-day period ending on such expiration date, provide to the qualified beneficiary the option of enrollment under a conversion health plan otherwise generally available under the plan.

(July 1, 1944, ch. 373, title XXII, §2202, as added Pub. L. 99–272, title X, §10003(a), Apr. 7, 1986, 100 Stat. 233; amended Pub. L. 99–514, title XVIII, §1895(d)(1)(C), (2)(C), (3)(C), (4)(C), Oct. 22, 1986, 100 Stat. 2937–2939; Pub. L. 101–239, title VI, §§6702(a), (b), 6801(b)(1)(A), (2)(A), (3)(A), Dec. 19, 1989, 103 Stat. 2295, 2297; Pub. L. 104–188, title I, §1704(g)(1)(C), Aug. 20, 1996, 110 Stat. 1880; Pub. L. 104–191, title IV, §421(a)(1), Aug. 21, 1996, 110 Stat. 2087; Pub. L. 111–5, div. B, title I, §1899F(c), Feb. 17, 2009, 123 Stat. 429; Pub. L. 111–344, title I, §116(c), Dec. 29, 2010, 124 Stat. 3616; Pub. L. 112–40, title II, §243(a)(5), Oct. 21, 2011, 125 Stat. 420.)

EDITORIAL NOTES

REFERENCES IN TEXT

The Social Security Act, referred to in par. (2)(A)(v), (vi), (D)(ii), and (E), is act Aug. 14, 1935, ch. 531, 49 Stat. 620. Titles II, XVI, and XVIII of the Social Security Act are classified generally to subchapters II (§401 et seq.), XVI (§1381 et seq.), and XVIII (§1395 et seq.), respectively, of chapter 7 of this title. For complete classification of this Act to the Code, see section 1305 of this title and Tables.

The Employee Retirement Income Security Act of 1974, referred to in par. (2)(D)(i), is Pub. L. 93–406, Sept. 2, 1974, 88 Stat. 829. Part 7 of subtitle B of title I of the Act is classified generally to part 7 (§1181 et seq.) of subtitle B of subchapter I of chapter 18 of Title 29, Labor. For complete classification of this Act to the Code, see Short Title note set out under section 1001 of Title 29 and Tables.

AMENDMENTS

2011—Par. (2)(A)(iv). Pub. L. 112–40 substituted "January 1, 2014" for "February 12, 2011".

2010—Par. (2)(A)(iv). Pub. L. 111–344 substituted "February 12, 2011" for "December 31, 2010".

2009—Par. (2)(A). Pub. L. 111–5, §1899F(c)(1), designated concluding provisions as cl. (v) and inserted heading.

Par. (2)(A)(iv) to (vi). Pub. L. 111–5, §1899F(c)(2), added cl. (iv) and redesignated former cls. (iv) and (v) as (v) and (vi), respectively.

1996—Par. (2)(A). Pub. L. 104–191, §421(a)(1)(A)(ii)(IV), inserted "(with respect to all qualified beneficiaries)" after "29 months" in concluding provisions.

Pub. L. 104–191, §421(a)(1)(A)(ii)(III), which directed amendment of concluding provisions by striking "with respect to such event,", was executed by striking that phrase, which did not contain a comma at end, before "is deemed a reference" to reflect the probable intent of Congress.

Pub. L. 104–191, §421(a)(1)(A)(ii)(I), (II), in concluding provisions, substituted "a qualified beneficiary" for "an individual" and "at any time during the first 60 days of continuation coverage under this subchapter" for "at the time of a qualifying event described in section 300bb–3(2) of this title".

Pub. L. 104–191, §421(a)(1)(A)(i), transferred sentence following cl. (iii) to appear as concluding provisions following cl. (iv).

Par. (2)(A)(iv). Pub. L. 104–188 amended heading and text of cl. (iv) generally. Prior to amendment, text read as follows: "In the case of an event described in section 300bb–3(4) of this title (without regard to whether such event is a qualifying event), the period of coverage for qualified beneficiaries other than the covered employee for such event or any subsequent qualifying event shall not terminate before the close of the 36-month period beginning on the date the covered employee becomes entitled to benefits under title XVIII of the Social Security Act."

Par. (2)(D)(i). Pub. L. 104–191, §421(a)(1)(B), inserted "(other than such an exclusion or limitation which does not apply to (or is satisfied by) such beneficiary by reason of chapter 100 of title 26, part 7 of subtitle B of title I of the Employee Retirement Income Security Act of 1974, or subchapter XXV of this chapter)" before ", or".

Par. (2)(E). Pub. L. 104–191, §421(a)(1)(C), substituted "at any time during the first 60 days of continuation coverage under this subchapter" for "at the time of a qualifying event described in section 300bb–3(2) of this title".

1989—Par. (2)(A). Pub. L. 101–239, §6702(a)(1), inserted after cl. (iii) "In the case of an individual who is determined, under title II or XVI of the Social Security Act, to have been disabled at the time of a qualifying event described in section 300bb–3(2) of this title, any reference in clause (i) or (ii) to 18 months with respect to such event is deemed a reference to 29 months, but only if the qualified beneficiary has provided notice of such determination under section 300bb–6(3) of this title before the end of such 18 months."

Par. (2)(A)(iv). Pub. L. 101–239, §6801(b)(1)(A), added cl. (iv).

Par. (2)(D). Pub. L. 101–239, §6801(b)(2)(A), substituted "entitlement" for "eligibility" in heading and inserted "which does not contain any exclusion or limitation with respect to any preexisting condition of such beneficiary" after "or otherwise)" in cl. (i).

Par. (2)(E). Pub. L. 101–239, §6702(a)(2), added subpar. (E).

Par. (3). Pub. L. 101–239, §6801(b)(3)(A), which directed the general amendment of the concluding provision was executed by amending the first sentence of the concluding provision generally to reflect the probable intent of Congress and amendment of concluding provision by Pub. L. 101–239, §6702(b). Prior to amendment, first sentence of the concluding provision read as follows: "If an election is made after the qualifying event, the plan shall permit payment for continuation coverage during the period preceding the election to be made within 45 days of the date of the election."

Pub. L. 101–239, §6702(b), inserted at end of concluding provision "In the case of an individual described in the last sentence of paragraph (2)(A), any reference in subparagraph (A) of this paragraph to '102 percent' is deemed a reference to '150 percent' for any month after the 18th month of continuation coverage described in clause (i) or (ii) of paragraph (2)(A)." See Amendment note above.

1986—Par. (1). Pub. L. 99–514, §1895(d)(1)(C), inserted at end "If coverage is modified under the plan for any group of similarly situated beneficiaries, such coverage shall also be modified in the same manner for all individuals who are qualified beneficiaries under the plan pursuant to this part in connection with such group."

Par. (2)(A). Pub. L. 99–514, §1895(d)(2)(C), amended subpar. (A) generally. Prior to amendment, subpar. (A) read as follows: "MAXIMUM PERIOD.—In the case of—

"(i) a qualifying event described in section 300bb–3(2) of this title (relating to terminations and reduced hours), the date which is 18 months after the date of the qualifying event, and

"(ii) any qualifying event not described in clause (i), the date which is 36 months after the date of the qualifying event."

Par. (2)(C). Pub. L. 99–514, §1895(d)(3)(C), inserted at end "The payment of any premium (other than any payment referred to in the last sentence of paragraph (3)) shall be considered to be timely if made within 30 days after the date due or within such longer period as applies to or under the plan."

Par. (2)(D). Pub. L. 99–514, §1895(d)(4)(C)(ii), (iii), substituted "Group health plan coverage" for "Reemployment" in heading, added cl. (i), and struck out former cl. (i) which read as follows: "a covered employee under any other group health plan, or".

Par. (2)(E). Pub. L. 99–514, §1895(d)(4)(C)(i), struck out subpar. (E), remarriage of spouse, which read as follows: "In the case of an individual who is a qualified beneficiary by reason of being the spouse of a covered employee, the date on which the beneficiary remarries and becomes covered under a group health plan."

STATUTORY NOTES AND RELATED SUBSIDIARIES

EFFECTIVE DATE OF 2011 AMENDMENT

Amendment by Pub. L. 112–40 applicable to periods of coverage which would (without regard to the amendments made by section 243 of Pub. L. 112–40) end on or after the date which is 30 days after Oct. 21, 2011, see section 243(b) of Pub. L. 112–40, set out as a note under section 4980B of Title 26, Internal Revenue Code.

EFFECTIVE DATE OF 2010 AMENDMENT

Amendment by Pub. L. 111–344 applicable to periods of coverage which would (without regard to such amendment) end on or after Dec. 31, 2010, see section 116(d) of Pub. L. 111–344, set out as a note under section 4980B of Title 26, Internal Revenue Code.

EFFECTIVE DATE OF 2009 AMENDMENT

Except as otherwise provided and subject to certain applicability provisions, amendment by Pub. L. 111–5 effective upon the expiration of the 90-day period beginning on Feb. 17, 2009, see section 1891 of Pub. L. 111–5, set out as an Effective and Termination Dates of 2009 Amendment note under section 2271 of Title 19, Customs Duties.

Amendment by Pub. L. 111–5 applicable to periods of coverage which would (without regard to amendment by Pub. L. 111–5) end on or after Feb. 17, 2009, see section 1899F(d) of Pub. L. 111–5, set out as a note under section 4980B of Title 26, Internal Revenue Code.

EFFECTIVE DATE OF 1996 AMENDMENTS

Amendment by Pub. L. 104–191 effective Jan. 1, 1997, regardless of whether the qualifying event occurred before, on, or after such date, see section 421(d) of Pub. L. 104–191, set out as a note under section 4980B of Title 26, Internal Revenue Code.

Amendment by Pub. L. 104–188 applicable to plan years beginning after Dec. 31, 1989, see section 1704(g)(2) of Pub. L. 104–188, set out as a note under section 4980B of Title 26.

EFFECTIVE DATE OF 1989 AMENDMENT

Pub. L. 101–239, title VI, §6702(d), 103 Stat. 2296, provided that: "The amendments made by this section [amending this section and section 300bb–6 of this title] shall apply to plan years beginning on or after the date of the enactment of this Act [Dec. 19, 1989], regardless of whether the qualifying event occurred before, on, or after such date."

Pub. L. 101–239, title VI, §6801(b)(1)(B), 103 Stat. 2297, provided that: "The amendments made by this paragraph [amending this section] shall apply to plan years beginning after December 31, 1989."

Pub. L. 101–239, title VI, §6801(b)(2)(B), 103 Stat. 2297, provided that: "The amendments made by subparagraph (A) [amending this section] shall apply to—

"(i) qualifying events occurring after December 31, 1989, and

"(ii) in the case of qualified beneficiaries who elected continuation coverage after December 31, 1988, the period for which the required premium was paid (or was attempted to be paid but was rejected as such)."

Pub. L. 101–239, title VI, §6801(b)(3)(B), 103 Stat. 2297, provided that: "The amendment made by subparagraph (A) [amending this section] shall apply to plan years beginning after December 31, 1989."

EFFECTIVE DATE OF 1986 AMENDMENT

Amendment by Pub. L. 99–514 effective, except as otherwise provided, as if included in enactment of the Consolidated Omnibus Budget Reconciliation Act of 1985, Pub. L. 99–272, see section 1895(e) of Pub. L. 99–514, set out as a note under section 162 of Title 26, Internal Revenue Code.

PLAN AMENDMENTS NOT REQUIRED UNTIL JANUARY 1, 1989

For provisions directing that if any amendments made by subtitle A or subtitle C of title XI [§§1101–1147 and 1171–1177] or title XVIII [§§1800–1899A] of Pub. L. 99–514 require an amendment to any plan, such plan amendment shall not be required to be made before the first plan year beginning on or after Jan. 1, 1989, see section 1140 of Pub. L. 99–514, as amended, set out as a note under section 401 of Title 26, Internal Revenue Code.

[1] So in original. This subchapter is not divided into parts.

[2] See 1989 Amendment note below.

§300bb–3. Qualifying event

For purposes of this subchapter, the term "qualifying event" means, with respect to any covered employee, any of the following events which, but for the continuation coverage required under this subchapter, would result in the loss of coverage of a qualified beneficiary:

(1) The death of the covered employee.

(2) The termination (other than by reason of such employee's gross misconduct), or reduction of hours, of the covered employee's employment.

(3) The divorce or legal separation of the covered employee from the employee's spouse.

(4) The covered employee becoming entitled to benefits under title XVIII of the Social Security Act [42 U.S.C. 1395 et seq.].

(5) A dependent child ceasing to be a dependent child under the generally applicable requirements of the plan.

(July 1, 1944, ch. 373, title XXII, §2203, as added Pub. L. 99–272, title X, §10003(a), Apr. 7, 1986, 100 Stat. 234.)

EDITORIAL NOTES

REFERENCES IN TEXT

The Social Security Act, referred to in par. (4), is act Aug. 14, 1935, ch. 531, 49 Stat. 620. Title XVIII of the Social Security Act is classified generally to subchapter XVIII (§1395 et seq.) of chapter 7 of this title. For complete classification of this Act to the Code, see section 1305 of this title and Tables.

§300bb–4. Applicable premium

For purposes of this subchapter—

(1) In general

The term "applicable premium" means, with respect to any period of continuation coverage of qualified beneficiaries, the cost to the plan for such period of the coverage for similarly situated beneficiaries with respect to whom a qualifying event has not occurred (without regard to whether such cost is paid by the employer or employee).

(2) Special rule for self-insured plans

To the extent that a plan is a self-insured plan—

(A) In general

Except as provided in subparagraph (B), the applicable premium for any period of continuation coverage of qualified beneficiaries shall be equal to a reasonable estimate of the cost of providing coverage for such period for similarly situated beneficiaries which—

(i) is determined on an actuarial basis, and

(ii) takes into account such factors as the Secretary may prescribe in regulations.

(B) Determination on basis of past cost

If a plan administrator elects to have this subparagraph apply, the applicable premium for any period of continuation coverage of qualified beneficiaries shall be equal to—

(i) the cost to the plan for similarly situated beneficiaries for the same period occurring during the preceding determination period under paragraph (3), adjusted by

(ii) the percentage increase or decrease in the implicit price deflator of the gross national product (calculated by the Department of Commerce and published in the Survey of Current Business) for the 12-month period ending on the last day of the sixth month of such preceding determination period.

(C) Subparagraph (B) not to apply where significant change

A plan administrator may not elect to have subparagraph (B) apply in any case in which there is any significant difference, between the determination period and the preceding determination period, in coverage under, or in employees covered by, the plan. The determination under the preceding sentence for any determination period shall be made at the same time as the determination under paragraph (3).

(3) Determination period

The determination of any applicable premium shall be made for a period of 12 months and shall be made before the beginning of such period.

(July 1, 1944, ch. 373, title XXII, §2204, as added Pub. L. 99–272, title X, §10003(a), Apr. 7, 1986,

100 Stat. 234.)

§300bb–5. Election

(a) In general

For purposes of this subchapter—

(1) Election period

The term "election period" means the period which—

(A) begins not later than the date on which coverage terminates under the plan by reason of a qualifying event,

(B) is of at least 60 days' duration, and

(C) ends not earlier than 60 days after the later of—

(i) the date described in subparagraph (A), or

(ii) in the case of any qualified beneficiary who receives notice under section 300bb–6(4) of this title, the date of such notice.

(2) Effect of election on other beneficiaries

Except as otherwise specified in an election, any election of continuation coverage by a qualified beneficiary described in subparagraph (A)(i) or (B) of section 300bb–8(3) of this title shall be deemed to include an election of continuation coverage on behalf of any other qualified beneficiary who would lose coverage under the plan by reason of the qualifying event. If there is a choice among types of coverage under the plan, each qualified beneficiary is entitled to make a separate selection among such types of coverage.

(b) Temporary extension of COBRA election period for certain individuals

(1) In general

In the case of a nonelecting TAA-eligible individual and notwithstanding subsection (a), such individual may elect continuation coverage under this subchapter during the 60-day period that begins on the first day of the month in which the individual becomes a TAA-eligible individual, but only if such election is made not later than 6 months after the date of the TAA-related loss of coverage.

(2) Commencement of coverage; no reach-back

Any continuation coverage elected by a TAA-eligible individual under paragraph (1) shall commence at the beginning of the 60-day election period described in such paragraph and shall not include any period prior to such 60-day election period.

(3) Preexisting conditions

With respect to an individual who elects continuation coverage pursuant to paragraph (1), the period—

(A) beginning on the date of the TAA-related loss of coverage, and

(B) ending on the first day of the 60-day election period described in paragraph (1),

shall be disregarded for purposes of determining the 63-day periods referred to in section 2701(c)(2),[1] section 1181(c)(2) of title 29, and section 9801(c)(2) of title 26.

(4) Definitions

For purposes of this subsection:

(A) Nonelecting TAA-eligible individual

The term "nonelecting TAA-eligible individual" means a TAA-eligible individual who—

(i) has a TAA-related loss of coverage; and

(ii) did not elect continuation coverage under this part [2] during the TAA-related election

period.

(B) TAA-eligible individual

The term "TAA-eligible individual" means—

(i) an eligible TAA recipient (as defined in paragraph (2) of section 35(c) of title 26), and

(ii) an eligible alternative TAA recipient (as defined in paragraph (3) of such section).

(C) TAA-related election period

The term "TAA-related election period" means, with respect to a TAA-related loss of coverage, the 60-day election period under this part [2] which is a direct consequence of such loss.

(D) TAA-related loss of coverage

The term "TAA-related loss of coverage" means, with respect to an individual whose separation from employment gives rise to being an TAA-eligible individual, the loss of health benefits coverage associated with such separation.

(July 1, 1944, ch. 373, title XXII, §2205, as added Pub. L. 99–272, title X, §10003(a), Apr. 7, 1986, 100 Stat. 235; amended Pub. L. 99–514, title XVIII, §1895(d)(5)(C), Oct. 22, 1986, 100 Stat. 2939; Pub. L. 107–210, div. A, title II, §203(e)(2), Aug. 6, 2002, 116 Stat. 970.)

EDITORIAL NOTES

REFERENCES IN TEXT

Section 2701, referred to in subsec. (b)(3), is a reference to section 2701 of act July 1, 1944. Section 2701, which was classified to section 300gg of this title, was renumbered section 2704, effective for plan years beginning on or after Jan. 1, 2014, with certain exceptions, and amended, by Pub. L. 111–148, title I, §§1201(2), 1563(c)(1), formerly §1562(c)(1), title X, §10107(b)(1), Mar. 23, 2010, 124 Stat. 154, 264, 911, and was transferred to section 300gg–3 of this title. A new section 2701 of act July 1, 1944, related to fair health insurance premiums, was added, effective for plan years beginning on or after Jan. 1, 2014, and amended, by Pub. L. 111–148, title I, §1201(4), title X, §10103(a), Mar. 23, 2010, 124 Stat. 155, 892, and is classified to section 300gg of this title.

AMENDMENTS

2002—Pub. L. 107–210 designated existing provisions as subsec. (a), inserted subsec. heading, and added subsec. (b).

1986—Par. (2). Pub. L. 99–514 inserted "of continuation coverage" after "any election" and inserted at end "If there is a choice among types of coverage under the plan, each qualified beneficiary is entitled to make a separate selection among such types of coverage."

STATUTORY NOTES AND RELATED SUBSIDIARIES

EFFECTIVE DATE OF 2002 AMENDMENT

Amendment by Pub. L. 107–210 applicable to petitions for certification filed under part 2 or 3 of subchapter II of chapter 12 of Title 19, Customs Duties, on or after the date that is 90 days after Aug. 6, 2002, except as otherwise provided, see section 151 of Pub. L. 107–210, set out as a note preceding section 2271 of Title 19.

EFFECTIVE DATE OF 1986 AMENDMENT

Amendment by Pub. L. 99–514 effective, except as otherwise provided, as if included in enactment of the Consolidated Omnibus Budget Reconciliation Act of 1985, Pub. L. 99–272, see section 1895(e) of Pub. L. 99–514, set out as a note under section 162 of Title 26, Internal Revenue Code.

CONSTRUCTION OF 2002 AMENDMENT

Nothing in amendment by Pub. L. 107–210, other than provisions relating to COBRA continuation coverage and reporting requirements, to be construed as creating new mandate on any party regarding health insurance coverage, see section 203(f) of Pub. L. 107–210, set out as a Construction note under section 35 of Title 26, Internal Revenue Code.

PLAN AMENDMENTS NOT REQUIRED UNTIL JANUARY 1, 1989

For provisions directing that if any amendments made by subtitle A or subtitle C of title XI [§§1101–1147 and 1171–1177] or title XVIII [§§1800–1899A] of Pub. L. 99–514 require an amendment to any plan, such plan amendment shall not be required to be made before the first plan year beginning on or after Jan. 1, 1989, see section 1140 of Pub. L. 99–514, as amended, set out as a note under section 401 of Title 26, Internal Revenue Code.

[1] See References in Text note below.

[2] So in original. This subchapter is not divided into parts.

§300bb–6. Notice requirements

In accordance with regulations prescribed by the Secretary—

(1) the group health plan shall provide, at the time of commencement of coverage under the plan, written notice to each covered employee and spouse of the employee (if any) of the rights provided under this subsection,[1]

(2) the employer of an employee under a plan must notify the plan administrator of a qualifying event described in paragraph (1), (2), or (4) of section 300bb–3 of this title within 30 days of the date of the qualifying event,

(3) each covered employee or qualified beneficiary is responsible for notifying the plan administrator of the occurrence of any qualifying event described in paragraph (3) or (5) of section 300bb–3 of this title within 60 days after the date of the qualifying event and each qualified beneficiary who is determined, under title II or XVI of the Social Security Act [42 U.S.C. 401 et seq., 1381 et seq.], to have been disabled at any time during the first 60 days of continuation coverage under this subchapter is responsible for notifying the plan administrator of such determination within 60 days after the date of the determination and for notifying the plan administrator within 30 days after the date of any final determination under such title or titles that the qualified beneficiary is no longer disabled, and

(4) the plan administrator shall notify—

(A) in the case of a qualifying event described in paragraph (1), (2), or (4) of section 300bb–3 of this title, any qualified beneficiary with respect to such event, and

(B) in the case of a qualifying event described in paragraph (3) or (5) of section 300bb–3 of this title where the covered employee notifies the plan administrator under paragraph (3), any qualified beneficiary with respect to such event,

of such beneficiary's rights under this subsection.[1]

For purposes of paragraph (4), any notification shall be made within 14 days of the date on which the plan administrator is notified under paragraph (2) or (3), whichever is applicable, and any such notification to an individual who is a qualified beneficiary as the spouse of the covered employee shall be treated as notification to all other qualified beneficiaries residing with such spouse at the time such notification is made.

(July 1, 1944, ch. 373, title XXII, §2206, as added Pub. L. 99–272, title X, §10003(a), Apr. 7, 1986, 100 Stat. 235; amended Pub. L. 99–514, title XVIII, §1895(d)(6)(C), Oct. 22, 1986, 100 Stat. 2939; Pub. L. 100–203, title IV, §4009(j)(8), Dec. 22, 1987, 101 Stat. 1330–59; Pub. L. 101–239, title VI, §6702(c), Dec. 19, 1989, 103 Stat. 2295; Pub. L. 104–191, title IV, §421(a)(2), Aug. 21, 1996, 110 Stat. 2088.)

EDITORIAL NOTES

REFERENCES IN TEXT

The Social Security Act, referred to in par. (3), is act Aug. 14, 1935, ch. 531, 49 Stat. 620. Titles II and XVI of the Social Security Act are classified generally to subchapters II (§401 et seq.) and XVI (§1381 et seq.), respectively, of chapter 7 of this title. For complete classification of this Act to the Code, see section 1305 of this title and Tables.

AMENDMENTS

1996—Par. (3). Pub. L. 104–191 substituted "at any time during the first 60 days of continuation coverage under this subchapter" for "at the time of a qualifying event described in section 300bb–3(2) of this title".

1989—Par. (3). Pub. L. 101–239 inserted "and each qualified beneficiary who is determined, under title II or XVI of the Social Security Act, to have been disabled at the time of a qualifying event described in section 300bb–3(2) of this title is responsible for notifying the plan administrator of such determination within 60 days after the date of the determination and for notifying the plan administrator within 30 days after the date of any final determination under such title or titles that the qualified beneficiary is no longer disabled" after "date of the qualifying event".

1987—Par. (3). Pub. L. 100–203 amended directory language of Pub. L. 99–514, see 1986 Amendment note below.

1986—Par. (3). Pub. L. 99–514, as amended by Pub. L. 100–203, inserted "within 60 days after the date of the qualifying event".

STATUTORY NOTES AND RELATED SUBSIDIARIES

EFFECTIVE DATE OF 1996 AMENDMENT

Amendment by Pub. L. 104–191 effective Jan. 1, 1997, regardless of whether the qualifying event occurred before, on, or after such date, see section 421(d) of Pub. L. 104–191, set out as a note under section 4980B of Title 26, Internal Revenue Code.

EFFECTIVE DATE OF 1989 AMENDMENT

Amendment by Pub. L. 101–239 applicable to plan years beginning on or after Dec. 19, 1989, regardless of whether the qualifying event occurred before, on, or after such date, see section 6702(d) of Pub. L. 101–239, set out as a note under section 300bb–2 of this title.

EFFECTIVE DATE OF 1987 AMENDMENT

Pub. L. 100–203, title IV, §4009(j)(8), Dec. 22, 1987, 101 Stat. 1330–59, provided that the amendment made by that section is effective as if included in Pub. L. 99–514.

EFFECTIVE DATE OF 1986 AMENDMENT

Amendment by Pub. L. 99–514 applicable only with respect to qualifying events occurring after Oct. 22, 1986, see section 1895(d)(6)(D) of Pub. L. 99–514, set out as a note under section 162 of Title 26, Internal Revenue Code.

NOTIFICATION TO COVERED EMPLOYEES

Pub. L. 99–272, title X, §10003(c), Apr. 7, 1986, 100 Stat. 236, provided that: "At the time that the amendments made by this section [enacting this subchapter] apply to a group health plan (covered under section 2201 of the Public Health Service Act [42 U.S.C. 300bb–1]), the plan shall notify each covered employee, and spouse of the employee (if any), who is covered under the plan at that time of the continuation coverage required under title XXII of such Act [42 U.S.C. 300bb–1 et seq.]. The notice furnished under this subsection is in lieu of notice that may otherwise be required under section 2206(1) of such Act [42 U.S.C. 300bb–6(1)] with respect to such individuals."

[1] *So in original. Probably should be "subchapter".*

§300bb–7. Enforcement

Any individual who is aggrieved by the failure of a State, political subdivision, or agency or instrumentality thereof, to comply with the requirements of this subchapter may bring an action for

appropriate equitable relief.

(July 1, 1944, ch. 373, title XXII, §2207, as added Pub. L. 99–272, title X, §10003(a), Apr. 7, 1986, 100 Stat. 236.)

STATUTORY NOTES AND RELATED SUBSIDIARIES

CONTINUED COVERAGE OF COSTS OF PEDIATRIC VACCINE UNDER CERTAIN GROUP HEALTH PLANS

Pub. L. 103–66, title XIII, §13631(d), Aug. 10, 1993, 107 Stat. 643, provided that:

"(1) REQUIREMENT.—The requirement of this paragraph, with respect to a group health plan for plan years beginning after the date of the enactment of this Act [Aug. 10, 1993], is that the group health plan not reduce its coverage of the costs of pediatric vaccines (as defined under section 1928(h)(6) of the Social Security Act [42 U.S.C. 1396s(h)(6)]) below the coverage it provided as of May 1, 1993.

"(2) ENFORCEMENT.—For purposes of section 2207 of the Public Health Service Act [42 U.S.C. 300bb–7], the requirement of paragraph (1) is deemed a requirement of title XXII of such Act [42 U.S.C. 300bb–1 et seq.]."

§300bb–8. Definitions

For purposes of this subchapter—

(1) Group health plan

The term "group health plan" has the meaning given such term in 5000(b) [1] of title 26. Such term shall not include any plan substantially all of the coverage under which is for qualified long-term care services (as defined in section 7702B(c) of title 26). Such term shall not include any qualified small employer health reimbursement arrangement (as defined in section 9831(d)(2) of title 26).

(2) Covered employee

The term "covered employee" means an individual who is (or was) provided coverage under a group health plan by virtue of the performance of services by the individual for 1 or more persons maintaining the plan (including as an employee defined in section 401(c)(1) of title 26).

(3) Qualified beneficiary

(A) In general

The term "qualified beneficiary" means, with respect to a covered employee under a group health plan, any other individual who, on the day before the qualifying event for that employee, is a beneficiary under the plan—

(i) as the spouse of the covered employee, or

(ii) as the dependent child of the employee.

Such term shall also include a child who is born to or placed for adoption with the covered employee during the period of continuation coverage under this subchapter.

(B) Special rule for terminations and reduced employment

In the case of a qualifying event described in section 300bb–3(2) of this title, the term "qualified beneficiary" includes the covered employee.

(4) Plan administrator

The term "plan administrator" has the meaning given the term "administrator" by section 1002(16)(A) of title 29.

(July 1, 1944, ch. 373, title XXII, §2208, as added Pub. L. 99–272, title X, §10003(a), Apr. 7, 1986, 100 Stat. 236; amended Pub. L. 100–647, title III, §3011(b)(7), Nov. 10, 1988, 102 Stat. 3625; Pub. L. 101–239, title VI, §6801(c)(1), Dec. 19, 1989, 103 Stat. 2297; Pub. L. 104–191, title I, §102(d),

title III, §321(d)(3), title IV, §421(a)(3), Aug. 21, 1996, 110 Stat. 1978, 2059, 2088; Pub. L. 114–255, div. C, title XVIII, §18001(c)(2), Dec. 13, 2016, 130 Stat. 1344.)

EDITORIAL NOTES

AMENDMENTS

2016—Par. (1). Pub. L. 114–255 inserted at end "Such term shall not include any qualified small employer health reimbursement arrangement (as defined in section 9831(d)(2) of title 26)."

1996—Par. (1). Pub. L. 104–191, §321(d)(3), inserted at end "Such term shall not include any plan substantially all of the coverage under which is for qualified long-term care services (as defined in section 7702B(c) of title 26)."

Pub. L. 104–191, §102(d), substituted "5000(b)" for "section 162(i)(2)".

Par. (3)(A). Pub. L. 104–191, §421(a)(3), inserted at end "Such term shall also include a child who is born to or placed for adoption with the covered employee during the period of continuation coverage under this subchapter."

1989—Par. (2). Pub. L. 101–239 substituted "the performance of services by the individual for 1 or more persons maintaining the plan (including as an employee defined in section 401(c)(1) of title 26)" for "the individual's employment or previous employment with an employer".

1988—Par. (1). Pub. L. 100–647 substituted "section 162(i)(2) of the Internal Revenue Code of 1986" for "section 162(i)(3) of the Internal Revenue Code of 1954", which for purposes of codification was translated as "section 162(i)(2) of title 26".

STATUTORY NOTES AND RELATED SUBSIDIARIES

EFFECTIVE DATE OF 2016 AMENDMENT

Pub. L. 114–255, div. C, title XVIII, §18001(c)(3), Dec. 13, 2016, 130 Stat. 1344, provided that: "The amendments made by this subsection [amending this section and section 300gg–91 of this title] shall apply to plan years beginning after December 31, 2016."

EFFECTIVE DATE OF 1996 AMENDMENT

Amendment by section 321(d)(3) of Pub. L. 104–191 applicable to contracts issued after Dec. 31, 1996, see section 321(f) of Pub. L. 104–191, set out as an Effective Date note under section 7702B of Title 26, Internal Revenue Code.

Amendment by section 421(a)(3) of Pub. L. 104–191 effective Jan. 1, 1997, regardless of whether the qualifying event occurred before, on, or after such date, see section 421(d) of Pub. L. 104–191, set out as a note under section 4980B of Title 26.

EFFECTIVE DATE OF 1989 AMENDMENT

Pub. L. 101–239, title VI, §6801(c)(2), Dec. 19, 1989, 103 Stat. 2298, provided that: "The amendment made by paragraph (1) [amending this section] shall apply to plan years beginning after December 31, 1989."

EFFECTIVE DATE OF 1988 AMENDMENT

Amendment by Pub. L. 100–647 applicable to taxable years beginning after Dec. 31, 1988, but not applicable to any plan for any plan year to which section 162(k) of Title 26, Internal Revenue Code (as in effect on the day before Nov. 10, 1988), did not apply by reason of section 10001(e)(2) of Pub. L. 99–272, see section 3011(d) of Pub. L. 100–647, set out as a note under section 162 of Title 26.

[1] So in original. Probably should be preceded by "section".

SUBCHAPTER XXI—RESEARCH WITH RESPECT TO ACQUIRED IMMUNE DEFICIENCY SYNDROME

EDITORIAL NOTES

PRIOR PROVISIONS

A prior subchapter XXI (§300cc et seq.), comprised of title XXIII of the Public Health Service Act, act July 1, 1944, ch. 373, 2301–2316, was renumbered title XXV, §§2501–2514, of the Public Health Service Act, and transferred to subchapter XXV (§300aaa et seq.) of this chapter, renumbered title XXVI, §§2601–2614, of the Public Health Service Act, renumbered title XXVII, §§2701–2714, of the Public Health Service Act, and renumbered title II, part B, §§231–244, of the Public Health Service Act, and transferred to part B (§238 et seq.) of subchapter I of this chapter.

PART A—ADMINISTRATION OF RESEARCH PROGRAMS

§300cc. Repealed. Pub. L. 109–482, title I, §104(b)(2)(C), Jan. 15, 2007, 120 Stat. 3693

Section, act July 1, 1944, ch. 373, title XXIII, §2301, as added Pub. L. 100–607, title II, §201(4), Nov. 4, 1988, 102 Stat. 3063; amended Pub. L. 102–531, title III, §312(d)(16), Oct. 27, 1992, 106 Stat. 3505, required an annual comprehensive report on all expenditures by Secretary with respect to AIDS.

A prior section 300cc, act July 1, 1944, §2301, was successively renumbered by subsequent acts and transferred, see section 238 of this title.

STATUTORY NOTES AND RELATED SUBSIDIARIES

EFFECTIVE DATE OF REPEAL

Repeal applicable only with respect to amounts appropriated for fiscal year 2007 or subsequent fiscal years, see section 109 of Pub. L. 109–482, set out as an Effective Date of 2007 Amendment note under section 281 of this title.

§300cc–1. Requirement of expediting awards of grants and contracts for research

(a) In general

The Secretary shall expedite the award of grants, contracts, and cooperative agreements for research projects relating to acquired immune deficiency syndrome (including such research projects initiated independently of any solicitation by the Secretary for proposals for such research projects).

(b) Time limitations with respect to certain applications

(1) With respect to programs of grants, contracts, and cooperative agreements described in subsection (a), any application submitted in response to a solicitation by the Secretary for proposals pursuant to such a program—

(A) may not be approved if the application is submitted after the expiration of the 3-month period beginning on the date on which the solicitation is issued; and

(B) shall be awarded, or otherwise finally acted upon, not later than the expiration of the 6-month period beginning on the expiration of the period described in subparagraph (A).

(2) If the Secretary makes a determination that it is not practicable to administer a program referred to in paragraph (1) in accordance with the time limitations described in such paragraph, the Secretary may adjust the time limitations accordingly.

(c) Requirements with respect to adjustments in time limitations

With respect to any program for which a determination described in subsection (b)(2) is made, the Secretary shall—

(1) if the determination is made before the Secretary issues a solicitation for proposals pursuant to the program, ensure that the solicitation describes the time limitations as adjusted by the

determination; and

(2) if the determination is made after the Secretary issues such a solicitation for proposals, issue a statement describing the time limitations as adjusted by the determination and individually notify, with respect to the determination, each applicant whose application is submitted before the expiration of the 3-month period beginning on the date on which the solicitation was issued.

(d) Annual reports to Congress

Except as provided in subsection (e), the Secretary shall annually prepare, for inclusion in the comprehensive report required in section 300cc [1] of this title, a report—

(A) summarizing programs for which the Secretary has made a determination described in subsection (b)(2), including a description of the time limitations as adjusted by the determination and including a summary of the solicitation issued by the Secretary for proposals pursuant to the program; and

(B) summarizing applications that—

(i) were submitted pursuant to a program of grants, contracts, or cooperative agreements referred to in paragraph (1) of subsection (b) for which a determination described in paragraph (2) of such subsection has not been made; and

(ii) were not processed in accordance with the time limitations described in such paragraph (1).

(e) Quarterly reports for fiscal year 1989

For fiscal year 1989, the report required in subsection (d) shall, not less than quarterly, be prepared and submitted to the Committee on Energy and Commerce of the House of Representatives and the Committee on Labor and Human Resources of the Senate.

(July 1, 1944, ch. 373, title XXIII, §2302, as added Pub. L. 100–607, title II, §201(4), Nov. 4, 1988, 102 Stat. 3063.)

EDITORIAL NOTES

REFERENCES IN TEXT

Section 300cc of this title, referred to in subsec. (d), was repealed by Pub. L. 109–482, title I, §104(b)(2)(C), Jan. 15, 2007, 120 Stat. 3693.

PRIOR PROVISIONS

A prior section 300cc–1, act July 1, 1944, §2302, was successively renumbered by subsequent acts and transferred, see section 238a of this title.

STATUTORY NOTES AND RELATED SUBSIDIARIES

CHANGE OF NAME

Committee on Labor and Human Resources of Senate changed to Committee on Health, Education, Labor, and Pensions of Senate by Senate Resolution No. 20, One Hundred Sixth Congress, Jan. 19, 1999.

Committee on Energy and Commerce of House of Representatives treated as referring to Committee on Commerce of House of Representatives by section 1(a) of Pub. L. 104–14, set out as a note preceding section 21 of Title 2, The Congress. Committee on Commerce of House of Representatives changed to Committee on Energy and Commerce of House of Representatives, and jurisdiction over matters relating to securities and exchanges and insurance generally transferred to Committee on Financial Services of House of Representatives by House Resolution No. 5, One Hundred Seventh Congress, Jan. 3, 2001.

DEVELOPMENT OF RAPID HIV TEST

Pub. L. 106–345, title V, §502, Oct. 20, 2000, 114 Stat. 1353, as amended by Pub. L. 114–255, div. A, title II, §2042(g), Dec. 13, 2016, 130 Stat. 1073, provided that:

"(a) EXPANSION, INTENSIFICATION, AND COORDINATION OF RESEARCH AND OTHER ACTIVITIES.—

"(1) IN GENERAL.—The Director of NIH shall expand, intensify, and coordinate research and other

activities of the National Institutes of Health with respect to the development of reliable and affordable tests for HIV disease that can rapidly be administered and whose results can rapidly be obtained (in this section referred to as 'rapid HIV test').

"(2) AUTHORIZATION OF APPROPRIATIONS.—For the purpose of carrying out this subsection, there are authorized to be appropriated such sums as may be necessary for each of the fiscal years 2001 through 2005.

"(b) PREMARKET REVIEW OF RAPID HIV TESTS.—

"(1) [sic] IN GENERAL.—Not later than 90 days after the date of the enactment of this Act [Oct. 20, 2000], the Secretary, in consultation with the Director of the Centers for Disease Control and Prevention and the Commissioner of Food and Drugs, shall submit to the appropriate committees of the Congress a report describing the progress made towards, and barriers to, the premarket review and commercial distribution of rapid HIV tests. The report shall—

"(A) assess the public health need for and public health benefits of rapid HIV tests, including the minimization of false positive results through the availability of multiple rapid HIV tests;

"(B) make recommendations regarding the need for the expedited review of rapid HIV test applications submitted to the Center for Biologics Evaluation and Research and, if such recommendations are favorable, specify criteria and procedures for such expedited review; and

"(C) specify whether the barriers to the premarket review of rapid HIV tests include the unnecessary application of requirements—

"(i) necessary to ensure the efficacy of devices for donor screening to rapid HIV tests intended for use in other screening situations; or

"(ii) for identifying antibodies to HIV subtypes of rare incidence in the United States to rapid HIV tests intended for use in screening situations other than donor screening.

"(c) GUIDELINES OF CENTERS FOR DISEASE CONTROL AND PREVENTION.—Promptly after commercial distribution of a rapid HIV test begins, the Secretary, acting through the Director of the Centers for Disease Control and Prevention, shall establish or update guidelines that include recommendations for States, hospitals, and other appropriate entities regarding the ready availability of such tests for administration to pregnant women who are in labor or in the late stage of pregnancy and whose HIV status is not known to the attending obstetrician."

LIMITATION ON EXPENDITURES FOR AIDS AND HIV ACTIVITIES

Pub. L. 104–146, §11, May 20, 1996, 110 Stat. 1373, provided that: "Notwithstanding any other provision of law, the total amounts of Federal funds expended in any fiscal year for AIDS and HIV activities may not exceed the total amounts expended in such fiscal year for activities related to cancer."

VACCINES FOR HUMAN IMMUNODEFICIENCY VIRUS

Pub. L. 103–43, title XIX, §1901(b), June 10, 1993, 107 Stat. 200, provided that:

"(1) IN GENERAL.—The Secretary of Health and Human Services, acting through the National Institutes of Health, shall develop a plan for the appropriate inclusion of HIV-infected women, including pregnant women, HIV-infected infants, and HIV-infected children in studies conducted by or through the National Institutes of Health concerning the safety and efficacy of HIV vaccines for the treatment and prevention of HIV infection. Such plan shall ensure the full participation of other Federal agencies currently conducting HIV vaccine studies and require that such studies conform fully to the requirements of part 46 of title 45, Code of Federal Regulations.

"(2) REPORT.—Not later than 180 days after the date of the enactment of this Act [June 10, 1993], the Secretary of Health and Human Services shall prepare and submit to the Committee on Energy and Commerce of the House of Representatives, and the Committee on Labor and Human Resources [now Committee on Health, Education, Labor, and Pensions] of the Senate, a report concerning the plan developed under paragraph (1).

"(3) IMPLEMENTATION.—Not later than 12 months after the date of the enactment of this Act, the Secretary of Health and Human Services shall implement the plan developed under paragraph (1), including measures for the full participation of other Federal agencies currently conducting HIV vaccine studies.

"(4) AUTHORIZATION OF APPROPRIATIONS.—For the purpose of carrying out this subsection, there are authorized to be appropriated such sums as may be necessary for each of the fiscal years 1994 through 1996."

EXECUTIVE DOCUMENTS

EX. ORD. NO. 12963. PRESIDENTIAL ADVISORY COUNCIL ON HIV/AIDS

Ex. Ord. No. 12963, June 14, 1995, 60 F.R. 31905, as amended by Ex. Ord. No. 13009, June 14, 1996, 61 F.R. 39799 [30799], provided:

By the authority vested in me as President by the Constitution and the laws of the United States of America, I hereby direct the Secretary of Health and Human Services to exercise her discretion as follows:

SECTION 1. *Establishment.* (a) The Secretary of Health and Human Services (the "Secretary") shall establish an HIV/AIDS Advisory Council (the "Advisory Council" or the "Council"), to be known as the Presidential Advisory Council on HIV/AIDS. The Advisory Council shall be composed of not more than 35 members to be appointed or designated by the Secretary. The Advisory Council shall comply with the Federal Advisory Committee Act, as amended ([former] 5 U.S.C. App.) [see 5 U.S.C. 1001 et seq.].

(b) The Secretary shall designate a Chairperson from among the members of the Advisory Council.

SEC. 2. *Functions*. The Advisory Council shall provide advice, information, and recommendations to the Secretary regarding programs and policies intended to (a) promote effective prevention of HIV disease, (b) advance research on HIV and AIDS, and (c) promote quality services to persons living with HIV disease and AIDS. The functions of the Advisory Council shall be solely advisory in nature. The Secretary shall provide the President with copies of all written reports provided to the Secretary by the Advisory Council.

SEC. 3. *Administration.* (a) The heads of executive departments and agencies shall, to the extent permitted by law, provide the Advisory Council with such information as it may require for purposes of carrying out its functions.

(b) Any members of the Advisory Council that receive compensation shall be compensated in accordance with Federal law. Committee members may be allowed travel expenses, including per diem in lieu of subsistence, to the extent permitted by law for persons serving intermittently in the Government service (5 U.S.C. section 5701–5707).

(c) To the extent permitted by law, and subject to the availability of appropriations, the Department of Health and Human Services shall provide the Advisory Council with such funds and support as may be necessary for the performance of its functions.

SEC. 4. *General Provisions*. (a) Notwithstanding the provisions of any other Executive order, any functions of the President under the Federal Advisory Committee Act that are applicable to the Advisory Council, except that of reporting annually to the Congress, shall be performed by the Department of Health and Human Services, in accordance with the guidelines and procedures established by the Administrator of General Services.

(b) This order is intended only to improve the internal management of the executive branch, and it is not intended to create any right, benefit, or trust responsibility, substantive or procedural, enforceable at law or equity by a party against the United States, its agencies, it officers, or any person.

WILLIAM J. CLINTON.

EXTENSION OF TERM OF PRESIDENTIAL ADVISORY COUNCIL ON HIV/AIDS

Term of Presidential Advisory Council on HIV/AIDS extended until Sept. 30, 2027, by Ex. Ord. No. 14354, Sept. 29, 2025, 90 F.R. 48145, set out as a note under section 1013 of Title 5, Government Organization and Employees.

Previous extensions of term of Presidential Advisory Council on HIV/AIDS were contained in the following prior Executive Orders:

Ex. Ord. No. 14109, Sept. 29, 2023, 88 F.R. 68447, extended term until Sept. 30, 2025.

Ex. Ord. No. 14048, Sept. 30, 2021, 86 F.R. 55465, extended term until Sept. 30, 2023.

Ex. Ord. No. 13889, Sept. 27, 2019, 84 F.R. 52743 extended term until Sept. 30, 2021.

Ex. Ord. No. 13811, Sept. 29, 2017, 82 F.R. 46363, extended term until Sept. 30, 2019.

Ex. Ord. No. 13708, Sept. 30, 2015, 80 F.R. 60271, extended term until Sept. 30, 2017.

EX. ORD. NO. 13649. ACCELERATING IMPROVEMENTS IN HIV PREVENTION AND CARE IN THE UNITED STATES THROUGH THE HIV CARE CONTINUUM INITIATIVE

Ex. Ord. No. 13649, July 15, 2013, 78 F.R. 43057, provided:

By the authority vested in me as President by the Constitution and the laws of the United States of America, and in order to further strengthen the capacity of the Federal Government to effectively respond to the ongoing domestic HIV epidemic, it is hereby ordered as follows:

SECTION 1. *Policy*. Addressing the domestic HIV epidemic is a priority of my Administration. In 2010, the White House released the first comprehensive National HIV/AIDS Strategy (Strategy), setting quantitative goals for reducing new HIV infections, improving health outcomes for people living with HIV, and reducing HIV-related health disparities. The Strategy will continue to serve as the blueprint for our national response to

the domestic epidemic. It has increased coordination, collaboration, and accountability across executive departments and agencies (agencies) with regard to addressing the epidemic. It has also focused our Nation's collective efforts on increasing the use of evidence-based approaches to prevention and care among populations and in regions where HIV is most concentrated.

Since the release of the Strategy, additional scientific discoveries have greatly enhanced our understanding of how to prevent and treat HIV. Accordingly, further Federal action is appropriate in response to these new developments. For example, a breakthrough research trial supported by the National Institutes of Health showed that initiating HIV treatment when the immune system was relatively healthy reduced HIV transmission by 96 percent. In addition, evidence suggests that early treatment may reduce HIV-related complications. These findings highlight the importance of prompt HIV diagnosis, and because of recent advances in HIV testing technology, HIV can be detected sooner and more rapidly than ever before.

Based on these and other data, recommendations for HIV testing and treatment have changed. The U.S. Preventive Services Task Force now recommends that clinicians screen all individuals ages 15 to 65 years for HIV, and the Department of Health and Human Services Guidelines for Use of Antiretroviral Agents now recommends offering treatment to all adolescents and adults diagnosed with HIV.

Furthermore, ongoing implementation of the Affordable Care Act provides a historic opportunity for Americans to access affordable, quality health care. The Act is expanding access to recommended preventive services with no out-of-pocket costs, including HIV testing, and, beginning in 2014, insurance companies will not be able to deny coverage based on pre-existing conditions, including HIV. Starting October 1, 2013, Americans can select the coverage that best suits them through the new Health Insurance Marketplace, and coverage will begin January 1, 2014.

Despite progress in combating HIV, important work remains. Since the publication of the Strategy, data released by the Centers for Disease Control and Prevention show that there are significant gaps along the HIV care continuum—the sequential stages of care from being diagnosed to receiving optimal treatment. Nearly one-fifth of the estimated 1.1 million people living with HIV in the United States are undiagnosed; one-third are not linked to medical care; nearly two-thirds are not engaged in ongoing care; and only one-quarter have the virus effectively controlled, which is necessary to maintain long-term health and reduce risk of transmission to others.

In light of these data, we must further clarify and focus our national efforts to prevent and treat HIV infection. It is the policy of my Administration that agencies implementing the Strategy prioritize addressing the continuum of HIV care, including by accelerating efforts to increase HIV testing, services, and treatment along the continuum. This acceleration will enable us to meet the goals of the Strategy and move closer to an AIDS-free generation.

SEC. 2. *Establishment of the HIV Care Continuum Initiative*. There is established the HIV Care Continuum Initiative (Initiative), to be overseen by the Director of the Office of National AIDS Policy. The Initiative will mobilize and coordinate Federal efforts in response to recent advances regarding how to prevent and treat HIV infection. The Initiative will support further integration of HIV prevention and care efforts; promote expansion of successful HIV testing and service delivery models; encourage innovative approaches to addressing barriers to accessing testing and treatment; and ensure that Federal resources are appropriately focused on implementing evidence-based interventions that improve outcomes along the HIV care continuum.

SEC. 3. *Establishment of the HIV Care Continuum Working Group*. There is established the HIV Care Continuum Working Group (Working Group) to support the Initiative. The Working Group shall coordinate Federal efforts to improve outcomes nationally across the HIV care continuum.

(a) *Membership*. The Working Group shall be co-chaired by the Director of the Office of National AIDS Policy and the Secretary of Health and Human Services or designee (Co-Chairs). In addition to the Co-Chairs, the Working Group shall consist of representatives from:

(i) the Department of Justice;

(ii) the Department of Labor;

(iii) the Department of Health and Human Services;

(iv) the Department of Housing and Urban Development;

(v) the Department of Veterans Affairs;

(vi) the Office of Management and Budget; and

(vii) other agencies and offices, as designated by the Co-Chairs.

(b) *Consultation*. The Working Group shall consult with the Presidential Advisory Council on HIV/AIDS, as appropriate.

(c) *Functions*. As part of the Initiative, the Working Group shall:

(i) request and review information from agencies describing efforts to improve testing, care, and treatment outcomes, and determine if there is appropriate emphasis on addressing the HIV care continuum in relation to

other work concerning the domestic epidemic;

(ii) review research on improving outcomes along the HIV care continuum;

(iii) obtain input from Federal grantees, affected communities, and other stakeholders to inform strategies to improve outcomes along the HIV care continuum;

(iv) identify potential impediments to improving outcomes along the HIV care continuum, including for populations at greatest risk for HIV infection, based on the efforts undertaken pursuant to paragraphs (i), (ii), and (iii) of this subsection;

(v) identify opportunities to address issues identified pursuant to paragraph (iv) of this subsection, and thereby improve outcomes along the HIV care continuum;

(vi) recommend ways to integrate efforts to improve outcomes along the HIV care continuum with other evidence-based strategies to combat HIV; and

(vii) specify how to better align and coordinate Federal efforts, both within and across agencies, to improve outcomes along the HIV care continuum.

(d) *Reporting.*

(i) Within 180 days of the date of this order, the Working Group shall provide recommendations to the President on actions that agencies can take to improve outcomes along the HIV care continuum.

(ii) Thereafter, the Director of the Office of National AIDS Policy shall include, as part of the annual report to the President pursuant to section 1(b) of my memorandum of July 13, 2010 (Implementation of the National HIV/AIDS Strategy), a report prepared by the Working Group on Government-wide progress in implementing this order. This report shall include a quantification of progress made in improving outcomes along the HIV care continuum.

SEC. 4. *General Provisions*. (a) Nothing in this order shall be construed to impair or otherwise affect:

(i) the authority granted by law to an executive department, agency, or the head thereof; or

(ii) the functions of the Director of the Office of Management and Budget relating to budgetary, administrative, or legislative proposals.

(b) This order shall be implemented consistent with applicable law and subject to the availability of appropriations.

(c) This order is not intended to, and does not, create any right or benefit, substantive or procedural, enforceable at law or in equity by any party against the United States, its departments, agencies, or entities, its officers, employees, or agents, or any other person.

BARACK OBAMA.

EX. ORD. NO. 13703. IMPLEMENTING THE NATIONAL HIV/AIDS STRATEGY FOR THE UNITED STATES FOR 2015–2020

Ex. Ord. No. 13703, July 30, 2015, 80 F.R. 46181, provided:

By the authority vested in me as President by the Constitution and the laws of the United States of America, and in order to ensure improved health outcomes for Americans at risk for or living with HIV/AIDS and achieve greater coordination across the Federal Government, I hereby order as follows:

SECTION 1. *Policy*. My Administration has made substantial progress in addressing the domestic HIV epidemic since the National HIV/AIDS Strategy for the United States (Strategy), the first of its kind, was released in July 2010. The Strategy has served as a blueprint for executive departments and agencies (agencies) as well as for community partners in the private and nonprofit sectors. This effort has led to increased coordination and collaboration among agencies and fostered the use of evidence-based policy approaches for improving HIV prevention and care.

Federal, State, and local agencies have contributed to significant improvements in health outcomes through their enhanced focus on the HIV care continuum—the sequential stages of care from being diagnosed to achieving viral suppression. Our partners across all levels of government and all sectors of society have also worked to ensure that all Americans living with HIV/AIDS receive our full support at every stage of their illness.

Further, my Administration has been committed to reducing the HIV-related disparities experienced by certain populations, including gay and bisexual men of all races and ethnicities, Black women and men, Latino women and men, people who inject drugs, youth aged 13–24, people in the Southern United States, and transgender women. Addressing the intersection between HIV/AIDS, violence against women and girls, and gender-related health disparities has also been a priority. The Working Group on the Intersection of HIV/AIDS, Violence Against Women and Girls, and Gender-related Health Disparities established in my memorandum of March 30, 2012, has focused its efforts on increasing screenings for HIV and intimate partner violence, addressing violence and trauma when supporting women in HIV care, and expanding public education efforts across all levels of government regarding HIV and violence against women and girls.

Today, I am releasing the National HIV/AIDS Strategy for the United States: Updated to 2020 (Updated Strategy) to build on this progress. The Updated Strategy integrates the recommendations of the HIV Care Continuum Working Group, established in Executive Order 13649 of July 15, 2013 (HIV Care Continuum Initiative), and the recommendations of the Working Group on the Intersection of HIV/AIDS, Violence Against Women and Girls, and Gender-related Health Disparities, so that their work can inform the Nation's response to the domestic HIV/AIDS epidemic. The Updated Strategy also takes into account recent research advancements in our understanding of HIV/AIDS, and builds on the historic successes of the Affordable Care Act, which is helping millions of Americans, including those who are living with HIV, access affordable, quality health care.

This order is designed to ensure successful implementation of the Updated Strategy by requiring coordination and collaboration by, and accountability of, the Federal Government; fostering enhanced and innovative partnerships with State, tribal, and local governments; and encouraging the commitment of all parts of society. The duties and authorities this order assigns are in addition to those assigned by my memorandum of July 13, 2010 (Implementation of the National HIV/AIDS Strategy). In light of recent progress and continuing challenges, we must continue to improve our national effort to reduce new HIV infections, increase access to care for people living with HIV, reduce HIV-related disparities and health inequities, and achieve greater coordination across all levels of government.

SEC. 2. *Role of the White House Office of National AIDS Policy (ONAP)*. (a) The Director of ONAP, in consultation with the Director of the Office of Management and Budget (OMB), shall be responsible for monitoring the implementation of the Updated Strategy.

(b) The Director of ONAP shall annually report to the President on the implementation of the Updated Strategy, including progress in meeting key targets and taking key actions identified in the Updated Strategy and the Federal Action Plan, an annual guidepost developed by ONAP in conjunction with agencies, designed to implement new efforts to address the domestic HIV/AIDS epidemic.

SEC. 3. *Lead Agency Responsibilities*. While the Updated Strategy will require a Government-wide effort in order to succeed fully, certain agencies have primary responsibilities and competencies in implementing the Updated Strategy.

(a) *Designation of Lead Agencies*. Lead agencies for implementing the Updated Strategy shall be:

(i) the Department of Defense;

(ii) the Department of Justice;

(iii) the Department of the Interior;

(iv) the Department of Labor;

(v) the Department of Health and Human Services;

(vi) the Department of Housing and Urban Development;

(vii) the Department of Education;

(viii) the Department of Veterans Affairs;

(ix) the Department of Homeland Security; and

(x) the Social Security Administration.

(b) *Lead Agency Action Plans*. Within 100 days of the date of this order, the head of each lead agency shall submit a report to ONAP and OMB on the agency's action plan for implementing the Updated Strategy. The plans shall assign responsibilities to agency officials, designate reporting structures for actions identified in the Federal Action Plan, and identify other appropriate actions to advance the Updated Strategy. The plans shall also include steps to strengthen coordination in planning, budgeting for, and evaluating domestic HIV/AIDS programs within and across agencies. Lead agencies are encouraged to consider, and reflect in their plans, steps to streamline grantee reporting requirements and funding announcements related to HIV/AIDS programs and activities.

(c) *Ongoing Responsibilities of Lead Agencies*. The head of each lead agency shall:

(i) designate an official responsible for coordinating the agency's ongoing efforts to implement the Updated Strategy;

(ii) develop and support a process for sharing progress reports, including status updates on achieving specific quantitative targets established by the Updated Strategy, with relevant agencies and ONAP on an annual basis, or at such other times as ONAP requests; and

(iii) in consultation with OMB, use the budget development process to prioritize programs and activities most critical to meeting the goals of the Updated Strategy.

SEC. 4. *Other Agency Responsibilities*. All agencies that support HIV/AIDS programs and activities shall ensure that, to the extent permitted by law, they are meeting the goals of the Updated Strategy.

(a) *Department of State*. Within 100 days of the date of this order, the Secretary of State shall submit to ONAP and OMB recommendations for improving the Government-wide response to the domestic HIV/AIDS

epidemic, based on lessons learned in implementing the President's Emergency Plan for AIDS Relief program.

(b) *Equal Employment Opportunity Commission (Commission)*. Within 100 days of the date of this order, the Chair of the Commission shall submit to ONAP and OMB recommendations for increasing employment opportunities for people living with HIV and a plan for addressing employment-related discrimination against people living with HIV, consistent with the Commission's authorities and other applicable law.

SEC. 5. *Role of the Presidential Advisory Council on HIV/AIDS (PACHA)*. The PACHA, which was established by Executive Order 12963 of June 14, 1995 (Presidential Advisory Council on HIV/AIDS), as amended, shall monitor the implementation of the Updated Strategy and make recommendations to the Secretary of Health and Human Services (Secretary) and to the Director of ONAP, as appropriate, concerning implementation and progress in achieving the Updated Strategy's goals.

SEC. 6. *National HIV/AIDS Strategy Federal Interagency Working Group*. There is established the National HIV/AIDS Strategy Federal Interagency Working Group (Federal Interagency Working Group) to support the implementation of the Updated Strategy.

(a) *Membership*. The Federal Interagency Working Group shall be co-chaired by the Director of ONAP and the Secretary or their designees. In addition to the Co-Chairs, the Federal Interagency Working Group shall consist of representatives from each lead agency, OMB, and any other agency or office designated by the Co-Chairs.

(b) *Consultation*. The Federal Interagency Working Group shall consult with the PACHA, as appropriate.

(c) *Outreach*. The Federal Interagency Working Group shall hold regular meetings and conduct outreach with representatives of private and nonprofit organizations, State, tribal, and local governments and agencies, elected officials, and other interested persons to assist the Federal Interagency Working Group in its efforts.

(d) *Functions*. As part of its efforts, the Federal Interagency Working Group shall:

(i) request and review information from agencies describing their efforts to implement the Updated Strategy;

(ii) share and disseminate best practices to combat the HIV epidemic among agencies and other stakeholders;

(iii) integrate new HIV-related research results into the overall implementation of the Updated Strategy;

(iv) obtain input from community partners, scientific and technical experts, and stakeholders in State, tribal, and local governments to inform implementation of the Updated Strategy;

(v) increase government and public awareness of HIV-related issues;

(vi) specify how to better align and coordinate Federal efforts, both within and across agencies, to improve health outcomes for Americans at risk for or living with HIV; and

(vii) integrate the Working Group on the Intersection of HIV/AIDS, Violence Against Women and Girls, and Gender-related Health Disparities into the implementation of the Updated Strategy.

(e) *Reporting.*

(i) Within 100 days of the date of this order, the Federal Interagency Working Group shall provide recommendations to the President on actions that agencies should take to implement the Updated Strategy through 2020.

(ii) The Director of ONAP shall include, as part of the Director's annual report to the President, a report prepared by the Federal Interagency Working Group concerning Government-wide progress in implementing the Updated Strategy.

SEC. 7. *General Provisions*. (a) Nothing in this order shall be construed to impair or otherwise affect:

(i) the authority granted by law to an executive department, agency, or the head thereof; or

(ii) the functions of the Director of OMB relating to budgetary, administrative, or legislative proposals.

(b) This order shall be implemented consistent with applicable law and subject to the availability of appropriations.

(c) This order is not intended to, and does not, create any right or benefit, substantive or procedural, enforceable at law or in equity by any party against the United States, its departments, agencies, or entities, its officers, employees, or agents, or any other person.

BARACK OBAMA.

IMPLEMENTATION OF THE NATIONAL HIV/AIDS STRATEGY

Memorandum of President of the United States, July 13, 2010, 75 F.R. 41687, provided:

Memorandum for the Heads of Executive Departments and Agencies

As we approach 30 years from the onset of the HIV/AIDS epidemic in the United States, new actions are needed to prevent HIV infection and better serve people living with HIV. The actions we take now will build upon a legacy of global leadership, national commitment, and sustained efforts on the part of Americans from all parts of the country and all walks of life to end the HIV epidemic in the United States and around the

world. I am committed to renewing national leadership to fight HIV/AIDS here at home, as we continue our efforts to fight HIV/AIDS around the world. My Administration has engaged in an extensive process to engage Americans and listen to their ideas for improving our national response to HIV/AIDS.

Today I am releasing a National HIV/AIDS Strategy for the United States (Strategy) and a National HIV/AIDS Strategy Federal Implementation Plan (Federal Implementation Plan), which identifies specific actions to be taken by Federal agencies to implement the Strategy's goals. While agencies already undertake many actions to address HIV/AIDS, successful implementation of the Strategy will require new levels of coordination, collaboration, and accountability. This will require the Federal Government to work in new ways across agency lines, as well as in enhanced and innovative partnerships with State, tribal, and local governments. Government cooperation at all levels, moreover, is not enough. Success will require the commitment of all parts of society, including businesses, faith communities, philanthropic organizations, scientific and medical communities, educational institutions, people living with HIV, and others. It is also necessary to sustain public commitment to ending the epidemic, and this calls for regular communications between governments at all levels to identify the challenges we face and report the progress we are making. To these ends, I hereby direct the following:

SECTION 1. *Role of the White House Office of National AIDS Policy (ONAP).*

(a) The Director of the ONAP, in consultation with the Office of Management and Budget (OMB), shall be responsible for setting the Administration's domestic HIV/AIDS priorities and monitoring the implementation of the Strategy. The Director of the ONAP shall convene regular meetings with representatives of executive departments and agencies (agencies) to coordinate HIV/AIDS-related policies, programs, and activities.

(b) The Director of the ONAP shall annually report to the President on the implementation of the Strategy, including progress in meeting key targets and taking key actions identified in the Strategy and the Federal Implementation Plan.

SEC. 2. *Lead Responsible Agencies*. While the Strategy requires a Government-wide effort in order to succeed fully, certain agencies have primary responsibilities and competencies in implementing the Strategy.

(a) *Designation of Lead Agencies*. Lead agencies for implementing the Strategy shall be:

(i) the Department of Health and Human Services;

(ii) the Department of Justice;

(iii) the Department of Labor;

(iv) the Department of Housing and Urban Development;

(v) the Department of Veterans Affairs; and

(vi) the Social Security Administration.

(b) *Lead Agency Implementation Plans*. Within 150 days of the date of this memorandum, the head of each lead agency shall submit a report to the ONAP and the OMB on the agency's operational plans for implementing the Strategy. The plans shall assign responsibilities to agency officials, designate reporting structures for actions identified in the Federal Implementation Plan, and identify other appropriate actions to advance the Strategy. The plans shall also include steps to strengthen coordination in planning, budgeting for, and evaluating domestic HIV/AIDS programs within and across agencies. Lead agencies are encouraged to consider, and reflect in their plans, steps to streamline grantee reporting requirements and funding announcements related to HIV/AIDS programs and activities.

(c) *Ongoing Responsibilities of Lead Agencies*. The head of each lead agency shall:

(i) designate an official responsible for coordinating the agency's ongoing efforts to implement the Strategy;

(ii) develop a process for sharing progress reports, including status updates on achieving specific quantitative targets established by the Strategy, with relevant agencies and the ONAP on an annual basis, or at such other times as the ONAP requests; and

(iii) in consultation with the OMB, use the budget development process to prioritize programs and activities most critical to meeting the goals of the Strategy.

SEC. 3. *Role of the Secretary of Health and Human Services*. The Secretary of Health and Human Services (Secretary), or the Secretary's designee, shall be responsible for improving coordination of domestic HIV/AIDS programs and activities across the Federal Government.

(a) *Coordination within the Department of Health and Human Services*. The Secretary, or the Secretary's designee, shall develop and implement specific plans and procedures for improving intra-departmental coordination and collaboration on HIV/AIDS care, research, and prevention services.

(b) *Coordination with Other Agencies*. The Secretary, or the Secretary's designee, shall be responsible for convening interagency efforts to improve coordination of HIV/AIDS programs and activities. This may include collaboration with governmental and nongovernmental entities to achieve the Federal Government's implementation and research priorities in the areas of highest impact.

(c) *Presidential Advisory Council on HIV/AIDS (PACHA)*. PACHA, which was established by Executive

Order 12963 of June 14, 1995 (Presidential Advisory Council on HIV/AIDS), as amended, shall monitor the implementation of the Strategy and make recommendations to the Secretary and to the Director of the ONAP, as appropriate, concerning implementation.

SEC. 4. *Responsibilities of Other Agencies*. All agencies that support HIV/AIDS programs and activities shall ensure that, to the extent permitted by law, they are meeting the goals of the Strategy.

(a) *Department of Defense*. Within 150 days of the date of this memorandum, the Secretary of Defense shall submit to the ONAP and the OMB a plan for aligning the health-care services provided by the Department of Defense with the Strategy, to the extent feasible and permitted by law. The plan shall address, in particular, HIV/AIDS prevention, care, and treatment.

(b) *Department of State*. Within 150 days of the date of this memorandum, the Secretary of State shall submit to the ONAP and the OMB recommendations for improving the Government-wide response to the domestic HIV/AIDS epidemic, based on lessons learned in implementing the President's Emergency Plan for AIDS Relief (PEPFAR) program.

(c) *Equal Employment Opportunity Commission (Commission)*. Within 150 days of the date of this memorandum, the Chair of the Commission shall submit to the ONAP and the OMB recommendations for increasing employment opportunities for people living with HIV and a plan for addressing employment-related discrimination against people living with HIV, consistent with the Commission's authorities and other applicable law.

SEC. 5. *General Provisions.*

(a) The heads of executive departments and agencies shall assist and provide information to the Director of the ONAP, consistent with applicable law, as may be necessary to implement the Strategy. Each agency shall bear its own expense for carrying out activities to implement the Strategy.

(b) Nothing in this memorandum shall be construed to impair or otherwise affect:

(i) authority granted by law to a department or agency or the head thereof, or to other executive branch officials; or

(ii) functions of the Director of the OMB relating to budgetary, administrative, or legislative proposals.

(c) This memorandum shall be implemented consistent with applicable law and subject to the availability of appropriations.

(d) This memorandum is not intended to, and does not, create any right or benefit, substantive or procedural, enforceable at law or in equity by any party against the United States, its departments, agencies, or entities, its officers, employees, or agents, or any other person.

SEC. 6. *Publication*. The Secretary is authorized and directed to publish this memorandum in the Federal Register.

BARACK OBAMA.

ESTABLISHING A WORKING GROUP ON THE INTERSECTION OF HIV/AIDS, VIOLENCE AGAINST WOMEN AND GIRLS, AND GENDER-RELATED HEALTH DISPARITIES

Memorandum of President of the United States, Mar. 30, 2012, 77 F.R. 20277, provided:

Memorandum for the Heads of Executive Departments and Agencies

Throughout our country, the spread of HIV/AIDS has had a devastating impact on many communities. In the United States, there are approximately 1.2 million people living with HIV/AIDS, including more than 290,000 women. Women and girls now account for 24 percent of all diagnoses of HIV infection among United States adults and adolescents. The domestic epidemic disproportionately affects women of color, with African Americans and Latinas constituting over 70 percent of new HIV cases in women. The spread of HIV/AIDS is, in and of itself, a primary concern to my Administration. However, gender-based violence and gender-related health disparities cannot be ignored when addressing the domestic public health threat of HIV/AIDS. HIV/AIDS programs often ignore the biological differences and the social, economic, and cultural inequities that make women and girls more vulnerable to HIV/AIDS. In our country, women and girls are all too frequently victimized by domestic violence and sexual assault, which can lead to greater risk for acquiring this disease. Teenage girls and young women ages 16–24 face the highest rates of dating violence and sexual assault. In addition, challenges in accessing proper health care can present obstacles to addressing HIV/AIDS. Gender-based violence continues to be an underreported, common problem that, if ignored, increases risks for HIV and may prevent women and girls from seeking prevention, treatment, and health services.

My Administration is committed to improving efforts to understand and address the intersection of HIV/AIDS, violence against women and girls, and gender-related health disparities. To do so, executive departments and agencies (agencies) must build on their current work addressing the intersection of these issues by improving data collection, research, intervention strategies, and training. In order to develop a comprehensive Government-wide approach to these issues that is data-driven, uses effective prevention and

care interventions, engages families and communities, supports research and data collection, and mobilizes both public and private sector resources, I direct the following:

SECTION 1. *Working Group on the Intersection of HIV/AIDS, Violence Against Women and Girls, and Gender-related Health Disparities*. There is established within the Executive Office of the President a Working Group on the Intersection of HIV/AIDS, Violence Against Women and Girls, and Gender-related Health Disparities (Working Group), to be co-chaired by the White House Advisor on Violence Against Women and the Director of the Office of National AIDS Policy (Co-Chairs). Within 60 days of the date of this memorandum, the Co-Chairs shall convene the first meeting of the Working Group.

(a) In addition to the Co-Chairs, the Working Group shall consist of representatives from:

(i) the Department of Justice;

(ii) the Department of the Interior;

(iii) the Department of Health and Human Services;

(iv) the Department of Education;

(v) the Department of Homeland Security;

(vi) the Department of Veterans Affairs;

(vii) the Department of Housing and Urban Development; and

(viii) the Office of Management and Budget.

(b) The Working Group shall consult with the Presidential Advisory Council on HIV/AIDS, as appropriate.

(c) The Department of State, the United States Agency for International Development, and the President's Emergency Plan for AIDS Relief Gender Technical Working Group shall act in an advisory capacity to the Working Group, providing information on lessons learned and evidence-based best practices based on their global experience addressing issues involving the intersection between HIV/AIDS and violence against women.

SEC. 2. *Mission and Functions of the Working Group*. (a) The Working Group shall coordinate agency efforts to address issues involving the intersection of HIV/AIDS, violence against women and girls, and gender-related health disparities. Such efforts shall include, but not be limited to:

(i) increasing government and public awareness of the need to address the intersection of HIV/AIDS, violence against women and girls, and gender-related health disparities, including sexual and reproductive health and access to health care;

(ii) sharing best practices, including demonstration projects and international work by agencies, as well as successful gender-specific strategies aimed at addressing risks that influence women's and girls' vulnerability to HIV infection and violence;

(iii) integrating sexual and reproductive health services, gender-based violence services, and HIV/AIDS services, where research demonstrates that doing so will result in improved and sustained health outcomes;

(iv) emphasizing evidence-based prevention activities that engage men and boys and highlight their role in the prevention of violence against women and HIV/AIDS infection;

(v) facilitating opportunities for partnerships among diverse organizations from the violence against women and girls, HIV/AIDS, and women's health communities to address the intersection of these issues;

(vi) ensuring that the needs of vulnerable and underserved groups are considered in any efforts to address issues involving the intersection of HIV/AIDS, violence against women and girls, and gender-related health disparities;

(vii) promoting research to better understand the intersection of the biological, behavioral, and social sciences bases for the relationship between increased HIV/AIDS risk, domestic violence, and gender-related health disparities; and

(viii) prioritizing, as appropriate, the efforts described in paragraphs (a)(i)–(vii) of this section with respect to women and girls of color, who represent the majority of females living with and at risk for HIV infection in the United States.

(b) The Working Group shall annually provide the President recommendations for updating the National HIV/AIDS Strategy. In addition, the Working Group shall provide information on:

(i) coordinated actions taken by the Working Group to meet its objectives and identify areas where the Federal Government has achieved integration and coordination in addressing the intersection of HIV/AIDS, violence against women and girls, and gender-related health disparities;

(ii) alternative means of making available gender-sensitive health care for women and girls through the integration of HIV/AIDS prevention and care services with intimate partner violence prevention and counseling as well as mental health and trauma services;

(iii) specific, evidence-based goals for addressing HIV among women, including HIV-related disparities among women of color, to inform the National HIV/AIDS Strategy Implementation Plan (for its biannual review);

(iv) research and data collection needs regarding HIV/AIDS, violence against women and girls, and gender-related health disparities to help develop more comprehensive data and targeted research (disaggregated by sex, gender, and gender identity, where practicable); and

(v) existing partnerships and potential areas of collaboration with other public or nongovernmental actors, taking into consideration the types of implementation or research objectives that other public or nongovernmental actors may be particularly well-situated to accomplish.

SEC. 3. *Outreach*. Consistent with the objectives of this memorandum and applicable law, the Working Group, in addition to regular meetings, shall conduct outreach with representatives of private and nonprofit organizations, State, tribal, and local government agencies, elected officials, and other interested persons to assist the Working Group in developing a detailed set of recommendations.

SEC. 4. *General Provisions*. (a) The heads of agencies shall assist and provide information to the Working Group, consistent with applicable law, as may be necessary to carry out the functions of the Working Group. Each agency and office shall bear its own expense for carrying out activities related to the Working Group.

(b) Nothing in this memorandum shall be construed to impair or otherwise affect:

(i) the authority granted by law to an executive department, agency, or the head thereof; or

(ii) the functions of the Director of the Office of Management and Budget relating to budgetary, administrative, or legislative proposals.

(c) This memorandum shall be implemented consistent with applicable law and subject to the availability of appropriations.

(d) This memorandum is not intended to, and does not, create any right or benefit, substantive or procedural, enforceable at law or in equity by any party against the United States, its departments, agencies, or entities, its officers, employees, or agents, or any other person.

(e) The Secretary of Health and Human Services is authorized and directed to publish this memorandum in the Federal Register.

BARACK OBAMA.

[1] *See References in Text note below.*

§300cc–2. Requirements with respect to processing of requests for personnel and administrative support

(a) In general

The Director of the Office of Personnel Management or the Administrator of General Services, as the case may be, shall respond to any priority request made by the Administrator of the Substance Abuse and Mental Health Services Administration, the Director of the Centers for Disease Control and Prevention, the Commissioner of Food and Drugs, or the Director of the National Institutes of Health, not later than 21 days after the date on which such request is made. If the Director of the Office of Personnel Management or the Administrator of General Services, as the case may be, does not disapprove a priority request during the 21-day period, the request shall be deemed to be approved.

(b) Notice to Secretary and to Assistant Secretary for Health

The Administrator of the Substance Abuse and Mental Health Services Administration, the Director of the Centers for Disease Control and Prevention, the Commissioner of Food and Drugs, and the Director of the National Institutes of Health, shall, respectively, transmit to the Secretary and the Assistant Secretary for Health a copy of each priority request made under this section by the agency head involved. The copy shall be transmitted on the date on which the priority request involved is made.

(c) "Priority request" defined

For purposes of this section, the term "priority request" means any request that—

(1) is designated as a priority request by the Administrator of the Substance Abuse and Mental Health Services Administration, the Director of the Centers for Disease Control and Prevention, the Commissioner of Food and Drugs, or the Director of the National Institutes of Health; and

(2)(A) is made to the Director of the Office of Personnel Management for the allocation of

personnel to carry out activities with respect to acquired immune deficiency syndrome; or

(B) is made to the Administrator of General Services for administrative support or space in carrying out such activities.

(July 1, 1944, ch. 373, title XXIII, §2303, as added Pub. L. 100–607, title II, §201(4), Nov. 4, 1988, 102 Stat. 3064; amended Pub. L. 102–321, title I, §§161, 163(b)(7), July 10, 1992, 106 Stat. 375, 376; Pub. L. 102–531, title III, §312(d)(17), Oct. 27, 1992, 106 Stat. 3505.)

EDITORIAL NOTES

PRIOR PROVISIONS

A prior section 300cc–2, act July 1, 1944, §2303, was successively renumbered by subsequent acts and transferred, see section 238b of this title.

AMENDMENTS

1992—Subsec. (a). Pub. L. 102–531 substituted "Centers for Disease Control and Prevention" for "Centers for Disease Control".

Pub. L. 102–321, §161, substituted "Administrator of the Substance Abuse and Mental Health Services Administration" for "Administrator of the Alcohol, Drug Abuse, and Mental Health Administration".

Subsec. (b). Pub. L. 102–531 substituted "Centers for Disease Control and Prevention" for "Centers for Disease Control".

Pub. L. 102–321, §163(b)(7)(A), substituted "Administrator of the Substance Abuse and Mental Health Services Administration" for "Administrator of the Alcohol, Drug Abuse, and Mental Health Administration".

Subsec. (c)(1). Pub. L. 102–531 substituted "Centers for Disease Control and Prevention" for "Centers for Disease Control".

Pub. L. 102–321, §163(b)(7)(B), substituted "Administrator of the Substance Abuse and Mental Health Services Administration" for "Administrator of the Alcohol, Drug Abuse, and Mental Health Administration".

STATUTORY NOTES AND RELATED SUBSIDIARIES

EFFECTIVE DATE OF 1992 AMENDMENT

Amendment by Pub. L. 102–321 effective Oct. 1, 1992, see section 801(c) of Pub. L. 102–321, set out as a note under section 236 of this title.

§300cc–3. Establishment of Research Advisory Committee

(a) In general

After consultation with the Commissioner of Food and Drugs, the Secretary, acting through the Director of the National Institute of Allergy and Infectious Diseases, shall establish within such Institute an advisory committee to be known as the AIDS Research Advisory Committee (hereafter in this section referred to as the "Committee").

(b) Composition

The Committee shall be composed of physicians whose clinical practice includes a significant number of patients with acquired immune deficiency syndrome.

(c) Duties

The Committee shall—

(1) advise the Director of such Institute (and may provide advice to the Directors of other agencies of the National Institutes of Health, as appropriate) on appropriate research activities to be undertaken with respect to clinical treatment of such syndrome, including advice with respect to—

(A) research on drugs for preventing or minimizing the development of symptoms or conditions arising from infection with the etiologic agent for such syndrome, including recommendations on the projects of research with respect to diagnosing immune deficiency and

with respect to predicting, diagnosing, preventing, and treating opportunistic cancers and infectious diseases; and

(B) research on the effectiveness of treating such symptoms or conditions with drugs that—

(i) are not approved by the Commissioner of Food and Drugs for the purpose of treating such symptoms or conditions; and

(ii) are being utilized for such purpose by individuals infected with such etiologic agent;

(2)(A) review ongoing publicly and privately supported research on clinical treatment for acquired immune deficiency syndrome, including research on drugs described in paragraph (1); and

(B) periodically issue, and make available to health care professionals, reports describing and evaluating such research;

(3) conduct studies and convene meetings for the purpose of determining the recommendations among physicians in clinical practice on clinical treatment of acquired immune deficiency syndrome, including treatment with the drugs described in paragraph (1); and

(4) conduct a study for the purpose of developing, with respect to individuals infected with the etiologic agent for acquired immune deficiency syndrome, a consensus among health care professionals on clinical treatments for preventing or minimizing the development of symptoms or conditions arising from infection with such etiologic agent.

(July 1, 1944, ch. 373, title XXIII, §2304, as added Pub. L. 100–607, title II, §201(4), Nov. 4, 1988, 102 Stat. 3065; amended Pub. L. 100–690, title II, §2617(a), Nov. 18, 1988, 102 Stat. 4240; Pub. L. 103–43, title XVIII, §1811(1), title XX, §2008(d)(1), June 10, 1993, 107 Stat. 199, 212.)

EDITORIAL NOTES

PRIOR PROVISIONS

A prior section 300cc–3, acts July 1, 1944, ch. 373, title XXIII, §2304, formerly title V, §504, 58 Stat. 710; June 25, 1948, ch. 654, §6, 62 Stat. 1018; 1953 Reorg. Plan No. 1, §§5, 8, eff. Apr. 11, 1953, 18 F.R. 2053, 67 Stat. 631; renumbered title XXI, §2104, Apr. 26, 1983, Pub. L. 98–24, §2(a)(1), 97 Stat. 176; renumbered title XXIII, §2304, Nov. 14, 1986, Pub. L. 99–660, title III, §311(a), 100 Stat. 3755, related to care of Service patients at Saint Elizabeths Hospital, prior to repeal by Pub. L. 98–621, §10(s), Nov. 8, 1984, 98 Stat. 3381, effective Oct. 1, 1987. Subsequent to repeal, section 2104 of title XXI of act July 1, 1944, was renumbered section 2304 of title XXIII of that act by section 311(a) of Pub. L. 99–660.

A prior section 300cc–4, acts July 1, 1944, ch. 373, title XXI, §2105, formerly title V, §505, 58 Stat. 710; 1953 Reorg. Plan No. 1, §§5, 8, eff. Apr. 11, 1953, 18 F.R. 2053, 67 Stat. 631; renumbered title XXI, §2105, Apr. 26, 1983, Pub. L. 98–24, §2(a)(1), 97 Stat. 176, provided procedures under which the Secretary could settle claims for damages from collisions or incident to the operation of vessels within a year of the accrual of such claims and not to exceed $3,000, prior to repeal by Pub. L. 99–117, §12(f), Oct. 7, 1985, 99 Stat. 495. Subsequent to repeal, section 2105 of title XXI of act July 1, 1944, was renumbered section 2305 of title XXIII of that act by Pub. L. 99–660, title III, §311(a), Nov. 14, 1986, 100 Stat. 3755.

Prior sections 300cc–5 to 300cc–10, act July 1, 1944, §§2306 to 2311, respectively, were successively renumbered by subsequent acts and transferred, see sections 238c to 238h of this title.

AMENDMENTS

1993—Pub. L. 103–43, §2008(d)(1)(A), substituted "Research Advisory Committee" for "Clinical Research Review Committee" in section catchline.

Subsec. (a). Pub. L. 103–43, §2008(d)(1)(B), substituted "AIDS Research Advisory Committee" for "AIDS Clinical Research Review Committee".

Subsec. (c)(1). Pub. L. 103–43, §1811(1), in introductory provisions inserted "(and may provide advice to the Directors of other agencies of the National Institutes of Health, as appropriate)" after "Director of such Institute" and in subpar. (A) inserted before semicolon at end ", including recommendations on the projects of research with respect to diagnosing immune deficiency and with respect to predicting, diagnosing, preventing, and treating opportunistic cancers and infectious diseases".

1988—Subsec. (c)(2)(B). Pub. L. 100–690 substituted semicolon for period.

STATUTORY NOTES AND RELATED SUBSIDIARIES

EFFECTIVE DATE OF 1988 AMENDMENT

Amendment by Pub. L. 100–690 effective immediately after enactment of Pub. L. 100–607, which was approved Nov. 4, 1988, see section 2600 of Pub. L. 100–690, set out as a note under section 242m of this title.

TERMINATION OF ADVISORY COMMITTEES

Advisory committees established after Jan. 5, 1973, to terminate not later than the expiration of the 2-year period beginning on the date of their establishment, unless, in the case of a committee established by the President or an officer of the Federal Government, such committee is renewed by appropriate action prior to the expiration of such 2-year period, or in the case of a committee established by the Congress, its duration is otherwise provided by law. See section 1013 of Title 5, Government Organization and Employees.

Pub. L. 93–641, §6, Jan. 4, 1975, 88 Stat. 2275, set out as a note under section 217a of this title, provided that an advisory committee established pursuant to the Public Health Service Act shall terminate at such time as may be specifically prescribed by an Act of Congress enacted after Jan. 4, 1975.

PART B—RESEARCH AUTHORITY

§300cc–11. Clinical evaluation units at National Institutes of Health

(a) In general

The Secretary, acting through the Director of the National Cancer Institute and the Director of the National Institute of Allergy and Infectious Diseases, shall for each such Institute establish a clinical evaluation unit at the Clinical Center at the National Institutes of Health. Each of the clinical evaluation units—

(1) shall conduct clinical evaluations of experimental treatments for acquired immune deficiency syndrome developed within the preclinical drug development program, including evaluations of methods of diagnosing immune deficiency and evaluations of methods of predicting, diagnosing, preventing, and treating opportunistic cancers and infectious diseases; and

(2) may conduct clinical evaluations of experimental treatments for such syndrome that are developed by any other national research institute of the National Institutes of Health or by any other entity.

(b) Personnel and administrative support

(1) For the purposes described in subsection (a), the Secretary, acting through the Director of the National Institutes of Health, shall provide each of the clinical evaluation units required in such subsection—

(A)(i) with not less than 50 beds; or

(ii) with an outpatient clinical capacity equal to not less than twice the outpatient clinical capacity, with respect to acquired immune deficiency syndrome, possessed by the Clinical Center of the National Institutes of Health on June 1, 1988; and

(B) with such personnel, such administrative support, and such other support services as may be necessary.

(2) Facilities, personnel, administrative support, and other support services provided pursuant to paragraph (1) shall be in addition to the number or level of facilities, personnel, administrative support, and other support services that otherwise would be available at the Clinical Center at the National Institutes of Health for the provision of clinical care for individuals with diseases or disorders.

(c) Authorization of appropriations

For the purpose of carrying out this section, there are authorized to be appropriated such sums as may be necessary.

(July 1, 1944, ch. 373, title XXIII, §2311, as added Pub. L. 100–607, title II, §201(4), Nov. 4, 1988, 102 Stat. 3066; amended Pub. L. 103–43, title XVIII, §1811(2), June 10, 1993,107 Stat. 199.)

EDITORIAL NOTES

PRIOR PROVISIONS

A prior section 300cc–11, act July 1, 1944, §2312, was successively renumbered by subsequent acts and transferred, see section 238i of this title.

AMENDMENTS

1993—Subsec. (a)(1). Pub. L. 103–43 inserted before semicolon at end ", including evaluations of methods of diagnosing immune deficiency and evaluations of methods of predicting, diagnosing, preventing, and treating opportunistic cancers and infectious diseases".

§300cc–12. Use of investigational new drugs with respect to acquired immune deficiency syndrome

(a) Encouragement of applications with respect to clinical trials

(1) If, in the determination of the Secretary, there is preliminary evidence that a new drug has effectiveness in humans with respect to the prevention or treatment of acquired immune deficiency syndrome, the Secretary shall, through statements published in the Federal Register—

(A) announce the fact of such determination; and

(B) with respect to the new drug involved, encourage an application for an exemption for investigational use of the new drug under regulations issued under section 355(i) of title 21.

(2)(A) The AIDS Research Advisory Committee established pursuant to section 300cc–3 of this title shall make recommendations to the Secretary with respect to new drugs appropriate for determinations described in paragraph (1).

(B) The Secretary shall, as soon as is practicable, determine the merits of recommendations received by the Secretary pursuant to subparagraph (A).

(b) Encouragement of applications with respect to treatment use in circumstances other than clinical trials

(1) In the case of a new drug with respect to which the Secretary has made a determination described in subsection (a) and with respect to which an exemption is in effect for purposes of section 355(i) of title 21, the Secretary shall—

(A) as appropriate, encourage the sponsor of the investigation of the new drug to submit to the Secretary, in accordance with regulations issued under such section, an application to use the drug in the treatment of individuals—

(i) who are infected with the etiologic agent for acquired immune deficiency syndrome; and

(ii) who are not participating in the clinical trials conducted pursuant to such exemption; and

(B) if such an application is approved, encourage, as appropriate, licensed medical practitioners to obtain, in accordance with such regulations, the new drug from such sponsor for the purpose of treating such individuals.

(2) If the sponsor of the investigation of a new drug described in paragraph (1) does not submit to the Secretary an application described in such paragraph (relating to treatment use), the Secretary shall, through statements published in the Federal Register, encourage, as appropriate, licensed medical practitioners to submit to the Secretary such applications in accordance with regulations described in such paragraph.

(c) Technical assistance with respect to treatment use

In the case of a new drug with respect to which the Secretary has made a determination described in subsection (a), the Secretary may, directly or through grants or contracts, provide technical assistance with respect to the process of—

(1) submitting to the Secretary applications for exemptions described in paragraph (1)(B) of such subsection;

(2) submitting to the Secretary applications described in subsection (b); and

(3) with respect to sponsors of investigations of new drugs, facilitating the transfer of new drugs from such sponsors to licensed medical practitioners.

(d) "New drug" defined

For purposes of this section, the term "new drug" has the meaning given such term in section 321 of title 21.

(July 1, 1944, ch. 373, title XXIII, §2312, as added Pub. L. 100–607, title II, §201(4), Nov. 4, 1988, 102 Stat. 3066; amended Pub. L. 103–43, title XX, §2008(d)(2), June 10, 1993, 107 Stat. 212.)

EDITORIAL NOTES

PRIOR PROVISIONS

A prior section 300cc–12, act July 1, 1944, §2313, was successively renumbered by subsequent acts and transferred, see section 238j of this title.

AMENDMENTS

1993—Subsec. (a)(2)(A). Pub. L. 103–43 substituted "AIDS Research Advisory Committee" for "AIDS Clinical Research Review Committee".

§300cc–13. Terry Beirn Community-Based AIDS Research Initiative

(a) In general

After consultation with the Commissioner of Food and Drugs, the Director of the National Institutes of Health, acting through the Director of the National Institute of Allergy and Infectious Diseases, may make grants to public entities and nonprofit private entities concerned with acquired immune deficiency syndrome, and may enter into contracts with public and private such [1] entities, for the purpose of planning and conducting, in the community involved, clinical trials of experimental treatments for infection with the etiologic agent for such syndrome that are approved by the Commissioner of Food and Drugs for investigational use under regulations issued under section 355 of title 21.

(b) Requirement of certain projects

(1) Financial assistance under subsection (a) shall include such assistance to community-based organizations and community health centers for the purpose of—

(A) retaining appropriate medical supervision;

(B) assisting with administration, data collection and record management; and

(C) conducting training of community physicians, nurse practitioners, physicians' assistants and other health professionals for the purpose of conducting clinical trials.

(2)(A) Financial assistance under subsection (a) shall include such assistance for demonstration projects designed to implement and conduct community-based clinical trials in order to provide access to the entire scope of communities affected by infections with the etiologic agent for acquired immune deficiency syndrome, including minorities, hemophiliacs and transfusion-exposed individuals, women, children, users of intravenous drugs, and individuals who are asymptomatic with respect to such infection.

(B) The Director of the National Institutes of Health may not provide financial assistance under this paragraph unless the application for such assistance is approved—

(i) by the Commissioner of Food and Drugs;

(ii) by a duly constituted Institutional Review Board that meets the requirements of part 56 of title 21, Code of Federal Regulations; and

(iii) by the Director of the National Institute of Allergy and Infectious Diseases.

(c) Participation of private industry, schools of medicine and primary providers

Programs carried out with financial assistance provided under subsection (a) shall be designed to encourage private industry and schools of medicine, osteopathic medicine, and existing consortia of primary care providers organized to conduct clinical research concerning acquired immune deficiency syndrome to participate in, and to support, the clinical trials conducted pursuant to the programs.

(d) Requirement of application

The Secretary may not provide financial assistance under subsection (a) unless—

(1) an application for the assistance is submitted to the Secretary;

(2) with respect to carrying out the purpose for which the assistance is to be made, the application provides assurances of compliance satisfactory to the Secretary; and

(3) the application otherwise is in such form, is made in such manner, and contains such agreements, assurances, and information as the Secretary determines to be necessary to carry out this section.

(e) Authorization of appropriations

(1) For the purpose of carrying out subsection (b)(1), there are authorized to be appropriated such sums as may be necessary for each of the fiscal years 1989 through 1996.

(2) For the purpose of carrying out subsection (b)(2), there are authorized to be appropriated such sums as may be necessary for each of the fiscal years 1989 through 1996.

(July 1, 1944, ch. 373, title XXIII, §2313, as added Pub. L. 100–607, title II, §201(4), Nov. 4, 1988, 102 Stat. 3068; amended Pub. L. 100–690, title II, §2617(b), Nov. 18, 1988, 102 Stat. 4240; Pub. L. 101–93, §6, Aug. 16, 1989, 103 Stat. 615; Pub. L. 102–96, §3, Aug. 14, 1991, 105 Stat. 481.)

EDITORIAL NOTES

PRIOR PROVISIONS

A prior section 300cc–13, act July 1, 1944, §2314, was successively renumbered by subsequent acts and transferred, see section 238k of this title.

AMENDMENTS

1991—Pub. L. 102–96, §3(1), substituted "Terry Beirn Community-Based AIDS Research Initiative" for "Community-based evaluations of experimental therapies" in section catchline.

Subsec. (c). Pub. L. 102–96, §3(2), substituted ", schools of medicine and primary providers" for "and schools of medicine" in heading and substituted "schools of medicine, osteopathic medicine, and existing consortia of primary care providers organized to conduct clinical research concerning acquired immune deficiency syndrome" for "schools of medicine and osteopathic medicine".

Subsec. (e). Pub. L. 102–96, §3(3), substituted "1996" for "1991" in pars. (1) and (2).

1989—Subsec. (c). Pub. L. 101–93 inserted "and osteopathic medicine" after "schools of medicine".

1988—Subsec. (a). Pub. L. 100–690, §2617(b)(1), which directed substitution of "through the Director of the National Institute of Allergy" for "through the National Institutes of Allergy", was executed by making substitution for "through the National Institute of Allergy" as the probable intent of Congress.

Subsec. (b)(2)(B)(iii). Pub. L. 100–690, §2617(b)(2), which directed substitution of "Institute" for "Institutes", could not be executed because "Institute" was singular in original.

STATUTORY NOTES AND RELATED SUBSIDIARIES

EFFECTIVE DATE OF 1988 AMENDMENT

Amendment by Pub. L. 100–690 effective immediately after enactment of Pub. L. 100–607, which was approved Nov. 4, 1988, see section 2600 of Pub. L. 100–690, set out as a note under section 242m of this title.

REFERENCE TO COMMUNITY, MIGRANT, PUBLIC HOUSING, OR HOMELESS HEALTH CENTER CONSIDERED REFERENCE TO HEALTH CENTER

Reference to community health center, migrant health center, public housing health center, or homeless health center considered reference to health center, see section 4(c) of Pub. L. 104–299, set out as a note under section 254b of this title.

FINDINGS AND SENSE OF CONGRESS

Pub. L. 102–96, §2, Aug. 14, 1991, 105 Stat. 481, provided that:

"(a) FINDINGS.—Congress finds that—

"(1) community-based clinical trials complement the National Institute of Allergy and Infectious Diseases' university-based research in order to provide increased access to experimental therapies;

"(2) community-based clinical trials provide an efficient and cost-effective means to develop new HIV-related treatments, benefiting all people living with HIV disease and other illnesses; and

"(3) because the community-based clinical trials model has a proven ability to conduct rapid trials that meet the very highest standards of scientific inquiry, this program should be reauthorized and significantly expanded.

"(b) SENSE OF CONGRESS.—It is the sense of Congress that, because of Terry Beirn's tireless efforts to foster a partnership among all parties invested in AIDS research (including the National Institutes of Health university-based research system, primary care physicians practicing in the community, and patients), the community-based clinical trials program should be renamed as the 'Terry Beirn Community-Based AIDS Research Initiative' in his honor."

[1] *So in original.*

§300cc–14. Evaluation of certain treatments

(a) Establishment of program

(1) After consultation with the AIDS Research Advisory Committee established pursuant to section 300cc–3 of this title, the Secretary shall establish a program for the evaluation of drugs that—

(A) are not approved by the Commissioner of Food and Drugs for the purpose of treatments with respect to acquired immune deficiency syndrome; and

(B) are being utilized for such purpose by individuals infected with the etiologic agent for such syndrome.

(2) The program established under paragraph (1) shall include evaluations of the effectiveness and the risks of the treatment involved, including the risks of foregoing treatments with respect to acquired immune deficiency syndrome that are approved by the Commissioner of Food and Drugs.

(b) Authority with respect to grants and contracts

(1) For the purpose of conducting evaluations required in subsection (a), the Secretary may make grants to, and enter into cooperative agreements and contracts with, public and nonprofit private entities.

(2) Nonprofit private entities under paragraph (1) may include nonprofit private organizations that—

(A) are established for the purpose of evaluating treatments with respect to acquired immune deficiency syndrome; and

(B) consist primarily of individuals infected with the etiologic agent for such syndrome.

(c) Scientific and ethical guidelines

(1) The Secretary shall establish appropriate scientific and ethical guidelines for the conduct of evaluations carried out pursuant to this section. The Secretary may not provide financial assistance under subsection (b)(1) unless the applicant for such assistance agrees to comply with such guidelines.

(2) The Secretary may establish the guidelines described in paragraph (1) only after consulting with—

(A) physicians whose clinical practice includes a significant number of individuals with acquired immune deficiency syndrome;

(B) individuals who are infected with the etiologic agent for such syndrome; and

(C) other individuals with appropriate expertise or experience.

(d) Authorization of appropriations

For the purpose of carrying out this section, there are authorized to be appropriated such sums as may be necessary.

(July 1, 1944, ch. 373, title XXIII, §2314, as added Pub. L. 100–607, title II, §201(4), Nov. 4, 1988, 102 Stat. 3069; amended Pub. L. 103–43, title XX, §2008(d)(3), June 10, 1993, 107 Stat. 212.)

EDITORIAL NOTES

PRIOR PROVISIONS

A prior section 300cc–14, act July 1, 1944, §2315, was successively renumbered by subsequent acts and transferred, see section 238l of this title.

AMENDMENTS

1993—Subsec. (a)(1). Pub. L. 103–43 substituted "AIDS Research Advisory Committee" for "Clinical Research Review Committee" in introductory provisions.

§300cc–15. Support of international efforts

(a) Grants and contracts for research

(1) Under section 242l of this title, the Secretary, acting through the Director of the National Institutes of Health—

(A) shall, for the purpose described in paragraph (2), make grants to, enter into cooperative agreements and contracts with, and provide technical assistance to, international organizations concerned with public health; and

(B) may, for such purpose, provide technical assistance to foreign governments.

(2) The purpose referred to in paragraph (1) is promoting and expediting international research and training concerning the natural history and pathogenesis of the human immunodeficiency virus and the development and evaluation of vaccines and treatments for acquired immune deficiency syndrome and opportunistic infections.

(b) Grants and contracts for additional purposes

After consultation with the Administrator of the Agency for International Development, the Secretary, acting through the Director of the Centers for Disease Control and Prevention, shall under section 242l of this title make grants to, enter into contracts with, and provide technical assistance to, international organizations concerned with public health and may provide technical assistance to foreign governments, in order to support—

(1) projects for training individuals with respect to developing skills and technical expertise for use in the prevention, diagnosis, and treatment of acquired immune deficiency syndrome; and

(2) epidemiological research relating to acquired immune deficiency syndrome.

(c) Special Programme of World Health Organization

Support provided by the Secretary pursuant to this section shall be in furtherance of the global strategy of the World Health Organization Special Programme on Acquired Immunodeficiency Syndrome.

(d) Preferences

In providing grants, cooperative agreements, contracts, and technical assistance under subsections (a) and (b), the Secretary shall—

(1) give preference to activities under such subsections conducted by, or in cooperation with, the World Health Organization; and

(2) with respect to activities carried out under such subsections in the Western Hemisphere, give preference to activities conducted by, or in cooperation with, the Pan American Health Organization or the World Health Organization.

(e) Requirement of application

The Secretary may not make a grant or enter into a cooperative agreement or contract under this section unless—

(1) an application for such assistance is submitted to the Secretary;

(2) with respect to carrying out the purpose for which such assistance is to be provided, the application provides assurances of compliance satisfactory to the Secretary; and

(3) the application otherwise is in such form, is made in such manner, and contains such agreements, assurances, and information as the Secretary determines to be necessary to carry out this section.

(f) Authorization of appropriations

For the purpose of carrying out this section, there are authorized to be appropriated such sums as may be necessary for each fiscal year.

(July 1, 1944, ch. 373, title XXIII, §2315, as added Pub. L. 100–607, title II, §201(4), Nov. 4, 1988, 102 Stat. 3070; amended Pub. L. 102–531, title III, §312(d)(18), Oct. 27, 1992, 106 Stat. 3505; Pub. L. 103–43, title XVIII, §1811(3), June 10, 1993, 107 Stat. 199.)

EDITORIAL NOTES

PRIOR PROVISIONS

A prior section 300cc–15, act July 1, 1944, §2316, was successively renumbered by subsequent acts and transferred, see section 238m of this title.

AMENDMENTS

1993—Subsec. (a)(2). Pub. L. 103–43, §1811(3)(A), substituted "international research and training concerning the natural history and pathogenesis of the human immunodeficiency virus and the development and evaluation of vaccines and treatments for acquired immune deficiency syndrome and opportunistic infections" for "international research concerning the development and evaluation of vaccines and treatments for acquired immune deficiency syndrome".

Subsec. (f). Pub. L. 103–43, §1811(3)(B), substituted "such sums as may be necessary for each fiscal year" for "there are authorized to be appropriated $40,000,000 for fiscal year 1989 and such sums as may be necessary for each of the fiscal years 1990 and 1991".

1992—Subsec. (b). Pub. L. 102–531 substituted "Centers for Disease Control and Prevention" for "Centers for Disease Control".

§300cc–16. Research centers

(a) In general

(1) The Secretary, acting through the Director of the National Institute of Allergy and Infectious Diseases, may make grants to, and enter into contracts with, public and nonprofit private entities to assist such entities in planning, establishing, or strengthening, and providing basic operating support for, centers for basic and clinical research into, and training in, advanced diagnostic, prevention, and treatment methods for acquired immune deficiency syndrome.

(2) A grant or contract under paragraph (1) shall be provided in accordance with policies established by the Secretary, acting through the Director of the National Institutes of Health, and after consultation with the advisory council for the National Institute of Allergy and Infectious

Diseases.

(3) The Secretary shall ensure that, as appropriate, clinical research programs carried out under paragraph (1) include as research subjects women, children, hemophiliacs, and minorities.

(b) Use of financial assistance

(1) Financial assistance under subsection (a) may be expended for—

(A) the renovation or leasing of space;

(B) staffing and other basic operating costs, including such patient care costs as are required for clinical research;

(C) clinical training with respect to acquired immune deficiency syndrome (including such training for allied health professionals); and

(D) demonstration purposes, including projects in the long-term monitoring and outpatient treatment of individuals infected with the etiologic agent for such syndrome.

(2) Financial assistance under subsection (a) may not be expended to provide research training for which Ruth L. Kirschstein National Research Service Awards may be provided under section 288 of this title.

(c) Duration of support

Support of a center under subsection (a) may be for not more than five years. Such period may be extended by the Director for additional periods of not more than five years each if the operations of such center have been reviewed by an appropriate technical and scientific peer review group established by the Director and if such group has recommended to the Director that such period should be extended.

(d) Authorization of appropriations

For the purpose of carrying out this section, there are authorized to be appropriated such sums as may be necessary.

(July 1, 1944, ch. 373, title XXIII, §2316, as added Pub. L. 100–607, title II, §201(4), Nov. 4, 1988, 102 Stat. 3071; amended Pub. L. 107–206, title I, §804(c), Aug. 2, 2002, 116 Stat. 874.)

EDITORIAL NOTES

AMENDMENTS

2002—Subsec. (b)(2). Pub. L. 107–206 substituted "Ruth L. Kirschstein National Research Service Awards" for "National Research Service Awards".

§300cc–17. Information services

(a) Establishment of program

The Secretary shall establish, maintain, and operate a program with respect to information on research, treatment, and prevention activities relating to infection with the etiologic agent for acquired immune deficiency syndrome. The program shall, with respect to the agencies of the Department of Health and Human Services, be integrated and coordinated.

(b) Toll-free telephone communications for health care entities

(1) After consultation with the Director of the Office of AIDS Research, the Administrator of the Health Resources and Services Administration, and the Director of the Centers for Disease Control and Prevention, the Secretary shall provide for toll-free telephone communications to provide medical and technical information with respect to acquired immune deficiency syndrome to health care professionals, allied health care providers, and to professionals providing emergency health services.

(2) Information provided pursuant to paragraph (1) shall include—

(A) information on prevention of exposure to, and the transmission of, the etiologic agent for

acquired immune deficiency syndrome; and

(B) information contained in the data banks established in subsections (c) and (d).

(c) Data bank on research information

(1) After consultation with the Director of the Office of AIDS Research, the Director of the Centers for Disease Control and Prevention, and the National Library of Medicine, the Secretary shall establish a data bank of information on the results of research with respect to acquired immune deficiency syndrome conducted in the United States and other countries.

(2) In carrying out paragraph (1), the Secretary shall collect, catalog, store, and disseminate the information described in such paragraph. To the extent practicable, the Secretary shall make such information available to researchers, physicians, and other appropriate individuals, of countries other than the United States.

(d) Data bank on clinical trials and treatments

(1) After consultation with the Commissioner of Food and Drugs, the AIDS Research Advisory Committee established under section 300cc–3 of this title, and the Director of the Office of AIDS Research, the Secretary shall, in carrying out subsection (a), establish a data bank of information on clinical trials and treatments with respect to infection with the etiologic agent for acquired immune deficiency syndrome (hereafter in this section referred to as the "Data Bank").

(2) In carrying out paragraph (1), the Secretary shall collect, catalog, store, and disseminate the information described in such paragraph. The Secretary shall disseminate such information through information systems available to individuals infected with the etiologic agent for acquired immune deficiency syndrome, to other members of the public, to health care providers, and to researchers.

(e) Requirements with respect to data bank on clinical trials and treatments

The Data Bank shall include the following:

(1) A registry of clinical trials of experimental treatments for acquired immune deficiency syndrome and related illnesses conducted under regulations promulgated pursuant to section 355 of title 21 that provides a description of the purpose of each experimental drug protocol either with the consent of the protocol sponsor, or when a trial to test efficacy begins. Information provided shall include eligibility criteria and the location of trial sites, and must be forwarded to the Data Bank by the sponsor of the trial not later than 21 days after the approval by the Food and Drug Administration.

(2) Information pertaining to experimental treatments for acquired immune deficiency syndrome that may be available under a treatment investigational new drug application that has been submitted to the Food and Drug Administration pursuant to part 312 of title 21, Code of Federal Regulations. The Data Bank shall also include information pertaining to the results of clinical trials of such treatments, with the consent of the sponsor, of such experimental treatments, including information concerning potential toxicities or adverse effects associated with the use or administration of such experimental treatment.

(July 1, 1944, ch. 373, title XXIII, §2317, as added Pub. L. 100–607, title II, §201(4), Nov. 4, 1988, 102 Stat. 3071; amended Pub. L. 100–690, title II, §2617(c), Nov. 18, 1988, 102 Stat. 4240; Pub. L. 102–531, title III, §312(d)(19), Oct. 27, 1992, 106 Stat. 3505; Pub. L. 103–43, title XX, §2008(d)(4), June 10, 1993, 107 Stat. 212.)

EDITORIAL NOTES

AMENDMENTS

1993—Subsec. (d)(1). Pub. L. 103–43 substituted "AIDS Research Advisory Committee established under section 300cc–3 of this title" for "Clinical Research Review Committee".

1992—Subsecs. (b)(1), (c)(1). Pub. L. 102–531 substituted "Centers for Disease Control and Prevention" for "Centers for Disease Control".

1988—Subsec. (e). Pub. L. 100–690 substituted "data bank on clinical trials and treatments" for "data bank" in heading.

STATUTORY NOTES AND RELATED SUBSIDIARIES

EFFECTIVE DATE OF 1988 AMENDMENT

Amendment by Pub. L. 100–690 effective immediately after enactment of Pub. L. 100–607, which was approved Nov. 4, 1988, see section 2600 of Pub. L. 100–690, set out as a note under section 242m of this title.

§300cc–18. Development of model protocols for clinical care of infected individuals

(a) In general

(1) The Secretary, acting through the Director of the National Institutes of Health and after consultation with the Director of the Agency for Healthcare Research and Quality, may make grants to public and nonprofit private entities for the establishment of projects to develop model protocols for the clinical care of individuals infected with the etiologic agent for acquired immune deficiency syndrome, including treatment and prevention of HIV infection and related conditions among women.

(2) The Secretary may not make a grant under paragraph (1) unless—

(A) the applicant for the grant is a provider of comprehensive primary care; or

(B) the applicant for the grant agrees, with respect to the project carried out pursuant to paragraph (1), to enter into a cooperative arrangement with an entity that is a provider of comprehensive primary care.

(b) Requirement of provision of certain services

The Secretary may not make a grant under subsection (a) unless the applicant for the grant agrees that, with respect to patients participating in the project carried out with the grant, services provided pursuant to the grant will include—

(1) monitoring, in clinical laboratories, of the condition of such patients;

(2) clinical intervention for infection with the etiologic agent for acquired immune deficiency syndrome, including measures for the prevention of conditions arising from the infection;

(3) information and counseling on the availability of treatments for such infection approved by the Commissioner of Food and Drugs, on the availability of treatments for such infection not yet approved by the Commissioner, and on the reports issued by the AIDS Research Advisory Committee under section 300cc–3(c)(2)(B) of this title;

(4) support groups; and

(5) information on, and referrals to, entities providing appropriate social support services.

(c) Limitation on imposition of charges for services

The Secretary may not make a grant under subsection (a) unless the applicant for the grant agrees that, if the applicant will routinely impose a charge for providing services pursuant to the grant, the applicant will not impose the charge on any individual seeking such services who is unable to pay the charge.

(d) Evaluation and reports

(1) The Secretary may not make a grant under subsection (a) unless the applicant for the grant agrees, with respect to the project carried out pursuant to subsection (a), to submit to the Secretary—

(A) information sufficient to assist in the replication of the model protocol developed pursuant to the project; and

(B) such reports as the Secretary may require.

(2) The Secretary shall provide for evaluations of projects carried out pursuant to subsection (a) and shall annually submit to the Congress a report describing such projects. The report shall include the findings made as a result of such evaluations and may include any recommendations of the

Secretary for appropriate administrative and legislative initiatives with respect to the program established in this section.

(e) Authorization of appropriations

For the purpose of carrying out this section, there are authorized to be appropriated such sums as may be necessary for each of the fiscal years 1989 through 1991, and such sums as may be necessary for each of the fiscal years 1994 through 1996.

(July 1, 1944, ch. 373, title XXIII, §2318, as added Pub. L. 100–607, title II, §201(4), Nov. 4, 1988, 102 Stat. 3073; amended Pub. L. 103–43, title XVIII, §1811(4), title XX, §2008(d)(5), June 10, 1993, 107 Stat. 199, 212; Pub. L. 106–129, §2(b)(2), Dec. 6, 1999, 113 Stat. 1670.)

EDITORIAL NOTES

AMENDMENTS

1999—Subsec. (a)(1). Pub. L. 106–129 substituted "Director of the Agency for Healthcare Research and Quality" for "Administrator for Health Care Policy and Research".

1993—Subsec. (a)(1). Pub. L. 103–43, §1811(4)(A), inserted ", acting through the Director of the National Institutes of Health and after consultation with the Administrator for Health Care Policy and Research," after "The Secretary" and ", including treatment and prevention of HIV infection and related conditions among women" after "syndrome".

Subsec. (b)(3). Pub. L. 103–43, §2008(d)(5), substituted "AIDS Research Advisory Committee" for "Clinical Research Review Committee".

Subsec. (e). Pub. L. 103–43, §1811(4)(B), inserted before period at end ", and such sums as may be necessary for each of the fiscal years 1994 through 1996".

STATUTORY NOTES AND RELATED SUBSIDIARIES

TERMINATION OF REPORTING REQUIREMENTS

For termination, effective May 15, 2000, of provisions in subsec. (d)(2) of this section relating to annual submission to Congress of reports describing projects carried out pursuant to subsec. (a) of this section, see section 3003 of Pub. L. 104–66, as amended, set out as a note under section 1113 of Title 31, Money and Finance, and page 94 of House Document No. 103–7.

§300cc–19. National blood resource education program

After consultation with the Director of the National Heart, Lung, and Blood Institute and the Commissioner of Food and Drugs, the Secretary shall establish a program of research and education regarding blood donations and transfusions to maintain and improve the safety of the blood supply. Education programs shall be directed at health professionals, patients, and the community to—

(1) in the case of the public and patients undergoing treatment—

(A) increase awareness that the process of donating blood is safe;

(B) promote the concept that blood donors are contributors to a national need to maintain an adequate and safe blood supply;

(C) encourage blood donors to donate more than once a year; and

(D) encourage repeat blood donors to recruit new donors;

(2) in the case of health professionals—

(A) improve knowledge, attitudes, and skills of health professionals in the appropriate use of blood and blood components;

(B) increase the awareness and understanding of health professionals regarding the risks versus benefits of blood transfusion; and

(C) encourage health professionals to consider alternatives to the administration of blood or blood components for their patients; and

(3) in the case of the community, increase coordination, communication, and collaboration among community, professional, industry, and government organizations regarding blood donation and transfusion issues.

(July 1, 1944, ch. 373, title XXIII, §2319, as added Pub. L. 100–607, title II, §201(4), Nov. 4, 1988, 102 Stat. 3074.)

§300cc–20. Additional authority with respect to research

(a) Data collection with respect to national prevalence

(1) The Secretary, acting through the Director of the Centers for Disease Control and Prevention, may, through representative sampling and other appropriate methodologies, provide for the continuous collection of data on the incidence in the United States of cases of acquired immune deficiency syndrome and of cases of infection with the etiologic agent for such syndrome. The Secretary may carry out the program of data collection directly or through cooperative agreements and contracts with public and nonprofit private entities.

(2) The Secretary shall encourage each State to enter into a cooperative agreement or contract under paragraph (1) with the Secretary in order to facilitate the prompt collection of the most recent accurate data on the incidence of cases described in such paragraph.

(3) The Secretary shall ensure that data collected under paragraph (1) includes data on the demographic characteristics of the population of individuals with cases described in paragraph (1), including data on specific subpopulations at risk of infection with the etiologic agent for acquired immune deficiency syndrome.

(4) In carrying out this subsection, the Secretary shall, for the purpose of assuring the utility of data collected under this section, request entities with expertise in the methodologies of data collection to provide, as soon as is practicable, assistance to the Secretary and to the States with respect to the development and utilization of uniform methodologies of data collection.

(5) The Secretary shall provide for the dissemination of data collected pursuant to this subsection. In carrying out this paragraph, the Secretary may publish such data as frequently as the Secretary determines to be appropriate with respect to the protection of the public health. The Secretary shall publish such data not less than once each year.

(b) Epidemiological and demographic data

(1) The Secretary, acting through the Director of the Centers for Disease Control and Prevention, shall develop an epidemiological data base and shall provide for long-term studies for the purposes of—

(A) collecting information on the demographic characteristics of the population of individuals infected with the etiologic agent for acquired immune deficiency syndrome and the natural history of such infection; and

(B) developing models demonstrating the long-term domestic and international patterns of the transmission of such etiologic agent.

(2) The Secretary may carry out paragraph (1) directly or through grants to, or cooperative agreeements [1] or contracts with, public and nonprofit private entities, including Federal agencies.

(c) Long-term research

The Secretary may make grants to public and nonprofit private entities for the purpose of assisting grantees in conducting long-term research into treatments for acquired immune deficiency syndrome developed from knowledge of the genetic nature of the etiologic agent for such syndrome.

(d) Social sciences research

The Secretary, acting through the Director of the National Institute of Mental Health, may make grants to public and nonprofit private entities for the purpose of assisting grantees in conducting scientific research into the psychological and social sciences as such sciences relate to acquired

immune deficiency syndrome.

(e) Authorization of appropriations

(1) For the purpose of carrying out this section, there are authorized to be appropriated such sums as may be necessary for each fiscal year.

(2) Amounts appropriated pursuant to paragraph (1) to carry out subsection (c) shall remain available until expended.

(July 1, 1944, ch. 373, title XXIII, §2320, as added Pub. L. 100–607, title II, §201(4), Nov. 4, 1988, 102 Stat. 3074; amended Pub. L. 100–690, title II, §2617(d), Nov. 18, 1988, 102 Stat. 4240; Pub. L. 102–531, title III, §312(d)(20), Oct. 27, 1992, 106 Stat. 3505; Pub. L. 103–43, title XVIII, §1811(5), (6), June 10, 1993, 107 Stat. 200.)

EDITORIAL NOTES

AMENDMENTS

1993—Subsec. (b)(1)(A). Pub. L. 103–43, §1811(5), inserted "and the natural history of such infection" after "syndrome".

Subsec. (e)(1). Pub. L. 103–43, §1811(6), substituted "fiscal year" for "of the fiscal years 1989 through 1991".

1992—Subsecs. (a)(1), (b)(1). Pub. L. 102–531 substituted "Centers for Disease Control and Prevention" for "Centers for Disease Control".

1988—Subsec. (a)(5). Pub. L. 100–690 substituted "subsection" for "section".

STATUTORY NOTES AND RELATED SUBSIDIARIES

EFFECTIVE DATE OF 1988 AMENDMENT

Amendment by Pub. L. 100–690 effective immediately after enactment of Pub. L. 100–607, which was approved Nov. 4, 1988, see section 2600 of Pub. L. 100–690, set out as a note under section 242m of this title.

[1] *So in original.*

PART C—RESEARCH TRAINING

§300cc–31. Fellowships and training

(a) In general

The Secretary, acting through the Director of the Centers for Disease Control and Prevention, shall establish fellowship and training programs to be conducted by the Centers for Disease Control and Prevention to train individuals to develop skills in epidemiology, surveillance, testing, counseling, education, information, and laboratory analysis relating to acquired immune deficiency syndrome. Such programs shall be designed to enable health professionals and health personnel trained under such programs to work, after receiving such training, in national and international efforts toward the prevention, diagnosis, and treatment of acquired immune deficiency syndrome.

(b) Programs conducted by National Institute of Mental Health

The Secretary, acting through the Director of the National Institute of Mental Health, shall conduct or support fellowship and training programs for individuals pursuing graduate or postgraduate study in order to train such individuals to conduct scientific research into the psychological and social sciences as such sciences relate to acquired immune deficiency syndrome.

(c) Relationship to limitation on number of employees

Any individual receiving a fellowship or receiving training under subsection (a) or (b) shall not be included in any determination of the number of full-time equivalent employees of the Department of Health and Human Services for the purpose of any limitation on the number of such employees established by law prior to, on, or after November 4, 1988.

(d) Authorization of appropriations

For the purpose of carrying out this section, there are authorized to be appropriated such sums as may be necessary for each fiscal year.

(July 1, 1944, ch. 373, title XXIII, §2341, as added Pub. L. 100–607, title II, §201(4), Nov. 4, 1988, 102 Stat. 3076; amended Pub. L. 100–690, title II, §2617(e), Nov. 18, 1988, 102 Stat. 4240; Pub. L. 102–531, title III, §312(d)(21), Oct. 27, 1992, 106 Stat. 3505; Pub. L. 103–43, title XVIII, §1811(7), June 10, 1993, 107 Stat. 200.)

EDITORIAL NOTES

AMENDMENTS

1993—Subsec. (d). Pub. L. 103–43 substituted "fiscal year" for "of the fiscal years 1989 through 1991".

1992—Subsec. (a). Pub. L. 102–531, which directed the substitution of "Centers for Disease Control and Prevention" for "Centers for Disease Control", was executed by making the substitution in two places to reflect the probable intent of Congress.

1988—Subsec. (c). Pub. L. 100–690 substituted "date of the enactment of the AIDS Amendments of 1988" for "date of the enactment of the AIDS Federal Policy Act of 1988" which for purposes of codification was translated as "November 4, 1988".

STATUTORY NOTES AND RELATED SUBSIDIARIES

EFFECTIVE DATE OF 1988 AMENDMENT

Amendment by Pub. L. 100–690 effective immediately after enactment of Pub. L. 100–607, which was approved Nov. 4, 1988, see section 2600 of Pub. L. 100–690, set out as a note under section 242m of this title.

PART D—OFFICE OF AIDS RESEARCH

EDITORIAL NOTES

CODIFICATION

Pub. L. 103–43, title XVIII, §1801(a)(1), (3), June 10, 1993, 107 Stat. 192, added part D designation and heading and struck out former part D designation and heading "Special Authorities of the Director of the National Institutes of Health".

SUBPART I—INTERAGENCY COORDINATION OF ACTIVITIES

EDITORIAL NOTES

CODIFICATION

Pub. L. 103–43, title XVIII, §1801(a)(3), June 10, 1993, 107 Stat. 192, added subpart I heading.

§300cc–40. Establishment of Office

(a) In general

There is established within the National Institutes of Health an office to be known as the Office of AIDS Research. The Office shall be headed by a director, who shall be appointed by the Secretary.

(b) Duties

(1) Interagency coordination of AIDS activities

With respect to acquired immune deficiency syndrome, the Director of the Office shall plan, coordinate, and evaluate research and other activities conducted or supported by the agencies of the National Institutes of Health. In carrying out the preceding sentence, the Director of the Office shall evaluate the AIDS activities of each of such agencies and shall provide for the periodic reevaluation of such activities.

(2) Consultations

The Director of the Office shall carry out this subpart (including developing and revising the plan required in section 300cc–40c of this title) in consultation with the heads of the agencies of the National Institutes of Health, with the advisory councils of the agencies, and with the advisory council established under section 300cc–40b of this title.

(3) Coordination

The Director of the Office shall act as the primary Federal official with responsibility for overseeing all AIDS research conducted or supported by the National Institutes of Health, and

(A) shall serve to represent the National Institutes of Health AIDS Research Program at all relevant Executive branch task forces and committees; and

(B) shall maintain communications with all relevant Public Health Service agencies and with various other departments of the Federal Government, to ensure the timely transmission of information concerning advances in AIDS research and the clinical treatment of acquired immune deficiency syndrome and its related conditions, between these various agencies for dissemination to affected communities and health care providers.

(July 1, 1944, ch. 373, title XXIII, §2351, as added Pub. L. 103–43, title XVIII, §1801(a)(3), June 10, 1993, 107 Stat. 192.)

§300cc–40a. Microbicide research

(a) Federal strategic plan

The Director of the Office shall—

(1) expedite the implementation of the Federal strategic plans required by section 283(a) of this title regarding the conduct and support of research on, and development of, a microbicide to prevent the transmission of the human immunodeficiency virus; and

(2) review and, as appropriate, revise such plan to prioritize funding and activities relative to their scientific urgency and potential market readiness.

(b) Coordination

In implementing, reviewing, and prioritizing elements of the plan described in subsection (a), the Director of the Office shall consult, as appropriate, with—

(1) representatives of other Federal agencies involved in microbicide research, including the Coordinator of United States Government Activities to Combat HIV/AIDS Globally, the Director of the Centers for Disease Control and Prevention, and the Administrator of the United States Agency for International Development;

(2) the microbicide research and development community; and

(3) health advocates.

(July 1, 1944, ch. 373, title XXIII, §2351A, as added Pub. L. 110–293, title II, §203(b), July 30, 2008, 122 Stat. 2940.)

EDITORIAL NOTES

PRIOR PROVISIONS

A prior section 300cc–40a, act July 1, 1944, ch. 373, title XXIII, §2352, as added Pub. L. 103–43, title XVIII, §1801(a)(3), June 10, 1993, 107 Stat. 193, which required the establishment of an advisory council and coordinating committees, was transferred to section 300cc–40b of this title.

STATUTORY NOTES AND RELATED SUBSIDIARIES

SENSE OF CONGRESS

Pub. L. 110–293, title II, §203(a), July 30, 2008, 122 Stat. 2940, provided that: "Congress recognizes the need and urgency to expand the range of interventions for preventing the transmission of human immunodeficiency virus (HIV), including nonvaccine prevention methods that can be controlled by women."

§300cc–40b. Advisory Council; coordinating committees

(a) Advisory Council

(1) In general

The Secretary shall establish an advisory council for the purpose of providing advice to the Director of the Office on carrying out this part. (Such council is referred to in this subsection as the "Advisory Council".)

(2) Composition, compensation, terms, chair, etc.

Subsections (b) through (g) of section 284a of this title apply to the Advisory Council to the same extent and in the same manner as such subsections apply to advisory councils for the national research institutes, except that—

(A) in addition to the ex officio members specified in section 284a(b)(2) of this title, there shall serve as such members of the Advisory Council a representative from the advisory council of each of the National Cancer Institute and the National Institute on Allergy and Infectious Diseases; and

(B) with respect to the other national research institutes, there shall serve as ex officio members of such Council, in addition to such members specified in subparagraph (A), a representative from the advisory council of each of the 2 institutes that receive the greatest funding for AIDS activities.

(b) Individual coordinating committees regarding research disciplines

(1) In general

The Director of the Office shall establish, for each research discipline in which any activity under the plan required in section 300cc–40c of this title is carried out, a committee for the purpose of providing advice to the Director of the Office on carrying out this part with respect to such discipline. (Each such committee is referred to in this subsection as a "coordinating committee".)

(2) Composition

Each coordinating committee shall be composed of representatives of the agencies of the National Institutes of Health with significant responsibilities regarding the research discipline involved.

(July 1, 1944, ch. 373, title XXIII, §2352, as added Pub. L. 103–43, title XVIII, §1801(a)(3), June 10, 1993, 107 Stat. 193.)

EDITORIAL NOTES

CODIFICATION

Section was formerly classified to section 300cc–40a of this title.

PRIOR PROVISIONS

A prior section 300cc–40b, act July 1, 1944, ch. 373, title XXIII, §2353, as added Pub. L. 103–43, title XVIII, §1801(a)(3), June 10, 1993, 107 Stat. 194, which required the establishment of a comprehensive plan, was transferred to section 300cc–40c of this title.

STATUTORY NOTES AND RELATED SUBSIDIARIES

TERMINATION OF ADVISORY COUNCILS

Advisory councils established after Jan. 5, 1973, to terminate not later than the expiration of the 2-year period beginning on the date of their establishment, unless, in the case of a council established by the President or an officer of the Federal Government, such council is renewed by appropriate action prior to the expiration of such 2-year period, or in the case of a council established by Congress, its duration is otherwise provided by law. See sections 1001(2) and 1013 of Title 5, Government Organization and Employees.

Pub. L. 93–641, §6, Jan. 4, 1975, 88 Stat. 2275, set out as a note under section 217a of this title, provided that an advisory committee established pursuant to the Public Health Service Act shall terminate at such time as may be specifically prescribed by an Act of Congress enacted after Jan. 4, 1975.

§300cc–40c. Comprehensive plan for expenditure of appropriations

(a) In general

Subject to the provisions of this section and other applicable law, the Director of the Office, in carrying out section 300cc–40 of this title, shall—

(1) establish a comprehensive plan for the conduct and support of all AIDS activities of the agencies of the National Institutes of Health (which plan shall be first established under this paragraph not later than 12 months after June 10, 1993);

(2) ensure that the Plan establishes priorities among the AIDS activities that such agencies are authorized to carry out;

(3) ensure that the Plan establishes objectives regarding such activities, describes the means for achieving the objectives, and designates the date by which the objectives are expected to be achieved;

(4) ensure that all amounts appropriated for such activities are expended in accordance with the Plan;

(5) review the Plan not less than annually, and revise the Plan as appropriate; and

(6) ensure that the Plan serves as a broad, binding statement of policies regarding AIDS activities of the agencies, but does not remove the responsibility of the heads of the agencies for the approval of specific programs or projects, or for other details of the daily administration of such activities, in accordance with the Plan.

(b) Certain components of Plan

With respect to AIDS activities of the agencies of the National Institutes of Health, the Director of the Office shall ensure that the Plan—

(1) provides for basic research;

(2) provides for applied research;

(3) provides for research that is conducted by the agencies;

(4) provides for research that is supported by the agencies;

(5) provides for proposals developed pursuant to solicitations by the agencies and for proposals developed independently of such solicitations; and

(6) provides for behavioral research and social sciences research.

(c) Budget estimates

(1) Full-funding budget

(A) With respect to a fiscal year, the Director of the Office shall prepare and submit directly to

the President, for review and transmittal to the Congress, a budget estimate for carrying out the Plan for the fiscal year, after reasonable opportunity for comment (but without change) by the Secretary, the Director of the National Institutes of Health, and the advisory council established under section 300cc–40b of this title. The budget estimate shall include an estimate of the number and type of personnel needs for the Office.

(B) The budget estimate submitted under subparagraph (A) shall estimate the amounts necessary for the agencies of the National Institutes of Health to carry out all AIDS activities determined by the Director of the Office to be appropriate, without regard to the probability that such amounts will be appropriated.

(2) Alternative budgets

(A) With respect to a fiscal year, the Director of the Office shall prepare and submit to the Secretary and the Director of the National Institutes of Health the budget estimates described in subparagraph (B) for carrying out the Plan for the fiscal year. The Secretary and such Director shall consider each of such estimates in making recommendations to the President regarding a budget for the Plan for such year.

(B) With respect to the fiscal year involved, the budget estimates referred to in subparagraph (A) for the Plan are as follows:

(i) The budget estimate submitted under paragraph (1).

(ii) A budget estimate developed on the assumption that the amounts appropriated will be sufficient only for—

(I) continuing the conduct by the agencies of the National Institutes of Health of existing AIDS activities (if approved for continuation), and continuing the support of such activities by the agencies in the case of projects or programs for which the agencies have made a commitment of continued support; and

(II) carrying out, of activities that are in addition to activities specified in subclause (I), only such activities for which the Director determines there is the most substantial need.

(iii) Such other budget estimates as the Director of the Office determines to be appropriate.

(d) Funding

(1) Authorization of appropriations

For the purpose of carrying out AIDS activities under the Plan, there are authorized to be appropriated such sums as may be necessary for each of the fiscal years 1994 through 1996.

(2) Receipt of funds

For the first fiscal year beginning after the date on which the Plan first established under subsection (a)(1) has been in effect for 12 months, and for each subsequent fiscal year, the Director of the Office shall receive directly from the President and the Director of the Office of Management and Budget all funds available for AIDS activities of the National Institutes of Health.

(3) Allocations for agencies

(A) Each fiscal year the Director of the Office shall, from the amounts received under paragraph (2) for the fiscal year, allocate to the agencies of the National Institutes of Health (in accordance with the Plan) all amounts available for such year for carrying out the AIDS activities specified in subsection (c)(2)(B)(ii)(I) for such year. Such allocation shall, to the extent practicable, be made not later than 15 days after the date on which the Director receives amounts under paragraph (2).

(B) Each fiscal year the Director of the Office shall, from the amounts received under paragraph (2) for the fiscal year, allocate to the agencies of the National Institutes of Health (in accordance with the Plan) all amounts available for such year for carrying out AIDS activities that are not referred to in subparagraph (A). Such allocation shall, to the extent practicable, be made not later than 30 days after the date on which the Director receives amounts under paragraph (2).

(July 1, 1944, ch. 373, title XXIII, §2353, as added Pub. L. 103–43, title XVIII, §1801(a)(3), June

10, 1993, 107 Stat. 194.)

EDITORIAL NOTES

CODIFICATION

Section was formerly classified to section 300cc–40b of this title.

§300cc–41. Additional authorities

(a) In general

In carrying out AIDS research, the Director of the Office—

(1) shall develop and expand clinical trials of treatments and therapies for infection with the etiologic agent for acquired immune deficiency syndrome, including such clinical trials for women, infants, children, hemophiliacs, and minorities;

(2) may establish or support the large-scale development and preclinical screening, production, or distribution of specialized biological materials and other therapeutic substances for AIDS research and set standards of safety and care for persons using such materials;

(3) may support—

(A) AIDS research conducted outside the United States by qualified foreign professionals if such research can reasonably be expected to benefit the people of the United States;

(B) collaborative research involving American and foreign participants; and

(C) the training of American scientists abroad and foreign scientists in the United States;

(4) may encourage and coordinate AIDS research conducted by any industrial concern that evidences a particular capability for the conduct of such research;

(5)(A) may acquire, improve, repair, operate, and maintain laboratories, other research facilities, equipment, and such other real or personal property as the Director of the Office determines necessary;

(B) may make grants for the construction or renovation of facilities; and

(C) may acquire, without regard to section 8141 of title 40 by lease or otherwise through the Administrator of General Services, buildings or parts of buildings in the District of Columbia or communities located adjacent to the District of Columbia for the use of the National Institutes of Health for a period not to exceed ten years; and

(6) subject to section 284(b)(2) of this title and without regard to section 3324 of title 31 and section 6101 of title 41, may enter into such contracts and cooperative agreements with any public agency, or with any person, firm, association, corporation, or educational institution, as may be necessary to expedite and coordinate research relating to acquired immune deficiency syndrome.

(b) Projects for cooperation among public and private health entities

In carrying out subsection (a), the Director of the Office shall establish projects to promote cooperation among Federal agencies, State, local, and regional public health agencies, and private entities, in research concerning the diagnosis, prevention, and treatment of acquired immune deficiency syndrome.

(July 1, 1944, ch. 373, title XXIII, §2354, formerly §2351, as added Pub. L. 100–607, title II, §201(4), Nov. 4, 1988, 102 Stat. 3076; renumbered §2354 and amended Pub. L. 103–43, title XVIII, §1801(a)(2), (b), June 10, 1993, 107 Stat. 192, 196; Pub. L. 109–482, title I, §104(b)(2)(D), Jan. 15, 2007, 120 Stat. 3693.)

EDITORIAL NOTES

CODIFICATION

In subsec. (a)(5)(C), "section 8141 of title 40" substituted for "the Act of March 3, 1877 (40 U.S.C. 34)" on

authority of Pub. L. 107–217, §5(c), Aug. 21, 2002, 116 Stat. 1303, the first section of which enacted Title 40, Public Buildings, Property, and Works.

In subsec. (a)(6), "section 6101 of title 41" substituted for "section 3709 of the Revised Statutes (41 U.S.C. 5)" on authority of Pub. L. 111–350, §6(c), Jan. 4, 2011, 124 Stat. 3854, which Act enacted Title 41, Public Contracts.

AMENDMENTS

2007—Subsecs. (b), (c). Pub. L. 109–482 redesignated subsec. (c) as (b) and struck out former subsec. (b). Subsec. (b) text read as follows: "The Director of the Office shall each fiscal year prepare and submit to the Secretary, for inclusion in the comprehensive report required in section 300cc(a) of this title, a report—

"(1) describing and evaluating the progress made in such fiscal year in research, treatment, and training with respect to acquired immune deficiency syndrome conducted or supported by the Institutes;

"(2) summarizing and analyzing expenditures made in such fiscal year for activities with respect to acquired immune deficiency syndrome conducted or supported by the National Institutes of Health; and

"(3) containing such recommendations as the Director considers appropriate."

1993—Pub. L. 103–43, §1801(b)(1), substituted "Additional" for "Establishment of" in section catchline.

Subsec. (a). Pub. L. 103–43, §1801(b)(2)(A), in introductory provisions substituted "AIDS research, the Director of the Office" for "research with respect to acquired immune deficiency syndrome, the Secretary, acting through the Director of the National Institutes of Health".

Subsec. (a)(1). Pub. L. 103–43, §1801(b)(2)(B), redesignated par. (3) as (1) and struck out former par. (1) which read as follows:

"(A) shall establish an office to be known as the Office of AIDS Research, which Office shall be headed by a Director appointed by the Director of the National Institutes of Health; and

"(B) shall provide administrative support and support services to the Director of such Office;".

Subsec. (a)(2). Pub. L. 103–43, §1801(b)(2)(B), (E), redesignated par. (4) as (2), substituted "AIDS research" for "research relating to acquired immune deficiency syndrome", and struck out former par. (2) which read as follows: "shall coordinate activities relating to acquired immune deficiency syndrome conducted by the national research institutes and the agencies of the National Institutes of Health;".

Subsec. (a)(3). Pub. L. 103–43, §1801(b)(2)(B), (C), (E), redesignated par. (5) as (3), struck out ", in consultation with the advisory council for the appropriate national research institute of the National Institutes of Health," after "may" in introductory provisions, and substituted "AIDS research" for "research relating to acquired immune deficiency syndrome" in subpar. (A). Former par. (3) redesignated (1).

Subsec. (a)(4). Pub. L. 103–43, §1801(b)(2)(B), (E), redesignated par. (6) as (4) and substituted "AIDS research" for "research relating to acquired immune deficiency syndrome". Former par. (4) redesignated (2).

Subsec. (a)(5). Pub. L. 103–43, §1801(b)(2)(B), (D), redesignated par. (7) as (5), in subpar. (A) struck out ", in consultation with such advisory council," after "may" and substituted "Director of the Office determines" for "Director of the National Institutes of Health determines", and in subpars. (B) and (C) struck out ", in consultation with such advisory council," after "may". Former par. (5) redesignated (3).

Subsec. (a)(6) to (8). Pub. L. 103–43, §1801(b)(2)(B), redesignated pars. (6) to (8) as (4) to (6), respectively.

Subsec. (b). Pub. L. 103–43, §1801(b)(3), substituted "The Director of the Office shall" for "The Director of the National Institutes of Health, acting through the Director of the Office of AIDS Research, shall".

Subsec. (c). Pub. L. 103–43, §1801(b)(4), substituted "the Director of the Office shall" for "the Director of the National Institutes of Health shall".

STATUTORY NOTES AND RELATED SUBSIDIARIES

EFFECTIVE DATE OF 2007 AMENDMENT

Amendment by Pub. L. 109–482 applicable only with respect to amounts appropriated for fiscal year 2007 or subsequent fiscal years, see section 109 of Pub. L. 109–482, set out as a note under section 281 of this title.

SUBPART II—EMERGENCY DISCRETIONARY FUND

§300cc–43. Emergency Discretionary Fund

(a) In general

(1) Establishment

There is established a fund consisting of such amounts as may be appropriated under subsection (g). Subject to the provisions of this section, the Director of the Office, after consultation with the advisory council established under section 300cc–40b of this title, may expend amounts in the Fund for the purpose of conducting and supporting such AIDS activities, including projects of AIDS research, as may be authorized in this chapter for the National Institutes of Health.

(2) Preconditions to use of Fund

Amounts in the Fund may be expended only if—

(A) the Director identifies the particular set of AIDS activities for which such amounts are to be expended;

(B) the set of activities so identified constitutes either a new project or additional AIDS activities for an existing project;

(C) the Director of the Office has made a determination that there is a significant need for such set of activities; and

(D) as of June 30 of the fiscal year preceding the fiscal year in which the determination is made, such need was not provided for in any appropriations Act passed by the House of Representatives to make appropriations for the Departments of Labor, Health and Human Services (including the National Institutes of Health), Education, and related agencies for the fiscal year in which the determination is made.

(3) Two-year use of Fund for project involved

In the case of an identified set of AIDS activities, obligations of amounts in the Fund may not be made for such set of activities after the expiration of the 2-year period beginning on the date on which the initial obligation of such amounts is made for such set.

(b) Peer review

With respect to an identified set of AIDS activities carried out with amounts in the Fund, this section may not be construed as waiving applicable requirements for peer review.

(c) Limitations on use of Fund

(1) Construction of facilities

Amounts in the Fund may not be used for the construction, renovation, or relocation of facilities, or for the acquisition of land.

(2) Congressional disapproval of projects

(A) Amounts in the Fund may not be expended for the fiscal year involved for an identified set of AIDS activities, or a category of AIDS activities, for which—

(i)(I) amounts were made available in an appropriations Act for the preceding fiscal year; and

(II) amounts are not made available in any appropriations Act for the fiscal year involved; or

(ii) amounts are by law prohibited from being expended.

(B) A determination under subparagraph (A)(i) of whether amounts have been made available in appropriations Acts for a fiscal year shall be made without regard to whether such Acts make available amounts for the Fund.

(3) Investment of Fund amounts

Amounts in the Fund may not be invested.

(d) Applicability of limitation regarding number of employees

The purposes for which amounts in the Fund may be expended include the employment of individuals necessary to carry out identified sets of AIDS activities approved under subsection (a). Any individual employed under the preceding sentence may not be included in any determination of the number of full-time equivalent employees for the Department of Health and Human Services for

the purpose of any limitation on the number of such employees established by law prior to, on, or after June 10, 1993.

(e) Definitions

For purposes of this section:

(1) The term "Fund" means the fund established in subsection (a).

(2) The term "identified set of AIDS activities" means a particular set of AIDS activities identified under subsection (a)(2)(A).

(f) Funding

(1) Authorization of appropriations

For the purpose of providing amounts for the Fund, there is authorized to be appropriated $100,000,000 for each of the fiscal years 1994 through 1996.

(2) Availability

Amounts appropriated for the Fund are available until expended.

(July 1, 1944, ch. 373, title XXIII, §2356, as added Pub. L. 103–43, title XVIII, §1802, June 10, 1993, 107 Stat. 196; amended Pub. L. 109–482, title I, §104(b)(2)(E), Jan. 15, 2007, 120 Stat. 3693.)

EDITORIAL NOTES

AMENDMENTS

2007—Subsecs. (e) to (g). Pub. L. 109–482 redesignated subsecs. (f) and (g) as (e) and (f), respectively, and struck out heading and text of former subsec. (e). Text read as follows: "Not later than February 1 of each fiscal year, the Director of the Office shall submit to the Committee on Energy and Commerce of the House of Representatives, and to the Committee on Labor and Human Resources of the Senate, a report on the identified sets of AIDS activities carried out during the preceding fiscal year with amounts in the Fund. The report shall provide a description of each such set of activities and an explanation of the reasons underlying the use of the Fund for the set."

STATUTORY NOTES AND RELATED SUBSIDIARIES

EFFECTIVE DATE OF 2007 AMENDMENT

Amendment by Pub. L. 109–482 applicable only with respect to amounts appropriated for fiscal year 2007 or subsequent fiscal years, see section 109 of Pub. L. 109–482, set out as a note under section 281 of this title.

SUBPART III—GENERAL PROVISIONS

§300cc–45. General provisions regarding Office

(a) Administrative support for Office

The Secretary, acting through the Director of the National Institutes of Health, shall provide administrative support and support services to the Director of the Office and shall ensure that such support takes maximum advantage of existing administrative structures at the agencies of the National Institutes of Health.

(b) Evaluation

Not later than 5 years after June 10, 1993, the Secretary shall conduct an evaluation to—

(1) determine the effect of this section on the planning and coordination of the AIDS research programs at the institutes, centers and divisions of the National Institutes of Health;

(2) evaluate the extent to which this part has eliminated the duplication of administrative resources among such Institutes, centers and divisions; and

(3) provide recommendations concerning future alterations with respect to this part.

(c) Definitions

For purposes of this part:

(1) The term "AIDS activities" means AIDS research and other activities that relate to acquired immune deficiency syndrome.

(2) The term "AIDS research" means research with respect to acquired immune deficiency syndrome.

(3) The term "Office" means the Office of AIDS Research.

(4) The term "Plan" means the plan required in section 300cc–40c(a)(1) of this title.

(July 1, 1944, ch. 373, title XXIII, §2359, as added Pub. L. 103–43, title XVIII, §1803, June 10, 1993, 107 Stat. 198; amended Pub. L. 109–482, title I, §104(b)(2)(F), Jan. 15, 2007, 120 Stat. 3693.)

EDITORIAL NOTES

AMENDMENTS

2007—Subsec. (b). Pub. L. 109–482 substituted "Evaluation" for "Evaluation and report" in heading, struck out par. (1) designation before "Not later than", redesignated subpars. (A) to (C) as pars. (1) to (3), respectively, and struck out heading and text of former par. (2). Text read as follows: "Not later than 1 year after the date on which the evaluation is commenced under paragraph (1), the Secretary shall prepare and submit to the Committee on Labor and Human Resources of the Senate, and the Committee on Energy and Commerce of the House of Representatives, a report concerning the results of such evaluation."

STATUTORY NOTES AND RELATED SUBSIDIARIES

EFFECTIVE DATE OF 2007 AMENDMENT

Amendment by Pub. L. 109–482 applicable only with respect to amounts appropriated for fiscal year 2007 or subsequent fiscal years, see section 109 of Pub. L. 109–482, set out as a note under section 281 of this title.

PART E—GENERAL PROVISIONS

§300cc–51. Definitions

For purposes of this subchapter:

(1) The term "infection", with respect to the etiologic agent for acquired immune deficiency syndrome, includes opportunistic cancers and infectious diseases and any other conditions arising from infection with such etiologic agent.

(2) The term "treatment", with respect to the etiologic agent for acquired immune deficiency syndrome, includes primary and secondary prophylaxis.

(July 1, 1944, ch. 373, title XXIII, §2361, as added Pub. L. 100–607, title II, §201(4), Nov. 4, 1988, 102 Stat. 3078; amended Pub. L. 103–43, title XVIII, §1811(8), June 10, 1993, 107 Stat. 200.)

EDITORIAL NOTES

AMENDMENTS

1993—Pub. L. 103–43 substituted provisions defining "infection" and "treatment" for former provisions which read as follows: "For purposes of this subchapter, the term 'infection with the etiologic agent for acquired immune deficiency syndrome' includes any condition arising from infection with such etiologic agent".

SUBCHAPTER XXII—HEALTH SERVICES WITH RESPECT TO ACQUIRED IMMUNE DEFICIENCY SYNDROME

PART A—FORMULA GRANTS TO STATES FOR HOME AND COMMUNITY-BASED HEALTH SERVICES

§§300dd to 300dd–14. Repealed. July 1, 1944, ch. 373, title XXIV, §2415, as added Nov. 4, 1988, Pub. L. 100–607, title II, §211, 102 Stat. 3088; amended Nov. 18, 1988, Pub. L. 100–690, title II, §2618(g), 102 Stat. 4241

Section 300dd, act July 1, 1944, ch. 373, title XXIV, §2401, as added Nov. 4, 1988, Pub. L. 100–607, title II, §211, 102 Stat. 3079, established program of formula grants for home and community-based health services.

Section 300dd–1, act July 1, 1944, ch. 373, title XXIV, §2402, as added Nov. 4, 1988, Pub. L. 100–607, title II, §211, 102 Stat. 3080; amended Nov. 18, 1988, Pub. L. 100–690, title II, §2618(a), 102 Stat. 4240, provided requirements for carrying out purpose of grants.

Section 300dd–2, act July 1, 1944, ch. 373, title XXIV, §2403, as added Nov. 4, 1988, Pub. L. 100–607, title II, §211, 102 Stat. 3081, required submission of description of intended uses of grant.

Section 300dd–3, act July 1, 1944, ch. 373, title XXIV, §2404, as added Nov. 4, 1988, Pub. L. 100–607, title II, §211, 102 Stat. 3081; amended Nov. 18, 1988, Pub. L. 100–690, title II, §2618(b), 102 Stat. 4240, restricted use of grants.

Section 300dd–4, act July 1, 1944, ch. 373, title XXIV, §2405, as added Nov. 4, 1988, Pub. L. 100–607, title II, §211, 102 Stat. 3082, required reports and audits by States.

Section 300dd–5, act July 1, 1944, ch. 373, title XXIV, §2406, as added Nov. 4, 1988, Pub. L. 100–607, title II, §211, 102 Stat. 3083, required additional agreements.

Section 300dd–6, act July 1, 1944, ch. 373, title XXIV, §2407, as added Nov. 4, 1988, Pub. L. 100–607, title II, §211, 102 Stat. 3084, required submission of application containing certain agreements and assurances.

Section 300dd–7, act July 1, 1944, ch. 373, title XXIV, §2408, as added Nov. 4, 1988, Pub. L. 100–607, title II, §211, 102 Stat. 3084, provided for determination of amount of allotments for States.

Section 300dd–8, act July 1, 1944, ch. 373, title XXIV, §2409, as added Nov. 4, 1988, Pub. L. 100–607, title II, §211, 102 Stat. 3085; amended Nov. 18, 1988, Pub. L. 100–690, title II, §2618(c), 102 Stat. 4241, related to failure to comply with agreements.

Section 300dd–9, act July 1, 1944, ch. 373, title XXIV, §2410, as added Nov. 4, 1988, Pub. L. 100–607, title II, §211, 102 Stat. 3087, prohibited certain false statements.

Section 300dd–10, act July 1, 1944, ch. 373, title XXIV, §2411, as added Nov. 4, 1988, Pub. L. 100–607, title II, §211, 102 Stat. 3087; amended Nov. 18, 1988, Pub. L. 100–690, title II, §2618(d), 102 Stat. 4241, authorized the Secretary to provide technical assistance and supplies and services in lieu of grant funds.

Section 300dd–11, act July 1, 1944, ch. 373, title XXIV, §2412, as added Nov. 4, 1988, Pub. L. 100–607, title II, §211, 102 Stat. 3087, required report by Secretary.

Section 300dd–12, act July 1, 1944, ch. 373, title XXIV, §2413, as added Nov. 4, 1988, Pub. L. 100–607, title II, §211, 102 Stat. 3087; amended Nov. 18, 1988, Pub. L. 100–690, title II, §2618(e), 102 Stat. 4241, defined terms for this part.

Section 300dd–13, act July 1, 1944, ch. 373, title XXIV, §2414, as added Nov. 4, 1988, Pub. L. 100–607, title II, §211, 102 Stat. 3088; amended Nov. 18, 1988, Pub. L. 100–690, title II, §2618(f), 102 Stat. 4241, provided funding.

Section 300dd–14, act July 1, 1944, ch. 373, title XXIV, §2415, as added Nov. 4, 1988, Pub. L. 100–607, title II, §211, 102 Stat. 3088; amended Nov. 18, 1988, Pub. L. 100–690, title II, §2618(g), 102 Stat. 4241, repealed this part effective with respect to appropriations made for any period after fiscal year 1990.

STATUTORY NOTES AND RELATED SUBSIDIARIES

EFFECTIVE DATE OF REPEAL

Repeal effective with respect to appropriations made for any period after fiscal year 1990, see section 2415 of act July 1, 1944, which was classified to former section 300dd–14 of this title.

PART B—SUBACUTE CARE

§300dd–21. Demonstration projects

(a) Definitions

As used in this section:

(1) The term "individuals infected with the etiologic agent for acquired immune deficiency syndrome" means individuals who have a disease, or are recovering from a disease, attributable to the infection of such individuals with such etiologic agent, and as a result of the effects of such disease, are in need of subacute-care services.

(2) The term "subacute care" means medical and health care services that are required for individuals recovering from acute care episodes that are less intensive than the level of care provided in acute-care hospitals, and includes skilled nursing care, hospice care, and other types of health services provided in other long-term-care facilities.

(b) Authorization to conduct three projects

The Secretary shall conduct three demonstration projects to determine the effectiveness and cost of providing the subacute-care services described in subsection (b) to individuals infected with the etiologic agent for acquired immune deficiency syndrome, and the impact of such services on the health status of such individuals.

(c) Services

(1) The services provided under each demonstration project shall be designed to meet the specific needs of individuals infected with the etiologic agent for acquired immune deficiency syndrome, and shall include—

(A) the care and treatment of such individuals by providing—

(i) subacute care;

(ii) emergency medical care and specialized diagnostic and therapeutic services as needed and where appropriate, either directly or through affiliation with a hospital that has experience in treating individuals with acquired immune deficiency syndrome; and

(iii) case management services to ensure, through existing services and programs whenever possible, appropriate discharge planning for such individuals; and

(B) technical assistance, to other facilities in the region served by such facility, that is directed toward education and training of physicians, nurses, and other health-care professionals in the subacute care and treatment of individuals infected with the etiologic agent for acquired immune deficiency syndrome.

(2) Services provided under each demonstration project may also include—

(A) hospice services;

(B) outpatient care; and

(C) outreach activities in the surrounding community to hospitals and other health-care facilities that serve individuals infected with the etiologic agent for acquired immune deficiency syndrome.

(d) Time and place

The demonstration projects shall be conducted—

(1) during a 4-year period beginning not later than 9 months after November 4, 1988; and

(2) at sites that—

(A) are geographically diverse and located in areas that are appropriate for the provision of

the required and authorized services; and

(B) have the highest incidence of cases of acquired immune deficiency syndrome and the greatest need for subacute-care services.

(e) Evaluation and report

The Secretary shall evaluate the operations of the demonstration projects and shall submit to the Committee on Energy and Commerce of the House of Representatives and the Committee on Labor and Human Resources of the Senate—

(1) not later than 18 months after the beginning of the first project, a preliminary report that contains—

(A) a description of the sites at which the projects are being conducted and of the services being provided in each project; and

(B) a preliminary evaluation of the experience of the projects in the first 12 months of operation; and

(2) not later than 6 months after the completion of the last project, a final report that contains—

(A) an assessment of the costs of subacute care for individuals infected with the etiologic agent for acquired immune deficiency syndrome, including a breakdown of all other sources of funding for the care provided to cover subacute care; and

(B) recommendations for appropriate legislative changes.

(f) Other research

Each demonstration project shall provide for other research to be carried out at the site of such demonstration project including—

(1) clinical research on acquired immune deficiency syndrome, concentrating on research on the neurological manifestations resulting from infection with the etiologic agent for such syndrome; and

(2) the study of the psychological and mental health issues related to such syndrome.

(g) Authorization of appropriations

(1) To carry out this section, there are authorized to be appropriated $10,000,000 for fiscal year 1989 and such sums as are necessary for each of the fiscal years 1990 through 1992.

(2) Amounts appropriated pursuant to paragraph (1) shall remain available until September 10, 1992.

(h) Services to veterans

The Secretary shall enter into an agreement with the Secretary of the Department of Veterans Affairs to ensure that appropriate provision will be made for the furnishing, through demonstration projects, of services to eligible veterans, under contract with the Department of Veterans Affairs pursuant to section 1720 of title 38.

(July 1, 1944, ch. 373, title XXIV, §2421, as added Pub. L. 100–607, title II, §211, Nov. 4, 1988, 102 Stat. 3088; amended Pub. L. 100–527, §10(1), (2), Oct. 25, 1988, 102 Stat. 2640, 2641; Pub. L. 100–690, title II, §2618(h), Nov. 18, 1988, 102 Stat. 4241; Pub. L. 102–83, §5(c)(2), Aug. 6, 1991, 105 Stat. 406.)

EDITORIAL NOTES

AMENDMENTS

1991—Subsec. (h). Pub. L. 102–83 substituted "section 1720 of title 38" for "section 620 of title 38".

1988—Subsec. (a)(1). Pub. L. 100–690, §2618(h)(1), substituted " 'individuals infected with the etiologic agent for acquired immune deficiency syndrome' means individuals who" for " 'patients infected with the human immunodeficiency virus' means persons who" and "such individuals with such etiologic agent" for "such person with the human immunodeficiency virus".

Subsec. (a)(2). Pub. L. 100–690, §2618(h)(2), substituted "individuals" for "persons".

Subsec. (b). Pub. L. 100–690, §2618(h)(3), substituted "individuals infected with the etiologic agent for

acquired immune deficiency syndrome" for "patients infected with the human immunodeficiency virus" and "such individuals" for "such patients".

Subsec. (c)(1). Pub. L. 100–690, §2618(h)(4)(A), in introductory provisions substituted "individuals infected with the etiologic agent for acquired immune deficiency syndrome" for "patients infected with the human immunodeficiency virus".

Subsec. (c)(1)(A). Pub. L. 100–690, §2618(h)(4)(B), substituted in introductory provisions "such individuals" for "such patients", in cl. (ii) "individuals with acquired immune deficiency syndrome" for "AIDS patients", and in cl. (iii) "such individuals" for "patients".

Subsec. (c)(1)(B), (2)(C). Pub. L. 100–690, §2618(h)(4)(C), (5), substituted "individuals infected with the etiologic agent for acquired immune deficiency syndrome" for "patients infected with the human immunodeficiency virus".

Subsec. (d)(2)(B). Pub. L. 100–690, §2618(h)(6), substituted "cases of acquired immune deficiency syndrome" for "AIDS cases".

Subsec. (e)(2)(A). Pub. L. 100–690, §2618(h)(7), substituted "individuals infected with the etiologic agent for acquired immune deficiency syndrome" for "patients infected with the human immunodeficiency virus".

Subsec. (f)(1). Pub. L. 100–690, §2618(h)(8), substituted "acquired immune deficiency syndrome" for "the acquired immunodeficiency syndrome" and "etiologic agent for such syndrome" for "human immunodeficiency virus".

Subsec. (f)(2). Pub. L. 100–690, §2618(h)(9), substituted "such syndrome" for "the acquired immunodeficiency syndrome".

Subsec. (g)(1). Pub. L. 100–690, §2618(h)(10), substituted "fiscal year 1989" for "fiscal year 1988" and "fiscal years 1990 through 1992" for "fiscal years 1989 through 1991".

Subsec. (h). Pub. L. 100–527 substituted "Secretary of the Department of Veterans Affairs" and "Department of Veterans Affairs" for "Administrator of the Veterans' Administration" and "Veterans' Administration", respectively.

STATUTORY NOTES AND RELATED SUBSIDIARIES

CHANGE OF NAME

Committee on Labor and Human Resources of Senate changed to Committee on Health, Education, Labor, and Pensions of Senate by Senate Resolution No. 20, One Hundred Sixth Congress, Jan. 19, 1999.

Committee on Energy and Commerce of House of Representatives treated as referring to Committee on Commerce of House of Representatives by section 1(a) of Pub. L. 104–14, set out as a note preceding section 21 of Title 2, The Congress. Committee on Commerce of House of Representatives changed to Committee on Energy and Commerce of House of Representatives, and jurisdiction over matters relating to securities and exchanges and insurance generally transferred to Committee on Financial Services of House of Representatives by House Resolution No. 5, One Hundred Seventh Congress, Jan. 3, 2001.

EFFECTIVE DATE OF 1988 AMENDMENTS

Amendment by Pub. L. 100–690 effective immediately after enactment of Pub. L. 100–607, which was approved Nov. 4, 1988, see section 2600 of Pub. L. 100–690, set out as a note under section 242m of this title.

Amendment by Pub. L. 100–527 effective Mar. 15, 1989, see section 18(a) of Pub. L. 100–527, set out as a Department of Veterans Affairs Act note under section 301 of Title 38, Veterans' Benefits.

PART C—OTHER HEALTH SERVICES

EDITORIAL NOTES

CODIFICATION

Prior to revision by Pub. L. 102–321, this part was comprised of subpart I, consisting of sections 300dd–31 to 300dd–33, and subpart II, consisting of section 300dd–41.

§300dd–31. Grants for anonymous testing

The Secretary may make grants to the States for the purpose of providing opportunities for individuals—

(1) to undergo counseling and testing with respect to the etiologic agent for acquired immune deficiency syndrome without being required to provide any information relating to the identity of the individuals; and

(2) to undergo such counseling and testing through the use of a pseudonym.

(July 1, 1944, ch. 373, title XXIV, §2431, as added Pub. L. 100–607, title II, §211, Nov. 4, 1988, 102 Stat. 3090.)

§300dd–32. Requirement of provision of certain counseling services

(a) Counseling before testing

The Secretary may not make a grant under section 300dd–31 of this title to a State unless the State agrees that, before testing an individual pursuant to such section, the State will provide to the individual appropriate counseling with respect to acquired immune deficiency syndrome (based on the most recent scientific data relating to such syndrome), including—

(1) measures for the prevention of exposure to, and the transmission of, the etiologic agent for such syndrome;

(2) the accuracy and reliability of the results of such testing;

(3) the significance of the results of such testing, including the potential for developing acquired immune deficiency syndrome; and

(4) encouraging individuals, as appropriate, to undergo testing for such etiologic agent and providing information on the benefits of such testing.

(b) Counseling of individuals with negative test results

The Secretary may not make a grant under section 300dd–31 of this title to a State unless the State agrees that, if the results of testing conducted pursuant to such section indicate that an individual is not infected with the etiologic agent for acquired immune deficiency syndrome, the State will review for the individual the information provided pursuant to subsection (a) with respect to such syndrome, including—

(1) the information described in paragraphs (1) through (3) of such subsection; and

(2) the appropriateness of further counseling, testing, and education of the individual with respect to acquired immune deficiency syndrome.

(c) Counseling of individuals with positive test results

The Secretary may not make a grant under section 300dd–31 of this title to a State unless the State agrees that, if the results of testing conducted pursuant to such section indicate that an individual is infected with the etiologic agent for acquired immune deficiency syndrome, the State will provide to the individual appropriate counseling with respect to such syndrome, including—

(1) reviewing the information described in paragraphs (1) through (3) of subsection (a);

(2) reviewing the appropriateness of further counseling, testing, and education of the individual with respect to acquired immune deficiency syndrome;

(3) the importance of not exposing others to the etiologic agent for acquired immune deficiency syndrome;

(4) the availability in the geographic area of any appropriate services with respect to health care, including mental health care and social and support services;

(5) the benefits of locating and counseling any individual by whom the infected individual may have been exposed to the etiologic agent for acquired immune deficiency syndrome and any individual whom the infected individual may have exposed to such etiologic agent; and

(6) the availability, if any, of the services of public health authorities with respect to locating and counseling any individual described in paragraph (5).

(d) Rule of construction with respect to counseling without testing

Agreements entered into pursuant to subsections (a) through (c) may not be construed to prohibit any grantee under section 300dd–31 of this title from expending the grant for the purpose of providing counseling services described in such subsections to an individual who will not undergo testing described in such section as a result of the grantee or the individual determining that such testing of the individual is not appropriate.

(e) Use of funds

(1) The purpose of this subpart [1] is to provide for counseling and testing services to prevent and reduce exposure to, and transmission of, the etiologic agent for acquired immune deficiency syndrome.

(2) All individuals receiving counseling pursuant to this subpart [1] are to be counseled about the harmful effects of promiscuous sexual activity and intravenous substance abuse, and the benefits of abstaining from such activities.

(3) None of the fund appropriated to carry out this subpart [1] may be used to provide counseling that is designed to promote or encourage, directly, homosexual or heterosexual sexual activity or intravenous drug abuse.

(4) Paragraph (3) may not be construed to prohibit a counselor who has already performed the counseling of an individual required by paragraph (2), to provide accurate information about means to reduce an individual's risk of exposure to, or the transmission of, the etiologic agent for acquired immune deficiency syndrome, provided that any informational materials used are not obscene.

(July 1, 1944, ch. 373, title XXIV, §2432, as added Pub. L. 100–607, title II, §211, Nov. 4, 1988, 102 Stat. 3090; amended Pub. L. 100–690, title II, §2618(i), Nov. 18, 1988, 102 Stat. 4242; Pub. L. 102–321, title I, §118(b)(1)(B), July 10, 1992, 106 Stat. 348.)

EDITORIAL NOTES

AMENDMENTS

1992—Subsec. (a). Pub. L. 102–321, which directed the substitution of "part" for "subpart" wherever appearing in subsec. (a), could not be executed because the word "subpart" does not appear in subsec. (a).

1988—Subsec. (c). Pub. L. 100–690, §2618(i)(1), substituted "indicate that an individual" for "indicate that the individual" in introductory provisions and "paragraph (5)" for "paragraph (4)" in par. (6).

Subsec. (e)(1) to (3). Pub. L. 100–690, §2618(i)(2), substituted "subpart" for "part".

STATUTORY NOTES AND RELATED SUBSIDIARIES

EFFECTIVE DATE OF 1992 AMENDMENT

Amendment by Pub. L. 102–321 effective Oct. 1, 1992, with provision for programs providing financial assistance, see section 801(c), (d) of Pub. L. 102–321, set out as a note under section 236 of this title.

EFFECTIVE DATE OF 1988 AMENDMENT

Amendment by Pub. L. 100–690 effective immediately after enactment of Pub. L. 100–607, which was approved Nov. 4, 1988, see section 2600 of Pub. L. 100–690, set out as a note under section 242m of this title.

[1] So in original. Probably should be "part".

§300dd–33. Funding

For the purpose of grants under section 300dd–31 of this title, there are authorized to be appropriated $100,000,000 for each of the fiscal years 1989 and 1990.

(July 1, 1944, ch. 373, title XXIV, §2433, as added Pub. L. 100–607, title II, §211, Nov. 4, 1988, 102 Stat. 3091.)

§300dd–41. Transferred

EDITORIAL NOTES

CODIFICATION

Section, act July 1, 1944, ch. 373, title XXIV, §2441, as added Nov. 4, 1988, Pub. L. 100–607, title II, §211, 102 Stat. 3092, which related to demonstration projects for individuals with positive AIDS test results, was renumbered section 520B of act July 1, 1944, by Pub. L. 102–321, title I, §118(a), July 10, 1992, 106 Stat. 348, and was transferred to section 290bb–33 of this title, prior to repeal by Pub. L. 106–310, div. B, title XXXII, §3201(b)(2), Oct. 17, 2000, 114 Stat. 1190.

SUBCHAPTER XXIII—PREVENTION OF ACQUIRED IMMUNE DEFICIENCY SYNDROME

§300ee. Use of funds

(a) In general

The purpose of this subchapter is to provide for the establishment of education and information programs to prevent and reduce exposure to, and the transmission of, the etiologic agent for acquired immune deficiency syndrome.

(b) Contents of programs

All programs of education and information receiving funds under this subchapter shall include information about the harmful effects of promiscuous sexual activity and intravenous substance abuse, and the benefits of abstaining from such activities.

(c) Limitation

None of the funds appropriated to carry out this subchapter may be used to provide education or information designed to promote or encourage, directly, homosexual or heterosexual sexual activity or intravenous substance abuse.

(d) Construction

Subsection (c) may not be construed to restrict the ability of an education program that includes the information required in subsection (b) to provide accurate information about various means to reduce an individual's risk of exposure to, or the transmission of, the etiologic agent for acquired immune deficiency syndrome, provided that any informational materials used are not obscene.

(July 1, 1944, ch. 373, title XXV, formerly title XV, §2500, as added Pub. L. 100–607, title II, §221, Nov. 4, 1988, 102 Stat. 3093; amended Pub. L. 100–690, title II, §2619(a), Nov. 18, 1988, 102 Stat. 4242; renumbered title XXV, Pub. L. 101–93, §5(e)(1), Aug. 16, 1989, 103 Stat. 612.)

EDITORIAL NOTES

AMENDMENTS

1988—Subsec. (a). Pub. L. 100–690 substituted "this subchapter" for "this part".

STATUTORY NOTES AND RELATED SUBSIDIARIES

EFFECTIVE DATE OF 1988 AMENDMENT

Amendment by Pub. L. 100–690 effective immediately after enactment of Pub. L. 100–607, which was approved Nov. 4, 1988, see section 2600 of Pub. L. 100–690, set out as a note under section 242m of this title.

§300ee–1. Establishment of office with respect to minority health and acquired immune deficiency syndrome

The Secretary of Health and Human Services, acting through the Director of the Centers for Disease Control and Prevention, shall establish an office for the purpose of ensuring that, in carrying out the duties of the Secretary with respect to prevention of acquired immune deficiency syndrome, the Secretary develops and implements prevention programs targeted at minority populations and provides appropriate technical assistance in the implementation of such programs.

(Pub. L. 100–607, title II, §252, Nov. 4, 1988, 102 Stat. 3108; Pub. L. 102–531, title III, §312(e)(2), Oct. 27, 1992, 106 Stat. 3506.)

EDITORIAL NOTES

CODIFICATION

Section was enacted as part of the AIDS Amendments of 1988 and as part of the Health Omnibus Programs Extension of 1988, and not as part of the Public Health Service Act which comprises this chapter.

AMENDMENTS

1992—Pub. L. 102–531 substituted "Centers for Disease Control and Prevention" for "Centers for Disease Control".

STATUTORY NOTES AND RELATED SUBSIDIARIES

REQUIREMENT OF STUDY WITH RESPECT TO MINORITY HEALTH AND ACQUIRED IMMUNE DEFICIENCY SYNDROME

Pub. L. 100–607, title II, §251, Nov. 4, 1988, 102 Stat. 3108, as amended by Pub. L. 100–690, title II, §2602(b), Nov. 18, 1988, 102 Stat. 4234, required the Secretary of Health and Human Services, acting through the Director of the Office of Minority Health, to conduct a Study With Respect to Minority Health and Acquired Immune Deficiency Syndrome and report to Congress on the findings no later than 12 months after Nov. 4, 1988.

§300ee–2. Information for health and public safety workers

(a) Development and dissemination of guidelines

Not later than 90 days after November 4, 1988, the Secretary of Health and Human Services (hereafter in this section referred to as the "Secretary"), acting through the Director of the Centers for Disease Control and Prevention, shall develop, issue, and disseminate emergency guidelines to all health workers and public safety workers (including emergency response employees) in the United States concerning—

(1) methods to reduce the risk in the workplace of becoming infected with the etiologic agent for acquired immune deficiency syndrome; and

(2) circumstances under which exposure to such etiologic agent may occur.

(b) Use in occupational standards

The Secretary shall transmit the guidelines issued under subsection (a) to the Secretary of Labor for use by the Secretary of Labor in the development of standards to be issued under the Occupational Safety and Health Act of 1970 [29 U.S.C. 651 et seq.].

(c) Development and dissemination of model curriculum for emergency response employees

(1) Not later than 90 days after November 4, 1988, the Secretary, acting through the Director of the Centers for Disease Control and Prevention, shall develop a model curriculum for emergency response employees with respect to the prevention of exposure to the etiologic agent for acquired immune deficiency syndrome during the process of responding to emergencies.

(2) In carrying out paragraph (1), the Secretary shall consider the guidelines issued by the Secretary under subsection (a).

(3) The model curriculum developed under paragraph (1) shall, to the extent practicable, include—

(A) information with respect to the manner in which the etiologic agent for acquired immune deficiency syndrome is transmitted; and

(B) information that can assist emergency response employees in distinguishing between conditions in which such employees are at risk with respect to such etiologic agent and conditions in which such employees are not at risk with respect [1] such etiologic agent.

(4) The Secretary shall establish a task force to assist the Secretary in developing the model curriculum required in paragraph (1). The Secretary shall appoint to the task force representatives of the Centers for Disease Control and Prevention, representatives of State governments, and representatives of emergency response employees.

(5) The Secretary shall—

(A) transmit to State public health officers copies of the guidelines and the model curriculum developed under paragraph (1) with the request that such officers disseminate such copies as appropriate throughout the State; and

(B) make such copies available to the public.

(Pub. L. 100–607, title II, §253, Nov. 4, 1988, 102 Stat. 3108; Pub. L. 100–690, title II, §2602(c), Nov. 18, 1988, 102 Stat. 4234; Pub. L. 102–531, title III, §312(e)(3), Oct. 27, 1992, 106 Stat. 3506.)

EDITORIAL NOTES

REFERENCES IN TEXT

The Occupational Safety and Health Act of 1970, referred to in subsec. (b), is Pub. L. 91–596, Dec. 29, 1970, 84 Stat. 1590, which is classified principally to chapter 15 (§651 et seq.) of Title 29, Labor. For complete classification of this Act to the Code, see Short Title note set out under section 651 of Title 29 and Tables.

CODIFICATION

Section was enacted as part of the AIDS Amendments of 1988 and as part of the Health Omnibus Programs Extension of 1988, and not as part of the Public Health Service Act which comprises this chapter.

AMENDMENTS

1992—Subsecs. (a), (c)(1), (4). Pub. L. 102–531 substituted "Centers for Disease Control and Prevention" for "Centers for Disease Control".

1988—Subsec. (a). Pub. L. 100–690 substituted "health workers and public safety workers" for "health workers, public safety workers".

STATUTORY NOTES AND RELATED SUBSIDIARIES

EFFECTIVE DATE OF 1988 AMENDMENT

Amendment by Pub. L. 100–690 effective immediately after enactment of Pub. L. 100–607, which was approved Nov. 4, 1988, see section 2600 of Pub. L. 100–690, set out as a note under section 242m of this title.

GUIDELINES FOR PREVENTION OF TRANSMISSION OF HUMAN IMMUNODEFICIENCY AND HEPATITIS B VIRUSES DURING INVASIVE PROCEDURES

Pub. L. 102–141, title VI, §633, Oct. 28, 1991, 105 Stat. 876, provided that: "Notwithstanding any other provision of law, each State Public Health Official shall, not later than one year after the date of enactment of this Act [Oct. 28, 1991], certify to the Secretary of Health and Human Services that guidelines issued by the Centers for Disease Control, or guidelines which are equivalent to those promulgated by the Centers for Disease Control concerning recommendations for preventing the transmission of the human immunodeficiency virus and the hepatitis B virus during exposure prone invasive procedures, except for emergency situations when the patient's life or limb is in danger, have been instituted in the State. State guidelines shall apply to health professionals practicing within the State and shall be consistent with Federal

law. Compliance with such guidelines shall be the responsibility of the State Public Health Official. Said responsibilities shall include a process for determining what appropriate disciplinary or other actions shall be taken to ensure compliance. If such certification is not provided under this section within the one-year period, the State shall be ineligible to receive assistance under the Public Health Service Act (42 U.S.C. 301 [201] et seq.) until such certification is provided, except that the Secretary may extend the time period for a State, upon application of such State, that additional time is required for instituting said guidelines."

[Centers for Disease Control changed to Centers for Disease Control and Prevention by Pub. L. 102–531, title III, §312, Oct. 27, 1992, 106 Stat. 3504.]

[1] *So in original. Probably should be "respect to".*

§300ee–3. Continuing education for health care providers

(a) In general

The Secretary of Health and Human Services (hereafter in this section referred to as the "Secretary") may make grants to nonprofit organizations composed of, or representing, health care providers to assist in the payment of the costs of projects to train such providers concerning—

(1) appropriate infection control procedures to reduce the transmission of the etiologic agent for acquired immune deficiency syndrome; and

(2) the provision of care and treatment to individuals with such syndrome or related illnesses.

(b) Limitation

The Secretary may make a grant under subsection (a) to an entity only if the entity will provide services under the grant in a geographic area, or to a population of individuals, not served by a program substantially similar to the program described in subsection (a).

(c) Requirement of matching funds

(1) The Secretary may not make a grant under subsection (a) unless the applicant for the grant agrees, with respect to the costs to be incurred by the applicant in carrying out the purpose described in such subsection, to make available, directly or through donations from public or private entities, non-Federal contributions (in cash or in kind under paragraph (2)) toward such costs in an amount equal to not less than $2 for each $1 of Federal funds provided in such payments.

(2) Non-Federal contributions required in paragraph (1) may be in cash or in kind, fairly evaluated, including plant, equipment, or services. Amounts provided by the Federal Government, or services assisted or subsidized to any significant extent by the Federal Government, may not be included in determining the amount of such non-Federal contributions.

(d) Requirement of application

The Secretary may not make a grant under subsection (a) unless—

(1) an application for the grant is submitted to the Secretary;

(2) with respect to carrying out the purpose for which the grant is to be made, the application provides assurances of compliance satisfactory to the Secretary; and

(3) the application otherwise is in such form, is made in such manner, and contains such agreements, assurances, and information as the Secretary determines to be necessary to carry out this section.

(e) Authorization of appropriations

For the purpose of carrying out this section, there are authorized to be appropriated such sums as may be necessary for each of the fiscal years 1989 through 1991.

(Pub. L. 100–607, title II, §254, Nov. 4, 1988, 102 Stat. 3109.)

EDITORIAL NOTES

CODIFICATION

Section was enacted as part of the AIDS Amendments of 1988 and as part of the Health Omnibus Programs Extension of 1988, and not as part of the Public Health Service Act which comprises this chapter.

§300ee–4. Technical assistance

The Secretary of Health and Human Services shall provide technical assistance to public and nonprofit private entities carrying out programs, projects, and activities relating to acquired immune deficiency syndrome.

(Pub. L. 100–607, title II, §255, Nov. 4, 1988, 102 Stat. 3110.)

EDITORIAL NOTES

CODIFICATION

Section was enacted as part of the AIDS Amendments of 1988 and as part of the Health Omnibus Programs Extension of 1988, and not as part of the Public Health Service Act which comprises this chapter.

§300ee–5. Use of funds to supply hypodermic needles or syringes for illegal drug use; prohibition

None of the funds provided under this Act or an amendment made by this Act shall be used to provide individuals with hypodermic needles or syringes so that such individuals may use illegal drugs, unless the Surgeon General of the Public Health Service determines that a demonstration needle exchange program would be effective in reducing drug abuse and the risk that the public will become infected with the etiologic agent for acquired immune deficiency syndrome.

(Pub. L. 100–607, title II, §256(b), Nov. 4, 1988, 102 Stat. 3110; Pub. L. 100–690, title II, §2602(d)(1), Nov. 18, 1988, 102 Stat. 4234.)

EDITORIAL NOTES

REFERENCES IN TEXT

This Act, referred to in text, is Pub. L. 100–607, Nov. 4, 1988, 102 Stat. 3048, known as the "Health Omnibus Programs Extension of 1988". For complete classification of this Act to the Code, see Short Title of 1988 Amendments note set out under section 201 of this title and Tables.

CODIFICATION

Section was enacted as part of the AIDS Amendments of 1988 and as part of the Health Omnibus Programs Extension of 1988, and not as part of the Public Health Service Act which comprises this chapter.

AMENDMENTS

1988—Pub. L. 100–690 substituted "Surgeon General of the Public Health Service" for "Surgeon General of the United States".

STATUTORY NOTES AND RELATED SUBSIDIARIES

EFFECTIVE DATE OF 1988 AMENDMENT

Amendment by Pub. L. 100–690 effective immediately after enactment of Pub. L. 100–607, which was approved Nov. 4, 1988, see section 2600 of Pub. L. 100–690, set out as a note under section 242m of this title.

§300ee–6. Transferred

EDITORIAL NOTES

CODIFICATION

Section, Pub. L. 100–607, title IX, §902, Nov. 4, 1988, 102 Stat. 3171; Pub. L. 100–690, title II, §2605(a), Nov. 18, 1988, 102 Stat. 4234, which provided for testing of State prisoners, was renumbered section 2648 of the Public Health Service Act by Pub. L. 101–381, title III, §301(b)(1), Aug. 18, 1990, 104 Stat. 615, and transferred to section 300ff–48 of this title, prior to repeal by Pub. L. 106–345, title III, §301(a), Oct. 20, 2000, 114 Stat. 1345.

PART A—FORMULA GRANTS TO STATES

§300ee–11. Establishment of program

(a) Allotments for States

For the purpose described in subsection (b), the Secretary shall for each of the fiscal years 1989 through 1991 make an allotment for each State in an amount determined in accordance with section 300ee–17 of this title. The Secretary shall make payments each such fiscal year to each State from the allotment for the State if the Secretary approves for the fiscal year involved an application submitted by the State pursuant to section 300ee–13 of this title.

(b) Purpose of grants

The Secretary may not make payments under subsection (a) for a fiscal year unless the State involved agrees to expend the payments only for the purpose of carrying out, in accordance with section 300ee–12 of this title, public information activities with respect to acquired immune deficiency syndrome.

(July 1, 1944, ch. 373, title XXV, formerly title XV, §2501, as added Pub. L. 100–607, title II, §221, Nov. 4, 1988, 102 Stat. 3093; renumbered title XXV, Pub. L. 101–93, §5(e)(1), Aug. 16, 1989, 103 Stat. 612.)

EDITORIAL NOTES

PRIOR PROVISIONS

A prior section 2501 of act July 1, 1944, was successively renumbered by subsequent acts, see section 238 of this title.

§300ee–12. Provisions with respect to carrying out purpose of grants

A State may expend payments received under section 300ee–11(a) of this title—

(1) to develop, establish, and conduct public information activities relating to the prevention and diagnosis of acquired immune deficiency syndrome for those populations or communities in the State in which there are a significant number of individuals at risk of infection with the etiologic agent for such syndrome;

(2) to develop, establish, and conduct such public information activities for the general public relating to the prevention and diagnosis of such syndrome;

(3) to develop, establish, and conduct activities to reduce risks relating to such syndrome, including research into the prevention of such syndrome;

(4) to conduct demonstration projects for the prevention of such syndrome;

(5) to provide technical assistance to public entities, to nonprofit private entities concerned with such syndrome, to schools, and to employers, for the purpose of developing information programs relating to such syndrome;

(6) with respect to education and training programs for the prevention of such syndrome, to conduct such programs for health professionals (including allied health professionals), public

safety workers (including emergency response employees), teachers, school administrators, and other appropriate education personnel;

(7) to conduct appropriate programs for educating school-aged children with respect to such syndrome, after consulting with local school boards;

(8) to make available to physicians and dentists in the State information with respect to acquired immune deficiency syndrome, including measures for the prevention of exposure to, and the transmission of, the etiologic agent for such syndrome (which information is updated not less than annually with the most recently available scientific date [1] relating to such syndrome);

(9) to carry out the initial implementation of recommendations contained in the guidelines and the model curriculum developed under section 300ee–2 of this title; and

(10) to make grants to public entities, and to nonprofit private entities concerned with acquired immune deficiency syndrome, for the purpose of the development, establishment, and expansion of programs for education directed toward individuals at increased risk of infection with the etiologic agent for such syndrome and activities to reduce the risks of exposure to such etiologic agent, with preference to programs directed toward populations in which there is significant evidence of such infection.

(July 1, 1944, ch. 373, title XXV, formerly title XV, §2502, as added Pub. L. 100–607, title II, §221, Nov. 4, 1988, 102 Stat. 3094; amended Pub. L. 100–690, title II, §2619(b), Nov. 18, 1988, 102 Stat. 4242; renumbered title XXV, Pub. L. 101–93, §5(e)(1), Aug. 16, 1989, 103 Stat. 612.)

EDITORIAL NOTES

PRIOR PROVISIONS

A prior section 2502 of act July 1, 1944, was successively renumbered by subsequent acts, see section 238a of this title.

AMENDMENTS

1988—Par. (9). Pub. L. 100–690 made technical amendment to reference to section 300ee–2 of this title to correct reference to corresponding provision of original act.

STATUTORY NOTES AND RELATED SUBSIDIARIES

EFFECTIVE DATE OF 1988 AMENDMENT

Amendment by Pub. L. 100–690 effective immediately after enactment of Pub. L. 100–607, which was approved Nov. 4, 1988, see section 2600 of Pub. L. 100–690, set out as a note under section 242m of this title.

[1] *So in original. Probably should be "data".*

§300ee–13. Requirement of submission of application containing certain agreements and assurances

(a) In general

The Secretary may not make payments under section 300ee–11(a) of this title for a fiscal year unless—

(1) the State involved submits to the Secretary a description of the purposes for which the State intends to expend the payments for the fiscal year;

(2) the description identifies the populations, areas, and localities in the State with a need for the services for which amounts may be provided by the State under this part;

(3) the description provides information relating to the programs and activities to be supported and services to be provided, including a description of the manner in which such programs and activities will be coordinated with any similar programs and activities of public and private entities;

(4) the State submits to the Secretary an application for the payments containing agreements in accordance with this part;

(5) the agreements are made through certification from the chief executive officer of the State;

(6) with respect to such agreements, the application provides assurances of compliance satisfactory to the Secretary; and

(7) the application otherwise is in such form, is made in such manner, and contains such agreements, assurances, and information as the Secretary determines to be necessary to carry out this part.

(b) Opportunity for public comment

The Secretary may not make payments under section 300ee–11(a) of this title for a fiscal year unless the State involved agrees that, in developing and carrying out the description required in subsection (a), the State will provide public notice with respect to the description (including any revisions) and will facilitate comments from interested persons.

(July 1, 1944, ch. 373, title XXV, formerly title XV, §2503, as added Pub. L. 100–607, title II, §221, Nov. 4, 1988, 102 Stat. 3095; amended Pub. L. 100–690, title II, §2619(c), Nov. 18, 1988, 102 Stat. 4242; renumbered title XXV, Pub. L. 101–93, §5(e)(1), Aug. 16, 1989, 103 Stat. 612.)

EDITORIAL NOTES

PRIOR PROVISIONS

A prior section 2503 of act July 1, 1944, was successively renumbered by subsequent acts, see section 238b of this title.

AMENDMENTS

1988—Subsec. (a)(3). Pub. L. 100–690 struck out "and" after semicolon.

STATUTORY NOTES AND RELATED SUBSIDIARIES

EFFECTIVE DATE OF 1988 AMENDMENT

Amendment by Pub. L. 100–690 effective immediately after enactment of Pub. L. 100–607, which was approved Nov. 4, 1988, see section 2600 of Pub. L. 100–690, set out as a note under section 242m of this title.

§300ee–14. Restrictions on use of grant

(a) In general

The Secretary may not make payments under section 300ee–11(a) of this title for a fiscal year unless the State involved agrees that the payments will not be expended—

(1) to provide inpatient services;

(2) to make cash payments to intended recipients of services;

(3) to purchase or improve real property (other than minor remodeling of existing improvements to real property) or to purchase major medical equipment; or

(4) to satisfy any requirement for the expenditure of non-Federal funds as a condition for the receipt of Federal funds.

(b) Limitation on administrative expenses

The Secretary may not make payments under section 300ee–11(a) of this title for a fiscal year unless the State involved agrees that the State will not expend more than 5 percent of the payments for administrative expenses with respect to carrying out the purpose described in section 300ee–11(b) of this title.

(July 1, 1944, ch. 373, title XXV, formerly title XV, §2504, as added Pub. L. 100–607, title II, §221, Nov. 4, 1988, 102 Stat. 3095; renumbered title XXV, Pub. L. 101–93, §5(e)(1), Aug. 16, 1989, 103 Stat. 612.)

EDITORIAL NOTES

PRIOR PROVISIONS

A prior section 2504 of act July 1, 1944, was successively renumbered by subsequent acts, see section 238c of this title.

§300ee–15. Requirement of reports and audits by States

(a) Reports

The Secretary may not make payments under section 300ee–11(a) of this title for a fiscal year unless the State involved agrees to prepare and submit to the Secretary an annual report in such form and containing such information as the Secretary determines to be necessary for—

(1) securing a record and a description of the purposes for which payments received by the State pursuant to such section were expended and of the recipients of such payments;

(2) determining whether the payments were expended in accordance with the needs within the State required to be identified pursuant to section 300ee–13(a)(2) of this title;

(3) determining whether the payments were expended in accordance with the purpose described in section 300ee–11(b) of this title; and

(4) determining the percentage of payments received pursuant to such section that were expended by the State for administrative expenses during the preceding fiscal year.

(b) Audits

(1) The Secretary may not make payments under section 300ee–11(a) of this title for a fiscal year unless the State involved agrees to establish such fiscal control and fund accounting procedures as may be necessary to ensure the proper disbursal of, and accounting for, amounts received by the State under such section.

(2) The Secretary may not make payments under section 300ee–11(a) of this title for a fiscal year unless the State involved agrees that—

(A) the State will provide for—

(i) a financial and compliance audit of such payments; or

(ii) a single financial and compliance audit of each entity administering such payments;

(B) the audit will be performed biennially and will cover expenditures in each fiscal year; and

(C) the audit will be conducted in accordance with standards established by the Comptroller General of the United States for the audit of governmental organizations, programs, activities, and functions.

(3) The Secretary may not make payments under section 300ee–11(a) of this title for a fiscal year unless the State involved agrees that, not later than 30 days after the completion of an audit under paragraph (2), the State will provide a copy of the audit report to the State legislature.

(4) For purposes of paragraph (2), the term "financial and compliance audit" means an audit to determine whether the financial statements of an audited entity present fairly the financial position, and the results of financial operations, of the entity in accordance with generally accepted accounting principles, and whether the entity has complied with laws and regulations that may have a material effect upon the financial statements.

(c) Availability to public

The Secretary may not make payments under section 300ee–11(a) of this title for a fiscal year unless the State involved agrees to make copies of the reports and audits described in this section available for public inspection.

(d) Evaluations by Comptroller General

The Comptroller General of the United States shall, from time to time, evaluate the expenditures

by States of payments received under section 300ee–11(a) of this title in order to ensure that expenditures are consistent with the provisions of this part.

(July 1, 1944, ch. 373, title XXV, formerly title XV, §2505, as added Pub. L. 100–607, title II, §221, Nov. 4, 1988, 102 Stat. 3095; amended Pub. L. 100–690, title II, §2619(d), Nov. 18, 1988, 102 Stat. 4242; renumbered title XXV, Pub. L. 101–93, §5(e)(1), Aug. 16, 1989, 103 Stat. 612.)

EDITORIAL NOTES

PRIOR PROVISIONS

A prior section 2505 of act July 1, 1944, was successively renumbered by subsequent acts, see section 238d of this title.

AMENDMENTS

1988—Subsec. (b)(1), (2). Pub. L. 100–690 substituted "make payments" for "payments".

STATUTORY NOTES AND RELATED SUBSIDIARIES

EFFECTIVE DATE OF 1988 AMENDMENT

Amendment by Pub. L. 100–690 effective immediately after enactment of Pub. L. 100–607, which was approved Nov. 4, 1988, see section 2600 of Pub. L. 100–690, set out as a note under section 242m of this title.

§300ee–16. Additional required agreements

(a) In general

The Secretary may not, except as provided in subsection (b), make payments under section 300ee–11(a) of this title for a fiscal year unless the State involved agrees that—

(1) all programs conducted or supported by the State with such payments will establish objectives for the program and will determine the extent to which the objectives are met;

(2) information provided under this part will be scientifically accurate and factually correct;

(3) in carrying out section 300ee–11(b) of this title, the State will give priority to programs described in section 300ee–12(10) of this title for individuals described in such section;

(4) with respect to a State in which there is a substantial number of individuals who are intravenous substance abusers, the State will place priority on activities under this part directed at such substance abusers;

(5) with respect to a State in which there is a significant incidence of reported cases of acquired immune deficiency syndrome, the State will—

(A) for the purpose described in subsection (b) of section 300ee–11 of this title, expend not less than 50 percent of payments received under subsection (a) of such section for a fiscal year—

(i) to make grants to public entities, to migrant health centers (as defined in section 254b(a) [1] of this title), to community health centers (as defined in section 254c(a) [1] of this title), and to nonprofit private entities concerned with acquired immune deficiency syndrome; or

(ii) to enter into contracts with public and private entities; and

(B) of the amounts reserved for a fiscal year by the State for expenditures required in subparagraph (A), expend not less than 50 percent to carry out section 300ee–12(10) of this title through grants to nonprofit private entities, including minority entities, concerned with acquired immune deficiency syndrome located in and representative of communities and subpopulations reflecting the local incidence of such syndrome;

(6) with respect to programs carried out pursuant to section 300ee–12(10) of this title, the State

will ensure that any applicant for a grant under such section agrees—

(A) that any educational or informational materials developed with a grant pursuant to such section will contain material, and be presented in a manner, that is specifically directed toward the group for which such materials are intended;

(B) to provide a description of the manner in which the applicant has planned the program in consultation with, and of the manner in which such applicant will consult during the conduct of the program with—

(i) appropriate local officials and community groups for the area to be served by the program;

(ii) organizations comprised of, and representing, the specific population to which the education or prevention effort is to be directed; and

(iii) individuals having expertise in health education and in the needs of the population to be served;

(C) to provide information demonstrating that the applicant has continuing relationships, or will establish continuing relationships, with a portion of the population in the service area that is at risk of infection with the etiologic agent for acquired immune deficiency syndrome and with public and private entities in such area that provide health or other support services to individuals with such infection;

(D) to provide a description of—

(i) the objectives established by the applicant for the conduct of the program; and

(ii) the methods the applicant will use to evaluate the activities conducted under the program to determine if such objectives are met; and

(E) such other information as the Secretary may prescribe;

(7) with respect to programs carried out pursuant to section 300ee–12(10) of this title, the State will give preference to any applicant for a grant pursuant to such section that is located in, has a history of service in, and will serve under the program, any geographic area in which—

(A) there is a significant incidence of acquired immune deficiency syndrome;

(B) there has been a significant increase in the incidence of such syndrome; or

(C) there is a significant risk of becoming infected with the etiologic agent for such syndrome;

(8) the State will establish reasonable criteria to evaluate the effective performance of entities that receive funds from payments made to the State under section 300ee–11(a) of this title and will establish procedures for procedural and substantive independent State review of the failure by the State to provide funds for any such entity;

(9) the State will permit and cooperate with Federal investigations undertaken in accordance with section 300ee–18(e) of this title;

(10) the State will maintain State expenditures for services provided pursuant to section 300ee–11 of this title at a level equal to not less than the average level of such expenditures maintained by the State for the 2-year period preceding the fiscal year for which the State is applying to receive payments.

(b) "Significant percentage" defined

For purposes of subsection (a)(5), the term "significant percentage" means at least a percentage of 1 percent of the number of reported cases of acquired immune deficiency syndrome in the United States.

(July 1, 1944, ch. 373, title XXV, formerly title XV, §2506, as added Pub. L. 100–607, title II, §221, Nov. 4, 1988, 102 Stat. 3097; amended Pub. L. 100–690, title II, §2619(d) [(e)], Nov. 18, 1988, 102 Stat. 4243; renumbered title XXV, Pub. L. 101–93, §5(e)(1), Aug. 16, 1989, 103 Stat. 612.)

EDITORIAL NOTES

REFERENCES IN TEXT

Sections 254b and 254c of this title, referred to in subsec. (a)(5)(A)(i), were in the original references to sections 329 and 330, meaning sections 329 and 330 of act July 1, 1944, which were omitted in the general amendment of subpart I (§254b et seq.) of part D of subchapter II of this chapter by Pub. L. 104–299, §2, Oct. 11, 1996, 110 Stat. 3626. Sections 2 and 3(a) of Pub. L. 104–299 enacted new sections 330 and 330A of act July 1, 1944, which are classified, respectively, to sections 254b and 254c of this title.

PRIOR PROVISIONS

A prior section 2506 of act July 1, 1944, was successively renumbered by subsequent acts, see section 238e of this title.

AMENDMENTS

1988—Subsec. (a). Pub. L. 100–690, §2619(d)(1) [(e)(1)], designated existing provisions as subsec. (a).

Subsec. (a)(5). Pub. L. 100–690, §2619(d)(2) [(e)(2)], struck out concluding provisions which read as follows: "(For purposes of this section, the term 'significant percentage' means at least a percentage of 1 percent of the number of reported cases of such syndrome in the United States);".

Subsec. (a)(8). Pub. L. 100–690, §2619(d)(3) [(e)(3)], substituted "funds from payments" for "funds from to payments" and struck out "and" after semicolon.

Subsec. (a)(9). Pub. L. 100–690, §2619(d)(4) [(e)(4)], substituted "section 300ee–18(e) of this title" for "section 300ee–19(e) of this title".

Subsec. (b). Pub. L. 100–690, §2619(d)(5) [(e)(5)], added subsec. (b).

STATUTORY NOTES AND RELATED SUBSIDIARIES

EFFECTIVE DATE OF 1988 AMENDMENT

Amendment by Pub. L. 100–690 effective immediately after enactment of Pub. L. 100–607, which was approved Nov. 4, 1988, see section 2600 of Pub. L. 100–690, set out as a note under section 242m of this title.

REFERENCE TO COMMUNITY, MIGRANT, PUBLIC HOUSING, OR HOMELESS HEALTH CENTER CONSIDERED REFERENCE TO HEALTH CENTER

Reference to community health center, migrant health center, public housing health center, or homeless health center considered reference to health center, see section 4(c) of Pub. L. 104–299, set out as a note under section 254b of this title.

[1] *See References in Text note below.*

§300ee–17. Determination of amount of allotments for States

(a) Minimum allotment

Subject to the extent of amounts made available in appropriation Acts, the allotment for a State under section 300ee–11(a) of this title for a fiscal year shall be the greater of—

(1) the applicable amount specified in subsection (b); or

(2) the amount determined in accordance with subsection (c).

(b) Determination of minimum allotment

(1) If the total amount appropriated under section 300ee–24(a) of this title for a fiscal year exceeds $100,000,000, the amount referred to in subsection (a)(1) shall be $300,000 for the fiscal year.

(2) If the total amount appropriated under section 300ee–24(a) of this title for a fiscal year equals or exceeds $50,000,000, but is less than $100,000,000, the amount referred to in subsection (a)(1) shall be $200,000 for the fiscal year.

(3) If the total amount appropriated under section 300ee–24(a) of this title for a fiscal year is less than $50,000,000, the amount referred to in subsection (a)(1) shall be $100,000 for the fiscal year.

(c) Determination under formula

(1) The amount referred to in subsection (a)(2) is the sum of—
(A) the amount determined under paragraph (2); and
(B) the amount determined under paragraph (3).

(2) The amount referred to in paragraph (1)(A) is the product of—
(A) an amount equal to 50 percent of the amounts appropriated pursuant to section 300ee–24(a) of this title; and
(B) a percentage equal to the quotient of—
(i) the population of the State involved; divided by
(ii) the population of the United States.

(3) The amount referred to in paragraph (1)(B) is the product of—
(A) an amount equal to 50 percent of the amounts appropriated pursuant to section 300ee–24(a) of this title; and
(B) a percentage equal to the quotient of—
(i) the number of additional cases of acquired immune deficiency syndrome reported to and confirmed by the Secretary for the State involved for the most recent fiscal year for which such data is available; divided by
(ii) the number of additional cases of such syndrome reported to and confirmed by the Secretary for the United States for such fiscal year.

(d) Disposition of certain funds appropriated for allotments

(1) Amounts described in paragraph (2) shall be allotted by the Secretary to States receiving payments under section 300ee–11(a) of this title for the fiscal year (other than any State referred to in paragraph (2)(C)). Such amounts shall be allotted according to a formula established by the Secretary. The formula shall be equivalent to the formula described in this section under which the allotment under section 300ee–11(a) of this title for the State for the fiscal year involved was determined.

(2) The amounts referred to in paragraph (1) are any amounts that are not paid to States under section 300ee–11(a) of this title as a result of—
(A) the failure of any State to submit an application under section 300ee–13 of this title;
(B) the failure, in the determination of the Secretary, of any State to prepare within a reasonable period of time such application in compliance with such section; or
(C) any State informing the Secretary that the State does not intend to expend the full amount of the allotment made to the State.

(July 1, 1944, ch. 373, title XXV, formerly title XV, §2507, as added Pub. L. 100–607, title II, §221, Nov. 4, 1988, 102 Stat. 3098; amended Pub. L. 100–690, title II, §2619(e) [(f)], Nov. 18, 1988, 102 Stat. 4243; renumbered title XXV and amended Pub. L. 101–93, §5(e)(1), (2), Aug. 16, 1989, 103 Stat. 612.)

EDITORIAL NOTES

PRIOR PROVISIONS

A prior section 2507 of act July 1, 1944, was successively renumbered by subsequent acts, see section 238f of this title.

AMENDMENTS

1989—Subsec. (a). Pub. L. 101–93, §5(e)(2), substituted "Subject to the extent of amounts made available in appropriation Acts, the allotment" for "The allotment".

1988—Subsec. (a)(1). Pub. L. 100–690, §2619(e)(1) [(f)(1)], substituted "applicable amount specified" for "amount described".

Subsec. (b)(1). Pub. L. 100–690, §2619(e)(2)(A)(i) [(f)(2)(A)(i)], made technical amendment to reference to section 300ee–24(a) of this title to correct reference to corresponding provision of original act.

Pub. L. 100–690, §2619(e)(2)(A)(ii) [(f)(2)(A)(ii)], substituted "subsection (a)(1) shall be" for "subsection

(a)(1) is".

Subsec. (b)(2), (3). Pub. L. 100–690, §2619(e)(2)(B), (C) [(f)(2)(B), (C)], substituted "subsection (a)(1) shall be" for "subsection (a)(1) is".

Subsec. (d). Pub. L. 100–690, §2619(e)(3) [(f)(3)], substituted "allotment under section 300ee–11(a) of this title" for "allotment" in par. (1) and "section 300ee–13 of this title" for "section 300ee–17 of this title" in par. (2)(A).

STATUTORY NOTES AND RELATED SUBSIDIARIES

EFFECTIVE DATE OF 1988 AMENDMENT

Amendment by Pub. L. 100–690 effective immediately after enactment of Pub. L. 100–607, which was approved Nov. 4, 1988, see section 2600 of Pub. L. 100–690, set out as a note under section 242m of this title.

§300ee–18. Failure to comply with agreements

(a) Repayment of payments

(1) The Secretary may, subject to subsection (c), require a State to repay any payments received by the State under section 300ee–11(a) of this title that the Secretary determines were not expended by the State in accordance with the agreements required to be contained in the application submitted by the State pursuant to section 300ee–13 of this title.

(2) If a State fails to make a repayment required in paragraph (1), the Secretary may offset the amount of the repayment against the amount of any payment due to be paid to the State under section 300ee–11(a) of this title.

(b) Withholding of payments

(1) The Secretary may, subject to subsection (c), withhold payments due under section 300ee–11(a) of this title if the Secretary determines that the State involved is not expending amounts received under such section in accordance with the agreements required to be contained in the application submitted by the State pursuant to section 300ee–13 of this title.

(2) The Secretary shall cease withholding payments from a State under paragraph (1) if the Secretary determines that there are reasonable assurances that the State will expend amounts received under section 300ee–11(a) of this title in accordance with the agreements referred to in such paragraph.

(3) The Secretary may not withhold funds under paragraph (1) from a State for a minor failure to comply with the agreements referred to in such paragraph.

(c) Opportunity for hearing

Before requiring repayment of payments under subsection (a)(1), or withholding payments under subsection (b)(1), the Secretary shall provide to the State an opportunity for a hearing conducted within the State.

(d) Prompt response to serious allegations

The Secretary shall promptly respond to any complaint of a substantial or serious nature that a State has failed to expend amounts received under section 300ee–11(a) of this title in accordance with the agreements required to be contained in the application submitted by the State pursuant to section 300ee–13 of this title.

(e) Investigations

(1) The Secretary shall conduct in several States in each fiscal year investigations of the expenditure of payments received by the States under section 300ee–11(a) of this title in order to evaluate compliance with the agreements required to be contained in the applications submitted to the Secretary pursuant to section 300ee–13 of this title.

(2) The Comptroller General of the United States may conduct investigations of the expenditure of funds received under section 300ee–11(a) of this title by a State in order to ensure compliance with

the agreements referred to in paragraph (1).

(3) Each State, and each entity receiving funds from payments made to a State under section 300ee–11(a) of this title, shall make appropriate books, documents, papers, and records available to the Secretary and the Comptroller General of the United States, or any of their duly authorized representatives, for examination, copying, or mechanical reproduction on or off the premises of the appropriate entity upon a reasonable request therefor.

(4)(A) In conducting any investigation in a State, the Secretary and the Comptroller General of the United States may not make a request for any information not readily available to the State, or to an entity receiving funds from payments made to the State under section 300ee–11(a) of this title, or make an unreasonable request for information to be compiled, collected, or transmitted in any form not readily available.

(B) Subparagraph (A) shall not apply to the collection, compilation, or transmittal of data in the course of a judicial proceeding.

(July 1, 1944, ch. 373, title XXV, formerly title XV, §2508, as added Pub. L. 100–607, title II, §221, Nov. 4, 1988, 102 Stat. 3099; amended Pub. L. 100–690, title II, §2619(f) [(g)], Nov. 18, 1988, 102 Stat. 4243; renumbered title XXV, Pub. L. 101–93, §5(e)(1), Aug. 16, 1989, 103 Stat. 612.)

EDITORIAL NOTES

PRIOR PROVISIONS

A prior section 2508 of act July 1, 1944, was successively renumbered by subsequent acts, see section 238g of this title.

AMENDMENTS

1988—Subsec. (a). Pub. L. 100–690, §2619(f)(1) [(g)(1)], substituted "300ee–13 of this title" for "300ee–17 of this title".

Subsec. (b). Pub. L. 100–690, §2619(f)(2) [(g)(2)], inserted "of payments" after "Withholding" in heading and substituted "300ee–13 of this title" for "300ee–17 of this title" in par. (1).

Subsecs. (d), (e)(1). Pub. L. 100–690, §2619(f)(3), (4) [(g)(3), (4)], substituted "300ee–13 of this title" for "300ee–17 of this title".

STATUTORY NOTES AND RELATED SUBSIDIARIES

EFFECTIVE DATE OF 1988 AMENDMENT

Amendment by Pub. L. 100–690 effective immediately after enactment of Pub. L. 100–607, which was approved Nov. 4, 1988, see section 2600 of Pub. L. 100–690, set out as a note under section 242m of this title.

§300ee–19. Prohibition against certain false statements

(a) In general

(1) A person may not knowingly make or cause to be made any false statement or representation of a material fact in connection with the furnishing of items or services for which amounts may be paid by a State from payments received by the State under section 300ee–11(a) of this title.

(2) A person with knowledge of the occurrence of any event affecting the right of the person to receive any amounts from payments made to the State under section 300ee–11(a) of this title may not conceal or fail to disclose any such event with the intent of fraudulently securing such amounts.

(b) Criminal penalty for violation of prohibition

Any person who violates a prohibition established in subsection (a) may for each violation be fined in accordance with title 18, or imprisoned for not more than 5 years, or both.

(July 1, 1944, ch. 373, title XXV, formerly title XV, §2509, as added Pub. L. 100–607, title II, §221, Nov. 4, 1988, 102 Stat. 3101; renumbered title XXV, Pub. L. 101–93, §5(e)(1), Aug. 16, 1989, 103 Stat. 612.)

EDITORIAL NOTES

PRIOR PROVISIONS

A prior section 2509 of act July 1, 1944, was successively renumbered by subsequent acts, see section 238h of this title.

§300ee–20. Technical assistance and provision by Secretary of supplies and services in lieu of grant funds

(a) Technical assistance

The Secretary may provide training and technical assistance to States with respect to the planning, development, and operation of any program or service carried out pursuant to this part. The Secretary may provide such technical assistance directly or through grants or contracts.

(b) Provision by Secretary of supplies and services in lieu of grant funds

(1) Upon the request of a State receiving payments under this part, the Secretary may, subject to paragraph (2), provide supplies, equipment, and services for the purpose of aiding the State in carrying out such part and, for such purpose, may detail to the State any officer or employee of the Department of Health and Human Services.

(2) With respect to a request described in paragraph (1), the Secretary shall reduce the amount of payments under section 300ee–11(a) of this title to the State by an amount equal to the costs of detailing personnel and the fair market value of any supplies, equipment, or services provided by the Secretary. The Secretary shall, for the payment of expenses incurred in complying with such request, expend the amounts withheld.

(July 1, 1944, ch. 373, title XXV, formerly title XV, §2510, as added Pub. L. 100–607, title II, §221, Nov. 4, 1988, 102 Stat. 3101; amended Pub. L. 100–690, title II, §2619(g) [(h)], Nov. 18, 1988, 102 Stat. 4243; renumbered title XXV, Pub. L. 101–93, §5(e)(1), Aug. 16, 1989, 103 Stat. 612.)

EDITORIAL NOTES

PRIOR PROVISIONS

A prior section 2510 of act July 1, 1944, was successively renumbered by subsequent acts, see section 238i of this title.

AMENDMENTS

1988—Subsec. (b)(2). Pub. L. 100–690 substituted "section 300ee–11(a) of this title" for "the program involved".

STATUTORY NOTES AND RELATED SUBSIDIARIES

EFFECTIVE DATE OF 1988 AMENDMENT

Amendment by Pub. L. 100–690 effective immediately after enactment of Pub. L. 100–607, which was approved Nov. 4, 1988, see section 2600 of Pub. L. 100–690, set out as a note under section 242m of this title.

§300ee–21. Evaluations

The Secretary shall, directly or through grants or contracts, evaluate the services provided and activities carried out with payments to States under this part.

(July 1, 1944, ch. 373, title XXV, formerly title XV, §2511, as added Pub. L. 100–607, title II, §221, Nov. 4, 1988, 102 Stat. 3101; renumbered title XXV, Pub. L. 101–93, §5(e)(1), Aug. 16, 1989, 103 Stat. 612.)

EDITORIAL NOTES

PRIOR PROVISIONS

A prior section 2511 of act July 1, 1944, was successively renumbered by subsequent acts, see section 238j of this title.

§300ee–22. Report by Secretary

The Secretary shall annually prepare a report on the activities of the States carried out pursuant to this part. Such report may include any recommendations of the Secretary for appropriate administrative and legislative initiatives. The report shall be submitted to the Congress through inclusion in the comprehensive report required in section 300cc(a) [1] of this title.

(July 1, 1944, ch. 373, title XXV, formerly title XV, §2512, as added Pub. L. 100–607, title II, §221, Nov. 4, 1988, 102 Stat. 3101; amended Pub. L. 100–690, title II, §2619(h) [(i)], Nov. 18, 1988, 102 Stat. 4243; renumbered title XXV, Pub. L. 101–93, §5(e)(1), Aug. 16, 1989, 103 Stat. 612.)

EDITORIAL NOTES

REFERENCES IN TEXT

Section 300cc of this title, referred to in text, was repealed by Pub. L. 109–482, title I, §104(b)(2)(C), Jan. 15, 2007, 120 Stat. 3693.

PRIOR PROVISIONS

A prior section 2512 of act July 1, 1944, was successively renumbered by subsequent acts, see section 238k of this title.

AMENDMENTS

1988—Pub. L. 100–690 substituted "section 300cc(a)" for "section 300cc".

STATUTORY NOTES AND RELATED SUBSIDIARIES

EFFECTIVE DATE OF 1988 AMENDMENT

Amendment by Pub. L. 100–690 effective immediately after enactment of Pub. L. 100–607, which was approved Nov. 4, 1988, see section 2600 of Pub. L. 100–690, set out as a note under section 242m of this title.

[1] *See References in Text note below.*

§300ee–23. Definition

For purposes of this part, the term "infection with the etiologic agent for acquired immune deficiency syndrome" includes any condition arising from such etiologic agent.

(July 1, 1944, ch. 373, title XXV, formerly title XV, §2513, as added Pub. L. 100–607, title II, §221, Nov. 4, 1988, 102 Stat. 3102; renumbered title XXV, Pub. L. 101–93, §5(e)(1), Aug. 16, 1989, 103 Stat. 612.)

EDITORIAL NOTES

PRIOR PROVISIONS

A prior section 2513 of act July 1, 1944, was successively renumbered by subsequent acts, see section 238l of this title.

§300ee–24. Funding

(a) Authorization of appropriations

For the purpose of making allotments under section 300ee–11(a) of this title, there are authorized to be appropriated $165,000,000 for fiscal year 1989 and such sums as may be necessary for each of the fiscal years 1990 and 1991.

(b) Availability to States

Any amounts paid to a State under section 300ee–11(a) of this title shall remain available to the State until the expiration of the 1-year period beginning on the date on which the State receives such amounts.

(July 1, 1944, ch. 373, title XXV, formerly title XV, §2514, as added Pub. L. 100–607, title II, §221, Nov. 4, 1988, 102 Stat. 3102; renumbered title XXV, Pub. L. 101–93, §5(e)(1), Aug. 16, 1989, 103 Stat. 612.)

EDITORIAL NOTES

PRIOR PROVISIONS

A prior section 2514 of act July 1, 1944, was successively renumbered by subsequent acts, see section 238m of this title.

PART B—NATIONAL INFORMATION PROGRAMS

§300ee–31. Availability of information to general public

(a) Comprehensive information plan

The Secretary, acting through the Director of the Centers for Disease Control and Prevention, shall annually prepare a comprehensive plan, including a budget, for a National Acquired Immune Deficiency Syndrome Information Program. The plan shall contain provisions to implement the provisions of this subchapter. The Director shall submit such plan to the Secretary. The authority established in this subsection may not be construed to be the exclusive authority for the Director to carry out information activities with respect to acquired immune deficiency syndrome.

(b) Clearinghouse

(1) The Secretary, acting through the Director of the Centers for Disease Control and Prevention, may establish a clearinghouse to make information concerning acquired immune deficiency syndrome available to Federal agencies, States, public and private entities, and the general public.

(2) The clearinghouse may conduct or support programs—

(A) to develop and obtain educational materials, model curricula, and methods directed toward reducing the transmission of the etiologic agent for acquired immune deficiency syndrome;

(B) to provide instruction and support for individuals who provide instruction in methods and techniques of education relating to the prevention of acquired immune deficiency syndrome and instruction in the use of the materials and curricula described in subparagraph (A); and

(C) to conduct, or to provide for the conduct of, the materials, curricula, and methods described in paragraph (1) and the efficacy of such materials, curricula, and methods in preventing infection with the the [1] etiologic agent for acquired immune deficiency syndrome.

(c) Toll-free telephone communications

The Secretary shall provide for the establishment and maintenance of toll-free telephone communications to provide information to, and respond to queries from, the public concerning acquired immune deficiency syndrome. Such communications shall be available on a 24-hour basis.

(July 1, 1944, ch. 373, title XXV, formerly title XV, §2521, as added Pub. L. 100–607, title II, §221, Nov. 4, 1988, 102 Stat. 3102; renumbered title XXV, Pub. L. 101–93, §5(e)(1), Aug. 16, 1989, 103 Stat. 612; amended Pub. L. 102–531, title III, §312(d)(22), Oct. 27, 1992, 106 Stat. 3505.)

EDITORIAL NOTES

AMENDMENTS

1992—Subsecs. (a), (b)(1). Pub. L. 102–531 substituted "Centers for Disease Control and Prevention" for "Centers for Disease Control".

[1] *So in original.*

§300ee–32. Public information campaigns

(a) In general

The Secretary, acting through the Director of the Centers for Disease Control and Prevention, may make grants to public entities, and to nonprofit private entities concerned with acquired immune deficiency syndrome, and shall enter into contracts with public and private entities, for the development and delivery of public service announcements and paid advertising messages that warn individuals about activities which place them at risk of infection with the etiologic agent for such syndrome.

(b) Requirement of application

The Secretary may not provide financial assistance under subsection (a) unless—

(1) an application for such assistance is submitted to the Secretary;

(2) with respect to carrying out the purpose for which the assistance is to be provided, the application provides assurances of compliance satisfactory to the Secretary; and

(3) the application otherwise is in such form, is made in such manner, and contains such agreements, assurances, and information as the Secretary determines to be necessary to carry out this section.

(July 1, 1944, ch. 373, title XXV, formerly title XV, §2522, as added Pub. L. 100–607, title II, §221, Nov. 4, 1988, 102 Stat. 3103; renumbered title XXV, Pub. L. 101–93, §5(e)(1), Aug. 16, 1989, 103 Stat. 612; amended Pub. L. 102–531, title III, §312(d)(23), Oct. 27, 1992, 106 Stat. 3505.)

EDITORIAL NOTES

AMENDMENTS

1992—Subsec. (a). Pub. L. 102–531 substituted "Centers for Disease Control and Prevention" for "Centers for Disease Control".

§300ee–33. Provision of information to underserved populations

(a) In general

The Secretary may make grants to public entities, to migrant health centers (as defined in section 254b(a) [1] of this title), to community health centers (as defined in section 254c(a) [1] of this title), and to nonprofit private entities concerned with acquired immune deficiency syndrome, for the purpose of assisting grantees in providing services to populations of individuals that are underserved with respect to programs providing information on the prevention of exposure to, and the transmission of, the etiologic agent for acquired immune deficiency syndrome.

(b) Preferences in making grants

In making grants under subsection (a), the Secretary shall give preference to any applicant for such a grant that has the ability to disseminate rapidly the information described in subsection (a) (including any national organization with such ability).

(July 1, 1944, ch. 373, title XXV, formerly title XV, §2523, as added Pub. L. 100–607, title II, §221, Nov. 4, 1988, 102 Stat. 3103; renumbered title XXV, Pub. L. 101–93, §5(e)(1), Aug. 16, 1989, 103 Stat. 612.)

EDITORIAL NOTES

REFERENCES IN TEXT

Sections 254b and 254c of this title, referred to in subsec. (a), were in the original references to sections 329 and 330, meaning sections 329 and 330 of act July 1, 1944, which were omitted in the general amendment of subpart I (§254b et seq.) of part D of subchapter II of this chapter by Pub. L. 104–299, §2, Oct. 11, 1996, 110 Stat. 3626. Sections 2 and 3(a) of Pub. L. 104–299 enacted new sections 330 and 330A of act July 1, 1944, which are classified, respectively, to sections 254b and 254c of this title.

STATUTORY NOTES AND RELATED SUBSIDIARIES

REFERENCE TO COMMUNITY, MIGRANT, PUBLIC HOUSING, OR HOMELESS HEALTH CENTER CONSIDERED REFERENCE TO HEALTH CENTER

Reference to community health center, migrant health center, public housing health center, or homeless health center considered reference to health center, see section 4(c) of Pub. L. 104–299, set out as a note under section 254b of this title.

[1] *See References in Text note below.*

§300ee–34. Authorization of appropriations

(a) In general

For the purpose of carrying out sections 300ee–31 through 300ee–33 of this title, there are authorized to be appropriated $105,000,000 for fiscal year 1989 and such sums as may be necessary for each of the fiscal years 1990 and 1991.

(b) Allocations

(1) Of the amounts appropriated pursuant to subsection (a), the Secretary shall make available $45,000,000 to carry out section 300ee–32 of this title and $30,000,000 to carry out this part through financial assistance to minority entities for the provision of services to minority populations.

(2) After consultation with the Director of the Office of Minority Health and with the Indian Health Service, the Secretary, acting through the Director of the Centers for Disease Control and Prevention, shall, not later than 90 days after November 4, 1988, publish guidelines to provide procedures for applications for funding pursuant to paragraph (1) and for public comment.

(July 1, 1944, ch. 373, title XXV, formerly title XV, §2524, as added Pub. L. 100–607, title II, §221, Nov. 4, 1988, 102 Stat. 3103; amended Pub. L. 100–690, title II, §2619(i) [(j)], Nov. 18, 1988, 102 Stat. 4244; renumbered title XXV, Pub. L. 101–93, §5(e)(1), Aug. 16, 1989, 103 Stat. 612; Pub. L. 102–531, title III, §312(d)(24), Oct. 27, 1992, 106 Stat. 3505.)

EDITORIAL NOTES

AMENDMENTS

1992—Subsec. (b)(2). Pub. L. 102–531 substituted "Centers for Disease Control and Prevention" for "Centers for Disease Control".

1988—Subsec. (b)(2). Pub. L. 100–690 substituted "the date of the enactment of the AIDS Amendments of

1988" for "the date of the enactment of this section", which for purposes of codification was translated as "November 4, 1988".

STATUTORY NOTES AND RELATED SUBSIDIARIES

EFFECTIVE DATE OF 1988 AMENDMENT

Amendment by Pub. L. 100–690 effective immediately after enactment of Pub. L. 100–607, which was approved Nov. 4, 1988, see section 2600 of Pub. L. 100–690, set out as a note under section 242m of this title.

SUBCHAPTER XXIV—HIV HEALTH CARE SERVICES PROGRAM

§300ff. Purpose

It is the purpose of this Act to provide emergency assistance to localities that are disproportionately affected by the Human Immunodeficiency Virus epidemic and to make financial assistance available to States and other public or private nonprofit entities to provide for the development, organization, coordination and operation of more effective and cost efficient systems for the delivery of essential services to individuals and families with HIV disease.

(Pub. L. 101–381, §2, Aug. 18, 1990, 104 Stat. 576.)

EDITORIAL NOTES

REFERENCES IN TEXT

This Act, referred to in text, is Pub. L. 101–381, Aug. 18, 1990, 104 Stat. 576, known as the Ryan White Comprehensive AIDS Resources Emergency Act of 1990, which enacted this subchapter, transferred section 300ee–6 of this title to section 300ff–48 of this title, amended sections 284a, 286, 287a, 287c–2, 289f, 290aa–3a, 299c–5, 300ff–48, and 300aaa to 300aaa–13 [now 238 to 238m] of this title, and enacted provisions set out as notes under sections 201, 300x–4, 300ff–11, 300ff–46, and 300ff–80 of this title. For complete classification of this Act to the Code, see Short Title of 1990 Amendment note set out under section 201 of this title and Tables.

CODIFICATION

Section was enacted as part of the Ryan White Comprehensive AIDS Resources Emergency Act of 1990, and not as part of the Public Health Service Act which comprises this chapter.

§300ff–1. Prohibition on use of funds

None of the funds made available under this Act, or an amendment made by this Act, shall be used to provide individuals with hypodermic needles or syringes so that such individuals may use illegal drugs.

(Pub. L. 101–381, title IV, §422, Aug. 18, 1990, 104 Stat. 628.)

EDITORIAL NOTES

REFERENCES IN TEXT

This Act, referred to in text, is Pub. L. 101–381, Aug. 18, 1990, 104 Stat. 576, known as the Ryan White Comprehensive AIDS Resources Emergency Act of 1990, which enacted this subchapter, transferred section 300ee–6 of this title to section 300ff–48 of this title, amended sections 284a, 286, 287a, 287c–2, 289f, 290aa–3a, 299c–5, 300ff–48, and 300aaa to 300aaa–13 [now 238 to 238m] of this title, and enacted provisions

set out as notes under sections 201, 300x–4, 300ff–11, 300ff–46, and 300ff–80 of this title. For complete classification of this Act to the Code, see Short Title of 1990 Amendment note set out under section 201 of this title and Tables.

CODIFICATION

Section was enacted as part of the Ryan White Comprehensive AIDS Resources Emergency Act of 1990, and not as part of the Public Health Service Act which comprises this chapter.

PART A—EMERGENCY RELIEF FOR AREAS WITH SUBSTANTIAL NEED FOR SERVICES

SUBPART I—GENERAL GRANT PROVISIONS

§300ff–11. Establishment of program of grants

(a) Eligible areas

The Secretary, acting through the Administrator of the Health Resources and Services Administration, shall, subject to subsections (b) through (c), make grants in accordance with section 300ff–13 of this title for the purpose of assisting in the provision of the services specified in section 300ff–14 of this title in any metropolitan area for which there has been reported to and confirmed by the Director of the Centers for Disease Control and Prevention a cumulative total of more than 2,000 cases of AIDS during the most recent period of 5 calendar years for which such data are available.

(b) Continued status as eligible area

Notwithstanding any other provision of this section, a metropolitan area that is an eligible area for a fiscal year continues to be an eligible area until the metropolitan area fails, for three consecutive fiscal years—

(1) to meet the requirements of subsection (a); and

(2) to have a cumulative total of 3,000 or more living cases of AIDS (reported to and confirmed by the Director of the Centers for Disease Control and Prevention) as of December 31 of the most recent calendar year for which such data is available.

(c) Boundaries

For purposes of determining eligibility under this subpart—

(1) with respect to a metropolitan area that received funding under this subpart in fiscal year 2006, the boundaries of such metropolitan area shall be the boundaries that were in effect for such area for fiscal year 1994; or

(2) with respect to a metropolitan area that becomes eligible to receive funding under this subpart in any fiscal year after fiscal year 2006, the boundaries of such metropolitan area shall be the boundaries that are in effect for such area when such area initially receives funding under this subpart.

(July 1, 1944, ch. 373, title XXVI, §2601, as added Pub. L. 101–381, title I, §101(3), Aug. 18, 1990, 104 Stat. 576; amended Pub. L. 102–531, title III, §312(d)(25), Oct. 27, 1992, 106 Stat. 3505; Pub. L. 104–146, §§3(a)(1), (2), 12(c)(1), May 20, 1996, 110 Stat. 1346, 1373; Pub. L. 109–415, title I, §§101(a), (b), 106(a), 107(b), title VII, §§702(1), 703, Dec. 19, 2006, 120 Stat. 2768, 2780, 2783, 2819, 2820; Pub. L. 111–87, §2(a)(1), (3)(A), Oct. 30, 2009, 123 Stat. 2885.)

EDITORIAL NOTES

PRIOR PROVISIONS

A prior section 2601 of act July 1, 1944, was successively renumbered by subsequent acts and transferred, see section 238 of this title.

AMENDMENTS

2009—Pub. L. 111–87 repealed Pub. L. 109–415, §703, and revived the provisions of this section as in effect on Sept. 30, 2009. See 2006 Amendment note and Effective Date of 2009 Amendment; Revival of Section note below.

2006—Pub. L. 109–415, §703, which directed repeal of this section effective Oct. 1, 2009, was itself repealed by Pub. L. 111–87, §2(a)(1), effective Sept. 30, 2009.

Subsec. (a). Pub. L. 109–415, §702(1), substituted "AIDS" for "acquired immune deficiency syndrome".

Pub. L. 109–415, §106(a), substituted "during the most recent period" for "for the most recent period".

Pub. L. 109–415, §101(b), substituted "through (c)" for "through (d)" and inserted "and confirmed by" after "reported to".

Subsecs. (b) to (d). Pub. L. 109–415, §§101(a), 107(b), added subsecs. (b) and (c), substituted "this subpart" for "this part" in subsec. (c) wherever appearing, and struck out former subsecs. (b) to (d) which related to requirement regarding confirmation of cases, requirements regarding population, and continued status as eligible area, respectively.

1996—Subsec. (a). Pub. L. 104–146, §12(c)(1), inserted "section" before "300ff–14".

Pub. L. 104–146, §3(a)(1)(B), substituted "metropolitan area for which there has been reported to the Director of the Centers for Disease Control and Prevention a cumulative total of more than 2,000 cases of acquired immune deficiency syndrome for the most recent period of 5 calendar years for which such data are available." for "metropolitan area for which, as of June 30, 1990, in the case of grants for fiscal year 1991, and as of March 31 of the most recent fiscal year for which such data is available in the case of a grant for any subsequent fiscal year—

"(1) there has been reported to and confirmed by the Director of the Centers for Disease Control and Prevention a cumulative total of more than 2,000 cases of acquired immune deficiency syndrome; or

"(2) the per capita incidence of cumulative cases of such syndrome (computed on the basis of the most recently available data on the population of the area) is not less than 0.0025."

Pub. L. 104–146, §3(a)(1)(A), substituted "subject to subsections (b) through (d)" for "subject to subsection (b)".

Subsecs. (c), (d). Pub. L. 104–146, §3(a)(2), added subsecs. (c) and (d).

1992—Subsecs. (a)(1), (b). Pub. L. 102–531 substituted "Centers for Disease Control and Prevention" for "Centers for Disease Control".

STATUTORY NOTES AND RELATED SUBSIDIARIES

EFFECTIVE DATE OF 2009 AMENDMENT; REVIVAL OF SECTION

Pub. L. 111–87, §2(a)(2), (3), Oct. 30, 2009, 123 Stat. 2885, provided that:

"(2) EFFECTIVE DATE.—Paragraph (1) [repealing section 703 of Pub. L. 109–415, formerly set out as an Effective Date of Repeal note below] shall take effect as if enacted on September 30, 2009.

"(3) CONTINGENCY PROVISIONS.—Notwithstanding section 703 of the Ryan White HIV/AIDS Treatment Modernization Act of 2006 (Public Law 109–415; 120 Stat. 2767 [2820]) [repealing this subchapter, formerly set out as an Effective Date of Repeal note below] and section 139 of the Continuing Appropriations Resolution, 2010 [123 Stat. 2048]—

"(A) the provisions of title XXVI of the Public Health Service Act (42 U.S.C. 300ff et seq.), as in effect on September 30, 2009, are hereby revived; and

"(B) the amendments made by this Act to title XXVI of the Public Health Service Act (42 U.S.C. 300ff et seq.) [see Tables for classification] shall apply to such title as so revived and shall take effect as if enacted on September 30, 2009."

EFFECTIVE DATE OF REPEAL

Pub. L. 109–415, title VII, §703, Dec. 19, 2006, 120 Stat. 2820, which provided for the repeal of this subchapter effective Oct. 1, 2009, was itself repealed by Pub. L. 111–87, §2(a)(1), Oct. 30, 2009, 123 Stat. 2885.

EFFECTIVE DATE OF 1996 AMENDMENT

Pub. L. 104–146, §13, May 20, 1996, 110 Stat. 1374, provided that:

"(a) IN GENERAL.—Except as provided in subsection (b), this Act [enacting sections 300ff–27a, 300ff–31, 300ff–33 to 300ff–37, 300ff–77, 300ff–78, and 300ff–101 of this title, amending this section and sections 294n, 300d, 300ff–12 to 300ff–17, 300ff–21 to 300ff–23, 300ff–26 to 300ff–29, 300ff–47 to 300ff–49, 300ff–51, 300ff–52, 300ff–54, 300ff–55, 300ff–64, 300ff–71, 300ff–74, 300ff–76, and 300ff–84 of this title, transferring section 294n of this title to section 300ff–111 of this title, repealing sections 300ff–18 and 300ff–30 of this title, and enacting provisions set out as notes under sections 201, 300cc, and 300ff–33 of this title and section 4103 of Title 5, Government Organization and Employees], and the amendments made by this Act, shall become effective on October 1, 1996.

"(b) EXCEPTION.—The amendments made by sections 3(a), 5, 6, and 7 of this Act to sections 2601(c), 2601(d), 2603(a), 2618(b), 2626, 2677, and 2691 of the Public Health Service Act [42 U.S.C. 300ff–11(c), (d), 300ff–13(a), 300ff–28(b), 300ff–34, 300ff–77, 300ff–101] shall become effective on the date of enactment of this Act [May 20, 1996]."

STUDIES BY INSTITUTE OF MEDICINE

Pub. L. 106–345, title V, §501, Oct. 20, 2000, 114 Stat. 1352, required the Secretary of Health and Human Services to request the Institute of Medicine or another appropriate entity to conduct a study of State surveillance systems on the prevalence of HIV and a study concerning the relationship between epidemiological measures and health care for certain individuals with HIV and to ensure that the former study be completed and a report submitted to congressional committees not later than 3 years after Oct. 20, 2000, and that the latter study be completed and a report submitted to congressional committees not later than 2 years after Oct. 20, 2000.

STUDY REGARDING HIV DISEASE IN RURAL AREAS

Pub. L. 101–381, title IV, §403, Aug. 18, 1990, 104 Stat. 622 directed Secretary of Health and Human Services, after consultation with Director of the Office of Rural Health Policy, to conduct study for purpose of estimating incidence and prevalence in rural areas of cases of acquired immune deficiency syndrome and cases of infection with etiologic agent for such syndrome and determine adequacy in rural areas of services for diagnosing and providing treatment for such cases that are in early stages of infection, and provided that, not later than 1 year after Aug. 18, 1990, Secretary was to submit report to Congress.

§300ff–12. Administration and planning council

(a) Administration

(1) In general

Assistance made available under grants awarded under this subpart shall be directed to the chief elected official of the city or urban county that administers the public health agency that provides outpatient and ambulatory services to the greatest number of individuals with AIDS, as reported to and confirmed by the Centers for Disease Control and Prevention, in the eligible area that is awarded such a grant.

(2) Requirements

(A) In general

To receive assistance under section 300ff–11(a) of this title, the chief elected official of the eligible area involved shall—

(i) establish, through intergovernmental agreements with the chief elected officials of the political subdivisions described in subparagraph (B), an administrative mechanism to allocate funds and services based on—

(I) the number of AIDS cases in such subdivisions;

(II) the severity of need for outpatient and ambulatory care services in such subdivisions; and

(III) the health and support services personnel needs of such subdivisions; and

(ii) establish an HIV health services planning council in accordance with subsection (b).

(B) Local political subdivision

The political subdivisions referred to in subparagraph (A) are those political subdivisions in the eligible area—

(i) that provide HIV-related health services; and

(ii) for which the number of cases reported for purposes of section 300ff–11(a) of this title constitutes not less than 10 percent of the number of such cases reported for the eligible area.

(b) HIV health services planning council

(1) Establishment

To be eligible for assistance under this subpart, the chief elected official described in subsection (a)(1) shall establish or designate an HIV health services planning council that shall reflect in its composition the demographics of the population of individuals with HIV/AIDS in the eligible area involved, with particular consideration given to disproportionately affected and historically underserved groups and subpopulations. Nominations for membership on the council shall be identified through an open process and candidates shall be selected based on locally delineated and publicized criteria. Such criteria shall include a conflict-of-interest standard that is in accordance with paragraph (5).

(2) Representation

The HIV health services planning council shall include representatives of—

(A) health care providers, including federally qualified health centers;

(B) community-based organizations serving affected populations and AIDS service organizations;

(C) social service providers, including providers of housing and homeless services;

(D) mental health and substance abuse providers;

(E) local public health agencies;

(F) hospital planning agencies or health care planning agencies;

(G) affected communities, including people with HIV/AIDS, members of a Federally recognized Indian tribe as represented in the population, individuals co-infected with hepatitis B or C and historically underserved groups and subpopulations;

(H) nonelected community leaders;

(I) State government (including the State medicaid agency and the agency administering the program under part B);

(J) grantees under subpart II [1] of part C;

(K) grantees under section 300ff–71 of this title, or, if none are operating in the area, representatives of organizations with a history of serving children, youth, women, and families living with HIV and operating in the area;

(L) grantees under other Federal HIV programs, including but not limited to providers of HIV prevention services; and

(M) representatives of individuals who formerly were Federal, State, or local prisoners, were released from the custody of the penal system during the preceding 3 years, and had HIV/AIDS as of the date on which the individuals were so released.

(3) Method of providing for council

(A) In general

In providing for a council for purposes of paragraph (1), a chief elected official receiving a grant under section 300ff–11(a) of this title may establish the council directly or designate an existing entity to serve as the council, subject to subparagraph (B).

(B) Consideration regarding designation of council

In making a determination of whether to establish or designate a council under subparagraph (A), a chief elected official receiving a grant under section 300ff–11(a) of this title shall give priority to the designation of an existing entity that has demonstrated experience in planning for the HIV health care service needs within the eligible area and in the implementation of such plans in addressing those needs. Any existing entity so designated shall be expanded to include

a broad representation of the full range of entities that provide such services within the geographic area to be served.

(4) Duties

The planning council established or designated under paragraph (1) shall—

(A) determine the size and demographics of the population of individuals with HIV/AIDS, as well as the size and demographics of the estimated population of individuals with HIV/AIDS who are unaware of their HIV status;

(B) determine the needs of such population, with particular attention to—

(i) individuals with HIV/AIDS who know their HIV status and are not receiving HIV-related services;

(ii) disparities in access and services among affected subpopulations and historically underserved communities; and

(iii) individuals with HIV/AIDS who do not know their HIV status;

(C) establish priorities for the allocation of funds within the eligible area, including how best to meet each such priority and additional factors that a grantee should consider in allocating funds under a grant based on the—

(i) size and demographics of the population of individuals with HIV/AIDS (as determined under subparagraph (A)) and the needs of such population (as determined under subparagraph (B));

(ii) demonstrated (or probable) cost effectiveness and outcome effectiveness of proposed strategies and interventions, to the extent that data are reasonably available;

(iii) priorities of the communities with HIV/AIDS for whom the services are intended;

(iv) coordination in the provision of services to such individuals with programs for HIV prevention and for the prevention and treatment of substance abuse, including programs that provide comprehensive treatment for such abuse;

(v) availability of other governmental and non-governmental resources, including the State medicaid plan under title XIX of the Social Security Act [42 U.S.C. 1396 et seq.] and the State Children's Health Insurance Program under title XXI of such Act [42 U.S.C. 1397aa et seq.] to cover health care costs of eligible individuals and families with HIV/AIDS; and

(vi) capacity development needs resulting from disparities in the availability of HIV-related services in historically underserved communities;

(D) develop a comprehensive plan for the organization and delivery of health and support services described in section 300ff–14 of this title that—

(i) includes a strategy for identifying individuals who know their HIV status and are not receiving such services and for informing the individuals of and enabling the individuals to utilize the services, giving particular attention to eliminating disparities in access and services among affected subpopulations and historically underserved communities, and including discrete goals, a timetable, and an appropriate allocation of funds;

(ii) includes a strategy to coordinate the provision of such services with programs for HIV prevention (including outreach and early intervention) and for the prevention and treatment of substance abuse (including programs that provide comprehensive treatment services for such abuse);

(iii) is compatible with any State or local plan for the provision of services to individuals with HIV/AIDS; and

(iv) includes a strategy, coordinated as appropriate with other community strategies and efforts, including discrete goals, a timetable, and appropriate funding, for identifying individuals with HIV/AIDS who do not know their HIV status, making such individuals aware of such status, and enabling such individuals to use the health and support services described in section 300ff–14 of this title, with particular attention to reducing barriers to routine testing and disparities in access and services among affected subpopulations and historically underserved communities;

(E) assess the efficiency of the administrative mechanism in rapidly allocating funds to the areas of greatest need within the eligible area, and at the discretion of the planning council, assess the effectiveness, either directly or through contractual arrangements, of the services offered in meeting the identified needs;

(F) participate in the development of the statewide coordinated statement of need initiated by the State public health agency responsible for administering grants under part B;

(G) establish methods for obtaining input on community needs and priorities which may include public meetings (in accordance with paragraph (7)), conducting focus groups, and convening ad-hoc panels; and

(H) coordinate with Federal grantees that provide HIV-related services within the eligible area.

(5) Conflicts of interest

(A) In general

The planning council under paragraph (1) may not be directly involved in the administration of a grant under section 300ff–11(a) of this title. With respect to compliance with the preceding sentence, the planning council may not designate (or otherwise be involved in the selection of) particular entities as recipients of any of the amounts provided in the grant.

(B) Required agreements

An individual may serve on the planning council under paragraph (1) only if the individual agrees that if the individual has a financial interest in an entity, if the individual is an employee of a public or private entity, or if the individual is a member of a public or private organization, and such entity or organization is seeking amounts from a grant under section 300ff–11(a) of this title, the individual will not, with respect to the purpose for which the entity seeks such amounts, participate (directly or in an advisory capacity) in the process of selecting entities to receive such amounts for such purpose.

(C) Composition of council

The following applies regarding the membership of a planning council under paragraph (1):

(i) Not less than 33 percent of the council shall be individuals who are receiving HIV-related services pursuant to a grant under section 300ff–11(a) of this title, are not officers, employees, or consultants to any entity that receives amounts from such a grant, and do not represent any such entity, and reflect the demographics of the population of individuals with HIV/AIDS as determined under paragraph (4)(A). For purposes of the preceding sentence, an individual shall be considered to be receiving such services if the individual is a parent of, or a caregiver for, a minor child who is receiving such services.

(ii) With respect to membership on the planning council, clause (i) may not be construed as having any effect on entities that receive funds from grants under any of parts B through F but do not receive funds from grants under section 300ff–11(a) of this title, on officers or employees of such entities, or on individuals who represent such entities.

(6) Grievance procedures

A planning council under paragraph (1) shall develop procedures for addressing grievances with respect to funding under this subpart, including procedures for submitting grievances that cannot be resolved to binding arbitration. Such procedures shall be described in the by-laws of the planning council and be consistent with the requirements of subsection (c).

(7) Public deliberations

With respect to a planning council under paragraph (1), the following applies:

(A) The council may not be chaired solely by an employee of the grantee under section 300ff–11(a) of this title.

(B) In accordance with criteria established by the Secretary:

(i) The meetings of the council shall be open to the public and shall be held only after

adequate notice to the public.

(ii) The records, reports, transcripts, minutes, agenda, or other documents which were made available to or prepared for or by the council shall be available for public inspection and copying at a single location.

(iii) Detailed minutes of each meeting of the council shall be kept. The accuracy of all minutes shall be certified to by the chair of the council.

(iv) This subparagraph does not apply to any disclosure of information of a personal nature that would constitute a clearly unwarranted invasion of personal privacy, including any disclosure of medical information or personnel matters.

(c) Grievance procedures

(1) Federal responsibility

(A) Models

The Secretary shall, through a process that includes consultations with grantees under this subpart and public and private experts in grievance procedures, arbitration, and mediation, develop model grievance procedures that may be implemented by the planning council under subsection (b)(1) and grantees under this subpart. Such model procedures shall describe the elements that must be addressed in establishing local grievance procedures and provide grantees with flexibility in the design of such local procedures.

(B) Review

The Secretary shall review grievance procedures established by the planning council and grantees under this subpart to determine if such procedures are adequate. In making such a determination, the Secretary shall assess whether such procedures permit legitimate grievances to be filed, evaluated, and resolved at the local level.

(2) Grantees

To be eligible to receive funds under this subpart, a grantee shall develop grievance procedures that are determined by the Secretary to be consistent with the model procedures developed under paragraph (1)(A). Such procedures shall include a process for submitting grievances to binding arbitration.

(d) Process for establishing allocation priorities

Promptly after the date of the submission of the report required in section 501(b) of the Ryan White CARE Act Amendments of 2000 (relating to the relationship between epidemiological measures and health care for certain individuals with HIV/AIDS), the Secretary, in consultation with planning councils and entities that receive amounts from grants under section 300ff–11(a) or 300ff–21 of this title, shall develop epidemiologic measures—

(1) for establishing the number of individuals living with HIV/AIDS who are not receiving HIV-related health services; and

(2) for carrying out the duties under subsection (b)(4) and section 300ff–27(b) of this title.

(e) Training guidance and materials

The Secretary shall provide to each chief elected official receiving a grant under section 300ff–11(a) of this title guidelines and materials for training members of the planning council under paragraph (1) regarding the duties of the council.

(July 1, 1944, ch. 373, title XXVI, §2602, as added Pub. L. 101–381, title I, §101(3), Aug. 18, 1990, 104 Stat. 577; amended Pub. L. 102–531, title III, §312(d)(26), Oct. 27, 1992, 106 Stat. 3505; Pub. L. 104–146, §3(b)(1), May 20, 1996, 110 Stat. 1347; Pub. L. 106–345, title I, §§101–102(c), 103, Oct. 20, 2000, 114 Stat. 1320–1323; Pub. L. 109–415, title I, §§106(b), 107(b), title VII, §§702(3), 703, Dec. 19, 2006, 120 Stat. 2780, 2783, 2820; Pub. L. 111–87, §§2(a)(1), (3)(A), 6(a), Oct. 30, 2009, 123 Stat. 2885, 2891.)

EDITORIAL NOTES

REFERENCES IN TEXT

Subpart II of part C, referred to in subsec. (b)(2)(J), was redesignated subpart I of part C of this subchapter by Pub. L. 106–345, title III, §301(b)(1), Oct. 20, 2000, 114 Stat. 1345, and is classified to section 300ff–51 et seq. of this title.

The Social Security Act, referred to in subsec. (b)(4)(C)(v), is act Aug. 14, 1935, ch. 531, 49 Stat. 620. Titles XIX and XXI of the Act are classified generally to subchapters XIX (§1396 et seq.) and XXI (§1397aa et seq.), respectively, of chapter 7 of this title. For complete classification of this Act to the Code, see section 1305 of this title and Tables.

Section 501 of the Ryan White CARE Act Amendments of 2000, referred to in subsec. (d), is section 501 of Pub. L. 106–345, which is set out as a note under section 300ff–11 of this title. Provisions relating to a report are contained in section 501(d) of Pub. L. 106–345.

PRIOR PROVISIONS

A prior section 2602 of act July 1, 1944, was successively renumbered by subsequent acts and transferred, see section 238a of this title.

AMENDMENTS

2009—Pub. L. 111–87, §2(a)(1), (3)(A), repealed Pub. L. 109–415, §703, and revived the provisions of this section as in effect on Sept. 30, 2009. See 2006 Amendment note and Effective Date of 2009 Amendment; Revival of Section note below.

Subsec. (b)(4)(A). Pub. L. 111–87, §6(a)(1), inserted ", as well as the size and demographics of the estimated population of individuals with HIV/AIDS who are unaware of their HIV status" before semicolon.

Subsec. (b)(4)(B)(iii). Pub. L. 111–87, §6(a)(2), added cl. (iii).

Subsec. (b)(4)(D)(iv). Pub. L. 111–87, §6(a)(3), added cl. (iv).

2006—Pub. L. 109–415, §703, which directed repeal of this section effective Oct. 1, 2009, was itself repealed by Pub. L. 111–87, §2(a)(1), effective Sept. 30, 2009.

Pub. L. 109–415, §702(3), substituted "HIV/AIDS" for "HIV disease" wherever appearing.

Pub. L. 109–415, §107(b), substituted "this subpart" for "this part" wherever appearing.

Subsec. (b)(2)(G). Pub. L. 109–415, §106(b), inserted ", members of a Federally recognized Indian tribe as represented in the population, individuals co-infected with hepatitis B or C" before "and historically underserved groups".

2000—Subsec. (b)(1). Pub. L. 106–345, §101(a)(1), substituted "demographics of the population of individuals with HIV disease in the eligible area involved," for "demographics of the epidemic in the eligible area involved,".

Subsec. (b)(2)(C). Pub. L. 106–345, §101(a)(2)(A), inserted before semicolon at end ", including providers of housing and homeless services".

Subsec. (b)(2)(G). Pub. L. 106–345, §101(a)(2)(B), struck out "or AIDS" after "HIV disease".

Subsec. (b)(2)(K). Pub. L. 106–345, §101(a)(2)(C), struck out "and" after semicolon.

Subsec. (b)(2)(L). Pub. L. 106–345, §101(a)(2)(D), substituted ", including but not limited to providers of HIV prevention services; and" for period at end.

Subsec. (b)(2)(M). Pub. L. 106–345, §101(a)(2)(E), added subpar. (M).

Subsec. (b)(3)(C). Pub. L. 106–345, §103(1), struck out heading and text of subpar. (C). Text read as follows: "A planning council may not be chaired solely by an employee of the grantee."

Subsec. (b)(4)(A), (B). Pub. L. 106–345, §102(a)(2), added subpars. (A) and (B). Former subpars. (A) and (B) redesignated (C) and (D), respectively.

Subsec. (b)(4)(C). Pub. L. 106–345, §102(a)(1), redesignated subpar. (A) as (C). Former subpar. (C) redesignated (E).

Subsec. (b)(4)(C)(i) to (vi). Pub. L. 106–345, §102(a)(3), added cls. (i) to (vi) and struck out former cls. (i) to (iv) which read as follows:

"(i) documented needs of the HIV-infected population;

"(ii) cost and outcome effectiveness of proposed strategies and interventions, to the extent that such data are reasonably available (either demonstrated or probable);

"(iii) priorities of the HIV-infected communities for whom the services are intended; and

"(iv) availability of other governmental and nongovernmental resources;".

Subsec. (b)(4)(D). Pub. L. 106–345, §102(a)(4), amended subpar. (D) generally. Prior to amendment, subpar. (D) read as follows: "develop a comprehensive plan for the organization and delivery of health services described in section 300ff–14 of this title that is compatible with any existing State or local plan regarding the provision of health services to individuals with HIV disease;".

Pub. L. 106–345, §102(a)(1), redesignated subpar. (B) as (D). Former subpar. (D) redesignated (F).

Subsec. (b)(4)(E), (F). Pub. L. 106–345, §102(a)(1), redesignated subpars. (C) and (D) as (E) and (F), respectively. Former subpar. (E) redesignated (G).

Subsec. (b)(4)(G). Pub. L. 106–345, §102(a)(1), (6)(A), redesignated subpar. (E) as (G) and substituted "public meetings (in accordance with paragraph (7))," for "public meetings,".

Subsec. (b)(4)(H). Pub. L. 106–345, §102(a)(5), (6)(B), (7), added subpar. (H).

Subsec. (b)(5)(C). Pub. L. 106–345, §101(b), added subpar. (C).

Subsec. (b)(7). Pub. L. 106–345, §103(2), added par. (7).

Subsec. (d). Pub. L. 106–345, §102(b), added subsec. (d).

Subsec. (e). Pub. L. 106–345, §102(c), added subsec. (e).

1996—Subsec. (b)(1). Pub. L. 104–146, §3(b)(1)(A)(ii), inserted at end "Nominations for membership on the council shall be identified through an open process and candidates shall be selected based on locally delineated and publicized criteria. Such criteria shall include a conflict-of-interest standard that is in accordance with paragraph (5)."

Pub. L. 104–146, §3(b)(1)(A)(i), substituted "reflect in its composition the demographics of the epidemic in the eligible area involved, with particular consideration given to disproportionately affected and historically underserved groups and subpopulations." for "include representatives of—

"(A) health care providers;

"(B) community-based and AIDS service organizations;

"(C) social service providers;

"(D) mental health care providers;

"(E) local public health agencies;

"(F) hospital planning agencies or health care planning agencies;

"(G) affected communities, including individuals with HIV disease;

"(H) non-elected community leaders;

"(I) State government;

"(J) grantees under subpart II of part C of this subchapter; and

"(K) the lead agency of any Health Resources and Services Administration adult and pediatric HIV-related care demonstration project operating in the area to be served."

Subsec. (b)(2). Pub. L. 104–146, §3(b)(1)(E), added par. (2). Former par. (2) redesignated (3).

Subsec. (b)(2)(C). Pub. L. 104–146, §3(b)(1)(B), added subpar. (C).

Subsec. (b)(3). Pub. L. 104–146, §3(b)(1)(D), redesignated par. (2) as (3). Former par. (3) redesignated (4).

Subsec. (b)(3)(A). Pub. L. 104–146, §3(b)(1)(C)(i), substituted "area, including how best to meet each such priority and additional factors that a grantee should consider in allocating funds under a grant based on the—" for "area;" and added cls. (i) to (iv).

Subsec. (b)(3)(B). Pub. L. 104–146, §3(b)(1)(C)(ii), struck out "and" at end.

Subsec. (b)(3)(C). Pub. L. 104–146, §3(b)(1)(C)(iii), substituted ", and at the discretion of the planning council, assess the effectiveness, either directly or through contractual arrangements, of the services offered in meeting the identified needs;" for period at end.

Subsec. (b)(3)(D), (E). Pub. L. 104–146, §3(b)(1)(C)(iv), added subpars. (D) and (E).

Subsec. (b)(4). Pub. L. 104–146, §3(b)(1)(D), redesignated par. (3) as (4).

Subsec. (b)(5), (6). Pub. L. 104–146, §3(b)(1)(F), added pars. (5) and (6).

Subsec. (c). Pub. L. 104–146, §3(b)(1)(F), added subsec. (c).

1992—Subsec. (a)(1). Pub. L. 102–531 substituted "Centers for Disease Control and Prevention" for "Centers for Disease Control".

STATUTORY NOTES AND RELATED SUBSIDIARIES

EFFECTIVE DATE OF 2009 AMENDMENT; REVIVAL OF SECTION

For provisions that repeal by section 2(a)(1) of Pub. L. 111–87 of section 703 of Pub. L. 109–415 be effective Sept. 30, 2009, that the provisions of this section as in effect on Sept. 30, 2009, be revived, and that amendment by section 6(a) of Pub. L. 111–87 be applicable to this section as so revived and effective as if enacted on Sept. 30, 2009, see section 2(a)(2), (3) of Pub. L. 111–87, set out as a note under section 300ff–11 of this title.

EFFECTIVE DATE OF 2000 AMENDMENT

Pub. L. 106–345, title VI, §601, Oct. 20, 2000, 114 Stat. 1355, provided that: "This Act [see section 1 of Pub. L. 106–345, set out as a Short Title of 2000 Amendments note under section 201 of this title] and the

amendments made by this Act take effect October 1, 2000, or upon the date of the enactment of this Act [Oct. 20, 2000], whichever occurs later."

EFFECTIVE DATE OF 1996 AMENDMENT

Amendment by Pub. L. 104–146 effective Oct. 1, 1996, see section 13 of Pub. L. 104–146, set out as a note under section 300ff–11 of this title.

[1] *See References in Text note below.*

§300ff–13. Type and distribution of grants

(a) Grants based on relative need of area

(1) In general

In carrying out section 300ff–11(a) of this title, the Secretary shall make a grant for each eligible area for which an application under section 300ff–15(a) of this title has been approved. Each such grant shall be made in an amount determined in accordance with paragraph (3).

(2) Expedited distribution

Not later than 60 days after an appropriation becomes available to carry out this subpart for a fiscal year, the Secretary shall, except in the case of waivers granted under section 300ff–15(c) [1] of this title, disburse 662/3 percent of the amount made available under section 300ff–20(b) of this title for carrying out this subpart for such fiscal year through grants to eligible areas under section 300ff–11(a) of this title, in accordance with paragraphs (3) and (4).

(3) Amount of grant

(A) In general

Subject to the extent of amounts made available in appropriations Acts, a grant made for purposes of this paragraph to an eligible area shall be made in an amount equal to the product of—

(i) an amount equal to the amount available for distribution under paragraph (2) for the fiscal year involved; and

(ii) the percentage constituted by the ratio of the distribution factor for the eligible area to the sum of the respective distribution factors for all eligible areas;

which product shall then, as applicable, be increased under paragraph (4).

(B) Distribution factor

For purposes of subparagraph (A)(ii), the term "distribution factor" means an amount equal to the living cases of HIV/AIDS (reported to and confirmed by the Director of the Centers for Disease Control and Prevention) in the eligible area involved, as determined under subparagraph (C).

(C) Living cases of HIV/AIDS

(i) Requirement of names-based reporting

Except as provided in clause (ii), the number determined under this subparagraph for an eligible area for a fiscal year for purposes of subparagraph (B) is the number of living names-based cases of HIV/AIDS that, as of December 31 of the most recent calendar year for which such data is available, have been reported to and confirmed by the Director of the Centers for Disease Control and Prevention.

(ii) Transition period; exemption regarding non-AIDS cases

For each of the fiscal years 2007 through 2012, an eligible area is, subject to clauses (iii) through (v), exempt from the requirement under clause (i) that living names-based non-AIDS

cases of HIV be reported unless—

(I) a system was in operation as of December 31, 2005, that provides sufficiently accurate and reliable names-based reporting of such cases throughout the State in which the area is located, subject to clause (viii); or

(II) no later than the beginning of fiscal year 2008 or a subsequent fiscal year through fiscal year 2012, the Secretary, in consultation with the chief executive of the State in which the area is located, determines that a system has become operational in the State that provides sufficiently accurate and reliable names-based reporting of such cases throughout the State.

(iii) Requirements for exemption for fiscal year 2007

For fiscal year 2007, an exemption under clause (ii) for an eligible area applies only if, by October 1, 2006—

(I)(aa) the State in which the area is located had submitted to the Secretary a plan for making the transition to sufficiently accurate and reliable names-based reporting of living non-AIDS cases of HIV; or

(bb) all statutory changes necessary to provide for sufficiently accurate and reliable reporting of such cases had been made; and

(II) the State had agreed that, by April 1, 2008, the State will begin accurate and reliable names-based reporting of such cases, except that such agreement is not required to provide that, as of such date, the system for such reporting be fully sufficient with respect to accuracy and reliability throughout the area.

(iv) Requirement for exemption as of fiscal year 2008

For each of the fiscal years 2008 through 2012, an exemption under clause (ii) for an eligible area applies only if, as of April 1, 2008, the State in which the area is located is substantially in compliance with the agreement under clause (iii)(II).

(v) Progress toward names-based reporting

For fiscal year 2009 or a subsequent fiscal year, the Secretary may terminate an exemption under clause (ii) for an eligible area if the State in which the area is located submitted a plan under clause (iii)(I)(aa) and the Secretary determines that the State is not substantially following the plan.

(vi) Counting of cases in areas with exemptions

(I) In general

With respect to an eligible area that is under a reporting system for living non-AIDS cases of HIV that is not names-based (referred to in this subparagraph as "code-based reporting"), the Secretary shall, for purposes of this subparagraph, modify the number of such cases reported for the eligible area in order to adjust for duplicative reporting in and among systems that use code-based reporting.

(II) Adjustment rate

The adjustment rate under subclause (I) for an eligible area shall be a reduction of 5 percent for fiscal years before fiscal year 2012 (and 6 percent for fiscal year 2012) in the number of living non-AIDS cases of HIV reported for the area.

(III) Increased adjustment for certain areas previously using code-based reporting

For purposes of this subparagraph for each of fiscal years 2010 through 2012, the Secretary shall deem the applicable number of living cases of HIV/AIDS in an area that were reported to and confirmed by the Centers for Disease Control and Prevention to be 3 percent higher than the actual number if—

(aa) for fiscal year 2007, such area was a transitional area;

(bb) fiscal year 2007 was the first year in which the count of living non-AIDS cases of HIV in such area, for purposes of this section, was based on a names-based reporting

system; and

(cc) the amount of funding that such area received under this part for fiscal year 2007 was less than 70 percent of the amount of funding (exclusive of funds that were identified as being for purposes of the Minority AIDS Initiative) that such area received under such part for fiscal year 2006.

(vii) Multiple political jurisdictions

With respect to living non-AIDS cases of HIV, if an eligible area is not entirely within one political jurisdiction and as a result is subject to more than one reporting system for purposes of this subparagraph:

(I) Names-based reporting under clause (i) applies in a jurisdictional portion of the area, or an exemption under clause (ii) applies in such portion (subject to applicable provisions of this subparagraph), according to whether names-based reporting or code-based reporting is used in such portion.

(II) If under subclause (I) both names-based reporting and code-based reporting apply in the area, the number of code-based cases shall be reduced under clause (vi).

(viii) List of eligible areas meeting standard regarding December 31, 2005

(I) In general

If an eligible area or portion thereof is in a State specified in subclause (II), the eligible area or portion shall be considered to meet the standard described in clause (ii)(I). No other eligible area or portion thereof may be considered to meet such standard.

(II) Relevant States

For purposes of subclause (I), the States specified in this subclause are the following: Alaska, Alabama, Arkansas, Arizona, Colorado, Florida, Indiana, Iowa, Idaho, Kansas, Louisiana, Michigan, Minnesota, Missouri, Mississippi, North Carolina, North Dakota, Nebraska, New Jersey, New Mexico, New York, Nevada, Ohio, Oklahoma, South Carolina, South Dakota, Tennessee, Texas, Utah, Virginia, Wisconsin, West Virginia, Wyoming, Guam, and the Virgin Islands.

(ix) Rules of construction regarding acceptance of reports

(I) Cases of AIDS

With respect to an eligible area that is subject to the requirement under clause (i) and is not in compliance with the requirement for names-based reporting of living non-AIDS cases of HIV, the Secretary shall, notwithstanding such noncompliance, accept reports of living cases of AIDS that are in accordance with such clause.

(II) Applicability of exemption requirements

The provisions of clauses (ii) through (viii) may not be construed as having any legal effect for fiscal year 2013 or any subsequent fiscal year, and accordingly, the status of a State for purposes of such clauses may not be considered after fiscal year 2012.

(x) Program for detecting inaccurate or fraudulent counting

The Secretary shall carry out a program to monitor the reporting of names-based cases for purposes of this subparagraph and to detect instances of inaccurate reporting, including fraudulent reporting.

(xi) Future fiscal years

For fiscal years beginning with fiscal year 2013, determinations under this paragraph shall be based only on living names-based cases of HIV/AIDS with respect to the area involved.

(D) Code-based areas; limitation on increase in grant

(i) In general

For each of the fiscal years 2007 through 2012, if code-based reporting (within the

meaning of subparagraph (C)(vi)) applies in an eligible area or any portion thereof as of the beginning of the fiscal year involved, then notwithstanding any other provision of this paragraph, the amount of the grant pursuant to this paragraph for such area for such fiscal year may not—

(I) for fiscal year 2007, exceed by more than 5 percent the amount of the grant for the area that would have been made pursuant to this paragraph and paragraph (4) for fiscal year 2006 (as such paragraphs were in effect for such fiscal year) if paragraph (2) (as so in effect) had been applied by substituting "662/3 percent" for "50 percent"; and

(II) for each of the fiscal years 2008 through 2012, exceed by more than 5 percent the amount of the grant pursuant to this paragraph and paragraph (4) for the area for the preceding fiscal year.

(ii) Use of amounts involved

For each of the fiscal years 2007 through 2012, amounts available as a result of the limitation under clause (i) shall be made available by the Secretary as additional amounts for grants pursuant to subsection (b) for the fiscal year involved, subject to paragraph (4) and section 300ff–20(d)(2) of this title.

(4) Increases in grant

(A) In general

For each eligible area that received a grant pursuant to this subsection for fiscal year 2009, the Secretary shall, for each of the fiscal years 2010 through 2013, increase the amount of the grant made pursuant to paragraph (3) for the area to ensure that the amount of the grant for the fiscal year involved is not less than the following amount, as applicable to such fiscal year:

(i) For fiscal year 2010, an amount equal to 95 percent of the sum of the amount of the grant made pursuant to paragraph (3) and this paragraph for fiscal year 2009.

(ii) For each of the fiscal years 2011 and 2012, an amount equal to 100 percent of the amount of the grant made pursuant to paragraph (3) and this paragraph for fiscal year 2010.

(iii) For fiscal year 2013, an amount equal to 92.5 percent of the amount of the grant made pursuant to paragraph (3) and this paragraph for fiscal year 2012.

(B) Source of funds for increase

(i) In general

From the amounts available for carrying out the single program referred to in section 300ff–19(d)(2)(C) of this title for a fiscal year (relating to supplemental grants), the Secretary shall make available such amounts as may be necessary to comply with subparagraph (A), subject to section 300ff–20(d)(2) of this title.

(ii) Pro rata reduction

If the amounts referred to in clause (i) for a fiscal year are insufficient to fully comply with subparagraph (A) for the year, the Secretary, in order to provide the additional funds necessary for such compliance, shall reduce on a pro rata basis the amount of each grant pursuant to this subsection for the fiscal year, other than grants for eligible areas for which increases under subparagraph (A) apply. A reduction under the preceding sentence may not be made in an amount that would result in the eligible area involved becoming eligible for such an increase.

(C) Limitation

This paragraph may not be construed as having any applicability after fiscal year 2013.

(b) Supplemental grants

(1) In general

Subject to subsection (a)(4)(B)(i) and section 300ff–20(d) of this title, the Secretary shall disburse the remainder of amounts not disbursed under subsection (a)(2) for such fiscal year for

the purpose of making grants under section 300ff–11(a) of this title to eligible areas whose application under section 300ff–15(b) of this title—

(A) contains a report concerning the dissemination of emergency relief funds under subsection (a) and the plan for utilization of such funds;

(B) demonstrates the need in such area, on an objective and quantified basis, for supplemental financial assistance to combat the HIV epidemic;

(C) demonstrates the existing commitment of local resources of the area, both financial and in-kind, to combating the HIV epidemic;

(D) demonstrates the ability of the area to utilize such supplemental financial resources in a manner that is immediately responsive and cost effective;

(E) demonstrates that resources will be allocated in accordance with the local demographic incidence of AIDS including appropriate allocations for services for infants, children, youth, women, and families with HIV/AIDS;

(F) demonstrates the inclusiveness of affected communities and individuals with HIV/AIDS;

(G) demonstrates the manner in which the proposed services are consistent with the local needs assessment and the statewide coordinated statement of need;

(H) demonstrates the ability of the applicant to expend funds efficiently by not having had, for the most recent grant year under subsection (a) for which data is available, more than 5 percent of grant funds under such subsection canceled, offset under subsection (c)(4), or covered by any waivers under subsection (c)(3); and

(I) demonstrates success in identifying individuals with HIV/AIDS as described in clauses (i) through (iii) of paragraph (2)(A).

(2) Amount of grant

(A) In general

The amount of each grant made for purposes of this subsection shall be determined by the Secretary based on a weighting of factors under paragraph (1), with demonstrated need under subparagraph (B) of such paragraph counting one-third, and demonstrated success in identifying individuals with HIV/AIDS who do not know their HIV status and making them aware of such status counting one-third. In making such determination, the Secretary shall consider—

(i) the number of individuals who have been tested for HIV/AIDS;

(ii) of those individuals described in clause (i), the number of individuals who tested for HIV/AIDS who are made aware of their status, including the number who test positive; and

(iii) of those individuals described in clause (ii), the number who have been referred to appropriate treatment and care.

(B) Demonstrated need

The factors considered by the Secretary in determining whether an eligible area has a demonstrated need for purposes of paragraph (1)(B) may include any or all of the following:

(i) The unmet need for such services, as determined under section 300ff–12(b)(4) of this title or other community input process as defined under section 300ff–19(d)(1)(A) of this title.

(ii) An increasing need for HIV/AIDS-related services, including relative rates of increase in the number of cases of HIV/AIDS.

(iii) The relative rates of increase in the number of cases of HIV/AIDS within new or emerging subpopulations.

(iv) The current prevalence of HIV/AIDS.

(v) Relevant factors related to the cost and complexity of delivering health care to individuals with HIV/AIDS in the eligible area.

(vi) The impact of co-morbid factors, including co-occurring conditions, determined relevant by the Secretary.

(vii) The prevalence of homelessness.

(viii) The prevalence of individuals described under section 300ff–12(b)(2)(M) of this title.

(ix) The relevant factors that limit access to health care, including geographic variation,

adequacy of health insurance coverage, and language barriers.

(x) The impact of a decline in the amount received pursuant to subsection (a) on services available to all individuals with HIV/AIDS identified and eligible under this subchapter.

(C) Priority in making grants

The Secretary shall provide funds under this subsection to an eligible area to address the decline or disruption of all EMA-provided services related to the decline in the amounts received pursuant to subsection (a) consistent with the grant award for the eligible area for fiscal year 2006, to the extent that the factor under subparagraph (B)(x) (relating to a decline in funding) applies to the eligible area.

(D) Increased adjustment for certain areas previously using code-based reporting

For purposes of this subsection for each of fiscal years 2010 through 2012, the Secretary shall deem the applicable number of living cases of HIV/AIDS in an area that were reported to and confirmed by the Centers for Disease Control and Prevention to be 3 percent higher than the actual number if the conditions described in items (aa) through (cc) of subsection (a)(3)(C)(vi)(III) are all satisfied.

(3) Remainder of amounts

In determining the amount of funds to be obligated under paragraph (1), the Secretary shall include amounts that are not paid to the eligible areas under expedited procedures under subsection (a)(2) as a result of—

(A) the failure of any eligible area to submit an application under section 300ff–15(c) [1] of this title; or

(B) any eligible area informing the Secretary that such eligible area does not intend to expend the full amount of its grant under such section.

(4) Failure to submit

(A) In general

The failure of an eligible area to submit an application for an expedited grant under subsection (a)(2) shall not result in such area being ineligible for a grant under this subsection.

(B) Application

The application of an eligible area submitted under section 300ff–15(b) of this title shall contain the assurances required under subsection (a) of such section if such eligible area fails to submit an application for an expedited grant under subsection (a)(2).

(c) Timeframe for obligation and expenditure of grant funds

(1) Obligation by end of grant year

Effective for fiscal year 2007 and subsequent fiscal years, funds from a grant award made pursuant to subsection (a) or (b) for a fiscal year are available for obligation by the eligible area involved through the end of the one-year period beginning on the date in such fiscal year on which funds from the award first become available to the area (referred to in this subsection as the "grant year for the award"), except as provided in paragraph (3)(A).

(2) Supplemental grants; cancellation of unobligated balance of grant award

Effective for fiscal year 2007 and subsequent fiscal years, if a grant award made pursuant to subsection (b) for an eligible area for a fiscal year has an unobligated balance as of the end of the grant year for the award—

(A) the Secretary shall cancel that unobligated balance of the award, and shall require the eligible area to return any amounts from such balance that have been disbursed to the area; and

(B) the funds involved shall be made available by the Secretary as additional amounts for grants pursuant to subsection (b) for the first fiscal year beginning after the fiscal year in which

the Secretary obtains the information necessary for determining that the balance is required under subparagraph (A) to be canceled, except that the availability of the funds for such grants is subject to subsection (a)(4) and section 300ff–20(d)(2) of this title as applied for such year.

(3) Formula grants; cancellation of unobligated balance of grant award; waiver permitting carryover

(A) In general

Effective for fiscal year 2007 and subsequent fiscal years, if a grant award made pursuant to subsection (a) for an eligible area for a fiscal year has an unobligated balance as of the end of the grant year for the award, the Secretary shall cancel that unobligated balance of the award, and shall require the eligible area to return any amounts from such balance that have been disbursed to the area, unless—

(i) before the end of the grant year, the chief elected official of the area submits to the Secretary a written application for a waiver of the cancellation, which application includes a description of the purposes for which the area intends to expend the funds involved; and

(ii) the Secretary approves the waiver.

(B) Expenditure by end of carryover year

With respect to a waiver under subparagraph (A) that is approved for a balance that is unobligated as of the end of a grant year for an award:

(i) The unobligated funds are available for expenditure by the eligible area involved for the one-year period beginning upon the expiration of the grant year (referred to in this subsection as the "carryover year").

(ii) If the funds are not expended by the end of the carryover year, the Secretary shall cancel that unexpended balance of the award, and shall require the eligible area to return any amounts from such balance that have been disbursed to the area.

(C) Use of cancelled balances

In the case of any balance of a grant award that is cancelled under subparagraph (A) or (B)(ii), the grant funds involved shall be made available by the Secretary as additional amounts for grants pursuant to subsection (b) for the first fiscal year beginning after the fiscal year in which the Secretary obtains the information necessary for determining that the balance is required under such subparagraph to be canceled, except that the availability of the funds for such grants is subject to subsection (a)(4) and section 300ff–20(d)(2) of this title as applied for such year.

(D) Corresponding reduction in future grant

(i) In general

In the case of an eligible area for which a balance from a grant award under subsection (a) is unobligated as of the end of the grant year for the award—

(I) the Secretary shall reduce, by the same amount as such unobligated balance (less any amount of such balance that is the subject of a waiver of cancellation under subparagraph (A)), the amount of the grant under such subsection for the first fiscal year beginning after the fiscal year in which the Secretary obtains the information necessary for determining that such balance was unobligated as of the end of the grant year (which requirement for a reduction applies without regard to whether a waiver under subparagraph (A) has been approved with respect to such balance); and

(II) the grant funds involved in such reduction shall be made available by the Secretary as additional funds for grants pursuant to subsection (b) for such first fiscal year, subject to subsection (a)(4) and section 300ff–20(d)(2) of this title;

except that this clause does not apply to the eligible area if the amount of the unobligated balance was 5 percent or less.

(ii) Relation to increases in grant

A reduction under clause (i) for an eligible area for a fiscal year may not be taken into account in applying subsection (a)(4) with respect to the area for the subsequent fiscal year.

(4) Authority regarding administration of provisions

In administering paragraphs (2) and (3) with respect to the unobligated balance of an eligible area, the Secretary may elect to reduce the amount of future grants to the area under subsection (a) or (b), as applicable, by the amount of any such unobligated balance in lieu of cancelling such amount as provided for in paragraph (2) or (3)(A). In such case, the Secretary may permit the area to use such unobligated balance for purposes of any such future grant. An amount equal to such reduction shall be available for use as additional amounts for grants pursuant to subsection (b), subject to subsection (a)(4) and section 300ff–20(d)(2) of this title. Nothing in this paragraph shall be construed to affect the authority of the Secretary under paragraphs (2) and (3), including the authority to grant waivers under paragraph (3)(A). The reduction in future grants authorized under this paragraph shall be notwithstanding the penalty required under paragraph (3)(D) with respect to unobligated funds.

(d) Compliance with priorities of HIV planning council

Notwithstanding any other provision of this subpart, the Secretary, in carrying out section 300ff–11(a) of this title, may not make any grant under subsection (a) or (b) to an eligible area unless the application submitted by such area under section 300ff–15 of this title for the grant involved demonstrates that the grants made under subsections (a) and (b) to the area for the preceding fiscal year (if any) were expended in accordance with the priorities applicable to such year that were established, pursuant to section 300ff–12(b)(4)(C) of this title, by the planning council serving the area.

(e) Report on the awarding of supplemental funds

Not later than 45 days after the awarding of supplemental funds under this section, the Secretary shall submit to Congress a report concerning such funds. Such report shall include information detailing—

(1) the total amount of supplemental funds available under this section for the year involved;

(2) the amount of supplemental funds used in accordance with the hold harmless provisions of subsection (a)(4);

(3) the amount of supplemental funds disbursed pursuant to subsection (b)(2)(C);

(4) the disbursement of the remainder of the supplemental funds after taking into account the uses described in paragraphs (2) and (3); and

(5) the rationale used for the amount of funds disbursed as described under paragraphs (2), (3), and (4).

(July 1, 1944, ch. 373, title XXVI, §2603, as added Pub. L. 101–381, title I, §101(3), Aug. 18, 1990, 104 Stat. 578; amended Pub. L. 101–502, §6(a), Nov. 3, 1990, 104 Stat. 1289; Pub. L. 102–531, title III, §312(d)(27), Oct. 27, 1992, 106 Stat. 3506; Pub. L. 104–146, §§3(b)(2), (3), 4, 6(c)(1), 12(c)(2), May 20, 1996, 110 Stat. 1349, 1350, 1364, 1367, 1373; Pub. L. 106–345, title I, §§102(d), 111, 112, Oct. 20, 2000, 114 Stat. 1323, 1326; Pub. L. 109–415, title I, §§102–104, 107(b), title VII, §§702(3), 703, Dec. 19, 2006, 120 Stat. 2768–2774, 2783, 2820; Pub. L. 111–87, §§2(a)(1), (3)(A), 3(a), 5(a), 6(b), 7(a), 8(a)(1), (b)(1)(A), (2)(A), (C), (c)(1), Oct. 30, 2009, 123 Stat. 2885, 2888, 2890, 2892–2894.)

EDITORIAL NOTES

REFERENCES IN TEXT

Section 300ff–15 of this title, referred to in subsecs. (a)(2) and (b)(3)(A), was amended by Pub. L. 104–146, §3(b)(5)(C), (D), May 20, 1996, 110 Stat. 1353, to add a new subsec. (c), relating to single application and grant awards, and redesignate former subsec. (c), relating to date for submission of grant applications, as (d).

PRIOR PROVISIONS

A prior section 2603 of act July 1, 1944, was successively renumbered by subsequent acts and transferred,

see section 238b of this title.

AMENDMENTS

2009—Pub. L. 111–87, §2(a)(1), (3)(A), repealed Pub. L. 109–415, §703, and revived the provisions of this section as in effect on Sept. 30, 2009. See 2006 Amendment note and Effective Date of 2009; Revival of Section note below.

Subsec. (a)(3)(C)(ii). Pub. L. 111–87, §3(a)(1)(A)(i), substituted "2012" for "2009" in introductory provisions.

Subsec. (a)(3)(C)(ii)(II). Pub. L. 111–87, §3(a)(1)(A)(ii), substituted "or a subsequent fiscal year through fiscal year 2012" for "or 2009".

Subsec. (a)(3)(C)(iv). Pub. L. 111–87, §3(a)(1)(B), substituted "2012" for "2010".

Subsec. (a)(3)(C)(v). Pub. L. 111–87, §3(a)(1)(C), inserted "or a subsequent fiscal year" after "2009".

Subsec. (a)(3)(C)(vi)(II). Pub. L. 111–87, §3(a)(1)(D), inserted "for fiscal years before fiscal year 2012 (and 6 percent for fiscal year 2012)" after "5 percent".

Subsec. (a)(3)(C)(vi)(III). Pub. L. 111–87, §7(a)(1), added subcl. (III).

Subsec. (a)(3)(C)(ix)(II). Pub. L. 111–87, §3(a)(1)(E), substituted "2013" for "2010" and "2012" for "2009".

Subsec. (a)(3)(C)(xi). Pub. L. 111–87, §3(a)(1)(F), added cl. (xi).

Subsec. (a)(3)(D)(i). Pub. L. 111–87, §3(a)(2)(A)(i), substituted "2012" for "2009" in introductory provisions.

Subsec. (a)(3)(D)(i)(II). Pub. L. 111–87, §3(a)(2)(A)(ii), substituted "through 2012" for "and 2009".

Subsec. (a)(3)(D)(ii). Pub. L. 111–87, §3(a)(2)(B), substituted "2012" for "2009".

Subsec. (a)(4)(A). Pub. L. 111–87, §5(a)(1), (2), substituted "2009" for "2006" and "2010 through 2013" for "2007 through 2009" in introductory provisions, added cls. (i) to (iii), and struck out former cls. (i) and (ii) which read as follows:

"(i) For fiscal year 2007, an amount equal to 95 percent of the amount of the grant that would have been made pursuant to paragraph (3) and this paragraph for fiscal year 2006 (as such paragraphs were in effect for such fiscal year) if paragraph (2) (as so in effect) had been applied by substituting '662/3 percent' for '50 percent'.

"(ii) For each of the fiscal years 2008 and 2009, an amount equal to 100 percent of the amount of the grant made pursuant to paragraph (3) and this paragraph for fiscal year 2007."

Subsec. (a)(4)(C). Pub. L. 111–87, §5(a)(3), substituted "2013" for "2009".

Subsec. (b)(1)(H). Pub. L. 111–87, §8(a)(1), (b)(2)(C), substituted "5 percent" for "2 percent" and "canceled, offset under subsection (c)(4)," for "canceled".

Subsec. (b)(1)(I). Pub. L. 111–87, §6(b)(1), added subpar. (I).

Subsec. (b)(2)(A). Pub. L. 111–87, §6(b)(2), substituted "one-third, and demonstrated success in identifying individuals with HIV/AIDS who do not know their HIV status and making them aware of such status counting one-third. In making such determination, the Secretary shall consider—" for "one-third." and added cls. (i) to (iii).

Subsec. (b)(2)(D). Pub. L. 111–87, §7(a)(2), added subpar. (D).

Subsec. (c)(3)(D)(i). Pub. L. 111–87, §8(b)(1)(A), substituted "5 percent" for "2 percent" in concluding provisions.

Subsec. (c)(3)(D)(i)(I). Pub. L. 111–87, §8(c)(1), inserted "(less any amount of such balance that is the subject of a waiver of cancellation under subparagraph (A))" after "unobligated balance".

Subsec. (c)(4). Pub. L. 111–87, §8(b)(2)(A), added par. (4).

2006—Pub. L. 109–415, §703, which directed repeal of this section effective Oct. 1, 2009, was itself repealed by Pub. L. 111–87, §2(a)(1), effective Sept. 30, 2009.

Subsec. (a)(2). Pub. L. 109–415, §107(b), substituted "this subpart" for "this part".

Pub. L. 109–415, §102(a), substituted "662/3 percent of the amount made available under section 300ff–20(b) of this title for carrying out this subpart" for "50 percent of the amount appropriated under section 300ff–77 of this title" and "paragraphs (3) and (4)" for "paragraph (3)" in first sentence and struck out last sentence which read as follows: "The Secretary shall reserve an additional percentage of the amount appropriated under section 300ff–77 of this title for a fiscal year for grants under this part to make grants to eligible areas under section 300ff–11(a) of this title in accordance with paragraph (4)."

Subsec. (a)(3)(A). Pub. L. 109–415, §102(d)(1), inserted concluding provisions.

Subsec. (a)(3)(B). Pub. L. 109–415, §102(b)(1), which directed the substitution of "living cases of HIV/AIDS (reported to and confirmed by the Director of the Centers for Disease Control and Prevention)" for

"estimated living cases of acquired immune deficiency syndrome", was executed by making the substitution for "estimated number of living cases of acquired immune deficiency syndrome", to reflect the probable intent of Congress.

Subsec. (a)(3)(C) to (E). Pub. L. 109–415, §102(b)(2), (c), added subpars. (C) and (D) and struck out former subpars. (C) to (E) which related to estimate of living cases, determination of Secretary regarding data on HIV cases, and unexpended funds, respectively.

Subsec. (a)(4). Pub. L. 109–415, §102(d)(2), reenacted heading without change and amended text generally, substituting provisions relating to increases in grant for each of the fiscal years 2007 through 2009 for provisions relating to increases in grant for the first through fifth or subsequent fiscal years in a protection period.

Subsec. (b)(1). Pub. L. 109–415, §103(1)(A), in introductory provisions, substituted "Subject to subsection (a)(4)(B)(i) and section 300ff–20(d) of this title, the Secretary shall" for "Not later than 150 days after the date on which appropriations are made under section 300ff–77 of this title for a fiscal year, the Secretary shall".

Subsec. (b)(1)(B). Pub. L. 109–415, §103(1)(B), substituted "demonstrates the need in such area, on an objective and quantified basis," for "demonstrates the severe need in such area".

Subsec. (b)(1)(E). Pub. L. 109–415, §702(3), substituted "HIV/AIDS" for "HIV disease".

Subsec. (b)(1)(F). Pub. L. 109–415, §103(1)(C), added subpar. (F) and struck out former subpar. (F) which read as follows: "demonstrates the inclusiveness of the planning council membership, with particular emphasis on affected communities and individuals with HIV disease; and".

Subsec. (b)(1)(H). Pub. L. 109–415, §103(1)(D), (E), added subpar. (H).

Subsec. (b)(2)(A). Pub. L. 109–415, §103(2)(A), substituted "demonstrated need" for "severe need".

Subsec. (b)(2)(B). Pub. L. 109–415, §103(2)(B), added subpar. (B) and struck out former subpar. (B) which related to severe need.

Subsec. (b)(2)(C), (D). Pub. L. 109–415, §103(2)(C), added subpar. (C) and struck out former subpars. (C) and (D) which related to mechanism to utilize data to determine prevalence of HIV disease and the phasing in, over a 3-year period beginning in fiscal year 1998, of the use of such mechanism to determine severe needs, respectively.

Subsec. (c). Pub. L. 109–415, §104(2), added subsec. (c). Former subsec. (c) redesignated (d).

Subsec. (d). Pub. L. 109–415, §107(b), substituted "this subpart" for "this part".

Pub. L. 109–415, §104(1), redesignated subsec. (c) as (d).

Subsec. (e). Pub. L. 109–415, §104(3), added subsec. (e).

2000—Subsec. (a)(2). Pub. L. 106–345, §111(a), substituted "for a fiscal year" for "for each of the fiscal years 1996 through 2000" in first sentence.

Subsec. (a)(3)(C)(i). Pub. L. 106–345, §111(b)(1)(A), inserted before semicolon ", except that (subject to subparagraph (D)), for grants made pursuant to this paragraph for fiscal year 2005 and subsequent fiscal years, the cases counted for each 12-month period beginning on or after July 1, 2004, shall be cases of HIV disease (as reported to and confirmed by such Director) rather than cases of acquired immune deficiency syndrome".

Subsec. (a)(3)(C). Pub. L. 106–345, §111(b)(1)(B), in concluding provisions, inserted before period at end of first sentence ", and shall be reported to the congressional committees of jurisdiction" and inserted at end "Updates shall as applicable take into account the counting of cases of HIV disease pursuant to clause (i)."

Subsec. (a)(3)(D), (E). Pub. L. 106–345, §111(b)(2), added subpar. (D) and redesignated former subpar. (D) as (E).

Subsec. (a)(4). Pub. L. 106–345, §111(c), amended heading and text of par. (4) generally. Prior to amendment, text read as follows: "With respect to an eligible area under section 300ff–11(a) of this title, the Secretary shall increase the amount of a grant under paragraph (2) for a fiscal year to ensure that such eligible area receives not less than—

"(A) with respect to fiscal year 1996, 100 percent;

"(B) with respect to fiscal year 1997, 99 percent;

"(C) with respect to fiscal year 1998, 98 percent;

"(D) with respect to fiscal year 1999, 96.5 percent; and

"(E) with respect to fiscal year 2000, 95 percent;

of the amount allocated for fiscal year 1995 to such entity under this subsection."

Subsec. (b)(1)(E). Pub. L. 106–345, §112(b), inserted "youth," after "children,".

Subsec. (b)(2). Pub. L. 106–345, §112(a)(1), substituted "Amount of grant" for "Definition" in heading.

Subsec. (b)(2)(A). Pub. L. 106–345, §112(a)(3), added subpar. (A). Former subpar. (A) redesignated (B).

Subsec. (b)(2)(B). Pub. L. 106–345, §112(a)(2), (4), redesignated subpar. (A) as (B) and added cls. (iv) to (vi). Former subpar. (B) redesignated (C).

Subsec. (b)(2)(C). Pub. L. 106–345, §112(a)(5)(C), inserted after second sentence "Such a mechanism shall

be modified to reflect the findings of the study under section 501(b) of the Ryan White CARE Act Amendments of 2000 (relating to the relationship between epidemiological measures and health care for certain individuals with HIV disease)."

Pub. L. 106–345, §112(a)(5)(B), in second sentence, substituted "18 months after October 20, 2000" for "2 years after May 20, 1996".

Pub. L. 106–345, §112(a)(5)(A), substituted "subparagraph (B)" for "subparagraph (A)" in two places.

Pub. L. 106–345, §112(a)(2), redesignated subpar. (B) as (C). Former subpar. (C) redesignated (D).

Subsec. (b)(2)(D). Pub. L. 106–345, §112(a)(2), (6), redesignated subpar. (C) as (D) and substituted "subparagraph (C)" for "subparagraph (B)".

Subsec. (b)(4). Pub. L. 106–345, §112(c)(1), (2), redesignated par. (5) as (4) and struck out heading and text of former par. (4). Text read as follows: "The amount of each grant made for purposes of this subsection shall be determined by the Secretary based on the application submitted by the eligible area under section 300ff–15(b) of this title."

Subsec. (b)(4)(B). Pub. L. 106–345, §112(c)(3), substituted "an expedited grant" for "an expedited grants".

Subsec. (b)(5). Pub. L. 106–345, §112(c)(2), redesignated par. (5) as (4).

Subsec. (c). Pub. L. 106–345, §102(d), substituted "section 300ff–12(b)(4)(C) of this title" for "section 300ff–12(b)(3)(A) of this title".

1996—Subsec. (a)(2). Pub. L. 104–146, §6(c)(1)(A), substituted "section 300ff–77" for "section 300ff–18".

Pub. L. 104–146, §3(b)(3)(A), inserted ", in accordance with paragraph (3)" after "section 300ff–11(a) of this title" and "The Secretary shall reserve an additional percentage of the amount appropriated under section 300ff–77 of this title for a fiscal year for grants under this part to make grants to eligible areas under section 300ff–11(a) of this title in accordance with paragraph (4)." at end.

Pub. L. 104–146, §3(b)(2)(A), substituted "Not later than 60 days after an appropriation becomes available to carry out this part for each of the fiscal years 1996 through 2000, the Secretary shall" for "Not later than—

"(A) 90 days after an appropriation becomes available to carry out this part for fiscal year 1991; and

"(B) 60 days after an appropriation becomes available to carry out this part for each of fiscal years 1992 through 1995;

the Secretary shall".

Subsec. (a)(3). Pub. L. 104–146, §4, amended par. (3) generally, revising and restating provisions of former subpars. (A) to (C) relating to amount of grants under par. (3) as subpars. (A) to (D).

Subsec. (a)(4). Pub. L. 104–146, §3(b)(3)(B), added par. (4).

Subsec. (b)(1). Pub. L. 104–146, §6(c)(1)(B), substituted "section 300ff–77" for "section 300ff–18" in introductory provisions.

Subsec. (b)(1)(F), (G). Pub. L. 104–146, §3(b)(2)(B)(i), added subpars. (F) and (G).

Subsec. (b)(2) to (4). Pub. L. 104–146, §3(b)(2)(B)(ii), (iii), added par. (2) and redesignated former pars. (2) and (3) as (3) and (4), respectively. Former par. (4) redesignated (5).

Subsec. (b)(4)(B). Pub. L. 104–146, §12(c)(2), which directed substitution of "an expedited grant" for "an expedited grants" in par. (4)(B), could not be executed because the words "an expedited grants" did not appear in par. (4)(B) subsequent to redesignation of par. (4) as (5) by Pub. L. 104–146, §3(b)(2)(B)(ii). See above.

Subsec. (b)(5). Pub. L. 104–146, §3(b)(2)(B)(ii), redesignated par. (4) as (5).

Subsec. (c). Pub. L. 104–146, §3(b)(3)(C), added subsec. (c).

1992—Subsec. (a)(3)(B)(i). Pub. L. 102–531 substituted "Centers for Disease Control and Prevention" for "Centers for Disease Control".

1990—Subsec. (a)(3). Pub. L. 101–502 amended par. (3) generally. Prior to amendment, par. (3) read as follows:

"(A) IN GENERAL.—Subject to the extent of amounts made available in appropriations Acts, a grant made for purposes of this paragraph for an eligible area shall be made in an amount equal to the sum of—

"(i) an amount determined in accordance with subparagraph (B); and

"(ii) an amount determined in accordance with subparagraph (C).

"(B) AMOUNT RELATING TO CUMULATIVE NUMBER OF CASES.—The amount referred to in clause (i) of subparagraph (A) is an amount equal to the product of—

"(i) an amount equal to 75 percent of the amounts available for distribution under paragraph (2) for the fiscal year involved; and

"(ii) a percentage equal to the quotient of—

"(I) the cumulative number of cases of acquired immune deficiency syndrome in the eligible area involved, as indicated by the number of such cases reported to and confirmed by the Director of the Centers for Disease Control on the applicable date described in section 300ff–11(a) of this title; divided by

"(II) the sum of the cumulative number of such cases in all eligible areas for which an application for a grant under paragraph (1) has been approved.

"(C) AMOUNT RELATING TO PER CAPITA INCIDENCE OF CASES.—The amount referred to in clause (ii) of subparagraph (A) is an amount equal to the product of—

"(i) an amount equal to 25 percent of the amounts available for distribution under paragraph (2) for the fiscal year involved; and

"(ii) a percentage developed by the Secretary through consideration of the ratio of—

"(I) the per capita incidence of cumulative cases of acquired immune deficiency syndrome in the eligible area involved (computed on the basis of the most recently available data on the population of the area); to

"(II) the per capita incidence of such cumulative cases in all eligible areas for which an application for a grant under paragraph (1) has been approved (computed on the basis of the most recently available data on the population of such areas)."

STATUTORY NOTES AND RELATED SUBSIDIARIES

EFFECTIVE DATE OF 2009 AMENDMENT; REVIVAL OF SECTION

For provisions that repeal by section 2(a)(1) of Pub. L. 111–87 of section 703 of Pub. L. 109–415 be effective Sept. 30, 2009, that the provisions of this section as in effect on Sept. 30, 2009, be revived, and that amendment by sections 3(a), 5(a), 6(b), 7(a), and 8(a)(1), (b)(1)(A), (2)(A), (C), (c)(1) of Pub. L. 111–87 be applicable to this section as so revived and effective as if enacted on Sept. 30, 2009, see section 2(a)(2), (3) of Pub. L. 111–87, set out as a note under section 300ff–11 of this title.

EFFECTIVE DATE OF 1996 AMENDMENT

Amendment by sections 3(b)(2), (3), 4, 6(c)(1)(B), and 12(c)(2) of Pub. L. 104–146 effective Oct. 1, 1996, and amendment by section 6(c)(1)(A) of Pub. L. 104–146 effective May 20, 1996, see section 13 of Pub. L. 104–146, set out as a note under section 300ff–11 of this title.

[1] *See References in Text note below.*

§300ff–14. Use of amounts

(a) Requirements

The Secretary may not make a grant under section 300ff–11(a) of this title to the chief elected official of an eligible area unless such political subdivision agrees that—

(1) subject to paragraph (2), the allocation of funds and services within the eligible area will be made in accordance with the priorities established, pursuant to section 300ff–12(b)(4)(C) of this title, by the HIV health services planning council that serves such eligible area;

(2) funds provided under section 300ff–11 of this title will be expended only for—

(A) core medical services described in subsection (c);

(B) support services described in subsection (d); and

(C) administrative expenses described in subsection (h); and

(3) the use of such funds will comply with the requirements of this section.

(b) Direct financial assistance to appropriate entities

(1) In general

The chief elected official of an eligible area shall use amounts from a grant under section 300ff–11 of this title to provide direct financial assistance to entities described in paragraph (2) for the purpose of providing core medical services and support services.

(2) Appropriate entities

Direct financial assistance may be provided under paragraph (1) to public or nonprofit private entities, or private for-profit entities if such entities are the only available provider of quality HIV

care in the area.

(c) Required funding for core medical services

(1) In general

With respect to a grant under section 300ff–11 of this title for an eligible area for a grant year, the chief elected official of the area shall, of the portion of the grant remaining after reserving amounts for purposes of paragraphs (1) and (5)(B)(i) of subsection (h), use not less than 75 percent to provide core medical services that are needed in the eligible area for individuals with HIV/AIDS who are identified and eligible under this subchapter (including services regarding the co-occurring conditions of the individuals).

(2) Waiver

(A) In general

The Secretary shall waive the application of paragraph (1) with respect to a chief elected official for a grant year if the Secretary determines that, within the eligible area involved—

(i) there are no waiting lists for AIDS Drug Assistance Program services under section 300ff–26 of this title; and

(ii) core medical services are available to all individuals with HIV/AIDS identified and eligible under this subchapter.

(B) Notification of waiver status

When informing the chief elected official of an eligible area that a grant under section 300ff–11 of this title is being made for the area for a grant year, the Secretary shall inform the official whether a waiver under subparagraph (A) is in effect for such year.

(3) Core medical services

For purposes of this subsection, the term "core medical services", with respect to an individual with HIV/AIDS (including the co-occurring conditions of the individual), means the following services:

(A) Outpatient and ambulatory health services.

(B) AIDS Drug Assistance Program treatments in accordance with section 300ff–26 of this title.

(C) AIDS pharmaceutical assistance.

(D) Oral health care.

(E) Early intervention services described in subsection (e).

(F) Health insurance premium and cost sharing assistance for low-income individuals in accordance with section 300ff–25 of this title.

(G) Home health care.

(H) Medical nutrition therapy.

(I) Hospice services.

(J) Home and community-based health services as defined under section 300ff–24(c) of this title.

(K) Mental health services.

(L) Substance abuse outpatient care.

(M) Medical case management, including treatment adherence services.

(d) Support services

(1) In general

For purposes of this section, the term "support services" means services, subject to the approval of the Secretary, that are needed for individuals with HIV/AIDS to achieve their medical outcomes (such as respite care for persons caring for individuals with HIV/AIDS, outreach services, medical transportation, linguistic services, and referrals for health care and support services).

(2) Medical outcomes

In this subsection, the term "medical outcomes" means those outcomes affecting the HIV-related clinical status of an individual with HIV/AIDS.

(e) Early intervention services

(1) In general

For purposes of this section, the term "early intervention services" means HIV/AIDS early intervention services described in section 300ff–51(e) of this title, with follow-up referral provided for the purpose of facilitating the access of individuals receiving the services to HIV-related health services. The entities through which such services may be provided under the grant include public health departments, emergency rooms, substance abuse and mental health treatment programs, detoxification centers, detention facilities, clinics regarding sexually transmitted diseases, homeless shelters, HIV/AIDS counseling and testing sites, health care points of entry specified by eligible areas, federally qualified health centers, and entities described in section 300ff–52(a) of this title that constitute a point of access to services by maintaining referral relationships.

(2) Conditions

With respect to an entity that proposes to provide early intervention services under paragraph (1), such paragraph shall apply only if the entity demonstrates to the satisfaction of the chief elected official for the eligible area involved that—

(A) Federal, State, or local funds are otherwise inadequate for the early intervention services the entity proposes to provide; and

(B) the entity will expend funds pursuant to such paragraph to supplement and not supplant other funds available to the entity for the provision of early intervention services for the fiscal year involved.

(f) Priority for women, infants, children, and youth

(1) In general

For the purpose of providing health and support services to infants, children, youth, and women with HIV/AIDS, including treatment measures to prevent the perinatal transmission of HIV, the chief elected official of an eligible area, in accordance with the established priorities of the planning council, shall for each of such populations in the eligible area use, from the grants made for the area under section 300ff–11(a) of this title for a fiscal year, not less than the percentage constituted by the ratio of the population involved (infants, children, youth, or women in such area) with HIV/AIDS to the general population in such area of individuals with HIV/AIDS.

(2) Waiver

With respect to the population involved, the Secretary may provide to the chief elected official of an eligible area a waiver of the requirement of paragraph (1) if such official demonstrates to the satisfaction of the Secretary that the population is receiving HIV-related health services through the State medicaid program under title XIX of the Social Security Act [42 U.S.C. 1396 et seq.], the State children's health insurance program under title XXI of such Act [42 U.S.C. 1397aa et seq.], or other Federal or State programs.

(g) Requirement of status as medicaid provider

(1) Provision of service

Subject to paragraph (2), the Secretary may not make a grant under section 300ff–11(a) of this title for the provision of services under this section in a State unless, in the case of any such service that is available pursuant to the State plan approved under title XIX of the Social Security Act [42 U.S.C. 1396 et seq.] for the State—

(A) the political subdivision involved will provide the service directly, and the political subdivision has entered into a participation agreement under the State plan and is qualified to receive payments under such plan; or

(B) the political subdivision will enter into an agreement with a public or nonprofit private entity under which the entity will provide the service, and the entity has entered into such a

participation agreement and is qualified to receive such payments.

(2) Waiver

(A) In general

In the case of an entity making an agreement pursuant to paragraph (1)(B) regarding the provision of services, the requirement established in such paragraph shall be waived by the HIV health services planning council for the eligible area if the entity does not, in providing health care services, impose a charge or accept reimbursement available from any third-party payor, including reimbursement under any insurance policy or under any Federal or State health benefits program.

(B) Determination

A determination by the HIV health services planning council of whether an entity referred to in subparagraph (A) meets the criteria for a waiver under such subparagraph shall be made without regard to whether the entity accepts voluntary donations for the purpose of providing services to the public.

(h) Administration

(1) Limitation

The chief elected official of an eligible area shall not use in excess of 10 percent of amounts received under a grant under this subpart for administrative expenses.

(2) Allocations by chief elected official

In the case of entities and subcontractors to which the chief elected official of an eligible area allocates amounts received by the official under a grant under this subpart, the official shall ensure that, of the aggregate amount so allocated, the total of the expenditures by such entities for administrative expenses does not exceed 10 percent (without regard to whether particular entities expend more than 10 percent for such expenses).

(3) Administrative activities

For purposes of paragraph (1), amounts may be used for administrative activities that include—

(A) routine grant administration and monitoring activities, including the development of applications for part A funds, the receipt and disbursal of program funds, the development and establishment of reimbursement and accounting systems, the development of a clinical quality management program as described in paragraph (5), the preparation of routine programmatic and financial reports, and compliance with grant conditions and audit requirements; and

(B) all activities associated with the grantee's contract award procedures, including the activities carried out by the HIV health services planning council as established under section 300ff–12(b) of this title, the development of requests for proposals, contract proposal review activities, negotiation and awarding of contracts, monitoring of contracts through telephone consultation, written documentation or onsite visits, reporting on contracts, and funding reallocation activities.

(4) Subcontractor administrative activities

For the purposes of this subsection, subcontractor administrative activities include—

(A) usual and recognized overhead activities, including established indirect rates for agencies;

(B) management oversight of specific programs funded under this subchapter; and

(C) other types of program support such as quality assurance, quality control, and related activities.

(5) Clinical quality management

(A) Requirement

The chief elected official of an eligible area that receives a grant under this subpart shall provide for the establishment of a clinical quality management program to assess the extent to

which HIV health services provided to patients under the grant are consistent with the most recent Public Health Service guidelines for the treatment of HIV/AIDS and related opportunistic infection, and as applicable, to develop strategies for ensuring that such services are consistent with the guidelines for improvement in the access to and quality of HIV health services.

(B) Use of funds

(i) In general

From amounts received under a grant awarded under this subpart for a fiscal year, the chief elected official of an eligible area may use for activities associated with the clinical quality management program required in subparagraph (A) not to exceed the lesser of—

(I) 5 percent of amounts received under the grant; or

(II) $3,000,000.

(ii) Relation to limitation on administrative expenses

The costs of a clinical quality management program under subparagraph (A) may not be considered administrative expenses for purposes of the limitation established in paragraph (1).

(i) Construction

A chief elected official may not use amounts received under a grant awarded under this subpart to purchase or improve land, or to purchase, construct, or permanently improve (other than minor remodeling) any building or other facility, or to make cash payments to intended recipients of services.

(July 1, 1944, ch. 373, title XXVI, §2604, as added Pub. L. 101–381, title I, §101(3), Aug. 18, 1990, 104 Stat. 580; amended Pub. L. 103–446, title XII, §1203(a)(3), Nov. 2, 1994, 108 Stat. 4689; Pub. L. 104–146, §3(b)(4), May 20, 1996, 110 Stat. 1351; Pub. L. 106–345, title I, §121, Oct. 20, 2000, 114 Stat. 1326; Pub. L. 109–415, title I, §§105, 107(b), title VII, §703, Dec. 19, 2006, 120 Stat. 2776, 2783, 2820; Pub. L. 111–87, §2(a)(1), (3)(A), Oct. 30, 2009, 123 Stat. 2885.)

EDITORIAL NOTES

REFERENCES IN TEXT

The Social Security Act, referred to in subsecs. (f)(2) and (g)(1), is act Aug. 14, 1935, ch. 531, 49 Stat. 620. Titles XIX and XXI of the Act are classified generally to subchapters XIX (§1396 et seq.) and XXI (§1397aa et seq.), respectively, of chapter 7 of this title. For complete classification of this Act to the Code, see section 1305 of this title and Tables.

PRIOR PROVISIONS

A prior section 2604 of act July 1, 1944, was successively renumbered by subsequent acts and transferred, see section 238c of this title.

AMENDMENTS

2009—Pub. L. 111–87 repealed Pub. L. 109–415, §703, and revived the provisions of this section as in effect on Sept. 30, 2009. See 2006 Amendment note and Effective Date of 2009 Amendment; Revival of Section note below.

2006—Pub. L. 109–415, §703, which directed repeal of this section effective Oct. 1, 2009, was itself repealed by Pub. L. 111–87, §2(a)(1), effective Sept. 30, 2009.

Pub. L. 109–415, §105, amended section generally. Prior to amendment, section related to requirements for allocation of funds, purposes for use of amounts, quality management program, expenditures for personnel, status of grantee as medicaid provider, administrative activities and expenses, and prohibited uses of amounts.

Subsecs. (h)(1), (2), (5)(A), (i). Pub. L. 109–415, §107(b), substituted "this subpart" for "this part".

2000—Subsec. (b)(1). Pub. L. 106–345, §121(a)(1), substituted "HIV-related services, as follows:" for "HIV-related—" in introductory provisions.

Subsec. (b)(1)(A). Pub. L. 106–345, §121(a)(2), substituted "Outpatient and ambulatory health services, including substance abuse treatment," for "outpatient and ambulatory health and support services, including case management, substance abuse treatment and" and substituted a period for "; and" at end.

Subsec. (b)(1)(B). Pub. L. 106–345, §121(a)(4), added subpar. (B). Former subpar. (B) redesignated (C).

Subsec. (b)(1)(C). Pub. L. 106–345, §121(a)(3), redesignated subpar. (B) as (C) and substituted "Inpatient" for "inpatient".

Subsec. (b)(1)(D). Pub. L. 106–345, §121(a)(5), added subpar. (D).

Subsec. (b)(3). Pub. L. 106–345, §121(b)(2), added par. (3). Former par. (3) redesignated (4).

Subsec. (b)(4). Pub. L. 106–345, §121(b)(1), (c), redesignated par. (3) as (4) and amended heading and text of par. (4) generally. Prior to amendment, text read as follows: "For the purpose of providing health and support services to infants, children, and women with HIV disease, including treatment measures to prevent the perinatal transmission of HIV, the chief elected official of an eligible area, in accordance with the established priorities of the planning council, shall use, from the grants made for the area under section 300ff–11(a) of this title for a fiscal year, not less than the percentage constituted by the ratio of the population in such area of infants, children, and women with acquired immune deficiency syndrome to the general population in such area of individuals with such syndrome."

Subsecs. (c) to (g). Pub. L. 106–345, §121(d), added subsec. (c) and redesignated former subsecs. (c) to (f) as (d) to (g), respectively.

1996—Subsec. (b)(1)(A). Pub. L. 104–146, §3(b)(4)(A), inserted ", substance abuse treatment and mental health treatment," after "case management" and "which shall include treatment education and prophylactic treatment for opportunistic infections," after "treatment services,".

Subsec. (b)(2)(A). Pub. L. 104–146, §3(b)(4)(B), inserted ", or private for-profit entities if such entities are the only available provider of quality HIV care in the area," after "nonprofit private entities," and substituted "homeless health centers, substance abuse treatment programs, and mental health programs" for "and homeless health centers".

Subsec. (b)(3). Pub. L. 104–146, §3(b)(4)(C), added par. (3).

Subsec. (e). Pub. L. 104–146, §3(b)(4)(C), struck out "and planning" after "Administration" in heading, designated existing provisions as par. (1), inserted par. heading, struck out "accounting, reporting, and program oversight functions" after "for administration,", inserted at end "In the case of entities and subcontractors to which such officer allocates amounts received by the officer under the grant, the officer shall ensure that, of the aggregate amount so allocated, the total of the expenditures by such entities for administrative expenses does not exceed 10 percent (without regard to whether particular entities expend more than 10 percent for such expenses).", and added pars. (2) and (3).

1994—Subsec. (b)(2)(A). Pub. L. 103–446 substituted "Department of Veterans Affairs facilities" for "Veterans Administration facilities".

STATUTORY NOTES AND RELATED SUBSIDIARIES

EFFECTIVE DATE OF 2009 AMENDMENT; REVIVAL OF SECTION

For provisions that repeal by section 2(a)(1) of Pub. L. 111–87 of section 703 of Pub. L. 109–415 be effective Sept. 30, 2009, and that the provisions of this section as in effect on Sept. 30, 2009, be revived, see section 2(a)(2), (3)(A) of Pub. L. 111–87, set out as a note under section 300ff–11 of this title.

EFFECTIVE DATE OF 1996 AMENDMENT

Amendment by Pub. L. 104–146 effective Oct. 1, 1996, see section 13 of Pub. L. 104–146, set out as a note under section 300ff–11 of this title.

§300ff–15. Application

(a) In general

To be eligible to receive a grant under section 300ff–11 of this title, an eligible area shall prepare and submit to the Secretary an application, in accordance with subsection (c) regarding a single application and grant award, at such time, in such form, and containing such information as the Secretary shall require, including assurances adequate to ensure—

(1)(A) that funds received under a grant awarded under this subpart will be utilized to supplement not supplant State funds made available in the year for which the grant is awarded to provide HIV-related services as described in section 300ff–14(b)(1) of this title;

(B) that the political subdivisions within the eligible area will maintain the level of expenditures by such political subdivisions for HIV-related services as described in section 300ff–14(b)(1) of

this title at a level that is equal to the level of such expenditures by such political subdivisions for the preceding fiscal year; and

(C) that political subdivisions within the eligible area will not use funds received under a grant awarded under this subpart in maintaining the level of expenditures for HIV-related services as required in subparagraph (B);

(2) that the eligible area has an HIV health services planning council and has entered into intergovernmental agreements pursuant to section 300ff–12 of this title, and has developed or will develop the comprehensive plan in accordance with section 300ff–12(b)(3)(B) [1] of this title;

(3) that entities within the eligible area that receive funds under a grant under this subpart will maintain appropriate relationships with entities in the eligible area served that constitute key points of access to the health care system for individuals with HIV/AIDS (including emergency rooms, substance abuse treatment programs, detoxification centers, adult and juvenile detention facilities, sexually transmitted disease clinics, HIV counseling and testing sites, mental health programs, and homeless shelters), and other entities under section [2] 300ff–14(b)(3) [1] and 300ff–52(a) of this title, for the purpose of facilitating early intervention for individuals newly diagnosed with HIV/AIDS and individuals knowledgeable of their HIV status but not in care;

(4) that the chief elected official of the eligible area will satisfy all requirements under section 300ff–14(c) of this title;

(5) that entities within the eligible area that will receive funds under a grant provided under section 300ff–11(a) of this title shall participate in an established HIV community-based continuum of care if such continuum exists within the eligible area;

(6) that funds received under a grant awarded under this subpart will not be utilized to make payments for any item or service to the extent that payment has been made, or can reasonably be expected to be made, with respect to that item or service—

(A) under any State compensation program, under an insurance policy, or under any Federal or State health benefits program (except for a program administered by or providing the services of the Indian Health Service); or

(B) by an entity that provides health services on a prepaid basis;

(7) to the maximum extent practicable, that—

(A) HIV health care and support services provided with assistance made available under this subpart will be provided without regard—

(i) to the ability of the individual to pay for such services; and

(ii) to the current or past health condition of the individual to be served;

(B) such services will be provided in a setting that is accessible to low-income individuals with HIV/AIDS; and

(C) a program of outreach will be provided to low-income individuals with HIV/AIDS to inform such individuals of such services;

(8) that the applicant has participated, or will agree to participate, in the statewide coordinated statement of need process where it has been initiated by the State public health agency responsible for administering grants under part B, and ensure that the services provided under the comprehensive plan are consistent with the statewide coordinated statement of need;

(9) that the eligible area has procedures in place to ensure that services provided with funds received under this subpart meet the criteria specified in section 300ff–14(b)(1) of this title; and

(10) that the chief elected official will submit to the lead State agency under section 300ff–27(b)(4) of this title, audits, consistent with Office of Management and Budget circular A133, regarding funds expended in accordance with this subpart every 2 years and shall include necessary client-based data to compile unmet need calculations and Statewide coordinated statements of need process.

(b) Application

An eligible area that desires to receive a grant under section 300ff–13(b) of this title shall prepare and submit to the Secretary an application, in accordance with subsection (c) regarding a single application and grant award, at such time, in such form, and containing such information as the Secretary shall require, including the information required under such subsection and information concerning—

(1) the number of individuals to be served within the eligible area with assistance provided under the grant, including the identification of individuals with HIV/AIDS as described in clauses (i) through (iii) of section 300ff–13(b)(2)(A) of this title;

(2) demographic data on the population of such individuals;

(3) the average cost of providing each category of HIV-related health services and the extent to which such cost is paid by third-party payors;

(4) the aggregate amounts expended for each such category of services;

(5) the manner in which the expected expenditures are related to the planning process for States that receive funding under part B (including the planning process described in section 300ff–27(b) of this title); and

(6) the expected expenditures and how those expenditures will improve overall client outcomes, as described under the State plan under section 300ff–27(b) of this title, and through additional outcomes measures as identified by the HIV health services planning council under section 300ff–12(b) of this title.

(c) Single application and grant award

(1) Application

The Secretary may phase in the use of a single application that meets the requirements of subsections (a) and (b) of section 300ff–13 of this title with respect to an eligible area that desires to receive grants under section 300ff–13 of this title for a fiscal year.

(2) Grant award

The Secretary may phase in the awarding of a single grant to an eligible area that submits an approved application under paragraph (1) for a fiscal year.

(d) Date certain for submission

(1) Requirement

Except as provided in paragraph (2), to be eligible to receive a grant under section 300ff–11(a) of this title for a fiscal year, an application under subsection (a) shall be submitted not later than 45 days after the date on which appropriations are made under section 300ff–77 of this title for the fiscal year.

(2) Exception

The Secretary may extend the time for the submission of an application under paragraph (1) for a period of not to exceed 60 days if the Secretary determines that the eligible area has made a good faith effort to comply with the requirement of such paragraph but has otherwise been unable to submit its application.

(3) Distribution by Secretary

Not later than 45 days after receiving an application that meets the requirements of subsection (a) from an eligible area, the Secretary shall distribute to such eligible area the amounts awarded under the grant for which the application was submitted.

(4) Redistribution

Any amounts appropriated in any fiscal year under this subpart and not obligated to an eligible entity as a result of the failure of such entity to submit an application shall be redistributed by the Secretary to other eligible entities in proportion to the original grants made to such eligible areas under section 300ff–11(a) of this title.

(e) Requirements regarding imposition of charges for services

(1) In general

The Secretary may not make a grant under section 300ff–11 of this title to an eligible area unless the eligible area provides assurances that in the provision of services with assistance provided under the grant—

(A) in the case of individuals with an income less than or equal to 100 percent of the official poverty line, the provider will not impose charges on any such individual for the provision of services under the grant;

(B) in the case of individuals with an income greater than 100 percent of the official poverty line, the provider—

(i) will impose a charge on each such individual for the provision of such services; and

(ii) will impose the charge according to a schedule of charges that is made available to the public;

(C) in the case of individuals with an income greater than 100 percent of the official poverty line and not exceeding 200 percent of such poverty line, the provider will not, for any calendar year, impose charges in an amount exceeding 5 percent of the annual gross income of the individual involved;

(D) in the case of individuals with an income greater than 200 percent of the official poverty line and not exceeding 300 percent of such poverty line, the provider will not, for any calendar year, impose charges in an amount exceeding 7 percent of the annual gross income of the individual involved; and

(E) in the case of individuals with an income greater than 300 percent of the official poverty line, the provider will not, for any calendar year, impose charges in an amount exceeding 10 percent of the annual gross income of the individual involved.

(2) Assessment of charge

With respect to compliance with the assurance made under paragraph (1), a grantee or entity receiving assistance under this subpart may, in the case of individuals subject to a charge for purposes of such paragraph—

(A) assess the amount of the charge in the discretion of the grantee, including imposing only a nominal charge for the provision of services, subject to the provisions of such paragraph regarding public schedules and regarding limitations on the maximum amount of charges; and

(B) take into consideration the medical expenses of individuals in assessing the amount of the charge, subject to such provisions.

(3) Applicability of limitation on amount of charge

The Secretary may not make a grant under section 300ff–11 of this title to an eligible area unless the eligible area agrees that the limitations established in subparagraphs (C), (D) and (E) of paragraph (1) regarding the imposition of charges for services applies to the annual aggregate of charges imposed for such services, without regard to whether they are characterized as enrollment fees, premiums, deductibles, cost sharing, copayments, coinsurance, or other charges.

(4) Waiver regarding secondary agreements

The requirements established in paragraphs (1) through (3) shall be waived in accordance with section 300ff–14(d)(2) [1] of this title.

(July 1, 1944, ch. 373, title XXVI, §2605, as added Pub. L. 101–381, title I, §101(3), Aug. 18, 1990, 104 Stat. 582; amended Pub. L. 104–146, §§3(b)(5), 6(c)(2), May 20, 1996, 110 Stat. 1352, 1368; Pub. L. 106–345, title I, §122, title V, §503(a)(1), Oct. 20, 2000, 114 Stat. 1329, 1354; Pub. L. 109–415, title I, §§106(c), 107(b), title VII, §§702(3), 703, Dec. 19, 2006, 120 Stat. 2781, 2783, 2820; Pub. L. 111–87, §§2(a)(1), (3)(A), 6(c), Oct. 30, 2009, 123 Stat. 2885, 2892.)

EDITORIAL NOTES

REFERENCES IN TEXT

Section 300ff–12(b) of this title, referred to in subsec. (a)(2), was amended by Pub. L. 104–146, §3(b)(1)(D), May 20, 1996, 110 Stat. 1348, to redesignate pars. (2) and (3) as (3) and (4), respectively. As so redesignated, par. (3)(B) relates to consideration regarding designation of councils and par. (4)(B) relates to development of a comprehensive plan.

Section 300ff–14 of this title, referred to in subsecs. (a)(3) and (e)(4), was amended generally by Pub. L. 109–415, title I, §105, Dec. 19, 2006, 120 Stat. 2776, and as so amended, it does not contain a subsec. (b)(3) and subsec. (d)(2) does not relate to waivers. Provisions similar to those in former subsecs. (b)(3) and (d)(2) are contained in subsecs. (e) and (g)(2), respectively.

PRIOR PROVISIONS

A prior section 2605 of act July 1, 1944, was successively renumbered by subsequent acts and transferred, see section 238d of this title.

AMENDMENTS

2009—Pub. L. 111–87, §2(a)(1), (3)(A), repealed Pub. L. 109–415, §703, and revived the provisions of this section as in effect on Sept. 30, 2009. See 2006 Amendment note and Effective Date of 2009 Amendment; Revival of Section note below.

Subsec. (b)(1). Pub. L. 111–87, §6(c), inserted ", including the identification of individuals with HIV/AIDS as described in clauses (i) through (iii) of section 300ff–13(b)(2)(A) of this title" before semicolon.

2006—Pub. L. 109–415, §703, which directed repeal of this section effective Oct. 1, 2009, was itself repealed by Pub. L. 111–87, §2(a)(1), effective Sept. 30, 2009.

Pub. L. 109–415, §107(b), substituted "this subpart" for "this part" wherever appearing.

Subsec. (a)(3). Pub. L. 109–415, §702(3), substituted "HIV/AIDS" for "HIV disease" in two places.

Subsec. (a)(6)(A). Pub. L. 109–415, §106(c)(1), inserted "(except for a program administered by or providing the services of the Indian Health Service)" before semicolon.

Subsec. (a)(7)(B), (C). Pub. L. 109–415, §702(3), which directed the substitution of "HIV/AIDS" for "HIV disease", was executed by making the substitution for "HIV-disease", to reflect the probable intent of Congress.

Subsec. (a)(10). Pub. L. 109–415, §106(c)(2), added par. (10).

Subsec. (b)(5), (6). Pub. L. 109–415, §106(c)(3), added pars. (5) and (6).

2000—Subsec. (a)(1)(A). Pub. L. 106–345, §122(b)(1)(A), substituted "services as described in section 300ff–14(b)(1) of this title" for "services to individuals with HIV disease".

Subsec. (a)(1)(B). Pub. L. 106–345, §122(b)(1)(B), substituted "services as described in section 300ff–14(b)(1) of this title" for "services for individuals with HIV disease".

Subsec. (a)(3) to (8). Pub. L. 106–345, §122(a), added pars. (3) and (4) and redesignated former pars. (3) to (6) as (5) to (8), respectively.

Subsec. (a)(9). Pub. L. 106–345, §122(b)(2)–(4), added par. (9).

Subsec. (d)(1). Pub. L. 106–345, §503(a)(1)(A), made technical amendment to reference in original act which appears in text as reference to section 300ff–77 of this title.

Subsec. (d)(4). Pub. L. 106–345, §503(a)(1)(B), inserted "section" before "300ff–11(a) of this title".

1996—Subsec. (a). Pub. L. 104–146, §3(b)(5)(A)(i), inserted ", in accordance with subsection (c) regarding a single application and grant award," after "application" in introductory provisions.

Subsec. (a)(1)(B). Pub. L. 104–146, §3(b)(5)(A)(ii), substituted "preceding fiscal year" for "1-year period preceding the first fiscal year for which a grant is received by the eligible area".

Subsec. (a)(6). Pub. L. 104–146, §3(b)(5)(A)(iii)–(v), added par. (6).

Subsec. (b). Pub. L. 104–146, §3(b)(5)(B), substituted "Application" for "Additional application" in heading and substituted "application, in accordance with subsection (c) regarding a single application and grant award," for "additional application" in introductory provisions.

Subsec. (c). Pub. L. 104–146, §3(b)(5)(D), added subsec. (c). Former subsec. (c) redesignated (d).

Subsec. (c)(1). Pub. L. 104–146, §6(c)(2), which directed substitution of "section 300ff–77 of this title" for "section 300ff–18 of this title" in subsec. (c)(1), could not be executed because phrase "section 300ff–18 of this title" did not appear in text of subsec. (c)(1) subsequent to redesignation of subsec. (c) as (d) by Pub. L. 104–146, §3(b)(5)(C). See below.

Subsec. (d). Pub. L. 104–146, §3(b)(5)(C), redesignated subsec. (c) as (d). Former subsec. (d) redesignated (e).

Subsec. (e). Pub. L. 104–146, §3(b)(5)(C), redesignated subsec. (d) as (e).

STATUTORY NOTES AND RELATED SUBSIDIARIES

EFFECTIVE DATE OF 2009 AMENDMENT; REVIVAL OF SECTION

For provisions that repeal by section 2(a)(1) of Pub. L. 111–87 of section 703 of Pub. L. 109–415 be effective Sept. 30, 2009, that the provisions of this section as in effect on Sept. 30, 2009, be revived, and that amendment by section 6(c) of Pub. L. 111–87 be applicable to this section as so revived and effective as if enacted on Sept. 30, 2009, see section 2(a)(2), (3) of Pub. L. 111–87, set out as a note under section 300ff–11 of this title.

EFFECTIVE DATE OF 1996 AMENDMENT

Amendment by Pub. L. 104–146 effective Oct. 1, 1996, see section 13 of Pub. L. 104–146, set out as a note under section 300ff–11 of this title.

[1] *See References in Text note below.*

[2] *So in original. Probably should be "sections".*

§300ff–16. Technical assistance

The Administrator of the Health Resources and Services Administration shall, beginning on August 18, 1990, provide technical assistance, including assistance from other grantees, contractors or subcontractors under this subchapter to assist newly eligible metropolitan areas in the establishment of HIV health services planning councils and, to assist entities in complying with the requirements of this subpart in order to make such entities eligible to receive a grant under this subpart. The Administrator may make planning grants available to metropolitan areas, in an amount not to exceed $75,000 for any metropolitan area, projected to be eligible for funding under section 300ff–11 of this title in the following fiscal year. Such grant amounts shall be deducted from the first year formula award to eligible areas accepting such grants. Not to exceed 1 percent of the amount appropriated for a fiscal year under section 300ff–77 of this title for grants under this subpart may be used to carry out this section.

(July 1, 1944, ch. 373, title XXVI, §2606, as added Pub. L. 101–381, title I, §101(3), Aug. 18, 1990, 104 Stat. 585; amended Pub. L. 104–146, §3(b)(6), May 20, 1996, 110 Stat. 1353; Pub. L. 109–415, title I, §107(b), title VII, §703, Dec. 19, 2006, 120 Stat. 2783, 2820; Pub. L. 111–87, §2(a)(1), (3)(A), Oct. 30, 2009, 123 Stat. 2885.)

EDITORIAL NOTES

PRIOR PROVISIONS

A prior section 2606 of act July 1, 1944, was successively renumbered by subsequent acts and transferred, see section 238e of this title.

AMENDMENTS

2009—Pub. L. 111–87 repealed Pub. L. 109–415, §703, and revived the provisions of this section as in effect on Sept. 30, 2009. See 2006 Amendment note and Effective Date of 2009 Amendment; Revival of Section note below.

2006—Pub. L. 109–415, §703, which directed repeal of this section effective Oct. 1, 2009, was itself repealed by Pub. L. 111–87, §2(a)(1), effective Sept. 30, 2009.

Pub. L. 109–415, §107(b), substituted "this subpart" for "this part" wherever appearing.

1996—Pub. L. 104–146 substituted "Administration shall" for "Administration may", inserted ", including assistance from other grantees, contractors or subcontractors under this subchapter to assist newly eligible metropolitan areas in the establishment of HIV health services planning councils and," after "technical assistance", and inserted at end "The Administrator may make planning grants available to metropolitan areas, in an amount not to exceed $75,000 for any metropolitan area, projected to be eligible for funding under section 300ff–11 of this title in the following fiscal year. Such grant amounts shall be deducted from the first

year formula award to eligible areas accepting such grants. Not to exceed 1 percent of the amount appropriated for a fiscal year under section 300ff–77 of this title for grants under this part may be used to carry out this section."

STATUTORY NOTES AND RELATED SUBSIDIARIES

EFFECTIVE DATE OF 2009 AMENDMENT; REVIVAL OF SECTION

For provisions that repeal by section 2(a)(1) of Pub. L. 111–87 of section 703 of Pub. L. 109–415 be effective Sept. 30, 2009, and that the provisions of this section as in effect on Sept. 30, 2009, be revived, see section 2(a)(2), (3)(A) of Pub. L. 111–87, set out as a note under section 300ff–11 of this title.

EFFECTIVE DATE OF 1996 AMENDMENT

Amendment by Pub. L. 104–146 effective Oct. 1, 1996, see section 13 of Pub. L. 104–146, set out as a note under section 300ff–11 of this title.

§300ff–17. Definitions

For purposes of this subpart:

(1) Eligible area

The term "eligible area" means a metropolitan area meeting the requirements of section 300ff–11 of this title that are applicable to the area.

(2) Metropolitan area

The term "metropolitan area" means an area that is referred to in the HIV/AIDS Surveillance Report of the Centers for Disease Control and Prevention as a metropolitan area, and that has a population of 50,000 or more individuals.

(July 1, 1944, ch. 373, title XXVI, §2607, as added Pub. L. 101–381, title I, §101(3), Aug. 18, 1990, 104 Stat. 585; amended Pub. L. 101–557, title IV, §401(b)(1), Nov. 15, 1990, 104 Stat. 2771; Pub. L. 102–531, title III, §312(d)(28), Oct. 27, 1992, 106 Stat. 3506; Pub. L. 104–146, §3(a)(3), May 20, 1996, 110 Stat. 1347; Pub. L. 109–415, title I, §§101(c), 107(b), title VII, §703, Dec. 19, 2006, 120 Stat. 2768, 2783, 2820; Pub. L. 111–87, §2(a)(1), (3)(A), Oct. 30, 2009, 123 Stat. 2885.)

EDITORIAL NOTES

PRIOR PROVISIONS

A prior section 2607 of act July 1, 1944, was successively renumbered by subsequent acts and transferred, see section 238f of this title.

AMENDMENTS

2009—Pub. L. 111–87 repealed Pub. L. 109–415, §703, and revived the provisions of this section as in effect on Sept. 30, 2009. See 2006 Amendment note and Effective Date of 2009 Amendment; Revival of Section note below.

2006—Pub. L. 109–415, §703, which directed repeal of this section effective Oct. 1, 2009, was itself repealed by Pub. L. 111–87, §2(a)(1), effective Sept. 30, 2009.

Pub. L. 109–415, §107(b), substituted "this subpart" for "this part" in introductory provisions.

Par. (2). Pub. L. 109–415, §101(c), substituted "area that is referred" for "area referred" and inserted ", and that has a population of 50,000 or more individuals" before period at end.

1996—Par. (1). Pub. L. 104–146 substituted "The term 'eligible area' means a metropolitan area meeting the requirements of section 300ff–11 of this title that are applicable to the area." for "The term 'eligible area' means a metropolitan area described in section 300ff–11(a) of this title."

1992—Par. (2). Pub. L. 102–531 substituted "Centers for Disease Control and Prevention" for "Centers for Disease Control".

1990—Par. (1). Pub. L. 101–557 substituted "300ff–11(a)" for "300ff–11(a)(1)".

STATUTORY NOTES AND RELATED SUBSIDIARIES

EFFECTIVE DATE OF 2009 AMENDMENT; REVIVAL OF SECTION

For provisions that repeal by section 2(a)(1) of Pub. L. 111–87 of section 703 of Pub. L. 109–415 be effective Sept. 30, 2009, and that the provisions of this section as in effect on Sept. 30, 2009, be revived, see section 2(a)(2), (3)(A) of Pub. L. 111–87, set out as a note under section 300ff–11 of this title.

EFFECTIVE DATE OF 1996 AMENDMENT

Amendment by Pub. L. 104–146 effective Oct. 1, 1996, see section 13 of Pub. L. 104–146, set out as a note under section 300ff–11 of this title.

§300ff–18. Repealed. Pub. L. 104–146, §6(b), May 20, 1996, 110 Stat. 1367

Section, act July 1, 1944, ch. 373, title XXVI, §2608, as added Aug. 18, 1990, Pub. L. 101–381, title I, §101(3), 104 Stat. 585, authorized appropriations for fiscal years 1991 through 1995.

STATUTORY NOTES AND RELATED SUBSIDIARIES

EFFECTIVE DATE OF REPEAL

Repeal effective Oct. 1, 1996, see section 13 of Pub. L. 104–146, set out as an Effective Date of 1996 Amendment note under section 300ff–11 of this title.

SUBPART II—TRANSITIONAL GRANTS

§300ff–19. Establishment of program

(a) In general

The Secretary, acting through the Administrator of the Health Resources and Services Administration, shall make grants for the purpose of providing services described in section 300ff–14 of this title in transitional areas, subject to the same provisions regarding the allocation of grant funds as apply under subsection (c) of such section.

(b) Transitional areas

For purposes of this section, the term "transitional area" means, subject to subsection (c), a metropolitan area for which there has been reported to and confirmed by the Director of the Centers for Disease Control and Prevention a cumulative total of at least 1,000, but fewer than 2,000, cases of AIDS during the most recent period of 5 calendar years for which such data are available.

(c) Certain eligibility rules

(1) Fiscal year 2011

With respect to grants under subsection (a) for fiscal year 2011, a metropolitan area that received funding under subpart I for fiscal year 2010 but does not for fiscal year 2011 qualify under such subpart as an eligible area and does not qualify under subsection (b) as a transitional area shall, notwithstanding subsection (b), be considered a transitional area.

(2) Continued status as transitional area

(A) In general

Notwithstanding subsection (b), a metropolitan area that is a transitional area for a fiscal year continues, except as provided in subparagraph (B), to be a transitional area until the metropolitan area fails, for three consecutive fiscal years—

(i) to qualify under such subsection as a transitional area; and

(ii) subject to subparagraphs (B) and (C), to have a cumulative total of 1,500 or more living cases of AIDS (reported to and confirmed by the Director of the Centers for Disease Control and Prevention) as of December 31 of the most recent calendar year for which such data is available.

(B) Permitting margin of error applicable to certain metropolitan areas

In applying subparagraph (A)(ii) for a fiscal year after fiscal year 2008, in the case of a metropolitan area that has a cumulative total of at least 1,400 (and fewer than 1,500) living cases of AIDS as of December 31 of the most recent calendar year for which such data is available, such area shall be treated as having met the criteria of such subparagraph if not more than 5 percent of the total from grants awarded to such area under this part is unobligated as of the end of the most recent fiscal year for which such data is available.

(C) Exception regarding status as eligible area

Subparagraphs (A) and (B) do not apply for a fiscal year if the metropolitan area involved qualifies under subpart I as an eligible area.

(d) Application of certain provisions of subpart I

(1) Administration; planning council

(A) In general

The provisions of section 300ff–12 of this title apply with respect to a grant under subsection (a) for a transitional area to the same extent and in the same manner as such provisions apply with respect to a grant under subpart I for an eligible area, except that, subject to subparagraph (B), the chief elected official of the transitional area may elect not to comply with the provisions of section 300ff–12(b) of this title if the official provides documentation to the Secretary that details the process used to obtain community input (particularly from those with HIV) in the transitional area for formulating the overall plan for priority setting and allocating funds from the grant under subsection (a).

(B) Exception

For each of the fiscal years 2007 through 2013, the exception described in subparagraph (A) does not apply if the transitional area involved received funding under subpart I for fiscal year 2006.

(2) Type and distribution of grants; timeframe for obligation and expenditure of grant funds

(A) Formula grants; supplemental grants

The provisions of section 300ff–13 of this title apply with respect to grants under subsection (a) to the same extent and in the same manner as such provisions apply with respect to grants under subpart I, subject to subparagraphs (B) and (C).

(B) Formula grants; increase in grant

For purposes of subparagraph (A), section 300ff–13(a)(4) of this title does not apply.

(C) Supplemental grants; single program with subpart I program

With respect to section 300ff–13(b) of this title as applied for purposes of subparagraph (A):

(i) The Secretary shall combine amounts available pursuant to such subparagraph with amounts available for carrying out section 300ff–13(b) of this title and shall administer the two programs as a single program.

(ii) In the single program, the Secretary has discretion in allocating amounts between eligible areas under subpart I and transitional areas under this section, subject to the eligibility criteria that apply under such section, and subject to section 300ff–13(b)(2)(C) of this title (relating to priority in making grants).

(iii) Pursuant to section 300ff–13(b)(1) of this title, amounts for the single program are subject to use under sections 300ff–13(a)(4) and 300ff–20(d)(1) of this title.

(3) Application; technical assistance; definitions

The provisions of sections 300ff–15, 300ff–16, and 300ff–17 of this title apply with respect to grants under subsection (a) to the same extent and in the same manner as such provisions apply with respect to grants under subpart I.

(July 1, 1944, ch. 373, title XXVI, §2609, as added and amended Pub. L. 109–415, title I, §107(a)(2), title VII, §703, Dec. 19, 2006, 120 Stat. 2781, 2820; Pub. L. 111–87, §§2(a)(1), (3)(A), 4(a), Oct. 30, 2009, 123 Stat. 2885, 2889.)

EDITORIAL NOTES

AMENDMENTS

2009—Pub. L. 111–87, §2(a)(1), (3)(A), repealed Pub. L. 109–415, §703, and revived the provisions of this section as in effect on Sept. 30, 2009. See 2006 Amendment note and Effective Date of 2009 Amendment; Revival of Section note below.

Subsec. (c)(1). Pub. L. 111–87, §4(a)(1), in heading substituted "2011" for "2007" and in text substituted "2011" for "2007" in two places and "2010" for "2006".

Subsec. (c)(2)(A)(ii). Pub. L. 111–87, §4(a)(2)(A), substituted "subject to subparagraphs (B) and (C), to have a" for "to have a".

Subsec. (c)(2)(B). Pub. L. 111–87, §4(a)(2)(B), (C), added subpar. (B). Former subpar. (B) redesignated (C).

Subsec. (c)(2)(C). Pub. L. 111–87, §4(a)(2)(B), (D), redesignated subpar. (B) as (C) and substituted "Subparagraphs (A) and (B) do not apply" for "Subparagraph (A) does not apply".

Subsec. (d)(1)(B). Pub. L. 111–87, §4(a)(3), substituted "2013" for "2009".

2006—Pub. L. 109–415, §703, which directed repeal of this section effective Oct. 1, 2009, was itself repealed by Pub. L. 111–87, §2(a)(1), effective Sept. 30, 2009.

STATUTORY NOTES AND RELATED SUBSIDIARIES

EFFECTIVE DATE OF 2009 AMENDMENT; REVIVAL OF SECTION

For provisions that repeal by section 2(a)(1) of Pub. L. 111–87 of section 703 of Pub. L. 109–415 be effective Sept. 30, 2009, that the provisions of this section as in effect on Sept. 30, 2009, be revived, and that amendment by section 4(a) of Pub. L. 111–87 be applicable to this section as so revived and effective as if enacted on Sept. 30, 2009, see section 2(a)(2), (3) of Pub. L. 111–87, set out as a note under section 300ff–11 of this title.

SUBPART III—GENERAL PROVISIONS

§300ff–20. Authorization of appropriations

(a) In general

For the purpose of carrying out this part, there are authorized to be appropriated $604,000,000 for fiscal year 2007, $626,300,000 for fiscal year 2008, $649,500,000 for fiscal year 2009, $681,975,000 for fiscal year 2010, $716,074,000 for fiscal year 2011, $751,877,000 for fiscal year 2012, and $789,471,000 for fiscal year 2013. Amounts appropriated under the preceding sentence for a fiscal year are available for obligation by the Secretary until the end of the second succeeding fiscal year.

(b) Reservation of amounts

(1) Fiscal year 2007

Of the amount appropriated under subsection (a) for fiscal year 2007, the Secretary shall reserve—

(A) $458,310,000 for grants under subpart I; and

(B) $145,690,000 for grants under section 300ff–19 of this title.

(2) Subsequent fiscal years

Of the amount appropriated under subsection (a) for fiscal year 2008 and each subsequent fiscal year—

(A) the Secretary shall reserve an amount for grants under subpart I; and

(B) the Secretary shall reserve an amount for grants under section 300ff–19 of this title.

(c) Transfer of certain amounts; change in status as eligible area or transitional area

Notwithstanding subsection (b):

(1) If a metropolitan area is an eligible area under subpart I for a fiscal year, but for a subsequent fiscal year ceases to be an eligible area by reason of section 300ff–11(b) of this title—

(A)(i) the amount reserved under paragraph (1)(A) or (2)(A) of subsection (b) of this section for the first such subsequent year of not being an eligible area is deemed to be reduced by an amount equal to the amount of the grant made pursuant to section 300ff–13(a) of this title for the metropolitan area for the preceding fiscal year; and

(ii)(I) if the metropolitan area qualifies for such first subsequent fiscal year as a transitional area under 300ff–19 [1] of this title, the amount reserved under paragraph (1)(B) or (2)(B) of subsection (b) for such fiscal year is deemed to be increased by an amount equal to the amount of the reduction under subparagraph (A) for such year; or

(II) if the metropolitan area does not qualify for such first subsequent fiscal year as a transitional area under 300ff–19 [1] of this title, an amount equal to the amount of such reduction is, notwithstanding subsection (a), transferred and made available for grants pursuant to section 300ff–28(a)(1) of this title, in addition to amounts available for such grants under section 300ff–31b of this title; and

(B) if a transfer under subparagraph (A)(ii)(II) is made with respect to the metropolitan area for such first subsequent fiscal year, then—

(i) the amount reserved under paragraph (1)(A) or (2)(A) of subsection (b) of this section for such year is deemed to be reduced by an additional $500,000; and

(ii) an amount equal to the amount of such additional reduction is, notwithstanding subsection (a), transferred and made available for grants pursuant to section 300ff–28(a)(1) of this title, in addition to amounts available for such grants under section 300ff–31b of this title.

(2) If a metropolitan area is a transitional area under section 300ff–19 of this title for a fiscal year, but for a subsequent fiscal year ceases to be a transitional area by reason of section 300ff–19(c)(2) of this title (and does not qualify for such subsequent fiscal year as an eligible area under subpart I)—

(A) the amount reserved under subsection (b)(2)(B) of this section for the first such subsequent fiscal year of not being a transitional area is deemed to be reduced by an amount equal to the total of—

(i) the amount of the grant that, pursuant to section 300ff–13(a) of this title, was made under section 300ff–19(d)(2)(A) of this title for the metropolitan area for the preceding fiscal year; and

(ii) $500,000; and

(B)(i) subject to clause (ii), an amount equal to the amount of the reduction under subparagraph (A) for such year is, notwithstanding subsection (a), transferred and made available for grants pursuant to section 300ff–28(a)(1) of this title, in addition to amounts available for such grants under section 300ff–31b of this title; and

(ii) for each of fiscal years 2010 through 2013, notwithstanding subsection (a)—

(I) there shall be transferred to the State containing the metropolitan area, for purposes described in section 300ff–22(a) of this title, an amount (which shall not be taken into account in applying section 300ff–28(a)(2)(H) of this title) equal to—

(aa) for the first fiscal year of the metropolitan area not being a transitional area, 75 percent of the amount described in subparagraph (A)(i) for such area;

(bb) for the second fiscal year of the metropolitan area not being a transitional area, 50 percent of such amount; and

(cc) for the third fiscal year of the metropolitan area not being a transitional area, 25 percent of such amount; and

(II) there shall be transferred and made available for grants pursuant to section 300ff–28(a)(1) of this title for the fiscal year, in addition to amounts available for such grants under section 300ff–31b of this title, an amount equal to the total amount of the reduction for such fiscal year under subparagraph (A), less the amount transferred for such fiscal year under subclause (I).

(3) If a metropolitan area is a transitional area under section 300ff–19 of this title for a fiscal year, but for a subsequent fiscal year qualifies as an eligible area under subpart I—

(A) the amount reserved under subsection (b)(2)(B) of this section for the first such subsequent fiscal year of becoming an eligible area is deemed to be reduced by an amount equal to the amount of the grant that, pursuant to section 300ff–13(a) of this title, was made under section 300ff–19(d)(2)(A) of this title for the metropolitan area for the preceding fiscal year; and

(B) the amount reserved under subsection (b)(2)(A) for such fiscal year is deemed to be increased by an amount equal to the amount of the reduction under subparagraph (A) for such year.

(d) Certain transfers; allocations between programs under subpart I

With respect to paragraphs (1)(B)(i) and (2)(A)(ii) of subsection (c), the Secretary shall administer any reductions under such paragraphs for a fiscal year in accordance with the following:

(1) The reductions shall be made from amounts available for the single program referred to in section 300ff–19(d)(2)(C) of this title (relating to supplemental grants).

(2) The reductions shall be made before the amounts referred to in paragraph (1) are used for purposes of section 300ff–13(a)(4) of this title.

(3) If the amounts referred to in paragraph (1) are not sufficient for making all the reductions, the reductions shall be reduced until the total amount of the reductions equals the total of the amounts referred to in such paragraph.

(e) Rules of construction regarding first subsequent fiscal year

Paragraphs (1) and (2) of subsection (c) apply with respect to each series of fiscal years during which a metropolitan area is an eligible area under subpart I or a transitional area under section 300ff–19 of this title for a fiscal year and then for a subsequent fiscal year ceases to be such an area by reason of section 300ff–11(b) or 300ff–19(c)(2) of this title, respectively, rather than applying to a single such series. Paragraph (3) of subsection (c) applies with respect to each series of fiscal years during which a metropolitan area is a transitional area under section 300ff–19 of this title for a fiscal year and then for a subsequent fiscal year becomes an eligible area under subpart I, rather than applying to a single such series.

(July 1, 1944, ch. 373, title XXVI, §2610, as added and amended Pub. L. 109–415, title I, §108, title VII, §703, Dec. 19, 2006, 120 Stat. 2783, 2820; Pub. L. 111–87, §§2(a)(1), (3)(A), (b), 4(b), Oct. 30, 2009, 123 Stat. 2885, 2889.)

EDITORIAL NOTES

AMENDMENTS

2009—Pub. L. 111–87, §2(a)(1), (3)(A), repealed Pub. L. 109–415, §703, and revived the provisions of this section as in effect on Sept. 30, 2009. See 2006 Amendment note and Effective Date of 2009 Amendment; Revival of Section note below.

Subsec. (a). Pub. L. 111–87, §2(b), substituted "$649,500,000 for fiscal year 2009, $681,975,000 for fiscal year 2010, $716,074,000 for fiscal year 2011, $751,877,000 for fiscal year 2012, and $789,471,000 for fiscal year 2013" for "and $649,500,000 for fiscal year 2009".

Subsec. (c)(2)(B). Pub. L. 111–87, §4(b), designated existing provisions as cl. (i), inserted "subject to clause (ii)," before "an amount equal to the amount", and added cl. (ii).

2006—Pub. L. 109–415, §703, which directed repeal of this section effective Oct. 1, 2009, was itself repealed by Pub. L. 111–87, §2(a)(1), effective Sept. 30, 2009.

STATUTORY NOTES AND RELATED SUBSIDIARIES

EFFECTIVE DATE OF 2009 AMENDMENT; REVIVAL OF SECTION

For provisions that repeal by section 2(a)(1) of Pub. L. 111–87 of section 703 of Pub. L. 109–415 be effective Sept. 30, 2009, that the provisions of this section as in effect on Sept. 30, 2009, be revived, and that amendment by sections 2(b) and 4(b) of Pub. L. 111–87 be applicable to this section as so revived and effective as if enacted on Sept. 30, 2009, see section 2(a)(2), (3) of Pub. L. 111–87, set out as a note under section 300ff–11 of this title.

[1] *So in original. Probably should be preceded by "section".*

PART B—CARE GRANT PROGRAM

SUBPART I—GENERAL GRANT PROVISIONS

EDITORIAL NOTES

CODIFICATION

Pub. L. 104–146, §7(b)(1), May 20, 1996, 110 Stat. 1368, added heading "SUBPART I—GENERAL GRANT PROVISIONS".

§300ff–21. Grants

The Secretary shall, subject to the availability of appropriations, make grants to States to enable such States to improve the quality, availability and organization of health care and support services for individuals and families with HIV/AIDS. The authority of the Secretary to provide grants under this section is subject to section 300ff–34(e)(2) [1] of this title (relating to the decrease in perinatal transmission of HIV/AIDS).

(July 1, 1944, ch. 373, title XXVI, §2611, as added Pub. L. 101–381, title II, §201, Aug. 18, 1990, 104 Stat. 586; amended Pub. L. 104–146, §§3(c)(1), 7(b)(2), May 20, 1996, 110 Stat. 1353, 1368; Pub. L. 106–345, title II, §201, Oct. 20, 2000, 114 Stat. 1329; Pub. L. 109–415, title II, §§201(c)(1), 204(a), title VII, §§702(3), 703, Dec. 19, 2006, 120 Stat. 2788, 2796, 2820; Pub. L. 111–87, §2(a)(1), (3)(A), Oct. 30, 2009, 123 Stat. 2885.)

EDITORIAL NOTES

REFERENCES IN TEXT

Section 300ff–34(e)(2) of this title, referred to in text, was repealed by Pub. L. 106–345, title II, §211(1), Oct. 20, 2000, 114 Stat. 1339.

PRIOR PROVISIONS

A prior section 2611 of act July 1, 1944, was successively renumbered by subsequent acts and transferred, see section 238j of this title.

AMENDMENTS

2009—Pub. L. 111–87 repealed Pub. L. 109–415, §703, and revived the provisions of this section as in effect on Sept. 30, 2009. See 2006 Amendment note and Effective Date of 2009 Amendment; Revival of Section note below.

2006—Pub. L. 109–415, §703, which directed repeal of this section effective Oct. 1, 2009, was itself repealed by Pub. L. 111–87, §2(a)(1), effective Sept. 30, 2009.

Pub. L. 109–415, §702(3), substituted "HIV/AIDS" for "HIV disease" in two places.

Pub. L. 109–415, §204(a), substituted "this section" for "this part".

Pub. L. 109–415, §201(c)(1), struck out subsec. (a) designation and heading before "The Secretary" and struck out subsec. (b) which related to priority for women, infants, and children.

2000—Subsec. (b). Pub. L. 106–345 amended heading and text of subsec. (b) generally. Prior to amendment, text read as follows: "For the purpose of providing health and support services to infants, children, and women with HIV disease, including treatment measures to prevent the perinatal transmission of HIV, a State shall use, of the funds allocated under this part to the State for a fiscal year, not less than the percentage constituted by the ratio of the population in the State of infants, children, and women with acquired immune deficiency syndrome to the general population in the State of individuals with such syndrome."

1996—Pub. L. 104–146, §3(c)(1), designated existing provisions as subsec. (a), inserted heading, and added subsec. (b).

Subsec. (a). Pub. L. 104–146, §7(b)(2), inserted at end "The authority of the Secretary to provide grants under this part is subject to section 300ff–34(e)(2) of this title (relating to the decrease in perinatal transmission of HIV disease)."

STATUTORY NOTES AND RELATED SUBSIDIARIES

EFFECTIVE DATE OF 2009 AMENDMENT; REVIVAL OF SECTION

For provisions that repeal by section 2(a)(1) of Pub. L. 111–87 of section 703 of Pub. L. 109–415 be effective Sept. 30, 2009, and that the provisions of this section as in effect on Sept. 30, 2009, be revived, see section 2(a)(2), (3)(A) of Pub. L. 111–87, set out as a note under section 300ff–11 of this title.

EFFECTIVE DATE OF 1996 AMENDMENT

Amendment by Pub. L. 104–146 effective Oct. 1, 1996, see section 13 of Pub. L. 104–146, set out as a note under section 300ff–11 of this title.

[1] *See References in Text note below.*

§300ff–22. General use of grants

(a) In general

A State may use amounts provided under grants made under section 300ff–21 of this title for—

(1) core medical services described in subsection (b);

(2) support services described in subsection (c); and

(3) administrative expenses described in section 300ff–28(b)(3) of this title.

(b) Required funding for core medical services

(1) In general

With respect to a grant under section 300ff–21 of this title for a State for a grant year, the State shall, of the portion of the grant remaining after reserving amounts for purposes of subparagraphs (A) and (E)(ii)(I) of section 300ff–28(b)(3) of this title, use not less than 75 percent to provide core medical services that are needed in the State for individuals with HIV/AIDS who are identified and eligible under this subchapter (including services regarding the co-occurring conditions of the individuals).

(2) Waiver

(A) In general

The Secretary shall waive the application of paragraph (1) with respect to a State for a grant year if the Secretary determines that, within the State—

(i) there are no waiting lists for AIDS Drug Assistance Program services under section 300ff–26 of this title; and

(ii) core medical services are available to all individuals with HIV/AIDS identified and eligible under this subchapter.

(B) Notification of waiver status

When informing a State that a grant under section 300ff–21 of this title is being made to the State for a fiscal year, the Secretary shall inform the State whether a waiver under subparagraph (A) is in effect for the fiscal year.

(3) Core medical services

For purposes of this subsection, the term "core medical services", with respect to an individual infected with HIV/AIDS (including the co-occurring conditions of the individual) means the following services:

(A) Outpatient and ambulatory health services.

(B) AIDS Drug Assistance Program treatments in accordance with section 300ff–26 of this title.

(C) AIDS pharmaceutical assistance.

(D) Oral health care.

(E) Early intervention services described in subsection (d).

(F) Health insurance premium and cost sharing assistance for low-income individuals in accordance with section 300ff–25 of this title.

(G) Home health care.

(H) Medical nutrition therapy.

(I) Hospice services.

(J) Home and community-based health services as defined under section 300ff–24(c) of this title.

(K) Mental health services.

(L) Substance abuse outpatient care.

(M) Medical case management, including treatment adherence services.

(c) Support services

(1) In general

For purposes of this subsection, the term "support services" means services, subject to the approval of the Secretary, that are needed for individuals with HIV/AIDS to achieve their medical outcomes (such as respite care for persons caring for individuals with HIV/AIDS, outreach services, medical transportation, linguistic services, and referrals for health care and support services).

(2) Definition of medical outcomes

In this subsection, the term "medical outcomes" means those outcomes affecting the HIV-related clinical status of an individual with HIV/AIDS.

(d) Early intervention services

(1) In general

For purposes of this section, the term "early intervention services" means HIV/AIDS early intervention services described in section 300ff–51(e) of this title, with follow-up referral provided for the purpose of facilitating the access of individuals receiving the services to HIV-related health services. The entities through which such services may be provided under the grant include public health departments, emergency rooms, substance abuse and mental health treatment programs,

detoxification centers, detention facilities, clinics regarding sexually transmitted diseases, homeless shelters, HIV/AIDS counseling and testing sites, health care points of entry specified by States, federally qualified health centers, and entities described in section 300ff–52(a) of this title that constitute a point of access to services by maintaining referral relationships.

(2) Conditions

With respect to an entity that proposes to provide early intervention services under paragraph (1), such paragraph shall apply only if the entity demonstrates to the satisfaction of the chief elected official for the State involved that—

(A) Federal, State, or local funds are otherwise inadequate for the early intervention services the entity proposes to provide; and

(B) the entity will expend funds pursuant to such subparagraph to supplement and not supplant other funds available to the entity for the provision of early intervention services for the fiscal year involved.

(e) Priority for women, infants, children, and youth

(1) In general

For the purpose of providing health and support services to infants, children, youth, and women with HIV/AIDS, including treatment measures to prevent the perinatal transmission of HIV, a State shall for each of such populations in the eligible area use, from the grants made for the area under section 300ff–11(a) of this title for a fiscal year, not less than the percentage constituted by the ratio of the population involved (infants, children, youth, or women in such area) with HIV/AIDS to the general population in such area of individuals with HIV/AIDS.

(2) Waiver

With respect to the population involved, the Secretary may provide to a State a waiver of the requirement of paragraph (1) if such State demonstrates to the satisfaction of the Secretary that the population is receiving HIV-related health services through the State medicaid program under title XIX of the Social Security Act [42 U.S.C. 1396 et seq.], the State children's health insurance program under title XXI of such Act [42 U.S.C. 1397aa et seq.], or other Federal or State programs.

(f) Construction

A State may not use amounts received under a grant awarded under section 300ff–21 of this title to purchase or improve land, or to purchase, construct, or permanently improve (other than minor remodeling) any building or other facility, or to make cash payments to intended recipients of services.

(July 1, 1944, ch. 373, title XXVI, §2612, as added Pub. L. 101–381, title II, §201, Aug. 18, 1990, 104 Stat. 586; amended Pub. L. 104–146, §3(c)(2), May 20, 1996, 110 Stat. 1354; Pub. L. 106–345, title II, §202, title V, §503(b), Oct. 20, 2000, 114 Stat. 1330, 1355; Pub. L. 109–415, title II, §201(a), title VII, §703, Dec. 19, 2006, 120 Stat. 2785, 2820; Pub. L. 111–87, §2(a)(1), (3)(A), Oct. 30, 2009, 123 Stat. 2885.)

EDITORIAL NOTES

REFERENCES IN TEXT

The Social Security Act, referred to in subsec. (e)(2), is act Aug. 14, 1935, ch. 531, 49 Stat. 620. Titles XIX and XXI of the Act are classified generally to subchapters XIX (§1396 et seq.) and XXI (§1397aa et seq.), respectively, of chapter 7 of this title. For complete classification of this Act to the Code, see section 1305 of this title and Tables.

CODIFICATION

Another section 3(c)(2) of Pub. L. 104–146 amended section 300ff–23 of this title.

PRIOR PROVISIONS

A prior section 2612 of act July 1, 1944, was successively renumbered by subsequent acts and transferred, see section 238k of this title.

AMENDMENTS

2009—Pub. L. 111–87 repealed Pub. L. 109–415, §703, and revived the provisions of this section as in effect on Sept. 30, 2009. See 2006 Amendment note and Effective Date of 2009; Revival of Section note below.

2006—Pub. L. 109–415, §703, which directed repeal of this section effective Oct. 1, 2009, was itself repealed by Pub. L. 111–87, §2(a)(1), effective Sept. 30, 2009.

Pub. L. 109–415, §201(a), reenacted section catchline without change and amended text generally, substituting provisions relating to general use of grants, required funding for core medical services, support and early intervention services, priority for women, infants, children, and youth, and prohibition against use of amounts for real property improvement or to make cash payments, for provisions relating to general use of grants, support services and outreach, early intervention services, and establishment of a quality management program in each State.

2000—Pub. L. 106–345, §202(1), designated existing provisions as subsec. (a) and inserted heading.

Subsec. (a)(1). Pub. L. 106–345, §503(b), made technical amendment to directory language of Pub. L. 104–146, §3(c)(2)(A)(iii). See 1996 Amendment note below.

Subsec. (b) to (d). Pub. L. 106–345, §202(2), added subsecs. (b) to (d).

1996—Pub. L. 104–146, §3(c)(2)(A), as amended by Pub. L. 106–345, §503(b), struck out "(a) In general" before "A State may use amounts", added par. (1), redesignated former pars. (1) to (4) as (2) to (5), respectively, substituted "therapeutics to treat HIV disease" for "treatments, that have been determined to prolong life or prevent serious deterioration of health," in par. (5), and inserted after par. (5) "Services described in paragraph (1) shall be delivered through consortia designed as described in paragraph (2), where such consortia exist, unless the State demonstrates to the Secretary that delivery of such services would be more effective when other delivery mechanisms are used. In making a determination regarding the delivery of services, the State shall consult with appropriate representatives of service providers and recipients of services who would be affected by such determination, and shall include in its demonstration to the Secretary the findings of the State regarding such consultation."

Subsec. (b). Pub. L. 104–146, §3(c)(2)(B), struck out heading and text of subsec. (b). Text read as follows: "A State shall use not less than 15 percent of funds allocated under this part to provide health and support services to infants, children, women, and families with HIV disease."

STATUTORY NOTES AND RELATED SUBSIDIARIES

EFFECTIVE DATE OF 2009 AMENDMENT; REVIVAL OF SECTION

For provisions that repeal by section 2(a)(1) of Pub. L. 111–87 of section 703 of Pub. L. 109–415 be effective Sept. 30, 2009, and that the provisions of this section as in effect on Sept. 30, 2009, be revived, see section 2(a)(2), (3)(A) of Pub. L. 111–87, set out as a note under section 300ff–11 of this title.

EFFECTIVE DATE OF 1996 AMENDMENT

Amendment by Pub. L. 104–146 effective Oct. 1, 1996, see section 13 of Pub. L. 104–146, set out as a note under section 300ff–11 of this title.

§300ff–23. Grants to establish HIV care consortia

(a) Consortia

A State may, subject to subsection (f), use amounts provided under a grant awarded under section 300ff–21 of this title to provide assistance under section 300ff–22(a) of this title to an entity that—

(1) is an association of one or more public, and one or more nonprofit private,[1] (or private for-profit providers or organizations if such entities are the only available providers of quality HIV care in the area) [1] health care and support service providers and community based organizations operating within areas determined by the State to be most affected by HIV/AIDS; and

(2) agrees to use such assistance for the planning, development and delivery, through the direct provision of services or through entering into agreements with other entities for the provision of

such services, of comprehensive outpatient health and support services for individuals with HIV/AIDS, that may include—

(A) essential health services such as case management services, medical, nursing, substance abuse treatment, mental health treatment, and dental care, diagnostics, monitoring, prophylactic treatment for opportunistic infections, treatment education to take place in the context of health care delivery, and medical follow-up services, mental health, developmental, and rehabilitation services, home health and hospice care; and

(B) essential support services such as transportation services, attendant care, homemaker services, day or respite care, benefits advocacy, advocacy services provided through public and nonprofit private entities, and services that are incidental to the provision of health care services for individuals with HIV/AIDS including nutrition services, housing referral services, and child welfare and family services (including foster care and adoption services).

An entity or entities of the type described in this subsection shall hereinafter be referred to in this subchapter as a "consortium" or "consortia".

(b) Assurances

(1) Requirement

To receive assistance from a State under subsection (a), an applicant consortium shall provide the State with assurances that—

(A) within any locality in which such consortium is to operate, the populations and subpopulations of individuals and families with HIV/AIDS have been identified by the consortium, particularly those experiencing disparities in access and services and those who reside in historically underserved communities;

(B) the service plan established under subsection (c)(2) by such consortium is consistent with the comprehensive plan under section 300ff–27(b)(4) of this title and addresses the special care and service needs of the populations and subpopulations identified under subparagraph (A); and

(C) except as provided in paragraph (2), the consortium will be a single coordinating entity that will integrate the delivery of services among the populations and subpopulations identified under subparagraph (A).

(2) Exception

Subparagraph (C) of paragraph (1) shall not apply to any applicant consortium that the State determines will operate in a community or locality in which it has been demonstrated by the applicant consortium that—

(A) subpopulations exist within the community to be served that have unique service requirements; and

(B) such unique service requirements cannot be adequately and efficiently addressed by a single consortium serving the entire community or locality.

(c) Application

(1) In general

To receive assistance from the State under subsection (a), a consortium shall prepare and submit to the State, an application that—

(A) demonstrates that the consortium includes agencies and community-based organizations—

(i) with a record of service to populations and subpopulations with HIV/AIDS requiring care within the community to be served; and

(ii) that are representative of populations and subpopulations reflecting the local incidence of HIV and that are located in areas in which such populations reside;

(B) demonstrates that the consortium has carried out an assessment of service needs within the geographic area to be served and, after consultation with the entities described in paragraph (2), has established a plan to ensure the delivery of services to meet such identified needs that

shall include—

(i) assurances that service needs will be addressed through the coordination and expansion of existing programs before new programs are created;

(ii) assurances that, in metropolitan areas, the geographic area to be served by the consortium corresponds to the geographic boundaries of local health and support services delivery systems to the extent practicable;

(iii) assurances that, in the case of services for individuals residing in rural areas, the applicant consortium shall deliver case management services that link available community support services to appropriate specialized medical services; and

(iv) assurances that the assessment of service needs and the planning of the delivery of services will include participation by individuals with HIV/AIDS;

(C) demonstrates that adequate planning has occurred to meet the special needs of families with HIV/AIDS, including family centered and youth centered care;

(D) demonstrates that the consortium has created a mechanism to evaluate periodically—

(i) the success of the consortium in responding to identified needs; and

(ii) the cost-effectiveness of the mechanisms employed by the consortium to deliver comprehensive care;

(E) demonstrates that the consortium will report to the State the results of the evaluations described in subparagraph (D) and shall make available to the State or the Secretary, on request, such data and information on the program methodology that may be required to perform an independent evaluation; and

(F) demonstrates that adequate planning occurred to address disparities in access and services and historically underserved communities.

(2) Consultation

In establishing the plan required under paragraph (1)(B), the consortium shall consult with—

(A)(i) the public health agency that provides or supports ambulatory and outpatient HIV-related health care services within the geographic area to be served; or

(ii) in the case of a public health agency that does not directly provide such HIV-related health care services such agency shall consult with an entity or entities that directly provide ambulatory and outpatient HIV-related health care services within the geographic area to be served;

(B) not less than one community-based organization that is organized solely for the purpose of providing HIV-related support services to individuals with HIV/AIDS;

(C) grantees under section 300ff–71 of this title, or, if none are operating in the area, representatives in the area of organizations with a history of serving children, youth, women, and families living with HIV; and

(D) the types of entities described in section 300ff–12(b)(2) of this title.

The organization to be consulted under subparagraph (B) shall be at the discretion of the applicant consortium.

(d) "Family centered care" defined

As used in section 300ff–21 of this title, the term "family centered care" means the system of services described in this section that is targeted specifically to the special needs of infants, children, women, and families. Family centered care shall be based on a partnership between parents, professionals, and the community designed to ensure an integrated, coordinated, culturally sensitive, and community-based continuum of care for children, women, and families with HIV/AIDS.

(e) Priority

In providing assistance under subsection (a), the State shall, among applicants that meet the requirements of this section, give priority—

(1) first to consortia that are receiving assistance from the Health Resources and Services Administration for adult and pediatric HIV-related care demonstration projects; and then

(2) to any other existing HIV care consortia.

(f) Allocation of funds; treatment as support services

For purposes of the requirement of section 300ff–22(b)(1) of this title, expenditures of grants under section 300ff–21 of this title for or through consortia under this section are deemed to be support services, not core medical services. The preceding sentence may not be construed as having any legal effect on the provisions of subsection (a) that relate to authorized expenditures of the grant.

(July 1, 1944, ch. 373, title XXVI, §2613, as added Pub. L. 101–381, title II, §201, Aug. 18, 1990, 104 Stat. 586; amended Pub. L. 104–146, §3(c)(2), May 20, 1996, 110 Stat. 1354; Pub. L. 106–345, title II, §203, Oct. 20, 2000, 114 Stat. 1331; Pub. L. 109–415, title II, §§201(b), 204(a), title VII, §§702(3), 703, Dec. 19, 2006, 120 Stat. 2787, 2796, 2820; Pub. L. 111–87, §2(a)(1), (3)(A), Oct. 30, 2009, 123 Stat. 2885.)

EDITORIAL NOTES

CODIFICATION

Another section 3(c)(2) of Pub. L. 104–146 amended section 300ff–22 of this title.

PRIOR PROVISIONS

A prior section 2613 of act July 1, 1944, was successively renumbered by subsequent acts and transferred, see section 238l of this title.

AMENDMENTS

2009—Pub. L. 111–87 repealed Pub. L. 109–415, §703, and revived the provisions of this section as in effect on Sept. 30, 2009. See 2006 Amendment note and Effective Date of 2009 Amendment; Revival of Section note below.

2006—Pub. L. 109–415, §703, which directed repeal of this section effective Oct. 1, 2009, was itself repealed by Pub. L. 111–87, §2(a)(1), effective Sept. 30, 2009.

Pub. L. 109–415, §702(3), substituted "HIV/AIDS" for "HIV disease" wherever appearing.

Subsec. (a). Pub. L. 109–415, §204(a), substituted "section 300ff–21 of this title" for "this part" in introductory provisions.

Pub. L. 109–415, §201(b)(1), in introductory provisions substituted "may, subject to subsection (f), use" for "may use" and "section 300ff–22(a) of this title" for "section 300ff–22(a)(1) of this title".

Subsec. (d). Pub. L. 109–415, §204(a), substituted "section 300ff–21 of this title" for "this part".

Subsec. (f). Pub. L. 109–415, §201(b)(2), added subsec. (f).

2000—Subsec. (b)(1)(A). Pub. L. 106–345, §203(1)(A), inserted ", particularly those experiencing disparities in access and services and those who reside in historically underserved communities" before semicolon.

Subsec. (b)(1)(B). Pub. L. 106–345, §203(1)(B), inserted "is consistent with the comprehensive plan under section 300ff–27(b)(4) of this title and" after "by such consortium".

Subsec. (c)(1)(F). Pub. L. 106–345, §203(2), added subpar. (F).

Subsec. (c)(2)(D). Pub. L. 106–345, §203(3), added subpar. (D).

1996—Subsec. (a)(1). Pub. L. 104–146, §3(c)(2)(A)(i), inserted "(or private for-profit providers or organizations if such entities are the only available providers of quality HIV care in the area)" after "nonprofit private,".

Subsec. (a)(2)(A). Pub. L. 104–146, §3(c)(2)(A)(ii), inserted "substance abuse treatment, mental health treatment," after "nursing," and "prophylactic treatment for opportunistic infections, treatment education to take place in the context of health care delivery," after "monitoring,".

Subsec. (c)(1)(C). Pub. L. 104–146, §3(c)(2)(B)(i), inserted "and youth centered" after "family centered".

Subsec. (c)(2)(C). Pub. L. 104–146, §3(c)(2)(B)(ii), added subpar. (C).

STATUTORY NOTES AND RELATED SUBSIDIARIES

EFFECTIVE DATE OF 2009 AMENDMENT; REVIVAL OF SECTION

For provisions that repeal by section 2(a)(1) of Pub. L. 111–87 of section 703 of Pub. L. 109–415 be effective Sept. 30, 2009, and that the provisions of this section as in effect on Sept. 30, 2009, be revived, see section 2(a)(2), (3)(A) of Pub. L. 111–87, set out as a note under section 300ff–11 of this title.

EFFECTIVE DATE OF 1996 AMENDMENT

Amendment by Pub. L. 104–146 effective Oct. 1, 1996, see section 13 of Pub. L. 104–146, set out as a note under section 300ff–11 of this title.

[1] *So in original. The comma probably should follow parenthetical phrase.*

§300ff–24. Grants for home- and community-based care

(a) Uses

A State may use amounts provided under a grant awarded under section 300ff–21 of this title to make grants under section 300ff–22(b)(3)(J) of this title to entities to—

(1) provide home- and community-based health services for individuals with HIV/AIDS pursuant to written plans of care prepared by a case management team, that shall include appropriate health care professionals, in such State for providing such services to such individuals;

(2) provide outreach services to individuals with HIV/AIDS, including those individuals in rural areas; and

(3) provide for the coordination of the provision of services under this section with the provision of HIV-related health services, including specialty care and vaccinations for hepatitis co-infection, provided by public and private entities.

(b) Priority

In awarding grants under subsection (a), a State shall give priority to entities that provide assurances to the State that—

(1) such entities will participate in HIV care consortia if such consortia exist within the State; and

(2) such entities will utilize amounts provided under such grants for the provision of home- and community-based services to low-income individuals with HIV/AIDS.

(c) "Home- and community-based health services" defined

As used in section 300ff–21 of this title, the term "home- and community-based health services"—

(1) means, with respect to an individual with HIV/AIDS, skilled health services furnished to the individual in the individual's home pursuant to a written plan of care established by a case management team, that shall include appropriate health care professionals, for the provision of such services and items described in paragraph (2);

(2) includes—

(A) durable medical equipment;

(B) home health aide services and personal care services furnished in the home of the individual;

(C) day treatment or other partial hospitalization services;

(D) home intravenous and aerosolized drug therapy (including prescription drugs administered as part of such therapy);

(E) routine diagnostic testing administered in the home of the individual; and

(F) appropriate mental health, developmental, and rehabilitation services; and

(3) does not include—

(A) inpatient hospital services; and

(B) nursing home and other long term care facilities.

(July 1, 1944, ch. 373, title XXVI, §2614, as added Pub. L. 101–381, title II, §201, Aug. 18, 1990, 104 Stat. 589; amended Pub. L. 109–415, title II, §§201(c)(2), 204(a), (b), title VII, §§702(3), 703,

Dec. 19, 2006, 120 Stat. 2788, 2796, 2820; Pub. L. 111–87, §2(a)(1), (3)(A), Oct. 30, 2009, 123 Stat. 2885.)

EDITORIAL NOTES

PRIOR PROVISIONS

A prior section 2614 of act July 1, 1944, was successively renumbered by subsequent acts and transferred, see section 238m of this title.

AMENDMENTS

2009—Pub. L. 111–87 repealed Pub. L. 109–415, §703, and revived the provisions of this section as in effect on Sept. 30, 2009. See 2006 Amendment note and Effective Date of 2009 Amendment; Revival of Section note below.

2006—Pub. L. 109–415, §703, which directed repeal of this section effective Oct. 1, 2009, was itself repealed by Pub. L. 111–87, §2(a)(1), effective Sept. 30, 2009.

Pub. L. 109–415, §702(3), substituted "HIV/AIDS" for "HIV disease" wherever appearing.

Subsec. (a). Pub. L. 109–415, §204(a), substituted "section 300ff–21 of this title" for "this part" in introductory provisions.

Pub. L. 109–415, §201(c)(2)(A), substituted "section 300ff–22(b)(3)(J) of this title" for "section 300ff–22(a)(2) of this title" in introductory provisions.

Subsec. (a)(3). Pub. L. 109–415, §204(b), inserted ", including specialty care and vaccinations for hepatitis co-infection," after "health services".

Subsec. (c). Pub. L. 109–415, §204(a), substituted "section 300ff–21 of this title" for "this part" in introductory provisions.

Subsec. (c)(2)(B). Pub. L. 109–415, §201(c)(2)(B), struck out "homemaker or" before "home health".

STATUTORY NOTES AND RELATED SUBSIDIARIES

EFFECTIVE DATE OF 2009 AMENDMENT; REVIVAL OF SECTION

For provisions that repeal by section 2(a)(1) of Pub. L. 111–87 of section 703 of Pub. L. 109–415 be effective Sept. 30, 2009, and that the provisions of this section as in effect on Sept. 30, 2009, be revived, see section 2(a)(2), (3)(A) of Pub. L. 111–87, set out as a note under section 300ff–11 of this title.

§300ff–25. Continuum of health insurance coverage

(a) In general

A State may use amounts received under a grant awarded under section 300ff–21 of this title to establish a program of financial assistance under section 300ff–22(b)(3)(F) of this title to assist eligible low-income individuals with HIV/AIDS in—

(1) maintaining a continuity of health insurance; or

(2) receiving medical benefits under a health insurance program, including risk-pools.

(b) Limitations

Assistance shall not be utilized under subsection (a)—

(1) to pay any costs associated with the creation, capitalization, or administration of a liability risk pool (other than those costs paid on behalf of individuals as part of premium contributions to existing liability risk pools); and

(2) to pay any amount expended by a State under title XIX of the Social Security Act [42 U.S.C. 1396 et seq.].

(July 1, 1944, ch. 373, title XXVI, §2615, as added Pub. L. 101–381, title II, §201, Aug. 18, 1990, 104 Stat. 590; amended Pub. L. 109–415, title II, §§201(c)(3), 204(a), title VII, §§702(3), 703, Dec. 19, 2006, 120 Stat. 2788, 2796, 2820; Pub. L. 111–87, §2(a)(1), (3)(A), Oct. 30, 2009, 123 Stat. 2885.)

EDITORIAL NOTES

REFERENCES IN TEXT

The Social Security Act, referred to in subsec. (b)(2), is act Aug. 14, 1935, ch. 531, 49 Stat. 620. Title XIX of the Social Security Act is classified generally to subchapter XIX (§1396 et seq.) of chapter 7 of this title. For complete classification of this Act to the Code, see section 1305 of this title and Tables.

AMENDMENTS

2009—Pub. L. 111–87 repealed Pub. L. 109–415, §703, and revived the provisions of this section as in effect on Sept. 30, 2009. See 2006 Amendment note and Effective Date of 2009 Amendment; Revival of Section note below.

2006—Pub. L. 109–415, §703, which directed repeal of this section effective Oct. 1, 2009, was itself repealed by Pub. L. 111–87, §2(a)(1), effective Sept. 30, 2009.

Subsec. (a). Pub. L. 109–415, §§201(c)(3), 204(a), 702(3), in introductory provisions, substituted "HIV/AIDS" for "HIV disease", "section 300ff–21 of this title" for "this part", and "section 300ff–22(b)(3)(F) of this title" for "section 300ff–22(a)(3) of this title".

STATUTORY NOTES AND RELATED SUBSIDIARIES

EFFECTIVE DATE OF 2009 AMENDMENT; REVIVAL OF SECTION

For provisions that repeal by section 2(a)(1) of Pub. L. 111–87 of section 703 of Pub. L. 109–415 be effective Sept. 30, 2009, and that the provisions of this section as in effect on Sept. 30, 2009, be revived, see section 2(a)(2), (3)(A) of Pub. L. 111–87, set out as a note under section 300ff–11 of this title.

§300ff–26. Provision of treatments

(a) In general

A State shall use a portion of the amounts provided under a grant awarded under section 300ff–21 of this title to establish a program under section 300ff–22(b)(3)(B) of this title to provide therapeutics to treat HIV/AIDS or prevent the serious deterioration of health arising from HIV/AIDS in eligible individuals, including measures for the prevention and treatment of opportunistic infections.

(b) Eligible individual

To be eligible to receive assistance from a State under this section an individual shall—

(1) have a medical diagnosis of HIV/AIDS; and

(2) be a low-income individual, as defined by the State.

(c) State duties

In carrying out this section the State shall—

(1) ensure that the therapeutics included on the list of classes of core antiretroviral therapeutics established by the Secretary under subsection (e) are, at a minimum, the treatments provided by the State pursuant to this section;

(2) provide assistance for the purchase of treatments determined to be eligible under paragraph (1), and the provision of such ancillary devices that are essential to administer such treatments;

(3) provide outreach to individuals with HIV/AIDS, and as appropriate to the families of such individuals;

(4) facilitate access to treatments for such individuals;

(5) document the progress made in making therapeutics described in subsection (a) available to individuals eligible for assistance under this section; and

(6) encourage, support, and enhance adherence to and compliance with treatment regimens, including related medical monitoring.

Of the amount reserved by a State for a fiscal year for use under this section, the State may not use more than 5 percent to carry out services under paragraph (6), except that the percentage applicable

with respect to such paragraph is 10 percent if the State demonstrates to the Secretary that such additional services are essential and in no way diminish access to the therapeutics described in subsection (a).

(d) Duties of Secretary

In carrying out this section, the Secretary shall review the current status of State drug reimbursement programs established under section 300ff–22(2) [1] of this title and assess barriers to the expanded availability of the treatments described in subsection (a). The Secretary shall also examine the extent to which States coordinate with other grantees under this subchapter to reduce barriers to the expanded availability of the treatments described in subsection (a).

(e) List of classes of core antiretroviral therapeutics

For purposes of subsection (c)(1), the Secretary shall develop and maintain a list of classes of core antiretroviral therapeutics, which list shall be based on the therapeutics included in the guidelines of the Secretary known as the Clinical Practice Guidelines for Use of HIV/AIDS Drugs, relating to drugs needed to manage symptoms associated with HIV. The preceding sentence does not affect the authority of the Secretary to modify such Guidelines.

(f) Use of health insurance and plans

(1) In general

In carrying out subsection (a), a State may expend a grant under section 300ff–21 of this title to provide the therapeutics described in such subsection by paying on behalf of individuals with HIV/AIDS the costs of purchasing or maintaining health insurance or plans whose coverage includes a full range of such therapeutics and appropriate primary care services.

(2) Limitation

The authority established in paragraph (1) applies only to the extent that, for the fiscal year involved, the costs of the health insurance or plans to be purchased or maintained under such paragraph do not exceed the costs of otherwise providing therapeutics described in subsection (a).

(g) Drug rebate program

A State shall ensure that any drug rebates received on drugs purchased from funds provided pursuant to this section are applied to activities supported under this subpart, with priority given to activities described under this section.

(July 1, 1944, ch. 373, title XXVI, §2616, as added Pub. L. 101–381, title II, §201, Aug. 18, 1990, 104 Stat. 590; amended Pub. L. 104–146, §3(c)(3), May 20, 1996, 110 Stat. 1355; Pub. L. 106–345, title II, §204, Oct. 20, 2000, 114 Stat. 1332; Pub. L. 109–415, title II, §§201(c)(4), 202, 204(a), title VII, §§702(3), 703, Dec. 19, 2006, 120 Stat. 2788, 2796, 2820; Pub. L. 111–87, §2(a)(1), (3)(A), Oct. 30, 2009, 123 Stat. 2885.)

EDITORIAL NOTES

REFERENCES IN TEXT

Section 300ff–22 of this title, referred to in subsec. (d), was amended generally by Pub. L. 109–415, title II, §201(a), Dec. 19, 2006, 120 Stat. 2785, and, as so amended, does not contain a par. (2).

AMENDMENTS

2009—Pub. L. 111–87 repealed Pub. L. 109–415, §703, and revived the provisions of this section as in effect on Sept. 30, 2009. See 2006 Amendment note and Effective Date of 2009 Amendment; Revival of Section note below.

2006—Pub. L. 109–415, §703, which directed repeal of this section effective Oct. 1, 2009, was itself repealed by Pub. L. 111–87, §2(a)(1), effective Sept. 30, 2009.

Subsec. (a). Pub. L. 109–415, §702(3), substituted "HIV/AIDS" for "HIV disease" in two places.

Pub. L. 109–415, §204(a), substituted "section 300ff–21 of this title" for "this part".

Pub. L. 109–415, §201(c)(4), substituted "section 300ff–22(b)(3)(B) of this title" for "section

300ff–22(a)(5) of this title".

Subsec. (b)(1). Pub. L. 109–415, §702(3), substituted "HIV/AIDS" for "HIV disease".

Subsec. (c)(1). Pub. L. 109–415, §202(a)(1), added par. (1) and struck out former par. (1) which read as follows: "determine, in accordance with guidelines issued by the Secretary, which treatments are eligible to be included under the program established under this section;".

Subsec. (c)(3). Pub. L. 109–415, §702(3), substituted "HIV/AIDS" for "HIV disease".

Subsec. (e). Pub. L. 109–415, §202(a)(3), added subsec. (e). Former subsec. (e) redesignated (f).

Subsec. (f). Pub. L. 109–415, §202(a)(2), redesignated subsec. (e) as (f).

Subsec. (f)(1). Pub. L. 109–415, §702(3), substituted "HIV/AIDS" for "HIV disease".

Pub. L. 109–415, §204(a), substituted "section 300ff–21 of this title" for "this part".

Subsec. (g). Pub. L. 109–415, §202(b), added subsec. (g).

2000—Subsec. (c). Pub. L. 106–345, §204(a), added par. (6) and concluding provisions.

Subsec. (e). Pub. L. 106–345, §204(b), added subsec. (e).

1996—Subsec. (a). Pub. L. 104–146, §3(c)(3)(A), substituted "shall use a portion of the amounts" for "may use amounts" and "section 300ff–22(a)(5) of this title to provide therapeutics to treat HIV disease" for "section 300ff–22(a)(4) of this title to provide treatments that have been determined to prolong life" and inserted before period ", including measures for the prevention and treatment of opportunistic infections".

Subsec. (c)(5). Pub. L. 104–146, §3(c)(3)(B), added par. (5).

Subsec. (d). Pub. L. 104–146, §3(c)(3)(C), added subsec. (d).

STATUTORY NOTES AND RELATED SUBSIDIARIES

EFFECTIVE DATE OF 2009 AMENDMENT; REVIVAL OF SECTION

For provisions that repeal by section 2(a)(1) of Pub. L. 111–87 of section 703 of Pub. L. 109–415 be effective Sept. 30, 2009, and that the provisions of this section as in effect on Sept. 30, 2009, be revived, see section 2(a)(2), (3)(A) of Pub. L. 111–87, set out as a note under section 300ff–11 of this title.

EFFECTIVE DATE OF 1996 AMENDMENT

Amendment by Pub. L. 104–146 effective Oct. 1, 1996, see section 13 of Pub. L. 104–146, set out as a note under section 300ff–11 of this title.

[1] *See References in Text note below.*

§300ff–27. State application

(a) In general

The Secretary shall not make a grant to a State under section 300ff–21 of this title for a fiscal year unless the State prepares and submits, to the Secretary, an application at such time, in such form, and containing such agreements, assurances, and information as the Secretary determines to be necessary to carry out section 300ff–21 of this title.

(b) Description of intended uses and agreements

The application submitted under subsection (a) shall contain—

(1) a detailed description of the HIV-related services provided in the State to individuals and families with HIV/AIDS during the year preceding the year for which the grant is requested, and the number of individuals and families receiving such services, that shall include—

(A) a description of the types of programs operated or funded by the State for the provision of HIV-related services during the year preceding the year for which the grant is requested and the methods utilized by the State to finance such programs;

(B) an accounting of the amount of funds that the State has expended for such services and programs during the year preceding the year for which the grant is requested; and

(C) information concerning—

(i) the number of individuals to be served with assistance provided under the grant;

(ii) demographic data on the population of the individuals to be served;

(iii) the average cost of providing each category of HIV-related health services and the extent to which such cost is paid by third-party payors; and

(iv) the aggregate amounts expended for each such category of services;

(2) a determination of the size and demographics of the population of individuals with HIV/AIDS in the State;

(3) a determination of the needs of such population, with particular attention to—

(A) individuals with HIV/AIDS who know their HIV status and are not receiving HIV-related services; and

(B) disparities in access and services among affected subpopulations and historically underserved communities;

(4) the designation of a lead State agency that shall—

(A) administer all assistance received under this part;

(B) conduct the needs assessment and prepare the State plan under paragraph (3);

(C) prepare all applications for assistance under this part;

(D) receive notices with respect to programs under this subchapter;

(E) every 2 years, collect and submit to the Secretary all audits, consistent with Office of Management and Budget circular A133, from grantees within the State, including audits regarding funds expended in accordance with this part; and

(F) carry out any other duties determined appropriate by the Secretary to facilitate the coordination of programs under this subchapter.[1]

(5) a comprehensive plan that describes the organization and delivery of HIV health care and support services to be funded with assistance received under section 300ff–21 of this title that shall include a description of the purposes for which the State intends to use such assistance, and that—

(A) establishes priorities for the allocation of funds within the State based on—

(i) size and demographics of the population of individuals with HIV/AIDS (as determined under paragraph (2)) and the needs of such population (as determined under paragraph (3));

(ii) availability of other governmental and non-governmental resources, including the State medicaid plan under title XIX of the Social Security Act [42 U.S.C. 1396 et seq.] and the State Children's Health Insurance Program under title XXI of such Act [42 U.S.C. 1397aa et seq.] to cover health care costs of eligible individuals and families with HIV/AIDS;

(iii) capacity development needs resulting from disparities in the availability of HIV-related services in historically underserved communities and rural communities; and

(iv) the efficiency of the administrative mechanism of the State for rapidly allocating funds to the areas of greatest need within the State;

(B) includes a strategy for identifying individuals who know their HIV status and are not receiving such services and for informing the individuals of and enabling the individuals to utilize the services, giving particular attention to eliminating disparities in access and services among affected subpopulations and historically underserved communities, and including discrete goals, a timetable, and an appropriate allocation of funds;

(C) includes a strategy to coordinate the provision of such services with programs for HIV prevention (including outreach and early intervention) and for the prevention and treatment of substance abuse (including programs that provide comprehensive treatment services for such abuse);

(D) describes the services and activities to be provided and an explanation of the manner in which the elements of the program to be implemented by the State with such assistance will maximize the quality of health and support services available to individuals with HIV/AIDS throughout the State;

(E) provides a description of the manner in which services funded with assistance provided

under section 300ff–21 of this title will be coordinated with other available related services for individuals with HIV/AIDS;

(F) provides a description of how the allocation and utilization of resources are consistent with the statewide coordinated statement of need (including traditionally underserved populations and subpopulations) developed in partnership with other grantees in the State that receive funding under this subchapter; and

(G) includes key outcomes to be measured by all entities in the State receiving assistance under this subchapter; and [2]

(6) an assurance that the public health agency administering the grant for the State will periodically convene a meeting of individuals with HIV/AIDS, members of a Federally recognized Indian tribe as represented in the State, representatives of grantees under each part under this subchapter, providers, and public agency representatives for the purpose of developing a statewide coordinated statement of need;

(7) an assurance by the State that—

(A) the public health agency that is administering the grant for the State engages in a public advisory planning process, including public hearings, that includes the participants under paragraph (6), and the types of entities described in section 300ff–12(b)(2) of this title, in developing the comprehensive plan under paragraph (5) and commenting on the implementation of such plan;

(B) the State will—

(i) to the maximum extent practicable, ensure that HIV-related health care and support services delivered pursuant to a program established with assistance provided under section 300ff–21 of this title will be provided without regard to the ability of the individual to pay for such services and without regard to the current or past health condition of the individual with HIV/AIDS;

(ii) ensure that such services will be provided in a setting that is accessible to low-income individuals with HIV/AIDS;

(iii) provide outreach to low-income individuals with HIV/AIDS to inform such individuals of the services available under section 300ff–21 of this title; and

(iv) in the case of a State that intends to use amounts provided under the grant for purposes described in section 300ff–25 of this title, submit a plan to the Secretary that demonstrates that the State has established a program that assures that—

(I) such amounts will be targeted to individuals who would not otherwise be able to afford health insurance coverage; and

(II) income, asset, and medical expense criteria will be established and applied by the State to identify those individuals who qualify for assistance under such program, and information concerning such criteria shall be made available to the public;

(C) the State will provide for periodic independent peer review to assess the quality and appropriateness of health and support services provided by entities that receive funds from the State under section 300ff–21 of this title;

(D) the State will permit and cooperate with any Federal investigations undertaken regarding programs conducted under section 300ff–21 of this title;

(E) the State will maintain HIV-related activities at a level that is equal to not less than the level of such expenditures by the State for the 1-year period preceding the fiscal year for which the State is applying to receive a grant under section 300ff–21 of this title;

(F) the State will ensure that grant funds are not utilized to make payments for any item or service to the extent that payment has been made, or can reasonably be expected to be made, with respect to that item or service—

(i) under any State compensation program, under an insurance policy, or under any Federal or State health benefits program; or

(ii) by an entity that provides health services on a prepaid basis (except for a program

administered by or providing the services of the Indian Health Service); and

(G) entities within areas in which activities under the grant are carried out will maintain appropriate relationships with entities in the area served that constitute key points of access to the health care system for individuals with HIV/AIDS (including emergency rooms, substance abuse treatment programs, detoxification centers, adult and juvenile detention facilities, sexually transmitted disease clinics, HIV counseling and testing sites, mental health programs, and homeless shelters), and other entities under section [3] 300ff–22(c) and 300ff–52(a) of this title, for the purpose of facilitating early intervention for individuals newly diagnosed with HIV/AIDS and individuals knowledgeable of their HIV status but not in care; and

(8) a comprehensive plan—

(A) containing an identification of individuals with HIV/AIDS as described in clauses (i) through (iii) of section 300ff–13(b)(2)(A) of this title and the strategy required under section 300ff–12(b)(4)(D)(iv) of this title;

(B) describing the estimated number of individuals within the State with HIV/AIDS who do not know their status;

(C) describing activities undertaken by the State to find the individuals described in subparagraph (A) and to make such individuals aware of their status;

(D) describing the manner in which the State will provide undiagnosed individuals who are made aware of their status with access to medical treatment for their HIV/AIDS; and

(E) describing efforts to remove legal barriers, including State laws and regulations, to routine testing.

(c) Requirements regarding imposition of charges for services

(1) In general

The Secretary may not make a grant under section 300ff–21 of this title to a State unless the State provides assurances that in the provision of services with assistance provided under the grant—

(A) in the case of individuals with an income less than or equal to 100 percent of the official poverty line, the provider will not impose charges on any such individual for the provision of services under the grant;

(B) in the case of individuals with an income greater than 100 percent of the official poverty line, the provider—

(i) will impose charges on each such individual for the provision of such services; and

(ii) will impose charges according to a schedule of charges that is made available to the public;

(C) in the case of individuals with an income greater than 100 percent of the official poverty line and not exceeding 200 percent of such poverty line, the provider will not, for any calendar year, impose charges in an amount exceeding 5 percent of the annual gross income of the individual involved;

(D) in the case of individuals with an income greater than 200 percent of the official poverty line and not exceeding 300 percent of such poverty line, the provider will not, for any calendar year, impose charges in an amount exceeding 7 percent of the annual gross income of the individual involved; and

(E) in the case of individuals with an income greater than 300 percent of the official poverty line, the provider will not, for any calendar year, impose charges in an amount exceeding 10 percent of the annual gross income of the individual involved.

(2) Assessment of charge

With respect to compliance with the assurance made under paragraph (1), a grantee under section 300ff–21 of this title may, in the case of individuals subject to a charge for purposes of

such paragraph—

(A) assess the amount of the charge in the discretion of the grantee, including imposing only a nominal charge for the provision of services, subject to the provisions of such paragraph regarding public schedules regarding limitation on the maximum amount of charges; and

(B) take into consideration the medical expenses of individuals in assessing the amount of the charge, subject to such provisions.

(3) Applicability of limitation on amount of charge

The Secretary may not make a grant under section 300ff–21 of this title unless the applicant of the grant agrees that the limitations established in subparagraphs (C), (D), and (E) of paragraph (1) regarding the imposition of charges for services applies to the annual aggregate of charges imposed for such services, without regard to whether they are characterized as enrollment fees, premiums, deductibles, cost sharing, copayments, coinsurance, or other charges.

(4) Waiver

(A) In general

The State shall waive the requirements established in paragraphs (1) through (3) in the case of an entity that does not, in providing health care services, impose a charge or accept reimbursement from any third-party payor, including reimbursement under any insurance policy or under any Federal or State health benefits program.

(B) Determination

A determination by the State of whether an entity referred to in subparagraph (A) meets the criteria for a waiver under such subparagraph shall be made without regard to whether the entity accepts voluntary donations regarding the provision of services to the public.

(d) Requirement of matching funds regarding State allotments

(1) In general

In the case of any State to which the criterion described in paragraph (3) applies, the Secretary may not make a grant under section 300ff–21 of this title unless the State agrees that, with respect to the costs to be incurred by the State in carrying out the program for which the grant was awarded, the State will, subject to subsection (b)(2),[4] make available (directly or through donations from public or private entities) non-Federal contributions toward such costs in an amount equal to—

(A) for the first fiscal year of payments under the grant, not less than 162/3 percent of such costs ($1 for each $5 of Federal funds provided in the grant);

(B) for any second fiscal year of such payments, not less than 20 percent of such costs ($1 for each $4 of Federal funds provided in the grant);

(C) for any third fiscal year of such payments, not less than 25 percent of such costs ($1 for each $3 of Federal funds provided in the grant);

(D) for any fourth fiscal year of such payments, not less than 331/3 percent of such costs ($1 for each $2 of Federal funds provided in the grant); and

(E) for any subsequent fiscal year of such payments, not less than 331/3 percent of such costs ($1 for each $2 of Federal funds provided in the grant).

(2) Determination of amount of non-Federal contribution

(A) In general

Non-Federal contributions required in paragraph (1) may be in cash or in kind, fairly evaluated, including plant, equipment, or services. Amounts provided by the Federal Government, and any portion of any service subsidized by the Federal Government, may not be included in determining the amount of such non-Federal contributions.

(B) Inclusion of certain amounts

(i) In making a determination of the amount of non-Federal contributions made by a State for

purposes of paragraph (1), the Secretary shall, subject to clause (ii), include any non-Federal contributions provided by the State for HIV-related services, without regard to whether the contributions are made for programs established pursuant to this subchapter;

(ii) In making a determination for purposes of clause (i), the Secretary may not include any non-Federal contributions provided by the State as a condition of receiving Federal funds under any program under this subchapter (except for the program established in section 300ff–21 of this title) or under other provisions of law.

(3) Applicability of requirement

(A) Number of cases

A State referred to in paragraph (1) is any State for which the number of cases of HIV/AIDS reported to and confirmed by the Director of the Centers for Disease Control and Prevention for the period described in subparagraph (B) constitutes in excess of 1 percent of the aggregate number of such cases reported to and confirmed by the Director for such period for the United States.

(B) Period of time

The period referred to in subparagraph (A) is the 2-year period preceding the fiscal year for which the State involved is applying to receive a grant under subsection (a).

(C) Puerto Rico

For purposes of paragraph (1), the number of cases of HIV/AIDS reported and confirmed for the Commonwealth of Puerto Rico for any fiscal year shall be deemed to be less than 1 percent.

(4) Diminished State contribution

With respect to a State that does not make available the entire amount of the non-Federal contribution referred to in paragraph (1), the State shall continue to be eligible to receive Federal funds under a grant under section 300ff–21 of this title, except that the Secretary in providing Federal funds under the grant shall provide such funds (in accordance with the ratios prescribed in paragraph (1)) only with respect to the amount of funds contributed by such State.

(July 1, 1944, ch. 373, title XXVI, §2617, as added Pub. L. 101–381, title II, §201, Aug. 18, 1990, 104 Stat. 590; amended Pub. L. 102–531, title III, §312(d)(29), Oct. 27, 1992, 106 Stat. 3506; Pub. L. 104–146, §§3(c)(4), 12(c)(3), May 20, 1996, 110 Stat. 1355, 1373; Pub. L. 106–345, title II, §205, Oct. 20, 2000, 114 Stat. 1332; Pub. L. 109–415, title II, §204(a), (c), (d), title VII, §§702(3), 703, Dec. 19, 2006, 120 Stat. 2796, 2797, 2820; Pub. L. 111–87, §§2(a)(1), (3)(A), 9, Oct. 30, 2009, 123 Stat. 2885, 2895.)

EDITORIAL NOTES

REFERENCES IN TEXT

The Social Security Act, referred to in subsec. (b)(5)(A)(ii), is act Aug. 14, 1935, ch. 531, 49 Stat. 620. Titles XIX and XXI of the Act are classified generally to subchapters XIX (§1396 et seq.) and XXI (§1397aa et seq.), respectively, of chapter 7 of this title. For complete classification of this Act to the Code, see section 1305 of this title and Tables.

Subsection (b)(2), referred to in subsec. (d)(1), was redesignated subsec. (b)(4) by Pub. L. 106–345, title II, §205(a)(1), Oct. 20, 2000, 114 Stat. 1332, and then subsec. (b)(5) by Pub. L. 109–415, title II, §204(c)(2), Dec. 19, 2006, 120 Stat. 2796.

AMENDMENTS

2009—Pub. L. 111–87, §2(a)(1), (3)(A), repealed Pub. L. 109–415, §703, and revived the provisions of this section as in effect on Sept. 30, 2009. See 2006 Amendment note and Effective Date of 2009 Amendment; Revival of Section note below.

Subsec. (b)(8). Pub. L. 111–87, §9, added par. (8).

2006—Pub. L. 109–415, §703, which directed repeal of this section effective Oct. 1, 2009, was itself repealed by Pub. L. 111–87, §2(a)(1), effective Sept, 30, 2009.

Pub. L. 109–415, §204(a), substituted "section 300ff–21 of this title" for "this part" wherever appearing in subsecs. (a), (b), (c)(2), and (d).

Subsec. (b). Pub. L. 109–415, §702(3), substituted "HIV/AIDS" for "HIV disease" wherever appearing.

Subsec. (b)(4). Pub. L. 109–415, §204(c)(1)(B), added par. (4). Former par. (4) redesignated (5).

Subsec. (b)(5). Pub. L. 109–415, §204(c)(1)(A), redesignated par. (4) as (5). Former par. (5) redesignated (6).

Subsec. (b)(5)(G). Pub. L. 109–415, §204(c)(1)(C), added subpar. (G).

Subsec. (b)(6). Pub. L. 109–415, §204(c)(2), inserted "members of a Federally recognized Indian tribe as represented in the State," before "representatives of grantees".

Pub. L. 109–415, §204(c)(1)(A), redesignated par. (5) as (6). Former par. (6) redesignated (7).

Subsec. (b)(7). Pub. L. 109–415, §204(c)(1)(A), redesignated par. (6) as (7).

Subsec. (b)(7)(A). Pub. L. 109–415, §204(c)(1)(D), substituted "paragraph (6)" for "paragraph (5)" and "paragraph (5)" for "paragraph (4)".

Subsec. (b)(7)(F)(ii). Pub. L. 109–415, §204(c)(3), inserted "(except for a program administered by or providing the services of the Indian Health Service)" before semicolon.

Subsec. (d)(3)(A), (C). Pub. L. 109–415, §204(d), substituted "HIV/AIDS" for "acquired immune deficiency syndrome".

2000—Subsec. (b)(2), (3). Pub. L. 106–345, §205(a)(2), added pars. (2) and (3). Former pars. (2) and (3) redesignated (4) and (5), respectively.

Subsec. (b)(4). Pub. L. 106–345, §205(a)(3)(A), (B), in introductory provisions substituted "comprehensive plan that describes the organization" for "comprehensive plan for the organization" and ", and that—" for ", including—".

Pub. L. 106–345, §205(a)(1), redesignated par. (2) as (4). Former par. (4) redesignated (6).

Subsec. (b)(4)(A) to (C). Pub. L. 106–345, §205(a)(3)(D), which directed the amendment of par. (4) by adding subpars. (A) to (C) "before subparagraph (C)", was executed by adding them before subpar. (D), to reflect the probable intent of Congress. Former subpars. (A) to (C) redesignated (D) to (F), respectively.

Subsec. (b)(4)(D). Pub. L. 106–345, §205(a)(3)(C), (E), redesignated subpar. (A) as (D) and inserted "describes" before "the services and activities".

Subsec. (b)(4)(E). Pub. L. 106–345, §205(a)(3)(C), (F), redesignated subpar. (B) as (E) and inserted "provides" before "a description".

Subsec. (b)(4)(F). Pub. L. 106–345, §205(a)(3)(C), (G), redesignated subpar. (C) as (F) and inserted "provides" before "a description".

Subsec. (b)(5). Pub. L. 106–345, §205(a)(1), (b)(1), redesignated par. (3) as (5) and substituted "HIV disease" for "HIV".

Subsec. (b)(6). Pub. L. 106–345, §205(a)(1), redesignated par. (4) as (6).

Subsec. (b)(6)(A). Pub. L. 106–345, §205(b)(2), amended subpar. (A) generally. Prior to amendment, subpar. (A) read as follows: "the public health agency that is administering the grant for the State will conduct public hearings concerning the proposed use and distribution of the assistance to be received under this part;".

Subsec. (b)(6)(G). Pub. L. 106–345, §205(c), added subpar. (G).

1996—Subsec. (b)(2)(C). Pub. L. 104–146, §3(c)(4)(A), added subpar. (C).

Subsec. (b)(3). Pub. L. 104–146, §3(c)(4)(C), added par. (3). Former par. (3) redesignated (4).

Subsec. (b)(4). Pub. L. 104–146, §3(c)(4)(B), redesignated par. (3) as (4).

Subsec. (b)(4)(B)(iv). Pub. L. 104–146, §12(c)(3), which directed amendment of par. (3)(B)(iv) by inserting "section" before "300ff–25", was executed by making the amendment in par. (4)(B)(iv) to reflect the probable intent of Congress and the redesignation of par. (3) as (4) by Pub. L. 104–146, §3(c)(4)(B). See above.

1992—Subsec. (d)(3)(A). Pub. L. 102–531 substituted "Centers for Disease Control and Prevention" for "Centers for Disease Control".

STATUTORY NOTES AND RELATED SUBSIDIARIES

EFFECTIVE DATE OF 2009 AMENDMENT; REVIVAL OF SECTION

For provisions that repeal by section 2(a)(1) of Pub. L. 111–87 of section 703 of Pub. L. 109–415 be effective Sept. 30, 2009, that the provisions of this section as in effect on Sept. 30, 2009, be revived, and that amendment by section 9 of Pub. L. 111–87 be applicable to this section as so revived and effective as if enacted on Sept. 30, 2009, see section 2(a)(2), (3) of Pub. L. 111–87, set out as a note under section 300ff–11 of this title.

EFFECTIVE DATE OF 1996 AMENDMENT

Amendment by Pub. L. 104–146 effective Oct. 1, 1996, see section 13 of Pub. L. 104–146, set out as a note under section 300ff–11 of this title.

[1] So in original. The period probably should be a semicolon.

[2] So in original. The word "and" probably should not appear.

[3] So in original. Probably should be "sections".

[4] See References in Text note below.

§300ff–27a. Spousal notification

(a) In general

The Secretary of Health and Human Services shall not make a grant under part B of title XXVI of the Public Health Service Act (42 U.S.C. 300ff–21 et seq.) to any State unless such State takes administrative or legislative action to require that a good faith effort be made to notify a spouse of a known HIV-infected patient that such spouse may have been exposed to the human immunodeficiency virus and should seek testing.

(b) Definitions

For purposes of this section:

(1) Spouse

The term "spouse" means any individual who is the marriage partner of an HIV-infected patient, or who has been the marriage partner of that patient at any time within the 10-year period prior to the diagnosis of HIV infection.

(2) HIV-infected patient

The term "HIV-infected patient" means any individual who has been diagnosed to be infected with the human immunodeficiency virus.

(3) State

The term "State" means any of the 50 States, the District of Columbia, or any territory of the United States.

(Pub. L. 104–146, §8, May 20, 1996, 110 Stat. 1372.)

EDITORIAL NOTES

REFERENCES IN TEXT

The Public Health Service Act, referred to in subsec. (a), is act July 1, 1944, ch. 373, 58 Stat. 682. Part B of title XXVI of the Act is classified generally to this part. For complete classification of this Act to the Code, see Short Title note set out under section 201 of this title and Tables.

CODIFICATION

Section was enacted as part of the Ryan White CARE Act Amendments of 1996, and not as part of the Public Health Service Act which comprises this chapter.

STATUTORY NOTES AND RELATED SUBSIDIARIES

EFFECTIVE DATE

Section effective Oct. 1, 1996, see section 13 of Pub. L. 104–146, set out as an Effective Date of 1996 Amendment note under section 300ff–11 of this title.

§300ff–28. Distribution of funds

(a) Amount of grant to State

(1) Minimum allotment

Subject to the extent of amounts made available under section 300ff–31b of this title, the amount of a grant to be made under section 300ff–21 of this title for—

(A) each of the 50 States, the District of Columbia, Guam, and the Virgin Islands (referred to in this paragraph as a "covered State") for a fiscal year shall be the greater of—

(i)(I) with respect to a covered State that has less than 90 living cases of AIDS, as determined under paragraph (2)(D), $200,000; or

(II) with respect to a covered State that has 90 or more living cases of AIDS, as determined under paragraph (2)(D), $500,000; and

(ii) an amount determined under paragraph (2) and then, as applicable, increased under paragraph (2)(H); and

(B) each territory other than Guam and the Virgin Islands shall be the greater of $50,000 or an amount determined under paragraph (2).

(2) Determination

(A) Formula

For purposes of paragraph (1), the amount referred to in this paragraph for a State (including a territory) for a fiscal year is, subject to subparagraphs (E) and (F)—

(i) an amount equal to the amount made available under section 300ff–31b of this title for the fiscal year involved for grants pursuant to paragraph (1), subject to subparagraph (F); and

(ii) the percentage constituted by the sum of—

(I) the product of 0.75 and the ratio of the State distribution factor for the State or territory (as determined under subsection (B)) to the sum of the respective State distribution factors for all States or territories;

(II) the product of .20 and the ratio of the non-EMA distribution factor for the State or territory (as determined under subparagraph (C)) to the sum of the respective non-EMA distribution factors for all States or territories; and

(III) if the State does not for such fiscal year contain any area that is an eligible area under subpart I of part A or any area that is a transitional area under section 300ff–19 of this title (referred to in this subclause as a "no-EMA State"), the product of 0.05 and the ratio of the number of cases that applies for the State under subparagraph (D) to the sum of the respective numbers of cases that so apply for all no-EMA States.

(B) State distribution factor

For purposes of subparagraph (A)(ii)(I), the term "State distribution factor" means an amount equal to the number of living cases of HIV/AIDS in the State involved, as determined under subparagraph (D).

(C) Non-EMA distribution factor

For purposes of subparagraph (A)(ii)(II), the term "non-ema [1] distribution factor" means an amount equal to the sum of—

(i) the number of living cases of HIV/AIDS in the State involved, as determined under subparagraph (D); less

(ii) a number equal to the sum of—

(I) the total number of living cases of HIV/AIDS that are within areas in such State that are eligible areas under subpart I of part A for the fiscal year involved, which individual number for an area is the number that applies under section 300ff–11 of this title for the area for such fiscal year; and

(II) the total number of such cases that are within areas in such State that are transitional

areas under section 300ff–19 of this title for such fiscal year, which individual number for an area is the number that applies under such section for the fiscal year.

(D) Living cases of HIV/AIDS

(i) Requirement of names-based reporting

Except as provided in clause (ii), the number determined under this subparagraph for a State for a fiscal year for purposes of subparagraph (B) is the number of living names-based cases of HIV/AIDS in the State that, as of December 31 of the most recent calendar year for which such data is available, have been reported to and confirmed by the Director of the Centers for Disease Control and Prevention.

(ii) Transition period; exemption regarding non-AIDS cases

For each of the fiscal years 2007 through 2012, a State is, subject to clauses (iii) through (v), exempt from the requirement under clause (i) that living non-AIDS names-based cases of HIV be reported unless—

(I) a system was in operation as of December 31, 2005, that provides sufficiently accurate and reliable names-based reporting of such cases throughout the State, subject to clause (vii); or

(II) no later than the beginning of fiscal year 2008 or a subsequent fiscal year through fiscal year 2012, the Secretary, after consultation with the chief executive of the State, determines that a system has become operational in the State that provides sufficiently accurate and reliable names-based reporting of such cases throughout the State.

(iii) Requirements for exemption for fiscal year 2007

For fiscal year 2007, an exemption under clause (ii) for a State applies only if, by October 1, 2006—

(I)(aa) the State had submitted to the Secretary a plan for making the transition to sufficiently accurate and reliable names-based reporting of living non-AIDS cases of HIV; or

(bb) all statutory changes necessary to provide for sufficiently accurate and reliable reporting of such cases had been made; and

(II) the State had agreed that, by April 1, 2008, the State will begin accurate and reliable names-based reporting of such cases, except that such agreement is not required to provide that, as of such date, the system for such reporting be fully sufficient with respect to accuracy and reliability throughout the area.

(iv) Requirement for exemption as of fiscal year 2008

For each of the fiscal years 2008 through 2012, an exemption under clause (ii) for a State applies only if, as of April 1, 2008, the State is substantially in compliance with the agreement under clause (iii)(II).

(v) Progress toward names-based reporting

For fiscal year 2009 or a subsequent fiscal year, the Secretary may terminate an exemption under clause (ii) for a State if the State submitted a plan under clause (iii)(I)(aa) and the Secretary determines that the State is not substantially following the plan.

(vi) Counting of cases in areas with exemptions

(I) In general

With respect to a State that is under a reporting system for living non-AIDS cases of HIV that is not names-based (referred to in this subparagraph as "code-based reporting"), the Secretary shall, for purposes of this subparagraph, modify the number of such cases reported for the State in order to adjust for duplicative reporting in and among systems that use code-based reporting.

(II) Adjustment rate

The adjustment rate under subclause (I) for a State shall be a reduction of 5 percent for fiscal years before fiscal year 2012 (and 6 percent for fiscal year 2012) in the number of living non-AIDS cases of HIV reported for the State.

(III) Increased adjustment for certain States previously using code-based reporting

For purposes of this subparagraph for each of fiscal years 2010 through 2012, the Secretary shall deem the applicable number of living cases of HIV/AIDS in a State that were reported to and confirmed by the Centers for Disease Control and Prevention to be 3 percent higher than the actual number if—

(aa) there is an area in such State that satisfies all of the conditions described in items (aa) through (cc) of section 300ff–13(a)(3)(C)(vi)(III) of this title; or

(bb)(AA) fiscal year 2007 was the first year in which the count of living non-AIDS cases of HIV in such area, for purposes of this part, was based on a names-based reporting system; and

(BB) the amount of funding that such State received under this part for fiscal year 2007 was less than 70 percent of the amount of funding that such State received under such part for fiscal year 2006.

(vii) List of States meeting standard regarding December 31, 2005

(I) In general

If a State is specified in subclause (II), the State shall be considered to meet the standard described in clause (ii)(I). No other State may be considered to meet such standard.

(II) Relevant States

For purposes of subclause (I), the States specified in this subclause are the following: Alaska, Alabama, Arkansas, Arizona, Colorado, Florida, Indiana, Iowa, Idaho, Kansas, Louisiana, Michigan, Minnesota, Missouri, Mississippi, North Carolina, North Dakota, Nebraska, New Jersey, New Mexico, New York, Nevada, Ohio, Oklahoma, South Carolina, South Dakota, Tennessee, Texas, Utah, Virginia, Wisconsin, West Virginia, Wyoming, Guam, and the Virgin Islands.

(viii) Rules of construction regarding acceptance of reports

(I) Cases of AIDS

With respect to a State that is subject to the requirement under clause (i) and is not in compliance with the requirement for names-based reporting of living non-AIDS cases of HIV, the Secretary shall, notwithstanding such noncompliance, accept reports of living cases of AIDS that are in accordance with such clause.

(II) Applicability of exemption requirements

The provisions of clauses (ii) through (vii) may not be construed as having any legal effect for fiscal year 2013 or any subsequent fiscal year, and accordingly, the status of a State for purposes of such clauses may not be considered after fiscal year 2012.

(ix) Program for detecting inaccurate or fraudulent counting

The Secretary shall carry out a program to monitor the reporting of names-based cases for purposes of this subparagraph and to detect instances of inaccurate reporting, including fraudulent reporting.

(x) Future fiscal years

For fiscal years beginning with fiscal year 2013, determinations under this paragraph shall be based only on living names-based cases of HIV/AIDS with respect to the State involved.

(E) Code-based States; limitation on increase in grant

(i) In general

For each of the fiscal years 2007 through 2012, if code-based reporting (within the

meaning of subparagraph (D)(vi)) applies in a State as of the beginning of the fiscal year involved, then notwithstanding any other provision of this paragraph, the amount of the grant pursuant to paragraph (1) for the State may not for the fiscal year involved exceed by more than 5 percent the amount of the grant pursuant to this paragraph for the State for the preceding fiscal year, except that the limitation under this clause may not result in a grant pursuant to paragraph (1) for a fiscal year that is less than the minimum amount that applies to the State under such paragraph for such fiscal year.

(ii) Use of amounts involved

For each of the fiscal years 2007 through 2012, amounts available as a result of the limitation under clause (i) shall be made available by the Secretary as additional amounts for grants pursuant to section 300ff–29a of this title, subject to subparagraph (H).

(F) Appropriations for treatment drug program

(i) Formula grants

With respect to the fiscal year involved, if under section 300ff–31b of this title an appropriations Act provides an amount exclusively for carrying out section 300ff–26 of this title, the portion of such amount allocated to a State shall be the product of—

(I) 100 percent of such amount, less the percentage reserved under clause (ii)(V); and

(II) the percentage constituted by the ratio of the State distribution factor for the State (as determined under subparagraph (B)) to the sum of the State distribution factors for all States;

which product shall then, as applicable, be increased under subparagraph (H).

(ii) Supplemental treatment drug grants

(I) In general

From amounts made available under subclause (V), the Secretary shall award supplemental grants to States described in subclause (II) to enable such States to purchase and distribute to eligible individuals under section 300ff–26(b) of this title pharmaceutical therapeutics described under subsections (c)(2) and (e) of such section.

(II) Eligible States

For purposes of subclause (I), a State shall be an eligible State if the State did not have unobligated funds subject to reallocation under subsection (d) in the previous fiscal year and, in accordance with criteria established by the Secretary, demonstrates a severe need for a grant under this clause. For purposes of determining severe need, the Secretary shall consider eligibility standards, formulary composition, the number of eligible individuals to whom a State is unable to provide therapeutics described in section 300ff–26(a) of this title, and an unanticipated increase of eligible individuals with HIV/AIDS.

(III) State requirements

The Secretary may not make a grant to a State under this clause unless the State agrees that the State will make available (directly or through donations of public or private entities) non-Federal contributions toward the activities to be carried out under the grant in an amount equal to $1 for each $4 of Federal funds provided in the grant, except that the Secretary may waive this subclause if the State has otherwise fully complied with section 300ff–27(d) of this title with respect to the grant year involved. The provisions of this subclause shall apply to States that are not required to comply with such section 300ff–27(d) of this title.

(IV) Use and coordination

Amounts made available under a grant under this clause shall only be used by the State to provide HIV/AIDS-related medications. The State shall coordinate the use of such amounts with the amounts otherwise provided under section 300ff–26(a) of this title in

order to maximize drug coverage.

(V) Funding

For the purpose of making grants under this clause, the Secretary shall each fiscal year reserve 5 percent of the amount referred to in clause (i) with respect to section 300ff–26 of this title.

(iii) Code-based States; limitation on increase in formula grant

The limitation under subparagraph (E)(i) applies to grants pursuant to clause (i) of this subparagraph to the same extent and in the same manner as such limitation applies to grants pursuant to paragraph (1), except that the reference to minimum grants does not apply for purposes of this clause. Amounts available as a result of the limitation under the preceding sentence shall be made available by the Secretary as additional amounts for grants under clause (ii) of this subparagraph.

(G) Repealed. Pub. L. 109–415, title II, §203(b)(2), Dec. 19, 2006, 120 Stat. 2792

(H) Increase in formula grants

(i) Assurance of amount

(I) General rule

For fiscal year 2010, the Secretary shall ensure, subject to clauses (ii) through (iv), that the total for a State of the grant pursuant to paragraph (1) and the grant pursuant to subparagraph (F) is not less than 95 percent of such total for the State for fiscal year 2009.

(II) Rule of construction

With respect to the application of subclause (I), the 95 percent requirement under such subclause shall apply with respect to each grant awarded under paragraph (1) and with respect to each grant awarded under subparagraph (F).

(ii) Fiscal years 2011 and 2012

For each of the fiscal years 2011 and 2012, the Secretary shall ensure that the total for a State of the grant pursuant to paragraph (1) and the grant pursuant to subparagraph (F) is not less than 100 percent of such total for the State for fiscal year 2010.

(iii) Fiscal year 2013

For fiscal year 2013, the Secretary shall ensure that the total for a State of the grant pursuant to paragraph (1) and the grant pursuant to subparagraph (F) is not less than 92.5 percent of such total for the State for fiscal year 2012.

(iv) Source of funds for increase

(I) In general

From the amount reserved under section 300ff–31b(b)(2) of this title for a fiscal year, and from amounts available for such section pursuant to subsection (d) of this section, the Secretary shall make available such amounts as may be necessary to comply with clause (i).

(II) Pro rata reduction

If the amounts referred to in subclause (I) for a fiscal year are insufficient to fully comply with clause (i) for the year, the Secretary, in order to provide the additional funds necessary for such compliance, shall reduce on a pro rata basis the amount of each grant pursuant to paragraph (1) for the fiscal year, other than grants for States for which increases under clause (i) apply and other than States described in paragraph (1)(A)(i)(I). A reduction under the preceding sentence may not be made in an amount that would result in the State involved becoming eligible for such an increase.

(v) Applicability

This paragraph may not be construed as having any applicability after fiscal year 2013.

(b) Allocation of assistance by States

(1) Allowances

Prior to allocating assistance under this subsection, a State shall consider the unmet needs of those areas that have not received financial assistance under part A.

(2) Planning and evaluations

Subject to paragraph (4) and except as provided in paragraph (5), a State may not use more than 10 percent of amounts received under a grant awarded under section 300ff–21 of this title for planning and evaluation activities.

(3) Administration

(A) In general

Subject to paragraph (4), and except as provided in paragraph (5), a State may not use more than 10 percent of amounts received under a grant awarded under section 300ff–21 of this title for administration.

(B) Allocations

In the case of entities and subcontractors to which a State allocates amounts received by the State under a grant under section 300ff–21 of this title, the State shall ensure that, of the aggregate amount so allocated, the total of the expenditures by such entities for administrative expenses does not exceed 10 percent (without regard to whether particular entities expend more than 10 percent for such expenses).

(C) Administrative activities

For the purposes of subparagraph (A), amounts may be used for administrative activities that include routine grant administration and monitoring activities, including a clinical quality management program under subparagraph (E).

(D) Subcontractor administrative costs

For the purposes of this paragraph, subcontractor administrative activities include—

(i) usual and recognized overhead, including established indirect rates for agencies;

(ii) management oversight of specific programs funded under this subchapter; and

(iii) other types of program support such as quality assurance, quality control, and related activities.

(E) Clinical quality management

(i) Requirement

Each State that receives a grant under section 300ff–21 of this title shall provide for the establishment of a clinical quality management program to assess the extent to which HIV health services provided to patients under the grant are consistent with the most recent Public Health Service guidelines for the treatment of HIV/AIDS and related opportunistic infection, and as applicable, to develop strategies for ensuring that such services are consistent with the guidelines for improvement in the access to and quality of HIV health services.

(ii) Use of funds

(I) In general

From amounts received under a grant awarded under section 300ff–21 of this title for a fiscal year, a State may use for activities associated with the clinical quality management program required in clause (i) not to exceed the lesser of—

(aa) 5 percent of amounts received under the grant; or

(bb) $3,000,000.

(II) Relation to limitation on administrative expenses

The costs of a clinical quality management program under clause (i) may not be considered administrative expenses for purposes of the limitation established in subparagraph (A).

(4) Limitation on use of funds

Except as provided in paragraph (5), a State may not use more than a total of 15 percent of amounts received under a grant awarded under section 300ff–21 of this title for the purposes described in paragraphs (2) and (3).

(5) Exception

With respect to a State that receives the minimum allotment under subsection (a)(1) for a fiscal year, such State, from the amounts received under a grant awarded under section 300ff–21 of this title for such fiscal year for the activities described in paragraphs (2) and (3), may, notwithstanding paragraphs (2) through (4), use not more than that amount required to support one full-time-equivalent employee.

(6) Construction

A State may not use amounts received under a grant awarded under section 300ff–21 of this title to purchase or improve land, or to purchase, construct, or permanently improve (other than minor remodeling) any building or other facility, or to make cash payments to intended recipients of services.

(c) Expedited distribution

(1) In general

Not less than 75 percent of the amounts received under a grant awarded to a State under section 300ff–21 of this title shall be obligated to specific programs and projects and made available for expenditure not later than—

(A) in the case of the first fiscal year for which amounts are received, 150 days after the receipt of such amounts by the State; and

(B) in the case of succeeding fiscal years, 120 days after the receipt of such amounts by the State.

(2) Public comment

Within the time periods referred to in paragraph (1), the State shall invite and receive public comment concerning methods for the utilization of such amounts.

(d) Reallocation

Any portion of a grant made to a State under section 300ff–21 of this title for a fiscal year that has not been obligated as described in subsection (c) ceases to be available to the State and shall be made available by the Secretary for grants under section 300ff–29a of this title, in addition to amounts made available for such grants under section 300ff–31b(b)(2) of this title.

(July 1, 1944, ch. 373, title XXVI, §2618, as added Pub. L. 101–381, title II, §201, Aug. 18, 1990, 104 Stat. 595; amended Pub. L. 102–531, title III, §312(d)(30), Oct. 27, 1992, 106 Stat. 3506; Pub. L. 104–146, §§3(c)(5), (g)(2), 5, 6(c)(3), May 20, 1996, 110 Stat. 1355, 1363, 1365, 1368; Pub. L. 105–392, title IV, §417, Nov. 13, 1998, 112 Stat. 3591; Pub. L. 106–345, title II, §206, Oct. 20, 2000, 114 Stat. 1334; Pub. L. 109–415, title II, §§203, 204(a), title VII, §§702(1), 703, Dec. 19, 2006, 120 Stat. 2789, 2796, 2819, 2820; Pub. L. 111–87, §§2(a)(1), (3)(A), 3(b), 5(b), (c)(1), 7(b), 10(b), Oct. 30, 2009, 123 Stat. 2885, 2888, 2890, 2891, 2893, 2895.)

EDITORIAL NOTES

AMENDMENTS

2009—Pub. L. 111–87, §2(a)(1), (3)(A), repealed Pub. L. 109–415, §703, and revived the provisions of this section as in effect on Sept. 30, 2009. See 2006 Amendment note and Effective Date of 2009 Amendment; Revival of Section note below.

Subsec. (a)(2)(A)(i). Pub. L. 111–87, §5(c)(1), substituted "subparagraph (F)" for "subparagraph (G)".

Subsec. (a)(2)(D)(ii). Pub. L. 111–87, §3(b)(1)(A)(i), substituted "2012" for "2009" in introductory provisions.

Subsec. (a)(2)(D)(ii)(II). Pub. L. 111–87, §3(b)(1)(A)(ii), substituted "or a subsequent fiscal year through fiscal year 2012" for "or 2009".

Subsec. (a)(2)(D)(iv). Pub. L. 111–87, §3(b)(1)(B), substituted "2012" for "2010".

Subsec. (a)(2)(D)(v). Pub. L. 111–87, §3(b)(1)(C), inserted "or a subsequent fiscal year" after "2009".

Subsec. (a)(2)(D)(vi)(II). Pub. L. 111–87, §3(b)(1)(D), inserted "for fiscal years before fiscal year 2012 (and 6 percent for fiscal year 2012)" after "5 percent".

Subsec. (a)(2)(D)(vi)(III). Pub. L. 111–87, §7(b), added subcl. (III).

Subsec. (a)(2)(D)(viii)(II). Pub. L. 111–87, §3(b)(1)(E), substituted "2013" for "2010" and "2012" for "2009".

Subsec. (a)(2)(D)(x). Pub. L. 111–87, §3(b)(1)(F), added cl. (x).

Subsec. (a)(2)(E)(i), (ii). Pub. L. 111–87, §3(b)(2), substituted "2012" for "2009".

Subsec. (a)(2)(F)(ii)(V). Pub. L. 111–87, §10(b), struck out ", subject to subclause (VI)" before period.

Subsec. (a)(2)(H)(i). Pub. L. 111–87, §5(b)(1), (c)(1), substituted "2010" for "2007" and "2009" for "2006" and substituted "subparagraph (F)" for "subparagraph (G)" in two places.

Subsec. (a)(2)(H)(ii). Pub. L. 111–87, §5(b)(3), (c)(1), in heading, substituted "2011 and 2012" for "2008 and 2009" and, in text, substituted "2011 and 2012" for "2008 and 2009", "subparagraph (F)" for "subparagraph (G)", and "2010" for "2007".

Pub. L. 111–87, §5(b)(2), redesignated cl. (iii) as (ii) and struck out former cl. (ii). Prior to amendment, text read as follows: "For purposes of clause (i) as applied for fiscal year 2007, the references in such clause to subparagraph (G) are deemed to be references to subparagraph (I) as such subparagraph was in effect for fiscal year 2006."

Subsec. (a)(2)(H)(iii). Pub. L. 111–87, §5(b)(4), added cl. (iii). Former cl. (iii) redesignated (ii).

Subsec. (a)(2)(H)(v). Pub. L. 111–87, §5(b)(5), substituted "2013" for "2009".

2006—Pub. L. 109–415, §703, which directed repeal of this section effective Oct. 1, 2009, was itself repealed by Pub. L. 111–87, §2(a)(1), effective Sept. 30, 2009.

Subsec. (a)(1). Pub. L. 109–415, §204(a), substituted "section 300ff–21 of this title" for "this part" in introductory provisions.

Pub. L. 109–415, §203(g)(1), substituted "section 300ff–31b of this title" for "section 300ff–77 of this title" in introductory provisions.

Subsec. (a)(1)(A). Pub. L. 109–415, §203(g)(2)(A), substituted "each of the 50 States, the District of Columbia, Guam, and the Virgin Islands (referred to in this paragraph as a 'covered State')" for "each of the several States and the District of Columbia" in introductory provisions.

Subsec. (a)(1)(A)(i)(I). Pub. L. 109–415, §702(1), substituted "AIDS" for "acquired immune deficiency syndrome".

Pub. L. 109–415, §203(g)(2)(B)(i), substituted "covered State" for "State or District".

Subsec. (a)(1)(A)(i)(II). Pub. L. 109–415, §702(1), substituted "AIDS" for "acquired immune deficiency syndrome".

Pub. L. 109–415, §203(g)(2)(B)(ii), substituted "covered State" for "State or District" and inserted "and" at end.

Subsec. (a)(1)(B). Pub. L. 109–415, §203(g)(3), substituted "each territory other than Guam and the Virgin Islands" for "each territory of the United States, as defined in paragraph (3),".

Subsec. (a)(2)(A). Pub. L. 109–415, §203(b)(1)(A), in introductory provisions substituted "For purposes of paragraph (1), the amount referred to in this paragraph for a State (including a territory) for a fiscal year is, subject to subparagraphs (E) and (F)" for "The amount referred to in paragraph (1)(A)(ii) for a State and paragraph (1)(B) for a territory of the United States shall be the product of", added cl. (i), and struck out former cl. (i) which read as follows:

"(i) an amount equal to the amount appropriated under section 300ff–77 of this title for the fiscal year involved for grants under this part, subject to subparagraphs (H) and (I); and".

Subsec. (a)(2)(A)(ii)(I). Pub. L. 109–415, §203(b)(1)(B)(i), substituted "0.75" for ".80" and struck out "and" at end.

Subsec. (a)(2)(A)(ii)(II). Pub. L. 109–415, §203(b)(1)(B)(ii), inserted "non-EMA" after "respective" and substituted "; and" for period at end.

Subsec. (a)(2)(A)(ii)(III). Pub. L. 109–415, §203(b)(1)(B)(iii), added subcl. (III).

Subsec. (a)(2)(B). Pub. L. 109–415, §203(a)(1)(A), substituted "number of living cases of HIV/AIDS in the State involved" for "estimated number of living cases of acquired immune deficiency syndrome in the eligible

area involved".

Subsec. (a)(2)(C)(i). Pub. L. 109–415, §203(g)(4), struck out "or territory" after "State".

Pub. L. 109–415, §203(a)(2)(A), substituted "number of living cases of HIV/AIDS" for "estimated number of living cases of acquired immune deficiency syndrome".

Subsec. (a)(2)(C)(ii). Pub. L. 109–415, §203(a)(2)(B), amended cl. (ii) generally. Prior to amendment, cl. (ii) read as follows: "the estimated number of living cases of acquired immune deficiency syndrome in such State or territory that are within an eligible area (as determined under part A of this subchapter)."

Subsec. (a)(2)(D). Pub. L. 109–415, §203(a)(1)(B), amended subpar. (D) generally. Prior to amendment, subpar. (D) related to estimating the number of living cases of acquired immune deficiency syndrome in a State or territory.

Subsec. (a)(2)(E). Pub. L. 109–415, §203(b)(3), added subpar (E).

Pub. L. 109–415, §203(b)(2), struck out heading and text of subpar. (E). Text read as follows: "If under section 300ff–13(a)(3)(D)(i) of this title the Secretary determines that data on cases of HIV disease are not sufficiently accurate and reliable, then notwithstanding subparagraph (D) of this paragraph, for any fiscal year prior to fiscal year 2007 the references in such subparagraph to cases of HIV disease do not have any legal effect."

Subsec. (a)(2)(F). Pub. L. 109–415, §203(b)(4), redesignated subpar. (I) as (F).

Pub. L. 109–415, §203(b)(2), struck out heading and text of subpar. (F). Text read as follows: "For purposes of subparagraph (D), the cost index for Puerto Rico, the Virgin Islands, and Guam shall be 1.0."

Subsec. (a)(2)(F)(i). Pub. L. 109–415, §203(c)(1), which directed amendment of subsec. (a)(2)(G)(i) by substituting "section 300ff–31b of this title" for "section 300ff–77 of this title" in introductory provisions, substituting a semicolon for a period at end of subcl. (II), and adding concluding provisions, was executed by making the amendment to subsec. (a)(2)(F)(i), to reflect the probable intent of Congress.

Subsec. (a)(2)(F)(ii). Pub. L. 109–415, §203(c)(2), which directed amendment of subsec. (a)(2)(G)(ii) by adding subcls. (I) to (III), striking out former subcls. (I) to (III), substituting "5 percent" for "3 percent" in subcl. (V), striking out subcl. (VI), and realigning margins, was executed by making the amendments to subsec. (a)(2)(F)(ii), to reflect the probable intent of Congress. Prior to amendment, subcls. (I) to (III) and (VI) related to supplemental grants to States to increase access to therapeutics described in section 300ff–26(a), eligibility for grants, requirements for grants, and reservation of amounts, respectively.

Subsec. (a)(2)(F)(iii). Pub. L. 109–415, §203(c)(3), which directed amendment of subsec. (a)(2)(G) by adding cl. (iii), was executed by making the amendment to subsec. (a)(2)(F), to reflect the probable intent of Congress.

Subsec. (a)(2)(G). Pub. L. 109–415, §203(b)(2), struck out heading and text of subpar. (G). Text read as follows: "The Secretary may, in determining the amount of a grant for a fiscal year under this subsection, adjust the grant amount to reflect the amount of unexpended and uncanceled grant funds remaining at the end of the fiscal year preceding the year for which the grant determination is to be made. The amount of any such unexpended funds shall be determined using the financial status report of the grantee."

Subsec. (a)(2)(H). Pub. L. 109–415, §203(d), added subpar. (H).

Pub. L. 109–415, §203(b)(2), struck out subpar. (H) which related to amount of grants in fiscal years 2001 to 2005.

Subsec. (a)(2)(I). Pub. L. 109–415, §203(b)(4), redesignated subpar. (I) as (F).

Subsec. (a)(3). Pub. L. 109–415, §203(g)(5), struck out par. (3), which defined "State" and "territory of the United States" as used in subsec. (a).

Subsec. (b)(1). Pub. L. 109–415, §203(e)(1), redesignated par. (2) as (1).

Subsec. (b)(2). Pub. L. 109–415, §204(a), substituted "section 300ff–21 of this title" for "this part".

Pub. L. 109–415, §203(e)(2), substituted "paragraph (4)" for "paragraph (5)" and "paragraph (5)" for "paragraph (6)".

Pub. L. 109–415, §203(e)(1), redesignated par. (3) as (2). Former par. (2) redesignated (1).

Subsec. (b)(3). Pub. L. 109–415, §203(e)(3), added subpars. (B) and (E), redesignated former subpars. (B) and (C) as (C) and (D), respectively, inserted ", including a clinical quality management program under subparagraph (E)" before period at end of subpar. (C), and, in subpar. (A), reenacted heading without change and amended text generally. Prior to amendment, subpar. (A) text read as follows: "Subject to paragraph (5) and except as provided in paragraph (6), a State may not use more than 10 percent of amounts received under a grant awarded under this part for administration. In the case of entities and subcontractors to which the State allocates amounts received by the State under the grant (including consortia under section 300ff–23 of this title), the State shall ensure that, of the aggregate amount so allocated, the total of the expenditures by such entities for administrative expenses does not exceed 10 percent (without regard to whether particular entities expend more than 10 percent for such expenses)."

Pub. L. 109–415, §203(e)(1), redesignated par. (4) as (3). Former par. (3) redesignated (2).

Subsec. (b)(4). Pub. L. 109–415, §204(a), substituted "section 300ff–21 of this title" for "this part".

Pub. L. 109–415, §203(e)(4), substituted "paragraph (5)" for "paragraph (6)" and "paragraphs (2) and (3)" for "paragraphs (3) and (4)".

Pub. L. 109–415, §203(e)(1), redesignated par. (5) as (4). Former par. (4) redesignated (3).

Subsec. (b)(5). Pub. L. 109–415, §204(a), substituted "section 300ff–21 of this title" for "this part".

Pub. L. 109–415, §203(e)(5), substituted "paragraphs (2) and (3), may, notwithstanding paragraphs (2) through (4)," for "paragraphs (3) and (4), may, notwithstanding paragraphs (3), (4), and (5),".

Pub. L. 109–415, §203(e)(1), redesignated par. (6) as (5). Former par. (5) redesignated (4).

Subsec. (b)(6). Pub. L. 109–415, §204(a), substituted "section 300ff–21 of this title" for "this part".

Pub. L. 109–415, §203(e)(1), redesignated par. (7) as (6). Former par. (6) redesignated (5).

Subsec. (b)(7). Pub. L. 109–415, §203(e)(1), redesignated par. (7) as (6).

Subsec. (c)(1). Pub. L. 109–415, §204(a), substituted "section 300ff–21 of this title" for "this part" in introductory provisions.

Subsec. (d). Pub. L. 109–415, §203(f), reenacted heading without change and amended text generally. Prior to amendment, text read as follows: "Any amounts appropriated in any fiscal year and made available to a State under this part that have not been obligated as described in subsection (d) of this section shall be repaid to the Secretary and reallotted to other States in proportion to the original grants made to such States."

2000—Subsec. (a). Pub. L. 106–345, §206(a)(1), redesignated subsec. (b) as (a).

Subsec. (a)(1)(A)(i). Pub. L. 106–345, §206(a)(2), substituted "$200,000" for "$100,000" in subcl. (I) and "$500,000" for "$250,000" in subcl. (II).

Subsec. (a)(1)(A)(ii). Pub. L. 106–345, §206(c)(1), inserted "and then, as applicable, increased under paragraph (2)(H)" before semicolon.

Subsec. (a)(1)(B). Pub. L. 106–345, §206(d), inserted "the greater of $50,000 or" after "shall be".

Subsec. (a)(2)(A)(i). Pub. L. 106–345, §206(c)(2)(A), substituted "subparagraphs (H) and (I)" for "subparagraph (H)".

Subsec. (a)(2)(D)(i). Pub. L. 106–345, §206(b)(1), inserted before semicolon ", except that (subject to subparagraph (E)), for grants made pursuant to this paragraph or section 300ff–30 of this title for fiscal year 2005 and subsequent fiscal years, the cases counted for each 12-month period beginning on or after July 1, 2004, shall be cases of HIV disease (as reported to and confirmed by such Director) rather than cases of acquired immune deficiency syndrome".

Subsec. (a)(2)(E) to (G). Pub. L. 106–345, §206(b)(2), (3), added subpar. (E) and redesignated former subpars. (E) and (F) as (F) and (G), respectively. Former subpar. (G) redesignated (H).

Subsec. (a)(2)(H). Pub. L. 106–345, §206(c)(2)(B), amended heading and text of subpar. (H) generally. Prior to amendment, text related to limitations on the amount of a grant awarded for fiscal years 1996 to 2000 to a State or territory under this part in relation to the amount received by the State or territory for fiscal year 1995.

Pub. L. 106–345, §206(b)(2), redesignated subpar. (G) as (H). Former subpar. (H) redesignated (I).

Subsec. (a)(2)(I). Pub. L. 106–345, §206(e), reenacted heading without change, designated existing provisions as cl. (i), inserted cl. (i) heading, redesignated former cls. (i) and (ii) as subcls. (I) and (II), respectively, in subcl. (I) inserted ", less the percentage reserved under clause (ii)(V)" before semicolon, and added cl. (ii).

Pub. L. 106–345, §206(b)(2), redesignated subpar. (H) as (I).

Subsec. (a)(3)(B). Pub. L. 106–345, §206(f), substituted "the Republic of the Marshall Islands, the Federated States of Micronesia, and the Republic of Palau, and only for purposes of paragraph (1) the Commonwealth of Puerto Rico" for "and the Republic of the Marshall Islands".

Subsecs. (b) to (e). Pub. L. 106–345, §206(a)(1), redesignated subsecs. (c) to (e) as (b) to (d), respectively.

1998—Subsec. (b)(3)(A). Pub. L. 105–392, §417(1), substituted ", the Commonwealth of Puerto Rico, the Virgin Islands, and Guam" for "and the Commonwealth of Puerto Rico".

Subsec. (b)(3)(B). Pub. L. 105–392, §417(2), struck out "the Virgin Islands, Guam" after "means".

1996—Subsec. (a). Pub. L. 104–146, §3(g)(2), struck out subsec. (a) which related to special projects of national significance.

Subsec. (a)(1). Pub. L. 104–146, §6(c)(3)(A), which directed amendment of subsec. (a)(1) by substituting "section 300ff–77" for "section 300ff–30", could not be executed because of the repeal of subsec. (a) by Pub. L. 104–146, §3(g)(2). See above.

Subsec. (b)(1). Pub. L. 104–146, §6(c)(3)(B), which directed amendment of subsec. (b)(1) by substituting "section 300ff–77 of this title" for "section 300ff–30 of this title", could not be executed because the words "section 300ff–30 of this title" did not appear subsequent to the general amendment of subsec. (b)(1) by Pub.

L. 104–146, §5. See below.

Pub. L. 104–146, §5, amended heading and text of par. (1) generally. Prior to amendment, text read as follows: "Subject to the extent of amounts made available under section 300ff–30 of this title, the amount of a grant to be made under this part for—

"(A) each of the several States and the District of Columbia for a fiscal year shall be the greater of—

"(i) $100,000, and

"(ii) an amount determined under paragraph (2); and

"(B) each territory of the United States, as defined in paragraph 3, shall be an amount determined under paragraph (2)."

Subsec. (b)(2). Pub. L. 104–146, §5, amended par. (2) generally, substituting subpars. (A) to (H) for former subpars. (A) and (B) relating to determination of amount of allotments.

Subsec. (c)(1). Pub. L. 104–146, §3(c)(5)(A), struck out heading and text of par. (1). Text read as follows: "In a State that has reported 1 percent or more of all AIDS cases reported to and confirmed by the Centers for Disease Control and Prevention in all States, not less than 50 percent of the amount received by the State under a grant awarded under this part shall be utilized for the creation and operation of community-based comprehensive care consortia under section 300ff–23 of this title, in those areas within the State in which the largest number of individuals with HIV disease reside."

Subsec. (c)(3), (4). Pub. L. 104–146, §3(c)(5)(B), amended pars. (3) and (4) generally. Prior to amendment, pars. (3) and (4) read as follows:

"(3) PLANNING AND EVALUATIONS.—A State may not use in excess of 5 percent of amounts received under a grant awarded under this part for planning and evaluation activities.

"(4) ADMINISTRATION.—A State may not use in excess of 5 percent of amounts received under a grant awarded under this part for administration, accounting, reporting, and program oversight functions."

Subsec. (c)(5) to (7). Pub. L. 104–146, §3(c)(5)(C), (D), added pars. (5) and (6) and redesignated former par. (5) as (7).

1992—Subsec. (c)(1). Pub. L. 102–531 substituted "Centers for Disease Control and Prevention" for "Centers for Disease Control".

STATUTORY NOTES AND RELATED SUBSIDIARIES

EFFECTIVE DATE OF 2009 AMENDMENT; REVIVAL OF SECTION

For provisions that repeal by section 2(a)(1) of Pub. L. 111–87 of section 703 of Pub. L. 109–415 be effective Sept. 30, 2009, that the provisions of this section as in effect on Sept. 30, 2009, be revived, and that amendment by sections 3(b), 5(b), (c)(1), 7(b), and 10(b) of Pub. L. 111–87 be applicable to this section as so revived and effective as if enacted on Sept. 30, 2009, see section 2(a)(2), (3) of Pub. L. 111–87, set out as a note under section 300ff–11 of this title.

EFFECTIVE DATE OF 1996 AMENDMENT

Amendment by sections 3(c)(5), (g)(2) and 6(c)(3)(A) of Pub. L. 104–146 effective Oct. 1, 1996, and amendment by sections 5 and 6(c)(3)(B) of Pub. L. 104–146 effective May 20, 1996, see section 13 of Pub. L. 104–146, set out as a note under section 300ff–11 of this title.

[1] *So in original. Probably should be "non-EMA".*

§300ff–29. Technical assistance

The Secretary shall provide technical assistance in administering and coordinating the activities authorized under section 300ff–22 of this title, including technical assistance for the development and implementation of statewide coordinated statements of need.

(July 1, 1944, ch. 373, title XXVI, §2619, as added Pub. L. 101–381, title II, §201, Aug. 18, 1990, 104 Stat. 597; amended Pub. L. 104–146, §3(c)(6), May 20, 1996, 110 Stat. 1356; Pub. L. 109–415, title VII, §703, Dec. 19, 2006, 120 Stat. 2820; Pub. L. 111–87, §2(a)(1), (3)(A), Oct. 30, 2009, 123 Stat. 2885.)

EDITORIAL NOTES

AMENDMENTS

2009—Pub. L. 111–87 repealed Pub. L. 109–415, §703, and revived the provisions of this section as in effect on Sept. 30, 2009. See 2006 Amendment note and Effective Date of 2009 Amendment; Revival of Section note below.

2006—Pub. L. 109–415, §703, which directed repeal of this section effective Oct. 1, 2009, was itself repealed by Pub. L. 111–87, §2(a)(1), effective Sept. 30, 2009.

1996—Pub. L. 104–146 substituted "shall" for "may" and inserted ", including technical assistance for the development and implementation of statewide coordinated statements of need" before period at end.

STATUTORY NOTES AND RELATED SUBSIDIARIES

EFFECTIVE DATE OF 2009 AMENDMENT; REVIVAL OF SECTION

For provisions that repeal by section 2(a)(1) of Pub. L. 111–87 of section 703 of Pub. L. 109–415 be effective Sept. 30, 2009, and that the provisions of this section as in effect on Sept. 30, 2009, be revived, see section 2(a)(2), (3)(A) of Pub. L. 111–87, set out as a note under section 300ff–11 of this title.

EFFECTIVE DATE OF 1996 AMENDMENT

Amendment by Pub. L. 104–146 effective Oct. 1, 1996, and amendment by section 6(c)(1)(A) of Pub. L. 104–146 effective May 20, 1996, see section 13 of Pub. L. 104–146, set out as a note under section 300ff–11 of this title.

§300ff–29a. Supplemental grants

(a) In general

For the purpose of providing services described in section 300ff–22(a) of this title, the Secretary shall make grants to States—

(1) whose applications under section 300ff–27 of this title have demonstrated the need in the State, on an objective and quantified basis, for supplemental financial assistance to provide such services; and

(2) that did not, for the most recent grant year pursuant to section 300ff–28(a)(1) or 300ff–28(a)(2)(F)(i) of this title for which data is available, have more than 5 percent of grant funds under such sections canceled, offset under section 300ff–31a(e) of this title, or covered by any waivers under section 300ff–31a(c) of this title.

(b) Demonstrated need

The factors considered by the Secretary in determining whether an eligible area has a demonstrated need for purposes of subsection (a)(1) may include any or all of the following:

(1) The unmet need for such services, as determined under section 300ff–27(b) of this title.

(2) An increasing need for HIV/AIDS-related services, including relative rates of increase in the number of cases of HIV/AIDS.

(3) The relative rates of increase in the number of cases of HIV/AIDS within new or emerging subpopulations.

(4) The current prevalence of HIV/AIDS.

(5) Relevant factors related to the cost and complexity of delivering health care to individuals with HIV/AIDS in the eligible area.

(6) The impact of co-morbid factors, including co-occurring conditions, determined relevant by the Secretary.

(7) The prevalence of homelessness.

(8) The prevalence of individuals described under section 300ff–12(b)(2)(M) of this title.

(9) The relevant factors that limit access to health care, including geographic variation, adequacy of health insurance coverage, and language barriers.

(10) The impact of a decline in the amount received pursuant to section 300ff–28 of this title on services available to all individuals with HIV/AIDS identified and eligible under this subchapter.

(c) Priority in making grants

The Secretary shall provide funds under this section to a State to address the decline in services related to the decline in the amounts received pursuant to section 300ff–28 of this title consistent with the grant award to the State for fiscal year 2006, to the extent that the factor under subsection (b)(10) (relating to a decline in funding) applies to the State.

(d) Report on the awarding of supplemental funds

Not later than 45 days after the awarding of supplemental funds under this section, the Secretary shall submit to Congress a report concerning such funds. Such report shall include information detailing—

(1) the total amount of supplemental funds available under this section for the year involved;

(2) the amount of supplemental funds used in accordance with the hold harmless provisions of section 300ff–28(a)(2) of this title;

(3) the amount of supplemental funds disbursed pursuant to subsection (c);

(4) the disbursement of the remainder of the supplemental funds after taking into account the uses described in paragraphs (2) and (3); and

(5) the rationale used for the amount of funds disbursed as described under paragraphs (2), (3), and (4).

(e) Core medical services

The provisions of section 300ff–22(b) of this title apply with respect to a grant under this section to the same extent and in the same manner as such provisions apply with respect to a grant made pursuant to section 300ff–28(a)(1) of this title.

(f) Applicability of grant authority

The authority to make grants under this section applies beginning with the first fiscal year for which amounts are made available for such grants under section 300ff–31b(b)(1) of this title.

(July 1, 1944, ch. 373, title XXVI, §2620, as added and amended Pub. L. 109–415, title II, §205(2), title VII, §703, Dec. 19, 2006, 120 Stat. 2797, 2820; Pub. L. 111–87, §§2(a)(1), (3)(A), 5(c)(2), 8(a)(2), (b)(2)(D), Oct. 30, 2009, 123 Stat. 2885, 2891, 2893, 2894.)

EDITORIAL NOTES

PRIOR PROVISIONS

A prior section 2620 of act July 1, 1944, was renumbered section 2621 and is classified to section 300ff–30 of this title.

Another prior section 2620 of act July 1, 1944, was classified to section 300ff–30 of this title prior to repeal by Pub. L. 104–146.

AMENDMENTS

2009—Pub. L. 111–87, §2(a)(1), (3)(A), repealed Pub. L. 109–415, §703, and revived the provisions of this section as in effect on Sept. 30, 2009. See 2006 Amendment note and Effective Date of 2009 Amendment; Revival of Section note below.

Subsec. (a)(2). Pub. L. 111–87, §§5(c)(2), 8(a)(2), (b)(2)(D), substituted "300ff–28(a)(2)(F)(i)" for "300ff–28(a)(2)(G)(i)", "5 percent" for "2 percent", and "canceled, offset under section 300ff–31a(e) of this title," for "canceled".

2006—Pub. L. 109–415, §703, which directed repeal of this section effective Oct. 1, 2009, was itself repealed by Pub. L. 111–87, §2(a)(1), effective Sept. 30, 2009.

STATUTORY NOTES AND RELATED SUBSIDIARIES

EFFECTIVE DATE OF 2009 AMENDMENT; REVIVAL OF SECTION

For provisions that repeal by section 2(a)(1) of Pub. L. 111–87 of section 703 of Pub. L. 109–415 be effective Sept. 30, 2009, that the provisions of this section as in effect on Sept. 30, 2009, be revived, and that amendment by sections 5(c)(2) and 8(a)(2), (b)(2)(D) of Pub. L. 111–87 be applicable to this section as so

revived and effective as if enacted on Sept. 30, 2009, see section 2(a)(2), (3) of Pub. L. 111–87, set out as a note under section 300ff–11 of this title.

§300ff–30. Emerging communities

(a) In general

The Secretary shall award supplemental grants to States determined to be eligible under subsection (b) to enable such States to provide comprehensive services of the type described in section 300ff–22(a) of this title to supplement the services otherwise provided by the State under a grant under this subpart in emerging communities within the State that are not eligible to receive grants under part A.

(b) Eligibility

To be eligible to receive a supplemental grant under subsection (a), a State shall—

(1) be eligible to receive a grant under this subpart;

(2) demonstrate the existence in the State of an emerging community as defined in subsection (d)(1);

(3) agree that the grant will be used to provide funds directly to emerging communities in the State, separately from other funds under this subchapter that are provided by the State to such communities; and

(4) submit the information described in subsection (c).

(c) Reporting requirements

A State that desires a grant under this section shall, as part of the State application submitted under section 300ff–27 of this title, submit a detailed description of the manner in which the State will use amounts received under the grant and of the severity of need. Such description shall include—

(1) a report concerning the dissemination of supplemental funds under this section and the plan for the utilization of such funds in the emerging community;

(2) a demonstration of the existing commitment of local resources, both financial and in-kind;

(3) a demonstration that the State will maintain HIV-related activities at a level that is equal to not less than the level of such activities in the State for the 1-year period preceding the fiscal year for which the State is applying to receive a grant under section 300ff–21 of this title;

(4) a demonstration of the ability of the State to utilize such supplemental financial resources in a manner that is immediately responsive and cost effective;

(5) a demonstration that the resources will be allocated in accordance with the local demographic incidence of AIDS including appropriate allocations for services for infants, children, women, and families with HIV/AIDS;

(6) a demonstration of the inclusiveness of the planning process, with particular emphasis on affected communities and individuals with HIV/AIDS; and

(7) a demonstration of the manner in which the proposed services are consistent with local needs assessments and the statewide coordinated statement of need.

(d) Definitions of emerging community

For purposes of this section, the term "emerging community" means a metropolitan area (as defined in section 300ff–17 of this title) for which there has been reported to and confirmed by the Director of the Centers for Disease Control and Prevention a cumulative total of at least 500, but fewer than 1,000, cases of AIDS during the most recent period of 5 calendar years for which such data are available.

(e) Continued status as emerging community

Notwithstanding any other provision of this section, a metropolitan area that is an emerging community for a fiscal year continues to be an emerging community until the metropolitan area fails, for three consecutive fiscal years—

(1) to meet the requirements of subsection (d); and

(2) to have a cumulative total of 750 or more living cases of AIDS (reported to and confirmed by the Director of the Centers for Disease Control and Prevention) as of December 31 of the most recent calendar year for which such data is available.

(f) Distribution

The amount of a grant under subsection (a) for a State for a fiscal year shall be an amount equal to the product of—

(1) the amount available under section 300ff–31b(b)(1) of this title for the fiscal year; and

(2) a percentage equal to the ratio constituted by the number of living cases of HIV/AIDS in emerging communities in the State to the sum of the respective numbers of such cases in such communities for all States.

(July 1, 1944, ch. 373, title XXVI, §2621, formerly §2620, as added Pub. L. 106–345, title II, §207(2), Oct. 20, 2000, 114 Stat. 1337; renumbered §2621 and amended Pub. L. 109–415, title II, §§204(a), 205(1), 206, title VII, §§702(3), 703, Dec. 19, 2006, 120 Stat. 2796, 2797, 2799, 2820; Pub. L. 111–87, §2(a)(1), (3)(A), Oct. 30, 2009, 123 Stat. 2885.)

EDITORIAL NOTES

PRIOR PROVISIONS

A prior section 300ff–30, act July 1, 1944, ch. 373, title XXVI, §2620, as added Aug. 18, 1990, Pub. L. 101–381, title II, §201, 104 Stat. 597, authorized appropriations for fiscal years 1991 through 1995, prior to repeal by Pub. L. 104–146, §§6(b), 13, May 20, 1996, 110 Stat. 1367, 1374, effective Oct. 1, 1996.

A prior section 2621 of act July 1, 1944, was classified to section 300ff–31 of this title, prior to repeal by Pub. L. 106–345.

AMENDMENTS

2009—Pub. L. 111–87 repealed Pub. L. 109–415, §703, and revived the provisions of this section as in effect on Sept. 30, 2009. See 2006 Amendment note and Effective Date of 2009 Amendment; Revival of Section note below.

2006—Pub. L. 109–415, §703, which directed repeal of this section effective Oct. 1, 2009, was itself repealed by Pub. L. 111–87, §2(a)(1), effective Sept. 30, 2009.

Pub. L. 109–415, §206(1), substituted "Emerging communities" for "Supplemental grants" in section catchline.

Subsec. (b)(3), (4). Pub. L. 109–415, §206(2), added par. (3) and redesignated former par. (3) as (4).

Subsec. (c)(3). Pub. L. 109–415, §204(a), substituted "section 300ff–21 of this title" for "this part".

Subsec. (c)(5), (6). Pub. L. 109–415, §702(3), substituted "HIV/AIDS" for "HIV disease".

Subsecs. (d) to (f). Pub. L. 109–415, §206(3), added subsecs. (d) to (f) and struck out former subsecs. (d) and (e) defining "emerging community" and relating to funding, respectively.

STATUTORY NOTES AND RELATED SUBSIDIARIES

EFFECTIVE DATE OF 2009 AMENDMENT; REVIVAL OF SECTION

For provisions that repeal by section 2(a)(1) of Pub. L. 111–87 of section 703 of Pub. L. 109–415 be effective Sept. 30, 2009, and that the provisions of this section as in effect on Sept. 30, 2009, be revived, see section 2(a)(2), (3)(A) of Pub. L. 111–87, set out as a note under section 300ff–11 of this title.

§300ff–31. Repealed. Pub. L. 106–345, title II, §207(1), Oct. 20, 2000, 114 Stat. 1337

Section, act July 1, 1944, ch. 373, title XXVI, §2621, as added Pub. L. 104–146, §3(c)(7), May 20, 1996, 110 Stat. 1356, related to coordination of planning and implementation of Federal HIV programs to facilitate the local development of a complete continuum of HIV-related services for individuals with HIV disease and those at risk of such disease and required a biennial report to Congress on coordination efforts.

§300ff–31a. Timeframe for obligation and expenditure of grant funds

(a) Obligation by end of grant year

Effective for fiscal year 2007 and subsequent fiscal years, funds from a grant award made to a State for a fiscal year pursuant to section 300ff–28(a)(1) or 300ff–28(a)(2)(F) of this title, or under section 300ff–29a or 300ff–30 of this title, are available for obligation by the State through the end of the one-year period beginning on the date in such fiscal year on which funds from the award first become available to the State (referred to in this section as the "grant year for the award"), except as provided in subsection (c)(1).

(b) Supplemental grants; cancellation of unobligated balance of grant award

Effective for fiscal year 2007 and subsequent fiscal years, if a grant award made to a State for a fiscal year pursuant to section 300ff–28(a)(2)(F)(ii) of this title, or under section 300ff–29a or 300ff–30 of this title, has an unobligated balance as of the end of the grant year for the award—

(1) the Secretary shall cancel that unobligated balance of the award, and shall require the State to return any amounts from such balance that have been disbursed to the State; and

(2) the funds involved shall be made available by the Secretary as additional amounts for grants pursuant to section 300ff–29a of this title for the first fiscal year beginning after the fiscal year in which the Secretary obtains the information necessary for determining that the balance is required under paragraph (1) to be canceled, except that the availability of the funds for such grants is subject to section 300ff–28(a)(2)(H) of this title as applied for such year.

(c) Formula grants; cancellation of unobligated balance of grant award; waiver permitting carryover

(1) In general

Effective for fiscal year 2007 and subsequent fiscal years, if a grant award made to a State for a fiscal year pursuant to section 300ff–28(a)(1) or 300ff–28(a)(2)(F)(i) of this title has an unobligated balance as of the end of the grant year for the award, the Secretary shall cancel that unobligated balance of the award, and shall require the State to return any amounts from such balance that have been disbursed to the State, unless—

(A) before the end of the grant year, the State submits to the Secretary a written application for a waiver of the cancellation, which application includes a description of the purposes for which the State intends to expend the funds involved; and

(B) the Secretary approves the waiver.

(2) Expenditure by end of carryover year

With respect to a waiver under paragraph (1) that is approved for a balance that is unobligated as of the end of a grant year for an award:

(A) The unobligated funds are available for expenditure by the State involved for the one-year period beginning upon the expiration of the grant year (referred to in this section as the "carryover year").

(B) If the funds are not expended by the end of the carryover year, the Secretary shall cancel that unexpended balance of the award, and shall require the State to return any amounts from such balance that have been disbursed to the State.

(3) Use of cancelled balances

In the case of any balance of a grant award that is cancelled under paragraph (1) or (2)(B), the grant funds involved shall be made available by the Secretary as additional amounts for grants under section 300ff–29a of this title for the first fiscal year beginning after the fiscal year in which the Secretary obtains the information necessary for determining that the balance is required under such paragraph to be canceled, except that the availability of the funds for such grants is subject to section 300ff–28(a)(2)(H) of this title as applied for such year.

(4) Corresponding reduction in future grant

(A) In general

In the case of a State for which a balance from a grant award made pursuant to section 300ff–28(a)(1) or 300ff–28(a)(2)(F)(i) of this title is unobligated as of the end of the grant year for the award—

(i) the Secretary shall reduce, by the same amount as such unobligated balance (less any amount of such balance that is the subject of a waiver of cancellation under paragraph (1)), the amount of the grant under such section for the first fiscal year beginning after the fiscal year in which the Secretary obtains the information necessary for determining that such balance was unobligated as of the end of the grant year (which requirement for a reduction applies without regard to whether a waiver under paragraph (1) has been approved with respect to such balance); and

(ii) the grant funds involved in such reduction shall be made available by the Secretary as additional funds for grants under section 300ff–29a of this title for such first fiscal year, subject to section 300ff–28(a)(2)(H) of this title;

except that this subparagraph does not apply to the State if the amount of the unobligated balance was 5 percent or less.

(B) Relation to increases in grant

A reduction under subparagraph (A) for a State for a fiscal year may not be taken into account in applying section 300ff–28(a)(2)(H) of this title with respect to the State for the subsequent fiscal year.

(d) Treatment of drug rebates

For purposes of this section, funds that are drug rebates referred to in section 300ff–26(g) of this title may not be considered part of any grant award referred to in subsection (a). If an expenditure of ADAP rebate funds would trigger a penalty under this section or a higher penalty than would otherwise have applied, the State may request that for purposes of this section, the Secretary deem the State's unobligated balance to be reduced by the amount of rebate funds in the proposed expenditure. Notwithstanding 300ff–28(a)(2)(F) [1] of this title, any unobligated amount under section 300ff–28(a)(2)(F)(ii)(V) of this title that is returned to the Secretary for reallocation shall be used by the Secretary for—

(1) the ADAP supplemental program if the Secretary determines appropriate; or

(2) for additional amounts for grants pursuant to section 300ff–29a of this title.

(e) Authority regarding administration of provisions

In administering subsections (b) and (c) with respect to the unobligated balance of a State, the Secretary may elect to reduce the amount of future grants to the State under section 300ff–28, 300ff–29a, or 300ff–30 of this title, as applicable, by the amount of any such unobligated balance in lieu of cancelling such amount as provided for in subsection (b) or (c)(1). In such case, the Secretary may permit the State to use such unobligated balance for purposes of any such future grant. An amount equal to such reduction shall be available for use as additional amounts for grants pursuant to section 300ff–29a of this title, subject to section 300ff–28(a)(2)(H) of this title. Nothing in this paragraph shall be construed to affect the authority of the Secretary under subsections (b) and (c), including the authority to grant waivers under subsection (c)(1). The reduction in future grants authorized under this subsection shall be notwithstanding the penalty required under subsection (c)(4) with respect to unobligated funds.

(July 1, 1944, ch. 373, title XXVI, §2622, as added and amended Pub. L. 109–415, title II, §207, title VII, §703, Dec. 19, 2006, 120 Stat. 2799, 2820; Pub. L. 111–87, §§2(a)(1), (3)(A), 5(c)(2)–(4), 8(b)(1)(B), (2)(B), (c)(2), 10(a), Oct. 30, 2009, 123 Stat. 2885, 2891, 2894, 2895.)

EDITORIAL NOTES

AMENDMENTS

2009—Pub. L. 111–87, §2(a)(1), (3)(A), repealed Pub. L. 109–415, §703, and revived the provisions of this

section as in effect on Sept. 30, 2009. See 2006 Amendment note and Effective Date of 2009 Amendment; Revival of Section note below.

Subsec. (a). Pub. L. 111–87, §5(c)(3), substituted "300ff–28(a)(2)(F)" for "300ff–28(a)(2)(G)".

Subsec. (b). Pub. L. 111–87, §5(c)(4), substituted "300ff–28(a)(2)(F)(ii)" for "300ff–28(a)(2)(G)(ii)" in introductory provisions.

Subsec. (c)(1). Pub. L. 111–87, §5(c)(2), substituted "300ff–28(a)(2)(F)(i)" for "300ff–28(a)(2)(G)(i)" in introductory provisions.

Subsec. (c)(4)(A). Pub. L. 111–87, §§5(c)(2), 8(b)(1)(B), substituted "300ff–28(a)(2)(F)(i)" for "300ff–28(a)(2)(G)(i)" in introductory provisions and "5 percent" for "2 percent" in concluding provisions.

Subsec. (c)(4)(A)(i). Pub. L. 111–87, §8(c)(2), inserted "(less any amount of such balance that is the subject of a waiver of cancellation under paragraph (1))" after "unobligated balance".

Subsec. (d). Pub. L. 111–87, §10(a), inserted at end "If an expenditure of ADAP rebate funds would trigger a penalty under this section or a higher penalty than would otherwise have applied, the State may request that for purposes of this section, the Secretary deem the State's unobligated balance to be reduced by the amount of rebate funds in the proposed expenditure. Notwithstanding 300ff–28(a)(2)(F) of this title, any unobligated amount under section 300ff–28(a)(2)(F)(ii)(V) of this title that is returned to the Secretary for reallocation shall be used by the Secretary for—

"(1) the ADAP supplemental program if the Secretary determines appropriate; or

"(2) for additional amounts for grants pursuant to section 300ff–29a of this title."

Subsec. (e). Pub. L. 111–87, §8(b)(2)(B), added subsec. (e).

2006—Pub. L. 109–415, §703, which directed repeal of this section effective Oct. 1, 2009, was itself repealed by Pub. L. 111–87, §2(a)(1), effective Sept. 30, 2009.

STATUTORY NOTES AND RELATED SUBSIDIARIES

EFFECTIVE DATE OF 2009 AMENDMENT; REVIVAL OF SECTION

For provisions that repeal by section 2(a)(1) of Pub. L. 111–87 of section 703 of Pub. L. 109–415 be effective Sept. 30, 2009, that the provisions of this section as in effect on Sept. 30, 2009, be revived, and that amendment by sections 5(c)(2)–(4), 8(b)(1)(B), (2)(B), (c)(2), and 10(a) of Pub. L. 111–87 be applicable to this section as so revived and effective as if enacted on Sept. 30, 2009, see section 2(a)(2), (3) of Pub. L. 111–87, set out as a note under section 300ff–1 of this title.

[1] So in original. Probably should be preceded by "section".

§300ff–31b. Authorization of appropriations

(a) In general

For the purpose of carrying out this subpart, there are authorized to be appropriated $1,195,500,000 for fiscal year 2007, $1,239,500,000 for fiscal year 2008, $1,285,200,000 for fiscal year 2009, $1,349,460,000 for fiscal year 2010, $1,416,933,000 for fiscal year 2011, $1,487,780,000 for fiscal year 2012, and $1,562,169,000 for fiscal year 2013. Amounts appropriated under the preceding sentence for a fiscal year are available for obligation by the Secretary until the end of the second succeeding fiscal year.

(b) Reservation of amounts

(1) Emerging communities

Of the amount appropriated under subsection (a) for a fiscal year, the Secretary shall reserve $5,000,000 for grants under section 300ff–30 of this title.

(2) Supplemental grants

(A) In general

Of the amount appropriated under subsection (a) for a fiscal year in excess of the 2006 adjusted amount, the Secretary shall reserve 1/3 for grants under section 300ff–29a of this title, except that the availability of the reserved funds for such grants is subject to section

300ff–28(a)(2)(H) of this title as applied for such year, and except that any amount appropriated exclusively for carrying out section 300ff–26 of this title (and, accordingly, distributed under section 300ff–28(a)(2)(F) of this title) is not subject to this subparagraph.

(B) 2006 adjusted amount

For purposes of subparagraph (A), the term "2006 adjusted amount" means the amount appropriated for fiscal year 2006 under section 300ff–77(b) of this title (as such section was in effect for such fiscal year), excluding any amount appropriated for such year exclusively for carrying out section 300ff–26 of this title (and, accordingly, distributed under section 300ff–28(a)(2)(I) of this title, as so in effect).

(July 1, 1944, ch. 373, title XXVI, §2623, as added and amended Pub. L. 109–415, title II, §208, title VII, §703, Dec. 19, 2006, 120 Stat. 2801, 2820; Pub. L. 111–87, §§2(a)(1), (3)(A), (c), 5(c)(3), Oct. 30, 2009, 123 Stat. 2885, 2891.)

EDITORIAL NOTES

AMENDMENTS

2009—Pub. L. 111–87, §2(a)(1), (3)(A), repealed Pub. L. 109–415, §703, and revived the provisions of this section as in effect on Sept. 30, 2009. See 2006 Amendment note and Effective Date of 2009 Amendment; Revival of Section note below.

Subsec. (a). Pub. L. 111–87, §2(c), substituted "$1,285,200,000 for fiscal year 2009, $1,349,460,000 for fiscal year 2010, $1,416,933,000 for fiscal year 2011, $1,487,780,000 for fiscal year 2012, and $1,562,169,000 for fiscal year 2013" for "and $1,285,200,000 for fiscal year 2009".

Subsec. (b)(2)(A). Pub. L. 111–87, §5(c)(3), substituted "300ff–28(a)(2)(F)" for "300ff–28(a)(2)(G)".

2006—Pub. L. 109–415, §703, which directed repeal of this section effective Oct. 1, 2009, was itself repealed by Pub. L. 111–87, §2(a)(1), effective Sept. 30, 2009.

STATUTORY NOTES AND RELATED SUBSIDIARIES

EFFECTIVE DATE OF 2009 AMENDMENT; REVIVAL OF SECTION

For provisions that repeal by section 2(a)(1) of Pub. L. 111–87 of section 703 of Pub. L. 109–415 be effective Sept. 30, 2009, that the provisions of this section as in effect on Sept. 30, 2009, be revived, and that amendment by sections 2(c) and 5(c)(3) of Pub. L. 111–87 be applicable to this section as so revived and effective as if enacted on Sept. 30, 2009, see section 2(a)(2), (3) of Pub. L. 111–87, set out as a note under section 300ff–11 of this title.

SUBPART II—PROVISIONS CONCERNING PREGNANCY AND PERINATAL TRANSMISSION OF HIV

§300ff–33. Early diagnosis grant program

(a) In general

In the case of States whose laws or regulations are in accordance with subsection (b), the Secretary, acting through the Centers for Disease Control and Prevention, shall make grants to such States for the purposes described in subsection (c).

(b) Description of compliant States

For purposes of subsection (a), the laws or regulations of a State are in accordance with this subsection if, under such laws or regulations (including programs carried out pursuant to the discretion of State officials), both of the policies described in paragraph (1) are in effect, or both of the policies described in paragraph (2) are in effect, as follows:

(1)(A) Voluntary opt-out testing of pregnant women.
(B) Universal testing of newborns.
(2)(A) Voluntary opt-out testing of clients at sexually transmitted disease clinics.
(B) Voluntary opt-out testing of clients at substance abuse treatment centers.

The Secretary shall periodically ensure that the applicable policies are being carried out and recertify compliance.

(c) Use of funds

A State may use funds provided under subsection (a) for HIV/AIDS testing (including rapid testing), prevention counseling, treatment of newborns exposed to HIV/AIDS, treatment of mothers infected with HIV/AIDS, and costs associated with linking those diagnosed with HIV/AIDS to care and treatment for HIV/AIDS.

(d) Application

A State that is eligible for the grant under subsection (a) shall submit an application to the Secretary, in such form, in such manner, and containing such information as the Secretary may require.

(e) Limitation on amount of grant

A grant under subsection (a) to a State for a fiscal year may not be made in an amount exceeding $10,000,000.

(f) Rule of construction

Nothing in this section shall be construed to pre-empt State laws regarding HIV/AIDS counseling and testing.

(g) Definitions

In this section:

(1) The term "voluntary opt-out testing" means HIV/AIDS testing—

(A) that is administered to an individual seeking other health care services; and

(B) in which—

(i) pre-test counseling is not required but the individual is informed that the individual will receive an HIV/AIDS test and the individual may opt out of such testing; and

(ii) for those individuals with a positive test result, post-test counseling (including referrals for care) is provided and confidentiality is protected.

(2) The term "universal testing of newborns" means HIV/AIDS testing that is administered within 48 hours of delivery to—

(A) all infants born in the State; or

(B) all infants born in the State whose mother's HIV/AIDS status is unknown at the time of delivery.

(h) Authorization of appropriations

Of the funds appropriated annually to the Centers for Disease Control and Prevention for HIV/AIDS prevention activities, $30,000,000 shall be made available for each of the fiscal years 2007 through 2009 for grants under subsection (a), of which $20,000,000 shall be made available for grants to States with the policies described in subsection (b)(1), and $10,000,000 shall be made available for grants to States with the policies described in subsection (b)(2). Funds provided under this section are available until expended.

(July 1, 1944, ch. 373, title XXVI, §2625, as added Pub. L. 104–146, §7(b)(3), May 20, 1996, 110 Stat. 1369; amended Pub. L. 106–345, title II, §212(a), Oct. 20, 2000, 114 Stat. 1339; Pub. L. 109–415, title II, §209, title VII, §703, Dec. 19, 2006, 120 Stat. 2802, 2820; Pub. L. 111–87, §2(a)(1), (3)(A), Oct. 30, 2009, 123 Stat. 2885.)

EDITORIAL NOTES

AMENDMENTS

2009—Pub. L. 111–87 repealed Pub. L. 109–415, §703, and revived the provisions of this section as in effect on Sept. 30, 2009. See 2006 Amendment note and Effective Date of 2009 Amendment; Revival of Section note below.

2006—Pub. L. 109–415, §703, which directed repeal of this section effective Oct. 1, 2009, was itself repealed by Pub. L. 111–87, §2(a)(1), effective Sept. 30, 2009.

Pub. L. 109–415, §209, amended section catchline and text generally, substituting provisions relating to early diagnosis grant program for provisions requiring State certification of measures to adopt CDC guidelines for pregnant women not later than 120 days after May 20, 1996, and authorizing additional funds if such certification was provided.

2000—Subsec. (c)(1)(F). Pub. L. 106–345, §212(a)(1), added subpar. (F).

Subsec. (c)(2). Pub. L. 106–345, §212(a)(2), amended heading and text of par. (2) generally. Prior to amendment, text read as follows: "For purposes of carrying out this subsection, there are authorized to be appropriated $10,000,000 for each of the fiscal years 1996 through 2000. Amounts made available under section 300ff–77 of this title for carrying out this part are not available for carrying out this section unless otherwise authorized."

Subsec. (c)(4). Pub. L. 106–345, §212(a)(3), added par. (4).

STATUTORY NOTES AND RELATED SUBSIDIARIES

EFFECTIVE DATE OF 2009 AMENDMENT; REVIVAL OF SECTION

For provisions that repeal by section 2(a)(1) of Pub. L. 111–87 of section 703 of Pub. L. 109–415 be effective Sept. 30, 2009, and that the provisions of this section as in effect on Sept. 30, 2009, be revived, see section 2(a)(2), (3)(A) of Pub. L. 111–87, set out as a note under section 300ff–11 of this title.

EFFECTIVE DATE

Section effective Oct. 1, 1996, see section 13 of Pub. L. 104–146, set out as an Effective Date of 1996 Amendment note under section 300ff–11 of this title.

PERINATAL TRANSMISSION OF HIV DISEASE; CONGRESSIONAL FINDINGS

Pub. L. 104–146, §7(a), May 20, 1996, 110 Stat. 1368, provided that: "The Congress finds as follows:

"(1) Research studies and statewide clinical experiences have demonstrated that administration of anti-retroviral medication during pregnancy can significantly reduce the transmission of the human immunodeficiency virus (commonly known as HIV) from an infected mother to her baby.

"(2) The Centers for Disease Control and Prevention have recommended that all pregnant women receive HIV counseling; voluntary, confidential HIV testing; and appropriate medical treatment (including anti-retroviral therapy) and support services.

"(3) The provision of such testing without access to such counseling, treatment, and services will not improve the health of the woman or the child.

"(4) The provision of such counseling, testing, treatment, and services can reduce the number of pediatric cases of acquired immune deficiency syndrome, can improve access to and provision of medical care for the woman, and can provide opportunities for counseling to reduce transmission among adults, and from mother to child.

"(5) The provision of such counseling, testing, treatment, and services can reduce the overall cost of pediatric cases of acquired immune deficiency syndrome.

"(6) The cancellation or limitation of health insurance or other health coverage on the basis of HIV status should be impermissible under applicable law. Such cancellation or limitation could result in disincentives for appropriate counseling, testing, treatment, and services.

"(7) For the reasons specified in paragraphs (1) through (6)—

"(A) routine HIV counseling and voluntary testing of pregnant women should become the standard of care; and

"(B) the relevant medical organizations as well as public health officials should issue guidelines making such counseling and testing the standard of care."

§300ff–34. Perinatal transmission of HIV/AIDS; contingent requirement regarding State grants under this part

(a) Annual determination of reported cases

A State shall annually determine the rate of reported cases of AIDS as a result of perinatal transmission among residents of the State.

(b) Causes of perinatal transmission

In determining the rate under subsection (a), a State shall also determine the possible causes of perinatal transmission. Such causes may include—

(1) the inadequate provision within the State of prenatal counseling and testing in accordance with the guidelines issued by the Centers for Disease Control and Prevention;

(2) the inadequate provision or utilization within the State of appropriate therapy or failure of such therapy to reduce perinatal transmission of HIV, including—

(A) that therapy is not available, accessible or offered to mothers; or

(B) that available therapy is offered but not accepted by mothers; or

(3) other factors (which may include the lack of prenatal care) determined relevant by the State.

(c) CDC reporting system

Not later than 4 months after May 20, 1996, the Director of the Centers for Disease Control and Prevention shall develop and implement a system to be used by States to comply with the requirements of subsections (a) and (b). The Director shall issue guidelines to ensure that the data collected is statistically valid.

(July 1, 1944, ch. 373, title XXVI, §2626, as added Pub. L. 104–146, §7(b)(3), May 20, 1996, 110 Stat. 1369; amended Pub. L. 104–166, §5(1), July 29, 1996, 110 Stat. 1449; Pub. L. 106–345, title II, §211(1), Oct. 20, 2000, 114 Stat. 1339; Pub. L. 109–415, title VII, §§702(3), 703, Dec. 19, 2006, 120 Stat. 2820; Pub. L. 111–87, §2(a)(1), (3)(A), Oct. 30, 2009, 123 Stat. 2885.)

EDITORIAL NOTES

AMENDMENTS

2009—Pub. L. 111–87 repealed Pub. L. 109–415, §703, and revived the provisions of this section as in effect on Sept. 30, 2009. See 2006 Amendment note and Effective Date of 2009 Amendment; Revival of Section note below.

2006—Pub. L. 109–415, §703, which directed repeal of this section effective Oct. 1, 2009, was itself repealed by Pub. L. 111–87, §2(a)(1), effective Sept. 30, 2009.

Pub. L. 109–415, §702(3), substituted "HIV/AIDS" for "HIV disease" in section catchline.

2000—Subsecs. (d) to (f). Pub. L. 106–345 struck out subsecs. (d) to (f), which related, respectively, to determination by Secretary, contingent applicability, and limitation regarding availability of funds.

1996—Subsec. (d). Pub. L. 104–166, §5(1)(A), substituted "(1) through (4)" for "(1) through (5)".

Subsec. (f). Pub. L. 104–166, §5(1)(B), substituted "(1) through (4)" for "(1) through (5)" in introductory provisions.

STATUTORY NOTES AND RELATED SUBSIDIARIES

EFFECTIVE DATE OF 2009 AMENDMENT; REVIVAL OF SECTION

For provisions that repeal by section 2(a)(1) of Pub. L. 111–87 of section 703 of Pub. L. 109–415 be effective Sept. 30, 2009, and that the provisions of this section as in effect on Sept. 30, 2009, be revived, see section 2(a)(2), (3)(A) of Pub. L. 111–87, set out as a note under section 300ff–11 of this title.

EFFECTIVE DATE

Section effective May 20, 1996, see section 13(b) of Pub. L. 104–146, set out as an Effective Date of 1996 Amendment note under section 300ff–11 of this title.

§§300ff–35, 300ff–36. Repealed. Pub. L. 106–345, title II, §211(2), Oct. 20, 2000, 114 Stat. 1339

Section 300ff–35, act July 1, 1944, ch. 373, title XXVI, §2627, as added Pub. L. 104–146, §7(b)(3), May 20, 1996, 110 Stat. 1371, related to testing of pregnant women and newborn infants for HIV disease.

Section 300ff–36, act July 1, 1944, ch. 373, title XXVI, §2628, as added Pub. L. 104–146, §7(b)(3), May 20, 1996, 110 Stat. 1372, related to report to Congress by Institute of Medicine.

§300ff–37. State HIV testing programs established prior to or after May 20, 1996

Nothing in this subpart shall be construed to disqualify a State from receiving grants under this subchapter if such State has established at any time prior to or after May 20, 1996, a program of mandatory HIV testing.

(July 1, 1944, ch. 373, title XXVI, §2627, formerly §2629, as added Pub. L. 104–146, §7(b)(3), May 20, 1996, 110 Stat. 1372; renumbered §2627, Pub. L. 106–345, title II, §211(3), Oct. 20, 2000, 114 Stat. 1339; amended Pub. L. 109–415, title VII, §703, Dec. 19, 2006, 120 Stat. 2820; Pub. L. 111–87, §2(a)(1), (3)(A), Oct. 30, 2009, 123 Stat. 2885.)

EDITORIAL NOTES

PRIOR PROVISIONS

A prior section 2627 of act July 1, 1944, was classified to section 300ff–35 of this title prior to repeal by Pub. L. 106–345.

AMENDMENTS

2009—Pub. L. 111–87 repealed Pub. L. 109–415, §703, and revived the provisions of this section as in effect on Sept. 30, 2009. See 2006 Amendment note and Effective Date of 2009 Amendment; Revival of Section note below.

2006—Pub. L. 109–415, §703, which directed repeal of this section effective Oct. 1, 2009, was itself repealed by Pub. L. 111–87, §2(a)(1), effective Sept. 30, 2009.

STATUTORY NOTES AND RELATED SUBSIDIARIES

EFFECTIVE DATE OF 2009 AMENDMENT; REVIVAL OF SECTION

For provisions that repeal by section 2(a)(1) of Pub. L. 111–87 of section 703 of Pub. L. 109–415 be effective Sept. 30, 2009, and that the provisions of this section as in effect on Sept. 30, 2009, be revived, see section 2(a)(2), (3)(A) of Pub. L. 111–87, set out as a note under section 300ff–11 of this title.

EFFECTIVE DATE

Section effective Oct. 1, 1996, see section 13 of Pub. L. 104–146, set out as an Effective Date of 1996 Amendment note under section 300ff–11 of this title.

§300ff–37a. Recommendations for reducing incidence of perinatal transmission

(a) Study by Institute of Medicine

(1) In general

The Secretary shall request the Institute of Medicine to enter into an agreement with the Secretary under which such Institute conducts a study to provide the following:

(A) For the most recent fiscal year for which the information is available, a determination of the number of newborn infants with HIV born in the United States with respect to whom the attending obstetrician for the birth did not know the HIV status of the mother.

(B) A determination for each State of any barriers, including legal barriers, that prevent or

discourage an obstetrician from making it a routine practice to offer pregnant women an HIV test and a routine practice to test newborn infants for HIV/AIDS in circumstances in which the obstetrician does not know the HIV status of the mother of the infant.

(C) Recommendations for each State for reducing the incidence of cases of the perinatal transmission of HIV, including recommendations on removing the barriers identified under subparagraph (B).

If such Institute declines to conduct the study, the Secretary shall enter into an agreement with another appropriate public or nonprofit private entity to conduct the study.

(2) Report

The Secretary shall ensure that, not later than 18 months after the effective date of this section, the study required in paragraph (1) is completed and a report describing the findings made in the study is submitted to the appropriate committees of the Congress, the Secretary, and the chief public health official of each of the States.

(b) Progress toward recommendations

In fiscal year 2004, the Secretary shall collect information from the States describing the actions taken by the States toward meeting the recommendations specified for the States under subsection (a)(1)(C).

(c) Submission of reports to Congress

The Secretary shall submit to the appropriate committees of the Congress reports describing the information collected under subsection (b).

(July 1, 1944, ch. 373, title XXVI, §2628, as added Pub. L. 106–345, title II, §213, Oct. 20, 2000, 114 Stat. 1342; amended Pub. L. 109–415, title VII, §§702(3), 703, Dec. 19, 2006, 120 Stat. 2820; Pub. L. 111–87, §2(a)(1), (3)(A), Oct. 30, 2009, 123 Stat. 2885.)

EDITORIAL NOTES

REFERENCES IN TEXT

The effective date of this section, referred to in subsec. (a)(2), is Oct. 20, 2000. See section 601 of Pub. L. 106–345, set out as an Effective Date of 2000 Amendment note under section 300ff–12 of this title.

PRIOR PROVISIONS

A prior section 2628 of act July 1, 1944, was classified to section 300ff–36 of this title prior to repeal by Pub. L. 106–345.

AMENDMENTS

2009—Pub. L. 111–87 repealed Pub. L. 109–415, §703, and revived the provisions of this section as in effect on Sept. 30, 2009. See 2006 Amendment note and Effective Date of 2009 Amendment; Revival of Section note below.

2006—Pub. L. 109–415, §703, which directed repeal of this section effective Oct. 1, 2009, was itself repealed by Pub. L. 111–87, §2(a)(1), effective Sept. 30, 2009.

Subsec. (a)(1)(B). Pub. L. 109–415, §702(3), substituted "HIV/AIDS" for "HIV disease".

STATUTORY NOTES AND RELATED SUBSIDIARIES

EFFECTIVE DATE OF 2009 AMENDMENT; REVIVAL OF SECTION

For provisions that repeal by section 2(a)(1) of Pub. L. 111–87 of section 703 of Pub. L. 109–415 be effective Sept. 30, 2009, and that the provisions of this section as in effect on Sept. 30, 2009, be revived, see section 2(a)(2), (3)(A) of Pub. L. 111–87, set out as a note under section 300ff–11 of this title.

SUBPART III—CERTAIN PARTNER NOTIFICATION PROGRAMS

§300ff–38. Grants for partner notification programs

(a) In general

In the case of States whose laws or regulations are in accordance with subsection (b), the Secretary, subject to subsection (c)(2), may make grants to the States for carrying out programs to provide partner counseling and referral services.

(b) Description of compliant State programs

For purposes of subsection (a), the laws or regulations of a State are in accordance with this subsection if under such laws or regulations (including programs carried out pursuant to the discretion of State officials) the following policies are in effect:

(1) The State requires that the public health officer of the State carry out a program of partner notification to inform partners of individuals with HIV/AIDS that the partners may have been exposed to the disease.

(2)(A) In the case of a health entity that provides for the performance on an individual of a test for HIV/AIDS, or that treats the individual for the disease, the State requires, subject to subparagraph (B), that the entity confidentially report the positive test results to the State public health officer in a manner recommended and approved by the Director of the Centers for Disease Control and Prevention, together with such additional information as may be necessary for carrying out such program.

(B) The State may provide that the requirement of subparagraph (A) does not apply to the testing of an individual for HIV/AIDS if the individual underwent the testing through a program designed to perform the test and provide the results to the individual without the individual disclosing his or her identity to the program. This subparagraph may not be construed as affecting the requirement of subparagraph (A) with respect to a health entity that treats an individual for HIV/AIDS.

(3) The program under paragraph (1) is carried out in accordance with the following:

(A) Partners are provided with an appropriate opportunity to learn that the partners have been exposed to HIV/AIDS, subject to subparagraph (B).

(B) The State does not inform partners of the identity of the infected individuals involved.

(C) Counseling and testing for HIV/AIDS are made available to the partners and to infected individuals, and such counseling includes information on modes of transmission for the disease, including information on prenatal and perinatal transmission and preventing transmission.

(D) Counseling of infected individuals and their partners includes the provision of information regarding therapeutic measures for preventing and treating the deterioration of the immune system and conditions arising from the disease, and the provision of other prevention-related information.

(E) Referrals for appropriate services are provided to partners and infected individuals, including referrals for support services and legal aid.

(F) Notifications under subparagraph (A) are provided in person, unless doing so is an unreasonable burden on the State.

(G) There is no criminal or civil penalty on, or civil liability for, an infected individual if the individual chooses not to identify the partners of the individual, or the individual does not otherwise cooperate with such program.

(H) The failure of the State to notify partners is not a basis for the civil liability of any health entity who under the program reported to the State the identity of the infected individual involved.

(I) The State provides that the provisions of the program may not be construed as prohibiting the State from providing a notification under subparagraph (A) without the consent of the infected individual involved.

(4) The State annually reports to the Director of the Centers for Disease Control and Prevention

the number of individuals from whom the names of partners have been sought under the program under paragraph (1), the number of such individuals who provided the names of partners, and the number of partners so named who were notified under the program.

(5) The State cooperates with such Director in carrying out a national program of partner notification, including the sharing of information between the public health officers of the States.

(c) Reporting system for cases of HIV/AIDS; preference in making grants

In making grants under subsection (a), the Secretary shall give preference to States whose reporting systems for cases of HIV/AIDS produce data on such cases that is sufficiently accurate and reliable for use for purposes of section 300ff–28(a)(2)(D)(i) of this title.

(d) Authorization of appropriations

For the purpose of carrying out this section, there is authorized to be appropriated $10,000,000 for each of the fiscal years 2007 through 2009.

(July 1, 1944, ch. 373, title XXVI, §2631, as added Pub. L. 106–345, title II, §221, Oct. 20, 2000, 114 Stat. 1343; amended Pub. L. 109–415, title II, §210, title VII, §§702(3), 703, Dec. 19, 2006, 120 Stat. 2803, 2820; Pub. L. 111–87, §2(a)(1), (3)(A), Oct. 30, 2009, 123 Stat. 2885.)

EDITORIAL NOTES

AMENDMENTS

2009—Pub. L. 111–87 repealed Pub. L. 109–415, §703, and revived the provisions of this section as in effect on Sept. 30, 2009. See 2006 Amendment note and Effective Date of 2009 Amendment; Revival of Section note below.

2006—Pub. L. 109–415, §703, which directed repeal of this section effective Oct. 1, 2009, was itself repealed by Pub. L. 111–87, §2(a)(1), effective Sept. 30, 2009.

Subsecs. (b), (c). Pub. L. 109–415, §702(3), substituted "HIV/AIDS" for "HIV disease" wherever appearing.

Subsec. (d). Pub. L. 109–415, §210, substituted "there is authorized to be appropriated $10,000,000 for each of the fiscal years 2007 through 2009." for "there are authorized to be appropriated $30,000,000 for fiscal year 2001, and such sums as may be necessary for each of the fiscal years 2002 through 2005."

STATUTORY NOTES AND RELATED SUBSIDIARIES

EFFECTIVE DATE OF 2009 AMENDMENT; REVIVAL OF SECTION

For provisions that repeal by section 2(a)(1) of Pub. L. 111–87 of section 703 of Pub. L. 109–415 be effective Sept. 30, 2009, and that the provisions of this section as in effect on Sept. 30, 2009, be revived, see section 2(a)(2), (3)(A) of Pub. L. 111–87, set out as a note under section 300ff–11 of this title.

PART C—EARLY INTERVENTION SERVICES

§§300ff–41 to 300ff–50. Repealed. Pub. L. 106–345, title III, §301(a), Oct. 20, 2000, 114 Stat. 1345

Section 300ff–41, act July 1, 1944, ch. 373, title XXVI, §2641, as added Pub. L. 101–381, title III, §301(a), Aug. 18, 1990, 104 Stat. 597; amended Pub. L. 102–531, title III, §312(d)(31), Oct. 27, 1992, 106 Stat. 3506, established program of formula grants to States.

Section 300ff–42, act July 1, 1944, ch. 373, title XXVI, §2642, as added Pub. L. 101–381, title III, §301(a), Aug. 18, 1990, 104 Stat. 599, related to provision of services through medicaid providers.

Section 300ff–43, act July 1, 1944, ch. 373, title XXVI, §2643, as added Pub. L. 101–381, title III, §301(a), Aug. 18, 1990, 104 Stat. 600; amended Pub. L. 102–531, title III, §312(d)(32), Oct. 27, 1992, 106 Stat. 3506, related to requirement of matching funds.

Section 300ff–44, act July 1, 1944, ch. 373, title XXVI, §2644, as added Pub. L. 101–381, title III, §301(a),

Aug. 18, 1990, 104 Stat. 601, related to the offering and encouraging of early intervention services.

Section 300ff–45, act July 1, 1944, ch. 373, title XXVI, §2645, as added Pub. L. 101–381, title III, §301(a), Aug. 18, 1990, 104 Stat. 602, related to notification of certain individuals receiving blood transfusions.

Section 300ff–46, act July 1, 1944, ch. 373, title XXVI, §2646, as added Pub. L. 101–381, title III, §301(a), Aug. 18, 1990, 104 Stat. 602, related to reporting and partner notification.

Section 300ff–47, act July 1, 1944, ch. 373, title XXVI, §2647, as added Pub. L. 101–381, title III, §301(a), Aug. 18, 1990, 104 Stat. 603; amended Pub. L. 101–502, §6(c), Nov. 3, 1990, 104 Stat. 1291; Pub. L. 104–146, §12(c)(4), May 20, 1996, 110 Stat. 1373, related to requirement of State law protection against intentional transmission.

Section 300ff–48, act July 1, 1944, ch. 373, title XXVI, §2648, formerly Pub. L. 100–607, title IX, §902, Nov. 4, 1988, 102 Stat. 3171; amended Pub. L. 100–690, title II, §2605(a), Nov. 18, 1988, 102 Stat. 4234; renumbered §2648 and amended Pub. L. 101–381, title III, §301(b), Aug. 18, 1990, 104 Stat. 614; Pub. L. 104–146, §12(c)(5), May 20, 1996, 110 Stat. 1374, related to testing and other early intervention services for State prisoners.

Section 300ff–49, act July 1, 1944, ch. 373, title XXVI, §2649, as added Pub. L. 101–381, title III, §301(a), Aug. 18, 1990, 104 Stat. 604; amended Pub. L. 101–502, §6(b), Nov. 3, 1990, 104 Stat. 1290; Pub. L. 102–531, title III, §312(d)(33), Oct. 27, 1992, 106 Stat. 3506; Pub. L. 104–146, §12(c)(6), May 20, 1996, 110 Stat. 1374, related to determination of amount of allotments.

Section 300ff–49a, act July 1, 1944, ch. 373, title XXVI, §2649A, as added Pub. L. 101–381, title III, §301(a), Aug. 18, 1990, 104 Stat. 605, related to miscellaneous prerequisites for the Secretary to make a grant.

Section 300ff–50, act July 1, 1944, ch. 373, title XXVI, §2650, as added Pub. L. 101–381, title III, §301(a), Aug. 18, 1990, 104 Stat. 606, authorized appropriations.

SUBPART I—CATEGORICAL GRANTS

EDITORIAL NOTES

CODIFICATION

Pub. L. 106–345, title III, §301(b)(1), Oct. 20, 2000, 114 Stat. 1345, redesignated subpart II "Categorical Grants" as subpart I.

PRIOR PROVISIONS

A prior subpart I, consisting of sections 300ff–41 to 300ff–50, related to formula grants for States, prior to repeal by Pub. L. 106–345, title III, §301(a), Oct. 20, 2000, 114 Stat. 1345.

§300ff–51. Establishment of a program

(a) In general

For the purposes described in subsection (b), the Secretary, acting through the Administrator of the Health Resources and Services Administration, may make grants to public and nonprofit private entities specified in section 300ff–52(a) of this title.

(b) Requirements

(1) In general

The Secretary may not make a grant under subsection (a) unless the applicant for the grant agrees to expend the grant only for—

(A) core medical services described in subsection (c);

(B) support services described in subsection (d); and

(C) administrative expenses as described in section 300ff–64(g)(3) of this title.

(2) Early intervention services

An applicant for a grant under subsection (a) shall expend not less than 50 percent of the amount received under the grant for the services described in subparagraphs (B) through (E) of

subsection (e)(1) for individuals with HIV/AIDS.

(c) Required funding for core medical services

(1) In general

With respect to a grant under subsection (a) to an applicant for a fiscal year, the applicant shall, of the portion of the grant remaining after reserving amounts for purposes of paragraphs (3) and (5) of section 300ff–64(g) of this title, use not less than 75 percent to provide core medical services that are needed in the area involved for individuals with HIV/AIDS who are identified and eligible under this subchapter (including services regarding the co-occurring conditions of the individuals).

(2) Waiver

(A) The Secretary shall waive the application of paragraph (1) with respect to an applicant for a grant if the Secretary determines that, within the service area of the applicant—

(i) there are no waiting lists for AIDS Drug Assistance Program services under section 300ff–26 of this title; and

(ii) core medical services are available to all individuals with HIV/AIDS identified and eligible under this subchapter.

(B) NOTIFICATION OF WAIVER STATUS.—When informing an applicant that a grant under subsection (a) is being made for a fiscal year, the Secretary shall inform the applicant whether a waiver under subparagraph (A) is in effect for the fiscal year.

(3) Core medical services

For purposes of this subsection, the term "core medical services", with respect to an individual with HIV/AIDS (including the co-occurring conditions of the individual) means the following services:

(A) Outpatient and ambulatory health services.

(B) AIDS Drug Assistance Program treatments under section 300ff–26 of this title.

(C) AIDS pharmaceutical assistance.

(D) Oral health care.

(E) Early intervention services described in subsection (e).

(F) Health insurance premium and cost sharing assistance for low-income individuals in accordance with section 300ff–25 of this title.

(G) Home health care.

(H) Medical nutrition therapy.

(I) Hospice services.

(J) Home and community-based health services as defined under section 300ff–24(c) of this title.

(K) Mental health services.

(L) Substance abuse outpatient care.

(M) Medical case management, including treatment adherence services.

(d) Support services

(1) In general

For purposes of this section, the term "support services" means services, subject to the approval of the Secretary, that are needed for individuals with HIV/AIDS to achieve their medical outcomes (such as respite care for persons caring for individuals with HIV/AIDS, outreach services, medical transportation, linguistic services, and referrals for health care and support services).

(2) Definition of medical outcomes

In this section, the term "medical outcomes" means those outcomes affecting the HIV-related clinical status of an individual with HIV/AIDS.

(e) Specification of early intervention services

(1) In general

The early intervention services referred to in this section are—

(A) counseling individuals with respect to HIV/AIDS in accordance with section 300ff–62 of this title;

(B) testing individuals with respect to HIV/AIDS, including tests to confirm the presence of the disease, tests to diagnose the extent of the deficiency in the immune system, and tests to provide information on appropriate therapeutic measures for preventing and treating the deterioration of the immune system and for preventing and treating conditions arising from HIV/AIDS;

(C) referrals described in paragraph (2);

(D) other clinical and diagnostic services regarding HIV/AIDS, and periodic medical evaluations of individuals with HIV/AIDS; and

(E) providing the therapeutic measures described in subparagraph (B).

(2) Referrals

The services referred to in paragraph (1)(C) are referrals of individuals with HIV/AIDS to appropriate providers of health and support services, including, as appropriate—

(A) to entities receiving amounts under part A or B for the provision of such services;

(B) to biomedical research facilities of institutions of higher education that offer experimental treatment for such disease, or to community-based organizations or other entities that provide such treatment; or

(C) to grantees under section 300ff–71 of this title, in the case of a pregnant woman.

(3) Requirement of availability of all early intervention services through each grantee

(A) In general

The Secretary may not make a grant under subsection (a) unless the applicant for the grant agrees that each of the early intervention services specified in paragraph (2) will be available through the grantee. With respect to compliance with such agreement, such a grantee may expend the grant to provide the early intervention services directly, and may expend the grant to enter into agreements with public or nonprofit private entities, or private for-profit entities if such entities are the only available provider of quality HIV care in the area, under which the entities provide the services.

(B) Other requirements

Grantees described in—

(i) subparagraphs (A), (D), (E), and (F) of section 300ff–52(a)(1) of this title shall use not less than 50 percent of the amount of such a grant to provide the services described in subparagraphs (A), (B), (D), and (E) of paragraph (1) directly and on-site or at sites where other primary care services are rendered; and

(ii) subparagraphs (B) and (C) of section 300ff–52(a)(1) of this title shall ensure the availability of early intervention services through a system of linkages to community-based primary care providers, and to establish mechanisms for the referrals described in paragraph (1)(C), and for follow-up concerning such referrals.

(July 1, 1944, ch. 373, title XXVI, §2651, as added Pub. L. 101–381, title III, §301(a), Aug. 18, 1990, 104 Stat. 606; amended Pub. L. 101–557, title IV, §401(b)(2), Nov. 15, 1990, 104 Stat. 2771; Pub. L. 104–146, §§3(d)(1), 12(c)(7), May 20, 1996, 110 Stat. 1357, 1374; Pub. L. 109–415, title III, §301(a), title VII, §703, Dec. 19, 2006, 120 Stat. 2803, 2820; Pub. L. 111–87, §2(a)(1), (3)(A), Oct. 30, 2009, 123 Stat. 2885.)

EDITORIAL NOTES

AMENDMENTS

2009—Pub. L. 111–87 repealed Pub. L. 109–415, §703, and revived the provisions of this section as in effect on Sept. 30, 2009. See 2006 Amendment note and Effective Date of 2009 Amendment; Revival of

Section note below.

2006—Pub. L. 109–415, §703, which directed repeal of this section effective Oct. 1, 2009, was itself repealed by Pub. L. 111–87, §2(a)(1), effective Sept. 30, 2009.

Pub. L. 109–415, §301(a), amended section catchline and text generally, reenacting subsec. (a) without change and substituting subsecs. (b) to (e) for former subsecs. (b) and (c), which related to purposes of grants and participation in a consortium, respectively.

1996—Subsec. (b)(1). Pub. L. 104–146, §3(d)(1)(A), inserted before period ", and unless the applicant agrees to expend not less than 50 percent of the grant for such services that are specified in subparagraphs (B) through (E) of such paragraph for individuals with HIV disease".

Subsec. (b)(3)(B). Pub. L. 104–146, §12(c)(7)(A), substituted "facilities" for "facility".

Subsec. (b)(4). Pub. L. 104–146, §3(d)(1)(B), designated existing provisions as subpar. (A) and inserted heading, inserted ", or private for-profit entities if such entities are the only available provider of quality HIV care in the area," after "nonprofit private entities", realigned margin, and added subpar. (B).

Subsec. (c). Pub. L. 104–146, §12(c)(7)(B), substituted "exists" for "exist".

1990—Subsec. (a). Pub. L. 101–557 substituted "section 300ff–52(a)" for "section 300ff–52(a)(1)".

STATUTORY NOTES AND RELATED SUBSIDIARIES

EFFECTIVE DATE OF 2009 AMENDMENT; REVIVAL OF SECTION

For provisions that repeal by section 2(a)(1) of Pub. L. 111–87 of section 703 of Pub. L. 109–415 be effective Sept. 30, 2009, and that the provisions of this section as in effect on Sept. 30, 2009, be revived, see section 2(a)(2), (3)(A) of Pub. L. 111–87, set out as a note under section 300ff–11 of this title.

EFFECTIVE DATE OF 1996 AMENDMENT

Amendment by Pub. L. 104–146 effective Oct. 1, 1996, see section 13 of Pub. L. 104–146, set out as a note under section 300ff–11 of this title.

§300ff–52. Minimum qualifications of grantees

(a) Eligible entities

(1) In general

The entities referred to in section 300ff–51(a) of this title are public entities and nonprofit private entities that are—

(A) federally-qualified health centers under section 1905(l)(2)(B) of the Social Security Act [42 U.S.C. 1396d(l)(2)(B)];

(B) grantees under section 300 of this title (regarding family planning) other than States;

(C) comprehensive hemophilia diagnostic and treatment centers;

(D) rural health clinics;

(E) health facilities operated by or pursuant to a contract with the Indian Health Service;

(F) community-based organizations, clinics, hospitals and other health facilities that provide early intervention services to those persons infected with HIV/AIDS through intravenous drug use; or

(G) nonprofit private entities that provide comprehensive primary care services to populations at risk of HIV/AIDS, including faith-based and community-based organizations.

(2) Underserved populations

Entities described in paragraph (1) shall serve underserved populations which may include minority populations and Native American populations, ex-offenders, individuals with comorbidities including hepatitis B or C, mental illness, or substance abuse, low-income populations, inner city populations, and rural populations.

(b) Status as medicaid provider

(1) In general

Subject to paragraph (2), the Secretary may not make a grant under section 300ff–51 of this title

for the provision of services described in subsection (b) of such section in a State unless, in the case of any such service that is available pursuant to the State plan approved under title XIX of the Social Security Act [42 U.S.C. 1396 et seq.] for the State—

(A) the applicant for the grant will provide the service directly, and the applicant has entered into a participation agreement under the State plan and is qualified to receive payments under such plan; or

(B) the applicant for the grant will enter into an agreement with a public or nonprofit private entity, or a private for-profit entity if such entity is the only available provider of quality HIV care in the area, under which the entity will provide the service, and the entity has entered into such a participation agreement and is qualified to receive such payments.

(2) Waiver regarding certain secondary agreements

(A) In the case of an entity making an agreement pursuant to paragraph (1)(B) regarding the provision of services, the requirement established in such paragraph regarding a participation agreement shall be waived by the Secretary if the entity does not, in providing health care services, impose a charge or accept reimbursement available from any third-party payor, including reimbursement under any insurance policy or under any Federal or State health benefits program.

(B) A determination by the Secretary of whether an entity referred to in subparagraph (A) meets the criteria for a waiver under such subparagraph shall be made without regard to whether the entity accepts voluntary donations regarding the provision of services to the public.

(July 1, 1944, ch. 373, title XXVI, §2652, as added Pub. L. 101–381, title III, §301(a), Aug. 18, 1990, 104 Stat. 607; amended Pub. L. 101–557, title IV, §401(b)(3), Nov. 15, 1990, 104 Stat. 2771; Pub. L. 104–146, §3(d)(2), May 20, 1996, 110 Stat. 1357; Pub. L. 107–251, title VI, §601(a), Oct. 26, 2002, 116 Stat. 1664; Pub. L. 108–163, §2(m)(3), Dec. 6, 2003, 117 Stat. 2023; Pub. L. 109–415, title III, §302(a), title VII, §703, Dec. 19, 2006, 120 Stat. 2806, 2820; Pub. L. 111–87, §2(a)(1), (3)(A), Oct. 30, 2009, 123 Stat. 2885.)

EDITORIAL NOTES

REFERENCES IN TEXT

The Social Security Act, referred to in subsec. (b)(1), is act Aug. 14, 1935, ch. 531, 49 Stat. 620. Title XIX of the Social Security Act is classified generally to subchapter XIX (§1396 et seq.) of chapter 7 of this title. For complete classification of this Act to the Code, see section 1305 of this title and Tables.

AMENDMENTS

2009—Pub. L. 111–87 repealed Pub. L. 109–415, §703, and revived the provisions of this section as in effect on Sept. 30, 2009. See 2006 Amendment note and Effective Date of 2009 Amendment; Revival of Section note below.

2006—Pub. L. 109–415, §703, which directed repeal of this section effective Oct. 1, 2009, was itself repealed by Pub. L. 111–87, §2(a)(1), effective Sept. 30, 2009.

Subsec. (a). Pub. L. 109–415, §302(a), amended heading and text of subsec. (a) generally, substituting provisions listing eligible entities and directing that such entities serve underserved populations for provisions listing eligible entities.

2003—Subsec. (a)(2). Pub. L. 108–163 substituted "254b(h)" for "256".

2002—Pub. L. 107–251, which directed the substitution of "254b(h)" for "256" in subsec. (2), could not be executed because section does not contain a subsec. (2).

1996—Subsec. (b)(1)(B). Pub. L. 104–146 inserted ", or a private for-profit entity if such entity is the only available provider of quality HIV care in the area," after "nonprofit private entity".

1990—Subsec. (a). Pub. L. 101–557 substituted "referred to in section 300ff–51(a) of this title" for "referred to in subsection (b) of this section", redesignated pars. (A) to (F) as (1) to (6), respectively, and substituted "nonprofit private entities that provide" for "a nonprofit private entity that provides" in par. (6).

STATUTORY NOTES AND RELATED SUBSIDIARIES

EFFECTIVE DATE OF 2009 AMENDMENT; REVIVAL OF SECTION

For provisions that repeal by section 2(a)(1) of Pub. L. 111–87 of section 703 of Pub. L. 109–415 be effective Sept. 30, 2009, and that the provisions of this section as in effect on Sept. 30, 2009, be revived, see section 2(a)(2), (3)(A) of Pub. L. 111–87, set out as a note under section 300ff–11 of this title.

EFFECTIVE DATE OF 2003 AMENDMENT

Amendment by Pub. L. 108–163 deemed to have taken effect immediately after the enactment of Pub. L. 107–251, see section 3 of Pub. L. 108–163, set out as a note under section 233 of this title.

EFFECTIVE DATE OF 1996 AMENDMENT

Amendment by Pub. L. 104–146 effective Oct. 1, 1996, see section 13 of Pub. L. 104–146, set out as a note under section 300ff–11 of this title.

REFERENCE TO COMMUNITY, MIGRANT, PUBLIC HOUSING, OR HOMELESS HEALTH CENTER CONSIDERED REFERENCE TO HEALTH CENTER

Reference to community health center, migrant health center, public housing health center, or homeless health center considered reference to health center, see section 4(c) of Pub. L. 104–299, set out as a note under section 254b of this title.

§300ff–53. Preferences in making grants

(a) In general

In making grants under section 300ff–51 of this title, the Secretary shall give preference to any qualified applicant experiencing an increase in the burden of providing services regarding HIV/AIDS, as indicated by the factors specified in subsection (b).

(b) Specification of factors

(1) In general

In the case of the geographic area with respect to which the entity involved is applying for a grant under section 300ff–51 of this title, the factors referred to in subsection (a), as determined for the period specified in paragraph (2), are—

(A) the number of cases of HIV/AIDS;

(B) the rate of increase in such cases;

(C) the lack of availability of early intervention services;

(D) the number of other cases of sexually transmitted diseases, and [1] the number of cases of tuberculosis and of drug abuse [2] and the number of cases of individuals co-infected with HIV/AIDS and hepatitis B or C;

(E) the rate of increase in each of the cases specified in subparagraph (D);

(F) the lack of availability of primary health services from providers other than such applicant; and

(G) the distance between such area and the nearest community that has an adequate level of availability of appropriate HIV-related services, and the length of time required to travel such distance.

(2) Relevant period of time

The period referred to in paragraph (1) is the 2-year period preceding the fiscal year for which the entity involved is applying to receive a grant under section 300ff–51 of this title.

(c) Equitable allocations

In providing preferences for purposes of subsection (b), the Secretary shall equitably allocate the preferences among urban and rural areas.

(d) Certain areas

Of the applicants who qualify for preference under this section—

(1) the Secretary shall give preference to applicants that will expend the grant under section 300ff–51 of this title to provide early intervention under such section in rural areas; and

(2) the Secretary shall give preference to areas that are underserved with respect to such services.

(July 1, 1944, ch. 373, title XXVI, §2653, as added Pub. L. 101–381, title III, §301(a), Aug. 18, 1990, 104 Stat. 608; amended Pub. L. 106–345, title III, §311, Oct. 20, 2000, 114 Stat. 1345; Pub. L. 109–415, title III, §302(b), title VII, §§702(3), 703, Dec. 19, 2006, 120 Stat. 2806, 2820; Pub. L. 111–87, §2(a)(1), (3)(A), Oct. 30, 2009, 123 Stat. 2885.)

EDITORIAL NOTES

AMENDMENTS

2009—Pub. L. 111–87 repealed Pub. L. 109–415, §703, and revived the provisions of this section as in effect on Sept. 30, 2009. See 2006 Amendment note and Effective Date of 2009 Amendment; Revival of Section note below.

2006—Pub. L. 109–415, §703, which directed repeal of this section effective Oct. 1, 2009, was itself repealed by Pub. L. 111–87, §2(a)(1), effective Sept. 30, 2009.

Subsec. (a). Pub. L. 109–415, §702(3), substituted "HIV/AIDS" for "HIV disease".

Subsec. (b)(1)(A). Pub. L. 109–415, §302(b)(1)(A), substituted "HIV/AIDS" for "acquired immune deficiency syndrome".

Subsec. (b)(1)(D). Pub. L. 109–415, §302(b)(1)(B), inserted "and the number of cases of individuals co-infected with HIV/AIDS and hepatitis B or C" before semicolon at end.

Subsec. (d)(2). Pub. L. 109–415, §302(b)(2), substituted "preference" for "special consideration".

2000—Subsec. (d). Pub. L. 106–345 added subsec. (d).

STATUTORY NOTES AND RELATED SUBSIDIARIES

EFFECTIVE DATE OF 2009 AMENDMENT; REVIVAL OF SECTION

For provisions that repeal by section 2(a)(1) of Pub. L. 111–87 of section 703 of Pub. L. 109–415 be effective Sept. 30, 2009, and that the provisions of this section as in effect on Sept. 30, 2009, be revived, see section 2(a)(2), (3)(A) of Pub. L. 111–87, set out as a note under section 300ff–11 of this title.

[1] So in original. The word "and" probably should not appear.

[2] So in original. A comma probably should appear.

§300ff–54. Miscellaneous provisions

(a) Services for individuals with hemophilia

In making grants under section 300ff–51 of this title, the Secretary shall ensure that any such grants made regarding the provision of early intervention services to individuals with hemophilia are made through the network of comprehensive hemophilia diagnostic and treatment centers.

(b) Technical assistance

The Secretary may, directly or through grants or contracts, provide technical assistance to nonprofit private entities regarding the process of submitting to the Secretary applications for grants under section 300ff–51 of this title, and may provide technical assistance with respect to the planning, development, and operation of any program or service carried out pursuant to such section.

(c) Planning and development grants

(1) In general

The Secretary may provide planning grants to public and nonprofit private entities for purposes of—

(A) enabling such entities to provide early intervention services; and

(B) assisting the entities in expanding their capacity to provide HIV/AIDS-related health

services, including early intervention services, in low-income communities and affected subpopulations that are underserved with respect to such services (subject to the condition that a grant pursuant to this subparagraph may not be expended to purchase or improve land, or to purchase, construct, or permanently improve, other than minor remodeling, any building or other facility).

(2) Requirement

The Secretary may only award a grant to an entity under paragraph (1) if the Secretary determines that the entity will use such grant to assist the entity in qualifying for a grant under section 300ff–51 of this title.

(3) Preference

In awarding grants under paragraph (1), the Secretary shall give preference to entities that provide primary care services in rural areas or to underserved populations.

(4) Amount and duration of grants

(A) Early intervention services

A grant under paragraph (1)(A) may be made in an amount not to exceed $50,000.

(B) Capacity development

(i) Amount

A grant under paragraph (1)(B) may be made in an amount not to exceed $150,000.

(ii) Duration

The total duration of a grant under paragraph (1)(B), including any renewal, may not exceed 3 years.

(5) Limitation

Not to exceed 5 percent of the amount appropriated for a fiscal year under section 300ff–55 of this title may be used to carry out this section.

(July 1, 1944, ch. 373, title XXVI, §2654, as added Pub. L. 101–381, title III, §301(a), Aug. 18, 1990, 104 Stat. 608; amended Pub. L. 104–146, §3(d)(3), May 20, 1996, 110 Stat. 1357; Pub. L. 106–345, title III, §312, Oct. 20, 2000, 114 Stat. 1345; Pub. L. 109–415, title III, §302(c), title VII, §703, Dec. 19, 2006, 120 Stat. 2807, 2820; Pub. L. 111–87, §2(a)(1), (3)(A), Oct. 30, 2009, 123 Stat. 2885.)

EDITORIAL NOTES

AMENDMENTS

2009—Pub. L. 111–87 repealed Pub. L. 109–415, §703, and revived the provisions of this section as in effect on Sept. 30, 2009. See 2006 Amendment note and Effective Date of 2009 Amendment; Revival of Section note below.

2006—Pub. L. 109–415, §703, which directed repeal of this section effective Oct. 1, 2009, was itself repealed by Pub. L. 111–87, §2(a)(1), effective Sept. 30, 2009.

Subsec. (c)(1)(A). Pub. L. 109–415, §302(c)(1)(A), struck out "HIV" after "provide".

Subsec. (c)(1)(B). Pub. L. 109–415, §302(c)(1)(B), substituted "HIV/AIDS-related" for "HIV-related".

Subsec. (c)(3). Pub. L. 109–415, §302(c)(2), substituted "areas or to underserved populations" for "or underserved communities".

2000—Subsec. (c)(1). Pub. L. 106–345, §312(a), substituted "planning grants to public and nonprofit private entities for purposes of—" and subpars. (A) and (B) for "planning grants, in an amount not to exceed $50,000 for each such grant, to public and nonprofit private entities for the purpose of enabling such entities to provide HIV early intervention services."

Subsec. (c)(4). Pub. L. 106–345, §312(b)(2), added par. (4). Former par. (4) redesignated (5).

Subsec. (c)(5). Pub. L. 106–345, §312(b)(1), (c), redesignated par. (4) as (5) and substituted "5 percent" for "1 percent".

1996—Subsec. (c). Pub. L. 104–146 added subsec. (c).

STATUTORY NOTES AND RELATED SUBSIDIARIES

EFFECTIVE DATE OF 2009 AMENDMENT; REVIVAL OF SECTION

For provisions that repeal by section 2(a)(1) of Pub. L. 111–87 of section 703 of Pub. L. 109–415 be effective Sept. 30, 2009, and that the provisions of this section as in effect on Sept. 30, 2009, be revived, see section 2(a)(2), (3)(A) of Pub. L. 111–87, set out as a note under section 300ff–11 of this title.

EFFECTIVE DATE OF 1996 AMENDMENT

Amendment by Pub. L. 104–146 effective Oct. 1, 1996, see section 13 of Pub. L. 104–146, set out as a note under section 300ff–11 of this title.

§300ff–55. Authorization of appropriations

For the purpose of making grants under section 300ff–51 of this title, there are authorized to be appropriated, $218,600,000 for fiscal year 2007, $226,700,000 for fiscal year 2008, $235,100,000 for fiscal year 2009, $246,855,000 for fiscal year 2010, $259,198,000 for fiscal year 2011, $272,158,000 for fiscal year 2012, and $285,766,000 for fiscal year 2013.

(July 1, 1944, ch. 373, title XXVI, §2655, as added Pub. L. 101–381, title III, §301(a), Aug. 18, 1990, 104 Stat. 609; amended Pub. L. 104–146, §3(d)(4), May 20, 1996, 110 Stat. 1358; Pub. L. 106–345, title III, §313, Oct. 20, 2000, 114 Stat. 1346; Pub. L. 109–415, title III, §303, title VII, §703, Dec. 19, 2006, 120 Stat. 2807, 2820; Pub. L. 111–87, §2(a)(1), (3)(A), (d), Oct. 30, 2009, 123 Stat. 2885, 2886.)

EDITORIAL NOTES

AMENDMENTS

2009—Pub. L. 111–87, §2(d), substituted "$235,100,000 for fiscal year 2009, $246,855,000 for fiscal year 2010, $259,198,000 for fiscal year 2011, $272,158,000 for fiscal year 2012, and $285,766,000 for fiscal year 2013" for "and $235,100,000 for fiscal year 2009".

Pub. L. 111–87, §2(a)(1), (3)(A), repealed Pub. L. 109–415, §703, and revived the provisions of this section as in effect on Sept. 30, 2009. See 2006 Amendment note and Effective Date of 2009 Amendment; Revival Section note below.

2006—Pub. L. 109–415, §703, which directed repeal of this section effective Oct. 1, 2009, was itself repealed by Pub. L. 111–87, §2(a)(1), effective Sept. 30, 2009.

Pub. L. 109–415, §303, substituted ", $218,600,000 for fiscal year 2007, $226,700,000 for fiscal year 2008, and $235,100,000 for fiscal year 2009" for "such sums as may be necessary for each of the fiscal years 2001 through 2005".

2000—Pub. L. 106–345 substituted "for each of the fiscal years 2001 through 2005" for "in each of the fiscal years 1996, 1997, 1998, 1999, and 2000".

1996—Pub. L. 104–146 substituted "such sums as may be necessary in each of the fiscal years 1996, 1997, 1998, 1999, and 2000." for "$75,000,000 for fiscal years 1991, and such sums as may be necessary for each of the fiscal years 1992 through 1995."

STATUTORY NOTES AND RELATED SUBSIDIARIES

EFFECTIVE DATE OF 2009 AMENDMENT; REVIVAL OF SECTION

For provisions that repeal by section 2(a)(1) of Pub. L. 111–87 of section 703 of Pub. L. 109–415 be effective Sept. 30, 2009, that the provisions of this section as in effect on Sept. 30, 2009, be revived, and that amendment by section 2(d) of Pub. L. 111–87 be applicable to this section as so revived and effective as if enacted on Sept. 30, 2009, see section 2(a)(2), (3) of Pub. L. 111–87, set out as a note under section 300ff–11 of this title.

EFFECTIVE DATE OF 1996 AMENDMENT

Amendment by Pub. L. 104–146 effective Oct. 1, 1996, see section 13 of Pub. L. 104–146, set out as a note

under section 300ff–11 of this title.

SUBPART II—GENERAL PROVISIONS

EDITORIAL NOTES

CODIFICATION

Pub. L. 106–345, title III, §301(b)(1), Oct. 20, 2000, 114 Stat. 1345, redesignated subpart III "General Provisions" as subpart II.

PRIOR PROVISIONS

A prior subpart II, consisting of sections 300ff–51 to 300ff–55, was redesignated subpart I of this part by Pub. L. 106–345, title III, §301(b)(1), Oct. 20, 2000, 114 Stat. 1345.

§300ff–61. Confidentiality and informed consent

(a) Confidentiality

The Secretary may not make a grant under this part unless, in the case of any entity applying for a grant under section 300ff–51 of this title, the entity agrees to ensure that information regarding the receipt of early intervention services pursuant to the grant is maintained confidentially in a manner not inconsistent with applicable law.

(b) Informed consent

The Secretary may not make a grant under this part unless the applicant for the grant agrees that, in testing an individual for HIV/AIDS, the applicant will test an individual only after the individual confirms that the decision of the individual with respect to undergoing such testing is voluntarily made.

(July 1, 1944, ch. 373, title XXVI, §2661, as added Pub. L. 101–381, title III, §301(a), Aug. 18, 1990, 104 Stat. 609; amended Pub. L. 106–345, title III, §301(b)(2), Oct. 20, 2000, 114 Stat. 1345; Pub. L. 109–415, title III, §304, title VII, §703, Dec. 19, 2006, 120 Stat. 2807, 2820; Pub. L. 111–87, §2(a)(1), (3)(A), Oct. 30, 2009, 123 Stat. 2885.)

EDITORIAL NOTES

AMENDMENTS

2009—Pub. L. 111–87 repealed Pub. L. 109–415, §703, and revived the provisions of this section as in effect on Sept. 30, 2009. See 2006 Amendment note and Effective Date of 2009 Amendment; Revival of Section note below.

2006—Pub. L. 109–415, §703, which directed repeal of this section effective Oct. 1, 2009, was itself repealed by Pub. L. 111–87, §2(a)(1), effective Sept. 30, 2009.

Pub. L. 109–415, §304, reenacted section catchline without change and amended text generally, substituting provisions relating to confidentiality and informed consent for provisions relating to confidentiality, informed written consent, and anonymous testing.

2000—Subsec. (a). Pub. L. 106–345 struck out par. (1) and par. (2) designation. Prior to amendment, par. (1) read as follows: "in the case of any State applying for a grant under section 300ff–41 of this title, the State agrees to ensure that information regarding the receipt of early intervention services is maintained confidentially pursuant to law or regulations in a manner not inconsistent with applicable law; and".

STATUTORY NOTES AND RELATED SUBSIDIARIES

EFFECTIVE DATE OF 2009 AMENDMENT; REVIVAL OF SECTION

For provisions that repeal by section 2(a)(1) of Pub. L. 111–87 of section 703 of Pub. L. 109–415 be effective Sept. 30, 2009, and that the provisions of this section as in effect on Sept. 30, 2009, be revived, see section 2(a)(2), (3)(A) of Pub. L. 111–87, set out as a note under section 300ff–11 of this title.

§300ff–62. Provision of certain counseling services

(a) Counseling of individuals with negative test results

The Secretary may not make a grant under this part unless the applicant for the grant agrees that, if the results of testing conducted for HIV/AIDS indicate that an individual does not have such condition, the applicant will provide the individual information, including—

(1) measures for prevention of, exposure to, and transmission of HIV/AIDS, hepatitis B, hepatitis C, and other sexually transmitted diseases;

(2) the accuracy and reliability of results of testing for HIV/AIDS, hepatitis B, and hepatitis C;

(3) the significance of the results of such testing, including the potential for developing AIDS, hepatitis B, or hepatitis C;

(4) the appropriateness of further counseling, testing, and education of the individual regarding HIV/AIDS and other sexually transmitted diseases;

(5) if diagnosed with chronic hepatitis B or hepatitis C co-infection, the potential of developing hepatitis-related liver disease and its impact on HIV/AIDS; and

(6) information regarding the availability of hepatitis B vaccine and information about hepatitis treatments.

(b) Counseling of individuals with positive test results

The Secretary may not make a grant under this part unless the applicant for the grant agrees that, if the results of testing for HIV/AIDS indicate that the individual has such condition, the applicant will provide to the individual appropriate counseling regarding the condition, including—

(1) information regarding—

(A) measures for prevention of, exposure to, and transmission of HIV/AIDS, hepatitis B, and hepatitis C;

(B) the accuracy and reliability of results of testing for HIV/AIDS, hepatitis B, and hepatitis C; and

(C) the significance of the results of such testing, including the potential for developing AIDS, hepatitis B, or hepatitis C;

(2) reviewing the appropriateness of further counseling, testing, and education of the individual regarding HIV/AIDS and other sexually transmitted diseases; and

(3) providing counseling—

(A) on the availability, through the applicant, of early intervention services;

(B) on the availability in the geographic area of appropriate health care, mental health care, and social and support services, including providing referrals for such services, as appropriate;

(C)(i) that explains the benefits of locating and counseling any individual by whom the infected individual may have been exposed to HIV/AIDS, hepatitis B, or hepatitis C and any individual whom the infected individual may have exposed to HIV/AIDS, hepatitis B, or hepatitis C; and

(ii) that emphasizes it is the duty of infected individuals to disclose their infected status to their sexual partners and their partners in the sharing of hypodermic needles; that provides advice to infected individuals on the manner in which such disclosures can be made; and that emphasizes that it is the continuing duty of the individuals to avoid any behaviors that will expose others to HIV/AIDS, hepatitis B, or hepatitis C; and

(D) on the availability of the services of public health authorities with respect to locating and counseling any individual described in subparagraph (C);

(4) if diagnosed with chronic hepatitis B or hepatitis C co-infection, the potential of developing

hepatitis-related liver disease and its impact on HIV/AIDS; and

(5) information regarding the availability of hepatitis B vaccine.

(c) Additional requirements regarding appropriate counseling

The Secretary may not make a grant under this part unless the applicant for the grant agrees that, in counseling individuals with respect to HIV/AIDS, the applicant will ensure that the counseling is provided under conditions appropriate to the needs of the individuals.

(d) Counseling of emergency response employees

The Secretary may not make a grant under this part to a State unless the State agrees that, in counseling individuals with respect to HIV/AIDS, the State will ensure that, in the case of emergency response employees, the counseling is provided to such employees under conditions appropriate to the needs of the employees regarding the counseling.

(e) Rule of construction regarding counseling without testing

Agreements made pursuant to this section may not be construed to prohibit any grantee under this part from expending the grant for the purpose of providing counseling services described in this section to an individual who does not undergo testing for HIV/AIDS as a result of the grantee or the individual determining that such testing of the individual is not appropriate.

(July 1, 1944, ch. 373, title XXVI, §2662, as added Pub. L. 101–381, title III, §301(a), Aug. 18, 1990, 104 Stat. 610; amended Pub. L. 106–345, title III, §321, Oct. 20, 2000, 114 Stat. 1346; Pub. L. 109–415, title III, §305, title VII, §703, Dec. 19, 2006, 120 Stat. 2807, 2820; Pub. L. 111–87, §2(a)(1), (3)(A), Oct. 30, 2009, 123 Stat. 2885.)

EDITORIAL NOTES

AMENDMENTS

2009—Pub. L. 111–87 repealed Pub. L. 109–415, §703, and revived the provisions of this section as in effect on Sept. 30, 2009. See 2006 Amendment note and Effective Date of 2009 Amendment; Revival of Section note below.

2006—Pub. L. 109–415, §703, which directed repeal of this section effective Oct. 1, 2009, was itself repealed by Pub. L. 111–87, §2(a)(1), effective Sept. 30, 2009.

Pub. L. 109–415, §305, reenacted heading without change and amended text generally, substituting provisions relating to counseling of individuals after testing for HIV/AIDS, appropriateness of conditions, counseling of emergency response employees, and counseling without testing, for provisions relating to counseling of individuals before and after testing, appropriateness of conditions, counseling of emergency response employees, and counseling without testing.

2000—Subsec. (c)(3). Pub. L. 106–345, §321(1), in introductory provisions struck out "on" after "counseling".

Subsec. (c)(3)(A), (B). Pub. L. 106–345, §321(2), inserted "on" before "the availability".

Subsec. (c)(3)(C). Pub. L. 106–345, §321(3), designated existing provisions as cl. (i), inserted "that explains" before "the benefits", and added cl. (ii).

Subsec. (c)(3)(D). Pub. L. 106–345, §321(2), inserted "on" before "the availability".

STATUTORY NOTES AND RELATED SUBSIDIARIES

EFFECTIVE DATE OF 2009 AMENDMENT; REVIVAL OF SECTION

For provisions that repeal by section 2(a)(1) of Pub. L. 111–87 of section 703 of Pub. L. 109–415 be effective Sept. 30, 2009, and that the provisions of this section as in effect on Sept. 30, 2009, be revived, see section 2(a)(2), (3)(A) of Pub. L. 111–87, set out as a note under section 300ff–11 of this title.

§300ff–63. Applicability of requirements regarding confidentiality, informed consent, and counseling

The Secretary may not make a grant under this part unless the applicant for the grant agrees that,

with respect to testing for HIV/AIDS, any such testing carried out by the applicant with funds appropriated through this chapter will be carried out in accordance with conditions described in sections 300ff–61 and 300ff–62 of this title.

(July 1, 1944, ch. 373, title XXVI, §2663, as added Pub. L. 101–381, title III, §301(a), Aug. 18, 1990, 104 Stat. 611; amended Pub. L. 109–415, title III, §306(a), title VII, §§702(3), 703, Dec. 19, 2006, 120 Stat. 2809, 2820; Pub. L. 111–87, §2(a)(1), (3)(A), Oct. 30, 2009, 123 Stat. 2885.)

EDITORIAL NOTES

AMENDMENTS

2009—Pub. L. 111–87 repealed Pub. L. 109–415, §703, and revived the provisions of this section as in effect on Sept. 30, 2009. See 2006 Amendment note and Effective Date of 2009 Amendment; Revival of Section note below.

2006—Pub. L. 109–415, §703, which directed repeal of this section effective Oct. 1, 2009, was itself repealed by Pub. L. 111–87, §2(a)(1), effective Sept. 30, 2009.

Pub. L. 109–415, §702(3), substituted "HIV/AIDS" for "HIV disease".

Pub. L. 109–415, §306(a), substituted "with funds appropriated through this chapter will be carried" for "will, without regard to whether such testing is carried out with Federal funds, be carried".

STATUTORY NOTES AND RELATED SUBSIDIARIES

EFFECTIVE DATE OF 2009 AMENDMENT; REVIVAL OF SECTION

For provisions that repeal by section 2(a)(1) of Pub. L. 111–87 of section 703 of Pub. L. 109–415 be effective Sept. 30, 2009, and that the provisions of this section as in effect on Sept. 30, 2009, be revived, see section 2(a)(2), (3)(A) of Pub. L. 111–87, set out as a note under section 300ff–11 of this title.

§300ff–64. Additional required agreements

(a) Reports to Secretary

The Secretary may not make a grant under this part unless—

(1) the applicant submits to the Secretary—

(A) a specification of the expenditures made by the applicant for early intervention services for the fiscal year preceding the fiscal year for which the applicant is applying to receive the grant;

(B) an estimate of the number of individuals to whom the applicant has provided such services for such fiscal year;

(C) information regarding how the expected expenditures of the grant are related to the planning process for localities funded under part A (including the planning process described in section 300ff–12 of this title) and for States funded under part B (including the planning process described in section 300ff–27(b) of this title); and

(D) a specification of the expected expenditures and how those expenditures will improve overall client outcomes, as described in the State plan under section 300ff–27(b) of this title;

(2) the applicant agrees to submit to the Secretary a report providing—

(A) the number of individuals to whom the applicant provides early intervention services pursuant to the grant;

(B) epidemiological and demographic data on the population of such individuals;

(C) the extent to which the costs of HIV-related health care for such individuals are paid by third-party payors;

(D) the average costs of providing each category of early intervention service; and

(E) the aggregate amounts expended for each such category;

(3) the applicant agrees to provide additional documentation to the Secretary regarding the

process used to obtain community input into the design and implementation of activities related to such grant; and

(4) the applicant agrees to submit, every 2 years, to the lead State agency under section 300ff–27(b)(4) of this title audits, consistent with Office of Management and Budget circular A133, regarding funds expended in accordance with this subchapter and shall include necessary client level data to complete unmet need calculations and Statewide coordinated statements of need process.

(b) Provision of opportunities for anonymous counseling and testing

The Secretary may not make a grant under this part unless the applicant for the grant agrees that, to the extent permitted under State law, regulation or rule, the applicant will offer substantial opportunities for an individual—

(1) to undergo counseling and testing regarding HIV/AIDS without being required to provide any information relating to the identity of the individual; and

(2) to undergo such counseling and testing through the use of a pseudonym.

(c) Prohibition against requiring testing as condition of receiving other health services

The Secretary may not make a grant under this part unless the applicant for the grant agrees that, with respect to an individual seeking health services from the applicant, the applicant will not require the individual to undergo testing for HIV as a condition of receiving any health services unless such testing is medically indicated in the provision of the health services sought by the individual.

(d) Maintenance of support

The Secretary may not make a grant under this part unless the applicant for the grant agrees to maintain the expenditures of the applicant for early intervention services at a level equal to not less than the level of such expenditures maintained by the State for the fiscal year preceding the fiscal year for which the applicant is applying to receive the grant.

(e) Requirements regarding imposition of charges for services

(1) In general

The Secretary may not make a grant under this part unless, subject to paragraph (5), the applicant for the grant agrees that—

(A) in the case of individuals with an income less than or equal to 100 percent of the official poverty line, the applicant will not impose a charge on any such individual for the provision of early intervention services under the grant;

(B) in the case of individuals with an income greater than 100 percent of the official poverty line, the applicant—

(i) will impose a charge on each such individual for the provision of such services; and

(ii) will impose the charge according to a schedule of charges that is made available to the public.

(2) Limitation on charges regarding individuals subject to charges

With respect to the imposition of a charge for purposes of paragraph (1)(B)(ii), the Secretary may not make a grant under this part unless, subject to paragraph (5), the applicant for the grant agrees that—

(A) in the case of individuals with an income greater than 100 percent of the official poverty line and not exceeding 200 percent of such poverty line, the applicant will not, for any calendar year, impose charges in an amount exceeding 5 percent of the annual gross income of the individual involved;

(B) in the case of individuals with an income greater than 200 percent of the official poverty line and not exceeding 300 percent of such poverty line, the applicant will not, for any calendar year, impose charges in an amount exceeding 7 percent of the annual gross income of the individual involved; and

(C) in the case of individuals with an income greater than 300 percent of the official poverty line, the applicant will not, for any calendar year, impose charges in an amount exceeding 10

percent of the annual gross income of the individual involved.

(3) Assessment of charge

With respect to compliance with the agreement made under paragraph (1), a grantee under this part may, in the case of individuals subject to a charge for purposes of such paragraph—

(A) assess the amount of the charge in the discretion of the grantee, including imposing only a nominal charge for the provision of services, subject to the provisions of such paragraph regarding public schedules and of paragraph (2) regarding limitations on the maximum amount of charges; and

(B) take into consideration the medical expenses of individuals in assessing the amount of the charge, subject to such provisions.

(4) Applicability of limitation on amount of charge

The Secretary may not make a grant under this part unless the applicant for the grant agrees that the limitations established in paragraph (2) regarding the imposition of charges for services applies to the annual aggregate of charges imposed for such services, without regard to whether they are characterized as enrollment fees, premiums, deductibles, cost sharing, copayments, coinsurance, or similar charges.

(5) Waiver regarding certain secondary agreements

The requirement established in paragraph (1)(B)(i) shall be waived by the Secretary in the case of any entity for whom the Secretary has granted a waiver under section 300ff–52(b)(2) of this title.

(f) Relationship to items and services under other programs

(1) In general

The Secretary may not make a grant under this part unless the applicant for the grant agrees that, subject to paragraph (2), the grant will not be expended by the applicant, or by any entity receiving amounts from the applicant for the provision of early intervention services, to make payment for any such service to the extent that payment has been made, or can reasonably be expected to be made, with respect to such service—

(A) under any State compensation program, under an insurance policy, or under any Federal or State health benefits program (except for a program administered by or providing the services of the Indian Health Service); or

(B) by an entity that provides health services on a prepaid basis.

(2) Applicability to certain secondary agreements for provision of services

An agreement made under paragraph (1) shall not apply in the case of an entity through which a grantee under this part provides early intervention services if the Secretary has provided a waiver under section 300ff–52(b)(2) of this title regarding the entity.

(g) Administration of grant

The Secretary may not make a grant under this part unless the applicant for the grant agrees that—

(1) the applicant will not expend amounts received pursuant to this part for any purpose other than the purposes described in the subpart under which the grant involved is made;

(2) the applicant will establish such procedures for fiscal control and fund accounting as may be necessary to ensure proper disbursement and accounting with respect to the grant;

(3) the applicant will not expend more than 10 percent of the grant for administrative expenses with respect to the grant, including planning and evaluation, except that the costs of a clinical quality management program under paragraph (5) may not be considered administrative expenses for purposes of such limitation;

(4) the applicant will submit evidence that the proposed program is consistent with the statewide coordinated statement of need and agree to participate in the ongoing revision of such statement of need; and

(5) the applicant will provide for the establishment of a clinical quality management program—

(A) to assess the extent to which medical services funded under this subchapter that are provided to patients are consistent with the most recent Public Health Service guidelines for the treatment of HIV/AIDS and related opportunistic infections, and as applicable, to develop strategies for ensuring that such services are consistent with the guidelines; and

(B) to ensure that improvements in the access to and quality of HIV health services are addressed.

(July 1, 1944, ch. 373, title XXVI, §2664, as added Pub. L. 101–381, title III, §301(a), Aug. 18, 1990, 104 Stat. 611; amended Pub. L. 104–146, §3(d)(5), May 20, 1996, 110 Stat. 1358; Pub. L. 106–345, title III, §§301(b)(3), 322, Oct. 20, 2000, 114 Stat. 1345, 1346; Pub. L. 109–415, title III, §§301(b), 306(b), (c), title VII, §§702(3), 703, Dec. 19, 2006, 120 Stat. 2806, 2809, 2820; Pub. L. 111–87, §2(a)(1), (3)(A), Oct. 30, 2009, 123 Stat. 2885.)

EDITORIAL NOTES

AMENDMENTS

2009—Pub. L. 111–87 repealed Pub. L. 109–415, §703, and revived the provisions of this section as in effect on Sept. 30, 2009. See 2006 Amendment note and Effective Date of 2009 Amendment; Revival of Section note below.

2006—Pub. L. 109–415, §703, which directed repeal of this section effective Oct. 1, 2009, was itself repealed by Pub. L. 111–87, §2(a)(1), effective Sept. 30, 2009.

Subsec. (a)(1)(C), (D). Pub. L. 109–415, §306(b)(1), added subpars. (C) and (D).

Subsec. (a)(3), (4). Pub. L. 109–415, §306(b)(2), (3), added pars. (3) and (4).

Subsec. (b)(1). Pub. L. 109–415, §702(3), substituted "HIV/AIDS" for "HIV disease".

Subsec. (f)(1)(A). Pub. L. 109–415, §306(c), inserted "(except for a program administered by or providing the services of the Indian Health Service)" before semicolon.

Subsec. (g)(3). Pub. L. 109–415, §301(b)(1), amended par. (3) generally. Prior to amendment, par. (3) read as follows: "the applicant will not expend more than 10 percent including planning and evaluation of the grant for administrative expenses with respect to the grant;".

Subsec. (g)(5). Pub. L. 109–415, §301(b)(2), inserted "clinical" before "quality management" in introductory provisions.

Subsec. (g)(5)(A). Pub. L. 109–415, §702(3), substituted "HIV/AIDS" for "HIV disease".

2000—Subsecs. (e)(5), (f)(2). Pub. L. 106–345, §301(b)(3)(A), (B), struck out "300ff–42(b) or" after "a waiver under section".

Subsec. (g)(3). Pub. L. 106–345, §322(1)(A), substituted "10 percent" for "7.5 percent".

Subsec. (g)(5). Pub. L. 106–345, §322(1)(B), (2), (3), added par. (5).

Subsec. (h). Pub. L. 106–345, §301(b)(3)(C), struck out heading and text of subsec. (h). Text read as follows: "A State may not use amounts received under a grant awarded under section 300ff–41 of this title to purchase or improve land, or to purchase, construct, or permanently improve (other than minor remodeling) any building or other facility, or to make cash payments to intended recipients of services."

1996—Subsec. (g)(3). Pub. L. 104–146, §3(d)(5)(B)(i), substituted "7.5 percent including planning and evaluation" for "5 percent".

Subsec. (g)(4). Pub. L. 104–146, §3(d)(5)(A), (B)(ii), (C), added par. (4).

STATUTORY NOTES AND RELATED SUBSIDIARIES

EFFECTIVE DATE OF 2009 AMENDMENT; REVIVAL OF SECTION

For provisions that repeal by section 2(a)(1) of Pub. L. 111–87 of section 703 of Pub. L. 109–415 be effective Sept. 30, 2009, and that the provisions of this section as in effect on Sept. 30, 2009, be revived, see section 2(a)(2), (3)(A) of Pub. L. 111–87, set out as a note under section 300ff–11 of this title.

EFFECTIVE DATE OF 1996 AMENDMENT

Amendment by Pub. L. 104–146 effective Oct. 1, 1996, see section 13 of Pub. L. 104–146, set out as a note under section 300ff–11 of this title.

§300ff–65. Requirement of submission of application containing certain agreements and assurances

The Secretary may not make a grant under this part unless—

(1) an application for the grant is submitted to the Secretary containing agreements and assurances in accordance with this part and containing the information specified in section 300ff–64(a)(1) of this title;

(2) with respect to such agreements, the application provides assurances of compliance satisfactory to the Secretary; and

(3) the application otherwise is in such form, is made in such manner, and contains such agreements, assurances, and information as the Secretary determines to be necessary to carry out this part.

(July 1, 1944, ch. 373, title XXVI, §2665, as added Pub. L. 101–381, title III, §301(a), Aug. 18, 1990, 104 Stat. 614; amended Pub. L. 109–415, title VII, §703, Dec. 19, 2006, 120 Stat. 2820; Pub. L. 111–87, §2(a)(1), (3)(A), Oct. 30, 2009, 123 Stat. 2885.)

EDITORIAL NOTES

AMENDMENTS

2009—Pub. L. 111–87 repealed Pub. L. 109–415, §703, and revived the provisions of this section as in effect on Sept. 30, 2009. See 2006 Amendment note and Effective Date of 2009 Amendment; Revival of Section note below.

2006—Pub. L. 109–415, §703, which directed repeal of this section effective Oct. 1, 2009, was itself repealed by Pub. L. 111–87, §2(a)(1), effective Sept. 30, 2009.

STATUTORY NOTES AND RELATED SUBSIDIARIES

EFFECTIVE DATE OF 2009 AMENDMENT; REVIVAL OF SECTION

For provisions that repeal by section 2(a)(1) of Pub. L. 111–87 of section 703 of Pub. L. 109–415 be effective Sept. 30, 2009, and that the provisions of this section as in effect on Sept. 30, 2009, be revived, see section 2(a)(2), (3)(A) of Pub. L. 111–87, set out as a note under section 300ff–11 of this title.

§300ff–66. Provision by Secretary of supplies and services in lieu of grant funds

(a) In general

Upon the request of a grantee under this part, the Secretary may, subject to subsection (b), provide supplies, equipment, and services for the purpose of aiding the grantee in providing early intervention services and, for such purpose, may detail to the State any officer or employee of the Department of Health and Human Services.

(b) Limitation

With respect to a request described in subsection (a), the Secretary shall reduce the amount of payments under the grant involved by an amount equal to the costs of detailing personnel and the fair market value of any supplies, equipment, or services provided by the Secretary. The Secretary shall, for the payment of expenses incurred in complying with such request, expend the amounts withheld.

(July 1, 1944, ch. 373, title XXVI, §2666, as added Pub. L. 101–381, title III, §301(a), Aug. 18, 1990, 104 Stat. 614; amended Pub. L. 109–415, title VII, §703, Dec. 19, 2006, 120 Stat. 2820; Pub. L. 111–87, §2(a)(1), (3)(A), Oct. 30, 2009, 123 Stat. 2885.)

EDITORIAL NOTES

AMENDMENTS

2009—Pub. L. 111–87 repealed Pub. L. 109–415, §703, and revived the provisions of this section as in

effect on Sept. 30, 2009. See 2006 Amendment note and Effective Date of 2009 Amendment; Revival of Section note below.

2006—Pub. L. 109–415, §703, which directed repeal of this section effective Oct. 1, 2009, was itself repealed by Pub. L. 111–87, §2(a)(1), effective Sept. 30, 2009.

STATUTORY NOTES AND RELATED SUBSIDIARIES

EFFECTIVE DATE OF 2009 AMENDMENT; REVIVAL OF SECTION

For provisions that repeal by section 2(a)(1) of Pub. L. 111–87 of section 703 of Pub. L. 109–415 be effective Sept. 30, 2009, and that the provisions of this section as in effect on Sept. 30, 2009, be revived, see section 2(a)(2), (3)(A) of Pub. L. 111–87, set out as a note under section 300ff–11 of this title.

§300ff–67. Use of funds

Counseling programs carried out under this part—

(1) shall not be designed to promote or encourage, directly, intravenous drug abuse or sexual activity, homosexual or heterosexual;

(2) shall be designed to reduce exposure to and transmission of HIV/AIDS by providing accurate information;

(3) shall provide information on the health risks of promiscuous sexual activity and intravenous drug abuse; and

(4) shall provide information on the transmission and prevention of hepatitis A, B, and C, including education about the availability of hepatitis A and B vaccines and assisting patients in identifying vaccination sites.

(July 1, 1944, ch. 373, title XXVI, §2667, as added Pub. L. 101–381, title III, §301(a), Aug. 18, 1990, 104 Stat. 614; amended Pub. L. 109–415, title VII, §§701, 702(3), 703, Dec. 19, 2006, 120 Stat. 2819, 2820; Pub. L. 111–87, §2(a)(1), (3)(A), Oct. 30, 2009, 123 Stat. 2885.)

EDITORIAL NOTES

AMENDMENTS

2009—Pub. L. 111–87 repealed Pub. L. 109–415, §703, and revived the provisions of this section as in effect on Sept. 30, 2009. See 2006 Amendment note and Effective Date of 2009 Amendment; Revival of Section note below.

2006—Pub. L. 109–415, §703, which directed repeal of this section effective Oct. 1, 2009, was itself repealed by Pub. L. 111–87, §2(a)(1), effective Sept. 30, 2009.

Par. (2). Pub. L. 109–415, §702(3), substituted "HIV/AIDS" for "HIV disease".

Par. (4). Pub. L. 109–415, §701, added par. (4).

STATUTORY NOTES AND RELATED SUBSIDIARIES

EFFECTIVE DATE OF 2009 AMENDMENT; REVIVAL OF SECTION

For provisions that repeal by section 2(a)(1) of Pub. L. 111–87 of section 703 of Pub. L. 109–415 be effective Sept. 30, 2009, and that the provisions of this section as in effect on Sept. 30, 2009, be revived, see section 2(a)(2), (3)(A) of Pub. L. 111–87, set out as a note under section 300ff–11 of this title.

PART D—WOMEN, INFANTS, CHILDREN, AND YOUTH

EDITORIAL NOTES

CODIFICATION

Part D of title XXVI of the Public Health Service Act, comprising this part, was originally added to act July 1, 1944, ch. 373, by Pub. L. 101–381, title IV, §401, Aug. 18, 1990, 104 Stat. 617, and amended by Pub. L. 104–146, May 20, 1996, 110 Stat. 1346; Pub. L. 102–531, Oct. 27, 1992, 106 Stat. 3469; Pub. L. 106–345, Oct. 20, 2000, 114 Stat. 1319; Pub. L. 108–173, Dec. 8, 2003, 117 Stat. 2066. Part D is shown herein, however, as having been added by Pub. L. 109–415, title IV, §401, Dec. 19, 2006, 120 Stat. 2810, without reference to those intervening amendments because of the extensive revision of part D by Pub. L. 109–415.

§300ff–71. Grants for coordinated services and access to research for women, infants, children, and youth

(a) In general

The Secretary, acting through the Administrator of the Health Resources and Services Administration, shall award grants to public and nonprofit private entities (including a health facility operated by or pursuant to a contract with the Indian Health Service) for the purpose of providing family-centered care involving outpatient or ambulatory care (directly or through contracts or memoranda of understanding) for women, infants, children, and youth with HIV/AIDS.

(b) Additional services for patients and families

Funds provided under grants awarded under subsection (a) may be used for the following support services:

(1) Family-centered care including case management.

(2) Referrals for additional services including—

(A) referrals for inpatient hospital services, treatment for substance abuse, and mental health services; and

(B) referrals for other social and support services, as appropriate.

(3) Additional services necessary to enable the patient and the family to participate in the program established by the applicant pursuant to such subsection including services designed to recruit and retain youth with HIV.

(4) The provision of information and education on opportunities to participate in HIV/AIDS-related clinical research.

(c) Coordination with other entities

A grant awarded under subsection (a) may be made only if the applicant provides an agreement that includes the following:

(1) The applicant will coordinate activities under the grant with other providers of health care services under this chapter, and under title V of the Social Security Act [42 U.S.C. 701 et seq.], including programs promoting the reduction and elimination of risk of HIV/AIDS for youth.

(2) The applicant will participate in the statewide coordinated statement of need under part B (where it has been initiated by the public health agency responsible for administering grants under part B) and in revisions of such statement.

(3) The applicant will every 2 years submit to the lead State agency under section 300ff–27(b)(4) of this title audits regarding funds expended in accordance with this subchapter and shall include necessary client-level data to complete unmet need calculations and Statewide coordinated statements of need process.

(d) Administration; application

A grant may only be awarded to an entity under subsection (a) if an application for the grant is submitted to the Secretary and the application is in such form, is made in such manner, and contains such agreements, assurances, and information as the Secretary determines to be necessary to carry out this section. Such application shall include the following:

(1) Information regarding how the expected expenditures of the grant are related to the planning process for localities funded under part A (including the planning process outlined in section 300ff–12 of this title) and for States funded under part B (including the planning process outlined

in section 300ff–27(b) of this title).

(2) A specification of the expected expenditures and how those expenditures will improve overall patient outcomes, as outlined as part of the State plan (under section 300ff–27(b) of this title) or through additional outcome measures.

(e) Annual review of programs; evaluations

(1) Review regarding access to and participation in programs

With respect to a grant under subsection (a) for an entity for a fiscal year, the Secretary shall, not later than 180 days after the end of the fiscal year, provide for the conduct and completion of a review of the operation during the year of the program carried out under such subsection by the entity. The purpose of such review shall be the development of recommendations, as appropriate, for improvements in the following:

(A) Procedures used by the entity to allocate opportunities and services under subsection (a) among patients of the entity who are women, infants, children, or youth.

(B) Other procedures or policies of the entity regarding the participation of such individuals in such program.

(2) Evaluations

The Secretary shall, directly or through contracts with public and private entities, provide for evaluations of programs carried out pursuant to subsection (a).

(f) Administrative expenses

(1) Limitation

A grantee may not use more than 10 percent of amounts received under a grant awarded under this section for administrative expenses.

(2) Clinical quality management program

A grantee under this section shall implement a clinical quality management program to assess the extent to which HIV health services provided to patients under the grant are consistent with the most recent Public Health Service guidelines for the treatment of HIV/AIDS and related opportunistic infection, and as applicable, to develop strategies for ensuring that such services are consistent with the guidelines for improvement in the access to and quality of HIV health services.

(g) Training and technical assistance

From the amounts appropriated under subsection (j) for a fiscal year, the Secretary may use not more than 5 percent to provide, directly or through contracts with public and private entities (which may include grantees under subsection (a)), training and technical assistance to assist applicants and grantees under subsection (a) in complying with the requirements of this section.

(h) Definitions

In this section:

(1) Administrative expenses

The term "administrative expenses" means funds that are to be used by grantees for grant management and monitoring activities, including costs related to any staff or activity unrelated to services or indirect costs.

(2) Indirect costs

The term "indirect costs" means costs included in a Federally negotiated indirect rate.

(3) Services

The term "services" means—

(A) services that are provided to clients to meet the goals and objectives of the program under this section, including the provision of professional, diagnostic, and therapeutic services by a primary care provider or a referral to and provision of specialty care; and

(B) services that sustain program activity and contribute to or help improve services under

subparagraph (A).

(i) Application to primary care services

Nothing in this part shall be construed as requiring funds under this part to be used for primary care services when payments are available for such services from other sources (including under titles XVIII, XIX, and XXI of the Social Security Act [42 U.S.C. 1395 et seq., 1396 et seq., 1397aa et seq.]).

(j) Authorization of appropriations

For the purpose of carrying out this section, there are authorized to be appropriated, $71,800,000 for each of the fiscal years 2007 through 2009, $75,390,000 for fiscal year 2010, $79,160,000 for fiscal year 2011, $83,117,000 for fiscal year 2012, and $87,273,000 for fiscal year 2013.

(July 1, 1944, ch. 373, title XXVI, §2671, as added and amended Pub. L. 109–415, title IV, §401, title VII, §703, Dec. 19, 2006, 120 Stat. 2810, 2820; Pub. L. 111–87, §§2(a)(1), (3)(A), (e), 11, Oct. 30, 2009, 123 Stat. 2885, 2886, 2895.)

EDITORIAL NOTES

REFERENCES IN TEXT

The Social Security Act, referred to in subsecs. (c)(1) and (i), is act Aug. 14, 1935, ch. 531, 49 Stat. 620. Titles V, XVIII, XIX, and XXI of the Act are classified generally to subchapters V (§701 et seq.), XVIII (§1395 et seq.), XIX (§1396 et seq.), and XXI (§1397aa et seq.), respectively, of chapter 7 of this title. For complete classification of this Act to the Code, see section 1305 of this title and Tables.

PRIOR PROVISIONS

Prior sections 300ff–71 to 300ff–78 were omitted in the general amendment of this part by Pub. L. 109–415.

Section 300ff–71, act July 1, 1944, ch. 373, title XXVI, §2671, as added Pub. L. 101–381, title IV, §401, Aug. 18, 1990, 104 Stat. 617; amended Pub. L. 104–146, §3(e), May 20, 1996, 110 Stat. 1358; Pub. L. 106–345, title IV, §401, Oct. 20, 2000, 114 Stat. 1347, related to grants for coordinated services and access to research for women, infants, children, and youth.

Section 300ff–72, act July 1, 1944, ch. 373, title XXVI, §2672, as added Pub. L. 101–381, title IV, §401, Aug. 18, 1990, 104 Stat. 618, contained provisions relating to blood banks.

Section 300ff–73, act July 1, 1944, ch. 373, title XXVI, §2673, as added Pub. L. 101–381, title IV, §401, Aug. 18, 1990, 104 Stat. 619; amended Pub. L. 106–345, title V, §503(a)(2), Oct. 20, 2000, 114 Stat. 1354, related to a research, evaluation, and assessment program.

Section 300ff–74, act July 1, 1944, ch. 373, title XXVI, §2674, as added Pub. L. 101–381, title IV, §401, Aug. 18, 1990, 104 Stat. 620; amended Pub. L. 104–146, §3(f), May 20, 1996, 110 Stat. 1362; Pub. L. 106–345, title IV, §411, Oct. 20, 2000, 114 Stat. 1350, related to evaluations and reports.

Section 300ff–75, act July 1, 1944, ch. 373, title XXVI, §2675, as added Pub. L. 101–381, title IV, §401, Aug. 18, 1990, 104 Stat. 620; amended Pub. L. 102–531, title III, §312(d)(34), Oct. 27, 1992, 106 Stat. 3506; Pub. L. 106–345, title IV, §§413, 414, Oct. 20, 2000, 114 Stat. 1350, 1351; Pub. L. 108–173, title IX, §900(e)(2)(G), Dec. 8, 2003, 117 Stat. 2372, related to coordination of Federal HIV programs. See section 300ff–81 of this title.

Section 300ff–75a, act July 1, 1944, ch. 373, title XXVI, §2675A, as added Pub. L. 106–345, title IV, §415, Oct. 20, 2000, 114 Stat. 1351, related to audits. See section 300ff–82 of this title.

Section 300ff–75b, act July 1, 1944, ch. 373, title XXVI, §2675B, as added Pub. L. 106–345, title IV, §416, Oct. 20, 2000, 114 Stat. 1351, related to administrative simplification.

Section 300ff–76, act July 1, 1944, ch. 373, title XXVI, §2676, as added Pub. L. 101–381, title IV, §401, Aug. 18, 1990, 104 Stat. 620; amended Pub. L. 104–146, §12(a), (c)(8), May 20, 1996, 110 Stat. 1373, 1374, defined terms for this subchapter. See section 300ff–88 of this title.

Section 300ff–77, act July 1, 1944, ch. 373, title XXVI, §2677, as added Pub. L. 104–146, §6(a), May 20, 1996, 110 Stat. 1367; amended Pub. L. 106–345, title IV, §417, Oct. 20, 2000, 114 Stat. 1352, authorized appropriations.

Section 300ff–78, act July 1, 1944, ch. 373, title XXVI, §2678, as added Pub. L. 104–146, §10, May 20, 1996, 110 Stat. 1373, prohibited promotion of certain activities. See section 300ff–84 of this title.

AMENDMENTS

2009—Pub. L. 111–87, §2(a)(1), (3)(A), repealed Pub. L. 109–415, §703, and revived the provisions of this section as in effect on Sept. 30, 2009. See 2006 Amendment note and Effective Date of 2009 Amendment; Revival of Section note below.

Subsec. (a). Pub. L. 111–87, §11(b), substituted "(directly or through contracts or memoranda of understanding)" for "(directly or through contracts)".

Subsec. (g). Pub. L. 111–87, §11(a)(2), substituted "subsection (j)" for "subsection (i)".

Subsec. (i). Pub. L. 111–87, §11(a)(3), added subsec. (i). Former subsec. (i) redesignated (j).

Pub. L. 111–87, §2(e), inserted ", $75,390,000 for fiscal year 2010, $79,160,000 for fiscal year 2011, $83,117,000 for fiscal year 2012, and $87,273,000 for fiscal year 2013" before period at end.

Subsec. (j). Pub. L. 111–87, §11(a)(1), redesignated subsec. (i) as (j).

2006—Pub. L. 109–415, §703, which directed repeal of this section effective Oct. 1, 2009, was itself repealed by Pub. L. 111–87, §2(a)(1), effective Sept. 30, 2009.

STATUTORY NOTES AND RELATED SUBSIDIARIES

EFFECTIVE DATE OF 2009 AMENDMENT; REVIVAL OF SECTION

For provisions that repeal by section 2(a)(1) of Pub. L. 111–87 of section 703 of Pub. L. 109–415 be effective Sept. 30, 2009, that the provisions of this section as in effect on Sept. 30, 2009, be revived, and that amendment by sections 2(e) and 11 of Pub. L. 111–87 be applicable to this section as so revived and effective as if enacted on Sept. 30, 2009, see section 2(a)(2), (3) of Pub. L. 111–87, set out as a note under section 300ff–11 of this title.

PART E—GENERAL PROVISIONS

EDITORIAL NOTES

CODIFICATION

Part E of title XXVI of the Public Health Service Act, comprising this part, was originally added to act July 1, 1944, ch. 373, by Pub. L. 101–381, title IV, §411(a), Aug. 18, 1990, 104 Stat. 622, and amended by Pub. L. 104–146, May 20, 1996, 110 Stat. 1346. Part E is shown herein, however, as having been added by Pub. L. 109–415, title IV, §501, Dec. 19, 2006, 120 Stat. 2812, without reference to the intervening amendments because of the extensive revision of part E by Pub. L. 109–415.

PRIOR PROVISIONS

A prior section 300ff–80, act July 1, 1944, ch. 373, title XXVI, §2680, as added Pub. L. 101–381, title IV, §411(a), Aug. 18, 1990, 104 Stat. 622, related to grants for implementation of recommendations in guidelines and model curriculum.

§300ff–81. Coordination

(a) Requirement

The Secretary shall ensure that the Health Resources and Services Administration, the Centers for Disease Control and Prevention, the Substance Abuse and Mental Health Services Administration, and the Centers for Medicare & Medicaid Services coordinate the planning, funding, and implementation of Federal HIV programs (including all minority AIDS initiatives of the Public Health Service, including under section 300ff–121 of this title) to enhance the continuity of care and prevention services for individuals with HIV/AIDS or those at risk of such disease. The Secretary shall consult with other Federal agencies, including the Department of Veterans Affairs, as needed and utilize planning information submitted to such agencies by the States and entities eligible for assistance under this subchapter.

(b) Report

The Secretary shall biennially prepare and submit to the appropriate committees of the Congress a report concerning the coordination efforts at the Federal, State, and local levels described in this section, including a description of Federal barriers to HIV program integration and a strategy for eliminating such barriers and enhancing the continuity of care and prevention services for individuals with HIV/AIDS or those at risk of such disease.

(c) Integration by State

As a condition of receipt of funds under this subchapter, a State shall provide assurances to the Secretary that health support services funded under this subchapter will be integrated with other such services, that programs will be coordinated with other available programs (including Medicaid), and that the continuity of care and prevention services of individuals with HIV/AIDS is enhanced.

(d) Integration by local or private entities

As a condition of receipt of funds under this subchapter, a local government or private nonprofit entity shall provide assurances to the Secretary that services funded under this subchapter will be integrated with other such services, that programs will be coordinated with other available programs (including Medicaid), and that the continuity of care and prevention services of individuals with HIV is enhanced.

(July 1, 1944, ch. 373, title XXVI, §2681, as added and amended Pub. L. 109–415, title V, §501, title VII, §703, Dec. 19, 2006, 120 Stat. 2812, 2820; Pub. L. 111–87, §2(a)(1), (3)(A), Oct. 30, 2009, 123 Stat. 2885.)

EDITORIAL NOTES

PRIOR PROVISIONS

A prior section 300ff–81, act July 1, 1944, ch. 373, title XXVI, §2681, as added Pub. L. 101–381, title IV, §411(a), Aug. 18, 1990, 104 Stat. 623, related to development and dissemination of list of infectious diseases, prior to the general amendment of this part by Pub. L. 109–415.

AMENDMENTS

2009—Pub. L. 111–87 repealed Pub. L. 109–415, §703, and revived the provisions of this section as in effect on Sept. 30, 2009. See 2006 Amendment note and Effective Date of 2009 Amendment; Revival of Section note below.

2006—Pub. L. 109–415, §703, which directed repeal of this section effective Oct. 1, 2009, was itself repealed by Pub. L. 111–87, §2(a)(1), effective Sept. 30, 2009.

STATUTORY NOTES AND RELATED SUBSIDIARIES

EFFECTIVE DATE OF 2009 AMENDMENT; REVIVAL OF SECTION

For provisions that repeal by section 2(a)(1) of Pub. L. 111–87 of section 703 of Pub. L. 109–415 be effective Sept. 30, 2009, and that the provisions of this section as in effect on Sept. 30, 2009, be revived, see section 2(a)(2), (3)(A) of Pub. L. 111–87, set out as a note under section 300ff–11 of this title.

§300ff–82. Audits

(a) In general

For fiscal year 2009, and each subsequent fiscal year, the Secretary may reduce the amounts of grants under this subchapter to a State or political subdivision of a State for a fiscal year if, with respect to such grants for the second preceding fiscal year, the State or subdivision fails to prepare audits in accordance with the procedures of section 7502 of title 31. The Secretary shall annually select representative samples of such audits, prepare summaries of the selected audits, and submit the summaries to the Congress.

(b) Posting on the Internet

All audits that the Secretary receives from the State lead agency under section 300ff–27(b)(4) of this title shall be posted, in their entirety, on the Internet website of the Health Resources and Services Administration.

(July 1, 1944, ch. 373, title XXVI, §2682, as added and amended Pub. L. 109–415, title V, §501, title VII, §703, Dec. 19, 2006, 120 Stat. 2813, 2820; Pub. L. 111–87, §2(a)(1), (3)(A), Oct. 30, 2009, 123 Stat. 2885.)

EDITORIAL NOTES

PRIOR PROVISIONS

A prior section 300ff–82, July 1, 1944, ch. 373, title XXVI, §2682, as added Pub. L. 101–381, title IV, §411(a), Aug. 18, 1990, 104 Stat. 623, related to routine notifications with respect to airborne infectious diseases in victims assisted, prior to the general amendment of this part by Pub. L. 109–415.

AMENDMENTS

2009—Pub. L. 111–87 repealed Pub. L. 109–415, §703, and revived the provisions of this section as in effect on Sept. 30, 2009. See 2006 Amendment note and Effective Date of 2009 Amendment; Revival of Section note below.

2006—Pub. L. 109–415, §703, which directed repeal of this section effective Oct. 1, 2009, was itself repealed by Pub. L. 111–87, §2(a)(1), effective Sept. 30, 2009.

STATUTORY NOTES AND RELATED SUBSIDIARIES

EFFECTIVE DATE OF 2009 AMENDMENT; REVIVAL OF SECTION

For provisions that repeal by section 2(a)(1) of Pub. L. 111–87 of section 703 of Pub. L. 109–415 be effective Sept. 30, 2009, and that the provisions of this section as in effect on Sept. 30, 2009, be revived, see section 2(a)(2), (3)(A) of Pub. L. 111–87, set out as a note under section 300ff–11 of this title.

§300ff–83. Public health emergency

(a) In general

In an emergency area and during an emergency period, the Secretary shall have the authority to waive such requirements of this subchapter to improve the health and safety of those receiving care under this subchapter and the general public, except that the Secretary may not expend more than 5 percent of the funds allocated under this subchapter for sections 300ff–29a of this title and section [1] 300ff–13(b) of this title.

(b) Emergency area and emergency period

In this section:

(1) Emergency area

The term "emergency area" means a geographic area in which there exists—

(A) an emergency or disaster declared by the President pursuant to the National Emergencies Act [50 U.S.C. 1601 et seq.] or the Robert T. Stafford Disaster Relief and Emergency Assistance Act [42 U.S.C. 5121 et seq.]; or

(B) a public health emergency declared by the Secretary pursuant to section 247d of this title.

(2) Emergency period

The term "emergency period" means the period in which there exists—

(A) an emergency or disaster declared by the President pursuant to the National Emergencies Act or the Robert T. Stafford Disaster Relief and Emergency Assistance Act; or

(B) a public health emergency declared by the Secretary pursuant to section 247d of this title.

(c) Unobligated funds

If funds under a grant under this section are not expended for an emergency in the fiscal year in which the emergency is declared, such funds shall be returned to the Secretary for reallocation under sections 300ff–13(b) and 300ff–29a of this title.

(July 1, 1944, ch. 373, title XXVI, §2683, as added and amended Pub. L. 109–415, title V, §501, title VII, §703, Dec. 19, 2006, 120 Stat. 2813, 2820; Pub. L. 111–87, §2(a)(1), (3)(A), Oct. 30, 2009, 123 Stat. 2885.)

EDITORIAL NOTES

REFERENCES IN TEXT

The National Emergencies Act, referred to in subsec. (b)(1)(A), (2)(A), is Pub. L. 94–412, Sept. 14, 1976, 90 Stat. 1255, which is classified principally to chapter 34 (§1601 et seq.) of Title 50, War and National Defense. For complete classification of this Act to the Code, see Short Title note set out under section 1601 of Title 50 and Tables.

The Robert T. Stafford Disaster Relief and Emergency Assistance Act, referred to in subsec. (b)(1)(A), (2)(A), is Pub. L. 93–288, May 22, 1974, 88 Stat. 143, which is classified principally to chapter 68 (§5121 et seq.) of this title. For complete classification of this Act to the Code, see Short Title note set out under section 5121 of this title and Tables.

PRIOR PROVISIONS

A prior section 300ff–83, act July 1, 1944, ch. 373, title XXVI, §2683, as added Pub. L. 101–381, title IV, §411(a), Aug. 18, 1990, 104 Stat. 624, related to request for notifications with respect to victims assisted, prior to the general amendment of this part by Pub. L. 109–415.

AMENDMENTS

2009—Pub. L. 111–87 repealed Pub. L. 109–415, §703, and revived the provisions of this section as in effect on Sept. 30, 2009. See 2006 Amendment note and Effective Date of 2009 Amendment; Revival of Section note below.

2006—Pub. L. 109–415, §703, which directed repeal of this section effective Oct. 1, 2009, was itself repealed by Pub. L. 111–87, §2(a)(1), effective Sept. 30, 2009.

STATUTORY NOTES AND RELATED SUBSIDIARIES

EFFECTIVE DATE OF 2009 AMENDMENT; REVIVAL OF SECTION

For provisions that repeal by section 2(a)(1) of Pub. L. 111–87 of section 703 of Pub. L. 109–415 be effective Sept. 30, 2009, and that the provisions of this section as in effect on Sept. 30, 2009, be revived, see section 2(a)(2), (3)(A) of Pub. L. 111–87, set out as a note under section 300ff–11 of this title.

[1] So in original. The word "section" probably should not appear.

§300ff–84. Prohibition on promotion of certain activities

None of the funds appropriated under this subchapter shall be used to fund AIDS programs, or to develop materials, designed to promote or encourage, directly, intravenous drug use or sexual activity, whether homosexual or heterosexual. Funds authorized under this subchapter may be used to provide medical treatment and support services for individuals with HIV.

(July 1, 1944, ch. 373, title XXVI, §2684, as added and amended Pub. L. 109–415, title V, §501, title VII, §703, Dec. 19, 2006, 120 Stat. 2814, 2820; Pub. L. 111–87, §2(a)(1), (3)(A), Oct. 30, 2009, 123 Stat. 2885.)

EDITORIAL NOTES

PRIOR PROVISIONS

A prior section 300ff–84, act July 1, 1944, ch. 373, title XXVI, §2684, as added Pub. L. 101–381, title IV,

§411(a), Aug. 18, 1990, 104 Stat. 626; amended Pub. L. 104–146, §12(c)(10), May 20, 1996, 110 Stat. 1374, related to procedures for notification of exposure, prior to the general amendment of this part by Pub. L. 109–415.

AMENDMENTS

2009—Pub. L. 111–87 repealed Pub. L. 109–415, §703, and revived the provisions of this section as in effect on Sept, 30, 2009. See 2006 Amendment note and Effective Date of 2009 Amendment; Revival of Section note below.

2006—Pub. L. 109–415, §703, which directed repeal of this section effective Oct. 1, 2009, was itself repealed by Pub. L. 111–87, §2(a)(1), effective Sept. 30, 2009.

STATUTORY NOTES AND RELATED SUBSIDIARIES

EFFECTIVE DATE OF 2009 AMENDMENT; REVIVAL OF SECTION

For provisions that repeal by section 2(a)(1) of Pub. L. 111–87 of section 703 of Pub. L. 109–415 be effective Sept. 30, 2009, and that the provisions of this section as in effect on Sept. 30, 2009, be revived, see section 2(a)(2), (3)(A) of Pub. L. 111–87, set out as a note under section 300ff–11 of this title.

§300ff–85. Privacy protections

(a) In general

The Secretary shall ensure that any information submitted to, or collected by, the Secretary under this subchapter excludes any personally identifiable information.

(b) Definition

In this section, the term "personally identifiable information" has the meaning given such term under the regulations promulgated under section 264(c) of the Health Insurance Portability and Accountability Act of 1996.

(July 1, 1944, ch. 373, title XXVI, §2685, as added and amended Pub. L. 109–415, title V, §501, title VII, §703, Dec. 19, 2006, 120 Stat. 2814, 2820; Pub. L. 111–87, §2(a)(1), (3)(A), Oct. 30, 2009, 123 Stat. 2885.)

EDITORIAL NOTES

REFERENCES IN TEXT

Section 264(c) of the Health Insurance Portability and Accountability Act of 1996, referred to in subsec. (b), is section 264(c) of Pub. L. 104–191, which is set out as a note under section 1320d–2 of this title.

PRIOR PROVISIONS

A prior section 300ff–85, act July 1, 1944, ch. 373, title XXVI, §2685, as added Pub. L. 101–381, title IV, §411(a), Aug. 18, 1990, 104 Stat. 626, related to notification of emergency response employees, prior to the general amendment of this part by Pub. L. 109–415.

AMENDMENTS

2009—Pub. L. 111–87 repealed Pub. L. 109–415, §703, and revived the provisions of this section as in effect on Sept. 30, 2009. See 2006 Amendment note and Effective Date of 2009 Amendment; Revival of Section note below.

2006—Pub. L. 109–415, §703, which directed repeal of this section effective Oct. 1, 2009, was itself repealed by Pub. L. 111–87, §2(a)(1), effective Sept. 30, 2009.

STATUTORY NOTES AND RELATED SUBSIDIARIES

EFFECTIVE DATE OF 2009 AMENDMENT; REVIVAL OF SECTION

For provisions that repeal by section 2(a)(1) of Pub. L. 111–87 of section 703 of Pub. L. 109–415 be effective Sept. 30, 2009, and that the provisions of this section as in effect on Sept. 30, 2009, be revived, see

section 2(a)(2), (3)(A) of Pub. L. 111–87, set out as a note under section 300ff–11 of this title.

§300ff–86. GAO report

The Comptroller General of the Government Accountability Office shall, not less than 1 year after October 30, 2009, submit to the appropriate committees of Congress a report describing Minority AIDS Initiative activities across the Department of Health and Human Services, including programs under this subchapter and programs at the Centers for Disease Control and Prevention, the Substance Abuse and Mental Health Services Administration, and other departmental agencies. Such report shall include a history of program activities within each relevant agency and a description of activities conducted, people served and types of grantees funded, and shall collect and describe best practices in community outreach and capacity-building of community based organizations serving the communities that are disproportionately affected by HIV/AIDS.

(July 1, 1944, ch. 373, title XXVI, §2686, as added and amended Pub. L. 109–415, title V, §501, title VII, §703, Dec. 19, 2006, 120 Stat. 2814, 2820; Pub. L. 111–87, §2(a)(1), (3)(A), (g), Oct. 30, 2009, 123 Stat. 2885, 2887.)

EDITORIAL NOTES

PRIOR PROVISIONS

A prior section 300ff–86, act July 1, 1944, ch. 373, title XXVI, §2686, as added Pub. L. 101–381, title IV, §411(a), Aug. 18, 1990, 104 Stat. 627, related to selection of designated officers, prior to the general amendment of this part by Pub. L. 109–415.

AMENDMENTS

2009—Pub. L. 111–87, §2(g), amended section generally. Prior to amendment, text read as follows: "The Comptroller General of the Government Accountability Office shall biennially submit to the appropriate committees of Congress a report that includes a description of Federal, State, and local barriers to HIV program integration, particularly for racial and ethnic minorities, including activities carried out under subpart III of part F, and recommendations for enhancing the continuity of care and the provision of prevention services for individuals with HIV/AIDS or those at risk for such disease. Such report shall include a demonstration of the manner in which funds under this subpart are being expended and to what extent the services provided with such funds increase access to prevention and care services for individuals with HIV/AIDS and build stronger community linkages to address HIV prevention and care for racial and ethnic minority communities."

Pub. L. 111–87, §2(a)(1), (3)(A), repealed Pub. L. 109–415, §703, and revived the provisions of this section as in effect on Sept. 30, 2009. See 2006 Amendment note and Effective Date of 2009 Amendment; Revival of Section note below.

2006—Pub. L. 109–415, §703, which directed repeal of this section effective Oct. 1, 2009, was itself repealed by Pub. L. 111–87, §2(a)(1), effective Sept. 30, 2009.

STATUTORY NOTES AND RELATED SUBSIDIARIES

EFFECTIVE DATE OF 2009 AMENDMENT; REVIVAL OF SECTION

For provisions that repeal by section 2(a)(1) of Pub. L. 111–87 of section 703 of Pub. L. 109–415 be effective Sept. 30, 2009, that the provisions of this section as in effect on Sept. 30, 2009, be revived, and that amendment by section 2(g) of Pub. L. 111–87 be applicable to this section as so revived and effective as if enacted on Sept. 30, 2009, see section 2(a)(2), (3) of Pub. L. 111–87, set out as a note under section 300ff–11 of this title.

§300ff–87. Severity of need index

(a) Development of index

Not later than September 30, 2008, the Secretary shall develop and submit to the appropriate committees of Congress a severity of need index in accordance with subsection (c).

(b) Definition of severity of need index

In this section, the term "severity of need index" means the index of the relative needs of individuals within a State or area, as identified by a number of different factors, and is a factor or set of factors that is multiplied by the number of living HIV/AIDS cases in a State or area, providing different weights to those cases based on needs. Such factors or set of factors may be different for different components of the provisions under this subchapter.

(c) Requirements for Secretarial submission

When the Secretary submits to the appropriate committees of Congress the severity of need index under subsection (a), the Secretary shall provide the following:

(1) Methodology for and rationale behind developing the severity of need index, including information related to the field testing of the severity of need index.

(2) An independent contractor analysis of activities carried out under paragraph (1).

(3) Information regarding the process by which the Secretary received community input regarding the application and development of the severity of need index.

(d) Annual reports

If the Secretary fails to submit the severity of need index under subsection (a) in either of fiscal years 2007 or 2008, the Secretary shall prepare and submit to the appropriate committees of Congress a report for such fiscal year—

(1) that updates progress toward having client level data;

(2) that updates the progress toward having a severity of need index, including information related to the methodology and process for obtaining community input; and

(3) that, as applicable, states whether the Secretary could develop a severity of need index before fiscal year 2009.

(July 1, 1944, ch. 373, title XXVI, §2687, as added and amended Pub. L. 109–415, title V, §501, title VII, §703, Dec. 19, 2006, 120 Stat. 2814, 2820; Pub. L. 111–87, §2(a)(1), (3)(A), Oct. 30, 2009, 123 Stat. 2885.)

EDITORIAL NOTES

PRIOR PROVISIONS

A prior section 300ff–87, act July 1, 1944, ch. 373, title XXVI, §2687, as added Pub. L. 101–381, title IV, §411(a), Aug. 18, 1990, 104 Stat. 627, related to limitations with respect to duties of medical facilities, prior to the general amendment of this part by Pub. L. 109–415.

AMENDMENTS

2009—Pub. L. 111–87 repealed Pub. L. 109–415, §703, and revived the provisions of this section as in effect on Sept. 30, 2009. See 2006 Amendment note and Effective Date of 2009 Amendment; Revival of Section note below.

2006—Pub. L. 109–415, §703, which directed repeal of this section effective Oct. 1, 2009, was itself repealed by Pub. L. 111–87, §2(a)(1), effective Sept. 30, 2009.

STATUTORY NOTES AND RELATED SUBSIDIARIES

EFFECTIVE DATE OF 2009 AMENDMENT; REVIVAL OF SECTION

For provisions that repeal by section 2(a)(1) of Pub. L. 111–87 of section 703 of Pub. L. 109–415 be effective Sept. 30, 2009, and that the provisions of this section as in effect on Sept. 30, 2009, be revived, see section 2(a)(2), (3)(A) of Pub. L. 111–87, set out as a note under section 300ff–11 of this title.

§300ff–87a. National HIV/AIDS testing goal

(a) In general

Not later than January 1, 2010, the Secretary shall establish a national HIV/AIDS testing goal of 5,000,000 tests for HIV/AIDS annually through federally-supported HIV/AIDS prevention, treatment, and care programs, including programs under this subchapter and other programs administered by the Centers for Disease Control and Prevention.

(b) Annual report

Not later than January 1, 2011, and annually thereafter, the Secretary, acting through the Director of the Centers for Disease Control and Prevention, shall submit to Congress a report describing, with regard to the preceding 12-month reporting period—

(1) whether the testing goal described in subsection (a) has been met;

(2) the total number of individuals tested through federally-supported and other HIV/AIDS prevention, treatment, and care programs in each State;

(3) the number of individuals who—

(A) prior to such 12-month period, were unaware of their HIV status; and

(B) through federally-supported and other HIV/AIDS prevention, treatment, and care programs, were diagnosed and referred into treatment and care during such period;

(4) any barriers, including State laws and regulations, that the Secretary determines to be a barrier to meeting the testing goal described in subsection (a);

(5) the amount of funding the Secretary determines necessary to meet the annual testing goal in the following 12 months and the amount of Federal funding expended to meet the testing goal in the prior 12-month period; and

(6) the most cost-effective strategies for identifying and diagnosing individuals who were unaware of their HIV status, including voluntary testing with pre-test counseling, routine screening including opt-out testing, partner counseling and referral services, and mass media campaigns.

(c) Review of program effectiveness

Not later than 1 year after October 30, 2009, the Secretary, in consultation with the Director of the Centers for Disease Control and Prevention, shall submit a report to Congress based on a comprehensive review of each of the programs and activities conducted by the Centers for Disease Control and Prevention as part of the Domestic HIV/AIDS Prevention Activities, including the following:

(1) The amount of funding provided for each program or activity.

(2) The primary purpose of each program or activity.

(3) The annual goals for each program or activity.

(4) The relative effectiveness of each program or activity with relation to the other programs and activities conducted by the Centers for Disease Control and Prevention, based on the—

(A) number of previously undiagnosed individuals with HIV/AIDS made aware of their status and referred into the appropriate treatment;

(B) amount of funding provided for each program or activity compared to the number of undiagnosed individuals with HIV/AIDS made aware of their status;

(C) program's contribution to the National HIV/AIDS testing goal; and

(D) progress made toward the goals described in paragraph (3).

(5) Recommendations if any to Congress on ways to allocate funding for domestic HIV/AIDS prevention activities and programs in order to achieve the National HIV/AIDS testing goal.

(d) Coordination with other Federal activities

In pursuing the National HIV/AIDS testing goal, the Secretary, where appropriate, shall consider and coordinate with other national strategies conducted by the Federal Government to address HIV/AIDS.

(July 1, 1944, ch. 373, title XXVI, §2688, as added Pub. L. 111–87, §12(2), Oct. 30, 2009, 123 Stat.

2896.)

EDITORIAL NOTES

PRIOR PROVISIONS

A prior section 2688 of act July 1, 1944, was renumbered section 2689 and is classified to section 300ff–88 of this title.

Another prior section 2688 of act July 1, 1944, was classified to section 300ff–88 of this title prior to the general amendment of this part by Pub. L. 109–415.

STATUTORY NOTES AND RELATED SUBSIDIARIES

EFFECTIVE DATE

Section effective as if enacted on Sept. 30, 2009, see section 2(a)(3)(B) of Pub. L. 111–87, set out as an Effective Date of 2009 Amendment; Revival of Section note under section 300ff–11 of this title.

§300ff–88. Definitions

For purposes of this subchapter:

(1) AIDS

The term "AIDS" means acquired immune deficiency syndrome.

(2) Co-occurring conditions

The term "co-occurring conditions" means one or more adverse health conditions in an individual with HIV/AIDS, without regard to whether the individual has AIDS and without regard to whether the conditions arise from HIV.

(3) Counseling

The term "counseling" means such counseling provided by an individual trained to provide such counseling.

(4) Family-centered care

The term "family-centered care" means the system of services described in this subchapter that is targeted specifically to the special needs of infants, children, women and families. Family-centered care shall be based on a partnership between parents, professionals, and the community designed to ensure an integrated, coordinated, culturally sensitive, and community-based continuum of care for children, women, and families with HIV/AIDS.

(5) Families with HIV/AIDS

The term "families with HIV/AIDS" means families in which one or more members have HIV/AIDS.

(6) HIV

The term "HIV" means infection with the human immunodeficiency virus.

(7) HIV/AIDS

(A) In general

The term "HIV/AIDS" means HIV, and includes AIDS and any condition arising from AIDS.

(B) Counting of cases

The term "living cases of HIV/AIDS", with respect to the counting of cases in a geographic area during a period of time, means the sum of—

(i) the number of living non-AIDS cases of HIV in the area; and

(ii) the number of living cases of AIDS in the area.

(C) Non-AIDS cases

The term "non-AIDS", with respect to a case of HIV, means that the individual involved has HIV but does not have AIDS.

(8) Human immunodeficiency virus

The term "human immunodeficiency virus" means the etiologic agent for AIDS.

(9) Official poverty line

The term "official poverty line" means the poverty line established by the Director of the Office of Management and Budget and revised by the Secretary in accordance with section 9902(2) of this title.

(10) Person

The term "person" includes one or more individuals, governments (including the Federal Government and the governments of the States), governmental agencies, political subdivisions, labor unions, partnerships, associations, corporations, legal representatives, mutual companies, joint-stock companies, trusts, unincorporated organizations, receivers, trustees, and trustees in cases under title 11.

(11) State

(A) In general

The term "State" means each of the 50 States, the District of Columbia, and each of the territories.

(B) Territories

The term "territory" means each of American Samoa, Guam, the Commonwealth of Puerto Rico, the Commonwealth of the Northern Mariana Islands, the Virgin Islands, the Republic of the Marshall Islands, the Federated States of Micronesia, and Palau.

(12) Youth with HIV

The term "youth with HIV" means individuals who are 13 through 24 years old and who have HIV/AIDS.

(July 1, 1944, ch. 373, title XXVI, §2689, formerly §2688, as added and amended Pub. L. 109–415, title V, §501, title VII, §703, Dec. 19, 2006, 120 Stat. 2815, 2820; renumbered §2689 and amended Pub. L. 111–87, §§2(a)(1), (3)(A), 12(1), Oct. 30, 2009, 123 Stat. 2885, 2896.)

EDITORIAL NOTES

PRIOR PROVISIONS

A prior section 300ff–88, act July 1, 1944, ch. 373, title XXVI, §2688, as added Pub. L. 101–381, title IV, §411(a), Aug. 18, 1990, 104 Stat. 627, provided rules of construction for former subpart II of this part, prior to the general amendment of this part by Pub. L. 109–415.

Prior sections 300ff–89 and 300ff–90 were omitted in the general amendment of this part by Pub. L. 109–415.

Section 300ff–89, act July 1, 1944, ch. 373, title XXVI, §2689, as added Pub. L. 101–381, title IV, §411(a), Aug. 18, 1990, 104 Stat. 628, related to injunctions regarding violations of former subpart II of this part.

Section 300ff–90, act July 1, 1944, ch. 373, title XXVI, §2690, as added Pub. L. 101–381, title IV, §411(a), Aug. 18, 1990, 104 Stat. 628, related to applicability of former subpart II of this part.

AMENDMENTS

2009—Pub. L. 111–87, §2(a)(1), (3)(A), repealed Pub. L. 109–415, §703, and revived the provisions of this section as in effect on Sept. 30, 2009. See 2006 Amendment note and Effective Date of 2009 Amendment; Revival of Section note below.

2006—Pub. L. 109–415, §703, which directed repeal of this section effective Oct. 1, 2009, was itself repealed by Pub. L. 111–87, §2(a)(1), effective Sept. 30, 2009.

STATUTORY NOTES AND RELATED SUBSIDIARIES

EFFECTIVE DATE OF 2009 AMENDMENT; REVIVAL OF SECTION

For provisions that repeal by section 2(a)(1) of Pub. L. 111–87 of section 703 of Pub. L. 109–415 be effective Sept. 30, 2009, and that the provisions of this section as in effect on Sept. 30, 2009, be revived, see section 2(a)(2), (3)(A) of Pub. L. 111–87, set out as a note under section 300ff–11 of this title.

PART F—DEMONSTRATION AND TRAINING

SUBPART I—SPECIAL PROJECTS OF NATIONAL SIGNIFICANCE

§300ff–101. Special projects of national significance

(a) In general

Of the amount appropriated under each of parts A, B, C, and D for each fiscal year, the Secretary shall use the greater of $20,000,000 or an amount equal to 3 percent of such amount appropriated under each such part, but not to exceed $25,000,000, to administer special projects of national significance to—

(1) quickly respond to emerging needs of individuals receiving assistance under this subchapter; and

(2) to fund special programs to develop a standard electronic client information data system to improve the ability of grantees under this subchapter to report client-level data to the Secretary.

(b) Grants

The Secretary shall award grants under subsection (a) to entities eligible for funding under parts A, B, C, and D based on—

(1) whether the funding will promote obtaining client level data as it relates to the creation of a severity of need index, including funds to facilitate the purchase and enhance the utilization of qualified health information technology systems;

(2) demonstrated ability to create and maintain a qualified health information technology system;

(3) the potential replicability of the proposed activity in other similar localities or nationally;

(4) the demonstrated reliability of the proposed qualified health information technology system across a variety of providers, geographic regions, and clients; and

(5) the demonstrated ability to maintain a safe and secure qualified health information system; or

(6) newly emerging needs of individuals receiving assistance under this subchapter.

(c) Coordination

The Secretary may not make a grant under this section unless the applicant submits evidence that the proposed program is consistent with the statewide coordinated statement of need, and the applicant agrees to participate in the ongoing revision process of such statement of need.

(d) Privacy protection

The Secretary may not make a grant under this section for the development of a qualified health information technology system unless the applicant provides assurances to the Secretary that the system will, at a minimum, comply with the privacy regulations promulgated under section 264(c) of the Health Insurance Portability and Accountability Act of 1996.

(e) Replication

The Secretary shall make information concerning successful models or programs developed under

this part available to grantees under this subchapter for the purpose of coordination, replication, and integration. To facilitate efforts under this subsection, the Secretary may provide for peer-based technical assistance for grantees funded under this part.

(July 1, 1944, ch. 373, title XXVI, §2691, as added Pub. L. 104–146, §3(g)(1), May 20, 1996, 110 Stat. 1362; amended Pub. L. 109–415, title VI, §601, title VII, §703, Dec. 19, 2006, 120 Stat. 2816, 2820; Pub. L. 111–87, §2(a)(1), (3)(A), Oct. 30, 2009, 123 Stat. 2885.)

EDITORIAL NOTES

REFERENCES IN TEXT

Section 264(c) of the Health Insurance Portability and Accountability Act of 1996, referred to in subsec. (d), is section 264(c) of Pub. L. 104–191, which is set out as a note under section 1320d–2 of this title.

AMENDMENTS

2009—Pub. L. 111–87 repealed Pub. L. 109–415, §703, and revived the provisions of this section as in effect on Sept. 30, 2009. See 2006 Amendment note and Effective Date of 2009 Amendment; Revival of Section note below.

2006—Pub. L. 109–415, §703, which directed repeal of this section effective Oct. 1, 2009, was itself repealed by Pub. L. 111–87, §2(a)(1), effective Sept. 30, 2009.

Pub. L. 109–415, §601, amended section generally. Prior to amendment, section related to use of funds for special projects of national significance.

STATUTORY NOTES AND RELATED SUBSIDIARIES

EFFECTIVE DATE OF 2009 AMENDMENT; REVIVAL OF SECTION

For provisions that repeal by section 2(a)(1) of Pub. L. 111–87 of section 703 of Pub. L. 109–415 be effective Sept. 30, 2009, and that the provisions of this section as in effect on Sept. 30, 2009, be revived, see section 2(a)(2), (3)(A) of Pub. L. 111–87, set out as a note under section 300ff–11 of this title.

SUBPART II—AIDS EDUCATION AND TRAINING CENTERS

§300ff–111. HIV/AIDS communities, schools, and centers

(a) Schools; centers

(1) In general

The Secretary may make grants and enter into contracts to assist public and nonprofit private entities and schools and academic health science centers in meeting the costs of projects—

(A) to train health personnel, including practitioners in programs under this subchapter and other community providers, in the diagnosis, treatment, and prevention of HIV/AIDS, including the prevention of the perinatal transmission of the disease, including measures for the prevention and treatment of opportunistic infections, and including (as applicable to the type of health professional involved), prenatal and other gynecological care for women with HIV/AIDS;

(B) to train the faculty of schools of, and graduate departments or programs of, medicine, nursing, osteopathic medicine, dentistry, public health, allied health, and mental health practice to teach health professions students to provide for the health care needs of individuals with HIV/AIDS;

(C) to develop and disseminate curricula and resource materials relating to the care and treatment of individuals with such disease and the prevention of the disease among individuals who are at risk of contracting the disease; and

(D) to develop protocols for the medical care of women with HIV/AIDS, including prenatal

and other gynecological care for such women.

(2) Preference in making grants

In making grants under paragraph (1), the Secretary shall give preference to qualified projects which will—

(A) train, or result in the training of, health professionals who will provide treatment for minority individuals and Native Americans with HIV/AIDS and other individuals who are at high risk of contracting such disease;

(B) train, or result in the training of, minority health professionals and minority allied health professionals to provide treatment for individuals with such disease; and

(C) train or result in the training of health professionals and allied health professionals to provide treatment for hepatitis B or C co-infected individuals.

(3) Application

No grant or contract may be made under paragraph (1) unless an application is submitted to the Secretary in such form, at such time, and containing such information, as the Secretary may prescribe.

(b) Dental schools

(1) In general

(A) Grants

The Secretary may make grants to dental schools and programs described in subparagraph (B) to assist such schools and programs with respect to oral health care to patients with HIV/AIDS.

(B) Eligible applicants

For purposes of this subsection, the dental schools and programs referred to in this subparagraph are dental schools and programs that were described in section 294o(b)(4)(B) of this title as such section was in effect on the day before November 13, 1998, and in addition dental hygiene programs that are accredited by the Commission on Dental Accreditation.

(2) Application

Each dental school or program described in section [1] the section referred to in paragraph (1)(B) may annually submit an application documenting the unreimbursed costs of oral health care provided to patients with HIV/AIDS by that school or hospital during the prior year.

(3) Distribution

The Secretary shall distribute the available funds among all eligible applicants, taking into account the number of patients with HIV/AIDS served and the unreimbursed oral health care costs incurred by each institution as compared with the total number of patients served and costs incurred by all eligible applicants.

(4) Maintenance of effort

The Secretary shall not make a grant under this subsection if doing so would result in any reduction in State funding allotted for such purposes.

(5) Community-based care

The Secretary may make grants to dental schools and programs described in paragraph (1)(B) that partner with community-based dentists to provide oral health care to patients with HIV/AIDS in unserved areas. Such partnerships shall permit the training of dental students and residents and the participation of community dentists as adjunct faculty.

(c) Authorization of appropriations

(1) Schools; centers

For the purpose of awarding grants under subsection (a), there are authorized to be appropriated

$34,700,000 for each of the fiscal years 2007 through 2009, $36,535,000 for fiscal year 2010, $38,257,000 for fiscal year 2011, $40,170,000 for fiscal year 2012, and $42,178,000 for fiscal year 2013.

(2) Dental schools

For the purpose of awarding grants under subsection (b), there are authorized to be appropriated $13,000,000 for each of the fiscal years 2007 through 2009, $13,650,000 for fiscal year 2010, $14,333,000 for fiscal year 2011, $15,049,000 for fiscal year 2012, and $15,802,000 for fiscal year 2013.

(July 1, 1944, ch. 373, title XXVI, §2692, formerly title VII, §776, as added Pub. L. 102–408, title I, §102, Oct. 13, 1992, 106 Stat. 2050; amended Pub. L. 102–531, title III, §313(a)(4), Oct. 27, 1992, 106 Stat. 3507; renumbered title XXVI, §2692, and amended Pub. L. 104–146, §3(h), May 20, 1996, 110 Stat. 1363; Pub. L. 104–166, §5(2), July 29, 1996, 110 Stat. 1449; Pub. L. 106–345, title IV, §402(a)(1), (b), (c), Oct. 20, 2000, 114 Stat. 1348, 1349; Pub. L. 109–415, title VI, §602, title VII, §§702(3), 703, Dec. 19, 2006, 120 Stat. 2817, 2820; Pub. L. 111–87, §2(a)(1), (3)(A), (f)(1), Oct. 30, 2009, 123 Stat. 2885, 2886.)

EDITORIAL NOTES

CODIFICATION

Section was formerly classified to section 294n of this title prior to renumbering by Pub. L. 104–146.

AMENDMENTS

2009—Pub. L. 111–87, §2(a)(1), (3)(A), repealed Pub. L. 109–415, §703, and revived the provisions of this section as in effect on Sept. 30, 2009. See 2006 Amendment note and Effective Date of 2009 Amendment; Revival of Section note below.

Subsec. (c)(1). Pub. L. 111–87, §2(f)(1)(A), substituted "are authorized" for "is authorized" and inserted ", $36,535,000 for fiscal year 2010, $38,257,000 for fiscal year 2011, $40,170,000 for fiscal year 2012, and $42,178,000 for fiscal year 2013" before period at end.

Subsec. (c)(2). Pub. L. 111–87, §2(f)(1)(B), substituted "are authorized" for "is authorized" and inserted ", $13,650,000 for fiscal year 2010, $14,333,000 for fiscal year 2011, $15,049,000 for fiscal year 2012, and $15,802,000 for fiscal year 2013" before period at end.

2006—Pub. L. 109–415, §703, which directed repeal of this section effective Oct. 1, 2009, was itself repealed by Pub. L. 111–87, §2(a)(1), effective Sept. 30, 2009.

Pub. L. 109–415, §702(3), substituted "HIV/AIDS" for "HIV disease" wherever appearing in text.

Subsec. (a)(2)(A). Pub. L. 109–415, §602(a)(1)(A), inserted "and Native Americans" after "minority individuals".

Subsec. (a)(2)(C). Pub. L. 109–415, §602(a)(1)(B), (2), (3), added subpar. (C).

Subsec. (c). Pub. L. 109–415, §602(b), reenacted heading without change and amended text generally, substituting provisions authorizing appropriations for fiscal years 2007 through 2009 for provisions authorizing appropriations for fiscal years 2001 through 2005.

2000—Subsec. (a)(1)(A). Pub. L. 106–345, §402(a)(1)(A), substituted "to train" for "training", substituted ", including" for "and including" after "transmission of the disease", and inserted ", and including (as applicable to the type of health professional involved), prenatal and other gynecological care for women with HIV disease" before semicolon at end.

Subsec. (a)(1)(D). Pub. L. 106–345, §402(a)(1)(B)–(D), added subpar. (D).

Subsec. (b)(1). Pub. L. 106–345, §402(b)(1), amended heading and text of par. (1) generally. Prior to amendment, text read as follows: "The Secretary may make grants to assist dental schools and programs described in section 294o(b)(4)(B) of this title with respect to oral health care to patients with HIV disease."

Subsec. (b)(2). Pub. L. 106–345, §402(b)(2), substituted "the section referred to in paragraph (1)(B)" for "294o(b)(4)(B) of this title".

Subsec. (b)(5). Pub. L. 106–345, §402(b)(3), added par. (5).

Subsec. (c)(1). Pub. L. 106–345, §402(c)(1), substituted "fiscal years 2001 through 2005" for "fiscal years 1996 through 2000".

Subsec. (c)(2). Pub. L. 106–345, §402(c)(2), amended heading and text of par. (2) generally. Prior to amendment, text read as follows: "For the purpose of grants under subsection (b) of this section, there are

authorized to be appropriated such sums as may be necessary for each of the fiscal years 1996 through 2000."

1996—Pub. L. 104–146, §3(h)(1), (2)(A), substituted "HIV/AIDS communities, schools, and centers" for "Acquired immune deficiency syndrome" as section catchline.

Subsec. (a)(1)(A). Pub. L. 104–166, §5(2)(A), substituted "in programs under this subchapter" for "in subchapter XXIV programs" and struck out "infection and" after "prevention of HIV".

Pub. L. 104–146, §3(h)(2)(B)(iii), added subpar. (A). Former subpar. (A) redesignated (B).

Subsec. (a)(1)(B). Pub. L. 104–146, §3(h)(2)(B)(iv), inserted "and" after semicolon.

Pub. L. 104–146, §3(h)(2)(B)(i), (ii), redesignated subpar. (A) as (B) and struck out former subpar. (B) which read as follows: "to train practitioners to provide for the health care needs of such individuals;".

Subsec. (a)(1)(C), (D). Pub. L. 104–146, §3(h)(2)(B)(i), (ii), redesignated subpar. (D) as (C) and struck out former subpar. (C) which read as follows: "with respect to improving clinical skills in the diagnosis, treatment, and prevention of such disease, to educate and train the health professionals and clinical staff of schools of medicine, osteopathic medicine, and dentistry; and".

Subsec. (c). Pub. L. 104–166, §5(2)(B), added subsec. (c) and struck out heading and text of former subsec. (c). Text read as follows: "For purposes of this section:

"(1) The term 'HIV disease' means infection with the human immunodeficiency virus, and includes any condition arising from such infection.

"(2) The term 'human immunodeficiency virus' means the etiologic agent for acquired immune deficiency syndrome."

Subsec. (d). Pub. L. 104–166, §5(2)(B), struck out heading and text of subsec. (d) relating to authorization of appropriations for fiscal years 1996 through 2000. Text read as follows: "There are authorized to be appropriated to carry out this section, such sums as may be necessary for each of the fiscal years 1996 through 2000."

Pub. L. 104–166, §5(2)(B), struck out heading and text of subsec. (d) relating to authorization of appropriations for fiscal years 1993 through 1995. Text read as follows:

"(1) SCHOOLS; CENTERS.—For the purpose of grants under subsection (a) of this section, there is authorized to be appropriated $23,000,000 for each of the fiscal years 1993 through 1995.

"(2) DENTAL SCHOOLS.—For the purpose of grants under subsection (b) of this section, there is authorized to be appropriated $7,000,000 for each of the fiscal years 1993 through 1995."

Pub. L. 104–146, §3(h)(4), added subsec. (d) relating to authorization of appropriations for fiscal years 1996 through 2000.

1992—Subsec. (a)(3). Pub. L. 102–531, which directed the substitution of "No grant" for "no grant" in par. (3), could not be executed because the words "no grant" did not appear in par. (3).

STATUTORY NOTES AND RELATED SUBSIDIARIES

EFFECTIVE DATE OF 2009 AMENDMENT; REVIVAL OF SECTION

For provisions that repeal by section 2(a)(1) of Pub. L. 111–87 of section 703 of Pub. L. 109–415 be effective Sept. 30, 2009, that the provisions of this section as in effect on Sept. 30, 2009, be revived, and that amendment by section 2(f)(1) of Pub. L. 111–87 be applicable to this section as so revived and effective as if enacted on Sept. 30, 2009, see section 2(a)(2), (3) of Pub. L. 111–87, set out as a note under section 300ff–11 of this title.

EFFECTIVE DATE OF 1996 AMENDMENT

Amendment by Pub. L. 104–146 effective Oct. 1, 1996, see section 13 of Pub. L. 104–146, set out as a note under section 300ff–11 of this title.

EFFECTIVE DATE OF 1992 AMENDMENT

Amendment by Pub. L. 102–531 effective immediately after enactment of Pub. L. 102–408, see section 313(c) of Pub. L. 102–531, set out as a note under section 292y of this title.

DISSEMINATION OF TREATMENT GUIDELINES; MEDICAL CONSULTATION ACTIVITIES

Pub. L. 106–345, title IV, §402(a)(2), Oct. 20, 2000, 114 Stat. 1349, provided that: "Not later than 90 days after the date of the enactment of this Act [Oct. 20, 2000], the Secretary of Health and Human Services shall issue and begin implementation of a strategy for the dissemination of HIV treatment information to health care providers and patients."

[1] *So in original.*

SUBPART III—MINORITY AIDS INITIATIVE

§300ff–121. Minority AIDS initiative

(a) In general

For the purpose of carrying out activities under this section to evaluate and address the disproportionate impact of HIV/AIDS on, and the disparities in access, treatment, care, and outcomes for, racial and ethnic minorities (including African Americans, Alaska Natives, Latinos, American Indians, Asian Americans, Native Hawaiians, and Pacific Islanders), there are authorized to be appropriated $131,200,000 for fiscal year 2007, $135,100,000 for fiscal year 2008, $139,100,000 for fiscal year 2009, $146,055,000 for fiscal year 2010, $153,358,000 for fiscal year 2011, $161,026,000 for fiscal year 2012, and $169,077,000 for fiscal year 2013. The Secretary shall develop a formula for the awarding of grants under subsections (b)(1)(A) and (b)(1)(B) that ensures that funding is provided based on the distribution of populations disproportionately impacted by HIV/AIDS.

(b) Certain activities

(1) In general

In carrying out the purpose described in subsection (a), the Secretary shall provide for—

(A) emergency assistance under part A;

(B) care grants under part B;

(C) early intervention services under part C;

(D) services through projects for HIV-related care under part D; and

(E) activities through education and training centers under section 300ff–111 of this title.

(2) Allocations among activities

Activities under paragraph (1) shall be carried out by the Secretary in accordance with the following:

(A) For supplemental grants to improve HIV-related health outcomes to reduce existing racial and ethnic health disparities, the Secretary shall, of the amount appropriated under subsection (a) for a fiscal year, reserve the following, as applicable:

(i) For fiscal year 2007, $43,800,000.

(ii) For fiscal year 2008, $45,400,000.

(iii) For fiscal year 2009, $47,100,000.

(iv) For fiscal year 2010, $46,738,000.

(v) For fiscal year 2011, $49,075,000.

(vi) For fiscal year 2012, $51,528,000.

(vii) For fiscal year 2013, $54,105,000.

(B) For grants used for supplemental support education and outreach services to increase the number of eligible racial and ethnic minorities who have access to treatment through the program under section 300ff–26 of this title for therapeutics, the Secretary shall, of the amount appropriated for a fiscal year under subsection (a), reserve the following, as applicable:

(i) For fiscal year 2007, $7,000,000.

(ii) For fiscal year 2008, $7,300,000.

(iii) For fiscal year 2009, $7,500,000.

(iv) For fiscal year 2010, $8,763,000.

(v) For fiscal year 2011, $9,202,000.

(vi) For fiscal year 2012, $9,662,000.

(vii) For fiscal year 2013, $10,145,000.

(C) For planning grants, capacity-building grants, and services grants to health care providers who have a history of providing culturally and linguistically appropriate care and services to racial and ethnic minorities, the Secretary shall, of the amount appropriated for a fiscal year under subsection (a), reserve the following, as applicable:

(i) For fiscal year 2007, $53,400,000.
(ii) For fiscal year 2008, $55,400,000.
(iii) For fiscal year 2009, $57,400,000.
(iv) For fiscal year 2010, $61,343,000.
(v) For fiscal year 2011, $64,410,000.
(vi) For fiscal year 2012, $67,631,000.
(vii) For fiscal year 2013, $71,012,000.

(D) For eliminating racial and ethnic disparities in the delivery of comprehensive, culturally and linguistically appropriate care services for HIV/AIDS for women, infants, children, and youth, the Secretary shall, of the amount appropriated under subsection (a), reserve the following, as applicable:

(i) For fiscal year 2010, $20,448,000.
(ii) For fiscal year 2011, $21,470,000.
(iii) For fiscal year 2012, $22,543,000.
(iv) For fiscal year 2013, $23,671,000.

(E) For increasing the training capacity of centers to expand the number of health care professionals with treatment expertise and knowledge about the most appropriate standards of HIV/AIDS-related treatments and medical care for racial and ethnic minority adults, adolescents, and children with HIV/AIDS, the Secretary shall, of the amount appropriated under subsection (a), reserve the following, as applicable:

(i) For fiscal year 2010, $8,763,000.
(ii) For fiscal year 2011, $9,201,000.
(iii) For fiscal year 2012, $9,662,000.
(iv) For fiscal year 2013, $10,144,000.

(c) Consistency with prior program

With respect to the purpose described in subsection (a), the Secretary shall carry out this section consistent with the activities carried out under this subchapter by the Secretary pursuant to the Departments of Labor, Health and Human Services, and Education, and Related Agencies Appropriations Act, 2002 (Public Law 107–116).

(d) Synchronization of minority AIDS initiative

For fiscal year 2010 and each subsequent fiscal year, the Secretary shall incorporate and synchronize the schedule of application submissions and funding availability under this section with the schedule of application submissions and funding availability under the corresponding provisions of this subchapter as follows:

(1) The schedule for carrying out subsection (b)(1)(A) shall be the same as the schedule applicable to emergency assistance under part A.

(2) The schedule for carrying out subsection (b)(1)(B) shall be the same as the schedule applicable to care grants under part B.

(3) The schedule for carrying out subsection (b)(1)(C) shall be the same as the schedule applicable to grants for early intervention services under part C.

(4) The schedule for carrying out subsection (b)(1)(D) shall be the same as the schedule applicable to grants for services through projects for HIV-related care under part D.

(5) The schedule for carrying out subsection (b)(1)(E) shall be the same as the schedule applicable to grants and contracts for activities through education and training centers under section 300ff–111 of this title.

(July 1, 1944, ch. 373, title XXVI, §2693, as added and amended Pub. L. 109–415, title VI, §603,

title VII, §§702(3), 703, Dec. 19, 2006, 120 Stat. 2818, 2820; Pub. L. 111–87, §2(a)(1), (3)(A), (f)(2), Oct. 30, 2009, 123 Stat. 2885, 2886.)

EDITORIAL NOTES

REFERENCES IN TEXT

The Departments of Labor, Health and Human Services, and Education, and Related Agencies Appropriations Act, 2002, referred to in subsec. (c), is Pub. L. 107–116, Jan. 10, 2002, 115 Stat. 2177. For complete classification of this Act to the Code, see Tables.

AMENDMENTS

2009—Pub. L. 111–87, §2(a)(1), (3)(A), repealed Pub. L. 109–415, §703, and revived the provisions of this section as in effect on Sept. 30, 2009. See 2006 Amendment note and Effective Date of 2009 Amendment; Revival of Section note below.

Subsec. (a). Pub. L. 111–87, §2(f)(2)(A), substituted "$139,100,000 for fiscal year 2009, $146,055,000 for fiscal year 2010, $153,358,000 for fiscal year 2011, $161,026,000 for fiscal year 2012, and $169,077,000 for fiscal year 2013. The Secretary shall develop a formula for the awarding of grants under subsections (b)(1)(A) and (b)(1)(B) that ensures that funding is provided based on the distribution of populations disproportionately impacted by HIV/AIDS." for "and $139,100,000 for fiscal year 2009."

Subsec. (b)(2)(A). Pub. L. 111–87, §2(f)(2)(B)(i), struck out "competitive," before "supplemental" in introductory provisions and added cls. (iv) to (vii).

Subsec. (b)(2)(B). Pub. L. 111–87, §2(f)(2)(B)(ii), struck out "competitive" before "grants" in introductory provisions and added cls. (iv) to (vii).

Subsec. (b)(2)(C)(iv) to (vii). Pub. L. 111–87, §2(f)(2)(B)(iii), added cls. (iv) to (vii).

Subsec. (b)(2)(D). Pub. L. 111–87, §2(f)(2)(B)(iv), substituted "the following, as applicable:" for "$18,500,000 for each of the fiscal years 2007 through 2009." and added cls. (i) to (iv).

Subsec. (b)(2)(E). Pub. L. 111–87, §2(f)(2)(B)(v), substituted "the following, as applicable:" for "$8,500,000 for each of the fiscal years 2007 through 2009." and added cls. (i) to (iv).

Subsec. (d). Pub. L. 111–87, §2(f)(2)(C), added subsec. (d).

2006—Pub. L. 109–415, §703, which directed repeal of this section effective Oct. 1, 2009, was itself repealed by Pub. L. 111–87, §2(a)(1), effective Sept. 30, 2009.

Subsec. (b)(2)(D), (E). Pub. L. 109–415, §702(3), substituted "HIV/AIDS" for "HIV disease" wherever appearing.

STATUTORY NOTES AND RELATED SUBSIDIARIES

EFFECTIVE DATE OF 2009 AMENDMENT; REVIVAL OF SECTION

For provisions that repeal by section 2(a)(1) of Pub. L. 111–87 of section 703 of Pub. L. 109–415 be effective Sept. 30, 2009, that the provisions of this section as in effect on Sept. 30, 2009, be revived, and that amendment by section 2(f)(2) of Pub. L. 111–87 be applicable to this section as so revived and effective as if enacted on Sept. 30, 2009, see section 2(a)(2), (3) of Pub. L. 111–87, set out as a note under section 300ff–11 of this title.

PART G—NOTIFICATION OF POSSIBLE EXPOSURE TO INFECTIOUS DISEASES

§300ff–131. Infectious diseases and circumstances relevant to notification requirements

(a) In general

Not later than 180 days after October 30, 2009, the Secretary shall complete the development of—

(1) a list of potentially life-threatening infectious diseases, including emerging infectious

diseases, to which emergency response employees may be exposed in responding to emergencies;

(2) guidelines describing the circumstances in which such employees may be exposed to such diseases, taking into account the conditions under which emergency response is provided; and

(3) guidelines describing the manner in which medical facilities should make determinations for purposes of section 300ff–133(d) of this title.

(b) Specification of airborne infectious diseases

The list developed by the Secretary under subsection (a)(1) shall include a specification of those infectious diseases on the list that are routinely transmitted through airborne or aerosolized means.

(c) Dissemination

The Secretary shall—

(1) transmit to State public health officers copies of the list and guidelines developed by the Secretary under subsection (a) with the request that the officers disseminate such copies as appropriate throughout the States; and

(2) make such copies available to the public.

(July 1, 1944, ch. 373, title XXVI, §2695, as added Pub. L. 111–87, §13, Oct. 30, 2009, 123 Stat. 2897.)

STATUTORY NOTES AND RELATED SUBSIDIARIES

EFFECTIVE DATE

Section effective as if enacted on Sept. 30, 2009, see section 2(a)(3)(B) of Pub. L. 111–87, set out as an Effective Date of 2009 Amendment; Revival of Section note under section 300ff–11 of this title.

§300ff–132. Routine notifications with respect to airborne infectious diseases in victims assisted

(a) Routine notification of designated officer

(1) Determination by treating facility

If a victim of an emergency is transported by emergency response employees to a medical facility and the medical facility makes a determination that the victim has an airborne infectious disease, the medical facility shall notify the designated officer of the emergency response employees who transported the victim to the medical facility of the determination.

(2) Determination by facility ascertaining cause of death

If a victim of an emergency is transported by emergency response employees to a medical facility and the victim dies at or before reaching the medical facility, the medical facility ascertaining the cause of death shall notify the designated officer of the emergency response employees who transported the victim to the initial medical facility of any determination by the medical facility that the victim had an airborne infectious disease.

(b) Requirement of prompt notification

With respect to a determination described in paragraph (1) or (2) of subsection (a), the notification required in each of such paragraphs shall be made as soon as is practicable, but not later than 48 hours after the determination is made.

(July 1, 1944, ch. 373, title XXVI, §2695A, as added Pub. L. 111–87, §13, Oct. 30, 2009, 123 Stat. 2898.)

STATUTORY NOTES AND RELATED SUBSIDIARIES

EFFECTIVE DATE

Section effective as if enacted on Sept. 30, 2009, see section 2(a)(3)(B) of Pub. L. 111–87, set out as an

Effective Date of 2009 Amendment; Revival of Section note under section 300ff–11 of this title.

§300ff–133. Request for notification with respect to victims assisted

(a) Initiation of process by employee

If an emergency response employee believes that the employee may have been exposed to an infectious disease by a victim of an emergency who was transported to a medical facility as a result of the emergency, and if the employee attended, treated, assisted, or transported the victim pursuant to the emergency, then the designated officer of the employee shall, upon the request of the employee, carry out the duties described in subsection (b) regarding a determination of whether the employee may have been exposed to an infectious disease by the victim.

(b) Initial determination by designated officer

The duties referred to in subsection (a) are that—

(1) the designated officer involved collect the facts relating to the circumstances under which, for purposes of subsection (a), the employee involved may have been exposed to an infectious disease; and

(2) the designated officer evaluate such facts and make a determination of whether, if the victim involved had any infectious disease included on the list issued under paragraph (1) of section 300ff–131(a) of this title, the employee would have been exposed to the disease under such facts, as indicated by the guidelines issued under paragraph (2) of such section.

(c) Submission of request to medical facility

(1) In general

If a designated officer makes a determination under subsection (b)(2) that an emergency response employee may have been exposed to an infectious disease, the designated officer shall submit to the medical facility to which the victim involved was transported a request for a response under subsection (d) regarding the victim of the emergency involved.

(2) Form of request

A request under paragraph (1) shall be in writing and be signed by the designated officer involved, and shall contain a statement of the facts collected pursuant to subsection (b)(1).

(d) Evaluation and response regarding request to medical facility

(1) In general

If a medical facility receives a request under subsection (c), the medical facility shall evaluate the facts submitted in the request and make a determination of whether, on the basis of the medical information possessed by the facility regarding the victim involved, the emergency response employee was exposed to an infectious disease included on the list issued under paragraph (1) of section 300ff–131(a) of this title, as indicated by the guidelines issued under paragraph (2) of such section.

(2) Notification of exposure

If a medical facility makes a determination under paragraph (1) that the emergency response employee involved has been exposed to an infectious disease, the medical facility shall, in writing, notify the designated officer who submitted the request under subsection (c) of the determination.

(3) Finding of no exposure

If a medical facility makes a determination under paragraph (1) that the emergency response employee involved has not been exposed to an infectious disease, the medical facility shall, in writing, inform the designated officer who submitted the request under subsection (c) of the determination.

(4) Insufficient information

(A) If a medical facility finds in evaluating facts for purposes of paragraph (1) that the facts are insufficient to make the determination described in such paragraph, the medical facility shall, in writing, inform the designated officer who submitted the request under subsection (c) of the insufficiency of the facts.

(B)(i) If a medical facility finds in making a determination under paragraph (1) that the facility possesses no information on whether the victim involved has an infectious disease included on the list under section 300ff–131(a) of this title, the medical facility shall, in writing, inform the designated officer who submitted the request under subsection (c) of the insufficiency of such medical information.

(ii) If after making a response under clause (i) a medical facility determines that the victim involved has an infectious disease, the medical facility shall make the determination described in paragraph (1) and provide the applicable response specified in this subsection.

(e) Time for making response

After receiving a request under subsection (c) (including any such request resubmitted under subsection (g)(2)), a medical facility shall make the applicable response specified in subsection (d) as soon as is practicable, but not later than 48 hours after receiving the request.

(f) Death of victim of emergency

(1) Facility ascertaining cause of death

If a victim described in subsection (a) dies at or before reaching the medical facility involved, and the medical facility receives a request under subsection (c), the medical facility shall provide a copy of the request to the medical facility ascertaining the cause of death of the victim, if such facility is a different medical facility than the facility that received the original request.

(2) Responsibility of facility

Upon the receipt of a copy of a request for purposes of paragraph (1), the duties otherwise established in this part regarding medical facilities shall apply to the medical facility ascertaining the cause of death of the victim in the same manner and to the same extent as such duties apply to the medical facility originally receiving the request.

(g) Assistance of public health officer

(1) Evaluation of response of medical facility regarding insufficient facts

(A) In the case of a request under subsection (c) to which a medical facility has made the response specified in subsection (d)(4)(A) regarding the insufficiency of facts, the public health officer for the community in which the medical facility is located shall evaluate the request and the response, if the designated officer involved submits such documents to the officer with the request that the officer make such an evaluation.

(B) As soon as is practicable after a public health officer receives a request under subparagraph (A), but not later than 48 hours after receipt of the request, the public health officer shall complete the evaluation required in such paragraph and inform the designated officer of the results of the evaluation.

(2) Findings of evaluation

(A) If an evaluation under paragraph (1)(A) indicates that the facts provided to the medical facility pursuant to subsection (c) were sufficient for purposes of determinations under subsection (d)(1)—

(i) the public health officer shall, on behalf of the designated officer involved, resubmit the request to the medical facility; and

(ii) the medical facility shall provide to the designated officer the applicable response specified in subsection (d).

(B) If an evaluation under paragraph (1)(A) indicates that the facts provided in the request to the medical facility were insufficient for purposes of determinations specified in subsection (c)—

(i) the public health officer shall provide advice to the designated officer regarding the collection and description of appropriate facts; and

(ii) if sufficient facts are obtained by the designated officer—

(I) the public health officer shall, on behalf of the designated officer involved, resubmit the request to the medical facility; and

(II) the medical facility shall provide to the designated officer the appropriate response under subsection (c).

(July 1, 1944, ch. 373, title XXVI, §2695B, as added Pub. L. 111–87, §13, Oct. 30, 2009, 123 Stat. 2898.)

STATUTORY NOTES AND RELATED SUBSIDIARIES

EFFECTIVE DATE

Section effective as if enacted on Sept. 30, 2009, see section 2(a)(3)(B) of Pub. L. 111–87, set out as an Effective Date of 2009 Amendment; Revival of Section note under section 300ff–11 of this title.

§300ff–134. Procedures for notification of exposure

(a) Contents of notification to officer

In making a notification required under section 300ff–132 of this title or section 300ff–133(d)(2) of this title, a medical facility shall provide—

(1) the name of the infectious disease involved; and

(2) the date on which the victim of the emergency involved was transported by emergency response employees to the medical facility involved.

(b) Manner of notification

If a notification under section 300ff–132 of this title or section 300ff–133(d)(2) of this title is mailed or otherwise indirectly made—

(1) the medical facility sending the notification shall, upon sending the notification, inform the designated officer to whom the notification is sent of the fact that the notification has been sent; and

(2) such designated officer shall, not later than 10 days after being informed by the medical facility that the notification has been sent, inform such medical facility whether the designated officer has received the notification.

(July 1, 1944, ch. 373, title XXVI, §2695C, as added Pub. L. 111–87, §13, Oct. 30, 2009, 123 Stat. 2901.)

STATUTORY NOTES AND RELATED SUBSIDIARIES

EFFECTIVE DATE

Section effective as if enacted on Sept. 30, 2009, see section 2(a)(3)(B) of Pub. L. 111–87, set out as an Effective Date of 2009 Amendment; Revival of Section note under section 300ff–11 of this title.

§300ff–135. Notification of employee

(a) In general

After receiving a notification for purposes of section 300ff–132 or 300ff–133(d)(2) of this title, a designated officer of emergency response employees shall, to the extent practicable, immediately notify each of such employees who—

(1) responded to the emergency involved; and

(2) as indicated by guidelines developed by the Secretary, may have been exposed to an

infectious disease.

(b) Certain contents of notification to employee

A notification under this subsection to an emergency response employee shall inform the employee of—

(1) the fact that the employee may have been exposed to an infectious disease and the name of the disease involved;

(2) any action by the employee that, as indicated by guidelines developed by the Secretary, is medically appropriate; and

(3) if medically appropriate under such criteria, the date of such emergency.

(c) Responses other than notification of exposure

After receiving a response under paragraph (3) or (4) of subsection (d) of section 300ff–133 of this title, or a response under subsection (g)(1) of such section, the designated officer for the employee shall, to the extent practicable, immediately inform the employee of the response.

(July 1, 1944, ch. 373, title XXVI, §2695D, as added Pub. L. 111–87, §13, Oct. 30, 2009, 123 Stat. 2901.)

STATUTORY NOTES AND RELATED SUBSIDIARIES

EFFECTIVE DATE

Section effective as if enacted on Sept. 30, 2009, see section 2(a)(3)(B) of Pub. L. 111–87, set out as an Effective Date of 2009 Amendment; Revival of Section note under section 300ff–11 of this title.

§300ff–136. Selection of designated officers

(a) In general

For the purposes of receiving notifications and responses and making requests under this part on behalf of emergency response employees, the public health officer of each State shall designate 1 official or officer of each employer of emergency response employees in the State.

(b) Preference in making designations

In making the designations required in subsection (a), a public health officer shall give preference to individuals who are trained in the provision of health care or in the control of infectious diseases.

(July 1, 1944, ch. 373, title XXVI, §2695E, as added Pub. L. 111–87, §13, Oct. 30, 2009, 123 Stat. 2901.)

STATUTORY NOTES AND RELATED SUBSIDIARIES

EFFECTIVE DATE

Section effective as if enacted on Sept. 30, 2009, see section 2(a)(3)(B) of Pub. L. 111–87, set out as an Effective Date of 2009 Amendment; Revival of Section note under section 300ff–11 of this title.

§300ff–137. Limitation with respect to duties of medical facilities

The duties established in this part for a medical facility—

(1) shall apply only to medical information possessed by the facility during the period in which the facility is treating the victim for conditions arising from the emergency, or during the 60-day period beginning on the date on which the victim is transported by emergency response employees to the facility, whichever period expires first; and

(2) shall not apply to any extent after the expiration of the 30-day period beginning on the expiration of the applicable period referred to in paragraph (1), except that such duties shall apply

with respect to any request under section 300ff–133(c) of this title received by a medical facility before the expiration of such 30-day period.

(July 1, 1944, ch. 373, title XXVI, §2695F, as added Pub. L. 111–87, §13, Oct. 30, 2009, 123 Stat. 2901.)

STATUTORY NOTES AND RELATED SUBSIDIARIES

EFFECTIVE DATE

Section effective as if enacted on Sept. 30, 2009, see section 2(a)(3)(B) of Pub. L. 111–87, set out as an Effective Date of 2009 Amendment; Revival of Section note under section 300ff–11 of this title.

§300ff–138. Miscellaneous provisions

(a) Liability of medical facilities, designated officers, public health officers, and governing entities

This part may not be construed to authorize any cause of action for damages or any civil penalty against any medical facility, any designated officer, any other public health officer, or any governing entity of such facility or officer for failure to comply with the duties established in this part.

(b) Testing

This part may not, with respect to victims of emergencies, be construed to authorize or require a medical facility to test any such victim for any infectious disease.

(c) Confidentiality

This part may not be construed to authorize or require any medical facility, any designated officer of emergency response employees, or any such employee, to disclose identifying information with respect to a victim of an emergency or with respect to an emergency response employee.

(d) Failure to provide emergency services

This part may not be construed to authorize any emergency response employee to fail to respond, or to deny services, to any victim of an emergency.

(e) Notification and reporting deadlines

In any case in which the Secretary determines that, wholly or partially as a result of a public health emergency that has been determined pursuant to section 247d(a) of this title, individuals or public or private entities are unable to comply with the requirements of this part, the Secretary may, notwithstanding any other provision of law, temporarily suspend, in whole or in part, the requirements of this part as the circumstances reasonably require. Before or promptly after such a suspension, the Secretary shall notify the Congress of such action and publish in the Federal Register a notice of the suspension.

(f) Continued application of State and local law

Nothing in this part shall be construed to limit the application of State or local laws that require the provision of data to public health authorities.

(July 1, 1944, ch. 373, title XXVI, §2695G, as added Pub. L. 111–87, §13, Oct. 30, 2009, 123 Stat. 2902.)

STATUTORY NOTES AND RELATED SUBSIDIARIES

EFFECTIVE DATE

Section effective as if enacted on Sept. 30, 2009, see section 2(a)(3)(B) of Pub. L. 111–87, set out as an Effective Date of 2009 Amendment; Revival of Section note under section 300ff–11 of this title.

§300ff–139. Injunctions regarding violation of prohibition

(a) In general

The Secretary may, in any court of competent jurisdiction, commence a civil action for the purpose of obtaining temporary or permanent injunctive relief with respect to any violation of this part.

(b) Facilitation of information on violations

The Secretary shall establish an administrative process for encouraging emergency response employees to provide information to the Secretary regarding violations of this part. As appropriate, the Secretary shall investigate alleged such [1] violations and seek appropriate injunctive relief.

(July 1, 1944, ch. 373, title XXVI, §2695H, as added Pub. L. 111–87, §13, Oct. 30, 2009, 123 Stat. 2902.)

STATUTORY NOTES AND RELATED SUBSIDIARIES

EFFECTIVE DATE

Section effective as if enacted on Sept. 30, 2009, see section 2(a)(3)(B) of Pub. L. 111–87, set out as an Effective Date of 2009 Amendment; Revival of Section note under section 300ff–11 of this title.

[1] *So in original.*

§300ff–140. Applicability of part

This part shall not apply in a State if the chief executive officer of the State certifies to the Secretary that the law of the State is substantially consistent with this part.

(July 1, 1944, ch. 373, title XXVI, §2695I, as added Pub. L. 111–87, §13, Oct. 30, 2009, 123 Stat. 2903.)

STATUTORY NOTES AND RELATED SUBSIDIARIES

EFFECTIVE DATE

Section effective as if enacted on Sept. 30, 2009, see section 2(a)(3)(B) of Pub. L. 111–87, set out as an Effective Date of 2009 Amendment; Revival of Section note under section 300ff–11 of this title.

SUBCHAPTER XXV—REQUIREMENTS RELATING TO HEALTH INSURANCE COVERAGE

EDITORIAL NOTES

CODIFICATION

Pub. L. 104–204, title VI, §604(a)(1), Sept. 26, 1996, 110 Stat. 2938, substituted "REQUIREMENTS RELATING TO HEALTH INSURANCE COVERAGE" for "ASSURING PORTABILITY, AVAILABILITY, AND RENEWABILITY OF HEALTH INSURANCE COVERAGE" as subchapter heading.

PRIOR PROVISIONS

A prior subchapter XXV (§300aaa et seq.), comprised of title XXVII of the Public Health Service Act, act July 1, 1944, ch. 373, §§2701 to 2714, was renumbered title II, part B, §§231 to 244, of the Public Health Service Act, and transferred to part B (§238 et seq.) of subchapter I of this chapter.

PART A—INDIVIDUAL AND GROUP MARKET REFORMS

EDITORIAL NOTES

CODIFICATION

Pub. L. 111–148, title I, §1001(1), Mar. 23, 2010, 124 Stat. 130, substituted "Individual and Group Market Reforms" for "Group Market Reforms" in part heading.

SUBPART I—GENERAL REFORM

EDITORIAL NOTES

CODIFICATION

Pub. L. 111–148, title I, §§1201(1), 1255, formerly §1253, title X, §10103(e), (f)(1), Mar. 23, 2010, 124 Stat. 154, 162, 895, substituted "SUBPART I—GENERAL REFORM" for "SUBPART 1—PORTABILITY, ACCESS, AND RENEWABILITY REQUIREMENTS" in subpart heading, effective for plan years beginning on or after Jan. 1, 2014.

§300gg. Fair health insurance premiums

(a) [1] Prohibiting discriminatory premium rates

(1) In general

With respect to the premium rate charged by a health insurance issuer for health insurance coverage offered in the individual or small group market—

(A) such rate shall vary with respect to the particular plan or coverage involved only by—

(i) whether such plan or coverage covers an individual or family;

(ii) rating area, as established in accordance with paragraph (2);

(iii) age, except that such rate shall not vary by more than 3 to 1 for adults (consistent with section 300gg–6(c) of this title); and

(iv) tobacco use, except that such rate shall not vary by more than 1.5 to 1; and

(B) such rate shall not vary with respect to the particular plan or coverage involved by any other factor not described in subparagraph (A).

(2) Rating area

(A) In general

Each State shall establish 1 or more rating areas within that State for purposes of applying the requirements of this subchapter.

(B) Secretarial review

The Secretary shall review the rating areas established by each State under subparagraph (A) to ensure the adequacy of such areas for purposes of carrying out the requirements of this subchapter. If the Secretary determines a State's rating areas are not adequate, or that a State does not establish such areas, the Secretary may establish rating areas for that State.

(3) Permissible age bands

The Secretary, in consultation with the National Association of Insurance Commissioners, shall define the permissible age bands for rating purposes under paragraph (1)(A)(iii).

(4) Application of variations based on age or tobacco use

With respect to family coverage under a group health plan or health insurance coverage, the rating variations permitted under clauses (iii) and (iv) of paragraph (1)(A) shall be applied based on the portion of the premium that is attributable to each family member covered under the plan or coverage.

(5) Special rule for large group market

If a State permits health insurance issuers that offer coverage in the large group market in the State to offer such coverage through the State Exchange (as provided for under section 18032(f)(2)(B) of this title), the provisions of this subsection shall apply to all coverage offered in such market (other than self-insured group health plans offered in such market) in the State.

(July 1, 1944, ch. 373, title XXVII, §2701, as added and amended Pub. L. 111–148, title I, §1201(4), title X, §10103(a), Mar. 23, 2010, 124 Stat. 155, 892.)

EDITORIAL NOTES

PRIOR PROVISIONS

A prior section 300gg, act July 1, 1944, ch. 373, title XXVII, §2701, as added Pub. L. 104–191, title I, §102(a), Aug. 21, 1996, 110 Stat. 1955; amended Pub. L. 111–3, title III, §311(b)(2), Feb. 4, 2009, 123 Stat. 70; Pub. L. 111–5, div. B, title I, §1899D(c), Feb. 17, 2009, 123 Stat. 426; Pub. L. 111–344, title I, §114(c), Dec. 29, 2010, 124 Stat. 3615; Pub. L. 112–40, title II, §242(a)(3), Oct. 21, 2011, 125 Stat. 419, which related to increased portability through limitation on preexisting condition exclusions, was renumbered section 2704 of act July 1, 1944, effective for plan years beginning on or after Jan. 1, 2014, with certain exceptions, and amended, by Pub. L. 111–148, title I, §§1201(2), 1563(c)(1), formerly §1562(c)(1), title X, §10107(b)(1), Mar. 23, 2010, 124 Stat. 154, 264, 911, and was transferred to section 300gg–3 of this title.

Another prior section 2701 of act July 1, 1944, was successively renumbered by subsequent acts and transferred, see section 238 of this title.

AMENDMENTS

2010—Subsec. (a)(5). Pub. L. 111–148, §10103(a), inserted "(other than self-insured group health plans offered in such market)" after "such market".

STATUTORY NOTES AND RELATED SUBSIDIARIES

EFFECTIVE DATE

Pub. L. 111–148, title I, §1255, formerly §1253, title X, §10103(e), (f)(1), Mar. 23, 2010, 124 Stat. 162, 895, provided that: "This subtitle [subtitle C (§§1201–1255) of title I of Pub. L. 111–148, enacting subchapter II of chapter 157 of this title and sections 300gg to 300gg–2 and 300gg–4 to 300gg–7 of this title, and amending sections 300gg–1 and 300gg–4 of this title and transferring former section 300gg of this title to section 300gg–3 of this title] (and the amendments made by this subtitle) shall become effective for plan years beginning on or after January 1, 2014, except that—

"(1) section 1251 [enacting section 18011 of this title] shall take effect on the date of enactment of this Act [Mar. 23, 2010]; and

"(2) the provisions of section 2704 of the Public Health Service Act [42 U.S.C. 300gg–3] (as amended by section 1201), as they apply to enrollees who are under 19 years of age, shall become effective for plan years beginning on or after the date that is 6 months after the date of enactment of this Act [Mar. 23, 2010].. [sic]"

Pub. L. 104–191, title I, §102(c), Aug. 21, 1996, 110 Stat. 1976, provided that:

"(1) IN GENERAL.—Except as provided in this subsection, part A of title XXVII of the Public Health Service Act [42 U.S.C. 300gg et seq.] (as added by subsection (a)) shall apply with respect to group health plans, and health insurance coverage offered in connection with group health plans, for plan years beginning after June 30, 1997.

"(2) DETERMINATION OF CREDITABLE COVERAGE.—

"(A) PERIOD OF COVERAGE.—

"(i) IN GENERAL.—Subject to clause (ii), no period before July 1, 1996, shall be taken into account under part A of title XXVII of the Public Health Service Act [42 U.S.C. 300gg et seq.] (as added

by this section) in determining creditable coverage.

"(ii) SPECIAL RULE FOR CERTAIN PERIODS.—The Secretary of Health and Human Services, consistent with section 104 [42 U.S.C. 300gg–92 note], shall provide for a process whereby individuals who need to establish creditable coverage for periods before July 1, 1996, and who would have such coverage credited but for clause (i) may be given credit for creditable coverage for such periods through the presentation of documents or other means.

"(B) CERTIFICATIONS, ETC.—

"(i) IN GENERAL.—Subject to clauses (ii) and (iii), subsection (e) of section 2701 [now 2704] of the Public Health Service Act [42 U.S.C. 300gg–3(e)] (as added by this section) shall apply to events occurring after June 30, 1996.

"(ii) NO CERTIFICATION REQUIRED TO BE PROVIDED BEFORE JUNE 1, 1997.—In no case is a certification required to be provided under such subsection before June 1, 1997.

"(iii) CERTIFICATION ONLY ON WRITTEN REQUEST FOR EVENTS OCCURRING BEFORE OCTOBER 1, 1996.—In the case of an event occurring after June 30, 1996, and before October 1, 1996, a certification is not required to be provided under such subsection unless an individual (with respect to whom the certification is otherwise required to be made) requests such certification in writing.

"(C) TRANSITIONAL RULE.—In the case of an individual who seeks to establish creditable coverage for any period for which certification is not required because it relates to an event occurring before June 30, 1996—

"(i) the individual may present other credible evidence of such coverage in order to establish the period of creditable coverage; and

"(ii) a group health plan and a health insurance issuer shall not be subject to any penalty or enforcement action with respect to the plan's or issuer's crediting (or not crediting) such coverage if the plan or issuer has sought to comply in good faith with the applicable requirements under the amendments made by this section [enacting this section and sections 300gg–1, 300gg–11 to 300gg–13, 300gg–21 to 300gg–23, 300gg–91, and 300gg–92 of this title and amending sections 300e and 300bb–8 of this title].

"(3) SPECIAL RULE FOR COLLECTIVE BARGAINING AGREEMENTS.—Except as provided in paragraph (2)(B), in the case of a group health plan maintained pursuant to 1 or more collective bargaining agreements between employee representatives and one or more employers ratified before the date of the enactment of this Act [Aug. 21, 1996], part A of title XXVII of the Public Health Service Act [42 U.S.C. 300gg et seq.] (other than section 2701(e) [now 2704(e)] thereof [42 U.S.C. 300gg–3(e)]) shall not apply to plan years beginning before the later of—

"(A) the date on which the last of the collective bargaining agreements relating to the plan terminates (determined without regard to any extension thereof agreed to after the date of the enactment of this Act), or

"(B) July 1, 1997.

For purposes of subparagraph (A), any plan amendment made pursuant to a collective bargaining agreement relating to the plan which amends the plan solely to conform to any requirement of such part shall not be treated as a termination of such collective bargaining agreement.

"(4) TIMELY REGULATIONS.—The Secretary of Health and Human Services, consistent with section 104 [42 U.S.C. 300gg–92 note], shall first issue by not later than April 1, 1997, such regulations as may be necessary to carry out the amendments made by this section [enacting this section and sections 300gg–1, 300gg–11 to 300gg–13, 300gg–21 to 300gg–23, 300gg–91, and 300gg–92 of this title and amending sections 300e and 300bb–8 of this title] and section 111 [enacting sections 300gg–41 to 300gg–44 and 300gg–61 to 300gg–63 of this title].

"(5) LIMITATION ON ACTIONS.—No enforcement action shall be taken, pursuant to the amendments made by this section, against a group health plan or health insurance issuer with respect to a violation of a requirement imposed by such amendments before January 1, 1998, or, if later, the date of issuance of regulations referred to in paragraph (4), if the plan or issuer has sought to comply in good faith with such requirements."

CONGRESSIONAL FINDINGS RELATING TO EXERCISE OF COMMERCE CLAUSE AUTHORITY; SEVERABILITY

Pub. L. 104–191, title I, §195, Aug. 21, 1996, 110 Stat. 1991, provided that:

"(a) FINDINGS RELATING TO EXERCISE OF COMMERCE CLAUSE AUTHORITY.—Congress finds the following in relation to the provisions of this title [enacting this subchapter and sections 1181 to 1183 and

1191 to 1191c of Title 29, Labor, amending sections 233, 300e, and 300bb–8 of this title and sections 1003, 1021, 1022, 1024, 1132, 1136, and 1144 of Title 29, and enacting provisions set out as notes under this section, section 300gg–92 of this title, and section 1181 of Title 29]:

"(1) Provisions in group health plans and health insurance coverage that impose certain preexisting condition exclusions impact the ability of employees to seek employment in interstate commerce, thereby impeding such commerce.

"(2) Health insurance coverage is commercial in nature and is in and affects interstate commerce.

"(3) It is a necessary and proper exercise of Congressional authority to impose requirements under this title on group health plans and health insurance coverage (including coverage offered to individuals previously covered under group health plans) in order to promote commerce among the States.

"(4) Congress, however, intends to defer to States, to the maximum extent practicable, in carrying out such requirements with respect to insurers and health maintenance organizations that are subject to State regulation, consistent with the provisions of the Employee Retirement Income Security Act of 1974 [29 U.S.C. 1001 et seq.].

"(b) SEVERABILITY.—If any provision of this title or the application of such provision to any person or circumstance is held to be unconstitutional, the remainder of this title and the application of the provisions of such to any person or circumstance shall not be affected thereby."

HEALTH COVERAGE AVAILABILITY STUDIES

Pub. L. 104–191, title I, §191, Aug. 21, 1996, 110 Stat. 1987, directed the Secretary of Health and Human Services to provide for a study on the effectiveness of the provisions of title I of Pub. L. 104–191 and the various State laws, in ensuring the availability of reasonably priced health coverage to employers and individuals and a study on access to, and choice of, health care providers and the cost and cost-effectiveness to health insurance issuers of providing access to out-of-network providers, and the potential impact of providing such access on the cost and quality of health insurance coverage, and to report to the appropriate committees of Congress on each of such studies not later than Jan. 1, 2000.

[1] *So in original. No subsec. (b) has been enacted.*

§300gg–1. Guaranteed availability of coverage

(a) Guaranteed issuance of coverage in the individual and group market

Subject to subsections (b) through (e),[1] each health insurance issuer that offers health insurance coverage in the individual or group market in a State must accept every employer and individual in the State that applies for such coverage.

(b) Enrollment

(1) Restriction

A health insurance issuer described in subsection (a) may restrict enrollment in coverage described in such subsection to open or special enrollment periods.

(2) Establishment

A health insurance issuer described in subsection (a) shall, in accordance with the regulations promulgated under paragraph (3), establish special enrollment periods for qualifying events (under section 1163 of title 29).

(3) Regulations

The Secretary shall promulgate regulations with respect to enrollment periods under paragraphs (1) and (2).

(c) Special rules for network plans

(1) In general

In the case of a health insurance issuer that offers health insurance coverage in the group and individual market through a network plan, the issuer may—

(A) limit the employers that may apply for such coverage to those with eligible individuals

who live, work, or reside in the service area for such network plan; and

(B) within the service area of such plan, deny such coverage to such employers and individuals if the issuer has demonstrated, if required, to the applicable State authority that—

(i) it will not have the capacity to deliver services adequately to enrollees of any additional groups or any additional individuals because of its obligations to existing group contract holders and enrollees, and

(ii) it is applying this paragraph uniformly to all employers and individuals without regard to the claims experience of those individuals, employers and their employees (and their dependents) or any health status-related factor relating to such individuals [1] employees and dependents.

(2) 180-day suspension upon denial of coverage

An issuer, upon denying health insurance coverage in any service area in accordance with paragraph (1)(B), may not offer coverage in the group or individual market within such service area for a period of 180 days after the date such coverage is denied.

(d) Application of financial capacity limits

(1) In general

A health insurance issuer may deny health insurance coverage in the group or individual market if the issuer has demonstrated, if required, to the applicable State authority that—

(A) it does not have the financial reserves necessary to underwrite additional coverage; and

(B) it is applying this paragraph uniformly to all employers and individuals in the group or individual market in the State consistent with applicable State law and without regard to the claims experience of those individuals, employers and their employees (and their dependents) or any health status-related factor relating to such individuals, employees and dependents.

(2) 180-day suspension upon denial of coverage

A health insurance issuer upon denying health insurance coverage in connection with group health plans in accordance with paragraph (1) in a State may not offer coverage in connection with group health plans in the group or individual market in the State for a period of 180 days after the date such coverage is denied or until the issuer has demonstrated to the applicable State authority, if required under applicable State law, that the issuer has sufficient financial reserves to underwrite additional coverage, whichever is later. An applicable State authority may provide for the application of this subsection on a service-area-specific basis.

(July 1, 1944, ch. 373, title XXVII, §2702, as added and amended Pub. L. 111–148, title I, §§1201(4), 1563(c)(8), formerly §1562(c)(8), title X, §10107(b)(1), Mar. 23, 2010, 124 Stat. 156, 266, 911.)

EDITORIAL NOTES

CODIFICATION

The text of section 300gg–11 of this title, which was amended and transferred to subsecs. (c) and (d) of this section by Pub. L. 111–148, §1563(c)(8), formerly §1562(c)(8), as renumbered by Pub. L. 111–148, §10107(b)(1), was based on act July 1, 1944, ch. 373, title XXVII, §2731, formerly §2711, as added Pub. L. 104–191, title I, §102(a), Aug. 21, 1996, 110 Stat. 1962; renumbered §2731, Pub. L. 111–148, title I, §1001(3), Mar. 23, 2010, 124 Stat. 130.

PRIOR PROVISIONS

A prior section 300gg–1, act July 1, 1944, ch. 373, title XXVII, §2702, as added Pub. L. 104–191, title I, §102(a), Aug. 21, 1996, 110 Stat. 1961; Pub. L. 110–233, title I, §102(a)(1)–(3), May 21, 2008, 122 Stat. 888, 890, which related to prohibition on discrimination against individual participants and beneficiaries based on health status, was amended by Pub. L. 111–148, title I, §1201(3), Mar. 23, 2010, 124 Stat. 154, effective for plan years beginning on or after Jan. 1, 2014, and was transferred to subsecs. (b) to (f) of section 300gg–4 of this title.

Another prior section 2702 of act July 1, 1944, was successively renumbered by subsequent acts and

transferred, see section 238a of this title.

AMENDMENTS

2010—Pub. L. 111–148, §1563(c)(8), formerly §1562(c)(8), as renumbered by Pub. L. 111–148, §10107(b)(1), transferred section 300gg–11 of this title to the end of this section after amending it by striking out the section catchline "Guaranteed availability of coverage for employers in group market", by striking out subsec. (a) which related to issuance of coverage in small group market, subsec. (b) which related to assurance of access in large group market, subsec. (e) which related to exception to requirement for failure to meet certain minimum participation or contribution rules, and subsec. (f) which related to exception for coverage offered only to bona fide association members, by amending subsec. (c) by substituting "group and individual" for "small group" in introductory provisions of par. (1), inserting "and individuals" after "employers" in introductory provisions of par. (1)(B), inserting "or any additional individuals" after "additional groups" in par. (1)(B)(i), substituting "and individuals without regard to the claims experience of those individuals, employers and their employees (and their dependents) or any health status-related factor relating to such individuals" for "without regard to the claims experience of those employers and their employees (and their dependents) or any health status-related factor relating to such" in par. (1)(B)(ii), and substituting "group or individual" for "small group" in par. (2), and by amending subsec. (d) by substituting "group or individual" for "small group" wherever appearing and substituting "all employers and individuals" for "all employers", "those individuals, employers" for "those employers", and "such individuals, employees" for "such employees" in par. (1)(B).

STATUTORY NOTES AND RELATED SUBSIDIARIES

EFFECTIVE DATE

Section effective for plan years beginning on or after Jan. 1, 2014, see section 1255 of Pub. L. 111–148, set out as a note under section 300gg of this title.

[1] *So in original.*

§300gg–2. Guaranteed renewability of coverage

(a) In general

Except as provided in this section, if a health insurance issuer offers health insurance coverage in the individual or group market, the issuer must renew or continue in force such coverage at the option of the plan sponsor or the individual, as applicable.

(b) General exceptions

A health insurance issuer may nonrenew or discontinue health insurance coverage offered in connection with a health insurance coverage offered in the group or individual market based only on one or more of the following:

(1) Nonpayment of premiums

The plan sponsor, or individual, as applicable, has failed to pay premiums or contributions in accordance with the terms of the health insurance coverage or the issuer has not received timely premium payments.

(2) Fraud

The plan sponsor, or individual, as applicable, has performed an act or practice that constitutes fraud or made an intentional misrepresentation of material fact under the terms of the coverage.

(3) Violation of participation or contribution rates

In the case of a group health plan, the plan sponsor has failed to comply with a material plan provision relating to employer contribution or group participation rules, pursuant to applicable State law.

(4) Termination of coverage

The issuer is ceasing to offer coverage in such market in accordance with subsection (c) and applicable State law.

(5) Movement outside service area

In the case of a health insurance issuer that offers health insurance coverage in the market through a network plan, there is no longer any enrollee in connection with such plan who lives, resides, or works in the service area of the issuer (or in the area for which the issuer is authorized to do business) and, in the case of the small group market, the issuer would deny enrollment with respect to such plan under section 2711(c)(1)(A).[1]

(6) Association membership ceases

In the case of health insurance coverage that is made available in the small or large group market (as the case may be) only through one or more bona fide associations, the membership of an employer in the association (on the basis of which the coverage is provided) ceases but only if such coverage is terminated under this paragraph uniformly without regard to any health status-related factor relating to any covered individual.

(c) Requirements for uniform termination of coverage

(1) Particular type of coverage not offered

In any case in which an issuer decides to discontinue offering a particular type of group or individual health insurance coverage, coverage of such type may be discontinued by the issuer in accordance with applicable State law in such market only if—

(A) the issuer provides notice to each plan sponsor or individual, as applicable, provided coverage of this type in such market (and participants and beneficiaries covered under such coverage) of such discontinuation at least 90 days prior to the date of the discontinuation of such coverage;

(B) the issuer offers to each plan sponsor or individual, as applicable, provided coverage of this type in such market, the option to purchase all (or, in the case of the large group market, any) other health insurance coverage currently being offered by the issuer to a group health plan or individual health insurance coverage in such market; and

(C) in exercising the option to discontinue coverage of this type and in offering the option of coverage under subparagraph (B), the issuer acts uniformly without regard to the claims experience of those sponsors or individuals, as applicable, or any health status-related factor relating to any participants or beneficiaries covered or new participants or beneficiaries who may become eligible for such coverage.

(2) Discontinuance of all coverage

(A) In general

In any case in which a health insurance issuer elects to discontinue offering all health insurance coverage in the individual or group market, or all markets, in a State, health insurance coverage may be discontinued by the issuer only in accordance with applicable State law and if—

(i) the issuer provides notice to the applicable State authority and to each plan sponsor or individual, as applicable,[2] (and participants and beneficiaries covered under such coverage) of such discontinuation at least 180 days prior to the date of the discontinuation of such coverage; and

(ii) all health insurance issued or delivered for issuance in the State in such market (or markets) are discontinued and coverage under such health insurance coverage in such market (or markets) is not renewed.

(B) Prohibition on market reentry

In the case of a discontinuation under subparagraph (A) in a market, the issuer may not provide for the issuance of any health insurance coverage in the market and State involved during the 5-year period beginning on the date of the discontinuation of the last health insurance

coverage not so renewed.

(d) Exception for uniform modification of coverage

At the time of coverage renewal, a health insurance issuer may modify the health insurance coverage for a product offered to a group health plan—

(1) in the large group market; or

(2) in the small group market if, for coverage that is available in such market other than only through one or more bona fide associations, such modification is consistent with State law and effective on a uniform basis among group health plans with that product.

(e) Application to coverage offered only through associations

In applying this section in the case of health insurance coverage that is made available by a health insurance issuer in the small or large group market to employers only through one or more associations, a reference to "plan sponsor" is deemed, with respect to coverage provided to an employer member of the association, to include a reference to such employer.

(July 1, 1944, ch. 373, title XXVII, §2703, as added and amended Pub. L. 111–148, title I, §§1201(4), 1563(c)(9), formerly §1562(c)(9), title X, §10107(b)(1), Mar. 23, 2010, 124 Stat. 156, 267, 911.)

EDITORIAL NOTES

REFERENCES IN TEXT

Section 2711, referred to in subsec. (b)(5), is a reference to section 2711 of act July 1, 1944. Section 2711, which was classified to section 300gg–11 of this title, was renumbered section 2731 and amended and transferred by Pub. L. 111–148, title I, §§1001(3), 1563(c)(8), formerly §1562(c)(8), title X, §10107(b)(1), Mar. 23, 2010, 124 Stat. 130, 266, 911, to the end of section 2702 of act July 1, 1944, as added by Pub. L. 111–148, title I, §1201(4), Mar. 23, 2010, 124 Stat. 156, and classified to section 300gg–1 of this title. A new section 2711 of act July 1, 1944, related to no lifetime or annual limits, was added by Pub. L. 111–148, title I, §1001(5), Mar. 23, 2010, 124 Stat. 131, effective for plan years beginning on or after the date that is 6 months after Mar. 23, 2010, and is classified to section 300gg–11 of this title.

CODIFICATION

The text of section 300gg–12 of this title, which was amended and transferred to subsecs. (b) to (e) of this section by Pub. L. 111–148, §1563(c)(9), formerly §1562(c)(9), as renumbered by Pub. L. 111–148, §10107(b)(1), was based on act July 1, 1944, ch. 373, title XXVII, §2732, formerly §2712, as added Pub. L. 104–191, title I, §102(a), Aug. 21, 1996, 110 Stat. 1964; renumbered §2732, Pub. L. 111–148, title I, §1001(3), Mar. 23, 2010, 124 Stat. 130.

PRIOR PROVISIONS

A prior section 2703 of act July 1, 1944, was successively renumbered by subsequent acts and transferred, see section 238b of this title.

AMENDMENTS

2010—Pub. L. 111–148, §1563(c)(9), formerly §1562(c)(9), as renumbered by Pub. L. 111–148, §10107(b)(1), transferred section 300gg–12 of this title to the end of this section after amending it by striking out the section catchline "Guaranteed renewability of coverage for employers in group market", by striking subsec. (a) which required a health insurance issuer offering coverage in connection with a group health plan to renew such coverage at the option of the plan sponsor, by amending subsec. (b) by substituting "health insurance coverage offered in the group or individual market" for "group health plan in the small or large group market" in introductory provisions, inserting ", or individual, as applicable," after "plan sponsor" in pars. (1) and (2), adding par. (3), and striking out former par. (3) which related to violation of participation or contribution rules, and by amending subsec. (c) by substituting "group or individual health insurance coverage" for "group health insurance coverage offered in the small or large group market" in introductory provisions of par. (1), inserting "or individual, as applicable," after "plan sponsor" in par. (1)(A) and (B), inserting "or individual health insurance coverage" in par. (1)(B), inserting "or individuals, as applicable," after "those sponsors" in par. (1)(C), substituting "individual or group market, or all markets," for "small group market or the large group market, or both markets," in introductory provisions of par. (2)(A), and

inserting "or individual, as applicable," after "plan sponsor" in par. (2)(A)(i). Amendment inserting "or individual health insurance coverage" in subsec. (c)(1)(B) was executed by making the insertion after "group health plan" as the probable intent of Congress, notwithstanding that the directory language did not specify where in subsec. (c)(1)(B) to make the insertion.

STATUTORY NOTES AND RELATED SUBSIDIARIES

EFFECTIVE DATE

Section effective for plan years beginning on or after Jan. 1, 2014, see section 1255 of Pub. L. 111–148, set out as a note under section 300gg of this title.

[1] *See References in Text note below.*

[2] *So in original.*

§300gg–3. Prohibition of preexisting condition exclusions or other discrimination based on health status

(a) In general

A group health plan and a health insurance issuer offering group or individual health insurance coverage may not impose any preexisting condition exclusion with respect to such plan or coverage.

(b) Definitions

For purposes of this part—

(1) Preexisting condition exclusion

(A) In general

The term "preexisting condition exclusion" means, with respect to coverage, a limitation or exclusion of benefits relating to a condition based on the fact that the condition was present before the date of enrollment for such coverage, whether or not any medical advice, diagnosis, care, or treatment was recommended or received before such date.

(B) Treatment of genetic information

Genetic information shall not be treated as a condition described in subsection (a)(1) [1] in the absence of a diagnosis of the condition related to such information.

(2) Enrollment date

The term "enrollment date" means, with respect to an individual covered under a group health plan or health insurance coverage, the date of enrollment of the individual in the plan or coverage or, if earlier, the first day of the waiting period for such enrollment.

(3) Late enrollee

The term "late enrollee" means, with respect to coverage under a group health plan, a participant or beneficiary who enrolls under the plan other than during—

(A) the first period in which the individual is eligible to enroll under the plan, or

(B) a special enrollment period under subsection (f).

(4) Waiting period

The term "waiting period" means, with respect to a group health plan and an individual who is a potential participant or beneficiary in the plan, the period that must pass with respect to the individual before the individual is eligible to be covered for benefits under the terms of the plan.

(c) Rules relating to crediting previous coverage

(1) "Creditable coverage" defined

For purposes of this subchapter, the term "creditable coverage" means, with respect to an individual, coverage of the individual under any of the following:

(A) A group health plan.

(B) Health insurance coverage.

(C) Part A or part B of title XVIII of the Social Security Act [42 U.S.C. 1395c et seq., 1395j et seq.].

(D) Title XIX of the Social Security Act [42 U.S.C. 1396 et seq.], other than coverage consisting solely of benefits under section 1928 [42 U.S.C. 1396s].

(E) Chapter 55 of title 10.

(F) A medical care program of the Indian Health Service or of a tribal organization.

(G) A State health benefits risk pool.

(H) A health plan offered under chapter 89 of title 5.

(I) A public health plan (as defined in regulations).

(J) A health benefit plan under section 2504(e) of title 22.

Such term does not include coverage consisting solely of coverage of excepted benefits (as defined in section 300gg–91(c) of this title).

(2) Not counting periods before significant breaks in coverage

(A) In general

A period of creditable coverage shall not be counted, with respect to enrollment of an individual under a group or individual health plan, if, after such period and before the enrollment date, there was a 63-day period during all of which the individual was not covered under any creditable coverage.

(B) Waiting period not treated as a break in coverage

For purposes of subparagraph (A) and subsection (d)(4), any period that an individual is in a waiting period for any coverage under a group or individual health plan (or for group health insurance coverage) or is in an affiliation period (as defined in subsection (g)(2)) shall not be taken into account in determining the continuous period under subparagraph (A).

(C) TAA-eligible individuals

In the case of plan years beginning before January 1, 2014—

(i) TAA pre-certification period rule

In the case of a TAA-eligible individual, the period beginning on the date the individual has a TAA-related loss of coverage and ending on the date that is 7 days after the date of the issuance by the Secretary (or by any person or entity designated by the Secretary) of a qualified health insurance costs credit eligibility certificate for such individual for purposes of section 7527 of title 26 shall not be taken into account in determining the continuous period under subparagraph (A).

(ii) Definitions

The terms "TAA-eligible individual" and "TAA-related loss of coverage" have the meanings given such terms in section 300bb–5(b)(4) of this title.

(3) Method of crediting coverage

(A) Standard method

Except as otherwise provided under subparagraph (B), for purposes of applying subsection (a)(3),[1] a group health plan, and a health insurance issuer offering group or individual health insurance coverage, shall count a period of creditable coverage without regard to the specific benefits covered during the period.

(B) Election of alternative method

A group health plan, or a health insurance issuer offering group or individual health

insurance, may elect to apply subsection (a)(3) [1] based on coverage of benefits within each of several classes or categories of benefits specified in regulations rather than as provided under subparagraph (A). Such election shall be made on a uniform basis for all participants and beneficiaries. Under such election a group health plan or issuer shall count a period of creditable coverage with respect to any class or category of benefits if any level of benefits is covered within such class or category.

(C) Plan notice

In the case of an election with respect to a group health plan under subparagraph (B) (whether or not health insurance coverage is provided in connection with such plan), the plan shall—

(i) prominently state in any disclosure statements concerning the plan, and state to each enrollee at the time of enrollment under the plan, that the plan has made such election, and

(ii) include in such statements a description of the effect of this election.

(D) Issuer notice

In the case of an election under subparagraph (B) with respect to health insurance coverage offered by an issuer in the individual or group group [2] market, the issuer—

(i) shall prominently state in any disclosure statements concerning the coverage, and to each employer at the time of the offer or sale of the coverage, that the issuer has made such election, and

(ii) shall include in such statements a description of the effect of such election.

(4) Establishment of period

Periods of creditable coverage with respect to an individual shall be established through presentation of certifications described in subsection (e) or in such other manner as may be specified in regulations.

(d) Exceptions

(1) Exclusion not applicable to certain newborns

Subject to paragraph (4), a group health plan, and a health insurance issuer offering group or individual health insurance coverage, may not impose any preexisting condition exclusion in the case of an individual who, as of the last day of the 30-day period beginning with the date of birth, is covered under creditable coverage.

(2) Exclusion not applicable to certain adopted children

Subject to paragraph (4), a group health plan, and a health insurance issuer offering group or individual health insurance coverage, may not impose any preexisting condition exclusion in the case of a child who is adopted or placed for adoption before attaining 18 years of age and who, as of the last day of the 30-day period beginning on the date of the adoption or placement for adoption, is covered under creditable coverage. The previous sentence shall not apply to coverage before the date of such adoption or placement for adoption.

(3) Exclusion not applicable to pregnancy

A group health plan, and health insurance issuer offering group or individual health insurance coverage, may not impose any preexisting condition exclusion relating to pregnancy as a preexisting condition.

(4) Loss if break in coverage

Paragraphs (1) and (2) shall no longer apply to an individual after the end of the first 63-day period during all of which the individual was not covered under any creditable coverage.

(e) Certifications and disclosure of coverage

(1) Requirement for certification of period of creditable coverage

(A) In general

A group health plan, and a health insurance issuer offering group or individual health insurance coverage, shall provide the certification described in subparagraph (B)—

(i) at the time an individual ceases to be covered under the plan or otherwise becomes covered under a COBRA continuation provision,

(ii) in the case of an individual becoming covered under such a provision, at the time the individual ceases to be covered under such provision, and

(iii) on the request on behalf of an individual made not later than 24 months after the date of cessation of the coverage described in clause (i) or (ii), whichever is later.

The certification under clause (i) may be provided, to the extent practicable, at a time consistent with notices required under any applicable COBRA continuation provision.

(B) Certification

The certification described in this subparagraph is a written certification of—

(i) the period of creditable coverage of the individual under such plan and the coverage (if any) under such COBRA continuation provision, and

(ii) the waiting period (if any) (and affiliation period, if applicable) imposed with respect to the individual for any coverage under such plan.

(C) Issuer compliance

To the extent that medical care under a group health plan consists of group health insurance coverage, the plan is deemed to have satisfied the certification requirement under this paragraph if the health insurance issuer offering the coverage provides for such certification in accordance with this paragraph.

(2) Disclosure of information on previous benefits

In the case of an election described in subsection (c)(3)(B) by a group health plan or health insurance issuer, if the plan or issuer enrolls an individual for coverage under the plan and the individual provides a certification of coverage of the individual under paragraph (1)—

(A) upon request of such plan or issuer, the entity which issued the certification provided by the individual shall promptly disclose to such requesting plan or issuer information on coverage of classes and categories of health benefits available under such entity's plan or coverage, and

(B) such entity may charge the requesting plan or issuer for the reasonable cost of disclosing such information.

(3) Regulations

The Secretary shall establish rules to prevent an entity's failure to provide information under paragraph (1) or (2) with respect to previous coverage of an individual from adversely affecting any subsequent coverage of the individual under another group health plan or health insurance coverage.

(f) Special enrollment periods

(1) Individuals losing other coverage

A group health plan, and a health insurance issuer offering group health insurance coverage in connection with a group health plan, shall permit an employee who is eligible, but not enrolled, for coverage under the terms of the plan (or a dependent of such an employee if the dependent is eligible, but not enrolled, for coverage under such terms) to enroll for coverage under the terms of the plan if each of the following conditions is met:

(A) The employee or dependent was covered under a group health plan or had health insurance coverage at the time coverage was previously offered to the employee or dependent.

(B) The employee stated in writing at such time that coverage under a group health plan or health insurance coverage was the reason for declining enrollment, but only if the plan sponsor or issuer (if applicable) required such a statement at such time and provided the employee with notice of such requirement (and the consequences of such requirement) at such time.

(C) The employee's or dependent's coverage described in subparagraph (A)—

(i) was under a COBRA continuation provision and the coverage under such provision was exhausted; or

(ii) was not under such a provision and either the coverage was terminated as a result of loss of eligibility for the coverage (including as a result of legal separation, divorce, death, termination of employment, or reduction in the number of hours of employment) or employer contributions toward such coverage were terminated.

(D) Under the terms of the plan, the employee requests such enrollment not later than 30 days after the date of exhaustion of coverage described in subparagraph (C)(i) or termination of coverage or employer contribution described in subparagraph (C)(ii).

(2) For dependent beneficiaries

(A) In general

If—

(i) a group health plan makes coverage available with respect to a dependent of an individual,

(ii) the individual is a participant under the plan (or has met any waiting period applicable to becoming a participant under the plan and is eligible to be enrolled under the plan but for a failure to enroll during a previous enrollment period), and

(iii) a person becomes such a dependent of the individual through marriage, birth, or adoption or placement for adoption,

the group health plan shall provide for a dependent special enrollment period described in subparagraph (B) during which the person (or, if not otherwise enrolled, the individual) may be enrolled under the plan as a dependent of the individual, and in the case of the birth or adoption of a child, the spouse of the individual may be enrolled as a dependent of the individual if such spouse is otherwise eligible for coverage.

(B) Dependent special enrollment period

A dependent special enrollment period under this subparagraph shall be a period of not less than 30 days and shall begin on the later of—

(i) the date dependent coverage is made available, or

(ii) the date of the marriage, birth, or adoption or placement for adoption (as the case may be) described in subparagraph (A)(iii).

(C) No waiting period

If an individual seeks to enroll a dependent during the first 30 days of such a dependent special enrollment period, the coverage of the dependent shall become effective—

(i) in the case of marriage, not later than the first day of the first month beginning after the date the completed request for enrollment is received;

(ii) in the case of a dependent's birth, as of the date of such birth; or

(iii) in the case of a dependent's adoption or placement for adoption, the date of such adoption or placement for adoption.

(3) Special rules for application in case of Medicaid and CHIP

(A) In general

A group health plan, and a health insurance issuer offering group health insurance coverage in connection with a group health plan, shall permit an employee who is eligible, but not enrolled, for coverage under the terms of the plan (or a dependent of such an employee if the dependent is eligible, but not enrolled, for coverage under such terms) to enroll for coverage under the terms of the plan if either of the following conditions is met:

(i) Termination of Medicaid or CHIP coverage

The employee or dependent is covered under a Medicaid plan under title XIX of the Social

Security Act [42 U.S.C. 1396 et seq.] or under a State child health plan under title XXI of such Act [42 U.S.C. 1397aa et seq.] and coverage of the employee or dependent under such a plan is terminated as a result of loss of eligibility for such coverage and the employee requests coverage under the group health plan (or health insurance coverage) not later than 60 days after the date of termination of such coverage.

(ii) Eligibility for employment assistance under Medicaid or CHIP

The employee or dependent becomes eligible for assistance, with respect to coverage under the group health plan or health insurance coverage, under such Medicaid plan or State child health plan (including under any waiver or demonstration project conducted under or in relation to such a plan), if the employee requests coverage under the group health plan or health insurance coverage not later than 60 days after the date the employee or dependent is determined to be eligible for such assistance.

(B) Coordination with Medicaid and CHIP

(i) Outreach to employees regarding availability of Medicaid and CHIP coverage

(I) In general

Each employer that maintains a group health plan in a State that provides medical assistance under a State Medicaid plan under title XIX of the Social Security Act [42 U.S.C. 1396 et seq.], or child health assistance under a State child health plan under title XXI of such Act [42 U.S.C. 1397aa et seq.], in the form of premium assistance for the purchase of coverage under a group health plan, shall provide to each employee a written notice informing the employee of potential opportunities then currently available in the State in which the employee resides for premium assistance under such plans for health coverage of the employee or the employee's dependents. For purposes of compliance with this subclause, the employer may use any State-specific model notice developed in accordance with section 1181(f)(3)(B)(i)(II) of title 29.

(II) Option to provide concurrent with provision of plan materials to employee

An employer may provide the model notice applicable to the State in which an employee resides concurrent with the furnishing of materials notifying the employee of health plan eligibility, concurrent with materials provided to the employee in connection with an open season or election process conducted under the plan, or concurrent with the furnishing of the summary plan description as provided in section 1024(b) of title 29.

(ii) Disclosure about group health plan benefits to States for Medicaid and CHIP eligible individuals

In the case of an enrollee in a group health plan who is covered under a Medicaid plan of a State under title XIX of the Social Security Act [42 U.S.C. 1396 et seq.] or under a State child health plan under title XXI of such Act [42 U.S.C. 1397aa et seq.], the plan administrator of the group health plan shall disclose to the State, upon request, information about the benefits available under the group health plan in sufficient specificity, as determined under regulations of the Secretary of Health and Human Services in consultation with the Secretary that require use of the model coverage coordination disclosure form developed under section 311(b)(1)(C) of the Children's Health Insurance [3] Reauthorization Act of 2009, so as to permit the State to make a determination (under paragraph (2)(B), (3), or (10) of section 2105(c) of the Social Security Act [42 U.S.C. 1397ee(c)(2)(B), (3), (10)] or otherwise) concerning the cost-effectiveness of the State providing medical or child health assistance through premium assistance for the purchase of coverage under such group health plan and in order for the State to provide supplemental benefits required under paragraph (10)(E) of such section or other authority.

(g) Use of affiliation period by HMOs as alternative to preexisting condition exclusion

(1) In general

A health maintenance organization which offers health insurance coverage in connection with a group health plan and which does not impose any preexisting condition exclusion allowed under subsection (a) with respect to any particular coverage option may impose an affiliation period for such coverage option, but only if—

(A) such period is applied uniformly without regard to any health status-related factors; and

(B) such period does not exceed 2 months (or 3 months in the case of a late enrollee).

(2) Affiliation period

(A) "Affiliation period" defined

For purposes of this subchapter, the term "affiliation period" means a period which, under the terms of the health insurance coverage offered by the health maintenance organization, must expire before the health insurance coverage becomes effective. The organization is not required to provide health care services or benefits during such period and no premium shall be charged to the participant or beneficiary for any coverage during the period.

(B) Beginning

Such period shall begin on the enrollment date.

(C) Runs concurrently with waiting periods

An affiliation period under a plan shall run concurrently with any waiting period under the plan.

(3) Alternative methods

A health maintenance organization described in paragraph (1) may use alternative methods, from those described in such paragraph, to address adverse selection as approved by the State insurance commissioner or official or officials designated by the State to enforce the requirements of this part for the State involved with respect to such issuer.

(July 1, 1944, ch. 373, title XXVII, §2704, formerly §2701, as added Pub. L. 104–191, title I, §102(a), Aug. 21, 1996, 110 Stat. 1955; amended Pub. L. 111–3, title III, §311(b)(2), Feb. 4, 2009, 123 Stat. 70; Pub. L. 111–5, div. B, title I, §1899D(c), Feb. 17, 2009, 123 Stat. 426; renumbered §2704 and amended Pub. L. 111–148, title I, §§1201(2), 1563(c)(1), formerly §1562(c)(1), title X, §10107(b)(1), Mar. 23, 2010, 124 Stat. 154, 264, 911; Pub. L. 111–344, title I, §114(c), Dec. 29, 2010, 124 Stat. 3615; Pub. L. 112–40, title II, §242(a)(3), (4), Oct. 21, 2011, 125 Stat. 419.)

EDITORIAL NOTES

REFERENCES IN TEXT

Subsection (a), referred to in subsecs. (b)(1)(B) and (c)(3)(A), (B), was struck out, and a new subsec. (a) was added, by Pub. L. 111–148, title I, §1201(2)(A), Mar. 23, 2010, 124 Stat. 154, and as so amended, subsec. (a) no longer contains paragraphs.

The Social Security Act, referred to in subsecs. (c)(1)(C), (D) and (f)(3)(A)(i), (B)(i)(I), (ii), is act Aug. 14, 1935, ch. 531, 49 Stat. 620. Parts A and B of title XVIII of the Act are classified generally to parts A (§1395c et seq.) and B (§1395j et seq.), respectively, of subchapter XVIII of chapter 7 of this title. Titles XIX and XXI of the Act are classified generally to subchapters XIX (§1396 et seq.) and XXI (§1397aa et seq.), respectively, of chapter 7 of this title. For complete classification of this Act to the Code, see section 1305 of this title and Tables.

Section 311(b)(1)(C) of the Children's Health Insurance Program Reauthorization Act of 2009, referred to in subsec. (f)(3)(B)(ii), is section 311(b)(1)(C) of Pub. L. 111–3, which is set out as a note under section 1181 of Title 29, Labor.

CODIFICATION

Section was classified to section 300gg of this title prior to amendment and renumbering by Pub. L. 111–148.

Section 242(a)(3) of Pub. L. 112–40 amended section 2701 of act July 1, 1944, "as in effect for plan years beginning before January 1, 2014", which was classified to section 300gg of this title prior to amendment and renumbering by Pub. L. 111–148. Section 242(a)(4) of Pub. L. 112–40 made identical amendment to section

2704 of act July 1, 1944, "as in effect for plan years beginning on or after January 1, 2014", which is set out as this section. See 2011 Amendment note below. For effective date of renumbering by section 1201(2) of Pub. L. 111–148, see Effective Date of 2010 Amendment note below.

PRIOR PROVISIONS

A prior section 2704 of act July 1, 1944, was renumbered section 2725 and is classified to section 300gg–25 of this title.

Another prior section 2704 of act July 1, 1944, was successively renumbered by subsequent acts and transferred, see section 238c of this title.

AMENDMENTS

2011—Subsec. (c)(2)(C). Pub. L. 112–40 substituted "January 1, 2014" for "February 13, 2011" in introductory provisions. See Codification note above.

2010—Pub. L. 111–148, §1201(2)(A), substituted "Prohibition of preexisting condition exclusions or other discrimination based on health status" for "Increased portability through limitation on preexisting condition exclusions" in section catchline, added subsec. (a), and struck out former subsec. (a) which related to limitation on preexisting condition exclusion period.

Subsec. (c)(2)(A), (B). Pub. L. 111–148, §1563(c)(1)(A)(i), formerly §1562(c)(1)(A)(i), as renumbered by Pub. L. 111–148, §10107(b)(1), substituted "group or individual health plan" for "group health plan".

Subsec. (c)(2)(C). Pub. L. 111–344 substituted "February 13, 2011" for "January 1, 2011" in introductory provisions.

Subsec. (c)(3)(A), (B). Pub. L. 111–148, §1563(c)(1)(A)(ii)(I), formerly §1562(c)(1)(A)(ii)(I), as renumbered by Pub. L. 111–148, §10107(b)(1), substituted "group or individual health insurance" for "group health insurance".

Subsec. (c)(3)(D). Pub. L. 111–148, §1563(c)(1)(A)(ii)(II), formerly §1562(c)(1)(A)(ii)(II), as renumbered by Pub. L. 111–148, §10107(b)(1), substituted "individual or group" for "small or large" in introductory provisions.

Subsec. (d)(1) to (3). Pub. L. 111–148, §1563(c)(1)(B), formerly §1562(c)(1)(B), as renumbered by Pub. L. 111–148, §10107(b)(1), substituted "group or individual health insurance" for "group health insurance".

Subsec. (e)(1)(A). Pub. L. 111–148, §1563(c)(1)(C), formerly §1562(c)(1)(C), as renumbered by Pub. L. 111–148, §10107(b)(1), substituted "group or individual health insurance" for "group health insurance" in introductory provisions.

2009—Subsec. (c)(2)(C). Pub. L. 111–5 added subpar. (C).

Subsec. (f)(3). Pub. L. 111–3 added par. (3).

STATUTORY NOTES AND RELATED SUBSIDIARIES

EFFECTIVE DATE OF 2011 AMENDMENT

Amendment by Pub. L. 112–40 applicable to plan years beginning after Feb. 12, 2011, with transitional rules, see section 242(b) of Pub. L. 112–40, set out as a note under section 9801 of Title 26, Internal Revenue Code.

EFFECTIVE DATE OF 2010 AMENDMENT

Amendment by Pub. L. 111–344 applicable to plan years beginning after Dec. 31, 2010, see section 114(d) of Pub. L. 111–344, set out as a note under section 9801 of Title 26, Internal Revenue Code.

Amendment by section 1201(2) of Pub. L. 111–148 effective for plan years beginning on or after Jan. 1, 2014, except that the provisions of this section, as they apply to enrollees who are under 19 years of age, effective for plan years beginning on or after the date that is 6 months after Mar. 23, 2010, see section 1255 of Pub. L. 111–148, set out as an Effective Date note under section 300gg of this title.

EFFECTIVE DATE OF 2009 AMENDMENT

Except as otherwise provided and subject to certain applicability provisions, amendment by Pub. L. 111–5 effective upon the expiration of the 90-day period beginning on Feb. 17, 2009, see section 1891 of Pub. L. 111–5, set out as an Effective and Termination Dates of 2009 Amendment note under section 2271 of Title 19, Customs Duties.

Amendment by Pub. L. 111–5 applicable to plan years beginning after Feb. 17, 2009, see section 1899D(d) of Pub. L. 111–5, set out as a note under section 9801 of Title 26, Internal Revenue Code.

Amendment by Pub. L. 111–3 effective Apr. 1, 2009, and applicable to child health assistance and medical

assistance provided on or after that date, with certain exceptions, see section 3 of Pub. L. 111–3, set out as an Effective Date note under section 1396 of this title.

[1] *See References in Text note below.*

[2] *So in original.*

[3] *So in original. Probably should be followed by the word "Program".*

§300gg–4. Prohibiting discrimination against individual participants and beneficiaries based on health status

(a) In general

A group health plan and a health insurance issuer offering group or individual health insurance coverage may not establish rules for eligibility (including continued eligibility) of any individual to enroll under the terms of the plan or coverage based on any of the following health status-related factors in relation to the individual or a dependent of the individual:

(1) Health status.
(2) Medical condition (including both physical and mental illnesses).
(3) Claims experience.
(4) Receipt of health care.
(5) Medical history.
(6) Genetic information.
(7) Evidence of insurability (including conditions arising out of acts of domestic violence).
(8) Disability.
(9) Any other health status-related factor determined appropriate by the Secretary.

(b) In premium contributions

(1) In general

A group health plan, and a health insurance issuer offering group or individual health insurance coverage, may not require any individual (as a condition of enrollment or continued enrollment under the plan) to pay a premium or contribution which is greater than such premium or contribution for a similarly situated individual enrolled in the plan on the basis of any health status-related factor in relation to the individual or to an individual enrolled under the plan as a dependent of the individual.

(2) Construction

Nothing in paragraph (1) shall be construed—

(A) to restrict the amount that an employer or individual may be charged for coverage under a group health plan except as provided in paragraph (3) or individual health coverage, as the case may be; or

(B) to prevent a group health plan, and a health insurance issuer offering group health insurance coverage, from establishing premium discounts or rebates or modifying otherwise applicable copayments or deductibles in return for adherence to programs of health promotion and disease prevention.

(3) No group-based discrimination on basis of genetic information

(A) In general

For purposes of this section, a group health plan, and health [1] insurance issuer offering group health insurance coverage in connection with a group health plan, may not adjust premium or contribution amounts for the group covered under such plan on the basis of genetic information.

(B) Rule of construction

Nothing in subparagraph (A) or in paragraphs (1) and (2) of subsection (d) shall be construed to limit the ability of a health insurance issuer offering group or individual health insurance coverage to increase the premium for an employer based on the manifestation of a disease or disorder of an individual who is enrolled in the plan. In such case, the manifestation of a disease or disorder in one individual cannot also be used as genetic information about other group members and to further increase the premium for the employer.

(c) Genetic testing

(1) Limitation on requesting or requiring genetic testing

A group health plan, and a health insurance issuer offering health insurance coverage in connection with a group health plan, shall not request or require an individual or a family member of such individual to undergo a genetic test.

(2) Rule of construction

Paragraph (1) shall not be construed to limit the authority of a health care professional who is providing health care services to an individual to request that such individual undergo a genetic test.

(3) Rule of construction regarding payment

(A) In general

Nothing in paragraph (1) shall be construed to preclude a group health plan, or a health insurance issuer offering health insurance coverage in connection with a group health plan, from obtaining and using the results of a genetic test in making a determination regarding payment (as such term is defined for the purposes of applying the regulations promulgated by the Secretary under part C of title XI of the Social Security Act [42 U.S.C. 1320d et seq.] and section 264 of the Health Insurance Portability and Accountability Act of 1996, as may be revised from time to time) consistent with subsection (a).

(B) Limitation

For purposes of subparagraph (A), a group health plan, or a health insurance issuer offering health insurance coverage in connection with a group health plan, may request only the minimum amount of information necessary to accomplish the intended purpose.

(4) Research exception

Notwithstanding paragraph (1), a group health plan, or a health insurance issuer offering health insurance coverage in connection with a group health plan, may request, but not require, that a participant or beneficiary undergo a genetic test if each of the following conditions is met:

(A) The request is made pursuant to research that complies with part 46 of title 45, Code of Federal Regulations, or equivalent Federal regulations, and any applicable State or local law or regulations for the protection of human subjects in research.

(B) The plan or issuer clearly indicates to each participant or beneficiary, or in the case of a minor child, to the legal guardian of such beneficiary, to whom the request is made that—

(i) compliance with the request is voluntary; and

(ii) non-compliance will have no effect on enrollment status or premium or contribution amounts.

(C) No genetic information collected or acquired under this paragraph shall be used for underwriting purposes.

(D) The plan or issuer notifies the Secretary in writing that the plan or issuer is conducting activities pursuant to the exception provided for under this paragraph, including a description of the activities conducted.

(E) The plan or issuer complies with such other conditions as the Secretary may by regulation require for activities conducted under this paragraph.

(d) Prohibition on collection of genetic information

(1) In general

A group health plan, and a health insurance issuer offering health insurance coverage in connection with a group health plan, shall not request, require, or purchase genetic information for underwriting purposes (as defined in section 300gg–91 of this title).

(2) Prohibition on collection of genetic information prior to enrollment

A group health plan, and a health insurance issuer offering health insurance coverage in connection with a group health plan, shall not request, require, or purchase genetic information with respect to any individual prior to such individual's enrollment under the plan or coverage in connection with such enrollment.

(3) Incidental collection

If a group health plan, or a health insurance issuer offering health insurance coverage in connection with a group health plan, obtains genetic information incidental to the requesting, requiring, or purchasing of other information concerning any individual, such request, requirement, or purchase shall not be considered a violation of paragraph (2) if such request, requirement, or purchase is not in violation of paragraph (1).

(e) Application to all plans

The provisions of subsections (a)(6), (b)(3), (c), and (d) and subsection (b)(1) and section 300gg–3 of this title with respect to genetic information, shall apply to group health plans and health insurance issuers without regard to section 300gg–21(a) [2] of this title.

(f) Genetic information of a fetus or embryo

Any reference in this part to genetic information concerning an individual or family member of an individual shall—

(1) with respect to such an individual or family member of an individual who is a pregnant woman, include genetic information of any fetus carried by such pregnant woman; and

(2) with respect to an individual or family member utilizing an assisted reproductive technology, include genetic information of any embryo legally held by the individual or family member.

(j) [3] Programs of health promotion or disease prevention

(1) General provisions

(A) General rule

For purposes of subsection (b)(2)(B), a program of health promotion or disease prevention (referred to in this subsection as a "wellness program") shall be a program offered by an employer that is designed to promote health or prevent disease that meets the applicable requirements of this subsection.

(B) No conditions based on health status factor

If none of the conditions for obtaining a premium discount or rebate or other reward for participation in a wellness program is based on an individual satisfying a standard that is related to a health status factor, such wellness program shall not violate this section if participation in the program is made available to all similarly situated individuals and the requirements of paragraph (2) are complied with.

(C) Conditions based on health status factor

If any of the conditions for obtaining a premium discount or rebate or other reward for participation in a wellness program is based on an individual satisfying a standard that is related to a health status factor, such wellness program shall not violate this section if the requirements of paragraph (3) are complied with.

(2) Wellness programs not subject to requirements

If none of the conditions for obtaining a premium discount or rebate or other reward under a wellness program as described in paragraph (1)(B) are based on an individual satisfying a standard that is related to a health status factor (or if such a wellness program does not provide such a reward), the wellness program shall not violate this section if participation in the program is made available to all similarly situated individuals. The following programs shall not have to comply with the requirements of paragraph (3) if participation in the program is made available to all similarly situated individuals:

(A) A program that reimburses all or part of the cost for memberships in a fitness center.

(B) A diagnostic testing program that provides a reward for participation and does not base any part of the reward on outcomes.

(C) A program that encourages preventive care related to a health condition through the waiver of the copayment or deductible requirement under group [1] health plan for the costs of certain items or services related to a health condition (such as prenatal care or well-baby visits).

(D) A program that reimburses individuals for the costs of smoking cessation programs without regard to whether the individual quits smoking.

(E) A program that provides a reward to individuals for attending a periodic health education seminar.

(3) Wellness programs subject to requirements

If any of the conditions for obtaining a premium discount, rebate, or reward under a wellness program as described in paragraph (1)(C) is based on an individual satisfying a standard that is related to a health status factor, the wellness program shall not violate this section if the following requirements are complied with:

(A) The reward for the wellness program, together with the reward for other wellness programs with respect to the plan that requires satisfaction of a standard related to a health status factor, shall not exceed 30 percent of the cost of employee-only coverage under the plan. If, in addition to employees or individuals, any class of dependents (such as spouses or spouses and dependent children) may participate fully in the wellness program, such reward shall not exceed 30 percent of the cost of the coverage in which an employee or individual and any dependents are enrolled. For purposes of this paragraph, the cost of coverage shall be determined based on the total amount of employer and employee contributions for the benefit package under which the employee is (or the employee and any dependents are) receiving coverage. A reward may be in the form of a discount or rebate of a premium or contribution, a waiver of all or part of a cost-sharing mechanism (such as deductibles, copayments, or coinsurance), the absence of a surcharge, or the value of a benefit that would otherwise not be provided under the plan. The Secretaries of Labor, Health and Human Services, and the Treasury may increase the reward available under this subparagraph to up to 50 percent of the cost of coverage if the Secretaries determine that such an increase is appropriate.

(B) The wellness program shall be reasonably designed to promote health or prevent disease. A program complies with the preceding sentence if the program has a reasonable chance of improving the health of, or preventing disease in, participating individuals and it is not overly burdensome, is not a subterfuge for discriminating based on a health status factor, and is not highly suspect in the method chosen to promote health or prevent disease.

(C) The plan shall give individuals eligible for the program the opportunity to qualify for the reward under the program at least once each year.

(D) The full reward under the wellness program shall be made available to all similarly situated individuals. For such purpose, among other things:

(i) The reward is not available to all similarly situated individuals for a period unless the wellness program allows—

(I) for a reasonable alternative standard (or waiver of the otherwise applicable standard) for obtaining the reward for any individual for whom, for that period, it is unreasonably difficult due to a medical condition to satisfy the otherwise applicable standard; and

(II) for a reasonable alternative standard (or waiver of the otherwise applicable standard)

for obtaining the reward for any individual for whom, for that period, it is medically inadvisable to attempt to satisfy the otherwise applicable standard.

(ii) If reasonable under the circumstances, the plan or issuer may seek verification, such as a statement from an individual's physician, that a health status factor makes it unreasonably difficult or medically inadvisable for the individual to satisfy or attempt to satisfy the otherwise applicable standard.

(E) The plan or issuer involved shall disclose in all plan materials describing the terms of the wellness program the availability of a reasonable alternative standard (or the possibility of waiver of the otherwise applicable standard) required under subparagraph (D). If plan materials disclose that such a program is available, without describing its terms, the disclosure under this subparagraph shall not be required.

(k) Existing programs

Nothing in this section shall prohibit a program of health promotion or disease prevention that was established prior to March 23, 2010, and applied with all applicable regulations, and that is operating on such date, from continuing to be carried out for as long as such regulations remain in effect.

(l) Wellness program demonstration project

(1) In general

Not later than July 1, 2014, the Secretary, in consultation with the Secretary of the Treasury and the Secretary of Labor, shall establish a 10-State demonstration project under which participating States shall apply the provisions of subsection (j) to programs of health promotion offered by a health insurance issuer that offers health insurance coverage in the individual market in such State.

(2) Expansion of demonstration project

If the Secretary, in consultation with the Secretary of the Treasury and the Secretary of Labor, determines that the demonstration project described in paragraph (1) is effective, such Secretaries may, beginning on July 1, 2017 expand such demonstration project to include additional participating States.

(3) Requirements

(A) Maintenance of coverage

The Secretary, in consultation with the Secretary of the Treasury and the Secretary of Labor, shall not approve the participation of a State in the demonstration project under this section unless the Secretaries determine that the State's project is designed in a manner that—

(i) will not result in any decrease in coverage; and

(ii) will not increase the cost to the Federal Government in providing credits under section 36B of title 26 or cost-sharing assistance under section 18071 of this title.

(B) Other requirements

States that participate in the demonstration project under this subsection—

(i) may permit premium discounts or rebates or the modification of otherwise applicable copayments or deductibles for adherence to, or participation in, a reasonably designed program of health promotion and disease prevention;

(ii) shall ensure that requirements of consumer protection are met in programs of health promotion in the individual market;

(iii) shall require verification from health insurance issuers that offer health insurance coverage in the individual market of such State that premium discounts—

(I) do not create undue burdens for individuals insured in the individual market;

(II) do not lead to cost shifting; and

(III) are not a subterfuge for discrimination;

(iv) shall ensure that consumer data is protected in accordance with the requirements of section 264(c) of the Health Insurance Portability and Accountability Act of 1996 (42 U.S.C. 1320d–2 note); and

(v) shall ensure and demonstrate to the satisfaction of the Secretary that the discounts or other rewards provided under the project reflect the expected level of participation in the wellness program involved and the anticipated effect the program will have on utilization or medical claim costs.

(m) Report

(1) In general

Not later than 3 years after March 23, 2010, the Secretary, in consultation with the Secretary of the Treasury and the Secretary of Labor, shall submit a report to the appropriate committees of Congress concerning—

(A) the effectiveness of wellness programs (as defined in subsection (j)) in promoting health and preventing disease;

(B) the impact of such wellness programs on the access to care and affordability of coverage for participants and non-participants of such programs;

(C) the impact of premium-based and cost-sharing incentives on participant behavior and the role of such programs in changing behavior; and

(D) the effectiveness of different types of rewards.

(2) Data collection

In preparing the report described in paragraph (1), the Secretaries shall gather relevant information from employers who provide employees with access to wellness programs, including State and Federal agencies.

(n) Regulations

Nothing in this section shall be construed as prohibiting the Secretaries of Labor, Health and Human Services, or the Treasury from promulgating regulations in connection with this section.

(July 1, 1944, ch. 373, title XXVII, §2705, as added and amended Pub. L. 111–148, title I, §1201(3), (4), Mar. 23, 2010, 124 Stat. 154, 156.)

EDITORIAL NOTES

REFERENCES IN TEXT

The Social Security Act, referred to in subsec. (c)(3)(A), is act Aug. 14, 1935, ch. 531, 49 Stat. 620. Part C of title XI of the Act is classified generally to part C (§1320d et seq.) of subchapter XI of chapter 7 of this title. For complete classification of this Act to the Code, see section 1305 of this title and Tables.

Section 264 of the Health Insurance Portability and Accountability Act of 1996, referred to in subsecs. (c)(3)(A) and (l)(3)(B)(iv), is section 264 of Pub. L. 104–191, which is set out as a note under section 1320d–2 of this title.

Section 300gg–21(a) of this title, referred to in subsec. (e), was in the original a reference to section 2735(a) of act July 1, 1944, and was translated as if it referred to section 2722(a) of that act to reflect the probable intent of Congress because of the renumbering of section 2735 as 2722 by Pub. L. 111–148, title I, §1563(c)(12)(D), formerly §1562(c)(12)(D), title X, §10107(b)(1), Mar. 23, 2010, 124 Stat. 269, 911. The act July 1, 1944, does not contain a section 2735.

CODIFICATION

The text of section 300gg–1 of this title, which was amended and transferred to subsecs. (b) to (f) of this section by Pub. L. 111–148, §1201(3), was based on act July 1, 1944, ch. 373, title XXVII, §2702, as added Pub. L. 104–191, title I, §102(a), Aug. 21, 1996, 110 Stat. 1961; amended Pub. L. 110–233, title I, §102(a)(1)–(3), May 21, 2008, 122 Stat. 888, 890.

PRIOR PROVISIONS

A prior section 300gg–4, act July 1, 1944, ch. 373, title XXVII, §2704, as added Pub. L. 104–204, title VI, §604(a)(3), Sept. 26, 1996, 110 Stat. 2939, which related to standards relating to benefits for mothers and

newborns, was renumbered section 2725 of act July 1, 1944, by Pub. L. 111–148, title I, §1001(2), Mar. 23, 2010, 124 Stat. 130, and transferred to section 300gg–25 of this title.

A prior section 2705 of act July 1, 1944, was renumbered section 2726 and is classified to section 300gg–26 of this title.

Another prior section 2705 of act July 1, 1944, was successively renumbered by subsequent acts and transferred, see section 238d of this title.

AMENDMENTS

2010—Pub. L. 111–148, §1201(3), transferred section 300gg–1 of this title to subsecs. (b) to (f) of this section after amending it by striking out the section catchline "Prohibiting discrimination against individual participants and beneficiaries based on health status", by striking subsec. (a) which prohibited discrimination against individual participants in group health plans based on certain health status-related factors, by amending subsec. (b) by substituting "health insurance issuer offering group or individual health insurance coverage" for "health insurance issuer offering health insurance coverage in connection with a group health plan" in pars. (1) and (3)(B) and by inserting "or individual" after "employer" and "or individual health coverage, as the case may be" before semicolon in par. (2)(A), and by amending subsec. (e) by substituting "(a)(6)" for "(a)(1)(F)" and "300gg–3" for "300gg" and making technical amendment to reference in original act which appears in text as reference to section 300gg–21(a) of this title.

STATUTORY NOTES AND RELATED SUBSIDIARIES

EFFECTIVE DATE

Section effective for plan years beginning on or after Jan. 1, 2014, see section 1255 of Pub. L. 111–148, set out as a note under section 300gg of this title.

[1] So in original. Probably should be preceded by "a".

[2] See References in Text note below.

[3] So in original. No subsecs. (g) to (i) have been enacted.

§300gg–5. Non-discrimination in health care

(a) Providers

A group health plan and a health insurance issuer offering group or individual health insurance coverage shall not discriminate with respect to participation under the plan or coverage against any health care provider who is acting within the scope of that provider's license or certification under applicable State law. This section shall not require that a group health plan or health insurance issuer contract with any health care provider willing to abide by the terms and conditions for participation established by the plan or issuer. Nothing in this section shall be construed as preventing a group health plan, a health insurance issuer, or the Secretary from establishing varying reimbursement rates based on quality or performance measures.

(b) Individuals

The provisions of section 218c [1] of title 29 (relating to non-discrimination) shall apply with respect to a group health plan or health insurance issuer offering group or individual health insurance coverage.

(July 1, 1944, ch. 373, title XXVII, §2706, as added Pub. L. 111–148, title I, §1201(4), Mar. 23, 2010, 124 Stat. 160.)

EDITORIAL NOTES

REFERENCES IN TEXT

Section 218c of title 29, referred to in subsec. (b), was in the original "section 1558 of the Patient Protection and Affordable Care Act", meaning section 1558 of Pub. L. 111–148, and was translated as meaning section 18C of act June 25, 1938, ch. 676, which was added by section 1558 of Pub. L. 111–148, to reflect the probable intent of Congress.

PRIOR PROVISIONS

A prior section 300gg–5, act July 1, 1944, ch. 373, title XXVII, §2705, as added Pub. L. 104–204, title VII, §703(a), Sept. 26, 1996, 110 Stat. 2947, and amended, which related to parity in mental health and substance use disorder benefits, was renumbered section 2726 of act July 1, 1944, and transferred to section 300gg–26 of this title.

A prior section 2706 of act July 1, 1944, was renumbered section 2727 and is classified to section 300gg–27 of this title.

Another prior section 2706 of act July 1, 1944, was successively renumbered by subsequent acts and transferred, see section 238e of this title.

STATUTORY NOTES AND RELATED SUBSIDIARIES

EFFECTIVE DATE

Section effective for plan years beginning on or after Jan. 1, 2014, see section 1255 of Pub. L. 111–148, set out as a note under section 300gg of this title.

IMPLEMENTING PROTECTIONS AGAINST PROVIDER DISCRIMINATION

Pub. L. 116–260, div. BB, title I, §108, Dec. 27, 2020, 134 Stat. 2859, provided that: "Not later than January 1, 2022, the Secretary of Health and Human Services, the Secretary of Labor, and the Secretary of the Treasury shall issue a proposed rule implementing the protections of section 2706(a) of the Public Health Service Act (42 U.S.C. 300gg–5(a)). The Secretaries shall accept and consider public comments on any proposed rule issued pursuant to this subsection for a period of 60 days after the date of such issuance. Not later than 6 months after the date of the conclusion of the comment period, the Secretaries shall issue a final rule implementing the protections of section 2706(a) of the Public Health Service Act (42 U.S.C. 300gg–5(a))."

[1] *See References in Text note below.*

§300gg–6. Comprehensive health insurance coverage

(a) Coverage for essential health benefits package

A health insurance issuer that offers health insurance coverage in the individual or small group market shall ensure that such coverage includes the essential health benefits package required under section 18022(a) of this title.

(b) Cost-sharing under group health plans

A group health plan shall ensure that any annual cost-sharing imposed under the plan does not exceed the limitations provided for under paragraph (1) of section 18022(c) [1] of this title.

(c) Child-only plans

If a health insurance issuer offers health insurance coverage in any level of coverage specified under section 18022(d) of this title, the issuer shall also offer such coverage in that level as a plan in which the only enrollees are individuals who, as of the beginning of a plan year, have not attained the age of 21.

(d) Dental only

This section shall not apply to a plan described in section 18031(d)(2)(B)(ii) [1] of this title.

(July 1, 1944, ch. 373, title XXVII, §2707, as added Pub. L. 111–148, title I, §1201(4), Mar. 23, 2010, 124 Stat. 161; amended Pub. L. 113–93, title II, §213(b), Apr. 1, 2014, 128 Stat. 1047.)

EDITORIAL NOTES

REFERENCES IN TEXT

Section 18022(c) of this title, referred to in subsec. (b), was in the original "section 1302(c)", and was translated as meaning section 1302(c) of Pub. L. 111–148, par. (1) of which relates to annual limitation on cost-sharing, to reflect the probable intent of Congress.

Section 18031(d)(2)(B)(ii) of this title, referred to in subsec. (d), was in the original "section 1302(d)(2)(B)(ii)(I)", and was translated as meaning section 1311(d)(2)(B)(ii) of Pub. L. 111–148, which relates to offering of stand-alone dental benefits, to reflect the probable intent of Congress.

PRIOR PROVISIONS

A prior section 300gg–6, act July 1, 1944, ch. 373, title XXVII, §2706, as added Pub. L. 105–277, div. A, §101(f) [title IX, §903(a)], Oct. 21, 1998, 112 Stat. 2681–337, 2681–438, which related to required coverage for reconstructive surgery following mastectomies, was renumbered section 2727 of act July 1, 1944, and transferred to section 300gg–27 of this title.

A prior section 2707 of act July 1, 1944, was renumbered section 2728 and is classified to section 300gg–28 of this title.

Another prior section 2707 of act July 1, 1944, was successively renumbered by subsequent acts and transferred, see section 238f of this title.

AMENDMENTS

2014—Subsec. (b). Pub. L. 113–93 substituted "paragraph (1)" for "paragraphs (1) and (2)".

STATUTORY NOTES AND RELATED SUBSIDIARIES

EFFECTIVE DATE OF 2014 AMENDMENT

Pub. L. 113–93, title II, §213(c), Apr. 1, 2014, 128 Stat. 1047, provided that: "The amendments made by this Act [probably means this section, amending this section and section 18022 of this title] shall be effective as if included in the enactment of the Patient Protection and Affordable Care Act (Public Law 111–148)."

EFFECTIVE DATE

Section effective for plan years beginning on or after Jan. 1, 2014, see section 1255 of Pub. L. 111–148, set out as a note under section 300gg of this title.

[1] *See References in Text note below.*

§300gg–7. Prohibition on excessive waiting periods

A group health plan and a health insurance issuer offering group health insurance coverage shall not apply any waiting period (as defined in section 300gg–3(b)(4) of this title) that exceeds 90 days.

(July 1, 1944, ch. 373, title XXVII, §2708, as added and amended Pub. L. 111–148, title I, §1201(4), title X, §10103(b), Mar. 23, 2010, 124 Stat. 161, 892.)

EDITORIAL NOTES

PRIOR PROVISIONS

A prior section 300gg–7, act July 1, 1944, ch. 373, title XXVII, §2707, as added Pub. L. 110–381, §2(b)(1), Oct. 9, 2008, 122 Stat. 4083, which related to coverage of dependent students on medically necessary leave of absence, was renumbered section 2728 of act July 1, 1944, and transferred to section 300gg–28 of this title.

A prior section 2708 of act July 1, 1944, was successively renumbered by subsequent acts and transferred, see section 238g of this title.

AMENDMENTS

2010—Pub. L. 111–148, §10103(b), struck out "or individual" after "offering group".

STATUTORY NOTES AND RELATED SUBSIDIARIES

EFFECTIVE DATE

Section effective for plan years beginning on or after Jan. 1, 2014, see section 1255 of Pub. L. 111–148, set out as a note under section 300gg of this title.

§300gg–8. Coverage for individuals participating in approved clinical trials

(a) Coverage

(1) In general

If a group health plan or a health insurance issuer offering group or individual health insurance coverage provides coverage to a qualified individual, then such plan or issuer—

(A) may not deny the individual participation in the clinical trial referred to in subsection (b)(2);

(B) subject to subsection (c), may not deny (or limit or impose additional conditions on) the coverage of routine patient costs for items and services furnished in connection with participation in the trial; and

(C) may not discriminate against the individual on the basis of the individual's participation in such trial.

(2) Routine patient costs

(A) Inclusion

For purposes of paragraph (1)(B), subject to subparagraph (B), routine patient costs include all items and services consistent with the coverage provided in the plan (or coverage) that is typically covered for a qualified individual who is not enrolled in a clinical trial.

(B) Exclusion

For purposes of paragraph (1)(B), routine patient costs does not include—

(i) the investigational item, device, or service, itself;

(ii) items and services that are provided solely to satisfy data collection and analysis needs and that are not used in the direct clinical management of the patient; or

(iii) a service that is clearly inconsistent with widely accepted and established standards of care for a particular diagnosis.

(3) Use of in-network providers

If one or more participating providers is participating in a clinical trial, nothing in paragraph (1) shall be construed as preventing a plan or issuer from requiring that a qualified individual participate in the trial through such a participating provider if the provider will accept the individual as a participant in the trial.

(4) Use of out-of-network

Notwithstanding paragraph (3), paragraph (1) shall apply to a qualified individual participating in an approved clinical trial that is conducted outside the State in which the qualified individual resides.

(b) Qualified individual defined

For purposes of subsection (a), the term "qualified individual" means an individual who is a participant or beneficiary in a health plan or with coverage described in subsection (a)(1) and who meets the following conditions:

(1) The individual is eligible to participate in an approved clinical trial according to the trial protocol with respect to treatment of cancer or other life-threatening disease or condition.

(2) Either—

(A) the referring health care professional is a participating health care provider and has concluded that the individual's participation in such trial would be appropriate based upon the

individual meeting the conditions described in paragraph (1); or

(B) the participant or beneficiary provides medical and scientific information establishing that the individual's participation in such trial would be appropriate based upon the individual meeting the conditions described in paragraph (1).

(c) Limitations on coverage

This section shall not be construed to require a group health plan, or a health insurance issuer offering group or individual health insurance coverage, to provide benefits for routine patient care services provided outside of the plan's (or coverage's) health care provider network unless out-of-network benefits are otherwise provided under the plan (or coverage).

(d) Approved clinical trial defined

(1) In general

In this section, the term "approved clinical trial" means a phase I, phase II, phase III, or phase IV clinical trial that is conducted in relation to the prevention, detection, or treatment of cancer or other life-threatening disease or condition and is described in any of the following subparagraphs:

(A) FEDERALLY FUNDED TRIALS.—The study or investigation is approved or funded (which may include funding through in-kind contributions) by one or more of the following:

(i) The National Institutes of Health.

(ii) The Centers for Disease Control and Prevention.

(iii) The Agency for Health Care Research and Quality.

(iv) The Centers for Medicare & Medicaid Services.

(v) cooperative [1] group or center of any of the entities described in clauses (i) through (iv) or the Department of Defense or the Department of Veterans Affairs.

(vi) A qualified non-governmental research entity identified in the guidelines issued by the National Institutes of Health for center support grants.

(vii) Any of the following if the conditions described in paragraph (2) are met:

(I) The Department of Veterans Affairs.

(II) The Department of Defense.

(III) The Department of Energy.

(B) The study or investigation is conducted under an investigational new drug application reviewed by the Food and Drug Administration.

(C) The study or investigation is a drug trial that is exempt from having such an investigational new drug application.

(2) Conditions for departments

The conditions described in this paragraph, for a study or investigation conducted by a Department, are that the study or investigation has been reviewed and approved through a system of peer review that the Secretary determines—

(A) to be comparable to the system of peer review of studies and investigations used by the National Institutes of Health, and

(B) assures unbiased review of the highest scientific standards by qualified individuals who have no interest in the outcome of the review.

(e) Life-threatening condition defined

In this section, the term "life-threatening condition" means any disease or condition from which the likelihood of death is probable unless the course of the disease or condition is interrupted.

(f) Construction

Nothing in this section shall be construed to limit a plan's or issuer's coverage with respect to clinical trials.

(g) Application to FEHBP

Notwithstanding any provision of chapter 89 of title 5, this section shall apply to health plans

offered under the program under such chapter.

(h) Preemption

Notwithstanding any other provision of this chapter, nothing in this section shall preempt State laws that require a clinical trials policy for State regulated health insurance plans that is in addition to the policy required under this section.

(July 1, 1944, ch. 373, title XXVII, §2709, as added Pub. L. 111–148, title X, §10103(c), Mar. 23, 2010, 124 Stat. 892.)

EDITORIAL NOTES

CODIFICATION

Another section 2709 of act July 1, 1944, is classified to section 300gg–9 of this title.

PRIOR PROVISIONS

A prior section 2709 of act July 1, 1944, was successively renumbered by subsequent acts and transferred, see section 238h of this title.

[1] So in original. Probably should be preceded by "A".

§300gg–9. Disclosure of information

(a) Disclosure of information by health plan issuers

In connection with the offering of any health insurance coverage to a small employer or an individual, a health insurance issuer—

(1) shall make a reasonable disclosure to such employer, or individual, as applicable,,[1] as part of its solicitation and sales materials, of the availability of information described in subsection (b), and

(2) upon request of such a [2] employer, or individual, as applicable,,[1] provide such information.

(b) Information described

(1) In general

Subject to paragraph (3), with respect to a health insurance issuer offering health insurance coverage to a [2] employer, or individual, as applicable,,[1] information described in this subsection is information concerning—

(A) the provisions of such coverage concerning issuer's right to change premium rates and the factors that may affect changes in premium rates; and

(B) the benefits and premiums available under all health insurance coverage for which the employer, or individual, as applicable, is qualified.

(2) Form of information

Information under this subsection shall be provided to employers, or individuals, as applicable, in a manner determined to be understandable by the average employer, or individual, as applicable,,[1] and shall be sufficient to reasonably inform employers, or individuals, as applicable, of their rights and obligations under the health insurance coverage.

(3) Exception

An issuer is not required under this section to disclose any information that is proprietary and trade secret information under applicable law.

(July 1, 1944, ch. 373, title XXVII, §2709, formerly §2713, as added Pub. L. 104–191, title I, §102(a), Aug. 21, 1996, 110 Stat. 1966; renumbered §2733, renumbered §2709, and amended Pub. L. 111–148, title I, §§1001(3), 1563(c)(10), formerly §1562(c)(10), title X, §10107(b)(1), Mar. 23,

2010, 124 Stat. 130, 268, 911.)

EDITORIAL NOTES

CODIFICATION

Section was formerly classified to section 300gg–13 of this title prior to renumbering by Pub. L. 111–148.

Another section 2709 of act July 1, 1944, is classified to section 300gg–8 of this title.

PRIOR PROVISIONS

A prior section 2709 of act July 1, 1944, was successively renumbered by subsequent acts and transferred, see section 238h of this title.

AMENDMENTS

2010—Subsec. (a). Pub. L. 111–148, §1563(c)(10)(A), formerly §1562(c)(10)(A), as renumbered by Pub. L. 111–148, §10107(b)(1), in introductory provisions substituted "small employer or an individual" for "small employer", in par. (1) inserted ", or individual, as applicable," after "employer", and in par. (2) substituted "employer, or individual, as applicable," for "small employer".

Subsec. (b)(1). Pub. L. 111–148, §1563(c)(10)(B)(i), formerly §1562(c)(10)(B)(i), as renumbered by Pub. L. 111–148, §10107(b)(1), in introductory provisions substituted "employer, or individual, as applicable," for "small employer", in subpar. (A), inserted "and" at end, struck out subpars. (B) and (C) which related to provisions of coverage relating to renewability of coverage and preexisting condition exclusions, respectively, in subpar. (D), inserted ", or individual, as applicable," after "employer", and redesignated subpar. (D) as (B).

Subsec. (b)(2). Pub. L. 111–148, §1563(c)(10)(B)(ii), formerly §1562(c)(10)(B)(ii), as renumbered by Pub. L. 111–148, §10107(b)(1), substituted "employer, or individual, as applicable," for "small employer" and "employers, or individuals, as applicable," for "small employers" in two places.

STATUTORY NOTES AND RELATED SUBSIDIARIES

EFFECTIVE DATE

Section applicable with respect to group health plans, and health insurance coverage offered in connection with group health plans, for plan years beginning after June 30, 1997, except as otherwise provided, see section 102(c) of Pub. L. 104–191, set out as a note under section 300gg of this title.

[1] So in original.

[2] So in original. Probably should be "an".

SUBPART II—IMPROVING COVERAGE

EDITORIAL NOTES

PRIOR PROVISIONS

A prior subpart 2, consisting of sections 300gg–4 to 300gg–7, related to other requirements, prior to repeal of the subpart designation and heading and transfer of sections 300gg–4 to 300gg–7 to 300gg–25 to 300gg–28, respectively, of this title by Pub. L. 111–148, title I, §§1001(2), 1563(c)(2), formerly §1562(c)(2), title X, §10107(b)(1), Mar. 23, 2010, 124 Stat. 130, 265, 911.

Another prior subpart 2, consisting of sections 300gg–11 to 300gg–13, related to provisions applicable only to health insurance issuers, was redesignated subpart 3 of this part by Pub. L. 104–204, title VI, §604(a)(2), Sept. 26, 1996, 110 Stat. 2939.

A prior subpart 3, consisting of sections 300gg–11 to 300gg–13, related to provisions applicable only to health insurance issuers, prior to repeal of the subpart designation and heading by Pub. L. 111–148, title I, §1563(c)(7), formerly §1562(c)(7), title X, §10107(b)(1), Mar. 23, 2010, 124 Stat. 266, 911.

A prior subpart 4, consisting of sections 300gg–21 to 300gg–23, which related to exclusion of plans, enforcement, and preemption, was redesignated subpart 2 of this part by Pub. L. 111–148, title I,

§1563(c)(11), formerly §1562(c)(11), title X, §10107(b)(1), Mar. 23, 2010, 124 Stat. 268, 911.

§300gg–11. No lifetime or annual limits

(a) Prohibition

(1) In general

A group health plan and a health insurance issuer offering group or individual health insurance coverage may not establish—

(A) lifetime limits on the dollar value of benefits for any participant or beneficiary; or

(B) except as provided in paragraph (2), annual limits on the dollar value of benefits for any participant or beneficiary.

(2) Annual limits prior to 2014

With respect to plan years beginning prior to January 1, 2014, a group health plan and a health insurance issuer offering group or individual health insurance coverage may only establish a restricted annual limit on the dollar value of benefits for any participant or beneficiary with respect to the scope of benefits that are essential health benefits under section 18022(b) of this title, as determined by the Secretary. In defining the term "restricted annual limit" for purposes of the preceding sentence, the Secretary shall ensure that access to needed services is made available with a minimal impact on premiums.

(b) Per beneficiary limits

Subsection (a) shall not be construed to prevent a group health plan or health insurance coverage from placing annual or lifetime per beneficiary limits on specific covered benefits that are not essential health benefits under section 18022(b) of this title, to the extent that such limits are otherwise permitted under Federal or State law.

(July 1, 1944, ch. 373, title XXVII, §2711, as added and amended Pub. L. 111–148, title I, §1001(5), title X, §10101(a), Mar. 23, 2010, 124 Stat. 131, 883.)

EDITORIAL NOTES

PRIOR PROVISIONS

A prior section 300gg–11, act July 1, 1944, ch. 373, title XXVII, §2711, as added Pub. L. 104–191, title I, §102(a), Aug. 21, 1996, 110 Stat. 1962, which related to guaranteed availability of coverage for employers in a group market, was renumbered section 2731 of act July 1, 1944, amended, and transferred to subsecs. (c) and (d) of section 300gg–1 of this title, by Pub. L. 111–148, title I, §§1001(3), 1563(c)(8), formerly §1562(c)(8), title X, §10107(b)(1), Mar. 23, 2010, 124 Stat. 130, 266, 911.

Another prior section 2711 of act July 1, 1944, was successively renumbered by subsequent acts and transferred, see section 238j of this title.

AMENDMENTS

2010—Pub. L. 111–148, §10101(a), amended section generally. Prior to amendment, text read as follows:

"(a) IN GENERAL.—A group health plan and a health insurance issuer offering group or individual health insurance coverage may not establish—

"(1) lifetime limits on the dollar value of benefits for any participant or beneficiary; or

"(2) unreasonable annual limits (within the meaning of section 223 of title 26) on the dollar value of benefits for any participant or beneficiary.

"(b) PER BENEFICIARY LIMITS.—Subsection (a) shall not be construed to prevent a group health plan or health insurance coverage that is not required to provide essential health benefits under section 18022(b) of this title from placing annual or lifetime per beneficiary limits on specific covered benefits to the extent that such limits are otherwise permitted under Federal or State law."

STATUTORY NOTES AND RELATED SUBSIDIARIES

EFFECTIVE DATE

Pub. L. 111–148, title I, §1004, Mar. 23, 2010, 124 Stat. 140, provided that:

"(a) IN GENERAL.—Except as provided for in subsection (b), this subtitle [subtitle A (§§1001–1004) of title I of Pub. L. 111–148, enacting this section and sections 300gg–12 to 300gg–15, 300gg–16 to 300gg–19, 300gg–93, and 300gg–94 of this title, amending former sections 300gg–11 and 300gg–12 of this title and sections 300gg–21 to 300gg–23 of this title, and transferring section 300gg–13 of this title to section 300gg–9 of this title and sections 300gg–4 to 300gg–7 of this title to sections 300gg–25 to 300gg–28 of this title, respectively] (and the amendments made by this subtitle) shall become effective for plan years beginning on or after the date that is 6 months after the date of enactment of this Act [Mar. 23, 2010], except that the amendments made by sections 1002 and 1003 [enacting sections 300gg–93 and 300gg–94 of this title] shall become effective for fiscal years beginning with fiscal year 2010.

"(b) SPECIAL RULE.—The amendments made by sections 1002 and 1003 [enacting sections 300gg–93 and 300gg–94 of this title] shall take effect on the date of enactment of this Act [Mar. 23, 2010]."

§300gg–12. Prohibition on rescissions

A group health plan and a health insurance issuer offering group or individual health insurance coverage shall not rescind such plan or coverage with respect to an enrollee once the enrollee is covered under such plan or coverage involved, except that this section shall not apply to a covered individual who has performed an act or practice that constitutes fraud or makes an intentional misrepresentation of material fact as prohibited by the terms of the plan or coverage. Such plan or coverage may not be cancelled except with prior notice to the enrollee, and only as permitted under section 300gg–2(b) [1] or 300gg–42(b) of this title.

(July 1, 1944, ch. 373, title XXVII, §2712, as added Pub. L. 111–148, title I, §1001(5), Mar. 23, 2010, 124 Stat. 131.)

EDITORIAL NOTES

REFERENCES IN TEXT

Section 300gg–2(b) of this title, referred to in text, was in the original a reference to section "2702(c)" of act July 1, 1944, which was translated as meaning section 2703(b) of act July 1, 1944, to reflect the probable intent of Congress. Section 2702(c), which is classified to section 300gg–1 of this title, relates to special rules for network plans, while section 2703(b) specifies the reasons for which a health insurance issuer may nonrenew or discontinue health insurance coverage offered in connection with a health insurance coverage offering in the group or individual market. Section 300gg–2(b) also parallels section 300gg–42(b) which appears in the same context in this section as the reference to section 300gg–2(b).

PRIOR PROVISIONS

A prior section 300gg–12, act July 1, 1944, ch. 373, title XXVII, §2712, as added Pub. L. 104–191, title I, §102(a), Aug. 21, 1996, 110 Stat. 1964, which related to guaranteed renewability of coverage for employers in a group market, was renumbered section 2732 of act July 1, 1944, amended, and transferred to subsecs. (b) to (e) of section 300gg–2 of this title, by Pub. L. 111–148, title I, §§1001(3), 1563(c)(9), formerly §1562(c)(9), title X, §10107(b)(1), Mar. 23, 2010, 124 Stat. 130, 267, 911.

Another prior section 2712 of act July 1, 1944, was successively renumbered by subsequent acts and transferred, see section 238k of this title.

STATUTORY NOTES AND RELATED SUBSIDIARIES

EFFECTIVE DATE

Section effective for plan years beginning on or after the date that is 6 months after Mar. 23, 2010, see section 1004 of Pub. L. 111–148, set out as a note under section 300gg–11 of this title.

[1] *See References in Text note below.*

§300gg–13. Coverage of preventive health services

(a) In general

A group health plan and a health insurance issuer offering group or individual health insurance coverage shall, at a minimum provide coverage for and shall not impose any cost sharing requirements for—

(1) evidence-based items or services that have in effect a rating of "A" or "B" in the current recommendations of the United States Preventive Services Task Force;

(2) immunizations that have in effect a recommendation from the Advisory Committee on Immunization Practices of the Centers for Disease Control and Prevention with respect to the individual involved; and [1]

(3) with respect to infants, children, and adolescents, evidence-informed preventive care and screenings provided for in the comprehensive guidelines supported by the Health Resources and Services Administration.[1]

(4) with respect to women, such additional preventive care and screenings not described in paragraph (1) as provided for in comprehensive guidelines supported by the Health Resources and Services Administration for purposes of this paragraph.[1]

(5) for the purposes of this chapter, and for the purposes of any other provision of law, the current recommendations of the United States Preventive Service Task Force regarding breast cancer screening, mammography, and prevention shall be considered the most current other than those issued in or around November 2009.

Nothing in this subsection shall be construed to prohibit a plan or issuer from providing coverage for services in addition to those recommended by United States Preventive Services Task Force or to deny coverage for services that are not recommended by such Task Force.

(b) Interval

(1) In general

The Secretary shall establish a minimum interval between the date on which a recommendation described in subsection (a)(1) or (a)(2) or a guideline under subsection (a)(3) is issued and the plan year with respect to which the requirement described in subsection (a) is effective with respect to the service described in such recommendation or guideline.

(2) Minimum

The interval described in paragraph (1) shall not be less than 1 year.

(c) Value-based insurance design

The Secretary may develop guidelines to permit a group health plan and a health insurance issuer offering group or individual health insurance coverage to utilize value-based insurance designs.

(July 1, 1944, ch. 373, title XXVII, §2713, as added Pub. L. 111–148, title I, §1001(5), Mar. 23, 2010, 124 Stat. 131.)

EDITORIAL NOTES

PRIOR PROVISIONS

A prior section 300gg–13, act July 1, 1944, ch. 373, title XXVII, §2713, as added Pub. L. 104–191, title I, §102(a), Aug. 21, 1996, 110 Stat. 1966, was renumbered section 2709 of act July 1, 1944, and transferred to section 300gg–9 of this title by Pub. L. 111–148, title I, §§1001(3), 1563(c)(10)(C), formerly §1562(c)(10)(C), title X, §10107(b)(1), Mar. 23, 2010, 124 Stat. 130, 268, 911.

Another prior section 2713 of act July 1, 1944, was successively renumbered by subsequent acts and transferred, see section 238l of this title.

STATUTORY NOTES AND RELATED SUBSIDIARIES

EFFECTIVE DATE

Section effective for plan years beginning on or after the date that is 6 months after Mar. 23, 2010, see section 1004 of Pub. L. 111–148, set out as a note under section 300gg–11 of this title.

RAPID COVERAGE OF PREVENTIVE SERVICES AND VACCINES FOR CORONAVIRUS

Pub. L. 116–136, div. A, title III, §3203, Mar. 27, 2020, 134 Stat. 367, provided that:

"(a) IN GENERAL.—Notwithstanding [section] 2713(b) of the Public Health Service Act (42 U.S.C. 300gg–13[(b)]), the Secretary of Health and Human Services, the Secretary of Labor, and the Secretary of the Treasury shall require group health plans and health insurance issuers offering group or individual health insurance to cover (without cost-sharing) any qualifying coronavirus preventive service, pursuant to section 2713(a) of the Public Health Service Act (42 U.S.C. 300gg–13(a)) (including the regulations under sections 2590.715–2713 of title 29, Code of Federal Regulations, section 54.9815–2713 of title 26, Code of Federal Regulations, and section 147.130 of title 45, Code of Federal Regulations (or any successor regulations)). The requirement described in this subsection shall take effect with respect to a qualifying coronavirus preventive service on the specified date described in subsection (b)(2).

"(b) DEFINITIONS.—For purposes of this section:

"(1) QUALIFYING CORONAVIRUS PREVENTIVE SERVICE.—The term 'qualifying coronavirus preventive service' means an item, service, or immunization that is intended to prevent or mitigate coronavirus disease 2019 and that is—

"(A) an evidence-based item or service that has in effect a rating of 'A' or 'B' in the current recommendations of the United States Preventive Services Task Force; or

"(B) an immunization that has in effect a recommendation from the Advisory Committee on Immunization Practices of the Centers for Disease Control and Prevention with respect to the individual involved.

"(2) SPECIFIED DATE.—The term 'specified date' means the date that is 15 business days after the date on which a recommendation is made relating to the qualifying coronavirus preventive service as described in such paragraph.

"(3) ADDITIONAL TERMS.—In this section, the terms 'group health plan', 'health insurance issuer', 'group health insurance coverage', and 'individual health insurance coverage' have the meanings given such terms in section 2791 of the Public Health Service Act (42 U.S.C. 300gg–91), section 733 of the Employee Retirement Income Security Act of 1974 (29 U.S.C. 1191b), and section 9832 of the Internal Revenue Code [26 U.S.C. 9832], as applicable."

[1] So in original.

[2] So in original. The period probably should be a semicolon.

§300gg–14. Extension of dependent coverage

(a) In general

A group health plan and a health insurance issuer offering group or individual health insurance coverage that provides dependent coverage of children shall continue to make such coverage available for an adult child until the child turns 26 years of age. Nothing in this section shall require a health plan or a health insurance issuer described in the preceding sentence to make coverage available for a child of a child receiving dependent coverage.

(b) Regulations

The Secretary shall promulgate regulations to define the dependents to which coverage shall be made available under subsection (a).

(c) Rule of construction

Nothing in this section shall be construed to modify the definition of "dependent" as used in title 26 with respect to the tax treatment of the cost of coverage.

(July 1, 1944, ch. 373, title XXVII, §2714, as added Pub. L. 111–148, title I, §1001(5), Mar. 23, 2010, 124 Stat. 132; amended Pub. L. 111–152, title II, §2301(b), Mar. 30, 2010, 124 Stat. 1082.)

EDITORIAL NOTES

PRIOR PROVISIONS

A prior section 2714 of act July 1, 1944, was successively renumbered by subsequent acts and transferred, see section 238m of this title.

AMENDMENTS

2010—Subsec. (a). Pub. L. 111–152 struck out "(who is not married)" after "adult child".

STATUTORY NOTES AND RELATED SUBSIDIARIES

EFFECTIVE DATE

Section effective for plan years beginning on or after the date that is 6 months after Mar. 23, 2010, see section 1004 of Pub. L. 111–148, set out as a note under section 300gg–11 of this title.

§300gg–15. Development and utilization of uniform explanation of coverage documents and standardized definitions

(a) In general

Not later than 12 months after March 23, 2010, the Secretary shall develop standards for use by a group health plan and a health insurance issuer offering group or individual health insurance coverage, in compiling and providing to applicants, enrollees, and policyholders or certificate holders a summary of benefits and coverage explanation that accurately describes the benefits and coverage under the applicable plan or coverage. In developing such standards, the Secretary shall consult with the National Association of Insurance Commissioners (referred to in this section as the "NAIC"), a working group composed of representatives of health insurance-related consumer advocacy organizations, health insurance issuers, health care professionals, patient advocates including those representing individuals with limited English proficiency, and other qualified individuals.

(b) Requirements

The standards for the summary of benefits and coverage developed under subsection (a) shall provide for the following:

(1) Appearance

The standards shall ensure that the summary of benefits and coverage is presented in a uniform format that does not exceed 4 pages in length and does not include print smaller than 12-point font.

(2) Language

The standards shall ensure that the summary is presented in a culturally and linguistically appropriate manner and utilizes terminology understandable by the average plan enrollee.

(3) Contents

The standards shall ensure that the summary of benefits and coverage includes—

(A) uniform definitions of standard insurance terms and medical terms (consistent with subsection (g)) so that consumers may compare health insurance coverage and understand the terms of coverage (or exception to such coverage);

(B) a description of the coverage, including cost sharing for—

(i) each of the categories of the essential health benefits described in subparagraphs (A) through (J) of section 18022(b)(1) of this title; and

(ii) other benefits, as identified by the Secretary;

(C) the exceptions, reductions, and limitations on coverage;

(D) the cost-sharing provisions, including deductible, coinsurance, and co-payment obligations;

(E) the renewability and continuation of coverage provisions;

(F) a coverage facts label that includes examples to illustrate common benefits scenarios, including pregnancy and serious or chronic medical conditions and related cost sharing, such scenarios to be based on recognized clinical practice guidelines;

(G) a statement of whether the plan or coverage—

(i) provides minimum essential coverage (as defined under section 5000A(f) of title 26); and

(ii) ensures that the plan or coverage share of the total allowed costs of benefits provided under the plan or coverage is not less than 60 percent of such costs;

(H) a statement that the outline is a summary of the policy or certificate and that the coverage document itself should be consulted to determine the governing contractual provisions; and

(I) a contact number for the consumer to call with additional questions and an Internet web address where a copy of the actual individual coverage policy or group certificate of coverage can be reviewed and obtained.

(c) Periodic review and updating

The Secretary shall periodically review and update, as appropriate, the standards developed under this section.

(d) Requirement to provide

(1) In general

Not later than 24 months after March 23, 2010, each entity described in paragraph (3) shall provide, prior to any enrollment restriction, a summary of benefits and coverage explanation pursuant to the standards developed by the Secretary under subsection (a) to—

(A) an applicant at the time of application;

(B) an enrollee prior to the time of enrollment or reenrollment, as applicable; and

(C) a policyholder or certificate holder at the time of issuance of the policy or delivery of the certificate.

(2) Compliance

An entity described in paragraph (3) is deemed to be in compliance with this section if the summary of benefits and coverage described in subsection (a) is provided in paper or electronic form.

(3) Entities in general

An entity described in this paragraph is—

(A) a health insurance issuer (including a group health plan that is not a self-insured plan) offering health insurance coverage within the United States; or

(B) in the case of a self-insured group health plan, the plan sponsor or designated administrator of the plan (as such terms are defined in section 1002(16) of title 29).

(4) Notice of modifications

If a group health plan or health insurance issuer makes any material modification in any of the terms of the plan or coverage involved (as defined for purposes of section 1022 of title 29) that is not reflected in the most recently provided summary of benefits and coverage, the plan or issuer shall provide notice of such modification to enrollees not later than 60 days prior to the date on which such modification will become effective.

(e) Preemption

The standards developed under subsection (a) shall preempt any related State standards that require a summary of benefits and coverage that provides less information to consumers than that

required to be provided under this section, as determined by the Secretary.

(f) Failure to provide

An entity described in subsection (d)(3) that willfully fails to provide the information required under this section shall be subject to a fine of not more than $1,000 for each such failure. Such failure with respect to each enrollee shall constitute a separate offense for purposes of this subsection.

(g) Development of standard definitions

(1) In general

The Secretary shall, by regulation, provide for the development of standards for the definitions of terms used in health insurance coverage, including the insurance-related terms described in paragraph (2) and the medical terms described in paragraph (3).

(2) Insurance-related terms

The insurance-related terms described in this paragraph are premium, deductible, co-insurance, co-payment, out-of-pocket limit, preferred provider, non-preferred provider, out-of-network co-payments, UCR (usual, customary and reasonable) fees, excluded services, grievance and appeals, and such other terms as the Secretary determines are important to define so that consumers may compare health insurance coverage and understand the terms of their coverage.

(3) Medical terms

The medical terms described in this paragraph are hospitalization, hospital outpatient care, emergency room care, physician services, prescription drug coverage, durable medical equipment, home health care, skilled nursing care, rehabilitation services, hospice services, emergency medical transportation, and such other terms as the Secretary determines are important to define so that consumers may compare the medical benefits offered by health insurance and understand the extent of those medical benefits (or exceptions to those benefits).

(July 1, 1944, ch. 373, title XXVII, §2715, as added and amended Pub. L. 111–148, title I, §1001(5), title X, §10101(b), Mar. 23, 2010, 124 Stat. 132, 884.)

EDITORIAL NOTES

AMENDMENTS

2010—Subsec. (a). Pub. L. 111–148, §10101(b), substituted "and providing to applicants, enrollees, and policyholders or certificate holders" for "and providing to enrollees".

STATUTORY NOTES AND RELATED SUBSIDIARIES

EFFECTIVE DATE

Section effective for plan years beginning on or after the date that is 6 months after Mar. 23, 2010, see section 1004 of Pub. L. 111–148, set out as a note under section 300gg–11 of this title.

§300gg–15a. Provision of additional information

A group health plan and a health insurance issuer offering group or individual health insurance coverage shall comply with the provisions of section 18031(e)(3) of this title, except that a plan or coverage that is not offered through an Exchange shall only be required to submit the information required to the Secretary and the State insurance commissioner, and make such information available to the public.

(July 1, 1944, ch. 373, title XXVII, §2715A, as added Pub. L. 111–148, title X, §10101(c), Mar. 23, 2010, 124 Stat. 884.)

§300gg–16. Prohibition on discrimination in favor of highly compensated individuals

(a) In general

A group health plan (other than a self-insured plan) shall satisfy the requirements of section 105(h)(2) of title 26 (relating to prohibition on discrimination in favor of highly compensated individuals).

(b) Rules and definitions

For purposes of this section—

(1) Certain rules to apply

Rules similar to the rules contained in paragraphs (3), (4), and (8) of section 105(h) of title 26 shall apply.

(2) Highly compensated individual

The term "highly compensated individual" has the meaning given such term by section 105(h)(5) of title 26.

(July 1, 1944, ch. 373, title XXVII, §2716, as added and amended Pub. L. 111–148, title I, §1001(5), title X, §10101(d), Mar. 23, 2010, 124 Stat. 135, 884.)

EDITORIAL NOTES

AMENDMENTS

2010—Pub. L. 111–148, §10101(d), amended section generally. Prior to amendment, text read as follows:

"(a) IN GENERAL.—The plan sponsor of a group health plan (other than a self-insured plan) may not establish rules relating to the health insurance coverage eligibility (including continued eligibility) of any full-time employee under the terms of the plan that are based on the total hourly or annual salary of the employee or otherwise establish eligibility rules that have the effect of discriminating in favor of higher wage employees.

"(b) LIMITATION.—Subsection (a) shall not be construed to prohibit a plan sponsor from establishing contribution requirements for enrollment in the plan or coverage that provide for the payment by employees with lower hourly or annual compensation of a lower dollar or percentage contribution than the payment required of similarly situated employees with a higher hourly or annual compensation."

STATUTORY NOTES AND RELATED SUBSIDIARIES

EFFECTIVE DATE

Section effective for plan years beginning on or after the date that is 6 months after Mar. 23, 2010, see section 1004 of Pub. L. 111–148, set out as a note under section 300gg–11 of this title.

§300gg–17. Ensuring the quality of care

(a) Quality reporting

(1) In general

Not later than 2 years after March 23, 2010, the Secretary, in consultation with experts in health care quality and stakeholders, shall develop reporting requirements for use by a group health plan, and a health insurance issuer offering group or individual health insurance coverage, with respect to plan or coverage benefits and health care provider reimbursement structures that—

(A) improve health outcomes through the implementation of activities such as quality reporting, effective case management, care coordination, chronic disease management, and

medication and care compliance initiatives, including through the use of the medical homes model as defined for purposes of section 3602 [1] of the Patient Protection and Affordable Care Act, for treatment or services under the plan or coverage;

(B) implement activities to prevent hospital readmissions through a comprehensive program for hospital discharge that includes patient-centered education and counseling, comprehensive discharge planning, and post discharge reinforcement by an appropriate health care professional;

(C) implement activities to improve patient safety and reduce medical errors through the appropriate use of best clinical practices, evidence based medicine, and health information technology under the plan or coverage; and

(D) implement wellness and health promotion activities.

(2) Reporting requirements

(A) In general

A group health plan and a health insurance issuer offering group or individual health insurance coverage shall annually submit to the Secretary, and to enrollees under the plan or coverage, a report on whether the benefits under the plan or coverage satisfy the elements described in subparagraphs (A) through (D) of paragraph (1).

(B) Timing of reports

A report under subparagraph (A) shall be made available to an enrollee under the plan or coverage during each open enrollment period.

(C) Availability of reports

The Secretary shall make reports submitted under subparagraph (A) available to the public through an Internet website.

(D) Penalties

In developing the reporting requirements under paragraph (1), the Secretary may develop and impose appropriate penalties for non-compliance with such requirements.

(E) Exceptions

In developing the reporting requirements under paragraph (1), the Secretary may provide for exceptions to such requirements for group health plans and health insurance issuers that substantially meet the goals of this section.

(b) Wellness and prevention programs

For purposes of subsection (a)(1)(D), wellness and health promotion activities may include personalized wellness and prevention services, which are coordinated, maintained or delivered by a health care provider, a wellness and prevention plan manager, or a health, wellness or prevention services organization that conducts health risk assessments or offers ongoing face-to-face, telephonic or web-based intervention efforts for each of the program's participants, and which may include the following wellness and prevention efforts:

(1) Smoking cessation.
(2) Weight management.
(3) Stress management.
(4) Physical fitness.
(5) Nutrition.
(6) Heart disease prevention.
(7) Healthy lifestyle support.
(8) Diabetes prevention.

(c) Protection of Second Amendment gun rights

(1) Wellness and prevention programs

A wellness and health promotion activity implemented under subsection (a)(1)(D) may not

require the disclosure or collection of any information relating to—

(A) the presence or storage of a lawfully-possessed firearm or ammunition in the residence or on the property of an individual; or

(B) the lawful use, possession, or storage of a firearm or ammunition by an individual.

(2) Limitation on data collection

None of the authorities provided to the Secretary under the Patient Protection and Affordable Care Act or an amendment made by that Act shall be construed to authorize or may be used for the collection of any information relating to—

(A) the lawful ownership or possession of a firearm or ammunition;

(B) the lawful use of a firearm or ammunition; or

(C) the lawful storage of a firearm or ammunition.

(3) Limitation on databases or data banks

None of the authorities provided to the Secretary under the Patient Protection and Affordable Care Act or an amendment made by that Act shall be construed to authorize or may be used to maintain records of individual ownership or possession of a firearm or ammunition.

(4) Limitation on determination of premium rates or eligibility for health insurance

A premium rate may not be increased, health insurance coverage may not be denied, and a discount, rebate, or reward offered for participation in a wellness program may not be reduced or withheld under any health benefit plan issued pursuant to or in accordance with the Patient Protection and Affordable Care Act or an amendment made by that Act on the basis of, or on reliance upon—

(A) the lawful ownership or possession of a firearm or ammunition; or

(B) the lawful use or storage of a firearm or ammunition.

(5) Limitation on data collection requirements for individuals

No individual shall be required to disclose any information under any data collection activity authorized under the Patient Protection and Affordable Care Act or an amendment made by that Act relating to—

(A) the lawful ownership or possession of a firearm or ammunition; or

(B) the lawful use, possession, or storage of a firearm or ammunition.

(d) Regulations

Not later than 2 years after March 23, 2010, the Secretary shall promulgate regulations that provide criteria for determining whether a reimbursement structure is described in subsection (a).

(e) Study and report

Not later than 180 days after the date on which regulations are promulgated under subsection (c),[2] the Government Accountability Office shall review such regulations and conduct a study and submit to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives a report regarding the impact the activities under this section have had on the quality and cost of health care.

(July 1, 1944, ch. 373, title XXVII, §2717, as added and amended Pub. L. 111–148, title I, §1001(5), title X, §10101(e), Mar. 23, 2010, 124 Stat. 135, 884.)

EDITORIAL NOTES

REFERENCES IN TEXT

Section 3602 of the Patient Protection and Affordable Care Act, referred to in subsec. (a)(1)(A), is section 3602 of Pub. L. 111–148 which is set out as a note under section 1305w–21 of this title but the reference probably should be to section 3502 of the Act which is set out as a note under section 256a–1 of this title.

The Patient Protection and Affordable Care Act, referred to in subsec. (c), is Pub. L. 111–148, Mar. 23, 2010, 124 Stat. 119. For complete classification of this Act to the Code, see Short Title note set out under section 18001 of this title and Tables.

AMENDMENTS

2010—Subsecs. (c) to (e). Pub. L. 111–148, §10101(e), added subsec. (c) and redesignated former subsecs. (c) and (d) as (d) and (e), respectively.

STATUTORY NOTES AND RELATED SUBSIDIARIES

EFFECTIVE DATE

Section effective for plan years beginning on or after the date that is 6 months after Mar. 23, 2010, see section 1004 of Pub. L. 111–148, set out as a note under section 300gg–11 of this title.

[1] *See References in Text note below.*

[2] *So in original. Probably should be "subsection (d),".*

§300gg–18. Bringing down the cost of health care coverage

(a) Clear accounting for costs

A health insurance issuer offering group or individual health insurance coverage (including a grandfathered health plan) shall, with respect to each plan year, submit to the Secretary a report concerning the ratio of the incurred loss (or incurred claims) plus the loss adjustment expense (or change in contract reserves) to earned premiums. Such report shall include the percentage of total premium revenue, after accounting for collections or receipts for risk adjustment and risk corridors and payments of reinsurance, that such coverage expends—

(1) on reimbursement for clinical services provided to enrollees under such coverage;

(2) for activities that improve health care quality; and

(3) on all other non-claims costs, including an explanation of the nature of such costs, and excluding Federal and State taxes and licensing or regulatory fees.

The Secretary shall make reports received under this section available to the public on the Internet website of the Department of Health and Human Services.

(b) Ensuring that consumers receive value for their premium payments

(1) Requirement to provide value for premium payments

(A) Requirement

Beginning not later than January 1, 2011, a health insurance issuer offering group or individual health insurance coverage (including a grandfathered health plan) shall, with respect to each plan year, provide an annual rebate to each enrollee under such coverage, on a pro rata basis, if the ratio of the amount of premium revenue expended by the issuer on costs described in paragraphs (1) and (2) of subsection (a) to the total amount of premium revenue (excluding Federal and State taxes and licensing or regulatory fees and after accounting for payments or receipts for risk adjustment, risk corridors, and reinsurance under sections 18061, 18062, and 18063 of this title) for the plan year (except as provided in subparagraph (B)(ii)), is less than—

(i) with respect to a health insurance issuer offering coverage in the large group market, 85 percent, or such higher percentage as a State may by regulation determine; or

(ii) with respect to a health insurance issuer offering coverage in the small group market or in the individual market, 80 percent, or such higher percentage as a State may by regulation determine, except that the Secretary may adjust such percentage with respect to a State if the Secretary determines that the application of such 80 percent may destabilize the individual market in such State.

(B) Rebate amount

(i) Calculation of amount

The total amount of an annual rebate required under this paragraph shall be in an amount equal to the product of—

(I) the amount by which the percentage described in clause (i) or (ii) of subparagraph (A) exceeds the ratio described in such subparagraph; and

(II) the total amount of premium revenue (excluding Federal and State taxes and licensing or regulatory fees and after accounting for payments or receipts for risk adjustment, risk corridors, and reinsurance under sections 18061, 18062, and 18063 of this title) for such plan year.

(ii) Calculation based on average ratio

Beginning on January 1, 2014, the determination made under subparagraph (A) for the year involved shall be based on the averages of the premiums expended on the costs described in such subparagraph and total premium revenue for each of the previous 3 years for the plan.

(2) Consideration in setting percentages

In determining the percentages under paragraph (1), a State shall seek to ensure adequate participation by health insurance issuers, competition in the health insurance market in the State, and value for consumers so that premiums are used for clinical services and quality improvements.

(3) Enforcement

The Secretary shall promulgate regulations for enforcing the provisions of this section and may provide for appropriate penalties.

(c) Definitions

Not later than December 31, 2010, and subject to the certification of the Secretary, the National Association of Insurance Commissioners shall establish uniform definitions of the activities reported under subsection (a) and standardized methodologies for calculating measures of such activities, including definitions of which activities, and in what regard such activities, constitute activities described in subsection (a)(2). Such methodologies shall be designed to take into account the special circumstances of smaller plans, different types of plans, and newer plans.

(d) Adjustments

The Secretary may adjust the rates described in subsection (b) if the Secretary determines appropriate on account of the volatility of the individual market due to the establishment of State Exchanges.

(e) Standard hospital charges

Each hospital operating within the United States shall for each year establish (and update) and make public (in accordance with guidelines developed by the Secretary) a list of the hospital's standard charges for items and services provided by the hospital, including for diagnosis-related groups established under section 1395ww(d)(4) of this title.

(July 1, 1944, ch. 373, title XXVII, §2718, as added and amended Pub. L. 111–148, title I, §1001(5), title X, §10101(f), Mar. 23, 2010, 124 Stat. 136, 885.)

EDITORIAL NOTES

AMENDMENTS

2010—Pub. L. 111–148, §10101(f), amended section generally. Prior to amendment, the section related to clear accounting for costs, ensuring that consumers receive value for premiums, standard hospital charges, and definitions.

STATUTORY NOTES AND RELATED SUBSIDIARIES

EFFECTIVE DATE

Section effective for plan years beginning on or after the date that is 6 months after Mar. 23, 2010, see section 1004 of Pub. L. 111–148, set out as a note under section 300gg–11 of this title.

§300gg–19. Appeals process

(a) Internal claims appeals

(1) In general

A group health plan and a health insurance issuer offering group or individual health insurance coverage shall implement an effective appeals process for appeals of coverage determinations and claims, under which the plan or issuer shall, at a minimum—

(A) have in effect an internal claims appeal process;

(B) provide notice to enrollees, in a culturally and linguistically appropriate manner, of available internal and external appeals processes, and the availability of any applicable office of health insurance consumer assistance or ombudsman established under section 300gg–93 of this title to assist such enrollees with the appeals processes; and

(C) allow an enrollee to review their file, to present evidence and testimony as part of the appeals process, and to receive continued coverage pending the outcome of the appeals process.

(2) Established processes

To comply with paragraph (1)—

(A) a group health plan and a health insurance issuer offering group health coverage shall provide an internal claims and appeals process that initially incorporates the claims and appeals procedures (including urgent claims) set forth at section 2560.503–1 of title 29, Code of Federal Regulations, as published on November 21, 2000 (65 Fed. Reg. 70256), and shall update such process in accordance with any standards established by the Secretary of Labor for such plans and issuers; and

(B) a health insurance issuer offering individual health coverage, and any other issuer not subject to subparagraph (A), shall provide an internal claims and appeals process that initially incorporates the claims and appeals procedures set forth under applicable law (as in existence on March 23, 2010), and shall update such process in accordance with any standards established by the Secretary of Health and Human Services for such issuers.

(b) External review

A group health plan and a health insurance issuer offering group or individual health insurance coverage—

(1) shall comply with the applicable State external review process for such plans and issuers that, at a minimum, includes the consumer protections set forth in the Uniform External Review Model Act promulgated by the National Association of Insurance Commissioners and is binding on such plans; or

(2) shall implement an effective external review process that meets minimum standards established by the Secretary through guidance and that is similar to the process described under paragraph (1)—

(A) if the applicable State has not established an external review process that meets the requirements of paragraph (1); or

(B) if the plan is a self-insured plan that is not subject to State insurance regulation (including a State law that establishes an external review process described in paragraph (1)).

(c) Secretary authority

The Secretary may deem the external review process of a group health plan or health insurance issuer, in operation as of March 23, 2010, to be in compliance with the applicable process established under subsection (b), as determined appropriate by the Secretary.

(July 1, 1944, ch. 373, title XXVII, §2719, as added and amended Pub. L. 111–148, title I, §1001(5),

title X, §10101(g), Mar. 23, 2010, 124 Stat. 137, 887.)

EDITORIAL NOTES

AMENDMENTS

2010—Pub. L. 111–148, §10101(g), amended section generally. Prior to amendment, section related to implementation of appeals process by group health plans and health insurance issuers.

STATUTORY NOTES AND RELATED SUBSIDIARIES

EFFECTIVE DATE

Section effective for plan years beginning on or after the date that is 6 months after Mar. 23, 2010, see section 1004 of Pub. L. 111–148, set out as a note under section 300gg–11 of this title.

CONSUMER PROTECTIONS THROUGH APPLICATION OF HEALTH PLAN EXTERNAL REVIEW IN CASES OF CERTAIN SURPRISE MEDICAL BILLS

Pub. L. 116–260, div. BB, title I, §110, Dec. 27, 2020, 134 Stat. 2861, provided that:

"(a) IN GENERAL.—In applying the provisions of section 2719(b) of the Public Health Service Act (42 U.S.C. 300gg–19(b)) to group health plans and health insurance issuers offering group or individual health insurance coverage, the Secretary of Health and Human Services, Secretary of Labor, and Secretary of the Treasury, shall require, beginning not later than January 1, 2022, the external review process described in paragraph (1) of such section to apply with respect to any adverse determination by such a plan or issuer under section 2799A–1 or 2799A–2 [probably means section 2799A–1 or 2799A–2 of the Public Health Service Act, 42 U.S.C. 300gg–111, 300gg–112], section 716 or 717 of the Employee Retirement Income Security Act of 1974 [29 U.S.C. 1185e, 1185f], or section 9816 or 9817 of the Internal Revenue Code of 1986 [26 U.S.C. 9816, 9817], including with respect to whether an item or service that is the subject to such a determination is an item or service to which such respective section applies.

"(b) DEFINITIONS.—The terms 'group health plan'; 'health insurance issuer'; 'group health insurance coverage', and 'individual health insurance coverage' have the meanings given such terms in section 2791 of the Public Health Service Act (42 U.S.C. 300gg–91), section 733 of the Employee Retirement Income Security Act (29 U.S.C. 1191b), and section 9832 of the Internal Revenue Code [26 U.S.C. 9832], as applicable."

§300gg–19a. Patient protections

(a) Choice of health care professional

If a group health plan, or a health insurance issuer offering group or individual health insurance coverage, requires or provides for designation by a participant, beneficiary, or enrollee of a participating primary care provider, then the plan or issuer shall permit each participant, beneficiary, and enrollee to designate any participating primary care provider who is available to accept such individual.

(b) Coverage of emergency services

(1) In general

If a group health plan, or a health insurance issuer offering group or individual health insurance issuer,[1] provides or covers any benefits with respect to services in an emergency department of a hospital, the plan or issuer shall cover emergency services (as defined in paragraph (2)(B))—

(A) without the need for any prior authorization determination;

(B) whether the health care provider furnishing such services is a participating provider with respect to such services;

(C) in a manner so that, if such services are provided to a participant, beneficiary, or enrollee—

(i) by a nonparticipating health care provider with or without prior authorization; or

(ii)(I) such services will be provided without imposing any requirement under the plan for

prior authorization of services or any limitation on coverage where the provider of services does not have a contractual relationship with the plan for the providing of services that is more restrictive than the requirements or limitations that apply to emergency department services received from providers who do have such a contractual relationship with the plan; and

(II) if such services are provided out-of-network, the cost-sharing requirement (expressed as a copayment amount or coinsurance rate) is the same requirement that would apply if such services were provided in-network; [2]

(D) without regard to any other term or condition of such coverage (other than exclusion or coordination of benefits, or an affiliation or waiting period, permitted under section 2701 [3] of this Act, section 1181 of title 29, or section 9801 of title 26, and other than applicable cost-sharing).

(2) Definitions

In this subsection:

(A) Emergency medical condition

The term "emergency medical condition" means a medical condition manifesting itself by acute symptoms of sufficient severity (including severe pain) such that a prudent layperson, who possesses an average knowledge of health and medicine, could reasonably expect the absence of immediate medical attention to result in a condition described in clause (i), (ii), or (iii) of section 1395dd(e)(1)(A) of this title.

(B) Emergency services

The term "emergency services" means, with respect to an emergency medical condition—

(i) a medical screening examination (as required under section 1395dd of this title) that is within the capability of the emergency department of a hospital, including ancillary services routinely available to the emergency department to evaluate such emergency medical condition, and

(ii) within the capabilities of the staff and facilities available at the hospital, such further medical examination and treatment as are required under section 1395dd of this title to stabilize the patient.

(C) Stabilize

The term "to stabilize", with respect to an emergency medical condition (as defined in subparagraph (A)), has the meaning give [4] in section 1395dd(e)(3) of this title.

(c) Access to pediatric care

(1) Pediatric care

In the case of a person who has a child who is a participant, beneficiary, or enrollee under a group health plan, or health insurance coverage offered by a health insurance issuer in the group or individual market, if the plan or issuer requires or provides for the designation of a participating primary care provider for the child, the plan or issuer shall permit such person to designate a physician (allopathic or osteopathic) who specializes in pediatrics as the child's primary care provider if such provider participates in the network of the plan or issuer.

(2) Construction

Nothing in paragraph (1) shall be construed to waive any exclusions of coverage under the terms and conditions of the plan or health insurance coverage with respect to coverage of pediatric care.

(d) Patient access to obstetrical and gynecological care

(1) General rights

(A) Direct access

A group health plan, or health insurance issuer offering group or individual health insurance coverage, described in paragraph (2) may not require authorization or referral by the plan, issuer, or any person (including a primary care provider described in paragraph (2)(B)) in the case of a female participant, beneficiary, or enrollee who seeks coverage for obstetrical or gynecological care provided by a participating health care professional who specializes in obstetrics or gynecology. Such professional shall agree to otherwise adhere to such plan's or issuer's policies and procedures, including procedures regarding referrals and obtaining prior authorization and providing services pursuant to a treatment plan (if any) approved by the plan or issuer.

(B) Obstetrical and gynecological care

A group health plan or health insurance issuer described in paragraph (2) shall treat the provision of obstetrical and gynecological care, and the ordering of related obstetrical and gynecological items and services, pursuant to the direct access described under subparagraph (A), by a participating health care professional who specializes in obstetrics or gynecology as the authorization of the primary care provider.

(2) Application of paragraph

A group health plan, or health insurance issuer offering group or individual health insurance coverage, described in this paragraph is a group health plan or coverage that—

(A) provides coverage for obstetric or gynecologic care; and

(B) requires the designation by a participant, beneficiary, or enrollee of a participating primary care provider.

(3) Construction

Nothing in paragraph (1) shall be construed to—

(A) waive any exclusions of coverage under the terms and conditions of the plan or health insurance coverage with respect to coverage of obstetrical or gynecological care; or

(B) preclude the group health plan or health insurance issuer involved from requiring that the obstetrical or gynecological provider notify the primary care health care professional or the plan or issuer of treatment decisions.

(e) Application

The provisions of this section shall not apply with respect to a group health plan, health insurance issuers, or group or individual health insurance coverage with respect to plan years beginning on or on [5] January 1, 2022.

(July 1, 1944, ch. 373, title XXVII, §2719A, as added Pub. L. 111–148, title X, §10101(h), Mar. 23, 2010, 124 Stat. 888; amended Pub. L. 116–260, div. BB, title I, §102(a)(3)(A), Dec. 27, 2020, 134 Stat. 2771.)

EDITORIAL NOTES

REFERENCES IN TEXT

Section 2701 of this Act, referred to in subsec. (b)(1)(D), is a reference to section 2701 of act July 1, 1944. Section 2701, which was classified to section 300gg of this title, was renumbered section 2704, effective for plan years beginning on or after Jan. 1, 2014, with certain exceptions, and amended, by Pub. L. 111–148, title I, §§1201(2), 1563(c)(1), formerly §1562(c)(1), title X, §10107(b)(1), Mar. 23, 2010, 124 Stat. 154, 264, 911, and was transferred to section 300gg–3 of this title. A new section 2701 of act July 1, 1944, related to fair health insurance premiums, was added, effective for plan years beginning on or after Jan. 1, 2014, and amended, by Pub. L. 111–148, title I, §1201(4), title X, §10103(a), Mar. 23, 2010, 124 Stat. 155, 892, and is classified to section 300gg of this title.

CODIFICATION

Pub. L. 111–148, which directed amendment of subpart II of part A of "title XVIII" of act July 1, 1944, by

inserting section 2719A after section 2719, was executed by making the insertion in subpart II of part A of title XXVII of the Act, to reflect the probable intent of Congress.

AMENDMENTS

2020—Subsec. (e). Pub. L. 116–260 added subsec. (e).

STATUTORY NOTES AND RELATED SUBSIDIARIES

EFFECTIVE DATE OF 2020 AMENDMENT

Amendment by Pub. L. 116–260 applicable with respect to plan years beginning on or after Jan. 1, 2022, see section 102(e) of div. BB of Pub. L. 116–260, set out as a note under section 8902 of Title 5, Government Organization and Employees.

[1] So in original. Probably should be "coverage,".

[2] So in original. The word "and" probably should appear.

[3] See References in Text note below.

[4] So in original. Probably should be "given".

[5] So in original.

§300gg–19b. Information on prescription drugs

(a) In general

A group health plan or a health insurance issuer offering group or individual health insurance coverage shall—

(1) not restrict, directly or indirectly, any pharmacy that dispenses a prescription drug to an enrollee in the plan or coverage from informing (or penalize such pharmacy for informing) an enrollee of any differential between the enrollee's out-of-pocket cost under the plan or coverage with respect to acquisition of the drug and the amount an individual would pay for acquisition of the drug without using any health plan or health insurance coverage; and

(2) ensure that any entity that provides pharmacy benefits management services under a contract with any such health plan or health insurance coverage does not, with respect to such plan or coverage, restrict, directly or indirectly, a pharmacy that dispenses a prescription drug from informing (or penalize such pharmacy for informing) an enrollee of any differential between the enrollee's out-of-pocket cost under the plan or coverage with respect to acquisition of the drug and the amount an individual would pay for acquisition of the drug without using any health plan or health insurance coverage.

(b) Definition

For purposes of this section, the term "out-of-pocket cost", with respect to acquisition of a drug, means the amount to be paid by the enrollee under the plan or coverage, including any cost-sharing (including any deductible, copayment, or coinsurance) and, as determined by the Secretary, any other expenditure.

(July 1, 1944, ch. 373, title XXVII, §2729, as added Pub. L. 115–263, §2, Oct. 10, 2018, 132 Stat. 3672.)

SUBPART 2—EXCLUSION OF PLANS; ENFORCEMENT; PREEMPTION

EDITORIAL NOTES

CODIFICATION

This subpart 2 designation and heading was transferred along with sections 300gg–21 to 300gg–23 of this title to appear before section 300gg–25 of this title to reflect the renumbering of the sections in the original act by Pub. L. 111–148, title I, §§1001(4), 1563(c)(12)(D), (13)(C), (14)(B), formerly §1562(c)(12)(D), (13)(C), (14)(B), title X, §10107(b)(1), Mar. 23, 2010, 124 Stat. 130, 269, 911.

Pub. L. 111–148, title I, §1563(c)(11), formerly §1562(c)(11), title X, §10107(b)(1), Mar. 23, 2010, 124 Stat. 268, 911, redesignated subpart 4 as subpart 2.

Pub. L. 104–204, title VI, §604(a)(2), Sept. 26, 1996, 110 Stat. 2939, redesignated subpart 3 as 4.

§300gg–21. Exclusion of certain plans

(a) Limitation on application of provisions relating to group health plans

(1) In general

The requirements of subparts 1 and 2 [1] and part D shall apply with respect to group health plans only—

(A) subject to paragraph (2), in the case of a plan that is a nonfederal governmental plan, and

(B) with respect to health insurance coverage offered in connection with a group health plan (including such a plan that is a church plan or a governmental plan).

(2) Treatment of non-Federal governmental plans

(A) Election to be excluded

Except as provided in subparagraph (D) or (E), if the plan sponsor of a nonfederal governmental plan which is a group health plan to which the provisions of subparts 1 and 2 [1] otherwise apply makes an election under this subparagraph (in such form and manner as the Secretary may by regulations prescribe), then the requirements of such subparts insofar as they apply directly to group health plans (and not merely to group health insurance coverage) shall not apply to such governmental plans for such period except as provided in this paragraph.

(B) Period of election

An election under subparagraph (A) shall apply—

(i) for a single specified plan year, or

(ii) in the case of a plan provided pursuant to a collective bargaining agreement, for the term of such agreement.

An election under clause (i) may be extended through subsequent elections under this paragraph.

(C) Notice to enrollees

Under such an election, the plan shall provide for—

(i) notice to enrollees (on an annual basis and at the time of enrollment under the plan) of the fact and consequences of such election, and

(ii) certification and disclosure of creditable coverage under the plan with respect to enrollees in accordance with section 2701(e).[1]

(D) Election not applicable to requirements concerning genetic information

The election described in subparagraph (A) shall not be available with respect to the provisions of subsections (a)(1)(F), (b)(3), (c), and (d) of section 2702 [1] and the provisions of sections 2701 [1] and 2702(b) [1] to the extent that such provisions apply to genetic information.

(E) Election not applicable

The election described in subparagraph (A) shall not be available with respect to the provisions of subparts I and II.

(F) Sunset of election option

(i) In general

Notwithstanding the preceding provisions of this paragraph—

(I) no election described in subparagraph (A) with respect to section 300gg–26 of this title may be made on or after December 29, 2022; and

(II) except as provided in clause (ii), no such election with respect to section 300gg–26 of this title expiring on or after the date that is 180 days after December 29, 2022, may be renewed.

(ii) Exception for certain collectively bargained plans

Notwithstanding clause (i)(II), a plan described in subparagraph (B)(ii) that is subject to multiple agreements described in such subparagraph of varying lengths and that has an election described in subparagraph (A) with respect to section 300gg–26 of this title in effect as of December 29, 2022, that expires on or after the date that is 180 days after December 29, 2022, may extend such election until the date on which the term of the last such agreement expires.

(b) Exception for certain benefits

The requirements of subparts 1 and 2 [1] and part D shall not apply to any individual coverage or any group health plan (or group health insurance coverage) in relation to its provision of excepted benefits described in section 300gg–91(c)(1) of this title.

(c) Exception for certain benefits if certain conditions met

(1) Limited, excepted benefits

The requirements of subparts 1 and 2 [1] and part D shall not apply to any individual coverage or any group health plan (and group health insurance coverage offered in connection with a group health plan) in relation to its provision of excepted benefits described in section 300gg–91(c)(2) of this title if the benefits—

(A) are provided under a separate policy, certificate, or contract of insurance; or

(B) are otherwise not an integral part of the plan.

(2) Noncoordinated, excepted benefits

The requirements of subparts 1 and 2 [1] and part D shall not apply to any individual coverage or any group health plan (and group health insurance coverage offered in connection with a group health plan) in relation to its provision of excepted benefits described in section 300gg–91(c)(3) of this title if all of the following conditions are met:

(A) The benefits are provided under a separate policy, certificate, or contract of insurance.

(B) There is no coordination between the provision of such benefits and any exclusion of benefits under any group health plan maintained by the same plan sponsor.

(C) Such benefits are paid with respect to an event without regard to whether benefits are provided with respect to such an event under any group health plan maintained by the same plan sponsor or, with respect to individual coverage, under any health insurance coverage maintained by the same health insurance issuer.

(3) Supplemental excepted benefits

The requirements of this part and part D shall not apply to any individual coverage or any group health plan (and group health insurance coverage) in relation to its provision of excepted benefits described in section 300gg–91(c)(4) [1] of this title if the benefits are provided under a separate policy, certificate, or contract of insurance.

(d) Treatment of partnerships

For purposes of this part and part D—

(1) Treatment as a group health plan

Any plan, fund, or program which would not be (but for this subsection) an employee welfare benefit plan and which is established or maintained by a partnership, to the extent that such plan, fund, or program provides medical care (including items and services paid for as medical care) to present or former partners in the partnership or to their dependents (as defined under the terms of the plan, fund, or program), directly or through insurance, reimbursement, or otherwise, shall be treated (subject to paragraph (2)) as an employee welfare benefit plan which is a group health plan.

(2) Employer

In the case of a group health plan, the term "employer" also includes the partnership in relation to any partner.

(3) Participants of group health plans

In the case of a group health plan, the term "participant" also includes—

(A) in connection with a group health plan maintained by a partnership, an individual who is a partner in relation to the partnership, or

(B) in connection with a group health plan maintained by a self-employed individual (under which one or more employees are participants), the self-employed individual,

if such individual is, or may become, eligible to receive a benefit under the plan or such individual's beneficiaries may be eligible to receive any such benefit.

(July 1, 1944, ch. 373, title XXVII, §2722, formerly §2721, as added Pub. L. 104–191, title I, §102(a), Aug. 21, 1996, 110 Stat. 1967; amended Pub. L. 104–204, title VI, §604(b)(1), Sept. 26, 1996, 110 Stat. 2940; Pub. L. 110–233, title I, §102(c), May 21, 2008, 122 Stat. 895; renumbered §2735, renumbered §2722, and amended Pub. L. 111–148, title I, §§1001(4), 1563(a), (c)(12), formerly §1562(a), (c)(12), title X, §10107(a), (b)(1), Mar. 23, 2010, 124 Stat. 130, 264, 268, 911; Pub. L. 116–260, div. BB, title I, §102(a)(3)(B), Dec. 27, 2020, 134 Stat. 2772; Pub. L. 117–328, div. FF, title I, §1321, Dec. 29, 2022, 136 Stat. 5697.)

EDITORIAL NOTES

REFERENCES IN TEXT

Subparts 1 and 2, referred to in subsecs. (a)(1), (2)(A), (b), and (c)(1), (2), were amended by Pub. L. 111–148, title I, §§1001(5), 1201(1), 1563(c)(2), (11), formerly §1562(c)(2), (11), title X, §10107(b)(1), Mar. 23, 2010, 124 Stat. 130, 154, 265, 268, 911. The subpart 1 designation and heading "PORTABILITY, ACCESS, AND RENEWABILITY REQUIREMENTS" were struck out and a new subpart I designation and heading "GENERAL REFORM" were enacted preceding section 300gg of this title, effective for plan years beginning on or after Jan. 1, 2014. A new subpart II designation and heading "IMPROVING COVERAGE" were enacted preceding section 300gg–11 of this title. The subpart 2 designation and heading "OTHER REQUIREMENTS" were struck out preceding section 300gg–4 of this title, and subpart 4 was redesignated as subpart 2 "EXCLUSION OF PLANS; ENFORCEMENT; PREEMPTION" preceding section 300gg–21 of this title.

Section 2701, referred to in subsec. (a)(2)(C)(ii), (D), is a reference to section 2701 of act July 1, 1944. Section 2701, which was classified to section 300gg of this title, was renumbered section 2704, effective for plan years beginning on or after Jan. 1, 2014, with certain exceptions, and amended, by Pub. L. 111–148, title I, §§1201(2), 1563(c)(1), formerly §1562(c)(1), title X, §10107(b)(1), Mar. 23, 2010, 124 Stat. 154, 264, 911, and was transferred to section 300gg–3 of this title. A new section 2701 of act July 1, 1944, related to fair health insurance premiums, was added, effective for plan years beginning on or after Jan. 1, 2014, and amended, by Pub. L. 111–148, title I, §1201(4), title X, §10103(a), Mar. 23, 2010, 124 Stat. 155, 892, and is classified to section 300gg of this title.

Section 2702, referred to in subsec. (a)(2)(D), is a reference to section 2702 of act July 1, 1944. Section 2702, which was classified to section 300gg–1 of this title, was amended by Pub. L. 111–148, title I, §1201(3), Mar. 23, 2010, 124 Stat. 154, and was transferred to subsecs. (b) to (f) of section 300gg–4 of this

title, effective for plan years beginning on or after Jan. 1, 2014. A new section 2702 of act July 1, 1944, related to guaranteed availability of coverage, was added by Pub. L. 111–148, title I, §1201(4), Mar. 23, 2010, 124 Stat. 156, effective for plan years beginning on or after Jan. 1, 2014, and is classified to section 300gg–1 of this title.

Section 300gg–91(c)(4) of this title, referred to in subsec. (c)(3), was in the original "section 27971(c)(4)" and was translated as reading "section 2791(c)(4)", meaning section 2791(c)(4) of act July 1, 1944, as added by Pub. L. 104–191, §102(a), to reflect the probable intent of Congress. Act July 1, 1944, does not contain a section 27971.

PRIOR PROVISIONS

A prior section 2722 of act July 1, 1944, was renumbered section 2723 and is classified to section 300gg–22 of this title.

AMENDMENTS

2022—Subsec. (a)(2)(F). Pub. L. 117–328 added subpar. (F).

2020—Subsecs. (a)(1), (b), (c)(1), (2). Pub. L. 116–260, §102(a)(3)(B)(i)–(iv), inserted "and part D" after "subparts 1 and 2" in introductory provisions of subsecs. (a)(1) and (c)(1), (2) and in subsec. (b).

Subsecs. (c)(3), (d). Pub. L. 116–260, §102(a)(3)(B)(v), (vi), inserted "and part D" after "this part".

2010—Pub. L. 111–148, §1563(c)(12)(B), formerly §1562(c)(12)(B), as renumbered by Pub. L. 111–148, §10107(b)(1), which directed amendment of section by substituting "subpart 1" for "subparts 1 through 3" wherever appearing, could not be executed because the words "subparts 1 through 3" did not appear subsequent to amendments by section 1563(a)(2)(A), (B)(ii), (3), (4)(A), (B)(i) of Pub. L. 111–148. See below.

Subsec. (a). Pub. L. 111–148, §1563(c)(12)(C), formerly §1562(c)(12)(C), as renumbered by Pub. L. 111–148, §10107(b)(1), redesignated subsec. (b) as (a).

Pub. L. 111–148, §§1563(a)(1) and 1563(c)(12)(A), formerly §§1562(a)(1) and 1562(c)(12)(A), as renumbered by Pub. L. 111–148, §10107(b)(1), made identical amendment, striking out subsec. (a). Prior to amendment, text read as follows: "The requirements of subparts 1 and 3 shall not apply to any group health plan (and health insurance coverage offered in connection with a group health plan) for any plan year if, on the first day of such plan year, such plan has less than 2 participants who are current employees."

Subsec. (b). Pub. L. 111–148, §1563(c)(12)(C), formerly §1562(c)(12)(C), as renumbered by Pub. L. 111–148, §10107(b)(1), redesignated subsec. (c) as (b). Former subsec. (b) redesignated (a).

Pub. L. 111–148, §1563(a)(2)(A), formerly §1562(a)(2)(A), as renumbered by Pub. L. 111–148, §10107(b)(1), substituted "subparts 1 and 2" for "subparts 1 through 3" in introductory provisions.

Pub. L. 111–148, §1563(a)(2)(B)(ii), formerly §1562(a)(2)(B)(ii), as renumbered by Pub. L. 111–148, §10107(b)(1), substituted "subparts 1 and 2" for "subparts 1 through 3".

Pub. L. 111–148, §1563(a)(2)(B)(i), formerly §1562(a)(2)(B)(i), as renumbered by Pub. L. 111–148, §10107(b)(1), substituted "subparagraph (D) or (E)" for "subparagraph (D)".

Subsec. (b)(2)(E). Pub. L. 111–148, §10107(a), substituted "subparts I and II" for "subpart 1".

Pub. L. 111–148, §1563(a)(2)(B)(iii), formerly §1562(a)(2)(B)(iii), as renumbered by Pub. L. 111–148, §10107(b)(1), added subpar. (E).

Subsec. (c). Pub. L. 111–148, §1563(c)(12)(C), formerly §1562(c)(12)(C), as renumbered by Pub. L. 111–148, §10107(b)(1), redesignated subsec. (d) as (c). Former subsec. (c) redesignated (b).

Pub. L. 111–148, §1563(a)(3), formerly §1562(a)(3), as renumbered by Pub. L. 111–148, §10107(b)(1), substituted "subparts 1 and 2 shall not apply to any individual coverage or any group" for "subparts 1 through 3 shall not apply to any group".

Subsec. (d). Pub. L. 111–148, §1563(c)(12)(C), formerly §1562(c)(12)(C), as renumbered by Pub. L. 111–148, §10107(b)(1), redesignated subsec. (e) as (d). Former subsec. (d) redesignated (c).

Pub. L. 111–148, §1563(a)(4)(A), formerly §1562(a)(4)(A), as renumbered by Pub. L. 111–148, §10107(b)(1), substituted "subparts 1 and 2 shall not apply to any individual coverage or any group" for "subparts 1 through 3 shall not apply to any group" in introductory provisions.

Pub. L. 111–148, §1563(a)(4)(B)(i), formerly §1562(a)(4)(B)(i), as renumbered by Pub. L. 111–148, §10107(b)(1), substituted "subparts 1 and 2 shall not apply to any individual coverage or any group" for "subparts 1 through 3 shall not apply to any group" in introductory provisions.

Subsec. (d)(2)(C). Pub. L. 111–148, §1563(a)(4)(B)(ii), formerly §1562(a)(4)(B)(ii), as renumbered by Pub. L. 111–148, §10107(b)(1), which directed amendment of subpar. (C) by inserting "or, with respect to

individual coverage, under any health insurance coverage maintained by the same health insurance issuer" without language specifying placement, was executed by making the insertion before period at end to reflect the probable intent of Congress.

Subsec. (d)(3). Pub. L. 111–148, §1563(a)(4)(C), formerly §1562(a)(4)(C), as renumbered by Pub. L. 111–148, §10107(b)(1), substituted "any individual coverage or any group" for "any group".

Subsec. (e). Pub. L. 111–148, §1563(c)(12)(C), formerly §1562(c)(12)(C), as renumbered by Pub. L. 111–148, §10107(b)(1), redesignated subsec. (e) as (d).

2008—Subsec. (b)(2)(A). Pub. L. 110–233, §102(c)(1), substituted "Except as provided in subparagraph (D), if the plan sponsor" for "If the plan sponsor".

Subsec. (b)(2)(D). Pub. L. 110–233, §102(c)(2), added subpar. (D).

1996—Subsec. (a). Pub. L. 104–204, §604(b)(1)(A), substituted "subparts 1 and 3" for "subparts 1 and 2".

Subsecs. (b) to (d). Pub. L. 104–204, §604(b)(1)(B), substituted "subparts 1 through 3" for "subparts 1 and 2" wherever appearing.

STATUTORY NOTES AND RELATED SUBSIDIARIES

EFFECTIVE DATE OF 2020 AMENDMENT

Amendment by Pub. L. 116–260 applicable with respect to plan years beginning on or after Jan. 1, 2022, see section 102(e) of div. BB of Pub. L. 116–260, set out as a note under section 8902 of Title 5, Government Organization and Employees.

EFFECTIVE DATE OF 2008 AMENDMENT

Pub. L. 110–233, title I, §102(d)(2), May 21, 2008, 122 Stat. 895, provided that: "The amendments made by this section [enacting section 300gg–53 of this title and amending this section and sections 300gg–1, 300gg–22, 300gg–61, and 300gg–91 of this title] shall apply—

"(A) with respect to group health plans, and health insurance coverage offered in connection with group health plans, for plan years beginning after the date that is 1 year after the date of enactment of this Act [May 21, 2008]; and

"(B) with respect to health insurance coverage offered, sold, issued, renewed, in effect, or operated in the individual market after the date that is 1 year after the date of enactment of this Act."

EFFECTIVE DATE OF 1996 AMENDMENT

Amendment by Pub. L. 104–204 applicable with respect to group health plans for plan years beginning on or after Jan. 1, 1998, see section 604(c) of Pub. L. 104–204 set out as an Effective Date note under section 300gg–25 of this title.

EFFECTIVE DATE

Section applicable with respect to group health plans, and health insurance coverage offered in connection with group health plans, for plan years beginning after June 30, 1997, except as otherwise provided, see section 102(c) of Pub. L. 104–191, set out as a note under section 300gg of this title.

REGULATIONS

Pub. L. 110–233, title I, §102(d)(1), May 21, 2008, 122 Stat. 895, provided that: "Not later than 12 months after the date of enactment of this Act [May 21, 2008], the Secretary of Health and Human Services shall issue final regulations to carry out the amendments made by this section [see Effective Date of 2008 Amendment note above]."

ASSURING COORDINATION

Pub. L. 110–233, title I, §106, May 21, 2008, 122 Stat. 905, provided that: "Except as provided in section 105(b)(1) [42 U.S.C. 1320d–9 note], the Secretary of Health and Human Services, the Secretary of Labor, and the Secretary of the Treasury shall ensure, through the execution of an interagency memorandum of understanding among such Secretaries, that—

"(1) regulations, rulings, and interpretations issued by such Secretaries relating to the same matter over which two or more such Secretaries have responsibility under this title [enacting sections 300gg–53 and 1320d–9 of this title and section 9834 of Title 26, Internal Revenue Code, amending this section, sections 300gg–1, 300gg–22, 300gg–61, 300gg–91, and 1395ss of this title, sections 9802 and 9832 of Title 26, and

sections 1132, 1182, and 1191b of Title 29, Labor, and enacting provisions set out as notes under this section, sections 1320d–9 and 1395ss of this title, section 9802 of Title 26, and section 1132 of Title 29] (and the amendments made by this title) are administered so as to have the same effect at all times; and

"(2) coordination of policies relating to enforcing the same requirements through such Secretaries in order to have a coordinated enforcement strategy that avoids duplication of enforcement efforts and assigns priorities in enforcement."

[1] *See References in Text note below.*

§300gg–22. Enforcement

(a) State enforcement

(1) State authority

Subject to section 300gg–23 [1] of this title, each State may require that health insurance issuers that issue, sell, renew, or offer health insurance coverage in the State in the individual or group market meet the requirements of this part and part D (other than section 300gg–121 of this title) with respect to such issuers.

(2) Failure to implement provisions

In the case of a determination by the Secretary that a State has failed to substantially enforce a provision (or provisions) in this part or part D (other than section 300gg–121 of this title) with respect to health insurance issuers in the State, the Secretary shall enforce such provision (or provisions) under subsection (b) insofar as they relate to the issuance, sale, renewal, and offering of health insurance coverage in connection with group health plans or individual health insurance coverage in such State.

(b) Secretarial enforcement authority

(1) Limitation

The provisions of this subsection shall apply to enforcement of a provision (or provisions) of this part or part D (other than section 300gg–121 of this title) only—

(A) as provided under subsection (a)(2); and

(B) with respect to individual health insurance coverage or group health plans that are non-Federal governmental plans.

(2) Imposition of penalties

In the cases described in paragraph (1)—

(A) In general

Subject to the succeeding provisions of this subsection, any non-Federal governmental plan that is a group health plan and any health insurance issuer that fails to meet a provision of this part or part D (other than section 300gg–121 of this title) applicable to such plan or issuer is subject to a civil money penalty under this subsection.

(B) Liability for penalty

In the case of a failure by—

(i) a health insurance issuer, the issuer is liable for such penalty, or

(ii) a group health plan that is a non-Federal governmental plan which is—

(I) sponsored by 2 or more employers, the plan is liable for such penalty, or

(II) not so sponsored, the employer is liable for such penalty.

(C) Amount of penalty

(i) In general

The maximum amount of penalty imposed under this paragraph is $100 for each day for

each individual with respect to which such a failure occurs.

(ii) Considerations in imposition

In determining the amount of any penalty to be assessed under this paragraph, the Secretary shall take into account the previous record of compliance of the entity being assessed with the applicable provisions of this part and part D (other than section 300gg–121 of this title) and the gravity of the violation.

(iii) Limitations

(I) Penalty not to apply where failure not discovered exercising reasonable diligence

No civil money penalty shall be imposed under this paragraph on any failure during any period for which it is established to the satisfaction of the Secretary that none of the entities against whom the penalty would be imposed knew, or exercising reasonable diligence would have known, that such failure existed.

(II) Penalty not to apply to failures corrected within 30 days

No civil money penalty shall be imposed under this paragraph on any failure if such failure was due to reasonable cause and not to willful neglect, and such failure is corrected during the 30-day period beginning on the first day any of the entities against whom the penalty would be imposed knew, or exercising reasonable diligence would have known, that such failure existed.

(D) Administrative review

(i) Opportunity for hearing

The entity assessed shall be afforded an opportunity for hearing by the Secretary upon request made within 30 days after the date of the issuance of a notice of assessment. In such hearing the decision shall be made on the record pursuant to section 554 of title 5. If no hearing is requested, the assessment shall constitute a final and unappealable order.

(ii) Hearing procedure

If a hearing is requested, the initial agency decision shall be made by an administrative law judge, and such decision shall become the final order unless the Secretary modifies or vacates the decision. Notice of intent to modify or vacate the decision of the administrative law judge shall be issued to the parties within 30 days after the date of the decision of the judge. A final order which takes effect under this paragraph shall be subject to review only as provided under subparagraph (E).

(E) Judicial review

(i) Filing of action for review

Any entity against whom an order imposing a civil money penalty has been entered after an agency hearing under this paragraph may obtain review by the United States district court for any district in which such entity is located or the United States District Court for the District of Columbia by filing a notice of appeal in such court within 30 days from the date of such order, and simultaneously sending a copy of such notice by registered mail to the Secretary.

(ii) Certification of administrative record

The Secretary shall promptly certify and file in such court the record upon which the penalty was imposed.

(iii) Standard for review

The findings of the Secretary shall be set aside only if found to be unsupported by substantial evidence as provided by section 706(2)(E) of title 5.

(iv) Appeal

Any final decision, order, or judgment of the district court concerning such review shall be

subject to appeal as provided in chapter 83 of title 28.

(F) Failure to pay assessment; maintenance of action

(i) Failure to pay assessment

If any entity fails to pay an assessment after it has become a final and unappealable order, or after the court has entered final judgment in favor of the Secretary, the Secretary shall refer the matter to the Attorney General who shall recover the amount assessed by action in the appropriate United States district court.

(ii) Nonreviewability

In such action the validity and appropriateness of the final order imposing the penalty shall not be subject to review.

(G) Payment of penalties

Except as otherwise provided, penalties collected under this paragraph shall be paid to the Secretary (or other officer) imposing the penalty and shall be available without appropriation and until expended for the purpose of enforcing the provisions with respect to which the penalty was imposed.

(3) Enforcement authority relating to genetic discrimination

(A) General rule

In the cases described in paragraph (1), notwithstanding the provisions of paragraph (2)(C), the succeeding subparagraphs of this paragraph shall apply with respect to an action under this subsection by the Secretary with respect to any failure of a health insurance issuer in connection with a group health plan, to meet the requirements of subsection (a)(1)(F), (b)(3), (c), or (d) of section 2702 [1] or section 2701 [1] or 2702(b)(1) [1] with respect to genetic information in connection with the plan.

(B) Amount

(i) In general

The amount of the penalty imposed under this paragraph shall be $100 for each day in the noncompliance period with respect to each participant or beneficiary to whom such failure relates.

(ii) Noncompliance period

For purposes of this paragraph, the term "noncompliance period" means, with respect to any failure, the period—

(I) beginning on the date such failure first occurs; and

(II) ending on the date the failure is corrected.

(C) Minimum penalties where failure discovered

Notwithstanding clauses (i) and (ii) of subparagraph (D):

(i) In general

In the case of 1 or more failures with respect to an individual—

(I) which are not corrected before the date on which the plan receives a notice from the Secretary of such violation; and

(II) which occurred or continued during the period involved;

the amount of penalty imposed by subparagraph (A) by reason of such failures with respect to such individual shall not be less than $2,500.

(ii) Higher minimum penalty where violations are more than de minimis

To the extent violations for which any person is liable under this paragraph for any year are more than de minimis, clause (i) shall be applied by substituting "$15,000" for "$2,500"

with respect to such person.

(D) Limitations

(i) Penalty not to apply where failure not discovered exercising reasonable diligence

No penalty shall be imposed by subparagraph (A) on any failure during any period for which it is established to the satisfaction of the Secretary that the person otherwise liable for such penalty did not know, and exercising reasonable diligence would not have known, that such failure existed.

(ii) Penalty not to apply to failures corrected within certain periods

No penalty shall be imposed by subparagraph (A) on any failure if—

(I) such failure was due to reasonable cause and not to willful neglect; and

(II) such failure is corrected during the 30-day period beginning on the first date the person otherwise liable for such penalty knew, or exercising reasonable diligence would have known, that such failure existed.

(iii) Overall limitation for unintentional failures

In the case of failures which are due to reasonable cause and not to willful neglect, the penalty imposed by subparagraph (A) for failures shall not exceed the amount equal to the lesser of—

(I) 10 percent of the aggregate amount paid or incurred by the employer (or predecessor employer) during the preceding taxable year for group health plans; or

(II) $500,000.

(E) Waiver by Secretary

In the case of a failure which is due to reasonable cause and not to willful neglect, the Secretary may waive part or all of the penalty imposed by subparagraph (A) to the extent that the payment of such penalty would be excessive relative to the failure involved.

(July 1, 1944, ch. 373, title XXVII, §2723, formerly §2722, as added Pub. L. 104–191, title I, §102(a), Aug. 21, 1996, 110 Stat. 1968; amended Pub. L. 110–233, title I, §102(a)(5), May 21, 2008, 122 Stat. 891; renumbered §2736, renumbered §2723, and amended Pub. L. 111–148, title I, §§1001(4), 1563(c)(13), formerly §1562(c)(13), title X, §10107(b)(1), Mar. 23, 2010, 124 Stat. 130, 269, 911; Pub. L. 116–260, div. BB, title I, §102(a)(3)(C), Dec. 27, 2020, 134 Stat. 2772; Pub. L. 119–75, div. J, title VII, §6701(a)(2), Feb. 3, 2026, 140 Stat. 713.)

EDITORIAL NOTES

REFERENCES IN TEXT

Section 300gg–23 of this title, referred to in subsec. (a)(1), was in the original section "2723", and was translated as meaning section 2724 of act July 1, 1944, to reflect the probable intent of Congress and the renumbering of section 2723 as 2724 by Pub. L. 111–148, title I, §§1001(4), 1563(c)(14)(B), formerly §1562(c)(14)(B), title X, §10107(b)(1), Mar. 23, 2010, 124 Stat. 130, 269, 911.

Section 2702, referred to in subsec. (b)(3)(A), is a reference to section 2702 of act July 1, 1944. Section 2702, which was classified to section 300gg–1 of this title, was amended by Pub. L. 111–148, title I, §1201(3), Mar. 23, 2010, 124 Stat. 154, and was transferred to subsecs. (b) to (f) of section 300gg–4 of this title, effective for plan years beginning on or after Jan. 1, 2014. A new section 2702, related to guaranteed availability of coverage, was added by Pub. L. 111–148, title I, §1201(4), Mar. 23, 2010, 124 Stat. 156, effective for plan years beginning on or after Jan. 1, 2014, and is classified to section 300gg–1 of this title.

Section 2701, referred to in subsec. (b)(3)(A), is a reference to section 2701 of act July 1, 1944. Section 2701, which was classified to section 300gg of this title, was renumbered section 2704, effective for plan years beginning on or after Jan. 1, 2014, with certain exceptions, and amended, by Pub. L. 111–148, title I, §§1201(2), 1563(c)(1), formerly §1562(c)(1), title X, §10107(b)(1), Mar. 23, 2010, 124 Stat. 154, 264, 911, and was transferred to section 300gg–3 of this title. A new section 2701 of act July 1, 1944, related to fair health insurance premiums, was added, effective for plan years beginning on or after Jan. 1, 2014, and amended, by Pub. L. 111–148, title I, §1201(4), title X, §10103(a), Mar. 23, 2010, 124 Stat. 155, 892, and is classified to section 300gg of this title.

PRIOR PROVISIONS

A prior section 2723 of act July 1, 1944, was renumbered section 2724 and is classified to section 300gg–23 of this title.

AMENDMENTS

2026—Pub. L. 119–75 inserted "(other than section 300gg–121 of this title" after "part D" wherever appearing.

2020—Subsec. (a)(1). Pub. L. 116–260, §102(a)(3)(C)(i), inserted "and part D" after "this part".

Subsecs. (a)(2), (b)(1), (2)(A). Pub. L. 116–260, §102(a)(3)(C)(ii)–(iv), inserted "or part D" after "this part".

Subsec. (b)(2)(C)(ii). Pub. L. 116–260, §102(a)(3)(C)(v), inserted "and part D" after "this part".

2010—Subsec. (a)(1). Pub. L. 111–148, §1563(c)(13)(A)(i), formerly §1562(c)(13)(A)(i), as renumbered by Pub. L. 111–148, §10107(b)(1), substituted "individual or group market" for "small or large group markets".

Subsec. (a)(2). Pub. L. 111–148, §1563(c)(13)(a)(ii), formerly §1562(c)(13)(A)(ii), as renumbered by Pub. L. 111–148, §10107(b)(1), inserted "or individual health insurance coverage" after "group health plans".

Subsec. (b)(1)(B). Pub. L. 111–148, §1563(c)(13)(B), formerly §1562(c)(13)(B), as renumbered by Pub. L. 111–148, §10107(b)(1), inserted "individual health insurance coverage or" after "with respect to".

2008—Subsec. (b)(3). Pub. L. 110–233 added par. (3).

STATUTORY NOTES AND RELATED SUBSIDIARIES

EFFECTIVE DATE OF 2020 AMENDMENT

Amendment by Pub. L. 116–260 applicable with respect to plan years beginning on or after Jan. 1, 2022, see section 102(e) of div. BB of Pub. L. 116–260, set out as a note under section 8902 of Title 5, Government Organization and Employees.

EFFECTIVE DATE OF 2008 AMENDMENT

Amendment by Pub. L. 110–233 applicable, with respect to group health plans and health insurance coverage offered in connection with group health plans, for plan years beginning after the date that is one year after May 21, 2008, and, with respect to health insurance coverage offered, sold, issued, renewed, in effect, or operated in the individual market, after the date that is one year after May 21, 2008, see section 102(d)(2) of Pub. L. 110–233, set out as a note under section 300gg–21 of this title.

EFFECTIVE DATE

Section applicable with respect to group health plans, and health insurance coverage offered in connection with group health plans, for plan years beginning after June 30, 1997, except as otherwise provided, see section 102(c) of Pub. L. 104–191, set out as a note under section 300gg of this title.

[1] *See References in Text note below.*

§300gg–23. Preemption; State flexibility; construction

(a) Continued applicability of State law with respect to health insurance issuers

(1) In general

Subject to paragraph (2) and except as provided in subsection (b), this part, part D, and part C insofar as it relates to this part or part D shall not be construed to supersede any provision of State law which establishes, implements, or continues in effect any standard or requirement solely relating to health insurance issuers in connection with individual or group health insurance coverage except to the extent that such standard or requirement prevents the application of a requirement of this part or part D.

(2) Continued preemption with respect to group health plans

Nothing in this part or part D shall be construed to affect or modify the provisions of section 1144 of title 29 with respect to group health plans.

(b) Special rules in case of portability requirements

(1) In general

Subject to paragraph (2), the provisions of this part relating to health insurance coverage offered by a health insurance issuer supersede any provision of State law which establishes, implements, or continues in effect a standard or requirement applicable to imposition of a preexisting condition exclusion specifically governed by section 701 [1] which differs from the standards or requirements specified in such section.

(2) Exceptions

Only in relation to health insurance coverage offered by a health insurance issuer, the provisions of this part do not supersede any provision of State law to the extent that such provision—

(i) substitutes for the reference to "6-month period" in section 2701(a)(1) [1] a reference to any shorter period of time;

(ii) substitutes for the reference to "12 months" and "18 months" in section 2701(a)(2) [1] a reference to any shorter period of time;

(iii) substitutes for the references to "63" days in sections 2701(c)(2)(A) [1] and 2701(d)(4)(A) [1] a reference to any greater number of days;

(iv) substitutes for the reference to "30-day period" in sections 2701(b)(2) [1] and 2701(d)(1) [1] a reference to any greater period;

(v) prohibits the imposition of any preexisting condition exclusion in cases not described in section 2701(d) [1] or expands the exceptions described in such section;

(vi) requires special enrollment periods in addition to those required under section 2701(f) [1]; or

(vii) reduces the maximum period permitted in an affiliation period under section 2701(g)(1)(B) [1].

(c) Rules of construction

Nothing in this part (other than section 2704) [1] or part D shall be construed as requiring a group health plan or health insurance coverage to provide specific benefits under the terms of such plan or coverage.

(d) Definitions

For purposes of this section—

(1) State law

The term "State law" includes all laws, decisions, rules, regulations, or other State action having the effect of law, of any State. A law of the United States applicable only to the District of Columbia shall be treated as a State law rather than a law of the United States.

(2) State

The term "State" includes a State (including the Northern Mariana Islands), any political subdivisions of a State or such Islands, or any agency or instrumentality of either.

(July 1, 1944, ch. 373, title XXVII, §2724, formerly §2723, as added Pub. L. 104–191, title I, §102(a), Aug. 21, 1996, 110 Stat. 1971; amended Pub. L. 104–204, title VI, §604(b)(2), Sept. 26, 1996, 110 Stat. 2941; renumbered §2737, renumbered §2724, and amended Pub. L. 111–148, title I, §§1001(4), 1563(c)(14), formerly §1562(c)(14), title X, §10107(b)(1), Mar. 23, 2010, 124 Stat. 130, 269, 911; Pub. L. 116–260, div. BB, title I, §102(a)(3)(D), Dec. 27, 2020, 134 Stat. 2772.)

EDITORIAL NOTES

REFERENCES IN TEXT

Section 2701, referred to in subsec. (b), is a reference to section 2701 of act July 1, 1944. Section 2701, which was classified to section 300gg of this title, was renumbered section 2704, effective for plan years beginning on or after Jan. 1, 2014, with certain exceptions, and amended, by Pub. L. 111–148, title I,

§§1201(2), 1563(c)(1), formerly §1562(c)(1), title X, §10107(b)(1), Mar. 23, 2010, 124 Stat. 154, 264, 911, and was transferred to section 300gg–3 of this title. A new section 2701 of act July 1, 1944, related to fair health insurance premiums, was added, effective for plan years beginning on or after Jan. 1, 2014, and amended, by Pub. L. 111–148, title I, §1201(4), title X, §10103(a), Mar. 23, 2010, 124 Stat. 155, 892, and is classified to section 300gg of this title.

Section 701, referred to in subsec. (b)(1), probably means "section 2701" of act July 1, 1944. See note above.

Section 2704, referred to in subsec. (c), is a reference to section 2704 of act July 1, 1944. Section 2704, which was classified to section 300gg–4 of this title, was renumbered section 2725, and amended by Pub. L. 111–148, title I, §§1001(2), 1563(c)(3), formerly §1562(c)(3), title X, §10107(b)(1), Mar. 23, 2010, 124 Stat. 130, 265, 911, and was transferred to section 300gg–25 of this title. A new section 2704 of act July 1, 1944, related to prohibition of preexisting condition exclusions or other discrimination based on health status, was added, effective for plan years beginning on or after Jan. 1, 2014, with certain exceptions, and amended, by Pub. L. 111–148, title I, §§1201(2), 1563(c)(1), formerly §1562(c)(1), title X, §10107(b)(1), Mar. 23, 2010, 124 Stat. 154, 264, 911, and is classified to section 300gg–3 of this title.

AMENDMENTS

2020—Subsec. (a)(1). Pub. L. 116–260, §102(a)(3)(D)(i), substituted "this part, part D, and part C insofar as it relates to this part or part D" for "this part and part C insofar as it relates to this part" and inserted "or part D" before period at end.

Subsec. (a)(2). Pub. L. 116–260, §102(a)(3)(D)(ii), inserted "or part D" after "this part".

Subsec. (c). Pub. L. 116–260, §102(a)(3)(D)(iii), inserted "or part D" after "this part (other than section 2704)".

2010—Subsec. (a)(1). Pub. L. 111–148, §1563(c)(14)(A), formerly §1562(c)(14)(A), as renumbered by Pub. L. 111–148, §10107(b)(1), inserted "individual or" before "group health insurance".

1996—Subsec. (c). Pub. L. 104–204 inserted "(other than section 2704)" after "part".

STATUTORY NOTES AND RELATED SUBSIDIARIES

EFFECTIVE DATE OF 2020 AMENDMENT

Amendment by Pub. L. 116–260 applicable with respect to plan years beginning on or after Jan. 1, 2022, see section 102(e) of div. BB of Pub. L. 116–260, set out as a note under section 8902 of Title 5, Government Organization and Employees.

EFFECTIVE DATE OF 1996 AMENDMENT

Amendment by Pub. L. 104–204 applicable with respect to group health plans for plan years beginning on or after Jan. 1, 1998, see section 604(c) of Pub. L. 104–204 set out as an Effective Date note under section 300gg–25 of this title.

EFFECTIVE DATE

Section applicable with respect to group health plans, and health insurance coverage offered in connection with group health plans, for plan years beginning after June 30, 1997, except as otherwise provided, see section 102(c) of Pub. L. 104–191, set out as a note under section 300gg of this title.

[1] *See References in Text note below.*

§300gg–25. Standards relating to benefits for mothers and newborns

(a) Requirements for minimum hospital stay following birth

(1) In general

A group health plan, and a health insurance issuer offering group or individual health insurance coverage, may not—

(A) except as provided in paragraph (2)—

(i) restrict benefits for any hospital length of stay in connection with childbirth for the mother or newborn child, following a normal vaginal delivery, to less than 48 hours, or

(ii) restrict benefits for any hospital length of stay in connection with childbirth for the mother or newborn child, following a cesarean section, to less than 96 hours, or

(B) require that a provider obtain authorization from the plan or the issuer for prescribing any length of stay required under subparagraph (A) (without regard to paragraph (2)).

(2) Exception

Paragraph (1)(A) shall not apply in connection with any group health plan or health insurance issuer in any case in which the decision to discharge the mother or her newborn child prior to the expiration of the minimum length of stay otherwise required under paragraph (1)(A) is made by an attending provider in consultation with the mother.

(b) Prohibitions

A group health plan, and a health insurance issuer offering group or individual health insurance coverage, may not—

(1) deny to the mother or her newborn child eligibility, or continued eligibility, to enroll or to renew coverage under the terms of the plan or coverage, solely for the purpose of avoiding the requirements of this section;

(2) provide monetary payments or rebates to mothers to encourage such mothers to accept less than the minimum protections available under this section;

(3) penalize or otherwise reduce or limit the reimbursement of an attending provider because such provider provided care to an individual participant or beneficiary in accordance with this section;

(4) provide incentives (monetary or otherwise) to an attending provider to induce such provider to provide care to an individual participant or beneficiary in a manner inconsistent with this section; or

(5) subject to subsection (c)(3), restrict benefits for any portion of a period within a hospital length of stay required under subsection (a) in a manner which is less favorable than the benefits provided for any preceding portion of such stay.

(c) Rules of construction

(1) Nothing in this section shall be construed to require a mother who is a participant or beneficiary—

(A) to give birth in a hospital; or

(B) to stay in the hospital for a fixed period of time following the birth of her child.

(2) This section shall not apply with respect to any group health plan, or any health insurance issuer offering group or individual health insurance coverage, which does not provide benefits for hospital lengths of stay in connection with childbirth for a mother or her newborn child.

(3) Nothing in this section shall be construed as preventing a group health plan or health insurance issuer from imposing deductibles, coinsurance, or other cost-sharing in relation to benefits for hospital lengths of stay in connection with childbirth for a mother or newborn child under the plan (or under health insurance coverage offered in connection with a group health plan), except that such coinsurance or other cost-sharing for any portion of a period within a hospital length of stay required under subsection (a) may not be greater than such coinsurance or cost-sharing for any preceding portion of such stay.

(d) Notice

A group health plan under this part shall comply with the notice requirement under section 1185(d) of title 29 with respect to the requirements of this section as if such section applied to such plan.

(e) Level and type of reimbursements

Nothing in this section shall be construed to prevent a group health plan or a health insurance issuer offering group or individual health insurance coverage from negotiating the level and type of

reimbursement with a provider for care provided in accordance with this section.

(f) Preemption; exception for health insurance coverage in certain States

(1) In general

The requirements of this section shall not apply with respect to health insurance coverage if there is a State law (as defined in section 300gg–23(d)(1) [1] of this title) for a State that regulates such coverage that is described in any of the following subparagraphs:

(A) Such State law requires such coverage to provide for at least a 48-hour hospital length of stay following a normal vaginal delivery and at least a 96-hour hospital length of stay following a cesarean section.

(B) Such State law requires such coverage to provide for maternity and pediatric care in accordance with guidelines established by the American College of Obstetricians and Gynecologists, the American Academy of Pediatrics, or other established professional medical associations.

(C) Such State law requires, in connection with such coverage for maternity care, that the hospital length of stay for such care is left to the decision of (or required to be made by) the attending provider in consultation with the mother.

(2) Construction

Section 300gg–23(a)(1) [1] of this title shall not be construed as superseding a State law described in paragraph (1).

(July 1, 1944, ch. 373, title XXVII, §2725, formerly §2704, as added Pub. L. 104–204, title VI, §604(a)(3), Sept. 26, 1996, 110 Stat. 2939; renumbered §2725 and amended Pub. L. 111–148, title I, §§1001(2), 1563(c)(3), formerly §1562(c)(3), title X, §10107(b)(1), Mar. 23, 2010, 124 Stat. 130, 265, 911.)

EDITORIAL NOTES

REFERENCES IN TEXT

Section 300gg–23 of this title, referred to in subsec. (f), was in the original section "2723", and was translated as meaning section 2724 of act July 1, 1944, to reflect the probable intent of Congress and the renumbering of section 2723 as 2724 by Pub. L. 111–148, title I, §§1001(4), 1563(c)(14)(B), formerly §1562(c)(14)(B), title X, §10107(b)(1), Mar. 23, 2010, 124 Stat. 130, 269, 911.

CODIFICATION

Section was formerly classified to section 300gg–4 of this title prior to renumbering by Pub. L. 111–148.

AMENDMENTS

2010—Subsec. (a)(1). Pub. L. 111–148, §1563(c)(3)(A), formerly §1562(c)(3)(A), as renumbered by Pub. L. 111–148, §10107(b)(1), substituted "group or individual health insurance coverage" for "group health insurance coverage" in introductory provisions.

Subsec. (b). Pub. L. 111–148, §1563(c)(3)(B)(i), formerly §1562(c)(3)(B)(i), as renumbered by Pub. L. 111–148, §10107(b)(1), substituted "group or individual health insurance coverage" for "group health insurance coverage in connection with a group health plan" in introductory provisions.

Subsec. (b)(1). Pub. L. 111–148, §1563(c)(3)(B)(ii), formerly §1562(c)(3)(B)(ii), as renumbered by Pub. L. 111–148, §10107(b)(1), substituted "plan or coverage" for "plan".

Subsec. (c)(2). Pub. L. 111–148, §1563(c)(3)(C)(i), formerly §1562(c)(3)(C)(i), as renumbered by Pub. L. 111–148, §10107(b)(1), substituted "health insurance issuer offering group or individual health insurance coverage" for "group health insurance coverage offered by a health insurance issuer".

Subsec. (c)(3). Pub. L. 111–148, §1563(c)(3)(C)(ii), formerly §1562(c)(3)(C)(ii), as renumbered by Pub. L. 111–148, §10107(b)(1), substituted "health insurance issuer" for "issuer".

Subsec. (e). Pub. L. 111–148, §1563(c)(3)(D), formerly §1562(c)(3)(D), as renumbered by Pub. L. 111–148, §10107(b)(1), substituted "group or individual health insurance coverage" for "group health insurance coverage".

STATUTORY NOTES AND RELATED SUBSIDIARIES

EFFECTIVE DATE

Pub. L. 104–204, title VI, §604(c), Sept. 26, 1996, 110 Stat. 2941, provided that: "The amendments made by this section [enacting this section and amending sections 300gg–21 and 300gg–23 of this title] shall apply with respect to group health plans for plan years beginning on or after January 1, 1998."

CONGRESSIONAL FINDINGS

Pub. L. 104–204, title VI, §602, Sept. 26, 1996, 110 Stat. 2935, provided that: "Congress finds that—

"(1) the length of post-delivery hospital stay should be based on the unique characteristics of each mother and her newborn child, taking into consideration the health of the mother, the health and stability of the newborn, the ability and confidence of the mother and the father to care for their newborn, the adequacy of support systems at home, and the access of the mother and her newborn to appropriate follow-up health care; and

"(2) the timing of the discharge of a mother and her newborn child from the hospital should be made by the attending provider in consultation with the mother."

[1] *See References in Text note below.*

§300gg–26. Parity in mental health and substance use disorder benefits

(a) In general

(1) Aggregate lifetime limits

In the case of a group health plan or a health insurance issuer offering group or individual health insurance coverage that provides both medical and surgical benefits and mental health or substance use disorder benefits—

(A) No lifetime limit

If the plan or coverage does not include an aggregate lifetime limit on substantially all medical and surgical benefits, the plan or coverage may not impose any aggregate lifetime limit on mental health or substance use disorder benefits.

(B) Lifetime limit

If the plan or coverage includes an aggregate lifetime limit on substantially all medical and surgical benefits (in this paragraph referred to as the "applicable lifetime limit"), the plan or coverage shall either—

(i) apply the applicable lifetime limit both to the medical and surgical benefits to which it otherwise would apply and to mental health and substance use disorder benefits and not distinguish in the application of such limit between such medical and surgical benefits and mental health and substance use disorder benefits; or

(ii) not include any aggregate lifetime limit on mental health or substance use disorder benefits that is less than the applicable lifetime limit.

(C) Rule in case of different limits

In the case of a plan or coverage that is not described in subparagraph (A) or (B) and that includes no or different aggregate lifetime limits on different categories of medical and surgical benefits, the Secretary shall establish rules under which subparagraph (B) is applied to such plan or coverage with respect to mental health and substance use disorder benefits by substituting for the applicable lifetime limit an average aggregate lifetime limit that is computed taking into account the weighted average of the aggregate lifetime limits applicable to such categories.

(2) Annual limits

In the case of a group health plan or a health insurance issuer offering group or individual health insurance coverage that provides both medical and surgical benefits and mental health or

substance use disorder benefits—

(A) No annual limit

If the plan or coverage does not include an annual limit on substantially all medical and surgical benefits, the plan or coverage may not impose any annual limit on mental health or substance use disorder benefits.

(B) Annual limit

If the plan or coverage includes an annual limit on substantially all medical and surgical benefits (in this paragraph referred to as the "applicable annual limit"), the plan or coverage shall either—

(i) apply the applicable annual limit both to medical and surgical benefits to which it otherwise would apply and to mental health and substance use disorder benefits and not distinguish in the application of such limit between such medical and surgical benefits and mental health and substance use disorder benefits; or

(ii) not include any annual limit on mental health or substance use disorder benefits that is less than the applicable annual limit.

(C) Rule in case of different limits

In the case of a plan or coverage that is not described in subparagraph (A) or (B) and that includes no or different annual limits on different categories of medical and surgical benefits, the Secretary shall establish rules under which subparagraph (B) is applied to such plan or coverage with respect to mental health and substance use disorder benefits by substituting for the applicable annual limit an average annual limit that is computed taking into account the weighted average of the annual limits applicable to such categories.

(3) Financial requirements and treatment limitations

(A) In general

In the case of a group health plan or a health insurance issuer offering group or individual health insurance coverage that provides both medical and surgical benefits and mental health or substance use disorder benefits, such plan or coverage shall ensure that—

(i) the financial requirements applicable to such mental health or substance use disorder benefits are no more restrictive than the predominant financial requirements applied to substantially all medical and surgical benefits covered by the plan (or coverage), and there are no separate cost sharing requirements that are applicable only with respect to mental health or substance use disorder benefits; and

(ii) the treatment limitations applicable to such mental health or substance use disorder benefits are no more restrictive than the predominant treatment limitations applied to substantially all medical and surgical benefits covered by the plan (or coverage) and there are no separate treatment limitations that are applicable only with respect to mental health or substance use disorder benefits.

(B) Definitions

In this paragraph:

(i) Financial requirement

The term "financial requirement" includes deductibles, copayments, coinsurance, and out-of-pocket expenses, but excludes an aggregate lifetime limit and an annual limit subject to paragraphs (1) and (2).

(ii) Predominant

A financial requirement or treatment limit is considered to be predominant if it is the most common or frequent of such type of limit or requirement.

(iii) Treatment limitation

The term "treatment limitation" includes limits on the frequency of treatment, number of

visits, days of coverage, or other similar limits on the scope or duration of treatment.

(4) Availability of plan information

The criteria for medical necessity determinations made under the plan with respect to mental health or substance use disorder benefits (or the health insurance coverage offered in connection with the plan with respect to such benefits) shall be made available by the plan administrator (or the health insurance issuer offering such coverage) in accordance with regulations to any current or potential participant, beneficiary, or contracting provider upon request. The reason for any denial under the plan (or coverage) of reimbursement or payment for services with respect to mental health or substance use disorder benefits in the case of any participant or beneficiary shall, on request or as otherwise required, be made available by the plan administrator (or the health insurance issuer offering such coverage) to the participant or beneficiary in accordance with regulations.

(5) Out-of-network providers

In the case of a plan or coverage that provides both medical and surgical benefits and mental health or substance use disorder benefits, if the plan or coverage provides coverage for medical or surgical benefits provided by out-of-network providers, the plan or coverage shall provide coverage for mental health or substance use disorder benefits provided by out-of-network providers in a manner that is consistent with the requirements of this section.

(6) Compliance program guidance document

(A) In general

Not later than 12 months after December 13, 2016, the Secretary, the Secretary of Labor, and the Secretary of the Treasury, in consultation with the Inspector General of the Department of Health and Human Services, the Inspector General of the Department of Labor, and the Inspector General of the Department of the Treasury, shall issue a compliance program guidance document to help improve compliance with this section, section 1185a of title 29, and section 9812 of title 26, as applicable. In carrying out this paragraph, the Secretaries may take into consideration the 2016 publication of the Department of Health and Human Services and the Department of Labor, entitled "Warning Signs - Plan or Policy Non-Quantitative Treatment Limitations (NQTLs) that Require Additional Analysis to Determine Mental Health Parity Compliance".

(B) Examples illustrating compliance and noncompliance

(i) In general

The compliance program guidance document required under this paragraph shall provide illustrative, de-identified examples (that do not disclose any protected health information or individually identifiable information) of previous findings of compliance and noncompliance with this section, section 1185a of title 29, or section 9812 of title 26, as applicable, based on investigations of violations of such sections, including—

(I) examples illustrating requirements for information disclosures and nonquantitative treatment limitations; and

(II) descriptions of the violations uncovered during the course of such investigations.

(ii) Nonquantitative treatment limitations

To the extent that any example described in clause (i) involves a finding of compliance or noncompliance with regard to any requirement for nonquantitative treatment limitations, the example shall provide sufficient detail to fully explain such finding, including a full description of the criteria involved for approving medical and surgical benefits and the criteria involved for approving mental health and substance use disorder benefits.

(iii) Access to additional information regarding compliance

In developing and issuing the compliance program guidance document required under this paragraph, the Secretaries specified in subparagraph (A)—

(I) shall enter into interagency agreements with the Inspector General of the Department of Health and Human Services, the Inspector General of the Department of Labor, and the Inspector General of the Department of the Treasury to share findings of compliance and noncompliance with this section, section 1185a of title 29, or section 9812 of title 26, as applicable; and

(II) shall seek to enter into an agreement with a State to share information on findings of compliance and noncompliance with this section, section 1185a of title 29, or section 9812 of title 26, as applicable.

(C) Recommendations

The compliance program guidance document shall include recommendations to advance compliance with this section, section 1185a of title 29, or section 9812 of title 26, as applicable, and encourage the development and use of internal controls to monitor adherence to applicable statutes, regulations, and program requirements. Such internal controls may include illustrative examples of nonquantitative treatment limitations on mental health and substance use disorder benefits, which may fail to comply with this section, section 1185a of title 29, or section 9812 of title 26, as applicable, in relation to nonquantitative treatment limitations on medical and surgical benefits.

(D) Updating the compliance program guidance document

The Secretary, the Secretary of Labor, and the Secretary of the Treasury, in consultation with the Inspector General of the Department of Health and Human Services, the Inspector General of the Department of Labor, and the Inspector General of the Department of the Treasury, shall update the compliance program guidance document every 2 years to include illustrative, de-identified examples (that do not disclose any protected health information or individually identifiable information) of previous findings of compliance and noncompliance with this section, section 1185a of title 29, or section 9812 of title 26, as applicable.

(7) Additional guidance

(A) In general

Not later than 12 months after December 13, 2016, the Secretary, the Secretary of Labor, and the Secretary of the Treasury shall issue guidance to group health plans and health insurance issuers offering group or individual health insurance coverage to assist such plans and issuers in satisfying the requirements of this section, section 1185a of title 29, or section 9812 of title 26, as applicable.

(B) Disclosure

(i) Guidance for plans and issuers

The guidance issued under this paragraph shall include clarifying information and illustrative examples of methods that group health plans and health insurance issuers offering group or individual health insurance coverage may use for disclosing information to ensure compliance with the requirements under this section, section 1185a of title 29, or section 9812 of title 26, as applicable, (and any regulations promulgated pursuant to such sections, as applicable).

(ii) Documents for participants, beneficiaries, contracting providers, or authorized representatives

The guidance issued under this paragraph shall include clarifying information and illustrative examples of methods that group health plans and health insurance issuers offering group or individual health insurance coverage may use to provide any participant, beneficiary, contracting provider, or authorized representative, as applicable, with documents containing information that the health plans or issuers are required to disclose to participants, beneficiaries, contracting providers, or authorized representatives to ensure compliance with this section, section 1185a of title 29, or section 9812 of title 26, as applicable, compliance

with any regulation issued pursuant to such respective section, or compliance with any other applicable law or regulation. Such guidance shall include information that is comparative in nature with respect to—

(I) nonquantitative treatment limitations for both medical and surgical benefits and mental health and substance use disorder benefits;

(II) the processes, strategies, evidentiary standards, and other factors used to apply the limitations described in subclause (I); and

(III) the application of the limitations described in subclause (I) to ensure that such limitations are applied in parity with respect to both medical and surgical benefits and mental health and substance use disorder benefits.

(C) Nonquantitative treatment limitations

The guidance issued under this paragraph shall include clarifying information and illustrative examples of methods, processes, strategies, evidentiary standards, and other factors that group health plans and health insurance issuers offering group or individual health insurance coverage may use regarding the development and application of nonquantitative treatment limitations to ensure compliance with this section, section 1185a of title 29, or section 9812 of title 26, as applicable, (and any regulations promulgated pursuant to such respective section), including—

(i) examples of methods of determining appropriate types of nonquantitative treatment limitations with respect to both medical and surgical benefits and mental health and substance use disorder benefits, including nonquantitative treatment limitations pertaining to—

(I) medical management standards based on medical necessity or appropriateness, or whether a treatment is experimental or investigative;

(II) limitations with respect to prescription drug formulary design; and

(III) use of fail-first or step therapy protocols;

(ii) examples of methods of determining—

(I) network admission standards (such as credentialing); and

(II) factors used in provider reimbursement methodologies (such as service type, geographic market, demand for services, and provider supply, practice size, training, experience, and licensure) as such factors apply to network adequacy;

(iii) examples of sources of information that may serve as evidentiary standards for the purposes of making determinations regarding the development and application of nonquantitative treatment limitations;

(iv) examples of specific factors, and the evidentiary standards used to evaluate such factors, used by such plans or issuers in performing a nonquantitative treatment limitation analysis;

(v) examples of how specific evidentiary standards may be used to determine whether treatments are considered experimental or investigative;

(vi) examples of how specific evidentiary standards may be applied to each service category or classification of benefits;

(vii) examples of methods of reaching appropriate coverage determinations for new mental health or substance use disorder treatments, such as evidence-based early intervention programs for individuals with a serious mental illness and types of medical management techniques;

(viii) examples of methods of reaching appropriate coverage determinations for which there is an indirect relationship between the covered mental health or substance use disorder benefit and a traditional covered medical and surgical benefit, such as residential treatment or hospitalizations involving voluntary or involuntary commitment; and

(ix) additional illustrative examples of methods, processes, strategies, evidentiary standards, and other factors for which the Secretary determines that additional guidance is necessary to improve compliance with this section, section 1185a of title 29, or section 9812 of title 26, as applicable.

(D) Public comment

Prior to issuing any final guidance under this paragraph, the Secretary shall provide a public comment period of not less than 60 days during which any member of the public may provide comments on a draft of the guidance.

(8) Compliance requirements

(A) Nonquantitative treatment limitation (NQTL) requirements

In the case of a group health plan or a health insurance issuer offering group or individual health insurance coverage that provides both medical and surgical benefits and mental health or substance use disorder benefits and that imposes nonquantitative treatment limitations (referred to in this section as "NQTLs") on mental health or substance use disorder benefits, such plan or issuer shall perform and document comparative analyses of the design and application of NQTLs and, beginning 45 days after December 27, 2020, make available to the applicable State authority (or, as applicable, to the Secretary of Labor or the Secretary of Health and Human Services), upon request, the comparative analyses and the following information:

(i) The specific plan or coverage terms or other relevant terms regarding the NQTLs and a description of all mental health or substance use disorder and medical or surgical benefits to which each such term applies in each respective benefits classification.

(ii) The factors used to determine that the NQTLs will apply to mental health or substance use disorder benefits and medical or surgical benefits.

(iii) The evidentiary standards used for the factors identified in clause (ii), when applicable, provided that every factor shall be defined, and any other source or evidence relied upon to design and apply the NQTLs to mental health or substance use disorder benefits and medical or surgical benefits.

(iv) The comparative analyses demonstrating that the processes, strategies, evidentiary standards, and other factors used to apply the NQTLs to mental health or substance use disorder benefits, as written and in operation, are comparable to, and are applied no more stringently than, the processes, strategies, evidentiary standards, and other factors used to apply the NQTLs to medical or surgical benefits in the benefits classification.

(v) The specific findings and conclusions reached by the group health plan or health insurance issuer with respect to the health insurance coverage, including any results of the analyses described in this subparagraph that indicate that the plan or coverage is or is not in compliance with this section.

(B) Secretary request process

(i) Submission upon request

The Secretary shall request that a group health plan or a health insurance issuer offering group or individual health insurance coverage submit the comparative analyses described in subparagraph (A) for plans that involve potential violations of this section or complaints regarding noncompliance with this section that concern NQTLs and any other instances in which the Secretary determines appropriate. The Secretary shall request not fewer than 20 such analyses per year.

(ii) Additional information

In instances in which the Secretary has concluded that the group health plan or health insurance issuer with respect to health insurance coverage has not submitted sufficient information for the Secretary to review the comparative analyses described in subparagraph (A), as requested under clause (i), the Secretary shall specify to the plan or issuer the information the plan or issuer must submit to be responsive to the request under clause (i) for the Secretary to review the comparative analyses described in subparagraph (A) for compliance with this section. Nothing in this paragraph shall require the Secretary to

conclude that a group health plan or health insurance issuer is in compliance with this section solely based upon the inspection of the comparative analyses described in subparagraph (A), as requested under clause (i).

(iii) Required action

(I) In general

In instances in which the Secretary has reviewed the comparative analyses described in subparagraph (A), as requested under clause (i), and determined that the group health plan or health insurance issuer is not in compliance with this section, the plan or issuer—

(aa) shall specify to the Secretary the actions the plan or issuer will take to be in compliance with this section and provide to the Secretary additional comparative analyses described in subparagraph (A) that demonstrate compliance with this section not later than 45 days after the initial determination by the Secretary that the plan or issuer is not in compliance; and

(bb) following the 45-day corrective action period under item (aa), if the Secretary makes a final determination that the plan or issuer still is not in compliance with this section, not later than 7 days after such determination, shall notify all individuals enrolled in the plan or applicable health insurance coverage offered by the issuer that the plan or issuer, with respect to such coverage, has been determined to be not in compliance with this section.

(II) Exemption from disclosure

Documents or communications produced in connection with the Secretary's recommendations to a group health plan or health insurance issuer shall not be subject to disclosure pursuant to section 552 of title 5.

(iv) Report

Not later than 1 year after December 27, 2020, and not later than October 1 of each year thereafter, the Secretary shall submit to Congress, and make publicly available, a report that contains—

(I) a summary of the comparative analyses requested under clause (i), including the identity of each group health plan or health insurance issuer, with respect to particular health insurance coverage that is determined to be not in compliance after the final determination by the Secretary described in clause (iii)(I)(bb);

(II) the Secretary's conclusions as to whether each group health plan or health insurance issuer submitted sufficient information for the Secretary to review the comparative analyses requested under clause (i) for compliance with this section;

(III) for each group health plan or health insurance issuer that did submit sufficient information for the Secretary to review the comparative analyses requested under clause (i), the Secretary's conclusions as to whether and why the plan or issuer is in compliance with the requirements under this section;

(IV) the Secretary's specifications described in clause (ii) for each group health plan or health insurance issuer that the Secretary determined did not submit sufficient information for the Secretary to review the comparative analyses requested under clause (i) for compliance with this section; and

(V) the Secretary's specifications described in clause (iii) of the actions each group health plan or health insurance issuer that the Secretary determined is not in compliance with this section must take to be in compliance with this section, including the reason why the Secretary determined the plan or issuer is not in compliance.

(C) Compliance program guidance document update process

(i) In general

The Secretary shall include instances of noncompliance that the Secretary discovers upon reviewing the comparative analyses requested under subparagraph (B)(i) in the compliance

program guidance document described in paragraph (6), as it is updated every 2 years, except that such instances shall not disclose any protected health information or individually identifiable information.

(ii) Guidance and regulations

Not later than 18 months after December 27, 2020, the Secretary shall finalize any draft or interim guidance and regulations relating to mental health parity under this section. Such draft guidance shall include guidance to clarify the process and timeline for current and potential participants and beneficiaries (and authorized representatives and health care providers of such participants and beneficiaries) with respect to plans to file complaints of such plans or issuers being in violation of this section, including guidance, by plan type, on the relevant State, regional, or national office with which such complaints should be filed.

(iii) State

The Secretary shall share information on findings of compliance and noncompliance discovered upon reviewing the comparative analyses requested under subparagraph (B)(i) shall be shared with the State where the group health plan is located or the State where the health insurance issuer is licensed to do business for coverage offered by a health insurance issuer in the group market, in accordance with paragraph (6)(B)(iii)(II).

(b) Construction

Nothing in this section shall be construed—

(1) as requiring a group health plan or a health insurance issuer offering group or individual health insurance coverage to provide any mental health or substance use disorder benefits; or

(2) in the case of a group health plan or a health insurance issuer offering group or individual health insurance coverage that provides mental health or substance use disorder benefits, as affecting the terms and conditions of the plan or coverage relating to such benefits under the plan or coverage, except as provided in subsection (a).

(c) Exemptions

(1) Small employer exemption

This section shall not apply to any group health plan and a health insurance issuer offering group or individual health insurance coverage for any plan year of a small employer (as defined in section 300gg–91(e)(4) of this title, except that for purposes of this paragraph such term shall include employers with 1 employee in the case of an employer residing in a State that permits small groups to include a single individual).

(2) Cost exemption

(A) In general

With respect to a group health plan or a health insurance issuer offering group or individual health insurance coverage, if the application of this section to such plan (or coverage) results in an increase for the plan year involved of the actual total costs of coverage with respect to medical and surgical benefits and mental health and substance use disorder benefits under the plan (as determined and certified under subparagraph (C)) by an amount that exceeds the applicable percentage described in subparagraph (B) of the actual total plan costs, the provisions of this section shall not apply to such plan (or coverage) during the following plan year, and such exemption shall apply to the plan (or coverage) for 1 plan year. An employer may elect to continue to apply mental health and substance use disorder parity pursuant to this section with respect to the group health plan (or coverage) involved regardless of any increase in total costs.

(B) Applicable percentage

With respect to a plan (or coverage), the applicable percentage described in this subparagraph shall be—

(i) 2 percent in the case of the first plan year in which this section is applied; and

(ii) 1 percent in the case of each subsequent plan year.

(C) Determinations by actuaries

Determinations as to increases in actual costs under a plan (or coverage) for purposes of this section shall be made and certified by a qualified and licensed actuary who is a member in good standing of the American Academy of Actuaries. All such determinations shall be in a written report prepared by the actuary. The report, and all underlying documentation relied upon by the actuary, shall be maintained by the group health plan or health insurance issuer for a period of 6 years following the notification made under subparagraph (E).

(D) 6-month determinations

If a group health plan (or a health insurance issuer offering coverage in connection with a group health plan) seeks an exemption under this paragraph, determinations under subparagraph (A) shall be made after such plan (or coverage) has complied with this section for the first 6 months of the plan year involved.

(E) Notification

(i) In general

A group health plan (or a health insurance issuer offering coverage in connection with a group health plan) that, based upon a certification described under subparagraph (C), qualifies for an exemption under this paragraph, and elects to implement the exemption, shall promptly notify the Secretary, the appropriate State agencies, and participants and beneficiaries in the plan of such election.

(ii) Requirement

A notification to the Secretary under clause (i) shall include—

(I) a description of the number of covered lives under the plan (or coverage) involved at the time of the notification, and as applicable, at the time of any prior election of the cost-exemption under this paragraph by such plan (or coverage);

(II) for both the plan year upon which a cost exemption is sought and the year prior, a description of the actual total costs of coverage with respect to medical and surgical benefits and mental health and substance use disorder benefits under the plan; and

(III) for both the plan year upon which a cost exemption is sought and the year prior, the actual total costs of coverage with respect to mental health and substance use disorder benefits under the plan.

(iii) Confidentiality

A notification to the Secretary under clause (i) shall be confidential. The Secretary shall make available, upon request and on not more than an annual basis, an anonymous itemization of such notifications, that includes—

(I) a breakdown of States by the size and type of employers submitting such notification; and

(II) a summary of the data received under clause (ii).

(F) Audits by appropriate agencies

To determine compliance with this paragraph, the Secretary may audit the books and records of a group health plan or health insurance issuer relating to an exemption, including any actuarial reports prepared pursuant to subparagraph (C), during the 6 year period following the notification of such exemption under subparagraph (E). A State agency receiving a notification under subparagraph (E) may also conduct such an audit with respect to an exemption covered by such notification.

(d) Separate application to each option offered

In the case of a group health plan that offers a participant or beneficiary two or more benefit package options under the plan, the requirements of this section shall be applied separately with respect to each such option.

(e) Definitions

For purposes of this section—

(1) Aggregate lifetime limit

The term "aggregate lifetime limit" means, with respect to benefits under a group health plan or health insurance coverage, a dollar limitation on the total amount that may be paid with respect to such benefits under the plan or health insurance coverage with respect to an individual or other coverage unit.

(2) Annual limit

The term "annual limit" means, with respect to benefits under a group health plan or health insurance coverage, a dollar limitation on the total amount of benefits that may be paid with respect to such benefits in a 12-month period under the plan or health insurance coverage with respect to an individual or other coverage unit.

(3) Medical or surgical benefits

The term "medical or surgical benefits" means benefits with respect to medical or surgical services, as defined under the terms of the plan or coverage (as the case may be), but does not include mental health or substance use disorder benefits.

(4) Mental health benefits

The term "mental health benefits" means benefits with respect to services for mental health conditions, as defined under the terms of the plan and in accordance with applicable Federal and State law.

(5) Substance use disorder benefits

The term "substance use disorder benefits" means benefits with respect to services for substance use disorders, as defined under the terms of the plan and in accordance with applicable Federal and State law.

(July 1, 1944, ch. 373, title XXVII, §2726, formerly §2705, as added Pub. L. 104–204, title VII, §703(a), Sept. 26, 1996, 110 Stat. 2947; amended Pub. L. 107–116, title VII, §701(b), Jan. 10, 2002, 115 Stat. 2228; Pub. L. 107–313, §2(b), Dec. 2, 2002, 116 Stat. 2457; Pub. L. 108–197, §2(b), Dec. 19, 2003, 117 Stat. 2898; Pub. L. 108–311, title III, §302(c), Oct. 4, 2004, 118 Stat. 1179; Pub. L. 109–151, §1(b), Dec. 30, 2005, 119 Stat. 2886; Pub. L. 109–432, div. A, title I, §115(c), Dec. 20, 2006, 120 Stat. 2941; Pub. L. 110–245, title IV, §401(c), June 17, 2008, 122 Stat. 1650; Pub. L. 110–343, div. C, title V, §512(b), (g)(2), Oct. 3, 2008, 122 Stat. 3885, 3892; renumbered §2726 and amended Pub. L. 111–148, title I, §§1001(2), 1563(c)(4), formerly §1562(c)(4), title X, §10107(b)(1), Mar. 23, 2010, 124 Stat. 130, 265, 911; Pub. L. 114–255, div. B, title XIII, §13001(a), (b), Dec. 13, 2016, 130 Stat. 1278, 1280; Pub. L. 116–260, div. BB, title II, §203(a)(1), Dec. 27, 2020, 134 Stat. 2900.)

EDITORIAL NOTES

CODIFICATION

Section was formerly classified to section 300gg–5 of this title prior to renumbering by Pub. L. 111–148.

AMENDMENTS

2020—Subsec. (a)(8). Pub. L. 116–260 added par. (8).

2016—Subsec. (a)(6), (7). Pub. L. 114–255 added pars. (6) and (7).

2010—Subsecs. (a), (b). Pub. L. 111–148, §1563(c)(4)(A), (B), formerly §1562(c)(4)(A), (B), as renumbered by Pub. L. 111–148, §10107(b)(1), substituted "or a health insurance issuer offering group or individual health insurance coverage" for "(or health insurance coverage offered in connection with such a plan)" wherever appearing.

Subsec. (c)(1). Pub. L. 111–148, §1563(c)(4)(C)(i), formerly §1562(c)(4)(C)(i), as renumbered by Pub. L. 111–148, §10107(b)(1), substituted "and a health insurance issuer offering group or individual health insurance coverage" for "(and group health insurance coverage offered in connection with a group health plan)".

Subsec. (c)(2)(A). Pub. L. 111–148, §1563(c)(4)(C)(ii), formerly §1562(c)(4)(C)(ii), as renumbered by Pub. L. 111–148, §10107(b)(1), substituted "or a health insurance issuer offering group or individual health insurance coverage" for "(or health insurance coverage offered in connection with such a plan)".

2008—Pub. L. 110–343, §512(g)(2), amended section catchline generally. Prior to amendment, catchline read as follows: "Parity in application of certain limits to mental health benefits".

Subsec. (a)(1), (2). Pub. L. 110–343, §512(b)(7), substituted "mental health or substance use disorder benefits" for "mental health benefits" wherever appearing in pars. (1)(introductory provisions), (A), and (B)(ii) and (2)(introductory provisions), (A), and (B)(ii).

Pub. L. 110–343, §512(b)(6), substituted "mental health and substance use disorder benefits" for "mental health benefits" wherever appearing in pars. (1)(B)(i) and (C) and (2)(B)(i) and (C).

Subsec. (a)(3) to (5). Pub. L. 110–343, §512(b)(1), added pars. (3) to (5).

Subsec. (b)(1). Pub. L. 110–343, §512(b)(7), substituted "mental health or substance use disorder benefits" for "mental health benefits".

Subsec. (b)(2). Pub. L. 110–343, §512(b)(2), amended par. (2) generally. Prior to amendment, par. (2) read as follows: "in the case of a group health plan (or health insurance coverage offered in connection with such a plan) that provides mental health benefits, as affecting the terms and conditions (including cost sharing, limits on numbers of visits or days of coverage, and requirements relating to medical necessity) relating to the amount, duration, or scope of mental health benefits under the plan or coverage, except as specifically provided in subsection (a) of this section (in regard to parity in the imposition of aggregate lifetime limits and annual limits for mental health benefits)."

Subsec. (c)(1). Pub. L. 110–343, §512(b)(3)(A), inserted "(as defined in section 300gg–91(e)(4) of this title, except that for purposes of this paragraph such term shall include employers with 1 employee in the case of an employer residing in a State that permits small groups to include a single individual)" before period at end.

Subsec. (c)(2). Pub. L. 110–343, §512(b)(3)(B), added par. (2) and struck out former par. (2). Prior to amendment, text read as follows: "This section shall not apply with respect to a group health plan (or health insurance coverage offered in connection with a group health plan) if the application of this section to such plan (or to such coverage) results in an increase in the cost under the plan (or for such coverage) of at least 1 percent."

Subsec. (e)(3). Pub. L. 110–343, §512(b)(7), substituted "mental health or substance use disorder benefits" for "mental health benefits".

Subsec. (e)(4). Pub. L. 110–343, §512(b)(7), which directed substitution of "mental health or substance use disorder benefits" for "mental health benefits" wherever appearing in this section (other than in any provision amended by section 512(b)(6) of Pub. L. 110–343), was not executed to par. (4) as added by Pub. L. 110–343, §512(b)(4), to reflect the probable intent of Congress. See below.

Pub. L. 110–343, §512(b)(4), added par. (4) and struck out former par. (4). Prior to amendment, text read as follows: "The term 'mental health benefits' means benefits with respect to mental health services, as defined under the terms of the plan or coverage (as the case may be), but does not include benefits with respect to treatment of substance abuse or chemical dependency."

Subsec. (e)(5). Pub. L. 110–343, §512(b)(4), added par. (5).

Subsec. (f). Pub. L. 110–343, §512(b)(5), struck out subsec. (f). Text read as follows: "This section shall not apply to benefits for services furnished—

"(1) on or after January 1, 2008, and before June 17, 2008, and

"(2) after December 31, 2008.."

Pub. L. 110–245 substituted "services furnished—" for "services furnished after December 31, 2007" and added pars. (1) and (2).

2006—Subsec. (f). Pub. L. 109–432 substituted "2007" for "2006".

2005—Subsec. (f). Pub. L. 109–151 substituted "December 31, 2006" for "December 31, 2005".

2004—Subsec. (f). Pub. L. 108–311 substituted "after December 31, 2005" for "on or after December 31, 2004".

2003—Subsec. (f). Pub. L. 108–197 substituted "December 31, 2004" for "December 31, 2003".

2002—Subsec. (f). Pub. L. 107–313 substituted "December 31, 2003" for "December 31, 2002".

Pub. L. 107–116 substituted "December 31, 2002" for "September 30, 2001".

STATUTORY NOTES AND RELATED SUBSIDIARIES

EFFECTIVE DATE OF 2008 AMENDMENT

Pub. L. 110–343, div. C, title V, §512(e), Oct. 3, 2008, 122 Stat. 3891, as amended by Pub. L. 110–460, §1,

Dec. 23, 2008, 122 Stat. 5123, provided that:

"(1) IN GENERAL.—The amendments made by this section [amending this section, section 9812 of Title 26, Internal Revenue Code, and section 1185a of Title 29, Labor] shall apply with respect to group health plans for plan years beginning after the date that is 1 year after the date of enactment of this Act [Oct. 3, 2008], regardless of whether regulations have been issued to carry out such amendments by such effective date, except that the amendments made by subsections (a)(5), (b)(5), and (c)(5) [amending this section, section 9812 of Title 26, and section 1185a of Title 29], relating to striking of certain sunset provisions, shall take effect on January 1, 2009.

"(2) SPECIAL RULE FOR COLLECTIVE BARGAINING AGREEMENTS.—In the case of a group health plan maintained pursuant to one or more collective bargaining agreements between employee representatives and one or more employers ratified before the date of the enactment of this Act [Oct. 3, 2008], the amendments made by this section shall not apply to plan years beginning before the later of—

"(A) the date on which the last of the collective bargaining agreements relating to the plan terminates (determined without regard to any extension thereof agreed to after the date of the enactment of this Act), or

"(B) January 1, 2010.

For purposes of subparagraph (A), any plan amendment made pursuant to a collective bargaining agreement relating to the plan which amends the plan solely to conform to any requirement added by this section shall not be treated as a termination of such collective bargaining agreement."

EFFECTIVE DATE

Pub. L. 104–204, title VII, §703(b), Sept. 26, 1996, 110 Stat. 2950, provided that: "The amendments made by this section [enacting this section] shall apply with respect to group health plans for plan years beginning on or after January 1, 1998."

REGULATIONS

Pub. L. 110–343, div. C, title V, §512(d), Oct. 3, 2008, 122 Stat. 3891, provided that: "Not later than 1 year after the date of enactment of this Act [Oct. 3, 2008], the Secretaries of Labor, Health and Human Services, and the Treasury shall issue regulations to carry out the amendments made by subsections (a), (b), and (c) [amending this section, section 9812 of Title 26, Internal Revenue Code, and section 1185a of Title 29, Labor], respectively."

IMPROVING COMPLIANCE

Pub. L. 114–255, div. B, title XIII, §13001(d), Dec. 13, 2016, 130 Stat. 1283, provided that:

"(1) IN GENERAL.—In the case that the Secretary of Health and Human Services, the Secretary of Labor, or the Secretary of the Treasury determines that a group health plan or health insurance issuer offering group or individual health insurance coverage has violated, at least 5 times, section 2726 of the Public Health Service Act (42 U.S.C. 300gg–26), section 712 of the Employee Retirement Income Security Act of 1974 (29 U.S.C. 1185a), or section 9812 of the Internal Revenue Code of 1986 [26 U.S.C. 9812], respectively, the appropriate Secretary shall audit plan documents for such health plan or issuer in the plan year following the Secretary's determination in order to help improve compliance with such section.

"(2) RULE OF CONSTRUCTION.—Nothing in this subsection shall be construed to limit the authority, as in effect on the day before the date of enactment of this Act [Dec. 13, 2016], of the Secretary of Health and Human Services, the Secretary of Labor, or the Secretary of the Treasury to audit documents of health plans or health insurance issuers."

CLARIFICATION OF EXISTING PARITY RULES

Pub. L. 114–255, div. B, title XIII, §13007, Dec. 13, 2016, 130 Stat. 1287, provided that: "If a group health plan or a health insurance issuer offering group or individual health insurance coverage provides coverage for eating disorder benefits, including residential treatment, such group health plan or health insurance issuer shall provide such benefits consistent with the requirements of section 2726 of the Public Health Service Act (42 U.S.C. 300gg–26), section 712 of the Employee Retirement Income Security Act of 1974 (29 U.S.C. 1185a), and section 9812 of the Internal Revenue Code of 1986 [26 U.S.C. 9812]."

ASSURING COORDINATION

Pub. L. 110–343, div. C, title V, §512(f), Oct. 3, 2008, 122 Stat. 3892, provided that: "The Secretary of Health and Human Services, the Secretary of Labor, and the Secretary of the Treasury may ensure, through the execution or revision of an interagency memorandum of understanding among such Secretaries, that—

"(1) regulations, rulings, and interpretations issued by such Secretaries relating to the same matter over which two or more such Secretaries have responsibility under this section [amending this section, section

9812 of Title 26, Internal Revenue Code, and section 1185a of Title 29, Labor, and enacting provisions set out as notes under this section] (and the amendments made by this section) are administered so as to have the same effect at all times; and

"(2) coordination of policies relating to enforcing the same requirements through such Secretaries in order to have a coordinated enforcement strategy that avoids duplication of enforcement efforts and assigns priorities in enforcement."

EXECUTIVE DOCUMENTS

MENTAL HEALTH AND SUBSTANCE USE DISORDER PARITY TASK FORCE

Memorandum of President of the United States, Mar. 29, 2016, 81 F.R. 19015, provided:

Memorandum for the Heads of Executive Departments and Agencies

My Administration has made behavioral health a priority and taken a number of steps to improve the prevention, early intervention, and treatment of mental health and substance use disorders. These actions are especially important in light of the prescription drug abuse and heroin epidemic as well as the suicide and substance use-related fatalities that have reversed increases in longevity in certain populations. One important response has been the expansion and implementation of mental health and substance use disorder parity protections to ensure that coverage for these benefits is comparable to coverage for medical and surgical care. The Affordable Care Act builds on the Paul Wellstone and Pete Domenici Mental Health Parity and Addiction Equity Act to expand mental health and substance use disorder benefits and Federal parity protections for more than 60 million Americans. To realize the promise of coverage expansion and parity protections in helping individuals with mental health and substance use disorders, executive departments and agencies need to work together to ensure that Americans are benefiting from the Federal parity protections the law intends. To that end, I hereby direct the following:

SECTION 1. *Mental Health and Substance Use Disorder Parity Task Force*. There is established an interagency Mental Health and Substance Use Disorder Parity Task Force (Task Force), which will identify and promote best practices for executive departments and agencies (agencies), as well as State agencies, to better ensure compliance with and implementation of requirements related to mental health and substance use disorder parity, and determine areas that would benefit from further guidance. The Director of the Domestic Policy Council shall serve as Chair of the Task Force.

(a) *Membership of the Task Force*. In addition to the Director of the Domestic Policy Council, the Task Force shall consist of the heads of the following agencies and offices, or their designees:

(i) the Department of the Treasury;

(ii) the Department of Defense;

(iii) the Department of Justice;

(iv) the Department of Labor;

(v) the Department of Health and Human Services;

(vi) the Department of Veterans Affairs;

(vii) the Office of Personnel Management;

(viii) the Office of National Drug Control Policy; and

(ix) such other agencies or offices as the President may designate.

At the request of the Chair, the Task Force may establish subgroups consisting exclusively of Task Force members or their designees under this section, as appropriate.

(b) *Administration of the Task Force*. The Department of Health and Human Services shall provide funding and administrative support for the Task Force to the extent permitted by law and within existing appropriations.

SEC. 2. *Mission and Functions of the Task Force*. The Task Force shall coordinate across agencies to:

(a) identify and promote best practices for compliance and implementation;

(b) identify and address gaps in guidance, particularly with regard to substance use disorder parity; and

(c) implement actions during its tenure and at its conclusion to advance parity in mental health and substance use disorder treatment.

SEC. 3. *Outreach*. Consistent with the objectives set out in section 2 of this memorandum, the Task Force, in accordance with applicable law, shall conduct outreach to patients, consumer advocates, health care providers, specialists in mental health care and substance use disorder treatment, employers, insurers, State regulators, and other stakeholders as the Task Force deems appropriate.

SEC. 4. *Transparency and Reports*. The Task Force shall present to the President a report before October 31, 2016, on its findings and recommendations, which shall be made public.

SEC. 5. *General Provisions*. (a) The heads of agencies shall assist and provide information to the Task

Force, consistent with applicable law, as may be necessary to carry out the functions of the Task Force.

(b) Nothing in this memorandum shall be construed to impair or otherwise affect:

(i) the authority granted by law to an executive department, agency, or the head thereof; or

(ii) the functions of the Director of the Office of Management and Budget relating to budgetary, administrative, or legislative proposals.

(c) This memorandum shall be implemented consistent with applicable law and subject to the availability of appropriations.

(d) This memorandum is not intended to, and does not, create any right or benefit, substantive or procedural, enforceable at law or in equity by any party against the United States, its departments, agencies, or entities, its officers, employees, or agents, or any other person.

(e) The Secretary of Health and Human Services is authorized and directed to publish this memorandum in the Federal Register.

BARACK OBAMA.

§300gg–27. Required coverage for reconstructive surgery following mastectomies

The provisions of section 1185b of title 29 shall apply to group health plans, and and [1] health insurance issuers offering group or individual health insurance coverage, as if included in this subpart.

(July 1, 1944, ch. 373, title XXVII, §2727, formerly §2706, as added Pub. L. 105–277, div. A, §101(f) [title IX, §903(a)], Oct. 21, 1998, 112 Stat. 2681–337, 2681–438; renumbered §2727 and amended Pub. L. 111–148, title I, §§1001(2), 1563(c)(5), formerly §1562(c)(5), title X, §10107(b)(1), Mar. 23, 2010, 124 Stat. 130, 266, 911.)

EDITORIAL NOTES

CODIFICATION

Section was formerly classified to section 300gg–6 of this title prior to renumbering by Pub. L. 111–148.

AMENDMENTS

2010—Pub. L. 111–148, §1563(c)(5), formerly §1562(c)(5), as renumbered by Pub. L. 111–148, §10107(b)(1), substituted "and health insurance issuers offering group or individual health insurance coverage" for "health insurance issuers providing health insurance coverage in connection with group health plans".

STATUTORY NOTES AND RELATED SUBSIDIARIES

EFFECTIVE DATE

Pub. L. 105–277, div. A, §101(f) [title IX, §903(c)(1)], Oct. 21, 1998, 112 Stat. 2681–337, 2681–438, provided that:

"(A) IN GENERAL.—The amendment made by subsection (a) [enacting this section] shall apply to group health plans for plan years beginning on or after the date of enactment of this Act [Oct. 21, 1998].

"(B) SPECIAL RULE FOR COLLECTIVE BARGAINING AGREEMENTS.—In the case of a group health plan maintained pursuant to 1 or more collective bargaining agreements between employee representatives and 1 or more employers, any plan amendment made pursuant to a collective bargaining agreement relating to the plan which amends the plan solely to conform to any requirement added by the amendment made by subsection (a) shall not be treated as a termination of such collective bargaining agreement."

[1] *So in original.*

§300gg–28. Coverage of dependent students on medically necessary leave of

absence

(a) Medically necessary leave of absence

In this section, the term "medically necessary leave of absence" means, with respect to a dependent child described in subsection (b)(2) in connection with a group health plan or individual health insurance coverage, a leave of absence of such child from a postsecondary educational institution (including an institution of higher education as defined in section 1002 of title 20), or any other change in enrollment of such child at such an institution, that—

(1) commences while such child is suffering from a serious illness or injury;

(2) is medically necessary; and

(3) causes such child to lose student status for purposes of coverage under the terms of the plan or coverage.

(b) Requirement to continue coverage

(1) In general

In the case of a dependent child described in paragraph (2), a group health plan, or a health insurance issuer that offers group or individual health insurance coverage, shall not terminate coverage of such child under such plan or health insurance coverage due to a medically necessary leave of absence before the date that is the earlier of—

(A) the date that is 1 year after the first day of the medically necessary leave of absence; or

(B) the date on which such coverage would otherwise terminate under the terms of the plan or health insurance coverage.

(2) Dependent child described

A dependent child described in this paragraph is, with respect to a group health plan or individual health insurance coverage, a beneficiary under the plan who—

(A) is a dependent child, under the terms of the plan or coverage, of a participant or beneficiary under the plan or coverage; and

(B) was enrolled in the plan or coverage, on the basis of being a student at a postsecondary educational institution (as described in subsection (a)), immediately before the first day of the medically necessary leave of absence involved.

(3) Certification by physician

Paragraph (1) shall apply to a group health plan or individual health insurance coverage only if the plan or issuer of the coverage has received written certification by a treating physician of the dependent child which states that the child is suffering from a serious illness or injury and that the leave of absence (or other change of enrollment) described in subsection (a) is medically necessary.

(c) Notice

A group health plan, and a health insurance issuer that offers group or individual health insurance coverage, shall include, with any notice regarding a requirement for certification of student status for coverage under the plan or coverage, a description of the terms of this section for continued coverage during medically necessary leaves of absence. Such description shall be in language which is understandable to the typical plan participant.

(d) No change in benefits

A dependent child whose benefits are continued under this section shall be entitled to the same benefits as if (during the medically necessary leave of absence) the child continued to be a covered student at the institution of higher education and was not on a medically necessary leave of absence.

(e) Continued application in case of changed coverage

If—

(1) a dependent child of a participant or beneficiary is in a period of coverage under a group health plan or individual health insurance coverage, pursuant to a medically necessary leave of

absence of the child described in subsection (b);

(2) the manner in which the participant or beneficiary is covered under the plan changes, whether through a change in health insurance coverage or health insurance issuer, a change between health insurance coverage and self-insured coverage, or otherwise; and

(3) the coverage as so changed continues to provide coverage of beneficiaries as dependent children,

this section shall apply to coverage of the child under the changed coverage for the remainder of the period of the medically necessary leave of absence of the dependent child under the plan in the same manner as it would have applied if the changed coverage had been the previous coverage.

(July 1, 1944, ch. 373, title XXVII, §2728, formerly §2707, as added Pub. L. 110–381, §2(b)(1), Oct. 9, 2008, 122 Stat. 4083; renumbered §2728 and amended Pub. L. 111–148, title I, §§1001(2), 1563(c)(6), formerly §1562(c)(6), title X, §10107(b)(1), Mar. 23, 2010, 124 Stat. 130, 266, 911.)

EDITORIAL NOTES

CODIFICATION

Section was formerly classified to section 300gg–7 of this title prior to renumbering by Pub. L. 111–148.

AMENDMENTS

2010—Subsec. (a). Pub. L. 111–148, §1563(c)(6)(A), formerly §1562(c)(6)(A), as renumbered by Pub. L. 111–148, §10107(b)(1), substituted "individual health insurance coverage" for "health insurance coverage offered in connection with such plan" in introductory provisions.

Subsec. (b)(1). Pub. L. 111–148, §1563(c)(6)(B)(i), formerly §1562(c)(6)(B)(i), as renumbered by Pub. L. 111–148, §10107(b)(1), substituted "or a health insurance issuer that offers group or individual health insurance coverage" for "or a health insurance issuer that provides health insurance coverage in connection with a group health plan" in introductory provisions.

Subsec. (b)(2). Pub. L. 111–148, §1563(c)(6)(B)(ii), formerly §1562(c)(6)(B)(ii), as renumbered by Pub. L. 111–148, §10107(b)(1), substituted "individual health insurance coverage" for "health insurance coverage offered in connection with the plan" in introductory provisions.

Subsec. (b)(3). Pub. L. 111–148, §1563(c)(6)(B)(iii), formerly §1562(c)(6)(B)(iii), as renumbered by Pub. L. 111–148, §10107(b)(1), substituted "individual health insurance coverage" for "health insurance coverage offered by an issuer in connection with such plan".

Subsec. (c). Pub. L. 111–148, §1563(c)(6)(C), formerly §1562(c)(6)(C), as renumbered by Pub. L. 111–148, §10107(b)(1), substituted "health insurance issuer that offers group or individual health insurance coverage" for "health insurance issuer providing health insurance coverage in connection with a group health plan".

Subsec. (e)(1). Pub. L. 111–148, §1563(c)(6)(D), formerly §1562(c)(6)(D), as renumbered by Pub. L. 111–148, §10107(b)(1), substituted "individual health insurance coverage" for "health insurance coverage offered in connection with such a plan".

STATUTORY NOTES AND RELATED SUBSIDIARIES

EFFECTIVE DATE

Section applicable with respect to plan years beginning on or after the date that is one year after Oct. 9, 2008, and to medically necessary leaves of absence beginning during such plan years, see section 2(d) of Pub. L. 110–381, set out as a note under section 9813 of Title 26, Internal Revenue Code.

PART B—INDIVIDUAL MARKET RULES

SUBPART 1—PORTABILITY, ACCESS, AND RENEWABILITY

REQUIREMENTS

§300gg–41. Guaranteed availability of individual health insurance coverage to certain individuals with prior group coverage

(a) Guaranteed availability

(1) In general

Subject to the succeeding subsections of this section and section 300gg–44 of this title, each health insurance issuer that offers health insurance coverage (as defined in section 300gg–91(b)(1) of this title) in the individual market in a State may not, with respect to an eligible individual (as defined in subsection (b)) desiring to enroll in individual health insurance coverage—

(A) decline to offer such coverage to, or deny enrollment of, such individual; or

(B) impose any preexisting condition exclusion (as defined in section 2701(b)(1)(A)) [1] with respect to such coverage.

(2) Substitution by State of acceptable alternative mechanism

The requirement of paragraph (1) shall not apply to health insurance coverage offered in the individual market in a State in which the State is implementing an acceptable alternative mechanism under section 300gg–44 of this title.

(b) "Eligible individual" defined

In this part, the term "eligible individual" means an individual—

(1)(A) for whom, as of the date on which the individual seeks coverage under this section, the aggregate of the periods of creditable coverage (as defined in section 2701(c)) [1] is 18 or more months and (B) whose most recent prior creditable coverage was under a group health plan, governmental plan, or church plan (or health insurance coverage offered in connection with any such plan);

(2) who is not eligible for coverage under (A) a group health plan, (B) part A or part B of title XVIII of the Social Security Act [42 U.S.C. 1395c et seq., 1395j et seq.], or (C) a State plan under title XIX of such Act [42 U.S.C. 1396 et seq.] (or any successor program), and does not have other health insurance coverage;

(3) with respect to whom the most recent coverage within the coverage period described in paragraph (1)(A) was not terminated based on a factor described in paragraph (1) or (2) of section 2712(b) [1] (relating to nonpayment of premiums or fraud);

(4) if the individual had been offered the option of continuation coverage under a COBRA continuation provision or under a similar State program, who elected such coverage; and

(5) who, if the individual elected such continuation coverage, has exhausted such continuation coverage under such provision or program.

(c) Alternative coverage permitted where no State mechanism

(1) In general

In the case of health insurance coverage offered in the individual market in a State in which the State is not implementing an acceptable alternative mechanism under section 300gg–44 of this title, the health insurance issuer may elect to limit the coverage offered under subsection (a) so long as it offers at least two different policy forms of health insurance coverage both of which—

(A) are designed for, made generally available to, and actively marketed to, and enroll both eligible and other individuals by the issuer; and

(B) meet the requirement of paragraph (2) or (3), as elected by the issuer.

For purposes of this subsection, policy forms which have different cost-sharing arrangements or different riders shall be considered to be different policy forms.

(2) Choice of most popular policy forms

The requirement of this paragraph is met, for health insurance coverage policy forms offered by an issuer in the individual market, if the issuer offers the policy forms for individual health insurance coverage with the largest, and next to largest, premium volume of all such policy forms offered by the issuer in the State or applicable marketing or service area (as may be prescribed in regulation) by the issuer in the individual market in the period involved.

(3) Choice of 2 policy forms with representative coverage

(A) In general

The requirement of this paragraph is met, for health insurance coverage policy forms offered by an issuer in the individual market, if the issuer offers a lower-level coverage policy form (as defined in subparagraph (B)) and a higher-level coverage policy form (as defined in subparagraph (C)) each of which includes benefits substantially similar to other individual health insurance coverage offered by the issuer in that State and each of which is covered under a method described in section 300gg–44(c)(3)(A) of this title (relating to risk adjustment, risk spreading, or financial subsidization).

(B) Lower-level of coverage described

A policy form is described in this subparagraph if the actuarial value of the benefits under the coverage is at least 85 percent but not greater than 100 percent of a weighted average (described in subparagraph (D)).

(C) Higher-level of coverage described

A policy form is described in this subparagraph if—

(i) the actuarial value of the benefits under the coverage is at least 15 percent greater than the actuarial value of the coverage described in subparagraph (B) offered by the issuer in the area involved; and

(ii) the actuarial value of the benefits under the coverage is at least 100 percent but not greater than 120 percent of a weighted average (described in subparagraph (D)).

(D) Weighted average

For purposes of this paragraph, the weighted average described in this subparagraph is the average actuarial value of the benefits provided by all the health insurance coverage issued (as elected by the issuer) either by that issuer or by all issuers in the State in the individual market during the previous year (not including coverage issued under this section), weighted by enrollment for the different coverage.

(4) Election

The issuer elections under this subsection shall apply uniformly to all eligible individuals in the State for that issuer. Such an election shall be effective for policies offered during a period of not shorter than 2 years.

(5) Assumptions

For purposes of paragraph (3), the actuarial value of benefits provided under individual health insurance coverage shall be calculated based on a standardized population and a set of standardized utilization and cost factors.

(d) Special rules for network plans

(1) In general

In the case of a health insurance issuer that offers health insurance coverage in the individual market through a network plan, the issuer may—

(A) limit the individuals who may be enrolled under such coverage to those who live, reside, or work within the service area for such network plan; and

(B) within the service area of such plan, deny such coverage to such individuals if the issuer has demonstrated, if required, to the applicable State authority that—

(i) it will not have the capacity to deliver services adequately to additional individual enrollees because of its obligations to existing group contract holders and enrollees and individual enrollees, and

(ii) it is applying this paragraph uniformly to individuals without regard to any health status-related factor of such individuals and without regard to whether the individuals are eligible individuals.

(2) 180-day suspension upon denial of coverage

An issuer, upon denying health insurance coverage in any service area in accordance with paragraph (1)(B), may not offer coverage in the individual market within such service area for a period of 180 days after such coverage is denied.

(e) [2] Application of financial capacity limits

(1) In general

A health insurance issuer may deny health insurance coverage in the individual market to an eligible individual if the issuer has demonstrated, if required, to the applicable State authority that—

(A) it does not have the financial reserves necessary to underwrite additional coverage; and

(B) it is applying this paragraph uniformly to all individuals in the individual market in the State consistent with applicable State law and without regard to any health status-related factor of such individuals and without regard to whether the individuals are eligible individuals.

(2) 180-day suspension upon denial of coverage

An issuer upon denying individual health insurance coverage in any service area in accordance with paragraph (1) may not offer such coverage in the individual market within such service area for a period of 180 days after the date such coverage is denied or until the issuer has demonstrated, if required under applicable State law, to the applicable State authority that the issuer has sufficient financial reserves to underwrite additional coverage, whichever is later. A State may provide for the application of this paragraph on a service-area-specific basis.

(e) [2] Market requirements

(1) In general

The provisions of subsection (a) shall not be construed to require that a health insurance issuer offering health insurance coverage only in connection with group health plans or through one or more bona fide associations, or both, offer such health insurance coverage in the individual market.

(2) Conversion policies

A health insurance issuer offering health insurance coverage in connection with group health plans under this subchapter shall not be deemed to be a health insurance issuer offering individual health insurance coverage solely because such issuer offers a conversion policy.

(f) Construction

Nothing in this section shall be construed—

(1) to restrict the amount of the premium rates that an issuer may charge an individual for health insurance coverage provided in the individual market under applicable State law; or

(2) to prevent a health insurance issuer offering health insurance coverage in the individual market from establishing premium discounts or rebates or modifying otherwise applicable copayments or deductibles in return for adherence to programs of health promotion and disease prevention.

(July 1, 1944, ch. 373, title XXVII, §2741, as added Pub. L. 104–191, title I, §111(a), Aug. 21, 1996, 110 Stat. 1978.)

EDITORIAL NOTES

REFERENCES IN TEXT

Section 2701 of this Act, referred to in subsecs. (a)(1)(B) and (b)(1)(A), is a reference to section 2701 of act July 1, 1944. Section 2701, which was classified to section 300gg of this title, was renumbered section 2704, effective for plan years beginning on or after Jan. 1, 2014, with certain exceptions, and amended, by Pub. L. 111–148, title I, §§1201(2), 1563(c)(1), formerly §1562(c)(1), title X, §10107(b)(1), Mar. 23, 2010, 124 Stat. 154, 264, 911, and was transferred to section 300gg–3 of this title. A new section 2701 of act July 1, 1944, related to fair health insurance premiums, was added, effective for plan years beginning on or after Jan. 1, 2014, and amended, by Pub. L. 111–148, title I, §1201(4), title X, §10103(a), Mar. 23, 2010, 124 Stat. 155, 892, and is classified to section 300gg of this title.

The Social Security Act, referred to in subsec. (b)(2), is act Aug. 14, 1935, ch. 531, 49 Stat. 620. Parts A and B of title XVIII of the Act are classified generally to parts A (§1395c et seq.) and B (§1395j et seq.) of subchapter XVIII of chapter 7 of this title. Title XIX of the Act is classified generally to subchapter XIX (§1396 et seq.) of chapter 7 of this title. For complete classification of this Act to the Code, see section 1305 of this title and Tables.

Section 2712, referred to in subsec. (b)(3), is a reference to section 2712 of act July 1, 1944. Section 2712, which was classified to section 300gg–12 of this title, was renumbered section 2732 and amended and transferred to subsecs. (b) to (e) of section 300gg–2 of this title by Pub. L. 111–148, title I, §§1001(3), 1563(c)(9), formerly §1562(c)(9), title X, §10107(b)(1), Mar. 23, 2010, 124 Stat. 130, 267, 911. A new section 2712 of act July 1, 1944, related to prohibition on rescissions, was added by Pub. L. 111–148, title I, §1001(5), Mar. 23, 2010, 124 Stat. 131, effective for plan years beginning on or after the date that is 6 months after Mar. 23, 2010, and is classified to section 300gg–12 of this title.

STATUTORY NOTES AND RELATED SUBSIDIARIES

EFFECTIVE DATE

Pub. L. 104–191, title I, §111(b), Aug. 21, 1996, 110 Stat. 1987, provided that:

"(1) IN GENERAL.—Except as provided in this subsection, part B of title XXVII of the Public Health Service Act [42 U.S.C. 300gg–41 et seq.] (as inserted by subsection (a)) shall apply with respect to health insurance coverage offered, sold, issued, renewed, in effect, or operated in the individual market after June 30, 1997, regardless of when a period of creditable coverage occurs.

"(2) APPLICATION OF CERTIFICATION RULES.—The provisions of section 102(d)(2) [102(c)(2)] of this Act [42 U.S.C. 300gg note] shall apply to section 2743 of the Public Health Service Act [42 U.S.C. 300gg–43] in the same manner as it applies to section 2701(e) [now 2704(e)] of such Act [42 U.S.C. 300gg–3(e)]."

[1] *See References in Text note below.*

[2] *So in original. Two subsecs. (e) have been enacted.*

§300gg–42. Guaranteed renewability of individual health insurance coverage

(a) In general

Except as provided in this section, a health insurance issuer that provides individual health insurance coverage to an individual shall renew or continue in force such coverage at the option of the individual.

(b) General exceptions

A health insurance issuer may nonrenew or discontinue health insurance coverage of an individual in the individual market based only on one or more of the following:

(1) Nonpayment of premiums

The individual has failed to pay premiums or contributions in accordance with the terms of the health insurance coverage or the issuer has not received timely premium payments.

(2) Fraud

The individual has performed an act or practice that constitutes fraud or made an intentional misrepresentation of material fact under the terms of the coverage.

(3) Termination of plan

The issuer is ceasing to offer coverage in the individual market in accordance with subsection (c) and applicable State law.

(4) Movement outside service area

In the case of a health insurance issuer that offers health insurance coverage in the market through a network plan, the individual no longer resides, lives, or works in the service area (or in an area for which the issuer is authorized to do business) but only if such coverage is terminated under this paragraph uniformly without regard to any health status-related factor of covered individuals.

(5) Association membership ceases

In the case of health insurance coverage that is made available in the individual market only through one or more bona fide associations, the membership of the individual in the association (on the basis of which the coverage is provided) ceases but only if such coverage is terminated under this paragraph uniformly without regard to any health status-related factor of covered individuals.

(c) Requirements for uniform termination of coverage

(1) Particular type of coverage not offered

In any case in which an issuer decides to discontinue offering a particular type of health insurance coverage offered in the individual market, coverage of such type may be discontinued by the issuer only if—

(A) the issuer provides notice to each covered individual provided coverage of this type in such market of such discontinuation at least 90 days prior to the date of the discontinuation of such coverage;

(B) the issuer offers to each individual in the individual market provided coverage of this type, the option to purchase any other individual health insurance coverage currently being offered by the issuer for individuals in such market; and

(C) in exercising the option to discontinue coverage of this type and in offering the option of coverage under subparagraph (B), the issuer acts uniformly without regard to any health status-related factor of enrolled individuals or individuals who may become eligible for such coverage.

(2) Discontinuance of all coverage

(A) In general

Subject to subparagraph (C), in any case in which a health insurance issuer elects to discontinue offering all health insurance coverage in the individual market in a State, health insurance coverage may be discontinued by the issuer only if—

(i) the issuer provides notice to the applicable State authority and to each individual of such discontinuation at least 180 days prior to the date of the expiration of such coverage, and

(ii) all health insurance issued or delivered for issuance in the State in such market are discontinued and coverage under such health insurance coverage in such market is not renewed.

(B) Prohibition on market reentry

In the case of a discontinuation under subparagraph (A) in the individual market, the issuer may not provide for the issuance of any health insurance coverage in the market and State involved during the 5-year period beginning on the date of the discontinuation of the last health insurance coverage not so renewed.

(d) Exception for uniform modification of coverage

At the time of coverage renewal, a health insurance issuer may modify the health insurance coverage for a policy form offered to individuals in the individual market so long as such modification is consistent with State law and effective on a uniform basis among all individuals with that policy form.

(e) Application to coverage offered only through associations

In applying this section in the case of health insurance coverage that is made available by a health insurance issuer in the individual market to individuals only through one or more associations, a reference to an "individual" is deemed to include a reference to such an association (of which the individual is a member).

(July 1, 1944, ch. 373, title XXVII, §2742, as added Pub. L. 104–191, title I, §111(a), Aug. 21, 1996, 110 Stat. 1982.)

STATUTORY NOTES AND RELATED SUBSIDIARIES

EFFECTIVE DATE

Section applicable with respect to health insurance coverage offered, sold, issued, renewed, in effect, or operated in the individual market after June 30, 1997, regardless of when a period of creditable coverage occurs, see section 111(b) of Pub. L. 104–191, set out as a note under section 300gg–41 of this title.

§300gg–43. Certification of coverage

The provisions of section 2701(e) [1] shall apply to health insurance coverage offered by a health insurance issuer in the individual market in the same manner as it applies to health insurance coverage offered by a health insurance issuer in connection with a group health plan in the small or large group market.

(July 1, 1944, ch. 373, title XXVII, §2743, as added Pub. L. 104–191, title I, §111(a), Aug. 21, 1996, 110 Stat. 1983.)

EDITORIAL NOTES

REFERENCES IN TEXT

Section 2701 of this Act, referred to in text, is a reference to section 2701 of act July 1, 1944. Section 2701, which was classified to section 300gg of this title, was renumbered section 2704, effective for plan years beginning on or after Jan. 1, 2014, with certain exceptions, and amended, by Pub. L. 111–148, title I, §§1201(2), 1563(c)(1), formerly §1562(c)(1), title X, §10107(b)(1), Mar. 23, 2010, 124 Stat. 154, 264, 911, and was transferred to section 300gg–3 of this title. A new section 2701 of act July 1, 1944, related to fair health insurance premiums, was added, effective for plan years beginning on or after Jan. 1, 2014, and amended, by Pub. L. 111–148, title I, §1201(4), title X, §10103(a), Mar. 23, 2010, 124 Stat. 155, 892, and is classified to section 300gg of this title.

STATUTORY NOTES AND RELATED SUBSIDIARIES

EFFECTIVE DATE

Section applicable with respect to health insurance coverage offered, sold, issued, renewed, in effect, or operated in the individual market after June 30, 1997, regardless of when a period of creditable coverage occurs, and provisions of section 102(c)(2) of Pub. L. 104–191, set out as a note under section 300gg of this title, applicable to this section in the same manner as it applies to section 300gg(e) of this title, see section 111(b) of Pub. L. 104–191, set out as a note under section 300gg–41 of this title.

[1] *See References in Text note below.*

§300gg–44. State flexibility in individual market reforms

(a) Waiver of requirements where implementation of acceptable alternative mechanism

(1) In general

The requirements of section 300gg–41 of this title shall not apply with respect to health insurance coverage offered in the individual market in the State so long as a State is found to be implementing, in accordance with this section and consistent with section 300gg–62(b) of this title, an alternative mechanism (in this section referred to as an "acceptable alternative mechanism")—

(A) under which all eligible individuals are provided a choice of health insurance coverage;

(B) under which such coverage does not impose any preexisting condition exclusion with respect to such coverage;

(C) under which such choice of coverage includes at least one policy form of coverage that is comparable to comprehensive health insurance coverage offered in the individual market in such State or that is comparable to a standard option of coverage available under the group or individual health insurance laws of such State; and

(D) in a State which is implementing—

(i) a model act described in subsection (c)(1),

(ii) a qualified high risk pool described in subsection (c)(2), or

(iii) a mechanism described in subsection (c)(3).

(2) Permissible forms of mechanisms

A private or public individual health insurance mechanism (such as a health insurance coverage pool or programs, mandatory group conversion policies, guaranteed issue of one or more plans of individual health insurance coverage, or open enrollment by one or more health insurance issuers), or combination of such mechanisms, that is designed to provide access to health benefits for individuals in the individual market in the State in accordance with this section may constitute an acceptable alternative mechanism.

(b) Application of acceptable alternative mechanisms

(1) Presumption

(A) In general

Subject to the succeeding provisions of this subsection, a State is presumed to be implementing an acceptable alternative mechanism in accordance with this section as of July 1, 1997, if, by not later than April 1, 1997, the chief executive officer of a State—

(i) notifies the Secretary that the State has enacted or intends to enact (by not later than January 1, 1998, or July 1, 1998, in the case of a State described in subparagraph (B)(ii)) any necessary legislation to provide for the implementation of a mechanism reasonably designed to be an acceptable alternative mechanism as of January 1, 1998,[1] (or, in the case of a State described in subparagraph (B)(ii), July 1, 1998); and

(ii) provides the Secretary with such information as the Secretary may require to review the mechanism and its implementation (or proposed implementation) under this subsection.

(B) Delay permitted for certain States

(i) Effect of delay

In the case of a State described in clause (ii) that provides notice under subparagraph (A)(i), for the presumption to continue on and after July 1, 1998, the chief executive officer of the State by April 1, 1998—

(I) must notify the Secretary that the State has enacted any necessary legislation to provide for the implementation of a mechanism reasonably designed to be an acceptable alternative mechanism as of July 1, 1998; and

(II) must provide the Secretary with such information as the Secretary may require to review the mechanism and its implementation (or proposed implementation) under this

subsection.

(ii) States described

A State described in this clause is a State that has a legislature that does not meet within the 12-month period beginning on August 21, 1996.

(C) Continued application

In order for a mechanism to continue to be presumed to be an acceptable alternative mechanism, the State shall provide the Secretary every 3 years with information described in subparagraph (A)(ii) or (B)(i)(II) (as the case may be).

(2) Notice

If the Secretary finds, after review of information provided under paragraph (1) and in consultation with the chief executive officer of the State and the insurance commissioner or chief insurance regulatory official of the State, that such a mechanism is not an acceptable alternative mechanism or is not (or no longer) being implemented, the Secretary—

(A) shall notify the State of—

(i) such preliminary determination, and

(ii) the consequences under paragraph (3) of a failure to implement such a mechanism; and

(B) shall permit the State a reasonable opportunity in which to modify the mechanism (or to adopt another mechanism) in a manner so that may be an acceptable alternative mechanism or to provide for implementation of such a mechanism.

(3) Final determination

If, after providing notice and opportunity under paragraph (2), the Secretary finds that the mechanism is not an acceptable alternative mechanism or the State is not implementing such a mechanism, the Secretary shall notify the State that the State is no longer considered to be implementing an acceptable alternative mechanism and that the requirements of section 300gg–41 of this title shall apply to health insurance coverage offered in the individual market in the State, effective as of a date specified in the notice.

(4) Limitation on secretarial authority

The Secretary shall not make a determination under paragraph (2) or (3) on any basis other than the basis that a mechanism is not an acceptable alternative mechanism or is not being implemented.

(5) Future adoption of mechanisms

If a State, after January 1, 1997, submits the notice and information described in paragraph (1), unless the Secretary makes a finding described in paragraph (3) within the 90-day period beginning on the date of submission of the notice and information, the mechanism shall be considered to be an acceptable alternative mechanism for purposes of this section, effective 90 days after the end of such period, subject to the second sentence of paragraph (1).

(c) Provision related to risk

(1) Adoption of NAIC models

The model act referred to in subsection (a)(1)(D)(i) is the Small Employer and Individual Health Insurance Availability Model Act (adopted by the National Association of Insurance Commissioners on June 3, 1996) insofar as it applies to individual health insurance coverage or the Individual Health Insurance Portability Model Act (also adopted by such Association on such date).

(2) Qualified high risk pool

For purposes of subsection (a)(1)(D)(ii), a "qualified high risk pool" described in this paragraph is a high risk pool that—

(A) provides to all eligible individuals health insurance coverage (or comparable coverage)

that does not impose any preexisting condition exclusion with respect to such coverage for all eligible individuals, and

(B) provides for premium rates and covered benefits for such coverage consistent with standards included in the NAIC Model Health Plan for Uninsurable Individuals Act (as in effect as of August 21, 1996).

(3) Other mechanisms

For purposes of subsection (a)(1)(D)(iii), a mechanism described in this paragraph—

(A) provides for risk adjustment, risk spreading, or a risk spreading mechanism (among issuers or policies of an issuer) or otherwise provides for some financial subsidization for eligible individuals, including through assistance to participating issuers; or

(B) is a mechanism under which each eligible individual is provided a choice of all individual health insurance coverage otherwise available.

(July 1, 1944, ch. 373, title XXVII, §2744, as added Pub. L. 104–191, title I, §111(a), Aug. 21, 1996, 110 Stat. 1984; amended Pub. L. 104–204, title VI, §605(b)(1), Sept. 26, 1996, 110 Stat. 2942.)

EDITORIAL NOTES

CODIFICATION

August 21, 1996, referred to in subsec. (b)(1)(B)(ii), was in the original "the date of enactment of this Act", which was translated as meaning the date of enactment of Pub. L. 104–191, which enacted this subchapter, to reflect the probable intent of Congress.

AMENDMENTS

1996—Subsec. (a)(1). Pub. L. 104–204 made technical amendment to reference in original act which appears in text as reference to section 300gg–62(b) of this title.

STATUTORY NOTES AND RELATED SUBSIDIARIES

EFFECTIVE DATE OF 1996 AMENDMENT

Pub. L. 104–204, title VI, §605(c), Sept. 26, 1996, 110 Stat. 2942, provided that: "The amendments made by this section [enacting section 300gg–51 of this title and amending this section and sections 300gg–61 and 300gg–62 of this title] shall apply with respect to health insurance coverage offered, sold, issued, renewed, in effect, or operated in the individual market on or after January 1, 1998."

EFFECTIVE DATE

Section applicable with respect to health insurance coverage offered, sold, issued, renewed, in effect, or operated in the individual market after June 30, 1997, regardless of when a period of creditable coverage occurs, see section 111(b) of Pub. L. 104–191, set out as a note under section 300gg–41 of this title.

[1] So in original. The comma probably should not appear.

§300gg–45. Relief for high risk pools

(a) Seed grants to States

The Secretary shall provide from the funds appropriated under subsection (d)(1)(A) a grant of up to $1,000,000 to each State that has not created a qualified high risk pool as of February 10, 2006, for the State's costs of creation and initial operation of such a pool.

(b) Grants for operational losses

(1) In general

In the case of a State that has established a qualified high risk pool that—

(A) restricts premiums charged under the pool to no more than 200 percent of the premium

for applicable standard risk rates;

(B) offers a choice of two or more coverage options through the pool; and

(C) has in effect a mechanism reasonably designed to ensure continued funding of losses incurred by the State in connection with operation of the pool after the end of the last fiscal year for which a grant is provided under this paragraph;

the Secretary shall provide, from the funds appropriated under paragraphs (1)(B)(i) and (2)(A) of subsection (d) and allotted to the State under paragraph (2), a grant for the losses incurred by the State in connection with the operation of the pool.

(2) Allotment

Subject to paragraph (4), the amounts appropriated under paragraphs (1)(B)(i) and (2)(A) of subsection (d) for a fiscal year shall be allotted and made available to the States (or the entities that operate the high risk pool under applicable State law) that qualify for a grant under paragraph (1) as follows:

(A) An amount equal to 40 percent of such appropriated amount for the fiscal year shall be allotted in equal amounts to each qualifying State that is one of the 50 States or the District of Columbia and that applies for a grant under this subsection.

(B) An amount equal to 30 percent of such appropriated amount for the fiscal year shall be allotted among qualifying States that apply for such a grant so that the amount allotted to such a State bears the same ratio to such appropriated amount as the number of uninsured individuals in the State bears to the total number of uninsured individuals (as determined by the Secretary) in all qualifying States that so apply.

(C) An amount equal to 30 percent of such appropriated amount for the fiscal year shall be allotted among qualifying States that apply for such a grant so that the amount allotted to a State bears the same ratio to such appropriated amount as the number of individuals enrolled in health care coverage through the qualified high risk pool of the State bears to the total number of individuals so enrolled through qualified high risk pools (as determined by the Secretary) in all qualifying States that so apply.

(3) Special rule for pools charging higher premiums

In the case of a qualified high risk pool of a State which charges premiums that exceed 150 percent of the premium for applicable standard risks, the State shall use at least 50 percent of the amount of the grant provided to the State to carry out this subsection to reduce premiums for enrollees.

(4) Limitation for territories

In no case shall the aggregate amount allotted and made available under paragraph (2) for a fiscal year to States that are not the 50 States or the District of Columbia exceed $1,000,000.

(c) Bonus grants for supplemental consumer benefits

(1) In general

In the case of a State that is one of the 50 States or the District of Columbia, that has established a qualified high risk pool, and that is receiving a grant under subsection (b)(1), the Secretary shall provide, from the funds appropriated under paragraphs (1)(B)(ii) and (2)(B) of subsection (d) and allotted to the State under paragraph (3), a grant to be used to provide supplemental consumer benefits to enrollees or potential enrollees (or defined subsets of such enrollees or potential enrollees) in qualified high risk pools.

(2) Benefits

A State shall use amounts received under a grant under this subsection to provide one or more of the following benefits:

(A) Low-income premium subsidies.

(B) A reduction in premium trends, actual premiums, or other cost-sharing requirements.

(C) An expansion or broadening of the pool of individuals eligible for coverage, such as

through eliminating waiting lists, increasing enrollment caps, or providing flexibility in enrollment rules.

(D) Less stringent rules, or additional waiver authority, with respect to coverage of pre-existing conditions.

(E) Increased benefits.

(F) The establishment of disease management programs.

(3) Allotment; limitation

The Secretary shall allot funds appropriated under paragraphs (1)(B)(ii) and (2)(B) of subsection (d) among States qualifying for a grant under paragraph (1) in a manner specified by the Secretary, but in no case shall the amount so allotted to a State for a fiscal year exceed 10 percent of the funds so appropriated for the fiscal year.

(4) Rule of construction

Nothing in this subsection shall be construed to prohibit a State that, on February 10, 2006, is in the process of implementing a program to provide benefits of the type described in paragraph (2), from being eligible for a grant under this subsection.

(d) Funding

(1) Appropriation for fiscal year 2006

There are authorized to be appropriated for fiscal year 2006—

(A) $15,000,000 to carry out subsection (a); and

(B) $75,000,000, of which, subject to paragraph (4)—

(i) two-thirds of the amount appropriated shall be made available for allotments under subsection (b)(2); and

(ii) one-third of the amount appropriated shall be made available for allotments under subsection (c)(3).

(2) Authorization of appropriations for fiscal years 2007 through 2010

There are authorized to be appropriated $75,000,000 for each of fiscal years 2007 through 2010, of which, subject to paragraph (4)—

(A) two-thirds of the amount appropriated for a fiscal year shall be made available for allotments under subsection (b)(2); and

(B) one-third of the amount appropriated for a fiscal year shall be made available for allotments under subsection (c)(3).

(3) Availability

Funds appropriated for purposes of carrying out this section for a fiscal year shall remain available for obligation through the end of the following fiscal year.

(4) Reallotment

If, on June 30 of each fiscal year for which funds are appropriated under paragraph (1)(B) or (2), the Secretary determines that all the amounts so appropriated are not allotted or otherwise made available to States, such remaining amounts shall be allotted and made available under subsection (b) among States receiving grants under subsection (b) for the fiscal year based upon the allotment formula specified in such subsection.

(5) No entitlement

Nothing in this section shall be construed as providing a State with an entitlement to a grant under this section.

(e) Applications

To be eligible for a grant under this section, a State shall submit to the Secretary an application at such time, in such manner, and containing such information as the Secretary may require.

(f) Annual report

The Secretary shall submit to Congress an annual report on grants provided under this section.

Each such report shall include information on the distribution of such grants among States and the use of grant funds by States.

(g) Definitions

In this section:

(1) Qualified high risk pool

(A) [1] In general

The term "qualified high risk pool" has the meaning given such term in section 300gg–44(c)(2) of this title, except that a State may elect to meet the requirement of subparagraph (A) of such section (insofar as it requires the provision of coverage to all eligible individuals) through providing for the enrollment of eligible individuals through an acceptable alternative mechanism (as defined for purposes of section 300gg–44 of this title) that includes a high risk pool as a component.

(2) Standard risk rate

The term "standard risk rate" means a rate—

(A) determined under the State high risk pool by considering the premium rates charged by other health insurers offering health insurance coverage to individuals in the insurance market served;

(B) that is established using reasonable actuarial techniques; and

(C) that reflects anticipated claims experience and expenses for the coverage involved.

(3) State

The term "State" means any of the 50 States and the District of Columbia and includes Puerto Rico, the Virgin Islands, Guam, American Samoa, and the Northern Mariana Islands.

(July 1, 1944, ch. 373, title XXVII, §2745, as added Pub. L. 107–210, div. A, title II, §201(b), Aug. 6, 2002, 116 Stat. 959; amended Pub. L. 109–172, §2, Feb. 10, 2006, 120 Stat. 185.)

EDITORIAL NOTES

AMENDMENTS

2006—Pub. L. 109–172 amended section generally, substituting provisions relating to relief for high risk pools for provisions relating to promotion of qualified high risk pools.

STATUTORY NOTES AND RELATED SUBSIDIARIES

CONSTRUCTION

Nothing in the amendments made by title II of Pub. L. 107–210, other than provisions relating to COBRA continuation coverage and reporting requirements, to be construed as creating a new mandate on any party regarding health insurance coverage, see section 203(f) of Pub. L. 107–210, set out as a note under section 35 of Title 26, Internal Revenue Code.

[1] So in original. No subpar. (B) has been enacted.

§300gg–46. Disclosure to enrollees of individual market coverage

(a) In general

A health insurance issuer offering individual health insurance coverage or a health insurance issuer offering short-term limited duration insurance coverage shall make disclosures to enrollees in such coverage, as described in subsection (b), and reports to the Secretary, as described in subsection (c), regarding direct or indirect compensation provided by the issuer to an agent or broker associated with enrolling individuals in such coverage.

(b) Disclosure

A health insurance issuer described in subsection (a) shall disclose to an enrollee the amount of direct or indirect compensation provided to an agent or broker for services provided by such agent or broker associated with plan selection and enrollment. Such disclosure shall be—

(1) made prior to the individual finalizing plan selection; and

(2) included on any documentation confirming the individual's enrollment.

(c) Reporting

A health insurance issuer described in subsection (a) shall annually report to the Secretary, prior to the beginning of open enrollment, any direct or indirect compensation provided to an agent or broker associated with enrolling individuals in such coverage.

(d) Rulemaking

Not later than 1 year after December 27, 2020, the Secretary shall finalize, through notice-and-comment rulemaking, the timing, form, and manner in which issuers described in subsection (a) are required to make the disclosures described in subsection (b) and the reports described in subsection (c). Such rulemaking may also include adjustments to notice requirements to reflect the different processes for plan renewals, in order to provide enrollees with full, timely information.

(July 1, 1944, ch. 373, title XXVII, §2746, as added Pub. L. 116–260, div. BB, title II, §202(c), Dec. 27, 2020, 134 Stat. 2899.)

STATUTORY NOTES AND RELATED SUBSIDIARIES

EFFECTIVE DATE

Section applicable beginning 1 year after Dec. 27, 2020, see section 202(e) of div. BB of Pub. L. 116–260, set out as an Effective Date of 2020 Amendment note under section 1108 of Title 29, Labor.

SUBPART 2—OTHER REQUIREMENTS

EDITORIAL NOTES

CODIFICATION

Pub. L. 110–233, title I, §102(b)(1)(A), May 21, 2008, 122 Stat. 892, redesignated this subpart, which was originally enacted as subpart 3 of part B of title XXVII of act July 1, 1944, as subpart 2.

§300gg–51. Standards relating to benefits for mothers and newborns

(a) In general

The provisions of section 2704 [1] (other than subsections (d) and (f)) shall apply to health insurance coverage offered by a health insurance issuer in the individual market in the same manner as it applies to health insurance coverage offered by a health insurance issuer in connection with a group health plan in the small or large group market.

(b) Notice requirement

A health insurance issuer under this part shall comply with the notice requirement under section 1185(d) of title 29 with respect to the requirements referred to in subsection (a) as if such section applied to such issuer and such issuer were a group health plan.

(c) Preemption; exception for health insurance coverage in certain States

(1) In general

The requirements of this section shall not apply with respect to health insurance coverage if there is a State law (as defined in section 300gg–23(d)(1) [1] of this title) for a State that regulates such coverage that is described in any of the following subparagraphs:

(A) Such State law requires such coverage to provide for at least a 48-hour hospital length of stay following a normal vaginal delivery and at least a 96-hour hospital length of stay following a cesarean section.

(B) Such State law requires such coverage to provide for maternity and pediatric care in accordance with guidelines established by the American College of Obstetricians and Gynecologists, the American Academy of Pediatrics, or other established professional medical associations.

(C) Such State law requires, in connection with such coverage for maternity care, that the hospital length of stay for such care is left to the decision of (or required to be made by) the attending provider in consultation with the mother.

(2) Construction

Section 300gg–62(a) of this title shall not be construed as superseding a State law described in paragraph (1).

(July 1, 1944, ch. 373, title XXVII, §2751, as added Pub. L. 104–204, title VI, §605(a)(4), Sept. 26, 1996, 110 Stat. 2941.)

EDITORIAL NOTES

REFERENCES IN TEXT

Section 2704, referred to in subsec. (a), is a reference to section 2704 of act July 1, 1944. Section 2704, which was classified to section 300gg–4 of this title, was renumbered section 2725, and amended by Pub. L. 111–148, title I, §§1001(2), 1563(c)(3), formerly §1562(c)(3), title X, §10107(b)(1), Mar. 23, 2010, 124 Stat. 130, 265, 911, and was transferred to section 300gg–25 of this title. A new section 2704 of act July 1, 1944, related to prohibition of preexisting condition exclusions or other discrimination based on health status, was added, effective for plan years beginning on or after Jan. 1, 2014, with certain exceptions, and amended, by Pub. L. 111–148, title I, §§1201(2), 1563(c)(1), formerly §1562(c)(1), title X, §10107(b)(1), Mar. 23, 2010, 124 Stat. 154, 264, 911, and is classified to section 300gg–3 of this title.

Section 300gg–23(d)(1) of this title, referred to in subsec. (c)(1), was in the original "section 2723(d)(1)", and was translated as meaning section 2724(d)(1) of act July 1, 1944, to reflect the probable intent of Congress and the renumbering of section 2723 as 2724 by Pub. L. 111–148, title I, §§1001(4), 1563(c)(14)(B), formerly §1562(c)(14)(B), title X, §10107(b)(1), Mar. 23, 2010, 124 Stat. 130, 269, 911.

STATUTORY NOTES AND RELATED SUBSIDIARIES

EFFECTIVE DATE

Section applicable to health insurance coverage offered, sold, issued, renewed, in effect, or operated in the individual market on or after Jan. 1, 1998, see section 605(c) of Pub. L. 104–204, set out as an Effective Date of 1996 Amendment note under section 300gg–44 of this title.

[1] *See References in Text note below.*

§300gg–52. Required coverage for reconstructive surgery following mastectomies

The provisions of section 2706 [1] shall apply to health insurance coverage offered by a health insurance issuer in the individual market in the same manner as they apply to health insurance coverage offered by a health insurance issuer in connection with a group health plan in the small or large group market.

(July 1, 1944, ch. 373, title XXVII, §2752, as added Pub. L. 105–277, div. A, §101(f) [title IX, §903(b)], Oct. 21, 1998, 112 Stat. 2681–337, 2681–438.)

EDITORIAL NOTES

REFERENCES IN TEXT

Section 2706, referred to in text, is a reference to section 2706 of act July 1, 1944. Section 2706, which was classified to section 300gg–6 of this title, was renumbered section 2727 and amended by Pub. L. 111–148, title I, §§1001(2), 1563(c)(5), formerly §1562(c)(5), title X, §10107(b)(1), Mar. 23, 2010, 124 Stat. 130, 266, 911, and was transferred to section 300gg–27 of this title. A new section 2706 of act July 1, 1944, related to non-discrimination in health care, was added, effective for plan years beginning on or after Jan. 1, 2014, by Pub. L. 111–148, title I, §1201(4), Mar. 23, 2010, 124 Stat. 160, and is classified to section 300gg–5 of this title.

STATUTORY NOTES AND RELATED SUBSIDIARIES

EFFECTIVE DATE

Pub. L. 105–277, div. A, §101(f) [title IX, §903(c)(2)], Oct. 21, 1998, 112 Stat. 2681–337, 2681–438, provided that: "The amendment made by subsection (b) [enacting this section] shall apply with respect to health insurance coverage offered, sold, issued, renewed, in effect, or operated in the individual market on or after the date of enactment of this Act [Oct. 21, 1998]."

[1] *See References in Text note below.*

§300gg–53. Prohibition of health discrimination on the basis of genetic information

(a) Prohibition on genetic information as a condition of eligibility

(1) In general

A health insurance issuer offering health insurance coverage in the individual market may not establish rules for the eligibility (including continued eligibility) of any individual to enroll in individual health insurance coverage based on genetic information.

(2) Rule of construction

Nothing in paragraph (1) or in paragraphs (1) and (2) of subsection (e) shall be construed to preclude a health insurance issuer from establishing rules for eligibility for an individual to enroll in individual health insurance coverage based on the manifestation of a disease or disorder in that individual, or in a family member of such individual where such family member is covered under the policy that covers such individual.

(b) Prohibition on genetic information in setting premium rates

(1) In general

A health insurance issuer offering health insurance coverage in the individual market shall not adjust premium or contribution amounts for an individual on the basis of genetic information concerning the individual or a family member of the individual.

(2) Rule of construction

Nothing in paragraph (1) or in paragraphs (1) and (2) of subsection (e) shall be construed to preclude a health insurance issuer from adjusting premium or contribution amounts for an individual on the basis of a manifestation of a disease or disorder in that individual, or in a family member of such individual where such family member is covered under the policy that covers such individual. In such case, the manifestation of a disease or disorder in one individual cannot also be used as genetic information about other individuals covered under the policy issued to such individual and to further increase premiums or contribution amounts.

(c) Prohibition on genetic information as preexisting condition

(1) In general

A health insurance issuer offering health insurance coverage in the individual market may not, on the basis of genetic information, impose any preexisting condition exclusion (as defined in section 2701(b)(1)(A)) [1] with respect to such coverage.

(2) Rule of construction

Nothing in paragraph (1) or in paragraphs (1) and (2) of subsection (e) shall be construed to preclude a health insurance issuer from imposing any preexisting condition exclusion for an individual with respect to health insurance coverage on the basis of a manifestation of a disease or disorder in that individual.

(d) Genetic testing

(1) Limitation on requesting or requiring genetic testing

A health insurance issuer offering health insurance coverage in the individual market shall not request or require an individual or a family member of such individual to undergo a genetic test.

(2) Rule of construction

Paragraph (1) shall not be construed to limit the authority of a health care professional who is providing health care services to an individual to request that such individual undergo a genetic test.

(3) Rule of construction regarding payment

(A) In general

Nothing in paragraph (1) shall be construed to preclude a health insurance issuer offering health insurance coverage in the individual market from obtaining and using the results of a genetic test in making a determination regarding payment (as such term is defined for the purposes of applying the regulations promulgated by the Secretary under part C of title XI of the Social Security Act [42 U.S.C. 1320d et seq.] and section 264 of the Health Insurance Portability and Accountability Act of 1996, as may be revised from time to time) consistent with subsection [2] (a) and (c).

(B) Limitation

For purposes of subparagraph (A), a health insurance issuer offering health insurance coverage in the individual market may request only the minimum amount of information necessary to accomplish the intended purpose.

(4) Research exception

Notwithstanding paragraph (1), a health insurance issuer offering health insurance coverage in the individual market may request, but not require, that an individual or a family member of such individual undergo a genetic test if each of the following conditions is met:

(A) The request is made pursuant to research that complies with part 46 of title 45, Code of Federal Regulations, or equivalent Federal regulations, and any applicable State or local law or regulations for the protection of human subjects in research.

(B) The issuer clearly indicates to each individual, or in the case of a minor child, to the legal guardian of such child, to whom the request is made that—

(i) compliance with the request is voluntary; and

(ii) non-compliance will have no effect on enrollment status or premium or contribution amounts.

(C) No genetic information collected or acquired under this paragraph shall be used for underwriting purposes.

(D) The issuer notifies the Secretary in writing that the issuer is conducting activities pursuant to the exception provided for under this paragraph, including a description of the

activities conducted.

(E) The issuer complies with such other conditions as the Secretary may by regulation require for activities conducted under this paragraph.

(e) Prohibition on collection of genetic information

(1) In general

A health insurance issuer offering health insurance coverage in the individual market shall not request, require, or purchase genetic information for underwriting purposes (as defined in section 300gg–91 of this title).

(2) Prohibition on collection of genetic information prior to enrollment

A health insurance issuer offering health insurance coverage in the individual market shall not request, require, or purchase genetic information with respect to any individual prior to such individual's enrollment under the plan in connection with such enrollment.

(3) Incidental collection

If a health insurance issuer offering health insurance coverage in the individual market obtains genetic information incidental to the requesting, requiring, or purchasing of other information concerning any individual, such request, requirement, or purchase shall not be considered a violation of paragraph (2) if such request, requirement, or purchase is not in violation of paragraph (1).

(f) Genetic information of a fetus or embryo

Any reference in this part to genetic information concerning an individual or family member of an individual shall—

(1) with respect to such an individual or family member of an individual who is a pregnant woman, include genetic information of any fetus carried by such pregnant woman; and

(2) with respect to an individual or family member utilizing an assisted reproductive technology, include genetic information of any embryo legally held by the individual or family member.

(July 1, 1944, ch. 373, title XXVII, §2753, as added Pub. L. 110–233, title I, §102(b)(1)(B), May 21, 2008, 122 Stat. 893.)

EDITORIAL NOTES

REFERENCES IN TEXT

Section 2701, referred to in subsec. (c)(1), is a reference to section 2701 of act July 1, 1944. Section 2701, which was classified to section 300gg of this title, was renumbered section 2704, effective for plan years beginning on or after Jan. 1, 2014, with certain exceptions, and amended, by Pub. L. 111–148, title I, §§1201(2), 1563(c)(1), formerly §1562(c)(1), title X, §10107(b)(1), Mar. 23, 2010, 124 Stat. 154, 264, 911, and was transferred to section 300gg–3 of this title. A new section 2701 of act July 1, 1944, related to fair health insurance premiums, was added, effective for plan years beginning on or after Jan. 1, 2014, and amended, by Pub. L. 111–148, title I, §1201(4), title X, §10103(a), Mar. 23, 2010, 124 Stat. 155, 892, and is classified to section 300gg of this title.

The Social Security Act, referred to in subsec. (d)(3)(A), is act Aug. 14, 1935, ch. 531, 49 Stat. 620. Part C of title XI of the Act is classified generally to part C (§1320d et seq.) of subchapter XI of chapter 7 of this title. For complete classification of this Act to the Code, see section 1305 of this title and Tables.

Section 264 of the Health Insurance Portability and Accountability Act of 1996, referred to in subsec. (d)(3)(A), is section 264 of Pub. L. 104–191, which is set out as a note under section 1320d–2 of this title.

CODIFICATION

Another section 2753 of act July 1, 1944, is classified to section 300gg–54 of this title.

STATUTORY NOTES AND RELATED SUBSIDIARIES

EFFECTIVE DATE

Section applicable, with respect to group health plans and health insurance coverage offered in connection with group health plans, for plan years beginning after the date that is one year after May 21, 2008, and, with respect to health insurance coverage offered, sold, issued, renewed, in effect, or operated in the individual market, after the date that is one year after May 21, 2008, see section 102(d)(2) of Pub. L. 110–233, set out as an Effective Date of 2008 Amendment note under section 300gg–21 of this title.

[1] *See References in Text note below.*

[2] *So in original. Probably should be "subsections".*

§300gg–54. Coverage of dependent students on medically necessary leave of absence

The provisions of section 2707 [1] shall apply to health insurance coverage offered by a health insurance issuer in the individual market in the same manner as they apply to health insurance coverage offered by a health insurance issuer in connection with a group health plan in the small or large group market.

(July 1, 1944, ch. 373, title XXVII, §2753, as added Pub. L. 110–381, §2(b)(2), Oct. 9, 2008, 122 Stat. 4084.)

EDITORIAL NOTES

REFERENCES IN TEXT

Section 2707, referred to in text, is a reference to section 2707 of act July 1, 1944. Section 2707, which was classified to section 300gg–7 of this title, was renumbered section 2728 and amended by Pub. L. 111–148, title I, §§1001(2), 1563(c)(6), formerly §1562(c)(6), title X, §10107(b)(1), Mar. 23, 2010, 124 Stat. 130, 266, 911, and was transferred to section 300gg–28 of this title. A new section 2707 of act July 1, 1944, related to comprehensive health insurance coverage, was added, effective for plan years beginning on or after Jan. 1, 2014, by Pub. L. 111–148, title I, §1201(4), Mar. 23, 2010, 124 Stat. 161, and is classified to section 300gg–6 of this title.

CODIFICATION

Section 2(b)(2) of Pub. L. 110–381, which directed amendment of subpart 3 of part B of title XXVII of act July 1, 1944, by adding this section at the end, was executed in this subpart, which is subpart 2 of part B of title XXVII of act July 1, 1944, to reflect the probable intent of Congress and the redesignation of subpart 3 as subpart 2 by Pub. L. 110–233, title I, §102(b)(1)(A), May 21, 2008, 122 Stat. 893.

Another section 2753 of act July 1, 1944, is classified to section 300gg–53 of this title.

STATUTORY NOTES AND RELATED SUBSIDIARIES

EFFECTIVE DATE

Section applicable with respect to plan years beginning on or after the date that is one year after Oct. 9, 2008, and to medically necessary leaves of absence beginning during such plan years, see section 2(d) of Pub. L. 110–381, set out as a note under section 9813 of Title 26, Internal Revenue Code.

[1] *See References in Text note below.*

SUBPART 3—GENERAL PROVISIONS

EDITORIAL NOTES

CODIFICATION

Another subpart 3 of part B of title XXVII of act July 1, 1944, was redesignated subpart 2 by Pub. L. 110–233, title I, §102(b)(1)(A), May 21, 2008, 122 Stat. 892, and is classified to subpart 2 (§300gg–51 et seq.) of this part.

§300gg–61. Enforcement

(a) State enforcement

(1) State authority

Subject to section 300gg–62 of this title, each State may require that health insurance issuers that issue, sell, renew, or offer health insurance coverage in the State in the individual market meet the requirements established under this part with respect to such issuers.

(2) Failure to implement requirements

In the case of a State that fails to substantially enforce the requirements set forth in this part with respect to health insurance issuers in the State, the Secretary shall enforce the requirements of this part under subsection (b) insofar as they relate to the issuance, sale, renewal, and offering of health insurance coverage in the individual market in such State.

(b) Secretarial enforcement authority

The Secretary shall have the same authority in relation to enforcement of the provisions of this part with respect to issuers of health insurance coverage in the individual market in a State as the Secretary has under section 300gg–22(b)(2) of this title, and section 300gg–22(b)(3) of this title [1] with respect to violations of genetic nondiscrimination provisions, in relation to the enforcement of the provisions of part A with respect to issuers of health insurance coverage in the small group market in the State.

(July 1, 1944, ch. 373, title XXVII, §2761, formerly §2745, as added Pub. L. 104–191, title I, §111(a), Aug. 21, 1996, 110 Stat. 1986; renumbered §2761 and amended Pub. L. 104–204, title VI, §605(a)(2), (b)(2), Sept. 26, 1996, 110 Stat. 2941, 2942; Pub. L. 110–233, title I, §102(b)(2), May 21, 2008, 122 Stat. 895.)

EDITORIAL NOTES

REFERENCES IN TEXT

Section 300gg–22(b)(2) of this title, and section 300gg–22(b)(3) of this title, referred to in subsec. (b), was in the original "section 2722(b)(2), and section 2722(b)(3)" and was translated as meaning section 2723(b)(2) and section 2723(b)(3) of act July 1, 1944, to reflect the probable intent of Congress and the renumbering of section 2722 as 2723 by Pub. L. 111–148, title I, §§1001(4), 1563(c)(13)(C), formerly §1562(c)(13)(C), title X, §10107(b)(1), Mar. 23, 2010, 124 Stat. 130, 269, 911.

AMENDMENTS

2008—Subsec. (b). Pub. L. 110–233 amended subsec. (b) generally. Prior to amendment, text read as follows: "The Secretary shall have the same authority in relation to enforcement of the provisions of this part with respect to issuers of health insurance coverage in the individual market in a State as the Secretary has under section 300gg–22(b)(2) of this title in relation to the enforcement of the provisions of part A of this subchapter with respect to issuers of health insurance coverage in the small group market in the State."

1996—Subsec. (a)(1). Pub. L. 104–204 made technical amendment to reference in original act which appears in text as reference to section 300gg–62 of this title.

STATUTORY NOTES AND RELATED SUBSIDIARIES

EFFECTIVE DATE OF 2008 AMENDMENT

Amendment by Pub. L. 110–233 applicable, with respect to group health plans and health insurance

coverage offered in connection with group health plans, for plan years beginning after the date that is one year after May 21, 2008, and, with respect to health insurance coverage offered, sold, issued, renewed, in effect, or operated in the individual market, after the date that is one year after May 21, 2008, see section 102(d)(2) of Pub. L. 110–233, set out as a note under section 300gg–21 of this title.

EFFECTIVE DATE OF 1996 AMENDMENT

Amendment by Pub. L. 104–204 applicable to health insurance coverage offered, sold, issued, renewed, in effect, or operated in the individual market on or after Jan. 1, 1998, see section 605(c) of Pub. L. 104–204, set out as a note under section 300gg–44 of this title.

EFFECTIVE DATE

Section applicable with respect to health insurance coverage offered, sold, issued, renewed, in effect, or operated in the individual market after June 30, 1997, regardless of when a period of creditable coverage occurs, see section 111(b) of Pub. L. 104–191, set out as a note under section 300gg–41 of this title.

[1] See References in Text note below.

§300gg–62. Preemption and application

(a) In general

Subject to subsection (b), nothing in this part (or part C insofar as it applies to this part) shall be construed to prevent a State from establishing, implementing, or continuing in effect standards and requirements unless such standards and requirements prevent the application of a requirement of this part.

(b) Rules of construction

(1) Nothing in this part (or part C insofar as it applies to this part) shall be construed to affect or modify the provisions of section 1144 of title 29.

(2) Nothing in this part (other than section 300gg–51 of this title) shall be construed as requiring health insurance coverage offered in the individual market to provide specific benefits under the terms of such coverage.

(c) Application of part A provisions

(1) In general

The provisions of part A shall apply to health insurance issuers providing health insurance coverage in the individual market in a State as provided for in such part.

(2) Clarification

To the extent that any provision of this part conflicts with a provision of part A with respect to health insurance issuers providing health insurance coverage in the individual market in a State, the provisions of such part A shall apply.

(July 1, 1944, ch. 373, title XXVII, §2762, formerly §2746, as added Pub. L. 104–191, title I, §111(a), Aug. 21, 1996, 110 Stat. 1987; renumbered §2762 and amended, Pub. L. 104–204, title VI, §605(a)(2), (b)(3), Sept. 26, 1996, 110 Stat. 2941, 2942; Pub. L. 111–148, title I, §1563(c)(15), formerly §1562(c)(15), title X, §10107(b)(1), Mar. 23, 2010, 124 Stat. 269, 911.)

EDITORIAL NOTES

AMENDMENTS

2010—Pub. L. 111–148, §1563(c)(15)(A), formerly §1562(c)(15)(A), as renumbered by Pub. L. 111–148, §10107(b)(1), inserted "and application" after "Preemption" in section catchline.

Subsec. (c). Pub. L. 111–148, §1563(c)(15)(B), formerly §1562(c)(15)(B), as renumbered by Pub. L. 111–148, §10107(b)(1), added subsec. (c).

1996—Subsec. (b). Pub. L. 104–204, §605(b)(3), designated existing provisions as par. (1) and added par.

(2).

STATUTORY NOTES AND RELATED SUBSIDIARIES

EFFECTIVE DATE OF 1996 AMENDMENT

Amendment by Pub. L. 104–204 applicable to health insurance coverage offered, sold, issued, renewed, in effect, or operated in the individual market on or after Jan. 1, 1998, see section 605(c) of Pub. L. 104–204, set out as a note under section 300gg–44 of this title.

EFFECTIVE DATE

Section applicable with respect to health insurance coverage offered, sold, issued, renewed, in effect, or operated in the individual market after June 30, 1997, regardless of when a period of creditable coverage occurs, see section 111(b) of Pub. L. 104–191, set out as a note under section 300gg–41 of this title.

§300gg–63. General exceptions

(a) Exception for certain benefits

The requirements of this part shall not apply to any health insurance coverage in relation to its provision of excepted benefits described in section 300gg–91(c)(1) of this title.

(b) Exception for certain benefits if certain conditions met

The requirements of this part shall not apply to any health insurance coverage in relation to its provision of excepted benefits described in paragraph (2), (3), or (4) of section 300gg–91(c) of this title if the benefits are provided under a separate policy, certificate, or contract of insurance.

(July 1, 1944, ch. 373, title XXVII, §2763, formerly §2747, as added Pub. L. 104–191, title I, §111(a), Aug. 21, 1996, 110 Stat. 1987; renumbered §2763, Pub. L. 104–204, title VI, §605(a)(2), Sept. 26, 1996, 110 Stat. 2941.)

STATUTORY NOTES AND RELATED SUBSIDIARIES

EFFECTIVE DATE

Section applicable with respect to health insurance coverage offered, sold, issued, renewed, in effect, or operated in the individual market after June 30, 1997, regardless of when a period of creditable coverage occurs, see section 111(b) of Pub. L. 104–191, set out as a note under section 300gg–41 of this title.

PART C—DEFINITIONS; MISCELLANEOUS PROVISIONS

§300gg–91. Definitions

(a) Group health plan

(1) Definition

The term "group health plan" means an employee welfare benefit plan (as defined in section 3(1) of the Employee Retirement Income Security Act of 1974 [29 U.S.C. 1002(1)]) to the extent that the plan provides medical care (as defined in paragraph (2)) and including items and services paid for as medical care) to employees or their dependents (as defined under the terms of the plan) directly or through insurance, reimbursement, or otherwise. Except for purposes of part C of title XI of the Social Security Act (42 U.S.C. 1320d et seq.), such term shall not include any qualified small employer health reimbursement arrangement (as defined in section 9831(d)(2) of title 26).

(2) Medical care

The term "medical care" means amounts paid for—

(A) the diagnosis, cure, mitigation, treatment, or prevention of disease, or amounts paid for the purpose of affecting any structure or function of the body,

(B) amounts paid for transportation primarily for and essential to medical care referred to in subparagraph (A), and

(C) amounts paid for insurance covering medical care referred to in subparagraphs (A) and (B).

(3) Treatment of certain plans as group health plan for notice provision

A program under which creditable coverage described in subparagraph (C), (D), (E), or (F) of section 2701(c)(1) [1] is provided shall be treated as a group health plan for purposes of applying section 2701(e).[1]

(b) Definitions relating to health insurance

(1) Health insurance coverage

The term "health insurance coverage" means benefits consisting of medical care (provided directly, through insurance or reimbursement, or otherwise and including items and services paid for as medical care) under any hospital or medical service policy or certificate, hospital or medical service plan contract, or health maintenance organization contract offered by a health insurance issuer.

(2) Health insurance issuer

The term "health insurance issuer" means an insurance company, insurance service, or insurance organization (including a health maintenance organization, as defined in paragraph (3)) which is licensed to engage in the business of insurance in a State and which is subject to State law which regulates insurance (within the meaning of section 514(b)(2) of the Employee Retirement Income Security Act of 1974 [29 U.S.C. 1144(b)(2)]). Such term does not include a group health plan.

(3) Health maintenance organization

The term "health maintenance organization" means—

(A) a Federally qualified health maintenance organization (as defined in section 300e(a) of this title),

(B) an organization recognized under State law as a health maintenance organization, or

(C) a similar organization regulated under State law for solvency in the same manner and to the same extent as such a health maintenance organization.

(4) Group health insurance coverage

The term "group health insurance coverage" means, in connection with a group health plan, health insurance coverage offered in connection with such plan.

(5) Individual health insurance coverage

The term "individual health insurance coverage" means health insurance coverage offered to individuals in the individual market, but does not include short-term limited duration insurance.

(c) Excepted benefits

For purposes of this subchapter, the term "excepted benefits" means benefits under one or more (or any combination thereof) of the following:

(1) Benefits not subject to requirements

(A) Coverage only for accident, or disability income insurance, or any combination thereof.

(B) Coverage issued as a supplement to liability insurance.

(C) Liability insurance, including general liability insurance and automobile liability insurance.

(D) Workers' compensation or similar insurance.

(E) Automobile medical payment insurance.

(F) Credit-only insurance.

(G) Coverage for on-site medical clinics.

(H) Other similar insurance coverage, specified in regulations, under which benefits for medical care are secondary or incidental to other insurance benefits.

(2) Benefits not subject to requirements if offered separately

(A) Limited scope dental or vision benefits.

(B) Benefits for long-term care, nursing home care, home health care, community-based care, or any combination thereof.

(C) Such other similar, limited benefits as are specified in regulations.

(3) Benefits not subject to requirements if offered as independent, noncoordinated benefits

(A) Coverage only for a specified disease or illness.

(B) Hospital indemnity or other fixed indemnity insurance.

(4) Benefits not subject to requirements if offered as separate insurance policy

Medicare supplemental health insurance (as defined under section 1395ss(g)(1) of this title), coverage supplemental to the coverage provided under chapter 55 of title 10, and similar supplemental coverage provided to coverage under a group health plan.

(d) Other definitions

(1) Applicable State authority

The term "applicable State authority" means, with respect to a health insurance issuer in a State, the State insurance commissioner or official or officials designated by the State to enforce the requirements of this subchapter for the State involved with respect to such issuer.

(2) Beneficiary

The term "beneficiary" has the meaning given such term under section 3(8) of the Employee Retirement Income Security Act of 1974 [29 U.S.C. 1002(8)].

(3) Bona fide association

The term "bona fide association" means, with respect to health insurance coverage offered in a State, an association which—

(A) has been actively in existence for at least 5 years;

(B) has been formed and maintained in good faith for purposes other than obtaining insurance;

(C) does not condition membership in the association on any health status-related factor relating to an individual (including an employee of an employer or a dependent of an employee);

(D) makes health insurance coverage offered through the association available to all members regardless of any health status-related factor relating to such members (or individuals eligible for coverage through a member);

(E) does not make health insurance coverage offered through the association available other than in connection with a member of the association; and

(F) meets such additional requirements as may be imposed under State law.

(4) COBRA continuation provision

The term "COBRA continuation provision" means any of the following:

(A) Section 4980B of title 26, other than subsection (f)(1) of such section insofar as it relates to pediatric vaccines.

(B) Part 6 of subtitle B of title I of the Employee Retirement Income Security Act of 1974 [29 U.S.C. 1161 et seq.], other than section 609 of such Act [29 U.S.C. 1169].

(C) Subchapter XX of this chapter.

(5) Employee

The term "employee" has the meaning given such term under section 3(6) of the Employee Retirement Income Security Act of 1974 [29 U.S.C. 1002(6)].

(6) Employer

The term "employer" has the meaning given such term under section 3(5) of the Employee Retirement Income Security Act of 1974 [29 U.S.C. 1002(5)], except that such term shall include only employers of two or more employees.

(7) Church plan

The term "church plan" has the meaning given such term under section 3(33) of the Employee Retirement Income Security Act of 1974 [29 U.S.C. 1002(33)].

(8) Governmental plan

(A) The term "governmental plan" has the meaning given such term under section 3(32) of the Employee Retirement Income Security Act of 1974 [29 U.S.C. 1002(32)] and any Federal governmental plan.

(B) FEDERAL GOVERNMENTAL PLAN.—The term "Federal governmental plan" means a governmental plan established or maintained for its employees by the Government of the United States or by any agency or instrumentality of such Government.

(C) NON-FEDERAL GOVERNMENTAL PLAN.—The term "non-Federal governmental plan" means a governmental plan that is not a Federal governmental plan.

(9) Health status-related factor

The term "health status-related factor" means any of the factors described in section 2702(a)(1). [1]

(10) Network plan

The term "network plan" means health insurance coverage of a health insurance issuer under which the financing and delivery of medical care (including items and services paid for as medical care) are provided, in whole or in part, through a defined set of providers under contract with the issuer.

(11) Participant

The term "participant" has the meaning given such term under section 3(7) of the Employee Retirement Income Security Act of 1974 [29 U.S.C. 1002(7)].

(12) Placed for adoption defined

The term "placement", or being "placed", for adoption, in connection with any placement for adoption of a child with any person, means the assumption and retention by such person of a legal obligation for total or partial support of such child in anticipation of adoption of such child. The child's placement with such person terminates upon the termination of such legal obligation.

(13) Plan sponsor

The term "plan sponsor" has the meaning given such term under section 3(16)(B) of the Employee Retirement Income Security Act of 1974 [29 U.S.C. 1002(16)(B)].

(14) State

The term "State" means each of the several States, the District of Columbia, Puerto Rico, the Virgin Islands, Guam, American Samoa, and the Northern Mariana Islands.

(15) Family member

The term "family member" means, with respect to any individual—

(A) a dependent (as such term is used for purposes of section 2701(f)(2)) [1] of such individual; and

(B) any other individual who is a first-degree, second-degree, third-degree, or fourth-degree relative of such individual or of an individual described in subparagraph (A).

(16) Genetic information

(A) In general

The term "genetic information" means, with respect to any individual, information about—

(i) such individual's genetic tests,

(ii) the genetic tests of family members of such individual, and

(iii) the manifestation of a disease or disorder in family members of such individual.

(B) Inclusion of genetic services and participation in genetic research

Such term includes, with respect to any individual, any request for, or receipt of, genetic services, or participation in clinical research which includes genetic services, by such individual or any family member of such individual.

(C) Exclusions

The term "genetic information" shall not include information about the sex or age of any individual.

(17) Genetic test

(A) In general

The term "genetic test" means an analysis of human DNA, RNA, chromosomes, proteins, or metabolites, that detects genotypes, mutations, or chromosomal changes.

(B) Exceptions

The term "genetic test" does not mean—

(i) an analysis of proteins or metabolites that does not detect genotypes, mutations, or chromosomal changes; or

(ii) an analysis of proteins or metabolites that is directly related to a manifested disease, disorder, or pathological condition that could reasonably be detected by a health care professional with appropriate training and expertise in the field of medicine involved.

(18) Genetic services

The term "genetic services" means—

(A) a genetic test;

(B) genetic counseling (including obtaining, interpreting, or assessing genetic information); or

(C) genetic education.

(19) Underwriting purposes

The term "underwriting purposes" means, with respect to any group health plan, or health insurance coverage offered in connection with a group health plan—

(A) rules for, or determination of, eligibility (including enrollment and continued eligibility) for benefits under the plan or coverage;

(B) the computation of premium or contribution amounts under the plan or coverage;

(C) the application of any pre-existing condition exclusion under the plan or coverage; and

(D) other activities related to the creation, renewal, or replacement of a contract of health insurance or health benefits.

(20) Qualified health plan

The term "qualified health plan" has the meaning given such term in section 18021(a) of this title.

(21) Exchange

The term "Exchange" means an American Health Benefit Exchange established under section 18031 of this title.

(e) Definitions relating to markets and small employers

For purposes of this subchapter:

(1) Individual market

(A) In general

The term "individual market" means the market for health insurance coverage offered to individuals other than in connection with a group health plan.

(B) Treatment of very small groups

(i) In general

Subject to clause (ii), such terms [2] includes coverage offered in connection with a group health plan that has fewer than two participants as current employees on the first day of the plan year.

(ii) State exception

Clause (i) shall not apply in the case of a State that elects to regulate the coverage described in such clause as coverage in the small group market.

(2) Large employer

The term "large employer" means, in connection with a group health plan with respect to a calendar year and a plan year, an employer who employed an average of at least 51 employees on business days during the preceding calendar year and who employs at least 2 employees on the first day of the plan year.

(3) Large group market

The term "large group market" means the health insurance market under which individuals obtain health insurance coverage (directly or through any arrangement) on behalf of themselves (and their dependents) through a group health plan maintained by a large employer.

(4) Small employer

The term "small employer" means, in connection with a group health plan with respect to a calendar year and a plan year, an employer who employed an average of at least 1 but not more than 50 employees on business days during the preceding calendar year and who employs at least 1 employees [3] on the first day of the plan year.

(5) Small group market

The term "small group market" means the health insurance market under which individuals obtain health insurance coverage (directly or through any arrangement) on behalf of themselves (and their dependents) through a group health plan maintained by a small employer.

(6) Application of certain rules in determination of employer size

For purposes of this subsection—

(A) Application of aggregation rule for employers

all [4] persons treated as a single employer under subsection (b), (c), (m), or (o) of section 414 of title 26 shall be treated as 1 employer.

(B) Employers not in existence in preceding year

In the case of an employer which was not in existence throughout the preceding calendar year, the determination of whether such employer is a small or large employer shall be based on the average number of employees that it is reasonably expected such employer will employ on business days in the current calendar year.

(C) Predecessors

Any reference in this subsection to an employer shall include a reference to any predecessor of such employer.

(7) State option to extend definition of small employer

Notwithstanding paragraphs (2) and (4), nothing in this section shall prevent a State from applying this subsection by treating as a small employer, with respect to a calendar year and a plan

year, an employer who employed an average of at least 1 but not more than 100 employees on business days during the preceding calendar year and who employs at least 1 employee on the first day of the plan year.

(July 1, 1944, ch. 373, title XXVII, §2791, as added Pub. L. 104–191, title I, §102(a), Aug. 21, 1996, 110 Stat. 1972; amended Pub. L. 110–233, title I, §102(a)(4), May 21, 2008, 122 Stat. 890; Pub. L. 111–148, title I, §1563(b), (c)(16), formerly §1562(b), (c)(16), title X, §10107(b)(1), Mar. 23, 2010, 124 Stat. 264, 269, 911; Pub. L. 114–60, §2(b), Oct. 7, 2015, 129 Stat. 543; Pub. L. 114–255, div. C, title XVIII, §18001(c)(1), Dec. 13, 2016, 130 Stat. 1344.)

EDITORIAL NOTES

REFERENCES IN TEXT

The Social Security Act, referred to in subsec. (a)(1), is act Aug. 14, 1935, ch. 531, 49 Stat. 620. Part C of title XI of the Act is classified generally to part C (§1320d et seq.) of subchapter XI of chapter 7 of this title. For complete classification of this Act to the Code, see section 1305 of this title and Tables.

Section 2701, referred to in subsecs. (a)(3) and (d)(15)(A), is a reference to section 2701 of act July 1, 1944. Section 2701, which was classified to section 300gg of this title, was renumbered section 2704, effective for plan years beginning on or after Jan. 1, 2014, with certain exceptions, and amended, by Pub. L. 111–148, title I, §§1201(2), 1563(c)(1), formerly §1562(c)(1), title X, §10107(b)(1), Mar. 23, 2010, 124 Stat. 154, 264, 911, and was transferred to section 300gg–3 of this title. A new section 2701 of act July 1, 1944, related to fair health insurance premiums, was added, effective for plan years beginning on or after Jan. 1, 2014, and amended, by Pub. L. 111–148, title I, §1201(4), title X, §10103(a), Mar. 23, 2010, 124 Stat. 155, 892, and is classified to section 300gg of this title.

The Employee Retirement Income Security Act of 1974, referred to in subsec. (d)(4)(B), is Pub. L. 93–406, Sept. 2, 1974, 88 Stat. 829. Part 6 of subtitle B of title I of the Act is classified generally to part 6 (§1161 et seq.) of subtitle B of subchapter I of chapter 18 of Title 29, Labor. For complete classification of this Act to the Code, see Short Title note set out under section 1001 of Title 29 and Tables.

Section 2702, referred to in subsec. (d)(9), is a reference to section 2702 of act July 1, 1944. Section 2702, which was classified to section 300gg–1 of this title, was amended by Pub. L. 111–148, title I, §1201(3), Mar. 23, 2010, 124 Stat. 154, and was transferred to subsecs. (b) to (f) of section 300gg–4 of this title, effective for plan years beginning on or after Jan. 1, 2014. A new section 2702, related to guaranteed availability of coverage, was added by Pub. L. 111–148, title I, §1201(4), Mar. 23, 2010, 124 Stat. 156, effective for plan years beginning on or after Jan. 1, 2014, and is classified to section 300gg–1 of this title.

AMENDMENTS

2016—Subsec. (a)(1). Pub. L. 114–255 inserted at end "Except for purposes of part C of title XI of the Social Security Act (42 U.S.C. 1320d et seq.), such term shall not include any qualified small employer health reimbursement arrangement (as defined in section 9831(d)(2) of title 26)."

2015—Subsec. (e)(2). Pub. L. 114–60, §2(b)(1), substituted "51" for "101".

Subsec. (e)(4). Pub. L. 114–60, §2(b)(2), substituted "50" for "100".

Subsec. (e)(7). Pub. L. 114–60, §2(b)(3), added par. (7).

2010—Subsec. (d)(20), (21). Pub. L. 111–148, §1563(b), formerly §1562(b), as renumbered by Pub. L. 111–148, §10107(b)(1), added pars. (20) and (21).

Subsec. (e)(2). Pub. L. 111–148, §1563(c)(16)(A), formerly §1562(c)(16)(A), as renumbered by Pub. L. 111–148, §10107(b)(1), substituted "101" for "51".

Subsec. (e)(4). Pub. L. 111–148, §1563(c)(16)(B), formerly §1562(c)(16)(B), as renumbered by Pub. L. 111–148, §10107(b)(1), substituted "100" for "50" and "at least 1" for "at least 2" in two places.

2008—Subsec. (d)(15) to (19). Pub. L. 110–233 added pars. (15) to (19).

STATUTORY NOTES AND RELATED SUBSIDIARIES

EFFECTIVE DATE OF 2016 AMENDMENT

Amendment by Pub. L. 114–255 applicable to plan years beginning after Dec. 31, 2016, see section 18001(c)(3) of Pub. L. 114–255, set out as a note under section 300bb–8 of this title.

EFFECTIVE DATE OF 2008 AMENDMENT

Amendment by Pub. L. 110–233 applicable, with respect to group health plans and health insurance coverage offered in connection with group health plans, for plan years beginning after the date that is one year after May 21, 2008, and, with respect to health insurance coverage offered, sold, issued, renewed, in effect, or operated in the individual market, after the date that is one year after May 21, 2008, see section 102(d)(2) of Pub. L. 110–233, set out as a note under section 300gg–21 of this title.

[1] See References in Text note below.

[2] So in original. Probably should be "term".

[3] So in original.

[4] So in original. Probably should be capitalized.

§300gg–92. Regulations

The Secretary, consistent with section 104 of the Health Care Portability and Accountability Act of 1996, may promulgate such regulations as may be necessary or appropriate to carry out the provisions of this subchapter. The Secretary may promulgate any interim final rules as the Secretary determines are appropriate to carry out this subchapter.

(July 1, 1944, ch. 373, title XXVII, §2792, as added Pub. L. 104–191, title I, §102(a), Aug. 21, 1996, 110 Stat. 1976.)

EDITORIAL NOTES

REFERENCES IN TEXT

Section 104 of the Health Care Portability and Accountability Act of 1996, referred to in text, probably means section 104 of the Health Insurance Portability and Accountability Act of 1996, Pub. L. 104–191, set out below.

STATUTORY NOTES AND RELATED SUBSIDIARIES

ASSURING COORDINATION AMONG DEPARTMENTS OF TREASURY, HEALTH AND HUMAN SERVICES, AND LABOR

Pub. L. 104–191, title I, §104, Aug. 21, 1996, 110 Stat. 1978, provided that: "The Secretary of the Treasury, the Secretary of Health and Human Services, and the Secretary of Labor shall ensure, through the execution of an interagency memorandum of understanding among such Secretaries, that—

"(1) regulations, rulings, and interpretations issued by such Secretaries relating to the same matter over which two or more such Secretaries have responsibility under this subtitle [subtitle A (§§101–104) of title I of Pub. L. 104–191, enacting this section, sections 300gg, 300gg–1, 300gg–11 to 300gg–13, 300gg–21 to 300gg–23, and 300gg–91 of this title, and sections 1181 to 1183 and 1191 to 1191c of Title 29, Labor, amending sections 300e and 300bb–8 of this title and sections 1003, 1021, 1022, 1024, 1132, 1136, and 1144 of Title 29, and enacting provisions set out as notes under section 300gg of this title and section 1181 of Title 29] (and the amendments made by this subtitle and section 401 [enacting sections 9801 to 9806 of Title 26, Internal Revenue Code]) are administered so as to have the same effect at all times; and

"(2) coordination of policies relating to enforcing the same requirements through such Secretaries in order to have a coordinated enforcement strategy that avoids duplication of enforcement efforts and assigns priorities in enforcement."

§300gg–93. Health insurance consumer information

(a) In general

The Secretary shall award grants to States to enable such States (or the Exchanges operating in such States) to establish, expand, or provide support for—

(1) offices of health insurance consumer assistance; or

(2) health insurance ombudsman programs.

(b) Eligibility

(1) In general

To be eligible to receive a grant, a State shall designate an independent office of health insurance consumer assistance, or an ombudsman, that, directly or in coordination with State health insurance regulators and consumer assistance organizations, receives and responds to inquiries and complaints concerning health insurance coverage with respect to Federal health insurance requirements and under State law.

(2) Criteria

A State that receives a grant under this section shall comply with criteria established by the Secretary for carrying out activities under such grant.

(c) Duties

The office of health insurance consumer assistance or health insurance ombudsman shall—

(1) assist with the filing of complaints and appeals, including filing appeals with the internal appeal or grievance process of the group health plan or health insurance issuer involved and providing information about the external appeal process;

(2) collect, track, and quantify problems and inquiries encountered by consumers;

(3) educate consumers on their rights and responsibilities with respect to group health plans and health insurance coverage;

(4) assist consumers with enrollment in a group health plan or health insurance coverage by providing information, referral, and assistance; and

(5) resolve problems with obtaining premium tax credits under section 36B of title 26.

(d) Data collection

As a condition of receiving a grant under subsection (a), an office of health insurance consumer assistance or ombudsman program shall be required to collect and report data to the Secretary on the types of problems and inquiries encountered by consumers. The Secretary shall utilize such data to identify areas where more enforcement action is necessary and shall share such information with State insurance regulators, the Secretary of Labor, and the Secretary of the Treasury for use in the enforcement activities of such agencies.

(e) Funding

(1) Initial funding

There is hereby appropriated to the Secretary, out of any funds in the Treasury not otherwise appropriated, $30,000,000 for the first fiscal year for which this section applies to carry out this section. Such amount shall remain available without fiscal year limitation.

(2) Authorization for subsequent years

There is authorized to be appropriated to the Secretary for each fiscal year following the fiscal year described in paragraph (1), such sums as may be necessary to carry out this section.

(July 1, 1944, ch. 373, title XXVII, §2793, as added Pub. L. 111–148, title I, §1002, Mar. 23, 2010, 124 Stat. 138.)

STATUTORY NOTES AND RELATED SUBSIDIARIES

EFFECTIVE DATE

Section effective for fiscal years beginning with fiscal year 2010, see section 1004(a) of Pub. L. 111–148, set out as a note under section 300gg–11 of this title.

Section effective Mar. 23, 2010, see section 1004(b) of Pub. L. 111–148, set out as a note under section

300gg–11 of this title.

§300gg–94. Ensuring that consumers get value for their dollars

(a) Initial premium review process

(1) In general

The Secretary, in conjunction with States, shall establish a process for the annual review, beginning with the 2010 plan year and subject to subsection (b)(2)(A), of unreasonable increases in premiums for health insurance coverage.

(2) Justification and disclosure

The process established under paragraph (1) shall require health insurance issuers to submit to the Secretary and the relevant State a justification for an unreasonable premium increase prior to the implementation of the increase. Such issuers shall prominently post such information on their Internet websites. The Secretary shall ensure the public disclosure of information on such increases and justifications for all health insurance issuers.

(b) Continuing premium review process

(1) Informing Secretary of premium increase patterns

As a condition of receiving a grant under subsection (c)(1), a State, through its Commissioner of Insurance, shall—

(A) provide the Secretary with information about trends in premium increases in health insurance coverage in premium rating areas in the State; and

(B) make recommendations, as appropriate, to the State Exchange about whether particular health insurance issuers should be excluded from participation in the Exchange based on a pattern or practice of excessive or unjustified premium increases.

(2) Monitoring by Secretary of premium increases

(A) In general

Beginning with plan years beginning in 2014, the Secretary, in conjunction with the States and consistent with the provisions of subsection (a)(2), shall monitor premium increases of health insurance coverage offered through an Exchange and outside of an Exchange.

(B) Consideration in opening Exchange

In determining under section 18032(f)(2)(B) of this title whether to offer qualified health plans in the large group market through an Exchange, the State shall take into account any excess of premium growth outside of the Exchange as compared to the rate of such growth inside the Exchange.

(c) Grants in support of process

(1) Premium review grants during 2010 through 2014

The Secretary shall carry out a program to award grants to States during the 5-year period beginning with fiscal year 2010 to assist such States in carrying out subsection (a), including—

(A) in reviewing and, if appropriate under State law, approving premium increases for health insurance coverage;

(B) in providing information and recommendations to the Secretary under subsection (b)(1); and

(C) in establishing centers (consistent with subsection (d)) at academic or other nonprofit institutions to collect medical reimbursement information from health insurance issuers, to analyze and organize such information, and to make such information available to such issuers, health care providers, health researchers, health care policy makers, and the general public.

(2) Funding

(A) In general

Out of all funds in the Treasury not otherwise appropriated, there are appropriated to the Secretary $250,000,000, to be available for expenditure for grants under paragraph (1) and subparagraph (B).

(B) Further availability for insurance reform and consumer protection

If the amounts appropriated under subparagraph (A) are not fully obligated under grants under paragraph (1) by the end of fiscal year 2014, any remaining funds shall remain available to the Secretary for grants to States for planning and implementing the insurance reforms and consumer protections under part A.

(C) Allocation

The Secretary shall establish a formula for determining the amount of any grant to a State under this subsection. Under such formula—

(i) the Secretary shall consider the number of plans of health insurance coverage offered in each State and the population of the State; and

(ii) no State qualifying for a grant under paragraph (1) shall receive less than $1,000,000, or more than $5,000,000 for a grant year.

(3) Parity implementation

(A) In general

Beginning during the first fiscal year that begins after December 29, 2022, the Secretary shall, out of funds made available pursuant to subparagraph (C), award grants to eligible States to enforce and ensure compliance with the mental health and substance use disorder parity provisions of section 300gg—26 of this title.

(B) Eligible State

A State shall be eligible for a grant awarded under this paragraph only if such State—

(i) submits to the Secretary an application for such grant at such time, in such manner, and containing such information as specified by the Secretary; and

(ii) agrees to request and review from health insurance issuers offering group or individual health insurance coverage the comparative analyses and other information required of such health insurance issuers under subsection (a)(8)(A) of section 300gg–26 of this title relating to the design and application of nonquantitative treatment limitations imposed on mental health or substance use disorder benefits.

(C) Authorization of appropriations

There are authorized to be appropriated $10,000,000 for each of the first five fiscal years beginning after December 29, 2022, to remain available until expended, for purposes of awarding grants under subparagraph (A).

(d) Medical reimbursement data centers

(1) Functions

A center established under subsection (c)(1)(C) shall—

(A) develop fee schedules and other database tools that fairly and accurately reflect market rates for medical services and the geographic differences in those rates;

(B) use the best available statistical methods and data processing technology to develop such fee schedules and other database tools;

(C) regularly update such fee schedules and other database tools to reflect changes in charges for medical services;

(D) make health care cost information readily available to the public through an Internet website that allows consumers to understand the amounts that health care providers in their area charge for particular medical services; and

(E) regularly publish information concerning the statistical methodologies used by the center to analyze health charge data and make such data available to researchers and policy makers.

(2) Conflicts of interest

A center established under subsection (c)(1)(C) shall adopt by-laws that ensures that the center (and all members of the governing board of the center) is independent and free from all conflicts of interest. Such by-laws shall ensure that the center is not controlled or influenced by, and does not have any corporate relation to, any individual or entity that may make or receive payments for health care services based on the center's analysis of health care costs.

(3) Rule of construction

Nothing in this subsection shall be construed to permit a center established under subsection (c)(1)(C) to compel health insurance issuers to provide data to the center.

(July 1, 1944, ch. 373, title XXVII, §2794, as added and amended Pub. L. 111–148, title I, §1003, title X, §10101(i), Mar. 23, 2010, 124 Stat. 139, 891; Pub. L. 117–328, div. FF, title I, §1331(a), Dec. 29, 2022, 136 Stat. 5698.)

EDITORIAL NOTES

PRIOR PROVISIONS

A prior section 2794 of act July 1, 1944, was renumbered section 2795 and is classified to section 300gg–95 of this title.

AMENDMENTS

2022—Subsec. (c)(3). Pub. L. 117–328 added par. (3).
2010—Subsec. (c)(1)(C). Pub. L. 111–148, §10101(i)(1), added subpar. (C).
Subsec. (d). Pub. L. 111–148, §10101(i)(2), added subsec. (d).

STATUTORY NOTES AND RELATED SUBSIDIARIES

EFFECTIVE DATE

Section effective for fiscal years beginning with fiscal year 2010, see section 1004(a) of Pub. L. 111–148, set out as a note under section 300gg–11 of this title.

Section effective Mar. 23, 2010, see section 1004(b) of Pub. L. 111–148, set out as a note under section 300gg–11 of this title.

§300gg–95. Uniform fraud and abuse referral format

The Secretary shall request the National Association of Insurance Commissioners to develop a model uniform report form for private health insurance issuer [1] seeking to refer suspected fraud and abuse to State insurance departments or other responsible State agencies for investigation. The Secretary shall request that the National Association of Insurance Commissioners develop recommendations for uniform reporting standards for such referrals.

(July 1, 1944, ch. 373, title XXVII, §2795, formerly §2794, as added Pub. L. 111–148, title VI, §6603, Mar. 23, 2010, 124 Stat. 780; renumbered §2795, Pub. L. 117–328, div. FF, title I, §1331(b), Dec. 29, 2022, 136 Stat. 5698.)

[1] *So in original. Probably should be "issuers".*

PART D—ADDITIONAL COVERAGE PROVISIONS

§300gg–111. Preventing surprise medical bills

(a) Coverage of emergency services

(1) In general

If a group health plan, or a health insurance issuer offering group or individual health insurance coverage, provides or covers any benefits with respect to services in an emergency department of a hospital or with respect to emergency services in an independent freestanding emergency department (as defined in paragraph (3)(D)), the plan or issuer shall cover emergency services (as defined in paragraph (3)(C))—

(A) without the need for any prior authorization determination;

(B) whether the health care provider furnishing such services is a participating provider or a participating emergency facility, as applicable, with respect to such services;

(C) in a manner so that, if such services are provided to a participant, beneficiary, or enrollee by a nonparticipating provider or a nonparticipating emergency facility—

(i) such services will be provided without imposing any requirement under the plan or coverage for prior authorization of services or any limitation on coverage that is more restrictive than the requirements or limitations that apply to emergency services received from participating providers and participating emergency facilities with respect to such plan or coverage, respectively;

(ii) the cost-sharing requirement is not greater than the requirement that would apply if such services were provided by a participating provider or a participating emergency facility;

(iii) such cost-sharing requirement is calculated as if the total amount that would have been charged for such services by such participating provider or participating emergency facility were equal to the recognized amount (as defined in paragraph (3)(H)) for such services, plan or coverage, and year;

(iv) the group health plan or health insurance issuer, respectively—

(I) not later than 30 calendar days after the bill for such services is transmitted by such provider or facility, sends to the provider or facility, as applicable, an initial payment or notice of denial of payment; and

(II) pays a total plan or coverage payment directly to such provider or facility, respectively (in accordance, if applicable, with the timing requirement described in subsection (c)(6)) that is, with application of any initial payment under subclause (I), equal to the amount by which the out-of-network rate (as defined in paragraph (3)(K)) for such services exceeds the cost-sharing amount for such services (as determined in accordance with clauses (ii) and (iii)) and year; and

(v) any cost-sharing payments made by the participant, beneficiary, or enrollee with respect to such emergency services so furnished shall be counted toward any in-network deductible or out-of-pocket maximums applied under the plan or coverage, respectively (and such in-network deductible and out-of-pocket maximums shall be applied) in the same manner as if such cost-sharing payments were made with respect to emergency services furnished by a participating provider or a participating emergency facility; and

(D) without regard to any other term or condition of such coverage (other than exclusion or coordination of benefits, or an affiliation or waiting period, permitted under section 300gg–3 of this title, including as incorporated pursuant to section 1185d of title 29 and section 9815 of title 26, and other than applicable cost-sharing).

(2) Audit process and regulations for qualifying payment amounts

(A) Audit process

(i) In general

Not later than October 1, 2021, the Secretary, in consultation with the Secretary of Labor and the Secretary of the Treasury, shall establish through rulemaking a process, in accordance with clause (ii), under which group health plans and health insurance issuers offering group

or individual health insurance coverage are audited by the Secretary or applicable State authority to ensure that—

(I) such plans and coverage are in compliance with the requirement of applying a qualifying payment amount under this section; and

(II) such qualifying payment amount so applied satisfies the definition under paragraph (3)(E) with respect to the year involved, including with respect to a group health plan or health insurance issuer described in clause (ii) of such paragraph (3)(E).

(ii) Audit samples

Under the process established pursuant to clause (i), the Secretary—

(I) shall conduct audits described in such clause, with respect to a year (beginning with 2022), of a sample with respect to such year of claims data from not more than 25 group health plans and health insurance issuers offering group or individual health insurance coverage; and

(II) may audit any group health plan or health insurance issuer offering group or individual health insurance coverage if the Secretary has received any complaint or other information about such plan or coverage, respectively, that involves the compliance of the plan or coverage, respectively, with either of the requirements described in subclauses (I) and (II) of such clause.

(iii) Reports

Beginning for 2022, the Secretary shall annually submit to Congress a report on the number of plans and issuers with respect to which audits were conducted during such year pursuant to this subparagraph.

(B) Rulemaking

Not later than July 1, 2021, the Secretary, in consultation with the Secretary of Labor and the Secretary of the Treasury, shall establish through rulemaking—

(i) the methodology the group health plan or health insurance issuer offering group or individual health insurance coverage shall use to determine the qualifying payment amount, differentiating by individual market, large group market, and small group market;

(ii) the information such plan or issuer, respectively, shall share with the nonparticipating provider or nonparticipating facility, as applicable, when making such a determination;

(iii) the geographic regions applied for purposes of this subparagraph, taking into account access to items and services in rural and underserved areas, including health professional shortage areas, as defined in section 254e of this title; and

(iv) a process to receive complaints of violations of the requirements described in subclauses (I) and (II) of subparagraph (A)(i) by group health plans and health insurance issuers offering group or individual health insurance coverage.

Such rulemaking shall take into account payments that are made by such plan or issuer, respectively, that are not on a fee-for-service basis. Such methodology may account for relevant payment adjustments that take into account quality or facility type (including higher acuity settings and the case-mix of various facility types) that are otherwise taken into account for purposes of determining payment amounts with respect to participating facilities. In carrying out clause (iii), the Secretary shall consult with the National Association of Insurance Commissioners to establish the geographic regions under such clause and shall periodically update such regions, as appropriate, taking into account the findings of the report submitted under section 109(a) of the No Surprises Act.

(3) Definitions

In this part and part E:

(A) Emergency department of a hospital

The term "emergency department of a hospital" includes a hospital outpatient department that

provides emergency services (as defined in subparagraph (C)(i)).

(B) Emergency medical condition

The term "emergency medical condition" means a medical condition manifesting itself by acute symptoms of sufficient severity (including severe pain) such that a prudent layperson, who possesses an average knowledge of health and medicine, could reasonably expect the absence of immediate medical attention to result in a condition described in clause (i), (ii), or (iii) of section 1867(e)(1)(A) of the Social Security Act [42 U.S.C. 1395dd(e)(1)(A)].

(C) Emergency services

(i) In general

The term "emergency services", with respect to an emergency medical condition, means—

(I) a medical screening examination (as required under section 1867 of the Social Security Act [42 U.S.C. 1395dd], or as would be required under such section if such section applied to an independent freestanding emergency department) that is within the capability of the emergency department of a hospital or of an independent freestanding emergency department, as applicable, including ancillary services routinely available to the emergency department to evaluate such emergency medical condition; and

(II) within the capabilities of the staff and facilities available at the hospital or the independent freestanding emergency department, as applicable, such further medical examination and treatment as are required under section 1395dd of this title, or as would be required under such section if such section applied to an independent freestanding emergency department, to stabilize the patient (regardless of the department of the hospital in which such further examination or treatment is furnished).

(ii) Inclusion of additional services

(I) In general

For purposes of this subsection and section 300gg–131 of this title, in the case of a participant, beneficiary, or enrollee who is enrolled in a group health plan or group or individual health insurance coverage offered by a health insurance issuer and who is furnished services described in clause (i) with respect to an emergency medical condition, the term "emergency services" shall include, unless each of the conditions described in subclause (II) are met, in addition to the items and services described in clause (i), items and services—

(aa) for which benefits are provided or covered under the plan or coverage, respectively; and

(bb) that are furnished by a nonparticipating provider or nonparticipating emergency facility (regardless of the department of the hospital in which such items or services are furnished) after the participant, beneficiary, or enrollee is stabilized and as part of outpatient observation or an inpatient or outpatient stay with respect to the visit in which the services described in clause (i) are furnished.

(II) Conditions

For purposes of subclause (I), the conditions described in this subclause, with respect to a participant, beneficiary, or enrollee who is stabilized and furnished additional items and services described in subclause (I) after such stabilization by a provider or facility described in subclause (I), are the following;

(aa) Such provider or facility determines such individual is able to travel using nonmedical transportation or nonemergency medical transportation.

(bb) Such provider furnishing such additional items and services satisfies the notice and consent criteria of section 300gg–132(d) of this title with respect to such items and services.

(cc) Such individual is in a condition to receive (as determined in accordance with guidelines issued by the Secretary pursuant to rulemaking) the information described in

section 300gg–132 of this title and to provide informed consent under such section, in accordance with applicable State law.

(dd) Such other conditions, as specified by the Secretary, such as conditions relating to coordinating care transitions to participating providers and facilities.

(D) Independent freestanding emergency department

The term "independent freestanding emergency department" means a health care facility that—

(i) is geographically separate and distinct and licensed separately from a hospital under applicable State law; and

(ii) provides any of the emergency services (as defined in subparagraph (C)(i)).

(E) Qualifying payment amount

(i) In general

The term "qualifying payment amount" means, subject to clauses (ii) and (iii), with respect to a sponsor of a group health plan and health insurance issuer offering group or individual health insurance coverage—

(I) for an item or service furnished during 2022, the median of the contracted rates recognized by the plan or issuer, respectively (determined with respect to all such plans of such sponsor or all such coverage offered by such issuer that are offered within the same insurance market (specified in subclause (I), (II), (III), or (IV) of clause (iv)) as the plan or coverage) as the total maximum payment (including the cost-sharing amount imposed for such item or service and the amount to be paid by the plan or issuer, respectively) under such plans or coverage, respectively, on January 31, 2019, for the same or a similar item or service that is provided by a provider in the same or similar specialty and provided in the geographic region in which the item or service is furnished, consistent with the methodology established by the Secretary under paragraph (2)(B), increased by the percentage increase in the consumer price index for all urban consumers (United States city average) over 2019, such percentage increase over 2020, and such percentage increase over 2021; and

(II) for an item or service furnished during 2023 or a subsequent year, the qualifying payment amount determined under this clause for such an item or service furnished in the previous year, increased by the percentage increase in the consumer price index for all urban consumers (United States city average) over such previous year.

(ii) New plans and coverage

The term "qualifying payment amount" means, with respect to a sponsor of a group health plan or health insurance issuer offering group or individual health insurance coverage in a geographic region in which such sponsor or issuer, respectively, did not offer any group health plan or health insurance coverage during 2019—

(I) for the first year in which such group health plan, group health insurance coverage, or individual health insurance coverage, respectively, is offered in such region, a rate (determined in accordance with a methodology established by the Secretary) for items and services that are covered by such plan or coverage and furnished during such first year; and

(II) for each subsequent year such group health plan, group health insurance coverage, or individual health insurance coverage, respectively, is offered in such region, the qualifying payment amount determined under this clause for such items and services furnished in the previous year, increased by the percentage increase in the consumer price index for all urban consumers (United States city average) over such previous year.

(iii) Insufficient information; newly covered items and services

In the case of a sponsor of a group health plan or health insurance issuer offering group or individual health insurance coverage that does not have sufficient information to calculate the median of the contracted rates described in clause (i)(I) in 2019 (or, in the case of a newly

covered item or service (as defined in clause (v)(III)), in the first coverage year (as defined in clause (v)(I)) for such item or service with respect to such plan or coverage) for an item or service (including with respect to provider type, or amount, of claims for items or services (as determined by the Secretary) provided in a particular geographic region (other than in a case with respect to which clause (ii) applies)) the term "qualifying payment amount"—

(I) for an item or service furnished during 2022 (or, in the case of a newly covered item or service, during the first coverage year for such item or service with respect to such plan or coverage), means such rate for such item or service determined by the sponsor or issuer, respectively, through use of any database that is determined, in accordance with rulemaking described in paragraph (2)(B), to not have any conflicts of interest and to have sufficient information reflecting allowed amounts paid to a health care provider or facility for relevant services furnished in the applicable geographic region (such as a State all-payer claims database);

(II) for an item or service furnished in a subsequent year (before the first sufficient information year (as defined in clause (v)(II)) for such item or service with respect to such plan or coverage), means the rate determined under subclause (I) or this subclause, as applicable, for such item or service for the year previous to such subsequent year, increased by the percentage increase in the consumer price index for all urban consumers (United States city average) over such previous year;

(III) for an item or service furnished in the first sufficient information year for such item or service with respect to such plan or coverage, has the meaning given the term qualifying payment amount in clause (i)(I), except that in applying such clause to such item or service, the reference to "furnished during 2022" shall be treated as a reference to furnished during such first sufficient information year, the reference to "in 2019" [1] shall be treated as a reference to such sufficient information year, and the increase described in such clause shall not be applied; and

(IV) for an item or service furnished in any year subsequent to the first sufficient information year for such item or service with respect to such plan or coverage, has the meaning given such term in clause (i)(II), except that in applying such clause to such item or service, the reference to "furnished during 2023 or a subsequent year" shall be treated as a reference to furnished during the year after such first sufficient information year or a subsequent year.

(iv) Insurance market

For purposes of clause (i)(I), a health insurance market specified in this clause is one of the following:

(I) The individual market.

(II) The large group market (other than plans described in subclause (IV)).

(III) The small group market (other than plans described in subclause (IV)).

(IV) In the case of a self-insured group health plan, other self-insured group health plans.

(v) Definitions

For purposes of this subparagraph:

(I) First coverage year

The term "first coverage year" means, with respect to a group health plan or group or individual health insurance coverage offered by a health insurance issuer and an item or service for which coverage is not offered in 2019 under such plan or coverage, the first year after 2019 for which coverage for such item or service is offered under such plan or health insurance coverage.

(II) First sufficient information year

The term "first sufficient information year" means, with respect to a group health plan or group or individual health insurance coverage offered by a health insurance issuer—

(aa) in the case of an item or service for which the plan or coverage does not have sufficient information to calculate the median of the contracted rates described in clause (i)(I) in 2019, the first year subsequent to 2022 for which the sponsor or issuer has such sufficient information to calculate the median of such contracted rates in the year previous to such first subsequent year; and

(bb) in the case of a newly covered item or service, the first year subsequent to the first coverage year for such item or service with respect to such plan or coverage for which the sponsor or issuer has sufficient information to calculate the median of the contracted rates described in clause (i)(I) in the year previous to such first subsequent year.

(III) Newly covered item or service

The term "newly covered item or service" means, with respect to a group health plan or group or individual health insurance issuer offering health insurance coverage, an item or service for which coverage was not offered in 2019 under such plan or coverage, but is offered under such plan or coverage in a year after 2019.

(F) Nonparticipating emergency facility; participating emergency facility

(i) Nonparticipating emergency facility

The term "nonparticipating emergency facility" means, with respect to an item or service and a group health plan or group or individual health insurance coverage offered by a health insurance issuer, an emergency department of a hospital, or an independent freestanding emergency department, that does not have a contractual relationship directly or indirectly with the plan or issuer, respectively, for furnishing such item or service under the plan or coverage, respectively.

(ii) Participating emergency facility

The term "participating emergency facility" means, with respect to an item or service and a group health plan or group or individual health insurance coverage offered by a health insurance issuer, an emergency department of a hospital, or an independent freestanding emergency department, that has a contractual relationship directly or indirectly with the plan or issuer, respectively, with respect to the furnishing of such an item or service at such facility.

(G) Nonparticipating providers; participating providers

(i) Nonparticipating provider

The term "nonparticipating provider" means, with respect to an item or service and a group health plan or group or individual health insurance coverage offered by a health insurance issuer, a physician or other health care provider who is acting within the scope of practice of that provider's license or certification under applicable State law and who does not have a contractual relationship with the plan or issuer, respectively, for furnishing such item or service under the plan or coverage, respectively.

(ii) Participating provider

The term "participating provider" means, with respect to an item or service and a group health plan or group or individual health insurance coverage offered by a health insurance issuer, a physician or other health care provider who is acting within the scope of practice of that provider's license or certification under applicable State law and who has a contractual relationship with the plan or issuer, respectively, for furnishing such item or service under the plan or coverage, respectively.

(H) Recognized amount

The term "recognized amount" means, with respect to an item or service furnished by a nonparticipating provider or nonparticipating emergency facility during a year and a group health plan or group or individual health insurance coverage offered by a health insurance

issuer—

(i) subject to clause (iii), in the case of such item or service furnished in a State that has in effect a specified State law with respect to such plan, coverage, or issuer, respectively; such a nonparticipating provider or nonparticipating emergency facility; and such an item or service, the amount determined in accordance with such law;

(ii) subject to clause (iii), in the case of such item or service furnished in a State that does not have in effect a specified State law, with respect to such plan, coverage, or issuer, respectively; such a nonparticipating provider or nonparticipating emergency facility; and such an item or service, the amount that is the qualifying payment amount (as defined in subparagraph (E)) [2] for such year and determined in accordance with rulemaking described in paragraph (2)(B)) [2] for such item or service; or

(iii) in the case of such item or service furnished in a State with an All-Payer Model Agreement under section 1115A of the Social Security Act [42 U.S.C. 1315a], the amount that the State approves under such system for such item or service so furnished.

(I) Specified State law

The term "specified State law" means, with respect to a State, an item or service furnished by a nonparticipating provider or nonparticipating emergency facility during a year and a group health plan or group or individual health insurance coverage offered by a health insurance issuer, a State law that provides for a method for determining the total amount payable under such a plan, coverage, or issuer, respectively (to the extent such State law applies to such plan, coverage, or issuer, subject to section 1144 of title 29) in the case of a participant, beneficiary, or enrollee covered under such plan or coverage and receiving such item or service from such a nonparticipating provider or nonparticipating emergency facility.

(J) Stabilize

The term "to stabilize", with respect to an emergency medical condition (as defined in subparagraph (B)), has the meaning give [3] in section 1867(e)(3) of the Social Security Act (42 U.S.C. 1395dd(e)(3)).

(K) Out-of-network rate

The term "out-of-network rate" means, with respect to an item or service furnished in a State during a year to a participant, beneficiary, or enrollee of a group health plan or group or individual health insurance coverage offered by a health insurance issuer receiving such item or service from a nonparticipating provider or nonparticipating emergency facility—

(i) subject to clause (iii), in the case of such item or service furnished in a State that has in effect a specified State law with respect to such plan, coverage, or issuer, respectively; such a nonparticipating provider or nonparticipating emergency facility; and such an item or service, the amount determined in accordance with such law;

(ii) subject to clause (iii), in the case such State does not have in effect such a law with respect to such item or service, plan, and provider or facility—

(I) subject to subclause (II), if the provider or facility (as applicable) and such plan or coverage agree on an amount of payment (including if such agreed on amount is the initial payment sent by the plan under subsection (a)(1)(C)(iv)(I), subsection (b)(1)(C), or section 300gg–112(a)(3)(A) of this title, as applicable, or is agreed on through open negotiations under subsection (c)(1)) with respect to such item or service, such agreed on amount; or

(II) if such provider or facility (as applicable) and such plan or coverage enter the independent dispute resolution process under subsection (c) and do not so agree before the date on which a certified IDR entity (as defined in paragraph (4) of such subsection) makes a determination with respect to such item or service under such subsection, the amount of such determination; or

(iii) in the case such State has an All-Payer Model Agreement under section 1115A of the Social Security Act [42 U.S.C. 1315a], the amount that the State approves under such system

for such item or service so furnished.

(L) Cost-sharing

The term "cost-sharing" includes copayments, coinsurance, and deductibles.

(b) Coverage of non-emergency services performed by nonparticipating providers at certain participating facilities

(1) In general

In the case of items or services (other than emergency services to which subsection (a) applies) for which any benefits are provided or covered by a group health plan or health insurance issuer offering group or individual health insurance coverage furnished to a participant, beneficiary, or enrollee of such plan or coverage by a nonparticipating provider (as defined in subsection (a)(3)(G)(i)) (and who, with respect to such items and services, has not satisfied the notice and consent criteria of section 300gg–132(d) of this title) with respect to a visit (as defined by the Secretary in accordance with paragraph (2)(B)) at a participating health care facility (as defined in paragraph (2)(A)), with respect to such plan or coverage, respectively, the plan or coverage, respectively—

(A) shall not impose on such participant, beneficiary, or enrollee a cost-sharing requirement for such items and services so furnished that is greater than the cost-sharing requirement that would apply under such plan or coverage, respectively, had such items or services been furnished by a participating provider (as defined in subsection (a)(3)(G)(ii));

(B) shall calculate such cost-sharing requirement as if the total amount that would have been charged for such items and services by such participating provider were equal to the recognized amount (as defined in subsection (a)(3)(H)) for such items and services, plan or coverage, and year;

(C) not later than 30 calendar days after the bill for such services is transmitted by such provider, shall send to the provider an initial payment or notice of denial of payment;

(D) shall pay a total plan or coverage payment directly, in accordance, if applicable, with the timing requirement described in subsection (c)(6), to such provider furnishing such items and services to such participant, beneficiary, or enrollee that is, with application of any initial payment under subparagraph (C), equal to the amount by which the out-of-network rate (as defined in subsection (a)(3)(K)) for such items and services involved exceeds the cost-sharing amount imposed under the plan or coverage, respectively, for such items and services (as determined in accordance with subparagraphs (A) and (B)) and year; and

(E) shall count toward any in-network deductible and in-network out-of-pocket maximums (as applicable) applied under the plan or coverage, respectively, any cost-sharing payments made by the participant, beneficiary, or enrollee (and such in-network deductible and out-of-pocket maximums shall be applied) with respect to such items and services so furnished in the same manner as if such cost-sharing payments were with respect to items and services furnished by a participating provider.

(2) Definitions

In this section:

(A) Participating health care facility

(i) In general

The term "participating health care facility" means, with respect to an item or service and a group health plan or health insurance issuer offering group or individual health insurance coverage, a health care facility described in clause (ii) that has a direct or indirect contractual relationship with the plan or issuer, respectively, with respect to the furnishing of such an item or service at the facility.

(ii) Health care facility described

A health care facility described in this clause, with respect to a group health plan or group

or individual health insurance coverage, is each of the following:

(I) A hospital (as defined in 1861(e) of the Social Security Act [42 U.S.C. 1395x(e)]).

(II) A hospital outpatient department.

(III) A critical access hospital (as defined in section 1861(mm)(1) of such Act [42 U.S.C. 1395x(mm)(1)]).

(IV) An ambulatory surgical center described in section 1833(i)(1)(A) of such Act [42 U.S.C. 1395l(i)(1)(A)].

(V) Any other facility, specified by the Secretary, that provides items or services for which coverage is provided under the plan or coverage, respectively.

(B) Visit

The term "visit" shall, with respect to items and services furnished to an individual at a health care facility, include equipment and devices, telemedicine services, imaging services, laboratory services, preoperative and postoperative services, and such other items and services as the Secretary may specify, regardless of whether or not the provider furnishing such items or services is at the facility.

(c) Determination of out-of-network rates to be paid by health plans; independent dispute resolution process

(1) Determination through open negotiation

(A) In general

With respect to an item or service furnished in a year by a nonparticipating provider or a nonparticipating facility, with respect to a group health plan or health insurance issuer offering group or individual health insurance coverage, in a State described in subsection (a)(3)(K)(ii) with respect to such plan or coverage and provider or facility, and for which a payment is required to be made by the plan or coverage pursuant to subsection (a)(1) or (b)(1), the provider or facility (as applicable) or plan or coverage may, during the 30-day period beginning on the day the provider or facility receives an initial payment or a notice of denial of payment from the plan or coverage regarding a claim for payment for such item or service, initiate open negotiations under this paragraph between such provider or facility and plan or coverage for purposes of determining, during the open negotiation period, an amount agreed on by such provider or facility, respectively, and such plan or coverage for payment (including any cost-sharing) for such item or service. For purposes of this subsection, the open negotiation period, with respect to an item or service, is the 30-day period beginning on the date of initiation of the negotiations with respect to such item or service.

(B) Accessing independent dispute resolution process in case of failed negotiations

In the case of open negotiations pursuant to subparagraph (A), with respect to an item or service, that do not result in a determination of an amount of payment for such item or service by the last day of the open negotiation period described in such subparagraph with respect to such item or service, the provider or facility (as applicable) or group health plan or health insurance issuer offering group or individual health insurance coverage that was party to such negotiations may, during the 4-day period beginning on the day after such open negotiation period, initiate the independent dispute resolution process under paragraph (2) with respect to such item or service. The independent dispute resolution process shall be initiated by a party pursuant to the previous sentence by submission to the other party and to the Secretary of a notification (containing such information as specified by the Secretary) and for purposes of this subsection, the date of initiation of such process shall be the date of such submission or such other date specified by the Secretary pursuant to regulations that is not later than the date of receipt of such notification by both the other party and the Secretary.

(2) Independent dispute resolution process available in case of failed open negotiations

(A) Establishment

Not later than 1 year after December 27, 2020, the Secretary, jointly with the Secretary of

Labor and the Secretary of the Treasury, shall establish by regulation one independent dispute resolution process (referred to in this subsection as the "IDR process") under which, in the case of an item or service with respect to which a provider or facility (as applicable) or group health plan or health insurance issuer offering group or individual health insurance coverage submits a notification under paragraph (1)(B) (in this subsection referred to as a "qualified IDR item or service"), a certified IDR entity under paragraph (4) determines, subject to subparagraph (B) and in accordance with the succeeding provisions of this subsection, the amount of payment under the plan or coverage for such item or service furnished by such provider or facility.

(B) Authority to continue negotiations

Under the independent dispute resolution process, in the case that the parties to a determination for a qualified IDR item or service agree on a payment amount for such item or service during such process but before the date on which the entity selected with respect to such determination under paragraph (4) makes such determination under paragraph (5), such amount shall be treated for purposes of subsection (a)(3)(K)(ii) as the amount agreed to by such parties for such item or service. In the case of an agreement described in the previous sentence, the independent dispute resolution process shall provide for a method to determine how to allocate between the parties to such determination the payment of the compensation of the entity selected with respect to such determination.

(C) Clarification

A nonparticipating provider may not, with respect to an item or service furnished by such provider, submit a notification under paragraph (1)(B) if such provider is exempt from the requirement under subsection (a) of section 300gg–132 of this title with respect to such item or service pursuant to subsection (b) of such section.

(3) Treatment of batching of items and services

(A) In general

Under the IDR process, the Secretary shall specify criteria under which multiple qualified IDR dispute items and services are permitted to be considered jointly as part of a single determination by an entity for purposes of encouraging the efficiency (including minimizing costs) of the IDR process. Such items and services may be so considered only if—

(i) such items and services to be included in such determination are furnished by the same provider or facility;

(ii) payment for such items and services is required to be made by the same group health plan or health insurance issuer;

(iii) such items and services are related to the treatment of a similar condition; and

(iv) such items and services were furnished during the 30 day [4] period following the date on which the first item or service included with respect to such determination was furnished or an alternative period as determined by the Secretary, for use in limited situations, such as by the consent of the parties or in the case of low-volume items and services, to encourage procedural efficiency and minimize health plan and provider administrative costs.

(B) Treatment of bundled payments

In carrying out subparagraph (A), the Secretary shall provide that, in the case of items and services which are included by a provider or facility as part of a bundled payment, such items and services included in such bundled payment may be part of a single determination under this subsection.

(4) Certification and selection of IDR entities

(A) In general

The Secretary, in consultation with the Secretary of Labor and Secretary of the Treasury, shall establish a process to certify (including to recertify) entities under this paragraph. Such process shall ensure that an entity so certified—

(i) has (directly or through contracts or other arrangements) sufficient medical, legal, and other expertise and sufficient staffing to make determinations described in paragraph (5) on a timely basis;

(ii) is not—

(I) a group health plan or health insurance issuer offering group or individual health insurance coverage, provider, or facility;

(II) an affiliate or a subsidiary of such a group health plan or health insurance issuer, provider, or facility; or

(III) an affiliate or subsidiary of a professional or trade association of such group health plans or health insurance issuers or of providers or facilities;

(iii) carries out the responsibilities of such an entity in accordance with this subsection;

(iv) meets appropriate indicators of fiscal integrity;

(v) maintains the confidentiality (in accordance with regulations promulgated by the Secretary) of individually identifiable health information obtained in the course of conducting such determinations;

(vi) does not under the IDR process carry out any determination with respect to which the entity would not pursuant to subclause (I), (II), or (III) of subparagraph (F)(i) be eligible for selection; and

(vii) meets such other requirements as determined appropriate by the Secretary.

(B) Period of certification

Subject to subparagraph (C), each certification (including a recertification) of an entity under the process described in subparagraph (A) shall be for a 5-year period.

(C) Revocation

A certification of an entity under this paragraph may be revoked under the process described in subparagraph (A) if the entity has a pattern or practice of noncompliance with any of the requirements described in such subparagraph.

(D) Petition for denial or withdrawal

The process described in subparagraph (A) shall ensure that an individual, provider, facility, or group health plan or health insurance issuer offering group or individual health insurance coverage may petition for a denial of a certification or a revocation of a certification with respect to an entity under this paragraph for failure of meeting a requirement of this subsection.

(E) Sufficient number of entities

The process described in subparagraph (A) shall ensure that a sufficient number of entities are certified under this paragraph to ensure the timely and efficient provision of determinations described in paragraph (5).

(F) Selection of certified IDR entity

The Secretary shall, with respect to the determination of the amount of payment under this subsection of an item or service, provide for a method—

(i) that allows for the group health plan or health insurance issuer offering group or individual health insurance coverage and the nonparticipating provider or the nonparticipating emergency facility (as applicable) involved in a notification under paragraph (1)(B) to jointly select, not later than the last day of the 3-business day period following the date of the initiation of the process with respect to such item or service, for purposes of making such determination, an entity certified under this paragraph that—

(I) is not a party to such determination or an employee or agent of such a party;

(II) does not have a material familial, financial, or professional relationship with such a party; and

(III) does not otherwise have a conflict of interest with such a party (as determined by the Secretary); and

(ii) that requires, in the case such parties do not make such selection by such last day, the Secretary to, not later than 6 business days after such date of initiation—

(I) select such an entity that satisfies subclauses (I) through (III) of clause (i)); [2] and

(II) provide notification of such selection to the provider or facility (as applicable) and the plan or issuer (as applicable) party to such determination.

An entity selected pursuant to the previous sentence to make a determination described in such sentence shall be referred to in this subsection as the "certified IDR entity" with respect to such determination.

(5) Payment determination

(A) In general

Not later than 30 days after the date of selection of the certified IDR entity with respect to a determination for a qualified IDR item or service, the certified IDR entity shall—

(i) taking into account the considerations specified in subparagraph (C), select one of the offers submitted under subparagraph (B) to be the amount of payment for such item or service determined under this subsection for purposes of subsection (a)(1) or (b)(1), as applicable; and

(ii) notify the provider or facility and the group health plan or health insurance issuer offering group or individual health insurance coverage party to such determination of the offer selected under clause (i).

(B) Submission of offers

Not later than 10 days after the date of selection of the certified IDR entity with respect to a determination for a qualified IDR item or service, the provider or facility and the group health plan or health insurance issuer offering group or individual health insurance coverage party to such determination—

(i) shall each submit to the certified IDR entity with respect to such determination—

(I) an offer for a payment amount for such item or service furnished by such provider or facility; and

(II) such information as requested by the certified IDR entity relating to such offer; and

(ii) may each submit to the certified IDR entity with respect to such determination any information relating to such offer submitted by either party, including information relating to any circumstance described in subparagraph (C)(ii).

(C) Considerations in determination

(i) In general

In determining which offer is the payment to be applied pursuant to this paragraph, the certified IDR entity, with respect to the determination for a qualified IDR item or service shall consider—

(I) the qualifying payment amounts (as defined in subsection (a)(3)(E)) for the applicable year for items or services that are comparable to the qualified IDR item or service and that are furnished in the same geographic region (as defined by the Secretary for purposes of such subsection) as such qualified IDR item or service; and

(II) subject to subparagraph (D), information on any circumstance described in clause (ii), such information as requested in subparagraph (B)(i)(II), and any additional information provided in subparagraph (B)(ii).

(ii) Additional circumstances

For purposes of clause (i)(II), the circumstances described in this clause are, with respect to a qualified IDR item or service of a nonparticipating provider, nonparticipating emergency facility, group health plan, or health insurance issuer of group or individual health insurance

coverage the following:

(I) The level of training, experience, and quality and outcomes measurements of the provider or facility that furnished such item or service (such as those endorsed by the consensus-based entity authorized in section 1890 of the Social Security Act [42 U.S.C. 1395aaa]).

(II) The market share held by the nonparticipating provider or facility or that of the plan or issuer in the geographic region in which the item or service was provided.

(III) The acuity of the individual receiving such item or service or the complexity of furnishing such item or service to such individual.

(IV) The teaching status, case mix, and scope of services of the nonparticipating facility that furnished such item or service.

(V) Demonstrations of good faith efforts (or lack of good faith efforts) made by the nonparticipating provider or nonparticipating facility or the plan or issuer to enter into network agreements and, if applicable, contracted rates between the provider or facility, as applicable, and the plan or issuer, as applicable, during the previous 4 plan years.

(D) Prohibition on consideration of certain factors

In determining which offer is the payment to be applied with respect to qualified IDR items and services furnished by a provider or facility, the certified IDR entity with respect to a determination shall not consider usual and customary charges, the amount that would have been billed by such provider or facility with respect to such items and services had the provisions of section 300gg–131 or 300gg–132 of this title (as applicable) not applied, or the payment or reimbursement rate for such items and services furnished by such provider or facility payable by a public payor, including under the Medicare program under title XVIII of the Social Security Act [42 U.S.C. 1395 et seq.], under the Medicaid program under title XIX of such Act [42 U.S.C. 1396 et seq.], under the Children's Health Insurance Program under title XXI of such Act [42 U.S.C. 1397aa et seq.], under the TRICARE program under chapter 55 of title 10, or under chapter 17 of title 38.

(E) Effects of determination

(i) In general

A determination of a certified IDR entity under subparagraph (A)—

(I) shall be binding upon the parties involved, in the absence of a fraudulent claim or evidence of misrepresentation of facts presented to the IDR entity involved regarding such claim; and

(II) shall not be subject to judicial review, except in a case described in any of paragraphs (1) through (4) of section 10(a) of title 9.

(ii) Suspension of certain subsequent IDR requests

In the case of a determination of a certified IDR entity under subparagraph (A), with respect to an initial notification submitted under paragraph (1)(B) with respect to qualified IDR items and services and the two parties involved with such notification, the party that submitted such notification may not submit during the 90-day period following such determination a subsequent notification under such paragraph involving the same other party to such notification with respect to such an item or service that was the subject of such initial notification.

(iii) Subsequent submission of requests permitted

In the case of a notification that pursuant to clause (ii) is not permitted to be submitted under paragraph (1)(B) during a 90-day period specified in such clause, if the end of the open negotiation period specified in paragraph (1)(A), that but for this clause would otherwise apply with respect to such notification, occurs during such 90-day period, such paragraph

(1)(B) shall be applied as if the reference in such paragraph to the 4-day period beginning on the day after such open negotiation period were instead a reference to the 30-day period beginning on the day after the last day of such 90-day period.

(iv) Reports

The Secretary, jointly with the Secretary of Labor and the Secretary of the Treasury, shall examine the impact of the application of clause (ii) and whether the application of such clause delays payment determinations or impacts early, alternative resolution of claims (such as through open negotiations), and shall submit to Congress, not later than 2 years after the date of implementation of such clause an interim report (and not later than 4 years after such date of implementation, a final report) on whether any group health plans or health insurance issuers offering group or individual health insurance coverage or types of such plans or coverage have a pattern or practice of routine denial, low payment, or down-coding of claims, or otherwise abuse the 90-day period described in such clause, including recommendations on ways to discourage such a pattern or practice.

(F) Costs of independent dispute resolution process

In the case of a notification under paragraph (1)(B) submitted by a nonparticipating provider, nonparticipating emergency facility, group health plan, or health insurance issuer offering group or individual health insurance coverage and submitted to a certified IDR entity—

(i) if such entity makes a determination with respect to such notification under subparagraph (A), the party whose offer is not chosen under such subparagraph shall be responsible for paying all fees charged by such entity; and

(ii) if the parties reach a settlement with respect to such notification prior to such a determination, each party shall pay half of all fees charged by such entity, unless the parties otherwise agree.

(6) Timing of payment

The total plan or coverage payment required pursuant to subsection (a)(1) or (b)(1), with respect to a qualified IDR item or service for which a determination is made under paragraph (5)(A) or with respect to an item or service for which a payment amount is determined under open negotiations under paragraph (1), shall be made directly to the nonparticipating provider or facility not later than 30 days after the date on which such determination is made.

(7) Publication of information relating to the IDR process

(A) Publication of information

For each calendar quarter in 2022 and each calendar quarter in a subsequent year, the Secretary shall make available on the public website of the Department of Health and Human Services—

(i) the number of notifications submitted under paragraph (1)(B) during such calendar quarter;

(ii) the size of the provider practices and the size of the facilities submitting notifications under paragraph (1)(B) during such calendar quarter;

(iii) the number of such notifications with respect to which a determination was made under paragraph (5)(A);

(iv) the information described in subparagraph (B) with respect to each notification with respect to which such a determination was so made;

(v) the number of times the payment amount determined (or agreed to) under this subsection exceeds the qualifying payment amount, specified by items and services;

(vi) the amount of expenditures made by the Secretary during such calendar quarter to carry out the IDR process;

(vii) the total amount of fees paid under paragraph (8) during such calendar quarter; and

(viii) the total amount of compensation paid to certified IDR entities under paragraph (5)(F) during such calendar quarter.

(B) Information

For purposes of subparagraph (A), the information described in this subparagraph is, with respect to a notification under paragraph (1)(B) by a nonparticipating provider, nonparticipating emergency facility, group health plan, or health insurance issuer offering group or individual health insurance coverage—

(i) a description of each item and service included with respect to such notification;

(ii) the geography in which the items and services with respect to such notification were provided;

(iii) the amount of the offer submitted under paragraph (5)(B) by the group health plan or health insurance issuer (as applicable) and by the nonparticipating provider or nonparticipating emergency facility (as applicable) expressed as a percentage of the qualifying payment amount;

(iv) whether the offer selected by the certified IDR entity under paragraph (5) to be the payment applied was the offer submitted by such plan or issuer (as applicable) or by such provider or facility (as applicable) and the amount of such offer so selected expressed as a percentage of the qualifying payment amount;

(v) the category and practice specialty of each such provider or facility involved in furnishing such items and services;

(vi) the identity of the health plan or health insurance issuer, provider, or facility, with respect to the notification;

(vii) the length of time in making each determination;

(viii) the compensation paid to the certified IDR entity with respect to the settlement or determination; and

(ix) any other information specified by the Secretary.

(C) IDR entity requirements

For 2022 and each subsequent year, an IDR entity, as a condition of certification as an IDR entity, shall submit to the Secretary such information as the Secretary determines necessary to carry out the provisions of this subsection.

(D) Clarification

The Secretary shall ensure the public reporting under this paragraph does not contain information that would disclose privileged or confidential information of a group health plan or health insurance issuer offering group or individual health insurance coverage or of a provider or facility.

(8) Administrative fee

(A) In general

Each party to a determination under paragraph (5) to which an entity is selected under paragraph (3) [5] in a year shall pay to the Secretary, at such time and in such manner as specified by the Secretary, a fee for participating in the IDR process with respect to such determination in an amount described in subparagraph (B) for such year.

(B) Amount of fee

The amount described in this subparagraph for a year is an amount established by the Secretary in a manner such that the total amount of fees paid under this paragraph for such year is estimated to be equal to the amount of expenditures estimated to be made by the Secretary for such year in carrying out the IDR process.

(9) Waiver authority

The Secretary may modify any deadline or other timing requirement specified under this subsection (other than the establishment date for the IDR process under paragraph (2)(A) and other than under paragraph (6)) in cases of extenuating circumstances, as specified by the Secretary, or to ensure that all claims that occur during a 90-day period described in paragraph

(5)(E)(ii), but with respect to which a notification is not permitted by reason of such paragraph to be submitted under paragraph (1)(B) during such period, are eligible for the IDR process.

(d) Certain access fees to certain databases

In the case of a sponsor of a group health plan or health insurance issuer offering group or individual health insurance coverage that, pursuant to subsection (a)(3)(E)(iii), uses a database described in such subsection to determine a rate to apply under such subsection for an item or service by reason of having insufficient information described in such subsection with respect to such item or service, such sponsor or issuer shall cover the cost for access to such database.

(e) Transparency regarding in-network and out-of-network deductibles and out-of-pocket limitations

A group health plan or a health insurance issuer offering group or individual health insurance coverage and providing or covering any benefit with respect to items or services shall include, in clear writing, on any physical or electronic plan or insurance identification card issued to the participants, beneficiaries, or enrollees in the plan or coverage the following:

(1) Any deductible applicable to such plan or coverage.

(2) Any out-of-pocket maximum limitation applicable to such plan or coverage.

(3) A telephone number and Internet website address through which such individual may seek consumer assistance information, such as information related to hospitals and urgent care facilities that have in effect a contractual relationship with such plan or coverage for furnishing items and services under such plan or coverage [6]

(f) Advanced explanation of benefits

(1) In general

For plan years beginning on or after January 1, 2022, each group health plan, or a health insurance issuer offering group or individual health insurance coverage shall, with respect to a notification submitted under section 300gg–136 of this title by a health care provider or health care facility to the plan or issuer for a participant, beneficiary, or enrollee under plan or coverage scheduled to receive an item or service from the provider or facility (or authorized representative of such participant, beneficiary, or enrollee), not later than 1 business day (or, in the case such item or service was so scheduled at least 10 business days before such item or service is to be furnished (or in the case of a request made to such plan or coverage by such participant, beneficiary, or enrollee), 3 business days) after the date on which the plan or coverage receives such notification (or such request), provide to the participant, beneficiary, or enrollee (through mail or electronic means, as requested by the participant, beneficiary, or enrollee) a notification (in clear and understandable language) including the following:

(A) Whether or not the provider or facility is a participating provider or a participating facility with respect to the plan or coverage with respect to the furnishing of such item or service and—

(i) in the case the provider or facility is a participating provider or facility with respect to the plan or coverage with respect to the furnishing of such item or service, the contracted rate under such plan or coverage for such item or service (based on the billing and diagnostic codes provided by such provider or facility); and

(ii) in the case the provider or facility is a nonparticipating provider or facility with respect to such plan or coverage, a description of how such individual may obtain information on providers and facilities that, with respect to such plan or coverage, are participating providers and facilities, if any.

(B) The good faith estimate included in the notification received from the provider or facility (if applicable) based on such codes.

(C) A good faith estimate of the amount the plan or coverage is responsible for paying for items and services included in the estimate described in subparagraph (B).

(D) A good faith estimate of the amount of any cost-sharing for which the participant,

beneficiary, or enrollee would be responsible for such item or service (as of the date of such notification).

(E) A good faith estimate of the amount that the participant, beneficiary, or enrollee has incurred toward meeting the limit of the financial responsibility (including with respect to deductibles and out-of-pocket maximums) under the plan or coverage (as of the date of such notification).

(F) In the case such item or service is subject to a medical management technique (including concurrent review, prior authorization, and step-therapy or fail-first protocols) for coverage under the plan or coverage, a disclaimer that coverage for such item or service is subject to such medical management technique.

(G) A disclaimer that the information provided in the notification is only an estimate based on the items and services reasonably expected, at the time of scheduling (or requesting) the item or service, to be furnished and is subject to change.

(H) Any other information or disclaimer the plan or coverage determines appropriate that is consistent with information and disclaimers required under this section.

(2) Authority to modify timing requirements in the case of specified items and services

(A) In general

In the case of a participant, beneficiary, or enrollee scheduled to receive an item or service that is a specified item or service (as defined in subparagraph (B)), the Secretary may modify any timing requirements relating to the provision of the notification described in paragraph (1) to such participant, beneficiary, or enrollee with respect to such item or service. Any modification made by the Secretary pursuant to the previous sentence may not result in the provision of such notification after such participant, beneficiary, or enrollee has been furnished such item or service.

(B) Specified item or service defined

For purposes of subparagraph (A), the term "specified item or service" means an item or service that has low utilization or significant variation in costs (such as when furnished as part of a complex treatment), as specified by the Secretary.

(July 1, 1944, ch. 373, title XXVII, §2799A–1, as added and amended Pub. L. 116–260, div. BB, title I, §§102(a)(1), 103(a), 107(a), 111(a), Dec. 27, 2020, 134 Stat. 2759, 2797, 2858, 2861.)

EDITORIAL NOTES

REFERENCES IN TEXT

Section 109(a) of the No Surprises Act, referred to in subsec. (a)(2)(B), is section 109(a) of Pub. L. 116–260, div. BB, title I, Dec. 27, 2020, 134 Stat. 2859, which is not classified to the Code.

The phrase "in 2019", referred to in subsec. (a)(3)(E)(iii)(III), does not appear in cl. (i)(I) of subsec. (a)(3)(E). However, subsec. (a)(3)(E)(iii)(III) of section 9816 of Title 26, Internal Revenue Code, which contains text similar to that in this subclause, refers to the phrase "on January 31, 2019", which does appear in cl. (i)(I).

The Social Security Act, referred to in subsec. (c)(5)(D), is act Aug. 14, 1935, ch. 531, 49 Stat. 620. Titles XVIII, XIX, and XXI of the Act are classified generally to subchapters XVIII (§1395 et seq.), XIX (§1396 et seq.), and XXI (§1397aa et seq.), respectively, of chapter 7 of this title. For complete classification of this Act to the Code, see section 1305 of this title and Tables.

AMENDMENTS

2020—Subsecs. (c), (d). Pub. L. 116–260, §103(a), added subsec. (c) and redesignated former subsec. (c) as (d).

Subsec. (e). Pub. L. 116–260, §107(a), added subsec. (e).

Subsec. (f). Pub. L. 116–260, §111(a), added subsec. (f).

STATUTORY NOTES AND RELATED SUBSIDIARIES

EFFECTIVE DATE OF 2020 AMENDMENT

Amendment by section 107(a) of div. BB of Pub. L. 116–260 applicable with respect to plan years beginning on or after Jan. 1, 2022, see section 107(d) of div. BB of Pub. L. 116–260, set out as a note under section 9816 of Title 26, Internal Revenue Code.

EFFECTIVE DATE

Section applicable with respect to plan years beginning on or after Jan. 1, 2022, see section 102(e) of div. BB of Pub. L. 116–260, set out as an Effective Date of 2020 Amendment note under section 8902 of Title 5, Government Organization and Employees.

[1] *See References in Text note below.*

[2] *Closing parentheses so in original.*

[3] *So in original. Probably should be "given".*

[4] *So in original. Probably should be "30-day".*

[5] *So in original. Probably should be "paragraph (4)".*

[6] *So in original. Probably should be followed by a period.*

§300gg–112. Ending surprise air ambulance bills

(a) In general

In the case of a participant, beneficiary, or enrollee who is in a group health plan or group or individual health insurance coverage offered by a health insurance issuer and who receives air ambulance services from a nonparticipating provider (as defined in section 300gg–111(a)(3)(G) of this title) with respect to such plan or coverage, if such services would be covered if provided by a participating provider (as defined in such section) with respect to such plan or coverage—

(1) the cost-sharing requirement with respect to such services shall be the same requirement that would apply if such services were provided by such a participating provider, and any coinsurance or deductible shall be based on rates that would apply for such services if they were furnished by such a participating provider;

(2) such cost-sharing amounts shall be counted towards the in-network deductible and in-network out-of-pocket maximum amount under the plan or coverage for the plan year (and such in-network deductible shall be applied) with respect to such items and services so furnished in the same manner as if such cost-sharing payments were with respect to items and services furnished by a participating provider; and

(3) the group health plan or health insurance issuer, respectively, shall—

(A) not later than 30 calendar days after the bill for such services is transmitted by such provider, send to the provider, an initial payment or notice of denial of payment; and

(B) pay a total plan or coverage payment, in accordance with, if applicable, subsection (b)(6), directly to such provider furnishing such services to such participant, beneficiary, or enrollee that is, with application of any initial payment under subparagraph (A), equal to the amount by which the out-of-network rate (as defined in section 300gg–111(a)(3)(K) of this title) for such services and year involved exceeds the cost-sharing amount imposed under the plan or coverage, respectively, for such services (as determined in accordance with paragraphs (1) and (2)).

(b) Determination of out-of-network rates to be paid by health plans; independent dispute resolution process

(1) Determination through open negotiation

(A) In general

With respect to air ambulance services furnished in a year by a nonparticipating provider, with respect to a group health plan or health insurance issuer offering group or individual health insurance coverage, and for which a payment is required to be made by the plan or coverage pursuant to subsection (a)(3), the provider or plan or coverage may, during the 30-day period beginning on the day the provider receives an initial payment or a notice of denial of payment from the plan or coverage regarding a claim for payment for such service, initiate open negotiations under this paragraph between such provider and plan or coverage for purposes of determining, during the open negotiation period, an amount agreed on by such provider, and such plan or coverage for payment (including any cost-sharing) for such service. For purposes of this subsection, the open negotiation period, with respect to air ambulance services, is the 30-day period beginning on the date of initiation of the negotiations with respect to such services.

(B) Accessing independent dispute resolution process in case of failed negotiations

In the case of open negotiations pursuant to subparagraph (A), with respect to air ambulance services, that do not result in a determination of an amount of payment for such services by the last day of the open negotiation period described in such subparagraph with respect to such services, the provider or group health plan or health insurance issuer offering group or individual health insurance coverage that was party to such negotiations may, during the 4-day period beginning on the day after such open negotiation period, initiate the independent dispute resolution process under paragraph (2) with respect to such item or service. The independent dispute resolution process shall be initiated by a party pursuant to the previous sentence by submission to the other party and to the Secretary of a notification (containing such information as specified by the Secretary) and for purposes of this subsection, the date of initiation of such process shall be the date of such submission or such other date specified by the Secretary pursuant to regulations that is not later than the date of receipt of such notification by both the other party and the Secretary.

(2) Independent dispute resolution process available in case of failed open negotiations

(A) Establishment

Not later than 1 year after December 27, 2020, the Secretary, jointly with the Secretary of Labor and the Secretary of the Treasury, shall establish by regulation one independent dispute resolution process (referred to in this subsection as the "IDR process") under which, in the case of air ambulance services with respect to which a provider or group health plan or health insurance issuer offering group or individual health insurance coverage submits a notification under paragraph (1)(B) (in this subsection referred to as a "qualified IDR air ambulance services"), a certified IDR entity under paragraph (4) determines, subject to subparagraph (B) and in accordance with the succeeding provisions of this subsection, the amount of payment under the plan or coverage for such services furnished by such provider.

(B) Authority to continue negotiations

Under the independent dispute resolution process, in the case that the parties to a determination for qualified IDR air ambulance services agree on a payment amount for such services during such process but before the date on which the entity selected with respect to such determination under paragraph (4) makes such determination under paragraph (5), such amount shall be treated for purposes of section 300gg–111(a)(3)(K)(ii) of this title as the amount agreed to by such parties for such services. In the case of an agreement described in the previous sentence, the independent dispute resolution process shall provide for a method to determine how to allocate between the parties to such determination the payment of the compensation of the entity selected with respect to such determination.

(C) Clarification

A nonparticipating provider may not, with respect to an item or service furnished by such provider, submit a notification under paragraph (1)(B) if such provider is exempt from the requirement under subsection (a) of section 300gg–132 of this title with respect to such item or service pursuant to subsection (b) of such section.

(3) Treatment of batching of services

The provisions of section 300gg–111(c)(3) of this title shall apply with respect to a notification submitted under this subsection with respect to air ambulance services in the same manner and to the same extent such provisions apply with respect to a notification submitted under section 300gg–111(c) of this title with respect to items and services described in such section.

(4) IDR entities

(A) Eligibility

An IDR entity certified under this subsection is an IDR entity certified under section 300gg–111(c)(4) of this title.

(B) Selection of certified IDR entity

The provisions of subparagraph (F) of section 300gg–111(c)(4) of this title shall apply with respect to selecting an IDR entity certified pursuant to subparagraph (A) with respect to the determination of the amount of payment under this subsection of air ambulance services in the same manner as such provisions apply with respect to selecting an IDR entity certified under such section with respect to the determination of the amount of payment under section 300gg–111(c) of this title of an item or service. An entity selected pursuant to the previous sentence to make a determination described in such sentence shall be referred to in this subsection as the "certified IDR entity" with respect to such determination.

(5) Payment determination

(A) In general

Not later than 30 days after the date of selection of the certified IDR entity with respect to a determination for qualified IDR ambulance services, the certified IDR entity shall—

(i) taking into account the considerations specified in subparagraph (C), select one of the offers submitted under subparagraph (B) to be the amount of payment for such services determined under this subsection for purposes of subsection (a)(3); and

(ii) notify the provider or facility and the group health plan or health insurance issuer offering group or individual health insurance coverage party to such determination of the offer selected under clause (i).

(B) Submission of offers

Not later than 10 days after the date of selection of the certified IDR entity with respect to a determination for qualified IDR air ambulance services, the provider and the group health plan or health insurance issuer offering group or individual health insurance coverage party to such determination—

(i) shall each submit to the certified IDR entity with respect to such determination—

(I) an offer for a payment amount for such services furnished by such provider; and

(II) such information as requested by the certified IDR entity relating to such offer; and

(ii) may each submit to the certified IDR entity with respect to such determination any information relating to such offer submitted by either party, including information relating to any circumstance described in subparagraph (C)(ii).

(C) Considerations in determination

(i) In general

In determining which offer is the payment to be applied pursuant to this paragraph, the certified IDR entity, with respect to the determination for a qualified IDR air ambulance

service shall consider—

(I) the qualifying payment amounts (as defined in section 300gg–111(a)(3)(E) of this title) for the applicable year for items or services that are comparable to the qualified IDR air ambulance service and that are furnished in the same geographic region (as defined by the Secretary for purposes of such subsection) as such qualified IDR air ambulance service; and

(II) subject to clause (iii), information on any circumstance described in clause (ii), such information as requested in subparagraph (B)(i)(II), and any additional information provided in subparagraph (B)(ii).

(ii) Additional circumstances

For purposes of clause (i)(II), the circumstances described in this clause are, with respect to air ambulance services included in the notification submitted under paragraph (1)(B) of a nonparticipating provider, group health plan, or health insurance issuer the following:

(I) The quality and outcomes measurements of the provider that furnished such services.

(II) The acuity of the individual receiving such services or the complexity of furnishing such services to such individual.

(III) The training, experience, and quality of the medical personnel that furnished such services.

(IV) Ambulance vehicle type, including the clinical capability level of such vehicle.

(V) Population density of the pick up location (such as urban, suburban, rural, or frontier).

(VI) Demonstrations of good faith efforts (or lack of good faith efforts) made by the nonparticipating provider or nonparticipating facility or the plan or issuer to enter into network agreements and, if applicable, contracted rates between the provider and the plan or issuer, as applicable, during the previous 4 plan years.

(iii) Prohibition on consideration of certain factors

In determining which offer is the payment amount to be applied with respect to qualified IDR air ambulance services furnished by a provider, the certified IDR entity with respect to such determination shall not consider usual and customary charges, the amount that would have been billed by such provider with respect to such services had the provisions of section 300gg–135 of this title not applied, or the payment or reimbursement rate for such services furnished by such provider payable by a public payor, including under the Medicare program under title XVIII of the Social Security Act [42 U.S.C. 1395 et seq.], under the Medicaid program under title XIX of such Act [42 U.S.C. 1396 et seq.], under the Children's Health Insurance Program under title XXI of such Act [42 U.S.C. 1397aa et seq.], under the TRICARE program under chapter 55 of title 10, or under chapter 17 of title 38.

(D) Effects of determination

The provisions of section 300gg–111(c)(5)(E) of this title shall apply with respect to a determination of a certified IDR entity under subparagraph (A), the notification submitted with respect to such determination, the services with respect to such notification, and the parties to such notification in the same manner as such provisions apply with respect to a determination of a certified IDR entity under section 300gg–111(c)(5)(E) of this title, the notification submitted with respect to such determination, the items and services with respect to such notification, and the parties to such notification.

(E) Costs of independent dispute resolution process

The provisions of section 300gg–111(c)(5)(F) of this title shall apply to a notification made under this subsection, the parties to such notification, and a determination under subparagraph (A) in the same manner and to the same extent such provisions apply to a notification under section 300gg–111(c) of this title, the parties to such notification and a determination made under section 300gg–111(c)(5)(A) of this title.

(6) Timing of payment

The total plan or coverage payment required pursuant to subsection (a)(3), with respect to qualified IDR air ambulance services for which a determination is made under paragraph (5)(A) or with respect to an air ambulance service for which a payment amount is determined under open negotiations under paragraph (1), shall be made directly to the nonparticipating provider not later than 30 days after the date on which such determination is made.

(7) Publication of information relating to the IDR process

(A) In general

For each calendar quarter in 2022 and each calendar quarter in a subsequent year, the Secretary shall publish on the public website of the Department of Health and Human Services—

(i) the number of notifications submitted under the IDR process during such calendar quarter;

(ii) the number of such notifications with respect to which a final determination was made under paragraph (5)(A);

(iii) the information described in subparagraph (B) with respect to each notification with respect to which such a determination was so made.[1]

(iv) the number of times the payment amount determined (or agreed to) under this subsection exceeds the qualifying payment amount;

(v) the amount of expenditures made by the Secretary during such calendar quarter to carry out the IDR process;

(vi) the total amount of fees paid under paragraph (8) during such calendar quarter; and

(vii) the total amount of compensation paid to certified IDR entities under paragraph (5)(E) during such calendar quarter.

(B) Information with respect to requests

For purposes of subparagraph (A), the information described in this subparagraph is, with respect to a notification under the IDR process of a nonparticipating provider, group health plan, or health insurance issuer offering group or individual health insurance coverage—

(i) a description of each air ambulance service included in such notification;

(ii) the geography in which the services included in such notification were provided;

(iii) the amount of the offer submitted under paragraph (2) by the group health plan or health insurance issuer (as applicable) and by the nonparticipating provider expressed as a percentage of the qualifying payment amount;

(iv) whether the offer selected by the certified IDR entity under paragraph (5) to be the payment applied was the offer submitted by such plan or issuer (as applicable) or by such provider and the amount of such offer so selected expressed as a percentage of the qualifying payment amount;

(v) ambulance vehicle type, including the clinical capability level of such vehicle;

(vi) the identity of the group health plan or health insurance issuer or air ambulance provider with respect to such notification;

(vii) the length of time in making each determination;

(viii) the compensation paid to the certified IDR entity with respect to the settlement or determination; and

(ix) any other information specified by the Secretary.

(C) IDR entity requirements

For 2022 and each subsequent year, an IDR entity, as a condition of certification as an IDR entity, shall submit to the Secretary such information as the Secretary determines necessary for the Secretary to carry out the provisions of this paragraph.

(D) Clarification

The Secretary shall ensure the public reporting under this paragraph does not contain

information that would disclose privileged or confidential information of a group health plan or health insurance issuer offering group or individual health insurance coverage or of a provider or facility.

(8) Administrative fee

(A) In general

Each party to a determination under paragraph (5) to which an entity is selected under paragraph (4) in a year shall pay to the Secretary, at such time and in such manner as specified by the Secretary, a fee for participating in the IDR process with respect to such determination in an amount described in subparagraph (B) for such year.

(B) Amount of fee

The amount described in this subparagraph for a year is an amount established by the Secretary in a manner such that the total amount of fees paid under this paragraph for such year is estimated to be equal to the amount of expenditures estimated to be made by the Secretary for such year in carrying out the IDR process.

(9) Waiver authority

The Secretary may modify any deadline or other timing requirement specified under this subsection (other than the establishment date for the IDR process under paragraph (2)(A) and other than under paragraph (6)) in cases of extenuating circumstances, as specified by the Secretary, or to ensure that all claims that occur during a 90-day period applied through paragraph (5)(D), but with respect to which a notification is not permitted by reason of such paragraph to be submitted under paragraph (1)(B) during such period, are eligible for the IDR process.

(c) Definitions

For purposes of this section:

(1) Air ambulance service

The term "air ambulance service" means medical transport by helicopter or airplane for patients.

(2) Qualifying payment amount

The term "qualifying payment amount" has the meaning given such term in section 300gg–111(a)(3) of this title.

(3) Nonparticipating provider

The term "nonparticipating provider" has the meaning given such term in section 300gg–111(a)(3) of this title.

(July 1, 1944, ch. 373, title XXVII, §2799A–2, as added Pub. L. 116–260, div. BB, title I, §105(a)(1), Dec. 27, 2020, 134 Stat. 2831.)

EDITORIAL NOTES

REFERENCES IN TEXT

The Social Security Act, referred to in subsec. (b)(5)(C)(iii), is act Aug. 14, 1935, ch. 531, 49 Stat. 620. Titles XVIII, XIX, and XXI of the Act are classified generally to subchapters XVIII (§1395 et seq.), XIX (§1396 et seq.), and XXI (§1397aa et seq.), respectively, of chapter 7 of this title. For complete classification of this Act to the Code, see section 1305 of this title and Tables.

STATUTORY NOTES AND RELATED SUBSIDIARIES

EFFECTIVE DATE

Section applicable with respect to plan years beginning on or after Jan. 1, 2022, see section 105(a)(4) of div. BB of Pub. L. 116–260, set out as a note under section 9817 of Title 26, Internal Revenue Code.

[1] *So in original. The period probably should be a semicolon.*

§300gg–113. Continuity of care

(a) Ensuring continuity of care with respect to terminations of certain contractual relationships resulting in changes in provider network status

(1) In general

In the case of an individual with benefits under a group health plan or group or individual health insurance coverage offered by a health insurance issuer and with respect to a health care provider or facility that has a contractual relationship with such plan or such issuer (as applicable) for furnishing items and services under such plan or such coverage, if, while such individual is a continuing care patient (as defined in subsection (b)) with respect to such provider or facility—

(A) such contractual relationship is terminated (as defined in subsection (b));

(B) benefits provided under such plan or such health insurance coverage with respect to such provider or facility are terminated because of a change in the terms of the participation of such provider or facility in such plan or coverage; or

(C) a contract between such group health plan and a health insurance issuer offering health insurance coverage in connection with such plan is terminated, resulting in a loss of benefits provided under such plan with respect to such provider or facility;

the plan or issuer, respectively, shall meet the requirements of paragraph (2) with respect to such individual.

(2) Requirements

The requirements of this paragraph are that the plan or issuer—

(A) notify each individual enrolled under such plan or coverage who is a continuing care patient with respect to a provider or facility at the time of a termination described in paragraph (1) affecting such provider or facility on a timely basis of such termination and such individual's right to elect continued transitional care from such provider or facility under this section;

(B) provide such individual with an opportunity to notify the plan or issuer of the individual's need for transitional care; and

(C) permit the patient to elect to continue to have benefits provided under such plan or such coverage, under the same terms and conditions as would have applied and with respect to such items and services as would have been covered under such plan or coverage had such termination not occurred, with respect to the course of treatment furnished by such provider or facility relating to such individual's status as a continuing care patient during the period beginning on the date on which the notice under subparagraph (A) is provided and ending on the earlier of—

(i) the 90-day period beginning on such date; or

(ii) the date on which such individual is no longer a continuing care patient with respect to such provider or facility.

(b) Definitions

In this section:

(1) Continuing care patient

The term "continuing care patient" means an individual who, with respect to a provider or facility—

(A) is undergoing a course of treatment for a serious and complex condition from the provider or facility;

(B) is undergoing a course of institutional or inpatient care from the provider or facility;

(C) is scheduled to undergo nonelective surgery from the provider, including receipt of postoperative care from such provider or facility with respect to such a surgery;

(D) is pregnant and undergoing a course of treatment for the pregnancy from the provider or facility; or

(E) is or was determined to be terminally ill (as determined under section 1395x(dd)(3)(A) of this title) and is receiving treatment for such illness from such provider or facility.

(2) Serious and complex condition

The term "serious and complex condition" means, with respect to a participant, beneficiary, or enrollee under a group health plan or group or individual health insurance coverage—

(A) in the case of an acute illness, a condition that is serious enough to require specialized medical treatment to avoid the reasonable possibility of death or permanent harm; or

(B) in the case of a chronic illness or condition, a condition that is— [1]

(i) is life-threatening, degenerative, potentially disabling, or congenital; and

(ii) requires specialized medical care over a prolonged period of time.

(3) Terminated

The term "terminated" includes, with respect to a contract, the expiration or nonrenewal of the contract, but does not include a termination of the contract for failure to meet applicable quality standards or for fraud.

(July 1, 1944, ch. 373, title XXVII, §2799A–3, as added Pub. L. 116–260, div. BB, title I, §113(a), Dec. 27, 2020, 134 Stat. 2868.)

STATUTORY NOTES AND RELATED SUBSIDIARIES

EFFECTIVE DATE

Section applicable with respect to plan years beginning on or after Jan. 1, 2022, see section 113(e) of div. BB of Pub. L. 116–260, set out as a note under section 9818 of Title 26, Internal Revenue Code.

[1] So in original. Probably should be "a condition that—".

§300gg–114. Maintenance of price comparison tool

A group health plan or a health insurance issuer offering group or individual health insurance coverage shall offer price comparison guidance by telephone and make available on the Internet website of the plan or issuer a price comparison tool that (to the extent practicable) allows an individual enrolled under such plan or coverage, with respect to such plan year, such geographic region, and participating providers with respect to such plan or coverage, to compare the amount of cost-sharing that the individual would be responsible for paying under such plan or coverage with respect to the furnishing of a specific item or service by any such provider.

(July 1, 1944, ch. 373, title XXVII, §2799A–4, as added Pub. L. 116–260, div. BB, title I, §114(a), Dec. 27, 2020, 134 Stat. 2874.)

STATUTORY NOTES AND RELATED SUBSIDIARIES

EFFECTIVE DATE

Section applicable with respect to plan years beginning on or after Jan. 1, 2022, see section 114(d) of div. BB of Pub. L. 116–260, set out as a note under section 9819 of Title 26, Internal Revenue Code.

§300gg–115. Protecting patients and improving the accuracy of provider directory information

(a) Provider directory information requirements

(1) In general

For plan years beginning on or after January 1, 2022, each group health plan and health insurance issuer offering group or individual health insurance coverage shall—

(A) establish the verification process described in paragraph (2);

(B) establish the response protocol described in paragraph (3);

(C) establish the database described in paragraph (4); and

(D) include in any directory (other than the database described in subparagraph (C)) containing provider directory information with respect to such plan or such coverage the information described in paragraph (5).

(2) Verification process

The verification process described in this paragraph is, with respect to a group health plan or a health insurance issuer offering group or individual health insurance coverage, a process—

(A) under which, not less frequently than once every 90 days, such plan or such issuer (as applicable) verifies and updates the provider directory information included on the database described in paragraph (4) of such plan or issuer of each health care provider and health care facility included in such database;

(B) that establishes a procedure for the removal of such a provider or facility with respect to which such plan or issuer has been unable to verify such information during a period specified by the plan or issuer; and

(C) that provides for the update of such database within 2 business days of such plan or issuer receiving from such a provider or facility information pursuant to section 300gg–139 of this title.

(3) Response protocol

The response protocol described in this paragraph is, in the case of an individual enrolled under a group health plan or group or individual health insurance coverage offered by a health insurance issuer who requests information through a telephone call or electronic, web-based, or Internet-based means on whether a health care provider or health care facility has a contractual relationship to furnish items and services under such plan or such coverage, a protocol under which such plan or such issuer (as applicable), in the case such request is made through a telephone call—

(A) responds to such individual as soon as practicable and in no case later than 1 business day after such call is received, through a written electronic or print (as requested by such individual) communication; and

(B) retains such communication in such individual's file for at least 2 years following such response.

(4) Database

The database described in this paragraph is, with respect to a group health plan or health insurance issuer offering group or individual health insurance coverage, a database on the public website of such plan or issuer that contains—

(A) a list of each health care provider and health care facility with which such plan or such issuer has a direct or indirect contractual relationship for furnishing items and services under such plan or such coverage; and

(B) provider directory information with respect to each such provider and facility.

(5) Information

The information described in this paragraph is, with respect to a print directory containing provider directory information with respect to a group health plan or individual or group health insurance coverage offered by a health insurance issuer, a notification that such information contained in such directory was accurate as of the date of publication of such directory and that an individual enrolled under such plan or such coverage should consult the database described in

paragraph (4) with respect to such plan or such coverage or contact such plan or the issuer of such coverage to obtain the most current provider directory information with respect to such plan or such coverage.

(6) Definition

For purposes of this subsection, the term "provider directory information" includes, with respect to a group health plan and a health insurance issuer offering group or individual health insurance coverage, the name, address, specialty, telephone number, and digital contact information of each health care provider or health care facility with which such plan or such issuer has a contractual relationship for furnishing items and services under such plan or such coverage.

(7) Rule of construction

Nothing in this section shall be construed to preempt any provision of State law relating to health care provider directories.

(b) Cost-sharing for services provided based on reliance on incorrect provider network information

(1) In general

For plan years beginning on or after January 1, 2022, in the case of an item or service furnished to a participant, beneficiary, or enrollee of a group health plan or group or individual health insurance coverage offered by a health insurance issuer by a nonparticipating provider or a nonparticipating facility, if such item or service would otherwise be covered under such plan or coverage if furnished by a participating provider or participating facility and if either of the criteria described in paragraph (2) applies with respect to such participant, beneficiary, or enrollee and item or service, the plan or coverage—

(A) shall not impose on such participant, beneficiary, or enrollee a cost-sharing amount for such item or service so furnished that is greater than the cost-sharing amount that would apply under such plan or coverage had such item or service been furnished by a participating provider; and

(B) shall apply the deductible or out-of-pocket maximum, if any, that would apply if such services were furnished by a participating provider or a participating facility.

(2) Criteria described

For purposes of paragraph (1), the criteria described in this paragraph, with respect to an item or service furnished to a participant, beneficiary, or enrollee of a group health plan or group or individual health insurance coverage offered by a health insurance issuer by a nonparticipating provider or a nonparticipating facility, are the following:

(A) The participant, beneficiary, or enrollee received through a database, provider directory, or response protocol described in subsection (a) information with respect to such item and service to be furnished and such information provided that the provider was a participating provider or facility was a participating facility, with respect to the plan for furnishing such item or service.

(B) The information was not provided, in accordance with subsection (a), to the participant, beneficiary, or enrollee and the participant, beneficiary, or enrollee requested through the response protocol described in subsection (a)(3) of the plan or coverage information on whether the provider was a participating provider or facility was a participating facility with respect to the plan for furnishing such item or service and was informed through such protocol that the provider was such a participating provider or facility was such a participating facility.

(c) Disclosure on patient protections against balance billing

For plan years beginning on or after January 1, 2022, each group health plan and health insurance issuer offering group or individual health insurance coverage shall make publicly available, post on a public website of such plan or issuer, and include on each explanation of benefits for an item or service with respect to which the requirements under section 300gg–111 of this title applies—

(1) information in plain language on—

(A) the requirements and prohibitions applied under sections 300gg–131 and 300gg–132 of this title (relating to prohibitions on balance billing in certain circumstances);

(B) if provided for under applicable State law, any other requirements on providers and facilities regarding the amounts such providers and facilities may, with respect to an item or service, charge a participant, beneficiary, or enrollee of such plan or coverage with respect to which such a provider or facility does not have a contractual relationship for furnishing such item or service under the plan or coverage after receiving payment from the plan or coverage for such item or service and any applicable cost sharing payment from such participant, beneficiary, or enrollee; and

(C) the requirements applied under section 300gg–111 of this title; and

(2) information on contacting appropriate State and Federal agencies in the case that an individual believes that such a provider or facility has violated any requirement described in paragraph (1) with respect to such individual.

(July 1, 1944, ch. 373, title XXVII, §2799A–5, as added Pub. L. 116–260, div. BB, title I, §116(a), Dec. 27, 2020, 134 Stat. 2878.)

§300gg–117. Other patient protections

(a) Choice of health care professional

If a group health plan, or a health insurance issuer offering group or individual health insurance coverage, requires or provides for designation by a participant, beneficiary, or enrollee of a participating primary care provider, then the plan or issuer shall permit each participant, beneficiary, and enrollee to designate any participating primary care provider who is available to accept such individual.

(b) Access to pediatric care

(1) Pediatric care

In the case of a person who has a child who is a participant, beneficiary, or enrollee under a group health plan, or group or individual health insurance coverage offered by a health insurance issuer, if the plan or issuer requires or provides for the designation of a participating primary care provider for the child, the plan or issuer shall permit such person to designate a physician (allopathic or osteopathic) who specializes in pediatrics as the child's primary care provider if such provider participates in the network of the plan or issuer.

(2) Construction

Nothing in paragraph (1) shall be construed to waive any exclusions of coverage under the terms and conditions of the plan or health insurance coverage with respect to coverage of pediatric care.

(c) Patient access to obstetrical and gynecological care

(1) General rights

(A) Direct access

A group health plan, or health insurance issuer offering group or individual health insurance coverage, described in paragraph (2) may not require authorization or referral by the plan, issuer, or any person (including a primary care provider described in paragraph (2)(B)) in the case of a female participant, beneficiary, or enrollee who seeks coverage for obstetrical or gynecological care provided by a participating health care professional who specializes in obstetrics or gynecology. Such professional shall agree to otherwise adhere to such plan's or issuer's policies and procedures, including procedures regarding referrals and obtaining prior authorization and providing services pursuant to a treatment plan (if any) approved by the plan or issuer.

(B) Obstetrical and gynecological care

A group health plan or health insurance issuer described in paragraph (2) shall treat the provision of obstetrical and gynecological care, and the ordering of related obstetrical and gynecological items and services, pursuant to the direct access described under subparagraph (A), by a participating health care professional who specializes in obstetrics or gynecology as the authorization of the primary care provider.

(2) Application of paragraph

A group health plan, or health insurance issuer offering group or individual health insurance coverage, described in this paragraph is a group health plan or health insurance coverage that—

(A) provides coverage for obstetric or gynecologic care; and

(B) requires the designation by a participant, beneficiary, or enrollee of a participating primary care provider.

(3) Construction

Nothing in paragraph (1) shall be construed to—

(A) waive any exclusions of coverage under the terms and conditions of the plan or health insurance coverage with respect to coverage of obstetrical or gynecological care; or

(B) preclude the group health plan or health insurance issuer involved from requiring that the obstetrical or gynecological provider notify the primary care health care professional or the plan or issuer of treatment decisions.

(July 1, 1944, ch. 373, title XXVII, §2799A–7, as added Pub. L. 116–260, div. BB, title I, §102(a)(2), Dec. 27, 2020, 134 Stat. 2770.)

STATUTORY NOTES AND RELATED SUBSIDIARIES

EFFECTIVE DATE

Section applicable with respect to plan years beginning on or after Jan. 1, 2022, see section 102(e) of Pub. L. 116–260, set out as an Effective Date of 2020 Amendment note under section 8902 of Title 5, Government Organization and Employees.

§300gg–118. Air ambulance report requirements

(a) In general

Each group health plan and health insurance issuer offering group or individual health insurance coverage shall submit to the Secretary, jointly with the Secretary of Labor and the Secretary of the Treasury—

(1) not later than the date that is 90 days after the last day of the first calendar year beginning on or after the date on which a final rule is promulgated pursuant to the rulemaking described in section 106(d) of the No Surprises Act, the information described in subsection (b) with respect to such plan year; and

(2) not later than the date that is 90 days after the last day of the calendar year immediately succeeding the plan year described in paragraph (1), such information with respect to such immediately succeeding plan year.

(b) Information described

For purposes of subsection (a), information described in this subsection, with respect to a group health plan or a health insurance issuer offering group or individual health insurance coverage, is each of the following:

(1) Claims data for air ambulance services furnished by providers of such services, disaggregated by each of the following factors:

(A) Whether such services were furnished on an emergent or nonemergent basis.

(B) Whether the provider of such services is part of a hospital-owned or sponsored program,

municipality-sponsored program, hospital independent partnership (hybrid) program, independent program, or tribally operated program in Alaska.

(C) Whether the transport in which the services were furnished originated in a rural or urban area.

(D) The type of aircraft (such as rotor transport or fixed wing transport) used to furnish such services.

(E) Whether the provider of such services has a contract with the plan or issuer, as applicable, to furnish such services under the plan or coverage, respectively.

(2) Such other information regarding providers of air ambulance services as the Secretary may specify.

(July 1, 1944, ch. 373, title XXVII, §2799A–8, as added Pub. L. 116–260, div. BB, title I, §106(b)(1), Dec. 27, 2020, 134 Stat. 2852.)

EDITORIAL NOTES

REFERENCES IN TEXT

Section 106(d) of the No Surprises Act, referred to in subsec. (a)(1), is section 106(d) of div. BB of Pub. L. 116–260, which is set out as a note below.

STATUTORY NOTES AND RELATED SUBSIDIARIES

REPORTING REQUIREMENTS REGARDING AIR AMBULANCE SERVICES

Pub. L. 116–260, div. BB, title I, §106, Dec. 27, 2020, 134 Stat. 2851, provided that:

"(a) REPORTING REQUIREMENTS FOR PROVIDERS OF AIR AMBULANCE SERVICES.—

"(1) IN GENERAL.—A provider of air ambulance services shall submit to the Secretary of Health and Human Services and the Secretary of Transportation—

"(A) not later than the date that is 90 days after the last day of the first calendar year beginning on or after the date on which a final rule is promulgated pursuant to the rulemaking described in subsection (d), the information described in paragraph (2) with respect to such plan year; and

"(B) not later than the date that is 90 days after the last day of the plan year immediately succeeding the plan year described in subparagraph (A), such information with respect to such immediately succeeding plan year.

"(2) INFORMATION DESCRIBED.—For purposes of paragraph (1), information described in this paragraph, with respect to a provider of air ambulance services, is each of the following:

"(A) Cost data, as determined appropriate by the Secretary of Health and Human Services, in consultation with the Secretary of Transportation, for air ambulance services furnished by such provider, separated to the maximum extent possible by air transportation costs associated with furnishing such air ambulance services and costs of medical services and supplies associated with furnishing such air ambulance services.

"(B) The number and location of all air ambulance bases operated by such provider.

"(C) The number and type of aircraft operated by such provider.

"(D) The number of air ambulance transports, disaggregated by payor mix, including—

"(i)(I) group health plans;

"(II) health insurance issuers; and

"(III) State and Federal Government payors; and

"(ii) uninsured individuals.

"(E) The number of claims of such provider that have been denied payment by a group health plan or health insurance issuer and the reasons for any such denials.

"(F) The number of emergency and nonemergency air ambulance transports, disaggregated by air ambulance base and type of aircraft.

"(G) Such other information regarding air ambulance services as the Secretary of Health and Human Services may specify.

"(b) REPORTING REQUIREMENTS FOR GROUP HEALTH PLANS AND HEALTH INSURANCE ISSUERS.—

"(1) PHSA.—[Enacted this section.]

"(2) ERISA.—

"(A) IN GENERAL.—[Enacted section 1185l of Title 29, Labor.]

"(B) CLERICAL AMENDMENT.—[Amended table of contents of the Employee Retirement Income Security Act of 1974.]

"(3) IRC.—

"(A) IN GENERAL.—[Enacted section 9823 of Title 26, Internal Revenue Code.]

"(B) CLERICAL AMENDMENT.—[Amended analysis preceding section 9811 of Title 26, Internal Revenue Code.]

"(c) PUBLICATION OF COMPREHENSIVE REPORT.—

"(1) IN GENERAL.—Not later than the date that is one year after the date described in subsection (a)(2) of section 2799A–8 of the Public Health Service Act [42 U.S.C. 300gg–118], of section 723 of the Employee Retirement Income Security Act of 1974 [29 U.S.C. 1185l], and of section 9823 of the Internal Revenue Code of 1986 [26 U.S.C. 9823], as such sections are added by subsection (b), the Secretary of Health and Human Services, in consultation with the Secretary of Transportation (referred to in this section as the 'Secretaries'), shall develop, and make publicly available (subject to paragraph (3)), a comprehensive report summarizing the information submitted under subsection (a) and the amendments made by subsection (b) and including each of the following:

"(A) The percentage of providers of air ambulance services that are part of a hospital-owned or sponsored program, municipality-sponsored program, hospital-independent partnership (hybrid) program, or independent program.

"(B) An assessment of the extent of competition among providers of air ambulance services on the basis of price and services offered, and any changes in such competition over time.

"(C) An assessment of the average charges for air ambulance services, amounts paid by group health plans and health insurance issuers offering group or individual health insurance coverage to providers of air ambulance services for furnishing such services, and amounts paid out-of-pocket by consumers, and any changes in such amounts paid over time.

"(D) An assessment of the presence of air ambulance bases in, or with the capability to serve, rural areas, and the relative growth in air ambulance bases in rural and urban areas over time.

"(E) Any evidence of gaps in rural access to providers of air ambulance services.

"(F) The percentage of providers of air ambulance services that have contracts with group health plans or health insurance issuers offering group or individual health insurance coverage to furnish such services under such plans or coverage, respectively.

"(G) An assessment of whether there are instances of unfair, deceptive, or predatory practices by providers of air ambulance services in collecting payments from patients to whom such services are furnished, such as referral of such patients to collections, lawsuits, and liens or wage garnishment actions.

"(H) An assessment of whether there are, within the air ambulance industry, instances of unreasonable industry concentration, excessive market domination, or other conditions that would allow at least one provider of air ambulance services to unreasonably increase prices or exclude competition in air ambulance services in a given geographic region.

"(I) An assessment of the frequency of patient balance billing, patient referrals to collections, lawsuits to collect balance bills, and liens or wage garnishment actions by providers of air ambulance services as part of a collections process across hospital-owned or sponsored programs, municipality-sponsored programs, hospital-independent partnership (hybrid) programs, tribally operated programs in Alaska, or independent programs, providers of air ambulance services operated by public agencies (such as a State or county health department), and other independent providers of air ambulance services.

"(J) An assessment of the frequency of claims appeals made by providers of air ambulance services to group health plans or health insurance issuers offering group or individual health insurance coverage with respect to air ambulance services furnished to enrollees of such plans or coverage, respectively.

"(K) Any other cost, quality, or other data relating to air ambulance services or the air ambulance industry, as determined necessary and appropriate by the Secretaries.

"(2) OTHER SOURCES OF INFORMATION.—The Secretaries may incorporate information from independent experts or third-party sources in developing the comprehensive report required under paragraph (1).

"(3) PROTECTION OF PROPRIETARY INFORMATION.—The Secretaries may not make publicly available under this subsection any proprietary information.

"(d) RULEMAKING.—Not later than the date that is one year after the date of the enactment of this Act [Dec. 27, 2020], the Secretary of Health and Human Services, in consultation with the Secretary of Transportation, shall, through notice and comment rulemaking, specify the form and manner in which reports described in subsection (a) and in the amendments made by subsection (b) shall be submitted to such Secretaries, taking into consideration (as applicable and to the extent feasible) any recommendations included in the report submitted by the Advisory Committee on Air Ambulance and Patient Billing under section 418(e) of the FAA Reauthorization Act of 2018 (Public Law 115–254; 49 U.S.C. 42301 note prec.).

"(e) CIVIL MONEY PENALTIES.—

"(1) IN GENERAL.—Subject to paragraph (2), a provider of air ambulance services who fails to submit all information required under subsection (a)(2) by the date described in subparagraph (A) or (B) of subsection (a)(1), as applicable, shall be subject to a civil money penalty of not more than $10,000.

"(2) EXCEPTION.—In the case of a provider of air ambulance services that submits only some of the information required under subsection (a)(2) by the date described in subparagraph (A) or (B) of subsection (a)(1), as applicable, the Secretary of Health and Human Services may waive the civil money penalty imposed under paragraph (1) if such provider demonstrates a good faith effort (as defined by the Secretary pursuant to regulation) in working with the Secretary to submit the remaining information required under subsection (a)(2).

"(3) PROCEDURE.—The provisions of section 1128A of the Social Security Act (42 U.S.C. 1320a–7a), other than subsections (a) and (b) and the first sentence of subsection (c)(1), shall apply to civil money penalties under this subsection in the same manner as such provisions apply to a penalty or proceeding under such section.

"(f) UNFAIR AND DECEPTIVE PRACTICES AND UNFAIR METHODS OF COMPETITION.—The Secretary of Transportation may use any information submitted under subsection (a) in determining whether a provider of air ambulance services has violated section 41712(a) of title 49, United States Code.

"(g) ADVISORY COMMITTEE ON AIR AMBULANCE QUALITY AND PATIENT SAFETY.—

"(1) ESTABLISHMENT.—Not later than the date that is 60 days after the date of the enactment of this Act [Dec. 27, 2020], the Secretary of Health and Human Services and the Secretary of Transportation, shall establish an Advisory Committee on Air Ambulance Quality and Patient Safety (referred to in this subsection as the 'Committee') for the purpose of reviewing options to establish quality, patient safety, and clinical capability standards for each clinical capability level of air ambulances.

"(2) MEMBERSHIP.—The Committee shall be composed of the following members:

"(A) The Secretary of Health and Human Services, or a designee of the Secretary, who shall serve as the Chair of the Committee.

"(B) The Secretary of Transportation, or a designee of the Secretary.

"(C) One representative, to be appointed by the Secretary of Health and Human Services, of each of the following:

"(i) State health insurance regulators.

"(ii) Health care providers.

"(iii) Group health plans and health insurance issuers offering group or individual health insurance coverage.

"(iv) Patient advocacy groups.

"(v) Accrediting bodies with experience in quality measures.

"(D) Three representatives of the air ambulance industry, to be appointed by the Secretary of Transportation.

"(E) Additional three representatives not covered under subparagraphs (A) through (D), as determined necessary and appropriate by the Secretary of Health and Human Services and Secretary of Transportation.

"(3) FIRST MEETING.—Not later than the date that is 90 days after the date of the enactment of this Act, the Committee shall hold its first meeting.

"(4) DUTIES.—The Committee shall study and make recommendations, as appropriate, to Congress regarding each of the following with respect to air ambulance services:

"(A) Qualifications of different clinical capability levels and tiering of such levels.

"(B) Patient safety and quality standards.

"(C) Options for improving service reliability during poor weather, night conditions, or other adverse conditions.

"(D) Differences between air ambulance vehicle types, services, and technologies, and other flight capability standards, and the impact of such differences on patient safety.

"(E) Clinical triage criteria for air ambulances.

"(5) REPORT.—Not later than the date that is 180 days after the date of the first meeting of the Committee, the Committee, in consultation with relevant experts and stakeholders, as appropriate, shall develop and make publicly available a report on any recommendations submitted to Congress under paragraph (4). The Committee may update such report, as determined appropriate by the Committee.

"(h) DEFINITIONS.—In this section, the terms 'group health plan', 'health insurance coverage', 'individual health insurance coverage', 'group health insurance coverage', and 'health insurance issuer' have the meanings given such terms in section 2791 of the Public Health Service Act (42 U.S.C. 300gg–91)."

§300gg–119. Increasing transparency by removing gag clauses on price and quality information

(a) [1] Increasing price and quality transparency for plan sponsors and group and individual market consumers

(1) Group health plans

A group health plan or health insurance issuer offering group health insurance coverage may not enter into an agreement with a health care provider, network or association of providers, third-party administrator, or other service provider offering access to a network of providers that would directly or indirectly restrict a group health plan or health insurance issuer offering such coverage from—

(A) providing provider-specific cost or quality of care information or data, through a consumer engagement tool or any other means, to referring providers, the plan sponsor, enrollees, or individuals eligible to become enrollees of the plan or coverage;

(B) electronically accessing de-identified claims and encounter information or data for each enrollee in the plan or coverage, upon request and consistent with the privacy regulations promulgated pursuant to section 264(c) of the Health Insurance Portability and Accountability Act of 1996, the amendments made by the Genetic Information Nondiscrimination Act of 2008, and the Americans with Disabilities Act of 1990 [42 U.S.C. 12101 et seq.], including, on a per claim basis—

(i) financial information, such as the allowed amount, or any other claim-related financial obligations included in the provider contract;

(ii) provider information, including name and clinical designation;

(iii) service codes; or

(iv) any other data element included in claim or encounter transactions; or

(C) sharing information or data described in subparagraph (A) or (B), or directing that such data be shared, with a business associate as defined in section 160.103 of title 45, Code of Federal Regulations (or successor regulations), consistent with the privacy regulations promulgated pursuant to section 264(c) of the Health Insurance Portability and Accountability Act of 1996, the amendments made by the Genetic Information Nondiscrimination Act of 2008, and the Americans with Disabilities Act of 1990 [42 U.S.C. 12101 et seq.].

(2) Individual health insurance coverage

A health insurance issuer offering individual health insurance coverage may not enter into an agreement with a health care provider, network or association of providers, or other service provider offering access to a network of providers that would directly or indirectly restrict the health insurance issuer from—

(A) providing provider-specific price or quality of care information, through a consumer engagement tool or any other means, to referring providers, enrollees, or individuals eligible to become enrollees of the plan or coverage; or

(B) sharing, for plan design, plan administration, and plan, financial, legal, and quality improvement activities, data described in subparagraph (A) with a business associate as defined in section 160.103 of title 45, Code of Federal Regulations (or successor regulations), consistent

with the privacy regulations promulgated pursuant to section 264(c) of the Health Insurance Portability and Accountability Act of 1996, the amendments made by the Genetic Information Nondiscrimination Act of 2008, and the Americans with Disabilities Act of 1990 [42 U.S.C. 12101 et seq.].

(3) Clarification regarding public disclosure of information

Nothing in paragraph (1)(A) or (2)(A) prevents a health care provider, network or association of providers, or other service provider from placing reasonable restrictions on the public disclosure of the information described in such paragraphs (1) and (2).

(4) Attestation

A group health plan or a health insurance issuer offering group or individual health insurance coverage shall annually submit to the Secretary an attestation that such plan or issuer of such coverage is in compliance with the requirements of this subsection.

(5) Rules of construction

Nothing in this section shall be construed to modify or eliminate existing privacy protections and standards under State and Federal law. Nothing in this subsection shall be construed to otherwise limit access by a group health plan, plan sponsor, or health insurance issuer to data as permitted under the privacy regulations promulgated pursuant to section 264(c) of the Health Insurance Portability and Accountability Act of 1996, the amendments made by the Genetic Information Nondiscrimination Act of 2008, and the Americans with Disabilities Act of 1990 [42 U.S.C. 12101 et seq.].

(July 1, 1944, ch. 373, title XXVII, §2799A–9, as added Pub. L. 116–260, div. BB, title II, §201(a), Dec. 27, 2020, 134 Stat. 2890.)

EDITORIAL NOTES

REFERENCES IN TEXT

Section 264(c) of the Health Insurance Portability and Accountability Act of 1996, referred to in subsec. (a)(1)(B), (C), (2)(B), (5), is section 264 of Pub. L. 104–191, which is set out as a note under section 1320d–2 of this title.

The Genetic Information Nondiscrimination Act of 2008, referred to in subsec. (a)(1)(B), (C), (2)(B), (5), is Pub. L. 110–233, May 21, 2008, 122 Stat. 881. For complete classification of this Act to the Code, see Short Title note set out under section 2000ff of this title and Tables.

The Americans with Disabilities Act of 1990, referred to in subsec. (a)(1)(B), (C), (2)(B), (5), is Pub. L. 101–336, July 26, 1990, 104 Stat. 327, which is classified principally to chapter 126 (§12101 et seq.) of this title. For complete classification of this Act to the Code, see Short Title note set out under section 12101 of this title and Tables.

[1] *So in original. There is no subsec. (b).*

§300gg–120. Reporting on pharmacy benefits and drug costs

(a) In general

Not later than 1 year after December 27, 2020, and not later than June 1 of each year thereafter, a group health plan or health insurance issuer offering group or individual health insurance coverage (except for a church plan) shall submit to the Secretary, the Secretary of Labor, and the Secretary of the Treasury the following information with respect to the health plan or coverage in the previous plan year:

(1) The beginning and end dates of the plan year.

(2) The number of enrollees.

(3) Each State in which the plan or coverage is offered.

(4) The 50 brand prescription drugs most frequently dispensed by pharmacies for claims paid by

the plan or coverage, and the total number of paid claims for each such drug.

(5) The 50 most costly prescription drugs with respect to the plan or coverage by total annual spending, and the annual amount spent by the plan or coverage for each such drug.

(6) The 50 prescription drugs with the greatest increase in plan expenditures over the plan year preceding the plan year that is the subject of the report, and, for each such drug, the change in amounts expended by the plan or coverage in each such plan year.

(7) Total spending on health care services by such group health plan or health insurance coverage, broken down by—

(A) the type of costs, including—

(i) hospital costs;

(ii) health care provider and clinical service costs, for primary care and specialty care separately;

(iii) costs for prescription drugs; and

(iv) other medical costs, including wellness services; and

(B) spending on prescription drugs by—

(i) the health plan or coverage; and

(ii) the enrollees.

(8) The average monthly premium—

(A) paid by employers on behalf of enrollees, as applicable; and

(B) paid by enrollees.

(9) Any impact on premiums by rebates, fees, and any other remuneration paid by drug manufacturers to the plan or coverage or its administrators or service providers, with respect to prescription drugs prescribed to enrollees in the plan or coverage, including—

(A) the amounts so paid for each therapeutic class of drugs; and

(B) the amounts so paid for each of the 25 drugs that yielded the highest amount of rebates and other remuneration under the plan or coverage from drug manufacturers during the plan year.

(10) Any reduction in premiums and out-of-pocket costs associated with rebates, fees, or other remuneration described in paragraph (9).

(b) Report

Not later than 18 months after the date on which the first report is required under subsection (a) and biannually thereafter, the Secretary, acting through the Assistant Secretary of Planning and Evaluation and in coordination with the Inspector General of the Department of Health and Human Services, shall make available on the internet website of the Department of Health and Human Services a report on prescription drug reimbursements under group health plans and group and individual health insurance coverage, prescription drug pricing trends, and the role of prescription drug costs in contributing to premium increases or decreases under such plans or coverage, aggregated in such a way as no drug or plan specific information will be made public.

(c) Privacy protections

No confidential or trade secret information submitted to the Secretary under subsection (a) shall be included in the report under subsection (b).

(July 1, 1944, ch. 373, title XXVII, §2799A–10, as added Pub. L. 116–260, div. BB, title II, §204(a), Dec. 27, 2020, 134 Stat. 2918.)

§300gg–121. Oversight of entities that provide pharmacy benefit management services

(a) In general

For plan years beginning on or after the date that is 30 months after February 3, 2026 (referred to in this subsection and subsection (b) as the "effective date"), a group health plan or a health insurance issuer offering group health insurance coverage, or an entity providing pharmacy benefit management services on behalf of such a plan or issuer, shall not enter into a contract, including an extension or renewal of a contract, entered into on or after the effective date, with an applicable entity unless such applicable entity agrees to—

(1) not limit or delay the disclosure of information to the group health plan (including such a plan offered through a health insurance issuer) in such a manner that prevents an entity providing pharmacy benefit management services on behalf of a group health plan or health insurance issuer offering group health insurance coverage from making the reports described in subsection (b); and

(2) provide the entity providing pharmacy benefit management services on behalf of a group health plan or health insurance issuer relevant information necessary to make the reports described in subsection (b).

(b) Reports

(1) In general

For plan years beginning on or after the effective date, in the case of any contract between a group health plan or a health insurance issuer offering group health insurance coverage offered in connection with such a plan and an entity providing pharmacy benefit management services on behalf of such plan or issuer, including an extension or renewal of such a contract, entered into on or after the effective date, the entity providing pharmacy benefit management services on behalf of such a group health plan or health insurance issuer, not less frequently than every 6 months (or, at the request of a group health plan, not less frequently than quarterly, and under the same conditions, terms, and cost of the semiannual report under this subsection), shall submit to the group health plan a report in accordance with this section. Each such report shall be made available to such group health plan in plain language, in a machine-readable format, and as the Secretary may determine, other formats. Each such report shall include the information described in paragraph (2).

(2) Information described

For purposes of paragraph (1), the information described in this paragraph is, with respect to drugs covered by a group health plan or group health insurance coverage offered by a health insurance issuer in connection with a group health plan during each reporting period—

(A) in the case of a group health plan that is offered by a specified large employer or that is a specified large plan, and is not offered as health insurance coverage, or in the case of health insurance coverage for which the election under paragraph (3) is made for the applicable reporting period—

(i) a list of drugs for which a claim was filed and, with respect to each such drug on such list—

(I) the contracted compensation paid by the group health plan or health insurance issuer for each covered drug (identified by the National Drug Code) to the entity providing pharmacy benefit management services or other applicable entity on behalf of the group health plan or health insurance issuer;

(II) the contracted compensation paid to the pharmacy, by any entity providing pharmacy benefit management services or other applicable entity on behalf of the group health plan or health insurance issuer, for each covered drug (identified by the National Drug Code);

(III) for each such claim, the difference between the amount paid under subclause (I) and the amount paid under subclause (II);

(IV) the proprietary name, established name or proper name, and the National Drug Code;

(V) for each claim for the drug (including original prescriptions and refills) and for each

dosage unit of the drug for which a claim was filed, the type of dispensing channel used to furnish the drug, including retail, mail order, or specialty pharmacy;

(VI) with respect to each drug dispensed, for each type of dispensing channel (including retail, mail order, or specialty pharmacy)—

(aa) whether such drug is a brand name drug or a generic drug, and—

(AA) in the case of a brand name drug, the wholesale acquisition cost, listed as cost per days supply and cost per dosage unit, on the date such drug was dispensed; and

(BB) in the case of a generic drug, the average wholesale price, listed as cost per days supply and cost per dosage unit, on the date such drug was dispensed; and

(bb) the total number of—

(AA) prescription claims (including original prescriptions and refills);

(BB) participants and beneficiaries for whom a claim for such drug was filed through the applicable dispensing channel;

(CC) dosage units and dosage units per fill of such drug; and

(DD) days supply of such drug per fill;

(VII) the net price per course of treatment or single fill, such as a 30-day supply or 90-day supply to the plan or coverage after rebates, fees, alternative discounts, or other remuneration received from applicable entities;

(VIII) the total amount of out-of-pocket spending by participants and beneficiaries on such drug, including spending through copayments, coinsurance, and deductibles, but not including any amounts spent by participants and beneficiaries on drugs not covered under the plan or coverage, or for which no claim is submitted under the plan or coverage;

(IX) the total net spending on the drug;

(X) the total amount received, or expected to be received, by the plan or issuer from any applicable entity in rebates, fees, alternative discounts, or other remuneration;

(XI) the total amount received, or expected to be received, by the entity providing pharmacy benefit management services, from applicable entities, in rebates, fees, alternative discounts, or other remuneration from such entities—

(aa) for claims incurred during the reporting period; and

(bb) that is related to utilization of such drug or spending on such drug; and

(XII) to the extent feasible, information on the total amount of remuneration for such drug, including copayment assistance dollars paid, copayment cards applied, or other discounts provided by each drug manufacturer (or entity administering copayment assistance on behalf of such drug manufacturer), to the participants and beneficiaries enrolled in such plan or coverage;

(ii) a list of each therapeutic class (as defined by the Secretary) for which a claim was filed under the group health plan or health insurance coverage during the reporting period, and, with respect to each such therapeutic class—

(I) the total gross spending on drugs in such class before rebates, price concessions, alternative discounts, or other remuneration from applicable entities;

(II) the net spending in such class after such rebates, price concessions, alternative discounts, or other remuneration from applicable entities;

(III) the total amount received, or expected to be received, by the entity providing pharmacy benefit management services, from applicable entities, in rebates, fees, alternative discounts, or other remuneration from such entities—

(aa) for claims incurred during the reporting period; and

(bb) that is related to utilization of drugs or drug spending;

(IV) the average net spending per 30-day supply and per 90-day supply by the plan or by

the issuer with respect to such coverage and its participants and beneficiaries, among all drugs within the therapeutic class for which a claim was filed during the reporting period;

(V) the number of participants and beneficiaries who filled a prescription for a drug in such class, including the National Drug Code for each such drug;

(VI) if applicable, a description of the formulary tiers and utilization mechanisms (such as prior authorization or step therapy) employed for drugs in that class; and

(VII) the total out-of-pocket spending under the plan or coverage by participants and beneficiaries, including spending through copayments, coinsurance, and deductibles, but not including any amounts spent by participants and beneficiaries on drugs not covered under the plan or coverage or for which no claim is submitted under the plan or coverage;

(iii) with respect to any drug for which gross spending under the group health plan or health insurance coverage exceeded $10,000 during the reporting period or, in the case that gross spending under the group health plan or coverage exceeded $10,000 during the reporting period with respect to fewer than 50 drugs, with respect to the 50 prescription drugs with the highest spending during the reporting period—

(I) a list of all other drugs in the same therapeutic class as such drug;

(II) if applicable, the rationale for the formulary placement of such drug in that therapeutic category or class, selected from a list of standard rationales established by the Secretary, in consultation with stakeholders; and

(III) any change in formulary placement compared to the prior plan year; and

(iv) in the case that such plan or issuer (or an entity providing pharmacy benefit management services on behalf of such plan or issuer) has an affiliated pharmacy or pharmacy under common ownership, including mandatory mail and specialty home delivery programs, retail and mail auto-refill programs, and cost sharing assistance incentives funded by an entity providing pharmacy benefit services—

(I) an explanation of any benefit design parameters that encourage or require participants and beneficiaries in the plan or coverage to fill prescriptions at mail order, specialty, or retail pharmacies;

(II) the percentage of total prescriptions dispensed by such pharmacies to participants or beneficiaries in such plan or coverage; and

(III) a list of all drugs dispensed by such pharmacies to participants or beneficiaries enrolled in such plan or coverage, and, with respect to each drug dispensed—

(aa) the amount charged, per dosage unit, per 30-day supply, or per 90-day supply (as applicable) to the plan or issuer, and to participants and beneficiaries;

(bb) the median amount charged to such plan or issuer, and the interquartile range of the costs, per dosage unit, per 30-day supply, and per 90-day supply, including amounts paid by the participants and beneficiaries, when the same drug is dispensed by other pharmacies that are not affiliated with or under common ownership with the entity and that are included in the pharmacy network of such plan or coverage;

(cc) the lowest cost per dosage unit, per 30-day supply and per 90-day supply, for each such drug, including amounts charged to the plan or coverage and to participants and beneficiaries, that is available from any pharmacy included in the network of such plan or coverage; and

(dd) the net acquisition cost per dosage unit, per 30-day supply, and per 90-day supply, if such drug is subject to a maximum price discount; and

(B) with respect to any group health plan, including group health insurance coverage offered in connection with such a plan, regardless of whether the plan or coverage is offered by a specified large employer or whether it is a specified large plan—

(i) a summary document for the group health plan that includes such information described in clauses (i) through (iv) of subparagraph (A), as specified by the Secretary through

guidance, program instruction, or otherwise (with no requirement of notice and comment rulemaking), that the Secretary determines useful to group health plans for purposes of selecting pharmacy benefit management services, such as an estimated net price to group health plan and participant or beneficiary, a cost per claim, the fee structure or reimbursement model, and estimated cost per participant or beneficiary;

(ii) a summary document for plans and issuers to provide to participants and beneficiaries, which shall be made available to participants or beneficiaries upon request to their group health plan (including in the case of group health insurance coverage offered in connection with such a plan), that—

(I) contains such information described in clauses (iii), (iv), (v), and (vi), as applicable, as specified by the Secretary through guidance, program instruction, or otherwise (with no requirement of notice and comment rulemaking) that the Secretary determines useful to participants or beneficiaries in better understanding the plan or coverage or benefits under such plan or coverage;

(II) contains only aggregate information; and

(III) states that participants and beneficiaries may request specific, claims-level information required to be furnished under subsection (c) from the group health plan or health insurance issuer; and

(iii) with respect to drugs covered by such plan or coverage during such reporting period—

(I) the total net spending by the plan or coverage for all such drugs;

(II) the total amount received, or expected to be received, by the plan or issuer from any applicable entity in rebates, fees, alternative discounts, or other remuneration; and

(III) to the extent feasible, information on the total amount of remuneration for such drugs, including copayment assistance dollars paid, copayment cards applied, or other discounts provided by each drug manufacturer (or entity administering copayment assistance on behalf of such drug manufacturer) to participants and beneficiaries;

(iv) amounts paid directly or indirectly in rebates, fees, or any other type of compensation (as defined in section 1108(b)(2)(B)(ii)(dd)(AA) of title 29) to brokerage firms, brokers, consultants, advisors, or any other individual or firm, for—

(I) the referral of the group health plan's or health insurance issuer's business to an entity providing pharmacy benefit management services, including the identity of the recipient of such amounts;

(II) consideration of the entity providing pharmacy benefit management services by the group health plan or health insurance issuer; or

(III) the retention of the entity by the group health plan or health insurance issuer;

(v) an explanation of any benefit design parameters that encourage or require participants and beneficiaries in such plan or coverage to fill prescriptions at mail order, specialty, or retail pharmacies that are affiliated with or under common ownership with the entity providing pharmacy benefit management services under such plan or coverage, including mandatory mail and specialty home delivery programs, retail and mail auto-refill programs, and cost-sharing assistance incentives directly or indirectly funded by such entity; and

(vi) total gross spending on all drugs under the plan or coverage during the reporting period.

(3) Opt-in for group health insurance coverage offered by a specified large employer or that is a specified large plan

In the case of group health insurance coverage offered in connection with a group health plan that is offered by a specified large employer or is a specified large plan, such group health plan may, on an annual basis, for plan years beginning on or after the date that is 30 months after February 3, 2026, elect to require an entity providing pharmacy benefit management services on behalf of the health insurance issuer to submit to such group health plan a report that includes all

of the information described in paragraph (2)(A), in addition to the information described in paragraph (2)(B).

(4) Privacy requirements

(A) In general

An entity providing pharmacy benefit management services on behalf of a group health plan or a health insurance issuer offering group health insurance coverage shall report information under paragraph (1) in a manner consistent with the privacy regulations promulgated under section 17932 of this title and consistent with the privacy regulations promulgated under the Health Insurance Portability and Accountability Act of 1996 in part 160 and subparts A and E of part 164 of title 45, Code of Federal Regulations (or successor regulations) (referred to in this paragraph as the "HIPAA privacy regulations") and shall restrict the use and disclosure of such information according to such privacy regulations and such HIPAA privacy regulations.

(B) Additional requirements

(i) In general

An entity providing pharmacy benefit management services on behalf of a group health plan or health insurance issuer offering group health insurance coverage that submits a report under paragraph (1) shall ensure that such report contains only summary health information, as defined in section 164.504(a) of title 45, Code of Federal Regulations (or successor regulations).

(ii) Restrictions

In carrying out this subsection, a group health plan shall comply with section 164.504(f) of title 45, Code of Federal Regulations (or a successor regulation), and a plan sponsor shall act in accordance with the terms of the agreement described in such section.

(C) Rule of construction

(i) Nothing in this section shall be construed to modify the requirements for the creation, receipt, maintenance, or transmission of protected health information under the HIPAA privacy regulations.

(ii) Nothing in this section shall be construed to affect the application of any Federal or State privacy or civil rights law, including the HIPAA privacy regulations, the Genetic Information Nondiscrimination Act of 2008 (Public Law 110–233) (including the amendments made by such Act), the Americans with Disabilities Act of 1990 (42 U.S.C. 12101 et seq.), section 794 of title 29, section 18116 of this title, title VI of the Civil Rights Act of 1964 (42 U.S.C. 2000d [1]), and title VII of the Civil Rights Act of 1964 (42 U.S.C. 2000e [1]).

(D) Written notice

Each plan year, group health plans, including with respect to group health insurance coverage offered in connection with a group health plan, shall provide to each participant or beneficiary written notice informing the participant or beneficiary of the requirement for entities providing pharmacy benefit management services on behalf of the group health plan or health insurance issuer offering group health insurance coverage to submit reports to group health plans under paragraph (1), as applicable, which may include incorporating such notification in plan documents provided to the participant or beneficiary, or providing individual notification.

(E) Limitation to business associates

A group health plan receiving a report under paragraph (1) may disclose such information only to the entity from which the report was received or to that entity's business associates as defined in section 160.103 of title 45, Code of Federal Regulations (or successor regulations) or as permitted by the HIPAA privacy regulations.

(F) Clarification regarding public disclosure of information

Nothing in this section shall prevent an entity providing pharmacy benefit management services on behalf of a group health plan or health insurance issuer offering group health insurance coverage, from placing reasonable restrictions on the public disclosure of the information contained in a report described in paragraph (1), except that such plan, issuer, or entity may not—

(i) restrict disclosure of such report to the Department of Health and Human Services, the Department of Labor, or the Department of the Treasury; or

(ii) prevent disclosure for the purposes of subsection (c), or any other public disclosure requirement under this section.

(G) Limited form of report

The Secretary shall define through rulemaking a limited form of the report under paragraph (1) required with respect to any group health plan established by a plan sponsor that is, or is affiliated with, a drug manufacturer, drug wholesaler, or other direct participant in the drug supply chain, in order to prevent anti-competitive behavior.

(5) Standard format and regulations

(A) In general

Not later than 18 months after February 3, 2026, the Secretary shall specify through rulemaking a standard format for entities providing pharmacy benefit management services on behalf of group health plans and health insurance issuers offering group health insurance coverage, to submit reports required under paragraph (1).

(B) Additional regulations

Not later than 18 months after February 3, 2026, the Secretary shall, through rulemaking, promulgate any other final regulations necessary to implement the requirements of this section. In promulgating such regulations, the Secretary shall, to the extent practicable, align the reporting requirements under this section with the reporting requirements under section 300gg–120 of this title.

(c) Requirement to provide information to participants or beneficiaries

A group health plan, including with respect to group health insurance coverage offered in connection with a group health plan, upon request of a participant or beneficiary, shall provide to such participant or beneficiary—

(1) the summary document described in subsection (b)(2)(B)(ii); and

(2) the information described in subsection (b)(2)(A)(i)(III) with respect to a claim made by or on behalf of such participant or beneficiary.

(d) Enforcement

(1) In general

The Secretary shall enforce this section. The enforcement authority under this subsection shall apply only with respect to group health plans (including group health insurance coverage offered in connection with such a plan) to which the requirements of subparts I and II of part A and part D apply in accordance with section 300gg–21 of this title, and with respect to entities providing pharmacy benefit management services on behalf of such plans and applicable entities providing services on behalf of such plans.

(2) Failure to provide information

A group health plan, a health insurance issuer offering group health insurance coverage, an entity providing pharmacy benefit management services on behalf of such a plan or issuer, or an applicable entity providing services on behalf of such a plan or issuer that violates subsection (a); an entity providing pharmacy benefit management services on behalf of such a plan or issuer that fails to provide the information required under subsection (b); or a group health plan that fails to

provide the information required under subsection (c), shall be subject to a civil monetary penalty in the amount of $10,000 for each day during which such violation continues or such information is not disclosed or reported.

(3) False information

A health insurance issuer, an entity providing pharmacy benefit management services, or a third party administrator providing services on behalf of such issuer offered by a health insurance issuer that knowingly provides false information under this section shall be subject to a civil monetary penalty in an amount not to exceed $100,000 for each item of false information. Such civil monetary penalty shall be in addition to other penalties as may be prescribed by law.

(4) Procedure

The provisions of section 1320a–7a of this title, other than subsections (a) and (b) and the first sentence of subsection (c)(1) of such section shall apply to civil monetary penalties under this subsection in the same manner as such provisions apply to a penalty or proceeding under such section.

(5) Waivers

The Secretary may waive penalties under paragraph (2), or extend the period of time for compliance with a requirement of this section, for an entity in violation of this section that has made a good-faith effort to comply with the requirements in this section.

(e) Rule of construction

Nothing in this section shall be construed to permit a health insurance issuer, group health plan, entity providing pharmacy benefit management services on behalf of a group health plan or health insurance issuer, or other entity to restrict disclosure to, or otherwise limit the access of, the Secretary to a report described in subsection (b)(1) or information related to compliance with subsections (a), (b), (c), or (d) by such issuer, plan, or entity.

(f) Definitions

In this section:

(1) Applicable entity

The term "applicable entity" means—

(A) an applicable group purchasing organization, drug manufacturer, distributor, wholesaler, rebate aggregator (or other purchasing entity designed to aggregate rebates), or associated third party;

(B) any subsidiary, parent, affiliate, or subcontractor of a group health plan, health insurance issuer, entity that provides pharmacy benefit management services on behalf of such a plan or issuer, or any entity described in subparagraph (A); or

(C) such other entity as the Secretary may specify through rulemaking.

(2) Applicable group purchasing organization

The term "applicable group purchasing organization" means a group purchasing organization that is affiliated with or under common ownership with an entity providing pharmacy benefit management services.

(3) Contracted compensation

The term "contracted compensation" means the sum of any ingredient cost and dispensing fee for a drug (inclusive of the out-of-pocket costs to the participant or beneficiary), or another analogous compensation structure that the Secretary may specify through regulations.

(4) Gross spending

The term "gross spending", with respect to prescription drug benefits under a group health plan or health insurance coverage, means the amount spent by a group health plan or health insurance issuer on prescription drug benefits, calculated before the application of rebates, fees, alternative discounts, or other remuneration.

(5) Net spending

The term "net spending", with respect to prescription drug benefits under a group health plan or health insurance coverage, means the amount spent by a group health plan or health insurance issuer on prescription drug benefits, calculated after the application of rebates, fees, alternative discounts, or other remuneration.

(6) Plan sponsor

The term "plan sponsor" has the meaning given such term in section 1002(16)(B) of title 29.

(7) Remuneration

The term "remuneration" has the meaning given such term by the Secretary through rulemaking, which shall be reevaluated by the Secretary every 5 years.

(8) Specified large employer

The term "specified large employer" means, in connection with a group health plan (including group health insurance coverage offered in connection with such a plan) established or maintained by a single employer, with respect to a calendar year or a plan year, as applicable, an employer who employed an average of at least 100 employees on business days during the preceding calendar year or plan year and who employs at least 1 employee on the first day of the calendar year or plan year.

(9) Specified large plan

The term "specified large plan" means a group health plan (including group health insurance coverage offered in connection with such a plan) established or maintained by a plan sponsor described in clause (ii) or (iii) of section 1002(16)(B) of title 29 that had an average of at least 100 participants on business days during the preceding calendar year or plan year, as applicable.

(10) Wholesale acquisition cost

The term "wholesale acquisition cost" has the meaning given such term in section 1395w–3a(c)(6)(B) of this title.

(July 1, 1944, ch. 373, title XXVII, §2799A–11, as added Pub. L. 119–75, div. J, title VII, §6701(a)(1), Feb. 3, 2026, 140 Stat. 703.)

EDITORIAL NOTES

REFERENCES IN TEXT

Section 1108(b)(2)(B)(ii)(dd)(AA) of title 29, referred to in subsec. (b)(2)(B)(iv), was in the original "section 408(b)(2)(B)(ii)(dd)(AA) of the Employee Retirement Income Security Act" and was translated as meaning section 408(b)(2)(B)(ii)(dd)(AA) of the Employee Retirement Income Security Act of 1974, to reflect the probable intent of Congress.

The Health Insurance Portability and Accountability Act of 1996, referred to in subsec. (b)(4)(A), is Pub. L. 104–191, Aug. 21, 1996, 110 Stat. 1936. For complete classification of this Act to the Code, see Short Title of 1996 Amendments note set out under section 201 of this title and Tables.

The Genetic Information Nondiscrimination Act of 2008, referred to in subsec. (b)(4)(C)(ii), is Pub. L. 110–233, May 21, 2008, 122 Stat. 881. For complete classification of this Act to the Code, see Short Title note set out under section 2000ff of this title and Tables.

The Americans with Disabilities Act of 1990, referred to in subsec. (b)(4)(C)(ii), is Pub. L. 101–336, July 26, 1990, 104 Stat. 327, which is classified principally to chapter 126 (§12101 et seq.) of this title. For complete classification of this Act to the Code, see Short Title note set out under section 12101 of this title and Tables.

The Civil Rights Act of 1964, referred to in subsec. (b)(4)(C)(ii), is Pub. L. 88–352, July 2, 1964, 78 Stat. 241. Title VI of the Act is classified generally to subchapter V (§2000d et seq.) of chapter 21 of this title. Title VII of the Act is classified generally to subchapter VI (§2000e et seq.) of chapter 21 of this title. For complete classification of this Act to the Code, see Short Title note set out under section 2000a of this title and Tables.

[1] *So in original. Probably should be followed by "et seq."*

PART E—HEALTH CARE PROVIDER REQUIREMENTS

STATUTORY NOTES AND RELATED SUBSIDIARIES

DEFINITIONS

For additional definitions applicable to this part, see section 300gg–111(a)(3) of this title.

§300gg–131. Balance billing in cases of emergency services

(a) In general

In the case of a participant, beneficiary, or enrollee with benefits under a group health plan or group or individual health insurance coverage offered by a health insurance issuer and who is furnished during a plan year beginning on or after January 1, 2022, emergency services (for which benefits are provided under the plan or coverage) with respect to an emergency medical condition with respect to a visit at an emergency department of a hospital or an independent freestanding emergency department—

(1) in the case that the hospital or independent freestanding emergency department is a nonparticipating emergency facility, the emergency department of a hospital or independent freestanding emergency department shall not bill, and shall not hold liable, the participant, beneficiary, or enrollee for a payment amount for such emergency services so furnished that is more than the cost-sharing requirement for such services (as determined in accordance with clauses (ii) and (iii) of section 300gg–111(a)(1)(C) of this title, of section 9816(a)(1)(C) of title 26, and of section 1185e(a)(1)(C) of title 29, as applicable); and

(2) in the case that such services are furnished by a nonparticipating provider, the health care provider shall not bill, and shall not hold liable, such participant, beneficiary, or enrollee for a payment amount for an emergency service furnished to such individual by such provider with respect to such emergency medical condition and visit for which the individual receives emergency services at the hospital or emergency department that is more than the cost-sharing requirement for such services furnished by the provider (as determined in accordance with clauses (ii) and (iii) of section 300gg–111(a)(1)(C) of this title, of section 9816(a)(1)(C) of title 26, and of section 1185e(a)(1)(C) of title 29, as applicable).

(b) Definition

In this section, the term "visit" shall have such meaning as applied to such term for purposes of section 300gg–111(b) of this title.

(July 1, 1944, ch. 373, title XXVII, §2799B–1, as added Pub. L. 116–260, div. BB, title I, §104(a), Dec. 27, 2020, 134 Stat. 2824.)

§300gg–132. Balance billing in cases of non-emergency services performed by nonparticipating providers at certain participating facilities

(a) In general

Subject to subsection (b), in the case of a participant, beneficiary, or enrollee with benefits under a group health plan or group or individual health insurance coverage offered by a health insurance issuer and who is furnished during a plan year beginning on or after January 1, 2022, items or services (other than emergency services to which section 300gg–131 of this title applies) for which benefits are provided under the plan or coverage at a participating health care facility by a nonparticipating provider, such provider shall not bill, and shall not hold liable, such participant, beneficiary, or enrollee for a payment amount for such an item or service furnished by such provider

with respect to a visit at such facility that is more than the cost-sharing requirement for such item or service (as determined in accordance with subparagraphs (A) and (B) of section 300gg–111(b)(1) of this title [1] of section 9816(b)(1) of title 26, and of section 1185e(b)(1) of title 29, as applicable).

(b) Exception

(1) In general

Subsection (a) shall not apply with respect to items or services (other than ancillary services described in paragraph (2)) furnished by a nonparticipating provider to a participant, beneficiary, or enrollee of a group health plan or group or individual health insurance coverage offered by a health insurance issuer, if the provider satisfies the notice and consent criteria of subsection (d).

(2) Ancillary services described

For purposes of paragraph (1), ancillary services described in this paragraph are, with respect to a participating health care facility—

(A) subject to paragraph (3), items and services related to emergency medicine, anesthesiology, pathology, radiology, and neonatology, whether or not provided by a physician or non-physician practitioner, and items and services provided by assistant surgeons, hospitalists, and intensivists;

(B) subject to paragraph (3), diagnostic services (including radiology and laboratory services);

(C) items and services provided by such other specialty practitioners, as the Secretary specifies through rulemaking; and

(D) items and services provided by a nonparticipating provider if there is no participating provider who can furnish such item or service at such facility.

(3) Exception

The Secretary may, through rulemaking, establish a list (and update such list periodically) of advanced diagnostic laboratory tests, which shall not be included as an ancillary service described in paragraph (2) and with respect to which subsection (a) would apply.

(c) Clarification

In the case of a nonparticipating provider that satisfies the notice and consent criteria of subsection (d) with respect to an item or service (referred to in this subsection as a "covered item or service"), such notice and consent criteria may not be construed as applying with respect to any item or service that is furnished as a result of unforeseen, urgent medical needs that arise at the time such covered item or service is furnished. For purposes of the previous sentence, a covered item or service shall not include an ancillary service described in subsection (b)(2).

(d) Notice and consent to be treated by a nonparticipating provider or nonparticipating facility

(1) In general

A nonparticipating provider or nonparticipating facility satisfies the notice and consent criteria of this subsection, with respect to items or services furnished by the provider or facility to a participant, beneficiary, or enrollee of a group health plan or group or individual health insurance coverage offered by a health insurance issuer, if the provider (or, if applicable, the participating health care facility on behalf of such provider) or nonparticipating facility—

(A) in the case that the participant, beneficiary, or enrollee makes an appointment to be furnished such items or services at least 72 hours prior to the date on which the individual is to be furnished such items or services, provides to the participant, beneficiary, or enrollee (or to an authorized representative of the participant, beneficiary, or enrollee) not later than 72 hours prior to the date on which the individual is furnished such items or services (or, in the case that the participant, beneficiary, or enrollee makes such an appointment within 72 hours of when such items or services are to be furnished, provides to the participant, beneficiary, or enrollee (or to an authorized representative of the participant, beneficiary, or enrollee) on such date the appointment is made), a written notice in paper or electronic form, as selected by the

participant, beneficiary, or enrollee, (and including electronic notification, as practicable) specified by the Secretary, not later than July 1, 2021, through guidance (which shall be updated as determined necessary by the Secretary) that—

(i) contains the information required under paragraph (2);

(ii) clearly states that consent to receive such items and services from such nonparticipating provider or nonparticipating facility is optional and that the participant, beneficiary, or enrollee may instead seek care from a participating provider or at a participating facility, with respect to such plan or coverage, as applicable, in which case the cost-sharing responsibility of the participant, beneficiary, or enrollee would not exceed such responsibility that would apply with respect to such an item or service that is furnished by a participating provider or participating facility, as applicable with respect to such plan; and

(iii) is available in the 15 most common languages in the geographic region of the applicable facility;

(B) obtains from the participant, beneficiary, or enrollee (or from such an authorized representative) the consent described in paragraph (3) to be treated by a nonparticipating provider or nonparticipating facility; and

(C) provides a signed copy of such consent to the participant, beneficiary, or enrollee through mail or email (as selected by the participant, beneficiary, or enrollee).

(2) Information required under written notice

For purposes of paragraph (1)(A)(i), the information described in this paragraph, with respect to a nonparticipating provider or nonparticipating facility and a participant, beneficiary, or enrollee of a group health plan or group or individual health insurance coverage offered by a health insurance issuer, is each of the following:

(A) Notification, as applicable, that the health care provider is a nonparticipating provider with respect to the health plan or the health care facility is a nonparticipating facility with respect to the health plan.

(B) Notification of the good faith estimated amount that such provider or facility may charge the participant, beneficiary, or enrollee for such items and services involved, including a notification that the provision of such estimate or consent to be treated under paragraph (3) does not constitute a contract with respect to the charges estimated for such items and services.

(C) In the case of a participating facility and a nonparticipating provider, a list of any participating providers at the facility who are able to furnish such items and services involved and notification that the participant, beneficiary, or enrollee may be referred, at their option, to such a participating provider.

(D) Information about whether prior authorization or other care management limitations may be required in advance of receiving such items or services at the facility.

(3) Consent described to be treated by a nonparticipating provider or nonparticipating facility

For purposes of paragraph (1)(B), the consent described in this paragraph, with respect to a participant, beneficiary, or enrollee of a group health plan or group or individual health insurance coverage offered by a health insurance issuer who is to be furnished items or services by a nonparticipating provider or nonparticipating facility, is a document specified by the Secretary, in consultation with the Secretary of Labor, through guidance that shall be signed by the participant, beneficiary, or enrollee before such items or services are furnished and that—

(A) acknowledges (in clear and understandable language) that the participant, beneficiary, or enrollee has been—

(i) provided with the written notice under paragraph (1)(A);

(ii) informed that the payment of such charge by the participant, beneficiary, or enrollee may not accrue toward meeting any limitation that the plan or coverage places on cost-sharing, including an explanation that such payment may not apply to an in-network deductible applied under the plan or coverage; and

(iii) provided the opportunity to receive the written notice under paragraph (1)(A) in the form selected by the participant, beneficiary or enrollee; and

(B) documents the date on which the participant, beneficiary, or enrollee received the written notice under paragraph (1)(A) and the date on which the individual signed such consent to be furnished such items or services by such provider or facility.

(4) Rule of construction

The consent described in paragraph (3), with respect to a participant, beneficiary, or enrollee of a group health plan or group or individual health insurance coverage offered by a health insurance issuer, shall constitute only consent to the receipt of the information provided pursuant to this subsection and shall not constitute a contractual agreement of the participant, beneficiary, or enrollee to any estimated charge or amount included in such information.

(e) Retention of certain documents

A nonparticipating facility (with respect to such facility or any nonparticipating provider at such facility) or a participating facility (with respect to nonparticipating providers at such facility) that obtains from a participant, beneficiary, or enrollee of a group health plan or group or individual health insurance coverage offered by a health insurance issuer (or an authorized representative of such participant, beneficiary, or enrollee) a written notice in accordance with subsection (d)(1)(B), with respect to furnishing an item or service to such participant, beneficiary, or enrollee, shall retain such notice for at least a 7-year period after the date on which such item or service is so furnished.

(f) Definitions

In this section:

(1) The terms "nonparticipating provider" and "participating provider" have the meanings given such terms, respectively, in subsection (a)(3) of section 300gg–111 of this title.

(2) The term "participating health care facility" has the meaning given such term in subsection (b)(2) of section 300gg–111 of this title.

(3) The term "nonparticipating facility" means—

(A) with respect to emergency services (as defined in section 300gg–111(a)(3)(C)(i) of this title) and a group health plan or group or individual health insurance coverage offered by a health insurance issuer, an emergency department of a hospital, or an independent freestanding emergency department, that does not have a contractual relationship with the plan or issuer, respectively, with respect to the furnishing of such services under the plan or coverage, respectively; and

(B) with respect to services described in section 300gg–111(a)(3)(C)(ii) of this title and a group health plan or group or individual health insurance coverage offered by a health insurance issuer, a hospital or an independent freestanding emergency department, that does not have a contractual relationship with the plan or issuer, respectively, with respect to the furnishing of such services under the plan or coverage, respectively.

(4) The term "participating facility" means—

(A) with respect to emergency services (as defined in clause (i) of section 300gg–111(a)(3)(C) of this title) that are not described in clause (ii) of such section and a group health plan or group or individual health insurance coverage offered by a health insurance issuer, an emergency department of a hospital, or an independent freestanding emergency department, that has a direct or indirect contractual relationship with the plan or issuer, respectively, with respect to the furnishing of such services under the plan or coverage, respectively; and

(B) with respect to services that pursuant to clause (ii) of section 300gg–111(a)(3)(C) of this title, of section 9816(a)(3) of title 26, and of section 1185e(a)(3) of title 29, as applicable are included as emergency services (as defined in clause (i) of such section and a group health plan or group or individual health insurance coverage offered by a health insurance issuer, a hospital

or an independent freestanding emergency department, that has a contractual relationship with the plan or coverage, respectively, with respect to the furnishing of such services under the plan or coverage, respectively.

(July 1, 1944, ch. 373, title XXVII, §2799B–2, as added Pub. L. 116–260, div. BB, title I, §104(a), Dec. 27, 2020, 134 Stat. 2824.)

[1] *So in original. Probably should be followed by a comma.*

§300gg–133. Provider requirements with respect to disclosure on patient protections against balance billing

Beginning not later than January 1, 2022, each health care provider and health care facility shall make publicly available, and (if applicable) post on a public website of such provider or facility and provide to individuals who are participants, beneficiaries, or enrollees of a group health plan or group or individual health insurance coverage offered by a health insurance issuer a one-page notice (either postal or electronic mail, as specified by the participant, beneficiary, or enrollee) in clear and understandable language containing information on—

(1) the requirements and prohibitions of such provider or facility under sections 300gg–131 and 300gg–132 of this title (relating to prohibitions on balance billing in certain circumstances);

(2) any other applicable State law requirements on such provider or facility regarding the amounts such provider or facility may, with respect to an item or service, charge a participant, beneficiary, or enrollee of a group health plan or group or individual health insurance coverage offered by a health insurance issuer with respect to which such provider or facility does not have a contractual relationship for furnishing such item or service under the plan or coverage, respectively, after receiving payment from the plan or coverage, respectively, for such item or service and any applicable cost-sharing payment from such participant, beneficiary, or enrollee; and

(3) information on contacting appropriate State and Federal agencies in the case that an individual believes that such provider or facility has violated any requirement described in paragraph (1) or (2) with respect to such individual.

(July 1, 1944, ch. 373, title XXVII, §2799B–3, as added Pub. L. 116–260, div. BB, title I, §104(a), Dec. 27, 2020, 134 Stat. 2829.)

§300gg–134. Enforcement

(a) State enforcement

(1) State authority

Each State may require a provider or health care facility (including a provider of air ambulance services) subject to the requirements of this part to satisfy such requirements applicable to the provider or facility.

(2) Failure to implement requirements

In the case of a determination by the Secretary that a State has failed to substantially enforce the requirements to which paragraph (1) applies with respect to applicable providers and facilities in the State, the Secretary shall enforce such requirements under subsection (b) insofar as they relate to violations of such requirements occurring in such State.

(3) Notification of applicable Secretary

A State may notify the Secretary of Labor, Secretary of Health and Human Services, or the Secretary of the Treasury, as applicable, of instances of violations of sections 300gg–131, 300gg–132, or 300gg–135 of this title with respect to participants, beneficiaries, or enrollees under

a group health plan or group or individual health insurance coverage, as applicable [1] offered by a health insurance issuer and any enforcement actions taken against providers or facilities as a result of such violations, including the disposition of any such enforcement actions.

(b) Secretarial enforcement authority

(1) In general

If a provider or facility is found by the Secretary to be in violation of a requirement to which subsection (a)(1) applies, the Secretary may apply a civil monetary penalty with respect to such provider or facility (including, as applicable, a provider of air ambulance services) in an amount not to exceed $10,000 per violation. The provisions of subsections (c) (with the exception of the first sentence of paragraph (1) of such subsection), (d), (e), (g), (h), (k), and (l) of section 1320a—7a of this title shall apply to a civil monetary penalty or assessment under this subsection in the same manner as such provisions apply to a penalty, assessment, or proceeding under subsection (a) of such section.

(2) Limitation

The provisions of paragraph (1) shall apply to enforcement of a provision (or provisions) specified in subsection (a)(1) only as provided under subsection (a)(2).

(3) Complaint process

The Secretary shall, through rulemaking, establish a process to receive consumer complaints of violations of such provisions and provide a response to such complaints within 60 days of receipt of such complaints.

(4) Exception

The Secretary shall waive the penalties described under paragraph (1) with respect to a facility or provider (including a provider of air ambulance services) who does not knowingly violate, and should not have reasonably known it violated, section 300gg–131 or 300gg–132 of this title (or, in the case of a provider of air ambulance services, section 300gg–135 of this title) with respect to a participant, beneficiary, or enrollee, if such facility or provider, within 30 days of the violation, withdraws the bill that was in violation of such provision and reimburses the health plan or enrollee, as applicable, in an amount equal to the difference between the amount billed and the amount allowed to be billed under the provision, plus interest, at an interest rate determined by the Secretary.

(5) Hardship exemption

The Secretary may establish a hardship exemption to the penalties under this subsection.

(c) Continued applicability of State law

The sections specified in subsection (a)(1) [2] shall not be construed to supersede any provision of State law which establishes, implements, or continues in effect any requirement or prohibition except to the extent that such requirement or prohibition prevents the application of a requirement or prohibition of such a section.

(July 1, 1944, ch. 373, title XXVII, §2799B–4, as added Pub. L. 116–260, div. BB, title I, §104(a), Dec. 27, 2020, 134 Stat. 2829.)

[1] So in original. Probably should be followed by a comma.

[2] So in original. Subsec. (a)(1) specifies "this part", but does not specify individual sections.

§300gg–135. Air ambulance services

In the case of a participant, beneficiary, or enrollee with benefits under a group health plan or group or individual health insurance coverage offered by a health insurance issuer and who is

furnished in a plan year beginning on or after January 1, 2022, air ambulance services (for which benefits are available under such plan or coverage) from a nonparticipating provider (as defined in section 300gg–111(a)(3)(G) of this title) with respect to such plan or coverage, such provider shall not bill, and shall not hold liable, such participant, beneficiary, or enrollee for a payment amount for such service furnished by such provider that is more than the cost-sharing amount for such service (as determined in accordance with paragraphs (1) and (2) of section 300gg–112(a) of this title, section 1185f(a) of title 29, or section 9817(a) of title 26, as applicable).

(July 1, 1944, ch. 373, title XXVII, §2799B–5, as added Pub. L. 116–260, div. BB, title I, §105(b), Dec. 27, 2020, 134 Stat. 2851.)

§300gg–136. Provision of information upon request and for scheduled appointments

Each health care provider and health care facility shall, beginning January 1, 2022, in the case of an individual who schedules an item or service to be furnished to such individual by such provider or facility at least 3 business days before the date such item or service is to be so furnished, not later than 1 business day after the date of such scheduling (or, in the case of such an item or service scheduled at least 10 business days before the date such item or service is to be so furnished (or if requested by the individual), not later than 3 business days after the date of such scheduling or such request)—

(1) inquire if such individual is enrolled in a group health plan, group or individual health insurance coverage offered by a health insurance issuer, or a Federal health care program (and if is so enrolled in such plan or coverage, seeking to have a claim for such item or service submitted to such plan or coverage); and

(2) provide a notification (in clear and understandable language) of the good faith estimate of the expected charges for furnishing such item or service (including any item or service that is reasonably expected to be provided in conjunction with such scheduled item or service and such an item or service reasonably expected to be so provided by another health care provider or health care facility), with the expected billing and diagnostic codes for any such item or service, to—

(A) in the case the individual is enrolled in such a plan or such coverage (and is seeking to have a claim for such item or service submitted to such plan or coverage), such plan or issuer of such coverage; and

(B) in the case the individual is not described in subparagraph (A) and not enrolled in a Federal health care program, the individual.

(July 1, 1944, ch. 373, title XXVII, §2799B–6, as added Pub. L. 116–260, div. BB, title I, §112, Dec. 27, 2020, 134 Stat. 2866.)

§300gg–137. Patient-provider dispute resolution

(a) In general

Not later than January 1, 2022, the Secretary shall establish a process (in this subsection referred to as the "patient-provider dispute resolution process") under which an uninsured individual, with respect to an item or service, who received, pursuant to section 300gg–136 of this title, from a health care provider or health care facility a good-faith estimate of the expected charges for furnishing such item or service to such individual and who after being furnished such item or service by such provider or facility is billed by such provider or facility for such item or service for charges that are substantially in excess of such estimate, may seek a determination from a selected dispute resolution entity for the charges to be paid by such individual (in lieu of such amount so billed) to such provider or facility for such item or service. For purposes of this subsection, the term "uninsured individual" means, with respect to an item or service, an individual who does not have benefits for such item or service under a group health plan, group or individual health insurance coverage offered by a health

insurance issuer, Federal health care program (as defined in section 1320a–7b(f) of this title), or a health benefits plan under chapter 89 of title 5 (or an individual who has benefits for such item or service under a group health plan or individual or group health insurance coverage offered by a health insurance issuer, but who does not seek to have a claim for such item or service submitted to such plan or coverage).

(b) Selection of entities

Under the patient-provider dispute resolution process, the Secretary shall, with respect to a determination sought by an individual under subsection (a), with respect to charges to be paid by such individual to a health care provider or health care facility described in such paragraph for an item or service furnished to such individual by such provider or facility, provide for—

(1) a method to select to make such determination an entity certified under subsection (d) that—

(A) is not a party to such determination or an employee or agent of such party;

(B) does not have a material familial, financial, or professional relationship with such a party; and

(C) does not otherwise have a conflict of interest with such a party (as determined by the Secretary); and

(2) the provision of a notification of such selection to the individual and the provider or facility (as applicable) party to such determination.

An entity selected pursuant to the previous sentence to make a determination described in such sentence shall be referred to in this subsection as the "selected dispute resolution entity" with respect to such determination.

(c) Administrative fee

The Secretary shall establish a fee to participate in the patient-provider dispute resolution process in such a manner as to not create a barrier to an uninsured individual's access to such process.

(d) Certification

The Secretary shall establish or recognize a process to certify entities under this subparagraph.[1] Such process shall ensure that an entity so certified satisfies at least the criteria specified in section 300gg–111(c) of this title.

(July 1, 1944, ch. 373, title XXVII, §2799B–7, as added Pub. L. 116–260, div. BB, title I, §112, Dec. 27, 2020, 134 Stat. 2867.)

[1] *So in original.*

§300gg–138. Continuity of care

A health care provider or health care facility shall, in the case of an individual furnished items and services by such provider or facility for which coverage is provided under a group health plan or group or individual health insurance coverage pursuant to section 300gg–113 of this title, section 9818 of title 26, or section 1185g of title 29—

(1) accept payment from such plan or such issuer (as applicable) (and cost-sharing from such individual, if applicable, in accordance with subsection (a)(2)(C) of such section 300gg–113 of this title, 9818 of title 26, or 1185g of title 29) for such items and services as payment in full for such items and services; and

(2) continue to adhere to all policies, procedures, and quality standards imposed by such plan or issuer with respect to such individual and such items and services in the same manner as if such termination had not occurred.

(July 1, 1944, ch. 373, title XXVII, §2799B–8, as added Pub. L. 116–260, div. BB, title I, §113(d), Dec. 27, 2020, 134 Stat. 2873.)

§300gg–139. Provider requirements to protect patients and improve the accuracy of provider directory information

(a) Provider business processes

Beginning not later than January 1, 2022, each health care provider and each health care facility shall have in place business processes to ensure the timely provision of provider directory information to a group health plan or a health insurance issuer offering group or individual health insurance coverage to support compliance by such plans or issuers with section 300gg–115(a)(1) of this title, section 1185i(a)(1) of title 29, or section 9820(a)(1) of title 26, as applicable. Such providers shall submit provider directory information to a plan or issuers, at a minimum—

(1) when the provider or facility begins a network agreement with a plan or with an issuer with respect to certain coverage;

(2) when the provider or facility terminates a network agreement with a plan or with an issuer with respect to certain coverage;

(3) when there are material changes to the content of provider directory information of the provider or facility described in section 300gg–115(a)(1) of this title, section 1185i(a)(1) of title 29, or section 9820(a)(1) of title 26, as applicable; and

(4) at any other time (including upon the request of such issuer or plan) determined appropriate by the provider, facility, or the Secretary.

(b) Refunds to enrollees

If a health care provider submits a bill to an enrollee based on cost-sharing for treatment or services provided by the health care provider that is in excess of the normal cost-sharing applied for such treatment or services provided in-network, as prohibited under section 300gg–115(b) of this title, section 1185i(b) of title 29, or section 9820(b) of title 26, as applicable, and the enrollee pays such bill, the provider shall reimburse the enrollee for the full amount paid by the enrollee in excess of the in-network cost-sharing amount for the treatment or services involved, plus interest, at an interest rate determined by the Secretary.

(c) Limitation

Nothing in this section shall prohibit a provider from requiring in the terms of a contract, or contract termination, with a group health plan or health insurance issuer—

(1) that the plan or issuer remove, at the time of termination of such contract, the provider from a directory of the plan or issuer described in section 300gg–115(a) of this title, section 1185i(a) of title 29, or section 9820(a) of title 26, as applicable; or

(2) that the plan or issuer bear financial responsibility, including under section 300gg–115(b) of this title, section 1185i(b) of title 29, or section 9820(b) of title 26, as applicable, for providing inaccurate network status information to an enrollee.

(d) Definition

For purposes of this section, the term "provider directory information" includes the names, addresses, specialty, telephone numbers, and digital contact information of individual health care providers, and the names, addresses, telephone numbers, and digital contact information of each medical group, clinic, or facility contracted to participate in any of the networks of the group health plan or health insurance coverage involved.

(e) Rule of construction

Nothing in this section shall be construed to preempt any provision of State law relating to health care provider directories.

(July 1, 1944, ch. 373, title XXVII, §2799B–9, as added Pub. L. 116–260, div. BB, title I, §116(e), Dec. 27, 2020, 134 Stat. 2887.)

SUBCHAPTER XXVI—NATIONAL ALL-HAZARDS PREPAREDNESS FOR PUBLIC HEALTH EMERGENCIES

EDITORIAL NOTES

CODIFICATION

Pub. L. 109–417, title I, §101(1), Dec. 19, 2006, 120 Stat. 2832, substituted "NATIONAL ALL-HAZARDS PREPAREDNESS FOR PUBLIC HEALTH EMERGENCIES" for "NATIONAL PREPAREDNESS FOR BIOTERRORISM AND OTHER PUBLIC HEALTH EMERGENCIES" in heading.

PART A—NATIONAL ALL-HAZARDS PREPAREDNESS AND RESPONSE PLANNING, COORDINATING, AND REPORTING

EDITORIAL NOTES

CODIFICATION

Pub. L. 109–417, title I, §101(2), Dec. 19, 2006, 120 Stat. 2832, substituted "National All-Hazards Preparedness" for "National Preparedness" in heading.

§300hh. Public health and medical preparedness and response functions

(a) In general

The Secretary of Health and Human Services shall lead all Federal public health and medical response to public health emergencies and incidents covered by the National Response Plan developed pursuant to section 314(6) [1] of title 6, or any successor plan.

(b) Interagency agreement

The Secretary, in collaboration with the Secretary of Veterans Affairs, the Secretary of Transportation, the Secretary of Defense, the Secretary of Homeland Security, and the head of any other relevant Federal agency, shall establish an interagency agreement, consistent with the National Response Plan or any successor plan, under which agreement the Secretary of Health and Human Services shall assume operational control of emergency public health and medical response assets, as necessary, in the event of a public health emergency, except that members of the armed forces under the authority of the Secretary of Defense shall remain under the command and control of the Secretary of Defense, as shall any associated assets of the Department of Defense.

(c) Coordination with Federal agencies

In leading the Federal public health and medical response to a declared or potential public health emergency, consistent with this section, the Secretary shall coordinate with, and may request support from, other Federal departments and agencies, as appropriate in order to carry out necessary activities and leverage the expertise of such departments and agencies, which may include the provision of assistance at the direction of the Secretary related to supporting the public health and medical response for States, localities, and Tribes.

(d) Annual report on emergency response and preparedness

The Secretary shall submit a written report each fiscal year to the Committee on Health, Education, Labor, and Pensions and the Committee on Appropriations of the Senate and the Committee on Energy and Commerce and the Committee on Appropriations of the House of Representatives, containing—

(1) updated information related to an assessment of the response to any public health emergency

declared, or otherwise in effect, during the previous fiscal year;

(2) findings related to drills and operational exercises completed in the previous fiscal year pursuant to section 300hh–10(b)(4)(G) of this title;

(3) the state of public health preparedness and response capabilities for chemical, biological, radiological, and nuclear threats, including emerging infectious diseases; and

(4) any challenges in preparing for or responding to such threats, as appropriate.

(July 1, 1944, ch. 373, title XXVIII, §2801, as added Pub. L. 107–188, title I, §101(a), June 12, 2002, 116 Stat. 596; amended Pub. L. 109–417, title I, §101(2), Dec. 19, 2006, 120 Stat. 2832; Pub. L. 117–328, div. FF, title II, §2103(b)(1), (d), Dec. 29, 2022, 136 Stat. 5711, 5714.)

EDITORIAL NOTES

REFERENCES IN TEXT

Section 314(6) of title 6, referred to in subsec. (a), was in the original "section 502(6) of the Homeland Security Act of 2002", and was translated as meaning section 504(6) of Pub. L. 107–296, to reflect the probable intent of Congress and the renumbering of section 502 as 504 by Pub. L. 109–295, title VI, §611(8), Oct. 4, 2006, 120 Stat. 1395.

AMENDMENTS

2022—Subsec. (c). Pub. L. 117–328, §2103(b)(1), added subsec. (c).

Subsec. (d). Pub. L. 117–328, §2103(d), added subsec. (d).

2006—Pub. L. 109–417 amended section generally. Prior to amendment, section consisted of subsecs. (a) to (d) relating to a national preparedness plan for carrying out health-related activities to prepare for and respond effectively to bioterrorism and other public health emergencies.

STATUTORY NOTES AND RELATED SUBSIDIARIES

DATA USE AGREEMENTS

Pub. L. 117–328, div. FF, title II, §2213(c), Dec. 29, 2022, 136 Stat. 5735, provided that:

"(1) INTERAGENCY DATA USE AGREEMENTS WITHIN THE DEPARTMENT OF HEALTH AND HUMAN SERVICES FOR PUBLIC HEALTH EMERGENCIES.—

"(A) IN GENERAL.—The Secretary of Health and Human Services (referred to in this subsection as the 'Secretary') shall, as appropriate, facilitate the development of, or updates to, memoranda of understanding, data use agreements, or other applicable interagency agreements regarding appropriate access, exchange, and use of public health data between the Centers for Disease Control and Prevention, the Office of the Assistant Secretary for Preparedness and Response, other relevant agencies or offices within the Department of Health and Human Services, and other relevant Federal agencies, in order to prepare for, identify, monitor, and respond to declared or potential public health emergencies.

"(B) REQUIREMENTS.—In carrying out activities pursuant to subparagraph (A), the Secretary shall—

"(i) ensure that the agreements and memoranda of understanding described in such subparagraph—

"(I) address the methods of granting access to data held by one agency or office with another to support the respective missions of such agencies or offices;

"(II) consider minimum necessary principles of data sharing for appropriate use;

"(III) include appropriate privacy and cybersecurity protections; and

"(IV) are subject to regular updates, as appropriate;

"(ii) collaborate with the Centers for Disease Control and Prevention, the Office of the Assistant Secretary for Preparedness and Response, the Office of the Chief Information Officer, and, as appropriate, the Office of the National Coordinator for Health Information Technology, and other entities within the Department of Health and Human Services; and

"(iii) consider the terms and conditions of any existing data use agreements with other public or private entities and any need for updates to such existing agreements, consistent with paragraph (2).

"(2) DATA USE AGREEMENTS WITH EXTERNAL ENTITIES.—The Secretary, acting through the Director of the Centers for Disease Control and Prevention and the Assistant Secretary for Preparedness and Response, may update memoranda of understanding, data use agreements, or other applicable agreements

and contracts to improve appropriate access, exchange, and use of public health data between the Centers for Disease Control and Prevention and the Office of the Assistant Secretary for Preparedness and Response and external entities, including State, Tribal, and territorial health departments, laboratories, hospitals and other health care providers, electronic health records vendors, and other entities, as applicable and appropriate, in order to prepare for, identify, monitor, and respond to declared or potential public health emergencies.

"(3) REPORT.—Not later than 90 days after the date of enactment of this Act [Dec. 29, 2022], the Secretary shall report to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives on the status of the agreements under this subsection."

GUIDANCE FOR PARTICIPATION IN EXERCISES AND DRILLS

Pub. L. 116–22, title III, §306, June 24, 2019, 133 Stat. 941, provided that: "Not later than 2 years after the date of enactment of this Act [June 24, 2019], the Secretary of Health and Human Services shall issue final guidance regarding the ability of personnel funded by programs authorized under this Act [see Tables for classification] (including the amendments made by this Act) to participate in drills and operational exercises related to all-hazards medical and public health preparedness and response. Such drills and operational exercises may include activities that incorporate medical surge capacity planning, medical countermeasure distribution and administration, and preparing for and responding to identified threats for that region. Such personnel may include State, local, Tribal, and territorial public health department or agency personnel funded under this Act (including the amendments made by this Act). The Secretary shall consult with the Department of Homeland Security, the Department of Defense, the Department of Veterans Affairs, and other applicable Federal departments and agencies as necessary and appropriate in the development of such guidance. The Secretary shall make the guidance available on the internet website of the Department of Health and Human Services."

GOVERNMENT ACCOUNTABILITY OFFICE REPORT

Pub. L. 107–188, title I, §157, June 12, 2002, 116 Stat. 633, provided that:

"(a) IN GENERAL [sic].—The Comptroller General shall submit to the Committee on Health, Education, Labor, and Pensions and the Committee on Appropriations of the Senate, and to the Committee on Energy and Commerce and the Committee on Appropriations of the House of Representatives, a report that describes—

"(1) Federal activities primarily related to research on, preparedness for, and the management of the public health and medical consequences of a bioterrorist attack against the civilian population;

"(2) the coordination of the activities described in paragraph (1);

"(3) the effectiveness of such efforts in preparing national, State, and local authorities to address the public health and medical consequences of a potential bioterrorist attack against the civilian population;

"(4) the activities and costs of the Civil Support Teams of the National Guard in responding to biological threats or attacks against the civilian population;

"(5) the activities of the working group under subsection (a) and the efforts made by such group to carry out the activities described in such subsection; and

"(6) the ability of private sector contractors to enhance governmental responses to biological threats or attacks."

[1] *See References in Text note below.*

§300hh–1. National Health Security Strategy

(a) In general

(1) Preparedness and response regarding public health emergencies

Beginning in 2018 and every four years thereafter, the Secretary shall prepare and submit to the relevant committees of Congress a coordinated strategy (to be known as the National Health Security Strategy) and any revisions thereof, and an accompanying implementation plan for public health emergency preparedness and response. Such National Health Security Strategy shall describe potential emergency health security threats and identify the process for achieving the preparedness goals described in subsection (b) to be prepared to identify and respond to such

threats and shall be consistent with the national preparedness goal (as described in section 314(a)(19) of title 6), the National Incident Management System (as defined in section 311(7) of such title), and the National Response Plan developed pursuant to section 314 of such title, or any successor plan.

(2) Evaluation of progress

The National Health Security Strategy shall include an evaluation of the progress made by Federal, State, local, and tribal entities, based on the evidence-based benchmarks and objective standards that measure levels of preparedness established pursuant to section 247d–3a(g) of this title. Such evaluation shall include aggregate and State-specific breakdowns of obligated funding spent by major category (as defined by the Secretary) for activities funded through awards pursuant to sections 247d–3a and 247d–3b of this title, and an analysis of any changes to the evidence-based benchmarks and objective standards under sections 247d–3a and 247d–3b of this title.

(3) Public health workforce

In 2022, the National Health Security Strategy shall include a national strategy for establishing an effective and prepared public health workforce, including defining the functions, capabilities, and gaps in such workforce (including gaps in the environmental health and animal health workforces, as applicable), describing the status of such workforce, identifying strategies to recruit, retain, and protect such workforce from workplace exposures during public health emergencies, and identifying current capabilities to meet the requirements of section 300hh–2 of this title.

(b) Preparedness goals

The National Health Security Strategy shall include provisions in furtherance of the following:

(1) Integration

Integrating public health and public and private medical capabilities with other first responder systems, including through—

(A) the periodic evaluation of Federal, State, local, and tribal preparedness and response capabilities through drills and exercises, including drills and exercises to ensure medical surge capacity for events without notice; and

(B) integrating public and private sector public health and medical donations and volunteers.

(2) Public health

Developing and sustaining Federal, State, local, and tribal essential public health security capabilities, including the following:

(A) Disease situational awareness domestically and abroad, including detection, identification, investigation, and related information technology activities.

(B) Disease containment including capabilities for isolation, quarantine, social distancing, decontamination, relevant health care services and supplies, and transportation and disposal of medical waste.

(C) Risk communication and public preparedness.

(D) Rapid distribution and administration of medical countermeasures.

(E) Response to environmental hazards.

(3) Medical

Increasing the preparedness, response capabilities, and surge capacity of hospitals, other health care facilities (including pharmacies, mental health facilities, and ambulatory care facilities and which may include dental health facilities), and trauma care, critical care, and emergency medical service systems, with respect to public health emergencies (including related availability, accessibility, and coordination), which shall include developing plans for the following:

(A) Strengthening public health emergency medical and trauma management and treatment capabilities.

(B) Fatality management.

(C) Coordinated medical triage and evacuation to appropriate medical institutions based on patient medical need, taking into account regionalized systems of care.

(D) Rapid distribution and administration of medical countermeasures.

(E) Effective utilization of any available public and private mobile medical assets (which may include such dental health assets) and integration of other Federal assets.

(F) Protecting health care workers and health care first responders from workplace exposures during a public health emergency or exposures to agents that could cause a public health emergency.

(G) Optimizing a coordinated and flexible approach to the emergency response and medical surge capacity of hospitals, other health care facilities, critical care, trauma care (which may include trauma centers), and emergency medical systems.

(4) At-risk individuals

(A) Taking into account the public health and medical needs of at-risk individuals, including the unique needs and considerations of individuals with disabilities, in the event of a public health emergency.

(B) For the purpose of this chapter, the term "at-risk individuals" means children, pregnant women, senior citizens and other individuals who have access or functional needs in the event of a public health emergency, as determined by the Secretary.

(5) Coordination

Minimizing duplication of, and ensuring coordination between, Federal, State, local, and tribal planning, preparedness, and response activities (including the State Emergency Management Assistance Compact and other applicable compacts). Such planning shall be consistent with the National Response Plan, or any successor plan, and National Incident Management System and the National Preparedness Goal.

(6) Continuity of operations

Maintaining vital public health and medical services to allow for optimal Federal, State, local, and tribal operations in the event of a public health emergency.

(7) Countermeasures

(A) Promoting strategic initiatives to advance countermeasures to diagnose, mitigate, prevent, or treat harm from any biological agent or toxin, chemical, radiological, or nuclear agent or agents, whether naturally occurring, unintentional, or deliberate.

(B) For purposes of this paragraph, the term "countermeasures" has the same meaning as the terms "qualified countermeasures" under section 247d–6a of this title, "qualified pandemic and epidemic products" under section 247d–6d of this title, and "security countermeasures" under section 247d–6b of this title.

(8) Medical and public health community resiliency

Strengthening the ability of States, local communities, and tribal communities to prepare for, respond to, and be resilient in the event of public health emergencies, whether naturally occurring, unintentional, or deliberate by—

(A) optimizing alignment and integration of medical and public health preparedness and response planning and capabilities with and into routine daily activities; and

(B) promoting familiarity with local medical and public health systems.

(9) Zoonotic disease, food, and agriculture

Improving coordination among Federal, State, local, Tribal, and territorial entities (including through consultation with the Secretary of Agriculture) to prevent, detect, and respond to outbreaks of plant or animal disease (including zoonotic disease) that could compromise national security resulting from a deliberate attack, a naturally occurring threat, the intentional adulteration of food, or other public health threats, taking into account interactions between animal health, human health, and animals' and humans' shared environment as directly related to public health emergency preparedness and response capabilities, as applicable.

(10) Global health security

Assessing current or potential health security threats from abroad to inform domestic public health preparedness and response capabilities.

(July 1, 1944, ch. 373, title XXVIII, §2802, as added Pub. L. 109–417, title I, §103, Dec. 19, 2006, 120 Stat. 2835; amended Pub. L. 113–5, title I, §101(a), Mar. 13, 2013, 127 Stat. 162; Pub. L. 116–22, title I, §101, title II, §203(d), title III, §303(a), June 24, 2019, 133 Stat. 906, 914, 935.)

EDITORIAL NOTES

AMENDMENTS

2019—Subsec. (a)(1). Pub. L. 116–22, §101(1)(A), substituted "2018" for "2014" and "Such National Health Security Strategy shall describe potential emergency health security threats and identify the process for achieving the preparedness goals described in subsection (b) to be prepared to identify and respond to such threats and shall be consistent with the national preparedness goal (as described in section 314(a)(19) of title 6), the National Incident Management System (as defined in section 311(7) of such title), and the National Response Plan developed pursuant to section 314 of such title, or any successor plan." for "Such National Health Security Strategy shall identify the process for achieving the preparedness goals described in subsection (b) and shall be consistent with the National Preparedness Goal, the National Incident Management System, and the National Response Plan developed pursuant to section 314(6) of title 6, or any successor plan."

Subsec. (a)(2). Pub. L. 116–22, §101(1)(B), inserted before period at end ", and an analysis of any changes to the evidence-based benchmarks and objective standards under sections 247d–3a and 247d–3b of this title".

Subsec. (a)(3). Pub. L. 116–22, §101(1)(C), substituted "2022" for "2009" and "gaps in such workforce (including gaps in the environmental health and animal health workforces, as applicable), describing the status of such workforce, identifying strategies" for "gaps in such workforce, and identifying strategies" and inserted ", and identifying current capabilities to meet the requirements of section 300hh–2 of this title" before period at end.

Subsec. (b)(2)(A). Pub. L. 116–22, §101(2)(A)(i), substituted "investigation, and related information technology activities" for "and investigation".

Subsec. (b)(2)(B). Pub. L. 116–22, §101(2)(A)(ii), substituted "decontamination, relevant health care services and supplies, and transportation and disposal of medical waste" for "and decontamination".

Subsec. (b)(2)(E). Pub. L. 116–22, §101(2)(A)(iii), added subpar. (E).

Subsec. (b)(3). Pub. L. 116–22, §101(2)(B)(i), substituted "including pharmacies, mental health facilities," for "including mental health" in introductory provisions.

Subsec. (b)(3)(F). Pub. L. 116–22, §101(2)(B)(ii), inserted "or exposures to agents that could cause a public health emergency" before period at end.

Subsec. (b)(3)(G). Pub. L. 116–22, §203(d), amended subpar. (G) generally. Prior to amendment, subpar. (G) read as follows: "Optimizing a coordinated and flexible approach to the medical surge capacity of hospitals, other health care facilities, critical care, trauma care (which may include trauma centers), and emergency medical systems."

Subsec. (b)(4)(B). Pub. L. 116–22, §303(a), substituted "this chapter," for "this section and sections 247d–3a, 247d–6, and 247d–7e of this title," and "access or functional" for "special".

Subsec. (b)(5). Pub. L. 116–22, §101(2)(C), inserted "and other applicable compacts" after "Compact".

Subsec. (b)(9), (10). Pub. L. 116–22, §101(2)(D), added pars. (9) and (10).

2013—Subsec. (a)(1). Pub. L. 113–5, §101(a)(1), substituted "2014" for "2009".

Subsec. (b)(1)(A). Pub. L. 113–5, §101(a)(2)(A), inserted ", including drills and exercises to ensure medical surge capacity for events without notice" after "through drills and exercises".

Subsec. (b)(3). Pub. L. 113–5, §101(a)(2)(B)(i), in introductory provisions, substituted "and ambulatory care facilities and which may include dental health facilities), and trauma care, critical care," for "facilities), and trauma care" and inserted "(including related availability, accessibility, and coordination)" after "public health emergencies".

Subsec. (b)(3)(A). Pub. L. 113–5, §101(a)(2)(B)(ii), inserted "and trauma" after "medical".

Subsec. (b)(3)(B). Pub. L. 113–5, §101(a)(2)(B)(iii), substituted "Fatality management" for "Medical evacuation and fatality management".

Subsec. (b)(3)(C), (D). Pub. L. 113–5, §101(a)(2)(B)(iv), (v), added subpar. (C) and redesignated former subpar. (C) as (D). Former subpar. (D) redesignated (E).

Subsec. (b)(3)(E). Pub. L. 113–5, §101(a)(2)(B)(iv), (vi), redesignated subpar. (D) as (E) and inserted "(which may include such dental health assets)" after "medical assets". Former subpar. (E) redesignated (F).

Subsec. (b)(3)(F). Pub. L. 113–5, §101(a)(2)(B)(iv), redesignated subpar. (E) as (F).

Subsec. (b)(3)(G). Pub. L. 113–5, §101(a)(2)(B)(vii), added subpar. (G).

Subsec. (b)(4)(A). Pub. L. 113–5, §101(a)(2)(C)(i), inserted ", including the unique needs and considerations of individuals with disabilities," after "needs of at-risk individuals".

Subsec. (b)(4)(B). Pub. L. 113–5, §101(a)(2)(C)(ii), inserted "the" before "purpose of this section".

Subsec. (b)(7), (8). Pub. L. 113–5, §101(a)(2)(D), added pars. (7) and (8).

EXECUTIVE DOCUMENTS

EX. ORD. NO. 13527. ESTABLISHING FEDERAL CAPABILITY FOR THE TIMELY PROVISION OF MEDICAL COUNTERMEASURES FOLLOWING A BIOLOGICAL ATTACK

Ex. Ord. No. 13527, Dec. 30, 2009, 75 F.R. 737, provided:

By the authority vested in me as President by the Constitution and the laws of the United States of America, it is hereby ordered as follows:

SECTION 1. *Policy*. It is the policy of the United States to plan and prepare for the timely provision of medical countermeasures to the American people in the event of a biological attack in the United States through a rapid Federal response in coordination with State, local, territorial, and tribal governments.

This policy would seek to: (1) mitigate illness and prevent death; (2) sustain critical infrastructure; and (3) complement and supplement State, local, territorial, and tribal government medical countermeasure distribution capacity.

SEC. 2. *United States Postal Service Delivery of Medical Countermeasures*. (a) The U.S. Postal Service has the capacity for rapid residential delivery of medical countermeasures for self administration across all communities in the United States. The Federal Government shall pursue a national U.S. Postal Service medical countermeasures dispensing model to respond to a large-scale biological attack.

(b) The Secretaries of Health and Human Services and Homeland Security, in coordination with the U.S. Postal Service, within 180 days of the date of this order, shall establish a national U.S. Postal Service medical countermeasures dispensing model for U.S. cities to respond to a large-scale biological attack, with anthrax as the primary threat consideration.

(c) In support of the national U.S. Postal Service model, the Secretaries of Homeland Security, Health and Human Services, and Defense, and the Attorney General, in coordination with the U.S. Postal Service, and in consultation with State and local public health, emergency management, and law enforcement officials, within 180 days of the date of this order, shall develop an accompanying plan for supplementing local law enforcement personnel, as necessary and appropriate, with local Federal law enforcement, as well as other appropriate personnel, to escort U.S. Postal workers delivering medical countermeasures.

SEC. 3. *Federal Rapid Response*. (a) The Federal Government must develop the capacity to anticipate and immediately supplement the capabilities of affected jurisdictions to rapidly distribute medical countermeasures following a biological attack. Implementation of a Federal strategy to rapidly dispense medical countermeasures requires establishment of a Federal rapid response capability.

(b) The Secretaries of Homeland Security and Health and Human Services, in coordination with the Secretary of Defense, within 90 days of the date of this order, shall develop a concept of operations and establish requirements for a Federal rapid response to dispense medical countermeasures to an affected population following a large-scale biological attack.

SEC. 4. *Continuity of Operations*. (a) The Federal Government must establish mechanisms for the provision of medical countermeasures to personnel performing mission-essential functions to ensure that mission-essential functions of Federal agencies continue to be performed following a biological attack.

(b) The Secretaries of Health and Human Services and Homeland Security, within 180 days of the date of this order, shall develop a plan for the provision of medical countermeasures to ensure that mission-essential functions of executive branch departments and agencies continue to be performed following a large-scale biological attack.

SEC. 5. *General Provisions.*

(a) Nothing in this order shall be construed to impair or otherwise affect:

(i) authority granted by law to a department or agency, or the head thereof; or

(ii) functions of the Director of the Office of Management and Budget relating to budgetary, administrative, or legislative proposals.

(b) This order shall be implemented consistent with applicable law and subject to the availability of appropriations.

(c) This order is not intended to, and does not, create any right or benefit, substantive or procedural, enforceable at law or in equity, by any party against the United States, its departments, agencies, or entities, its officers, employees, or agents, or any other person.

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§300hh–2. Enhancing medical surge capacity

(a) Study of enhancing medical surge capacity

As part of the joint review described in section 300hh–11(b) of this title, the Secretary shall evaluate the benefits and feasibility of improving the capacity of the Department of Health and Human Services to provide additional medical surge capacity to local communities in the event of a public health emergency. Such study shall include an assessment of the need for and feasibility of improving surge capacity through—

(1) acquisition and operation of mobile medical assets by the Secretary to be deployed, on a contingency basis, to a community in the event of a public health emergency;

(2) integrating the practice of telemedicine within the National Disaster Medical System; and

(3) other strategies to improve such capacity as determined appropriate by the Secretary.

(b) Authority to acquire and operate mobile medical assets

In addition to any other authority to acquire, deploy, and operate mobile medical assets, the Secretary may acquire, deploy, and operate mobile medical assets if, taking into consideration the evaluation conducted under subsection (a), such acquisition, deployment, and operation is determined to be beneficial and feasible in improving the capacity of the Department of Health and Human Services to provide additional medical surge capacity to local communities in the event of a public health emergency.

(c) Using Federal facilities to enhance medical surge capacity

(1) Analysis

The Secretary shall conduct an analysis of whether there are Federal facilities which, in the event of a public health emergency, could practicably be used as facilities in which to provide health care.

(2) Memoranda of understanding

If, based on the analysis conducted under paragraph (1), the Secretary determines that there are Federal facilities which, in the event of a public health emergency, could be used as facilities in which to provide health care, the Secretary shall, with respect to each such facility, seek to conclude a memorandum of understanding with the head of the Department or agency that operates such facility that permits the use of such facility to provide health care in the event of a public health emergency.

(July 1, 1944, ch. 373, title XXVIII, §2803, as added Pub. L. 109–417, title III, §302(a), Dec. 19, 2006, 120 Stat. 2855.)

§300hh–3. Office of Pandemic Preparedness and Response Policy

(a) In general

There is established in the Executive Office of the President an Office of Pandemic Preparedness and Response Policy (referred to in this section as the "Office"), which shall be headed by a Director (referred to in this section as the "Director") appointed by the President and who shall be compensated at the rate provided for level II of the Executive Schedule in section 5313 of title 5. The President is authorized to appoint not more than 2 Associate Directors, who shall be compensated at a rate not to exceed that provided for level III of the Executive Schedule in section 5314 of such title. Associate Directors shall perform such functions as the Director may prescribe.

(b) Functions of the Director

The primary function of the Director is to provide advice, within the Executive Office of the President, on policy related to preparedness for, and response to, pandemic and other biological threats that may impact national security, and support strategic coordination and communication with respect to relevant activities across the Federal Government. In addition to such other functions and activities as the President may assign, the Director, consistent with applicable laws and the National Response Framework, shall—

(1) serve as the principal advisor to the President on all matters related to pandemic preparedness and response policy and make recommendations to the President regarding pandemic and other biological threats that may impact national security;

(2) coordinate Federal activities to prepare for, and respond to, pandemic and other biological threats, by—

(A) providing strategic direction to the heads of applicable Federal departments, agencies, and offices, including—

(i) the establishment, implementation, prioritization, and assessment of policy goals and objectives across the Executive Office of the President and such departments, agencies, and offices;

(ii) supporting the assessment and clarification of roles and responsibilities related to such Federal activities; and

(iii) supporting the development and implementation of metrics and performance measures to evaluate the extent to which applicable activities meet such goals and objectives;

(B) providing, in consultation with the Secretary of Health and Human Services and the heads of other relevant Federal departments, agencies, and offices, leadership with respect to the National Biodefense Strategy and related activities pursuant to section 104 of title 6 and section 105 of title 6;

(C) facilitating coordination and communication between such Federal departments, agencies, and offices to improve preparedness for, and response to, such threats;

(D) ensuring that the authorities, capabilities, and expertise of each such department, agency, and office are appropriately leveraged to facilitate the whole-of-Government response to such threats;

(E) overseeing coordination of Federal efforts to prepare for and support the production, supply, and distribution of relevant medical products and supplies during a response to a pandemic or other biological threat, as applicable and appropriate, including supporting Federal efforts to assess any relevant vulnerabilities in the supply chain of such products and supplies, and identify opportunities for private entities to engage with the Federal Government to address medical product and medical supply needs during such a response;

(F) overseeing coordination of Federal efforts for the basic and advanced research, development, manufacture, and procurement of medical countermeasures for such threats, including by—

(i) serving, with the Secretary of Health and Human Services, as co-Chair of the Public Health Emergency Medical Countermeasures Enterprise established pursuant to section 300hh–10a of this title;

(ii) promoting coordination between the medical countermeasure research, development, and procurement activities of respective Federal departments and agencies, including to advance the discovery and development of new medical products and technologies;

(G) convening heads of Federal departments and agencies, as appropriate, on topics related to capabilities to prepare for, and respond to, such threats;

(H) assessing and advising on international cooperation in preparing for, and responding to, such threats to advance the national security objectives of the United States; and

(I) overseeing other Federal activities to assess preparedness for, and responses to, such threats, including—

(i) drills and operational exercises conducted pursuant to applicable provisions of law; and

(ii) Federal after-action reports developed following such drills and exercises or a response to a pandemic or other biological threat;

(3) promote and support the development of relevant expertise and capabilities within the Federal Government to ensure that the United States can quickly detect, identify, and respond to such threats, and provide recommendations, as appropriate, to the President;

(4) consult with the Director of the Office of Management and Budget and other relevant officials within the Executive Office of the President, including the Assistant to the President for National Security Affairs and the Director of the Office of Science and Technology Policy, regarding activities related to preparing for, and responding to, such threats and relevant research and emerging technologies that may advance the biosecurity and preparedness and response goals of the Federal Government;

(5) identify opportunities to leverage current and emerging technologies, including through public-private partnerships, as appropriate, to address such threats and advance the preparedness and response goals of the Federal Government; and

(6) ensure that findings of Federal after-action reports conducted pursuant to paragraph (2)(I)(ii) are implemented to the maximum extent feasible within the Federal Government.

(c) Support from other agencies

Each department, agency, and instrumentality of the executive branch of the Federal Government, including any independent agency, is authorized to support the Director by providing the Director such information as the Director determines necessary to carry out the functions of the Director under this section.

(d) Preparedness outlook report

(1) In general

Within its first year of operation, the Director, in consultation with the heads of relevant Federal departments and agencies and other officials within the Executive Office of the President, shall through a report submitted to the President and made available to the public, to the extent practicable, identify and describe situations and conditions which warrant special attention within the next 5 years, involving current and emerging problems of national significance related to pandemic or other biological threats, and opportunities for, and the barriers to, the research, development, and procurement of medical countermeasures to adequately respond to such threats.

(2) Revisions

The Office shall revise the report under paragraph (1) not less than once every 5 years and work with relevant Federal officials to address the problems, barriers, opportunities, and actions identified under this report through the development of the President's Budgets and programs.

(e) Interdepartmental working group

The Director shall lead an interdepartmental working group that will meet on a regular basis to evaluate national biosecurity and pandemic preparedness issues and make recommendations to the heads of applicable Federal departments, agencies and offices. The working group shall consist of representatives from—

(1) the Office of Pandemic Preparedness and Response Policy, to serve as the chair;

(2) the Department of Health and Human Services;

(3) the Department of Homeland Security;

(4) the Department of Defense;

(5) the Office of Management and Budget; and

(6) other Federal Departments and agencies.

(f) Industry Liaison

(1) In general

Not later than 10 days after the initiation of a Federal response to a pandemic or other biological threat that may pose a risk to national security, the Director shall appoint an Industry Liaison within the Office of Pandemic Preparedness and Response Policy to serve until the termination of such response.

(2) Activities

The Industry Liaison shall—

(A) not later than 20 days after the initiation of such response, identify affected industries and develop a plan to regularly communicate with, and receive input from, affected industries;

(B) work with relevant Federal departments and agencies to support information sharing and coordination with industry stakeholders; and

(C) communicate, and support the provision of technical assistance, as applicable, with private entities interested in supporting such response, which may include entities not historically involved in the public health or medical sectors, as applicable and appropriate.

(g) Additional functions of the Director

The Director, in addition to the other duties and functions set forth in this section—

(1) shall—

(A) serve as a member of the Domestic Policy Council and the National Security Council;

(B) serve as a member of the Intergovernmental Science, Engineering, and Technology Advisory Panel under section 6614(b) of this title and the Federal Coordinating Council for Science, Engineering and Technology under section 6651 of this title;

(C) consult with State, Tribal, local, and territorial governments, industry, academia, professional societies, and other stakeholders, as appropriate;

(D) use for administrative purposes, on a reimbursable basis, the available services, equipment, personnel, and facilities of Federal, State, and local agencies; and

(E) at the President's request, perform such other duties and functions and enter into contracts and other arrangements for studies, analyses, and related services with public or private entities, as applicable and appropriate; and

(2) may hold such hearings in various parts of the United States as necessary to determine the views of the entities and individuals referred to in paragraph (1) and of the general public, concerning national needs and trends in pandemic preparedness and response.

(h) Staffing and detailees

In carrying out functions under this section, the Director may—

(1) appoint not more than 25 individuals to serve as employees of the Office as necessary to carry out this section;

(2) fix the compensation of such personnel at a rate to be determined by the Director, up to the amount of annual compensation (excluding expenses) specified in section 102 of title 3;

(3) utilize the services of consultants, which may include by obtaining services described under section 3109(b) of title 5, at rates not to exceed the rate of basic pay for level IV of the Executive Schedule; and

(4) direct, with the concurrence of the Secretary of a department or head of an agency, the temporary reassignment within the Federal Government of personnel employed by such department or agency, in order to carry out the functions of the Office.

(i) Preparedness review and report

The Director, in consultation with the heads of applicable Federal departments, agencies, and offices, shall—

(1) not later than 1 year after December 29, 2022, conduct a review of applicable Federal strategies, policies, procedures, and after-action reports to identify gaps and inefficiencies related to pandemic preparedness and response;

(2) not later than 18 months after December 29, 2022, and every 2 years thereafter, submit to the President and the Committee on Health, Education, Labor, and Pensions of the Senate and the

Committee on Energy and Commerce of the House of Representatives a report describing—

(A) current and emerging pandemic and other biological threats that pose a significant level of risk to national security;

(B) the roles and responsibilities of the Federal Government in preparing for, and responding to, such threats;

(C) the findings of the review conducted under paragraph (1);

(D) any barriers or limitations related to addressing such findings;

(E) current and planned activities to update Federal strategies, policies, and procedures to address such findings, consistent with applicable laws and the National Response Framework;

(F) current and planned activities to support the development of expertise within the Federal Government pursuant to subsection (b)(3); and

(G) opportunities to improve Federal preparedness and response capacities and capabilities through the use of current and emerging technologies.

(j) Nonduplication of effort

The Director shall ensure that activities carried out under this section do not unnecessarily duplicate the efforts of other Federal departments, agencies, and offices.

(Pub. L. 117–328, div. FF, title II, §2104, Dec. 29, 2022, 136 Stat. 5715.)

EDITORIAL NOTES

REFERENCES IN TEXT

Level IV of the Executive Schedule, referred to in subsec. (h)(3), is set out in section 5315 of Title 5, Government Organization and Employees.

CODIFICATION

Section was enacted as part of the Prepare for and Respond to Existing Viruses, Emerging New Threats, and Pandemics Act, also known as the PREVENT Pandemics Act, and also as part of the Health Extenders, Improving Access to Medicare, Medicaid, and CHIP, and Strengthening Public Health Act of 2022, and not as part of the Public Health Service Act which comprises this chapter.

Section is comprised of section 2104 of div. FF of Pub. L. 117–328. Subsec. (k) of section 2104 of div. FF of Pub. L. 117–328 amended sections 300hh–10a, 6614, and 6651 of this title and section 3021 of Title 50, War and National Defense.

EXECUTIVE DOCUMENTS

EX. ORD. NO. 14122. COVID–19 AND PUBLIC HEALTH PREPAREDNESS AND RESPONSE

Ex. Ord. No. 14122, Apr. 12, 2024, 89 F.R. 27355, provided:

By the authority vested in me as President by the Constitution and the laws of the United States of America, it is hereby ordered as follows:

SECTION 1. *Policy*. The Office of Pandemic Preparedness and Response Policy (OPPR), established by the Congress in December 2022 under section 2104 of Public Law 117—328 [42 U.S.C. 300hh–3], is playing a critical role in the Federal Government's pandemic preparedness efforts. The OPPR is providing advice, within the Executive Office of the President, on policy related to preparedness for, and response to, pandemic and other biological threats that may impact national security. The OPPR is also supporting my Administration's continued work to address COVID–19 and other public health threats, facilitating coordination and communication among executive departments and agencies to ensure that the United States can quickly detect, identify, and respond to such threats as necessary. At this stage of my Administration's response to COVID–19, I have determined that certain Executive Orders are no longer necessary and that certain roles and responsibilities established by other Executive Orders related to COVID–19 should be transferred to the OPPR.

SEC. 2. *Revocations*. Executive Order 13910 of March 23, 2020 (Preventing Hoarding of Health and Medical Resources to Respond to the Spread of COVID–19) [50 U.S.C. 4512 note], Executive Order 13991 of January 20, 2021 (Protecting the Federal Workforce and Requiring Mask-Wearing) [42 U.S.C. 247d note], and Executive Order 13998 of January 21, 2021 (Promoting COVID–19 Safety in Domestic and International Travel) [42 U.S.C. 247d note], are hereby revoked.

SEC. 3. *Transfer of Responsibilities*. Responsibilities and duties of the Coordinator of the COVID–19 Response and Counselor to the President (COVID–19 Response Coordinator), including responsibilities and duties specified in Executive Order 13987 of January 20, 2021 (Organizing and Mobilizing the United States Government to Provide a Unified and Effective Response to Combat COVID–19 and to Provide United States Leadership on Global Health and Security), Executive Order 13994 of January 21, 2021 (Ensuring a Data-Driven Response to COVID–19 and Future High-Consequence Public Health Threats), and Executive Order 13996 of January 21, 2021 (Establishing the COVID–19 Pandemic Testing Board and Ensuring a Sustainable Public Health Workforce for COVID–19 and Other Biological Threats) [42 U.S.C. 247d notes], are transferred to the Director of the OPPR. The positions of COVID–19 Response Coordinator and Deputy Coordinator of the COVID–19 Response, as established by section 2 of Executive Order 13987, are hereby terminated.

SEC. 4. *General Provisions*. (a) Nothing in this order shall be construed to impair or otherwise affect:

(i) the authority granted by law to an executive department or agency, or the head thereof; or

(ii) the functions of the Director of the Office of Management and Budget relating to budgetary, administrative, or legislative proposals.

(b) This order shall be implemented consistent with applicable law and subject to the availability of appropriations.

(c) This order is not intended to, and does not, create any right or benefit, substantive or procedural, enforceable at law or in equity by any party against the United States, its departments, agencies, or entities, its officers, employees, or agents, or any other person.

J.R. BIDEN, JR.

PART B—ALL-HAZARDS EMERGENCY PREPAREDNESS AND RESPONSE

EDITORIAL NOTES

CODIFICATION

Pub. L. 109–417, title I, §102(a)(1), Dec. 19, 2006, 120 Stat. 2832, inserted "All-Hazards" before "Emergency Preparedness" in heading.

§300hh–10. Coordination of preparedness for and response to all-hazards public health emergencies

(a) In general

There is established within the Department of Health and Human Services the position of the Assistant Secretary for Preparedness and Response. The President, with the advice and consent of the Senate, shall appoint an individual to serve in such position. Such Assistant Secretary shall report to the Secretary.

(b) Duties

Subject to the authority of the Secretary, the Assistant Secretary for Preparedness and Response shall utilize experience related to public health emergency preparedness and response, biodefense, medical countermeasures, and other relevant topics to carry out the following functions:

(1) Leadership

Serve as the principal advisor to the Secretary on all matters related to Federal public health and medical preparedness and response for public health emergencies and, consistent with the National Response Framework and other applicable provisions of law, assist the Secretary in carrying out the functions under section 300hh of this title.

(2) Personnel

Register, credential, organize, train, equip, and have the authority to deploy Federal public

health and medical personnel under the authority of the Secretary, including the National Disaster Medical System, and coordinate such personnel with the Medical Reserve Corps and the Emergency System for Advance Registration of Volunteer Health Professionals.

(3) Countermeasures

Oversee advanced research, development, and procurement of qualified countermeasures (as defined in section 247d–6a of this title), security countermeasures (as defined in section 247d–6b of this title), and qualified pandemic or epidemic products (as defined in section 247d–6d of this title).

(4) Coordination

(A) Federal integration

Coordinate with relevant Federal officials to ensure integration of Federal preparedness and response activities for public health emergencies.

(B) State, local, and tribal integration

Coordinate with State, local, and tribal public health officials, the Emergency Management Assistance Compact, health care systems, and emergency medical service systems to ensure effective integration of Federal public health and medical assets during a public health emergency.

(C) Emergency medical services

Promote improved emergency medical services medical direction, system integration, research, and uniformity of data collection, treatment protocols, and policies with regard to public health emergencies.

(D) Policy coordination and strategic direction

Provide integrated policy coordination and strategic direction, before, during, and following public health emergencies, with respect to all matters related to Federal public health and medical preparedness and execution and deployment of the Federal response for public health emergencies and incidents covered by the National Response Plan described in section 314(a)(6) of title 6, or any successor plan; and such Federal responses covered by the National Cybersecurity Incident Response Plan developed under section 660(b) of title 6, including public health emergencies or incidents related to cybersecurity threats that present a threat to national health security.

(E) Identification of inefficiencies

Identify and minimize gaps, duplication, and other inefficiencies in medical and public health preparedness and response activities and recommend actions necessary to overcome these obstacles, such as—

(i) improving coordination with relevant Federal officials;

(ii) partnering with other public or private entities to leverage capabilities maintained by such entities, as appropriate and consistent with this subsection; and

(iii) coordinating efforts to support or establish new capabilities, as appropriate.

(F) Coordination of grants and agreements

Align and coordinate medical and public health grants and cooperative agreements as applicable to preparedness and response activities authorized under this chapter, to the extent possible, including program requirements, timelines, and measurable goals, and in consultation with the Secretary of Homeland Security, to—

(i) optimize and streamline medical and public health preparedness and response capabilities and the ability of local communities to respond to public health emergencies; and

(ii) gather and disseminate best practices among grant and cooperative agreement recipients, as appropriate.

(G) Drill and operational exercises

Carry out drills and operational exercises each year, including national-level and State-level full-scale exercises not less than once every 4 years, in consultation with the Department of Homeland Security, the Department of Defense, the Department of Veterans Affairs, and other applicable Federal departments and agencies, as necessary and appropriate, to identify, inform, and address gaps in and policies related to all-hazards medical and public health preparedness and response, including exercises—

(i) based on [1]

(I) identified threats for which countermeasures are available and for which no countermeasures are available; and

(II) unknown threats for which no countermeasures are available;

(ii) that assess the ability of the Strategic National Stockpile, as appropriate, to provide medical countermeasures, medical products, and other supplies, including ancillary medical supplies, to support the response to a public health emergency or potential public health emergency, including a threat that requires the large-scale and simultaneous deployment of stockpiles and a long-term public health and medical response; and

(iii) conducted in coordination with State and local health officials.

(H) National security priority

On a periodic basis consult with, as applicable and appropriate, the Assistant to the President for National Security Affairs, to provide an update on, and discuss, medical and public health preparedness and response activities pursuant to this chapter and the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 301 et seq.], including progress on the development, approval, clearance, and licensure of medical countermeasures.

(I) Threat awareness

Coordinate with the Director of the Centers for Disease Control and Prevention, the Director of National Intelligence, the Secretary of Homeland Security, the Assistant to the President for National Security Affairs, the Secretary of Defense, and other relevant Federal officials, such as the Secretary of Agriculture, to maintain a current assessment of national security threats and inform preparedness and response capabilities based on the range of the threats that have the potential to result in a public health emergency.

(J) Medical product and supply capacity planning

Coordinate efforts within the Department of Health and Human Services to support—

(i) preparedness for medical product and medical supply needs directly related to responding to chemical, biological, radiological, or nuclear threats, including emerging infectious diseases, and incidents covered by the National Response Framework, including—

(I) sharing information, including with appropriate stakeholders, related to the anticipated need for, and availability of, such products and supplies during such responses;

(II) supporting activities, which may include public-private partnerships, to maintain capacity of medical products and medical supplies, as applicable and appropriate; and

(III) planning for potential surges in medical supply needs for purposes of a response to such a threat; and

(ii) situational awareness with respect to anticipated need for, and availability of, such medical products and medical supplies within the United States during a response to such a threat.

(5) Logistics

In coordination with the Secretary of Veterans Affairs, the Secretary of Homeland Security, the General Services Administration, and other public and private entities, provide logistical support for medical and public health aspects of Federal responses to public health emergencies. Such logistical support shall include working with other relevant Federal, State, local, Tribal, and territorial public health officials and private sector entities to identify the critical infrastructure

assets, systems, and networks needed for the proper functioning of the health care and public health sectors that need to be maintained through any emergency or disaster, including entities capable of assisting with, responding to, and mitigating the effect of a public health emergency, including a public health emergency determined by the Secretary pursuant to section 247d(a) of this title or an emergency or major disaster declared by the President under the Robert T. Stafford Disaster Relief and Emergency Assistance Act or the National Emergencies Act, including by establishing methods to exchange critical information and deliver products consumed or used to preserve, protect, or sustain life, health, or safety, and sharing of specialized expertise.

(6) Leadership

Provide leadership in international programs, initiatives, and policies that deal with public health and medical emergency preparedness and response.

(7) Countermeasures budget plan

Develop, and update not later than March 15 of each year, a coordinated 5-year budget plan based on the medical countermeasure priorities described in subsection (d), including with respect to chemical, biological, radiological, and nuclear agent or agents that may present a threat to the Nation, including such agents that are novel or emerging infectious diseases, and the corresponding efforts to develop qualified countermeasures (as defined in section 247d–6a of this title), security countermeasures (as defined in section 247d–6b of this title), and qualified pandemic or epidemic products (as defined in section 247d–6d of this title) for each such threat. Each such plan shall—

(A) include consideration of the entire medical countermeasures enterprise, including—

(i) basic research and advanced research and development;

(ii) approval, clearance, licensure, and authorized uses of products;

(iii) procurement, stockpiling, maintenance, and potential replenishment (including manufacturing capabilities) of all products in the Strategic National Stockpile;

(iv) the availability of technologies that may assist in the advanced research and development of countermeasures and opportunities to use such technologies to accelerate and navigate challenges unique to countermeasure research and development; and

(v) potential deployment, distribution, and utilization of medical countermeasures; development of clinical guidance and emergency use instructions for the use of medical countermeasures; and, as applicable, potential postdeployment activities related to medical countermeasures;

(B) inform prioritization of resources and include measurable outputs and outcomes to allow for the tracking of the progress made toward identified priorities;

(C) identify medical countermeasure life-cycle costs to inform planning, budgeting, and anticipated needs within the continuum of the medical countermeasure enterprise consistent with section 247d–6b of this title;

(D) identify the full range of anticipated medical countermeasure needs related to research and development, procurement, and stockpiling, including the potential need for indications, dosing, and administration technologies, and other countermeasure needs as applicable and appropriate;

(E) be made available, not later than March 15 of each year, to the Committee on Appropriations and the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Appropriations and the Committee on Energy and Commerce of the House of Representatives; and

(F) not later than March 15 of each year, be made publicly available in a manner that does not compromise national security.

(c) Functions

The Assistant Secretary for Preparedness and Response shall—

(1) have lead responsibility within the Department of Health and Human Services for

emergency preparedness and response policy coordination and strategic direction;

(2) have authority over and responsibility for—

(A) the National Disaster Medical System pursuant to section 300hh–11 of this title;

(B) the Hospital Preparedness Cooperative Agreement Program pursuant to section 247d–3b of this title;

(C) the Biomedical Advanced Research and Development Authority pursuant to section 247d–7e of this title;

(D) the Medical Reserve Corps pursuant to section 300hh–15 of this title;

(E) the Emergency System for Advance Registration of Volunteer Health Professionals pursuant to section 247d–7b of this title; and

(F) administering grants and related authorities related to trauma care under parts A through C of subchapter X, such authority to be transferred by the Secretary from the Administrator of the Health Resources and Services Administration to such Assistant Secretary;

(3) exercise the responsibilities and authorities of the Secretary with respect to the coordination of—

(A) the Public Health Emergency Preparedness Cooperative Agreement Program pursuant to section 247d–3a of this title;

(B) the Strategic National Stockpile pursuant to section 247d–6b of this title; and

(C) the Cities Readiness Initiative; and

(4) assume other duties as determined appropriate by the Secretary.

(d) Public Health Emergency Medical Countermeasures Enterprise Strategy and Implementation Plan

(1) In general

Not later than March 15, 2020, and biennially thereafter, the Assistant Secretary for Preparedness and Response shall develop and submit to the appropriate committees of Congress a coordinated strategy and accompanying implementation plan for medical countermeasures to address chemical, biological, radiological, and nuclear threats. In developing such a plan, the Assistant Secretary for Preparedness and Response shall consult with the Public Health Emergency Medical Countermeasures Enterprise established under section 300hh–10a of this title. Such strategy and plan shall be known as the "Public Health Emergency Medical Countermeasures Enterprise Strategy and Implementation Plan".

(2) Requirements

The plan under paragraph (1) shall—

(A) describe the chemical, biological, radiological, and nuclear agent or agents that may present a threat to the Nation and the corresponding efforts to develop qualified countermeasures (as defined in section 247d–6a of this title), security countermeasures (as defined in section 247d–6b of this title), or qualified pandemic or epidemic products (as defined in section 247d–6d of this title) for each threat;

(B) evaluate the progress of all activities with respect to such countermeasures or products, including research, advanced research, development, procurement, stockpiling, deployment, distribution, and utilization;

(C) identify and prioritize near-, mid-, and long-term needs with respect to such countermeasures or products, and ancillary medical supplies to assist with the utilization of such countermeasures or products, to address a chemical, biological, radiological, and nuclear threat or threats;

(D) identify, with respect to each category of threat, a summary of all awards and contracts, including advanced research and development and procurement, that includes—

(i) the time elapsed from the issuance of the initial solicitation or request for a proposal to the adjudication (such as the award, denial of award, or solicitation termination); and

(ii) an identification of projected timelines, anticipated funding allocations, benchmarks,

and milestones for each medical countermeasure priority under subparagraph (C), including projected needs with regard to replenishment of the Strategic National Stockpile;

(E) be informed by the recommendations of the National Biodefense Science Board pursuant to section 247d–7g of this title;

(F) evaluate progress made in meeting timelines, allocations, benchmarks, and milestones identified under subparagraph (D)(ii);

(G) report on the amount of funds available for procurement in the special reserve fund as defined in section 247d–6b(h) of this title and the impact this funding will have on meeting the requirements under section 247d–6b of this title;

(H) incorporate input from Federal, State, local, and tribal stakeholders;

(I) identify the progress made in meeting the medical countermeasure priorities for at-risk individuals (as defined in [2] 300hh–1(b)(4)(B) of this title), as applicable under subparagraph (C), including with regard to the projected needs for related stockpiling and replenishment of the Strategic National Stockpile, including by addressing the needs of pediatric populations with respect to such countermeasures and products in the Strategic National Stockpile, including—

(i) a list of such countermeasures and products necessary to address the needs of pediatric populations;

(ii) a description of measures taken to coordinate with the Office of Pediatric Therapeutics of the Food and Drug Administration to maximize the labeling, dosages, and formulations of such countermeasures and products for pediatric populations;

(iii) a description of existing gaps in the Strategic National Stockpile and the development of such countermeasures and products to address the needs of pediatric populations; and

(iv) an evaluation of the progress made in addressing priorities identified pursuant to subparagraph (C);

(J) identify the use of authority and activities undertaken pursuant to sections 247d–6a(b)(1), 247d–6a(b)(2), 247d–6a(b)(3), 247d–6a(c), 247d–6a(d), 247d–6a(e), 247d–6b(c)(7)(C)(iii), 247d–6b(c)(7)(C)(iv), and 247d–6b(c)(7)(C)(v) of this title, and subsections (a)(1), (b)(1), and (e) of section 564 of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 360bbb–3], by summarizing—

(i) the particular actions that were taken under the authorities specified, including, as applicable, the identification of the threat agent, emergency, or the biomedical countermeasure with respect to which the authority was used;

(ii) the reasons underlying the decision to use such authorities, including, as applicable, the options that were considered and rejected with respect to the use of such authorities;

(iii) the number of, nature of, and other information concerning the persons and entities that received a grant, cooperative agreement, or contract pursuant to the use of such authorities, and the persons and entities that were considered and rejected for such a grant, cooperative agreement, or contract, except that the report need not disclose the identity of any such person or entity;

(iv) whether, with respect to each procurement that is approved by the President under section 247d–6b(c)(6) of this title, a contract was entered into within one year after such approval by the President; and

(v) with respect to section 247d–6a(d) of this title, for the 2-year period for which the report is submitted, the number of persons who were paid amounts totaling $100,000 or greater and the number of persons who were paid amounts totaling at least $50,000 but less than $100,000; and

(K) be made publicly available.

(3) GAO report

(A) In general

Not later than 1 year after the date of the submission to the Congress of the first Public Health Emergency Medical Countermeasures Enterprise Strategy and Implementation Plan, the Comptroller General of the United States shall conduct an independent evaluation, and submit to the appropriate committees of Congress a report, concerning such Strategy and Implementation Plan.

(B) Content

The report described in subparagraph (A) shall review and assess—

(i) the near-term, mid-term, and long-term medical countermeasure needs and identified priorities of the Federal Government pursuant to paragraph (2)(C);

(ii) the activities of the Department of Health and Human Services with respect to advanced research and development pursuant to section 247d–7e of this title; and

(iii) the progress made toward meeting the timelines, allocations, benchmarks, and milestones identified in the Public Health Emergency Medical Countermeasures Enterprise Strategy and Implementation Plan under this subsection.

(e) Protection of national security

In carrying out subsections (b)(7) and (d), the Secretary shall ensure that information and items that could compromise national security, contain confidential commercial information, or contain proprietary information are not disclosed.

(f) Protection of national security from threats

(1) In general

In carrying out subsection (b)(3), the Assistant Secretary for Preparedness and Response shall implement strategic initiatives or activities to address threats, including pandemic influenza and which may include a chemical, biological, radiological, or nuclear agent (including any such agent with a significant potential to become a pandemic), that pose a significant level of risk to public health and national security based on the characteristics of such threat. Such initiatives shall include activities to—

(A) accelerate and support the advanced research, development, manufacturing capacity, procurement, and stockpiling of countermeasures, including initiatives under section 247d–7e(c)(4)(F) of this title;

(B) support the development and manufacturing of virus seeds, clinical trial lots, and stockpiles of novel virus strains; and

(C) maintain or improve preparedness activities, including for pandemic influenza.

(2) Authorization of appropriations

(A) In general

To carry out this subsection, there is authorized to be appropriated $250,000,000 for each of fiscal years 2019 through 2023.

(B) Supplement, not supplant

Amounts appropriated under this paragraph shall be used to supplement and not supplant funds provided under sections 247d–7e(d) and 247d–6b(g) of this title.

(C) Documentation required

The Assistant Secretary for Preparedness and Response, in accordance with subsection (b)(7), shall document amounts expended for purposes of carrying out this subsection, including amounts appropriated under the heading "Public Health and Social Services Emergency Fund" under the heading "Office of the Secretary" under title II of division H of the Consolidated Appropriations Act, 2018 (Public Law 115–141) and allocated to carrying out section 247d–7e(c)(4)(F) of this title.

(g) Appearances before Congress

(1) In general

Each fiscal year, the Assistant Secretary for Preparedness and Response shall appear before the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives at hearings, on topics such as—

(A) coordination of Federal activities to prepare for, and respond to, public health emergencies;

(B) activities and capabilities of the Strategic National Stockpile, including whether, and the degree to which, recommendations made pursuant to section 300hh–10a(c)(1)(A) of this title have been met;

(C) support for State, local, and Tribal public health and medical preparedness;

(D) activities implementing the countermeasures budget plan described under subsection (b)(7), including—

(i) any challenges in meeting the full range of identified medical countermeasure needs; and

(ii) progress in supporting advanced research, development, and procurement of medical countermeasures, pursuant to subsection (b)(3);

(E) the strategic direction of, and activities related to, the sustainment of manufacturing surge capacity and capabilities for medical countermeasures pursuant to section 247d–7e of this title and the distribution and deployment of such countermeasures;

(F) any additional objectives, activities, or initiatives that have been carried out or are planned by the Assistant Secretary for Preparedness and Response and associated challenges, as appropriate;

(G) the specific all-hazards threats that the Assistant Secretary for Preparedness and Response is preparing to address, or that are being addressed, through the activities described in subparagraphs (A) through (F); and

(H) objectives, activities, or initiatives related to the coordination and consultation required under subsections (b)(4)(H) and (b)(4)(I), in a manner consistent with paragraph (3), as appropriate.

(2) Clarifications

(A) Waiver authority

The Chair of the Committee on Health, Education, Labor, and Pensions of the Senate or the Chair of the Committee on Energy and Commerce of the House of Representatives may waive the requirements of paragraph (1) for the applicable fiscal year with respect to the applicable Committee.

(B) Scope of requirements

The requirements of this subsection shall not be construed to impact the appearance of other Federal officials or the Assistant Secretary at hearings of either Committee described in paragraph (1) at other times and for purposes other than the times and purposes described in paragraph (1) [3]

(3) Closed hearings

Information that is not appropriate for disclosure during an open hearing under paragraph (1) in order to protect national security may instead be discussed in a closed hearing that immediately follows such open hearing.

(July 1, 1944, ch. 373, title XXVIII, §2811, as added Pub. L. 109–417, title I, §102(a)(3), Dec. 19, 2006, 120 Stat. 2833; amended Pub. L. 113–5, title I, §102(a), Mar. 13, 2013, 127 Stat. 163; Pub. L. 114–255, div. A, title III, §3083, Dec. 13, 2016, 130 Stat. 1141; Pub. L. 116–22, title III, §302(a), (b), title IV, §§401, 402(b), 404(b), title V, §501, title VII, §703(b), June 24, 2019, 133 Stat. 934, 942, 943, 948, 950, 963; Pub. L. 117–263, div. G, title LXXI, §7143(d)(4), Dec. 23, 2022, 136 Stat. 3663; Pub. L. 117–328, div. FF, title II, §2103(b)(2), (c), Dec. 29, 2022, 136 Stat. 5712, 5713.)

EDITORIAL NOTES

REFERENCES IN TEXT

The Federal Food, Drug, and Cosmetic Act, referred to in subsec. (b)(4)(H), is act June 25, 1938, ch. 675, 52 Stat. 1040, which is classified generally to chapter 9 (§301 et seq.) of Title 21, Food and Drugs. For complete classification of this Act to the Code, see section 301 of Title 21 and Tables.

The Robert T. Stafford Disaster Relief and Emergency Assistance Act, referred to in subsec. (b)(5), is Pub. L. 93–288, May 22, 1974, 88 Stat. 143, which is classified principally to chapter 68 (§5121 et seq.) of this title. For complete classification of this Act to the Code, see Short Title note set out under section 5121 of this title and Tables.

The National Emergencies Act, referred to in subsec. (b)(5), is Pub. L. 94–412, Sept. 14, 1976, 90 Stat. 1255, which is classified principally to chapter 34 (§1601 et seq.) of Title 50, War and National Defense. For complete classification of this Act to the Code, see Short Title note set out under section 1601 of Title 50 and Tables.

The Consolidated Appropriations Act, 2018, referred to in subsec. (f)(2)(C), is Pub. L. 115–141, Mar. 23, 2018, 132 Stat. 348. Title II of division H of the Act is title II of div. H of Pub. L. 115–141, Mar. 23, 2018, 132 Stat. 714, which is not classified to the Code. For complete classification of this Act to the Code, see Tables.

PRIOR PROVISIONS

A prior section 2811 of act July 1, 1944, was renumbered section 2812 and is classified to section 300hh–11 of this title.

AMENDMENTS

2022—Subsec. (b)(1). Pub. L. 117–328, §2103(b)(2)(A), inserted "and, consistent with the National Response Framework and other applicable provisions of law, assist the Secretary in carrying out the functions under section 300hh of this title" after "emergencies".

Subsec. (b)(4)(D). Pub. L. 117–263 substituted "section 660(b) of title 6" for "section 228(c) of the Homeland Security Act of 2002 (6 U.S.C. 149(c))".

Subsec. (b)(4)(E). Pub. L. 117–328, §2103(b)(2)(B)(i), substituted "recommend actions necessary to overcome these obstacles, such as—" and cls. (i) to (iii) for "the actions necessary to overcome these obstacles."

Subsec. (b)(4)(G). Pub. L. 117–328, §2103(b)(2)(B)(ii), inserted "each year, including national-level and State-level full-scale exercises not less than once every 4 years" after "operational exercises", substituted "exercises—" and "(i) based on" for "exercises based on—", added cls. (ii) and (iii), and redesignated former cls. (i) and (ii) as subcls. (I) and (II), respectively, of cl. (i).

Subsec. (b)(4)(J). Pub. L. 117–328, §2103(b)(2)(B)(iii), added subpar. (J).

Subsec. (g). Pub. L. 117–328, §2103(c), added subsec. (g).

2019—Subsec. (b). Pub. L. 116–22, §401(1), inserted "utilize experience related to public health emergency preparedness and response, biodefense, medical countermeasures, and other relevant topics to" after "shall" in introductory provisions.

Subsec. (b)(4)(D). Pub. L. 116–22, §703(b), amended subpar. (D) generally. Prior to amendment, text read as follows: "Provide integrated policy coordination and strategic direction with respect to all matters related to Federal public health and medical preparedness and execution and deployment of the Federal response for public health emergencies and incidents covered by the National Response Plan developed pursuant to section 314(a)(6) of title 6, or any successor plan, before, during, and following public health emergencies."

Subsec. (b)(4)(I). Pub. L. 116–22, §401(2), added subpar. (I).

Subsec. (b)(5). Pub. L. 116–22, §302(a), inserted at end "Such logistical support shall include working with other relevant Federal, State, local, Tribal, and territorial public health officials and private sector entities to identify the critical infrastructure assets, systems, and networks needed for the proper functioning of the health care and public health sectors that need to be maintained through any emergency or disaster, including entities capable of assisting with, responding to, and mitigating the effect of a public health emergency, including a public health emergency determined by the Secretary pursuant to section 247d(a) of this title or an emergency or major disaster declared by the President under the Robert T. Stafford Disaster Relief and Emergency Assistance Act or the National Emergencies Act, including by establishing methods to exchange critical information and deliver products consumed or used to preserve, protect, or sustain life, health, or safety, and sharing of specialized expertise."

Subsec. (b)(7). Pub. L. 116–22, §501(1), substituted "March 15" for "March 1" in introductory provisions.

Subsec. (b)(7)(A)(iii) to (v). Pub. L. 116–22, §501(2), added cls. (iii) to (v) and struck out former cl. (iii)

which read as follows: "procurement, stockpiling, maintenance, and replenishment of all products in the Strategic National Stockpile;".

Subsec. (b)(7)(D) to (F). Pub. L. 116–22, §501(3), (4), added subpar. (D) and redesignated former subpars. (D) and (E) as (E) and (F), respectively.

Subsec. (d)(1). Pub. L. 116–22, §402(b)(1), substituted "Not later than March 15, 2020, and biennially thereafter" for "Not later than 180 days after March 13, 2013, and every year thereafter" and "Public Health Emergency Medical Countermeasures Enterprise established under section 300hh–10a of this title" for "Director of the Biomedical Advanced Research and Development Authority, the Director of the National Institutes of Health, the Director of the Centers for Disease Control and Prevention, and the Commissioner of Food and Drugs".

Subsec. (d)(2)(C). Pub. L. 116–22, §302(b), inserted ", and ancillary medical supplies to assist with the utilization of such countermeasures or products," after "products".

Subsec. (d)(2)(J)(v). Pub. L. 116–22, §402(b)(2), substituted "2-year period" for "one-year period".

Subsec. (f). Pub. L. 116–22, §404(b), added subsec. (f).

2016—Subsec. (b)(7). Pub. L. 114–255, §3083(1), in introductory provisions, substituted "Develop, and update not later than March 1 of each year, a coordinated 5-year budget plan based on the medical countermeasure priorities described in subsection (d), including with respect to chemical, biological, radiological, and nuclear agent or agents that may present a threat to the Nation, including such agents that are novel or emerging infectious diseases, and the corresponding efforts to develop qualified countermeasures (as defined in section 247d–6a of this title), security countermeasures (as defined in section 247d–6b of this title), and qualified pandemic or epidemic products (as defined in section 247d–6d of this title) for each such threat." for "Develop, and update on an annual basis, a coordinated 5-year budget plan based on the medical countermeasure priorities described in subsection (d)."

Subsec. (b)(7)(D). Pub. L. 114–255, §3083(3), substituted ", not later than March 15 of each year, to the Committee on Appropriations and the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Appropriations and the Committee on Energy and Commerce of the House of Representatives; and" for "to the appropriate committees of Congress upon request."

Subsec. (b)(7)(E). Pub. L. 114–255, §3083(2), (4), added subpar. (E).

2013—Subsec. (b)(3). Pub. L. 113–5, §102(a)(1)(A), inserted ", security countermeasures (as defined in section 247d–6b of this title)," after "qualified countermeasures (as defined in section 247d–6a of this title)".

Subsec. (b)(4)(D) to (H). Pub. L. 113–5, §102(a)(1)(B), added subpars. (D) to (H).

Subsec. (b)(7). Pub. L. 113–5, §102(a)(1)(C), added par. (7).

Subsec. (c). Pub. L. 113–5, §102(a)(2), added subsec. (c) and struck out former subsec. (c) which directed that the Assistant Secretary would have authority over and responsibility for the National Disaster Medical System and the Hospital Preparedness Cooperative Agreement Program, would exercise the responsibilities and authorities of the Secretary with respect to the coordination of the Medical Reserve Corps, the Emergency System for Advance Registration of Volunteer Health Professionals, the Strategic National Stockpile, and the Cities Readiness Initiative, and would assume other duties as determined appropriate by the Secretary.

Subsecs. (d), (e). Pub. L. 113–5, §102(a)(3), added subsecs. (d) and (e).

STATUTORY NOTES AND RELATED SUBSIDIARIES

TRANSFER OF FUNCTIONS

Pub. L. 109–417, title I, §102(b), Dec. 19, 2006, 120 Stat. 2834, provided that:

"(1) TRANSFER OF FUNCTIONS.—There shall be transferred to the Office of the Assistant Secretary for Preparedness and Response the functions, personnel, assets, and liabilities of the Assistant Secretary for Public Health Emergency Preparedness as in effect on the day before the date of enactment of this Act [Dec. 19, 2006].

"(2) REFERENCES.—Any reference in any Federal law, Executive order, rule, regulation, or delegation of authority, or any document of or pertaining to the Assistant Secretary for Public Health Emergency Preparedness as in effect the day before the date of enactment of this Act, shall be deemed to be a reference to the Assistant Secretary for Preparedness and Response."

INTERAGENCY COORDINATION PLAN

Pub. L. 113–5, title I, §102(b), Mar. 13, 2013, 127 Stat. 168, provided that: "In the first Public Health Emergency [Medical] Countermeasures Enterprise Strategy and Implementation Plan submitted under subsection (d) of section 2811 of the Public Health Service Act (42 U.S.C. 300hh–10) (as added by subsection (a)(3)), the Secretary of Health and Human Services, in consultation with the Secretary of Defense, shall

include a description of the manner in which the Department of Health and Human Services is coordinating with the Department of Defense regarding countermeasure activities to address chemical, biological, radiological, and nuclear threats. Such report shall include information with respect to—

"(1) the research, advanced research, development, procurement, stockpiling, and distribution of countermeasures to meet identified needs; and

"(2) the coordination of efforts between the Department of Health and Human Services and the Department of Defense to address countermeasure needs for various segments of the population."

[1] *So in original. Probably should be followed by a dash.*

[2] *So in original. The word "section" probably should appear.*

[3] *So in original. Probably should be followed by a period.*

§300hh–10a. Public Health Emergency Medical Countermeasures Enterprise

(a) In general

The Secretary shall establish the Public Health Emergency Medical Countermeasures Enterprise (referred to in this section as the "PHEMCE"). The Assistant Secretary for Preparedness and Response and the Director of the Office of Pandemic Preparedness and Response Policy shall serve as co-chairs of the PHEMCE.

(b) Members

The PHEMCE shall include each of the following members, or the designee of such members:

(1) The Assistant Secretary for Preparedness and Response.
(2) The Director of the Centers for Disease Control and Prevention.
(3) The Director of the National Institutes of Health.
(4) The Commissioner of Food and Drugs.
(5) The Secretary of Defense.
(6) The Secretary of Homeland Security.
(7) The Secretary of Agriculture.
(8) The Secretary of Veterans Affairs.
(9) The Director of National Intelligence.
(10) The Director of the Office of Pandemic Preparedness and Response Policy.
(11) Representatives of any other Federal agency, which may include the Director of the Biomedical Advanced Research and Development Authority, the Director of the Strategic National Stockpile, the Director of the National Institute of Allergy and Infectious Diseases, and the Director of the Office of Public Health Preparedness and Response, as the Secretary determines appropriate.

(c) Functions

(1) In general

The functions of the PHEMCE shall include the following:

(A) Utilize a process to make recommendations to the Secretary regarding research, advanced research, development, procurement, stockpiling, deployment, distribution, and utilization with respect to countermeasures, as defined in section 247d–6b(c) of this title, including prioritization based on the health security needs of the United States. Such recommendations shall be informed by, when available and practicable, the National Health Security Strategy pursuant to section 300hh–1 of this title, the Strategic National Stockpile needs pursuant to section 247d–6b of this title, and assessments of current national security threats, including chemical, biological, radiological, and nuclear threats, including emerging infectious diseases. In the event that members of the PHEMCE do not agree upon a recommendation, the Secretary shall provide a determination regarding such recommendation.

(B) Identify national health security needs, including gaps in public health preparedness and response related to countermeasures and challenges to addressing such needs (including any regulatory challenges), and support alignment of countermeasure procurement with recommendations to address such needs under subparagraph (A).

(C) Assist the Secretary in developing strategies related to logistics, deployment, distribution, dispensing, and use of countermeasures that may be applicable to the activities of the strategic national stockpile under section 247d–6b(a) of this title.

(D) Provide consultation for the development of the strategy and implementation plan under section 300hh–10(d) of this title.

(2) Input

In carrying out subparagraphs (B) and (C) of paragraph (1), the PHEMCE shall solicit and consider input from State, local, Tribal, and territorial public health departments or officials, as appropriate.

(July 1, 1944, ch. 373, title XXVIII, §2811–1, as added Pub. L. 116–22, title IV, §402(a), June 24, 2019, 133 Stat. 942; amended Pub. L. 117–328, div. FF, title II, §2104(k)(1), Dec. 29, 2022, 136 Stat. 5719.)

EDITORIAL NOTES

PRIOR PROVISIONS

A prior section 300hh–10a, act July 1, 1944, ch. 373, title XXVIII, §2811A, as added Pub. L. 113–5, title I, §103, Mar. 13, 2013, 127 Stat. 168; amended Pub. L. 116–22, title III, §305(a), June 24, 2019, 133 Stat. 936, which related to the National Advisory Committee on Children and Disasters, was transferred to section 300hh–10b of this title.

AMENDMENTS

2022—Subsec. (a). Pub. L. 117–328, §2104(k)(1)(A), substituted "and the Director of the Office of Pandemic Preparedness and Response Policy shall serve as co-chairs" for "shall serve as chair".

Subsec. (b)(10), (11). Pub. L. 117–328, §2104(k)(1)(B), added par. (10) and redesignated former par. (10) as (11).

§300hh–10b. National Advisory Committee on Children and Disasters

(a) Establishment

The Secretary, in consultation with the Secretary of Homeland Security, shall establish an advisory committee to be known as the "National Advisory Committee on Children and Disasters" (referred to in this section as the "Advisory Committee").

(b) Duties

The Advisory Committee shall—

(1) provide advice and consultation with respect to the activities carried out pursuant to section 300hh–16 of this title, as applicable and appropriate;

(2) evaluate and provide input with respect to the medical, mental, behavioral, developmental, and public health needs of children as they relate to preparation for, response to, and recovery from all-hazards emergencies;

(3) provide advice and consultation with respect to State emergency preparedness and response activities and children, including related drills and exercises pursuant to the preparedness goals under section 300hh–1(b) of this title; and

(4) provide advice and consultation with respect to continuity of care and education for all children and supporting parents and caregivers during all-hazards emergencies.

(c) Additional duties

The Advisory Committee may provide advice and recommendations to the Secretary with respect

to children and the medical and public health grants and cooperative agreements as applicable to preparedness and response activities authorized under this subchapter and subchapter II.

(d) Membership

(1) In general

The Secretary, in consultation with such other Secretaries as may be appropriate, shall appoint not to exceed 25 members to the Advisory Committee. In appointing such members, the Secretary shall ensure that the total membership of the Advisory Committee is an odd number.

(2) Required non-Federal members

The Secretary, in consultation with such other heads of Federal agencies as may be appropriate, shall appoint to the Advisory Committee under paragraph (1) at least 13 individuals, including—

(A) at least 2 non-Federal professionals with expertise in pediatric medical disaster planning, preparedness, response, or recovery;

(B) at least 2 representatives from State, local, Tribal, or territorial agencies with expertise in pediatric disaster planning, preparedness, response, or recovery;

(C) at least 4 members representing health care professionals, which may include members with expertise in pediatric emergency medicine; pediatric trauma, critical care, or surgery; the treatment of pediatric patients affected by chemical, biological, radiological, or nuclear agents, including emerging infectious diseases; pediatric mental or behavioral health related to children affected by a public health emergency; or pediatric primary care;

(D) at least 4 non-Federal members representing child care settings, State or local educational agencies, individuals with expertise in children with disabilities, and parents; and

(E) other members as the Secretary determines appropriate, of whom—

(i) at least one such member shall represent a children's hospital;

(ii) at least one such member shall be an individual with expertise in children and youth with special health care needs; and

(iii) at least one such member shall be an individual with expertise in the needs of parents or family caregivers, including the parents or caregivers of children with disabilities.

(3) Federal members

The Advisory Committee under paragraph (1) shall include the following Federal members or their designees (who may be nonvoting members, as determined by the Secretary):

(A) The Assistant Secretary for Preparedness and Response.

(B) The Director of the Biomedical Advanced Research and Development Authority.

(C) The Director of the Centers for Disease Control and Prevention.

(D) The Commissioner of Food and Drugs.

(E) The Director of the National Institutes of Health.

(F) The Assistant Secretary of the Administration for Children and Families.

(G) The Administrator of the Health Resources and Services Administration.

(H) The Administrator of the Federal Emergency Management Agency.

(I) The Administrator of the Administration for Community Living.

(J) The Secretary of Education.

(K) Representatives from such Federal agencies (such as the Substance Abuse and Mental Health Services Administration and the Department of Homeland Security) as the Secretary determines appropriate to fulfill the duties of the Advisory Committee under subsections (b) and (c).

(4) Term of appointment

Each member of the Advisory Committee appointed under paragraph (2) shall serve for a term of 3 years, except that the Secretary may adjust the terms of the Advisory Committee appointees serving on June 24, 2019, or appointees who are initially appointed after such date, in order to provide for a staggered term of appointment for all members.

(5) Consecutive appointments; maximum terms

A member appointed under paragraph (2) may serve not more than 3 terms on the Advisory Committee, and not more than two of such terms may be served consecutively.

(e) Meetings

The Advisory Committee shall meet not less than biannually. At least one meeting per year shall be an in-person meeting.

(f) Coordination

The Secretary shall coordinate duties and activities authorized under this section in accordance with section 300hh–10e of this title.

(g) Sunset

The Advisory Committee shall terminate on December 31, 2026.

(July 1, 1944, ch. 373, title XXVIII, §2811A, as added Pub. L. 113–5, title I, §103, Mar. 13, 2013, 127 Stat. 168; amended Pub. L. 116–22, title III, §305(a), June 24, 2019, 133 Stat. 936; Pub. L. 117–328, div. FF, title II, §2236, Dec. 29, 2022, 136 Stat. 5756; Pub. L. 118–15, div. B, title III, §2333(a), Sept. 30, 2023, 137 Stat. 96; Pub. L. 118–22, div. B, title II, §203(d)(1), Nov. 17, 2023, 137 Stat. 121; Pub. L. 118–35, div. B, title I, §103(d)(1), Jan. 19, 2024, 138 Stat. 5; Pub. L. 118–42, div. G, title I, §103(d)(1), Mar. 9, 2024, 138 Stat. 398; Pub. L. 118–158, div. C, title I, §3103(d)(1), Dec. 21, 2024, 138 Stat. 1763; Pub. L. 119–4, div. B, title I, §2103(d)(1), Mar. 15, 2025, 139 Stat. 41; Pub. L. 119–37, div. F, title I, §6103(d)(1), Nov. 12, 2025, 139 Stat. 630; Pub. L. 119–75, div. J, title IV, §6403(d), Feb. 3, 2026, 140 Stat. 688.)

EDITORIAL NOTES

CODIFICATION

Section was formerly classified to section 300hh–10a of this title.

AMENDMENTS

2026—Subsec. (g). Pub. L. 119–75 substituted "December 31, 2026" for "January 30, 2026".

2025—Subsec. (g). Pub. L. 119–37 substituted "January 30, 2026" for "September 30, 2025".

Pub. L. 119–4 substituted "September 30, 2025" for "March 31, 2025".

2024—Subsec. (g). Pub. L. 118–158 substituted "March 31, 2025" for "December 31, 2024".

Pub. L. 118–42 substituted "December 31, 2024" for "March 8, 2024".

Pub. L. 118–35 substituted "March 8, 2024" for "January 19, 2024".

2023—Subsec. (g). Pub. L. 118–22 substituted "January 19, 2024" for "November 17, 2023".

Pub. L. 118–15 substituted "November 17, 2023" for "September 30, 2023".

2022—Subsec. (b)(2). Pub. L. 117–328, §2236(1)(A)(i), substituted ", behavioral, developmental" for "and behavioral".

Subsec. (b)(4). Pub. L. 117–328, §2236(1)(A)(ii)–(C), added par. (4).

Subsec. (d)(2)(D), (E). Pub. L. 117–328, §2236(2)(A)–(C), added subpar. (D) and redesignated former subpar. (D) as (E).

Subsec. (d)(2)(E)(ii) to (iv). Pub. L. 117–328, §2236(2)(D), redesignated cls. (iii) and (iv) as (ii) and (iii), respectively, and struck out former cl. (ii) which read as follows: "at least one such member shall be an individual with expertise in schools or child care settings;".

2019—Subsec. (b)(2). Pub. L. 116–22, §305(a)(1), inserted ", mental and behavioral," after "medical".

Subsec. (d)(1). Pub. L. 116–22, §305(a)(2)(A), substituted "25 members" for "15 members".

Subsec. (d)(2) to (5). Pub. L. 116–22, §305(a)(2)(B), added pars. (2) to (5) and struck out former par. (2) which related to required members of the Advisory Committee.

Subsec. (e). Pub. L. 116–22, §305(a)(3), inserted at end "At least one meeting per year shall be an in-person meeting."

Subsec. (f). Pub. L. 116–22, §305(a)(5), added subsec. (f). Former subsec. (f) redesignated (g).

Subsec. (g). Pub. L. 116–22, §305(a)(4), (6), redesignated subsec. (f) as (g) and substituted "2023" for "2018".

§300hh–10c. National Advisory Committee on Seniors and Disasters

(a) Establishment

The Secretary, in consultation with the Secretary of Homeland Security and the Secretary of Veterans Affairs, shall establish an advisory committee to be known as the National Advisory Committee on Seniors and Disasters (referred to in this section as the "Advisory Committee").

(b) Duties

The Advisory Committee shall—

(1) provide advice and consultation with respect to the activities carried out pursuant to section 300hh–16 of this title, as applicable and appropriate;

(2) evaluate and provide input with respect to the medical and public health needs of seniors related to preparation for, response to, and recovery from all-hazards emergencies; and

(3) provide advice and consultation with respect to State emergency preparedness and response activities relating to seniors, including related drills and exercises pursuant to the preparedness goals under section 300hh–1(b) of this title.

(c) Additional duties

The Advisory Committee may provide advice and recommendations to the Secretary with respect to seniors and the medical and public health grants and cooperative agreements as applicable to preparedness and response activities under this subchapter and subchapter III.

(d) Membership

(1) In general

The Secretary, in consultation with such other heads of agencies as appropriate, shall appoint not more than 17 members to the Advisory Committee. In appointing such members, the Secretary shall ensure that the total membership of the Advisory Committee is an odd number.

(2) Required members

The Advisory Committee shall include Federal members or their designees (who may be nonvoting members, as determined by the Secretary) and non-Federal members, as follows:

(A) The Assistant Secretary for Preparedness and Response.

(B) The Director of the Biomedical Advanced Research and Development Authority.

(C) The Director of the Centers for Disease Control and Prevention.

(D) The Commissioner of Food and Drugs.

(E) The Director of the National Institutes of Health.

(F) The Administrator of the Centers for Medicare & Medicaid Services.

(G) The Administrator of the Administration for Community Living.

(H) The Administrator of the Federal Emergency Management Agency.

(I) The Under Secretary for Health of the Department of Veterans Affairs.

(J) At least 2 non-Federal health care professionals with expertise in geriatric medical disaster planning, preparedness, response, or recovery.

(K) At least 2 representatives of State, local, Tribal, or territorial agencies with expertise in geriatric disaster planning, preparedness, response, or recovery.

(L) Representatives of such other Federal agencies (such as the Department of Energy and the Department of Homeland Security) as the Secretary determines necessary to fulfill the duties of the Advisory Committee.

(e) Meetings

The Advisory Committee shall meet not less frequently than biannually. At least one meeting per year shall be an in-person meeting.

(f) Coordination

The Secretary shall coordinate duties and activities authorized under this section in accordance with section 300hh–10e of this title.

(g) Sunset

(1) In general

The Advisory Committee shall terminate on December 31, 2026.

(2) Extension of Committee

Not later than October 1, 2022, the Secretary shall submit to Congress a recommendation on whether the Advisory Committee should be extended.

(July 1, 1944, ch. 373, title XXVIII, §2811B, as added Pub. L. 116–22, title III, §305(b), June 24, 2019, 133 Stat. 938; amended Pub. L. 118–15, div. B, title III, §2333(b), Sept. 30, 2023, 137 Stat. 96; Pub. L. 118–22, div. B, title II, §203(d)(2), Nov. 17, 2023, 137 Stat. 121; Pub. L. 118–35, div. B, title I, §103(d)(2), Jan. 19, 2024, 138 Stat. 5; Pub. L. 118–42, div. G, title I, §103(d)(2), Mar. 9, 2024, 138 Stat. 398; Pub. L. 118–158, div. C, title I, §3103(d)(2), Dec. 21, 2024, 138 Stat. 1764; Pub. L. 119–4, div. B, title I, §2103(d)(2), Mar. 15, 2025, 139 Stat. 41; Pub. L. 119–37, div. F, title I, §6103(d)(2), Nov. 12, 2025, 139 Stat. 630; Pub. L. 119–75, div. J, title IV, §6403(e), Feb. 3, 2026, 140 Stat. 688.)

EDITORIAL NOTES

AMENDMENTS

2026—Subsec. (g)(1). Pub. L. 119–75 substituted "December 31, 2026" for "January 30, 2026".
2025—Subsec. (g)(1). Pub. L. 119–37 substituted "January 30, 2026" for "September 30, 2025".
Pub. L. 119–4 substituted "September 30, 2025" for "March 31, 2025".
2024—Subsec. (g)(1). Pub. L. 118–158 substituted "March 31, 2025" for "December 31, 2024".
Pub. L. 118–42 substituted "December 31, 2024" for "March 8, 2024".
Pub. L. 118–35 substituted "March 8, 2024" for "January 19, 2024".
2023—Subsec. (g)(1). Pub. L. 118–22 substituted "January 19, 2024" for "November 17, 2023".
Pub. L. 118–15 substituted "November 17, 2023" for "September 30, 2023".

§300hh–10d. National Advisory Committee on Individuals With Disabilities and Disasters

(a) Establishment

The Secretary, in consultation with the Secretary of Homeland Security, shall establish a national advisory committee to be known as the National Advisory Committee on Individuals with Disabilities and Disasters (referred to in this section as the "Advisory Committee").

(b) Duties

The Advisory Committee shall—

(1) provide advice and consultation with respect to activities carried out pursuant to section 300hh–16 of this title, as applicable and appropriate;

(2) evaluate and provide input with respect to the medical, public health, and accessibility needs of individuals with disabilities related to preparation for, response to, and recovery from all-hazards emergencies; and

(3) provide advice and consultation with respect to State emergency preparedness and response activities, including related drills and exercises pursuant to the preparedness goals under section 300hh–1(b) of this title.

(c) Membership

(1) In general

The Secretary, in consultation with such other heads of agencies and departments as appropriate, shall appoint not more than 17 members to the Advisory Committee. In appointing such members, the Secretary shall ensure that the total membership of the Advisory Committee is

an odd number.

(2) Required members

The Advisory Committee shall include Federal members or their designees (who may be nonvoting members, as determined by the Secretary) and non-Federal members, as follows:

(A) The Assistant Secretary for Preparedness and Response.

(B) The Administrator of the Administration for Community Living.

(C) The Director of the Biomedical Advanced Research and Development Authority.

(D) The Director of the Centers for Disease Control and Prevention.

(E) The Commissioner of Food and Drugs.

(F) The Director of the National Institutes of Health.

(G) The Administrator of the Federal Emergency Management Agency.

(H) The Chair of the National Council on Disability.

(I) The Chair of the United States Access Board.

(J) The Under Secretary for Health of the Department of Veterans Affairs.

(K) At least 2 non-Federal health care professionals with expertise in disability accessibility before, during, and after disasters, medical and mass care disaster planning, preparedness, response, or recovery.

(L) At least 2 representatives from State, local, Tribal, or territorial agencies with expertise in disaster planning, preparedness, response, or recovery for individuals with disabilities.

(M) At least 2 individuals with a disability with expertise in disaster planning, preparedness, response, or recovery for individuals with disabilities.

(d) Meetings

The Advisory Committee shall meet not less frequently than biannually. At least one meeting per year shall be an in-person meeting.

(e) Disability defined

For purposes of this section, the term "disability" has the meaning given such term in section 12102 of this title.

(f) Coordination

The Secretary shall coordinate duties and activities authorized under this section in accordance with section 300hh–10e of this title.

(g) Sunset

(1) In general

The Advisory Committee shall terminate on December 31, 2026.

(2) Recommendation

Not later than October 1, 2022, the Secretary shall submit to Congress a recommendation on whether the Advisory Committee should be extended.

(July 1, 1944, ch. 373, title XXVIII, §2811C, as added Pub. L. 116–22, title III, §305(c), June 24, 2019, 133 Stat. 939; amended Pub. L. 118–15, div. B, title III, §2333(c), Sept. 30, 2023, 137 Stat. 96; Pub. L. 118–22, div. B, title II, §203(d)(3), Nov. 17, 2023, 137 Stat. 121; Pub. L. 118–35, div. B, title I, §103(d)(3), Jan. 19, 2024, 138 Stat. 5; Pub. L. 118–42, div. G, title I, §103(d)(3), Mar. 9, 2024, 138 Stat. 398; Pub. L. 118–158, div. C, title I, §3103(d)(3), Dec. 21, 2024, 138 Stat. 1764; Pub. L. 119–4, div. B, title I, §2103(d)(3), Mar. 15, 2025, 139 Stat. 41; Pub. L. 119–37, div. F, title I, §6103(d)(3), Nov. 12, 2025, 139 Stat. 630; Pub. L. 119–75, div. J, title IV, §6403(f), Feb. 3, 2026, 140 Stat. 688.)

EDITORIAL NOTES

AMENDMENTS

2026—Subsec. (g)(1). Pub. L. 119–75 substituted "December 31, 2026" for "January 30, 2026".

2025—Subsec. (g)(1). Pub. L. 119–37 substituted "January 30, 2026" for "September 30, 2025".
Pub. L. 119–4 substituted "September 30, 2025" for "March 31, 2025".
2024—Subsec. (g)(1). Pub. L. 118–158 substituted "March 31, 2025" for "December 31, 2024".
Pub. L. 118–42 substituted "December 31, 2024" for "March 8, 2024".
Pub. L. 118–35 substituted "March 8, 2024" for "January 19, 2024".
2023—Subsec. (g)(1). Pub. L. 118–22 substituted "January 19, 2024" for "November 17, 2023".
Pub. L. 118–15 substituted "November 17, 2023" for "September 30, 2023".

§300hh–10e. Advisory Committee Coordination

(a) In general

The Secretary shall coordinate duties and activities authorized under sections 300hh–10b, 300hh–10c, and 300hh–10d of this title, and make efforts to reduce unnecessary or duplicative reporting, or unnecessary duplicative meetings and recommendations under such sections, as practicable. Members of the advisory committees authorized under such sections, or their designees, shall annually meet to coordinate any recommendations, as appropriate, that may be similar, duplicative, or overlapping with respect to addressing the needs of children, seniors, and individuals with disabilities during public health emergencies. If such coordination occurs through an in-person meeting, it shall not be considered the required in-person meetings under any of sections 300hh–10b(e), 300hh–10c(e), or 300hh–10d(d) of this title.

(b) Coordination and alignment

The Secretary, acting through the employee designated pursuant to section 300hh–16 of this title, shall align preparedness and response programs or activities to address similar, dual, or overlapping needs of children, seniors, and individuals with disabilities, and any challenges in preparing for and responding to such needs.

(c) Notification

The Secretary shall annually notify the congressional committees of jurisdiction regarding the steps taken to coordinate, as appropriate, the recommendations under this section, and provide a summary description of such coordination.

(July 1, 1944, ch. 373, title XXVIII, §2811D, as added Pub. L. 116–22, title III, §305(d), June 24, 2019, 133 Stat. 941.)

§300hh–11. National Disaster Medical System

(a) National Disaster Medical System

(1) In general

The Secretary shall provide for the operation in accordance with this section of a system to be known as the National Disaster Medical System. The Secretary shall designate the Assistant Secretary for Preparedness and Response as the head of the National Disaster Medical System, subject to the authority of the Secretary.

(2) Federal and State collaborative System

(A) In general

The National Disaster Medical System shall be a coordinated effort by the Federal agencies specified in subparagraph (B), working in collaboration with the States and other appropriate public or private entities, to carry out the purposes described in paragraph (3).

(B) Participating Federal agencies

The Federal agencies referred to in subparagraph (A) are the Department of Health and Human Services, the Department of Homeland Security, the Department of Defense, and the

Department of Veterans Affairs.

(3) Purpose of System

(A) In general

The Secretary may activate the National Disaster Medical System to—

(i) provide health services, health-related social services, other appropriate human services, and appropriate auxiliary services to respond to the needs of victims of a public health emergency, including at-risk individuals as applicable (whether or not determined to be a public health emergency under section 247d of this title); or

(ii) be present at locations, and for limited periods of time, specified by the Secretary on the basis that the Secretary has determined that a location is at risk of a public health emergency during the time specified, or there is a significant potential for a public health emergency.

(B) Ongoing activities

The National Disaster Medical System shall carry out such ongoing activities as may be necessary to prepare for the provision of services described in subparagraph (A) in the event that the Secretary activates the National Disaster Medical System for such purposes.

(C) Considerations for at-risk populations

The Secretary shall take steps to ensure that an appropriate specialized and focused range of public health and medical capabilities are [1] represented in the National Disaster Medical System, which take [2] into account the needs of at-risk individuals, in the event of a public health emergency.

(D) Administration

The Secretary may determine and pay claims for reimbursement for services under subparagraph (A) directly or through contracts that provide for payment in advance or by way of reimbursement.

(E) Test for mobilization of System

During the one-year period beginning on December 19, 2006, the Secretary shall conduct an exercise to test the capability and timeliness of the National Disaster Medical System to mobilize and otherwise respond effectively to a bioterrorist attack or other public health emergency that affects two or more geographic locations concurrently. Thereafter, the Secretary may periodically conduct such exercises regarding the National Disaster Medical System as the Secretary determines to be appropriate.

(b) Modifications

(1) In general

Taking into account the findings from the joint review described under paragraph (2), the Secretary shall modify the policies of the National Disaster Medical System as necessary.

(2) Joint review and medical surge capacity strategic plan

(A) Review

Not later than 180 days after June 24, 2019, the Secretary, in coordination with the Secretary of Homeland Security, the Secretary of Defense, and the Secretary of Veterans Affairs, shall conduct a joint review of the National Disaster Medical System. Such review shall include—

(i) an evaluation of medical surge capacity, as described in section 300hh–2(a) of this title;

(ii) an assessment of the available workforce of the intermittent disaster response personnel described in subsection (c);

(iii) the capacity of the workforce described in clause (ii) to respond to all hazards, including capacity to simultaneously respond to multiple public health emergencies and the capacity to respond to a nationwide public health emergency;

(iv) the effectiveness of efforts to recruit, retain, and train such workforce; and
(v) gaps that may exist in such workforce and recommendations for addressing such gaps.

(B) Updates

As part of the National Health Security Strategy under section 300hh–1 of this title, the Secretary shall update the findings from the review under subparagraph (A) and provide recommendations to modify the policies of the National Disaster Medical System as necessary.

(3) Participation agreements for non-Federal entities

In carrying out paragraph (1), the Secretary shall establish criteria regarding the participation of States and private entities in the National Disaster Medical System, including criteria regarding agreements for such participation. The criteria shall include the following:

(A) Provisions relating to the custody and use of Federal personal property by such entities, which may in the discretion of the Secretary include authorizing the custody and use of such property to respond to emergency situations for which the National Disaster Medical System has not been activated by the Secretary pursuant to subsection (a)(3)(A). Any such custody and use of Federal personal property shall be on a reimbursable basis.

(B) Provisions relating to circumstances in which an individual or entity has agreements with both the National Disaster Medical System and another entity regarding the provision of emergency services by the individual. Such provisions shall address the issue of priorities among the agreements involved.

(c) Intermittent disaster-response personnel

(1) In general

For the purpose of assisting the National Disaster Medical System in carrying out duties under this section, the Secretary may appoint individuals to serve as intermittent personnel of such System in accordance with applicable civil service laws and regulations.

(2) Liability

For purposes of section 233(a) of this title and the remedies described in such section, an individual appointed under paragraph (1) shall, while acting within the scope of such appointment, be considered to be an employee of the Public Health Service performing medical, surgical, dental, or related functions. With respect to the participation of individuals appointed under paragraph (1) in training programs authorized by the Assistant Secretary for Preparedness and Response or a comparable official of any Federal agency specified in subsection (a)(2)(B), acts of individuals so appointed that are within the scope of such participation shall be considered within the scope of the appointment under paragraph (1) (regardless of whether the individuals receive compensation for such participation).

(3) Notification

Not later than 30 days after the date on which the Secretary determines the number of intermittent disaster-response personnel of the National Disaster Medical System is insufficient to address a public health emergency or potential public health emergency, the Secretary shall submit to the congressional committees of jurisdiction a notification detailing—

(A) the impact such shortage could have on meeting public health needs and emergency medical personnel needs during a public health emergency; and

(B) any identified measures to address such shortage.

(4) Certain appointments

(A) In general

If the Secretary determines that the number of intermittent disaster response personnel within the National Disaster Medical System under this section is insufficient to address a public health emergency or potential public health emergency, the Secretary may appoint candidates directly to personnel positions for intermittent disaster response within such system. The Secretary shall provide updates on the number of vacant or unfilled positions within such

system to the congressional committees of jurisdiction each quarter for which this authority is in effect.

(B) Sunset

The authority under this paragraph shall expire on December 31, 2026.

(5) Omitted

(d) Certain employment issues regarding intermittent appointments

(1) Intermittent disaster-response appointee

For purposes of this subsection, the term "intermittent disaster-response appointee" means an individual appointed by the Secretary under subsection (c).

(2) Compensation for work injuries

(A) In general

An intermittent disaster-response appointee shall, while acting in the scope of such appointment, be considered to be an employee of the Public Health Service performing medical, surgical, dental, or related functions, and an injury sustained by such an individual shall be deemed "in the performance of duty", for purposes of chapter 81 of title 5 pertaining to compensation for work injuries.

(B) Application to training programs

With respect to the participation of individuals appointed under subsection (c) in training programs authorized by the Assistant Secretary for Preparedness and Response or a comparable official of any Federal agency specified in subsection (a)(2)(B), injuries sustained by such an individual, while acting within the scope of such participation, also shall be deemed "in the performance of duty" for purposes of chapter 81 of title 5 (regardless of whether the individuals receive compensation for such participation).

(C) Responsibility of Labor Secretary

In the event of an injury to such an intermittent disaster-response appointee, the Secretary of Labor shall be responsible for making determinations as to whether the claimant is entitled to compensation or other benefits in accordance with chapter 81 of title 5.

(D) Computation of pay

In the event of an injury to such an intermittent disaster response appointee, the position of the employee shall be deemed to be "one which would have afforded employment for substantially a whole year", for purposes of section 8114(d)(2) of such title.

(E) Continuation of pay

The weekly pay of such an employee shall be deemed to be the hourly pay in effect on the date of the injury multiplied by 40, for purposes of computing benefits under section 8118 of such title.

(3) Employment and reemployment rights

(A) In general

Service as an intermittent disaster-response appointee when the Secretary activates the National Disaster Medical System or when the individual participates in a training program authorized by the Assistant Secretary for Preparedness and Response or a comparable official of any Federal agency specified in subsection (a)(2)(B) shall be deemed "service in the uniformed services" for purposes of chapter 43 of title 38 pertaining to employment and reemployment rights of individuals who have performed service in the uniformed services (regardless of whether the individual receives compensation for such participation). All rights and obligations of such persons and procedures for assistance, enforcement, and investigation shall be as provided for in chapter 43 of title 38.

(B) Notice of absence from position of employment

Preclusion of giving notice of service by necessity of Service as an intermittent disaster-response appointee when the Secretary activates the National Disaster Medical System shall be deemed preclusion by "military necessity" for purposes of section 4312(b) of title 38 pertaining to giving notice of absence from a position of employment. A determination of such necessity shall be made by the Secretary, in consultation with the Secretary of Defense, and shall not be subject to judicial review.

(4) Limitation

An intermittent disaster-response appointee shall not be deemed an employee of the Department of Health and Human Services for purposes other than those specifically set forth in this section.

(e) Rule of construction regarding use of commissioned corps

If the Secretary assigns commissioned officers of the Regular or Reserve Corps [3] to serve with the National Disaster Medical System, such assignments do not affect the terms and conditions of their appointments as commissioned officers of the Regular or Reserve Corps, respectively (including with respect to pay and allowances, retirement, benefits, rights, privileges, and immunities).

(f) Definition

For purposes of this section, the term "auxiliary services" includes mortuary services, veterinary services, and other services that are determined by the Secretary to be appropriate with respect to the needs referred to in subsection (a)(3)(A).

(g) Authorization of appropriations

For the purpose of providing for the Assistant Secretary for Preparedness and Response and the operations of the National Disaster Medical System, other than purposes for which amounts in the Public Health Emergency Fund under section 247d of this title are available, there are authorized to be appropriated $57,400,000 for each of fiscal years 2019 through 2023.

(July 1, 1944, ch. 373, title XXVIII, §2812, formerly §2811, as added Pub. L. 107–188, title I, §102(a), June 12, 2002, 116 Stat. 599; renumbered §2812 and amended Pub. L. 109–417, title I, §102(a)(2), (4), title III, §301(a), Dec. 19, 2006, 120 Stat. 2832, 2834, 2853; Pub. L. 113–5, title I, §104, Mar. 13, 2013, 127 Stat. 170; Pub. L. 114–113, div. H, title V, §527, Dec. 18, 2015, 129 Stat. 2653; Pub. L. 116–22, title III, §301(a), (d)(1), June 24, 2019, 133 Stat. 931, 933; Pub. L. 117–43, div. D, title I, §3101, Sept. 30, 2021, 135 Stat. 379; Pub. L. 117–70, div. C, title I, §2101, Dec. 3, 2021, 135 Stat. 1504; Pub. L. 117–86, div. B, title I, §1101, Feb. 18, 2022, 136 Stat. 17; Pub. L. 117–103, div. P, title I, §101, Mar. 15, 2022, 136 Stat. 789; Pub. L. 118–15, div. B, title III, §2331, Sept. 30, 2023, 137 Stat. 95; Pub. L. 118–22, div. B, title II, §203(e), Nov. 17, 2023, 137 Stat. 121; Pub. L. 118–35, div. B, title I, §103(e), Jan. 19, 2024, 138 Stat. 5; Pub. L. 118–42, div. G, title I, §103(e), Mar. 9, 2024, 138 Stat. 399; Pub. L. 118–158, div. C, title I, §3103(e), Dec. 21, 2024, 138 Stat. 1764; Pub. L. 119–4, div. B, title I, §2103(e), Mar. 15, 2025, 139 Stat. 41; Pub. L. 119–37, div. F, title I, §6103(e), Nov. 12, 2025, 139 Stat. 630; Pub. L. 119–75, div. J, title IV, §6403(g), Feb. 3, 2026, 140 Stat. 688.)

EDITORIAL NOTES

CODIFICATION

Subsec. (c)(5) of this section was omitted in light of section 301(d)(3) of Pub. L. 116–22, which provided that the amendment adding subsec. (c)(5) would cease to have force or effect on Oct. 1, 2021. See 2019 Amendment and Termination Date of 2019 Amendment notes below.

AMENDMENTS

2026—Subsec. (c)(4)(B). Pub. L. 119–75 substituted "December 31, 2026" for "January 30, 2026".
2025—Subsec. (c)(4)(B). Pub. L. 119–37 substituted "January 30, 2026" for "September 30, 2025".
Pub. L. 119–4 substituted "September 30, 2025" for "March 31, 2025".
2024—Subsec. (c)(4)(B). Pub. L. 118–158 substituted "March 31, 2025" for "December 31, 2024".

Pub. L. 118–42 substituted "December 31, 2024" for "March 8, 2024".

Pub. L. 118–35 substituted "March 8, 2024" for "January 19, 2024".

2023—Subsec. (c)(4)(B). Pub. L. 118–22 substituted "January 19, 2024" for "November 17, 2023".

Pub. L. 118–15 substituted "November 17, 2023" for "September 30, 2023".

2022—Subsec. (c)(4)(B). Pub. L. 117–103 substituted "September 30, 2023" for "March 11, 2022".

Pub. L. 117–86 substituted "March 11, 2022" for "February 18, 2022".

2021—Subsec. (c)(4)(B). Pub. L. 117–70 substituted "February 18, 2022" for "December 3, 2021".

Pub. L. 117–43 substituted "December 3, 2021" for "September 30, 2021".

2019—Subsec. (a)(3)(A)(ii). Pub. L. 116–22, §301(a)(1), amended cl. (ii) generally. Prior to amendment, cl. (ii) read as follows: "be present at locations, and for limited periods of time, specified by the Secretary on the basis that the Secretary has determined that a location is at risk of a public health emergency during the time specified."

Subsec. (b)(2). Pub. L. 116–22, §301(a)(2), amended par. (2) generally. Prior to amendment, text read as follows: "Not later than 180 days after December 19, 2006, the Secretary, in coordination with the Secretary of Homeland Security, the Secretary of Defense, and the Secretary of Veterans Affairs, shall conduct a joint review of the National Disaster Medical System. Such review shall include an evaluation of medical surge capacity, as described by section 300hh–2(a) of this title. As part of the National Health Security Strategy under section 300hh–1 of this title, the Secretary shall update the findings from such review and further modify the policies of the National Disaster Medical System as necessary."

Subsec. (c)(3), (4). Pub. L. 116–22, §301(a)(3), added pars. (3) and (4).

Subsec. (c)(5). Pub. L. 116–22, §301(d)(1), added par. (5), which ceased to have force or effect on Oct. 1, 2021. Text read as follows: "Individuals appointed to serve under this subsection shall be considered eligible for benefits under part L of title I of the Omnibus Crime Control and Safe Streets Act of 1968. The Secretary shall provide notification to any eligible individual of any effect such designation may have on other benefits for which such individual is eligible, including benefits from private entities." See Termination Date of 2019 Amendment note below.

Subsec. (g). Pub. L. 116–22, §301(a)(4), substituted "$57,400,000 for each of fiscal years 2019 through 2023" for "$52,700,000 for each of fiscal years 2014 through 2018".

2015—Subsec. (d)(2). Pub. L. 114–113 designated first, second, and third sentences of existing provisions as subpars. (A), (B), and (C), respectively, realigned margins, inserted subpar. headings, and added subpars. (D) and (E).

2013—Subsec. (a)(3)(A)(i). Pub. L. 113–5, §104(1)(A), inserted ", including at-risk individuals as applicable" after "victims of a public health emergency".

Subsec. (a)(3)(C) to (E). Pub. L. 113–5, §104(1)(B), (C), added subpars. (C) and (D) and redesignated former subpar. (C) as (E).

Subsec. (g). Pub. L. 113–5, §104(2), substituted "$52,700,000 for each of fiscal years 2014 through 2018" for "such sums as may be necessary for each of the fiscal years 2007 through 2011".

2006—Pub. L. 109–417, §301(a)(1), substituted "National Disaster Medical System" for "Coordination of preparedness for and response to bioterrorism and other public health emergencies" in section catchline.

Subsec. (a). Pub. L. 109–417, §301(a)(2), (3), redesignated subsec. (b) as (a) and struck out former subsec. (a) which related to establishment of position and duties of Assistant Secretary for Public Health Emergency Preparedness.

Subsec. (a)(2)(B). Pub. L. 109–417, §301(a)(4)(A), substituted "Department of Homeland Security" for "Federal Emergency Management Agency".

Subsec. (a)(3)(C). Pub. L. 109–417, §301(a)(4)(B), substituted "December 19, 2006" for "June 12, 2002".

Subsec. (b). Pub. L. 109–417, §301(a)(5), substituted "Modifications" for "Criteria" in heading, added pars. (1) and (2), redesignated former par. (2) as (3), and struck out heading and text of former par. (1). Text read as follows: "The Secretary shall establish criteria for the operation of the National Disaster Medical System."

Pub. L. 109–417, §301(a)(3), redesignated subsec. (c) as (b). Former subsec. (b) redesignated (a).

Subsec. (b)(1). Pub. L. 109–417, §102(a)(4), substituted "Assistant Secretary for Preparedness and Response" for "Assistant Secretary for Public Health Emergency Preparedness".

Subsec. (b)(3)(A). Pub. L. 109–417, §301(a)(6), substituted "subsection (a)(3)(A)" for "subsection (b)(3)(A)".

Subsec. (c). Pub. L. 109–417, §301(a)(3), redesignated subsec. (d) as (c). Former subsec. (c) redesignated (b).

Subsec. (c)(2). Pub. L. 109–417, §301(a)(6), substituted "subsection (a)(2)(B)" for "subsection (b)(2)(B)".

Subsec. (d). Pub. L. 109–417, §301(a)(7), substituted "subsection (c)" for "subsection (d)" in pars. (1) and (2).

Pub. L. 109–417, §301(a)(6), substituted "subsection (a)(2)(B)" for "subsection (b)(2)(B)" in pars. (2) and (3)(A).

Pub. L. 109–417, §301(a)(3), redesignated subsec. (e) as (d). Former subsec. (d) redesignated (c).

Subsec. (d)(2). Pub. L. 109–417, §102(a)(4), substituted "Assistant Secretary for Preparedness and Response" for "Assistant Secretary for Public Health Emergency Preparedness".

Subsec. (e). Pub. L. 109–417, §301(a)(3), redesignated subsec. (f) as (e). Former subsec. (e) redesignated (d).

Subsec. (e)(2), (3)(A). Pub. L. 109–417, §102(a)(4), substituted "Assistant Secretary for Preparedness and Response" for "Assistant Secretary for Public Health Emergency Preparedness".

Subsec. (f). Pub. L. 109–417, §301(a)(6), substituted "subsection (a)(3)(A)" for "subsection (b)(3)(A)".

Pub. L. 109–417, §301(a)(3), redesignated subsec. (g) as (f). Former subsec. (f) redesignated (e).

Subsec. (g). Pub. L. 109–417, §301(a)(8), substituted "2007 through 2011" for "2002 through 2006".

Pub. L. 109–417, §301(a)(3), redesignated subsec. (h) as (g). Former subsec. (g) redesignated (f).

Subsec. (h). Pub. L. 109–417, §301(a)(3), redesignated subsec. (h) as (g).

Pub. L. 109–417, §102(a)(4), substituted "Assistant Secretary for Preparedness and Response" for "Assistant Secretary for Public Health Emergency Preparedness".

STATUTORY NOTES AND RELATED SUBSIDIARIES

CHANGE OF NAME

Reference to Reserve Corps of the Public Health Service deemed to be a reference to the Ready Reserve Corps, see section 204(c)(3) of this title.

TERMINATION DATE OF 2019 AMENDMENT

Amendment by section 301(d)(1) of Pub. L. 116–22 to cease to have force or effect on Oct. 1, 2021, see section 301(d)(3) of Pub. L. 116–22, set out as a note under section 10284 of Title 34, Crime Control and Law Enforcement.

TRANSFER OF FUNCTIONS

Pub. L. 109–417, title III, §301(b), Dec. 19, 2006, 120 Stat. 2854, provided that: "There shall be transferred to the Secretary of Health and Human Services the functions, personnel, assets, and liabilities of the National Disaster Medical System of the Department of Homeland Security, including the functions of the Secretary of Homeland Security and the Under Secretary for Emergency Preparedness and Response relating thereto."

Pub. L. 109–295, title III, Oct. 4, 2006, 120 Stat. 1372, provided in part: "That the total amount appropriated and, notwithstanding any other provision of law, the functions, personnel, assets, and liabilities of the National Disaster Medical System established under section 2811(b) [now 2812(a)] of the Public Health Service Act (42 U.S.C. 300hh–11(b) [now 300hh–11(a)]), including any functions of the Secretary of Homeland Security relating to such System, shall be permanently transferred to the Secretary of the Department of Health and Human Services effective January 1, 2007."

For transfer of functions, personnel, assets, and liabilities of the National Disaster Medical System of the Department of Health and Human Services, including the functions of the Secretary of Health and Human Services and the Assistant Secretary for Public Health Emergency Preparedness (now Assistant Secretary for Preparedness and Response) relating thereto, to the Secretary of Homeland Security, and for treatment of related references, see former section 313(5) and sections 551(d), 552(d), and 557 of Title 6, Domestic Security, and the Department of Homeland Security Reorganization Plan of November 25, 2002, as modified, set out as a note under section 542 of Title 6.

[1] So in original. Probably should be "is".

[2] So in original. Probably should be "takes".

[3] See Change of Name note below.

§300hh–12. Transferred

EDITORIAL NOTES

CODIFICATION

Section, Pub. L. 107–188, title I, §121, June 12, 2002, 116 Stat. 611, as amended, which related to Strategic National Stockpile, was renumbered section 319F–2 of the Public Health Service Act by Pub. L. 108–276, §3(a)(1), July 21, 2004, 118 Stat. 842 and is classified to section 247d–6b of this title.

§300hh–13. Evaluation of new and emerging technologies regarding bioterrorist attack and other public health emergencies

(a) In general

The Secretary of Health and Human Services (referred to in this section as the "Secretary") shall promptly carry out a program to periodically evaluate new and emerging technologies that, in the determination of the Secretary, are designed to improve or enhance the ability of public health or safety officials to conduct public health surveillance activities relating to a bioterrorist attack or other public health emergency.

(b) Certain activities

In carrying out this subsection, the Secretary shall, to the extent practicable—

(1) survey existing technology programs funded by the Federal Government for potentially useful technologies;

(2) promptly issue a request, as necessary, for information from non-Federal public and private entities for ongoing activities in this area; and

(3) evaluate technologies identified under paragraphs (1) and (2) pursuant to subsection (c).

(c) Consultation and evaluation

In carrying out subsection (b)(3), the Secretary shall consult with the working group under section 247d–6(a) [1] of this title, as well as other appropriate public, nonprofit, and private entities, to develop criteria for the evaluation of such technologies and to conduct such evaluations.

(d) Report

Not later than 180 days after June 12, 2002, and periodically thereafter, the Secretary shall submit to the Committee on Energy and Commerce of the House of Representatives, and the Committee on Health, Education, Labor, and Pensions of the Senate, a report on the activities under this section.

(Pub. L. 107–188, title I, §126, June 12, 2002, 116 Stat. 615.)

EDITORIAL NOTES

REFERENCES IN TEXT

Section 247d–6 of this title, referred to in subsec. (c), was amended by Pub. L. 109–417, title III, §304, Dec. 19, 2006, 120 Stat. 2859, and as so amended, subsec. (a) of section 247d–6 no longer relates to a working group.

CODIFICATION

Section was enacted as part of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002, and not as part of the Public Health Service Act which comprises this chapter.

[1] *See References in Text note below.*

§300hh–14. Protection of health and safety during disasters

(a) Definitions

In this section:

(1) Certified monitoring program

The term "certified monitoring program" means a medical monitoring program—

(A) in which a participating responder is a participant as a condition of the employment of such participating responder; and

(B) that the Secretary of Health and Human Services certifies includes an adequate baseline medical screening.

(2) Disaster area

The term "disaster area" means an area in which the President has declared a major disaster (as that term is defined in section 5122 of this title), during the period of such declaration.

(3) High exposure level

The term "high exposure level" means a level of exposure to a substance of concern that is for such a duration, or of such a magnitude, that adverse effects on human health can be reasonably expected to occur, as determined by the President, acting through the Secretary of Health and Human Services, in accordance with human monitoring or environmental or other appropriate indicators.

(4) Individual

The term "individual" includes—

(A) a worker or volunteer who responds to a disaster, either natural or manmade, involving any mode of transportation in the United States or disrupting the transportation system of the United States, including—

(i) a police officer;

(ii) a firefighter;

(iii) an emergency medical technician;

(iv) any participating member of an urban search and rescue team; and

(v) any other relief or rescue worker or volunteer that the President, acting through the Secretary of Health and Human Services, determines to be appropriate;

(B) a worker who responds to a disaster, either natural or manmade, involving any mode of transportation in the United States or disrupting the transportation system of the United States, by assisting in the cleanup or restoration of critical infrastructure in and around a disaster area;

(C) a person whose place of residence is in a disaster area, caused by either a natural or manmade disaster involving any mode of transportation in the United States or disrupting the transportation system of the United States;

(D) a person who is employed in or attends school, child care, or adult day care in a building located in a disaster area, caused by either a natural or manmade disaster involving any mode of transportation in the United States or disrupting the transportation system of the United States, of the United States; and

(E) any other person that the President, acting through the Secretary of Health and Human Services, determines to be appropriate.

(5) Participating responder

The term "participating responder" means an individual described in paragraph (4)(A).

(6) Program

The term "program" means a program described in subsection (b) that is carried out for a disaster area.

(7) Substance of concern

The term "substance of concern" means a chemical or other substance that is associated with potential acute or chronic human health effects, the risk of exposure to which could potentially be increased as the result of a disaster, as determined by the President, acting through the Secretary of Health and Human Services, and in coordination with the Agency for Toxic Substances and

Disease Registry, the Environmental Protection Agency, the Centers for Disease Control and Prevention, the National Institutes of Health, the Federal Emergency Management Agency, the Occupational Health and Safety Administration, and other agencies.

(b) Program

(1) In general

If the President, acting through the Secretary of Health and Human Services, determines that 1 or more substances of concern are being, or have been, released in an area declared to be a disaster area and disrupts the transportation system of the United States, the President, acting through the Secretary of Health and Human Services, may carry out a program for the coordination, protection, assessment, monitoring, and study of the health and safety of individuals with high exposure levels to ensure that—

(A) the individuals are adequately informed about and protected against potential health impacts of any substance of concern in a timely manner;

(B) the individuals are monitored and studied over time, including through baseline and followup clinical health examinations, for—

(i) any short- and long-term health impacts of any substance of concern; and

(ii) any mental health impacts;

(C) the individuals receive health care referrals as needed and appropriate; and

(D) information from any such monitoring and studies is used to prevent or protect against similar health impacts from future disasters.

(2) Activities

A program under paragraph (1) may include such activities as—

(A) collecting and analyzing environmental exposure data;

(B) developing and disseminating information and educational materials;

(C) performing baseline and followup clinical health and mental health examinations and taking biological samples;

(D) establishing and maintaining an exposure registry;

(E) studying the short- and long-term human health impacts of any exposures through epidemiological and other health studies; and

(F) providing assistance to individuals in determining eligibility for health coverage and identifying appropriate health services.

(3) Timing

To the maximum extent practicable, activities under any program carried out under paragraph (1) (including baseline health examinations) shall be commenced in a timely manner that will ensure the highest level of public health protection and effective monitoring.

(4) Participation in registries and studies

(A) In general

Participation in any registry or study that is part of a program carried out under paragraph (1) shall be voluntary.

(B) Protection of privacy

The President, acting through the Secretary of Health and Human Services, shall take appropriate measures to protect the privacy of any participant in a registry or study described in subparagraph (A).

(C) Priority

(i) In general

Except as provided in clause (ii), the President, acting through the Secretary of Health and Human Services, shall give priority in any registry or study described in subparagraph (A) to

the protection, monitoring and study of the health and safety of individuals with the highest level of exposure to a substance of concern.

(ii) Modifications

Notwithstanding clause (i), the President, acting through the Secretary of Health and Human Services, may modify the priority of a registry or study described in subparagraph (A), if the President, acting through the Secretary of Health and Human Services, determines such modification to be appropriate.

(5) Cooperative agreements

(A) In general

The President, acting through the Secretary of Health and Human Services, may carry out a program under paragraph (1) through a cooperative agreement with a medical institution, including a local health department, or a consortium of medical institutions.

(B) Selection criteria

To the maximum extent practicable, the President, acting through the Secretary of Health and Human Services, shall select, to carry out a program under paragraph (1), a medical institution or a consortium of medical institutions that—

(i) is located near—

(I) the disaster area with respect to which the program is carried out; and

(II) any other area in which there reside groups of individuals that worked or volunteered in response to the disaster; and

(ii) has appropriate experience in the areas of environmental or occupational health, toxicology, and safety, including experience in—

(I) developing clinical protocols and conducting clinical health examinations, including mental health assessments;

(II) conducting long-term health monitoring and epidemiological studies;

(III) conducting long-term mental health studies; and

(IV) establishing and maintaining medical surveillance programs and environmental exposure or disease registries.

(6) Involvement

(A) In general

In carrying out a program under paragraph (1), the President, acting through the Secretary of Health and Human Services, shall involve interested and affected parties, as appropriate, including representatives of—

(i) Federal, State, and local government agencies;

(ii) groups of individuals that worked or volunteered in response to the disaster in the disaster area;

(iii) local residents, businesses, and schools (including parents and teachers);

(iv) health care providers;

(v) faith based organizations; and

(vi) other organizations and persons.

(B) Committees

Involvement under subparagraph (A) may be provided through the establishment of an advisory or oversight committee or board.

(7) Privacy

The President, acting through the Secretary of Health and Human Services, shall carry out each program under paragraph (1) in accordance with regulations relating to privacy promulgated under section 264(c) of the Health Insurance Portability and Accountability Act of 1996 (42 U.S.C. 1320d–2 note; Public Law 104–191).

(8) Existing programs

In carrying out a program under paragraph (1), the President, acting through the Secretary of Health and Human Services, may—

(A) include the baseline clinical health examination of a participating responder under a certified monitoring programs; [1] and

(B) substitute the baseline clinical health examination of a participating responder under a certified monitoring program for a baseline clinical health examination under paragraph (1).

(c) Reports

Not later than 1 year after the establishment of a program under subsection (b)(1), and every 5 years thereafter, the President, acting through the Secretary of Health and Human Services, or the medical institution or consortium of such institutions having entered into a cooperative agreement under subsection (b)(5), may submit a report to the Secretary of Homeland Security, the Secretary of Labor, the Administrator of the Environmental Protection Agency, and appropriate committees of Congress describing the programs and studies carried out under the program.

(d) National Academy of Sciences report on disaster area health and environmental protection and monitoring

(1) In general

The Secretary of Health and Human Services, the Secretary of Homeland Security, and the Administrator of the Environmental Protection Agency shall jointly enter into a contract with the National Academy of Sciences to conduct a study and prepare a report on disaster area health and environmental protection and monitoring.

(2) Participation of experts

The report under paragraph (1) shall be prepared with the participation of individuals who have expertise in—

(A) environmental health, safety, and medicine;
(B) occupational health, safety, and medicine;
(C) clinical medicine, including pediatrics;
(D) environmental toxicology;
(E) epidemiology;
(F) mental health;
(G) medical monitoring and surveillance;
(H) environmental monitoring and surveillance;
(I) environmental and industrial hygiene;
(J) emergency planning and preparedness;
(K) public outreach and education;
(L) State and local health departments;
(M) State and local environmental protection departments;
(N) functions of workers that respond to disasters, including first responders;
(O) public health; and
(P) family services, such as counseling and other disaster-related services provided to families.

(3) Contents

The report under paragraph (1) shall provide advice and recommendations regarding protecting and monitoring the health and safety of individuals potentially exposed to any chemical or other substance associated with potential acute or chronic human health effects as the result of a disaster, including advice and recommendations regarding—

(A) the establishment of protocols for monitoring and responding to chemical or substance releases in a disaster area to protect public health and safety, including—

(i) chemicals or other substances for which samples should be collected in the event of a disaster, including a terrorist attack;

(ii) chemical- or substance-specific methods of sample collection, including sampling methodologies and locations;

(iii) chemical- or substance-specific methods of sample analysis;

(iv) health-based threshold levels to be used and response actions to be taken in the event that thresholds are exceeded for individual chemicals or other substances;

(v) procedures for providing monitoring results to—

(I) appropriate Federal, State, and local government agencies;

(II) appropriate response personnel; and

(III) the public;

(vi) responsibilities of Federal, State, and local agencies for—

(I) collecting and analyzing samples;

(II) reporting results; and

(III) taking appropriate response actions; and

(vii) capabilities and capacity within the Federal Government to conduct appropriate environmental monitoring and response in the event of a disaster, including a terrorist attack; and

(B) other issues specified by the Secretary of Health and Human Services, the Secretary of Homeland Security, and the Administrator of the Environmental Protection Agency.

(4) Authorization of appropriations

There are authorized to be appropriated such sums as are necessary to carry out this subsection.

(Pub. L. 109–347, title VII, §709, Oct. 13, 2006, 120 Stat. 1947.)

EDITORIAL NOTES

REFERENCES IN TEXT

Section 264(c) of the Health Insurance Portability and Accountability Act of 1996, referred to in subsec. (b)(7), is section 264(c) of Pub. L. 104–191, which is set out as a note under section 1320d–2 of this title.

CODIFICATION

Section was enacted as part of the Security and Accountability For Every Port Act of 2006, also known as the SAFE Port Act, and not as part of the Public Health Service Act which comprises this chapter.

[1] So in original. Probably should be "program;".

§300hh–15. Volunteer Medical Reserve Corps

(a) In general

Not later than 180 days after December 19, 2006, the Secretary, in collaboration with State, local, and tribal officials, shall build on State, local, and tribal programs in existence on December 19, 2006, to establish and maintain a Medical Reserve Corps (referred to in this section as the "Corps") to provide for an adequate supply of volunteers in the case of a Federal, State, local, or tribal public health emergency. The Secretary may appoint a Director to head the Corps and oversee the activities of the Corps chapters that exist at the State, local, Tribal, and territorial levels.

(b) State, local, and tribal coordination

The Corps shall be established using existing State, local, and tribal teams and shall not alter such teams.

(c) Composition

The Corps shall be composed of individuals who—

(1)(A) are health professionals who have appropriate professional training and expertise as determined appropriate by the Director of the Corps; or

(B) are non-health professionals who have an interest in serving in an auxiliary or support capacity to facilitate access to health care services in a public health emergency;

(2) are certified in accordance with the certification program developed under subsection (d);

(3) are geographically diverse in residence;

(4) have registered and carry out training exercises with a local chapter of the Medical Reserve Corps; and

(5) indicate whether they are willing to be deployed outside the area in which they reside in the event of a public health emergency.

(d) Certification; drills

(1) Certification

The Director, in collaboration with State, local, and tribal officials, shall establish a process for the periodic certification of individuals who volunteer for the Corps, as determined by the Secretary, which shall include the completion by each individual of the core training programs developed under section 247d–6 of this title, as required by the Director. Such certification shall not supercede State licensing or credentialing requirements.

(2) Drills

In conjunction with the core training programs referred to in paragraph (1), and in order to facilitate the integration of trained volunteers into the health care system at the local level, Corps members shall engage in periodic training exercises to be carried out at the local level. Such training exercises shall, as appropriate and applicable, incorporate the needs of at-risk individuals in the event of a public health emergency.

(e) Deployment

During a public health emergency, the Secretary shall have the authority to activate and deploy willing members of the Corps to areas of need, taking into consideration the public health and medical expertise required, with the concurrence of the State, local, or tribal officials from the area where the members reside.

(f) Expenses and transportation

While engaged in performing duties as a member of the Corps pursuant to an assignment by the Secretary (including periods of travel to facilitate such assignment), members of the Corps who are not otherwise employed by the Federal Government shall be allowed travel or transportation expenses, including per diem in lieu of subsistence.

(g) Identification

The Secretary, in cooperation and consultation with the States, shall develop a Medical Reserve Corps Identification Card that describes the licensure and certification information of Corps members, as well as other identifying information determined necessary by the Secretary.

(h) Intermittent disaster-response personnel

(1) In general

For the purpose of assisting the Corps in carrying out duties under this section, during a public health emergency, the Secretary may appoint selected individuals to serve as intermittent personnel of such Corps in accordance with applicable civil service laws and regulations. In all other cases, members of the Corps are subject to the laws of the State in which the activities of the Corps are undertaken.

(2) Applicable protections

Subsections (c)(2), (d), and (e) of section 300hh–11 of this title shall apply to an individual appointed under paragraph (1) in the same manner as such subsections apply to an individual

appointed under section 300hh–11(c) of this title.

(3) Limitation

State, local, and tribal officials shall have no authority to designate a member of the Corps as Federal intermittent disaster-response personnel, but may request the services of such members.

(i) Authorization of appropriations

There is authorized to be appropriated to carry out this section, $11,200,000 for each of fiscal years 2019 through 2023.

(July 1, 1944, ch. 373, title XXVIII, §2813, as added Pub. L. 109–417, title III, §303(a), Dec. 19, 2006, 120 Stat. 2856; amended Pub. L. 113–5, title II, §203(b)(2), Mar. 13, 2013, 127 Stat. 175; Pub. L. 116–22, title III, §301(b), June 24, 2019, 133 Stat. 932.)

EDITORIAL NOTES

AMENDMENTS

2019—Subsec. (a). Pub. L. 116–22, §301(b)(1), substituted "The Secretary may appoint a Director to head the Corps and oversee the activities of the Corps chapters that exist at the State, local, Tribal, and territorial levels." for "The Corps shall be headed by a Director who shall be appointed by the Secretary and shall oversee the activities of the Corps chapters that exist at the State, local, and tribal levels."

Subsec. (i). Pub. L. 116–22, §301(b)(2), substituted "2019 through 2023" for "2014 through 2018".

2013—Subsec. (d)(2). Pub. L. 113–5, §203(b)(2)(A), inserted at end "Such training exercises shall, as appropriate and applicable, incorporate the needs of at-risk individuals in the event of a public health emergency."

Subsec. (i). Pub. L. 113–5, §203(b)(2)(B), substituted "$11,200,000 for each of fiscal years 2014 through 2018" for "$22,000,000 for fiscal year 2007, and such sums as may be necessary for each of fiscal years 2008 through 2011".

§300hh–16. At-risk individuals

The Secretary, acting through such employee of the Department of Health and Human Services as determined by the Secretary and designated publicly (which may, at the discretion of the Secretary, involve the appointment or designation of an individual as the Director of At-Risk Individuals), shall—

(1) monitor emerging issues and concerns as they relate to medical and public health preparedness and response for at-risk individuals in the event of a public health emergency declared by the Secretary under section 247d of this title;

(2) oversee the implementation of the preparedness goals described in section 300hh–1(b) of this title with respect to the public health and medical needs of at-risk individuals in the event of a public health emergency, as described in section 300hh–1(b)(4) of this title;

(3) assist other Federal agencies responsible for planning for, responding to, and recovering from public health emergencies in addressing the needs of at-risk individuals;

(4) provide guidance to and ensure that recipients of State and local public health grants include preparedness and response strategies and capabilities that take into account the medical and public health needs of at-risk individuals in the event of a public health emergency, as described in section 247d–3a(b)(2)(A)(iii) of this title;

(5) ensure that the contents of the strategic national stockpile take into account at-risk populations as described in section 300hh–1(b)(4)(B) of this title;

(6) oversee curriculum development for the public health and medical response training program on medical management of casualties, as it concerns at-risk individuals as described in subparagraphs (A) through (C) of section 247d–6(a)(2) of this title;

(7) disseminate and, as appropriate, update novel and best practices of outreach to and care of at-risk individuals before, during, and following public health emergencies in as timely a manner as is practicable, including from the time a public health threat is identified;

(8) ensure that public health and medical information distributed by the Department of Health and Human Services during a public health emergency is delivered in a manner that takes into account the range of communication needs of the intended recipients, including at-risk individuals; and

(9) facilitate coordination to ensure that, in implementing the situational awareness and biosurveillance network under section 247d–4 of this title, the Secretary considers incorporating data and information from Federal, State, local, Tribal, and territorial public health officials and entities relevant to detecting emerging public health threats that may affect at-risk individuals, such as pregnant and postpartum women and infants, including adverse health outcomes of such populations related to such emerging public health threats.

(July 1, 1944, ch. 373, title XXVIII, §2814, as added Pub. L. 109–417, title I, §102(d), Dec. 19, 2006, 120 Stat. 2834; amended Pub. L. 113–5, title I, §101(b), Mar. 13, 2013, 127 Stat. 163; Pub. L. 116–22, title III, §303(c), June 24, 2019, 133 Stat. 935.)

EDITORIAL NOTES

AMENDMENTS

2019—Par. (9). Pub. L. 116–22 added par. (9).

2013—Par. (1). Pub. L. 113–5, §101(b)(4), added par. (1). Former par. (1) redesignated (2).

Par. (2). Pub. L. 113–5, §101(b)(3), (5), redesignated par. (1) as (2) and amended it generally. Prior to amendment, par. (2) read as follows: "oversee the implementation of the National Preparedness goal of taking into account the public health and medical needs of at-risk individuals in the event of a public health emergency, as described in section 300hh–1(b)(4) of this title;". Former par. (2) redesignated (3).

Par. (3). Pub. L. 113–5, §101(b)(3), redesignated par. (2) as (3). Former par. (3) redesignated (4).

Par. (4). Pub. L. 113–5, §101(b)(3), redesignated par. (3) as (4). Former par. (4) redesignated (5).

Pub. L. 113–5, §101(b)(2), substituted "300hh–1(b)(4)(B)" for "300hh–10(b)(3)(B)".

Par. (5). Pub. L. 113–5, §101(b)(1), (3), redesignated par. (4) as (5) and struck out former par. (5) which read as follows: "oversee the progress of the Advisory Committee on At-Risk Individuals and Public Health Emergencies established under section 247d–6(b)(2) of this title and make recommendations with a focus on opportunities for action based on the work of the Committee;".

Pars. (7), (8). Pub. L. 113–5, §101(b)(1), (6), added pars. (7) and (8) and struck out former pars. (7) and (8) which read as follows:

"(7) disseminate novel and best practices of outreach to and care of at-risk individuals before, during, and following public health emergencies; and

"(8) not later than one year after December 19, 2006, prepare and submit to Congress a report describing the progress made on implementing the duties described in this section."

§300hh–17. Emergency response coordination of primary care providers

The Secretary, acting through Administrator [1] of the Health Resources and Services Administration, and in coordination with the Assistant Secretary for Preparedness and Response, shall

(1) provide guidance and technical assistance to health centers funded under section 254b of this title and to State and local health departments and emergency managers to integrate health centers into State and local emergency response plans and to better meet the primary care needs of populations served by health centers during public health emergencies; and

(2) encourage employees at health centers funded under section 254b of this title to participate in emergency medical response programs including the National Disaster Medical System authorized in section 300hh–11 of this title, the Volunteer Medical Reserve Corps authorized in section 300hh–15 of this title, and the Emergency System for Advance Registration of Health Professions Volunteers authorized in section 247d–7b of this title.

(July 1, 1944, ch. 373, title XXVIII, §2815, as added Pub. L. 110–355, §6(a), Oct. 8, 2008, 122 Stat. 3994.)

[1] *So in original. Probably should be preceded by "the".*

PART C—STRENGTHENING PUBLIC HEALTH SURVEILLANCE SYSTEMS

§300hh–31. Epidemiology-laboratory capacity grants

(a) In general

Subject to the availability of appropriations, the Secretary, acting through the Director of the Centers for Disease Control and Prevention, shall establish an Epidemiology and Laboratory Capacity Grant Program to award grants to State health departments as well as local health departments and tribal jurisdictions that meet such criteria as the Director determines appropriate. Academic centers that assist State and eligible local and tribal health departments may also be eligible for funding under this section as the Director determines appropriate. Grants shall be awarded under this section to assist public health agencies in improving surveillance for, and response to, infectious diseases and other conditions of public health importance by—

(1) strengthening epidemiologic capacity to identify and monitor the occurrence of infectious diseases, including mosquito and other vector-borne diseases, and other conditions of public health importance;

(2) enhancing laboratory practice as well as systems to report test orders and results electronically;

(3) improving information systems including developing and maintaining an information exchange using national guidelines and complying with capacities and functions determined by an advisory council established and appointed by the Director; and

(4) developing and implementing prevention and control strategies.

(b) Authorization of appropriations

There are authorized to be appropriated to carry out this section $190,000,000 for each of fiscal years 2019 through 2023, of which—

(1) not less than $95,000,000 shall be made available each such fiscal year for activities under paragraphs (1) and (4) of subsection (a);

(2) not less than $60,000,000 shall be made available each such fiscal year for activities under subsection (a)(3); and

(3) not less than $32,000,000 shall be made available each such fiscal year for activities under subsection (a)(2).

(July 1, 1944, ch. 373, title XXVIII, §2821, as added Pub. L. 111–148, title IV, §4304, Mar. 23, 2010, 124 Stat. 584; amended Pub. L. 116–22, title VI, §607(b), June 24, 2019, 133 Stat. 960.)

EDITORIAL NOTES

AMENDMENTS

2019—Subsec. (a)(1). Pub. L. 116–22, §607(b)(1), inserted ", including mosquito and other vector-borne diseases," after "infectious diseases".

Subsec. (b). Pub. L. 116–22, §607(b)(2), substituted "2019 through 2023" for "2010 through 2013" in introductory provisions.

§300hh–32. Enhanced support to assist health departments in addressing vector-borne diseases

(a) In general

The Secretary, acting through the Director of the Centers for Disease Control and Prevention, may enter into cooperative agreements with health departments of States, political subdivisions of States, and Indian Tribes and Tribal organizations in areas at high risk of vector-borne diseases in order to increase capacity to identify, report, prevent, and respond to such diseases and related outbreaks.

(b) Eligibility

To be eligible to enter into a cooperative agreement under this section, an entity described in subsection (a) shall prepare and submit to the Secretary an application at such time, in such manner, and containing such information as the Secretary may require, including a plan that describes—

(1) how the applicant proposes to develop or expand programs to address vector-borne disease risks, including through—

(A) related training and workforce development;

(B) programmatic efforts to improve capacity to identify, report, prevent, and respond to such disease and related outbreaks; and

(C) other relevant activities identified by the Director of the Centers for Disease Control and Prevention, as appropriate;

(2) the manner in which the applicant will coordinate with other Federal, Tribal, and State agencies and programs, as applicable, related to vector-borne diseases, as well as other relevant public and private organizations or agencies; and

(3) the manner in which the applicant will evaluate the effectiveness of any program carried out under the cooperative agreement.

(c) Authorization of appropriations

For the purposes of carrying out this section, there are authorized to be appropriated $20,000,000 for each of fiscal years 2026 through 2030.

(July 1, 1944, ch. 373, title XXVIII, §2822, as added Pub. L. 116–94, div. N, title I, §404(c), Dec. 20, 2019, 133 Stat. 3118; amended Pub. L. 119–118, §2(b), Sept. 30, 2026, 140 Stat. 1062.)

EDITORIAL NOTES

AMENDMENTS

2026—Subsec. (c). Pub. L. 119–118 substituted "2026 through 2030" for "2021 through 2025".

§300hh–33. Public health data system modernization

(a) Expanding CDC and public health department capabilities

(1) In general

The Secretary, acting through the Director of the Centers for Disease Control and Prevention, shall—

(A) conduct activities to expand, modernize, improve, and sustain applicable public health data systems used by the Centers for Disease Control and Prevention, including with respect to the interoperability and improvement of such systems (including as it relates to preparedness for, prevention and detection of, and response to public health emergencies); and

(B) award grants or cooperative agreements to State, local, Tribal, or territorial public health departments for the expansion and modernization of public health data systems, to assist public health departments and public health laboratories in—

(i) assessing current data infrastructure capabilities and gaps to—

(I) improve and increase consistency in data collection, storage, and analysis; and

(II) as appropriate, improve dissemination of public health-related information;

(ii) improving secure public health data collection, transmission, exchange, maintenance, and analysis, including with respect to demographic data, as appropriate;

(iii) improving the secure exchange of data between the Centers for Disease Control and Prevention, State, local, Tribal, and territorial public health departments, public health laboratories, public health organizations, and health care providers, including by public health officials in multiple jurisdictions within such State, as appropriate, and by simplifying and supporting reporting by health care providers, as applicable, pursuant to State law, including through the use of health information technology;

(iv) enhancing the interoperability of public health data systems (including systems created or accessed by public health departments) with health information technology, including with health information technology certified under section 300jj–11(c)(5) of this title;

(v) supporting and training data systems, data science, and informatics personnel;

(vi) supporting earlier disease and health condition detection, such as through near real-time data monitoring, to support rapid public health responses;

(vii) supporting activities within the applicable jurisdiction related to the expansion and modernization of electronic case reporting; and

(viii) developing and disseminating information related to the use and importance of public health data.

(2) Data standards

(A) In general

In carrying out paragraph (1), the Secretary, acting through the Director of the Centers for Disease Control and Prevention, shall, not later than 2 years after December 29, 2022, in consultation with the Office of the National Coordinator for Health Information Technology, designate data and technology standards (including standards for interoperability) for public health data systems, with deference given to standards published by consensus-based standards development organizations with public input and voluntary consensus-based standards bodies.

(B) No duplicative efforts

(i) In general

In carrying out the requirements of this paragraph, the Secretary, in consultation with the Office of the National Coordinator for Health Information Technology, may use input gathered (including input and recommendations gathered from the Health Information Technology Advisory Committee), and materials developed, prior to December 29, 2022.

(ii) Designation of standards

Consistent with sections 17901 and 17902 of this title, the data and technology standards designated pursuant to this paragraph shall align with the standards and implementation specifications previously adopted by the Secretary pursuant to section 300jj–14 of this title, as applicable.

(C) Privacy and security

Nothing in this paragraph shall be construed as modifying applicable Federal or State information privacy or security law.

(3) Public-private partnerships

The Secretary may develop and utilize public-private partnerships for technical assistance, training, and related implementation support for State, local, Tribal, and territorial public health departments, and the Centers for Disease Control and Prevention, on the expansion and modernization of electronic case reporting and public health data systems, as applicable.

(b) Requirements

(1) Health information technology standards

The Secretary may not award a grant or cooperative agreement under subsection (a)(1)(B)

unless the applicant uses or agrees to use standards endorsed by the National Coordinator for Health Information Technology pursuant to section 300jj–11(c)(1) of this title or adopted by the Secretary under section 300jj–14 of this title.

(2) Waiver

The Secretary may waive the requirement under paragraph (1) with respect to an applicant if the Secretary determines that the activities under subsection (a)(1)(B) cannot otherwise be carried out within the applicable jurisdiction.

(3) Application

A State, local, Tribal, or territorial health department applying for a grant or cooperative agreement under this section shall submit an application to the Secretary at such time and in such manner as the Secretary may require. Such application shall include information describing—

(A) the activities that will be supported by the grant or cooperative agreement; and

(B) how the modernization of the public health data systems involved will support or impact the public health infrastructure of the health department, including a description of remaining gaps, if any, and the actions needed to address such gaps.

(c) Strategy and implementation plan

Not later than 180 days after December 27, 2020, the Secretary, acting through the Director of the Centers for Disease Control and Prevention, shall submit to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives a coordinated strategy and an accompanying implementation plan that identifies and demonstrates the measures the Secretary will utilize to—

(1) update and improve applicable public health data systems used by the Centers for Disease Control and Prevention; and

(2) carry out the activities described in this section to support the improvement of State, local, Tribal, and territorial public health data systems.

(d) Consultation

The Secretary, acting through the Director of the Centers for Disease Control and Prevention, shall consult with State, local, Tribal, and territorial health departments, professional medical and public health associations, associations representing hospitals or other health care entities, health information technology experts, and other appropriate public or private entities regarding the plan and grant program to modernize public health data systems pursuant to this section. Activities under this subsection may include the provision of technical assistance and training related to the exchange of information by such public health data systems used by relevant health care and public health entities at the local, State, Federal, Tribal, and territorial levels, and the development and utilization of public-private partnerships for implementation support applicable to this section.

(e) Report to Congress

Not later than 1 year after December 27, 2020, the Secretary shall submit a report to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives that includes—

(1) a description of any barriers to—

(A) public health authorities implementing interoperable public health data systems and electronic case reporting;

(B) the exchange of information pursuant to electronic case reporting;

(C) reporting by health care providers using such public health data systems, as appropriate, and pursuant to State law; or

(D) improving demographic data collection or analysis;

(2) an assessment of the potential public health impact of implementing electronic case reporting and interoperable public health data systems; and

(3) a description of the activities carried out pursuant to this section.

(f) Electronic case reporting

In this section, the term "electronic case reporting" means the automated identification, generation, and bilateral exchange of reports of health events among electronic health record or health information technology systems and public health authorities.

(g) Authorization of appropriations

To carry out this section, there are authorized to be appropriated $100,000,000 for each of fiscal years 2021 through 2025.

(July 1, 1944, ch. 373, title XXVIII, §2823, as added Pub. L. 116–260, div. BB, title III, §314, Dec. 27, 2020, 134 Stat. 2929; amended Pub. L. 117–328, div. FF, title II, §2213(a), Dec. 29, 2022, 136 Stat. 5734.)

EDITORIAL NOTES

AMENDMENTS

2022—Subsec. (a)(2). Pub. L. 117–328 designated existing provisions as subpar. (A) and inserted heading, substituted "shall, not later than 2 years after December 29, 2022," for "shall, as appropriate and", and added subpars. (B) and (C).

STATUTORY NOTES AND RELATED SUBSIDIARIES

IMPROVING STATE, LOCAL, AND TRIBAL PUBLIC HEALTH DATA

Pub. L. 117–328, div. FF, title II, §2213(e), Dec. 29, 2022, 136 Stat. 5737, provided that:

"(1) IN GENERAL.—The Secretary of Health and Human Services (referred to in this section as the 'Secretary') shall award grants, contracts, or cooperative agreements to eligible entities for purposes of identifying, developing, or disseminating best practices in electronic health information and the use of designated data standards and implementation specifications, including privacy standards, to improve the quality and completeness of data, including demographic data used for public health purposes.

"(2) ELIGIBLE ENTITIES.—To be eligible to receive an award under this subsection an entity shall—

"(A) be a health care provider, academic medical center, community-based organization, State, local governmental entity, Indian Tribe or Tribal organization (as such terms are defined in section 4 of the Indian Self Determination and Education Assistance Act (25 U.S.C. 5304)), urban Indian organization (as defined in section 4 of the Indian Health Care Improvement Act (25 U.S.C. 1603)), or other appropriate public or private nonprofit entity, or a consortia of any such entities; and

"(B) submit an application to the Secretary at such time, in such manner, and containing such information as the Secretary may require.

"(3) ACTIVITIES.—Entities receiving awards under this subsection shall use such award to develop and test best practices for training health care providers to use standards and implementation specifications that assist in the capture, access, exchange, and use of electronic health information, deidentified as applicable, such as demographic information, disability status, veteran status, and functional status. Such activities shall include, at a minimum—

"(A) improving, understanding, and using data standards and implementation specifications;

"(B) developing or identifying methods to improve communication with patients in a culturally- and linguistically-appropriate manner, including to better capture information related to demographics of such individuals;

"(C) developing methods for accurately categorizing and recording patient responses using available data standards;

"(D) educating providers regarding the utility of such information for public health purposes and the importance of accurate collection and recording of such data; and

"(E) providing information regarding how data will be deidentified if used for such public health purposes, as applicable and appropriate.

"(4) REPORTING.—

"(A) REPORTING BY AWARD RECIPIENTS.—Each recipient of an award under this subsection shall submit to the Secretary a report on the results of best practices identified, developed, or disseminated through such award.

"(B) REPORT TO CONGRESS.—Not later than 1 year after the completion of the program under this

subsection, the Secretary shall submit a report to Congress on the success of best practices developed under such program, opportunities for further dissemination of such best practices, and recommendations for improving the capture, access, exchange, and use of information to improve public health and reduce health disparities.

"(5) NON-DUPLICATION OF EFFORTS.—The Secretary shall ensure that the activities and programs carried out under this subsection are free of unnecessary duplication of effort."

§300hh–34. Genomic sequencing, analytics, and public health surveillance of pathogens program

(a) Genomic sequencing, analytics, and public health surveillance of pathogens program

The Secretary, acting through the Director of the Centers for Disease Control and Prevention and in consultation with the Director of the National Institutes of Health and heads of other departments and agencies, as appropriate, shall strengthen and expand activities related to genomic sequencing of pathogens, including through new and innovative approaches and technology for the detection, characterization, and sequencing of pathogens, analytics, and public health surveillance, including—

(1) continuing and expanding activities, which may include existing genomic sequencing activities related to advanced molecular detection, to—

(A) identify and respond to emerging infectious disease threats; and

(B) identify the potential use of genomic sequencing technologies, advanced computing, and other advanced technology to inform surveillance activities and incorporate the use of such technologies, as appropriate, into related activities;

(2) providing technical assistance and guidance to State, Tribal, local, and territorial public health departments to increase the capacity of such departments to perform genomic sequencing of pathogens, including recipients of funding under section 300hh–31 of this title;

(3) carrying out activities to enhance the capabilities of the public health workforce with respect to pathogen genomics, epidemiology, and bioinformatics, including through training; and

(4) continuing and expanding activities, as applicable, with public and private entities, including relevant departments and agencies, laboratories, academic institutions, and industry.

(b) Partnerships

For the purposes of carrying out the activities described in subsection (a), the Secretary, acting through the Director of the Centers for Disease Control and Prevention, may award grants, contracts, or cooperative agreements to entities, including academic and other laboratories, with expertise in genomic sequencing for public health purposes, including new and innovative approaches to, and related technology for, the detection, characterization, and sequencing of pathogens.

(c) Centers of excellence

(1) In general

The Secretary shall, as appropriate, award grants, contracts, or cooperative agreements to public health agencies for the establishment or operation of centers of excellence to promote innovation in pathogen genomics and molecular epidemiology to improve the control of and response to pathogens that may cause a public health emergency. Such centers shall, as appropriate—

(A) identify and evaluate the use of genomics, or other related technologies that may advance public health preparedness and response;

(B) improve the identification, development, and use of tools for integrating and analyzing genomic and epidemiologic data;

(C) assist with genomic surveillance of, and response to, infectious diseases, including analysis of pathogen genomic data;

(D) conduct applied research to improve public health surveillance of, and response to, infectious diseases through innovation in pathogen genomics and molecular epidemiology; and

(E) develop and provide training materials for experts in the fields of genomics,

microbiology, bioinformatics, epidemiology, and other fields, as appropriate.

(2) Requirements

To be eligible for an award under paragraph (1), an entity shall submit to the Secretary an application containing such information as the Secretary may require, including a description of how the entity will partner, as applicable, with academic institutions or a consortium of academic partners that have relevant expertise, such as microbial genomics, molecular epidemiology, or the application of bioinformatics or statistics.

(July 1, 1944, ch. 373, title XXVIII, §2824, as added Pub. L. 117–328, div. FF, title II, §2212(b), Dec. 29, 2022, 136 Stat. 5733.)

STATUTORY NOTES AND RELATED SUBSIDIARIES

GUIDANCE SUPPORTING GENOMIC SEQUENCING OF PATHOGENS COLLABORATION

Pub. L. 117–328, div. FF, title II, §2212(a), Dec. 29, 2022, 136 Stat. 5732, provided that: "The Secretary of Health and Human Services (referred to in this section as the 'Secretary'), in consultation with the heads of other Federal departments or agencies, as appropriate, shall issue guidance to support collaboration relating to genomic sequencing of pathogens, including the use of new and innovative approaches and technology for the detection, characterization, and sequencing of pathogens, to improve public health surveillance and preparedness and response activities, consistent with section 2824 of the Public Health Service Act [42 U.S.C. 300hh–34], as added by subsection (b). Such guidance shall address the secure sharing, for public health surveillance purposes, of specimens of such pathogens, between appropriate entities and public health authorities, consistent with the regulations promulgated under section 264(c) of the Health Insurance Portability and Accountability Act of 1996 [Pub. L. 104–191] (42 U.S.C. 1320d–2 note), as applicable, and in a manner that protects personal privacy to the extent required by applicable privacy law, at a minimum, and the appropriate use of sequence data derived from such specimens."

§300hh–35. Epidemic forecasting and outbreak analytics

(a) In general

The Secretary, acting through the Director of the Centers for Disease Control and Prevention, shall continue activities related to the development of infectious disease outbreak analysis capabilities to enhance the prediction, modeling, and forecasting of potential public health emergencies and other infectious disease outbreaks, which may include activities to support preparedness for, and response to, such emergencies and outbreaks. In carrying out this subsection, the Secretary shall identify strategies to include and leverage, as appropriate, the capabilities to public and private entities, which may include conducting such activities through collaborative partnerships with public and private entities, including academic institutions, and other Federal agencies, consistent with section 247d–4 of this title, as applicable.

(b) Considerations

In carrying out subsection (a), the Secretary, acting through the Director of the Centers for Disease Control and Prevention, may consider public health data and, as appropriate, other data sources related to preparedness for, or response to, public health emergencies and infectious disease outbreaks.

(c) Annual reports

Not later than 1 year after December 29, 2022, and annually thereafter for each of the subsequent 4 years, the Secretary shall prepare and submit a report, to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives, regarding an update on progress on activities conducted under this section to develop infectious disease outbreak analysis capabilities and any additional information relevant to such efforts.

(July 1, 1944, ch. 373, title XXVIII, §2825, as added Pub. L. 117–328, div. FF, title II, §2214, Dec.

29, 2022, 136 Stat. 5739.)

§300hh–36. Leadership exchange pilot for public health and medical preparedness and response positions at the Department of Health and Human Services

(a) In general

The Secretary may, not later than 1 year after December 29, 2022, establish a voluntary program to provide additional training to individuals in eligible positions, as described in subsection (c), to support the continuous professional development of such individuals.

(b) Criteria

(1) Duration

The program under subsection (a) shall provide for fellowships, details, or other relevant placements with Federal agencies or departments, or State or local health departments, pursuant to the guidance issued under paragraph (2), for a maximum period of 2 years.

(2) Guidance

The Secretary shall issue guidance establishing criteria for identifying placements that demonstrate ongoing sufficient mastery of knowledge, skills, and abilities to satisfy the field experience criteria under the program established under subsection (a), including assignments and experiences that develop public health and medical preparedness and response expertise.

(c) Eligible position

For purposes of subsection (a), the term "eligible position" means any position at the Department of Health and Human Services at or above grade GS–13 of the General Schedule, or the equivalent, for which not less than 50 percent of the time of such position is spent on activities related to public health preparedness or response.

(d) Pilot period and final report

The pilot program authorized under this section shall not exceed 5 years. Not later than 90 days after the end of the program, the Secretary shall issue a report to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives that includes—

(1) the number of individuals who participated in such pilot, as applicable;

(2) a description of the professional growth experience in which individuals participated; and

(3) an assessment of the outcomes of such program, including a recommendation on whether such program should be continued.

(July 1, 1944, ch. 373, title XXVIII, §2826, as added Pub. L. 117–328, div. FF, title II, §2226, Dec. 29, 2022, 136 Stat. 5750.)

EDITORIAL NOTES

REFERENCES IN TEXT

The General Schedule, referred to in subsec. (c), is set out under section 5332 of Title 5, Government Organization and Employees.

§300hh–37. One Health framework

(a) One Health framework

The Secretary of Health and Human Services (referred to in this section as the "Secretary"), acting through the Director of the Centers for Disease Control and Prevention, shall develop, or update as

appropriate, in coordination with other Federal departments and agencies, as appropriate, a One Health framework to address zoonotic diseases and advance public health preparedness.

(b) One Health coordination

The Secretary, acting through the Director of the Centers for Disease Control and Prevention, shall coordinate with the Secretary of Agriculture and the Secretary of the Interior to develop a One Health coordination mechanism at the Federal level to strengthen One Health collaboration related to prevention, detection, control, and response for zoonotic diseases and related One Health work across the Federal Government.

(c) Reporting

Not later than 1 year after December 29, 2022, the Secretary shall submit to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives a report providing an update on the activities under subsections (a) and (b).

(Pub. L. 117–328, div. FF, title II, §2235, Dec. 29, 2022, 136 Stat. 5755.)

EDITORIAL NOTES

CODIFICATION

Section was enacted as part of the Prepare for and Respond to Existing Viruses, Emerging New Threats, and Pandemics Act, also known as the PREVENT Pandemics Act, and also as part of the Health Extenders, Improving Access to Medicare, Medicaid, and CHIP, and Strengthening Public Health Act of 2022, and not as part of the Public Health Service Act which comprises this chapter.

SUBCHAPTER XXVII—LIFESPAN RESPITE CARE

§300ii. Definitions

In this subchapter:

(1) Adult with a special need

The term "adult with a special need" means a person 18 years of age or older who requires care or supervision to—

(A) meet the person's basic needs;

(B) prevent physical self-injury or injury to others; or

(C) avoid placement in an institutional facility.

(2) Aging and disability resource center

The term "aging and disability resource center" means an entity administering a program established by the State, as part of the State's system of long-term care, to provide a coordinated system for providing—

(A) comprehensive information on available public and private long-term care programs, options, and resources;

(B) personal counseling to assist individuals in assessing their existing or anticipated long-term care needs, and developing and implementing a plan for long-term care designed to meet their specific needs and circumstances; and

(C) consumer access to the range of publicly supported long-term care programs for which consumers may be eligible, by serving as a convenient point of entry for such programs.

(3) Child with a special need

The term "child with a special need" means an individual less than 18 years of age who requires care or supervision beyond that required of children generally to—

(A) meet the child's basic needs; or
(B) prevent physical injury, self-injury, or injury to others.

(4) Eligible State agency

The term "eligible State agency" means a State agency that—
(A) administers the State's program under the Older Americans Act of 1965 [42 U.S.C. 3001 et seq.], administers the State's program under title XIX of the Social Security Act [42 U.S.C. 1396 et seq.], or is designated by the Governor of such State to administer the State's programs under this subchapter;
(B) is an aging and disability resource center;
(C) works in collaboration with a public or private nonprofit statewide respite care coalition or organization; and
(D) demonstrates—
(i) an ability to work with other State and community-based agencies;
(ii) an understanding of respite care and family caregiver issues across all age groups, disabilities, and chronic conditions; and
(iii) the capacity to ensure meaningful involvement of family members, family caregivers, and care recipients.

(5) Family caregiver

The term "family caregiver" means an unpaid family member, a foster parent, or another unpaid individual, who provides in-home monitoring, management, supervision, or treatment of a child or adult with a special need.

(6) Lifespan respite care

The term "lifespan respite care" means a coordinated system of accessible, community-based respite care services for family caregivers of children or adults with special needs.

(7) Respite care

The term "respite care" means planned or emergency care provided to a child or adult with a special need in order to provide temporary relief to the family caregiver of that child or adult.

(8) State

The term "State" means any of the several States, the District of Columbia, the Virgin Islands of the United States, the Commonwealth of Puerto Rico, Guam, American Samoa, and the Commonwealth of the Northern Mariana Islands.

(July 1, 1944, ch. 373, title XXIX, §2901, as added Pub. L. 109–442, §2, Dec. 21, 2006, 120 Stat. 3291; amended Pub. L. 119–75, div. J, title V, §6506(a), Feb. 3, 2026, 140 Stat. 693.)

EDITORIAL NOTES

REFERENCES IN TEXT

The Older Americans Act of 1965, referred to in par. (4)(A), is Pub. L. 89–73, July 14, 1965, 79 Stat. 218, which is classified generally to chapter 35 (§3001 et seq.) of this title. For complete classification of this Act to the Code, see Short Title note set out under section 3001 of this title and Tables.

The Social Security Act, referred to in par. (4)(A), is act Aug. 14, 1935, ch. 531, 49 Stat. 620. Title XIX of the Act is classified generally to subchapter XIX (§1396 et seq.) of chapter 7 of this title. For complete classification of this Act to the Code, see section 1305 of this title and Tables.

AMENDMENTS

2026—Par. (5). Pub. L. 119–75 substituted "unpaid individual" for "unpaid adult".

§300ii–1. Lifespan respite care grants and cooperative agreements

(a) Purposes

The purposes of this section are—

(1) to expand and enhance respite care services to family caregivers;

(2) to improve the statewide dissemination and coordination of respite care; and

(3) to provide, supplement, or improve access and quality of respite care services to family caregivers, thereby reducing family caregiver strain.

(b) Authorization

Subject to subsection (e), the Secretary is authorized to award grants or cooperative agreements for the purposes described in subsection (a) to eligible State agencies for which an application is submitted pursuant to subsection (d).

(c) Federal lifespan approach

In carrying out this section, the Secretary shall work in cooperation with the National Family Caregiver Support Program of the Administration on Aging and other respite care programs within the Department of Health and Human Services to ensure coordination of respite care services for family caregivers of children and adults with special needs.

(d) Application

(1) Submission

Each Governor desiring the eligible State agency of his or her State to receive a grant or cooperative agreement under this section shall submit an application on behalf of such agency to the Secretary at such time, in such manner, and containing such information as the Secretary shall require.

(2) Contents

Each application submitted under this section shall include—

(A) a description of the eligible State agency's—

(i) ability to work with other State and community-based agencies;

(ii) understanding of respite care and family caregiver issues across all age groups, disabilities, and chronic conditions; and

(iii) capacity to ensure meaningful involvement of family members, family caregivers, and care recipients;

(B) with respect to the population of family caregivers to whom respite care information or services will be provided or for whom respite care workers and volunteers will be recruited and trained, a description of—

(i) the population of family caregivers;

(ii) the extent and nature of the respite care needs of that population;

(iii) existing respite care services for that population, including numbers of family caregivers being served and extent of unmet need;

(iv) existing methods or systems to coordinate respite care information and services to the population at the State and local level and extent of unmet need;

(v) how respite care information dissemination and coordination, respite care services, respite care worker and volunteer recruitment and training programs, or training programs for family caregivers that assist such family caregivers in making informed decisions about respite care services will be provided using grant or cooperative agreement funds;

(vi) a plan for administration, collaboration, and coordination of the proposed respite care activities with other related services or programs offered by public or private, nonprofit entities, including area agencies on aging;

(vii) how the population, including family caregivers, care recipients, and relevant public or private agencies, will participate in the planning and implementation of the proposed respite care activities;

(viii) how the proposed respite care activities will make use, to the maximum extent feasible, of other Federal, State, and local funds, programs, contributions, other forms of

reimbursements, personnel, and facilities;

(ix) respite care services available to family caregivers in the eligible State agency's State or locality, including unmet needs and how the eligible State agency's plan for use of funds will improve the coordination and distribution of respite care services for family caregivers of children and adults with special needs;

(x) the criteria used to identify family caregivers eligible for respite care services;

(xi) how the quality and safety of any respite care services provided will be monitored, including methods to ensure that respite care workers and volunteers are appropriately screened and possess the necessary skills to care for the needs of the care recipient in the absence of the family caregiver; and

(xii) the results expected from proposed respite care activities and the procedures to be used for evaluating those results;

(C) assurances that, where appropriate, the eligible State agency will have a system for maintaining the confidentiality of care recipient and family caregiver records; and

(D) a memorandum of agreement regarding the joint responsibility for the eligible State agency's lifespan respite program between—

(i) the eligible State agency; and

(ii) a public or private nonprofit statewide respite coalition or organization.

(e) Priority; considerations

When awarding grants or cooperative agreements under this section, the Secretary shall—

(1) give priority to eligible State agencies that the Secretary determines show the greatest likelihood of implementing or enhancing lifespan respite care statewide; and

(2) give consideration to eligible State agencies that are building or enhancing the capacity of their long-term care systems to respond to the comprehensive needs, including respite care needs, of their residents.

(f) Use of grant or cooperative agreement funds

(1) In general

(A) Required uses of funds

Each eligible State agency awarded a grant or cooperative agreement under this section shall use all or part of the funds—

(i) to develop or enhance lifespan respite care at the State and local levels;

(ii) to provide respite care services for family caregivers caring for children or adults;

(iii) to train and recruit respite care workers and volunteers;

(iv) to provide information to caregivers about available respite and support services; and

(v) to assist caregivers in gaining access to such services.

(B) Optional uses of funds

Each eligible State agency awarded a grant or cooperative agreement under this section may use part of the funds for—

(i) training programs for family caregivers to assist such family caregivers in making informed decisions about respite care services;

(ii) other services essential to the provision of respite care as the Secretary may specify; or

(iii) training and education for new caregivers.

(2) Subcontracts

Each eligible State agency awarded a grant or cooperative agreement under this section may carry out the activities described in paragraph (1) directly or by grant to, or contract with, public or private entities.

(3) Matching funds

(A) In general

With respect to the costs of the activities to be carried out under paragraph (1), a condition for the receipt of a grant or cooperative agreement under this section is that the eligible State agency agrees to make available (directly or through donations from public or private entities) non-Federal contributions toward such costs in an amount that is not less than 25 percent of such costs.

(B) Determination of amount contributed

Non-Federal contributions required by subparagraph (A) may be in cash or in kind, fairly evaluated, including plant, equipment, or services. Amounts provided by the Federal Government, or services assisted or subsidized to any significant extent by the Federal Government, may not be included in determining the amount of such non-Federal contributions.

(g) Term of grants or cooperative agreements

(1) In general

The Secretary shall award grants or cooperative agreements under this section for terms that do not exceed 5 years.

(2) Renewal

The Secretary may renew a grant or cooperative agreement under this section at the end of the term of the grant or cooperative agreement determined under paragraph (1).

(h) Maintenance of effort

Funds made available under this section shall be used to supplement and not supplant other Federal, State, and local funds available for respite care services.

(July 1, 1944, ch. 373, title XXIX, §2902, as added Pub. L. 109–442, §2, Dec. 21, 2006, 120 Stat. 3292.)

§300ii–2. National lifespan respite resource center

(a) Establishment

The Secretary may award a grant or cooperative agreement to a public or private nonprofit entity to establish a National Resource Center on Lifespan Respite Care (referred to in this section as the "center").

(b) Purposes of the center

The center shall—

(1) maintain a national database on lifespan respite care;

(2) provide training and technical assistance to State, community, and nonprofit respite care programs; and

(3) provide information, referral, and educational programs to the public on lifespan respite care.

(July 1, 1944, ch. 373, title XXIX, §2903, as added Pub. L. 109–442, §2, Dec. 21, 2006, 120 Stat. 3295.)

§300ii–3. Data collection and reporting

(a) In general

Each State agency awarded a grant or cooperative agreement under section 300ii–1 of this title shall report such data, information, and metrics as the Secretary may require for purposes of—

(1) evaluating State programs and activities funded pursuant to such grant or cooperative agreement, including any results pursuant to section 300ii–1(d)(2)(B)(xii) of this title; and

(2) identifying effective programs and activities funded pursuant to section 300ii–1 of this title.

(b) Report

Not later than October 1, 2023, the Secretary shall submit a report to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives regarding the outcomes of the programs and activities funded pursuant to section 300ii–1 of this title, including any effective programs and activities identified.

(July 1, 1944, ch. 373, title XXIX, §2904, as added Pub. L. 109–442, §2, Dec. 21, 2006, 120 Stat. 3295; amended Pub. L. 116–324, §2(a), Jan. 5, 2021, 134 Stat. 5085.)

EDITORIAL NOTES

AMENDMENTS

2021—Pub. L. 116–324 amended section generally. Prior to amendment, section required the Secretary to report to Congress by Jan. 1, 2009, on the activities undertaken under this subchapter.

§300ii–4. Authorization of appropriations

There are authorized to be appropriated to carry out this subchapter, $10,000,000 for each of fiscal years 2026 through 2030.

(July 1, 1944, ch. 373, title XXIX, §2905, as added Pub. L. 109–442, §2, Dec. 21, 2006, 120 Stat. 3296; amended Pub. L. 116–324, §2(b), Jan. 5, 2021, 134 Stat. 5085; Pub. L. 119–75, div. J, title V, §6506(b), Feb. 3, 2026, 140 Stat. 693.)

EDITORIAL NOTES

AMENDMENTS

2026—Pub. L. 119–75 substituted "fiscal years 2026 through 2030" for "fiscal years 2020 through fiscal year 2024".

2021—Pub. L. 116–324 substituted "subchapter, $10,000,000 for each of fiscal years 2020 through fiscal year 2024." for "subchapter—

"(1) $30,000,000 for fiscal year 2007;

"(2) $40,000,000 for fiscal year 2008;

"(3) $53,330,000 for fiscal year 2009;

"(4) $71,110,000 for fiscal year 2010; and

"(5) $94,810,000 for fiscal year 2011."

SUBCHAPTER XXVIII—HEALTH INFORMATION TECHNOLOGY AND QUALITY

§300jj. Definitions

In this subchapter:

(1) Certified EHR technology

The term "certified EHR technology" means a qualified electronic health record that is certified pursuant to section 300jj–11(c)(5) of this title as meeting standards adopted under section 300jj–14 of this title that are applicable to the type of record involved (as determined by the Secretary, such as an ambulatory electronic health record for office-based physicians or an inpatient hospital electronic health record for hospitals).

(2) Enterprise integration

The term "enterprise integration" means the electronic linkage of health care providers, health

plans, the government, and other interested parties, to enable the electronic exchange and use of health information among all the components in the health care infrastructure in accordance with applicable law, and such term includes related application protocols and other related standards.

(3) Health care provider

The term "health care provider" includes a hospital, skilled nursing facility, nursing facility, home health entity or other long term care facility, health care clinic, community mental health center (as defined in section 300x–2(b)(1) of this title), renal dialysis facility, blood center, ambulatory surgical center described in section 1395l(i) of this title,[1] emergency medical services provider, Federally qualified health center, group practice, a pharmacist, a pharmacy, a laboratory, a physician (as defined in section 1395x(r) of this title), a practitioner (as described in section 1395u(b)(18)(C) of this title), a provider operated by, or under contract with, the Indian Health Service or by an Indian tribe (as defined in the Indian Self-Determination and Education Assistance Act [25 U.S.C. 5301 et seq.]), tribal organization, or urban Indian organization (as defined in section 1603 of title 25), a rural health clinic, a covered entity under section 256b of this title, an ambulatory surgical center described in section 1395l(i) of this title,[1] a therapist (as defined in section 1395w–4(k)(3)(B)(iii) of this title), and any other category of health care facility, entity, practitioner, or clinician determined appropriate by the Secretary.

(4) Health information

The term "health information" has the meaning given such term in section 1320d(4) of this title.

(5) Health information technology

The term "health information technology" means hardware, software, integrated technologies or related licenses, intellectual property, upgrades, or packaged solutions sold as services that are designed for or support the use by health care entities or patients for the electronic creation, maintenance, access, or exchange of health information [2]

(6) Health plan

The term "health plan" has the meaning given such term in section 1320d(5) of this title.

(7) HIT Advisory Committee

The term "HIT Advisory Committee" means such Committee established under section 300jj–12(a) of this title.

(8) Individually identifiable health information

The term "individually identifiable health information" has the meaning given such term in section 1320d(6) of this title.

(9) Interoperability

The term "interoperability", with respect to health information technology, means such health information technology that—

(A) enables the secure exchange of electronic health information with, and use of electronic health information from, other health information technology without special effort on the part of the user;

(B) allows for complete access, exchange, and use of all electronically accessible health information for authorized use under applicable State or Federal law; and

(C) does not constitute information blocking as defined in section 300jj–52(a) of this title.

(10) Laboratory

The term "laboratory" has the meaning given such term in section 263a(a) of this title.

(11) National Coordinator

The term "National Coordinator" means the head of the Office of the National Coordinator for Health Information Technology established under section 300jj–11(a) of this title.

(12) Pharmacist

The term "pharmacist" has the meaning given such term in section 384(2) [3] of title 21.

(13) Qualified electronic health record

The term "qualified electronic health record" means an electronic record of health-related information on an individual that—

(A) includes patient demographic and clinical health information, such as medical history and problem lists;

(B) has the capacity—

(i) to provide clinical decision support;

(ii) to support physician order entry;

(iii) to capture and query information relevant to health care quality; and

(iv) to exchange electronic health information with, and integrate such information from other sources; and

(C) includes, or is capable of including, a real-time benefit tool that conveys patient-specific real-time cost and coverage information with respect to prescription drugs that, with respect to any health information technology certified for electronic prescribing, the technology shall be capable of incorporating the information described in clauses (i) through (iii) of paragraph (2)(B) of section 1395w–104(o) of this title at a time specified by the Secretary but not before the Secretary adopts a standard for such tools as described in paragraph (1) of such section.

(15) [4] State

The term "State" means each of the several States, the District of Columbia, Puerto Rico, the Virgin Islands, Guam, American Samoa, and the Northern Mariana Islands.

(July 1, 1944, ch. 373, title XXX, §3000, as added Pub. L. 111–5, div. A, title XIII, §13101, Feb. 17, 2009, 123 Stat. 228; amended Pub. L. 114–255, div. A, title IV, §4003(a), (e)(2)(B), Dec. 13, 2016, 130 Stat. 1165, 1174; Pub. L. 116–260, div. CC, title I, §119(b), Dec. 27, 2020, 134 Stat. 2952.)

EDITORIAL NOTES

REFERENCES IN TEXT

The Indian Self-Determination and Education Assistance Act, referred to in par. (3), is Pub. L. 93–638, Jan. 4, 1975, 88 Stat. 2203, which is classified principally to chapter 46 (§5301 et seq.) of Title 25, Indians. For complete classification of this Act to the Code, see Short Title note set out under section 5301 of Title 25 and Tables.

AMENDMENTS

2020—Par. (13)(C). Pub. L. 116–260 added subpar. (C).

2016—Par. (7). Pub. L. 114–255, §4003(e)(2)(B), added par. (7) and struck out former par. (7). Prior to amendment, text read as follows: "The term 'HIT Policy Committee' means such Committee established under section 300jj–12(a) of this title."

Par. (8). Pub. L. 114–255, §4003(e)(2)(B)(i), redesignated par. (9) as (8) and struck out former par. (8). Prior to amendment, text of par. (8) read as follows: "The term 'HIT Standards Committee' means such Committee established under section 300jj–13(a) of this title."

Par. (9). Pub. L. 114–255, §4003(e)(2)(B)(i), redesignated par. (10) as (9). Former par. (9) redesignated (8).

Par. (10). Pub. L. 114–255, §4003(e)(2)(B)(i), redesignated par. (11) as (10). Former par. (10) redesignated (9).

Pub. L. 114–255, §4003(a)(2), added par. (10). Former par. (10) redesignated (11).

Pars. (11) to (14). Pub. L. 114–255, §4003(e)(2)(B)(i), redesignated pars. (12) to (14) as (11) to (13), respectively. Former par. (11) redesignated (10).

Pub. L. 114–255, §4003(a)(1), redesignated pars. (10) to (13) as (11) to (14), respectively. Former par. (14) redesignated (15).

Par. (15). Pub. L. 114–255, §4003(a)(1), redesignated par. (14) as (15).

STATUTORY NOTES AND RELATED SUBSIDIARIES

ASSISTING DOCTORS AND HOSPITALS IN IMPROVING QUALITY OF CARE FOR PATIENTS

Pub. L. 111–5, div. A, title XIII, §13103, as added by Pub. L. 114–255, div. A, title IV, §4001(a)(1), Dec. 13, 2016, 130 Stat. 1157, provided that:

"(a) REDUCTION IN BURDENS GOAL.—The Secretary of Health and Human Services (referred to in this section as the 'Secretary'), in consultation with providers of health services, health care suppliers of services, health care payers, health professional societies, health information technology developers, health care quality organizations, health care accreditation organizations, public health entities, States, and other appropriate entities, shall, in accordance with subsection (b)—

"(1) establish a goal with respect to the reduction of regulatory or administrative burdens (such as documentation requirements) relating to the use of electronic health records;

"(2) develop a strategy for meeting the goal established under paragraph (1); and

"(3) develop recommendations for meeting the goal established under paragraph (1).

"(b) STRATEGY AND RECOMMENDATIONS.—

"(1) IN GENERAL.—To achieve the goal established under subsection (a)(1), the Secretary, in consultation with the entities described in such subsection, shall, not later than 1 year after the date of enactment of the 21st Century Cures Act [Dec. 13, 2016], develop a strategy and recommendations to meet the goal in accordance with this subsection.

"(2) STRATEGY.—The strategy developed under paragraph (1) shall address the regulatory and administrative burdens (such as documentation requirements) relating to the use of electronic health records. Such strategy shall include broad public comment and shall prioritize—

"(A)(i) incentives for meaningful use of certified EHR technology for eligible professionals and hospitals under sections 1848(a)(7) and 1886(b)(3)(B)(ix), respectively, of the Social Security Act (42 U.S.C. 1395w–4(a)(7), 1395ww(b)(3)(B)(ix));

"(ii) the program for making payments under section 1903(a)(3)(F) of the Social Security Act (42 U.S.C. 1396b(a)(3)(F)) to encourage the adoption and use of certified EHR technology by Medicaid providers;

"(iii) the Merit-based Incentive Payment System under section 1848(q) of the Social Security Act (42 U.S.C. 1395w–4(q));

"(iv) alternative payment models (as defined in section 1833(z)(3)(C) of the Social Security Act (42 U.S.C. 1395l(z)(3)(C));

"(v) the Hospital Value-Based Purchasing Program under section 1886(o) of the Social Security Act (42 U.S.C. 1395ww(o)); and

"(vi) other value-based payment programs, as the Secretary determines appropriate;

"(B) health information technology certification;

"(C) standards and implementation specifications, as appropriate;

"(D) activities that provide individuals access to their electronic health information;

"(E) activities related to protecting the privacy of electronic health information;

"(F) activities related to protecting the security of electronic health information;

"(G) activities related to facilitating health and clinical research;

"(H) activities related to public health;

"(I) activities related to aligning and simplifying quality measures across Federal programs and other payers;

"(J) activities related to reporting clinical data for administrative purposes; and

"(K) other areas, as the Secretary determines appropriate.

"(3) RECOMMENDATIONS.—The recommendations developed under paragraph (1) shall address—

"(A) actions that improve the clinical documentation experience;

"(B) actions that improve patient care;

"(C) actions to be taken by the Secretary and by other entities; and

"(D) other areas, as the Secretary determines appropriate, to reduce the reporting burden required of health care providers.

"(4) FACA.—The Federal Advisory Committee Act ([former] 5 U.S.C. App.) [see 5 U.S.C. 1001 et seq.] shall not apply to the development of the goal, strategies, or recommendations described in this section.

"(c) APPLICATION OF CERTAIN REGULATORY REQUIREMENTS.—A physician (as defined in section 1861(r)(1) of the Social Security Act [42 U.S.C. 1395x(r)(1)]), to the extent consistent with applicable State law, may delegate electronic medical record documentation requirements specified in regulations promulgated by the Centers for Medicare & Medicaid Services to a person performing a scribe function who is not such physician if such physician has signed and verified the documentation."

[1] So in original. The words "ambulatory surgical center described in section 1395l(i) of this title" appear in two places.

[2] So in original. Probably should be followed by a period.

[3] So in original. Probably should be "(a)(2)".

[4] So in original. There is no par. (14).

PART A—PROMOTION OF HEALTH INFORMATION TECHNOLOGY

§300jj–11. Office of the National Coordinator for Health Information Technology

(a) Establishment

There is established within the Department of Health and Human Services an Office of the National Coordinator for Health Information Technology (referred to in this section as the "Office"). The Office shall be headed by a National Coordinator who shall be appointed by the Secretary and shall report directly to the Secretary.

(b) Purpose

The National Coordinator shall perform the duties under subsection (c) in a manner consistent with the development of a nationwide health information technology infrastructure that allows for the electronic use and exchange of information and that—

(1) ensures that each patient's health information is secure and protected, in accordance with applicable law;

(2) improves health care quality, reduces medical errors, reduces health disparities, and advances the delivery of patient-centered medical care;

(3) reduces health care costs resulting from inefficiency, medical errors, inappropriate care, duplicative care, and incomplete information;

(4) provides appropriate information to help guide medical decisions at the time and place of care;

(5) ensures the inclusion of meaningful public input in such development of such infrastructure;

(6) improves the coordination of care and information among hospitals, laboratories, physician offices, and other entities through an effective infrastructure for the secure and authorized exchange of health care information;

(7) improves public health activities and facilitates the early identification and rapid response to public health threats and emergencies, including bioterror events and infectious disease outbreaks;

(8) facilitates health and clinical research and health care quality;

(9) promotes early detection, prevention, and management of chronic diseases;

(10) promotes a more effective marketplace, greater competition, greater systems analysis, increased consumer choice, and improved outcomes in health care services; and

(11) improves efforts to reduce health disparities.

(c) Duties of the National Coordinator

(1) Standards

The National Coordinator shall—

(A) review and determine whether to endorse each standard, implementation specification, and certification criterion for the electronic exchange and use of health information that is

recommended by the HIT Advisory Committee under section 300jj–12 of this title for purposes of adoption under section 300jj–14 of this title;

(B) make such determinations under subparagraph (A), and report to the Secretary such determinations, not later than 45 days after the date the recommendation is received by the Coordinator; and

(C) review Federal health information technology investments to ensure that Federal health information technology programs are meeting the objectives of the strategic plan published under paragraph (3).

(2) HIT policy coordination

(A) In general

The National Coordinator shall coordinate health information technology policy and programs of the Department with those of other relevant executive branch agencies with a goal of avoiding duplication of efforts and of helping to ensure that each agency undertakes health information technology activities primarily within the areas of its greatest expertise and technical capability and in a manner towards a coordinated national goal.

(B) HIT Advisory Committee

The National Coordinator shall be a leading member in the establishment and operations of the HIT Advisory Committee and shall serve as a liaison between that Committee and the Federal Government.

(3) Strategic plan

(A) In general

The National Coordinator shall, in consultation with other appropriate Federal agencies (including the National Institute of Standards and Technology), update the Federal Health IT Strategic Plan (developed as of June 3, 2008) to include specific objectives, milestones, and metrics with respect to the following:

(i) The electronic exchange and use of health information and the enterprise integration of such information.

(ii) The utilization of an electronic health record for each person in the United States by 2014.

(iii) The incorporation of privacy and security protections for the electronic exchange of an individual's individually identifiable health information.

(iv) Ensuring security methods to ensure appropriate authorization and electronic authentication of health information and specifying technologies or methodologies for rendering health information unusable, unreadable, or indecipherable.

(v) Specifying a framework for coordination and flow of recommendations and policies under this part among the Secretary, the National Coordinator, the HIT Advisory Committee, and other health information exchanges and other relevant entities.

(vi) Methods to foster the public understanding of health information technology.

(vii) Strategies to enhance the use of health information technology in improving the quality of health care, reducing medical errors, reducing health disparities, improving public health, increasing prevention and coordination with community resources, and improving the continuity of care among health care settings.

(viii) Specific plans for ensuring that populations with unique needs, such as children, are appropriately addressed in the technology design, as appropriate, which may include technology that automates enrollment and retention for eligible individuals.

(B) Collaboration

The strategic plan shall be updated through collaboration of public and private entities.

(C) Measurable outcome goals

The strategic plan update shall include measurable outcome goals.

(D) Publication

The National Coordinator shall republish the strategic plan, including all updates.

(4) Website

The National Coordinator shall maintain and frequently update an Internet website on which there is posted information on the work, schedules, reports, recommendations, and other information to ensure transparency in promotion of a nationwide health information technology infrastructure.

(5) Certification

(A) In general

The National Coordinator, in consultation with the Director of the National Institute of Standards and Technology, shall keep or recognize a program or programs for the voluntary certification of health information technology as being in compliance with applicable certification criteria adopted under this part. Such program shall include, as appropriate, testing of the technology in accordance with section 17911(b) of this title.

(B) Certification criteria described

In this subchapter, the term "certification criteria" means, with respect to standards and implementation specifications for health information technology, criteria to establish that the technology meets such standards and implementation specifications.

(C) Health information technology for medical specialties and sites of service

(i) In general

The National Coordinator shall encourage, keep, or recognize, through existing authorities, the voluntary certification of health information technology under the program developed under subparagraph (A) for use in medical specialties and sites of service for which no such technology is available or where more technological advancement or integration is needed.

(ii) Specific medical specialties

The Secretary shall accept public comment on specific medical specialties and sites of service, in addition to those described in clause (i), for the purpose of selecting additional specialties and sites of service as necessary.

(iii) Health information technology for pediatrics

Not later than 18 months after December 13, 2016, the Secretary, in consultation with relevant stakeholders, shall make recommendations for the voluntary certification of health information technology for use by pediatric health providers to support the health care of children. Not later than 2 years after December 13, 2016, the Secretary shall adopt certification criteria under section 300jj–14 of this title to support the voluntary certification of health information technology for use by pediatric health providers to support the health care of children.

(D) Conditions of certification

Not later than 1 year after December 13, 2016, the Secretary, through notice and comment rulemaking, shall require, as a condition of certification and maintenance of certification for programs maintained or recognized under this paragraph, consistent with other conditions and requirements under this subchapter, that the health information technology developer or entity—

(i) does not take any action that constitutes information blocking as defined in section 300jj–52(a) of this title;

(ii) provides assurances satisfactory to the Secretary that such developer or entity, unless for legitimate purposes specified by the Secretary, will not take any action described in clause (i) or any other action that may inhibit the appropriate exchange, access, and use of electronic health information;

(iii) does not prohibit or restrict communication regarding—
(I) the usability of the health information technology;
(II) the interoperability of the health information technology;
(III) the security of the health information technology;
(IV) relevant information regarding users' experiences when using the health information technology;
(V) the business practices of developers of health information technology related to exchanging electronic health information; and
(VI) the manner in which a user of the health information technology has used such technology;

(iv) has published application programming interfaces and allows health information from such technology to be accessed, exchanged, and used without special effort through the use of application programming interfaces or successor technology or standards, as provided for under applicable law, including providing access to all data elements of a patient's electronic health record to the extent permissible under applicable privacy laws;
(v) has successfully tested the real world use of the technology for interoperability (as defined in section 300jj of this title) in the type of setting in which such technology would be marketed;
(vi) provides to the Secretary an attestation that the developer or entity—
(I) has not engaged in any of the conduct described in clause (i);
(II) has provided assurances satisfactory to the Secretary in accordance with clause (ii);
(III) does not prohibit or restrict communication as described in clause (iii);
(IV) has published information in accordance with clause (iv);
(V) ensures that its technology allows for health information to be exchanged, accessed, and used, in the manner described in clause (iv); and
(VI) has undertaken real world testing as described in clause (v); and

(vii) submits reporting criteria in accordance with section 300jj–19a(b) of this title.

(E) Compliance with conditions of certification

The Secretary may encourage compliance with the conditions of certification described in subparagraph (D) and take action to discourage noncompliance, as appropriate.

(6) Reports and publications

(A) Report on additional funding or authority needed

Not later than 12 months after February 17, 2009, the National Coordinator shall submit to the appropriate committees of jurisdiction of the House of Representatives and the Senate a report on any additional funding or authority the Coordinator or the HIT Policy Committee or HIT Standards Committee requires to evaluate and develop standards, implementation specifications, and certification criteria, or to achieve full participation of stakeholders in the adoption of a nationwide health information technology infrastructure that allows for the electronic use and exchange of health information.

(B) Implementation report

The National Coordinator shall prepare a report that identifies lessons learned from major public and private health care systems in their implementation of health information technology, including information on whether the technologies and practices developed by such systems may be applicable to and usable in whole or in part by other health care providers.

(C) Assessment of impact of HIT on communities with health disparities and uninsured, underinsured, and medically underserved areas

The National Coordinator shall assess and publish the impact of health information technology in communities with health disparities and in areas with a high proportion of

individuals who are uninsured, underinsured, and medically underserved individuals (including urban and rural areas) and identify practices to increase the adoption of such technology by health care providers in such communities, and the use of health information technology to reduce and better manage chronic diseases.

(D) Evaluation of benefits and costs of the electronic use and exchange of health information

The National Coordinator shall evaluate and publish evidence on the benefits and costs of the electronic use and exchange of health information and assess to whom these benefits and costs accrue.

(E) Resource requirements

The National Coordinator shall estimate and publish resources required annually to reach the goal of utilization of an electronic health record for each person in the United States by 2014, including—

(i) the required level of Federal funding;

(ii) expectations for regional, State, and private investment;

(iii) the expected contributions by volunteers to activities for the utilization of such records; and

(iv) the resources needed to establish a health information technology workforce sufficient to support this effort (including education programs in medical informatics and health information management).

(7) Assistance

The National Coordinator may provide financial assistance to consumer advocacy groups and not-for-profit entities that work in the public interest for purposes of defraying the cost to such groups and entities to participate under, whether in whole or in part, the National Technology Transfer Act of 1995 (15 U.S.C. 272 note).[1]

(8) Governance for nationwide health information network

The National Coordinator shall establish a governance mechanism for the nationwide health information network.

(9) Support for interoperable networks exchange

(A) In general

The National Coordinator shall, in collaboration with the National Institute of Standards and Technology and other relevant agencies within the Department of Health and Human Services, for the purpose of ensuring full network-to-network exchange of health information, convene public-private and public-public partnerships to build consensus and develop or support a trusted exchange framework, including a common agreement among health information networks nationally. Such convention may occur at a frequency determined appropriate by the Secretary.

(B) Establishing a trusted exchange framework

(i) In general

Not later than 6 months after December 13, 2016, the National Coordinator shall convene appropriate public and private stakeholders to develop or support a trusted exchange framework for trust policies and practices and for a common agreement for exchange between health information networks. The common agreement may include—

(I) a common method for authenticating trusted health information network participants;

(II) a common set of rules for trusted exchange;

(III) organizational and operational policies to enable the exchange of health information among networks, including minimum conditions for such exchange to occur; and

(IV) a process for filing and adjudicating noncompliance with the terms of the common agreement.

(ii) Technical assistance

The National Coordinator, in collaboration with the National Institute of Standards and Technology, shall provide technical assistance on how to implement the trusted exchange framework and common agreement under this paragraph.

(iii) Pilot testing

The National Coordinator, in consultation with the National Institute of Standards and Technology, shall provide for the pilot testing of the trusted exchange framework and common agreement established or supported under this subsection (as authorized under section 17911 of this title). The National Coordinator, in consultation with the National Institute of Standards and Technology, may delegate pilot testing activities under this clause to independent entities with appropriate expertise.

(C) Publication of a trusted exchange framework and common agreement

Not later than 1 year after convening stakeholders under subparagraph (A), the National Coordinator shall publish on its public Internet website, and in the Federal register,[2] the trusted exchange framework and common agreement developed or supported under subparagraph (B). Such trusted exchange framework and common agreement shall be published in a manner that protects proprietary and security information, including trade secrets and any other protected intellectual property.

(D) Directory of participating health information networks

(i) In general

Not later than 2 years after convening stakeholders under subparagraph (A), and annually thereafter, the National Coordinator shall publish on its public Internet website a list of the health information networks that have adopted the common agreement and are capable of trusted exchange pursuant to the common agreement developed or supported under paragraph [3] (B).

(ii) Process

The Secretary shall, through notice and comment rulemaking, establish a process for health information networks that voluntarily elect to adopt the trusted exchange framework and common agreement to attest to such adoption of the framework and agreement.

(E) Application of the trusted exchange framework and common agreement

As appropriate, Federal agencies contracting or entering into agreements with health information exchange networks may require that as each such network upgrades health information technology or trust and operational practices, such network may adopt, where available, the trusted exchange framework and common agreement published under subparagraph (C).

(F) Rule of construction

(i) General adoption

Nothing in this paragraph shall be construed to require a health information network to adopt the trusted exchange framework or common agreement.

(ii) Adoption when exchange of information is within network

Nothing in this paragraph shall be construed to require a health information network to adopt the trusted exchange framework or common agreement for the exchange of electronic health information between participants of the same network.

(iii) Existing frameworks and agreements

The trusted exchange framework and common agreement published under subparagraph (C) shall take into account existing trusted exchange frameworks and agreements used by health information networks to avoid the disruption of existing exchanges between

participants of health information networks.

(iv) Application by Federal agencies

Notwithstanding clauses (i), (ii), and (iii), Federal agencies may require the adoption of the trusted exchange framework and common agreement published under subparagraph (C) for health information exchanges contracting with or entering into agreements pursuant to subparagraph (E).

(v) Consideration of ongoing work

In carrying out this paragraph, the Secretary shall ensure the consideration of activities carried out by public and private organizations related to exchange between health information exchanges to avoid duplication of efforts.

(d) Detail of Federal employees

(1) In general

Upon the request of the National Coordinator, the head of any Federal agency is authorized to detail, with or without reimbursement from the Office, any of the personnel of such agency to the Office to assist it in carrying out its duties under this section.

(2) Effect of detail

Any detail of personnel under paragraph (1) shall—

(A) not interrupt or otherwise affect the civil service status or privileges of the Federal employee; and

(B) be in addition to any other staff of the Department employed by the National Coordinator.

(3) Acceptance of detailees

Notwithstanding any other provision of law, the Office may accept detailed personnel from other Federal agencies without regard to whether the agency described under paragraph (1) is reimbursed.

(e) Chief Privacy Officer of the Office of the National Coordinator

Not later than 12 months after February 17, 2009, the Secretary shall appoint a Chief Privacy Officer of the Office of the National Coordinator, whose duty it shall be to advise the National Coordinator on privacy, security, and data stewardship of electronic health information and to coordinate with other Federal agencies (and similar privacy officers in such agencies), with State and regional efforts, and with foreign countries with regard to the privacy, security, and data stewardship of electronic individually identifiable health information.

(July 1, 1944, ch. 373, title XXX, §3001, as added Pub. L. 111–5, div. A, title XIII, §13101, Feb. 17, 2009, 123 Stat. 230; amended Pub. L. 114–255, div. A, title IV, §§4001(b), 4002(a), 4003(b), (e)(2)(A)(i), (ii), (C), Dec. 13, 2016, 130 Stat. 1158, 1159, 1165, 1174.)

EDITORIAL NOTES

REFERENCES IN TEXT

The National Technology Transfer Act of 1995 (15 U.S.C. 272 note), referred to in subsec. (c)(7), probably means section 12(d) of Pub. L. 104–113, known as the National Technology Transfer and Advancement Act of 1995, which is set out as a note under section 272 of Title 15, Commerce and Trade.

AMENDMENTS

2016—Subsec. (c)(1)(A). Pub. L. 114–255, §4003(e)(2)(C)(i), substituted "under section 300jj–12 of this title" for "under section 300jj–13 of this title".

Pub. L. 114–255, §4003(e)(2)(A)(i), substituted "HIT Advisory Committee" for "HIT Standards Committee".

Subsec. (c)(2)(B). Pub. L. 114–255, §4003(e)(2)(C)(ii), added subpar. (B) and struck out former subpar. (B). Prior to amendment, text read as follows: "The National Coordinator shall be a leading member in the

establishment and operations of the HIT Policy Committee and the HIT Standards Committee and shall serve as a liaison among those two Committees and the Federal Government."

Subsec. (c)(3)(A)(v). Pub. L. 114–255, §4003(e)(2)(A)(ii), which directed amendment of this section by substituting "HIT Advisory Committee" for "HIT Policy Committee and the HIT Standards Committee" wherever appearing, was executed to cl. (v) by making the substitution for "HIT Policy Committee, the HIT Standards Committee", to reflect the probable intent of Congress.

Subsec. (c)(5)(C). Pub. L. 114–255, §4001(b), added subpar. (C).

Subsec. (c)(5)(D), (E). Pub. L. 114–255, §4002(a), added subpars. (D) and (E).

Subsec. (c)(6)(A). Pub. L. 114–255, §4003(e)(2)(A)(i), which directed amendment of this section by substituting "HIT Advisory Committee" for both "HIT Policy Committee" and "HIT Standards Committee" wherever appearing, but not within the term "HIT Policy Committee or the HIT Standards Committee", was not executed to subpar. (A) as provided in the exception, notwithstanding text that reads "HIT Policy Committee or HIT Standards Committee", to reflect the probable intent of Congress.

Subsec. (c)(9). Pub. L. 114–255, §4003(b), added par. (9).

STATUTORY NOTES AND RELATED SUBSIDIARIES

PROVIDER DIGITAL CONTACT INFORMATION INDEX

Pub. L. 114–255, div. A, title IV, §4003(c), Dec. 13, 2016, 130 Stat. 1167, provided that:

"(1) IN GENERAL.—Not later than 3 years after the date of enactment of this Act [Dec. 13, 2016], the Secretary of Health and Human Services (referred to in this subsection as the 'Secretary') shall, directly or through a partnership with a private entity, establish a provider digital contact information index to provide digital contact information for health professionals and health facilities.

"(2) USE OF EXISTING INDEX.—In establishing the initial index under paragraph (1), the Secretary may utilize an existing provider directory to make such digital contact information available.

"(3) CONTACT INFORMATION.—An index established under this subsection shall ensure that contact information is available at the individual health care provider level and at the health facility or practice level.

"(4) RULE OF CONSTRUCTION.—

"(A) IN GENERAL.—The purpose of this subsection is to encourage the exchange of electronic health information by providing the most useful, reliable, and comprehensive index of providers possible. In furthering such purpose, the Secretary shall include all health professionals and health facilities applicable to provide a useful, reliable, and comprehensive index for use in the exchange of health information.

"(B) LIMITATION.—In no case shall exclusion from the index of providers be used as a measure to achieve objectives other [than] the objectives described in subparagraph (A)."

[1] *See References in Text note below.*

[2] *So in original. Probably should be "Register,".*

[3] *So in original. Probably should be "subparagraph".*

§300jj–12. Health Information Technology Advisory Committee

(a) Establishment

There is established a Health Information Technology Advisory Committee (referred to in this section as the "HIT Advisory Committee") to recommend to the National Coordinator, consistent with the implementation of the strategic plan described in section 300jj–11(c)(3) of this title, policies, and, for purposes of adoption under section 300jj–14 of this title, standards, implementation specifications, and certification criteria, relating to the implementation of a health information technology infrastructure, nationally and locally, that advances the electronic access, exchange, and use of health information. Such Committee shall serve to unify the roles of, and replace, the HIT Policy Committee and the HIT Standards Committee, as in existence before December 13, 2016.

(b) Duties

(1) Recommendations on policy framework to advance an interoperable health information technology infrastructure

(A) In general

The HIT Advisory Committee shall recommend to the National Coordinator a policy framework for adoption by the Secretary consistent with the strategic plan under section 300jj–11(c)(3) of this title for advancing the target areas described in this subsection. Such policy framework shall seek to prioritize achieving advancements in the target areas specified in subparagraph (B) of paragraph (2) and may, to the extent consistent with this section, incorporate policy recommendations made by the HIT Policy Committee, as in existence before December 13, 2016.

(B) Updates

The HIT Advisory Committee shall propose updates to such recommendations to the policy framework and make new recommendations, as appropriate.

(2) General duties and target areas

(A) In general

The HIT Advisory Committee shall recommend to the National Coordinator for purposes of adoption under section 300jj–14 of this title, standards, implementation specifications, and certification criteria and an order of priority for the development, harmonization, and recognition of such standards, specifications, and certification criteria. Such recommendations shall include recommended standards, architectures, and software schemes for access to electronic individually identifiable health information across disparate systems including user vetting, authentication, privilege management, and access control.

(B) Priority target areas

For purposes of this section, the HIT Advisory Committee shall make recommendations under subparagraph (A) with respect to at least each of the following target areas:

(i) Achieving a health information technology infrastructure, nationally and locally, that allows for the electronic access, exchange, and use of health information, including through technology that provides accurate patient information for the correct patient, including exchanging such information, and avoids the duplication of patient records.

(ii) The promotion and protection of privacy and security of health information in health information technology, including technologies that allow for an accounting of disclosures and protections against disclosures of individually identifiable health information made by a covered entity for purposes of treatment, payment, and health care operations (as such terms are defined for purposes of the regulation promulgated under section 264(c) of the Health Insurance Portability and Accountability Act of 1996), including for the segmentation and protection from disclosure of specific and sensitive individually identifiable health information with the goal of minimizing the reluctance of patients to seek care.

(iii) The facilitation of secure access by an individual to such individual's protected health information and access to such information by a family member, caregiver, or guardian acting on behalf of a patient, including due to age-related and other disability, cognitive impairment, or dementia.

(iv) Subject to subparagraph (D), any other target area that the HIT Advisory Committee identifies as an appropriate target area to be considered under this subparagraph.

(C) Additional target areas

For purposes of this section, the HIT Advisory Committee may make recommendations under subparagraph (A), in addition to areas described in subparagraph (B), with respect to any of the following areas:

(i) The use of health information technology to improve the quality of health care, such as by promoting the coordination of health care and improving continuity of health care among health care providers, reducing medical errors, improving population health, reducing chronic

disease, and advancing research and education.

(ii) The use of technologies that address the needs of children and other vulnerable populations.

(iii) The use of electronic systems to ensure the comprehensive collection of patient demographic data, including at a minimum, race, ethnicity, primary language, and gender information.

(iv) The use of self-service, telemedicine, home health care, and remote monitoring technologies.

(v) The use of technologies that meet the needs of diverse populations.

(vi) The use of technologies that support—

(I) data for use in quality and public reporting programs;

(II) public health; or

(III) drug safety.

(vii) The use of technologies that allow individually identifiable health information to be rendered unusable, unreadable, or indecipherable to unauthorized individuals when such information is transmitted in a health information network or transported outside of the secure facilities or systems where the disclosing covered entity is responsible for security conditions.

(viii) The use of a certified health information technology for each individual in the United States.

(D) Authority for temporary additional priority target areas

For purposes of subparagraph (B)(iv), the HIT Advisory Committee may identify an area to be considered for purposes of recommendations under this subsection as a target area described in subparagraph (B) if—

(i) the area is so identified for purposes of responding to new circumstances that have arisen in the health information technology community that affect the interoperability, privacy, or security of health information, or affect patient safety; and

(ii) at least 30 days prior to treating such area as if it were a target area described in subparagraph (B), the National Coordinator provides adequate notice to Congress of the intent to treat such area as so described.

(E) Focus of committee work

It is the sense of Congress that the HIT Advisory Committee shall focus its work on the priority areas described in subparagraph (B) before proceeding to other work under subparagraph (C).

(3) Rules relating to recommendations for standards, implementation specifications, and certification criteria

(A) In general

The HIT Advisory Committee shall recommend to the National Coordinator standards, implementation specifications, and certification criteria described in subsection (a), which may include standards, implementation specifications, and certification criteria that have been developed, harmonized, or recognized by the HIT Advisory Committee or predecessor committee. The HIT Advisory Committee shall update such recommendations and make new recommendations as appropriate, including in response to a notification sent under section 300jj–14(a)(2)(B) of this title. Such recommendations shall be consistent with the latest recommendations made by the Committee.

(B) Harmonization

The HIT Advisory Committee may recognize harmonized or updated standards from an entity or entities for the purpose of harmonizing or updating standards and implementation specifications in order to achieve uniform and consistent implementation of the standards and

implementation specification.

(C) Pilot testing of standards and implementation specifications

In the development, harmonization, or recognition of standards and implementation specifications, the HIT Advisory Committee for purposes of recommendations under paragraph (2)(B), shall, as appropriate, provide for the testing of such standards and specifications by the National Institute for Standards and Technology under section 17911(a) of this title.

(D) Consistency

The standards, implementation specifications, and certification criteria recommended under paragraph (2)(B) shall be consistent with the standards for information transactions and data elements adopted pursuant to section 1320d–2 of this title.

(E) Special rule related to interoperability

Any recommendation made by the HIT Advisory Committee after December 13, 2016, with respect to interoperability of health information technology shall be consistent with interoperability as described in section 300jj of this title.

(4) Forum

The HIT Advisory Committee shall serve as a forum for the participation of a broad range of stakeholders with specific expertise in policies, including technical expertise, relating to the matters described in paragraphs (1), (2), and (3) to provide input on the development, harmonization, and recognition of standards, implementation specifications, and certification criteria necessary for the development and adoption of health information technology infrastructure nationally and locally that allows for the electronic access, exchange, and use of health information.

(5) Schedule

Not later than 30 days after the date on which the HIT Advisory Committee first meets, such HIT Advisory Committee shall develop a schedule for the assessment of policy recommendations developed under paragraph (1). The HIT Advisory Committee shall update such schedule annually. The Secretary shall publish such schedule in the Federal Register.

(6) Public input

The HIT Advisory Committee shall conduct open public meetings and develop a process to allow for public comment on the schedule described in paragraph (5) and recommendations described in this subsection. Under such process comments shall be submitted in a timely manner after the date of publication of a recommendation under this subsection.

(c) Measured progress in advancing priority areas

(1) In general

For purposes of this section, the National Coordinator, in collaboration with the Secretary, shall establish, and update as appropriate, objectives and benchmarks for advancing and measuring the advancement of the priority target areas described in subsection (b)(2)(B).

(2) Annual progress reports on advancing interoperability

(A) In general

The HIT Advisory Committee, in consultation with the National Coordinator, shall annually submit to the Secretary and Congress a report on the progress made during the preceding fiscal year in—

(i) achieving a health information technology infrastructure, nationally and locally, that allows for the electronic access, exchange, and use of health information; and

(ii) meeting the objectives and benchmarks described in paragraph (1).

(B) Content

Each such report shall include, for a fiscal year—

(i) a description of the work conducted by the HIT Advisory Committee during the preceding fiscal year with respect to the areas described in subsection (b)(2)(B);

(ii) an assessment of the status of the infrastructure described in subparagraph (A), including the extent to which electronic health information is appropriately and readily available to enhance the access, exchange, and the use of electronic health information between users and across technology offered by different developers;

(iii) the extent to which advancements have been achieved with respect to areas described in subsection (b)(2)(B);

(iv) an analysis identifying existing gaps in policies and resources for—

(I) achieving the objectives and benchmarks established under paragraph (1); and

(II) furthering interoperability throughout the health information technology infrastructure;

(v) recommendations for addressing the gaps identified in clause (iii); and

(vi) a description of additional initiatives as the HIT Advisory Committee and National Coordinator determine appropriate.

(3) Significant advancement determination

The Secretary shall periodically, based on the reports submitted under this subsection, review the target areas described in subsection (b)(2)(B), and, based on the objectives and benchmarks established under paragraph (1), the Secretary shall determine if significant advancement has been achieved with respect to such an area. Such determination shall be taken into consideration by the HIT Advisory Committee when determining to what extent the Committee makes recommendations for an area other than an area described in subsection (b)(2)(B).

(d) Membership and operations

(1) In general

The National Coordinator shall take a leading position in the establishment and operations of the HIT Advisory Committee.

(2) Membership

The membership of the HIT Advisory Committee shall—

(A) include at least 25 members, of which—

(i) no fewer than 2 members are advocates for patients or consumers of health information technology;

(ii) 3 members are appointed by the Secretary, 1 of whom shall be appointed to represent the Department of Health and Human Services and 1 of whom shall be a public health official;

(iii) 2 members are appointed by the majority leader of the Senate;

(iv) 2 members are appointed by the minority leader of the Senate;

(v) 2 members are appointed by the Speaker of the House of Representatives;

(vi) 2 members are appointed by the minority leader of the House of Representatives; and

(vii) such other members are appointed by the Comptroller General of the United States; and

(B) at least reflect providers, ancillary health care workers, consumers, purchasers, health plans, health information technology developers, researchers, patients, relevant Federal agencies, and individuals with technical expertise on health care quality, system functions, privacy, security, and on the electronic exchange and use of health information, including the use standards for such activity.

(3) Participation

The members of the HIT Advisory Committee shall represent a balance among various sectors of the health care system so that no single sector unduly influences the recommendations of the

Committee.

(4) Terms

(A) In general

The terms of the members of the HIT Advisory Committee shall be for 3 years, except that the Secretary shall designate staggered terms of the members first appointed.

(B) Vacancies

Any member appointed to fill a vacancy in the membership of the HIT Advisory Committee that occurs prior to the expiration of the term for which the member's predecessor was appointed shall be appointed only for the remainder of that term. A member may serve after the expiration of that member's term until a successor has been appointed. A vacancy in the HIT Advisory Committee shall be filled in the manner in which the original appointment was made.

(C) Limits

Members of the HIT Advisory Committee shall be limited to two 3-year terms, for a total of not to exceed 6 years of service on the Committee.

(5) Outside involvement

The HIT Advisory Committee shall ensure an opportunity for the participation in activities of the Committee of outside advisors, including individuals with expertise in the development of policies and standards for the electronic exchange and use of health information, including in the areas of health information privacy and security.

(6) Quorum

A majority of the members of the HIT Advisory Committee shall constitute a quorum for purposes of voting, but a lesser number of members may meet and hold hearings.

(7) Consideration

The National Coordinator shall ensure that the relevant and available recommendations and comments from the National Committee on Vital and Health Statistics are considered in the development of policies.

(8) Assistance

For the purposes of carrying out this section, the Secretary may provide or ensure that financial assistance is provided by the HIT Advisory Committee to defray in whole or in part any membership fees or dues charged by such Committee to those consumer advocacy groups and not-for-profit entities that work in the public interest as a party of their mission.

(e) Application of chapter 10 of title 5

Chapter 10 of title 5, other than section 1013 of title 5, shall apply to the HIT Advisory Committee.

(f) Publication

The Secretary shall provide for publication in the Federal Register and the posting on the Internet website of the Office of the National Coordinator for Health Information Technology of all policy recommendations made by the HIT Advisory Committee under this section.

(July 1, 1944, ch. 373, title XXX, §3002, as added Pub. L. 114–255, div. A, title IV, §4003(e)(1), Dec. 13, 2016, 130 Stat. 1168; amended Pub. L. 117–286, §4(a)(246), Dec. 27, 2022, 136 Stat. 4332.)

EDITORIAL NOTES

REFERENCES IN TEXT

Section 264(c) of the Health Insurance Portability and Accountability Act of 1996, referred to in subsec. (b)(2)(B)(ii), is section 264(c) of Pub. L. 104–191, which is set out as a note under section 1320d–2 of this

title.

PRIOR PROVISIONS

A prior section 300jj–12, act July 1, 1944, ch. 373, title XXX, §3002, as added Pub. L. 111–5, div. A, title XIII, §13101, Feb. 17, 2009, 123 Stat. 234, related to the establishment, duties, and membership of the HIT Policy Committee, prior to repeal by Pub. L. 114–255, div. A, title IV, §4003(e)(1), Dec. 13, 2016, 130 Stat. 1168.

AMENDMENTS

2022—Subsec. (e). Pub. L. 117–286 substituted "chapter 10 of title 5" for "FACA" in heading and "Chapter 10 of title 5, other than section 1013 of title 5," for "The Federal Advisory Committee Act (5 U.S.C. App.), other than section 14 of such Act," in text.

STATUTORY NOTES AND RELATED SUBSIDIARIES

TRANSITION TO THE HIT ADVISORY COMMITTEE

Pub. L. 114–255, div. A, title IV, §4003(e)(3), Dec. 13, 2016, 130 Stat. 1175, provided that: "The Secretary of Health and Human Services shall provide for an orderly and timely transition to the HIT Advisory Committee established under amendments made by this section [enacting this section and section 300jj–13 of this title, amending sections 300jj, 300jj–11, 300jj–14, 300jj–17, 300jj–18, and 300jj–51 of this title, and repealing former sections 300jj–12 and 300jj–13 of this title]."

§300jj–13. Setting priorities for standards adoption

(a) Identifying priorities

(1) In general

Not later than 6 months after the date on which the HIT Advisory Committee first meets, the National Coordinator shall periodically convene the HIT Advisory Committee to—

(A) identify priority uses of health information technology, focusing on priorities—

(i) arising from the implementation of the incentive programs for the meaningful use of certified EHR technology, the Merit-based Incentive Payment System, Alternative Payment Models, the Hospital Value-Based Purchasing Program, and any other value-based payment program determined appropriate by the Secretary;

(ii) related to the quality of patient care;

(iii) related to public health;

(iv) related to clinical research;

(v) related to the privacy and security of electronic health information;

(vi) related to innovation in the field of health information technology;

(vii) related to patient safety;

(viii) related to the usability of health information technology;

(ix) related to individuals' access to electronic health information; and

(x) other priorities determined appropriate by the Secretary;

(B) identify existing standards and implementation specifications that support the use and exchange of electronic health information needed to meet the priorities identified in subparagraph (A); and

(C) publish a report summarizing the findings of the analysis conducted under subparagraphs (A) and (B) and make appropriate recommendations.

(2) Prioritization

In identifying such standards and implementation specifications under paragraph (1)(B), the HIT Advisory Committee shall prioritize standards and implementation specifications developed by consensus-based standards development organizations.

(3) Guidelines for review of existing standards and specifications

In consultation with the consensus-based entity described in section 1395aaa of this title and other appropriate Federal agencies, the analysis of existing standards under paragraph (1)(B) shall include an evaluation of the need for a core set of common data elements and associated value sets to enhance the ability of certified health information technology to capture, use, and exchange structured electronic health information.

(b) Review of adopted standards

(1) In general

Beginning 5 years after December 13, 2016, and every 3 years thereafter, the National Coordinator shall convene stakeholders to review the existing set of adopted standards and implementation specifications and make recommendations with respect to whether to—

(A) maintain the use of such standards and implementation specifications; or

(B) phase out such standards and implementation specifications.

(2) Priorities

The HIT Advisory Committee, in collaboration with the National Institute for Standards and Technology, shall annually and through the use of public input, review and publish priorities for the use of health information technology, standards, and implementation specifications to support those priorities.

(c) Rule of construction

Nothing in this section shall be construed to prevent the use or adoption of novel standards that improve upon the existing health information technology infrastructure and facilitate the secure exchange of health information.

(July 1, 1944, ch. 373, title XXX, §3003, as added Pub. L. 114–255, div. A, title IV, §4003(f), Dec. 13, 2016, 130 Stat. 1175.)

EDITORIAL NOTES

PRIOR PROVISIONS

A prior section 300jj–13, act July 1, 1944, ch. 373, title XXX, §3003, as added Pub. L. 111–5, div. A, title XIII, §13101, Feb. 17, 2009, 123 Stat. 238, related to the establishment, duties, and membership of the HIT Standards Committee, prior to repeal by Pub. L. 114–255, div. A, title IV, §4003(e)(1), Dec. 13, 2016, 130 Stat. 1168.

§300jj–14. Process for adoption of endorsed recommendations; adoption of initial set of standards, implementation specifications, and certification criteria

(a) Process for adoption of endorsed recommendations

(1) Review of endorsed standards, implementation specifications, and certification criteria

Not later than 90 days after the date of receipt of standards, implementation specifications, or certification criteria endorsed under section 300jj–11(c) of this title, the Secretary, in consultation with representatives of other relevant Federal agencies, shall jointly review such standards, implementation specifications, or certification criteria and shall determine whether or not to propose adoption of such standards, implementation specifications, or certification criteria.

(2) Determination to adopt standards, implementation specifications, and certification criteria

If the Secretary determines—

(A) to propose adoption of any grouping of such standards, implementation specifications, or certification criteria, the Secretary shall, by regulation under section 553 of title 5, determine whether or not to adopt such grouping of standards, implementation specifications, or

certification criteria; or

(B) not to propose adoption of any grouping of standards, implementation specifications, or certification criteria, the Secretary shall notify the National Coordinator and the HIT Advisory Committee in writing of such determination and the reasons for not proposing the adoption of such recommendation.

(3) Publication

The Secretary shall provide for publication in the Federal Register of all determinations made by the Secretary under paragraph (1).

(b) Adoption of standards, implementation specifications, and certification criteria

(1) In general

Not later than December 31, 2009, the Secretary shall, through the rulemaking process consistent with subsection (a)(2)(A), adopt an initial set of standards, implementation specifications, and certification criteria for the areas required for consideration under section 300jj–12(b)(2)(B) [1] of this title. The rulemaking for the initial set of standards, implementation specifications, and certification criteria may be issued on an interim, final basis.

(2) Application of current standards, implementation specifications, and certification criteria

The standards, implementation specifications, and certification criteria adopted before February 17, 2009, through the process existing through the Office of the National Coordinator for Health Information Technology may be applied towards meeting the requirement of paragraph (1).

(3) Subsequent standards activity

The Secretary shall adopt additional standards, implementation specifications, and certification criteria as necessary and consistent with the schedule published under section 300jj–12(b)(4) of this title.

(c) Deference to standards development organizations

In adopting and implementing standards under this section, the Secretary shall give deference to standards published by standards development organizations and voluntary consensus-based standards bodies.

(July 1, 1944, ch. 373, title XXX, §3004, as added Pub. L. 111–5, div. A, title XIII, §13101, Feb. 17, 2009, 123 Stat. 240; amended Pub. L. 114–255, div. A, title IV, §4003(d), (e)(2)(A)(i), (D), Dec. 13, 2016, 130 Stat. 1168, 1174, 1175.)

EDITORIAL NOTES

REFERENCES IN TEXT

Section 300jj–12(b)(2)(B) of this title, referred to in subsec. (b)(1), related to areas of health information technology required to be considered by the HIT Policy Committee and was repealed by Pub. L. 114–255, div. A, title IV, §4003(e)(1), Dec. 13, 2016, 130 Stat. 1168.

AMENDMENTS

2016—Subsec. (a)(2)(B). Pub. L. 114–255, §4003(e)(2)(A)(i), substituted "HIT Advisory Committee" for "HIT Standards Committee".

Subsec. (b)(3). Pub. L. 114–255, §4003(e)(2)(D), substituted "300jj–12(b)(4)" for "300jj–13(b)(2)".

Subsec. (c). Pub. L. 114–255, §4003(d), added subsec. (c).

STATUTORY NOTES AND RELATED SUBSIDIARIES

LEVERAGING ELECTRONIC HEALTH RECORDS TO IMPROVE PATIENT CARE

Pub. L. 114–255, div. A, title IV, §4005, Dec. 13, 2016, 130 Stat. 1180, provided that:

"(a) REQUIREMENT RELATING TO REGISTRIES.—

"(1) IN GENERAL.—To be certified in accordance with title XXX of the Public Health Service Act

(42 U.S.C. 300jj et seq.), electronic health records shall be capable of transmitting to, and where applicable, receiving and accepting data from, registries in accordance with standards recognized by the Office of the National Coordinator for Health Information Technology, including clinician-led clinical data registries, that are also certified to be technically capable of receiving and accepting from, and where applicable, transmitting data to certified electronic health record technology in accordance with such standards.

"(2) RULE OF CONSTRUCTION.—Nothing in this subsection shall be construed to require the certification of registries beyond the technical capability to exchange data in accordance with applicable recognized standards.

"(b) DEFINITION.—For purposes of this Act [see Tables for classification], the term 'clinician-led clinical data registry' means a clinical data repository—

"(1) that is established and operated by a clinician-led or controlled, tax-exempt (pursuant to section 501(c) of the Internal Revenue Code of 1986 [26 U.S.C. 501(c)]), professional society or other similar clinician-led or -controlled organization, or such organization's controlled affiliate, devoted to the care of a population defined by a particular disease, condition, exposure or therapy;

"(2) that is designed to collect detailed, standardized data on an ongoing basis for medical procedures, services, or therapies for particular diseases, conditions, or exposures;

"(3) that provides feedback to participants who submit reports to the repository;

"(4) that meets standards for data quality including—

"(A) systematically collecting clinical and other health care data, using standardized data elements and having procedures in place to verify the completeness and validity of those data; and

"(B) being subject to regular data checks or audits to verify completeness and validity; and

"(5) that provides ongoing participant training and support.

"(c) TREATMENT OF HEALTH INFORMATION TECHNOLOGY DEVELOPERS WITH RESPECT TO PATIENT SAFETY ORGANIZATIONS.—

"(1) IN GENERAL.—In applying part C of title IX of the Public Health Service Act (42 U.S.C. 299b–21 et seq.), a health information technology developer shall be treated as a provider (as defined in section 921 of such Act [42 U.S.C. 299b–21]) for purposes of reporting and conducting patient safety activities concerning improving clinical care through the use of health information technology that could result in improved patient safety, health care quality, or health care outcomes.

"(2) REPORT.—Not later than 4 years after the date of enactment of this Act [Dec. 13, 2016], the Secretary of Health and Human Services shall submit to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives, a report concerning best practices and current trends voluntarily provided, without identifying individual providers or disclosing or using protected health information or individually identifiable information, by patient safety organizations to improve the integration of health information technology into clinical practice."

[1] *See References in Text note below.*

§300jj–15. Application and use of adopted standards and implementation specifications by Federal agencies

For requirements relating to the application and use by Federal agencies of the standards and implementation specifications adopted under section 300jj–14 of this title, see section 17901 of this title.

(July 1, 1944, ch. 373, title XXX, §3005, as added Pub. L. 111–5, div. A, title XIII, §13101, Feb. 17, 2009, 123 Stat. 241.)

§300jj–16. Voluntary application and use of adopted standards and implementation specifications by private entities

(a) In general

Except as provided under section 13112 of the HITECH Act [42 U.S.C. 17902], nothing in such Act or in the amendments made by such Act shall be construed—

(1) to require a private entity to adopt or comply with a standard or implementation specification adopted under section 300jj–14 of this title; or

(2) to provide a Federal agency authority, other than the authority such agency may have under other provisions of law, to require a private entity to comply with such a standard or implementation specification.

(b) Rule of construction

Nothing in this part shall be construed to require that a private entity that enters into a contract with the Federal Government apply or use the standards and implementation specifications adopted under section 300jj–14 of this title with respect to activities not related to the contract.

(July 1, 1944, ch. 373, title XXX, §3006, as added Pub. L. 111–5, div. A, title XIII, §13101, Feb. 17, 2009, 123 Stat. 241.)

EDITORIAL NOTES

REFERENCES IN TEXT

The HITECH Act, referred to in subsec. (a), is title XIII of div. A and title IV of div. B of Pub. L. 111–5, Feb. 17, 2009, 123 Stat. 226, 467, also known as the Health Information Technology for Economic and Clinical Health Act. For complete classification of this Act to the Code, see Short Title of 2009 Amendment note set out under section 201 of this title and Tables.

§300jj–17. Federal health information technology

(a) In general

The National Coordinator shall support the development and routine updating of qualified electronic health record technology (as defined in section 300jj of this title) consistent with subsections (b) and (c) and make available such qualified electronic health record technology unless the Secretary determines through an assessment that the needs and demands of providers are being substantially and adequately met through the marketplace.

(b) Certification

In making such electronic health record technology publicly available, the National Coordinator shall ensure that the qualified electronic health record technology described in subsection (a) is certified under the program developed under section 300jj–11(c)(3) of this title to be in compliance with applicable standards adopted under section 300jj–12(a)(2) [1] of this title.

(c) Authorization to charge a nominal fee

The National Coordinator may impose a nominal fee for the adoption by a health care provider of the health information technology system developed or approved under subsection [2] (a) and (b). Such fee shall take into account the financial circumstances of smaller providers, low income providers, and providers located in rural or other medically underserved areas.

(d) Rule of construction

Nothing in this section shall be construed to require that a private or government entity adopt or use the technology provided under this section.

(July 1, 1944, ch. 373, title XXX, §3007, as added Pub. L. 111–5, div. A, title XIII, §13101, Feb. 17, 2009, 123 Stat. 241; amended Pub. L. 114–255, div. A, title IV, §4003(e)(2)(E), Dec. 13, 2016, 130 Stat. 1175.)

EDITORIAL NOTES

AMENDMENTS

2016—Subsec. (b). Pub. L. 114–255 substituted "300jj–12(a)(2)" for "300jj–13(a)".

[1] *So in original. No par. (2) of section 300jj–12(a) has been enacted.*

[2] *So in original. Probably should be "subsections".*

§300jj–18. Transitions

(a) ONCHIT

To the extent consistent with section 300jj–11 of this title, all functions, personnel, assets, liabilities, and administrative actions applicable to the National Coordinator for Health Information Technology appointed under Executive Order No. 13335 or the Office of such National Coordinator on the date before February 17, 2009, shall be transferred to the National Coordinator appointed under section 300jj–11(a) of this title and the Office of such National Coordinator as of February 17, 2009.

(b) National eHealth Collaborative

Nothing in sections [1] 300jj–12 of this title or this subsection shall be construed as prohibiting the AHIC Successor, Inc. doing business as the National eHealth Collaborative from modifying its charter, duties, membership, and any other structure or function required to be consistent with section [2] 300jj–12 and 300jj–13 [3] of this title so as to allow the Secretary to recognize such AHIC Successor, Inc. as the HIT Advisory Committee.

(c) Consistency of recommendations

In carrying out section 300jj–12(b)(2) of this title, until recommendations are made by the HIT Advisory Committee,[4] recommendations of the HIT Advisory Committee [4] shall be consistent with the most recent recommendations made by such AHIC Successor, Inc.

(July 1, 1944, ch. 373, title XXX, §3008, as added Pub. L. 111–5, div. A, title XIII, §13101, Feb. 17, 2009, 123 Stat. 241; amended Pub. L. 114–255, div. A, title IV, §4003(e)(2)(A)(i), (iii), (F), Dec. 13, 2016, 130 Stat. 1174, 1175.)

EDITORIAL NOTES

REFERENCES IN TEXT

Executive Order No. 13335, referred to in subsec. (a), is set out as a note under section 300u of this title.

Section 300jj–13 of this title, referred to in subsec. (b), was repealed, and a new section 300jj–13 was enacted by Pub. L. 114–255, div. A, title IV, §4003(e)(1), (f), Dec. 13, 2016, 130 Stat. 1168, 1175.

AMENDMENTS

2016—Subsec. (b). Pub. L. 114–255, §4003(e)(2)(F)(i), struck out "or 300jj–13" after "Nothing in sections 300jj–12".

Pub. L. 114–255, §4003(e)(2)(A)(iii), substituted "HIT Advisory Committee" for "HIT Policy Committee or the HIT Standards Committee".

Subsec. (c). Pub. L. 114–255, §4003(e)(2)(F)(ii), substituted "300jj–12(b)(2)" for "300jj–13(b)(1)(A)".

Pub. L. 114–255, §4003(e)(2)(A)(i), substituted "HIT Advisory Committee" for "HIT Policy Committee" after "recommendations are made by the" and "HIT Advisory Committee" for "HIT Standards Committee" after "recommendations of the". See section 300jj–12(a) of this title.

[1] *So in original. Probably should be "section".*

[2] *So in original. Probably should be "sections".*

[3] *See References in Text note below.*

[4] *So in original. See 2016 Amendment note below.*

§300jj–19. Miscellaneous provisions

(a) Relation to HIPAA privacy and security law

(1) In general

With respect to the relation of this subchapter to HIPAA privacy and security law:

(A) This subchapter may not be construed as having any effect on the authorities of the Secretary under HIPAA privacy and security law.

(B) The purposes of this subchapter include ensuring that the health information technology standards and implementation specifications adopted under section 300jj–14 of this title take into account the requirements of HIPAA privacy and security law.

(2) Definition

For purposes of this section, the term "HIPAA privacy and security law" means—

(A) the provisions of part C of title XI of the Social Security Act [42 U.S.C. 1320d et seq.], section 264 of the Health Insurance Portability and Accountability Act of 1996, and subtitle D of title IV [1] of the Health Information Technology for Economic and Clinical Health Act; and

(B) regulations under such provisions.

(b) Flexibility

In administering the provisions of this subchapter, the Secretary shall have flexibility in applying the definition of health care provider under section 300jj(3) of this title, including the authority to omit certain entities listed in such definition when applying such definition under this subchapter, where appropriate.

(c) Promoting patient access to electronic health information through health information exchanges

(1) In general

The Secretary shall use existing authorities to encourage partnerships between health information exchange organizations and networks and health care providers, health plans, and other appropriate entities with the goal of offering patients access to their electronic health information in a single, longitudinal format that is easy to understand, secure, and may be updated automatically.

(2) Education of providers

The Secretary, in coordination with the Office for Civil Rights of the Department of Health and Human Services, shall—

(A) educate health care providers on ways of leveraging the capabilities of health information exchanges (or other relevant platforms) to provide patients with access to their electronic health information;

(B) clarify misunderstandings by health care providers about using health information exchanges (or other relevant platforms) for patient access to electronic health information; and

(C) to the extent practicable, educate providers about health information exchanges (or other relevant platforms) that employ some or all of the capabilities described in paragraph (1).

(3) Requirements

In carrying out paragraph (1), the Secretary, in coordination with the Office for Civil Rights, shall issue guidance to health information exchanges related to best practices to ensure that the electronic health information provided to patients is—

(A) private and secure;

(B) accurate;

(C) verifiable; and

(D) where a patient's authorization to exchange information is required by law, easily exchanged pursuant to such authorization.

(4) Rule of construction

Nothing in this subsection shall be construed to preempt State laws applicable to patient consent for the access of information through a health information exchange (or other relevant platform) that provide protections to patients that are greater than the protections otherwise provided for under applicable Federal law.

(d) Efforts to promote access to health information

The National Coordinator and the Office for Civil Rights of the Department of Health and Human Services shall jointly promote patient access to health information in a manner that would ensure that such information is available in a form convenient for the patient, in a reasonable manner, without burdening the health care provider involved.

(e) Accessibility of patient records

(1) Accessibility and updating of information

(A) In general

The Secretary, in consultation with the National Coordinator, shall promote policies that ensure that a patient's electronic health information is accessible to that patient and the patient's designees, in a manner that facilitates communication with the patient's health care providers and other individuals, including researchers, consistent with such patient's consent.

(B) Updating education on accessing and exchanging personal health information

To promote awareness that an individual has a right of access to inspect, obtain a copy of, and transmit to a third party a copy of such individual's protected health information pursuant to the Health Information Portability and Accountability Act, Privacy Rule (subpart E of part 164 of title 45, Code of Federal Regulations), the Director of the Office for Civil Rights, in consultation with the National Coordinator, shall assist individuals and health care providers in understanding a patient's rights to access and protect personal health information under the Health Insurance Portability and Accountability Act of 1996 (Public Law 104–191), including providing best practices for requesting personal health information in a computable format, including using patient portals or third-party applications and common cases when a provider is permitted to exchange and provide access to health information.".[2]

(2) Certifying usability for patients

In carrying out certification programs under section 300jj–11(c)(5) of this title, the National Coordinator may require that—

(A) the certification criteria support—

(i) patient access to their electronic health information, including in a single longitudinal format that is easy to understand, secure, and may be updated automatically;

(ii) the patient's ability to electronically communicate patient-reported information (such as family history and medical history); and

(iii) patient access to their personal electronic health information for research at the option of the patient; and

(B) the HIT Advisory Committee develop and prioritize standards, implementation specifications, and certification criteria required to help support patient access to electronic health information, patient usability, and support for technologies that offer patients access to their electronic health information in a single, longitudinal format that is easy to understand, secure, and may be updated automatically.

(July 1, 1944, ch. 373, title XXX, §3009, as added Pub. L. 111–5, div. A, title XIII, §13101, Feb. 17, 2009, 123 Stat. 242; amended Pub. L. 114–255, div. A, title IV, §4006(a), Dec. 13, 2016, 130 Stat. 1181.)

EDITORIAL NOTES

REFERENCES IN TEXT

The Social Security Act, referred to in subsec. (a)(2)(A), is act Aug. 14, 1935, ch. 531, 49 Stat. 620. Part C of title XI of the Act is classified generally to part C (§1320d et seq.) of subchapter XI of chapter 7 of this title. For complete classification of this Act to the Code, see section 1305 of this title and Tables.

The Health Insurance Portability and Accountability Act of 1996, referred to in subsecs. (a)(2)(A) and (e)(1)(B), is Pub. L. 104–191, Aug. 21, 1996, 110 Stat. 1936. Section 264 of the Act is set out as a note under section 1320d–2 of this title. For complete classification of this Act to the Code, see Short Title of 1996 Amendments note set out under section 201 of this title and Tables.

The Health Information Technology for Economic and Clinical Health Act, referred to in subsec. (a)(2)(A), is title XIII of div. A and title IV of div. B of Pub. L. 111–5, Feb. 17, 2009, 123 Stat. 226, 467, also known as the HITECH Act. Subtitle D of title IV of the Act probably means subtitle D of title XIII of div. A of the Act, which is classified generally to subchapter III (§17921 et seq.) of chapter 156 of this title. Title IV of div. B of the Act does not contain a subtitle D. For complete classification of this Act to the Code, see Short Title of 2009 Amendment note set out under section 201 of this title and Tables.

AMENDMENTS

2016—Subsecs. (c) to (e). Pub. L. 114–255 added subsecs. (c) to (e).

[1] *See References in Text note below.*

[2] *So in original.*

§300jj–19a. Electronic health record reporting program

(a) Reporting criteria

(1) Convening of stakeholders

Not later than 1 year after December 13, 2016, the Secretary shall convene stakeholders, as described in paragraph (2), for the purpose of developing the reporting criteria in accordance with paragraph (3).

(2) Development of reporting criteria

The reporting criteria under this subsection shall be developed through a public, transparent process that reflects input from relevant stakeholders, including—

(A) health care providers, including primary care and specialty care health care professionals;
(B) hospitals and hospital systems;
(C) health information technology developers;
(D) patients, consumers, and their advocates;
(E) data sharing networks, such as health information exchanges;
(F) authorized certification bodies and testing laboratories;
(G) security experts;
(H) relevant manufacturers of medical devices;
(I) experts in health information technology market economics;
(J) public and private entities engaged in the evaluation of health information technology performance;
(K) quality organizations, including the consensus based entity described in section 1395aaa of this title;
(L) experts in human factors engineering and the measurement of user-centered design; and
(M) other entities or individuals, as the Secretary determines appropriate.

(3) Considerations for reporting criteria

The reporting criteria developed under this subsection—

(A) shall include measures that reflect categories including—
(i) security;
(ii) usability and user-centered design;
(iii) interoperability;
(iv) conformance to certification testing; and
(v) other categories, as appropriate to measure the performance of electronic health record technology;

(B) may include categories such as—
(i) enabling the user to order and view the results of laboratory tests, imaging tests, and other diagnostic tests;
(ii) submitting, editing, and retrieving data from registries such as clinician-led clinical data registries;
(iii) accessing and exchanging information and data from and through health information exchanges;
(iv) accessing and exchanging information and data from medical devices;
(v) accessing and exchanging information and data held by Federal, State, and local agencies and other applicable entities useful to a health care provider or other applicable user in the furtherance of patient care;
(vi) accessing and exchanging information from other health care providers or applicable users;
(vii) accessing and exchanging patient generated information;
(viii) providing the patient or an authorized designee with a complete copy of their health information from an electronic record in a computable format;
(ix) providing accurate patient information for the correct patient, including exchanging such information, and avoiding the duplication of patients records; and
(x) other categories regarding performance, accessibility,[1] as the Secretary determines appropriate; and

(C) shall be designed to ensure that small and startup health information technology developers are not unduly disadvantaged by the reporting criteria.

(4) Modifications

After the reporting criteria have been developed under paragraph (3), the Secretary may convene stakeholders and conduct a public comment period for the purpose of modifying the reporting criteria developed under such paragraph.

(b) Participation

As a condition of maintaining certification under section 300jj–11(c)(5)(D) of this title, a developer of certified electronic health records shall submit to an appropriate recipient of a grant, contract, or agreement under subsection (c)(1) responses to the criteria developed under subsection (a), with respect to all certified technology offered by such developer.

(c) Reporting program

(1) In general

Not later than 1 year after December 13, 2016, the Secretary shall award grants, contracts, or agreements to independent entities on a competitive basis to support the convening of stakeholders as described in subsection (a)(2), collect the information required to be reported in accordance with the criteria established as described subsection (a)(3), and develop and implement a process in accordance with paragraph (5) and report such information to the Secretary.

(2) Applications

An independent entity that seeks a grant, contract, or agreement under this subsection shall submit an application to the Secretary at such time, in such manner, and containing such

information as the Secretary may reasonably require, including a description of—

(A) the proposed method for reviewing and summarizing information gathered based on reporting criteria established under subsection (a);

(B) if applicable, the intended focus on a specific subset of certified electronic health record technology users, such as health care providers, including primary care, specialty care, and care provided in rural settings; hospitals and hospital systems; and patients, consumers, and patients and consumer advocates;

(C) the plan for widely distributing reports described in paragraph (6);

(D) the period for which the grant, contract, or agreement is requested, which may be up to 2 years; and

(E) the budget for reporting program participation, and whether the eligible independent entity intends to continue participation after the period of the grant, contract, or agreement.

(3) Considerations for independent entities

In awarding grants, contracts, and agreements under paragraph (1), the Secretary shall give priority to independent entities with appropriate expertise in health information technology usability, interoperability, and security (especially entities with such expertise in electronic health records) with respect to—

(A) health care providers, including primary care, specialty care, and care provided in rural settings;

(B) hospitals and hospital systems; and

(C) patients, consumers, and patient and consumer advocates.

(4) Limitations

(A) Assessment and redetermination

Not later than 4 years after December 13, 2016, and every 2 years thereafter, the Secretary, in consultation with stakeholders, shall—

(i) assess performance of the recipients of the grants, contracts, and agreements under paragraph (1) based on quality and usability of reports described in paragraph (6); and

(ii) re-determine grants, contracts, and agreements as necessary.

(B) Prohibitions on participation

The Secretary may not award a grant, contract, or cooperative agreement under paragraph (1) to—

(i) a proprietor of certified health information technology or a business affiliate of such a proprietor;

(ii) a developer of certified health information technology; or

(iii) a State or local government agency.

(5) Feedback

Based on reporting criteria established under subsection (a), the recipients of grants, contracts, and agreements under paragraph (1) shall develop and implement a process to collect and verify confidential feedback on such criteria from—

(A) health care providers, patients, and other users of certified electronic health record technology; and

(B) developers of certified electronic health record technology.

(6) Reports

(A) Development of reports

Each recipient of a grant, contract, or agreement under paragraph (1) shall report on the information reported to such recipient pursuant to subsection (a) and the user feedback collected under paragraph (5) by preparing summary reports and detailed reports of such information.

(B) Distribution of reports

Each recipient of a grant, contract, or agreement under paragraph (1) shall submit the reports

prepared under subparagraph (A) to the Secretary for public distribution in accordance with subsection (d).

(d) Publication

The Secretary shall distribute widely, as appropriate, and publish, on the Internet website of the Office of the National Coordinator—

(1) the reporting criteria developed under subsection (a); and

(2) the summary and detailed reports under subsection (c)(6).

(e) Review

Each recipient of a grant, contract, or agreement under paragraph (1) shall develop and implement a process through which participating electronic health record technology developers may review and recommend changes to the reports created under subsection (c)(6) for products developed by such developer prior to the publication of such report under subsection (d).

(f) Additional resources

The Secretary may provide additional resources on the Internet website of the Office of the National Coordinator to better inform consumers of health information technology. Such reports may be carried out through partnerships with private organizations with appropriate expertise.

(July 1, 1944, ch. 373, title XXX, §3009A, as added Pub. L. 114–255, div. A, title IV, §4002(c), Dec. 13, 2016, 130 Stat. 1161.)

[1] So in original. Probably should be "performance or accessibility,".

PART B—INCENTIVES FOR THE USE OF HEALTH INFORMATION TECHNOLOGY

§300jj–31. Immediate funding to strengthen the health information technology infrastructure

(a) In general

The Secretary shall, using amounts appropriated under section 300jj–38 of this title, invest in the infrastructure necessary to allow for and promote the electronic exchange and use of health information for each individual in the United States consistent with the goals outlined in the strategic plan developed by the National Coordinator (and as available) under section 300jj–11 of this title. The Secretary shall invest funds through the different agencies with expertise in such goals, such as the Office of the National Coordinator for Health Information Technology, the Health Resources and Services Administration, the Agency for Healthcare Research and Quality, the Centers of Medicare & Medicaid Services, the Centers for Disease Control and Prevention, and the Indian Health Service to support the following:

(1) Health information technology architecture that will support the nationwide electronic exchange and use of health information in a secure, private, and accurate manner, including connecting health information exchanges, and which may include updating and implementing the infrastructure necessary within different agencies of the Department of Health and Human Services to support the electronic use and exchange of health information.

(2) Development and adoption of appropriate certified electronic health records for categories of health care providers not eligible for support under title XVIII or XIX of the Social Security Act [42 U.S.C. 1395 et seq., 1396 et seq.] for the adoption of such records.

(3) Training on and dissemination of information on best practices to integrate health information technology, including electronic health records, into a provider's delivery of care, consistent with best practices learned from the Health Information Technology Research Center

developed under section 300jj–32(b) of this title, including community health centers receiving assistance under section 254b of this title, covered entities under section 256b of this title, and providers participating in one or more of the programs under titles XVIII, XIX, and XXI of the Social Security Act [42 U.S.C. 1395 et seq., 1396 et seq., 1397aa et seq.] (relating to Medicare, Medicaid, and the State Children's Health Insurance Program).

(4) Infrastructure and tools for the promotion of telemedicine, including coordination among Federal agencies in the promotion of telemedicine.

(5) Promotion of the interoperability of clinical data repositories or registries.

(6) Promotion of technologies and best practices that enhance the protection of health information by all holders of individually identifiable health information.

(7) Improvement and expansion of the use of health information technology by public health departments.

(b) Coordination

The Secretary shall ensure funds under this section are used in a coordinated manner with other health information promotion activities.

(c) Additional use of funds

In addition to using funds as provided in subsection (a), the Secretary may use amounts appropriated under section 300jj–38 of this title to carry out health information technology activities that are provided for under laws in effect on February 17, 2009.

(d) Standards for acquisition of health information technology

To the greatest extent practicable, the Secretary shall ensure that where funds are expended under this section for the acquisition of health information technology, such funds shall be used to acquire health information technology that meets applicable standards adopted under section 300jj–14 of this title. Where it is not practicable to expend funds on health information technology that meets such applicable standards, the Secretary shall ensure that such health information technology meets applicable standards otherwise adopted by the Secretary.

(July 1, 1944, ch. 373, title XXX, §3011, as added Pub. L. 111–5, div. A, title XIII, §13301, Feb. 17, 2009, 123 Stat. 246.)

EDITORIAL NOTES

REFERENCES IN TEXT

The Social Security Act, referred to in subsec. (a)(2), (3), is act Aug. 14, 1935, ch. 531, 49 Stat. 620. Titles XVIII, XIX, and XXI of the Act are classified generally to subchapters XVIII (§1395 et seq.), XIX (§1396 et seq.), and XXI (§1397aa et seq.) of chapter 7 of this title, respectively. For complete classification of this Act to the Code, see section 1305 of this title and Tables.

§300jj–32. Health information technology implementation assistance

(a) Health information technology extension program

To assist health care providers to adopt, implement, and effectively use certified EHR technology that allows for the electronic exchange and use of health information, the Secretary, acting through the Office of the National Coordinator, shall establish a health information technology extension program to provide health information technology assistance services to be carried out through the Department of Health and Human Services. The National Coordinator shall consult with other Federal agencies with demonstrated experience and expertise in information technology services, such as the National Institute of Standards and Technology, in developing and implementing this program.

(b) Health Information Technology Research Center

(1) In general

The Secretary shall create a Health Information Technology Research Center (in this section referred to as the "Center") to provide technical assistance and develop or recognize best practices to support and accelerate efforts to adopt, implement, and effectively utilize health information technology that allows for the electronic exchange and use of information in compliance with standards, implementation specifications, and certification criteria adopted under section 300jj–14 of this title.

(2) Input

The Center shall incorporate input from—

(A) other Federal agencies with demonstrated experience and expertise in information technology services such as the National Institute of Standards and Technology;

(B) users of health information technology, such as providers and their support and clerical staff and others involved in the care and care coordination of patients, from the health care and health information technology industry; and

(C) others as appropriate.

(3) Purposes

The purposes of the Center are to—

(A) provide a forum for the exchange of knowledge and experience;

(B) accelerate the transfer of lessons learned from existing public and private sector initiatives, including those currently receiving Federal financial support;

(C) assemble, analyze, and widely disseminate evidence and experience related to the adoption, implementation, and effective use of health information technology that allows for the electronic exchange and use of information including through the regional centers described in subsection (c);

(D) provide technical assistance for the establishment and evaluation of regional and local health information networks to facilitate the electronic exchange of information across health care settings and improve the quality of health care;

(E) provide technical assistance for the development and dissemination of solutions to barriers to the exchange of electronic health information; and

(F) learn about effective strategies to adopt and utilize health information technology in medically underserved communities.

(c) Health information technology regional extension centers

(1) In general

The Secretary shall provide assistance for the creation and support of regional centers (in this subsection referred to as "regional centers") to provide technical assistance and disseminate best practices and other information learned from the Center to support and accelerate efforts to adopt, implement, and effectively utilize health information technology that allows for the electronic exchange and use of information in compliance with standards, implementation specifications, and certification criteria adopted under section 300jj–14 of this title. Activities conducted under this subsection shall be consistent with the strategic plan developed by the National Coordinator, (and, as available) under section 300jj–11 of this title.

(2) Affiliation

Regional centers shall be affiliated with any United States-based nonprofit institution or organization, or group thereof, that applies and is awarded financial assistance under this section. Individual awards shall be decided on the basis of merit.

(3) Objective

The objective of the regional centers is to enhance and promote the adoption of health information technology through—

(A) assistance with the implementation, effective use, upgrading, and ongoing maintenance of health information technology, including electronic health records, to healthcare providers nationwide;

(B) broad participation of individuals from industry, universities, and State governments;

(C) active dissemination of best practices and research on the implementation, effective use, upgrading, and ongoing maintenance of health information technology, including electronic health records, to health care providers in order to improve the quality of healthcare and protect the privacy and security of health information;

(D) participation, to the extent practicable, in health information exchanges;

(E) utilization, when appropriate, of the expertise and capability that exists in Federal agencies other than the Department; and

(F) integration of health information technology, including electronic health records, into the initial and ongoing training of health professionals and others in the healthcare industry that would be instrumental to improving the quality of healthcare through the smooth and accurate electronic use and exchange of health information.

(4) Regional assistance

Each regional center shall aim to provide assistance and education to all providers in a region, but shall prioritize any direct assistance first to the following:

(A) Public or not-for-profit hospitals or critical access hospitals.

(B) Federally qualified health centers (as defined in section 1395x(aa)(4) of this title).

(C) Entities that are located in rural and other areas that serve uninsured, underinsured, and medically underserved individuals (regardless of whether such area is urban or rural).

(D) Individual or small group practices (or a consortium thereof) that are primarily focused on primary care.

(5) Financial support

The Secretary may provide financial support to any regional center created under this subsection for a period not to exceed four years. The Secretary may not provide more than 50 percent of the capital and annual operating and maintenance funds required to create and maintain such a center, except in an instance of national economic conditions which would render this cost-share requirement detrimental to the program and upon notification to Congress as to the justification to waive the cost-share requirement.

(6) Notice of program description and availability of funds

The Secretary shall publish in the Federal Register, not later than 90 days after February 17, 2009, a draft description of the program for establishing regional centers under this subsection. Such description shall include the following:

(A) A detailed explanation of the program and the programs [1] goals.

(B) Procedures to be followed by the applicants.

(C) Criteria for determining qualified applicants.

(D) Maximum support levels expected to be available to centers under the program.

(7) Application review

The Secretary shall subject each application under this subsection to merit review. In making a decision whether to approve such application and provide financial support, the Secretary shall consider at a minimum the merits of the application, including those portions of the application regarding—

(A) the ability of the applicant to provide assistance under this subsection and utilization of health information technology appropriate to the needs of particular categories of health care providers;

(B) the types of service to be provided to health care providers;

(C) geographical diversity and extent of service area; and

(D) the percentage of funding and amount of in-kind commitment from other sources.

(8) Biennial evaluation

Each regional center which receives financial assistance under this subsection shall be evaluated biennially by an evaluation panel appointed by the Secretary. Each evaluation panel shall be

composed of private experts, none of whom shall be connected with the center involved, and of Federal officials. Each evaluation panel shall measure the involved center's performance against the objective specified in paragraph (3). The Secretary shall not continue to provide funding to a regional center unless its evaluation is overall positive.

(9) Continuing support

After the second year of assistance under this subsection, a regional center may receive additional support under this subsection if it has received positive evaluations and a finding by the Secretary that continuation of Federal funding to the center was in the best interest of provision of health information technology extension services.

(July 1, 1944, ch. 373, title XXX, §3012, as added Pub. L. 111–5, div. A, title XIII, §13301, Feb. 17, 2009, 123 Stat. 247.)

[1] *So in original.*

§300jj–33. State grants to promote health information technology

(a) In general

The Secretary, acting through the National Coordinator, shall establish a program in accordance with this section to facilitate and expand the electronic movement and use of health information among organizations according to nationally recognized standards.

(b) Planning grants

The Secretary may award a grant to a State or qualified State-designated entity (as described in subsection (f)) that submits an application to the Secretary at such time, in such manner, and containing such information as the Secretary may specify, for the purpose of planning activities described in subsection (d).

(c) Implementation grants

The Secretary may award a grant to a State or qualified State designated [1] entity that—

(1) has submitted, and the Secretary has approved, a plan described in subsection (e) (regardless of whether such plan was prepared using amounts awarded under subsection (b); [2] and

(2) submits an application at such time, in such manner, and containing such information as the Secretary may specify.

(d) Use of funds

Amounts received under a grant under subsection (c) shall be used to conduct activities to facilitate and expand the electronic movement and use of health information among organizations according to nationally recognized standards through activities that include—

(1) enhancing broad and varied participation in the authorized and secure nationwide electronic use and exchange of health information;

(2) identifying State or local resources available towards a nationwide effort to promote health information technology;

(3) complementing other Federal grants, programs, and efforts towards the promotion of health information technology;

(4) providing technical assistance for the development and dissemination of solutions to barriers to the exchange of electronic health information;

(5) promoting effective strategies to adopt and utilize health information technology in medically underserved communities;

(6) assisting patients in utilizing health information technology;

(7) encouraging clinicians to work with Health Information Technology Regional Extension Centers as described in section 300jj–32 of this title, to the extent they are available and valuable;

(8) supporting public health agencies' authorized use of and access to electronic health

information;

(9) promoting the use of electronic health records for quality improvement including through quality measures reporting; and

(10) such other activities as the Secretary may specify.

(e) Plan

(1) In general

A plan described in this subsection is a plan that describes the activities to be carried out by a State or by the qualified State-designated entity within such State to facilitate and expand the electronic movement and use of health information among organizations according to nationally recognized standards and implementation specifications.

(2) Required elements

A plan described in paragraph (1) shall—

(A) be pursued in the public interest;

(B) be consistent with the strategic plan developed by the National Coordinator, (and, as available) under section 300jj–11 of this title;

(C) include a description of the ways the State or qualified State-designated entity will carry out the activities described in subsection (b); and

(D) contain such elements as the Secretary may require.

(f) Qualified State-designated entity

For purposes of this section, to be a qualified State-designated entity, with respect to a State, an entity shall—

(1) be designated by the State as eligible to receive awards under this section;

(2) be a not-for-profit entity with broad stakeholder representation on its governing board;

(3) demonstrate that one of its principal goals is to use information technology to improve health care quality and efficiency through the authorized and secure electronic exchange and use of health information;

(4) adopt nondiscrimination and conflict of interest policies that demonstrate a commitment to open, fair, and nondiscriminatory participation by stakeholders; and

(5) conform to such other requirements as the Secretary may establish.

(g) Required consultation

In carrying out activities described in subsections (b) and (c), a State or qualified State-designated entity shall consult with and consider the recommendations of—

(1) health care providers (including providers that provide services to low income and underserved populations);

(2) health plans;

(3) patient or consumer organizations that represent the population to be served;

(4) health information technology vendors;

(5) health care purchasers and employers;

(6) public health agencies;

(7) health professions schools, universities and colleges;

(8) clinical researchers;

(9) other users of health information technology such as the support and clerical staff of providers and others involved in the care and care coordination of patients; and

(10) such other entities, as may be determined appropriate by the Secretary.

(h) Continuous improvement

The Secretary shall annually evaluate the activities conducted under this section and shall, in awarding grants under this section, implement the lessons learned from such evaluation in a manner so that awards made subsequent to each such evaluation are made in a manner that, in the

determination of the Secretary, will lead towards the greatest improvement in quality of care, decrease in costs, and the most effective authorized and secure electronic exchange of health information.

(i) Required match

(1) In general

For a fiscal year (beginning with fiscal year 2011), the Secretary may not make a grant under this section to a State unless the State agrees to make available non-Federal contributions (which may include in-kind contributions) toward the costs of a grant awarded under subsection (c) in an amount equal to—

(A) for fiscal year 2011, not less than $1 for each $10 of Federal funds provided under the grant;

(B) for fiscal year 2012, not less than $1 for each $7 of Federal funds provided under the grant; and

(C) for fiscal year 2013 and each subsequent fiscal year, not less than $1 for each $3 of Federal funds provided under the grant.

(2) Authority to require State match for fiscal years before fiscal year 2011

For any fiscal year during the grant program under this section before fiscal year 2011, the Secretary may determine the extent to which there shall be required a non-Federal contribution from a State receiving a grant under this section.

(July 1, 1944, ch. 373, title XXX, §3013, as added Pub. L. 111–5, div. A, title XIII, §13301, Feb. 17, 2009, 123 Stat. 250.)

[1] So in original. Probably should be "State-designated".

[2] So in original. Another closing parenthesis probably should precede the semicolon.

§300jj–34. Competitive grants to States and Indian tribes for the development of loan programs to facilitate the widespread adoption of certified EHR technology

(a) In general

The National Coordinator may award competitive grants to eligible entities for the establishment of programs for loans to health care providers to conduct the activities described in subsection (e).

(b) Eligible entity defined

For purposes of this subsection, the term "eligible entity" means a State or Indian tribe (as defined in the Indian Self-Determination and Education Assistance Act [25 U.S.C. 5301 et seq.]) that—

(1) submits to the National Coordinator an application at such time, in such manner, and containing such information as the National Coordinator may require;

(2) submits to the National Coordinator a strategic plan in accordance with subsection (d) and provides to the National Coordinator assurances that the entity will update such plan annually in accordance with such subsection;

(3) provides assurances to the National Coordinator that the entity will establish a Loan Fund in accordance with subsection (c);

(4) provides assurances to the National Coordinator that the entity will not provide a loan from the Loan Fund to a health care provider unless the provider agrees to—

(A) submit reports on quality measures adopted by the Federal Government (by not later than 90 days after the date on which such measures are adopted), to—

(i) the Administrator of the Centers for Medicare & Medicaid Services (or his or her designee), in the case of an entity participating in the Medicare program under title XVIII of

the Social Security Act [42 U.S.C. 1395 et seq.] or the Medicaid program under title XIX of such Act [42 U.S.C. 1396 et seq.]; or

(ii) the Secretary in the case of other entities;

(B) demonstrate to the satisfaction of the Secretary (through criteria established by the Secretary) that any certified EHR technology purchased, improved, or otherwise financially supported under a loan under this section is used to exchange health information in a manner that, in accordance with law and standards (as adopted under section 300jj–14 of this title) applicable to the exchange of information, improves the quality of health care, such as promoting care coordination; and [1]

(C) comply with such other requirements as the entity or the Secretary may require;

(D) include a plan on how health care providers involved intend to maintain and support the certified EHR technology over time;

(E) include a plan on how the health care providers involved intend to maintain and support the certified EHR technology that would be purchased with such loan, including the type of resources expected to be involved and any such other information as the State or Indian Tribe, respectively, may require; and

(5) agrees to provide matching funds in accordance with subsection (h).

(c) Establishment of fund

For purposes of subsection (b)(3), an eligible entity shall establish a certified EHR technology loan fund (referred to in this subsection as a "Loan Fund") and comply with the other requirements contained in this section. A grant to an eligible entity under this section shall be deposited in the Loan Fund established by the eligible entity. No funds authorized by other provisions of this subchapter to be used for other purposes specified in this subchapter shall be deposited in any Loan Fund.

(d) Strategic plan

(1) In general

For purposes of subsection (b)(2), a strategic plan of an eligible entity under this subsection shall identify the intended uses of amounts available to the Loan Fund of such entity.

(2) Contents

A strategic plan under paragraph (1), with respect to a Loan Fund of an eligible entity, shall include for a year the following:

(A) A list of the projects to be assisted through the Loan Fund during such year.

(B) A description of the criteria and methods established for the distribution of funds from the Loan Fund during the year.

(C) A description of the financial status of the Loan Fund as of the date of submission of the plan.

(D) The short-term and long-term goals of the Loan Fund.

(e) Use of funds

Amounts deposited in a Loan Fund, including loan repayments and interest earned on such amounts, shall be used only for awarding loans or loan guarantees, making reimbursements described in subsection (g)(4)(A), or as a source of reserve and security for leveraged loans, the proceeds of which are deposited in the Loan Fund established under subsection (c). Loans under this section may be used by a health care provider to—

(1) facilitate the purchase of certified EHR technology;

(2) enhance the utilization of certified EHR technology (which may include costs associated with upgrading health information technology so that it meets criteria necessary to be a certified EHR technology);

(3) train personnel in the use of such technology; or

(4) improve the secure electronic exchange of health information.

(f) Types of assistance

Except as otherwise limited by applicable State law, amounts deposited into a Loan Fund under this section may only be used for the following:

(1) To award loans that comply with the following:

(A) The interest rate for each loan shall not exceed the market interest rate.

(B) The principal and interest payments on each loan shall commence not later than 1 year after the date the loan was awarded, and each loan shall be fully amortized not later than 10 years after the date of the loan.

(C) The Loan Fund shall be credited with all payments of principal and interest on each loan awarded from the Loan Fund.

(2) To guarantee, or purchase insurance for, a local obligation (all of the proceeds of which finance a project eligible for assistance under this subsection) if the guarantee or purchase would improve credit market access or reduce the interest rate applicable to the obligation involved.

(3) As a source of revenue or security for the payment of principal and interest on revenue or general obligation bonds issued by the eligible entity if the proceeds of the sale of the bonds will be deposited into the Loan Fund.

(4) To earn interest on the amounts deposited into the Loan Fund.

(5) To make reimbursements described in subsection (g)(4)(A).

(g) Administration of loan funds

(1) Combined financial administration

An eligible entity may (as a convenience and to avoid unnecessary administrative costs) combine, in accordance with applicable State law, the financial administration of a Loan Fund established under this subsection with the financial administration of any other revolving fund established by the entity if otherwise not prohibited by the law under which the Loan Fund was established.

(2) Cost of administering fund

Each eligible entity may annually use not to exceed 4 percent of the funds provided to the entity under a grant under this section to pay the reasonable costs of the administration of the programs under this section, including the recovery of reasonable costs expended to establish a Loan Fund which are incurred after February 17, 2009.

(3) Guidance and regulations

The National Coordinator shall publish guidance and promulgate regulations as may be necessary to carry out the provisions of this section, including—

(A) provisions to ensure that each eligible entity commits and expends funds allotted to the entity under this section as efficiently as possible in accordance with this subchapter and applicable State laws; and

(B) guidance to prevent waste, fraud, and abuse.

(4) Private sector contributions

(A) In general

A Loan Fund established under this section may accept contributions from private sector entities, except that such entities may not specify the recipient or recipients of any loan issued under this subsection. An eligible entity may agree to reimburse a private sector entity for any contribution made under this subparagraph, except that the amount of such reimbursement may not be greater than the principal amount of the contribution made.

(B) Availability of information

An eligible entity shall make publicly available the identity of, and amount contributed by, any private sector entity under subparagraph (A) and may issue letters of commendation or

make other awards (that have no financial value) to any such entity.

(h) Matching requirements

(1) In general

The National Coordinator may not make a grant under subsection (a) to an eligible entity unless the entity agrees to make available (directly or through donations from public or private entities) non-Federal contributions in cash to the costs of carrying out the activities for which the grant is awarded in an amount equal to not less than $1 for each $5 of Federal funds provided under the grant.

(2) Determination of amount of non-Federal contribution

In determining the amount of non-Federal contributions that an eligible entity has provided pursuant to subparagraph (A),[2] the National Coordinator may not include any amounts provided to the entity by the Federal Government.

(i) Effective date

The Secretary may not make an award under this section prior to January 1, 2010.

(July 1, 1944, ch. 373, title XXX, §3014, as added Pub. L. 111–5, div. A, title XIII, §13301, Feb. 17, 2009, 123 Stat. 253.)

EDITORIAL NOTES

REFERENCES IN TEXT

The Indian Self-Determination and Education Assistance Act, referred to in subsec. (b), is Pub. L. 93–638, Jan. 4, 1975, 88 Stat. 2203, which is classified principally to chapter 46 (§5301 et seq.) of Title 25, Indians. For complete classification of this Act to the Code, see Short Title note set out under section 5301 of Title 25 and Tables.

The Social Security Act, referred to in subsec. (b)(4)(A)(i), is act Aug. 14, 1935, ch. 531, 49 Stat. 620. Titles XVIII and XIX of the Act are classified generally to subchapters XVIII (§1395 et seq.) and XIX (§1396 et seq.), respectively, of chapter 7 of this title. For complete classification of this Act to the Code, see section 1305 of this title and Tables.

[1] So in original. The word "and" probably should appear at end of subpar. (D).

[2] So in original. Probably means "paragraph (1),".

§300jj–35. Demonstration program to integrate information technology into clinical education

(a) In general

The Secretary may award grants under this section to carry out demonstration projects to develop academic curricula integrating certified EHR technology in the clinical education of health professionals. Such awards shall be made on a competitive basis and pursuant to peer review.

(b) Eligibility

To be eligible to receive a grant under subsection (a), an entity shall—

(1) submit to the Secretary an application at such time, in such manner, and containing such information as the Secretary may require;

(2) submit to the Secretary a strategic plan for integrating certified EHR technology in the clinical education of health professionals to reduce medical errors, increase access to prevention, reduce chronic diseases, and enhance health care quality;

(3) be—

(A) a school of medicine, osteopathic medicine, dentistry, or pharmacy, a graduate program

in behavioral or mental health, or any other graduate health professions school;

(B) a graduate school of nursing or physician assistant studies;

(C) a consortium of two or more schools described in subparagraph (A) or (B); or

(D) an institution with a graduate medical education program in medicine, osteopathic medicine, dentistry, pharmacy, nursing, or physician assistance studies;

(4) provide for the collection of data regarding the effectiveness of the demonstration project to be funded under the grant in improving the safety of patients, the efficiency of health care delivery, and in increasing the likelihood that graduates of the grantee will adopt and incorporate certified EHR technology, in the delivery of health care services; and

(5) provide matching funds in accordance with subsection (d).

(c) Use of funds

(1) In general

With respect to a grant under subsection (a), an eligible entity shall—

(A) use grant funds in collaboration with 2 or more disciplines; and

(B) use grant funds to integrate certified EHR technology into community-based clinical education.

(2) Limitation

An eligible entity shall not use amounts received under a grant under subsection (a) to purchase hardware, software, or services.

(d) Financial support

The Secretary may not provide more than 50 percent of the costs of any activity for which assistance is provided under subsection (a), except in an instance of national economic conditions which would render the cost-share requirement under this subsection detrimental to the program and upon notification to Congress as to the justification to waive the cost-share requirement.

(e) Evaluation

The Secretary shall take such action as may be necessary to evaluate the projects funded under this section and publish, make available, and disseminate the results of such evaluations on as wide a basis as is practicable.

(f) Reports

Not later than 1 year after February 17, 2009, and annually thereafter, the Secretary shall submit to the Committee on Health, Education, Labor, and Pensions and the Committee on Finance of the Senate, and the Committee on Energy and Commerce of the House of Representatives a report that—

(1) describes the specific projects established under this section; and

(2) contains recommendations for Congress based on the evaluation conducted under subsection (e).

(July 1, 1944, ch. 373, title XXX, §3015, as added Pub. L. 111–5, div. A, title XIII, §13301, Feb. 17, 2009, 123 Stat. 256.)

§300jj–36. Information technology professionals in health care

(a) In general

The Secretary, in consultation with the Director of the National Science Foundation, shall provide assistance to institutions of higher education (or consortia thereof) to establish or expand medical health informatics education programs, including certification, undergraduate, and masters degree programs, for both health care and information technology students to ensure the rapid and effective utilization and development of health information technologies (in the United States health care infrastructure).

(b) Activities

Activities for which assistance may be provided under subsection (a) may include the following:

(1) Developing and revising curricula in medical health informatics and related disciplines.

(2) Recruiting and retaining students to the program involved.

(3) Acquiring equipment necessary for student instruction in these programs, including the installation of testbed networks for student use.

(4) Establishing or enhancing bridge programs in the health informatics fields between community colleges and universities.

(c) Priority

In providing assistance under subsection (a), the Secretary shall give preference to the following:

(1) Existing education and training programs.

(2) Programs designed to be completed in less than six months.

(July 1, 1944, ch. 373, title XXX, §3016, as added Pub. L. 111–5, div. A, title XIII, §13301, Feb. 17, 2009, 123 Stat. 257.)

§300jj–37. General grant and loan provisions

(a) Reports

The Secretary may require that an entity receiving assistance under this part shall submit to the Secretary, not later than the date that is 1 year after the date of receipt of such assistance, a report that includes—

(1) an analysis of the effectiveness of the activities for which the entity receives such assistance, as compared to the goals for such activities; and

(2) an analysis of the impact of the project on health care quality and safety.

(b) Requirement to improve quality of care and decrease in costs

The National Coordinator shall annually evaluate the activities conducted under this part and shall, in awarding grants, implement the lessons learned from such evaluation in a manner so that awards made subsequent to each such evaluation are made in a manner that, in the determination of the National Coordinator, will result in the greatest improvement in the quality and efficiency of health care.

(July 1, 1944, ch. 373, title XXX, §3017, as added Pub. L. 111–5, div. A, title XIII, §13301, Feb. 17, 2009, 123 Stat. 257.)

§300jj–38. Authorization for appropriations

For the purposes of carrying out this part, there is authorized to be appropriated such sums as may be necessary for each of the fiscal years 2009 through 2013.

(July 1, 1944, ch. 373, title XXX, §3018, as added Pub. L. 111–5, div. A, title XIII, §13301, Feb. 17, 2009, 123 Stat. 258.)

PART C—OTHER PROVISIONS

§300jj–51. Health information technology enrollment standards and protocols

(a) In general

(1) Standards and protocols

Not later than 180 days after March 23, 2010,[1] the Secretary, in consultation with the HIT Advisory Committee, shall develop interoperable and secure standards and protocols that facilitate enrollment of individuals in Federal and State health and human services programs, as determined by the Secretary.

(2) Methods

The Secretary shall facilitate enrollment in such programs through methods determined appropriate by the Secretary, which shall include providing individuals and third parties authorized by such individuals and their designees notification of eligibility and verification of eligibility required under such programs.

(b) Content

The standards and protocols for electronic enrollment in the Federal and State programs described in subsection (a) shall allow for the following:

(1) Electronic matching against existing Federal and State data, including vital records, employment history, enrollment systems, tax records, and other data determined appropriate by the Secretary to serve as evidence of eligibility and in lieu of paper-based documentation.

(2) Simplification and submission of electronic documentation, digitization of documents, and systems verification of eligibility.

(3) Reuse of stored eligibility information (including documentation) to assist with retention of eligible individuals.

(4) Capability for individuals to apply, recertify and manage their eligibility information online, including at home, at points of service, and other community-based locations.

(5) Ability to expand the enrollment system to integrate new programs, rules, and functionalities, to operate at increased volume, and to apply streamlined verification and eligibility processes to other Federal and State programs, as appropriate.

(6) Notification of eligibility, recertification, and other needed communication regarding eligibility, which may include communication via email and cellular phones.

(7) Other functionalities necessary to provide eligibles with streamlined enrollment process.

(c) Approval and notification

With respect to any standard or protocol developed under subsection (a) that has been approved by the HIT Advisory Committee, the Secretary—

(1) shall notify States of such standards or protocols; and

(2) may require, as a condition of receiving Federal funds for the health information technology investments, that States or other entities incorporate such standards and protocols into such investments.

(d) Grants for implementation of appropriate enrollment HIT

(1) In general

The Secretary shall award grant [2] to eligible entities to develop new, and adapt existing, technology systems to implement the HIT enrollment standards and protocols developed under subsection (a) (referred to in this subsection as "appropriate HIT technology").

(2) Eligible entities

To be eligible for a grant under this subsection, an entity shall—

(A) be a State, political subdivision of a State, or a local governmental entity; and

(B) submit to the Secretary an application at such time, in such manner, and containing—

(i) a plan to adopt and implement appropriate enrollment technology that includes—

(I) proposed reduction in maintenance costs of technology systems;

(II) elimination or updating of legacy systems; and

(III) demonstrated collaboration with other entities that may receive a grant under this section that are located in the same State, political subdivision, or locality;

(ii) an assurance that the entity will share such appropriate enrollment technology in accordance with paragraph (4); and

(iii) such other information as the Secretary may require.

(3) Sharing

(A) In general

The Secretary shall ensure that appropriate enrollment HIT adopted under grants under this subsection is made available to other qualified State, qualified political subdivisions of a State, or other appropriate qualified entities (as described in subparagraph (B)) at no cost.

(B) Qualified entities

The Secretary shall determine what entities are qualified to receive enrollment HIT under subparagraph (A), taking into consideration the recommendations of the HIT Advisory Committee.

(July 1, 1944, ch. 373, title XXX, §3021, as added Pub. L. 111–148, title I, §1561, Mar. 23, 2010, 124 Stat. 262; amended Pub. L. 114–255, div. A, title IV, §4003(e)(2)(A)(ii), Dec. 13, 2016, 130 Stat. 1174.)

EDITORIAL NOTES

REFERENCES IN TEXT

March 23, 2010, referred to in subsec. (a)(1), was in the original "the date of enactment of this title", which was translated as meaning the date of enactment of Pub. L. 111–148, which enacted this part, to reflect the probable intent of Congress.

AMENDMENTS

2016—Subsecs. (a)(1), (c), (d)(3)(B). Pub. L. 114–255 substituted "HIT Advisory Committee" for "HIT Policy Committee and the HIT Standards Committee".

[1] See References in Text note below.

[2] So in original. Probably should be "grants".

§300jj–52. Information blocking

(a) Definition

(1) In general

In this section, the term "information blocking" means a practice that—

(A) except as required by law or specified by the Secretary pursuant to rulemaking under paragraph (3), is likely to interfere with, prevent, or materially discourage access, exchange, or use of electronic health information; and

(B)(i) if conducted by a health information technology developer, exchange, or network, such developer, exchange, or network knows, or should know, that such practice is likely to interfere with, prevent, or materially discourage the access, exchange, or use of electronic health information; or

(ii) if conducted by a health care provider, such provider knows that such practice is unreasonable and is likely to interfere with, prevent, or materially discourage access, exchange, or use of electronic health information.

(2) Practices described

The information blocking practices described in paragraph (1) may include—

(A) practices that restrict authorized access, exchange, or use under applicable State or

Federal law of such information for treatment and other permitted purposes under such applicable law, including transitions between certified health information technologies;

(B) implementing health information technology in nonstandard ways that are likely to substantially increase the complexity or burden of accessing, exchanging, or using electronic health information; and

(C) implementing health information technology in ways that are likely to—

(i) restrict the access, exchange, or use of electronic health information with respect to exporting complete information sets or in transitioning between health information technology systems; or

(ii) lead to fraud, waste, or abuse, or impede innovations and advancements in health information access, exchange, and use, including care delivery enabled by health information technology.

(3) Rulemaking

The Secretary, through rulemaking, shall identify reasonable and necessary activities that do not constitute information blocking for purposes of paragraph (1).

(4) No enforcement before exception identified

The term "information blocking" does not include any practice or conduct occurring prior to the date that is 30 days after December 13, 2016.

(5) Consultation

The Secretary may consult with the Federal Trade Commission in promulgating regulations under this subsection, to the extent that such regulations define practices that are necessary to promote competition and consumer welfare.

(6) Application

The term "information blocking", with respect to an individual or entity, shall not include an act or practice other than an act or practice committed by such individual or entity.

(7) Clarification

In carrying out this section, the Secretary shall ensure that health care providers are not penalized for the failure of developers of health information technology or other entities offering health information technology to such providers to ensure that such technology meets the requirements to be certified under this subchapter.

(b) Inspector General authority

(1) In general

The inspector general of the Department of Health and Human Services (referred to in this section as the "Inspector General") may investigate any claim that—

(A) a health information technology developer of certified health information technology or other entity offering certified health information technology—

(i) submitted a false attestation under section 300jj–11(c)(5)(D)(vii) of this title; or

(ii) engaged in information blocking;

(B) a health care provider engaged in information blocking; or

(C) a health information exchange or network engaged in information blocking.

(2) Penalties

(A) Developers, networks, and exchanges

Any individual or entity described in subparagraph (A) or (C) of paragraph (1) that the Inspector General, following an investigation conducted under this subsection, determines to have committed information blocking shall be subject to a civil monetary penalty determined by the Secretary for all such violations identified through such investigation, which may not exceed $1,000,000 per violation. Such determination shall take into account factors such as the

nature and extent of the information blocking and harm resulting from such information blocking, including, where applicable, the number of patients affected, the number of providers affected, and the number of days the information blocking persisted.

(B) Providers

Any individual or entity described in subparagraph (B) of paragraph (1) determined by the Inspector General to have committed information blocking shall be referred to the appropriate agency to be subject to appropriate disincentives using authorities under applicable Federal law, as the Secretary sets forth through notice and comment rulemaking.

(C) Procedure

The provisions of section 1320a–7a of this title (other than subsections (a) and (b) of such section) shall apply to a civil money penalty applied under this paragraph in the same manner as such provisions apply to a civil money penalty or proceeding under such section 1320a–7a(a) of this title.

(D) Recovered penalty funds

The amounts recovered under this paragraph shall be allocated as follows:

(i) Annual operating expenses

Each year following the establishment of the authority under this subsection, the Office of the Inspector General shall provide to the Secretary an estimate of the costs to carry out investigations under this section. Such estimate may include reasonable reserves to account for variance in annual amounts recovered under this paragraph. There is authorized to be appropriated for purposes of carrying out this section an amount equal to the amount specified in such estimate for the fiscal year.

(ii) Application to other programs

The amounts recovered under this paragraph and remaining after amounts are made available under clause (i) shall be transferred to the Federal Hospital Insurance Trust Fund under section 1395i of this title and the Federal Supplementary Medical Insurance Trust Fund under section 1395t of this title, in such proportion as the Secretary determines appropriate.

(E) Authorization of appropriations

There is authorized to be appropriated to the Office of the Inspector General to carry out this section $10,000,000, to remain available until expended.

(3) Resolution of claims

(A) In general

The Office of the Inspector General, if such Office determines that a consultation regarding the health privacy and security rules promulgated under section 264(c) of the Health Insurance Portability and Accountability Act of 1996 (42 U.S.C. 1320d–2 note) will resolve an information blocking claim, may refer such instances of information blocking to the Office for Civil Rights of the Department of Health and Human Services for resolution.

(B) Limitation on liability

If a health care provider or health information technology developer makes information available based on a good faith reliance on consultations with the Office for Civil Rights of the Department of Health and Human Services pursuant to a referral under subparagraph (A), with respect to such information, the health care provider or developer shall not be liable for such disclosure or disclosures made pursuant to subparagraph (A).

(4) Application of authorities under Inspector General Act of 1978

In carrying out this subsection, the Inspector General shall have the same authorities as provided under section 6 of the Inspector General Act of 1978 (5 U.S.C. App.).[1]

(c) Identifying barriers to exchange of certified health information technology

(1) Trusted exchange defined

In this section, the term "trusted exchange" with respect to certified electronic health records means that the certified electronic health record technology has the technical capability to enable secure health information exchange between users and multiple certified electronic health record technology systems.

(2) Guidance

The National Coordinator, in consultation with the Office for Civil Rights of the Department of Health and Human Services, shall issue guidance on common legal, governance, and security barriers that prevent the trusted exchange of electronic health information.

(3) Referral

The National Coordinator and the Office for Civil Rights of the Department of Health and Human Services may refer to the Inspector General instances or patterns of refusal to exchange health information with an individual or entity using certified electronic health record technology that is technically capable of trusted exchange and under conditions when exchange is legally permissible.

(d) Additional provisions

(1) Information sharing provisions

The National Coordinator may serve as a technical consultant to the Inspector General and the Federal Trade Commission for purposes of carrying out this section. The National Coordinator may, notwithstanding any other provision of law, share information related to claims or investigations under subsection (b) with the Federal Trade Commission for purposes of such investigations and shall share information with the Inspector General, as required by law.

(2) Protection from disclosure of information

Any information that is received by the National Coordinator in connection with a claim or suggestion of possible information blocking and that could reasonably be expected to facilitate identification of the source of the information—

(A) shall not be disclosed by the National Coordinator except as may be necessary to carry out the purpose of this section;

(B) shall be exempt from mandatory disclosure under section 552 of title 5, as provided by subsection (b)(3) of such section; and

(C) may be used by the Inspector General or Federal Trade Commission for reporting purposes to the extent that such information could not reasonably be expected to facilitate identification of the source of such information.

(3) Standardized process

(A) In general

The National Coordinator shall implement a standardized process for the public to submit reports on claims of—

(i) health information technology products or developers of such products (or other entities offering such products to health care providers) not being interoperable or resulting in information blocking;

(ii) actions described in subsection (b)(1) that result in information blocking as described in subsection (a); and

(iii) any other act described in subsection (a).

(B) Collection of information

The standardized process implemented under subparagraph (A) shall provide for the collection of such information as the originating institution, location, type of transaction, system and version, timestamp, terminating institution, locations, system and version, failure notice, and other related information.

(4) Nonduplication of penalty structures

In carrying out this subsection, the Secretary shall, to the extent possible, ensure that penalties do not duplicate penalty structures that would otherwise apply with respect to information blocking and the type of individual or entity involved as of the day before December 13, 2016.

(July 1, 1944, ch. 373, title XXX, §3022, as added Pub. L. 114–255, div. A, title IV, §4004, Dec. 13, 2016, 130 Stat. 1176; amended Pub. L. 116–321, §2(a), Jan. 5, 2021, 134 Stat. 5073.)

EDITORIAL NOTES

REFERENCES IN TEXT

Section 264(c) of the Health Insurance Portability and Accountability Act of 1996, referred to in subsec. (b)(3)(A), is section 264(c) of Pub. L. 104–191, which is set out as a note under section 1320d–2 of this title.

Section 6 of the Inspector General Act of 1978, referred to in subsec. (b)(4), is section 6 of Pub. L. 95–452, which was set out in the Appendix to Title 5, Government Organization and Employees, and was repealed and restated as section 406 of Title 5 by Pub. L. 117–286, §§3(b), 7, Dec. 27, 2022, 136 Stat. 4218, 4361.

AMENDMENTS

2021—Subsec. (b)(4). Pub. L. 116–321 added par. (4).

STATUTORY NOTES AND RELATED SUBSIDIARIES

EFFECTIVE DATE OF 2021 AMENDMENT

Pub. L. 116–321, §2(b), Jan. 5, 2021, 134 Stat. 5073, provided that: "The amendment made by subsection (a) [amending this section] shall take effect as if included in the enactment of the 21st Century Cures Act (Public Law 114–255)."

[1] *See References in Text note below.*

SUBCHAPTER XXIX—DATA COLLECTION, ANALYSIS, AND QUALITY

§300kk. Data collection, analysis, and quality

(a) Data collection

(1) In general

The Secretary shall ensure that, by not later than 2 years after March 23, 2010, any federally conducted or supported health care or public health program, activity or survey (including Current Population Surveys and American Community Surveys conducted by the Bureau of Labor Statistics and the Bureau of the Census) collects and reports, to the extent practicable—

(A) data on race, ethnicity, sex, primary language, and disability status for applicants, recipients, or participants;

(B) data at the smallest geographic level such as State, local, or institutional levels if such data can be aggregated;

(C) sufficient data to generate statistically reliable estimates by racial, ethnic, sex, primary language, and disability status subgroups for applicants, recipients or participants using, if needed, statistical oversamples of these subpopulations; and

(D) any other demographic data as deemed appropriate by the Secretary regarding health disparities.

(2) Collection standards

In collecting data described in paragraph (1), the Secretary or designee shall—

(A) use Office of Management and Budget standards, at a minimum, for race and ethnicity measures;

(B) develop standards for the measurement of sex, primary language, and disability status;

(C) develop standards for the collection of data described in paragraph (1) that, at a minimum—

(i) collects self-reported data by the applicant, recipient, or participant; and

(ii) collects data from a parent or legal guardian if the applicant, recipient, or participant is a minor or legally incapacitated;

(D) survey health care providers and establish other procedures in order to assess access to care and treatment for individuals with disabilities and to identify—

(i) locations where individuals with disabilities access primary, acute (including intensive), and long-term care;

(ii) the number of providers with accessible facilities and equipment to meet the needs of the individuals with disabilities, including medical diagnostic equipment that meets the minimum technical criteria set forth in section 794f of title 29; and

(iii) the number of employees of health care providers trained in disability awareness and patient care of individuals with disabilities; and

(E) require that any reporting requirement imposed for purposes of measuring quality under any ongoing or federally conducted or supported health care or public health program, activity, or survey includes requirements for the collection of data on individuals receiving health care items or services under such programs activities [1] by race, ethnicity, sex, primary language, and disability status.

(3) Data management

In collecting data described in paragraph (1), the Secretary, acting through the National Coordinator for Health Information Technology shall—

(A) develop national standards for the management of data collected; and

(B) develop interoperability and security systems for data management.

(b) Data analysis

(1) [2] In general

For each federally conducted or supported health care or public health program or activity, the Secretary shall analyze data collected under paragraph (a) to detect and monitor trends in health disparities (as defined for purposes of section 285t [3] of this title) at the Federal and State levels.

(c) Data reporting and dissemination

(1) In general

The Secretary shall make the analyses described in (b) [4] available to—

(A) the Office of Minority Health;

(B) the National Center on Minority Health and Health Disparities;

(C) the Agency for Healthcare Research and Quality;

(D) the Centers for Disease Control and Prevention;

(E) the Centers for Medicare & Medicaid Services;

(F) the Indian Health Service and epidemiology centers funded under the Indian Health Care Improvement Act [25 U.S.C. 1601 et seq.];

(G) the Office of Rural health; [5]

(H) other agencies within the Department of Health and Human Services; and

(I) other entities as determined appropriate by the Secretary.

(2) Reporting of data

The Secretary shall report data and analyses described in (a) [6] and (b) through—

(A) public postings on the Internet websites of the Department of Health and Human Services; and

(B) any other reporting or dissemination mechanisms determined appropriate by the Secretary.

(3) Availability of data

The Secretary may make data described in (a) and (b) available for additional research, analyses, and dissemination to other Federal agencies, non-governmental entities, and the public, in accordance with any Federal agency's data user agreements.

(d) Limitations on use of data

Nothing in this section shall be construed to permit the use of information collected under this section in a manner that would adversely affect any individual.

(e) Protection and sharing of data

(1) Privacy and other safeguards

The Secretary shall ensure (through the promulgation of regulations or otherwise) that—

(A) all data collected pursuant to subsection (a) is protected—

(i) under privacy protections that are at least as broad as those that the Secretary applies to other health data under the regulations promulgated under section 264(c) of the Health Insurance Portability and Accountability Act of 1996 (Public Law 104–191; 110 Stat. 2033); and

(ii) from all inappropriate internal use by any entity that collects, stores, or receives the data, including use of such data in determinations of eligibility (or continued eligibility) in health plans, and from other inappropriate uses, as defined by the Secretary; and

(B) all appropriate information security safeguards are used in the collection, analysis, and sharing of data collected pursuant to subsection (a).

(2) Data sharing

The Secretary shall establish procedures for sharing data collected pursuant to subsection (a), measures relating to such data, and analyses of such data, with other relevant Federal and State agencies including the agencies, centers, and entities within the Department of Health and Human Services specified in subsection (c)(1)..[1]

(f) Data on rural underserved populations

The Secretary shall ensure that any data collected in accordance with this section regarding racial and ethnic minority groups are also collected regarding underserved rural and frontier populations.

(g) Authorization of appropriations

For the purpose of carrying out this section, there are authorized to be appropriated such sums as may be necessary for each of fiscal years 2010 through 2014.

(h) Requirement for implementation

Notwithstanding any other provision of this section, data may not be collected under this section unless funds are directly appropriated for such purpose in an appropriations Act.

(i) Consultation

The Secretary shall consult with the Director of the Office of Personnel Management, the Secretary of Defense, the Secretary of Veterans Affairs, the Director of the Bureau of the Census, the Commissioner of Social Security, and the head of other appropriate Federal agencies in carrying out this section.

(July 1, 1944, ch. 373, title XXXI, §3101, as added Pub. L. 111–148, title IV, §4302(a), Mar. 23, 2010, 124 Stat. 578.)

EDITORIAL NOTES

REFERENCES IN TEXT

Section 285t of this title, referred to in subsec. (b)(1), was in the original "section 485E", meaning section 485E of act July 1, 1944, which was renumbered section 464z–3 by Pub. L. 111–148, title X, §10334(c)(1)(D)(i), Mar. 23, 2010, 124 Stat. 973, and is classified to section 285t of this title. The act of July 1, 1944, no longer contains a section 485E.

The Indian Health Care Improvement Act, referred to in subsec. (c)(1)(F), is Pub. L. 94–437, Sept. 30, 1976, 90 Stat. 1400, which is classified principally to chapter 18 (§1601 et seq.) of Title 25, Indians. For complete classification of this Act to the Code, see Short Title note set out under section 1601 of Title 25 and Tables.

Section 264(c) of the Health Insurance Portability and Accountability Act of 1996 (Public Law 104–191; 110 Stat. 2033), referred to in subsec. (e)(1)(A)(i), is set out as a note under section 1320d–2 of this title.

[1] So in original.

[2] So in original. No par. (2) has been enacted.

[3] See References in Text note below.

[4] So in original. Probably should be preceded by "subsection".

[5] So in original. Probably should be "Health;".

[6] So in original. Probably should be preceded by "subsections".

SUBCHAPTER XXX—COMMUNITY LIVING ASSISTANCE SERVICES AND SUPPORTS

§§300*ll* to 300*ll*–9. Repealed. Pub. L. 112–240, title VI, §642(a), Jan. 2, 2013, 126 Stat. 2358

Section 300ll, act July 1, 1944, ch. 373, title XXXII, §3201, as added Pub. L. 111–148, title VIII, §8002(a)(1), Mar. 23, 2010, 124 Stat. 828, established the purpose of this subchapter.

Section 300ll–1, act July 1, 1944, ch. 373, title XXXII, §3202, as added Pub. L. 111–148, title VIII, §8002(a)(1), Mar. 23, 2010, 124 Stat. 828, set out definitions.

Section 300ll–2, act July 1, 1944, ch. 373, title XXXII, §3203, as added and amended Pub. L. 111–148, title VIII, §8002(a)(1), title X, §10801(a)(1), Mar. 23, 2010, 124 Stat. 830, 1015, required the Secretary to develop at least 3 actuarially sound benefit plans as alternatives for consideration for designation by the Secretary as the CLASS Independence Benefit Plan.

Section 300ll–3, act July 1, 1944, ch. 373, title XXXII, §3204, as added and amended Pub. L. 111–148, title VIII, §8002(a)(1), title X, §10801(a)(2), Mar. 23, 2010, 124 Stat. 834, 1015, related to enrollment and disenrollment requirements.

Section 300ll–4, act July 1, 1944, ch. 373, title XXXII, §3205, as added Pub. L. 111–148, title VIII, §8002(a)(1), Mar. 23, 2010, 124 Stat. 836, related to benefits and determination of eligibility.

Section 300ll–5, act July 1, 1944, ch. 373, title XXXII, §3206, as added Pub. L. 111–148, title VIII, §8002(a)(1), Mar. 23, 2010, 124 Stat. 842, related to the CLASS Independence Fund.

Section 300ll–6, act July 1, 1944, ch. 373, title XXXII, §3207, as added Pub. L. 111–148, title VIII, §8002(a)(1), Mar. 23, 2010, 124 Stat. 844, created the CLASS Independence Advisory Council.

Section 300ll–7, act July 1, 1944, ch. 373, title XXXII, §3208, as added Pub. L. 111–148, title VIII, §8002(a)(1), Mar. 23, 2010, 124 Stat. 845, related to solvency and fiscal independence of the CLASS program and required regulations and annual reports.

Section 300ll–8, act July 1, 1944, ch. 373, title XXXII, §3209, as added Pub. L. 111–148, title VIII,

§8002(a)(1), Mar. 23, 2010, 124 Stat. 845, required the Inspector General of the Department of Health and Human Services to submit an annual report on CLASS program progress and waste, fraud, and abuse.

Section 300ll–9, act July 1, 1944, ch. 373, title XXXII, §3210, as added Pub. L. 111–148, title VIII, §8002(a)(1), Mar. 23, 2010, 124 Stat. 846, provided that the CLASS program would be treated for tax purposes as a qualified long-term care insurance contract for qualified long-term care services.

STATUTORY NOTES AND RELATED SUBSIDIARIES

EFFECTIVE DATE

Pub. L. 111–148, title VIII, §8002(e), Mar. 23, 2010, 124 Stat. 847, which provided that the amendments made by section 8002(a), (b), and (d) (enacting this subchapter, amending section 1396a of this title, and amending provisions set out as a note under section 1396p of this title) were effective on Jan. 1, 2011, was repealed by Pub. L. 112–240, title VI, §642(b)(1), Jan. 2, 2013, 126 Stat. 2358.

CONSTRUCTION

Pub. L. 111–148, title VIII, §8002(f), Mar. 23, 2010, 124 Stat. 847, which provided that nothing in title VIII of Pub. L. 111–148 (enacting this subchapter, amending section 1396a of this title, enacting provisions set out as notes under this section and section 201 of this title, and amending provisions set out as a note under section 1396p of this title) was intended to replace or displace public or private disability insurance benefits, including such benefits for income replacement, was repealed by Pub. L. 112–240, title VI, §642(b)(1), Jan. 2, 2013, 126 Stat. 2358.

PERSONAL CARE ATTENDANTS WORKFORCE ADVISORY PANEL

Pub. L. 111–148, title VIII, §8002(c), Mar. 23, 2010, 124 Stat. 846, which required the Secretary of Health and Human Services to establish a Personal Care Attendants Workforce Advisory Panel for the purpose of examining and advising the Secretary and Congress on workforce issues related to personal care attendant workers and which set out membership requirements for the Panel, was repealed by Pub. L. 112–240, title VI, §642(b)(1), Jan. 2, 2013, 126 Stat. 2358.

SUBCHAPTER XXXI—WORLD TRADE CENTER HEALTH PROGRAM

PART A—ESTABLISHMENT OF PROGRAM; ADVISORY COMMITTEE

§300mm. Establishment of World Trade Center Health Program

(a) In general

There is hereby established within the Department of Health and Human Services a program to be known as the World Trade Center Health Program, which shall be administered by the WTC Program Administrator, to provide beginning on July 1, 2011—

(1) medical monitoring and treatment benefits to eligible emergency responders and recovery and cleanup workers (including those who are Federal employees) who responded to the September 11, 2001, terrorist attacks; and

(2) initial health evaluation, monitoring, and treatment benefits to residents and other building occupants and area workers in New York City who were directly impacted and adversely affected by such attacks.

(b) Components of program

The WTC Program includes the following components:

(1) Medical monitoring for responders

Medical monitoring under section 300mm–21 of this title, including clinical examinations and

long-term health monitoring and analysis for enrolled WTC responders who were likely to have been exposed to airborne toxins that were released, or to other hazards, as a result of the September 11, 2001, terrorist attacks.

(2) Initial health evaluation for survivors

An initial health evaluation under section 300mm–31 of this title, including an evaluation to determine eligibility for followup monitoring and treatment.

(3) Followup monitoring and treatment for WTC-related health conditions for responders and survivors

Provision under sections 300mm–22, 300mm–32, and 300mm–33 of this title of followup monitoring and treatment and payment, subject to the provisions of subsection (d), for all medically necessary health and mental health care expenses of an individual with respect to a WTC-related health condition (including necessary prescription drugs).

(4) Outreach

Establishment under section 300mm–2 of this title of an education and outreach program to potentially eligible individuals concerning the benefits under this subchapter.

(5) Clinical data collection and analysis

Collection and analysis under section 300mm–3 of this title of health and mental health data relating to individuals receiving monitoring or treatment benefits in a uniform manner in collaboration with the collection of epidemiological data under section 300mm–52 of this title.

(6) Research on health conditions

Establishment under part C of a research program on health conditions resulting from the September 11, 2001, terrorist attacks.

(c) No cost sharing

Monitoring and treatment benefits and initial health evaluation benefits are provided under part B without any deductibles, copayments, or other cost sharing to an enrolled WTC responder or certified-eligible WTC survivor. Initial health evaluation benefits are provided under part B without any deductibles, copayments, or other cost sharing to a screening-eligible WTC survivor.

(d) Preventing fraud and unreasonable administrative costs

(1) Fraud

The Inspector General of the Department of Health and Human Services shall develop and implement a program to review the WTC Program's health care expenditures to detect fraudulent or duplicate billing and payment for inappropriate services. This subchapter is a Federal health care program (as defined in section 1320a–7b(f) of this title) and is a health plan (as defined in section 1320a–7c(c) of this title) for purposes of applying sections 1320a–7 through 1320a–7e of this title.

(2) Unreasonable administrative costs

The Inspector General of the Department of Health and Human Services shall develop and implement a program to review the WTC Program for unreasonable administrative costs, including with respect to infrastructure, administration, and claims processing.

(e) Quality assurance

The WTC Program Administrator working with the Clinical Centers of Excellence shall develop and implement a quality assurance program for the monitoring and treatment delivered by such Centers of Excellence and any other participating health care providers. Such program shall include—

(1) adherence to monitoring and treatment protocols;

(2) appropriate diagnostic and treatment referrals for participants;

(3) prompt communication of test results to participants; and

(4) such other elements as the Administrator specifies in consultation with the Clinical Centers of Excellence.

(f) Annual program report

(1) In general

Not later than 6 months after the end of each fiscal year in which the WTC Program is in operation, the WTC Program Administrator shall submit an annual report to the Congress on the operations of this subchapter for such fiscal year and for the entire period of operation of the program.

(2) Contents included in report

Each annual report under paragraph (1) shall include at least the following:

(A) Eligible individuals

Information for each clinical program described in paragraph (3)—

(i) on the number of individuals who applied for certification under part B and the number of such individuals who were so certified;

(ii) of the individuals who were certified, on the number who received monitoring under the program and the number of such individuals who received medical treatment under the program;

(iii) with respect to individuals so certified who received such treatment, on the WTC-related health conditions for which they were treated; and

(iv) on the projected number of individuals who will be certified under part B in the succeeding fiscal year and the succeeding 10-year period.

(B) Monitoring, initial health evaluation, and treatment costs

For each clinical program so described—

(i) information on the costs of monitoring and initial health evaluation and the costs of treatment and on the estimated costs of such monitoring, evaluation, and treatment in the succeeding fiscal year; and

(ii) an estimate of the cost of medical treatment for WTC-related health conditions that have been paid for or reimbursed by workers' compensation, by public or private health plans, or by New York City under section 300mm–41 of this title.

(C) Administrative costs

Information on the cost of administering the program, including costs of program support, data collection and analysis, and research conducted under the program.

(D) Administrative experience

Information on the administrative performance of the program, including—

(i) the performance of the program in providing timely evaluation of and treatment to eligible individuals; and

(ii) a list of the Clinical Centers of Excellence and other providers that are participating in the program.

(E) Scientific reports

A summary of the findings of any new scientific reports or studies on the health effects associated with exposure described in section 300mm–5(1) of this title, including the findings of research conducted under subsection (a) or (c) of section 300mm–51 of this title.

(F) Advisory Committee recommendations

A list of recommendations by the WTC Scientific/Technical Advisory Committee on additional WTC Program eligibility criteria and on additional WTC-related health conditions and the action of the WTC Program Administrator concerning each such recommendation.

(3) Separate clinical programs described

In paragraph (2), each of the following shall be treated as a separate clinical program of the

WTC Program:

(A) Firefighters and related personnel

The benefits provided for enrolled WTC responders described in section 300mm–21(a)(2)(A) of this title.

(B) Other WTC responders

The benefits provided for enrolled WTC responders not described in subparagraph (A).

(C) WTC survivors

The benefits provided for screening-eligible WTC survivors and certified-eligible WTC survivors in section 300mm–31(a) of this title.

(g) Notification to Congress upon reaching 80 percent of eligibility numerical limits

The Secretary shall promptly notify the Congress of each of the following:

(1) When the number of enrollments of WTC responders subject to the limit established under section 300mm–21(a)(4) of this title has reached 80 percent of such limit.

(2) When the number of certifications for certified-eligible WTC survivors subject to the limit established under section 300mm–31(a)(3) of this title has reached 80 percent of such limit.

(h) Consultation

The WTC Program Administrator shall engage in ongoing outreach and consultation with relevant stakeholders, including the WTC Health Program Steering Committees and the Advisory Committee under section 300mm–1 of this title, regarding the implementation and improvement of programs under this subchapter.

(i) GAO studies

(1) Report

Not later than 18 months after December 18, 2015, the Comptroller General of the United States shall submit to the Committee on Energy and Commerce of the House of Representatives and the Committee on Health, Education, Labor, and Pensions of the Senate a report that assesses, with respect to the WTC Program, the effectiveness of each of the following:

(A) The quality assurance program developed and implemented under subsection (e).

(B) The procedures for providing certifications of coverage of conditions as WTC-related health conditions for enrolled WTC responders under section 300mm–22(b)(2)(B)(iii) of this title and for screening-eligible WTC survivors and certified-eligible WTC survivors under such section as applied under section 300mm–32(a) of this title.

(C) Any action under the WTC Program to ensure appropriate payment (including the avoidance of improper payments), including determining the extent to which individuals enrolled in the WTC Program are eligible for workers compensation or sources of health coverage, ascertaining the liability of such compensation or sources of health coverage, and making recommendations for ensuring effective and efficient coordination of benefits for individuals enrolled in the WTC Program that does not place an undue burden on such individuals.

(2) Subsequent assessments

Not later than 6 years and 6 months after December 18, 2015, and every 5 years thereafter through fiscal year 2042, the Comptroller General of the United States shall—

(A) consult the Committee on Energy and Commerce of the House of Representatives and the Committee on Health, Education, Labor, and Pensions of the Senate on the objectives in assessing the WTC Program; and

(B) prepare and submit to such Committees a report that assesses the WTC Program for the applicable reporting period, including the objectives described in subparagraph (A).

(j) Regulations

The WTC Program Administrator is authorized to promulgate such regulations as the

Administrator determines necessary to administer this subchapter.

(k) Termination

The WTC Program shall terminate on October 1, 2090.

(July 1, 1944, ch. 373, title XXXIII, §3301, as added Pub. L. 111–347, title I, §101, Jan. 2, 2011, 124 Stat. 3624; amended Pub. L. 114–113, div. O, title III, §302(b), Dec. 18, 2015, 129 Stat. 2998; Pub. L. 117–328, div. FF, title VII, §7702(c), Dec. 29, 2022, 136 Stat. 5967.)

EDITORIAL NOTES

AMENDMENTS

2022—Subsec. (f)(2)(E). Pub. L. 117–328 substituted "subsection (a) or (c) of section 300mm–51 of this title" for "section 300mm–51(a) of this title".

2015—Subsecs. (i) to (k). Pub. L. 114–113 added subsecs. (i) to (k).

§300mm–1. WTC Health Program Scientific/Technical Advisory Committee; WTC Health Program Steering Committees

(a) Advisory Committee

(1) Establishment

The WTC Program Administrator shall establish an advisory committee to be known as the WTC Health Program Scientific/Technical Advisory Committee (in this subsection referred to as the "Advisory Committee") to review scientific and medical evidence and to make recommendations to the Administrator on additional WTC Program eligibility criteria and on additional WTC-related health conditions.

(2) Composition

The WTC Program Administrator shall appoint the members of the Advisory Committee and shall include at least—

(A) 4 occupational physicians, at least 2 of whom have experience treating WTC rescue and recovery workers;

(B) 1 physician with expertise in pulmonary medicine;

(C) 2 environmental medicine or environmental health specialists;

(D) 2 representatives of WTC responders;

(E) 2 representatives of certified-eligible WTC survivors;

(F) an industrial hygienist;

(G) a toxicologist;

(H) an epidemiologist; and

(I) a mental health professional.

(3) Meetings

The Advisory Committee shall meet at such frequency as may be required to carry out its duties.

(4) Reports

The WTC Program Administrator shall provide for publication of recommendations of the Advisory Committee on the public Web site established for the WTC Program.

(5) Duration

Notwithstanding any other provision of law, the Advisory Committee shall continue in operation during the period in which the WTC Program is in operation.

(6) Application of chapter 10 of title 5

Except as otherwise specifically provided, the Advisory Committee shall be subject to Chapter [1]

10 of title 5.

(b) WTC Health Program Steering Committees

(1) Consultation

The WTC Program Administrator shall consult with 2 steering committees (each in this section referred to as a "Steering Committee") that are established as follows:

(A) WTC Responders Steering Committee

One Steering Committee, to be known as the WTC Responders Steering Committee, for the purpose of receiving input from affected stakeholders and facilitating the coordination of monitoring and treatment programs for the enrolled WTC responders under subpart 1 of part B.

(B) WTC Survivors Steering Committee

One Steering Committee, to be known as the WTC Survivors Steering Committee, for the purpose of receiving input from affected stakeholders and facilitating the coordination of initial health evaluations, monitoring, and treatment programs for screening-eligible and certified-eligible WTC survivors under subpart 2 of part B.

(2) Membership

(A) WTC Responders Steering Committee

(i) Representation

The WTC Responders Steering Committee shall include—

(I) representatives of the Centers of Excellence providing services to WTC responders;

(II) representatives of labor organizations representing firefighters, police, other New York City employees, and recovery and cleanup workers who responded to the September 11, 2001, terrorist attacks; and

(III) 3 representatives of New York City, 1 of whom will be selected by the police commissioner of New York City, 1 by the health commissioner of New York City, and 1 by the mayor of New York City.

(ii) Initial membership

The WTC Responders Steering Committee shall initially be composed of members of the WTC Monitoring and Treatment Program Steering Committee (as in existence on the day before January 2, 2011).

(B) WTC Survivors Steering Committee

(i) Representation

The WTC Survivors Steering Committee shall include representatives of—

(I) the Centers of Excellence providing services to screening-eligible and certified-eligible WTC survivors;

(II) the population of residents, students, and area and other workers affected by the September 11, 2001, terrorist attacks;

(III) screening-eligible and certified-eligible survivors receiving initial health evaluations, monitoring, or treatment under subpart 2 of part B and organizations advocating on their behalf; and

(IV) New York City.

(ii) Initial membership

The WTC Survivors Steering Committee shall initially be composed of members of the WTC Environmental Health Center Survivor Advisory Committee (as in existence on the day before January 2, 2011).

(C) Additional appointments

Each Steering Committee may recommend, if approved by a majority of voting members of the Committee, additional members to the Committee.

(D) Vacancies

A vacancy in a Steering Committee shall be filled by an individual recommended by the Steering Committee.

(July 1, 1944, ch. 373, title XXXIII, §3302, as added Pub. L. 111–347, title I, §101, Jan. 2, 2011, 124 Stat. 3627; amended Pub. L. 117–286, §4(a)(247), Dec. 27, 2022, 136 Stat. 4333.)

EDITORIAL NOTES

AMENDMENTS

2022—Subsec. (a)(6). Pub. L. 117–286 substituted "chapter 10 of title 5" for "FACA" in heading and "Chapter 10 of title 5." for "the Federal Advisory Committee Act." in text.

[1] *So in original. Probably should not be capitalized.*

§300mm–2. Education and outreach

The WTC Program Administrator shall institute a program that provides education and outreach on the existence and availability of services under the WTC Program. The outreach and education program—

(1) shall include—

(A) the establishment of a public Web site with information about the WTC Program;

(B) meetings with potentially eligible populations;

(C) development and dissemination of outreach materials informing people about the program; and

(D) the establishment of phone information services; and

(2) shall be conducted in a manner intended—

(A) to reach all affected populations; and

(B) to include materials for culturally and linguistically diverse populations.

(July 1, 1944, ch. 373, title XXXIII, §3303, as added Pub. L. 111–347, title I, §101, Jan. 2, 2011, 124 Stat. 3629.)

§300mm–3. Uniform data collection and analysis

(a) In general

The WTC Program Administrator shall provide for the uniform collection of data, including claims data (and analysis of data and regular reports to the Administrator) on the prevalence of WTC-related health conditions and the identification of new WTC-related health conditions. Such data shall be collected for all individuals provided monitoring or treatment benefits under part B and regardless of their place of residence or Clinical Center of Excellence through which the benefits are provided. The WTC Program Administrator shall provide, through the Data Centers or otherwise, for the integration of such data into the monitoring and treatment program activities under this subchapter.

(b) Coordinating through Centers of Excellence

Each Clinical Center of Excellence shall collect data described in subsection (a) and report such data to the corresponding Data Center for analysis by such Data Center.

(c) Collaboration with WTC Health Registry

The WTC Program Administrator shall provide for collaboration between the Data Centers and the World Trade Center Health Registry described in section 300mm–52 of this title.

(d) Privacy

The data collection and analysis under this section shall be conducted and maintained in a manner that protects the confidentiality of individually identifiable health information consistent with applicable statutes and regulations, including, as applicable, HIPAA privacy and security law (as defined in section 300jj–19(a)(2) of this title) and section 552a of title 5.

(July 1, 1944, ch. 373, title XXXIII, §3304, as added Pub. L. 111–347, title I, §101, Jan. 2, 2011, 124 Stat. 3629.)

§300mm–4. Clinical Centers of Excellence and Data Centers

(a) In general

(1) Contracts with Clinical Centers of Excellence

The WTC Program Administrator shall, subject to subsection (b)(1)(B), enter into contracts with Clinical Centers of Excellence (as defined in subsection (b)(1)(A))—

(A) for the provision of monitoring and treatment benefits and initial health evaluation benefits under part B;

(B) for the provision of outreach and retention activities to individuals eligible for such monitoring and treatment benefits, for initial health evaluation benefits, and for followup to individuals who are enrolled in the monitoring program;

(C) for the provision of counseling for benefits under part B, with respect to WTC-related health conditions, for individuals eligible for such benefits;

(D) for the provision of counseling for benefits for WTC-related health conditions that may be available under workers' compensation or other benefit programs for work-related injuries or illnesses, health insurance, disability insurance, or other insurance plans or through public or private social service agencies and assisting eligible individuals in applying for such benefits;

(E) for the provision of translational and interpretive services for program participants who are not English language proficient; and

(F) for the collection and reporting of data, including claims data, in accordance with section 300mm–3 of this title.

(2) Contracts with Data Centers

(A) In general

The WTC Program Administrator shall enter into contracts with one or more Data Centers (as defined in subsection (b)(2))—

(i) for receiving, analyzing, and reporting to the WTC Program Administrator on data, in accordance with section 300mm–3 of this title, that have been collected and reported to such Data Centers by the corresponding Clinical Centers of Excellence under subsection (b)(1)(B)(iii);

(ii) for the development of monitoring, initial health evaluation, and treatment protocols, with respect to WTC-related health conditions;

(iii) for coordinating the outreach and retention activities conducted under paragraph (1)(B) by each corresponding Clinical Center of Excellence;

(iv) for establishing criteria for the credentialing of medical providers participating in the nationwide network under section 300mm–23 of this title;

(v) for coordinating and administering the activities of the WTC Health Program Steering Committees established under section 300mm–1(b) [1] of this title; and

(vi) for meeting periodically with the corresponding Clinical Centers of Excellence to obtain input on the analysis and reporting of data collected under clause (i) and on the development of monitoring, initial health evaluation, and treatment protocols under clause (ii).

(B) Medical provider selection

The medical providers under subparagraph (A)(iv) shall be selected by the WTC Program Administrator on the basis of their experience treating or diagnosing the health conditions included in the list of WTC-related health conditions.

(C) Clinical discussions

In carrying out subparagraph (A)(ii), a Data Center shall engage in clinical discussions across the WTC Program to guide treatment approaches for individuals with a WTC-related health condition.

(D) Transparency of data

A contract entered into under this subsection with a Data Center shall require the Data Center to make any data collected and reported to such Center under subsection (b)(1)(B)(iii) available to health researchers and others as provided in the CDC/ATSDR Policy on Releasing and Sharing Data.

(3) Authority for contracts to be class specific

A contract entered into under this subsection with a Clinical Center of Excellence or a Data Center may be with respect to one or more class of enrolled WTC responders, screening-eligible WTC survivors, or certified-eligible WTC survivors.

(4) Use of cooperative agreements

Any contract under this subchapter between the WTC Program Administrator and a Data Center or a Clinical Center of Excellence may be in the form of a cooperative agreement.

(5) Review on feasibility of consolidating Data Centers

Not later than July 1, 2011, the Comptroller General of the United States shall submit to the Committee on Energy and Commerce of the House of Representatives and the Committee on Health, Education, Labor, and Pensions of the Senate a report on the feasibility of consolidating Data Centers into a single Data Center.

(b) Centers of Excellence

(1) Clinical Centers of Excellence

(A) Definition

For purposes of this subchapter, the term "Clinical Center of Excellence" means a Center that demonstrates to the satisfaction of the Administrator that the Center—

(i) uses an integrated, centralized health care provider approach to create a comprehensive suite of health services under this subchapter that are accessible to enrolled WTC responders, screening-eligible WTC survivors, or certified-eligible WTC survivors;

(ii) has experience in caring for WTC responders and screening-eligible WTC survivors or includes health care providers who have been trained pursuant to section 300mm–23(c) of this title;

(iii) employs health care provider staff with expertise that includes, at a minimum, occupational medicine, environmental medicine, trauma-related psychiatry and psychology, and social services counseling; and

(iv) meets such other requirements as specified by the Administrator.

(B) Contract requirements

The WTC Program Administrator shall not enter into a contract with a Clinical Center of Excellence under subsection (a)(1) unless the Center agrees to do each of the following:

(i) Establish a formal mechanism for consulting with and receiving input from representatives of eligible populations receiving monitoring and treatment benefits under part B from such Center.

(ii) Coordinate monitoring and treatment benefits under part B with routine medical care provided for the treatment of conditions other than WTC-related health conditions.

(iii) Collect and report to the corresponding Data Center data, including claims data, in

accordance with section 300mm–3(b) of this title.

(iv) Have in place safeguards against fraud that are satisfactory to the Administrator, in consultation with the Inspector General of the Department of Health and Human Services.

(v) Treat or refer for treatment all individuals who are enrolled WTC responders or certified-eligible WTC survivors with respect to such Center who present themselves for treatment of a WTC-related health condition.

(vi) Have in place safeguards, consistent with section 300mm–3(d) of this title, to ensure the confidentiality of an individual's individually identifiable health information, including requiring that such information not be disclosed to the individual's employer without the authorization of the individual.

(vii) Use amounts paid under subsection (c)(1) only for costs incurred in carrying out the activities described in subsection (a), other than those described in subsection (a)(1)(A).

(viii) Utilize health care providers with occupational and environmental medicine expertise to conduct physical and mental health assessments, in accordance with protocols developed under subsection (a)(2)(A)(ii).

(ix) Communicate with WTC responders and screening-eligible and certified-eligible WTC survivors in appropriate languages and conduct outreach activities with relevant stakeholder worker or community associations.

(x) Meet all the other applicable requirements of this subchapter, including regulations implementing such requirements.

(C) Transition rule to ensure continuity of care

The WTC Program Administrator shall to the maximum extent feasible ensure continuity of care in any period of transition from monitoring and treatment of an enrolled WTC responder or certified-eligible WTC survivor by a provider to a Clinical Center of Excellence or a health care provider participating in the nationwide network under section 300mm–23 of this title.

(2) Data Centers

For purposes of this subchapter, the term "Data Center" means a Center that the WTC Program Administrator determines has the capacity to carry out the responsibilities for a Data Center under subsection (a)(2).

(3) Corresponding centers

For purposes of this subchapter, a Clinical Center of Excellence and a Data Center shall be treated as "corresponding" to the extent that such Clinical Center and Data Center serve the same population group.

(c) Payment for infrastructure costs

(1) In general

The WTC Program Administrator shall reimburse a Clinical Center of Excellence for the fixed infrastructure costs of such Center in carrying out the activities described in part B at a rate negotiated by the Administrator and such Centers. Such negotiated rate shall be fair and appropriate and take into account the number of enrolled WTC responders receiving services from such Center under this subchapter.

(2) Fixed infrastructure costs

For purposes of paragraph (1), the term "fixed infrastructure costs" means, with respect to a Clinical Center of Excellence, the costs incurred by such Center that are not otherwise reimbursable by the WTC Program Administrator under section 300mm–22(c) of this title for patient evaluation, monitoring, or treatment but which are needed to operate the WTC program such as the costs involved in outreach to participants or recruiting participants, data collection and analysis, social services for counseling patients on other available assistance outside the WTC program, and the development of treatment protocols. Such term does not include costs for new construction or other capital costs.

(d) GAO analysis

Not later than July 1, 2011, the Comptroller General shall submit to the Committee on Energy and Commerce of the House of Representatives and the Committee on Health, Education, Labor, and Pensions of the Senate an analysis on whether Clinical Centers of Excellence with which the WTC Program Administrator enters into a contract under this section have financial systems that will allow for the timely submission of claims data for purposes of section 300mm–3 of this title and subsections (a)(1)(F) and (b)(1)(B)(iii).

(July 1, 1944, ch. 373, title XXXIII, §3305, as added Pub. L. 111–347, title I, §101, Jan. 2, 2011, 124 Stat. 3630; amended Pub. L. 114–113, div. O, title III, §302(c), Dec. 18, 2015, 129 Stat. 2998.)

EDITORIAL NOTES

REFERENCES IN TEXT

Section 300mm–1(b) of this title, referred to in subsec. (a)(2)(A)(v), was in the original "section 3002(b)" and was translated as meaning section 3302(b) of act July 1, 1944, to reflect the probable intent of Congress.

AMENDMENTS

2015—Subsec. (a)(1)(B). Pub. L. 114–113, §302(c)(1)(A), inserted "and retention" after "outreach".

Subsec. (a)(2)(A)(iii). Pub. L. 114–113, §302(c)(1)(B), inserted "and retention" after "outreach".

Subsec. (b)(1)(B)(vi). Pub. L. 114–113, §302(c)(2), substituted "section 300mm–3(d)" for "section 300mm–3(c)".

[1] *See References in Text note below.*

§300mm–5. Definitions

In this subchapter:

(1) The term "aggravating" means, with respect to a health condition, a health condition that existed on September 11, 2001, and that, as a result of exposure to airborne toxins, any other hazard, or any other adverse condition resulting from the September 11, 2001, terrorist attacks, requires medical treatment that is (or will be) in addition to, more frequent than, or of longer duration than the medical treatment that would have been required for such condition in the absence of such exposure.

(2) The term "certified-eligible WTC survivor" has the meaning given such term in section 300mm–31(a)(2) of this title.

(3) The terms "Clinical Center of Excellence" and "Data Center" have the meanings given such terms in section 300mm–4 of this title.

(4) The term "enrolled WTC responder" means a WTC responder enrolled under section 300mm–21(a)(3) of this title.

(5) The term "Federal agency" means an agency, office, or other establishment in the executive, legislative, or judicial branch of the Federal Government.

(6) The term "initial health evaluation" includes, with respect to an individual, a medical and exposure history, a physical examination, and additional medical testing as needed to evaluate whether the individual has a WTC-related health condition and is eligible for treatment under the WTC Program.

(7) The term "list of WTC-related health conditions" means—

(A) for WTC responders, the health conditions listed in section 300mm–22(a)(3) of this title; and

(B) for screening-eligible and certified-eligible WTC survivors, the health conditions listed in section 300mm–32(b) of this title.

(8) The term "New York City disaster area" means the area within New York City that is—

(A) the area of Manhattan that is south of Houston Street; and

(B) any block in Brooklyn that is wholly or partially contained within a 1.5-mile radius of the former World Trade Center site.

(9) The term "New York metropolitan area" means an area, specified by the WTC Program Administrator, within which WTC responders and eligible WTC screening-eligible survivors who reside in such area are reasonably able to access monitoring and treatment benefits and initial health evaluation benefits under this subchapter through a Clinical Center of Excellence described in subparagraphs (A), (B), or (C) of section 300mm–4(b)(1) of this title.

(10) The term "screening-eligible WTC survivor" has the meaning given such term in section 300mm–31(a)(1) of this title.

(11) Any reference to "September 11, 2001" shall be deemed a reference to the period on such date subsequent to the terrorist attacks at the World Trade Center, Shanksville, Pennsylvania, or the Pentagon, as applicable, on such date.

(12) The term "September 11, 2001, terrorist attacks" means the terrorist attacks that occurred on September 11, 2001, in New York City, in Shanksville, Pennsylvania, and at the Pentagon, and includes the aftermath of such attacks.

(13) The term "uniformed services" has the meaning given the term in section 101(a) of title 10.

(14) The term "WTC Health Program Steering Committee" means such a Steering Committee established under section 300mm–1(b) of this title.

(15) The term "WTC Program" means the Word Trade Center Health Program established under section 300mm(a) of this title.

(16)(A) The term "WTC Program Administrator" means—

(i) subject to subparagraph (B), with respect to paragraphs (3) and (4) of section 300mm–21(a) of this title (relating to enrollment of WTC responders), section 300mm–22(c) of this title and the corresponding provisions of section 300mm–32 of this title (relating to payment for initial health evaluation, monitoring, and treatment,[1] paragraphs (1)(C), (2)(B), and (3) of section 300mm–31(a) of this title (relating to determination or certification of screening-eligible or certified-eligible WTC responders), and subpart 3 of part B (relating to payor provisions), an official in the Department of Health and Human Services, to be designated by the Secretary; and

(ii) with respect to any other provision of this subchapter, the Director of the National Institute for Occupational Safety and Health, or a designee of such Director.

(B) In no case may the Secretary designate under subparagraph (A)(i) the Director of the National Institute for Occupational Safety and Health or a designee of such Director with respect to section 300mm–32 of this title (relating to payment for initial health evaluation, monitoring, and treatment).

(17) The term "WTC-related health condition" is defined in section 300mm–22(a) of this title.

(18) The term "WTC responder" is defined in section 300mm–21(a) of this title.

(19) The term "WTC Scientific/Technical Advisory Committee" means such Committee established under section 300mm–1(a) of this title.

(July 1, 1944, ch. 373, title XXXIII, §3306, as added Pub. L. 111–347, title I, §101, Jan. 2, 2011, 124 Stat. 3633; amended Pub. L. 118–31, div. A, title XVIII, §1851(a)(1), Dec. 22, 2023, 137 Stat. 706.)

EDITORIAL NOTES

AMENDMENTS

2023—Pars. (5) to (19). Pub. L. 118–31 added pars. (5) and (13) and redesignated former pars. (5) to (11) and (12) to (17) as (6) to (12) and (14) to (19), respectively.

[1] *So in original. A closing parenthesis probably should precede the comma.*

PART B—PROGRAM OF MONITORING, INITIAL HEALTH EVALUATIONS, AND TREATMENT

SUBPART 1—WTC RESPONDERS

§300mm–21. Identification of WTC responders and provision of WTC-related monitoring services

(a) WTC responder defined

(1) In general

For purposes of this subchapter, the term "WTC responder" means any of the following individuals, subject to paragraph (4):

(A) Currently identified responder

An individual who has been identified as eligible for monitoring under the arrangements as in effect on January 2, 2011, between the National Institute for Occupational Safety and Health and—

(i) the consortium coordinated by Mt. Sinai Hospital in New York City that coordinates the monitoring and treatment for enrolled WTC responders other than with respect to those covered under the arrangement with the Fire Department of New York City; or

(ii) the Fire Department of New York City.

(B) Responder who meets current eligibility criteria

An individual who meets the current eligibility criteria described in paragraph (2).

(C) Responder who meets modified eligibility criteria

An individual who—

(i) performed rescue, recovery, demolition, debris cleanup, or other related services in the New York City disaster area in response to the September 11, 2001, terrorist attacks, regardless of whether such services were performed by a State or Federal employee or member of the National Guard or otherwise; and

(ii) meets such eligibility criteria relating to exposure to airborne toxins, other hazards, or adverse conditions resulting from the September 11, 2001, terrorist attacks as the WTC Program Administrator, after consultation with the WTC Scientific/Technical Advisory Committee, determines appropriate.

The WTC Program Administrator shall not modify such eligibility criteria on or after the date that the number of enrollments of WTC responders has reached 80 percent of the limit described in paragraph (4) or on or after the date that the number of certifications for certified-eligible WTC survivors under section 300mm–31(a)(2)(B) of this title has reached 80 percent of the limit described in section 300mm–31(a)(3) of this title.

(2) Current eligibility criteria

The eligibility criteria described in this paragraph for an individual is that the individual is described in any of the following categories:

(A) Firefighters and related personnel

The individual—

(i) was a member of the Fire Department of New York City (whether fire or emergency personnel, active or retired) who participated at least one day in the rescue and recovery

effort at any of the former World Trade Center sites (including Ground Zero, Staten Island Landfill, and the New York City Chief Medical Examiner's Office) for any time during the period beginning on September 11, 2001, and ending on July 31, 2002; or

(ii)(I) is a surviving immediate family member of an individual who was a member of the Fire Department of New York City (whether fire or emergency personnel, active or retired) and was killed at the World Trade site on September 11, 2001; and

(II) received any treatment for a WTC-related health condition described in section 300mm–22(a)(1)(A)(ii) of this title (relating to mental health conditions) on or before September 1, 2008.

(B) Law enforcement officers and WTC rescue, recovery, and cleanup workers

The individual—

(i) worked or volunteered onsite in rescue, recovery, debris cleanup, or related support services in lower Manhattan (south of Canal St.), the Staten Island Landfill, or the barge loading piers, for at least 4 hours during the period beginning on September 11, 2001, and ending on September 14, 2001, for at least 24 hours during the period beginning on September 11, 2001, and ending on September 30, 2001, or for at least 80 hours during the period beginning on September 11, 2001, and ending on July 31, 2002;

(ii)(I) was a member of the Police Department of New York City (whether active or retired) or a member of the Port Authority Police of the Port Authority of New York and New Jersey (whether active or retired) who participated onsite in rescue, recovery, debris cleanup, or related services in lower Manhattan (south of Canal St.), including Ground Zero, the Staten Island Landfill, or the barge loading piers, for at least 4 hours during the period beginning September 11, 2001, and ending on September 14, 2001;

(II) participated onsite in rescue, recovery, debris cleanup, or related services at Ground Zero, the Staten Island Landfill, or the barge loading piers, for at least one day during the period beginning on September 11, 2001, and ending on July 31, 2002;

(III) participated onsite in rescue, recovery, debris cleanup, or related services in lower Manhattan (south of Canal St.) for at least 24 hours during the period beginning on September 11, 2001, and ending on September 30, 2001; or

(IV) participated onsite in rescue, recovery, debris cleanup, or related services in lower Manhattan (south of Canal St.) for at least 80 hours during the period beginning on September 11, 2001, and ending on July 31, 2002;

(iii) was an employee of the Office of the Chief Medical Examiner of New York City involved in the examination and handling of human remains from the World Trade Center attacks, or other morgue worker who performed similar post-September 11 functions for such Office staff, during the period beginning on September 11, 2001, and ending on July 31, 2002;

(iv) was a worker in the Port Authority Trans-Hudson Corporation Tunnel for at least 24 hours during the period beginning on February 1, 2002, and ending on July 1, 2002; or

(v) was a vehicle-maintenance worker who was exposed to debris from the former World Trade Center while retrieving, driving, cleaning, repairing, and maintaining vehicles contaminated by airborne toxins from the September 11, 2001, terrorist attacks during a duration and period described in subparagraph (A).

(C) Responders to the September 11 attacks at the Pentagon and Shanksville, Pennsylvania

The individual—

(i)(I) was a member of a fire or police department (whether fire or emergency personnel, active or retired), worked for a recovery or cleanup contractor, or was a volunteer; and performed rescue, recovery, demolition, debris cleanup, or other related services at the Pentagon site of the terrorist-related aircraft crash of September 11, 2001, during the period beginning on September 11, 2001, and ending on the date on which the cleanup of the site was concluded, as determined by the WTC Program Administrator;

(II) was a member of a fire or police department (whether fire or emergency personnel, active or retired), worked for a recovery or cleanup contractor, or was a volunteer; and performed rescue, recovery, demolition, debris cleanup, or other related services at the Shanksville, Pennsylvania, site of the terrorist-related aircraft crash of September 11, 2001, during the period beginning on September 11, 2001, and ending on the date on which the cleanup of the site was concluded, as determined by the WTC Program Administrator;

(III) was an employee of the Department of Defense or any other Federal agency, worked during the period beginning on September 11, 2001, and ending on September 18, 2001, for a contractor of the Department of Defense or any other Federal agency, or was a member of a regular or reserve component of the uniformed services; and performed rescue, recovery, demolition, debris cleanup, or other related services at the Pentagon site of the terrorist-related aircraft crash of September 11, 2001, during the period beginning on September 11, 2001, and ending on the date on which the cleanup of the site was concluded, as determined by the WTC Program Administrator; or

(IV) was an employee of the Department of Defense or any other Federal agency, worked during the period beginning on September 11, 2001, and ending on September 18, 2001, for a contractor of the Department of Defense or any other Federal agency, or was a member of a regular or reserve component of the uniformed services; and performed rescue, recovery, demolition, debris cleanup, or other related services at the Shanksville, Pennsylvania, site of the terrorist-related aircraft crash of September 11, 2001, during the period beginning on September 11, 2001, and ending on the date on which the cleanup of the site was concluded, as determined by the WTC Program Administrator; and

(ii) is determined by the WTC Program Administrator to be at an increased risk of developing a WTC-related health condition as a result of exposure to airborne toxins, other hazards, or adverse conditions resulting from the September 11, 2001, terrorist attacks, and meets such eligibility criteria related to such exposures, as the WTC Program Administrator determines are appropriate, after consultation with the WTC Scientific/Technical Advisory Committee.

(3) Enrollment process

(A) In general

The WTC Program Administrator shall establish a process for enrolling WTC responders in the WTC Program. Under such process—

(i) WTC responders described in paragraph (1)(A) shall be deemed to be enrolled in such Program;

(ii) subject to clause (iii), the Administrator shall enroll in such program individuals who are determined to be WTC responders;

(iii) the Administrator shall deny such enrollment to an individual if the Administrator determines that the numerical limitation in paragraph (4) on enrollment of WTC responders has been met;

(iv) there shall be no fee charged to the applicant for making an application for such enrollment;

(v) the Administrator shall make a determination on such an application not later than 60 days after the date of filing the application; and

(vi) an individual who is denied enrollment in such Program shall have an opportunity to appeal such determination in a manner established under such process.

(B) Timing

(i) Currently identified responders

In accordance with subparagraph (A)(i), the WTC Program Administrator shall enroll an individual described in paragraph (1)(A) in the WTC Program not later than July 1, 2011.

(ii) Other responders

In accordance with subparagraph (A)(ii) and consistent with paragraph (4), the WTC

Program Administrator shall enroll any other individual who is determined to be a WTC responder in the WTC Program at the time of such determination.

(4) Numerical limitation on eligible WTC responders

(A) Limit

(i) In general

The total number of individuals not described in paragraph (1)(A) or (2)(A)(ii) or subclause (III) or (IV) of paragraph (2)(C)(i) who may be enrolled under paragraph (3)(A)(ii) shall not exceed 75,000 at any time, of which no more than 2,500 may be individuals enrolled based on modified eligibility criteria established under paragraph (1)(C).

(ii) Certain responders to the September 11 attacks at the Pentagon and Shanksville, Pennsylvania

The total number of individuals who may be enrolled under paragraph (3)(A)(ii) based on eligibility criteria described in subclause (III) or (IV) of paragraph (2)(C)(i) shall not exceed 500 at any time.

(B) Process

In implementing subparagraph (A), the WTC Program Administrator shall—

(i) limit the number of enrollments made under paragraph (3)—

(I) in accordance with such subparagraph; and

(II) to such number, as determined by the Administrator based on the best available information and subject to amounts available under this subchapter, that will ensure sufficient funds will be available to provide treatment and monitoring benefits under this subchapter, with respect to all individuals who are enrolled; and

(ii) provide priority (subject to paragraph (3)(A)(i)) in such enrollments in the order in which individuals apply for enrollment under paragraph (3).

(5) Disqualification of individuals on terrorist watch list

No individual who is on the terrorist watch list maintained by the Department of Homeland Security shall qualify as an eligible WTC responder. Before enrolling any individual as a WTC responder in the WTC Program under paragraph (3), the Administrator, in consultation with the Secretary of Homeland Security, shall determine whether the individual is on such list.

(b) Monitoring benefits

(1) In general

In the case of an enrolled WTC responder (other than one described in subsection (a)(2)(A)(ii)), the WTC Program shall provide for monitoring benefits that include monitoring consistent with protocols approved by the WTC Program Administrator and including clinical examinations and long-term health monitoring and analysis. In the case of an enrolled WTC responder who is an active member of the Fire Department of New York City, the responder shall receive such benefits as part of the individual's periodic company medical exams.

(2) Provision of monitoring benefits

The monitoring benefits under paragraph (1) shall be provided through the Clinical Center of Excellence for the type of individual involved or, in the case of an individual residing outside the New York metropolitan area, under an arrangement under section 300mm–23 of this title.

(July 1, 1944, ch. 373, title XXXIII, §3311, as added Pub. L. 111–347, title I, §101, Jan. 2, 2011, 124 Stat. 3635; amended Pub. L. 114–113, div. O, title III, §302(d), Dec. 18, 2015, 129 Stat. 2999; Pub. L. 116–59, div. B, title VI, §1602(a), Sept. 27, 2019, 133 Stat. 1107; Pub. L. 117–328, div. FF, title VII, §7701(b)(1), Dec. 29, 2022, 136 Stat. 5965; Pub. L. 118–31, div. A, title XVIII, §1851(a)(2), (c)(1), Dec. 22, 2023, 137 Stat. 706, 708.)

EDITORIAL NOTES

AMENDMENTS

2023—Subsec. (a)(2)(C)(i)(III), (IV). Pub. L. 118–31, §1851(a)(2)(A), added subcls. (III) and (IV).

Subsec. (a)(4)(A). Pub. L. 118–31, §1851(a)(2)(B), substituted "Limit" for "In general" in subpar. heading, designated existing provisions as cl. (i) and inserted cl. heading, inserted "or subclause (III) or (IV) of paragraph (2)(C)(i)" after "or (2)(A)(ii)", and added cl. (ii).

Subsec. (a)(4)(B)(i)(II). Pub. L. 118–31, §1851(c)(1), substituted "this subchapter" for "sections 300mm–61 and 300mm–62 of this title".

2022—Subsec. (a)(4)(B)(i)(II). Pub. L. 117–328 substituted "sections 300mm–61 and 300mm–62 of this title" for "section 300mm–61 of this title".

2019—Subsec. (a)(4)(A). Pub. L. 116–59 substituted "75,000" for "25,000".

2015—Subsec. (a)(4)(B)(i)(II). Pub. L. 114–113 struck out "through the end of fiscal year 2020" after "who are enrolled".

STATUTORY NOTES AND RELATED SUBSIDIARIES

RULE OF CONSTRUCTION

Pub. L. 116–59, div. B, title VI, §1602(c), Sept. 27, 2019, 133 Stat. 1107, provided that: "Nothing in this section [amending this section and section 300mm–31 of this title], or the amendments made by this section, shall alter the annual limitations on amounts appropriated to the World Trade Center Health Program Fund under section 3351(a)(2) of the Public Health Service Act (42 U.S.C. 300mm–61(a)(2))."

§300mm–22. Treatment of enrolled WTC responders for WTC-related health conditions

(a) WTC-related health condition defined

(1) In general

For purposes of this subchapter, the term "WTC-related health condition" means a condition that—

(A)(i) is an illness or health condition for which exposure to airborne toxins, any other hazard, or any other adverse condition resulting from the September 11, 2001, terrorist attacks, based on an examination by a medical professional with experience in treating or diagnosing the health conditions included in the applicable list of WTC-related health conditions, is substantially likely to be a significant factor in aggravating, contributing to, or causing the illness or health condition, as determined under paragraph (2); or

(ii) is a mental health condition for which such attacks, based on an examination by a medical professional with experience in treating or diagnosing the health conditions included in the applicable list of WTC-related health conditions, is substantially likely to be a significant factor in aggravating, contributing to, or causing the condition, as determined under paragraph (2); and

(B) is included in the applicable list of WTC-related health conditions or—

(i) with respect to a WTC responder, is provided certification of coverage under subsection (b)(2)(B)(iii); or

(ii) with respect to a screening-eligible WTC survivor or certified-eligible WTC survivor, is provided certification of coverage under subsection (b)(2)(B)(iii), as applied under section 300mm–32(a) of this title.

In the case of a WTC responder described in section 300mm–21(a)(2)(A)(ii) of this title (relating to a surviving immediate family member of a firefighter), such term does not include an illness or health condition described in subparagraph (A)(i).

(2) Determination

The determination under paragraph (1) or subsection (b) of whether the September 11, 2001,

terrorist attacks were substantially likely to be a significant factor in aggravating, contributing to, or causing an individual's illness or health condition shall be made based on an assessment of the following:

(A) The individual's exposure to airborne toxins, any other hazard, or any other adverse condition resulting from the terrorist attacks. Such exposure shall be—

(i) evaluated and characterized through the use of a standardized, population-appropriate questionnaire approved by the Director of the National Institute for Occupational Safety and Health; and

(ii) assessed and documented by a medical professional with experience in treating or diagnosing health conditions included on the list of WTC-related health conditions.

(B) The type of symptoms and temporal sequence of symptoms. Such symptoms shall be—

(i) assessed through the use of a standardized, population-appropriate medical questionnaire approved by the Director of the National Institute for Occupational Safety and Health and a medical examination; and

(ii) diagnosed and documented by a medical professional described in subparagraph (A)(ii).

(3) List of health conditions for WTC responders

The list of health conditions for WTC responders consists of the following:

(A) Aerodigestive disorders

(i) Interstitial lung diseases.
(ii) Chronic respiratory disorder—fumes/vapors.
(iii) Asthma.
(iv) Reactive airways dysfunction syndrome (RADS).
(v) WTC-exacerbated chronic obstructive pulmonary disease (COPD).
(vi) Chronic cough syndrome.
(vii) Upper airway hyperreactivity.
(viii) Chronic rhinosinusitis.
(ix) Chronic nasopharyngitis.
(x) Chronic laryngitis.
(xi) Gastroesophageal reflux disorder (GERD).
(xii) Sleep apnea exacerbated by or related to a condition described in a previous clause.

(B) Mental health conditions

(i) Posttraumatic stress disorder (PTSD).
(ii) Major depressive disorder.
(iii) Panic disorder.
(iv) Generalized anxiety disorder.
(v) Anxiety disorder (not otherwise specified).
(vi) Depression (not otherwise specified).
(vii) Acute stress disorder.
(viii) Dysthymic disorder.
(ix) Adjustment disorder.
(x) Substance abuse.

(C) Musculoskeletal disorders for certain WTC responders

In the case of a WTC responder described in paragraph (4), a condition described in such paragraph.

(D) Additional conditions

Any cancer (or type of cancer) or other condition added, pursuant to paragraph (5) or (6), to the list under this paragraph.

(4) Musculoskeletal disorders

(A) In general

For purposes of this subchapter, in the case of a WTC responder who received any treatment for a WTC-related musculoskeletal disorder on or before September 11, 2003, the list of health conditions in paragraph (3) shall include:

(i) Low back pain.

(ii) Carpal tunnel syndrome (CTS).

(iii) Other musculoskeletal disorders.

(B) Definition

The term "WTC-related musculoskeletal disorder" means a chronic or recurrent disorder of the musculoskeletal system caused by heavy lifting or repetitive strain on the joints or musculoskeletal system occurring during rescue or recovery efforts in the New York City disaster area in the aftermath of the September 11, 2001, terrorist attacks.

(5) Cancer

(A) In general

The WTC Program Administrator shall periodically conduct a review of all available scientific and medical evidence, including findings and recommendations of Clinical Centers of Excellence, published in peer-reviewed journals to determine if, based on such evidence, cancer or a certain type of cancer should be added to the applicable list of WTC-related health conditions. The WTC Program Administrator shall conduct the first review under this subparagraph not later than 180 days after January 2, 2011.

(B) Proposed regulations and rulemaking

Based on the periodic reviews under subparagraph (A), if the WTC Program Administrator determines that cancer or a certain type of cancer should be added to such list of WTC-related health conditions, the WTC Program Administrator shall propose regulations, through rulemaking, to add cancer or the certain type of cancer to such list.

(C) Final regulations

Based on all the available evidence in the rulemaking record, the WTC Program Administrator shall make a final determination of whether cancer or a certain type of cancer should be added to such list of WTC-related health conditions. If such a determination is made to make such an addition, the WTC Program Administrator shall by regulation add cancer or the certain type of cancer to such list.

(D) Determinations not to add cancer or certain types of cancer

In the case that the WTC Program Administrator determines under subparagraph (B) or (C) that cancer or a certain type of cancer should not be added to such list of WTC-related health conditions, the WTC Program Administrator shall publish an explanation for such determination in the Federal Register. Any such determination to not make such an addition shall not preclude the addition of cancer or the certain type of cancer to such list at a later date.

(6) Addition of health conditions to list for WTC responders

(A) In general

Whenever the WTC Program Administrator determines that a proposed rule should be promulgated to add a health condition to the list of health conditions in paragraph (3), the Administrator may request a recommendation of the Advisory Committee or may publish such a proposed rule in the Federal Register in accordance with subparagraph (D).

(B) Administrator's options after receipt of petition

In the case that the WTC Program Administrator receives a written petition by an interested party to add a health condition to the list of health conditions in paragraph (3), not later than 90 days after the date of receipt of such petition the Administrator shall—

(i) request a recommendation of the Advisory Committee;

(ii) publish a proposed rule in the Federal Register to add such health condition, in accordance with subparagraph (D);

(iii) publish in the Federal Register the Administrator's determination not to publish such a proposed rule and the basis for such determination; or

(iv) publish in the Federal Register a determination that insufficient evidence exists to take action under clauses (i) through (iii).

(C) Action by Advisory Committee

In the case that the Administrator requests a recommendation of the Advisory Committee under this paragraph, with respect to adding a health condition to the list in paragraph (3), the Advisory Committee shall submit to the Administrator such recommendation not later than 90 days after the date of such request or by such date (not to exceed 180 days after such date of request) as specified by the Administrator. Not later than 90 days after the date of receipt of such recommendation, the Administrator shall, in accordance with subparagraph (D), publish in the Federal Register a proposed rule with respect to such recommendation or a determination not to propose such a proposed rule and the basis for such determination.

(D) Publication

The WTC Program Administrator shall, with respect to any proposed rule under this paragraph—

(i) publish such proposed rule in accordance with section 553 of title 5; and

(ii) provide interested parties a period of 30 days after such publication to submit written comments on the proposed rule.

The WTC Program Administrator may extend the period described in clause (ii) upon a finding of good cause. In the case of such an extension, the Administrator shall publish such extension in the Federal Register.

(E) Interested party defined

For purposes of this paragraph, the term "interested party" includes a representative of any organization representing WTC responders, a nationally recognized medical association, a Clinical or Data Center, a State or political subdivision, or any other interested person.

(F) Independent peer reviews

Prior to issuing a final rule to add a health condition to the list in paragraph (3), the WTC Program Administrator shall provide for an independent peer review of the scientific and technical evidence that would be the basis for issuing such final rule.

(G) Additional advisory committee recommendations

(i) Program policies

(I) Existing policies

Not later than 1 year after December 18, 2015, the WTC Program Administrator shall request the Advisory Committee to review and evaluate the policies and procedures, in effect at the time of the review and evaluation, that are used to determine whether sufficient evidence exists to support adding a health condition to the list in paragraph (3).

(II) Subsequent policies

Prior to establishing any substantive new policy or procedure used to make the determination described in subclause (I) or prior to making any substantive amendment to any policy or procedure described in such subclause, the WTC Program Administrator shall request the Advisory Committee to review and evaluate such substantive policy, procedure, or amendment.

(ii) Identification of individuals conducting independent peer reviews

Not later than 1 year after December 18, 2015, and not less than every 2 years thereafter,

the WTC Program Administrator shall seek recommendations from the Advisory Committee regarding the identification of individuals to conduct the independent peer reviews under subparagraph (F).

(b) Coverage of treatment for WTC-related health conditions

(1) Determination for enrolled WTC responders based on a WTC-related health condition

(A) In general

If a physician at a Clinical Center of Excellence that is providing monitoring benefits under section 300mm–21 of this title for an enrolled WTC responder makes a determination that the responder has a WTC-related health condition that is in the list in subsection (a)(3) and that exposure to airborne toxins, other hazards, or adverse conditions resulting from the September 1, 2001, terrorist attacks is substantially likely to be a significant factor in aggravating, contributing to, or causing the condition—

(i) the physician shall promptly transmit such determination to the WTC Program Administrator and provide the Administrator with the medical facts supporting such determination; and

(ii) on and after the date of such transmittal and subject to subparagraph (B), the WTC Program shall provide for payment under subsection (c) for medically necessary treatment for such condition.

(B) Review; certification; appeals

(i) Review

A Federal employee designated by the WTC Program Administrator shall review determinations made under subparagraph (A).

(ii) Certification

The Administrator shall provide a certification of such condition based upon reviews conducted under clause (i). Such a certification shall be provided unless the Administrator determines that the responder's condition is not a WTC-related health condition in the list in subsection (a)(3) or that exposure to airborne toxins, other hazards, or adverse conditions resulting from the September 1, 2001, terrorist attacks is not substantially likely to be a significant factor in aggravating, contributing to, or causing the condition.

(iii) Appeal process

The Administrator shall establish, by rule, a process for the appeal of determinations under clause (ii).

(2) Determination based on medically associated WTC-related health conditions

(A) In general

If a physician at a Clinical Center of Excellence determines pursuant to subsection (a) that the enrolled WTC responder has a health condition described in subsection (a)(1)(A) that is not in the list in subsection (a)(3) but which is medically associated with a WTC-related health condition—

(i) the physician shall promptly transmit such determination to the WTC Program Administrator and provide the Administrator with the facts supporting such determination; and

(ii) the Administrator shall make a determination under subparagraph (B) with respect to such physician's determination.

(B) Procedures for review, certification, and appeal

The WTC Program Administrator shall, by rule, establish procedures for the review and certification of physician determinations under subparagraph (A). Such rule shall provide for—

(i) the timely review of such a determination by a physician panel with appropriate expertise for the condition and recommendations to the WTC Program Administrator;

(ii) not later than 60 days after the date of the transmittal under subparagraph (A)(i), a determination by the WTC Program Administrator on whether or not the condition involved is described in subsection (a)(1)(A) and is medically associated with a WTC-related health condition;

(iii) certification in accordance with paragraph (1)(B)(ii) of coverage of such condition if determined to be described in subsection (a)(1)(A) and medically associated with a WTC-related health condition; and

(iv) a process for appeals of determinations relating to such conditions.

(C) Inclusion in list of health conditions

If the WTC Program Administrator provides certification under subparagraph (B)(iii) for coverage of a condition, the Administrator may, pursuant to subsection (a)(6), add the condition to the list in subsection (a)(3).

(D) Conditions already declined for inclusion in list

If the WTC Program Administrator publishes a determination under subsection (a)(6)(B) not to include a condition in the list in subsection (a)(3), the WTC Program Administrator shall not provide certification under subparagraph (B)(iii) for coverage of the condition. In the case of an individual who is certified under subparagraph (B)(iii) with respect to such condition before the date of the publication of such determination the previous sentence shall not apply.

(3) Requirement of medical necessity

(A) In general

In providing treatment for a WTC-related health condition, a physician or other provider shall provide treatment that is medically necessary and in accordance with medical treatment protocols established under subsection (d).

(B) Regulations relating to medical necessity

For the purpose of this subchapter, the WTC Program Administrator shall issue regulations specifying a standard for determining medical necessity with respect to health care services and prescription pharmaceuticals, a process for determining whether treatment furnished and pharmaceuticals prescribed under this subchapter meet such standard (including any prior authorization requirement), and a process for appeal of a determination under subsection (c)(3).

(4) Scope of treatment covered

(A) In general

The scope of treatment covered under this subsection includes services of physicians and other health care providers, diagnostic and laboratory tests, prescription drugs, inpatient and outpatient hospital services, and other medically necessary treatment.

(B) Pharmaceutical coverage

With respect to ensuring coverage of medically necessary outpatient prescription drugs, such drugs shall be provided, under arrangements made by the WTC Program Administrator, directly through participating Clinical Centers of Excellence or through one or more outside vendors.

(C) Transportation expenses for nationwide network

The WTC Program Administrator may provide for necessary and reasonable transportation and expenses incident to the securing of medically necessary treatment through the nationwide network under section 300mm–23 of this title involving travel of more than 250 miles and for which payment is made under this section in the same manner in which individuals may be furnished necessary and reasonable transportation and expenses incident to services involving travel of more than 250 miles under regulations implementing section 7384t(c) of this title.

(5) Provision of treatment pending certification

With respect to an enrolled WTC responder for whom a determination is made by an examining physician under paragraph (1) or (2), but for whom the WTC Program Administrator has not yet

determined whether to certify the determination, the WTC Program Administrator may establish by rule a process through which the Administrator may approve the provision of medical treatment under this subsection (and payment under subsection (c)) with respect to such responder and such responder's WTC-related health condition (under such terms and conditions as the Administrator may provide) until the Administrator makes a decision on whether to certify the determination.

(c) Payment for initial health evaluation, monitoring, and treatment of WTC-related health conditions

(1) Medical treatment

(A) Use of FECA payment rates

(i) In general

Subject to clause (ii):

(I) Subject to subparagraphs (B) and (C), the WTC Program Administrator shall reimburse costs for medically necessary treatment under this subchapter for WTC-related health conditions according to the payment rates that would apply to the provision of such treatment and services by the facility under the Federal Employees Compensation Act.

(II) For treatment not covered under subclause (i) or subparagraph (B), the WTC Program Administrator shall establish by regulation a reimbursement rate for such treatment.

(ii) Exception

In no case shall payments for products or services under clause (i) be made at a rate higher than the Office of Worker's Compensation Programs in the Department [1] Labor would pay for such products or services rendered at the time such products or services were provided.

(B) Pharmaceuticals

(i) In general

The WTC Program Administrator shall establish a program for paying for the medically necessary outpatient prescription pharmaceuticals prescribed under this subchapter for WTC-related health conditions through one or more contracts with outside vendors.

(ii) Competitive bidding

Under such program the Administrator shall—

(I) select one or more appropriate vendors through a Federal competitive bid process; and

(II) select the lowest bidder (or bidders) meeting the requirements for providing pharmaceutical benefits for participants in the WTC Program.

(iii) Treatment of FDNY participants

Under such program the Administrator may enter into an agreement with a separate vendor to provide pharmaceutical benefits to enrolled WTC responders for whom the Clinical Center of Excellence is described in section 300mm—4 of this title if such an arrangement is deemed necessary and beneficial to the program by the WTC Program Administrator.

(iv) Pharmaceuticals

Not later than July 1, 2011, the Comptroller General of the United States shall submit to the Committee on Energy and Commerce of the House of Representatives and the Committee on Health, Education, Labor, and Pensions of the Senate a report on whether existing Federal pharmaceutical purchasing programs can provide pharmaceutical benefits more efficiently and effectively than through the WTC program.

(C) Improving quality and efficiency through modification of payment amounts and methodologies

The WTC Program Administrator may modify the amounts and methodologies for making payments for initial health evaluations, monitoring, or treatment, if, taking into account utilization and quality data furnished by the Clinical Centers of Excellence under section 300mm–4(b)(1)(B)(iii) of this title, the Administrator determines that a bundling, capitation, pay for performance, or other payment methodology would better ensure high quality and efficient delivery of initial health evaluations, monitoring, or treatment to an enrolled WTC responder, screening-eligible WTC survivor, or certified-eligible WTC survivor.

(2) Monitoring and initial health evaluation

The WTC Program Administrator shall reimburse the costs of monitoring and the costs of an initial health evaluation provided under this subchapter at a rate set by the Administrator by regulation.

(3) Determination of medical necessity

(A) Review of medical necessity and protocols

As part of the process for reimbursement or payment under this subsection, the WTC Program Administrator shall provide for the review of claims for reimbursement or payment for the provision of medical treatment to determine if such treatment is medically necessary and in accordance with medical treatment protocols established under subsection (d).

(B) Withholding of payment for medically unnecessary treatment

The Administrator shall withhold such reimbursement or payment for treatment that the Administrator determines is not medically necessary or is not in accordance with such medical treatment protocols.

(d) Medical treatment protocols

(1) Development

The Data Centers shall develop medical treatment protocols for the treatment of enrolled WTC responders and certified-eligible WTC survivors for health conditions included in the applicable list of WTC-related health conditions.

(2) Approval

The medical treatment protocols developed under paragraph (1) shall be subject to approval by the WTC Program Administrator.

(July 1, 1944, ch. 373, title XXXIII, §3312, as added Pub. L. 111–347, title I, §101, Jan. 2, 2011, 124 Stat. 3639; amended Pub. L. 114–113, div. O, title III, §302(e), Dec. 18, 2015, 129 Stat. 2999.)

EDITORIAL NOTES

REFERENCES IN TEXT

The Federal Employees Compensation Act, referred to in subsec. (c)(1)(A)(i)(I), is act Sept. 7, 1916, ch. 458, 39 Stat. 742. The act was repealed, and the provisions thereof were reenacted as subchapter I (§8101 et seq.) of chapter 81 of Title 5, Government Organization and Employees, by Pub. L. 89–554, Sept. 6, 1966, 80 Stat. 378.

AMENDMENTS

2015—Subsec. (a)(6)(B). Pub. L. 114–113, §302(e)(1)(A), substituted "90 days" for "60 days" in introductory provisions.

Subsec. (a)(6)(C). Pub. L. 114–113, §302(e)(1)(B), substituted "90 days" for "60 days" in two places.

Subsec. (a)(6)(F), (G). Pub. L. 114–113, §302(e)(2), added subpars. (F) and (G).

[1] *So in original. The word "of" probably should appear.*

§300mm–23. National arrangement for benefits for eligible individuals outside New York

(a) In general

In order to ensure reasonable access to benefits under this part for individuals who are enrolled WTC responders, screening-eligible WTC survivors, or certified-eligible WTC survivors and who reside in any State, as defined in section 201(f) of this title, outside the New York metropolitan area, the WTC Program Administrator shall establish a nationwide network of health care providers to provide monitoring and treatment benefits and initial health evaluations near such individuals' areas of residence in such States. Nothing in this subsection shall be construed as preventing such individuals from being provided such monitoring and treatment benefits or initial health evaluation through any Clinical Center of Excellence.

(b) Network requirements

Any health care provider participating in the network under subsection (a) shall—

(1) meet criteria for credentialing established by the Data Centers;

(2) follow the monitoring, initial health evaluation, and treatment protocols developed under section 300mm–4(a)(2)(A)(ii) of this title;

(3) collect and report data in accordance with section 300mm–3 of this title; and

(4) meet such fraud, quality assurance, and other requirements as the WTC Program Administrator establishes, including sections 1320a–7 through 1320a–7e of this title, as applied by section 300mm(d) of this title.

(c) Training and technical assistance

The WTC Program Administer [1] may provide, including through contract, for the provision of training and technical assistance to health care providers participating in the network under subsection (a).

(d) Provision of services through the VA

(1) In general

The WTC Program Administrator may enter into an agreement with the Secretary of Veterans Affairs for the Secretary to provide services under this section through facilities of the Department of Veterans Affairs.

(2) National program

Not later than July 1, 2011, the Comptroller General of the United States shall submit to the Committee on Energy and Commerce of the House of Representatives and the Committee on Health, Education, Labor, and Pensions of the Senate a report on whether the Department of Veterans Affairs can provide monitoring and treatment services to individuals under this section more efficiently and effectively than through the nationwide network to be established under subsection (a).

(July 1, 1944, ch. 373, title XXXIII, §3313, as added Pub. L. 111–347, title I, §101, Jan. 2, 2011, 124 Stat. 3647.)

[1] So in original. Probably should be "Administrator".

SUBPART 2—WTC SURVIVORS

§300mm–31. Identification and initial health evaluation of screening-eligible and certified-eligible WTC survivors

(a) Identification of screening-eligible WTC survivors and certified-eligible WTC survivors

(1) Screening-eligible WTC survivors

(A) Definition

In this subchapter, the term "screening-eligible WTC survivor" means, subject to subparagraph (C) and paragraph (3), an individual who is described in any of the following clauses:

(i) Currently identified survivor

An individual, including a WTC responder, who has been identified as eligible for medical treatment and monitoring by the WTC Environmental Health Center as of January 2, 2011.

(ii) Survivor who meets current eligibility criteria

An individual who is not a WTC responder, for purposes of the initial health evaluation under subsection (b), claims symptoms of a WTC-related health condition and meets any of the current eligibility criteria described in subparagraph (B).

(iii) Survivor who meets modified eligibility criteria

An individual who is not a WTC responder, for purposes of the initial health evaluation under subsection (b), claims symptoms of a WTC-related health condition and meets such eligibility criteria relating to exposure to airborne toxins, other hazards, or adverse conditions resulting from the September 11, 2001, terrorist attacks as the WTC Administrator determines, after consultation with the Data Centers described in section 300mm–4 of this title and the WTC Scientific/Technical Advisory Committee and WTC Health Program Steering Committees under section 300mm–1 of this title.

The Administrator shall not modify such criteria under clause (iii) on or after the date that the number of certifications for certified-eligible WTC survivors under paragraph (2)(B) has reached 80 percent of the limit described in paragraph (3) or on or after the date that the number of enrollments of WTC responders has reached 80 percent of the limit described in section 300mm–21(a)(4) of this title.

(B) Current eligibility criteria

The eligibility criteria described in this subparagraph for an individual are that the individual is described in any of the following clauses:

(i) A person who was present in the New York City disaster area in the dust or dust cloud on September 11, 2001.

(ii) A person who worked, resided, or attended school, childcare, or adult daycare in the New York City disaster area for—

(I) at least 4 days during the 4-month period beginning on September 11, 2001, and ending on January 10, 2002; or

(II) at least 30 days during the period beginning on September 11, 2001, and ending on July 31, 2002.

(iii) Any person who worked as a cleanup worker or performed maintenance work in the New York City disaster area during the 4-month period described in subparagraph (B)(i) and had extensive exposure to WTC dust as a result of such work.

(iv) A person who was deemed eligible to receive a grant from the Lower Manhattan Development Corporation Residential Grant Program, who possessed a lease for a residence or purchased a residence in the New York City disaster area, and who resided in such residence during the period beginning on September 11, 2001, and ending on May 31, 2003.

(v) A person whose place of employment—

(I) at any time during the period beginning on September 11, 2001, and ending on May 31, 2003, was in the New York City disaster area; and

(II) was deemed eligible to receive a grant from the Lower Manhattan Development

Corporation WTC Small Firms Attraction and Retention Act program or other government incentive program designed to revitalize the lower Manhattan economy after the September 11, 2001, terrorist attacks.

(C) Application and determination process for screening eligibility

(i) In general

The WTC Program Administrator in consultation with the Data Centers shall establish a process for individuals, other than individuals described in subparagraph (A)(i), to be determined to be screening-eligible WTC survivors. Under such process—

(I) there shall be no fee charged to the applicant for making an application for such determination;

(II) the Administrator shall make a determination on such an application not later than 60 days after the date of filing the application;

(III) the Administrator shall make such a determination relating to an applicant's compliance with this subchapter and shall not determine that an individual is not so eligible or deny written documentation under clause (ii) to such individual unless the Administrator determines that—

(aa) based on the application submitted, the individual does not meet the eligibility criteria; or

(bb) the numerical limitation on certifications of certified-eligible WTC survivors set forth in paragraph (3) has been met; and

(IV) an individual who is determined not to be a screening-eligible WTC survivor shall have an opportunity to appeal such determination in a manner established under such process.

(ii) Written documentation of screening-eligibility

(I) In general

In the case of an individual who is described in subparagraph (A)(i) or who is determined under clause (i) (consistent with paragraph (3)) to be a screening-eligible WTC survivor, the WTC Program Administrator shall provide an appropriate written documentation of such fact.

(II) Timing

(aa) Currently identified survivors

In the case of an individual who is described in subparagraph (A)(i), the WTC Program Administrator shall provide the written documentation under subclause (I) not later than July 1, 2011.

(bb) Other members

In the case of another individual who is determined under clause (i) and consistent with paragraph (3) to be a screening-eligible WTC survivor, the WTC Program Administrator shall provide the written documentation under subclause (I) at the time of such determination.

(2) Certified-eligible WTC survivors

(A) Definition

The term "certified-eligible WTC survivor" means, subject to paragraph (3), a screening-eligible WTC survivor who the WTC Program Administrator certifies under subparagraph (B) to be eligible for followup monitoring and treatment under this subpart.

(B) Certification of eligibility for monitoring and treatment

(i) In general

The WTC Program Administrator shall establish a certification process under which the

Administrator shall provide appropriate certification to screening-eligible WTC survivors who, pursuant to the initial health evaluation under subsection (b), are determined to be eligible for followup monitoring and treatment under this subpart.

(ii) Timing

(I) Currently identified survivors

In the case of an individual who is described in paragraph (1)(A)(i), the WTC Program Administrator shall provide the certification under clause (i) not later than July 1, 2011.

(II) Other members

In the case of another individual who is determined under clause (i) to be eligible for followup monitoring and treatment, the WTC Program Administrator shall provide the certification under such clause at the time of such determination.

(3) Numerical limitation on certified-eligible WTC survivors

(A) In general

The total number of individuals not described in paragraph (1)(A)(i) who may be certified as certified-eligible WTC survivors under paragraph (2)(B) shall not exceed 75,000 at any time.

(B) Process

In implementing subparagraph (A), the WTC Program Administrator shall—

(i) limit the number of certifications provided under paragraph (2)(B)—

(I) in accordance with such subparagraph; and

(II) to such number, as determined by the Administrator based on the best available information and subject to amounts made available under this subchapter, that will ensure sufficient funds will be available to provide treatment and monitoring benefits under this subchapter, with respect to all individuals receiving such certifications; and

(ii) provide priority in such certifications in the order in which individuals apply for a determination under paragraph (2)(B).

(4) Disqualification of individuals on terrorist watch list

No individual who is on the terrorist watch list maintained by the Department of Homeland Security shall qualify as a screening-eligible WTC survivor or a certified-eligible WTC survivor. Before determining any individual to be a screening-eligible WTC survivor under paragraph (1) or certifying any individual as a certified eligible [1] WTC survivor under paragraph (2), the Administrator, in consultation with the Secretary of Homeland Security, shall determine whether the individual is on such list.

(b) Initial health evaluation to determine eligibility for followup monitoring or treatment

(1) In general

In the case of a screening-eligible WTC survivor, the WTC Program shall provide for an initial health evaluation to determine if the survivor has a WTC-related health condition and is eligible for followup monitoring and treatment benefits under the WTC Program. Initial health evaluation protocols under section 300mm–4(a)(2)(A)(ii) of this title shall be subject to approval by the WTC Program Administrator.

(2) Initial health evaluation providers

The initial health evaluation described in paragraph (1) shall be provided through a Clinical Center of Excellence with respect to the individual involved.

(3) Limitation on initial health evaluation benefits

Benefits for an initial health evaluation under this subpart for a screening-eligible WTC survivor shall consist only of a single medical initial health evaluation consistent with initial health evaluation protocols described in paragraph (1). Nothing in this paragraph shall be

construed as preventing such an individual from seeking additional medical initial health evaluations at the expense of the individual.

(July 1, 1944, ch. 373, title XXXIII, §3321, as added Pub. L. 111–347, title I, §101, Jan. 2, 2011, 124 Stat. 3648; amended Pub. L. 114–113, div. O, title III, §302(f), Dec. 18, 2015, 129 Stat. 3000; Pub. L. 116–59, div. B, title VI, §1602(b), Sept. 27, 2019, 133 Stat. 1107; Pub. L. 117–328, div. FF, title VII, §7701(b)(2), Dec. 29, 2022, 136 Stat. 5965; Pub. L. 118–31, div. A, title XVIII, §1851(c)(2), Dec. 22, 2023, 137 Stat. 708.)

EDITORIAL NOTES

AMENDMENTS

2023—Subsec. (a)(3)(B)(i)(II). Pub. L. 118–31 substituted "this subchapter" for "sections 300mm–61 and 300mm–62 of this title".

2022—Subsec. (a)(3)(B)(i)(II). Pub. L. 117–328 substituted "sections 300mm–61 and 300mm–62 of this title" for "section 300mm–61 of this title".

2019—Subsec. (a)(3)(A). Pub. L. 116–59 substituted "75,000" for "25,000".

2015—Subsec. (a)(3)(B)(i)(II). Pub. L. 114–113 struck out "through the end of fiscal year 2020" after "certifications".

STATUTORY NOTES AND RELATED SUBSIDIARIES

RULE OF CONSTRUCTION

Nothing in amendment made by Pub. L. 116–59 to alter the annual limitations on amounts appropriated to the World Trade Center Health Program Fund under section 300mm–61(a)(2) of this title, see section 1602(c) of Pub. L. 116–59, set out as a note under section 300mm–21 of this title.

[1] *So in original. Probably should be "certified-eligible".*

§300mm–32. Followup monitoring and treatment of certified-eligible WTC survivors for WTC-related health conditions

(a) In general

Subject to subsection (b), the provisions of sections 300mm–21 and 300mm–22 of this title shall apply to followup monitoring and treatment of WTC-related health conditions for certified-eligible WTC survivors in the same manner as such provisions apply to the monitoring and treatment of WTC-related health conditions for enrolled WTC responders.

(b) List of WTC-related health conditions for survivors

The list of health conditions for screening-eligible WTC survivors and certified-eligible WTC survivors consists of the following:

(1) Aerodigestive disorders

(A) Interstitial lung diseases.
(B) Chronic respiratory disorder—fumes/vapors.
(C) Asthma.
(D) Reactive airways dysfunction syndrome (RADS).
(E) WTC-exacerbated chronic obstructive pulmonary disease (COPD).
(F) Chronic cough syndrome.
(G) Upper airway hyperreactivity.
(H) Chronic rhinosinusitis.
(I) Chronic nasopharyngitis.
(J) Chronic laryngitis.
(K) Gastroesophageal reflux disorder (GERD).

(L) Sleep apnea exacerbated by or related to a condition described in a previous clause.

(2) Mental health conditions

(A) Posttraumatic stress disorder (PTSD).
(B) Major depressive disorder.
(C) Panic disorder.
(D) Generalized anxiety disorder.
(E) Anxiety disorder (not otherwise specified).
(F) Depression (not otherwise specified).
(G) Acute stress disorder.
(H) Dysthymic disorder.
(I) Adjustment disorder.
(J) Substance abuse.

(3) Additional conditions

Any cancer (or type of cancer) or other condition added to the list in section 300mm–22(a)(3) of this title pursuant to paragraph (5) or (6) of section 300mm–22(a) of this title, as such provisions are applied under subsection (a) with respect to certified-eligible WTC survivors.

(July 1, 1944, ch. 373, title XXXIII, §3322, as added Pub. L. 111–347, title I, §101, Jan. 2, 2011, 124 Stat. 3652.)

§300mm–33. Followup monitoring and treatment of other individuals with WTC-related health conditions

(a) In general

Subject to subsection (c), the provisions of section 300mm–32 of this title shall apply to the followup monitoring and treatment of WTC-related health conditions in the case of individuals described in subsection (b) in the same manner as such provisions apply to the followup monitoring and treatment of WTC-related health conditions for certified-eligible WTC survivors.

(b) Individuals described

An individual described in this subsection is an individual who, regardless of location of residence—

(1) is not an enrolled WTC responder or a certified-eligible WTC survivor; and

(2) is diagnosed at a Clinical Center of Excellence with a WTC-related health condition for certified-eligible WTC survivors.

(c) Limitation

(1) In general

The WTC Program Administrator shall limit benefits for any fiscal year under subsection (a) in a manner so that payments under this section for such fiscal year do not exceed the amount specified in paragraph (2) for such fiscal year.

(2) Limitation

The amount specified in this paragraph for—

(A) the last calendar quarter of fiscal year 2011 is $5,000,000;

(B) fiscal year 2012 is $20,000,000; or

(C) a succeeding fiscal year is the amount specified in this paragraph for the previous fiscal year increased by the annual percentage increase in the medical care component of the consumer price index for all urban consumers.

(July 1, 1944, ch. 373, title XXXIII, §3323, as added Pub. L. 111–347, title I, §101, Jan. 2, 2011, 124 Stat. 3652.)

SUBPART 3—PAYOR PROVISIONS

§300mm–41. Payment of claims

(a) In general

Except as provided in subsections (b) and (c), the cost of monitoring and treatment benefits and initial health evaluation benefits provided under subparts 1 and 2 of this part shall be paid for by the WTC Program from (as applicable) the Funds established under sections 300mm–61, 300mm–62, 300mm–63, and 300mm–64 of this title.

(b) Workers' compensation payment

(1) In general

Subject to paragraph (2), payment for treatment under subparts 1 and 2 of this part of a WTC-related health condition of an individual that is work-related shall be reduced or recouped to the extent that the WTC Program Administrator determines that payment has been made, or can reasonably be expected to be made, under a workers' compensation law or plan of the United States, a State, or a locality, or other work-related injury or illness benefit plan of the employer of such individual, for such treatment. The provisions of clauses (iii), (iv), (v), and (vi) of paragraph (2)(B) of section 1862(b) of the Social Security Act [42 U.S.C. 1395y(b)] and paragraphs (3) and (4) of such section shall apply to the recoupment under this subsection of a payment to the WTC Program (with respect to a workers' compensation law or plan, or other work-related injury or illness plan of the employer involved, and such individual) in the same manner as such provisions apply to the reimbursement of a payment under section 1862(b)(2) of such Act [42 U.S.C. 1395y(b)(2)] to the Secretary (with respect to such a law or plan and an individual entitled to benefits under title XVIII of such Act [42 U.S.C. 1395 et seq.]) except that any reference in such paragraph (4) to payment rates under title XVIII of the Social Security Act shall be deemed a reference to payment rates under this subchapter.

(2) Exception

Paragraph (1) shall not apply for any quarter, with respect to any workers' compensation law or plan, including line of duty compensation, to which New York City is obligated to make payments, if, in accordance with terms specified under the contract under subsection (d)(1)(A), New York City has made the full payment required under such contract for such quarter.

(3) Rules of construction

Nothing in this subchapter shall be construed to affect, modify, or relieve any obligations under a worker's compensation law or plan, other work-related injury or illness benefit plan of an employer, or any health insurance plan.

(c) Health insurance coverage

(1) In general

In the case of an individual who has a WTC-related health condition that is not work-related and has health coverage for such condition through any public or private health plan (including health benefits under title XVIII, XIX, or XXI of the Social Security Act [42 U.S.C. 1395 et seq., 1396 et seq., 1397aa et seq.]) the provisions of section 1862(b) of the Social Security Act [42 U.S.C. 1395y(b)] shall apply to such a health plan and such individual in the same manner as they apply to group [1] health plan and an individual entitled to benefits under title XVIII of such Act pursuant to section 226(a) of such Act [42 U.S.C. 426(a)]. Any costs for items and services covered under such plan that are not reimbursed by such health plan, due to the application of deductibles, copayments, coinsurance, other cost sharing, or otherwise, are reimbursable under this

subchapter to the extent that they are covered under the WTC Program. The program under this subchapter shall not be treated as a legally liable party for purposes of applying section 1902(a)(25) of the Social Security Act [42 U.S.C. 1396a(a)(25)].

(2) Recovery by individual providers

Nothing in paragraph (1) shall be construed as requiring an entity providing monitoring and treatment under this subchapter to seek reimbursement under a health plan with which the entity has no contract for reimbursement.

(3) Maintenance of required minimum essential coverage

No payment may be made for monitoring and treatment under this subchapter for an individual for a month (beginning with July 2014) if with respect to such month the individual—

(A) is an applicable individual (as defined in subsection (d) of section 5000A of title 26) for whom the exemption under subsection (e) of such section does not apply; and

(B) is not covered under minimum essential coverage, as required under subsection (a) of such section.

(d) Required contribution by New York City in program costs

(1) Contract requirement

(A) In general

No funds may be disbursed from the World Trade Center Health Program Fund under section 300mm–61 of this title or the World Trade Center Health Program Special Fund under section 300mm–63 of this title unless New York City has entered into a contract with the WTC Program Administrator under which New York City agrees, in a form and manner specified by the Administrator, to pay the full contribution described in subparagraph (B) in accordance with this subsection on a timely basis, plus any interest owed pursuant to subparagraph (E)(i). Such contract shall specify the terms under which New York City shall be considered to have made the full payment required for a quarter for purposes of subsection (b)(2).

(B) Full contribution amount

Under such contract, with respect to each calendar quarter of fiscal year 2016 and of each subsequent fiscal year through fiscal year 2090, the full contribution amount under this subparagraph shall be equal to 10 percent of the expenditures in carrying out this subchapter for the respective quarter (excluding any expenditures from amounts in the World Trade Center Health Program Supplemental Fund under section 300mm–62 of this title or the World Trade Center Health Program Fund for Certain WTC Responders at the Pentagon and Shanksville, Pennsylvania under section 300mm–64 of this title).

(C) Satisfaction of payment obligation

The payment obligation under such contract may not be satisfied through any of the following:

(i) An amount derived from Federal sources.

(ii) An amount paid before January 2, 2011.

(iii) An amount paid to satisfy a judgment or as part of a settlement related to injuries or illnesses arising out of the September 11, 2001, terrorist attacks.

(D) Timing of contribution

The payment obligation under such contract for a calendar quarter in a fiscal year shall be paid not later than the last day of the second succeeding calendar quarter.

(E) Compliance

(i) Interest for late payment

If New York City fails to pay to the WTC Program Administrator pursuant to such contract the amount required for any calendar quarter by the day specified in subparagraph (D), interest shall accrue on the amount not so paid at the rate (determined by the Administrator)

based on the average yield to maturity, plus 1 percentage point, on outstanding municipal bonds issued by New York City with a remaining maturity of at least 1 year.

(ii) Recovery of amounts owed

The amounts owed to the WTC Program Administrator under such contract shall be recoverable by the United States in an action in the same manner as payments made under title XVIII of the Social Security Act [42 U.S.C. 1395 et seq.] may be recoverable in an action brought under section 1862(b)(2)(B)(iii) of such Act [42 U.S.C. 1395y(b)(2)(B)(iii)].

(F) Deposit in fund

The WTC Program Administer shall deposit amounts paid under such contract into the World Trade Center Health Program Fund under section 300mm–61 of this title.

(2) Payment of New York City share of monitoring and treatment costs

With respect to each calendar quarter for which a contribution is required by New York City under the contract under paragraph (1), the WTC Program Administrator shall—

(A) provide New York City with an estimate of such amount of the required contribution at the beginning of such quarter and with an updated estimate of such amount at the beginning of each of the subsequent 2 quarters;

(B) bill such amount directly to New York City; and

(C) certify periodically, for purposes of this subsection, whether or not New York City has paid the amount so billed.

Such amount shall initially be estimated by the WTC Program Administrator and shall be subject to adjustment and reconciliation based upon actual expenditures in carrying out this subchapter (excluding any expenditures from amounts in the World Trade Center Health Program Supplemental Fund under section 300mm–62 of this title or the World Trade Center Health Program Fund for Certain WTC Responders at the Pentagon and Shanksville, Pennsylvania under section 300mm–64 of this title).

(3) Rule of construction

Nothing in this subsection shall be construed as authorizing the WTC Administrator, with respect to a fiscal year, to reduce the numerical limitation under section 300mm–21(a)(4) or 300mm–31(a)(3) of this title for such fiscal year if New York City fails to comply with paragraph (1) for a calendar quarter in such fiscal year.

(e) Work-related described

For the purposes of this section, a WTC-related health condition shall be treated as a condition that is work-related if—

(1) the condition is diagnosed in an enrolled WTC responder, or in an individual who qualifies as a certified-eligible WTC survivor on the basis of being a rescue, recovery, or cleanup worker; or

(2) with respect to the condition the individual has filed and had established a claim under a workers' compensation law or plan of the United States or a State, or other work-related injury or illness benefit plan of the employer of such individual.

(July 1, 1944, ch. 373, title XXXIII, §3331, as added Pub. L. 111–347, title I, §101, Jan. 2, 2011, 124 Stat. 3653; amended Pub. L. 114–113, div. O, title III, §302(g), Dec. 18, 2015, 129 Stat. 3000; Pub. L. 117–328, div. FF, title VII, §7701(b)(3), Dec. 29, 2022, 136 Stat. 5965; Pub. L. 118–31, div. A, title XVIII, §1851(c)(3), Dec. 22, 2023, 137 Stat. 708.)

EDITORIAL NOTES

REFERENCES IN TEXT

The Social Security Act, referred to in subsecs. (b)(1), (c)(1), and (d)(1)(E)(ii), is act Aug. 14, 1935, ch. 531, 49 Stat. 620. Titles XVIII, XIX, and XXI of the Act are classified generally to subchapters XVIII (§1395

et seq.), XIX (§1396 et seq.), and XXI (§1397aa et seq.), respectively, of chapter 7 of this title. For complete classification of this Act to the Code, see section 1305 of this title and Tables.

AMENDMENTS

2023—Subsec. (a). Pub. L. 118–31, §1851(c)(3)(A), substituted "(as applicable) the Funds established under sections 300mm–61, 300mm–62, 300mm–63, and 300mm–64 of this title" for "the World Trade Center Health Program Fund and the World Trade Center Health Program Supplemental Fund".

Subsec. (d)(1)(A). Pub. L. 118–31, §1851(c)(3)(B)(i), inserted "or the World Trade Center Health Program Special Fund under section 300mm–63 of this title" after "section 300mm–61 of this title".

Subsec. (d)(1)(B). Pub. L. 118–31, §1851(c)(3)(B)(ii), inserted "or the World Trade Center Health Program Fund for Certain WTC Responders at the Pentagon and Shanksville, Pennsylvania under section 300mm–64 of this title" after "section 300mm–62 of this title".

Subsec. (d)(2). Pub. L. 118–31, §1851(c)(3)(B)(iii), in concluding provisions, inserted "or the World Trade Center Health Program Fund for Certain WTC Responders at the Pentagon and Shanksville, Pennsylvania under section 300mm–64 of this title" after "section 300mm–62 of this title".

2022—Subsec. (a). Pub. L. 117–328, §7701(b)(3)(A), inserted "and the World Trade Center Health Program Supplemental Fund" before period at end.

Subsec. (d)(1)(B). Pub. L. 117–328, §7701(b)(3)(B)(i), inserted "(excluding any expenditures from amounts in the World Trade Center Health Program Supplemental Fund under section 300mm–62 of this title)" before period at end.

Subsec. (d)(2). Pub. L. 117–328, §7701(b)(3)(B)(ii), in concluding provisions, inserted "(excluding any expenditures from amounts in the World Trade Center Health Program Supplemental Fund under section 300mm–62 of this title)" before period at end.

2015—Subsec. (d)(1)(B). Pub. L. 114–113 substituted "each calendar quarter of fiscal year 2016 and of each subsequent fiscal year through fiscal year 2090," for "the last calendar quarter of fiscal year 2011 and each calendar quarter in fiscal years 2012 through 2015" and struck out "and with respect to calendar quarters in fiscal year 2016, such full contribution amount shall be equal to 1/9 of the Federal expenditures in carrying out this subchapter for the respective quarter" before period at end.

[1] *So in original. Probably should be preceded by "a".*

§300mm–42. Administrative arrangement authority

The WTC Program Administrator may enter into arrangements with other government agencies, insurance companies, or other third-party administrators to provide for timely and accurate processing of claims under sections 300mm–22, 300mm–23, 300mm–32, and 300mm–33 of this title.

(July 1, 1944, ch. 373, title XXXIII, §3332, as added Pub. L. 111–347, title I, §101, Jan. 2, 2011, 124 Stat. 3656.)

PART C—RESEARCH INTO CONDITIONS

§300mm–51. Research regarding certain health conditions related to September 11 terrorist attacks

(a) In general

The WTC Program Administrator shall conduct or support—

(1) research on physical and mental health conditions that may be related to the September 11, 2001, terrorist attacks;

(2) research on diagnosing WTC-related health conditions, in the case of conditions for which there has been diagnostic uncertainty; and

(3) research on treating WTC-related health conditions, in the case of conditions for which there has been treatment uncertainty.

The Administrator may provide such support through continuation and expansion of research that was initiated before January 2, 2011, and through the World Trade Center Health Registry (referred to in section 300mm–52 of this title), through a Clinical Center of Excellence, or through a Data Center.

(b) Types of research

The research under subsection (a)(1) shall include epidemiologic and other research studies on WTC-related health conditions or emerging conditions—

(1) among enrolled WTC responders and certified-eligible WTC survivors under treatment and individuals who were exposed within a geographic area related to the September 11, 2001, terrorist attacks in a manner similar to the exposure within such geographic area experienced by individuals meeting the eligibility criteria under section 300mm–21(a)(2) or 300mm–31(a)(1)(B) of this title; and

(2) in sampled populations outside the New York City disaster area in Manhattan as far north as 14th Street and in Brooklyn, along with control populations, to identify potential for long-term adverse health effects in less exposed populations.

(c) Research cohort for emerging health impacts on youth

(1) In general

The WTC Program Administrator, in consultation with the Secretary of Education, shall establish a research cohort of sufficient size to conduct future research studies on the health and educational impacts of exposure to airborne toxins, or any other hazard or adverse condition, resulting from the September 11, 2001, terrorist attacks, including on the population of individuals who were 21 years of age or younger at the time of exposure, including such individuals who are screening-eligible WTC survivors or certified-eligible WTC survivors.

(2) Populations studied

The research cohort under paragraph (1) may include—

(A) individuals who, on September 11, 2001, were 21 years of age or younger and were—

(i) outside the New York City disaster area; and

(ii) in—

(I) the area of Manhattan not further north than 14th Street; or

(II) Brooklyn; and

(B) control populations, including populations of individuals who, on September 11, 2001, were 21 years of age or younger.

(d) Consultation

The WTC Program Administrator shall carry out this section in consultation with the WTC Scientific/Technical Advisory Committee.

(e) Application of privacy and human subject protections

The privacy and human subject protections applicable to research conducted under this section shall not be less than such protections applicable to research conducted or funded by the Department of Health and Human Services.

(July 1, 1944, ch. 373, title XXXIII, §3341, as added Pub. L. 111–347, title I, §101, Jan. 2, 2011, 124 Stat. 3656; amended Pub. L. 117–328, div. FF, title VII, §7702(a), Dec. 29, 2022, 136 Stat. 5966.)

EDITORIAL NOTES

AMENDMENTS

2022—Subsec. (a). Pub. L. 117–328, §7702(a)(1)(A), substituted "The WTC" for "With respect to individuals, including enrolled WTC responders and certified-eligible WTC survivors, receiving monitoring or treatment under part B, the WTC" in introductory provisions.

Subsec. (a)(2), (3). Pub. L. 117–328, §7702(a)(1)(B), struck out "of such individuals" after "WTC-related health conditions".

Subsec. (b)(1). Pub. L. 117–328, §7702(a)(2), inserted "and individuals who were exposed within a geographic area related to the September 11, 2001, terrorist attacks in a manner similar to the exposure within such geographic area experienced by individuals meeting the eligibility criteria under section 300mm–21(a)(2) or 300mm–31(a)(1)(B) of this title" after "treatment".

Subsecs. (c) to (e). Pub. L. 117–328, §7702(a)(3), (4), added subsec. (c) and redesignated former subsecs. (c) and (d) as (d) and (e), respectively.

§300mm–52. World Trade Center Health Registry

For the purpose of ensuring ongoing data collection relating to victims of the September 11, 2001, terrorist attacks, the WTC Program Administrator shall ensure that a registry of such victims is maintained that is at least as comprehensive as the World Trade Center Health Registry maintained under the arrangements in effect as of January 1, 2015, with the New York City Department of Health and Mental Hygiene.

(July 1, 1944, ch. 373, title XXXIII, §3342, as added Pub. L. 111–347, title I, §101, Jan. 2, 2011, 124 Stat. 3657; amended Pub. L. 114–113, div. O, title III, §302(h), Dec. 18, 2015, 129 Stat. 3000.)

EDITORIAL NOTES

AMENDMENTS

2015—Pub. L. 114–113 substituted "January 1, 2015" for "April 20, 2009".

PART D—FUNDING

§300mm–61. World Trade Center Health Program Fund

(a) Establishment of Fund

(1) In general

There is established a fund to be known as the World Trade Center Health Program Fund (referred to in this section as the "Fund").

(2) Funding

Out of any money in the Treasury not otherwise appropriated, there shall be deposited into the Fund for fiscal year 2016 and each subsequent fiscal year through fiscal year 2090—

(A) the Federal share, consisting of an amount equal to—

(i) for fiscal year 2016, $330,000,000;

(ii) for fiscal year 2017, $345,610,000;

(iii) for fiscal year 2018, $380,000,000;

(iv) for fiscal year 2019, $440,000,000;

(v) for fiscal year 2020, $485,000,000;

(vi) for fiscal year 2021, $501,000,000;

(vii) for fiscal year 2022, $518,000,000;

(viii) for fiscal year 2023, $535,000,000;

(ix) for fiscal year 2024, $552,000,000;

(x) for fiscal year 2025, $570,000,000;

(xi) for each of fiscal years 2026 through 2040—

(I) the amount determined under this subparagraph for the previous fiscal year multiplied by 1.07; multiplied by

(II) the ratio of—

(aa) the total number of individuals enrolled in the WTC Program on July 1 of such previous fiscal year; to

(bb) the total number of individuals so enrolled on July 1 of the fiscal year prior to such previous fiscal year; and

(xii) for each subsequent fiscal year through fiscal year 2090, the amount specified under this subparagraph for the previous fiscal year increased by the percentage increase in the consumer price index for all urban consumers (all items; United States city average) as estimated by the Secretary for the 12-month period ending with March of the previous year; plus

(B) the New York City share, consisting of the amount contributed under the contract under section 300mm–41(d) of this title.

(3) Contract requirement

(A) In general

No funds may be disbursed from the Fund unless New York City has entered into a contract with the WTC Program Administrator under section 300mm–41(d)(1) of this title.

(B) Breach of contract

In the case of a failure to pay the amount so required under the contract—

(i) the amount is recoverable under subparagraph (E)(ii) of such section;

(ii) such failure shall not affect the disbursement of amounts from the Fund; and

(iii) the Federal share described in paragraph (2)(A) shall not be increased by the amount so unpaid.

(4) Amounts from prior fiscal years

Amounts that were deposited, or identified for deposit, into the Fund for any fiscal year under paragraph (2), as such paragraph was in effect on the day before December 18, 2015, that were not expended in carrying out this subchapter for any such fiscal year, shall remain deposited, or be deposited, as the case may be, into the Fund.

(5) Amounts to remain available until expended

Amounts deposited into the Fund under this subsection, including amounts deposited under paragraph (2) as in effect on the day before December 18, 2015, for a fiscal year shall remain available, for the purposes described in this subchapter, until expended for such fiscal year and any subsequent fiscal year through fiscal year 2090.

(b) Mandatory funds for monitoring, initial health evaluations, treatment, and claims processing

(1) In general

The amounts deposited into the Fund under subsection (a)(2) shall be available, without further appropriation, consistent with paragraph (2) and subsection (c), to carry out part B and sections 300mm(e), 300mm(f), 300mm–1(a), 300mm–1(b), 300mm–2, 300mm–3, 300mm–4(a)(1), 300mm–4(a)(2), 300mm–4(c), 300mm–51, and 300mm–52 of this title.

(2) Limitation on mandatory funding

This subchapter does not establish any Federal obligation for payment of amounts in excess of the amounts available from the Fund for such purpose or as available from the World Trade Center Health Program Supplemental Fund under section 300mm–62 of this title, the World Trade Center Health Program Special Fund under section 300mm–63 of this title, or the World Trade

Center Health Program Fund for Certain WTC Responders at the Pentagon and Shanksville, Pennsylvania under section 300mm–64 of this title.

(3) Limitation on authorization for further appropriations

This subchapter does not establish any authorization for appropriation of amounts in excess of the amounts available from the Fund under paragraph (1) or as available from the World Trade Center Health Program Supplemental Fund under section 300mm–62 of this title, the World Trade Center Health Program Special Fund under section 300mm–63 of this title, or the World Trade Center Health Program Fund for Certain WTC Responders at the Pentagon and Shanksville, Pennsylvania under section 300mm–64 of this title.

(4) Limitation for research cohort for emerging health impacts on youth

Notwithstanding paragraph (1), the amounts made available under such paragraph may not be used for fiscal years 2023 through 2032 to carry out subsection (c) of section 300mm–51 of this title.

(c) Limits on spending for certain purposes

Of the amounts made available under subsection (b)(1), not more than each of the following amounts may be available for each of the following purposes:

(1) Surviving immediate family members of firefighters

For the purposes of carrying out part B with respect to WTC responders described in section 300mm–21(a)(2)(A)(ii) of this title—

(A) for fiscal year 2016, the amount determined for such fiscal year under subparagraph (C) [1] as in effect on the day before December 18, 2015; and

(B) for each subsequent fiscal year, the amount specified under this paragraph for the previous fiscal year increased by the percentage increase in the consumer price index for all urban consumers (all items; United States city average) as estimated by the Secretary for the 12-month period ending with March of the previous year.

(2) WTC Health Program Scientific/Technical Advisory Committee

For the purpose of carrying out section 300mm–1(a) of this title—

(A) for fiscal year 2016, $200,000; [2]

(B) for each subsequent fiscal year, the amount specified under this paragraph for the previous fiscal year increased by the percentage increase in the consumer price index for all urban consumers (all items; United States city average) as estimated by the Secretary for the 12-month period ending with March of the previous year.

(3) Education and outreach

For the purpose of carrying out section 300mm–2 of this title, for fiscal year 2016 and each subsequent fiscal year, $750,000.

(4) Uniform data collection

For the purpose of carrying out section 300mm–3 of this title and for reimbursing Data Centers (as defined in section 300mm–4(b)(2) of this title) for the costs incurred by such Centers in carrying out activities under contracts entered into under section 300mm–4(a)(2) of this title—

(A) for fiscal year 2016, the amount determined for such fiscal year under subparagraph (C) as in effect on the day before December 18, 2015;

(B) for fiscal year 2017, $15,000,000; and

(C) for each subsequent fiscal year, the amount specified under this paragraph for the previous fiscal year increased by the percentage increase in the consumer price index for all urban consumers (all items; United States city average) as estimated by the Secretary for the 12-month period ending with March of the previous year.

(5) Research regarding certain health conditions

For the purpose of carrying out section 300mm–51 of this title—

(A) for fiscal year 2016, the amount determined for such fiscal year under subparagraph (C) [1] as in effect on the day before December 18, 2015; and

(B) for each subsequent fiscal year, the amount specified under this paragraph for the previous fiscal year increased by the percentage increase in the consumer price index for all urban consumers (all items; United States city average) as estimated by the Secretary for the 12-month period ending with March of the previous year.

(6) World Trade Center Health Registry

For the purpose of carrying out section 300mm–52 of this title—

(A) for fiscal year 2016, the amount determined for such fiscal year under subparagraph (C) [1] as in effect on the day before December 18, 2015; and

(B) for each subsequent fiscal year, the amount specified under this paragraph for the previous fiscal year increased by the percentage increase in the consumer price index for all urban consumers (all items; United States city average) as estimated by the Secretary for the 12-month period ending with March of the previous year.

(July 1, 1944, ch. 373, title XXXIII, §3351, as added Pub. L. 111–347, title I, §101, Jan. 2, 2011, 124 Stat. 3657; amended Pub. L. 114–113, div. O, title III, §302(a), Dec. 18, 2015, 129 Stat. 2996; Pub. L. 117–328, div. FF, title VII, §§7701(b)(4), 7702(b), Dec. 29, 2022, 136 Stat. 5966, 5967; Pub. L. 118–31, div. A, title XVIII, §1851(c)(4), Dec. 22, 2023, 137 Stat. 708; Pub. L. 119–75, div. J, title IV, §6411(a), Feb. 3, 2026, 140 Stat. 688.)

EDITORIAL NOTES

REFERENCES IN TEXT

Subparagraph (C) as in effect on the day before December 18, 2015, referred to in subsec. (c)(1)(A), (5)(A), (6)(A), refers to subpar. (C) as in effect on the day before the amendments made by Pub. L. 114–113, which redesignated subpar. (C) as (B) in pars. (1), (5), and (6) of subsec. (c). See 2015 Amendment notes below.

PRIOR PROVISIONS

A prior section 300aaa, act July 1, 1944, ch. 373, title XXVII, §2701, formerly title V, §501, 58 Stat. 709, as amended, which related to gifts for benefit of Service, was renumbered section 231 of title II of act July 1, 1944, by Pub. L. 103–43, title XX, §2010(a)(1)–(3), June 10, 1993, 107 Stat. 213, and transferred to section 238 of this title.

A prior section 300aaa–1, act July 1, 1944, ch. 373, title XXVII, §2702, formerly title V, §502, 58 Stat. 710, as amended, which related to use of immigration station hospitals, was renumbered section 232 of title II of act July 1, 1944, by Pub. L. 103–43, title XX, §2010(a)(1)–(3), June 10, 1993, 107 Stat. 213, and transferred to section 238a of this title.

A prior section 300aaa–2, act July 1, 1944, ch. 373, title XXVII, §2703, formerly title V, §503, 58 Stat. 710, as amended, which related to disposition of money collected for care of patients, was renumbered section 233 of title II of act July 1, 1944, by Pub. L. 103–43, title XX, §2010(a)(1)–(3), June 10, 1993, 107 Stat. 213, and transferred to section 238b of this title.

A prior section 300aaa–3, act July 1, 1944, ch. 373, title XXVII, §2704, formerly title V, §506, 58 Stat. 710, as amended, which related to transportation of remains of officers, was renumbered section 234 of title II of act July 1, 1944, by Pub. L. 103–43, title XX, §2010(a)(1)–(3), June 10, 1993, 107 Stat. 213, and transferred to section 238c of this title.

A prior section 300aaa–4, act July 1, 1944, ch. 373, title XXVII, §2705, formerly title V, §507, as added June 24, 1967, Pub. L. 90–31, §5, 81 Stat. 79, and amended, which related to availability of appropriations for grants to Federal institutions, was renumbered section 235 of title II of act July 1, 1944, by Pub. L. 103–43, title XX, §2010(a)(1)–(3), June 10, 1993, 107 Stat. 213, and transferred to section 238d of this title.

A prior section 300aaa–5, act July 1, 1944, ch. 373, title XXVII, §2706, formerly title V, §508, 58 Stat. 711, as amended, which related to transfer of funds for continuance of transferred functions, was renumbered section 236 of title II of act July 1, 1944, by Pub. L. 103–43, title XX, §2010(a)(1)–(3), June 10, 1993, 107 Stat. 213, and transferred to section 238e of this title.

A prior section 300aaa–6, act July 1, 1944, ch. 373, title XXVII, §2707, formerly title V, §509, 58 Stat. 711, as amended, which related to availability of appropriations, was renumbered section 237 of title II of act July 1, 1944, by Pub. L. 103–43, title XX, §2010(a)(1)–(3), June 10, 1993, 107 Stat. 213, and transferred to section

238f of this title.

A prior section 300aaa–7, act July 1, 1944, ch. 373, title XXVII, §2708, formerly title V, §510, 58 Stat. 711, as amended, which related to wearing of uniforms, was renumbered section 238 of title II of act July 1, 1944, by Pub. L. 103–43, title XX, §2010(a)(1)–(3), June 10, 1993, 107 Stat. 213, and transferred to section 238g of this title.

A prior section 300aaa–8, act July 1, 1944, ch. 373, title XXVII, §2709, formerly title V, §511, 58 Stat. 711, as amended, which related to annual report of Surgeon General, was renumbered section 239 of title II of act July 1, 1944, by Pub. L. 103–43, title XX, §2010(a)(1)–(3), June 10, 1993, 107 Stat. 213, and transferred to section 238h of this title.

A prior section 300aaa–9, act July 1, 1944, ch. 373, title XXVII, §2710, formerly title V, §512, as added Oct. 15, 1968, Pub. L. 90–574, title V, §503(a), 82 Stat. 1012, and amended, which related to memorials and other acknowledgements for contributions to the health of the Nation, was renumbered section 240 of title II of act July 1, 1944, by Pub. L. 103–43, title XX, §2010(a)(1)–(3), June 10, 1993, 107 Stat. 213, and transferred to section 238i of this title.

A prior section 300aaa–10, act July 1, 1944, ch. 373, title XXVII, §2711, formerly title V, §513, as added June 30, 1970, Pub. L. 91–296, title IV, §401(a), 84 Stat. 351, and amended, which related to evaluation of programs, was renumbered section 241 of title II of act July 1, 1944, by Pub. L. 103–43, title XX, §2010(a)(1)–(3), June 10, 1993, 107 Stat. 213, and transferred to section 238j of this title.

A prior section 300aaa–11, act July 1, 1944, ch. 373, title XXVII, §2712, formerly title V, §514, as added Nov. 9, 1978, Pub. L. 95–623, §11(e), 92 Stat. 3456, and amended, which related to contract authority, was renumbered section 242 of title II of act July 1, 1944, by Pub. L. 103–43, title XX, §2010(a)(1)–(3), June 10, 1993, 107 Stat. 213, and transferred to section 238k of this title.

A prior section 300aaa–12, act July 1, 1944, ch. 373, title XXVII, §2713, formerly title V, §515, formerly Pub. L. 88–164, title II, §225, as added Pub. L. 94–63, title III, §303, July 29, 1975, 89 Stat. 326, and amended, which related to recovery by United States of base amount plus interest in certain circumstances, was renumbered section 243 of title II of act July 1, 1944, by Pub. L. 103–43, title XX, §2010(a)(1)–(3), June 10, 1993, 107 Stat. 213, and transferred to section 238l of this title.

A prior section 300aaa–13, act July 1, 1944, ch. 373, title XXVII, §2714, formerly title XXI, §2116, as added Apr. 7, 1986, Pub. L. 99–272, title XVII, §17003, 100 Stat. 359, and amended, which related to use of fiscal agents, was renumbered section 244 of title II of act July 1, 1944, by Pub. L. 103–43, title XX, §2010(a)(1)–(3), June 10, 1993, 107 Stat. 213, and transferred to section 238m of this title.

AMENDMENTS

2026—Subsec. (a)(2)(A)(xi), (xii). Pub. L. 119–75 added cl. (xi) and redesignated former cl. (xi) as (xii).

2023—Subsec. (b)(2). Pub. L. 118–31, §1851(c)(4)(A), inserted ", the World Trade Center Health Program Special Fund under section 300mm–63 of this title, or the World Trade Center Health Program Fund for Certain WTC Responders at the Pentagon and Shanksville, Pennsylvania under section 300mm–64 of this title" before period at end.

Subsec. (b)(3). Pub. L. 118–31, §1851(c)(4)(B), inserted ", the World Trade Center Health Program Special Fund under section 300mm–63 of this title, or the World Trade Center Health Program Fund for Certain WTC Responders at the Pentagon and Shanksville, Pennsylvania under section 300mm–64 of this title" before period at end.

2022—Subsec. (b)(2). Pub. L. 117–328, §7701(b)(4)(A), inserted "or as available from the World Trade Center Health Program Supplemental Fund under section 300mm–62 of this title" before period at end.

Subsec. (b)(3). Pub. L. 117–328, §7701(b)(4)(B), inserted "or as available from the World Trade Center Health Program Supplemental Fund under section 300mm–62 of this title" before period at end.

Subsec. (b)(4). Pub. L. 117–328, §7702(b), added par. (4).

2015—Subsec. (a)(2). Pub. L. 114–113, §302(a)(1)(A)(i), substituted "fiscal year 2016 and each subsequent fiscal year through fiscal year 2090" for "each of fiscal years 2012 through 2016 (and the last calendar quarter of fiscal year 2011)" in introductory provisions.

Subsec. (a)(2)(A). Pub. L. 114–113, §302(a)(1)(A)(ii), added subpar. (A) and struck out former subpar. (A) which read as follows: "the Federal share, consisting of an amount equal to the lesser of—

"(i) 90 percent of the expenditures in carrying out this subchapter for the respective fiscal year (initially based on estimates, subject to subsequent reconciliation based on actual expenditures); or

"(ii)(I) $71,000,000 for the last calendar quarter of fiscal year 2011, $318,000,000 for fiscal year 2012, $354,000,000 for fiscal year 2013, $382,000,000 for fiscal year 2014, and $431,000,000 for fiscal year 2015; and

"(II) subject to paragraph (4), an additional amount for fiscal year 2016 from unexpended amounts for

previous fiscal years; plus".

Subsec. (a)(4), (5). Pub. L. 114–113, §302(a)(1)(B), added pars. (4) and (5) and struck out former par. (4). Prior to amendment, text of par. (4) read as follows: "Beginning with fiscal year 2016, in no case shall the share of Federal funds deposited into the Fund under paragraph (2) for such fiscal year and previous fiscal years and quarters exceed the sum of the amounts specified in paragraph (2)(A)(ii)(I)."

Subsec. (b)(1). Pub. L. 114–113, §302(a)(2), substituted "sections 300mm(e), 300mm(f), 300mm–1(a), 300mm–1(b), 300mm–2, 300mm–3, 300mm–4(a)(1), 300mm–4(a)(2), 300mm–4(c), 300mm–51, and 300mm–52 of this title" for "sections 300mm–1(a), 300mm–2, 300mm–3, 300mm–4(a)(2), 300mm–4(c), 300mm–51, and 300mm–52 of this title".

Subsec. (c)(1)(A). Pub. L. 114–113, §302(a)(3)(A)(iii), amended subpar. (A) generally. Prior to amendment, subpar. (A) read as follows: "for the last calendar quarter of fiscal year 2011, $100,000;".

Subsec. (c)(1)(B), (C). Pub. L. 114–113, §302(a)(3)(A)(i), (ii), redesignated subpar. (C) as (B) and struck out former subpar. (B) which read as follows: "for fiscal year 2012, $400,000; and".

Subsec. (c)(2)(A). Pub. L. 114–113, §302(a)(3)(B)(i), amended subpar. (A) generally. Prior to amendment, subpar. (A) read as follows: "for the last calendar quarter of fiscal year 2011, $25,000;".

Subsec. (c)(2)(B), (C). Pub. L. 114–113, §302(a)(3)(B)(ii), (iii), redesignated subpar. (C) as (B) and struck out former subpar. (B) which read as follows: "for fiscal year 2012, $100,000; and".

Subsec. (c)(3). Pub. L. 114–113, §302(a)(3)(C), substituted "section 300mm–2 of this title, for fiscal year 2016 and each subsequent fiscal year, $750,000." for "section 300mm–2 of this title—

"(A) for the last calendar quarter of fiscal year 2011, $500,000;

"(B) for fiscal year 2012, $2,000,000; and

"(C) for each subsequent fiscal year, the amount specified under this paragraph for the previous fiscal year increased by the percentage increase in the consumer price index for all urban consumers (all items; United States city average) as estimated by the Secretary for the 12-month period ending with March of the previous year."

Subsec. (c)(4)(A), (B). Pub. L. 114–113, §302(a)(3)(D), added subpars. (A) and (B) and struck out former subpars. (A) and (B) which read as follows:

"(A) for the last calendar quarter of fiscal year 2011, $2,500,000;

"(B) for fiscal year 2012, $10,000,000; and".

Subsec. (c)(5)(A). Pub. L. 114–113, §302(a)(3)(E)(iii), amended subpar. (A) generally. Prior to amendment, subpar. (A) read as follows: "for the last calendar quarter of fiscal year 2011, $3,750,000;".

Subsec. (c)(5)(B), (C). Pub. L. 114–113, §302(a)(3)(E)(i), (ii), redesignated subpar. (C) as (B) and struck out former subpar. (B) which read as follows: "for fiscal year 2012, $15,000,000; and".

Subsec. (c)(6)(A). Pub. L. 114–113, §302(a)(3)(F)(iii), amended subpar. (A) generally. Prior to amendment, subpar. (A) read as follows: "for the last calendar quarter of fiscal year 2011, $1,750,000;".

Subsec. (c)(6)(B), (C). Pub. L. 114–113, §302(a)(3)(F)(i), (ii), redesignated subpar. (C) as (B) and struck out former subpar. (B) which read as follows: "for fiscal year 2012, $7,000,000; and".

[1] See References in Text note below.

[2] So in original. Probably should be followed by "and".

§300mm–62. Supplemental Fund

(a) In general

There is established a fund to be known as the World Trade Center Health Program Supplemental Fund (referred to in this section as the "Supplemental Fund"), consisting of amounts deposited into the Fund under subsection (b).

(b) Amount

Out of any money in the Treasury not otherwise appropriated, there is appropriated for fiscal year 2023 $1,000,000,000, for deposit into the Supplemental Fund, which amounts shall remain available through fiscal year 2032.

(c) Uses of funds

Amounts deposited into the Supplemental Fund under subsection (b) shall be available, without

further appropriation and without regard to any spending limitation under section 300mm–61(c) of this title, to the WTC Program Administrator as needed at the discretion of such Administrator, for carrying out any provision in this title, including sections 300mm–2 and 300mm–51(c) of this title.

(d) Return of funds

Any unobligated amounts that remain in the Supplemental Fund on September 30, 2032, shall be deposited into the Treasury as miscellaneous receipts.

(July 1, 1944, ch. 373, title XXXIII, §3352, as added Pub. L. 117–328, div. FF, title VII, §7701(a), Dec. 29, 2022, 136 Stat. 5965; Pub. L. 119–75, div. J, title IV, §6411(c)(1), Feb. 3, 2026, 140 Stat. 689.)

EDITORIAL NOTES

AMENDMENTS

2026—Subsec. (d). Pub. L. 119–75 substituted "Any unobligated amounts" for "Any amounts".

§300mm–63. Special Fund

(a) In general

There is established a fund to be known as the World Trade Center Health Program Special Fund (referred to in this section as the "Special Fund"), consisting of amounts deposited into the Special Fund under subsection (b).

(b) Amount

Out of any money in the Treasury not otherwise appropriated, there is appropriated for fiscal year 2024 $444,000,000 for deposit into the Special Fund, which amounts shall remain available in such Fund through fiscal year 2033.

(c) Uses of funds

Amounts deposited into the Special Fund under subsection (b) shall be available, without further appropriation and without regard to any spending limitation under section 300mm–61(c) of this title, to the WTC Program Administrator as needed at the discretion of such Administrator, for carrying out any provision in this subchapter (including sections 300mm–2 and 300mm–51(c) of this title).

(d) Remaining amounts

Any unobligated amounts that remain in the Special Fund on September 30, 2033, shall be deposited into the Treasury as miscellaneous receipts.

(July 1, 1944, ch. 373, title XXXIII, §3353, as added Pub. L. 118–31, div. A, title XVIII, §1851(b), Dec. 22, 2023, 137 Stat. 707; Pub. L. 119–75, div. J, title IV, §6411(c)(2), Feb. 3, 2026, 140 Stat. 689.)

EDITORIAL NOTES

AMENDMENTS

2026—Subsec. (d). Pub. L. 119–75 substituted "Any unobligated amounts" for "Any amounts".

§300mm–64. Pentagon/Shanksville Fund

(a) In general

There is established a fund to be known as the World Trade Center Health Program Fund for Certain WTC Responders at the Pentagon and Shanksville, Pennsylvania (referred to in this section as the "Pentagon/Shanksville Fund"), consisting of amounts deposited into the Pentagon/Shanksville

Fund under subsection (b).

(b) Amount

Out of any money in the Treasury not otherwise appropriated, there is appropriated for fiscal year 2024 $232,000,000 for deposit into the Pentagon/Shanksville Fund, which amounts shall remain available in such Fund through fiscal year 2033.

(c) Uses of funds

(1) In general

Amounts deposited into the Pentagon/Shanksville Fund under subsection (b) shall be available, without further appropriation and without regard to any spending limitation under section 300mm–61(c) of this title, to the WTC Program Administrator for the purpose of carrying out section 300mm–22 of this title with regard to WTC responders enrolled in the WTC Program based on eligibility criteria described in subclause (III) or (IV) of section 300mm–21(a)(2)(C)(i) of this title.

(2) Limitation on other funding

Notwithstanding sections 300mm–41(a), 300mm–61(b)(1), 300mm–62(c), and 300mm–63(c) of this title, and any other provision in this subchapter, for the period of fiscal years 2024 through 2033, no amounts made available under this subchapter other than those amounts appropriated under subsection (b) may be available for the purpose described in paragraph (1).

(d) Remaining amounts

Any unobligated amounts that remain in the Pentagon/Shanksville Fund on September 30, 2033, shall be deposited into the Treasury as miscellaneous receipts.

(July 1, 1944, ch. 373, title XXXIII, §3354, as added Pub. L. 118–31, div. A, title XVIII, §1851(b), Dec. 22, 2023, 137 Stat. 708; Pub. L. 119–75, div. J, title IV, §6411(c)(3), Feb. 3, 2026, 140 Stat. 689.)

EDITORIAL NOTES

AMENDMENTS

2026—Subsec. (d). Pub. L. 119–75 substituted "Any unobligated amounts" for "Any amounts".